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Table 15.1.1a.1 Indications for Tigecycline Use – On/Off Label Use by Country - Greece

	Before RMM (N=15)	After RMM (N=12)	Overall (N=27)
On-Label Indications (cIAI or cSSTI in adult patients)	9(60.0%)	9(75.0%)	18(66.7%)
Off-Label Indications (other infection or use in pediatric patients)	6(40.0%)	3(25.0%)	9(33.3%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1 Indications for Tigecycline Use – On/Off Label Use by Country - UK

	Before RMM (N=169)	After RMM (N=75)	Overall (N=244)
On-Label Indications (cIAI or cSSTI in adult patients)	65(38.5%)	42(56.0%)	107(43.9%)
Off-Label Indications (other infection or use in pediatric patients)	104(61.5%)	33(44.0%)	137(56.1%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1 Indications for Tigecycline Use – On/Off Label Use by Country - Italy

	Before RMM (N=26)	After RMM (N=64)	Overall (N=90)
On-Label Indications (cIAI or cSSTI in adult patients)	18(69.2%)	50(78.1%)	68(75.6%)
Off-Label Indications (other infection or use in pediatric patients)	8(30.8%)	14(21.9%)	22(24.4%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.1 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Germany

	Before RMM (N=19)	After RMM (N=33)	Overall (N=52)
Site 1001			
On-Label Indications (cIAI or cSSTI in adult patients)	18(94.7%)	28(84.8%)	46(88.5%)
Off-Label Indications (other infection or use in pediatric patients)	1(5.3%)	5(15.2%)	6(11.5%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.1 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Germany

	Before RMM (N=62)	After RMM (N=36)	Overall (N=98)
Site 1015			
On-Label Indications (cIAI or cSSTI in adult patients)	28(45.2%)	23(63.9%)	51(52.0%)
Off-Label Indications (other infection or use in pediatric patients)	34(54.8%)	13(36.1%)	47(48.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.1 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Germany

	Before RMM (N=39)	After RMM (N=43)	Overall (N=82)
Site 1024			
On-Label Indications (cIAI or cSSTI in adult patients)	13(33.3%)	21(48.8%)	34(41.5%)
Off-Label Indications (other infection or use in pediatric patients)	26(66.7%)	22(51.2%)	48(58.5%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.1 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Germany

	Before RMM (N=26)	After RMM (N=57)	Overall (N=83)
Site 1027			
On-Label Indications (cIAI or cSSTI in adult patients)	23(88.5%)	54(94.7%)	77(92.8%)
Off-Label Indications (other infection or use in pediatric patients)	3(11.5%)	3(5.3%)	6(7.2%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.2 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Austria

	Before RMM (N=38)	After RMM (N=51)	Overall (N=89)
Site 1016			
On-Label Indications (cIAI or cSSTI in adult patients)	15(39.5%)	24(47.1%)	39(43.8%)
Off-Label Indications (other infection or use in pediatric patients)	23(60.5%)	27(52.9%)	50(56.2%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.2 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Austria

	Before RMM (N=5)	After RMM (N=7)	Overall (N=12)
Site 1020			
On-Label Indications (cIAI or cSSTI in adult patients)	0(0.0%)	1(14.3%)	1(8.3%)
Off-Label Indications (other infection or use in pediatric patients)	5(100.0%)	6(85.7%)	11(91.7%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.3 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Greece

	Before RMM (N=1)	After RMM (N=0)	Overall (N=1)
Site 1004			
On-Label Indications (cIAI or cSSTI in adult patients)	0(0.0%)		0(0%)
Off-Label Indications (other infection or use in pediatric patients)	1(100.0%)		1(100%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.3 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Greece

	Before RMM (N=14)	After RMM (N=12)	Overall (N=26)
Site 1006			
On-Label Indications (cIAI or cSSTI in adult patients)	9(64.3%)	9(75.0%)	18(69.2%)
Off-Label Indications (other infection or use in pediatric patients)	5(35.7%)	3(25.0%)	8(30.8%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.4 Indications for Tigecycline Use – On/Off Label Use by Country and Site - UK

	Before RMM (N=167)	After RMM (N=67)	Overall (N=234)
Site 1023			
On-Label Indications (cIAI or cSSTI in adult patients)	64(38.3%)	41(61.2%)	105(44.9%)
Off-Label Indications (other infection or use in pediatric patients)	103(61.7%)	26(38.8%)	129(55.1%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.4 Indications for Tigecycline Use – On/Off Label Use by Country and Site - UK

	Before RMM (N=2)	After RMM (N=8)	Overall (N=10)
Site 1030			
On-Label Indications (cIAI or cSSTI in adult patients)	1(50.0%)	1(12.5%)	2(20.0%)
Off-Label Indications (other infection or use in pediatric patients)	1(50.0%)	7(87.5%)	8(80.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.5 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Italy

	Before RMM (N=12)	After RMM (N=0)	Overall (N=12)
Site 1002			
On-Label Indications (cIAI or cSSTI in adult patients)	6(50.0%)		6(50.0%)
Off-Label Indications (other infection or use in pediatric patients)	6(50.0%)		6(50.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.5 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Italy

	Before RMM (N=11)	After RMM (N=19)	Overall (N=30)
Site 1017			
On-Label Indications (cIAI or cSSTI in adult patients)	10(90.9%)	18(94.7%)	28(93.3%)
Off-Label Indications (other infection or use in pediatric patients)	1(9.1%)	1(5.3%)	2(6.7%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.1.1a.1.5 Indications for Tigecycline Use – On/Off Label Use by Country and Site - Italy

	Before RMM (N=3)	After RMM (N=45)	Overall (N=48)
Site 1018			
On-Label Indications (cIAI or cSSTI in adult patients)	2(66.7%)	32(71.1%)	34(70.8%)
Off-Label Indications (other infection or use in pediatric patients)	1(33.3%)	13(28.9%)	14(29.2%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.2.0 Patient Demographics – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Age on Admission (years)								
n	373	129	42	202	314	142	60	112
Mean(SD)	63.2(15.98)	62.0(14.46)	63.4(16.48)	64.0(16.81)	59.2(16.66)	59.0(15.01)	60.2(16.04)	58.8(18.94)
Median	65.0	63.0	65.0	66.0	62.0	62.0	61.0	62.0
Min, Max	14.0,97.0	22.0,95.0	21.0,86.0	14.0,97.0	12.0,94.0	19.0,86.0	22.0,90.0	12.0,94.0
Missing	0	0	0	0	0	0	0	0
Age on Admission (Category)								
n	373	129	42	202	314	142	60	112
<18 years	2(0.5%)	0(0.0%)	0(0.0%)	2(1.0%)	5(1.6%)	0(0.0%)	0(0.0%)	5(4.5%)
18-44 years	49(13.1%)	14(10.9%)	7(16.7%)	28(13.9%)	50(15.9%)	23(16.2%)	10(16.7%)	17(15.2%)
45-64 years	141(37.8%)	59(45.7%)	15(35.7%)	67(33.2%)	130(41.4%)	65(45.8%)	26(43.3%)	39(34.8%)
65+ years	181(48.5%)	56(43.4%)	20(47.6%)	105(52.0%)	129(41.1%)	54(38.0%)	24(40.0%)	51(45.5%)
Missing	0	0	0	0	0	0	0	0
Gender								
n	373	129	42	202	314	142	60	112
Male	177(47.5%)	62(48.1%)	20(47.6%)	95(47.0%)	180(57.3%)	90(63.4%)	29(48.3%)	61(54.5%)
Female	196(52.5%)	67(51.9%)	22(52.4%)	107(53.0%)	134(42.7%)	52(36.6%)	31(51.7%)	51(45.5%)
Missing	0	0	0	0	0	0	0	0
Weight (kg)								
n	267	100	37	130	259	124	51	84
Mean(SD)	76.2(19.96)	72.8(16.87)	78.4(23.52)	78.2(20.84)	77.8(21.55)	77.7(19.60)	84.7(23.10)	73.9(22.55)
Median	74.0	70.0	71.0	76.2	75.0	75.0	81.0	70.6
Min, Max	35.0,169.0	35.0,140.0	40.0,143.0	39.8,169.0	36.6,185.0	40.0,142.0	40.0,185.0	36.6,155.0
Missing	106	29	5	72	55	18	9	28
Height (cm)								
n	236	89	31	116	234	111	43	80
Mean (SD)	169.7(9.43)	170.2(9.56)	166.0(9.29)	170.2(9.23)	169.3(9.60)	170.9(9.90)	168.0(8.23)	167.8(9.62)
Median	170.0	170.0	168.0	170.0	170.0	170.0	168.0	168.0
Min, Max	150.0,195.0	150.0,195.0	150.0,186.0	150.0,187.0	141.0,198.0	146.0,198.0	152.0,190.0	141.0,192.0
Missing	137	40	11	86	80	31	17	32

	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
BMI (kg/m2)								
n	107	32	16	59	71	22	15	34
Mean (SD)	27.1(7.08)	25.3(6.39)	26.3(3.98)	28.3(7.89)	27.6(7.43)	27.1(6.45)	29.0(7.02)	27.2(8.28)
Median	26.0	23.5	26.0	27.0	27.0	26.6	29.0	25.0
Min, Max	18.0,55.0	18.0,41.0	19.0,33.6	18.0,55.0	18.0,56.2	18.0,46.0	19.0,47.0	18.1,56.2
Missing	266	97	26	143	243	120	45	78

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.2.0 Patient Demographics – Primary Analysis Set (PAS) population (continued)

	All Patients (N=687)			
	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Age on Admission (years)				
n	687	271	102	314
Mean(SD)	61.4(16.40)	60.4(14.79)	61.5(16.22)	62.1(17.74)
Median	63.0	62.0	63.5	65.0
Min, Max	12.0,97.0	19.0,95.0	21.0,90.0	12.0,97.0
Missing	0	0	0	0
Age on Admission (Category)				
n	687	271	102	314
<18 years	7(1.0%)	0(0.0%)	0(0.0%)	7(2.2%)
18-44 years	99(14.4%)	37(13.7%)	17(16.7%)	45(14.3%)
45-64 years	271(39.4%)	124(45.8%)	41(40.2%)	106(33.8%)
65+ years	310(45.1%)	110(40.6%)	44(43.1%)	156(49.7%)
Missing	0	0	0	0
Gender				
n	687	271	102	314
Male	357(52.0%)	152(56.1%)	49(48.0%)	156(49.7%)
Female	330(48.0%)	119(43.9%)	53(52.0%)	158(50.3%)
Missing	0	0	0	0
Weight (kg)				
n	526	224	88	214
Mean(SD)	77.0(20.76)	75.5(18.55)	82.0(23.35)	76.5(21.58)
Median	75.0	74.0	77.0	74.4
Min, Max	35.0,185.0	35.0,142.0	40.0,185.0	36.6,169.0
Missing	161	47	14	100
Height (cm)				
n	470	200	74	196
Mean (SD)	169.5(9.51)	170.6(9.73)	167.2(8.69)	169.3(9.44)
Median	170.0	170.0	168.0	170.0
Min, Max	141.0,198.0	146.0,198.0	150.0,190.0	141.0,192.0
Missing	217	71	28	118
BMI (kg/m2)				

	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
n	178	54	31	93
Mean (SD)	27.3(7.20)	26.1(6.42)	27.6(5.74)	27.9(8.01)
Median	26.0	24.5	27.0	27.0
Min, Max	18.0,56.2	18.0,46.0	19.0,47.0	18.0,56.2
Missing	509	217	71	221

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.2.0a Patient Demographics – Full Analysis Set (FAS) population

	Before RMM (N=399)				After RMM (N=378)			
	Any Indication (n=399)	cIAI (n=144)	cSSTI (n=45)	Off-label (n=210)	Any Indication (n=378)	cIAI (n=183)	cSSTI (n=69)	Off-label (n=126)
Age on Admission (years)								
n	399	144	45	210	378	183	69	126
Mean(SD)	63.3(15.96)	62.9(14.26)	63.3(16.25)	63.6(17.02)	59.7(16.39)	59.6(14.83)	61.2(15.98)	58.9(18.68)
Median	65.0	64.0	65.0	66.0	62.0	62.0	64.0	62.0
Min, Max	14.0,97.0	22.0,95.0	21.0,86.0	14.0,97.0	12.0,94.0	19.0,92.0	22.0,90.0	12.0,94.0
Missing	0	0	0	0	0	0	0	0
Age on Admission (Category)								
n	399	144	45	210	378	183	69	126
<18 years	2(0.5%)	0(0.0%)	0(0.0%)	2(1.0%)	5(1.3%)	0(0.0%)	0(0.0%)	5(4.0%)
18-44 years	52(13.0%)	14(9.7%)	7(15.6%)	31(14.8%)	58(15.3%)	27(14.8%)	11(15.9%)	20(15.9%)
45-64 years	150(37.6%)	64(44.4%)	17(37.8%)	69(32.9%)	156(41.3%)	84(45.9%)	27(39.1%)	45(35.7%)
65+ years	195(48.9%)	66(45.8%)	21(46.7%)	108(51.4%)	159(42.1%)	72(39.3%)	31(44.9%)	56(44.4%)
Missing	0	0	0	0	0	0	0	0
Gender								
n	399	144	45	210	378	183	69	126
Male	194(48.6%)	71(49.3%)	22(48.9%)	101(48.1%)	221(58.5%)	119(65.0%)	34(49.3%)	68(54.0%)
Female	205(51.4%)	73(50.7%)	23(51.1%)	109(51.9%)	157(41.5%)	64(35.0%)	35(50.7%)	58(46.0%)
Missing	0	0	0	0	0	0	0	0
Weight (kg)								
n	289	112	40	137	305	152	57	96
Mean(SD)	76.0(19.76)	72.8(16.42)	77.2(23.26)	78.1(20.93)	76.8(20.64)	76.9(18.66)	83.2(22.39)	72.9(21.77)
Median	74.0	70.0	70.0	76.0	75.0	75.0	80.0	70.0
Min, Max	35.0,169.0	35.0,140.0	40.0,143.0	39.8,169.0	36.6,185.0	40.0,142.0	40.0,185.0	36.6,155.0
Missing	110	32	5	73	73	31	12	30
Height (cm)								
n	250	97	33	120	280	139	49	92
Mean (SD)	169.7(9.32)	170.1(9.35)	166.3(9.39)	170.3(9.16)	169.6(9.40)	170.8(9.47)	168.7(8.54)	168.3(9.58)
Median	170.0	170.0	168.0	170.0	170.0	170.0	168.0	168.5
Min, Max	150.0,195.0	150.0,195.0	150.0,186.0	150.0,187.0	141.0,198.0	146.0,198.0	152.0,190.0	141.0,192.0
Missing	149	47	12	90	98	44	20	34

	Any Indication (n=399)	cIAI (n=144)	cSSTI (n=45)	Off-label (n=210)	Any Indication (n=378)	cIAI (n=183)	cSSTI (n=69)	Off-label (n=126)
BMI (kg/m2)								
n	117	38	18	61	118	51	21	46
Mean (SD)	26.9(6.83)	25.3(5.94)	26.0(3.80)	28.2(7.81)	26.3(6.49)	26.1(5.33)	27.5(6.75)	26.1(7.55)
Median	26.0	24.0	25.4	27.0	25.0	25.0	28.0	24.3
Min, Max	18.0,55.0	18.0,41.0	19.0,33.6	18.0,55.0	18.0,56.2	18.0,46.0	19.0,47.0	18.0,56.2
Missing	282	106	27	149	260	132	48	80

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.2.0a Patient Demographics – Full Analysis Set (FAS) population (continued)

	All Patients (N=777)			
	Any Indication (n=777)	cIAI (n=327)	cSSTI (n=114)	Off-label (n=336)
Age on Admission (years)				
n	777	327	114	336
Mean(SD)	61.5(16.26)	61.1(14.65)	62.0(16.05)	61.8(17.78)
Median	64.0	63.0	64.5	65.0
Min, Max	12.0,97.0	19.0,95.0	21.0,90.0	12.0,97.0
Missing	0	0	0	0
Age on Admission (Category)				
n	777	327	114	336
<18 years	7(0.9%)	0(0.0%)	0(0.0%)	7(2.1%)
18-44 years	110(14.2%)	41(12.5%)	18(15.8%)	51(15.2%)
45-64 years	306(39.4%)	148(45.3%)	44(38.6%)	114(33.9%)
65+ years	354(45.6%)	138(42.2%)	52(45.6%)	164(48.8%)
Missing	0	0	0	0
Gender				
n	777	327	114	336
Male	415(53.4%)	190(58.1%)	56(49.1%)	169(50.3%)
Female	362(46.6%)	137(41.9%)	58(50.9%)	167(49.7%)
Missing	0	0	0	0
Weight (kg)				
n	594	264	97	233
Mean(SD)	76.4(20.20)	75.1(17.83)	80.7(22.83)	76.0(21.39)
Median	74.2	74.0	76.0	73.2
Min, Max	35.0,185.0	35.0,142.0	40.0,185.0	36.6,169.0
Missing	183	63	17	103
Height (cm)				
n	530	236	82	212
Mean (SD)	169.7(9.36)	170.5(9.41)	167.7(8.91)	169.4(9.38)
Median	170.0	170.0	168.0	170.0
Min, Max	141.0,198.0	146.0,198.0	150.0,190.0	141.0,192.0
Missing	247	91	32	124
BMI (kg/m2)				
n	235	89	39	107
Mean (SD)	26.6(6.66)	25.8(5.58)	26.8(5.57)	27.3(7.73)

	Any Indication (n=777)	cIAI (n=327)	cSSTI (n=114)	Off-label (n=336)
Median	26.0	24.7	26.0	26.0
Min, Max	18.0,56.2	18.0,46.0	19.0,47.0	18.0,56.2
Missing	542	238	75	229

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_DEMO
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Table 15.3.0 Medical History – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=130)	cSSTI (n=42)	Off-label (n=201)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Immunocompromised state	69(18.5%)	32(24.8%)	4(9.5%)	33(16.3%)	68(21.7%)	39(27.5%)	6(10.0%)	23(20.5%)
HIV/AIDS	3(0.8%)	2(1.6%)	0(0.0%)	1(0.5%)	2(0.6%)	0(0.0%)	0(0.0%)	2(1.8%)
Organ transplantation	31(8.3%)	18(14.0%)	1(2.4%)	12(5.9%)	36(11.5%)	26(18.3%)	1(1.7%)	9(8.0%)
Recent chemotherapy*	28(7.5%)	8(6.2%)	3(7.1%)	17(8.4%)	23(7.3%)	11(7.7%)	3(5.0%)	9(8.0%)
Recent use of anti-TNF agents or other biologic immunomodifiers*	8(2.1%)	5(3.9%)	0(0.0%)	3(1.5%)	16(5.1%)	14(9.9%)	0(0.0%)	2(1.8%)
Radiation or steroid treatment	19(5.1%)	8(6.2%)	1(2.4%)	10(5.0%)	17(5.4%)	8(5.6%)	1(1.7%)	8(7.1%)
Etiology of immunocompromise unspecified	3(0.8%)	0(0.0%)	0(0.0%)	3(1.5%)	3(1.0%)	0(0.0%)	1(1.7%)	2(1.8%)
Malignancy	104(27.9%)	46(35.7%)	9(21.4%)	49(24.3%)	104(33.1%)	64(45.1%)	11(18.3%)	29(25.9%)
Leukemia	11(2.9%)	1(0.8%)	0(0.0%)	10(5.0%)	8(2.5%)	2(1.4%)	1(1.7%)	5(4.5%)
Lymphoma	9(2.4%)	2(1.6%)	2(4.8%)	5(2.5%)	8(2.5%)	4(2.8%)	0(0.0%)	4(3.6%)
Non-metastatic solid Tumor	52(13.9%)	33(25.6%)	3(7.1%)	16(7.9%)	52(16.6%)	34(23.9%)	6(10.0%)	12(10.7%)
Metastatic disease	24(6.4%)	9(7.0%)	3(7.1%)	12(5.9%)	29(9.2%)	20(14.1%)	3(5.0%)	6(5.4%)
Malignancy type unspecified	10(2.7%)	3(2.3%)	1(2.4%)	6(3.0%)	9(2.9%)	6(4.2%)	1(1.7%)	2(1.8%)
Liver disease	56(15.0%)	33(25.6%)	6(14.3%)	17(8.4%)	72(22.9%)	54(38.0%)	4(6.7%)	14(12.5%)
Mild liver disease	10(2.7%)	5(3.9%)	1(2.4%)	4(2.0%)	16(5.1%)	9(6.3%)	3(5.0%)	4(3.6%)
Moderate to severe liver disease	39(10.5%)	26(20.2%)	4(9.5%)	9(4.5%)	50(15.9%)	39(27.5%)	1(1.7%)	10(8.9%)
Other or not otherwise specified liver disease	7(1.9%)	2(1.6%)	1(2.4%)	4(2.0%)	6(1.9%)	6(4.2%)	0(0.0%)	0(0.0%)
Severe renal disease	50(13.4%)	17(13.2%)	5(11.9%)	28(13.9%)	47(15.0%)	16(11.3%)	6(10.0%)	25(22.3%)
Moderate renal disease	31(8.3%)	13(10.1%)	4(9.5%)	14(6.9%)	41(13.1%)	28(19.7%)	5(8.3%)	8(7.1%)
Diabetes with end organ damage	29(7.8%)	5(3.9%)	2(4.8%)	22(10.9%)	22(7.0%)	6(4.2%)	7(11.7%)	9(8.0%)
Diabetes without end organ damage	63(16.9%)	28(21.7%)	5(11.9%)	30(14.9%)	58(18.5%)	31(21.8%)	8(13.3%)	19(17.0%)
Cardiovascular disease	138(37.0%)	43(33.3%)	22(52.4%)	73(36.1%)	114(36.3%)	33(23.2%)	32(53.3%)	49(43.8%)
Myocardial infarction	28(7.5%)	11(8.5%)	4(9.5%)	13(6.4%)	34(10.8%)	13(9.2%)	8(13.3%)	13(11.6%)
Congestive heart failure	22(5.9%)	9(7.0%)	4(9.5%)	9(4.5%)	22(7.0%)	3(2.1%)	6(10.0%)	13(11.6%)
Cerebrovascular Disease	25(6.7%)	8(6.2%)	4(9.5%)	13(6.4%)	13(4.1%)	6(4.2%)	1(1.7%)	6(5.4%)
Peripheral vascular Disease	32(8.6%)	6(4.7%)	9(21.4%)	17(8.4%)	18(5.7%)	4(2.8%)	5(8.3%)	9(8.0%)

