

A Technology-Based Industry

- From clinical research to regulatory processes to manufacturing and beyond, technology is now well-entrenched in every part of the pharmaceutical industry

Technology is part and parcel of the life sciences. It both shapes current and future innovations and, in the age of personalized medicine, is increasingly entrenched in the innovation itself.

Technology is key to each stage of the development journey. During clinical trials, digital technologies are used to engage patients, collect data, analyze data, streamline processes, and support decision-making.

Digital technologies are being leveraged to automate certain repetitive regulatory and compliance processes, and increasingly companies are applying technology solutions to streamline manufacturing operations and the supply chain.

21st Century Medicine

Pharma and biotech companies have been shifting their focus toward targeted therapeutics and away from blockbuster, mass patient medications. The result is precision medicine, which uses patients' genes and personal data to more accurately diagnose, treat, and prevent disease.

New technologies that are changing the face of medicine include chimeric antigen receptor T-cell (CAR-T) therapies. For example, Yescarta from Gilead removes T-cells from a patient's blood, genetically modifies them to identify and target tumor cells, and infuses them back into the blood stream.

Natural language processing is being leveraged to advance precision medicine research. For example, researchers at Washington University are using NLP to extract high quality phenotypic data from clinical sources (such as electronic health records) to develop registries of patients with certain diseases, such as breast cancer, Alzheimer's, and diabetes.

Companies are developing new modalities to further advance novel drug discovery. For example, scientists at AstraZeneca are developing a range of nanoparticles that aim to deliver the company's new modalities to previously undruggable targets and control the release of these treatments in ways that are easy for

patients to use. New modalities include oligonucleotides, mRNA and Anticalin proteins.

Another company focused on next-generation technology is i20 Therapeutics, which is seeking to enable people to replace therapies currently delivered via injection with pills. The company has developed a technology that uses a unique coating so drugs can safely pass through the digestive system and dissolve in the small intestine.

Digital therapeutics are also coming to the fore — either on their own or in combination with medications or devices, to treat physical, mental, and behavioral conditions. An example is CogniviveVR, a virtual reality platform focused on post-stroke rehabilitation.

Automation on the Rise

Robotics and automation are becoming an integral part of the pharmaceutical industry as companies look for ways to improve productivity.

Robotics has also become key to ensuring high-quality clean room capabilities, a requirement in manufacturing. And automation has become an even greater priority in the wake of the COVID-19 pandemic, which highlighted concerns over labor shortages, as well as the risk posed to people in certain parts of the supply chain. This has led more companies to look at automating tasks such as carton handling by using automated warehouse solutions, for example storage and retrieval systems and automated guided vehicles.

Robotics, artificial intelligence, the Internet of Things and advanced computing collectively make up what is being called Industry 4.0, which is revolutionizing manufacturing. Through Industry 4.0, manufacturers can potentially realize higher output, improved safety and quality, better value, more agility, and less waste. It is a revolution that “brings together advanced manufacturing technologies to enable integrated, autonomous, and self-organizing manufacturing systems that operate independent of human involvement,” according to Industry 4.0 for pharmaceutical

manufacturing: Preparing for the smart factories of the future, *International Journal of Pharmaceutics*, June 2021.

Regulatory, logistical, and technical challenges will need to be overcome to realize Industry 4.0, but it would allow real-time monitoring, control, and prediction for manufacturers and higher quality drugs with more reliable supply chains for patients.

Another area where automation technologies could revolutionize the industry is regulatory. Preparing accurate and detailed documents for regulatory submissions involves bringing together data from multiple functions and systems. By their very nature, regulatory submissions are rules-based and time-consuming. Robotic process automation (RPA) tools speed up and improve the process of gathering data and make it easier to compile accurate, thorough reports. However, for RPA to work effectively, systems need to speak to one another so they can exchange information.

Steps to enabling better management of data in order to enable greater automation include: have data in a single repository, ideally cloud-based, to eliminate data entry duplication and scrambling to find data in local files and servers; apply data standardization and master data management to achieve data quality and integrity; apply analytics to past submission data to improve future submissions and preempt questions from regulatory authorities; and adopt a digitized approach to creating submission documents using templates to automatically compile documents from existing data.

Technology and the Patient

It's not just the technology itself that is changing the pharmaceutical industry; it's also patients and how they use technology. Today, patients or consumers want to be included and engaged in their health journey, and pharmaceutical companies are responding by looking for ways to offer a complete digital package that enhances the patient experience. That has led to the creation of devices and apps to

support patients taking a medicine — made possible by advances in digital innovation.

More and more pharma companies are moving toward a platform approach, which combines drug development with service, data and software to deliver wellness, not simply treat illness. To achieve these goals, companies are partnering with technology and data companies so patients get the solutions they need.

As an example, Lilly has collaborated with Apple and Evidation Health on a feasibility study using an iPhone, Apple Watch, iPad and Beddit sleep monitoring device together with digital apps to determine whether it was possible to differentiate people with mild

cognitive impairment (MCI) and mild Alzheimer's. The company is also working with diabetes technology companies, including Dexcom and Ypsomed, integrating those solutions into Lilly's to improve diabetes management.

AstraZeneca is looking at ways to engage both healthcare professionals and patients digitally to improve health outcomes. For example, with asthma, the company is looking at ways to analyze individual data using AI to identify triggers, such as an asthma attack and predict and prevent future ones by keeping care teams updated and revolutionizing how it engages with patients so they can better control their condition.

