

ICH ICSR TRANSMISSION IDENTIFICATION (BATCH WRAPPER)

Type of Messages in Batch: ICHICSR
Batch Number: RECOVERY-SUSAR-022-1

IDENTIFICATION OF THE CASE SAFETY REPORT

Sender's (Case) Safety Report Unique Identifier: GB-VA000001940-RECOVERY-SUSAR-022
Date of Creation: 31/03/2025 13:42:00
Type of Report: Report from studies
Date Report Was First Received from Source: 20/03/2025
Date of Most Recent Information for this Report: 24/03/2025
Are Additional Documents Available? No
Does This Case Fulfil the Local Criteria for an Expedited Report? Yes
Worldwide Unique Case Identification Number: GB-VA000001940-RECOVERY-SUSAR-022
First Sender of this Case: Other
Other Case Identifiers in Previous Transmissions: No
Report Nullification / Amendment:
Reason for Nullification / Amendment:

INFORMATION ON SENDER OF CASE SAFETY REPORT

Sender Type: Pharmaceutical company
Sender's Organisation: VA000001940
Sender's Department:
Sender's Title:
Sender's Given Name:
Sender's Middle Name:
Sender's Family Name:
Sender's Street Address:
Sender's City:
Sender's State or Province:
Sender's Postcode:
Sender's Country Code:
Sender's Telephone:
Sender's Fax:
Sender's Email Address: leon.peto@ndph.ox.ac.uk

PRIMARY SOURCE(S) OF INFORMATION

Reporter (1/1)

Reporter's Title:
Reporter's Given Name:
Reporter's Middle Name:
Reporter's Family Name:
Reporter's Organisation:
Reporter's Department:
Reporter's Street Address:
Reporter's City: Gothenburg
Reporter's State or Province:
Reporter's Postcode:
Reporter's Telephone:
Reporter's Country Code: SE
Qualification: Physician
Primary Source for Regulatory Purposes: Yes

PATIENT CHARACTERISTICS

Patient (name or initials):
Patient Medical Record Number(s) and the Source(s) of the Record Number (GP Medical Record Number):
Patient Medical Record Number(s) and the Source(s) of

the Record Number (Specialist Record Number):

Patient Medical Record Number(s) and the Source(s) of the Record Number (Hospital Record Number):

Patient Medical Record Number(s) and the Source(s) of the Record Number (Investigation Number):

Date of Birth:

Age at Time of Onset of Reaction / Event: 48 years

Gestation Period When Reaction / Event Was Observed in the Foetus:

Patient Age Group (as per reporter):

Body Weight (kg):

Height (cm):

Sex: Female

Last Menstrual Period Date:

RELEVANT MEDICAL HISTORY AND CONCURRENT CONDITIONS (NOT INCLUDING REACTION / EVENT)

Relevant Medical History and Concurrent Conditions (not including reaction / event):

Concomitant Therapies:

Relevant Medical History and Concurrent Conditions (not including reaction / event) (1/1)

MedDRA Version for Medical History: 27.1

Medical History (disease / surgical procedure / etc.) (MedDRA code): Hypothyroidism

Start Date:

Continuing: Yes

End Date:

Comment:

Family History:

REACTION / EVENT

Reaction / Event (1/1)

Reaction / Event as Reported by the Primary Source in Native Language: Bradycardia

Reaction / Event as Reported by the Primary Source Language: eng

Reaction / Event as Reported by the Primary Source for Translation:

MedDRA Version for Reaction / Event: 27.1

Reaction / Event (MedDRA code): Sinus bradycardia

Term Highlighted by the Reporter:

Results in Death: No

Life Threatening: No

Caused / Prolonged Hospitalisation: Yes

Disabling / Incapacitating: No

Congenital Anomaly / Birth Defect: No

Other Medically Important Condition: No

Date of Start of Reaction / Event: 19/03/2025

Date of End of Reaction / Event: 21/03/2025

Duration of Reaction / Event: 2 days

Outcome of Reaction / Event at the Time of Last Observation: recovered/resolved

Medical Confirmation by Healthcare Professional:

Identification of the Country Where the Reaction / Event Occurred: Sweden

STUDY IDENTIFICATION

Study Identification (1/1)

Study Name: RECOVERY Trial

Sponsor Study Number: 281712

Study Type Where Reaction(s) / Event(s) Were Observed: Clinical trials

Study Registration (1/1)

Study Registration Number:	2023-507441-29-00
Study Registration Country:	European Union

DRUG INFORMATION

Drug (1/10)

Characterisation of Drug Role:	Suspect
Medicinal Product Name as Reported by the Primary Source:	DEXAMETHASONE
Invented name part:	
Scientific name part:	
Trademark name part:	
Strength name part:	
Form name part:	
Container name part:	
Device name part:	
Intended name part:	
Identification of the Country Where the Drug Was Obtained:	
Investigational Product Blinded:	
Authorisation / Application Number:	
Country of Authorisation / Application:	
Name of Holder / Applicant:	
Cumulative Dose to First Reaction:	18 mg
Gestation Period at time of Exposure:	
Action(s) taken with Drug:	Drug withdrawn
Additional information on Drug (free text):	
Additional information on Drug (coded):	

Indication for Use in Case (1/1)

Indication as Reported by the Primary Source:	influenza pneumonia
MedDRA Version for Indication:	27.1
Indication (MedDRA code):	Influenza

Dosage and Relevant Information (1/1)

Dose:	6 mg
Number of Units in the Interval:	24
Definition of the Time Interval Unit:	hour
Date and Time of Start of Drug:	18/03/2025
Date and Time of Last Administration:	20/03/2025
Duration of Drug Administration:	2 days
Batch / Lot Number:	<unknown>
Dosage Text:	6mg once daily
Pharmaceutical Dose Form (free text):	
Pharmaceutical Dose Form TermID:	()
Route of Administration (free text):	
Route of Administration TermID:	Oral use
Parent Route of Administration (free text):	
Parent Route of Administration TermID:	

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed:	Sinus bradycardia
Time Interval between Beginning of Drug Administration and Start of Reaction / Event:	24 hours
Time Interval between Last Dose of Drug and Start of Reaction / Event:	
Did Reaction Recur on Re-administration?:	no / not applicable

Assessment of Relatedness of Drug to Reaction(s)/Event(s) (1/1)

Source of Assessment:	
Method of Assessment:	
Result of Assessment:	
EU Source of Assessment:	Investigator
EU Method of Assessment:	EU Method of Assessment
EU Result of Assessment:	Reasonable possibility

Drug (2/10)

Characterisation of Drug Role:	Concomitant
Medicinal Product Name as Reported by the Primary Source:	LEVOTHYROXINE
Invented name part:	
Scientific name part:	
Trademark name part:	
Strength name part:	
Form name part:	
Container name part:	
Device name part:	
Intended name part:	
Identification of the Country Where the Drug Was Obtained:	
Investigational Product Blinded:	
Authorisation / Application Number:	
Country of Authorisation / Application:	
Name of Holder / Applicant:	
Cumulative Dose to First Reaction:	
Gestation Period at time of Exposure:	
Action(s) taken with Drug:	
Additional information on Drug (free text):	
Additional information on Drug (coded):	

Dosage and Relevant Information (1/1)

Dose:	75 ug
Number of Units in the Interval:	1
Definition of the Time Interval Unit:	day
Date and Time of Start of Drug:	
Date and Time of Last Administration:	
Duration of Drug Administration:	
Batch / Lot Number:	
Dosage Text:	
Pharmaceutical Dose Form (free text):	
Pharmaceutical Dose Form TermID:	()
Route of Administration (free text):	
Route of Administration TermID:	
Parent Route of Administration (free text):	
Parent Route of Administration TermID:	Oral use

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed:	Sinus bradycardia
Time Interval between Beginning of Drug Administration and Start of Reaction / Event:	
Time Interval between Last Dose of Drug and Start of Reaction / Event:	
Did Reaction Recur on Re-administration?:	

Drug (3/10)

