

INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. Your declaration will not be accepted if any fields are left empty. You are responsible for the accuracy and completeness of the submitted information.

The form is designed to be filled in electronically and to be transmitted to the ENCePP Secretariat by email; in parallel, a copy of the form should be uploaded to the <u>EU PAS Register</u>.

First Name:	Lia	
Last Name:	Gutiérrez	
Organisation / Research Centre :	RTI Health Solutions	
Country:	Spain	
Contact e-mail Address: <i>Igutierrez@rti.org</i>		
	Intravenous Iron Postauthorisation Safe Severe Hypersensitivity Reactions	ty Study (PASS): Evaluation of the Risk of
Study Reference Number: I	EUPAS 2 0 7 2 0	
Are you the (Primary) Lead	Investigator of the above study?	No 🗌 Yes 🖌
Are you an investigator/res	earcher contributing to the above study	No 🖌 Yes 🗌

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

2.1 Employment

No 🕢 Yes ()

No 🕢

Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

2.2 Financial Interest

Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

2.3 Patent

Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

2.4 Consultancy

Consultancy for a pharmaceutical company during the past 3 years of study application?

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No

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2.5 Strategic Advisory Role

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

2.6 Grant / Funding

Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

No

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments	
Multiple pharmaceutical companies fund studies and activities through contracts with my employer including AstraZeneca, Helsinn, Leo Pharma, Merck, Novartis, Servier, Vifor & IV iron consortium	http://www.encepp.eu/encepp/links.htm? id=19407&resourceType=ResearchCentre	

SECTION 3: ANY OTHER INTERESTS

No 🕢 Yes ()

In this section you should declare any other interests to be made known to the public.

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

No \bigcirc Yes ()



Yes ()

Yes 🔘

Yes 🕢

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FULL NAME:	Lia Gutiérrez	Date:	30/11/2017
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First Name:	Joan	
Last Name:	Fortuny	
Organisation / Research Centre :	RTI Health Solutions	
Country:	Spain	
Contact e-mail Address:	jfortuny@rti.org]
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Yes 🕢

Yes (

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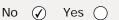
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FULL NAME:	Joan Fortuny	Date:	30/11/2017
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First Name:	Susana		
Last Name:	Perez Gutthann		
Organisation / Research Centre :	RTI Health Solutions		
Country:	Spain		
Contact e-mail Address:	s: sperez@rti.org		
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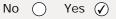
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Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Period:	Current (Past
From Month: 06	From Year:	2016
Name of Pharmaceu	utical Company	Almirall
Type of consultancy:		Skilarence PASS

Please specify	the pharmaceutical	company, types of consultancy and dates when fees/honoraria paid:	
Period:	Current	○ Past	

From Month: 11 From Year: 20	14
Name of Pharmaceutical Company:	Roche
Type of consultancy:	Ocrelizumab PASS

Please specify the	pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:
Period:		Past
From Month:	04 From Year: 20)14
Name of Pharmaceutical Company:		Servier
Type of consu	Iltancy:	General pharmacoepidemiology, Vastarel PASS

2.5 Strategic Advisory Role

No 🔘 Yes 🕢

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Please specify the pharmaceutical company, t	ype of strategic advisory role and dates:		
Period: O Current 🕢 Pas	st		
From Month: 03 From Year: 2012	To Month: 12 To Year: 2016		
Name of Pharmaceutical Company: Ori	ion		
Type of strategic advisory role:	xDUS study steering group		
Please specify the pharmaceutical company, t	ype of strategic advisory role and dates:		
Period: O Current 🖉 Pas	st		
From Month: 11 From Year: 2013 To Month: 07 To Year: 2015			
Name of Pharmaceutical Company: Amgen			
Type of strategic advisory role:	ocolumab RMP advisory group		
Please specify the pharmaceutical company, t	ype of strategic advisory role and dates:		
Period: 🖉 Current 🔿 Pas	st		
From Month: 03 From Year: 2013			
Name of Pharmaceutical Company: Se	rvier		
Type of strategic advisory role:	otelos EU ADR PASS advisory group		

