DSMC Safety Report Form- Completion Guidelines

Section 1-Protocol Status

1. **IRB#:** This is the RASCAL number.
2. **Protocol Title:** The full protocol title should be entered here.
3. **Reporting Interval**: The frequency in which the study is monitored by the DSMC (e.g., 3 months). This is indicated in the automated emails sent to the study teams.
4. **Reporting Period:** The time interval for which the data was collected from the previous reporting period until the next reporting period (e.g. 10/1/2023 – 1/1/2014). The first date of the new reporting period should be the day ***after*** the last reporting period end date (there should be no lapse between reporting periods.
5. **Date of Initial IRB approval:** The date the protocol was initially accepted and approved by the IRB.
6. **Does the study require CPDM to monitor?** - Please check either yes or no.
7. **Trial Type:** - Please check either *Single Center IST* or *Multicenter IST*. If this is a *Multicenter IST*, please include the list of affiliate sub-sites that are active and open to enrollment.

Section 2-Enrollment Status

8. **Current Enrollment Status-** Please choose the enrollment status. (e.g. open to enrollment, closed to enrollment or enrollment pause/ hold).
9. **What is the approved accrual target across all sites (per datasheet)?** – The accrual target should be accurate and the most recently approved target as per the *Subjects* section of the current approved datasheet.
10. **What is the actual accrual to date? –** The current accrual information. ***This number does not include screen failures or subjects who withdrew consent prior to enrollment.***
    - **If this is a multi-center IIT, please include both total study-wide accrual and CUIMC accrual**.
    - **What is the number of patients enrolled at CUIMC**- The current accrual information.
11. **Number of patients still active on treatment** – The number of patients still receiving study treatment.
12. **Number of patients in long-term follow up –** The number of patients who have discontinued study treatment but are still in follow-up for this study (e.g., Safety follow up, survival follow up, etc.).
13. **Number of patients off study** – The number of subjects that are completely off study (no longer being followed and data is no longer being collected).
14. **Number of patients who withdrew or were removed from study treatment for any other reason -** The number of subjects that discontinued study treatment or were removed from study due to withdrawal of consent or other reason (e.g., Adverse Event, PI discretion).

Section 3-Patient Status Reasons

15. **Patients who are considered unevaluable**- If any, please include the list of patients' IDs.
16. **Patients who discontinued study treatment due to unacceptable toxicity**? – The number of patients taken off treatment due to toxicity-If any, please include the list of patients' IDs.
17. **Patients who withdrew consent from study treatment** -If any, please include the list of patients' IDs.
18. **Patients who were removed from study treatment per investigator discretion** - The number of patients taken off treatment by the investigator for reasons other than unacceptable toxicity that are not accounted for in questions above. If any, please include the list of patients' IDs. ***Do not include screen failures.***

Section 4- Protocol Major Violations and Unanticipated Problems

19. **Did any Major Violations and/or Unanticipated Problems occur throughout the life of this study?** - Please check *yes* or *no*. If yes, please complete the details below.
20. **Major Violation / UP (include Site and Patient Study ID)**– Please provide a brief narrative of the major violation (including site and patient study ID), date of violation/UP and whether a protocol amendment was initiated/implemented due to the event. If a protocol amendment was initiated, please provide a brief description of the amendment.

Section 5- Serious Adverse Events and Dose Limiting Toxicities

21. **Did any patients experience SAEs or DLTs during this reporting period?** - Please check *yes* or *no*. If yes, please complete the details below. SAE/DLT start date (*or* initial reporting date to the DSMC), must fall within reporting period indicated in Section 1 Q4.
    If responding yes, the details provided must reflect information submitted on the SAE/DLT report form and/or Velos database.
    - **Patient Study ID -**Please provide the patient's study ID.
    - **CTCAE Term and Grade -** Please provide the CTCAE term and grade based on CTCAE reporting version guidelines.
    - **Start Date - End Date** - Please provide the period of the start date to the end date.
    - **Related to Study Drug? (Yes/No, if multiple, specify for each drug)** - Please specify yes or no. Please specify yes/no if related to the study drug for each SAE/DLT if more than one.
    - **Is the event a DLT? (Yes/No)** - Please specify yes or no.

Section 6- Adverse Events

22. **Did any patients experience an adverse event ≥ grade 3? -** Please check yes or no. If yes, please complete the details below. Please utilize the Velos Adverse Event report to provide the remaining details.
    - **List Study-wide Toxicities by keyword:** Please list the toxicities, which occurred across the study. If this is an multicenter study, please list the toxicities which occurred at both CUIMC and sub-sites.
    - **Grade (≥3 events):** Grade of the toxicity based on CTCAE reporting version guidelines. Please only report Grades 3 and above. ***Please **bold** new adverse events ≥ grade 3 that occurred during this reporting period.
    - **Number of CUIMC Patients**: The total number of CUIMC patients who have experienced this toxicity.
    - **Number of Patients Experiencing this Toxicity (Study-wide):** The total number of patients (from CUIMC and the sub-sites) who have experienced this toxicity.

Section 7- Phase I Therapeutic Trials

Not Applicable - Please check the not applicable box if this is not a Phase 1 IST.

23. **Has the dose escalation schema in the protocol been followed?** - Please check yes or no.
24. **Which cohort is currently accruing patients?** – Please enter the cohort currently accruing. This information should be current.
25. **Has the Maximum Tolerated Dose (MTD) Been Reached?** - Please check yes or no. If yes, please specify the dose.
26. **Total # of Dose Limiting Toxicities (List DLTs below)** – Please include the DLT term, Study ID and Patient cohort below. This information should be current.

Section 8- Phase II Therapeutic Trials

Not Applicable - Please check the not applicable box if this is not a Phase 2 IST.

27. **Has this trial demonstrated efficacy?** - Please check the box to indicate yes, no, or insufficient data to determine at this time.

Section 9- Analyses and Publication

28. **Has the primary objective been met? -** Please check *yes* or *no*. If yes, please specify the date it was met and state the primary objective per protocol. This must be confirmed by the Sponsor Investigator
29. **Has an interim analysis been completed for this study?** - Please check *yes* or *no*. If yes, please attach the analysis report and supporting data.
30. **Has an abstract, manuscript, or poster been drafted/published for this study?** – Please check *yes* or *no*. If yes, please attach the required documents. This information should be current.

Section 10- Closure

31. **If this protocol employs an early stopping rule, please define it -** Please cut and paste the stopping rule from the protocol. If there is no stopping rule, please write "N/A."
32. **Are there any plans to close the study in the near future?** - Please check *yes* or *no*. If *yes*, please specify and explain the reason behind the upcoming closure.
33. **Is this the last safety report to be submitted to the DSMC?** – Please check *yes* or *no*. The response must be confirmed by the QA Clinical Research Manager.

PI Signature and Date: Please have the PI sign and date this form.

Quick notes about Safety Reports:

- After a protocol has been approved by the PRMC and IRB and it is determined that the HICCC DSMC is required, the protocol will be reviewed by the DSMC to determine reporting frequency.
- Please do not leave fields blank. If there is no information for a particular field please enter "N/A."
- Please remember to change the reporting period for every new safety reported submitted.
- Always make sure new information is in **BOLD font**.
- If you have a question regarding when or if safety reports are due for your study please contact Mariangela Agovino and Brian Siaw for the DSMC at ma3655@cumc.columbia.edu and bs3478@cumc.columbia.edu respectively and the HICCC DSMC at dsmc_hiccc@cumc.columbia.edu.