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

Jean-Marc LeBideau
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Life Science Track

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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**

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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

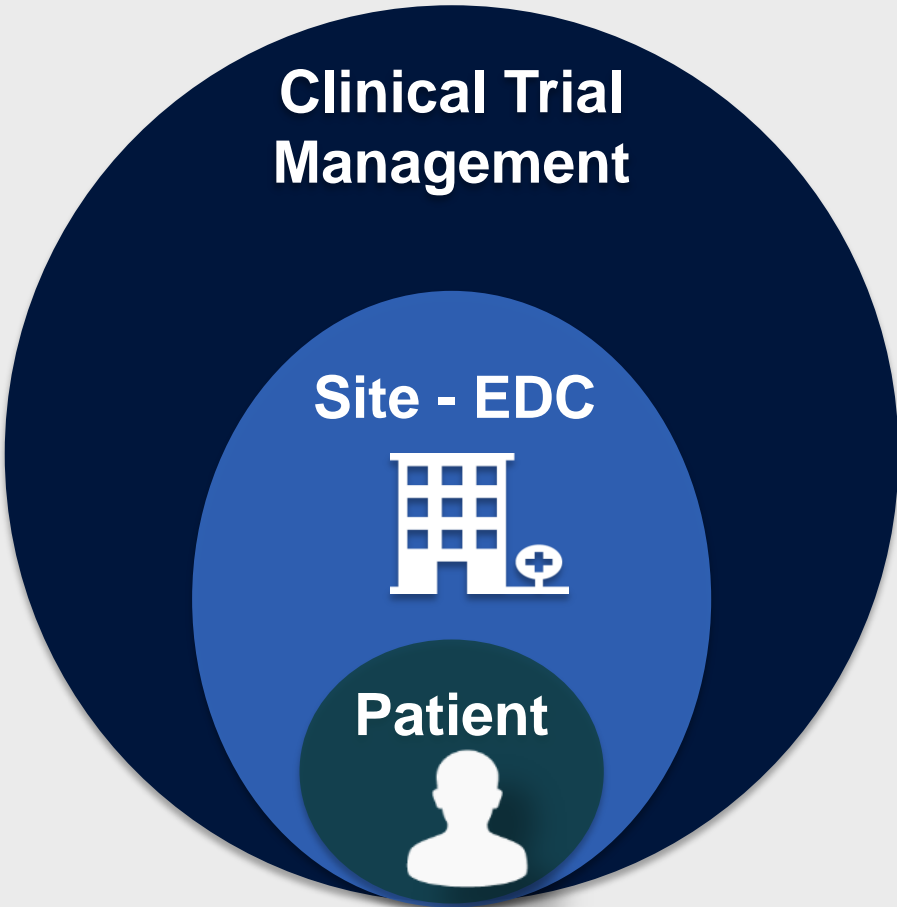assisting clients in pharmaceutical, biotechnology, and medical device industries

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PHARMA INDUSTRY CHALLENGE

Patent Submission

20 years

Patent Expiration

2004 - 2006

Development Phase | Therapy in Market

2013 - 2015

Development Phase | Therapy in Market

+25%
Time to develop a drug

2018 -

Development Phase | Therapy in Market

Digital Transformation
enables optimization and faster time to market

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

THE PAST
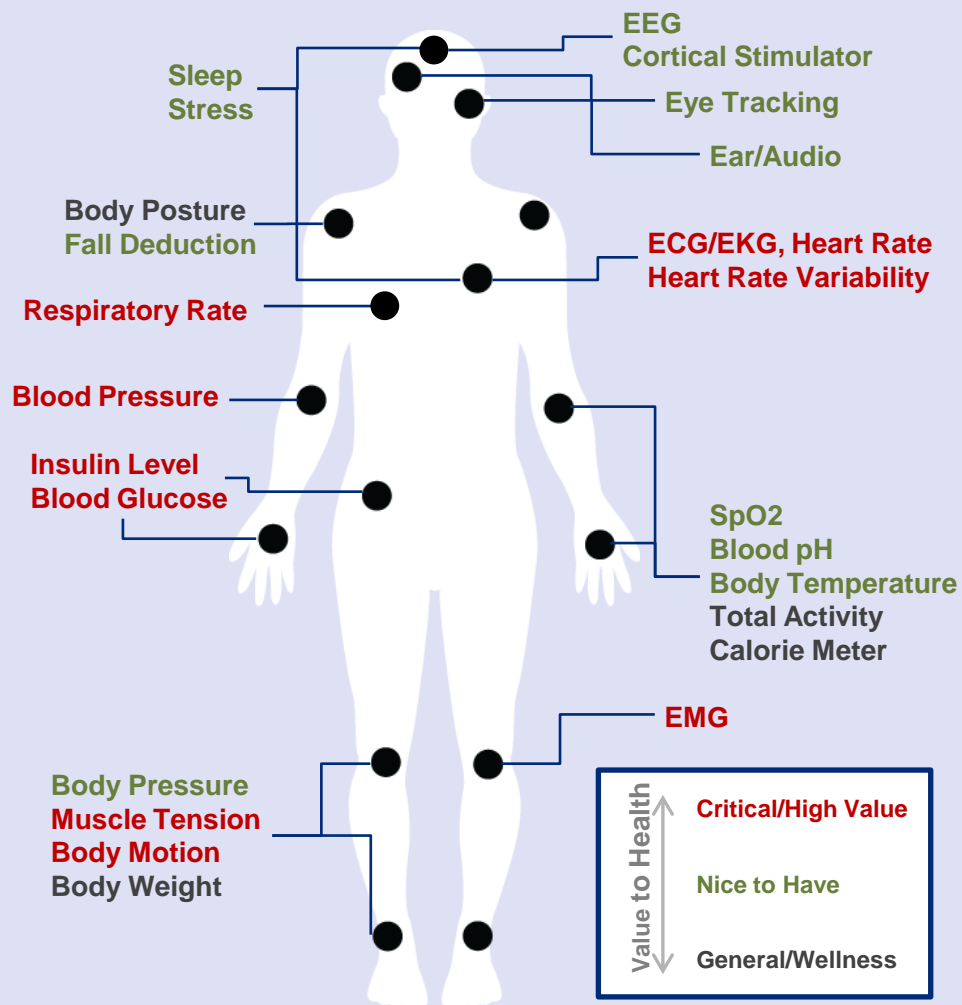Patient interaction centralized through site

Clinical Trial Management

Site - EDC

Patient

THE FUTURE
Direct – multi-channel - patient interactions

Clinical Trial Management

Patient direct

Sensor

Patient

eCOA

Patient App

EHR

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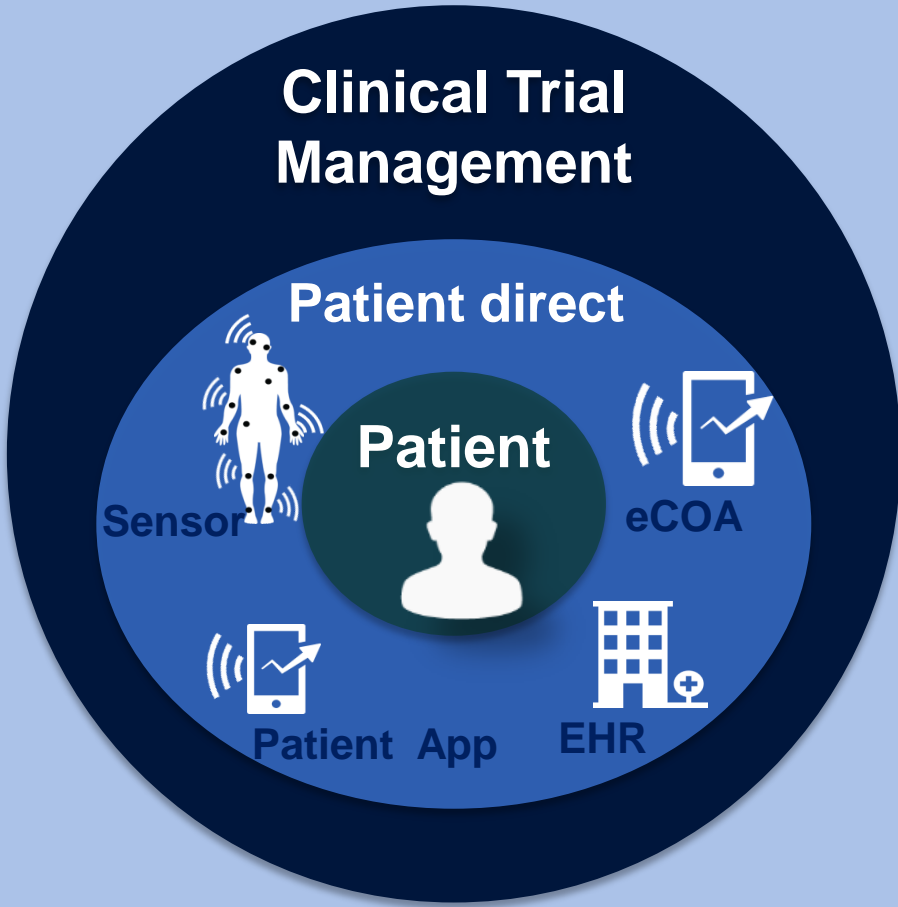
PATIENT DIRECT DATA ACQUISITION IS AT THE CORE OF DIGITAL TRANSFORMATION IN PHARMA – AND HEALTH CARE

Wearables Harnessing Human Body Data/Biometrics*

- **EEG Cortical Stimulator**
- **Eye Tracking**
- **Ear/Audio**
- **Sleep Stress**
- **Body Posture Fall Deduction**
- **ECG/EKG, Heart Rate Heart Rate Variability**
- **Respiratory Rate**
- **Blood Pressure**
- **Insulin Level Blood Glucose**
- **SpO2 Blood pH Body Temperature Total Activity Calorie Meter**
- **EMG**
- **Body Pressure Muscle Tension Body Motion Body Weight**

Value to Health:
- **Critical/High Value**
- **Nice to Have**
- **General/Wellness**

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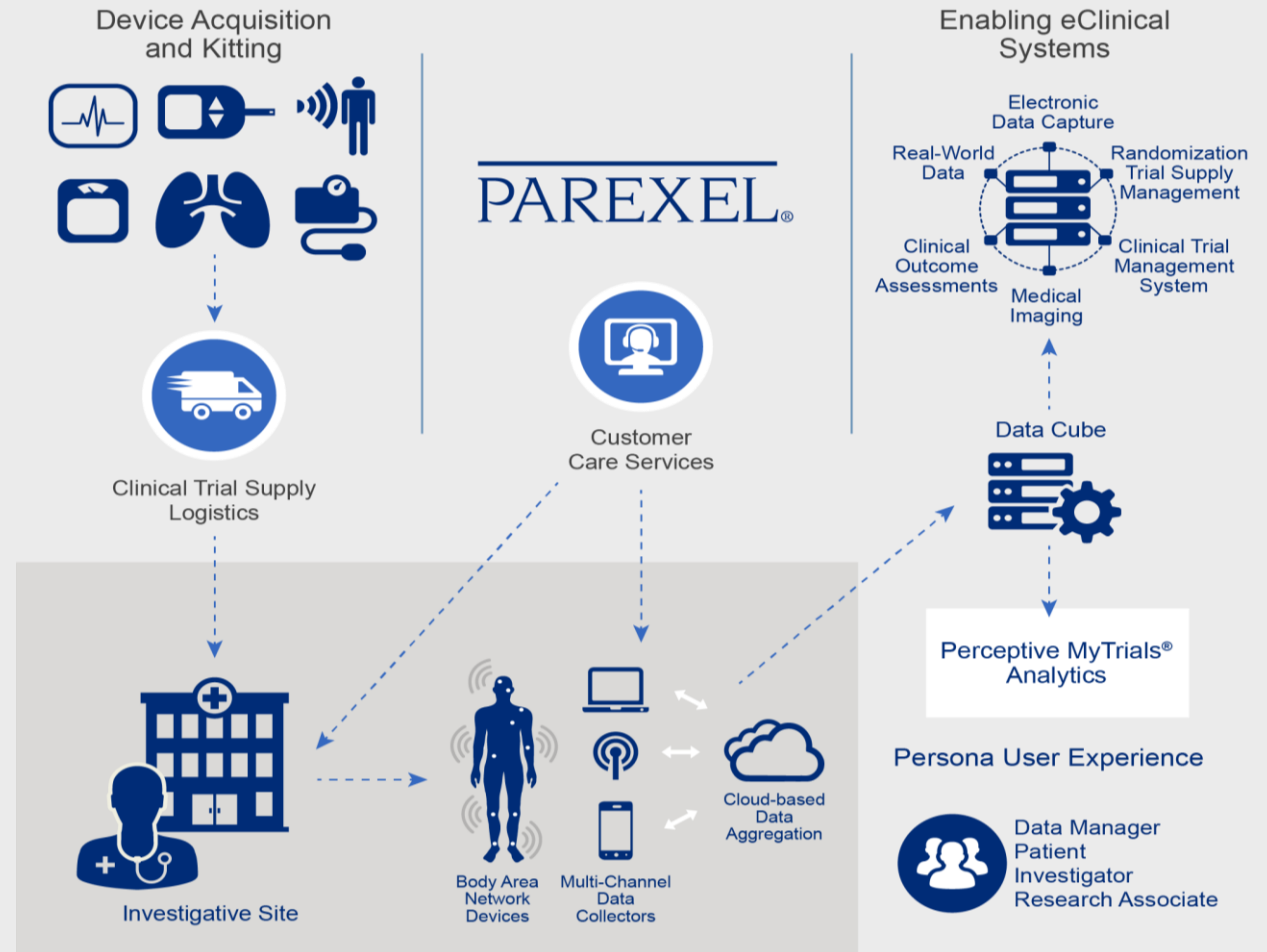
* Adapted with permission of Frost & Sullivan
** Source: Frost & Sullivan, "*Wearable Technologies in Clinical and Consumer Health*", 2016

