Digital Health

Center for Devices and Radiological Health

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Trends and next steps

User tolerance…

Computing power

Computing platforms

Software location

…part of a socio technical system + …among many new stakeholders
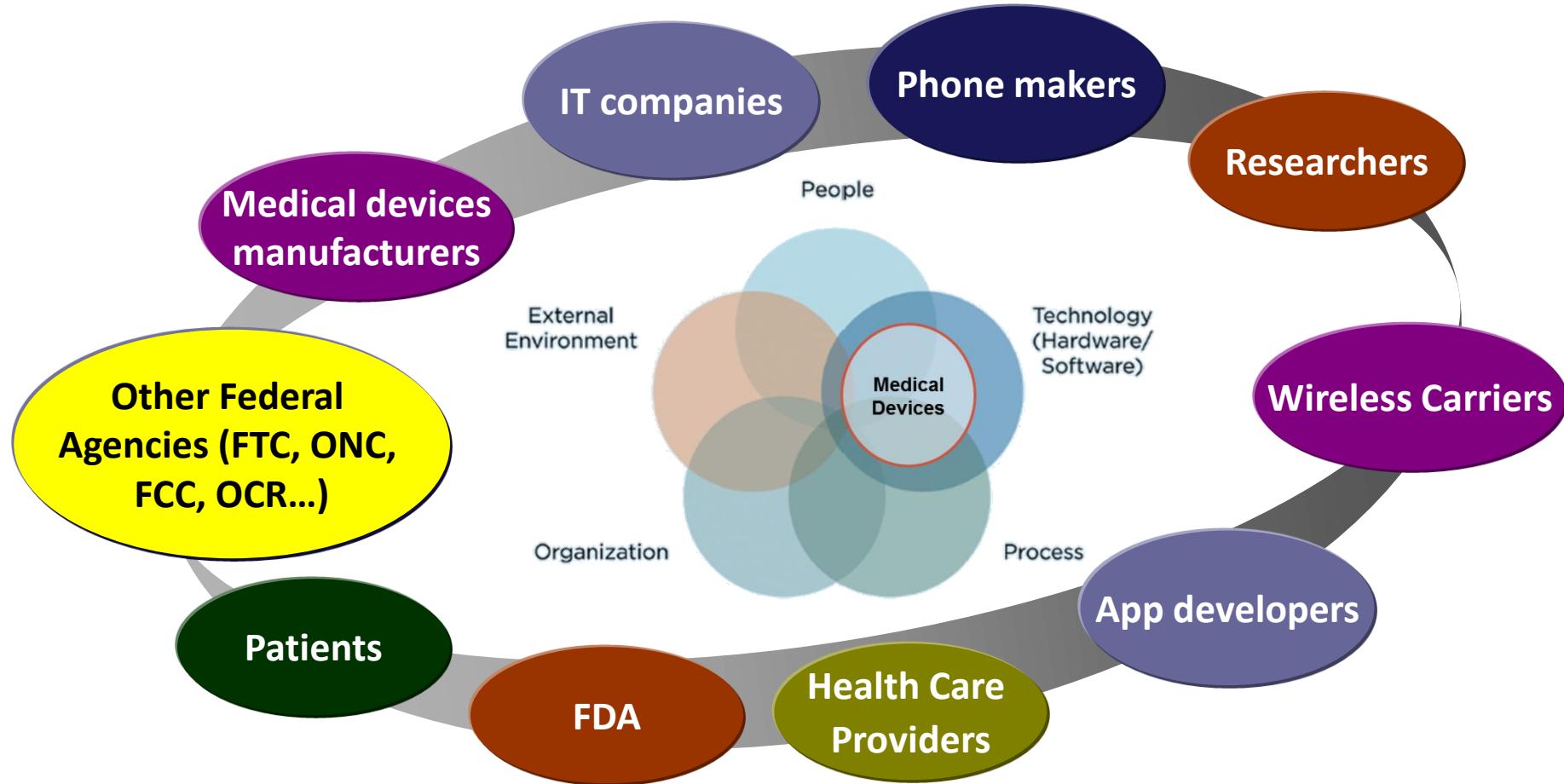
Digital Health Systems

interoperability

Home Health

Wireless Connectivity
IN MEDICAL DEVICES

MDDS

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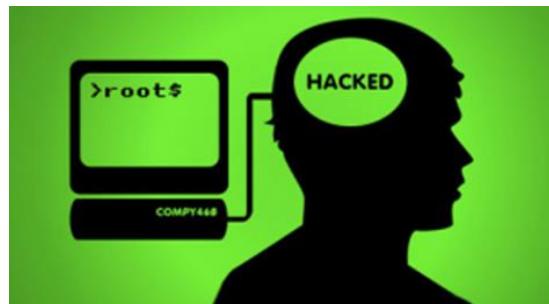
Device security

Mobile medical apps (MMA)

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Enforcement Discretion

focus of oversight

MMA

Lower risk mobile apps that meet "device" definition but not considered "MMA"
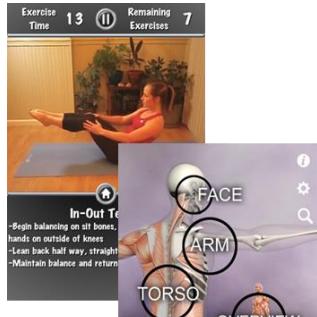
No regulatory requirements
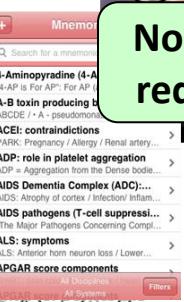
Mobile apps not considered "medical devices"

Mobile apps that meet "device" definition that are either intended
- To be used as an accessory to already regulated medical device, **or**
- To transform a mobile platform into a regulated medical device.

Oversight Principles
– for flexibility and scalability

Platform independent

Promote innovation

Promote patient engagement

Protect patient safety

Functionality focused

Narrowly tailored

Risk based