



Declaration of Interests for ENCePP SEAL Studies

INTRODUCTION

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The form is designed to be filled in electronically, printed and signed. A PDF scan of the signed copy should be uploaded to the [EU PAS Register](#).

SECTION 1: PERSONAL DETAILS

First Name:

Cécile

Last Name:

Droz-Perroteau

Organisation / Research Centre :

Bordeaux PharmacoEpi
Plateforme de recherche en Pharmaco-épidémiologie
CIC Bordeaux CIC1401
Service de Pharmacologie médicale

Case 41 Bâtiment du Tondu, 1er étage
146 rue Léo Saignat, 33076 Bordeaux cedex

Country:

France

Contact e-mail Address:

cecile.droz@u-bordeaux.fr

DOAC study

Study Reference Number: EUPAS

1 6 0 1 4

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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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Abott, Aptalis, AstraZeneca, Bayer, Baxter, Biogen, BMS, Boehringer, Erempharma, Helsinn, Janssen-Cilag, Lilly, Lunbeck, Merck Serono, Novartis, Nycomed, Pierre Fabre, Sanofi, Stallergenes, Vifor.	During the past 3 years, Bordeaux PharmacoEpi Platform has received research funding and unconditional grants that have contributed indiscriminately to the salaries of its employees, notably from pharmaceutical companies listed here.

SECTION 3: ANY OTHER INTERESTS

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FULL NAME:

Cécile Droz-Perroteau

Date:

03/11/2016

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Name of Pharmaceutical Company	Comments
For the IMI-EU-PROTECT project EFPIA company support was received.	The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) project was supported by the Innovative Medicine Initiative Joint Undertaking (www.imi.europa.eu) under Grant Agreement no 115004, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

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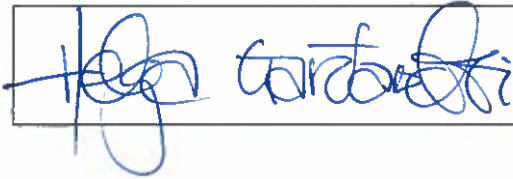
FULL NAME:

Helga Gardarsdottir

Date:

04/11/2016

SIGNATURE:





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SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="Christiane"/>
Last Name:	<input type="text" value="Gasse"/>
Organisation / Research Centre :	<input type="text" value="Aarhus University, National Centre for register-based Research"/>
Country:	<input type="text" value="Denmark"/>
Contact e-mail Address:	<input type="text" value="cg@econ.au.dk"/>

Study Reference Number: EUPAS

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Eli Lilly	Research collaboration
LA-SER Analytica	Research collaboration

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SECTION 1: PERSONAL DETAILS

First Name:

Rolf

Last Name:

Groenwold

Organisation / Research Centre :

UMC Utrecht

Country:

The Netherlands

Contact e-mail Address:

r.h.h.groenwold@umcutrecht.nl

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

1	6	0	1	4
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SECTION 1: PERSONAL DETAILS

First Name:

Rianne

Last Name:

van den Ham

Organisation / Research Centre :

Utrecht Institute for Pharmaceutical Sciences

Country:

The Netherlands

Contact e-mail Address:

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

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My husband is currently an employee of Chiesi Pharmaceuticals

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FULL NAME:

Rianne van den Ham

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SECTION 1: PERSONAL DETAILS

First Name:

CONSUELO

Last Name:

HUERTA

Organisation / Research Centre :

SPANISH AGENCY FOR MEDICINES AND MEDICAL DEVICES-
AEMPS

Country:

Spain

Contact e-mail Address:

chuerta_fcsai@bifap.aemps.es

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

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Are you the (Primary) Lead Investigator of the above study?

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First Name:

Luisa

Last Name:

Ibáñez

Organisation / Research Centre :

Fundació Institut Català de Farmacologia (FICF)

Country:

Spain

Contact e-mail Address:

li@icf.uab.es

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Olaf

Last Name:

Klungel

Organisation / Research Centre :

Universiteit Utrecht

Country:

The Netherlands

Contact e-mail Address:

o.h.klungel@uu.nl

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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.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
GSK	Grant to our research group (Pharmacoepidemiology & Clinical Pharmacology) for methodological Health Technology Assessment research not related to specific products.

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?

Our division has received grants from private-public initiatives such as IMI (PROTECT, EU2P). I am also involved in the IMI-Getreal project as part of my part-time appointment at the Julius Center for Health Sciences & Primary Care at the University Medical Center Utrecht

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.

