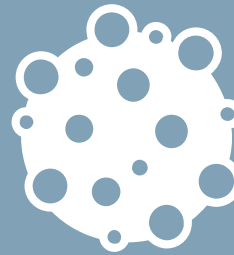




Global Reach



Speed & Delivery



Therapeutic Knowledge



Creative Solutions

Biometrics monitoring devices – A digital revolution

Sugam Salvi

PPD[®]

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Digital Health

- + Digital health is the convergence of digital technologies with health, healthcare, living, and society to enhance the efficiency of healthcare delivery and make medicines more personalized and precise.
- + According to the U.S Food and Drug Administration (FDA), digital health could be mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine
- + Digital healthcare is a multi-disciplinary domain involving many stakeholders, including clinicians, researchers and scientists with a wide range of expertise in healthcare, engineering, social sciences, public health, health economics and data management.



Healthcare - Trends and Digital Opportunities

+ Trends

- + Outcomes-based care is moving to center stage
- + Patients are becoming more engaged
- + More information is available about product performance
- + New competitors are moving in

+ Opportunities

- + Personalized care: Sensors and digital services for tailored, 24/7 treatment
- + Fuller engagement: Omnichannel conversations with physicians and patients
- + Data-driven insight: Advanced analytics to increase pipeline and commercial value
- + Real-time responsiveness: Automated processes to improve cost, reactions, and agility

Digital Healthcare in Clinical Trials

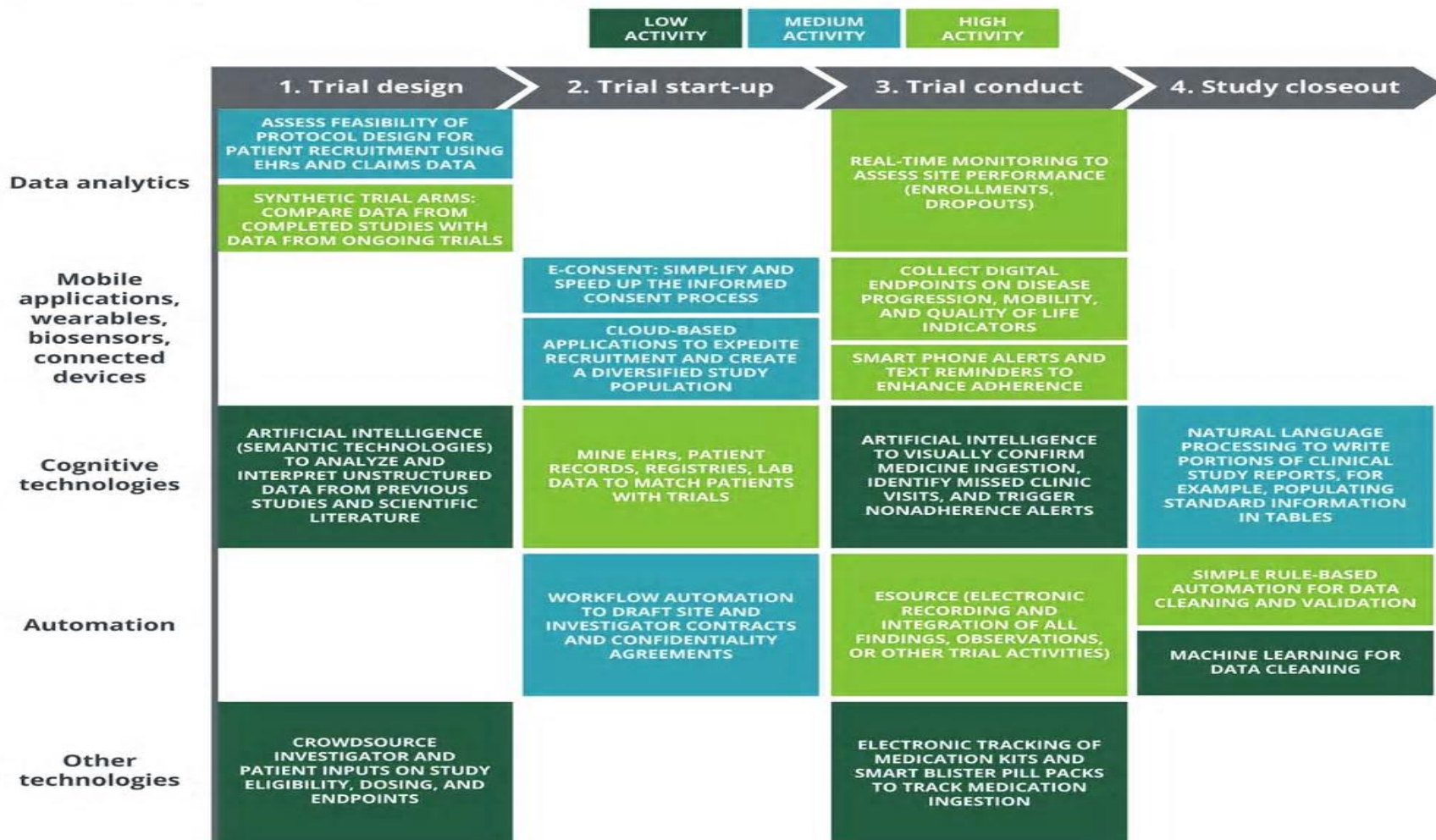
Digital health, the use of mobile computing and communication technologies as an integral new models of care is seen as one potential solution.

Digital Health Technologies will help:

- + Improve Protocol Compliance
- + Faster Enrollments
- + Real Time Study Tracking
- + Continuous Remote Monitoring
- + Greater Patient Engagement
- + Richer Datasets with greater accuracy
- + Medication Adherence
- + Simple, Virtual, Visit-less trials
- + Connect all stakeholders
- + Reduced Cost
- + Enhanced Safety, Personalized Treatment
- + New insights from existing data

Digital Healthcare in Clinical Trials

Figure 2. Application of digital technology in clinical trials



Source: Deloitte Center for Health Solutions interviews with industry stakeholders.

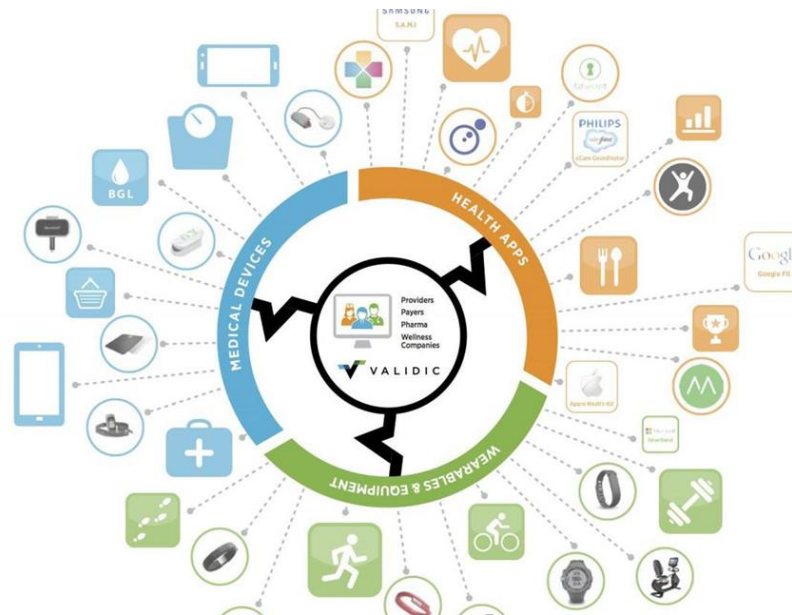
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Biometrics Monitoring Devices (BMDs)

Regulatory authorities are evaluating novel ways to assess health, disease progression and treatment effects. Biometric monitoring devices (BMDs) can be viewed as path to a deeper understanding of disease processes and the status of patients

a BMD can be defined as a biosensor that collects objective data on

- + a biological recognition element (for example, blood glucose or sodium levels),
- + anatomical structure (for example, tumour size, infarct size or hippocampal volume)
- + integrated physiological parameter (for example, heart rate, blood pressure, mobility, speech and sleep patterns, social engagement or speed of information processing).



Key Considerations for BMDs

Defining: the concept of interest the context of use

- If device is intended to support an efficacy claim, a link between the device readout and an efficacy parameter of interest needs to be established
- It has to be supplemented by the device analytical performance data indicating that the device is appropriate for an intended use.

Data Standards

- Currently, there is no interoperable uniformity for BMD-derived data.
- Development of uniform data standards and terminology, processing principles for similar sets of data would provide a scientifically based consent on the way to record, structure and report data generated by BMDs.

Good Clinical Practice

- Use of BMDs for exploratory work or internal decision-making is becoming a more routine practice. Development of Good Clinical Practice (GCP) standards will be crucial to enable the ethical and correct use of BMD-derived data.

Regulatory Approach

- + FDA is focused on Digital Health as
 - + Many medical devices now have the ability to connect to and communicate with other devices or systems. Devices that are already FDA approved or cleared are being updated to add digital features. New types of devices that already have these capabilities are being explored.
 - + Many stakeholders are involved in digital health activities, including patients, health care practitioners, researchers, traditional medical device industry firms, and firms new to FDA regulatory requirements, such as mobile application developers.

Regulatory Approach

- + The FDA's Center for Devices and Radiological Health (CDRH) has established the Digital Health Program. The action plan lays out the CDRH's vision for fostering digital health innovation while continuing to protect and promote the public health, including:
 - + Issuing guidance to provide clarity on the medical software provisions of the 21st Century Cures legislation;
 - + Launching an innovative pilot precertification program to work with our customers to develop a new approach to digital health technology oversight (FDA Pre-Cert for Software); and
 - + Building FDA's bench strength and expertise in CDRH's digital health unit and cybersecurity.

Regulatory Approach

- + US and European legislation seems headed in different directions concerning scope, consent, data sharing, and processing.
- + In the US,
 - + the data obtained via medical devices are covered by HIPAA and require patient consent for data collection and sharing.
 - + the data obtained by consumer-grade devices, can be shared in a deidentified, aggregate manner without explicit stipulation concerning who will have access to the data.
- + In the EU, new General Data Protection Regulation (GDPR) regulations do not draw distinctions pertaining to a device type and cover all data generated by wearable devices or apps in the medical context. Additionally, the EU requires clearly defined purposes for data use, consent for data reuse and sharing, and allows patients to withdraw their consent at any time.

Challenges

+ **What is slowing the digital revolution?**

- + Lack of long term user engagement
- + Lack of data validity and reliability
- + Psychological resistance to technology
- + Inability to break out of pilot stage

+ **The challenges of managing IoT in digital health**

- + Data correlation with clinical significance
- + Isolated data and lack of actionable data
- + Commercial vs medical grade solutions/devices
- + Multiplicity of solutions- interchangeability and interoperability
- + Security and privacy
- + Connectivity Challenges
- + Regulations

Future...