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	Any Indication (n=373)	cIAI (n=130)	cSSTI (n=42)	Off-label (n=201)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Other or not otherwise specified cardiovascular disease	75(20.1%)	22(17.1%)	12(28.6%)	41(20.3%)	70(22.3%)	18(12.7%)	20(33.3%)	32(28.6%)
Peptic ulcer disease	6(1.6%)	4(3.1%)	0(0.0%)	2(1.0%)	13(4.1%)	7(4.9%)	3(5.0%)	3(2.7%)
Chronic pulmonary disease	50(13.4%)	17(13.2%)	7(16.7%)	26(12.9%)	34(10.8%)	8(5.6%)	6(10.0%)	20(17.9%)
Connective tissue disease	6(1.6%)	1(0.8%)	1(2.4%)	4(2.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Dementia	8(2.1%)	2(1.6%)	2(4.8%)	4(2.0%)	5(1.6%)	2(1.4%)	1(1.7%)	2(1.8%)
Hemiplegia	5(1.3%)	1(0.8%)	1(2.4%)	3(1.5%)	7(2.2%)	5(3.5%)	2(3.3%)	0(0.0%)
Recent neutropenia*	11(2.9%)	5(3.9%)	0(0.0%)	6(3.0%)	10(3.2%)	4(2.8%)	1(1.7%)	5(4.5%)
Mild	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	3(1.0%)	2(1.4%)	0(0.0%)	1(0.9%)
Moderate	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Severe	4(1.1%)	1(0.8%)	0(0.0%)	3(1.5%)	5(1.6%)	0(0.0%)	1(1.7%)	4(3.6%)
Not known	3(0.8%)	0(0.0%)	0(0.0%)	3(1.5%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)

*Recent – Within 6 months of hospital admission.
cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, HIV/AIDS=Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome, RMM=Risk Minimization Measure, TNF=Tumor Necrosis Factor.
Data cut-off date: 22May2014
Analysis dataset: A_COMB
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Table 15.3.0 Medical History – Primary Analysis Set (PAS) population (continued)

	All patients (N=687)			
	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Immunocompromised state	137(19.9%)	71(26.2%)	10(9.8%)	56(17.8%)
HIV/AIDS	5(0.7%)	2(0.7%)	0(0.0%)	3(1.0%)
Organ transplantation	67(9.8%)	44(16.2%)	2(2.0%)	21(6.7%)
Recent chemotherapy*	51(7.4%)	19(7.0%)	6(5.9%)	26(8.3%)
Recent use of anti-TNF agents or other biologic immunomodifiers*	24(3.5%)	19(7.0%)	0(0.0%)	5(1.6%)
Radiation or steroid treatment	36(5.2%)	16(5.9%)	2(2.0%)	18(5.7%)
Etiology of immunocompromise unspecified	6(0.9%)	0(0.0%)	1(1.0%)	5(1.6%)
Malignancy	208(30.3%)	110(40.6%)	20(19.6%)	78(24.8%)
Leukemia	19(2.8%)	3(1.1%)	1(1.0%)	15(4.8%)
Lymphoma	17(2.5%)	6(2.2%)	2(2.0%)	9(2.9%)
Non-metastatic solid Tumor	104(15.1%)	67(24.7%)	9(8.8%)	28(8.9%)
Metastatic disease	53(7.7%)	29(10.7%)	6(5.9%)	18(5.7%)
Malignancy type unspecified	19(2.8%)	9(3.3%)	2(2.0%)	8(2.5%)
Liver disease	128(18.6%)	87(32.1%)	10(9.8%)	31(9.9%)
Mild liver disease	26(3.8%)	14(5.2%)	4(3.9%)	8(2.5%)
Moderate to severe liver disease	89(13.0%)	65(24.0%)	5(4.9%)	19(6.1%)
Other or not otherwise specified liver disease	13(1.9%)	8(3.0%)	1(1.0%)	4(1.3%)
Severe renal disease	97(14.1%)	33(12.2%)	11(10.8%)	53(16.9%)
Moderate renal disease	72(10.5%)	41(15.1%)	9(8.8%)	22(7.0%)
Diabetes with end organ damage	51(7.4%)	11(4.1%)	9(8.8%)	31(9.9%)
Diabetes without end organ damage	121(17.6%)	59(21.8%)	13(12.7%)	49(15.6%)
Cardiovascular disease	252(36.7%)	76(28.0%)	54(52.9%)	122(38.9%)
Myocardial infarction	62(9.0%)	24(8.9%)	12(11.8%)	26(8.3%)
Congestive heart failure	44(6.4%)	12(4.4%)	10(9.8%)	22(7.0%)
Cerebrovascular Disease	38(5.5%)	14(5.2%)	5(4.9%)	19(6.1%)
Peripheral vascular Disease	50(7.3%)	10(3.7%)	14(13.7%)	26(8.3%)
Other or not otherwise specified cardiovascular disease	145(21.1%)	40(14.8%)	32(31.4%)	73(23.2%)

	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Peptic ulcer disease	19(2.8%)	11(4.1%)	3(2.9%)	5(1.6%)
Chronic pulmonary disease	84(12.2%)	25(9.2%)	13(12.7%)	46(14.6%)
Connective tissue disease	7(1.0%)	1(0.4%)	2(2.0%)	4(1.3%)
Dementia	13(1.9%)	4(1.5%)	3(2.9%)	6(1.9%)
Hemiplegia	12(1.7%)	6(2.2%)	3(2.9%)	3(1.0%)
Recent neutropenia*	21(3.1%)	9(3.3%)	1(1.0%)	11(3.5%)
Mild	5(0.7%)	4(1.5%)	0(0.0%)	1(0.3%)
Moderate	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Severe	9(1.3%)	1(0.4%)	1(1.0%)	7(2.2%)
Not known	4(0.6%)	1(0.4%)	0(0.0%)	3(1.0%)

*Recent – Within 6 months of hospital admission.
cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, HIV/AIDS=Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome, RMM=Risk Minimization Measure, TNF=Tumor Necrosis Factor.
Data cut-off date: 22May2014
Analysis dataset: A_COMB
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Table 15.4.0 History of Antibiotic Use Prior to Tigecycline – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Other Antibiotic Use 7 Days prior to Tigecycline								
n	369	129	42	198	303	141	57	105
Yes	255(69.1%)	97(75.2%)	37(88.1%)	121(61.1%)	264(87.1%)	122(86.5%)	43(75.4%)	99(94.3%)
No	114(30.9%)	32(24.8%)	5(11.9%)	77(38.9%)	39(12.9%)	19(13.5%)	14(24.6%)	6(5.7%)
Missing	4	0	0	4	11	1	3	7
If Yes to Other Antibiotic Use, please specify								
n#	255	97	37	121	264	122	43	99
Amikacin	1(0.4%)	0(0.0%)	0(0.0%)	1(0.8%)	4(1.5%)	0(0.0%)	1(2.3%)	3(3.0%)
Amoxicillin /clavulanate	4(1.6%)	1(1.0%)	3(8.1%)	0(0.0%)	4(1.5%)	3(2.5%)	0(0.0%)	1(1.0%)
Aztreonam	3(1.2%)	0(0.0%)	0(0.0%)	3(2.5%)	7(2.7%)	3(2.5%)	1(2.3%)	3(3.0%)
Bactrim	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Cefepime	5(2.0%)	1(1.0%)	2(5.4%)	2(1.7%)	5(1.9%)	1(0.8%)	2(4.7%)	2(2.0%)
Cefotaxime	2(0.8%)	0(0.0%)	1(2.7%)	1(0.8%)	1(0.4%)	0(0.0%)	1(2.3%)	0(0.0%)
Cefpirome	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.8%)	1(0.8%)	1(2.3%)	0(0.0%)
Ceftriaxone	10(3.9%)	4(4.1%)	1(2.7%)	5(4.1%)	6(2.3%)	2(1.6%)	1(2.3%)	3(3.0%)
Ceftazidime	14(5.5%)	2(2.1%)	1(2.7%)	11(9.1%)	7(2.7%)	1(0.8%)	1(2.3%)	5(5.1%)
Colistin	5(2.0%)	1(1.0%)	0(0.0%)	4(3.3%)	8(3.0%)	1(0.8%)	1(2.3%)	6(6.1%)
Ciprofloxacin	64(25.1%)	22(22.7%)	6(16.2%)	36(29.8%)	45(17.0%)	21(17.2%)	5(11.6%)	19(19.2%)
Doripenem	5(2.0%)	0(0.0%)	0(0.0%)	5(4.1%)	1(0.4%)	1(0.8%)	0(0.0%)	0(0.0%)
Gentamicin	10(3.9%)	4(4.1%)	1(2.7%)	5(4.1%)	8(3.0%)	3(2.5%)	2(4.7%)	3(3.0%)
Imipenem /cilastatin	16(6.3%)	7(7.2%)	0(0.0%)	9(7.4%)	20(7.6%)	13(10.7%)	3(7.0%)	4(4.0%)
Levofloxacin	10(3.9%)	2(2.1%)	3(8.1%)	5(4.1%)	6(2.3%)	5(4.1%)	0(0.0%)	1(1.0%)
Linezolid	16(6.3%)	4(4.1%)	2(5.4%)	10(8.3%)	27(10.2%)	5(4.1%)	8(18.6%)	14(14.1%)
Meropenem	74(29.0%)	31(32.0%)	9(24.3%)	34(28.1%)	96(36.4%)	44(36.1%)	12(27.9%)	40(40.4%)
Metronidazole	56(22.0%)	23(23.7%)	3(8.1%)	30(24.8%)	45(17.0%)	22(18.0%)	9(20.9%)	14(14.1%)
Piperacillin /tazobactam	53(20.8%)	23(23.7%)	8(21.6%)	22(18.2%)	52(19.7%)	28(23.0%)	8(18.6%)	16(16.2%)
Piperacillin	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Rifampicin	4(1.6%)	0(0.0%)	1(2.7%)	3(2.5%)	5(1.9%)	0(0.0%)	0(0.0%)	5(5.1%)
Teicoplanin	12(4.7%)	4(4.1%)	2(5.4%)	6(5.0%)	13(4.9%)	2(1.6%)	1(2.3%)	10(10.1%)

	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Vancomycin	70(27.5%)	23(23.7%)	8(21.6%)	39(32.2%)	78(29.5%)	34(27.9%)	14(32.6%)	30(30.3%)
Other*	94(36.9%)	28(28.9%)	20(54.1%)	46(38.0%)	112(42.4%)	47(38.5%)	21(48.8%)	44(44.4%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
# represents number of patients who responded 'Yes' to <<Was the patient treated with any other antibiotics during hospitalization within 7 days PRIOR to initiating Tigecycline?>>
*Please refer to Listing 2 for further specification.
Data cut-off date: 22May2014
Analysis dataset: A_MEDS
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Table 15.4.0 History of Antibiotic Use Prior to Tigecycline – Primary Analysis Set (PAS) population (continued)

	All Patients (N=687)			
	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Other Antibiotic Use 7 Days prior to Tigecycline				
n	672	270	99	303
Yes	519(77.2%)	219(81.1%)	80(80.8%)	220(72.6%)
No	153(22.8%)	51(18.9%)	19(19.2%)	83(27.4%)
Missing	15	1	3	11
If Yes to Other Antibiotic Use, please specify				
n#	519	219	80	220
Amikacin	5(1.0%)	0(0.0%)	1(1.3%)	4(1.8%)
Amoxicillin /clavulanate	8(1.5%)	4(1.8%)	3(3.8%)	1(0.5%)
Aztreonam	10(1.9%)	3(1.4%)	1(1.3%)	6(2.7%)
Bactrim	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Cefepime	10(1.9%)	2(0.9%)	4(5.0%)	4(1.8%)
Cefotaxime	3(0.6%)	0(0.0%)	2(2.5%)	1(0.5%)
Cefpirome	2(0.4%)	1(0.5%)	1(1.3%)	0(0.0%)
Ceftriaxone	16(3.1%)	6(2.7%)	2(2.5%)	8(3.6%)
Ceftazidime	21(4.0%)	3(1.4%)	2(2.5%)	16(7.3%)
Colistin	13(2.5%)	2(0.9%)	1(1.3%)	10(4.5%)
Ciprofloxacin	109(21.0%)	43(19.6%)	11(13.8%)	55(25.0%)
Doripenem	6(1.2%)	1(0.5%)	0(0.0%)	5(2.3%)
Gentamicin	18(3.5%)	7(3.2%)	3(3.8%)	8(3.6%)
Imipenem /cilastatin	36(6.9%)	20(9.1%)	3(3.8%)	13(5.9%)
Levofloxacin	16(3.1%)	7(3.2%)	3(3.8%)	6(2.7%)
Linezolid	43(8.3%)	9(4.1%)	10(12.5%)	24(10.9%)
Meropenem	170(32.8%)	75(34.2%)	21(26.3%)	74(33.6%)
Metronidazole	101(19.5%)	45(20.5%)	12(15.0%)	44(20.0%)
Piperacillin /tazobactam	105(20.2%)	51(23.3%)	16(20.0%)	38(17.3%)
Piperacillin	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Rifampicin	9(1.7%)	0(0.0%)	1(1.3%)	8(3.6%)
Teicoplanin	25(4.8%)	6(2.7%)	3(3.8%)	16(7.3%)

	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Vancomycin	148(28.5%)	57(26.0%)	22(27.5%)	69(31.4%)
Other*	206(39.7%)	75(34.2%)	41(51.3%)	90(40.9%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
# represents number of patients who responded 'Yes' to <<Was the patient treated with any other antibiotics during hospitalization within 7 days PRIOR to initiating Tigecycline?>>
*Please refer to Listing 2 for further specification.
Data cut-off date: 22May2014
Analysis dataset: A_MEDS
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Table 15.4.1 Medication History: Most Common (Top 5) Other Antibiotic Use – Primary Analysis Set (PAS) population

	Before RMM (N=373)		After RMM (N=314)		All Patients (N=687)	
Other Antibiotic Use:	Antibiotic	n(%)	Antibiotic	n(%)	Antibiotic	n(%)
	CEFUROXIME	13(3.5%)	CEFUROXIME	10(3.2%)	CEFUROXIME	23(3.3%)
	CLINDAMYCIN	11(2.9%)	CLINDAMYCIN	10(3.2%)	CLINDAMYCIN	21(3.1%)
	DAPTOMYCIN	9(2.4%)	FLUCONAZOLE	10(3.2%)	CLARITHROMYCIN	16(2.3%)
	CLARITHROMYCIN	8(2.1%)	ERYTHROMYCIN	9(2.9%)	ERYTHROMYCIN	14(2.0%)
	FOSFOMYCIN	7(1.9%)	CLARITHROMYCIN	8(2.5%)	FLUCONAZOLE	14(2.0%)
	MOXIFLOXACIN	7(1.9%)				

RMM=Risk Minimization Measure
Other Antibiotics are converted to capital letters. No other modification was carried out.
Data cut-off date: 22May2014
Analysis dataset: A_MEDS
Created by Y:\Pfizer\Tygacil\Tables\Table4.1.sas

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Table 15.5.0 Surgical History – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Surgical Procedure or Other Therapeutic Interventions prior to Tigecycline								
Yes	170(45.6%)	79(61.2%)	29(69.0%)	62(30.7%)	233(74.2%)	133(93.7%)	40(66.7%)	60(53.6%)
No	200(53.6%)	48(37.2%)	12(28.6%)	140(69.3%)	81(25.8%)	9(6.3%)	20(33.3%)	52(46.4%)
Not documented	3(0.8%)	2(1.6%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Surgical procedures, specify Preferred Term								
Abdominal cavity drainage	8(2.1%)	6(4.7%)	0(0.0%)	2(1.0%)	9(2.9%)	8(5.6%)	0(0.0%)	1(0.9%)
Abdominal hernia repair	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Abdominoplasty	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Abscess drainage	9(2.4%)	4(3.1%)	4(9.5%)	1(0.5%)	15(4.8%)	12(8.5%)	0(0.0%)	3(2.7%)
Abscess management	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Acute respiratory failure	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Adhesiolysis	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	4(1.3%)	4(2.8%)	0(0.0%)	0(0.0%)
Aneurysm repair	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Angioplasty	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Anorectal operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Aortic aneurysm repair	2(0.5%)	1(0.8%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Aortic bypass	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Aortic surgery	2(0.5%)	1(0.8%)	0(0.0%)	1(0.5%)	2(0.6%)	1(0.7%)	1(1.7%)	0(0.0%)
Aortic valve replacement	5(1.3%)	0(0.0%)	1(2.4%)	4(2.0%)	8(2.5%)	0(0.0%)	3(5.0%)	5(4.5%)
Appendicectomy	3(0.8%)	1(0.8%)	0(0.0%)	2(1.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Arterial graft	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Arterial repair	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Arteriogram coronary	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Aspiration pleural cavity	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Bile duct exploration	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Bile duct stent removal	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Biliary anastomosis	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Biliary drainage	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Biliary sphincterotomy	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Biliary tract operation	3(0.8%)	3(2.3%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Biopsy kidney	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Biopsy liver	2(0.5%)	2(1.5%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Biopsy lymph gland	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Bladder operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Bone marrow transplant	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Bone operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Brachytherapy to uterus	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Brain tumour operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	1(1.7%)	1(0.9%)
Breast reconstruction	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Bronchoscopy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
CSF shunt removal	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Caesarean section	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Cardiac pacemaker insertion	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	3(1.0%)	0(0.0%)	2(3.3%)	1(0.9%)
Cardiac pacemaker removal	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Catheterisation cardiac	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Central venous catheter removal	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	3(1.0%)	3(2.1%)	0(0.0%)	0(0.0%)
Central venous catheterisation	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Chest tube insertion	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Chest wall operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Cholangiogram	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	1(0.7%)	0(0.0%)	1(0.9%)
Cholangiostomy	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Cholecystectomy	4(1.1%)	2(1.6%)	0(0.0%)	2(1.0%)	4(1.3%)	4(2.8%)	0(0.0%)	0(0.0%)
Cholelithotomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Colectomy	13(3.5%)	12(9.3%)	1(2.4%)	0(0.0%)	19(6.1%)	15(10.6%)	1(1.7%)	3(2.7%)
Colon fistula repair	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Colonoscopy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	3(1.0%)	0(0.0%)	0(0.0%)	3(2.7%)
Colostomy	5(1.3%)	4(3.1%)	0(0.0%)	1(0.5%)	6(1.9%)	5(3.5%)	1(1.7%)	0(0.0%)
Computerised tomogram	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Coronary angioplasty	2(0.5%)	0(0.0%)	2(4.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Coronary arterial stent insertion	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	1(1.7%)	1(0.9%)
Coronary artery bypass	6(1.6%)	1(0.8%)	1(2.4%)	4(2.0%)	8(2.5%)	0(0.0%)	3(5.0%)	5(4.5%)
Coronary revascularisation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Craniotomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Cystoscopy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Cytoreductive surgery	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Debridement	7(1.9%)	1(0.8%)	4(9.5%)	2(1.0%)	21(6.7%)	6(4.2%)	9(15.0%)	6(5.4%)
Drain of cerebral subdural space	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	1(1.7%)	1(0.9%)
Drain placement	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Duodenectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	1(0.7%)	0(0.0%)	1(0.9%)
Empyema drainage	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Endoscopic retrograde cholangiopancreatography	4(1.1%)	3(2.3%)	0(0.0%)	1(0.5%)	5(1.6%)	2(1.4%)	0(0.0%)	3(2.7%)
Endoscopy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Enema administration	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Enterostomy	4(1.1%)	3(2.3%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Explorative laparotomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	6(1.9%)	4(2.8%)	0(0.0%)	2(1.8%)
External fixation of fracture	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	1(1.7%)	1(0.9%)

