

## ABOUT THE GOOD CLINICAL TRIALS COLLABORATIVE

The Good Clinical Trials Collaborative (GCTC) was launched in June 2020, supported by the Wellcome Trust, the Bill and Melinda Gates Foundation and the African Academy of Sciences. The Collaborative was set up to enable the development and adoption of new guidance to support a more effective regulatory environment for Randomized Controlled Trials (RCTs) enabling researchers to efficiently conduct trials that are needed to improve health and care.

This guidance is available for review and comment at goodtrials.org/feedback between 4 August and 1 September 2021. We invite you to participate in this consultation to help strengthen its quality and applicability. The final guidance will be published in late 2021.

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#### **FOREWORD**

In early 2020, COVID-19 spread rapidly around the world having a dramatic impact on every aspect of our lives. RCTs, so critical for evaluating the safety and efficacy of treatments and other health interventions, were no exception. Clinical trials already running were frequently suspended, with some never restarting. Methods of trial delivery had to be altered rapidly at a time of emergency and unprecedented stress on patients, the health care systems, and those who work in them. Many new trials in the planning stage simply never started.

In response to the COVID-19 crisis, the clinical trial community had to innovate – to implement new ways of working, redesign scientific protocols, and consider different ways to interact with patients, collect data, or administer trial interventions and treatments.

The GCTC survey summarises that experience. It provides a snapshot in the second half of 2020. It reveals both successes and failures in dealing with the crisis. We present these findings, largely without comment or analysis, to help inform an open dialogue about how RCTs should be designed and conducted in the future.

There are many lessons to learn, but perhaps the most important is that RCTs have never been more important in evaluating the role of healthcare interventions. Repeatedly we have seen the fallacy of rolling out healthcare interventions that are not based on sound evidence from randomised trials.

For example, huge numbers of patients hospitalised with COVID-19 were given treatments such as hydroxychloroquine and convalescent plasma which RCTs have subsequently shown to have no meaningful benefit, while corticosteroids such as dexamethasone were widely believed to be contraindicated or harmful until RCTs demonstrated their critical role in improving survival.

COVID-19 has revealed significant flaws in the way in which many trials are traditionally designed, delivered, and regulated. There is now, more than ever, an absolute need to move to guidance and regulatory approaches that focus on the principles of high-quality RCTs, allowing for innovation and flexibility in the way in which these principles are enacted in any particular circumstance. Our mission at the Good Clinical Trials Collaborative is to facilitate the development and implementation of guidance based on the fundamental scientific and ethical principles of randomised controlled trials. This principle-led approach offers hope and benefit to patients and the health care systems that care for them.

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July 2021

#### INTRODUCTION

The first wave of the COVID-19 pandemic accelerated and expanded the adoption of long-discussed methods of adapting trial delivery, including the use of digital, remote and decentralised approaches. The experience of implementing these methods, during the turbulence of a pandemic, provides an opportunity for the clinical trials eco-system to learn, not only about the merits of these methods, but what they highlight about how clinical trials are designed and delivered.

This report provides a window into the workings of the clinical trials ecosystem during the second half of 2020. We hope the findings will help inform and encourage an open dialogue between clinical trialists, clinical trial participants, funders, regulatory authorities and government agencies, around how clinical trials are currently delivered and what improvements could be made.

The report is based on a survey which was open to all researchers involved in the delivery of RCTs. It was launched on 8 June 2020 and closed on 20 July 2020 and completed by 540 respondents representing 47 countries.

The report addresses the positive and negatives of specific adaptations, as reported to us in the survey. It then presents the wider themes that emerged across multiple adaptations, and what these themes highlight about the current system of trial design and delivery.

We hope this contributes to a much-needed robust discussion over the survey findings, and the lessons we can draw from them.

#### **FINDINGS**

Few clinical trials were able to avoid disruption during the pandemic. 95% of clinical trials in our survey reported being impacted by the pandemic and of those, 56% were able to continue with adaptations. Over a third (37%) of respondents said their trials had been paused or suspended, but only a very small proportion (2%) of all trials were cancelled because of the pandemic.

