Decentralized Clinical Trials as a Patient Recruitment Solution

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Faculty Disclosure

In compliance with ACCME Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial services(s) discussed in this educational activity.

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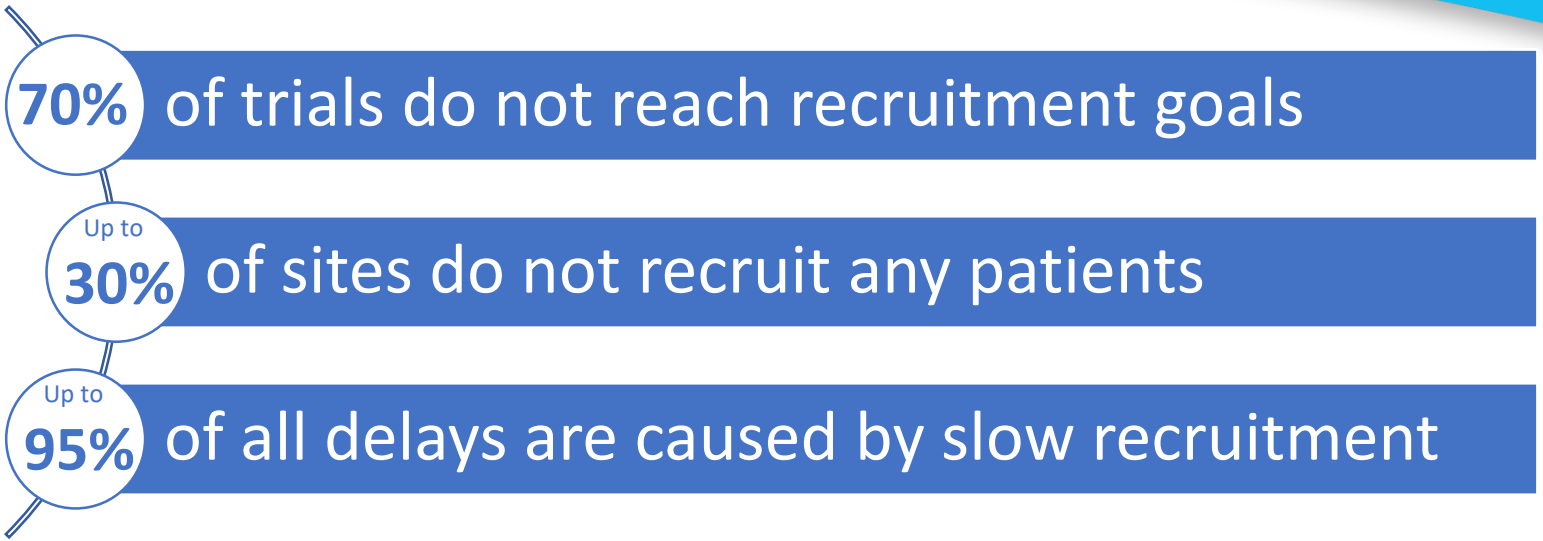
FDA – Scott Gotlieb Speech January 28, 2019

….**Pragmatic and hybrid clinical trials, including decentralized trials** that are conducted at the point of care – and that incorporate real world evidence (RWE) - **can help clinical trials become more agile and efficient** by reducing administrative burdens on sponsors and those conducting trials, and can allow patients to receive treatments from community providers without compromising the quality of the trial or the integrity of the data that's being collected.
RWE also has the potential to make America's health care system more competitive and efficient as validated outcomes measures based on real world data are incorporated into value-based payment contracts. …..

Why Clinical Trials Need Change

- **70%** of patients live more than 2 hours away from a study site
- **<5%** of eligible patients participate in clinical research
- **49%** of participants drop out before study completion
- **48%** of trial sites miss enrollment targets

