Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

Trial without a brick-and-mortar site…..

Decentralized Clinical Trials:

- Also known as hybrid, virtual, remote or Direct to Patients (DtP) trials, where part of or all of the trial happens outside a traditional physical clinic or trial site

Never done or known before:

- Though the term Decentralized Trials was more used during this pandemic that hit us in 2020, it was first time initiated in 2011, when entirely web-based trial, REMOTE, under an Investigational New Drug application, was carried out by Pfizer
- COVID-19 pandemic significantly catalyzed the adoption of decentralized clinical trials due to physical distancing and health-system resources packed in COVID-19-related care

Why 'YES' to DCT ??? What are the Pros…..

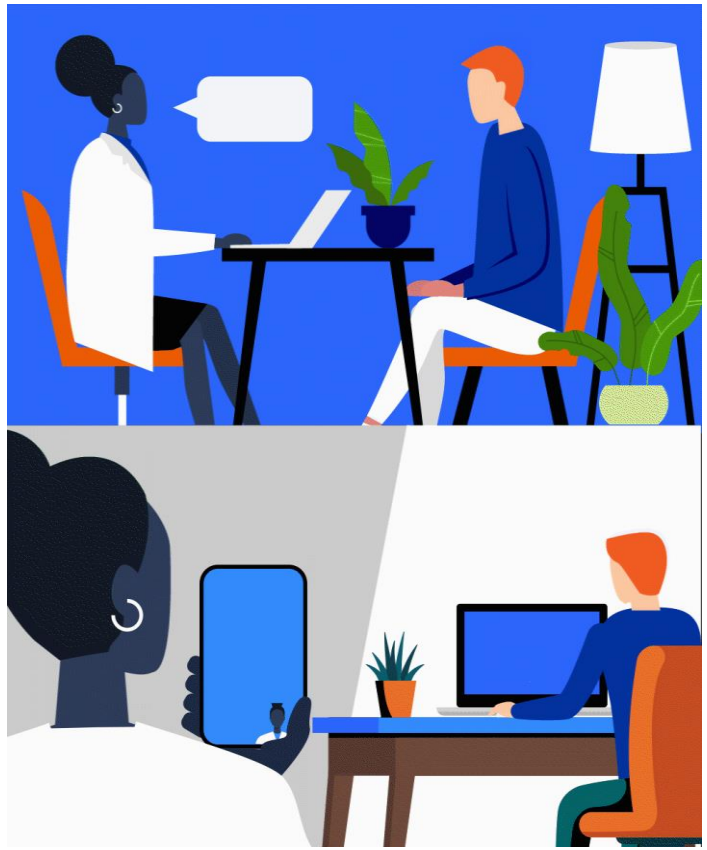
- **Controlling Clinical Study attrition**
  - Helping in Patient recruitment and retention
  - Use of digital technology for recruitment help participants to identify trials for which they are eligible and researchers or healthcare professionals to identify potentially suitable participants for their trial
  - **Examples of Digital Technologies used:** automated SMS; audio and video messages; radio and television advertising; online advertising; social media, smartphone apps, pop-up computer screen reminders and emails
- **More Flexibility:**
  - Provides patient-centered approach by allowing used of virtual tools such as telemedicine and wearable devices to carry out remote visits and monitor data
  - Regulatory committees have created guidance/instructions to follow the use of alternative clinical-trial approaches (such as remote monitoring, drug shipments to patient homes, home nursing, and alternative sites)
- **Management of therapy:**
  - Direct-to-patient shipment of the therapy (drug or medical device)
  - Time required for distribution, inventories and storage-related logistics for study supplies
  - Will always be compliant to with Good Clinical Practice (GCP)
- **Improved data diversity:**
  - Decrease geographic barriers
  - Diverse populations can be included, thus enhancing integrity of study
  - Gathering more diverse and applicable data by monitoring patients remotely in real-time

Why 'YES' to DCT ??? What are the Pros.....

