



# CLINICAL TRIAL TRANSPARENCY IN NORWAY

Mapping unreported drug trials



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Mapping unreported drug trials

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**” We advocate full transparency of which clinical trials are ongoing and ensuring all results are disclosed in a timely manner... full transparency on results advances both scientific understanding and timelines for product development and ultimately enables access to essential medicines.**

*Dr Tedros Adhanom Ghebreyesus, World Health Organisation*

**” Lack of transparency in clinical trials harms patients. The timely posting of summary results is an ethical and scientific obligation.**

*Transparency International and Cochrane*

**” Legislation or supporting regulations [should include] sanctions if a clinical trial is not registered and/or results are not reported.**

*WHO Transparency and Accountability Assessment Tool*

# 1. KEY FINDINGS AND RECOMMENDATIONS

## OBLIGATION TO REPORT THE RESULTS OF ALL TRIALS

Failure to report clinical trial results is [not a victimless crime](#). It has substantial negative consequences for patients and public health.

[European Union \(EU\) rules adopted in July 2014](#) require the sponsors (organisations that conduct a trial) of each clinical trial registered on the EU Clinical Trials Register to post those trials' summary results to the registry within 12 months of trial completion (6 months for paediatric trials).

These rules also apply to trials completed before 2014 and apply irrespective of whether a trial's outcomes have been published in the academic literature. Thus, all of the clinical trials identified in this report as missing summary results are [in violation of European Union transparency rules](#) that were designed to protect the interests of patients and taxpayers. These rules fully [apply in Norway](#).

## KEY FINDINGS

The findings presented in this report reflect EU Trials Tracker data on the 13 Norwegian clinical trial sponsors that had launched at least five drug trials as of 28 February 2021.

The 13 largest clinical trial sponsors based in Norway have between them registered 204 clinical trials of investigative medicinal products on the EU Clinical Trial Register.

Of these, only 25 drug trials – an implausibly low number – are marked as having been completed more than a year ago, and thus should have results available. Results are only available on the registry for 6 of those verifiably due trials (24 %). Results are missing for the other 19 verifiably due trials (76 %).

**Overall, the 13 largest Norwegian clinical trial sponsors have failed to fully make public around a hundred clinical trial results.**

Oslo University Hospital, by far the largest sponsor in Norway, alone accounts for an estimated 44 missing results. Precise figures are not available because many Norwegian sponsors are failing to keep data on the registry up to date.

None of the major Norwegian sponsors is fully compliant with European transparency rules.

Reporting rates in Norway are far lower than in other European countries, including Austria, Denmark, Germany, Ireland, and the UK.

## RECOMMENDATIONS

- **Norwegian trial sponsors** should establish central oversight over their clinical trial registry data, adopt policies that reflect WHO best practices, audit existing registry records, and upload missing clinical trial results as rapidly as possible. [See here for useful tools](#).
- **The national medicines regulator Legemiddelverket** should [contact trial sponsors whose results are overdue, ensure that data on the register is consistent and accurate](#), monitor compliance, and develop a mechanism for routinely and automatically [imposing sanctions](#) as soon as the EU Clinical Trials Regulation comes into force in late 2021.
- **The Norwegian government** should review the [UK's national clinical trial transparency strategy](#) and explore the possibility of adopting a similar approach in Norway.
- **The Research Council of Norway** should fully implement their commitments resulting from signing the [WHO Joint Statement](#).

## 2. ESTIMATED NUMBER OF CLINICAL TRIALS MISSING RESULTS

The 13 largest trial sponsors in Norway have run a total of 204 drug trials, but have made public the results for only 6 of those trials on the European registry. In total, an estimated 96 Norwegian clinical trials are currently missing results on the registry.

Between them, the six Norwegian trial sponsors with the largest clinical research portfolios have failed to make an estimated 78 due trial results public (Figure 1). Oslo University Hospital alone accounts for an estimated 44 missing results, nearly half the national total.

Precise figures are not available because Norwegian sponsors and the Norwegian medicines regulator have failed to ensure that registry data is kept up to date.

