# MONITORING PLAN

**Author:**

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

**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: 1Date:  | Previous versions  |  [ ] n/aor 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:**

|  |  |  |
| --- | --- | --- |
| **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:**

|  |
| --- |
| 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: |