Declaration of Interests for ENCePP SEAL Studies

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:	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 interests 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: EUPAS 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 ☐ 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.
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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

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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	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 ✓ 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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☑ 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 Date: 22/08/2017

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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:	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 interests are declared (further referred to as `the study'):

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Takeda Pharma A/S	mandatory PASS, requested by regulatory authorities	X
H. Lundbeck A/S	mandatory PASS, requested by regulatory authorities	X

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FULL NAME: Tania Schink Date: 22/08/2017

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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/researcher contributing to the above study No ☐ Yes ☑

2.5 Strategic Advisory Role

No ⊘ Yes ◯

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

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2.6 Grant / Funding

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Please specify the pharmaceutical company:

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

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FULL NAME: nicholas moore Date: 29/09/2017

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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: EUPAS | 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 ☐ Yes ☑

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No ○ Yes ☑

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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: ○ Current ☑ Past

From Month: 06 From Year: 2015 To Month: 09 To Year: 2015

Name of Pharmaceutical Company: BMS

Type of consultancy: Scientific board for pharmacoepidemiologic studies

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

Period: ○ Current ☑ Past

From Month: 03 From Year: 2015 To Month: 06 To Year: 2016

Name of Pharmaceutical Company: UPSA

Type of consultancy: Consultancy for study methodology

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

Period: ☑ Current ○ Past

From Month: 09 From Year: 2014

Name of Pharmaceutical Company: ASPEN

Type of consultancy: Consultancy for study methodology and analysis

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

Period: ○ Current ○ Past

From Month: 09 From Year: 2014

Name of Pharmaceutical Company: GSK

Type of consultancy: Consultancy for study methodology and analysis

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

Period: ○ Current ○ Past

From Month: 09 From Year: 2014

Name of Pharmaceutical Company: Lundbeck

Type of consultancy: Consultancy for study methodology and analysis

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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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 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

SECTION 3: ANY OTHER INTERESTS

No ✓ Yes ○

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FULL NAME: Patrick Blin Date: 03/08/2017

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SECTION 1: PERSONAL 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: EUPAS | 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 ☐ Yes ☑

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2.3 Patent

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Patent for a medicinal product?

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2.5 Strategic Advisory Role

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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
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FULL NAME: Régis Lassalle Date: 03/08/2017

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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: EUPAS | 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 ☐ Yes ☑

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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

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FULL NAME: Helle Kieler Date: 15/08/2017

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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*

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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

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?

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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: Ingvild Odsbu Date: 15/08/2017

Submit Form by Email

Declaration of Interests for ENCePP SEAL Studies

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.

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: EUPAS | 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 ☐ Yes ☑

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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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.

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FULL NAME: Marie Linder Date: 15/08/2017

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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: EUPAS | 2 | 0 | 7 | 2 | 0 |

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

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FULL NAME: Zoltan Thinsz Date: 15/08/2017

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SECTION 1: PERSONAL 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/researcher contributing to the above study No ☐ Yes ☑

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Please specify the pharmaceutical company and dates when employed:

Period: ⊘ Current ◯ Past

From Month: 01 From Year: 2010

Name of Pharmaceutical Company: PHARMO Institute 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 ⊘ Yes ◯

Patent for a medicinal product?
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SECTION 3: ANY OTHER INTERESTS

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FULL NAME: Irene Bezemer Date: 08/08/2017

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Declaration of Interests for ENCePP SEAL Studies

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SECTION 1: PERSONAL DETAILS

First Name:	Jetty
Last Name:	Overbeek
Organisation / Research Centre :	PHARMO Institute for Drug Outcomes Research
Country:	Netherlands
Contact e-mail Address:	*jetty.overbeek@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/researcher contributing to the above study No ☐ Yes ☑

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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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 Month: 10 From Year: 2008

Name of Pharmaceutical Company: PHARMO Institute 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 ⊘ 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.

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FULL NAME: Jetty Overbeek Date: 21/07/2017

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SECTION 1: PERSONAL 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) Lead Investigator of the above study? No ☑ Yes ☐

Are you an investigator/researcher contributing to the above study No ☐ Yes ☑

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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Please specify the pharmaceutical company and dates when employed:

Period: ⊘ Current ◯ Past

From Month: 05 From Year: 2014

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

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Patent for a medicinal product?
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FULL NAME: Lisa Smits Date: 25/07/2017

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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: EUPAS | 2 | 0 | 7 | 2 | 0 |

Are you the (Primary) Lead Investigator of the above study? No ☑ Yes ☐

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FULL NAME: Gero von Gersdorff Date: 09/10/2017

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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: EUPAS | 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 ☐ Yes ☑

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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

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 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: Katherine Rascher Date: 09/10/2017

Submit Form by Email

Declaration of Interests for ENCePP SEAL Studies

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 EU PAS Register.

SECTION 1: PERSONAL DETAILS

First Name:	Mathias
Last Name:	Schaller
Organisation / Research Centre :	QiN Programm / Medizinische Klinik II der Universität zu Köln
Country:	Germany
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 | 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 ☐ 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.

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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.
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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: Mathias Ellenius Date: 29.09.2017

Submit Form by Email

Declaration of Interests for ENCePP SEAL Studies

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.

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/researcher contributing to the above study No ☐ Yes ☑

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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Please specify the pharmaceutical company:

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

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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☑ 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: VERA EHRENSTEIN Date: 30/11/2017

Submit Form by Email