



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:

Alejandro

Last Name:

ARANA

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

aarana@rti.org

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

Study Reference Number: EUPAS

2	1	7	6	9
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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

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

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No Yes

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

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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Over 100 pharma and biotech companies (including all top 50) fund studies through contracts with my employer including EU PAS-registered studies for Bayer, LEO Pharma, Servier, Merck Sharpe & Dohme Corp., Astra Zeneca, Boehringer Ingelheim, Shire Pharmaceuticals, Eli Lilly, Vifor & IV iron consortium.	http://www.encepp.eu/encepp/viewResource.htm?id=19407

SECTION 3: ANY OTHER INTERESTS

No Yes

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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:

Alejandro ARANA

Date:

22/12/2017

Submit Form by Email



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SECTION 1: PERSONAL DETAILS

First Name:

Arlene

Last Name:

Gallagher

Organisation / Research Centre :

Clinical Practice Research Datalink (CPRD)
MHRA, 151 Buckingham Palace Road
London SW1W 9SZ

Country:

United Kingdom

Contact e-mail Address:

arlene.gallagher@mhra.gov.uk

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

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FULL NAME:

Arlene Gallagher

Date:

15/12/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Anton

Last Name:

Pottegård

Organisation / Research Centre :

University of Southern Denmark

Country:

Denmark

Contact e-mail Address:

apottegaard@health.sdu.dk

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

Study Reference Number: EUPAS

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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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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
LEO Pharma	(Future) Grant for coordinating a phase-IV safety study

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FULL NAME:

Anton Pottegård

Date:

29/11/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Brian

Last Name:

Calingaert

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

bcalingaert@rti.org

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study.

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Name of Pharmaceutical Company	Comments
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FULL NAME:

Brian Calingaert

Date:

29/11/2017

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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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FULL NAME:

Daniel Dedman

Date:

15/12/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Eline

Last Name:

Houben

Organisation / Research Centre :

PHARMO Institute for Drug Outcomes Research

Country:

Netherlands

Contact e-mail Address:

eline.houben@pharmo.nl

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

Study Reference Number: EUPAS

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FULL NAME:

Eline Houben

Date:

07/12/2017

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SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="Helen"/>
Last Name:	<input type="text" value="Booth"/>
Organisation / Research Centre :	<input type="text" value="Clinical Practice Research Datalink (CPRD)
MHRA, 151 Buckingham Palace Road
London SW1W 9SZ"/>
Country:	<input type="text" value="United Kingdom"/>
Contact e-mail Address:	<input type="text" value="helen.booth@mhra.gov.uk"/>
	<input type="text" value="Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study"/>

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FULL NAME:

Helen Booth

Date:

15/12/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Josine

Last Name:

Kuiper

Organisation / Research Centre :

PHARMO Institute for Drug Outcomes Research

Country:

Netherlands

Contact e-mail Address:

josine.kuiper@pharmo.nl

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Period: Current Past

From Month: From Year:

Name of Pharmaceutical Company:

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FULL NAME:

Josine Kuiper

Date:

07/12/2017

Submit Form by Email



Declaration of Interests for ENCePP SEAL Studies

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SECTION 1: PERSONAL DETAILS

First Name:

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

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Type of consultancy:

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Name of Pharmaceutical Company	Comments
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FULL NAME:

James Kaye

Date:

29/11/2017

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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

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

Study Reference Number: EUPAS

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FULL NAME:

Jetty Overbeek

Date:

07/12/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Kenneth

Last Name:

Rothman

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

krothman@rti.org

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

Study Reference Number: EUPAS

2	1	7	6	9
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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:

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Name of Pharmaceutical Company	Comments
Many pharma and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for Bayer, LEO Pharma, Servier, Merck Sharpe & Dohme Corp., Astra Zeneca, Boehringer Ingelheim, Shire Pharmaceuticals, Eli Lilly, Vifor & IV iron consortium.	

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SECTION 1: PERSONAL DETAILS

First Name:

Lia

Last Name:

GUTIERREZ

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

lgutierrez@rti.org

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

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2 | 1 | 7 | 6 | 9

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FULL NAME:

Lia GUTIERREZ

Date:

04/12/2017

Submit Form by Email



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SECTION 1: PERSONAL DETAILS

First Name:

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

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SECTION 1: PERSONAL DETAILS

First Name:

Ron

Last Name:

Herings

Organisation / Research Centre :

PHARMO Institute for Drug Outcomes Research

Country:

Netherlands

Contact e-mail Address:

ron.herings@pharmo.nl

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

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:

Ron Herings

Date:

07/12/2017

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SECTION 1: PERSONAL DETAILS

First Name:

Susana

Last Name:

Perez-Gutthann

Organisation / Research Centre :

RTI Health Solutions

Country:

Spain

Contact e-mail Address:

sperez@rti.org

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study

Study Reference Number: EUPAS

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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.

Please specify the pharmaceutical company, type of strategic advisory role and dates:

Period: Current Past

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

Name of Pharmaceutical Company:

Type of strategic advisory role:

Please specify the pharmaceutical company, type of strategic advisory role and dates:

Period: Current Past

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

Name of Pharmaceutical Company:

Type of strategic advisory role:

Please specify the pharmaceutical company, type of strategic advisory role and dates:

Period: Current Past

From Month: From Year:

Name of Pharmaceutical Company:

Type of strategic advisory role:

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
Over 100 pharma and biotech companies (including all top 50) fund studies through contracts with my employer including EU PAS-registered studies for Bayer, LEO Pharma, Servier, Merck Sharpe & Dohme Corp., Astra Zeneca, Boehringer Ingelheim, Shire Pharmaceuticals, Eli Lilly, Vifor & IV iron consortium.	http://www.encepp.eu/encepp/viewResource.htm?id=19407

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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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:

Date:



Declaration of Interests for ENCePP SEAL Studies

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SECTION 1: PERSONAL DETAILS

First Name:

Anders

Last Name:

Sundström

Organisation / Research Centre :

Centre for Pharamcoepidemiology
Karolinska Institutet
Stockholm

Country:

Sweden

Contact e-mail Address:

anders.sundstrom@ki.se

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study.

Study Reference Number: EUPAS

2	1	7	6	9
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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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Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

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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
MSD	Post-authorization safety study
Novartis	Post-authorization safety study
Astellas	Post-authorization safety study
Bayer	Drug utilization study

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FULL NAME:

Anders Sundström

Date:

13/12/2017

Submit Form by Email



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SECTION 1: PERSONAL DETAILS

First Name:

Helle

Last Name:

Kieler

Organisation / Research Centre :

Centre for Pharmacoepidemiology
Karolinska Institutet
Stockholm

Country:

Sweden

Contact e-mail Address:

helle.kieler@ki.se

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study.

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Novartis	Post-authorization study
Astellas	Post-authorization study
Bayer	Drug utilization study

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SECTION 1: PERSONAL DETAILS

First Name:

Tobias

Last Name:

Svensson

Organisation / Research
Centre :

Centre for Pharmacoepidemiology
Karolinska Institutet
Stockholm

Country:

Sweden

Contact e-mail Address:

tobias.svensson@ki.se

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FULL NAME:

Tobias Svensson

Date:

13/12/2017

Submit Form by Email



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SECTION 1: PERSONAL DETAILS

First Name:

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

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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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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
LEO Pharma	Grant as mentioned in 2.4

SECTION 3: ANY OTHER INTERESTS

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FULL NAME:

Jesper Hallas

Date:

01/01/2018

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