



Single Day Event

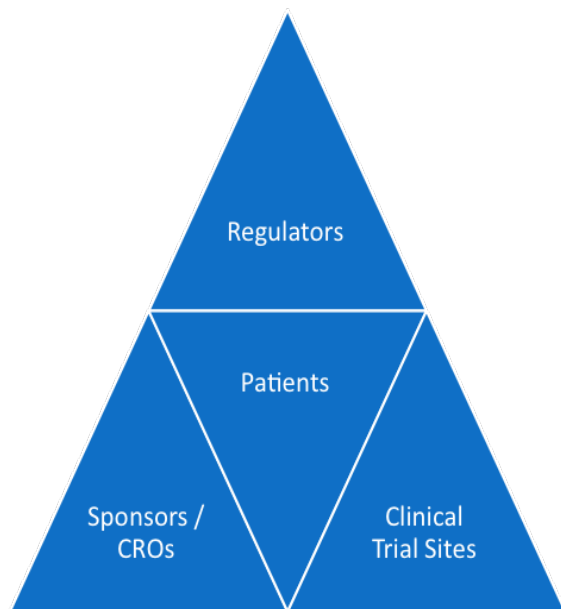
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Premier Research

Innovative Technologies & Patient Centricity

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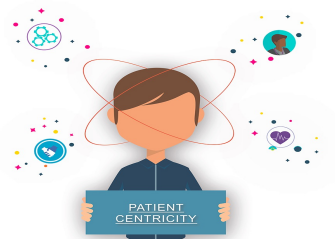
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Basis of Clinical Trials...



- Patient – Core of Clinical Trials
- Putting the Patient first
- One way Street or two-way street?
 - Everything what patient do is to support us
– Are we doing everything to support patients?
 - Collecting data Vs. Continuous information to their disease condition

Patient Centricity



What is Patient Centricity?

- The process of designing a service or solution around the patient
- Putting the Patient first – to achieve best experience and outcome
- Study Design: Measuring what matters?
- Minimal inconvenience to patients
- Enhance Patient Communication & Engagement
- Empower patients through technology
- Involvement of family and friends
- Explore Virtual Clinical Trials: Right technologies to achieve Patient Centricity & to enhance patient participation
- End trial with positive patient experience: Ensure patient feel valued

Patient Centricity - Definition evolution

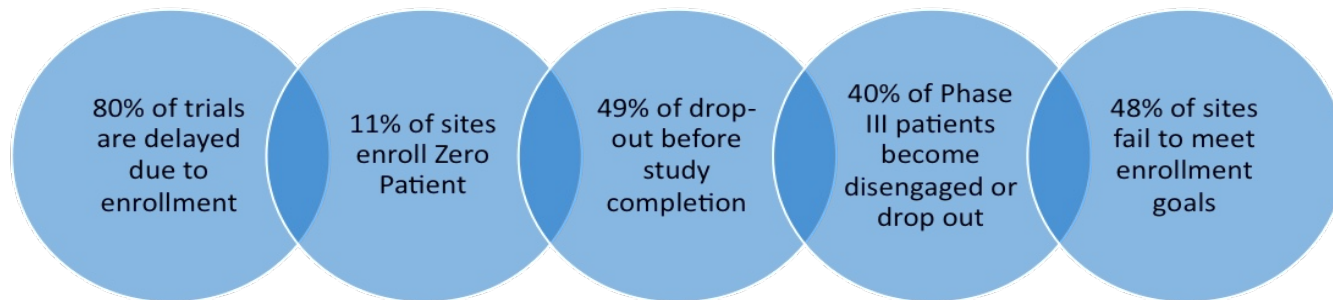
Europe	North America
<u>Every person is included</u> ¹ for the <u>benefit of the individual patient</u> ²	<u>Educate patients and caregivers</u> ³ in a <u>culturally-sensitive way</u> ⁴ to access the health and care system. Implement a standard of excellence for <u>all stakeholders</u> ¹ in the health and care system which provides <u>respectful, accountable and transparent</u> ⁴ care that meets <u>individual's rights and needs</u> ²
Where <u>empathetic, responsible, sustained</u> ⁴ and innovative <u>partnership</u> ⁵ leads to where <u>everyone matters</u> ¹ for the ongoing <u>benefit of the patient</u> ²	<u>Open</u> ⁴ and continued <u>engagement</u> ⁵ among <u>patients, caregivers, healthcare providers, payers and the biopharmaceutical industry</u> ¹ to <u>share knowledge</u> ³ with <u>respect and compassion</u> ⁴ to offer the <u>best possible outcome for that person and their family</u> ²