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hann Date: 30/11/2017
nann Date: 30/11/20



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First Name:	Catherine	
Last Name:	Johannes	
Organisation / Research Centre :	RTI Health Solutions	
Country:	United States of America	
Contact e-mail Address:	cjohannes@rti.org	
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Yes ()

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FULL NAME: Catherine Johannes Date: 30/11/2017



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First Name:	Lawrence	
Last Name:	Rasouliyan	
Organisation / Research Centre :	RTI Health Solutions	
Country:	Spain	
Contact e-mail Address:	lrasouliyan@rti.org]
	Intravenous Iron Postauthorisation Safe Severe Hypersensitivity Reactions	ty Study (PASS): Evaluation of the Risk of
Study Reference Number:	EUPAS 2 0 7 2 0	
Are you the (Primary) Lead	Investigator of the above study?	No 🖌 Yes 🗌
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Please specify the pharmaceutical company:

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No 🕢 Yes ()

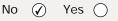
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Yes 🔘

Yes 🕢



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FULL NAME: Lawrence Rasouliyan Date: 30/11/2017



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First Name:	Kenneth					
Last Name:	Rothman					
Organisation / Research Centre :	RTI Health Solutions					
Country:	United States of America				_	
Contact e-mail Address:	krothman@rti.org					
	IV Iron PASS					
Study Reference Number:	EUPAS 2 0 7 2 0					
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Are you an investigator/res	earcher contributing to the above study	No	Yes	\checkmark		

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Yes 🔘

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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments	
	RTI Health Solutions contracts with various pharmaceutical companies, and I engage in projects as a full-time employee of RTI Health Solutions.	

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FULL NAME:	Kenneth Rothman	Date:	27/07/2017
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Last Name:	Aguado	
Organisation / Research Centre :	RTI Health Solutions	
Country:	Spain	
Contact e-mail Address:	jaguado@rti.org]
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Name of harmaceutical Company	Comments	
	http://www.encepp.eu/encepp/links.htm? id=19407&resourceType=ResearchCentre	

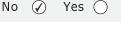
SECTION 3: ANY OTHER INTERESTS

No 🕢 Yes 🔿

In this section you should declare any other interests to be made known to the public.

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

No 🕢 Yes 🔿



Yes 🔘

Yes 🕢

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

 \checkmark I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:	Jaume Aguado	Date:	07/09/2017



INTRODUCTION

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The form is designed to be filled in electronically and to be transmitted to the ENCePP Secretariat by email; in parallel, a copy of the form should be uploaded to the EU PAS Register.

First Name:	David	
Last Name:	Rampton	
Organisation / Research Centre :	Barts and the London School of Medicin London	e and Dentistry,
Country:	United Kingdom	
Contact e-mail Address:	d.rampton@qmul.ac.uk	
	IV Iron PASS	
Study Reference Number	: EUPAS 2 0 7 2 0	
Are you the (Primary) Lea	d Investigator of the above study?	No 🖌 Yes
Are you an investigator/re	esearcher contributing to the above study	No Yes 🖌

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

2.1 Employment

Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

2.2 Financial Interest

Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

2.3 Patent

Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

2.4 Consultancy

No () Yes	\oslash
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No 🕢 Yes 🔿

Consultancy for a pharmaceutical company during the past 3 years of study application?

Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria.

Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Period: O Current Q	Past	
From Month: 01 From Year: 2	015 To Month: 06 To Year: 2015	
Name of Pharmaceutical Company:	Shire	
Type of consultancy:	Judging travel award applications and research competit	ion

2.5 Strategic Advisory Role

No 🔿 Yes 🕢

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

Please specify the pharmaceutical company, type of strategic advisory role and dates:

Period:	C Current	Past			
From Month:	06 From Year: 20	015	To Month:	09 To Year:	2015
Name of Pharm	aceutical Company:	Atlantic Healt	hcare		
Type of strategic advisory role:		Consultancy of	on new drug		



No 🕢 Yes 🔿

2.6 Grant / Funding

No 🕢 Yes 🔿

Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

SECTION 3: ANY OTHER INTERESTS No 🕢 Yes 🔿

In this section you should declare any other interests to be made known to the public.

