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Welcome

A Workshop on Managing App Development Under FDA Regulation

Stanford University

January 28, 2014

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Agenda

Schedule

8:00 a.m. – 8:10 a.m.	Welcome and Introductions
8:10 a.m. – 8:30 a.m.	FDA Introductory Comments on the Final Mobile Medical Applications Guidance
8:30 a.m. – 9:30 a.m.	Scope of FDA Regulation: Analyzing the New FDA Guidance
9:30 a.m. – 10:30 a.m.	Panel Discussion: Regulatory Strategies
10:30 a.m. – 10:45 a.m.	Break
10:45 a.m. – 11:15 a.m.	EU Regulatory Update: Strategies for Global Regulatory Compliance
11:15 a.m. – 12:00 p.m.	Panel Discussion: Business Strategies for Bringing New Apps to Market
12:00 p.m. – 12:30 p.m.	FDA Q&A
12:30 p.m.	Adjourn

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How to Ask Questions

MMARoadshowQues@gmail.com

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FDA Introductory Comments on the Final Mobile Medical Applications Guidance

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Digital Health

Center for Devices and Radiological Health

Bakul Patel

FDA

C·D·R·H
Center for Devices and Radiological Health

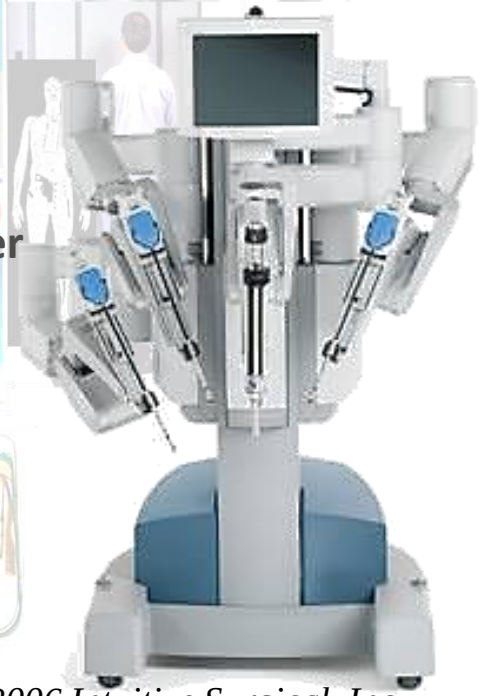
Vision

- **Patients** in the U.S. have **access** to high-quality, safe, and effective medical devices of public health importance first in the world.
- The U.S. is the world's leader in regulatory science, medical device **innovation** and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and **facilitates** device approval or clearance.
- Devices are legally marketed in the U.S. and remain **safe, effective, and of high-quality.**
- Consumers, patients, their caregivers, and providers have **access to understandable science-based information** about medical devices and use this information to make health care decisions.

Medical device

The Section 201(h) of the Food, Drugs and Cosmetics Act defines a medical device as any product with medical purpose that does not achieve its principal intended purposes by chemical action or by being metabolized.

- As simple as a tongue depressor or a thermometer
- As complex as robotic surgery devices



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A risk based approach for medical devices since 1976

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)

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Smart Regulation

Platform independent

Promote innovation

Promote patient engagement

Protect patient safety

Functionality focused

Narrowly tailored

Risk based

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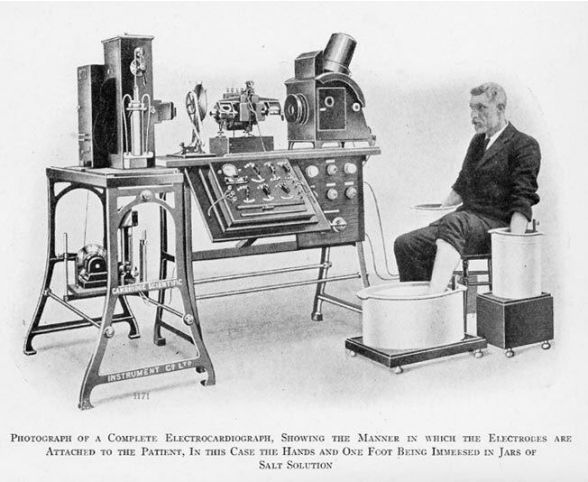
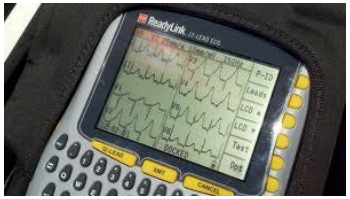
Functionality focused (EKG machine)



PHOTOGRAPH OF A COMPLETE ELECTROCARDIOGRAPH, SHOWING THE MANNER IN WHICH THE ELECTRODES ARE ATTACHED TO THE PATIENT, IN THIS CASE THE HANDS AND ONE FOOT BEING IMMERSED IN JARS OF SALT SOLUTION



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500 million

Smartphone users will be using health apps by 2015[1]

1 Research2Guidance 2010

"By the end of 2017, the total mHealth market revenue will have grown by 61% (CAGR) to reach US$26 billion." [2]

[2] research2guidance report 2013-2017

FDA's approach

- **Smart regulation**
  - Focus oversight on higher patient risk technology /software
  - Selective use of regulatory tools appropriate for technology
  - Scaling back from traditional approach (Class I, Class II Class III)
  - Relying on a quality systems approach

- **Examples of recent actions**
  - MDDS down classification – no premarket submission
  - Mobile medical apps – focused on a small subset – promoting innovation in mHealth through smart regulations

Health related mobile apps –landscape

- *Apple App Store – 43,000 apps (health related categories)*
  - *Healthcare & Fitness (23,728) + Medical (19,484)* (according to http://148apps.biz/ as reported on September 09, 2013)

- *"The **healthcare apps market is dominated by exercise apps** …. Sleep and meditation, and weight loss apps are expected to grow at the highest CAGR during the forecast period."* – September 2013 Researchandmarket report -- http://www.researchandmarkets.com/research/6hlqd6/mhealth_apps_and

- *Breakdown of available health-related apps – M. Shaw., Health digest news*
  - ***96 %*** *-- Calorie counting, Cardiovascular fitness, Strength training, Sleep improvement – consumer focused*
  - *remaining 4 % -- more specialized apps, for e.g. remote patient monitoring."*

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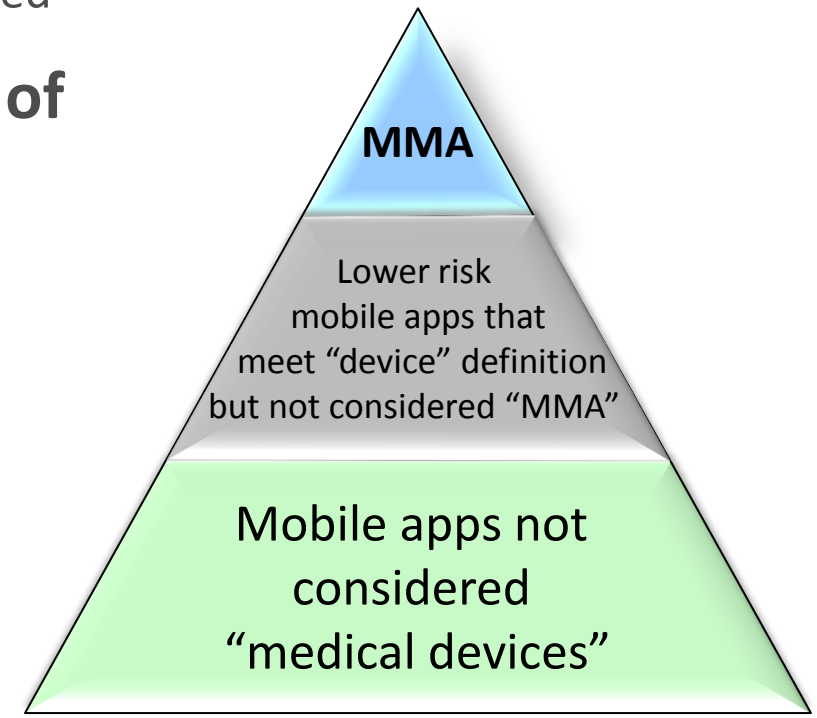
Focused oversight

- **Focuses only on traditionally regulated functionality**
  - Cleared, approved or otherwise regulated
- **Provides users with same level of assurance of patient safety**
- **Identifies types app that FDA does not intend to enforce requirements**
- **Clarifies what is not a device – (Outside of FDA's Jurisdiction)**



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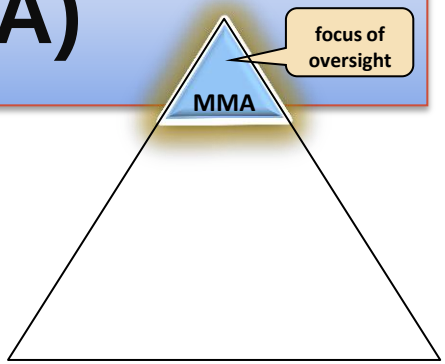
Mobile medical apps (MMA)



"mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ; and either is intended:

- to be used as an accessory to a regulated medical device; **or**
- to transform a mobile platform into a regulated medical device

Examples in Section V-A + Appendix C

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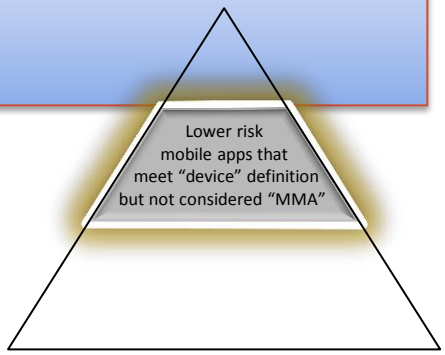
Mobile apps – under enforcement Discretion



- **Examples.. (See Section V-B + Appendix B)**
  - Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes, obesity or other disease or conditions
  - Apps that provide calculator tools such as Mean arterial pressure, Glascow Coma Scale score, APGAR score, NIH Stroke Scale
  - Apps that provide a clinician with best practice treatment guidelines for common illnesses or conditions
  - Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients, healthcare providers, and caregivers

