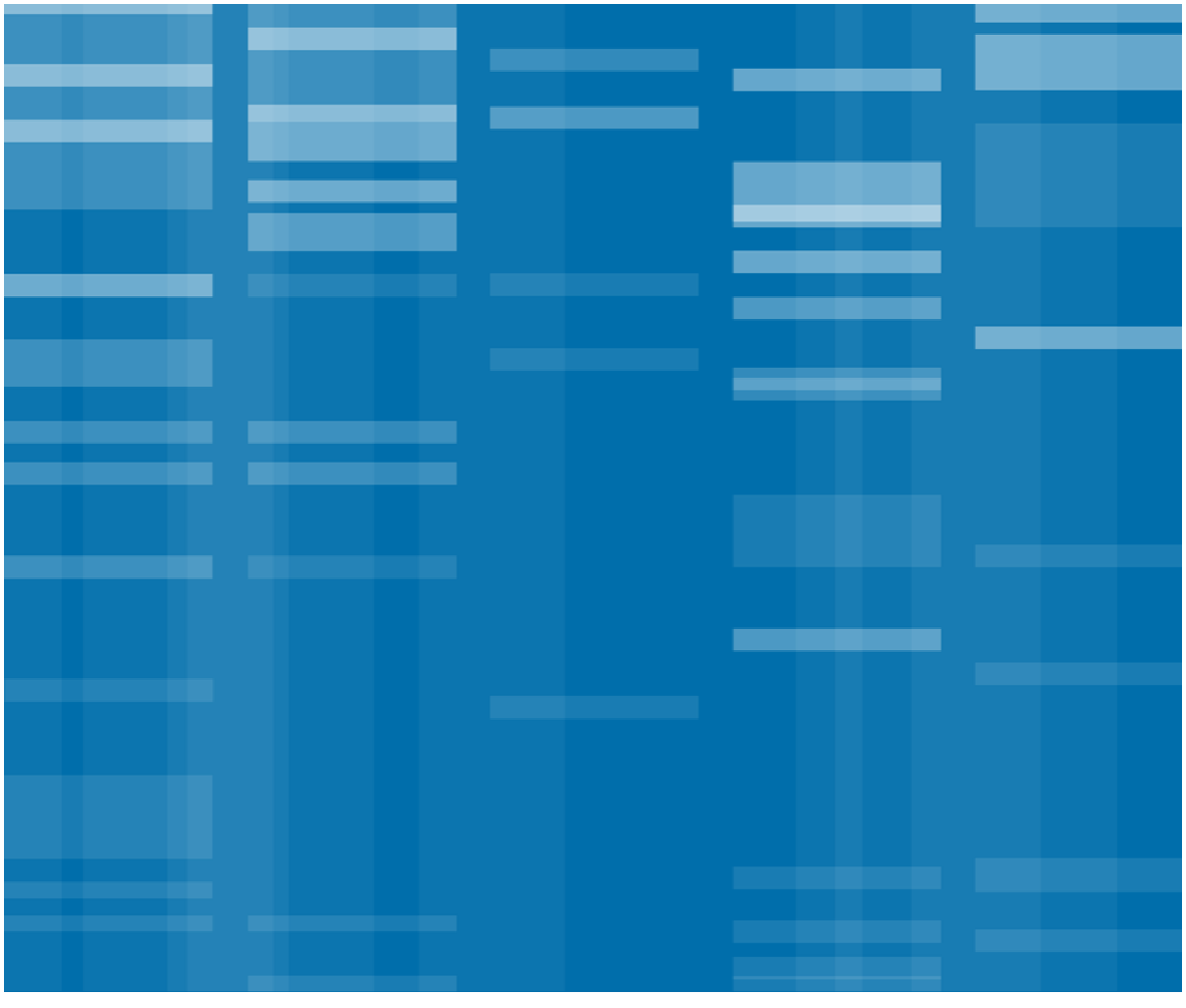
LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Annual report 2017

Clinical trials of medicines



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Contents

1 Summary

This annual report contains the most important figures from the Clinical Trials unit.

The Clinical Trials unit notes that the number of applications for clinical trials of medicines vary from month to month and from year to year. In 2017, the number of applications for clinical trials of medicines increased compared to 2016.

In 2017, the Danish Medicines Agency received 324 applications for clinical trials of medicines in humans, which is a 13% increase compared to the number of applications received in 2016.

Denmark's share of the total number of clinical trial applications in the EU has increased from 9% in 2015 and 10% in 2016 to 12% in 2017 despite the fact that the period recorded a fall in the total number of trials in the EU.

