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How COVID-19 Is Transforming Perceptions And Approaches To Clinical Research

Source: Worldwide Clinical Trials and Kineticos Life Sciences
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The COVID-19 pandemic has forever changed our perceptions of clinical research—but *how* has it changed them? That was the underlying question in a recent two-part survey of C-Suite executives.

The Biopharma Confidence Index (BCI)[1] has measured confidence in the biopharma industry's economy among C-Suite executives since 2015. Coincidentally, the newest BCI survey launched in November 2019, before COVID-19 was fully identified. With the emergence of COVID-19 and the implementation of lockdowns across the globe, the survey team took advantage of the unique opportunity to conduct a second assessment in April-May 2020.

Both surveys asked an identical set of 259 questions. The executives polled work for biopharma companies with facilities in the United States, Europe, and the Asia-Pacific region. Examining their opinions pre-COVID-19 (n=113) and again in the midst of the pandemic (n=133) revealed several interesting shifts, most notably:

- Higher confidence in the positive impact of digital health technologies on the industry in the next 12 months—up from 11 percent to 36 percent.
- Increased confidence in the positive impact of artificial intelligence (AI) and machine learning (ML) in the next 12 months—up from 11 percent to 25 percent.
- Growing confidence that real-world evidence (RWE) capability will increase significantly—up from 17 percent to 29 percent.
- Reduced confidence in the positive impact of the regulatory landscape in the next 12 months—down from 53 percent to 28 percent.

By taking a deeper look into what fuels these attitude shifts, we gain a clearer picture of how COVID-19 may transform the industry.

Underlying drivers

Digital health technology, AI, ML and RWE have existed within biopharma for years. COVID-19 did not cause sponsors to hit the digital and AI "on" switch suddenly.

However, the onset of COVID-19 did shine an unexpected spotlight on initiatives that have quietly waited in the wings for decades. It has made sponsors think longer and harder about the benefits of using digital technology, RWE and AI to disrupt the traditional "linear and sequential" clinical trial process.[2] The global need to rapidly create, produce and distribute a COVID-19 vaccine has brought about the unprecedented acceptance of non-traditional approaches to clinical development—as well as unparalleled collaboration.

Moreover, the need to push forward with existing product development has raised fresh awareness of the importance of site and patient engagement. Creative solutions for recruiting and retaining patients have become necessary during pandemic-related lockdowns. As a result, we have seen an extra emphasis on protocols designed to be site- and patient-friendly, while still supporting robust data collection and patient safety.

In a nutshell: The pandemic has forced the acceleration of what historically is solid—but very slow—innovation in drug and device development processes. The BCI results indicate that biopharma executives are starting to see the benefits of digitization and advanced data and analytics through a clearer and sharper lens.

Regulatory observations

Despite executives' increased confidence in digital technology, AI, ML and RWE, their declining confidence in the regulatory landscape is worth contemplation. Given the timing of the surveys, one could surmise that their views might have been colored somewhat by the political hot-potato in the U.S. that involved high-profile emergency use authorizations (EUAs) and their subsequent withdrawals by the Food and Drug Administration (FDA).[3] Keeping in mind that the BCI is meant to gauge perceptions only, the results may simply disclose that executives perceive some disarray in the regulatory COVID-19 response.

If that is indeed driving decreased regulatory confidence, then it must also be stated that executives may be overlooking a critical aspect of

this complicated situation. Namely, transparency.

Throughout the pandemic, the FDA, in particular, has intensified its efforts to be transparent, with the ultimate aim of fostering greater collaboration and faster development of a COVID-19 vaccine. In practice, that has meant giving the public more vision into the inner workings of a regulatory agency. Unfortunately, that can look a bit messy sometimes—especially during a complex crisis when events and evidence change by the hour. Perhaps it is unavoidable that regulatory transparency may at times create a negative public perception, but that does not validate a return to closed doors. Instead, we should consider that the downward BCI regulatory confidence number may very well be the result of a very positive long-term commitment to transparency.

Potential industry changes

It has been said that necessity is the mother of all invention. The demands to treat and prevent COVID-19 have encouraged faster, more engaging and more collaborative clinical development processes. Paired with the executive opinions voiced through the BCI, we might reasonably expect these industry changes to gain momentum:

- **The acceleration of digital technology**. The pandemic is inspiring innovation in virtual techniques. Consideration of digital trials, for example, is starting to move from a "nice-to-have" to a "must-have." No doubt, sponsors will continue to pivot their planned clinical trials to ensure there are virtual solutions—whether totally virtual or virtual/in-person hybrids.

  Going forward, stakeholders may be more open to using virtual techniques to alleviate challenges commonly experienced with trials involving rare disease or difficult-to-reach patient sets. While such issues existed pre-pandemic, the infrastructure and regulatory innovations spurred by COVID-19 now allow sponsors to think in ways they couldn't—or didn't have to—before.
- **Further opportunities for RWE, AI and ML.** The breathtaking speed at which COVID-19 vaccine trials are progressing is both a testament to industry cooperation and a renewed warning that clinical development must never compromise patient safety. In that endeavor, data is king. The confidence in digital technology alongside RWE, AI and ML may show a growing acceptance of their combined potential to safely shorten the development cycle. Against the coronavirus backdrop, executives may have a greater appreciation for the ease and speed with which digital technology can collect large quantities of data from trial and real-world settings—as well as the utility of using AI and ML to help make sense of it all.
- **Long-term regulatory change**. COVID-19 has thrust regulatory agencies worldwide under the proverbial microscope. Under intense scrutiny, longstanding processes have had to evolve seemingly overnight. Consequently, we've seen compressed review and response timelines, collaboration with stakeholders across the continuum, and the aforementioned rise in transparency. Prevailing wisdom tells us there is no going back. "If we could do it for COVID-19…" is sure to be the reaction to any attempts to retreat to slower, siloed or opaque processes.

A more transparent and digitized future

A *Clinical Leader* industry trends article[4] published just before the pandemic rather poignantly noted, *"… the respondents we spoke to identified culture and inertia as the largest overall barriers to progress."* The authors also cited greater awareness of clinical trials and stronger collaboration as key elements required to advance clinical research.

For now, at least, the COVID-19 pandemic has swept those concerns away. It has brought clinical trials to the forefront of public awareness. The industry has demonstrated to the world just how quickly it can collaborate and adapt. Inertia is no longer an option. The BCI survey indicates that as a result of COVID-19, biopharma executives may be warming to the use of digitization, AI, ML and RWE as positive disruptors. In an indirect manner, their BCI responses may also herald an era of more regulatory transparency going forward.

One thing is certain: We will not—and must not—go back to the way things were. We all have a role to play in improving drug development for the betterment of humanity.

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