





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%

The Promise of Clinical Trials: Transforming Tomorrow's Health

SCRI Clinical Trials Symposium 2024

30 - 31 Jul 2024 • Raffles City Convention Centre

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

IMP, Medical Device,
Post Marketing Surveillance Clinical Trials



Benefits and Challenges of DCTs

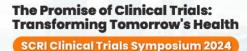


- Digitalizing clinical trials
- Resilience
- Convenience for subjects and staff
 - → Time and cost-saving
- Active and passive data collection
- New sources of data
 - → broader picture of how subjects feel or function
- Meeting patients where they are
 - → improving representativeness



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
 - ightarrow 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



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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:

- C. Petrini, C. Mannelli, L. Riva, S. Gainotti, G. Gussoni (2022): Decentralized clinical trials (DCTs): A few ethical considerations. Front. Public Health 10:1081150. doi: 10.3389/fpubh.2022.1081150
- FDA (2023): Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders
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