

## FDA PROPOSES GIVING CLINICAL RESEARCH SPONSORS MORE INPUT PRIOR TO IDE SUBMISSIONS

The U.S. Food and Drug Administration ("FDA") has issued draft guidance on its Investigational Device Exemption ("IDE") process for medical devices, titled [Decisions for Investigational Device Exemption Clinical Investigations](#). The draft guidance introduces a new pre-decisional IDE review process, through which medical device sponsors can seek the FDA's input on significant issues before submitting an IDE. In addition, the FDA has issued a statement detailing modifications to its IDE technology platform that will change how sponsors report research matters to the agency.

### THE PRE-DECISIONAL IDE REVIEW PROCESS

The FDA currently offers two processes to assist sponsors that have products requiring clinical research: the full IDE process and a pre-submission process. If the FDA's new proposal is implemented, the agency will introduce a third process, which targets sponsors that are not quite ready to submit an IDE but that have progressed well beyond the general pre-submission stage.

The FDA's proposal is a result of industry complaints about current processes. The general pre-submission process has a ninety-day or more review timeline, whereas the more demanding IDE process has only a thirty-day timeline. Therefore, to save time, many sponsors submit IDEs before the nuances of the research are fully understood and address any issues through change requests during the research. However, there is no assurance that the FDA will accept requested changes or allow related data to be used to support medical device premarket submissions.

The FDA's proposed, voluntary process is intended to give sponsors detailed feedback on significant issues earlier in the process to reduce time delays, interactions with the agency during the research and uncertainty about the value of the research. It is most applicable to sponsors who have not gone through an earlier pre-submission process and will be ready to submit an IDE after a few remaining significant issues are addressed. Significant issues that might be addressed through the process are those that may otherwise result in an IDE application disapproval, a condition of approval or would not support a market approval or clearance. The process is limited to pivotal trials that require an IDE and cannot be used for non-significant risk trials, exempt trials or clinical trials conducted wholly outside of the U.S.

To initiate the proposed pre-decisional IDE review process, a sponsor submits a request for agency review of potential issues. If the review is granted, the sponsor will meet with the FDA, after which the sponsor may either respond to the agency's comments or request that the pre-decisional IDE be converted to an IDE. If the sponsor requests a conversion to an IDE, the FDA will issue a decision letter within fifteen days. If the sponsor submits a focused response instead, the agency will either email comments to the sponsor or allow the sponsor to repeat the pre-decisional IDE one more time.

### TIMELINE CHALLENGES MAY REMAIN

As proposed, within five days of receiving the pre-decisional IDE application from the sponsor, the FDA must determine if the application is complete and ready for substantive review. If accepted for review, the FDA will then have thirty days to conduct an in-depth review. The agency must then schedule a meeting with the sponsor to take place within fifteen days after the end of the review. If the sponsor does not request a conversion to an IDE after the meeting, the FDA will provide comprehensive written feedback within fifteen days of the meeting.

These are very aggressive timelines, and if the agency struggles to meet them, the program could be of limited benefit to sponsors. The FDA has experienced difficulties meeting comparative timelines under its 510(k) Refuse to Accept policy and is unlikely to commit additional resources to the process because of federal budget cuts. As a result, to meet its timeline obligations, the agency may give feedback that is overly conservative or that simply sends the issue back to the sponsor for additional work.

### NEW TECHNOLOGY EQUALS NEW TYPES OF DOCUMENTATION

The FDA has also switched to a new technology platform that the industry must use when submitting documents relating to IDEs and emergency use authorization applications. According to the [FDA's statement](#), the new technology is intended to help the agency better track research activity milestones, particularly for multiple studies, such as feasibility or pivotal studies, under a single original IDE

submission number.

Because each subsequent submission to an IDE can only be assigned to one study in the new system, sponsors will see changes in three primary ways. First, reports are now separate subtypes of a study and not supplements or amendments. Second, deficiency letter responses will not be considered supplements but will be considered amendments to the relevant original IDE, IDE supplement or IDE report. Third, each IDE submission must address only one submission purpose, so documents containing multiple requests or combining multiple purposes, such as combining a change request with a deficiency letter response, will no longer be accepted.

## **PRACTICAL TAKEAWAYS**

The proposed pre-decisional IDE review process could present helpful opportunities to obtain the final FDA input prior to the submission of IDE applications and could be especially beneficial to those entities that have already gathered pre-clinical or foreign clinical data intended for use in a premarket submission. However, if a specific outcome from the FDA is desired, then sponsors will need strong arguments and a deep understanding of the agency's IDE and premarket rules to counteract any conservative approach from the agency that could arise because of its short timeline obligations.

If you have questions about either of these FDA clinical research initiatives, please contact:

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