|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PROJECT DETAILS** | | | | | | |
| **Project Title:** | Click or tap here to enter text. | | | | | |
| **Trial Acronym:** | Click or tap here to enter text. | | | **Project ref. no:** | | Click or tap here to enter text. |
| **Coordinating Principal Investigator (CPI)/Sponsor-Investigator:** | **Name** | Click or tap here to enter text. | | | | |
| **Dept or Group** | Click or tap here to enter text. | | | | |
| **Institution** | Click or tap here to enter text. | | | | |
| **Phone** | Click or tap here to enter text. | | | **Email** | Click or tap here to enter text. |
| **Contact Person:**  *(if different from above)* | **Name** | Click or tap here to enter text. | | | | |
| **Dept or Group** | Click or tap here to enter text. | | | | |
| **Institution** | Click or tap here to enter text. | | | | |
| **Phone** | Click or tap here to enter text. | | | **Email** | Click or tap here to enter text. |
| **PRIOR SPONSORSHIP COMMITTEE ASSESSMENT** | | | | | | |
| *Please complete these fields using the MCRI Sponsorship Committee’s response on the last returned Progress Update Report or Sponsorship Committee Meeting minutes.* | | | | | | |
| **Date of Last Review:** | Click or tap to enter a date. | | **Review interval:** | | | Choose an item. |
| **Risk Rating:** | Choose an item. | | | | | |
| **Response to Prior Action Points / Key Concerns:** | Click or tap here to enter text. | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **PROGRESS SUMMARY** | | | | | | | |
| **Date of this Report:** | Click or tap to enter a date. | | | | | | |
| **Report period start date:** | Click or tap to enter a date. | **Report period end date:** | | | | Click or tap to enter a date. | |
| **Please indicate if there have been any changes to the following documents and attach an update to this report:** | **Document** | **Update attached?** | **Version no.** | | | **Version Date** | |
| Research Protocol | Yes | # | | | Click or tap to enter a date. | |
| *Data Management Plan* | Yes | # | | | Click or tap to enter a date. | |
| *Data Sharing Plan* | Yes | # | | | Click or tap to enter a date. | |
| *Monitoring Plan* | Yes | # | | | Click or tap to enter a date. | |
| Risk Assessment Matrix | Yes | # | | | Click or tap to enter a date. | |
| Research Budget | Yes | # | | | Click or tap to enter a date. | |
| **Current Trial Status:** | Choose an item. | | | | | | |
| **Project Summary:**  *2-3 sentences describing the overall progress of the study eg. recruitment targets. Attach supporting documents if required.* | Click or tap here to enter text. | | | | | | |
| **Please specify any developments which may affect trial funding since the last budget review:**  *I.e. New grants, greater than expected costs, delays, etc.* | Click or tap here to enter text. | | | | | | |
| **RECRUITMENT** | | | | | | | |
| **Date of first HREC/EC/IRB Approval** *(either locally or globally)* | Click or tap to enter a date. | | | | | | |
| **Date of first Participant Randomised / Registered**  *(i.e. First Patient First Visit, FPFV)* | Click or tap to enter a date. | | | | | | |
| **Participant recruitment number** *(Totals for all HREC/EC/IRB approved sites)* | **Target recruitment** | # | | **Actual recruitment** *(to date)* | | | # |
| **Withdrawn** | # | | **Completed research project** | | | # |
| **Lost to Follow-Up** | # | |  | | | |
| Have there been delays in recruitment? If yes, please detail why | Yes  No | Click or tap here to enter text. | | | | | |
| **STUDY COMPLETION** | | | | | | | |
| **Date of Last Enrolment**  *Last Patient First Visit (LPFV), i.e. end of accrual* | Click or tap to enter a date. | | | | Planned  Actual | | |
| **Date of Last Study Visit**  *Last Patient Last Visit (LPLV), i.e. end of follow-up* | Click or tap to enter a date. | | | | Planned  Actual | | |
| **Date of Database Lock** | Click or tap to enter a date. | | | | Planned  Actual | | |
| **Date Statistical Report Finalised** | Click or tap to enter a date. | | | | Planned  Actual | | |
| **Publications, seminars, & conferences**  *Attach listing if required. Please include submitted and future publications* | Click or tap here to enter text. | | | | | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **MONITORING** | | | | | | | | |
| **Date of last Trial Steering Committee Meeting (or planned first meeting).** | | | Click or tap to enter a date. | **Date of last DSMB / SMC / Medical Monitor Review (or planned first meeting).** | | | | Click or tap to enter a date. |
| **Brief Description of Monitoring Activities undertaken since last report** | | | Click or tap here to enter text. | | | | | |
| **Have all monitoring activities occurred as per the Monitoring Plan?** | | | o Yes o No | **Are all trial records, including source documents, trial database, and the Trial Master File (TMF), audit ready and being kept in a manner compliant with ICH GCP?** | | | | o Yes o No |
| **If no to either of the above, please detail why:** | | | Click or tap here to enter text. | | | | | |
| **Has a Non-Compliance Line Listing been submitted with this Report? If not, please detail why:** | | **Attached?** | | **If No or N/A, please detail why:** | | | | |
| 🞏 Yes  o No *(please detail)*  o NA *(please detail)* | | Click or tap here to enter text. | | | | |
| **SAFETY REPORTING** | | | | | | | | |
| **Safety / Non-Compliance Events since last Progress Update Report to SC:** | | | **Event** | **# Since last SC update** | **Reported as per** [**Safety / Non-compliance Reporting Procedures**](https://www.mcri.edu.au/research/training-and-resources/launching-pad#_Risk_management) | | **If no, please detail why**  *Attach additional page(s) to this document if necessary* | |
| Serious Breach Reports | **#** | Yes  No | | Click or tap here to enter text. | |
| Suspected Unexpected Serious Adverse Reaction (SUSAR) | **#** | Yes  No | | Click or tap here to enter text. | |
| Significant Safety Issue (SSI) | **#** | Yes  No | | Click or tap here to enter text. | |
| Urgent Safety Measure (USM) | **#** | Yes  No | | Click or tap here to enter text. | |
| **Has an AE and SAE Line Listing been submitted with this Report? If not, please detail why:** | | | **Attached?** | **If No or N/A, please detail why:** | | | | |
| 🞏 Yes  o No *(please detail)*  o NA *(please detail)* | Click or tap here to enter text. | | | | |
| **Have all newly identified safety and non-compliance concerns been addressed in the updated Risk Assessment?** | | | Yes  No *(please detail)*  NA *(please detail)* | Click or tap here to enter text. | | | | |
| **DECLARATION** | | | | | | | | |
| The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in accordance with the protocol. All Serious Breaches have been reported to both the MCRI Sponsorship Committee and the reviewing HREC. All events which significantly alter the Risk Profile of the trial have been reported to the Sponsorship Committee. The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007 (updated 2018)) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended, and where applicable, all international regulations and guidelines. | | | | | | | | |
| **Sponsor-Investigator** | Signature | | | | | Date | | |
| Click or tap to enter a date. | | |

**For MCRI Sponsorship Committee to Complete:**

|  |  |
| --- | --- |
| Submission Date | Click or tap to enter a date. |
| Date of review by Committee Chair (or delegate) | Click or tap to enter a date. |
| Date of review by Sponsorship Committee | Click or tap to enter a date. |
| Post review Trial Risk Rating | Choose an item. |
| Review Period | Click or tap here to enter text. |
| Comments | Click or tap here to enter text. |