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

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I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the EU PAS Register.

FULL NAME:	David Rampton	Date:	24/07/2017
	S	ubmit Form by	Email



INTRODUCTION

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First Name:	Edeltraut
Last Name:	Prof. Dr. med. Garbe
Organisation / Research Centre :	University of Bremen
Country:	Germany
Contact e-mail Address:	garbe@uni-bremen.de
	Intravenous Iron Postauthorization Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions
Study Reference Number:	EUPAS 2 0 7 2 0
Are you the (Primary) Lea	d Investigator of the above study? No 🗸 Yes
Are you an investigator/re	esearcher contributing to the above study No 🗌 Yes 🗸

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within th past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

2.1 Employment

No 🕢 Yes 🔿

V Yes

Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, productior and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

No

2.2 Financial Interest

Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independentl managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

2.3 Patent

DI

Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

2.4 Consultancy



No 🕢 Yes 🔿

Consultancy for a pharmaceutical company during the past 3 years of study application?

Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria.

Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Period:	○ Current Ø	Past				
From Month:	01 From Year: 2	016	To Month:	12	To Year:	2016
Name of Pharn	naceutical Company:	Bayer AG				
Type of consu	Iltancy:	Scientific ad treatment o	visor on studie f prostate cance	s related t er	o heart failu	re and

Please specify the pharmaceutical compar	ny, types of consultancy and dates when fees/honoraria paid:
Period: 🖉 Current 🔿	Past
From Month: 02 From Year: 20	011
Name of Pharmaceutical Company:	Nycomed/Takeda/AstraZeneca
Type of consultancy:	Member of Scientific Advisory Committee and later Principal Investigator of PASS study concerning roflumilast
Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:
Period: 🖉 Current 🔿	Past
From Month: 09 From Year: 20	015
Name of Pharmaceutical Company:	Astellas
Type of consultancy:	Chair of Scientific Advisory Board concerning PASS study regarding Mirabegron

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

2.6 Grant / Funding

No 🕢 Yes 🔾

Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

SECTION 3: ANY OTHER INTERESTS No @ Yes ()

In this section you should declare any other interests to be made known to the public.

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FULL NAME:

Edeltraut Prof. Dr. med. Garbe

Date: 10/09/2017



INTRODUCTION

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First Name:	Jacques
Last Name:	Benichou
Organisation / Research Centre :	University of Rouen and Rouen University Hospital
Country:	France
Contact e-mail Address:	jacques.benichou@chu-rouen.fr
	Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions
Study Reference Number: I	EUPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No 🔽 Yes
Are you an investigator/res	earcher contributing to the above study No 🗌 Yes 🔽

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

2.1 Employment

No 🕑 Yes 🔘

Yes ()

Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

2.2 Financial Interest

Financial interests in the capital of a pharmaceutical company?

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No

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2.3 Patent

Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

2.4 Consultancy

٧o	\bigcirc	Yes	\bigcirc
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No 🕢 Yes 🔿

Consultancy for a pharmaceutical company during the past 3 years of study application?

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Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Period: 🖉 Currer	nt 🔿 Past
From Month: 01 Fro	m Year: 2013
Name of Pharmaceutical C	Company: Pierre Fabre
Type of consultancy:	Member of Data Monitoring Committee of clinical trial

Please specify the pharmaceutical company, ty	pes of consultancy and dates when fees/honoraria paid:

Period:	Current	Past
From Month:	01 From Year: 20	015
Name of Pharmaceutical Company:		Vertex
Type of consu	ultancy:	Member of Scientific Committee of clinical trial

