Sciteline

Decentralized trials:
A new patient-researcher compact

Reducing patient burden by shifting to decentralized trial design

Traditional Approach to Clinical Trials

Before December 2019, a majority of clinical trials required patients to attend in-person site visits, lasting several hours, at times multiple times a week or a month. Patient dairies would be necessary to collect self-reported outcomes and to show how patients are progressing within their treatment.

Many patient recruitment and retention strategies rely on the willingness of the participant to travel to and from the local study center. Transportation is a long-standing particular challenge for elderly participants. Regardless of patient age, long travel times, particularly in urban areas can dissuade participation. The complexity of the traditional trial process requires patients to be physically available at trial centres at predefined times for data collection. Some patients make the decision to relocate closer to the site during the study in order to reduce the impact on their work and personal lives (while most participants are not in a position to do so[1]). It's not surprising then that some reports suggest only 80% of trials fail to meet their patient enrollment timelines when you consider patient burden. The knock on effect of timeline delays is every rising drug development costs[2].

What if patients could join a trial remotely from the comfort of their home?

Decentralized, virtual or hybrid trials enables a wide and diverse patient population to engage with the trial virtually from the comfort of their home, effectively removing geographic limitations. These models offer advantages for patients and researchers alike:

- **Reduce patient burden:** drastically reduce the scheduling and travel burden on patients – providing care from the comfort of the patient's home.
- **Increase diversity:** expand the access of the study to subjects that would have been unable to participant under more traditional trial protocols – connecting to a move diverse population of patients across a wider geographic scale.
- **Efficiency gains:** clinical trials take a long time and depend on

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092479/#bib19

[2] https://osp.od.nih.gov/wp-content/uploads/2014/11/Poster%20Abstractsrev_FINAL%20mh.pdf

the continuous monitoring of many participants; the remote collection of data will significantly improve data management processes and bring efficiency gains

How can Sciteline Help?

Sciteline's Virtual Clinical Trial (VCT) product provides digitized workflows that allow researchers to engage with participants virtually throughout the study. Our product includes:

Screening and Enrollment:

- **Pre-screening:** screen participants for eligibility and ineligibility (I/E) criteria before they enrol in a study. Once digitized, harness I/E insights to calibrate your enrolment plans

- **e-Consent:** follow a digital workflow to enrol your patients into your study and collect patient informed consent. Couple this workflow with our virtual visit capability to better inform and empower patients to make knowledgeable decisions based on the risks and benefits of the study

Patient Monitoring and Visits

- **Virtual Visits & Chat:** reduce patient travel to your site by providing a virtual option for the patient to connect with the research team. Provide your patients with optionality in how they communicate with your research team through our synchronous and asynchronous communication options

- **Electronic Patient Reported Outcomes (ePRO):** collect real time patient reported outcome data through surveys, questionnaires and diaries without requiring the patient to come into the clinic.

- **Reminder notifications and safety alerts:** improve trial compliance by sending friendly reminders to patients to complete their surveys and questionnaires. Once submitted, our product can immediately alert your research team of adverse events, safety concerns or other events of interests.

Dashboards and Visualization:

- **Visualization:** visualize your study data in near real time to observe trends in patient recruitment, drop-outs, upcoming events and protocol compliance.

Mobile Device:

- **Android/iOS:** 62% of users access the internet by using their mobile phones[3]. Provide your participants with a mobile trial option to drive higher engagement

[3] https://quoracreative.com/article/mobile-marketing-statistics

About Sciteline

Sciteline combines creative thinking, innovation and cross industry leadership experience to develop decentralized trial solutions to help solve some of Canada's most challenging issues in clinical research. Our mission is to accelerate the generation of new knowledge by enabling researchers to achieve their best work while connecting them with a diverse population of patients. We believe that by reducing the patient burden by changing the status quo, we can lower the cost of delivering new drugs and medical devices to patients.

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Research organizations small and large continue to respond to a rapidly changing landscape and strive to pursue innovative solutions to address today's challenges. Sciteline understands the complexity of these challenges and works with clients to drive progress in digital adoption in clinical research.