Annex 4 Specific Adverse Drug Reaction Follow-up Forms

Vifor Pharma

FOR GDS 171: PREGNANCY REPORT V01

REPORT ON EXPOSURE TO MEDICINES DURING PREGNANCY Part 1

Name of Vifor Drug (Trade name / IMP): _____

Clinical Trial Protocol Identifier (if applicable): _____

Patients Initials / No: _____ Country: _____ Local Reference No: _____

Details of Mother and Pregnancy

Date / Year of Birth: / / (dd/mmm/yyyy) Age: Occupation:

Previous Pregnancy

Yes ☐ No ☐ Total no. of pregnancies: _____ Normal Deliveries: _____

Abortions (Spontaneous): _____ Abortions (performed): _____

Relevant Medical History:
(including pregnancy risk factors, Pre-eclampsia, eclampsia, smoking, alcohol, environmental & occupational exposures etc.)

Relevant Family History:
(hereditary diseases e.g. hypertension, diabetes)

Current Pregnancy

First day of Last Menstruation: / / (dd/mmm/yyyy) Expected Delivery Date: / / (dd/mmm/yyyy)

Gestational age of foetus (specify at time of exposure / time of reporting) : _____

Ultrasound performed? Yes ☐ No ☐ If yes, findings if any: _____

Any complications, infections or illnesses during pregnancy? Yes ☐ No ☐

If yes, elaborate: _____

Drug Exposure during Pregnancy

Mother /Father Exposure	Suspect Drug/ Concomitant medication	Product Name (Trade / IMP) Batch no.	Total Daily Dose (Units)	Therapy Start date	Therapy Stop date	Indication for use	Route of application (oral, infusion, injection)

_____ _____

Place, Date (dd/mmm/yyyy) **Name/ Signature/Stamp of Reporter**

Vifor Pharma

FOR GDS 171: PREGNANCY REPORT V01

REPORT ON EXPOSURE TO MEDICINES DURING PREGNANCY Part 2

Information on Outcome of Pregnancy

Name of Vifor Drug (Trade name/IMP)**:** _____

Clinical Trial Protocol Identifier (if applicable): _____

Patients Initials / No: _____ Country: _____ Local Reference No: _____

Outcome of Pregnancy

☐ Full Term — Normal delivery or Caesarean: _____

☐ Premature Birth — If premature birth, gestational age: _____ weeks

☐ Spontaneous Miscarriage

☐ Elective termination — Medical Reason? ☐ Yes ☐ No

If yes, specify: _____

Details / Comments (if any): _____

☐ Healthy Baby ☐ Multiple Births

☐ Sick Baby (e.g. Birth trauma, infection etc.) ☐ Congenital anomaly or Birth defect ☐ Still Birth

Date of Birth _____ (dd/mmm/yyyy) Sex ☐ Male ☐ Female

Size: _____ Weight: _____ APGAR scores, if provided (Birth/5/10 mins.) _____

Details / Comments (if any): _____

Please comment on any abnormal condition or occurrence regarding outcome of pregnancy and/or birth/delivery.

Is there a suspicion that adverse outcome of pregnancy is related to exposure to Product?

☐ Yes ☐ No

Please elaborate: _____

_____ _____

Place, Date (dd/mmm/yyyy) **Name/ Signature/Stamp of Reporter**

Please always send both Part I and Part II of the form to safety.VIT@viforpharma.com or fax to: +0041 58851 8659

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Targeted Questionnaire for Evaluating Hepatic Events

Enter the Vifor Coding Number for this Questionnaire:

Please check the following sections to include in the Targeted Questionnaire:

1. **Patient Demography** ☐
2. **Medical History and Risk Factors** ☐
3. **Relevant Drug History** ☐
4. **Information on Suspect Iron Product** ☐
5. **Adverse Event Information** ☐
6. **Lab Test Results** ☐
7. **Reporter Details** *(Required)* ☑

Generate Questionnaire

NOTE: Macros must be enabled in order to create Questionnaires using this template.

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Targeted Questionnaire for Evaluating Hepatic Events

Vifor Coding Number:

1. Patient Demography

Gender: ☐ Male ☐ Female Age: Year of Birth:

Weight: kg Height: cm Body Mass Index:

2. Medical History and Risk Factors

Information on medical history incl. concomitant disorders (diagnoses, family medical history, pregnancies, risk factors):

Please indicate if the following conditions are either part of the patient's medical history or are still active conditions.

Diagnosis/Disease		
Drug allergy	☐ Yes (specify):	☐ No
Previous hepatic drug reactions	☐ Yes (specify):	☐ No
Family history of liver disease	☐ Yes (specify):	☐ No
Viral hepatitis	☐ Yes (specify):	☐ No
Alcoholic liver disease	☐ Yes (specify):	☐ No
Autoimmune hepatitis	☐ Yes (specify):	☐ No
Haemochromatosis	☐ Yes (specify):	☐ No
Nonalcoholic steatosis (NASH)	☐ Yes (specify):	☐ No
Liver cirrhosis	☐ Yes (specify):	☐ No
Liver transplantation	☐ Yes (specify):	☐ No
Other	☐ Yes (specify):	☐ No
Renal disease	☐ Yes (specify):	☐ No
Pancreatic disorder	☐ Yes (specify):	☐ No

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Heart failure	☐ Yes (specify):	☐ No
Diabetes mellitus	☐ Yes (specify):	☐ No
Inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis)	☐ Yes (specify):	☐ No
Cancer	☐ Yes (specify):	☐ No
Autoimmune disease	☐ Yes (specify):	☐ No

Procedures/Treatments		
Surgical procedures	☐ Yes (specify):	☐ No
Other organ transplant	☐ Yes (specify):	☐ No
Dialysis: ☐ Haemodialysis ☐ Peritoneal Dialysis	☐ Yes (tick one and specify):	☐ No

Risk Factors		
Close contact to people infected with hepatitis	☐ Yes (specify):	☐ No
IV drug abuse	☐ Yes (specify):	☐ No
Alcohol abuse	☐ Yes (specify):	☐ No
Recent foreign travel	☐ Yes (specify):	☐ No

Please specify any other relevant medical history or risk factors for hepatic events in this patient:

3. Relevant Drug History

Enter medication other than those taken to treat the AE: (If required please complete a separate page or attach the patient's drug list)

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Name of Product (Trade Name or Active Ingredient)	Dosage Regimen	Duration of Administration (hours:min)	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)	Indication
		:			
		:			
		:			
		:			
		:			

Previous exposure to any iron product (PO; IM; IV)? ☐ YES (please specify below) ☐ NO

Name of Product (Trade Name AND Active Ingredient)	Dosage Regimen	Dilution (if applicable)	Start date (dd/mmm/yyyy)	Stop date (dd/mmm/yyyy)	If an adverse event occurred, please specify

4. Information on Suspect Iron Product

Trade name: Active Ingredient:

Batch Nr.:

Indication (with underlying disease):

Administration: Dosage: mg Iron Frequency of administration:

Start Date: (dd/mmm/yyyy) End Date: (dd/mmm/yyyy)

Start Time: : (hours:min) Stop Time: : (hours:min)

Mode of Application:

☐ IV drip infusion Dilution: ml in ml sterile 0.9% NaCl solution
Duration of administration (hours:min): :

☐ IV bolus injection Duration of administration (hours:min): :

☐ intramuscular Duration of administration (hours:min): :

☐ oral Dosage form:

5. Adverse Event Information

Enter information about adverse event(s) which occurred during/after administration of suspected iron product:

Nr.	**Adverse event (AE)**	**AE occurred during or after administration?**	**AE Start Date/ AE Start Time**	**AE Stop Date/ AE Stop Time**	**Outcome[1]**	**If outcome was considered as 4 or 6, please specify**	**Serious[2]**	**Serious Criteria[3]**	**Causal Relationship[4]**	**Baseline/post-event investigations (if appropriate, please attach investigational results)**
I.										

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Nr.	Adverse event (AE)	AE occurred during or after admini-stration?	AE Start Date/ AE Start Time	AE Stop Date/ AE Stop Time	Outcome(1)	If outcome was considered as 4 or 6, please specify	Serious(2)	Serious Criteria (3)	Causal Relationship(4)	Baseline/post-event investigations (if appropriate, please attach investigational results)
II.										
III.										
IV.										
V.										
VI.										
VII.										
VIII.										
IX.										
X.										

