

Modern Technologies & Partnerships Enabling Next Generation Patient Centric Research.

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Since time immemorial, the clinical trials process has been principally driven by a site-centric approach i.e. face to face interactions at the site. While this has been the default in an era where digitalization and smart mobility was not widely prevalent, the evolving technological landscape has unearthed many inefficiencies in the existing process that were hitherto unknown. To name a few, physicians are compelled to base their conclusions on single point evaluations obtained at the site-patient visits. In addition, often events are picked up 'behind the facts' i.e. when the patient actually reports it during face to face meetings, or in some cases they are simply missed. All these scenarios may have serious safety implications. Patients, as well are required to spend many hours traveling to the site, need to wait for odd hours in waiting rooms, etc. that puts an extremely high burden on their normal way of living. Some patients might also feel uncomfortable and stressed in a hospital setting, the so-called 'white coat syndrome', reflecting in their elevated measurements and activities, thereby providing an incorrect assessment of their actual medical condition. In addition, the current site-centric approach focusses predominantly on patients living near a site location, leaving others with no opportunity to participate. Equitable access to clinical trials is also compromised across other levels: e.g. visually impaired or motor-disabled patients might be unable to read the written study instructions or complete the assessments.

For many years, we talked about 'patient centricity' and multiple initiatives as well were launched (e.g. eConsent^{[1][2]}, eLabel^[3]) but if we look to its broader implementation, it really lags behind. Why? First of all, the traditional business case model might not be so evident for programs focusing on qualitative benefits for patients. Secondly, the big "what if", "can we do this", "what about privacy" "what will health authorities say" questions are deeply embedded in the psyche of life science companies, making it hard to roll out new approaches or newer ways of working. Third, product technology companies too have jumped on to the 'patient centricity' bandwagon, with more than 300,000 mobile health apps^[4] launched across various app stores, but which consumer will ever find its way through this dense jungle of independent and non-integrated technology solutions? We really need to significantly change our way of working if we truly want to talk about patient-centricity.

Impact of Covid-19 on clinical trials

The current widespread COVID-19 pandemic has till now affected roughly 10 mn. people^[5] worldwide and had rendered many countries and economies helpless with its rapid pace of outbreak. It had compelled many countries to adopt strict lockdown measures and social distancing norms. Fortunately, quite a few countries have relaxed lockdown measures and moved to a 'restricted' normal, being extremely mindful of the fact that the fight against this epidemic is not over yet with a second wave of breakouts very likely. Life Science companies are working around the clock to develop a vaccine but even the most optimistic timing to have it available on a broad world scale is somewhere in 2021^[6].

Clinical Trials have been significantly impacted by Covid-19, with social distancing guidelines completely freezing face-to-face interactions at the site. Ongoing studies have been put on hold, while planned studies too have seen cancellations. The most debilitating impact has been on clinical research and development of much-needed novel drugs for critical ailments such as cancer, dementia, coronary heart diseases, Parkinson's, etc. that have seen its clinical trial activities paused.

However, Covid-19 has also demonstrated that patient-physician interactions can be carried out remotely (e.g. skype), that vital signs and others assessment can be done remotely (e.g. smart devices), that adopting other engagement models (e.g. local physicians, home nurses) are possible. Patients across age groups (especially senior citizens who were totally not yet familiar with these technologies) have learnt and adopted mobile technologies. And it has worked. Did it manifest smoothly? Absolutely not, but it surely opened our eyes to the fact that novel technologies or alternative way of interactions are not all so complex or scary to use, that they can work efficiently, that they can bring value, etc.

So let's take these learnings from this pandemic crisis to see how can we further improve existing solutions, what are the real needs of patients and sites, how to better support and train, how to re-think and streamline the tsunami of standalone and non-integrated technologies. Only by working together on solutions that truly benefit the industry and patient fraternity will empower us to overcome future pandemics adroitly and with minimum possible economic, social and human impact.

The birth of true patient-centric trials and next generation of clinical research

So how do we imbibe our learnings of the Covid-19 pandemic into account and move to a state that eliminates the inefficiencies linked with the traditional site-centric approach described earlier? How can we move to a world where clinical trials is embedded into the daily lives of patients – a concept also referred to as decentralized trials or virtual trials? And can we even move one step further and start leveraging technology to support a novel way of conducting research?

Within TCS, we have been leveraging our in-depth modern technology knowhow from diverse industry sectors such as banking industry, life sciences, healthcare, etc. This, combined with our extensive hands-on business expertise in clinical, regulatory and safety domain and in close partnership with pharma companies, patients, sites, suppliers and many others has enabled us to develop innovative solutions that can move the needle in patient-centricity and help us reach the next frontier in clinical research.

