Decentralized Clinical Trials

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History of topics in JPMA annual meeting by clinical evaluation committee

2016
- Research ethics
- Data reliability / Quality management

2017
- Registry-based Clinical Trials

2018
- AI leveraged for clinical research

2019
- Virtual Clinical Trial
Agenda

• The need for change & problem set
• Definition of Decentralized Clinical Trial (DCT)
  – Key enablers
  – Several DCT models
• Case study
• Moving ahead to Next Generation Trials?
Technology is rapidly evolving, providing opportunities to reimagine pharma R&D

- Cloud Computing
- Social Platforms
- Wearables
- Multi-Channel Customer Experience
- Internet of Things
- Telemedicine
- Sensor Technology
- Big Data & Advanced Analytics
- Robotic Process Automation
- Artificial Intelligence
- Drones
- 3D Printing
- Augmented / Virtual Reality
- Blockchain
- Voice Interaction
- Augmented Reality
- Virtual Reality
- Location-Based Services
- Gamification
- Smart Devices
- Cloud Computing
- Social Platforms
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- Voice Interaction
- Augmented Reality
- Virtual Reality
- Location-Based Services
- Gamification
- Smart Devices
- Internet of Things
- Mobile
- Mature
- Labs
- Early
- Everyone
Our current site model

Represents area of population that is accessible to each investigator site
What if...

We transformed our current multi-site model into a faster moving, patient centric solution that builds clinical trial that are convenient and accessible to patients.
Defining Decentralized Clinical Trials (DCTs)

“Decentralized Clinical Trials are those conducted with the patient located outside of clinical research centers for either some or all of the required trial procedures“
Traditional Study Visit Model

Visit 1
Visit 2
Visit 3
Visit 4
Visit 5
Visit 6
EOS
FUP

Day 0
Day x

Traditional On-Site Visit
Local Health Care Provider
At Patient’s Home Visit
At Patient’s Home Visit, supported by Home Nurse
DCT Models – Fully Remote Trials

Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | EOS | FUP

Day 0 → Day x

Traditional On-Site Visit | Local Health Care Provider | At Patient’s Home Visit | At Patient’s Home Visit, supported by Home Nurse
DCTs-What’s enablers?

- Decentralized Clinical Trials
- Trial conducted in whatever setting is best for participant and study
- Telemedicine based trial visits
- Digital Recruitment
- Remote Consent
- Direct to Patient Drug Delivery
- ePRO & Engagement
- Connected Sensors & Novel Endpoints
- Home Nursing & Local Care Providers
Flexible DCT models
-Not one-size-fits-all approach

Traditional Visit Model

Visit 1  Visit 2  Visit 3  Visit 4  Visit 5  Visit 6  EOS  FUP

Day 0  Day 120

Visit 1  Visit 2  Visit 3  Visit 4  Visit 5  Visit 6  EOS  FUP

Hybrid Visit Model

Traditional On-Site Visit  Local Health Care Provider  At Patient's Home Visit  At Patient's Home Visit, supported by Home Nurse
DCTs-What’s benefit?

**Patient**
- Reduces the number of onsite visits and site burden
- Reduces patient burden & increases willingness to participate and be compliant

**Investigator & Regulatory**
- Increases opportunity for contextually relevant data capture
- Narrows gap between clinical trial & real world experience

**Sponsor**
- Expands access to eligible participants
- Reduces cost to setup and manage sites

Novartis Global Drug Development
DCT Settings Case Study
A study to compare conventional & patient-centered remote study models

Low Back Pain

Patient-Centered Remote Arm
- Pre-screening call
- eICF by email
- eICF Signed
- Study equipment shipped
- Patients ready to use eDiary
- Tele Visit
- Tele Visit
- Study equipment shipped back

Conventional Arm
- eICF signed at clinic
- Patients take home study equipment for use
- Tele Visit
- Site Visit
- Study equipment returned onsite

Sources:
Adapted from: Sommer C et al. Contemporary Clinical Trials Communications, 11: 120-6, 2018
PCRT Settings Case Study
A study to compare conventional & patient-centered remote study models

Key Results
- **>3 times** higher recruitment rate achieved in decentralized model vs conventional model (18 pts vs 5pts)
- **~30% of patients** from decentralized arm recruited from rural areas
- Successful remote consent process
- Use of sensors & ePRO feasible

<table>
<thead>
<tr>
<th>Recruitment metrics</th>
<th>Decentralized</th>
<th>Conventional</th>
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<tbody>
<tr>
<td>Enrolled Number (city/town/rural)</td>
<td>18 (8/5/5)</td>
<td>5 (4/1/0)</td>
</tr>
<tr>
<td>Average enrolled number of patients per month</td>
<td>4.5</td>
<td>1.25</td>
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<tr>
<td>Completed Number</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>Discontinued Number</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Completing study recruitment rate</td>
<td>89%</td>
<td>60%</td>
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</tbody>
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Sources:
Adapted from: Sommer C et al. Contemporary Clinical Trials Communications, 11: 120-6, 2018
## SWOT Analysis for DCT in Japan

<table>
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<tr>
<th>Strength</th>
<th>Opportunity</th>
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| • Technology-advanced  
• High-prevalence of mobile devices  
• Highly-experienced, globally-renowned medical experts | • Super-aging society  
• The highest clinical study costs  
• Demand for transforming ways in all stakeholders |

<table>
<thead>
<tr>
<th>Weakness</th>
<th>Threat</th>
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| • No regulatory platform / guidance  
• Insufficient infrastructure / limited experiences of remote clinical diagnosis | • Too conservative mindset  
• Behind global advance including not only US, but also China, EU etc. |
Thank you