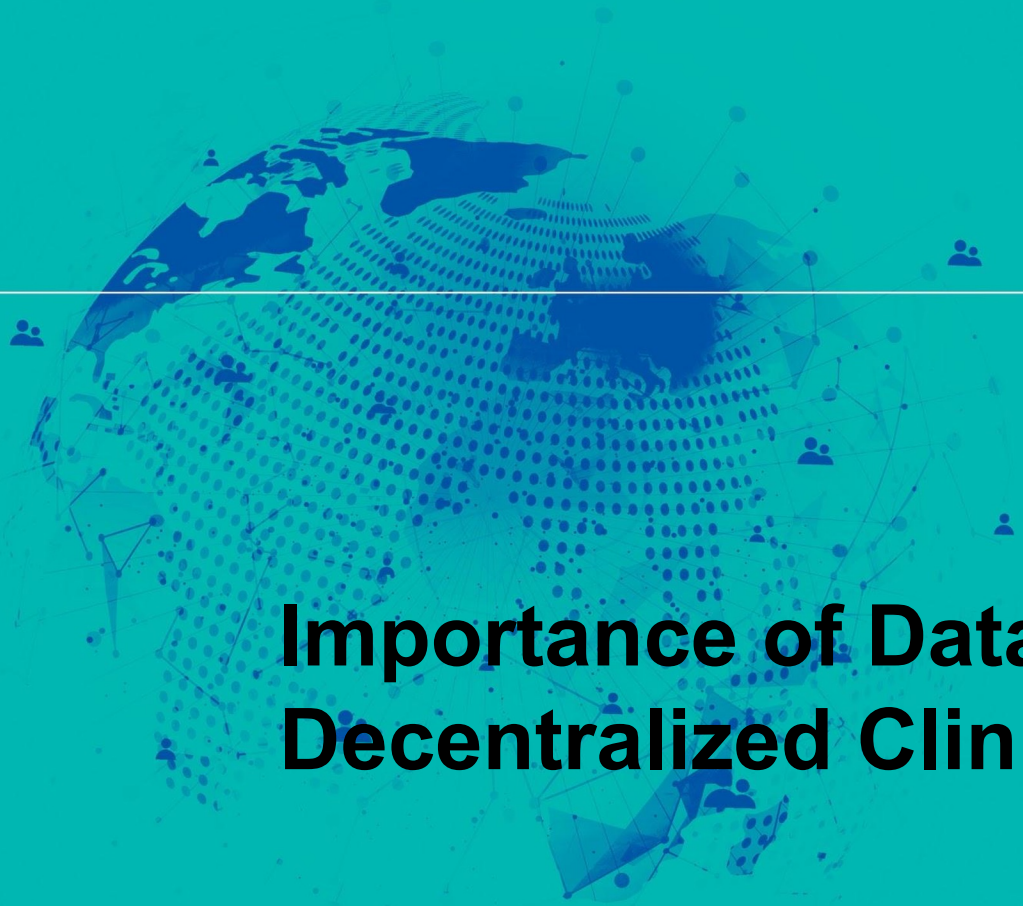


phuse·virtual

Single Day Event

Inder Sachdeva & Neeraj Pandey,
Cognizant Technology Solutions

Importance of Data Visualization in Decentralized Clinical Trials

phuse.global

DISCLAIMER

Content, Views and Opinions Expressed in this presentation are solely of the **Author/s** & **Presenters** and do not necessarily represent official policy or position or views of **Cognizant.**