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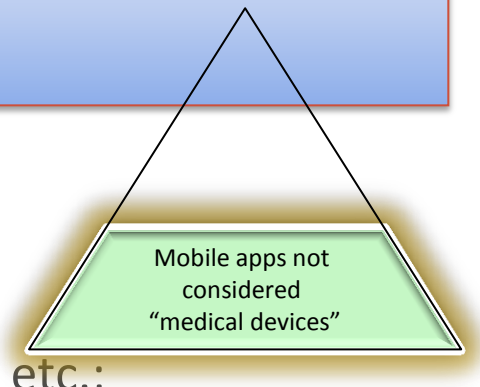
Mobile apps – not medical devices

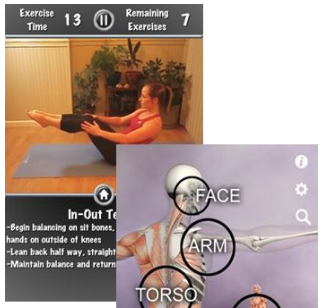


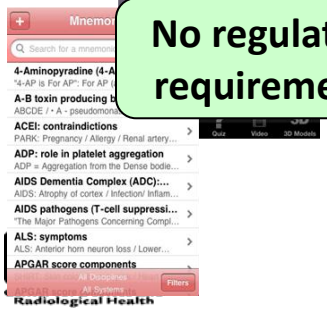
- **Appendix A**
- Library of clinical descriptions for diseases and conditions;
- Medical flash cards with medical images, pictures, graphs, etc.;
- Medical board certification or recertification preparation apps;
- Games that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills.
- Allow users to input pill shape, color or imprint and displays pictures and names of pills that match this description;
- Find the closest medical facilities and doctors to the user's location;
- Help guide patients to ask appropriate questions to their physician
- Help patients track, review and pay medical claims and bills online;
- Manage or schedule hospital rooms or bed spaces

Mobile medical apps (MMA)

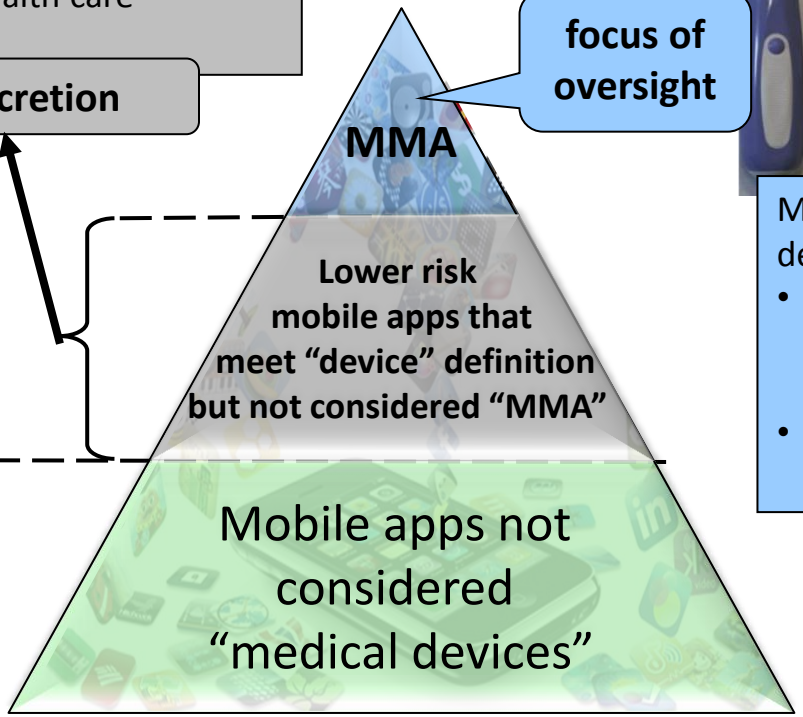
- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Enforcement Discretion





No regulatory requirements



focus of oversight

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.

Addressing evolving landscape

- **Web page for mobile medical app**
  - http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm

- **FDA, on this website intends to have a list of**
  - exemplary types that we intend to exercise enforcement discretion

- **Questions – MobileMedicalApps@FDA.HHS.gov**

- **Provide internal coordination to maintain consistent policy decisions related to mobile medical apps**

Scope of FDA Regulation: Analyzing the New FDA Guidance

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What does FDA Consider a Regulated App?

Kim Tyrrell-Knott

Presented at the mma ROADSHOW

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Topics

1. Understanding Intended Use
2. Which apps does FDA regulate?
3. What about hardware?
4. The CDS Conundrum
5. Who does FDA regulate?
6. Path forward

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Device Definition

Section 201(h) of the Federal Food, Drug, and Cosmetic Act, defines a medical device as:

> "... an instrument, apparatus, implement, machine, **contrivance**, implant, in vitro reagent, or other similar or related article, including any **component, part, or accessory**, which is ... [either]
>
> **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."

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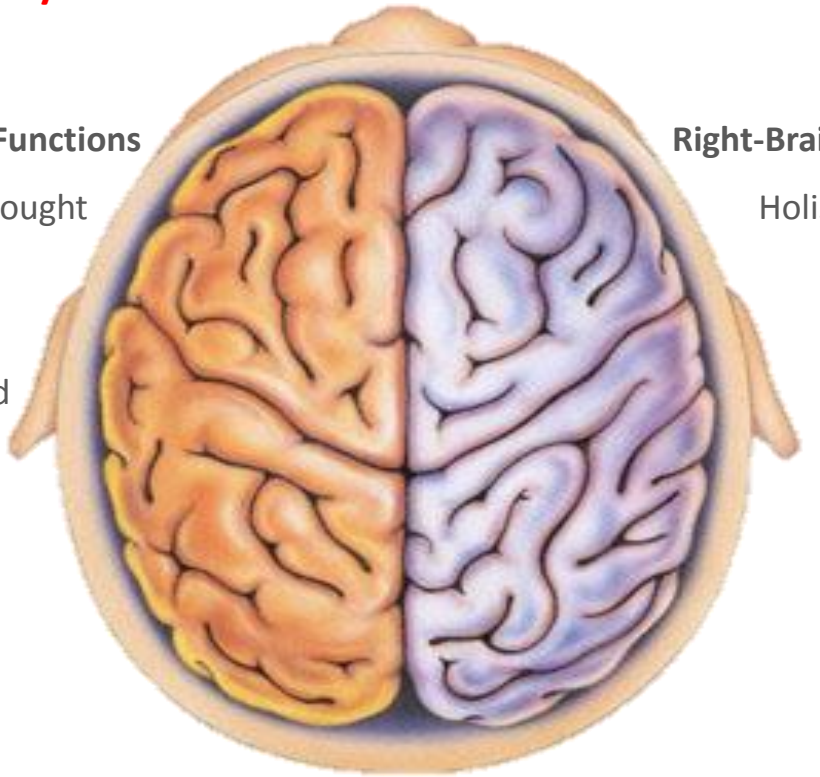
for the next two slides

EXPERIENCE =

USABILITY/ANALYTIC + DESIGN CREATIVE



Left-Brain Functions

Analytic Thought

Logic

Language

Science and math

Right-Brain Functions

Holistic Thought

Intuition

Creativity

Art and music

Use this side

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Judging Intended Use

- **Words:**
  - External (e.g. labeling, sales lit. advertising, sales pitches)
  - Internal (e.g. business planning, sales force memos, training programs)
- **Actions:**
  - Design features (i.e. uniquely medical features)
  - Distribution (e.g. medical channels)
  - Where do your sales people visit?
- **Circumstances (inferences):**
  - How legitimate are non medical uses?
  - Sales volume related to medical use

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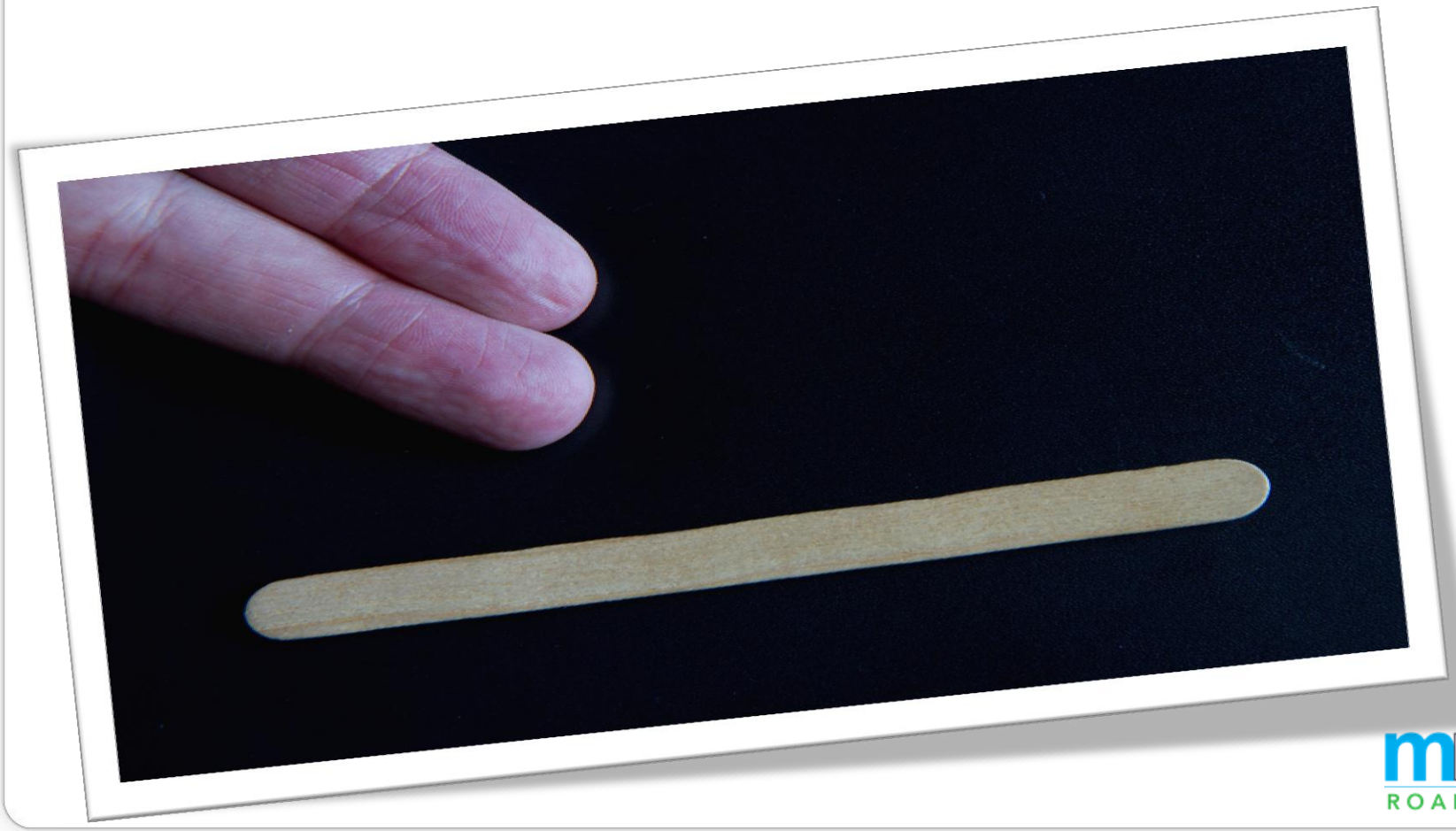
Case Study