In this report we describe the specific adaptations that respondents reported and explore themes that were reflected across different adaptations and point to broader considerations.

#### **Adaptations**

Respondents indicated that many of the adaptations implemented during the pandemic were successful and should be taken forward to future trials (see Annex 1).

#### Remote visits and use of local services

A variety of national and local pandemic measures, such as travel restrictions or lockdowns, limited the ability of participants and trial staff to attend central trial sites. As a result, many trials adopted a decentralised approach, involving use of local rather than central services, and home visits. These adaptations attempted to reduce participant travel and minimise face-to-face contact. For example, some trials used alternative primary care sites to deliver an intervention or conduct outcome collection, such as general practice clinics or pharmacies, rather than a hospital or specialist centres. Home visits were used to reduce the number of people participants came into contact with (for example in hospital waiting rooms) while retaining personal interaction with trial staff.

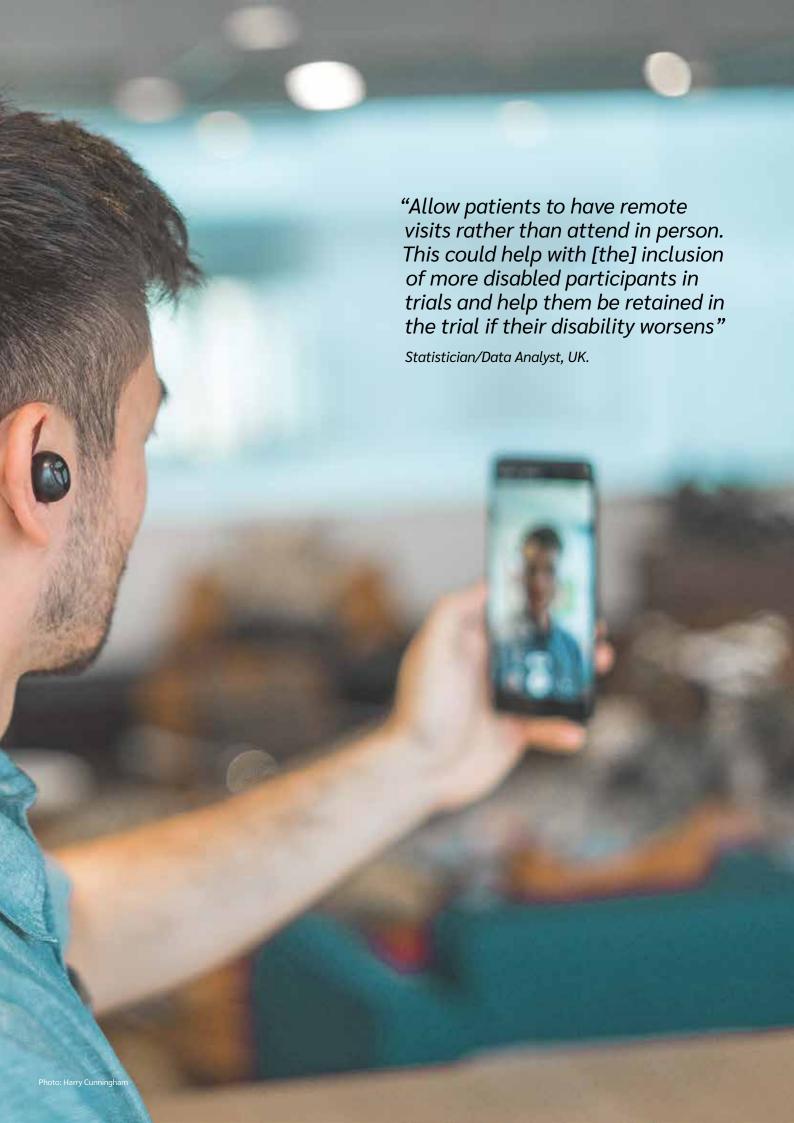
This decentralised approach was reported to improve the patient experience; online or local assessments, and the delivery of interventions, were deemed to be more accessible and convenient. One respondent suggested this could help widen participation and retention in trials by making it easier for some groups, such as those with reduced mobility, to be involved.

Where necessary, some trials used local rather than central laboratories to process samples. Where reliable results could be gathered from local facilities this made better use of dispersed resources at a time when laboratory infrastructure was being put under pressure by the pandemic.

Some trials were impeded by a lack of resource resulting in additional work for some staff.
Respondents also raised concerns that decentralisation made the trial harder to manage. Notwithstanding these concerns, overall these changes were viewed favourably.

"[We] tried to encourage sites to send our central lab kits to local labs, however no sites have actually done this because there are extra logistics involved"

Sponsor.



#### Consenting processes

Methods of gaining consent remotely or electronically were viewed favourably by respondents and highlighted as a change they would likely implement again. Remote consent could include gaining consent verbally on the telephone, using tablet computers at centres to register consent, or other means of recording participant consent without physically signing a document. Remote consenting practices would reduce reliance on paper forms, which the pandemic showed to be inflexible to remote working and telemedicine. It was also suggested this increased flexibility could aid participant recruitment.

"Make more use of remote contact where possible without compromising the trial outcomes. Our trial already makes use of telephone consent, and electronic CRFs [Case Report Form] where data is input directly at source. This enables us to adapt more easily to the changes required as a result of COVID."

Clinical research co-ordinator/Trial Manager, UK.

Respondents reflected on the inefficiencies in many of the methods currently used to record consent. Some shared their view that consenting practices can be over-cautious or repetitive, and that it may be possible to reduce the number of times a participant is asked to consent; especially when changes are made that do not affect the grounds on which consent was initially given. It was suggested this type of repetition could be eliminated without any additional risk to the trial participant.

Respondents also suggested ways that consent could be streamlined and simplified, such as reviewing the current requirements for participants to sign consent forms in the presence of the researcher/investigator. This would allow consent to be collected remotely more easily. Some respondents expressed reservations around the length of time needed to gain necessary approvals (e.g. ethics committees or regulators) for remote consenting or inadequate resources to support e-consent, such as the appropriate IT infrastructure to collect, store and access consent remotely and securely.

#### Data collection

The pandemic forced many trials to explore alternative strategies for collecting key trial data. Where some

trials continued routine data collection, with increased infection control measures, many trials shifted to remote data collection, through methods such as virtual assessments, samples sent by post and the use of electronic Case Report Forms (CRFs).

The shift to remote and hybrid working highlighted the reliance of many trials on paper rather than electronic CRFs. Respondents expressed frustration at the use of paper CRFs, which posed both logistical and data protection challenges during remote working. Some respondents suggested that they were better able to manage the shift to remote and hybrid forms of working because they were already using electronic CRFs.

"If data could be collected just using electronic data capture systems that would be more beneficial, efficient and more cost-effective."

Clinical research co-ordinator / Trial Manager, UK.

"Electronic case report forms should have been done - but our clinical trials unit/organisation only uses paper case report forms. Hence they did not have infrastructure in place to allow this change to occur...due to lack of infrastructure, funding, expertise."

Investigator, UK.

Respondents highlighted some of the limitations with remote data collection. Not all outputs were suitable for remote collection, resulting in a reduction in the total amount of data collected. For example, collecting physiological data (such as imaging and blood biochemistry) proved to be particularly difficult remotely. Trials directly reliant on these measures could therefore not continue.

Some trials chose to prioritise data collection for primary trial outcomes only, in order to focus resources and increase feasibility. Some respondents expressed concerns that this prioritisation and reduction in data collected could limit opportunities to explore additional trial outcomes, while others noted that prioritisation enabled the trial to continue with a reduced burden and improved efficiency. Respondents suggested this prioritisation may improve participant experience by reducing the number of tests and interventions they had to undergo.

"Reduce the amount of data collected. So much data was collected that the clean-up process has been exceedingly painful. Much of that data will never be analysed, and was not critical to answering either the main study question or the secondary hypotheses."