Re-Cap

PHUSE SDE – Bangalore July 2019

- Future of Clinical Trials and Data Management

PHUSE SDE – Pune 2020

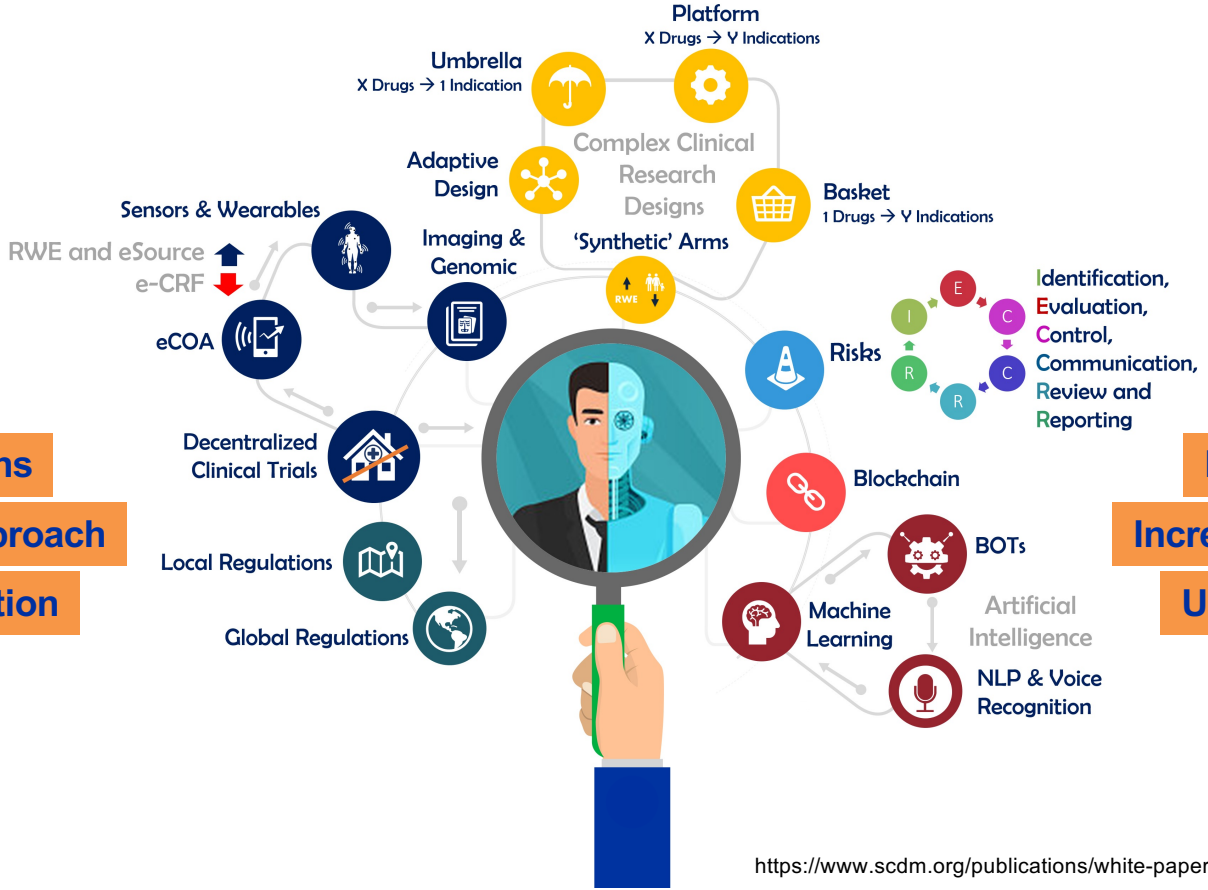
- Digital Clinical. FSP transformation to Meet the Data Sciences Dream

Evolving World of Clinical Research

Trial Designs

Risk Based Approach

Decentralization



Newer Devices

Increasing Regulations

Use of AI/ML/NLP

https://www.scdm.org/publications/white-papers/

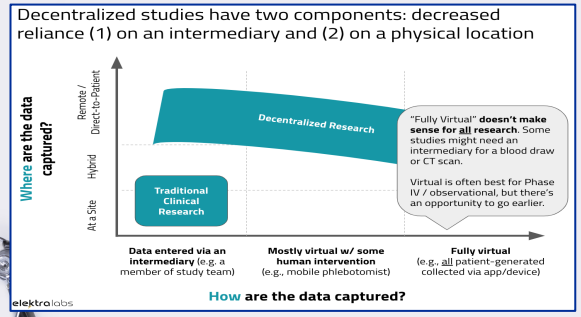
Decentralized Clinical trials (DCT)

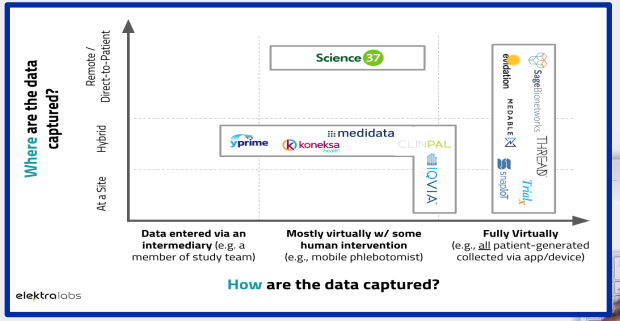
- From past few years, Pharma industry is really looking for Innovative way to collect data and conduct trails to reduce cost and benefitting more patients