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Extracorporeal membrane oxygenation	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	3(1.0%)	0(0.0%)	1(1.7%)	2(1.8%)
Fasciotomy	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Fistula repair	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Foot amputation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	1(1.7%)	1(0.9%)
Foot operation	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Foraminotomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Fracture reduction	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Fracture treatment	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Gallbladder fistula repair	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Gastrectomy	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	5(1.6%)	4(2.8%)	1(1.7%)	0(0.0%)
Gastric bypass	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Gastric ulcer surgery	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Gastroenterostomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Gastrointestinal tube insertion	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Haemangioma removal	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Haematoma evacuation	3(0.8%)	1(0.8%)	1(2.4%)	1(0.5%)	7(2.2%)	3(2.1%)	1(1.7%)	3(2.7%)
Haemodialysis	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Hand amputation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Hepatectomy	9(2.4%)	9(7.0%)	0(0.0%)	0(0.0%)	13(4.1%)	12(8.5%)	0(0.0%)	1(0.9%)
Hepatic embolisation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Hepaticojejunostomy	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	2(0.6%)	1(0.7%)	0(0.0%)	1(0.9%)
Hernia hiatus repair	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Hernia repair	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Hip arthroplasty	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	5(1.6%)	1(0.7%)	2(3.3%)	2(1.8%)
Hysterectomy	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Hysterosalpingo-oophorectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Ileectomy	3(0.8%)	3(2.3%)	0(0.0%)	0(0.0%)	3(1.0%)	2(1.4%)	1(1.7%)	0(0.0%)
Ileocolectomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	4(1.3%)	4(2.8%)	0(0.0%)	0(0.0%)
Ileocolostomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Ileostomy	6(1.6%)	4(3.1%)	1(2.4%)	1(0.5%)	5(1.6%)	5(3.5%)	0(0.0%)	0(0.0%)
Impaired healing	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Incisional hernia repair	2(0.5%)	1(0.8%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Internal fixation of fracture	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	1(0.7%)	1(1.7%)	0(0.0%)
Intervertebral disc operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Intestinal anastomosis	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	4(1.3%)	2(1.4%)	1(1.7%)	1(0.9%)
Intestinal fistula repair	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Intestinal operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Intestinal resection	2(0.5%)	1(0.8%)	0(0.0%)	1(0.5%)	8(2.5%)	5(3.5%)	2(3.3%)	1(0.9%)
Intestinal stent insertion	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Intramedullary rod insertion	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Jaw operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Jejunal operation	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Jejunectomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Jejunostomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Joint irrigation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Laparoscopy	3(0.8%)	2(1.6%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Laparotomy	14(3.8%)	11(8.5%)	2(4.8%)	1(0.5%)	36(11.5%)	26(18.3%)	3(5.0%)	7(6.3%)
Large intestine anastomosis	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Leg amputation	6(1.6%)	1(0.8%)	2(4.8%)	3(1.5%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Liver transplant	13(3.5%)	9(7.0%)	1(2.4%)	3(1.5%)	16(5.1%)	13(9.2%)	1(1.7%)	2(1.8%)
Lung lobectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Lung transplant	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	0(0.0%)	2(1.8%)
Lymphadenectomy	3(0.8%)	3(2.3%)	0(0.0%)	0(0.0%)	2(0.6%)	1(0.7%)	0(0.0%)	1(0.9%)
Malignant tumour excision	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Mediastinoscopy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Medical device removal	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Mitral valve replacement	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	3(1.0%)	2(1.4%)	0(0.0%)	1(0.9%)
Nephrectomy	2(0.5%)	0(0.0%)	0(0.0%)	2(1.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Nephrostomy	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Nephrostomy tube placement	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Oesophageal dilatation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Oesophageal operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Oesophageal variceal ligation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Oesophagectomy	2(0.5%)	0(0.0%)	1(2.4%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Oesophagogastroduodenoscopy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Oesophagogastroscopy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Omentectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	3(1.0%)	2(1.4%)	1(1.7%)	0(0.0%)
Oral surgery	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Osteosynthesis	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Pancreas transplant	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Pancreatectomy	5(1.3%)	4(3.1%)	0(0.0%)	1(0.5%)	8(2.5%)	6(4.2%)	0(0.0%)	2(1.8%)
Pancreatic operation	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Pancreaticoduodenectomy	5(1.3%)	1(0.8%)	2(4.8%)	2(1.0%)	5(1.6%)	5(3.5%)	0(0.0%)	0(0.0%)
Pancreaticogastrostomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Paracentesis	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Partial lung resection	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	0(0.0%)	2(1.8%)
Pelvic exploration	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Pelvic pouch procedure	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Penile repair	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Pericardial excision	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Peripheral artery angioplasty	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Peripheral artery bypass	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Peritoneal lavage	13(3.5%)	12(9.3%)	0(0.0%)	1(0.5%)	25(8.0%)	20(14.1%)	2(3.3%)	3(2.7%)
Portoenterostomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Procoagulant therapy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Proctocolectomy	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Pulmonary endarterectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Radical cystectomy	2(0.5%)	1(0.8%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Radical hysterectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Radical neck dissection	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Removal of renal transplant	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Renal transplant	5(1.3%)	2(1.5%)	1(2.4%)	2(1.0%)	4(1.3%)	2(1.4%)	0(0.0%)	2(1.8%)
Resection of rectum	2(0.5%)	2(1.5%)	0(0.0%)	0(0.0%)	7(2.2%)	5(3.5%)	1(1.7%)	1(0.9%)
Rib excision	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Scrotal operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Sigmoidectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Skeletal traction	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Skin graft	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(3.3%)	0(0.0%)
Skin operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Small intestinal anastomosis	3(0.8%)	3(2.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Small intestinal resection	8(2.1%)	6(4.6%)	1(2.4%)	1(0.5%)	8(2.5%)	7(4.9%)	1(1.7%)	0(0.0%)
Small intestine operation	3(0.8%)	1(0.8%)	0(0.0%)	2(1.0%)	5(1.6%)	4(2.8%)	0(0.0%)	1(0.9%)
Spinal cord drainage	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Spinal decompression	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Spinal fusion surgery	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Spinal laminectomy	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Splenectomy	5(1.3%)	1(0.8%)	0(0.0%)	4(2.0%)	3(1.0%)	1(0.7%)	0(0.0%)	2(1.8%)
Stem cell transplant	3(0.8%)	0(0.0%)	0(0.0%)	3(1.5%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Subdural haematoma evacuation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Surgical vascular shunt	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Suture insertion	3(0.8%)	0(0.0%)	0(0.0%)	3(1.5%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Testicular operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Therapeutic embolisation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	2(1.4%)	0(0.0%)	0(0.0%)
Thoracic cavity drainage	4(1.1%)	1(0.8%)	2(4.8%)	1(0.5%)	5(1.6%)	1(0.7%)	0(0.0%)	4(3.5%)
Thoracic operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Thrombectomy	2(0.5%)	1(0.8%)	0(0.0%)	1(0.5%)	3(1.0%)	0(0.0%)	1(1.7%)	2(1.8%)
Thromboembolectomy	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Toe amputation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	0(0.0%)	2(1.8%)
Tracheostomy	8(2.1%)	2(1.6%)	0(0.0%)	6(3.0%)	11(3.5%)	3(2.1%)	2(3.3%)	6(5.4%)
Transurethral bladder resection	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Tricuspid valve repair	2(0.5%)	0(0.0%)	1(2.4%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Tumour excision	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Umbilical hernia repair	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Ureterectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Urethrectomy	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Urostomy	2(0.5%)	2(1.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Urostomy closure	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vaginal operation	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vaginectomy	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vascular graft	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Venous operation	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	2(0.6%)	1(0.7%)	0(0.0%)	1(0.9%)
Venous repair	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vertebroplasty	1(0.3%)	0(0.0%)	1(2.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vesicoureteral reflux surgery	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)

	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Vulval operation	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Vulvectomy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(1.7%)	0(0.0%)
Wound closure	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	4(1.3%)	1(0.7%)	3(5.0%)	0(0.0%)
Wound drainage	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Wound treatment	10(2.7%)	3(2.3%)	3(7.1%)	4(2.0%)	33(10.5%)	14(9.9%)	14(23.3%)	5(4.5%)
UNCODED TERMS	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SURG
Created by Y:\Pfizer\Tygacil\Tables\Table5.0.sas

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Table 15.5.0 Surgical History – Primary Analysis Set (PAS) population (continued)

	All Patients (N=687)			
	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Surgical Procedure or Other Therapeutic Interventions prior to Tigecycline				
Yes	403(58.7%)	212(78.2%)	69(67.6%)	122(38.9%)
No	281(40.9%)	57(21.0%)	32(31.4%)	192(61.1%)
Not documented	3(0.4%)	2(0.7%)	1(1.0%)	0(0.0%)
Surgical procedures, specify Preferred Term				
Abdominal cavity drainage	17(2.5%)	14(5.2%)	0(0.0%)	3(1.0%)
Abdominal hernia repair	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Abdominoplasty	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Abscess drainage	24(3.5%)	16(5.9%)	4(3.9%)	4(1.3%)
Abscess management	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Acute respiratory failure	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Adhesiolysis	4(0.6%)	4(1.5%)	0(0.0%)	0(0.0%)
Aneurysm repair	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Angioplasty	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Anorectal operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Aortic aneurysm repair	2(0.3%)	1(0.4%)	1(1.0%)	0(0.0%)
Aortic bypass	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Aortic surgery	4(0.6%)	2(0.7%)	1(1.0%)	1(0.3%)
Aortic valve replacement	13(1.9%)	0(0.0%)	4(3.9%)	9(2.9%)
Appendicectomy	4(0.6%)	2(0.7%)	0(0.0%)	2(0.6%)
Arterial graft	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Arterial repair	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Arteriogram coronary	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Aspiration pleural cavity	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Bile duct exploration	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Bile duct stent removal	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Biliary anastomosis	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Biliary drainage	2(0.3%)	0(0.0%)	0(0.0%)	2(0.6%)
Biliary sphincterotomy	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Biliary tract operation	4(0.6%)	4(1.5%)	0(0.0%)	0(0.0%)
Biopsy kidney	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Biopsy liver	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Biopsy lymph gland	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Bladder operation	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Bone marrow transplant	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Bone operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Brachytherapy to uterus	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Brain tumour operation	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Breast reconstruction	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Bronchoscopy	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
CSF shunt removal	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Caesarean section	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Cardiac pacemaker insertion	4(0.6%)	0(0.0%)	3(2.9%)	1(0.3%)
Cardiac pacemaker removal	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Catheterisation cardiac	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Central venous catheter removal	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Central venous catheterisation	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Chest tube insertion	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Chest wall operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Cholangiogram	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Cholangiostomy	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Cholecystectomy	8(1.2%)	6(2.2%)	0(0.0%)	2(0.6%)
Cholelithotomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Colectomy	32(4.7%)	27(10.0%)	2(2.0%)	3(1.0%)
Colon fistula repair	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Colonoscopy	4(0.6%)	1(0.4%)	0(0.0%)	3(1.0%)
Colostomy	11(1.6%)	9(3.3%)	1(1.0%)	1(0.3%)
Computerised tomogram	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Coronary angioplasty	2(0.3%)	0(0.0%)	2(2.0%)	0(0.0%)
Coronary arterial stent insertion	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Coronary artery bypass	14(2.0%)	1(0.4%)	4(3.9%)	9(2.9%)
Coronary revascularisation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Craniotomy	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Cystoscopy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Cytoreductive surgery	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Debridement	28(4.1%)	7(2.6%)	13(12.7%)	8(2.5%)
Drain of cerebral subdural space	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Drain placement	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Duodenectomy	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Empyema drainage	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Endoscopic retrograde cholangiopancreatography	9(1.3%)	5(1.8%)	0(0.0%)	4(1.3%)
Endoscopy	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Enema administration	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Enterostomy	4(0.6%)	3(1.1%)	1(1.0%)	0(0.0%)
Explorative laparotomy	6(0.9%)	4(1.5%)	0(0.0%)	2(0.6%)
External fixation of fracture	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Extracorporeal membrane oxygenation	4(0.6%)	0(0.0%)	1(1.0%)	3(1.0%)
Fasciotomy	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Fistula repair	2(0.3%)	1(0.4%)	1(1.0%)	0(0.0%)

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Foot amputation	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Foot operation	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Foraminotomy	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Fracture reduction	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Fracture treatment	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Gallbladder fistula repair	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Gastrectomy	7(1.0%)	6(2.2%)	1(1.0%)	0(0.0%)
Gastric bypass	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Gastric ulcer surgery	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Gastroenterostomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Gastrointestinal tube insertion	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Haemangioma removal	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Haematoma evacuation	10(1.5%)	4(1.5%)	2(2.0%)	4(1.3%)
Haemodialysis	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Hand amputation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Hepatectomy	22(3.2%)	21(7.7%)	0(0.0%)	1(0.3%)
Hepatic embolisation	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Hepaticojejunostomy	4(0.6%)	3(1.1%)	0(0.0%)	1(0.3%)
Hernia hiatus repair	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Hernia repair	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Hip arthroplasty	6(0.9%)	1(0.4%)	3(2.9%)	2(0.6%)
Hysterectomy	3(0.4%)	2(0.7%)	1(1.0%)	0(0.0%)
Hysterosalpingo-oophorectomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Ileectomy	6(0.9%)	5(1.8%)	1(1.0%)	0(0.0%)
Ileocolectomy	5(0.7%)	5(1.8%)	0(0.0%)	0(0.0%)
Ileocolostomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Ileostomy	11(1.6%)	9(3.3%)	1(1.0%)	1(0.3%)
Impaired healing	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Incisional hernia repair	2(0.3%)	1(0.4%)	1(1.0%)	0(0.0%)
Internal fixation of fracture	2(0.3%)	1(0.4%)	1(1.0%)	0(0.0%)
Intervertebral disc operation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Intestinal anastomosis	6(0.9%)	4(1.5%)	1(1.0%)	1(0.3%)
Intestinal fistula repair	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Intestinal operation	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Intestinal resection	10(1.5%)	6(2.2%)	2(2.0%)	2(0.6%)
Intestinal stent insertion	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Intramedullary rod insertion	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Jaw operation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Jejunal operation	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Jejunectomy	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Jejunostomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Joint irrigation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Laparoscopy	3(0.4%)	2(0.7%)	1(1.0%)	0(0.0%)
Laparotomy	50(7.3%)	37(13.7%)	5(4.9%)	8(2.5%)
Large intestine anastomosis	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Leg amputation	7(1.0%)	1(0.4%)	2(2.0%)	4(1.3%)

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Liver transplant	29(4.2%)	22(8.1%)	2(2.0%)	5(1.6%)
Lung lobectomy	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Lung transplant	2(0.3%)	0(0.0%)	0(0.0%)	2(0.6%)
Lymphadenectomy	5(0.7%)	4(1.5%)	0(0.0%)	1(0.3%)
Malignant tumour excision	2(0.3%)	0(0.0%)	0(0.0%)	2(0.6%)
Mediastinoscopy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Medical device removal	2(0.3%)	1(0.4%)	1(1.0%)	0(0.0%)
Mitral valve replacement	4(0.6%)	2(0.7%)	0(0.0%)	2(0.6%)
Nephrectomy	4(0.6%)	2(0.7%)	0(0.0%)	2(0.6%)
Nephrostomy	3(0.4%)	2(0.7%)	0(0.0%)	1(0.3%)
Nephrostomy tube placement	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Oesophageal dilatation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Oesophageal operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Oesophageal variceal ligation	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Oesophagectomy	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Oesophagogastroduodenoscopy	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Oesophagogastroscopy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Omentectomy	3(0.4%)	2(0.7%)	1(1.0%)	0(0.0%)
Oral surgery	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Osteosynthesis	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Pancreas transplant	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Pancreatectomy	13(1.9%)	10(3.7%)	0(0.0%)	3(1.0%)
Pancreatic operation	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Pancreaticoduodenectomy	10(1.5%)	6(2.2%)	2(2.0%)	2(0.6%)
Pancreaticogastrostomy	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Paracentesis	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Partial lung resection	2(0.3%)	0(0.0%)	0(0.0%)	2(0.6%)
Pelvic exploration	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Pelvic pouch procedure	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Penile repair	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Pericardial excision	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Peripheral artery angioplasty	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Peripheral artery bypass	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Peritoneal lavage	38(5.5%)	32(11.8%)	2(2.0%)	4(1.3%)
Portoenterostomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Procoagulant therapy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Proctocolectomy	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Pulmonary endarterectomy	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Radical cystectomy	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Radical hysterectomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Radical neck dissection	2(0.3%)	0(0.0%)	0(0.0%)	2(0.6%)
Removal of renal transplant	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Renal transplant	9(1.3%)	4(1.5%)	1(1.0%)	4(1.3%)
Resection of rectum	9(1.3%)	7(2.6%)	1(1.0%)	1(0.3%)
Rib excision	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Scrotal operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Sigmoidectomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Skeletal traction	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Skin graft	2(0.3%)	0(0.0%)	2(2.0%)	0(0.0%)
Skin operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Small intestinal anastomosis	3(0.4%)	3(1.1%)	0(0.0%)	0(0.0%)
Small intestinal resection	16(2.3%)	13(4.8%)	2(2.0%)	1(0.3%)
Small intestine operation	8(1.2%)	5(1.8%)	0(0.0%)	3(1.0%)
Spinal cord drainage	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Spinal decompression	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Spinal fusion surgery	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Spinal laminectomy	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Splenectomy	8(1.2%)	2(0.7%)	0(0.0%)	6(1.9%)
Stem cell transplant	4(0.6%)	0(0.0%)	0(0.0%)	4(1.3%)
Subdural haematoma evacuation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Surgical vascular shunt	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Suture insertion	4(0.6%)	0(0.0%)	1(1.0%)	3(1.0%)
Testicular operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Therapeutic embolisation	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Thoracic cavity drainage	9(1.3%)	2(0.7%)	2(2.0%)	5(1.6%)
Thoracic operation	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Thrombectomy	5(0.7%)	1(0.4%)	1(1.0%)	3(1.0%)
Thromboembolectomy	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Toe amputation	2(0.3%)	0(0.0%)	0(0.0%)	2(0.6%)
Tracheostomy	19(2.8%)	5(1.8%)	2(2.0%)	12(3.8%)
Transurethral bladder resection	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Tricuspid valve repair	2(0.3%)	0(0.0%)	1(1.0%)	1(0.3%)
Tumour excision	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Umbilical hernia repair	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Ureterectomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Urethrectomy	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Urostomy	2(0.3%)	2(0.7%)	0(0.0%)	0(0.0%)
Urostomy closure	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Vaginal operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Vaginectomy	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Vascular graft	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Venous operation	3(0.4%)	2(0.7%)	0(0.0%)	1(0.3%)
Venous repair	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Vertebroplasty	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Vesicoureteral reflux surgery	1(0.1%)	1(0.4%)	0(0.0%)	0(0.0%)
Vulval operation	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Vulvectomy	1(0.1%)	0(0.0%)	1(1.0%)	0(0.0%)
Wound closure	5(0.7%)	2(0.7%)	3(2.9%)	0(0.0%)
Wound drainage	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Wound treatment	43(6.3%)	17(6.3%)	17(16.7%)	9(2.9%)
UNCODED TERMS	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SURG
Created by Y:\Pfizer\Tygacil\Tables\Table5.0.sas

