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14. Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

14.1 Disposition

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.1 / 1: Disposition by sex (All patients)

	Male (N=83460)	Female (N=67083)	Missing (N=1690)	Total (N=152233)
All patients	83460 (100.0%)	67083 (100.0%)	1690 (100.0%)	152233 (100.0%)
Full analysis set for sex	80816 (96.8%)	64217 (95.7%)	0	145033 (95.3%)
Complete cases analysis set for sex	74986 (89.8%)	57864 (86.3%)	0	132850 (87.3%)
Excluded from full analysis set for sex	2644 (3.2%)	2866 (4.3%)	1690 (100.0%)	7200 (4.7%)
did not meet criterion a)	841 (1.0%)	986 (1.5%)	56 (3.3%)	1883 (1.2%)
did not meet criterion b)	1808 (2.2%)	1886 (2.8%)	18 (1.1%)	3712 (2.4%)
did not meet criterion c)	0	0	1690 (100.0%)	1690 (1.1%)
Excluded from complete cases analysis set for sex	8474 (10.2%)	9219 (13.7%)	1690 (100.0%)	19383 (12.7%)
Part of full analysis set for sex, with additionally:				
missing confounder d)	5053 (6.1%)	5778 (8.6%)	0	10831 (7.1%)
missing confounder e)	457 (0.5%)	331 (0.5%)	0	788 (0.5%)
missing confounder f)	358 (0.4%)	285 (0.4%)	0	643 (0.4%)
missing confounder g)	358 (0.4%)	285 (0.4%)	0	643 (0.4%)

The full analysis set for sex consists of patients, who

a) received an injection with Iopromide of the iodine concentrations of 300 mg/mL or 370 mg/mL at the discretion of the Radiologist

b) are deemed as either a case or a control for the primary analysis and

c) have sex recorded.

The complete cases analysis set consists of patients who are in the full primary analysis set and, additionally, have non-missing values for a pre-specified list of covariates:

d) age, e) injection route, f) contrast medium dose, g) dose of iodine in contrast medium.

No missing values were recorded for other pre-specified confounders:

Concomitant Disease: Coronary heart disease, Concomitant Disease: Hypertension arterial, Concomitant Disease: Diabetes mellitus,

Concomitant Disease: Reduced general condition, Concomitant Disease: Allergy, Concomitant Disease: Asthma bronchial,

Concomitant Disease: Contrast media reaction, Concomitant Disease: Other, Specific CM risk factor, Pre-treatment.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.1 / 2: Disposition by race (All patients)

	Asian (N=51697)	White (N=9886)	Black (N=31)	Other (N=237)	Missing (N=90382)	Total (N=152233)
All patients	51697 (100.0%)	9886 (100.0%)	31 (100.0%)	237 (100.0%)	90382 (100.0%)	152233 (100.0%)
Full analysis set for race	50217 (97.1%)	8984 (90.9%)	30 (96.8%)	181 (76.4%)	0	59412 (39.0%)
Complete cases analysis set for race	49621 (96.0%)	6182 (62.5%)	24 (77.4%)	164 (69.2%)	0	55991 (36.8%)
Excluded from full analysis set for race	1480 (2.9%)	902 (9.1%)	1 (3.2%)	56 (23.6%)	90382 (100.0%)	92821 (61.0%)
did not meet criterion a)	23 (<0.1%)	119 (1.2%)	1 (3.2%)	0	1740 (1.9%)	1883 (1.2%)
did not meet criterion b)	1457 (2.8%)	783 (7.9%)	0	56 (23.6%)	1416 (1.6%)	3712 (2.4%)
did not meet criterion c)	0	0	0	0	90382 (100.0%)	90382 (59.4%)
Excluded from complete cases analysis set for race	2076 (4.0%)	3704 (37.5%)	7 (22.6%)	73 (30.8%)	90382 (100.0%)	96242 (63.2%)
Part of full analysis set for race, with additionally:				0		
missing confounder d)	481 (0.9%)	2638 (26.7%)	6 (19.4%)	16 (6.8%)	0	3141 (2.1%)
missing confounder e)	53 (0.1%)	133 (1.3%)	0	1 (0.4%)	0	187 (0.1%)
missing confounder f)	57 (0.1%)	13 (0.1%)	0	0	0	70 (<0.1%)
missing confounder g)	57 (0.1%)	13 (0.1%)	0	0	0	70 (<0.1%)
missing confounder h)	53 (0.1%)	63 (0.6%)	0	0	0	116 (<0.1%)

The full analysis set for race consists of patients, who

a) received an injection with Iopromide of the iodine concentrations of 300 mg/mL or 370 mg/mL at the discretion of the Radiologist

b) are deemed as either a case or a control for the primary analysis and

c) have race recorded.

The complete cases analysis set consists of patients who are in the full primary analysis set and, additionally, have non-missing values for a pre-specified list of covariates:

d) age, e) injection route, f) contrast medium dose, g) dose of iodine in contrast medium, h) sex.

No missing values were recorded for other pre-specified confounders:

Concomitant Disease: Coronary heart disease, Concomitant Disease: Hypertension arterial, Concomitant Disease: Diabetes mellitus, Concomitant Disease: Reduced

general condition, Concomitant Disease: Allergy, Concomitant Disease: Asthma bronchial, Concomitant Disease: Contrast media reaction, Concomitant Disease:

Other, Specific CM risk factor, Pre-treatment.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.1 / 3: Disposition by geographical region (All patients)

	Africa (N=400)	Asia (excl. China) (N=34412)	China (N=37513)	Europe (N=72807)	North America (N=7101)	Total (N=152233)
All patients	400 (100.0%)	34412 (100.0%)	37513 (100.0%)	72807 (100.0%)	7101 (100.0%)	152233 (100.0%)
Full analysis set for geographical region	398 (99.5%)	32971 (95.8%)	36928 (98.4%)	69561 (95.5%)	6791 (95.6%)	146649 (96.3%)
Complete cases analysis set for geographical region	387 (96.8%)	32096 (93.3%)	36787 (98.1%)	63580 (87.3%)	0	132850 (87.3%)
Excluded from full analysis set for geographical region	2 (0.5%)	1441 (4.2%)	585 (1.6%)	3246 (4.5%)	310 (4.4%)	5584 (3.7%)
did not meet criterion a)	0	126 (0.4%)	3 (<0.1%)	1728 (2.4%)	26 (0.4%)	1883 (1.2%)
did not meet criterion b)	2 (0.5%)	1315 (3.8%)	582 (1.6%)	1528 (2.1%)	285 (4.0%)	3712 (2.4%)
Excluded from complete cases analysis set for geographical region	13 (3.3%)	2316 (6.7%)	726 (1.9%)	9227 (12.7%)	7101 (100.0%)	19383 (12.7%)
Part of full analysis set for geographical region, with additionally:					21 (0.3%)	
missing confounder d)	3 (0.8%)	516 (1.5%)	121 (0.3%)	3568 (4.9%)	6791 (95.6%)	10999 (7.2%)
missing confounder e)	1 (0.3%)	137 (0.4%)	0	678 (0.9%)	1 (<0.1%)	817 (0.5%)
missing confounder f)	4 (1.0%)	96 (0.3%)	0	582 (0.8%)	2 (<0.1%)	684 (0.4%)
missing confounder g)	4 (1.0%)	96 (0.3%)	0	582 (0.8%)	2 (<0.1%)	684 (0.4%)
missing confounder h)	3 (0.8%)	192 (0.6%)	23 (<0.1%)	1377 (1.9%)	21 (0.3%)	1616 (1.1%)

The full analysis set for geographical region consists of patients, who

a) received an injection with Iopromide of the iodine concentrations of 300 mg/mL or 370 mg/mL at the discretion of the Radiologist

b) are deemed as either a case or a control for the primary analysis and

c) have geographical region recorded.

The complete cases analysis set consists of patients who are in the full primary analysis set and, additionally, have non-missing values for a pre-specified list of covariates:

d) age, e) injection route, f) contrast medium dose, g) dose of iodine in contrast medium, h) sex.

No missing values were recorded for other pre-specified confounders:

Concomitant Disease: Coronary heart disease, Concomitant Disease: Hypertension arterial, Concomitant Disease: Diabetes mellitus, Concomitant Disease: Reduced general condition,

Concomitant Disease: Allergy, Concomitant Disease: Asthma bronchial, Concomitant Disease: Contrast media reaction, Concomitant Disease: Other, Specific CM risk factor, Pre-

treatment.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.1 / 4: Disposition by country/region (All patients)

	China (N=37513)	Germany (N=47137)	South Korea (N=13994)	Missing (N=53589)	Total (N=152233)
All patients	37513 (100.0%)	47137 (100.0%)	13994 (100.0%)	53589 (100.0%)	152233 (100.0%)
Full analysis set for country/region	36928 (98.4%)	45618 (96.8%)	13745 (98.2%)	50358 (94.0%)	146649 (96.3%)
Complete cases analysis set for country/region	36787 (98.1%)	40766 (86.5%)	13731 (98.1%)	41566 (77.6%)	132850 (87.3%)
Excluded from full analysis set for country/region	585 (1.6%)	1519 (3.2%)	249 (1.8%)	3231 (6.0%)	5584 (3.7%)
did not meet criterion a)	3 (<0.1%)	871 (1.8%)	0	1009 (1.9%)	1883 (1.2%)
did not meet criterion b)	582 (1.6%)	649 (1.4%)	249 (1.8%)	2232 (4.2%)	3712 (2.4%)
did not meet criterion c)	0	0	0	53589 (100.0%)	53589 (35.2%)
Excluded from complete cases analysis set for country/region	726 (1.9%)	6371 (13.5%)	263 (1.9%)	12023 (22.4%)	19383 (12.7%)
Part of full analysis set for country/region, with additionally:					
missing confounder d)	121 (0.3%)	3089 (6.6%)	5 (<0.1%)	7784 (14.5%)	10999 (7.2%)
missing confounder e)	0	337 (0.7%)	2 (<0.1%)	478 (0.9%)	817 (0.5%)
missing confounder f)	0	547 (1.2%)	1 (<0.1%)	136 (0.3%)	684 (0.4%)
missing confounder g)	0	547 (1.2%)	1 (<0.1%)	136 (0.3%)	684 (0.4%)
missing confounder h)	23 (<0.1%)	1059 (2.2%)	7 (<0.1%)	527 (1.0%)	1616 (1.1%)

The full analysis set for country/region consists of patients, who

a) received an injection with Iopromide of the iodine concentrations of 300 mg/mL or 370 mg/mL at the discretion of the Radiologist

b) are deemed as either a case or a control for the primary analysis and

c) have country/region recorded.

The complete cases analysis set consists of patients who are in the full primary analysis set and, additionally, have non-missing values for a pre-specified list of covariates:

d) age, e) injection route, f) contrast medium dose, g) dose of iodine in contrast medium, h) sex.

No missing values were recorded for other pre-specified confounders:

Concomitant Disease: Coronary heart disease, Concomitant Disease: Hypertension arterial, Concomitant Disease: Diabetes mellitus, Concomitant Disease: Reduced

general condition, Concomitant Disease: Allergy, Concomitant Disease: Asthma bronchial, Concomitant Disease: Contrast media reaction, Concomitant Disease:

Other, Specific CM risk factor, Pre-treatment.

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14.2 Demographics by sex, race, geographical region and country/region

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 1: Demographics by sex (Full analysis set for sex)

	Male (N=80816)	Female (N=64217)	Total (N=145033)
Study			
PMS I	37814 (46.8%)	33238 (51.8%)	71052 (49.0%)
IMAGE	24550 (30.4%)	17707 (27.6%)	42257 (29.1%)
TRUST	11157 (13.8%)	6198 (9.7%)	17355 (12.0%)
Ultravist in CT	7295 (9.0%)	7074 (11.0%)	14369 (9.9%)
Age group			
< 18	1665 (2.1%)	1389 (2.2%)	3054 (2.1%)
>= 18 and < 50	20675 (25.6%)	16873 (26.3%)	37548 (25.9%)
>= 50 and < 65	28977 (35.9%)	20960 (32.6%)	49937 (34.4%)
>= 65 years old	24446 (30.2%)	19217 (29.9%)	43663 (30.1%)
Not specified	5053 (6.3%)	5778 (9.0%)	10831 (7.5%)
Geographical region			
Africa	259 (0.3%)	136 (0.2%)	395 (0.3%)
Asia (excl. China)	18553 (23.0%)	14226 (22.2%)	32779 (22.6%)
China	23141 (28.6%)	13764 (21.4%)	36905 (25.4%)
Europe	35950 (44.5%)	32234 (50.2%)	68184 (47.0%)
North America	2913 (3.6%)	3857 (6.0%)	6770 (4.7%)
Country/Region (China, Germany, South Korea)			
China	23141 (42.8%)	13764 (33.5%)	36905 (38.8%)
Germany	23030 (42.6%)	21529 (52.3%)	44559 (46.8%)
South Korea	7889 (14.6%)	5849 (14.2%)	13738 (14.4%)
Ultravist concentration			
Ultravist - 300	49532 (61.3%)	43742 (68.1%)	93274 (64.3%)
Ultravist - 370	31284 (38.7%)	20475 (31.9%)	51759 (35.7%)
Race			
Asian	30531 (37.8%)	19633 (30.6%)	50164 (34.6%)
White	4896 (6.1%)	4025 (6.3%)	8921 (6.2%)
Black	21 (<0.1%)	9 (<0.1%)	30 (<0.1%)
Other	80 (<0.1%)	101 (0.2%)	181 (0.1%)
Not specified	45288 (56.0%)	40449 (63.0%)	85737 (59.1%)



Table 14.2 / 1: Demographics by sex (Full analysis set for sex)

	Male (N=80816)	Female (N=64217)	Total (N=145033)
Age [years]			
n	75763	58439	134202
Nmiss	5053	5778	10831
Mean (SD)	56.1 (15.6)	55.7 (16.5)	55.9 (16.0)
Median	58.0	58.0	58.0
Q1, Q3	47.0, 67.0	46.0, 68.0	47.0, 68.0
Min, Max	0, 105	0, 105	0, 105

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Table 14.2 / 2: Demographics by race (Full analysis set for race)

	Asian (N=50217)	White (N=8984)	Black (N=30)	Other (N=181)	Total (N=59412)
Study					
IMAGE	32841 (65.4%)	8984 (100.0%)	30 (100.0%)	181 (100.0%)	42036 (70.8%)
TRUST	17376 (34.6%)	0	0	0	17376 (29.2%)
Age group					
< 18	844 (1.7%)	215 (2.4%)	1 (3.3%)	3 (1.7%)	1063 (1.8%)
>= 18 and < 50	14035 (27.9%)	1388 (15.4%)	8 (26.7%)	81 (44.8%)	15512 (26.1%)
>= 50 and < 65	20727 (41.3%)	2788 (31.0%)	6 (20.0%)	37 (20.4%)	23558 (39.7%)
>= 65 years old	14130 (28.1%)	1955 (21.8%)	9 (30.0%)	44 (24.3%)	16138 (27.2%)
Not specified	481 (1.0%)	2638 (29.4%)	6 (20.0%)	16 (8.8%)	3141 (5.3%)
Geographical region					
Asia (excl. China)	13263 (26.4%)	42 (0.5%)	13 (43.3%)	159 (87.8%)	13477 (22.7%)
China	36908 (73.5%)	6 (<0.1%)	0	0	36914 (62.1%)
Europe	46 (<0.1%)	8936 (99.5%)	17 (56.7%)	22 (12.2%)	9021 (15.2%)
Country/Region (China, Germany, South Korea)					
China	36908 (90.6%)	6 (0.3%)	0	0	36914 (85.6%)
Germany	12 (<0.1%)	2353 (99.7%)	6 (100.0%)	16 (100.0%)	2387 (5.5%)
South Korea	3826 (9.4%)	0	0	0	3826 (8.9%)
Ultravist concentration					
Ultravist - 300	20898 (41.6%)	3517 (39.1%)	8 (26.7%)	113 (62.4%)	24536 (41.3%)
Ultravist - 370	29319 (58.4%)	5467 (60.9%)	22 (73.3%)	68 (37.6%)	34876 (58.7%)
Sex					
Male	30531 (60.8%)	4896 (54.5%)	21 (70.0%)	80 (44.2%)	35528 (59.8%)
Female	19633 (39.1%)	4025 (44.8%)	9 (30.0%)	101 (55.8%)	23768 (40.0%)
Not specified	53 (0.1%)	63 (0.7%)	0	0	116 (0.2%)



Table 14.2 / 2: Demographics by race (Full analysis set for race)

	Asian (N=50217)	White (N=8984)	Black (N=30)	Other (N=181)	Total (N=59412)
Age [years]					
n	49736	6346	24	165	56271
Nmiss	481	2638	6	16	3141
Mean (SD)	55.5 (14.8)	56.1 (15.8)	52.4 (19.8)	50.7 (17.5)	55.6 (14.9)
Median	57.0	58.0	52.0	49.0	57.0
Q1, Q3	47.0, 66.0	49.0, 67.0	35.5, 69.0	38.0, 66.0	47.0, 66.0
Min, Max	0, 105	0, 93	9, 82	10, 85	0, 105

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Table 14.2 / 3: Demographics by geographical region (Full analysis set for geographical region)

	Africa (N=398)	Asia (excl. China) (N=32971)	China (N=36928)	Europe (N=69561)	North America (N=6791)	Total (N=146649)
Study						
PMS I	398 (100.0%)	14077 (42.7%)	0	50968 (73.3%)	6791 (100.0%)	72234 (49.3%)
IMAGE	0	13625 (41.3%)	19552 (52.9%)	9314 (13.4%)	0	42491 (29.0%)
TRUST	0	0	17376 (47.1%)	0	0	17376 (11.8%)
Ultravist in CT	0	5269 (16.0%)	0	9279 (13.3%)	0	14548 (9.9%)
Age group						
< 18	7 (1.8%)	1342 (4.1%)	345 (0.9%)	1397 (2.0%)	0	3091 (2.1%)
>= 18 and < 50	188 (47.2%)	11959 (36.3%)	9231 (25.0%)	16576 (23.8%)	0	37954 (25.9%)
>= 50 and < 65	154 (38.7%)	11189 (33.9%)	16214 (43.9%)	22881 (32.9%)	0	50438 (34.4%)
>= 65 years old	46 (11.6%)	7965 (24.2%)	11017 (29.8%)	25139 (36.1%)	0	44167 (30.1%)
Not specified	3 (0.8%)	516 (1.6%)	121 (0.3%)	3568 (5.1%)	6791 (100.0%)	10999 (7.5%)
Ultravist concentration						
Ultravist - 300	296 (74.4%)	22648 (68.7%)	13694 (37.1%)	52995 (76.2%)	4896 (72.1%)	94529 (64.5%)
Ultravist - 370	102 (25.6%)	10323 (31.3%)	23234 (62.9%)	16566 (23.8%)	1895 (27.9%)	52120 (35.5%)
Sex						
Male	259 (65.1%)	18553 (56.3%)	23141 (62.7%)	35950 (51.7%)	2913 (42.9%)	80816 (55.1%)
Female	136 (34.2%)	14226 (43.1%)	13764 (37.3%)	32234 (46.3%)	3857 (56.8%)	64217 (43.8%)
Not specified	3 (0.8%)	192 (0.6%)	23 (<0.1%)	1377 (2.0%)	21 (0.3%)	1616 (1.1%)
Race						
Asian	0	13263 (40.2%)	36908 (>99.9%)	46 (<0.1%)	0	50217 (34.2%)
White	0	42 (0.1%)	6 (<0.1%)	8936 (12.8%)	0	8984 (6.1%)
Black	0	13 (<0.1%)	0	17 (<0.1%)	0	30 (<0.1%)
Other	0	159 (0.5%)	0	22 (<0.1%)	0	181 (0.1%)
Not specified	398 (100.0%)	19494 (59.1%)	14 (<0.1%)	60540 (87.0%)	6791 (100.0%)	87237 (59.5%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



Table 14.2 / 3: Demographics by geographical region (Full analysis set for geographical region)

	Africa (N=398)	Asia (excl. China) (N=32971)	China (N=36928)	Europe (N=69561)	North America (N=6791)	Total (N=146649)
Age [years]						
n	395	32455	36807	65993	0	135650
Nmiss	3	516	121	3568	6791	10999
Mean (SD)	48.8 (13.3)	51.5 (17.2)	57.0 (13.6)	57.5 (16.3)	. (.)	55.9 (16.0)
Median	50.0	53.0	58.0	60.0	.	58.0
Q1, Q3	40.0, 57.0	41.0, 64.0	49.0, 66.0	48.0, 69.0	., .	47.0, 68.0
Min, Max	3, 82	0, 103	0, 105	0, 101	., .	0, 105

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=522)	BULGARIA (N=291)	SWITZERLAND (N=1404)	CHINA (N=36928)	GERMANY (N=45618)	ESTONIA (N=173)	EGYPT (N=298)	SPAIN (N=1906)	FINLAND (N=443)
Study									
PMS I	0	291 (100.0%)	1404 (100.0%)	0	33918 (74.4%)	173 (100.0%)	298 (100.0%)	1906 (100.0%)	443 (100.0%)
IMAGE	522 (100.0%)	0	0	19552 (52.9%)	2521 (5.5%)	0	0	0	0
TRUST	0	0	0	17376 (47.1%)	0	0	0	0	0
Ultravist in CT	0	0	0	0	9179 (20.1%)	0	0	0	0
Age group									
< 18	3 (0.6%)	1 (0.3%)	11 (0.8%)	345 (0.9%)	265 (0.6%)	29 (16.8%)	7 (2.3%)	17 (0.9%)	16 (3.6%)
>= 18	130 (24.9%)	49 (16.8%)	384 (27.4%)	9231 (25.0%)	10783 (23.6%)	53 (30.6%)	168 (56.4%)	429 (22.5%)	88 (19.9%)
and < 50									
>= 50	249 (47.7%)	143 (49.1%)	453 (32.3%)	16214 (43.9%)	14543 (31.9%)	42 (24.3%)	106 (35.6%)	584 (30.6%)	159 (35.9%)
and < 65									
>= 65	138 (26.4%)	70 (24.1%)	553 (39.4%)	11017 (29.8%)	16938 (37.1%)	49 (28.3%)	14 (4.7%)	871 (45.7%)	173 (39.1%)
years old									
Not specified	2 (0.4%)	28 (9.6%)	3 (0.2%)	121 (0.3%)	3089 (6.8%)	0	3 (1.0%)	5 (0.3%)	7 (1.6%)
Geographical region									
Africa	0	0	0	0	0	0	298 (100.0%)	0	0
Asia	0	0	0	0	0	0	0	0	0
(excl. China)									
China	0	0	0	36928 (100.0%)	0	0	0	0	0
Europe	522 (100.0%)	291 (100.0%)	1404 (100.0%)	0	45618 (100.0%)	173 (100.0%)	0	1906 (100.0%)	443 (100.0%)
North America	0	0	0	0	0	0	0	0	0
Ultravist concentration									
Ultravist - 300	2 (0.4%)	79 (27.1%)	1206 (85.9%)	13694 (37.1%)	41339 (90.6%)	170 (98.3%)	296 (99.3%)	1360 (71.4%)	428 (96.6%)
Ultravist - 370	520 (99.6%)	212 (72.9%)	198 (14.1%)	23234 (62.9%)	4279 (9.4%)	3 (1.7%)	2 (0.7%)	546 (28.6%)	15 (3.4%)

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=522)	BULGARIA (N=291)	SWITZERLAND (N=1404)	CHINA (N=36928)	GERMANY (N=45618)	ESTONIA (N=173)	EGYPT (N=298)	SPAIN (N=1906)	FINLAND (N=443)
Sex									
Male	342 (65.5%)	212 (72.9%)	692 (49.3%)	23141 (62.7%)	23030 (50.5%)	80 (46.2%)	180 (60.4%)	1127 (59.1%)	235 (53.0%)
Female	173 (33.1%)	78 (26.8%)	683 (48.6%)	13764 (37.3%)	21529 (47.2%)	93 (53.8%)	115 (38.6%)	759 (39.8%)	190 (42.9%)
Not specified	7 (1.3%)	1 (0.3%)	29 (2.1%)	23 (<0.1%)	1059 (2.3%)	0	3 (1.0%)	20 (1.0%)	18 (4.1%)
Race									
Asian	0	0	0	36908 (>99.9%)	12 (<0.1%)	0	0	0	0
White	510 (97.7%)	0	0	6 (<0.1%)	2353 (5.2%)	0	0	0	0
Black	0	0	0	0	6 (<0.1%)	0	0	0	0
Other	0	0	0	0	16 (<0.1%)	0	0	0	0
Not specified	12 (2.3%)	291 (100.0%)	1404 (100.0%)	14 (<0.1%)	43231 (94.8%)	173 (100.0%)	298 (100.0%)	1906 (100.0%)	443 (100.0%)
Age [years]									
n	520	263	1401	36807	42529	173	295	1901	436
Nmiss	2	28	3	121	3089	0	3	5	7
Mean (SD)	56.4 (12.4)	57.2 (10.3)	57.7 (16.1)	57.0 (13.6)	58.6 (15.2)	47.0 (21.9)	45.7 (12.7)	60.0 (16.1)	58.2 (18.3)
Median	56.0	58.0	60.0	58.0	61.0	51.0	47.0	62.0	60.0
Q1, Q3	49.0, 65.0	52.0, 65.0	47.0, 70.0	49.0, 66.0	49.0, 70.0	33.0, 67.0	37.0, 54.0	50.0, 72.0	50.0, 71.0
Min,	12, 81	2, 84	6, 94	0, 105	0, 100	4, 81	3, 82	0, 94	0, 101
Max									

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region) (cont.)

	CROATIA (N=432)	HUNGARY (N=219)	INDONESIA (N=692)	IRAN (N=5088)	ITALY (N=695)	JORDAN (N=1668)	KOREA (SOUTH) (N=13745)	LITHUANIA (N=2380)	LATVIA (N=399)	MOLDOVA (N=358)
Study										
PMS I	432 (100.0%)	0	0	0	167 (24.0%)	1668 (100.0%)	9916 (72.1%)	2380 (100.0%)	399 (100.0%)	0
IMAGE	0	219 (100.0%)	692 (100.0%)	144 (2.8%)	528 (76.0%)	0	3829 (27.9%)	0	0	358 (100.0%)
TRUST	0	0	0	0	0	0	0	0	0	0
Ultravist in CT	0	0	0	4944 (97.2%)	0	0	0	0	0	0
Age group										
< 18	9 (2.1%)	0	33 (4.8%)	261 (5.1%)	4 (0.6%)	102 (6.1%)	315 (2.3%)	359 (15.1%)	0	0
>= 18	127 (29.4%)	32 (14.6%)	343 (49.6%)	2042 (40.1%)	114 (16.4%)	700 (42.0%)	4146 (30.2%)	430 (18.1%)	124 (31.1%)	7 (2.0%)
and < 50										
>= 50	132 (30.6%)	101 (46.1%)	208 (30.1%)	1492 (29.3%)	193 (27.8%)	615 (36.9%)	5217 (38.0%)	698 (29.3%)	133 (33.3%)	29 (8.1%)
and < 65										
>= 65	157 (36.3%)	86 (39.3%)	91 (13.2%)	1274 (25.0%)	381 (54.8%)	237 (14.2%)	4062 (29.6%)	870 (36.6%)	142 (35.6%)	34 (9.5%)
years old										
Not specified	7 (1.6%)	0	17 (2.5%)	19 (0.4%)	3 (0.4%)	14 (0.8%)	5 (<0.1%)	23 (1.0%)	0	288 (80.4%)
Geographical region										
Africa	0	0	0	0	0	0	0	0	0	0
Asia	0	0	692 (100.0%)	5088 (100.0%)	0	1668 (100.0%)	13745 (100.0%)	0	0	0
(excl. China)										
China	0	0	0	0	0	0	0	0	0	0
Europe	432 (100.0%)	219 (100.0%)	0	0	695 (100.0%)	0	0	2380 (100.0%)	399 (100.0%)	358 (100.0%)
North America	0	0	0	0	0	0	0	0	0	0
Ultravist concentration										
Ultravist - 300	293 (67.8%)	134 (61.2%)	364 (52.6%)	4954 (97.4%)	89 (12.8%)	239 (14.3%)	10563 (76.8%)	1524 (64.0%)	399 (100.0%)	4 (1.1%)
Ultravist - 370	139 (32.2%)	85 (38.8%)	328 (47.4%)	134 (2.6%)	606 (87.2%)	1429 (85.7%)	3182 (23.2%)	856 (36.0%)	0	354 (98.9%)

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region) (cont.)

	CROATIA (N=432)	HUNGARY (N=219)	INDONESIA (N=692)	IRAN (N=5088)	ITALY (N=695)	JORDAN (N=1668)	KOREA (SOUTH) (N=13745)	LITHUANIA (N=2380)	LATVIA (N=399)	MOLDOVA (N=358)
Sex										
Male	223 (51.6%)	121 (55.3%)	377 (54.5%)	2586 (50.8%)	393 (56.5%)	1171 (70.2%)	7889 (57.4%)	1294 (54.4%)	181 (45.4%)	169 (47.2%)
Female	186 (43.1%)	96 (43.8%)	314 (45.4%)	2461 (48.4%)	296 (42.6%)	472 (28.3%)	5849 (42.6%)	1084 (45.5%)	218 (54.6%)	175 (48.9%)
Not specified	23 (5.3%)	2 (0.9%)	1 (0.1%)	41 (0.8%)	6 (0.9%)	25 (1.5%)	7 (<0.1%)	2 (<0.1%)	0	14 (3.9%)
Race										
Asian	0	1 (0.5%)	662 (95.7%)	1 (<0.1%)	3 (0.4%)	0	3826 (27.8%)	0	0	1 (0.3%)
White	0	210 (95.9%)	14 (2.0%)	0	511 (73.5%)	0	0	0	0	353 (98.6%)
Black	0	0	6 (0.9%)	0	7 (1.0%)	0	0	0	0	0
Other	0	3 (1.4%)	10 (1.4%)	143 (2.8%)	1 (0.1%)	0	0	0	0	0
Not specified	432 (100.0%)	5 (2.3%)	0	4944 (97.2%)	173 (24.9%)	1668 (100.0%)	9919 (72.2%)	2380 (100.0%)	399 (100.0%)	4 (1.1%)
Age [years]										
n	425	219	675	5069	692	1654	13740	2357	399	70
Nmiss	7	0	17	19	3	14	5	23	0	288
Mean (SD)	55.9 (16.5)	60.8 (11.7)	46.6 (16.1)	49.8 (18.8)	62.9 (15.0)	48.0 (16.4)	55.0 (15.3)	51.8 (23.1)	57.0 (15.4)	64.2 (11.6)
Median	59.0	62.0	47.0	52.0	66.0	50.0	57.0	59.0	59.0	63.5
Q1, Q3	45.0, 68.0	55.0, 69.0	37.0, 57.0	37.0, 65.0	56.0, 74.0	39.0, 60.0	46.0, 66.0	41.0, 69.0	47.0, 70.0	56.0, 75.0
Min, Max	0, 93	20, 87	1, 87	0, 97	0, 90	0, 90	0, 101	0, 93	18, 87	32, 87

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region) (cont.)

	MALAYSIA (N=863)	PHILIPPINES (N=4175)	PAKISTAN (N=1398)	POLAND (N=2749)	ROMANIA (N=2397)	REPUBLIC OF SERBIA (N=682)	RUSSIA (N=614)	SAUDI ARABIA (N=742)	SINGAPORE (N=1657)	SLOVENIA (N=4787)
Study										
PMS I	0	1769 (42.4%)	0	1049 (38.2%)	1271 (53.0%)	682 (100.0%)	0	235 (31.7%)	0	4787 (100.0%)
IMAGE	863 (100.0%)	2406 (57.6%)	1398 (100.0%)	1700 (61.8%)	1026 (42.8%)	0	614 (100.0%)	182 (24.5%)	1657 (100.0%)	0
TRUST	0	0	0	0	0	0	0	0	0	0
Ultravist in CT	0	0	0	0	100 (4.2%)	0	0	325 (43.8%)	0	0
Age group										
< 18	1 (0.1%)	289 (6.9%)	195 (13.9%)	100 (3.6%)	269 (11.2%)	19 (2.8%)	61 (9.9%)	33 (4.4%)	13 (0.8%)	47 (1.0%)
>= 18	243 (28.2%)	1761 (42.2%)	606 (43.3%)	682 (24.8%)	521 (21.7%)	258 (37.8%)	191 (31.1%)	300 (40.4%)	637 (38.4%)	1239 (25.9%)
and < 50										
>= 50	398 (46.1%)	1170 (28.0%)	267 (19.1%)	1072 (39.0%)	968 (40.4%)	235 (34.5%)	239 (38.9%)	260 (35.0%)	647 (39.0%)	1505 (31.4%)
and < 65										
>= 65	221 (25.6%)	856 (20.5%)	122 (8.7%)	890 (32.4%)	609 (25.4%)	169 (24.8%)	123 (20.0%)	120 (16.2%)	355 (21.4%)	1953 (40.8%)
years old										
Not	0	99 (2.4%)	208 (14.9%)	5 (0.2%)	30 (1.3%)	1 (0.1%)	0	29 (3.9%)	5 (0.3%)	43 (0.9%)
specified										
Geographical region										
Africa	0	0	0	0	0	0	0	0	0	0
Asia	863 (100.0%)	4175 (100.0%)	1398 (100.0%)	0	0	0	0	742 (100.0%)	1657 (100.0%)	0
(excl. China)										
China	0	0	0	0	0	0	0	0	0	0
Europe	0	0	0	2749 (100.0%)	2397 (100.0%)	682 (100.0%)	614 (100.0%)	0	0	4787 (100.0%)
North	0	0	0	0	0	0	0	0	0	0
America										
Ultravist concentration										
Ultravist - 300	423 (49.0%)	3041 (72.8%)	587 (42.0%)	782 (28.4%)	53 (2.2%)	272 (39.9%)	276 (45.0%)	379 (51.1%)	261 (15.8%)	2840 (59.3%)
Ultravist - 370	440 (51.0%)	1134 (27.2%)	811 (58.0%)	1967 (71.6%)	2344 (97.8%)	410 (60.1%)	338 (55.0%)	363 (48.9%)	1396 (84.2%)	1947 (40.7%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region) (cont.)

	MALAYSIA (N=863)	PHILIPPINES (N=4175)	PAKISTAN (N=1398)	POLAND (N=2749)	ROMANIA (N=2397)	REPUBLIC OF SERBIA (N=682)	RUSSIA (N=614)	SAUDI ARABIA (N=742)	SINGAPORE (N=1657)	SLOVENIA (N=4787)
Sex										
Male	530 (61.4%)	2173 (52.0%)	757 (54.1%)	1469 (53.4%)	1497 (62.5%)	416 (61.0%)	317 (51.6%)	466 (62.8%)	934 (56.4%)	2393 (50.0%)
Female	329 (38.1%)	1976 (47.3%)	594 (42.5%)	1273 (46.3%)	860 (35.9%)	255 (37.4%)	286 (46.6%)	255 (34.4%)	715 (43.2%)	2349 (49.1%)
Not specified	4 (0.5%)	26 (0.6%)	47 (3.4%)	7 (0.3%)	40 (1.7%)	11 (1.6%)	11 (1.8%)	21 (2.8%)	8 (0.5%)	45 (0.9%)
Race										
Asian	858 (99.4%)	2382 (57.1%)	1291 (92.3%)	0	1 (<0.1%)	0	27 (4.4%)	178 (24.0%)	1623 (97.9%)	0
White	1 (0.1%)	11 (0.3%)	2 (0.1%)	1699 (61.8%)	990 (41.3%)	0	545 (88.8%)	3 (0.4%)	8 (0.5%)	0
Black	0	1 (<0.1%)	0	0	0	0	2 (0.3%)	0	6 (0.4%)	0
Other	0	0	0	0	0	0	1 (0.2%)	0	5 (0.3%)	0
Not specified	4 (0.5%)	1781 (42.7%)	105 (7.5%)	1050 (38.2%)	1406 (58.7%)	682 (100.0%)	39 (6.4%)	561 (75.6%)	15 (0.9%)	4787 (100.0%)
Age [years]										
n	863	4076	1190	2744	2367	681	614	713	1652	4744
Nmiss	0	99	208	5	30	1	0	29	5	43
Mean (SD)	55.2 (13.0)	47.8 (19.1)	39.1 (20.1)	55.9 (16.7)	50.9 (20.7)	51.4 (17.1)	49.1 (19.1)	48.9 (16.8)	52.0 (15.3)	58.4 (15.5)
Median	56.0	49.0	41.0	58.0	55.0	53.0	53.0	50.0	53.0	61.0
Q1, Q3	48.0, 65.0	35.0, 62.0	24.0, 54.0	48.0, 68.0	44.0, 65.0	40.0, 64.0	38.0, 62.0	38.0, 60.0	42.0, 62.0	48.0, 70.0
Min, Max	15, 85	0, 102	0, 91	0, 95	0, 93	0, 88	0, 84	0, 94	8, 92	0, 94

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region) (cont.)

	SLOVAKIA (N=1255)	THAILAND (N=562)	TURKEY (N=332)	TAIWAN (N=768)	UKRAINE (N=1905)	UNITED STATES (N=6791)	VIETNAM (N=1613)	SOUTH AFRICA (N=100)	Total (N=146649)
Study									
PMS I	1255 (100.0%)	294 (52.3%)	332 (100.0%)	195 (25.4%)	79 (4.1%)	6791 (100.0%)	0	100 (100.0%)	72234 (49.3%)
IMAGE	0	268 (47.7%)	0	573 (74.6%)	1826 (95.9%)	0	1613 (100.0%)	0	42491 (29.0%)
TRUST	0	0	0	0	0	0	0	0	17376 (11.8%)
Ultravist in CT	0	0	0	0	0	0	0	0	14548 (9.9%)
Age group									
< 18	49 (3.9%)	24 (4.3%)	6 (1.8%)	15 (2.0%)	132 (6.9%)	0	61 (3.8%)	0	3091 (2.1%)
>= 18	341 (27.2%)	181 (32.2%)	132 (39.8%)	259 (33.7%)	462 (24.3%)	0	741 (45.9%)	20 (20.0%)	37954 (25.9%)
and < 50									
>= 50	425 (33.9%)	193 (34.3%)	119 (35.8%)	255 (33.2%)	859 (45.1%)	0	467 (29.0%)	48 (48.0%)	50438 (34.4%)
and < 65									
>= 65	435 (34.7%)	144 (25.6%)	67 (20.2%)	237 (30.9%)	431 (22.6%)	0	246 (15.3%)	32 (32.0%)	44167 (30.1%)
years old									
Not specified	5 (0.4%)	20 (3.6%)	8 (2.4%)	2 (0.3%)	21 (1.1%)	6791 (100.0%)	98 (6.1%)	0	10999 (7.5%)
Geographical region									
Africa	0	0	0	0	0	0	0	100 (100.0%)	398 (0.3%)
Asia	0	562 (100.0%)	0	768 (100.0%)	0	0	1613 (100.0%)	0	32971 (22.5%)
(excl. China)									
China	0	0	0	0	0	0	0	0	36928 (25.2%)
Europe	1255 (100.0%)	0	332 (100.0%)	0	1905 (100.0%)	0	0	0	69561 (47.4%)
North America	0	0	0	0	0	6791 (100.0%)	0	0	6791 (4.6%)
Ultravist concentration									
Ultravist - 300	764 (60.9%)	257 (45.7%)	277 (83.4%)	164 (21.4%)	704 (37.0%)	4896 (72.1%)	1416 (87.8%)	0	94529 (64.5%)
Ultravist - 370	491 (39.1%)	305 (54.3%)	55 (16.6%)	604 (78.6%)	1201 (63.0%)	1895 (27.9%)	197 (12.2%)	100 (100.0%)	52120 (35.5%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 4: Demographics by country/region (Full analysis set for country/region) (cont.)

	SLOVAKIA (N=1255)	THAILAND (N=562)	TURKEY (N=332)	TAIWAN (N=768)	UKRAINE (N=1905)	UNITED STATES (N=6791)	VIETNAM (N=1613)	SOUTH AFRICA (N=100)	Total (N=146649)
Sex									
Male	661 (52.7%)	306 (54.4%)	174 (52.4%)	477 (62.1%)	924 (48.5%)	2913 (42.9%)	887 (55.0%)	79 (79.0%)	80816 (55.1%)
Female	562 (44.8%)	253 (45.0%)	153 (46.1%)	288 (37.5%)	936 (49.1%)	3857 (56.8%)	720 (44.6%)	21 (21.0%)	64217 (43.8%)
Not specified	32 (2.5%)	3 (0.5%)	5 (1.5%)	3 (0.4%)	45 (2.4%)	21 (0.3%)	6 (0.4%)	0	1616 (1.1%)
Race									
Asian	0	266 (47.3%)	0	568 (74.0%)	1 (<0.1%)	0	1608 (99.7%)	0	50217 (34.2%)
White	0	0	0	3 (0.4%)	1765 (92.7%)	0	0	0	8984 (6.1%)
Black	0	0	0	0	2 (0.1%)	0	0	0	30 (<0.1%)
Other	0	0	0	0	1 (<0.1%)	0	1 (<0.1%)	0	181 (0.1%)
Not specified	1255 (100.0%)	296 (52.7%)	332 (100.0%)	197 (25.7%)	136 (7.1%)	6791 (100.0%)	4 (0.2%)	100 (100.0%)	87237 (59.5%)
Age [years]									
n	1250	542	324	766	1884	0	1515	100	135650
Nmiss	5	20	8	2	21	6791	98	0	10999
Mean (SD)	55.3 (17.3)	53.4 (17.1)	51.0 (15.5)	54.8 (17.0)	52.2 (17.0)	. (.)	47.9 (16.9)	57.9 (10.5)	55.9 (16.0)
Median	58.0	55.0	53.0	55.0	55.0	.	48.0	58.0	58.0
Q1, Q3	46.0, 68.0	45.0, 65.0	40.0, 63.0	44.0, 68.0	46.5, 63.0	., .	37.0, 59.0	51.0, 66.0	47.0, 68.0
Min, Max	0, 96	0, 90	0, 83	5, 93	0, 88	., .	0, 103	32, 82	0, 105

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Table 14.2 / 5: Demographics by sex (Complete cases analysis set for sex)

	Male (N=74986)	Female (N=57864)	Total (N=132850)
Study			
PMS I	33960 (45.3%)	28620 (49.5%)	62580 (47.1%)
IMAGE	22770 (30.4%)	16151 (27.9%)	38921 (29.3%)
TRUST	11110 (14.8%)	6176 (10.7%)	17286 (13.0%)
Ultravist in CT	7146 (9.5%)	6917 (12.0%)	14063 (10.6%)
Age group			
< 18	1629 (2.2%)	1349 (2.3%)	2978 (2.2%)
>= 18 and < 50	20507 (27.3%)	16714 (28.9%)	37221 (28.0%)
>= 50 and < 65	28679 (38.2%)	20763 (35.9%)	49442 (37.2%)
>= 65 years old	24171 (32.2%)	19038 (32.9%)	43209 (32.5%)
Geographical region			
Africa	256 (0.3%)	131 (0.2%)	387 (0.3%)
Asia (excl. China)	18189 (24.3%)	13907 (24.0%)	32096 (24.2%)
China	23064 (30.8%)	13723 (23.7%)	36787 (27.7%)
Europe	33477 (44.6%)	30103 (52.0%)	63580 (47.9%)
Country/Region (China, Germany, South Korea)			
China	23064 (44.4%)	13723 (34.9%)	36787 (40.3%)
Germany	21000 (40.4%)	19766 (50.3%)	40766 (44.7%)
South Korea	7885 (15.2%)	5846 (14.9%)	13731 (15.0%)
Ultravist concentration			
Ultravist - 300	45360 (60.5%)	39209 (67.8%)	84569 (63.7%)
Ultravist - 370	29626 (39.5%)	18655 (32.2%)	48281 (36.3%)
Race			
Asian	30226 (40.3%)	19395 (33.5%)	49621 (37.4%)
White	3435 (4.6%)	2747 (4.7%)	6182 (4.7%)
Black	18 (<0.1%)	6 (<0.1%)	24 (<0.1%)
Other	72 (<0.1%)	92 (0.2%)	164 (0.1%)
Not specified	41235 (55.0%)	35624 (61.6%)	76859 (57.9%)

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Table 14.2 / 5: Demographics by sex (Complete cases analysis set for sex)

	Male (N=74986)	Female (N=57864)	Total (N=132850)
Age [years]			
n	74986	57864	132850
Nmiss	0	0	0
Mean (SD)	56.1 (15.6)	55.7 (16.4)	55.9 (16.0)
Median	58.0	58.0	58.0
Q1, Q3	47.0, 67.0	46.0, 68.0	47.0, 68.0
Min, Max	0, 105	0, 105	0, 105

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Table 14.2 / 6: Demographics by race (Complete cases analysis set for race)

	Asian (N=49621)	White (N=6182)	Black (N=24)	Other (N=164)	Total (N=55991)
Study					
IMAGE	32335 (65.2%)	6182 (100.0%)	24 (100.0%)	164 (100.0%)	38705 (69.1%)
TRUST	17286 (34.8%)	0	0	0	17286 (30.9%)
Age group					
< 18	838 (1.7%)	210 (3.4%)	1 (4.2%)	3 (1.8%)	1052 (1.9%)
>= 18 and < 50	13979 (28.2%)	1370 (22.2%)	8 (33.3%)	80 (48.8%)	15437 (27.6%)
>= 50 and < 65	20694 (41.7%)	2713 (43.9%)	6 (25.0%)	37 (22.6%)	23450 (41.9%)
>= 65 years old	14110 (28.4%)	1889 (30.6%)	9 (37.5%)	44 (26.8%)	16052 (28.7%)
Geographical region					
Asia (excl. China)	12820 (25.8%)	40 (0.6%)	13 (54.2%)	158 (96.3%)	13031 (23.3%)
China	36768 (74.1%)	6 (<0.1%)	0	0	36774 (65.7%)
Europe	33 (<0.1%)	6136 (99.3%)	11 (45.8%)	6 (3.7%)	6186 (11.0%)
Country/Region (China, Germany, South Korea)					
China	36768 (90.6%)	6 (18.8%)	0	0	36774 (90.5%)
Germany	0	26 (81.3%)	0	0	26 (<0.1%)
South Korea	3821 (9.4%)	0	0	0	3821 (9.4%)
Ultravist concentration					
Ultravist - 300	20588 (41.5%)	1518 (24.6%)	2 (8.3%)	103 (62.8%)	22211 (39.7%)
Ultravist - 370	29033 (58.5%)	4664 (75.4%)	22 (91.7%)	61 (37.2%)	33780 (60.3%)
Sex					
Male	30226 (60.9%)	3435 (55.6%)	18 (75.0%)	72 (43.9%)	33751 (60.3%)
Female	19395 (39.1%)	2747 (44.4%)	6 (25.0%)	92 (56.1%)	22240 (39.7%)
Age [years]					
n	49621	6182	24	164	55991
Nmiss	0	0	0	0	0
Mean (SD)	55.6 (14.7)	56.0 (15.8)	52.4 (19.8)	50.8 (17.5)	55.6 (14.9)
Median	57.0	58.0	52.0	49.0	57.0
Q1, Q3	47.0, 66.0	49.0, 67.0	35.5, 69.0	38.5, 66.5	47.0, 66.0
Min, Max	0, 105	0, 93	9, 82	10, 85	0, 105

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Table 14.2 / 7: Demographics by geographical region (Complete cases analysis set for geographical region)

	Africa (N=387)	Asia (excl. China) (N=32096)	China (N=36787)	Europe (N=63580)	Total (N=132850)
Study					
PMS I	387 (100.0%)	13800 (43.0%)	0	48393 (76.1%)	62580 (47.1%)
IMAGE	0	13122 (40.9%)	19501 (53.0%)	6298 (9.9%)	38921 (29.3%)
TRUST	0	0	17286 (47.0%)	0	17286 (13.0%)
Ultravist in CT	0	5174 (16.1%)	0	8889 (14.0%)	14063 (10.6%)
Age group					
< 18	7 (1.8%)	1286 (4.0%)	345 (0.9%)	1340 (2.1%)	2978 (2.2%)
>= 18 and < 50	184 (47.5%)	11810 (36.8%)	9229 (25.1%)	15998 (25.2%)	37221 (28.0%)
>= 50 and < 65	150 (38.8%)	11097 (34.6%)	16202 (44.0%)	21993 (34.6%)	49442 (37.2%)
>= 65 years old	46 (11.9%)	7903 (24.6%)	11011 (29.9%)	24249 (38.1%)	43209 (32.5%)
Ultravist concentration					
Ultravist - 300	286 (73.9%)	22132 (69.0%)	13642 (37.1%)	48509 (76.3%)	84569 (63.7%)
Ultravist - 370	101 (26.1%)	9964 (31.0%)	23145 (62.9%)	15071 (23.7%)	48281 (36.3%)
Sex					
Male	256 (66.1%)	18189 (56.7%)	23064 (62.7%)	33477 (52.7%)	74986 (56.4%)
Female	131 (33.9%)	13907 (43.3%)	13723 (37.3%)	30103 (47.3%)	57864 (43.6%)
Race					
Asian	0	12820 (39.9%)	36768 (>99.9%)	33 (<0.1%)	49621 (37.4%)
White	0	40 (0.1%)	6 (<0.1%)	6136 (9.7%)	6182 (4.7%)
Black	0	13 (<0.1%)	0	11 (<0.1%)	24 (<0.1%)
Other	0	158 (0.5%)	0	6 (<0.1%)	164 (0.1%)
Not specified	387 (100.0%)	19065 (59.4%)	13 (<0.1%)	57394 (90.3%)	76859 (57.9%)
Age [years]					
n	387	32096	36787	63580	132850
Nmiss	0	0	0	0	0
Mean (SD)	48.8 (13.3)	51.6 (17.2)	57.0 (13.6)	57.5 (16.3)	55.9 (16.0)
Median	50.0	53.0	58.0	60.0	58.0
Q1, Q3	40.0, 58.0	41.0, 64.0	49.0, 66.0	48.0, 69.0	47.0, 68.0
Min, Max	3, 82	0, 103	0, 105	0, 101	0, 105

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=513)	BULGARIA (N=258)	SWITZERLAND (N=1367)	CHINA (N=36787)	GERMANY (N=40766)	ESTONIA (N=155)	EGYPT (N=287)	SPAIN (N=1827)	FINLAND (N=417)
Study									
PMS I	0	258 (100.0%)	1367 (100.0%)	0	31951 (78.4%)	155 (100.0%)	287 (100.0%)	1827 (100.0%)	417 (100.0%)
IMAGE	513 (100.0%)	0	0	19501 (53.0%)	26 (<0.1%)	0	0	0	0
TRUST	0	0	0	17286 (47.0%)	0	0	0	0	0
Ultravist in CT	0	0	0	0	8789 (21.6%)	0	0	0	0
Age group									
< 18	3 (0.6%)	0	11 (0.8%)	345 (0.9%)	254 (0.6%)	16 (10.3%)	7 (2.4%)	17 (0.9%)	15 (3.6%)
>= 18	128 (25.0%)	48 (18.6%)	372 (27.2%)	9229 (25.1%)	10335 (25.4%)	51 (32.9%)	164 (57.1%)	416 (22.8%)	82 (19.7%)
and < 50									
>= 50	244 (47.6%)	141 (54.7%)	446 (32.6%)	16202 (44.0%)	13881 (34.1%)	41 (26.5%)	102 (35.5%)	560 (30.7%)	158 (37.9%)
and < 65									
>= 65	138 (26.9%)	69 (26.7%)	538 (39.4%)	11011 (29.9%)	16296 (40.0%)	47 (30.3%)	14 (4.9%)	834 (45.6%)	162 (38.8%)
years old									
Geographical region									
Africa	0	0	0	0	0	0	287 (100.0%)	0	0
Asia	0	0	0	0	0	0	0	0	0
(excl. China)									
China	0	0	0	36787 (100.0%)	0	0	0	0	0
Europe	513 (100.0%)	258 (100.0%)	1367 (100.0%)	0	40766 (100.0%)	155 (100.0%)	0	1827 (100.0%)	417 (100.0%)
Ultravist concentration									
Ultravist	2 (0.4%)	63 (24.4%)	1172 (85.7%)	13642 (37.1%)	37217 (91.3%)	152 (98.1%)	286 (99.7%)	1336 (73.1%)	406 (97.4%)
- 300									
Ultravist	511 (99.6%)	195 (75.6%)	195 (14.3%)	23145 (62.9%)	3549 (8.7%)	3 (1.9%)	1 (0.3%)	491 (26.9%)	11 (2.6%)
- 370									
Sex									
Male	340 (66.3%)	197 (76.4%)	687 (50.3%)	23064 (62.7%)	21000 (51.5%)	74 (47.7%)	177 (61.7%)	1087 (59.5%)	231 (55.4%)
Female	173 (33.7%)	61 (23.6%)	680 (49.7%)	13723 (37.3%)	19766 (48.5%)	81 (52.3%)	110 (38.3%)	740 (40.5%)	186 (44.6%)

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=513)	BULGARIA (N=258)	SWITZERLAND (N=1367)	CHINA (N=36787)	GERMANY (N=40766)	ESTONIA (N=155)	EGYPT (N=287)	SPAIN (N=1827)	FINLAND (N=417)
Race									
Asian	0	0	0	36768 (>99.9%)	0	0	0	0	0
White	508 (99.0%)	0	0	6 (<0.1%)	26 (<0.1%)	0	0	0	0
Black	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0
Not specified	5 (1.0%)	258 (100.0%)	1367 (100.0%)	13 (<0.1%)	40740 (>99.9%)	155 (100.0%)	287 (100.0%)	1827 (100.0%)	417 (100.0%)
Age [years]									
n	513	258	1367	36787	40766	155	287	1827	417
Nmiss	0	0	0	0	0	0	0	0	0
Mean (SD)	56.5 (12.4)	57.4 (9.5)	57.7 (16.1)	57.0 (13.6)	58.6 (15.2)	50.1 (19.8)	45.7 (12.8)	59.9 (16.2)	58.2 (18.0)
Median	56.0	58.0	60.0	58.0	61.0	53.0	47.0	62.0	60.0
Q1, Q3	49.0, 65.0	52.0, 65.0	47.0, 70.0	49.0, 66.0	49.0, 70.0	37.0, 68.0	37.0, 54.0	50.0, 72.0	50.0, 71.0
Min, Max	12, 81	27, 84	6, 94	0, 105	0, 100	4, 81	3, 82	0, 94	0, 101

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region) (cont.)

	CROATIA (N=387)	HUNGARY (N=217)	INDONESIA (N=656)	IRAN (N=5012)	ITALY (N=683)	JORDAN (N=1572)	KOREA (SOUTH) (N=13731)	LITHUANIA (N=2335)	LATVIA (N=399)	MOLDOVA (N=10)
Study										
PMS I	387 (100.0%)	0	0	0	163 (23.9%)	1572 (100.0%)	9907 (72.2%)	2335 (100.0%)	399 (100.0%)	0
IMAGE	0	217 (100.0%)	656 (100.0%)	144 (2.9%)	520 (76.1%)	0	3824 (27.8%)	0	0	10 (100.0%)
TRUST	0	0	0	0	0	0	0	0	0	0
Ultravist in CT	0	0	0	4868 (97.1%)	0	0	0	0	0	0
Age group										
< 18	9 (2.3%)	0	33 (5.0%)	261 (5.2%)	4 (0.6%)	75 (4.8%)	315 (2.3%)	344 (14.7%)	0	0
>= 18	120 (31.0%)	32 (14.7%)	328 (50.0%)	2028 (40.5%)	112 (16.4%)	664 (42.2%)	4141 (30.2%)	428 (18.3%)	124 (31.1%)	0
and < 50										
>= 50	118 (30.5%)	100 (46.1%)	205 (31.3%)	1471 (29.3%)	191 (28.0%)	602 (38.3%)	5216 (38.0%)	696 (29.8%)	133 (33.3%)	7 (70.0%)
and < 65										
>= 65	140 (36.2%)	85 (39.2%)	90 (13.7%)	1252 (25.0%)	376 (55.1%)	231 (14.7%)	4059 (29.6%)	867 (37.1%)	142 (35.6%)	3 (30.0%)
years old										
Geographical region										
Africa	0	0	0	0	0	0	0	0	0	0
Asia (excl. China)	0	0	656 (100.0%)	5012 (100.0%)	0	1572 (100.0%)	13731 (100.0%)	0	0	0
China	0	0	0	0	0	0	0	0	0	0
Europe	387 (100.0%)	217 (100.0%)	0	0	683 (100.0%)	0	0	2335 (100.0%)	399 (100.0%)	10 (100.0%)
Ultravist concentration										
Ultravist - 300	255 (65.9%)	132 (60.8%)	340 (51.8%)	4878 (97.3%)	89 (13.0%)	197 (12.5%)	10553 (76.9%)	1509 (64.6%)	399 (100.0%)	0
Ultravist - 370	132 (34.1%)	85 (39.2%)	316 (48.2%)	134 (2.7%)	594 (87.0%)	1375 (87.5%)	3178 (23.1%)	826 (35.4%)	0	10 (100.0%)
Sex										
Male	214 (55.3%)	121 (55.8%)	362 (55.2%)	2568 (51.2%)	389 (57.0%)	1139 (72.5%)	7885 (57.4%)	1273 (54.5%)	181 (45.4%)	8 (80.0%)
Female	173 (44.7%)	96 (44.2%)	294 (44.8%)	2444 (48.8%)	294 (43.0%)	433 (27.5%)	5846 (42.6%)	1062 (45.5%)	218 (54.6%)	2 (20.0%)

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region) (cont.)

	CROATIA (N=387)	HUNGARY (N=217)	INDONESIA (N=656)	IRAN (N=5012)	ITALY (N=683)	JORDAN (N=1572)	KOREA (SOUTH) (N=13731)	LITHUANIA (N=2335)	LATVIA (N=399)	MOLDOVA (N=10)
Race										
Asian	0	1 (0.5%)	627 (95.6%)	1 (<0.1%)	3 (0.4%)	0	3821 (27.8%)	0	0	1 (10.0%)
White	0	210 (96.8%)	14 (2.1%)	0	504 (73.8%)	0	0	0	0	8 (80.0%)
Black	0	0	6 (0.9%)	0	7 (1.0%)	0	0	0	0	0
Other	0	3 (1.4%)	9 (1.4%)	143 (2.9%)	1 (0.1%)	0	0	0	0	0
Not specified	387 (100.0%)	3 (1.4%)	0	4868 (97.1%)	168 (24.6%)	1572 (100.0%)	9910 (72.2%)	2335 (100.0%)	399 (100.0%)	1 (10.0%)
Age [years]										
n	387	217	656	5012	683	1572	13731	2335	399	10
Nmiss	0	0	0	0	0	0	0	0	0	0
Mean (SD)	55.3 (16.8)	60.8 (11.8)	46.8 (16.1)	49.8 (18.8)	62.9 (15.0)	48.9 (15.7)	55.0 (15.3)	52.1 (22.9)	57.0 (15.4)	60.4 (6.7)
Median	58.0	62.0	48.0	52.0	66.0	50.0	57.0	59.0	59.0	59.5
Q1, Q3	45.0, 68.0	55.0, 69.0	38.0, 57.0	37.0, 64.0	56.0, 74.0	40.0, 60.0	46.0, 66.0	42.0, 69.0	47.0, 70.0	55.0, 65.0
Min, Max	0, 89	20, 87	1, 87	0, 97	0, 90	0, 90	0, 101	0, 93	18, 87	51, 72

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region) (cont.)

