Parallel Session 2.6

Complex & Innovative Trial Design – a deep dive into device driven data acquisition

Presented by: **Nina Christine Reyes Ráfales**

Manager, Clinical Data Management, IQVIA

COMPLEX & INNOVATIVE TRIAL DESIGN – A DEEP DIVE INTO DEVICE DRIVEN DATA ACQUISITION

Nina Reyes

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Agenda

+ Presenter introduction
+ Device Driven Data Acquisition – what it means
+ Device Driven Data Acquisition – why we need it
+ Device Driven Data Acquisition – best practice
+ Q&A

Today's Speaker

+ Nina Reyes Ráfales, Manager, Clinical Data Management at IQVIA

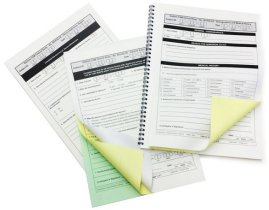
+ With a big "THANK YOU" to: Jeff Noll IQVIA Connected Devices, Lead

For your support

Devices in Research - what does that mean?

Data Acquisition than…

Folders over Folders of patient data in offices full of fireproof filing cabinets containing paper CRF



Open Slido please and tell me... How can we describe this? *Give me some adverbs! You have 60 seconds.*

What was next?

From RDE to EDC

Wiki says:

- An **electronic data capture** (**EDC**) system is a computerized system designed for the collection of clinical data in electronic format. EDC replaces the traditional paper-based data collection methodology to streamline data collection and expedite the time to market for drugs and medical devices. EDC solutions are widely adopted by pharmaceutical companies and contract research organizations (CRO).

- EDC is often cited as having its origins in remote data entry (RDE) software, which surfaced in the life sciences market in the late 1980s and early 1990s.

And what an innovation this was back in the 90s!

And now?
In the middle of the next evolution:
Device Driven Data Acquisition

How can we define this?

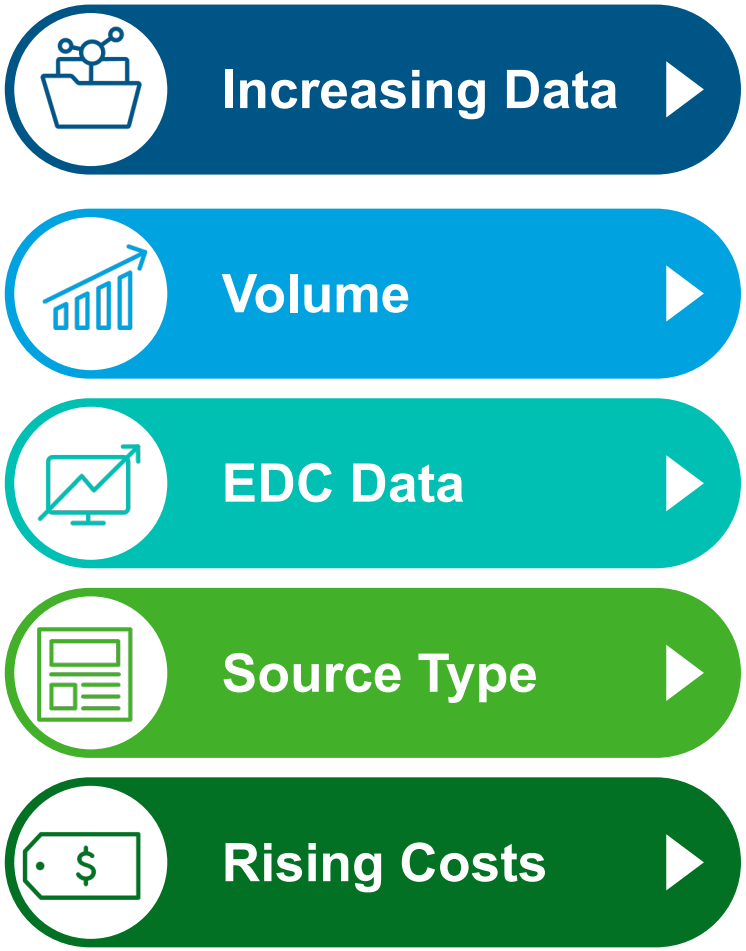
The collection of clinical trial data directly from the patient via connected devices / sensors / wearables to reduce dependency on less efficient, more burdensome EDC systems.

But, now let us again interact a bit. Eyes on your devices and open Slido please:

Let's brainstorm → What comes to your mind when you think about Device Driven Data Acquisition?

Give me your ideas!

Devices in Research - Trends



All the data generated between the beginning of time and the year 2000, is the same that is now generated every min of every day.[1]

The body of healthcare data is doubling every 2 years.[2]

Only 20% – 30% of data points collected in EDC

By 2020, >200m wearable shipments expected, 1.8m articles published annually[3]

Processing costs increase exponentially

Registered clinical trials using connected devices grew more than tenfold[4], to roughly 1,170 trials in 2018.

Forecasts suggest sales will double by 2023[5].

1. Marr, Bernard. Why only one of the 5 Vs of big data really matters. 10 March 2015. http://www.ibmbigdatahub.com/blog/why-only-one-5-vs-big-data-really-matters
2. European Medicines Agency. Identifying Opportunities for 'Big Data' in medicines development and regulatory science. November 14-15 2016. http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/02/WC500221938.pdf
3. IDC Forecasts Wearables Shipments to Reach 213.6 Million Units Worldwide in 2020 with Watches and Wristbands Driving Volume While Clothing and Eyewear Gain Traction. 15 June 2016. https://www.idc.com/getdoc.jsp?containerId=prUS41530816
4. https://www.nature.com/articles/s41746-020-0259-x/figures/2
5. https://www.businesswire.com/news/home/20190516005571/en/World-Market-Connected-Wearables-4th-Edition-Shipments

Devices in Research - Trends

Glucose Monitoring

Beginning in 2015 and increasing steadily 2018-2020 in endocrinology trials, connected glucose meters and continuous glucose monitors have been used to track diabetes patients and their outcomes as well as the impact of experimental drugs on glucose in other therapy areas.

Blood Pressure

Ambulatory, office and home blood pressure monitors are used across multiple therapy areas to help ensure detection of hypertension or anti-hypertensive effects of drugs, with ABPM showing growth over the past few years. Recent additions are the used of cuffless BP sensors using optical photoplethysmography (PPG) technology and central BP measurement.

