



## 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 [EU PAS Register](#).

### 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: Britta

Last Name: Haenisch

Organisation / Research Centre: Federal Institute for Drugs and Medical Devices

Country: Germany

Contact e-mail Address: [britta.haenisch@bfarm.de](mailto:britta.haenisch@bfarm.de)

Study title in which context interests are declared (further referred to as 'the study'): Use cases for development, optimisation and implementation of artificial intelligence methods for real world data analyses in regulatory decision-making and health technology assessment along the product lifecycle (Real4Reg)

Study Reference Number: EUPAS

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):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of consultancy:

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:

Comments:

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.

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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: *Britta Haenisch*

Date: 22 June 2023

*Britta Haenisch*

Note:

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### 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: Jesper

Last Name: Kjær

Organisation / Research Centre: Danish Medicines Agency (DKMA)

Country: Denmark

Contact e-mail Address: jkjr@dkma.dk

Study title in which context interests are declared (further referred to as 'the study'): Use cases for development, optimisation and implementation of artificial intelligence methods for real world data analyses in regulatory decision-making and health technology assessment along the product lifecycle (Real4Reg)

Study Reference Number: EUPAS

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To (month and year):

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To (month and year):

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

Type of shares or financial interest:

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Share Value (please select):

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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.

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Name of medicinal product:

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Name of medicinal product:

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Name of Pharmaceutical Company:

Name of medicinal product:

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If you ticked 'Past':

To (month and year):

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Type of consultancy:

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?

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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

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1.

If the answer to the above is YES:

Please specify the pharmaceutical company:

Name of Pharmaceutical Company:

Comments:

2.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company:

Comments:

3.

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Name of Pharmaceutical Company:

Comments:

**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 [EU PAS Register](#)

FULL NAME: Jesper Kjær

Date: 2023-JUN-21

Note:

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### 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: Anna-Maija

Last Name: Tolppanen

Organisation / Research Centre: University of Eastern Finland, School of Pharmacy

Country: Finland

Contact e-mail Address: anna-maija.tolppanen@uef.fi

Study title in which context interests are declared (further referred to as 'the study'): Use cases for development, optimisation and implementation of artificial intelligence methods for real world data analyses in regulatory decision-making and health technology assessment along the product lifecycle (Real4Reg)

Study Reference Number: EUPAS

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

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If you ticked 'Past':

To (month and year):

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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?

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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?

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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):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of consultancy:

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: Amgen  
  
Comments: Research grant paid through the institution of employment (2021-2023)

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)

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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: Anna-Maija Tolppanen  
Date: 14.6.2023

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.



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### 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: Holger

Last Name: Fröhlich

Organisation / Research Centre:  
Fraunhofer Society / Fraunhofer Institute for Algorithms and Scientific Computing

Country: Germany

Contact e-mail Address: holger.froehlich@scai.fraunhofer.de

Study title in which context interests are declared (further referred to as 'the study'): Real4Reg

Study Reference Number: EUPAS

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

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

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Please specify the pharmaceutical company and dates when employed:

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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':

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## 2.2 Financial Interest No Yes

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

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Type of shares or financial interest:

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Type of shares or financial interest:

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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.

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1.

Name of Pharmaceutical Company:

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Type of consultancy:

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Period: Current  Past

From (month and year):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of consultancy:

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From (month and year):



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Type of consultancy:

## 2.5 Strategic Advisory Role No Yes

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1.  
If the answer to the above is YES:  
Please specify the pharmaceutical company:

Name of Pharmaceutical Company: Abbvie

Comments: The research project together with Abbvie has no relation to Real4Reg.

2.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company: UCB

Comments: The research project together with UCB has no relation to Real4Reg.

3.

Please specify the pharmaceutical company:

Name of Pharmaceutical Company:

Comments:

**SECTION 3: ANY OTHER INTERESTS** No  Yes

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FULL NAME: Holger Fröhlich

Date: 14 June 2023



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### 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: Cláudia

Last Name: Furtado

Organisation / Research Centre: INFARMED, I.P.

Country: Portugal

Contact e-mail Address: claudia.furtadonfarmed.pt

Study title in which context interests are declared (further referred to as 'the study'):

Real4Reg

Study Reference Number: EUPAS

Please select one:

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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):

If you ticked 'Past':

To (month and year):

Name of Pharmaceutical Company:

Type of consultancy:

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:

Comments:

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 [EU PAS Register](#)

FULL NAME: Claudia Indira Xavier Furtado

Date: 15/06/2023

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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.