

INTRODUCTION

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

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

SECTION 1: PERSONAL DETAILS

First Name:	Elena
Last Name:	Rivero
Organisation / Research Centre :	RTI Health Solutions
Country:	Spain
Contact e-mail Address:	erivero@rti.org
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	:UPAS
Are you the (Primary) Lead	Investigator of the above study? No No Yes
Are you an investigator/rese	earcher contributing to the above study No 🗸 Yes 🗌

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY	
	pharmaceutical industry that you currently have or had within the tick 'Yes' to the relevant questions. All questions in this part must	
2.1 Employment	No 🕢 Yes 🔾	
	during past 3 years of study application? companies which contribute to research, development, production nt relates to salaries currently being directly paid to you by a	
2.2 Financial Interest	No 🕢 Yes 🔘	
	maceutical company? s of a pharmaceutical company with the exclusion of independently 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 centre, and you as individual are the beneficiary.	owned by either you as individual or your organisation/ research	
2.4 Consultancy	No 🕢 Yes 🔾	
Consultancy refers to provision of advice or services including but not limited to reviewing activities, data of contractual arrangements or any form of remune	y during the past 3 years of study application? It to a pharmaceutical company excluding the concerned study and a monitoring, statistical analysis, end point committees, regardless ration such as consulting fees or honoraria. Sidered a consultancy but should be indicated if subject to fee or	
2.5 Strategic Advisory Role No 🕜 Yes 🔾		
study application? Participation with the right to vote on/influence the role of providing advice/expressing opinions on the	harmaceutical company during the past 3 years of output in a (scientific) advisory board/steering committee with the future strategy, direction or development activities of a or product-related strategy, regardless of contractual arrangements	
2.6 Grant / Funding	No 🔾 Yes 🕢	
study contract?	company which is currently being received by your research group, inteer, and you receive no personal gain.	
Please specify the pharmaceutical company:		
Name of Pharmaceutical Company	Comments	
Many pharmaceutical and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for LEO Pharma, Merck Sharp & Dohme LLC, Acadia Pharmaceuticals Inc., Takeda, Merck Healthcare KGaA, Janssen, Astra Zeneca, Bayer AG, Biohaven Pharmaceuticals Holding Company Limited, H. Lundbeck A/S, Almirall S.A., Pfizer Inc	https://www.encepp.eu/encepp/viewResource.htm? id=48288	

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: Elena Rivero Date: 12/05/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Jérémy
Last Name:	Jové
Organisation / Research Centre :	Bordeaux PharmacoEpi (BPE)
Country:	France
Contact e-mail Address:	jeremy.jove@u-bordeaux.fr
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	SUPAS 1 0 4 0 8
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/rese	parcher contributing to the above study. No D. Ves. 7

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 Ves
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 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 Ves
Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.
2.5 Strategic Advisory Role No Yes
Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.
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Grant/funding from a pharmaceutical company other than funds contemplated in the concerned
study contract? Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.
SECTION 3: ANY OTHER INTERESTS No Yes
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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: Jérémy Jové Date: 13/04/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Mary
Last Name:	Anthony
Organisation / Research Centre :	RTI Health Solutions
Country:	United States of America
Contact e-mail Address:	manthony@rti.org
Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085	
Study Reference Number:	EUPAS
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/res	searcher contributing to the above study No 🗆 Yes 🕡

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY	
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	during past 3 years of study application? companies which contribute to research, development, production nt relates to salaries currently being directly paid to you by a	
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	maceutical company? s of a pharmaceutical company with the exclusion of independently 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 centre, and you as individual are the beneficiary.	owned by either you as individual or your organisation/ research	
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2.5 Strategic Advisory Role No 🕜 Yes 🔾		
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study contract?	company which is currently being received by your research group, inteer, and you receive no personal gain.	
Please specify the pharmaceutical company:		
Name of Pharmaceutical Company	Comments	
Many pharmaceutical and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for LEO Pharma, Merck Sharp & Dohme LLC, Acadia Pharmaceuticals Inc., Takeda, Merck Healthcare KGaA, Janssen, Astra Zeneca, Bayer AG, Biohaven Pharmaceuticals Holding Company Limited, H. Lundbeck A/S, Almirall S.A., Pfizer Inc	https://www.encepp.eu/encepp/viewResource.htm? id=48288	