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Table 15.6.0 Hospitalization – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Ward of Admission								
n	373	129	42	202	314	142	60	112
Surgical	168(45.0%)	78(60.5%)	18(42.9%)	72(35.6%)	159(50.6%)	88(62.0%)	31(51.7%)	40(35.7%)
Medical	88(23.6%)	25(19.4%)	10(23.8%)	53(26.2%)	50(15.9%)	19(13.4%)	7(11.7%)	24(21.4%)
Hemato-oncology	22(5.9%)	4(3.1%)	1(2.4%)	17(8.4%)	14(4.5%)	6(4.2%)	0(0.0%)	8(7.1%)
ICU	50(13.4%)	12(9.3%)	7(16.7%)	31(15.3%)	57(18.2%)	18(12.7%)	14(23.3%)	25(22.3%)
Infectious disease	16(4.3%)	2(1.6%)	1(2.4%)	13(6.4%)	9(2.9%)	0(0.0%)	2(3.3%)	7(6.3%)
Other*	29(7.8%)	8(6.2%)	5(11.9%)	16(7.9%)	25(8.0%)	11(7.7%)	6(10.0%)	8(7.1%)
Missing	0	0	0	0	0	0	0	0
Standard measures of patient's disease prior to Tigecycline available?								
n	373	129	42	202	314	142	60	112
Yes	234(62.7%)	88(68.2%)	21(50.0%)	125(61.9%)	171(54.5%)	89(62.7%)	28(46.7%)	54(48.2%)
No	139(37.3%)	41(31.8%)	21(50.0%)	77(38.1%)	143(45.5%)	53(37.3%)	32(53.3%)	58(51.8%)
Missing	0	0	0	0	0	0	0	0
APACHE II Score								
n	116	47	15	54	124	75	16	33
Mean (SD)	24.3(8.63)	23.1(9.29)	22.1(7.20)	25.9(8.24)	22.7(8.09)	21.3(8.00)	22.2(8.07)	25.9(7.61)
Median	23.5	24.0	22.0	24.5	23.0	21.0	20.5	27.0
Min, Max	3,44	3,40	9,38	12,44	3,40	3,39	11,40	11,36
Missing	257	82	27	148	190	67	44	79
APACHE II (Categorical)								
n	116	47	15	54	124	75	16	33
< 15	15(12.9%)	10(21.3%)	2(13.3%)	3(5.6%)	24(19.4%)	17(22.7%)	3(18.8%)	4(12.1%)
>= 15	101(87.1%)	37(78.7%)	13(86.7%)	51(94.4%)	100(80.6%)	58(77.3%)	13(81.3%)	29(87.9%)
Missing	257	82	27	148	190	67	44	79
SAPS II								
n	118	48	15	55	123	75	16	32
Mean (SD)	51.9(20.57)	51.4(23.49)	42.8(17.56)	54.8(18.00)	48.3(19.48)	45.4(19.64)	47.2(18.18)	55.9(18.18)
Median	51.0	52.0	42.0	51.0	45.0	45.0	43.5	54.0
Min, Max	7,111	7,104	19,80	25,111	9,104	9,104	19,78	28,96

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Missing	255	81	27	147	191	67	44	80
MODS								
n	1	0	0	1	0	0	0	0
Mean (SD)	6.0()			6.0()				
Median	6.0			6.0				
Min, Max	6,6			6,6				
Missing	372	129	42	201	314	142	60	112
SOFA								
n	109	47	12	50	119	74	15	30
Mean (SD)	8.3(4.67)	7.7(4.52)	5.1(4.08)	9.7(4.51)	8.1(5.30)	7.4(5.35)	6.8(4.16)	10.2(5.22)
Median	8.0	7.0	5.5	9.0	8.0	7.0	5.0	10.0
Min, Max	0,19	0,19	0,12	1,19	0,22	0,22	1,15	1,22
Missing	264	82	30	152	195	68	45	82
Glasgow Coma Scale								
n	169	66	13	90	128	69	17	42
Mean (SD)	11.4(4.56)	11.0(4.65)	11.2(4.49)	11.6(4.54)	10.7(4.58)	11.1(4.42)	11.6(4.31)	9.7(4.86)
Median	14.0	14.0	12.0	15.0	11.5	13.0	14.0	10.0
Min, Max	3,15	3,15	3,15	3,15	3,15	3,15	3,15	3,15
Missing	204	63	29	112	186	73	43	70
Child Pugh Score								
n	6	5	1	0	7	6	0	1
A (5-6)	0(0.0%)	0(0.0%)	0(0.0%)		2(28.6%)	1(16.7%)		1(100.0%)
B (7-9)	3(50.0%)	2(40.0%)	1(100.0%)		1(14.3%)	1(16.7%)		0(0.0%)
C (10-15)	3(50.0%)	3(60.0%)	0(0.0%)		4(57.1%)	4(66.7%)		0(0.0%)
Missing	367	124	41	202	307	136	60	111

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, MODS=Multiple Organ Dysfunction Score,
RMM=Risk Minimization Measure, SAPS=Simplified Acute Physiology Score, SOFA=Sepsis-related Organ Failure Assessment.
*Please refer to Listing 3 for further specification.
Data cut-off date: 22May2014
Analysis dataset: A_HOSP
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Table 15.6.0 Hospitalization – Primary Analysis Set (PAS) population (continued)

	All Patients (N=687)			
	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Ward of Admission				
n	687	271	102	314
Surgical	327(47.6%)	166(61.3%)	49(48.0%)	112(35.7%)
Medical	138(20.1%)	44(16.2%)	17(16.7%)	77(24.5%)
Hemato-oncology	36(5.2%)	10(3.7%)	1(1.0%)	25(8.0%)
ICU	107(15.6%)	30(11.1%)	21(20.6%)	56(17.8%)
Infectious disease	25(3.6%)	2(0.7%)	3(2.9%)	20(6.4%)
Other*	54(7.9%)	19(7.0%)	11(10.8%)	24(7.6%)
Missing	0	0	0	0
Standard measures of patient's disease prior to Tigecycline available?				
n	687	271	102	314
Yes	405(59.0%)	177(65.3%)	49(48.0%)	179(57.0%)
No	282(41.0%)	94(34.7%)	53(52.0%)	135(43.0%)
Missing	0	0	0	0
APACHE II Score				
n	240	122	31	87
Mean (SD)	23.5(8.38)	22.0(8.53)	22.1(7.53)	25.9(7.96)
Median	23.0	21.0	22.0	26.0
Min, Max	3,44	3,40	9,40	11,44
Missing	447	149	71	227
APACHE II (Categorical)				
n	240	122	31	87
< 15	39(16.3%)	27(22.1%)	5(16.1%)	7(8.0%)
>= 15	201(83.8%)	95(77.9%)	26(83.9%)	80(92.0%)
Missing	447	149	71	227
SAPS II				
n	241	123	31	87
Mean (SD)	50.1(20.06)	47.7(21.34)	45.1(17.73)	55.2(17.97)
Median	48.0	46.0	43.0	52.0
Min, Max	7,111	7,104	19,80	25,111
Missing	446	148	71	227

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
MODS				
n	1	0	0	1
Mean (SD)	6.0()			6.0()
Median	6.0			6.0
Min, Max	6,6			6,6
Missing	686	271	102	313
SOFA				
n	228	121	27	80
Mean (SD)	8.2(5.00)	7.5(5.03)	6.0(4.14)	9.9(4.76)
Median	8.0	7.0	5.0	9.5
Min, Max	0,22	0,22	0,15	1,22
Missing	459	150	75	234
Glasgow Coma Scale				
n	297	135	30	132
Mean (SD)	11.1(4.57)	11.1(4.52)	11.5(4.32)	11.0(4.71)
Median	14.0	14.0	14.0	14.0
Min, Max	3,15	3,15	3,15	3,15
Missing	390	136	72	182
Child Pugh Score				
n	13	11	1	1
A (5-6)	2(15.4%)	1(9.1%)	0(0.0%)	1(100.0%)
B (7-9)	4(30.8%)	3(27.3%)	1(100.0%)	0(0.0%)
C (10-15)	7(53.8%)	7(63.6%)	0(0.0%)	0(0.0%)
Missing	674	260	101	313

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, MODS=Multiple Organ Dysfunction Score,
RMM=Risk Minimization Measure, SAPS=Simplified Acute Physiology Score, SOFA=Sepsis-related Organ Failure Assessment.
*Please refer to Listing 3 for further specification.
Data cut-off date: 22May2014
Analysis dataset: A_HOSP
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Table 15.6.1 Hospitalization: Most Common (Top 5) Patient Admission/Discharge Diagnoses – Primary Analysis Set (PAS) population

	Before RMM (N=373)		After RMM (N=314)		All Patients (N=687)	
Admission Diagnoses:	Diagnoses	n(%)	Diagnoses	n(%)	Diagnoses	n(%)
	Cholangitis	16(4.3%)	Arterial Hypertension	23(7.3%)	Arterial Hypertension	37(5.4%)
	Arterial Hypertension	14(3.8%)	Hypertension	14(4.5%)	Hypertension	28(4.1%)
	Hypertension	14(3.8%)	Diabetes Mellitus	12(3.8%)	Diabetes Mellitus	24(3.5%)
	Cholecystitis	13(3.5%)	Atrial Fibrillation	12(3.8%)	Atrial Fibrillation	20(2.9%)
	Diabetes Mellitus	12(3.2%)	Pneumonia	11(3.5%)	Cholangitis	19(2.8%)
					Pneumonia	19(2.8%)
Discharge Diagnoses:	Diagnoses	n(%)	Diagnoses	n(%)	Diagnoses	n(%)
	Pneumonia	23(6.2%)	Arterial Hypertension	27(8.6%)	Pneumonia	49(7.1%)
	Acute Kidney Failure	21(5.6%)	Pneumonia	26(8.3%)	Acute Kidney Failure	45(6.6%)
	Sepsis	21(5.6%)	Septic Shock	26(8.3%)	Sepsis	45(6.6%)
	Sirs	21(5.6%)	Acute Kidney Failure	24(7.6%)	Sirs	44(6.4%)
	Cholangitis	20(5.4%)	Sepsis	24(7.6%)	Arterial Hypertension	41(6.0%)
			Sirs	23(7.3%)	Septic Shock	41(6.0%)

RMM=Risk Minimization Measure
Data cut-off date: 22May2014
Analysis dataset: A_DIAGA and A_DIAGD
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Table 15.6.2 Hospitalization: Most Common (Top 5) Ward of Admission – Primary Analysis Set (PAS) population

	Before RMM (N=373)		After RMM (N=314)		All Patients (N=687)	
Ward of Admission:	Ward	n(%)	Ward	n(%)	Ward	n(%)
	GASTROENTEROLOGY	5(1.3%)	VASCULAR	3(1.0%)	GASTROENTEROLOGY	7(1.0%)
	CARDIOLOGY	4(1.1%)	RESPIRATORY	3(1.0%)	CARDIOLOGY	5(0.7%)
	UROLOGY	4(1.1%)	GASTROENTEROLOGY	2(0.6%)	UROLOGY	5(0.7%)
	VASCULAR	2(0.5%)	HEPATOLOGY	2(0.6%)	VASCULAR	5(0.7%)
	ELDERLY CARE	2(0.5%)	NEPHROLOGY	2(0.6%)	RESPIRATORY	4(0.6%)
			COLORECTAL	2(0.6%)		

RMM=Risk Minimization Measure
All Wards of Admission are converted to capital letters. No other modification was carried out.
Data cut-off date: 22May2014
Analysis dataset: A_HOSP
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Table 15.7.0 Tigecycline Treatment Characteristics – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Monotherapy	198(53.1%)	68(52.7%)	17(40.5%)	113(55.9%)	122(38.9%)	62(43.7%)	26(43.3%)	34(30.4%)
Combination Therapy	175(46.9%)	61(47.3%)	25(59.5%)	89(44.1%)	192(61.1%)	80(56.3%)	34(56.7%)	78(69.6%)
Amikacin	3(0.8%)	1(0.8%)	1(2.4%)	1(0.5%)	6(1.9%)	0(0.0%)	3(5.0%)	3(2.7%)
Amoxicillin/ clavulanate	2(0.5%)	1(0.8%)	1(2.4%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Aztreonam	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	2(0.6%)	1(0.7%)	1(1.7%)	0(0.0%)
Bactrim	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Cefepime	6(1.6%)	1(0.8%)	2(4.8%)	3(1.5%)	12(3.8%)	2(1.4%)	4(6.7%)	6(5.4%)
Cefotaxime	1(0.3%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Cefpirome	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Ceftriaxone	2(0.5%)	0(0.0%)	0(0.0%)	2(1.0%)	3(1.0%)	2(1.4%)	0(0.0%)	1(0.9%)
Ceftazidime	31(8.3%)	4(3.1%)	5(11.9%)	22(10.9%)	28(8.9%)	10(7.0%)	3(5.0%)	15(13.4%)
Colistin	8(2.1%)	1(0.8%)	1(2.4%)	6(3.0%)	16(5.1%)	3(2.1%)	4(6.7%)	9(8.0%)
Ciprofloxacin	31(8.3%)	11(8.5%)	2(4.8%)	18(8.9%)	36(11.5%)	16(11.3%)	4(6.7%)	16(14.3%)
Daptomycin	3(0.8%)	0(0.0%)	1(2.4%)	2(1.0%)	2(0.6%)	1(0.7%)	0(0.0%)	1(0.9%)
Doripenem	4(1.1%)	1(0.8%)	0(0.0%)	3(1.5%)	1(0.3%)	1(0.7%)	0(0.0%)	0(0.0%)
Gentamicin	8(2.1%)	2(1.6%)	3(7.1%)	3(1.5%)	10(3.2%)	0(0.0%)	3(5.0%)	7(6.3%)
Imipenem/ cilastatin	5(1.3%)	3(2.3%)	0(0.0%)	2(1.0%)	13(4.1%)	10(7.0%)	0(0.0%)	3(2.7%)
Levofloxacin	7(1.9%)	1(0.8%)	1(2.4%)	5(2.5%)	2(0.6%)	0(0.0%)	0(0.0%)	2(1.8%)
Linezolid	9(2.4%)	1(0.8%)	3(7.1%)	5(2.5%)	16(5.1%)	3(2.1%)	7(11.7%)	6(5.4%)
Meropenem	39(10.5%)	20(15.5%)	6(14.3%)	13(6.4%)	49(15.6%)	18(12.7%)	9(15.0%)	22(19.6%)
Metronidazole	33(8.8%)	10(7.8%)	3(7.1%)	20(9.9%)	18(5.7%)	5(3.5%)	5(8.3%)	8(7.1%)
Moxifloxacin	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	5(1.6%)	2(1.4%)	0(0.0%)	3(2.7%)
Piperacillin/ tazobactam	5(1.3%)	3(2.3%)	1(2.4%)	1(0.5%)	9(2.9%)	4(2.8%)	2(3.3%)	3(2.7%)
Piperacillin	1(0.3%)	1(0.8%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Rifampicin	2(0.5%)	0(0.0%)	1(2.4%)	1(0.5%)	2(0.6%)	0(0.0%)	1(1.7%)	1(0.9%)
Teicoplanin	4(1.1%)	0(0.0%)	0(0.0%)	4(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(0.9%)
Temocillin	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vancomycin	34(9.1%)	13(10.1%)	4(9.5%)	17(8.4%)	32(10.2%)	10(7.0%)	5(8.3%)	17(15.2%)
Other*	60(16.1%)	23(17.8%)	11(26.2%)	26(12.9%)	76(24.2%)	36(25.4%)	12(20.0%)	28(25.0%)
Duration of Treatment (days)								

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
n	373	129	42	202	314	142	60	112
Mean (SD)	8.6(10.25)	8.6(12.50)	10.9(8.29)	8.1(8.91)	10.3(7.66)	9.4(6.85)	12.1(9.54)	10.4(7.38)
Median	7.0	7.0	9.0	6.0	8.0	8.0	10.0	8.0
Min, Max	1,138	1,138	1,35	1,94	1,47	1,47	2,43	1,34
Missing	0	0	0	0	0	0	0	0
Duration of Treatment (days)								
n	373	129	42	202	314	142	60	112
< 2	15(4.0%)	8(6.2%)	2(4.8%)	5(2.5%)	6(1.9%)	3(2.1%)	0(0.0%)	3(2.7%)
2-5	131(35.1%)	36(27.9%)	7(16.7%)	88(43.6%)	80(25.5%)	37(26.1%)	16(26.7%)	27(24.1%)
6-14	183(49.1%)	72(55.8%)	24(57.1%)	87(43.1%)	158(50.3%)	76(53.5%)	24(40.0%)	58(51.8%)
>=15	44(11.8%)	13(10.1%)	9(21.4%)	22(10.9%)	70(22.3%)	26(18.3%)	20(33.3%)	24(21.4%)
Missing	0	0	0	0	0	0	0	0
Total Number of Doses								
n	373	129	42	202	314	142	60	112
Mean (SD)	13.0(12.75)	13.3(13.86)	16.6(15.36)	12.0(11.25)	16.6(13.95)	16.3(12.50)	16.7(16.40)	16.9(14.38)
Median	10.0	11.0	11.5	9.0	13.0	12.5	12.0	14.0
Min, Max	1,138	1,138	1,62	1,103	1,85	1,84	2,85	1,69
Missing	0	0	0	0	0	0	0	0
Loading Dose								
n	373	130	42	201	315	142	60	113
< 100 mg	29(7.8%)	14(10.8%)	2(4.8%)	13(6.5%)	47(14.9%)	28(19.7%)	8(13.3%)	11(9.7%)
100 mg	303(81.2%)	106(81.5%)	31(73.8%)	166(82.6%)	224(71.1%)	98(69.0%)	40(66.7%)	86(76.1%)
> 100 mg	24(6.4%)	6(4.6%)	6(14.3%)	12(6.0%)	36(11.4%)	13(9.2%)	9(15.0%)	14(12.4%)
No loading dose	17(4.6%)	4(3.1%)	3(7.1%)	10(5.0%)	8(2.5%)	3(2.1%)	3(5.0%)	2(1.8%)
Missing	0	0	0	0	0	0	0	0
Maintenance Dose								
n	372	130	42	200	314	142	60	112
< 25 mg	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
25 mg	6(1.6%)	5(3.8%)	0(0.0%)	1(0.5%)	7(2.2%)	6(4.2%)	0(0.0%)	1(0.9%)
50 mg	318(85.5%)	112(86.2%)	31(73.8%)	175(87.5%)	227(72.3%)	99(69.7%)	42(70.0%)	86(76.8%)
> 50 mg	43(11.6%)	12(9.2%)	9(21.4%)	22(11.0%)	80(25.5%)	37(26.1%)	18(30.0%)	25(22.3%)
No maintenance Dose	5(1.3%)	1(0.8%)	2(4.8%)	2(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Missing	1	0	0	1	1	0	0	1
Treatment Interruptions#								
n	373	130	42	201	315	142	60	113
Yes	28(7.5%)	6(4.6%)	1(2.4%)	21(10.4%)	18(5.7%)	12(8.5%)	1(1.7%)	5(4.4%)
No	345(92.5%)	124(95.4%)	41(97.6%)	180(89.6%)	297(94.3%)	130(91.5%)	59(98.3%)	108(95.6%)
Missing	0	0	0	0	0	0	0	0

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	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Duration of Interruptions (days)								
n	28	6	1	21	18	12	1	5
Mean (SD)	9.6(20.30)	6.3(10.25)	24.0()	9.9(22.72)	5.2(7.25)	4.3(3.84)	31.0()	2.4(1.95)
Median	2.0	2.0	24.0	2.0	3.5	3.5	31.0	1.0
Min, Max	1,104	1,27	24,24	1,104	1,31	1,12	31,31	1,5
Missing	345	124	41	180	297	130	59	108
Ward at the time of first dose								
n	373	130	42	201	315	142	60	113
Surgical	103(27.6%)	38(29.2%)	6(14.3%)	59(29.4%)	52(16.5%)	20(14.1%)	16(26.7%)	16(14.2%)
Medical	63(16.9%)	12(9.2%)	9(21.4%)	42(20.9%)	22(7.0%)	4(2.8%)	7(11.7%)	11(9.7%)
ICU	162(43.4%)	71(54.6%)	23(54.8%)	68(33.8%)	212(67.3%)	112(78.9%)	32(53.3%)	68(60.2%)
Infectious disease	16(4.3%)	2(1.5%)	1(2.4%)	13(6.5%)	8(2.5%)	0(0.0%)	2(3.3%)	6(5.3%)
Other	29(7.8%)	7(5.4%)	3(7.1%)	19(9.5%)	21(6.7%)	6(4.2%)	3(5.0%)	12(10.6%)
Missing	0	0	0	0	0	0	0	0
Patient State when Initiating Tigecycline								
n	172	66	15	91	165	90	27	48
Sepsis	103(59.9%)	40(60.6%)	9(60.0%)	54(59.3%)	78(47.3%)	38(42.2%)	18(66.7%)	22(45.8%)
Severe Sepsis	26(15.1%)	9(13.6%)	3(20.0%)	14(15.4%)	15(9.1%)	6(6.7%)	1(3.7%)	8(16.7%)
Septic Shock	35(20.3%)	13(19.7%)	3(20.0%)	19(20.9%)	37(22.4%)	16(17.8%)	8(29.6%)	13(27.1%)
Severe Inflammatory Response Syndrome	8(4.7%)	4(6.1%)	0(0.0%)	4(4.4%)	35(21.2%)	30(33.3%)	0(0.0%)	5(10.4%)
Missing	201	64	27	110	150	52	33	65