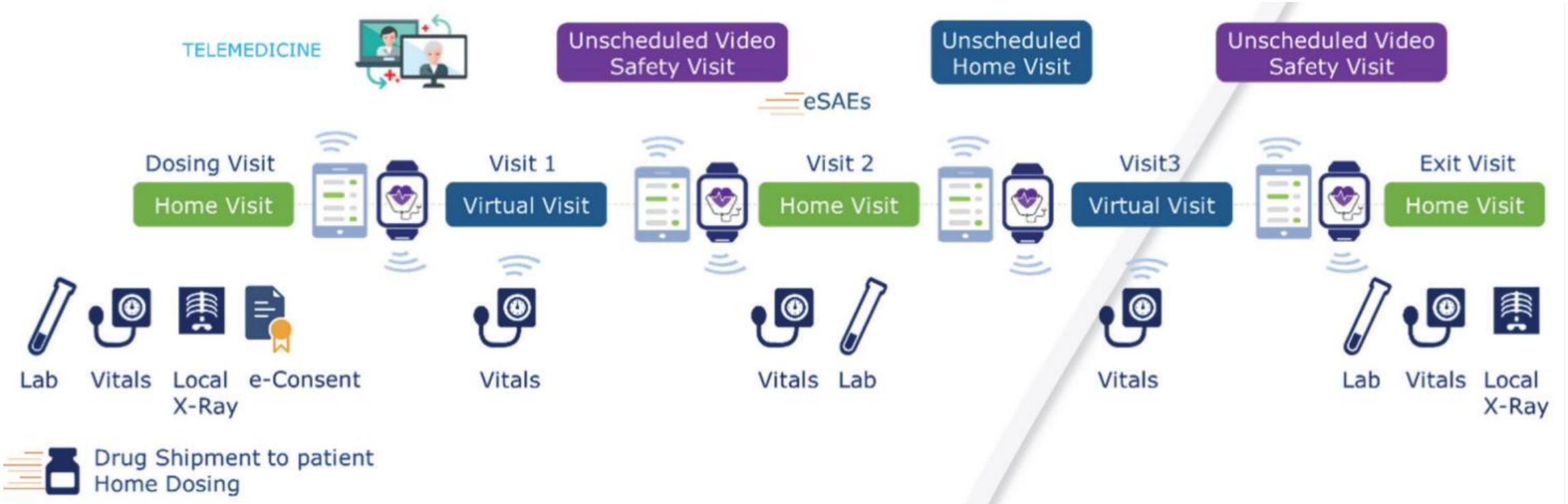
- **Real-time communication with patients**
  - Improves relationship between the patient and the researcher/clinician
  - Using ePRO, telemedicine, eReminders, made Patients life burden free (travel, getting appointments, Physicians availability etc.)

- **Improved reliability and accuracy of data:**
  - Collecting data using technology keeps data organized and safe
  - Tools are validated and used as standard
  - Digital end points can be primary end points

