

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:	Jonas
Last Name:	Reinold
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology - BIPS
Country:	Germany
Contact e-mail Address:	reinold@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
Study Reference Number: E	UPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No \square Yes \square
Are you an investigator/rese	earcher contributing to the above study No \square Yes \square

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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. No O Yes O 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. Yes (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. Yes (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. Yes O 2.4 Consultancy 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. Yes 🔾 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. No O Yes O 2.6 Grant / Funding 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 Add Χ Bayer Pharma AG mandatory PASS, requested by regulatory authorities

Name of Pharmaceutical Company

Comments

Add

Bayer Pharma AG

mandatory PASS, requested by regulatory authorities

X

Takeda Pharma A/S

mandatory PASS, requested by regulatory authorities

X

H. Lundbeck A/S

mandatory PASS, requested by regulatory authorities

X

SECTION 3: ANY OTHER INTERESTS

No O Yes O

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?

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.

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: Jonas Reinold

Submit Form by Email

Reset Form

Print Form

Save



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:	Tania
Last Name:	Schink
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology - BIPS
Country:	Germany
Contact e-mail Address:	schink@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
Study Reference Number: E	SUPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No $igspace$ Yes $igspace$
Are you an investigator/rese	earcher contributing to the above study No 🗌 Yes 🖺

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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. No O Yes O 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. Yes (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. Yes (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. Yes O 2.4 Consultancy 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. Yes 🔾 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. No O Yes O 2.6 Grant / Funding 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 Add Χ Bayer Pharma AG mandatory PASS, requested by regulatory authorities

Name of Pharmaceutical Company

Comments

Add

Bayer Pharma AG

mandatory PASS, requested by regulatory authorities

X

Takeda Pharma A/S

mandatory PASS, requested by regulatory authorities

X

H. Lundbeck A/S

mandatory PASS, requested by regulatory authorities

X

SECTION 3: ANY OTHER INTERESTS

No O Yes O

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?

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.

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: Tania Schink

Date: 22/08/2017

Submit Form by Email

Reset Form

Print Form

Save



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

First Name:	nicholas
Last Name:	moore
Organisation / Research Centre :	Bordeaux PharmacoEpi
Country:	France
Contact e-mail Address:	nicholas.moore@u-bordeaux.fr
	IV Iron post-authorisation safety study: evaluation of risk of severe hypersensitivity reactions
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 📝

2.5 Strategic Advisory Role	No ② Yes 〇
study application? Participation with the right to vote on/influence the role of providing advice/expressing opinions on the	harmaceutical company during the past 3 years of output in a (scientific) advisory board/steering committee with the future strategy, direction or development activities of a or product-related strategy, regardless of contractual arrangements
2.6 Grant / Funding	No ○ Yes ②
study contract?	company other than funds contemplated in the concerned company which is currently being received by your research group, nteer, and you receive no personal gain.
Name of Pharmaceutical Company	Comments
Many pharma companies	PASS and PAES studies (see Encepp register. Financial aspects are managed by the university of Bordeaux and Adera
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 th to members of your family?	at present a potential conflict of interest, including matters relating
Further to the interests declared above, I do hereby facts that should be made public in relation to the α	declare on my honour that I do not have any further interests or onduct of the study.
Should there be any change of the above due to the ENCePP Secretariat and complete a new Declaration	ϵ fact that I acquire additional interests, I shall promptly notify the of Interests detailing the changes.
I confirm the information declared on this form information being stored electronically and published	n is accurate to the best of my knowledge and I consent to my d on the <u>EU PAS Register</u> .
FULL NAME: nicholas moore	Date: 29/09/2017
So	ubmit Form by Email



RODUCTION

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

First Name:	Patrick
Last Name:	Blin
Organisation / Research Centre :	Bordeaux PharmacoEpi, Bordeaux CIC1401
Country:	France
Contact e-mail Address:	patrick.blin@u-bordeaux.fr
	IV Iron Postauthorisation Safety Study: Evaluation of 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	earcher contributing to the above study No Yes 🗸

