Mobile Clinical Trials and CDRH's Regulation of Devices

CTTI Expert Meeting:
Scientific and Technological Issues Surrounding the Use of Mobile Devices in Clinical Trials

Ken Skodacek / Dharmesh Patel
FDA/CDRH
June 15, 2017
Disclosure

I have no financial conflicts.

I work for FDA and love my job.
Nearly 98% of clinical research professionals plan to use digital technologies to collect patient data within the next five years...

http://jamanetwork.com/journals/jamacardiology/article-abstract/2566167
Overview of Medical Device Regulation

• FDA/CDRH is responsible for regulating firms that manufacture, repacking, relabel, and/or import medical devices sold in the US

• Defined in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act

• "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  – recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  – intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  – intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
How will FDA regulate the technology?

How can the technology be used to improve the clinical trial?
Important Notes

• Many mobile technologies are marketed and sold as consumer devices but might be used in healthcare or clinical investigations.

• FDA clearance or approval of a technology grants authorization for marketing and sales of medical devices, which are typically associated with specific claims related to use as a medical device.

• **Use of the technology in a clinical trial does NOT mean that the technology would be regulated as a medical device.**

• Use of a mobile technology in a clinical investigation, whether or not it is cleared or approved by FDA as a medical device, still requires careful consideration, given the potential impact on the investigation.
Use in Clinical Investigations

Recruiting

Screening

Consent

Subject Follow-up & Evaluation

What are the intended goals and unintended effects?

Clinical Study Process
Potential Options

1. Evaluating the technology as a tool in a controlled setting
2. Recruiting, screening, and improving subject compliance
3. Gathering data to better understand subjects or an investigational device
4. Gathering data to support a secondary endpoint
5. Gathering data to support a primary endpoint
6. Evaluating the technology as an investigational medical device
Regulation of Clinical Investigations

FDA/CDRH is also responsible for regulating entities involved in the conduct of clinical investigations.

<table>
<thead>
<tr>
<th>Sponsors and investigators</th>
<th>21 CFR Parts 50, 54, 312, &amp; 812</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Review Boards</td>
<td>21 CFR Part 56</td>
</tr>
</tbody>
</table>

Inclusive of the evaluation of the investigational drug, device, or biologic, any tools being used in a trial would be considered in the **overall context of how those tools are being used** as well as the overall benefits and risks to subjects.
Recent Updates to Medical Device Law

• 21st Century Cures Act
• Clarifies regulation of medical software
• Sec 3060 amends Section 520 of FDCA
• Codifies CDRH’s oversight of software, agnostic to the platform, including mobile technology
Cautionary Note

In Your Mind:
- Fetch my emails!
- Navigate to John's house.
- Show me the news!
- Send this photo to Lynn!
- Y-y-yes master.

In Reality:
- Charge me!
- Gimme some wifi! Now!
- New email! Read!
- Answer this call!
- A restaurant! Check in!
- Y-y-yes master.
Ken Skodacek
Ken.Skodacek@fda.hhs.gov

Dharmesh Patel
Dharmesh.Patel@fda.hhs.gov