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No

✓ Yes

✓

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FULL NAME: Mary Anthony Date: 12/05/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Alejandro
Last Name:	Arana
Organisation / Research Centre :	RTI Health Solutions
Country:	United States of America
Contact e-mail Address:	aarana@rti.org
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	SUPAS 1 0 4 0 8
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/rese	earcher contributing to the above study No 🗍 Yes 🗸

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered. 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. 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. Please specify type of shares and financial interest (excluding investment funds) of: Share Value (please select) Type of shares or financial interest ROVI SA More than 10,000 EUR or equivalent 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 🕢 Yes (Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium. 2.5 Strategic Advisory Role Yes (Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration. 2.6 Grant / Funding No () 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	
	https://www.encepp.eu/encepp/viewResource.htm? id=48288	

SECTION 3: ANY OTHER INTERESTS No Ves
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Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?
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\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: Alejandro Arana Date: 12/05/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Meghan
Last Name:	Barczewski
Organisation / Research Centre :	Carelon Research
Country:	United States of America
Contact e-mail Address:	Meghan.Barczewski@carelon.com
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	EUPAS 1 0 4 0 8
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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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 independentl 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 Ves
Consultancy for a pharmaceutical company during the past 3 years of study application? Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria. Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.
2.5 Strategic Advisory Role No Ves
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Grant/funding from a pharmaceutical company other than funds contemplated in the concerned
study contract? Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group irrespective of whether you are employed or a volunteer, and you receive no personal gain.
SECTION 3: ANY OTHER INTERESTS No Yes
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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: Meghan Barczewski Date: 18/04/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Christine
Last Name:	Bui
Organisation / Research Centre :	RTI Health Solutions
Country:	United States of America
Contact e-mail Address:	cbui@rti.org
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number:	EUPAS U
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/res	rearcher contributing to the above study. No \(\sqrt{Ves} \)

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY		
	pharmaceutical industry that you currently have or had within the tick 'Yes' to the relevant questions. All questions in this part must		
2.1 Employment	No 🕢 Yes 🔾		
	during past 3 years of study application? companies which contribute to research, development, production nt relates to salaries currently being directly paid to you by a		
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		
Many pharmaceutical and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for LEO Pharma, Merck Sharp & Dohme LLC, Acadia Pharmaceuticals Inc., Takeda, Merck Healthcare KGaA, Janssen, Astra Zeneca, Bayer AG, Biohaven Pharmaceuticals Holding Company Limited, H. Lundbeck A/S, Almirall S.A., Pfizer Inc	https://www.encepp.eu/encepp/viewResource.htm? id=48288		

SECTION 3: ANY OTHER INTERESTS

No

✓ Yes

✓

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FULL NAME:	Christine Bui	Date:	12/05/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Brian	
Last Name:	Calingaert	
Organisation / Research Centre :	RTI Health Solutions	
Country:	United States of America	
Contact e-mail Address:	bcalingaert@rti.org	
Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085		
Study Reference Number:	EUPAS .	
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 🔽	

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY		
	e pharmaceutical industry that you currently have or had within the tick 'Yes' to the relevant questions. All questions in this part must		
2.1 Employment	No ⊘ Yes ○		
Pharmaceutical company includes supply or service	during past 3 years of study application? companies which contribute to research, development, production ent relates to salaries currently being directly paid to you by a		
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2.6 Grant / Funding	No ○ Yes ②		
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Please specify the pharmaceutical company:			
Name of Pharmaceutical Company	Comments		
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SECTION 3: ANY OTHER INTERESTS

No **⊘** Yes ○

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FULL NAME: Brian Calingaert Date: 12/04/2023

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SECTION 1: PERSONAL DETAILS

First Name:	Brett	
Last Name:	Doherty	
Organisation / Research Centre :	Carelon Research	
Country:	United States of America	
Contact e-mail Address:	brett.doherty@carelon.com	
Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085		
Study Reference Number: EUPAS 1 0 4 0 8		
Are you the (Primary) Lead Investigator of the above study? No 🗌 Yes 🗸		
Are you an investigator/researcher contributing to the above study. No 📝 Yes		

