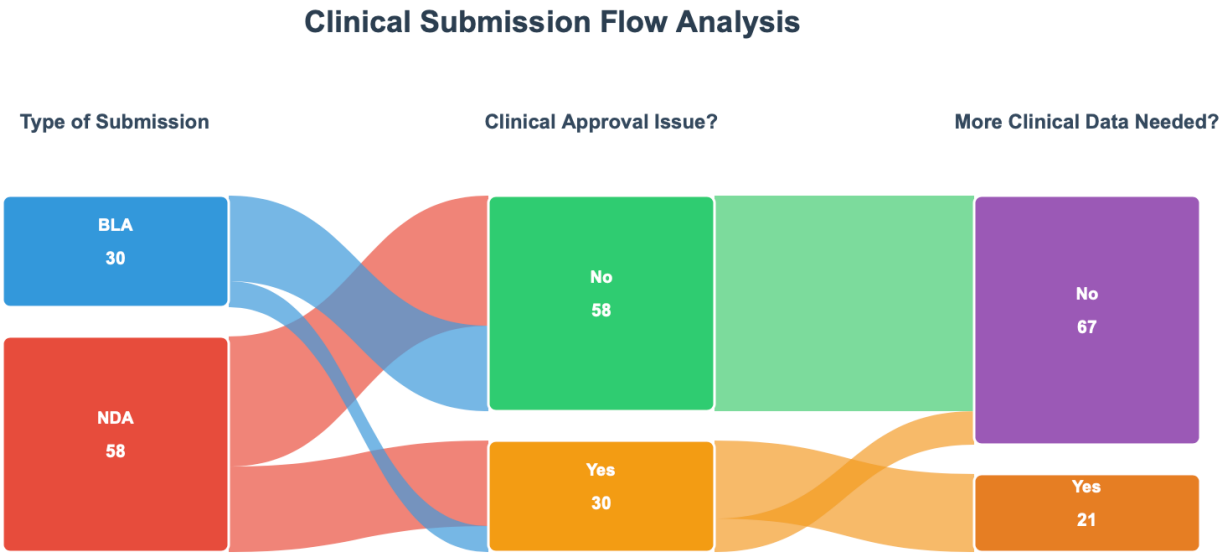
If an applicant receives a non-approval letter due to clinical issues, what's the chance they will have to conduct another clinical study?

Among the Complete Response Letters (CRLs) recently made public by FDA, 34% (30/88) cited clinical issues. But 24% (21/88) said there was a need to collect additional clinical data.

The alluvial diagram below illustrates the fate of these NDA and BLA submissions. At first glance it seems that a third (9/30) might not require additional clinical data. However, if you read the CRLs, these tend to be situations in which Facility or Quality issues precluded a final clinical review. For such products, it's too early to tell if additional clinical data will be needed.

If you were conducting due diligence on a development program and learned it had clinical issues but FDA had not asked for another clinical study, it might be a good idea to determine if FDA put a condition on that!



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