Listed below are some of focus areas of TCS Connected Clinical Trials (part of TCS ADD platform) to incorporate clinical trials in patient's personal life:

- **Consent:** shift from the traditional site-based consenting process to an electronic multimedia consenting, accessible any time, any place and integrated with other clinical systems (e.g. RTSM/IRT)
- **Connect:** enable virtual and secure patient-site connections, and where needed supplement with face-to-face interactions via at-home nurses services, local office treating physicians, etc.
- **Guide:** provide personalized, real-time and motivational notifications, easy-to-understand instructions and alerts to support patients at home during the jungle of assessments and/or to support local nurses & physicians with the patient assessments.

- **Collect:** enable real-time and automated data collection at home via mobile devices, smart medication, smart devices, wearables, etc. and equip, and if necessary, alert, sites with e.g. data of vital signs, medication intake, adverse events, images to maximize patient's safety and wellness.
- **Track:** enable automated analysis, oversight and tracking of various trial activities, e.g. medication delivery, laboratory and blood collections, to improve data quality and integrity and patient's safety.

Technology can act as a great enabler in achieving all of the above scenarios and enable broad patient's access to clinical trials, any time, any place, and irrespective of their location or additional disabilities. For example, audio and voice-enabled technologies can support visually impaired or motor-disabled patients.

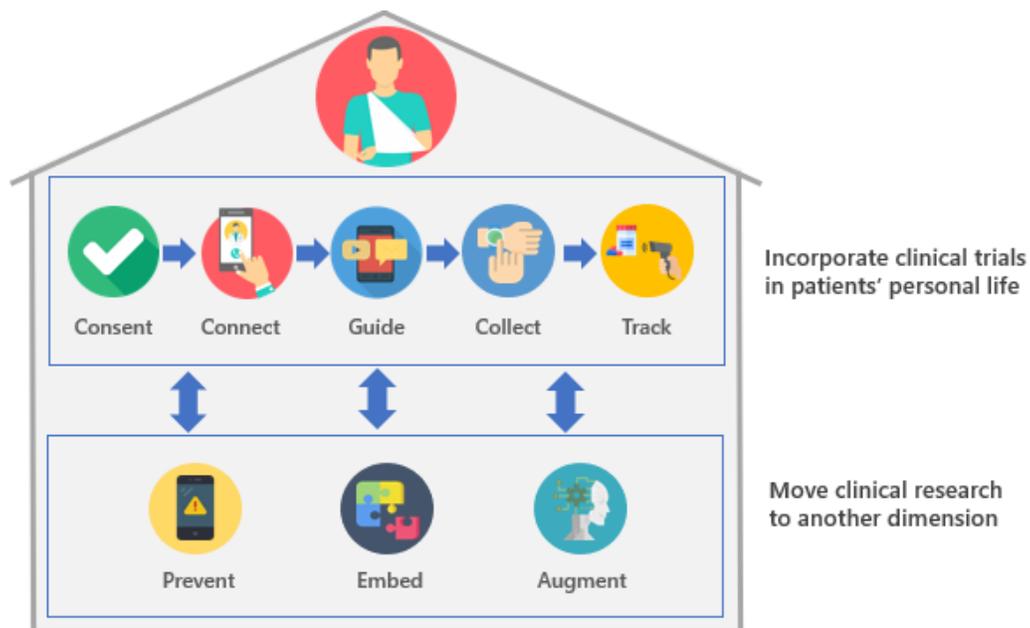


Figure 1: Modern technologies enabling the next generation of patient-centric research

When looking to the next level of drug development, TCS' patient centric focus can be categorized into 3 domains:

- **Prevent:** enable predictive and preventive models by leveraging cognitive and real-time analytics to monitor patient condition and behaviour and pro-actively avoid certain events, with potential safety implications, to occur.
- **Embed:** establish novel ecosystems, involving diverse clinical and healthcare partners to provide a seamless and invisible transition between clinical research and healthcare.
- **Augment:** enable novel insights and data models by leveraging the power of artificial intelligence, machine learning and cognitive analysis on the huge quantum of structured and unstructured data. Electronic medical records, social media, devices, etc comprise some of the data flows that are often beyond the realms of human handling capacity.

To note, most of these technologies already exist and have proven their value in other industries as well and some forward-looking companies did already step into it together with TCS. Thus, let us not be scared to be bold and redesign the entire clinical research domain with the patient at the centre.

The need for cross-industry ecosystems and partnerships

There is a very well-known adage, 'If you want to go fast, go alone. If you want to go far, go together'. Partnership and collaborations is part of TCS' DNA. Building truly global ecosystems that symbiotically bring various industries and services together, drive digital partnerships and enable collaborations between sites, patients, ethics committees, health authorities, pharma companies etc is the only effective way we will be able to achieve true patient centricity and speed up the development and access to new medicines for patients in need.

