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Avoid these 5 real-world data pitfalls when planning your patient registry, natural history, or other clinical studies

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When clinical investigators and study coordinators start planning a new study design in the new normal, speed and efficiency are paramount.

Running a clinical study takes careful planning. Whether this is your 1st clinical study or your 21st, the last thing you probably want to do is waste resources on delays caused by easily-preventable hurdles in data collection.

Traditionally, major bottlenecks occur during study startup, eligibility screening, informed consent (including assent in pediatric studies), and patient travel to the clinical site(s). Researchers eager to get the ball rolling on their study can save time and logistical burden by stopping these bottlenecks before they begin.

Here are *five rules to overcome the major pitfalls* that can derail your clinical study.

1. **Don't toggle between multiple software to manage the study:**

   Study teams spend long hours coordinating study logistics using multiple *a la carte* tools including email, text messaging, phone, video communication, calendar scheduling, form building, and electronic signatures. Juggling all of these tools to manage your sensitive human studies may eventually get the job done, but at the cost of data quality, information security, procedural compliance, and trial efficiency.

   If this seems familiar to you, don't worry. You are not alone. Although technology has generally outpaced clinical trial demands, there were no quality, validated, secure, and affordable integrated solutions that could enable you to coordinate all the logistical aspects of the study execution in one place. The good news is, researchers have better options today.

2. **Don’t expect your clinical team to manually configure & execute the study:**

   The attrition of study subjects during screening and recruitment process is the biggest cause of study delays and failures. Not planning to automate the process means that you have set implicit expectations for your study team to do this manually. This can be a disaster, especially in studies targeting to enroll more than 100 participants.

   Be sure to select a software that allows you to automate repetitive, manual tasks and search or filter participants based on relevant factors in the patient data. Automation will not replace study members, but it will save clinical teams valuable time that can be devoted towards ensuring data quality, saving costs, and maximizing the chances of study success.

3. **Don’t confuse informed consent with collecting signatures (electronic or otherwise)**:

   Informed consent is an ethical and legal obligation for researchers using human subjects. Institutional review boards (IRBs) view the process of obtaining informed consent as *divine*. But this does not mean it has to be done manually during one-on-one, in-person consultations between subjects and clinicians like the same ol’ days.

   A clinical trial undergoes an average of 2-3 protocol amendments requiring re-consenting of study subjects. A software solution that enables the investigator team to remotely and electronically consent each participant with or without in-person site visits has now become a critical factor in ensuring study success.

   Savvy investigators will be sure to automate and integrate the informed consent process wherever possible. Cloud software that supports bi-directional communication between the study team and their subjects—written, oral, and video—flexibly facilitates informed consent and well as other routine dialogs carried out in the study.

4. **Don’t skip planning for travel restrictions that could halt in-person office visits:**

   Coordinating diverse patient groups across territories has been a major accomplishment for modern medicine. However, many studies each year shut down when recruitment goals are missed and patient retention falls off.

   Before the COVID-19 pandemic, it was common for the travel burden on participants and their loved ones to delay clinical studies. The international health crisis exacerbated this issue. Unfortunately, clinical studies that did not adapt to the travel restrictions imposed by governments, clinics, or self-imposed by would-be participants were halted or scrapped altogether. However, regulatory amendments around telemedicine and others did enable COVID-19 vaccine trials and other critical trials to continue even during the pandemic. It is now time to adopt newer tools that help achieve this for all clinical studies including the real world data collection, patient registry, and other long-term follow up studies.

   If the pandemic has taught clinical research stakeholders anything, it is that we must be nimble and flexible to complete study milestones on time. The ability to begin and complete a study that is years in the making may depend on how quickly researchers

can adapt to fully remote and touch-less subject recruitment, study visits, and communication.

5. **Don't limit your study participants to a specific mobile device manufacturer(s)**:

   Some of the tools developed to organize clinical studies work only on specific hardware platforms and mobile devices such as IOS (Apple) or Android (Google, various).

   Medtechs aiming to claim the financial benefits from appearing in exclusive app stores may not be aware of how taking this action can harm the clinical studies they sought out to support. This approach has been shown to be less effective in accelerating subject recruitment. Patient diversity is also more difficult to achieve when a single mobile device manufacturer is selected, explicit or implied. For researchers seeking equity and reach in their studies, a cloud solution that can work on a variety of mobile devices in a bring your own device (BYOD) model may be more appropriate.

To keep up with the time-sensitive demands of clinical studies, academic hospitals, patient advocacy groups, clinical research organizations (CROs), and clinical trial sponsors should make a strong effort to select an integrated, automated, compliant cloud software that can scale with their growing patient populations and can be accessed in a BYOD model at all times. At Jeeva, we are so passionate about making clinical research efficient that we conducted discovery interviews with over five hundred stakeholders in the last couple years and now have a simple, user-friendly, integrated cloud-based software platform that combines best-in-class solutions together into a single affordable cloud-based solution. Following the 5 steps above to overcome common research pitfalls can maximize the probability of success, save about 70% burden (hundreds of hours), and ensure great user experience in your clinical study.

Because each clinical study is different, researchers and coordinators must be careful in selecting the right solution for their specific study objectives. Though it may seem complicated with the growing number of options and specialties available, it is easier than you may think to choose a suitable cloud solution for your study. By adopting a checklist of key features or metrics that matter for your particular study, you can select a software solution that best fits your study needs. Then, you're off to the races, track study progress, create data summaries, and prepare for regulatory compliance audits—all in one place.

To learn more about how Jeeva SaaS addresses these and many other expensive challenges in clinical research, schedule an appointment for a free consultation or demo on the Jeeva calendar.

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