Vitals

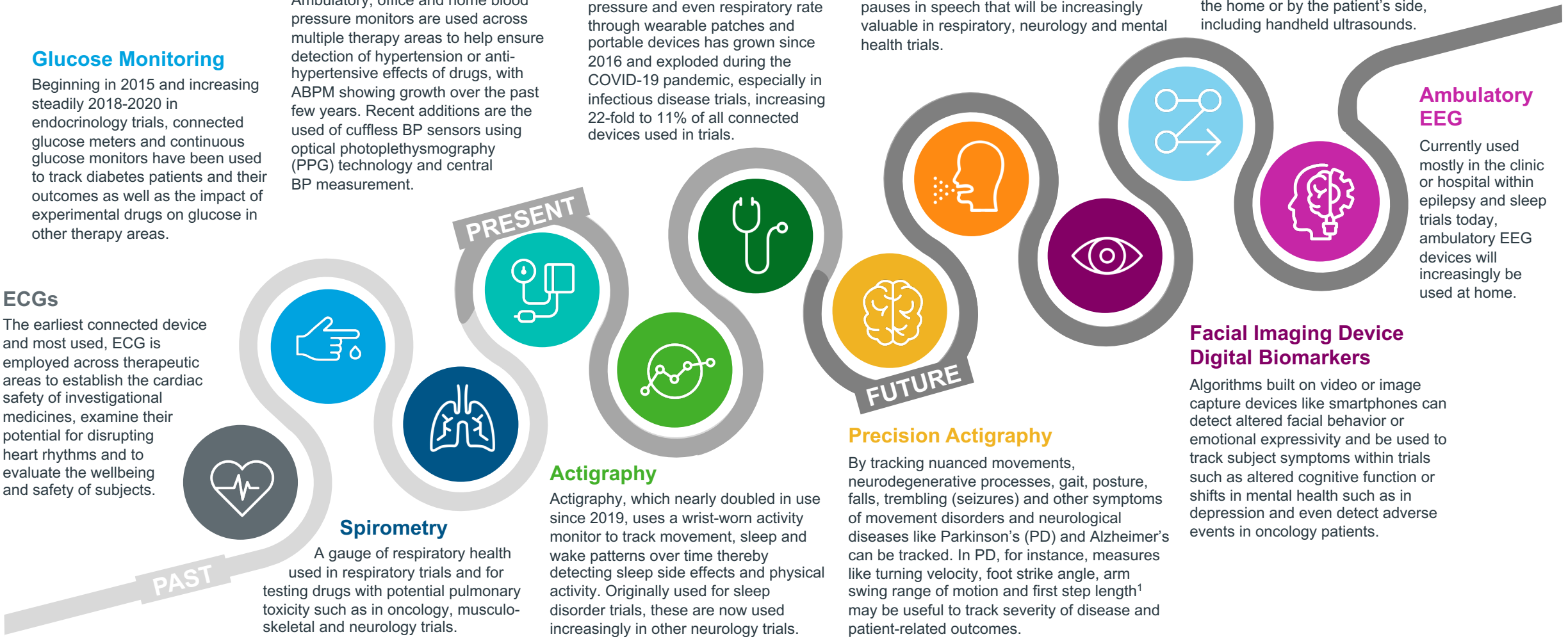
The home-based monitoring of SpO2, temperature, heart rate, blood pressure and even respiratory rate through wearable patches and portable devices has grown since 2016 and exploded during the COVID-19 pandemic, especially in infectious disease trials, increasing 22-fold to 11% of all connected devices used in trials.

Voice/Audio Device Biomarkers

Algorithms built on sensors using sensitive microphones may be used to detect breathing abnormalities, cough type, or pauses in speech that will be increasingly valuable in respiratory, neurology and mental health trials.

Handheld/Smaller Imaging Devices

New, smaller imaging devices are being created that can be used at the home or by the patient's side, including handheld ultrasounds.



Ambulatory EEG

Currently used mostly in the clinic or hospital within epilepsy and sleep trials today, ambulatory EEG devices will increasingly be used at home.

ECGs

The earliest connected device and most used, ECG is employed across therapeutic areas to establish the cardiac safety of investigational medicines, examine their potential for disrupting heart rhythms and to evaluate the wellbeing and safety of subjects.

Facial Imaging Device Digital Biomarkers

Algorithms built on video or image capture devices like smartphones can detect altered facial behavior or emotional expressivity and be used to track subject symptoms within trials such as altered cognitive function or shifts in mental health such as in depression and even detect adverse events in oncology patients.

Spirometry

A gauge of respiratory health used in respiratory trials and for testing drugs with potential pulmonary toxicity such as in oncology, musculo-skeletal and neurology trials.

Actigraphy

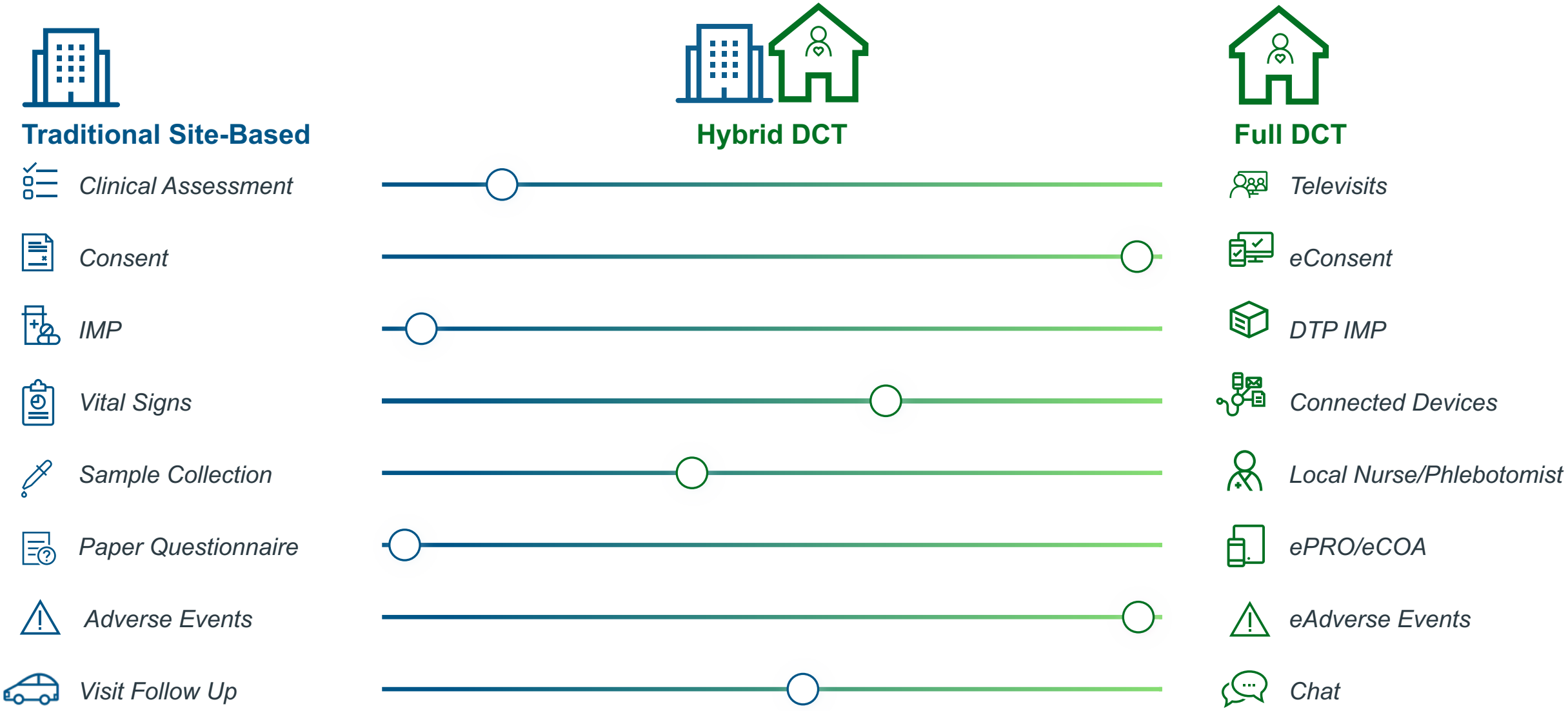
Actigraphy, which nearly doubled in use since 2019, uses a wrist-worn activity monitor to track movement, sleep and wake patterns over time thereby detecting sleep side effects and physical activity. Originally used for sleep disorder trials, these are now used increasingly in other neurology trials.