	OF INTERESTS REPAIRED TO PHARMACEUTICAL INDUSTRY
	interests in the pharmaceutical industry that you currently have or had within the declare please tick 'Yes' to the relevant questions. All questions in this part must
2.1 Employment	No ⊘ Yes ○
Pharmaceutical company includes sur	cal company during past 3 years of study application? oply or service companies which contribute to research, development, production uct. Employment relates to salaries currently being directly paid to you by a
2.2 Financial Interest	No ⊘ Yes ○
Financial interests relate to current he	ral of a pharmaceutical company? olding of shares of a pharmaceutical company with the exclusion of independently schemes that are not exclusively based on the pharmaceutical sector.
2.3 Patent	No ⊘ Yes ○
Patent for a medicinal product Relates to a patent for a medicinal pr centre, and you as individual are the	oduct currently owned by either you as individual or your organisation/ research
2.4 Consultancy	Nò ○ Yes ⊘
Consultancy refers to provision of advinctuding but not limited to reviewing of contractual arrangements or any for Note that conference/seminar attendations around the conference of the confe	ical company during the past 3 years of study application? vice or services to a pharmaceutical company excluding the concerned study and activities, data monitoring, statistical analysis, end point committees, regardless orm of remuneration such as consulting fees or honoraria. Ance is not considered a consultancy but should be indicated if subject to fee or y, types of consultancy and dates when fees/honoraria paid:
	Past
From Month: 06 From Year: 20	
Name of Pharmaceutical Company:	BMS
Type of consultancy:	Scientific board for pharmacoepidemiologic studies
Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:
Period: Current	Past
From Month: 03 From Year: 20	To Month: 06 To Year: 2016
Name of Pharmaceutical Company:	UPSA
Type of consultancy:	Consultancy for study methodology
Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:
	Past
From Month: 09 From Year: 20	14
Name of Pharmaceutical Company:	ASPEN
Type of consultancy:	Consultancy for study methodology and analysis

Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:
Period: Current C	Past
From Month: 09 From Year: 20	114
Name of Pharmaceutical Company:	GSK
Type of consultancy:	Consultancy for study methodology and analysis
Please specify the pharmaceutical compan	y, types of consultancy and dates when fees/honoraria paid:
Period: Current C	Past
From Month: 09 From Year: 20	14
Name of Pharmaceutical Company:	Lundbeck
Type of consultancy:	Consultancy for study methodology and analysis
2.5 Strategic Advisory Role	No ⊘ Yes ○
study application? Participation with the right to vote on, role of providing advice/expressing op	vities of a pharmaceutical company during the past 3 years of (influence the output in a (scientific) advisory board/steering committee with the vinions on the future strategy, direction or development activities of a ms of general or product-related strategy, regardless of contractual arrangements
2.6 Grant / Funding	No ○ Yes ⊘
study contract? Refers to a grant or funding from a ph irrespective of whether you are emplo	ceutical company other than funds contemplated in the concerned company which is currently being received by your research group, yed or a volunteer, and you receive no personal gain.
Please specify the pharmaceutical company	😭 - 발리로하는 시키는 - 그리고 그리고를 분뿔한 경로받아 뭐 이 박모양.

