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NORWEGIAN CLINICAL
RESEARCH INFRASTRUCTURES NETWORK

Procedures for clinical drug trials and other clinical interventional and observational studies

Hi,

Several procedures and templates have now been updated.

For clinical drug trials:

This will be the last release describing the current legislation before the release of procedures reflecting the new regulation 536/2014. Most documents are in English, some in Norwegian. Please find all the documents here.

The Flowchart for use of the procedures has been updated and is now in English. We will soon release a video that explains how to use the flowchart.

The two main changes concerning:

Safety:

Learning material has been developed.

All procedures and templates have been revised emphasizing the role of the medical monitor (one or several medical doctors) for any trial.

For international trials, there is a need to be aware of the requirements in other countries and to be able to fulfill them. One of these requirements may be to be able to report SUSARs through EudraVigilance, a European safety database. St. Olav Hospital (SOH) and Oslo University Hospital (OUH) are planning to get certified to enter data into the database. For any sponsor to be able to use the services at SOH and OUH, the sponsor needs to appoint a Responsible Person (RP), see 2-16 Vedl 02 Eudravigilance registration and SUSAR reporting. So while the sponsors get their RP in place, SOH and OUH will pursue the certification.

For those who will require the services from SOH or OUH, there will be a need to get a data processing agreement in place, Data Processing Agreement SUSAR Reporting, and a trial specific agreement. We will come back with more information later.

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Monitoring:

The documents are now reflecting the pandemic. Don't worry, the monitors have been adapting to the pandemics quite early after SARS-CoV impacted the health care system.

All monitoring reporting templates have been updated.

The requirement to have a data processing agreement in place for monitoring with other institutions than the monitor's own institution has been added.

For details, see attachment 1.

For other clinical interventional and observational studies

The guideline for studies that are not drug trials nor medical device trials, but fall under "Helseforskningsloven" (the Health research act) has been updated to include also observational studies. The guideline has been expanded to include guidance for specific types of interventions and monitoring reports that can be used by monitors.

Best regards

Anne Mathilde Henden Kvamme
Cathrine Haga Hartveit
Martha Colban
On behalf of NorCRIN Work package 2

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Attachment 1

Revisions done in February 2021

Document	Revision undertaken
Roles and Responsibilities in Clinical Trials	Added that local agreements between the university and the hospital defining the sponsor may apply. Added roles of medical monitor and coordinating investigator. Ensuring a protocol deviation handling plan is in place has been added to the tasks for lead monitor.
1-07 Co-monitoring	The SOP has been changed to reflect that the aim of co-monitoring is to increase harmonization across the regions and ensure compliance with the trial's monitoring plan.
1-07 Vedl 01 Co-monitoring Visit Report	Restructured the questions to focus on unresolved / significant issues or issues to be shared with the monitor group.
2-01 Vedl 04 DMC charter	Has been made more user-friendly.
2-01 SOP 2-02 Quality and Risk Management	Last release was by a mistake without changes (but said there were changes).
2-02 Vedl 01 Risikovurdering	The following items for discussion have been added: The informed consent document should include information about the monitor's right to review the medical records. Reporting from lab about outliers Are lab analysis methods established for all analysis? If not, when will it be in place? Will it have consequences for the duration of the trial?
2-02 Vedl 03 Monitoring plan	A section about monitoring during pandemics has been added. Training on protocol deviations and serious breaches on initiation visit has been added in addition to the possibility to include follow up on deviation as a monitoring activity. Possibility of monitoring using a videoconference system has been added.
2-09 Vedl 16 Mal Screening log	New format. Person identifiable information such as date of birth has been removed.
2-09 Vedl 17 Template Screening log	New format. Person identifiable information such as date of birth has been removed.
2-12 Vedl 01 Avtale med forskningsstøtte	Updated to include SUSAR recording and reporting through EudraVigilance