	MALAYSIA (N=859)	PHILIPPINES (N=3987)	PAKISTAN (N=1153)	POLAND (N=2713)	ROMANIA (N=2245)	REPUBLIC OF SERBIA (N=656)	RUSSIA (N=599)	SAUDI ARABIA (N=680)	SINGAPORE (N=1639)	SLOVENIA (N=4688)
Study										
PMS I	0	1645 (41.3%)	0	1014 (37.4%)	1198 (53.4%)	656 (100.0%)	0	197 (29.0%)	0	4688 (100.0%)
IMAGE	859 (100.0%)	2342 (58.7%)	1153 (100.0%)	1699 (62.6%)	947 (42.2%)	0	599 (100.0%)	177 (26.0%)	1639 (100.0%)	0
TRUST	0	0	0	0	0	0	0	0	0	0
Ultravist in CT	0	0	0	0	100 (4.5%)	0	0	306 (45.0%)	0	0
Age group										
< 18	1 (0.1%)	280 (7.0%)	183 (15.9%)	99 (3.6%)	262 (11.7%)	18 (2.7%)	59 (9.8%)	27 (4.0%)	13 (0.8%)	46 (1.0%)
>= 18	240 (27.9%)	1723 (43.2%)	590 (51.2%)	677 (25.0%)	502 (22.4%)	247 (37.7%)	185 (30.9%)	291 (42.8%)	633 (38.6%)	1226 (26.2%)
and < 50										
>= 50	398 (46.3%)	1143 (28.7%)	260 (22.5%)	1057 (39.0%)	910 (40.5%)	229 (34.9%)	235 (39.2%)	245 (36.0%)	642 (39.2%)	1491 (31.8%)
and < 65										
>= 65	220 (25.6%)	841 (21.1%)	120 (10.4%)	880 (32.4%)	571 (25.4%)	162 (24.7%)	120 (20.0%)	117 (17.2%)	351 (21.4%)	1925 (41.1%)
years old										
Geographical region										
Africa	0	0	0	0	0	0	0	0	0	0
Asia (excl. China)	859 (100.0%)	3987 (100.0%)	1153 (100.0%)	0	0	0	0	680 (100.0%)	1639 (100.0%)	0
China	0	0	0	0	0	0	0	0	0	0
Europe	0	0	0	2713 (100.0%)	2245 (100.0%)	656 (100.0%)	599 (100.0%)	0	0	4688 (100.0%)
Ultravist concentration										
Ultravist - 300	419 (48.8%)	2925 (73.4%)	480 (41.6%)	780 (28.8%)	49 (2.2%)	254 (38.7%)	271 (45.2%)	355 (52.2%)	259 (15.8%)	2773 (59.2%)
Ultravist - 370	440 (51.2%)	1062 (26.6%)	673 (58.4%)	1933 (71.2%)	2196 (97.8%)	402 (61.3%)	328 (54.8%)	325 (47.8%)	1380 (84.2%)	1915 (40.8%)
Sex										
Male	530 (61.7%)	2087 (52.3%)	646 (56.0%)	1455 (53.6%)	1414 (63.0%)	405 (61.7%)	315 (52.6%)	442 (65.0%)	926 (56.5%)	2370 (50.6%)
Female	329 (38.3%)	1900 (47.7%)	507 (44.0%)	1258 (46.4%)	831 (37.0%)	251 (38.3%)	284 (47.4%)	238 (35.0%)	713 (43.5%)	2318 (49.4%)

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region) (cont.)

	MALAYSIA (N=859)	PHILIPPINES (N=3987)	PAKISTAN (N=1153)	POLAND (N=2713)	ROMANIA (N=2245)	REPUBLIC OF SERBIA (N=656)	RUSSIA (N=599)	SAUDI ARABIA (N=680)	SINGAPORE (N=1639)	SLOVENIA (N=4688)
Race										
Asian	857 (99.8%)	2319 (58.2%)	1093 (94.8%)	0	1 (<0.1%)	0	26 (4.3%)	174 (25.6%)	1608 (98.1%)	0
White	1 (0.1%)	11 (0.3%)	1 (<0.1%)	1698 (62.6%)	916 (40.8%)	0	538 (89.8%)	2 (0.3%)	8 (0.5%)	0
Black	0	1 (<0.1%)	0	0	0	0	2 (0.3%)	0	6 (0.4%)	0
Other	0	0	0	0	0	0	1 (0.2%)	0	5 (0.3%)	0
Not specified	1 (0.1%)	1656 (41.5%)	59 (5.1%)	1015 (37.4%)	1328 (59.2%)	656 (100.0%)	32 (5.3%)	504 (74.1%)	12 (0.7%)	4688 (100.0%)
Age [years]										
n	859	3987	1153	2713	2245	656	599	680	1639	4688
Nmiss	0	0	0	0	0	0	0	0	0	0
Mean (SD)	55.3 (12.9)	47.8 (19.1)	39.3 (20.0)	55.8 (16.8)	50.7 (20.9)	51.4 (17.1)	49.2 (19.0)	49.0 (16.6)	52.0 (15.3)	58.4 (15.5)
Median	56.0	49.0	41.0	58.0	55.0	54.0	53.0	50.0	53.0	61.0
Q1, Q3	48.0, 65.0	35.0, 62.0	25.0, 54.0	48.0, 68.0	44.0, 65.0	40.0, 64.0	38.0, 62.0	38.0, 60.0	42.0, 62.0	48.0, 70.0
Min, Max	15, 85	0, 102	0, 91	0, 95	0, 93	0, 88	0, 84	0, 94	8, 92	0, 94

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVAKIA (N=1187)	THAILAND (N=538)	TURKEY (N=319)	TAIWAN (N=763)	UKRAINE (N=1839)	VIETNAM (N=1506)	SOUTH AFRICA (N=100)	Total (N=132850)
Study								
PMS I	1187 (100.0%)	287 (53.3%)	319 (100.0%)	192 (25.2%)	72 (3.9%)	0	100 (100.0%)	62580 (47.1%)
IMAGE	0	251 (46.7%)	0	571 (74.8%)	1767 (96.1%)	1506 (100.0%)	0	38921 (29.3%)
TRUST	0	0	0	0	0	0	0	17286 (13.0%)
Ultravist in CT	0	0	0	0	0	0	0	14063 (10.6%)
Age group								
< 18	49 (4.1%)	22 (4.1%)	6 (1.9%)	15 (2.0%)	128 (7.0%)	61 (4.1%)	0	2978 (2.2%)
>= 18	332 (28.0%)	179 (33.3%)	131 (41.1%)	259 (33.9%)	450 (24.5%)	734 (48.7%)	20 (20.0%)	37221 (28.0%)
and < 50								
>= 50	400 (33.7%)	193 (35.9%)	117 (36.7%)	255 (33.4%)	838 (45.6%)	467 (31.0%)	48 (48.0%)	49442 (37.2%)
and < 65								
>= 65	406 (34.2%)	144 (26.8%)	65 (20.4%)	234 (30.7%)	423 (23.0%)	244 (16.2%)	32 (32.0%)	43209 (32.5%)
years old								
Geographical region								
Africa	0	0	0	0	0	0	100 (100.0%)	387 (0.3%)
Asia (excl. China)	0	538 (100.0%)	0	763 (100.0%)	0	1506 (100.0%)	0	32096 (24.2%)
China	0	0	0	0	0	0	0	36787 (27.7%)
Europe	1187 (100.0%)	0	319 (100.0%)	0	1839 (100.0%)	0	0	63580 (47.9%)
Ultravist concentration								
Ultravist - 300	701 (59.1%)	250 (46.5%)	265 (83.1%)	162 (21.2%)	684 (37.2%)	1314 (87.3%)	0	84569 (63.7%)
Ultravist - 370	486 (40.9%)	288 (53.5%)	54 (16.9%)	601 (78.8%)	1155 (62.8%)	192 (12.7%)	100 (100.0%)	48281 (36.3%)
Sex								
Male	632 (53.2%)	297 (55.2%)	171 (53.6%)	475 (62.3%)	913 (49.6%)	832 (55.2%)	79 (79.0%)	74986 (56.4%)
Female	555 (46.8%)	241 (44.8%)	148 (46.4%)	288 (37.7%)	926 (50.4%)	674 (44.8%)	21 (21.0%)	57864 (43.6%)

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Table 14.2 / 8: Demographics by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVAKIA (N=1187)	THAILAND (N=538)	TURKEY (N=319)	TAIWAN (N=763)	UKRAINE (N=1839)	VIETNAM (N=1506)	SOUTH AFRICA (N=100)	Total (N=132850)
Race								
Asian	0	249 (46.3%)	0	567 (74.3%)	1 (<0.1%)	1504 (99.9%)	0	49621 (37.4%)
White	0	0	0	3 (0.4%)	1728 (94.0%)	0	0	6182 (4.7%)
Black	0	0	0	0	2 (0.1%)	0	0	24 (<0.1%)
Other	0	0	0	0	1 (<0.1%)	1 (<0.1%)	0	164 (0.1%)
Not specified	1187 (100.0%)	289 (53.7%)	319 (100.0%)	193 (25.3%)	107 (5.8%)	1 (<0.1%)	100 (100.0%)	76859 (57.9%)
Age [years]								
n	1187	538	319	763	1839	1506	100	132850
Nmiss	0	0	0	0	0	0	0	0
Mean (SD)	55.0 (17.4)	53.6 (16.8)	50.8 (15.6)	54.7 (16.9)	52.2 (17.0)	47.9 (16.9)	57.9 (10.5)	55.9 (16.0)
Median	58.0	55.0	52.0	55.0	55.0	49.0	58.0	58.0
Q1, Q3	46.0, 68.0	45.0, 65.0	40.0, 63.0	44.0, 68.0	47.0, 63.0	37.0, 59.0	51.0, 66.0	47.0, 68.0
Min, Max	0, 96	0, 90	0, 83	5, 93	0, 88	0, 103	32, 82	0, 105

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adsl_demog.sas 01DEC2022 15:12
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Table 14.2 / 9: Concomitant diseases by sex (Full analysis set for sex)

	Male N=80816 (100%)	Female N=64217 (100%)	Total N=145033 (100%)
Number (%) of patients with at least one concomitant disease finding	39372 (48.7%)	28414 (44.2%)	67786 (46.7%)
Hypertension arterial	10667 (13.2%)	6836 (10.6%)	17503 (12.1%)
Coronary heart disease	8193 (10.1%)	4174 (6.5%)	12367 (8.5%)
Diabetes mellitus	6534 (8.1%)	4741 (7.4%)	11275 (7.8%)
Reduced general condition	4166 (5.2%)	3174 (4.9%)	7340 (5.1%)
Specific contrast media risk factor	2605 (3.2%)	3141 (4.9%)	5746 (4.0%)
Allergy	1802 (2.2%)	2460 (3.8%)	4262 (2.9%)
Asthma bronchial	506 (0.6%)	401 (0.6%)	907 (0.6%)
Contrast media reaction	390 (0.5%)	405 (0.6%)	795 (0.5%)
Other	12267 (15.2%)	9378 (14.6%)	21645 (14.9%)
None specified	15299 (18.9%)	11358 (17.7%)	26657 (18.4%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

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Table 14.2 / 10: Concomitant diseases by race (Full analysis set for race)

	Asian N=50217 (100%)	White N=8984 (100%)	Black N=30 (100%)	Other N=181 (100%)	Total N=59412 (100%)
Number (%) of patients with at least one concomitant disease finding	36439 (72.6%)	7632 (85.0%)	22 (73.3%)	123 (68.0%)	44216 (74.4%)
Hypertension arterial	12984 (25.9%)	2991 (33.3%)	5 (16.7%)	8 (4.4%)	15988 (26.9%)
Diabetes mellitus	4976 (9.9%)	926 (10.3%)	1 (3.3%)	10 (5.5%)	5913 (10.0%)
Coronary heart disease	2650 (5.3%)	2056 (22.9%)	4 (13.3%)	9 (5.0%)	4719 (7.9%)
Reduced general condition	3859 (7.7%)	609 (6.8%)	1 (3.3%)	6 (3.3%)	4475 (7.5%)
Specific contrast media risk factor	1539 (3.1%)	494 (5.5%)	1 (3.3%)	11 (6.1%)	2045 (3.4%)
Allergy	996 (2.0%)	303 (3.4%)	0	2 (1.1%)	1301 (2.2%)
Asthma bronchial	396 (0.8%)	181 (2.0%)	1 (3.3%)	9 (5.0%)	587 (1.0%)
Contrast media reaction	184 (0.4%)	43 (0.5%)	0	0	227 (0.4%)
Other	9818 (19.6%)	2311 (25.7%)	2 (6.7%)	57 (31.5%)	12188 (20.5%)
None specified	20866 (41.6%)	5541 (61.7%)	17 (56.7%)	91 (50.3%)	26515 (44.6%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 11: Concomitant diseases by geographical region (Full analysis set for geographical region)

	Africa N=398 (100%)	Asia (excl. China) N=32971 (100%)	China N=36928 (100%)	Europe N=69561 (100%)	North America N=6791 (100%)	Total N=146649 (100%)
Number (%) of patients with at least one concomitant disease finding	199 (50.0%)	15664 (47.5%)	25841 (70.0%)	24405 (35.1%)	2270 (33.4%)	68379 (46.6%)
Hypertension arterial	0	2236 (6.8%)	11169 (30.2%)	4174 (6.0%)	0	17579 (12.0%)
Coronary heart disease	85 (21.4%)	3214 (9.7%)	1396 (3.8%)	7196 (10.3%)	624 (9.2%)	12515 (8.5%)
Diabetes mellitus	31 (7.8%)	2085 (6.3%)	3989 (10.8%)	4855 (7.0%)	428 (6.3%)	11388 (7.8%)
Reduced general condition	10 (2.5%)	849 (2.6%)	3413 (9.2%)	3014 (4.3%)	127 (1.9%)	7413 (5.1%)
Specific contrast media risk factor	52 (13.1%)	1122 (3.4%)	977 (2.6%)	3099 (4.5%)	568 (8.4%)	5818 (4.0%)
Allergy	19 (4.8%)	720 (2.2%)	689 (1.9%)	2358 (3.4%)	529 (7.8%)	4315 (2.9%)
Asthma bronchial	0	354 (1.1%)	156 (0.4%)	407 (0.6%)	0	917 (0.6%)
Contrast media reaction	33 (8.3%)	94 (0.3%)	148 (0.4%)	481 (0.7%)	48 (0.7%)	804 (0.5%)
Other	61 (15.3%)	4857 (14.7%)	6780 (18.4%)	8992 (12.9%)	1176 (17.3%)	21866 (14.9%)
None specified	0	9353 (28.4%)	11707 (31.7%)	5739 (8.3%)	0	26799 (18.3%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 12: Concomitant diseases by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA N=522 (100%)	BULGARIA N=291 (100%)	SWITZERLAND N=1404 (100%)	CHINA N=36928 (100%)	GERMANY N=45618 (100%)	ESTONIA N=173 (100%)	EGYPT N=298 (100%)	SPAIN N=1906 (100%)	FINLAND N=443 (100%)
Number (%) of patients with at least one concomitant disease finding	522 (100.0%)	141 (48.5%)	232 (16.5%)	25841 (70.0%)	13533 (29.7%)	19 (11.0%)	125 (41.9%)	536 (28.1%)	40 (9.0%)
Hypertension arterial	253 (48.5%)	0	0	11169 (30.2%)	1558 (3.4%)	0	0	0	0
Coronary heart disease	282 (54.0%)	58 (19.9%)	45 (3.2%)	1396 (3.8%)	3249 (7.1%)	6 (3.5%)	23 (7.7%)	186 (9.8%)	4 (0.9%)
Diabetes mellitus	132 (25.3%)	28 (9.6%)	40 (2.8%)	3989 (10.8%)	3143 (6.9%)	5 (2.9%)	23 (7.7%)	168 (8.8%)	14 (3.2%)
Reduced general condition	11 (2.1%)	9 (3.1%)	51 (3.6%)	3413 (9.2%)	1595 (3.5%)	0	5 (1.7%)	91 (4.8%)	1 (0.2%)
Specific contrast media risk factor	11 (2.1%)	10 (3.4%)	72 (5.1%)	977 (2.6%)	2191 (4.8%)	3 (1.7%)	42 (14.1%)	30 (1.6%)	14 (3.2%)
Allergy	6 (1.1%)	10 (3.4%)	70 (5.0%)	689 (1.9%)	1655 (3.6%)	3 (1.7%)	10 (3.4%)	28 (1.5%)	14 (3.2%)
Asthma bronchial	4 (0.8%)	0	0	156 (0.4%)	297 (0.7%)	0	0	0	0
Contrast media reaction	2 (0.4%)	0	3 (0.2%)	148 (0.4%)	342 (0.7%)	0	32 (10.7%)	3 (0.2%)	0
Other	119 (22.8%)	61 (21.0%)	89 (6.3%)	6780 (18.4%)	5659 (12.4%)	7 (4.0%)	50 (16.8%)	213 (11.2%)	12 (2.7%)
None specified	200 (38.3%)	0	0	11707 (31.7%)	1294 (2.8%)	0	0	0	0

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 12: Concomitant diseases by country/region (Full analysis set for country/region) (cont.)

	CROATIA N=432 (100%)	HUNGARY N=219 (100%)	INDONESIA N=692 (100%)	IRAN N=5088 (100%)	ITALY N=695 (100%)	JORDAN N=1668 (100%)	KOREA (SOUTH) N=13745 (100%)	LITHUANIA N=2380 (100%)	LATVIA N=399 (100%)	MOLDOVA N=358 (100%)
Number (%) of patients with at least one concomitant disease finding	140 (32.4%)	166 (75.8%)	458 (66.2%)	1344 (26.4%)	493 (70.9%)	1136 (68.1%)	5129 (37.3%)	980 (41.2%)	36 (9.0%)	358 (100.0%)
Hypertension arterial	0	88 (40.2%)	45 (6.5%)	409 (8.0%)	148 (21.3%)	0	383 (2.8%)	0	0	209 (58.4%)
Coronary heart disease	32 (7.4%)	61 (27.9%)	72 (10.4%)	326 (6.4%)	36 (5.2%)	977 (58.6%)	617 (4.5%)	759 (31.9%)	15 (3.8%)	14 (3.9%)
Diabetes mellitus	27 (6.3%)	48 (21.9%)	31 (4.5%)	206 (4.0%)	64 (9.2%)	221 (13.2%)	562 (4.1%)	79 (3.3%)	16 (4.0%)	15 (4.2%)
Reduced general condition	49 (11.3%)	1 (0.5%)	33 (4.8%)	140 (2.8%)	10 (1.4%)	2 (0.1%)	176 (1.3%)	47 (2.0%)	0	38 (10.6%)
Specific contrast media risk factor	23 (5.3%)	27 (12.3%)	13 (1.9%)	210 (4.1%)	65 (9.4%)	2 (0.1%)	195 (1.4%)	41 (1.7%)	2 (0.5%)	3 (0.8%)
Allergy	23 (5.3%)	24 (11.0%)	5 (0.7%)	116 (2.3%)	53 (7.6%)	2 (0.1%)	144 (1.0%)	30 (1.3%)	2 (0.5%)	3 (0.8%)
Asthma bronchial	0	5 (2.3%)	8 (1.2%)	100 (2.0%)	10 (1.4%)	0	27 (0.2%)	0	0	1 (0.3%)
Contrast media reaction	0	1 (0.5%)	0	9 (0.2%)	6 (0.9%)	0	28 (0.2%)	12 (0.5%)	0	1 (0.3%)
Other	50 (11.6%)	37 (16.9%)	69 (10.0%)	496 (9.7%)	96 (13.8%)	266 (15.9%)	2201 (16.0%)	331 (13.9%)	3 (0.8%)	171 (47.8%)
None specified	0	113 (51.6%)	342 (49.4%)	82 (1.6%)	355 (51.1%)	0	3425 (24.9%)	0	0	343 (95.8%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

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Table 14.2 / 12: Concomitant diseases by country/region (Full analysis set for country/region) (cont.)

	MALAYSIA N=863 (100%)	PHILIPPINES N=4175 (100%)	PAKISTAN N=1398 (100%)	POLAND N=2749 (100%)	ROMANIA N=2397 (100%)	REPUBLIC OF SERBIA N=682 (100%)	RUSSIA N=614 (100%)	SAUDI ARABIA N=742 (100%)	SINGAPORE N=1657 (100%)	SLOVENIA N=4787 (100%)
Number (%) of patients with at least one concomitant disease finding	816 (94.6%)	2562 (61.4%)	1138 (81.4%)	2246 (81.7%)	1298 (54.2%)	201 (29.5%)	565 (92.0%)	358 (48.2%)	1090 (65.8%)	884 (18.5%)
Hypertension arterial	387 (44.8%)	374 (9.0%)	132 (9.4%)	649 (23.6%)	493 (20.6%)	0	209 (34.0%)	6 (0.8%)	305 (18.4%)	0
Coronary heart disease	409 (47.4%)	442 (10.6%)	17 (1.2%)	787 (28.6%)	934 (39.0%)	134 (19.6%)	73 (11.9%)	264 (35.6%)	60 (3.6%)	110 (2.3%)
Diabetes mellitus	266 (30.8%)	325 (7.8%)	121 (8.7%)	280 (10.2%)	223 (9.3%)	20 (2.9%)	35 (5.7%)	73 (9.8%)	144 (8.7%)	335 (7.0%)
Reduced general condition	5 (0.6%)	134 (3.2%)	269 (19.2%)	186 (6.8%)	48 (2.0%)	19 (2.8%)	43 (7.0%)	11 (1.5%)	1 (<0.1%)	352 (7.4%)
Specific contrast media risk factor	83 (9.6%)	297 (7.1%)	68 (4.9%)	213 (7.7%)	33 (1.4%)	32 (4.7%)	37 (6.0%)	15 (2.0%)	67 (4.0%)	71 (1.5%)
Allergy	48 (5.6%)	238 (5.7%)	21 (1.5%)	122 (4.4%)	26 (1.1%)	26 (3.8%)	25 (4.1%)	6 (0.8%)	15 (0.9%)	64 (1.3%)
Asthma bronchial	38 (4.4%)	56 (1.3%)	37 (2.6%)	55 (2.0%)	9 (0.4%)	0	10 (1.6%)	9 (1.2%)	51 (3.1%)	0
Contrast media reaction	1 (0.1%)	20 (0.5%)	11 (0.8%)	46 (1.7%)	1 (<0.1%)	6 (0.9%)	2 (0.3%)	0	2 (0.1%)	7 (0.1%)
Other	380 (44.0%)	750 (18.0%)	141 (10.1%)	1104 (40.2%)	340 (14.2%)	10 (1.5%)	106 (17.3%)	53 (7.1%)	323 (19.5%)	260 (5.4%)
None specified	713 (82.6%)	1550 (37.1%)	1055 (75.5%)	1217 (44.3%)	416 (17.4%)	0	514 (83.7%)	17 (2.3%)	863 (52.1%)	0

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

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Table 14.2 / 12: Concomitant diseases by country/region (Full analysis set for country/region) (cont.)

	SLOVAKIA N=1255 (100%)	THAILAND N=562 (100%)	TURKEY N=332 (100%)	TAIWAN N=768 (100%)	UKRAINE N=1905 (100%)	UNITED STATES N=6791 (100%)	VIETNAM N=1613 (100%)	SOUTH AFRICA N=100 (100%)	Total N=146649 (100%)
Number (%) of patients with at least one concomitant disease finding	288 (22.9%)	310 (55.2%)	152 (45.8%)	476 (62.0%)	1575 (82.7%)	2270 (33.4%)	847 (52.5%)	74 (74.0%)	68379 (46.6%)
Hypertension arterial	0	42 (7.5%)	0	134 (17.4%)	567 (29.8%)	0	19 (1.2%)	0	17579 (12.0%)
Coronary heart disease	91 (7.3%)	8 (1.4%)	52 (15.7%)	17 (2.2%)	268 (14.1%)	624 (9.2%)	5 (0.3%)	62 (62.0%)	12515 (8.5%)
Diabetes mellitus	85 (6.8%)	56 (10.0%)	25 (7.5%)	72 (9.4%)	73 (3.8%)	428 (6.3%)	8 (0.5%)	8 (8.0%)	11388 (7.8%)
Reduced general condition	49 (3.9%)	26 (4.6%)	29 (8.7%)	26 (3.4%)	385 (20.2%)	127 (1.9%)	26 (1.6%)	5 (5.0%)	7413 (5.1%)
Specific contrast media risk factor	48 (3.8%)	42 (7.5%)	32 (9.6%)	102 (13.3%)	141 (7.4%)	568 (8.4%)	28 (1.7%)	10 (10.0%)	5818 (4.0%)
Allergy	48 (3.8%)	26 (4.6%)	26 (7.8%)	75 (9.8%)	100 (5.2%)	529 (7.8%)	24 (1.5%)	9 (9.0%)	4315 (2.9%)
Asthma bronchial	0	8 (1.4%)	0	17 (2.2%)	16 (0.8%)	0	3 (0.2%)	0	917 (0.6%)
Contrast media reaction	0	10 (1.8%)	6 (1.8%)	12 (1.6%)	43 (2.3%)	48 (0.7%)	1 (<0.1%)	1 (1.0%)	804 (0.5%)
Other	143 (11.4%)	65 (11.6%)	48 (14.5%)	57 (7.4%)	133 (7.0%)	1176 (17.3%)	56 (3.5%)	11 (11.0%)	21866 (14.9%)
None specified	0	189 (33.6%)	0	289 (37.6%)	1287 (67.6%)	0	828 (51.3%)	0	26799 (18.3%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

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Table 14.2 / 13: Concomitant diseases by sex (Complete cases analysis set for sex)

	Male N=74986 (100%)	Female N=57864 (100%)	Total N=132850 (100%)
Number (%) of patients with at least one concomitant disease finding	36675 (48.9%)	25730 (44.5%)	62405 (47.0%)
Hypertension arterial	10229 (13.6%)	6490 (11.2%)	16719 (12.6%)
Coronary heart disease	7495 (10.0%)	3748 (6.5%)	11243 (8.5%)
Diabetes mellitus	6098 (8.1%)	4286 (7.4%)	10384 (7.8%)
Reduced general condition	3961 (5.3%)	2971 (5.1%)	6932 (5.2%)
Specific contrast media risk factor	2324 (3.1%)	2583 (4.5%)	4907 (3.7%)
Allergy	1583 (2.1%)	1976 (3.4%)	3559 (2.7%)
Asthma bronchial	462 (0.6%)	358 (0.6%)	820 (0.6%)
Contrast media reaction	362 (0.5%)	355 (0.6%)	717 (0.5%)
Other	11189 (14.9%)	8145 (14.1%)	19334 (14.6%)
None specified	14305 (19.1%)	10520 (18.2%)	24825 (18.7%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

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Table 14.2 / 14: Concomitant diseases by race (Complete cases analysis set for race)

	Asian N=49621 (100%)	White N=6182 (100%)	Black N=24 (100%)	Other N=164 (100%)	Total N=55991 (100%)
Number (%) of patients with at least one concomitant disease finding	36121 (72.8%)	5501 (89.0%)	18 (75.0%)	116 (70.7%)	41756 (74.6%)
Hypertension arterial	12896 (26.0%)	2300 (37.2%)	3 (12.5%)	8 (4.9%)	15207 (27.2%)
Diabetes mellitus	4933 (9.9%)	663 (10.7%)	0	9 (5.5%)	5605 (10.0%)
Coronary heart disease	2633 (5.3%)	1818 (29.4%)	2 (8.3%)	9 (5.5%)	4462 (8.0%)
Reduced general condition	3810 (7.7%)	473 (7.7%)	1 (4.2%)	5 (3.0%)	4289 (7.7%)
Specific contrast media risk factor	1520 (3.1%)	316 (5.1%)	1 (4.2%)	10 (6.1%)	1847 (3.3%)
Allergy	985 (2.0%)	201 (3.3%)	0	1 (0.6%)	1187 (2.1%)
Asthma bronchial	387 (0.8%)	108 (1.7%)	1 (4.2%)	9 (5.5%)	505 (0.9%)
Contrast media reaction	183 (0.4%)	29 (0.5%)	0	0	212 (0.4%)
Other	9761 (19.7%)	1547 (25.0%)	2 (8.3%)	53 (32.3%)	11363 (20.3%)
None specified	20658 (41.6%)	3903 (63.1%)	13 (54.2%)	86 (52.4%)	24660 (44.0%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 15: Concomitant diseases by geographical region (Complete cases analysis set for geographical region)

	Africa N=387 (100%)	Asia (excl. China) N=32096 (100%)	China N=36787 (100%)	Europe N=63580 (100%)	Total N=132850 (100%)
Number (%) of patients with at least one concomitant disease finding	194 (50.1%)	15261 (47.5%)	25753 (70.0%)	21197 (33.3%)	62405 (47.0%)
Hypertension arterial	0	2191 (6.8%)	11117 (30.2%)	3411 (5.4%)	16719 (12.6%)
Coronary heart disease	84 (21.7%)	3144 (9.8%)	1393 (3.8%)	6622 (10.4%)	11243 (8.5%)
Diabetes mellitus	30 (7.8%)	2032 (6.3%)	3973 (10.8%)	4349 (6.8%)	10384 (7.8%)
Reduced general condition	8 (2.1%)	787 (2.5%)	3407 (9.3%)	2730 (4.3%)	6932 (5.2%)
Specific contrast media risk factor	51 (13.2%)	1097 (3.4%)	973 (2.6%)	2786 (4.4%)	4907 (3.7%)
Allergy	19 (4.9%)	705 (2.2%)	686 (1.9%)	2149 (3.4%)	3559 (2.7%)
Asthma bronchial	0	344 (1.1%)	155 (0.4%)	321 (0.5%)	820 (0.6%)
Contrast media reaction	32 (8.3%)	92 (0.3%)	148 (0.4%)	445 (0.7%)	717 (0.5%)
Other	60 (15.5%)	4752 (14.8%)	6758 (18.4%)	7764 (12.2%)	19334 (14.6%)
None specified	0	9131 (28.4%)	11682 (31.8%)	4012 (6.3%)	24825 (18.7%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 16: Concomitant diseases by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA N=513 (100%)	BULGARIA N=258 (100%)	SWITZERLAND N=1367 (100%)	CHINA N=36787 (100%)	GERMANY N=40766 (100%)	ESTONIA N=155 (100%)	EGYPT N=287 (100%)	SPAIN N=1827 (100%)	FINLAND N=417 (100%)
Number (%) of patients with at least one concomitant disease finding	513 (100.0%)	132 (51.2%)	226 (16.5%)	25753 (70.0%)	11026 (27.0%)	18 (11.6%)	120 (41.8%)	497 (27.2%)	35 (8.4%)
Hypertension arterial	246 (48.0%)	0	0	11117 (30.2%)	1063 (2.6%)	0	0	0	0
Coronary heart disease	277 (54.0%)	54 (20.9%)	44 (3.2%)	1393 (3.8%)	2820 (6.9%)	6 (3.9%)	22 (7.7%)	163 (8.9%)	3 (0.7%)
Diabetes mellitus	130 (25.3%)	27 (10.5%)	39 (2.9%)	3973 (10.8%)	2714 (6.7%)	5 (3.2%)	22 (7.7%)	158 (8.6%)	12 (2.9%)
Reduced general condition	11 (2.1%)	8 (3.1%)	47 (3.4%)	3407 (9.3%)	1415 (3.5%)	0	3 (1.0%)	87 (4.8%)	0
Specific contrast media risk factor	11 (2.1%)	10 (3.9%)	71 (5.2%)	973 (2.6%)	1905 (4.7%)	3 (1.9%)	41 (14.3%)	28 (1.5%)	14 (3.4%)
Allergy	6 (1.2%)	10 (3.9%)	69 (5.0%)	686 (1.9%)	1472 (3.6%)	3 (1.9%)	10 (3.5%)	26 (1.4%)	14 (3.4%)
Asthma bronchial	4 (0.8%)	0	0	155 (0.4%)	211 (0.5%)	0	0	0	0
Contrast media reaction	2 (0.4%)	0	3 (0.2%)	148 (0.4%)	309 (0.8%)	0	31 (10.8%)	3 (0.2%)	0
Other	118 (23.0%)	56 (21.7%)	86 (6.3%)	6758 (18.4%)	4739 (11.6%)	6 (3.9%)	49 (17.1%)	202 (11.1%)	10 (2.4%)
None specified	198 (38.6%)	0	0	11682 (31.8%)	7 (<0.1%)	0	0	0	0

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 16: Concomitant diseases by country/region (Complete cases analysis set for country/region) (cont.)

	CROATIA N=387 (100%)	HUNGARY N=217 (100%)	INDONESIA N=656 (100%)	IRAN N=5012 (100%)	ITALY N=683 (100%)	JORDAN N=1572 (100%)	KOREA (SOUTH) N=13731 (100%)	LITHUANIA N=2335 (100%)	LATVIA N=399 (100%)	MOLDOVA N=10 (100%)
Number (%) of patients with at least one concomitant disease finding	119 (30.7%)	164 (75.6%)	448 (68.3%)	1320 (26.3%)	485 (71.0%)	1092 (69.5%)	5122 (37.3%)	949 (40.6%)	36 (9.0%)	10 (100.0%)
Hypertension arterial	0	87 (40.1%)	43 (6.6%)	403 (8.0%)	146 (21.4%)	0	382 (2.8%)	0	0	1 (10.0%)
Coronary heart disease	28 (7.2%)	61 (28.1%)	71 (10.8%)	319 (6.4%)	36 (5.3%)	954 (60.7%)	616 (4.5%)	756 (32.4%)	15 (3.8%)	5 (50.0%)
Diabetes mellitus	21 (5.4%)	47 (21.7%)	31 (4.7%)	201 (4.0%)	62 (9.1%)	216 (13.7%)	561 (4.1%)	77 (3.3%)	16 (4.0%)	2 (20.0%)
Reduced general condition	42 (10.9%)	1 (0.5%)	33 (5.0%)	136 (2.7%)	10 (1.5%)	2 (0.1%)	176 (1.3%)	36 (1.5%)	0	0
Specific contrast media risk factor	22 (5.7%)	25 (11.5%)	13 (2.0%)	208 (4.2%)	65 (9.5%)	2 (0.1%)	195 (1.4%)	41 (1.8%)	2 (0.5%)	3 (30.0%)
Allergy	22 (5.7%)	22 (10.1%)	5 (0.8%)	114 (2.3%)	53 (7.8%)	2 (0.1%)	144 (1.0%)	30 (1.3%)	2 (0.5%)	3 (30.0%)
Asthma bronchial	0	5 (2.3%)	8 (1.2%)	100 (2.0%)	10 (1.5%)	0	27 (0.2%)	0	0	1 (10.0%)
Contrast media reaction	0	1 (0.5%)	0	9 (0.2%)	6 (0.9%)	0	28 (0.2%)	12 (0.5%)	0	1 (10.0%)
Other	41 (10.6%)	36 (16.6%)	67 (10.2%)	487 (9.7%)	92 (13.5%)	243 (15.5%)	2199 (16.0%)	305 (13.1%)	3 (0.8%)	6 (60.0%)
None specified	0	111 (51.2%)	334 (50.9%)	82 (1.6%)	351 (51.4%)	0	3421 (24.9%)	0	0	10 (100.0%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 16: Concomitant diseases by country/region (Complete cases analysis set for country/region) (cont.)

	MALAYSIA N=859 (100%)	PHILIPPINES N=3987 (100%)	PAKISTAN N=1153 (100%)	POLAND N=2713 (100%)	ROMANIA N=2245 (100%)	REPUBLIC OF SERBIA N=656 (100%)	RUSSIA N=599 (100%)	SAUDI ARABIA N=680 (100%)	SINGAPORE N=1639 (100%)	SLOVENIA N=4688 (100%)
Number (%) of patients with at least one concomitant disease finding	813 (94.6%)	2471 (62.0%)	975 (84.6%)	2211 (81.5%)	1202 (53.5%)	196 (29.9%)	553 (92.3%)	335 (49.3%)	1079 (65.8%)	868 (18.5%)
Hypertension arterial	387 (45.1%)	361 (9.1%)	112 (9.7%)	649 (23.9%)	454 (20.2%)	0	207 (34.6%)	6 (0.9%)	303 (18.5%)	0
Coronary heart disease	409 (47.6%)	425 (10.7%)	15 (1.3%)	763 (28.1%)	876 (39.0%)	131 (20.0%)	72 (12.0%)	246 (36.2%)	60 (3.7%)	110 (2.3%)
Diabetes mellitus	266 (31.0%)	315 (7.9%)	100 (8.7%)	273 (10.1%)	204 (9.1%)	19 (2.9%)	35 (5.8%)	67 (9.9%)	143 (8.7%)	330 (7.0%)
Reduced general condition	4 (0.5%)	130 (3.3%)	217 (18.8%)	174 (6.4%)	41 (1.8%)	18 (2.7%)	41 (6.8%)	10 (1.5%)	1 (<0.1%)	345 (7.4%)
Specific contrast media risk factor	82 (9.5%)	287 (7.2%)	61 (5.3%)	212 (7.8%)	24 (1.1%)	32 (4.9%)	37 (6.2%)	15 (2.2%)	66 (4.0%)	70 (1.5%)
Allergy	48 (5.6%)	230 (5.8%)	20 (1.7%)	121 (4.5%)	17 (0.8%)	26 (4.0%)	25 (4.2%)	6 (0.9%)	15 (0.9%)	63 (1.3%)
Asthma bronchial	37 (4.3%)	54 (1.4%)	31 (2.7%)	55 (2.0%)	9 (0.4%)	0	10 (1.7%)	9 (1.3%)	50 (3.1%)	0
Contrast media reaction	1 (0.1%)	18 (0.5%)	11 (1.0%)	46 (1.7%)	0	6 (0.9%)	2 (0.3%)	0	2 (0.1%)	7 (0.1%)
Other	378 (44.0%)	711 (17.8%)	126 (10.9%)	1098 (40.5%)	287 (12.8%)	9 (1.4%)	105 (17.5%)	47 (6.9%)	320 (19.5%)	255 (5.4%)
None specified	710 (82.7%)	1509 (37.8%)	921 (79.9%)	1216 (44.8%)	360 (16.0%)	0	502 (83.8%)	17 (2.5%)	853 (52.0%)	0

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 16: Concomitant diseases by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVAKIA N=1187 (100%)	THAILAND N=538 (100%)	TURKEY N=319 (100%)	TAIWAN N=763 (100%)	UKRAINE N=1839 (100%)	VIETNAM N=1506 (100%)	SOUTH AFRICA N=100 (100%)	Total N=132850 (100%)
Number (%) of patients with at least one concomitant disease finding	274 (23.1%)	299 (55.6%)	149 (46.7%)	473 (62.0%)	1534 (83.4%)	834 (55.4%)	74 (74.0%)	62405 (47.0%)
Hypertension arterial	0	42 (7.8%)	0	133 (17.4%)	558 (30.3%)	19 (1.3%)	0	16719 (12.6%)
Coronary heart disease	88 (7.4%)	7 (1.3%)	52 (16.3%)	17 (2.2%)	262 (14.2%)	5 (0.3%)	62 (62.0%)	11243 (8.5%)
Diabetes mellitus	82 (6.9%)	54 (10.0%)	24 (7.5%)	70 (9.2%)	72 (3.9%)	8 (0.5%)	8 (8.0%)	10384 (7.8%)
Reduced general condition	47 (4.0%)	26 (4.8%)	28 (8.8%)	26 (3.4%)	379 (20.6%)	26 (1.7%)	5 (5.0%)	6932 (5.2%)
Specific contrast media risk factor	43 (3.6%)	41 (7.6%)	32 (10.0%)	102 (13.4%)	136 (7.4%)	25 (1.7%)	10 (10.0%)	4907 (3.7%)
Allergy	43 (3.6%)	25 (4.6%)	26 (8.2%)	75 (9.8%)	96 (5.2%)	21 (1.4%)	9 (9.0%)	3559 (2.7%)
Asthma bronchial	0	8 (1.5%)	0	17 (2.2%)	16 (0.9%)	3 (0.2%)	0	820 (0.6%)
Contrast media reaction	0	10 (1.9%)	6 (1.9%)	12 (1.6%)	41 (2.2%)	1 (<0.1%)	1 (1.0%)	717 (0.5%)
Other	135 (11.4%)	63 (11.7%)	47 (14.7%)	56 (7.3%)	128 (7.0%)	55 (3.7%)	11 (11.0%)	19334 (14.6%)
None specified	0	181 (33.6%)	0	287 (37.6%)	1257 (68.4%)	816 (54.2%)	0	24825 (18.7%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.2 / 17: Pre-treatment by sex (Full analysis set for sex)

	Male N=80816 (100%)	Female N=64217 (100%)	Total N=145033 (100%)
Corticosteroids	6497 (8.0%)	4184 (6.5%)	10681 (7.4%)
H1/H2 Blocker	2145 (2.7%)	1495 (2.3%)	3640 (2.5%)
H1/H2 Blocker or Corticosteroids	17 (<0.1%)	18 (<0.1%)	35 (<0.1%)
Other	3885 (4.8%)	2122 (3.3%)	6007 (4.1%)
None specified	129 (0.2%)	139 (0.2%)	268 (0.2%)

Multiple responses possible.
Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18
End of table

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Table 14.2 / 18: Pre-treatment by race (Full analysis set for race)

	Asian N=50217 (100%)	White N=8984 (100%)	Black N=30 (100%)	Other N=181 (100%)	Total N=59412 (100%)
Corticosteroids	8428 (16.8%)	99 (1.1%)	1 (3.3%)	9 (5.0%)	8537 (14.4%)
H1/H2 Blocker	324 (0.6%)	148 (1.6%)	0	0	472 (0.8%)
Other	2720 (5.4%)	218 (2.4%)	0	0	2938 (4.9%)
None specified	48 (<0.1%)	188 (2.1%)	0	1 (0.6%)	237 (0.4%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 19: Pre-treatment by geographical region (Full analysis set for geographical region)

	Africa N=398 (100%)	Asia (excl. China) N=32971 (100%)	China N=36928 (100%)	Europe N=69561 (100%)	North America N=6791 (100%)	Total N=146649 (100%)
Corticosteroids	6 (1.5%)	1728 (5.2%)	8003 (21.7%)	927 (1.3%)	79 (1.2%)	10743 (7.3%)
H1/H2 Blocker	19 (4.8%)	1845 (5.6%)	221 (0.6%)	1411 (2.0%)	202 (3.0%)	3698 (2.5%)
H1/H2 Blocker or Corticosteroids	0	3 (<0.1%)	0	33 (<0.1%)	0	36 (<0.1%)
Other	102 (25.6%)	2840 (8.6%)	870 (2.4%)	2249 (3.2%)	15 (0.2%)	6076 (4.1%)
None specified	0	55 (0.2%)	3 (<0.1%)	215 (0.3%)	0	273 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 20: Pre-treatment by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA N=522 (100%)	BULGARIA N=291 (100%)	SWITZERLAND N=1404 (100%)	CHINA N=36928 (100%)	GERMANY N=45618 (100%)	ESTONIA N=173 (100%)	EGYPT N=298 (100%)	SPAIN N=1906 (100%)	FINLAND N=443 (100%)
Corticosteroids	3 (0.6%)	5 (1.7%)	36 (2.6%)	8003 (21.7%)	341 (0.7%)	0	5 (1.7%)	18 (0.9%)	1 (0.2%)
H1/H2 Blocker	48 (9.2%)	3 (1.0%)	17 (1.2%)	221 (0.6%)	693 (1.5%)	2 (1.2%)	19 (6.4%)	65 (3.4%)	0
H1/H2 Blocker or Corticosteroids	0	0	0	0	33 (<0.1%)	0	0	0	0
Other	110 (21.1%)	30 (10.3%)	6 (0.4%)	870 (2.4%)	885 (1.9%)	0	2 (0.7%)	72 (3.8%)	0
None specified	0	0	0	3 (<0.1%)	28 (<0.1%)	0	0	0	0

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 20: Pre-treatment by country/region (Full analysis set for country/region) (cont.)

	CROATIA N=432 (100%)	HUNGARY N=219 (100%)	INDONESIA N=692 (100%)	IRAN N=5088 (100%)	ITALY N=695 (100%)	JORDAN N=1668 (100%)	KOREA (SOUTH) N=13745 (100%)	LITHUANIA N=2380 (100%)	LATVIA N=399 (100%)	MOLDOVA N=358 (100%)
Corticosteroids	6 (1.4%)	0	28 (4.0%)	39 (0.8%)	28 (4.0%)	686 (41.1%)	304 (2.2%)	21 (0.9%)	0	1 (0.3%)
H1/H2 Blocker	0	0	3 (0.4%)	35 (0.7%)	18 (2.6%)	641 (38.4%)	882 (6.4%)	15 (0.6%)	0	58 (16.2%)
H1/H2 Blocker or Corticosteroids	0	0	0	3 (<0.1%)	0	0	0	0	0	0
Other	12 (2.8%)	27 (12.3%)	64 (9.2%)	48 (0.9%)	1 (0.1%)	437 (26.2%)	1141 (8.3%)	732 (30.8%)	0	33 (9.2%)
None specified	0	0	0	3 (<0.1%)	1 (0.1%)	0	0	0	0	1 (0.3%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 20: Pre-treatment by country/region (Full analysis set for country/region) (cont.)

	MALAYSIA N=863 (100%)	PHILIPPINES N=4175 (100%)	PAKISTAN N=1398 (100%)	POLAND N=2749 (100%)	ROMANIA N=2397 (100%)	REPUBLIC OF SERBIA N=682 (100%)	RUSSIA N=614 (100%)	SAUDI ARABIA N=742 (100%)	SINGAPORE N=1657 (100%)
Corticosteroids	96 (11.1%)	328 (7.9%)	28 (2.0%)	27 (1.0%)	165 (6.9%)	12 (1.8%)	6 (1.0%)	77 (10.4%)	68 (4.1%)
H1/H2 Blocker	2 (0.2%)	229 (5.5%)	4 (0.3%)	26 (0.9%)	11 (0.5%)	24 (3.5%)	2 (0.3%)	36 (4.9%)	0
H1/H2 Blocker or Corticosteroids	0	0	0	0	0	0	0	0	0
Other	503 (58.3%)	329 (7.9%)	56 (4.0%)	79 (2.9%)	0	211 (30.9%)	17 (2.8%)	220 (29.6%)	3 (0.2%)
None specified	0	25 (0.6%)	25 (1.8%)	0	3 (0.1%)	0	21 (3.4%)	1 (0.1%)	1 (<0.1%)

Multiple responses possible.

Baycr: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 20: Pre-treatment by country/region (Full analysis set for country/region) (cont.)

	SLOVENIA N=4787 (100%)	SLOVAKIA N=1255 (100%)	THAILAND N=562 (100%)	TURKEY N=332 (100%)	TAIWAN N=768 (100%)	UKRAINE N=1905 (100%)	UNITED STATES N=6791 (100%)	VIETNAM N=1613 (100%)	SOUTH AFRICA N=100 (100%)	Total N=146649 (100%)
Corticosteroids	22 (0.5%)	154 (12.3%)	58 (10.3%)	28 (8.4%)	10 (1.3%)	53 (2.8%)	79 (1.2%)	6 (0.4%)	1 (1.0%)	10743 (7.3%)
H1/H2 Blocker	43 (0.9%)	362 (28.8%)	10 (1.8%)	21 (6.3%)	1 (0.1%)	3 (0.2%)	202 (3.0%)	2 (0.1%)	0	3698 (2.5%)
H1/H2 Blocker or Corticosteroids	0	0	0	0	0	0	0	0	0	36 (<0.1%)
Other	13 (0.3%)	5 (0.4%)	19 (3.4%)	2 (0.6%)	20 (2.6%)	14 (0.7%)	15 (0.2%)	0	100 (100.0%)	6076 (4.1%)
None specified	0	0	0	0	0	161 (8.5%)	0	0	0	273 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 21: Pre-treatment by sex (Complete cases analysis set for sex)

	Male N=74986 (100%)	Female N=57864 (100%)	Total N=132850 (100%)
Corticosteroids	6424 (8.6%)	4078 (7.0%)	10502 (7.9%)
H1/H2 Blocker	1960 (2.6%)	1322 (2.3%)	3282 (2.5%)
H1/H2 Blocker or Corticosteroids	16 (<0.1%)	18 (<0.1%)	34 (<0.1%)
Other	3754 (5.0%)	2041 (3.5%)	5795 (4.4%)
None specified	121 (0.2%)	131 (0.2%)	252 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 22: Pre-treatment by race (Complete cases analysis set for race)

	Asian N=49621 (100%)	White N=6182 (100%)	Black N=24 (100%)	Other N=164 (100%)	Total N=55991 (100%)
Corticosteroids	8382 (16.9%)	76 (1.2%)	1 (4.2%)	9 (5.5%)	8468 (15.1%)
H1/H2 Blocker	319 (0.6%)	79 (1.3%)	0	0	398 (0.7%)
Other	2690 (5.4%)	167 (2.7%)	0	0	2857 (5.1%)
None specified	40 (<0.1%)	182 (2.9%)	0	0	222 (0.4%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 23: Pre-treatment by geographical region (Complete cases analysis set for geographical region)

	Africa N=387 (100%)	Asia (excl. China) N=32096 (100%)	China N=36787 (100%)	Europe N=63580 (100%)	Total N=132850 (100%)
Corticosteroids	6 (1.6%)	1669 (5.2%)	7970 (21.7%)	857 (1.3%)	10502 (7.9%)
H1/H2 Blocker	17 (4.4%)	1786 (5.6%)	219 (0.6%)	1260 (2.0%)	3282 (2.5%)
H1/H2 Blocker or Corticosteroids	0	3 (<0.1%)	0	31 (<0.1%)	34 (<0.1%)
Other	102 (26.4%)	2774 (8.6%)	868 (2.4%)	2051 (3.2%)	5795 (4.4%)
None specified	0	44 (0.1%)	3 (<0.1%)	205 (0.3%)	252 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 24: Pre-treatment by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA N=513 (100%)	BULGARIA N=258 (100%)	SWITZERLAND N=1367 (100%)	CHINA N=36787 (100%)	GERMANY N=40766 (100%)	ESTONIA N=155 (100%)	EGYPT N=287 (100%)	SPAIN N=1827 (100%)	FINLAND N=417 (100%)
Corticosteroids	3 (0.6%)	5 (1.9%)	33 (2.4%)	7970 (21.7%)	304 (0.7%)	0	5 (1.7%)	18 (1.0%)	1 (0.2%)
H1/H2 Blocker	48 (9.4%)	3 (1.2%)	17 (1.2%)	219 (0.6%)	629 (1.5%)	2 (1.3%)	17 (5.9%)	52 (2.8%)	0
H1/H2 Blocker or Corticosteroids	0	0	0	0	31 (<0.1%)	0	0	0	0
Other	110 (21.4%)	30 (11.6%)	6 (0.4%)	868 (2.4%)	777 (1.9%)	0	2 (0.7%)	48 (2.6%)	0
None specified	0	0	0	3 (<0.1%)	22 (<0.1%)	0	0	0	0

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 24: Pre-treatment by country/region (Complete cases analysis set for country/region) (cont.)

	CROATIA N=387 (100%)	HUNGARY N=217 (100%)	INDONESIA N=656 (100%)	IRAN N=5012 (100%)	ITALY N=683 (100%)	JORDAN N=1572 (100%)	KOREA (SOUTH) N=13731 (100%)	LITHUANIA N=2335 (100%)	LATVIA N=399 (100%)	MOLDOVA N=10 (100%)
Corticosteroids	5 (1.3%)	0	28 (4.3%)	39 (0.8%)	27 (4.0%)	656 (41.7%)	304 (2.2%)	21 (0.9%)	0	0
H1/H2 Blocker	0	0	3 (0.5%)	35 (0.7%)	17 (2.5%)	611 (38.9%)	882 (6.4%)	15 (0.6%)	0	1 (10.0%)
H1/H2 Blocker or Corticosteroids	0	0	0	3 (<0.1%)	0	0	0	0	0	0
Other	10 (2.6%)	26 (12.0%)	62 (9.5%)	48 (1.0%)	1 (0.1%)	428 (27.2%)	1140 (8.3%)	715 (30.6%)	0	0
None specified	0	0	0	3 (<0.1%)	1 (0.1%)	0	0	0	0	1 (10.0%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 24: Pre-treatment by country/region (Complete cases analysis set for country/region) (cont.)

	MALAYSIA N=859 (100%)	PHILIPPINES N=3987 (100%)	PAKISTAN N=1153 (100%)	POLAND N=2713 (100%)	ROMANIA N=2245 (100%)	REPUBLIC OF SERBIA N=656 (100%)	RUSSIA N=599 (100%)	SAUDI ARABIA N=680 (100%)	SINGAPORE N=1639 (100%)
Corticosteroids	95 (11.1%)	306 (7.7%)	27 (2.3%)	27 (1.0%)	160 (7.1%)	12 (1.8%)	6 (1.0%)	75 (11.0%)	66 (4.0%)
H1/H2 Blocker	2 (0.2%)	207 (5.2%)	4 (0.3%)	26 (1.0%)	10 (0.4%)	24 (3.7%)	2 (0.3%)	29 (4.3%)	0
H1/H2 Blocker or Corticosteroids	0	0	0	0	0	0	0	0	0
Other	501 (58.3%)	300 (7.5%)	48 (4.2%)	75 (2.8%)	0	204 (31.1%)	17 (2.8%)	206 (30.3%)	2 (0.1%)
None specified	0	21 (0.5%)	18 (1.6%)	0	2 (<0.1%)	0	21 (3.5%)	1 (0.1%)	1 (<0.1%)

Multiple responses possible.

Baycr: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 24: Pre-treatment by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVENIA N=4688 (100%)	SLOVAKIA N=1187 (100%)	THAILAND N=538 (100%)	TURKEY N=319 (100%)	TAIWAN N=763 (100%)	UKRAINE N=1839 (100%)	VIETNAM N=1506 (100%)	SOUTH AFRICA N=100 (100%)	Total N=132850 (100%)
Corticosteroids	22 (0.5%)	147 (12.4%)	57 (10.6%)	27 (8.5%)	10 (1.3%)	39 (2.1%)	6 (0.4%)	1 (1.0%)	10502 (7.9%)
H1/H2 Blocker	43 (0.9%)	349 (29.4%)	10 (1.9%)	19 (6.0%)	1 (0.1%)	3 (0.2%)	2 (0.1%)	0	3282 (2.5%)
H1/H2 Blocker or Corticosteroids	0	0	0	0	0	0	0	0	34 (<0.1%)
Other	12 (0.3%)	5 (0.4%)	19 (3.5%)	2 (0.6%)	20 (2.6%)	13 (0.7%)	0	100 (100.0%)	5795 (4.4%)
None specified	0	0	0	0	0	158 (8.6%)	0	0	252 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.2 / 25: Exposure by sex (Full analysis set for sex)

	Male (N=80816)	Female (N=64217)	Total (N=145033)
Injection route			
Intravenous	61779 (76.4%)	54135 (84.3%)	115914 (79.9%)
Intra-arterial	18580 (23.0%)	9751 (15.2%)	28331 (19.5%)
Other	214 (0.3%)	183 (0.3%)	397 (0.3%)
Not specified	175 (0.2%)	127 (0.2%)	302 (0.2%)
Missing	68 (<0.1%)	21 (<0.1%)	89 (<0.1%)
Examination region ¹			
Abdomen	14834 (18.4%)	12039 (18.7%)	26873 (18.5%)
Cardiac / Cardiac Vessels	14958 (18.5%)	8059 (12.5%)	23017 (15.9%)
Thorax	8060 (10.0%)	5932 (9.2%)	13992 (9.6%)
Pelvis	3886 (4.8%)	4311 (6.7%)	8197 (5.7%)
Head / Brain	3273 (4.0%)	3391 (5.3%)	6664 (4.6%)
Kidney / Renal Vessels	2742 (3.4%)	1960 (3.1%)	4702 (3.2%)
Neck	1483 (1.8%)	1219 (1.9%)	2702 (1.9%)
Blood Vessels	1228 (1.5%)	723 (1.1%)	1951 (1.3%)
Limbs	273 (0.3%)	141 (0.2%)	414 (0.3%)
Joints	27 (<0.1%)	19 (<0.1%)	46 (<0.1%)
Other	690 (0.9%)	443 (0.7%)	1133 (0.8%)
Not specified	4 (<0.1%)	5 (<0.1%)	9 (<0.1%)
Missing	37836 (46.8%)	33271 (51.8%)	71107 (49.0%)
Indication ¹			
Tumour/Suspicion of Tumour	14798 (18.3%)	11662 (18.2%)	26460 (18.2%)
Pain	3962 (4.9%)	3581 (5.6%)	7543 (5.2%)
Post-Therapy-Control	4313 (5.3%)	3213 (5.0%)	7526 (5.2%)
Staging	3035 (3.8%)	2423 (3.8%)	5458 (3.8%)
Inflammatory Diseases	2402 (3.0%)	1976 (3.1%)	4378 (3.0%)
Infarct/Suspicion of Infarct	2186 (2.7%)	1278 (2.0%)	3464 (2.4%)
Haemorrhage	539 (0.7%)	409 (0.6%)	948 (0.7%)
Trauma	407 (0.5%)	209 (0.3%)	616 (0.4%)
Other	15192 (18.8%)	9304 (14.5%)	24496 (16.9%)
Not specified	26 (<0.1%)	33 (<0.1%)	59 (<0.1%)
Missing	38073 (47.1%)	33473 (52.1%)	71546 (49.3%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 25: Exposure by sex (Full analysis set for sex)

	Male (N=80816)	Female (N=64217)	Total (N=145033)
Dose [ml]			
n	80458	63932	144390
Nmiss	358	285	643
Mean (SD)	102.839 (49.129)	95.828 (39.822)	99.735 (45.378)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 120.000	75.000, 100.000	75.000, 110.000
Min, Max	1.00, 800.00	2.00, 600.00	1.00, 800.00
Dose			
<100 ml	32497 (40.2%)	27786 (43.3%)	60283 (41.6%)
100 - <150 ml	36539 (45.2%)	29819 (46.4%)	66358 (45.8%)
150 - <200 ml	7037 (8.7%)	4610 (7.2%)	11647 (8.0%)
200 - <300 ml	3223 (4.0%)	1308 (2.0%)	4531 (3.1%)
>=300 ml	1162 (1.4%)	409 (0.6%)	1571 (1.1%)
Not specified	358 (0.4%)	285 (0.4%)	643 (0.4%)
Dose of iodine [g]			
n	80458	63932	144390
Nmiss	358	285	643
Mean (SD)	33.834 (17.995)	30.901 (14.008)	32.536 (16.415)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	22.500, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	0.60, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	12637 (15.6%)	11576 (18.0%)	24213 (16.7%)
>20 - 40 g	51496 (63.7%)	42875 (66.8%)	94371 (65.1%)
>40 - 60 g	11681 (14.5%)	7712 (12.0%)	19393 (13.4%)
>60 g	4644 (5.7%)	1769 (2.8%)	6413 (4.4%)
Not specified	358 (0.4%)	285 (0.4%)	643 (0.4%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 25: Exposure by sex (Full analysis set for sex)

	Male (N=80816)	Female (N=64217)	Total (N=145033)
Type of examination			
CT	33034 (40.9%)	31626 (49.2%)	64660 (44.6%)
CT (multislice)	19102 (23.6%)	14016 (21.8%)	33118 (22.8%)
Angiocardiology ²	7741 (9.6%)	4814 (7.5%)	12555 (8.7%)
Urography	5784 (7.2%)	4899 (7.6%)	10683 (7.4%)
CT (singleslice)	2163 (2.7%)	1816 (2.8%)	3979 (2.7%)
Angiography	1259 (1.6%)	596 (0.9%)	1855 (1.3%)
Phlebography	127 (0.2%)	199 (0.3%)	326 (0.2%)
DSA	150 (0.2%)	113 (0.2%)	263 (0.2%)
PTCA	137 (0.2%)	39 (<0.1%)	176 (0.1%)
PTA	54 (<0.1%)	29 (<0.1%)	83 (<0.1%)
Other	4951 (6.1%)	2041 (3.2%)	6992 (4.8%)
Not specified	6314 (7.8%)	4029 (6.3%)	10343 (7.1%)
Contrast quality			
Excellent	41401 (51.2%)	32275 (50.3%)	73676 (50.8%)
Good	35154 (43.5%)	28373 (44.2%)	63527 (43.8%)
Adequate	3535 (4.4%)	3004 (4.7%)	6539 (4.5%)
Moderate	335 (0.4%)	216 (0.3%)	551 (0.4%)
Non diagnostic	34 (<0.1%)	24 (<0.1%)	58 (<0.1%)
Not specified	357 (0.4%)	325 (0.5%)	682 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 26: Exposure by race (Full analysis set for race)

	Asian (N=50217)	White (N=8984)	Black (N=30)	Other (N=181)	Total (N=59412)
Injection route					
Intravenous	31676 (63.1%)	6925 (77.1%)	28 (93.3%)	177 (97.8%)	38806 (65.3%)
Intra-arterial	18488 (36.8%)	1926 (21.4%)	2 (6.7%)	3 (1.7%)	20419 (34.4%)
Other	33 (<0.1%)	65 (0.7%)	0	1 (0.6%)	99 (0.2%)
Missing	20 (<0.1%)	68 (0.8%)	0	0	88 (0.1%)
Examination region ¹					
Cardiac / Cardiac Vessels	20998 (41.8%)	1850 (20.6%)	2 (6.7%)	17 (9.4%)	22867 (38.5%)
Abdomen	15255 (30.4%)	3645 (40.6%)	11 (36.7%)	78 (43.1%)	18989 (32.0%)
Thorax	6936 (13.8%)	2469 (27.5%)	8 (26.7%)	35 (19.3%)	9448 (15.9%)
Pelvis	3524 (7.0%)	1338 (14.9%)	4 (13.3%)	51 (28.2%)	4917 (8.3%)
Head / Brain	3015 (6.0%)	1227 (13.7%)	5 (16.7%)	26 (14.4%)	4273 (7.2%)
Kidney / Renal Vessels	2892 (5.8%)	867 (9.7%)	8 (26.7%)	16 (8.8%)	3783 (6.4%)
Neck	1518 (3.0%)	304 (3.4%)	2 (6.7%)	11 (6.1%)	1835 (3.1%)
Blood Vessels	972 (1.9%)	679 (7.6%)	2 (6.7%)	15 (8.3%)	1668 (2.8%)
Limbs	228 (0.5%)	128 (1.4%)	0	0	356 (0.6%)
Joints	23 (<0.1%)	2 (<0.1%)	0	0	25 (<0.1%)
Other	701 (1.4%)	309 (3.4%)	1 (3.3%)	8 (4.4%)	1019 (1.7%)
Not specified	3 (<0.1%)	6 (<0.1%)	0	0	9 (<0.1%)
Indication ¹					
Tumour/Suspicion of Tumour	17172 (34.2%)	3451 (38.4%)	6 (20.0%)	43 (23.8%)	20672 (34.8%)
Pain	3855 (7.7%)	1540 (17.1%)	7 (23.3%)	64 (35.4%)	5466 (9.2%)
Post-Therapy-Control	3875 (7.7%)	1362 (15.2%)	8 (26.7%)	15 (8.3%)	5260 (8.9%)
Staging	2226 (4.4%)	1394 (15.5%)	1 (3.3%)	8 (4.4%)	3629 (6.1%)
Infarct/Suspicion of Infarct	1996 (4.0%)	1052 (11.7%)	1 (3.3%)	13 (7.2%)	3062 (5.2%)
Inflammatory Diseases	2407 (4.8%)	581 (6.5%)	1 (3.3%)	12 (6.6%)	3001 (5.1%)
Haemorrhage	594 (1.2%)	166 (1.8%)	1 (3.3%)	2 (1.1%)	763 (1.3%)
Trauma	289 (0.6%)	90 (1.0%)	0	3 (1.7%)	382 (0.6%)
Other	21133 (42.1%)	1426 (15.9%)	8 (26.7%)	64 (35.4%)	22631 (38.1%)
Not specified	17 (<0.1%)	45 (0.5%)	0	0	62 (0.1%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.2 / 26: Exposure by race (Full analysis set for race)

	Asian (N=50217)	White (N=8984)	Black (N=30)	Other (N=181)	Total (N=59412)
Dose [ml]					
n	50160	8971	30	181	59342
Nmiss	57	13	0	0	70
Mean (SD)	100.217 (52.454)	98.289 (50.991)	88.833 (40.635)	102.017 (26.773)	99.925 (52.175)
Median	90.000	100.000	90.000	100.000	95.000
Q1, Q3	70.000, 100.000	70.000, 100.000	50.000, 120.000	100.000, 120.000	70.000, 100.000
Min, Max	2.00, 800.00	1.00, 600.00	25.00, 190.00	10.00, 155.00	1.00, 800.00
Dose					
<100 ml	25938 (51.7%)	3976 (44.3%)	15 (50.0%)	37 (20.4%)	29966 (50.4%)
100 - <150 ml	17757 (35.4%)	4085 (45.5%)	13 (43.3%)	129 (71.3%)	21984 (37.0%)
150 - <200 ml	2903 (5.8%)	348 (3.9%)	2 (6.7%)	15 (8.3%)	3268 (5.5%)
200 - <300 ml	2628 (5.2%)	368 (4.1%)	0	0	2996 (5.0%)
>=300 ml	934 (1.9%)	194 (2.2%)	0	0	1128 (1.9%)
Not specified	57 (0.1%)	13 (0.1%)	0	0	70 (0.1%)
Dose of iodine [g]					
n	50160	8971	30	181	59342
Nmiss	57	13	0	0	70
Mean (SD)	34.482 (19.783)	33.847 (18.828)	30.792 (13.580)	33.525 (10.559)	34.381 (19.618)
Median	30.000	30.000	29.800	30.000	30.000
Q1, Q3	24.000, 37.000	22.500, 37.000	18.500, 37.000	30.000, 37.500	24.000, 37.000
Min, Max	0.60, 296.00	0.37, 222.00	9.25, 57.00	3.00, 57.35	0.37, 296.00
Dose of iodine					
<=20 g	8067 (16.1%)	1757 (19.6%)	9 (30.0%)	18 (9.9%)	9851 (16.6%)
>20 - 40 g	32398 (64.5%)	5585 (62.2%)	15 (50.0%)	122 (67.4%)	38120 (64.2%)
>40 - 60 g	5547 (11.0%)	1066 (11.9%)	6 (20.0%)	41 (22.7%)	6660 (11.2%)
>60 g	4148 (8.3%)	563 (6.3%)	0	0	4711 (7.9%)
Not specified	57 (0.1%)	13 (0.1%)	0	0	70 (0.1%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 26: Exposure by race (Full analysis set for race)

	Asian (N=50217)	White (N=8984)	Black (N=30)	Other (N=181)	Total (N=59412)
Type of examination					
CT (multislice)	28134 (56.0%)	4699 (52.3%)	14 (46.7%)	158 (87.3%)	33005 (55.6%)
Angiocardiography ²	11007 (21.9%)	1160 (12.9%)	1 (3.3%)	2 (1.1%)	12170 (20.5%)
CT (singleslice)	2130 (4.2%)	1753 (19.5%)	9 (30.0%)	4 (2.2%)	3896 (6.6%)
Angiography	215 (0.4%)	573 (6.4%)	0	1 (0.6%)	789 (1.3%)
Phlebography	125 (0.2%)	198 (2.2%)	0	2 (1.1%)	325 (0.5%)
DSA	115 (0.2%)	91 (1.0%)	1 (3.3%)	0	207 (0.3%)
CT	7 (<0.1%)	1 (<0.1%)	0	0	8 (<0.1%)
Other	6905 (13.8%)	105 (1.2%)	0	3 (1.7%)	7013 (11.8%)
Not specified	1579 (3.1%)	404 (4.5%)	5 (16.7%)	11 (6.1%)	1999 (3.4%)
Contrast quality					
Excellent	29404 (58.6%)	4263 (47.5%)	9 (30.0%)	28 (15.5%)	33704 (56.7%)
Good	18812 (37.5%)	4467 (49.7%)	19 (63.3%)	148 (81.8%)	23446 (39.5%)
Adequate	1841 (3.7%)	219 (2.4%)	2 (6.7%)	4 (2.2%)	2066 (3.5%)
Moderate	151 (0.3%)	11 (0.1%)	0	1 (0.6%)	163 (0.3%)
Non diagnostic	7 (<0.1%)	10 (0.1%)	0	0	17 (<0.1%)
Not specified	2 (<0.1%)	14 (0.2%)	0	0	16 (<0.1%)

¹ Multiple responses possible.

