Description

The COVID-19 pandemic has “paused” many clinical trials. Moreover, it also delayed potential medical treatment for many diseases. There was a substantial shift in resources such as healthcare facilities and staff, to help COVID-19 patients. Eventually, with “stay-at-home” restrictions, trials in-progress had to find other means of collecting data and administering treatment devices or drugs at short notice. In some cases, this led to a gap in treatment and data collection.

> Are you a researcher working in a lab during the pandemic? Enago invites you to participate in a global survey on the re-opening and functioning of research laboratories in this pandemic-ridden world. The survey ends on January 31, 2021.

Slowly but gradually, clinical trials are restarting again. However, they are restarting in an era that is commonly referred to as “the new normal”. So now, we need to continue our research with an added variable, namely the COVID-19 factor.

COVID-19 Factor Challenges

Resuming clinical trials does not simply mean reopening trial sites, and welcoming participants, and staff back. COVID-19 is twice as infectious as the H1N1 influenza virus. It is still a threat and this threat needs to be managed. Restarting clinical trials brings certain obstacles:

1. ### Recruitment

   Stay-at-home restrictions mean a decrease in clinical trial enrolments. It may be challenging to enlist participants for a trial.

2. ### Travel

   Clinical trial participants may not be able to travel for treatment and monitoring.

3. **Quarantine requirements**

   Interruptions may occur if staff or participants come into contact with an infected person, requiring them to go into self-quarantine.

4. **Supply chain**

   Any interruptions in the manufacture or delivery of treatment products will cause gaps in treatment.

5. **Safety**

   All clinical trial protocols need to be updated with new safety standard operating procedures (SOPs). This includes participant and staff screening, use of personal protective equipment (PPE), and social distancing measures.

6. **Decontamination**

   SOPs to decontaminate examination areas and waiting rooms need to be implemented.

7. **Uncertainty**

   We cannot predict all scenarios that may unfold in the future. The possibility of future lockdowns or regulatory measures that arise as we learn more about COVID-19 may affect even well-thought-out plans.

8. **Costs**

   New SOPs, PPE, and extra decontamination of facilities will add extra costs to clinical trials.

9. **Missing Data**

   Some trials may have missed treatments and/or monitoring of trial participants due to COVID-19. How can the trial data still be statistically relevant and useful?

Conquering the COVID-19 Factor

The FDA has published guidelines for clinical trials during the COVID-19 pandemic. Planning and communication are key to overcoming the obstacles that the COVID-19 pandemic brings to clinical

trials. This could be an opportunity to perform clinical trials more efficiently and may even offer a few advantages:

1. **Plan A, B, and C**

   It is important to have contingency plans in place. Plan for all the possible scenarios you can think of and document plans for each. This includes delays in supplies, treatment, and data collection. Think of the statistical analyses that will make your data meaningful for each scenario.

2. **Remote access**

   The development of remote monitoring such as telephone calls and video conferencing could enlarge and broaden the sample population. Remote monitoring could, for example, make trials available to rural populations if technology allows. Besides, drones could be used to deliver drugs to rural areas for example.

3. **Record-keeping**

   Document all deviations from the protocol and record any gaps in data with explanations.

4. **Decontamination**

   Set up SOPs for decontamination between participants. For instance, leaving the room unoccupied for a stipulated period of time (depending on the air exchange in the room) between participants to ventilate the area.

5. **Safety**

   Prescreen anyone who enters the trial site, provide PPE, and enable physical distancing in waiting areas.

6. **Assessment**

   Sponsors should continually assess and oversee safety procedures of trial sites and keep up to date with emerging regulatory guidelines.

Regulating Remote Data Collection

The process of collecting clinical trial data remotely must be compliant with the relevant regulatory board. Risk-based monitoring, ensures any risks that could affect the quality or safety of a trial are

identified, assessed, monitored, and mitigated.

The integrity and quality of the data are essential. For example, telehealth solutions must meet the following principles:

- The data collection must be lawful, fair, and transparent.
- Collect only that data which is essential to meet the objectives of the trial.
- Process data accurately and keep it up to date.
- Limit storage of data that permits identification.
- Collect and store data confidentially and securely.

These requirements vary between different countries. For example, the European Union is stricter than the United States with regards to telehealth methods.

As indicated above, the privacy of trial participant data is paramount. Chat, screenshot, and recording functions must be restricted when collecting data from trial participants.

Furthermore, all trial source documents must meet ALCOA standards, they must be “attributable, legible, contemporaneous, original, accurate, and complete”.

Any changes to clinical trial protocols typically need to be approved by a regulatory review board before they can be implemented. The FDA regulations state that changes may be implemented without review in order to eliminate immediate hazards and protect trial participants. Measures to limit COVID-19 exposure would fall into this category. However, protocol changes must be recorded and reported later.

It is best to contact your clinical trial regulatory body as soon as possible to confirm the correct procedure, before restarting the trials.

Restarting Clinical Trials: The Road Ahead

Clinical trials are complex. Right from the making of the trial product to its testing and analysis, regulatory authorities need to know all the details. There are no cutting corners. The safety of clinical trial participants comes first, which is why such strict measures are in place. At the same time, clinical trials often collect sensitive and personal information from trial participants, which needs to be stored safely and confidentially.

As clinical trials restart, competition for resources and results will be stronger than ever. There is a backlog of trial research in addition to a new urgent focus for COVID-19 treatments. Further, sponsors and regulatory authorities will need to work together closely, and swiftly to conquer the COVID-19 factor challenges. Moreover, it is also an opportunity to do things differently in the future.

Have your labs restarted clinical trials? What do you think will be the challenges in resuming clinical trials? Please share your thoughts with us in the comments.

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