

CLINICAL INTERVENTIONAL TRIALS AT AKERSHUS UNIVERSITY HOSPITAL

Summary

Clinical interventional trials have been a specific area of focus for Ahus since 2015. During this period (2015- ongoing), Ahus has strategically and purposefully invested in strengthening the infrastructure for initiating, conducting, and concluding clinical interventional trials. For industry-initiated clinical interventional trials, the goal is to offer patients safer and better treatments and to develop improved and more tailored treatments for individual patients. Ahus have also encouraged and supported researcher-initiated (academic) clinical interventional trials. Accordingly, to strengthen the competence and capacity to conduct clinical interventional trials is essential for Ahus, both to provide better patient' treatment but also to improve research. Through clinical interventional trials, Ahus can contribute to a sustainable healthcare service in Norway, which is continuously evolving.

Throughout this period, strategic efforts and a number of specific initiatives have been undertaken at all levels of the hospital to support and develop infrastructure for clinical interventional trials (see table 1). These initiatives are a result of national, regional and local collaboration and strategies, national governmental action plans, white papers and political objectives. Key initiatives are implemented in the organization in compliance to strategic decisions at the hospital level (see table 2), integrated into action plans at various levels at Ahus and continuously refined, supplemented and improved. These strategic efforts have resulted in key elements considered necessary to provide a solid and sustainable clinical interventional trial ecosystem (see figure 1).

Table 1: Key initiatives with relevance to clinical interventional trials, 2015 – 2022:

Year	Key initiatives
2015	National joint website for clinical interventional trials (www.helsenorge.no)
2015	NorCRIN I where Ahus led WP "Collaboration with industry" 2015-2022 (www.norcrin.no)
2015	Establishment of local ICH-GCP course at Ahus (collaboration with Oslo university hospital)
2016	Development of in-house pathway for industry-initiated clinical interventional trials (see figure 2)
2016	Establishment of internal database for clinical interventional trials
2016	Establishment of «one stop shop» mail for clinical interventional trials
2017	Introduction of "International Clinical Trial Day"
2018	Distribution of reports on the status of clinical interventional trials to all divisions/clinics every quarter
2019	Establishment of clinical research outpatient clinic at Ahus Nordbyhagen
2019	In-house pathway for industry-initiated clinical interventional trials presented in The health industry report to the Storting – Meld. St. 18 (2018-2019) (white paper)
2019	Biannual meetings between the division of research and innovation and the clinical divisions/clinics with clinical interventional trials as part of the agenda
2020	Opening of clinical research outpatient clinic at Ahus Nordbyhagen
2020	Kongsvinger hospital transferred to Ahus

2020	First official national reporting of clinical interventional trials
2020	NorCRIN II. Ahus leads WP on pragmatic studies
2020	Establishment of one-on-one meeting with industry
2021	Launch of National Action Plan for Clinical trials (i-1206b_kliniske_studier_uu.pdf (regjeringen.no))
2021	Presentation of clinical research outpatient clinic in Action Plan for Clinical trials
2021	Launch of The Government Audit Office report for clinical trials (Dokument 3:9 (2020-2021) (riksrevisjonen.no))
2021	Presentation of the in-house pathway for industry-initiated clinical interventional trials in the Government Audit Office report for clinical trials
2021	Establishment and launch of NorTrials. Ahus lead center for cardiovascular diseases (www.nortrials.no)
2021	Finalizing 3D lab
2022	Opening of clinical research outpatient clinic at Ahus Gardermoen
2022	Implementation of the new clinical trial regulation and clinical trials information system (CTIS)
2022	Establishment of Akershus Clinical Research Center (ACR), which provides one-stop-shop help for researcher-initiated clinical trials

Table 2: Key cases to the Board of directors, Ahus, with relevance to clinical interventional trials, 2015-2022