² Category angiocardiography includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 27: Exposure by geographical region (Full analysis set for geographical region)

	Africa (N=398)	Asia (excl. China) (N=32971)	China (N=36928)	Europe (N=69561)	North America (N=6791)	Total (N=146649)
Injection route						
Intravenous	293 (73.6%)	29232 (88.7%)	19487 (52.8%)	61797 (88.8%)	6534 (96.2%)	117343 (80.0%)
Intra-arterial	104 (26.1%)	3602 (10.9%)	17441 (47.2%)	7086 (10.2%)	256 (3.8%)	28489 (19.4%)
Other	0	112 (0.3%)	0	298 (0.4%)	0	410 (0.3%)
Not specified	1 (0.3%)	4 (<0.1%)	0	310 (0.4%)	1 (<0.1%)	316 (0.2%)
Missing	0	21 (<0.1%)	0	70 (0.1%)	0	91 (<0.1%)
Examination region ¹						
Abdomen	0	9391 (28.5%)	9120 (24.7%)	8563 (12.3%)	0	27074 (18.5%)
Cardiac / Cardiac Vessels	0	1418 (4.3%)	19735 (53.4%)	1905 (2.7%)	0	23058 (15.7%)
Thorax	0	4197 (12.7%)	4394 (11.9%)	5510 (7.9%)	0	14101 (9.6%)
Pelvis	0	4407 (13.4%)	1635 (4.4%)	2221 (3.2%)	0	8263 (5.6%)
Head / Brain	0	2663 (8.1%)	1168 (3.2%)	2895 (4.2%)	0	6726 (4.6%)
Kidney / Renal Vessels	0	2132 (6.5%)	1185 (3.2%)	1425 (2.0%)	0	4742 (3.2%)
Neck	0	1147 (3.5%)	802 (2.2%)	768 (1.1%)	0	2717 (1.9%)
Blood Vessels	0	257 (0.8%)	865 (2.3%)	845 (1.2%)	0	1967 (1.3%)
Limbs	0	74 (0.2%)	176 (0.5%)	165 (0.2%)	0	415 (0.3%)
Joints	0	16 (<0.1%)	15 (<0.1%)	15 (<0.1%)	0	46 (<0.1%)
Other	0	604 (1.8%)	172 (0.5%)	372 (0.5%)	0	1148 (0.8%)
Not specified	0	4 (<0.1%)	0	16 (<0.1%)	0	20 (<0.1%)
Missing	398 (100.0%)	14103 (42.8%)	0	50997 (73.3%)	6791 (100.0%)	72289 (49.3%)
Indication ¹						
Tumour/Suspicion of Tumour	0	7409 (22.5%)	11565 (31.3%)	7646 (11.0%)	0	26620 (18.2%)
Pain	0	3108 (9.4%)	1783 (4.8%)	2706 (3.9%)	0	7597 (5.2%)
Post-Therapy-Control	0	2283 (6.9%)	2257 (6.1%)	3048 (4.4%)	0	7588 (5.2%)
Staging	0	1281 (3.9%)	1590 (4.3%)	2639 (3.8%)	0	5510 (3.8%)
Inflammatory Diseases	0	1546 (4.7%)	1341 (3.6%)	1520 (2.2%)	0	4407 (3.0%)
Infarct/Suspicion of Infarct	0	1112 (3.4%)	1046 (2.8%)	1330 (1.9%)	0	3488 (2.4%)
Haemorrhage	0	309 (0.9%)	365 (1.0%)	280 (0.4%)	0	954 (0.7%)
Trauma	0	289 (0.9%)	136 (0.4%)	193 (0.3%)	0	618 (0.4%)
Other	0	3622 (11.0%)	18440 (49.9%)	2534 (3.6%)	0	24596 (16.8%)
Not specified	0	22 (<0.1%)	0	55 (<0.1%)	0	77 (<0.1%)
Missing	398 (100.0%)	14294 (43.4%)	0	51253 (73.7%)	6791 (100.0%)	72736 (49.6%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 27: Exposure by geographical region (Full analysis set for geographical region)

	Africa (N=398)	Asia (excl. China) (N=32971)	China (N=36928)	Europe (N=69561)	North America (N=6791)	Total (N=146649)
Dose [ml]						
n	394	32875	36928	68979	6789	145965
Nmiss	4	96	0	582	2	684
Mean (SD)	102.363 (94.883)	100.454 (44.143)	105.457 (54.382)	94.759 (40.296)	114.784 (31.503)	99.700 (45.337)
Median	50.000	100.000	100.000	100.000	100.000	100.000
Q1, Q3	50.000, 150.000	70.000, 124.000	80.000, 100.000	75.000, 100.000	100.000, 140.000	75.000, 110.000
Min, Max	16.00, 650.00	2.00, 800.00	2.00, 500.00	1.00, 800.00	10.00, 470.00	1.00, 800.00
Dose						
<100 ml	232 (58.3%)	12140 (36.8%)	18282 (49.5%)	29157 (41.9%)	1087 (16.0%)	60898 (41.5%)
100 - <150 ml	59 (14.8%)	16851 (51.1%)	12691 (34.4%)	33367 (48.0%)	4192 (61.7%)	67160 (45.8%)
150 - <200 ml	62 (15.6%)	3112 (9.4%)	2606 (7.1%)	4555 (6.5%)	1428 (21.0%)	11763 (8.0%)
200 - <300 ml	20 (5.0%)	552 (1.7%)	2488 (6.7%)	1438 (2.1%)	63 (0.9%)	4561 (3.1%)
>=300 ml	21 (5.3%)	220 (0.7%)	861 (2.3%)	462 (0.7%)	19 (0.3%)	1583 (1.1%)
Not specified	4 (1.0%)	96 (0.3%)	0	582 (0.8%)	2 (<0.1%)	684 (0.5%)
Dose of iodine [g]						
n	394	32875	36928	68979	6789	145965
Nmiss	4	96	0	582	2	684
Mean (SD)	34.660 (36.263)	32.250 (15.149)	36.651 (20.744)	30.014 (13.910)	36.553 (10.542)	32.514 (16.394)
Median	15.000	30.000	30.000	30.000	37.000	30.000
Q1, Q3	15.000, 55.500	22.200, 39.000	25.900, 37.000	22.500, 36.000	30.000, 44.400	24.000, 37.000
Min, Max	4.80, 240.50	0.60, 296.00	0.60, 185.00	0.30, 240.50	3.00, 173.90	0.30, 296.00
Dose of iodine						
<=20 g	217 (54.5%)	7625 (23.1%)	3107 (8.4%)	13194 (19.0%)	324 (4.8%)	24467 (16.7%)
>20 - 40 g	74 (18.6%)	17873 (54.2%)	26251 (71.1%)	47355 (68.1%)	3943 (58.1%)	95496 (65.1%)
>40 - 60 g	62 (15.6%)	6642 (20.1%)	3665 (9.9%)	6753 (9.7%)	2427 (35.7%)	19549 (13.3%)
>60 g	41 (10.3%)	735 (2.2%)	3905 (10.6%)	1677 (2.4%)	95 (1.4%)	6453 (4.4%)
Not specified	4 (1.0%)	96 (0.3%)	0	582 (0.8%)	2 (<0.1%)	684 (0.5%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.2 / 27: Exposure by geographical region (Full analysis set for geographical region)

	Africa (N=398)	Asia (excl. China) (N=32971)	China (N=36928)	Europe (N=69561)	North America (N=6791)	Total (N=146649)
Type of examination						
CT	175 (44.0%)	15826 (48.0%)	0	43377 (62.4%)	6191 (91.2%)	65569 (44.7%)
CT (multislice)	0	8914 (27.0%)	19447 (52.7%)	4879 (7.0%)	0	33240 (22.7%)
Angiocardiology ²	2 (0.5%)	799 (2.4%)	10295 (27.9%)	1486 (2.1%)	0	12582 (8.6%)
Urography	117 (29.4%)	800 (2.4%)	0	9733 (14.0%)	325 (4.8%)	10975 (7.5%)
CT (singleslice)	0	2160 (6.6%)	30 (<0.1%)	1847 (2.7%)	0	4037 (2.8%)
Angiography	4 (1.0%)	389 (1.2%)	2 (<0.1%)	1453 (2.1%)	33 (0.5%)	1881 (1.3%)
Phlebography	0	126 (0.4%)	1 (<0.1%)	203 (0.3%)	0	330 (0.2%)
DSA	0	130 (0.4%)	18 (<0.1%)	116 (0.2%)	0	264 (0.2%)
PTCA	0	34 (0.1%)	0	145 (0.2%)	0	179 (0.1%)
PTA	0	0	0	84 (0.1%)	0	84 (<0.1%)
Other	0	65 (0.2%)	6843 (18.5%)	105 (0.2%)	0	7013 (4.8%)
Not specified	100 (25.1%)	3728 (11.3%)	292 (0.8%)	6133 (8.8%)	242 (3.6%)	10495 (7.2%)
Contrast quality						
Excellent	363 (91.2%)	14357 (43.5%)	22952 (62.2%)	33619 (48.3%)	3147 (46.3%)	74438 (50.8%)
Good	34 (8.5%)	16493 (50.0%)	12766 (34.6%)	31932 (45.9%)	3056 (45.0%)	64281 (43.8%)
Adequate	0	1980 (6.0%)	1105 (3.0%)	2986 (4.3%)	547 (8.1%)	6618 (4.5%)
Moderate	1 (0.3%)	98 (0.3%)	98 (0.3%)	320 (0.5%)	38 (0.6%)	555 (0.4%)
Non diagnostic	0	7 (<0.1%)	7 (<0.1%)	41 (<0.1%)	3 (<0.1%)	58 (<0.1%)
Not specified	0	36 (0.1%)	0	663 (1.0%)	0	699 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=522)	BULGARIA (N=291)	SWITZERLAND (N=1404)	CHINA (N=36928)	GERMANY (N=45618)	ESTONIA (N=173)	EGYPT (N=298)
Injection route							
Intravenous	231 (44.3%)	51 (17.5%)	1366 (97.3%)	19487 (52.8%)	43170 (94.6%)	155 (89.6%)	293 (98.3%)
Intra-arterial	291 (55.7%)	236 (81.1%)	36 (2.6%)	17441 (47.2%)	2111 (4.6%)	0	4 (1.3%)
Other	0	0	2 (0.1%)	0	104 (0.2%)	18 (10.4%)	0
Not specified	0	4 (1.4%)	0	0	231 (0.5%)	0	1 (0.3%)
Missing	0	0	0	0	2 (<0.1%)	0	0
Examination region ¹							
Abdomen	29 (5.6%)	0	0	9120 (24.7%)	5946 (13.0%)	0	0
Cardiac / Cardiac Vessels	295 (56.5%)	0	0	19735 (53.4%)	60 (0.1%)	0	0
Thorax	154 (29.5%)	0	0	4394 (11.9%)	3717 (8.1%)	0	0
Pelvis	2 (0.4%)	0	0	1635 (4.4%)	1199 (2.6%)	0	0
Head / Brain	42 (8.0%)	0	0	1168 (3.2%)	1905 (4.2%)	0	0
Kidney / Renal Vessels	1 (0.2%)	0	0	1185 (3.2%)	973 (2.1%)	0	0
Neck	4 (0.8%)	0	0	802 (2.2%)	542 (1.2%)	0	0
Blood Vessels	102 (19.5%)	0	0	865 (2.3%)	235 (0.5%)	0	0
Limbs	0	0	0	176 (0.5%)	48 (0.1%)	0	0
Joints	0	0	0	15 (<0.1%)	13 (<0.1%)	0	0
Other	0	0	0	172 (0.5%)	105 (0.2%)	0	0
Not specified	0	0	0	0	0	0	0
Missing	0	291 (100.0%)	1404 (100.0%)	0	33947 (74.4%)	173 (100.0%)	298 (100.0%)
Indication ¹							
Tumour/Suspicion of Tumour	44 (8.4%)	0	0	11565 (31.3%)	4953 (10.9%)	0	0
Pain	264 (50.6%)	0	0	1783 (4.8%)	1467 (3.2%)	0	0
Post-Therapy-Control	19 (3.6%)	0	0	2257 (6.1%)	2129 (4.7%)	0	0
Staging	22 (4.2%)	0	0	1590 (4.3%)	1431 (3.1%)	0	0
Inflammatory Diseases	31 (5.9%)	0	0	1341 (3.6%)	1191 (2.6%)	0	0
Infarct/Suspicion of Infarct	251 (48.1%)	0	0	1046 (2.8%)	281 (0.6%)	0	0
Haemorrhage	4 (0.8%)	0	0	365 (1.0%)	177 (0.4%)	0	0
Trauma	8 (1.5%)	0	0	136 (0.4%)	107 (0.2%)	0	0
Other	22 (4.2%)	0	0	18440 (49.9%)	1608 (3.5%)	0	0
Not specified	0	0	0	0	3 (<0.1%)	0	0
Missing	0	291 (100.0%)	1404 (100.0%)	0	34198 (75.0%)	173 (100.0%)	298 (100.0%)

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=522)	BULGARIA (N=291)	SWITZERLAND (N=1404)	CHINA (N=36928)	GERMANY (N=45618)	ESTONIA (N=173)	EGYPT (N=298)
Dose [ml]							
n	522	291	1401	36928	45071	173	294
Nmiss	0	0	3	0	547	0	4
Mean (SD)	109.416 (50.126)	148.110 (111.857)	119.975 (34.998)	105.457 (54.382)	97.529 (30.401)	53.988 (19.108)	62.214 (22.545)
Median	100.000	100.000	120.000	100.000	100.000	50.000	50.000
Q1, Q3	80.000, 120.000	80.000, 200.000	100.000, 150.000	80.000, 100.000	80.000, 100.000	40.000, 60.000	50.000, 70.000
Min, Max	50.00, 450.00	30.00, 800.00	20.00, 300.00	2.00, 500.00	1.00, 500.00	10.00, 100.00	16.00, 150.00
Dose							
<100 ml	185 (35.4%)	88 (30.2%)	284 (20.2%)	18282 (49.5%)	16835 (36.9%)	170 (98.3%)	232 (77.9%)
100 - <150 ml	232 (44.4%)	89 (30.6%)	582 (41.5%)	12691 (34.4%)	24509 (53.7%)	3 (1.7%)	59 (19.8%)
150 - <200 ml	64 (12.3%)	33 (11.3%)	503 (35.8%)	2606 (7.1%)	3088 (6.8%)	0	3 (1.0%)
200 - <300 ml	30 (5.7%)	44 (15.1%)	31 (2.2%)	2488 (6.7%)	550 (1.2%)	0	0
>=300 ml	11 (2.1%)	37 (12.7%)	1 (<0.1%)	861 (2.3%)	89 (0.2%)	0	0
Not specified	0	0	3 (0.2%)	0	547 (1.2%)	0	4 (1.3%)
Dose of iodine [g]							
n	522	291	1401	36928	45071	173	294
Nmiss	0	0	3	0	547	0	4
Mean (SD)	40.457 (18.557)	51.864 (37.479)	36.956 (10.483)	36.651 (20.744)	29.926 (10.029)	16.269 (5.796)	18.712 (6.867)
Median	37.000	37.000	37.000	30.000	30.000	15.000	15.000
Q1, Q3	29.600, 44.400	29.600, 74.000	30.000, 45.000	25.900, 37.000	24.000, 30.000	12.000, 18.000	15.000, 21.000
Min, Max	18.50, 166.50	11.10, 240.00	6.00, 90.00	0.60, 185.00	0.30, 185.00	3.00, 30.00	4.80, 45.00
Dose of iodine							
<=20 g	32 (6.1%)	62 (21.3%)	87 (6.2%)	3107 (8.4%)	4256 (9.3%)	132 (76.3%)	217 (72.8%)
>20 - 40 g	331 (63.4%)	88 (30.2%)	667 (47.5%)	26251 (71.1%)	36285 (79.5%)	41 (23.7%)	74 (24.8%)
>40 - 60 g	117 (22.4%)	57 (19.6%)	638 (45.4%)	3665 (9.9%)	4032 (8.8%)	0	3 (1.0%)
>60 g	42 (8.0%)	84 (28.9%)	9 (0.6%)	3905 (10.6%)	498 (1.1%)	0	0
Not specified	0	0	3 (0.2%)	0	547 (1.2%)	0	4 (1.3%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=522)	BULGARIA (N=291)	SWITZERLAND (N=1404)	CHINA (N=36928)	GERMANY (N=45618)	ESTONIA (N=173)	EGYPT (N=298)
Type of examination							
CT	0	49 (16.8%)	1318 (93.9%)	0	31772 (69.6%)	0	175 (58.7%)
CT (multislice)	211 (40.4%)	0	0	19447 (52.7%)	1385 (3.0%)	0	0
Angiocardiography ²	230 (44.1%)	64 (22.0%)	8 (0.6%)	10295 (27.9%)	43 (<0.1%)	0	0
Urography	0	0	17 (1.2%)	0	7649 (16.8%)	153 (88.4%)	117 (39.3%)
CT (singleslice)	60 (11.5%)	0	0	30 (<0.1%)	869 (1.9%)	0	0
Angiography	0	38 (13.1%)	1 (<0.1%)	2 (<0.1%)	50 (0.1%)	0	4 (1.3%)
Phlebography	19 (3.6%)	0	0	1 (<0.1%)	30 (<0.1%)	0	0
DSA	2 (0.4%)	0	0	18 (<0.1%)	50 (0.1%)	0	0
PTCA	0	6 (2.1%)	0	0	35 (<0.1%)	0	0
PTA	0	0	22 (1.6%)	0	28 (<0.1%)	0	0
Other	0	0	0	6843 (18.5%)	28 (<0.1%)	0	0
Not specified	0	134 (46.0%)	38 (2.7%)	292 (0.8%)	3679 (8.1%)	20 (11.6%)	2 (0.7%)
Contrast quality							
Excellent	420 (80.5%)	259 (89.0%)	423 (30.1%)	22952 (62.2%)	21376 (46.9%)	47 (27.2%)	276 (92.6%)
Good	102 (19.5%)	30 (10.3%)	922 (65.7%)	12766 (34.6%)	21414 (46.9%)	98 (56.6%)	21 (7.0%)
Adequate	0	2 (0.7%)	51 (3.6%)	1105 (3.0%)	1933 (4.2%)	24 (13.9%)	0
Moderate	0	0	8 (0.6%)	98 (0.3%)	236 (0.5%)	4 (2.3%)	1 (0.3%)
Non diagnostic	0	0	0	7 (<0.1%)	27 (<0.1%)	0	0
Not specified	0	0	0	0	632 (1.4%)	0	0

¹ Multiple responses possible.

² Category angiocardiography includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	SPAIN (N=1906)	FINLAND (N=443)	CROATIA (N=432)	HUNGARY (N=219)	INDONESIA (N=692)	IRAN (N=5088)	ITALY (N=695)
Injection route							
Intravenous	1682 (88.2%)	443 (100.0%)	286 (66.2%)	79 (36.1%)	572 (82.7%)	5088 (100.0%)	643 (92.5%)
Intra-arterial	176 (9.2%)	0	131 (30.3%)	140 (63.9%)	102 (14.7%)	0	50 (7.2%)
Other	43 (2.3%)	0	7 (1.6%)	0	18 (2.6%)	0	2 (0.3%)
Not specified	5 (0.3%)	0	8 (1.9%)	0	0	0	0
Missing	0	0	0	0	0	0	0
Examination region ¹							
Abdomen	0	0	0	39 (17.8%)	113 (16.3%)	3035 (59.7%)	387 (55.7%)
Cardiac / Cardiac Vessels	0	0	0	140 (63.9%)	114 (16.5%)	136 (2.7%)	7 (1.0%)
Thorax	0	0	0	30 (13.7%)	75 (10.8%)	1488 (29.2%)	320 (46.0%)
Pelvis	0	0	0	39 (17.8%)	37 (5.3%)	2401 (47.2%)	193 (27.8%)
Head / Brain	0	0	0	22 (10.0%)	134 (19.4%)	747 (14.7%)	136 (19.6%)
Kidney / Renal Vessels	0	0	0	0	192 (27.7%)	362 (7.1%)	46 (6.6%)
Neck	0	0	0	2 (0.9%)	21 (3.0%)	369 (7.3%)	70 (10.1%)
Blood Vessels	0	0	0	0	6 (0.9%)	145 (2.8%)	23 (3.3%)
Limbs	0	0	0	0	9 (1.3%)	20 (0.4%)	5 (0.7%)
Joints	0	0	0	0	0	4 (<0.1%)	0
Other	0	0	0	2 (0.9%)	47 (6.8%)	60 (1.2%)	19 (2.7%)
Not specified	0	0	0	0	0	0	0
Missing	1906 (100.0%)	443 (100.0%)	432 (100.0%)	0	0	25 (0.5%)	167 (24.0%)
Indication ¹							
Tumour/Suspicion of Tumour	0	0	0	29 (13.2%)	246 (35.5%)	1659 (32.6%)	260 (37.4%)
Pain	0	0	0	64 (29.2%)	148 (21.4%)	958 (18.8%)	14 (2.0%)
Post-Therapy-Control	0	0	0	19 (8.7%)	14 (2.0%)	622 (12.2%)	149 (21.4%)
Staging	0	0	0	36 (16.4%)	8 (1.2%)	609 (12.0%)	113 (16.3%)
Inflammatory Diseases	0	0	0	0	27 (3.9%)	359 (7.1%)	27 (3.9%)
Infarct/Suspicion of Infarct	0	0	0	30 (13.7%)	76 (11.0%)	149 (2.9%)	10 (1.4%)
Haemorrhage	0	0	0	0	14 (2.0%)	76 (1.5%)	3 (0.4%)
Trauma	0	0	0	0	7 (1.0%)	123 (2.4%)	1 (0.1%)
Other	0	0	0	133 (60.7%)	206 (29.8%)	811 (15.9%)	91 (13.1%)
Not specified	0	0	0	0	0	0	3 (0.4%)
Missing	1906 (100.0%)	443 (100.0%)	432 (100.0%)	0	0	210 (4.1%)	167 (24.0%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	SPAIN (N=1906)	FINLAND (N=443)	CROATIA (N=432)	HUNGARY (N=219)	INDONESIA (N=692)	IRAN (N=5088)	ITALY (N=695)
Dose [ml]							
n	1900	441	432	219	692	5067	694
Nmiss	6	2	0	0	0	21	1
Mean (SD)	115.904 (46.856)	108.857 (21.477)	92.317 (53.055)	107.288 (74.354)	68.439 (50.211)	106.867 (30.022)	115.739 (35.349)
Median	100.000	118.000	90.000	90.000	50.000	100.000	120.000
Q1, Q3	100.000, 120.000	100.000, 120.000	50.000, 100.000	50.000, 120.000	50.000, 80.000	100.000, 120.000	100.000, 130.000
Min, Max	20.00, 650.00	14.00, 200.00	10.00, 300.00	4.00, 400.00	5.00, 600.00	5.00, 350.00	1.00, 350.00
Dose							
<100 ml	297 (15.6%)	64 (14.4%)	217 (50.2%)	111 (50.7%)	537 (77.6%)	833 (16.4%)	123 (17.7%)
100 - <150 ml	1381 (72.5%)	376 (84.9%)	128 (29.6%)	65 (29.7%)	123 (17.8%)	3492 (68.6%)	485 (69.8%)
150 - <200 ml	141 (7.4%)	0	51 (11.8%)	16 (7.3%)	6 (0.9%)	623 (12.2%)	55 (7.9%)
200 - <300 ml	48 (2.5%)	1 (0.2%)	33 (7.6%)	18 (8.2%)	14 (2.0%)	111 (2.2%)	26 (3.7%)
>=300 ml	33 (1.7%)	0	3 (0.7%)	9 (4.1%)	12 (1.7%)	8 (0.2%)	5 (0.7%)
Not specified	6 (0.3%)	2 (0.5%)	0	0	0	21 (0.4%)	1 (0.1%)
Dose of iodine [g]							
n	1900	441	432	219	692	5067	694
Nmiss	6	2	0	0	0	21	1
Mean (SD)	37.412 (17.811)	32.803 (6.196)	29.354 (15.799)	34.434 (22.960)	23.073 (17.717)	32.270 (9.196)	41.744 (13.178)
Median	36.000	35.400	30.000	30.000	18.500	30.000	39.000
Q1, Q3	30.000, 37.000	30.000, 36.000	15.000, 37.000	18.000, 40.700	15.000, 29.600	30.000, 36.000	37.000, 44.400
Min, Max	7.40, 240.50	4.20, 60.00	3.00, 90.00	1.20, 120.00	1.85, 180.00	1.50, 105.00	0.37, 129.50
Dose of iodine							
<=20 g	62 (3.3%)	23 (5.2%)	196 (45.4%)	73 (33.3%)	412 (59.5%)	321 (6.3%)	18 (2.6%)
>20 - 40 g	1485 (77.9%)	391 (88.3%)	148 (34.3%)	91 (41.6%)	247 (35.7%)	3828 (75.2%)	334 (48.1%)
>40 - 60 g	245 (12.9%)	27 (6.1%)	79 (18.3%)	27 (12.3%)	12 (1.7%)	904 (17.8%)	307 (44.2%)
>60 g	108 (5.7%)	0	9 (2.1%)	28 (12.8%)	21 (3.0%)	14 (0.3%)	35 (5.0%)
Not specified	6 (0.3%)	2 (0.5%)	0	0	0	21 (0.4%)	1 (0.1%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	SPAIN (N=1906)	FINLAND (N=443)	CROATIA (N=432)	HUNGARY (N=219)	INDONESIA (N=692)	IRAN (N=5088)	ITALY (N=695)
Type of examination							
CT	1595 (83.7%)	443 (100.0%)	209 (48.4%)	0	0	4944 (97.2%)	100 (14.4%)
CT (multislice)	0	0	0	79 (36.1%)	176 (25.4%)	144 (2.8%)	418 (60.1%)
Angiocardiology ²	30 (1.6%)	0	2 (0.5%)	58 (26.5%)	54 (7.8%)	0	0
Urography	51 (2.7%)	0	77 (17.8%)	0	0	0	0
CT (singleslice)	0	0	0	0	198 (28.6%)	0	83 (11.9%)
Angiography	39 (2.0%)	0	11 (2.5%)	82 (37.4%)	26 (3.8%)	0	0
Phlebography	0	0	0	0	3 (0.4%)	0	0
DSA	1 (<0.1%)	0	1 (0.2%)	0	20 (2.9%)	0	0
PTCA	0	0	0	0	0	0	0
PTA	0	0	9 (2.1%)	0	0	0	5 (0.7%)
Other	0	0	0	0	22 (3.2%)	0	0
Not specified	190 (10.0%)	0	123 (28.5%)	0	193 (27.9%)	0	89 (12.8%)
Contrast quality							
Excellent	704 (36.9%)	68 (15.3%)	268 (62.0%)	129 (58.9%)	168 (24.3%)	1407 (27.7%)	210 (30.2%)
Good	881 (46.2%)	356 (80.4%)	143 (33.1%)	89 (40.6%)	494 (71.4%)	2770 (54.4%)	383 (55.1%)
Adequate	274 (14.4%)	17 (3.8%)	21 (4.9%)	1 (0.5%)	29 (4.2%)	866 (17.0%)	99 (14.2%)
Moderate	41 (2.2%)	0	0	0	1 (0.1%)	16 (0.3%)	2 (0.3%)
Non diagnostic	1 (<0.1%)	0	0	0	0	2 (<0.1%)	0
Not specified	5 (0.3%)	2 (0.5%)	0	0	0	27 (0.5%)	1 (0.1%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	JORDAN (N=1668)	KOREA (SOUTH) (N=13745)	LITHUANIA (N=2380)	LATVIA (N=399)	MOLDOVA (N=358)	MALAYSIA (N=863)	PHILIPPINES (N=4175)
Injection route							
Intravenous	547 (32.8%)	12684 (92.3%)	1503 (63.2%)	399 (100.0%)	296 (82.7%)	419 (48.6%)	3578 (85.7%)
Intra-arterial	1065 (63.8%)	1059 (7.7%)	853 (35.8%)	0	1 (0.3%)	444 (51.4%)	551 (13.2%)
Other	54 (3.2%)	1 (<0.1%)	24 (1.0%)	0	60 (16.8%)	0	31 (0.7%)
Not specified	2 (0.1%)	1 (<0.1%)	0	0	0	0	0
Missing	0	0	0	0	1 (0.3%)	0	15 (0.4%)
Examination region ¹							
Abdomen	0	2586 (18.8%)	0	0	111 (31.0%)	292 (33.8%)	752 (18.0%)
Cardiac / Cardiac Vessels	0	300 (2.2%)	0	0	0	440 (51.0%)	229 (5.5%)
Thorax	0	786 (5.7%)	0	0	4 (1.1%)	279 (32.3%)	442 (10.6%)
Pelvis	0	887 (6.5%)	0	0	5 (1.4%)	238 (27.6%)	42 (1.0%)
Head / Brain	0	72 (0.5%)	0	0	116 (32.4%)	76 (8.8%)	625 (15.0%)
Kidney / Renal Vessels	0	54 (0.4%)	0	0	44 (12.3%)	10 (1.2%)	200 (4.8%)
Neck	0	176 (1.3%)	0	0	2 (0.6%)	66 (7.6%)	139 (3.3%)
Blood Vessels	0	17 (0.1%)	0	0	48 (13.4%)	1 (0.1%)	57 (1.4%)
Limbs	0	15 (0.1%)	0	0	5 (1.4%)	1 (0.1%)	18 (0.4%)
Joints	0	1 (<0.1%)	0	0	0	0	5 (0.1%)
Other	0	8 (<0.1%)	0	0	63 (17.6%)	29 (3.4%)	141 (3.4%)
Not specified	0	0	0	0	0	0	0
Missing	1668 (100.0%)	9916 (72.1%)	2380 (100.0%)	399 (100.0%)	0	0	1769 (42.4%)
Indication ¹							
Tumour/Suspicion of Tumour	0	1946 (14.2%)	0	0	164 (45.8%)	263 (30.5%)	877 (21.0%)
Pain	0	466 (3.4%)	0	0	24 (6.7%)	33 (3.8%)	407 (9.7%)
Post-Therapy-Control	0	1070 (7.8%)	0	0	9 (2.5%)	109 (12.6%)	152 (3.6%)
Staging	0	230 (1.7%)	0	0	0	78 (9.0%)	151 (3.6%)
Inflammatory Diseases	0	170 (1.2%)	0	0	41 (11.5%)	28 (3.2%)	317 (7.6%)
Infarct/Suspicion of Infarct	0	264 (1.9%)	0	0	10 (2.8%)	254 (29.4%)	304 (7.3%)
Haemorrhage	0	12 (<0.1%)	0	0	25 (7.0%)	5 (0.6%)	103 (2.5%)
Trauma	0	4 (<0.1%)	0	0	21 (5.9%)	4 (0.5%)	77 (1.8%)
Other	0	256 (1.9%)	0	0	84 (23.5%)	270 (31.3%)	428 (10.3%)
Not specified	0	0	0	0	0	0	0
Missing	1668 (100.0%)	9916 (72.1%)	2380 (100.0%)	399 (100.0%)	0	0	1769 (42.4%)

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	JORDAN (N=1668)	KOREA (SOUTH) (N=13745)	LITHUANIA (N=2380)	LATVIA (N=399)	MOLDOVA (N=358)	MALAYSIA (N=863)	PHILIPPINES (N=4175)
Dose [ml]							
n	1666	13744	2380	399	358	863	4156
Nmiss	2	1	0	0	0	0	19
Mean (SD)	104.621 (76.805)	121.626 (28.882)	64.691 (31.313)	69.511 (28.098)	62.690 (39.631)	99.933 (55.200)	70.126 (33.206)
Median	100.000	120.000	50.000	50.000	50.000	100.000	50.000
Q1, Q3	50.000, 150.000	100.000, 140.000	50.000, 100.000	40.000, 100.000	40.000, 100.000	50.000, 100.000	50.000, 100.000
Min, Max	2.00, 600.00	8.00, 450.00	10.00, 260.00	40.00, 120.00	4.00, 200.00	2.00, 450.00	2.00, 600.00
Dose							
<100 ml	823 (49.3%)	1573 (11.4%)	1648 (69.2%)	231 (57.9%)	217 (60.6%)	356 (41.3%)	2853 (68.3%)
100 - <150 ml	399 (23.9%)	10014 (72.9%)	697 (29.3%)	168 (42.1%)	125 (34.9%)	361 (41.8%)	1201 (28.8%)
150 - <200 ml	249 (14.9%)	1974 (14.4%)	13 (0.5%)	0	15 (4.2%)	62 (7.2%)	60 (1.4%)
200 - <300 ml	106 (6.4%)	153 (1.1%)	22 (0.9%)	0	1 (0.3%)	75 (8.7%)	35 (0.8%)
>=300 ml	89 (5.3%)	30 (0.2%)	0	0	0	9 (1.0%)	7 (0.2%)
Not specified	2 (0.1%)	1 (<0.1%)	0	0	0	0	19 (0.5%)
Dose of iodine [g]							
n	1666	13744	2380	399	358	863	4156
Nmiss	2	1	0	0	0	0	19
Mean (SD)	38.105 (28.719)	38.401 (10.070)	21.811 (12.408)	20.853 (8.430)	23.134 (14.603)	33.831 (20.933)	22.516 (11.749)
Median	37.000	37.000	15.000	15.000	18.500	30.000	18.500
Q1, Q3	18.500, 55.500	33.000, 43.500	15.000, 37.000	12.000, 30.000	14.800, 37.000	18.500, 36.000	15.000, 30.000
Min, Max	0.60, 222.00	2.40, 166.50	3.00, 96.20	12.00, 36.00	1.48, 74.00	0.60, 166.50	0.60, 222.00
Dose of iodine							
<=20 g	730 (43.8%)	239 (1.7%)	1499 (63.0%)	212 (53.1%)	215 (60.1%)	267 (30.9%)	2435 (58.3%)
>20 - 40 g	486 (29.1%)	8213 (59.8%)	844 (35.5%)	187 (46.9%)	127 (35.5%)	418 (48.4%)	1580 (37.8%)
>40 - 60 g	255 (15.3%)	5076 (36.9%)	13 (0.5%)	0	15 (4.2%)	73 (8.5%)	98 (2.3%)
>60 g	195 (11.7%)	216 (1.6%)	24 (1.0%)	0	1 (0.3%)	105 (12.2%)	43 (1.0%)
Not specified	2 (0.1%)	1 (<0.1%)	0	0	0	0	19 (0.5%)

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	JORDAN (N=1668)	KOREA (SOUTH) (N=13745)	LITHUANIA (N=2380)	LATVIA (N=399)	MOLDOVA (N=358)	MALAYSIA (N=863)	PHILIPPINES (N=4175)
Type of examination							
CT	237 (14.2%)	8787 (63.9%)	1167 (49.0%)	399 (100.0%)	1 (0.3%)	0	1101 (26.4%)
CT (multislice)	0	3829 (27.9%)	0	0	286 (79.9%)	417 (48.3%)	1474 (35.3%)
Angiocardiology ²	59 (3.5%)	5 (<0.1%)	16 (0.7%)	0	0	437 (50.6%)	121 (2.9%)
Urography	272 (16.3%)	38 (0.3%)	307 (12.9%)	0	0	0	380 (9.1%)
CT (singleslice)	0	0	0	0	0	2 (0.2%)	469 (11.2%)
Angiography	89 (5.3%)	10 (<0.1%)	106 (4.5%)	0	1 (0.3%)	7 (0.8%)	157 (3.8%)
Phlebography	0	0	0	0	0	0	2 (<0.1%)
DSA	0	0	0	0	0	0	79 (1.9%)
PTCA	17 (1.0%)	0	16 (0.7%)	0	0	0	15 (0.4%)
PTA	0	0	0	0	0	0	0
Other	0	0	0	0	61 (17.0%)	0	19 (0.5%)
Not specified	994 (59.6%)	1076 (7.8%)	768 (32.3%)	0	9 (2.5%)	0	358 (8.6%)
Contrast quality							
Excellent	1544 (92.6%)	6722 (48.9%)	1209 (50.8%)	163 (40.9%)	159 (44.4%)	409 (47.4%)	2197 (52.6%)
Good	117 (7.0%)	6720 (48.9%)	990 (41.6%)	212 (53.1%)	197 (55.0%)	425 (49.2%)	1845 (44.2%)
Adequate	4 (0.2%)	282 (2.1%)	176 (7.4%)	24 (6.0%)	1 (0.3%)	28 (3.2%)	115 (2.8%)
Moderate	0	19 (0.1%)	5 (0.2%)	0	1 (0.3%)	1 (0.1%)	16 (0.4%)
Non diagnostic	1 (<0.1%)	2 (<0.1%)	0	0	0	0	1 (<0.1%)
Not specified	2 (0.1%)	0	0	0	0	0	1 (<0.1%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	PAKISTAN (N=1398)	POLAND (N=2749)	ROMANIA (N=2397)	REPUBLIC OF SERBIA (N=682)	RUSSIA (N=614)	SAUDI ARABIA (N=742)	SINGAPORE (N=1657)
Injection route							
Intravenous	1394 (99.7%)	2048 (74.5%)	1047 (43.7%)	446 (65.4%)	609 (99.2%)	452 (60.9%)	1652 (99.7%)
Intra-arterial	3 (0.2%)	678 (24.7%)	1271 (53.0%)	219 (32.1%)	1 (0.2%)	284 (38.3%)	0
Other	0	17 (0.6%)	5 (0.2%)	3 (0.4%)	3 (0.5%)	5 (0.7%)	0
Not specified	0	6 (0.2%)	13 (0.5%)	14 (2.1%)	0	1 (0.1%)	0
Missing	1 (<0.1%)	0	61 (2.5%)	0	1 (0.2%)	0	5 (0.3%)
Examination region ¹							
Abdomen	442 (31.6%)	597 (21.7%)	77 (3.2%)	0	331 (53.9%)	178 (24.0%)	775 (46.8%)
Cardiac / Cardiac Vessels	5 (0.4%)	268 (9.7%)	851 (35.5%)	0	12 (2.0%)	177 (23.9%)	12 (0.7%)
Thorax	258 (18.5%)	367 (13.4%)	36 (1.5%)	0	86 (14.0%)	128 (17.3%)	422 (25.5%)
Pelvis	175 (12.5%)	262 (9.5%)	16 (0.7%)	0	34 (5.5%)	108 (14.6%)	465 (28.1%)
Head / Brain	412 (29.5%)	387 (14.1%)	50 (2.1%)	0	100 (16.3%)	29 (3.9%)	216 (13.0%)
Kidney / Renal Vessels	155 (11.1%)	68 (2.5%)	11 (0.5%)	0	100 (16.3%)	15 (2.0%)	321 (19.4%)
Neck	108 (7.7%)	52 (1.9%)	5 (0.2%)	0	17 (2.8%)	52 (7.0%)	146 (8.8%)
Blood Vessels	7 (0.5%)	82 (3.0%)	125 (5.2%)	0	30 (4.9%)	3 (0.4%)	11 (0.7%)
Limbs	3 (0.2%)	41 (1.5%)	63 (2.6%)	0	2 (0.3%)	1 (0.1%)	4 (0.2%)
Joints	1 (<0.1%)	0	0	0	2 (0.3%)	4 (0.5%)	0
Other	115 (8.2%)	30 (1.1%)	137 (5.7%)	0	14 (2.3%)	30 (4.0%)	158 (9.5%)
Not specified	4 (0.3%)	0	5 (0.2%)	0	1 (0.2%)	0	0
Missing	0	1049 (38.2%)	1271 (53.0%)	682 (100.0%)	0	236 (31.8%)	0
Indication ¹							
Tumour/Suspicion of Tumour	617 (44.1%)	704 (25.6%)	75 (3.1%)	0	391 (63.7%)	74 (10.0%)	772 (46.6%)
Pain	338 (24.2%)	254 (9.2%)	381 (15.9%)	0	16 (2.6%)	85 (11.5%)	248 (15.0%)
Post-Therapy-Control	46 (3.3%)	314 (11.4%)	6 (0.3%)	0	71 (11.6%)	40 (5.4%)	83 (5.0%)
Staging	50 (3.6%)	460 (16.7%)	23 (1.0%)	0	157 (25.6%)	39 (5.3%)	50 (3.0%)
Inflammatory Diseases	312 (22.3%)	110 (4.0%)	9 (0.4%)	0	62 (10.1%)	95 (12.8%)	88 (5.3%)
Infarct/Suspicion of Infarct	37 (2.6%)	145 (5.3%)	358 (14.9%)	0	7 (1.1%)	4 (0.5%)	9 (0.5%)
Haemorrhage	15 (1.1%)	30 (1.1%)	24 (1.0%)	0	5 (0.8%)	1 (0.1%)	40 (2.4%)
Trauma	21 (1.5%)	23 (0.8%)	14 (0.6%)	0	9 (1.5%)	15 (2.0%)	11 (0.7%)
Other	184 (13.2%)	237 (8.6%)	240 (10.0%)	0	42 (6.8%)	228 (30.7%)	476 (28.7%)
Not specified	22 (1.6%)	0	11 (0.5%)	0	2 (0.3%)	0	0
Missing	0	1049 (38.2%)	1276 (53.2%)	682 (100.0%)	0	242 (32.6%)	0

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	PAKISTAN (N=1398)	POLAND (N=2749)	ROMANIA (N=2397)	REPUBLIC OF SERBIA (N=682)	RUSSIA (N=614)	SAUDI ARABIA (N=742)	SINGAPORE (N=1657)
Dose [ml]							
n	1361	2748	2392	680	614	731	1653
Nmiss	37	1	5	2	0	11	4
Mean (SD)	64.691 (27.530)	94.349 (57.361)	96.018 (74.864)	76.193 (35.327)	80.020 (31.523)	136.869 (94.020)	68.290 (16.930)
Median	50.000	80.000	60.000	60.000	87.500	100.000	70.000
Q1, Q3	50.000, 90.000	60.000, 100.000	50.000, 130.000	50.000, 100.000	50.000, 100.000	100.000, 150.000	50.000, 80.000
Min, Max	6.00, 200.00	4.00, 500.00	5.00, 600.00	20.00, 300.00	2.00, 165.00	5.00, 800.00	25.00, 135.00
Dose							
<100 ml	1033 (73.9%)	1636 (59.5%)	1324 (55.2%)	404 (59.2%)	321 (52.3%)	131 (17.7%)	1589 (95.9%)
100 - <150 ml	296 (21.2%)	736 (26.8%)	607 (25.3%)	226 (33.1%)	261 (42.5%)	403 (54.3%)	64 (3.9%)
150 - <200 ml	31 (2.2%)	180 (6.5%)	119 (5.0%)	47 (6.9%)	32 (5.2%)	84 (11.3%)	0
200 - <300 ml	1 (<0.1%)	135 (4.9%)	269 (11.2%)	2 (0.3%)	0	49 (6.6%)	0
>=300 ml	0	61 (2.2%)	73 (3.0%)	1 (0.1%)	0	64 (8.6%)	0
Not specified	37 (2.6%)	1 (<0.1%)	5 (0.2%)	2 (0.3%)	0	11 (1.5%)	4 (0.2%)
Dose of iodine [g]							
n	1361	2748	2392	680	614	731	1653
Nmiss	37	1	5	2	0	11	4
Mean (SD)	22.232 (9.950)	33.277 (21.063)	35.460 (27.741)	25.386 (10.757)	27.219 (11.304)	47.197 (36.108)	24.400 (5.848)
Median	18.500	29.600	22.200	22.200	29.600	37.000	25.900
Q1, Q3	15.000, 30.000	18.500, 37.000	18.500, 48.100	18.500, 30.000	18.500, 37.000	30.000, 55.500	18.500, 29.600
Min, Max	1.80, 74.00	1.48, 185.00	1.50, 222.00	6.00, 111.00	0.60, 61.05	1.50, 296.00	9.25, 49.95
Dose of iodine							
<=20 g	818 (58.5%)	741 (27.0%)	1118 (46.6%)	261 (38.3%)	185 (30.1%)	90 (12.1%)	505 (30.5%)
>20 - 40 g	508 (36.3%)	1505 (54.7%)	527 (22.0%)	362 (53.1%)	375 (61.1%)	402 (54.2%)	1140 (68.8%)
>40 - 60 g	34 (2.4%)	318 (11.6%)	401 (16.7%)	55 (8.1%)	53 (8.6%)	103 (13.9%)	8 (0.5%)
>60 g	1 (<0.1%)	184 (6.7%)	346 (14.4%)	2 (0.3%)	1 (0.2%)	136 (18.3%)	0
Not specified	37 (2.6%)	1 (<0.1%)	5 (0.2%)	2 (0.3%)	0	11 (1.5%)	4 (0.2%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	PAKISTAN (N=1398)	POLAND (N=2749)	ROMANIA (N=2397)	REPUBLIC OF SERBIA (N=682)	RUSSIA (N=614)	SAUDI ARABIA (N=742)	SINGAPORE (N=1657)
Type of examination							
CT	0	571 (20.8%)	907 (37.8%)	313 (45.9%)	0	384 (51.8%)	0
CT (multislice)	702 (50.2%)	1214 (44.2%)	0	0	536 (87.3%)	0	1521 (91.8%)
Angiocardiology ²	0	209 (7.6%)	767 (32.0%)	0	0	123 (16.6%)	0
Urography	0	53 (1.9%)	126 (5.3%)	119 (17.4%)	0	56 (7.5%)	0
CT (singleslice)	515 (36.8%)	124 (4.5%)	0	0	70 (11.4%)	11 (1.5%)	0
Angiography	3 (0.2%)	167 (6.1%)	274 (11.4%)	107 (15.7%)	1 (0.2%)	50 (6.7%)	0
Phlebography	0	6 (0.2%)	10 (0.4%)	0	0	0	0
DSA	0	59 (2.1%)	0	0	0	0	0
PTCA	0	14 (0.5%)	71 (3.0%)	3 (0.4%)	0	1 (0.1%)	0
PTA	0	0	7 (0.3%)	1 (0.1%)	0	0	0
Other	0	0	9 (0.4%)	0	6 (1.0%)	0	0
Not specified	178 (12.7%)	332 (12.1%)	226 (9.4%)	139 (20.4%)	1 (0.2%)	117 (15.8%)	136 (8.2%)
Contrast quality							
Excellent	446 (31.9%)	1266 (46.1%)	1421 (59.3%)	318 (46.6%)	372 (60.6%)	672 (90.6%)	488 (29.5%)
Good	838 (59.9%)	1407 (51.2%)	948 (39.5%)	331 (48.5%)	223 (36.3%)	62 (8.4%)	934 (56.4%)
Adequate	104 (7.4%)	67 (2.4%)	23 (1.0%)	30 (4.4%)	18 (2.9%)	3 (0.4%)	220 (13.3%)
Moderate	8 (0.6%)	7 (0.3%)	1 (<0.1%)	2 (0.3%)	0	1 (0.1%)	15 (0.9%)
Non diagnostic	0	1 (<0.1%)	1 (<0.1%)	0	0	0	0
Not specified	2 (0.1%)	1 (<0.1%)	3 (0.1%)	1 (0.1%)	1 (0.2%)	4 (0.5%)	0

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	SLOVENIA (N=4787)	SLOVAKIA (N=1255)	THAILAND (N=562)	TURKEY (N=332)	TAIWAN (N=768)	UKRAINE (N=1905)	UNITED STATES (N=6791)
Injection route							
Intravenous	4298 (89.8%)	1101 (87.7%)	532 (94.7%)	298 (89.8%)	728 (94.8%)	1646 (86.4%)	6534 (96.2%)
Intra-arterial	477 (10.0%)	129 (10.3%)	30 (5.3%)	34 (10.2%)	40 (5.2%)	252 (13.2%)	256 (3.8%)
Other	9 (0.2%)	1 (<0.1%)	0	0	0	0	0
Not specified	3 (<0.1%)	24 (1.9%)	0	0	0	2 (0.1%)	1 (<0.1%)
Missing	0	0	0	0	0	5 (0.3%)	0
Examination region ¹							
Abdomen	0	0	127 (22.6%)	0	336 (43.8%)	1046 (54.9%)	0
Cardiac / Cardiac Vessels	0	0	0	0	0	272 (14.3%)	0
Thorax	0	0	88 (15.7%)	0	0	796 (41.8%)	0
Pelvis	0	0	0	0	0	471 (24.7%)	0
Head / Brain	0	0	37 (6.6%)	0	0	137 (7.2%)	0
Kidney / Renal Vessels	0	0	22 (3.9%)	0	572 (74.5%)	182 (9.6%)	0
Neck	0	0	22 (3.9%)	0	0	74 (3.9%)	0
Blood Vessels	0	0	8 (1.4%)	0	0	200 (10.5%)	0
Limbs	0	0	1 (0.2%)	0	0	1 (<0.1%)	0
Joints	0	0	0	0	0	0	0
Other	0	0	5 (0.9%)	0	0	2 (0.1%)	0
Not specified	0	0	0	0	0	10 (0.5%)	0
Missing	4787 (100.0%)	1255 (100.0%)	294 (52.3%)	332 (100.0%)	195 (25.4%)	79 (4.1%)	6791 (100.0%)
Indication ¹							
Tumour/Suspicion of Tumour	0	0	106 (18.9%)	0	7 (0.9%)	1026 (53.9%)	0
Pain	0	0	15 (2.7%)	0	149 (19.4%)	222 (11.7%)	0
Post-Therapy-Control	0	0	100 (17.8%)	0	7 (0.9%)	332 (17.4%)	0
Staging	0	0	25 (4.4%)	0	3 (0.4%)	397 (20.8%)	0
Inflammatory Diseases	0	0	3 (0.5%)	0	33 (4.3%)	49 (2.6%)	0
Infarct/Suspicion of Infarct	0	0	5 (0.9%)	0	1 (0.1%)	238 (12.5%)	0
Haemorrhage	0	0	2 (0.4%)	0	23 (3.0%)	12 (0.6%)	0
Trauma	0	0	3 (0.5%)	0	0	10 (0.5%)	0
Other	0	0	44 (7.8%)	0	413 (53.8%)	77 (4.0%)	0
Not specified	0	0	0	0	0	36 (1.9%)	0
Missing	4787 (100.0%)	1255 (100.0%)	294 (52.3%)	332 (100.0%)	195 (25.4%)	79 (4.1%)	6791 (100.0%)

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	SLOVENIA (N=4787)	SLOVAKIA (N=1255)	THAILAND (N=562)	TURKEY (N=332)	TAIWAN (N=768)	UKRAINE (N=1905)	UNITED STATES (N=6791)
Dose [ml]							
n	4786	1246	561	332	768	1900	6789
Nmiss	1	9	1	0	0	5	2
Mean (SD)	65.434 (35.404)	92.687 (37.504)	96.235 (23.741)	92.807 (62.692)	61.064 (25.847)	104.008 (67.494)	114.784 (31.503)
Median	50.000	100.000	100.000	100.000	50.000	100.000	100.000
Q1, Q3	50.000, 100.000	70.000, 100.000	95.000, 100.000	50.000, 100.000	50.000, 50.000	50.000, 100.000	100.000, 140.000
Min, Max	10.00, 400.00	2.00, 400.00	5.00, 200.00	12.00, 400.00	40.00, 300.00	5.00, 500.00	10.00, 470.00
Dose							
<100 ml	3519 (73.5%)	556 (44.3%)	157 (27.9%)	148 (44.6%)	652 (84.9%)	779 (40.9%)	1087 (16.0%)
100 - <150 ml	1101 (23.0%)	591 (47.1%)	385 (68.5%)	152 (45.8%)	106 (13.8%)	853 (44.8%)	4192 (61.7%)
150 - <200 ml	93 (1.9%)	50 (4.0%)	18 (3.2%)	11 (3.3%)	2 (0.3%)	44 (2.3%)	1428 (21.0%)
200 - <300 ml	66 (1.4%)	45 (3.6%)	1 (0.2%)	12 (3.6%)	7 (0.9%)	105 (5.5%)	63 (0.9%)
>=300 ml	7 (0.1%)	4 (0.3%)	0	9 (2.7%)	1 (0.1%)	119 (6.2%)	19 (0.3%)
Not specified	1 (<0.1%)	9 (0.7%)	1 (0.2%)	0	0	5 (0.3%)	2 (<0.1%)
Dose of iodine [g]							
n	4786	1246	561	332	768	1900	6789
Nmiss	1	9	1	0	0	5	2
Mean (SD)	21.063 (10.856)	30.305 (12.236)	32.383 (8.040)	29.559 (23.359)	21.241 (7.475)	36.244 (25.096)	36.553 (10.542)
Median	18.000	30.000	36.000	30.000	18.500	30.000	37.000
Q1, Q3	15.000, 30.000	24.000, 37.000	30.000, 37.000	15.000, 30.000	18.500, 18.500	18.500, 37.000	30.000, 44.400
Min, Max	3.00, 120.00	0.60, 148.00	1.50, 60.00	3.60, 148.00	14.80, 90.00	1.50, 185.00	3.00, 173.90
Dose of iodine							
<=20 g	3144 (65.7%)	213 (17.0%)	64 (11.4%)	131 (39.5%)	609 (79.3%)	534 (28.0%)	324 (4.8%)
>20 - 40 g	1435 (30.0%)	878 (70.0%)	431 (76.7%)	168 (50.6%)	145 (18.9%)	1086 (57.0%)	3943 (58.1%)
>40 - 60 g	172 (3.6%)	132 (10.5%)	66 (11.7%)	13 (3.9%)	10 (1.3%)	52 (2.7%)	2427 (35.7%)
>60 g	35 (0.7%)	23 (1.8%)	0	20 (6.0%)	4 (0.5%)	228 (12.0%)	95 (1.4%)
Not specified	1 (<0.1%)	9 (0.7%)	1 (0.2%)	0	0	5 (0.3%)	2 (<0.1%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	SLOVENIA (N=4787)	SLOVAKIA (N=1255)	THAILAND (N=562)	TURKEY (N=332)	TAIWAN (N=768)	UKRAINE (N=1905)	UNITED STATES (N=6791)
Type of examination							
CT	3205 (67.0%)	1056 (84.1%)	257 (45.7%)	272 (81.9%)	116 (15.1%)	0	6191 (91.2%)
CT (multislice)	0	0	0	0	0	750 (39.4%)	0
Angiocardiology ²	10 (0.2%)	0	0	18 (5.4%)	0	31 (1.6%)	0
Urography	1051 (22.0%)	39 (3.1%)	17 (3.0%)	25 (7.5%)	37 (4.8%)	66 (3.5%)	325 (4.8%)
CT (singleslice)	0	0	238 (42.3%)	0	0	641 (33.6%)	0
Angiography	377 (7.9%)	11 (0.9%)	26 (4.6%)	5 (1.5%)	0	183 (9.6%)	33 (0.5%)
Phlebography	0	0	0	0	0	138 (7.2%)	0
DSA	3 (<0.1%)	0	0	0	28 (3.6%)	0	0
PTCA	0	0	0	0	1 (0.1%)	0	0
PTA	6 (0.1%)	6 (0.5%)	0	0	0	0	0
Other	0	0	21 (3.7%)	0	0	1 (<0.1%)	0
Not specified	135 (2.8%)	143 (11.4%)	3 (0.5%)	12 (3.6%)	586 (76.3%)	95 (5.0%)	242 (3.6%)
Contrast quality							
Excellent	3494 (73.0%)	782 (62.3%)	108 (19.2%)	91 (27.4%)	6 (0.8%)	440 (23.1%)	3147 (46.3%)
Good	1220 (25.5%)	448 (35.7%)	363 (64.6%)	204 (61.4%)	608 (79.2%)	1334 (70.0%)	3056 (45.0%)
Adequate	63 (1.3%)	17 (1.4%)	73 (13.0%)	36 (10.8%)	150 (19.5%)	109 (5.7%)	547 (8.1%)
Moderate	8 (0.2%)	1 (<0.1%)	17 (3.0%)	1 (0.3%)	4 (0.5%)	3 (0.2%)	38 (0.6%)
Non diagnostic	2 (<0.1%)	0	1 (0.2%)	0	0	9 (0.5%)	3 (<0.1%)
Not specified	0	7 (0.6%)	0	0	0	10 (0.5%)	0

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	VIETNAM (N=1613)	SOUTH AFRICA (N=100)	Total (N=146649)
Injection route			
Intravenous	1586 (98.3%)	0	117343 (80.0%)
Intra-arterial	24 (1.5%)	100 (100.0%)	28489 (19.4%)
Other	3 (0.2%)	0	410 (0.3%)
Not specified	0	0	316 (0.2%)
Missing	0	0	91 (<0.1%)
Examination region ¹			
Abdomen	755 (46.8%)	0	27074 (18.5%)
Cardiac / Cardiac Vessels	5 (0.3%)	0	23058 (15.7%)
Thorax	231 (14.3%)	0	14101 (9.6%)
Pelvis	54 (3.3%)	0	8263 (5.6%)
Head / Brain	315 (19.5%)	0	6726 (4.6%)
Kidney / Renal Vessels	229 (14.2%)	0	4742 (3.2%)
Neck	48 (3.0%)	0	2717 (1.9%)
Blood Vessels	2 (0.1%)	0	1967 (1.3%)
Limbs	2 (0.1%)	0	415 (0.3%)
Joints	1 (<0.1%)	0	46 (<0.1%)
Other	11 (0.7%)	0	1148 (0.8%)
Not specified	0	0	20 (<0.1%)
Missing	0	100 (100.0%)	72289 (49.3%)
Indication ¹			
Tumour/Suspicion of Tumour	842 (52.2%)	0	26620 (18.2%)
Pain	261 (16.2%)	0	7597 (5.2%)
Post-Therapy-Control	40 (2.5%)	0	7588 (5.2%)
Staging	38 (2.4%)	0	5510 (3.8%)
Inflammatory Diseases	114 (7.1%)	0	4407 (3.0%)
Infarct/Suspicion of Infarct	9 (0.6%)	0	3488 (2.4%)
Haemorrhage	18 (1.1%)	0	954 (0.7%)
Trauma	24 (1.5%)	0	618 (0.4%)
Other	306 (19.0%)	0	24596 (16.8%)
Not specified	0	0	77 (<0.1%)
Missing	0	100 (100.0%)	72736 (49.6%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	VIETNAM (N=1613)	SOUTH AFRICA (N=100)	Total (N=146649)
Dose [ml]			
n	1613	100	145965
Nmiss	0	0	684
Mean (SD)	54.616 (18.142)	220.400 (123.990)	99.700 (45.337)
Median	50.000	150.000	100.000
Q1, Q3	50.000, 70.000	150.000, 235.000	75.000, 110.000
Min, Max	10.00, 150.00	150.00, 650.00	1.00, 800.00
Dose			
<100 ml	1603 (99.4%)	0	60898 (41.5%)
100 - <150 ml	7 (0.4%)	0	67160 (45.8%)
150 - <200 ml	3 (0.2%)	59 (59.0%)	11763 (8.0%)
200 - <300 ml	0	20 (20.0%)	4561 (3.1%)
>=300 ml	0	21 (21.0%)	1583 (1.1%)
Not specified	0	0	684 (0.5%)
Dose of iodine [g]			
n	1613	100	145965
Nmiss	0	0	684
Mean (SD)	16.821 (5.515)	81.548 (45.876)	32.514 (16.394)
Median	15.000	55.500	30.000
Q1, Q3	15.000, 21.000	55.500, 86.950	24.000, 37.000
Min, Max	3.00, 45.00	55.50, 240.50	0.30, 296.00
Dose of iodine			
<=20 g	1135 (70.4%)	0	24467 (16.7%)
>20 - 40 g	475 (29.4%)	0	95496 (65.1%)
>40 - 60 g	3 (0.2%)	59 (59.0%)	19549 (13.3%)
>60 g	0	41 (41.0%)	6453 (4.4%)
Not specified	0	0	684 (0.5%)

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Table 14.2 / 28: Exposure by country/region (Full analysis set for country/region) (cont.)