The percentage breakdown of commercially sponsored and non-commercially sponsored applications in 2017 (58% and 42%, respectively) is comparable to the figures for 2016. Likewise, the percentage breakdown of multinational and national applications in 2017 (63% and 34%, respectively) is on level with the distribution in 2016.

Non-commercial sponsors continue to dominate the number of phase IV trials, and commercial sponsors dominate the number of phase III trials. Whereas 2016 saw a balanced distribution across phase II and phase III trials, phase II trials dominate in 2017. 2017 also saw significant increases in both early phase trials and phase IV trials.

Compared to 2016, a fall was recorded in the expected number of Danish trial subjects included in 2017 in spite of a rise in the total number of submitted clinical trial applications.

2
Increase in the number of clinical trial applications

In 2017, the Danish Medicines Agency received 324 applications for clinical trials of medicines in humans, which is 13% more compared to the number of applications received in 2016, see Figure 1.

Altogether 311 of the 324 valid applications were granted, corresponding to 96% of all trials applied for in 2017. Three applications were rejected, and ten applications were withdrawn by the applicants before the review process had finished.

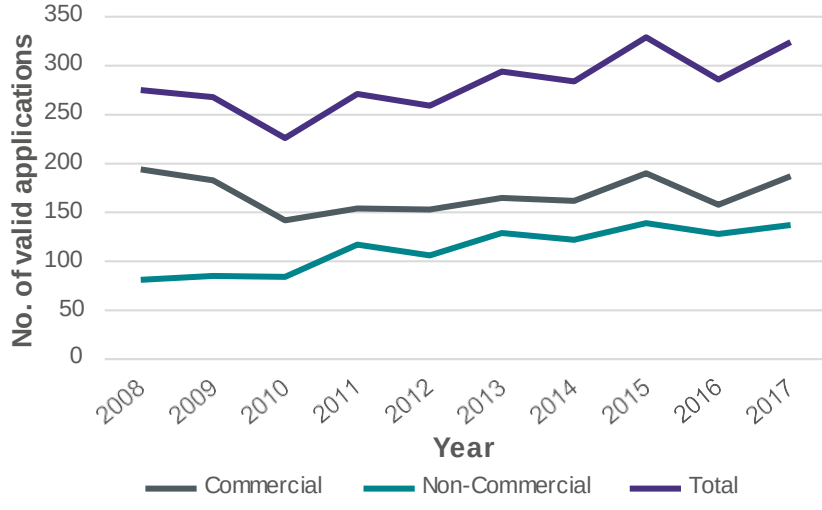

Figure 1. Development in the number of clinical trial applications from 2008-2017

The increase in applications for clinical trials of medicines for humans was recorded for both commercial and non-commercial sponsors, see Table 1.

Number of clinical trials notified to the Danish Medicines Agency			
Year	Commercial sponsor	Non-commercial sponsor	Total
2013	165	129	294
2014	162	122	284
2015	190	139	329
2016	158	128	286
2017	187	137	324

Table 1. Number of clinical trial applications submitted through 2013-2017 by type of sponsor.

In 2017, the Danish Medicines Agency also received 14 applications for clinical trials of veterinary medicines one of which was rejected.

3
Unchanged distribution of multinational and national trials

Of the 324 clinical trial applications, 203 involve trials that are conducted both in Denmark and other countries (multinational trials), whereas a little more than a third of the trials (121) are conducted exclusively in Denmark (national trials). The percentage breakdown of multinational and national applications in 2017 (63% and 34%, respectively) is on level with the distribution in 2016 (62% and 38%), see Table 2.

	Multinational trials			National trials		
	Commercial	Non-commercial	All trials	Commercial	Non-commercial	All trials
2013	148	29	177	17	100	117
2014	152	32	184	10	90	100
2015	177	30	207	13	109	122
2016	151	26	177	7	102	109
2017	174	29	203	13	108	121

Table 2. Distribution of multinational and national trials by type of sponsor through 2013-2017.

4
Increase in the number of phase I and phase IV trials

The distribution of applications by development phase and sponsor type continues the trend from the year before. Accordingly, non-commercial sponsors continue to dominate the number of phase IV trials, and commercial sponsors dominate the number of phase III trials, see Figure 2.

Whereas 2016 saw an even distribution of phase II and phase III trials, phase II trials dominate in 2017. 2017 also saw significant increases in both early phase trials and phase IV trials.

It should be noted that an application for a clinical trial may cover several phases, and the below figure is therefore not representative of the total number of trials.

