By Taren Grom

Looking Forward To…

… AI adoption, chat bots, clinical collaboration, innovative drug development, Internet of everything, living commercial models, and patient power. As part of this special Year in Preview issue, we asked our thought leaders to provide their insights on some of the trends they are tracking going into 2019 and beyond.

AI Adoption

RICHARD DAVIES
VP, Solution Expert, CluePoints

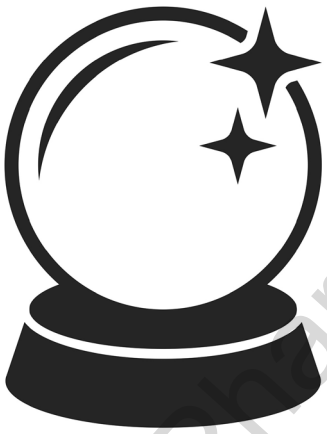
The application of artificial intelligence and machine learning within the R&D process to guide disparate stakeholders through the planning and execution of clinical trials through targeted risk management is both a current capability and an evolving trend. This helps support the industry as it moves to implement risk-based everything (RBX), a holistic approach to quality management within its operations.

PRAKRITESWAR SANTIKARY, PH.D.
Chief Data Officer, ERT

We are seeing an increase in the acceptance and adoption of artificial intelligence (AI) and emerging technologies such as the cloud and data lakes for cutting costs, improving data quality, improving trial efficiencies, and reducing trial times, all of which help clinical trial sponsors bring new drugs to the market faster.

By augmenting and assisting human intelligence, leveraging data and making clinical trial predictions to detect trends, risks and outcomes, AI — combined with big data — holds the potential to solve even more of today's key clinical trial challenges.

We see the use of AI continuing to expand, especially in several categories. First, AI can make clinical trials intelligent. AI-driven protocol designs powered by AI algorithms and deep learning techniques can reduce trial complexities by analyzing operational data from historical cases, measuring drug response, predicting trial risks and site performance and using predictive criteria to determine whether a drug will result in a positive or negative outcome, whether patients will drop out, and/or if trials will be successful. Second, AI can opitimize patient recruitment/retention. By extracting pertinent EMR information, sifting through physicians' notes, reading binary data from images and medical scans and comparing them with the inclusion and exclusion criteria of ongoing clinical trials, AI can accelerate clinical trial patient recruitment and improve patient retention during lengthy trials. Third, AI can provide greater insights for smarter decision-making. The promise of detecting patterns using AI, machine learning and deep learning techniques when managing vast volumes of clinical research data and using it to accelerate drug discovery is tantalizing. For example, with these tools, biotechnology or pharma companies could combine all their early stage data to determine in which indication a drug is more likely to succeed.



Editor's Note: See upcoming January 2019 issue of PharmaVOICE for its cover story on AI: Molecule to Market. And the October 2019 Showcase on Artificial Intelligence and Machine Learning.

Bioethics

COURTNEY NOAH, PH.D.
VP, Marketing, BioIVT

We are acutely aware of the importance of regulatory oversight for the ethical procurement of human biological specimens (HBS). There is a growing need for specimens to fulfill the promise of precision medicine. But as the standard of care shifts to less invasive therapeutic options, the availability of HBS has decreased. In addition, the public is more aware and conscious of the use of HBS in research, specifically drug and companion diagnostic development, as well as wary about the potential sharing of confidential information. It is a companywide focus for BioIVT, to ensure that all HBS sourced via any of our divisions are ethically procured, quality processed, and associated with the appropriate clinical data to ensure researchers are able to derive actionable data from their use."

Chat Bots

CHRIS CULLMANN
Head of Digital, Ogilvy Health

Patients, caregivers, and physicians have one thing in common: They want simplicity, whether it be in user experience, access to information, or getting a response to their questions easily.

Bots are becoming a popular choice — regardless of the flavor they appear — to provide information, route users to services, or quicken access to otherwise undiscoverable information.

Bots captured marketers' attention this year, and whether they are attached to AI or simply act as an interface to a decision tree, they are providing 24-hour access to people who want answers and a little bit of help finding them. I expect to see an explosion of automated, bot-based tools for all healthcare audiences in 2019.

(Editor's Note: See last year's Year in Preview issue on the Chat Bot revolution.)

Clinical Collaboration

BARINDER MARHOK
Associate VP, Head of Life Sciences R&D Practice, and Venture Partner, Cognizant

The digitization of clinical trials is one of the biggest trends we are tracking and influencing. This is not just adopting cloud-based solutions but relooking at the underlying business process and applying the power of artificial intelligence (AI), automation, and analytics. The goal is to enable greater collaboration between all stakeholders in the clinical trials landscape and optimize each sub-component of the clinical development value chain.