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, ICU=Intensive Care Unit, RMM=Risk Minimization Measure.
*Please refer to Listing 4 for further specification.
#Please refer to Listing 5 for further specification.
**Treatment interruption is defined as interruption of Tigecycline therapy for more than 24 hours.
Data cut-off date: 22May2014
Analysis dataset: A_TREAT
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Table 15.7.0 Tigecycline Treatment Characteristics – Primary Analysis Set (PAS) population (continued)

	All Patients (N=687)			
	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Monotherapy	320(46.6%)	130(48.0%)	43(42.2%)	147(46.8%)
Combination Therapy	367(53.4%)	141(52.0%)	59(57.8%)	167(53.2%)
Amikacin	9(1.3%)	1(0.4%)	4(3.9%)	4(1.3%)
Amoxicillin/ clavulanate	3(0.4%)	1(0.4%)	1(1.0%)	1(0.3%)
Aztreonam	3(0.4%)	1(0.4%)	1(1.0%)	1(0.3%)
Bactrim	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Cefepime	18(2.6%)	3(1.1%)	6(5.9%)	9(2.9%)
Cefotaxime	1(0.1%)	0(0.0%)	0(0.0%)	1(0.3%)
Cefpirome	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Ceftriaxone	5(0.7%)	2(0.7%)	0(0.0%)	3(1.0%)
Ceftazidime	59(8.6%)	14(5.2%)	8(7.8%)	37(11.8%)
Colistin	24(3.5%)	4(1.5%)	5(4.9%)	15(4.8%)
Ciprofloxacin	67(9.8%)	27(10.0%)	6(5.9%)	34(10.8%)
Daptomycin	5(0.7%)	1(0.4%)	1(1.0%)	3(1.0%)
Doripenem	5(0.7%)	2(0.7%)	0(0.0%)	3(1.0%)
Gentamicin	18(2.6%)	2(0.7%)	6(5.9%)	10(3.2%)
Imipenem/ cilastatin	18(2.6%)	13(4.8%)	0(0.0%)	5(1.6%)
Levofloxacin	9(1.3%)	1(0.4%)	1(1.0%)	7(2.2%)
Linezolid	25(3.6%)	4(1.5%)	10(9.8%)	11(3.5%)
Meropenem	88(12.8%)	38(14.0%)	15(14.7%)	35(11.1%)
Metronidazole	51(7.4%)	15(5.5%)	8(7.8%)	28(8.9%)
Moxifloxacin	5(0.7%)	2(0.7%)	0(0.0%)	3(1.0%)
Piperacillin/ tazobactam	14(2.0%)	7(2.6%)	3(2.9%)	4(1.3%)
Piperacillin	2(0.3%)	1(0.4%)	0(0.0%)	1(0.3%)
Rifampicin	4(0.6%)	0(0.0%)	2(2.0%)	2(0.6%)
Teicoplanin	5(0.7%)	0(0.0%)	0(0.0%)	5(1.6%)
Temocillin	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vancomycin	66(9.6%)	23(8.5%)	9(8.8%)	34(10.8%)
Other*	136(19.8%)	59(21.8%)	23(22.5%)	54(17.2%)
Duration of Treatment (days)				
n	687	271	102	314

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Mean (SD)	9.4(9.18)	9.0(9.94)	11.6(9.03)	8.9(8.45)
Median	7.0	7.0	9.0	7.0
Min, Max	1,138	1,138	1,43	1,94
Missing	0	0	0	0
Duration of Treatment (days)				
n	687	271	102	314
< 2	21(3.1%)	11(4.1%)	2(2.0%)	8(2.5%)
2-5	211(30.7%)	73(26.9%)	23(22.5%)	115(36.6%)
6-14	341(49.6%)	148(54.6%)	48(47.1%)	145(46.2%)
>=15	114(16.6%)	39(14.4%)	29(28.4%)	46(14.6%)
Missing	0	0	0	0
Total Number of Doses				
n	687	271	102	314
Mean (SD)	14.6(13.42)	14.8(13.23)	16.6(15.91)	13.8(12.65)
Median	11.0	12.0	12.0	10.5
Min, Max	1,138	1,138	1,85	1,103
Missing	0	0	0	0
Loading Dose				
n	687	271	102	314
< 100 mg	76(11.1%)	42(15.5%)	10(9.8%)	24(7.6%)
100 mg	526(76.6%)	203(74.9%)	71(69.6%)	252(80.3%)
> 100 mg	60(8.7%)	19(7.0%)	15(14.7%)	26(8.3%)
No loading dose	25(3.6%)	7(2.6%)	6(5.9%)	12(3.8%)
Missing	0	0	0	0
Maintenance Dose				
n	686	271	102	312
< 25 mg	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
25 mg	13(1.9%)	11(4.1%)	0(0.0%)	2(0.6%)
50 mg	544(79.4%)	210(77.5%)	73(71.6%)	261(83.7%)
> 50 mg	123(18.0%)	49(18.1%)	27(26.5%)	47(15.1%)
No maintenance Dose	5(0.7%)	1(0.4%)	2(2.0%)	2(0.6%)
Missing	2	0	0	2
Treatment Interruptions**				
n	687	271	102	314
Yes	46(6.7%)	17(6.3%)	2(2.0%)	27(8.6%)
No	641(93.3%)	254(93.7%)	100(98.0%)	287(91.4%)
Missing	0	0	0	0

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	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Duration of Interruptions (days)				
n	46	17	2	27
Mean (SD)	7.9(16.49)	3.6(3.44)	27.5(4.95)	9.1(20.47)
Median	2.5	3.0	27.5	2.0
Min, Max	1,104	1,12	24,31	1,104
Missing	641	254	100	287
Ward at the time of first dose				
n	687	271	102	314
Surgical	155(22.6%)	58(21.4%)	22(21.6%)	75(23.9%)
Medical	85(12.4%)	16(5.9%)	16(15.7%)	53(16.9%)
ICU	373(54.3%)	182(67.2%)	55(53.9%)	136(43.3%)
Infectious disease	24(3.5%)	2(0.7%)	3(2.9%)	19(6.1%)
Other#	50(7.3%)	13(4.8%)	6(5.9%)	31(9.9%)
Missing	0	0	0	0
Patient State when Initiating Tigecycline				
n	337	155	42	140
Sepsis	181(53.7%)	78(50.3%)	27(64.3%)	76(54.3%)
Severe Sepsis	41(12.2%)	15(9.7%)	4(9.5%)	22(15.7%)
Septic Shock	72(21.4%)	28(18.1%)	11(26.2%)	33(23.6%)
Severe Inflammatory Response Syndrome	43(12.8%)	34(21.9%)	0(0.0%)	9(6.4%)
Missing	350	116	60	174

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, ICU=Intensive Care Unit, RMM=Risk Minimization Measure.
*Please refer to Listing 4 for further specification.
#Please refer to Listing 5 for further specification.
**Treatment interruption is defined as interruption of Tigecycline therapy for more than 24 hours.
Data cut-off date: 22May2014
Analysis dataset: A_TREAT
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Table 15.7.1 Tigecycline Treatment Characteristics: Most Common (Top 5) Other Combination Therapy – Primary Analysis Set (PAS) population

	Before RMM (N=373)		After RMM (N=314)		All Patients (N=687)	
Other Combination Therapy:	Antibiotic	n(%)	Antibiotic	n(%)	Antibiotic	n(%)
	FLUCONAZOLE	12(3.2%)	FLUCONAZOLE	14(4.5%)	FLUCONAZOLE	26(3.8%)
	TOBRAMYCIN	6(1.6%)	COTRIMOXAZOL	7(2.2%)	TOBRAMYCIN	10(1.5%)
	ERYTHROMYCIN	5(1.3%)	FOSFOMYCIN	6(1.9%)	COTRIMOXAZOL	9(1.3%)
	FOSFOMYCIN	3(0.8%)	TOBRAMYCIN	4(1.3%)	ERYTHROMYCIN	9(1.3%)
	CLARITHROMYCIN	3(0.8%)	ERYTHROMYCIN	4(1.3%)	FOSFOMYCIN	9(1.3%)
			ERYTHROCIN	4(1.3%)		
			CLINDAMYCIN	4(1.3%)		

RMM=Risk Minimization Measure
All 'Other Combination Therapy' are converted to capital letters. No other modification was carried out.
Data cut-off date: 22May2014
Analysis dataset: A_TREAT

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Table 15.8.0 Patient Disposition – Primary Analysis Set (PAS) population

	Before RMM (N=373)				After RMM (N=314)			
	Any Indication (n=373)	cIAI (n=129)	cSSTI (n=42)	Off-label (n=202)	Any Indication (n=314)	cIAI (n=142)	cSSTI (n=60)	Off-label (n=112)
Disposition at Discharge								
Alive	268(71.8%)	90(69.8%)	32(76.2%)	146(72.3%)	201(64.0%)	87(61.3%)	49(81.7%)	65(58.0%)
Dead*	105(28.2%)	39(30.2%)	10(23.8%)	56(27.7%)	113(36.0%)	55(38.7%)	11(18.3%)	47(42.0%)
Unknown	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
*Please refer to Listing 6 for further specification of primary causes of death.
Data cut-off date: 22May2014
Analysis dataset: A_DISCHG
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Table 15.8.0 Patient Disposition – Primary Analysis Set (PAS) population (continued)

	Any Indication (n=687)	cIAI (n=271)	cSSTI (n=102)	Off-label (n=314)
Disposition at Discharge				
Alive	469(68.3%)	177(65.1%)	81(79.4%)	212(67.5%)
Death*	218(31.7%)	94(34.7%)	21(20.6%)	102(32.5%)
Unknown	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
*Please refer to Listing 6 for further specification of primary causes of death.
Data cut-off date: 22May2014
Analysis dataset: A_DISCHG
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Table 15.9.0 Superinfection Endpoints – Modified Primary Analysis Set (mPAS) population

	Before RMM(n=105)		After RMM(n=94)		All Patients(n=199)	
	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
Number of patients treated with Tigecycline for approved indications	82(78.1%)	23(21.9%)	69(73.4%)	25(26.6%)	151(75.9%)	48(24.1%)
Number of patients with POTENTIAL superinfection cases among patients treated with Tigecycline for approved indications	23(28.0%)	3(13.0%)	26(37.7%)	8(32.0%)	49(32.5%)	11(22.9%)
ADJUDICATED case status	N=23	N=3	N=26	N=8	N=49	N=11
Definite	2(8.7%)	1(33.3%)	0(0.0%)	1(12.5%)	2(4.1%)	2(18.2%)
Probable	1(4.3%)	0(0.0%)	3(11.5%)	1(12.5%)	4(8.2%)	1(9.1%)
Not a case	17(73.9%)	1(33.3%)	22(84.6%)	5(62.5%)	39(79.6%)	6(54.5%)
Insufficient information	3(13.0%)	1(33.3%)	1(3.8%)	1(12.5%)	4(8.2%)	2(18.2%)
If status='Not a case'	N=17	N=1	N=22	N=5	N=39	N=6
A. Lacking clinical signs and symptoms of superinfection	2(11.8%)	0(0.0%)	2(9.1%)	0(0.0%)	4(10.3%)	0(0.0%)
B. Same organism is cultured from the same site as initial infection	1(5.9%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.6%)	0(0.0%)
C. Inadequate surgical control	1(5.9%)	0(0.0%)	4(18.2%)	0(0.0%)	5(12.8%)	0(0.0%)
Other reason (as combination of above)±						
A and B	2(11.8%)	0(0.0%)	0(0.0%)	1(20.0%)	2(5.1%)	1(16.7%)
A and C	3(17.6%)	0(0.0%)	6(27.3%)	2(40.0%)	9(23.1%)	2(33.3%)
B and C	1(5.9%)	0(0.0%)	6(27.3%)	0(0.0%)	7(17.9%)	0(0.0%)
A, B and C	1(5.9%)	0(0.0%)	1(4.5%)	0(0.0%)	2(5.1%)	0(0.0%)
Other reasons (not included in above)**	6(35.3%)	1(100.0%)	3(13.6%)	2(40.0%)	9(23.1%)	3(50.0%)
Pathogen Associated with Superinfection*#	N=3	N=1	N=3	N=2	N=6	N=3
Staphylococcus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Enterococcus spp.	3(100.0%)	0(0.0%)	1(33.3%)	1(50.0%)	4(66.7%)	1(33.3%)
Streptococcus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Other gram-positive	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
E-coli	1(33.3%)	0(0.0%)	1(33.3%)	0(0.0%)	2(33.3%)	0(0.0%)
Proteus spp.	1(33.3%)	0(0.0%)	0(0.0%)	1(50.0%)	1(16.7%)	1(33.3%)
Klebsiella spp.	2(66.7%)	0(0.0%)	1(33.3%)	0(0.0%)	3(50.0%)	0(0.0%)
Enterobacter spp.	0(0.0%)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(33.3%)

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	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
Citrobacter spp.	0(0.0%)	0(0.0%)	0(0.0%)	1(50.0%)	0(0.0%)	1(33.3%)
Serratia spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Haemophilus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Morganella morganii	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Acinetobacter spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
P.aeruginosa	0(0.0%)	0(0.0%)	1(33.3%)	0(0.0%)	1(16.7%)	0(0.0%)
Other gram-negative	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Bacteroides spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Peptostreptococcus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Clostridium spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Prevotella spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Other anaerobes	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Time to Onset of Superinfection * (days)	N=3	N=1	N=3	N=2	N=6	N=3
n	3	1	3	2	6	3
Mean (SD)	17.3(9.87)	9.0()	13.0(3.61)	13.0(8.49)	15.2(7.05)	11.7(6.43)
Median	22.0	9.0	14.0	13.0	15.0	9.0
Min, Max	6,24	9,9	9,16	7,19	6,24	7,19
Missing	0	0	0	0	0	0

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
* For definite and probable superinfection
±Cases where reason includes more than the combination of reasons specified in the categories mentioned below will be classified under 'Other reasons not included in above' category
**Please refer to Listing 7 for listing of other reasons not specified in the table for classifying event as ‘not a case’ of superinfection.
#Percentages may not add to 100% as one superinfection case can be associated with multiple pathogens.
Data cut-off date: 22May2014
Analysis dataset: A_SUPER
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Table 15.9.0a Sensitivity Analysis: Superinfection Endpoints – Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)		After RMM (n=134)		All patients (n=255)	
	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
Number of patients treated with Tigecycline for approved indications	96(79.3%)	25(20.7%)	101(75.4%)	33(24.6%)	197(77.3%)	58(22.7%)
Number of patients with POTENTIAL superinfection cases among patients treated with Tigecycline for approved indications	26(27.1%)	3(12.0%)	32(31.7%)	9(27.3%)	58(29.4%)	12(20.7%)
ADJUDICATED case status	N=26	N=3	N=32	N=9	N=58	N=12
Definite	3(11.5%)	1(33.3%)	0(0.0%)	1(11.1%)	3(5.2%)	2(16.7%)
Probable	1(3.8%)	0(0.0%)	4(12.5%)	1(11.1%)	5(8.6%)	1(8.3%)
Not a case	19(73.1%)	1(33.3%)	26(81.3%)	5(55.6%)	45(77.6%)	6(50.0%)
Insufficient information	3(11.5%)	1(33.3%)	2(6.3%)	2(22.2%)	5(8.6%)	3(25.0%)
If status='Not a case'	N=19	N=1	N=26	N=5	N=45	N=6
A. Lacking clinical signs and symptoms of superinfection	2(10.5%)	0(0.0%)	3(11.5%)	0(0.0%)	5(11.1%)	0(0.0%)
B. Same organism is cultured from the same site as initial infection	1(5.3%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.2%)	0(0.0%)
C. Inadequate surgical control	1(5.3%)	0(0.0%)	5(19.2%)	0(0.0%)	6(13.3%)	0(0.0%)
Other reason (as combination of above)±						
A and B	2(10.5%)	0(0.0%)	0(0.0%)	1(20.0%)	2(4.4%)	1(16.7%)
A and C	4(21.1%)	0(0.0%)	7(26.9%)	2(40.0%)	11(24.4%)	2(33.3%)
B and C	1(5.3%)	0(0.0%)	6(23.1%)	0(0.0%)	7(15.6%)	0(0.0%)
A, B and C	1(5.3%)	0(0.0%)	2(7.7%)	0(0.0%)	3(6.7%)	0(0.0%)
Other reasons (not included in above)**	7(36.8%)	1(100.0%)	3(11.5%)	2(40.0%)	10(22.2%)	3(50.0%)
Pathogen Associated with Superinfection*#	N=4	N=1	N=4	N=2	N=8	N=3
Staphylococcus spp.	1(25.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(12.5%)	0(0.0%)
Enterococcus spp.	3(75.0%)	0(0.0%)	1(25.0%)	1(50.0%)	4(50.0%)	1(33.3%)
Streptococcus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Other gram-positive	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
E-coli	1(25.0%)	0(0.0%)	1(25.0%)	0(0.0%)	2(25.0%)	0(0.0%)
Proteus spp.	1(25.0%)	0(0.0%)	0(0.0%)	1(50.0%)	1(12.5%)	1(33.3%)
Klebsiella spp.	2(50.0%)	0(0.0%)	1(25.0%)	0(0.0%)	3(37.5%)	0(0.0%)
Enterobacter spp.	0(0.0%)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(33.3%)
Citrobacter spp.	0(0.0%)	0(0.0%)	0(0.0%)	1(50.0%)	0(0.0%)	1(33.3%)

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	Before RMM (n=121)		After RMM (n=134)		All patients (n=255)	
	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
Serratia spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Haemophilus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Morganella morganii	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Acinetobacter spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
P.aeruginosa	0(0.0%)	0(0.0%)	2(50.0%)	0(0.0%)	2(25.0%)	0(0.0%)
Other gram-negative	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Bacteroides spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Peptostreptococcus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Clostridium spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Prevotella spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Other anaerobes	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Time to Onset of Superinfection * (days)	N=4	N=1	N=4	N=2	N=8	N=3
n	4	1	4	2	8	3
Mean (SD)	17.3(8.06)	9.0()	13.3(2.99)	13.0(8.49)	15.3(6.02)	11.7(6.43)
Median	19.5	9.0	14.0	13.0	15.0	9.0
Min, Max	6,24	9,9	9,16	7,19	6,24	7,19
Missing	0	0	0	0	0	0

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
* For definite and probable superinfection
±Cases where reason includes more than the combination of reasons specified in the categories mentioned below will be classified under 'Other reasons not included in above' category
**Please refer to Listing 7 for listing of other reasons not specified in the table for classifying event as ‘not a case’ of superinfection.
#Percentages may not add to 100% as one superinfection case can be associated with multiple pathogens.
Data cut-off date: 22May2014
Analysis dataset: A_SUPER
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Table 15.9.1 Incidence of Definite Superinfection – Modified Primary Analysis Set (mPAS) population