I make these. Do I need to worry about FDA?



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Determining the Intended Use of a Stick

Statements suggesting Popsicle Stick	Statements suggesting Pediatric Tongue Depressor
It's a popsicle stick	It's a Pediatric Tongue Depressor
Sterilized to food grade	Sterilized to medical grade
Kids love it	Young patients love it
Makes popsicles last longer	Narrow enough to access those hard to reach places in a kid's mouth

Tastes Great

Wikimedia Commons

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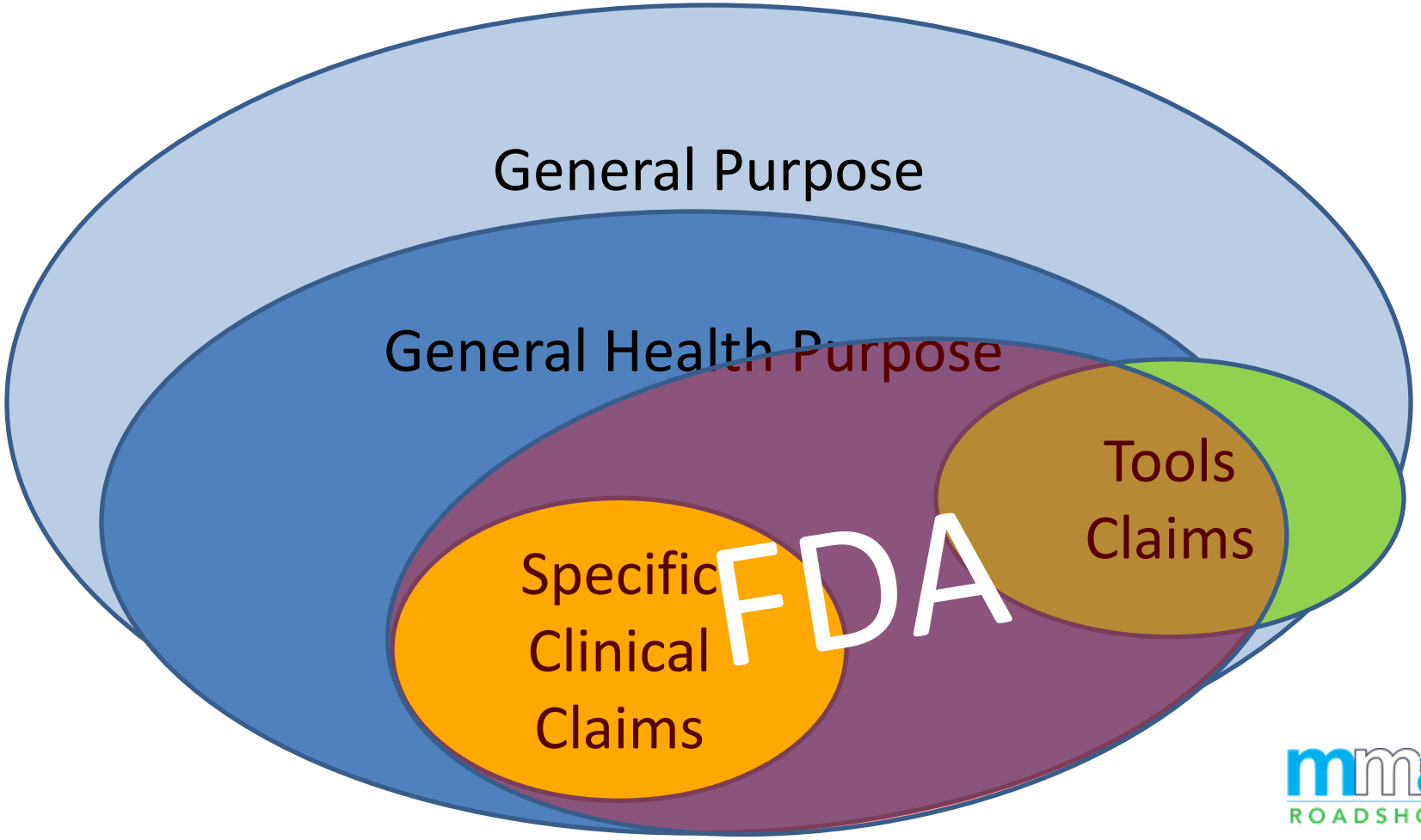
Flavors of Intended Use



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Topics

1. Understanding Intended Use
2. **Which apps does FDA regulate?**
3. What about hardware?
4. The CDS Conundrum
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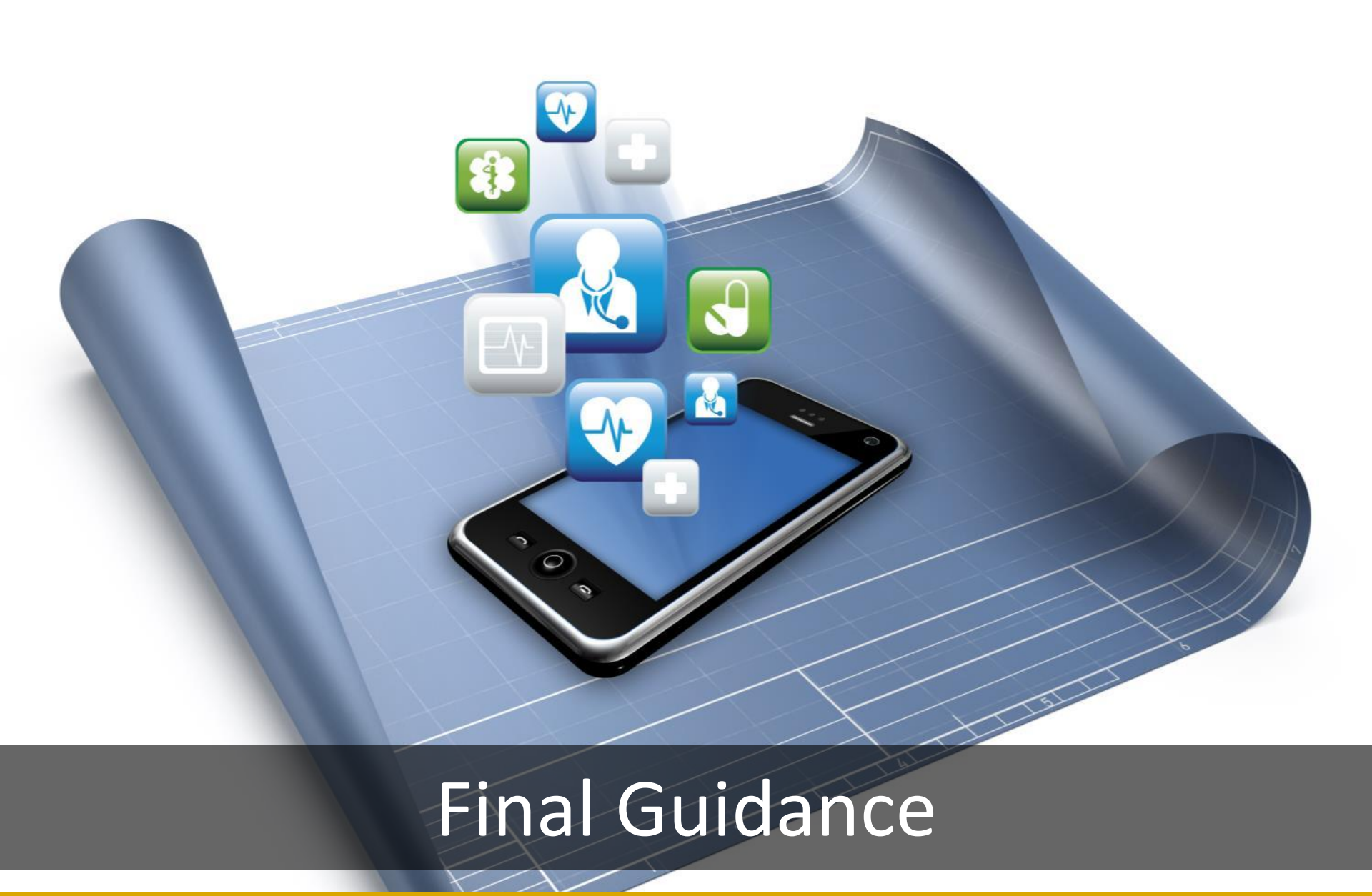