Name of Pharmaceutical Company	Comments
Aptalis	Drug utilisation study, safety and pharmacokinetic study of Pylera® in real-life
Astrazeneca	Benefit-risk of antiplatelet agents during secondary prevention of Acute coronary syndrome in France
Astrazeneca	Health outcomes, resource use, costs in patients with stable coronary artery disease in France
Bayer	Benefit-risk of arterial thrombotic prevention with rivaroxaban for atrial fibrillation in France
Biogen France	Effectiveness of Tecfidera® in multiple sclerosis in France
BMS	Benefit-risk of antithrombotic treatments after orthopedic surgery in France
Boehringer	Benefit-risk of anticoagulants in nonvalvular atrial fibrillation in France
Janssen Cilag	Therapeutic strategy in metastatic castration-resistant prostate cancer in France
Janssen France	Assessment of the treatment-resistant depression in France
Lundbeck	Assessment of Selincro® in real-life
Merck Serono	Assessment of targeted therapies in patients with colorectal cancer treated with Erbitux® in first line treatment
Novartis	Post inscription studies of ranibizumab for visual impairment due to diabetic macular edema and retinal vein occlusion
Novartis	Assessment of the inhalation systems handling in patients with COPD in real-life
Novartis Pharma AG	A Phase IIIb, multicentre, open-label study of nilotinib in adult patients with newly diagnosed Philadelphia chromosome positive and/or BCR-ABL positive CML in chronic phase
Pierre Fabre	Observational cohort study of myocardial infarction with long-term follow-up in France
Sanofi-Aventis	Assessment of cabazitaxel in real-life
Stallergenes	Assessment of Oralair® in real-life
	James Control of the

SECTION 3: ANY OTHER INTERESTS

Nο				

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?

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.

	•		9	3
	he information declared on this form is a g stored electronically and published on			knowledge and I consent to my
FULL NAME:	Patrick Blin	Date:	03/08/2017	

Submit Form by Email

Page 5 of 5

Version-number 1.5



INTRODUCTION	
the provisions of the ENCel	ur personal details and your declaration of interests to be made public in line with PP Code of Conduct. All parts must be duly completed. Your declaration will not e left empty. You are responsible for the accuracy and completeness of the
	filled in electronically and to be transmitted to the ENCePP Secretariat by email; rm should be uploaded to the <u>EU PAS Register</u> .
SECTION 1: PERSONA	L'DETAILS
First Name:	Régis
Last Name:	Lassalle
Organisation / Research Centre :	Bordeaux PharmacoEpi platform - CIC Bordeaux CIC1401
Country:	France
Contact e-mail Address:	regis.lassalle@u-bordeaux.fr
	IV Iron Postauthorisation Safety Study: Evaluation of Risk of Severe Hypersensitivity Reactions
Study Reference Number: E	TUPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No 📝 Yes 🗌
Are you an investigator/rese	earcher contributing to the above study No 🔲 Yes 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 () 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 No ⟨✓) Yes () 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. No (/) Yes () 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. No (7) Yes (2.4 Consultancy 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. 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.

2.6 Grant / Funding

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

No () Yes (/)

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
Aptalis	Drug utilisation study, safety and pharmacokinetic study of Pylera® in real-life
Astrazeneca	Benefit-risk of antiplatelet agents during secondary prevention of Acute coronary syndrome in France
Astrazeneca	Health outcomes, resource use, costs in patients with stable coronary artery disease in France
Bayer	Benefit-risk of arterial thrombotic prevention with rivaroxaban for atrial fibrillation in France
Biogen France	Effectiveness of Tecfidera® in multiple sclerosis in France
BMS	Benefit-risk of antithrombotic treatments after orthopedic surgery in France
Boehringer	Benefit-risk of anticoagulants in nonvalvular atrial fibrillation in France
Janssen	Therapeutic strategy in metastatic castration-resistant prostate cancer in France
Janssen	Assessment of the treatment-resistant depression in France
Lundbeck	Assessment of Selincro® in real-life
Merck Serono	Assessment of targeted therapies in patients with colorectal cancer treated with Erbitux® in first line treatment
Novartis	Post inscription studies of ranibizumab for visual impairment due to diabetic macular edema and retinal vein occlusion
Novartis	Assessment of the inhalation systems handling in patients with COPD in real-life
Novartis	A Phase IIIb, multicentre, open-label study of nilotinib in adult patients with newly diagnosed Philadelphia chromosome positive and/or BCR-ABL positive CML in chronic phase
Pierre Fabre	Observational cohort study of myocardial infarction with long-term follow-up in France
Sanofi-Aventis	Assessment of cabazitaxel in real-life
Stallergenes	Assessment of Oralair® in real-life

SECTION 3: ANY OTHER INTERESTS

Régis Lassalle

FULL NAME:

No 🕢 Yes	\cdot
----------	---------

03/08/2017

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?

