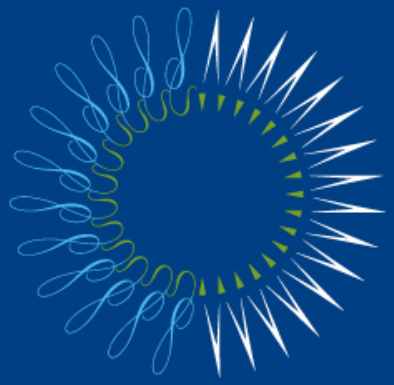


THE PEW CHARITABLE TRUSTS

New FDA Proposals to Expedite Medical Device Development

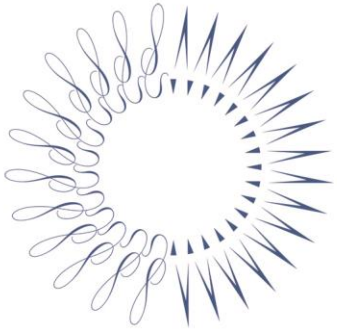
June 19, 2014

The Pew Charitable Trusts

Pew is an independent, non-profit research and public policy organization.

Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

- Unique device identifier (UDI)
- Medical device registries
- Accelerating device innovation



THE PEW CHARITABLE TRUSTS

FDA Proposals to Expedite Medical Device Development

- Jeff Shuren, Director, CDRH, FDA
- Ross Jaffe, Managing Director, Versant Ventures
- Bray Patrick-Lake, CEO, PFO Research Foundation
- David Holmes, Professor of Medicine, Mayo Clinic
- Moderator: Josh Rising, The Pew Charitable Trusts

Questions?

GoToWebinar: Type your question or raise your hand

Twitter: #deviceinnovation

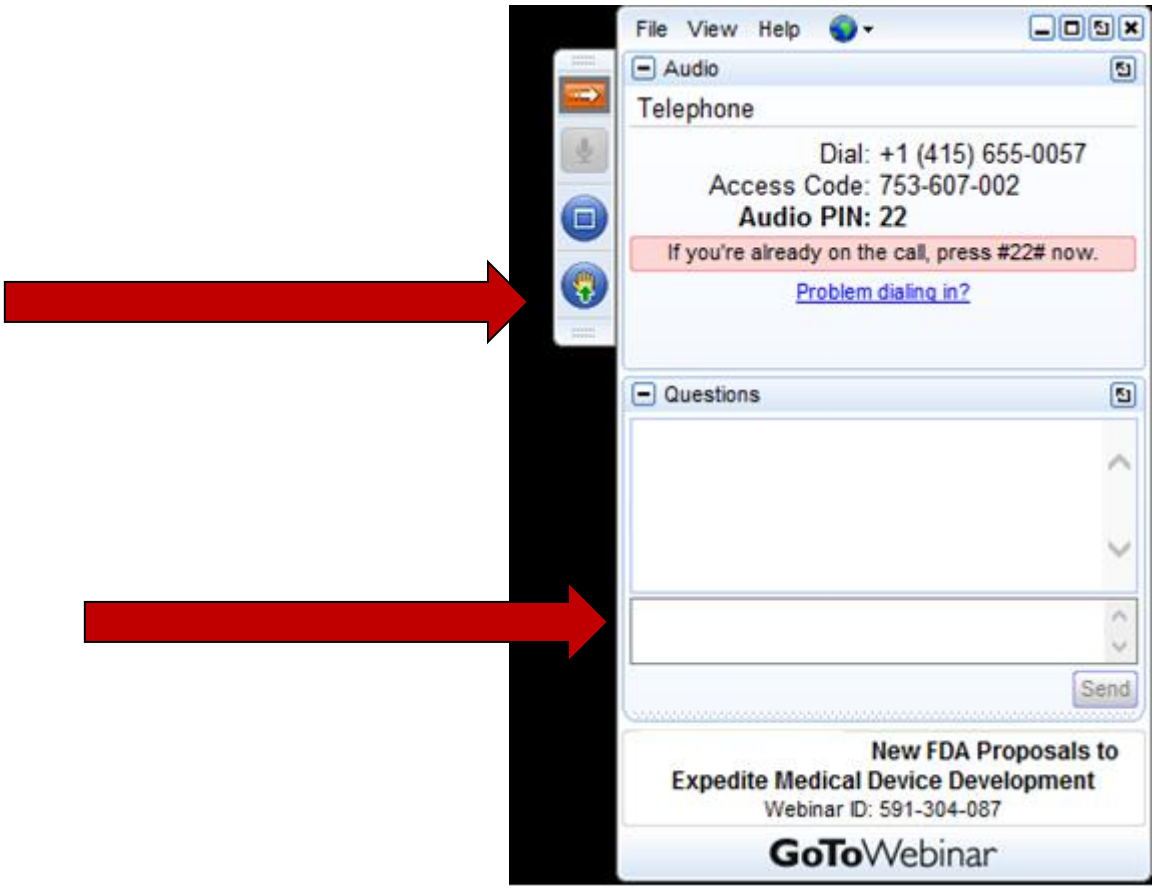
Questions?

Raise your hand, and we will unmute you to ask your question

- or -

Type in your question

- or -



#deviceinnovation

New FDA Guidance Documents

- Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions

- Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

New FDA Guidance Documents

Premarket-Postmarket Balance

"Getting the right balance between premarket and postmarket data collection—specifically, where appropriate, a greater reliance on postmarket collection—can reduce the extent of premarket data submission and directly impact when patients will have access to high-quality, safe and effective medical devices."

Enhanced Postmarket Requirements

"FDA believes that the implementation of our 2012 strategy for a National Medical Device Postmarket Surveillance System … could address certain limitations with the current medical device surveillance program and allow for a greater shift of premarket data collection to the postmarket setting for appropriate devices"

Expedited Access PMA as Outlined by FDA

- For devices that address a serious unmet medical need
- Features include:
  - Interactive review, case manager, senior management
  - Priority review
  - Less manufacturing information in some cases
- Types of data:
  - Intermediate and surrogate endpoints
  - Two-phase studies
  - Alternative designs for diagnostics
- Postmarket Controls
  - Post-approval study and other requirements

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Thank you

Josh Rising, MD
Director, Medical Devices
The Pew Charitable Trusts
jrising@pewtrusts.org