Declaration of Interests for ENCePP SEAL Studies

INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Fabian
Last Name:	Otto-Sobotka
Organisation / Research Centre :	Carl von Ossietzky University Oldenburg Division for Epidemiology and Biometry Ammerländer Heerstraße 140 26129 Oldenburg
Country:	Germany
Contact e-mail Address:	*fabian.otto-sobotka@uni-oldenburg.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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No ☑ Yes ○

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FULL NAME: Fabian Otto-Sobotka Date: 30/01/2019

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SECTION 1: PERSONAL DETAILS

First Name:	Jan Thies
Last Name:	Soller
Organisation / Research Centre :	Carl von Ossietzky University Oldenburg Division for Epidemiology and Biometry Ammerländer Heerstraße 140 26129 Oldenburg
Country:	Germany
Contact e-mail Address:	*jan.thies.soller@uni-oldenburg.de*

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SECTION 1: PERSONAL DETAILS

First Name:	Lara Yasmin
Last Name:	Disselhoff
Organisation / Research Centre :	Carl von Ossietzky University Oldenburg Division for Epidemiology and Biometry Ammerländer Heerstraße 140 26129 Oldenburg
Country:	Germany
Contact e-mail Address:	*lara.yasmin.disselhoff@uni-oldenburg.de*

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FULL NAME: Lara Yasmin Disselhoff Date: 30/01/2019

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SECTION 1: PERSONAL DETAILS

First Name:	Clémentine
Last Name:	Lacueille
Organisation / Research Centre :	Bordeaux PharmacoEpi - Bordeaux CIC 1401
Country:	France
Contact e-mail Address:	*clementine.lacueille@u-bordeaux.fr*

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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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
AstraZeneca	Assessment of the high risk and unmet need in patients with coronary artery disease and type 2 diabetes 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
Biogen USA	Multiple sclerosis natural history study 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 KGaA	Malignancies in multiple sclerosis in France
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
Shire	Assessment of the burden of dry eye disease in France
Stallergenes	Assessment of Oralair® in real-life

SECTION 3: ANY OTHER INTERESTS

No ✓ Yes ○

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FULL NAME: Clémentine Lacueille Date: 11/01/2019

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SECTION 1: PERSONAL DETAILS

First Name:	Estelle
Last Name:	Guiard
Organisation / Research Centre :	Bordeaux PharmacoEpi - Bordeaux CIC 1401
Country:	France
Contact e-mail Address:	*estelle.guiard@u-bordeaux.fr*

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: Estelle Guiard Date: 11/01/2019

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SECTION 1: PERSONAL DETAILS

First Name:	Alina
Last Name:	Ludewig
Organisation / Research Centre :	Leibniz Institut - BIPS, Bremen
Country:	Germany
Contact e-mail Address:	*ludewig@leibniz-bips.de*

Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions

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FULL NAME: Alina Ludewig Date: 05/02/2019

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SECTION 1: PERSONAL DETAILS

First Name:	Inga
Last Name:	Schaffer
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology - BIPS
Country:	Germany
Contact e-mail Address:	*schaffer@leibniz-bips.de*

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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: Inga Schaffer Date: 07/01/2019

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:	Carla
Last Name:	Franzoni
Organisation / Research Centre :	RTI Health Solutions
Country:	Spain
Contact e-mail Address:	*cfranzoni@rti.org*

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?

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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Multiple pharmaceutical companies fund studies and activities through contracts with my employer including Bayer, Shire, Merck, Janssen, and others.	http://www.encepp.eu/encepp/links.htm?id=19407&resourceType=ResearchCenter

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FULL NAME: Carla Franzoni Date: 05/02/2019

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