

#### 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 and to be transmitted to the ENCePP Secretariat by email; in parallel, a copy of the form should be uploaded to the <u>EU PAS Register</u>.

#### 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:                         | Jonas  |
|-------------------------------------|--|
| Last Name:                          | Reinold  |
| Organisation / Research<br>Centre : | Leibniz Institute for Prevention Research and Epidemiology -<br>BIPS   |
|                                     |  |
| Country:                            | Germany  |
| Contact e-mail Address:             | reinold@leibniz-bips.de  |
| Study title in which context in     | terests are declared (further referred to as `the study'):   |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of<br>Severe Hypersensitivity Reactions |
| Study Reference Number: E           |  |
| Are you the (Primary) Lead          | Investigator of the above study? No 🖆 Yes 🗌  |
| Are you an investigator/res         | earcher contributing to the above study No 🗌 Yes 🎦   |

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.

No 🔿

No

No 🔿

No 🔿

No 🔿

Yes 🔘

Yes 〇

Yes 🔿

Yes 🔘

Yes 🔘

No 🔘 Yes 🔘

No 🔿 Yes 🔾

#### 2.1 Employment

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

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

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

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#### 2.5 Strategic Advisory Role

Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

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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:

| Comments  | Add   |
|---|---|
| mandatory PASS, requested by regulatory authorities | Х   |
| mandatory PASS, requested by regulatory authorities | Х   |
| mandatory PASS, requested by regulatory authorities | Х   |
|   | mandatory PASS, requested by regulatory authorities |

#### SECTION 3: ANY OTHER INTERESTS

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Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

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 $\square$  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 <u>EU PAS Register</u>.

| FULL NAME: | Jonas Reinold | Date: 22/08/2017     |      |
|------------|---------------|----------------------|------|
|            |               | Submit Form by Email |      |
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Enter your full name, your organisation/research centre name and the country where your organisation/ research centre is registered.

| First Name:                         | Tania   |
|-------------------------------------|---|
| Last Name:                          | Schink  |
| Organisation / Research<br>Centre : | Leibniz Institute for Prevention Research and Epidemiology -<br>BIPS  |
|                                     |   |
| Country:                            | Germany   |
| Contact e-mail Address:             | schink@leibniz-bips.de  |
| Study title in which context int    | erests are declared (further referred to as `the study'):   |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number: E           | UPAS 2 0 7 2 0  |
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No 🔿

No

No 🔿

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No 🔿

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Yes 〇

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Yes 🔘

No 🔘 Yes 🔘

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|---|---|
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| FULL NAME: | Tania Schink | Date: 22/08/2017     |      |
|------------|--------------|----------------------|------|
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| First Name:                         | Eyyub Ebu-Bekir  |   |
|-------------------------------------|--|---|
| Last Name:                          | Öztürk   |   |
| Organisation / Research<br>Centre : | Leibniz Institute for Prevention Researc<br>BIPS                             | h and Epidemiology -                        |
| Country:                            | Germany  |   |
| Contact e-mail Address:             | oeztuerk@leibniz-bips.de   |   |
|                                     | Intravenous Iron Postauthorisation Safe<br>Severe Hypersensitivity Reactions | ety Study (PASS): Evaluation of the Risk of |
| Study Reference Number:             | EUPAS 2 0 7 2 0  |   |
| Are you the (Primary) Lead          | Investigator of the above study?   | No 🖌 Yes 🗌                                  |
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#### **2.1 Employment**

No 🕢 Yes 🔾

Yes 🔘

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No

 $\bigcirc$ 

#### 2.3 Patent

#### 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

| ١o | $\checkmark$ | Yes | $\bigcirc$ |
|----|--------------|-----|------------|
|----|--------------|-----|------------|

Yes 🔘

No 🕢 Yes 🔿

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

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No

 $(\mathbf{\Lambda})$ 

No 🔿 Yes 🕢

No 🕢 Yes 🔿

#### 2.5 Strategic Advisory Role

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Please specify the pharmaceutical company:

| Name of Pharmaceutical Company | Comments  |  |
|--------------------------------|---|--|
| Bayer Pharma AG                | mandatory PASS, requested by regulatory authorities |  |
| Takeda Pharma A/S              | mandatory PASS, requested by regulatory authorities |  |
| H. Lundbeck A/S                | mandatory PASS, requested by regulatory authorities |  |