We believe 2019 is the year that multi-sponsor, multi-vendor collaboration with sites goes viral — and the industry will benefit exponentially from those stakeholders that took risks and invested significant resources in collaborative platforms three to five years ago.

These benefits include not only speed, efficiencies, and cost-savings, but most importantly access to larger and more diverse patient populations seeking hope and healing.

We see 2019 as a break-out year for patient-focused adaptive trials, real-time risk assessment of clinical trials, and orchestration of on-demand labs. Pharma companies are willing to make incremental but immediate progress toward their vision of a digital future by integrating wearable technologies, the Internet of Things (IoT), analytics, automation, and AI into their legacy systems, wherever and whenever the opportunity exists, rather than wait for end-to-end solutions to become available. As learnings are applied to more and more use cases, we expect digitization of clinical trials to accelerate.

SAM OSMAN
CEO, Cenduit

There are lots of trends making noise, the two biggest of which are virtualization, or the direct-to-patient model and secondly protocol amendments. There will always be new trends that are in vogue. What this means for us: the need to be flexible in our delivery model while maintaining quality. We are helping clients adopt the direct-to-patient model by breaking away from the traditional method of shipping drugs to sites, and putting them directly into the hands of patients while minimizing waste.

On the flip side, we're seeing increased complexity in clinical trials being driven by protocol changes. Historically, you'd receive a protocol and have anywhere from three weeks to three months to build the study. Those days are gone. Pharma is asking providers to build flexibility into studies allowing for rapid protocol changes. For studies in active enrollment or treatment, the need to react to protocol updates is even further heightened. This need for unprecedented agility and flexibility will proliferate into 2019.

Ultimately, whether its new models like direct to patient or an increasing number of protocol amendments, we're being tasked to rethink our processes and how we work with our partners. Randomization schemas and resupply/dosage algorithms are among the highest risk factors in clinical trials and we're looking to leverage other best practices from other industries to help us react faster while still containing risk.

JIM STREETER
VP of Product Management, Oracle Health Sciences

Pharmaceutical companies are working diligently to align with key stakeholders, such as healthcare providers and payers in order to bring clinical trials as a care option to patients. Currently, it is estimated that fewer than 1% of the population in the United States participates in clinical trials, yet 72% say they would if recommended by a doctor. New technologies have the potential to help drive change. Specifically, we have to provide tools to bridge the gaps between pharma, physicians, and patients — whereby patients are given the option, by their doctors, to participate in a clinical trial as a care option.

As always, patient enrollment has been a challenge for clinical R&D, and with a model where the entire ecosystem is working in tandem, we would see an uptick in patient enrollment, giving pharma the statistical data they need to move a trial forward. Some drug makers and patients are already moving the needle. We are seeing an uptick in the number of patients enrolling in more trials via their physician's recommendations. An example of this is in stage 4 cancer patients who are enrolling in clinical trials as a care option that could save their lives.

While there is a long road ahead and challenges to be overcome, we are seeing change now. Patients are going to help drive this forward as they demand to have clinical trials as a care option outside of terminal illnesses. Physicians are jumping on board and looking at ways to engage with payers. I see technology as the foundation for connecting all stakeholders and the glue that holds it together.

Innovative Drug Development

ELLEN LEINFUSS
Chief Commercial Officer, Certara

The biggest trend that we are tracking is the application of innovative technology to optimize and accelerate drug development and patient access. We created a scientific- and technology-driven global positioning system (GPS) that is fueled by a wide array of predictive analytics focused on answering a range of questions such as: How does the body react to this drug and how does the drug react to the body? How will this drug perform in real-world patients? What is the right value and pricing for this drug in the global marketplace?

The FDA routinely encourages the use of modeling and simulation (M&S), not only by including it in the 21st Century Cures Act, PDUFA VI, and GDUFA II, but also by crafting numerous guidance documents and hosting educational forums on the topic. Other regulators have followed suit, with EMA recently upgrading its M&S working group to a working party, and PMDA releasing its own guidance. Furthermore, in June, FDA finalized its guidance for using EHR data to support approvals of new indications for already-approved drugs or for meeting post-approval requirements.

FDA Commissioner Dr. Gottlieb's recent remarks underscore his position regarding the value of new technology. He cited, "the more widespread use of modeling and simulation, the greater use of real-world evidence in the pre- and post-market setting, and the adoption of better tools for collecting and evaluating more real-time safety information after products are approved" among the new scientific domains that have been introduced into the development and review process.

