## (-1)EPD

## 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, printed and signed. A PDF scan of the signed copy should be uploaded to the EU PAS Register.

## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research Centre:

Country:
Contact e-mail Address:
$\square$
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
$\square$
cecile.droz@u-bordeaux.fr
DOAC study

Study Reference Number: EUPAS
 16 0 4

Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study

NoYes No $\square$ 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 <br> No <br> 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 (1) Yes $\bigcirc$

## 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 (d) Yes $\bigcirc$

## 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 ( 1 ) Yes $\bigcirc$

## Consultancy for a pharmaceutical company during the past $\mathbf{3}$ 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



## Strategic Advisory role on activities of a pharmaceutical company during the past $\mathbf{3}$ 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 $\bigcirc$ Yes ( 1
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 |
| :--- | :--- |
| Abott, Aptalis, AstraZeneca, Bayer, Baxter, <br> Biogen, BMS, Boehringer, Erempharma, Helsinn, <br> Janssen-Cilag, Lilly, Lunbeck, Merck Serono, <br> Novartis, Nycomed, Pierre Fabre, Sanofi, <br> Stallergenes, Vifor. | During the past 3 years, Bordeaux PharmacoEpi Platform has <br> received research funding and unconditional grants that <br> have contributed indiscriminately to the salaries of its <br> employees, notably from pharmaceutical companies listed <br> here. |

## SECTION 3: ANY OTHER INTERESTS

## 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.


## Encep

## Declaration of Interests for ENCePP SEAL Studies

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## SECTION 1: PERSONAL DETAILS

First Name:

Country:


Organisation / Research Centre :

Universiteit Utrecht, Utrecht, The Netherlands (UU)

Contact e-mail Address:
The Netherlands
h.gardarsdottir@uu.nl
"Characterising the risk of major bleeding in patients with Non-Valvular Atriai 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?
Are you an investigator/researcher contributing to the above study

| No $\square$ | Yes $\square$ |
| :--- | :--- |
| No $\square$ | Yes |

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

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### 2.1 Employment <br> No <br> Yes $\bigcirc$

Employment in a pharmaceutical company during past 3 years of study application?
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### 2.2 Financial Interest



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
(0) 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 (7) 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 (1) Yes $O$

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

## 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: Helga Gardarsdottir
SIGNATURE:


## Encpp

## Declaration of Interests for ENCePP SEAL Studies

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## SECTION 1: PERSONAL DETAILS


"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

\section*{| 1 | 6 | 0 | 1 |  |
| :--- | :--- | :--- | :--- | :--- |}

Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study

| No $X$ | Yes $\square$ |
| :--- | :--- |
| No $\square$ | Yes $X$ |

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### 2.3 Patent <br> No (1) Yes

## Patent for a medicinal product?

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### 2.4 Consultancy

No (()) Yes

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

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### 2.5 Strategic Advisory Role

No
(1) Yes

Strategic Advisory role on activities of a pharmaceutical company during the past $\mathbf{3}$ years of study application?
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Please specify the pharmaceutical company:

| Name of Pharmaceutical Company | Comments |
| :--- | :--- |
| Eli Lilly | Research collaboration |
| LA-SER Analytica | Research collaboration |

## SECTION 3: ANY OTHER INTERESTS

No ( 1 ) Yes $\bigcirc$

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## (ensep)

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SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre :
$\square$
Rolf
Groenwold


## Country:

$\square$
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 |
| :--- | :--- | :--- | :--- | :--- |

| Are you the (Primary) Lead Investigator of the above study? | No $\quad \checkmark$ | Yes $\quad \square$ |
| :--- | :--- | :--- |
| Are you an investigator/researcher contributing to the above study | No $\quad \square$ | Yes |

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Financial interests in the capital of a pharmaceutical company?
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### 2.3 Patent

No (1) Yes

## Patent for a medicinal product?

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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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### 2.6 Grant / Funding

No

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## SECTION 3: ANY OTHER INTERESTS

No ( 1 Yes $\bigcirc$

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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.
Rolf Groenwold

[^0]
## SIGNATURE:


$\square$

## 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:
$\square$
van den Ham
Utrecht Institute for Pharmaceutical Sciences

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
60
14
Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study No

Yes
NoYes

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

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### 2.1 Employment <br> No (0) Yes

## Employment in a pharmaceutical company during past $\mathbf{3}$ years of study application?

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### 2.2 Financial Interest <br> No <br> Yes $\bigcirc$

## 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 $\bigcirc$

## 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 $\mathbf{3}$ 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 $\bigcirc$

## Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? <br> 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 <br> No

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 $\bigcirc$ 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?

