## DSM Report: Data Safety and Monitoring Report

## for an Investigator-Initiated Study

You will be notified by the UVM Cancer Center’s Data Safety and Monitoring Committee (DSMC) regarding when your specific DSM Report will be due. The due date is based on the month your study originally opened and then the Risk Level and monitoring frequency assigned by the UVMCC Protocol Review and Monitoring Committee. The intent of this DSM Report is to provide aggregated data to the DSMC.

CHRMS # \_\_\_\_\_\_\_\_

Date of Study Activation: \_\_\_/\_\_\_/\_\_\_

Date of this Submission: \_\_\_/\_\_\_/\_\_\_

*Interventional Treatment Studies: complete Sections 1, 2, and 3*

*Non-Interventional investigator-initiated cancer study: Complete Sections 2 and 3*

**Section 1:**

1. *Phase I Clinical Trial If this is Phase II or III, skip to B.*

Note that safety and monitoring reports are to be submitted to the DSMC after completing each odd numbered dose level (i.e., 1, 3, 5, etc.), or more frequently if requested by the DSMC. A final safety and monitoring report must be submitted to the DSMC within three months of defining the maximum tolerated dose (MTD).

Current Accrual Status: (please mark one and provide requested information)

[ ]  Accruing to a Phase I dose level (please indicate dosage tier)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Completed Phase I enrollment. Please indicate DLT that halted escalation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. *Phase II or III Clinical Trials*

Current Accrual Status:

[ ]  Accruing to Phase II portion of study

Does this portion have an early stopping rule for toxicity?

 [ ]  Yes [ ]  No [ ]  N/A (study has not reached a decision point at the time of this report)

If Yes, please attach a summary of your assessment of the data that you used to either stop or continue.

Does this portion have an early stopping rule for efficacy?

 [ ]  Yes [ ]  No [ ]  N/A (study has not reached a decision point at the time of this report)

If Yes, please attach a summary of your assessment of the data that you used to either stop or continue.

**Section 2:**

Have there been changes/amendments to the protocol since the last DSM Report?. \_\_ Yes \_\_\_ No

If yes, please summarize the amendments/changes:

Is outcome data available (for example, an interim analysis)? [ ]  Yes [ ]  No

If yes, please comment: (for therapeutic studies, you may refer to Section 1 in your answer here)

**Section 3: *Aggregate of Data and Safety Monitoring Information***

* Participant Status

Please attach a summary of all subjects that have been enrolled and their current status (e.g., on treatment, off study, in follow-up, etc.). **Please attach or use DSM Report Table 1 to provide this information.**

* Study Progress

Please attach a summary of the study progress: the number of patients and their treatment duration or participation duration. **Please attach or use DSM Report Table 2 to provide this information.**

* Protocol Deviations

Please attach a summary of protocol deviations that have occurred and provide a justification. **Please attach or use DSM Report Table 3 to provide this information.**

* Toxicities and Adverse Events

For interventional trials: Please attach a toxicity summary that indicates the number and severity of toxicities observed and adverse events. Please provide your overall impression of the toxicity observed to date (i.e. is it consistent with what you anticipated?) **Please attach or use DSM Report Table 4 and Listings 1 through 3 to provide this information.**

For non-interventional trials: **fill in “N/A” for DSM Report Table 4 and “N/A” for Listings 1 through 3.**

* If the protocol is complete, please also attach a lay summary, final study findings, future plans, and publications and complete the last page of this DSM Report.

## DSM Report Table 1: Participant Enrollment Status

CHRMS # \_\_\_\_\_\_\_\_

Data as of (date):\_\_\_\_\_\_\_\_\_

Check that the tally of percentages of categories equals 100%. This means the categories “Active,” “Completed Study Procedures,” “Completed Study Entirely”, “Discontinued Treatment,” and “Discontinued from Study” each captures a different participant (a single participant is not listed in two categories).

|   | **N** | **%** |
| --- | --- | --- |
| **Active** |  |  |
|  Gender | Male: Female: Unknown: |
|  Ethnicity | Hispanic/Latino: Non-Hispanic: Unknown:  |
|  Race | White: African American: American Indian/Alaskan Native: Asian: Hawaiian/Pacific Islander: Unknown/Two Races/Other: |
| Number of Active that were recruited in last three months |  |  |
|  | **N** | **%** |
| **Completed Study Procedures (& being followed for outcomes)** |  |  |
|  Gender | Male: Female: Unknown: |
|  Ethnicity | Hispanic/Latino: Non-Hispanic: Unknown: |
|  Race | White: African American: American Indian/Alaskan Native: Asian: Hawaiian/Pacific Islander: Unknown/Two Races/Other: |
|  | **N** | **%** |
| **Completed Study Entirely (no longer being followed)** |  |  |
| Gender | Male: Female: Unknown:  |
| Ethnicity | Hispanic/Latino: Non-Hispanic: Unknown:  |
| Race | White: African American: American Indian/Alaskan Native: Asian:Hawaiian/Pacific Islander: Unknown/Two Races/Other:  |
|  | **N** | **%** |
| **Discontinued Treatment but Follow-up Continuing** |  |  |
| Personal Reason |   |  |
| Serious Adverse Event/ AE |   |  |
|   | **N** | **%** |
| **Discontinued from Study** |  |  |
| Lost to Follow-Up |   |  |
| SAE/AE |   |  |
| Withdrew Consent |  |  |
| Personal Reason |  |  |