Recruitment is Problem #1



Each day a drug is delayed to market, sponsors can lose **up to 8 M$**

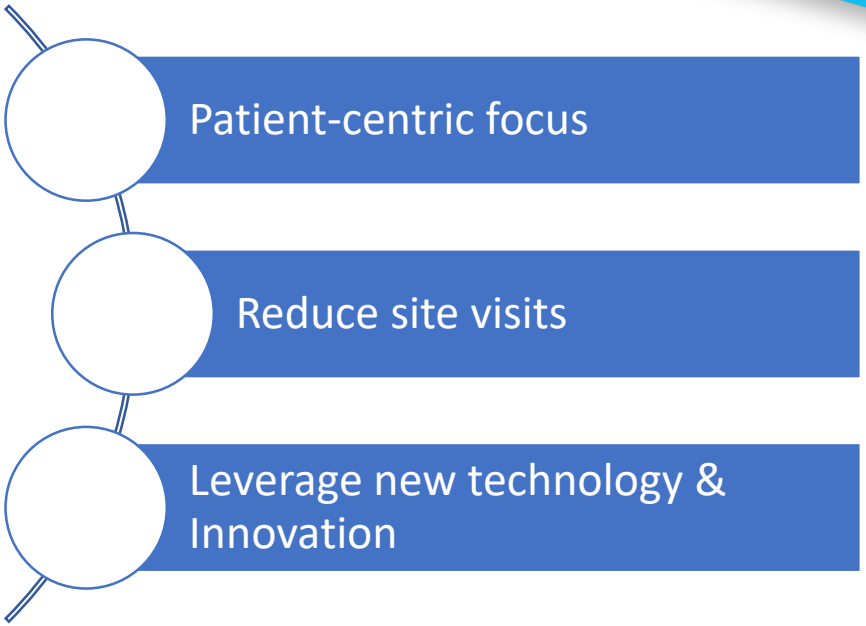
Decentralized Clinical Trials is Promising Solution

- Use new recruitment methods
  - Social media
  - Advocacy groups
  - Genetic profile companies and biobanks
  - Physicians networks
- Bring the trial to participant
  - Not tied to geographic areas or study sites
  - May involve local health care professionals
- Make optimal use of technology
  - Video conferencing for recruitment and study visits
  - Tablets and smarthones for data collection and subject management, BYOD as option
  - Direct data capture technology
  - Patient reported data

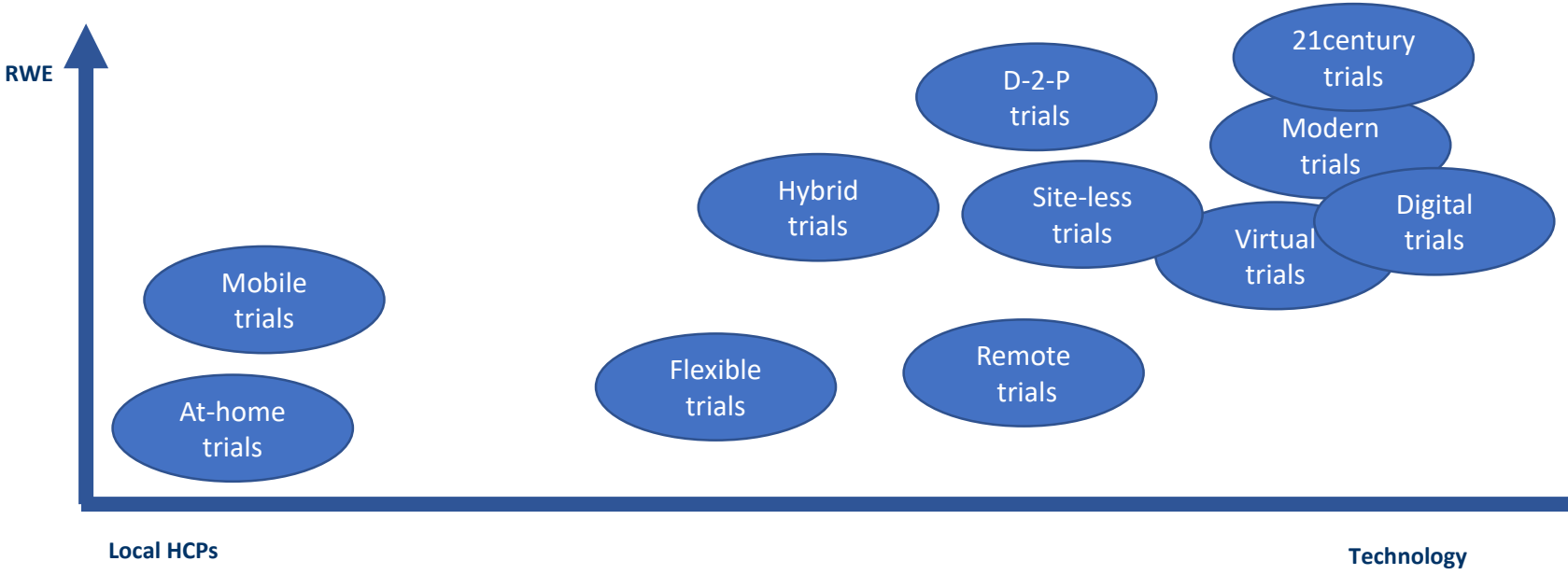
What are Decentralized Clinical Trials?

