



## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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### 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 ☐

#### 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.

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Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Abbott, 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 PharmacoeEpi 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

No ☒ Yes ☐

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FULL NAME:

Cécile Droz-Perroteau

Date:

03/11/2016

SIGNATURE:





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### SECTION 1: PERSONAL DETAILS

First Name:

Helga

Last Name:

Gardarsdottir

Organisation / Research  
Centre :

Universiteit Utrecht, Utrecht, The Netherlands (UU)

Country:

The Netherlands

Contact e-mail Address:

*h.gardarsdottir@uu.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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Name of Pharmaceutical Company	Comments
For the IMI-EU-PROTECT project EFPIA company support was received.	The Pharmacoeconomic Research on Outcomes of Therapeutics by a European Consortium (PROTECT) project was supported by the Innovative Medicine Initiative Joint Undertaking ( <a href="http://www.imi.europa.eu">www.imi.europa.eu</a> ) 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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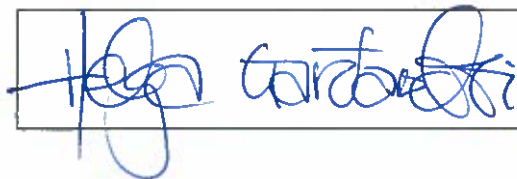
FULL NAME:

Helga Gardarsdottir

Date:

04/11/2016

SIGNATURE:









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Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

Study Reference Number: EUPAS

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Eli Lilly	Research collaboration
LA-SER Analytica	Research collaboration

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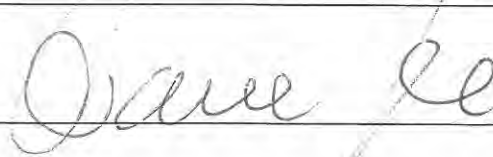
FULL NAME:

Christiane Gasse

Date:

02/11/2016

SIGNATURE:





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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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FULL NAME: Rolf Groenwold

Date: 02/11/2016

SIGNATURE:









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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

1 6 0 1 4

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

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

My husband is currently an employee of Chiesi Pharmaceuticals

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FULL NAME:

Rianne van den Ham

Date:

04/11/2016

SIGNATURE:



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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

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CONSUELO HUERTA

Date:

02/11/2016

SIGNATURE:





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### SECTION 1: PERSONAL DETAILS

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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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: Luisa Ibáñez

Date: 03/11/2016

SIGNATURE:

*Luisa Ibáñez*

## 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:

Olaf

Last Name:

Klungel

Organisation / Research Centre :

Universiteit Utrecht

Country:

The Netherlands

Contact e-mail Address:

*o.h.klungel@uu.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

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.

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.

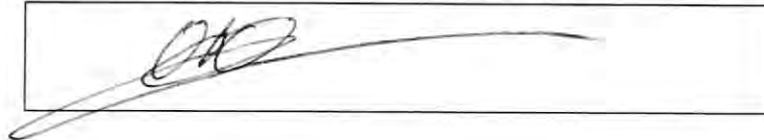
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FULL NAME: Olaf Klungel

Date: 07/11/2016

SIGNATURE:





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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\\_fcslai@bifap.aemps.es](mailto:emartin_fcslai@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

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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### 2.5 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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☒ 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:

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

No ☐

Yes ☒



## SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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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:

Dolores Montero

Date:

08/11/2016

SIGNATURE:





## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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### SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="nicholas"/>
Last Name:	<input type="text" value="moore"/>
Organisation / Research Centre :	<input type="text" value="Bordeaux Pharmacoepi"/>
Country:	<input type="text" value="France"/>
Contact e-mail Address:	<input type="text" value="nicholas.moore@u-bordeaux.fr"/>
	<input type="text" value="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 ☒



## SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.

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:

Name of Pharmaceutical Company:

Type of consultancy:

## 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
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 ☐

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

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FULL NAME:

Date:

SIGNATURE:

A handwritten signature in black ink, appearing to be 'Nicholas Moore', is written over a large rectangular box. The signature is fluid and cursive, with a long horizontal stroke extending to the right.



## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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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?

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### 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?

