



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.

A PDF copy of this form should be uploaded to the HMA-EMA Catalogue.

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: J. Bradley

Last Name: Layton

Organisation / Research Centre: RTI Health Solutions

Country: United States

Contact e-mail Address: jblayton@rti.org

Study title in which context interests are declared (further referred to as 'the study'): VACVAC4EU Postauthorisation Effectiveness Study of BIMERVAX® Vaccine in Europe

Study Reference Number: HMA-EMA Catalogue: 1000000337

Please select one:

I am the (Primary) Lead Investigator of the above study: Yes

I am 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 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.

If the answer to the above is YES:

Please specify the pharmaceutical company and dates when employed:

1.

Period: Current Past

Name of Pharmaceutical Company:

From (month and year):

If you ticked 'Past':

To (month and year):

2.

Period: Current Past

Name of Pharmaceutical Company:

From (month and year):

If you ticked 'Past':

To (month and year):

3.

Period: Current Past

Name of Pharmaceutical Company:

From (month and year):

If you ticked 'Past':

To (month and year):

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.

If the answer to the above is YES:

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

1.

Share Value (please select):

Less than 10,000 EUR or equivalent More than 10,000 EUR or equivalent

Type of shares or financial interest:

2.

Share Value (please select):

Less than 10,000 EUR or equivalent More than 10,000 EUR or equivalent

Type of shares or financial interest:

3.

Share Value (please select):

Less than 10,000 EUR or equivalent More than 10,000 EUR or equivalent

Type of shares or financial interest:

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.

If the answer to the above is YES:

Please specify the pharmaceutical company and the medicinal product:

1.

Name of Pharmaceutical Company:

Name of medicinal product:

2.

Name of Pharmaceutical Company:

Name of medicinal product:

3.

Name of Pharmaceutical Company:

Name of medicinal product:

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.

If the answer to the above is YES:

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

1.

Period: Current Past

From (month and year): November 2017

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company: Multiple pharmaceutical companies fund studies and activities through contracts with my employer. Information available in RTI-HS registration in HMA-EMA Catalogue.

Type of consultancy: Methods, study design, study implementation

2.

Period: Current Past

From (month and year):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of consultancy:

3.

Period: Current Past

From (month and year):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of consultancy:

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.

If the answer to the above is YES:

Please specify the pharmaceutical company, type of strategic advisory role and dates:

1.

Period: Current Past

From (month and year):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of strategic advisory role:

2.

Period: Current Past

From (month and year):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of strategic advisory role:

3.

Period: Current Past

From (month and year):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of strategic advisory role:

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.

1.

If the answer to the above is **YES**:

Please specify the pharmaceutical company:

Name of Pharmaceutical Company: Multiple pharmaceutical companies fund studies and activities through contracts with my employer.

Comments: Information available in RTI-HS registration in HMA-EMA Catalogue.

2.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company:

Comments:

3.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company:

Comments:

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 HMA-EMA Catalogue

FULL NAME: J. Bradley Layton

Date: 07 October 2024



Electronically signed by: Bradley Layton
Reason: I am an authorized signatory and I approve this document.
Date: Oct 7, 2024 10:04 EDT

Note:

In case you need to declare more items than three in any of the sections, please submit the remaining ones in a separate form.

01_DeclarationofInterests-Annex5

Final Audit Report

2024-10-07

| | |
|-----------------|--|
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