Date	Topics to the Board of directors, Ahus, 2015 - 2022
22.09.2015	National joint website for clinical interventional trials - helsenorge.no
04.12.2018	Decision on the establishment of "project; clinical research outpatient clinic"
04.06.2019	Decision on the evaluation of research level 1 and level 2 – including clinical interventional trials
17.12.2019	Decision concerning incentive for research equivalent to 25 % of revenues from industry-initiated clinical interventional trials
20.10.2020	Decision on action plan for research level 1 and level 2
16.03.2021	Presentation of the National action plan for clinical trials and NorTrials
25.05.2021	Presentation of the mandate for clinical research outpatient clinic and prioritization criteria
04.06.2021	Presentation of the The Government Audit Office report for clinical trials
19.10.2021	Presentation of status of clinical interventional trials and clinical research outpatient clinic
30.11.2021	Presentation of the work «The values in clinical interventional trials».
08.11.2022	Evaluation of «project; clinical research outpatient clinic"
06.12.2022	Decision concerning "project clinical research outpatient clinic" concludes and transitioned to operations

Figure 1: Key elements considered necessary to provide a solid and sustainable clinical trials ecosystem both nationally and internationally



Background

It is a political objective to strengthen health research and to provide more patients access to experimental treatment through clinical interventional trials. In 2021, the Norwegian Government released the action plan for clinical trials 2021-2025 with an overarching vision that clinical research should be integrated into all clinical practices and patient care ([i-1206b kliniske studier uu.pdf \(regjeringen.no\)](#)). The Action plan stated that the goal was to double the number of clinical interventional trials recruiting patients in the specialized health system between 2021-2025, and that 5% of the patients in specialized health services should participate in clinical interventional trials by the year 2025. The Government Audit Office report released in May 2021 concludes that the number of clinical interventional trials and patients participating needs to be increased ([Dokument 3:9 \(2020–2021\) \(riksrevisjonen.no\)](#)).

In clinical interventional trials, we examine the effects new treatment methods have on patients. This can involve testing medical equipment, a technology, a drug, a surgical procedure, or a method for treatment or rehabilitation. The purpose may also be to investigate other changes in a treatment regimen. The aim is to obtain reliable knowledge about how safe and effective these new treatment methods are.

Developments at Ahus

Ahus started in 2015 to implement strategies and initiatives targeting clinical interventional trials at all levels at the hospital.

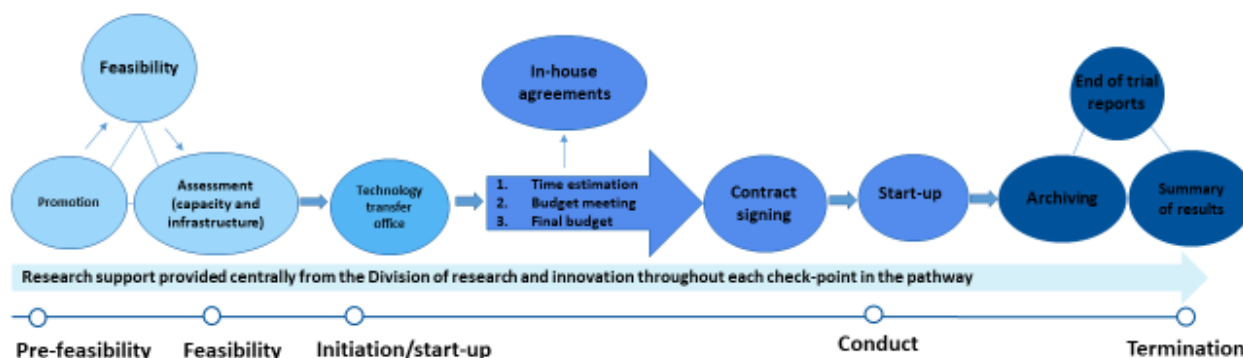
We have especially succeeded in creating an in-house pathway specially adapted for industry-initiated clinical interventional trials (see figure 2). This pathway is optimized to ensure a professional, streamlined and efficient initiation of new clinical interventional trials and illustrates the different checkpoints necessary to maintain throughout the lifespan of the trial. Routines and guidelines have been developed consecutively to ensure compliance with



international, national and local guidelines and legislation. This pathway can easily be adapted to researcher-initiated clinical interventional trials.