Final Guidance

FDA draws the line between regulated/unregulated

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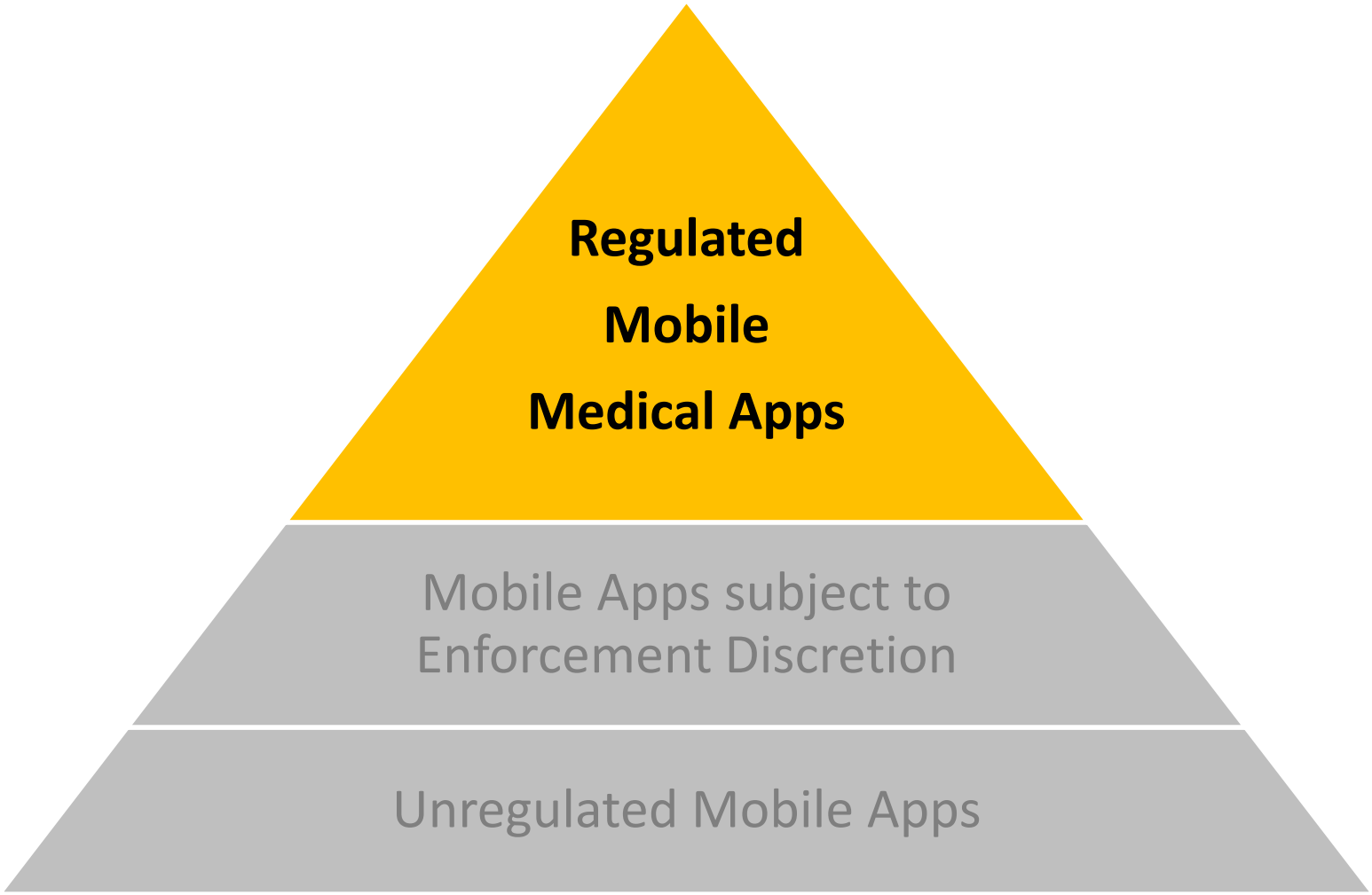
What gets regulated?



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Mobile Medical Apps

- Focus on functionality and risk to patients regardless of platform
- Look at what FDA has regulated in the past.

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Mobile Medical Apps

1. Accessories to a medical device
   - Mobile apps that are an "extension" to a medical device by connecting to the device to
     - Control the device or
     - Display, store, analyze, or transmit patient-specific medical device data

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Success may depend on accessories
Collegehumor.com

Example: control medical devices

www.blessthisstuff.com

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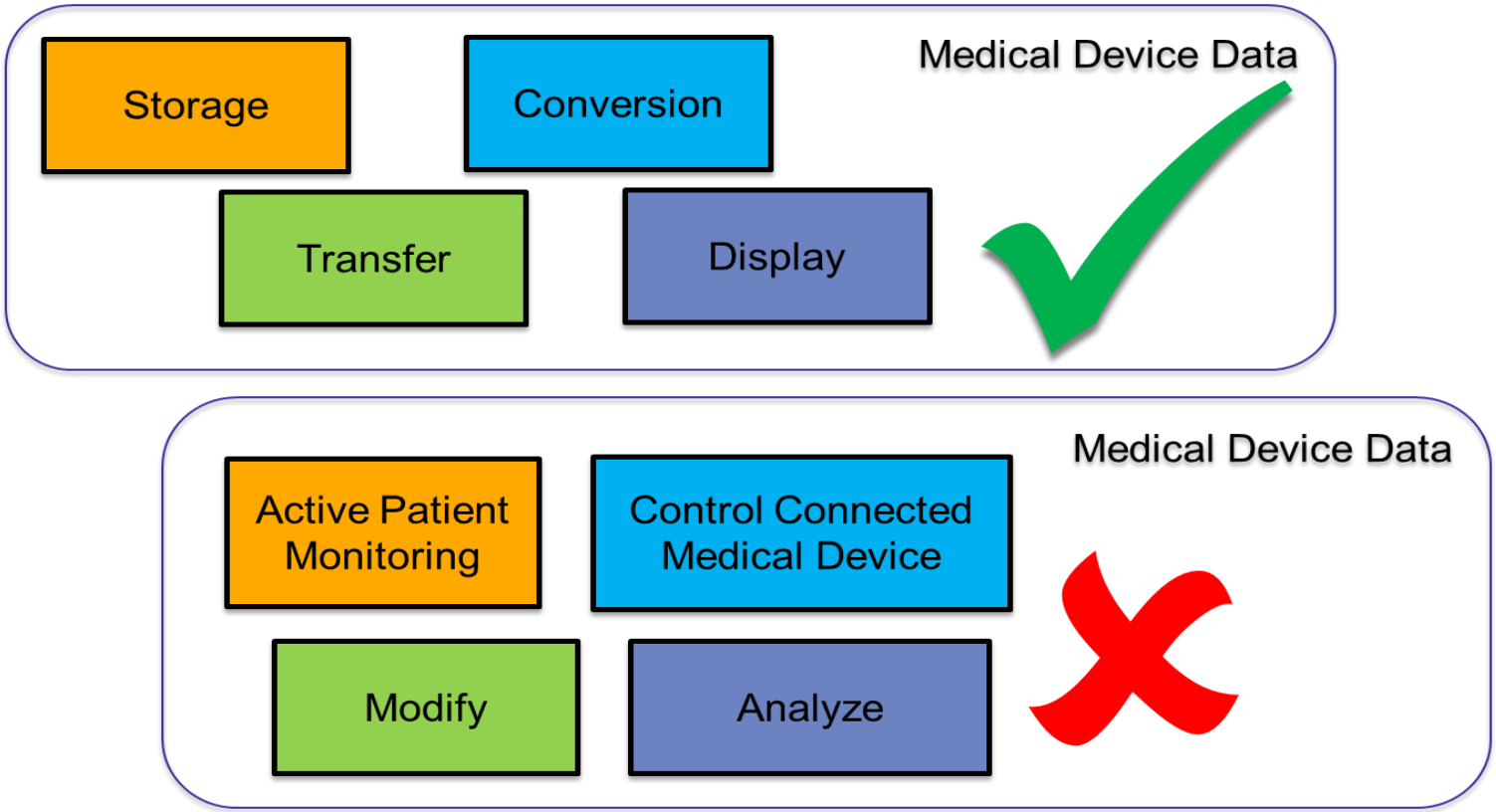
Example: MDDS



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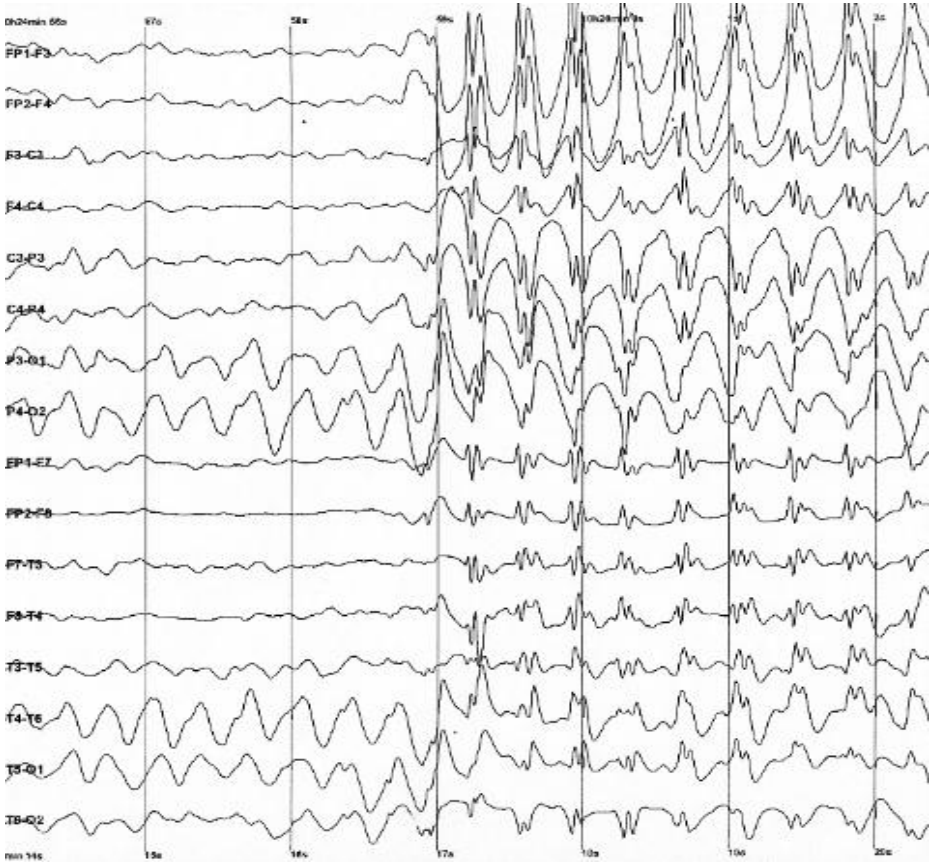
Example: display patient-specific medical device data



luciddreamingapp.com

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Mobile Medical Apps

2. Functionalities similar to currently regulated medical devices
    a. Using special medical attachments
    b. Using generic attachments
    c. Using no attachments

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Example

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Mobile Medical Apps

3. [CDS]
    a. performing patient-specific analysis and
    b. providing patient-specific diagnosis, or treatment recommendations.