2-12 Vedl 03 Mal avtale multisenterstudie	The agreement has been modified to be more in line with the English template for international studies. Also the formatting with blue and red colours has been introduced. A section with definitions has been added. PI's responsibility for safety reporting has been clarified. Data management and sharing of data has been updated with regards to GDPR. Everything regarding financials has been gathered under a specific section. The publication and ownership sections have been changed. Force majeure has been added.
2-12 Vedl 13 NCI Disclosure and Commitment Form	Developed as part of the safety SOPs revision.
SOP LM 2-14 Monitoring	Added that off-site monitoring can be considered when on-site monitoring is restricted/not allowed due to e.g. pandemics. Added that if the monitor is employed at an another institution than sponsor, the sponsor should ensure a data handling agreement is signed.
SOP LM Monitoring for monitors	Added instructions on how to use "not applicable" and "not checked" boxes. Added use of DSURs in international trials. Added monitor's role in assisting wiht risk-based Monitoring Plan, Protocol Deviation Handling Plan and Data Processing Agreement if applicable. Rectified minor mistakes.
2-14 Vedl 01 Initieringsrapport monitorering	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 02 Study Initiation Monitoring Report	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 03 Monitoreringsrapport	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 04 Monitoring Report	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 05 Avslutningsrapport monitorering	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 06 Close-out Monitoring Report	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 07 Monitorering av forskningsbiobank	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting
2-14 Vedl 08 Biobank Monitoring Report	Instructions have been added. These are visible when the paragraph mark is activated. "Not applicable" boxes are now white and do therefore not require commenting

2-14 Vedl 11 Databehandleravtale	New. Data Processing Agreement for studies monitored from other institution
SOP 2-16 Safety planning	New SOP. Introducing medical monitor and use of "Safety Reporting Specifics". Specifics for international trials. Possibility for use of Eudravigilance
2-16 vedl 01 Safety reporting specifics	New document. Defines roles and requirements for safety reporting. Section 5.0 is especially important for international trials.
2-16 Vedl 02 Eudravigilance registration and SUSAR reporting	New working instruction for CTUs offering reporting through Eudravigilance
2-16 Vedl 03 Data Processing Agreement SUSAR reporting	New document. For use when contracting CTU for registration and reporting in EudraVigilance
SOP 3-04 Safety reporting	This SOP will replace SOP 3-04 version 3.1 and SOP no. 3-06 version 3.0. Included urgent safety measures and pregnancies.
3-04 Vedl 01 DSUR template	Reviewed. No major changes.
SOP 3-06 Årsrapportering	Removed. Is replaced by SOP 3-04.
3-06 Vedl 01 Template DSUR	Removed. Is replaced by 3-04 Vedl 01.
CIO Guideline for interventional and observational studies	Replaces AI Guideline for Clinical Interventional Studies v.1.0. Observational studies included, Monitoring visit reports included, Enclosures with study type specific guides included
AI App 01 Protocol v2.0	Retired. Trancelerate template linked in LM SOP to be used instead
CIO App 02 Delegation log	Updated from AI to CIO only
CIO App 03 Accountability of intervention	Updated from AI to CIO only
CIO App 04 Screening log	Updated from AI to CIO, removed subject initials and only capturing birth year, not full date
CIO App 05 Subject ID log	Updated from AI to CIO only
CIO App 08 Table of Content ISF	Updated from AI to CIO only
CIO App 09 Table of Content TMF multicentre study	Updated from AI to CIO only
CIO App 10 Table of Content ISF-TMF single centre study	Updated from AI to CIO only
CIO App 11 Initiation Report CIO	New. Facilitating interventional and observational studies
CIO App 12 Monitoring Report CIO	New. Facilitating interventional and observational studies
CIO App 13 Close-Out Report	New. Facilitating interventional and observational studies

CIO	
AI App 06 Data management plan v.1.0	Retired. LM SOP to be used instead
AI App 07 Database lock form v.1.0	Retired. LM SOP to be used instead