A centralized research support specialized in initiating clinical interventional trials provide support to the divisions/clinics throughout each checkpoint in the pathway, and this support is an important supplement to the research support implemented in the divisions/clinics.

Figure 2: In-house pathway for industry-initiated clinical interventional trials



Development of outpatient clinics dedicated research

Clinical research outpatient clinics are areas specifically designed to ensure that trials can be conducted smoothly and efficiently. These clinics are a significant complement to the hospital's existing infrastructure for clinical interventional trials and can contribute to a further increase of new trials. Ahus have established clinical research outpatient clinics at three locations: at Ahus Nordbyhagen, Ahus Gardermoen, and Ahus Kongsvinger. The infrastructure can be used by all study teams at the hospital and consists of examination rooms, basic medical equipment, and access to a lab, sampling chairs, workstations, and waiting areas. A dedicated outpatient clinic for children and youth is also developed and recently implemented at Ahus.

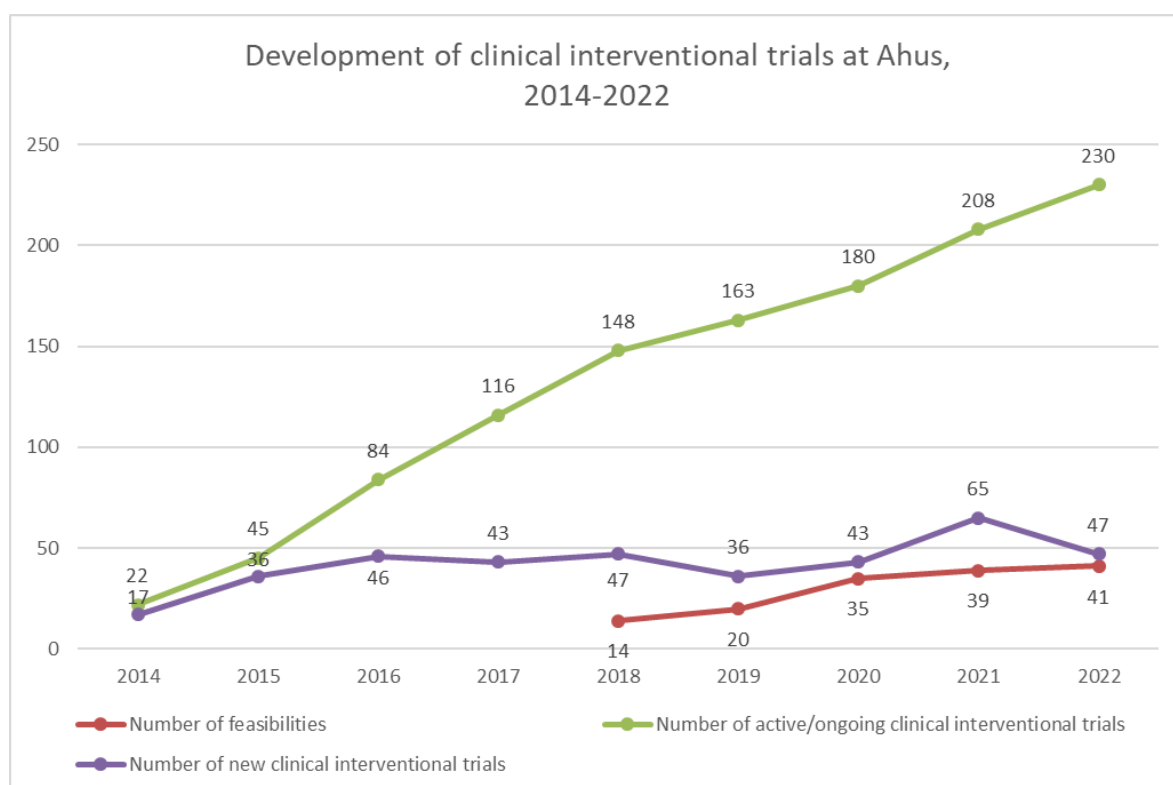
Participation in national initiatives related to clinical trials

Ahus has participated as a partner in the Norwegian Clinical Research Infrastructure (NorCRIN) since 2015. The work is organized into work packages, with all university hospitals participating. Ahus has previously led Work package 4 – Cooperation with the industry (NorCRIN I) and is currently leading Work package 13 – Pragmatic clinical trials (NorCRIN II). Ahus is also member of the national partnership NorTrials that was established on assignment from the Ministry of health and Care Services in 2021 and was officially launched in May 2022. The NorTrials center for cardiovascular diseases is located at Ahus.

