

Case statistics on the quality of clinical trial applications

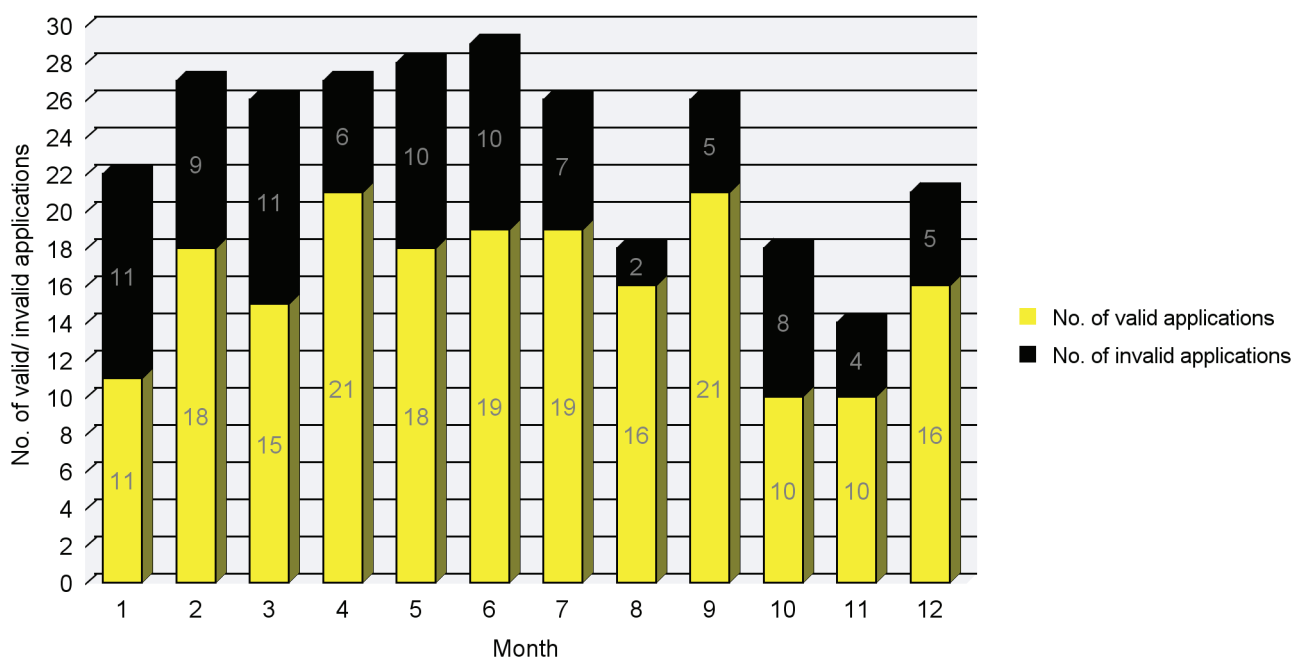
The Danish Medicines Agency reviews clinical trial applications. A sizeable share of the applications are invalid when we receive them in the Danish Medicines Agency. The chart shows how many of the applications are valid when we receive them.

When we receive an application, we validate the application to make sure it contains the required information. If we have no remarks to the application, we consider it valid. Our validation is to ensure that we do not have to interrupt the assessment because of missing information.

It appears from the Danish Medicines Agency's guideline which components must be included in the application. If the application is invalid, we will not commence our review.

The bar chart shows the distribution between valid and invalid applications at the time of notification to the Danish Medicines Agency

Clinical trials notified in 2016



	Valid applications	Invalid applications	Applications in total
1 January	11	11	22
2 February	18	9	27
3 March	15	11	26
4 April	21	6	27
5 May	18	10	28
6 June	19	10	29
7 July	19	7	26
8 August	16	2	18
9 September	21	5	26
10 October	10	8	18
11 November	10	4	14
12 December	16	5	21
Total:	194	88	282