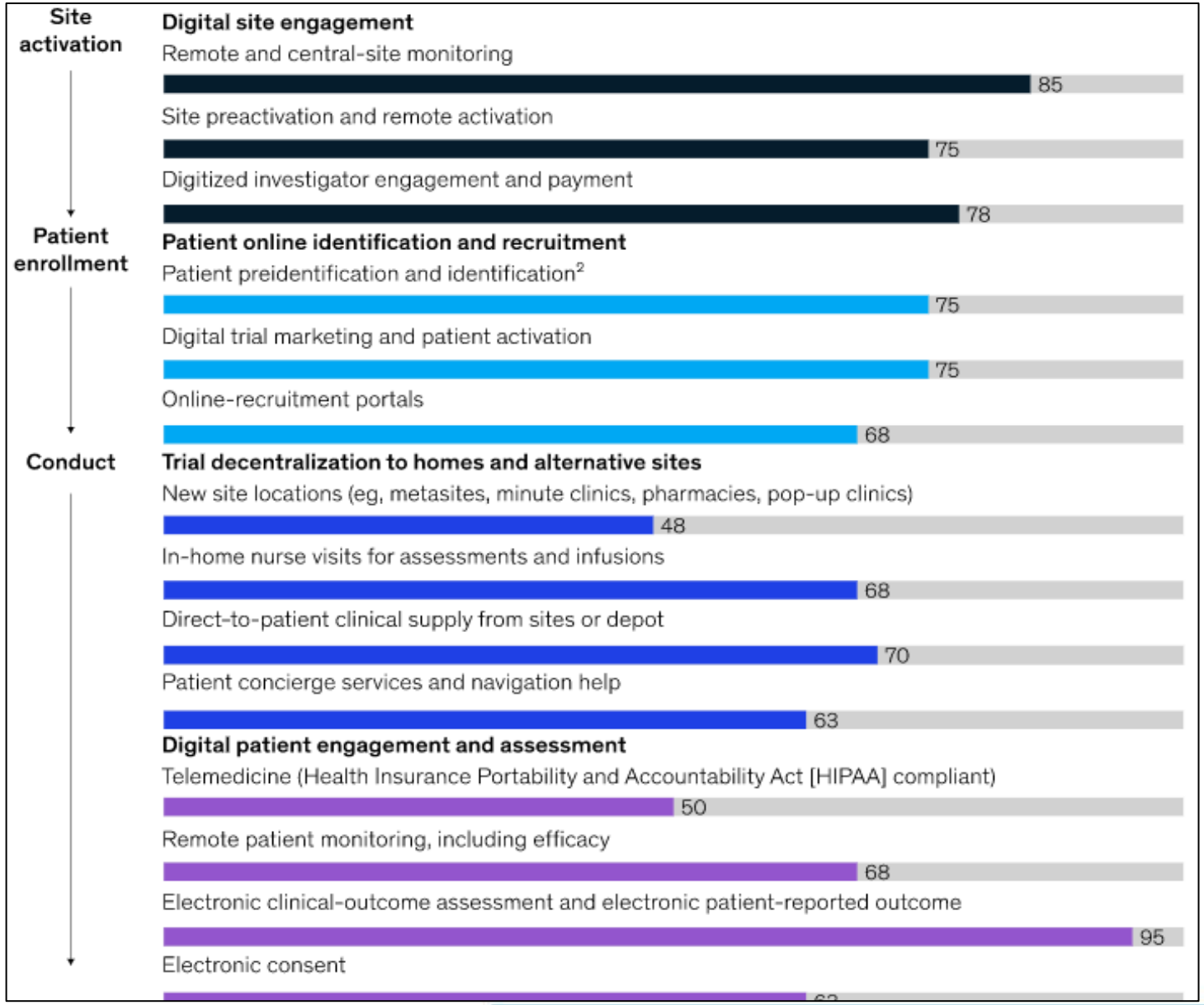
- **Easier reporting and analysis of results:**
  - Validated tools enable data collection and sharing to be standardized
  - Real time data would make Rapid identification and reporting of adverse events
  - Enabling a speedy medical intervention in case of need.



Graphic Representation of Decentralized Clinical Trial



Activities in Clinical Trial that can be handled Remotely



Why 'No' to DCT ??? What are the Cons…..

- **Complex digital technologies**
  - Limits the possibilities of enrolment and retention
- **Digital health data collection**
  - Critical issues in data collected as data are collected in a less protected environment
- **Personal data protection and cyber security**
  - Problems related to any accidental leaks of sensitive data or cyber attacks
- **Managing and processing higher volume of patient data**
  - Issues in collecting and processing data received from digital tools
- **Relationship between the patient and the doctor/ research team**
  - Cannot provide a full and systematic substitute for the doctor/ patient relationship and for direct clinical assessment
  - Can prove relatively ineffective in terms of patient involvement or incorrect use of Instruments
- **Continuity of patient care**
  - Inconsistency of visiting HCPs could potentially be distressing
- **Management of therapy**
  - Logistic problems (e.g., failure to deliver, or delay in doing so)
  - Not all medications can be delivered in direct-to-patient mode
  - Some of study procedures require doctor's intervention.

Why 'No' to DCT ??? What are the Cons…..

- **Time management**
  - Visiting multiple patients in one day
  - Travelling between locations efficiently and on time while maintaining the high standard of care they would deliver on-site
- **Data analysis:**
  - Complex procedure of standardization of results received from local clinical laboratories and diagnostic facilities
- **Technological failure**
  - Error Bugs would result n a loss of patient data, as there will be no expert on hand to provide immediate guidance or fixes
  - Disrupt or delay the trial progression by corrupting results
  - Technologies fail to provide adequate health services or recent updates as per regulatory requirements.
  - Inadequate telecommunications infrastructure. Clinicians/researchers become the help desk for resolving technical/ logistic difficulties (expected supplies not reaching the patient's home or being delivered late, technical problems with sensors or wearables, etc.)
- **Logistics:**
  - Non-availability of suitable, certified laboratories and healthcare services
  - Finding specially-trained couriers to deliver medication and other medical supplies and equipment safely and legally
- **Finding new technology vendors**
  - Difficult to find and approve vendors in a timely way to avoid delay in trials
- **Patient attitude**
  - Some patients may be more comfortable being seen in person, especially where they are unsure about administering tests or using technology.