Avoca Quality Consortium (AQC) definition

- DCT deploy a wide range of digital technologies to collect safety and efficacy data from study participants, **normally** from the **comfort of the patients' own home**. The specific digital technologies used for data collection vary by study but can include telemedicine, wearable/sensor devices, eConsent, electronic clinical outcome assessments (eCOA), and electronic health (eHealth) records.



Decentralized Trials are also known as:



Evolution of Hybrid Trials

At-home clinical trial services

No technology involved

- Selected study visits performed by trained nurses
  - blood draws
  - IP Administration
  - Training support
- Seldomly incorporated in study protocol
- Optional for sites
- In CEE countries rarely used

Remote visits

Application of Technology

- Some examination procedures done remotely
- Mobile apps
- At-home data collection
- Wearable technology
- Telemedicine video chat

Hybrid Trials

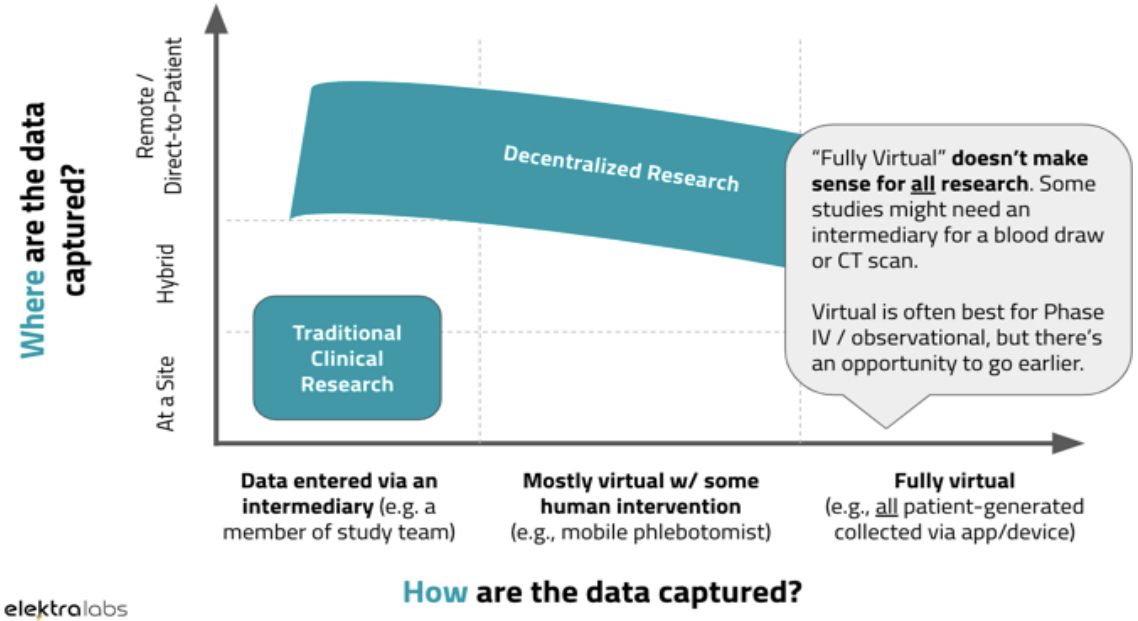
- **Local Health Care providers**
- Wide range of Standard of Care services from

- **Application of Technology**
- E-Consent
- Mobile Apps
- Telemedicine

Virtual Trails Limitations

Relevance	• Less than 1% studies can be designed as 100% virtual
Patient Satisfaction	• Technology burden on Patients • No direct contact with study Teams
Retention	• Fast enrollment • Poor retention