My husband is currently an employee of Chiesi Pharmaceuticals

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: | Rianne van den Ham | Date: |
| :--- | :--- | :--- |
| SIGNATURE: |  |  |
|  |  |  |

## Ensed

## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research Centre :

Country:
Contact e-mail Address:
$\square$
HUERTA
SPANISH AGENCY FOR MEDICINES AND MEDICAL DEVICESAEMPS

## Spain

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


Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study

No

NoYesV

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

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### 2.1. Employment <br> No <br> ( $)$ Yes $\bigcirc$

## 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 <br> No (D) Yes $\bigcirc$

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
(D) 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 (1) 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 (1) 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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## SECTION 3: ANY OTHER INTERESTS No © Yes $\bigcirc$

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FULL NAME:


Date: 02/11/2016
SIGNATURE:


## EnGep

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SECTION 1: PERSONAL DETAILS

| First Name: | Luisa |
| :--- | :--- |
| Last Name: | Ibáñez |
| Organisation / Research | Fundació Institut Català de Farmacologia (FICF) |
| Centre : |  |
|  |  |
| Country: | Spain |
| Contact e-mail Address: | li@icf.uab.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


Are you the (Primary) Lead Investigator of the above study? No $\square$ Yes Are you an investigator/researcher contributing to the above study NoYes

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### 2.1 Employment

$$
\text { No (1) Yes } O
$$

## Employment in a pharmaceutical company during past $\mathbf{3}$ years of study application?

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2.3 Patent
No () Yes

## Patent for a medicinal product?

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### 2.4 Consultancy <br> No (1) Yes

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Luisa Ibáñez

Date: 03/11/2016
SIGNATURE:
Mujc Iscere2

## 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 wit 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, printed and signed. A PDF scan of the signed copy should be uploaded to the EU PAS Register.

## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre :

Country:
Contact e-mail Address:
Olaf
Klungel
Universiteit Utrecht

The Netherlands
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 $\square$
Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study


## 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
(d) Yes $\bigcirc$

## 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 (1) 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
( $) \mathrm{Yes}$

## 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 (1) Yes

## Consultancy for a pharmaceutical company during the past $\mathbf{3}$ 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 |  |  |
| :--- | :--- | :--- |
| GSK |  <br> Clinical Pharmacology) for methodological Health Technology |  |
| Assessment research not related to specific products. |  |  |

## SECTION 3: ANY OTHER INTERESTS No $\bigcirc$ Yes (จ)

## 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.

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.

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research Centre :

Country:
Contact e-mail Address:
$\square$
MARTÍN MERINO
Agencia Española de Medicamentos y Productos Sanitarios, Madrid, Spain (AEMPS) / BIFAP
Spain
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


Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study


Yes
NoYes $\square$

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FULL NAME:
SIGNATURE:


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## SECTION 1: PERSONAL DETAILS

## Dolores <br> Dolores

Agencia Espanola de Medicame Agencia Espaid, Spain (AEMPS)

First Name:
Organisation / Research
Centre:
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

\section*{Study Reference Number: EUPAS | 1 | 6 | 0 | 1 | 4 |
| :--- | :--- | :--- | :--- | :--- |
|  |  |  |  |  |}

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

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$$

$\square$
$\stackrel{y}{\succ}$
$\square$

$\stackrel{8}{2}$ | $\square$ |
| :--- |
| ㅇ |
|  |

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### 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 pharmaceutical company.

> 2.2 Financial Interest
Patent for a medicinal product?

### 2.3 Patent

### 2.4 Consultancy

2.5 Strategic Advisory Role or any form of remuneration.
2.6 Grant / Funding
Grant/fundract?
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
No

$$
\text { Yes } \bigcirc
$$

No (v)
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> Yes 2.5 Strat

## SECTION 3: ANY OTHER INTERESTS <br> No (, <br> No (d) Yes $\bigcirc$ <br> In this section you should declare any other interests to be made known to the public.