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:				
Period:		Past		
From Month:	01 From Year: 20)11		
Name of Pharmaceutical Company:		Servier		
Type of consu	ultancy:	Member of Data Monitoring Committee of clinical trial		

Version-number	1.5

Period: 🖉 Current	Past	
From Month: 01 From Year: 20	009	
Name of Pharmaceutical Company:	Servier	
Type of consultancy:	Member of Scientific Committee of observational pharmacoepidemiological study	
Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:	
Period: 🕜 Current 🔿	Past	
From Month: 01 From Year: 20	012	
Name of Pharmaceutical Company:	Astra Zeneca	
Type of consultancy:	Member of scientific committee of two observational pharmacoepidemiological studies	
Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:	

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Period: 🖉 Current 🔿	Past
From Month: 01 From Year: 20	12
Name of Pharmaceutical Company:	BMS
	Member of Scientific Committee of observational pharmacoepidemiological study

2.5 Strategic Advisory Role

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

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No 🕢 Yes 🔿

No 🕢 Yes 🔿

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FULL NAME:	ULL NAME: Jacques Benichou		25/10/2017	



INTRODUCTION

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First Name:	kathleen					
Last Name:	iwalsh					
Organisation / Research	cincinnati children's hospital			1		
<i></i>					2	
Country:	United States of America		3			
Contact e-mail Address:	kathleen.waish@cchmc.org	1			2	
r	1					t-
		а.				ţ
Study Reference Number	EUPAS 2 0 7 2 0					
Are you the (Primary) Lea	d Investigator of the above study?	No Z	Yes			
are you an investigator/re	esearcner contributing to the above study		Yes	M		

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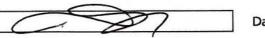
Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

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U I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the EU PAS Register.

FULL NAME:



Date:

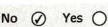
No () Yes (

No () Yes ()

No () Yes ()

No () Yes ()





No () Yes ()

No () Yes ()

54



INTRODUCTION

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First Name:	Jochen
Last Name:	Dress
Organisation / Research Centre :	German Institut of Medical Documentation and Information
Country:	Germany
Contact e-mail Address:	jochen.dress@dimdi.de
	Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions
Study Reference Number:	EUPAS 2 0 7 2 0
Are you the (Primary) Lead	I Investigator of the above study? No \checkmark Yes
Are you an investigator/res	searcher contributing to the above study No \square Yes \checkmark

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No 🕢 Yes 🔿

Yes 🔿

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No \bigcirc

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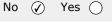
FULL NAME:	Jochen Dress	Date:	08/08/2017



No 🕢 Yes 🔿



No 🕢 Yes 🔿





INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Gunnar	
Last Name:	Toft	
Organisation / Research Centre :	Department of Clinical Epidemiology, Aa	arhus University Hospital
Country:	Denmark	
Contact e-mail Address:	gunnar.toft@clin.au.dk	
	IV Iron PASS	
Study Reference Number:	EUPAS 2 0 7 2 0	
Are you the (Primary) Lead	Investigator of the above study?	No 🖌 Yes 🗌
Are you an investigator/res	earcher contributing to the above study	No 🗌 Yes 🗸

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

2.1 Employment

No 🕢 Yes 🔾

No 🕢 Yes 🔿

No 🕢 Yes 🔿

Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

2.2 Financial Interest

Financial interests in the capital of a pharmaceutical company?

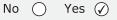
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honorarium.

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Period:	🕢 Current	Ο	Past
From Month:	From Year	:	
Name of Pharm	aceutical Compan	y:	Pfizer
Type of consu	ltancy:		Epidemiological assistance

Please specify the pharmaceutica	al company,	types of	consultancy ar	nd dates w	vhen fees/	honoraria paid:
----------------------------------	-------------	----------	----------------	------------	------------	-----------------

Period:	🕢 Current	O Past
From Month:	From Year	
Name of Pharm	aceutical Compan	y: Roche
Type of consu	ltancy:	Epidemiological assistance