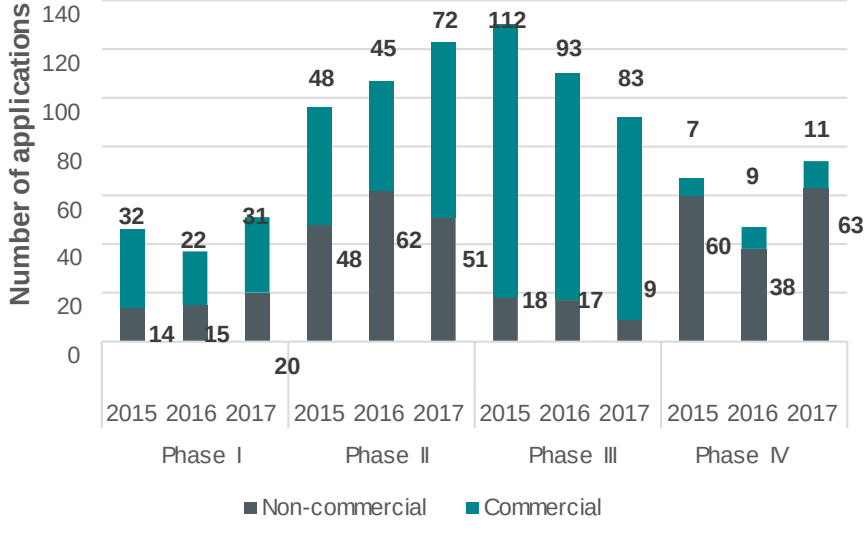

Figure 2. Breakdown of the number of trials by development phase and sponsor type through 2015-2017.

5
Decrease in the expected number of trial subjects

It is expected that a total of 18,341 Danish trial subjects will be included in the 324 applications that were received in 2017. The expected number of Danish trial subjects has thus decreased compared to 2016 despite the fact that the total number of clinical trials applied for has increased, see Figure 3.

However, the number of patients planned to be included in commercial and non-commercial trials is relatively stable throughout the period 2015-2017.

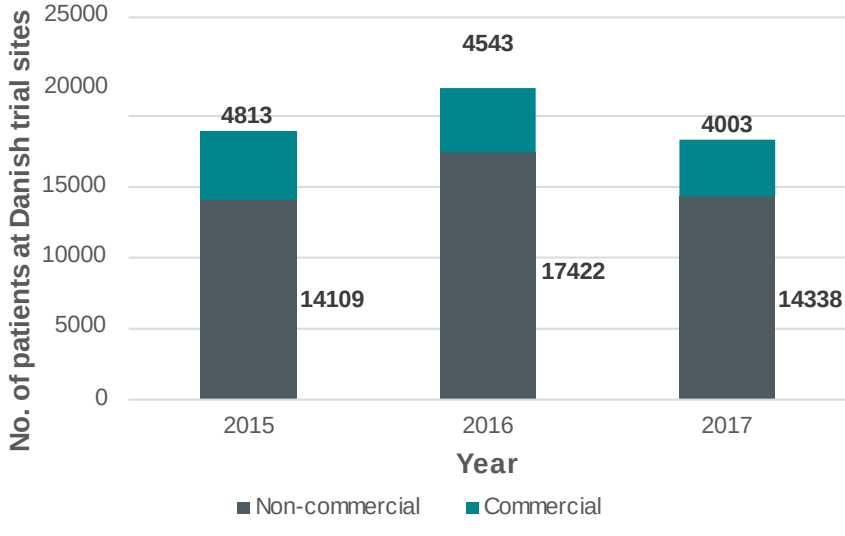

Figure 3. Number of patients expected to be included at Danish trial sites by sponsor type through 2015-2017.

6
Denmark's share of EU trials

A search in the common European database of clinical trials of medicines, EudraCT, shows a general downward trend in the number of clinical trial applications throughout the EU in the period 2015-2017. The total number of clinical trials applied for throughout the EU has thus fallen by 23% from 2015 to 2017. In the meantime, Denmark's share of the total number of clinical trial applications in the EU has increased from 9% in 2015 and 10% in 2016 to 12% in 2017, see figure 4. The same trend is recorded for phase I trials where Denmark's share of trials has also increased, despite an overall decrease in the number of trials across the EU.