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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 Ves
Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application? Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.
2.6 Grant / Funding No Ves
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: Brett Doherty Date: 17/04/2023

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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 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:	Maria	
Last Name:	Guzman	
Organisation / Research Centre :	Carelon Research	
Country:	United States of America	
Contact e-mail Address:	maria.guzman@carelon.com	
Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085		
Study Reference Number: I	EUPAS 1 0 4 0 8	
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	

SECTION 2: DECLARATION OF INTERESTS R	ELATED TO PHARMACEUTICAL INDUSTRY
	aceutical industry that you currently have or had within the es' to the relevant questions. All questions in this part must
2.1 Employment	No 🕢 Yes 🔾
Employment in a pharmaceutical company durin Pharmaceutical company includes supply or service comparand maintenance of a medicinal product. Employment relat pharmaceutical company.	nies which contribute to research, development, production
2.2 Financial Interest	No 🕢 Yes 🔾
Financial interests in the capital of a pharmaceur Financial interests relate to current holding of shares of a pmanaged investment funds/pensions schemes that are not	harmaceutical 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 centre, and you as individual are the beneficiary.	I by either you as individual 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 phincluding but not limited to reviewing activities, data monitor of contractual arrangements or any form of remuneration so Note that conference/seminar attendance is not considered honorarium.	narmaceutical company excluding the concerned study and oring, statistical analysis, end point committees, regardless such as consulting fees or honoraria.
2.5 Strategic Advisory Role	No 🕢 Yes 🔾
role of providing advice/expressing opinions on the future s	in a (scientific) advisory board/steering committee with the
2.6 Grant / Funding	No O Yes O
study contract?	other than funds contemplated in the concerned by which is currently being received by your research group, and you receive no personal gain.
SECTION 3: ANY OTHER INTERESTS	No Yes
In this section you should declare any other	r interests to be made known to the public.
Any other relationships/conditions/circumstances that preseto members of your family?	ent a potential conflict of 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 of	
Should there be any change of the above due to the fact th ENCePP Secretariat and complete a new Declaration of Inte	
✓ I confirm the information declared on this form is accommodation being stored electronically and published on the	urate to the best of my knowledge and I consent to my e <u>EU PAS Register</u> .
FULL NAME: Maria Guzman	Date: 21/04/2023

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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	Ahanah	
First Name:	Abenah	
Last Name:	Harding	
Organisation / Research Centre :	RTI Health Solutions	
Country:	United States of America	
Contact e-mail Address:	aharding@rti.org	
Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085		
Study Reference Number:	EUPAS	
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌	
Are you an investigator/res	searcher contributing to the above study. No \(\sqrt{Yes} \)	

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY		
	pharmaceutical industry that you currently have or had within the tick 'Yes' to the relevant questions. All questions in this part must		
2.1 Employment	No 🕢 Yes 🔾		
	during past 3 years of study application? companies which contribute to research, development, production nt relates to salaries currently being directly paid to you by a		
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		
Many pharmaceutical and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for LEO Pharma, Merck Sharp & Dohme LLC, Acadia Pharmaceuticals Inc., Takeda, Merck Healthcare KGaA, Janssen, Astra Zeneca, Bayer AG, Biohaven Pharmaceuticals Holding Company Limited, H. Lundbeck A/S, Almirall S.A., Pfizer Inc	https://www.encepp.eu/encepp/viewResource.htm? id=48288		

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: Abenah Harding Date: 12/05/2023

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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Alison	
Last Name:	Kawai	
Organisation / Research Centre :	RTI Health Solutions	
Country:	United States of America	
Contact e-mail Address:	akawai@rti.org	
Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085		
Study Reference Number: E	EUPAS	
Are you the (Primary) Lead	Investigator of the above study? No ✓ Yes □	
Are you an investigator/rese	earcher contributing to the above study No 🗍 Yes 🔽	