2.5 Strategic Advisory Role

No 🕢 Yes 🔘

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

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No 🕢 Yes 🔿

Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

SECTION 3: ANY OTHER INTERESTS

No 🕢 Yes 🔘

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Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

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 \checkmark I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:	Gunnar Toft	Date:	04/09/2017
		Submit Form by E	mail



INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	HENRIK TOFT			
Last Name:	SØRENSEN			
Organisation / Research Centre :	DEPARTMENT OF CLINICAL EPIDEMIOLO AARHUS UNIVERSITY HOSPITAL AARHUS	DGY		
Country:	Denmark			
Contact e-mail Address:	ve@clin.au.dk			
	Intravenous Iron Postauthorisation Safe Severe Hypersensitivity Reactions	ty Study (PASS):	Evaluation of the Risk of
Study Reference Number: E	UPAS 2 0 7 2 0			
Are you the (Primary) Lead	Investigator of the above study?	No 🖌	Yes	
Are you an investigator/researcher contributing to the above study No \square Yes \checkmark				\checkmark

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

2.1 Employment

Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

2.2 Financial Interest

Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

2.3 Patent

Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

2.4 Consultancy

Consultancy for a pharmaceutical company during the past 3 years of study application?

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2.5 Strategic Advisory Role

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

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Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

Please specify the pharmaceutical company:

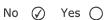
Name of Pharmaceutical Company	Comments	
	Institutional research grants administered by Aarhus University. I am a salaried employee of Aarhus University.	

SECTION 3: ANY OTHER INTERESTS

In this section you should declare any other interests to be made known to the public.

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

No 🕢 Yes 🔿



No () Yes (?)

No 🕢 Yes 🔿



o 🕢 Yes 🔿	I
o 🕢 Yes	0

No 🕢 Yes 🔿

No 🕢 Yes 🔿

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

Submit Form by Email

 \checkmark I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:	HENRIK TOFT SØRENSEN	Date:	29/09/2017



INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. Your declaration will not be accepted if any fields are left empty. You are responsible for the accuracy and completeness of the submitted information.

The form is designed to be filled in electronically and to be transmitted to the ENCePP Secretariat by email; in parallel, a copy of the form should be uploaded to the <u>EU PAS Register</u>.

SECTION 1: PERSONAL DETAILS

Enter your full name, your organisation/research centre name and the country where your organisation/ research centre is registered.

First Name:	Bianca
Last Name:	Kollhorst
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology - BIPS
Country:	Germany
Contact e-mail Address:	kollhorst@leibniz-bips.de
Study title in which context int	erests are declared (further referred to as `the study'):
	Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions
Study Reference Number: E	UPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No 🖄 Yes 🗌
Are you an investigator/rese	archer contributing to the above study No 🗌 Yes 🏾

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No 🔿

No

No 🔿

No 🔿

No 🔿

Yes 🔘

Yes 〇

Yes 🔿

Yes 🔘

Yes 🔘

No 🔘 Yes 🔘

No 🔿 Yes 🔾

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Please specify the pharmaceutical company:

Comments	Add
mandatory PASS, requested by regulatory authorities	Х
mandatory PASS, requested by regulatory authorities	Х
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	mandatory PASS, requested by regulatory authorities

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 \square I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:	Bianca Kollhorst	Date: 22/08/2017	
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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

Enter your full name, your organisation/research centre name and the country where your organisation/ research centre is registered.

First Name:	Federica Edith		
Last Name:	Pisa		
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology - BIPS		
Country:	Germany		
country.			
Contact e-mail Address:	pisa@leibniz-bips.de		
Study title in which context in	terests are declared (further referred to as `the study'):		
	Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions		
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No 🔿

No

No 🔿

No 🔿

No 🔿

Yes 🔘

Yes 〇

Yes 🔿

Yes 🔘

Yes 🔘

No 🔘 Yes 🔘

No 🔿 Yes 🔾

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Comments	
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FULL NAME:	Federica Edith Pisa	Date: 22/08/20	17
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