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	2.86%(0.59%,8.12%)	1.06%(0.03%,5.79%)	2.01%(0.55%,5.07%)
Incidence by Age			
< 65	3.64%(0.44%,12.53%)	1.79%(0.05%,9.55%)	2.70%(0.56%,7.70%)
>=65	2.00%(0.05%,10.65%)	0.00%(0.00%,0.00%)	1.14%(0.03%,6.17%)
Incidence by Gender			
Male	6.12%(1.28%,16.87%)	0.00%(0.00%,0.00%)	2.80%(0.58%,7.98%)
Female	0.00%(0.00%,0.00%)	2.78%(0.07%,14.53%)	1.09%(0.03%,5.91%)
Incidence by Infection Type			
cIAI	2.44%(0.30%,8.53%)	0.00%(0.00%,0.00%)	1.32%(0.16%,4.70%)
cSSTI	4.35%(0.11%,21.95%)	4.00%(0.10%,20.35%)	4.17%(0.51%,14.25%)
Incidence by Therapy Type			
Monotherapy	0.00%(0.00%,0.00%)	3.23%(0.08%,16.70%)	1.27%(0.03%,6.85%)
Combination	5.26%(1.10%,14.62%)	0.00%(0.00%,0.00%)	2.50%(0.52%,7.13%)
Incidence by History of Previous Antibiotic Therapy			
Yes	3.49%(0.73%,9.86%)	1.23%(0.03%,6.69%)	2.40%(0.66%,6.02%)
No	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
APACHE II >=15	3.23%(0.08%,16.70%)	0.00%(0.00%,0.00%)	1.64%(0.04%,8.80%)
APACHE II Not Available	2.94%(0.36%,10.22%)	1.64%(0.04%,8.80%)	2.33%(0.48%,6.65%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.88%(0.15%,28.69%)	0.00%(0.00%,0.00%)	3.45%(0.09%,17.76%)
6-14	2.70%(0.33%,9.42%)	0.00%(0.00%,0.00%)	1.56%(0.19%,5.53%)
>=15	0.00%(0.00%,0.00%)	3.57%(0.09%,18.35%)	2.38%(0.06%,12.57%)

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
1-3	3.85%(0.47%,13.21%)	0.00%(0.00%,0.00%)	2.02%(0.25%,7.11%)
4-6	4.35%(0.11%,21.95%)	0.00%(0.00%,0.00%)	2.22%(0.06%,11.77%)
7+	0.00%(0.00%,0.00%)	12.50%(0.32%,52.65%)	6.25%(0.16%,30.23%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.9.1a Sensitivity Analysis: Incidence of Definite Superinfection – Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	3.31%(0.91%,8.25%)	0.75%(0.02%,4.09%)	1.96%(0.64%,4.52%)
Incidence by Age			
< 65	3.39%(0.41%,11.71%)	1.37%(0.03%,7.40%)	2.27%(0.47%,6.50%)
>=65	3.23%(0.39%,11.17%)	0.00%(0.00%,0.00%)	1.63%(0.20%,5.75%)
Incidence by Gender			
Male	6.67%(1.85%,16.20%)	0.00%(0.00%,0.00%)	2.76%(0.76%,6.91%)
Female	0.00%(0.00%,0.00%)	2.04%(0.05%,10.85%)	0.91%(0.02%,4.96%)
Incidence by Infection Type			
cIAI	3.13%(0.65%,8.86%)	0.00%(0.00%,0.00%)	1.52%(0.32%,4.39%)
cSSTI	4.00%(0.10%,20.35%)	3.03%(0.08%,15.76%)	3.45%(0.42%,11.91%)
Incidence by Therapy Type			
Monotherapy	1.89%(0.05%,10.07%)	2.17%(0.06%,11.53%)	2.02%(0.25%,7.11%)
Combination	4.41%(0.92%,12.36%)	0.00%(0.00%,0.00%)	1.92%(0.40%,5.52%)
Incidence by History of Previous Antibiotic Therapy			
Yes	3.96%(1.09%,9.83%)	0.91%(0.02%,4.96%)	2.37%(0.77%,5.44%)
No	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
APACHE II >=15	3.23%(0.08%,16.70%)	0.00%(0.00%,0.00%)	1.64%(0.04%,8.80%)
APACHE II Not Available	3.61%(0.75%,10.20%)	1.00%(0.03%,5.45%)	2.19%(0.60%,5.50%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.56%(0.14%,27.29%)	0.00%(0.00%,0.00%)	3.03%(0.08%,15.76%)
6-14	2.53%(0.31%,8.85%)	0.00%(0.00%,0.00%)	1.24%(0.15%,4.42%)
>=15	4.17%(0.11%,21.12%)	2.70%(0.07%,14.16%)	3.28%(0.40%,11.35%)

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
1-3	5.17%(1.08%,14.38%)	0.00%(0.00%,0.00%)	2.42%(0.50%,6.91%)
4-6	3.70%(0.09%,18.97%)	0.00%(0.00%,0.00%)	1.67%(0.04%,8.94%)
7+	0.00%(0.00%,0.00%)	9.09%(0.23%,41.28%)	4.55%(0.12%,22.84%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.9.2 Incidence of Definite and Probable Superinfection – Modified Primary Analysis Set (mPAS) population

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	3.81%(1.05%,9.47%)	5.32%(1.75%,11.98%)	4.52%(2.09%,8.41%)
Incidence by Age			
< 65	5.45%(1.14%,15.12%)	5.36%(1.12%,14.87%)	5.41%(2.01%,11.39%)
>=65	2.00%(0.05%,10.65%)	5.26%(0.64%,17.75%)	3.41%(0.71%,9.64%)
Incidence by Gender			
Male	6.12%(1.28%,16.87%)	5.17%(1.08%,14.38%)	5.61%(2.09%,11.81%)
Female	1.79%(0.05%,9.55%)	5.56%(0.68%,18.66%)	3.26%(0.68%,9.23%)
Incidence by Infection Type			
cIAI	3.66%(0.76%,10.32%)	4.35%(0.91%,12.18%)	3.97%(1.47%,8.45%)
cSSTI	4.35%(0.11%,21.95%)	8.00%(0.98%,26.03%)	6.25%(1.31%,17.20%)
Incidence by Therapy Type			
Monotherapy	0.00%(0.00%,0.00%)	6.45%(0.79%,21.42%)	2.53%(0.31%,8.85%)
Combination	7.02%(1.95%,17.00%)	4.76%(0.99%,13.29%)	5.83%(2.38%,11.65%)
Incidence by History of Previous Antibiotic Therapy			
Yes	4.65%(1.28%,11.48%)	6.17%(2.03%,13.82%)	5.39%(2.49%,9.98%)
No	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
APACHE II >=15	6.45%(0.79%,21.42%)	3.33%(0.08%,17.22%)	4.92%(1.03%,13.71%)
APACHE II Not Available	2.94%(0.36%,10.22%)	6.56%(1.82%,15.95%)	4.65%(1.73%,9.85%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.88%(0.15%,28.69%)	0.00%(0.00%,0.00%)	3.45%(0.09%,17.76%)
6-14	4.05%(0.84%,11.39%)	5.56%(1.16%,15.39%)	4.69%(1.74%,9.92%)
>=15	0.00%(0.00%,0.00%)	7.14%(0.88%,23.50%)	4.76%(0.58%,16.16%)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	5.88%(0.15%,28.69%)	2.56%(0.06%,13.48%)
1-3	3.85%(0.47%,13.21%)	2.13%(0.05%,11.29%)	3.03%(0.63%,8.60%)

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
4-6	8.70%(1.07%,28.04%)	9.09%(1.12%,29.16%)	8.89%(2.48%,21.22%)
7+	0.00%(0.00%,0.00%)	12.50%(0.32%,52.65%)	6.25%(0.16%,30.23%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.9.2a Sensitivity Analysis: Incidence of Definite and Probable Superinfection – Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	4.13%(1.36%,9.38%)	4.48%(1.66%,9.49%)	4.31%(2.17%,7.59%)
Incidence by Age			
< 65	5.08%(1.06%,14.15%)	5.48%(1.51%,13.44%)	5.30%(2.16%,10.62%)
>=65	3.23%(0.39%,11.17%)	3.28%(0.40%,11.35%)	3.25%(0.89%,8.12%)
Incidence by Gender			
Male	6.67%(1.85%,16.20%)	4.71%(1.30%,11.61%)	5.52%(2.41%,10.58%)
Female	1.64%(0.04%,8.80%)	4.08%(0.50%,13.98%)	2.73%(0.57%,7.76%)
Incidence by Infection Type			
cIAI	4.17%(1.15%,10.33%)	3.96%(1.09%,9.83%)	4.06%(1.77%,7.84%)
cSSTI	4.00%(0.10%,20.35%)	6.06%(0.74%,20.23%)	5.17%(1.08%,14.38%)
Incidence by Therapy Type			
Monotherapy	1.89%(0.05%,10.07%)	4.35%(0.53%,14.84%)	3.03%(0.63%,8.60%)
Combination	5.88%(1.63%,14.38%)	4.55%(1.25%,11.23%)	5.13%(2.24%,9.85%)
Incidence by History of Previous Antibiotic Therapy			
Yes	4.95%(1.63%,11.18%)	4.55%(1.49%,10.29%)	4.74%(2.30%,8.54%)
No	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
APACHE II >=15	6.45%(0.79%,21.42%)	3.33%(0.08%,17.22%)	4.92%(1.03%,13.71%)
APACHE II Not Available	3.61%(0.75%,10.20%)	5.00%(1.64%,11.28%)	4.37%(1.91%,8.43%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.56%(0.14%,27.29%)	0.00%(0.00%,0.00%)	3.03%(0.08%,15.76%)
6-14	3.80%(0.79%,10.70%)	3.66%(0.76%,10.32%)	3.73%(1.38%,7.93%)
>=15	4.17%(0.11%,21.12%)	8.11%(1.70%,21.91%)	6.56%(1.82%,15.95%)

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	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	8.33%(1.03%,27.00%)	4.08%(0.50%,13.98%)
1-3	5.17%(1.08%,14.38%)	1.52%(0.04%,8.16%)	3.23%(0.89%,8.05%)
4-6	7.41%(0.91%,24.29%)	6.06%(0.74%,20.23%)	6.67%(1.85%,16.20%)
7+	0.00%(0.00%,0.00%)	9.09%(0.23%,41.28%)	4.55%(0.12%,22.84%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.9.3 Sensitivity Analysis: Incidence of Superinfection (definite + probable + insufficient information cases) – Modified Primary Analysis Set (mPAS) population

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	7.62%(3.35%,14.46%)	7.45%(3.05%,14.74%)	7.54%(4.28%,12.13%)
Incidence by Age			
< 65	7.27%(2.02%,17.59%)	5.36%(1.12%,14.87%)	6.31%(2.57%,12.56%)
>=65	8.00%(2.22%,19.23%)	10.53%(2.94%,24.80%)	9.09%(4.01%,17.13%)
Incidence by Gender			
Male	10.20%(3.40%,22.23%)	5.17%(1.08%,14.38%)	7.48%(3.28%,14.20%)
Female	5.36%(1.12%,14.87%)	11.11%(3.11%,26.06%)	7.61%(3.11%,15.05%)
Incidence by Infection Type			
cIAI	7.32%(2.73%,15.25%)	5.80%(1.60%,14.18%)	6.62%(3.22%,11.84%)
cSSTI	8.70%(1.07%,28.04%)	12.00%(2.55%,31.22%)	10.42%(3.47%,22.66%)
Incidence by Therapy Type			
Monotherapy	4.17%(0.51%,14.25%)	9.68%(2.04%,25.75%)	6.33%(2.09%,14.16%)
Combination	10.53%(3.96%,21.52%)	6.35%(1.76%,15.47%)	8.33%(4.07%,14.79%)
Incidence by History of Previous Antibiotic Therapy			
Yes	8.14%(3.34%,16.05%)	8.64%(3.55%,17.00%)	8.38%(4.66%,13.67%)
No	5.26%(0.13%,26.03%)	0.00%(0.00%,0.00%)	3.13%(0.08%,16.22%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	33.33%(0.84%,90.57%)	11.11%(0.28%,48.25%)
APACHE II >=15	6.45%(0.79%,21.42%)	3.33%(0.08%,17.22%)	4.92%(1.03%,13.71%)
APACHE II Not Available	8.82%(3.31%,18.22%)	8.20%(2.72%,18.10%)	8.53%(4.33%,14.75%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	11.76%(1.46%,36.44%)	8.33%(0.21%,38.48%)	10.34%(2.19%,27.35%)
6-14	8.11%(3.03%,16.82%)	5.56%(1.16%,15.39%)	7.03%(3.27%,12.93%)
>=15	0.00%(0.00%,0.00%)	10.71%(2.27%,28.23%)	7.14%(1.50%,19.48%)

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
Incidence by Charlson Comorbidity Score			
0	4.55%(0.12%,22.84%)	5.88%(0.15%,28.69%)	5.13%(0.63%,17.32%)
1-3	7.69%(2.14%,18.54%)	4.26%(0.52%,14.54%)	6.06%(2.26%,12.73%)
4-6	13.04%(2.78%,33.59%)	9.09%(1.12%,29.16%)	11.11%(3.71%,24.05%)
7+	0.00%(0.00%,0.00%)	25.00%(3.19%,65.09%)	12.50%(1.55%,38.35%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.9.3a Sensitivity Analysis: Incidence of Superinfection (definite + probable + insufficient information cases) – Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	7.44%(3.46%,13.65%)	7.46%(3.64%,13.30%)	7.45%(4.55%,11.39%)
Incidence by Age			
< 65	6.78%(1.88%,16.46%)	6.85%(2.26%,15.26%)	6.82%(3.16%,12.55%)
>=65	8.06%(2.67%,17.83%)	8.20%(2.72%,18.10%)	8.13%(3.97%,14.44%)
Incidence by Gender			
Male	10.00%(3.76%,20.51%)	5.88%(1.94%,13.20%)	7.59%(3.85%,13.17%)
Female	4.92%(1.03%,13.71%)	10.20%(3.40%,22.23%)	7.27%(3.19%,13.83%)
Incidence by Infection Type			
cIAI	7.29%(2.98%,14.45%)	5.94%(2.21%,12.48%)	6.60%(3.56%,11.02%)
cSSTI	8.00%(0.98%,26.03%)	12.12%(3.40%,28.20%)	10.34%(3.89%,21.17%)
Incidence by Therapy Type			
Monotherapy	5.66%(1.18%,15.66%)	8.70%(2.42%,20.79%)	7.07%(2.89%,14.03%)
Combination	8.82%(3.31%,18.22%)	6.82%(2.54%,14.25%)	7.69%(4.04%,13.05%)
Incidence by History of Previous Antibiotic Therapy			
Yes	7.92%(3.48%,15.01%)	8.18%(3.81%,14.96%)	8.06%(4.76%,12.59%)
No	5.00%(0.13%,24.87%)	0.00%(0.00%,0.00%)	2.38%(0.06%,12.57%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	25.00%(0.63%,80.59%)	9.09%(0.23%,41.28%)
APACHE II >=15	6.45%(0.79%,21.42%)	3.33%(0.08%,17.22%)	4.92%(1.03%,13.71%)
APACHE II Not Available	8.43%(3.46%,16.61%)	8.00%(3.52%,15.16%)	8.20%(4.66%,13.16%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	11.11%(1.38%,34.71%)	6.67%(0.17%,31.95%)	9.09%(1.92%,24.33%)
6-14	7.59%(2.84%,15.80%)	4.88%(1.34%,12.02%)	6.21%(3.02%,11.13%)
>=15	4.17%(0.11%,21.12%)	13.51%(4.54%,28.77%)	9.84%(3.70%,20.19%)
Incidence by Charlson Comorbidity Score			

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
0	4.00%(0.10%,20.35%)	8.33%(1.03%,27.00%)	6.12%(1.28%,16.87%)
1-3	8.62%(2.86%,18.98%)	4.55%(0.95%,12.71%)	6.45%(2.83%,12.32%)
4-6	11.11%(2.35%,29.16%)	9.09%(1.92%,24.33%)	10.00%(3.76%,20.51%)
7+	0.00%(0.00%,0.00%)	18.18%(2.28%,51.78%)	9.09%(1.12%,29.16%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.10.0 Lack of Efficacy Endpoints – Modified Primary Analysis Set (mPAS) population

	Before RMM(n=105)		After RMM(n=94)		All Patients(n=199)	
	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
Number of patients treated with Tigecycline for approved indications	82(78.1%)	23(21.9%)	69(73.4%)	25(26.6%)	151(75.9%)	48(24.1%)
Number of patients with POTENTIAL lack of efficacy cases among patients treated with Tigecycline for approved indications	38(46.3%)	9(39.1%)	44(63.8%)	16(64.0%)	82(54.3%)	25(52.1%)
ADJUDICATED case status	N=38	N=9	N=44	N=16	N=82	N=25
Definite	1(2.6%)	0(0.0%)	1(2.3%)	0(0.0%)	2(2.4%)	0(0.0%)
Probable	0(0.0%)	2(22.2%)	6(13.6%)	1(6.3%)	6(7.3%)	3(12.0%)
Not a case	31(81.6%)	6(66.7%)	36(81.8%)	13(81.3%)	67(81.7%)	19(76.0%)
Insufficient information	6(15.8%)	1(11.1%)	1(2.3%)	2(12.5%)	7(8.5%)	3(12.0%)
If status='Not a case'	N=31	N=6	N=36	N=13	N=67	N=19
A. Evidence of clinical improvement after Tigecycline therapy	8(25.8%)	1(16.7%)	3(8.3%)	2(15.4%)	11(16.4%)	3(15.8%)
B. Clinically significant positive culture of an organism not susceptible to Tigecycline at baseline	1(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.5%)	0(0.0%)
C. Death not due to the infection treated with Tigecycline	1(3.2%)	0(0.0%)	0(0.0%)	2(15.4%)	1(1.5%)	2(10.5%)
D. Inadequate surgical control	5(16.1%)	0(0.0%)	7(19.4%)	1(7.7%)	12(17.9%)	1(5.3%)
Other reasons (as combination of above)#						
A and B	1(3.2%)	0(0.0%)	0(0.0%)	2(15.4%)	1(1.5%)	2(10.5%)
A and C	1(3.2%)	2(33.3%)	1(2.8%)	0(0.0%)	2(3.0%)	2(10.5%)
A and D	4(12.9%)	0(0.0%)	7(19.4%)	4(30.8%)	11(16.4%)	4(21.1%)
B and D	5(16.1%)	1(16.7%)	3(8.3%)	1(7.7%)	8(11.9%)	2(10.5%)
C and D	0(0.0%)	1(16.7%)	6(16.7%)	0(0.0%)	6(9.0%)	1(5.3%)
A and C and D	1(3.2%)	0(0.0%)	1(2.8%)	0(0.0%)	2(3.0%)	0(0.0%)
B and C and D	0(0.0%)	0(0.0%)	1(2.8%)	0(0.0%)	1(1.5%)	0(0.0%)
Other reasons (not included in above)*	4(12.9%)	1(16.7%)	7(19.4%)	1(7.7%)	11(16.4%)	2(10.5%)

	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
#Cases where reason includes more than the combination of reasons specified in the categories mentioned below will be classified under 'Other reasons (not included in above)' category.
*Please refer to Listing 8 for listing of other reasons for classifying event as 'not a case' of lack of efficacy
Data cut-off date: 22May2014
Analysis dataset: A_EFFIC
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Table 15.10.0a Sensitivity Analysis: Lack of Efficacy Endpoints – Modified Full Analysis Set (mFAS) population

	Before RMM(n=121)		After RMM(n=134)		All Patients(n=255)	
	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
Number of patients treated with Tigecycline for approved indications	96(79.3%)	25(20.7%)	101(75.4%)	33(24.6%)	197(77.3%)	58(22.7%)
Number of patients with POTENTIAL lack of efficacy cases among patients treated with Tigecycline for approved indications	45(46.9%)	9(36.0%)	68(67.3%)	19(57.6%)	113(57.4%)	28(48.3%)
ADJUDICATED case status	N=45	N=9	N=68	N=19	N=113	N=28
Definite	1(2.2%)	0(0.0%)	1(1.5%)	0(0.0%)	2(1.8%)	0(0.0%)
Probable	0(0.0%)	2(22.2%)	6(8.8%)	1(5.3%)	6(5.3%)	3(10.7%)
Not a case	37(82.2%)	6(66.7%)	53(77.9%)	15(78.9%)	90(79.6%)	21(75.0%)
Insufficient information	7(15.6%)	1(11.1%)	8(11.8%)	3(15.8%)	15(13.3%)	4(14.3%)
If status='Not a case'	N=37	N=6	N=53	N=15	N=90	N=21
A. Evidence of clinical improvement after Tigecycline therapy	8(21.6%)	1(16.7%)	4(7.5%)	2(13.3%)	12(13.3%)	3(14.3%)
B. Clinically significant positive culture of an organism not susceptible to Tigecycline at baseline	1(2.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.1%)	0(0.0%)
C. Death not due to the infection treated with Tigecycline	1(2.7%)	0(0.0%)	0(0.0%)	2(13.3%)	1(1.1%)	2(9.5%)
D. Inadequate surgical control	5(13.5%)	0(0.0%)	9(17.0%)	1(6.7%)	14(15.6%)	1(4.8%)
Other reasons (as combination of above)#						
A and B	1(2.7%)	0(0.0%)	0(0.0%)	2(13.3%)	1(1.1%)	2(9.5%)
A and C	2(5.4%)	2(33.3%)	1(1.9%)	0(0.0%)	3(3.3%)	2(9.5%)
A and D	5(13.5%)	0(0.0%)	9(17.0%)	5(33.3%)	14(15.6%)	5(23.8%)
B and C	0(0.0%)	0(0.0%)	1(1.9%)	0(0.0%)	1(1.1%)	0(0.0%)
B and D	6(16.2%)	1(16.7%)	6(11.3%)	2(13.3%)	12(13.3%)	3(14.3%)
C and D	0(0.0%)	1(16.7%)	7(13.2%)	0(0.0%)	7(7.8%)	1(4.8%)
A and B and D	0(0.0%)	0(0.0%)	1(1.9%)	0(0.0%)	1(1.1%)	0(0.0%)
A and C and D	1(2.7%)	0(0.0%)	2(3.8%)	0(0.0%)	3(3.3%)	0(0.0%)

	cIAI	cSSTI	cIAI	cSSTI	cIAI	cSSTI
B and C and D	0(0.0%)	0(0.0%)	2(3.8%)	0(0.0%)	2(2.2%)	0(0.0%)
Other reasons (not included in above)*	7(18.9%)	1(16.7%)	11(20.8%)	1(6.7%)	18(20.0%)	2(9.5%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
#Cases where reason includes more than the combination of reasons specified in the categories mentioned below will be classified under 'Other reasons (not included in above)' category.
*Please refer to Listing 8 for listing of other reasons for classifying event as 'not a case' of lack of efficacy
Data cut-off date: 22May2014
Analysis dataset: A_EFFIC
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Table 15.10.1 Incidence of Definite Lack of Efficacy - Modified Primary Analysis Set (mPAS) population

