Webinar - Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions Final Guidance - February 23, 2017

Tell Us What You Think: Take Our Survey on Medical Device Webinars.

Webinar Materials

- Printable Slides (PDF - 273KB)

The FDA published a final guidance clarifying key factors it considers when assessing the benefits and risks of Investigational Device Exemption (IDE) submissions for human clinical study.

The final guidance:

- Enhances the predictability, consistency and transparency of the IDE review process;
- Provides a common understanding between the FDA staff and clinical trials sponsors on what information informs the benefit-risk assessment of an IDE submission; and
- Facilitates the incorporation of evidence and knowledge from different domains—clinical, nonclinical and patient—to support a comprehensive, balanced decision-making approach.

Also included in the guidance is a framework for benefit-risk assessment that we are recommending IDE sponsors provide as part of their application. The framework

outlines a preferred approach for summarizing the key considerations in the benefit-risk assessment for the device, with hypothetical assessments as examples.

Release of this guidance is part of the FDA's on-going efforts to improve patient access to new devices by strengthening and streamlining clinical trials. It does not change sponsor requirements.

FDA will host a webinar on Thursday, February 23, 2017 to help manufacturers and other interested stakeholders understand the information provided in this final guidance document.

Following a brief presentation, the FDA will respond to questions.

Webinar details:

Registration is not necessary.

- Date: Thursday, February 23, 2017
- Time: 12:30 p.m. – 2 p.m. Eastern Time (please connect by 12:15 p.m.)

To hear the presentation and ask questions:
Dial: 800-475-0553; passcode: 1759468 | International: 1-415-228-5009; passcode: 1759468
Conference number: PW2531042

To view the slide presentation during the webinar:
https://www.mymeetings.com/nc/join.php?i=PW2531042&p=1759468&t=c

Due to expected high participation of this webinar, please use the following link to access the live presentation if the previous link returns an error message upon logging in: https://www.livemeeting.com/cc/events_vbc1/join?id=PW2531042&role=attend&pw=1759468

Following the webinar, a transcript, recording and slides will be available at: http://www.fda.gov/CDRHWebinar. The slide presentation will be available at this site on the morning of the webinar.

If you have any questions regarding this guidance document, please contact CDRH's Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov, or by phone 1-800-638-2041, or 301-796-7100.

Food and Drug Administration
Center for Devices and Radiological Health

More in Workshops & Conferences (Medical Devices)

2017 Medical Device Meetings and Workshops

2016 Medical Device Meetings and Workshops

Medical Device Webinars and Stakeholder Calls

Page Last Updated: 02/23/2017
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA