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## How digital is evolving at pharmas

BY KAREN TKACH TUZMAN, SENIOR EDITOR



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As pharmas struggle with how to embrace, define and deploy digital technology, they are settling in on models that ingrain digital leadership in the C-suite and teams across the organization. The magnitude of these teams' impact will depend on the degree to which they're empowered with infrastructure, talent and seats at the table to take on mission-critical questions.

Defining digital, including its scope and potential, has been an ongoing conversation in biotech.

For pharmas, that definition is centering on data science, and how it can be leveraged to accelerate, improve and expand a wide range of business functions, including R&D, manufacturing and commercialization.

"The value is in the data. If you can't capture that, there's no value," Karan Arora, chief commercial digital officer at AstraZeneca plc (LSE:AZN; NASDAQ:AZN), told BioCentury.

As of 2019, almost all pharmas had at least tiptoed into digital strategies, but fewer than half brought digital leadership into its C-suite. In some cases, digital leaders left or changed position, as pharmas iterated on how to build and embed the new area within the organizations.

Now, three quarters of pharmas have chief digital or information officers, and the last few years have seen a transformation in the data at their disposal.

Pharmas' focus is more on using data to advance their core businesses than on developing standalone digital products. That has pushed them to take on the arduous task of cleaning, structuring and centralizing decades of internal data.

To be successful, the digital teams need to be steeped enough in the company's pipeline to identify the right applications, and empowered by governance structures to ask the right questions.

For example, Janssen's Najat Khan says digital teams will require more access to longitudinal data, user-friendly platforms that gather data in one place, a diverse talent pool, rigorous checks for bias, and concrete examples of success. Khan is chief data science officer at Janssen R&D Data Sciences, and global head of R&D strategy and operations at the Johnson & Johnson (NYSE:JNJ) unit.

"Unless you make the examples real, it's hard to get buy-in," said Khan.

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## A spectrum of applications

A common thread among pharmas is a goal to use digital technologies to deliver comprehensive solutions for patients, with a focus on intervening earlier in disease and increasing adherence to treatment — the Biopharma 3.0 model laid out in BioCentury’s 2018 Back to School essay.

“The holy grail in all of this is a seamless, end-to-end journey of the patient from pre-diagnosis to staying on medication,” said Thorsten Rall, global head digital transformation & innovation and SVP at Novartis AG (SIX:NOVN; NYSE:NVS).

The applications today span the drug discovery spectrum, ranging from discovering new molecular targets, selecting sites and participants for clinical trials, microtargeting sales forces, and supply chain sensing.

In some cases, digital teams have chosen applications with an eye toward quickly generating proof of concept for their approach.

For Janssen’s Najat, that meant prioritizing clinical development over discovery, because of the faster timelines to return on investment, and focusing on early wins in the form of “minimal viable products” instead of large, long-term programs. “That was a strategic move, because you can lose steam in an organization,” she said.

One example was building a machine learning model to determine where to set up trial sites for COVID-19 vaccines three months ahead of time. The model enabled J&J to anticipate the importance of establishing sites in the Midwest and South of the U.S. when the virus was still predominantly on the country’s coasts, and to prioritize South Africa as a primary trial site. As a result, the company was able to make its trials more efficient and diverse, capture data on emerging variants, and reduce sample size by 25%.

Another focus has been digitizing pathology slides and using machine learning algorithms to help screen patients for tumor mutations associated with features in the images, with the goal of speeding up trial recruitment. “Do I add a new device, or do I use something everybody already uses? What can we do with data we already have?” said Khan.

GlaxoSmithKline plc (LSE:GSK; NYSE:GSK) is deploying data science early in the pipeline to reshape target discovery.

Evidence that genetic target validation can double success rates led the pharma to invest in building a platform that iteratively generates predictive models of different genes’ roles in disease based on “trillions of data points” from human genetics data and high-throughput functional genomics experiments, said GSK SVP of Medicinal Science & Technology Tony Wood.

GSK’s machine learning model, which parses the results of these experiments along with the pharma’s historical data, partner databases and published literature, “allows you to play What If Machine” to propose new targets and design optimal experiments to prove or refute hypotheses, said Kim Branson, GSK’s SVP and global head of artificial intelligence and machine learning.

“It’s rare for a big pharma to be spending money doing experiments with the express purpose of generating data, not for a drug, but for a model,” Branson said.

According to Branson, about 70% of the targets in GSK’s early stage pipeline now have genetic validation; several of these stemmed from the pharma’s 2018 collaboration with 23andMe Holding Co. (NASDAQ:ME). One is a Phase I cancer program targeting CD96, a part of the TIGIT axis in immuno-oncology, where GSK has invested heavily via a \$635 million deal with iTeos Therapeutics Inc. (NASDAQ:ITOS).

Rall told BioCentury that Novartis’ digital organization, launched by former Chief Digital Officer Bertrand Bodson in 2018, first explored a diverse range of applications through pilot programs, and has narrowed its focus as it matured. “We moved away from too many small local solutions that were cheap to launch, but costly to maintain,” he said.

Novartis’ digital priorities over the last three years included building two key R&D tools: SENSE Bridge, which tracks, analyzes and predicts the status of hundreds of trials around the world, and data42, which unites more than two million patient-years of data under a single analytics platform.

In manufacturing, better data streams are enabling more timely decision-making, which has been especially critical for managing supply chain challenges during the pandemic, said GSK Chief Digital and Technology Officer Karenann Terrell.