Possible Solutions to Overcome Challenges

- **Tool/Device validation**
  - Tool/Device should be robust and validated to 100% accuracy
  - Data accuracy checks should be Implemented at the time of collection of data.
  - The programming of gate keeper checks would also be very helpful in maintaining the data accuracy and limiting the errors to happen during collection of useful data via various devices.

- **Tool/Device usability:**
  - Need to create device/tool as simple as possible for the subjects to understand and use it and able to enter the data.
  - Sponsors/CROs should train subjects/trial personnel
  - Manuals should be created for subject's reference
  - Should have support always ready and contingency plan in place for cases of device/tool malfunction.
- **Tool/Device Privacy:**
  - Implement biometrics to operate tool/device by the subject so no one else can access the device/tool or data.
  - Data should be collected and transferred to a centralized platform having capability to distinguish unblinded data is accessible by unblinded team only and not available for blinded team.
  - There can be a threat detector implanted in device to alarm if it is being hacked
- **Tool/Device data format**
  - Ensure even if data coming from multiple source to standardize the data at a centralized platform so data is useable for analysis and submission.
  - Ensure the data collected is having same dimensions and device/tool have ability to convert the data into standard format.

Possible Solutions to Overcome Challenges

- **External Data:**
  - Ability to integrate/import external data received in any format (sas, excel, txt, etc.)
  - Ability to convert multiple external vendor datasets into a standard dataset.
  - Ability to join external datasets using unique identified such as Subject, Site, Visit, DEMOG data etc.
- **EDC integration with external tool:**
  - Ability to convert multiple studies datasets into standard dataset using simple function or with minimal programming support to run standard DM manual listings on standard datasets.
  - Ability to integrate EDC with external tool to track all study data (Clinical Data) as well as operational data (Study Metrics).
  - Ability to integrate EDC with the external tool to facilitate raising query within the tool to reflect in EDC.
- **Data Review:**
  - Notification or pop-up for real time data review as soon as date is entered
  - Dataset /EDC integration to review and raise the queries within the tool to avoid opening EDC.
  - Ability to give output category per Country, Site, Subject, Visit, Subject Status, Data Compliance, Data Completeness etc.
  - Ability to combine 2 or more than 2 datasets using simple drag-drop function.
  - Tool should have the pre-defined checks in place and should be deployed in less time for team to start their work.
  - Tool support excel, word, graph and other analytics / data visualization.
- **Running Study Metrics:**
  - Ability to perform query/CRF trend analysis within tool.
  - Integration with EDC to help generate standard study metrics reports to have a consistent structure of reports.
  - Ability to generate study reports on ad-hoc basis.
  - Ability to integrate with EDC and import external data to populate CPT within the tool.

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Collaboration: Working Together For a Better Future

"Alone we can do so little; together we can do so much"

Collaboration: In common terms is the action of working with someone to produce or create something.

Healthcare Professionals from different platforms / roles, stakeholders from different industries cooperatively working together, sharing responsibility for problem-solving and making decisions to formulate and carry out plans for patient care

Importance of Collaboration:

- helps to prevent medication errors
- Improve the patient experience
- Reduce time for Drug Development
- Deliver better patient outcomes
- Can reduce healthcare costs

Collaboration: Is Working Together helping Mitigate Challenges ?

- **Sanofi and Insilico Medicine**
  - Sanofi using Insilico's 'Pharma.AI' platform to advance drug development process

- **Google Cloud and Epic**
  - Enabling customers to run their Epic workloads on Google Cloud
  - Gains in Efficiency, Innovation, and Security.

