Designing decentralized clinical trials with a patient-centric approach

Henna Alanko  
Optimapharm/Crown CRO, Bayer  
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Understanding patients with decentralized clinical trials

Agenda:

Part I: Supporting patient engagement with patient-centricity

Part II: Improving clinical trial experience with decentralized clinical trials
Part I: What is patient centricity?

Putting the patient first

Achieving the best experience and outcome

Understanding characteristics

Considering social - and financial - perspectives

Expressing preferences and expectations

Defining the value of healthcare interventions: benefits vs. possible risks
Initiatives of the patient perspective in clinical trials

- Patient engagement
- Quality of care
- Common language
- Alignment of best practices
Implementation of patient-centric initiatives

- Positive impact on patient’s experience
- Effective & sustainable organization
- Standardized, quantifiable metrics
- Impactful and relative value

Beneficial activities
Part II: Introduction to decentralized clinical trials

Digital methods

Patient-centric solutions

Fully or partly remote activities

Main access to cancer clinical trials in traditional and decentralized model in Finland.

Traditional multi-site model

Decentralized site model

University hospitals (n=5)
Transforming the way we run clinical trials

Improving clinical trials by 2030

- Fully Integrated Into Health Processes
- Designed With A Quality Approach
- Maximally Leveraging All Available Data
- Improving Population Health

A critical part of the Evidence Generating System

Encouraging and engaging patients

- Improved trial participant retention
- Greater control, convenience, and comfort for participants
- Increased participant diversity

Source: CTTI 2018
Factors to consider in the design of decentralized clinical trials

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Basis for co-operation</th>
<th>Factors to define level of remoteness</th>
<th>Final outcome</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>Motivation</td>
<td>Technical aspects</td>
<td>+ Interested to participate</td>
</tr>
<tr>
<td>Gender</td>
<td>Adherence</td>
<td>Social aspects</td>
<td>Virtual clinical trial</td>
</tr>
<tr>
<td>Residency</td>
<td>Trust</td>
<td>Safety aspects</td>
<td>Hybrid clinical trial</td>
</tr>
<tr>
<td>Therapy area, severity, chronic</td>
<td></td>
<td>Patient care relationship</td>
<td>Traditional clinical trial</td>
</tr>
<tr>
<td>Persons in the household</td>
<td></td>
<td></td>
<td>Not interested to participate</td>
</tr>
<tr>
<td>Clinical trial experience</td>
<td></td>
<td></td>
<td>Communication</td>
</tr>
</tbody>
</table>
Defining the level of remoteness

Location
Data capture methods
Telemedicine tools with appropriate measures
Safety monitoring

Operational aspects
Effect on the trial design
Clinical implications
Fit For Purpose Technology
Acceptability, usability, and tolerability
Participant experience

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Patients` views on remote healthcare 1/2

- Health-related data
- Safety monitoring
- Time and costs
- Information change
- Suitability
- Social encounter
Patients` views on remote healthcare 2/2

DCTs:

- Avoid too many devices
- Increase understanding on normal variation
- Consider needed procedures:
  1) amount, frequency
  2) individual abilities
- Replace major of the meetings:
  1) remote settings
  2) visits at appropriate local healthcare facilities
- Decide the timing and level of remoteness
- Provide the access to HCP, peer- and mental support
- Estimate device capabilities
- Better healthcare and clinical trial experience

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Thank you!