Ethics / Regulatory affairs personnel, US

The quality of data obtained through remote data collection, particularly where participants measure their own outcomes, was raised as an area of concern. It was noted that some home tests were less accurate than those administered by trained staff, and other home tests proved too inaccurate or unreliable to yield useful results.

Respondents reflected that the use of reliable home tests and specialist equipment - such as home blood pressure or lung function testing equipment - could help improve the results of data collected remotely and where concern exists regarding results, it is important to establish whether the accuracy of the test is sufficient for the requirements of the study.

#### Direct-to-patient delivery

In switching to remote trial delivery, many trials implemented a direct-to-patient service model where trial services or interventions travelled to the patient, including where an investigational product is shipped to participants' homes. In circumstances where the pandemic had made visits to trial sites difficult or impossible, this allowed trials to continue when they otherwise may not have been able to. Most respondents who made this adaptation said they would look to use direct-to-patient delivery methods again in future trials.

# "[It would be beneficial to] increase the possibilities of remote visits, drug delivery [and] event reporting"

Investigator (multi-site), Italy.

Despite generally being viewed favourably, respondents raised concerns about logistical barriers, such as postal service delays, to direct-to-patient services. Country-level regulations prohibiting or restricting what can be sent by post or courier were also raised as a problem. Some trials cited additional complications when shipping medical products across international borders. Maintaining data protection, privacy and blinding were also concerns.

Due to a combination of these factors, most respondents felt direct-to-patient services made trials

harder to administer. Some recognised this increased logistical burden but felt it remained worthwhile for its potential benefits to participant experience, such as increased convenience.

Implementing these changes during a pandemic may explain some of the difficulties experienced. The use of direct-to-patient strategies was highlighted as one that many trialists would apply to future trials, where feasibility could be assessed during the trial planning stage. Where appropriate, allowing the option of direct-to-patient services could increase trial flexibility and resilience.

#### **Participant Recruitment**

Some respondents suggested that, due to the pandemic, recruitment was paused without enough consideration of the long-term impact it would have on the trial, such as the consequences of a smaller sample size. Many respondents voiced frustration at what they perceived to be premature decisions taken centrally, without dialogue with trial sites.

# "Stopping recruitment was a challenging decision to reverse and may have been done too early in some countries."

Investigator, UK

Severe interruption to participant recruitment may be an unavoidable consequence of the pandemic. However, respondents indicated that several of the adaptations mentioned above would aid recruitment by making trials more flexible and reducing the burden of, and barriers to, participation in clinical trials.

