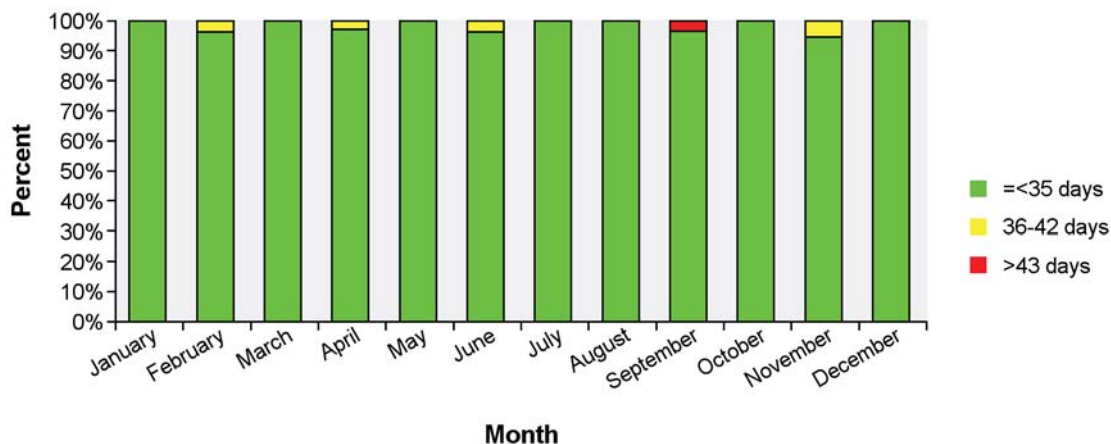


Assessment times for applications for authorisation of clinical trials 2020

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. At the initiative of the Danish Medicines Agency, this aim has now been sharpened to 35 days in preparation for the shorter deadlines under the new regulation. 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 35 days.
- Yellow bars represent applications assessed within 35-42 days.
- Red bars represent applications where the assessment time of 42 days has been exceeded.

Applications that were processed before the national application through the Voluntary Harmonization Procedure (VHP) before the national application are not included in the overview

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

Assessment times for applications for authorisation of clinical trials 2020

In the below table, all days are calendar days:

	<36 days	Percent <36	36-42 days	Percent 36-42	>42 days	Percent >42
January	30	100%	0	0%	0	0%
February	25	96%	1	4%	0	0%
March	27	100%	0	0%	0	0%
April	32	97%	1	3%	0	0%
May	22	100%	0	0%	0	0%
June	23	96%	1	4%	0	0%
July	38	100%	0	0%	0	0%
August	18	100%	0	0%	0	0%
September	26	96%	0	0%	1	4%
October	28	100%	0	0%	0	0%
November	34	94%	2	6%	0	0%
December	31	100%	0	0%	0	0%
Sum:	334		5		1	