*Adoption rules for template end users:.*

***Template Purpose****: This template is a working document for end users following 16.2.6, Manage Clinical Studies global procedure* ***PEPF-QMS-V01-0014: Clinical Study Plan Procedure****. The template has been aligned to this process. It is a tool, and not a requirement. It may be customized, as needed, to the study protocol, study product(s), and/or Philips Business group. However, ensure any customization remains in alignment with the applicable global procedure.*

*This template defines the suggested content (in black text) and the suggested format.*

***Template End Users Instructions:***

*To create a document, take the following considerations into account:*

* *Remove ‘Template’ from the header*
* *Keep black text without angle brackets as is;*
* *Any changes to black text without angle brackets (customization) should be checked against the applicable 16.2.6 Manage Clinical Study procedure to ensure continued alignment*
* *Replace black text between angle brackets in the template with relevant project content*
* *Replace black text between angle brackets in the footer with appropriate content*
* *Upon completion of this template, remove all red text throughout the document. This includes “Template Purpose” and “Template End User Instructions” above, as well as any additional instructions in the main body of the document.*

**Introduction**

The Clinical Study Plan will be prepared after the clinical study alignment between key stakeholders with agreement to proceed with the clinical study. The Clinical Study Manager/ Lead will prepare this Clinical Study Plan. The Clinical Study Plan will be updated as required according to Good Clinical Documentation Practices and version control standards. If the Clinical Study Plan is revised, it is the responsibility of the Clinical Study Manager/Lead to notify appropriate stakeholders, per the Study Request Form as well as the Clinical Study Team and associated Vendors and study sites about the potential impact resulting from the change.

**BG Stakeholders**

|  |  |
| --- | --- |
| **Primary Point of Contact** |  |
| **Project Manager** |  |
| **Marketing Lead** |  |
| **Principal Investigator** | Dr. White |
| **Clinical/Science Lead** |  |
| **Medical Monitor** |  |
| **Regulatory Affairs Lead** |  |
| **Legal Representative** |  |
| **Privacy Officer** | afadfsdf |

|  |  |
| --- | --- |
| **Clinical Study Alignment & Agreement to Proceed** | <Version/date of Study Request Form (SRF)> to which alignment and agreement to proceed was reached>  (e.g. Study Request Form v2.0 12Sept17) |
| <Summary of Final Alignment and Agreement to Proceed, including date(s)>  (e.g., On 30Sept2017, the <BG> key stakeholders attended a Study Alignment meeting and reviewed the above referenced SRF, protocol synopsis/overview, and risks-mitigation strategy. Agreement was reached to proceed with the study according to these key documents. Signatures were collected. See Study Alignment Meeting Minutes attached to the SRF in the TMF)  Note: This alignment is between key stakeholders of the sponsoring Philips Business, as designated on the SRF. Key stakeholders from Clinical & Regulatory Affairs Study Team (e.g., Clinical Study Manager, Biostatistician, etc.) may also attend. |

Note, the above section may be kept in a separate document.

### Clinical Study Scope

Describe and/or provide a short summary on the following study elements:

|  |  |
| --- | --- |
| **Philips Sponsor** | <Philips Business or Group> |
| **Protocol Title** | Protocol\_Title\_Example |
| **Protocol ID** | SRC-AI-Example-2020-12345 |
| **Study Objectives** | <Main scientific objectives> |
| **Subjects** | <Total number planned: screening, randomization, and completion> |
| <Summary of subject characteristics> |
| **Sites** | <Indicate number of sites> |
| **Countries** | <List countr(ies) where the study will be conducted> |
| **Product Description** | Example\_description\_text |