	VIETNAM (N=1613)	SOUTH AFRICA (N=100)	Total (N=146649)
Type of examination			
CT	0	0	65569 (44.7%)
CT (multislice)	651 (40.4%)	0	33240 (22.7%)
Angiocardiology ²	0	2 (2.0%)	12582 (8.6%)
Urography	0	0	10975 (7.5%)
CT (singleslice)	727 (45.1%)	0	4037 (2.8%)
Angiography	21 (1.3%)	0	1881 (1.3%)
Phlebography	121 (7.5%)	0	330 (0.2%)
DSA	3 (0.2%)	0	264 (0.2%)
PTCA	0	0	179 (0.1%)
PTA	0	0	84 (<0.1%)
Other	3 (0.2%)	0	7013 (4.8%)
Not specified	87 (5.4%)	98 (98.0%)	10495 (7.2%)
Contrast quality			
Excellent	190 (11.8%)	87 (87.0%)	74438 (50.8%)
Good	1317 (81.6%)	13 (13.0%)	64281 (43.8%)
Adequate	106 (6.6%)	0	6618 (4.5%)
Moderate	0	0	555 (0.4%)
Non diagnostic	0	0	58 (<0.1%)
Not specified	0	0	699 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas

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Table 14.2 / 29: Exposure by sex (Complete cases analysis set for sex)

	Male (N=74986)	Female (N=57864)	Total (N=132850)
Injection route			
Intravenous	56722 (75.6%)	48297 (83.5%)	105019 (79.1%)
Intra-arterial	18264 (24.4%)	9567 (16.5%)	27831 (20.9%)
Examination region ¹			
Abdomen	13998 (18.7%)	11274 (19.5%)	25272 (19.0%)
Cardiac / Cardiac Vessels	14809 (19.7%)	8019 (13.9%)	22828 (17.2%)
Thorax	7521 (10.0%)	5529 (9.6%)	13050 (9.8%)
Pelvis	3649 (4.9%)	4083 (7.1%)	7732 (5.8%)
Head / Brain	3026 (4.0%)	3072 (5.3%)	6098 (4.6%)
Kidney / Renal Vessels	2417 (3.2%)	1721 (3.0%)	4138 (3.1%)
Neck	1394 (1.9%)	1172 (2.0%)	2566 (1.9%)
Blood Vessels	1083 (1.4%)	660 (1.1%)	1743 (1.3%)
Limbs	255 (0.3%)	131 (0.2%)	386 (0.3%)
Joints	25 (<0.1%)	18 (<0.1%)	43 (<0.1%)
Other	561 (0.7%)	374 (0.6%)	935 (0.7%)
Not specified	3 (<0.1%)	5 (<0.1%)	8 (<0.1%)
Missing	33980 (45.3%)	28648 (49.5%)	62628 (47.1%)
Indication ¹			
Tumour/Suspicion of Tumour	14086 (18.8%)	10986 (19.0%)	25072 (18.9%)
Pain	3717 (5.0%)	3318 (5.7%)	7035 (5.3%)
Post-Therapy-Control	3980 (5.3%)	2987 (5.2%)	6967 (5.2%)
Staging	2858 (3.8%)	2304 (4.0%)	5162 (3.9%)
Inflammatory Diseases	2192 (2.9%)	1799 (3.1%)	3991 (3.0%)
Infarct/Suspicion of Infarct	2138 (2.9%)	1243 (2.1%)	3381 (2.5%)
Haemorrhage	480 (0.6%)	355 (0.6%)	835 (0.6%)
Trauma	381 (0.5%)	188 (0.3%)	569 (0.4%)
Other	14710 (19.6%)	8905 (15.4%)	23615 (17.8%)
Not specified	25 (<0.1%)	29 (<0.1%)	54 (<0.1%)
Missing	34197 (45.6%)	28824 (49.8%)	63021 (47.4%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 29: Exposure by sex (Complete cases analysis set for sex)

	Male (N=74986)	Female (N=57864)	Total (N=132850)
Dose [ml]			
n	74986	57864	132850
Nmiss	0	0	0
Mean (SD)	102.526 (49.512)	95.018 (40.282)	99.256 (45.873)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 120.000	70.000, 100.000	75.000, 110.000
Min, Max	1.00, 800.00	2.00, 600.00	1.00, 800.00
Dose			
<100 ml	30865 (41.2%)	26095 (45.1%)	56960 (42.9%)
100 - <150 ml	33699 (44.9%)	26317 (45.5%)	60016 (45.2%)
150 - <200 ml	6214 (8.3%)	3799 (6.6%)	10013 (7.5%)
200 - <300 ml	3092 (4.1%)	1253 (2.2%)	4345 (3.3%)
>=300 ml	1116 (1.5%)	400 (0.7%)	1516 (1.1%)
Dose of iodine [g]			
n	74986	57864	132850
Nmiss	0	0	0
Mean (SD)	33.796 (18.177)	30.676 (14.243)	32.437 (16.651)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	22.500, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	0.60, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	11956 (15.9%)	10861 (18.8%)	22817 (17.2%)
>20 - 40 g	48179 (64.3%)	39035 (67.5%)	87214 (65.6%)
>40 - 60 g	10396 (13.9%)	6267 (10.8%)	16663 (12.5%)
>60 g	4455 (5.9%)	1701 (2.9%)	6156 (4.6%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.2 / 29: Exposure by sex (Complete cases analysis set for sex)

	Male (N=74986)	Female (N=57864)	Total (N=132850)
Type of examination			
CT	29916 (39.9%)	27572 (47.6%)	57488 (43.3%)
CT (multislice)	18163 (24.2%)	13109 (22.7%)	31272 (23.5%)
Angiocardiology ²	7701 (10.3%)	4793 (8.3%)	12494 (9.4%)
Urography	5492 (7.3%)	4605 (8.0%)	10097 (7.6%)
CT (singleslice)	1638 (2.2%)	1377 (2.4%)	3015 (2.3%)
Angiography	1230 (1.6%)	566 (1.0%)	1796 (1.4%)
Phlebography	118 (0.2%)	178 (0.3%)	296 (0.2%)
DSA	123 (0.2%)	98 (0.2%)	221 (0.2%)
PTCA	132 (0.2%)	33 (<0.1%)	165 (0.1%)
PTA	49 (<0.1%)	29 (<0.1%)	78 (<0.1%)
Other	4879 (6.5%)	1974 (3.4%)	6853 (5.2%)
Not specified	5545 (7.4%)	3530 (6.1%)	9075 (6.8%)
Contrast quality			
Excellent	38663 (51.6%)	29147 (50.4%)	67810 (51.0%)
Good	32445 (43.3%)	25595 (44.2%)	58040 (43.7%)
Adequate	3206 (4.3%)	2621 (4.5%)	5827 (4.4%)
Moderate	314 (0.4%)	184 (0.3%)	498 (0.4%)
Non diagnostic	29 (<0.1%)	24 (<0.1%)	53 (<0.1%)
Not specified	329 (0.4%)	293 (0.5%)	622 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 30: Exposure by race (Complete cases analysis set for race)

	Asian (N=49621)	White (N=6182)	Black (N=24)	Other (N=164)	Total (N=55991)
Injection route					
Intravenous	31242 (63.0%)	4309 (69.7%)	23 (95.8%)	161 (98.2%)	35735 (63.8%)
Intra-arterial	18379 (37.0%)	1873 (30.3%)	1 (4.2%)	3 (1.8%)	20256 (36.2%)
Examination region ¹					
Cardiac / Cardiac Vessels	20886 (42.1%)	1748 (28.3%)	1 (4.2%)	17 (10.4%)	22652 (40.5%)
Abdomen	15107 (30.4%)	2357 (38.1%)	9 (37.5%)	74 (45.1%)	17547 (31.3%)
Thorax	6855 (13.8%)	1712 (27.7%)	6 (25.0%)	28 (17.1%)	8601 (15.4%)
Pelvis	3455 (7.0%)	967 (15.6%)	4 (16.7%)	48 (29.3%)	4474 (8.0%)
Head / Brain	2915 (5.9%)	818 (13.2%)	4 (16.7%)	23 (14.0%)	3760 (6.7%)
Kidney / Renal Vessels	2793 (5.6%)	416 (6.7%)	7 (29.2%)	13 (7.9%)	3229 (5.8%)
Neck	1497 (3.0%)	211 (3.4%)	2 (8.3%)	9 (5.5%)	1719 (3.1%)
Blood Vessels	962 (1.9%)	485 (7.8%)	1 (4.2%)	13 (7.9%)	1461 (2.6%)
Limbs	225 (0.5%)	105 (1.7%)	0	0	330 (0.6%)
Joints	22 (<0.1%)	1 (<0.1%)	0	0	23 (<0.1%)
Other	669 (1.3%)	143 (2.3%)	1 (4.2%)	7 (4.3%)	820 (1.5%)
Not specified	2 (<0.1%)	5 (<0.1%)	0	0	7 (<0.1%)
Indication ¹					
Tumour/Suspicion of Tumour	16964 (34.2%)	2391 (38.7%)	5 (20.8%)	42 (25.6%)	19402 (34.7%)
Pain	3736 (7.5%)	1192 (19.3%)	5 (20.8%)	60 (36.6%)	4993 (8.9%)
Post-Therapy-Control	3858 (7.8%)	877 (14.2%)	6 (25.0%)	12 (7.3%)	4753 (8.5%)
Staging	2212 (4.5%)	1137 (18.4%)	1 (4.2%)	7 (4.3%)	3357 (6.0%)
Infarct/Suspicion of Infarct	1980 (4.0%)	989 (16.0%)	1 (4.2%)	13 (7.9%)	2983 (5.3%)
Inflammatory Diseases	2368 (4.8%)	275 (4.4%)	1 (4.2%)	8 (4.9%)	2652 (4.7%)
Haemorrhage	581 (1.2%)	67 (1.1%)	1 (4.2%)	2 (1.2%)	651 (1.2%)
Trauma	284 (0.6%)	51 (0.8%)	0	3 (1.8%)	338 (0.6%)
Other	20916 (42.2%)	792 (12.8%)	7 (29.2%)	55 (33.5%)	21770 (38.9%)
Not specified	15 (<0.1%)	39 (0.6%)	0	0	54 (<0.1%)
Dose [ml]					
n	49621	6182	24	164	55991
Nmiss	0	0	0	0	0
Mean (SD)	100.534 (52.419)	100.304 (56.199)	81.042 (37.066)	104.665 (25.781)	100.512 (52.787)
Median	90.000	100.000	75.000	100.000	95.000
Q1, Q3	70.000, 100.000	60.000, 100.000	50.000, 100.000	100.000, 120.000	70.000, 100.000
Min, Max	2.00, 800.00	1.00, 500.00	25.00, 150.00	10.00, 155.00	1.00, 800.00

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Table 14.2 / 30: Exposure by race (Complete cases analysis set for race)

	Asian (N=49621)	White (N=6182)	Black (N=24)	Other (N=164)	Total (N=55991)
Dose					
<100 ml	25533 (51.5%)	2853 (46.2%)	14 (58.3%)	24 (14.6%)	28424 (50.8%)
100 - <150 ml	17660 (35.6%)	2536 (41.0%)	9 (37.5%)	125 (76.2%)	20330 (36.3%)
150 - <200 ml	2889 (5.8%)	291 (4.7%)	1 (4.2%)	15 (9.1%)	3196 (5.7%)
200 - <300 ml	2611 (5.3%)	325 (5.3%)	0	0	2936 (5.2%)
>=300 ml	928 (1.9%)	177 (2.9%)	0	0	1105 (2.0%)
Dose of iodine [g]					
n	49621	6182	24	164	55991
Nmiss	0	0	0	0	0
Mean (SD)	34.596 (19.776)	35.627 (20.703)	29.490 (13.728)	34.387 (10.432)	34.707 (19.860)
Median	30.000	33.000	27.750	30.000	30.000
Q1, Q3	24.000, 37.000	22.200, 37.000	18.500, 37.000	30.000, 40.405	24.000, 37.000
Min, Max	0.60, 296.00	0.37, 185.00	9.25, 55.50	3.00, 57.35	0.37, 296.00
Dose of iodine					
<=20 g	7766 (15.7%)	1382 (22.4%)	8 (33.3%)	13 (7.9%)	9169 (16.4%)
>20 - 40 g	32206 (64.9%)	3328 (53.8%)	11 (45.8%)	110 (67.1%)	35655 (63.7%)
>40 - 60 g	5525 (11.1%)	969 (15.7%)	5 (20.8%)	41 (25.0%)	6540 (11.7%)
>60 g	4124 (8.3%)	503 (8.1%)	0	0	4627 (8.3%)
Type of examination					
CT (multislice)	27903 (56.2%)	3108 (50.3%)	10 (41.7%)	150 (91.5%)	31171 (55.7%)
Angiocardiography ²	10947 (22.1%)	1148 (18.6%)	1 (4.2%)	2 (1.2%)	12098 (21.6%)
CT (singleslice)	2006 (4.0%)	936 (15.1%)	8 (33.3%)	1 (0.6%)	2951 (5.3%)
Angiography	211 (0.4%)	562 (9.1%)	0	1 (0.6%)	774 (1.4%)
Phlebography	124 (0.2%)	172 (2.8%)	0	0	296 (0.5%)
DSA	105 (0.2%)	61 (1.0%)	0	0	166 (0.3%)
CT	7 (<0.1%)	0	0	0	7 (<0.1%)
Other	6835 (13.8%)	16 (0.3%)	0	2 (1.2%)	6853 (12.2%)
Not specified	1483 (3.0%)	179 (2.9%)	5 (20.8%)	8 (4.9%)	1675 (3.0%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



Table 14.2 / 30: Exposure by race (Complete cases analysis set for race)

	Asian (N=49621)	White (N=6182)	Black (N=24)	Other (N=164)	Total (N=55991)
Contrast quality					
Excellent	29178 (58.8%)	2796 (45.2%)	5 (20.8%)	23 (14.0%)	32002 (57.2%)
Good	18499 (37.3%)	3179 (51.4%)	17 (70.8%)	136 (82.9%)	21831 (39.0%)
Adequate	1788 (3.6%)	183 (3.0%)	2 (8.3%)	4 (2.4%)	1977 (3.5%)
Moderate	149 (0.3%)	7 (0.1%)	0	1 (0.6%)	157 (0.3%)
Non diagnostic	7 (<0.1%)	9 (0.1%)	0	0	16 (<0.1%)
Not specified	0	8 (0.1%)	0	0	8 (<0.1%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.2 / 31: Exposure by geographical region (Complete cases analysis set for geographical region)

	Africa (N=387)	Asia (excl. China) (N=32096)	China (N=36787)	Europe (N=63580)	Total (N=132850)
Injection route					
Intravenous	284 (73.4%)	28556 (89.0%)	19436 (52.8%)	56743 (89.2%)	105019 (79.1%)
Intra-arterial	103 (26.6%)	3540 (11.0%)	17351 (47.2%)	6837 (10.8%)	27831 (20.9%)
Examination region ¹					
Abdomen	0	9198 (28.7%)	9101 (24.7%)	25272 (19.0%) (N=132850)	
Cardiac / Cardiac Vessels	0	1397 (4.4%)	19640 (53.4%)	22828 (17.2%) (N=132850)	
Thorax	0	4089 (12.7%)	4381 (11.9%)	13050 (9.8%) (N=132850)	
Pelvis	0	4293 (13.4%)	1633 (4.4%)	7732 (5.8%) (N=132850)	
Head / Brain	0	2539 (7.9%)	1165 (3.2%)	6098 (4.6%) (N=132850)	
Kidney / Renal Vessels	0	2026 (6.3%)	1182 (3.2%)	4138 (3.1%) (N=132850)	
Neck	0	1117 (3.5%)	801 (2.2%)	2566 (1.9%) (N=132850)	
Blood Vessels	0	250 (0.8%)	858 (2.3%)	1743 (1.3%) (N=132850)	
Limbs	0	73 (0.2%)	174 (0.5%)	386 (0.3%) (N=132850)	
Joints	0	15 (<0.1%)	15 (<0.1%)	43 (<0.1%) (N=132850)	
Other	0	568 (1.8%)	171 (0.5%)	935 (0.7%) (N=132850)	
Not specified	0	2 (<0.1%)	0	8 (<0.1%) (N=132850)	
Missing	387 (100.0%)	13826 (43.1%)	0	62628 (47.1%) (N=132850)	
Indication ¹					
Tumour/Suspicion of Tumour	0	7175 (22.4%)	11540 (31.4%)	25072 (18.9%) (N=132850)	
Pain	0	2977 (9.3%)	1779 (4.8%)	7035 (5.3%) (N=132850)	
Post-Therapy-Control	0	2258 (7.0%)	2253 (6.1%)	6967 (5.2%) (N=132850)	
Staging	0	1269 (4.0%)	1585 (4.3%)	5162 (3.9%) (N=132850)	
Inflammatory Diseases	0	1498 (4.7%)	1335 (3.6%)	3991 (3.0%) (N=132850)	
Infarct/Suspicion of Infarct	0	1092 (3.4%)	1044 (2.8%)	3381 (2.5%) (N=132850)	
Haemorrhage	0	295 (0.9%)	364 (1.0%)	835 (0.6%) (N=132850)	
Trauma	0	282 (0.9%)	136 (0.4%)	569 (0.4%) (N=132850)	
Other	0	3465 (10.8%)	18344 (49.9%)	23615 (17.8%) (N=132850)	
Not specified	0	15 (<0.1%)	0	54 (<0.1%) (N=132850)	
Missing	387 (100.0%)	14011 (43.7%)	0	63021 (47.4%) (N=132850)	

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 31: Exposure by geographical region (Complete cases analysis set for geographical region)

	Africa (N=387)	Asia (excl. China) (N=32096)	China (N=36787)	Europe (N=63580)	Total (N=132850)
Dose [ml]					
n	387	32096	36787	63580	132850
Nmiss	0	0	0	0	0
Mean (SD)	103.078 (95.557)	101.216 (43.706)	105.439 (54.345)	94.666 (40.289)	99.256 (45.873)
Median	50.000	100.000	100.000	100.000	100.000
Q1, Q3	50.000, 150.000	70.000, 130.000	80.000, 100.000	75.000, 100.000	75.000, 110.000
Min, Max	16.00, 650.00	2.00, 800.00	2.00, 500.00	1.00, 800.00	1.00, 800.00
Dose					
<100 ml	226 (58.4%)	11572 (36.1%)	18212 (49.5%)	26950 (42.4%)	56960 (42.9%)
100 - <150 ml	58 (15.0%)	16692 (52.0%)	12653 (34.4%)	30613 (48.1%)	60016 (45.2%)
150 - <200 ml	62 (16.0%)	3076 (9.6%)	2594 (7.1%)	4281 (6.7%)	10013 (7.5%)
200 - <300 ml	20 (5.2%)	545 (1.7%)	2472 (6.7%)	1308 (2.1%)	4345 (3.3%)
>=300 ml	21 (5.4%)	211 (0.7%)	856 (2.3%)	428 (0.7%)	1516 (1.1%)
Dose of iodine [g]					
n	387	32096	36787	63580	132850
Nmiss	0	0	0	0	0
Mean (SD)	34.928 (36.521)	32.476 (14.998)	36.644 (20.732)	29.968 (13.878)	32.437 (16.651)
Median	15.000	30.000	30.000	30.000	30.000
Q1, Q3	15.000, 55.500	24.000, 39.000	25.900, 37.000	22.500, 36.000	24.000, 37.000
Min, Max	4.80, 240.50	0.60, 296.00	0.60, 185.00	0.30, 240.50	0.30, 296.00
Dose of iodine					
<=20 g	212 (54.8%)	7135 (22.2%)	3084 (8.4%)	12386 (19.5%)	22817 (17.2%)
>20 - 40 g	72 (18.6%)	17645 (55.0%)	26171 (71.1%)	43326 (68.1%)	87214 (65.6%)
>40 - 60 g	62 (16.0%)	6597 (20.6%)	3649 (9.9%)	6355 (10.0%)	16663 (12.5%)
>60 g	41 (10.6%)	719 (2.2%)	3883 (10.6%)	1513 (2.4%)	6156 (4.6%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.2 / 31: Exposure by geographical region (Complete cases analysis set for geographical region)

	Africa (N=387)	Asia (excl. China) (N=32096)	China (N=36787)	Europe (N=63580)	Total (N=132850)
Type of examination					
CT	170 (43.9%)	15651 (48.8%)	0	41667 (65.5%)	57488 (43.3%)
Urography	113 (29.2%)	727 (2.3%)	0	9257 (14.6%)	10097 (7.6%)
CT (multislice)	0	8707 (27.1%)	19397 (52.7%)	3168 (5.0%)	31272 (23.5%)
Angiocardiology ²	2 (0.5%)	787 (2.5%)	10242 (27.8%)	1463 (2.3%)	12494 (9.4%)
Angiography	3 (0.8%)	381 (1.2%)	2 (<0.1%)	1410 (2.2%)	1796 (1.4%)
CT (singleslice)	0	2027 (6.3%)	29 (<0.1%)	959 (1.5%)	3015 (2.3%)
Phlebography	0	123 (0.4%)	1 (<0.1%)	172 (0.3%)	296 (0.2%)
PTCA	0	33 (0.1%)	0	132 (0.2%)	165 (0.1%)
DSA	0	120 (0.4%)	18 (<0.1%)	83 (0.1%)	221 (0.2%)
PTA	0	0	0	78 (0.1%)	78 (<0.1%)
Other	0	31 (<0.1%)	6806 (18.5%)	16 (<0.1%)	6853 (5.2%)
Not specified	99 (25.6%)	3509 (10.9%)	292 (0.8%)	5175 (8.1%)	9075 (6.8%)
Contrast quality					
Excellent	352 (91.0%)	14014 (43.7%)	22849 (62.1%)	30595 (48.1%)	67810 (51.0%)
Good	34 (8.8%)	16028 (49.9%)	12733 (34.6%)	29245 (46.0%)	58040 (43.7%)
Adequate	0	1918 (6.0%)	1101 (3.0%)	2808 (4.4%)	5827 (4.4%)
Moderate	1 (0.3%)	96 (0.3%)	97 (0.3%)	304 (0.5%)	498 (0.4%)
Non diagnostic	0	7 (<0.1%)	7 (<0.1%)	39 (<0.1%)	53 (<0.1%)
Not specified	0	33 (0.1%)	0	589 (0.9%)	622 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=513)	BULGARIA (N=258)	SWITZERLAND (N=1367)	CHINA (N=36787)	GERMANY (N=40766)	ESTONIA (N=155)	EGYPT (N=287)
Injection route							
Intra-arterial	286 (55.8%)	231 (89.5%)	36 (2.6%)	17351 (47.2%)	1962 (4.8%)	0	3 (1.0%)
Intravenous	227 (44.2%)	27 (10.5%)	1331 (97.4%)	19436 (52.8%)	38804 (95.2%)	155 (100.0%)	284 (99.0%)
Examination region ¹							
Abdomen	28 (5.5%)	0	0	9101 (24.7%)	4517 (11.1%)	0	0
Cardiac / Cardiac Vessels	290 (56.5%)	0	0	19640 (53.4%)	30 (<0.1%)	0	0
Thorax	154 (30.0%)	0	0	4381 (11.9%)	2816 (6.9%)	0	0
Pelvis	2 (0.4%)	0	0	1633 (4.4%)	807 (2.0%)	0	0
Head / Brain	42 (8.2%)	0	0	1165 (3.2%)	1528 (3.7%)	0	0
Kidney / Renal Vessels	1 (0.2%)	0	0	1182 (3.2%)	523 (1.3%)	0	0
Neck	4 (0.8%)	0	0	801 (2.2%)	429 (1.1%)	0	0
Blood Vessels	99 (19.3%)	0	0	858 (2.3%)	141 (0.3%)	0	0
Limbs	0	0	0	174 (0.5%)	29 (<0.1%)	0	0
Joints	0	0	0	15 (<0.1%)	12 (<0.1%)	0	0
Other	0	0	0	171 (0.5%)	53 (0.1%)	0	0
Not specified	0	0	0	0	0	0	0
Missing	0	258 (100.0%)	1367 (100.0%)	0	31973 (78.4%)	155 (100.0%)	287 (100.0%)
Indication ¹							
Tumour/Suspicion of Tumour	42 (8.2%)	0	0	11540 (31.4%)	3867 (9.5%)	0	0
Pain	258 (50.3%)	0	0	1779 (4.8%)	1079 (2.6%)	0	0
Post-Therapy-Control	19 (3.7%)	0	0	2253 (6.1%)	1564 (3.8%)	0	0
Staging	22 (4.3%)	0	0	1585 (4.3%)	1119 (2.7%)	0	0
Inflammatory Diseases	31 (6.0%)	0	0	1335 (3.6%)	874 (2.1%)	0	0
Infarct/Suspicion of Infarct	246 (48.0%)	0	0	1044 (2.8%)	231 (0.6%)	0	0
Haemorrhage	4 (0.8%)	0	0	364 (1.0%)	100 (0.2%)	0	0
Trauma	8 (1.6%)	0	0	136 (0.4%)	86 (0.2%)	0	0
Other	22 (4.3%)	0	0	18344 (49.9%)	1031 (2.5%)	0	0
Not specified	0	0	0	0	0	0	0
Missing	0	258 (100.0%)	1367 (100.0%)	0	32176 (78.9%)	155 (100.0%)	287 (100.0%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=513)	BULGARIA (N=258)	SWITZERLAND (N=1367)	CHINA (N=36787)	GERMANY (N=40766)	ESTONIA (N=155)	EGYPT (N=287)
Dose [ml]							
n	513	258	1367	36787	40766	155	287
Nmiss	0	0	0	0	0	0	0
Mean (SD)	108.938 (48.598)	158.372 (113.753)	119.843 (34.833)	105.439 (54.345)	97.667 (30.638)	57.065 (17.225)	62.199 (22.638)
Median	100.000	120.000	120.000	100.000	100.000	50.000	50.000
Q1, Q3	80.000, 120.000	100.000, 200.000	100.000, 150.000	80.000, 100.000	80.000, 100.000	40.000, 70.000	50.000, 70.000
Min, Max	50.00, 450.00	35.00, 800.00	25.00, 300.00	2.00, 500.00	1.00, 500.00	20.00, 100.00	16.00, 150.00
Dose							
<100 ml	182 (35.5%)	62 (24.0%)	279 (20.4%)	18212 (49.5%)	15158 (37.2%)	152 (98.1%)	226 (78.7%)
100 - <150 ml	228 (44.4%)	85 (32.9%)	568 (41.6%)	12653 (34.4%)	22111 (54.2%)	3 (1.9%)	58 (20.2%)
150 - <200 ml	64 (12.5%)	32 (12.4%)	490 (35.8%)	2594 (7.1%)	2900 (7.1%)	0	3 (1.0%)
200 - <300 ml	29 (5.7%)	42 (16.3%)	29 (2.1%)	2472 (6.7%)	512 (1.3%)	0	0
>=300 ml	10 (1.9%)	37 (14.3%)	1 (<0.1%)	856 (2.3%)	85 (0.2%)	0	0
Dose of iodine [g]							
n	513	258	1367	36787	40766	155	287
Nmiss	0	0	0	0	0	0	0
Mean (SD)	40.280 (17.992)	55.502 (37.827)	36.931 (10.440)	36.644 (20.732)	29.924 (10.082)	17.201 (5.231)	18.684 (6.845)
Median	37.000	44.400	37.000	30.000	30.000	15.000	15.000
Q1, Q3	29.600, 44.400	31.450, 74.000	30.000, 45.000	25.900, 37.000	24.000, 30.000	12.000, 21.000	15.000, 21.000
Min, Max	18.50, 166.50	12.95, 240.00	7.50, 90.00	0.60, 185.00	0.30, 185.00	6.00, 30.00	4.80, 45.00
Dose of iodine							
<=20 g	31 (6.0%)	37 (14.3%)	85 (6.2%)	3084 (8.4%)	3909 (9.6%)	114 (73.5%)	212 (73.9%)
>20 - 40 g	326 (63.5%)	85 (32.9%)	651 (47.6%)	26171 (71.1%)	32639 (80.1%)	41 (26.5%)	72 (25.1%)
>40 - 60 g	116 (22.6%)	54 (20.9%)	623 (45.6%)	3649 (9.9%)	3770 (9.2%)	0	3 (1.0%)
>60 g	40 (7.8%)	82 (31.8%)	8 (0.6%)	3883 (10.6%)	448 (1.1%)	0	0

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region)

	BOSNIA AND HERZEGOVINA (N=513)	BULGARIA (N=258)	SWITZERLAND (N=1367)	CHINA (N=36787)	GERMANY (N=40766)	ESTONIA (N=155)	EGYPT (N=287)
Type of examination							
Angiocardiology ²	225 (43.9%)	64 (24.8%)	8 (0.6%)	10242 (27.8%)	41 (0.1%)	0	0
Angiography	0	36 (14.0%)	1 (<0.1%)	2 (<0.1%)	46 (0.1%)	0	3 (1.0%)
DSA	2 (0.4%)	0	0	18 (<0.1%)	17 (<0.1%)	0	0
Phlebography	18 (3.5%)	0	0	1 (<0.1%)	1 (<0.1%)	0	0
CT (singleslice)	60 (11.7%)	0	0	29 (<0.1%)	9 (<0.1%)	0	0
CT (multislice)	208 (40.5%)	0	0	19397 (52.7%)	4 (<0.1%)	0	0
CT	0	26 (10.1%)	1285 (94.0%)	0	30340 (74.4%)	0	170 (59.2%)
Urography	0	0	16 (1.2%)	0	7220 (17.7%)	153 (98.7%)	113 (39.4%)
PTCA	0	6 (2.3%)	0	0	31 (<0.1%)	0	0
PTA	0	0	22 (1.6%)	0	24 (<0.1%)	0	0
Other	0	0	0	6806 (18.5%)	0	0	0
Not specified	0	126 (48.8%)	35 (2.6%)	292 (0.8%)	3033 (7.4%)	2 (1.3%)	1 (0.3%)
Contrast quality							
Excellent	413 (80.5%)	227 (88.0%)	410 (30.0%)	22849 (62.1%)	18945 (46.5%)	44 (28.4%)	265 (92.3%)
Good	100 (19.5%)	29 (11.2%)	899 (65.8%)	12733 (34.6%)	19210 (47.1%)	93 (60.0%)	21 (7.3%)
Adequate	0	2 (0.8%)	50 (3.7%)	1101 (3.0%)	1800 (4.4%)	14 (9.0%)	0
Moderate	0	0	8 (0.6%)	97 (0.3%)	221 (0.5%)	4 (2.6%)	1 (0.3%)
Non diagnostic	0	0	0	7 (<0.1%)	25 (<0.1%)	0	0
Not specified	0	0	0	0	565 (1.4%)	0	0

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SPAIN (N=1827)	FINLAND (N=417)	CROATIA (N=387)	HUNGARY (N=217)	INDONESIA (N=656)	IRAN (N=5012)	ITALY (N=683)
Injection route							
Intra-arterial	173 (9.5%)	0	123 (31.8%)	139 (64.1%)	101 (15.4%)	0	48 (7.0%)
Intravenous	1654 (90.5%)	417 (100.0%)	264 (68.2%)	78 (35.9%)	555 (84.6%)	5012 (100.0%)	635 (93.0%)
Examination region ¹							
Abdomen	0	0	0	39 (18.0%)	107 (16.3%)	2984 (59.5%)	381 (55.8%)
Cardiac / Cardiac Vessels	0	0	0	139 (64.1%)	113 (17.2%)	134 (2.7%)	7 (1.0%)
Thorax	0	0	0	30 (13.8%)	71 (10.8%)	1466 (29.2%)	316 (46.3%)
Pelvis	0	0	0	39 (18.0%)	24 (3.7%)	2365 (47.2%)	190 (27.8%)
Head / Brain	0	0	0	21 (9.7%)	134 (20.4%)	741 (14.8%)	134 (19.6%)
Kidney / Renal Vessels	0	0	0	0	187 (28.5%)	361 (7.2%)	45 (6.6%)
Neck	0	0	0	2 (0.9%)	21 (3.2%)	364 (7.3%)	68 (10.0%)
Blood Vessels	0	0	0	0	6 (0.9%)	142 (2.8%)	22 (3.2%)
Limbs	0	0	0	0	9 (1.4%)	20 (0.4%)	5 (0.7%)
Joints	0	0	0	0	0	4 (<0.1%)	0
Other	0	0	0	2 (0.9%)	33 (5.0%)	59 (1.2%)	17 (2.5%)
Not specified	0	0	0	0	0	0	0
Missing	1827 (100.0%)	417 (100.0%)	387 (100.0%)	0	0	25 (0.5%)	163 (23.9%)
Indication ¹							
Tumour/Suspicion of Tumour	0	0	0	29 (13.4%)	236 (36.0%)	1631 (32.5%)	255 (37.3%)
Pain	0	0	0	64 (29.5%)	144 (22.0%)	948 (18.9%)	14 (2.0%)
Post-Therapy-Control	0	0	0	19 (8.8%)	14 (2.1%)	614 (12.3%)	148 (21.7%)
Staging	0	0	0	36 (16.6%)	8 (1.2%)	603 (12.0%)	112 (16.4%)
Inflammatory Diseases	0	0	0	0	27 (4.1%)	356 (7.1%)	27 (4.0%)
Infarct/Suspicion of Infarct	0	0	0	29 (13.4%)	76 (11.6%)	146 (2.9%)	10 (1.5%)
Haemorrhage	0	0	0	0	14 (2.1%)	75 (1.5%)	3 (0.4%)
Trauma	0	0	0	0	7 (1.1%)	122 (2.4%)	1 (0.1%)
Other	0	0	0	132 (60.8%)	184 (28.0%)	794 (15.8%)	91 (13.3%)
Not specified	0	0	0	0	0	0	2 (0.3%)
Missing	1827 (100.0%)	417 (100.0%)	387 (100.0%)	0	0	205 (4.1%)	163 (23.9%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SPAIN (N=1827)	FINLAND (N=417)	CROATIA (N=387)	HUNGARY (N=217)	INDONESIA (N=656)	IRAN (N=5012)	ITALY (N=683)
Dose [ml]							
n	1827	417	387	217	656	5012	683
Nmiss	0	0	0	0	0	0	0
Mean (SD)	115.407 (46.238)	108.950 (20.829)	91.863 (52.045)	107.677 (74.571)	69.738 (50.900)	106.863 (30.028)	115.612 (34.249)
Median	100.000	118.000	100.000	90.000	50.000	100.000	120.000
Q1, Q3	100.000, 120.000	100.000, 120.000	50.000, 100.000	50.000, 120.000	50.000, 85.500	100.000, 120.000	100.000, 130.000
Min, Max	20.00, 650.00	14.00, 200.00	10.00, 300.00	4.00, 400.00	8.00, 600.00	5.00, 350.00	1.00, 300.00
Dose							
<100 ml	275 (15.1%)	56 (13.4%)	192 (49.6%)	109 (50.2%)	503 (76.7%)	824 (16.4%)	121 (17.7%)
100 - <150 ml	1350 (73.9%)	360 (86.3%)	120 (31.0%)	65 (30.0%)	121 (18.4%)	3456 (69.0%)	478 (70.0%)
150 - <200 ml	132 (7.2%)	0	45 (11.6%)	16 (7.4%)	6 (0.9%)	613 (12.2%)	54 (7.9%)
200 - <300 ml	39 (2.1%)	1 (0.2%)	28 (7.2%)	18 (8.3%)	14 (2.1%)	111 (2.2%)	26 (3.8%)
>=300 ml	31 (1.7%)	0	2 (0.5%)	9 (4.1%)	12 (1.8%)	8 (0.2%)	4 (0.6%)
Dose of iodine [g]							
n	1827	417	387	217	656	5012	683
Nmiss	0	0	0	0	0	0	0
Mean (SD)	37.092 (17.516)	32.799 (6.051)	29.332 (15.516)	34.572 (23.017)	23.551 (17.961)	32.271 (9.200)	41.680 (12.771)
Median	36.000	35.400	30.000	30.000	18.500	30.000	39.000
Q1, Q3	30.000, 37.000	30.000, 36.000	15.000, 37.000	18.000, 40.700	15.000, 30.000	30.000, 36.000	37.000, 44.400
Min, Max	7.40, 240.50	4.20, 60.00	3.00, 90.00	1.20, 120.00	2.40, 180.00	1.50, 105.00	0.37, 111.00
Dose of iodine							
<=20 g	58 (3.2%)	19 (4.6%)	175 (45.2%)	72 (33.2%)	384 (58.5%)	314 (6.3%)	17 (2.5%)
>20 - 40 g	1450 (79.4%)	378 (90.6%)	136 (35.1%)	90 (41.5%)	239 (36.4%)	3791 (75.6%)	329 (48.2%)
>40 - 60 g	226 (12.4%)	20 (4.8%)	68 (17.6%)	27 (12.4%)	12 (1.8%)	893 (17.8%)	303 (44.4%)
>60 g	93 (5.1%)	0	8 (2.1%)	28 (12.9%)	21 (3.2%)	14 (0.3%)	34 (5.0%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SPAIN (N=1827)	FINLAND (N=417)	CROATIA (N=387)	HUNGARY (N=217)	INDONESIA (N=656)	IRAN (N=5012)	ITALY (N=683)
Type of examination							
Angiocardiology ²	30 (1.6%)	0	2 (0.5%)	58 (26.7%)	53 (8.1%)	0	0
Angiography	37 (2.0%)	0	10 (2.6%)	81 (37.3%)	26 (4.0%)	0	0
DSA	1 (<0.1%)	0	1 (0.3%)	0	20 (3.0%)	0	0
Phlebography	0	0	0	0	3 (0.5%)	0	0
CT (singleslice)	0	0	0	0	183 (27.9%)	0	81 (11.9%)
CT (multislice)	0	0	0	78 (35.9%)	176 (26.8%)	144 (2.9%)	412 (60.3%)
CT	1568 (85.8%)	417 (100.0%)	191 (49.4%)	0	0	4868 (97.1%)	100 (14.6%)
Urography	51 (2.8%)	0	73 (18.9%)	0	0	0	0
PTCA	0	0	0	0	0	0	0
PTA	0	0	8 (2.1%)	0	0	0	5 (0.7%)
Other	0	0	0	0	5 (0.8%)	0	0
Not specified	140 (7.7%)	0	102 (26.4%)	0	190 (29.0%)	0	85 (12.4%)
Contrast quality							
Excellent	684 (37.4%)	62 (14.9%)	247 (63.8%)	128 (59.0%)	164 (25.0%)	1378 (27.5%)	206 (30.2%)
Good	827 (45.3%)	336 (80.6%)	123 (31.8%)	88 (40.6%)	466 (71.0%)	2728 (54.4%)	379 (55.5%)
Adequate	271 (14.8%)	17 (4.1%)	17 (4.4%)	1 (0.5%)	25 (3.8%)	862 (17.2%)	95 (13.9%)
Moderate	41 (2.2%)	0	0	0	1 (0.2%)	15 (0.3%)	2 (0.3%)
Non diagnostic	1 (<0.1%)	0	0	0	0	2 (<0.1%)	0
Not specified	3 (0.2%)	2 (0.5%)	0	0	0	27 (0.5%)	1 (0.1%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	JORDAN (N=1572)	KOREA (SOUTH) (N=13731)	LITHUANIA (N=2335)	LATVIA (N=399)	MOLDOVA (N=10)	MALAYSIA (N=859)	PHILIPPINES (N=3987)
Injection route							
Intra-arterial	1044 (66.4%)	1058 (7.7%)	847 (36.3%)	0	0	444 (51.7%)	532 (13.3%)
Intravenous	528 (33.6%)	12673 (92.3%)	1488 (63.7%)	399 (100.0%)	10 (100.0%)	415 (48.3%)	3455 (86.7%)
Examination region ¹							
Abdomen	0	2583 (18.8%)	0	0	1 (10.0%)	291 (33.9%)	743 (18.6%)
Cardiac / Cardiac Vessels	0	298 (2.2%)	0	0	0	440 (51.2%)	218 (5.5%)
Thorax	0	786 (5.7%)	0	0	0	278 (32.4%)	440 (11.0%)
Pelvis	0	887 (6.5%)	0	0	0	237 (27.6%)	39 (1.0%)
Head / Brain	0	72 (0.5%)	0	0	1 (10.0%)	74 (8.6%)	608 (15.2%)
Kidney / Renal Vessels	0	54 (0.4%)	0	0	9 (90.0%)	10 (1.2%)	189 (4.7%)
Neck	0	176 (1.3%)	0	0	0	66 (7.7%)	138 (3.5%)
Blood Vessels	0	17 (0.1%)	0	0	0	1 (0.1%)	55 (1.4%)
Limbs	0	15 (0.1%)	0	0	0	1 (0.1%)	17 (0.4%)
Joints	0	1 (<0.1%)	0	0	0	0	4 (0.1%)
Other	0	8 (<0.1%)	0	0	0	29 (3.4%)	131 (3.3%)
Not specified	0	0	0	0	0	0	0
Missing	1572 (100.0%)	9907 (72.2%)	2335 (100.0%)	399 (100.0%)	0	0	1645 (41.3%)
Indication ¹							
Tumour/Suspicion of Tumour	0	1946 (14.2%)	0	0	9 (90.0%)	262 (30.5%)	868 (21.8%)
Pain	0	463 (3.4%)	0	0	0	33 (3.8%)	403 (10.1%)
Post-Therapy-Control	0	1069 (7.8%)	0	0	0	109 (12.7%)	151 (3.8%)
Staging	0	230 (1.7%)	0	0	0	78 (9.1%)	149 (3.7%)
Inflammatory Diseases	0	170 (1.2%)	0	0	0	27 (3.1%)	310 (7.8%)
Infarct/Suspicion of Infarct	0	263 (1.9%)	0	0	0	254 (29.6%)	292 (7.3%)
Haemorrhage	0	12 (<0.1%)	0	0	0	5 (0.6%)	94 (2.4%)
Trauma	0	4 (<0.1%)	0	0	0	4 (0.5%)	76 (1.9%)
Other	0	256 (1.9%)	0	0	1 (10.0%)	268 (31.2%)	403 (10.1%)
Not specified	0	0	0	0	0	0	0
Missing	1572 (100.0%)	9907 (72.2%)	2335 (100.0%)	399 (100.0%)	0	0	1645 (41.3%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	JORDAN (N=1572)	KOREA (SOUTH) (N=13731)	LITHUANIA (N=2335)	LATVIA (N=399)	MOLDOVA (N=10)	MALAYSIA (N=859)	PHILIPPINES (N=3987)
Dose [ml]							
n	1572	13731	2335	399	10	859	3987
Nmiss	0	0	0	0	0	0	0
Mean (SD)	105.857 (76.831)	121.644 (28.862)	64.726 (31.202)	69.511 (28.098)	46.000 (18.974)	100.049 (55.276)	70.477 (33.105)
Median	100.000	120.000	50.000	50.000	40.000	100.000	50.000
Q1, Q3	50.000, 150.000	100.000, 140.000	50.000, 100.000	40.000, 100.000	40.000, 40.000	50.000, 100.000	50.000, 100.000
Min, Max	10.00, 600.00	8.00, 450.00	10.00, 260.00	40.00, 120.00	40.00, 100.00	2.00, 450.00	3.00, 600.00
Dose							
<100 ml	765 (48.7%)	1568 (11.4%)	1618 (69.3%)	231 (57.9%)	9 (90.0%)	354 (41.2%)	2720 (68.2%)
100 - <150 ml	381 (24.2%)	10010 (72.9%)	683 (29.3%)	168 (42.1%)	1 (10.0%)	359 (41.8%)	1171 (29.4%)
150 - <200 ml	239 (15.2%)	1970 (14.3%)	13 (0.6%)	0	0	62 (7.2%)	57 (1.4%)
200 - <300 ml	103 (6.6%)	153 (1.1%)	21 (0.9%)	0	0	75 (8.7%)	32 (0.8%)
>=300 ml	84 (5.3%)	30 (0.2%)	0	0	0	9 (1.0%)	7 (0.2%)
Dose of iodine [g]							
n	1572	13731	2335	399	10	859	3987
Nmiss	0	0	0	0	0	0	0
Mean (SD)	38.632 (28.744)	38.407 (10.067)	21.799 (12.379)	20.853 (8.430)	17.020 (7.020)	33.884 (20.961)	22.602 (11.693)
Median	37.000	37.000	15.000	15.000	14.800	30.000	18.500
Q1, Q3	18.500, 55.500	33.000, 43.500	15.000, 37.000	12.000, 30.000	14.800, 14.800	18.500, 36.000	15.000, 30.000
Min, Max	3.00, 222.00	2.40, 166.50	3.00, 96.20	12.00, 36.00	14.80, 37.00	0.60, 166.50	0.90, 222.00
Dose of iodine							
<=20 g	677 (43.1%)	237 (1.7%)	1470 (63.0%)	212 (53.1%)	9 (90.0%)	265 (30.8%)	2313 (58.0%)
>20 - 40 g	463 (29.5%)	8206 (59.8%)	829 (35.5%)	187 (46.9%)	1 (10.0%)	416 (48.4%)	1540 (38.6%)
>40 - 60 g	244 (15.5%)	5072 (36.9%)	13 (0.6%)	0	0	73 (8.5%)	94 (2.4%)
>60 g	188 (12.0%)	216 (1.6%)	23 (1.0%)	0	0	105 (12.2%)	40 (1.0%)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	JORDAN (N=1572)	KOREA (SOUTH) (N=13731)	LITHUANIA (N=2335)	LATVIA (N=399)	MOLDOVA (N=10)	MALAYSIA (N=859)	PHILIPPINES (N=3987)
Type of examination							
Angiocardiology ²	55 (3.5%)	5 (<0.1%)	16 (0.7%)	0	0	437 (50.9%)	117 (2.9%)
Angiography	88 (5.6%)	10 (<0.1%)	106 (4.5%)	0	0	7 (0.8%)	156 (3.9%)
DSA	0	0	0	0	0	0	69 (1.7%)
Phlebography	0	0	0	0	0	0	2 (<0.1%)
CT (singleslice)	0	0	0	0	0	2 (0.2%)	467 (11.7%)
CT (multislice)	0	3824 (27.8%)	0	0	1 (10.0%)	413 (48.1%)	1456 (36.5%)
CT	227 (14.4%)	8781 (64.0%)	1161 (49.7%)	399 (100.0%)	0	0	1047 (26.3%)
Urography	263 (16.7%)	38 (0.3%)	298 (12.8%)	0	0	0	336 (8.4%)
PTCA	17 (1.1%)	0	16 (0.7%)	0	0	0	15 (0.4%)
PTA	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	6 (0.2%)
Not specified	922 (58.7%)	1073 (7.8%)	738 (31.6%)	0	9 (90.0%)	0	316 (7.9%)
Contrast quality							
Excellent	1465 (93.2%)	6716 (48.9%)	1180 (50.5%)	163 (40.9%)	5 (50.0%)	406 (47.3%)	2109 (52.9%)
Good	102 (6.5%)	6712 (48.9%)	977 (41.8%)	212 (53.1%)	5 (50.0%)	424 (49.4%)	1751 (43.9%)
Adequate	2 (0.1%)	282 (2.1%)	173 (7.4%)	24 (6.0%)	0	28 (3.3%)	110 (2.8%)
Moderate	0	19 (0.1%)	5 (0.2%)	0	0	1 (0.1%)	16 (0.4%)
Non diagnostic	1 (<0.1%)	2 (<0.1%)	0	0	0	0	1 (<0.1%)
Not specified	2 (0.1%)	0	0	0	0	0	0

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	PAKISTAN (N=1153)	POLAND (N=2713)	ROMANIA (N=2245)	REPUBLIC OF SERBIA (N=656)	RUSSIA (N=599)	SAUDI ARABIA (N=680)	SINGAPORE (N=1639)
Injection route							
Intra-arterial	3 (0.3%)	669 (24.7%)	1239 (55.2%)	215 (32.8%)	1 (0.2%)	267 (39.3%)	0
Intravenous	1150 (99.7%)	2044 (75.3%)	1006 (44.8%)	441 (67.2%)	598 (99.8%)	413 (60.7%)	1639 (100.0%)
Examination region ¹							
Abdomen	374 (32.4%)	597 (22.0%)	76 (3.4%)	0	320 (53.4%)	173 (25.4%)	768 (46.9%)
Cardiac / Cardiac Vessels	5 (0.4%)	267 (9.8%)	780 (34.7%)	0	12 (2.0%)	172 (25.3%)	12 (0.7%)
Thorax	219 (19.0%)	367 (13.5%)	36 (1.6%)	0	86 (14.4%)	119 (17.5%)	418 (25.5%)
Pelvis	125 (10.8%)	262 (9.7%)	16 (0.7%)	0	34 (5.7%)	102 (15.0%)	463 (28.2%)
Head / Brain	347 (30.1%)	387 (14.3%)	48 (2.1%)	0	99 (16.5%)	26 (3.8%)	215 (13.1%)
Kidney / Renal Vessels	97 (8.4%)	68 (2.5%)	11 (0.5%)	0	100 (16.7%)	14 (2.1%)	314 (19.2%)
Neck	93 (8.1%)	52 (1.9%)	5 (0.2%)	0	17 (2.8%)	49 (7.2%)	143 (8.7%)
Blood Vessels	6 (0.5%)	82 (3.0%)	66 (2.9%)	0	29 (4.8%)	3 (0.4%)	11 (0.7%)
Limbs	3 (0.3%)	41 (1.5%)	61 (2.7%)	0	2 (0.3%)	1 (0.1%)	4 (0.2%)
Joints	1 (<0.1%)	0	0	0	1 (0.2%)	4 (0.6%)	0
Other	105 (9.1%)	30 (1.1%)	79 (3.5%)	0	13 (2.2%)	29 (4.3%)	158 (9.6%)
Not specified	2 (0.2%)	0	4 (0.2%)	0	1 (0.2%)	0	0
Missing	0	1014 (37.4%)	1198 (53.4%)	656 (100.0%)	0	198 (29.1%)	0
Indication ¹							
Tumour/Suspicion of Tumour	502 (43.5%)	704 (25.9%)	75 (3.3%)	0	382 (63.8%)	71 (10.4%)	761 (46.4%)
Pain	261 (22.6%)	254 (9.4%)	378 (16.8%)	0	15 (2.5%)	85 (12.5%)	244 (14.9%)
Post-Therapy-Control	45 (3.9%)	314 (11.6%)	6 (0.3%)	0	68 (11.4%)	36 (5.3%)	83 (5.1%)
Staging	49 (4.2%)	460 (17.0%)	23 (1.0%)	0	150 (25.0%)	38 (5.6%)	50 (3.1%)
Inflammatory Diseases	281 (24.4%)	110 (4.1%)	9 (0.4%)	0	59 (9.8%)	92 (13.5%)	88 (5.4%)
Infarct/Suspicion of Infarct	34 (2.9%)	144 (5.3%)	345 (15.4%)	0	7 (1.2%)	4 (0.6%)	9 (0.5%)
Haemorrhage	12 (1.0%)	30 (1.1%)	22 (1.0%)	0	5 (0.8%)	1 (0.1%)	40 (2.4%)
Trauma	18 (1.6%)	23 (0.8%)	14 (0.6%)	0	9 (1.5%)	13 (1.9%)	11 (0.7%)
Other	138 (12.0%)	237 (8.7%)	175 (7.8%)	0	41 (6.8%)	217 (31.9%)	473 (28.9%)
Not specified	15 (1.3%)	0	11 (0.5%)	0	2 (0.3%)	0	0
Missing	0	1014 (37.4%)	1203 (53.6%)	656 (100.0%)	0	203 (29.9%)	0

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	PAKISTAN (N=1153)	POLAND (N=2713)	ROMANIA (N=2245)	REPUBLIC OF SERBIA (N=656)	RUSSIA (N=599)	SAUDI ARABIA (N=680)	SINGAPORE (N=1639)
Dose [ml]							
n	1153	2713	2245	656	599	680	1639
Nmiss	0	0	0	0	0	0	0
Mean (SD)	65.765 (28.246)	93.808 (56.801)	91.544 (70.088)	76.930 (35.064)	80.058 (31.457)	138.479 (92.287)	68.281 (16.863)
Median	50.000	80.000	60.000	60.000	80.000	100.000	70.000
Q1, Q3	50.000, 100.000	60.000, 100.000	50.000, 130.000	50.000, 100.000	50.000, 100.000	100.000, 150.000	50.000, 80.000
Min, Max	10.00, 200.00	4.00, 500.00	5.00, 600.00	20.00, 300.00	5.00, 165.00	10.00, 800.00	25.00, 135.00
Dose							
<100 ml	857 (74.3%)	1628 (60.0%)	1286 (57.3%)	387 (59.0%)	316 (52.8%)	106 (15.6%)	1577 (96.2%)
100 - <150 ml	264 (22.9%)	726 (26.8%)	583 (26.0%)	219 (33.4%)	251 (41.9%)	390 (57.4%)	62 (3.8%)
150 - <200 ml	31 (2.7%)	170 (6.3%)	106 (4.7%)	47 (7.2%)	32 (5.3%)	76 (11.2%)	0
200 - <300 ml	1 (<0.1%)	131 (4.8%)	216 (9.6%)	2 (0.3%)	0	48 (7.1%)	0
>=300 ml	0	58 (2.1%)	54 (2.4%)	1 (0.2%)	0	60 (8.8%)	0
Dose of iodine [g]							
n	1153	2713	2245	656	599	680	1639
Nmiss	0	0	0	0	0	0	0
Mean (SD)	22.688 (10.265)	33.066 (20.872)	33.807 (25.972)	25.638 (10.613)	27.210 (11.284)	47.654 (35.586)	24.399 (5.837)
Median	18.500	29.600	22.200	22.200	29.600	37.000	25.900
Q1, Q3	15.000, 30.000	18.500, 37.000	18.500, 48.100	18.500, 30.000	18.500, 37.000	30.000, 55.500	18.500, 29.600
Min, Max	3.00, 74.00	1.48, 185.00	1.50, 222.00	6.00, 111.00	1.50, 61.05	3.70, 296.00	9.25, 49.95
Dose of iodine							
<=20 g	676 (58.6%)	734 (27.1%)	1083 (48.2%)	248 (37.8%)	182 (30.4%)	66 (9.7%)	499 (30.4%)
>20 - 40 g	442 (38.3%)	1495 (55.1%)	509 (22.7%)	351 (53.5%)	363 (60.6%)	392 (57.6%)	1132 (69.1%)
>40 - 60 g	34 (2.9%)	308 (11.4%)	379 (16.9%)	55 (8.4%)	53 (8.8%)	92 (13.5%)	8 (0.5%)
>60 g	1 (<0.1%)	176 (6.5%)	274 (12.2%)	2 (0.3%)	1 (0.2%)	130 (19.1%)	0

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	PAKISTAN (N=1153)	POLAND (N=2713)	ROMANIA (N=2245)	REPUBLIC OF SERBIA (N=656)	RUSSIA (N=599)	SAUDI ARABIA (N=680)	SINGAPORE (N=1639)
Type of examination							
Angiocardiology ²	0	209 (7.7%)	752 (33.5%)	0	0	120 (17.6%)	0
Angiography	3 (0.3%)	165 (6.1%)	263 (11.7%)	106 (16.2%)	1 (0.2%)	47 (6.9%)	0
DSA	0	59 (2.2%)	0	0	0	0	0
Phlebography	0	6 (0.2%)	10 (0.4%)	0	0	0	0
CT (singleslice)	421 (36.5%)	124 (4.6%)	0	0	68 (11.4%)	11 (1.6%)	0
CT (multislice)	610 (52.9%)	1214 (44.7%)	0	0	524 (87.5%)	0	1510 (92.1%)
CT	0	567 (20.9%)	870 (38.8%)	311 (47.4%)	0	365 (53.7%)	0
Urography	0	53 (2.0%)	122 (5.4%)	116 (17.7%)	0	36 (5.3%)	0
PTCA	0	12 (0.4%)	66 (2.9%)	1 (0.2%)	0	0	0
PTA	0	0	6 (0.3%)	1 (0.2%)	0	0	0
Other	0	0	9 (0.4%)	0	6 (1.0%)	0	0
Not specified	119 (10.3%)	304 (11.2%)	147 (6.5%)	121 (18.4%)	0	101 (14.9%)	129 (7.9%)
Contrast quality							
Excellent	381 (33.0%)	1249 (46.0%)	1301 (58.0%)	297 (45.3%)	363 (60.6%)	618 (90.9%)	483 (29.5%)
Good	694 (60.2%)	1389 (51.2%)	918 (40.9%)	326 (49.7%)	219 (36.6%)	54 (7.9%)	922 (56.3%)
Adequate	70 (6.1%)	67 (2.5%)	21 (0.9%)	30 (4.6%)	17 (2.8%)	3 (0.4%)	219 (13.4%)
Moderate	8 (0.7%)	7 (0.3%)	1 (<0.1%)	2 (0.3%)	0	1 (0.1%)	15 (0.9%)
Non diagnostic	0	1 (<0.1%)	1 (<0.1%)	0	0	0	0
Not specified	0	0	3 (0.1%)	1 (0.2%)	0	4 (0.6%)	0

