

Case statistics on the quality of clinical trial applications

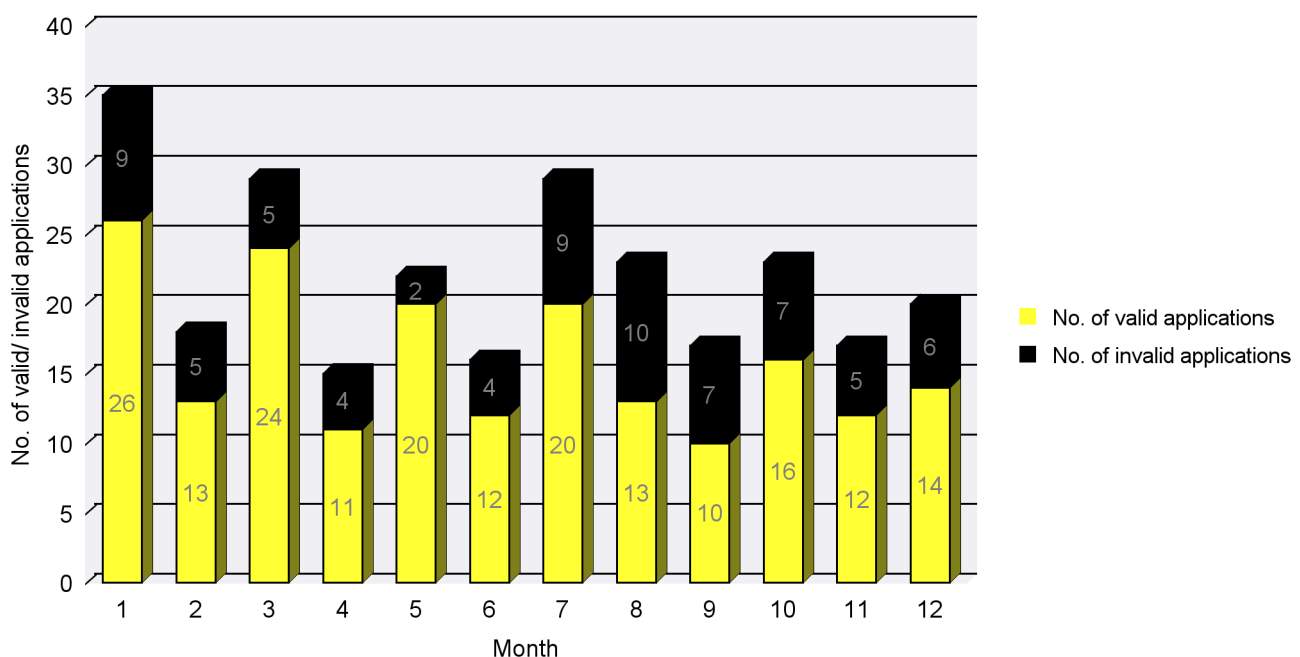
The Danish Health and Medicines Authority reviews clinical trial applications. A sizeable share of the applications are invalid when we receive them in the Danish Health and Medicines Authority. The chart shows how many of the applications are valid when we receive them.

When we receive an application in the Danish Health and Medicines Authority, 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 the applications we receive are complete (valid) to avoid having to interrupt the assessment because of missing information.

It appears from the Danish Health and Medicines Authority'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 Health and Medicines Authority.

Clinical trials notified in 2012



	Valid applications	Invalid applications	Applications in total
1 January	26	9	35
2 February	13	5	18
3 March	24	5	29
4 April	11	4	15
5 May	20	2	22
6 June	12	4	16
7 July	20	9	29
8 August	13	10	23
9 September	10	7	17
10 October	16	7	23
11 November	12	5	17
12 December	14	6	20
Total:	191	73	264