* *These are examples. Use categories relevant to protocol.*

### DSM Report Table 2: Treatment or Participation Duration for All Participants

CHRMS # \_\_\_\_\_\_\_\_

Data as of (date):\_\_\_\_\_\_\_\_\_

| **Time in Study\*****Total N=**  | **Number of participants who completed each milestone** | **%** |
| --- | --- | --- |
| **Visit 1** |  |  |
| **Visit 2** |  |  |
| **Visit 3** |  |  |
| **Visit 4** |  |  |
| **Completed Study** |  |  |

*\* Needs to be protocol specific and can be shown by visits, days, weeks, months, or treatment periods.*

## DSM Report Table 3: Protocol Deviation Report

CHRMS # \_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

|  |
| --- |
| **Protocol Deviations** |
| **Deviation\*** | **Date** | **Explanation and any Corrective Actions Taken** | **Increased Risk for Participants (as Determined by PI)? Yes or No** | **Reported to IRB?** |
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*\*Possible deviations may include:*

* *Did not meet inclusion/exclusion criteria*
* *Visit noncompliance/incomplete visit*
* *Participant taking concomitant drugs which are not allowed*
* *Assessments outside protocol window*
* *Failure to obtain informed consent*

###

## DSM Report Table 4: Adverse Event Report

Interventional trial? [ ]  Yes [ ]  No

 If “yes,” complete the table/listing below.

CHRMS # \_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

|  |
| --- |
| **Number of Patients with Toxicity for all Cycles and all Dose Levels to Date\*** |
| **Dose Level** | **AE (toxicity)** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
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\*please note in the table those toxicities that were dose-limiting

Impression of side effects/toxicity to date:

### DSM Report Listing 1: Serious Adverse Events

Interventional trial? [ ]  Yes [ ]  No

 If “yes,” complete the table/listing below.

CHRMS # \_\_\_\_\_\_\_\_

Data as of (date):\_\_\_\_\_\_\_\_\_

| **Participant ID** | **Onset Date** | **Stop Date** | **Expected** **(Y/N)** | **Relationship to Intervention\*** | **Outcome\*\*** | **Description of SAE** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
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*\* Definite, Possible, Not Related*

*\*\* Outcome:*

 *Recovered, without treatment*

 *Recovered, with treatment*

 *Still Present, no treatment*

 *Still Present, being treated*

 *Residual effect(s) present – no treatment*

 *Residual effect(s) present- being treated*

 *Subject died*

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### DSM Report Listing 2: Deaths

Interventional trial? [ ]  Yes [ ]  No

 If “yes,” complete the table/listing below.

CHRMS # \_\_\_\_\_\_\_\_

Data as of (date):\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Participant ID** | **Date of Death** | **Cause of Death** | **Relationship to Intervention\*** |
| --- | --- | --- | --- |
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 *\* Definite, Possible, Not Related*

### DSM Report Listing 3: Adverse Events \*

Interventional trial? [ ]  Yes [ ]  No

 If “yes,” complete the table/listing below.

CHRMS # \_\_\_\_\_\_\_\_

Data as of (date):\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Participant ID** | **Days on Intervention when AE initially identified** | **Preferred Term** | **Relationship to Intervention\*\*** | **Severity (Grade)** | **Serious (Y/N)** | **Outcome\*\*\*** |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |

*\* This listing could be provided in two ways – sorted by Preferred Term or sorted by Participant ID.*

*\*\* Definite, Possible, Not Related*

*\*\*\* Outcome:*

 *Recovered, without treatment*

 *Recovered, with treatment*

 *Still Present, no treatment*

 *Still Present, being treated*

 *Residual effect(s) present – no treatment*

 *Residual effect(s) present- being treated*

 *Subject died*

**DSM Report: Final Study Report**

*Please complete this page if the study has been completed since the last time this DSM Report was submitted to the DSMC.*

CHRMS # \_\_\_\_\_\_\_\_

Data as of (date):\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Success of accrual of patients or cases:**

Accrual goal: \_\_\_\_\_\_

Actual accrual: \_\_\_\_\_\_

Please explain if this study encountered any problems in accruing patients/cases:

**2. Plan to publish:**  \_\_\_\_Yes \_\_\_\_No

If yes, please explain your current stage in the plan to publish this study:

**3. Summary of findings:**

This can be an abstract that you have already drafted. Please attach the abstract OR limit your answer to 3 paragraphs.

If study information is not yet available to summarize findings, please describe your timeline for accomplishing this (for example, let DSMC know that a subsequent report will be sent to the DSMC by a certain time).