FROM
Fondazione per la Ricerca Ospedale di Bergamo

Ospedale Papa Giovanni XXIII

Sistema Socio Sanitario
Regione Lombardia
ASST Papa Giovanni XXIII

SERIOUS ADVERSE EVENT EVALUATION FORM

Trial Code		*<Specify "EUDRACT"*	
Protocol Title			
Suspected IMP(s)			
Patient ID #		**Centre # -**	_____
SAE – Investigator Term			
The present evaluation is relevant to	☐ Initial Report ☐ Follow-up # ____ Received by FROM on _____/_____/_____		

A) *TO BE COMPLETED BY THE RESPONSIBLE FOR PHARMACOVIGILANCE ACTIVITIES:*

Was the report forwarded to the concerned Drug Companies?	☐ No ☐ **Yes ***

If yes, date of transmission _____/_____/_____

B) *TO BE COMPLETED BY THE RESPONSIBLE FOR PHARMACOVIGILANCE ACTIVITIES:*

1. Is the reported event serious?	☐ No ☐ **Yes ***

Under which ICH criteria does the event meet the category for serious:	☐ Death ☐ Life threatening ☐ Hospitalization Required / Prolonged	☐ Disabling or incapacitating ☐ Congenital anomaly ☐ Other / Medically significant	
Is there a reasonable relationship between the reported event and the IMP(s)? ☐ No ☐ **Yes** Did the <u>investigator</u> assess the event as at least possibly related to the IMP(s)? ☐ No ☐ **Yes**		**2. At least one positive relationship assessment ?**	☐ No ☐ **Yes ***
3. If both answers above = "YES" → Is the reported event unexpected with respect to the IMP's known safety profile?			☐ No ☐ **Yes *** ☐ Not applicable
If yes, is this in : ☐ Nature ☐ Severity ☐ Seriousness ☐ Outcome ☐ Other			

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* If ALL 3 answers above = "Yes" → case to be processed as

 Suspect Unexpected Serious Adverse Reaction (SUSAR)

→ complete SUSAR Evaluation Form for each concerned trial

→ Expedited Reporting to:

SERIOUS ADVERSE EVENT EVALUATION FORM

• **ECs, CAs, Investigators involved in the present trial** • **ECs, CAs, Investigators of other FROM-sponsored trials using the same IMP(s)** • **EudraVigilance**	☐ within **7** days ☐ within **15** days _____/_____/_____ **Deadline date for sending**

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Case Id #	

Queries to be issued and comments:

MEDICAL ADVISOR'S ASSESSMENT REQUIRED	☐ Immediately, to complete the present assessment ☐ Within 1 weeks for confirmation of the present ☐ NO (provide comment in section above)

_____/_____/_____
Date

_____
Responsible for Pharmacovigilance Signature

SERIOUS ADVERSE EVENT EVALUATION FORM

B) **MEDICAL ADVISOR'S ASSESSMENT REQUIRED***:*

Is the Responsible for Pharmacovigilance's Assessment confirmed?   ☐ yes   ☐ no

Further queries to be issued and comments:

_____/_____/_____

Date of contact

_____

Reporter's Signature

_____/_____/_____

Date of assessment

_____

Safety Assessment responsible's Signature