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Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?
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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre:

Country:
Contact e-mail Address:


Bordeaux Pharmacoepi

France
nicholas.moore@u-bordeaux.fr

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

Study Reference Number: EUPAS $\square$
Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study
NoYes

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

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### 2.1 Employment

No
(D) Yes $\bigcirc$

## Employment in a pharmaceutical company during past 3 years of study application?

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### 2.2 Financial Interest

No
(1) 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
(1) 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

NoYes (1)

## 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 company, types of consultancy and dates when fees/honoraria paid:
Period:
( 8 Current
C Past
From Month: $\square$ From Year: 2013
Name of Pharmaceutical Company: Merck
Type of consultancy:
Data safety monitoring board

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

| Period: | $\subset$ Current $\subset$ Past |
| :--- | :--- |
| From Month: | $\square$ From Year: 2014 |

Name of Pharmaceutical Company: IPSEN
Type of consultancy:
Advice on pharmacoepidemiological methods

Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:


Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:
Period: $\subset$ Current $\neg$ Past
From Month: $\square$ From Year: 2015 To Month: $\square$ To Year: 2015
Name of Pharmaceutical Company: Pfizer
Type of consultancy:
expert advice on risks of low-dose ibuprofen and paracetamol (advisory board meeting)

### 2.5 Strategic Advisory Role

No (1) 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 <br> No <br> $\bigcirc$ Yes <br> (1)

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 (1) Yes $\bigcirc$

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

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

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research Centre :

Country:
Contact e-mail Address:
Marietta

Rottenkolber
Klinikum der Universitaet Muenchen, Munich, Germany
$\square$
Germany
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?
Are you an investigator/researcher contributing to the above study NoYes

NoYes


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

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### 2.1 Employment

No O Yes

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### 2.2 Financial Interest



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

O 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
0 Yes $\bigcirc$
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



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 $\bigcirc$ res $\bigcirc$
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 $\bigcirc$

In this section you should declare any other interests to be made known to the public.
Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?
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FULL NAME:


SIGNATURE:


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First Name:
Last Name:
Organisation / Research Centre :

Country:
Contact e-mail Address:

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

## Spain

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 <br> $\square$ 14

Are you the (Primary) Lead Investigator of the above study?
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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 <br> Centre : | -Department of Clinical Pharmacology, School of Medicine, <br> Faculty of Health, Witten/Herdecke University, Witten, Germany <br> -Pilipp Keee-Institute for Clinical Pharmacology, HELIOS Clinic <br> 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

\section*{| 1 | 6 | 0 | 1 | 4 |
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FULL NAME:
SIGNATURE:

$\square$

## EnGep

## 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:
Last Name:
Organisation / Research
Centre :

Country:
Contact e-mail Address:
$\square$
Souverein
Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University
$\square$
P.C.Souverein@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 $\square$4

Are you the (Primary) Lead Investigator of the above study? No V Yes Are you an investigator/researcher contributing to the above study NoYes

## 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 (O) Yes $O$

## Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service compenies 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

$$
\text { No (O) Yes } O
$$

## 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
(C) 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

## 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
(v) 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

## 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 $\bigcirc$

## 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.

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## Encpp

## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre :

Country:
Contact e-mail Address:
$\square$
Thisted Horsdal
National Centre for Register-based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University, Aarhus, Denmark

## Denmark

horsdal@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 $\square$
Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study
NoYes
NoYes


## 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

## 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 (1) Yes $\bigcirc$

## 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
(D) 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 (D) 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 <br> No (V) Yes $\bigcirc$

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 $\bigcirc$

## 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?
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$\checkmark$ 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:


SIGNATURE: $\square$
$\square$

## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research Centre :

Country:
Contact e-mail Address:

| Xavier |
| :--- |
| Vidal |

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

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 $\sqrt{ }$ Yes
Are you an investigator/researcher contributing to the above study NoYes


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 (1) Yes $\bigcirc$

## 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 <br> No <br> Yes $\bigcirc$

## 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 $\bigcirc$

## Consultancy for a pharmaceutical company during the past $\mathbf{3}$ 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 $\bigcirc$

## Strategic Advisory role on activities of a pharmaceutical company during the past $\mathbf{3}$ 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 <br> No ( $)$ Yes $\bigcirc$

## 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 (1) Yes $\bigcirc$

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

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

## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre :

Country:
Contact e-mail Address:
$\square$
Wimberley Böttger
National Centre for Register-based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University, Aarhus, Denmark,
$\square$
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


| Are you the (Primary) Lead Investigator of the above study? | No | $\boxed{l}$ Yes |  |  |
| :--- | :--- | :--- | :--- | :--- |
| Are you an investigator/researcher contributing to the above study | No | $\square$ | Yes | $\square$ |