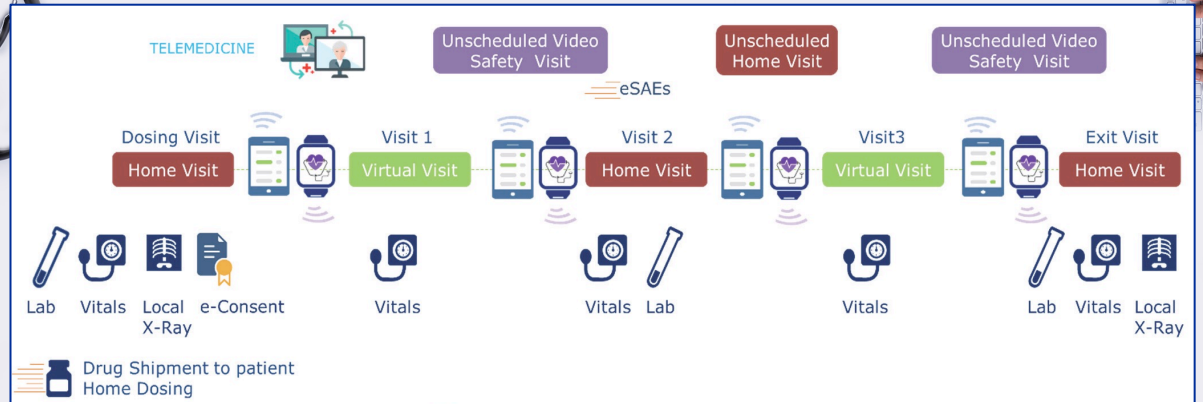
  Decentralizing the data collection has helped wider possibilities to fast track the overall outcome of clinical trial with lesser resources.

  COVID Pandemic in way gave push to all *parties (Sponsors, Patients, Investigators, Labs, Regulators)* to better accept the benefits of Decentralization. This helped find innovative ways to continue on hold trials as well planning to full DCT Trials.

Decentralized Trials







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https://blog.andreacoravos.com/decentralized-clinical-trials-e9dbde90ea95

Decentralized Clinical trials (DCT)

- Technology Enablements:
  - Drug logistics management
  - Remote/Virtual Consenting
  - Decentralized Labs for coherent data collection
  - Wearables for real time data collection
  - Medical Health apps for Patient Connect sessions.

Key differences

Conventional Trials	DCT Trials
Via observation / measurement	Via connected devices and/or patient engagement tools
Patients and study personnel together	Patients alone physically (generally), sometimes visited at their home, but potentially with support through technology
Research Purpose or Research -specific data only	Research-specific and/or personal health-related data for Patient Care Too
Pre-specified intervals per protocol	Pre-specified intervals, on demand, and/or continuously

Reference: The Evolution of Clinical Data Management to Clinical Data Science (Part 2) Society for Clinical Data Management Reflection Paper

