Zentralinstitut
für Seelische
Gesundheit

IMMERSE – report on sponsor/site inspection to SC meeting

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Reason for inspection:

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Reason for inspection:
validating a new checklist for other clinical investigations

Sponsor inspection: findings

Critical findings: NONE!

Major findings: 1

Monitoring

a. Monitoring plan is not adequate for monitoring according to ISO 14155 (6.7, 7.3, 9.2.3 c, 9.2.4.2, 9.2.4.5b)
b. So far, no 100% SDV of ICFs performed by the CRO
c. Qualification of monitoring staff is inadequate (Daniela Penn, Sophie Penn)
d. SIV reports did not list all individuals that were present (this has been corrected in the meantime)
e. Monitoring reports have not been signed by the sponsor

As for quality assurance, the sponsor must ensure adequate and regular monitoring of the clinical investigation from now on. We strongly recommend that the monitor (medX) prepares more extensive and detailed monitoring reports

Sponsor inspection: findings

Minor findings: 6

1. Information For Use
   a. Section on vigilance and SAE is not required for other clinical investigations

The instructions for use must be revised and only refer to the use of the MoMent App or MoMent Management Console and be submitted to the EC and CA with the next amendment.

2. Insurance
   a. The terms and conditions of the insurance refer not to the MDR.

The sponsor must immediately request the valid terms and conditions of insurance from the insurance company and pass them on to the investigational sites, which are requested to hand them out to participants (patients and clinicians).

Sponsor inspection: findings

3. CIP

a. The section on vigilance and SAE includes definitions of the MDR and ISO 13155 and mentions that AEs are monitored after completion of the clinical investigation, but does not include the required timelines for investigators to report AEs to the sponsor.

The CIP shall be amended/revised by the sponsor with regard to the vigilance system according to MDR in conjunction with the MPDG. The definitions and reporting requirements in the eCRF must correspond to those mentioned in the CIP. In the next amendment the new version of the CIP needs to be submitted to EC and CA.

4. Contracts

a. Investigator Site contracts need to be signed by all parties (has been corrected in the meantime)

b. Some individuals have responsibilities at the clinical investigation site (Mannheim) and as delegates of the sponsor. This has to be described more clearly and data integrity has to be assured.

The responsibilities of the individuals, who work simultaneously for the sponsor and at the clinical investigation site (Mannheim) must be described more clearly.

Sponsor inspection: findings

5. Selection of sites

a. The selection reports (qualification of the sites) for the clinical investigation sites in the Slovak republic were not available in the TMF.

The relevant documents by the Slovak sites have been stored in the TMF in the meantime (thanks, Adam and Iveta!)

6. Deviations

a. The sponsor is responsible for documenting all deviations (9.2.3 b DIN EN ISO 14155). The inspector recommends to combine the list of deviations with the CAPA plan.

Inspection of clinical investigation site: findings

Critical findings: NONE!

Major findings: 1

Investigators

a. All investigators have to be approved by the ethics committee

If investigators are added to clinical investigation sites during the clinical investigation, an amendment must be submitted to the EC and CA. The qualification of investigators must be approved by the EC.

Inspection of clinical investigation site: findings

Minor findings: 5

1. Insurance
   a. the terms and conditions of the insurance refer to the MPG, not MPDG (MDR)

The sponsor must immediately obtain the valid terms and conditions from the insurer, pass them on to clinical investigation sites, which, in turn, must hand them out to patients and clinicians.

2. Delegation Log
   a. Responsibilities/tasks of the roles ‘intervention support’ and ‘assessor’ have to be specified in more detail
   b. The tasks/roles need to be disentangled

Delegation log should be revised

Inspection of clinical investigation site: findings

Minor findings: 5

3. Monitoring Report
   a. In the remote monitoring report, only the signed eCRF forms were monitored and only 2 queries were included

From now on, we strongly recommend that the Monitor produces more detailed follow-up letters indicating what has been monitored and the queries that still need to be for the site. The principal investigator of the site needs to sign the monitoring reports.

4. Informed consent forms
   a. Must include the dates provided personally by participants and investigators
   b. Both legal representatives / parents need to sign informed consents for minors

ICF needs to be revised and submitted to EC in the next amendment

Inspection of clinical investigation site: findings

Minor findings: 5

5. Device Accountability Log
   a. as the investigational device is an app, it is not possible to complete/maintain a device accountability log

The site should consider whether completing a different list (other than the device accountability log) may be more useful and whether the current list can be dropped

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Thank you!