In all cases, the definitions were shaped by the values that participants had originally identified as being most important to patients; ¹Inclusiveness; ²Sharing goals that are patient and family-centred; ³Empowering patients to take control of their own health; ⁴Working in a way that shows respect, compassion and openness; ⁵Working in partnership.



Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family

Industry Challenges & Patient Centricity & Technology



Patient Centricity and Technology:

- Patient Centric Clinical Trials enroll double the number of patients in half the time
- High chances of drug getting launched
- Safety of Patients not compromised
- High Quality Data
- Improved Efficiency / Productivity

Innovation across the Clinical Trial value chain:

Protocol Design & Site Selection

- Decentralised Trial Design

Patient Recruitment

- Revamp patient recruitment using AI/ML

Patient Engagement & Data Collection

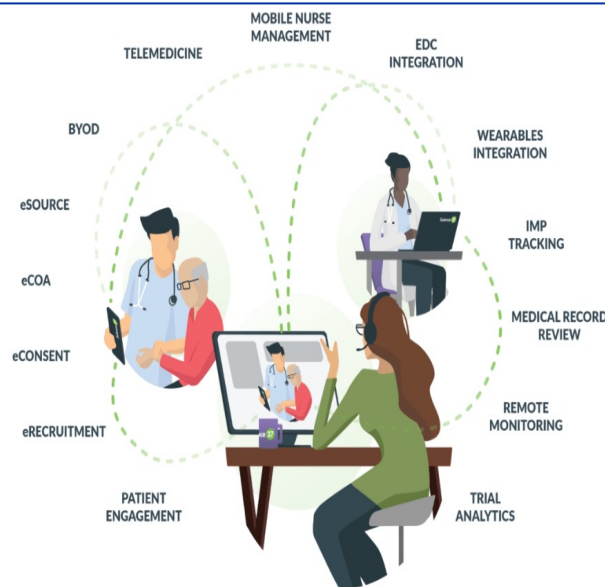
- Remote patient monitoring using DCT

Data Management, Analytics & Insights

- Usage of RWD
- Controlled automation

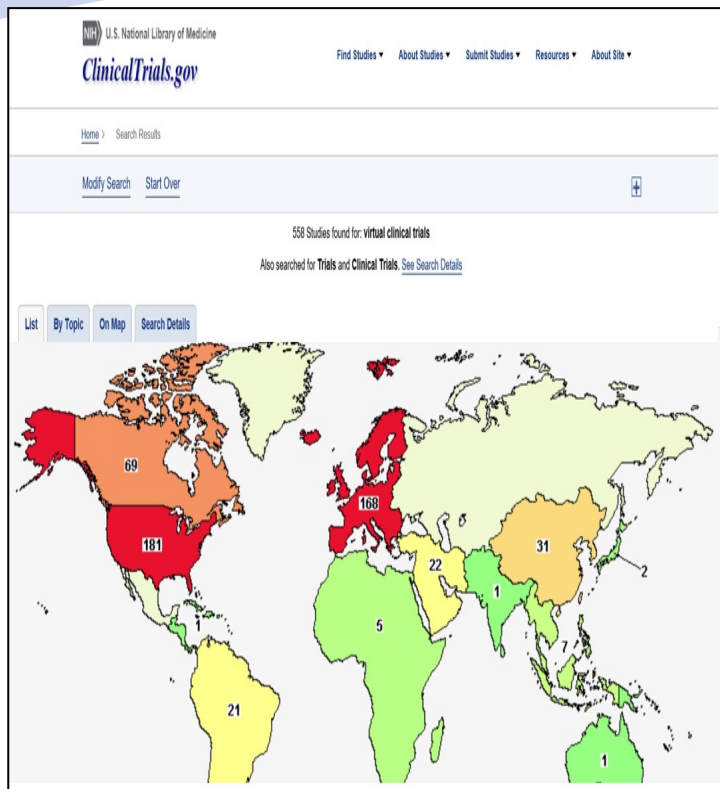
Operations and Supply Chain Logistics

- Supply Chain Optimisation



Source: Science 37

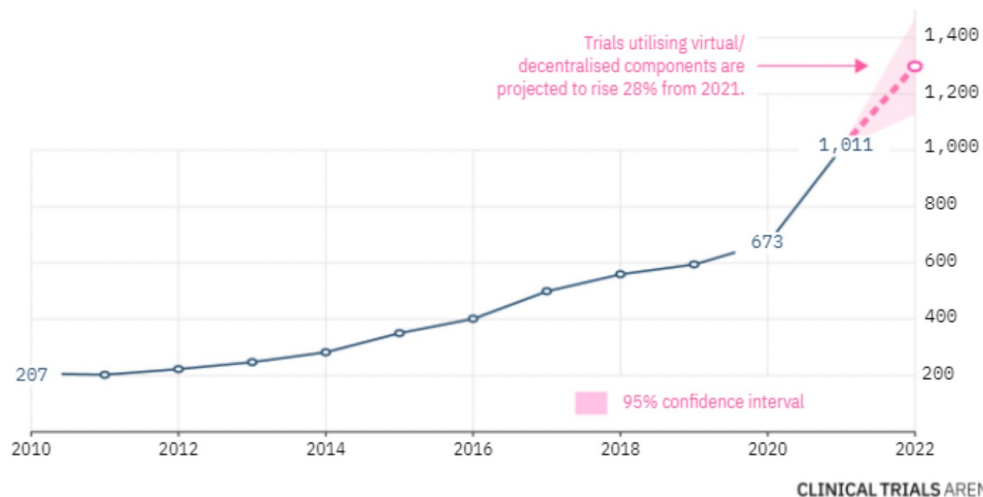
Rise of Innovative Technologies & Virtual Clinical Trials:



Decentralised Elements & Innovative Technologies

A record number of drug trials are expected to utilise decentralised elements in 2022

Initiated worldwide drug trials identified as involving virtual/decentralised components



Technologies:

- eConsent
- Web-based questionnaires
- Telemedicine
- Remote monitoring – sensor/device/tracker
- Remote monitoring – glucose
- Remote monitoring – blood pressure
- AI/ML/DL
- Block-chain
- VR Head Mounted Display