Precision Actigraphy

By tracking nuanced movements, neurodegenerative processes, gait, posture, falls, trembling (seizures) and other symptoms of movement disorders and neurological diseases like Parkinson's (PD) and Alzheimer's can be tracked. In PD, for instance, measures like turning velocity, foot strike angle, arm swing range of motion and first step length[1] may be useful to track severity of disease and patient-related outcomes.

Source: IQVIA Institute for Human Data Science. Digital Health Trends 2021: Innovation, Evidence, Regulation, Adoption.
Note: Includes devices used for safety as well as efficacy evaluations. 1 MDPI. How to Select Balance Measures Sensitive to Parkinson's Disease from Body-Worn Inertial Sensors – Separating the Trees from the Forest. Available from: https://www.mdpi.com/1424-8220/19/15/3320/html

Devices in Research // Trial Design – Trends



Devices in Research – why we need it!

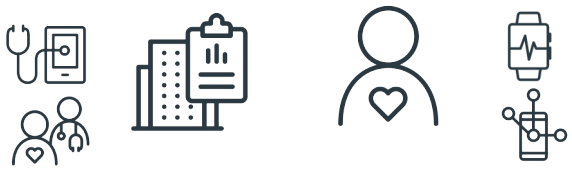
Patient Focused Drug Development Trends Drive Demand for Connected Device Solutions

Accelerated patient-centric drug development/data access

Customer Need

Site Based patient access/ data collection → *Hybrid* → *Patient based data access/collection*

- Clinical Sites continue to be the primary source of clinical data in future trials.
- Medical records data is largely inaccessible to the global patient population
- Sites continue to perform most patient recruitment and retention work.



- **Clinical Source data derived both from clinical sites and from the patients themselves, via wearables, in-home care, and ePRO**
- Patients have increasing, yet localized access and decision-making rights to a subset of their medical records data,
- Sites still capture and monitor the majority of source data.
- Patient recruitment and engagement becomes a collaborative effort between sites and CROs.

Current & Evolving Priorities

- **Primary source data for a trial driven by ePRO, wearables, and other patient-centric mechanisms**
- Blockchain and other technologies along with expanded regulation enable secure, patient-mediated medical record exchange.
- Direct to patient is the cornerstone model for clinical trial patient enrollment and retention.

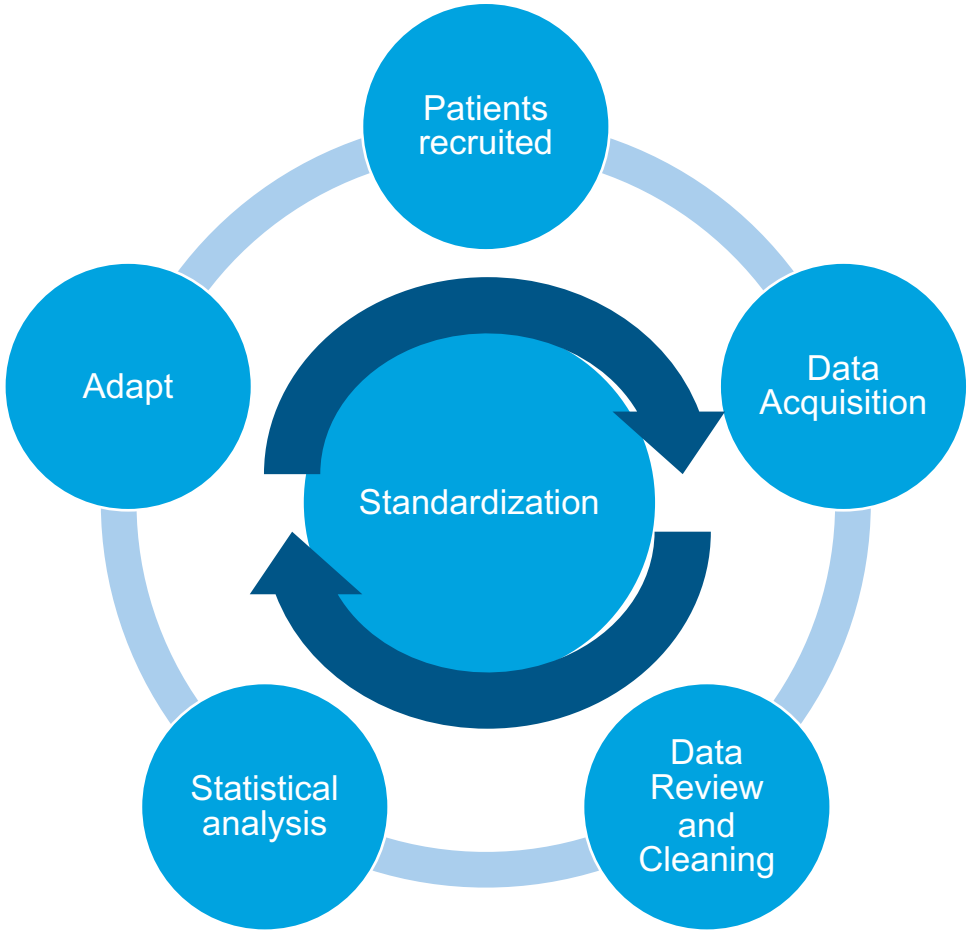
CRO Role

"Silent partner" role, defer to Sites → *Significant, direct interactions with patients.*

Better Solutions: Success of complex & innovative designs

Ability of design to out-perform more traditional design types

- Ability to make decisions
- Endpoint time to recruitment ratio
- Quickly ingesting data
- Standardized
- Capture as close to source as possible
- High quality data



Device Driven Data Acquisition: Value Across Development Lifecycle

Phase I

Connected Devices streams bi-directional, real-time data ensuring **highest level of safety** for patients. Using a high-quality connected Devices Digital Platform enables **seamless data-collection and enhanced study set-up, improving study efficiency.**

Phase II

Connected Devices provides the opportunity to **collect data from multiple endpoints across all therapeutic areas**, ensuring quality and consistency of data

Phase III

Connected Devices enables **hybrid and decentralized trials**, providing medically-validated **endpoint data collection to diverse and compromised patient populations** in remote corners of the world

Phase IV

Connected Devices has multiple patient-centric form factors, enabling **highest level of protocol adherence and reduced deviations, while reducing impacts on quality of life during trial participation.**

