MedStar Health

It's how we treat people.

Decentralized Clinical Trials (DCTs)

A patient-centric approach to clinical trials conducted outside traditional settings

Hiwot Guebre-Xabiher, CCRC
Administrative Director-Oncology Research

What are Decentralized Trials (DCT)?

Trials where traditional in-person visits and procedures are replaced or supplemented with remote and at-home activities.

Key features:

- Participants can engage in the trial from their homes or local healthcare
- Utilize digital health technologies (telemedicine, wearable devices, mobile apps etc..)
- Remote monitoring of participants by clinical staff, reducing the need for frequent visit to central clinical sites.

Traditional Centralized

All trial activities are conducted at the clinical research site

Hybrid

Some trial activities are conducted virtually; some are conducted at the site and/or through home health professionals.

Completely Decentralized

All trial activities are conducted virtually. Trial supplies and medicines are delivered directly to the patient.

MedStar Health

DCTs-Before and During the Pandemic

Before the Pandemic:

Traditional Site-Centric Approach

- Clinical trials were primarily conducted at physical clinical sites.
- Patients had to visit sites for treatments, tests, and data collection.

Limited Use of Remote Technologies

- Use of telemedicine and remote monitoring was minimal.
- Patient engagement was primarily face-to-face.

Geographical Limitations

- Trials often required patients to live near clinical trial sites.
- Limited participation from patients in rural or underserved areas.

Slower Recruitment and Enrollment

- Recruitment processes were lengthier due to reliance on in-person interactions and travel.

During the Pandemic:

Rapid Adoption of Remote Technologies

- Widespread implementation of telemedicine, virtual visits, and eConsent.
- Remote monitoring of patients through wearable devices and mobile health apps.

Shift to Patient-Centric, Home-Based Models

- Trials adapted to allow patients to participate from their homes.
- Home healthcare services (e.g., nursing visits, lab draws) became more common.

Wider Geographic Reach

- Participants could enroll from a broader geographic range, including underserved populations.
- Virtual participation made trials accessible to patients who otherwise couldn't travel.

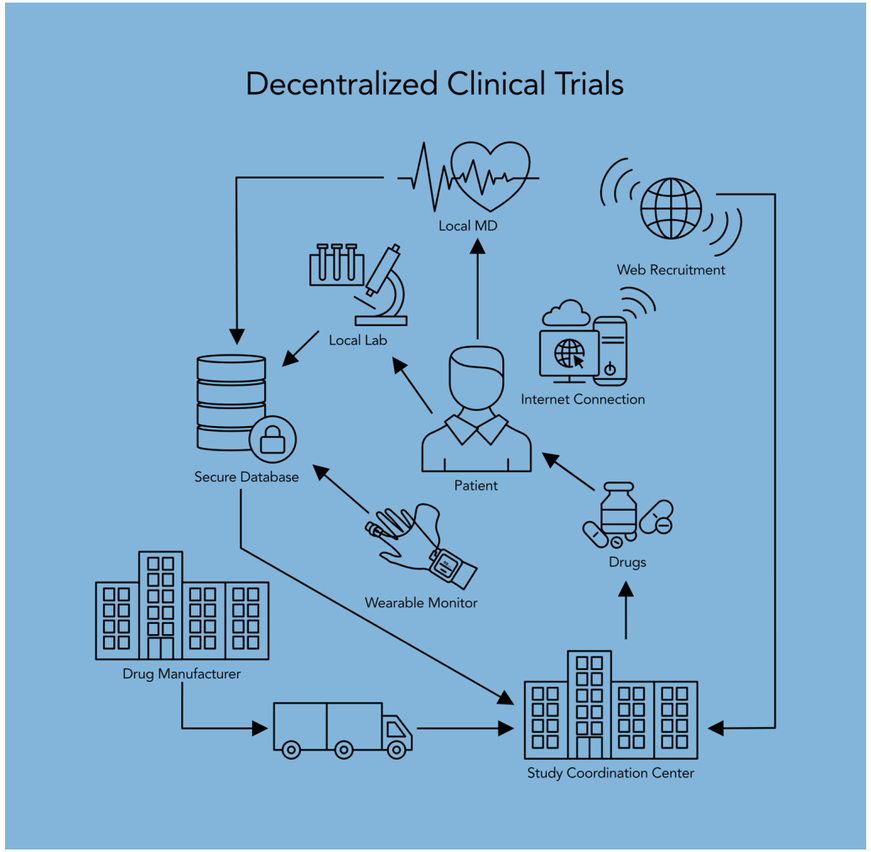
Faster Recruitment and Enrollment

- Virtual tools allowed for faster screening, onboarding, and enrollment.
- Remote consent processes increased patient participation.

Flexibility and Adaptability

- Regulatory bodies (e.g., FDA, EMA) provided temporary guidelines for the use of decentralized trial elements.
- Trial designs became more flexible, with a focus on patient safety and data integrity.

Key Components of DCTs



- **Remote patient monitoring (e.g., wearable devices tracking vitals in real time)**
- **Telemedicine consultations (e.g., virtual visits with investigators and research staff)**
- **Direct-to-patient drug delivery (e.g., courier services ensuring timely medication distribution)**
- **Mobile health technologies and digital data collection (e.g., smartphone apps for symptom tracking)**
- **eConsent (e.g., secure electronic platforms for obtaining informed consent remotely)**
- **Home healthcare services (e.g., trained nurses conducting in-home assessments and sample collection)**

MedStar Health

Key Benefits of Research eConsent (Interlace)

- Content flexibility
- Embedded educational links-
- Remote consenting & re-consenting
- Version management
- Audit trails
- Signed consent sent to EMR
- Role-based access & security
- Dashboard status management
- 21 CFR 11 compliant
- Meets regulatory requirements

MedStar Health

Key Benefits of Remote Medication Dispensing

Improved Patient Adherence:

Timely delivery and automated reminders help ensure patients stay on track with their treatment regimens, increasing compliance.

Enhanced Convenience:

Reduces the need for frequent travel, making it easier for patients, especially those in remote areas, to participate in trials.

Broader Access to Trials:

Facilitates participation for patients in rural or underserved areas, broadening the pool of participants and improving study diversity.

Better Data Monitoring:

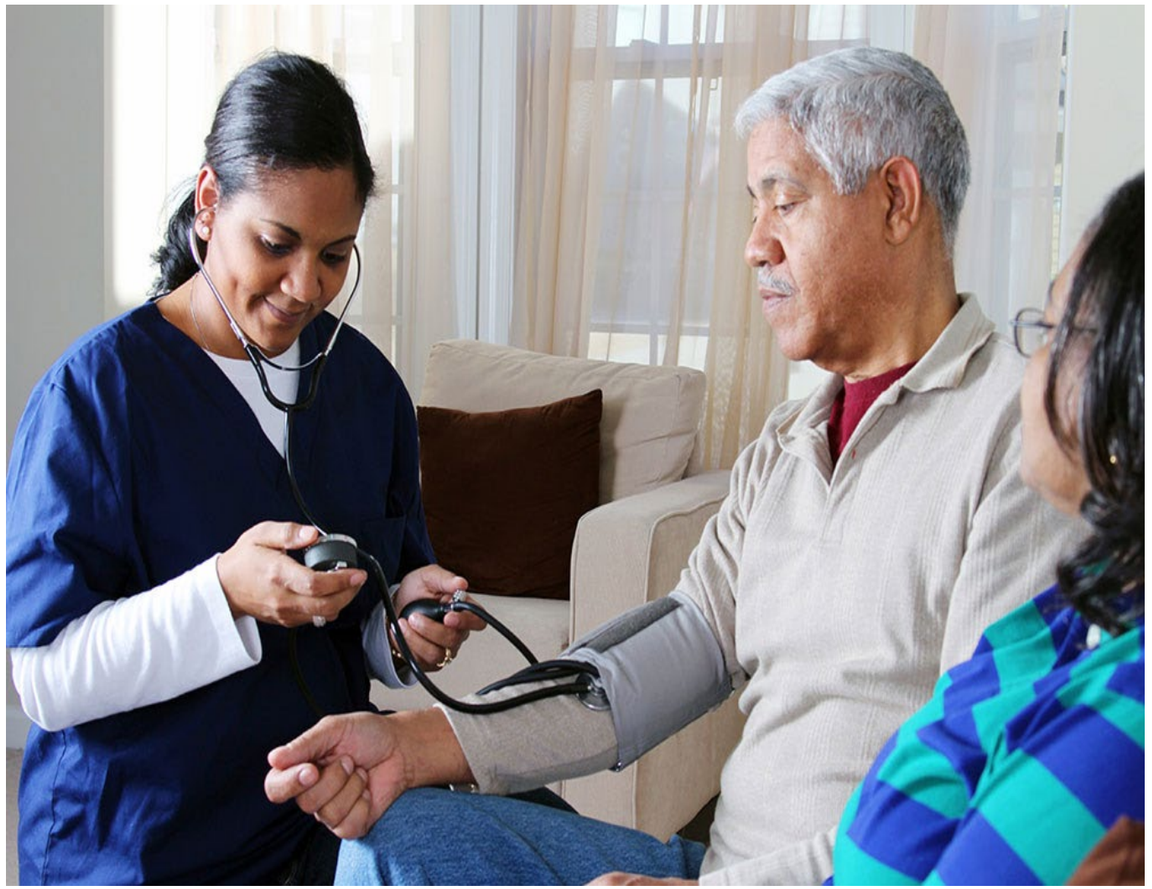
Real-time tracking of medication delivery and adherence enhances data accuracy and supports continuous patient monitoring.

