

INTRODUCTION

SECTION 1: PERSONAL DETAILS

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 <u>EU PAS Register</u>.

Cécile First Name: Droz-Perroteau Last Name: Bordeaux PharmacoEpi Organisation / Research Plateforme de recherche en Pharmaco-épidémiologie Centre: CIC Bordeaux CIC1401 Service de Pharmacologie médicale Case 41 Bâtiment du Tondu, 1er étage 146 rue Léo Saignat, 33076 Bordeaux cedex France Country: cecile.droz@u-bordeaux.fr Contact e-mail Address: DOAC study 1 6 0 Study Reference Number: EUPAS Yes Are you the (Primary) Lead Investigator of the above study? 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. No (7) Yes () 2.1 Employment Employment in a pharmaceutical company during past 3 years of study application? Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company. No (7) Yes (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. No (Yes (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

2.4 Consultancy

No Ø 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

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

centre, and you as individual are the beneficiary.

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 ②

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

SECTION 3: ANY OTHER INTERESTS

No (7) Yes (

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

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

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the EU PAS Register.

FULL NAME:	Cécile Droz-Perroteau	Date:	03/11/2016
SIGNATURE:			



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First Name:	Helga
Last Name:	Gardarsdottir
Organisation / Research Centre :	Universiteit Utrecht, Utrecht, The Netherlands (UU)
Country:	The Netherlands
Contact e-mail Address:	h.gardarsdottir@uu.nl
	"Characterising the risk of major bleeding in patients with Non-Valvular 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) Lea	ad Investigator of the above study? No No Yes
Are you an investigator/re	esearcher 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 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. No (7) Yes (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. No (7) Yes (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. No (7) Yes () 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. No (7) Yes () 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. No (Yes (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. Please specify the pharmaceutical company: Comments Name of Pharmaceutical Company The Pharmacoepidemiological Research on Outcomes of For the IMI-EU-PROTECT project EFPIA company Therapeutics by a European ConsorTium (PROTECT)project support was received. was supported by the Innovative Medicine Initiative Joint Undertaking (www.imi.europa.eu) under Grant Agreement no 115004, resources of which are composed of financial contribution from the European Union's Seventh Framework

SECTION 3: ANY OTHER INTERESTS

No 🕢 Yes 🔘

Programme (FP7/2007-2013) and EFPIA companies'

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in kind contribution.

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:

Helga Gardarsdottir

Date:

04/11/2016

SIGNATURE:





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Christiane First Name: Last Name: Gasse Organisation / Research Aarhsu University, National Centre for register-based Research Centre: Denmark Country: Contact e-mail Address: cg@econ.au.dk "Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU" Study Reference Number: EUPAS 1 6 0 Are you the (Primary) Lead Investigator of the above study? Yes Are you an investigator/researcher contributing to the above study X

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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

pharmaceutical company.

No (7) Yes (

Patent for a medicinal product?

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

SECTION 3: ANY OTHER INTERESTS

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FULL NAME:	Christiane Gasse	Date:	02/11/2016
SIGNATURE:	01000	00)
	Jane	190	



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SECTION 1: PERSONAL DETAILS

First Name:	Rolf
Last Name:	Groenwold
Organisation / Research Centre :	UMC Utrecht
Country:	The Netherlands
Contact e-mail Address:	r.h.h.groenwold@umcutrecht.nl
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number: E	EUPAS 1 6 0 1 4
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/res	earcher contributing to the above study No 🗔 Yes 🗸

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✓ Yes

✓ 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.

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✓ Yes

✓

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

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No ✓ Yes ✓ **SECTION 3: ANY OTHER INTERESTS**

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√	I confirm the	e information	declared on	this form	is accurat	e to the	best of	my kno	wledge and	I consent	to my
inforn	nation being	stored electr	onically and	published	on the <u>El</u>	PAS Re	<u>egister</u> .				

FULL NAME:	Rolf Groenwold	Date:	02/11/2016
SIGNATURE:	DD	7	
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SECTION 1: PERSONAL DETAILS

First Name:	Rianne
Last Name:	van den Ham
Organisation / Research Centre :	Utrecht Institute for Pharmaceutical Sciences
Country:	The Netherlands
Contact e-mail Address:	
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number: E	EUPAS 1 6 0 1 4
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/rese	earcher contributing to the above study No 🗍 Yes 🔽

Page 1 of 3 Version-number 1.4

In this section you must declare any interests in the pharmac past 3 years. If you have interests to declare please tick 'Yes be answered.			
2.1 Employment	No 🕑	Yes 🔘)
Employment in a pharmaceutical company during Pharmaceutical company includes supply or service companies and maintenance of a medicinal product. Employment relates pharmaceutical company.	es which co	ntribute	to research, development, production
2.2 Financial Interest	No 🕑	Yes 🔾)
Financial interests in the capital of a pharmaceutic Financial interests relate to current holding of shares of a pharmaceutic managed investment funds/pensions schemes that are not expensions.	armaceutica	al compa	
2.3 Patent	No 🕑	Yes 🔘)
Patent for a medicinal product? Relates to a patent for a medicinal product currently owned becentre, and you as individual are the beneficiary.	oy either yo	ou as ind	lividual or your organisation/ research
2.4 Consultancy	No 🕑	Yes 🔘	
Consultancy for a pharmaceutical company during Consultancy refers to provision of advice or services to a pha including but not limited to reviewing activities, data monitor of contractual arrangements or any form of remuneration suc Note that conference/seminar attendance is not considered a honorarium.	rmaceutica ing, statisti ch as consu	il compa ical anal ilting fee	ny excluding the concerned study and ysis, end point committees, regardless or honoraria.
2.5 Strategic Advisory Role	No 🕑	Yes 🔘)
Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or productor any form of remuneration.	a (scientifi ategy, dire	c) adviso	ory board/steering committee with the development activities of a
2.6 Grant / Funding	No 🕑	Yes 🔘)
Grant/funding from a pharmaceutical company of study contract?	ther than	funds	contemplated in the concerned
Refers to a grant or funding from a pharmaceutical company irrespective of whether you are employed or a volunteer, and			
SECTION 3: ANY OTHER INTERESTS	No 🔾	Yes 🕜)
In this section you should declare any other	interests	s to be	e made known to the public.
Any other relationships/conditions/circumstances that present to members of your family?	it a potentia	al conflic	ct of interest, including matters relating
My husband is currently an employee of Chiesi Pharmaceutic	cals		

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

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I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:	Rianne van den Ham	Date:	04/11/2016
SIGNATURE:			

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rst Name:	CONSUELO
ii st Name.	
ast Name:	HUERTA
Organisation / Research Centre :	SPANISH AGENCY FOR MEDICINES AND MEDICAL DEVICES-AEMPS
Country:	Spain
Contact e-mail Address:	chuerta_fcsai@bifap.aemps.es
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants
	in the EU
Study Reference Number	