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVENIA (N=4688)	SLOVAKIA (N=1187)	THAILAND (N=538)	TURKEY (N=319)	TAIWAN (N=763)	UKRAINE (N=1839)	VIETNAM (N=1506)
Injection route							
Intra-arterial	465 (9.9%)	125 (10.5%)	29 (5.4%)	32 (10.0%)	40 (5.2%)	246 (13.4%)	22 (1.5%)
Intravenous	4223 (90.1%)	1062 (89.5%)	509 (94.6%)	287 (90.0%)	723 (94.8%)	1593 (86.6%)	1484 (98.5%)
Examination region ¹							
Abdomen	0	0	117 (21.7%)	0	335 (43.9%)	1014 (55.1%)	723 (48.0%)
Cardiac / Cardiac Vessels	0	0	0	0	0	266 (14.5%)	5 (0.3%)
Thorax	0	0	84 (15.6%)	0	0	775 (42.1%)	208 (13.8%)
Pelvis	0	0	0	0	0	456 (24.8%)	51 (3.4%)
Head / Brain	0	0	34 (6.3%)	0	0	134 (7.3%)	288 (19.1%)
Kidney / Renal Vessels	0	0	21 (3.9%)	0	570 (74.7%)	173 (9.4%)	209 (13.9%)
Neck	0	0	21 (3.9%)	0	0	71 (3.9%)	46 (3.1%)
Blood Vessels	0	0	7 (1.3%)	0	0	196 (10.7%)	2 (0.1%)
Limbs	0	0	1 (0.2%)	0	0	1 (<0.1%)	2 (0.1%)
Joints	0	0	0	0	0	0	1 (<0.1%)
Other	0	0	5 (0.9%)	0	0	2 (0.1%)	11 (0.7%)
Not specified	0	0	0	0	0	1 (<0.1%)	0
Missing	4688 (100.0%)	1187 (100.0%)	287 (53.3%)	319 (100.0%)	192 (25.2%)	72 (3.9%)	0
Indication ¹							
Tumour/Suspicion of Tumour	0	0	101 (18.8%)	0	7 (0.9%)	994 (54.1%)	790 (52.5%)
Pain	0	0	14 (2.6%)	0	149 (19.5%)	217 (11.8%)	233 (15.5%)
Post-Therapy-Control	0	0	92 (17.1%)	0	7 (0.9%)	318 (17.3%)	38 (2.5%)
Staging	0	0	23 (4.3%)	0	3 (0.4%)	386 (21.0%)	38 (2.5%)
Inflammatory Diseases	0	0	3 (0.6%)	0	33 (4.3%)	48 (2.6%)	111 (7.4%)
Infarct/Suspicion of Infarct	0	0	4 (0.7%)	0	1 (0.1%)	233 (12.7%)	9 (0.6%)
Haemorrhage	0	0	1 (0.2%)	0	23 (3.0%)	12 (0.7%)	18 (1.2%)
Trauma	0	0	3 (0.6%)	0	0	10 (0.5%)	24 (1.6%)
Other	0	0	39 (7.2%)	0	411 (53.9%)	76 (4.1%)	282 (18.7%)
Not specified	0	0	0	0	0	24 (1.3%)	0
Missing	4688 (100.0%)	1187 (100.0%)	287 (53.3%)	319 (100.0%)	192 (25.2%)	72 (3.9%)	0

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVENIA (N=4688)	SLOVAKIA (N=1187)	THAILAND (N=538)	TURKEY (N=319)	TAIWAN (N=763)	UKRAINE (N=1839)	VIETNAM (N=1506)
Dose [ml]							
n	4688	1187	538	319	763	1839	1506
Nmiss	0	0	0	0	0	0	0
Mean (SD)	65.339 (35.162)	90.988 (35.036)	96.493 (23.533)	93.110 (63.621)	60.907 (25.744)	104.418 (68.021)	55.349 (18.041)
Median	50.000	100.000	100.000	100.000	50.000	100.000	50.000
Q1, Q3	50.000, 100.000	70.000, 100.000	95.000, 100.000	50.000, 100.000	50.000, 50.000	50.000, 100.000	50.000, 70.000
Min, Max	10.00, 400.00	2.00, 400.00	5.00, 200.00	12.00, 400.00	40.00, 300.00	5.00, 500.00	10.00, 150.00
Dose							
<100 ml	3449 (73.6%)	541 (45.6%)	150 (27.9%)	140 (43.9%)	650 (85.2%)	759 (41.3%)	1498 (99.5%)
100 - <150 ml	1082 (23.1%)	569 (47.9%)	370 (68.8%)	148 (46.4%)	103 (13.5%)	815 (44.3%)	5 (0.3%)
150 - <200 ml	85 (1.8%)	41 (3.5%)	17 (3.2%)	10 (3.1%)	2 (0.3%)	44 (2.4%)	3 (0.2%)
200 - <300 ml	66 (1.4%)	33 (2.8%)	1 (0.2%)	12 (3.8%)	7 (0.9%)	103 (5.6%)	0
>=300 ml	6 (0.1%)	3 (0.3%)	0	9 (2.8%)	1 (0.1%)	118 (6.4%)	0
Dose of iodine [g]							
n	4688	1187	538	319	763	1839	1506
Nmiss	0	0	0	0	0	0	0
Mean (SD)	21.038 (10.775)	29.891 (11.670)	32.414 (7.969)	29.702 (23.741)	21.192 (7.429)	36.390 (25.325)	17.058 (5.456)
Median	18.000	30.000	36.000	30.000	18.500	30.000	15.000
Q1, Q3	15.000, 30.000	24.000, 37.000	30.000, 37.000	15.000, 30.000	18.500, 18.500	18.500, 37.000	15.000, 21.000
Min, Max	3.00, 120.00	0.60, 148.00	1.50, 60.00	3.60, 148.00	14.80, 90.00	1.50, 185.00	3.00, 45.00
Dose of iodine							
<=20 g	3081 (65.7%)	203 (17.1%)	59 (11.0%)	127 (39.8%)	607 (79.6%)	520 (28.3%)	1038 (68.9%)
>20 - 40 g	1411 (30.1%)	851 (71.7%)	416 (77.3%)	161 (50.5%)	143 (18.7%)	1043 (56.7%)	465 (30.9%)
>40 - 60 g	162 (3.5%)	116 (9.8%)	63 (11.7%)	11 (3.4%)	9 (1.2%)	51 (2.8%)	3 (0.2%)
>60 g	34 (0.7%)	17 (1.4%)	0	20 (6.3%)	4 (0.5%)	225 (12.2%)	0

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SLOVENIA (N=4688)	SLOVAKIA (N=1187)	THAILAND (N=538)	TURKEY (N=319)	TAIWAN (N=763)	UKRAINE (N=1839)	VIETNAM (N=1506)
Type of examination							
Angiocardiology ²	10 (0.2%)	0	0	18 (5.6%)	0	30 (1.6%)	0
Angiography	365 (7.8%)	11 (0.9%)	25 (4.6%)	4 (1.3%)	0	178 (9.7%)	19 (1.3%)
DSA	3 (<0.1%)	0	0	0	28 (3.7%)	0	3 (0.2%)
Phlebography	0	0	0	0	0	137 (7.4%)	118 (7.8%)
CT (singleslice)	0	0	223 (41.4%)	0	0	617 (33.6%)	720 (47.8%)
CT (multislice)	0	0	0	0	0	727 (39.5%)	574 (38.1%)
CT	3149 (67.2%)	1020 (85.9%)	250 (46.5%)	263 (82.4%)	113 (14.8%)	0	0
Urography	1035 (22.1%)	36 (3.0%)	17 (3.2%)	23 (7.2%)	37 (4.8%)	61 (3.3%)	0
PTCA	0	0	0	0	1 (0.1%)	0	0
PTA	6 (0.1%)	6 (0.5%)	0	0	0	0	0
Other	0	0	20 (3.7%)	0	0	1 (<0.1%)	0
Not specified	120 (2.6%)	114 (9.6%)	3 (0.6%)	11 (3.4%)	584 (76.5%)	88 (4.8%)	72 (4.8%)
Contrast quality							
Excellent	3413 (72.8%)	741 (62.4%)	102 (19.0%)	87 (27.3%)	6 (0.8%)	430 (23.4%)	186 (12.4%)
Good	1203 (25.7%)	422 (35.6%)	349 (64.9%)	196 (61.4%)	606 (79.4%)	1294 (70.4%)	1220 (81.0%)
Adequate	62 (1.3%)	17 (1.4%)	70 (13.0%)	35 (11.0%)	147 (19.3%)	95 (5.2%)	100 (6.6%)
Moderate	8 (0.2%)	1 (<0.1%)	16 (3.0%)	1 (0.3%)	4 (0.5%)	3 (0.2%)	0
Non diagnostic	2 (<0.1%)	0	1 (0.2%)	0	0	9 (0.5%)	0
Not specified	0	6 (0.5%)	0	0	0	8 (0.4%)	0

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SOUTH AFRICA (N=100)	Total (N=132850)
Injection route		
Intra-arterial	100 (100.0%)	27831 (20.9%)
Intravenous	0	105019 (79.1%)
Examination region ¹		
Abdomen	25272 (19.0%) (N=132850)	
Cardiac / Cardiac Vessels	22828 (17.2%) (N=132850)	
Thorax	13050 (9.8%) (N=132850)	
Pelvis	7732 (5.8%) (N=132850)	
Head / Brain	6098 (4.6%) (N=132850)	
Kidney / Renal Vessels	4138 (3.1%) (N=132850)	
Neck	2566 (1.9%) (N=132850)	
Blood Vessels	1743 (1.3%) (N=132850)	
Limbs	386 (0.3%) (N=132850)	
Joints	43 (<0.1%) (N=132850)	
Other	935 (0.7%) (N=132850)	
Not specified	8 (<0.1%) (N=132850)	
Missing	62628 (47.1%) (N=132850)	
Indication ¹		
Tumour/Suspicion of Tumour	25072 (18.9%) (N=132850)	
Pain	7035 (5.3%) (N=132850)	
Post-Therapy-Control	6967 (5.2%) (N=132850)	
Staging	5162 (3.9%) (N=132850)	
Inflammatory Diseases	3991 (3.0%) (N=132850)	
Infarct/Suspicion of Infarct	3381 (2.5%) (N=132850)	
Haemorrhage	835 (0.6%) (N=132850)	
Trauma	569 (0.4%) (N=132850)	
Other	23615 (17.8%) (N=132850)	
Not specified	54 (<0.1%) (N=132850)	
Missing	63021 (47.4%) (N=132850)	

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SOUTH AFRICA (N=100)	Total (N=132850)
Dose [ml]		
n	100	132850
Nmiss	0	0
Mean (SD)	220.400 (123.990)	99.256 (45.873)
Median	150.000	100.000
Q1, Q3	150.000, 235.000	75.000, 110.000
Min, Max	150.00, 650.00	1.00, 800.00
Dose		
<100 ml	0	56960 (42.9%)
100 - <150 ml	0	60016 (45.2%)
150 - <200 ml	59 (59.0%)	10013 (7.5%)
200 - <300 ml	20 (20.0%)	4345 (3.3%)
>=300 ml	21 (21.0%)	1516 (1.1%)
Dose of iodine [g]		
n	100	132850
Nmiss	0	0
Mean (SD)	81.548 (45.876)	32.437 (16.651)
Median	55.500	30.000
Q1, Q3	55.500, 86.950	24.000, 37.000
Min, Max	55.50, 240.50	0.30, 296.00
Dose of iodine		
<=20 g	0	22817 (17.2%)
>20 - 40 g	0	87214 (65.6%)
>40 - 60 g	59 (59.0%)	16663 (12.5%)
>60 g	41 (41.0%)	6156 (4.6%)

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Table 14.2 / 32: Exposure by country/region (Complete cases analysis set for country/region) (cont.)

	SOUTH AFRICA (N=100)	Total (N=132850)
Type of examination		
Angiocardiology ²	2 (2.0%)	12494 (9.4%)
Angiography	0	1796 (1.4%)
DSA	0	221 (0.2%)
Phlebography	0	296 (0.2%)
CT (singleslice)	0	3015 (2.3%)
CT (multislice)	0	31272 (23.5%)
CT	0	57488 (43.3%)
Urography	0	10097 (7.6%)
PTCA	0	165 (0.1%)
PTA	0	78 (<0.1%)
Other	0	6853 (5.2%)
Not specified	98 (98.0%)	9075 (6.8%)
Contrast quality		
Excellent	87 (87.0%)	67810 (51.0%)
Good	13 (13.0%)	58040 (43.7%)
Adequate	0	5827 (4.4%)
Moderate	0	498 (0.4%)
Non diagnostic	0	53 (<0.1%)
Not specified	0	622 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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14.3 Demographics by sex, race, geographical region and country/region (cases and controls)

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Table 14.3 / 1: Disposition by cases and controls groups (All patients)

	Controls (N=147613)	Cases (N=908)	Others (N=3712)	Total (N=152233)
All patients	147613 (100.0%)	908 (100.0%)	3712 (100.0%)	152233 (100.0%)
Full analysis set for sex	144130 (97.6%)	903 (99.4%)	0	145033 (95.3%)
Complete cases analysis set for sex	132032 (89.4%)	818 (90.1%)	0	132850 (87.3%)
Excluded from full analysis set for sex	3483 (2.4%)	5 (0.6%)	3712 (100.0%)	7200 (4.7%)
did not meet criterion a)	1869 (1.3%)	3 (0.3%)	11 (0.3%)	1883 (1.2%)
did not meet criterion b)	0	0	3712 (100.0%)	3712 (2.4%)
did not meet criterion c1)	0	0	3712 (100.0%)	3712 (2.4%)
Excluded from complete cases analysis set for sex	15581 (10.6%)	90 (9.9%)	3712 (100.0%)	19383 (12.7%)
Part of full analysis set for sex, with additionally:				
missing confounder d)	10752 (7.3%)	79 (8.7%)	0	10831 (7.1%)
missing confounder e)	786 (0.5%)	2 (0.2%)	0	788 (0.5%)
missing confounder f)	638 (0.4%)	5 (0.6%)	0	643 (0.4%)
missing confounder g)	638 (0.4%)	5 (0.6%)	0	643 (0.4%)
Full analysis set for race	59034 (40.0%)	378 (41.6%)	0	59412 (39.0%)
Complete cases analysis set for race	55634 (37.7%)	357 (39.3%)	0	55991 (36.8%)
Excluded from full analysis set for race	88579 (60.0%)	530 (58.4%)	3712 (100.0%)	92821 (61.0%)
did not meet criterion a)	1869 (1.3%)	3 (0.3%)	11 (0.3%)	1883 (1.2%)
did not meet criterion b)	0	0	3712 (100.0%)	3712 (2.4%)
did not meet criterion c2)	0	0	3712 (100.0%)	3712 (2.4%)
Excluded from complete cases analysis set for race	91979 (62.3%)	551 (60.7%)	3712 (100.0%)	96242 (63.2%)
Part of full analysis set for race, with additionally:				
missing confounder d)	3121 (2.1%)	20 (2.2%)	0	3141 (2.1%)
missing confounder e)	187 (0.1%)	0	0	187 (0.1%)
missing confounder f)	69 (<0.1%)	1 (0.1%)	0	70 (<0.1%)
missing confounder g)	69 (<0.1%)	1 (0.1%)	0	70 (<0.1%)
missing confounder h)	116 (<0.1%)	0	0	116 (<0.1%)
Full analysis set for geographical region	145744 (98.7%)	905 (99.7%)	0	146649 (96.3%)
Complete cases analysis set for geographical region	132032 (89.4%)	818 (90.1%)	0	132850 (87.3%)
Excluded from full analysis set for geographical region	1869 (1.3%)	3 (0.3%)	3712 (100.0%)	5584 (3.7%)
did not meet criterion a)	1869 (1.3%)	3 (0.3%)	11 (0.3%)	1883 (1.2%)

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Table 14.3 / 1: Disposition by cases and controls groups (All patients)

	Controls (N=147613)	Cases (N=908)	Others (N=3712)	Total (N=152233)
did not meet criterion b)	0	0	3712 (100.0%)	3712 (2.4%)
did not meet criterion c3)	0	0	3712 (100.0%)	3712 (2.4%)
Excluded from complete cases analysis set for geographical region	15581 (10.6%)	90 (9.9%)	3712 (100.0%)	19383 (12.7%)
Part of full analysis set for geographical region, with additionally:				
missing confounder d)	10920 (7.4%)	79 (8.7%)	0	10999 (7.2%)
missing confounder e)	815 (0.6%)	2 (0.2%)	0	817 (0.5%)
missing confounder f)	679 (0.5%)	5 (0.6%)	0	684 (0.4%)
missing confounder g)	679 (0.5%)	5 (0.6%)	0	684 (0.4%)
missing confounder h)	1614 (1.1%)	2 (0.2%)	0	1616 (1.1%)
Full analysis set for country/region	145744 (98.7%)	905 (99.7%)	0	146649 (96.3%)
Complete cases analysis set for country/region	132032 (89.4%)	818 (90.1%)	0	132850 (87.3%)
Excluded from full analysis set for country/region	1869 (1.3%)	3 (0.3%)	3712 (100.0%)	5584 (3.7%)
did not meet criterion a)	1869 (1.3%)	3 (0.3%)	11 (0.3%)	1883 (1.2%)
did not meet criterion b)	0	0	3712 (100.0%)	3712 (2.4%)
did not meet criterion c4)	0	0	3712 (100.0%)	3712 (2.4%)
Excluded from complete cases analysis set for country/region	15581 (10.6%)	90 (9.9%)	3712 (100.0%)	19383 (12.7%)
Part of full analysis set for country/region, with additionally:				
missing confounder d)	10920 (7.4%)	79 (8.7%)	0	10999 (7.2%)
missing confounder e)	815 (0.6%)	2 (0.2%)	0	817 (0.5%)
missing confounder f)	679 (0.5%)	5 (0.6%)	0	684 (0.4%)
missing confounder g)	679 (0.5%)	5 (0.6%)	0	684 (0.4%)
missing confounder h)	1614 (1.1%)	2 (0.2%)	0	1616 (1.1%)

The full analysis set for sex / race / geographical region / country/region consists of patients, who

a) received an injection with Iopromide of the iodine concentrations of 300 mg/mL or 370 mg/mL at the discretion of the Radiologist

b) are deemed as either a case or a control for the primary analysis and

c1) have sex recorded, c2) have race recorded, c3) have geographical region recorded, c4) have country/region recorded.

The complete cases analysis set consists of patients who are in the full primary analysis set and, additionally, have non-missing values for a pre-specified list of covariates:

d) age, e) injection route, f) contrast medium dose, g) dose of iodine in contrast medium, h) sex.

No missing values were recorded for other pre-specified confounders:

Concomitant Disease: Coronary heart disease, Concomitant Disease: Hypertension arterial, Concomitant Disease: Diabetes mellitus, Concomitant Disease: Reduced general condition, Concomitant Disease: Allergy, Concomitant Disease: Asthma bronchial, Concomitant Disease: Contrast media reaction, Concomitant Disease: Other, Specific CM risk factor, Pre-treatment.

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**Table 14.3 / 2: Number of subjects, cases and controls and proportion of cases among all subjects by country
(Analysis sets for geographical region)**

Geographical Region	Country	Full analysis set for geographical region				Complete case analysis set for geographical region			
		Total (N)	Cases (n ca)	Controls (n co)	Proportion of cases (n ca/N) (%)	Total (N)	Cases (n ca)	Controls (n co)	Proportion of cases (n ca/N) (%)
Asia	CHINA	36928	152	36776	0.41	36787	151	36636	0.41
	INDONESIA	692	15	677	2.17	656	15	641	2.29
	IRAN	5088	66	5022	1.30	5012	66	4946	1.32
	JORDAN	1668	9	1659	0.54	1572	8	1564	0.51
	KOREA (SOUTH)	13745	105	13640	0.76	13731	105	13626	0.76
	MALAYSIA	863	7	856	0.81	859	7	852	0.81
	PAKISTAN	1398	4	1394	0.29	1153	2	1151	0.17
	PHILIPPINES	4175	41	4134	0.98	3987	35	3952	0.88
	SAUDI ARABIA	742	9	733	1.21	680	8	672	1.18
	SINGAPORE	1657	52	1605	3.14	1639	52	1587	3.17
	TAIWAN	768	13	755	1.69	763	13	750	1.70
	THAILAND	562	16	546	2.85	538	15	523	2.79
	VIETNAM	1613	1	1612	0.06	1506	0	1506	0.00
Europe	BOSNIA AND HERZEGOVINA	522	0	522	0.00	513	0	513	0.00
	BULGARIA	291	1	290	0.34	258	1	257	0.39
	CROATIA	432	1	431	0.23	387	1	386	0.26
	ESTONIA	173	0	173	0.00	155	0	155	0.00
	FINLAND	443	1	442	0.23	417	0	417	0.00
	GERMANY	45618	234	45384	0.51	40766	213	40553	0.52
	HUNGARY	219	0	219	0.00	217	0	217	0.00
	ITALY	695	10	685	1.44	683	10	673	1.46
	LATVIA	399	0	399	0.00	399	0	399	0.00
	LITHUANIA	2380	1	2379	0.04	2335	1	2334	0.04
	MOLDOVA	358	2	356	0.56	10	2	8	20.00
	POLAND	2749	31	2718	1.13	2713	31	2682	1.14
	REPUBLIC OF SERBIA	682	4	678	0.59	656	4	652	0.61
	ROMANIA	2397	3	2394	0.13	2245	3	2242	0.13
	RUSSIA	614	10	604	1.63	599	10	589	1.67
	SLOVAKIA	1255	1	1254	0.08	1187	0	1187	0.00
	SLOVENIA	4787	37	4750	0.77	4688	37	4651	0.79
	SPAIN	1906	8	1898	0.42	1827	8	1819	0.44
	SWITZERLAND	1404	12	1392	0.85	1367	12	1355	0.88
	TURKEY	332	2	330	0.60	319	2	317	0.63
	UKRAINE	1905	6	1899	0.31	1839	6	1833	0.33

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**Table 14.3 / 2: Number of subjects, cases and controls and proportion of cases among all subjects by country
(Analysis sets for geographical region)**

Geographical Region	Country	Full analysis set for geographical region				Complete case analysis set for geographical region			
		Total (N)	Cases (n ca)	Controls (n co)	Proportion of cases (n ca/N) (%)	Total (N)	Cases (n ca)	Controls (n co)	Proportion of cases (n ca/N) (%)
Africa	EGYPT	298	0	298	0.00	287	0	287	0.00
	SOUTH AFRICA	100	0	100	0.00	100	0	100	0.00
North America	UNITED STATES	6791	51	6740	0.75	0	0	0	0.00
Total	Total	146649	905	145744	0.62	132850	818	132032	0.62

No subject from North America is included in the Complete case analysis set for geographical region (age not available).

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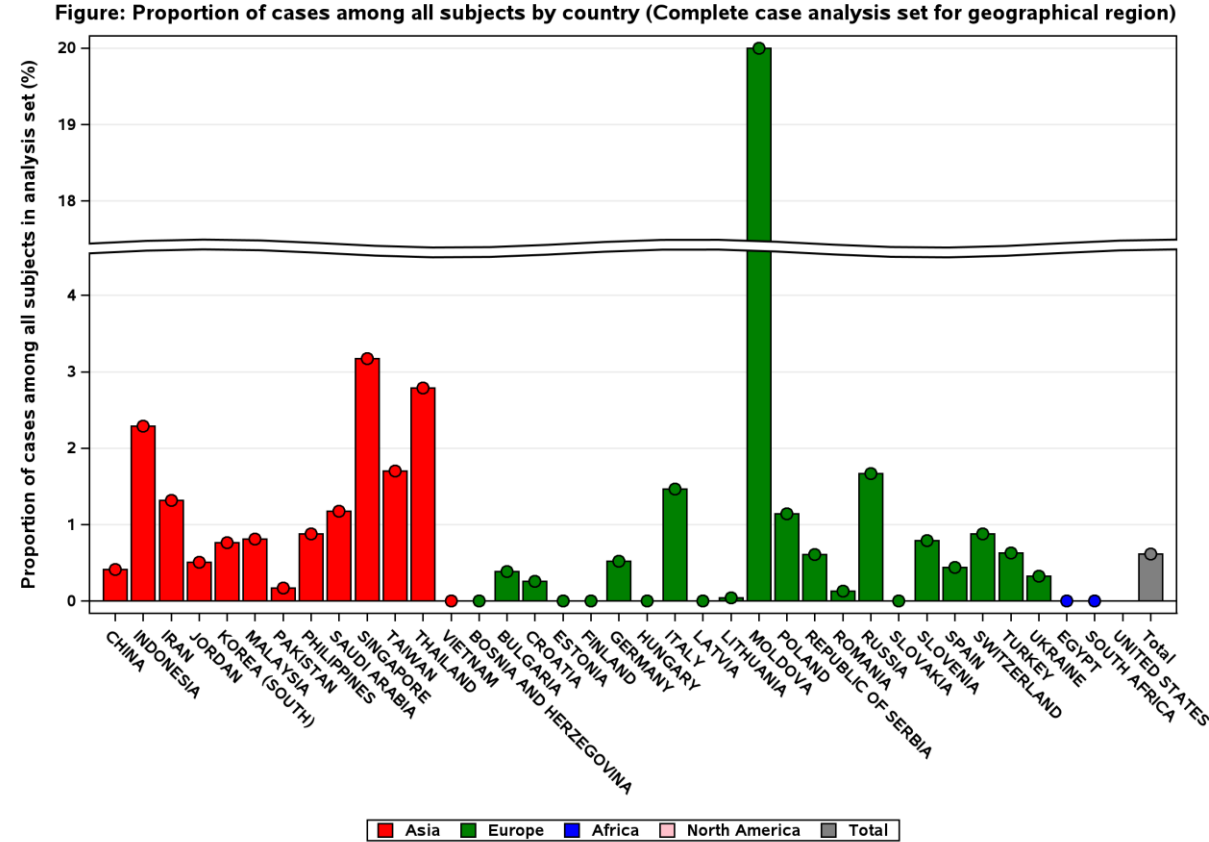
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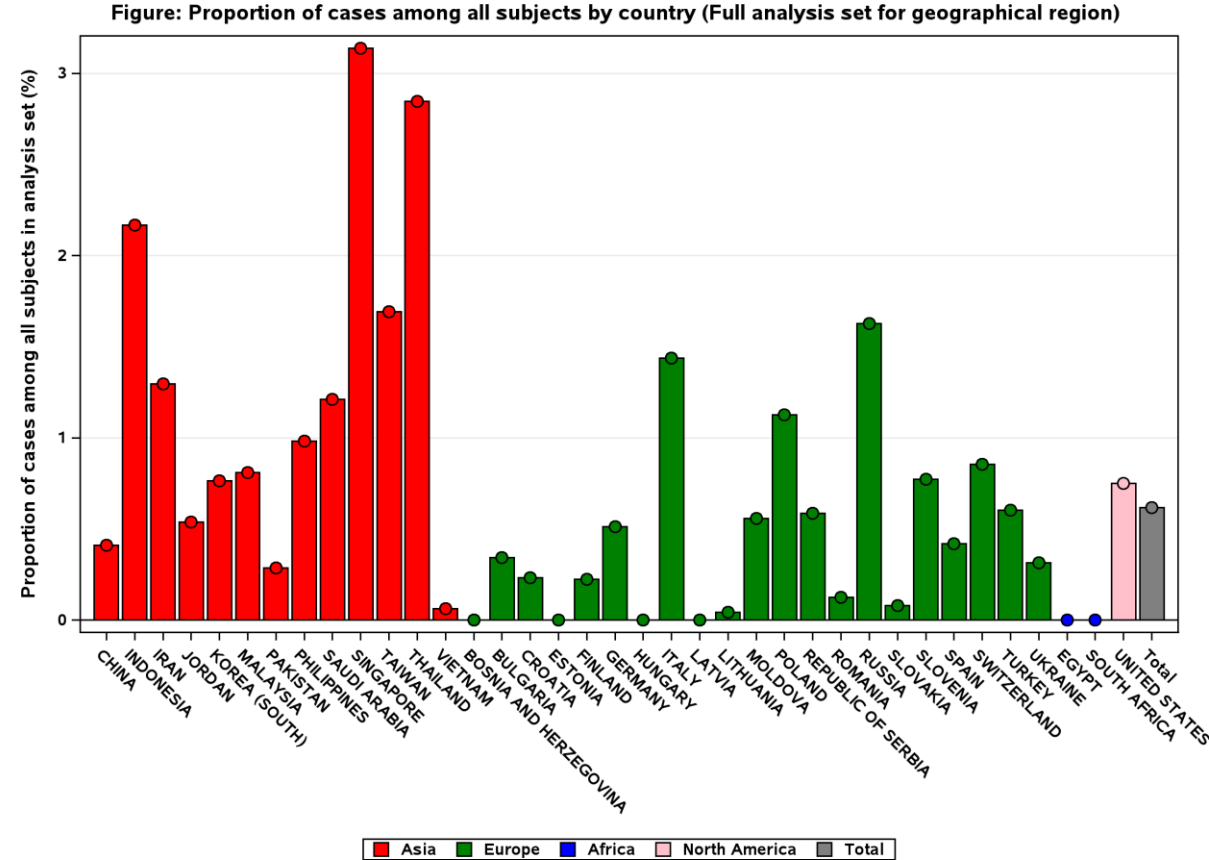


Figure 14.3 / 1: Proportion of cases among all subjects by country (Complete case analysis set for geographical region)



No subject from North America is included in the Complete case analysis set for geographical region (age not available).
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Figure 14.3 / 2: Proportion of cases among all subjects by country (Full analysis set for geographical region)



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Table 14.3 / 3: Demographics by cases and controls groups (Full analysis set for sex)

	Controls (N=144130)	Cases (N=903)	Total (N=145033)
Study			
PMS I	70640 (49.0%)	412 (45.6%)	71052 (49.0%)
IMAGE	41893 (29.1%)	364 (40.3%)	42257 (29.1%)
TRUST	17338 (12.0%)	17 (1.9%)	17355 (12.0%)
Ultravist in CT	14259 (9.9%)	110 (12.2%)	14369 (9.9%)
Age group			
< 18	3040 (2.1%)	14 (1.6%)	3054 (2.1%)
>= 18 and < 50	37211 (25.8%)	337 (37.3%)	37548 (25.9%)
>= 50 and < 65	49629 (34.4%)	308 (34.1%)	49937 (34.4%)
>= 65 years old	43498 (30.2%)	165 (18.3%)	43663 (30.1%)
Not specified	10752 (7.5%)	79 (8.7%)	10831 (7.5%)
Geographical region			
Africa	395 (0.3%)	0	395 (0.3%)
Asia (excl. China)	32442 (22.5%)	337 (37.3%)	32779 (22.6%)
China	36753 (25.5%)	152 (16.8%)	36905 (25.4%)
Europe	67821 (47.1%)	363 (40.2%)	68184 (47.0%)
North America	6719 (4.7%)	51 (5.6%)	6770 (4.7%)
Country/Region (China, Germany, South Korea)			
China	36753 (38.8%)	152 (31.0%)	36905 (38.8%)
Germany	44325 (46.8%)	234 (47.7%)	44559 (46.8%)
South Korea	13633 (14.4%)	105 (21.4%)	13738 (14.4%)
Ultravist concentration			
Ultravist - 300	92657 (64.3%)	617 (68.3%)	93274 (64.3%)
Ultravist - 370	51473 (35.7%)	286 (31.7%)	51759 (35.7%)
Sex			
Male	80374 (55.8%)	442 (48.9%)	80816 (55.7%)
Female	63756 (44.2%)	461 (51.1%)	64217 (44.3%)

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Table 14.3 / 3: Demographics by cases and controls groups (Full analysis set for sex)

	Controls (N=144130)	Cases (N=903)	Total (N=145033)
Race			
Asian	49857 (34.6%)	307 (34.0%)	50164 (34.6%)
White	8858 (6.1%)	63 (7.0%)	8921 (6.2%)
Black	30 (<0.1%)	0	30 (<0.1%)
Other	173 (0.1%)	8 (0.9%)	181 (0.1%)
Not specified	85212 (59.1%)	525 (58.1%)	85737 (59.1%)
Age [years]			
n	133378	824	134202
Nmiss	10752	79	10831
Mean (SD)	55.9 (16.0)	50.9 (15.7)	55.9 (16.0)
Median	58.0	52.0	58.0
Q1, Q3	47.0, 68.0	41.0, 62.0	47.0, 68.0
Min, Max	0, 105	5, 97	0, 105

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adsl_demog.sas 01DEC2022 15:12
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Table 14.3 / 4: Demographics by cases and controls groups (Full analysis set for race)

	Controls (N=59034)	Cases (N=378)	Total (N=59412)
Study			
IMAGE	41675 (70.6%)	361 (95.5%)	42036 (70.8%)
TRUST	17359 (29.4%)	17 (4.5%)	17376 (29.2%)
Age group			
< 18	1054 (1.8%)	9 (2.4%)	1063 (1.8%)
>= 18 and < 50	15364 (26.0%)	148 (39.2%)	15512 (26.1%)
>= 50 and < 65	23414 (39.7%)	144 (38.1%)	23558 (39.7%)
>= 65 years old	16081 (27.2%)	57 (15.1%)	16138 (27.2%)
Not specified	3121 (5.3%)	20 (5.3%)	3141 (5.3%)
Geographical region			
Asia (excl. China)	13314 (22.6%)	163 (43.1%)	13477 (22.7%)
China	36762 (62.3%)	152 (40.2%)	36914 (62.1%)
Europe	8958 (15.2%)	63 (16.7%)	9021 (15.2%)
Country/Region (China, Germany, South Korea)			
China	36762 (85.7%)	152 (73.8%)	36914 (85.6%)
Germany	2372 (5.5%)	15 (7.3%)	2387 (5.5%)
South Korea	3787 (8.8%)	39 (18.9%)	3826 (8.9%)
Ultravist concentration			
Ultravist - 300	24339 (41.2%)	197 (52.1%)	24536 (41.3%)
Ultravist - 370	34695 (58.8%)	181 (47.9%)	34876 (58.7%)
Sex			
Male	35337 (59.9%)	191 (50.5%)	35528 (59.8%)
Female	23581 (39.9%)	187 (49.5%)	23768 (40.0%)
Not specified	116 (0.2%)	0	116 (0.2%)
Race			
Asian	49910 (84.5%)	307 (81.2%)	50217 (84.5%)
White	8921 (15.1%)	63 (16.7%)	8984 (15.1%)
Black	30 (<0.1%)	0	30 (<0.1%)
Other	173 (0.3%)	8 (2.1%)	181 (0.3%)

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Table 14.3 / 4: Demographics by cases and controls groups (Full analysis set for race)

	Controls (N=59034)	Cases (N=378)	Total (N=59412)
Age [years]			
n	55913	358	56271
Nmiss	3121	20	3141
Mean (SD)	55.6 (14.9)	49.5 (15.2)	55.6 (14.9)
Median	57.0	51.0	57.0
Q1, Q3	47.0, 66.0	39.0, 60.0	47.0, 66.0
Min, Max	0, 105	5, 85	0, 105

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Table 14.3 / 5: Demographics by cases and controls groups (Full analysis set for geographical region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Study			
PMS I	71820 (49.3%)	414 (45.7%)	72234 (49.3%)
IMAGE	42127 (28.9%)	364 (40.2%)	42491 (29.0%)
TRUST	17359 (11.9%)	17 (1.9%)	17376 (11.8%)
Ultravist in CT	14438 (9.9%)	110 (12.2%)	14548 (9.9%)
Age group			
< 18	3077 (2.1%)	14 (1.5%)	3091 (2.1%)
>= 18 and < 50	37615 (25.8%)	339 (37.5%)	37954 (25.9%)
>= 50 and < 65	50130 (34.4%)	308 (34.0%)	50438 (34.4%)
>= 65 years old	44002 (30.2%)	165 (18.2%)	44167 (30.1%)
Not specified	10920 (7.5%)	79 (8.7%)	10999 (7.5%)
Geographical region			
Africa	398 (0.3%)	0	398 (0.3%)
Asia (excl. China)	32633 (22.4%)	338 (37.3%)	32971 (22.5%)
China	36776 (25.2%)	152 (16.8%)	36928 (25.2%)
Europe	69197 (47.5%)	364 (40.2%)	69561 (47.4%)
North America	6740 (4.6%)	51 (5.6%)	6791 (4.6%)
Country/Region (China, Germany, South Korea)			
China	36776 (38.4%)	152 (31.0%)	36928 (38.4%)
Germany	45384 (47.4%)	234 (47.7%)	45618 (47.4%)
South Korea	13640 (14.2%)	105 (21.4%)	13745 (14.3%)
Ultravist concentration			
Ultravist - 300	93910 (64.4%)	619 (68.4%)	94529 (64.5%)
Ultravist - 370	51834 (35.6%)	286 (31.6%)	52120 (35.5%)
Sex			
Male	80374 (55.1%)	442 (48.8%)	80816 (55.1%)
Female	63756 (43.7%)	461 (50.9%)	64217 (43.8%)
Not specified	1614 (1.1%)	2 (0.2%)	1616 (1.1%)

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Table 14.3 / 5: Demographics by cases and controls groups (Full analysis set for geographical region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Race			
Asian	49910 (34.2%)	307 (33.9%)	50217 (34.2%)
White	8921 (6.1%)	63 (7.0%)	8984 (6.1%)
Black	30 (<0.1%)	0	30 (<0.1%)
Other	173 (0.1%)	8 (0.9%)	181 (0.1%)
Not specified	86710 (59.5%)	527 (58.2%)	87237 (59.5%)
Age [years]			
n	134824	826	135650
Nmiss	10920	79	10999
Mean (SD)	55.9 (16.0)	50.9 (15.7)	55.9 (16.0)
Median	58.0	52.0	58.0
Q1, Q3	47.0, 68.0	40.0, 62.0	47.0, 68.0
Min, Max	0, 105	5, 97	0, 105

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Table 14.3 / 6: Demographics by cases and controls groups (Full analysis set for country/region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Study			
PMS I	71820 (49.3%)	414 (45.7%)	72234 (49.3%)
IMAGE	42127 (28.9%)	364 (40.2%)	42491 (29.0%)
TRUST	17359 (11.9%)	17 (1.9%)	17376 (11.8%)
Ultravist in CT	14438 (9.9%)	110 (12.2%)	14548 (9.9%)
Age group			
< 18	3077 (2.1%)	14 (1.5%)	3091 (2.1%)
>= 18 and < 50	37615 (25.8%)	339 (37.5%)	37954 (25.9%)
>= 50 and < 65	50130 (34.4%)	308 (34.0%)	50438 (34.4%)
>= 65 years old	44002 (30.2%)	165 (18.2%)	44167 (30.1%)
Not specified	10920 (7.5%)	79 (8.7%)	10999 (7.5%)
Geographical region			
Africa	398 (0.3%)	0	398 (0.3%)
Asia (excl. China)	32633 (22.4%)	338 (37.3%)	32971 (22.5%)
China	36776 (25.2%)	152 (16.8%)	36928 (25.2%)
Europe	69197 (47.5%)	364 (40.2%)	69561 (47.4%)
North America	6740 (4.6%)	51 (5.6%)	6791 (4.6%)
Country/Region (China, Germany, South Korea)			
China	36776 (38.4%)	152 (31.0%)	36928 (38.4%)
Germany	45384 (47.4%)	234 (47.7%)	45618 (47.4%)
South Korea	13640 (14.2%)	105 (21.4%)	13745 (14.3%)
Ultravist concentration			
Ultravist - 300	93910 (64.4%)	619 (68.4%)	94529 (64.5%)
Ultravist - 370	51834 (35.6%)	286 (31.6%)	52120 (35.5%)
Sex			
Male	80374 (55.1%)	442 (48.8%)	80816 (55.1%)
Female	63756 (43.7%)	461 (50.9%)	64217 (43.8%)
Not specified	1614 (1.1%)	2 (0.2%)	1616 (1.1%)

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Table 14.3 / 6: Demographics by cases and controls groups (Full analysis set for country/region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Race			
Asian	49910 (34.2%)	307 (33.9%)	50217 (34.2%)
White	8921 (6.1%)	63 (7.0%)	8984 (6.1%)
Black	30 (<0.1%)	0	30 (<0.1%)
Other	173 (0.1%)	8 (0.9%)	181 (0.1%)
Not specified	86710 (59.5%)	527 (58.2%)	87237 (59.5%)
Age [years]			
n	134824	826	135650
Nmiss	10920	79	10999
Mean (SD)	55.9 (16.0)	50.9 (15.7)	55.9 (16.0)
Median	58.0	52.0	58.0
Q1, Q3	47.0, 68.0	40.0, 62.0	47.0, 68.0
Min, Max	0, 105	5, 97	0, 105

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adsl_demog.sas 01DEC2022 15:12
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Table 14.3 / 7: Demographics by cases and controls groups (Complete cases analysis set for sex)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Study			
PMS I	62229 (47.1%)	351 (42.9%)	62580 (47.1%)
IMAGE	38579 (29.2%)	342 (41.8%)	38921 (29.3%)
TRUST	17270 (13.1%)	16 (2.0%)	17286 (13.0%)
Ultravist in CT	13954 (10.6%)	109 (13.3%)	14063 (10.6%)
Age group			
< 18	2964 (2.2%)	14 (1.7%)	2978 (2.2%)
>= 18 and < 50	36886 (27.9%)	335 (41.0%)	37221 (28.0%)
>= 50 and < 65	49137 (37.2%)	305 (37.3%)	49442 (37.2%)
>= 65 years old	43045 (32.6%)	164 (20.0%)	43209 (32.5%)
Geographical region			
Africa	387 (0.3%)	0	387 (0.3%)
Asia (excl. China)	31770 (24.1%)	326 (39.9%)	32096 (24.2%)
China	36636 (27.7%)	151 (18.5%)	36787 (27.7%)
Europe	63239 (47.9%)	341 (41.7%)	63580 (47.9%)
Country/Region (China, Germany, South Korea)			
China	36636 (40.3%)	151 (32.2%)	36787 (40.3%)
Germany	40553 (44.7%)	213 (45.4%)	40766 (44.7%)
South Korea	13626 (15.0%)	105 (22.4%)	13731 (15.0%)
Ultravist concentration			
Ultravist - 300	84020 (63.6%)	549 (67.1%)	84569 (63.7%)
Ultravist - 370	48012 (36.4%)	269 (32.9%)	48281 (36.3%)
Sex			
Male	74575 (56.5%)	411 (50.2%)	74986 (56.4%)
Female	57457 (43.5%)	407 (49.8%)	57864 (43.6%)
Race			
Asian	49320 (37.4%)	301 (36.8%)	49621 (37.4%)
White	6134 (4.6%)	48 (5.9%)	6182 (4.7%)
Black	24 (<0.1%)	0	24 (<0.1%)
Other	156 (0.1%)	8 (1.0%)	164 (0.1%)
Not specified	76398 (57.9%)	461 (56.4%)	76859 (57.9%)

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Table 14.3 / 7: Demographics by cases and controls groups (Complete cases analysis set for sex)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Age [years]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	56.0 (16.0)	50.9 (15.8)	55.9 (16.0)
Median	58.0	52.0	58.0
Q1, Q3	47.0, 68.0	41.0, 62.0	47.0, 68.0
Min, Max	0, 105	5, 97	0, 105

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Table 14.3 / 8: Demographics by cases and controls groups (Complete cases analysis set for race)

	Controls (N=55634)	Cases (N=357)	Total (N=55991)
Study			
IMAGE	38364 (69.0%)	341 (95.5%)	38705 (69.1%)
TRUST	17270 (31.0%)	16 (4.5%)	17286 (30.9%)
Age group			
< 18	1043 (1.9%)	9 (2.5%)	1052 (1.9%)
>= 18 and < 50	15290 (27.5%)	147 (41.2%)	15437 (27.6%)
>= 50 and < 65	23306 (41.9%)	144 (40.3%)	23450 (41.9%)
>= 65 years old	15995 (28.8%)	57 (16.0%)	16052 (28.7%)
Geographical region			
Asia (excl. China)	12873 (23.1%)	158 (44.3%)	13031 (23.3%)
China	36623 (65.8%)	151 (42.3%)	36774 (65.7%)
Europe	6138 (11.0%)	48 (13.4%)	6186 (11.0%)
Country/Region (China, Germany, South Korea)			
China	36623 (90.6%)	151 (79.5%)	36774 (90.5%)
Germany	26 (<0.1%)	0	26 (<0.1%)
South Korea	3782 (9.4%)	39 (20.5%)	3821 (9.4%)
Ultravist concentration			
Ultravist - 300	22030 (39.6%)	181 (50.7%)	22211 (39.7%)
Ultravist - 370	33604 (60.4%)	176 (49.3%)	33780 (60.3%)
Sex			
Male	33568 (60.3%)	183 (51.3%)	33751 (60.3%)
Female	22066 (39.7%)	174 (48.7%)	22240 (39.7%)
Race			
Asian	49320 (88.7%)	301 (84.3%)	49621 (88.6%)
White	6134 (11.0%)	48 (13.4%)	6182 (11.0%)
Black	24 (<0.1%)	0	24 (<0.1%)
Other	156 (0.3%)	8 (2.2%)	164 (0.3%)

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Table 14.3 / 8: Demographics by cases and controls groups (Complete cases analysis set for race)

	Controls (N=55634)	Cases (N=357)	Total (N=55991)
Age [years]			
n	55634	357	55991
Nmiss	0	0	0
Mean (SD)	55.6 (14.9)	49.5 (15.2)	55.6 (14.9)
Median	57.0	51.0	57.0
Q1, Q3	47.0, 66.0	39.0, 60.0	47.0, 66.0
Min, Max	0, 105	5, 85	0, 105

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adsl_demog.sas 01DEC2022 15:12
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Table 14.3 / 9: Demographics by cases and controls groups (Complete cases analysis set for geographical region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Study			
PMS I	62229 (47.1%)	351 (42.9%)	62580 (47.1%)
IMAGE	38579 (29.2%)	342 (41.8%)	38921 (29.3%)
TRUST	17270 (13.1%)	16 (2.0%)	17286 (13.0%)
Ultravist in CT	13954 (10.6%)	109 (13.3%)	14063 (10.6%)
Age group			
< 18	2964 (2.2%)	14 (1.7%)	2978 (2.2%)
>= 18 and < 50	36886 (27.9%)	335 (41.0%)	37221 (28.0%)
>= 50 and < 65	49137 (37.2%)	305 (37.3%)	49442 (37.2%)
>= 65 years old	43045 (32.6%)	164 (20.0%)	43209 (32.5%)
Geographical region			
Africa	387 (0.3%)	0	387 (0.3%)
Asia (excl. China)	31770 (24.1%)	326 (39.9%)	32096 (24.2%)
China	36636 (27.7%)	151 (18.5%)	36787 (27.7%)
Europe	63239 (47.9%)	341 (41.7%)	63580 (47.9%)
Country/Region (China, Germany, South Korea)			
China	36636 (40.3%)	151 (32.2%)	36787 (40.3%)
Germany	40553 (44.7%)	213 (45.4%)	40766 (44.7%)
South Korea	13626 (15.0%)	105 (22.4%)	13731 (15.0%)
Ultravist concentration			
Ultravist - 300	84020 (63.6%)	549 (67.1%)	84569 (63.7%)
Ultravist - 370	48012 (36.4%)	269 (32.9%)	48281 (36.3%)
Sex			
Male	74575 (56.5%)	411 (50.2%)	74986 (56.4%)
Female	57457 (43.5%)	407 (49.8%)	57864 (43.6%)

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Table 14.3 / 9: Demographics by cases and controls groups (Complete cases analysis set for geographical region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Race			
Asian	49320 (37.4%)	301 (36.8%)	49621 (37.4%)
White	6134 (4.6%)	48 (5.9%)	6182 (4.7%)
Black	24 (<0.1%)	0	24 (<0.1%)
Other	156 (0.1%)	8 (1.0%)	164 (0.1%)
Not specified	76398 (57.9%)	461 (56.4%)	76859 (57.9%)
Age [years]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	56.0 (16.0)	50.9 (15.8)	55.9 (16.0)
Median	58.0	52.0	58.0
Q1, Q3	47.0, 68.0	41.0, 62.0	47.0, 68.0
Min, Max	0, 105	5, 97	0, 105

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adsl_demog.sas 01DEC2022 15:12
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Table 14.3 / 10: Demographics by cases and controls groups (Complete cases analysis set for country/region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Study			
PMS I	62229 (47.1%)	351 (42.9%)	62580 (47.1%)
IMAGE	38579 (29.2%)	342 (41.8%)	38921 (29.3%)
TRUST	17270 (13.1%)	16 (2.0%)	17286 (13.0%)
Ultravist in CT	13954 (10.6%)	109 (13.3%)	14063 (10.6%)
Age group			
< 18	2964 (2.2%)	14 (1.7%)	2978 (2.2%)
>= 18 and < 50	36886 (27.9%)	335 (41.0%)	37221 (28.0%)
>= 50 and < 65	49137 (37.2%)	305 (37.3%)	49442 (37.2%)
>= 65 years old	43045 (32.6%)	164 (20.0%)	43209 (32.5%)
Geographical region			
Africa	387 (0.3%)	0	387 (0.3%)
Asia (excl. China)	31770 (24.1%)	326 (39.9%)	32096 (24.2%)
China	36636 (27.7%)	151 (18.5%)	36787 (27.7%)
Europe	63239 (47.9%)	341 (41.7%)	63580 (47.9%)
Country/Region (China, Germany, South Korea)			
China	36636 (40.3%)	151 (32.2%)	36787 (40.3%)
Germany	40553 (44.7%)	213 (45.4%)	40766 (44.7%)
South Korea	13626 (15.0%)	105 (22.4%)	13731 (15.0%)
Ultravist concentration			
Ultravist - 300	84020 (63.6%)	549 (67.1%)	84569 (63.7%)
Ultravist - 370	48012 (36.4%)	269 (32.9%)	48281 (36.3%)
Sex			
Male	74575 (56.5%)	411 (50.2%)	74986 (56.4%)
Female	57457 (43.5%)	407 (49.8%)	57864 (43.6%)

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Table 14.3 / 10: Demographics by cases and controls groups (Complete cases analysis set for country/region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Race			
Asian	49320 (37.4%)	301 (36.8%)	49621 (37.4%)
White	6134 (4.6%)	48 (5.9%)	6182 (4.7%)
Black	24 (<0.1%)	0	24 (<0.1%)
Other	156 (0.1%)	8 (1.0%)	164 (0.1%)
Not specified	76398 (57.9%)	461 (56.4%)	76859 (57.9%)
Age [years]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	56.0 (16.0)	50.9 (15.8)	55.9 (16.0)
Median	58.0	52.0	58.0
Q1, Q3	47.0, 68.0	41.0, 62.0	47.0, 68.0
Min, Max	0, 105	5, 97	0, 105

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adsl_demog.sas 01DEC2022 15:12
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Table 14.3 / 11: Concomitant diseases by cases and controls groups (Full analysis set for sex)

	Controls N=144130 (100%)	Cases N=903 (100%)	Total N=145033 (100%)
Number (%) of patients with at least one concomitant disease finding	67263 (46.7%)	523 (57.9%)	67786 (46.7%)
Hypertension arterial	17425 (12.1%)	78 (8.6%)	17503 (12.1%)
Coronary heart disease	12309 (8.5%)	58 (6.4%)	12367 (8.5%)
Diabetes mellitus	11199 (7.8%)	76 (8.4%)	11275 (7.8%)
Reduced general condition	7294 (5.1%)	46 (5.1%)	7340 (5.1%)
Specific contrast media risk factor	5616 (3.9%)	130 (14.4%)	5746 (4.0%)
Allergy	4167 (2.9%)	95 (10.5%)	4262 (2.9%)
Asthma bronchial	892 (0.6%)	15 (1.7%)	907 (0.6%)
Contrast media reaction	770 (0.5%)	25 (2.8%)	795 (0.5%)
Other	21481 (14.9%)	164 (18.2%)	21645 (14.9%)
None specified	26419 (18.3%)	238 (26.4%)	26657 (18.4%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.3 / 12: Concomitant diseases by cases and controls groups (Full analysis set for race)

	Controls N=59034 (100%)	Cases N=378 (100%)	Total N=59412 (100%)
Number (%) of patients with at least one concomitant disease finding	43926 (74.4%)	290 (76.7%)	44216 (74.4%)
Hypertension arterial	15928 (27.0%)	60 (15.9%)	15988 (26.9%)
Diabetes mellitus	5887 (10.0%)	26 (6.9%)	5913 (10.0%)
Coronary heart disease	4703 (8.0%)	16 (4.2%)	4719 (7.9%)
Reduced general condition	4459 (7.6%)	16 (4.2%)	4475 (7.5%)
Specific contrast media risk factor	2010 (3.4%)	35 (9.3%)	2045 (3.4%)
Allergy	1276 (2.2%)	25 (6.6%)	1301 (2.2%)
Asthma bronchial	583 (1.0%)	4 (1.1%)	587 (1.0%)
Contrast media reaction	221 (0.4%)	6 (1.6%)	227 (0.4%)
Other	12107 (20.5%)	81 (21.4%)	12188 (20.5%)
None specified	26278 (44.5%)	237 (62.7%)	26515 (44.6%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.3 / 13: Concomitant diseases by cases and controls groups (Full analysis set for geographical region)

	Controls N=145744 (100%)	Cases N=905 (100%)	Total N=146649 (100%)
Number (%) of patients with at least one concomitant disease finding	67856 (46.6%)	523 (57.8%)	68379 (46.6%)
Hypertension arterial	17501 (12.0%)	78 (8.6%)	17579 (12.0%)
Coronary heart disease	12457 (8.5%)	58 (6.4%)	12515 (8.5%)
Diabetes mellitus	11312 (7.8%)	76 (8.4%)	11388 (7.8%)
Reduced general condition	7367 (5.1%)	46 (5.1%)	7413 (5.1%)
Specific contrast media risk factor	5688 (3.9%)	130 (14.4%)	5818 (4.0%)
Allergy	4220 (2.9%)	95 (10.5%)	4315 (2.9%)
Asthma bronchial	902 (0.6%)	15 (1.7%)	917 (0.6%)
Contrast media reaction	779 (0.5%)	25 (2.8%)	804 (0.5%)
Other	21702 (14.9%)	164 (18.1%)	21866 (14.9%)
None specified	26561 (18.2%)	238 (26.3%)	26799 (18.3%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

End of table

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Table 14.3 / 14: Concomitant diseases by cases and controls groups (Full analysis set for country/region)

	Controls N=145744 (100%)	Cases N=905 (100%)	Total N=146649 (100%)
Number (%) of patients with at least one concomitant disease finding	67856 (46.6%)	523 (57.8%)	68379 (46.6%)
Hypertension arterial	17501 (12.0%)	78 (8.6%)	17579 (12.0%)
Coronary heart disease	12457 (8.5%)	58 (6.4%)	12515 (8.5%)
Diabetes mellitus	11312 (7.8%)	76 (8.4%)	11388 (7.8%)
Reduced general condition	7367 (5.1%)	46 (5.1%)	7413 (5.1%)
Specific contrast media risk factor	5688 (3.9%)	130 (14.4%)	5818 (4.0%)
Allergy	4220 (2.9%)	95 (10.5%)	4315 (2.9%)
Asthma bronchial	902 (0.6%)	15 (1.7%)	917 (0.6%)
Contrast media reaction	779 (0.5%)	25 (2.8%)	804 (0.5%)
Other	21702 (14.9%)	164 (18.1%)	21866 (14.9%)
None specified	26561 (18.2%)	238 (26.3%)	26799 (18.3%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.3 / 15: Concomitant diseases by cases and controls groups (Complete cases analysis set for sex)

	Controls N=132032 (100%)	Cases N=818 (100%)	Total N=132850 (100%)
Number (%) of patients with at least one concomitant disease finding	61923 (46.9%)	482 (58.9%)	62405 (47.0%)
Hypertension arterial	16645 (12.6%)	74 (9.0%)	16719 (12.6%)
Coronary heart disease	11194 (8.5%)	49 (6.0%)	11243 (8.5%)
Diabetes mellitus	10316 (7.8%)	68 (8.3%)	10384 (7.8%)
Reduced general condition	6887 (5.2%)	45 (5.5%)	6932 (5.2%)
Specific contrast media risk factor	4793 (3.6%)	114 (13.9%)	4907 (3.7%)
Allergy	3477 (2.6%)	82 (10.0%)	3559 (2.7%)
Asthma bronchial	805 (0.6%)	15 (1.8%)	820 (0.6%)
Contrast media reaction	695 (0.5%)	22 (2.7%)	717 (0.5%)
Other	19182 (14.5%)	152 (18.6%)	19334 (14.6%)
None specified	24594 (18.6%)	231 (28.2%)	24825 (18.7%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.3 / 16: Concomitant diseases by cases and controls groups (Complete cases analysis set for race)

	Controls N=55634 (100%)	Cases N=357 (100%)	Total N=55991 (100%)
Number (%) of patients with at least one concomitant disease finding	41478 (74.6%)	278 (77.9%)	41756 (74.6%)
Hypertension arterial	15151 (27.2%)	56 (15.7%)	15207 (27.2%)
Diabetes mellitus	5580 (10.0%)	25 (7.0%)	5605 (10.0%)
Coronary heart disease	4446 (8.0%)	16 (4.5%)	4462 (8.0%)
Reduced general condition	4273 (7.7%)	16 (4.5%)	4289 (7.7%)
Specific contrast media risk factor	1815 (3.3%)	32 (9.0%)	1847 (3.3%)
Allergy	1165 (2.1%)	22 (6.2%)	1187 (2.1%)
Asthma bronchial	501 (0.9%)	4 (1.1%)	505 (0.9%)
Contrast media reaction	206 (0.4%)	6 (1.7%)	212 (0.4%)
Other	11286 (20.3%)	77 (21.6%)	11363 (20.3%)
None specified	24430 (43.9%)	230 (64.4%)	24660 (44.0%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.3 / 17: Concomitant diseases by cases and controls groups (Complete cases analysis set for geographical region)

	Controls N=132032 (100%)	Cases N=818 (100%)	Total N=132850 (100%)
Number (%) of patients with at least one concomitant disease finding	61923 (46.9%)	482 (58.9%)	62405 (47.0%)
Hypertension arterial	16645 (12.6%)	74 (9.0%)	16719 (12.6%)
Coronary heart disease	11194 (8.5%)	49 (6.0%)	11243 (8.5%)
Diabetes mellitus	10316 (7.8%)	68 (8.3%)	10384 (7.8%)
Reduced general condition	6887 (5.2%)	45 (5.5%)	6932 (5.2%)
Specific contrast media risk factor	4793 (3.6%)	114 (13.9%)	4907 (3.7%)
Allergy	3477 (2.6%)	82 (10.0%)	3559 (2.7%)
Asthma bronchial	805 (0.6%)	15 (1.8%)	820 (0.6%)
Contrast media reaction	695 (0.5%)	22 (2.7%)	717 (0.5%)
Other	19182 (14.5%)	152 (18.6%)	19334 (14.6%)
None specified	24594 (18.6%)	231 (28.2%)	24825 (18.7%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

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Table 14.3 / 18: Concomitant diseases by cases and controls groups (Complete cases analysis set for country/region)

	Controls N=132032 (100%)	Cases N=818 (100%)	Total N=132850 (100%)
Number (%) of patients with at least one concomitant disease finding	61923 (46.9%)	482 (58.9%)	62405 (47.0%)
Hypertension arterial	16645 (12.6%)	74 (9.0%)	16719 (12.6%)
Coronary heart disease	11194 (8.5%)	49 (6.0%)	11243 (8.5%)
Diabetes mellitus	10316 (7.8%)	68 (8.3%)	10384 (7.8%)
Reduced general condition	6887 (5.2%)	45 (5.5%)	6932 (5.2%)
Specific contrast media risk factor	4793 (3.6%)	114 (13.9%)	4907 (3.7%)
Allergy	3477 (2.6%)	82 (10.0%)	3559 (2.7%)
Asthma bronchial	805 (0.6%)	15 (1.8%)	820 (0.6%)
Contrast media reaction	695 (0.5%)	22 (2.7%)	717 (0.5%)
Other	19182 (14.5%)	152 (18.6%)	19334 (14.6%)
None specified	24594 (18.6%)	231 (28.2%)	24825 (18.7%)

Multiple responses possible.