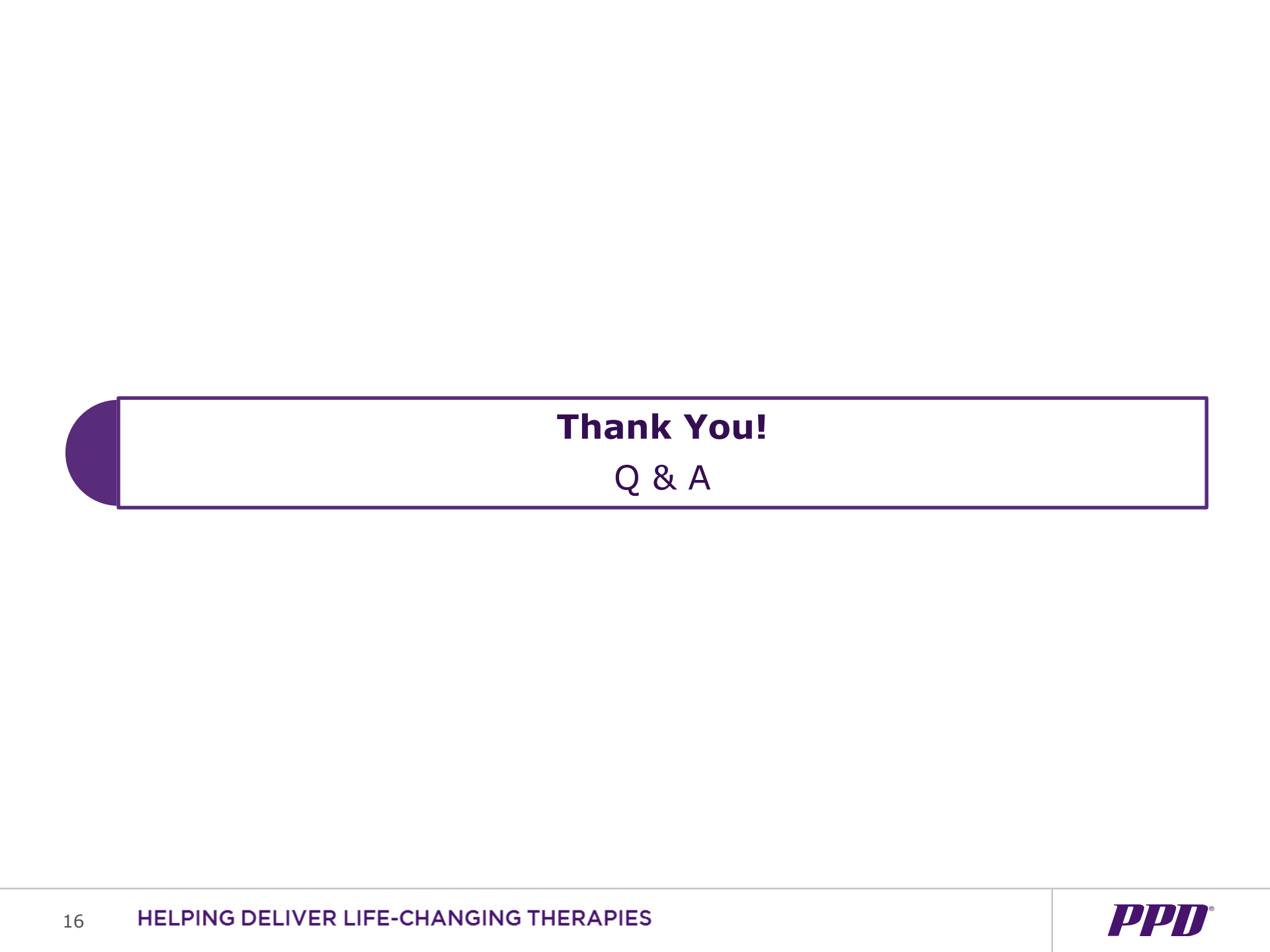
- + BMDs are promising and have the potential to fundamentally change healthcare and drug development by changing the means of collecting, processing, and visualizing health data
- + The scientific community would benefit from frequent information exchange to share the results and learnings that would facilitate the development and adoption of best practices for technology implementation, data collection, analysis, and interpretation



- + All clinical trials will involve continuous remote monitoring of participant physiology / performance
- + Data is streamed from the participant to the cloud, and analyzed in real-time for automated change detections
- + Earlier & automated identification of adverse events, and therapeutic response are SOP
- + Algorithm-driven notifications / assessments to participant/health care professional will enable timely changes in health care delivery

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Thank You!

Q & A