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	0.95%(0.02%,5.19%)	1.06%(0.03%,5.79%)	1.01%(0.12%,3.58%)
Incidence by Age			
< 65	1.82%(0.05%,9.72%)	1.79%(0.05%,9.55%)	1.80%(0.22%,6.36%)
>=65	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Gender			
Male	2.04%(0.05%,10.85%)	1.72%(0.04%,9.24%)	1.87%(0.23%,6.59%)
Female	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Infection Type			
cIAI	1.22%(0.03%,6.61%)	1.45%(0.04%,7.81%)	1.32%(0.16%,4.70%)
cSSTI	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Therapy Type			
Monotherapy	0.00%(0.00%,0.00%)	3.23%(0.08%,16.70%)	1.27%(0.03%,6.85%)
Combination	1.75%(0.04%,9.39%)	0.00%(0.00%,0.00%)	0.83%(0.02%,4.56%)
Incidence by History of Previous Antibiotic Therapy			
Yes	1.16%(0.03%,6.31%)	1.23%(0.03%,6.69%)	1.20%(0.15%,4.26%)
No	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	33.33%(0.84%,90.57%)	11.11%(0.28%,48.25%)
APACHE II >=15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
APACHE II Not Available	1.47%(0.04%,7.92%)	0.00%(0.00%,0.00%)	0.78%(0.02%,4.24%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.88%(0.15%,28.69%)	0.00%(0.00%,0.00%)	3.45%(0.09%,17.76%)
6-14	0.00%(0.00%,0.00%)	1.85%(0.05%,9.89%)	0.78%(0.02%,4.28%)
>=15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
1-3	1.92%(0.05%,10.26%)	0.00%(0.00%,0.00%)	1.01%(0.03%,5.50%)

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
4-6	0.00%(0.00%,0.00%)	4.55%(0.12%,22.84%)	2.22%(0.06%,11.77%)
7+	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.10.1a Sensitivity Analysis: Incidence of Definite Lack of Efficacy - Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	0.83%(0.02%,4.52%)	0.75%(0.02%,4.09%)	0.78%(0.10%,2.80%)
Incidence by Age			
< 65	1.69%(0.04%,9.09%)	1.37%(0.03%,7.40%)	1.52%(0.18%,5.37%)
>=65	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Gender			
Male	1.67%(0.04%,8.94%)	1.18%(0.03%,6.38%)	1.38%(0.17%,4.89%)
Female	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Infection Type			
cIAI	1.04%(0.03%,5.67%)	0.99%(0.03%,5.39%)	1.02%(0.12%,3.62%)
cSSTI	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Therapy Type			
Monotherapy	0.00%(0.00%,0.00%)	2.17%(0.06%,11.53%)	1.01%(0.03%,5.50%)
Combination	1.47%(0.04%,7.92%)	0.00%(0.00%,0.00%)	0.64%(0.02%,3.52%)
Incidence by History of Previous Antibiotic Therapy			
Yes	0.99%(0.03%,5.39%)	0.91%(0.02%,4.96%)	0.95%(0.11%,3.38%)
No	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	25.00%(0.63%,80.59%)	9.09%(0.23%,41.28%)
APACHE II >=15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
APACHE II Not Available	1.20%(0.03%,6.53%)	0.00%(0.00%,0.00%)	0.55%(0.01%,3.01%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.56%(0.14%,27.29%)	0.00%(0.00%,0.00%)	3.03%(0.08%,15.76%)
6-14	0.00%(0.00%,0.00%)	1.22%(0.03%,6.61%)	0.62%(0.02%,3.41%)
>=15	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
1-3	1.72%(0.04%,9.24%)	0.00%(0.00%,0.00%)	0.81%(0.02%,4.41%)

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
4-6	0.00%(0.00%,0.00%)	3.03%(0.08%,15.76%)	1.67%(0.04%,8.94%)
7+	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.10.2 Incidence of Definite and Probable Lack of Efficacy – Modified Primary Analysis Set (mPAS) population

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	2.86%(0.59%,8.12%)	8.51%(3.75%,16.08%)	5.53%(2.79%,9.68%)
Incidence by Age			
< 65	1.82%(0.05%,9.72%)	7.14%(1.98%,17.29%)	4.50%(1.48%,10.20%)
>=65	4.00%(0.49%,13.71%)	10.53%(2.94%,24.80%)	6.82%(2.54%,14.25%)
Incidence by Gender			
Male	6.12%(1.28%,16.87%)	8.62%(2.86%,18.98%)	7.48%(3.28%,14.20%)
Female	0.00%(0.00%,0.00%)	8.33%(1.75%,22.47%)	3.26%(0.68%,9.23%)
Incidence by Infection Type			
cIAI	1.22%(0.03%,6.61%)	10.14%(4.18%,19.79%)	5.30%(2.31%,10.17%)
cSSTI	8.70%(1.07%,28.04%)	4.00%(0.10%,20.35%)	6.25%(1.31%,17.20%)
Incidence by Therapy Type			
Monotherapy	0.00%(0.00%,0.00%)	16.13%(5.45%,33.73%)	6.33%(2.09%,14.16%)
Combination	5.26%(1.10%,14.62%)	4.76%(0.99%,13.29%)	5.00%(1.86%,10.57%)
Incidence by History of Previous Antibiotic Therapy			
Yes	3.49%(0.73%,9.86%)	8.64%(3.55%,17.00%)	5.99%(2.91%,10.74%)
No	0.00%(0.00%,0.00%)	7.69%(0.19%,36.03%)	3.13%(0.08%,16.22%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	33.33%(0.84%,90.57%)	11.11%(0.28%,48.25%)
APACHE II >=15	6.45%(0.79%,21.42%)	0.00%(0.00%,0.00%)	3.28%(0.40%,11.35%)
APACHE II Not Available	1.47%(0.04%,7.92%)	11.48%(4.74%,22.22%)	6.20%(2.72%,11.85%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.88%(0.15%,28.69%)	0.00%(0.00%,0.00%)	3.45%(0.09%,17.76%)
6-14	2.70%(0.33%,9.42%)	12.96%(5.37%,24.90%)	7.03%(3.27%,12.93%)
>=15	0.00%(0.00%,0.00%)	3.57%(0.09%,18.35%)	2.38%(0.06%,12.57%)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	5.88%(0.15%,28.69%)	2.56%(0.06%,13.48%)
1-3	3.85%(0.47%,13.21%)	4.26%(0.52%,14.54%)	4.04%(1.11%,10.02%)

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
4-6	4.35%(0.11%,21.95%)	18.18%(5.19%,40.28%)	11.11%(3.71%,24.05%)
7+	0.00%(0.00%,0.00%)	12.50%(0.32%,52.65%)	6.25%(0.16%,30.23%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.10.2a Sensitivity Analysis: Incidence of Definite and Probable Lack of Efficacy – Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	2.48%(0.51%,7.07%)	5.97%(2.61%,11.42%)	4.31%(2.17%,7.59%)
Incidence by Age			
< 65	1.69%(0.04%,9.09%)	5.48%(1.51%,13.44%)	3.79%(1.24%,8.62%)
>=65	3.23%(0.39%,11.17%)	6.56%(1.82%,15.95%)	4.88%(1.81%,10.32%)
Incidence by Gender			
Male	5.00%(1.04%,13.92%)	5.88%(1.94%,13.20%)	5.52%(2.41%,10.58%)
Female	0.00%(0.00%,0.00%)	6.12%(1.28%,16.87%)	2.73%(0.57%,7.76%)
Incidence by Infection Type			
cIAI	1.04%(0.03%,5.67%)	6.93%(2.83%,13.76%)	4.06%(1.77%,7.84%)
cSSTI	8.00%(0.98%,26.03%)	3.03%(0.08%,15.76%)	5.17%(1.08%,14.38%)
Incidence by Therapy Type			
Monotherapy	0.00%(0.00%,0.00%)	10.87%(3.62%,23.57%)	5.05%(1.66%,11.39%)
Combination	4.41%(0.92%,12.36%)	3.41%(0.71%,9.64%)	3.85%(1.42%,8.18%)
Incidence by History of Previous Antibiotic Therapy			
Yes	2.97%(0.62%,8.44%)	6.36%(2.60%,12.67%)	4.74%(2.30%,8.54%)
No	0.00%(0.00%,0.00%)	4.55%(0.12%,22.84%)	2.38%(0.06%,12.57%)
Incidence by Disease Severity			
APACHE II < 15	0.00%(0.00%,0.00%)	25.00%(0.63%,80.59%)	9.09%(0.23%,41.28%)
APACHE II >=15	6.45%(0.79%,21.42%)	0.00%(0.00%,0.00%)	3.28%(0.40%,11.35%)
APACHE II Not Available	1.20%(0.03%,6.53%)	7.00%(2.86%,13.89%)	4.37%(1.91%,8.43%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	5.56%(0.14%,27.29%)	0.00%(0.00%,0.00%)	3.03%(0.08%,15.76%)
6-14	2.53%(0.31%,8.85%)	8.54%(3.50%,16.80%)	5.59%(2.59%,10.35%)
>=15	0.00%(0.00%,0.00%)	2.70%(0.07%,14.16%)	1.64%(0.04%,8.80%)
Incidence by Charlson Comorbidity Score			
0	0.00%(0.00%,0.00%)	4.17%(0.11%,21.12%)	2.04%(0.05%,10.85%)

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
1-3	3.45%(0.42%,11.91%)	3.03%(0.37%,10.52%)	3.23%(0.89%,8.05%)
4-6	3.70%(0.09%,18.97%)	12.12%(3.40%,28.20%)	8.33%(2.76%,18.39%)
7+	0.00%(0.00%,0.00%)	9.09%(0.23%,41.28%)	4.55%(0.12%,22.84%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.10.3 Sensitivity Analysis: Incidence of Lack of Efficacy (definite + probable + insufficient information cases) – Modified Primary Analysis Set (mPAS) population

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	9.52%(4.66%,16.82%)	11.70%(5.99%,19.97%)	10.55%(6.65%,15.68%)
Incidence by Age			
< 65	9.09%(3.02%,19.95%)	10.71%(4.03%,21.88%)	9.91%(5.05%,17.04%)
>=65	10.00%(3.33%,21.81%)	13.16%(4.41%,28.09%)	11.36%(5.59%,19.91%)
Incidence by Gender			
Male	16.33%(7.32%,29.66%)	10.34%(3.89%,21.17%)	13.08%(7.34%,20.98%)
Female	3.57%(0.44%,12.31%)	13.89%(4.67%,29.50%)	7.61%(3.11%,15.05%)
Incidence by Infection Type			
cIAI	8.54%(3.50%,16.80%)	11.59%(5.14%,21.57%)	9.93%(5.67%,15.85%)
cSSTI	13.04%(2.78%,33.59%)	12.00%(2.55%,31.22%)	12.50%(4.73%,25.25%)
Incidence by Therapy Type			
Monotherapy	8.33%(2.32%,19.98%)	16.13%(5.45%,33.73%)	11.39%(5.34%,20.53%)
Combination	10.53%(3.96%,21.52%)	9.52%(3.58%,19.59%)	10.00%(5.27%,16.82%)
Incidence by History of Previous Antibiotic Therapy			
Yes	10.47%(4.90%,18.94%)	12.35%(6.08%,21.53%)	11.38%(6.99%,17.20%)
No	5.26%(0.13%,26.03%)	7.69%(0.19%,36.03%)	6.25%(0.77%,20.81%)
Incidence by Disease Severity			
APACHE II < 15	16.67%(0.42%,64.12%)	66.67%(9.43%,99.16%)	33.33%(7.49%,70.07%)
APACHE II >=15	6.45%(0.79%,21.42%)	0.00%(0.00%,0.00%)	3.28%(0.40%,11.35%)
APACHE II Not Available	10.29%(4.24%,20.07%)	14.75%(6.98%,26.17%)	12.40%(7.26%,19.36%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	17.65%(3.80%,43.43%)	0.00%(0.00%,0.00%)	10.34%(2.19%,27.35%)
6-14	9.46%(3.89%,18.52%)	16.67%(7.92%,29.29%)	12.50%(7.32%,19.50%)
>=15	0.00%(0.00%,0.00%)	7.14%(0.88%,23.50%)	4.76%(0.58%,16.16%)
Incidence by Charlson Comorbidity Score			
0	4.55%(0.12%,22.84%)	5.88%(0.15%,28.69%)	5.13%(0.63%,17.32%)

	Before RMM (n=105)	After RMM (n=94)	All patients (n=199)
1-3	11.54%(4.35%,23.44%)	10.64%(3.55%,23.10%)	11.11%(5.68%,19.01%)
4-6	13.04%(2.78%,33.59%)	18.18%(5.19%,40.28%)	15.56%(6.49%,29.46%)
7+	0.00%(0.00%,0.00%)	12.50%(0.32%,52.65%)	6.25%(0.16%,30.23%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.10.3a Sensitivity Analysis: Incidence of Lack of Efficacy (definite + probable + insufficient information cases) – Modified Full Analysis Set (mFAS) population

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
	Pct (95% CI)	Pct (95% CI)	Pct (95% CI)
Overall Incidence	9.09%(4.63%,15.68%)	14.18%(8.76%,21.25%)	11.76%(8.08%,16.37%)
Incidence by Age			
< 65	10.17%(3.82%,20.83%)	13.70%(6.77%,23.75%)	12.12%(7.09%,18.94%)
>=65	8.06%(2.67%,17.83%)	14.75%(6.98%,26.17%)	11.38%(6.36%,18.36%)
Incidence by Gender			
Male	15.00%(7.10%,26.57%)	12.94%(6.64%,21.98%)	13.79%(8.63%,20.50%)
Female	3.28%(0.40%,11.35%)	16.33%(7.32%,29.66%)	9.09%(4.45%,16.08%)
Incidence by Infection Type			
cIAI	8.33%(3.67%,15.76%)	14.85%(8.56%,23.31%)	11.68%(7.55%,17.00%)
cSSTI	12.00%(2.55%,31.22%)	12.12%(3.40%,28.20%)	12.07%(4.99%,23.30%)
Incidence by Therapy Type			
Monotherapy	7.55%(2.09%,18.21%)	15.22%(6.34%,28.87%)	11.11%(5.68%,19.01%)
Combination	10.29%(4.24%,20.07%)	13.64%(7.25%,22.61%)	12.18%(7.49%,18.36%)
Incidence by History of Previous Antibiotic Therapy			
Yes	9.90%(4.85%,17.46%)	16.36%(10.00%,24.62%	13.27%(9.00%,18.61%)
No	5.00%(0.13%,24.87%)	4.55%(0.12%,22.84%)	4.76%(0.58%,16.16%)
Incidence by Disease Severity			
APACHE II < 15	14.29%(0.36%,57.87%)	50.00%(6.76%,93.24%)	27.27%(6.02%,60.97%)
APACHE II >=15	6.45%(0.79%,21.42%)	0.00%(0.00%,0.00%)	3.28%(0.40%,11.35%)
APACHE II Not Available	9.64%(4.25%,18.11%)	17.00%(10.23%,25.82%	13.66%(9.04%,19.50%)
Incidence by Tigecycline Therapy Duration (days)			
<2	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)	0.00%(0.00%,0.00%)
2-5	16.67%(3.58%,41.42%)	6.67%(0.17%,31.95%)	12.12%(3.40%,28.20%)
6-14	10.13%(4.47%,18.98%)	18.29%(10.62%,28.37%	14.29%(9.28%,20.66%)
>=15	0.00%(0.00%,0.00%)	8.11%(1.70%,21.91%)	4.92%(1.03%,13.71%)
Incidence by Charlson Comorbidity Score			
0	4.00%(0.10%,20.35%)	4.17%(0.11%,21.12%)	4.08%(0.50%,13.98%)

	Before RMM (n=121)	After RMM (n=134)	All patients (n=255)
1-3	10.34%(3.89%,21.17%)	13.64%(6.43%,24.31%)	12.10%(6.93%,19.17%)
4-6	11.11%(2.35%,29.16%)	18.18%(6.98%,35.46%)	15.00%(7.10%,26.57%)
7+	9.09%(0.23%,41.28%)	27.27%(6.02%,60.97%)	18.18%(5.19%,40.28%)

cIAI= Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.11.0 Analysis of Off-label use: Exploratory Logistic Regression Analysis – Primary Analysis Set (PAS) population

	Adjusted Odds Ratio (95% CIs)
Study Period	
Before RMM	Reference
After RMM	0.657 (0.460, 0.938)
Age	
< 65	Reference
>=65	1.094 (0.769, 1.556)
Gender	
Male	Reference
Female	0.834 (0.589, 1.180)
Previous Antibiotic Therapy	
Yes	Reference
No	0.837 (0.535, 1.310)
Country	
Germany	Reference
Austria	2.463 (1.476, 4.110)
Greece	0.452 (0.182, 1.123)
UK	1.585 (1.042, 2.413)
Number of Co-morbidities	
0	Reference
1-3	1.094 (0.681, 1.758)
4 or more	1.056 (0.512, 2.177)
Previous surgical procedures	
Yes	Reference
No	4.521 (3.101, 6.590)

RMM = Risk Minimization Measure
Data cut-off date: 22May2014
Analysis dataset: A_SENS
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Table 15.12.0 Bacterial Pathogen Characteristics – Primary Analysis Set (PAS) population

	Before RMM (N=373)		After RMM (N=314)		All Patients (N=687)	
	No. of Patients with pathogen	No.(%) of Patients with resistant phenotype of the pathogen / phenotype *	No. of Patients with pathogen	No.(%) of Patients with resistant phenotype of the pathogen / phenotype *	No. of Patients with pathogen	No.(%) of Patients with resistant phenotype of the pathogen / phenotype *
Gram-positive	150	53(35.3%)	214	89(41.6%)	364	142(39.0%)
Staphylococcus spp.	87	32(36.8%)	106	49(46.2%)	193	81(42.0%)
Enterococcus spp.	79	23(29.1%)	145	44(30.3%)	224	67(29.9%)
Streptococcus spp.	18	0(0.0%)	31	1(3.2%)	49	1(2.0%)
Other	7	0(0.0%)	14	1(7.1%)	21	1(4.8%)
Gram-negative	128	45(35.2%)	143	44(30.8%)	271	89(32.8%)
E-coli	45	18(40.0%)	66	18(27.3%)	111	36(32.4%)
Proteus spp.	7	0(0.0%)	12	0(0.0%)	19	0(0.0%)
Klebsiella spp.	37	17(45.9%)	41	12(29.3%)	78	29(37.2%)
Enterobacter spp.	7	1(14.3%)	15	1(6.7%)	22	2(9.1%)
Citrobacter spp.	3	0(0.0%)	3	1(33.3%)	6	1(16.7%)
Serratia spp.	2	0(0.0%)	4	1(25.0%)	6	1(16.7%)
Haemophilus spp.	1	0(0.0%)	0	0(0.0%)	1	0(0.0%)
Morganella morganii	0	0(0.0%)	6	0(0.0%)	6	0(0.0%)
Acinetobacter spp.	4	2(50.0%)	3	0(0.0%)	7	2(28.6%)
P.aeruginosa	25	4(16.0%)	32	13(40.6%)	57	17(29.8%)
Other	40	7(17.5%)	28	3(10.7%)	68	10(14.7%)
Anaerobes	25	1(4.0%)	24	0(0.0%)	49	1(2.0%)
Bacteroides spp.	7	1(14.3%)	11	0(0.0%)	18	1(5.6%)
Peptostreptococcus spp.	0	0(0.0%)	0	0(0.0%)	0	0(0.0%)
Clostridium spp.	12	0(0.0%)	11	0(0.0%)	23	0(0.0%)
Prevotella spp.	2	0(0.0%)	2	0(0.0%)	4	0(0.0%)
Other	4	0(0.0%)	2	0(0.0%)	6	0(0.0%)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, RMM=Risk Minimization Measure.
*Includes MRSA=Methicillin-resistant Staphylococcus aureus, MRCNS=Methicillin-resistant coagulase-negative Staphylococcus, VRE=Vancomycin-resistant Enterococcus, ESBLPO=Extended-spectrum beta-lactamase producing organism, CPO=Carbapenemase-producing organism, Other MDRO=Other multi-drug-resistant organism.
Data cut-off date: 22May2014
Analysis dataset: A_PATH