SECTION 2: DECLARATION OF INTERESTS RE	LATED TO BUADMACEUTICAL INDUSTRY
In this section you must declare any interests in the pharmac past 3 years. If you have interests to declare please tick 'Yes be answered.	ceutical industry that you currently have or had within the
2.1 Employment	No Ø Yes
Employment in a pharmaceutical company during Pharmaceutical company includes supply or service companie and maintenance of a medicinal product. Employment relates pharmaceutical company.	es which contribute to research, development, production
2.2 Financial Interest	No Ø Yes
Financial interests in the capital of a pharmaceut Financial interests relate to current holding of shares of a pharmaceut managed investment funds/pensions schemes that are not ex-	armaceutical company with the exclusion of independently
2.3 Patent	No 🕢 Yes 🔘
Patent for a medicinal product? Relates to a patent for a medicinal product currently owned be centre, and you as individual are the beneficiary.	by either you as individual or your organisation/ research
2.4 Consultancy	No Ø Yes
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2.5 Strategic Advisory Role	No 🕢 Yes 🔾
Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or productor any form of remuneration.	a (scientific) advisory board/steering committee with the rategy, direction or development activities of a
2.6 Grant / Funding	No Ø Yes
Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company irrespective of whether you are employed or a volunteer, and	which is currently being received by your research group,
SECTION 3: ANY OTHER INTERESTS	No Ø Yes
In this section you should declare any other	interests to be made known to the public.
Any other relationships/conditions/circumstances that present to members of your family?	at a potential conflict of interest, including matters relating
Further to the interests declared above, I do hereby declare of facts that should be made public in relation to the conduct of	
Should there be any change of the above due to the fact that ENCePP Secretariat and complete a new Declaration of Interes	
✓ I confirm the information declared on this form is accur information being stored electronically and published on the	
FULL NAME: CONSUELO HUERTA D	Pate: 02/11/2016

SIGNATURE:
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SECTION 1: PERSONAL DETAILS

First Name .	Trutes
First Name:	Luisa
Last Name:	Ibáñez
Organisation / Research Centre :	Fundació Institut Català de Farmacologia (FICF)
Country:	Spain
Contact e-mail Address:	li@icf.uab.es
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number:	EUPAS 1 6 0 1 4
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes
Are you an investigator/res	searcher contributing to the above study No 🔲 Yes 🗸

and the second s					-		
In this section yo	ou must declare any int	erests in the phar	maceutica	al ind	ustry	that y	MACEUTICAL INDUSTRY ou currently have or had within the ons. All questions in this part must
2.1 Employn	nent		No	0	Yes	0	
Pharmaceutical of	of a medicinal product	y or service comp	anies whi	ch co	ntribu	ute to r	udy application? research, development, production being directly paid to you by a
2.2 Financia	Interest		No	0	Yes	0	
Financial interest		ing of shares of a	pharmace	eutica	al con	npany	with the exclusion of independently pharmaceutical sector.
2.3 Patent			No		Yes	0	
Relates to a pate	nedicinal product? nt for a medicinal products as individual are the be		ed by eith	er yo	u as	individ	ual or your organisation/ research
2.4 Consulta	ncy		No	Ø	Yes	0	
Consultancy refe including but not of contractual are	rs to provision of advice limited to reviewing ac angements or any form	e or services to a tivities, data mon n of remuneration	pharmace itoring, st such as c	utica atisti onsu	l com cal ar Iting	pany e nalysis, fees or	of study application? excluding the concerned study and end point committees, regardless honoraria. d be indicated if subject to fee or
2.5 Strategic	Advisory Role		No	Ø	Yes	0	
study applicat Participation with role of providing pharmaceutical c or any form of re	tion? the right to vote on/in advice/expressing opinion ompany either in terms muneration.	fluence the outpu	t in a (scie strategy,	entific directed st	c) addiction	visory l or deve gy, rega	uring the past 3 years of board/steering committee with the elopment activities of a ardless of contractual arrangements
2.6 Grant / F			No		Yes		
study contract Refers to a grant	t?	maceutical compa	any which	is cu	rrent	ly bein	ntemplated in the concerned greceived by your research group, all gain.
SECTION 3:	ANY OTHER INTE	RESTS	No	Ø	Yes	0	
In this section	on you should dec	clare any other	er inter	ests	to	be m	ade known to the public.
Any other relation to members of you		nstances that pre	sent a pot	tentia	l con	flict of	interest, including matters relating
	erests declared above, be made public in relat				ur th	at I do	not have any further interests or
	any change of the above at and complete a new						terests, I shall promptly notify the es.
	e information declared stored electronically a						nowledge and I consent to my
FULL NAME:	Luisa Ibáñez		Date:	03	/11/2	016	
SIGNATURE:	lus c Is	vez_					



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First Name:	Olaf					
ast Name:	Klungel					
Organisation / Research Centre :	Universiteit Utrecht					
Country:	The Netherlands]	
ontact e-mail Address:	o.h.klungel@uu.nl					
	Characterising the risk of major bleed Fibrillation: non-interventional study in the EU					
Study Reference Number	: EUPAS 1 6 0 1 4					
Are you the (Primary) Lea	ad Investigator of the above study?	No	✓	Yes		
And was an investigator/	esearcher contributing to the above study	/ No		Yes		

Page 1 of 3 Version-number

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Patent for a medicinal product? Relates to a patent for a medicinal product current centre, and you as individual are the beneficiary.	ly owned by eith	ner y	ou as	individual or your organisation/ researc	h
2.4 Consultancy	No	Ø	Yes	0	
Consultancy refers to provision of advice or service including but not limited to reviewing activities, da of contractual arrangements or any form of remun Note that conference/seminar attendance is not cohonorarium. 2.5 Strategic Advisory Role	ta monitoring, si eration such as i insidered a consi	tatist consu ultan	ical ar	nalysis, end point committees, regardle fees or honoraria. I should be indicated if subject to fee or	SS
Strategic Advisory role on activities of a participation? Participation with the right to vote on/influence the role of providing advice/expressing opinions on the pharmaceutical company either in terms of general or any form of remuneration.	output in a (sci	entifi	c) adv	visory board/steering committee with th	
2.6 Grant / Funding	No	0	Yes	Ø	
Grant/funding from a pharmaceutical cor study contract? Refers to a grant or funding from a pharmaceutical irrespective of whether you are employed or a volu Please specify the pharmaceutical company:	company which	is cu	rrenti	y being received by your research group	
Name of Pharmaceutical Company				Comments	
GSK	Clinical Pharma	colo	gy) for	r methodological Health Technology related to specific products.	
SECTION 3: ANY OTHER INTERESTS In this section you should declare any Any other relationships/conditions/circumstances the members of your family?		ests		be made known to the public.	

Page 2 of 3

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.

 \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 <u>EU PAS Register</u>.

FULL NAME:	Olaf Klungel	Date:	07/11/2016
SIGNATURE:	OH2		



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 <u>EU PAS Register</u>.

