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Guest Editorial

Research Today Presents Unique Challenges We've Not Dealt with in Modern Times

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A well-oiled research team is a clinical trial sponsor's dream. An interested sponsor is a welcomed partner for an investigator, bringing him/her a lucrative revenue stream, industry prestige and, often, colleague envy. Timely enrollment goals are met, impeccable data collected, and seasoned research staff is devoted exclusively to studies. Sponsors, sites and subjects are rewarded. Once a site is a proven deliverer, repeat performances are virtually guaranteed.

Even in the best of times, conducting research can be a dilemma to navigate flawlessly. These seemingly smooth and effortless times have diminished, if not altogether become extinct due to the dreaded P word: pandemic. The worries, the whines and the woes. We are now coming upon the 3rd year of the SARS 2 Covid-19 global pandemic that continues to wax and wane, but has yet to wind down completely.

This has majorly impacted the area of research. Below are some of the key obstacles that plague clinical trial timelines:

- Subject visits occurring within protocol window in heightened pandemic peaks.
- Potential subjects' lack of commitment to enroll or stay enrolled once consented due to pandemic uncertainty.
- Subjects' apprehension of virus exposure during study visits.
- Research staff shortage due to lack of funding or interested prospects to work.
- Clinic staff shortage, pulling research staff to fill in, thus taking precious research manpower away.
- Principal Investigator and/or Sub Investigator illness, halting study progress.
- If surgical procedures are part of the clinical trial, Operating Room schedules, facilities and staff may add to the snags.
- Due to pandemic emergency approvals, country agencies, such as the US FDA, are backlogged on approvals which delay or pause study timelines.

The best research teams make sure that communication between PI, research coordinator, and entire staff are in place and occur regularly. When in crisis or survival mode, the first areas to get compromised or cancelled are staff meetings, communications, hiring,

training and studies! Sometimes it's necessary and that's alright until the crisis has passed, but then get back on track with good practices for optimal success.

When determining if your practice is research ready now, regardless if you are new to research or vastly experienced in clinical trials, carefully consider all of your strengths, weaknesses, opportunities and threats, (SWOT Analysis). Assess regularly and certainly each and every time you contemplate taking on a new study. Include your key staff to participate in your SWOT analysis. If determined that you want to proceed but are not fully ready now, work on those factors to shift you into ready now. If the answer is no, not at all, the sponsor and your staff will thank and respect you for saying no. When you all agree that you are truly ready, willing and able to proceed, then do so with commitment, determination and passion.

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