Higher Patient Retention:

The convenience and consistency of remote dispensing help reduce drop-out rates, keeping patients engaged throughout the trial.

Key Benefits of Home HealthCare in DCTs

- Improves Patient Convenience & Retention – Reduces travel burden, making participation easier.
- Increases Diversity & Accessibility–Enables participation from remote and underserved populations
- Enhances Data Collection & Real-World Insights – Provides accurate, real-time health monitoring.
- Improves Safety & Patient Outcomes – Allows early intervention and continuous monitoring.
- Reduces Costs – Lowers expenses related to site visits and patient transportation.
- Supports Specialized Care – Enables trials for fragile, immunocompromised, or elderly patients
- Enhances Efficiency & Compliance – Ensures high-quality data while maintaining regulatory standards.



MedStar Health

Challenges in DCTs

Technology Barriers: Not all patients are comfortable with or have access to the necessary technology.

Data Security: Ensuring patient data is protected in a digital environment.

Regulatory Compliance: Meeting regulatory requirements remotely.

Site Coordination: Managing remote sites can require additional logistics.

Patient Engagement: Keeping patients engaged in a remote setting

MedStar Health

Role of Clinical Research Coordinators in DCTs

Participant Recruitment & Enrollment: Overseeing virtual consent processes and educating patients about the trial.

Data Collection & Monitoring: Ensuring data integrity and accurate remote data collection.

Patient Support: Providing remote assistance, resolving technical issues, and addressing patient concerns.

Regulatory Compliance: Ensuring adherence to protocols and regulatory requirements, even remotely.

Coordination with Remote Sites: Managing logistics and communication with patients, local healthcare providers, and other stakeholders.

MedStar Health

Case Study: Successful DCT Implementation

A collaboration between MedStar Health Home Care, the Advanced Heart Failure Program at the MedStar Vascular Institute and MedStar Health Research Institute (MHRI) is expanding access to clinical trials by offering at-home research participation.

Type of Assessments completed by MedStar Health Home Care nurses:

- Vital signs
- Screening for any symptoms and recording AEs
- Checking on any changes in medications
- Administer the IP and teaching providing education
- Drawing blood

Key Outcomes:

✅ Increased patient access & convenience
✅ Reduced transportation barriers
✅ More diverse patient participation
✅ Faster visits (30-45 minutes)

Current Progress:

✅ 9-10 home visits successfully completed

MedStar Health

Best Practices for Implementing a Successful DCT

Comprehensive Training: Equip CRCs and other trial staff with the skills and knowledge for DCT management.

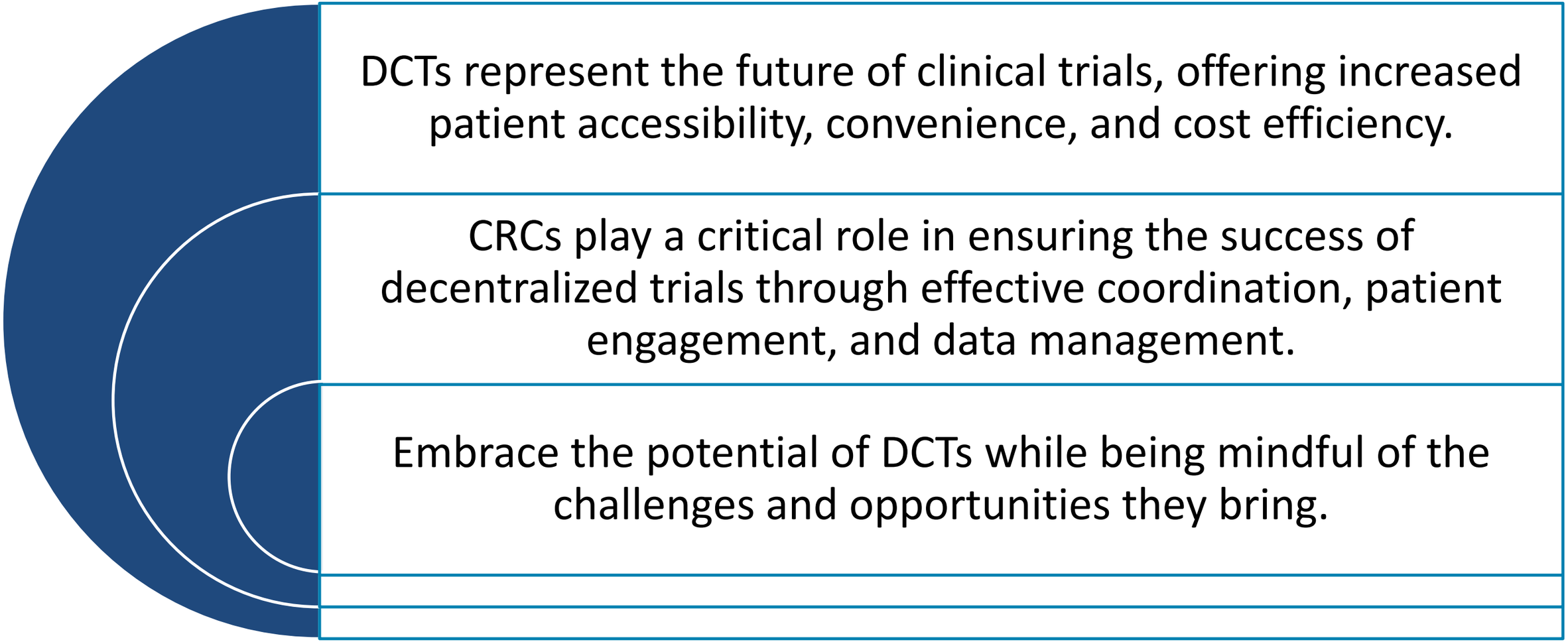
Strong Communication: Maintain clear communication channels with patients, research teams, and remote sites.

Robust Patient Support: Ensure accessible and responsive support for patients, especially those with limited technology experience.

Clear Protocols: Establish protocols for remote data collection, patient monitoring, and emergency management.

MedStar Health

Growing Role of DCTs in Clinical Research



MedStar Health

The Future of Decentralized Clinical Trials

- Wider Adoption: Increased use of DCTs in diverse therapeutic areas.
- AI and Machine Learning: Integration of AI for better patient monitoring and data analysis
- Increasing community engagement and outreach
- Hybrid Models: Combination of centralized and decentralized approaches for maximum flexibility

MedStar Health

Questions?