SECTION 1: PERSONAL DETAILS

First Name:	ELISA
Last Name:	MARTÍN MERINO
Organisation / Research Centre :	Agencia Española de Medicamentos y Productos Sanitarios, Madrid, Spain (AEMPS) / BIFAP
Country:	Spain
Contact e-mail Address:	emartin_fcsai@bifap.aemps.es
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number	: EUPAS 1 6 0 1 4
Are you the (Primary) Lea	ad Investigator of the above study? No ✓ Yes ☐
Are you an investigator/re	esearcher contributing to the above study No Yes 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered. 2.1 Employment No (7) 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 (7) Yes (Financial interests in the capital of a pharmaceutical company? Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector. No (7) Yes (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.

No (7) Yes (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 (Yes (

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

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

2.6 Grant / Funding No (7) Yes ()

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

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

SECTION 3: ANY OTHER INTERESTS No (Yes (

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

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

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the 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:	ELISA MARTÍN MERINO	Date:	02/11/2016
SIGNATURE:	- Author	46	
age 2 of 3	10	9	



Studies Declaration of Interests for ENCePP SEAL

INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. Your declaration will not be accepted if any fields are left empty. You are responsible for the accuracy and completeness of the submitted information.

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PERSONAL DETAILS
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SECTION
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First Name:	Dolores
Last Name:	Montero
Organisation / Research Centre :	Agencia Espanola de Medicamentos y ProductosSanitarios, Madrid, Spain (AEMPS)
Country:	Spain
Contact e-mail Address:	dmontero@aemps.es
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number: EUPAS	:: EUPAS 1 6 0 1 4
Are you the (Primary) Lea	No 🗸 Yes
Are you an investigator/re	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

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

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.

Financial Interest 2.2

0 2

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

Yes 0 9N

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.

Consultancy

Yes 0 9

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

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

0

5

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

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 Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the or any form of remuneration.

2.6 Grant / Funding

Yes ((S) 9

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

Yes 0 No

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

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

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study. Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:

SIGNATURE:

Dolores Montero

Date:

08/11/2016

Page 2 of 3



INTRODUCTION

SECTION 1: PERSONAL DETAILS

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First Name: nicholas Last Name: moore Organisation / Research Bordeaux Pharmacoepi Centre: Country: France Contact e-mail Address: nicholas.moore@u-bordeaux.fr EMA tender: Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU Study Reference Number: EUPAS Are you the (Primary) Lead Investigator of the above study? Yes Are you an investigator/researcher contributing to the above study No Yes

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered. 2.1 Employment No (1) 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 (7) 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 Yes (Patent for a medicinal product? Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary. 2.4 Consultancy No (Yes (Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium. Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid: Period: Current C Past From Month: 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: Current Past From Month: From Year: 2014 Name of Pharmaceutical Company: **IPSEN** Advice on pharmacoepidemiological methods Type of consultancy: Please specify the pharmaceutical company, types of consultancy and dates when fees/honoraria paid:

Page 2 of 4

Period:

From Month:

Type of consultancy:

C Current

Name of Pharmaceutical Company:

Past

servier

To Month:

scientific and surveillance committee for PASS

From Year: 2011

2016

To Year:

Please specify the pharmaceutical compar	ny, types of consultancy and dates when fees/honoraria paid:
Period: Current C	Past
From Month: From Year: 20	To Month: 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 ② Yes 〇
Participation with the right to vote on role of providing advice/expressing or	vities of a pharmaceutical company during the past 3 years of /influence the output in a (scientific) advisory board/steering committee with the pinions on the future strategy, direction or development activities of a ms of general or product-related strategy, regardless of contractual arrangements
2.6 Grant / Funding	No ○ Yes ⊘
Refers to a grant or funding from a ph	narmaceutical company other than funds contemplated in the concerned by the concerned parmaceutical company which is currently being received by your research group, byed or a volunteer, and you receive no personal gain.
Name of Pharmaceutical Comp	any Comments
Helsinn	SALT (EUPAS2181) ended 2014
SANOFI	GROC (EUPAS3105) ended 2012
Bayer	BROTHER (EUPAS14567) Ongoing
Pierre Fabre	EOLE (EUPAS10726) ends 2017
ALLERGAN	Pylera DUS (EUPAS3901 SEAL) ending
NOVARTIS	INHALER (EUPAS10753) ending
Stallergenes	EVORA (EUPAS9358) End 2016
ALLERGAN	SAPHARY (EUPAS3142 SEAL) Ending
Astrazeneca	HORUS (EUPAS5816) ending
BMS	ATTOS (EUPAS11521) ongoing
Lundbeck	USE-PACT (EUPAS11854)
SANOFI	FUJI (EUPAS10391 SEAL)
Boehringer	ENGEL (EUPAS6616)
Astra-Zeneca	SPACE-AA (EUPAS5987)

SECTION 3: ANY OTHER INTERESTS

No ⊘ Yes ○

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

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 <u>EU PAS Register</u>.

FULL NAME:	nicholas moore	Date:	09/11/2016
SIGNATURE:			



INTRODUCTION

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SECTION 1: PERSONAL DETAILS First Name: Marietta Last Name: Rottenkolber Organisation / Research Klinikum der Universitaet Muenchen, Munich, Germany Centre: Country: Germany Contact e-mail Address: marietta.rottenkolber@med.uni-muenche Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU Study Reference Number: EUPAS 1 6 0 1 4 Are you the (Primary) Lead Investigator of the above study? Yes Are you an investigator/researcher contributing to the above study No | Yes

SECTION 2: DECLARATION OF INTERESTS RELAT	TED 1	O PI	HARM	MACEUTICAL INDUSTRY
In this section you must declare any interests in the pharma past 3 years. If you have interests to declare please tick 'Ye be answered.	aceutions' to t	al ind he re	dustry levant	that you currently have or had within the questions. All questions in this part must
2.1 Employment	No	0	Yes	0
Employment in a pharmaceutical company during pas Pharmaceutical company includes supply or service compan and maintenance of a medicinal product. Employment relate pharmaceutical company.	ies wh	ich c	ontrib	ute to research, development, production
2.2 Financial Interest	No	0	Yes	0
Financial interests in the capital of a pharmaceutical of Financial interests relate to current holding of shares of a pharmaged investment funds/pensions schemes that are not of the capital of the pharmaceutical of the	harma	ceutic	al cor	mpany with the exclusion of independently on the pharmaceutical sector.
2.3 Patent	No	0	Yes	0
Patent for a medicinal product? Relates to a patent for a medicinal product currently owned centre, and you as individual are the beneficiary.	by eit	her y	ou as	individual or your organisation/ research
2.4 Consultancy	No	0	Yes	0
Consultancy for a pharmaceutical company during the Consultancy refers to provision of advice or services to a phincluding but not limited to reviewing activities, data monito contractual arrangements or any form of remuneration such Note that conference/seminar attendance is not considered honorarium.	oring,	eutic statis nsult	al con tical a ing fe	npany excluding the concerned study and nalysis, end point committees, regardless of es or honoraria.
2.5 Strategic Advisory Role	No	0	Yes	0
Strategic Advisory role on activities of a pharmaceutic application? Participation with the right to vote on/influence the output is role of providing advice/expressing opinions on the future st pharmaceutical company either in terms of general or produced or any form of remuneration.	n a (se trateg	cientii	ic) ac	lvisory board/steering committee with the or development activities of a
2.6 Grant / Funding	No	0	Yes	0
Grant/funding from a pharmaceutical company other contract? Refers to a grant or funding from a pharmaceutical company				

SECTION 3: ANY OTHER INTERESTS

No O Yes O

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

irrespective of whether you are employed or a volunteer, and you receive no personal gain.