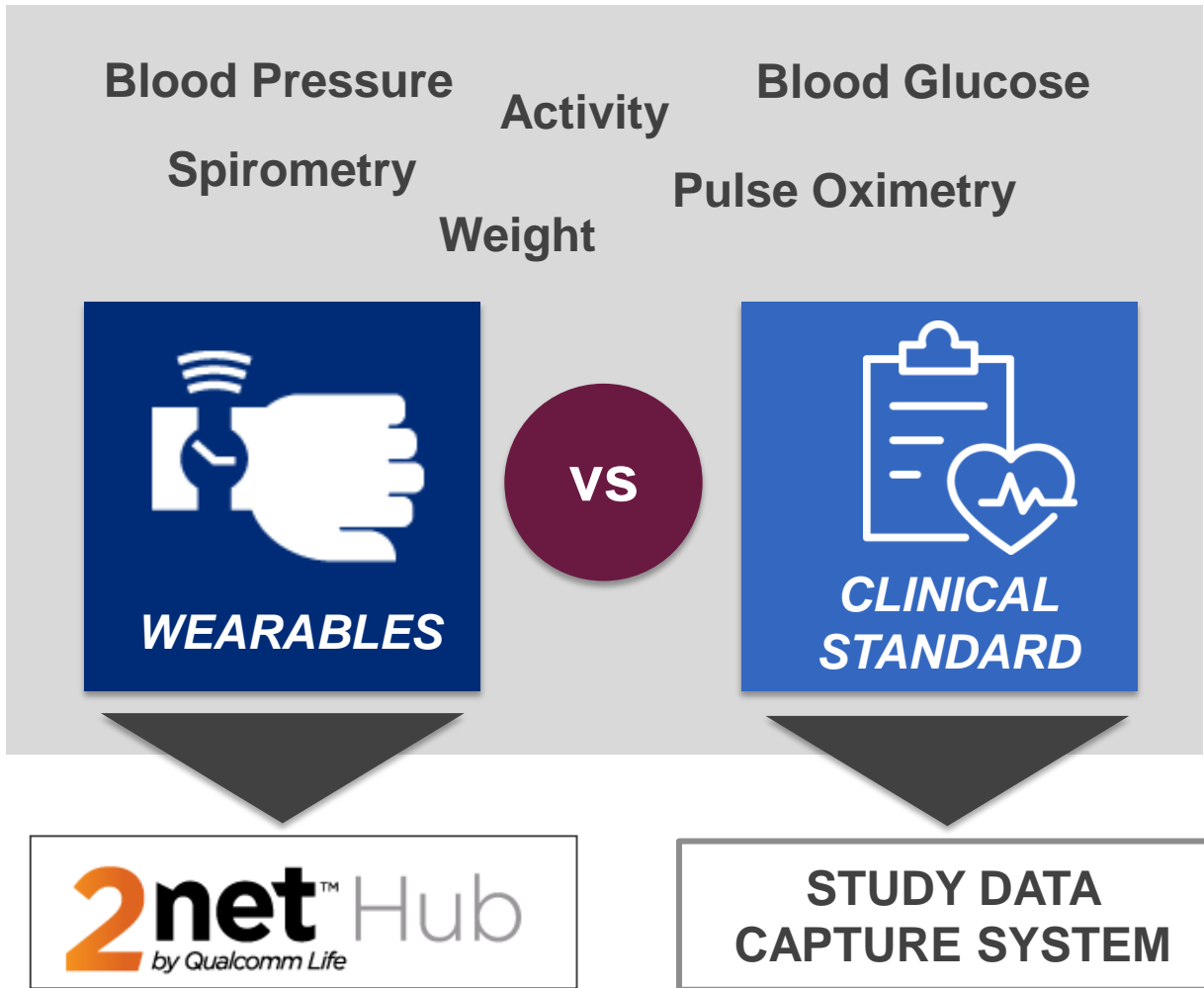## End-to-end Sensor-based Solution

- 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.

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EXPLORATORY STUDY: COMPARE WEARABLES WITH STANDARDS DATA COLLECTION TOOLS

Blood Pressure

Activity

Blood Glucose

Spirometry

Pulse Oximetry

Weight

WEARABLES

VS

CLINICAL STANDARD

2net™ Hub by Qualcomm Life

STUDY DATA CAPTURE SYSTEM

- 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

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PATIENT DIRECT PLATFORM : OVERVIEW OF COMPONENTS

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

PATIENT DIRECT

Pulse Oximetry · Blood Pressure · Blood Glucose · Spirometry · Weight · Activity
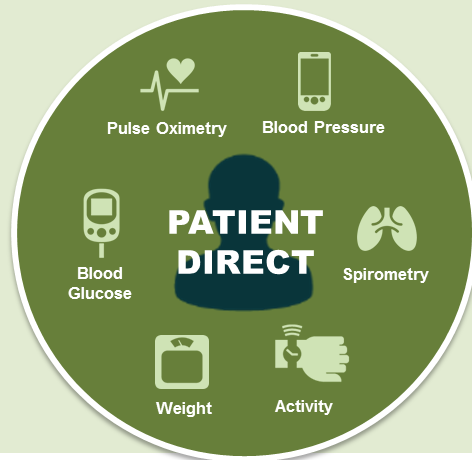
DEVICE INSTRUCTION

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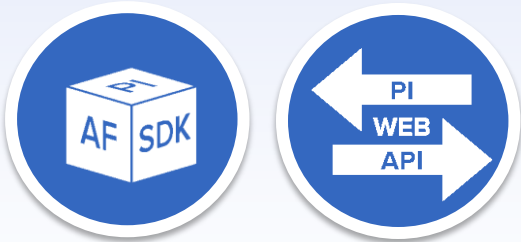- Update data export specification for data management

