Digital Health

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- FDA policy for regulating connected health products still emerging.
- Seemingly minor design/marketing changes can significantly impact regulatory requirements.
- Human Factors receiving increased scrutiny.
- Responsibilities when multiple parties involved.
- More focus on software development/changes.
- Communication security, especially for wireless.
- Software failures cause of nearly 20% of medical device recalls.

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Current trends of Mobile health app market

45,000+
mHealth publishers

3Billion+
apps downloaded in 2015

100+ Employees
size of most publishers

- Mostly targeting chronic diseases.
  Centralized care organizations possible future customer segment
- Follow-up monitoring - greatest impact during the next five years
- Influencing behavior change is seen as having biggest impact today through use of dashboards, reminders and a channel to HCP

Research 2 Guidance, mHealth App Developer Economics 2015

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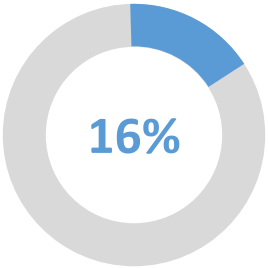
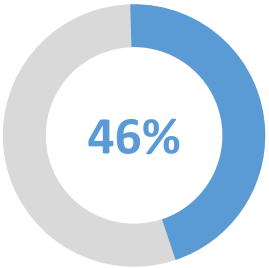
Current trends of Mobile health app market

Mobile applications with their patients

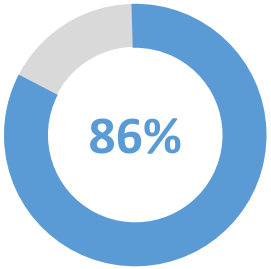
TODAY

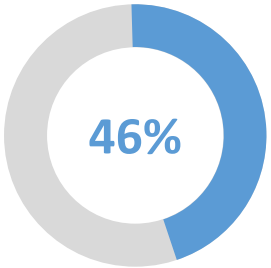


NEXT 5 Years



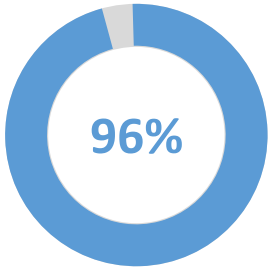
Increase knowledge of their patients' conditions,



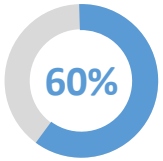


Improve relationships with patients

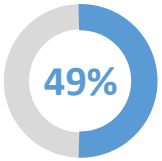
Improved consumers quality of life



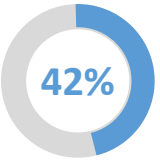
Usage



Activity & workouts



Calories



Weight loss

2015 survey of 500 professionals by Research Now

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FDA Guidance and Standards

- No specific Clinical Decision Support software guidance to date.
- Guidance on mobile medical apps, medical device data systems, cybersecurity, off-the-shelf software, and general software development exist.
- Draft guidance for Software as a Medical Device (SaaMD) and clinical trials used to support these.
- Draft guidance related to deciding when a new 510(k) is needed that highlights software.
- IMDRF has issued other guidance on SaaMD that FDA has provided input in.
- FDA recognition of IEC 62304 and several of the IEC 11073 Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

FDA

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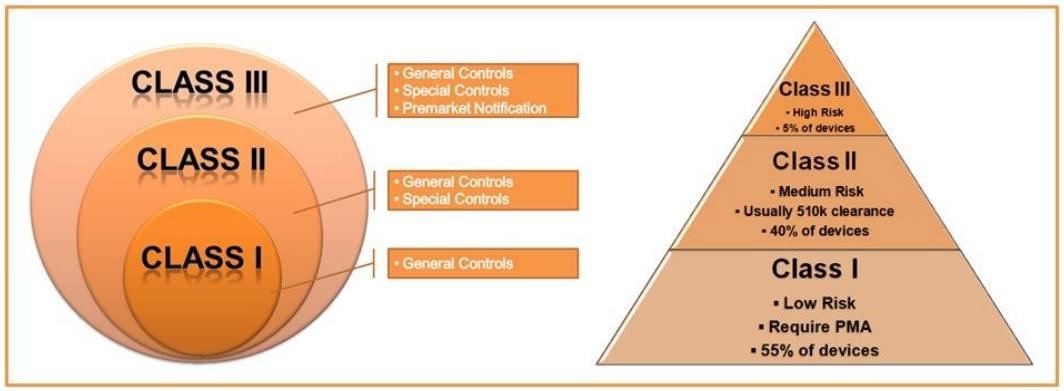
FDA Classification Assessment

