Monitoring rules

Setting up the monitoring plan

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1) What is the Monitoring?

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

2) Who is the Clinical Monitor?

The person with direct access to patient's medical records to verify data and /or procedure acting within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

(*Guideline for GCP-CPMP/ICH/135/95*)

Monitoring rules

Trial monitoring procedures should be described in such a way as to:

- make clear the responsibilities of the staff involved, including their organisation training and relationship to other trial staff, (i.e. arrangements for central monitoring),

- decide the frequency and nature of site visits and how the results of monitoring inform other activities such as the training of personnel at study sites.

- provide valuable information that can be used to improve trial methods and to focus further training.

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This document is intended to collect all the decisions made and information needed for pratical monitoring purpose, it will not supersede the protocol in any way.

It is to be used to avoid scatering of decisions and recommandations related to trial monitoring in different documents.

Monitoring guidelines will be revised on a regular basis and sent to CRAs that should discard previous version.

Monitoring plan containts 1/3

- ***Rationale***
- ***Abbreviations***
- ***Standard Operating Procedures (SOPs)***
- ***Site Visits: (SIV, RMV, COV)***

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Monitoring plan containts 2/3

- ***Source data verification***
- ***Previous and concomitant medication***
- ***Handling of blood samples***
- ***Handling Protocol Deviations***

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Monitoring plan containts 3/3

- ***DCF workflow***
- ***ADRs , AEs and SAEs:***
- ***Monitoring visit reports flow***
- ***Sending of documents to Sponsor***

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Monitoring plan

Let's go exercise……Monitoring Guidelines_scheme_exc_MLP.pdf

Thank you for your attention

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