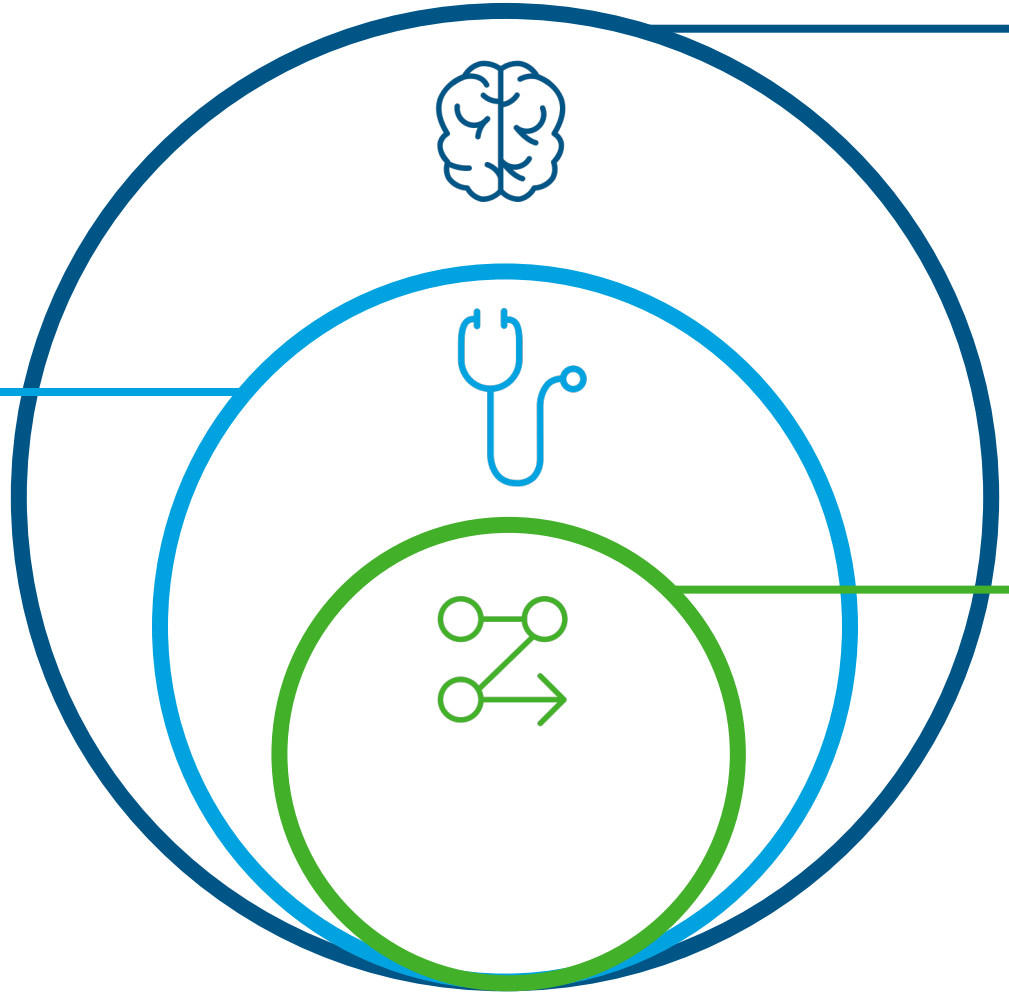
Devices in Research // Impact - Trends

SPONSOR

- Create better engagement channels across study teams: sponsors, sites and patients
- Improve transparency to give sponsors on-demand access to trial progress and updates

SITE

- Simple, highly configurable workflows to speed study execution
- Improve site satisfaction
- Ease site administrative burden



PATIENT

- Purpose-built solutions delivering a convenient end-to-end patient experience
- Reduce patient burden
- Improve engagement, compliance and retention

Devices in Research – better devices = better data BEST PRACTICE

Better Devices // Influencing Selection

Accessible

- Familiar connected devices
- Personal and home devices

Engaging

- Reminders and chat features
- Call center (Help)

Easy To Use

- Clear instructions
- Clean interface
- Multi-lingual

Better Devices // Qualification of Partners

60 – 90 Days

Requirements | Qualification | On-Boarding | Improvement

Identification & Selection

- Horizon Scanning
- Cross-Functional Team
- Portfolio Requirements
- Novel Innovation/ Technology
- Optimized for Study Requirements

Cross-Functional Assessment

- Risk-Based Assessment
- Multi-Disciplinary Approach
  - IT Security
  - Data Privacy
  - Quality Assurance
  - Legal
  - Finance

Comprehensive Contracting

- Global Master Service Agreements
- Service Level Agreements
- Study-Specific Contracts, Work Orders
- PO Terms & Conditions

Metrics Based Governance

- Review Performance Metrics/KPIs
- Strategic Alignment
- Expectation Setting
- Drives Continuous Improvement

Better Data // Source Quality

Comprehensive eSource strategy leads to a higher quality of data being collected and analyzed

Manual Data Entry

- **Up to 30%** of data received from sites can contain data entry errors within:
  Demographics
  Visit Number/Sequence
  Procedure Results

Poor Data Quality

- **Inexperienced Sites** need help to collect quality procedure data that stand alone devices often can't provide.

Non-Expert Analysis

- **Up to 50%** of ECG Machine Measurements don't agree with Cardiologists. Timely expert analysis can be crucial in screening decisions.