Characterisation of Drug Role:	Concomitant
Medicinal Product Name as Reported by the Primary Source:	OSELTAMIVIR
Invented name part:	
Scientific name part:	
Trademark name part:	
Strength name part:	
Form name part:	
Container name part:	
Device name part:	
Intended name part:	
Identification of the Country Where the Drug Was Obtained:	
Investigational Product Blinded:	
Authorisation / Application Number:	
Country of Authorisation / Application:	
Name of Holder / Applicant:	
Cumulative Dose to First Reaction:	
Gestation Period at time of Exposure:	
Action(s) taken with Drug:	
Additional information on Drug (free text):	
Additional information on Drug (coded):	

Dosage and Relevant Information (1/1)

Dose:	75 mg
Number of Units in the Interval:	1
Definition of the Time Interval Unit:	day
Date and Time of Start of Drug:	
Date and Time of Last Administration:	
Duration of Drug Administration:	
Batch / Lot Number:	
Dosage Text:	
Pharmaceutical Dose Form (free text):	
Pharmaceutical Dose Form TermID:	()
Route of Administration (free text):	
Route of Administration TermID:	Oral use
Parent Route of Administration (free text):	
Parent Route of Administration TermID:	

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed:	Sinus bradycardia
Time Interval between Beginning of Drug Administration and Start of Reaction / Event:	
Time Interval between Last Dose of Drug and Start of Reaction / Event:	
Did Reaction Recur on Re-administration?:	

Drug (4/10)

Characterisation of Drug Role:	Concomitant
Medicinal Product Name as Reported by the Primary Source:	PARACETAMOL
Invented name part:	

Scientific name part:
 Trademark name part:
 Strength name part:
 Form name part:
 Container name part:
 Device name part:
 Intended name part:
 Identification of the Country Where the Drug Was Obtained:
 Investigational Product Blinded:
 Authorisation / Application Number:
 Country of Authorisation / Application:
 Name of Holder / Applicant:
 Cumulative Dose to First Reaction:
 Gestation Period at time of Exposure:
 Action(s) taken with Drug:
 Additional information on Drug (free text):
 Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose:	1 g
Number of Units in the Interval:	6
Definition of the Time Interval Unit:	hour
Date and Time of Start of Drug:	
Date and Time of Last Administration:	
Duration of Drug Administration:	
Batch / Lot Number:	
Dosage Text:	
Pharmaceutical Dose Form (free text):	
Pharmaceutical Dose Form TermID:	()
Route of Administration (free text):	
Route of Administration TermID:	
Parent Route of Administration (free text):	
Parent Route of Administration TermID:	Oral use

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed:	Sinus bradycardia
Time Interval between Beginning of Drug Administration and Start of Reaction / Event:	
Time Interval between Last Dose of Drug and Start of Reaction / Event:	
Did Reaction Recur on Re-administration?:	

Drug (5/10)

Characterisation of Drug Role:	Concomitant
Medicinal Product Name as Reported by the Primary Source:	CEFOTAXIME - INJECTION
Invented name part:	
Scientific name part:	
Trademark name part:	
Strength name part:	
Form name part:	
Container name part:	
Device name part:	

Intended name part:

Identification of the Country Where the Drug Was Obtained:

Investigational Product Blinded:

Authorisation / Application Number:

Country of Authorisation / Application:

Name of Holder / Applicant:

Cumulative Dose to First Reaction:

Gestation Period at time of Exposure:

Action(s) taken with Drug:

Additional information on Drug (free text):

Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose:	2 g
Number of Units in the Interval:	8
Definition of the Time Interval Unit:	hour
Date and Time of Start of Drug:	
Date and Time of Last Administration:	
Duration of Drug Administration:	
Batch / Lot Number:	
Dosage Text:	
Pharmaceutical Dose Form (free text):	
Pharmaceutical Dose Form TermID:	()
Route of Administration (free text):	
Route of Administration TermID:	Intravenous use
Parent Route of Administration (free text):	
Parent Route of Administration TermID:	

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed:	Sinus bradycardia
Time Interval between Beginning of Drug Administration and Start of Reaction / Event:	
Time Interval between Last Dose of Drug and Start of Reaction / Event:	
Did Reaction Recur on Re-administration?:	