Technology: The Future of Pharma

Across all parts of the business, technologies are shaking up how pharma operates. Companies are leveraging blockchain to protect data and address counterfeit medicines. They are making greater use of real-world data enabled by IoT, sensors, and wearables to transform innovation. Technology innovations will continue to emerge and will be leveraged by industry in new ways. One thing is certain: no part of the industry is untouched by technology. ^{PV}

EXECUTIVE VIEWPOINTS



Scott Thompson
Co-CEO,
Acceleration Point

Triggering Action

Over the next year the technology that will have the biggest impact on business operations are platforms that trigger action from available data. In recent years, business operations have invested in core systems, data warehouses, and analytics platforms. Now with so much data available it is time for engines that automate analysis and actions. These engines include suggesting HCPs to engage with to drive outcomes, which study sites need follow up, and cues for taking action on other operational processes.

Digitizing Scientific Information

The biggest trend we are tracking is the movement of scientific dissemination to the digital space across social media, news, forums, and video platforms. We

recently reviewed 50,000 HCP accounts from our Kwello Digital Listening platform and we hit a milestone this year as more than 50% of HCPs had contributed or were mentioned in relevant scientific content online.



Scott Snyder
Chief Digital Officer,
EVERSANA

Digital Health Adoption

Digital health adoption has exploded throughout the pandemic, making both physicians and patients of all ages more comfortable sharing health data through digital touchpoints. Automation is helping streamline labor-intensive activities (e.g., patient benefits verification), while chatbots are guiding patients through the program enrollment process, ultimately reducing the burden on the HCP and office staff. And finally, leveraging artificial intelligence (AI) is enabling predictive insights and next best actions across all

activities and touch points based on historic and real-time data.

Digital Therapeutics

The biggest trend we are tracking is how fast digital therapeutics (DTx) and digital medicines will ramp to become a vital part of the overall prescription therapy market. Significant investments poured into digital health solutions (\$24 billion in 2020), resulting in 23 DTx solutions in market and 89 in early-stage development. As more digital therapies are approved, successful commercialization will require an innovative, end-to-end model designed to accelerate speed to market, minimize risk and optimize investments.



Mark Brown
VP, Global Patient and
Site Solutions,
IQVIA

Journey-Enhancing Technologies

Technologies that bring the journey to

EXECUTIVE VIEWPOINTS

the individual will have a transformative impact on the patient experience. Applying voice-activated engagement technologies such as Alexa and Siri will allow hands-free access to trials. The use of speech biomarkers to identify and track disease progression will continue to evolve and provide additional opportunities for evaluation without travel outside the home. On-request access to medical records and the ability to augment that data with information feeds from wearables, fitness devices, and environmental monitors will provide a clearer path to a personal wellness journey.

Bringing Trials to Participants

The biggest trend we are tracking is the change from bringing participants to trials to bringing trials to participants. Part is patient willingness to accept remotely provided healthcare — telemed: part of this is decentralization, part of this is increased specificity of inclusion-exclusion criteria, and part of it is a change in regulatory considerations around data management and enrollment. Our strategic focus on patient-centricity, diversity, and site and patient experience drives our investments and technology strategies.



Lynne Sager
VP, Periapproval and Commercialization
Labcorp Drug Development

EHR Interfaces

One exciting technological opportunity is interfacing with electronic health records (EHR) platforms. The ability to provide both thoughtful messaging to

providers within the EHR environment and supporting a streamlined flow of data direct from the EHR to access and reimbursement hub programs will prove critical to our business; it allows providers to interface with us directly, rather than using a portal or sending faxes. Additionally, artificial intelligence-enhanced and supported technologies — like business intelligence and benefit verifications — will have a major impact on our business now and in the future.

RPA Automation

Leveraging advancements around AI and robotic processing automation (RPA) are critical to meeting patient needs. Efficiencies gained by employing RPA technology means faster processing of information, which can help physicians quickly assess the optimal course of treatment. By deploying AI-enhanced technologies we can better predict patient needs and more efficiently provide access to the types of support they need most.



Ralph Greene
eDetail Platform Supervisor and Technical Lead,
Ogilvy Health

Mobile and Wearable Devices

By using mobile and wearable devices, a pharmaceutical company will be able to gather clinical trial participant data in a more detailed and timely fashion. Mobile devices could allow patients to participate who might not be able to because of accessibility or location issues. A wearable could track additional biometric data providing insights that might otherwise be impossible for researchers to obtain.



Joe Tozzini
Digital Development Manager,
Ogilvy Health

AI and Music

As a musician I constantly track the new tech advancements in the industry, so it's difficult to ignore the potential AI has to change the way musicians play, write, compose, record, and produce music. As AI in music evolves, there is opportunity to create unique patient experiences using AI's capabilities to make a real impact for our clients' brands.



Sagar Anisingaraju
Chief Strategy Officer,
Saama

Fast-Tracking Therapies

AI-powered data analytics solutions, leveraged so effectively during the pandemic to slingshot COVID-19 vaccines to market, are transforming the life sciences on clinical trial, enterprise, and industry levels. The past two years provided the tail wind for accelerating adoption of AI-powered technology solutions to make fast-tracking of novel therapies the norm, not the exception.

AI-Powered Data Analytics

We are tracking the ongoing integration of AI-powered data analytics solutions with industry's business strategies to continue driving innovation and make the decade-long drug development process obsolete across the spectrum of therapeutic categories.

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For this year's program, stakeholders from medicines research, global regulation, and healthcare will join to analyze the challenges for safety and pharmacovigilance efforts in this uncertain environment and examine effective strategies for addressing gaps and needs. New approaches and collaborations that build on the foundation of sound pharmacovigilance principles to optimize safety and pharmacovigilance practice and ensure safe medicines for patients will be explored, in a global and regional context.

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