Retrospective review of connected device implementations, and risk mitigation for collection of digital biomarkers

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Introduction

Nathan Noakes, Sensor Solutions Director

- Over 16 years clinical research experience, 10 years at Parexel
- Architect of sensors and connected devices solution within Scientific Data Organisation
- Technology lead for actigraphy, working closely with ActiGraph
- Liaison for cross-functional team within Parexel including Medical Directors, clinical operations and regulatory expertise

Parexel's global footprint

North America

11 offices: California (2), Colorado, Georgia, Maryland, Massachusetts (3), New Jersey, North Carolina, Pennsylvania

5,042 employees

Europe

29 offices: Belgium, Croatia, Czech Republic, Denmark, France (2), Georgia, Germany, Hungary, Ireland, Italy, Lithuania, Netherlands, Poland (2), Romania, Russia (2), Serbia, Spain, Sweden, Switzerland (2), Ukraine, United Kingdom (5)

5,337 employees

Latin America

3 offices: Argentina, Brazil, Mexico

958 employees

Middle East & Africa

5 offices: Israel, Turkey (2), South Africa (2)

624 employees

Asia Pacific

24 offices: Australia (2), China (5), Hong Kong, India (5), Indonesia, Japan (3), Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand, Vietnam

8,799 employees

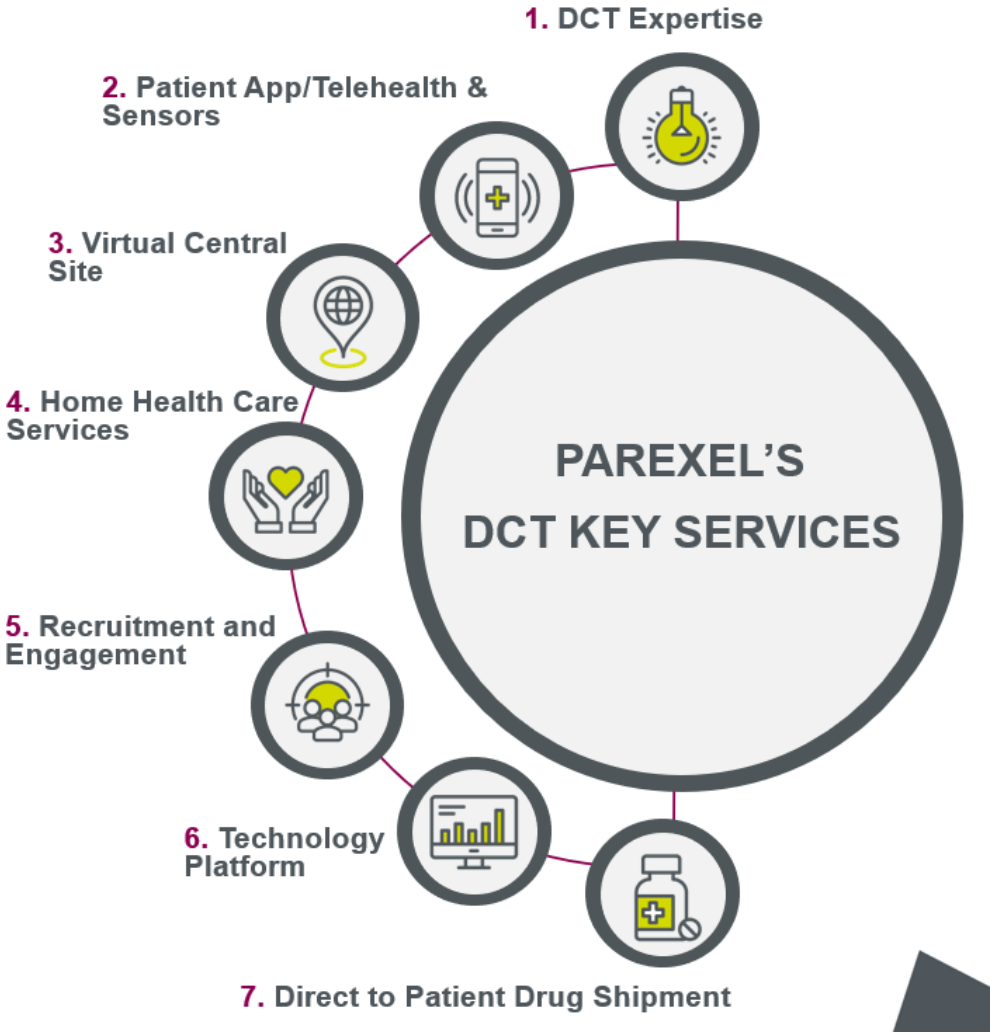
Parexel has 20,760 employees worldwide located in 72 offices

