Medrio's COVID-19 Pandemic Guide

WE'RE IN THIS TOGETHER.

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We know that the most immediate impact on the industry is the need to maintain current trials in operation. Decisions are currently being made in regard to trial continuation. In our Pandemic Guide, you will find links to critical resources, challenges the industry is currently facing, and practical solutions to those challenges.

Taking Immediate Action

Many patients and participants are withdrawing or missing visits due to COVID-19. We are here to help you think through the critical action items that are putting your trial at risk, and to offer easy solutions to maintain study continuity.

Below is an outline of areas impacted by the pandemic and actions to consider for managing your trials during these challenging times (click any to jump to that section):

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1 Trial Visits and Procedures

Immediate Considerations

- FDA recommends:
  - Stop any trial tests or assessments that will cause unnecessary safety risk to the patient/participant
  - Modify process steps necessary to protect the safety of site research nurses
  - Include in the final CSR report or in a study separate trial document:
    - Contingency measures implemented to manage COVID-19 pandemic
    - List of all participants affected by COVID-19 and how their participation was altered
    - List of decisions made when and who by, that address the impact of implemented contingency measures

Solutions

- **Medrio's ePRO** can be leveraged to identify subpopulations who benefit from prioritized telemedicine follow ups and allow patients to respond to surveys/questionnaires directly on a device of their choosing.
- **Medrio's DDC** mobile application may be used to support:
  - Home health visits where study nurses/team can visit the patient and collect data electronically without relying on an internet connection.
  - A transition to remote monitoring by replacing paper source with electronic source
- Medrio study builds and mid-study changes are quick and simple:
  - Medrio build times are the fastest in the industry and mid-study changes can be configured in a controlled and compliant manner without additional cost or reliance on Medrio staff.

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2 Data Collection

Immediate Considerations

- FDA recommends:
  - Data Management Plan (DMP) or Statistical Analysis Plan (SAP) is to be reviewed before database lock to identify how protocol deviations related to COVID-19 will be handled for the missing data.
  - At the end of the trial, the Clinical Study Report (CSR) must include de-identified data of all COVID-19 impacted patients/participants. In order to do so, tracking reasons for assessments and/or visits is crucial, in particular the flagging of missing data, if it was COVID-19 related.

Solutions

- Medrio's reporting allows you to add and filter by key values. Missing data is recorded as "Not Done" within Medrio's subgroups feature allowing you to easily identify missing data.
- When COVID-19 impact is captured in the study, subject status rules may be leveraged to automate status changes. Medrio recommends marking a new status called 'COVID-19 Withdrawn'. This will then allow study teams to easily filter where needed for reporting.
- Support decentralized data collection through:
  - The use of apps/wearables and use Medrio's bulk upload tool to import the data
  - **Medrio's DDC** with home health or telehealth visits so data can be captured without dependence on an internet connection
  - **Medrio's ePRO** to capture data directly from patients/participants
- Additional examples of **Medrio EDC**-supported changes:
  - An additional field can be added to capture the specific reason for a missed assessment.
  - Queries using customized query designations to flag COVID-19 related responses

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3 Trial Monitoring

Immediate Considerations

- Self isolation and border restrictions are prohibiting Monitors from fulfilling their site monitoring visits per the schedule required in the Clinical Monitoring Plan (CMP). We suggest evaluating the pandemic impact on monitoring visits schedules and data cleaning timelines along with updates to the CMP to reflect the response to COVID-19.
- It may become difficult for monitors to perform Source Data Verification (SDV).

Solutions

- Medrio's preconfigured reports are real-time, and our BYO and advanced reporting platforms provide highly customizable reports refreshed roughly **15 times per day.** These reports provide metadata – query counts, data and approval statuses – along with access to clinical data that may be used during casebook review and reconciliation.
- Implement **Medrio's Direct Data Capture (DDC)** and/or **eConsent** tools so that data and consent forms can be monitored remotely. Not only will this prevent unnecessary travel, but also it can save time and cost, eliminating the need for SDV.
- Another option may be to request that sites process documents to remove / redact PHI and blinding information, then make them available to CRAs in electronic format via Medrio file attachments so that monitoring may continue remotely, despite travel restrictions.