Specific contrast media risk factor: allergy, asthma bronchial or contrast media reaction.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_admh_disease.sas 01DEC2022 15:15

End of table

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



Table 14.3 / 19: Pre-treatment by cases and controls groups (Full analysis set for sex)

	Controls N=144130 (100%)	Cases N=903 (100%)	Total N=145033 (100%)
Corticosteroids	10614 (7.4%)	67 (7.4%)	10681 (7.4%)
H1/H2 Blocker	3609 (2.5%)	31 (3.4%)	3640 (2.5%)
H1/H2 Blocker or Corticosteroids	34 (<0.1%)	1 (0.1%)	35 (<0.1%)
Other	5970 (4.1%)	37 (4.1%)	6007 (4.1%)
None specified	266 (0.2%)	2 (0.2%)	268 (0.2%)

Multiple responses possible.
Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18
End of table



Table 14.3 / 20: Pre-treatment by cases and controls groups (Full analysis set for race)

	Controls N=59034 (100%)	Cases N=378 (100%)	Total N=59412 (100%)
Corticosteroids	8497 (14.4%)	40 (10.6%)	8537 (14.4%)
H1/H2 Blocker	465 (0.8%)	7 (1.9%)	472 (0.8%)
Other	2916 (4.9%)	22 (5.8%)	2938 (4.9%)
None specified	235 (0.4%)	2 (0.5%)	237 (0.4%)

Multiple responses possible.
Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18
End of table

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Table 14.3 / 21: Pre-treatment by cases and controls groups (Full analysis set for geographical region)

	Controls N=145744 (100%)	Cases N=905 (100%)	Total N=146649 (100%)
Corticosteroids	10676 (7.3%)	67 (7.4%)	10743 (7.3%)
H1/H2 Blocker	3667 (2.5%)	31 (3.4%)	3698 (2.5%)
H1/H2 Blocker or Corticosteroids	35 (<0.1%)	1 (0.1%)	36 (<0.1%)
Other	6039 (4.1%)	37 (4.1%)	6076 (4.1%)
None specified	271 (0.2%)	2 (0.2%)	273 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.3 / 22: Pre-treatment by cases and controls groups (Full analysis set for country/region)

	Controls N=145744 (100%)	Cases N=905 (100%)	Total N=146649 (100%)
Corticosteroids	10676 (7.3%)	67 (7.4%)	10743 (7.3%)
H1/H2 Blocker	3667 (2.5%)	31 (3.4%)	3698 (2.5%)
H1/H2 Blocker or Corticosteroids	35 (<0.1%)	1 (0.1%)	36 (<0.1%)
Other	6039 (4.1%)	37 (4.1%)	6076 (4.1%)
None specified	271 (0.2%)	2 (0.2%)	273 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

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Table 14.3 / 23: Pre-treatment by cases and controls groups (Complete cases analysis set for sex)

	Controls N=132032 (100%)	Cases N=818 (100%)	Total N=132850 (100%)
Corticosteroids	10442 (7.9%)	60 (7.3%)	10502 (7.9%)
H1/H2 Blocker	3258 (2.5%)	24 (2.9%)	3282 (2.5%)
H1/H2 Blocker or Corticosteroids	33 (<0.1%)	1 (0.1%)	34 (<0.1%)
Other	5759 (4.4%)	36 (4.4%)	5795 (4.4%)
None specified	250 (0.2%)	2 (0.2%)	252 (0.2%)

Multiple responses possible.
Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18
End of table

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



Table 14.3 / 24: Pre-treatment by cases and controls groups (Complete cases analysis set for race)

	Controls N=55634 (100%)	Cases N=357 (100%)	Total N=55991 (100%)
Corticosteroids	8429 (15.2%)	39 (10.9%)	8468 (15.1%)
H1/H2 Blocker	391 (0.7%)	7 (2.0%)	398 (0.7%)
Other	2835 (5.1%)	22 (6.2%)	2857 (5.1%)
None specified	220 (0.4%)	2 (0.6%)	222 (0.4%)

Multiple responses possible.
Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18
End of table

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Table 14.3 / 25: Pre-treatment by cases and controls groups (Complete cases analysis set for geographical region)

	Controls N=132032 (100%)	Cases N=818 (100%)	Total N=132850 (100%)
Corticosteroids	10442 (7.9%)	60 (7.3%)	10502 (7.9%)
H1/H2 Blocker	3258 (2.5%)	24 (2.9%)	3282 (2.5%)
H1/H2 Blocker or Corticosteroids	33 (<0.1%)	1 (0.1%)	34 (<0.1%)
Other	5759 (4.4%)	36 (4.4%)	5795 (4.4%)
None specified	250 (0.2%)	2 (0.2%)	252 (0.2%)

Multiple responses possible.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18

End of table

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Table 14.3 / 26: Pre-treatment by cases and controls groups (Complete cases analysis set for country/region)

	Controls N=132032 (100%)	Cases N=818 (100%)	Total N=132850 (100%)
Corticosteroids	10442 (7.9%)	60 (7.3%)	10502 (7.9%)
H1/H2 Blocker	3258 (2.5%)	24 (2.9%)	3282 (2.5%)
H1/H2 Blocker or Corticosteroids	33 (<0.1%)	1 (0.1%)	34 (<0.1%)
Other	5759 (4.4%)	36 (4.4%)	5795 (4.4%)
None specified	250 (0.2%)	2 (0.2%)	252 (0.2%)

Multiple responses possible.
Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adcm_premed.sas 01DEC2022 15:18
End of table

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Table 14.3 / 27: Exposure by cases and controls groups (Full analysis set for sex)

	Controls (N=144130)	Cases (N=903)	Total (N=145033)
Injection route			
Intravenous	115072 (79.8%)	842 (93.2%)	115914 (79.9%)
Intra-arterial	28272 (19.6%)	59 (6.5%)	28331 (19.5%)
Other	396 (0.3%)	1 (0.1%)	397 (0.3%)
Not specified	301 (0.2%)	1 (0.1%)	302 (0.2%)
Missing	89 (<0.1%)	0	89 (<0.1%)
Examination region ¹			
Abdomen	26638 (18.5%)	235 (26.0%)	26873 (18.5%)
Cardiac / Cardiac Vessels	22970 (15.9%)	47 (5.2%)	23017 (15.9%)
Thorax	13876 (9.6%)	116 (12.8%)	13992 (9.6%)
Pelvis	8105 (5.6%)	92 (10.2%)	8197 (5.7%)
Head / Brain	6616 (4.6%)	48 (5.3%)	6664 (4.6%)
Kidney / Renal Vessels	4647 (3.2%)	55 (6.1%)	4702 (3.2%)
Neck	2681 (1.9%)	21 (2.3%)	2702 (1.9%)
Blood Vessels	1938 (1.3%)	13 (1.4%)	1951 (1.3%)
Limbs	413 (0.3%)	1 (0.1%)	414 (0.3%)
Joints	46 (<0.1%)	0	46 (<0.1%)
Other	1117 (0.8%)	16 (1.8%)	1133 (0.8%)
Not specified	9 (<0.1%)	0	9 (<0.1%)
Missing	70695 (49.0%)	412 (45.6%)	71107 (49.0%)
Indication ¹			
Tumour/Suspicion of Tumour	26236 (18.2%)	224 (24.8%)	26460 (18.2%)
Pain	7479 (5.2%)	64 (7.1%)	7543 (5.2%)
Post-Therapy-Control	7479 (5.2%)	47 (5.2%)	7526 (5.2%)
Staging	5419 (3.8%)	39 (4.3%)	5458 (3.8%)
Inflammatory Diseases	4339 (3.0%)	39 (4.3%)	4378 (3.0%)
Infarct/Suspicion of Infarct	3439 (2.4%)	25 (2.8%)	3464 (2.4%)
Haemorrhage	942 (0.7%)	6 (0.7%)	948 (0.7%)
Trauma	614 (0.4%)	2 (0.2%)	616 (0.4%)
Other	24380 (16.9%)	116 (12.8%)	24496 (16.9%)
Not specified	59 (<0.1%)	0	59 (<0.1%)
Missing	71131 (49.4%)	415 (46.0%)	71546 (49.3%)

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Table 14.3 / 27: Exposure by cases and controls groups (Full analysis set for sex)

	Controls (N=144130)	Cases (N=903)	Total (N=145033)
Dose [ml]			
n	143492	898	144390
Nmiss	638	5	643
Mean (SD)	99.749 (45.397)	97.460 (42.224)	99.735 (45.378)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 110.000	75.000, 110.000	75.000, 110.000
Min, Max	1.00, 800.00	4.00, 600.00	1.00, 800.00
Dose			
<100 ml	59872 (41.5%)	411 (45.5%)	60283 (41.6%)
100 - <150 ml	65949 (45.8%)	409 (45.3%)	66358 (45.8%)
150 - <200 ml	11589 (8.0%)	58 (6.4%)	11647 (8.0%)
200 - <300 ml	4517 (3.1%)	14 (1.6%)	4531 (3.1%)
>=300 ml	1565 (1.1%)	6 (0.7%)	1571 (1.1%)
Not specified	638 (0.4%)	5 (0.6%)	643 (0.4%)
Dose of iodine [g]			
n	143492	898	144390
Nmiss	638	5	643
Mean (SD)	32.544 (16.426)	31.193 (14.492)	32.536 (16.415)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	24.000, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	1.48, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	24071 (16.7%)	142 (15.7%)	24213 (16.7%)
>20 - 40 g	93764 (65.1%)	607 (67.2%)	94371 (65.1%)
>40 - 60 g	19261 (13.4%)	132 (14.6%)	19393 (13.4%)
>60 g	6396 (4.4%)	17 (1.9%)	6413 (4.4%)
Not specified	638 (0.4%)	5 (0.6%)	643 (0.4%)

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Table 14.3 / 27: Exposure by cases and controls groups (Full analysis set for sex)

	Controls (N=144130)	Cases (N=903)	Total (N=145033)
Type of examination			
CT	64250 (44.6%)	410 (45.4%)	64660 (44.6%)
CT (multislice)	32812 (22.8%)	306 (33.9%)	33118 (22.8%)
Angiocardiology ²	12536 (8.7%)	19 (2.1%)	12555 (8.7%)
Urography	10616 (7.4%)	67 (7.4%)	10683 (7.4%)
CT (singleslice)	3957 (2.7%)	22 (2.4%)	3979 (2.7%)
Angiography	1850 (1.3%)	5 (0.6%)	1855 (1.3%)
Phlebography	326 (0.2%)	0	326 (0.2%)
DSA	263 (0.2%)	0	263 (0.2%)
PTCA	174 (0.1%)	2 (0.2%)	176 (0.1%)
PTA	83 (<0.1%)	0	83 (<0.1%)
Other	6983 (4.8%)	9 (1.0%)	6992 (4.8%)
Not specified	10280 (7.1%)	63 (7.0%)	10343 (7.1%)
Contrast quality			
Excellent	73356 (50.9%)	320 (35.4%)	73676 (50.8%)
Good	63040 (43.7%)	487 (53.9%)	63527 (43.8%)
Adequate	6479 (4.5%)	60 (6.6%)	6539 (4.5%)
Moderate	536 (0.4%)	15 (1.7%)	551 (0.4%)
Non diagnostic	51 (<0.1%)	7 (0.8%)	58 (<0.1%)
Not specified	668 (0.5%)	14 (1.6%)	682 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

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Table 14.3 / 28: Exposure by cases and controls groups (Full analysis set for race)

	Controls (N=59034)	Cases (N=378)	Total (N=59412)
Injection route			
Intravenous	38455 (65.1%)	351 (92.9%)	38806 (65.3%)
Intra-arterial	20392 (34.5%)	27 (7.1%)	20419 (34.4%)
Other	99 (0.2%)	0	99 (0.2%)
Missing	88 (0.1%)	0	88 (0.1%)
Examination region ¹			
Cardiac / Cardiac Vessels	22823 (38.7%)	44 (11.6%)	22867 (38.5%)
Abdomen	18826 (31.9%)	163 (43.1%)	18989 (32.0%)
Thorax	9360 (15.9%)	88 (23.3%)	9448 (15.9%)
Pelvis	4860 (8.2%)	57 (15.1%)	4917 (8.3%)
Head / Brain	4242 (7.2%)	31 (8.2%)	4273 (7.2%)
Kidney / Renal Vessels	3735 (6.3%)	48 (12.7%)	3783 (6.4%)
Neck	1818 (3.1%)	17 (4.5%)	1835 (3.1%)
Blood Vessels	1660 (2.8%)	8 (2.1%)	1668 (2.8%)
Limbs	356 (0.6%)	0	356 (0.6%)
Joints	25 (<0.1%)	0	25 (<0.1%)
Other	1005 (1.7%)	14 (3.7%)	1019 (1.7%)
Not specified	9 (<0.1%)	0	9 (<0.1%)
Indication ¹			
Tumour/Suspicion of Tumour	20502 (34.7%)	170 (45.0%)	20672 (34.8%)
Pain	5420 (9.2%)	46 (12.2%)	5466 (9.2%)
Post-Therapy-Control	5225 (8.9%)	35 (9.3%)	5260 (8.9%)
Staging	3598 (6.1%)	31 (8.2%)	3629 (6.1%)
Infarct/Suspicion of Infarct	3042 (5.2%)	20 (5.3%)	3062 (5.2%)
Inflammatory Diseases	2969 (5.0%)	32 (8.5%)	3001 (5.1%)
Haemorrhage	759 (1.3%)	4 (1.1%)	763 (1.3%)
Trauma	380 (0.6%)	2 (0.5%)	382 (0.6%)
Other	22535 (38.2%)	96 (25.4%)	22631 (38.1%)
Not specified	62 (0.1%)	0	62 (0.1%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.3 / 28: Exposure by cases and controls groups (Full analysis set for race)

	Controls (N=59034)	Cases (N=378)	Total (N=59412)
Dose [ml]			
n	58965	377	59342
Nmiss	69	1	70
Mean (SD)	99.992 (52.243)	89.459 (38.957)	99.925 (52.175)
Median	95.000	85.000	95.000
Q1, Q3	70.000, 100.000	70.000, 100.000	70.000, 100.000
Min, Max	1.00, 800.00	20.00, 600.00	1.00, 800.00
Dose			
<100 ml	29726 (50.4%)	240 (63.5%)	29966 (50.4%)
100 - <150 ml	21857 (37.0%)	127 (33.6%)	21984 (37.0%)
150 - <200 ml	3262 (5.5%)	6 (1.6%)	3268 (5.5%)
200 - <300 ml	2993 (5.1%)	3 (0.8%)	2996 (5.0%)
>=300 ml	1127 (1.9%)	1 (0.3%)	1128 (1.9%)
Not specified	69 (0.1%)	1 (0.3%)	70 (0.1%)
Dose of iodine [g]			
n	58965	377	59342
Nmiss	69	1	70
Mean (SD)	34.411 (19.646)	29.701 (13.848)	34.381 (19.618)
Median	30.000	29.600	30.000
Q1, Q3	24.000, 37.000	24.000, 33.300	24.000, 37.000
Min, Max	0.37, 296.00	6.00, 222.00	0.37, 296.00
Dose of iodine			
<=20 g	9792 (16.6%)	59 (15.6%)	9851 (16.6%)
>20 - 40 g	37845 (64.1%)	275 (72.8%)	38120 (64.2%)
>40 - 60 g	6621 (11.2%)	39 (10.3%)	6660 (11.2%)
>60 g	4707 (8.0%)	4 (1.1%)	4711 (7.9%)
Not specified	69 (0.1%)	1 (0.3%)	70 (0.1%)

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Table 14.3 / 28: Exposure by cases and controls groups (Full analysis set for race)

	Controls (N=59034)	Cases (N=378)	Total (N=59412)
Type of examination			
CT (multislice)	32700 (55.4%)	305 (80.7%)	33005 (55.6%)
Angiocardiology ²	12153 (20.6%)	17 (4.5%)	12170 (20.5%)
CT (singleslice)	3875 (6.6%)	21 (5.6%)	3896 (6.6%)
Angiography	787 (1.3%)	2 (0.5%)	789 (1.3%)
Phlebography	325 (0.6%)	0	325 (0.5%)
DSA	207 (0.4%)	0	207 (0.3%)
CT	8 (<0.1%)	0	8 (<0.1%)
Other	7004 (11.9%)	9 (2.4%)	7013 (11.8%)
Not specified	1975 (3.3%)	24 (6.3%)	1999 (3.4%)
Contrast quality			
Excellent	33564 (56.9%)	140 (37.0%)	33704 (56.7%)
Good	23245 (39.4%)	201 (53.2%)	23446 (39.5%)
Adequate	2037 (3.5%)	29 (7.7%)	2066 (3.5%)
Moderate	155 (0.3%)	8 (2.1%)	163 (0.3%)
Non diagnostic	17 (<0.1%)	0	17 (<0.1%)
Not specified	16 (<0.1%)	0	16 (<0.1%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.3 / 29: Exposure by cases and controls groups (Full analysis set for geographical region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Injection route			
Intravenous	116499 (79.9%)	844 (93.3%)	117343 (80.0%)
Intra-arterial	28430 (19.5%)	59 (6.5%)	28489 (19.4%)
Other	409 (0.3%)	1 (0.1%)	410 (0.3%)
Not specified	315 (0.2%)	1 (0.1%)	316 (0.2%)
Missing	91 (<0.1%)	0	91 (<0.1%)
Examination region ¹			
Abdomen	26839 (18.4%)	235 (26.0%)	27074 (18.5%)
Cardiac / Cardiac Vessels	23011 (15.8%)	47 (5.2%)	23058 (15.7%)
Thorax	13985 (9.6%)	116 (12.8%)	14101 (9.6%)
Pelvis	8171 (5.6%)	92 (10.2%)	8263 (5.6%)
Head / Brain	6678 (4.6%)	48 (5.3%)	6726 (4.6%)
Kidney / Renal Vessels	4687 (3.2%)	55 (6.1%)	4742 (3.2%)
Neck	2696 (1.8%)	21 (2.3%)	2717 (1.9%)
Blood Vessels	1954 (1.3%)	13 (1.4%)	1967 (1.3%)
Limbs	414 (0.3%)	1 (0.1%)	415 (0.3%)
Joints	46 (<0.1%)	0	46 (<0.1%)
Other	1132 (0.8%)	16 (1.8%)	1148 (0.8%)
Not specified	20 (<0.1%)	0	20 (<0.1%)
Missing	71875 (49.3%)	414 (45.7%)	72289 (49.3%)
Indication ¹			
Tumour/Suspicion of Tumour	26396 (18.1%)	224 (24.8%)	26620 (18.2%)
Pain	7533 (5.2%)	64 (7.1%)	7597 (5.2%)
Post-Therapy-Control	7541 (5.2%)	47 (5.2%)	7588 (5.2%)
Staging	5471 (3.8%)	39 (4.3%)	5510 (3.8%)
Inflammatory Diseases	4368 (3.0%)	39 (4.3%)	4407 (3.0%)
Infarct/Suspicion of Infarct	3463 (2.4%)	25 (2.8%)	3488 (2.4%)
Haemorrhage	948 (0.7%)	6 (0.7%)	954 (0.7%)
Trauma	616 (0.4%)	2 (0.2%)	618 (0.4%)
Other	24480 (16.8%)	116 (12.8%)	24596 (16.8%)
Not specified	77 (<0.1%)	0	77 (<0.1%)
Missing	72319 (49.6%)	417 (46.1%)	72736 (49.6%)

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Table 14.3 / 29: Exposure by cases and controls groups (Full analysis set for geographical region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Dose [ml]			
n	145065	900	145965
Nmiss	679	5	684
Mean (SD)	99.714 (45.355)	97.466 (42.220)	99.700 (45.337)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 110.000	75.000, 110.000	75.000, 110.000
Min, Max	1.00, 800.00	4.00, 600.00	1.00, 800.00
Dose			
<100 ml	60486 (41.5%)	412 (45.5%)	60898 (41.5%)
100 - <150 ml	66750 (45.8%)	410 (45.3%)	67160 (45.8%)
150 - <200 ml	11705 (8.0%)	58 (6.4%)	11763 (8.0%)
200 - <300 ml	4547 (3.1%)	14 (1.5%)	4561 (3.1%)
>=300 ml	1577 (1.1%)	6 (0.7%)	1583 (1.1%)
Not specified	679 (0.5%)	5 (0.6%)	684 (0.5%)
Dose of iodine [g]			
n	145065	900	145965
Nmiss	679	5	684
Mean (SD)	32.522 (16.405)	31.190 (14.487)	32.514 (16.394)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	24.000, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	1.48, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	24324 (16.7%)	143 (15.8%)	24467 (16.7%)
>20 - 40 g	94889 (65.1%)	607 (67.1%)	95496 (65.1%)
>40 - 60 g	19416 (13.3%)	133 (14.7%)	19549 (13.3%)
>60 g	6436 (4.4%)	17 (1.9%)	6453 (4.4%)
Not specified	679 (0.5%)	5 (0.6%)	684 (0.5%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.3 / 29: Exposure by cases and controls groups (Full analysis set for geographical region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Type of examination			
CT	65158 (44.7%)	411 (45.4%)	65569 (44.7%)
CT (multislice)	32934 (22.6%)	306 (33.8%)	33240 (22.7%)
Angiocardiology ²	12563 (8.6%)	19 (2.1%)	12582 (8.6%)
Urography	10907 (7.5%)	68 (7.5%)	10975 (7.5%)
CT (singleslice)	4015 (2.8%)	22 (2.4%)	4037 (2.8%)
Angiography	1876 (1.3%)	5 (0.6%)	1881 (1.3%)
Phlebography	330 (0.2%)	0	330 (0.2%)
DSA	264 (0.2%)	0	264 (0.2%)
PTCA	177 (0.1%)	2 (0.2%)	179 (0.1%)
PTA	84 (<0.1%)	0	84 (<0.1%)
Other	7004 (4.8%)	9 (1.0%)	7013 (4.8%)
Not specified	10432 (7.2%)	63 (7.0%)	10495 (7.2%)
Contrast quality			
Excellent	74116 (50.9%)	322 (35.6%)	74438 (50.8%)
Good	63794 (43.8%)	487 (53.8%)	64281 (43.8%)
Adequate	6558 (4.5%)	60 (6.6%)	6618 (4.5%)
Moderate	540 (0.4%)	15 (1.7%)	555 (0.4%)
Non diagnostic	51 (<0.1%)	7 (0.8%)	58 (<0.1%)
Not specified	685 (0.5%)	14 (1.5%)	699 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.3 / 30: Exposure by cases and controls groups (Full analysis set for country/region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Injection route			
Intravenous	116499 (79.9%)	844 (93.3%)	117343 (80.0%)
Intra-arterial	28430 (19.5%)	59 (6.5%)	28489 (19.4%)
Other	409 (0.3%)	1 (0.1%)	410 (0.3%)
Not specified	315 (0.2%)	1 (0.1%)	316 (0.2%)
Missing	91 (<0.1%)	0	91 (<0.1%)
Examination region ¹			
Abdomen	26839 (18.4%)	235 (26.0%)	27074 (18.5%)
Cardiac / Cardiac Vessels	23011 (15.8%)	47 (5.2%)	23058 (15.7%)
Thorax	13985 (9.6%)	116 (12.8%)	14101 (9.6%)
Pelvis	8171 (5.6%)	92 (10.2%)	8263 (5.6%)
Head / Brain	6678 (4.6%)	48 (5.3%)	6726 (4.6%)
Kidney / Renal Vessels	4687 (3.2%)	55 (6.1%)	4742 (3.2%)
Neck	2696 (1.8%)	21 (2.3%)	2717 (1.9%)
Blood Vessels	1954 (1.3%)	13 (1.4%)	1967 (1.3%)
Limbs	414 (0.3%)	1 (0.1%)	415 (0.3%)
Joints	46 (<0.1%)	0	46 (<0.1%)
Other	1132 (0.8%)	16 (1.8%)	1148 (0.8%)
Not specified	20 (<0.1%)	0	20 (<0.1%)
Missing	71875 (49.3%)	414 (45.7%)	72289 (49.3%)
Indication ¹			
Tumour/Suspicion of Tumour	26396 (18.1%)	224 (24.8%)	26620 (18.2%)
Pain	7533 (5.2%)	64 (7.1%)	7597 (5.2%)
Post-Therapy-Control	7541 (5.2%)	47 (5.2%)	7588 (5.2%)
Staging	5471 (3.8%)	39 (4.3%)	5510 (3.8%)
Inflammatory Diseases	4368 (3.0%)	39 (4.3%)	4407 (3.0%)
Infarct/Suspicion of Infarct	3463 (2.4%)	25 (2.8%)	3488 (2.4%)
Haemorrhage	948 (0.7%)	6 (0.7%)	954 (0.7%)
Trauma	616 (0.4%)	2 (0.2%)	618 (0.4%)
Other	24480 (16.8%)	116 (12.8%)	24596 (16.8%)
Not specified	77 (<0.1%)	0	77 (<0.1%)
Missing	72319 (49.6%)	417 (46.1%)	72736 (49.6%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.3 / 30: Exposure by cases and controls groups (Full analysis set for country/region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Dose [ml]			
n	145065	900	145965
Nmiss	679	5	684
Mean (SD)	99.714 (45.355)	97.466 (42.220)	99.700 (45.337)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 110.000	75.000, 110.000	75.000, 110.000
Min, Max	1.00, 800.00	4.00, 600.00	1.00, 800.00
Dose			
<100 ml	60486 (41.5%)	412 (45.5%)	60898 (41.5%)
100 - <150 ml	66750 (45.8%)	410 (45.3%)	67160 (45.8%)
150 - <200 ml	11705 (8.0%)	58 (6.4%)	11763 (8.0%)
200 - <300 ml	4547 (3.1%)	14 (1.5%)	4561 (3.1%)
>=300 ml	1577 (1.1%)	6 (0.7%)	1583 (1.1%)
Not specified	679 (0.5%)	5 (0.6%)	684 (0.5%)
Dose of iodine [g]			
n	145065	900	145965
Nmiss	679	5	684
Mean (SD)	32.522 (16.405)	31.190 (14.487)	32.514 (16.394)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	24.000, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	1.48, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	24324 (16.7%)	143 (15.8%)	24467 (16.7%)
>20 - 40 g	94889 (65.1%)	607 (67.1%)	95496 (65.1%)
>40 - 60 g	19416 (13.3%)	133 (14.7%)	19549 (13.3%)
>60 g	6436 (4.4%)	17 (1.9%)	6453 (4.4%)
Not specified	679 (0.5%)	5 (0.6%)	684 (0.5%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.3 / 30: Exposure by cases and controls groups (Full analysis set for country/region)

	Controls (N=145744)	Cases (N=905)	Total (N=146649)
Type of examination			
CT	65158 (44.7%)	411 (45.4%)	65569 (44.7%)
CT (multislice)	32934 (22.6%)	306 (33.8%)	33240 (22.7%)
Angiocardiology ²	12563 (8.6%)	19 (2.1%)	12582 (8.6%)
Urography	10907 (7.5%)	68 (7.5%)	10975 (7.5%)
CT (singleslice)	4015 (2.8%)	22 (2.4%)	4037 (2.8%)
Angiography	1876 (1.3%)	5 (0.6%)	1881 (1.3%)
Phlebography	330 (0.2%)	0	330 (0.2%)
DSA	264 (0.2%)	0	264 (0.2%)
PTCA	177 (0.1%)	2 (0.2%)	179 (0.1%)
PTA	84 (<0.1%)	0	84 (<0.1%)
Other	7004 (4.8%)	9 (1.0%)	7013 (4.8%)
Not specified	10432 (7.2%)	63 (7.0%)	10495 (7.2%)
Contrast quality			
Excellent	74116 (50.9%)	322 (35.6%)	74438 (50.8%)
Good	63794 (43.8%)	487 (53.8%)	64281 (43.8%)
Adequate	6558 (4.5%)	60 (6.6%)	6618 (4.5%)
Moderate	540 (0.4%)	15 (1.7%)	555 (0.4%)
Non diagnostic	51 (<0.1%)	7 (0.8%)	58 (<0.1%)
Not specified	685 (0.5%)	14 (1.5%)	699 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.3 / 31: Exposure by cases and controls groups (Complete cases analysis set for sex)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Injection route			
Intravenous	104257 (79.0%)	762 (93.2%)	105019 (79.1%)
Intra-arterial	27775 (21.0%)	56 (6.8%)	27831 (20.9%)
Examination region ¹			
Abdomen	25045 (19.0%)	227 (27.8%)	25272 (19.0%)
Cardiac / Cardiac Vessels	22782 (17.3%)	46 (5.6%)	22828 (17.2%)
Thorax	12942 (9.8%)	108 (13.2%)	13050 (9.8%)
Pelvis	7641 (5.8%)	91 (11.1%)	7732 (5.8%)
Head / Brain	6053 (4.6%)	45 (5.5%)	6098 (4.6%)
Kidney / Renal Vessels	4087 (3.1%)	51 (6.2%)	4138 (3.1%)
Neck	2546 (1.9%)	20 (2.4%)	2566 (1.9%)
Blood Vessels	1730 (1.3%)	13 (1.6%)	1743 (1.3%)
Limbs	385 (0.3%)	1 (0.1%)	386 (0.3%)
Joints	43 (<0.1%)	0	43 (<0.1%)
Other	920 (0.7%)	15 (1.8%)	935 (0.7%)
Not specified	8 (<0.1%)	0	8 (<0.1%)
Missing	62277 (47.2%)	351 (42.9%)	62628 (47.1%)
Indication ¹			
Tumour/Suspicion of Tumour	24856 (18.8%)	216 (26.4%)	25072 (18.9%)
Pain	6975 (5.3%)	60 (7.3%)	7035 (5.3%)
Post-Therapy-Control	6920 (5.2%)	47 (5.7%)	6967 (5.2%)
Staging	5126 (3.9%)	36 (4.4%)	5162 (3.9%)
Inflammatory Diseases	3956 (3.0%)	35 (4.3%)	3991 (3.0%)
Infarct/Suspicion of Infarct	3356 (2.5%)	25 (3.1%)	3381 (2.5%)
Haemorrhage	830 (0.6%)	5 (0.6%)	835 (0.6%)
Trauma	568 (0.4%)	1 (0.1%)	569 (0.4%)
Other	23503 (17.8%)	112 (13.7%)	23615 (17.8%)
Not specified	54 (<0.1%)	0	54 (<0.1%)
Missing	62667 (47.5%)	354 (43.3%)	63021 (47.4%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.3 / 31: Exposure by cases and controls groups (Complete cases analysis set for sex)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Dose [ml]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	99.275 (45.890)	96.258 (42.801)	99.256 (45.873)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 110.000	75.000, 105.000	75.000, 110.000
Min, Max	1.00, 800.00	4.00, 600.00	1.00, 800.00
Dose			
<100 ml	56565 (42.8%)	395 (48.3%)	56960 (42.9%)
100 - <150 ml	59657 (45.2%)	359 (43.9%)	60016 (45.2%)
150 - <200 ml	9968 (7.5%)	45 (5.5%)	10013 (7.5%)
200 - <300 ml	4332 (3.3%)	13 (1.6%)	4345 (3.3%)
>=300 ml	1510 (1.1%)	6 (0.7%)	1516 (1.1%)
Dose of iodine [g]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	32.447 (16.661)	30.899 (14.792)	32.437 (16.651)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	24.000, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	1.48, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	22684 (17.2%)	133 (16.3%)	22817 (17.2%)
>20 - 40 g	86653 (65.6%)	561 (68.6%)	87214 (65.6%)
>40 - 60 g	16555 (12.5%)	108 (13.2%)	16663 (12.5%)
>60 g	6140 (4.7%)	16 (2.0%)	6156 (4.6%)

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Table 14.3 / 31: Exposure by cases and controls groups (Complete cases analysis set for sex)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Type of examination			
CT	57128 (43.3%)	360 (44.0%)	57488 (43.3%)
CT (multislice)	30981 (23.5%)	291 (35.6%)	31272 (23.5%)
Angiocardiology ²	12476 (9.4%)	18 (2.2%)	12494 (9.4%)
Urography	10038 (7.6%)	59 (7.2%)	10097 (7.6%)
CT (singleslice)	2996 (2.3%)	19 (2.3%)	3015 (2.3%)
Angiography	1791 (1.4%)	5 (0.6%)	1796 (1.4%)
Phlebography	296 (0.2%)	0	296 (0.2%)
DSA	221 (0.2%)	0	221 (0.2%)
PTCA	163 (0.1%)	2 (0.2%)	165 (0.1%)
PTA	78 (<0.1%)	0	78 (<0.1%)
Other	6844 (5.2%)	9 (1.1%)	6853 (5.2%)
Not specified	9020 (6.8%)	55 (6.7%)	9075 (6.8%)
Contrast quality			
Excellent	67533 (51.1%)	277 (33.9%)	67810 (51.0%)
Good	57586 (43.6%)	454 (55.5%)	58040 (43.7%)
Adequate	5774 (4.4%)	53 (6.5%)	5827 (4.4%)
Moderate	485 (0.4%)	13 (1.6%)	498 (0.4%)
Non diagnostic	46 (<0.1%)	7 (0.9%)	53 (<0.1%)
Not specified	608 (0.5%)	14 (1.7%)	622 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.3 / 32: Exposure by cases and controls groups (Complete cases analysis set for race)

	Controls (N=55634)	Cases (N=357)	Total (N=55991)
Injection route			
Intravenous	35404 (63.6%)	331 (92.7%)	35735 (63.8%)
Intra-arterial	20230 (36.4%)	26 (7.3%)	20256 (36.2%)
Examination region ¹			
Cardiac / Cardiac Vessels	22609 (40.6%)	43 (12.0%)	22652 (40.5%)
Abdomen	17389 (31.3%)	158 (44.3%)	17547 (31.3%)
Thorax	8521 (15.3%)	80 (22.4%)	8601 (15.4%)
Pelvis	4418 (7.9%)	56 (15.7%)	4474 (8.0%)
Head / Brain	3732 (6.7%)	28 (7.8%)	3760 (6.7%)
Kidney / Renal Vessels	3185 (5.7%)	44 (12.3%)	3229 (5.8%)
Neck	1703 (3.1%)	16 (4.5%)	1719 (3.1%)
Blood Vessels	1453 (2.6%)	8 (2.2%)	1461 (2.6%)
Limbs	330 (0.6%)	0	330 (0.6%)
Joints	23 (<0.1%)	0	23 (<0.1%)
Other	807 (1.5%)	13 (3.6%)	820 (1.5%)
Not specified	7 (<0.1%)	0	7 (<0.1%)
Indication ¹			
Tumour/Suspicion of Tumour	19238 (34.6%)	164 (45.9%)	19402 (34.7%)
Pain	4951 (8.9%)	42 (11.8%)	4993 (8.9%)
Post-Therapy-Control	4718 (8.5%)	35 (9.8%)	4753 (8.5%)
Staging	3328 (6.0%)	29 (8.1%)	3357 (6.0%)
Infarct/Suspicion of Infarct	2963 (5.3%)	20 (5.6%)	2983 (5.3%)
Inflammatory Diseases	2624 (4.7%)	28 (7.8%)	2652 (4.7%)
Haemorrhage	648 (1.2%)	3 (0.8%)	651 (1.2%)
Trauma	337 (0.6%)	1 (0.3%)	338 (0.6%)
Other	21677 (39.0%)	93 (26.1%)	21770 (38.9%)
Not specified	54 (<0.1%)	0	54 (<0.1%)
Dose [ml]			
n	55634	357	55991
Nmiss	0	0	0
Mean (SD)	100.583 (52.853)	89.487 (39.739)	100.512 (52.787)
Median	95.000	85.000	95.000
Q1, Q3	70.000, 100.000	70.000, 100.000	70.000, 100.000
Min, Max	1.00, 800.00	20.00, 600.00	1.00, 800.00

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Table 14.3 / 32: Exposure by cases and controls groups (Complete cases analysis set for race)

	Controls (N=55634)	Cases (N=357)	Total (N=55991)
Dose			
<100 ml	28191 (50.7%)	233 (65.3%)	28424 (50.8%)
100 - <150 ml	20216 (36.3%)	114 (31.9%)	20330 (36.3%)
150 - <200 ml	3190 (5.7%)	6 (1.7%)	3196 (5.7%)
200 - <300 ml	2933 (5.3%)	3 (0.8%)	2936 (5.2%)
>=300 ml	1104 (2.0%)	1 (0.3%)	1105 (2.0%)
Dose of iodine [g]			
n	55634	357	55991
Nmiss	0	0	0
Mean (SD)	34.739 (19.888)	29.784 (14.136)	34.707 (19.860)
Median	30.000	28.500	30.000
Q1, Q3	24.000, 37.000	24.000, 33.300	24.000, 37.000
Min, Max	0.37, 296.00	6.00, 222.00	0.37, 296.00
Dose of iodine			
<=20 g	9112 (16.4%)	57 (16.0%)	9169 (16.4%)
>20 - 40 g	35398 (63.6%)	257 (72.0%)	35655 (63.7%)
>40 - 60 g	6501 (11.7%)	39 (10.9%)	6540 (11.7%)
>60 g	4623 (8.3%)	4 (1.1%)	4627 (8.3%)
Type of examination			
CT (multislice)	30880 (55.5%)	291 (81.5%)	31171 (55.7%)
Angiocardiology ²	12082 (21.7%)	16 (4.5%)	12098 (21.6%)
CT (singleslice)	2932 (5.3%)	19 (5.3%)	2951 (5.3%)
Angiography	772 (1.4%)	2 (0.6%)	774 (1.4%)
Phlebography	296 (0.5%)	0	296 (0.5%)
DSA	166 (0.3%)	0	166 (0.3%)
CT	7 (<0.1%)	0	7 (<0.1%)
Other	6844 (12.3%)	9 (2.5%)	6853 (12.2%)
Not specified	1655 (3.0%)	20 (5.6%)	1675 (3.0%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



Table 14.3 / 32: Exposure by cases and controls groups (Complete cases analysis set for race)

	Controls (N=55634)	Cases (N=357)	Total (N=55991)
Contrast quality			
Excellent	31874 (57.3%)	128 (35.9%)	32002 (57.2%)
Good	21636 (38.9%)	195 (54.6%)	21831 (39.0%)
Adequate	1951 (3.5%)	26 (7.3%)	1977 (3.5%)
Moderate	149 (0.3%)	8 (2.2%)	157 (0.3%)
Non diagnostic	16 (<0.1%)	0	16 (<0.1%)
Not specified	8 (<0.1%)	0	8 (<0.1%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.3 / 33: Exposure by cases and controls groups (Complete cases analysis set for geographical region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Injection route			
Intravenous	104257 (79.0%)	762 (93.2%)	105019 (79.1%)
Intra-arterial	27775 (21.0%)	56 (6.8%)	27831 (20.9%)
Examination region ¹			
Abdomen	25045 (19.0%)	227 (27.8%)	25272 (19.0%)
Cardiac / Cardiac Vessels	22782 (17.3%)	46 (5.6%)	22828 (17.2%)
Thorax	12942 (9.8%)	108 (13.2%)	13050 (9.8%)
Pelvis	7641 (5.8%)	91 (11.1%)	7732 (5.8%)
Head / Brain	6053 (4.6%)	45 (5.5%)	6098 (4.6%)
Kidney / Renal Vessels	4087 (3.1%)	51 (6.2%)	4138 (3.1%)
Neck	2546 (1.9%)	20 (2.4%)	2566 (1.9%)
Blood Vessels	1730 (1.3%)	13 (1.6%)	1743 (1.3%)
Limbs	385 (0.3%)	1 (0.1%)	386 (0.3%)
Joints	43 (<0.1%)	0	43 (<0.1%)
Other	920 (0.7%)	15 (1.8%)	935 (0.7%)
Not specified	8 (<0.1%)	0	8 (<0.1%)
Missing	62277 (47.2%)	351 (42.9%)	62628 (47.1%)
Indication ¹			
Tumour/Suspicion of Tumour	24856 (18.8%)	216 (26.4%)	25072 (18.9%)
Pain	6975 (5.3%)	60 (7.3%)	7035 (5.3%)
Post-Therapy-Control	6920 (5.2%)	47 (5.7%)	6967 (5.2%)
Staging	5126 (3.9%)	36 (4.4%)	5162 (3.9%)
Inflammatory Diseases	3956 (3.0%)	35 (4.3%)	3991 (3.0%)
Infarct/Suspicion of Infarct	3356 (2.5%)	25 (3.1%)	3381 (2.5%)
Haemorrhage	830 (0.6%)	5 (0.6%)	835 (0.6%)
Trauma	568 (0.4%)	1 (0.1%)	569 (0.4%)
Other	23503 (17.8%)	112 (13.7%)	23615 (17.8%)
Not specified	54 (<0.1%)	0	54 (<0.1%)
Missing	62667 (47.5%)	354 (43.3%)	63021 (47.4%)

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Table 14.3 / 33: Exposure by cases and controls groups (Complete cases analysis set for geographical region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Dose [ml]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	99.275 (45.890)	96.258 (42.801)	99.256 (45.873)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 110.000	75.000, 105.000	75.000, 110.000
Min, Max	1.00, 800.00	4.00, 600.00	1.00, 800.00
Dose			
<100 ml	56565 (42.8%)	395 (48.3%)	56960 (42.9%)
100 - <150 ml	59657 (45.2%)	359 (43.9%)	60016 (45.2%)
150 - <200 ml	9968 (7.5%)	45 (5.5%)	10013 (7.5%)
200 - <300 ml	4332 (3.3%)	13 (1.6%)	4345 (3.3%)
>=300 ml	1510 (1.1%)	6 (0.7%)	1516 (1.1%)
Dose of iodine [g]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	32.447 (16.661)	30.899 (14.792)	32.437 (16.651)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	24.000, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	1.48, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	22684 (17.2%)	133 (16.3%)	22817 (17.2%)
>20 - 40 g	86653 (65.6%)	561 (68.6%)	87214 (65.6%)
>40 - 60 g	16555 (12.5%)	108 (13.2%)	16663 (12.5%)
>60 g	6140 (4.7%)	16 (2.0%)	6156 (4.6%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.3 / 33: Exposure by cases and controls groups (Complete cases analysis set for geographical region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Type of examination			
CT	57128 (43.3%)	360 (44.0%)	57488 (43.3%)
CT (multislice)	30981 (23.5%)	291 (35.6%)	31272 (23.5%)
Angiocardiology ²	12476 (9.4%)	18 (2.2%)	12494 (9.4%)
Urography	10038 (7.6%)	59 (7.2%)	10097 (7.6%)
CT (singleslice)	2996 (2.3%)	19 (2.3%)	3015 (2.3%)
Angiography	1791 (1.4%)	5 (0.6%)	1796 (1.4%)
Phlebography	296 (0.2%)	0	296 (0.2%)
DSA	221 (0.2%)	0	221 (0.2%)
PTCA	163 (0.1%)	2 (0.2%)	165 (0.1%)
PTA	78 (<0.1%)	0	78 (<0.1%)
Other	6844 (5.2%)	9 (1.1%)	6853 (5.2%)
Not specified	9020 (6.8%)	55 (6.7%)	9075 (6.8%)
Contrast quality			
Excellent	67533 (51.1%)	277 (33.9%)	67810 (51.0%)
Good	57586 (43.6%)	454 (55.5%)	58040 (43.7%)
Adequate	5774 (4.4%)	53 (6.5%)	5827 (4.4%)
Moderate	485 (0.4%)	13 (1.6%)	498 (0.4%)
Non diagnostic	46 (<0.1%)	7 (0.9%)	53 (<0.1%)
Not specified	608 (0.5%)	14 (1.7%)	622 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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Table 14.3 / 34: Exposure by cases and controls groups (Complete cases analysis set for country/region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Injection route			
Intravenous	104257 (79.0%)	762 (93.2%)	105019 (79.1%)
Intra-arterial	27775 (21.0%)	56 (6.8%)	27831 (20.9%)
Examination region ¹			
Abdomen	25045 (19.0%)	227 (27.8%)	25272 (19.0%)
Cardiac / Cardiac Vessels	22782 (17.3%)	46 (5.6%)	22828 (17.2%)
Thorax	12942 (9.8%)	108 (13.2%)	13050 (9.8%)
Pelvis	7641 (5.8%)	91 (11.1%)	7732 (5.8%)
Head / Brain	6053 (4.6%)	45 (5.5%)	6098 (4.6%)
Kidney / Renal Vessels	4087 (3.1%)	51 (6.2%)	4138 (3.1%)
Neck	2546 (1.9%)	20 (2.4%)	2566 (1.9%)
Blood Vessels	1730 (1.3%)	13 (1.6%)	1743 (1.3%)
Limbs	385 (0.3%)	1 (0.1%)	386 (0.3%)
Joints	43 (<0.1%)	0	43 (<0.1%)
Other	920 (0.7%)	15 (1.8%)	935 (0.7%)
Not specified	8 (<0.1%)	0	8 (<0.1%)
Missing	62277 (47.2%)	351 (42.9%)	62628 (47.1%)
Indication ¹			
Tumour/Suspicion of Tumour	24856 (18.8%)	216 (26.4%)	25072 (18.9%)
Pain	6975 (5.3%)	60 (7.3%)	7035 (5.3%)
Post-Therapy-Control	6920 (5.2%)	47 (5.7%)	6967 (5.2%)
Staging	5126 (3.9%)	36 (4.4%)	5162 (3.9%)
Inflammatory Diseases	3956 (3.0%)	35 (4.3%)	3991 (3.0%)
Infarct/Suspicion of Infarct	3356 (2.5%)	25 (3.1%)	3381 (2.5%)
Haemorrhage	830 (0.6%)	5 (0.6%)	835 (0.6%)
Trauma	568 (0.4%)	1 (0.1%)	569 (0.4%)
Other	23503 (17.8%)	112 (13.7%)	23615 (17.8%)
Not specified	54 (<0.1%)	0	54 (<0.1%)
Missing	62667 (47.5%)	354 (43.3%)	63021 (47.4%)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.3 / 34: Exposure by cases and controls groups (Complete cases analysis set for country/region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Dose [ml]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	99.275 (45.890)	96.258 (42.801)	99.256 (45.873)
Median	100.000	100.000	100.000
Q1, Q3	75.000, 110.000	75.000, 105.000	75.000, 110.000
Min, Max	1.00, 800.00	4.00, 600.00	1.00, 800.00
Dose			
<100 ml	56565 (42.8%)	395 (48.3%)	56960 (42.9%)
100 - <150 ml	59657 (45.2%)	359 (43.9%)	60016 (45.2%)
150 - <200 ml	9968 (7.5%)	45 (5.5%)	10013 (7.5%)
200 - <300 ml	4332 (3.3%)	13 (1.6%)	4345 (3.3%)
>=300 ml	1510 (1.1%)	6 (0.7%)	1516 (1.1%)
Dose of iodine [g]			
n	132032	818	132850
Nmiss	0	0	0
Mean (SD)	32.447 (16.661)	30.899 (14.792)	32.437 (16.651)
Median	30.000	30.000	30.000
Q1, Q3	24.000, 37.000	24.000, 36.000	24.000, 37.000
Min, Max	0.30, 296.00	1.48, 222.00	0.30, 296.00
Dose of iodine			
<=20 g	22684 (17.2%)	133 (16.3%)	22817 (17.2%)
>20 - 40 g	86653 (65.6%)	561 (68.6%)	87214 (65.6%)
>40 - 60 g	16555 (12.5%)	108 (13.2%)	16663 (12.5%)
>60 g	6140 (4.7%)	16 (2.0%)	6156 (4.6%)

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Table 14.3 / 34: Exposure by cases and controls groups (Complete cases analysis set for country/region)

	Controls (N=132032)	Cases (N=818)	Total (N=132850)
Type of examination			
CT	57128 (43.3%)	360 (44.0%)	57488 (43.3%)
CT (multislice)	30981 (23.5%)	291 (35.6%)	31272 (23.5%)
Angiocardiology ²	12476 (9.4%)	18 (2.2%)	12494 (9.4%)
Urography	10038 (7.6%)	59 (7.2%)	10097 (7.6%)
CT (singleslice)	2996 (2.3%)	19 (2.3%)	3015 (2.3%)
Angiography	1791 (1.4%)	5 (0.6%)	1796 (1.4%)
Phlebography	296 (0.2%)	0	296 (0.2%)
DSA	221 (0.2%)	0	221 (0.2%)
PTCA	163 (0.1%)	2 (0.2%)	165 (0.1%)
PTA	78 (<0.1%)	0	78 (<0.1%)
Other	6844 (5.2%)	9 (1.1%)	6853 (5.2%)
Not specified	9020 (6.8%)	55 (6.7%)	9075 (6.8%)
Contrast quality			
Excellent	67533 (51.1%)	277 (33.9%)	67810 (51.0%)
Good	57586 (43.6%)	454 (55.5%)	58040 (43.7%)
Adequate	5774 (4.4%)	53 (6.5%)	5827 (4.4%)
Moderate	485 (0.4%)	13 (1.6%)	498 (0.4%)
Non diagnostic	46 (<0.1%)	7 (0.9%)	53 (<0.1%)
Not specified	608 (0.5%)	14 (1.7%)	622 (0.5%)

¹ Multiple responses possible.

² Category angiocardiology includes elective PCI.

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adex_exposure.sas 01DEC2022 15:19

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14.4 Analysis of risk of hypersensitivity reactions

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.4 / 1: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for sex)

	Cases (N=903)	Controls (N=144130)	Odds Ratio (95% CI)
Sex			
Male	442 (48.9%)	80374 (55.8%)	1.000
Female	461 (51.1%)	63756 (44.2%)	1.315 (1.154; 1.499)
Race			
Asian	307 (34.0%)	49857 (34.6%)	0.866 (0.660; 1.136)
White	63 (7.0%)	8858 (6.1%)	1.000
Black	0	30 (<0.1%)	<0.001 (<0.001; -)
Other	8 (0.9%)	173 (0.1%)	6.502 (3.069; 13.776)
missing	525 (58.1%)	85212 (59.1%)	-
Country / geographical region category 1 (China vs. Germany)			
China	152 (16.8%)	36753 (25.5%)	0.783 (0.638; 0.961)
Germany	234 (25.9%)	44325 (30.8%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	152 (16.8%)	36753 (25.5%)	0.537 (0.418; 0.689)
Korea (South)	105 (11.6%)	13633 (9.5%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	152 (16.8%)	36753 (25.5%)	0.393 (0.321; 0.481)
rest of APAC	250 (27.7%)	23767 (16.5%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	152 (16.8%)	36753 (25.5%)	0.591 (0.497; 0.704)
rest of the world	751 (83.2%)	107377 (74.5%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	105 (11.6%)	13633 (9.5%)	0.538 (0.418; 0.693)
rest of APAC	145 (16.1%)	10134 (7.0%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	105 (11.6%)	13633 (9.5%)	1.260 (1.027; 1.545)
rest of the world	798 (88.4%)	130497 (90.5%)	1.000

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Table 14.4 / 1: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for sex)

	Cases (N=903)	Controls (N=144130)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	234 (25.9%)	44325 (30.8%)	0.685 (0.544; 0.864)
Korea (South)	105 (11.6%)	13633 (9.5%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	234 (25.9%)	44325 (30.8%)	0.961 (0.775; 1.192)
rest of Europe	129 (14.3%)	23496 (16.3%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	234 (25.9%)	44325 (30.8%)	0.788 (0.678; 0.914)
rest of the world	669 (74.1%)	99805 (69.2%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	489 (54.2%)	69195 (48.0%)	1.000
Europe	363 (40.2%)	67821 (47.1%)	0.757 (0.661; 0.868)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	363 (40.2%)	67821 (47.1%)	1.000
China	152 (16.8%)	36753 (25.5%)	0.773 (0.639; 0.934)
Indonesia	15 (1.7%)	676 (0.5%)	4.146 (2.460; 6.987)
Iran	66 (7.3%)	4981 (3.5%)	2.476 (1.902; 3.223)
Jordan	8 (0.9%)	1635 (1.1%)	0.914 (0.453; 1.845)
Korea (South)	105 (11.6%)	13633 (9.5%)	1.439 (1.157; 1.789)
Malaysia	7 (0.8%)	852 (0.6%)	1.535 (0.724; 3.253)
Pakistan	4 (0.4%)	1347 (0.9%)	0.555 (0.207; 1.488)
Philippines	41 (4.5%)	4108 (2.9%)	1.865 (1.348; 2.579)
Saudi Arabia	9 (1.0%)	712 (0.5%)	2.362 (1.214; 4.594)
Singapore	52 (5.8%)	1597 (1.1%)	6.084 (4.530; 8.169)
Taiwan	13 (1.4%)	752 (0.5%)	3.230 (1.849; 5.643)
Thailand	16 (1.8%)	543 (0.4%)	5.505 (3.313; 9.147)
Vietnam	1 (0.1%)	1606 (1.1%)	0.116 (0.016; 0.829)

Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.4 / 1: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for sex)

	Cases (N=903)	Controls (N=144130)	Odds Ratio (95% CI)
Age group			
< 18	14 (1.6%)	3040 (2.1%)	1.214 (0.703; 2.098)
>= 18 and < 50	337 (37.3%)	37211 (25.8%)	2.387 (1.981; 2.878)
>= 50 and < 65	308 (34.1%)	49629 (34.4%)	1.636 (1.354; 1.977)
>= 65 years old	165 (18.3%)	43498 (30.2%)	1.000
Not specified	79 (8.7%)	10752 (7.5%)	1.937 (1.480; 2.535)
Contrast medium application			
Intravenous	842 (93.2%)	115072 (79.8%)	1.000
Intra-arterial	59 (6.5%)	28272 (19.6%)	0.285 (0.219; 0.371)
Other	1 (0.1%)	396 (0.3%)	0.345 (0.048; 2.459)
Not specified	1 (0.1%)	301 (0.2%)	0.454 (0.064; 3.238)
missing	0	89 (<0.1%)	-
Concomitant Disease: Coronary heart disease			
No	845 (93.6%)	131821 (91.5%)	1.000
Yes	58 (6.4%)	12309 (8.5%)	0.736 (0.563; 0.960)
Concomitant Disease: Hypertension arterial			
No	825 (91.4%)	126705 (87.9%)	1.000
Yes	78 (8.6%)	17425 (12.1%)	0.687 (0.545; 0.868)
Concomitant Disease: Diabetes mellitus			
No	827 (91.6%)	132931 (92.2%)	1.000
Yes	76 (8.4%)	11199 (7.8%)	1.091 (0.862; 1.381)
Concomitant Disease: Reduced general condition			
No	857 (94.9%)	136836 (94.9%)	1.000
Yes	46 (5.1%)	7294 (5.1%)	1.007 (0.748; 1.356)
Concomitant Disease: Allergy			
No	808 (89.5%)	139963 (97.1%)	1.000
Yes	95 (10.5%)	4167 (2.9%)	3.949 (3.186; 4.895)
Concomitant Disease: Asthma bronchial			
No	888 (98.3%)	143238 (99.4%)	1.000
Yes	15 (1.7%)	892 (0.6%)	2.713 (1.622; 4.538)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.4 / 1: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for sex)

	Cases (N=903)	Controls (N=144130)	Odds Ratio (95% CI)
Concomitant Disease: Contrast media reaction			
No	878 (97.2%)	143360 (99.5%)	1.000
Yes	25 (2.8%)	770 (0.5%)	5.305 (3.543; 7.943)
Concomitant Disease: Other			
No	739 (81.8%)	122649 (85.1%)	1.000
Yes	164 (18.2%)	21481 (14.9%)	1.267 (1.069; 1.502)
Specific CM risk factor			
No	494 (54.7%)	87403 (60.6%)	1.000
Yes	409 (45.3%)	56727 (39.4%)	1.276 (1.119; 1.455)
Pre-medication Flag			
No	787 (87.2%)	125932 (87.4%)	1.000
Yes	116 (12.8%)	18198 (12.6%)	1.020 (0.839; 1.240)
Contrast medium dose			
<100 ml	411 (45.5%)	59872 (41.5%)	1.000
100 - <150 ml	409 (45.3%)	65949 (45.8%)	0.903 (0.788; 1.036)
150 - <200 ml	58 (6.4%)	11589 (8.0%)	0.729 (0.553; 0.960)
200 - <300 ml	14 (1.6%)	4517 (3.1%)	0.452 (0.265; 0.770)
>=300 ml	6 (0.7%)	1565 (1.1%)	0.559 (0.249; 1.252)
Not specified	5 (0.6%)	638 (0.4%)	1.142 (0.471; 2.767)
Dose of iodine in CM			
<=20 g	142 (15.7%)	24071 (16.7%)	1.000
>20 - 40 g	607 (67.2%)	93764 (65.1%)	1.097 (0.914; 1.318)
>40 - 60 g	132 (14.6%)	19261 (13.4%)	1.162 (0.916; 1.473)
>60 g	17 (1.9%)	6396 (4.4%)	0.451 (0.272; 0.746)
Not specified	5 (0.6%)	638 (0.4%)	1.328 (0.543; 3.252)

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Table 14.4 / 1: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for sex)

	Cases (N=903)	Controls (N=144130)	Odds Ratio (95% CI)
Ultravist concentration			
Ultravist - 300	617 (68.3%)	92657 (64.3%)	1.000
Ultravist - 370	286 (31.7%)	51473 (35.7%)	0.834 (0.725; 0.960)

CM = Contrast media.
Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.
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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.4 / 2: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for race)

	Cases (N=378)	Controls (N=59034)	Odds Ratio (95% CI)
Sex			
Male	191 (50.5%)	35337 (59.9%)	1.000
Female	187 (49.5%)	23581 (39.9%)	1.467 (1.199; 1.796)
missing	0	116 (0.2%)	-
Race			
Asian	307 (81.2%)	49910 (84.5%)	0.871 (0.664; 1.143)
White	63 (16.7%)	8921 (15.1%)	1.000
Black	0	30 (<0.1%)	<0.001 (<0.001; -)
Other	8 (2.1%)	173 (0.3%)	6.548 (3.090; 13.874)
Country / geographical region category 1 (China vs. Germany)			
China	152 (40.2%)	36762 (62.3%)	0.654 (0.384; 1.113)
Germany	15 (4.0%)	2372 (4.0%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	152 (40.2%)	36762 (62.3%)	0.401 (0.282; 0.572)
Korea (South)	39 (10.3%)	3787 (6.4%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	152 (40.2%)	36762 (62.3%)	0.329 (0.262; 0.414)
rest of APAC	147 (38.9%)	11712 (19.8%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	152 (40.2%)	36762 (62.3%)	0.407 (0.332; 0.501)
rest of the world	226 (59.8%)	22272 (37.7%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	39 (10.3%)	3787 (6.4%)	0.756 (0.523; 1.092)
rest of APAC	108 (28.6%)	7925 (13.4%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	39 (10.3%)	3787 (6.4%)	1.678 (1.203; 2.342)
rest of the world	339 (89.7%)	55247 (93.6%)	1.000

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.4 / 2: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for race)

	Cases (N=378)	Controls (N=59034)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	15 (4.0%)	2372 (4.0%)	0.614 (0.338; 1.116)
Korea (South)	39 (10.3%)	3787 (6.4%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	15 (4.0%)	2372 (4.0%)	0.868 (0.485; 1.552)
rest of Europe	48 (12.7%)	6586 (11.2%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	15 (4.0%)	2372 (4.0%)	0.987 (0.588; 1.657)
rest of the world	363 (96.0%)	56662 (96.0%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	315 (83.3%)	50076 (84.8%)	1.000
Europe	63 (16.7%)	8958 (15.2%)	1.118 (0.852; 1.467)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	63 (16.7%)	8958 (15.2%)	1.000
China	152 (40.2%)	36762 (62.3%)	0.588 (0.438; 0.789)
Indonesia	15 (4.0%)	677 (1.1%)	3.150 (1.784; 5.562)
Iran	8 (2.1%)	136 (0.2%)	8.367 (3.934; 17.798)
Korea (South)	39 (10.3%)	3787 (6.4%)	1.464 (0.980; 2.187)
Malaysia	7 (1.9%)	852 (1.4%)	1.168 (0.533; 2.559)
Pakistan	4 (1.1%)	1289 (2.2%)	0.441 (0.160; 1.214)
Philippines	18 (4.8%)	2376 (4.0%)	1.077 (0.637; 1.822)
Saudi Arabia	4 (1.1%)	177 (0.3%)	3.213 (1.157; 8.925)
Singapore	52 (13.8%)	1590 (2.7%)	4.650 (3.209; 6.740)
Taiwan	10 (2.6%)	561 (1.0%)	2.535 (1.294; 4.966)
Thailand	5 (1.3%)	261 (0.4%)	2.724 (1.087; 6.828)
Vietnam	1 (0.3%)	1608 (2.7%)	0.089 (0.012; 0.638)
Age group			
< 18	9 (2.4%)	1054 (1.8%)	2.409 (1.189; 4.879)
>= 18 and < 50	148 (39.2%)	15364 (26.0%)	2.718 (2.001; 3.692)
>= 50 and < 65	144 (38.1%)	23414 (39.7%)	1.735 (1.276; 2.359)
>= 65 years old	57 (15.1%)	16081 (27.2%)	1.000
Not specified	20 (5.3%)	3121 (5.3%)	1.808 (1.085; 3.013)

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Table 14.4 / 2: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for race)

	Cases (N=378)	Controls (N=59034)	Odds Ratio (95% CI)
Contrast medium application			
Intravenous	351 (92.9%)	38455 (65.1%)	1.000
Intra-arterial	27 (7.1%)	20392 (34.5%)	0.145 (0.098; 0.215)
Other	0	99 (0.2%)	<0.001 (<0.001; -)
missing	0	88 (0.1%)	-
Concomitant Disease: Coronary heart disease			
No	362 (95.8%)	54331 (92.0%)	1.000
Yes	16 (4.2%)	4703 (8.0%)	0.511 (0.309; 0.843)
Concomitant Disease: Hypertension arterial			
No	318 (84.1%)	43106 (73.0%)	1.000
Yes	60 (15.9%)	15928 (27.0%)	0.511 (0.387; 0.673)
Concomitant Disease: Diabetes mellitus			
No	352 (93.1%)	53147 (90.0%)	1.000
Yes	26 (6.9%)	5887 (10.0%)	0.667 (0.447; 0.994)
Concomitant Disease: Reduced general condition			
No	362 (95.8%)	54575 (92.4%)	1.000
Yes	16 (4.2%)	4459 (7.6%)	0.541 (0.328; 0.893)
Concomitant Disease: Allergy			
No	353 (93.4%)	57758 (97.8%)	1.000
Yes	25 (6.6%)	1276 (2.2%)	3.206 (2.129; 4.828)
Concomitant Disease: Asthma bronchial			
No	374 (98.9%)	58451 (99.0%)	1.000
Yes	4 (1.1%)	583 (1.0%)	1.072 (0.399; 2.882)
Concomitant Disease: Contrast media reaction			
No	372 (98.4%)	58813 (99.6%)	1.000
Yes	6 (1.6%)	221 (0.4%)	4.295 (1.897; 9.723)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.4 / 2: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for race)

	Cases (N=378)	Controls (N=59034)	Odds Ratio (95% CI)
Concomitant Disease: Other			
No	297 (78.6%)	46927 (79.5%)	1.000
Yes	81 (21.4%)	12107 (20.5%)	1.057 (0.826; 1.353)
Specific CM risk factor			
No	202 (53.4%)	25578 (43.3%)	1.000
Yes	176 (46.6%)	33456 (56.7%)	0.666 (0.544; 0.816)
Pre-medication Flag			
No	312 (82.5%)	47557 (80.6%)	1.000
Yes	66 (17.5%)	11477 (19.4%)	0.877 (0.672; 1.144)
Contrast medium dose			
<100 ml	240 (63.5%)	29726 (50.4%)	1.000
100 - <150 ml	127 (33.6%)	21857 (37.0%)	0.720 (0.580; 0.893)
150 - <200 ml	6 (1.6%)	3262 (5.5%)	0.228 (0.101; 0.513)
200 - <300 ml	3 (0.8%)	2993 (5.1%)	0.124 (0.040; 0.388)
≥300 ml	1 (0.3%)	1127 (1.9%)	0.110 (0.016; 0.784)
Not specified	1 (0.3%)	69 (0.1%)	1.795 (0.248; 12.978)
Dose of iodine in CM			
≤20 g	59 (15.6%)	9792 (16.6%)	1.000
>20 - 40 g	275 (72.8%)	37845 (64.1%)	1.206 (0.910; 1.599)
>40 - 60 g	39 (10.3%)	6621 (11.2%)	0.978 (0.652; 1.467)
>60 g	4 (1.1%)	4707 (8.0%)	0.141 (0.051; 0.388)
Not specified	1 (0.3%)	69 (0.1%)	2.405 (0.329; 17.607)
Ultravist concentration			
Ultravist - 300	197 (52.1%)	24339 (41.2%)	1.000
Ultravist - 370	181 (47.9%)	34695 (58.8%)	0.645 (0.526; 0.789)

CM = Contrast media.

Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.4 / 3: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for geographical region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Sex			
Male	442 (48.8%)	80374 (55.1%)	1.000
Female	461 (50.9%)	63756 (43.7%)	1.315 (1.154; 1.499)
missing	2 (0.2%)	1614 (1.1%)	-
Race			
Asian	307 (33.9%)	49910 (34.2%)	0.871 (0.664; 1.143)
White	63 (7.0%)	8921 (6.1%)	1.000
Black	0	30 (<0.1%)	<0.001 (<0.001; -)
Other	8 (0.9%)	173 (0.1%)	6.548 (3.090; 13.874)
missing	527 (58.2%)	86710 (59.5%)	-
Country / geographical region category 1 (China vs. Germany)			
China	152 (16.8%)	36776 (25.2%)	0.802 (0.653; 0.984)
Germany	234 (25.9%)	45384 (31.1%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	152 (16.8%)	36776 (25.2%)	0.537 (0.418; 0.689)
Korea (South)	105 (11.6%)	13640 (9.4%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	152 (16.8%)	36776 (25.2%)	0.394 (0.322; 0.482)
rest of APAC	250 (27.6%)	23825 (16.3%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	152 (16.8%)	36776 (25.2%)	0.598 (0.502; 0.712)
rest of the world	753 (83.2%)	108968 (74.8%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	105 (11.6%)	13640 (9.4%)	0.541 (0.420; 0.696)
rest of APAC	145 (16.0%)	10185 (7.0%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	105 (11.6%)	13640 (9.4%)	1.272 (1.037; 1.560)
rest of the world	800 (88.4%)	132104 (90.6%)	1.000

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

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Table 14.4 / 3: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for geographical region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	234 (25.9%)	45384 (31.1%)	0.670 (0.532; 0.844)
Korea (South)	105 (11.6%)	13640 (9.4%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	234 (25.9%)	45384 (31.1%)	0.944 (0.762; 1.171)
rest of Europe	130 (14.4%)	23813 (16.3%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	234 (25.9%)	45384 (31.1%)	0.771 (0.664; 0.895)
rest of the world	671 (74.1%)	100360 (68.9%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	490 (54.1%)	69409 (47.6%)	1.000
Europe	364 (40.2%)	69197 (47.5%)	0.745 (0.650; 0.854)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	364 (40.2%)	69197 (47.5%)	1.000
China	152 (16.8%)	36776 (25.2%)	0.786 (0.650; 0.950)
Indonesia	15 (1.7%)	677 (0.5%)	4.212 (2.499; 7.098)
Iran	66 (7.3%)	5022 (3.4%)	2.498 (1.919; 3.252)
Jordan	9 (1.0%)	1659 (1.1%)	1.031 (0.531; 2.002)
Korea (South)	105 (11.6%)	13640 (9.4%)	1.463 (1.177; 1.820)
Malaysia	7 (0.8%)	856 (0.6%)	1.555 (0.734; 3.294)
Pakistan	4 (0.4%)	1394 (1.0%)	0.545 (0.203; 1.463)
Philippines	41 (4.5%)	4134 (2.8%)	1.885 (1.363; 2.608)
Saudi Arabia	9 (1.0%)	733 (0.5%)	2.334 (1.200; 4.540)
Singapore	52 (5.7%)	1605 (1.1%)	6.159 (4.587; 8.270)
Taiwan	13 (1.4%)	755 (0.5%)	3.273 (1.874; 5.718)
Thailand	16 (1.8%)	546 (0.4%)	5.571 (3.353; 9.255)
Vietnam	1 (0.1%)	1612 (1.1%)	0.118 (0.017; 0.840)

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Table 14.4 / 3: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for geographical region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Age group			
< 18	14 (1.5%)	3077 (2.1%)	1.213 (0.702; 2.096)
>= 18 and < 50	339 (37.5%)	37615 (25.8%)	2.403 (1.994; 2.896)
>= 50 and < 65	308 (34.0%)	50130 (34.4%)	1.638 (1.356; 1.980)
>= 65 years old	165 (18.2%)	44002 (30.2%)	1.000
Not specified	79 (8.7%)	10920 (7.5%)	1.929 (1.474; 2.525)
Contrast medium application			
Intravenous	844 (93.3%)	116499 (79.9%)	1.000
Intra-arterial	59 (6.5%)	28430 (19.5%)	0.286 (0.220; 0.373)
Other	1 (0.1%)	409 (0.3%)	0.337 (0.047; 2.404)
Not specified	1 (0.1%)	315 (0.2%)	0.438 (0.061; 3.124)
missing	0	91 (<0.1%)	-
Concomitant Disease: Coronary heart disease			
No	847 (93.6%)	133287 (91.5%)	1.000
Yes	58 (6.4%)	12457 (8.5%)	0.733 (0.562; 0.957)
Concomitant Disease: Hypertension arterial			
No	827 (91.4%)	128243 (88.0%)	1.000
Yes	78 (8.6%)	17501 (12.0%)	0.691 (0.548; 0.872)
Concomitant Disease: Diabetes mellitus			
No	829 (91.6%)	134432 (92.2%)	1.000
Yes	76 (8.4%)	11312 (7.8%)	1.089 (0.861; 1.379)
Concomitant Disease: Reduced general condition			
No	859 (94.9%)	138377 (94.9%)	1.000
Yes	46 (5.1%)	7367 (5.1%)	1.006 (0.747; 1.354)
Concomitant Disease: Allergy			
No	810 (89.5%)	141524 (97.1%)	1.000
Yes	95 (10.5%)	4220 (2.9%)	3.933 (3.173; 4.876)
Concomitant Disease: Asthma bronchial			
No	890 (98.3%)	144842 (99.4%)	1.000
Yes	15 (1.7%)	902 (0.6%)	2.707 (1.618; 4.528)

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions



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Table 14.4 / 3: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for geographical region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Concomitant Disease: Contrast media reaction			
No	880 (97.2%)	144965 (99.5%)	1.000
Yes	25 (2.8%)	779 (0.5%)	5.290 (3.533; 7.920)
Concomitant Disease: Other			
No	741 (81.9%)	124042 (85.1%)	1.000
Yes	164 (18.1%)	21702 (14.9%)	1.265 (1.068; 1.499)
Specific CM risk factor			
No	496 (54.8%)	88486 (60.7%)	1.000
Yes	409 (45.2%)	57258 (39.3%)	1.274 (1.118; 1.453)
Pre-medication Flag			
No	789 (87.2%)	127394 (87.4%)	1.000
Yes	116 (12.8%)	18350 (12.6%)	1.021 (0.840; 1.241)
Contrast medium dose			
<100 ml	412 (45.5%)	60486 (41.5%)	1.000
100 - <150 ml	410 (45.3%)	66750 (45.8%)	0.902 (0.786; 1.034)
150 - <200 ml	58 (6.4%)	11705 (8.0%)	0.727 (0.552; 0.958)
200 - <300 ml	14 (1.5%)	4547 (3.1%)	0.452 (0.265; 0.771)
>=300 ml	6 (0.7%)	1577 (1.1%)	0.559 (0.249; 1.252)
Not specified	5 (0.6%)	679 (0.5%)	1.081 (0.446; 2.620)
Dose of iodine in CM			
<=20 g	143 (15.8%)	24324 (16.7%)	1.000
>20 - 40 g	607 (67.1%)	94889 (65.1%)	1.088 (0.906; 1.306)
>40 - 60 g	133 (14.7%)	19416 (13.3%)	1.165 (0.919; 1.477)
>60 g	17 (1.9%)	6436 (4.4%)	0.450 (0.272; 0.744)
Not specified	5 (0.6%)	679 (0.5%)	1.253 (0.512; 3.065)

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Table 14.4 / 3: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for geographical region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Ultravist concentration			
Ultravist - 300	619 (68.4%)	93910 (64.4%)	1.000
Ultravist - 370	286 (31.6%)	51834 (35.6%)	0.837 (0.727; 0.963)

CM = Contrast media.
Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.
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Table 14.4 / 4: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for country/region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Sex			
Male	442 (48.8%)	80374 (55.1%)	1.000
Female	461 (50.9%)	63756 (43.7%)	1.315 (1.154; 1.499)
missing	2 (0.2%)	1614 (1.1%)	-
Race			
Asian	307 (33.9%)	49910 (34.2%)	0.871 (0.664; 1.143)
White	63 (7.0%)	8921 (6.1%)	1.000
Black	0	30 (<0.1%)	<0.001 (<0.001; -)
Other	8 (0.9%)	173 (0.1%)	6.548 (3.090; 13.874)
missing	527 (58.2%)	86710 (59.5%)	-
Country / geographical region category 1 (China vs. Germany)			
China	152 (16.8%)	36776 (25.2%)	0.802 (0.653; 0.984)
Germany	234 (25.9%)	45384 (31.1%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	152 (16.8%)	36776 (25.2%)	0.537 (0.418; 0.689)
Korea (South)	105 (11.6%)	13640 (9.4%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	152 (16.8%)	36776 (25.2%)	0.394 (0.322; 0.482)
rest of APAC	250 (27.6%)	23825 (16.3%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	152 (16.8%)	36776 (25.2%)	0.598 (0.502; 0.712)
rest of the world	753 (83.2%)	108968 (74.8%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	105 (11.6%)	13640 (9.4%)	0.541 (0.420; 0.696)
rest of APAC	145 (16.0%)	10185 (7.0%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	105 (11.6%)	13640 (9.4%)	1.272 (1.037; 1.560)
rest of the world	800 (88.4%)	132104 (90.6%)	1.000

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Table 14.4 / 4: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for country/region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	234 (25.9%)	45384 (31.1%)	0.670 (0.532; 0.844)
Korea (South)	105 (11.6%)	13640 (9.4%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	234 (25.9%)	45384 (31.1%)	0.944 (0.762; 1.171)
rest of Europe	130 (14.4%)	23813 (16.3%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	234 (25.9%)	45384 (31.1%)	0.771 (0.664; 0.895)
rest of the world	671 (74.1%)	100360 (68.9%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	490 (54.1%)	69409 (47.6%)	1.000
Europe	364 (40.2%)	69197 (47.5%)	0.745 (0.650; 0.854)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	364 (40.2%)	69197 (47.5%)	1.000
China	152 (16.8%)	36776 (25.2%)	0.786 (0.650; 0.950)
Indonesia	15 (1.7%)	677 (0.5%)	4.212 (2.499; 7.098)
Iran	66 (7.3%)	5022 (3.4%)	2.498 (1.919; 3.252)
Jordan	9 (1.0%)	1659 (1.1%)	1.031 (0.531; 2.002)
Korea (South)	105 (11.6%)	13640 (9.4%)	1.463 (1.177; 1.820)
Malaysia	7 (0.8%)	856 (0.6%)	1.555 (0.734; 3.294)
Pakistan	4 (0.4%)	1394 (1.0%)	0.545 (0.203; 1.463)
Philippines	41 (4.5%)	4134 (2.8%)	1.885 (1.363; 2.608)
Saudi Arabia	9 (1.0%)	733 (0.5%)	2.334 (1.200; 4.540)
Singapore	52 (5.7%)	1605 (1.1%)	6.159 (4.587; 8.270)
Taiwan	13 (1.4%)	755 (0.5%)	3.273 (1.874; 5.718)
Thailand	16 (1.8%)	546 (0.4%)	5.571 (3.353; 9.255)
Vietnam	1 (0.1%)	1612 (1.1%)	0.118 (0.017; 0.840)

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Table 14.4 / 4: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for country/region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Age group			
< 18	14 (1.5%)	3077 (2.1%)	1.213 (0.702; 2.096)
>= 18 and < 50	339 (37.5%)	37615 (25.8%)	2.403 (1.994; 2.896)
>= 50 and < 65	308 (34.0%)	50130 (34.4%)	1.638 (1.356; 1.980)
>= 65 years old	165 (18.2%)	44002 (30.2%)	1.000
Not specified	79 (8.7%)	10920 (7.5%)	1.929 (1.474; 2.525)
Contrast medium application			
Intravenous	844 (93.3%)	116499 (79.9%)	1.000
Intra-arterial	59 (6.5%)	28430 (19.5%)	0.286 (0.220; 0.373)
Other	1 (0.1%)	409 (0.3%)	0.337 (0.047; 2.404)
Not specified	1 (0.1%)	315 (0.2%)	0.438 (0.061; 3.124)
missing	0	91 (<0.1%)	-
Concomitant Disease: Coronary heart disease			
No	847 (93.6%)	133287 (91.5%)	1.000
Yes	58 (6.4%)	12457 (8.5%)	0.733 (0.562; 0.957)
Concomitant Disease: Hypertension arterial			
No	827 (91.4%)	128243 (88.0%)	1.000
Yes	78 (8.6%)	17501 (12.0%)	0.691 (0.548; 0.872)
Concomitant Disease: Diabetes mellitus			
No	829 (91.6%)	134432 (92.2%)	1.000
Yes	76 (8.4%)	11312 (7.8%)	1.089 (0.861; 1.379)
Concomitant Disease: Reduced general condition			
No	859 (94.9%)	138377 (94.9%)	1.000
Yes	46 (5.1%)	7367 (5.1%)	1.006 (0.747; 1.354)
Concomitant Disease: Allergy			
No	810 (89.5%)	141524 (97.1%)	1.000
Yes	95 (10.5%)	4220 (2.9%)	3.933 (3.173; 4.876)
Concomitant Disease: Asthma bronchial			
No	890 (98.3%)	144842 (99.4%)	1.000
Yes	15 (1.7%)	902 (0.6%)	2.707 (1.618; 4.528)

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Table 14.4 / 4: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for country/region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Concomitant Disease: Contrast media reaction			
No	880 (97.2%)	144965 (99.5%)	1.000
Yes	25 (2.8%)	779 (0.5%)	5.290 (3.533; 7.920)
Concomitant Disease: Other			
No	741 (81.9%)	124042 (85.1%)	1.000
Yes	164 (18.1%)	21702 (14.9%)	1.265 (1.068; 1.499)
Specific CM risk factor			
No	496 (54.8%)	88486 (60.7%)	1.000
Yes	409 (45.2%)	57258 (39.3%)	1.274 (1.118; 1.453)
Pre-medication Flag			
No	789 (87.2%)	127394 (87.4%)	1.000
Yes	116 (12.8%)	18350 (12.6%)	1.021 (0.840; 1.241)
Contrast medium dose			
<100 ml	412 (45.5%)	60486 (41.5%)	1.000
100 - <150 ml	410 (45.3%)	66750 (45.8%)	0.902 (0.786; 1.034)
150 - <200 ml	58 (6.4%)	11705 (8.0%)	0.727 (0.552; 0.958)
200 - <300 ml	14 (1.5%)	4547 (3.1%)	0.452 (0.265; 0.771)
>=300 ml	6 (0.7%)	1577 (1.1%)	0.559 (0.249; 1.252)
Not specified	5 (0.6%)	679 (0.5%)	1.081 (0.446; 2.620)
Dose of iodine in CM			
<=20 g	143 (15.8%)	24324 (16.7%)	1.000
>20 - 40 g	607 (67.1%)	94889 (65.1%)	1.088 (0.906; 1.306)
>40 - 60 g	133 (14.7%)	19416 (13.3%)	1.165 (0.919; 1.477)
>60 g	17 (1.9%)	6436 (4.4%)	0.450 (0.272; 0.744)
Not specified	5 (0.6%)	679 (0.5%)	1.253 (0.512; 3.065)

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Table 14.4 / 4: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Full analysis set for country/region)

	Cases (N=905)	Controls (N=145744)	Odds Ratio (95% CI)
Ultravist concentration			
Ultravist - 300	619 (68.4%)	93910 (64.4%)	1.000
Ultravist - 370	286 (31.6%)	51834 (35.6%)	0.837 (0.727; 0.963)

CM = Contrast media.
Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.
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Table 14.4 / 5: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for sex)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Sex			
Male	411 (50.2%)	74575 (56.5%)	1.000
Female	407 (49.8%)	57457 (43.5%)	1.285 (1.120; 1.475)
Race			
Asian	301 (36.8%)	49320 (37.4%)	0.780 (0.574; 1.059)
White	48 (5.9%)	6134 (4.6%)	1.000
Black	0	24 (<0.1%)	<0.001 (<0.001; -)
Other	8 (1.0%)	156 (0.1%)	6.553 (3.049; 14.085)
missing	461 (56.4%)	76398 (57.9%)	-
Country / geographical region category 1 (China vs. Germany)			
China	151 (18.5%)	36636 (27.7%)	0.785 (0.637; 0.967)
Germany	213 (26.0%)	40553 (30.7%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	151 (18.5%)	36636 (27.7%)	0.535 (0.417; 0.687)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	151 (18.5%)	36636 (27.7%)	0.399 (0.326; 0.489)
rest of APAC	242 (29.6%)	23437 (17.8%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	151 (18.5%)	36636 (27.7%)	0.589 (0.494; 0.704)
rest of the world	667 (81.5%)	95396 (72.3%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	105 (12.8%)	13626 (10.3%)	0.552 (0.427; 0.713)
rest of APAC	137 (16.7%)	9811 (7.4%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	105 (12.8%)	13626 (10.3%)	1.280 (1.042; 1.572)
rest of the world	713 (87.2%)	118406 (89.7%)	1.000

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Table 14.4 / 5: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for sex)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	213 (26.0%)	40553 (30.7%)	0.682 (0.539; 0.862)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	213 (26.0%)	40553 (30.7%)	0.931 (0.747; 1.160)
rest of Europe	128 (15.6%)	22686 (17.2%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	213 (26.0%)	40553 (30.7%)	0.794 (0.679; 0.929)
rest of the world	605 (74.0%)	91479 (69.3%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	477 (58.3%)	68406 (51.8%)	1.000
Europe	341 (41.7%)	63239 (47.9%)	0.773 (0.673; 0.889)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	341 (41.7%)	63239 (47.9%)	1.000
China	151 (18.5%)	36636 (27.7%)	0.764 (0.631; 0.926)
Indonesia	15 (1.8%)	641 (0.5%)	4.340 (2.573; 7.321)
Iran	66 (8.1%)	4946 (3.7%)	2.475 (1.898; 3.226)
Jordan	8 (1.0%)	1564 (1.2%)	0.949 (0.470; 1.916)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.429 (1.147; 1.780)
Malaysia	7 (0.9%)	852 (0.6%)	1.524 (0.719; 3.230)
Pakistan	2 (0.2%)	1151 (0.9%)	0.322 (0.080; 1.295)
Philippines	35 (4.3%)	3952 (3.0%)	1.642 (1.158; 2.329)
Saudi Arabia	8 (1.0%)	672 (0.5%)	2.208 (1.091; 4.469)
Singapore	52 (6.4%)	1587 (1.2%)	6.077 (4.520; 8.170)
Taiwan	13 (1.6%)	750 (0.6%)	3.214 (1.839; 5.619)
Thailand	15 (1.8%)	523 (0.4%)	5.319 (3.149; 8.984)
Vietnam	0	1506 (1.1%)	<0.001 (<0.001; >999.999)
Age group			
< 18	14 (1.7%)	2964 (2.2%)	1.240 (0.717; 2.142)
>= 18 and < 50	335 (41.0%)	36886 (27.9%)	2.384 (1.977; 2.875)
>= 50 and < 65	305 (37.3%)	49137 (37.2%)	1.629 (1.347; 1.971)
>= 65 years old	164 (20.0%)	43045 (32.6%)	1.000

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Table 14.4 / 5: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for sex)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Contrast medium application			
Intravenous	762 (93.2%)	104257 (79.0%)	1.000
Intra-arterial	56 (6.8%)	27775 (21.0%)	0.276 (0.210; 0.362)
Concomitant Disease: Coronary heart disease			
No	769 (94.0%)	120838 (91.5%)	1.000
Yes	49 (6.0%)	11194 (8.5%)	0.688 (0.515; 0.919)
Concomitant Disease: Hypertension arterial			
No	744 (91.0%)	115387 (87.4%)	1.000
Yes	74 (9.0%)	16645 (12.6%)	0.689 (0.543; 0.876)
Concomitant Disease: Diabetes mellitus			
No	750 (91.7%)	121716 (92.2%)	1.000
Yes	68 (8.3%)	10316 (7.8%)	1.070 (0.834; 1.372)
Concomitant Disease: Reduced general condition			
No	773 (94.5%)	125145 (94.8%)	1.000
Yes	45 (5.5%)	6887 (5.2%)	1.058 (0.782; 1.430)
Concomitant Disease: Allergy			
No	736 (90.0%)	128555 (97.4%)	1.000
Yes	82 (10.0%)	3477 (2.6%)	4.119 (3.271; 5.188)
Concomitant Disease: Asthma bronchial			
No	803 (98.2%)	131227 (99.4%)	1.000
Yes	15 (1.8%)	805 (0.6%)	3.045 (1.819; 5.099)
Concomitant Disease: Contrast media reaction			
No	796 (97.3%)	131337 (99.5%)	1.000
Yes	22 (2.7%)	695 (0.5%)	5.225 (3.399; 8.033)
Concomitant Disease: Other			
No	666 (81.4%)	112850 (85.5%)	1.000
Yes	152 (18.6%)	19182 (14.5%)	1.343 (1.126; 1.603)

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Table 14.4 / 5: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for sex)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Specific CM risk factor			
No	446 (54.5%)	80085 (60.7%)	1.000
Yes	372 (45.5%)	51947 (39.3%)	1.286 (1.120; 1.476)
Pre-medication Flag			
No	715 (87.4%)	114482 (86.7%)	1.000
Yes	103 (12.6%)	17550 (13.3%)	0.940 (0.764; 1.156)
Contrast medium dose			
<100 ml	395 (48.3%)	56565 (42.8%)	1.000
100 - <150 ml	359 (43.9%)	59657 (45.2%)	0.862 (0.747; 0.995)
150 - <200 ml	45 (5.5%)	9968 (7.5%)	0.646 (0.475; 0.881)
200 - <300 ml	13 (1.6%)	4332 (3.3%)	0.430 (0.247; 0.747)
>=300 ml	6 (0.7%)	1510 (1.1%)	0.569 (0.254; 1.276)
Dose of iodine in CM			
<=20 g	133 (16.3%)	22684 (17.2%)	1.000
>20 - 40 g	561 (68.6%)	86653 (65.6%)	1.104 (0.914; 1.335)
>40 - 60 g	108 (13.2%)	16555 (12.5%)	1.113 (0.863; 1.435)
>60 g	16 (2.0%)	6140 (4.7%)	0.445 (0.265; 0.747)
Ultravist concentration			
Ultravist - 300	549 (67.1%)	84020 (63.6%)	1.000
Ultravist - 370	269 (32.9%)	48012 (36.4%)	0.857 (0.741; 0.993)

CM = Contrast media.

Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.

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Table 14.4 / 6: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for race)

	Cases (N=357)	Controls (N=55634)	Odds Ratio (95% CI)
Sex			
Male	183 (51.3%)	33568 (60.3%)	1.000
Female	174 (48.7%)	22066 (39.7%)	1.447 (1.175; 1.782)
Race			
Asian	301 (84.3%)	49320 (88.7%)	0.780 (0.574; 1.059)
White	48 (13.4%)	6134 (11.0%)	1.000
Black	0	24 (<0.1%)	<0.001 (<0.001; -)
Other	8 (2.2%)	156 (0.3%)	6.553 (3.049; 14.085)
Country / geographical region category 1 (China vs. Germany)			
China	151 (42.3%)	36623 (65.8%)	>999.999 (<0.001; -)
Germany	0	26 (<0.1%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	151 (42.3%)	36623 (65.8%)	0.400 (0.281; 0.569)
Korea (South)	39 (10.9%)	3782 (6.8%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	151 (42.3%)	36623 (65.8%)	0.329 (0.261; 0.413)
rest of APAC	144 (40.3%)	11473 (20.6%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	151 (42.3%)	36623 (65.8%)	0.380 (0.308; 0.470)
rest of the world	206 (57.7%)	19011 (34.2%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	39 (10.9%)	3782 (6.8%)	0.755 (0.522; 1.093)
rest of APAC	105 (29.4%)	7691 (13.8%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	39 (10.9%)	3782 (6.8%)	1.681 (1.204; 2.349)
rest of the world	318 (89.1%)	51852 (93.2%)	1.000

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Table 14.4 / 6: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for race)

	Cases (N=357)	Controls (N=55634)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	0	26 (<0.1%)	<0.001 (<0.001; -)
Korea (South)	39 (10.9%)	3782 (6.8%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	0	26 (<0.1%)	<0.001 (<0.001; -)
rest of Europe	48 (13.4%)	6112 (11.0%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	0	26 (<0.1%)	<0.001 (<0.001; -)
rest of the world	357 (100.0%)	55608 (>99.9%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	309 (86.6%)	49496 (89.0%)	1.000
Europe	48 (13.4%)	6138 (11.0%)	1.253 (0.923; 1.700)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	48 (13.4%)	6138 (11.0%)	1.000
China	151 (42.3%)	36623 (65.8%)	0.527 (0.381; 0.730)
Indonesia	15 (4.2%)	641 (1.2%)	2.992 (1.666; 5.374)
Iran	8 (2.2%)	136 (0.2%)	7.522 (3.491; 16.206)
Korea (South)	39 (10.9%)	3782 (6.8%)	1.319 (0.863; 2.016)
Malaysia	7 (2.0%)	851 (1.5%)	1.052 (0.474; 2.332)
Pakistan	2 (0.6%)	1092 (2.0%)	0.234 (0.057; 0.965)
Philippines	17 (4.8%)	2314 (4.2%)	0.939 (0.539; 1.637)
Saudi Arabia	4 (1.1%)	172 (0.3%)	2.974 (1.060; 8.340)
Singapore	52 (14.6%)	1575 (2.8%)	4.222 (2.841; 6.274)
Taiwan	10 (2.8%)	560 (1.0%)	2.283 (1.149; 4.538)
Thailand	4 (1.1%)	245 (0.4%)	2.088 (0.747; 5.836)
Vietnam	0	1505 (2.7%)	<0.001 (<0.001; -)
Age group			
< 18	9 (2.5%)	1043 (1.9%)	2.421 (1.195; 4.904)
>= 18 and < 50	147 (41.2%)	15290 (27.5%)	2.698 (1.985; 3.666)
>= 50 and < 65	144 (40.3%)	23306 (41.9%)	1.734 (1.275; 2.358)
>= 65 years old	57 (16.0%)	15995 (28.8%)	1.000

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Table 14.4 / 6: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for race)

	Cases (N=357)	Controls (N=55634)	Odds Ratio (95% CI)
Contrast medium application			
Intravenous	331 (92.7%)	35404 (63.6%)	1.000
Intra-arterial	26 (7.3%)	20230 (36.4%)	0.138 (0.092; 0.205)
Concomitant Disease: Coronary heart disease			
No	341 (95.5%)	51188 (92.0%)	1.000
Yes	16 (4.5%)	4446 (8.0%)	0.540 (0.327; 0.893)
Concomitant Disease: Hypertension arterial			
No	301 (84.3%)	40483 (72.8%)	1.000
Yes	56 (15.7%)	15151 (27.2%)	0.497 (0.374; 0.662)
Concomitant Disease: Diabetes mellitus			
No	332 (93.0%)	50054 (90.0%)	1.000
Yes	25 (7.0%)	5580 (10.0%)	0.675 (0.449; 1.015)
Concomitant Disease: Reduced general condition			
No	341 (95.5%)	51361 (92.3%)	1.000
Yes	16 (4.5%)	4273 (7.7%)	0.564 (0.341; 0.932)
Concomitant Disease: Allergy			
No	335 (93.8%)	54469 (97.9%)	1.000
Yes	22 (6.2%)	1165 (2.1%)	3.071 (1.987; 4.746)
Concomitant Disease: Asthma bronchial			
No	353 (98.9%)	55133 (99.1%)	1.000
Yes	4 (1.1%)	501 (0.9%)	1.247 (0.464; 3.355)
Concomitant Disease: Contrast media reaction			
No	351 (98.3%)	55428 (99.6%)	1.000
Yes	6 (1.7%)	206 (0.4%)	4.606 (2.033; 10.436)
Concomitant Disease: Other			
No	280 (78.4%)	44348 (79.7%)	1.000
Yes	77 (21.6%)	11286 (20.3%)	1.081 (0.839; 1.392)

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Table 14.4 / 6: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for race)

	Cases (N=357)	Controls (N=55634)	Odds Ratio (95% CI)
Specific CM risk factor			
No	189 (52.9%)	24054 (43.2%)	1.000
Yes	168 (47.1%)	31580 (56.8%)	0.677 (0.550; 0.834)
Pre-medication Flag			
No	292 (81.8%)	44330 (79.7%)	1.000
Yes	65 (18.2%)	11304 (20.3%)	0.873 (0.667; 1.143)
Contrast medium dose			
<100 ml	233 (65.3%)	28191 (50.7%)	1.000
100 - <150 ml	114 (31.9%)	20216 (36.3%)	0.682 (0.545; 0.854)
150 - <200 ml	6 (1.7%)	3190 (5.7%)	0.228 (0.101; 0.512)
200 - <300 ml	3 (0.8%)	2933 (5.3%)	0.124 (0.040; 0.387)
>=300 ml	1 (0.3%)	1104 (2.0%)	0.110 (0.015; 0.782)
Dose of iodine in CM			
<=20 g	57 (16.0%)	9112 (16.4%)	1.000
>20 - 40 g	257 (72.0%)	35398 (63.6%)	1.161 (0.870; 1.548)
>40 - 60 g	39 (10.9%)	6501 (11.7%)	0.959 (0.637; 1.443)
>60 g	4 (1.1%)	4623 (8.3%)	0.138 (0.050; 0.381)
Ultravist concentration			
Ultravist - 300	181 (50.7%)	22030 (39.6%)	1.000
Ultravist - 370	176 (49.3%)	33604 (60.4%)	0.637 (0.518; 0.785)

CM = Contrast media.

Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.

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Table 14.4 / 7: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for geographical region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Sex			
Male	411 (50.2%)	74575 (56.5%)	1.000
Female	407 (49.8%)	57457 (43.5%)	1.285 (1.120; 1.475)
Race			
Asian	301 (36.8%)	49320 (37.4%)	0.780 (0.574; 1.059)
White	48 (5.9%)	6134 (4.6%)	1.000
Black	0	24 (<0.1%)	<0.001 (<0.001; -)
Other	8 (1.0%)	156 (0.1%)	6.553 (3.049; 14.085)
missing	461 (56.4%)	76398 (57.9%)	-
Country / geographical region category 1 (China vs. Germany)			
China	151 (18.5%)	36636 (27.7%)	0.785 (0.637; 0.967)
Germany	213 (26.0%)	40553 (30.7%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	151 (18.5%)	36636 (27.7%)	0.535 (0.417; 0.687)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	151 (18.5%)	36636 (27.7%)	0.399 (0.326; 0.489)
rest of APAC	242 (29.6%)	23437 (17.8%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	151 (18.5%)	36636 (27.7%)	0.589 (0.494; 0.704)
rest of the world	667 (81.5%)	95396 (72.3%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	105 (12.8%)	13626 (10.3%)	0.552 (0.427; 0.713)
rest of APAC	137 (16.7%)	9811 (7.4%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	105 (12.8%)	13626 (10.3%)	1.280 (1.042; 1.572)
rest of the world	713 (87.2%)	118406 (89.7%)	1.000

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Table 14.4 / 7: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for geographical region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	213 (26.0%)	40553 (30.7%)	0.682 (0.539; 0.862)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	213 (26.0%)	40553 (30.7%)	0.931 (0.747; 1.160)
rest of Europe	128 (15.6%)	22686 (17.2%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	213 (26.0%)	40553 (30.7%)	0.794 (0.679; 0.929)
rest of the world	605 (74.0%)	91479 (69.3%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	477 (58.3%)	68406 (51.8%)	1.000
Europe	341 (41.7%)	63239 (47.9%)	0.773 (0.673; 0.889)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	341 (41.7%)	63239 (47.9%)	1.000
China	151 (18.5%)	36636 (27.7%)	0.764 (0.631; 0.926)
Indonesia	15 (1.8%)	641 (0.5%)	4.340 (2.573; 7.321)
Iran	66 (8.1%)	4946 (3.7%)	2.475 (1.898; 3.226)
Jordan	8 (1.0%)	1564 (1.2%)	0.949 (0.470; 1.916)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.429 (1.147; 1.780)
Malaysia	7 (0.9%)	852 (0.6%)	1.524 (0.719; 3.230)
Pakistan	2 (0.2%)	1151 (0.9%)	0.322 (0.080; 1.295)
Philippines	35 (4.3%)	3952 (3.0%)	1.642 (1.158; 2.329)
Saudi Arabia	8 (1.0%)	672 (0.5%)	2.208 (1.091; 4.469)
Singapore	52 (6.4%)	1587 (1.2%)	6.077 (4.520; 8.170)
Taiwan	13 (1.6%)	750 (0.6%)	3.214 (1.839; 5.619)
Thailand	15 (1.8%)	523 (0.4%)	5.319 (3.149; 8.984)
Vietnam	0	1506 (1.1%)	<0.001 (<0.001; >999.999)
Age group			
< 18	14 (1.7%)	2964 (2.2%)	1.240 (0.717; 2.142)
>= 18 and < 50	335 (41.0%)	36886 (27.9%)	2.384 (1.977; 2.875)
>= 50 and < 65	305 (37.3%)	49137 (37.2%)	1.629 (1.347; 1.971)
>= 65 years old	164 (20.0%)	43045 (32.6%)	1.000

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Table 14.4 / 7: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for geographical region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Contrast medium application			
Intravenous	762 (93.2%)	104257 (79.0%)	1.000
Intra-arterial	56 (6.8%)	27775 (21.0%)	0.276 (0.210; 0.362)
Concomitant Disease: Coronary heart disease			
No	769 (94.0%)	120838 (91.5%)	1.000
Yes	49 (6.0%)	11194 (8.5%)	0.688 (0.515; 0.919)
Concomitant Disease: Hypertension arterial			
No	744 (91.0%)	115387 (87.4%)	1.000
Yes	74 (9.0%)	16645 (12.6%)	0.689 (0.543; 0.876)
Concomitant Disease: Diabetes mellitus			
No	750 (91.7%)	121716 (92.2%)	1.000
Yes	68 (8.3%)	10316 (7.8%)	1.070 (0.834; 1.372)
Concomitant Disease: Reduced general condition			
No	773 (94.5%)	125145 (94.8%)	1.000
Yes	45 (5.5%)	6887 (5.2%)	1.058 (0.782; 1.430)
Concomitant Disease: Allergy			
No	736 (90.0%)	128555 (97.4%)	1.000
Yes	82 (10.0%)	3477 (2.6%)	4.119 (3.271; 5.188)
Concomitant Disease: Asthma bronchial			
No	803 (98.2%)	131227 (99.4%)	1.000
Yes	15 (1.8%)	805 (0.6%)	3.045 (1.819; 5.099)
Concomitant Disease: Contrast media reaction			
No	796 (97.3%)	131337 (99.5%)	1.000
Yes	22 (2.7%)	695 (0.5%)	5.225 (3.399; 8.033)
Concomitant Disease: Other			
No	666 (81.4%)	112850 (85.5%)	1.000
Yes	152 (18.6%)	19182 (14.5%)	1.343 (1.126; 1.603)

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Table 14.4 / 7: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for geographical region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Specific CM risk factor			
No	446 (54.5%)	80085 (60.7%)	1.000
Yes	372 (45.5%)	51947 (39.3%)	1.286 (1.120; 1.476)
Pre-medication Flag			
No	715 (87.4%)	114482 (86.7%)	1.000
Yes	103 (12.6%)	17550 (13.3%)	0.940 (0.764; 1.156)
Contrast medium dose			
<100 ml	395 (48.3%)	56565 (42.8%)	1.000
100 - <150 ml	359 (43.9%)	59657 (45.2%)	0.862 (0.747; 0.995)
150 - <200 ml	45 (5.5%)	9968 (7.5%)	0.646 (0.475; 0.881)
200 - <300 ml	13 (1.6%)	4332 (3.3%)	0.430 (0.247; 0.747)
≥300 ml	6 (0.7%)	1510 (1.1%)	0.569 (0.254; 1.276)
Dose of iodine in CM			
≤20 g	133 (16.3%)	22684 (17.2%)	1.000
>20 - 40 g	561 (68.6%)	86653 (65.6%)	1.104 (0.914; 1.335)
>40 - 60 g	108 (13.2%)	16555 (12.5%)	1.113 (0.863; 1.435)
>60 g	16 (2.0%)	6140 (4.7%)	0.445 (0.265; 0.747)
Ultravist concentration			
Ultravist - 300	549 (67.1%)	84020 (63.6%)	1.000
Ultravist - 370	269 (32.9%)	48012 (36.4%)	0.857 (0.741; 0.993)

CM = Contrast media.

Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.

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Table 14.4 / 8: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for country/region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Sex			
Male	411 (50.2%)	74575 (56.5%)	1.000
Female	407 (49.8%)	57457 (43.5%)	1.285 (1.120; 1.475)
Race			
Asian	301 (36.8%)	49320 (37.4%)	0.780 (0.574; 1.059)
White	48 (5.9%)	6134 (4.6%)	1.000
Black	0	24 (<0.1%)	<0.001 (<0.001; -)
Other	8 (1.0%)	156 (0.1%)	6.553 (3.049; 14.085)
missing	461 (56.4%)	76398 (57.9%)	-
Country / geographical region category 1 (China vs. Germany)			
China	151 (18.5%)	36636 (27.7%)	0.785 (0.637; 0.967)
Germany	213 (26.0%)	40553 (30.7%)	1.000
Country / geographical region category 2 (China vs. South Korea)			
China	151 (18.5%)	36636 (27.7%)	0.535 (0.417; 0.687)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.000
Country / geographical region category 3 (China vs. rest of APAC)			
China	151 (18.5%)	36636 (27.7%)	0.399 (0.326; 0.489)
rest of APAC	242 (29.6%)	23437 (17.8%)	1.000
Country / geographical region category 4 (China vs. rest of the world)			
China	151 (18.5%)	36636 (27.7%)	0.589 (0.494; 0.704)
rest of the world	667 (81.5%)	95396 (72.3%)	1.000
Country / geographical region category 5 (South Korea vs. rest of APAC)			
Korea (South)	105 (12.8%)	13626 (10.3%)	0.552 (0.427; 0.713)
rest of APAC	137 (16.7%)	9811 (7.4%)	1.000
Country / geographical region category 6 (South Korea vs. rest of the world)			
Korea (South)	105 (12.8%)	13626 (10.3%)	1.280 (1.042; 1.572)
rest of the world	713 (87.2%)	118406 (89.7%)	1.000

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Table 14.4 / 8: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for country/region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Country / geographical region category 7 (Germany vs. South Korea)			
Germany	213 (26.0%)	40553 (30.7%)	0.682 (0.539; 0.862)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.000
Country / geographical region category 8 (Germany vs. rest of Europe)			
Germany	213 (26.0%)	40553 (30.7%)	0.931 (0.747; 1.160)
rest of Europe	128 (15.6%)	22686 (17.2%)	1.000
Country / geographical region category 9 (Germany vs. rest of the world)			
Germany	213 (26.0%)	40553 (30.7%)	0.794 (0.679; 0.929)
rest of the world	605 (74.0%)	91479 (69.3%)	1.000
Country / geographical region category 10 (Europe vs. Asia)			
Asia	477 (58.3%)	68406 (51.8%)	1.000
Europe	341 (41.7%)	63239 (47.9%)	0.773 (0.673; 0.889)
Country/Region (Asian Countries/Regions vs. Europe)			
Europe	341 (41.7%)	63239 (47.9%)	1.000
China	151 (18.5%)	36636 (27.7%)	0.764 (0.631; 0.926)
Indonesia	15 (1.8%)	641 (0.5%)	4.340 (2.573; 7.321)
Iran	66 (8.1%)	4946 (3.7%)	2.475 (1.898; 3.226)
Jordan	8 (1.0%)	1564 (1.2%)	0.949 (0.470; 1.916)
Korea (South)	105 (12.8%)	13626 (10.3%)	1.429 (1.147; 1.780)
Malaysia	7 (0.9%)	852 (0.6%)	1.524 (0.719; 3.230)
Pakistan	2 (0.2%)	1151 (0.9%)	0.322 (0.080; 1.295)
Philippines	35 (4.3%)	3952 (3.0%)	1.642 (1.158; 2.329)
Saudi Arabia	8 (1.0%)	672 (0.5%)	2.208 (1.091; 4.469)
Singapore	52 (6.4%)	1587 (1.2%)	6.077 (4.520; 8.170)
Taiwan	13 (1.6%)	750 (0.6%)	3.214 (1.839; 5.619)
Thailand	15 (1.8%)	523 (0.4%)	5.319 (3.149; 8.984)
Vietnam	0	1506 (1.1%)	<0.001 (<0.001; >999.999)
Age group			
< 18	14 (1.7%)	2964 (2.2%)	1.240 (0.717; 2.142)
>= 18 and < 50	335 (41.0%)	36886 (27.9%)	2.384 (1.977; 2.875)
>= 50 and < 65	305 (37.3%)	49137 (37.2%)	1.629 (1.347; 1.971)
>= 65 years old	164 (20.0%)	43045 (32.6%)	1.000

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Table 14.4 / 8: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for country/region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Contrast medium application			
Intravenous	762 (93.2%)	104257 (79.0%)	1.000
Intra-arterial	56 (6.8%)	27775 (21.0%)	0.276 (0.210; 0.362)
Concomitant Disease: Coronary heart disease			
No	769 (94.0%)	120838 (91.5%)	1.000
Yes	49 (6.0%)	11194 (8.5%)	0.688 (0.515; 0.919)
Concomitant Disease: Hypertension arterial			
No	744 (91.0%)	115387 (87.4%)	1.000
Yes	74 (9.0%)	16645 (12.6%)	0.689 (0.543; 0.876)
Concomitant Disease: Diabetes mellitus			
No	750 (91.7%)	121716 (92.2%)	1.000
Yes	68 (8.3%)	10316 (7.8%)	1.070 (0.834; 1.372)
Concomitant Disease: Reduced general condition			
No	773 (94.5%)	125145 (94.8%)	1.000
Yes	45 (5.5%)	6887 (5.2%)	1.058 (0.782; 1.430)
Concomitant Disease: Allergy			
No	736 (90.0%)	128555 (97.4%)	1.000
Yes	82 (10.0%)	3477 (2.6%)	4.119 (3.271; 5.188)
Concomitant Disease: Asthma bronchial			
No	803 (98.2%)	131227 (99.4%)	1.000
Yes	15 (1.8%)	805 (0.6%)	3.045 (1.819; 5.099)
Concomitant Disease: Contrast media reaction			
No	796 (97.3%)	131337 (99.5%)	1.000
Yes	22 (2.7%)	695 (0.5%)	5.225 (3.399; 8.033)
Concomitant Disease: Other			
No	666 (81.4%)	112850 (85.5%)	1.000
Yes	152 (18.6%)	19182 (14.5%)	1.343 (1.126; 1.603)

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Table 14.4 / 8: Risk of hypersensitivity reactions. Distribution of covariates in cases and controls and unadjusted odds ratios (Complete cases analysis set for country/region)

	Cases (N=818)	Controls (N=132032)	Odds Ratio (95% CI)
Specific CM risk factor			
No	446 (54.5%)	80085 (60.7%)	1.000
Yes	372 (45.5%)	51947 (39.3%)	1.286 (1.120; 1.476)
Pre-medication Flag			
No	715 (87.4%)	114482 (86.7%)	1.000
Yes	103 (12.6%)	17550 (13.3%)	0.940 (0.764; 1.156)
Contrast medium dose			
<100 ml	395 (48.3%)	56565 (42.8%)	1.000
100 - <150 ml	359 (43.9%)	59657 (45.2%)	0.862 (0.747; 0.995)
150 - <200 ml	45 (5.5%)	9968 (7.5%)	0.646 (0.475; 0.881)
200 - <300 ml	13 (1.6%)	4332 (3.3%)	0.430 (0.247; 0.747)
≥300 ml	6 (0.7%)	1510 (1.1%)	0.569 (0.254; 1.276)
Dose of iodine in CM			
≤20 g	133 (16.3%)	22684 (17.2%)	1.000
>20 - 40 g	561 (68.6%)	86653 (65.6%)	1.104 (0.914; 1.335)
>40 - 60 g	108 (13.2%)	16555 (12.5%)	1.113 (0.863; 1.435)
>60 g	16 (2.0%)	6140 (4.7%)	0.445 (0.265; 0.747)
Ultravist concentration			
Ultravist - 300	549 (67.1%)	84020 (63.6%)	1.000
Ultravist - 370	269 (32.9%)	48012 (36.4%)	0.857 (0.741; 0.993)

CM = Contrast media.

Cases: Patients with a typical and unequivocal anaphylactoid, i.e. allergy-like reaction. Controls: Patients without any reported AE.

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Table 14.4 / 9: Summary and analysis of risk of hypersensitivity reactions. Model for sex without covariates. (Complete cases analysis set for sex)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Sex	Male	1.000	0.0004
	Female	1.280 (1.116; 1.469)	
Age group	< 18	1.236 (0.715; 2.136)	<.0001
	>= 18 and < 50	2.379 (1.973; 2.869)	
	>= 50 and < 65	1.638 (1.354; 1.981)	
	>= 65 years old	1.000	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including sex as fixed effect and age category as covariates.

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Table 14.4 / 10: Summary and analysis of risk of hypersensitivity reactions. Model for race without covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Race	Asian	0.769 (0.566; 1.045)	<.0001
	White	1.000	
	Black	<0.001 (<0.001; >999.999)	
	Other	5.486 (2.538; 11.858)	
Age group	< 18	2.338 (1.153; 4.739)	<.0001
	>= 18 and < 50	2.688 (1.977; 3.654)	
	>= 50 and < 65	1.745 (1.283; 2.374)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0009
	Female	1.423 (1.155; 1.753)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including race as fixed effect and age category and sex as covariates.

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Table 14.4 / 11: Summary and analysis of risk of hypersensitivity reactions. Model for race (Asian and White only) without covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Race (Asian & White only)	Asian	0.767 (0.564; 1.042)	0.0899
	White	1.000	
Age group	< 18	2.420 (1.192; 4.913)	<.0001
	>= 18 and < 50	2.794 (2.047; 3.815)	
	>= 50 and < 65	1.745 (1.277; 2.385)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0014
	Female	1.409 (1.141; 1.740)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including race (Asian and White only) as fixed effect and age category and sex as covariates.

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Table 14.4 / 12: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: APAC, Europe, Rest of the World) without covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	APAC	1.706 (1.445; 2.015)	<.0001
	Europe	1.000	
	Rest of the World	0.952 (0.805; 1.127)	
Age group	< 18	1.115 (0.645; 1.929)	<.0001
	>= 18 and < 50	2.248 (1.862; 2.715)	
	>= 50 and < 65	1.610 (1.330; 1.949)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0006
	Female	1.275 (1.111; 1.464)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (Levels: APAC, Europe, Rest of the World) as fixed effect and age category and sex as covariates.

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Table 14.4 / 13: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) without covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	Asia (excl. China)	1.761 (1.509; 2.054)	<.0001
	China	0.755 (0.622; 0.916)	
	Europe	1.000	
	Rest of the World	<0.001 (<0.001; >999.999)	
Age group	< 18	1.025 (0.592; 1.775)	<.0001
	>= 18 and < 50	2.174 (1.799; 2.627)	
	>= 50 and < 65	1.618 (1.337; 1.959)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0011
	Female	1.258 (1.096; 1.444)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) as fixed effect and age category and sex as covariates.

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Table 14.4 / 14: Summary and analysis of risk of hypersensitivity reactions. Model for country/region without covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (China, Germany, South Korea)	China	0.774 (0.626; 0.956)	<.0001
	Germany	1.000	
	South Korea	1.397 (1.104; 1.769)	
Age group	< 18	1.513 (0.614; 3.729)	<.0001
	>= 18 and < 50	2.266 (1.780; 2.886)	
	>= 50 and < 65	1.543 (1.210; 1.967)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0785
	Female	1.178 (0.981; 1.415)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region as fixed effect and age category and sex as covariates.

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Table 14.4 / 15: Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe) without covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (Asian Countries/Regions vs. Europe)	Europe	1.000	<.0001
	Saudi Arabia	1.984 (0.979; 4.021)	
	Singapore	5.474 (4.066; 7.370)	
	Taiwan	3.093 (1.768; 5.411)	
	Thailand	4.995 (2.954; 8.445)	
	Vietnam	<0.001 (<0.001; >999.999)	
	China	0.755 (0.623; 0.916)	
	Indonesia	3.691 (2.184; 6.239)	
	Iran	2.237 (1.713; 2.921)	
	Jordan	0.864 (0.427; 1.747)	
	Korea (South)	1.371 (1.100; 1.708)	
	Malaysia	1.453 (0.685; 3.083)	
	Pakistan	0.278 (0.069; 1.119)	
	Philippines	1.465 (1.031; 2.081)	
Age group	< 18	1.122 (0.647; 1.945)	<.0001
	>= 18 and < 50	2.188 (1.810; 2.645)	
	>= 50 and < 65	1.616 (1.334; 1.956)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0018
	Female	1.247 (1.086; 1.432)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region (Levels: Asian countries/regions vs. Europe) as fixed effect and age category and sex as covariates.

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**Table 14.4 / 16: Summary and analysis of risk of hypersensitivity reactions. Model for sex.
Identification of covariates. (Complete cases analysis set for sex)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.293 (0.223; 0.386)		
Concomitant Disease: Coronary heart disease	No	1.000	0.1519	No
	Yes	0.808 (0.603; 1.082)		
Concomitant Disease: Hypertension arterial	No	1.000	0.0451	Yes
	Yes	0.781 (0.613; 0.995)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0830	Yes
	Yes	1.250 (0.971; 1.608)		
Concomitant Disease: Reduced general condition	No	1.000	0.4842	No
	Yes	1.114 (0.824; 1.506)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	3.879 (3.077; 4.889)		
Concomitant Disease: Asthma bronchial	No	1.000	<.0001	Yes
	Yes	3.184 (1.901; 5.334)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	5.013 (3.258; 7.714)		
Concomitant Disease: Other	No	1.000	0.0001	Yes
	Yes	1.421 (1.190; 1.697)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.448 (1.258; 1.666)		
Pre-medication Flag	No	1.000	0.6422	No
	Yes	0.952 (0.774; 1.172)		
Categorized dose	<100 ml	1.000	0.0097	Yes
	100 - <150 ml	0.892 (0.772; 1.030)		
	150 - <200 ml	0.683 (0.501; 0.931)		
	200 - <300 ml	0.477 (0.274; 0.831)		

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**Table 14.4 / 16: Summary and analysis of risk of hypersensitivity reactions. Model for sex.
Identification of covariates. (Complete cases analysis set for sex)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	>=300 ml	0.621 (0.277; 1.395)		
Categorized dose of iodine	<=20 g	1.000	0.0058	Yes
	>20 - 40 g	1.150 (0.948; 1.395)		
	>40 - 60 g	1.205 (0.930; 1.560)		
	>60 g	0.509 (0.302; 0.858)		
Contrast Medium	Ultravist - 300	1.000	0.1087	No
	Ultravist - 370	0.886 (0.765; 1.027)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including sex as fixed effect and age category as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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**Table 14.4 / 17: Summary and analysis of risk of hypersensitivity reactions. Model for race.
Identification of covariates. (Complete cases analysis set for race)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.153 (0.102; 0.229)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0243	Yes
	Yes	0.551 (0.329; 0.925)		
Concomitant Disease: Hypertension arterial	No	1.000	0.0004	Yes
	Yes	0.585 (0.436; 0.785)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.2793	No
	Yes	0.797 (0.528; 1.202)		
Concomitant Disease: Reduced general condition	No	1.000	0.0184	Yes
	Yes	0.546 (0.330; 0.903)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	2.975 (1.921; 4.608)		
Concomitant Disease: Asthma bronchial	No	1.000	0.8200	No
	Yes	1.123 (0.414; 3.044)		
Concomitant Disease: Contrast media reaction	No	1.000	0.0003	Yes
	Yes	4.549 (2.001; 10.343)		
Concomitant Disease: Other	No	1.000	0.5172	No
	Yes	1.088 (0.843; 1.402)		
Specific CM risk factor	No	1.000	0.0059	Yes
	Yes	0.739 (0.596; 0.917)		
Pre-medication Flag	No	1.000	0.6293	No
	Yes	0.935 (0.712; 1.228)		
Categorized dose	<100 ml	1.000	<.0001	Yes
	100 - <150 ml	0.679 (0.540; 0.853)		
	150 - <200 ml	0.252 (0.111; 0.568)		
	200 - <300 ml	0.143 (0.046; 0.447)		

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Table 14.4 / 17: Summary and analysis of risk of hypersensitivity reactions. Model for race.
Identification of covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	>=300 ml	0.121 (0.017; 0.865)		
Categorized dose of iodine	<=20 g	1.000	0.0006	Yes
	>20 - 40 g	1.258 (0.935; 1.691)		
	>40 - 60 g	1.109 (0.730; 1.686)		
	>60 g	0.174 (0.063; 0.482)		
Contrast Medium	Ultravist - 300	1.000	0.0005	Yes
	Ultravist - 370	0.684 (0.552; 0.847)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including race as fixed effect and age category, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.4 / 18: Summary and analysis of risk of hypersensitivity reactions. Model for race (Asian and White only). Identification of covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.154 (0.103; 0.231)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0293	Yes
	Yes	0.562 (0.335; 0.944)		
Concomitant Disease: Hypertension arterial	No	1.000	0.0005	Yes
	Yes	0.594 (0.443; 0.797)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.3269	No
	Yes	0.814 (0.539; 1.228)		
Concomitant Disease: Reduced general condition	No	1.000	0.0117	Yes
	Yes	0.513 (0.305; 0.862)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	2.997 (1.935; 4.643)		
Concomitant Disease: Asthma bronchial	No	1.000	0.6013	No
	Yes	1.302 (0.483; 3.509)		
Concomitant Disease: Contrast media reaction	No	1.000	0.0003	Yes
	Yes	4.576 (2.013; 10.400)		
Concomitant Disease: Other	No	1.000	0.7209	No
	Yes	1.049 (0.808; 1.361)		
Specific CM risk factor	No	1.000	0.0047	Yes
	Yes	0.731 (0.588; 0.909)		
Pre-medication Flag	No	1.000	0.6845	No
	Yes	0.945 (0.719; 1.242)		
Categorized dose	<100 ml	1.000	<.0001	Yes
	100 - <150 ml	0.679 (0.539; 0.855)		
	150 - <200 ml	0.220 (0.090; 0.535)		
	200 - <300 ml	0.143 (0.046; 0.448)		

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Table 14.4 / 18: Summary and analysis of risk of hypersensitivity reactions. Model for race (Asian and White only). Identification of covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	>=300 ml	0.121 (0.017; 0.867)		
Categorized dose of iodine	<=20 g	1.000	0.0007	Yes
	>20 - 40 g	1.249 (0.928; 1.681)		
	>40 - 60 g	1.100 (0.720; 1.682)		
	>60 g	0.174 (0.063; 0.481)		
Contrast Medium	Ultravist - 300	1.000	0.0007	Yes
	Ultravist - 370	0.689 (0.555; 0.855)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including race (Asian and White only) as fixed effect and age category, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.4 / 19: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: APAC, Europe, Rest of the World). Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.292 (0.220; 0.387)		
Concomitant Disease: Coronary heart disease	No	1.000	0.1833	No
	Yes	0.820 (0.612; 1.098)		
Concomitant Disease: Hypertension arterial	No	1.000	0.1403	No
	Yes	0.829 (0.645; 1.064)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0600	Yes
	Yes	1.274 (0.990; 1.640)		
Concomitant Disease: Reduced general condition	No	1.000	0.2272	No
	Yes	1.206 (0.890; 1.635)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	3.954 (3.133; 4.989)		
Concomitant Disease: Asthma bronchial	No	1.000	<.0001	Yes
	Yes	2.976 (1.775; 4.989)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	5.238 (3.401; 8.069)		
Concomitant Disease: Other	No	1.000	0.0002	Yes
	Yes	1.404 (1.175; 1.678)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.528 (1.323; 1.763)		
Pre-medication Flag	No	1.000	0.6945	No
	Yes	0.958 (0.775; 1.185)		
Categorized dose	<100 ml	1.000	0.0096	Yes
	100 - <150 ml	0.868 (0.751; 1.004)		
	150 - <200 ml	0.659 (0.483; 0.899)		

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Table 14.4 / 19: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: APAC, Europe, Rest of the World). Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Categorized dose of iodine	200 - <300 ml	0.516 (0.296; 0.899)	0.0049	Yes
	>=300 ml	0.684 (0.304; 1.540)		
	<=20 g	1.000		
	>20 - 40 g	1.248 (1.026; 1.517)		
	>40 - 60 g	1.163 (0.897; 1.507)	0.1930	No
	>60 g	0.589 (0.348; 1.000)		
Contrast Medium	Ultravist - 300	1.000	0.1930	No
	Ultravist - 370	0.903 (0.775; 1.053)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (Levels: APAC, Europe, Rest of the World) as fixed effect and age category, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.4 / 20: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World). Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.320 (0.241; 0.425)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0431	Yes
	Yes	0.739 (0.551; 0.991)		
Concomitant Disease: Hypertension arterial	No	1.000	0.5836	No
	Yes	0.932 (0.724; 1.200)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0407	Yes
	Yes	1.302 (1.011; 1.676)		
Concomitant Disease: Reduced general condition	No	1.000	0.0751	Yes
	Yes	1.320 (0.972; 1.791)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	3.976 (3.151; 5.018)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0001	Yes
	Yes	2.748 (1.638; 4.612)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	5.605 (3.636; 8.643)		
Concomitant Disease: Other	No	1.000	<.0001	Yes
	Yes	1.441 (1.206; 1.722)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.591 (1.379; 1.836)		
Pre-medication Flag	No	1.000	0.8906	No
	Yes	0.985 (0.797; 1.218)		
Categorized dose	<100 ml	1.000	0.0013	Yes
	100 - <150 ml	0.814 (0.704; 0.942)		
	150 - <200 ml	0.612 (0.449; 0.836)		

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Table 14.4 / 20: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World). Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Categorized dose of iodine	200 - <300 ml	0.527 (0.302; 0.918)	0.0063	Yes
	>=300 ml	0.683 (0.304; 1.536)		
	<=20 g	1.000		
	>20 - 40 g	1.266 (1.042; 1.537)		
	>40 - 60 g	1.133 (0.874; 1.468)	0.7639	No
	>60 g	0.639 (0.377; 1.083)		
Contrast Medium	Ultravist - 300	1.000	0.7639	No
	Ultravist - 370	0.977 (0.837; 1.139)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) as fixed effect and age category, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.4 / 21: Summary and analysis of risk of hypersensitivity reactions. Model for country/region. Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.245 (0.166; 0.362)		
Concomitant Disease: Coronary heart disease	No	1.000	0.6687	No
	Yes	0.904 (0.568; 1.438)		
Concomitant Disease: Hypertension arterial	No	1.000	<.0001	Yes
	Yes	0.397 (0.256; 0.615)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.3123	No
	Yes	0.810 (0.539; 1.219)		
Concomitant Disease: Reduced general condition	No	1.000	0.8594	No
	Yes	0.961 (0.616; 1.499)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	3.765 (2.723; 5.205)		
Concomitant Disease: Asthma bronchial	No	1.000	0.1032	No
	Yes	2.277 (0.846; 6.128)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	4.642 (2.530; 8.517)		
Concomitant Disease: Other	No	1.000	0.2260	No
	Yes	1.167 (0.909; 1.497)		
Specific CM risk factor	No	1.000	0.1271	No
	Yes	1.169 (0.957; 1.428)		
Pre-medication Flag	No	1.000	0.8119	No
	Yes	1.035 (0.780; 1.373)		
Categorized dose	<100 ml	1.000	0.0125	Yes
	100 - <150 ml	0.821 (0.671; 1.006)		
	150 - <200 ml	0.674 (0.459; 0.989)		
	200 - <300 ml	0.327 (0.134; 0.796)		

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Table 14.4 / 21: Summary and analysis of risk of hypersensitivity reactions. Model for country/region. Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	>=300 ml	0.218 (0.030; 1.556)		
Categorized dose of iodine	<=20 g	1.000	0.0050	Yes
	>20 - 40 g	1.344 (0.909; 1.985)		
	>40 - 60 g	1.544 (0.986; 2.418)		
	>60 g	0.341 (0.130; 0.891)		
Contrast Medium	Ultravist - 300	1.000	<.0001	Yes
	Ultravist - 370	0.482 (0.371; 0.626)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region as fixed effect and age category, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.4 / 22: Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe). Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	<.0001	Yes
	Intra-arterial	0.326 (0.244; 0.435)		
Concomitant Disease: Coronary heart disease	No	1.000	0.1231	No
	Yes	0.788 (0.581; 1.067)		
Concomitant Disease: Hypertension arterial	No	1.000	0.2330	No
	Yes	0.857 (0.665; 1.105)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0531	Yes
	Yes	1.285 (0.997; 1.658)		
Concomitant Disease: Reduced general condition	No	1.000	0.0395	Yes
	Yes	1.380 (1.016; 1.876)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	3.982 (3.145; 5.040)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0020	Yes
	Yes	2.284 (1.352; 3.858)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	5.481 (3.543; 8.478)		
Concomitant Disease: Other	No	1.000	<.0001	Yes
	Yes	1.437 (1.202; 1.720)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.601 (1.385; 1.851)		
Pre-medication Flag	No	1.000	0.4921	No
	Yes	1.080 (0.867; 1.346)		
Categorized dose	<100 ml	1.000	0.0123	Yes
	100 - <150 ml	0.833 (0.710; 0.977)		
	150 - <200 ml	0.649 (0.471; 0.894)		

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Table 14.4 / 22: Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe). Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Categorized dose of iodine	200 - <300 ml	0.541 (0.309; 0.945)	0.0194	Yes
	>=300 ml	0.716 (0.317; 1.616)		
	<=20 g	1.000		
	>20 - 40 g	1.244 (1.009; 1.532)		
	>40 - 60 g	1.262 (0.951; 1.675)	0.0551	Yes
	>60 g	0.662 (0.388; 1.130)		
Contrast Medium	Ultravist - 300	1.000	0.0551	Yes
	Ultravist - 370	0.849 (0.718; 1.004)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region (Levels: Asian countries/regions vs. Europe) as fixed effect and age category, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.4 / 23: Summary and analysis of risk of hypersensitivity reactions. Model for sex with important covariates. (Complete cases analysis set for sex)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Sex	Male	1.000	0.0374
	Female	1.159 (1.009; 1.332)	
Age group	< 18	1.268 (0.725; 2.217)	<.0001
	>= 18 and < 50	2.346 (1.937; 2.842)	
	>= 50 and < 65	1.742 (1.438; 2.109)	
	>= 65 years old	1.000	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.232 (0.169; 0.319)	
Concomitant Disease: Hypertension arterial	No	1.000	0.6273
	Yes	1.070 (0.813; 1.408)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0049
	Yes	1.484 (1.128; 1.954)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.230 (2.486; 4.197)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0020
	Yes	2.298 (1.355; 3.898)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	3.768 (2.400; 5.916)	
Concomitant Disease: Other	No	1.000	0.0181
	Yes	1.305 (1.047; 1.628)	
Specific CM risk factor	No	1.000	0.1772
	Yes	1.158 (0.936; 1.434)	
Categorized dose	<100 ml	1.000	0.0005
	100 - <150 ml	0.758 (0.641; 0.897)	
	150 - <200 ml	0.421 (0.274; 0.645)	
	200 - <300 ml	0.678 (0.271; 1.697)	

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Table 14.4 / 23: Summary and analysis of risk of hypersensitivity reactions. Model for sex with important covariates. (Complete cases analysis set for sex)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	>=300 ml	1.043 (0.282; 3.856)	
Categorized dose of iodine	<=20 g	1.000	<.0001
	>20 - 40 g	1.291 (1.042; 1.600)	
	>40 - 60 g	2.414 (1.692; 3.444)	
	>60 g	1.703 (0.581; 4.989)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including sex as fixed effect and age category as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only sex, age and that confounder variable as covariate.

