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# FDA details recommendations for live case presentations during medical device clinical trials in final guidance

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This month, the U.S. Food and Drug Administration (FDA or the agency) issued a final guidance on live case presentations as part of clinical trials conducted under an approved (or conditionally approved) investigational device exemption (IDE). A live case presentation involves treatment of a human subject with an investigational device and is a live or prerecorded broadcast of that investigational surgical or percutaneous procedure, typically narrated. Live case presentations may also include an expert panel and/or audience interaction.

FDA advises that live case presentations are not without risks and, in fact, may increase risks to the subject. For example, there may be an increased risk of infection due to increased number of nonmedical personnel and broadcast equipment in the sterile environment of the operating room and prolongation of the medical procedure may lead to increased blood loss, anesthesia time, or radiation exposure. Thus, FDA states that live case presentations should not cause any significant changes to the investigational protocol and are not appropriate for investigational devices under expanded access.

The appropriate use of a live case presentation during IDE clinical trials must be reviewed by FDA and/or an Institutional Review Board (IRB). Specifically, a live case presentation involving a significant risk device, as defined under 21 Code of Federal Regulations § 812.3(m), requires approval by both FDA (vis-a-vis an IDE application or IDE supplement) and an IRB, whereas live case presentations involving a non-significant risk device generally only require approval by an IRB.

FDA recommends that study sponsors consider whether they intend to conduct a live case presentation early in development and if so, encourages them to include relevant information in the investigational plan of the original IDE. However, FDA acknowledged industry's feedback that details regarding the live case presentation may not be available at the time of the original IDE application, adding that such a request may be made in a supplement to the IDE. The agency also indicated in both the draft and final guidance that a live case presentation may not be appropriate for novel devices for which the risk profile is unknown or only limited information is available. In the final guidance, FDA adds that a live case presentation may be acceptable even when involving a high-risk procedure if the risks are well understood, risk mitigations are in

place, subjects are selected with appropriate clinical and anatomic characteristics, and adequate informed consent is obtained in accordance with 21 Code of Federal Regulations Part 50.

For entities considering a live case presentation, either early in study development or as part of a planned supplement, a detailed assessment of the potential risks to subjects and the need for either FDA or IRB review, the ability to adequately inform subjects of those risks and obtain their consent, and the impact of the live case on study design and data analysis all need to be considered. If you are planning live case presentation(s), be sure to include the information specified in the FDA guidance in your IDE or IDE supplement, including the number of cases anticipated, a justification for the live case presentation(s) and details (e.g., date, location, investigator) if known, informed consent, risk-mitigation methods, and effect on the existing study plan.

While a prior draft guidance issued in 2014 included a lengthy discussion of FDA's concern that a live case presentation could be used to promote or test market an investigational device in violation of FDA's prohibition against such activity and called for this to be addressed in the IDE application or supplement requesting the live case presentation, this discussion is entirely omitted from the final guidance. Nevertheless, FDA continues to require that sponsors not use live case presentations to promote or test market their investigational devices or to represent that the investigational device is safe or effective for the purposes for which it is being investigated, consistent with its long-standing policy.[1] Along these lines, because the purpose of live case demonstrations is typically to increase awareness of the study for recruitment of potential investigators and study subjects, FDA also maintains that a live case presentation request is not appropriate for a study nearing completion, which may appear to be promotional in nature.

To fully leverage live case presentations, sponsors should engage with FDA early in development, even where specific details about the live case presentation may not yet be known. Although the draft guidance left the impression that live case demonstrations had fallen into disfavor with FDA, the final guidance may indicate a more favorable view of live case presentations, providing a viable pathway for sponsors to utilize this important study recruitment tool. It may also signal FDA's acceptance of some level of non-promotional scientific exchange by medical device clinical trial sponsors. As described above, FDA intends to focus its review on the risk analysis, the informed consent, and the impact of live case presentations on the study design and data analysis, rather than on whether the live case demonstration amounts to promotion of the investigational device in violation of the Federal Food, Drug, and Cosmetic Act.

[1] See *Preparing Notices of Availability of Investigational Medical Devices for Recruiting Study Subjects* (March 1999), available here.

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