DEVICES INTEGRATION

- Ensure Qualcomm Eco System integration
- Build ability to process messages from Qualcomm 2Net Platform

Device

2net Platform
by Qualcomm Life

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COMPONENTS OF THE SYSTEM: *MANAGE*

PI AF SDK / Web API

- Data ingress to PI Server
- Connects to Azure and in-House data streams

PI AF / DATA ARCHIVE

- Persistent storage of wearable data with context
- Quick, easy creation and management of elements through templates

PI VISION

- View data in PI Server live
- Used to confirm data flow when taking measurements with wearable device
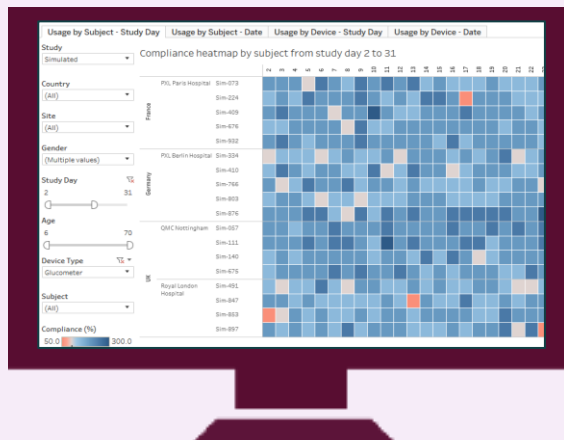
PI INTEGRATOR FOR BUSINESS ANALYTICS

- Scheduled export of key parameters every 30 minutes
- Output powers overview dashboards for data monitoring

COMPONENTS OF THE SYSTEM: *ANALYZE*

COMPLIANCE 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
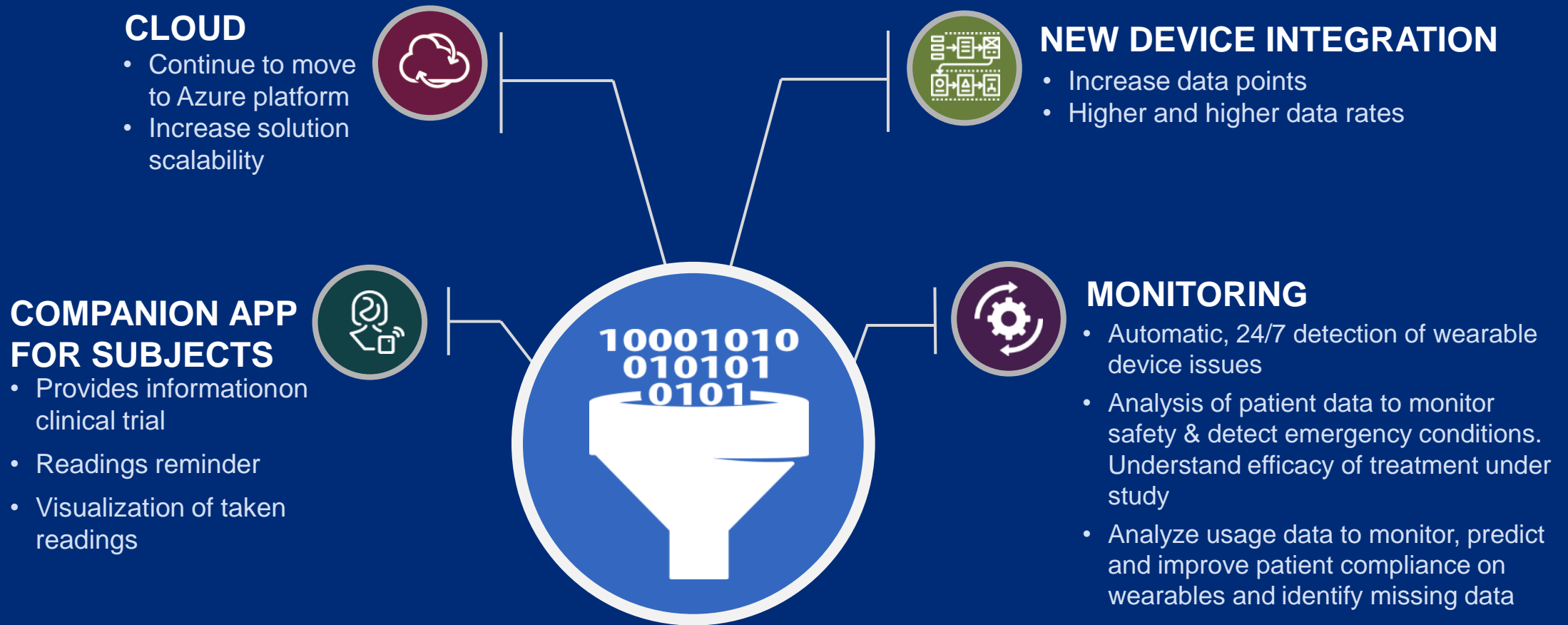
- Drill down for more detail
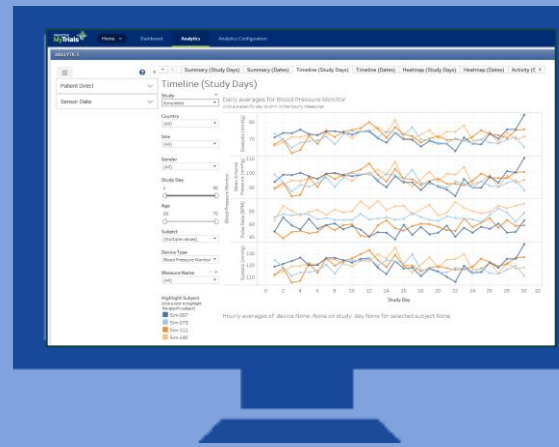
MONITORING