## 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

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 (1) Yes $\bigcirc$

## 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 (1) Yes $\bigcirc$

## 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 (1) Yes $\bigcirc$

## 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 (D) 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
(D) Yes $\bigcirc$

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 (1) Yes ○

In this section you should declare any other interests to be made known to the public.
Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

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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:
Maria Theresa Wimberley Böttger
Date:
04/11/2016
SIGNATURE:

$\square$

## enspp

## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research Centre :

Country:
Contact e-mail Address:

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

Germany
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 | 1 | 6 | 0 | 1 | 4 |
| :--- | :--- | :--- | :--- | :--- |

Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study


## 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 (1) Yes

## Employment in a pharmaceutical company during past $\mathbf{3}$ 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 (1) Yes $\bigcirc$

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 (1) Yes $\bigcirc$

## 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 (1) Yes $\bigcirc$

## 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 (1) Yes $\bigcirc$

## Strategic Advisory role on activities of a pharmaceutical company during the past $\mathbf{3}$ 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 <br> No (1) Yes $O$

## 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 (ㄱ) Yes $\bigcirc$

## 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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$\square$

## Geg

## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

| First Name: | Elena |
| :--- | :--- |
| Last Name: | Ballarín |
| Organisation / Research Fundació Institut Català de Farmacologia(FICF), Hospital <br> Centre:  <br>   <br>   <br> Universitari Vall d'Hebron.  <br> Country: Spain <br> Contact e-mail Address: eb@icf.uab.cat |  |

Charasterising 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 $\square$
Are you the (Primary) Lead Investigator of the above study?
NoYes
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

Yes

## Employment in a pharmaceutical company during past $\mathbf{3}$ 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 <br> No <br> Yes $\bigcirc$

## 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 (V) Yes $\bigcirc$

## 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

## 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

## Strategic Advisory role on activities of a pharmaceutical company during the past $\mathbf{3}$ 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 (V) Yes $\bigcirc$

## 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 $\bigcirc$

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

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?
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## Declaration of Interests for ENCePP SEAL Studies

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre :

Country:
Contact e-mail Address:
$\square$
Lassalle
Plateform Bordeaux PharmacoEpi (BPE) - INSERM CIC1401
$\square$
France
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 | 1 | 6 | 0 | 1 | 4 |
| :--- | :--- | :--- | :--- | :--- |

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

Are you an investigator/researcher contributing to the above study NoYes v

## 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 ( $(1)$ Yes $\bigcirc$

## 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 $\bigcirc$

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 <br> No <br> Yes $\bigcirc$

## 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 (จ) Yes $\bigcirc$

## Consultancy for a pharmaceutical company during the past $\mathbf{3}$ 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 <br> No (®) Yes $\bigcirc$

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 ( 1 ) Yes $\bigcirc$
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

## 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.
$\checkmark$ 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

## INTRODUCTION

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## SECTION 1: PERSONAL DETAILS

First Name:
Last Name:
Organisation / Research
Centre :

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

Country:
Contact e-mail Address:

Spain
Imleon@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 $\square$
Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study

| No | $\square$ | Yes |
| :--- | :--- | :--- | :--- |
|  |  |  |
| No |  |  |
| $\square$ | Yes | $\square$ |

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 <br> No () Yes

## Employment in a pharmaceutical company during past $\mathbf{3}$ 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 (v) Yes $\bigcirc$

## 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

## 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 $\mathbf{3}$ 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 $(\mathbb{J}$ Yes $\bigcirc$

## Strategic Advisory role on activities of a pharmaceutical company during the past $\mathbf{3}$ 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 <br> No

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 $\bigcirc$

## 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.
$\checkmark$ 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:
Luz M León-Muñoz
Date:

\section*{encep}

\section*{Declaration of Interests for ENCePP SEAL Studies}

\section*{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*{SECTION 1: PERSONAL DETAILS}
First Name:
\begin{tabular}{|l|}
\hline Marie Louise \\
\hline De Bruin \\
\hline
\end{tabular}

Organisation / Research Centre :

Country:
Contact e-mail Address: \(\square\)

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 \begin{tabular}{|l|l|l|l|l|}
\hline 1 & 6 & 0 & 1 & 4 \\
\hline
\end{tabular}
\begin{tabular}{lllll} 
Are you the (Primary) Lead Investigator of the above study? & No & \(\boxed{v}\) & Yes & \(\square\) \\
Are you an investigator/researcher contributing to the above study & No & \(\square\) & Yes & \(\square\)
\end{tabular}

\section*{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.