- **Google Cloud with Hackensack Meridian Health, LifePoint Health, and Mayo Clinic and Others**
  - Develop "accelerators", will help healthcare leaders and administrators find the data they need much more easily
  - Google technology is also providing clinicians with more precise image technology to help determine if patients are at higher risk for tumor

- **Oracle's acquisition with Cerner**
  - Oracle utilizing electronic health records and improves everything from claims processing to managing the supply chain

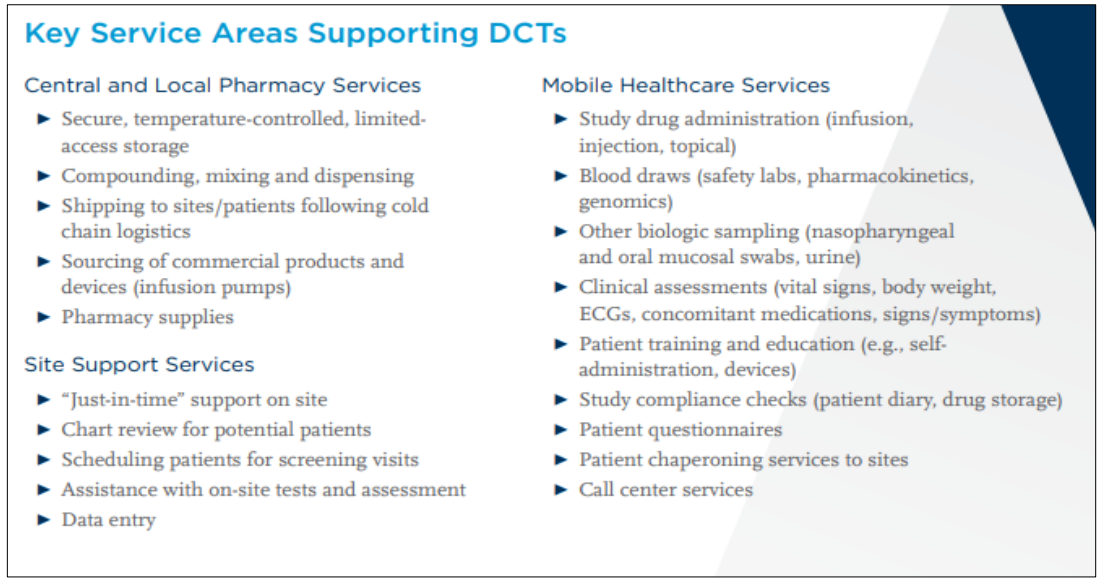
- **PPD collaborated with Medable and Science 37**
  - Direct-to-patient and direct-from-patient models
  - Incorporating home health care nursing,
  - Study drug administration,
  - Sample collection
  - Pickup and return of study materials
  - Digital solutions such as eConsent, telemedicine, devices/wearables, eCOA, ePRO

Collaboration: Is Working Together helping Mitigate Challenges ?

- **Datavant with Medable**
  - Datavant to integrate its tech into Medable's decentralized trials platform, which will see trial teams combine real-world health records, claims, diagnostic and other sources with their clinical trial data.

- **Covance + Medable:**
  - Covance, Patient and Site Interface with Medable's modular software platform
  - Provide access to applications encourage patients in study participation – eConsent, ePRO, eCOA
  - Enable remote data collection
  - Increase engagement between Patients, sites and Investigators

- **Covance acquires GlobalCare**



Collaboration: Is Working Together helping Mitigate Challenges ?

- **Signant Health acquisition of VirTrial**
  - VirTrial's tele-research platform, which includes secure video, audio, chat, and connected medical device capabilities for decentralized patient-site interaction and assessments
  - Signant with a solution to address remote site startup and monitoring
  - Remotely conduct site evaluation, initiation, and monitoring visits

- **ERT and Bioclinica become Clario**
  - Trial Anywhere™ offers sites and sponsors more clinical trial options, empowers patient choice, and provides the means to create diversity within clinical trials improving health equity

- **Syneos Health and Illingworth Research Group**
  - Illingworth Research Group, a leading provider of clinical research home health services

- **ICON and PRA**
  - World’s most advanced healthcare intelligence and clinical research organization

- **Collaboration for fighting against cyberattacks**
  - Hospitals have suffered hundreds of cyberattacks in 2022. Two out of three healthcare IT professionals (67%) said their organizations had a significant cybersecurity incident in the past 12 months. As per Cybersecurity analysts' healthcare industry lags in terms of strengthening their defenses.
  - Clearwater and CynergisTek, who are cybersecurity firm join with healthcare industry and other highly regulated industries

Collaboration Is Redefining The Future Of Healthcare… especially for Decentralized Clinical Trials