(1) For specifying Outcome, please use the coding system below:
1 = Ongoing 2 = Recovering 3 = Recovered without Sequelae 4 = Recovered with Sequelae 5 = Fatal 6 = Unknown

(2) For specifying Serious Assessment for an adverse event, please use the coding system below:
S = Serious NS = Not serious

(3) For specifying Serious Criteria, please use the coding list (1-6) below. According to ICH-E2A guidelines a serious adverse event is any untoward medical occurrence that at any dose:
1 = Results in death 2 = Life-threatening 3= Requires inpatient hospitalisation or prolongation of existing hospitalisation
4 = Results in persistent or significant disability/incapacity 5 = Congenital anomaly/birth defect
6 = Considered a medical important event (e.g., patient requires intervention to prevent one of the other outcomes listed above)

(4) For specifying Causal Relationship please use the coding system below:
NR = Not related R = Related

If patient died, please enter date: (dd/mmm/yyyy) Was an autopsy performed? ☐ YES ☐ NO

Did patient receive treatment for any of the reported AE(s)? ☐ YES (please enter AE and medication administered for treatment below) ☐ NO

Adverse Event (use corresponding roman numerals from table on page 4)	Name of Product (Trade Name or Active Ingredient)	Dosage Regimen	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)

Did this patient receive any non-drug treatment? ☐ YES (please specify below) ☐ NO

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6. Laboratory Test/Investigation Results

Please provide SI (International Systems of Units) if available. Otherwise, as reported.

☐ Labs Attached (tick box if lab results are attached).

Please indicate if any of the following tests have been performed, and provide the results:

Lab results should be attached whenever possible. If lab results cannot be attached, please **type** (DO NOT handwrite) the results in the space below.

	Baseline Values (Prior to the Event)		Values (After the Event)		Reference Range (if applicable)	Pending?
	Date (dd/mmm/yyyy)	Value (include units)	Date (dd/mmm/yyyy)	Value (include units)		
Bilirubin Direct						☐ Yes
Bilirubin Indirect						☐ Yes
Alanine aminotransferase (ALT)						☐ Yes
Aspartate aminotransferase (AST)						☐ Yes
Alkaline phosphatase (ALP)						☐ Yes
Gamma-glutamyltransferase (Gamma-GT)						☐ Yes
C-Reactive Protein (CRP)						☐ Yes
Lactate dehydrogenase (LDH)						☐ Yes
Albumin						☐ Yes
Full Blood Count (FBC) / Complete Blood Count (CBC)						☐ Yes
Eosinophil count						☐ Yes
Neutrophil count						☐ Yes
Prothrombin Time/INR						☐ Yes
Activated Partial Thromboplastin Time (APTT)						☐ Yes
Amylase						☐ Yes
Clotting factors (please specify) _____						☐ Yes

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	Baseline Values (Prior to the Event)		Values (After the Event)		Reference Range (if applicable)	Pending?
	Date (dd/mmm/yyyy)	Value (include units)	Date (dd/mmm/yyyy)	Value (include units)		
Liver biopsy Please attach biopsy report if available						☐ Yes
CT Scan						☐ Yes
MRI						☐ Yes
Ultrasound						☐ Yes
Other(please specify):						☐ Yes
_____						☐ Yes
_____						☐ Yes
_____						

Serology Results

Please indicate if any of the following tests have been performed, and indicate the result (if available):

Test	Conducted?	Date (dd/mmm/yyyy)	Results
Hepatitis A	☐ Yes ☐ No		
Hepatitis B	☐ Yes ☐ No		
Hepatitis C	☐ Yes ☐ No		
Anti-CMV	☐ Yes ☐ No		
Anti-EBV	☐ Yes ☐ No		
Anti-Nuclear AB	☐ Yes ☐ No		
Anti-mitochondrial AB	☐ Yes ☐ No		
Other: Please specify	☐ Yes ☐ No		

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7. Reporter Details	
Name of Reporter:	**Profession of Reporter:**
Name & Address of the Institution:	**Country:** **Telephone:** **Fax:** **e-mail:**

Handwritten signature of reporting person:

Date: _____ (dd/mmm/yyyy)

Targeted Questionnaire - Hypersensitivity Reaction reports

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1. Patient details:

Initials (First name / family name): ..... Date of Birth: ..... Age: .....

Gender: M ☐ F ☐ Weight (in kg): ..... Height (in cm): .....