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.

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> .

Submit Form by Email

Date:



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

First Name:	Helle
Last Name:	Kieler
Organisation / Research Centre :	Karolinska Institutet/Centre for Pharmacoepidemiology
Country:	Sweden
Contact e-mail Address:	helle.kieler@ki.se
	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	earcher contributing to the above study No 🗌 Yes 📝

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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 ✓
----------------	----------------

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 No 🕜 Yes 🔾

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	No 🕜 Yes 🔘	
------------	------------	--

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

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

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.

2.6 Grant / Funding	No ○ Yes ②

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
Pfizer	Post-Authorization Safety Study
AstraZeneca	Post-Authorization Safety Study
Leo	Post-Authorization Safety Study
Janssen	Post-Authorization Safety Study
Bayer	Drug Utilization Study
MSD	Post-Authorization Safety Study
Novartis	Post-Authorization Safety Study
Astellas	Post-Authorization Safety Study

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? 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. 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: Helle Kieler Date: 15/08/2017

Submit Form by Email



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

First Name:	Ingvild
Last Name:	Odsbu
Organisation / Research Centre :	Karolinska Institutet/Centre for Pharmacoepidemiology
Country:	Sweden
Contact e-mail Address:	ingvild.odsbu@ki.se
	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 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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 ✓
----------------	----------------

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 No 🕜 Yes 🔾

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	No 🕜 Yes 🔘	
------------	------------	--

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

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

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.

2.6 Grant / Funding	No ○ Yes ②

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
Pfizer	Post-Authorization Safety Study
AstraZeneca	Post-Authorization Safety Study
Leo	Post-Authorization Safety Study
Janssen	Post-Authorization Safety Study
Bayer	Drug Utilization Study
MSD	Post-Authorization Safety Study
Novartis	Post-Authorization Safety Study
Astellas	Post-Authorization Safety Study

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? 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. 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: Ingvild Odsbu Date: 15/08/2017

Submit Form by Email



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

First Name:	Marie
Last Name:	Linder
Organisation / Research Centre :	Karolinska Institutet/Centre for Pharmacoepidemiology
Country:	Sweden
Contact e-mail Address:	marie.linder@ki.se
	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	earcher contributing to the above study No 🗌 Yes 📝

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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 ✓
----------------	----------------

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 No 🕜 Yes 🔾

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	No 🕜 Yes 🔘	
------------	------------	--

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

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

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.

2.6 Grant / Funding	No ○ Yes ②

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
Pfizer	Post-Authorization Safety Study
AstraZeneca	Post-Authorization Safety Study
Leo	Post-Authorization Safety Study
Janssen	Post-Authorization Safety Study
Bayer	Drug Utilization Study
MSD	Post-Authorization Safety Study
Novartis	Post-Authorization Safety Study
Astellas	Post-Authorization Safety Study

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? 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. 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: Marie Linder Date: 15/08/2017

Submit Form by Email



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

First Name:	Zoltan
Last Name:	Thinsz
Organisation / Research Centre :	Karolinska Institutet/Centre for Pharmacoepidemiology
Country:	Sweden
Contact e-mail Address:	zoltan.thinsz@ki.se
	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	earcher contributing to the above study No 🗌 Yes 📝

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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 ✓
----------------	----------------

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 No 🕜 Yes 🔾

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	No 🕢 Yes 🔘	
------------	------------	--

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

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

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.

