C-Suite Survey Underscores Digital Technology's Growing Role in Clinical Trials

APPLIED CLINICAL TRIALS

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Findings from the most recent Biopharma Confidence Index show that the pandemic has substantially influenced biopharma executives' expectations in key areas like artificial intelligence/machine learning and real-world evidence.

The COVID-19 pandemic has swiftly altered the course of clinical trials globally. While much attention has been paid to its negative consequences, a recent set of surveys suggests COVID-19 may act as a pivot-point and change agent in four areas of the biopharma industry:

1. Digital technology
2. Artificial intelligence (AI) and machine learning
3. Regulation
4. Real-world evidence (RWE)

Several findings in the most recent Biopharma Confidence Index (BCI) show that the pandemic has substantially influenced biopharma executives' expectations in these key areas. This article will present those findings, as well as discuss some of their practical implications for clinical trials going forward.

Survey description and selected findings

The BCI is designed to measure the confidence of the industry's C-Suite and executive leadership. Respondents represent biopharma companies with facilities in the United States, Europe, andthe Asia-Pacific region. The survey includes 259 questions about six key business indicators: capital markets, deal landscape, clinical development, regulatory affairs, commercialization, and business model and workforce.

The latest BCI survey was conducted twice:

- in November 2019, just before the novel coronavirus was identified (n=113).
- in April-May 2020, after the implementation of regional lockdowns due to COVID-19 (n=133).

Both surveys asked identical questions to enable valid comparison of executives' sentiments pre- and post-COVID-19. In this article, we'll specifically focus on takeaways gleaned from two questions:

- Question 1: "Over the next 12 months, what is your confidence that the *[element]* will have a positive impact on the biopharma industry?"

Responses indicate that executives' sureness in digital health technologies rose 25% and their convictions about AI and machine learning increased 15%, but their confidence in the positive impact of the regulatory landscape dropped by 25%. (Other results will remain outside the scope of this article.)

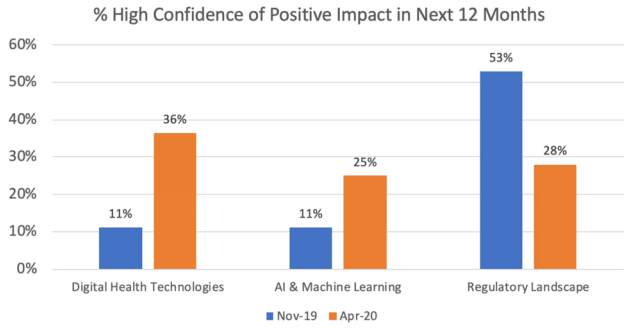

Figure 1: % High Confidence of Positive Impact in Next 12 Months

- Question 2: "What is your confidence whether that the following innovations will positively impact the biopharma industry in the next 12 months?"

Responses show that the percentage of executives who believe real-world evidence (RWE) capability will increase significantly went up by 12%. (Other results will remain outside the scope of this article.)

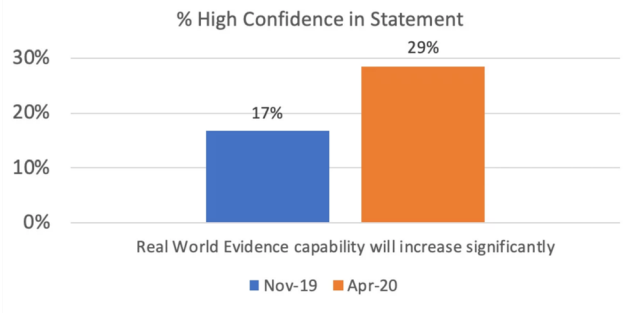

Figure 2: % High Confidence in Statement

An interconnected picture

With all of the data collected by the BCI surveys, why emphasize these particular findings?

As we reviewed the data, many of the results simply confirmed already well-documented industry trends. However, the meaningful change in confidence surrounding digital technologies, AI/machine learning, RWE, and the regulatory landscape may reveal a larger interconnected picture.

Digital technology is not new to the clinical trial space, but one could argue that significant adoption has never reached much more than a slow simmer. Until the pandemic disrupted in-person contact, sponsor companies and regulatory agencies hesitated to embrace virtual trials. The BCI data affirms that COVID-19 is forcing the industry to think carefully about how to weave digital technologies into every stage of drug development—and it is seeing potential benefits for doing so.

Moving consent documentation from paper to glass, for instance, is just the very beginning of the digital technology evolution for clinical trials. The question is not *whether* to incorporate wearables, biosensors, etc. We have found that sponsor companies now are seeking guidance about *how* they should use such technologies to find patients, retain them and collect necessary data.

