**TRIAL MASTER FILE (TMF) QUALITY ASSURANCE (QA) PLANNING FORM**

**PART 1: Trial Details**

*To be completed by the Central Trial Coordinating Team*

|  |  |
| --- | --- |
| **Protocol Title** | <Insert Protocol Title> |
| **Protocol Number** | <Insert Protocol Number> |
| **Sponsor-Investigator Name** | <Insert Name> |
| **Trial Coordinator Name** | <Insert Name> |
| **Date Form Completed** | <Insert Date> |

**PART 2: Summary of TMF and SIF Files for Review**

*To be completed by the Central Trial Coordinating Team*

|  |  |
| --- | --- |
| **Name of Central Trial Coordinating Team Member Responsible for TMF/SIFs** | <Insert Name> |
| **Central Trial Coordinating Team Member Email Address** | <Insert Email Address> |
| **Current Approved Protocol Version No and Date** | Version No: ­­­­­<Insert No.> Dated: <Insert Date>  |
| **Current Approved Master PICF Version No. and Date** | Version No: ­­­­­<Insert No.> Dated: <Insert Date>  |
| **Trial Type** | [ ]  Pilot Study[ ]  Single Site[ ]  Multi-Site |
| **Current Trial Status** | [ ]  Currently Recruiting - not all sites active/open to recruitment[ ]  Currently Recruiting - all sites active/open to recruitment[ ]  Closed to Recruitment – in Follow-Up Phase[ ]  In Data Analysis Phase[ ]  Prior to Archiving |
| **TMF Source** | [ ]  Paper TMF Binder[ ]  Florence eBinders; *specify name of Binder:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  SharePoint; *specify location:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Network Drive; *specify location:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other; *specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **TMF/SIF Format** | [ ]  TMF and individual SIFs[ ]  Combined TMF/SIF |
| **Indicate the TMF Binders/Folders Not Subject or Not Applicable for Review** | <Specify any TMF Binders/Folders not subject to QA review>*e.g. Folder 22 – Investigational Product or Not Applicable; all sections/folders subject to review.* |
| **Name of SIF Selected for Review:** | *Add/Delete the number of SIFs, as needed:*1. <insert name of SIF #1>
2. <insert name of SIF #2>
3. <insert name of SIF #3>
4. <insert name of SIF #4>
5. <insert name of SIF #5>
 |
| **Indicate the SIF Binders/Folders Not Subject or Not Applicable for Review** | <Specify any SIF Binders/Folders not subject to QA review>*e.g. Folder 22 – Investigational Product or Not Applicable; all sections/folders subject to review.* |

*Add/Delete rows from the following table, as needed:*

|  |  |
| --- | --- |
| **SIF #1:** <name of SIF #1) | **Current Approved Site-Specific PICF Version No. and Date** |
| <insert version #> | <insert date> |
| **SIF #2:** <name of SIF #2) | **Current Approved Site-Specific PICF Version No. and Date** |
| <insert version #> | <insert date> |
| **SIF #3:** <name of SIF #3) | **Current Approved Site-Specific PICF Version No. and Date** |
| <insert version #> | <insert date> |
| **SIF #4:** <name of SIF #4) | **Current Approved Site-Specific PICF Version No. and Date** |
| <insert version #> | <insert date> |
| **SIF #5:** <name of SIF #5) | **Current Approved Site-Specific PICF Version No. and Date** |
| <insert version #> | <insert date> |

**PART 3: Nominated Peer Reviewer and Timelines of Review**

*To be completed by the Sponsorship Committee / Sponsorship Committee Representative.*

|  |  |
| --- | --- |
| **Nominated Peer Reviewer Name** | <Insert Peer Reviewer Name> |
| **Peer Reviewer Email Address** | <Insert Email Address> |
| **Reason for Review:** | [ ]  Routine Annual[ ]  Ad hoc; *specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Percentage of SIFs to be Reviewed:** | [ ]  20% [ ]  Single-SiteOther; *specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **TMF QA Review Timelines** |
| **TASK** | **DURATION** | **COMMENCEMENT DATE** | **COMPLETION DATE** |
| **TMF Peer Review** | *<3 weeks>* | *dd/mmm/yyyy* | *dd/mmm/yyyy* |
| **Initial Corrective Actions by Research Team** | *<3 weeks>* | *dd/mmm/yyyy* | *dd/mmm/yyyy* |
| **Sponsorship Committee Review** | *<2 weeks>* | *dd/mmm/yyyy* | *dd/mmm/yyyy* |
| **CAPA Implementation** *(as applicable)* | *As applicable* | *dd/mmm/yyyy* | *dd/mmm/yyyy* |

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| --- |
| **This TMF QA Plan is approved and agreed to by:**  |
| Name/Role: **Plan Developer/Sponsorship Committee Representative** | Name/Role: **Sponsor-Investigator** | Name/Role: **Peer Reviewer** |
| Signature: | Signature: | Signature: |
| Date of Approval: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_\_\_ | Date of Approval: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_\_\_ | Date of Approval: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_\_\_ |

***Upon completion, a copy of this form must be forwarded to the Research Team (for filing in the TMF) and the nominated Peer Reviewer for their acknowledgement, acceptance of the QA Review Plan and to assist with conducting the TMF QA Review.***