|  |
| --- |
| Protocol Summary - Master Disclosure Document for Interventional Studies |

| The Information on this page will not be posted |
| --- |
| Before using this template for authoring, refer to the supplemental instructions on [Find-IT](https://tinyurl.gsk.com/MDD%20for%20interventional%20studies). This template is used for ALL Interventional studies that evaluate the safety, efficacy or effectiveness of a GSK product.  Master Disclosure Document (MDD) serves as the source document to disclose protocol related information across different clinical trial registers (e.g. ClinicalTrials.gov, EU Clinical Trials Information System (EU CTIS) and/or GSK/ViiV Clinical Study Register) as required by external regulations and/or GSK policy. Check in TMF for the latest version of the template before initiating a new MDD. As information from the approved MDD will be disclosed on publicly available clinical trial register(s) as required by applicable regulations and GSK policy, minimize inclusion of information that may be considered commercially confidential. |

|  |  |
| --- | --- |
| Title of study | Click or tap here to enter text. |
| Study identifier /CTMS number | Click here to enter text. |
| European Union (EU) Clinical Trial Regulation (EU CTR) number (if applicable) | Click or tap here to enter text. |
| Is this an Applicable Clinical Trial (ACT)? | Choose an item. |
| Trial registers where the study will be disclosed | Choose an item. |
| MDD version date | MDD Version X.0 based on final protocol version X /protocol amendment x dated dd-mm-yyyy |
| Approver: | |
| **Clinical Lead/equivalent** | Click or tap here to enter text. |

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Summary of changes table

Information included in the MDD should be aligned with that in the study protocol, in line with Data integrity principles. In exceptional cases, where the information in the MDD is different to that in the protocol (e.g. less detailed, more specific, endpoints details not disclosed due to confidential reasons etc.), the key differences should be captured in the table below.

This table is for internal documentation purposes and will not be disclosed on external registers.

**Any additions or deletions made as part of amendments are captured in the below table.**

**List of main changes in the MDD compared to the protocol with the rationale for change:**

|  |  |  |
| --- | --- | --- |
| Section # and Name of the field  {Add section number and name} | Description of Change  {Describe the main changes made in the MDD as compared to the protocol} | Brief Rationale  {Provide rationale for this specific change} |
|  |  |  |

# Sections to be Completed for ClinicalTrials.gov, EU CTIS and GSK Study Register/ViiV Study Register

## Identification

|  |  |  |
| --- | --- | --- |
| Unique Protocol ID | Click here to enter text. | |
| Brief title | Click or tap here to enter text. | |
| *Acronym* | Click here to enter text. | |
| *CTMS abbreviated title [EU only]* | Click or tap here to enter text. | |
| Official title of the trial | Click or tap here to enter text. | |
| *Secondary IDs* | Click or tap here to enter text. | |
| *Secondary ID type* | Choose an item. | Click or tap here to enter text. |
| Sponsor | Choose an item. | |
| *Collaborators* | Click or tap here to enter text. | |

## Study Description

|  |  |
| --- | --- |
| Brief summary | Click here to enter text. |
| *Detailed description* | Click here to enter text. |
| Main objective(s) [EU only] | Click here to enter text. |
| Secondary objective(s) [EU only] | Click here to enter text. |
| Data monitoring committee | Choose an item. |

## Conditions and Keywords

|  |  |
| --- | --- |
| *Keywords* | Click here to enter text. |
| Medical condition(s) investigated [EU only] | Click here to enter text. |
| Therapeutic area [EU only] | Choose an item. |
| Rare disease [EU only] | Choose an item. |