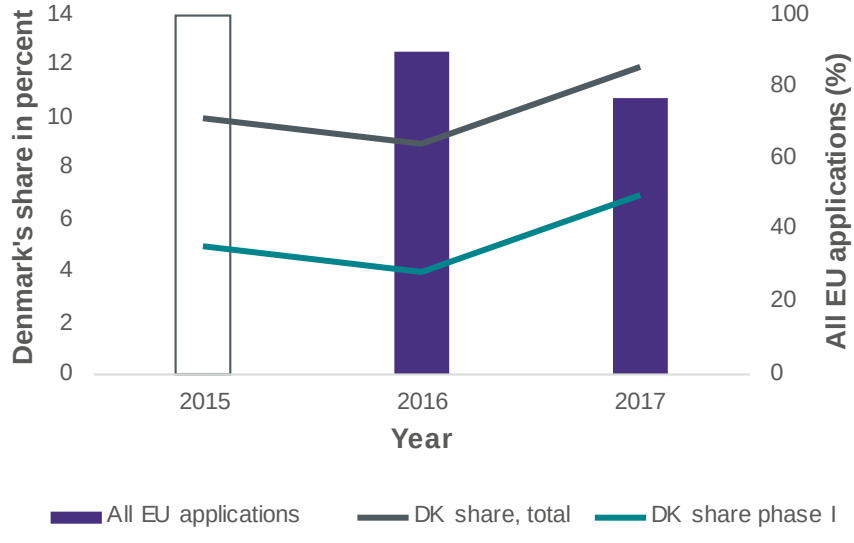

Figure 4. The development in number of clinical trial applications in the EU with 2015 as baseline and Denmark's share of all phases, specifically phase I (including FIH) from 2015-2017.

7
Voluntary Harmonisation Procedure

Since 2009 it has been possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries through the Voluntary Harmonisation Procedure (VHP). The procedure is offered by the European working group CTFG Clinical Trials Facilitation Group, which was formed by the Heads of Medicines Agencies in 2004 with the purpose of coordinating and seeking harmonisation of decisions and administrative procedures related to the GCP Directive 2001/20/EC, which came into force in 2004.

Denmark continued to play a significant part in the VHP procedure in 2017 and thus participated in 29% of the total number of trials up from 19% in 2016. Denmark's increased participation is to be seen in relation to the general downward trend recorded for the total number of applications assessed under the VHP procedure, see Figure 5.

Denmark was the Reference Member State in nine cases from 2017, which means Denmark took a leading role in the assessment of VHP applications. The Danish Medicines Agency will maintain its focus on taking the leading role in as many VHP cases as possible in 2018.

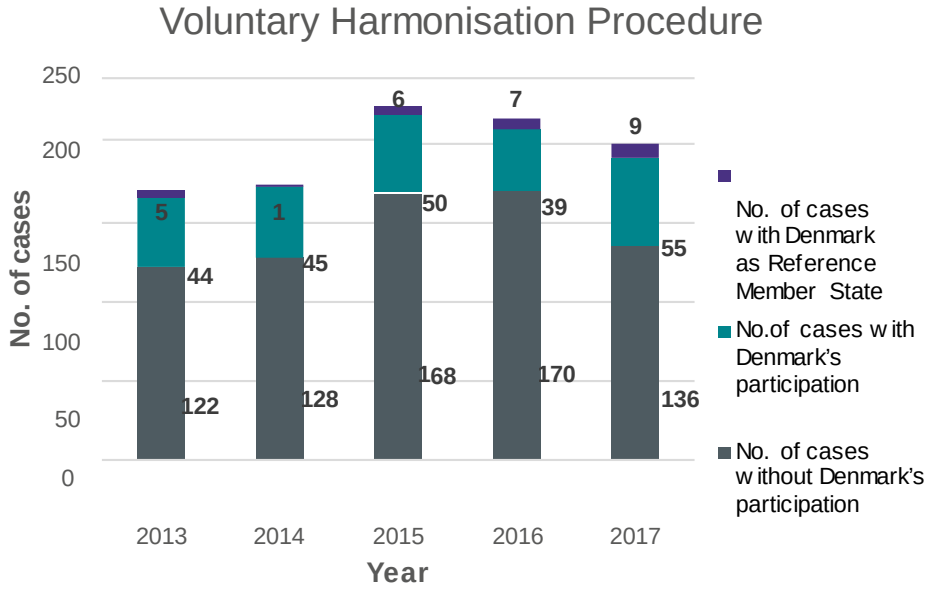

Figure 5. Number of trials reviewed under the Voluntary Harmonisation Procedure through 2013-2017.

7.1 Important information about the report

This report is primarily based on data from EudraCT, the common European database, which was established with the implementation of Directive 2001/20/EC in 2004. Data was extracted in March and April 2018 and represent a snapshot of the data and data quality of EudraCT. The data from other EU countries have not necessarily been validated to the same degree as in Denmark, which causes greater uncertainty when making international comparisons. It is expected that this uncertainty about the figures in the EU has the same year-to-year variation, which is why it is only trends that are explored.

The annual report presents data for all clinical trials for which the Danish Medicines Agency received a valid application in 2017. The report therefore also covers trials that may have been reviewed in 2018.

The annual report does not reflect the total clinical assessment of medicines in Denmark, as many trials are conducted over several years.