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Pharma's Clinical Ops Digital Maturity: Patient Experience Tools Lag

by Anju Ghangurde

Digital maturity of clinical operations at several big pharma firms varies significantly with the gap between best-in-class and the industry average narrowest for site selection tools, recruitment capabilities, and automation, a study has indicated. Digital patient experience tools figure among the least mature capabilities.

Digital patient experience tools and automation platforms are the least mature capabilities in clinical operations across a set of global pharma firms, though industry's overall digital excellence maturity score rates as 'fair', a recent report by DT Consulting has indicated.

The study, which surveyed senior clinical operations leaders across 12 large-to-midsize pharma companies saw some firms rate their maturity as excellent, though "neither the industry as a whole nor any individual capability is", the assessment indicated. However, the average maturity across nine capabilities was rated as "good", most notably site selection and data capture tools and technologies.

Companies covered in the study were *Janssen.*, *Gilead.*, *MSD*, *Sanofi*, *AbbVie.*, *Bayer*, *Bristol Myers Squibb Company*, *GSK*, *Pfizer.*, *Otsuka.*, *Bharat Serums And Vaccines* and *CSL Behring*.

Francesca Properzi, director, DT Consulting, told *Scrip* that one of the key reasons why patient experience tools were less mature than other capabilities is the concern about patients' ability to use these tools and this apprehension starts from clinical investigators.

"More evidence and use cases are needed to develop best practices and to increase adoption. There is also a factor related to costs that shouldn't be underestimated," Properzi explained.

Costs and change management processes are also behind the lack of maturity of automation capabilities. The executive cited the example of robotic process automation, a platform which

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holds significant potential in reducing timings and streamlining repetitive, time-consuming tasks.

On the role of wearables in improving patient experience and enabling better data aggregation and new clinical endpoints, Properzi said she sees "unprecedented potential" for such devices to improve not only patient experience, by reducing travel requirements to clinical sites, but also better disease surveillance to prove the safety and efficacy of drug candidates.

A study published in *BMJ Open* had previously found that the number of trial clinic visits (which ranged from two to 166) was the second key driver of trial costs after the largest single factor namely the number of patients required to establish treatment effects. The study's statistical model showed trial costs rose exponentially with these two variables; virtual technologies can pare these, DT pointed out last year.

Decentralized Trial Technologies An 'Encumbrance' For Site Personnel, US Survey Shows

By Vibha Sharma

19 Dec 2022
The Association of Clinical Research Professionals says the perspective of personnel working at clinical research sites must be taken into account to ensure the effective implementation of decentralized clinical trials.

Read the full article here

Nevertheless, significant challenges exist with the integration of wearables into clinical trial processes. Data access, choosing the correct wearable device for the type of digital endpoints needed, and communication/education to patients are all factors that still limit their usage in clinical research, Properzi explained.

"From our conversations with senior leaders, we know that regulatory approval can still be a significant burden. More case studies are needed to facilitate the adoption across the industry and collaboration between key stakeholders."

Such co-operation is clearly vital more so given pharma's efforts to accelerate the adoption of decentralized clinical trials (DCTs) that often turn to technological solutions such as wearables, direct-to-patient portals, online recruitment platforms, for various activities but may pose certain challenges at the site level. For instance, a recent survey by the US-based Association of Clinical Research Professionals, among a string of findings, indicated that DCT technologies were an "encumbrance rather than an enabler" for site personnel (see side bar).

Industry experts have also long emphasized that before integrating a wearable device into a study, it is critical to evaluate factors such as the 'fit-for-purpose' validation and whether the

regulatory classification supports the use case, besides assessing privacy and security aspects. (Also see "*'Let's Be Ambitious,' EMA Official Says Of Tackling GDPR Issues In Clinical Trials*" - Pink Sheet, 31 Oct, 2022.)

While wearables were being deployed in trials even prior to COVID-19, the pandemic perhaps added further momentum to their use amid the huge thrust towards digital health technologies. In 2018, management consulting firm Kaiser Associates had estimated that by 2025, 70% of trials would incorporate wearables.

Leaders, Laggards Struggle Most With Same Capabilities

DT Consulting's study, based on self-reported maturity, also indicated that the most digitally mature firm excels in majority of capabilities, but strikingly outdoes the industry in data capture technology, study design, and participant experience tools.

In contrast, the gap between best-in-class and the industry average is the smallest for site selection tools, recruitment capabilities, and automation, the evaluation that applies the consulting firm's Digital Excellence Maturity Assessment (DEMA) framework indicated.

"Leaders and laggards succeed and struggle the most with the same capabilities," declared the consulting firm which is part of Indegene, a digital-first, life sciences commercialization company.

DEMA evaluated pharma's ability to apply digital technology to end-to-end study execution and the participant experiences that ensue. It scores maturity based on overall capability creation and adoption.

The study group firms also rated themselves highly in capabilities such as site selection, patient data capture/analytics, though Properzi asserted that industry's digital maturity in these areas is good but still not excellent. "There is still a good margin for improvement, particularly in the adoption of the most advanced best practices, related to capturing clinical sites and participant experiences as well as data integration," she stated.

It's, however, important to note that the digital maturity score is not calculated based on the level of adoption but on the number of best practices that the clinical operations teams "deliberately and consistently" follow to enable certain capabilities.