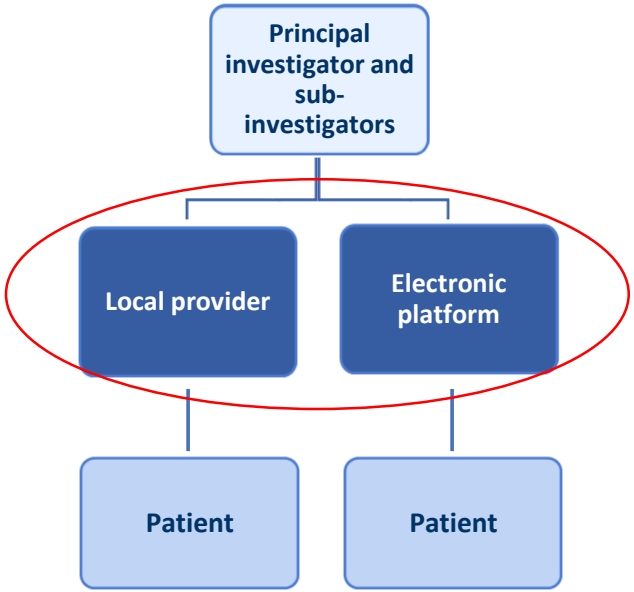
Where and how are the data captured



elektralabs

As presented by Ray Dorsey, November 28, 2018; Coravos, 2018. Published on https://blog.andreacoravos.com/decentralized-clinical-trials-e9dbde90ea95

Decentralized Clinical Trials – what is new?

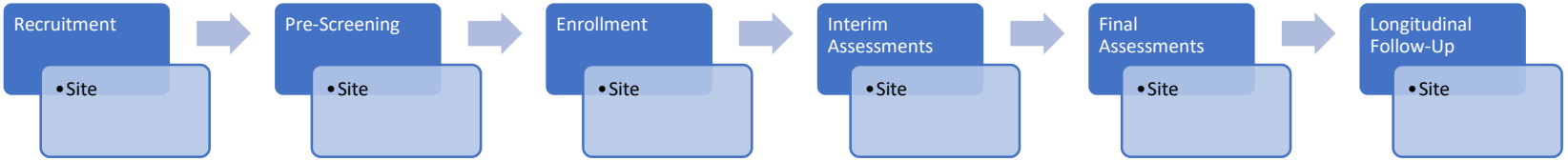


PI Sub-PI	•Substantial role •Qualified by experience and training •Requires knowledge of study to perform his function
Local Provider	•Experience and training to perform clinical function •May not require knowledge of study •phlebotomist, radiologist, pathologist, endoscopist
Electronic platform	•Communication: phone, videoconference, chat •Data capture: biosensors, ePRO tools, diaries •Security and data integrity
Patient	•Informed consent •Usable technology, tech support •Adequate communications

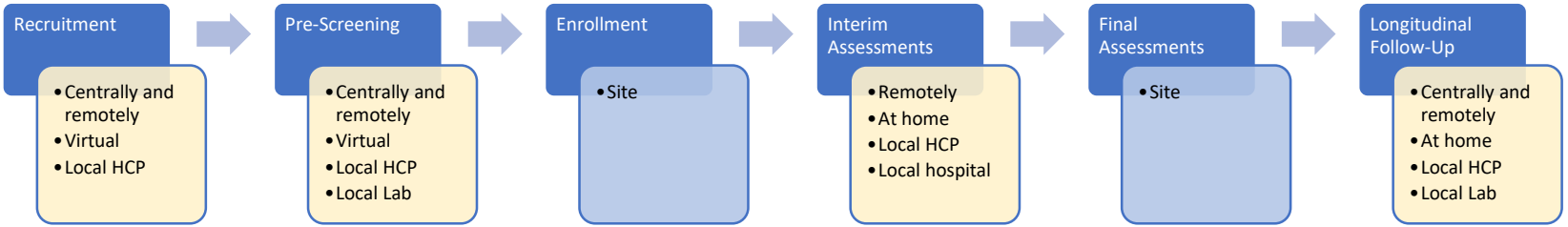
FDA *Decentralized Trials: Policy Considerations; FDA, November 2018*

Current and Future Models for Clinical Trials

Current



Future



Need to bring primary care to clinical research

Patient-centric Clinical Trials
At-home clinical trials
Decentralized Clinical Trials
Remote visits
Telemedicine

Patient Identification Centers
Database search
GP checks
Opportunistic participant identification

Satellite Investigative Site
Decentralized Clinical Trials
Sub-Investigator
Co-Investigator

