wipro.com

Clinical Trials at a Digital Inflection Point

Clinical trials are regulated and required to bring new, safe, efficacious and innovative medicines to market. However, the clinical trials' phase, in any new medicine development, is the most time consuming, costliest stage and often the molecule being developed does not make it to NDA filing.

Over the years, the Pharmaceutical industry has invested heavily to try and reduce cycle times and costs in clinical trials, while improving quality and rates of success. In the mid-to-late 1990s through clinical trial process redesign, in the early-to-late 2000s through Business Process Outsourcing (BPO) and in the 2010s though targeted initiatives such as risk-based monitoring. However, none of these have succeeded in having a true transformational effect on the overall clinical trial process. In fact, the overall cost of bringing a new medicine to market has continued to escalate and there has been no significant change in clinical trial cycle times. A study by a US-based academic research group pegs the drug development cost at over $2.5 billion.

Now, however, just as convergence of digital technologies is beginning to have a profound impact on the business models of many industries, they offer similar transformational potential when applied to the clinical trials process. For example, in recruitment of patients and monitoring of the clinical trials, digital technologies offer unprecedented opportunity to re-engineer the process entirely and do things in a truly transformative way. And this benefits all stakeholders involved in clinical development – the subject (patient), the physician (investigator), the clinical trial organisation and the pharma company.

"Large scale adoption of digital technologies in clinical trials holds significant promise in bringing innovative medicines to market faster without compromising quality or escalating costs, when applied across development areas such as protocol design, recruitment and monitoring of patients, and data verification and analysis. They also support pharmaceutical companies' execution of strategies in going "beyond the pill," and not just providing treatments, but better outcomes for patients, Providers and Payers," says

Abhishek Singh,

Practice Director, Healthcare & Life Sciences at Everest Group

Taking a deep digital dive

When we subsequently refer to a digitalized clinical trial, we will refer to a clinical trial that leverages the convergence of Mobility, wearables, IoT with Cloud-based Clinical Data Warehouse, Analytics and Integration to a pharmaceutical company's existing e-clinical systems.

Companies have been conducting limited pilots, leveraging the digital ecosystem in selected areas for a while, e.g. recruiting patients for a single clinical trial leveraging digital channels. The industry has collected early proof points that they have been able to reach a larger and more geographically dispersed eligible patient population faster. We are now entering the exciting stage where companies are making bigger bets and are starting to incorporate digital into their strategy. For example, Sanofi's stated policy to include a "Digital Health Strategy" with the development of each molecule or Novartis' partnership with Qualcomm to start a Digital Venture Fund or Pfizer's collaboration with IBM in utilizing IoT to manage Parkinson's disease.

Digital technologies in clinical trials offer opportunities to improve quality, timelines and costs (see Figure 1).

Impact On	Clinical Trial Design	Site Initiation & Recruitment	Site Monitoring	Data Management & Analysis	Clinical Trial Reporting
Quality	✓	✓	✓	✓	✓
Time		✓	✓	✓	
Costs		✓	✓	✓	

Figure 1: Clinical Trials Process – Touch Points

Clinical Trial Design: All clinical trials start with a synopsis and later the writing of a full clinical trial protocol, outlining the clinical study and its target end points. At the moment, this is a "one-size fits all" for the patients involved.

In digitalized clinical trials, sensors and disposable devices, such as smart pills, small digestible cameras, will allow for a much higher volume, granularity and accuracy of data that can be collected. This data will enable research to leverage insights derived from it and feed back into the clinical trial design process to make protocols more patient centric. For example, sprucing up the patient selection process by letting stakeholders know

which subjects respond better to the therapy, reducing the number of patients that may be exposed to unwanted side effects, adjusting the number and types of procedures through a better understanding of the patient type, et al. This continuous stream of data will also feed into the early stages of development and be an enabler of personalized medicine development and, ultimately, personalized healthcare.