Seriousness criteria No ☐ Yes ☐ If yes specify:

☐ Patient died

☐ Involved or prolonged patient hospitalization

☐ Involved persistence of significant disability

☐ Life-threatening

☐ Congenital anomaly

Was the patient treated in the office No ☐ Yes ☐ Unknown ☐

Did the patient go the Emergency room No ☐ Yes ☐ Unknown ☐

Was the subject hospitalized No ☐ Yes ☐ Unknown ☐

Start of the AE (date): ..... Clearing of the AE (date): .....

2. Eliciting medication:

Indication: .....

Iron preparation:

Brand name / generic name	Administered dose	Route of application	Start date	End date	Duration

Pre-medication: no ☐ yes ☐ unknown ☐ If yes, please specify:

Substance	Brand name / generic name	Administered dose (mg)	Route of application	Date	Time
Antihistamines					
Corticosteroids					
Other substance					

Other medication (ACE inhibitors, beta blockers etc.):

Brand name / generic name	Administered dose	Route of application	Start date	End date	Duration

Targeted Questionnaire - Hypersensitivity Reaction reports

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3. Chronology:

3.1 Time to onset (Interval between drug start and first symptoms): ☐ minutes: ..... ☐ hours: ..... ☐ days: .....

3.2 Time to recovery (Duration until symptoms subsided): ☐ minutes: ..... ☐ hours:..... ☐ days: .....

3.3 Previous exposure with same iron medication: no ☐ yes ☐ Unknown ☐ If yes, please specify:

- Date: ..... Adverse reaction: no ☐ yes ☐ Unknown ☐ .....

3.4 Previous exposure with other iron medication: no ☐ yes ☐ Unknown ☐ If yes, please specify:

- Date: ..... Adverse reaction: no ☐ yes ☐ Unknown ☐ .....

3.5 Later exposure with the same iron medication: no ☐ yes ☐ Unknown ☐ If yes, please specify:

- Date: ..... Adverse reaction: no ☐ yes ☐ Unknown ☐ .....

3.6 Later exposure with other iron medication: no ☐ yes ☐ Unknown ☐ If yes, please specify:

- Date: ..... Adverse reaction: no ☐ yes ☐ Unknown ☐ .....

Targeted Questionnaire - Hypersensitivity Reaction reports

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4. Clinical reaction:

4.1 Skin / mucosa:

- Pruritus (itch): no ☐ yes ☐ Unknown ☐ If yes: local ☐ generalized ☐
- Flush face / upper chest: no ☐ yes ☐ Unknown ☐
- Flush generalized: no ☐ yes ☐ Unknown ☐
- Angioedema skin: no ☐ yes ☐ Unknown ☐ Location: .....
- Urticaria: no ☐ yes ☐ Unknown ☐ Location: .....
- Angioedema lips / eyelids: no ☐ yes ☐ Unknown ☐
- Angioedema oral mucosa: no ☐ yes ☐ Unknown ☐
- Angioedema tongue: no ☐ yes ☐ Unknown ☐
- Other skin lesions, e.g. macules, papules, purpuric lesions, vesicles / bullae (blisters), pustules (please specify type, location): .....

4.2 Respiratory symptoms:

- Cough: no ☐ yes ☐ Unknown ☐
- Dyspnea: no ☐ yes ☐ Unknown ☐
- Hyperventilation: no ☐ yes ☐ Unknown ☐
- Wheezing / bronchospasm: no ☐ yes ☐ Unknown ☐ PEFR or FEV1 (if known): ..... l/s
- Respiratory distress: no ☐ yes ☐ Unknown ☐
- Respiratory arrest: no ☐ yes ☐ Unknown ☐
- Rhinitis: no ☐ yes ☐ Unknown ☐
- Conjunctivitis: no ☐ yes ☐ Unknown ☐
- Other (please specify): .....

4.3 Gastrointestinal symptoms:

- Nausea / emesis: no ☐ yes ☐ Unknown ☐
- Abdominal pain / colics: no ☐ yes ☐ Unknown ☐
- Diarrhea: no ☐ yes ☐ Unknown ☐
- Stool incontinence: no ☐ yes ☐ Unknown ☐
- Other (please specify): .....