Digital capability in screening and consent was among the areas which reflected a significant gap between the best company in the study and industry average. On the reasons for the divergence given that eConsent was seen as among the most frequently adopted technologies during the pandemic, Properzi noted that eConsent is one of the capabilities for which best practices are crucial to delivering value. "Best-in-class companies excel in delivering an efficient process".

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Aligning Budgets With Strategic Objectives

The consulting group's report, which applied the DEMA framework to clinical operations organizations in large pharma firms for the first time, also indicated that most of the companies in the study had a definitive vision and strategy for digital transformation in clinical trials and saw areas like the adoption of decentralized approaches as pivotal; organizational budgets, though, weren't always aligned with the strategic objectives.

Properzi said that while most firms had dedicated budgets to digital transformation projects, just half dedicate a budget to patient experience improvement even though they say it's very important.

"The challenge in aligning budgets internally to consistently deliver on digital capability is significant for most large pharma companies. COVID-19 had certainly an impact on digital organizational readiness but companies still need to find an alignment of interests across different departments," the executive stated.

Over 40% of the firms in the survey indicated that the strategy for digital transformation of their clinical operations wasn't aligned with departments such as medical affairs and commercial, but they were working on that aspect. (The base number of companies may vary in the study depending on the number of firms that responded to specific queries).

Indegene CTO On Pharma And Blockchain's Promise Of Better Accountability, Trust

By Anju Ghangurde

09 Sep 2022
Indegene's chief technology officer, Tarun Mathur, talks to *Scrip* about blockchain's potential in a number of areas across pharma's operations including the clinical supply chain and trials as well as its role in enabling improved trust in the healthcare data ecosystem.

Read the full article here

Industry experts have over the recent past emphasized that a siloed approach isn't ideal as companies embark on a wider digital transformation effort, though there may, at times, be some fundamental boundaries around compliance aspects. (Also see "*Boehringer Ingelheim's Formula For Scaling Transformation, Digitization*" - Scrip, 27 Sep, 2022.)

A senior executive from Bayer had earlier underscored that digital should not exist in a silo or solely for the purpose of 'doing digital' but needs to have a close business partnership with the P&L [profit and loss]-holding functions of the organization. "It exists for the purpose of engaging with customers, driving business results and better education of healthcare professionals/patients/payors and ultimately contributing to health outcomes," Brian Cantwell, vice-president, digital strategy and operations at Bayer Pharmaceuticals, US, stressed at the

time. (Also see "*Bayer Execs On Digital Acceleration, Getting The Building Blocks Right*" - Scrip, 29 Sep, 2020.)

Properzi said that a key concept of digital transformation is the focus on the customer experience and insights-driven customer service; this should not take place in a silo-ed approach and pharma leaders do recognize this the survey suggested. At the same time, however, certain processes, tools, and systems are purely for the purpose of clinical operations versus medical affairs and commercial.

"Other processes and tools may not be combined from a compliance perspective. These are substantial hurdles to a holistic digital transformation approach," she added.

DCT Approaches Are Here To Stay

The DT Consulting study signaled that 33% of the companies had allocated a budget to digital transformation to support trial sites while 58% set aside a budget to decentralized /virtual clinical trial projects.

While there is an increasing trend towards DCT approaches "which is here to stay" Properzi said it is also creating challenges for allocating specific budgets, such as "covering costs and compensation for sites using technology and also managing expectations of different departments involved in DCT implementation".

The seeming momentum towards decentralized trials notwithstanding, 33% of the companies covered did not have a leadership position that includes a remit around that area. Properzi said that data was indeed very surprising.

While the change of organizational culture towards digital is not perceived as a challenge by senior leaders, "there is a misalignment of digital strategy and drivers/objectives versus budgeting. This is a very important topic for senior leaders and one that was frequently raised during our discussions; they feel this is an issue to be addressed as a priority," she explained.

Include Patient Feedback In Best Practices

The report also sets out four main actions to propel pharma's clinical operations towards digital excellence, emphasizing that a key competitive differentiation will be to integrate the voice of the patient in all clinical trial processes; closing the 'digital efficiency and effectiveness gap' is another area to focus on.

The consulting firm said that best-in-class firms include participant feedback in their digital capability best practices, starting from study design and preliminary trial stages for protocol optimization.

“Hybrid and fully decentralized trials are making it increasingly important to identify patient needs and expectations to avoid poor recruitment rates or patient disengagement during the course of the study,” it said.

The study also talks about aligning budget, skills, and talent to make clinical trials future-ready and to draw from best-in-class customer experience not only in the pharma industry, but also sectors like media, retail, and travel.

Properzi said that there are several lessons that pharma can learn from other industries. For instance, in areas like dedicated content to engage with customers along the entire customer journey, keeping them interested and motivated. (Also see "*Digital Acceleration And ‘Broken’ Customer Experience: What Pharma Should Look Out For*" - Scrip, 29 Sep, 2021.)

She referred to how Netflix uses data to analyze and categorize content and understand which categories fit which specific group of people best. The use of a content management system sees "who is visiting your website, what they are looking at, and any information they provide, with this data, you can tailor the content to the specific customer", the executive added.