In addition to pharma companies, let us a look at other partnerships that TCS Life Sciences & Healthcare is focused on –

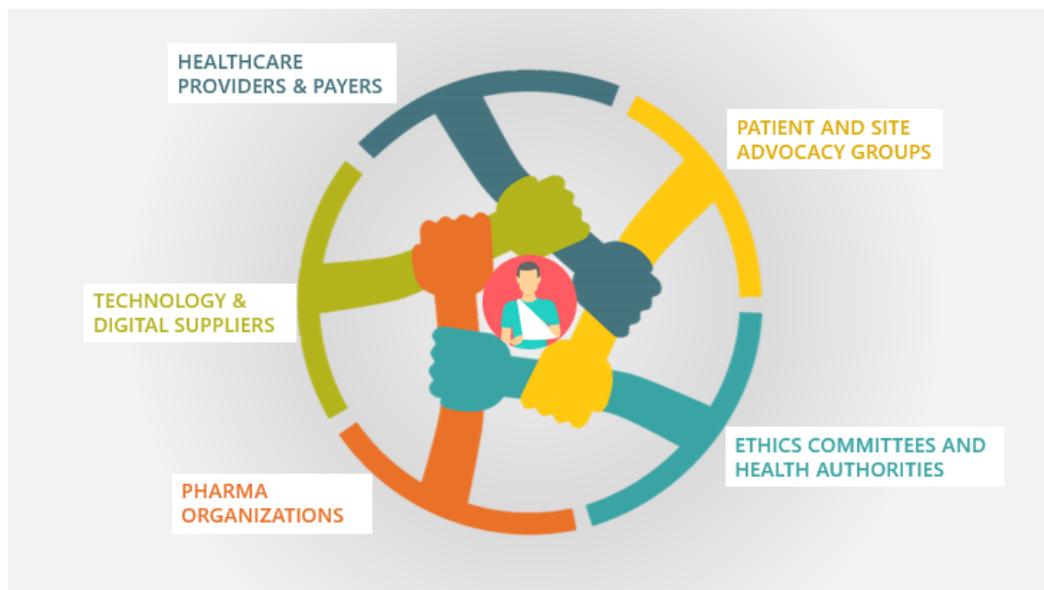


Figure 2: A few key cross-industry collaborations with patient at the center

Clinical Trial stakeholders: involve patients and sites at every step of the clinical trial process, starting from the early design phase, augmented by TCS research facility labs for hands-on experience. Also, the incredible value of seeking early input of ethics committees, health authorities, etc on novel technologies and approaches in clinical research is a domain that often remains significantly underestimated but that needs to change.

Technology and digital suppliers: enable seamless integration between various systems, smart devices, wearables, etc using a flexible, plug and play platform, respecting the unique features of each solution. Adopt a single sign on, single source of truth and most importantly single app or portal interface for patients and sites.

Healthcare providers and other organizations: establish novel ecosystems & partnerships with healthcare providers, @home services, patient and site advocacy groups, payers, etc to name a few.

Collaboration and partnerships cross-industry and feedback loops should become the new normal.

Each company acts in line with their capabilities

The Covid-19 pandemic situation has prompted responses of diverse magnitude from pharma organizations around the world. Some companies have rapidly implemented basic digital functionalities to support critical studies, others have adopted a more holistic view by halting its current research and exploring an integrated approach to be prepared for the future. Each company has devised its own roll out plan, in line with their internal & external infrastructure, skill and resources.

It is, however, imperative that all pharma companies evolve their vision and do not fall back towards the traditional site-centric approach once the Covid-19 pandemic is over and its lockdown restrictions are released. It is important that all stakeholders understand, imbibe and embed the lessons learnt during the pandemic.

Conclusion

The Covid-19 pandemic has been a negative chapter for the entire world. However, it has also taught us valuable lessons on the current functioning of patient-centric clinical research process with its fragmented and isolated technology landscape comprising of 300,000+ health apps. It has also highlighted us of the various internal and external clinical systems and the numerous disconnects and inconsistencies in place. More importantly, It has opened our eyes towards an alternative and achievable approach, thereby suggesting that the big “what if”, “can we do this”, “what about health authorities” etc. questions are really not as scary as they sound.

Covid-19 has opened up a world of opportunities to move to the next generation of clinical trials augmented by digital technologies and with patient at its centre. Clinical trials accessible for any patient, any time, any place and in line with their personal preference is possible. Providing personalized support, enabling automated and integrated processes and even moving towards preventive and novel research are just some examples of what the future promises to hold. Let all of us come together, make the digital-led approach work, drive true patient centric clinical trials and effectively bring medicines that are required the most to the patient that need them the most.

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