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

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

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I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME: Rollenholber Marieta

1.4

Date: 4.11.2016

SIGNATURE:



INTRODUCTION

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Mònica First Name: Sabaté Last Name: Fundació Institut català de Farmacologia (FICF), Barcelona, Organisation / Research Centre: Spain Spain Country: Contact e-mail Address: msg@icf.uab.cat Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU. Study Reference Number: EUPAS Are you the (Primary) Lead Investigator of the above study? Are you an investigator/researcher contributing to the above study 1 No Yes

	DECLARATION OF INTE								
	you must declare any interests in you have interests to declare pl								
2.1 Employ	ment		No	②	Yes	0			
Pharmaceutical	in a pharmaceutical comp company includes supply or ser te of a medicinal product. Emplo company.	vice comp	panies wh	ich co	ntrib	ute to res	search, dev	elopment, p	
2.2 Financia	al Interest		No	Ø	Yes	0			
Financial interes	erests in the capital of a p sts relate to current holding of s ment funds/pensions schemes t	nares of a	pharmad	eutica	al cor	npany wi			pendently
2.3 Patent			No	0	Yes	0			
Relates to a pat	medicinal product? ent for a medicinal product curn as individual are the beneficiary		ed by eith	ner yo	u as	individua	l or your o	rganisation/	research
2.4 Consulta	ancy		No	0	Yes	0			
Consultancy reference including but no of contractual are	for a pharmaceutical comp ers to provision of advice or servent t limited to reviewing activities, rrangements or any form of reme rence/seminar attendance is not	rices to a data mor uneration	pharmace nitoring, s n such as	eutica tatisti consu	l com cal a lting	npany exe nalysis, e fees or h	cluding the end point co onoraria.	concerned s ommittees, r	tudy and egardless
2.5 Strategi	c Advisory Role		No	Ø	Yes	0			
study applica Participation wit role of providing	h the right to vote on/influence advice/expressing opinions on company either in terms of gene	the outpu	it in a (sc e strategy	ientifi , dire	c) ad	visory bo	ard/steerir	ng committee ivities of a	e with the
2.6 Grant /	Funding		No	Ø	Yes	0			
study contract Refers to a gran	g from a pharmaceutical oct? t or funding from a pharmaceution or a very sound	cal comp	any which	is cu	rrent	ly being	received by		
SECTION 3:	ANY OTHER INTERESTS		No	Ø	Yes	0			
In this secti	on you should declare a	ny oth	er inte	rests	s to	be ma	de know	n to the	public.
Any other relation to members of y	onships/conditions/circumstance our family?	s that pre	esent a po	tentia	al con	iflict of in	terest, incl	uding matte	rs relating
	terests declared above, I do her be made public in relation to the				ur th	at I do n	ot have an	y further inte	erests or
	any change of the above due to riat and complete a new Declara							II promptly r	notify the
	he information declared on this g stored electronically and publi						wledge and	d I consent t	o my
FULL NAME:	Mònica Sabaté		Date:	03	/11/2	016			

SIGNATURE:

Page 2 of 3

Version-number 1.



INTRODUCTION

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First Name:	Sven		
Last Name:	Schmiedl		
Organisation / Research Centre :	- Department of Clinical Pharmacology, School of Medicine, Faculty of Health, Witten/Herdecke University, Witten, Germany - Philipp Klee-Institute for Clinical Pharmacology, HELIOS Clinic Wuppertal, Wuppertal, Germany		
Country:	Germany		
Contact e-mail Address:	sven.schmiedl@helios-kliniken.de		
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU		
Study Reference Number: EUPAS 1 6 0 1 4			
Are you the (Primary) Lead Investigator of the above study? No Yes			
Are you an investigator/researcher contributing to the above study No \square Yes \checkmark			

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
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 ② Yes ○
Financial interests in the capital of a pharmaceutical company? Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.
2.3 Patent No ⊘ Yes ○
Patent for a medicinal product?
Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.
2.4 Consultancy No 🕢 Yes 🔘
Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.
2.5 Strategic Advisory Role No 🕢 Yes 🔘
Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangement or any form of remuneration.
2.6 Grant / Funding No 🕢 Yes 🔾
Grant/funding from a pharmaceutical company other than funds contemplated in the concerned
study contract? Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.
SECTION 3: ANY OTHER INTERESTS No Ves O
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.
$\boxed{\prime}$ I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u> .
FULL NAME: Sven Schmiedl Date: 04/11/2016 SIGNATURE: Company Old

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INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. Your declaration will not be accepted if any fields are left empty. You are responsible for the accuracy and completeness of the submitted information.

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SECTION 1: PERSO	NAL DETAILS
First Name:	Patrick
Last Name:	Souverein
Organisation / Research Centre :	Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University
Country:	The Netherlands
Contact e-mail Address:	P.C.Souverein@uu.nl
	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) Lea	ad Investigator of the above study? No 🗹 Yes 🗌
Are you an investigator/re	esearcher contributing to the above study No Yes

SECTION 2: DEGLARATION OF INTERESTS	the best being the property of the party of	AND REAL PROPERTY AND ADDRESS OF THE PARTY AND		
In this section you must declare any interests in the pha past 3 years. If you have interests to declare please tick be answered.	rmaceutical ind 'Yes' to the rele	ustry that you currently evant questions. All que	have or had within the stions in this part must	
2.1 Employment	No 🕑	Yes 🔘		
Employment in a pharmaceutical company du Pharmaceutical company includes supply or service compand maintenance of a medicinal product. Employment repharmaceutical company.	panies which co	ntribute to research, de	velopment, production	
2.2 Financial Interest	No 🕢	Yes 🔘		
Financial interests in the capital of a pharmac Financial interests relate to current holding of shares of a managed investment funds/pensions schemes that are n	pharmaceutica	al company with the exc	lusion of independently tical sector.	
2.3 Patent	No 🕝	Yes 🔘		
Patent for a medicinal product? Relates to a patent for a medicinal product currently own centre, and you as individual are the beneficiary.	ned by either yo	ou as individual or your (organisation/ research	
2.4 Consultancy	No 🕑	Yes 🔘		
Consultancy for a pharmaceutical company du Consultancy refers to provision of advice or services to a including but not limited to reviewing activities, data more of contractual arrangements or any form of remuneration Note that conference/seminar attendance is not consider honorarium.	pharmaceutica nitoring, statisti n such as consu	I company excluding the cal analysis, end point of liting fees or honoraria.	e concerned study and committees, regardless	
2.5 Strategic Advisory Role	No ②	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 O		
Grant/funding from a pharmaceutical companistudy contract? Refers to a grant or funding from a pharmaceutical compirrespective of whether you are employed or a volunteer,	any which is cu	rrently being received b		
SECTION 3: ANY OTHER INTERESTS	No 🕑	Yes 🔘		
In this section you should declare any oth	er interests	to be made know	vn to the public.	
Any other relationships/conditions/circumstances that proto members of your family?	esent a potentia	al conflict of interest, inc	cluding matters relating	
Further to the interests declared above, I do hereby declared that should be made public in relation to the conduction t	are on my hono ct of the study.	our that I do not have ar	ny further interests or	
Should there be any change of the above due to the fact ENCePP Secretariat and complete a new Declaration of Ir	that I acquire a nterests detailin	additional interests, I sho g the changes.	all promptly notify the	
I confirm the information declared on this form is a information being stored electronically and published on			nd I consent to my	
FULL NAME: Patrick Souverein	Date: 02	2/11/2016		

