Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

Data & Safety Monitoring Review PI Narrative Form for Externally Monitored Studies

Version 2
Revised: 3/14/2018

Instructions: The following will be submitted upon request:

Requirements for Industry-Sponsored Studies

- PI Narrative Form
- Supporting safety data from Biostat Console in OnCore *(if applicable, see question # 4a for instructions)*
- Supporting safety data from sponsor *(if applicable, see question # 4a for instructions)*

Requirements for NCTN/ NCI CIRB Studies

- PI Narrative Form
- Most recent DSMB report and/or Study Report from sponsor
- Supporting safety data from Biostat Console in OnCore *(if applicable, see question # 4a for instructions)*

Requirements for External Investigator-Initiated Studies

- PI Narrative Form
- Most recent DSMB report and/or summary
- Supporting safety data from Biostat Console in OnCore *(if applicable, see question # 4a for instructions)*

Date: | **HIC #:** | **PI:**

Title:

1. Describe the objectives of the study.

2. Describe the study's design and treatment administration.

3. If the study has multiple phases and/or specific cohorts, please indicate below which phase(s)/cohort(s) you are participating in.

Data & Safety Monitoring Review PI Narrative Form for Externally Monitored Studies

Version 2
Revised: 3/14/2018

SAFETY DATA:

4a. Are the AEs for this protocol viewable in the DSMC Console in OnCore?

◯ Yes

◯ No

If no, please provide supporting safety data via the Biostat Console in OnCore.
Instructions: eCRFs/Calendars --> Biostat Console --> Data Export --> AE Form *click on export and export to excel and submit as a separate attachment with this form.*
If this information is not available through the Biostat Console, please provide a summary of the AEs from the sponsor.

4b. How many SAEs have been reported in each cohort?

4c. Have any of the SAEs been unexpected and related? *If yes, provide a detailed explanation of the event(s).*

4d. How many deaths have occurred on study? *Include the site and if deemed related for each death?*

4e. Are there updated or new toxicity concerns regarding the investigational products(s) not previously specified in the protocol? If yes, please provide a detailed explanation.

5. Summarize the Efficacy Results.
Summarize response data for Yale subjects. If the sponsor has provided any updates on efficacy data of the study/ recent publishing of data, please include this information.

6. Please state your conclusions to date and future plans for this study.

7. Have at least 90% of the eCRFs been completed?

- Per DSMC policy, no more than 10% of the eCRF data should be outstanding at any given time while the trial is active.
- Calculation= (*To Do Forms + Started Forms) ÷ (Total # of Forms- Planned # of Forms)*

◯ Yes ◯ No

Additional comments:

Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

Data & Safety Monitoring Review PI Narrative Form for Externally Monitored Studies

Version 2
Revised: 3/14/2018

8. Has OnCore been verified for accuracy and completeness? (Please ensure that all SAEs & deviations have been entered.)
OnCore DSMC Console Export Report should be used to verify that all information in OnCore is up-to-date for committee review

◯ Yes ◯ No

Additional comments:

9. Is the information provided in this form the most recent information?
i.e. the most recent information since the last report to the DSMC

◯ Yes
◯ No

If no, please explain:

Enter digital signature here:
(or print & sign document)

As a reminder...

Effective April 2015, all new submissions to the PRC of studies that are externally monitored will not require annual DSMC review unless otherwise determined by the Protocol Review Committee (PRC) or DSMC. Deviations and SAEs for all YCC trials will continue to be reviewed on a monthly basis.

The Principal Investigator or research team designee will update OnCore with all deviations and SAEs per the FDA definition (http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm); within 5 business days of their discovery from the time of each subject's first intervention thru 30 days after the last intervention, unless the protocol dictates SAE reporting after consent or a longer follow-up period for SAE reporting.

The Principal Investigator in conjunction with the research team designee in each Disease Aligned Research Team (DART) will review monitoring reports from external sponsors to ensure that all applicable deviations and SAEs identified are entered into OnCore in order to facilitate a complete monthly report of SAEs and deviations for the DSMC review.