FDA E-Team Perspective on the Use of Mobile Apps in Clinical Investigations

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Mobile apps in clinical investigations

- **Leonard Sacks** (Office of Medical Policy, CDER, FDA)-

  Topic: Mobile apps- new opportunities in the design of clinical investigations

- **Ron Fitzmartin** (Office of Strategic Programs, CDER, FDA)-

  Topic: Mobile apps- considerations related to data standards

- **Jonathan Helfgott** (Associate Director for Risk Science (Acting), Office of Scientific Investigations, CDER, FDA)-

  Topic: Inspection of Mobile apps for integrity and performance

Mobile apps universe

- Mobile devices can capture an endless variety of information remotely.
- They may include:
  - cellphones capturing the patient's response to a PRO
  - cellphone cameras capturing the appearance of a lesion
  - customized sensors that measure and transmit physiological information e.g. sensors that detect tremors, movement in joints, heart rate irregularities, pedometers ergonometers, you name it.

Universe con't.

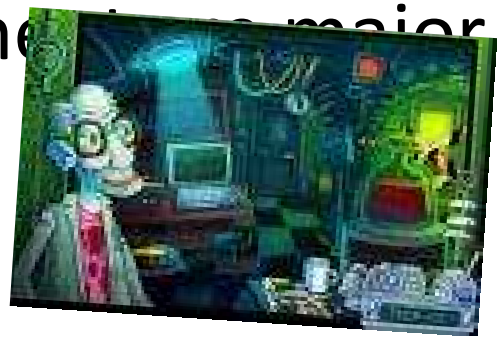
- Cell phones and tablets are already built for capturing and sending information- they are just acting as platforms
- Cameras represent existing technologies being adapted for a medical use
- Finally there are customized sensors specifically designed to make clinical measurements

Considerations for these technologies

- For existing platforms like tablets and cellphones, these look like computers without wires.
- Adoption of these is already covered to some extent by guidances and regulations that Jonathan will mention.
- The principles that apply are the traditional “ Attributable, Legible, Contemporaneous, Original and Accurate”.

Considerations for these technologies

- When existing functions are adapted for clinical use, new considerations may include standardization, reproducibility, user error etc.
- In the case of a customized sensor, the performance of the device and the clinical relevance of the measureme[illegible] major considerations



Regulatory framework

- Devices used in clinical care are subject to device regulations
- Devices used in clinical research are currently evaluated on a case by case basis, by review divisions in consultation with other experts in CDRH or elsewhere

Opportunities

- Patient centered studies- patient participates from home, able to monitor physiological responses, patient reports, medication adherence
- Eliminates missing data and losses-to-follow-up
- Facilitates more frequent and even continuous data acquisition- e.g. ECG, EEG, motion sensor

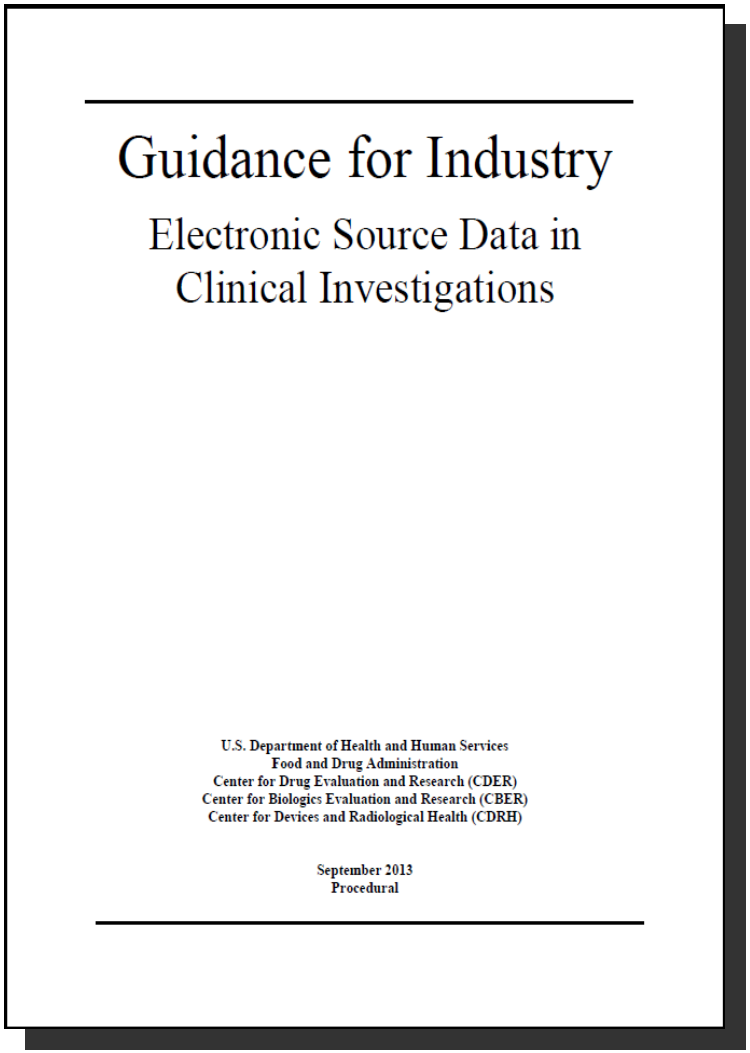
- More objective data from sensors
- Patient convenience and increased participation and access to trials
- Improved safety through rapid detection of adverse events

Challenges

- ‘Attributability’ of data
- Ensuring responsible use of devices
- Reduced contact with healthcare givers
- Reduced supervision
- Not suitable for in certain trial settings e.g. ICU
- Validation of instruments

Perspective

- At the threshold of a revolution in clinical studies
- We can monitor a spacecraft on Mars
- We can move 500 people from New York to Beijing almost completely electronically
- There is barely a financial function that cannot be performed electronically
- It's time for clinical research to catch up


Guidance for Industry

Electronic Source Data in Clinical Investigations

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

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Procedural

"…promotes capturing source data in electronic form…,"

[assists] *"in ensuring the reliability, quality, integrity, and traceability of electronic source data."*

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

- **Data Capture: *Source Data Capture***

3. Automatic Transmission of Data from Devices or Instruments Directly to the eCRF
   - •No paper required
   - •Improved data quality and availability
   - •Documentation of Source is important (e.g., intervening data management process)
   - **•Best Case!**
4. Transmission of Data from PRO Instruments to the eCRF
   - •No paper required
   - •Improved data quality and availability
   - •Documentation of Source is important (e.g., intervening data management process)
   - **•Best Case!**