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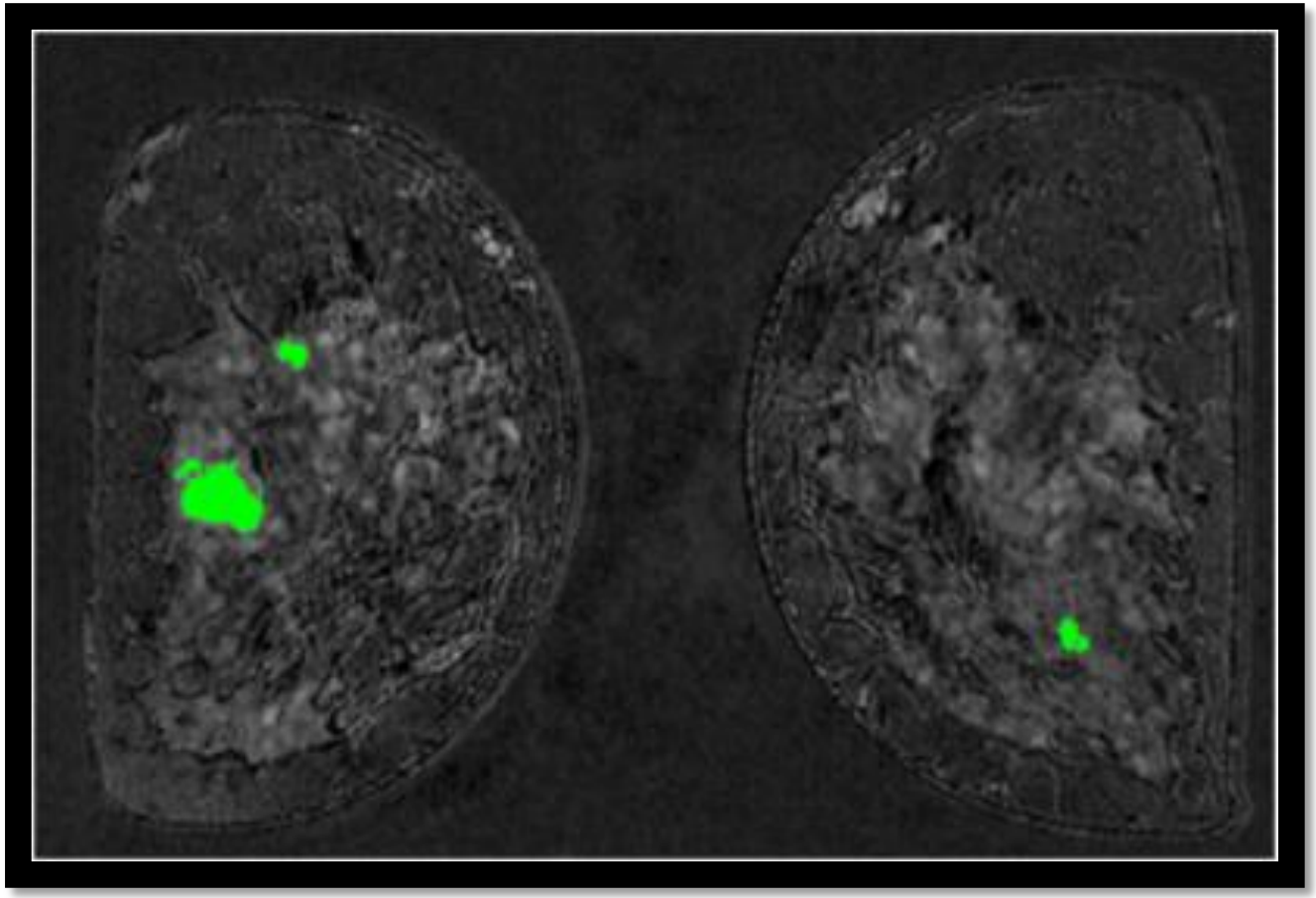
Example



vomweg.net

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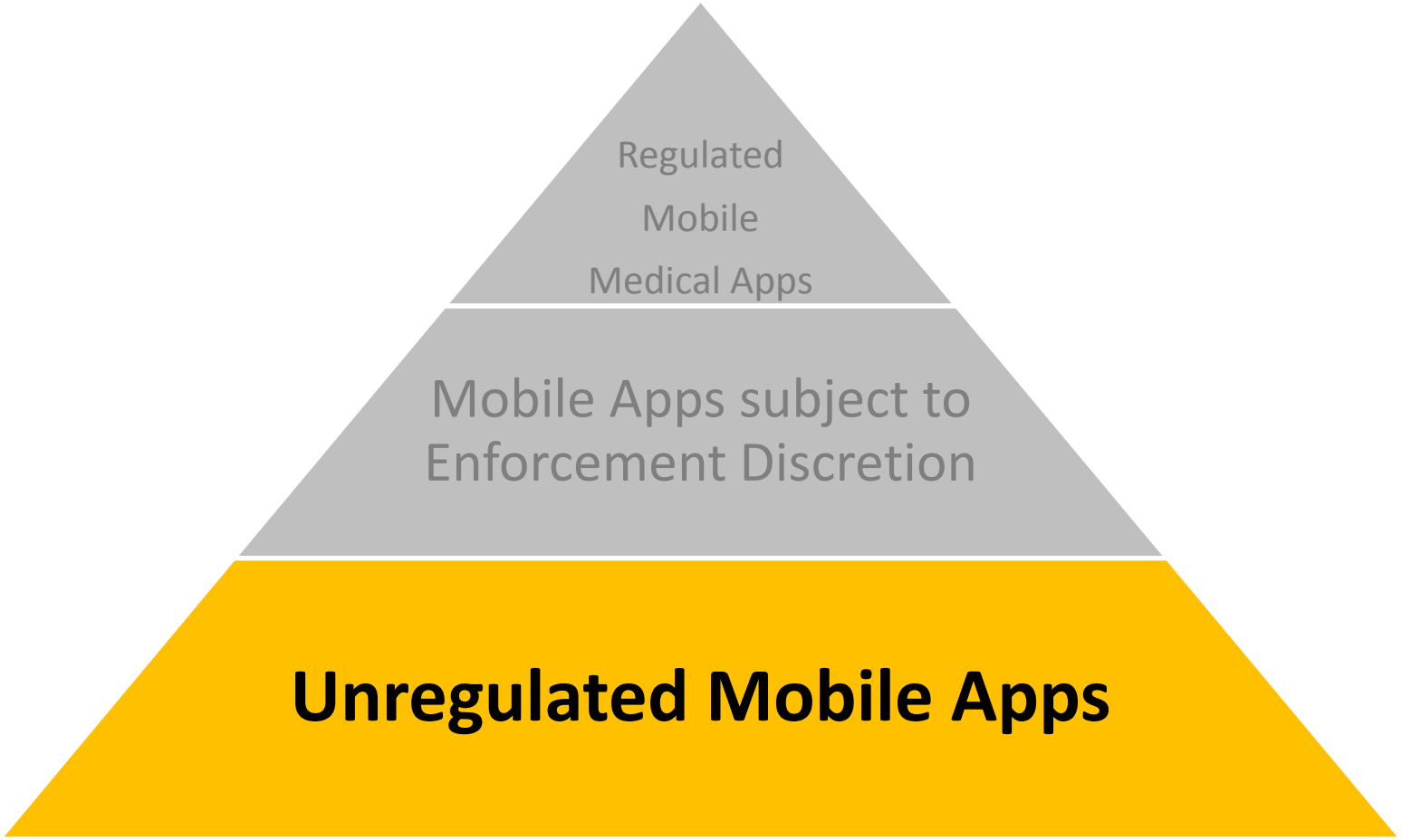
Unregulated Mobile Apps



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Unregulated Mobile Apps
5 categories

1. Electronic copies of medical textbooks
2. Educational tools
3. Facilitate patient access to information
4. Business operations in healthcare settings (accounting, billing)
5. Generic aid (e.g. magnifying glass)

