**EudraCT no:** (if applicable)

|  |  |  |
| --- | --- | --- |
| **Version No.** | **Version date** | **Description of Changes** |
| 1.0 |  | NA |
|  |  |  |

**Trial Manager:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Chief Investigator:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sponsor Representative:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

Contents

[1. Trial Overview 3](#_Toc497401172)

[2. Trial responsibilities 3](#_Toc497401173)

[3. Trial monitoring overview 3](#_Toc497401174)

[4. Trial monitoring plan 4](#_Toc497401175)

[5. Trial team monitoring of the trial 5](#_Toc497401176)

[6. Independent monitoring of the trial 5](#_Toc497401177)

[7. Pre-activation monitoring of the trial – initiation meeting 5](#_Toc497401178)

[8. Triggered monitoring of the trial 5](#_Toc497401179)

[9. Monitoring of the trial at trial closure 5](#_Toc497401180)

# Trial Overview

|  |  |
| --- | --- |
| **Trial phase** |  |
| **Estimated number of sites** |  |
| **Sponsor** |  |
| **Risk assessment** (*Version no. & date)* |  |
| **Planned number of participants** |  |
| **Chief Investigator** |  |
| **Trial/Data Manager(s)** |  |
| **Clinical Research Facility(ies)** |  |
| **Investigational Medical Product(s)** |  |
| Approx. start/open date (1st site) |  |
| Length of follow-up period |  |

# Trial responsibilities

[Please outline]

***Swansea Trials Unit***

***Site research staff (e.g. research nurses)***

***Site NHS staff (e.g. medical staff, administrators)***

***Laboratory staff (if applicable)***

***Pharmacy staff (if applicable)***

# Trial monitoring overview

[Please give an overview of the plans for research project monitoring, based on the risk assessment completed]

*Suggested further areas for monitoring below:*

|  |  |
| --- | --- |
| **Trial Master File contents** |  |
| **Trial site file contents** |  |
| **Consent documentation** |  |
| **Safety reporting** |  |
| **IMP accountability** |  |
| **Trial amendments** |  |
| **Roles & Responsibilities** |  |
| **Potential deviations or protocol violations** |  |
| **Key trial decisions** |  |
| **Data Management** |  |

# Trial monitoring plan

[Please add or remove items as required]

**4.1 Monitoring Overview – Initiation & Training**

|  |  |  |
| --- | --- | --- |
| Type of Monitoring | Monitoring Activity and Frequency | Responsibility |
| **Trial Initiation (i.e. Sponsor initiation meeting)** |  |  |
| **Site/**  **Investigator training** |  |  |
| **Set out site green light procedure** |  |  |
| **On-going training** |  |  |

**4.2 Monitoring Overview – On-site Monitoring**

|  |  |  |
| --- | --- | --- |
| Type of Monitoring | Monitoring Activity and Frequency | Responsibility |
|  |  |  |
|  | Areas of monitoring at site are as follows  ***1. Investigator Site File*** |  |
|  | ***2. Protocol deviations*** |  |
|  | ***3. Trial Team delegation log*** |  |
|  | ***4. IMP*** |  |
|  | ***5. Trial subjects, eligibility & source verification data*** |  |
|  | ***6. Serious adverse events*** |  |
|  | ***7. Lab equipment*** |  |
|  | ***8. Material transfer logs*** |  |

**4.3 Monitoring Overview – Central Monitoring**

|  |  |  |
| --- | --- | --- |
| Type of Monitoring | Monitoring Activity and Frequency | Responsibility |
| Data quality |  |  |
| Data completeness |  |  |
| Safety |  |  |
| Protocol deviations |  |  |
| Logs/GCP/CVs |  |  |
| IMP |  |  |

# Trial team monitoring of the trial

[Please outline here]

|  |  |  |  |
| --- | --- | --- | --- |
| **Monitoring group** | **Monitoring Activity and Frequency** | **Frequency** | **Managed by** |
| TMG |  |  |  |
|  |  |  |  |

# Independent monitoring of the trial

[Please outline]

|  |  |  |  |
| --- | --- | --- | --- |
| **Monitoring group** | **Monitoring Activity and Frequency** | **Frequency** | **Managed by** |
| TSC |  |  |  |
| DSC |  |  |  |

# Pre-activation monitoring of the trial – initiation meeting

[Please outline]

* Essential Documents held in TMF & ISF

# Triggered monitoring of the trial

[Please outline]

Causes of triggers:

1.

2.

# Monitoring of the trial at trial closure

At trial closure, the following checks should be undertaken:

|  |  |  |
| --- | --- | --- |
|  | **Monitoring Activity and Frequency** | **Responsibility** |
| **CRFs** |  |  |
| **Samples** |  |  |
| **Laboratory equipment** |  |  |
| **TMF** |  |  |
| **ISF** |  |  |
| **Pharmacy files** |  |  |
| **IMP** |  |  |
| **SAEs** |  |  |