Results

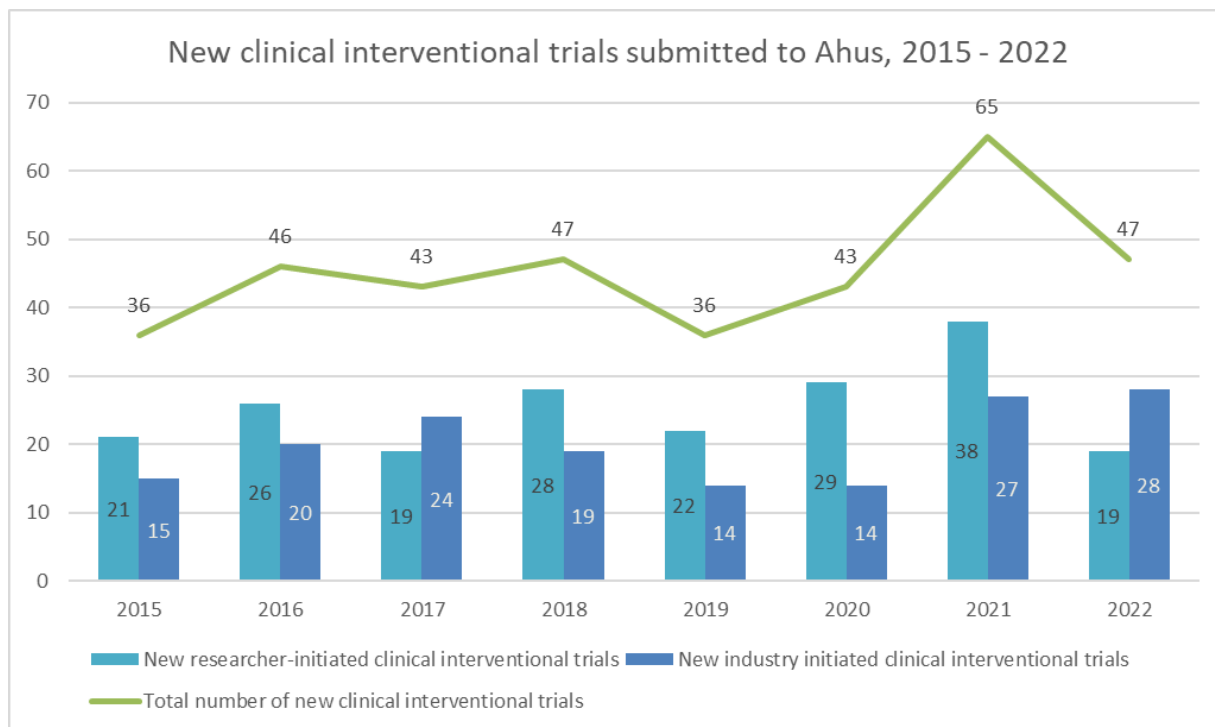
Ahus has seen a positive development in the number of clinical interventional trials from 2015 to 2022. Figure 3 shows different parameters that have been registered in this period starting from 2014 and 2018 (zero point measurements) and are closely monitored.

Figure 3: The green line shows the number of active/ongoing clinical interventional trials and include both industry-initiated and researcher-initiated trials that have a valid project period from the Regional Committees for Medical and Health Research Ethics (REK). The purple line shows the number of new clinical interventional trials that are allocated to Ahus and include both industry-initiated and researcher-initiated trials. The red line shows the number of feasibilities from industry (requests for new trials) that Ahus has received through the “one-stop-shop” contact points that have been established nationally and locally.



