Decentralized Clinical Trials Benefits and Challenges

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The Promise of Clinical Trials:
Transforming Tomorrow's Health

SCRI Clinical Trials Symposium 2024

30 - 31 Jul 2024 • Raffles City Convention Centre

SINGAPORE CLINICAL RESEARCH INSTITUTE

clincase

Geographical Coverage

USA
Europe
Asia

SUBJECTS
100,000+

STUDIES
400+

COUNTRIES
20+

Hosting >150+ clinical studies; completed >250 studies

80% of studies through CROs

Academic Studies 15%, Commercial Studies 85%

Phase I/II: 30%, Phase III: 30%, Phase IV/NIS: 40%

IMP, Medical Device, Post Marketing Surveillance Clinical Trials

Benefits and Challenges of DCTs

Benefits

- Digitalizing clinical trials
- Resilience
- Convenience for subjects and staff
  → Time and cost-saving
- Active and passive data collection
- New sources of data
  → broader picture of how subjects feel or function
- Meeting patients where they are
  → improving representativeness

Challenges

- Avoiding isolation of the patient
- Still little regulatory framework
- Medicinal products that require special storage, e.g. cold chain

- Ensuring data integrity and quality
- Maintaining privacy and confidentiality
  → technological solutions need to keep the balance

Benefits and Challenges of DCTs

Ethical Considerations

- Data must be processed for specified, explicit, and legitimate purposes
  → endpoints must be clinically meaningful and the data adequately captured
- Bridging digital divides

Solutions

- Advanced monitoring approaches
- Hybrid trials
- Case study - success story:
  - Initial site visit allows for gathering regular Informed Consent
  - Low to medium complexity trials with lower safety risk profile
  - Patients with reduced mobility
  - Self-administrable IMP

The Future of DCTs

Changes in trial design

- Adaptive study designs
- Ongoing risk-balancing, supported by machine learning and AI

Outreach to more underrepresented patient groups

Sources and further reading:

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Thank You!