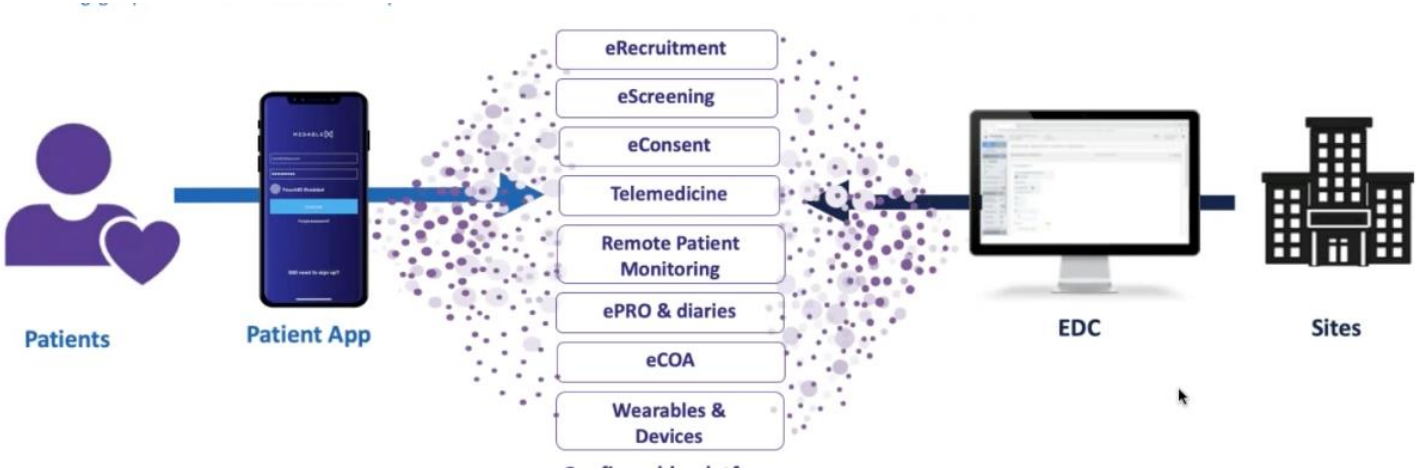
Practice-based Research Network
Conduct of clinical trials
Study facilities
Study Team
- Co-Investigator
- Sub-Investigator
- Study Nurses
- Clinical Trials Coordinators

Technologies Used in DCT

Connected devices, wearables and sensors for patients in the „real world”

Technologies Used in DCT

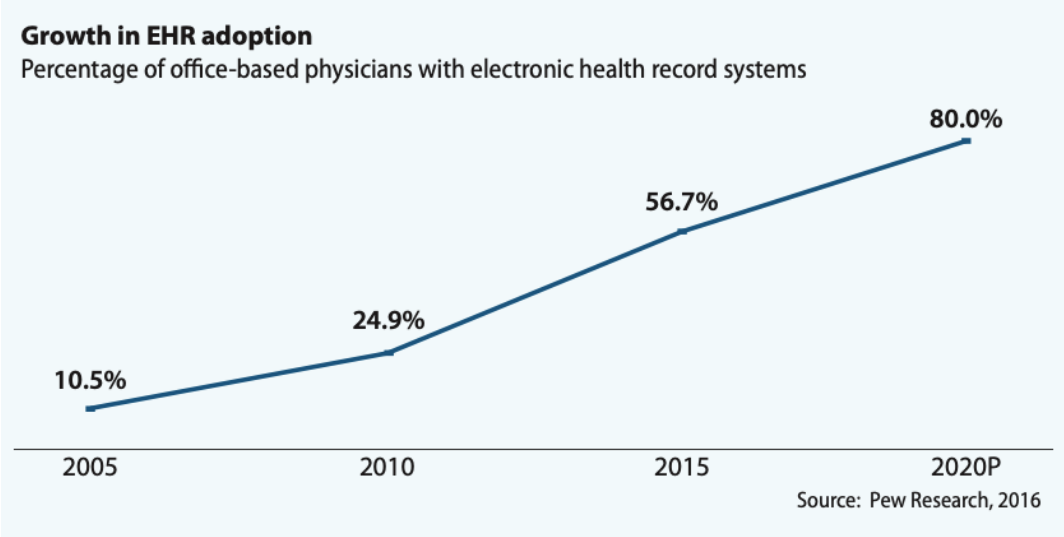
Configurable platform applications connect all patient and site data



Will Patients Use the Technology?