4.4 Cardiovascular symptoms:

- Tachycardia: no ☐ yes ☐ Unknown ☐ Beats per minute: .....
- Arrhythmia: no ☐ yes ☐ Unknown ☐
- Hypotension: no ☐ yes ☐ Unknown ☐ BP (systolic/diastolic): ..... mmHg
- Collapse: no ☐ yes ☐ Unknown ☐
- Loss of consciousness: no ☐ yes ☐ Unknown ☐
- Cardiovascular arrest: no ☐ yes ☐ Unknown ☐
- Other (please specify): .....

Targeted Questionnaire - Hypersensitivity Reaction reports

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4.5 Other / general symptoms:

- Feeling of impending doom: no ☐ yes ☐ Unknown ☐
- Metallic taste: no ☐ yes ☐ Unknown ☐
- Urine incontinence: no ☐ yes ☐ Unknown ☐
- Lower back pain: no ☐ yes ☐ Unknown ☐
- Headache: no ☐ yes ☐ Unknown ☐
- Fever: no ☐ yes ☐ Unknown ☐ Temperature: ..... °C
- Lymph node swelling: no ☐ yes ☐ Unknown ☐ Localization: .....
- Arthralgia: no ☐ yes ☐ Unknown ☐ Localization: .....
- Arthritis: no ☐ yes ☐ Unknown ☐ Localization: .....
- Myalgia: no ☐ yes ☐ Unknown ☐ Localization: .....

5. Prior history / underlying disorders:

5.1 Co-factors / risk factors:

- Concurrent infection: no ☐ yes ☐ Unknown ☐ If yes, please specify: (e.g. viral, bacterial, other): .....
- Exercises / effort / stress: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Pregnancy: no ☐ yes ☐ Unknown ☐ If yes, week of gestation: .....
- Alcohol: no ☐ yes ☐ Unknown ☐
- Smoking: no ☐ yes ☐ Unknown ☐
- Mastocytosis: no ☐ yes ☐ Unknown Mast cell tryptase level baseline: ..... ng/ml
- Other conditions: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....

5.2 Allergic disorders: Allergen:

- Atopic allergy (hay fever): no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Asthma, allergic: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Food hypersensitivity: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Hymenoptera venom allergy: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Drug hypersensitivity: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Recurrent / chronic urticaria, angioedema: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Recurrent / eczematous exanthemas: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....

5.3 Underlying disorders:

- Cardiovascular disease: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Respiratory disease: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Kidney disease: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Hematological disease: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Malignancy: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Autoimmune disorder: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....
- Psychological condition: no ☐ yes ☐ Unknown ☐ If yes, please specify: .....

Targeted Questionnaire - Hypersensitivity Reaction reports

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6. Diagnosis based on:

- Clinical manifestation / chronology: no ☐ yes ☐
- Photography of skin lesions: no ☐ yes ☐
- Laboratory analysis:
  - Mast cell tryptase: no ☐ yes ☐ Date / time: ..... Level: ..... ng/ml
  - Hematology: no ☐ yes ☐ Date / time: .....
  - Chemistry: no ☐ yes ☐ Date / time: .....
- Skin test
  - Prick test Negative ☐ Positive ☐ Unknown ☐
  - Intradermal test Negative ☐ Positive ☐ Unknown ☐
  - Lymphocyte Transformation Test Negative ☐ Positive ☐ Unknown ☐
- Other (please specify): .....

7. Management of AE:

- Stop of infusion: no ☐ yes ☐ Unknown ☐ After, time: ..... minutes
- Emergency treatment: no ☐ yes ☐ Unknown ☐ If yes, please specify:

Substance	Brand name / generic name	Dose	Route of application	Date	Time
Antihistamines					
Epinephrine/adrenaline					
Corticosteroids					
Bronchodilatator					
Schock treatment (plasma expander, IV fluids)					

- Other emergency treatment (e.g. infusion, oxygen etc.): no ☐ yes ☐ Unknown ☐ If yes, please specify:

  .....

  .....

  .....
- Response to emergency treatment (e.g. infusion, oxygen etc.): no ☐ yes ☐ Unknown ☐

  If no, please specify: .....

  .....

  If yes, please specify (response): .....

  .....

  In: ☐ minutes: ..... ☐ hours: ..... ☐ days: .....