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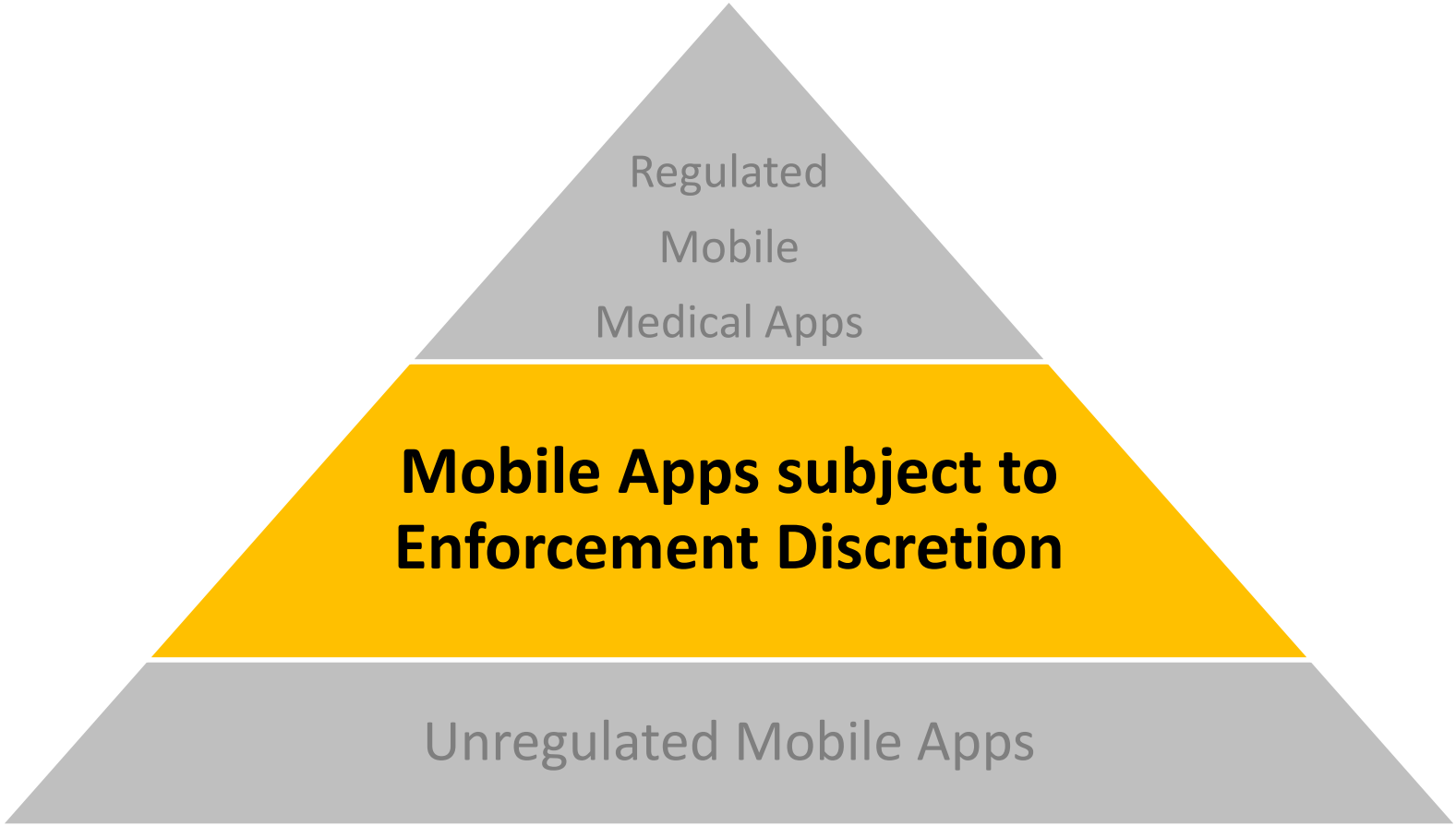
Mobile Apps subject to Enforcement Discretion



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The Law is Not Always Clear

Ihatepeas.com

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Mobile Apps subject to Enforcement Discretion

FDA decided to exempt low risk devices, however

- May not meet definition of medical device
- May not be forever exempt
- Recommend quality system

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Enforcement Discretion Categories

1. Patient motivators
2. Patient day-timers
3. Access to contextually relevant information
4. Certain telemedicine products
5. Simple professional calculators
6. Connections to EHR's

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Open issues

- Wellness versus disease
- Accessory definition
- Line between software modules
- The CDS conundrum

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Topics

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Hardware

- FDA does not regulate:
  - Your smartphone
  - Your tablet
- Usually

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Other hardware

- If sold for a medical device intended use
  - Generic accessories
  - Wellness sensors

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Clinical Decision Support Software

- "This guidance does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making."
- Will be addressed as part of FDASIA

But then final guidance includes CDS at every turn

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What do we know today on CDS?

- September 2011 preliminary definition on CDS

Information

- Data from a medical device
- Environmental data (e.g., pollen count, temp.)
- Demographic data (e.g., age, sex, socio-economic status)

→

Conversion

- Algorithms (fixed or iterative)
- Formulae
- Database look-ups or comparisons
- Rules or associations

→

Clinical Decision

- Patient-specific
- Actionable result

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Examples of CDS in FDA classification regulations

1 to 8 of 8 Results
for *calculator*

Results per page 10

New Search | Export To Excel | Help

Product Code	Device Name		Regulation Number	Device Class
PDT	Burn Resuscitation Decision Support Software	Predictive Pulmonary-Function Value Calc...	868.1890	2
NDC	Calculator, Drug Dose	Predictive Pulmonary-Function Value Calc...	868.1890	2
BTY	Calculator, Predicted Values, Pulmonary Function	Predictive Pulmonary-Function Value Calc...	868.1890	2
BZC	Calculator, Pulmonary Function Data	Pulmonary-Function Data Calculator	868.1880	2
BZM	Calculator, Pulmonary Function Interpretator (Diag ...	Diagnostic Pulmonary-Function Interpreta...	868.1900	2
JQP	Calculator/Data Processing Module, For Clinical Us ...	Calculator/Data Processing Module For Cl...	862.2100	1
MPT	Contraception Calculator			Unclassified
NVV	Digital Image, Storage And Communications, Non-Dia ...	Calculator/Data Processing Module For Cl...	862.2100	1

Page Last Updated: 09/02/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Examples of CDS in Enforcement Discretion

- Use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities
- Use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider
- Guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type of health care facility most appropriate to their needs

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Who gets regulated?

- Definition of “manufacturer”
  - Need to understand “specification developer”
    - Who controls the specs?
    - Who controls the claims?
- Distributors are not manufacturers
  - But they are distributors
- Not regulated:
  - General IT
  - Communications firms

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Apps Made by Doctors

- Doctor's apps for their own professional use are unregulated
  - May share with colleagues in their group practice
- Questions
  - What is a group practice?
  - Does the doctor need to code?

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6. **Path forward**

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Living Document

- Final Guidance not static
  - Use of dynamic webpage
  - Public disclosure of questions?

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Path Forward

- Final Guidance addresses scope of FDA regulation
- Next
  - HOW FDA will regulate
  - Transition from Guidance to enforcement
    - Crowd-funding issue

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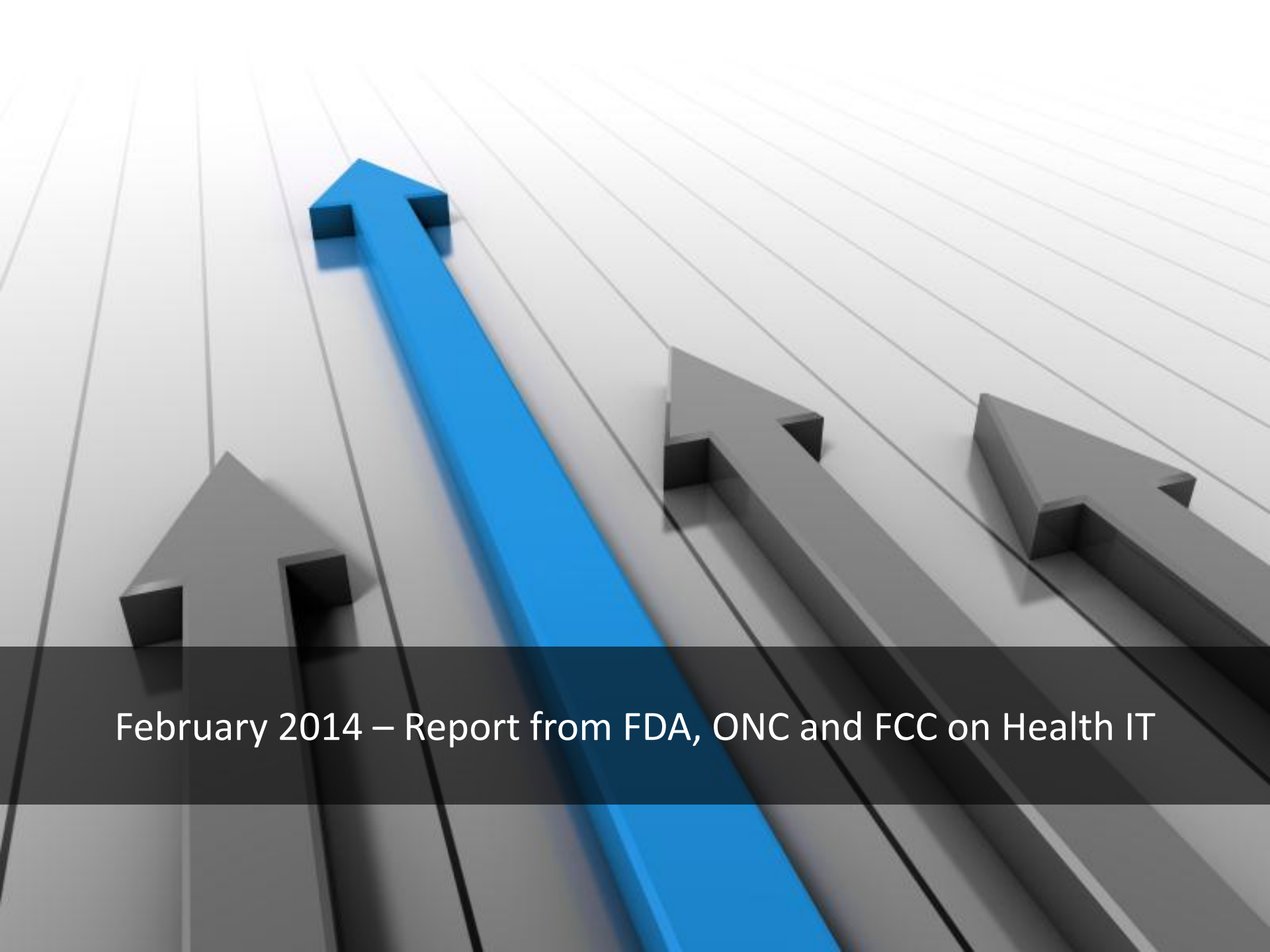
February 2014 – Report from FDA, ONC and FCC on Health IT

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More Resources

- FDA Regulation of Mobile Health
  - Free eBook
  - 2nd edition, November, 2013, 80% new
  - www.MobiHealthNews.com (download)
- Roadshow on Managing App Dev. Under FDA
  - major engineering schools
  - Speakers from companies with FDA cleared apps
  - FDA
  - www.mhealthregulatorycoalition.org

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Questions?

Kim Tyrrell-Knott

ktyrrellknott@ebglaw.com

Panel Discussion: Regulatory Strategies

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Regulatory and Quality
A Case Study and Panel Discussion

Bethany J. Hills

Presented at the mma ROADSHOW

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Diabetes Tracking App

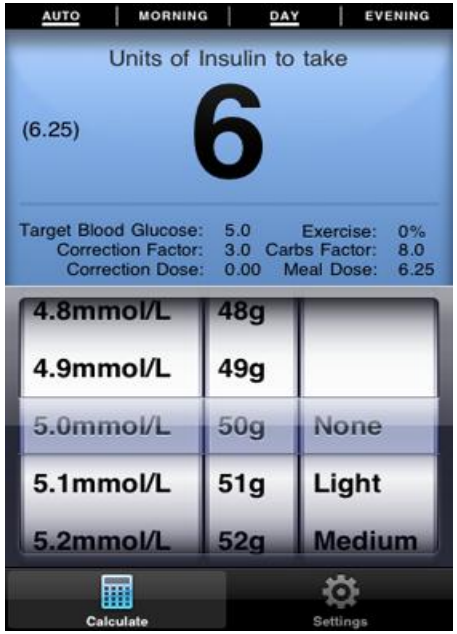
- **Description of the device:**
  - App allows users to enter their blood glucose data.
  - App can read QR codes for food labels, provide carb count, meal options and recipes.

- **Intended use:**

App intended to help patients with diabetes

  - Maintain healthy, diabetes-friendly diet
  - Track their blood glucose, carb intake, exercise
  - Remind user to take blood glucose reading and insulin at pre-set times
  - Calculate the amount of insulin based on carb ratio, correction factor, glucose reading and target glucose level, and other relevant factors

www.diabeticnerd.com



apps.structiva.com

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Heart Rate Apps

- **Description of the device:**
  - User places tip of finger on camera lens, and app measures heart rate

www.heavy.com

- **Intended use:**

  App is intended:
  - To capture heart rate and provide feedback to user about their level of stress and suggestions on managing stress.
  - To be used by athletes to capture heart rate, calculate in and out of target ranges and track measurements over time as part of training program. Data can be shared with user's coach and team members.
  - To be used by a patient with heart disease capture heart rate, calculate in and out of target ranges and track measurements over time as part of long term therapy planning. Data can be shared with doctor and family members.

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Questions?

Bethany J. Hills

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Break

How to Ask Questions

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EU Regulatory Update: Strategies for Global Regulatory Compliance

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AWARDED MOST INNOVATIVE LAWFIRM 2013

mHealth in the EU

Erik Vollebregt
www.axonlawyers.com

Presented at the

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health
food
technology

Agenda

- mHealth relevant recent EU developments relating to:
- Software as standalone medical device
- Accessories
- Wellness / disease / health
- Data protection

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EU political background

eHealth Action Plan 2012 – 2020

- Struggles with Lisbon competences ("EU action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.")

DIRECTORATE-GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A
ECONOMIC AND SCIENTIFIC POLICY

Economic and Monetary Affairs
Employment and Social Affairs
Environment, Public Health and Food Safety
Industry, Research and Energy
Internal Market and Consumer Protection

Workshop on e-Health

EUROPEAN COMMISSION

Brussels, 6.12.2012
COM(2012) 736 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century

{SWD(2012) 413 final}
{SWD(2012) 414 final}

IMDRF International Medical Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-3 MANAGEMENT COMMITTEE

19 to 21 March 2013

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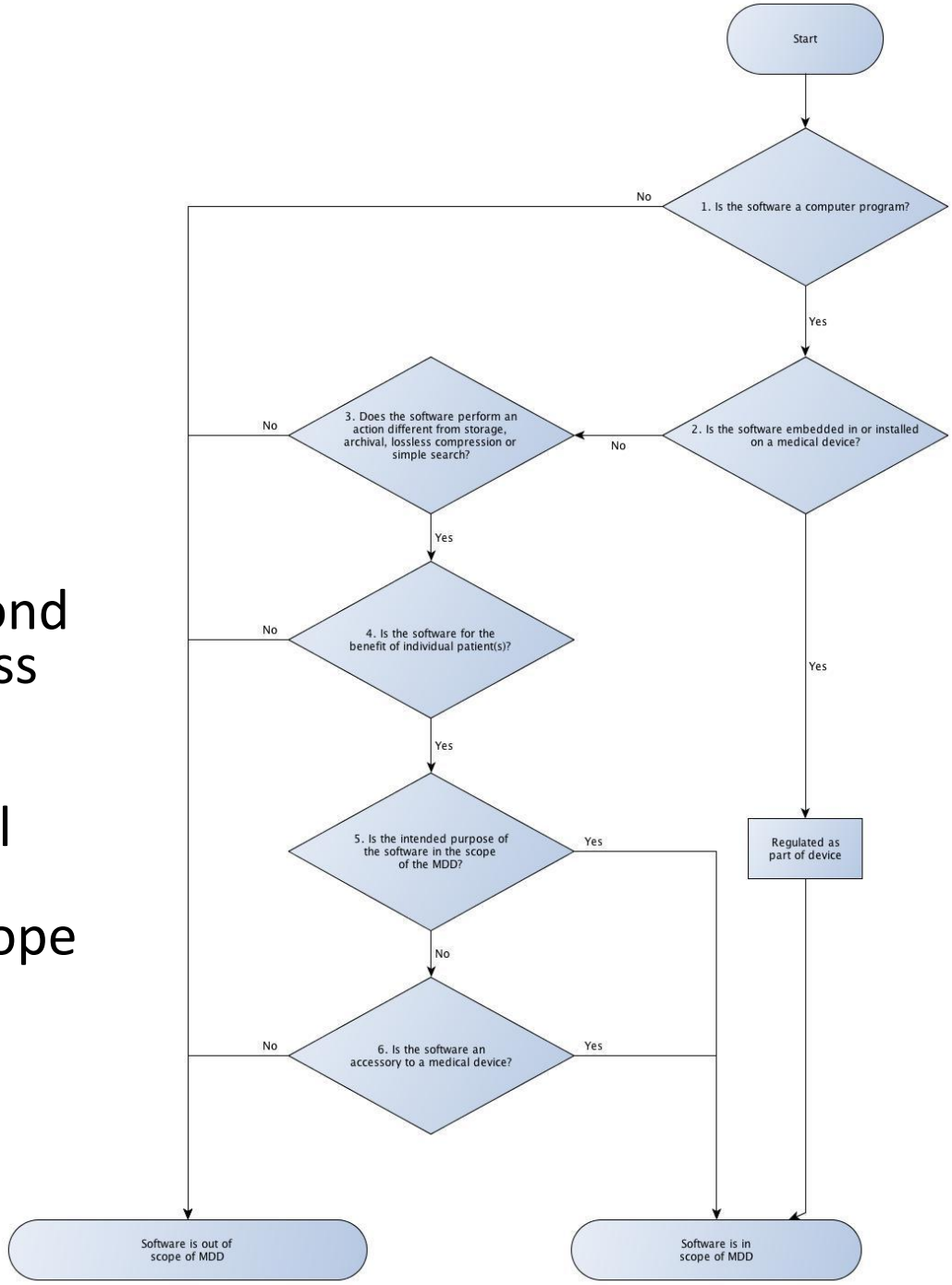
Standalone software as medical device

- Standalone software as medical device MEDDEV 2.1/6 currently under revision
- Some new requirements software validation and verification under proposed new medical devices rules
    - Introduction of ‘mobile computing platform’

MEDDEV 2.1/6 medical devices simple version

1. Computer program?
2. Stand alone?
3. What action does it perform on data? [beyond storage, archival, lossless compression, simple search]
4. For benefit of individual patients?
5. Intended purpose in scope of MDD?
6. Accessory?



