Chief Medical OFFICERS

Chief Medical Officers have a big remit when it comes to overseeing their organization's clinical trial strategies as well as keeping the patient voice top of mind.

DR. DAVID ANDREWS

Tracking Neo-Antigens

The biggest trend in the immuno-oncology space is the pursuit of a successful solid tumor immunotherapy, which would be a major breakthrough for the treatment of cancers with significant unmet needs. We are seeing a newer class of cancer rejection antigens in this space that are entirely absent from the normal human genome referred to as neo-antigens. They will be of particular relevance to solid tumor immunotherapy and should be derived from an inclusive autologous cell source. This approach will necessarily require regional cell processing. Led by CAR-T technology, autologous cell production is trending toward regional production, which I think, in terms of time and quality, will ultimately prove to be more beneficial for patients. In the case of solid tumors, there is no other choice because malignant cells begin to perish the minute they are removed from the patient and need to be processed as a living cell preparation within a day or two of tumor tissue acquisition. As someone who has devoted my career to exploring treatments for intractable cancers, I am quite enthused about this trend and what it can mean for patients.

Mixing Medicine and Technology

The CMO's role now and in the future is to ensure that any scientific breakthrough offers patients greater benefits beyond incremental improvements and to make sure the voice of the patient is always at the core of what we do. This is being manifested in newer so-called adaptive clinical trial designs we are incorporating. As we continue to enter the digital health age, the CMO is also required to apply the latest technology to the field of medicine and empower patients to be more proactive about their health. Finally, the pandemic has impacted how trials are conducted and it's our job to align our organizations with new and creative ways to keep trials on track and continue to advance medicine and treatments.

DR. KRISTEN BUCK

A Pathway to Recovery

The pathway to recovery as a result of the COVID-19 pandemic is the biggest trend currently being tracked. This active recovery includes ensuring our employees, subjects/patients, and sponsors are appropriately safeguarded. Additional focus is given to monitoring on-going clinical trials and applying agile solutions to minimize disruption and preserve continued data and trial integrity.

Defining the Value Proposition

To successfully adapt to emerging pharmaceutical trends, the CMO role will likely become further involved in understanding and defining the overall value proposition for an organization, the portfolio of offerings, and the biotechnologies that are changing medical practice. The CMO will likely be positioned to further champion the voice of the patient and to ensure appropriate data and analytics are driving clinical decisions.

DR. LINDSAY MCNAIR

Rethinking Clinical Studies

It's hard to think of anything beyond COVID-19. The pandemic is going to have significant effects on the way we design and conduct research studies. It's brought attention and real discussion — not just within the research community, but in the public eye — to so many topics; the need for good public education about drug development and clinical trials, moving trials out of sites and making them more accessible for research participants, and the need for diversity in our participant populations that truly reflects the communities affected by illnesses. The amazingly rapid start-up of so many clinical trials has shown how efficiently our clinical processes can move, and hopefully the lessons learned about innovation and stripping out long-held practices that no longer add value will continue to be part of what we do moving forward.

Getting Creative with Trial Designs

The CMO role is, of course, very different depending on the type and size of the organization. I think the biggest evolution of the role will be seen for the CMOs who work with smaller and emerging biopharma companies, guiding the drug development efforts. The old paradigm of Phase I/Phase II/Phase III studies and recycling old study designs with new agents is disappearing fast. CMOs will need to be creative and thoughtful to champion new clinical trial designs, which can answer questions more efficiently and incorporate patient-centered endpoints. They will need to encourage teams to let go of old habits, to take advantage of new tools, and to use data-based decision making in study conduct as well as design.

The Commanders & Chiefs

DAVID ANDREWS, M.D.
Chief Medical Office and Co-Founder, Imvax

Imvax is a clinical-stage biotechnology company whose groundbreaking personalized neo-antigen immunotherapy, IGV-001, is being studied in patients with glioblastoma multiforme (GBM), and whose proprietary technology has the potential to advance care for patients with serious, unmet medical needs in other solid tumor cancers.

KRISTEN BUCK, M. D.
Chief Medical Officer, ICON

ICON is a global provider of outsourced drug and device development and commercialization services to pharmaceutical, biotechnology, medical device, and government and public health organizations.

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