8. Outcome: **Date end** **Time end**

- Complete recovery: no ☐ yes ☐ ....
- Surveillance: no ☐ yes ☐ ....
- Hospitalization: no ☐ yes ☐ ....
- Temporary sequelae: no ☐ yes ☐ ....

Targeted Questionnaire - Hypersensitivity Reaction reports

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- Permanent sequelae: no ☐ yes ☐ ....
- Death: no ☐ yes ☐ ....
- Unknown ☐

9. Reporting Physician:

Name: ..... E-mail: ..... Phone no. .....

Address: ..... Fax no. .....

Date: ..... Signature: .....

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Targeted Questionnaire for Evaluating Infection Related Events

Enter the Vifor Coding Number for this Questionnaire:

Please check the following sections to include in the Targeted Questionnaire:

1. **Patient Demography** ☐
2. **Medical History and Risk Factors** ☐
3. **Relevant Drug History** ☐
4. **Information on Suspect Iron Product** ☐
5. **Adverse Event Information** ☐
6. **Laboratory Text/Investigation Results** ☐
7. **Reporter Details** *(Required)* ☑

Generate Questionnaire

NOTE: Macros must be enabled in order to create Questionnaires using this template.

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Targeted Questionnaire for Evaluating Infection Related Events

Vifor Coding Number:

1. Patient Demography

Gender: ☐ Male ☐ Female Age: Year of Birth:

Weight: kg Height: cm Body Mass Index:

2. Medical History and Risk Factors

Information on medical history incl. concomitant disorders (diagnoses, family medical history, pregnancies, risk factors):

Please indicate if the following conditions are either part of the patient's medical history or are still active conditions.

Diagnosis/Disease		
Diabetes mellitus	☐ Yes (specify):	☐ No
Renal disease	☐ Yes (specify):	☐ No
Hepatitis/liver diseases	☐ Yes (specify):	☐ No
Auto-immune disease	☐ Yes (specify):	☐ No
HIV infection	☐ Yes (specify):	☐ No
Malnutrition	☐ Yes (specify):	☐ No

Procedures/Treatments		
Endoscopic procedures	☐ Yes (specify):	☐ No
Splenectomy	☐ Yes (specify):	☐ No
Organ transplantation	☐ Yes (specify):	☐ No
Haematological stem cell transplantation	☐ Yes (specify):	☐ No
Dialysis: ☐ Haemodialysis ☐ Peritoneal Dialysis	☐ Yes (tick one and specify):	☐ No
Other surgical procedures	☐ Yes (specify):	☐ No
Blood transfusion	☐ Yes (specify):	☐ No

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Steroid treatment	☐ Yes (specify):	☐ No
Anti-TNF antibodies treatment	☐ Yes (specify):	☐ No
Cytotoxic therapy	☐ Yes (specify):	☐ No
Other immunosuppressant drugs	☐ Yes (specify):	☐ No
Catheter/Port Use		
Short-term urinary catheter	☐ Yes (specify):	☐ No
Long-term urinary catheter	☐ Yes (specify):	☐ No
Other catheter/port	☐ Yes (specify):	☐ No
Other		
Recent foreign travel	☐ Yes (specify):	☐ No
Previous infection	☐ Yes (specify):	☐ No
IV drug abuse	☐ Yes (specify):	☐ No

Please specify any other relevant medical history or risk factors for infections in this patient:

3. Relevant Drug History

Enter medication other than those taken to treat the AE: (If required please complete a separate page or attach the patient's drug list)

Name of Product (Trade Name or Active Ingredient)	Dosage Regimen	Duration of Administration (hours:min)	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)	Indication
		:			
		:			
		:			
		:			
		:			

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Previous exposure to any iron product (PO; IM; IV)?	☐ YES (please specify below)	☐ NO

Name of Product (Trade Name AND Active Ingredient)	Dosage Regimen	Dilution (if applicable)	Start date (dd/mmm/yyyy)	Stop date (dd/mmm/yyyy)	If an adverse event occurred, please specify

4. Information on Suspect Iron Product

Trade name: Active Ingredient:

Batch Nr.:

Indication (with underlying disease):

Administration:	Dosage: mg Iron	Frequency of administration:
Start Date:	(dd/mmm/yyyy)	End Date: (dd/mmm/yyyy)
Start Time: :	(hours:min)	Stop Time: : (hours:min)

Mode of Application:

