

Case statistics on the quality of clinical trial applications

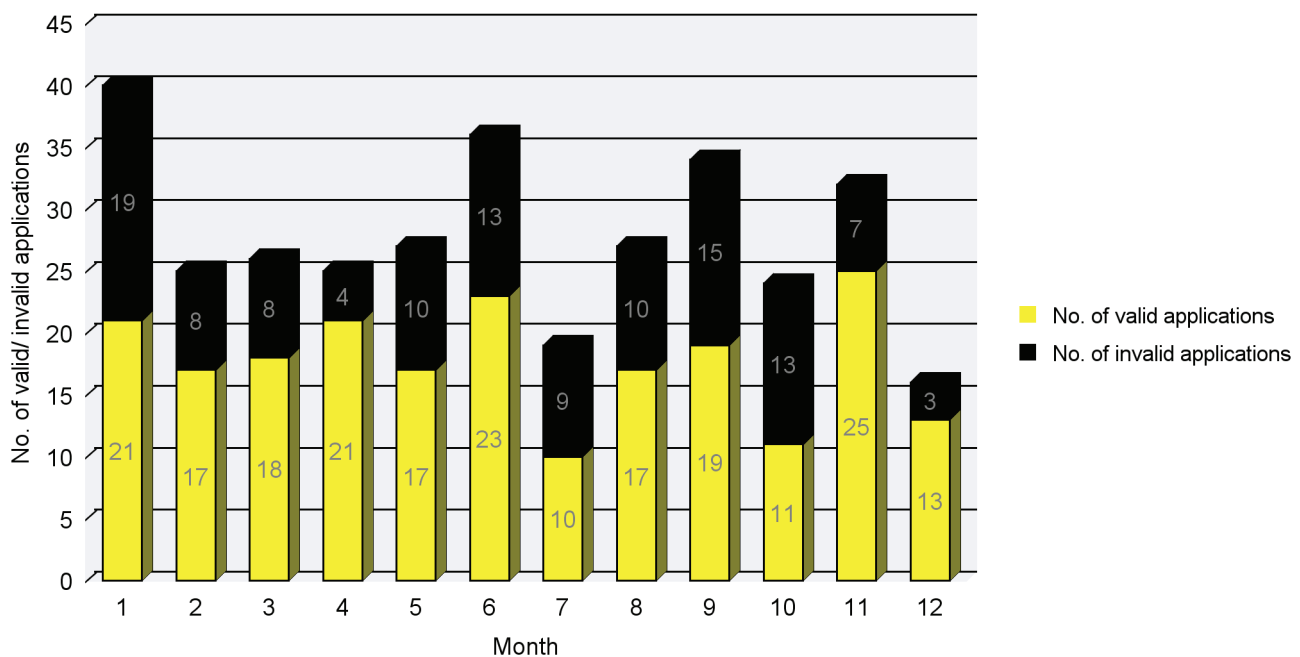
The Danish Medicines Agency reviews clinical trial applications. A sizeable share of the applications are invalid when we receive them in the Danish Medicines Agency. The chart shows how many of the applications are valid when we receive them.

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 2015



	Valid applications	Invalid applications	Applications in total
1 January	21	19	40
2 February	17	8	25
3 March	18	8	26
4 April	21	4	25
5 May	17	10	27
6 June	23	13	36
7 July	10	9	19
8 August	17	10	27
9 September	19	15	34
10 October	11	13	24
11 November	25	7	32
12 December	13	3	16
Total:	212	119	331