Site Initiation and Recruitment: Better targeted protocols will, in turn, lead to higher recruitment rates and improved patient retention rates, as protocols are focused on a specific patient type. In addition, the ability to provide constant insights into their health and the knowledge that somebody is monitoring their data can help make patients feel at ease about the clinical trial. This, in turn, can help spur increased interest in participation, higher recruitment and retention rates. Companies will increasingly use new media channels to recruit subjects (patients) for clinical trials.

Site Monitoring: Digital technologies will open up avenues to continuously collect, analyse and transmit patient data back to the clinical trial team. It will allow for passive clinical trial adherence for the patient, with as little inconvenience as possible. For instance, it will bring down/remove travel time to clinical trial centres. For the pharmaceutical company, it can significantly reduce monitoring efforts and costs in terms of limiting data that needs to be reviewed and cut down unnecessary monitoring visits to the clinical trial centres.

Data Management and Analysis / Clinical Trial Reporting: The direct capture of clinical trial data from connected devices will significantly reduce the number of on-site visits and Source Data Verification (SDV) required. This will help reduce trial costs and enable the pharma company to lock their clinical database faster for subsequent analysis.

Spinning a holistic plan

While technology is a key enabler of the digital journey in the clinical trial process, this requires alignment with digital strategy, organization and process.

Companies should start by defining a comprehensive **strategy** for how they would implement digital across their clinical trials. Perhaps the biggest decision is: whether the digital strategy for clinical trials should only focus on enabling the trial itself or if it should also be part of supporting differentiated claims about the molecule being developed.

Digitalization of clinical trials will make it necessary to create new roles and align the **organization** to the digital needs. For instance, there may be need for a Clinical Trial Board to decide on an overall digital strategy and direction for implementation. A Digital Clinical Strategist, who will be

part of the clinical project team, will take the lead in defining which aspects of the clinical trial to apply digital to and then enable it. Implementing new competencies in the data management and statistical analysis team will be required as there would be changes to the data management and statistical analysis plan to cope with a continuous stream of data. Clinical IT will also play a key role in the clinical project team to integrate and handle large volumes of data.

