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| **RG#:       Principal Investigator:** |
| **Protocol Title:       Date Form Completed:** |

**The information provided in this form should be in accordance with the**

**Data and Safety Monitoring Plan written in the protocol.**

**Submit completed form and attachments to Clinical Research Support at** **DSM@fredhutch.org****.**

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| **A. Summary of progress since the last DSMC review:** |
| **Summary:** **Total Subjects Enrolled to Date:** |

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| **B. Data and Safety Monitoring Board (DSMB)** |
| **Does this study have an independent data monitoring committee (DMC) or DSMB that has met in the last year?**[ ]  **Yes** – Submit a copy of any available DSMB Result Letters, along with applicable meeting minutes and DSMB reports since the last DSMC review.[ ]  **No** – Complete sections C – J**How often does the DSMB meet?**[ ]  Monthly [ ]  Quarterly [ ]  Biannually [ ]  Annually [ ]  Other (please elaborate): **Next DSMB review will occur:****Additional Notes:**  |



Only complete the following sections if the study does not have a DSMB

OR

the study has a DSMB that did not meet in the last year

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| **C. Adverse Events (AEs)** |
| Provide all AEs that have occurred since the study opened. |
| [ ]  None – Subjects were followed, as described in the protocol, and no AEs were reported.  |
| [ ]  AEs were reported and a cumulative table organized by type and grade, as described in the protocol, is provided below.* + - * Report must include the category; toxicity; grade and number of events.
			* For multicenter studies where the Cancer Consortium is not the coordinating center, report only local events.
			* For multicenter studies where the Cancer Consortium is the coordinating center, report study wide events.
			* Include Grade 5 events for reporting number of deaths on study.
 |
| Number of subjects represented in the AE table below:       |

*Example Table 1: Adverse Events*

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| --- | --- | --- |
| *Category (CTCAE)* | *Adverse Event/Toxicity* | *Grade and Number (N) of events* |
| *1* | *2* | *3* | *4* | *5* |
| *Gastrointestinal Disorders* | *Nausea* |  | *1* | *2* |  |  |
| *Gastrointestinal Disorders* | *Pancreatitis* |  |  |  | *1* |  |
| *Vascular disorders* | *Hypertension* |  | *3* |  |  |  |

*Example Table 2: Adverse Events*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Category* | ***CTC Term*** | ***Grade*** | ***Number of Events*** | ***Maximum Attribution*** |
| *Gastrointestinal Disorders* | *Nausea* | *3* | *8* | *Unlikely* |
| *Gastrointestinal Disorders* | *Pancreatitis* | *4* | *1* | *Possibly* |
| *Vascular Disorders* | *Hypertension* | *2* | *4* | *Unrelated* |

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| **D. Serious Adverse Events (SAEs)** |
| Provide the SAEs with expedited reporting to the IRB since the study opened. |
| [ ]  **None** |
| **Subject ID#** | **Serious Adverse Event** | **IRB Report Date** | **Agent** | **Subject Initial Outcome** | **Description** |
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| **E. Primary Endpoint** |
| The primary endpoint is |

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| **F. Dose Escalation** [ ]  **Not Applicable** |
| **Dose Escalation (or multi-dose level) definition:** For each subject enrolled to date, provide cohort and dose assignment. Add rows as needed so that each subject enrolled to date is represented in their own row.If a dose modification as per protocol was used, indicate the dose level and modification. |
| **Subject ID#** | **Cohort** | **Study Drug Dose Level/Modification** |
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| **G. Dose Limiting Toxicities (DLT)** [ ]  **Not Applicable** |
| **Provide the dose limiting toxicity (DLT) definition**  |  |
| **The DLT definition can be found in the protocol on page(s):** |  |
| **Identify DLTs** (add more rows, if needed): | Dose Level | Total # of Subjects at dose level | Total # of Subjects Experienced DLT |
|       |       |       |
|       |       |       |
|       |       |       |

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| **H. Study Stopping Rules** [ ]  **Not Applicable** |
| **Provide protocol-defined stopping rules** |  |
| **Study stopping rules can be found in the protocol on page(s):** |  |
| **Have any study stopping rules been met?** | [ ]  Yes [ ]  No |
| **Identify events that count toward stopping rule** (add more rows, if needed)**:** | Stopping rule: | # of Subjects/Events met Stopping Rule |
|       |       |
|       |       |
|       |       |

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| **I. Deaths of Subjects**  |
| **Have there been any deaths of study subjects (for any cause) since the study opened?** [ ]  **No**[ ]  **Yes**       total deaths       unrelated to treatment      related to treatmentIf unknown cause of death, please explain:       |

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| **J. Unanticipated Problems** |
| Provide the unanticipated problems reported to the IRB since the study opened.  |
| [ ]  **None** |
| **RNI#** | **IRB Report Date** | **Description**  |
|  |  |  |
|  |  |  |