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4 Increase Safety Monitoring

Immediate Considerations

- If AE symptoms are COVID-19 related, they still must be entered as an event:
  - Any hospitalisation is always recorded as a SAE
  - Quarantined at home is recorded as an Adverse Event
  - If COVID-19 illness diagnosis is confirmed, then AE or SAE causality is 'Not Related to IP'

Solutions

- Consider configuring automatic email notifications on the Adverse Events Form to send an alert message to the study project team if AE symptom causality is 'COVID-19' or severity is 'Serious.'

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5 Informed Consent

Immediate Considerations

- Patient/Participant has the right to immediately withdraw from their study due to COVID-19 (a phone discussion is all that is needed, but this withdrawal is documented by the study team).
- Social isolation means restricting all in person face-to-face contact between the Investigator and patient/participant during the consenting process.
- Use of telehealth solutions (video conferencing) between patient and Investigator provides an opportunity for a patient/participant to ask questions and the Investigator to respond. The Investigator can also verify the patient/participant understands the nature of the trial.
- FDA recommends all changes to protocol or consent forms be updated and implemented without IRB/IEB approval or before filing an amendment to the IND or IDE; however, these changes must eventually be reported.
- Patient/Participant must sign an updated version of the consent form, outlining all study changes that have occurred due to COVID-19.

Solutions

- Within **Medrio EDC**, consider the following study database changes:
  - Subject Status is changed to 'Withdrawn' if patient/participant withdraws from the study
  - Create a 'Consent' tracking form to capture key information via the following questions:
    - » Did patient/participant withdraw consent due to COVID-19?
    - » Name of the Investigator who performed the consent telehealth or phone call consult?
    - » Date and time of the telehealth or phone call consult between the Investigator and patient/participant?
    - » Was the Investigator satisfied that the patient/participant understood the updated consent form?

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6 Essential Documentation

Immediate Considerations

- Trials which rely heavily on paper documents with wet signatures will be the most impacted.
- Trial teams will now need to use electronic signatures, and more importantly the electronic signature must be 21 CFR Part 11 compliant.

Solutions

- **Electronic Data Capture**
  - Many control or change documents can be set up as a form.
  - Approved Medrio users can log in and respond to certain questions, which help track decisions and approvals.
  - Within the monitoring function, a signature type can be set up and added to a form. This will then provide the space for an authorised user to provide their electronic signature through Medrio user access.

Regulatory COVID-19 Reference Guidelines

Click any of the images below to visit their website.

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NHMRC

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In Short?

We are all in this together. Medrio is committed to advancing the development of new therapeutics by continuing to support clinical trials currently in development. As challenges continue to mount, we are offering a proven immediate solution with an easy button. Medrio offers a unified eClinical platform that can be configured rapidly without programming and deployed in a decentralized manner. The platform includes a fully hosted **EDC database**, an offline enabled **Direct Data Capture application (DDC)**, BYOD **ePRO**, targeted remote monitoring, BYO reporting, and on-demand data accessibility. Medrio also supports bulk importing capabilities that can be used in combination with fast set-up times to rescue trials that were designed in a way that does not support a decentralized approach.

About Medrio

Medrio is the leading provider of eClinical technology for early-phase pharma, device, and diagnostics clinical trials. Founded in 2005, the company's cloud-based EDC, Direct Data Capture, eConsent, and ePRO solutions deliver fast, flexible, and easy-to-use tools for the collection and management of clinical data and patient reported outcome responses. Study sponsors and contract research organizations have used Medrio extensively in clinical trials across a wide array of therapeutic areas, with notable success in oncology, infectious disease, and more. Medrio has extensive experience in all study phases and leads the market in early-phase trials. The company serves over 600 customers globally, with headquarters in San Francisco and offices in numerous domestic and international locations. For more information, please visit **www.medrio.com**.

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