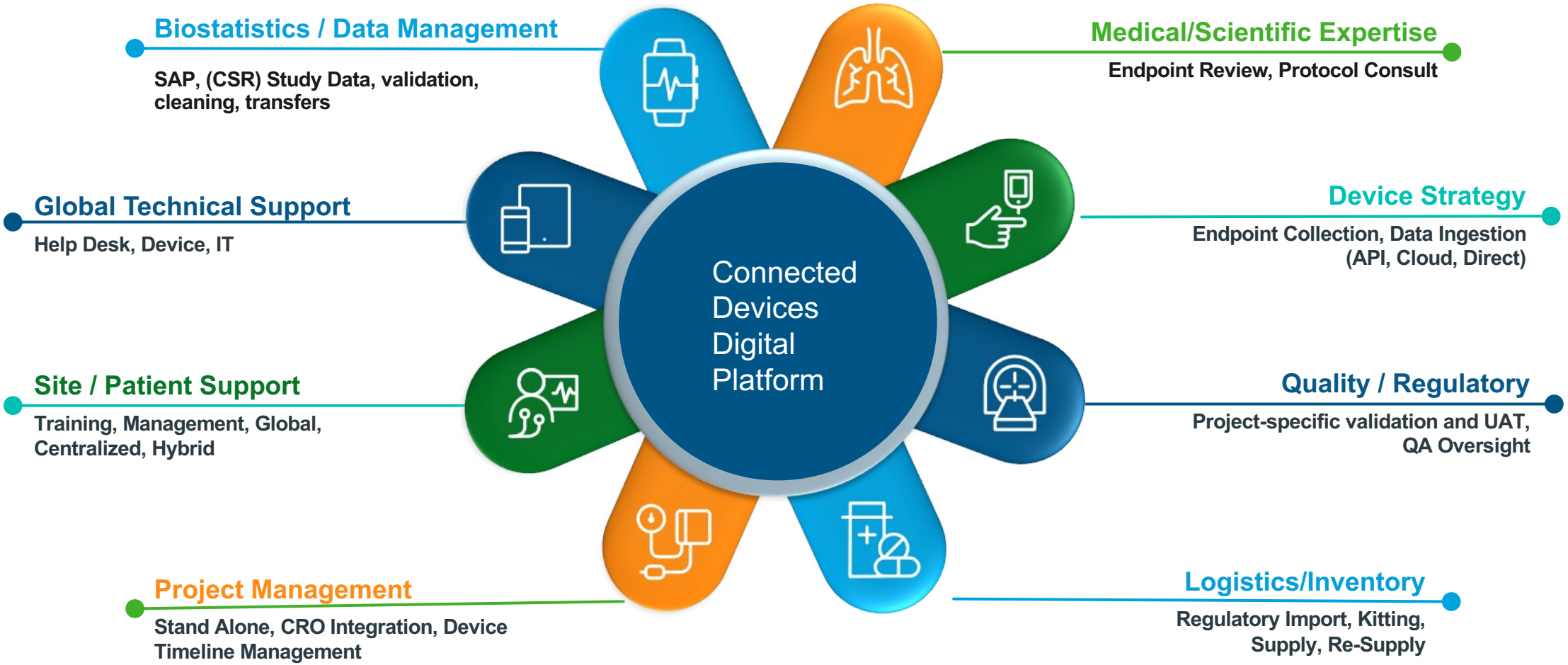
Data Access

- **Less than 50%** of devices used on trials in the past had any means to capture users or limit their actions to ensure data integrity.

Many of these issues are directly related to the fact that most devices weren't designed for clinical trials.

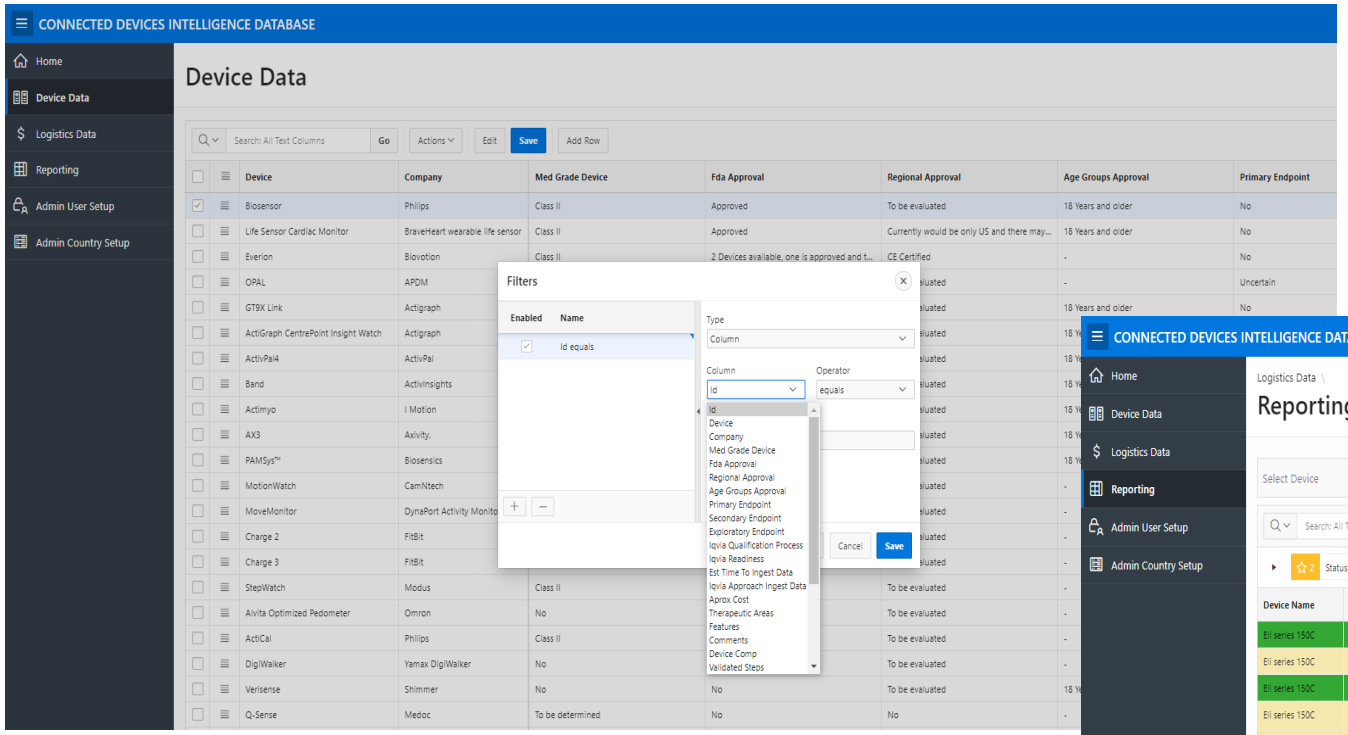
- Paper-based/manual data collection transcribed into CRFs
- No QC, high query/failure rates
- Source data stored at sites; copies sent for analysis
- Expert analysts often can't help with timely decision making