SIGNATURE:



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 <u>EU PAS Register</u>.

First Name:	Henriette
Last Name:	Thisted Horsdal
Organisation / Research Centre :	National Centre for Register-based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University, Aarhus, Denmark
Country:	Denmark
Contact e-mail Address:	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 1 6 0 1 4
Are you the (Primary) Lea	ad Investigator of the above study? No 🗸 Yes
Are you an investigator/re	esearcher contributing to the above study No 🗌 Yes 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRYIn 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 Ves O

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 Ves

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 Ves O

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

Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria.

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

2.5 Strategic Advisory Role No 🕢 Yes 🔾

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

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

2.6 Grant / Funding No V 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

Yes

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

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

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the <u>EU PAS Register</u>.

FULL NAME:	Henriette Thisted Horsdal	Date:	04/11/2016
SIGNATURE:	Henriette Thisted.	Honde	ul



INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. Your declaration will not be accepted if any fields are left empty. You are responsible for the accuracy and completeness of the submitted information.

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First Name:	Xavier
Last Name:	Vidal
Organisation / Research Centre :	Fundació Institut Català de Farmacologia (FICF), Barcelona, Spain
Country:	Spain
Contact e-mail Address:	xvg@icf.uab.cat
	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) Lea	ad Investigator of the above study? No 📝 Yes 🗌
Are you an investigator/r	esearcher contributing to the above study No Yes

SECTION 2: DECLARATION OF INTERESTS	ELATED TO PHAR	MACEUTICAL INDUSTRY
In this section you must declare any interests in the pharm past 3 years. If you have interests to declare please tick 'n be answered.		
2.1 Employment	No ⊘ Yes ○	
Employment in a pharmaceutical company duri Pharmaceutical company includes supply or service compa and maintenance of a medicinal product. Employment rela pharmaceutical company.	ies which contribute to	research, development, production
2.2 Financial Interest	No ⊘ Yes ○	
Financial interests in the capital of a pharmace Financial interests relate to current holding of shares of a managed investment funds/pensions schemes that are not	harmaceutical company	
2.3 Patent	No 🕢 Yes 🔾	
Patent for a medicinal product? Relates to a patent for a medicinal product currently owne centre, and you as individual are the beneficiary.	by either you as individ	ual or your organisation/ research
2.4 Consultancy	No ⊘ Yes ○	
Consultancy for a pharmaceutical company dur Consultancy refers to provision of advice or services to a p including but not limited to reviewing activities, data moni of contractual arrangements or any form of remuneration Note that conference/seminar attendance is not considered honorarium.	narmaceutical company or oring, statistical analysis uch as consulting fees o	excluding the concerned study and , end point committees, regardless r honoraria.
2.5 Strategic Advisory Role	No Ø Yes	
Strategic Advisory role on activities of a pharm study application? Participation with the right to vote on/influence the output role of providing advice/expressing opinions on the future pharmaceutical company either in terms of general or produced or any form of remuneration.	n a (scientific) advisory trategy, direction or dev	board/steering committee with the relopment activities of a
2.6 Grant / Funding	No ② Yes 〇	
Grant/funding from a pharmaceutical company study contract? Refers to a grant or funding from a pharmaceutical compairrespective of whether you are employed or a volunteer, as	y which is currently beir	g received by your research group,
SECTION 3: ANY OTHER INTERESTS	No Ø Yes O	
In this section you should declare any other	r interests to be m	ade known to the public.
Any other relationships/conditions/circumstances that presto members of your family?	ent a potential conflict of	f interest, including matters relating
Further to the interests declared above, I do hereby declared facts that should be made public in relation to the conduct		o not have any further interests or
Should there be any change of the above due to the fact t ENCePP Secretariat and complete a new Declaration of Int		
✓ I confirm the information declared on this form is accommodation being stored electronically and published on the		knowledge and I consent to my
FULL NAME: Xavier Vidal SIGNATURE:	Date: 03/11/2016	
age 2 of 3		



INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. Your declaration will not be accepted if any fields are left empty. You are responsible for the accuracy and completeness of the submitted information.

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First Name:	Maria Theresa
Last Name:	Wimberley Böttger
Organisation / Research Centre :	National Centre for Register-based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University, Aarhus, Denmark,
Country:	Denmark
Contact e-mail Address:	tw@econ.au.dk
	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number	: EUPAS 1 6 0 1 4
Are you the (Primary) Lea	ad Investigator of the above study? No 🗸 Yes
Are you an investigator/re	esearcher contributing to the above study No 🗌 Yes 📝

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions, All questions in this part must be answered. 2.1 Employment No (7) 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, productic and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

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.

(V) Yes (

No (7) Yes (

No (2) Yes (

No (7) Yes (

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

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 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

2.6 Grant / Funding

No (7) Yes (

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

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

SECTION 3: ANY OTHER INTERESTS

No (7) Yes ()

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

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

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the ENCePP Secretariat and complete a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the EU PAS Register.

FULL NAME:	Maria Theresa Wimberley Böttger

Date:

04/11/2016

SIGNATURE:

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Theresa Wimberley

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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 <u>EU PAS Register</u>.