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY		
	e pharmaceutical industry that you currently have or had within the tick 'Yes' to the relevant questions. All questions in this part must		
2.1 Employment	No 🕢 Yes 🔾		
	during past 3 years of study application? companies which contribute to research, development, production at relates to salaries currently being directly paid to you by a		
2.2 Financial Interest	No 🕢 Yes 🔾		
	maceutical company? s of a pharmaceutical company with the exclusion of independently 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 O Yes 🕢		
Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract? Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain. Please specify the pharmaceutical company:			
Name of Pharmaceutical Company	Comments		
Many pharmaceutical and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for LEO Pharma, Merck Sharp & Dohme LLC, Acadia Pharmaceuticals Inc., Takeda, Merck Healthcare KGaA, Janssen, Astra Zeneca, Bayer AG, Biohaven Pharmaceuticals Holding Company Limited, H. Lundbeck A/S, Almirall S.A., Pfizer Inc.	https://www.encepp.eu/encepp/viewResource.htm? id=48288		

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: Alison Kawai Date: 12/04/2023

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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Stephan
Last Name:	Lanes
Organisation / Research Centre :	Carelon Research
Country:	United States of America
Contact e-mail Address:	stephan.lanes@carelon.com
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	EUPAS 1 0 4 0 8
Are you the (Primary) Lead Investigator of the above study? No 🗸 Yes	
Are you an investigator/researcher contributing to the above study No ☐ Yes ✓	

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY
In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.
2.1 Employment No V Yes
Employment in a pharmaceutical company during past 3 years of study application? Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.
2.2 Financial Interest No 🔗 Yes 🔾
Financial interests in the capital of a pharmaceutical company? Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.
2.3 Patent No 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 🕢 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 Ves
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 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: Stephan Lanes Date: 12/05/2023

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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Andrea
Last Name:	Margulis
Organisation / Research Centre :	RTI Health Solutions
Country:	Spain
Contact e-mail Address:	amargulis@rti.org
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	SUPAS 1 0 4 8 5
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/rese	earcher contributing to the above study No 🗍 Yes 🗸

SECTION 2: DECLARATION OF INTERE	STS RELATED TO PHARMACEUTICAL INDUSTRY	
	pharmaceutical industry that you currently have or had within the tick 'Yes' to the relevant questions. All questions in this part must	
2.1 Employment	No 🕢 Yes 🔾	
	during past 3 years of study application? companies which contribute to research, development, production nt relates to salaries currently being directly paid to you by a	
2.2 Financial Interest	No 🕢 Yes 🔘	
	maceutical company? s of a pharmaceutical company with the exclusion of independently 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 centre, and you as individual are the beneficiary.	owned by either you as individual or your organisation/ research	
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.		
Please specify the pharmaceutical company:		
Name of Pharmaceutical Company	Comments	
Many pharmaceutical and biotech companies fund studies through contracts with my employer including EU PAS-registered studies for LEO Pharma, Merck Sharp & Dohme LLC, Acadia Pharmaceuticals Inc., Takeda, Merck Healthcare KGaA, Janssen, Astra Zeneca, Bayer AG, Biohaven Pharmaceuticals Holding Company Limited, H. Lundbeck A/S, Almirall S.A., Pfizer Inc	https://www.encepp.eu/encepp/viewResource.htm? id=48288	

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: Andrea Margulis Date: 12/05/2023

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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Jonas
Last Name:	Reinold
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology – BIPS
Country:	Germany
Contact e-mail Address:	reinold@leibniz-bips.de
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	UPAS
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/rese	earcher contributing to the above study No 🗀 Yes 🕡

SECTION 2: DECLARATION OF INTERESTS RE	ELATED TO PHARMACEUTICAL 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 🕢 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 🕢 Yes 🔾
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	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 b centre, and you as individual are the beneficiary.	by either you as individual 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 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.	armaceutical company excluding the concerned study and ring, statistical analysis, end point committees, regardless ch as consulting fees or honoraria.
2.5 Strategic Advisory Role	No 🕢 Yes 🔾
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 (scientific) advisory board/steering committee with the rategy, direction or development activities of a
2.6 Grant / Funding	No O 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 Please specify the pharmaceutical company:	which is currently being received by your research group,