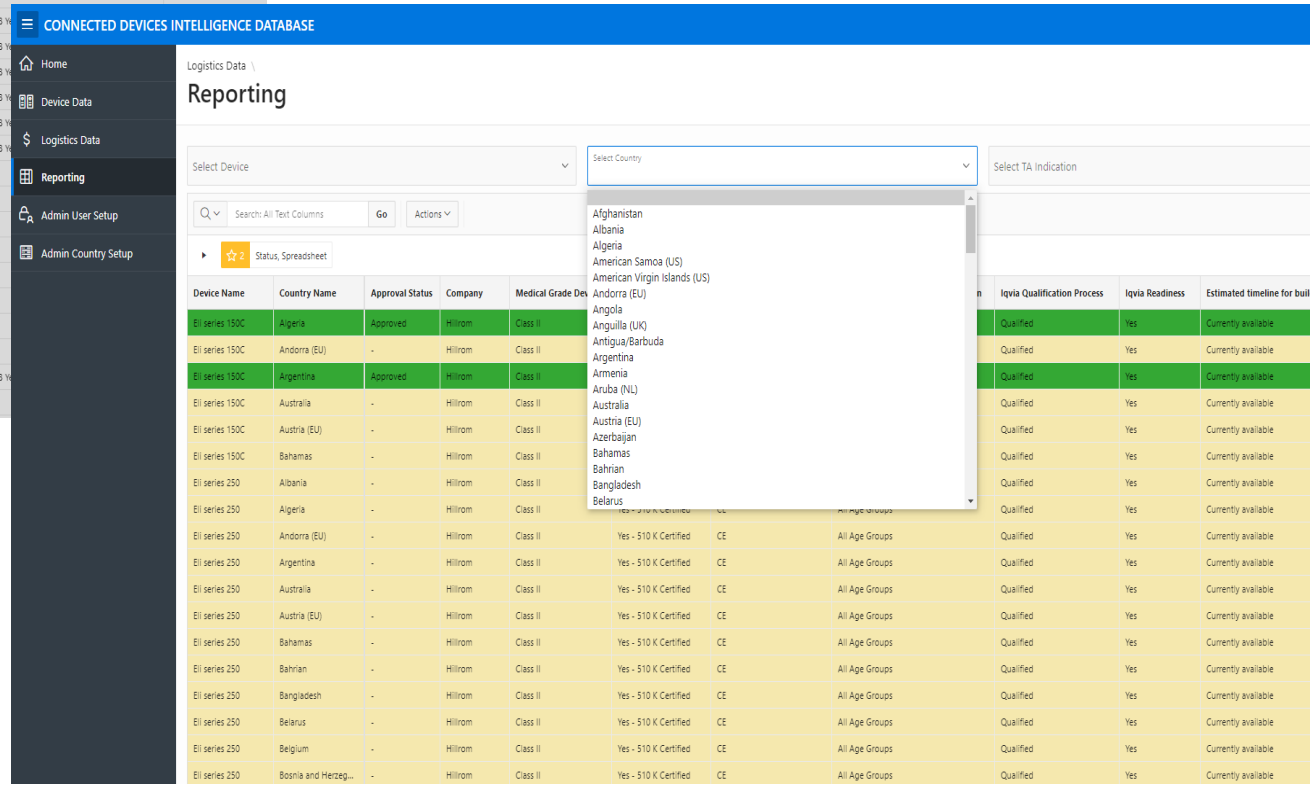
Better Devices // Support Services

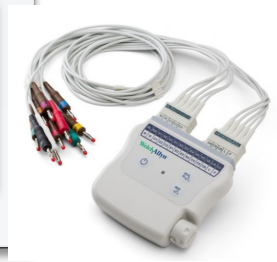


Better Devices // Data Driven Selection Methods

Endpoint Strategy, Logistics, Regulatory, Cost

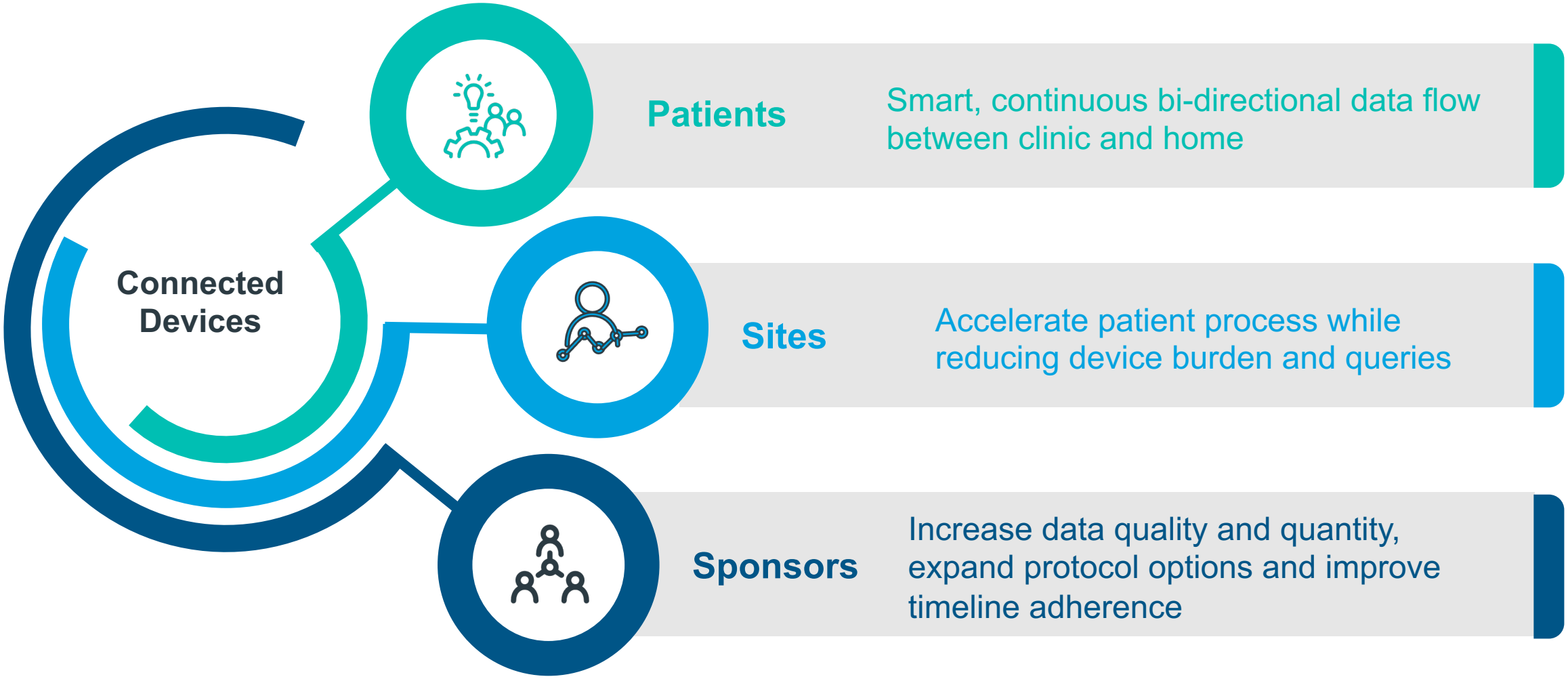






Better Data // Ease of Use

Delivers user-specific benefits across the trial continuum



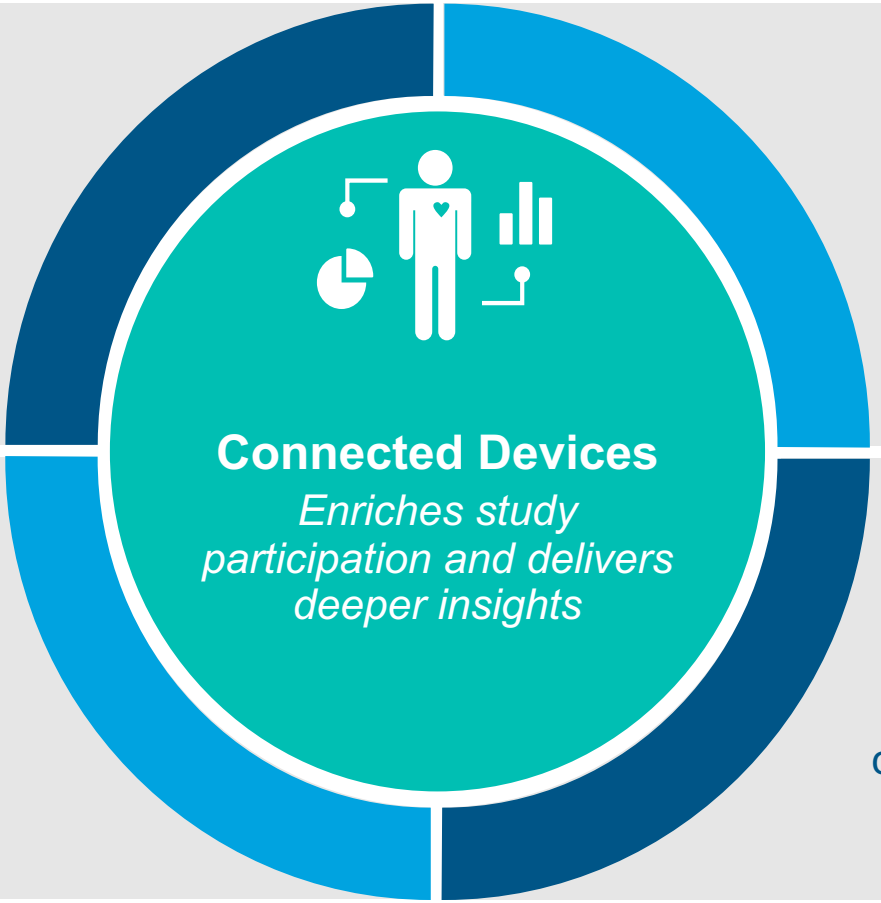
Better Data // Enriched Data

Superior insights

Access cleaner data faster driving proactive decisions with deeper insights through near real-time comprehensive **data generated *closer to the patient***