**Risks & Mitigation Strategy**

|  |  |  |  |
| --- | --- | --- | --- |
| **Anticipated Risks** | | **Anticipated Risk Level** | **Mitigations** |
| <risk summary> e.g. recruitment | | <low, medium, high> | <mitigation summary> |
| <risk summary> e.g. retention | | <low, medium, high> | <mitigation summary> |
| <risk summary> e.g. IEC/IRB approval | | <low, medium, high> | <mitigation summary> |
| <risk summary> e.g. unique system or testing requirements | | <low, medium, high> | <mitigation summary> |
| <risk summary> e.g. protocol and/or gcp compliance | | <low, medium, high> | <mitigation summary> |
| <risk summary> e.g. device risks to subject, malfunction, failure | | <low, medium, high> | <mitigation summary> |
| <risk summary> e.g. prior experience with PI/site | | <low, medium, high> | <mitigation summary> |
| **Site Training Requirements** | <on system, device, study information applicable to CRO, staff and sites, etc> | | |

Note: The SRF may be attached/embedded to address items listed above. Reference where appropriate if the completed form is attached.

### Clinical Study Timeline

The following are key timeline milestones, and will be reported as KPIs in CTMS.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Milestone:** | **Protocol Development** | **EDC/Data Collection Tool Development** | **Site Initiation** | **Study Duration** | **Database Lock** | **Clinical Study Report** |
| **Description:** | First draft protocol to final protocol release (excludes amendments) | Protocol release to database/data collection tool live - data collection live | Protocol release to first site activated | First participant In to last participant out | Last participant out to database lock | Database lock to final signed clinical study report |
| **Start Definition:** | Date of Protocol Development Start | Date CRF templates provided to DM team. | Date of Internal sign-off and submitted to regulatory body | Date of First Participant First Visit | Date of Last Participant Last Visit | Date of Database Lock |
| **Planned Start** | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> |
| **Actual Start** | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> |
| **End Definition:** | Version date of protocol submitted to regulatory body (CA/FDA/IRB/EC), whichever is 1st. (Excludes Amendments) | Date of Database released to production and available | Date of Site initiation (agreements executed, products delivered, staff trained, IRB/EC approval, Database activated, site initiation letter) | Date of Last Participant Last Visit | Date of Database Lock | Date of final signature on completed CSR |
| **Planned End** | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> |
| **Actual End** | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> | <DATE> |

Other Study Milestones (if applicable)

|  |  |  |  |
| --- | --- | --- | --- |
| **Milestone:** | **Contract Approval**  **Date** | **Actual**  **Shipment** | **Target release date for shipment to study sites** |
| **Planned Start** | <DATE> | <DATE> | <DATE> |
| **Actual Start** | <DATE> | <DATE> | <DATE> |
|  |  |  |  |
| **Planned End** | <DATE> | <DATE> | <DATE> |
| **Actual End** | <DATE> | <DATE> | <DATE> |

**Key Performance Indicators (KPIs)**

Information related to the clinical study shall be captured in CTMS including the unique protocol ID, study objectives, number of study subjects, and clinical sites among other relevant study elements.

During the study the following performance metrics (e.g. on target; performance meets requirements,) will be tracked as Study and Site milestones in CTMS:

|  |
| --- |
| **KPIs** (include, as applicable)**:** |
| **Study Start-up:** |
| Protocol Development on target? |
| Database Build/Release on target? |
| Site Activation; study start (FSFV) on target? |
| **Mid-Study Performance:** |
| Study Recruitment on target? |
| Study Enrollment (LSFV) on target? |
| Completion of Study Procedures/Visits on target? |
| Monitoring Visits and Reports on target? |
| CRO Performance meets contract requirements? |
| Vendor Performance meets contract requirements? |
| **End-Study/Final Performance:** |
| Study Duration (FSFV-LSLV) on target, per study timeline? |
| Did the study meet the Primary Objective? |
| Did the study meet the Publication Strategy? |
| Did the study generate a new/updated Claim(s) as planned? |
| Did the study result in ‘no’ CAPAs? |
| Did the study result in ‘no’ SAEs or USADEs? |
| Did the study meet the target Enrollment? |
| Database Locked on target, per study timeline? |
| Results Communicated to stakeholders on target? |
| Clinical Study Report on target, per study timeline? |

### Study Resources / Outsourcing

Following are the key roles for this study, including any outsourced vendors:

Add additional roles, as applicable to the study. If a role in Not Applicable, indicate NA. If a role is outsourced, list vendor name and include in the Vendor section.

| **Role** | **Name and FTE # Required** (e.g., 0.25, 0.5, 0.75, 1.0, etc) | **Planned Training** |
| --- | --- | --- |
| Clinical Study Manager |  |  |
| Clinical Development Scientist |  |  |
| Clinical Operations Lead |  |  |
| Clinical Research Associate(s) |  |  |
| Clinical Research Coordinator |  |  |
| Data Manager |  |  |
| Biostatistician(s) |  |  |
| Medical Monitor |  |  |
| Privacy Officer |  |  |
| Medical Writer |  |  |
| <Other> |  |  |

|  |  |  |
| --- | --- | --- |
| **Vendor** | **Name** | **Outsourced Activities** |
| CRO | <Name> | * <Activity Outsourced> * <Activity Outsourced> |
| Laboratory/Reader | <Name> | * <Activity Outsourced> * <Activity Outsourced> |
| Site/Investigator(s) | <Site Name>  <Investigator(s) Name(s)> | * <Activity Outsourced> * <Activity Outsourced> |
| IRB/IEC | <Name> | * <Activity Outsourced> * <Activity Outsourced> |
| <Other> | <Name> | * <Activity Outsourced> |

### Responsibilities, Accountabilities, Consulted & Informed (RACI)

The following individuals/roles are responsible, accountable, consulted and informed on the study documentation preparation, review and approval, as applicable:

* If a similar document exists with a different name, update the document name accordingly
* For each document/activity, name the individual(s) / role (see above Role table) in the appropriate RACI cell
* If a RACI is not applicable at the document/activity level, indicate NA in the cell
* If a document/activity does not apply to a clinical study, based on the study type (e.g, feasibility study), indicate NA in all 4 RACI cells

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document(s)/Activity** | **(R)esponsible** (Owner/Executor) | **(A)ccountable** (Reviewer/Approver)  \*(R) is accountable to (A) | **(C)onsulted** (Informs/ Reviews/ Contributes) | **(I)nformed** (Notified of Results) |
| Study Request Form | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Study Start-up Checklist | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| CTMS Study Registration | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Design | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Risk Assessment Document(s) (e.g. product release/assurance safe for human use) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Plan | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| CTMS Updating | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Investigator Brochure | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Protocol | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Statisticial Analysis Plan | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Site Selection & Qualification Report | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Vendor Qualification Report | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Vendor Oversight & Delegation Plan | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Site and Vendor Contracts | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Budget and Resource Administration | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Site Regualtory File Development, Shipment | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Trial Master File Maintenance & Reconciliation | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| <Subject Consent Document> | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Informed Consent Form Checklist | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Privacy Impact Assessment | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Regulatory Agency Submissions & Reports | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| IRB/IEC Submission Documentation & Reports | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Registration Determination Document (e.g., ClinTrials.gov Registration Decison) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Source Document Templates | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| EDC/CRF Development | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Data Management Plan | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| User Acceptance Testing of EDC | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Product Release Document(s) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Product Shipment | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Site Readiness Checklist | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Investigational Product Accountability Document(s) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Monitoring Plan | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Site Training Documents | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Monitoring Reports | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Query Issue & Resolution | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Trial Master File/Site Regulatory File Audit Checklist(s) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Adverse Event Assessment & Reporting Documentation (e.g., Safety & Deviation Review/Sign-Off Form, etc) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Product Deficiency Assessment & Reporting Documentation | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Database Lock/Unlock Form(s) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Evidence Dissemination (e.g. summary report, interal results communications/presentations, manuscripts, etc.) | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Clinical Study Report | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| Study Closure Checklist | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |
| End Study Documentation Reconciliation & Archiving Documentation | <Name(s)> | <Name(s)> | <Name(s)> | <Name(s)> |

### Applicable Regulations and Guidances.

This study involves evaluation of <study product(s)>: <Indicate product classification and risk level, as appropriate> e.g., Class I 510k exempt medical devices, Non-Significant Risk. One prototype and one commercially released device.