\subsection*{2.1 Employment \\ No (1) Yes}

\section*{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.

\subsection*{2.2 Financial Interest}

No ( \(\downarrow\) Yes \(\bigcirc\)

\section*{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.

\subsection*{2.3 Patent}

No (1) Yes

\section*{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.

\subsection*{2.4 Consultancy}

No
Yes \(\bigcirc\)

\section*{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.

\subsection*{2.5 Strategic Advisory Role \\ No (1) Yes \(\bigcirc\)}

\section*{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.}

\subsection*{2.6 Grant / Funding No \(\bigcirc\) Yes (1)}

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:
\begin{tabular}{|l|l|}
\hline \multicolumn{1}{|c|}{ Name of Pharmaceutical Company } & \\
\hline Novo Nordisk & \multicolumn{1}{c|}{ Comments } \\
\hline FhD/post-doc grant to Copenhagen Centre for Regulatory \\
Science
\end{tabular}

\section*{SECTION 3: ANY OTHER INTERESTS}

No \(\bigcirc\) 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?
see annex

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.
\(\square\) 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: Marie Louise De Bruin Date: \(11 / 01 / 2018\)

\section*{Annex to Section 3: Any Other Interests Declaration of Interests - study reference no. EUPAS16014}

I am appointed as professor in Regulatory Science, which chair is funded by the University of Copenhagen. In addition, I am director of the Copenhagen Institute of Regulatory Science (CORS), based at the same university. CORS is a cross-faculty university anchored institution involving various public (Danish Medicines Agency, Copenhagen University) and private stakeholders (Novo Nordisk, Lundbeck, Ferring pharmaceuticals, LEO pharma) as well as patient organisations (Rare Diseases Denmark). The center is purely devoted to the scientific aspects of the regulatory field and with a patient-oriented focus and the research is not company-specific product or directly company related.

Apart from my position at the University of Copenhagen, I am part-time employed by Utrecht University as senior researcher conducting research under the umbrella of the Utrecht-WHO Collaborating Centre for Pharmaceutical Policy and Regulation. This Centre receives no direct funding or donations from private parties, including pharma industry. Research funding from public-private partnerships, e.g. IMI, The Escher Project (http://escher.lygature.org/) is accepted under the condition that no companyspecific product or company related study is conducted. The Centre has received unrestricted research funding from public sources, e.g. World Health Organisation (WHO), Netherlands Organisation for Health Research and Development (ZonMW), the Dutch National Health Care Institute (ZIN), EU 7th Framework Program (FP7), the Dutch Medicines Evaluation Board (MEB), and the Dutch Ministry of Health.
\[
11-1-2018
\]

\section*{Declaration of Interests for ENCePP SEAL Studies}

\section*{INTRODUCTION}

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\section*{SECTION 1: PERSONAL DETAILS}

\section*{First Name:}

Last Name:
Organisation / Research Centre :
\begin{tabular}{|l|}
\hline Morten \\
\hline Andersen \\
\hline
\end{tabular}

University of Copenhagen
Department of Drug Design and Pharmacology
ENCePP centre:
Pharmacoepidemiology Research Collaboration

\section*{Country:}

Contact e-mail Address:
\(\square\)
Denmark
morten.andersen@sund.ku.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 \(\square\)
Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above study


\section*{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.

\subsection*{2.1 Employment}

No ( \()\) Yes \(\bigcirc\)

\section*{Employment in a pharmaceutical company during past \(\mathbf{3}\) 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.

\section*{2. 2 Financial Interest}

No ( () Yes \(\bigcirc\)

\section*{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.

\subsection*{2.3 Patent}

No ((1) Yes \(\bigcirc\)

\section*{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.

\subsection*{2.4 Consultancy}

No ( \()\) Yes \(\bigcirc\)
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.

\subsection*{2.5 Strategic Advisory Role \\ No (1) Yes}

\section*{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.

\subsection*{2.6 Grant / Funding \\ No \\  \\ Yes (1)}

\section*{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:
\begin{tabular}{|l|l|}
\hline \multicolumn{1}{|c|}{ Name of Pharmaceutical Company } & \multicolumn{1}{c|}{ Comments } \\
\hline Novo Nordisk Foundation & \begin{tabular}{l} 
Grant to the University of Copenhagen supporting \\
Professorship in Pharmacovigilance
\end{tabular} \\
\hline Janssen & \begin{tabular}{l} 
Grant to Karolinska Institutet supporting methodological \\
pharmacoepidemiological project
\end{tabular} \\
\hline
\end{tabular}

\section*{SECTION 3: ANY OTHER INTERESTS \\ No \(\bigcirc\) Yes ( \()\)}

\section*{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?