- Worldwide more people use a cellphone than a toothbrush
- The average person spends five hours a day on their smartphone
- More than 50% of people use smartphone immediately after waking up
- 85% check their smarthone while speaking with other people
- The average person checks their phone every 10 minutes

Will local HCPs Use the Technology?

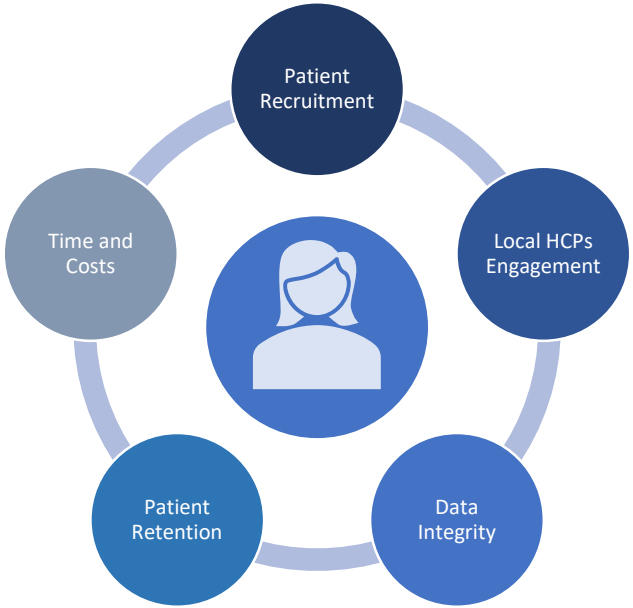


What is telemedicine

Live videoconferencing (synchronous)	• Live, interactive consultation between primary care and specialist professional • May involve primary care professional providing a consultation with a patient or specialist assisting the primary care physician in diagnosis
Store and forward (asynchronous)	• Transmission of diagnostic images, vital signs, video clips for later review • Enables primary care physician providing a consultation
Remote patient monitoring	• Uses devices to remotely collect and send data to healthcare provider or to remote testing facility • Continuous monitoring of vital signs, ECG, blood glucose etc.
Mobile health (mHealth)	• Consumer medical and health information includes the use of internet and wireless devices

IQVIA Virtual Trials

DCT – The Value Proposition



- Expanded patient reach and diversity without geographic constraints
- Enrollment through various channels (EHR, internet, social media)
- Patient convenience

- Opportunity to add research as treatment option
- Scientific and intellectual interest in new therapies and treatments
- New pool of naive sites and investigators

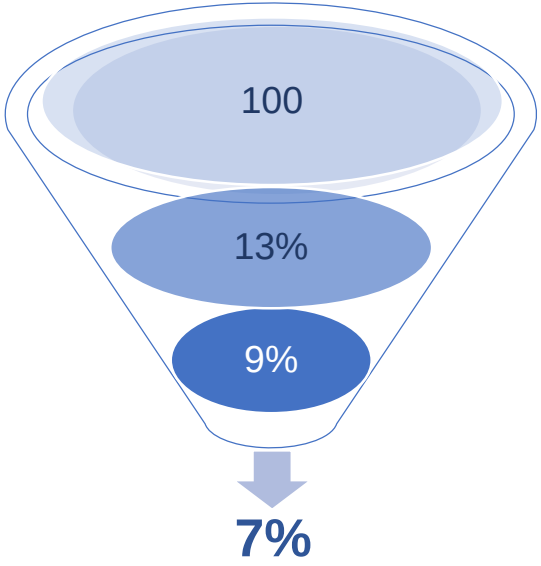
- More timely data through mHealth and wearables
- Quality data collection
- Provide sponsors with timely access to data

- Reduced burden of site visits to patients
- Increased collaboration and patient engagement
- Higher satisfaction of patient and site

- Faster enrollment and increased retention lead to earlier data availability
- Reduced costs due to efficiency and predictability
- Accelerated timelines

ADAPTABLE serves as a model of evidence generation to answer critical, pragmatic questions quickly

