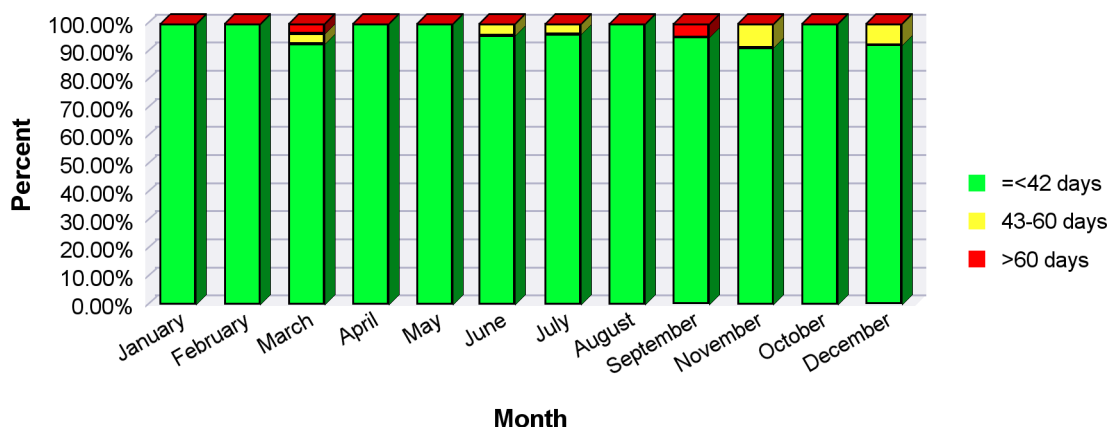


Assessment times for clinical trial applicati 2012

According to an agreement with the industry, the Danish Health and Medicines Authority must assess applications for authorisation of clinical trials within 30 working days. The chart shows the assessment times for applications received by the Danish Health and Medicines Authority during each month of the year.

- Green bars represent applications assessed within the time limit of 30 days. The common European time limit for assessing applications is 60 days, which corresponds to approximately 45 working days.
- Yellow bars, if any, represent applications assessed within 31-45 working days.
- Red bars, if any, represent applications where the maximum of 45 working days has been exceeded.



The assessment time is calculated from the day the Danish Health and Medicines Authority receives a valid application. This date is registered as the “start time” of the application. On receipt of an application, the Danish Health and Medicines Authority immediately sends an acknowledgement letter to the applicant, advising the applicant whether the initial review of the application has given rise to remarks or whether the application is valid (i.e. complete). The “end date” is the day when the Danish Health and Medicines Authority sends its first reply to the applicant. This is the end date registered for each month in the chart. Hence, an application completed in February has not necessarily been submitted to us in February, but could have been submitted in e.g. December.

In the below table, all days are calendar days:

	<43 days	Percent <43	43-60 days	Percent 43-60	>60 days	Percent >60
January	24	100	0	0	0	0
February	26	100	0	0	0	0
March	25	92.59	1	3.7	1	3.7

Assessment times for clinical trial applicati 2012

	<43 days	Percent <43	43-60 days	Percent 43-60	>60 days	Percent >60
April	26	100	0	0	0	0
May	22	100	0	0	0	0
June	22	95.65	1	4.35	0	0
July	24	96	1	4	0	0
August	25	100	0	0	0	0
September	19	95	0	0	1	5
November	21	91.3	2	8.7	0	0
October	18	100	0	0	0	0
December	12	92.31	1	7.69	0	0