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Table 14.4 / 24: Summary and analysis of risk of hypersensitivity reactions. Model for race with important covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Race	Asian	0.869 (0.626; 1.208)	<.0001
	White	1.000	
	Black	<0.001 (<0.001; >999.999)	
	Other	5.609 (2.550; 12.336)	
Age group	< 18	1.842 (0.884; 3.837)	<.0001
	>= 18 and < 50	2.106 (1.537; 2.885)	
	>= 50 and < 65	1.770 (1.299; 2.412)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0352
	Female	1.255 (1.016; 1.550)	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.156 (0.098; 0.247)	
Concomitant Disease: Coronary heart disease	No	1.000	0.1048
	Yes	0.645 (0.380; 1.096)	
Concomitant Disease: Hypertension arterial	No	1.000	0.5545
	Yes	1.112 (0.783; 1.578)	
Concomitant Disease: Reduced general condition	No	1.000	0.0007
	Yes	0.391 (0.228; 0.671)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.346 (2.091; 5.355)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	6.818 (2.858; 16.264)	
Specific CM risk factor	No	1.000	0.7814
	Yes	0.963 (0.735; 1.261)	
Categorized dose	<100 ml	1.000	<.0001
	100 - <150 ml	0.525 (0.399; 0.690)	
	150 - <200 ml	0.244 (0.095; 0.627)	

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Table 14.4 / 24: Summary and analysis of risk of hypersensitivity reactions. Model for race with important covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	200 - <300 ml	0.520 (0.031; 8.673)	
	>=300 ml	0.315 (0.010; 9.758)	
Categorized dose of iodine	<=20 g	1.000	0.0003
	>20 - 40 g	1.528 (1.117; 2.090)	
	>40 - 60 g	3.218 (1.894; 5.470)	
	>60 g	1.292 (0.075; 22.119)	
Contrast Medium	Ultravist - 300	1.000	0.9897
	Ultravist - 370	0.998 (0.792; 1.258)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including race as fixed effect and age category, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only race, age, sex and that confounder variable as covariate.

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Table 14.4 / 25: Summary and analysis of risk of hypersensitivity reactions. Model for race (Asian and White only) with important covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Race (Asian & White only)	Asian	0.873 (0.628; 1.213)	0.4170
	White	1.000	
Age group	< 18	1.899 (0.909; 3.965)	<.0001
	>= 18 and < 50	2.187 (1.589; 3.009)	
	>= 50 and < 65	1.770 (1.293; 2.425)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0482
	Female	1.240 (1.002; 1.535)	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.155 (0.098; 0.246)	
Concomitant Disease: Coronary heart disease	No	1.000	0.1329
	Yes	0.666 (0.392; 1.132)	
Concomitant Disease: Hypertension arterial	No	1.000	0.4681
	Yes	1.140 (0.801; 1.622)	
Concomitant Disease: Reduced general condition	No	1.000	0.0006
	Yes	0.375 (0.215; 0.654)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.390 (2.116; 5.431)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	6.874 (2.880; 16.409)	
Specific CM risk factor	No	1.000	0.6747
	Yes	0.943 (0.716; 1.241)	
Categorized dose	<100 ml	1.000	<.0001
	100 - <150 ml	0.521 (0.394; 0.688)	
	150 - <200 ml	0.220 (0.080; 0.604)	
	200 - <300 ml	0.486 (0.028; 8.532)	

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Table 14.4 / 25: Summary and analysis of risk of hypersensitivity reactions. Model for race (Asian and White only) with important covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	>=300 ml	0.294 (0.009; 9.491)	
Categorized dose of iodine	<=20 g	1.000	0.0002
	>20 - 40 g	1.517 (1.109; 2.075)	
	>40 - 60 g	3.333 (1.950; 5.696)	
	>60 g	1.374 (0.076; 24.734)	
Contrast Medium	Ultravist - 300	1.000	0.9129
	Ultravist - 370	1.013 (0.802; 1.279)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including race (Asian and White only) as fixed effect and age category, sex as well as all identified important confounder variables as covariates. A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only race (Asian and White only), age, sex and that confounder variable as covariate.

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Table 14.4 / 26: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: APAC, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	APAC	1.705 (1.434; 2.028)	<.0001
	Europe	1.000	
	Rest of the World	1.236 (1.032; 1.481)	
Age group	< 18	1.166 (0.666; 2.041)	<.0001
	>= 18 and < 50	2.185 (1.801; 2.650)	
	>= 50 and < 65	1.671 (1.379; 2.025)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0224
	Female	1.176 (1.023; 1.352)	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.240 (0.175; 0.331)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0041
	Yes	1.500 (1.138; 1.977)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.418 (2.623; 4.454)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0036
	Yes	2.195 (1.292; 3.729)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	3.976 (2.531; 6.244)	
Concomitant Disease: Other	No	1.000	0.0258
	Yes	1.282 (1.031; 1.595)	
Specific CM risk factor	No	1.000	0.1855
	Yes	1.148 (0.936; 1.408)	
Categorized dose	<100 ml	1.000	0.0017
	100 - <150 ml	0.748 (0.631; 0.887)	
	150 - <200 ml	0.488 (0.318; 0.750)	

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Table 14.4 / 26: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: APAC, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Categorized dose of iodine	200 - <300 ml	0.855 (0.338; 2.158)	0.0006
	>=300 ml	1.343 (0.360; 5.004)	
	<=20 g	1.000	
	>20 - 40 g	1.366 (1.094; 1.705)	
	>40 - 60 g	2.104 (1.470; 3.010)	
	>60 g	1.412 (0.479; 4.164)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including geographical region (Levels: APAC, Europe, Rest of the World) as fixed effect and age category, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only geographical region (Levels: APAC, Europe, Rest of the World), age, sex and that confounder variable as covariate.

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Table 14.4 / 27: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	Asia (excl. China)	1.839 (1.567; 2.157)	<.0001
	China	0.949 (0.766; 1.176)	
	Europe	1.000	
	Rest of the World	<0.001 (<0.001; >999.999)	
Age group	< 18	1.110 (0.634; 1.944)	<.0001
	>= 18 and < 50	2.156 (1.776; 2.617)	
	>= 50 and < 65	1.677 (1.383; 2.032)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0377
	Female	1.159 (1.008; 1.333)	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.275 (0.198; 0.382)	
Concomitant Disease: Coronary heart disease	No	1.000	0.7746
	Yes	0.954 (0.692; 1.316)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0122
	Yes	1.435 (1.082; 1.902)	
Concomitant Disease: Reduced general condition	No	1.000	0.9505
	Yes	0.989 (0.698; 1.401)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.222 (2.440; 4.255)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0131
	Yes	1.967 (1.153; 3.354)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	4.003 (2.537; 6.316)	
Concomitant Disease: Other	No	1.000	0.0646

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.4 / 27: Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Yes	1.246 (0.987; 1.575)	
Specific CM risk factor	No	1.000	0.1066
	Yes	1.221 (0.958; 1.556)	
Categorized dose	<100 ml	1.000	<.0001
	100 - <150 ml	0.684 (0.575; 0.813)	
	150 - <200 ml	0.446 (0.290; 0.685)	
	200 - <300 ml	0.733 (0.293; 1.833)	
	>=300 ml	1.136 (0.308; 4.194)	
Categorized dose of iodine	<=20 g	1.000	0.0001
	>20 - 40 g	1.494 (1.196; 1.866)	
	>40 - 60 g	2.212 (1.546; 3.165)	
	>60 g	1.677 (0.574; 4.900)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) as fixed effect and age category, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World), age, sex and that confounder variable as covariate.

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Table 14.4 / 28: Summary and analysis of risk of hypersensitivity reactions. Model for country/region with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (China, Germany, South Korea)	China	1.344 (1.057; 1.710)	0.0099
	Germany	1.000	
	South Korea	1.415 (1.076; 1.861)	
Age group	< 18	1.304 (0.522; 3.257)	<.0001
	>= 18 and < 50	1.978 (1.549; 2.524)	
	>= 50 and < 65	1.528 (1.198; 1.949)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.2588
	Female	1.112 (0.925; 1.337)	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.335 (0.209; 0.536)	
Concomitant Disease: Hypertension arterial	No	1.000	0.1434
	Yes	0.707 (0.445; 1.125)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	4.052 (2.900; 5.660)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	4.126 (2.202; 7.733)	
Categorized dose	<100 ml	1.000	0.0006
	100 - <150 ml	0.708 (0.567; 0.883)	
	150 - <200 ml	0.331 (0.198; 0.555)	
	200 - <300 ml	0.390 (0.098; 1.561)	
	>=300 ml	0.341 (0.028; 4.127)	
Categorized dose of iodine	<=20 g	1.000	<.0001
	>20 - 40 g	1.343 (0.887; 2.033)	
	>40 - 60 g	3.263 (1.879; 5.667)	
	>60 g	2.199 (0.435; 11.122)	
Contrast Medium	Ultravist - 300	1.000	0.0028

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Table 14.4 / 28: Summary and analysis of risk of hypersensitivity reactions. Model for country/region with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Ultravist - 370	0.651 (0.492; 0.863)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including country/region as fixed effect and age category, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only country/region, age, sex and that confounder variable as covariate.

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Table 14.4 / 29: Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe) with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (Asian Countries/Regions vs. Europe)	Europe	1.000	<.0001
	Saudi Arabia	2.814 (1.380; 5.738)	
	Singapore	4.658 (3.356; 6.465)	
	Taiwan	2.675 (1.485; 4.820)	
	Thailand	4.274 (2.503; 7.296)	
	Vietnam	<0.001 (<0.001; >999.999)	
	China	0.973 (0.784; 1.208)	
	Indonesia	4.444 (2.602; 7.590)	
	Iran	2.266 (1.720; 2.984)	
	Jordan	1.662 (0.809; 3.415)	
	Korea (South)	1.341 (1.051; 1.713)	
	Malaysia	1.682 (0.785; 3.602)	
	Pakistan	0.259 (0.064; 1.049)	
	Philippines	1.452 (1.009; 2.087)	
Age group	< 18	1.198 (0.683; 2.102)	<.0001
	>= 18 and < 50	2.165 (1.783; 2.628)	
	>= 50 and < 65	1.665 (1.374; 2.018)	
	>= 65 years old	1.000	
Sex	Male	1.000	0.0355
	Female	1.162 (1.010; 1.336)	
Contrast medium application	Intravenous	1.000	<.0001
	Intra-arterial	0.269 (0.191; 0.378)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0177
	Yes	1.406 (1.061; 1.862)	
Concomitant Disease: Reduced general condition	No	1.000	0.6797
	Yes	1.075 (0.762; 1.518)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.326 (2.528; 4.378)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0368

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Table 14.4 / 29: Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe) with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Yes	1.771 (1.036; 3.028)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	4.067 (2.575; 6.421)	
Concomitant Disease: Other	No	1.000	0.0380
	Yes	1.273 (1.013; 1.599)	
Specific CM risk factor	No	1.000	0.1903
	Yes	1.165 (0.927; 1.464)	
Categorized dose	<100 ml	1.000	0.0017
	100 - <150 ml	0.747 (0.622; 0.897)	
	150 - <200 ml	0.436 (0.278; 0.682)	
	200 - <300 ml	0.644 (0.256; 1.618)	
	>=300 ml	0.968 (0.262; 3.582)	
Categorized dose of iodine	<=20 g	1.000	0.0003
	>20 - 40 g	1.362 (1.078; 1.722)	
	>40 - 60 g	2.349 (1.590; 3.471)	
	>60 g	1.864 (0.632; 5.494)	
Contrast Medium	Ultravist - 300	1.000	0.7708
	Ultravist - 370	1.027 (0.857; 1.231)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including country/region (Levels: Asian countries/regions vs. Europe) as fixed effect and age category, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only country/region (Levels: Asian countries/regions vs. Europe), age, sex and that confounder variable as covariate.

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14.5 Sensitivity analysis of risk of hypersensitivity reactions

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Table 14.5 / 1: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for sex without covariates. (Complete cases analysis set for sex)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Sex	Male	1.000	0.0025
	Female	1.237 (1.078; 1.420)	
Age group	< 18	1.081 (0.625; 1.869)	<.0001
	>= 18 and < 50	2.196 (1.819; 2.650)	
	>= 50 and < 65	1.678 (1.386; 2.031)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.114 (0.069; 0.188)	
	41288	0.659 (0.568; 0.766)	
	82020	0.925 (0.745; 1.150)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including sex as fixed effect and age category and study as covariates.

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Table 14.5 / 2: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for race without covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Race	Asian	1.093 (0.803; 1.489)	<.0001
	White	1.000	
	Black	<0.001 (<0.001; >999.999)	
	Other	5.888 (2.727; 12.716)	
Age group	< 18	1.669 (0.823; 3.384)	<.0001
	>= 18 and < 50	2.167 (1.592; 2.949)	
	>= 50 and < 65	1.793 (1.318; 2.439)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.114 (0.069; 0.189)	
Sex	Male	1.000	0.0082
	Female	1.326 (1.076; 1.634)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including race as fixed effect and age category, study and sex as covariates.

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Table 14.5 / 3: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (levels: APAC, Europe, Rest of the World) without covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	APAC	1.609 (1.338; 1.934)	<.0001
	Europe	1.000	
	Rest of the World	1.155 (0.940; 1.418)	
Age group	< 18	1.010 (0.584; 1.748)	<.0001
	>= 18 and < 50	2.101 (1.739; 2.540)	
	>= 50 and < 65	1.649 (1.362; 1.996)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.125 (0.075; 0.209)	
	41288	0.749 (0.626; 0.898)	
	82020	1.115 (0.885; 1.405)	
Sex	Male	1.000	0.0022
	Female	1.241 (1.081; 1.425)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (levels: APAC, Europe, Rest of the World) as fixed effect and age category, study and sex as covariates.

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Table 14.5 / 4: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) without covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	Asia (excl. China)	1.541 (1.302; 1.823)	<.0001
	China	0.895 (0.694; 1.154)	
	Europe	1.000	
	Rest of the World	<0.001 (<0.001; >999.999)	
Age group	< 18	0.965 (0.558; 1.671)	<.0001
	>= 18 and < 50	2.072 (1.714; 2.505)	
	>= 50 and < 65	1.635 (1.351; 1.980)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.142 (0.085; 0.239)	
	41288	0.668 (0.553; 0.806)	
	82020	0.860 (0.678; 1.091)	
Sex	Male	1.000	0.0025
	Female	1.237 (1.078; 1.420)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) as fixed effect and age category, study and sex as covariates.

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Table 14.5 / 5: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region without covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (China, Germany, South Korea)	China	0.828 (0.523; 1.311)	0.0231
	Germany	1.000	
	South Korea	1.254 (0.941; 1.671)	
Age group	< 18	1.339 (0.543; 3.304)	<.0001
	>= 18 and < 50	2.108 (1.653; 2.689)	
	>= 50 and < 65	1.593 (1.249; 2.032)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.144 (0.085; 0.242)	
	41288	0.640 (0.430; 0.952)	
	82020	0.739 (0.444; 1.230)	
Sex	Male	1.000	0.1330
	Female	1.150 (0.958; 1.381)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region as fixed effect and age category, study and sex as covariates.

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Table 14.5 / 6: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe) without covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (Asian Countries/Regions vs. Europe)	Europe	1.000	<.0001
	Saudi Arabia	1.904 (0.932; 3.890)	
	Singapore	3.999 (2.813; 5.684)	
	Taiwan	2.434 (1.365; 4.342)	
	Thailand	4.359 (2.557; 7.428)	
	Vietnam	<0.001 (<0.001; >999.999)	
	China	0.895 (0.680; 1.179)	
	Indonesia	2.718 (1.556; 4.748)	
	Iran	2.387 (1.650; 3.453)	
	Jordan	0.903 (0.446; 1.830)	
	Korea (South)	1.276 (1.017; 1.601)	
	Malaysia	1.055 (0.486; 2.290)	
	Pakistan	0.206 (0.051; 0.840)	
	Philippines	1.235 (0.853; 1.787)	
Age group	< 18	1.054 (0.608; 1.827)	<.0001
	>= 18 and < 50	2.084 (1.724; 2.521)	
	>= 50 and < 65	1.623 (1.340; 1.965)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.143 (0.085; 0.240)	
	41288	0.700 (0.562; 0.872)	
	82020	0.679 (0.479; 0.961)	
Sex	Male	1.000	0.0030
	Female	1.233 (1.074; 1.416)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region (Levels: Asian countries/regions vs. Europe) as fixed effect and age category, study and sex as covariates.

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**Table 14.5 / 7: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for sex. Identification of covariates. (Complete cases analysis set for sex)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.0015	Yes
	Intra-arterial	0.593 (0.430; 0.819)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0107	Yes
	Yes	0.683 (0.509; 0.915)		
Concomitant Disease: Hypertension arterial	No	1.000	0.1270	No
	Yes	1.223 (0.944; 1.584)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0004	Yes
	Yes	1.586 (1.231; 2.044)		
Concomitant Disease: Reduced general condition	No	1.000	0.3957	No
	Yes	0.876 (0.645; 1.189)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.272 (3.382; 5.397)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0003	Yes
	Yes	2.619 (1.555; 4.411)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	6.079 (3.938; 9.384)		
Concomitant Disease: Other	No	1.000	0.0001	Yes
	Yes	1.426 (1.191; 1.707)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.576 (1.362; 1.824)		
Pre-medication Flag	No	1.000	0.5336	No
	Yes	0.935 (0.757; 1.155)		
Categorized dose	<100 ml	1.000	0.7270	No
	100 - <150 ml	0.912 (0.787; 1.056)		
	150 - <200 ml	0.871 (0.635; 1.193)		
	200 - <300 ml	0.885 (0.505; 1.549)		

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**Table 14.5 / 7: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for sex. Identification of covariates. (Complete cases analysis set for sex)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	>=300 ml	1.107 (0.491; 2.496)		
Categorized dose of iodine	<=20 g	1.000	0.1641	No
	>20 - 40 g	1.077 (0.886; 1.308)		
	>40 - 60 g	1.321 (1.020; 1.712)		
	>60 g	0.981 (0.577; 1.668)		
Contrast Medium	Ultravist - 300	1.000	0.1381	No
	Ultravist - 370	1.126 (0.962; 1.318)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including sex as fixed effect and age category, study as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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**Table 14.5 / 8: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for race. Identification of covariates. (Complete cases analysis set for race)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.0035	Yes
	Intra-arterial	0.378 (0.197; 0.726)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0009	Yes
	Yes	0.420 (0.251; 0.702)		
Concomitant Disease: Hypertension arterial	No	1.000	0.4645	No
	Yes	1.123 (0.823; 1.531)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.2251	No
	Yes	1.295 (0.853; 1.965)		
Concomitant Disease: Reduced general condition	No	1.000	0.0004	Yes
	Yes	0.400 (0.242; 0.661)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.055 (2.602; 6.319)		
Concomitant Disease: Asthma bronchial	No	1.000	0.9670	No
	Yes	1.021 (0.377; 2.765)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	8.847 (3.809; 20.551)		
Concomitant Disease: Other	No	1.000	0.3020	No
	Yes	1.144 (0.886; 1.475)		
Specific CM risk factor	No	1.000	0.3721	No
	Yes	0.906 (0.730; 1.125)		
Pre-medication Flag	No	1.000	0.3087	No
	Yes	0.867 (0.660; 1.141)		
Categorized dose	<100 ml	1.000	0.0117	Yes
	100 - <150 ml	0.708 (0.563; 0.890)		
	150 - <200 ml	0.533 (0.233; 1.218)		
	200 - <300 ml	0.401 (0.125; 1.280)		

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**Table 14.5 / 8: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for race. Identification of covariates. (Complete cases analysis set for race)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	>=300 ml	0.284 (0.039; 2.049)		
Categorized dose of iodine	<=20 g	1.000	0.1151	No
	>20 - 40 g	1.145 (0.850; 1.542)		
	>40 - 60 g	1.425 (0.934; 2.174)		
	>60 g	0.466 (0.165; 1.315)		
Contrast Medium	Ultravist - 300	1.000	0.2487	No
	Ultravist - 370	1.138 (0.913; 1.419)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including race as fixed effect and age category, study, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.5 / 9: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for geographical region (levels: APAC, Europe, Rest of the World).
Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.0020	Yes
	Intra-arterial	0.602 (0.436; 0.830)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0230	Yes
	Yes	0.712 (0.531; 0.954)		
Concomitant Disease: Hypertension arterial	No	1.000	0.0791	Yes
	Yes	1.264 (0.973; 1.642)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0005	Yes
	Yes	1.570 (1.218; 2.024)		
Concomitant Disease: Reduced general condition	No	1.000	0.7200	No
	Yes	0.945 (0.693; 1.288)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.360 (3.447; 5.517)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0005	Yes
	Yes	2.517 (1.493; 4.246)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	6.230 (4.032; 9.626)		
Concomitant Disease: Other	No	1.000	0.0001	Yes
	Yes	1.421 (1.186; 1.702)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.626 (1.405; 1.882)		
Pre-medication Flag	No	1.000	0.4876	No
	Yes	0.927 (0.748; 1.149)		
Categorized dose	<100 ml	1.000	0.3840	No
	100 - <150 ml	0.879 (0.758; 1.019)		
	150 - <200 ml	0.800 (0.582; 1.100)		

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Table 14.5 / 9: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for geographical region (levels: APAC, Europe, Rest of the World).
Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Categorized dose of iodine	200 - <300 ml	0.894 (0.510; 1.567)	0.3780	No
	>=300 ml	1.166 (0.517; 2.632)		
	<=20 g	1.000		
	>20 - 40 g	1.140 (0.934; 1.391)		
	>40 - 60 g	1.255 (0.966; 1.631)	0.1000	No
	>60 g	1.047 (0.615; 1.783)		
Contrast Medium	Ultravist - 300	1.000	0.1000	No
	Ultravist - 370	1.142 (0.975; 1.337)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (levels: APAC, Europe, Rest of the World) as fixed effect and age category, study, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.5 / 10: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World). Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.0003	Yes
	Intra-arterial	0.551 (0.398; 0.761)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0071	Yes
	Yes	0.668 (0.498; 0.896)		
Concomitant Disease: Hypertension arterial	No	1.000	0.1407	No
	Yes	1.218 (0.937; 1.585)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0010	Yes
	Yes	1.531 (1.187; 1.974)		
Concomitant Disease: Reduced general condition	No	1.000	0.9829	No
	Yes	1.003 (0.735; 1.369)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.337 (3.429; 5.485)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0009	Yes
	Yes	2.416 (1.432; 4.076)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	6.567 (4.246; 10.158)		
Concomitant Disease: Other	No	1.000	0.0002	Yes
	Yes	1.407 (1.175; 1.686)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.606 (1.388; 1.859)		
Pre-medication Flag	No	1.000	0.5682	No
	Yes	0.940 (0.759; 1.164)		
Categorized dose	<100 ml	1.000	0.2556	No
	100 - <150 ml	0.862 (0.743; 1.000)		

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Table 14.5 / 10: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World). Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	150 - <200 ml	0.771 (0.561; 1.060)		
	200 - <300 ml	0.830 (0.474; 1.454)		
	>=300 ml	1.047 (0.464; 2.364)		
Categorized dose of iodine	<=20 g	1.000	0.2278	No
	>20 - 40 g	1.208 (0.987; 1.478)		
	>40 - 60 g	1.260 (0.970; 1.637)		
	>60 g	1.008 (0.593; 1.714)		
Contrast Medium	Ultravist - 300	1.000	0.2215	No
	Ultravist - 370	1.104 (0.942; 1.295)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) as fixed effect and age category, study, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.5 / 11: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region. Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.5666	No
	Intra-arterial	0.853 (0.495; 1.470)		
Concomitant Disease: Coronary heart disease	No	1.000	0.2133	No
	Yes	0.745 (0.468; 1.185)		
Concomitant Disease: Hypertension arterial	No	1.000	0.3882	No
	Yes	0.816 (0.514; 1.295)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.5304	No
	Yes	1.141 (0.756; 1.722)		
Concomitant Disease: Reduced general condition	No	1.000	0.0607	Yes
	Yes	0.649 (0.413; 1.020)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.446 (3.198; 6.182)		
Concomitant Disease: Asthma bronchial	No	1.000	0.1324	No
	Yes	2.161 (0.792; 5.893)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	5.914 (3.206; 10.909)		
Concomitant Disease: Other	No	1.000	0.2488	No
	Yes	1.163 (0.900; 1.504)		
Specific CM risk factor	No	1.000	0.0260	Yes
	Yes	1.257 (1.028; 1.536)		
Pre-medication Flag	No	1.000	0.5253	No
	Yes	0.912 (0.685; 1.213)		
Categorized dose	<100 ml	1.000	0.6831	No
	100 - <150 ml	0.861 (0.702; 1.056)		
	150 - <200 ml	0.907 (0.610; 1.348)		

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Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

Table 14.5 / 11: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region. Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Categorized dose of iodine	200 - <300 ml	0.782 (0.314; 1.949)	0.0517	Yes
	>=300 ml	0.651 (0.089; 4.746)		
	<=20 g	1.000		
	>20 - 40 g	1.020 (0.685; 1.517)		
	>40 - 60 g	1.460 (0.924; 2.306)	0.0256	Yes
	>60 g	0.761 (0.284; 2.039)		
Contrast Medium	Ultravist - 300	1.000	0.0256	Yes
	Ultravist - 370	0.744 (0.574; 0.965)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region as fixed effect and age category, study, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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**Table 14.5 / 12: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for country/region (Levels: Asian countries/regions vs. Europe).
Identification of covariates. (Complete cases analysis set for country/region)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.0007	Yes
	Intra-arterial	0.558 (0.397; 0.783)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0129	Yes
	Yes	0.679 (0.500; 0.921)		
Concomitant Disease: Hypertension arterial	No	1.000	0.2548	No
	Yes	1.167 (0.895; 1.521)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0012	Yes
	Yes	1.529 (1.183; 1.976)		
Concomitant Disease: Reduced general condition	No	1.000	0.7430	No
	Yes	1.054 (0.771; 1.440)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.441 (3.499; 5.636)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0033	Yes
	Yes	2.204 (1.301; 3.732)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	6.449 (4.153; 10.014)		
Concomitant Disease: Other	No	1.000	0.0001	Yes
	Yes	1.430 (1.191; 1.716)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.650 (1.421; 1.915)		
Pre-medication Flag	No	1.000	0.9998	No
	Yes	1.000 (0.801; 1.248)		
Categorized dose	<100 ml	1.000	0.3430	No
	100 - <150 ml	0.861 (0.733; 1.011)		
	150 - <200 ml	0.780 (0.564; 1.080)		

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Table 14.5 / 12: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for country/region (Levels: Asian countries/regions vs. Europe).
Identification of covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Categorized dose of iodine	200 - <300 ml	0.825 (0.469; 1.453)	0.3340	No
	>=300 ml	1.041 (0.455; 2.380)		
	<=20 g	1.000		
	>20 - 40 g	1.143 (0.923; 1.415)		
	>40 - 60 g	1.298 (0.974; 1.729)	0.7157	No
	>60 g	1.007 (0.585; 1.733)		
	Ultravist - 300	1.000		
Contrast Medium	Ultravist - 370	0.968 (0.815; 1.151)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including country/region (Levels: Asian countries/regions vs. Europe) as fixed effect and age category, study, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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**Table 14.5 / 13: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for sex with important covariates. (Complete cases analysis set for sex)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Sex	Male	1.000	0.0409
	Female	1.156 (1.006; 1.328)	
Age group	< 18	1.114 (0.643; 1.930)	<.0001
	>= 18 and < 50	2.212 (1.825; 2.680)	
	>= 50 and < 65	1.700 (1.403; 2.060)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.145 (0.078; 0.268)	
	41288	0.669 (0.570; 0.786)	
	82020	0.839 (0.672; 1.047)	
Contrast medium application	Intravenous	1.000	0.0081
	Intra-arterial	0.615 (0.429; 0.881)	
Concomitant Disease: Coronary heart disease	No	1.000	0.0780
	Yes	0.736 (0.524; 1.035)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0009
	Yes	1.596 (1.211; 2.104)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.491 (2.669; 4.566)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0075
	Yes	2.070 (1.214; 3.529)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	4.161 (2.642; 6.556)	
Concomitant Disease: Other	No	1.000	0.0192
	Yes	1.300 (1.044; 1.620)	
Specific CM risk factor	No	1.000	0.3415

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Table 14.5 / 13: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for sex with important covariates. (Complete cases analysis set for sex)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Yes	1.110 (0.895; 1.377)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).
Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).
Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including sex as fixed effect and age category, study as well as all identified important confounder variables as covariates.
A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only sex, age, study and that confounder variable as covariate.
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**Table 14.5 / 14: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for race with important covariates. (Complete cases analysis set for race)**

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Race	Asian	0.972 (0.704; 1.344)	<.0001
	White	1.000	
	Black	<0.001 (<0.001; >999.999)	
	Other	6.159 (2.810; 13.497)	
Age group	< 18	1.391 (0.683; 2.835)	0.0004
	>= 18 and < 50	1.942 (1.424; 2.649)	
	>= 50 and < 65	1.737 (1.276; 2.365)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.161 (0.067; 0.388)	
Sex	Male	1.000	0.0595
	Female	1.225 (0.992; 1.512)	
Contrast medium application	Intravenous	1.000	0.2473
	Intra-arterial	0.651 (0.314; 1.348)	
Concomitant Disease: Coronary heart disease	No	1.000	0.0126
	Yes	0.488 (0.277; 0.857)	
Concomitant Disease: Reduced general condition	No	1.000	0.0002
	Yes	0.379 (0.229; 0.628)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.358 (2.141; 5.265)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	6.966 (2.945; 16.475)	
Categorized dose	<100 ml	1.000	0.0137
	100 - <150 ml	0.688 (0.547; 0.866)	
	150 - <200 ml	0.572 (0.248; 1.318)	
	200 - <300 ml	0.534 (0.161; 1.764)	



Table 14.5 / 14: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for race with important covariates. (Complete cases analysis set for race)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	≥300 ml	0.327 (0.045; 2.375)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).
Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).
Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including race as fixed effect and age category, study, sex as well as all identified important confounder variables as covariates.
A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only race, age, study, sex and that confounder variable as covariate.
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Table 14.5 / 15: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (levels: APAC, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	APAC	1.665 (1.383; 2.006)	<.0001
	Europe	1.000	
	Rest of the World	1.334 (1.080; 1.648)	
Age group	< 18	1.054 (0.607; 1.827)	<.0001
	>= 18 and < 50	2.126 (1.752; 2.580)	
	>= 50 and < 65	1.668 (1.377; 2.022)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.141 (0.074; 0.266)	
	41288	0.839 (0.690; 1.020)	
	82020	1.045 (0.826; 1.323)	
Sex	Male	1.000	0.0289
	Female	1.168 (1.016; 1.342)	
Contrast medium application	Intravenous	1.000	0.0082
	Intra-arterial	0.615 (0.429; 0.882)	
Concomitant Disease: Coronary heart disease	No	1.000	0.0909
	Yes	0.745 (0.530; 1.048)	
Concomitant Disease: Hypertension arterial	No	1.000	0.2139
	Yes	1.195 (0.902; 1.582)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0021
	Yes	1.545 (1.171; 2.038)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.565 (2.718; 4.676)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0104
	Yes	2.013 (1.178; 3.439)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001

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Table 14.5 / 15: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (levels: APAC, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Yes	4.289 (2.716; 6.771)	
Concomitant Disease: Other	No	1.000	0.0174
	Yes	1.313 (1.049; 1.643)	
Specific CM risk factor	No	1.000	0.3744
	Yes	1.107 (0.884; 1.387)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including geographical region (levels: APAC, Europe, Rest of the World) as fixed effect and age category, study, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only geographical region (levels: APAC, Europe, Rest of the World), age, study, sex and that confounder variable as covariate.

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Table 14.5 / 16: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region	Asia (excl. China)	1.646 (1.387; 1.953)	<.0001
	China	1.008 (0.777; 1.308)	
	Europe	1.000	
	Rest of the World	<0.001 (<0.001; >999.999)	
Age group	< 18	0.996 (0.574; 1.728)	<.0001
	>= 18 and < 50	2.084 (1.718; 2.528)	
	>= 50 and < 65	1.658 (1.368; 2.009)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.185 (0.098; 0.352)	
	41288	0.737 (0.604; 0.899)	
	82020	0.841 (0.659; 1.071)	
Sex	Male	1.000	0.0401
	Female	1.157 (1.007; 1.330)	
Contrast medium application	Intravenous	1.000	0.0035
	Intra-arterial	0.581 (0.403; 0.836)	
Concomitant Disease: Coronary heart disease	No	1.000	0.0813
	Yes	0.737 (0.523; 1.039)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0036
	Yes	1.511 (1.145; 1.994)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.403 (2.595; 4.463)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0196
	Yes	1.894 (1.108; 3.238)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001

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Table 14.5 / 16: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Yes	4.338 (2.748; 6.846)	
Concomitant Disease: Other	No	1.000	0.0465
	Yes	1.253 (1.004; 1.565)	
Specific CM risk factor	No	1.000	0.1346
	Yes	1.181 (0.950; 1.469)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World) as fixed effect and age category, study, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only geographical region (Levels: Asia (excl. China), China, Europe, Rest of the World), age, study, sex and that confounder variable as covariate.

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Table 14.5 / 17: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (China, Germany, South Korea)	China	1.101 (0.687; 1.764)	0.2061
	Germany	1.000	
	South Korea	1.287 (0.952; 1.741)	
Age group	< 18	1.360 (0.543; 3.405)	<.0001
	>= 18 and < 50	2.034 (1.590; 2.601)	
	>= 50 and < 65	1.561 (1.223; 1.992)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.141 (0.079; 0.250)	
	41288	0.639 (0.424; 0.963)	
	82020	0.737 (0.440; 1.235)	
Sex	Male	1.000	0.2328
	Female	1.119 (0.931; 1.345)	
Concomitant Disease: Reduced general condition	No	1.000	0.0570
	Yes	0.627 (0.388; 1.014)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.906 (2.687; 5.679)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	4.052 (2.140; 7.669)	
Specific CM risk factor	No	1.000	0.6475
	Yes	1.057 (0.834; 1.339)	
Categorized dose of iodine	<=20 g	1.000	0.0448
	>20 - 40 g	1.025 (0.689; 1.527)	
	>40 - 60 g	1.487 (0.941; 2.349)	
	>60 g	0.821 (0.303; 2.228)	
Contrast Medium	Ultravist - 300	1.000	0.0137

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Table 14.5 / 17: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Ultravist - 370	0.717 (0.550; 0.934)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including country/region as fixed effect and age category, study, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only country/region, age, study, sex and that confounder variable as covariate.

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Table 14.5 / 18: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe) with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Country/Region (Asian Countries/Regions vs. Europe)	Europe	1.000	<.0001
	Saudi Arabia	2.684 (1.302; 5.535)	
	Singapore	4.021 (2.815; 5.744)	
	Taiwan	1.930 (1.073; 3.472)	
	Thailand	3.837 (2.242; 6.568)	
	Vietnam	<0.001 (<0.001; >999.999)	
	China	0.963 (0.728; 1.276)	
	Indonesia	3.185 (1.817; 5.582)	
	Iran	2.735 (1.893; 3.952)	
	Jordan	1.338 (0.649; 2.761)	
	Korea (South)	1.343 (1.066; 1.692)	
	Malaysia	1.041 (0.475; 2.285)	
	Pakistan	0.195 (0.048; 0.795)	
	Philippines	1.143 (0.790; 1.654)	
Age group	< 18	1.080 (0.621; 1.877)	<.0001
	>= 18 and < 50	2.082 (1.715; 2.528)	
	>= 50 and < 65	1.632 (1.346; 1.978)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.181 (0.095; 0.344)	
	41288	0.734 (0.583; 0.924)	
	82020	0.608 (0.428; 0.865)	
Sex	Male	1.000	0.0415
	Female	1.156 (1.006; 1.329)	
Contrast medium application	Intravenous	1.000	0.0067
	Intra-arterial	0.598 (0.413; 0.867)	
Concomitant Disease: Coronary heart disease	No	1.000	0.0706
	Yes	0.727 (0.515; 1.027)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0052
	Yes	1.488 (1.126; 1.967)	

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Table 14.5 / 18: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for country/region (Levels: Asian countries/regions vs. Europe) with important covariates. (Complete cases analysis set for country/region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.511 (2.670; 4.618)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0385
	Yes	1.766 (1.031; 3.027)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001
	Yes	4.309 (2.725; 6.815)	
Concomitant Disease: Other	No	1.000	0.0519
	Yes	1.249 (0.998; 1.562)	
Specific CM risk factor	No	1.000	0.1424
	Yes	1.179 (0.946; 1.469)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including country/region (Levels: Asian countries/regions vs. Europe) as fixed effect and age category, study, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only country/region (Levels: Asian countries/regions vs. Europe), age, study, sex and that confounder variable as covariate.

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Table 14.5 / 19: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (levels: Asia, Europe, Rest of the World) without covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region 4	Asia	1.425 (1.201; 1.689)	0.0003
	Europe	1.000	
	Rest of the World	<0.001 (<0.001; >999.999)	
Age group	< 18	1.023 (0.592; 1.770)	<.0001
	>= 18 and < 50	2.104 (1.741; 2.542)	
	>= 50 and < 65	1.647 (1.360; 1.994)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.108 (0.065; 0.178)	
	41288	0.820 (0.685; 0.981)	
	82020	1.071 (0.853; 1.344)	
Sex	Male	1.000	0.0015
	Female	1.250 (1.089; 1.435)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (levels: Asia, Europe, Rest of the World) as fixed effect and age category, study and sex as covariates.

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Table 14.5 / 20: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for geographical region (levels: Asia, Europe, Rest of the World).
Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
Contrast medium application	Intravenous	1.000	0.0027	Yes
	Intra-arterial	0.611 (0.442; 0.843)		
Concomitant Disease: Coronary heart disease	No	1.000	0.0180	Yes
	Yes	0.702 (0.524; 0.941)		
Concomitant Disease: Hypertension arterial	No	1.000	0.0377	Yes
	Yes	1.319 (1.016; 1.712)		
Concomitant Disease: Diabetes mellitus	No	1.000	0.0002	Yes
	Yes	1.613 (1.251; 2.078)		
Concomitant Disease: Reduced general condition	No	1.000	0.3876	No
	Yes	0.874 (0.643; 1.187)		
Concomitant Disease: Allergy	No	1.000	<.0001	Yes
	Yes	4.500 (3.558; 5.690)		
Concomitant Disease: Asthma bronchial	No	1.000	0.0002	Yes
	Yes	2.682 (1.592; 4.519)		
Concomitant Disease: Contrast media reaction	No	1.000	<.0001	Yes
	Yes	6.766 (4.375; 10.462)		
Concomitant Disease: Other	No	1.000	<.0001	Yes
	Yes	1.453 (1.214; 1.739)		
Specific CM risk factor	No	1.000	<.0001	Yes
	Yes	1.623 (1.403; 1.878)		
Pre-medication Flag	No	1.000	0.2634	No
	Yes	0.886 (0.716; 1.096)		
Categorized dose	<100 ml	1.000	0.4093	No
	100 - <150 ml	0.880 (0.759; 1.021)		
	150 - <200 ml	0.809 (0.588; 1.111)		

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Table 14.5 / 20: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions.
Model for geographical region (levels: Asia, Europe, Rest of the World).
Identification of covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value	Important variable (Yes/No)
	200 - <300 ml	0.895 (0.511; 1.569)		
	>=300 ml	1.166 (0.517; 2.630)		
Categorized dose of iodine	<=20 g	1.000	0.4205	No
	>20 - 40 g	1.045 (0.860; 1.269)		
	>40 - 60 g	1.228 (0.945; 1.596)		
	>60 g	0.995 (0.585; 1.693)		
Contrast Medium	Ultravist - 300	1.000	0.0723	Yes
	Ultravist - 370	1.155 (0.987; 1.351)		

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on logistic regression models including geographical region (levels: Asia, Europe, Rest of the World) as fixed effect and age category, study, sex as well as one additional confounder as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1.

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Table 14.5 / 21: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (levels: Asia, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
Geographical Region 4	Asia	1.586 (1.335; 1.885)	<.0001
	Europe	1.000	
	Rest of the World	<0.001 (<0.001; >999.999)	
Age group	< 18	1.055 (0.608; 1.830)	<.0001
	>= 18 and < 50	2.116 (1.744; 2.567)	
	>= 50 and < 65	1.658 (1.368; 2.009)	
	>= 65 years old	1.000	
Study	14692	1.000	<.0001
	15454	0.121 (0.065; 0.226)	
	41288	0.966 (0.792; 1.178)	
	82020	1.109 (0.872; 1.411)	
Sex	Male	1.000	0.0230
	Female	1.175 (1.023; 1.351)	
Contrast medium application	Intravenous	1.000	0.0024
	Intra-arterial	0.566 (0.391; 0.818)	
Concomitant Disease: Coronary heart disease	No	1.000	0.0459
	Yes	0.706 (0.502; 0.994)	
Concomitant Disease: Hypertension arterial	No	1.000	0.1820
	Yes	1.209 (0.915; 1.599)	
Concomitant Disease: Diabetes mellitus	No	1.000	0.0013
	Yes	1.571 (1.192; 2.069)	
Concomitant Disease: Allergy	No	1.000	<.0001
	Yes	3.664 (2.797; 4.801)	
Concomitant Disease: Asthma bronchial	No	1.000	0.0077
	Yes	2.068 (1.212; 3.527)	
Concomitant Disease: Contrast media reaction	No	1.000	<.0001

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Table 14.5 / 21: Sensitivity analysis. Summary and analysis of risk of hypersensitivity reactions. Model for geographical region (levels: Asia, Europe, Rest of the World) with important covariates. (Complete cases analysis set for geographical region)

Covariate	Covariate Level	Odds Ratio (95% CI)	Wald p-value
	Yes	4.513 (2.854; 7.137)	
Concomitant Disease: Other	No	1.000	0.0085
	Yes	1.350 (1.080; 1.687)	
Specific CM risk factor	No	1.000	0.4915
	Yes	1.082 (0.865; 1.353)	
Contrast Medium	Ultravist - 300	1.000	0.0070
	Ultravist - 370	1.256 (1.064; 1.483)	

Cases group is defined as patients who experienced at least one hypersensitivity reaction (HSR).

Control group is defined as patients without reported AEs (to avoid misclassification by unspecific reactions, which could be either procedure related or HSRs).

Odds ratios (95% confidence interval) and p-values (two-sided Wald test) are based on a logistic regression model including geographical region (levels: Asia, Europe, Rest of the World) as fixed effect and age category, study, sex as well as all identified important confounder variables as covariates.

A confounder was considered important when its effect, represented by a descriptive Wald test p-value, was below 0.1 in a logistic regression model with only geographical region (levels: Asia, Europe, Rest of the World), age, study, sex and that confounder variable as covariate.

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14.6 Occurrence of hypersensitivity reactions

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Table 14.6 / 1: Occurrence and risk differences of hypersensitivity reactions by sex. MedDRA preferred terms (Full analysis set for sex)

Preferred term MedDRA version 21.0	Male N=80816 (100%)	Female N=64217 (100%)	Risk Difference Female vs Male	Total N=145033 (100%)
All patients with any hypersensitivity reaction	442 (0.5%)	461 (0.7%)	0.17%	903 (0.6%)
Pruritus	159 (0.2%)	184 (0.3%)	0.09%	343 (0.2%)
Urticaria	141 (0.2%)	138 (0.2%)	0.04%	279 (0.2%)
Rash	101 (0.1%)	99 (0.2%)	0.03%	200 (0.1%)
Erythema	48 (<0.1%)	66 (0.1%)	0.04%	114 (<0.1%)
Dyspnoea	47 (<0.1%)	53 (<0.1%)	0.02%	100 (<0.1%)
Cough	43 (<0.1%)	48 (<0.1%)	0.02%	91 (<0.1%)
Sneezing	46 (<0.1%)	33 (<0.1%)	-0.01%	79 (<0.1%)
Bronchospasm	5 (<0.1%)	5 (<0.1%)	<0.00%	10 (<0.1%)
Throat irritation	4 (<0.1%)	1 (<0.1%)	-0.00%	5 (<0.1%)
Face oedema	0	4 (<0.1%)	0.01%	4 (<0.1%)
Dysphagia	1 (<0.1%)	2 (<0.1%)	<0.00%	3 (<0.1%)
Nasal congestion	1 (<0.1%)	2 (<0.1%)	<0.00%	3 (<0.1%)
Dysphonia	0	2 (<0.1%)	<0.00%	2 (<0.1%)
Eye swelling	2 (<0.1%)	0	-0.00%	2 (<0.1%)
Anaphylactic shock	0	1 (<0.1%)	<0.00%	1 (<0.1%)
Lacrimation increased	0	1 (<0.1%)	<0.00%	1 (<0.1%)
Laryngeal oedema	0	1 (<0.1%)	<0.00%	1 (<0.1%)
Respiratory arrest	0	1 (<0.1%)	<0.00%	1 (<0.1%)
Rhinitis	1 (<0.1%)	0	-0.00%	1 (<0.1%)

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Table 14.6 / 2: Occurrence and risk differences of hypersensitivity reactions by race. MedDRA preferred terms (Full analysis set for race)

Preferred term MedDRA version 21.0	Asian N=50217 (100%)	White N=8984 (100%)	Black N=30 (100%)	Other N=181 (100%)	Risk Difference Asian vs White	Risk Difference Black vs White	Risk Difference Other vs White	Total N=59412 (100%)
All patients with any hypersensitivity reaction	307 (0.6%)	63 (0.7%)	0	8 (4.4%)	-0.09%	-0.70%	3.72%	378 (0.6%)
Urticaria	104 (0.2%)	18 (0.2%)	0	3 (1.7%)	0.01%	-0.20%	1.46%	125 (0.2%)
Pruritus	83 (0.2%)	25 (0.3%)	0	2 (1.1%)	-0.11%	-0.28%	0.83%	110 (0.2%)
Rash	82 (0.2%)	3 (<0.1%)	0	0	0.13%	-0.03%	-0.03%	85 (0.1%)
Erythema	37 (<0.1%)	18 (0.2%)	0	2 (1.1%)	-0.13%	-0.20%	0.90%	57 (<0.1%)
Sneezing	30 (<0.1%)	5 (<0.1%)	0	0	<0.00%	-0.06%	-0.06%	35 (<0.1%)
Dyspnoea	21 (<0.1%)	7 (<0.1%)	0	2 (1.1%)	-0.04%	-0.08%	1.03%	30 (<0.1%)
Cough	12 (<0.1%)	6 (<0.1%)	0	2 (1.1%)	-0.04%	-0.07%	1.04%	20 (<0.1%)
Bronchospasm	3 (<0.1%)	1 (<0.1%)	0	1 (0.6%)	-0.01%	-0.01%	0.54%	5 (<0.1%)
Anaphylactic shock	1 (<0.1%)	0	0	0	<0.00%	<0.00%	<0.00%	1 (<0.1%)
Dysphonia	1 (<0.1%)	0	0	0	<0.00%	<0.00%	<0.00%	1 (<0.1%)
Eye swelling	1 (<0.1%)	0	0	0	<0.00%	<0.00%	<0.00%	1 (<0.1%)
Respiratory arrest	1 (<0.1%)	0	0	0	<0.00%	<0.00%	<0.00%	1 (<0.1%)
Throat irritation	0	1 (<0.1%)	0	0	-0.01%	-0.01%	-0.01%	1 (<0.1%)

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Table 14.6 / 3: Occurrence and risk differences of hypersensitivity reactions by geographical region (levels: APAC, Europe, Rest of the World, North America). MedDRA preferred terms (Full analysis set for geographical region)

Preferred term MedDRA version 21.0	APAC N=25473 (100%)	Europe N=69561 (100%)	North America N=6791 (100%)	Rest of the World N=44824 (100%)	Risk Difference APAC vs Europe	Risk Difference Rest of the World vs Europe	Risk Difference North America vs Europe	Total N=146649 (100%)
All patients with any hypersensitivity reaction	254 (1.0%)	364 (0.5%)	51 (0.8%)	236 (0.5%)	0.47%	<0.00%	0.23%	905 (0.6%)
Pruritus	101 (0.4%)	151 (0.2%)	32 (0.5%)	59 (0.1%)	0.18%	-0.09%	0.25%	343 (0.2%)
Urticaria	143 (0.6%)	73 (0.1%)	24 (0.4%)	39 (<0.1%)	0.46%	-0.02%	0.25%	279 (0.2%)
Rash	14 (<0.1%)	102 (0.1%)	6 (<0.1%)	79 (0.2%)	-0.09%	0.03%	-0.06%	201 (0.1%)
Erythema	30 (0.1%)	54 (<0.1%)	0	30 (<0.1%)	0.04%	-0.01%	-0.08%	114 (<0.1%)
Dyspnoea	17 (<0.1%)	49 (<0.1%)	1 (<0.1%)	33 (<0.1%)	-0.00%	<0.00%	-0.06%	100 (<0.1%)
Cough	12 (<0.1%)	61 (<0.1%)	4 (<0.1%)	15 (<0.1%)	-0.04%	-0.05%	-0.03%	92 (<0.1%)
Sneezing	18 (<0.1%)	29 (<0.1%)	6 (<0.1%)	26 (<0.1%)	0.03%	0.02%	0.05%	79 (<0.1%)
Bronchospasm	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	6 (<0.1%)	0.01%	0.01%	0.01%	10 (<0.1%)
Throat irritation	0	4 (<0.1%)	1 (<0.1%)	0	-0.01%	-0.01%	0.01%	5 (<0.1%)
Face oedema	0	4 (<0.1%)	0	0	-0.01%	-0.01%	-0.01%	4 (<0.1%)
Dysphagia	0	3 (<0.1%)	0	0	-0.00%	-0.00%	-0.00%	3 (<0.1%)
Nasal congestion	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0	<0.00%	-0.00%	0.01%	3 (<0.1%)
Dysphonia	1 (<0.1%)	1 (<0.1%)	0	0	<0.00%	-0.00%	-0.00%	2 (<0.1%)
Eye swelling	0	1 (<0.1%)	0	1 (<0.1%)	-0.00%	<0.00%	-0.00%	2 (<0.1%)
Anaphylactic shock	0	0	0	1 (<0.1%)	<0.00%	<0.00%	<0.00%	1 (<0.1%)
Lacrimation increased	0	1 (<0.1%)	0	0	-0.00%	-0.00%	-0.00%	1 (<0.1%)
Laryngeal oedema	0	1 (<0.1%)	0	0	-0.00%	-0.00%	-0.00%	1 (<0.1%)
Respiratory arrest	0	0	0	1 (<0.1%)	<0.00%	<0.00%	<0.00%	1 (<0.1%)
Rhinitis	0	1 (<0.1%)	0	0	-0.00%	-0.00%	-0.00%	1 (<0.1%)

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Table 14.6 / 4: Occurrence and risk differences of hypersensitivity reactions by country/region (levels: Germany, South Korea, China). MedDRA preferred terms (Full analysis set for country/region)

Preferred term	China	Germany	South Korea	Risk Difference	Risk Difference	Total
MedDRA version 21.0	N=36928 (100%)	N=45618 (100%)	N=13745 (100%)	South Korea vs Germany	China vs Germany	N=96291 (100%)
All patients with any hypersensitivity reaction	152 (0.4%)	234 (0.5%)	105 (0.8%)	0.25%	-0.10%	491 (0.5%)
Pruritus	28 (<0.1%)	107 (0.2%)	40 (0.3%)	0.06%	-0.16%	175 (0.2%)
Rash	77 (0.2%)	74 (0.2%)	0	-0.16%	0.05%	151 (0.2%)
Urticaria	18 (<0.1%)	42 (<0.1%)	74 (0.5%)	0.45%	-0.04%	134 (0.1%)
Erythema	11 (<0.1%)	39 (<0.1%)	3 (<0.1%)	-0.06%	-0.06%	53 (<0.1%)
Sneezing	18 (<0.1%)	24 (<0.1%)	10 (<0.1%)	0.02%	-0.00%	52 (<0.1%)
Cough	2 (<0.1%)	46 (0.1%)	2 (<0.1%)	-0.09%	-0.10%	50 (<0.1%)
Dyspnoea	12 (<0.1%)	26 (<0.1%)	8 (<0.1%)	<0.00%	-0.02%	46 (<0.1%)
Face oedema	0	4 (<0.1%)	0	-0.01%	-0.01%	4 (<0.1%)
Dysphagia	0	3 (<0.1%)	0	-0.01%	-0.01%	3 (<0.1%)
Throat irritation	0	3 (<0.1%)	0	-0.01%	-0.01%	3 (<0.1%)
Bronchospasm	2 (<0.1%)	0	0	<0.00%	0.01%	2 (<0.1%)
Dysphonia	0	1 (<0.1%)	1 (<0.1%)	0.01%	-0.00%	2 (<0.1%)
Eye swelling	1 (<0.1%)	1 (<0.1%)	0	-0.00%	<0.00%	2 (<0.1%)
Anaphylactic shock	1 (<0.1%)	0	0	<0.00%	<0.00%	1 (<0.1%)
Lacrimation increased	0	1 (<0.1%)	0	-0.00%	-0.00%	1 (<0.1%)
Laryngeal oedema	0	1 (<0.1%)	0	-0.00%	-0.00%	1 (<0.1%)
Nasal congestion	0	0	1 (<0.1%)	0.01%	<0.00%	1 (<0.1%)
Respiratory arrest	1 (<0.1%)	0	0	<0.00%	<0.00%	1 (<0.1%)
Rhinitis	0	1 (<0.1%)	0	-0.00%	-0.00%	1 (<0.1%)

Bayer: /var/swan/root/bhc/864877/22133/stat/main01/prod/analysis/pgms/t_adae_ana_rea.sas 01DEC2022 15:33
End of table