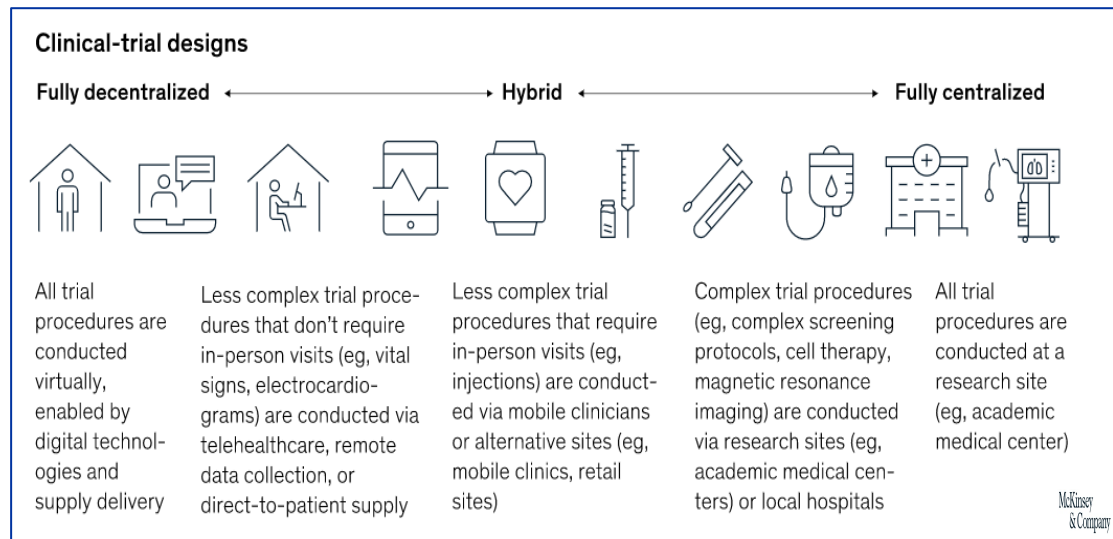
Non-Tech Component:

- Remote delivery/care – drug delivery & home nursing: Logistical & financial challenges involving hiring, training, & deploying CT professionals to conduct assessments in patients' homes

* Trial categories by start date. Includes interventional drug trials which GlobalData identified as mentioning decentralized/virtual components in clinical registry protocols. 2021 figures include trials scheduled to begin before the end of the year.

Source: GlobalData

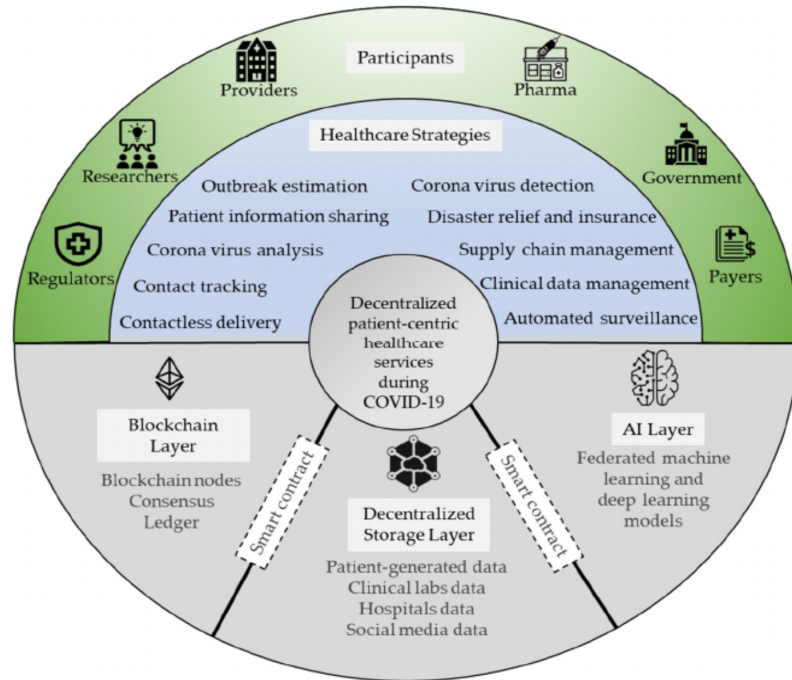
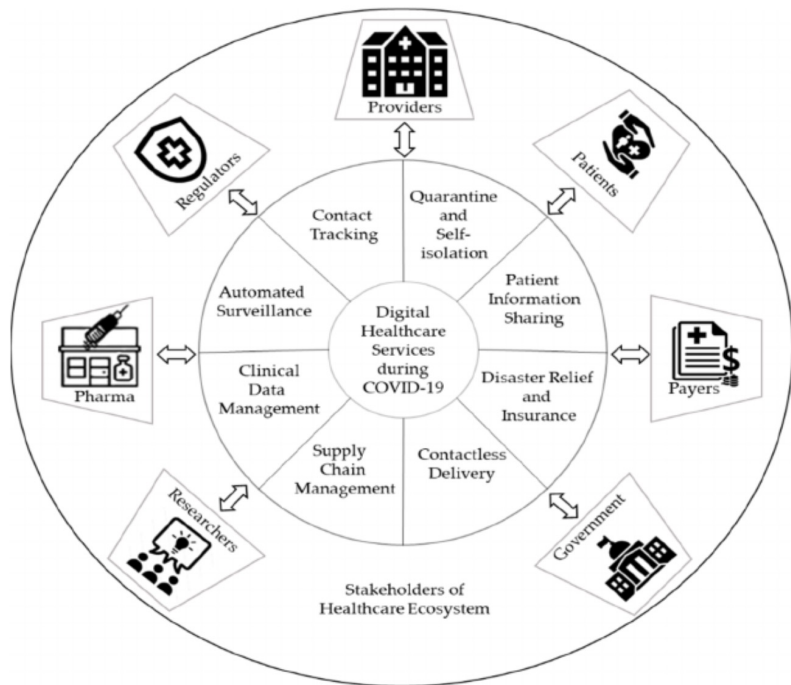
The Sliding Scale of Decentralization:



- Evaluation of Risk vs. Benefit
- Data Quality vs. Investment / ROI
- Process to identify nearby Medical Facility with right infrastructure to provide medical care
- Patient under reporting AE / SAE: Strong Tele-medicine process & access to virtual study coordinators
- Data interoperability
- IP Distribution, Storage, compliance and Regulation
- Patient Literacy and Infrastructure

Decentralised Clinical Trials meet patients where they are: Right balance of Technology & Patient Centricity
Ensuring support to patients throughout the journey

COVID19 Case Study: AI/DL, Block-Chain & Patient Centricity



A Blockchain and Artificial Intelligence-Based, Patient-Centric Healthcare System for Combating the COVID-19 Pandemic: Opportunities and Applications

August 2021 | Healthcare 1019
DOI:10.3390/healthcare10081019
License: CC BY 4.0

A case of Consent:

- ICF size for lung cancer study 15-34 pages (average 21 pages)
- Reading level 10th grade but average American reads at an 8th grade level
- Research was conducted on 2 focus groups:
 - participants who have enrolled in clinical trials
 - and the other group consisted of individuals with no prior trial experience
- When asked what information they would like to see included, participants said:
 - A clear explanation of eligibility criteria
 - A note that the study is optional
 - Information on what is being tested and what the patient can expect as treatment (for example, experimental therapy vs standard care)
 - Where the trial is happening so the patient knows how much travel is involved
 - A brief privacy statement
 - An explanation of the protocol that outlines how the treatment is given and how frequently
 - The duration of the study and what comes after study treatment is finished
- Conclusion: Consent forms could be improved by a patient-centric addendum highlighting key points, a study suggest

Promising Future...

Engage

Patient Centric Clinical Research

- Amplify patient centricity
- Collaborate with Patients & patient communities / advocacy groups
- Ease patient access & reduce burden
- Transform patient care without compromising on patient's safety & privacy

Innovate

Continuing technological advancement

- Improve adherence to Protocol
- Capture patient centered endpoints & Product value propositions
- Include more decentralised approach with right set of technologies
- Continue to use new insights from RWD

Execute

Compliance, Efficiencies, Quality, Time & Cost

- Ensure regulatory compliance: Engage regulators in the process
- Expedite patient enrolment, improve retention & include more diverse patient population
- Reduce manual work on repetitive tasks & Encourage automation using new age technologies: Continue to improve Data Accuracy

Thank you all



**The Global Healthcare
Data Science Community**

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