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Decentralised Clinical Trials:

Eine aktuelle Statusanalyse

XVII. Expertengespräch

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Agenda

- Definition
- DCT Vorteile
- DCT Bedenken
- Status DCT in Deutschland
- Technologieplattform
- Workflow
- Regulatorische Überlegungen
- DCT und Patientenpopulation
- DCT und Zentren
- Ausblick

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Definition

DECENTRALIZED TRIALS (DCTs): DEFINITIONS

- U.S. Food and Drug Administration (FDA) (Eric Pittman): Defines DCTs as "clinical trials using digital technologies to have remote interactions with real subjects"[3]
- FDA (Eric Pittman): Defines virtual trials as "preclinical trials conducted in silico or on models"
- Academic Perspective: DCTs are those that use remote technologies (mHealth, sensors, telemedicine, etc.) to interact with subjects away from central research facilities.
- Clinical Trials Transformation Initiative (CTTI): DCTs are defined as "those executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model (e.g., a study where investigational medical products are shipped directly to the trial subjects)."[4]

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Definition DCT

- Any study where most of the data originates away from the clinic utilizing virtual tools, such as video or telephone calls, or electronic sensors.
- Goal of the DCT model is to provide GCP-compliant, IRB-approved, investigational study plans that rely on sponsor-designated data collection outside a traditional research site.
- Hybrid DCTs include a more balanced mix of centralized and decentralized elements.

DCT Benefits

- A reduction in the need for sponsor resources, with fewer study subject site visits, lower professional service fee budgets, lower subject transportation costs, fewer site monitoring visits, more rapid enrollment, fewer missed visits, and overall shorter study durations

- A reduction in study site resources that need to be dedicated to clinical studies including space requirements (e.g., subject training areas and study supplies), and fewer tasks for study site personnel

- A better, more convenient study subject experience with fewer, shorter clinic visits and less frequent face-to-face contact

DCT Concerns

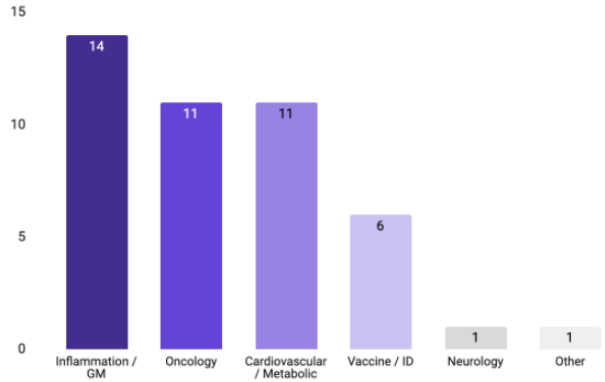
- Potential for missed opportunities to detect safety signals
- An increase in data errors or fraudulent practices
- Increased reliance on study subject compliance

Status DCT Deutschland

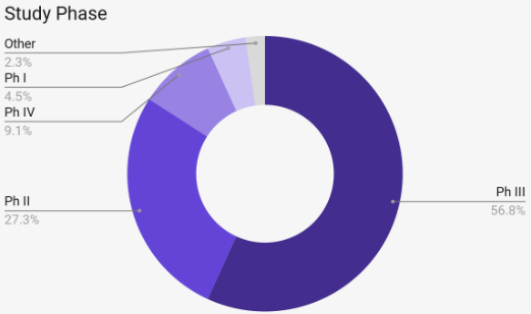
Global Experience

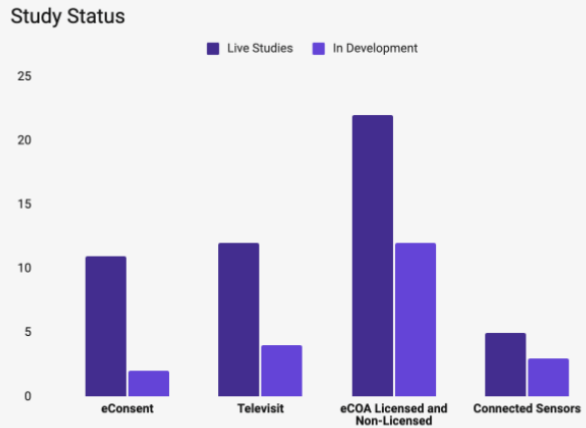
Germany

Therapeutic Area



We know that DCTs can be delivered across almost all TAs because we have done it.





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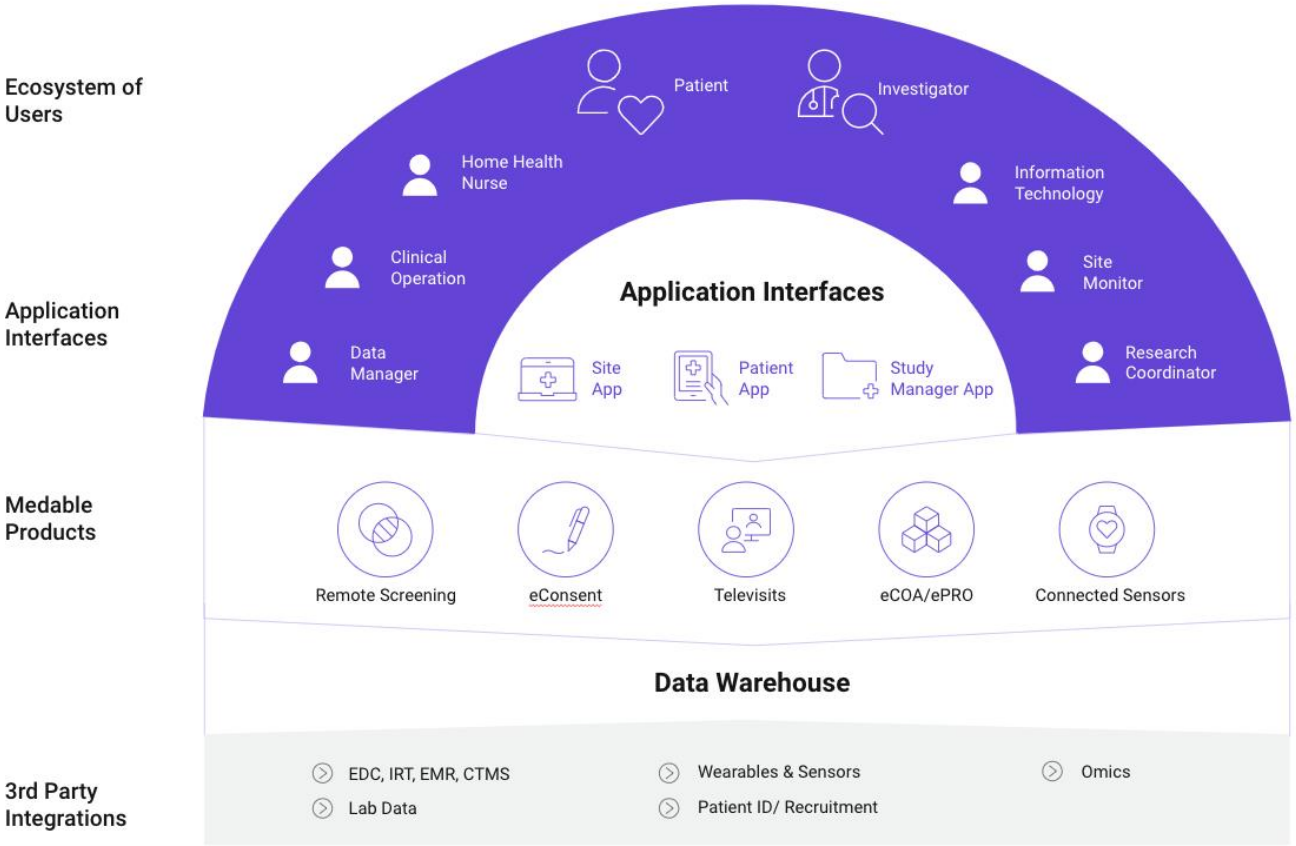
Technologieplattform



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Workflow

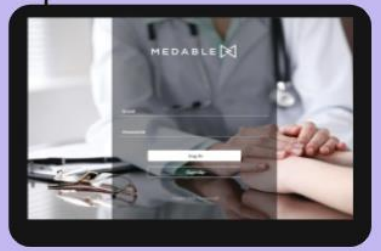
Patient identification via data partners, campaigns, and site point of care

Patient authentication & consent for pre-screening

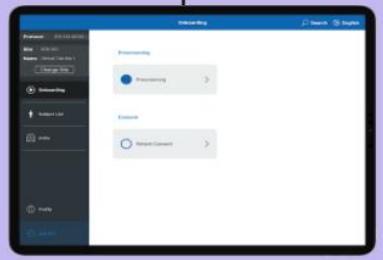
Patient confirmation of I/E criteria & willingness to participate

Patient consents and enrolls in study

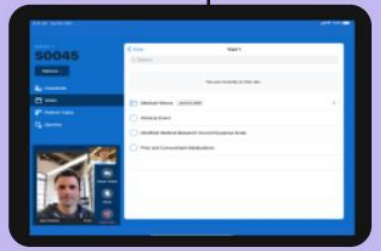
Source | **Identify** | **Screen (I/E)** | **Enroll & Consent**



Source 10,000+ patients a day



Quickly determine patient eligibility



Remote informed screening, consent, and enrollment

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Regulatorische Überlegungen

- Clinical Trial Regulation (CTR) No. 536/2014 EU
- EU 2017/745 Medizinprodukte
- ICH E6 R3
- Danish Agency Guidance
- CFR21 Part 11
- HIPAA
- GDPR
- ISO 27001:2013
- ISO 13485

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Regulatorische Überlegungen – eConsent

Green List Countries

Countries where eConsent and eSignature are broadly accepted with Regulatory guidance available

Examples: USA, UK, Canada, Australia, Denmark, Brazil

Yellow List Countries

Countries where eConsent and eSignature have been accepted however there are considerations to account for.

Examples: Netherlands, Belgium, Germany, China, Japan

Red List Countries

Countries where eSignatures are not permitted however eConsent can be used to present informed consent information, or where DP regulations prevent the use of eConsent

Examples: Switzerland, Austria, France, Bulgaria

DCT und Patienten

TeleCOA

Engaged to review and provide feedback on site-facing and patient-facing apps.

Design

Provided input on highly visible app and website with detailed review and website retooled.

Diary

Reviewed sickle cell pain diary mockups, wording, and workflows to streamline patient-facing diary

Beta Testing

Wearable Beta Testing prior to provisioning enabled a more patient-friendly device

Patient Access

Leveraged personal and professional connections for harder-to-reach populations

Barrier Identification

Reviewed mobile app and patient engagement materials to identify barriers to recruit and retention

Subject Matter Expertise

Used for blogs, videos, bid defense attendance and industry speaking engagements

UX Insight

Provide insight on UX/product solutions to adjust verbiage and incorporate patient preferences

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DCT und Zentren

1

Established Methods

Historically site success has relied on repeatable processes

2

Personal Connection

Face to face relationships have helped sites recruit and retain patients

3

Oversight

Responsibility for oversight and safety falls on the shoulders of the Principal Investigator – decentralized trials often makes them feel as though they can't provide the same level of patient oversight

4

Tech Capacity

Sites feel that some participants are not as tech savvy as we expect they are and will require lots of hand holding – more than in a traditional set up

5

Tech Disconnect

The same could be said for site staff as well. Technology can still be scary for them, or there is some sense of loss of control if they themselves are not physically completing tasks that tech is now changing

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Change Management

New Interfaces

Participants need to learn to navigate new apps, reminders, and ways of interacting with one another via telemedicine

New Workflows

Patients, sites, CRAs, and study teams all need to learn new processes for how a study will be conducted

New Data Sources

Study teams need to integrate, monitor, and harmonize new data sources from eConsents, eCOAs, sensors, and more

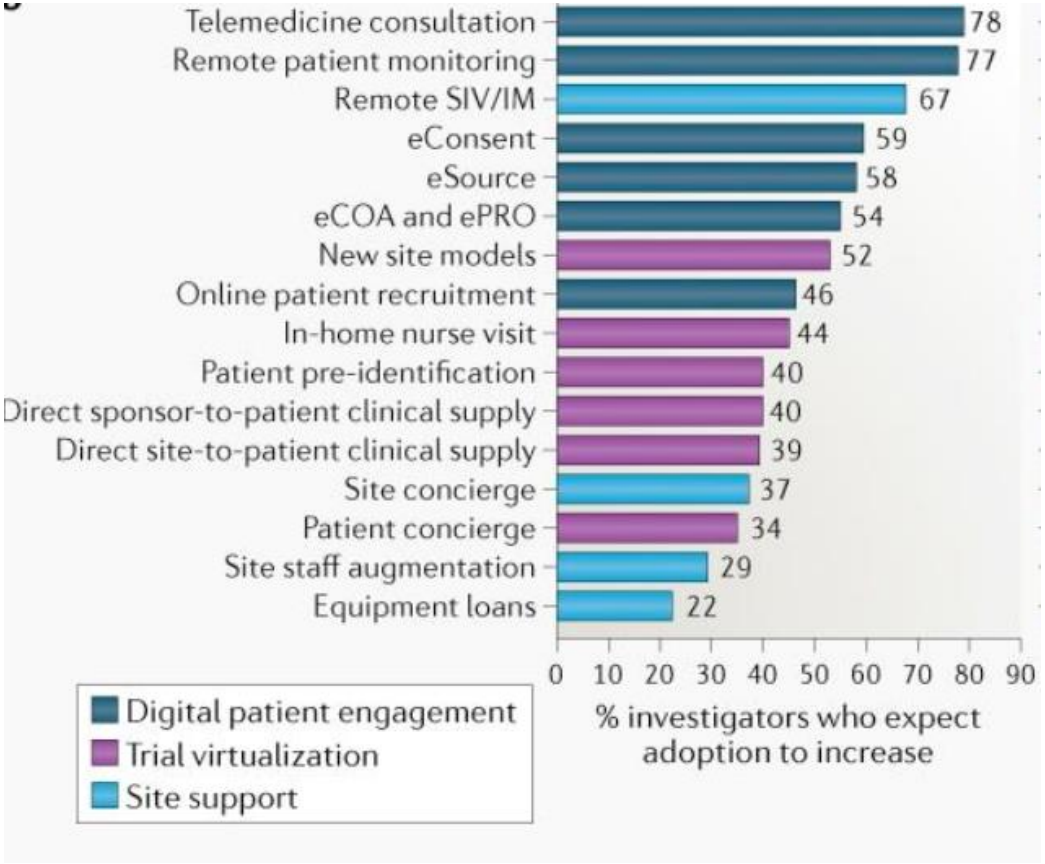
New Regulations

Study teams need to adapt to new guidelines and regulations that vary significantly by location

New Concerns

- **Regulators:** will the data be reliable?
- **Patients**: will this be safe?
- **Doctors**: why change the status quo?
- **CRAs**: how do we control for risk?
- **Study teams**: how can I be confident regulators will accept DCT data?

Ausblick


Telemedicine consultation 78
Remote patient monitoring 77
Remote SIV/IM 67
eConsent 59
eSource 58
eCOA and ePRO 54
New site models 52
Online patient recruitment 46
In-home nurse visit 44
Patient pre-identification 40
Direct sponsor-to-patient clinical supply 40
Direct site-to-patient clinical supply 39
Site concierge 37
Patient concierge 34
Site staff augmentation 29
Equipment loans 22
0 10 20 30 40 50 60 70 80 90
% investigators who expect adoption to increase
Digital patient engagement
Trial virtualization
Site support

Ausblick

- Nur ein Pandemie-Effekt?
- Disruptive Effect
- No „One size fits All“
- Hybride Studien
- Site Centric to Patient Centric
- Rare Diseases
- Diversity
- Technologie
- Artificial Intelligence/Machine Learning
- Change Management

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Herzlichen Dank!

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