

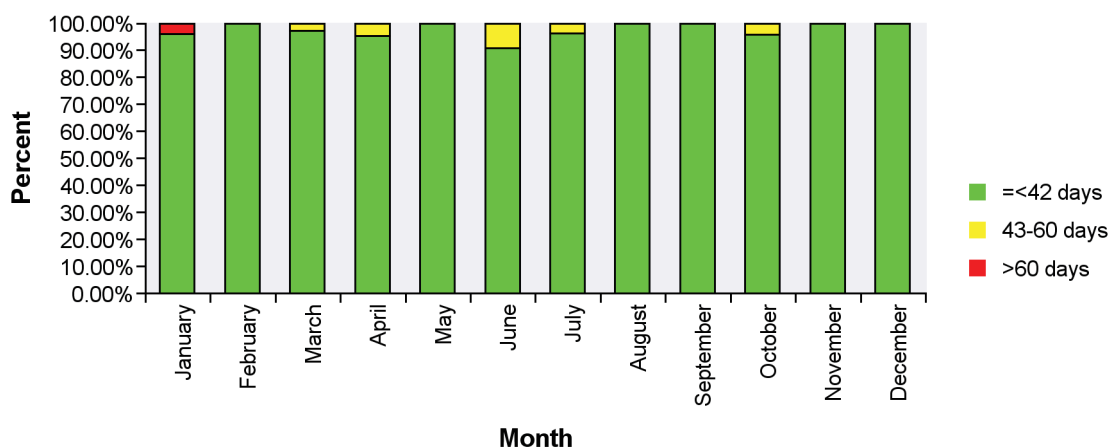
Assessment times for applications for authorisation of clinical trials 2018

The Danish Medicines Agency must assess a valid application for authorisation of a clinical trial within 60 days.

According to an agreement with the industry, the Danish Medicines Agency aims to give a first reply within 42 days. In the first reply, we may grant authorisation to initiate the trial or give grounds for non-acceptance, which require further assessment within the 60 day time limit.

The chart shows the assessment times until the first reply per month for the applications we have assessed in the current year.

- Green bars represent applications assessed within the time limit of 42 days.
- Yellow bars represent applications assessed within 43-60 days.
- Red bars represent applications where the maximum assessment time of 60 days has been exceeded.



Once we have assessed whether an application is valid, we will acknowledge receipt of the application. It will appear from the acknowledgement letter whether the application is valid or whether the assessment is postponed until we have received the missing material.

The assessment time is calculated from the date the Danish Medicines Agency registers that an application is valid to the date when we sent the first reply to the applicant. The assessment is not necessarily completed when we send the first reply, because we may have given grounds for non-acceptance or set terms that the applicant must submit answers to before the assessment can be completed.

Note that for clinical trials with medicines for gene therapy and somatic cell therapy and medicines containing genetically modified organisms, we may extend the assessment time to 90 days before we make the final decision. These trials are included in the above chart and the assessment time until the first reply is typically more than 42 days.

<http://lmst.dk/da/medicin/regulering/kliniske-forsog/sagsbehandlingstider/>

In the below table, all days are calendar days:

Assessment times for applications for authorisation of clinical trials 2018

	<43 days	Percent <43	43-60 days	Percent 43-60	>60 days	Percent >60
January	25	96.15	0	0	1	3.85
February	25	100	0	0	0	0
March	34	97.14	1	2.86	0	0
April	20	95.24	1	4.76	0	0
May	30	100	0	0	0	0
June	20	90.91	2	9.09	0	0
July	26	96.3	1	3.7	0	0
August	16	100	0	0	0	0
September	22	100	0	0	0	0
October	23	95.83	1	4.17	0	0
November	35	100	0	0	0	0
December	17	100	0	0	0	0