

# Danish Medicines Agency takes tougher action to ensure the publication of clinical trial results

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**A fine or imprisonment of up to four months is the ultimate punishment if the results from clinical trials of medicines are not published. The Danish Medicines Agency will be taking a tougher line on investigators – the so-called sponsors of clinical trials of medicines – if they do not publish the results of the trials they carry out.**

We still see sponsors of clinical trials of medicines – especially non-commercial sponsors like universities/hospitals – who fail to publish the results from clinical trials despite their obligation to do so. The Danish Medicines Agency will therefore be taking stronger action against these sponsors to ensure important knowledge from medical research becomes available.

## **More clinical trial results are being published – but some are still missing**

A survey carried out last year showed that only 23.6% of the non-commercial sponsors in Denmark fulfil their obligation to publish the results from clinical trials of medicines. The Danish Medicines Agency responded by making the sponsors aware of their obligations. We sent out a statement to remind the sponsors to publish all relevant protocols and results from clinical trials, but we also issued warnings to those sponsors (primarily non-commercial sponsors) who had not published their clinical trial results. And it paid off: At the close of 2019, the results of altogether 90 clinical trials in Denmark were overdue, but now several of these sponsors have uploaded the results. But it is still not good enough.

“Having access to the results of clinical trials is essential to public health because it enables patients, healthcare professionals, health authorities and political players to make informed decisions about healthcare and medical research. It also assures the trial subjects that their voluntary participation in clinical trials is useful because the results have been compiled and published for the benefit of all. We must therefore ensure that all the results from clinical trials in Denmark are published in compliance with the law”, said Helle Harder, Head of Unit in the Danish Medicines Agency.

## **With the legal basis in place, enforcement is next**

Under the current clinical trials legislation in Denmark, sponsors who fail to publish the results of clinical trials in time are liable to a fine or imprisonment of up to four months. The Danish Medicines Agency cannot itself issue a fine or sentence sponsors to imprisonment but must go through the public prosecutor. And the Danish Medicines Agency intends to use this legal basis in future.

“We are already planning the process and have also sent reminders to the sponsors, and if they ignore this, we will investigate their case and act according to the procedure we have planned”, explained Helle Harder.

Further reading: [Only one in four non-commercial sponsors publish clinical trial results \(in Danish only\)](#).

The sponsor of a clinical trial is directly responsible for submitting the trial results to the European database EudraCT. When the sponsor has submitted the results to EudraCT, the information automatically becomes available to the public after approximately 14 days.

A sponsor could be a pharmaceutical company or another private company or fund that finances a clinical trial, or it could be a research university or other public institution – the so-called non-commercial sponsors.

### Did you get answers to your questions?

Yes	No
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