I have in the past 5 years been principal investigator or investigator in observational studies of drug safety, utilisation and effectiveness funded by the pharmaceutical industry (AstraZeneca, MSD, Pfizer, H. Lundbeck \& Mertz, Novartis) with grants received by Karolinska Institutet. I have personally received fees for leading and teaching courses in pharmacoepidemiology at Atrium (previously Medicademy, the Danish Association for the Pharmaceutical Industry), where I am also a member of the steering group for the pharmacovigilance education (no remuneration).
I am employed full time at the University of Copenhagen, part time at the University of Southern Denmark and associated with Karolinska Institutet. These universities receive funding from several pharmaceutical companies for research projects in which I am not involved.

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.


Submit Form by Email

\section*{Encep}

\section*{Declaration of Interests}

\section*{INTRODUCTION}

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For ENCePP Seal studies only: the completed form is to be transmitted to the ENCePP Secretariat by email.

\section*{SECTION 1: PERSONAL DETAILS}

First Name:
Last Name
Organisation / Research Centre :

\section*{Country:}

Contact e-mail Address:
\begin{tabular}{|l|}
\hline Mia \\
\hline Aakjær \\
\hline
\end{tabular}

Pharmacovigilance Research Group
Department of Drug Design and Pharmacology University of Copenhagen

\section*{Denmark}
mia.aakjaer@sund.ku.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 \begin{tabular}{|l|l|l|l|l|}
\hline 1 & 6 & 0 & 1 & 4
\end{tabular}

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

Are you an investigator/researcher contributing to the above study

No

NoYes

\section*{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.

\subsection*{2.1 Employment}

No \(\bigcirc\) Yes ( \()\)

\section*{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:


\subsection*{2.2 Financial Interest}

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.

\subsection*{2.3 Patent}

No \(\qquad\) Yes

\section*{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.

\subsection*{2.4 Consultancy}

\section*{No ( ( ) Yes \(\bigcirc\)}

\section*{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.

\subsection*{2.5 Strategic Advisory Role \\ No (1) Yes \(\bigcirc\)}

\section*{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.

\subsection*{2.6 Grant / Funding No \(\bigcirc\) Yes ( \()\)}

\section*{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:
\begin{tabular}{|l|l|}
\hline Name of Pharmaceutical Company & \multicolumn{1}{c|}{ Comments } \\
\hline Novo Nordisk Foundation & \begin{tabular}{l} 
Grant to the University of Copenhagen supporting the \\
Pharmacovigilance Research Group
\end{tabular} \\
\hline
\end{tabular}

\section*{SECTION 3: ANY OTHER INTERESTS}

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 EU PAS Register.

FULL NAME: Mia Aakjær
Date: 29/05/2018 Submit Form by Email

\section*{(Encep}

\section*{Declaration of Interests for ENCePP SEAL Studies}

\section*{INTRODUCTION}

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\section*{ECLON I: PERSONAL DETAILS}

First Name:
Last Name:
Organisation / Research
Centre:

Country:
Contact e-mail Address:

Roman
Gerlach
National Association of Statutory Health Insurance Physicians of Bavaria, Munich, Germany

\section*{Germany}
roman.gerlach@kvb.de

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

Study Reference Number: EUPAS 16 \(0 \quad 1\)

Are you the (Primary) Lead Investigator of the above study?
Are you an investigator/researcher contributing to the above studyYes NoYes

\section*{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.

\subsection*{2.1 Employment}

No
(-) Yes \(\bigcirc\)

\section*{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.

\subsection*{2.2 Financial Interest}

No
(v) Yes \(O\)

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.

\subsection*{2.3 Patent}

No
(d) Yes 0

\section*{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.

\subsection*{2.4 Consultancy \\ No (©) Yes \(\bigcirc\)}

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.

\subsection*{2.5 Strategic Advisory Role}

No

\section*{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
(0) Yes \(O\)

\section*{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*{SECTION 3: ANY OTHER INTERESTS No © Yes ○}

\section*{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.


Date: 24/04/2017
FULL NAME:```


[^0]:    Date:
    02/11/2016