The remaining seven trial sponsors have small portfolios (8 or fewer trials each), precluding meaningful estimates of how many of their trials are overdue. However, registry records indicate

that these smaller sponsors are also in violation of transparency rules:

- Five small sponsors have verifiably failed to report due results: Algipharma (2 results missing), ArcticZymes Technologies (2 missing), Clavis Pharma (2 missing), Photocure (1 missing) and Santosolve (3 missing).
- The remaining two small sponsors (University Hospital of North Norway and University of Bergen) have trials in their portfolios that were launched over ten years ago but are still marked as «ongoing»; these trials have almost certainly been completed and should have results.

Future reports by TranspariMED and Dam Foundation will track Norwegian sponsors' progress over time. Sponsors can use TranspariMED's [collection of transparency tools](#) to learn how to improve their performance.

### NUMBER OF MISSING CLINICAL TRIAL RESULTS

Six largest Norwegian sponsors, March 2021 (estimate)

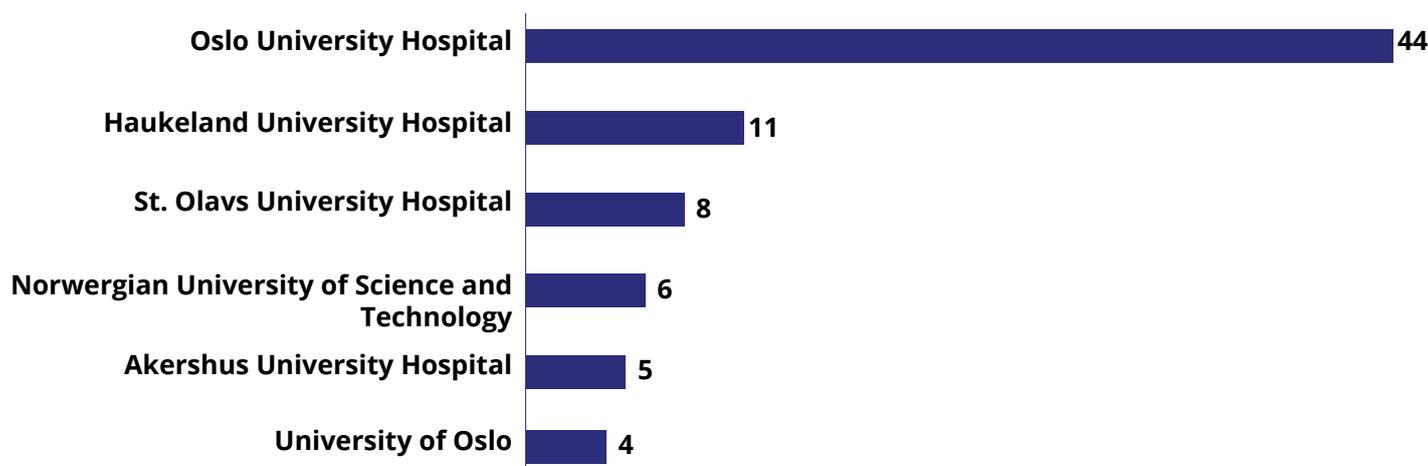


Figure 1. Number of missing clinical trial results for the six largest Norwegian sponsors.

Note: The estimates above are based on the assumption that half of all trials in institutions' portfolios were completed a year or longer ago. Please see the methodology section for details.

# 3. DATA QUALITY PROBLEMS

## INTRODUCTION

Quality problems with Norwegian sponsors' entries on the European Clinical Trial Register include incomplete, incorrect, inconsistent and out-of-date data. While the examples below are taken from Oslo University Hospital's portfolio of 89 trials, the same issues can be found in the portfolios of many other Norwegian trial sponsors.

## INCONSISTENT DATA

Data for 9 out of Oslo University Hospital's 89 drug trials are inconsistent:

- 2 trials lack any form of trial status.
- 2 trials are marked as «completed» but lack a completion date in the protocol.
- 5 trials are listed as «ongoing» but also have a completion date<sup>1</sup>.

For all of those trials, it is impossible to definitively determine whether results are due or not.

## FALSE «ONGOING» TRIALS

Out of Oslo University Hospital's 89 drug trials, 76 are marked as «ongoing» on the register. However, many of those trials were almost certainly completed years ago. For example, 10 trials that started before 2010 are still listed as «ongoing» over a decade later, an implausibly high number (Figure 2).

## IMPACT ON PATIENTS AND MEDICAL PROGRESS

These data quality issues negatively impact patients and undermine medical progress:

- Health technology assessment agencies, horizon scanners, systematic reviewers and medical researchers cannot find relevant trials, and/or cannot reliably determine whether a trial

is still ongoing or has been prematurely ended, terminated, or completed. This makes it [difficult to gain an overview](#) of the complete scientific evidence base on a medicine.

- Clinicians, patient groups and patients cannot reliably determine which trials may currently be recruiting patients, [making enrolment more difficult](#) for patients and recruitment more difficult for sponsors. This drives up the cost and slows down the pace of medical research.
- Compliance with EU reporting rules is undermined because the correct number of due trials is impossible to determine.

## THE ROLE AND RESPONSIBILITY OF LEGEMIDDELVERKET

The problems flagged above may originate with trial sponsors, with national medicines regulator Legemiddelverket, or with both. When a trial is completed, the sponsor should send an «End of Trial Notification» to the national regulator; the regulator should then update the status of the trial on the registry and also enter the completion date (sponsors cannot do this themselves).

If either party fails to perform its role, the registry does not get updated. It is impossible to discern from registry records whether Norwegian sponsors sent some or all of the required notifications to Legemiddelverket.

As the national regulator, Legemiddelverket is partly responsible for safeguarding the quality of Norwegian trial data on the European register. Legemiddelverket should engage in a dialogue with Norwegian trial sponsors and work together with them to improve data quality and [ensure that data on the register are consistent and accurate](#).

<sup>1</sup> One of these trials has posted results, but is not counted as verifiably due with results in this report because it is not verifiably due. The results of that trial were uploaded in September 2020.



Status	Trial ID	Title	Completion date
Ongoing	→ 2004-000799-15	DOES BENFOTIAMINE SUPPLEMENTATION REDUCE SERUM LEVELS OF ADVANCED GLYCATION END PRODUCTS AND BIOCHEMICAL MARKERS OF VASCULAR DYSFUNCTION IN TYPE 1 DIABETES?	
Ongoing	→ 2004-002732-25	Safety and efficacy of levosimendan in patients with acute myocardial infarction complicated by symptomatic left ventricular failure	
Ongoing	→ 2004-004488-31	Does cyclosporine A reduce the insulin secretion from the pancreas?	

Figure 2. EU Trials tracker screenshot showing trials started in 2004 still listed as ongoing.

## 4. FEEDBACK FROM NORWEGIAN STAKEHOLDERS

Prior to publication of this report, Dam Foundation reached out to national medicines regulator Legemiddelverket and the country's six largest trial sponsors with a draft copy of this report and asked them to share their

perspectives on trial reporting. Their responses are reproduced below. Dam Foundation and TranspariMED would like to thank these stakeholders for sharing their perspectives.

### RESPONSE FROM LEGEMIDDELVERKET

*The Norwegian Medicines Agency supports the principles and the intentions described in the guidelines related to transparency in clinical trial results. It is however our opinion that publication of study results is the main responsibility of the sponsor. This responsibility is described in EU-guidelines.*

*The Norwegian Medicines Agency would like to emphasize that we always work to prioritize all the tasks in our portfolio, and to carry out our work at an appropriate level. This includes our commitments in the European network. Due to the implementation of the clinical trial regulation in January 2022, we find it justifiable not to introduce a new system for a follow up of the sponsor's responsibility, but rather wait for the opportunities in the new EU-portal and database. In addition, we would like to point out that the total number of not reported trials are low compared to the total number of clinical trial applications.*

