



## Declaration of Interests for ENCePP SEAL Studies

### INTRODUCTION

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

The form is designed to be filled in electronically, printed and signed. A PDF scan of the signed copy should be uploaded to the [ENCePP E-Register of Studies](#).

### SECTION 1: PERSONAL DETAILS

First Name:

Klaas

Last Name:

Heinemann

Organisation / Research Centre :

ZEG - Berlin Center for Epidemiology and Health Research

Country:

Germany

Contact e-mail Address:

k.heinemann@zeg-berlin.de

European Active Surveillance Study of LCS-12 (EURAS-LCS12)

ENCePP Study Reference Number: ENCePP/SDPP/

6 4 7 6

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

No ☐ Yes ☒

Are you an investigator/researcher contributing to the above study

No ☒ Yes ☐

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

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

### 2.1 Employment

No ☒ Yes ☐

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

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

### 2.2 Financial Interest

No ☒ Yes ☐

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

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

### 2.3 Patent

No ☒ Yes ☐

#### Patent for a medicinal product?

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

### 2.4 Consultancy

No ☐ Yes ☒

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

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

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

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

Period: ☒ Current ☐ Past

From Month:  From Year:

Name of Pharmaceutical Company:

Type of consultancy:

A consultancy agreement was necessary for participation at an US expert meeting to present study results of a finalized post-authorization safety study. There was no remuneration for the participation at this meeting, travel costs were paid by ZEG.

### 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  |
|--------------------------------|---|
| Merck Inc                      | ZEG-Berlin is conducting three post-authorization studies that have been requested by FDA and/or EMA and is receiving unconditional grants for these studies from Merck. These studies are supervised by an independent safety monitoring and advisory council. Two of the studies have been awarded with an ENCePP seal. |
| Bayer AG                       | ZEG-Berlin is conducting five post-authorization studies that have been requested by FDA and/or EMA and is receiving unconditional grants for these studies from Bayer. These studies are supervised by an independent safety monitoring and advisory council. Two of the studies have been awarded with an ENCePP seal.  |
| Gedeon Richter                 | ZEG-Berlin is preparing a post-authorization study that has been requested by EMA, and is receiving an unconditional grant for this study from Gedeon Richter. This study will be supervised by an independent safety monitoring and advisory council.  |

### 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 [ENCePP E-Register of Studies](#).

FULL NAME:

Klaas Heinemann

Date:

12/05/2014

SIGNATURE:

