

The Future is Connected

Apps & More



Medical Diagnostics & Devices Workshop, University of Cambridge

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Commercially Confidential

ConnHlth-P-167 v0.1

INTRODUCTION



creating competitive **advantage**

NORTHROP GRUMMAN



PHILIPS



eHealth

Telehealth

Digital Health

**Health &
Wellness**

**QUANTIFIED
SELF**

**Connected
Health**

mHealth

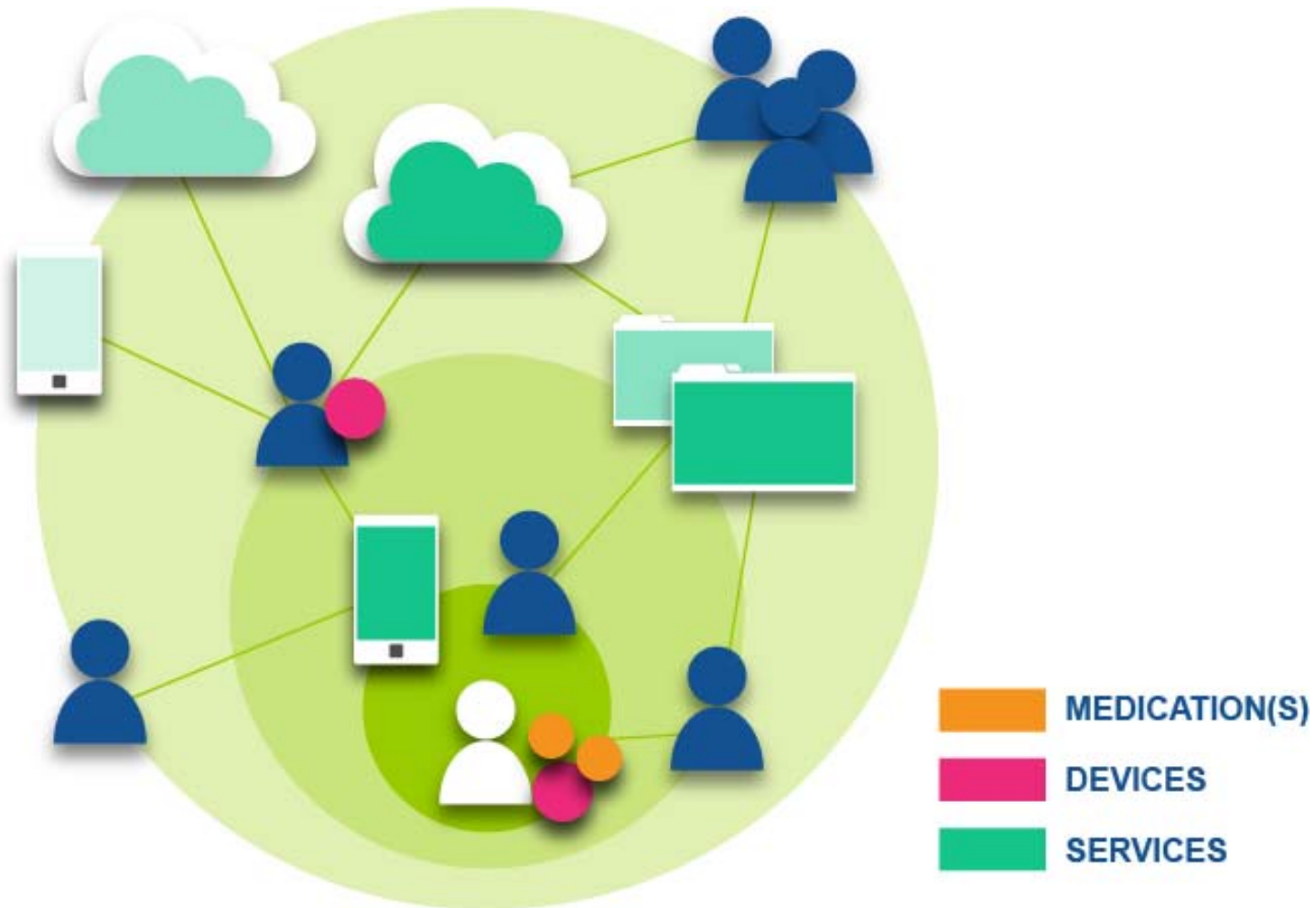
Telemedicine

Health 2.0

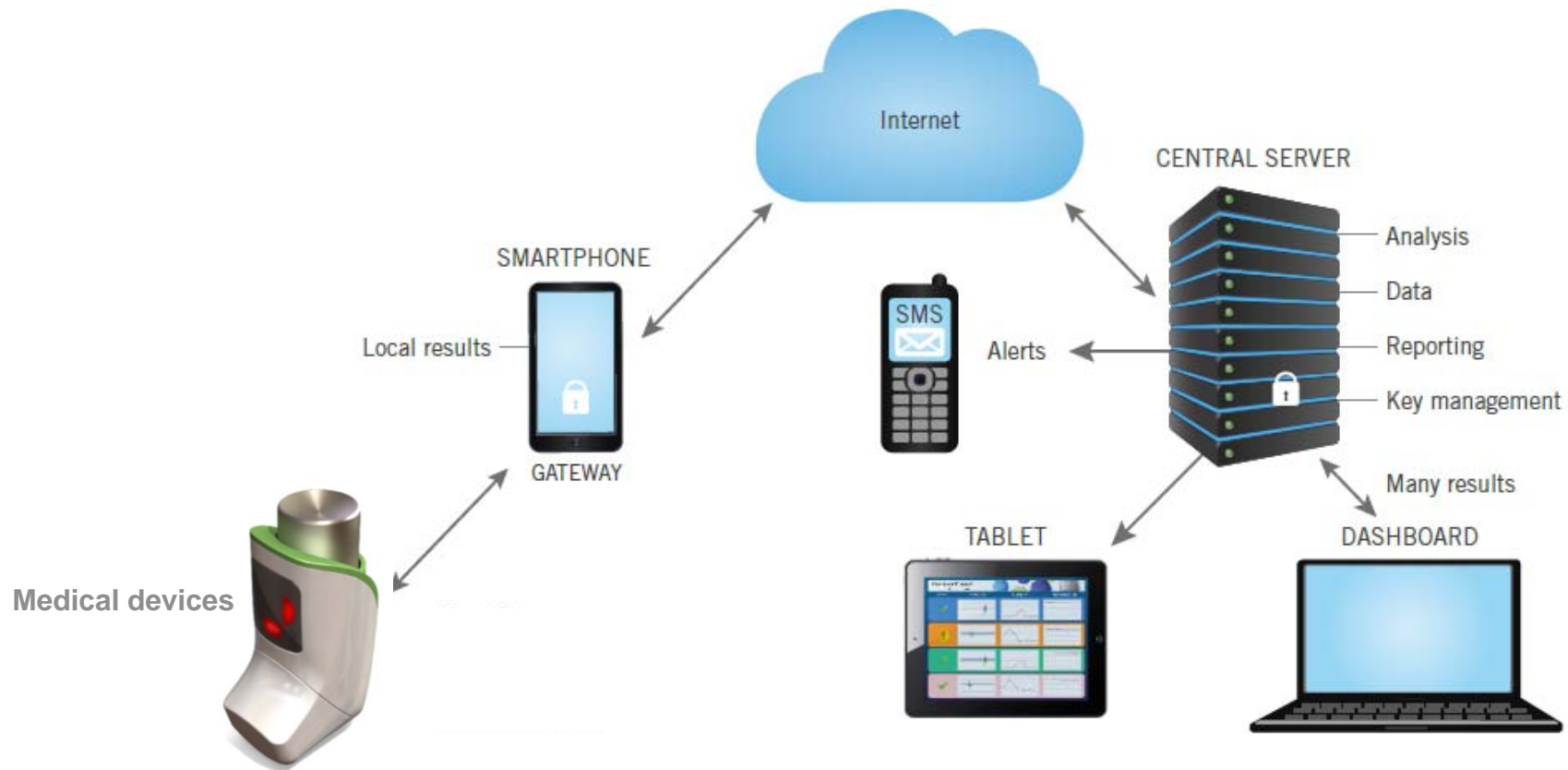
Key factors are fuelling the interest and growth in Digital Health



An ecosystem made possible via digital tools & data analysis has the potential for improving outcomes and expanding market share



The technology components include connected medical products, off-the-shelf mobile platforms and back end infrastructure



DEVELOPING CONNECTED HEALTH SOLUTIONS

CONNECTED SYSTEM DESIGN – STEP 1

MARKET

Who is our target audience?
What do they need?

Who are our competitors?
How can we differentiate?

MONEY

Who will pay?
What is the best business
model for us?

Will/ how our device/
solution be reimbursed?

Can I provide a
service?

CONNECTED HEALTH OPPORTUNITY

What technology is the
best choice for our
device?

Should we go
wireless?

Should we develop an app?

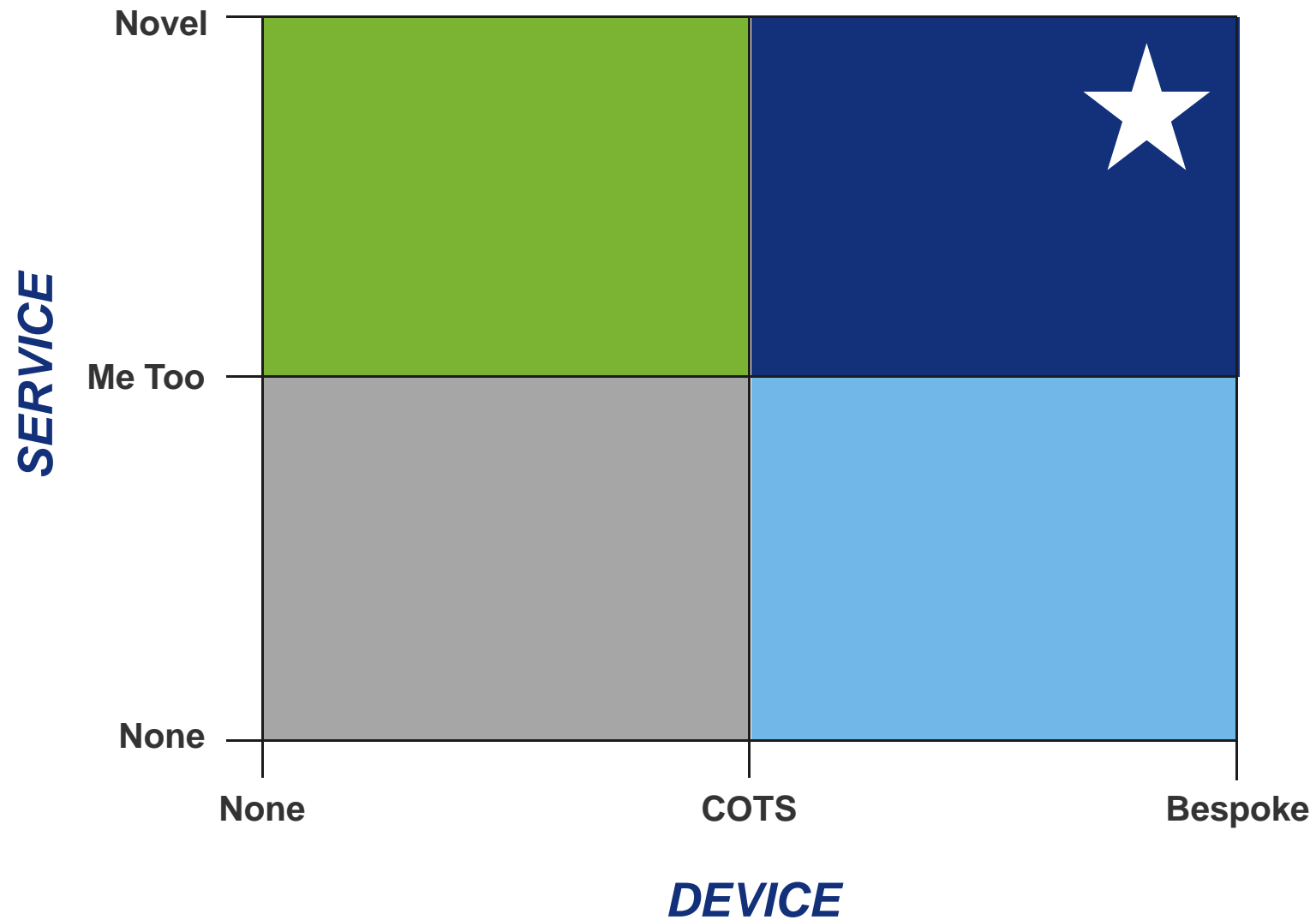
TECHNOLOGY

Will the FDA regulate our
device/app?

Will regulations affect our
technology or feature choices?

REGULATIONS

Think end to end - consider your opportunities



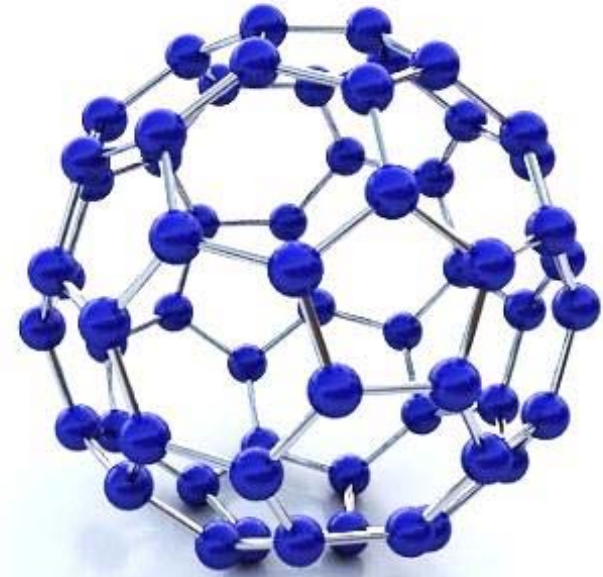
Design the end-to-end user experience



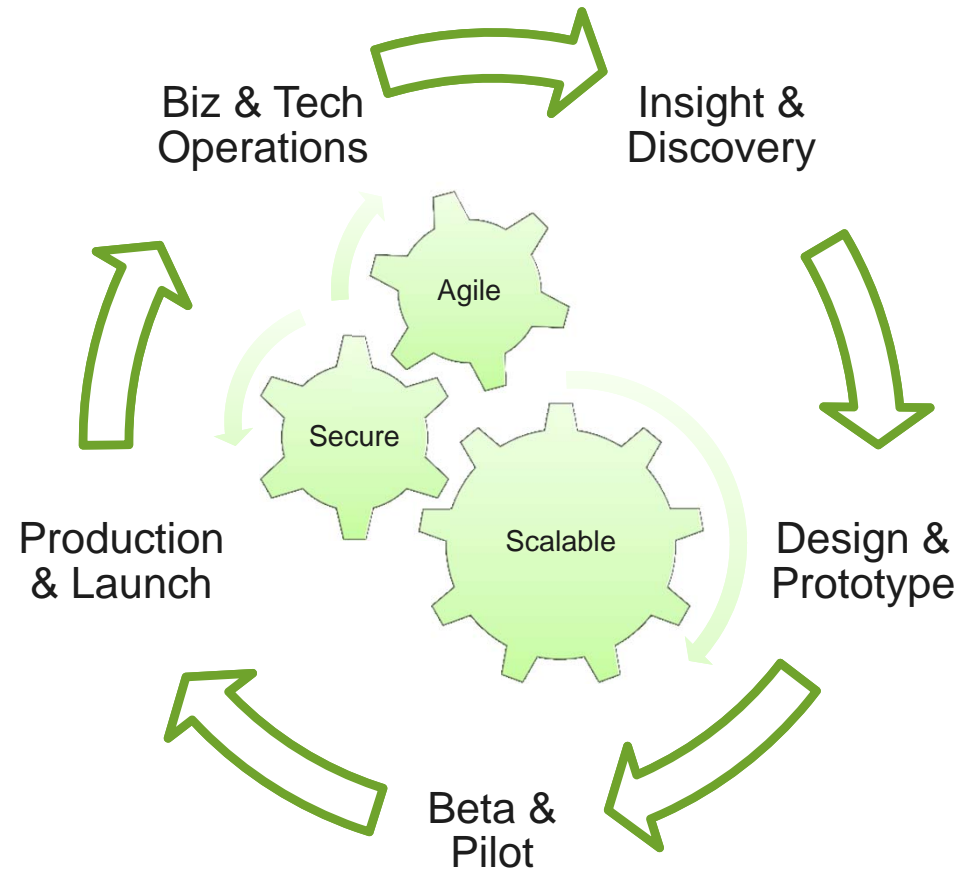
Develop



or

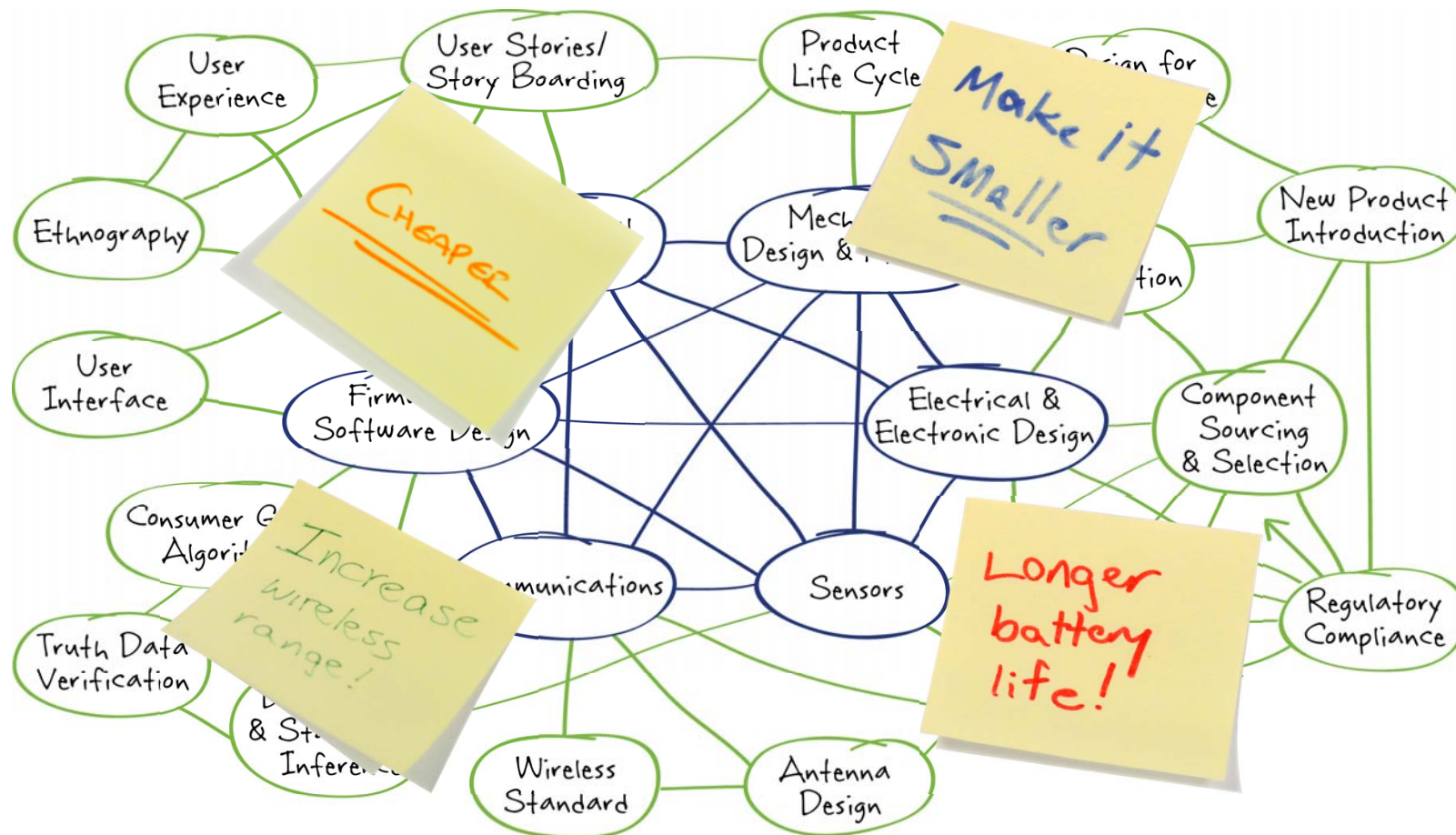


Iterate



SOME IMPORTANT ASPECTS

Defining a System Architecture to meet all your goals is a tricky balance



Demanding applications can result in conflicting design requirements.

A different strategy is required to keep up with fast moving consumer electronics



Is your App a Medical Device?

Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 25, 2013

The draft of this guidance was issued on July 21, 2011.

For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov. For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCC) by calling 1-800-835-4709 or 301-827-1800.



U.S. Department of Health and Human Service
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Diagnose
Detect
Interpret
Analyse
Calculate
Convert
Control



Medicines & Healthcare
products
Regulatory Agency

[See more information about this Guidance](#)

Guidance

Medical device stand-alone software including apps

Published 8 August 2014

Contents

- Stand-alone software
- Intended purpose of a medical device
- Systems
- Existing guidance
- Software apps
- Decision support or decision making software
- Telehealth
- Requirements
- Further considerations for specific software
- Other software types that may be medical devices
- Disclaimers
- Software that is not a medical device
- More information



**THINK SYSTEM
UNDERSTAND THE NEEDS
PLAN TO ADAPT**

THANK YOU

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SOME INTERESTING PROJECTS

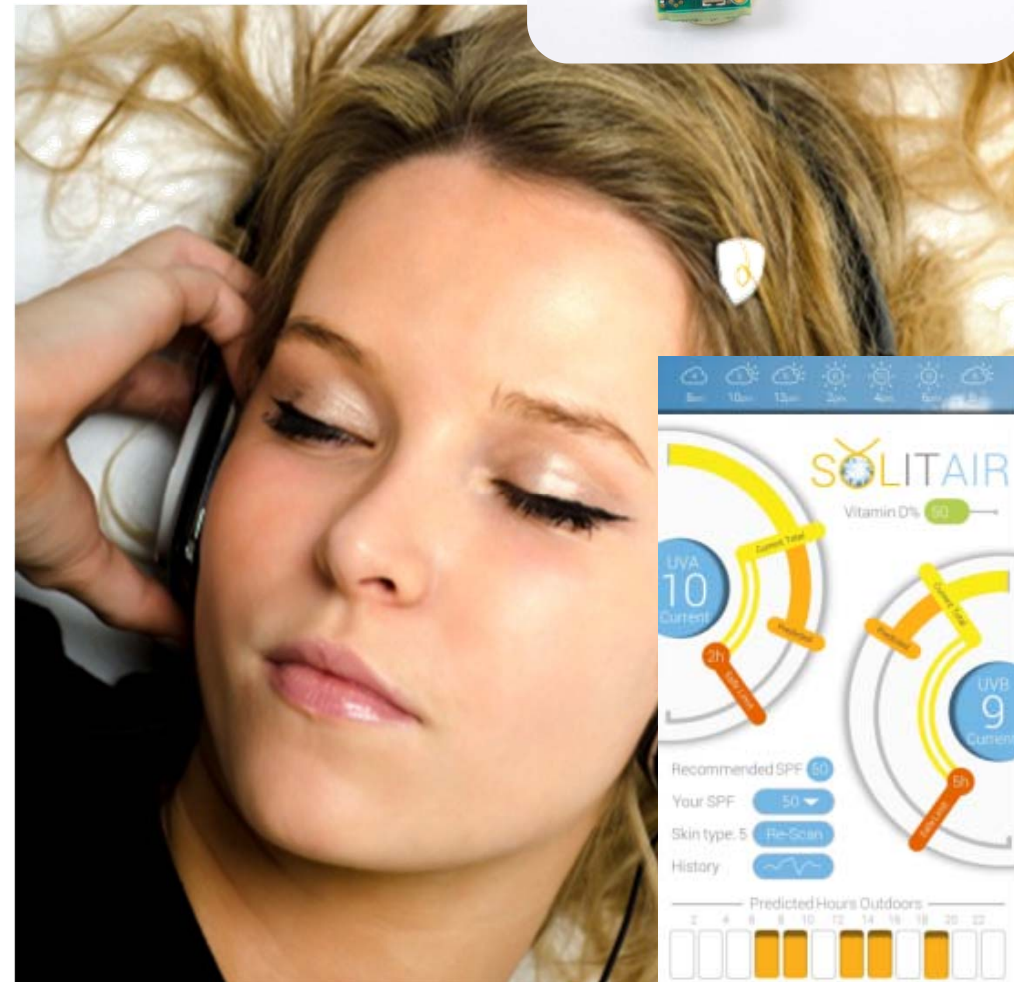
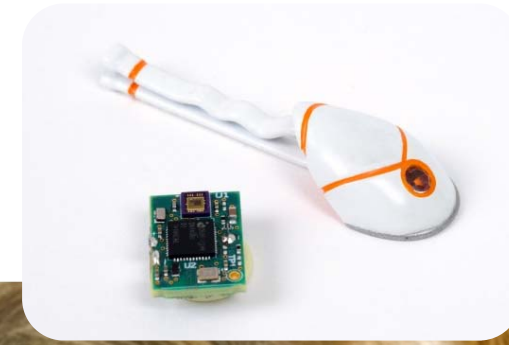
Labless Diagnostics Smartphone App

- Using the smartphone's processing power and camera for optically-read diagnostic technologies such as lateral flow assays, opens the door to a range of diagnostic opportunities previously limited to laboratory equipment
- Applying the correct image processing algorithms can give high quality analysis in remote locations such as patient's home, hard to reach communities, or developing regions.
- A guided user interface experience provided by a well-designed app can put this diagnostic ability in the hands of a patient without the need for a clinician.



Skin care with real time personalized feedback

- Wearables are becoming invisible; fashion items with a purpose
- UV sensor and weather data fused to calculate exposure levels
- Measured data fused with information on skin type (determined via camera) results in the ability to deliver personalized advice
 - Opens opportunity for a new business model – selling skin care rather than sun screen products



Closed loop therapy

- Wireless implant + wearable sensor enables continuous monitoring and modification of neurostimulation therapy
- Wearable sensor monitors tremors, sends data to physician.
- Bluetooth Smart enabled implant can be controlled via doctor's tablet to change therapy in response to tremor data