- Classification of a device is still the same approach.
  - Does it meet the definition of a medical device based upon the intended use?
  - Based on the intended use, what is the risk and does this match any existing device classifications or other devices FDA regulates?
  - For SaaMD in the US, need to also ask whether it is or could be under enforcement discretion.



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Ray Silkaitis

Developing an App for a Combination Product

The views expressed herein represent those of the author and do not necessarily represent the views or practices of the author's employer or any other party.

Developing an App for a Combination Product

How to handle regulatory determinations of mobile apps with a branded drug?

- Rule of thumb, the **intended use, potential risk to patients / users**, and **device description** determines the extent to which regulatory requirements will be required for the software products.
- Because of the branded drug, context in which the app is being used and information presented in the user interface (UI) are significant to the determination of the regulatory pathway.
- Consider the quality system requirements

Developing an App for a Combination Product

- Context of App Use
  - Consider now a “system” where it is “connected” to the combination product?
    - Does the filing scenario change if the signal is broadcast vs interactive but not controlling?
  - How are dosing schedules presented?
    - What happens after a reminder is made?
  - To whom should the submission be made – CDRH/CDER?
  - What is the indication for use of the connected sensor?

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Other Considerations

- Health Authorities are only one of the regulatory bodies for mobile apps/medical software. Non-health authority regulatory requirements also apply.
  - The Centers for Medicare and Medicaid Services (CMS); Office of the National Coordinator for Health Information Technology (ONC).
- Licensing Requirements:
  - BluetoothR Special Interest Group (SIG)
- Privacy requirements:
  - FTC Section 5 Enforcement
  - Health Insurance Portability and Accountability Act (HIPAA)
- State Health Privacy and Security Laws
- State Data Breach Notification Laws

Survey of "Branded" Pharma Apps Features

All addressed

- Important Safety Information (ISI)
- Acceptance Terms
- Privacy Disclosure
- Package Insert

Available Features were Variable

- Reminders
- Diary
- Rewards

Case Study Questions

Case Study Questions
Part C

Does the addition of wireless connectivity change the product classification?

- Does the intended use change?
- What are the new risks?
- Who will use the data and for what purpose?
- Impact of new draft “deciding when” guidance documents?

What claims can each company make regarding the wireless connectivity?

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The company wants to launch the IVD in stages, without BT connection first and then add the connection later. Would the geo location, local weather and UV exposure information be under enforcement discretion? Would a submission to CDER or CDRH be needed?

- Pre-submission recommended?

Case Study Questions
Part D

What is the device classification of BetterUVCalc?

- What is the intended use?
- Who will use it?
- What are the risks?
- Are there other similar devices (SaaMD) regulated by FDA?

What responsibility does FastSW and BestEver have regarding changes to their respective products?
Does WeTest have any responsibilities regarding changes to their device?

- Who owns the design and intended use claims?

What are the regulatory hurdles to approval or clearance?

- What evidence is needed?
- Are there existing standards or predicates to compare against?

How will a generic version of BlockUV impact FastSW?

- What algorithm was used and how was it validated?

Are there any additional cross-labeling concerns if BetterUVCalc is modified to use results from TestUV as well as the BlockUV dosing calculation to aid in determining how well a patient might respond to use of Block UV?

- What algorithm was used and how was it validated?