Improve site and patient experience

And reduce burden for ***increased recruitment and better engagement***



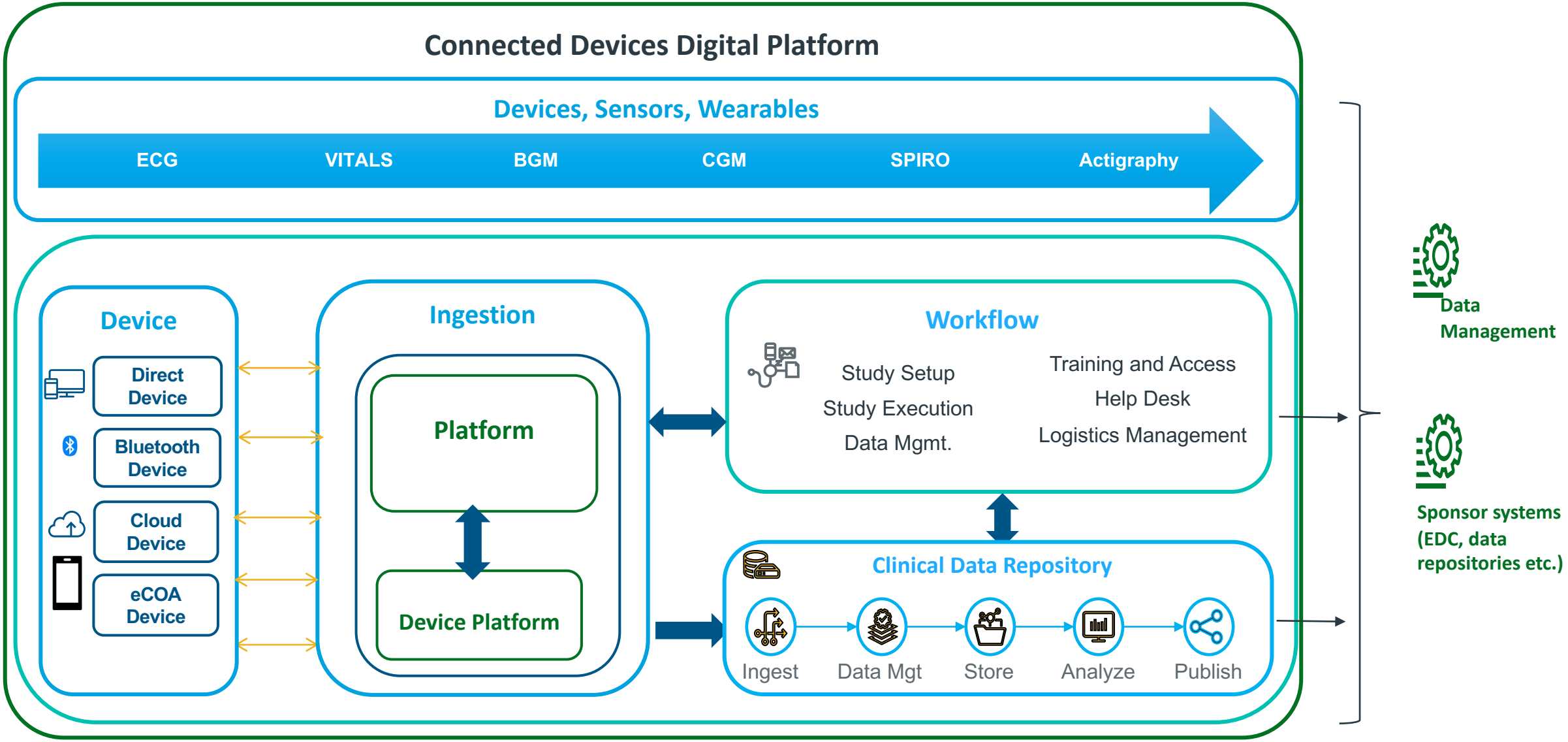
Increased efficiency

Reduce study queries with ***continuous, bi-directional, clean***, **near *real-time data***

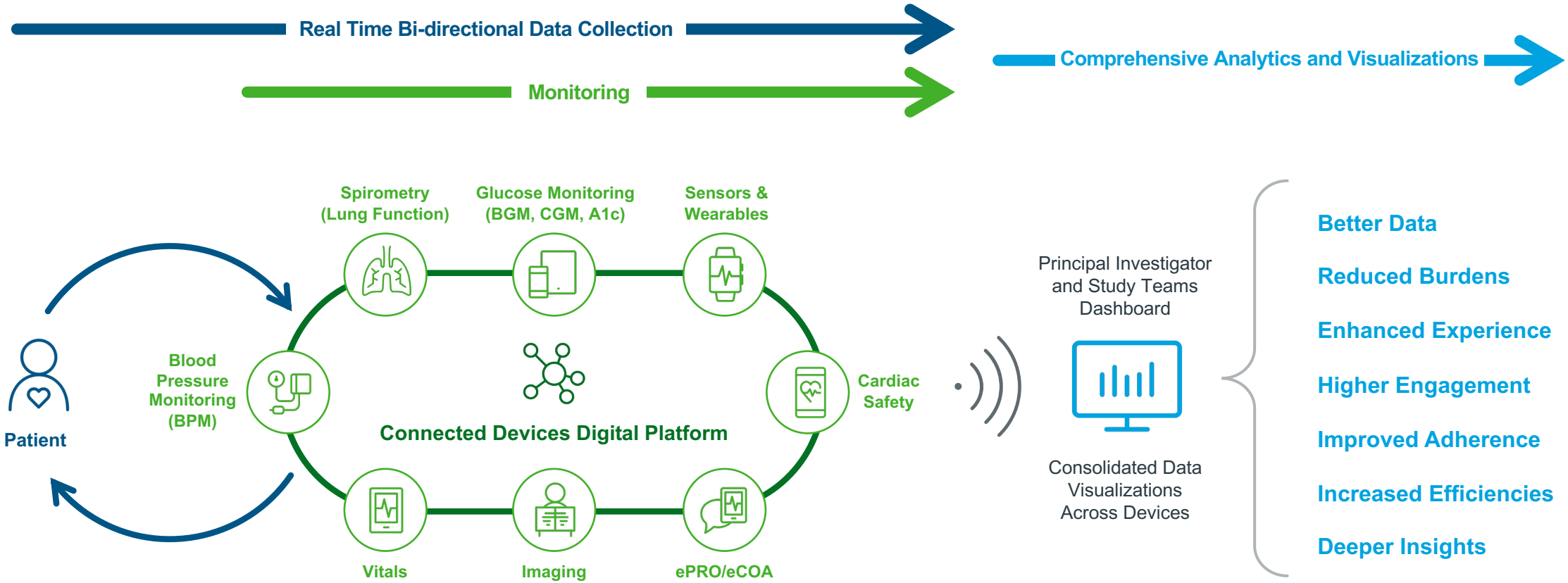
Technology-driven value

Regulatory compliant **solutions delivering clinical trial optimization** to consolidate, verify and analyze continuous data flow

Better Data // Flexible Ingestion Platform

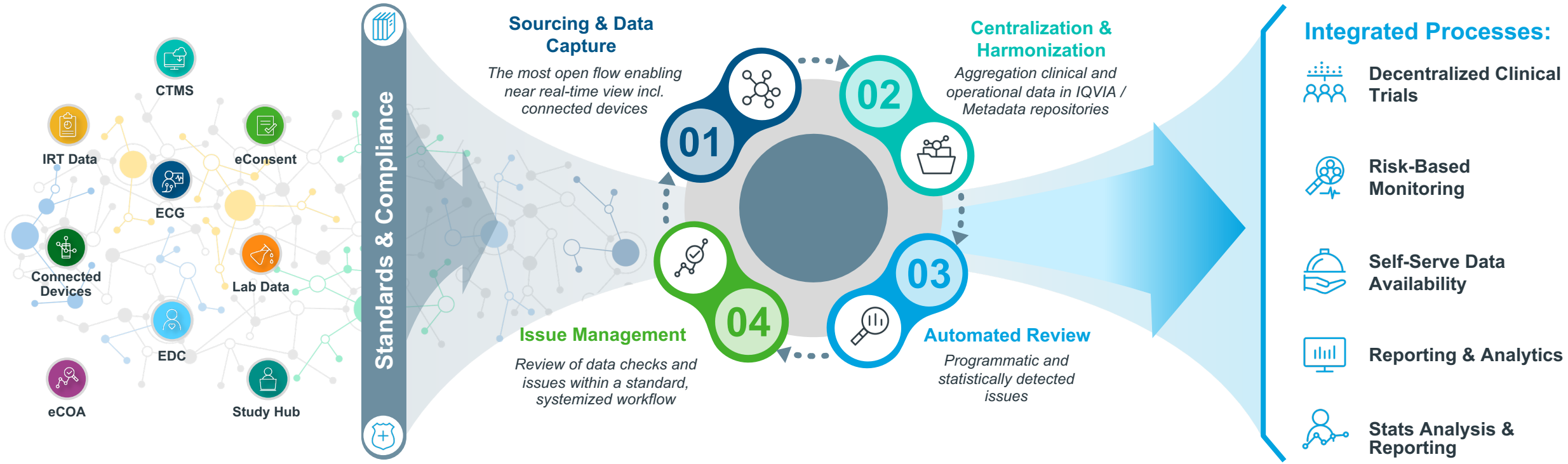


Device Data Acquisition Strategy: CDDP eSource Platform



Better Solutions

A robust solution that meets the new demands of the market



100% Data Ingestion Automation

Data-Driven Standardized Process

Real-Time Data Cleaning

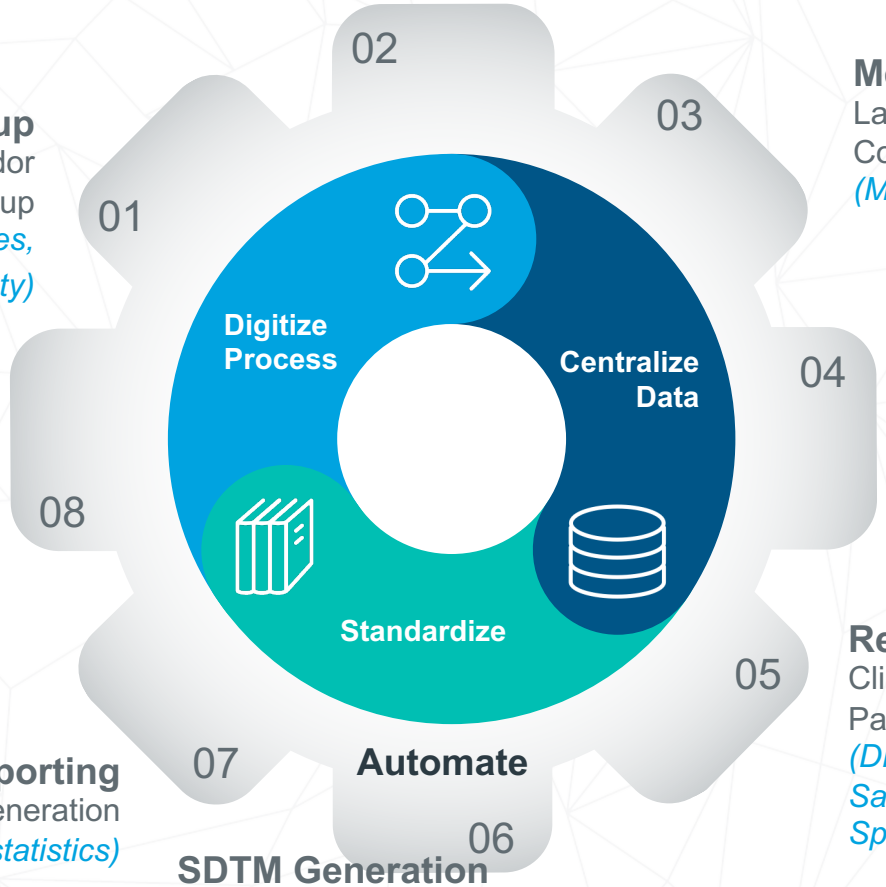
Real-Time Flow & Access

Better Solutions // Data Ecosystem

The data is what connects us - A single ecosystem for all data-centric activities

Data Cleaning
Data Acquisition, Data Review, Report Generation, Reconciliation, Vendor Communication
(Data Management)

Study Set-up
DMP, SAP, EDC Design, Vendor Data Set-up
(DM, Bios, Connected Devices, Medical, Safety)



Medical Safety & Data Review
Lab Review, Safety Review, Communication with Sites
(Medical)

Risk-Based Monitoring
SLDR, KRIs
(Centralized Monitoring)

CSR Creation
Content Authoring
(Medical Writing)

Reporting & Analytics
Clinical Analytics, Data Insights, Clean Patient Tracking
(DM, Bios, Connected Devices, Medical, Safety, Clinical, Project Management, Sponsors)

Analysis & Reporting
ADaM and TFL generation
(Biostatistics)

SDTM Generation
Define.XML, Code generation
(Biostatistics)

Robust, flexible ecosystem provides a single model to support new trial types focused on speed and data transparency

- Complex / Adaptive Study Designs
- Decentralized Clinical Trials

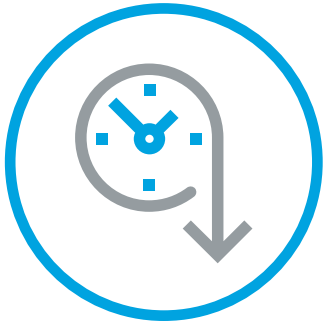
Better Solutions // Increased Data Value

Reduce risk

Early exploration of doses

Comparative analysis versus other compounds

Synthetic control arms



Reduce timelines

Virtual trials

Synthetic control arms

Master protocols

Adaptive designs

Thanks for your attention and enjoy your meal!

☺