☐ IV drip infusion	Dilution: ml in ml sterile 0.9% NaCl solution
	Duration of administration (hours:min): :
☐ IV bolus injection	Duration of administration (hours:min): :
☐ intramuscular	Duration of administration (hours:min): :
☐ oral	Dosage form:

5. Adverse Event Information

Enter information about adverse event(s) which occurred during/after administration of suspected iron product:

Nr.	Adverse event (AE)	AE occurred during or after administration?	AE Start Date/ AE Start Time	AE Stop Date/ AE Stop Time	Outcome(1)	If outcome was considered as 4 or 6, please specify	Serious(2)	Serious Criteria (3)	Causal Relationship(4)	Baseline/post-event investigations (if appropriate, please attach investigational results)
I.										
II.										
III.										
IV.										
V.										
VI.										
VII.										
VIII.										
IX.										
X.										

(1) For specifying Outcome, please use the coding system below:
1 = Ongoing 2 = Recovering 3 = Recovered without Sequelae 4 = Recovered with Sequelae 5 = Fatal 6 = Unknown

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Nr.	Adverse event (AE)	AE occurred during or after administration?	AE Start Date/ AE Start Time	AE Stop Date/ AE Stop Time	Outcome(1)	If outcome was considered as 4 or 6, please specify	Serious(2)	Serious Criteria (3)	Causal Relationship(4)	Baseline/post-event investigations (if appropriate, please attach investigational results)

(2) For specifying Serious Assessment for an adverse event, please use the coding system below:
S = Serious NS = Not serious

(3) For specifying Serious Criteria, please use the coding list (1-6) below. According to ICH-E2A guidelines a serious adverse event is any untoward medical occurrence that at any dose:
1 = Results in death 2 = Life-threatening 3= Requires inpatient hospitalisation or prolongation of existing hospitalisation
4 = Results in persistent or significant disability/incapacity 5 = Congenital anomaly/birth defect
6 = Considered a medical important event (e.g., patient requires intervention to prevent one of the other outcomes listed above)

(4) For specifying Causal Relationship please use the coding system below:
NR = Not related R = Related

If patient died, please enter date: (dd/mmm/yyyy) Was an autopsy performed? ☐ YES ☐ NO

Did patient receive treatment for any of the reported AE(s)? ☐ YES (please enter AE and medication administered for treatment below) ☐ NO

Adverse Event (use corresponding roman numerals from table on page 4)	Name of Product (Trade Name or Active Ingredient)	Dosage Regimen	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)

Did this patient receive any non-drug treatment? ☐ YES (please specify below) ☐ NO

6. Laboratory Test/Investigation Results

Please provide SI (International Systems of Units) if available. Otherwise, as reported.

☐ Labs Attached (tick box if lab results are attached).

Please indicate if any of the following tests have been performed, and provide the results:
Lab results should be attached whenever possible. If lab results cannot be attached, please **type** (DO NOT handwrite) the results in the space below.

	Baseline Values (Prior to the Event)		Values (After the Event)		Reference Range (if applicable)	Pending?
	Date (dd/mmm/yyyy)	Value (include units)	Date (dd/mmm/yyyy)	Value (include units)		
CRP (C-reactive protein)						☐ Yes
ESR (Erythrocyte sedimentation rate)						☐ Yes
White Blood Cell count						☐ Yes

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	Baseline Values (Prior to the Event)		Values (After the Event)		Reference Range (if applicable)	Pending?
	Date (dd/mmm/yyyy)	Value (include units)	Date (dd/mmm/yyyy)	Value (include units)		
Neutrophil count						☐ Yes
Eosinophil count						☐ Yes
Lymphocyte count						☐ Yes
PCR (specify): _____						☐ Yes
Blood culture						☐ Yes
Histology (specify): _____						☐ Yes
Chest x-ray						☐ Yes
CT scan						☐ Yes
MRI						☐ Yes
Ultrasound						☐ Yes
Other Please specify below all other relevant tests:						
_____						☐ Yes
_____						☐ Yes
_____						☐ Yes

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7. Reporter Details	
Name of Reporter:	**Profession of Reporter:**
Name & Address of the Institution:	**Country:** **Telephone:** **Fax:** **e-mail:**

Handwritten signature of reporting person:

Date: _____ (dd/mmm/yyyy)