### RESPONSE FROM THE RESEARCH COUNCIL OF NORWAY

*Prospective registration of studies and rapid publication of results are important to ensure full transparency in medical and health studies involving human participants. This will help to reduce redundant research and further promote ethical and moral perspectives and support accountability and integrity in – and benefit from – research.*

*The Research Council of Norway endorses WHO Joint statement on public disclosure of results from clinical trials and has implemented requirements and guidelines according to this statement for projects resulting from calls in 2020 and forward on. A further goal is to monitor the compliance of the requirements in a manner that is efficient and as automated as it can be. The plan is to make the outputs from the monitoring process publicly available on [www.helseomsorg21monitor.no](http://www.helseomsorg21monitor.no).*

*Although monitoring of compliance of the guidelines is both desirable and important, one should acknowledge that this has some challenges, and one should strive to find solutions that provide the least possible burden for the project manager and the project owner.*

## RESPONSE FROM OSLO UNIVERSITY HOSPITAL (OUH)

*OUHs understanding of the problem concerning missing reports in the EU Clinical Trials Register*

- *The issue is missing summary reports in this register, it is not an evaluation of the willingness to make the results public. Nearly all of the studies from the years 2004-15 that are completed (but listed as «Ongoing») have results published in research articles.*
- *Among the 38 trials from the years 2004-15 there are 10 trials that is still recruiting or collecting data, but there is nevertheless a substantial (and systematic) lack of reporting summary data.*
- *The situation for the trials with inconsistent data are similar, the only surprise is that the system allows inconsistent registering.*

*The reasons for missing summary reports and inconsistent reporting*

- *The researchers lack of attention and knowledge about summary reports in the EU Clinical Trials Register.*
- *«End of trial» may need further clarification when a trial is a part of a larger trial that will continue.*
- *Other issues have been the top priority so far. The hospitals routines and attention has been on starting more trials, registering the trials, web-announcements ([www.helsenorge.no](http://www.helsenorge.no)) and reporting patient inclusion, in line with the health authorities' priorities.*
- *The lack of suitable software and enough dedicated personnel for guidance and administrative follow-up of registers and reporting.*

*What has been done and what will be done*

- *The requirements for registering and reporting trials are stated in the hospitals written routines and standard operating procedures and reminders are given in GCP-courses and when monitoring is concluded.*
- *The routines and procedures will be revised and the requirements for summary reports will be further specified and highlighted, as well as the departments responsibility to follow-up.*
- *Researchers and heads of departments will be informed and motivated for fulfillment of all the requirements through courses and annual reviews, and there will be special calls for submitting the reports that currently are missing.*
- *OUH will strive for better use of existing or new systems and software to support reporting and reuse of data across different platforms.*
- *OUH will try to secure funding for better local support and guidance from the regional CTU.*

## RESPONSE FROM AKERSHUS UNIVERSITY HOSPITAL (AHUS)

*How Ahus perceives the problem with inconsistent trial reporting*

- *Ahus acknowledges the results of this report and the responsibility and obligation as a sponsor to be compliant with European transparency rules and the Helsinki declaration. Ahus will work to further identify trials that are overdue and with missing results, and strive to bring recommendations presented in this report into action.*

*What Ahus believe is the reasons for the inconsistent trial reporting*

- *We believe the inconsistency of trial reporting can be due to conditions at two levels, the hospital level and within each research team. We acknowledge that our procedures at a general level lack detailed*

information about reporting clinical trials and results in the EU Clinical Trial Register. Our procedures describe Clinicaltrials.gov as the recommended international register for clinical trials, and clinical trials are therefore likely to be reported in Clinicaltrials.gov rather than in the EU Clinical Trial Register. In each research team, lack of attention is contributing to inconsistent reporting in addition to time constraints and shortage of easy access to information about reporting.

*How Ahus has worked and will continue to work to maintain transparency for clinical trials*

- Ahus has taken several measures to provide information to the research teams about registering and reporting for clinical trials. Ahus has executive procedures for clinical trials describing the role and responsibilities of the sponsor and investigator, and the specific task for reporting clinical trials. The Regional Research Support provides mandatory courses in Good Clinical Practice, which addresses the responsibility and task of reporting clinical trials. The task of reporting is also a check-point at the final monitoring visit of a clinical trial. As a continuation, we will include the details about registering and reporting clinical trials in the EU Clinical Trial Register in our procedures at the hospital level. We will also build competence to guide research teams on how to correctly report clinical trials. As partners in the Norwegian Clinical Infrastructure Network, we will continue to work on sharing best practice nationwide for maintaining clinical trial transparency as a sponsor.

## **RESPONSE FROM UNIVERSITY OF OSLO (UIO)**

*UiO is a university with a large range of health research projects, but the number of clinical drug trials where UiO serves as sponsor is marginal. For this reason, lack of reporting in the EU Clinical Trial Registry has probably not been addressed as a critical area.*

*Given that UiO rarely is the sponsor of clinical drug trials, it can also be challenging for project managers to keep track of reporting requirements.*

*UiO is in the process of initiating a comprehensive revision work where, among other things, the procedures in UiO's quality system for medical and health research will be reviewed and updated. In this work, it will be natural to include the requirements for reporting in the EU Clinical Trial Register in the description of procedures for clinical drug trials. Furthermore, it will be important to inform relevant research communities about this requirement.*

## **RESPONSE FROM ST. OLAVS UNIVERSITY HOSPITAL AND NORWEGIAN UNIVERSITY OF SCIENCE AND TECHNOLOGY (NTNU)**

*Why are there many unreported drug trials?*

- Project leaders are responsible for reporting drug trials in clinicaltrial.gov. Unfortunately, the researchers do not get notifications automatically from the website when it is time to update the information. To register in EU Clinical Trial Register (EUCTR) the researchers have to log on to EudraCT to register the name of the sponsor of the research. There are no automatic notifications related to this either. The Norwegian Medicines Agency has a key role in this process but they do not notify the researchers about deadlines.
- NTNU/St. Olavs hospital have no dedicated superusers responsible for registration in EUCTR. We have reasons to believe that there are only a few clinical trials with a Norwegian sponsor at NTNU/St. Olavs.

*This makes it difficult for administrative employees to get the necessary experience working with EUCTR.*

*How we can improve the situation?*

- The Norwegian Medicines Agency has the main responsibility for EUCTR in Norway. We think that the best solution for Norwegian institutions is that the Norwegian Medicines Agency strengthens their capacity to register projects in EUCTRA and follow up on each project.*
- Project leaders have few incentives to publish their results within a year after data collection, but we think that this will change in the coming years due to the [new guidelines from the Norwegian Research Council that were announced in 2020](#).*

## **RESPONSE FROM HAUKELAND UNIVERSITY HOSPITAL**

*Lack of reporting*

- Helse Bergen HF takes note of the lack of reporting and is concerned that the guidelines for reporting end results have not been followed.*

*Contributing reasons for inadequate reporting*

- There may be several reasons for inadequate reporting of study results in the EU Trials Tracker. This is most likely due to the lack of knowledge of the reporting requirement. Currently, there is no central coordination of registration of studies in EudraCT. These are followed up by the clinicians themselves, often without access to research support staff. The reporting of study results is extensive and requires structured data. If paper case report forms or simpler tools have been used, the reporting can be demanding for the researcher. Previously, publications could be included in the results section, but not in recent years.*

*How to improve the situation*

- From January 2022, reporting of clinical drug trials will be done in the Clinical Trial Information System (CTIS). Helse Bergen HF has chosen to use a centralized model, precisely to obtain a good overview of all studies that are registered with Helse Bergen as a sponsor. This will also enable better routines for following up the reporting of results.*
- Our procedures for clinical drug trials also include information on the reporting requirements. We will follow up through a strengthened focus on this in Helse Bergen HF's courses in Good Clinical Practice. Additionally, dedicated research staff will discuss these issues with the researchers at the completion of studies where Helse Bergen HF is responsible sponsor.*
- To start with, we will specifically address the studies in this report by contacting those responsible and inform them about the importance of reporting.*

# 5. WHY THIS MATTERS

## RELEVANCE TO PUBLIC HEALTH AND CLINICAL PRACTICE

Failure to report clinical trial results is not a victimless crime. A 2017 [report](#) by Transparency International and Cochrane documents that a failure to fully report trial results has substantial negative consequences:

- Patients are harmed.
- Public health agencies cannot make informed decisions.
- Public health funds are wasted.
- Medical progress is slowed down.

## LEGAL AND REGULATORY FRAMEWORK.

[European Union rules adopted in July 2014](#)

require each and every clinical trial registered on the EU Clinical Trials Registry to post summary results to the registry within 12 months of trial completion (6 months for paediatric trials). These rules also apply to trials completed before 2014 and apply irrespective of whether a trial's outcomes have been published in the academic literature.

Thus, all of the clinical trials identified in this report as missing summary results are in violation of EU transparency rules that were designed to protect the interests of patients and taxpayers. Once the EU Clinical Trial Regulation comes into force, national regulators will have the power to fine institutions for not uploading trial results to the European trial registry.

Through its membership in the EEA, Norway is [obliged to adhere to these European Union transparency provisions](#).

## CONCERNS ABOUT RESEARCH WASTE

Unreported trials contribute nothing to progress in science and public health and are therefore

costly [research waste](#). In the past, unreported clinical trial results have [caused public health losses amounting to billions of Euros and have led to the deaths of countless patients](#). For this reason, the Declaration of Helsinki has made reporting the results of every clinical trial a [universal ethical obligation](#) for all medical researchers worldwide.

While not all trials lacking results on the European trial registry are completely unreported, the best available evidence suggests that [around half of all trials missing results on the registry](#) have also not reported their results in academic journals. Thus, many trials run by the sponsors covered in this report are in acute danger of becoming [research waste](#) unless their results are made public soon.

Norwegian pharmaceutical companies, universities and hospitals should review their clinical trial portfolios across the EU registry, the US registry ClinicalTrials.gov, and other WHO primary trial registries, identify those trials that have remained completely unreported, and ensure that their results are made public as soon as possible.

## GLOBAL BEST PRACTICES

[WHO standards](#) require every sponsor of an interventional trial to post its results on every public registry where it was registered within 12 months of its primary completion date. Importantly, the WHO has explicitly stated that publishing trial results in the academic literature is not an acceptable substitute for posting trial results to public registries.

[Best practices jointly set out by Cochrane and Transparency International](#) also state that «summary results for all clinical trials should be posted on the registries where they were originally registered within 12 months of study completion». The two health integrity groups note



*The two health integrity groups note that retrospectively posting the results of all past trials to registries «would improve healthcare delivery and government agencies' decision-making on resource allocations, as well as saving billions of dollars' worth of medical research from being lost forever».*

that retrospectively posting the results of all past trials to registries «would improve healthcare delivery and government agencies' decision-making on resource allocations, as well as saving billions of dollars' worth of medical research from being lost forever».

Similarly, the trial reporting [benchmark set out by the AllTrials campaign](#) states that «[a] summary of results (...) should be posted where a trial was registered within one year of completion of a trial».

### **WHY IS POSTING TRIAL RESULTS TO REGISTRIES SO IMPORTANT?**

There are [good reasons](#) why global best practices require posting results of all trials onto registries:

- Posting results onto registries accelerates medical progress because the 12-month

timeline permits far more rapid results sharing than the slow academic publication process allows.

- Posting results to registries minimises the risk of a trial never having its results reported and becoming research waste, which can happen when a principal investigator dies or leaves their post during the prolonged process of submitting an academic paper to a succession of medical journals.
- Research shows that trial results posted on registries typically give a more comprehensive and accurate picture of patient-relevant trial outcomes than corresponding journal articles do.
- Results posted on registries are easier to locate and are open access.
- Registry reporting facilitates the comparison of trial outcomes with a trial's originally stated

aims and, thus, discourages harmful research malpractices such as [HARKing, p-hacking](#) and the «silent» suppression, addition or [switching of the selected outcomes](#).

