

Clinical Study Request Form

Complete for each clinical study prior to study enrollment and according to 16.2.6 Managing Clinical Studies PEPF.

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| **MINIMUM REQUIREMENTS FOR CTMS REGISTRATION**  **(Please ensure all of the information in the table below is entered before submitting this form to the CTMS Admin at** [DL\_ClinicalStudyRequestFormSubmission@philips.com](mailto:DL_ClinicalStudyRequestFormSubmission@philips.com). **All human testing and research sponsored or supported by Philips must be registered in CTMS)** | | | |
| **Clinical Classification**  **Governance Board (CCGB)**  **Classification Decision Date:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **CCGB Members:**  **Clinical\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Regulatory \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Innovation/PRC/Other:\_\_\_\_\_\_\_\_\_\_\_\_** | **CCGB Classification:**  **Clinical Investigation**  **Clinical Study**  **Consumer Product Test**  **No Safeguards Required**  **Additional Safeguards Required (specify)**  **Consumer Preference Test**  **No Safeguards Required**  **Additional Safeguards Required (specify)**  **Secondary Data Analysis**  **No Safeguards Required**  **Additional Safeguards Required (specify)**  **Market Research** | **CCGB Recommended Safeguards with Philips Clinical and Scientific Affairs Support:**  **IRB/EC Full Submission**  **IRB/EC Request Waiver**  **Clinical Study Protocol Modifications (attached)**  **Clinical Study Informed Consent Modifications (attached)**  **Submit for Legal Review**  **Submit for HR Review**  **Submit for Privacy Review**  **Other (specify):** | |
| **PROJECT INFORMATION** | | | |
| **Business Group** |  | | |
| **Business Innovation Unit and Location** |  | | |
| **Project Name** | Study\_Name\_Test | | |
| **Year of Protocol Start** |  | | |
| **Primary Project Contact** | Study\_Lead\_Test | | |
| **Countries** |  | | |
| **Study is intended to Support** | Clinical or Medical Claim  Peer Reviewed Publication  Product Verification or Validation  Product Feasibility/Early Research/Development  Competitor Product Assessment | | Regulatory Submission  Clinical Evaluation (Supporting MDR product conformity)  Other (specify):\_\_\_\_\_\_\_\_ |
| **Clinical Study Sponsor** | Philips Sponsored  Philips Supported (Investigator Initiated Study) | | |
| **STUDY PRODUCT** | | | |
| **Product Name(s)** |  | | |
| **Product Release Status (date if known)** |  | | |
| **Product Regulatory Status (indicate status by country and product)** |  | | |

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| **BUSINESS STAKEHOLDERS** | | | |
| **Project Manager**   N/A |  | | |
| **Clinical Lead** |  | | |
| **Medical Monitor**  N/A |  |  | |
| **Regulatory Affairs Lead**  N/A |  | | |
| **Product Development (e.g., Engineering, R&D, Innovation & Development, Clinical Science, Product Research Center (PRC), ISE, Philips Research)**  N/A |  | | |
| **DM/Stats Lead**  N/A |  | | |
| **Privacy Officer** | Monica Sanches | | |
| **Other Key Project Team Members /Stakeholders** | Marketing:  Legal Representative:  Other: | |  |

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| **Request INPUTs** | | | | | | | | | | | | | |
| 1. **Objectives of Study:** |  | | | | | | | | | | | | |
| 1. **Study Requirements** | **How will study be managed:** | | | | | | | | | **Clinical Study Role** | | **Name of Employee filling role** | |
|  | **Philips Managed (specify who will manage study)**  Philips Clinical and Scientific Affairs  Philips on campus study – (specify Dept.)\_\_\_  Product Research Center (PRC) (specify Site:)\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other (specify): | | | | | | | | Clinical Study Manager | |  | |
| Clinical Research Associate | |  | |
| Data Management Lead  N/A | |  | |
| Biostatistics Lead  N/A | |  | |
|  |  | **Externally Managed**  **(approved supplier ARIBA #/Vendor # and Clinical Vendor Qualification Report required in Trial Master File)** | | | | | | | CRO: | |  | |
| Other: | |  | |
|  | **Specify activities to be outsourced:** | | | | | | |  |  | | | |
|  |  | Study Management | | |  | Data Management | |  | Data Monitoring Committee/Clinical Events Committee (Adjudication) | | | |
|  |  | Monitoring | | |  | Statistics | |  | Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  |  | Safety Monitoring | | |  | Laboratory Analysis | |  |  | | | |
|  |  | Recruitment | | |  | Image Management | |  |  | | | |
| **3. Device/Product Classification** | Class I  Class II/IIA/IIB  Class III  Cosmetic | | | Consumer (not-regulated in country where it is being tested)  Wellness  Combination  Other:\_\_\_\_\_ | | | | | | | | | |
| **4. Study Design Proposed** | **Target Population Characteristics:** | | | | Normal Healthy  Pregnant  Other (specify clinical characteristics): | | | | | | | | |
| **Target Age Range:**  **(multiple categories may be selected as applicable)** | | | | Adult  Elderly  Pediatric  Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | |
| **Target Number of Subjects:** | | | |  | | | | | | | | |
| **Target Number of Sites:** | | | |  | | | | | | | | |
| **Relevant Prior Clinical Studies:** | | | |  | | | | | | | | |
| **General Study Design Comments:** | | | |  | | | | | | | | |
| **5. Add Other Key Inputs**  **(report ANY that may impact**  **Trial Design, Site Selection or**  **Timeline considerations)** | **Desired Target Date for Study Results:** | | | | | | |  | | | | | |
| **Project Budget:** | | | | | | |  | | | | | |
| **Project Number/Cost Center #:** | | | | | | |  | | | | | |
| **Other Inputs:** | | | | | | |  | | | | | |
| **6. Registry Requirements** | Yes, project needs registration  No, project does not need registration | | | | | | | **Applicable Registry:** | | | | | |
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| **7. Privacy** | **Type of Personal Data: (PIA or self-assessment completed)** | | | | | | | Image or biometric data capture | | | | | |
| Personal technology (application, software install) | | | | | |
| Other Personal Identifying Information/Personal Data | | | Specify: | | |
| PIA or Self-Assessment Completed | | | Specify: | | |
| **8. Document Revision History** | | | | | | | | | | | | | |
| **Version** | **Date** | | | | | | | **Author** | | | **Description of Change** | | **Reason for Change** |
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This study request form will be updated to reflect changes until the Clinical Study Plan is finalized

Filed: Trial Master File

# Document history

| **Version** | **Release Date** | **Author** | **Description of changes** | **Change Request** |
| --- | --- | --- | --- | --- |
| 1 | See OpenText approve date | Christina Villar | Initial Release | NA |
| 2 | See OpenText approve date | Christina Villar | Added the Section for the Clinical Classification Governance Board decisions and other minor edits | CDI-CR-732 |