Data MATRIX anti-crisis solutions to ensure the continuity of trials

The pharmaceutical industry and CROs have been struggling with a number of challenges since the outbreak of Coronavirus (COVID-19), and the one topping the list which is to ensure the continuity of trials. With the emerging hurdles of enrollment, study start-up, patient retention and site visits, the situation calls for alternative models to be employed by sponsors, such as using advanced technologies, which help the companies to shake off inertia and ensure the continuity of trials with minimal losses and the highest compliance.

In their recent series of guidance the FDA, EMA, and regional Ministries of Health encourage the retention of the continuity of launched trials, and to resort to virtualizing the trials as much as possible under the circumstances. Moreover, in its recent emergency guidance, the FDA encourages trial sponsors to leverage on the technological solutions which can help to facilitate trials under the current circumstances and ensure their continuity.

Data MATRIX delivers solutions that respond to the specific clinical trial needs of our sponsors. Operating even during the challenging times of pandemic, our team is there to design the best strategy for our clients to keep obtaining clean data, while providing alternative solutions for patients' safety.

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency

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"As part of this assessment, sponsors should carefully consider the following aspects of clinical trial conduct when deciding how or whether to proceed with a clinical trial...
Assessing the continued availability of, and support for, information technology systems and any other technological tools that are needed to support the trial. Are current contingency plans adequate for the types of disruptions that might be anticipated? What other plans can be put in place to minimize any potential disruption?"....
If the technology is available, electronic methods of obtaining informed consent should be considered."...

Data MATRIX is ready to provide its solutions to each of the main types of challenges facing clinical trials:

Through the following breakdown of the key challenges which impede the global clinical research landscape, we will demonstrate how some of them can be mitigated with the application of Data MATRIX solutions.

Challenge	Solution
1 **Keeping track of the current situation development.**	Data MATRIX's fast and clean data stream allows for instant assessment of the situation regarding patient enrollment rates, diary filling-out rate, on-site situation etc.
2 **Ensure the continuity of a trial and data capture**	Data MATRIX offers solutions which can support remote site-patient interactions. **Data MATRIX ePRO** (Electronic Patient-reported Outcome) for example, enables remote collection of patient data which then goes directly into EDC. In the meantime, an investigator can track the data online and act accordingly. Also important is that data can be entered both on a sponsor-owned device as well as on a patient's personal mobile device. The solution is designed with a focus on patient centricity and patient experience with a variety of useful interface features. Patients, for instance, do not need to memorize when they need to access the app or create reminders for it. All the notifications for filling out the questionnaires show up offline as well.
3 **Need for a speedy trial start-up (e.g.vaccine trials)**	The pandemic has created a vital and urgent need for a vaccine and treatment drugs. Clearly, timelines within such studies are among the key priorities. Our EDC platform allows sponsors to launch clinical trials within the shortest timelines, speeding up the start-up by up to 30% percent, making it possible to launch a trial within 1.5-2 months. Additionally, the solution enables the quick processing and analysis of clinical data, with the guarantee of compliance, leanness and validity. This and the speed of incoming data will allow the investigators to make decisions within the shortest time, thus shortening the path from drug to patient, making **Data MATRIX EDC** a unique platform for timeline optimization.
4 **Need to stop the screening process immediately**	Within our risk-mitigation action plan such a need arose in several projects, and in response to the issues, a special code was created for DBAs to be able to perform the task.

Challenge

Need for additional lab analysis that has not been proposed by Protocol or a CRF design (especially applicable to Covid and pneumonia studies)

Solution

Data MATRIX EDC can accommodate such manipulations if the need arises, saving the crucial resource of time.

Summary

Clinical trial sponsors and CROs need patients to remain committed to study protocols, which requires the use of proven tools to retain patient engagement during clinical trials. Also, it is clear that the best strategy for all study initiators under the circumstances should be built around:

- Moving toward trial virtualization
- Mitigation of the challenges of patients not being able to visit sites
- Rapid and safe implementation of protocol amendment
- Trial participants' safety at the forefront of all considerations

Data MATRIX solutions can be customized to the best of their capacity and ensure that sponsor's trials are not compromised while ensuring that patients continue receiving treatment without being unnecessarily exposed to the unfavorable environment caused by the pandemic. We encourage sponsors to turn to eClinical in these critical times to be able to embrace and adopt decentralized and hybrid trials and ensure overall trial continuity.

Operating even during the challenging times of a pandemic, our team is there to design the best strategy for our clients to keep obtaining clean data, while ensuring patients' safety.