



Declaration of Interests for ENCePP SEAL Studies

INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:

Lia

Last Name:

Gutiérrez

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

lgutierrez@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
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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

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

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

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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.

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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.

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

SECTION 3: ANY OTHER INTERESTS

No Yes

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

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

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.

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FULL NAME:

Lia Gutiérrez

Date:

30/11/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Joan

Last Name:

Fortuny

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

jfortuny@rti.org

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Name of Pharmaceutical Company	Comments
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FULL NAME:

Joan Fortuny

Date:

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First Name:

Susana

Last Name:

Perez Gutthann

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

sperez@rti.org

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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:

Name of Pharmaceutical Company:

Type of consultancy:

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Period: Current Past

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

Name of Pharmaceutical Company:

Type of strategic advisory role:

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FULL NAME:

Susana Perez Gutthann

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First Name:

Catherine

Last Name:

Johannes

Organisation / Research Centre :

RTI Health Solutions

Country:

United States of America

Contact e-mail Address:

cjohannes@rti.org

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Catherine Johannes

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First Name:

Lawrence

Last Name:

Rasouliyan

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

lrasouliyan@rti.org

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

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FULL NAME:

Lawrence Rasouliyan

Date:

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SECTION 1: PERSONAL DETAILS

First Name:

Kenneth

Last Name:

Rothman

Organisation / Research Centre :

RTI Health Solutions

Country:

United States of America

Contact e-mail Address:

krothman@rti.org

IV Iron PASS

Study Reference Number: EUPAS 2 0 7 2 0

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

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FULL NAME:

Kenneth Rothman

Date:

27/07/2017

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First Name:

Jaume

Last Name:

Aguado

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

jaguado@rti.org

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FULL NAME:

Jaume Aguado

Date:

07/09/2017

Submit Form by Email



Declaration of Interests for ENCePP SEAL Studies

INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:

Ryan

Last Name:

Ziemiecki

Organisation / Research Centre :

RTI Health Solutions

Country:

United States of America

Contact e-mail Address:

rziemiecki@rti.org

Intravenous Iron Postauthorization Safety Study: 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

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?

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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
Multiple pharmaceutical companies fund studies and activities through contracts with my employer including Otsuka, Bayer, Leo Pharma, Astellas, Janssen, Servier, BMS, Merck, AZ, Almirall, BI, Shire, Lilly, Vifor & IV iron consortium	http://www.encepp.eu/encepp/links.htm?id=19407&resourceType=ResearchCentre

SECTION 3: ANY OTHER INTERESTS

No Yes

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

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

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FULL NAME:

Ryan Ziemiecki

Date:

08/09/2017

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SECTION 1: PERSONAL DETAILS

First Name:

David

Last Name:

Rampton

Organisation / Research Centre :

Barts and the London School of Medicine and Dentistry, London

Country:

United Kingdom

Contact e-mail Address:

d.rampton@qmul.ac.uk

IV Iron PASS

Study Reference Number: EUPAS 2 0 7 2 0

Are you the (Primary) 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, 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, type of strategic advisory role and dates:

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Type of strategic advisory role:

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FULL NAME:

David Rampton

Date:

24/07/2017

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SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="Edeltraut"/>
Last Name:	<input type="text" value="Prof. Dr. med. Garbe"/>
Organisation / Research Centre :	<input type="text" value="University of Bremen"/>
Country:	<input type="text" value="Germany"/>
Contact e-mail Address:	<input type="text" value="garbe@uni-bremen.de"/>

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

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SECTION 1: PERSONAL DETAILS

First Name:

Jacques

Last Name:

Benichou

Organisation / Research
Centre :

University of Rouen and Rouen University Hospital

Country:

France

Contact e-mail Address:

jacques.benichou@chu-rouen.fr

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

Study Reference Number: 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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From Month: From Year:

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Type of consultancy:

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From Month: From Year:

Name of Pharmaceutical Company:

Type of consultancy:

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FULL NAME:

Jacques Benichou

Date:

25/10/2017

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SECTION 1: PERSONAL DETAILS

First Name:

kathleen

Last Name:

walsh

Organisation / Research Centre:

cincinnati children's hospital

Country:

United States of America

Contact e-mail Address:

kathleen.walsh@cchmc.org

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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FULL NAME:



Date:

8/4/07



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SECTION 1: PERSONAL DETAILS

First Name:

Jochen

Last Name:

Dress

Organisation / Research Centre :

German Institut of Medical Documentation and Information

Country:

Germany

Contact e-mail Address:

jochen.dress@dimdi.de

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

Study Reference Number: EUPAS

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FULL NAME:

Jochen Dress

Date:

08/08/2017



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SECTION 1: PERSONAL DETAILS

First Name:

Gunnar

Last Name:

Toft

Organisation / Research Centre :

Department of Clinical Epidemiology, Aarhus University Hospital

Country:

Denmark

Contact e-mail Address:

gunnar.toft@clin.au.dk

IV Iron PASS

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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FULL NAME:

Gunnar Toft

Date:

04/09/2017

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Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

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.

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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

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
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.

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:

HENRIK TOFT SØRENSEN

Date:

29/09/2017

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

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="Bianca"/>
Last Name:	<input type="text" value="Kollhorst"/>
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="kollhorst@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

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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

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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:	<input type="text" value="Federica Edith"/>
Last Name:	<input type="text" value="Pisa"/>
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="pisa@leibniz-bips.de"/>

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