The study is being conducted at <#> study site<s> in <country(ies) where the study will be conducted>. The following regulations, GCPs and guidances apply:

|  |
| --- |
| <applicable federal reguations> (e.g., FDA 21 CFR Part 812.2b, Abbreviated Requirements) |
| <applicable GCPs> (e.g., ICH E6 GCPs, ISO 14155, etc.) |
| <other> (e.g., FDA Guidance for Industry; Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring) |

### Applicable Operating Procedures

The following 16.2.6 Manage Clinical Studies Operating Procedures shall be followed for this clinical study: (Note: enter the local procedure number at the Business, Market or SVAL organization, accountable for the clinical study execution)

|  |  |  |  |
| --- | --- | --- | --- |
| **Operating Procedure Short Name** | **Yes** (input local QMS Doc ID) | **No** (x) | **Explain Rationale if No is Selected** |
| Philips PQMS Standard: Pre-Clinical / Clinical Studies Controls | PBMS-QMS-S-0003 |  |  |
| Philips Global Clinical Studies Quality Procedure (CSQP) |  |  |  |
| Clinical Study Plan Procedure |  |  |  |
| CRO/Vendor Qualification and Management Procedure |  |  |  |
| Investigator Initiated Study Management Procedure |  |  |  |
| Site Regulatory File and Trial Master File Procedure |  |  |  |
| Investigational Product Management Procedure |  |  |  |
| Protocol Procedure |  |  |  |
| Investigator Brochure Procedure |  |  |  |
| Informed Consent Procedure |  |  |  |
| IRB/IEC Submission and Approval Procedure |  |  |  |
| Monitoring Procedure |  |  |  |
| Monitoring Plan Procedure |  |  |  |
| Data Management Plan Procedure |  |  |  |
| Statistical Analysis Plan Procedure |  |  |  |
| Database Lock Procedure |  |  |  |
| Clinical Study Registration Procedure |  |  |  |
| Adverse Event Monitoring Procedure |  |  |  |
| Product Deficiency Procedure |  |  |  |
| Risk Assessment Procedure |  |  |  |
| Clinical Study Report Procedure |  |  |  |
| Study Start-Up CHECKLIST |  |  |  |
| Informed Consent Form CHECKLIST |  |  |  |
| Trial Master File/Site Regulatory File Documents CHECKLIST |  |  |  |
| Study Closure CHECKLIST |  |  |  |
| Site Readiness CHECKLIST |  |  |  |
| Clinical Study Request FORM |  |  |  |
| CTMS Registration and Updating WI |  |  |  |

# Appendices

*Include appendices as applicable to complete document. If appendices are not necessary, this section may be removed.*

# Document Revision History

| **Version** | **Date** | **Author** | **Description of Change** | **Reason for Change** |
| --- | --- | --- | --- | --- |
| <number> | <date> | <end user/author> | <’Initial Release’ or description of change(s)> | <specify> |
|  |  |  |  |  |
|  |  |  |  |  |

# Document Approval History

*Include the table below if this section is required.*

*This section is for any documents requiring approval (e.g., clinical study protocol, clinical study report, etc.).*

*Clinical Study Protocols should be approved by a Clinical Operations Manager and/or, Clinical Development Manager, and the Biostatistician.*

*Clinical Study Reports should be approved by the Clinical Study Lead, Clinical Operations Manager and/or, Clinical Development Manager, and the Biostatistician.*

*Consider additional local requirements for approvers: e.g., Medical Monitor, Manager in Regulatory Affairs, Clinical Scientific Lead, etc.*

*Note: For those documents that will end up in a Design History File, approvals should be collected.*

*Before submitting the document for approval, make sure all changes are accepted/rejected and all comments are deleted.*

*If approval is not necessary, this section may be removed*

| **Approved by** | **Role / Function** | **Signature & Date** |
| --- | --- | --- |
| <name> | <role/function> | <signature and date> |
|  |  |  |
|  |  |  |