First Name:	Katrin					
Last Name:	Janhsen					
Organisation / Research Centre :	a) University Witten / Herdecke b) Hochschule für Gesundheit Bochum (Sciences)	(Unive	ersity	of App	blied	
Country:	Germany					
Contact e-mail Address:	katrin.janhsen@hs-gesundheit.de					
	Characterising the risk of major bleedin Fibrillation: non-interventional study of in the EU					
Study Reference Number	: EUPAS 1 6 0 1 4					
Are you the (Primary) Lea	d Investigator of the above study?	No	1	Yes		
Are you an investigator/re	esearcher contributing to the above study	No		Yes	V	

SECTION 2: DECLARATION OF INTERESTS RE	LAT	ED 1	O P	HA	RMACEUTICAL INDUSTRY
In this section you must declare any interests in the pharmac past 3 years. If you have interests to declare please tick 'Yes' be answered.					
2.1 Employment	No	0	Yes	0	
Employment in a pharmaceutical company during Pharmaceutical company includes supply or service companie and maintenance of a medicinal product. Employment relates pharmaceutical company.	s whi	ch co	ntribu	ute t	to research, development, production
2.2 Financial Interest	No	0	Yes	0	
Financial interests in the capital of a pharmaceuti Financial interests relate to current holding of shares of a pharmaceuti managed investment funds/pensions schemes that are not ex	rmac	eutic	al cor	npar	ny with the exclusion of independently the pharmaceutical sector.
2.3 Patent	No	0	Yes	0	
Patent for a medicinal product? Relates to a patent for a medicinal product currently owned b centre, and you as individual are the beneficiary.	y eitl	ner yo	ou as	indi	vidual or your organisation/ research
2.4 Consultancy	No	0	Yes	0	
Consultancy for a pharmaceutical company during Consultancy refers to provision of advice or services to a pharmaceuting but not limited to reviewing activities, data monitori of contractual arrangements or any form of remuneration such Note that conference/seminar attendance is not considered a honorarium.	maceng, s h as	eutica tatist consu	I com ical a Ilting	npan naly fees	y excluding the concerned study and sis, end point committees, regardless or honoraria.
2.5 Strategic Advisory Role	No	\bigcirc	Yes	0	
Strategic Advisory role on activities of a pharmace study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future strapharmaceutical company either in terms of general or productor any form of remuneration.	a (sc	ientif	ic) ad	viso or c	ry board/steering committee with the development activities of a
2.6 Grant / Funding	No	0	Yes	0	
Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company					
irrespective of whether you are employed or a volunteer, and	you	recei	ve no	per	sonal gain.
SECTION 3: ANY OTHER INTERESTS	No	Ø	Yes	0	
In this section you should declare any other i	nte	rest	s to	be	made known to the public.
Any other relationships/conditions/circumstances that present to members of your family?	t a po	otenti	al cor	nflict	of interest, including matters relating
Further to the interests declared above, I do hereby declare of facts that should be made public in relation to the conduct of				at I	do not have any further interests or
Should there be any change of the above due to the fact that ENCePP Secretariat and complete a new Declaration of Intere					
$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $					y knowledge and I consent to my
FULL NAME: Katon Janksen D.	ate:	22.	11.	16	2

ege 2 of 3 Version-number 1

SIGNATURE:



INTRODUCTION

SECTION 1: PERSONAL DETAILS

Are you an investigator/researcher contributing to the above study

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 <u>EU PAS Register</u>.

Elena First Name: Last Name: Ballarín Organisation / Research Fundació Institut Català de Farmacologia(FICF), Hospital Universitari Vall d'Hebron. Centre: Country: Spain 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 1 6 0 1 4 Are you the (Primary) Lead Investigator of the above study? No

No

1

SECTION 2: DECLARATION OF INTERESTS RE	LATE	n T	O P	HARMACEUTICA	INDUSTRY
In this section you must declare any interests in the pharmac past 3 years. If you have interests to declare please tick 'Yes be answered.	ceutica	l ind	ustry	that you currently have	e or had within the
2.1 Employment	No	Ø	Yes	0	
Employment in a pharmaceutical company during Pharmaceutical company includes supply or service companie and maintenance of a medicinal product. Employment relates pharmaceutical company.	es whic	h co	ntrib	ute to research, develo	pment, production
2.2 Financial Interest	No	0	Yes	0	
Financial interests in the capital of a pharmaceutic Financial interests relate to current holding of shares of a pharmaceutic investment funds/pensions schemes that are not expensions.	armace	eutica	al cor	npany with the exclusi	
2.3 Patent	No	0	Yes	0	
Patent for a medicinal product? Relates to a patent for a medicinal product currently owned becentre, and you as individual are the beneficiary.	oy eithe	er yo	u as	individual or your orga	nisation/ research
2.4 Consultancy	No	0	Yes	0	
Consultancy for a pharmaceutical company during Consultancy refers to provision of advice or services to a pha including but not limited to reviewing activities, data monitor of contractual arrangements or any form of remuneration suc Note that conference/seminar attendance is not considered a honorarium.	rmaceuring, sta ch as co	utica atisti onsu	l com cal a lting	pany excluding the conalysis, end point com- fees or honoraria.	ncerned study and mittees, regardless
nonorariam.					
2.5 Strategic Advisory Role	No	Ø	Yes	0	
	a (scie	al co	ompa c) ad	any during the pas visory board/steering of or development activit	committee with the cies of a
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or produc	a (scie	entifi dired	omp c) ad ction crateg	any during the passivisory board/steering of or development activity, regardless of control	committee with the cies of a
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or produc or any form of remuneration.	a (scie rategy, ct-relate No ther to	entification direction of the control of the contro	c) ad ction crates Yes fun	visory board/steering of or development activiting, regardless of control ds contemplated in the pass of the pass	committee with the cies of a actual arrangements on the concerned
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or produc or any form of remuneration. 2.6 Grant / Funding Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company	a (scie rategy, ct-relate No ther to	entification direction of the control of the contro	yes fun	visory board/steering of or development activiting, regardless of control ds contemplated in the pass of control dy being received by your personal gain.	committee with the cies of a actual arrangements on the concerned
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or produc or any form of remuneration. 2.6 Grant / Funding Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company irrespective of whether you are employed or a volunteer, and	a (scierategy, ct-related No at ther to the dyou re	entifii directed st	c) addition trates Yes fun rrent e no	visory board/steering of or development activiting, regardless of control ds contemplated in the personal gain.	committee with the cies of a actual arrangements on the concerned our research group,
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or produc or any form of remuneration. 2.6 Grant / Funding Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company irrespective of whether you are employed or a volunteer, and SECTION 3: ANY OTHER INTERESTS	a (scie rategy, ct-relate No ther to which d you re	al coentification of the coentification of t	yes fun Yes yes fun Yes to no	visory board/steering of or development activiting, regardless of control ds contemplated in the personal gain. be made known	committee with the dies of a actual arrangements on the concerned our research group,
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or productor any form of remuneration. 2.6 Grant / Funding Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company irrespective of whether you are employed or a volunteer, and SECTION 3: ANY OTHER INTERESTS In this section you should declare any other in Any other relationships/conditions/circumstances that present	a (scierategy, ct-relate No ther to No interest a potential potent	al coentification directly dir	Yes fun Yes to	any during the passivisory board/steering of development activiting, regardless of control development activiting, regardless of control development activiting, regardless of control development activiting activities act	committee with the dies of a actual arrangements on the concerned our research group, to the public.
2.5 Strategic Advisory Role Strategic Advisory role on activities of a pharmac study application? Participation with the right to vote on/influence the output in role of providing advice/expressing opinions on the future str pharmaceutical company either in terms of general or productor any form of remuneration. 2.6 Grant / Funding Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company irrespective of whether you are employed or a volunteer, and SECTION 3: ANY OTHER INTERESTS In this section you should declare any other in the section will be a section of the section of t	No sther to hon my lite a pot the stu	al coentification of the coentification of t	Yes fun Yes to Yes to	any during the passivisory board/steering of development activiting, regardless of contract of the contemplated in the contemp	committee with the ties of a actual arrangements in the concerned our research group, ito the public. In gratters relating arriver interests or