Parexel's decentralized clinical trials experience

Tech is an enabler

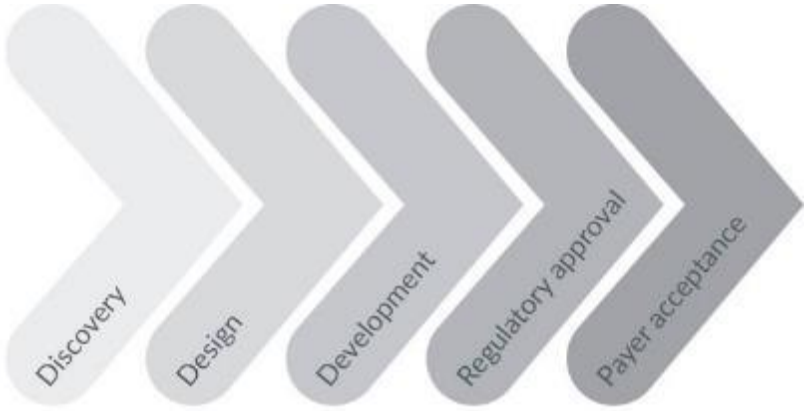
All studies can be DCT

Embracing DCT as a mindset



- 80+ Trials with a sensor or connected device
- 240+ Decentralized Trials
- 1200+ DTP Shipments
- 330+ Patient App/eCOA Projects
- 3,000+ Clinical Technology Integrations

Engaging patients directly and early in clinical protocol design supports better patient outcomes



- Starting with the end in mind – focusing on the patients who will benefit from your product
- Determining the optimal mix of innovations to implement at each of the critical steps along the path to delivering new medicines

Our fresh bench to bedside/bedside back to bench philosophy

- Bringing the information learned, through real-world evidence, back to the bench to help identify additional potential indications and/or innovative approaches to develop new treatments
- Informing basic research and development, to deliver positive benefits to patients and learn from their experience in clinical trials and the real world

I think that clinical trials, especially those with minorities and in certain areas, need to be accessible for those with limitations both physically and financially

Patient

US, Female

American Indian or Alaska Native

With Heart™

Why use a sensor or connected device?

Situation

- **>40,000** clinical studies recruiting in U.S. alone
- **85%** fail to retain enough patients
- **80%** delayed due to recruitment challenges
- **70%** of potential participants live ≥2 hours from nearest study site
- **30%** average drop-out rate
- Face-to-face consultations increasingly not possible

Challenges

- Patients experience practical, financial and geographical barriers to participation
- Highly conservative industry
- Approach to trial design and implementation has traditionally evolved slowly
- COVID-19 pandemic posed new challenges but helped to accelerate adoption of novel technologies

How can sensors overcome these challenges?

Selecting fit for purpose devices

Patient recruitment and retention

Implementation timelines

Remote monitoring

Patient engagement

Selecting fit for purpose devices

- Review landscape of available technologies for medical, technical and operational suitability
  - Not all devices will be appropriate
  - Must be equivalent to clinic standards and suitable for regulatory submission
- Validate use of the technology ahead of application into a trial
  - More than just the sensor, this includes the platform it sits on and operating procedures it is subject to

How can sensors overcome these challenges?

- Selecting fit for purpose devices
- **Patient recruitment and retention**
- Implementation timelines
- Remote monitoring
- Patient engagement

Patient recruitment and retention

- Ability to participate in a trial that would otherwise not be possible
  - Reduction in need for site visits through use of sensors
  - The technology should be an integral part of the protocol
- Devices should be as easy to use as possible
  - As far as possible, you want the patient to not have to think about using the sensor

How can sensors overcome these challenges?

- Selecting fit for purpose devices
- Patient recruitment and retention
- **Implementation timelines**
- Remote monitoring
- Patient engagement

Implementation timelines

- Incorporate sensors early in the discussion
  - Qualification of a new technology can several months
  - Use the opportunity to gain first hand experience of the devices
- Leverage experience for a smooth deployment
  - Maintain a working log of risks and their mitigations
  - Work collaboratively with your supplier or CRO to map out project plan

How can sensors overcome these challenges?