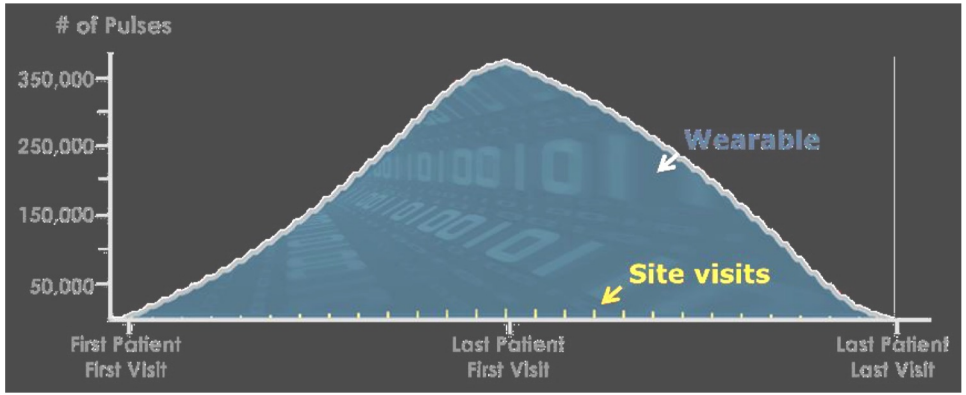
Study Level differences…

Header	Conventional Approach	DCT Approach
Subject identification	As per site practice	Subjects pool from patient registry, social media, legacy info, healthcare pro.
Informed consent	On site traditional approach	eConsent done remotely
ECG/VS/PE	At visit schedule as per protocol	Data transmitted through wearable device/ remotely
Labs	At visit schedule as per protocol	Data transmitted remotely, or through wearable device or mobile labs
COMMED / AE	At visits	Remote/diaries
Medication	Dispensed and instructions at site	Courier , Telemedicine & 24/7 helpline
QoL questionnaires	At visits, data collected by staff by conducting patient interview	Remote
Diary card	Paper based	eDiaries
Monitoring	SDV done at sites	Remote monitoring

What is changing..

Reference: The Evolution of Clinical Data Management to Clinical Data Science (Part 2) Society for Clinical Data Management Reflection Paper

Quantum of Data Collected..



Volume

Conventional: 20's to 70's of datapoints for 2-5 patient per week (i.e., few datapoints per CRF)

Decentralized: 100's to 500's of datapoints for 20-50 patient per week (i.e., few datapoints per CRF)

Figure above shows the expected volume of actigraphy data generated by wearables (in blue) compared to data generated from site visits (in orange).

The protocol requires 260 patients to be treated for 6 months. The enrollment period is estimated to last 6 months. With wearable device set to transmit data every minute, wearables would generate a pulse reading more than 68 million times. In comparison, pulse would only be generated 3,380 times through site visits, assuming patient's visits every 2 weeks.

Reference: The Evolution of Clinical Data Management to Clinical Data Science (Part 2) Society for Clinical Data Management Reflection Paper

Variety, Frequency, Speed, Type..

Head	Conventional Trials	DCT/eSource Trials
Variety	EDC centric including local labs and PK External data mostly limited to IxRS, central labs and eCOA	Scope expanded to regular, imaging, video, sensors and wearables (i.e., sequenced data), structured and unstructured data
Velocity	Days, weeks and months Data entered in eCRF days after patient's visits	Real time data RESTful APIs providing interoperability between computer systems
Veracity	Manual/scientific Reviews Mainly confirmed through SDV and queries (100% error free)	AI-driven automation of issue detection and resolution Real time Data visualizations tool for 100% error free
Value	Focused on regulatory submissions	Focused on regulatory submissions Continuous data insights on patients (e.g., safety, behavior, etc.)

Newer Challenges

- How can we monitor the data?
- Will data collected remotely be as good as data collected on-site?
- How can we manage patient follow-up without in-person visits?
- How can we ensure data quality and accuracy (e.g diary data)
- How accurately will monitor intercurrent event ?
- How to tackle Technology challenges delays or data uploaded with incorrect time stamp ?
- How to manage Possible Human error ?
- How and when data cleaning activities will be performed ?

Key Solutions..

Real time monitoring with Technology support – Medical health devices

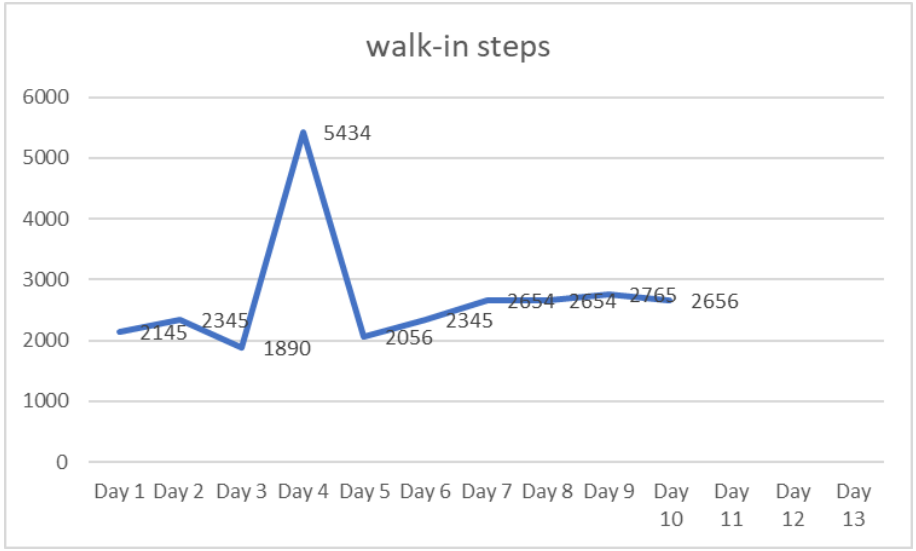
Data Visualizations – to check quality of data, real time monitoring using AI

