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'Pivotal Time For CROs': ICON CEO Cutler On Changing APAC Trial Trends

by Lisa Takagi

The CEO of one the global top-five CROs points out a larger opportunity in decentralized trials that might be a "game changer" in the global pharma industry over the next five years. He also refers to the need to accept new technologies by both clinical trial sites and regulators.

As one of the top five contract research organizations (CROs) globally, *ICON PLC* has witnessed a significant paradigm shift in clinical trials during the COVID-19 pandemic.

Dr Steve Cutler, CEO of the Dublin, Ireland-based firm, which raised its profile by running a global trial of *Pfizer Inc.*/*BioNTech SE*'s COVID-19 vaccine Comirnaty (BNT162b2) amid the pandemic, described to *Scrip* what he sees as a "pivotal moment" for clinical trials within the past 30 years.

To drive innovation faster for the benefit of the entire pharmaceutical industry, there are several challenges to be overcome - not only by CROs, but also by local trial sites and regulatory agencies.

In an exclusive interview with *Scrip* in Tokyo, Cutler and Dr Atsushi Ogawa, general manager of ICON Japan, revealed the company's vision for the next five years of global clinical trials.

Pandemic As A Catalyst

When ICON was running the Comirnaty trials in Argentina, its team in Japan was playing a key role monitoring the studies remotely. Although this was not its first remote monitoring attempt, the pandemic accelerated the shift towards acceptance of the digital technology allowing more decentralized trials, Cutler told *Scrip*.

"The pandemic has really been a catalyst for improving the way we run, and become more efficient in the way we run, trials, that's what we learned." He added that in the US, ICON is

doing more and more remote monitoring, while in Europe the transition is slower because of privacy protection regulations. (Also see "*'Let's Be Ambitious,' EMA Official Says Of Tackling GDPR Issues In Clinical Trials*" - Pink Sheet, 31 Oct, 2022.)

Today, Cutler sees two main elements of the shift: scientific factors enabling new modalities such as gene therapy; and technology such as mobile devices and apps that allow decentralized monitoring, along with access to electronic records allowing efficient processing. He also points out the general growth in attention to, and investments, in the biotech sector, another driving force for clinical trials on a global scale.

"The opportunity for us to bring all that together and create an environment and process that allow us to get drugs to the market, devices to the market faster...it certainly has been around."

On the other hand, Cutler suggested there is still some "work to do" around maintaining access to medical records and using various systems to ensure integrity in clinical trials.

Building, Maintaining A Focus On Trials

Amid the significant shift around clinical trials towards digital technology, ICON completed the acquisition of another global CRO, *PRA Health Sciences, Inc.*, in July 2021 in an approximately $12bn deal. Having resources on a truly worldwide scale is one ICON's core strengths as a CRO and it has built on that through the series of acquisitions, said Cutler.

Still, the firm is maintaining its strategic focus on clinical trial services, which it sees as another key strong point among the global top five CROs. Cutler made it clear to *Scrip* that ICON is not entering the data-selling or commercial services markets. Instead, its "big differentiator," as Cutler describes it, is its global network of clinical research sites known as the Accellacare Site Network.

Deal Watch: ICON, PRA Health Form Massive CRO In $12bn Merger

By Joseph Haas

24 Feb 2021
Plus deals involving Sanofi/SIRION, Merck KGAA/Day One, Beijing Tide/Graviton, Vaccinex/Surface Oncology, Athena/Tris, Biomunex/Onward, Cellectis/Cytovia

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ICON also has additional recourse to move towards decentralized trials through the use of approaches such as home healthcare nurses, an "e-consent" system to sign off participation in studies and wearable devices that can collect data directly from patients. "Technologies and data that we have globally as a corporation, that allows us to add an advantage against our competitors," Cutler told *Scrip*.

APAC Opportunities And Challenges

The interview took place during an APAC tour by Cutler, which included India, South Korea and Australia, as well as Japan. He stated today the region has an increasingly important role in global development as "sponsors are always interested in developing drugs in APAC, because it helps them to get registration."

"As the populations [in APAC] become wealthier, particularly in countries like China and even in India, the proportion of GDP that will be spent on healthcare or on new drugs I think would go up and the pharma industry sees that."

But while the potential need for Asian clinical trials expands, some challenges remain. One is the lack of clarity in regulations in countries such as China, although in this case it has the benefit of a large potential patient population for studies. There is also a cost challenge due to those regulations. For example, in addition to its three global central laboratory facilities in Singapore, Dublin and Farmingdale (US), ICON has a small lab in China because the country does not allow trial samples to be exported.

Another cost barrier is accessing technology "to become more productive" in a market like Japan, Cutler added. Ogawa admitted the pandemic had become an opportunity for his team to transform the way clinical trials are performed in Japan "from the very much labor-intensive, face-to-face interactions into more technologically-supported virtual approaches to improve cost-wise productivity."

Ogawa told *Scrip* the transformation provides greater opportunities for ICON in Japan, given the country has a high level of medical practice and ICON has capabilities for various services required for clinical development, ranging from regulatory consultations to the new drug application and post-NDA phases.

"Partly because of our history to start up a PRA franchise in Japan [i.e., expanded capability as a result of the acquisition] and partnering with the largest Japanese pharmaceutical company *Takeda Pharmaceutical Co. Ltd.*, we have so many talented clinical development professionals to cover the entire spectrum of the needs of clinical development in Japan. These are the strengths we have for [our customers in] Japan."

APAC Vision For Next Five Years

ICON is keen to expand its capabilities in APAC even further. For example, in Japan the firm has been planning to double its headcount to 2,000 in the next five years, along with growth in individual staff productivity, local trial sites and engagement with regulators.

Cutler observed the trend towards decentralized trials has the potential to become a game changer for the entire pharma industry by raising productivity, as more and more investigators and countries become more open to conducting this type of study through the use of digital

resources.

“In a longer term, the decentralized trial train has left the station,” the CEO said, pointing out the trend had shown him a bigger opportunity for some organizations and the industry to further lower the cost of drug development over the next few years.

“When you've got a clinical trial, from start to finish it’s usually not much shorter than sort of three years – two-year trials are short clinical trials. Phase-III [trials] are often three or four years.

"If you can make that reliably two years or even 18 months, you can absolutely change the game cost-wise.”