Name of Pharmaceutical Company	Comments	
Sanofi	EMA-requested PASS	
LEO Pharma	EMA-requested PASS	
Sanofi-Genzyme	EMA-requested PASS	
Novartis	EMA-requested PASS	
Eli Lilly	EMA-requested PASS	
Bayer AG	EMA-requested PASS	
Ferring Pharmaceuticals	EMA-requested PASS	
UCB	EMA-requested PASS	
Pharmanovia	EMA-requested PASS	
Bristol-Myers Squibb	EMA-requested PASS	
Abbvie	EMA-requested PASS	

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:	Jonas Reinold	Date:	12/05/2023
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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:	Laure
Last Name:	Carcaillon-Bentata
Organisation / Research Centre :	Bordeaux PharmacoEpi (BPE)
Country:	France
Contact e-mail Address:	laure.carcaillon-bentata@u-bordeaux.fr
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number:	EUPAS 1 0 4 0 8
Are you the (Primary) Lea	d Investigator of the above study? No 📝 Yes 🗌
Are you an investigator/re	searcher contributing to the above study No Yes

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

In this section you must declare any interests in the pharmace past 3 years. If you have interests to declare please tick 'Yes' be answered.				
2.1 Employment	No	\oslash	Yes	\circ
Employment in a pharmaceutical company during Pharmaceutical company includes supply or service companies and maintenance of a medicinal product. Employment relates pharmaceutical company.	s whi	ch co	ntribu	ute to research, development, production
2.2 Financial Interest	No	\odot	Yes	0
Financial interests in the capital of a pharmaceutic Financial interests relate to current holding of shares of a pharmanaged investment funds/pensions schemes that are not ex-	rmac	eutic	al con	npany with the exclusion of independently
2.3 Patent	No	\bigcirc	Yes	\circ
Patent for a medicinal product? Relates to a patent for a medicinal product currently owned by centre, and you as individual are the beneficiary.	eith (ier yd	u as	individual or your organisation/ research
2.4 Consultancy	No	\oslash	Yes	0
Consultancy for a pharmaceutical company during Consultancy refers to provision of advice or services to a phar including but not limited to reviewing activities, data monitoring of contractual arrangements or any form of remuneration such Note that conference/seminar attendance is not considered a chonorarium.	mace ng, si n as e	utica tatisti consu	I com cal ar Iting	pany excluding the concerned study and nalysis, end point committees, regardless fees or honoraria.
2.5 Strategic Advisory Role	No	\oslash	Yes	\circ
Strategic Advisory role on activities of a pharmace study application? Participation with the right to vote on/influence the output in a role of providing advice/expressing opinions on the future strapharmaceutical company either in terms of general or product or any form of remuneration.	ı (sci tegy	entifi , dire	c) adv	visory board/steering committee with the or development activities of a
2.6 Grant / Funding	No	\oslash	Yes	0
Grant/funding from a pharmaceutical company of study contract? Refers to a grant or funding from a pharmaceutical company virrespective of whether you are employed or a volunteer, and	vhich	is cu	ırrent	ly being received by your research group,
SECTION 3: ANY OTHER INTERESTS	No	\odot	Yes	0
In this section you should declare any other in	nter	ests	s to	be made known to the public.
Any other relationships/conditions/circumstances that present to members of your family?	а ро	tentia	al con	flict 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 t			ur th	at I do not have any further interests or
Should there be any change of the above due to the fact that a ENCEPP Secretariat and complete a new Declaration of Interes				
$\boxed{/}$ I confirm the information declared on this form is accurainformation being stored electronically and published on the E				

Page 2 of 3 Version-number 1

Date:

18/04/2023

Laure Carcaillon-Bentata

FULL NAME:



INTRODUCTION

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

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

SECTION 1: PERSONAL DETAILS

First Name:	Régis
Last Name:	Lassalle
Organisation / Research Centre :	Platform Bordeaux PharmacoEpi (BPE)
Country:	France
Contact e-mail Address:	regis.lassalle@u-bordeaux.fr
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number:	EUPAS 1 0 4 0 8
Are you the (Primary) Lead	Investigator of the above study? No 🗸 Yes 🗌
Are you an investigator/res	searcher contributing to the above study No 🗌 Yes 📝