## Study Design

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Primary purpose | Choose an item. | **Scope of the trial (EU only)** | Diagnosis  Prophylaxis  Therapy  Safety  Efficacy  Pharmacokinetic  Pharmacodynamic  Bioequivalence  Dose response  Pharmacogenetic  Pharmacogenomic  Pharmacoeconomic  Others | |
| Study Phase | Choose an item. | | | |
| Type of human pharmacology (Phase 1) study (EU only) | Choose an item. | Click here to enter text. | | |
| Interventional study model | Choose an item. | *Model description* | | Click or tap here to enter text. |
| Allocation | Choose an item. | | | |
| Anticipated date of results (EU only) | Click here to enter text. | | | |
| Number of arms | Click or tap here to enter text. | | | |
| Masking type  (EU only) | Choose an item. | Masked roles | Participant  Care Provider  Investigator  Outcomes Assessor  No Masking  Monitor (EU only)  Data Analyst (EU only) | |
| *Masking description / Blinding implementation details* | Click here to enter text. | | | |

## Arms / Groups and Interventions

|  |  |  |  |
| --- | --- | --- | --- |
| Arms  *Repeat below rows depending on number of arms* | | | |
| Arm / Group Label | Click here to enter text. | Arm / Group type | Choose an item. |
| Arm / Group description | Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Interventions  *Repeat below rows depending on number of interventions* | | | |
| Intervention name | Click here to enter text. | Intervention type | Choose an item. |
| Intervention description | Click here to enter text. | | |
| *Other names* | Click here to enter text. | | |
| Relationship between Arms & Interventions  *Repeat below rows depending on number of arms)* | | | |
| Arm | Click or tap here to enter text. | Intervention | Click or tap here to enter text. |

## Primary and Secondary Outcome Measures

Complete a table below for each endpoint

**Note**: Outcome measure description is a conditionally required field. This can be left blank if the outcome measure title provides sufficient description of the evaluation.

### Outcome Measure 1

|  |  |
| --- | --- |
| Outcome measure type | Choose an item. |
| Outcome measure title | Click here to enter text. |
| *Outcome measure description* | Click here to enter text. |
| Time frame | Click here to enter text. |

## Eligibility Criteria

|  |  |  |  |
| --- | --- | --- | --- |
| Sex | Choose an item. | | |
| *Gender based* | Choose an item. | *Gender eligibility description* | Click here to enter text. |
| Age Limits | Minimum age | Click here to enter text. | Choose an item. |
| Maximum age | Click here to enter text. | Choose an item. |
| Age ranges (EU only) | In utero | Click or tap here to enter text. | |
| 0-17 years | Click or tap here to enter text. | |
| 18-64 years | Click here to enter text. | |
| 65+ years | Click here to enter text. | |
| Accepts healthy volunteers | Click here to enter text. | | |
| Study population types (EU only) | Patients  Specific vulnerable populations  Women of childbearing potential not using contraception  Women of childbearing potential using contraception  Pregnant women  Nursing women  Emergency situation  Participants incapable of giving consent  Others (vulnerable populations)  Click here to enter text. | | |
| Inclusion criteria | Click here to enter text. | | |
| Exclusion criteria | Click here to enter text. | | |

**Note:** If there are specific national or local register requirements for submitting the Clinical Trial Application (CTA) in Mexico or other countries that use the centrally approved MDD for protocol registration, ensure to include the complete list of inclusion and exclusion criteria. Also, inform the study team about this requirement.

## Rationale for Protocol Amendments and Study Termination/ Cancellation

|  |  |
| --- | --- |
| Study Termination / Cancellation | |
| Recruitment status | Choose an item. |
| Why study stopped | Click here to enter text. |

# Sections to be Completed by the CTT Team with Input from the Study Team

## US Food and Drug Administration (FDA) Information – IND/IDE Information

|  |  |
| --- | --- |
| Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information | |
| U.S. FDA IND/IDE study | Choose an item. |
| FDA center (formerly IND/IDE grantor) | Choose an item. |
| IND/IDE number | Click here to enter text. |
| *IND serial number* | Click here to enter text. |
| US FDA regulated drug | Choose an item. |
| Product exported from US | Choose an item. |
| Availability of expanded access | Choose an item. |
| Expanded access record National Clinical Trial (NCT) number | Click here to enter text. |
| *Plan to share IPD data* | Choose an item. |

# Links

|  |  |
| --- | --- |
| url | Description |