



## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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### 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: EUPAS

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

No  Yes

Are you an investigator/researcher contributing to the above study

No  Yes

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

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

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No  Yes

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### 2.3 Patent

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FULL NAME:

Elena Rivero

Date:

12/05/2023

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FULL NAME:

Jérémy Jové

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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*

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FULL NAME:

Mary Anthony

Date:

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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

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Please specify type of shares and financial interest (excluding investment funds) of:

Share Value (please select)	Type of shares or financial interest
More than 10,000 EUR or equivalent	ROVI SA

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FULL NAME:

Alejandro Arana

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FULL NAME:

Brian Calingaert

Date:

12/04/2023

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## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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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

## 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.

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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.

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FULL NAME:

Brett Doherty

Date:

17/04/2023

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### SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

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/researcher contributing to the above study No  Yes

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FULL NAME:

Maria Guzman

Date:

21/04/2023

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### SECTION 1: PERSONAL DETAILS

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

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No  Yes

Are you an investigator/researcher contributing to the above study

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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	<a href="https://www.encepp.eu/encepp/viewResource.htm?id=48288">https://www.encepp.eu/encepp/viewResource.htm?id=48288</a>

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FULL NAME:

Abenah Harding

Date:

12/05/2023

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Organisation / Research Centre :

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Contact e-mail Address:

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FULL NAME:

Stephan Lanes

Date:

12/05/2023

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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: EUPAS 

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Are you an investigator/researcher contributing to the above study No  Yes

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FULL NAME:

Andrea Margulis

Date:

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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

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

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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

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First Name:

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Country:

Contact e-mail Address:

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/researcher contributing to the above study No  Yes

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

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

### 2.1 Employment

No  Yes

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

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

### 2.2 Financial Interest

No  Yes

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

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

### 2.3 Patent

No  Yes

#### Patent for a medicinal product?

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

### 2.4 Consultancy

No  Yes

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

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

FULL NAME:

Laure Carcaillon-Bentata

Date:

18/04/2023



## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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### SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data  
Study Reference Number: EUPAS104085

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FULL NAME:

Régis Lassalle

Date:

17/04/2023

Submit Form by Email



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### SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="Séverine"/>
Last Name:	<input type="text" value="Lignot-Maleyran"/>
Organisation / Research Centre :	<input type="text" value="Bordeaux PharmacoEpi (BPE)"/>
Country:	<input type="text" value="France"/>
Contact e-mail Address:	<input type="text" value="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
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Study Reference Number: EUPAS 

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- Are you the (Primary) Lead Investigator of the above study?    No     Yes
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FULL NAME:

Séverine Lignot-Maleyran

Date:

18/04/2023



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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: EUPAS

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

No  Yes

Are you an investigator/researcher contributing to the above study

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Please specify the pharmaceutical company:

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

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