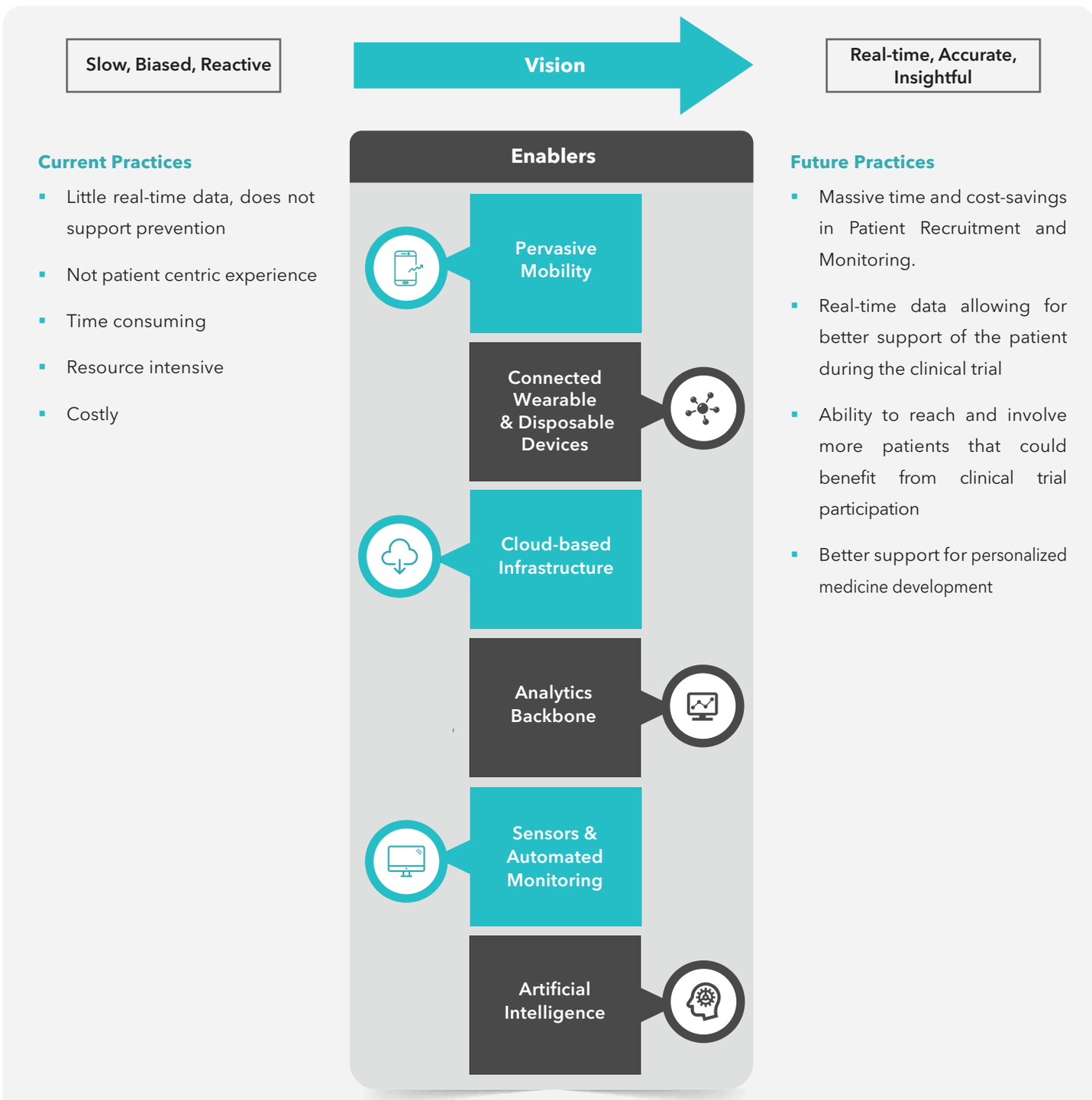

Figure 2: Enablers Of Digital Trial

Implementing a digitalized clinical trial requires a complete technology-led rethink of the clinical trial process. For instance, recruitment of patients may mean digital marketing/social media skillsets for the clinical trial team. How should data be collected and analysed? There may be a need to integrate digitally collected data with any other non-digitally collected ones, validation of digital versus non-digitally collected data, new procedures, SOPs, templates for the data management and statistical analysis. How and when to use the technologies may be good for Phase I studies, whereas for later phases of the trial there will be a need for FDA-cleared medical devices. Other potential hurdles to digitalization include infrastructure, validation, security of clinical trials.

Moving toward better outcomes

Digitalization of clinical trials will soon become the norm for the industry. It also holds the promise that in the not-too-distant future Pharmaceutical companies will not just treat diseases but also have the digital tools to support patients managing their disease, after the medicine has been approved, with better outcomes for patients, Providers and Payers.

About the author

Hans Poulsen is a Consultant for Wipro's Health & Life Sciences business. Hans has over 20 years' experience in consulting for Health & Life Sciences companies and R&D organizations. He has published and spoken extensively on growth and innovation strategy for R&D organizations and has had his work covered by the FT, Reuters and the Nikkei Investor Daily. He has presented at industry conferences at the Drug Information Association (DIA), Citibank Investor Conference and Wharton School – Mack Institute for Innovation Management.

About Wipro

Wipro Limited (NYSE: WIT, BSE: 507685, NSE: WIPRO) is a leading information technology, consulting and business process services company that delivers solutions to enable its clients do business better. Wipro delivers winning business outcomes through its deep industry experience and a 360 degree view of "Business through Technology." By combining digital strategy, customer centric design, advanced analytics and product engineering approach, Wipro helps its clients create successful and adaptive businesses. A company recognized globally for its comprehensive portfolio of services, strong commitment to sustainability and good corporate citizenship, Wipro has a dedicated workforce of over 170,000, serving clients across 6 continents. For more information, please visit **wipro.com** or write to us at **info@wipro.com**.

DO BUSINESS BETTER

CONSULTING | SYSTEM INTEGRATION | BUSINESS PROCESS SERVICES

IND/BRD/NOV 2016-JAN 2018