Date:

03/02/2017

Page 2 of 3

Elena Ballarín

FULL NAME:



INTRODUCTION	
the provisions of the ENG	your personal details and your declaration of interests to be made public in line with CePP Code of Conduct. All parts must be duly completed. Your declaration will not are left empty. You are responsible for the accuracy and completeness of the
The form is designed to lin parallel, a copy of the	be filled in electronically and to be transmitted to the ENCePP Secretariat by email; form should be uploaded to the <u>EU PAS Register</u> .
SECTION 1: PERSON	NAL DETAILS
First Name:	Régis
Last Name:	Lassalle
Organisation / Research Centre :	Plateform Bordeaux PharmacoEpi (BPE) - INSERM CIC1401
Country:	France
Contact e-mail Address:	regis.lassalle@u-bordeaux.fr
	"Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
Study Reference Number	: EUPAS 1 6 0 1 4
Are you the (Primary) Lea	nd Investigator of the above study? No 📝 Yes 🗌
Are you an investigator/re	esearcher 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 y be answered.	ou have interests to declare please tick '	Yes' to the	releva	ant questic	ons. All questions in this part must
2.1 Employn	nent	No (Ø Y	'es 🔘	
Pharmaceutical of	n a pharmaceutical company dur company includes supply or service compa e of a medicinal product. Employment rela company.	anies which	h cont	ribute to re	esearch, development, production
2.2 Financia	Interest	No (⊘ Y	'es 🔘	
Financial interest	rests in the capital of a pharmace is relate to current holding of shares of a ment funds/pensions schemes that are no	pharmacei	utical	company v	
2.3 Patent		No (Ø Y	′es 🔘	
Relates to a pate	nedicinal product? Int for a medicinal product currently owned as individual are the beneficiary.	ed by eithe	er you	as individu	ual or your organisation/ research
2.4 Consulta	ncy	No (Ø Y	′es 🔘	
Consultancy refe including but not of contractual are	or a pharmaceutical company during to provision of advice or services to a limited to reviewing activities, data mon rangements or any form of remuneration ence/seminar attendance is not considered.	pharmaceu itoring, sta such as co	itical c itistica insulti	company e al analysis, ing fees or	xcluding the concerned study and end point committees, regardless honoraria.
2.5 Strategic	Advisory Role	No (′es 🔘	
study applicate Participation with role of providing	n the right to vote on/influence the outpu advice/expressing opinions on the future company either in terms of general or pro	t in a (scie strategy,	ntific) directi	advisory t	poard/steering committee with the elopment activities of a
2.6 Grant / I	Funding	No (√ Y	′es 🔾	
study contract Refers to a grant		y other tl	han f	unds cor	ntemplated in the concerned
irrespective of w	or funding from a pharmaceutical compa hether you are employed or a volunteer,	any which i and you re	is curr eceive	ently being no person	g received by your research group, al gain.
	or funding from a pharmaceutical compa hether you are employed or a volunteer, ANY OTHER INTERESTS	and you re	eceive	rently being no person	g received by your research group, al gain.
SECTION 3:	hether you are employed or a volunteer,	and you re	eceive Ø Y	no person	al gain.
SECTION 3:	hether you are employed or a volunteer, ANY OTHER INTERESTS on you should declare any other nships/conditions/circumstances that pre	and you re No (er intere	eceive Ø Y ests	no person es to be ma	al gain. ade known to the public.
SECTION 3: In this section Any other relation to members of your Further to the interpretation	hether you are employed or a volunteer, ANY OTHER INTERESTS on you should declare any other nships/conditions/circumstances that pre	nd you re No (er interessent a potente on my h	eceive Y ests ential	no person 'es to be macconflict of	al gain. ade known to the public. interest, including matters relating
SECTION 3: In this section Any other relation to members of your further to the interest that should should there be	hether you are employed or a volunteer, ANY OTHER INTERESTS on you should declare any other nships/conditions/circumstances that pre- our family? terests declared above, I do hereby declare	No (er interests on my had of the stu	eceive Yests ential honou udy.	r that I do	al gain. ade known to the public. interest, including matters relating not have any further interests or terests, I shall promptly notify the
SECTION 3: In this section Any other relation to members of your further to the interest of the section of the	ANY OTHER INTERESTS on you should declare any other nships/conditions/circumstances that pre- our family? terests declared above, I do hereby declar be made public in relation to the conduct any change of the above due to the fact	No (er interests a potential of the stute that I acquire terests detections of the stute terest detections of the	eceive Yests ential honou udy. lire ad tailing	r that I do ditional int the chang	ade known to the public. interest, including matters relating not have any further interests or terests, I shall promptly notify the es.

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INTRODUCTION

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The form is designed to be filled in electronically and to be transmitted to the ENCePP Secretariat by email; in parallel, a copy of the form should be uploaded to the <u>EU PAS Register</u>.

SECTION 1: PERSONAL DETAILS

First Name:	Luz M			
Last Name:	León-Muñoz			
Organisation / Research Centre :	División de Farmacoepidemiología y Farmacovigilancia Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) Spanish Agency for Medicines and Medical Devices (AEMPS)			
Country:	Spain			
Contact e-mail Address:	lmleon@aemps.es			
Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagula in the EU				
Study Reference Number: EUPAS 1 6 0 1 4				
Are you the (Primary) Lead	Investigator of the above study? No ✓ Yes			
Are you an investigator/researcher contributing to the above study No Yes				

Page 1 of 3 Version-number 1.5

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 (7) 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 Yes (Financial interests in the capital of a pharmaceutical company? Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector. 2.3 Patent No 🕢 Yes () Patent for a medicinal product? Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary. Yes () 2.4 Consultancy No 🕢 Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium. 2.5 Strategic Advisory Role Yes (Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration. 2.6 Grant / Funding No (7) Yes (Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract? Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain. **SECTION 3: ANY OTHER INTERESTS** No 🕢 Yes (In this section you should declare any other interests to be made known to the public. Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family? Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study. Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly notify the 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:** Luz M León-Muñoz Date: 19/01/2017

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INTRODUCTION

SECTION 1: PERSONAL DETAILS

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 <u>EU PAS Register</u>.

First Name: Marie Louise Last Name: De Bruin Organisation / Research University of Copenhagen Centre: Country: Denmark Contact e-mail Address: marieke.debruin@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 1 6 0 1 4 Are you the (Primary) Lead Investigator of the above study? Yes Are you an investigator/researcher contributing to the above study 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	2.1	Emp	loym	ent
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Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

2.2 Financial Interest

No 🕢 Yes 🔿

Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

2.3 Patent

No 🕢 Yes 🔾

Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

2.4 Consultancy

No (Yes (

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

Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.

