ADVERSE EVENT REPORT FORM

For Affiliates

Version effective: 24Jan2020

SOBIAFF

Adverse Event Supplier details

Name of Sobi Affiliate or External Service provider: _____ Email: _____

If solicited report provide details

Program title: _____ Service provider name: _____

Safety Information – including Adverse Events (AEs) & Special Situations

Date Sobi or Service provider first received the Safety Info (dd/Mmm/yyyy): _____ Country (of occurrence of AEs): _____

Local reference number for report: _____

Patient Details

Initials: _____ ☐ Male ☐ Female Date of Birth (dd/Mmm/yyyy): _____ Age (at onset of event): _____

Sobi Product involved	Indication	Dose, Units (at AE start)	Frequency	Route	Start Date dd/Mmm/yyyy	Stop Date dd/Mmm/yyyy

Batch number (LOT): _____ ☐ Asked but unknown Expiry date (dd/Mmm/yyyy): _____ ☐ Asked but unknown

Serialisation number (GTIN/SN number): _____ ☐ Asked but unknown

Adverse Events (AEs) or Special Situations reported to Service provider

Describe the Safety Information disclosed by reporter, and include: Event Start date, action taken with Sobi Drug treatment, Outcome of Event

Did the reporter consider that there is a reasonable possibility that any of the AE(s) may have been caused by the suspect drug? ☐ Yes ☐ No

Per reporter: What other factors may have contributed to the event(s)?

If fatal outcome, provide cause of death and a comment on its possible relationship to the Sobi Drug Involved:

Concomitant Drug(s) and Medical History

Please list Concomitant Drug(s), excluding drugs for treatment of the AEs, and relevant Medical History:

Details about the Reporter of the safety information to Service Provider

Reporter's Qualification:	☐ Physician	☐ Nurse	☐ Pharmacist	☐ Other HCP (specify):
	☐ Non HCP (specify):			

Reporter agrees to be contacted for follow-up: ☐ Yes ☐ No - If yes, add contact details:

Person completing this form

Name:	Title:
E-mail:	Phone:
Date completing this form (dd/Mmm/yyyy):	Signature:
Quality check performed by:	Date quality check performed (dd/Mmm/yyyy):

The information and personal data provided on this form will be recorded and processed electronically by Swedish Orphan Biovitrum AB (publ). The information provided will be used for the purpose of drug safety surveillance.

Please return to: adverseevent@sobi.com

ADVERSE EVENT REPORT FORM for Affiliates
SUPPLEMENTARY GUIDANCE DOCUMENT
24Jan2020

General Instructions:

- The format of the AER form (.docx) should not be modified or changed/saved to another format type.
- Dates should always be entered in the following format (dd/Mmm/yyyy) e.g. 01/Jan/2019.
- Complete the form with all available information using the grey fields. Try to be as specific as possible. E.g. if patient has experienced bruising or pain, please specify location (e.g. injection site) if available. Ask reporter if unclear.
- Do not use abbreviations. For instance, if information is not available or not applicable, enter "Not available" or "Not applicable", do not enter "NA".
- If the reporter was a non-healthcare professional, please do not enter their names in the form without consent.

Specific Instructions:

Date Sobi or Service provider first received the Safety Info: This should reflect the date of awareness.

> Note: When information is reported in writing, the awareness date is when the e-mail, post, fax etc. was received and not the date when the information was read.

Adverse Event Supplier details: Used for reconciliation purposes by Global Drug Safety. Add name of Safety Hub or for non Hubs add name of the External Service provider as applicable.

Country (of occurrence of AEs): the full name of the country of occurrence should be used.

E.g for reports from the USA: United States of America should be used.
For reports from Scotland, England, Wales and Northern Ireland: United Kingdom should be used.

Local reference number for report: to be completed for all reports as applicable for identification and reconciliation purposes.

Indication: do not use numeric codes or abbreviations.

Product Dose and Frequency: enter the product dose as it is at start of reported event(s) and specify number of individual doses per interval. E.g. patient receives a total daily dose of 40 mg. Strength of product is 20 mg/dosage form and the patient receives 2 dosage forms daily. This would be entered as Dose "20 mg" and Frequency "2x1 daily".

Product Start date: avoid leaving field blank. Enter date in format dd/Mmm/yyyy. If asked but unknown, enter unknown. Blank fields will be interpreted as not asked.

> Note: start date should indicate start of the current dose. If dose adjustments have been made (e.g. dose escalations over time) this should be entered in the adverse event details free-text field.

Product Stop date: avoid leaving field blank. Enter date in format dd/Mmm/yyyy.

> Note: If treatment has not been discontinued, enter "Ongoing". Blank fields will be interpreted as not asked unless otherwise specified in the event details free-text field e.g. temporarily interruption, dose reduction etc.

Batch number (LOT), expiry date and serialisation number (GTIN/SN number)**:** should always be requested. If asked but unknown, the check box should be ticked. When the check box is left blank, it will be interpreted as not asked.

Serialisation (GTIN/SN) number should be provided in the following format: GTIN 00000012345678 – SN 00000012345678.