Industry Average



Interested Patients

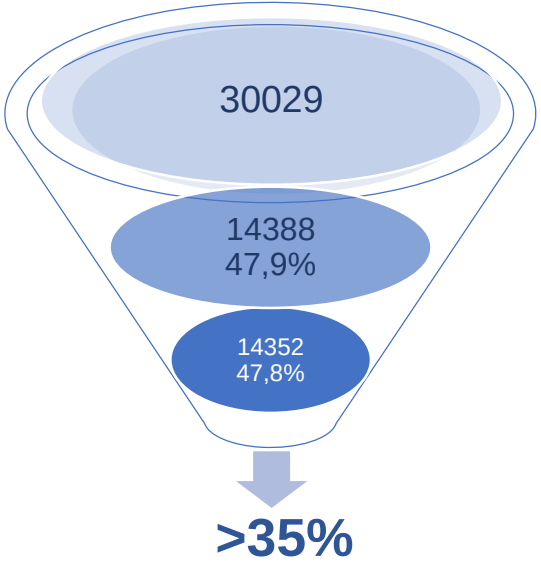
Consented Patients

Randomized Patients

Completed Study

Adaptable
The Aspirin Study

Pragmatic study on 15 000 patient



Adopted from Virtrial Webinar

Benefits of Decentralized Clinical Trials

Patient Centricity:

- DCTs offer a more patient-centric approach by allowing patients to participate in clinical trials from their home.

Population Diversity:

- Access to a larger geographical footprint might result in a more diverse patient population.

Patient Recruitment:

- DCTs also require less frequent site visits, enhancing patient recruitment.

Patient Retention:

- By requiring fewer site visits, DCTs decrease the burden for both patients and caregivers, contributing to patient retention.

Benefits of Decentralized Clinical Trials

Collection of Additional Data:

- DCTs can collect a greater quantity of data from patients over time than what might be collected in traditional site-based clinical studies.

Reduction in Source Data Verification:

- DCTs deliver data from the source, thereby reducing the need for data verification.

Additional Capacity at the Site:

- DCTs can reduce the time, burden, and cost of managing patients at the investigator site and expand the number of trials they can conduct simultaneously.

Pathway to Virtual Clinical Trials:

- Biopharmaceutical companies often have a tendency toward conservative, risk-averse behaviors. With DCTs, these companies can incrementally adopt digital practices, moving the industry toward the future of virtual clinical trials.

DCT - Challenges to Overcome

- Culture Shift
  - A new way of thinking for sponsors, CROs, sites, patients and regulators
- Logistical Issues
  - Shipping of drugs, devices, biologics and samples (Amazon, Uber, local taxi services)
- Self Identification/Verification
  - How to avoid patient enrollment errors and fraud
- Oversight
  - New responsibilities for study coordinators and monitors
- Regulatory Challenges
  - USA - CTTI guidelines
  - EU – T*rials@Home: Center of Excellence – Remote Decentralised Clinical Trials*
  - GDPR and data security laws
  - Country specific laws on telemedicine use

Decentralized Clinical Trials CTTI Recommendations

Telemedicine, mobile, and local HCPs (e.g., family physicians, general practitioners) have been involved extensively in healthcare delivery but have yet to be widely incorporated into the design and conduct of clinical trials. This is due in part to legal, regulatory, and practical considerations, which are viewed as potential barriers.

DCTs using telemedicine and other emerging and novel information technology (IT) services offer the potential for local HCPs to participate in clinical trials. This may provide several advantages compared to traditional clinical trials conducted at more centralized clinical trial sites, including the following:

- Faster trial participant recruitment, which can accelerate trial participant access to important medical interventions and reduce costs for sponsors.
- Improved trial participant retention, which may reduce missing data, shorten clinical trial timelines, and improve data interpretability.
- Greater control, convenience, and comfort for trial participants by offering at-home or local patient care.
- Increased diversity of the population enrolled in clinical trials.
- An opportunity for home administration or home use of the IMP, which may be more representative of real-world administration/use post-approval.

EU project - Trials@Home:

Remote Clinical Trials in Europe: Trials@Home Receives $44m for 5-Year Study Centering on Remote Trials

Oct 10, 2019 | Patient-Centric Trials, Patient-Centricity, Remote Clinical Trials | 0 comments 228 views

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In a 5-year, $44 million dollar major European project to bring clinical trials to the home, the Trials@Home consortium explore the opportunities of moving studies from the clinic to the home in the form of Remote Decentralized Clinical Trials (RDCTs). The goal: make it easier for participants to participate in a clinical trial from the comfort of their home. The University Medical Center Utrecht and Sanofi have been selected to coordinate the effort. An EU-centric deal, little information is shared initially. Is Patient-Centricity coming to Europe?

