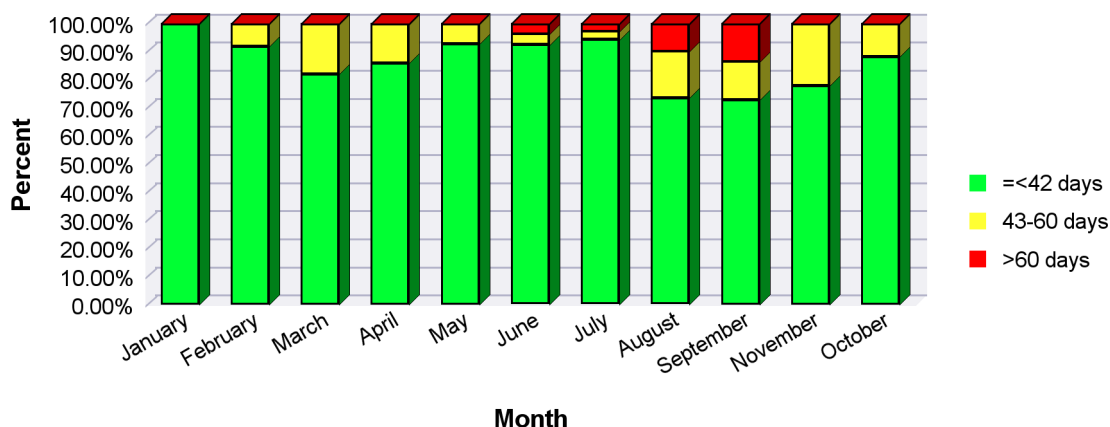


Assessment times for clinical trial applications 2013

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	27	100	0	0	0	0
February	11	91.67	1	8.33	0	0
March	27	81.82	6	18.18	0	0

Assessment times for clinical trial applications 2013

	<43 days	Percent <43	43-60 days	Percent 43-60	>60 days	Percent >60
April	18	85.71	3	14.29	0	0
May	25	92.59	2	7.41	0	0
June	24	92.31	1	3.85	1	3.85
July	32	94.12	1	2.94	1	2.94
August	22	73.33	5	16.67	3	10
September	16	72.73	3	13.64	3	13.64
November	14	77.78	4	22.22	0	0
October	22	88	3	12	0	0