2.5 Strategic Advisory Role

No

✓ Yes

✓

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

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

2.6 Grant / Funding

No () Yes ()

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

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments
Novo Nordisk	PhD/post-doc grant to Copenhagen Centre for Regulatory Science
Ferring Pharmaceuticals	PhD/post-doc grant to Copenhagen Centre for Regulatory Science
LEO Pharma	PhD/post-doc grant to Copenhagen Centre for Regulatory Science
Lundbeck	PhD/post-doc grant to Copenhagen Centre for Regulatory Science

SECTION 3: ANY OTHER INTERESTS

No ○ Yes ②

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

to members of		ices that present a potential conflict of interest, including matters relating
see annex		
facts that should Should there be ENCePP Secreta	d be made public in relation to any change of the above due riat and complete a new Decla	to the fact that I acquire additional interests, I shall promptly notify the tration of Interests detailing the changes.
information beir	g stored electronically and pul	is form is accurate to the best of my knowledge and I consent to my blished on the <u>EU PAS Register</u> .
FULL NAME:	Marie Louise De Bruin	Date: 11/01/2018 Submit Form by Email

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 company-specific 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.

11-1-5018



INTRODUCTION

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First Name:	Morten			
Last Name:	Andersen			
Organisation / Research Centre :	University of Copenhagen Department of Drug Design and Pharmacology ENCePP centre: Pharmacoepidemiology Research Collaboration			
Country:	Denmark			
Contact e-mail Address:	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 Anticoagulan in the EU				
Study Reference Number: EUPAS 1 6 0 1 4				
Are you the (Primary) Lead I	Investigator of the above study? No 🗸 Yes			
Are you an investigator/rese	archer contributing to the above study No 🗌 Yes 🗸			

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 (7) 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 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 (7) 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 Yes () Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration. 2.6 Grant / Funding No () Yes () Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract? Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain. Please specify the pharmaceutical company: Name of Pharmaceutical Company Comments Novo Nordisk Foundation Grant to the University of Copenhagen supporting Professorship in Pharmacovigilance Janssen Grant to Karolinska Institutet supporting methodological pharmacoepidemiological project

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

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRYIn this section you must declare any interests in the pharmaceutical industry that you currently have or had within the

ige 2 of 3

SECTION 3: ANY OTHER INTERESTS

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 <u>EU PAS Register</u>.

FULL NAME:

Morten Andersen

Date:

24/01/2018

] flekyller

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Declaration of Interests

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. You are responsible for the accuracy and completeness of the submitted information.

The form is designed to be filled in electronically; a copy of the form should be uploaded to the $\underline{\text{EU PAS}}$ $\underline{\text{Register}}$.

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

First Name:	Mia
Last Name:	Aakjær
Organisation / Research Centre :	Pharmacovigilance Research Group Department of Drug Design and Pharmacology University of Copenhagen
Country:	Denmark
Contact e-mail Address:	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 1 6 0 1 4
Are you the (Primary) Lead	Investigator of the above study? No \checkmark Yes
Are you an investigator/res	earcher contributing to the above study No Yes 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered. 2.1 Employment No () Yes () Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production

and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.
Please specify the pharmaceutical company and dates when employed:
Period: Current Past
From Month: 10 From Year: 2014 To Month: 05 To Year: 2016
Name of Pharmaceutical Company: H. Lundbeck A/S (part time student assistant)
2.2 Financial Interest No 🕢 Yes 🔾
Financial interests in the capital of a pharmaceutical company? Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.
2.3 Patent No V 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	\bigcirc	Yes (C
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Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria.

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

2.5 Strategic Advisory Role	No 🕢	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.

2.6 Grant / Funding	No 🔘 Yes 🕢
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Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company	Comments		
Novo Nordisk Foundation	Grant to the University of Copenhagen supporting the Pharmacovigilance Research Group		

SECTION 3: ANY OTHER INTERESTS

Mia Aakjær

FULL NAME:

No (7) Yes ()

In this section you should declare any other interests of commercial, financial, institutional or personal nature to be made known to the public.*

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family? (*see definition in Annex 1 of ENCePP Code of Conduct)

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly complete and upload a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the EU PAS Register. 29/05/2018

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Date:



INTRODUCTION

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First Name:	Roman
Last Name:	Gerlach
Organisation / Research Centre :	National Association of Statutory Health Insurance Physicians of Bavaria, Munich, Germany
Country:	Germany
Contact e-mail Address:	roman.gerlach@kvb.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) Lea	d Investigator of the above study? No 🕝 Yes 🗌
Are you an investigator/re	esearcher contributing to the above study No 🗍 Yes 🔽

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

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be answered.	·				
2.1 Employme	ent	No	Θ	Yes	0
Pharmaceutical cor	a pharmaceutical company during mpany includes supply or service companies of a medicinal product. Employment relates mpany.	s whi	ch cor	ntribu	ute to research, development, production
2.2 Financial 1	Interest	No	\odot	Yes	0
Financial interests	ests in the capital of a pharmaceution relate to current holding of shares of a phatent funds/pensions schemes that are not ex	rmac	eutica	ıl con	npany with the exclusion of independently
2.3 Patent		No	\odot	Yes	\circ
Relates to a patent	edicinal product? for a medicinal product currently owned be individual are the beneficiary.	y eith	ier yo	u as	individual or your organisation/ research
2.4 Consultan	су	No	Θ	Yes	\circ
Consultancy refers including but not li of contractual arra	r a pharmaceutical company during to provision of advice or services to a phar mited to reviewing activities, data monitori ngements or any form of remuneration suc ce/seminar attendance is not considered a	mace ng, s h as	eutica tatisti consu	l com cal a lting	npany excluding the concerned study and nalysis, end point committees, regardless fees or honoraria.
2.5 Strategic	Advisory Role	No	\bigcirc	Yes	\circ
study application Participation with the role of providing according as	the right to vote on/influence the output in dvice/expressing opinions on the future stra mpany either in terms of general or produc	a (sc ategy	ientifi , dire	c) ad ction	visory board/steering committee with the or development activities of a
2.6 Grant / Fu	unding	No	Θ	Yes	0
	from a pharmaceutical company ot	her	than	fun	ds contemplated in the concerned
	r or funding from a pharmaceutical company ether you are employed or a volunteer, and				
SECTION 3: A	NY OTHER INTERESTS	No	\bigcirc	Yes	\circ
In this section	n you should declare any other i	nte	rest	s to	be made known to the public.
Any other relations to members of you	ships/conditions/circumstances that presen ur family?	t a po	otentii	al cor	nflict of interest, including matters relating
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 being	information declared on this form is accurate stored electronically and published on the f	ate to	the l	oest (gister	of my knowledge and I consent to my
FULL NAME: F	Roman Gerlach D	ate:	24	1/04/	2017

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