Ahus aim to be an attractive and preferred partner in both industry-initiated and researcher-initiated clinical interventional trials. Figure 4 shows the distribution of new clinical interventional trials submitted to Ahus from 2015 -2022. The results shows on average a balance between industry-initiated and researcher-initiated clinical interventional trials, and an increase of 30 % in the total number of new trials submitted to Ahus from 2015 to 2022. There was in 2021 an all-time-high in number of new trials, probably partly explained by increased number of trials related to the COVID-19 pandemic.

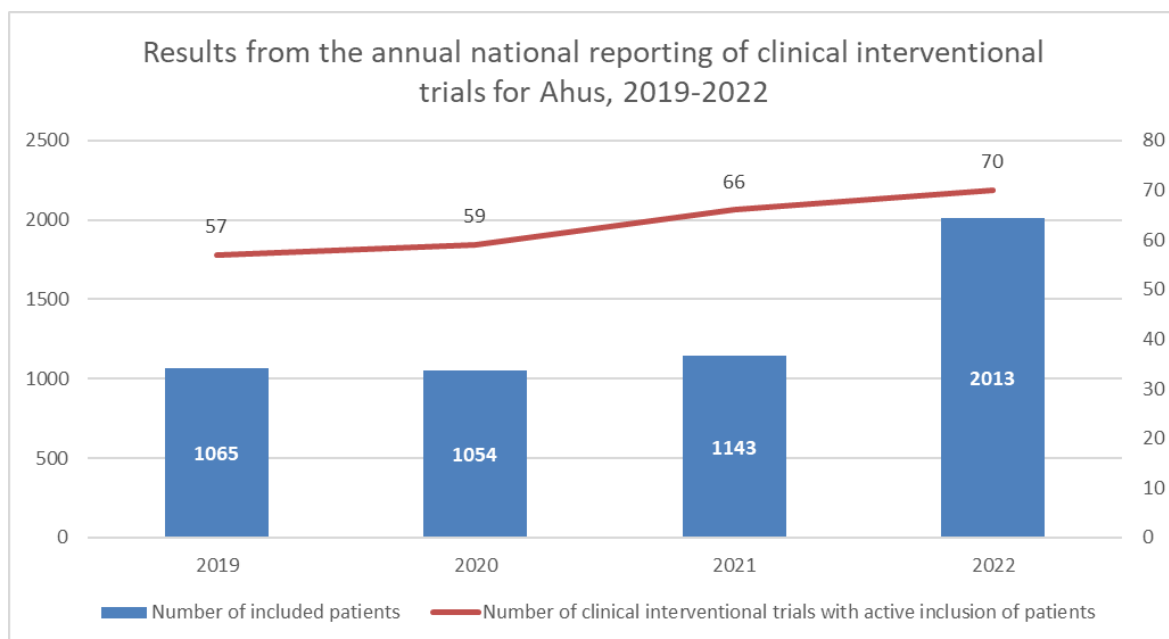
Figure 4: Development and distribution of new researcher-initiated and industry-initiated clinical interventional trials at Ahus 2015-2022. Green line shows the total number of new trials.



A national reporting of clinical interventional trials and number of included patients was implemented in 2019. The results from the national reporting in 2021 represents the zero-point measurement, and clinical interventional trials was implemented as an indicator in the [“National system for measuring research and innovation activity in healthcare organizations and competence centers outside the specialist healthcare service”](#). This national reporting also serve to accommodate the goals presented in the Action plan 2021-2025 released by the Norwegian Government in 2021.

Figure 5 shows the results from this national reporting from Ahus 2019-2022. The percentage increase in number of clinical interventional trials including patients from 2021 to 2022 was 6 %, and the percentage increase in included patients 76 %.

Figure 5: Shows the results from the annual national reporting of clinical interventional trials for Ahus from 2019 to 2022.



Conclusion

Ahus will continue to develop and enhance infrastructure at all levels at the hospital. The result so far shows that the hospital has managed to build competence and capacity to perform both industry-initiated and research-initiated clinical interventional trials and is a testament to Ahus as an attractive site/partner for new trials. This infrastructure and now-how is a result of a strategic investment at a hospital level combined with a joint effort across disciplines, therapeutic areas, leader involvement and local and external collaboration.