Drug (6/10)

Characterisation of Drug Role:	Concomitant
Medicinal Product Name as Reported by the Primary Source:	ONDANSETRON
Invented name part:	
Scientific name part:	
Trademark name part:	
Strength name part:	
Form name part:	
Container name part:	
Device name part:	
Intended name part:	
Identification of the Country Where the Drug Was Obtained:	
Investigational Product Blinded:	
Authorisation / Application Number:	
Country of Authorisation / Application:	
Name of Holder / Applicant:	

Cumulative Dose to First Reaction:
Gestation Period at time of Exposure:
Action(s) taken with Drug:
Additional information on Drug (free text):
Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose: 4 mg
Number of Units in the Interval:
Definition of the Time Interval Unit:
Date and Time of Start of Drug:
Date and Time of Last Administration:
Duration of Drug Administration:
Batch / Lot Number:
Dosage Text:
Pharmaceutical Dose Form (free text):
Pharmaceutical Dose Form TermID: ()
Route of Administration (free text):
Route of Administration TermID: Oral use
Parent Route of Administration (free text):
Parent Route of Administration TermID:

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed: Sinus bradycardia
Time Interval between Beginning of Drug Administration and Start of Reaction / Event:
Time Interval between Last Dose of Drug and Start of Reaction / Event:
Did Reaction Recur on Re-administration?:

Drug (7/10)

Characterisation of Drug Role: Concomitant
Medicinal Product Name as Reported by the Primary Source: IBUPROFEN
Invented name part:
Scientific name part:
Trademark name part:
Strength name part:
Form name part:
Container name part:
Device name part:
Intended name part:
Identification of the Country Where the Drug Was Obtained:
Investigational Product Blinded:
Authorisation / Application Number:
Country of Authorisation / Application:
Name of Holder / Applicant:
Cumulative Dose to First Reaction:
Gestation Period at time of Exposure:
Action(s) taken with Drug:
Additional information on Drug (free text):
Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose: 400 mg

Number of Units in the Interval:

Definition of the Time Interval Unit:

Date and Time of Start of Drug:

Date and Time of Last Administration:

Duration of Drug Administration:

Batch / Lot Number:

Dosage Text:

Pharmaceutical Dose Form (free text):

Pharmaceutical Dose Form TermID: ()

Route of Administration (free text):

Route of Administration TermID: Oral use

Parent Route of Administration (free text):

Parent Route of Administration TermID:

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed: Sinus bradycardia

Time Interval between Beginning of Drug Administration and Start of Reaction / Event:

Time Interval between Last Dose of Drug and Start of Reaction / Event:

Did Reaction Recur on Re-administration?:

Drug (8/10)

Characterisation of Drug Role: Concomitant

Medicinal Product Name as Reported by the Primary Source: IPRATROPIUM

Invented name part:

Scientific name part:

Trademark name part:

Strength name part:

Form name part:

Container name part:

Device name part:

Intended name part:

Identification of the Country Where the Drug Was Obtained:

Investigational Product Blinded:

Authorisation / Application Number:

Country of Authorisation / Application:

Name of Holder / Applicant:

Cumulative Dose to First Reaction:

Gestation Period at time of Exposure:

Action(s) taken with Drug:

Additional information on Drug (free text):

Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose: 500 ug

Number of Units in the Interval: 1

Definition of the Time Interval Unit: day

Date and Time of Start of Drug:

Date and Time of Last Administration:

Duration of Drug Administration:

Batch / Lot Number:

Dosage Text:

Pharmaceutical Dose Form (free text):

Pharmaceutical Dose Form TermID: ()

Route of Administration (free text):

Route of Administration TermID: Inhalation use

Parent Route of Administration (free text):

Parent Route of Administration TermID:

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed: Sinus bradycardia

Time Interval between Beginning of Drug Administration and Start of Reaction / Event:

Time Interval between Last Dose of Drug and Start of Reaction / Event:

Did Reaction Recur on Re-administration?:

Drug (9/10)

