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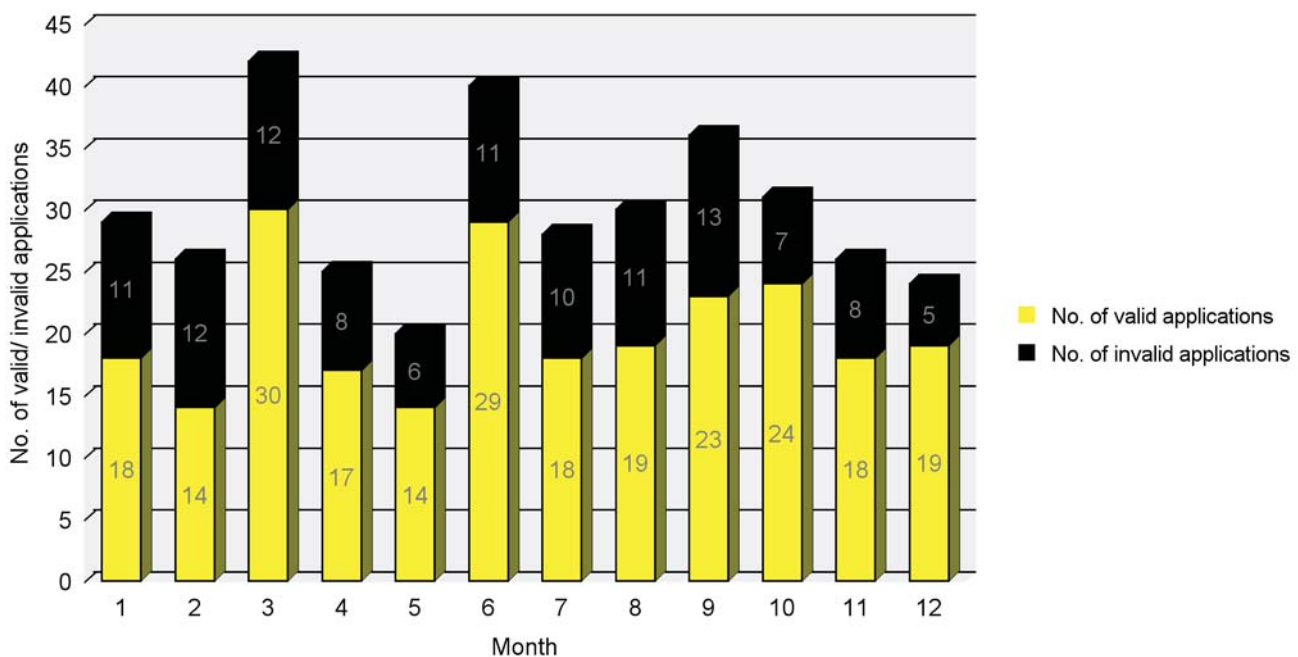
The Danish Medicines Agency reviews clinical trial applications. A sizeable share of the applications are invalid when we receive them in the Danish Medicines Agency. The chart shows how many of the applications are valid when we receive them.

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 2020

		Valid applications	Invalid applications	Applications in total
1	January	18	11	29
2	February	14	12	26
3	March	30	12	42
4	April	17	8	25
5	May	14	6	20
6	June	29	11	40
7	July	18	10	28
8	August	19	11	30
9	September	23	13	36
10	October	24	7	31
11	November	18	8	26
12	December	19	5	24
	Total:	243	114	357