

Final report

Project: *Nordic Strategic Workshops 2019-2024*

Background

The Nordic Monitoring Network (NORM) brings together professionals involved in monitoring and quality assurance of academic clinical trials across the Nordic countries. Initiated in 2011 and formally established in October 2012, the network benefits from a shared cultural foundation and comparable levels of expertise among its members.

A key objective of NORM is to enhance collaboration between the Nordic GCP Units, aiming to harmonize quality assessments of clinical trials conducted within the region. Members convene at NORM meetings to exchange knowledge and address monitoring-related challenges.

In each country, GCP Unit staff participate in national networks that hold regular meetings and foster collaboration. These national structures serve as effective platforms for implementing Nordic-level initiatives locally. For further information see [Nordisk samarbejde - GCP-Enhederne](#).

The history of funding from NTA

NORM has received funding from NTA as shown below. The funding has significantly contributed to the progress of NORM's work. Without this funding, NORM would never have become the well-functioning network it is today, where members know and actively make use of each other's expertise.

2013: NTA Implementation Project 250.000 NOK

The project was completed and reported in 2016

2016: NTA Implementation Project 250.000 NOK

The project has been prolonged and will be finalized in 2026

2018: Nordic Strategic Workshop 115.000 NOK

The project is completed and reported here

Project plan

Project Plan:

- 1) Including Iceland in the Nordic Monitoring Network, and support establishment of an Icelandic GCP-Unit.
- 2) Registrations of legislative changes in the Nordic countries in connection with the implementation of the REGULATION (EU) No 536/2014 on clinical trials on medicinal products for human use in 2019.
- 3) Experiences with Risk Based Monitoring after implementation of new Addendum to ICH GCP

Participants

Project leader:

Birgitte Vilsbøll Hansen, Head of the GCP-unit, Copenhagen University Hospitals, Denmark. Replaced by Pernille Ask Aabo, Head of the GCP-unit, Copenhagen University Hospitals, Denmark

Project members:

Leena Partanen, Clinical Research Institute HUCH Ltd, Helsinki, Finland. Replaced by Susanna Helkkula. The wellbeing services county of Southwest Finland, Turku University Hospital, Finland

Birgitte Lid Adamsen, Department of Clinical Research Support Oslo University Hospital, Norway. Replaced by Tanja Igland, Helse Bergen, Bergen, Norway

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Administrative manager:

Annette Jørgensen, Head of the GCP-unit, Aarhus University Hospital, Aarhus University, Denmark

Deliverables:

Including Iceland in the Nordic Monitoring Network, and support establishment of an Icelandic GCP-Unit

Since 2018, there has been significant development in monitoring practices for academic studies at Landspítali, in part due to the hospital's participation in the NORM network. This collaboration has been highly beneficial, both for the hospital's Clinical Research Center (CRC) and the broader research environment at Landspítali.

The NORM network has directly and indirectly supported the training of monitors at the hospital. Although Landspítali does not have a dedicated monitoring service, three staff members — employed in other roles within the hospital — have been trained and now undertake monitoring tasks as independent contractors. These monitors continue to receive support from the CRC, which facilitates their work by assisting with contracts, documentation, and connections within the NORM network.

NORM has served as an important platform for exchanging experiences, seeking expert opinions, and accessing data developed by other participating centers. The collaboration has significantly raised awareness and understanding of the importance of monitoring in academic research.

Registrations of legislative changes in the Nordic countries in connection with the implementation of the REGULATION (EU) No 536/2014 on clinical trials on medicinal products for human use in 2019

Regulation 536/2014 came into force on 31 January 2022 as binding legislation across all Nordic countries. Each country has implemented its own national supplementary legislation, which has not posed any significant barriers to Nordic clinical research.

The main challenge has been the implementation of the CTIS portal. In this context, knowledge sharing within the NORM network has proven to be highly valuable and supportive.

Experiences with Risk Based Monitoring after implementation of new Addendum to ICH GCP

Risk-Based Monitoring (RBM) continues to be a critical and widely discussed area within clinical trial operations. The risk-based approach, which also includes the use of centralised monitoring, offers the potential to improve data quality while simultaneously reducing the scope—and thereby the cost—of monitoring activities. Discussions and experience sharing on risk-based monitoring are a regular and important part of the programme at all NORM meetings. The aim is to promote a shared understanding and support the harmonisation of monitoring practices across the Nordic countries.

Activities:

List of NORM-meetings and milestones

When	Who and where	Focus om the following topics
September 2019	Oslo 53 participants	Monitoring of academic studies in Iceland Risk assessment Training of monitors Experiences from CTU in Oslo
Copenhagen 2023	Copenhagen 66 participants	Clinical trials on medical Devices Preparation for ICH GCP R3 The sponsor in academic settings Challenges in monitoring Low intervention trials and trials with advanced Therapy Medicinal Products
October 2024	Uppsala 87 participants	Central monitoring Sponsor Oversight and serious breach Sponsor responsibilities in academic studies eTMF CTIS New revision of the Declaration of Helsinki Experiences from Uppsala Clinical Research Center

Board meetings:

2019-3-18 Teams	2023-02-15 Teams	2024-05-15 Teams
2019-5-20 and 2019-5-21 Reykjavík	2023-03-22 Teams	2024-05-27 Teams
2019-6-28 Teams	2023-04-12 Teams	2024-06-13 Teams
2019-8-19 Teams	2023-05-04 Teams	2024-06-26 Teams
2019-9-16 and 2019-9-17 Oslo	2023-06-08 Teams	2024-10-03 Teams
2020-3-13 Teams	2023-07-04 Teams	
2020-09-14 Teams	2023-08-16 Teams	
2021-01-27 Teams	2023-09-25 Teams	
2021-05-05 Teams	2024-01-29 Teams	
2022-01-18 Teams	2024-03-04 Teams	
2023-01-16 UCR, Uppsala	2024-04-29 Teams	

Financial Report

Financial report enclosed.

On behalf of the Group

26. September 2025

Annette Jørgensen

Administrative Manager

Enclosed:

Financial Report