- Measurement transmission and processing times monitored

- Increase average times for transmission per device may indicate device user issues

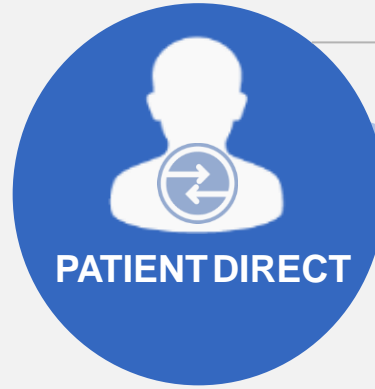- Increase in processing time for platform component could indicate a bottleneck

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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

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FUTURE PATIENT DIRECT PLATFORM

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CONCLUSIONS

SEE THE SENSORS
BOOUTH #27

PATIENT DIRECT

SENSORS JOURNEY

ROBUST PLATFORM
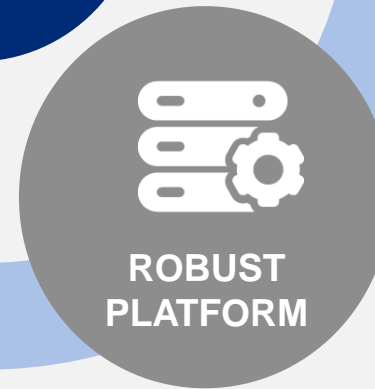
PLATFORM EXPANSION

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

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Director Engineering Solution Incubator

PAREXEL International

Questions

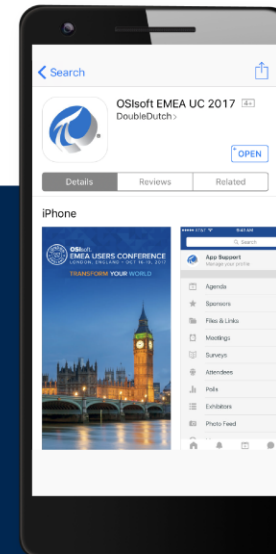Please wait for the **microphone** before asking your questions

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