Characterisation of Drug Role: Concomitant

Medicinal Product Name as Reported by the Primary Source: SALBUTAMOL

Invented name part:

Scientific name part:

Trademark name part:

Strength name part:

Form name part:

Container name part:

Device name part:

Intended name part:

Identification of the Country Where the Drug Was Obtained:

Investigational Product Blinded:

Authorisation / Application Number:

Country of Authorisation / Application:

Name of Holder / Applicant:

Cumulative Dose to First Reaction:

Gestation Period at time of Exposure:

Action(s) taken with Drug:

Additional information on Drug (free text):

Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose: 2.5 mg

Number of Units in the Interval: 1

Definition of the Time Interval Unit: day

Date and Time of Start of Drug:

Date and Time of Last Administration:

Duration of Drug Administration:

Batch / Lot Number:

Dosage Text:

Pharmaceutical Dose Form (free text):

Pharmaceutical Dose Form TermID: ()

Route of Administration (free text):

Route of Administration TermID: Inhalation use

Parent Route of Administration (free text):

Parent Route of Administration TermID:

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed: Sinus bradycardia

Time Interval between Beginning of Drug Administration and Start of Reaction / Event:

Time Interval between Last Dose of Drug and Start of Reaction / Event:

Did Reaction Recur on Re-administration?:

Drug (10/10)

Characterisation of Drug Role: Concomitant

Medicinal Product Name as Reported by the Primary Source: ETHYLMORPHINE

Invented name part:

Scientific name part:

Trademark name part:

Strength name part:

Form name part:

Container name part:

Device name part:

Intended name part:

Identification of the Country Where the Drug Was Obtained:

Investigational Product Blinded:

Authorisation / Application Number:

Country of Authorisation / Application:

Name of Holder / Applicant:

Cumulative Dose to First Reaction:

Gestation Period at time of Exposure:

Action(s) taken with Drug:

Additional information on Drug (free text):

Additional information on Drug (coded):

Dosage and Relevant Information (1/1)

Dose: 62.5 mg

Number of Units in the Interval: 1

Definition of the Time Interval Unit: day

Date and Time of Start of Drug:

Date and Time of Last Administration:

Duration of Drug Administration:

Batch / Lot Number:

Dosage Text:

Pharmaceutical Dose Form (free text):

Pharmaceutical Dose Form TermID: ()

Route of Administration (free text):

Route of Administration TermID: Oral use

Parent Route of Administration (free text):

Parent Route of Administration TermID:

Drug-reaction(s) / Event(s) Matrix (1/1)

Reaction(s) / Event(s) Assessed: Sinus bradycardia

Time Interval between Beginning of Drug Administration and Start of Reaction / Event:

Time Interval between Last Dose of Drug and Start of Reaction / Event:

Did Reaction Recur on Re-administration?:

NARRATIVE CASE SUMMARY AND FURTHER INFORMATION

Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information:

Patient was admitted to hospital on 16th March 2025 with bilateral pulmonary consolidation and found to be influenza PCR positive. Required supplemental oxygen via nasal cannula (3 L/min). CRP elevated at 140 ml/dL. Enrolled in the RECOVERY trial on 17th March and allocated dexamethasone. 24 hours after starting dexamethasone she developed asymptomatic sinus bradycardia with occasional nodal rhythm. Heart rate was as low as 32 beats per minute. Dexamethasone was stopped on 20th March, and the patient had prolonged admission for cardiac monitoring. The bradycardia resolved within the next 24 hours and she was discharged on 21st March.

Reporter's Comments:

2025-03-20

We would like to report an SAE in the Recovery trial.

Patient no XXXX, included on March 17th, developed bradycardia 24 hrs after administration of first dose of dexamethasone.

Study team was informed this morning at 9.00 am (March 20th).

No symptoms but heart rate as low as 32 per minute.

Requires monitoring and prolonged hospitalization.

Dexamethasone is withdrawn.

Follow-up is ongoing.

2025-03-24

Patient no XXXX was discharged Friday March 21st. Her bradychardia resolved after discontinuation of dexamethasone. We think it had a potential, although not certain, association with study drug.

Sender's comments: