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The FDA Influence For Optimising Pivotal Drug Studies

According to a study published in JAMA, one-quarter of recent new drug approvals occurred without any meeting between the FDA and the pharmaceutical companies. Even if a meeting did take place, the pharmaceutical companies did not comply with one-quarter of the recommendations made by the FDA regarding study design or primary outcome.

Federal regulations encourage meetings during the design phase of pivotal studies as they often generate recommendations for improving research. However, pharmaceutical companies are not required to have these meetings nor are they bound to follow any recommendations.

Steven Woloshin, M.D., M.S., of the Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, N.H., and colleagues reviewed and analysed 200 FDA documents for 35 new drugs approved between February 1, 2011, and February 29, 2012. All FDA comments and recommendations about pivotal study design or primary outcomes were analysed by the researchers. The research team also characterised the effect of recommendations on study quality.

The analysis revealed that of the 35 new drug approvals, companies met with the FDA for only 28 of them. Overall, the FDA made 53 recommendations with respect to design (e.g., controls, doses, study length) or primary outcome for 21 approvals. Fifty-one recommendations were related to the study quality and two as having an uncertain effect. Companies complied with 40 of the 53 recommendations. Examples of non-compliance included a request for randomized trials of brentuximab and crizotinib, but the companies conducted uncontrolled studies. Other cases included primary outcome choice (e.g., progression free instead of overall survival) and drug (active comparator) doses tested.

With respect to the pivotal trial protocols, companies can also request the FDA for a review. If the FDA endorses the protocol, then it cannot object to any study design issues at the time of drug approval. As per this analysis, only 21 of the 35 new drug approvals were asked to be reviewed by the FDA. Out of these 21, the FDA endorsed the protocol for 12.

The study authors believe that FDA review of pivotal trials with binding recommendations should be mandatory as it could be an effective way to optimise study quality. They also believe that such a review can be even more important with increasingly flexible approval pathways. “An independent FDA-commissioned report suggested that stronger early FDA involvement could avoid deficiencies that delay approval of effective drugs and more clearly identify ineffective or harmful ones.”

Source: JAMA
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