# MONITORING PLAN

**Author:**

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| --- | --- | --- | --- |
| Name | Designation | Signature | Date |
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**Approval Signatures:**

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| Name | Designation | Signature | Date |
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| 1. **Study details:**  |  |  |  |  | | --- | --- | --- | --- | | TASC (R&D) reference: |  | | | | EudraCT Number: |  | | | | Study title: |  | | | | CI/PI name: |  | | | | Monitoring plan version: | Version: 1  Date: | Previous versions | n/a  or Version | | If an update to a previous version explain the circumstances |  | | | | Type of study: | CTIMP | Non-CTIMP | | | Sponsor name: |  | | | | Sites: | Single centre | Multi-centre | | | Proposed start date/ recruitment period/  follow up/ LPLV: |  | | |  1. **Rationale for monitoring plan:**  |  |  | | --- | --- | | CTIMP |  | | High risk non-CTIMP |  | | Risk assessment recommendation |  | | Hosted study |  | | Investigator request |  | | Other |  | | | | | |  |
| 1. **Risks**  |  | | --- | | Have any particular risks been identified for the study and how will monitoring strategy mitigate these risks? |      1. **Study oversight Committees:** | | | | |  |
|  | Y | N | N/A |  | | |
| Trial management group |  |  |  |  | | |
| Independent data monitoring committee |  |  |  |  | | |
| Trial steering committee |  |  |  |  | | |
| TCTU management committee |  |  |  |  | | |
| Comments: | | | |  | | |

1. Study Activities:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Y | N | N/A |
| Investigator training/Investigator meetings |  |  |  |
| Validated randomisation process |  |  |  |
| Trial data recorded on validated database or sent to co-ordinating centre |  |  |  |
| Central PV reporting procedure (if CTIMP) |  |  |  |
| Experienced Investigator and research team |  |  |  |
| Comments: | | | |

**Study sites:**

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| --- | --- | --- |
| **Study site** | **Name of NHS Hospital/Organisation** | **Expected Participant Numbers** |
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***Note: Should further sites be added after the monitoring plan has been written this document will not require to be re-issued.***

1. **Summary of planned monitoring visits and reporting:**

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| --- |
| Site Initiation visit  yes  no  n/a  If yes: frequency and timing |
| Detail of activities to be carried out at the Site Initiation Visit (SIV): |
| On site monitoring visits  yes  no  n/a |
| Detail of activities to be carried out at the onsite monitoring visits: |
| Remote monitoring visits  yes  no  n/a |
| Detail of activities to be carried out at the remote (via video conferencing) monitoring visits: |
| Close out visit  yes  no  n/a |
| Detail of activities to be carried out at the Close out visit: |
| Centralised monitoring  yes  no  n/a |
| Detail of activities to be carried out by Centralised monitoring: |
| Other  yes  no  n/a |

1. Completed/Signed off Monitoring reports will be sent to:

|  |  |
| --- | --- |
| **Name** | **Designation** |
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**Strategy for achieving resolution of monitoring action points:**

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| Resolution of monitoring action points will be requested by the monitor at the below times: |
| In the event of non-response who will be notified: |
| Strategy for achieving complete resolution of action points: |

1. Escalation/De-escalation of Monitoring Activity:

|  |
| --- |
| Under what circumstances will monitoring activity be increased or decreased: |
| How will change of activity be decided and by whom: |
| Describe how this will be documented: |