



Fallback to business as usual or the seed for a new mindset and actual change?

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2020 has been fully dominated by the pandemic which has impacted millions of people not least the healthcare industry and healthcare systems. It has forced trials to halt, site-visits to be stopped, kept patients out of their trial visits and has left us scrambling to keep trials open at all. We have had to deal with this as an industry in a time when we ourselves have been working from home, at the mercy of virtual meetings and suddenly more dependent on technology than ever (and let’s face it, we are not an industry who is most agile or keen on rapid changes).

If we think we are impacted, it is nothing compared to the healthcare system (and thereby the trial sites). Sites had to adapt overnight to either taking care of COVID patients (at an extreme workload) or trying to keep treating patients suffering with other conditions, whilst controlling the risk of spreading infection amongst personnel and patients.

Although the pandemic is far from over, I do believe recovery can and will start soon. The big question is if we have the “strength” to change and do things differently. Can we use this disruption as a re-set to get some (desperately needed) more substantial change going? Can we use our learnings as an industry after being more dependent on technology than ever (both in the work and private setting)? Can we use the development speed of the vaccines as proof that things actually *can* be done radically different?

I’ll try to predict the answer to some of these questions through a more concrete example of trial recruitment and execution back up and running. Here, it is easy to look at the “pre-pandemic” trends like patient centricity, virtual trials etc., developments that introduce new interaction-paths and new technology. And, yes, the pandemic will surely give this development a push, though most trials are not there yet. For 2021 – and to get clinical trials back up and running - sites are still key.

Whether it be prediction or hope, I do think we need to get the sites going again and get them to *want* to be running trials again. And to do that, we must put sites in the centre for a while. I think the companies that will succeed with enrolling sites and get trials and recruitment “re-started” will be the ones that can offer a solution and a support that actually works for the sites. Companies that truly take a holistic view of the reality of the trial sites; what works and what does not, those that have a dialogue with sites on feasible solutions for virtual site visits and remote SDR/SDV etc., those that are striving to combine IRT, EDC, ePRO etc., in the best way for the site and not because they are preferred by the internal functions at the CRO or sponsor. Companies that implement solutions such as site portals (TTC TrialHub, Longboat and Firecrest) are helping the site first – not the sponsor.

We must realize that we, the sponsors and CROs, do this for a living. For sites, it is, in most cases, an “add on” to their core work and mission. Although we might be spending our entire work-day using a system, the vast majority of users and usage-hours are not coming from us but the site personnel. Hence, the overall technology “solution” must be put together with the site in focus. Not solely, and not at the expense of sponsor/CRO processes, but in focus. How many of us can honestly say that that’s the way our trials are set-up?

My prediction is that if we succeed, 2021 can be a year not only of recovery, but also the start of breaking up some of the outdated approaches and set-ups. If we fail, 2021 will be another year of survival, scrambling to get our trials - at best- not closed.

We will not see a revolution or leaps of evolution in 2021: we will not (sorry to say) have the strength for radical change. However, we will see small things that have a significant and differentiating impact. Small changes in practice but representing a fundamental difference - a *change in mindset*, things *can* and *should* be done *differently*.

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