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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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FULL NAME:

Rottenkolber Marietta



Date: 4.11.2016

SIGNATURE:

H. Rotte-Lohr



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### SECTION 1: PERSONAL DETAILS

First Name:

Mònica

Last Name:

Sabaté

Organisation / Research  
Centre :

Fundació Institut català de Farmacologia (FICF), Barcelona,  
Spain

Country:

Spain

Contact e-mail Address:

msg@icf.uab.cat

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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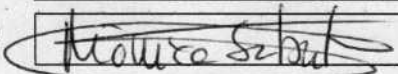
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FULL NAME: Mònica Sabaté

Date: 03/11/2016

SIGNATURE:





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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

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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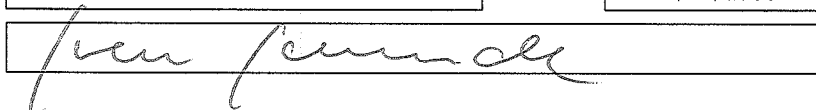
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FULL NAME: Sven Schmiedl

Date: 04/11/2016

SIGNATURE:



--



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### SECTION 1: PERSONAL DETAILS

First Name:

Patrick

Last Name:

Souverein

Organisation / Research  
Centre :

Division of Pharmacoepidemiology and Clinical Pharmacology,  
Utrecht Institute for Pharmaceutical Sciences, Utrecht  
University

Country:

The Netherlands

Contact e-mail Address:

P.C.Souverein@uu.nl

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Patrick Souverein

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### SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="Henriette"/>
Last Name:	<input type="text" value="Thisted Horsdal"/>
Organisation / Research Centre :	<input type="text" value="National Centre for Register-based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University, Aarhus, Denmark"/>
Country:	<input type="text" value="Denmark"/>
Contact e-mail Address:	<input type="text" value="horsdal@econ.au.dk"/>
	<input type="text" value="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"/>

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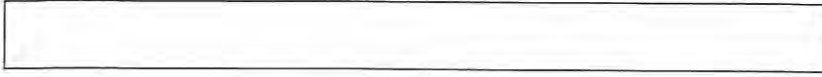
FULL NAME: Henriette Thisted Horsdal

Date: 04/11/2016

SIGNATURE:

Henriette Thisted Horsdal







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### SECTION 1: PERSONAL DETAILS

First Name:

Xavier

Last Name:

Vidal

Organisation / Research  
Centre :

Fundació Institut Català de Farmacologia (FICF), Barcelona,  
Spain

Country:

Spain

Contact e-mail Address:

xvg@icf.uab.cat

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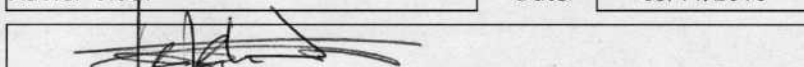
FULL NAME:

Xavier Vidal

Date:

03/11/2016

SIGNATURE:





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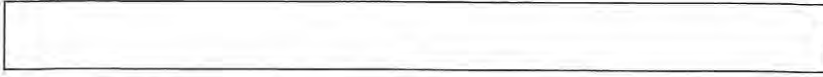
FULL NAME: Maria Theresa Wimberley Böttger

Date: 04/11/2016

SIGNATURE:

*Theresa Wimberley*







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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

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FULL NAME:

Katrin Jankusek

Date:

22.11.16

SIGNATURE:

K Jankusek

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Elena

Last Name:

Ballarín

Organisation / Research  
Centre :

Fundació Institut Català de Farmacologia(FICF), Hospital  
Universitari Vall d'Hebron.

Country:

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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:

Régis

Last Name:

Lassalle

Organisation / Research Centre :

Plateform Bordeaux PharmacoeEpi (BPE) - INSERM CIC1401

Country:

France

Contact e-mail Address:

regis.lassalle@u-bordeaux.fr

"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?

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 ☐

### 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: Régis Lassalle

Date: 07/02/2017



## Declaration of Interests for ENCePP SEAL Studies

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### SECTION 1: PERSONAL DETAILS

First Name:

Luz M

Last Name:

León-Muñoz

Organisation / Research  
Centre :

División de Farmacoepidemiología y Farmacovigilancia  
Agencia Española de Medicamentos y Productos Sanitarios  
(AEMPS)  
Spanish Agency for Medicines and Medical Devices (AEMPS)

Country:

Spain

Contact e-mail Address:

lmleon@aemps.es

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FULL NAME:

Luz M León-Muñoz

Date:

19/01/2017

Submit Form by Email