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| FULL NAME: | Eyyub Ebu-Bekir Öztürk | Date: | 22/08/2017 |
|------------|------------------------|-------|------------|
|            |                        |       |            |

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| First Name:                         | nicholas   |
|-------------------------------------|--|
| Last Name:                          | moore  |
| Organisation / Research<br>Centre : | Bordeaux PharmacoEpi   |
| Country:                            | France   |
| Contact e-mail Address:             | nicholas.moore@u-bordeaux.fr   |
|                                     | IV Iron post-authorisation safety study: evaluation of risk of severe hypersensitivity reactions |
| Study Reference Number: E           | UPAS 2 0 7 2 0   |
| Are you the (Primary) Lead          | Investigator of the above study? No 📝 Yes 🗌  |
| Are you an investigator/rese        | earcher contributing to the above study No $\square$ Yes $\checkmark$                            |

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Please specify the pharmaceutical company:

| Name of Pharmaceutical Company | Comments  |  |
|--------------------------------|---|--|
| Many pharma companies          | PASS and PAES studies (see Encepp register. Financial aspects are managed by the university of Bordeaux and Adera |  |
|                                |   |  |

#### **SECTION 3: ANY OTHER INTERESTS**

No 🕢 Yes 🔿

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|            |                |       |            | ř – |
|------------|----------------|-------|------------|-----|
| FULL NAME: | nicholas moore | Date: | 29/09/2017 |     |

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No 🕢 Yes 🔿

No () Yes ()



ENTRODUCTION 2

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| First Name:                         | Patrick  |
|-------------------------------------|--|
| Last Name:                          | Blin   |
| Organisation / Research<br>Centre : | Bordeaux PharmacoEpi, Bordeaux CIC1401   |
| Country:                            | France   |
| Contact e-mail Address:             | patrick.blin@u-bordeaux.fr   |
|                                     | IV Iron Postauthorisation Safety Study: Evaluation of Risk of Severe<br>Hypersensitivity Reactions |
| Study Reference Number: E           | UPAS 2 0 7 2 0   |
| Are you the (Primary) Lead          | Investigator of the above study? No $\checkmark$ Yes   |
| Are you an investigator/rese        | archer contributing to the above study No $\square$ Yes $\checkmark$                               |

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No 🕢 Yes 🔿

Yes ()

Yes (

No () Yes (?)

No 🕢

#### 2.1 Employment

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

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No 🔗

#### 2.3 Patent

#### Patent for a medicinal product?

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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:                         | C Current 🧭      | Past   |           |    |          |      |
|---------------------------------|------------------|--|-----------|----|----------|------|
| From Month:                     | 06 From Year: 20 | 015  | To Month: | 09 | To Year: | 2015 |
| Name of Pharmaceutical Company: |                  | BMS  |           |    |          |      |
| Type of consultancy:            |                  | Scientific board for pharmacoepidemiologic studies |           |    |          |      |
|                                 |                  |  |           |    |          |      |

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

| From Month: 03 From Year: 2015 To Month: 06 To Year: 2016 |  |
|---|--|
| Name of Pharmaceutical Company: UPSA                      |  |
| Type of consultancy: Consultancy for study methodology    |  |

| Please specify the pharmaceutical company | y, types of consultancy and dates when fees/honoraria paid: |
|---|---|
| Period: $Q^{*}$ Current $\bigcirc$        | Past  |
| From Month: 09 From Year: 20              | )14   |
| Name of Pharmaceutical Company:           | ASPEN   |
| Type of consultancy:                      | Consultancy for study methodology and analysis              |
|   |   |

| Diasce specify the pharmaceutical compa | ny, types of consultancy and dates when fees/honoraria | n nateli |  |
|---|--|----------|--|
| riedae apeeny the pharmaceutical compa  | riy, types of consultancy and dates when rees/honorana | α μαια.  |  |

| Period: Current C               | Past   |
|---------------------------------|--|
| From Month: 09 From Year: 2     | 014  |
| Name of Pharmaceutical Company: | GSK  |
| Type of consultancy:            | Consultancy for study methodology and analysis |
|                                 |  |