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

be answered.	res to the relevant questions. All questions in this part must
2.1 Employment	No 🕢 Yes 🔾
Employment in a pharmaceutical company duri Pharmaceutical company includes supply or service company and maintenance of a medicinal product. Employment relapharmaceutical company.	anies which contribute to research, development, production
2.2 Financial Interest	No ② Yes 〇
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 no	pharmaceutical 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 owner centre, and you as individual are the beneficiary.	ed by either you as individual or your organisation/ research
2.4 Consultancy	No 🕜 Yes 🔾
including but not limited to reviewing activities, data mon of contractual arrangements or any form of remuneration	pharmaceutical company excluding the concerned study and itoring, statistical analysis, end point committees, regardless
2.5 Strategic Advisory Role	No 🕜 Yes 🔾
role of providing advice/expressing opinions on the future	t in a (scientific) advisory board/steering committee with the
2.6 Grant / Funding	No 🕢 Yes 🔾
study contract?	other than funds contemplated in the concerned any which is currently being received by your research group, and you receive no personal gain.
SECTION 3: ANY OTHER INTERESTS	No 🕢 Yes 🔾
In this section you should declare any other	er interests to be made known to the public.
Any other relationships/conditions/circumstances that pre to members of your family?	sent a potential conflict of interest, including matters relating
Further to the interests declared above, I do hereby declared facts that should be made public in relation to the conduction to the conduction of the conduc	re on my honour that I do not have any further interests or t of the study.
Should there be any change of the above due to the fact to ENCePP Secretariat and complete a new Declaration of In	that I acquire additional interests, I shall promptly notify the terests detailing the changes.
✓ I confirm the information declared on this form is ac information being stored electronically and published on t	ccurate to the best of my knowledge and I consent to my he EU PAS Register.
FULL NAME: Régis Lassalle	Date: 17/04/2023

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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Séverine
Last Name:	Lignot-Maleyran
Organisation / Research Centre :	Bordeaux PharmacoEpi (BPE)
Country:	France
Contact e-mail Address:	severine.lignot@u-bordeaux.fr
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number	: EUPAS 1 0 4 0 8
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 Silves [7]

SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered. 2.1 Employment Employment in a pharmaceutical company during past 3 years of study application? Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a

pharmaceutical company. 2.2 Financial Interest No (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 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. 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 (7) 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 (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 conse	ent to my
information being stored electronically and published on the EU PAS Register.	

	<u></u>		,
FULL NAME:	Séverine Lignot-Maleyran	Date:	18/04/2023

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INTRODUCTION

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SECTION 1: PERSONAL DETAILS

First Name:	Ulrike
Last Name:	Haug
Organisation / Research Centre :	Leibniz Institute for Prevention Research and Epidemiology – BIPS
Country:	Germany
Contact e-mail Address:	haug@leibniz-bips.de
	Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data Study Reference Number: EUPAS104085
Study Reference Number: E	EUPAS
Are you the (Primary) Lead	Investigator of the above study? No 🗌 Yes 🗸
Are you an investigator/rese	earcher contributing to the above study No 🗸 Yes

SECTION 2: DECLARATION OF INTERESTS RE	LATED TO PHARMACEUTICAL 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 🕜 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 🕜 Yes 🔾
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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.	irmaceutical company excluding the concerned study and ring, statistical analysis, end point committees, regardless ch as consulting fees or honoraria.
2.5 Strategic Advisory Role	No 🕢 Yes 🔾
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 (scientific) advisory board/steering committee with the rategy, direction or development activities of a
2.6 Grant / Funding	No O 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 Please specify the pharmaceutical company:	which is currently being received by your research group,

Name of Pharmaceutical Company	Comments	
Sanofi	EMA-requested PASS	
LEO Pharma	EMA-requested PASS	
Sanofi-Genzyme	EMA-requested PASS	
Novartis	EMA-requested PASS	
Eli Lilly	EMA-requested PASS	
Bayer AG	EMA-requested PASS	
Ferring Pharmaceuticals	EMA-requested PASS	
UCB	EMA-requested PASS	
Pharmanovia	EMA-requested PASS	
Bristol-Myers Squibb	EMA-requested PASS	
Abbvie	EMA-requested PASS	

SECTION 3: ANY OTHER INTERESTS

No 🗸	Yes	
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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:	Ulrike Haug	Date:	12/05/2023
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