CRF 9 - ADVERSE EVENT INITIAL EVALUATION FORM

A1.Participant's ID number C C C - C C C C **A2. Center** _____

AI0. Research staff completing the form _____

PLEASE COMPLETE THIS FORM WITHIN 24h FROM WHEN YOU LEARN OF THE EVENT

ADVERSE EVENT INITIAL EVALUATION

AI1. Event number C C C C (note: fill this with the number provided by the $2R^2$ website)

AI2. Date of completion of CRF9 C C C C C C C C C
D D M M M Y Y Y Y

AI3. Regarding study medication status**, choose one:**

- C Study medication was stopped before the study participant completed the full course **(go to AI4)**
- C Study medication was already completed < 30 days ago **(go to AI5)**
- C Study medication was already completed 30 days ago or more
  (STOP HERE. If not already done, complete "End of treatment form" CRF6)
- C Study medication was not stopped **(STOP HERE)**

AI4. Why was study medication stopped? **(choose one)**

- C Treating team stopped medication due to potential adverse event
- C Study participant stopped medication due to potential adverse event and treating team agrees.
- C Study participant permanently stopped medication due to intolerance BUT treating team feels they should not stop **(STOP HERE and COMPLETE "End of treatment form" CRF-6)**
- C Study participant permanently stopped medication for other reasons BUT treating team feels they should not stop **(STOP HERE and COMPLETE "End of treatment form" CRF6)**

CRF 9 - ADVERSE EVENT INITIAL EVALUATION FORM

A1.Participant's ID number C C C - C C C C **A2. Center** _____

DESCRIPTION OF ADVERSE EVENT AND INVESTIGATIONS DONE

Which was the most important reason for stopping study medication*? (choose one or more, as applies)	**Which of the following MANDATORY TESTS were undertaken for this event? (choose all that applies except if differently specified)**
☐ Death (AI5)	Choose one: AI6. ☐Autopsy AI7. ☐ Verbal autopsy
☐ Hepatotoxicity (AI8)	AI9. ☐ Liver function test AI10. ☐ Complete blood count AI11. ☐ International normalized ratio AI12. ☐ HIV AI13. ☐ HAV AI14. ☐ HBV AI15. ☐ HCV **(note: HIV, HAV, HBV and HCV are requested unless already known positive)** AI16. ☐ Abdominal/liver ultrasound (not mandatory)
☐ Hematologic (AI17)	AI18. ☐ B12, folate, iron studies AI19. ☐ Complete blood count and differential.
☐ Drug interaction (AI20)	AI21. Specify which investigations were done **(note: write "none" if no investigation was done)**: _____
☐ Gastrointestinal intolerance (AI22)	AI23. ☐ Liver function test AI24. ☐ Complete blood count AI25. ☐ Amylase AI26. ☐ Pregnancy test AI27. ☐ Date of last menstrual period was asked AI28. ☐ Abdominal/liver ultrasound (not mandatory)
☐ Pregnancy (AI29)	AI30. ☐ Pregnancy test AI31. ☐ Date of last menstrual period was asked
☐ Rash (AI32)	AI33. ☐ Complete blood count and differential AI34. ☐ Flow rate (if wheezing)
☐ Possible active TB (AI35)	**STOP here and complete Active TB Initial form- CRF 11**
☐ Other (AI36), AI37. Specify _____	AI38. Specify which investigations were done **(note: write "none" if no investigation was done):** _____

***NOTE in case study medication was already completed but less then 2 weeks prior, choose the most important reason for this adverse event**.

AI39. Was any other investigation done (a part from the one already listed in AI15-AI37)? ☐No ☐Yes

AI40. If yes, please specify _____

AI41. Was the participant referred to other specialists? ☐No ☐Yes **(reminder: if yes, SPECIFY in Narrative)**

AI42. Was the participant hospitalized? ☐No ☐Yes **(reminder: if yes, SPECIFY in Narrative)**

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A1.Participant's ID number C C C - C C C C **A2. Center** _____

HISTORY OF ADVERSE EVENT

AI43. Date of onset of symptoms C C C C C C C C C
D D M M M Y Y Y Y

AI44. Date in which study participant took the last dose of study medication C C C C C C C C C
D D M M M Y Y Y Y

AI 44.1 . Date on which site PI became aware of event.

C C C C C C C C C
D D M M M Y Y Y Y

AI45. **Describe the symptoms and the current history of the event using as much detail as possible. Make sure that all the points below are mentioned in the narrative. If any of these points are not known, please write "NOT DONE/NOT KNOWN".**

1) Time at which medication is usually taken
2) Number of hours between ingestion of medication and onset of symptoms
3) Actions taken by the study participant that made it better
4) Actions taken by the study participant that made it worse
5) If participant had any recent alcohol use
6) If participant had any recent new medication
7) If participant had any recent exposure to allergens or food
8) If participant had any past history of disease *(as GI problems, liver disease, recreational drug use, transfusion, personal & family allergies)*
9) Physical exam results
10) Test done and results
11) Study medication re-challenge
12) Hospitalization and referral to other specialists

NOTE: Please do not specify the planned duration (4 months or 2 months) of the study medication, but use exact dates (i.e. 19-Jan-2020) as much as possible.

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A1.Participant's ID number C C C - C C C C **A2. Center** _____

INITIAL IMPRESSION OF TREATING TEAM and TREATMENT PLAN

AI46. Initial impression of grading severity **(choose one) (Refer to SOP for explanations of grading)**

☐Grade 1 ☐Grade 2 ☐Grade 3 ☐Grade 4 ☐Grade 5

AI47. Initial impression of relationship to therapy **(choose one)**

☐Unsure ☐None ☐Unlikely ☐Possible ☐Probable

AI48. Action regarding study medication:

☐ Held study medication

☐ Permanently discontinued study medication **(if permanently discontinued, complete End of Treatment form - CRF 6)**

AI48.1 In the opinion of site PI, this event was :

☐ Expected (i.e. listed in protocol, and/or well-known and described adverse event with study drug)

☐ Unexpected

----------ONLY ON PAPER CRF----------

Date Initial Adverse Event Form (CRF9) was submitted to coordinating center:

C C C C C C C C C

D D M M M Y Y Y Y

_____ _____

PRINT name site Principal Investigator (PI) Signature of site PI

_____ _____

PRINT name person completing the form Signature of person completing the form

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