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

| Period:       | C Current C         | Past   |
|---------------|---------------------|--|
| From Month:   | 09 From Year: 20    | 014  |
| Name of Pharn | naceutical Company: | Lundbeck                                       |
| Type of consu | ultancy:            | Consultancy for study methodology and analysis |
|               |                     |  |

2.5 Strategic Advisory Role

No 🕢 Yes 🔿

No 🔿 Yes 🕢

# Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

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| Name of Pharmaceutical Company | Comments   |
|--------------------------------|--|
| Aptalis                        | Drug utilisation study, safety and pharmacokinetic study of Pylera $\ensuremath{\mathbb{R}}$ in real-life  |
| Astrazeneca                    | Benefit-risk of antiplatelet agents during secondary prevention of Acute coronary syndrome in France   |
| Astrazeneca                    | Health outcomes, resource use, costs in patients with stable coronary artery disease in France   |
| Bayer                          | Benefit-risk of arterial thrombotic prevention with rivaroxaban for atrial fibrillation in France  |
| Biogen France                  | Effectiveness of Tecfidera® in multiple sclerosis in France  |
| BMS                            | Benefit-risk of antithrombotic treatments after orthopedic surgery in France   |
| Boehringer                     | Benefit-risk of anticoagulants in nonvalvular atrial fibrillation in France  |
| Janssen Cilag                  | Therapeutic strategy in metastatic castration-resistant prostate cancer in France  |
| Janssen France                 | Assessment of the treatment-resistant depression in France   |
| Lundbeck                       | Assessment of Selincro® in real-life   |
| Merck Serono                   | Assessment of targeted therapies in patients with colorectal cancer treated with Erbitux® in first line treatment  |
| Novartis                       | Post inscription studies of ranibizumab for visual impairment due to diabetic macular edema and retinal vein occlusion   |
| Novartis                       | Assessment of the inhalation systems handling in patients with COPD in real-life   |
| Novartis Pharma AG             | A Phase IIIb, multicentre, open-label study of nilotinib in<br>adult patients with newly diagnosed Philadelphia<br>chromosome positive and/or BCR-ABL positive CML in<br>chronic phase |
| Pierre Fabre                   | Observational cohort study of myocardial infarction with long-term follow-up in France   |
| Sanofi-Aventis                 | Assessment of cabazitaxel in real-life   |
| Stallergenes                   | Assessment of Oralair® in real-life  |

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FULL NAME:

Patrick Blin

Date: 03/08/2017

No 🕢 Yes 🔿

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Version-number 1.5



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| First Name:                         | Régis   |                              |
|-------------------------------------|---|------------------------------|
| Last Name:                          | Lassalle  |                              |
| Organisation / Research<br>Centre : | Bordeaux PharmacoEpi platform - CIC E                                 | Bordeaux CIC1401             |
| Country:                            | France  |                              |
| Contact e-mail Address:             | regis.lassalle@u-bordeaux.fr  |                              |
|                                     | IV Iron Postauthorisation Safety Study:<br>Hypersensitivity Reactions | Evaluation of Risk of Severe |
| Study Reference Number:             | EUPAS 2 0 7 2 0   |                              |
| Are you the (Primary) Lea           | d Investigator of the above study?                                    | No 🖌 Yes 🗌                   |
| Are you an investigator/re          | searcher contributing to the above study                              | No 🔲 Yes 🗸                   |

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No () Yes ()

No 🕢 Yes 🔿

No (2) Yes ()

No 🕢 Yes 🔿



No 🕢 Yes 🔿

No 🕢 Yes 🔿

| Name of Pharmaceutical Company | Comments   |  |  |
|--------------------------------|--|--|--|
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| Astrazeneca                    | Benefit-risk of antiplatelet agents during secondary prevention of Acute coronary syndrome in France   |  |  |
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| Boehringer                     | Benefit-risk of anticoagulants in nonvalvular atrial fibrillation in France  |  |  |
| Janssen                        | Therapeutic strategy in metastatic castration-resistant prostate cancer in France  |  |  |
| Janssen                        | Assessment of the treatment-resistant depression in France   |  |  |
| Lundbeck                       | Assessment of Selincro® in real-life   |  |  |
| Merck Serono                   | Assessment of targeted therapies in patients with colorectal cancer treated with Erbitux® in first line treatment  |  |  |
| Novartis                       | Post inscription studies of ranibizumab for visual impairment due to diabetic macular edema and retinal vein occlusion   |  |  |
| Novartis                       | Assessment of the inhalation systems handling in patients with COPD in real-life   |  |  |
| Novartis                       | A Phase IIIb, multicentre, open-label study of nilotinib in<br>adult patients with newly diagnosed Philadelphia<br>chromosome positive and/or BCR-ABL positive CML in<br>chronic phase |  |  |
| Pierre Fabre                   | Observational cohort study of myocardial infarction with<br>long-term follow-up in France  |  |  |
| Sanofi-Aventis                 | Assessment of cabazitaxel in real-life   |  |  |
| Stallergenes                   | Assessment of Oralair® in real-life  |  |  |

#### 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?

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 $\checkmark$  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 <u>EU PAS Register</u>.

| FULL NAME: | Régis Lassalle |       | ] Date:      | 03/08/2017 |
|------------|----------------|-------|--------------|------------|
|            |                |       |              |            |
|            |                | Submi | it Form by E | Email      |

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| First Name:                         | Helle   |
|-------------------------------------|---|
| Last Name:                          | Kieler  |
| Organisation / Research<br>Centre : | Karolinska Institutet/Centre for Pharmacoepidemiology   |
| Country:                            | Sweden  |
| Contact e-mail Address:             | helle.kieler@ki.se  |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number:             | EUPAS 2 0 7 2 0   |
| Are you the (Primary) Lead          | Investigator of the above study? No 🖌 Yes   |
| Are you an investigator/res         | earcher contributing to the above study No 🗌 Yes 🖌  |

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No

#### 2.3 Patent

#### 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

| ١o | $\checkmark$ | Yes | $\bigcirc$ |
|----|--------------|-----|------------|
|----|--------------|-----|------------|

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

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#### 2.5 Strategic Advisory Role

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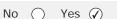
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|--------------------------------|---------------------------------|--|
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| Janssen                        | Post-Authorization Safety Study |  |
| Bayer                          | Drug Utilization Study          |  |
| MSD                            | Post-Authorization Safety Study |  |
| Novartis                       | Post-Authorization Safety Study |  |
| Astellas                       | Post-Authorization Safety Study |  |



Yes ()

No 🕢 Yes 🔿

Yes ()

No 🕢 Yes 🔿

 $\mathbf{\Gamma}$ 

#### **SECTION 3: ANY OTHER INTERESTS**

No 🕢 Yes 🔿

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| FULL NAME: | Helle Kieler | Date: | 15/08/2017 |
|------------|--------------|-------|------------|
|------------|--------------|-------|------------|

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| First Name:                         | Ingvild   |
|-------------------------------------|---|
| Last Name:                          | Odsbu   |
| Organisation / Research<br>Centre : | Karolinska Institutet/Centre for Pharmacoepidemiology   |
| Country:                            | Sweden  |
| Contact e-mail Address:             | ingvild.odsbu@ki.se   |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number:             | EUPAS 2 0 7 2 0   |
| Are you the (Primary) Lead          | Investigator of the above study? No 🖌 Yes   |
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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

| ١o | $\checkmark$ | Yes | $\bigcirc$ |
|----|--------------|-----|------------|
|----|--------------|-----|------------|

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No

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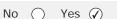
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| AstraZeneca                    | Post-Authorization Safety Study |  |
| Leo                            | Post-Authorization Safety Study |  |
| Janssen                        | Post-Authorization Safety Study |  |
| Bayer                          | Drug Utilization Study          |  |
| MSD                            | Post-Authorization Safety Study |  |
| Novartis                       | Post-Authorization Safety Study |  |
| Astellas                       | Post-Authorization Safety Study |  |



Yes ()

No 🕢 Yes 🔿

Yes ()

No 🕢 Yes 🔿

 $\mathbf{\Gamma}$ 

#### **SECTION 3: ANY OTHER INTERESTS**

No 🕢 Yes 🔿

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| FULL NAME: | Ingvild Odsbu | Date: | 15/08/2017 |
|------------|---------------|-------|------------|
|------------|---------------|-------|------------|

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| First Name:                         | Marie   |
|-------------------------------------|---|
| Last Name:                          | Linder  |
| Organisation / Research<br>Centre : | Karolinska Institutet/Centre for Pharmacoepidemiology   |
| Country:                            | Sweden  |
| Contact e-mail Address:             | marie.linder@ki.se  |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number:             | EUPAS 2 0 7 2 0   |
| Are you the (Primary) Lead          | Investigator of the above study? No 🖌 Yes   |
| Are you an investigator/res         | earcher contributing to the above study No 🗌 Yes 🖌  |

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| ١o | $\checkmark$ | Yes | $\bigcirc$ |
|----|--------------|-----|------------|
|----|--------------|-----|------------|

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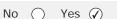
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| MSD                            | Post-Authorization Safety Study |  |
| Novartis                       | Post-Authorization Safety Study |  |
| Astellas                       | Post-Authorization Safety Study |  |



Yes ()

No 🕢 Yes 🔿

Yes ()

No 🕢 Yes 🔿

 $\mathbf{\Gamma}$ 

#### **SECTION 3: ANY OTHER INTERESTS**

No 🕢 Yes 🔿

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| FULL NAME: | Marie Linder | Date: | 15/08/2017 |
|------------|--------------|-------|------------|
|------------|--------------|-------|------------|

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| First Name:                         | Zoltan  |
|-------------------------------------|---|
| Last Name:                          | Thinsz  |
| Organisation / Research<br>Centre : | Karolinska Institutet/Centre for Pharmacoepidemiology   |
| Country:                            | Sweden  |
| Contact e-mail Address:             | zoltan.thinsz@ki.se   |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number: E           | UPAS 2 0 7 2 0  |
| Are you the (Primary) Lead          | Investigator of the above study? No 🖌 Yes   |
| Are you an investigator/rese        | earcher contributing to the above study No $\square$ Yes $\checkmark$   |

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| ١o | $\checkmark$ | Yes | $\bigcirc$ |
|----|--------------|-----|------------|
|----|--------------|-----|------------|

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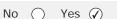
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| MSD                            | Post-Authorization Safety Study |  |
| Novartis                       | Post-Authorization Safety Study |  |
| Astellas                       | Post-Authorization Safety Study |  |



Yes ()

No 🕢 Yes 🔿

Yes ()

No 🕢 Yes 🔿

 $\mathbf{\Gamma}$ 

#### **SECTION 3: ANY OTHER INTERESTS**

No 🕢 Yes 🔿

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| FULL NAME: Zoltar | n Thinsz | Date: | 15/08/2017 |
|-------------------|----------|-------|------------|
|-------------------|----------|-------|------------|

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<u>.</u>....

. .

| First Name:                         | Irene  |         |              |        |              |            |         |    |
|-------------------------------------|--|---------|--------------|--------|--------------|------------|---------|----|
| Last Name:                          | Bezemer  |         |              |        |              |            |         |    |
| Organisation / Research<br>Centre : | PHARMO Institute for Drug Outcomes R   | esearc  | h            |        |              |            |         |    |
| Country:                            | Netherlands  |         |              |        |              | _          |         |    |
| Contact e-mail Address:             | irene.bezemer@pharmo.nl  |         |              |        |              |            |         |    |
|                                     | Intravenous Iron Postauthorisation Safe<br>Severe Hypersensitivity Reactions | ety Sti | ıdy (I       | PASS): | Evalua       | ation of t | he Risk | of |
| Study Reference Number:             | EUPAS 2 0 7 2 0  |         |              |        |              |            |         |    |
| Are you the (Primary) Lead          | Investigator of the above study?   | No      | $\checkmark$ | Yes    |              |            |         |    |
| Are you an investigator/res         | earcher contributing to the above study                                      | No      |              | Yes    | $\checkmark$ |            |         |    |

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Please specify the pharmaceutical company and dates when employed:

| Period:       | 🖓 Current 🛛 🤇       | Past  |
|---------------|---------------------|---|
| From Month:   | 01 From Year: 2     | 010   |
| Name of Pharr | maceutical Company: | PHARMO Institute for Drug Outcomes Research |

### 2.2 Financial Interest

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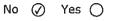
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No 🕢 Yes 🔿

No () Yes ()

No 🕢 Yes 🔿

No 🕢 Yes 🔿

No 🕢 Yes 🔿

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| FULL NAME: | Irene Bezemer | Date: | 08/08/2017 |  |
|------------|---------------|-------|------------|--|
|            | L             | 1     |            |  |

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| First Name:                         | Jetty  |          |        |              |             |        |
|-------------------------------------|--|----------|--------|--------------|-------------|--------|
| Last Name:                          | Overbeek   |          |        |              |             |        |
| Organisation / Research<br>Centre : | PHARMO Institute for Drug Outcomes R   | esearch  |        |              |             |        |
| Country:                            | Netherlands  |          |        |              |             |        |
| Contact e-mail Address:             | jetty.overbeek@pharmo.nl   |          |        |              |             |        |
|                                     | Intravenous Iron Postauthorisation Safe<br>Severe Hypersensitivity Reactions | ty Study | (PASS) | Evaluati     | on of the R | isk of |
| Study Reference Number:             | EUPAS 2 0 7 2 0  |          |        |              |             |        |
| Are you the (Primary) Leac          | Investigator of the above study?   | No 🗸     | Yes    |              |             |        |
| Are you an investigator/res         | earcher contributing to the above study                                      | No 🗌     | Yes    | $\checkmark$ |             |        |

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No 🔿 Yes ⊘

No 🕢 Yes 🔿

No 🕢 Yes 🔿

No (2) Yes ()

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.

Please specify the pharmaceutical company and dates when employed:

| Period:       | 📿 Current        | C Past   |  |
|---------------|------------------|--|--|
| From Month:   | 10 From Yea      | ar: 2008   |  |
| Name of Pharr | naceutical Compa | any: PHARMO Institute for Drug Outcomes Research |  |
|               |                  |  |  |

#### 2.2 Financial Interest

# 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

#### 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

| 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

# 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 🔿

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.

#### SECTION 3: ANY OTHER INTERESTS

#### 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.

 $\checkmark$  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 <u>EU PAS Register</u>.

| FULL NAME: | Jetty Overbeek |       | Date:       | 21/07/2017 |
|------------|----------------|-------|-------------|------------|
|            |                |       |             |            |
|            |                | Submi | t Form by E | mail       |



# INTRODUCTION

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The form is designed to be filled in electronically and to be transmitted to the ENCePP Secretariat by email; in parallel, a copy of the form should be uploaded to the <u>EU PAS Register</u>.

| First Name:                         | Lisa  |
|-------------------------------------|---|
| Last Name:                          | Smits   |
| Organisation / Research<br>Centre : | PHARMO Institute for Drug Outcomes Research   |
| Country:                            | Netherlands   |
| Contact e-mail Address:             | lisa.smits@pharmo.nl  |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number: I           | EUPAS 2 0 7 2 0   |
| Are you the (Primary) Lead          | Investigator of the above study? No 📝 Yes   |
| Are you an investigator/res         | earcher contributing to the above study No 🔲 Yes 🔽  |

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 | 0 | Yes | $\oslash$ |
|----|---|-----|-----------|
|----|---|-----|-----------|

No 🕢 Yes 🔿

No (2) 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. Please specify the pharmaceutical company and dates when employed: Period: Past $\sim$

| From Month:   | 05      | From Year:   | 2014                                       |
|---------------|---------|--------------|--|
| Name of Pharm | naceuti | cal Company: | PHARMO Intitute for Drug Outcomes Research |

# 2.2 Financial Interest

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No () Yes ()

No 🕢 Yes 🔿

No () Yes ()

| ۱e | past | З | year |
|----|------|---|------|

No (2) Yes ()

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 $\checkmark$  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 <u>EU PAS Register</u>.

| FULL NAME: | Lisa Smits |       | Date:       | 25/07/2017 |
|------------|------------|-------|-------------|------------|
|            |            |       | -           |            |
|            |            | Submi | t Form by E | mail       |



