

Research Progress Report Form

For Office Use:

Date received: _____ (dd/mm/yy)

Application Reference No.: _____

Research identification

| | |
|-------------|--|
| Study title | |
|-------------|--|

| | | | |
|------------------------|--|----------------------|----------------|
| GHK Reference No. | | Study start date | ____/____/____ |
| Protocol no. | | Anticipated end date | ____/____/____ |
| Principal investigator | | | |

Research Progress Report

| | | | |
|--|--|---------------|----------------------------------|
| Research Report sequence no. | | Report period | ____/____/____ to ____/____/____ |
| Maximum number of participants/samples/records planned (local) : _____ | | | |
| No. completed study | | No. recruited | |
| No. withdrew | | | |
| Withdrawal reasons: | | | |

Changes

| | |
|--------------------------|----------------|
| Study protocol change | [] Yes [] No |
| Investigator change | [] Yes [] No |
| Have they been reported? | [] Yes [] No |
| Nature of change: | |

Summary of Serious Adverse Events

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Does the SAE affect the study, and how?

Yes No

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|--|

Summary of Complaints from Subjects

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Interim Analysis of Data

According to schedule Yes No Not Applicable

Updated Information

| | |
|---|--|
| Updated information that may affect a subject's willingness to continue (e.g. recall of investigation product) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| New evidence that addresses the research hypothesis | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Describe new information and actions taken: | |
| Is the 'Certificate of Insurance' (if applicable) of the study still valid? Please attach renewed 'Certificate of Insurance' if the present one is expired. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Public disclosure of this Clinical Trial*

**Defined by World Health Organization (WHO) as any experimental study which prospectively allocates humans to a medical intervention. For reporting purposes, it includes non-randomised Phase I trials, randomised Phase I, II or III trials, and Phase IV or post-licensure trials of health products if they involve prospective designs (with or without randomisation).*

Source: Statement on Public Disclosure of Clinical Trial Results <http://www.who.int/ictpr/results/reporting/en/>

| | |
|---|---|
| Is this study a Clinical Trial? | <input type="checkbox"/> Yes (Proceed to answer the next question) <input type="checkbox"/> No (no need to answer the following questions) |
| This clinical trial is registered in a publicly available, free to access, searchable clinical trial registry | <input type="checkbox"/> Yes (Proceed to answer the next question) <input type="checkbox"/> No (no need to answer the following questions) |
| Name of the clinical trial registry | |
| Registry identifier code/number for this clinical trial | |

Current progress of Study

Continue according to the plan

Extend study period, due to:

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Premature termination, due to:

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Report by:

| Name | Signature | Date |
|------|-----------|------|
| | | |