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Table 15.12.1 Bacterial Pathogen Analysis by Indication for Use – Primary Analysis Set (PAS) population

	cIAI (N=271)		cSSTI (N=102)		Off-label Indication (N=314)	
	Before RMM (n=129)	After RMM (n=142)	Before RMM (n=42)	After RMM (n=60)	Before RMM (n=202)	After RMM (n=112)
Gram-positive*	66(51.2%)	111(78.2%)	20(47.6%)	33(55.0%)	64(31.7%)	69(61.6%)
Staphylococcus spp.	28(21.7%)	40(28.2%)	15(35.7%)	25(41.7%)	44(21.8%)	41(36.6%)
Enterococcus spp.	47(36.4%)	85(59.9%)	9(21.4%)	20(33.3%)	23(11.4%)	40(35.7%)
Streptococcus spp.	7(5.4%)	20(14.1%)	1(2.4%)	4(6.7%)	10(5.0%)	6(5.4%)
Other	3(2.3%)	6(4.2%)	0(0.0%)	1(1.7%)	4(2.0%)	7(6.3%)
Gram-negative*	55(42.6%)	73(51.4%)	14(33.3%)	26(43.3%)	59(29.2%)	43(38.4%)
E-coli	19(14.7%)	34(23.9%)	3(7.1%)	8(13.3%)	23(11.4%)	23(20.5%)
Proteus spp.	3(2.3%)	6(4.2%)	1(2.4%)	4(6.7%)	3(1.5%)	1(0.9%)
Klebsiella spp.	13(10.1%)	25(17.6%)	4(9.5%)	8(13.3%)	20(9.9%)	7(6.3%)
Enterobacter spp.	2(1.6%)	9(6.3%)	2(4.8%)	2(3.3%)	3(1.5%)	4(3.6%)
Citrobacter spp.	0(0.0%)	0(0.0%)	0(0.0%)	1(1.7%)	3(1.5%)	2(1.8%)
Serratia spp.	1(0.8%)	1(0.7%)	1(2.4%)	2(3.3%)	0(0.0%)	1(0.9%)
Haemophilus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.5%)	0(0.0%)
Morganella morganii	0(0.0%)	3(2.1%)	0(0.0%)	2(3.3%)	0(0.0%)	1(0.9%)
Acinetobacter spp.	1(0.8%)	2(1.4%)	2(4.8%)	0(0.0%)	1(0.5%)	1(0.9%)
P.aeruginosa	15(11.6%)	15(10.6%)	1(2.4%)	6(10.0%)	9(4.5%)	11(9.8%)
Other	19(14.7%)	12(8.5%)	4(9.5%)	4(6.7%)	17(8.4%)	12(10.7%)
Anaerobes*	10(7.8%)	13(9.2%)	2(4.8%)	2(3.3%)	13(6.4%)	9(8.0%)
Bacteroides spp.	5(3.9%)	7(4.9%)	0(0.0%)	1(1.7%)	2(1.0%)	3(2.7%)
Peptostreptococcus spp.	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Clostridium spp.	3(2.3%)	6(4.2%)	0(0.0%)	0(0.0%)	9(4.5%)	5(4.5%)
Prevotella spp.	0(0.0%)	0(0.0%)	1(2.4%)	1(1.7%)	1(0.5%)	1(0.9%)
Other	2(1.6%)	1(0.7%)	1(2.4%)	0(0.0%)	1(0.5%)	1(0.9%)
Multi-drug resistant organism	26(20.2%)	44(31.0%)	18(42.9%)	27(45.0%)	39(19.3%)	46(41.1%)
MRSA	4(3.1%)	6(4.2%)	5(11.9%)	7(11.7%)	11(5.4%)	14(12.5%)
MR-CNS	2(1.6%)	6(4.2%)	1(2.4%)	6(10.0%)	3(1.5%)	5(4.5%)
VRE	9(7.0%)	22(15.5%)	5(11.9%)	8(13.3%)	4(2.0%)	10(8.9%)
ESBLPO	12(9.3%)	13(9.2%)	7(16.7%)	5(8.3%)	15(7.4%)	10(8.9%)
CPO	3(2.3%)	4(2.8%)	1(2.4%)	2(3.3%)	1(0.5%)	5(4.5%)
Other	6(4.7%)	4(2.8%)	3(7.1%)	7(11.7%)	10(5.0%)	10(8.9%)

	Before RMM (n=129)	After RMM (n=142)	Before RMM (n=42)	After RMM (n=60)	Before RMM (n=202)	After RMM (n=112)

cIAI=Complicated Intra-Abdominal Infection, cSSTI=Complicated Skin or Soft Tissue Infection, CPO=Carbapenemase-producing organism,
ESBLPO=Extended-spectrum beta-lactamase producing organism, MRSA=Methicillin-resistant Staphylococcus aureus,
MRCNS=Methicillin-resistant coagulase-negative Staphylococcus, RMM=Risk Minimization Measure, VRE=Vancomycin-resistant Enterococcus.
* Please refer to Listing 9 for individual pathogen listings by species
Data cut-off date: 22May2014
Analysis dataset: A_PATH
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Table 15.13.0 Hospital Characteristics-Primary Analysis Set (PAS) population

	All Hospital or Ward (N=10)
Center Type	
n	10
University	9(90.0%)
Public	1(10.0%)
Private	0(0.0%)
Other	0(0.0%)
Missing	0
Number of Beds at Hospital/Medical Center#	
n	10
Min, Max	344,3222
Missing	0
Number of ICU±	
n	10
Min, Max	1,26
Missing	0
Patients come from	
n	10
Specific Ward(s)/department(s)	6(60.0%)
Hospital (as a whole)	4(40.0%)
Missing	0
Event could have affected Tigecycline prescribing patterns	
Before RMM	
n	10
No	9(90.0%)
Cannot be disclosed	0(0.0%)
Yes*	1(10.0%)
Missing	0
After RMM	
n	10
No	9(90.0%)
Cannot be disclosed	0(0.0%)
Yes*	1(10.0%)
Missing	0

ICU=Intensive Care unit, RMM=Risk Minimization Measure.
#Mean (SD) and Median cannot be interpreted as 3 wards come from the same hospital. The number of beds at this hospital was variously reported as 3200 beds by 2 wards and 3222 by one ward.
±Mean (SD) and Median cannot be interpreted as 3 wards come from the same hospital. The number of ICUs at these 3 wards range from 19 to 26.
* Please refer to Listing 10 for information on events that could have affected Tigecycline prescribing patterns.
Data cut-off date: 22May2014
Analysis dataset: A_SITE
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Table 15.13.0a Hospital Characteristics-Full Analysis Set (FAS) population

	All Hospital or Ward (N=13)
Center Type	
n	13
University	12(92.3%)
Public	1(7.7%)
Private	0(0.0%)
Other	0(0.0%)
Missing	0
Number of Beds at Hospital/Medical Center#	
n	13
Min, Max	344,3222
Missing	0
Number of ICU#	
n	13
Min, Max	1,26
Missing	0
Patients come from	
n	13
Specific Ward(s)/department(s)	6(46.2%)
Hospital (as a whole)	7(53.8%)
Missing	0
Event could have affected Tigecycline prescribing patterns	
Before RMM	
n	13
No	11(84.6%)
Cannot be disclosed	0(0.0%)
Yes*	2(15.4%)
Missing	0
After RMM	
n	13
No	11(84.6%)
Cannot be disclosed	0(0.0%)
Yes*	2(15.4%)
Missing	0

ICU=Intensive Care unit, RMM=Risk Minimization Measure.
#Mean (SD) and Median cannot be interpreted as 3 wards come from the same hospital. The number of beds at this hospital was variously reported as 3200 beds by 2 wards and 3222 by one ward.
±Mean (SD) and Median cannot be interpreted as 3 wards come from the same hospital. The number of ICUs at these 3 wards range from 19 to 26.
* Please refer to Listing 10 for information on events that could have affected Tigecycline prescribing patterns.
Data cut-off date: 22May2014
Analysis dataset: A_SITE
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Table 15.14.0 Adverse events by System Organ Class (SOC) and Preferred Term (PT) – Primary Analysis Set (PAS) population

System Organ Class (SOC) Preferred Term (PT)	Patients n (%)	Events n
Number of Patients with at least one AE	8 (1.2%)	11
Gastrointestinal disorders	1 (0.1%)	1
Nausea	1 (0.1%)	1
Hepatobiliary disorders	1 (0.1%)	1
Cholecystitis	1 (0.1%)	1
Immune system disorders	1 (0.1%)	2
Drug hypersensitivity	1 (0.1%)	2
Infections and infestations	4 (0.6%)	5
Pneumonia	2 (0.3%)	2
Pseudomonas infection	2 (0.3%)	2
Sepsis	1 (0.1%)	1
Investigations	1 (0.1%)	1
Hepatic enzyme increased	1 (0.1%)	1
Skin and subcutaneous tissue disorders	1 (0.1%)	1
Rash pruritic	1 (0.1%)	1

AE=Adverse Event
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.0a Adverse events by System Organ Class (SOC) and Preferred Term (PT) – Full Analysis Set (FAS) population

System Organ Class (SOC) Preferred Term (PT)	Patients n (%)	Events n
Number of Patients with at least one AE	8 (1.0%)	11
Gastrointestinal disorders	1 (0.1%)	1
Nausea	1 (0.1%)	1
Hepatobiliary disorders	1 (0.1%)	1
Cholecystitis	1 (0.1%)	1
Immune system disorders	1 (0.1%)	2
Drug hypersensitivity	1 (0.1%)	2
Infections and infestations	4 (0.5%)	5
Pneumonia	2 (0.3%)	2
Pseudomonas infection	2 (0.3%)	2
Sepsis	1 (0.1%)	1
Investigations	1 (0.1%)	1
Hepatic enzyme increased	1 (0.1%)	1
Skin and subcutaneous tissue disorders	1 (0.1%)	1
Rash pruritic	1 (0.1%)	1

AE=Adverse Event
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.1 Adverse Events by Severity – Primary Analysis Set (PAS) population

Adverse Events by Severity - Primary Analysis Set (PAS) population

	Mild		Moderate		Severe		Unknown	
System Organ Class(SOC) Preferred Term (PT)	Patients n (%)	Events n	Patients n (%)	Events n	Patients n (%)	Events n	Patients n (%)	Events n
Number of Patients with at least one AE	4 (0.6%)	5	1 (0.1%)	1	2 (0.3%)	4	1 (0.1%)	1
Gastrointestinal disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Nausea	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Hepatobiliary disorders	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Cholecystitis	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Immune system disorders	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Drug hypersensitivity	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Infections and infestations	0 (0.0%)	0	1 (0.1%)	1	2 (0.3%)	3	1 (0.1%)	1
Pneumonia	0 (0.0%)	0	1 (0.1%)	1	1 (0.1%)	1	0 (0.0%)	0
Pseudomonas infection	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	1 (0.1%)	1
Sepsis	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Investigations	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Hepatic enzyme increased	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Skin and subcutaneous tissue disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Rash pruritic	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0

AE=Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.1a Adverse Events by Severity – Full Analysis Set (FAS) population

Adverse Events by Severity - Full Analysis Set (FAS) population

System Organ Class(SOC) Preferred Term (PT)	Mild Patients n (%)	Mild Events n	Moderate Patients n (%)	Moderate Events n	Severe Patients n (%)	Severe Events n	Unknown Patients n (%)	Unknown Events n
Number of Patients with at least one AE	4 (0.5%)	5	1 (0.1%)	1	2 (0.3%)	4	1 (0.1%)	1
Gastrointestinal disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Nausea	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Hepatobiliary disorders	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Cholecystitis	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Immune system disorders	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Drug hypersensitivity	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Infections and infestations	0 (0.0%)	0	1 (0.1%)	1	2 (0.3%)	3	1 (0.1%)	1
Pneumonia	0 (0.0%)	0	1 (0.1%)	1	1 (0.1%)	1	0 (0.0%)	0
Pseudomonas infection	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	1 (0.1%)	1
Sepsis	0 (0.0%)	0	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Investigations	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Hepatic enzyme increased	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Skin and subcutaneous tissue disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Rash pruritic	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0

AE=Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.2 Adverse Events by Action Taken – Primary Analysis Set (PAS) population

	Overall (N=687)					
	Stopped		Continued at a different dosage		Unchanged	
System Organ Class(SOC) Preferred Term (PT)	Patients n (%)	Events n	Patients n (%)	Events n	Patients n (%)	Events n
Number of Patients with at least one AE	6 (0.9%)	7	0 (0.0%)	0	0 (0.0%)	0
Gastrointestinal disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Nausea	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Hepatobiliary disorders	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Cholecystitis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Immune system disorders	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0
Drug hypersensitivity	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0
Infections and infestations	2 (0.3%)	2	0 (0.0%)	0	0 (0.0%)	0
Pneumonia	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Pseudomonas infection	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Sepsis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Investigations	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Hepatic enzyme increased	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Skin and subcutaneous tissue disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Rash pruritic	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0

AE=Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.2a Adverse Events by Action Taken – Full Analysis Set (FAS) population

	Overall (N=777)					
	Stopped		Continued at a different dosage		Unchanged	
System Organ Class(SOC) Preferred Term (PT)	Patients n (%)	Events n	Patients n (%)	Events n	Patients n (%)	Events n
Number of Patients with at least one AE	6 (0.8%)	7	0 (0.0%)	0	0 (0.0%)	0
Gastrointestinal disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Nausea	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Hepatobiliary disorders	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Cholecystitis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Immune system disorders	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0
Drug hypersensitivity	1 (0.1%)	2	0 (0.0%)	0	0 (0.0%)	0
Infections and infestations	2 (0.3%)	2	0 (0.0%)	0	0 (0.0%)	0
Pneumonia	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Pseudomonas infection	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Sepsis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Investigations	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Hepatic enzyme increased	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Skin and subcutaneous tissue disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Rash pruritic	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0

AE=Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.3 Adverse Events by Outcome – Primary Analysis Set (PAS) population

Overall (N=687)

System Organ Class(SOC) Preferred Term (PT)	Worsened Patients n (%)	 Events n	Resolved Patients n (%)	 Events n	Resolved with sequelae Patients n (%)	 Events n
Number of Patients with at least one AE	0 (0.0%)	0	5 (0.7%)	6	0 (0.0%)	0
Gastrointestinal disorders	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Nausea	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Hepatobiliary disorders	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Cholecystitis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Immune system disorders	0 (0.0%)	0	1 (0.1%)	2	0 (0.0%)	0
Drug hypersensitivity	0 (0.0%)	0	1 (0.1%)	2	0 (0.0%)	0
Infections and infestations	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Pneumonia	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Pseudomonas infection	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Sepsis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Investigations	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Hepatic enzyme increased	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Skin and subcutaneous tissue disorders	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Rash pruritic	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0

AE=Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.14.3a Adverse Events by Outcome – Full Analysis Set (FAS) population

	Overall (N=777)					
	Worsened		Resolved		Resolved with sequelae	
System Organ Class(SOC) Preferred Term (PT)	Patients n (%)	Events n	Patients n (%)	Events n	Patients n (%)	Events n
Number of Patients with at least one AE	0 (0.0%)	0	5 (0.6%)	6	0 (0.0%)	0
Gastrointestinal disorders	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Nausea	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Hepatobiliary disorders	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Cholecystitis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Immune system disorders	0 (0.0%)	0	1 (0.1%)	2	0 (0.0%)	0
Drug hypersensitivity	0 (0.0%)	0	1 (0.1%)	2	0 (0.0%)	0
Infections and infestations	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Pneumonia	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Pseudomonas infection	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Sepsis	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Investigations	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Hepatic enzyme increased	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Skin and subcutaneous tissue disorders	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0
Rash pruritic	0 (0.0%)	0	1 (0.1%)	1	0 (0.0%)	0

AE=Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.15.0 Serious Adverse events by System Organ Class (SOC) and Preferred Term (PT) – Primary Analysis Set (PAS) population

System Organ Class(SOC) Preferred Term (PT)	Overall (N=687) Patients n (%)	 Events n
Number of Patients with at least one SAE	5 (0.7%)	8
Hepatobiliary disorders	1 (0.1%)	1
Cholecystitis	1 (0.1%)	1
Immune system disorders	1 (0.1%)	2
Drug hypersensitivity	1 (0.1%)	2
Infections and infestations	4 (0.6%)	5
Pneumonia	2 (0.3%)	2
Pseudomonas infection	2 (0.3%)	2
Sepsis	1 (0.1%)	1

SAE=Adverse Event
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.15.0a Serious Adverse events by System Organ Class (SOC) and Preferred Term (PT) – Full Analysis Set (FAS) population

	Overall (N=777)	
System Organ Class(SOC) Preferred Term (PT)	Patients n (%)	Events n
Number of Patients with at least one SAE	5 (0.6%)	8
Hepatobiliary disorders	1 (0.1%)	1
Cholecystitis	1 (0.1%)	1
Immune system disorders	1 (0.1%)	2
Drug hypersensitivity	1 (0.1%)	2
Infections and infestations	4 (0.5%)	5
Pneumonia	2 (0.3%)	2
Pseudomonas infection	2 (0.3%)	2
Sepsis	1 (0.1%)	1

SAE=Adverse Event
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.15.1 Serious Adverse Events by Seriousness Criteria – Primary Analysis Set (PAS) population

Overall (N=687)

System Organ Class(SOC) Preferred Term (PT)	Death Patients n (%)	Death Events n	Life-Threatening Patients n (%)	Life-Threatening Events n	Hospitalization Patients n (%)	Hospitalization Events n
Number of Patients with at least one SAE	3 (0.4%)	5	0 (0.0%)	0	3 (0.4%)	3
Hepatobiliary disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Cholecystitis	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Immune system disorders	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Drug hypersensitivity	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Infections and infestations	3 (0.4%)	4	0 (0.0%)	0	3 (0.4%)	3
Pneumonia	1 (0.1%)	1	0 (0.0%)	0	1 (0.1%)	1
Pseudomonas infection	2 (0.3%)	2	0 (0.0%)	0	2 (0.3%)	2
Sepsis	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0

SAE=Serious Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
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Table 15.15.1a Serious Adverse Events by Seriousness Criteria – Full Analysis Set (FAS) population

Overall (N=777)

System Organ Class(SOC) Preferred Term (PT)	Death Patients n (%)	Death Events n	Life-Threatening Patients n (%)	Life-Threatening Events n	Hospitalization Patients n (%)	Hospitalization Events n
Number of Patients with at least one SAE	3 (0.4%)	5	0 (0.0%)	0	3 (0.4%)	3
Hepatobiliary disorders	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Cholecystitis	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0
Immune system disorders	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Drug hypersensitivity	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
Infections and infestations	3 (0.4%)	4	0 (0.0%)	0	3 (0.4%)	3
Pneumonia	1 (0.1%)	1	0 (0.0%)	0	1 (0.1%)	1
Pseudomonas infection	2 (0.3%)	2	0 (0.0%)	0	2 (0.3%)	2
Sepsis	1 (0.1%)	1	0 (0.0%)	0	0 (0.0%)	0

SAE=Serious Adverse Event.
Data cut-off date: 22May2014
Analysis dataset: A_ADAE
Created by Y:\Pfizer\Tygacil\Tables\Table15.1a.sas