# Learning from Decentralised Clinical Trial (DCT) experiences: a qualitative analysis of interviews with stakeholders

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## Introduction

### Objective:

To identify actionable learning points from key stakeholders to inform the future design and conduct of decentralised clinical trials (DCTs).

### Background:

The COVID-19 pandemic and technological developments have increased interest in decentralised clinical trial (DCT) methods. By using digital technology and other means, a key aim is to make clinical trials more accessible for participants. Although recent advances in communications technology have permitted new approaches to trial activities such as telemedicine visits, data capture using mobile devices, and online participant-reported outcomes, DCTs are not without their challenges.

## Methods:

- Forty-eight semi-structured interviews conducted with senior managers, trial managers, technology experts, principal investigators, clinical investigators, research scientists, research nurses, vendors, patient representatives, and project assistants between 31/01/2020 and 26/06/2020.
- Interviews audio recorded and transcribed.
- Data (transcripts) coded using a thematic approach.
- Ethical approval granted by the University of Dundee School of Medicine Research Ethics Committee (SMED REC number 20/07, 27th January 2020)

## Results: Actionable Learning Points

## Participant Focused

### Involving Participants in:

- Identifying the research question ensured it was of high value to participants:

> *"…it's because it's retinopathy, blindness is the number one fear of people with diabetes, and these are people that have been told they've got changes to their eyes and there's nothing we can do about it." Interviewee 0049 Trial Staff (clinical/research)*

- Designing recruitment materials made trials more relatable.
- Creating websites and portals, ensured they were easy to navigate with clear calls to action.

### Providing Feedback:

- About trial progress made trial participants feel more like collaborators, while feedback from devices was thought to facilitate self-management:

> *"The study did not treat patients as passive…. It said you …you report your blood pressure… whether you're taking new medication…if anything else changes, you're in charge, you tell us… Real collaboration." Interviewee 0058 Patient Representative*

### Reducing Burden:

- Interviewees observed instances of participant incomprehension and 'digital overload' indicating the presence of cognitive and psychological burdens.

## Trial-Focused

### Shared Understanding

- Involve partners such as vendors and regulators early, clearly describing the anticipated participant journey, to avoid later misunderstandings.
- Build strong relationships with organisations holding routinely collected data to assist access and enable responses to changes in requirements.

### Multiple Modes of Data Capture

- Use multiple modes of data capture to mitigate missing data and unexpected problems with data access, ensuring timely reporting of relevant events.
- Collect participant-centric endpoints, such as quality of life, to supplement conventional measurements and capture information important to participants.

### Mitigate Transferred Burden

- Consider the possible cognitive and psychological burdens for staff of remote working caused by logistics, technological problems and isolation. Develop measures to mitigate burden:

> *"Our administrators were quite good at sending us an email if you were out at a [primary care] practice to deal with something. But sometimes you would be busy, and there would be a lot of things coming through, and it's quite difficult keeping track." Interviewee 0008 Trial Staff (clinical/research)*

### Flexible Responses to the Unexpected

- COVID-19 restrictions highlighted the value of contingency planning in the event of staff redeployment, delays in clinical activities, and approvals.

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## Conclusion

Technological developments, and the COVID-19 pandemic, have increased the use of DCT methods. However, DCTs continue to face challenges in implementing novel technologies. Although DCTs may lessen the logistical burden of trial participation, they can introduce other burdens for staff and participants. Maximising patient and partner involvement, employing well-tested technology and simplifying how participants and trial personnel experience DCT methods may facilitate their successful implementation.