

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.

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SECTION 1: PERSONAL DETAILS

First Name:	Elizabeth
Last Name:	Crellin
Organisation / Research Centre :	Clinical Practice Research Datalink (CPRD), Medicines and Healthcare products Regulatory Agency
Country:	United Kingdom
Contact e-mail Address:	elizabeth.crellin@mhra.gov.uk
	Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) Study: Extension Phase
Study Reference Number: E	UPAS 2 1 7 6 9
Are you the (Primary) Lead	Investigator of the above study? No ✓ Yes
Are you an investigator/rese	earcher 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. No (Yes (2.1 Employment 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 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. No 🕢 2.3 Patent 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 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 (7) 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

Page 2 of 3 Version-number 1.5

Date:

07/02/2019

 $| \mathbf{V} |$ I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my

ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

information being stored electronically and published on the EU PAS Register.

Elizabeth Crellin

FULL NAME:

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SECTION 1: PERSONAL DETAILS

First Name:	Lars Christian			
Last Name:	Lund			
Organisation / Research Centre :	Clinical Pharmacology and Pharmacy, Deparment of Public Health, University of Southern Denmark			
Country:	Denmark			
Contact e-mail Address:	lclund@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 2 1 7 6 9				
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 🔾
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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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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.

Please specify the pharmaceutical compar	y, types of consultancy and dates when fees/honoraria paid:		
Period:	Past		
From Month: From Year:			
Name of Pharmaceutical Company: Menarini International			
Type of consultancy:	Trial Physician, Clinical Trial Unit, University of Southern Denmark. Trial: "Febuxostat Versus Allopurinol Streamlined Trial". Sponsor: University of Dundee. Trial financed by: Menarini International.		

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 Ves	
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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.

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 <u>EU PAS Register</u>.

FULL NAME: Lars Christian Lund D

Date: 08/02/2019

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SECTION 1: PERSONAL DETAILS

First Name:	Karin	
Last Name:	Gembert	
Organisation / Research Centre :	Centre for Pharmacoepidemiology Karolinska Institutet Stockholm	
Country:	Sweden	
Contact e-mail Address:	karin.gembert@ki.se	
	Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteriods. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) study.	
Study Reference Number:	EUPAS 2 1 7 6 9	
Are you the (Primary) Lead Investigator of the above study? No 🗸 Yes		
Are you an investigator/res	searcher 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.

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2.1 Employment No O 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.
Please specify the pharmaceutical company and dates when employed:
Period: Current Past From Month: 11 From Year: 2005 To Month: 08 To Year: 2018
Name of Pharmaceutical Company: H. Lundbeck A/S
2.2 Financial Interest No V 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 Ves
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 Ves
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 O 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	
AbbVie		Post-authorization safety study	
Astellas	Post-authorization safety study		
Bayer	ayer Drug utilization study		
Janssen		Post-authorization safety study	
Leo Pharma Post-authorization safety study		Post-authorization safety study	
Pfizer		Post-authorization safety study	
SECTION 3:	ANY OTHER INTERESTS	No 🕜 Yes 🔾	
In this section you should declare any other interests of commercial, financial, institutional or personal nature 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? (*see definition in Annex 1 of ENCePP Code of Conduct)			
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 complete and upload 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 <u>EU PAS Register</u> .			
FULL NAME:	Karin Gembert	Date: 14/02/2019	
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SECTION 1: PERSONAL DETAILS

First Name:	Camilla		
Last Name:	Byström		
Organisation / Research Centre :	Centre for Pharmacoepidemiology Karolinska Institutet Stockholm		
Country:	Sweden		
Contact e-mail Address:	camilla.bystrom@ki.se		
Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus and Corticosteriods. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) study.			
Study Reference Number:	EUPAS 2 1 7 6 9		
Are you the (Primary) Lead	d Investigator of the above study? No 🗸 Yes 🗌		
Are you an investigator/re	searcher contributing to the above study No Yes 🗸		

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Leo Pharma Post-authorization safety study Pfizer Post-authorization safety study

SECTION 3: ANY OTHER INTERESTS

No 🕢 Yes ()

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FULL NAME:	Camilla Byström	Date:	14/02/2019
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SECTION 1: PERSONAL DETAILS

First Name:	Marcus
Last Name:	Schmitt-Egenolf
Organisation / Research Centre :	Dep. of Public Health & Clinical Medicine Dermatology, Umeå University SE-901 85 Umeå, Sweden Phone: +46 (0)90 785 2875 marcus.schmitt-egenolf@umu.se www.derma.org
Country:	Sweden
Contact e-mail Address:	marcus.schmitt-egenolf@umu.se
	Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteriods. Protopic JOint European Longitudinal Lymphoma and skin cancer Evaluation (JOELLE) study.
Study Reference Number: EUPAS 2 1 7 6 9	
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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: Marcus Schmitt-Egenolf Date: 14/02/2019

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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
	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: I	EUPAS 2 1 7 6 9
Are you the (Primary) Lead Investigator of the above study? No ✓ Yes	
Are you an investigator/researcher contributing to the above study. No	

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http://www.encepp.eu/encepp/viewResource.htm?id=19407 PASregistered studies for LEO Pharma, Servier, Merck Sharpe & Dohme Corp., Astra Zeneca, Vifor & IV iron consortium.

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 <u>EU PAS Register</u>.

FULL NAME: Carla Franzoni Date: 14/02/2019

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