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| First Name:                         | Gero   |  |
|-------------------------------------|--|--|
| Last Name:                          | von Gersdorff  |  |
| Organisation / Research<br>Centre : | University Hospital of Cologne<br>Department of Medicine II - QiN-group<br>Gleueler Strasse 176-178<br>50935 Cologne - Köln<br>Germany |  |
| Country:                            | Germany  |  |
| Contact e-mail Address:             | gero.von-gersdorff@uk-koeln.de   | ]  |
|                                     | Intravenous Iron Postauthorisation Safe<br>Severe Hypersensitivity Reactions   | ty Study (PASS): Evaluation of the Risk of |
| Study Reference Number:             | EUPAS 2 0 7 2 0  |  |
| Are you the (Primary) Leac          | Investigator of the above study?   | No 🖌 Yes 🗌                                 |
| Are you an investigator/res         | earcher contributing to the above study  | 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: | Gero von Gersdorff | Date: | 09/10/2017 |
|------------|--------------------|-------|------------|
|------------|--------------------|-------|------------|



No 🕢 Yes 🔿

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No Yes 🔘  $\bigcirc$ 

No 🕢 Yes 🔿

No 🕢 Yes 🔿



# INTRODUCTION

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| First Name:                         | Katherine  |  |
|-------------------------------------|--|--|
| Last Name:                          | Rascher  |  |
| Organisation / Research<br>Centre : | University Hospital of Cologne<br>Department of Medicine II - QiN-group<br>Gleueler Strasse 176-178<br>50935 Cologne - Köln<br>Germany |  |
| Country:                            | Germany  |  |
| Contact e-mail Address:             | katherine.rascher@uk-koeln.de  | ]  |
|                                     | Intravenous Iron Postauthorisation Safe<br>Severe Hypersensitivity Reactions   | ty Study (PASS): Evaluation of the Risk of |
| Study Reference Number:             | EUPAS 2 0 7 2 0  |  |
| Are you the (Primary) Lead          | Investigator of the above study?   | No 🖌 Yes 🗌                                 |
| Are you an investigator/res         | earcher contributing to the above study  | No 🗌 Yes 🖌                                 |

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Yes 🔘

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No

 $\bigcirc$ 

No 🕢 Yes 🔿

No 🕢 Yes 🔿

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No

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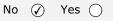
Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family?

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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: Katherine Rascher Date: 0 | 09/10/2017 |
|--------------------------------------|------------|
|--------------------------------------|------------|



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Yes 🔘



No 🕢 Yes 🔿



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| First Name:                         | Mathias  |  |
|-------------------------------------|--|--|
| Last Name:                          | Schaller   |  |
| Organisation / Research<br>Centre : | QiN Programm / Medizinische Klinik II de                                     | er Universität zu Köln                     |
|                                     |  |  |
| Country:                            | Germany  |  |
| Contact e-mail Address:             | mathias.schaller@uk-koeln.de   |  |
|                                     | Intravenous Iron Postauthorisation Safe<br>Severe Hypersensitivity Reactions | ty Study (PASS): Evaluation of the Risk of |
|                                     |  |  |
| Study Reference Number: I           | EUPAS 2 0 7 2 0  |  |
| Are you the (Primary) Lead          | Investigator of the above study?   | No 🖌 Yes 🗌                                 |
| Are you an investigator/res         | earcher contributing to the above study                                      | 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 <u>EU PAS Register</u>.

| FULL NAME: | Mathias | Celea lev | Date: | 24.07.2017 |
|------------|---------|-----------|-------|------------|



No 🕢 Yes 🔿

No () Yes ()

No 🕢 Yes ()

No 🕢 Yes 🔿



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| First Name:                         | VERA  |
|-------------------------------------|---|
| Last Name:                          | EHRENSTEIN  |
| Organisation / Research<br>Centre : | DEPARTMENT OF CLINICAL EPIDEMIOLOGY<br>AARHUS UNIVERSITY HOSPITAL<br>AARHUS   |
| Country:                            | Denmark   |
| Contact e-mail Address:             | ve@clin.au.dk   |
|                                     | Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions |
| Study Reference Number: E           | UPAS 2 0 7 2 0  |
| Are you the (Primary) Lead          | Investigator of the above study? No 🗸 Yes   |
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Please specify the pharmaceutical company:

| Name of Pharmaceutical Company | Comments   |  |
|--------------------------------|--|--|
|                                | Institutional research grants administered by Aarhus<br>University. I am a salaried employee of Aarhus University. |  |

No

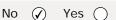
 $(\checkmark)$ 

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Yes 🔘

Yes 🔘

Yes 🕢

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FULL NAME: VERA EHRENSTEIN Date: 30/11/2017