- Selecting fit for purpose devices
- Patient recruitment and retention
- Implementation timelines
- **Remote monitoring**
- Patient engagement

Remote monitoring

- Take advantage of near-real time data from the sensors
  - Visibility of meaningful data remotely is key
  - Pair with telehealth solutions or other technologies
- Identify key barriers to patient compliance
  - Set thresholds for follow up with site and patient
  - Identify trends and intervene early

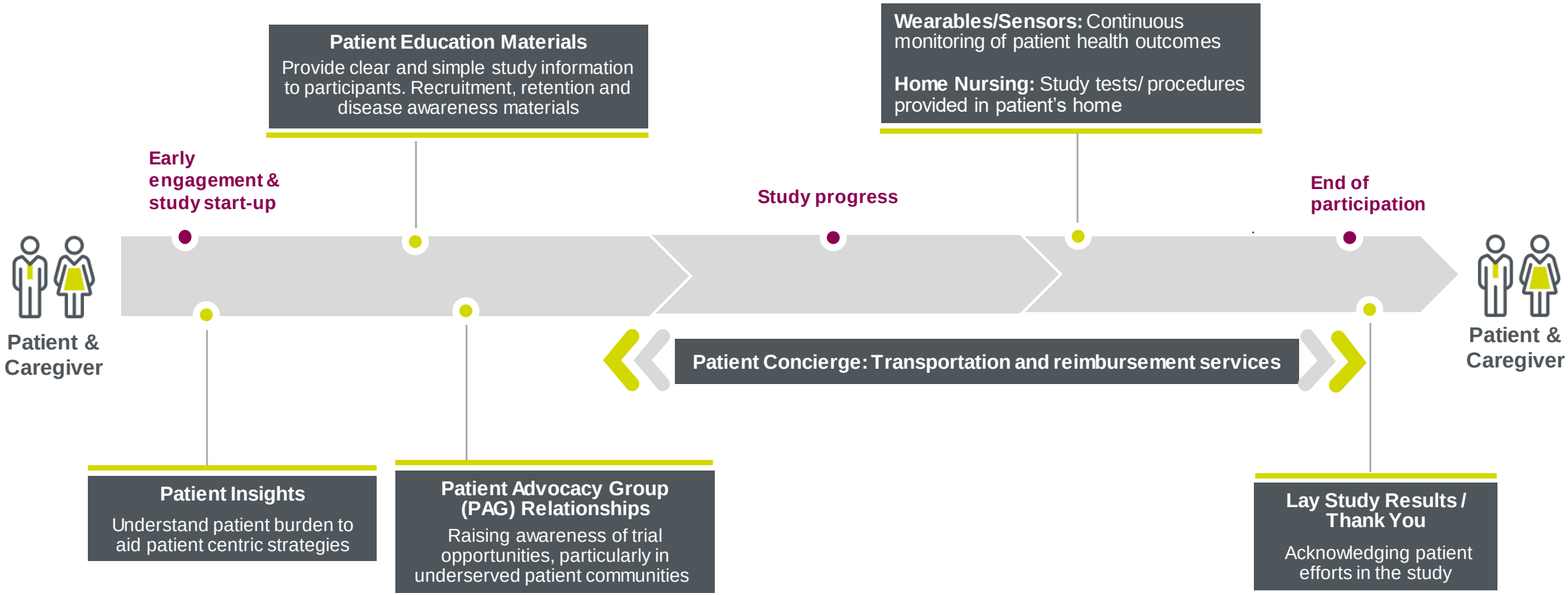
How can sensors overcome these challenges?

- Selecting fit for purpose devices
- Patient recruitment and retention
- Implementation timelines
- Remote monitoring
- **Patient engagement**

Patient engagement

- Demonstrate the value to the site and the patient
  - Sites are busy and their time is competed over
  - Wherever possible, make data insights available to the patient
- Invest heavily in training and onboarding of sites
  - Guides should be clear and concise
  - In-person or teleconference training sessions

Focusing on the patient throughout the study



Value-based care to improve: Patient/Site Engagement › Awareness › Enrollment › Adherence › Retention

Key takeaways

- The use of sensors and connected devices in clinical trials continues to grow year on year
- Actigraphy and vital signs are key measures that have broad applicability

- Start with the end in mind – what data you intend to collect, and how it will achieve the needs of the clinical trial

- These technologies allow for collection of data that would otherwise not be possible and lead to a reduction in costs due to fewer site visits

Deployment of a technology is more than just the sensor

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Questions

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Thank you