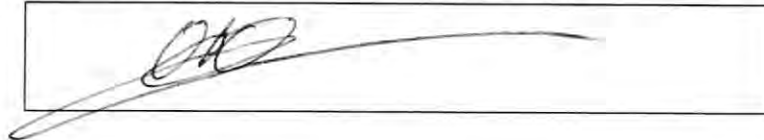
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SECTION 1: PERSONAL DETAILS

First Name:

ELISA

Last Name:

MARTÍN MERINO

Organisation / Research Centre :

Agencia Española de Medicamentos y Productos Sanitarios, Madrid, Spain (AEMPS) / BIFAP

Country:

Spain

Contact e-mail Address:

emartin_fcsai@bifap.aemps.es

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

1	6	0	1	4
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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

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FULL NAME:

ELISA MARTÍN MERINO

Date:

02/11/2016

SIGNATURE:





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SECTION 1: PERSONAL DETAILS

First Name:

Dolores

Last Name:

Montero

Organisation / Research Centre :

Agencia Espanola de Medicamentos y ProductosSanitarios,
Madrid, Spain (AEMPS)

Country:

Spain

Contact e-mail Address:

dmontero@aemps.es

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

1 6 0 1 4

Are you the (Primary) Lead Investigator of the above study?

No Yes

Are you an investigator/researcher contributing to the above study

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FULL NAME:

Dolores Montero

Date:

08/11/2016

SIGNATURE:





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SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

EMA tender: Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

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, types of consultancy and dates when fees/honoraria paid:

Period: Current Past

From Month: From Year:

Name of Pharmaceutical Company:

Type of consultancy:

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:

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:

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:

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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Helsinn	SALT (EUPAS2181) ended 2014
SANOFI	GROC (EUPAS3105) ended 2012
Bayer	BROTHER (EUPAS14567) Ongoing
Pierre Fabre	EOLE (EUPAS10726) ends 2017
ALLERGAN	Pylera DUS (EUPAS3901 SEAL) ending
NOVARTIS	INHALER (EUPAS10753) ending
Stallergenes	EVORA (EUPAS9358) End 2016
ALLERGAN	SAPHARY (EUPAS3142 SEAL) Ending
Astrazeneca	HORUS (EUPAS5816) ending
BMS	ATTOS (EUPAS11521) ongoing
Lundbeck	USE-PACT (EUPAS11854)
SANOFI	FUJI (EUPAS10391 SEAL)
Boehringer	ENGEL (EUPAS6616)
Astra-Zeneca	SPACE-AA (EUPAS5987)

SECTION 3: ANY OTHER INTERESTS

No Yes

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Declaration of Interests for ENCePP SEAL Studies

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SECTION 1: PERSONAL DETAILS

First Name:

Marietta

Last Name:

Rottenkolber

Organisation / Research Centre :

Klinikum der Universitaet Muenchen, Munich, Germany

Country:

Germany

Contact e-mail Address:

marietta.rottenkolber@med.uni-muenche

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

1 6 0 1 4

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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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

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Patent for a medicinal product?

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FULL NAME:

Rottenkolber Marietta



Date: 4.11.2016

SIGNATURE:

H. Rotte Lohr



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SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU.

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:

Sven

Last Name:

Schmiedl

Organisation / Research Centre :

- Department of Clinical Pharmacology, School of Medicine,
Faculty of Health, Witten/Herdecke University, Witten, Germany
- Philipp Klee-Institute for Clinical Pharmacology, HELIOS Clinic
Wuppertal, Wuppertal, Germany

Country:

Germany

Contact e-mail Address:

sven.schmiedl@helios-kliniken.de

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

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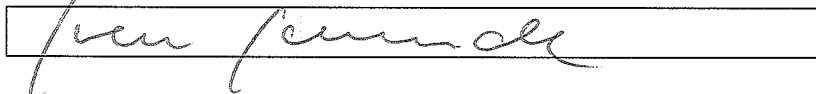
FULL NAME:

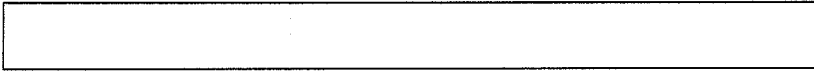
Sven Schmiedl

Date:

04/11/2016

SIGNATURE:







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Country:

Contact e-mail Address:

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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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SECTION 3: ANY OTHER INTERESTS

No Yes

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FULL NAME:

Patrick Souverein

Date:

02/11/2016

SIGNATURE:





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

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

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Financial interests in the capital of a pharmaceutical company?

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2.3 Patent

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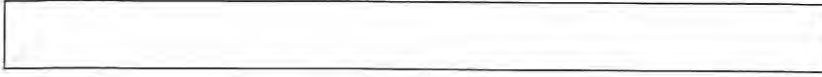
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FULL NAME:

Xavier Vidal

Date:

03/11/2016

SIGNATURE:





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SECTION 1: PERSONAL DETAILS

First Name:

Maria Theresa

Last Name:

Wimberley Böttger

Organisation / Research Centre :

National Centre for Register-based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University, Aarhus, Denmark,

Country:

Denmark

Contact e-mail Address:

tw@econ.au.dk

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS 1 6 0 1 4

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:

Katrin

Last Name:

Janhsen

Organisation / Research Centre :

a) University Witten / Herdecke
b) Hochschule für Gesundheit Bochum (University of Applied Sciences)

Country:

Germany

Contact e-mail Address:

katrin.janhsen@hs-gesundheit.de

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Study Reference Number: EUPAS

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FULL NAME:

Katrin Jankusew

Date:

22.11.16

SIGNATURE:

K Jankusew