In the current environment, digital technology has gone from a "nice-to-have" to an essential part of keeping trials up and running. Yet even when the disruption from COVID-19 subsides, it's highly unlikely that the industry will ever go back to dismissing digital approaches within the drug development cycle. The ability to layer AI/machine learning on top of the data gathered via digital health technologies is opening new doors that won't be closed again.

The intersection of digital, AI, RWE and regulation

Although the spike in confidence in digital health technology earns merits on its own, it also probably plays a foundational role in how industry executives viewed the other elements addressed in the BCI surveys. The rising support for AI/machine learning and RWE, in particular, would seem to have strong links.

It stands to reason that increased reliance on digital technologies makes it easier and faster for sponsor companies to gather clinical trial data and RWE. Likewise, as digital technologies collect increasing volumes of data, AI/machine learning will be necessary to analyze it all with speed and accuracy.

What the BCI numbers may illustrate is that any skepticism about the use of digital health technology and AI to amass and analyze trial data and RWE is quickly vanishing. In the quest for a COVID-19 vaccine, for example, we see enthusiasm for using AI to help validate data and derive better answers for patients faster. The historic drug development cycle of anywhere from six years to 10 years or more[1] is simply unacceptable. Thus, there is higher confidence that the right combination of digital technology, AI and RWE can safely speed up trials and overall development time.

The question, of course, is what that "right combination" looks like from operational and regulatory perspectives.

During the pandemic, some regulatory agencies such as the U.S. Food and Drug Administration (FDA) have worked hard to be collaborative and transparent in their processes. They have granted emergency use authorizations (EUAs)[2] and made other concessions to hurry potential therapies into clinicians' and patients' hands. They have even taken time to acknowledge their need and desire to work faster and more collaboratively.[3]

Yet, in practice, a cautious approach is sure to remain—as is appropriate for the regulatory function. Some healthy regulatory skepticism is certain to arise out of lessons learned from COVID-19, as well as recent digital health misadventures[4] such as the Theranos blood test violations.

For regulatory agencies worldwide, COVID-19 has become a pilot program. They've had to evolve in the public eye—and without any reduction in their non-COVID-19 demands. Many are figuring out how to work better, faster and with more scientific rigor so they can be of greater service to humanity. But the downward trend in regulatory confidence reflected in the BCI surveys illustrate that within industry leadership, there may not be enough appreciation for how complicated such evolution can be.

Implications for the future

How the industry adapts to digital technology advances won't resemble its past approach. The genie is permanently out of the bottle. So, although adaptation will mean different things to different stakeholders, all must be prepared for the effects of further digital health technologies and data.

Digital technologies and AI will affect how sponsors and contract research organizations run clinical trials and how regulatory agencies assess them—including how regulators view post-approval RWE requirements. They will pay additional attention to safeguarding and validating data collection, as well as its use and extrapolation.

Will regulators consider new levels of data protection in addition to HIPAA, GDPR and other privacy and security rules? What data extrapolations will be allowed to support a product's safety and efficacy story? How will RWE analysis impact product approvals and sales strategies? These are just a few of the questions that the industry must address.

Greater confidence in technology, AI and RWE may let us step away from stringent trial inclusion/exclusion criteria earlier, allowing us to rely on evidence generated as therapies are used in actual daily life. Sponsor companies should expect to see the traditional "line in the sand" between clinical trial data and post-approval data blur. It's likely to move backward, with an increased volume of Phase IV trials and RWE. While that would move products from trial to market sooner, it puts the onus on sponsors to collect, analyze and report data faster and more accurately within regulatory confines.

From a regulatory perspective, data validation and data disparities probably will come under greater scrutiny—especially for trials involving major indications across the globe. Careful consideration will need to be given to inconsistencies in the way data is collected and reported in different geographic regions and for different patient populations.

All signs point to digital acceleration

The executive perceptions measured by the most recent BCI demonstrate the industry's heightened confidence in the future direction of digital health technologies, AI/machine learning and RWE. They also highlight the need for regulatory agencies to keep pace with technology and data developments.

Each of these factors is but one piece in the clinical trial and drug development puzzle. Each presents benefits and challenges on its own, but they are interwoven as well. Viewed together, the double-digit changes in attitudes toward these four elements signal that biopharma executives believe the industry is accelerating toward a permanently altered state.

Change never comes without hiccups, but the acceleration is there. Transformations in these four areas in response to COVID-19 promise to converge, touching every aspect of clinical trials and drug development.

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