



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 EU PAS Register.

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

SECTION 1: PERSONAL DETAILS

Enter your full name, your organisation/research centre name and the country where your organisation/research centre is registered.

First Name:	<input type="text" value="Klaas"/>
Last Name:	<input type="text" value="Dr Heinemann"/>
Organisation / Research Centre :	<input type="text" value="ZEG – Berlin Center for Epidemiology and Health Research GmbH
Invalidenstraße 115
10115 Berlin, Germany"/>
Country:	<input type="text" value="Germany"/>
Contact e-mail Address:	<input type="text" value="k.heinemann@zeg-berlin.de"/>
Study title in which context interests are declared (further referred to as 'the study'):	<input type="text" value="International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study (INAS-NEES)"/>

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?

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
Gedeon Richter	PASS RIVET CC / RCS
Bayer	PASS EURAS LCS 12
Myovant	REPLACE-CV study
Abbott	PEARLY study
Organon	LIDEAM study

SECTION 3: ANY OTHER INTERESTS

No ☒ 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.

FULL NAME:

Klaas Dr Heinemann

Date:

21/12/2022



Submit Form by Email