

Virtual Clinical Trials: Challenges & Opportunities

Lessons Learned from Interventional Virtual Clinical Trials

Kim Hawkins, Sanofi

Clinical Operations Lead, Sanofi Genzyme

Background

Developing new medicines/health solutions and improving patient health rely on the successful conduct of clinical trials to generate relevant safety and efficacy data

Recruitment and retention of patients are one of the most challenging aspects in clinical trial protocol adherence. Main barriers/hurdles are

- Lack of patients' awareness of clinical trials
- Distance to the clinical site
- The burden on patients, including the duration and number of clinical visits
- 30% dropout rate of patients who consented

➔ Emerging digital technology enables **Decentralised Clinical Trials (DCTs)**, a disruptive approach setting the trial around the patient rather than a centralised trial setting

Opportunities

- Increased flexibility of patient follow-up during clinical trials, reducing the geographic burden both on patients and hospitals
- Increase the participation of more diverse populations in clinical trials
- Increase the frequency and quality of data collection; possible decreases in sample size
- Improve patient recruitment and retention in trials
- Adapt to specific patient populations such as rare diseases where geography can be limiting to participation

➡ Accelerate clinical research and the access of patients to innovative therapies

Challenges

Operational

- Data integration/source data
- DTP IMP delivery
- Patient management
- Increased internal resources

Ethical

- Patient advertisement
- Esource/econsent

Regulatory

- Endpoint validation

Change Management

- New way of working
- Risk to trials/development path

Lessons Learned

- Selection of trials
 - Therapeutic areas, phase of research
 - Best fit
- “All or nothing”
 - Hybrid/solutions
 - Fully remote
- ROI
- Trial design/fit to model