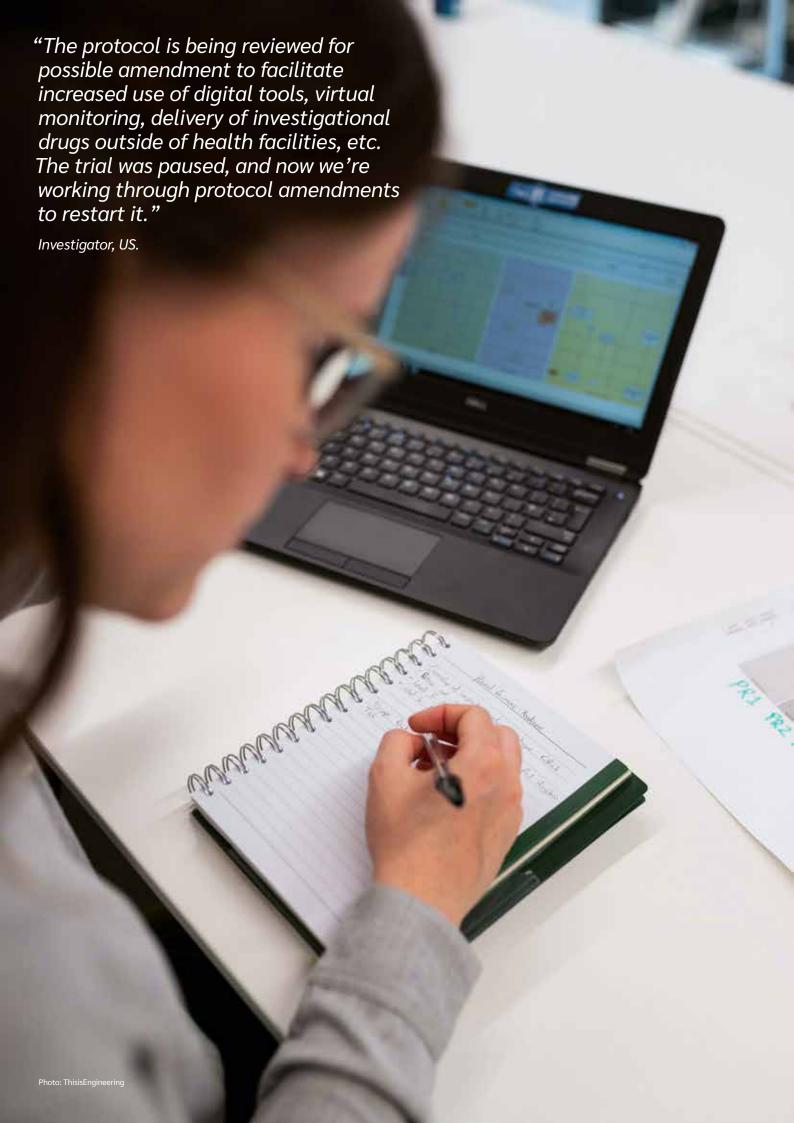
#### **Themes**

In addition to the specific adaptations discussed above, the GCTC survey highlighted common themes that appeared across many different adaptations. This section will explore these themes in more detail.

#### **Protocols**

Making changes to trial protocols can be time consuming for those running the trial, and lead to delays and cancellation if approvals are not received in time. Our survey indicated that trialists want greater flexibility to be built into trial protocols, so they are more resilient and better able to adapt to unforeseen events.

Over half of respondents to our survey had to make adaptations for their trial to continue, many of which required formal protocol amendments. Of the trialists who responded that their trial had been paused, suspended or cancelled, many stated the timeline for approval as the reason changes were not implemented,



or they were currently working through amendments so that the trial could continue. Respondents reported that delayed approval caused problems including patients having to stop receiving treatment, loss of primary data, and some suggesting that they did not try to implement adaptations because they anticipated that the approval process would take too long.

Respondents noted that protocols should allow for pragmatic adaptations without the requirement for new approval. For example, a flexible protocol may describe the need for a consultation but not dictate how it will be conducted, allowing the option for inperson, phone or video-call consultations, depending on the circumstances. One respondent suggested that "pragmatic" protocols of this nature are rarely approved.

"It would be ideal for the protocol to have options for remote follow up and IP delivery options written in case they were required to prevent amendments."

Clinical research co-ordinator/Trial manager, Australia

However, respondents underlined the need to maintain robust scientific scrutiny of substantial protocol deviations.

#### Streamlining approvals

Respondents suggested that a more coordinated approach to the amendment review process could make dealing with protocol amendments more efficient and prevent damaging delays.

Trials with multi-centre studies responded that they would benefit from ethics reviews being valid for all participating centres, whether such studies are global, regional, national or local. A more streamlined process could contribute to less unnecessary work for trialists and reduce the number of amendments each centre must process.

"Definitely have the protocol ethics approval and regulatory approval done at a global level, rather than at individual country level - required a lot of repetition for the same trial which was basically a multi-centre trial."

Ethics/Regulatory affairs personnel, Europe.

Although better coordination and streamlining approval processes would bring benefits, respondents noted that this should be balanced with the need to ensure the approval process is still robust and sensitive to the local circumstances and community views.

#### "Certain review processes are still required. When moving too fast, the project is more error-prone"

Funding officer, Belgium.

#### Resources

The lack of appropriate resource, ranging from the speed of home internet connections to staff time and training, negatively impacted the ability of trials to show greater flexibility during the pandemic.

Where respondents raised concerns about implementing innovative adaptations, the concern focused predominantly on issues around inappropriate resource, rather than the adaptation itself. For example, respondents noted that some staff could not conduct electronic/telephone follow-up from home as they did not have the right equipment or had issues with the quality of their internet connection. Concern about lack of resource was reflected in responses across several remote processes such as consenting, data collection, direct-to-patient delivery and use of local services.

"Recruitment and baseline assessment was suspended but parts could have taken place remotely had the resource been in place (measurement staff were home-based with limited airtime, internet access and privacy)."

Senior researcher, South Africa.

Staff availability and training was a recurring resource issue. Some said that attempts to use more decentralised approaches were limited by the capacity of local clinic staff. For example, one respondent reported that local staff did not have the time to administer trial medication due to the high volume of staff sickness. Problems with staff availability were exacerbated by staff being re-deployed to front-line roles and to COVID-related duties. In cases where staff were available, they did not always have the required training or experience to undertake novel processes, such as remote data collection.

Remote staff training received mixed feedback with some praising the increased efficiency and inclusivity of online training, while others expressed concern about the lack of face-to-face interaction and how this may negatively impact relationship and team building.

#### Risk of shifting burden

When asked to try and evaluate the success of new methods of trial delivery, a common question arose: are these new approaches reducing the burden or just shifting it to other parts of the system? For example, the direct-to-patient services could shift the burden from trained staff to trial participants and their carers.

"One of the assessments needs to be carried out by the mother at home now which adds burden to her and may not be as accurate as if done by a researcher in clinic."

Clinical research co-ordinator/Trial manager, UK.

Respondents articulated that the suitability of seemingly beneficial approaches must be considered carefully to identify potentially unforeseen or displaced costs. For example, direct-to-patient delivery may reduce the workload for site staff, who would no longer have to conduct the intervention, but increase it for administrative staff, who might have to deal with the increased logistical burden of organising and monitoring deliveries.

Survey responses also suggested that no adaptation is likely to be universally beneficial, and different trials may experience the same type of adaptation in different ways. One respondent noted that remote monitoring, including online assessments, reduced the burden on staff and participants by providing greater flexibility, while another felt that remote monitoring was much more time consuming for staff.

Respondents noted that many of the adaptations discussed in this report could improve participant experience but at the expense of staff time and effort. Home visits are a notable example of this. Staff traveling to participants homes will take more time compared to using a central site, but home visits would greatly reduce the burden of participating in a trial.

"Giving the option to have remote follow-up visits to relieve the burden on participants and hopefully make the trial more attractive to them. This does shift the extra effort to sites who now have more admin e.g. organising video consultations and pharmacy coordinating posting out IMP."

Clinical research co-ordinator/Trial manager, UK.

#### Communication

The introduction of remote practices meant that, where infrastructure allowed, there was enhanced opportunity for communication and collaboration between the whole trial team. For example, one of the respondents noted that the data, statistics and safety teams were able to be more involved in the protocol development through virtual meetings. Respondents highlighted the importance of regular meetings between the trial team and investigators, particularly around protocol amendments, and noted that remote practices make this easier.

"The situation [COVID pandemic] highlighted the importance of having a proactive team and that having regular meetings remotely was more important than waiting until the next available date when everyone could meet in person."

Statistician/Data analyst, UK.

Respondents noted that poor communication, especially around amendments and changes to the trial protocol, posed a risk. Good communication was reported to be essential in reducing this risk and ensuring that the participant experience was not negatively impacted. Regular communication, facilitated through remote practices, can therefore help to address safety concerns.

While acknowledging the benefits of virtual communication, there was a preference for face to face interaction among some respondents, who argued that participants may feel more comfortable, and be more open, when communicating in person. It was also suggested that certain signals or nuances in communication may be harder to notice remotely. Remote methods made it possible to continue to obtain useful information during the pandemic, but many suggested that video appointments are not of the same quality as face-to-face interaction, particularly in studies with vulnerable populations or dealing with sensitive issues

"I think better quality data is obtained when interviews on sensitive issues are undertaken face-to-face by an interviewer whom the interviewee knows and trusts than when this is done electronically."

Investigator, UK.

"There are a lot of subtleties to seeing tuberculosis participants ideally visits should be face to face with clinicians"

Investigator, South Africa.

Respondents suggested that it was harder to maintain engagement through virtual communication. For example, one respondent reported that study questionnaires were only completed by 50% of participants when sent via email compared to 100% when done in person at the clinic.

#### CONCLUSION

The COVID-19 pandemic forced many in the clinical trial ecosystem to make significant adjustments to usual ways of working. In doing so they demonstrated the viability of a range of pragmatic and innovative practices for running and managing clinical trials. These approaches should now be considered when designing new clinical trials to improve efficiency, participant experience, and reduce costs. The pandemic has also highlighted areas where structural barriers make it difficult for innovative adaptations to be fully utilised.

Increasing flexibility – based on scientific and ethical principles of RCTs - is key to making the most of innovative adaptations, overcoming the structural barriers to change, and improving the resilience of clinical trials. This survey highlighted three ways in which flexibility in clinical trials can be increased.

#### 1. Simplify trial protocols

High level protocols – which contain enough detail to ensure safety and robust scrutiny, while allowing adaptability to unforeseen events – will encourage trials to use innovative approaches, where appropriate, without the need for formal protocol amendments. This could save time and improve quality for trials and for those running, overseeing, and participating in them.

## 2. Ensure appropriate infrastructure and resource are in place to support innovative adaptations

The successful adoption of flexible and decentralised approaches, such as remote data collection and direct-to-patient services, requires resources to facilitate and support their introduction and use. Failing to support innovative adaptations with suitable resource risks undermining their success.

## 3. Coordinated and streamlined review processes can increase trial efficiency and resilience

This survey and report are predominantly focused on those working in trial planning and delivery. However, trial regulation and approval processes also need to be considered when evaluating how the eco-system can work better. For example, greater coordination of ethics and regulatory reviews would streamline amendment approval and reduce unnecessary work for trialists. In addition, simplified protocols that allow greater flexibility will need approval by, and the support of, regulatory authorities.

A proportional and evidence-based approach is needed to ensure any changes to increase flexibility also serve the interests of participants and uphold the fundamental principles of randomized clinical trials.

Our assessment of survey responses leads us to conclude that RCTs that are flexible are more resilient and better able to adapt to changing circumstances. Flexibility within protocols to best meet the underlying and scientific principles of clinical trials will allow innovative adaptations to be better utilised – encouraging those managing trials to use the most appropriate method for any given situation. Over time, this will make clinical trials more efficient and cost effective and will improve participant experience.

#### **METHODOLOGY**

#### **About the survey**

The Good Clinical Trials Collaborative survey launched on 8 June 2020 and closed on 20 July 2020. The survey was open to all researchers involved in the delivery of RCTs. It was actively promoted via the Wellcome Trust's social media channels and subsequently distributed organically through social media sharing. Additionally, it was actively promoted to a range of global membership and network organisations with a stated interest in trial delivery.

#### **About the respondents**

- We received 540 complete responses from clinical trialists from 47 countries, with most respondents from the UK (304).
- Most of the respondents were Clinical Research Co-ordinators/Trial Managers (113) or Investigators (113), predominately based at universities (244) and hospitals (79), with some from Pharma, Biotech or Contract Research Organisations (36).
- Respondents had an average (mean) of 11.3 years of experience of conducting clinical trials.
- Just under half (45%) of all responses related to experience with Phase III trials.
- About two-thirds (62%) of trials were investigating drug treatments.
- 352 of the trials were non-COVID trials and 43 were COVID related.
- Less than a third (22.8%) of trials included <100 participants; one third (30.8%) included 101-500 participants; and just under half (45.1%) of trials included >501 participants.

#### Free text analysis

Responses were given in free text format. The responses were separated into 1,085 smaller excerpts based on common delimiters which were automatically clustered based on similarity. We then manually assigned identifying tags to each cluster based on their content and re-assigned excerpts that had been mis-identified to more appropriate clusters. Finally, we grouped similar clusters together to ensure that each tag related to a discrete topic. There were 40 tags in total. This resulted in each individual response being assigned multiple relevant tags based on its content; for example, a response referring to data collection and remote monitoring would be assigned both tags.

#### Limitations

The main limitation is an overrepresentation of respondents from the UK. This skew in UK respondents may affect the generalisability of some conclusions. Due to the nature of the research and sample, all conclusions should be considered indicative and subject to further exploration.

#### REFERENCES

#### **Annex 1: Response Visualisations**

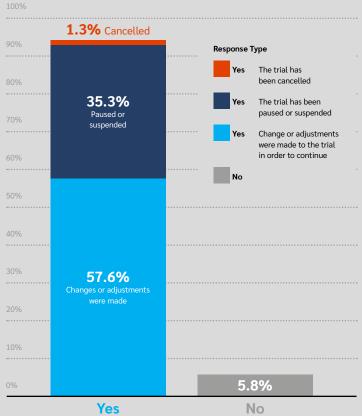
### Has the clinical trial been impacted by the COVID-19 pandemic?

Percentage of people who answered Q6.4 Q6.4 sample size = 360

This graph represents the responses to Q6.4: Has the clinical trial been impacted by the COVID-19 pandemic?

It shows the breakdown of trials that were impacted by the pandemic and were either cancelled; paused/ suspended or had to make adjustments or changes to continue. It also captures trials that were not impacted by the pandemic.

The sample size for this question was 360 respondents.

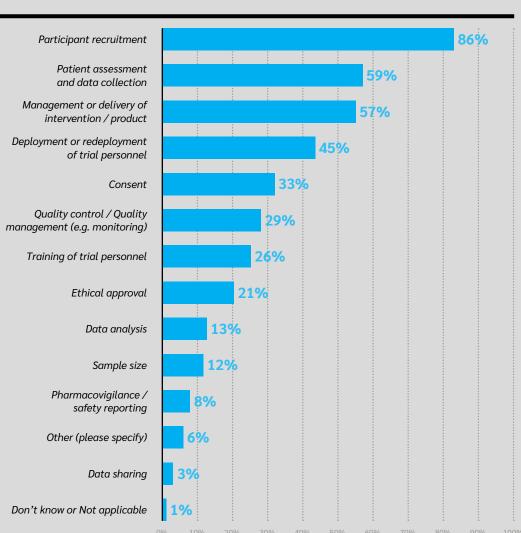


# What are the main reasons for trials being paused or suspended?

Percentage of respondents who selected the reason for why their trial was paused or suspended (multiple selection question). Total sample size = 143

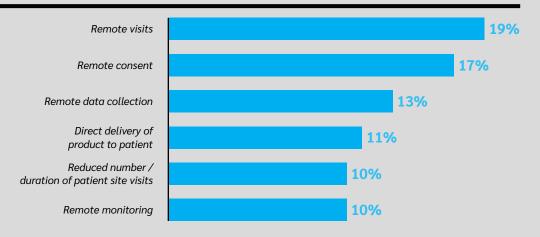
This graph represents responses to the following question: Q7.2 - There may have been specific reasons why the trial had to be cancelled, paused or suspended. Do those reasons relate to these areas below?

The total sample size for this question was 143 respondents. Respondents were able to select multiple options that applied to their experience.



## Which changes would you apply to future trials?

Percentage of respondents where part of their response related to the category tag. Total sample size = 157



This graph captures the responses of those 157 respondents who opted for 'yes' to the following question: Q10.5 Would you apply the changes or adjustments to future trials, whether or not they are run in a pandemic context? Respondents were given a free text box to write out which changes and adjustments they would apply to future trials. The qualitative responses were then tagged to their corresponding category type e.g. 'remote consent'.

This graph displays the most popular changes/ adjustments that were expressed by respondents. Remote visits, remote consent and remote data collection were the top three changes/adjustments reflected in responses.

#### **Annex 2: Report Preparation**

The survey and report have been prepared by the Good Clinical Trials Collaborative secretariat.

Nick Medhurst – Policy and Advocacy Lead

Nana Shimosako – Project Manager

Alice Barney - Team Coordinator

Isabel Smith - Graduate Trainee

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