Internet of Everything

BRYAN SILVERMAN
CEO, ObvioHealth

The transformation within healthcare is the continued corralling of disparate systems and their data; very much like a blockchain element and thinking. It is going from an IoT to an IoE (Internet of Everything); creating a centralization of siloed and fragmented systems while maintaining their decentralized status. This ecosystem with one powerful organization and/or a coupling of organizations — think Google, Apple, and Amazon combining forces — will create a homogeneity for both providers and purchasers of healthcare products and services thus creating patient, consumer, and HCP centricity with an "electronic bridge" into myriad verticals and channels globally.

Healthcare issues are globally shared by every country. It is a core need in every country and a common cost-driver in every country. Innovation, along with its cousins technology and data, will continue to fuel the metamorphosis of how clinical studies are performed. The digitization of clinical studies positively impacts time, recruitment capabilities, efficiencies in execution of clinical studies and patient-facing transparency. Digital innovation takes the enormity of global data captured and puts it into the palm of your hand. The world suddenly becomes a smaller place — made possible by big data.

A Living Commercial Model

JAMIE ANTIS
Managing Director, Accenture Life Sciences

One of the biggest buzzwords across pharma commercial organizations right now is the shift to "agile." But the ambition around becoming agile is so trendy at the moment that it's quite possible some have lost sight of what they are truly trying to achieve. We believe that shift of commercial models needs to be broader than just a focus on agile and needs to be more of a shift to what we call a living commercial business — one that is proactively predicting what business events might disrupt and putting plans in place to target new opportunities, one where change is now considered to be normal and all commercial leaders are required to embrace the change, one where insights are constantly being generated to challenge the status quo to drive new innovation, and one that is so deeply rooted in an understanding of customer needs that all experiences are deemed meaningful and relevant. This doesn't mean that being agile isn't important because it is. But just being agile without embracing some of the other organizational and cultural change that needs to happen will not be enough.

Patient Power

LINDSAY MCNAIR, M.D.
Chief Medical Officer, WIRB-Copernicus Group

While it is showing more staying power than a trend, the biggest movement we continue to track is that of making clinical trials more patient-centric. We see evidence of this movement in so many aspects of clinical research: clinical protocols that include endpoints that are important to the experience of the patient population; efforts by regulatory agencies to drive patient-focused drug development; the biopharma partners that we work with, who are including patients earlier in protocol writing to assess the burdens of study participation; more interest in virtual or site-less clinical trials that move study visits out of clinics and into participants' homes; and imaginative platforms to better inform and connect interested patients with potential clinical trials.

Further, in our own ongoing work with the participation of patient advocates, we continue to improve the informed consent process. Incorporating the patient voice into the conceptualization, design, and conduct of clinical trials can only help to ensure that new treatments being developed will be clinically meaningful to the patients and families fighting those diseases and conditions.

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The meaningful integration of the patient voice into R&D stages and initiatives, and the intelligent integration of customer data sets to arrive at more realistic insights and more applicable and effective recommendations, are by far the biggest trends we're seeing.

When it comes to earlier-stage product and trial development, we are focused on understanding and exploring how, where, and when real-world patient voice and experience insights can lead to increased recruitment and retention, better, and more practical protocol design and outcome measures. Our collective industry goal is better trial design that places better treatments more quickly into the hands of patients and healthcare providers.

In terms of data integration, we are fascinated by the potential of strategically integrating what have previously been thought of as separate and siloed sets of customer data. This can paint an altogether richer, more dynamic, and more realistic picture of the healthcare experience.

In the last decade, so much of the focus has been on chasing the proprietary and biggest data. Now, almost everyone has proprietary data and just because data is big, doesn't mean it meaningfully addresses business and healthcare-changing questions or decisions. It doesn't mean that an organization knows what to do with it. The key is and will increasingly be identifying and integrating the right data as indicators of attitudes, behavior, and opportunity.

CHRISTOPHER TOBIAS, PH.D.
President, Dudnyk

The empowered patient is transforming how medicine is practiced, especially in the area of rare disease. Recognizing how to understand, support, and guide informed and passionate patients and/or their caregivers is an essential key to the shared responsibility required for a healthcare provider to deliver quality healthcare.

We as an industry need to better identify and support how to create that shared responsibility to help ensure an accurate diagnosis, treatment decision, and support throughout each patient's journey. These principles are not only foundational to our educational and promotional support of a rare disease product, but also in the ongoing quest to improve how medicine can be practiced.

(Editor's Note: See the upcoming special April 2019 Patient VOICE issue for additional coverage on the topics — from molecule to market — that impact patients.) PV

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