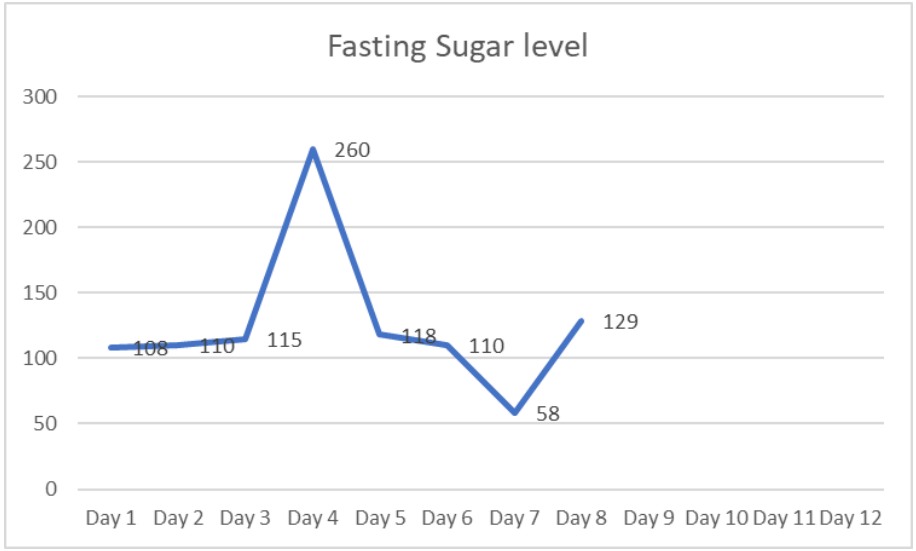
Real time Data Visualization

Real time data visualization can help to quickly look on and possible data issues

- Missing data
- unusual distributions/pattern of data
- Outliers / extreme values

Real time data visualization

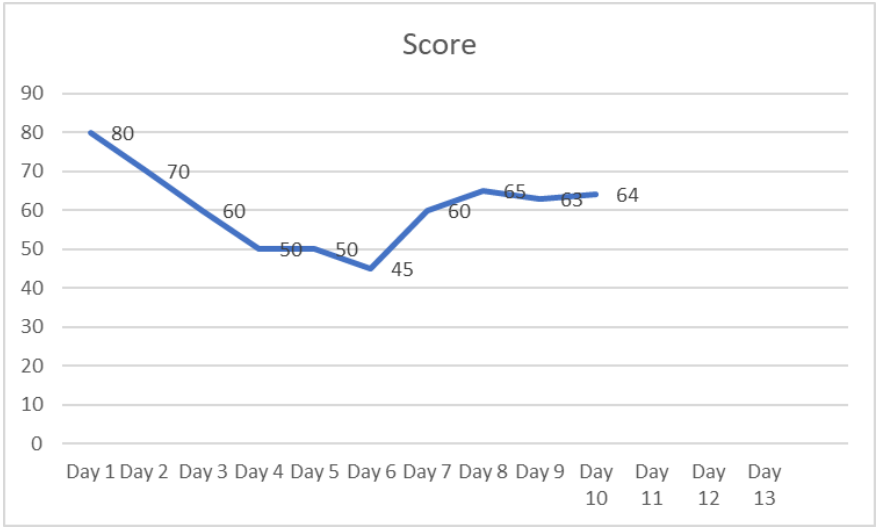


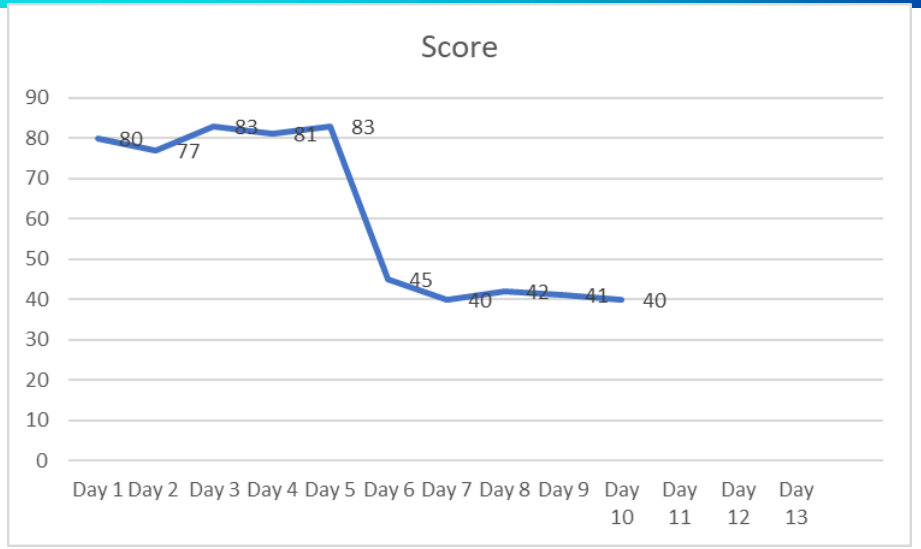


Day 3: how many hours a day do you wear your device
Day 4: how can sudden spike came in data

Day 4: is patient missed dose or consumed high calories food
Day 7: Needed a repeat test or something wrong with device

Real time data visualization

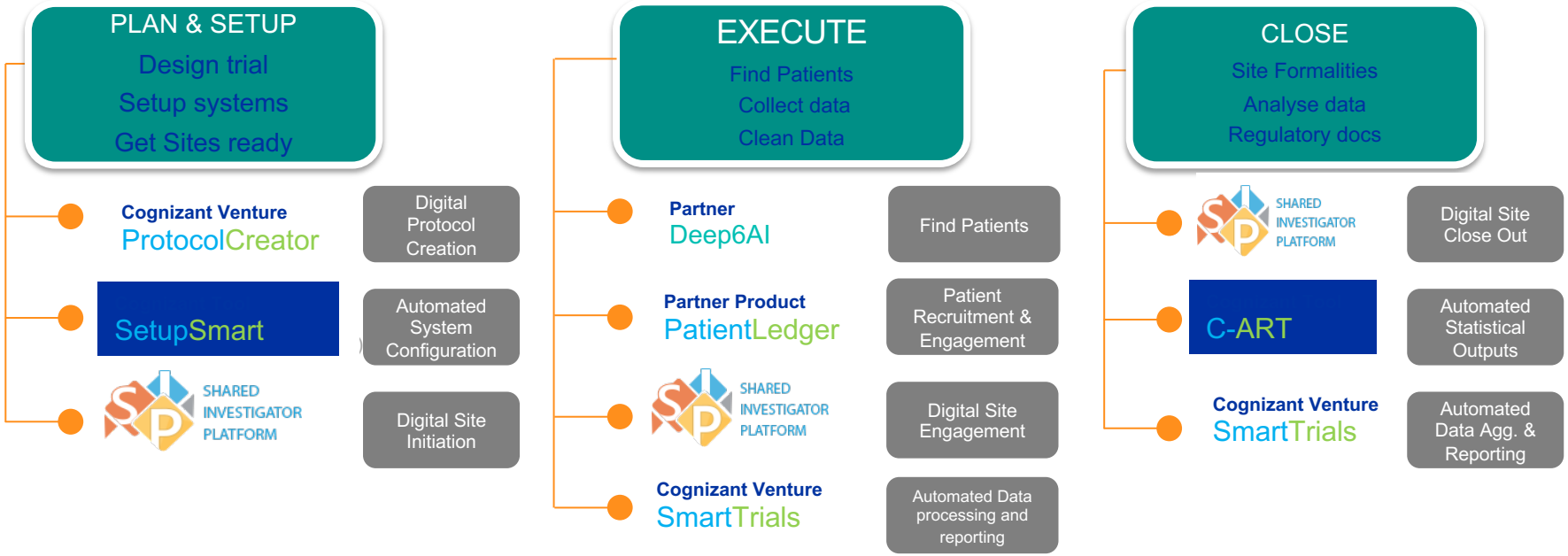




Day 7: change NOTED in pattern or trend

Day 6: is patient taken any rescue medication – need confirmation and decide to continue or terminate from study

Cognizant investment in accelerating Clinical Trials



SIGNIFICANTLY IMPROVED USER EXPERIENCE & LOWERED COSTS

Thank you

The Global Healthcare Data Science Community

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