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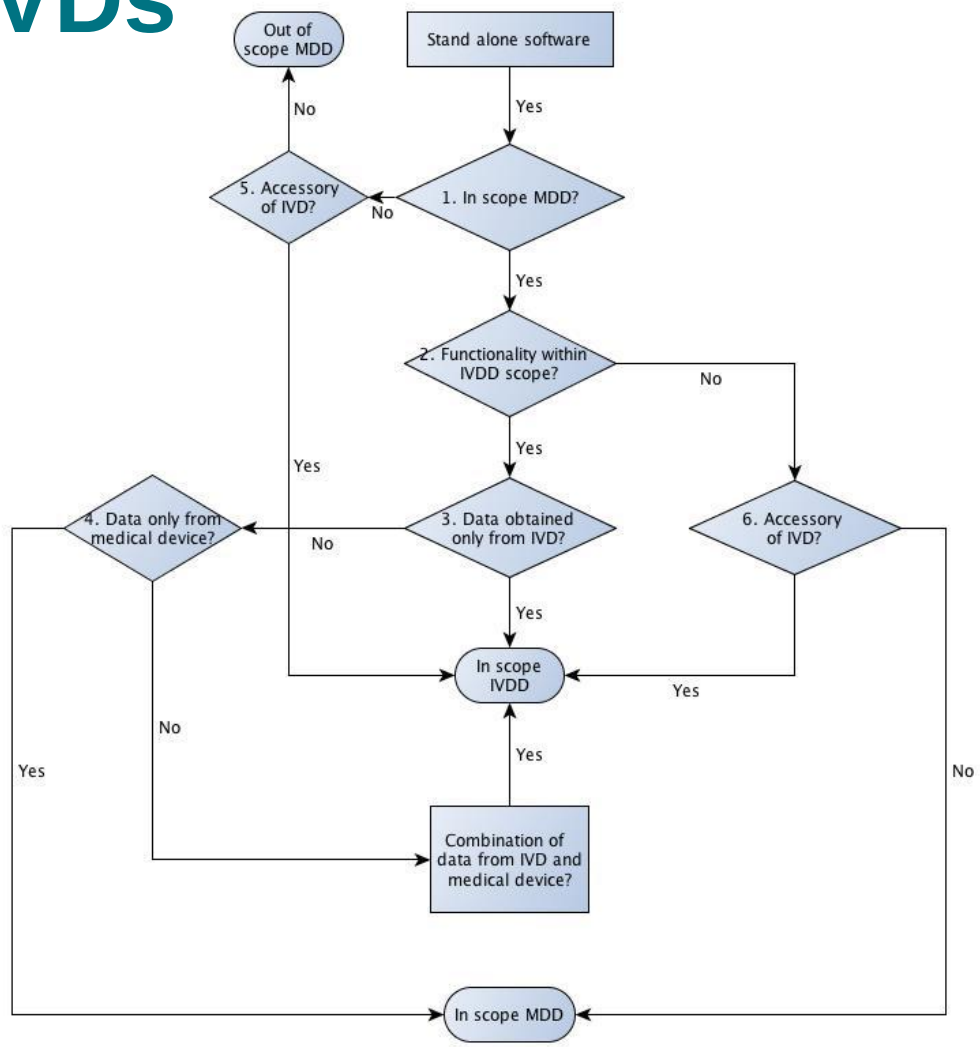
MEDDEV 2.1/6 IVDs simple version

1. In scope MDD?
2. In scope IVDD?
3. Data obtained only from IVD?
4. Data obtained from medical device?
5. Accessory?
6. Accessory?



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Standalone software as medical device

- Proposed new expansive definition of 'medical device' that will impact mobile health

Article 2
Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific direct or indirect medical purposes of:

– diagnosis, prevention, monitoring, prediction, treatment or alleviation of disease,

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Accessories

- Accessories are regulated as medical devices, even if they are not medical devices themselves
- Accessory 2.0 under new MDR and IVDD proposals:

  > "an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable or assist the device(s) to be used in accordance with its/their intended purpose(s)"

- Addition of concept "or assist" potentially enlarges the scope considerably

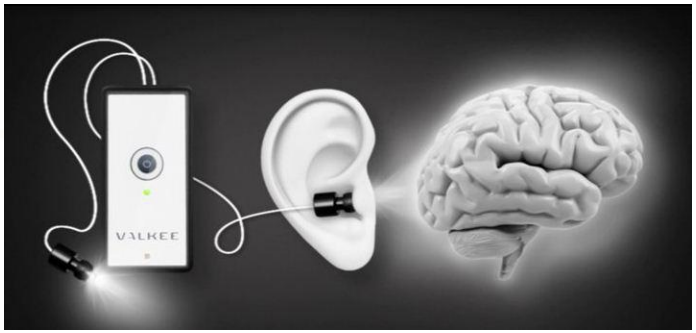
Health and Well-being

- EU concept of medical device is binary – yes or no?
- Medical as opposed to general health/well-being -> no EU position yet
- Expected Green Paper from European Commission
- EU Court (Brain Products case C-219/11) on definition of "medical device":
    - requires "medical context" as opposed to non-medical use, e.g. in sports
    - regulate from a public health protection perspective (risk to user)

Enforcement climate

- Member states direct increasing enforcement efforts to software
- Member states interpret scope of software medical device very differently

- Higher risk mobile apps (hearing aids, light therapy)
    - Subject to unannounced inspections by notified body



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EU privacy requirements for (healthcare) apps

- Article 29 Working Party
  - lack of transparency on app collected data
  - lack of free and informed consent – consent does not meet user requirements (users want a more granular choice) and – closely connected to transparency – must understand what an app does before they can give valid consent
  - poor security measures – risk of unauthorized processing of data, which, in case of healthcare apps, will mostly concern sensitive personal data
  - disregard for the principle of **purpose limitation** – a controller should not process more personal data than necessary for the purpose defined and the period necessary.

Data Protection

- EU Parliament LIBE Committee
- Proposed EU General Data Protection Regulation
  - Art. 81 and 83 specific provisions on use of health data
    - Focus on consent, which in turn is difficult to obtain
    - Strict requirements for data processing in health research

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Data Protection

- Privacy-by-design/privacy-by-default requirements
- Software that captures health data must be compliant *by default* with the design requirements
- Design requirements are not clearly defined

Data Protection

- Data subject's right
  - Right to correct, information, be forgotten and of erasure problematic in clinical context
  - Right to request interoperable and open source format copy of processed data
  - Right to understand automated processing logic

Data protection

- Privacy by design requirements
  - Software and mobile devices must be designed for default compliance
- Company burden
  - ➢ Mandatory privacy officer
  - ➢ Extremely large fines

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Medical devices and data protection regulation proposals

- Progress of regulations in light of EU elections May 2014
- Google official on personal title: ‘Data protection proposal is dead’
- Some member states: ‘Rather no medical devices regulation than flawed regulation’
- EU officials: ‘Finish proposals in time’

Google Data Chief Says ‘Flawed’
EU Privacy Law Is Dead

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IMDRF

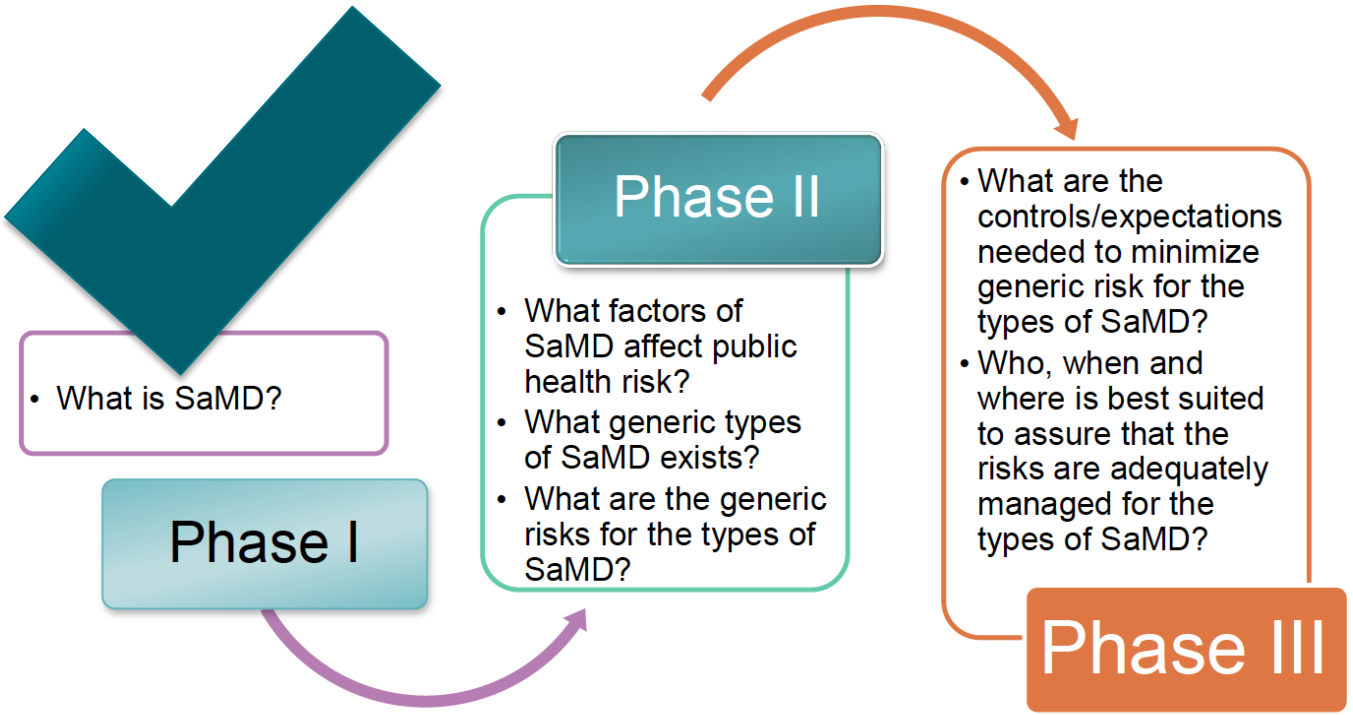
- Seeks international regulatory convergence
- EU proposed definitions diverge wildly from IMDRF Key Definitions

IMDRF

- Software as Medical Device Work Item
  - Phase I: define when software is a medical device
    - Software as a Medical Device (SaMD): Key Definitions document adopted (9 December 2013)
  - Phase II: risk stratification based on intended use and benefits and risks to patients and consumers
  - Phase III: identify controls for common expectations of all stakeholders

IMDRF

- In 2014, the Chair will be held by the US FDA. The IMDRF-5 meeting will take place in San Francisco on 25-27 March 2014



Phase 2: Framework document in progress

Questions?

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THANKS FOR YOUR ATTENTION

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Question time

Block our calendar for your 15 min free appointment by phone

Who

When

›Submit

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Panel Discussion: Business Strategies for Bringing New Apps to Market

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FDA Q&A

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Thank You