Project information

Trials@Home

Grant agreement ID: 831458

Status
Ongoing project

Start date	End date
1 September 2019	**31 August 2024**

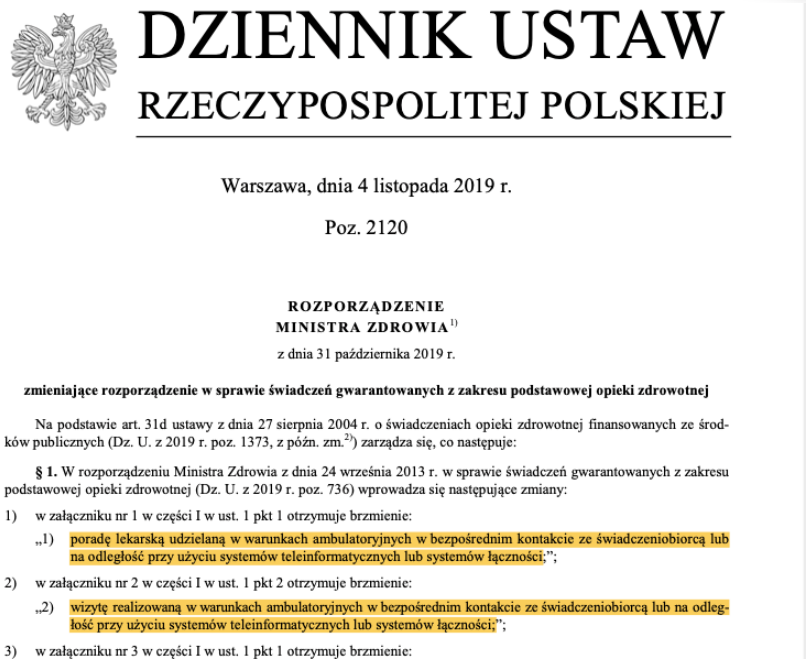
Funded under:
H2020-EU.3.1.7.

Overall budget:
€ 38 331 269,75

EU contribution
€ 19 036 997,50

Coordinated by:
UNIVERSITAIR MEDISCH CENTRUM UTRECHT
Netherlands

New regulations are coming!



DZIENNIK USTAW
RZECZYPOSPOLITEJ POLSKIEJ

Warszawa, dnia 4 listopada 2019 r.

Poz. 2120

ROZPORZĄDZENIE
MINISTRA ZDROWIA[1)]

z dnia 31 października 2019 r.

zmieniające rozporządzenie w sprawie świadczeń gwarantowanych z zakresu podstawowej opieki zdrowotnej

Na podstawie art. 31d ustawy z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. z 2019 r. poz. 1373, z późn. zm.[2)]) zarządza się, co następuje:

§ 1. W rozporządzeniu Ministra Zdrowia z dnia 24 września 2013 r. w sprawie świadczeń gwarantowanych z zakresu podstawowej opieki zdrowotnej (Dz. U. z 2019 r. poz. 736) wprowadza się następujące zmiany:

1) w załączniku nr 1 w części I w ust. 1 pkt 1 otrzymuje brzmienie:

„1) poradę lekarską udzielaną w warunkach ambulatoryjnych w bezpośrednim kontakcie ze świadczeniobiorcą lub na odległość przy użyciu systemów teleinformatycznych lub systemów łączności;";

2) w załączniku nr 2 w części I w ust. 1 pkt 2 otrzymuje brzmienie:

„2) wizytę realizowaną w warunkach ambulatoryjnych w bezpośrednim kontakcie ze świadczeniobiorcą lub na odległość przy użyciu systemów teleinformatycznych lub systemów łączności;";

3) w załączniku nr 3 w części I w ust. 1 pkt 1 otrzymuje brzmienie:

FDA – Scott Gotlieb Statement - March 14, 2019

….**Unfortunately, we've seen a continued reluctance to adopt innovative approaches among sponsors and clinical research organizations.** In some cases, the business model adopted by the clinical trial establishment just isn't compatible with the kind of positive but disruptive changes that certain innovations can enable. We appreciate that scientific and technical complexity is a real and ongoing challenge, but industry and academia also need to invest in and leverage these approaches and develop new incentives that reward collaboration and data sharing across the clinical research enterprise….

"The biggest innovations of the 21st century will be at the intersection of biology and technology."
Steve Jobs