



## 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

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

First Name:	<input type="text" value="Jonas"/>
Last Name:	<input type="text" value="Reinold"/>
Organisation / Research Centre :	<input type="text" value="Leibniz Institute for Prevention Research and Epidemiology - BIPS"/>
Country:	<input type="text" value="Germany"/> <input type="button" value="v"/>
Contact e-mail Address:	<input type="text" value="reinold@leibniz-bips.de"/>

Study title in which context interests are declared (further referred to as 'the study'):

Study Reference Number: EUPAS

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.

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.

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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

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

First Name:	<input type="text" value="Tania"/>
Last Name:	<input type="text" value="Schink"/>
Organisation / Research Centre :	<input type="text" value="Leibniz Institute for Prevention Research and Epidemiology - BIPS"/>
Country:	<input type="text" value="Germany"/> <input type="button" value="v"/>
Contact e-mail Address:	<input type="text" value="schink@leibniz-bips.de"/>

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FULL NAME:

Tania Schink

Date:

22/08/2017

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First Name:

Eyyub Ebu-Bekir

Last Name:

Öztürk

Organisation / Research Centre :

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Country:

Germany

Contact e-mail Address:

oeztuerk@leibniz-bips.de

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

Study Reference Number: EUPAS 

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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 

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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
Many pharma companies	PASS and PAES studies (see Encepp register. Financial aspects are managed by the university of Bordeaux and Adera

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

Period:  Current  Past

From Month:  From Year:  To Month:  To Year:

Name of Pharmaceutical Company:

Type of consultancy:

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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

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Biogen France	Effectiveness of Tecfidera® in multiple sclerosis in France
BMS	Benefit-risk of antithrombotic treatments after orthopedic surgery in France
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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 

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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
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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*

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

Study Reference Number: EUPAS 

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

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First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

Study Reference Number: EUPAS

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

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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 

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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 

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FULL NAME:

Irene Bezemer

Date:

08/08/2017

Submit Form by Email



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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

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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

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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 :

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Germany

Country:

Germany

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*gero.von-gersdorff@uk-koeln.de*

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

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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:

Gero von Gersdorff

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:

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

## 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 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

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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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### 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 

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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 Colvaux*

Date:

*24.07.2017*

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### 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 

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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
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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FULL NAME:

VERA EHRENSTEIN

Date:

30/11/2017

Submit Form by Email