WHAT ARE THE COMPONENTS OF ENSURING SENSORS AND WEARABLES ARE APPLIED CORRECTLY IN CLINICAL TRIALS?

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Life Science Track
AGENDA

What are the Components of Ensuring Sensors and Wearables are Applied Correctly in Clinical Trials?

• About PAREXEL
• Wearable in Clinical Trials
• PAREXEL Patient Sensor Solution
• Use Case Review
• Platform Component Review
• Future
ABOUT PAREXEL

• A leading global biopharmaceutical services organization, focused on clinical development and commercialization.

• We are 18,000 employees worldwide located in 85 offices - physicians, technologists, business process experts, and more

• We are dedicated to support drug development and bring new drugs to market

30+ years
assisting clients in pharmaceutical, biotechnology, and medical device industries
**Digital Transformation** enables optimization and faster time to market.

- **2004 - 2006**
  - Development Phase
  - Therapy in Market

- **2013 - 2015**
  - Development Phase
  - Therapy in Market

- **2018 -**
  - Development Phase
  - Therapy in Market

**20 years**

**Patent Submission** → **Patent Expiration**

**Time to develop a drug**

+25%
PATIENTS ARE AT THE CENTER, INCREASING QUALITY AND SPEED OF CLINICAL TRIAL EXECUTION

**THE PAST**
Patient interaction centralized through site

- Clinical Trial Management
- Site - EDC
- Patient

**THE FUTURE**
Direct – multi-channel - patient interactions

- Clinical Trial Management
- Patient direct
- Sensor
- Patient App
- EHR
- eCOA
PATIENT DIRECT DATA ACQUISITION IS AT THE CORE OF DIGITAL TRANSFORMATION IN PHARMA – AND HEALTH CARE

Pharma companies are increasingly using patient sensors to measure efficacy, safety and COST benefit of new drugs:
- Empower patient
- Access to new type of data (real time, continuous)
- Increased safety through tele monitoring by doctors
- Faster and less costly trials

There are many sensors available today, though not many have high value for drug development; this is evolving.

Many biometric data are collected through direct to smartphones/data transmission hubs ready-paired.

PAREXEL developed a platform to manage patient direct data acquisition, scalable for petabytes of data.

Expected revenue in wearables: $18.9B in 2020, growing at 29.9% CAGR**

* Adapted with permission of Frost & Sullivan
** Source: Frost & Sullivan, "Wearable Technologies in Clinical and Consumer Health", 2016

Wearables Harnessing Human Body Data/Biometrics*

- EEG
- Cortical Stimulator
- Eye Tracking
- Ear/Audio
- ECG/EKG, Heart Rate
- Heart Rate Variability
- Sleep
- Stress
- Body Posture
- Fall Deduction
- Respiratory Rate
- Blood Pressure
- Insulin Level
- Blood Glucose
- SpO2
- Body Temperature
- Total Activity
- Calorie Meter
- EMG
- Body Pressure
- Muscle Tension
- Body Motion
- Body Weight
- Critical/High Value
- Nice to Have
- General/Wellness
NEXT GENERATION PATIENT SENSORS PLATFORM
IN THE CONNECTED JOURNEY™

End-to-end Sensor-based Solution

- Facilitates the remote collection of study subject data via medical devices.
- Collection of clinical data via wearables and sensors could replace or reduce the number of clinical assessments and/or on-site visits during clinical trials.
- Reduces burden on trial participants and sites as well as decrease trial costs.
EXPLORATORY STUDY: COMPARE WEARABLES WITH STANDARDS DATA COLLECTION TOOLS

- Observe the Agreement in results between a set of sensors compared to Clinical Standard reference methods
- Compare in-house (on site) and at-home compliance
- Assess the Usability of devices by Subjects
- Evaluate the required format/level of subject Instructions

Blood Pressure
Activity
Blood Glucose
Spirometry
Pulse Oximetry
Weight

WEARABLES

vs

CLINICAL STANDARD

STUDY DATA CAPTURE SYSTEM
PATIENT DIRECT PLATFORM: OVERVIEW OF COMPONENTS

Capture

Manage

Analyze

- Pulse Oximetry
- Blood Pressure
- Blood Glucose
- Weight
- Activity

PAREXEL PLATFORM: OVERVIEW OF COMPONENTS

- 2net Hub
- 2net Platform
- Qualcomm LIFE

PATIENT DIRECT

- Spirometry
COMPONENTS OF THE SYSTEM: CAPTURE

**DEVICES SELECTION & EVALUATION**
- General selection
  - Certifications
  - Brochures / Manuals
  - Accuracy / Calibration
  - Medical Assessment
- Metrology: check accuracy vs simulator or clinical standard
- Integration feasibility/ check list

**DEVICE INSTRUCTION**
- Create guides for study sites and participants
- Update data export specification for data management

**DEVICES INTEGRATION**
- Ensure Qualcomm Eco System integration
- Build ability to process messages from Qualcomm 2Net Platform
### COMPONENTS OF THE SYSTEM: **MANAGE**

<table>
<thead>
<tr>
<th>PI AF SDK / Web API</th>
<th>PI AF / DATA ARCHIVE</th>
<th>PI VISION</th>
<th>PI INTEGRATOR FOR BUSINESS ANALYTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Data ingress to PI Server</td>
<td>• Persistent storage of wearable data with context</td>
<td>• View data in PI Server live</td>
<td>• Scheduled export of key parameters every 30 minutes</td>
</tr>
<tr>
<td>• Connects to Azure and in-House data streams</td>
<td>• Quick, easy creation and management of elements through templates</td>
<td>• Used to confirm data flow when taking measurements with wearable device</td>
<td>• Output powers overview dashboards for data monitoring</td>
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</table>
COMPONENTS OF THE SYSTEM: ANALYZE

COMPILATION VISUALIZATIONS

- Graphical overview of Subjects compliance
- Powered by Tableau
- Filterable by type of results, study, country, site and subject demographics

RESULTS VISUALIZATIONS

- Customizable displays of wearable device data
- Plot individual data streams from multiple devices and Subjects
- Drill down for more detail

MONITORING

- Measurement transmission and processing times monitored
- Increase average times for transmission per device may indicate device user issues
- Increase in processing time for platform component could indicate a bottleneck
PATIENT DIRECT PLATFORM: FUTURE

CLOUD
• Continue to move to Azure platform
• Increase solution scalability

NEW DEVICE INTEGRATION
• Increase data points
• Higher and higher data rates

COMPANION APP FOR SUBJECTS
• Provides information on clinical trial
• Readings reminder
• Visualization of taken readings

MONITORING
• Automatic, 24/7 detection of wearable device issues
• Analysis of patient data to monitor safety & detect emergency conditions. Understand efficacy of treatment under study
• Analyze usage data to monitor, predict and improve patient compliance on wearables and identify missing data

FUTURE PATIENT DIRECT PLATFORM
Patient direct data collection will impact the way we do drug development.

We started the journey with a set of sensors, showing their added value comparatively to “standard” data collection through doctors.

Scalable solutions around patient direct data acquisition, requires a platform which integrates several technologies using OSIsoft to support data management.

We developed a first release of the platform and are expanding for large volume / high frequency data.

See the Sensors Booth #27.
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PAREXEL International
Questions

Please wait for the **microphone** before asking your questions

State your name & company

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