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.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Pfizer	Post-Authorization Safety Study
AstraZeneca	Post-Authorization Safety Study
Leo	Post-Authorization Safety Study
Janssen	Post-Authorization Safety Study
Bayer	Drug Utilization Study
MSD	Post-Authorization Safety Study
Novartis	Post-Authorization Safety Study
Astellas	Post-Authorization Safety Study

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? 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. 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: Zoltan Thinsz Date: 15/08/2017

Submit Form by Email



INTRODUCTION	
the provisions of the ENC	our personal details and your declaration of interests to be made public in line with a PP Code of Conduct. All parts must be duly completed. Your declaration will not re left empty. You are responsible for the accuracy and completeness of the
	e filled in electronically and to be transmitted to the ENCePP Secretariat by email; orm should be uploaded to the <u>EU PAS Register</u> .
SECTION 1: PERSON	AL DETAILS
First Name:	Irene
Last Name:	Bezemer
Organisation / Research Centre :	PHARMO Institute for Drug Outcomes Research
Country:	Netherlands
Contact e-mail Address:	irene.bezemer@pharmo.nl
	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	Investigator of the above study? No 📝 Yes 🗌
Are you an investigator/re	searcher contributing to the above study No 🗌 Yes 🔽

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 () 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. Please specify the pharmaceutical company and dates when employed: Period: Current Past From Year: 2010 From Month: Name of Pharmaceutical Company: PHARMO Institute for Drug Outcomes Research 2.2 Financial Interest No (7) Yes (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. No (7) Yes (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 ⋂ 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. 2.5 Strategic Advisory Role No (7) 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.

2.6 Grant / Funding No Ø Yes O

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 ② Yes ①

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?

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.

✓ I confirm to	he information declared on this form is a	ccurate to	the best of my kr	nowledge and I consent to my
information bein	g stored electronically and published on	the <u>EU PA</u>	<u>S Register</u> .	
FULL NAME:	Irene Bezemer	Date:	08/08/2017	

Submit Form by Email



INTRODUCTION		# 1 m				
the provisions of the ENCe be accepted if any fields a submitted information. The form is designed to be	our personal details and your of PPP Code of Conduct. All parts re left empty. You are response filled in electronically and to borm should be uploaded to the	must be duly sible for the action be transmitte	complete ccuracy a d to the I	ed. Your nd com	r declaration pleteness of	will not the
SECTION 1: PERSON	AL DETAILS					
First Name:	Jetty					
Last Name:	Overbeek					
Organisation / Research Centre :	PHARMO Institute for Drug Out	comes Researci	1			
Country:	Netherlands					
Contact e-mail Address:	jetty.overbeek@pharmo.nl					
	Intravenous Iron Postauthorisa Severe Hypersensitivity Reaction		dy (PASS)	: Evalua	tion of the Ris	sk of
Study Reference Number:	EUPAS 2 0 7 2 0					
Are you the (Primary) Lead	l Investigator of the above study	? No	✓ Yes			
Are you an investigator/res	searcher contributing to the above	e studv No	☐ Yes	7		

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 () 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. Please specify the pharmaceutical company and dates when employed: Period: Q Current C Past From Year: 2008 From Month: Name of Pharmaceutical Company: PHARMO Institute for Drug Outcomes Research 2.2 Financial Interest Yes () 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 No (7) Yes (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 (7) 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. 2.5 Strategic Advisory Role No (7) 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. 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 ② Yes 〇

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?

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: Jetty Overbeek Date: 21/07/2017

Submit Form by Email



INTRODUCTION	
the provisions of the ENC	your personal details and your declaration of interests to be made public in line with CePP Code of Conduct. All parts must be duly completed. Your declaration will not are left empty. You are responsible for the accuracy and completeness of the
	be filled in electronically and to be transmitted to the ENCePP Secretariat by email; form should be uploaded to the <u>EU PAS Register</u> .
SECTION 1: PERSON	IAL DETAILS
First Name:	Lisa
Last Name:	Smits
Organisation / Research Centre :	PHARMO Institute for Drug Outcomes Research
Country:	Netherlands
Contact e-mail Address:	lisa.smits@pharmo.nl
	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) Lea	ad Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/re	esearcher contributing to the above study No 🗌 Yes 📝

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 ② 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. Please specify the pharmaceutical company and dates when employed: Period: Current Past | From Year: |2014 From Month: 105 Name of Pharmaceutical Company: PHARMO Intitute for Drug Outcomes Research 2.2 Financial Interest No ⟨✓) Yes () 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 No (7) Yes (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 (7) 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. 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. 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,

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

No (7) Yes (

irrespective of whether you are employed or a volunteer, and you receive no personal gain.