Please see the [report by Cochrane and Transparency International](#) for further details and links to the relevant literature.

## **UPLOADING RESULTS TO TRIAL REGISTRIES TYPICALLY PRECEDES PUBLICATION IN ACADEMIC JOURNALS**

[There is no recorded case](#), ever, in which a manuscript was rejected by a journal because the trial results had already been uploaded to a trial registry.

Academic journals will accept articles reporting a trial's outcomes even if that trial's outcomes have already been made public in a trial registry. The International Committee of Medical Journal Editors has [explicitly stated](#) that the posting of summary results to trial registries is not considered prior publication by academic journals. Thus, because results reporting on registries is typically faster than academic publication, making trial results public on registries before they are published in an academic journal is becoming the new norm in scientific communications.

# ANNEX 1: DATA TABLE

The following table displays the data used in this report. All data were extracted from the EU Trials Tracker on 15 March 2021, and reflect publicly visible EUCTR data as of 28 February 2021.

Sponsor (link to trials tracker)	Trials	Results due	With results	No results	True missings (est.)
<a href="#">Oslo University Hospital</a>	89	4	0	4	44
<a href="#">Haukeland University Hospital</a>	23	2	0	2	11
<a href="#">St. Olavs University Hospital</a>	16	0	0	0	8
<a href="#">Norwegian University of Science and Technology (NTNU)</a>	13	2	0	2	6
<a href="#">Akershus University Hospital</a>	10	0	0	0	5
<a href="#">University of Oslo</a>	10	2	1	1	4
<a href="#">Clavis Pharma</a>	8	2	0	2	
<a href="#">Photocure</a>	8	4	3	1	
<a href="#">University Hospital of North Norway</a>	6	0	0	0	
<a href="#">University of Bergen</a>	6	0	0	0	
<a href="#">Algipharma</a>	5	4	2	2	
<a href="#">ArcticZymes Technologies</a>	5	2	0	2	
<a href="#">Santosolve</a>	5	3	0	3	
<b>TOTAL</b>	<b>204</b>	<b>25</b>	<b>6</b>	<b>19</b>	

# ANNEX 2: METHODOLOGY AND LIMITATIONS

## METHODOLOGY

### DATA EXTRACTION

The EU Clinical Trial Register (EUCTR) was scraped and processed using [EU TrialsTracker](#) code and the standard methodology to determine the reporting status of each trial. As part of the process, free-text sponsor names are normalised for display on the website.

Alongside the standard EUCTR scraper, a second scraper was run to obtain detailed sponsor info from section B of each EUCTR country level protocol (specifically the sponsor name, country, and sponsor status). This detailed sponsor information was then combined with the processed EU TrialsTracker data, and normalisation data, to extract all trials with a Norwegian sponsor.

The data in this report reflects data publicly available on EUCTR as of 28 February 2021.

The codes used are available on Github:

- [EU Trials Tracker](#) code and data.
- EUCTR Sponsor section scraper.
- The [code](#) for generating the dataset.

### COHORT SELECTION

The main cohort for this study consists of all clinical trial sponsors headquartered in Norway that had sponsored 5 or more clinical trials on EUCTR as of 28 February 2021.

The full data set listed 15 sponsors with 5 or more trials listed. Based on a manual search of sponsor websites, [Boehringer Ingelheim](#) (100% of due trials reported) and [Merck Sharp & Dohme](#) (99.8% reported) were excluded because they are companies headquartered outside Norway.

This process yielded 13 clinical trial sponsors

located in Norway that have sponsored 5 or more trials listed on EUCTR.

### MEASURING VERIFIABLE SPONSOR PERFORMANCE

Data on the clinical trial performance of each of the 13 sponsors was manually extracted from the [EU Trials Tracker](#) on 15 March 2021.