SECTION 3: ANY OTHER INTERESTS

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

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.

☑ 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:	Lisa Smits	 Date:	25/07/2017
	***	 -	

Submit Form by Email



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

First Name:	Gero
Last Name:	von Gersdorff
Organisation / Research Centre :	University Hospital of Cologne Department of Medicine II - QiN-group Gleueler Strasse 176-178 50935 Cologne - Köln Germany
Country:	Germany
Contact e-mail Address:	gero.von-gersdorff@uk-koeln.de
	Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions
Study Reference Number: E	EUPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No \checkmark Yes
Are you an investigator/rese	earcher contributing to the above study No \(\sime\) Yes \(\sime\)

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 🔾 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 Yes () 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 No (Yes () 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. No (Yes (2.4 Consultancy 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. 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. 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. No (Yes (**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? 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.

Page 2 of 3 Version-number 1.5

Date:

09/10/2017

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.

Gero von Gersdorff

FULL NAME:

Submit Form by Email



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

First Name:	Katherine
Last Name:	Rascher
Organisation / Research Centre :	University Hospital of Cologne Department of Medicine II - QiN-group Gleueler Strasse 176-178 50935 Cologne - Köln Germany
Country:	Germany
Contact e-mail Address:	katherine.rascher@uk-koeln.de
	Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions
Study Reference Number: E	EUPAS 2 0 7 2 0
Are you the (Primary) Lead	Investigator of the above study? No 📝 Yes
Are you an investigator/rese	earcher contributing to the above study No 🗆 Yes 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 🔾 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 Yes () 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 No (Yes () 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. No (Yes (2.4 Consultancy 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. 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. 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. No (Yes (**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? 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.

Page 2 of 3 Version-number 1.5

Date:

09/10/2017

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.

Katherine Rascher

FULL NAME:

Submit Form by Email



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 First Name: Mathias Last Name: Schaller Organisation / Research QiN Programm / Medizinische Klinik II der Universität zu Köln Centre: Germany Country: Contact e-mail Address: mathias.schaller@uk-koeln.de Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions Study Reference Number: EUPAS |2 | Are you the (Primary) Lead Investigator of the above study? Are you an investigator/researcher contributing to the above study

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 ⟨ Yes () 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 (7) 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. 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. 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? 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

Page 2 of 3

FULL NAME:

ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

information being stored electronically and published on the EU PAS Register.

Mattige Celealer

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my

Submit Form by Email



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

First Name:	VERA
Last Name:	EHRENSTEIN
Organisation / Research Centre :	DEPARTMENT OF CLINICAL EPIDEMIOLOGY AARHUS UNIVERSITY HOSPITAL AARHUS
Country:	Denmark
Contact e-mail Address:	ve@clin.au.dk
	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	Investigator of the above study? No 🗸 Yes
Are you an investigator/res	searcher contributing to the above study. No

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY 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 () 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. Yes () 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 No 🕢 Yes () 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. 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. 2.6 Grant / Funding Yes 🕢 Grant/funding from a pharmaceutical company other than funds contemplated in the concerned 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: Comments Name of Pharmaceutical Company Several pharmaceutical companies Institutional research grants administered by Aarhus University. I am a salaried employee of Aarhus University. No 🕢 Yes (

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?

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.

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: VERA EHRENSTEIN Date: 30/11/2017

Submit Form by Email