The tracker data reflected trials results that were publicly available on EUCTR as of 28 February 2021. Due to delays by the European Medicines Agency in making public trial results submitted by sponsors, the tracker data might not include all trial results that were uploaded by sponsors during February 2021. Thus, the data in this report reflect sponsors' trial reporting performance as of early February 2021.

The EU Trials Tracker was built by the [EBM Data Lab](#), University of Oxford, and its methodology [published in a peer reviewed paper](#). The tracker is based exclusively on data that are publicly available on the EU Clinical Trial Register; the tracker is updated on a monthly basis. To the best of the author's knowledge, to date no instances of a trial incorrectly flagged as being due and missing results by the EU Trials Tracker based on registry records have been detected. The EU Trials Tracker individually lists every trial flagged as overdue, and includes a link back to the original registry entry for every trial. Thus, all data in this report is externally replicable.

### ESTIMATING THE TRUE NUMBER OF TRIALS MISSING RESULTS

Because the national regulator and trial sponsors in Norway have collectively failed to ensure that data on the European trial register is accurate and up to date, many completed trials are falsely marked as «ongoing» or lack a completion date. This makes it impossible to precisely determine the real number of trials missing results.

Estimates on the number of trials missing results were calculated based on the assumption that 50% of each institution's trials were completed more than a year ago and are therefore currently due to upload their results. For the six largest Norwegian sponsors, TranspariMED divided the total number of trials per institution in half to arrive at an estimate of these due trials, and then subtracted the number of trials listed as both «due» and «reported» by the EU Trials Tracker. The resulting numbers were rounded down to the next integer if applicable.

The 50% assumption is based on the fact that the European register captures trials that began as early as 2004, and trials usually only run for a few years. Therefore, the register contains many trials that have been completed. In the trial portfolios of [major sponsors in other European countries](#) for which more reliable data are available, around half of all trials are marked as being due to report results.<sup>2</sup>

## LIMITATIONS

### RELIANCE ON ESTIMATES OF TRIALS MISSING RESULTS

Many Norwegian trials are almost certainly falsely marked as «ongoing» in the registry even though they were in fact completed long ago (see above). However, the exact number of such trials is impossible to determine based on registry data.

### UNDERCOUNTING OF RESULTS POSTED

The Tracker lists trials with results that are not marked as completed and/or lack a completion date in the protocol as having «inconsistent data»; such trials are not counted as «reported» by the Tracker or in this report. The number of such trials is low; for example, only 1 out of Oslo University Hospital's 89 trials falls into this category.

### ASSIGNING TRIALS TO SPONSORS

Sponsor names are not normalised in EUCTR, so the EU Trials Tracker team had to manually normalise all sponsor names. If sponsors consider that trials have been incorrectly allocated to them, they can [contact the EU Trials Tracker team](#), which will review their claim and,

if appropriate, reallocate the relevant trials to a different sponsoring institution. Such changes will become publicly visible at the beginning of the following month, after the Tracker has undergone its regular monthly update.

### TRIALS NOT LISTED ON THE EU CLINICAL TRIAL REGISTER

The data in this report exclusively cover clinical trials that were registered on the EU Clinical Trial Register. Under EU rules, all clinical trials of investigative medicinal products (CTIMPs) conducted in the European Union must be registered on the EU Clinical Trial Register, and must post their results there within 12 months of trial completion.

Non-drug trials, including trials of medical devices (e.g. pacemakers) and non-drug treatments (e.g. surgery or physiotherapy), cannot be registered on the EU Clinical Trial Register and are thus registered on other trial registries. [Such trials can be of even greater medical importance than drug trials](#), and sponsors are required to make their results public under [global ethics rules](#). However, assessing Norwegian sponsors' reporting performance for these non-drug trials is beyond the scope of this report.

<sup>2</sup> For example, data on Imperial College London's trial portfolio can be considered reasonably reliable because the university has reported over 97% of its verifiably due trials, has nearly no trials with inconsistent completion data, and has few very old trials that are still marked as 'ongoing'. Out of Imperial's 139 trials total, 76 trials (55%) are marked as being due to report results.



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