“We’re no longer looking at what was made and shipped yesterday,” she said. “We’re getting information in real time about where medications are needed the most.”

On the commercial front, digital tools are increasing the precision and timeliness of targeting strategies, and crossing the line into disease management solutions.

“You don’t send reps out based on prescription data anymore. Instead, you’re looking at, does this institution have patients who are at risk, where are there gaps in care, and what is the education we need to target to patients,” said AZ’s Arora.

He cited AZ’s AMAZE disease management platform, which includes a patient app and clinician dashboard, as an example of a digital tool that could enable more precise commercial targeting. The pharma and partner Massachusetts General Hospital are testing AMAZE’s ability to identify at-risk

individuals and improve clinical outcomes among heart failure and asthma patients.

AMAZE is also geared to support clinical development, he said. “It also becomes a de facto platform to recruit patients, conduct decentralized trials, integrate into electronic medical records, find gaps in care, design protocols to include more diverse patients, and understand where a therapy best fits for a patient.”

Rall highlighted a Novartis program with Ada Health GmbH that uses Ada’s symptom assessment and care navigation app in earlier diagnosis of axial spondyloarthritis and psoriatic arthritis, as well as an “AI nurse” partnership with Tencent Holdings Ltd. (HKEX:700) in China focused on digital chronic disease management for heart failure. Tencent has a similar “AI doctor” partnership with Merck KGaA (Xetra:MRK) to increase public knowledge of disease and treatment options within Merck’s China healthcare business.

## Path to digital maturity

A common theme is that the path to digital maturity requires investing in data ecosystems.

“This is the secret to how we scaled from 10 to 100 products,” said Janssen’s Khan of the company’s MedAI platform, which brings preclinical, clinical and real-world data under one roof, and also serves as a community hub where data scientists can share models and apps. “The decision to invest had to come from the top.”

Unified data platforms are essential for engaging and retaining pharma’s highly sought after digital workforce. “GSK made an investment about five years ago to bring historical data together and standardize it in one place. That investment is what drew me to come to GSK,” said Branson.

When it comes to building such platforms, it’s worth looking outside, James Kugler, chief digital officer at Merck KGaA, told BioCentury. “The best way to lose data scientists is to have them spend 90% of their time structuring data.”

He said Merck KGaA partnered with Palantir Technologies Inc. to address “the least sexy problem” of making data structured and usable in a secure environment with proper governance and a good user interface.

GSK’s Terrell said her team stopped thinking about these outside companies as vendors. “That’s an old way of thinking, ‘I know what’s best, and I pay you to do it.’ These are strategic partners who co-work with us to define and develop projects, and usually have first-in-class, leading-edge scale capabilities,” she said.

More challenging than building the infrastructure was “changing hearts and minds” about the role of data scientists

in a pharma organization, said Khan. “They have to be around the table with the clinicians and supply chain folks. That sounds easy, but it’s one of the hardest things to do.”

Now, she said, “a lot of the senior leaders on my team sit on the leadership teams of therapeutic areas. They’re deeply embedded in the top layer of strategy and execution.”

The key to breaking through was building a team with deep understanding and humility about the drug development process, who approached clinicians in a non-threatening way that encouraged brainstorming. “We could have bought a data science company and brought it into J&J, but people underestimate the importance of cultural integration,” Khan said.

According to Khan, Janssen’s digital team is now in a place where “80% of the time it’s a data scientist proposing questions, or it’s done jointly,” she said. “You don’t want to be a support group, or reactive, you want to be proactive.”

AZ’s Arora thinks a digital team’s credibility at a pharma is essential for meeting its goals.

“Where central digital officers haven’t been successful, the pharma’s maturity level on the digital curve was not that high,” he said. “When things go well, commercial leaders take credit, when things don’t go well, the digital leaders screwed up.”

He thinks being embedded in a specific business area is also important. Arora is one of three chief digital officers at AZ, focused on commercial; the other two are in charge of digital for R&D and infrastructure. “I start out with, what is the problem for my business area, rather than, here’s my shiny tool, what is the use case,” he said. “Building that mindset takes time.”

Gregg Talbert, head of digital & personalized healthcare and pharma partnering at Roche (SIX:ROG; OTCQX:RHHBY) and Genentech Inc. told BioCentury the “grassroots” origins of Roche’s digital organization, which got its start via the company’s partnerships and later acquisitions of Flatiron Health Inc. and Foundation Medicine Inc., led to a structure that is partly decentralized, and partly “a center of mass driving new ideas and technologies.”

“What that evolved into was a recognition that we needed to be more proactive corporately, while allowing different areas to keep their grassroots exploration,” he said. “We see increasingly the idea that personalized health care and digital should actually exist within the strategies of the different therapeutic areas.”

His team includes members who are individually aligned with key stakeholders at Roche Pharma Research and Early Development (pRED) and Genentech Research and Early

Development (gRED), as well as late-stage and commercial teams.

Kugler thinks that in the long run, pharma digital organizations will be most successful if they are absorbed and distributed throughout the company.

“A chief digital officer is like a chief electrical officer, eventually you just figure out electricity,” he said. “This isn’t something the digital organization should be running forever. The business areas should be bringing it into their cores.”

However, he believes digital programs at pharmas require special consideration from an ethical point of view.

Because Merck KGaA is a majority family-owned company where the board is personally liable, it has sought to approach new technologies with ethical implications such as gene editing “in a way that withstands personal liability,” Kugler said. “We replicated that concept with the digital space, starting with a bioethics advisory panel.”

## Sourcing talent

While workforce constraints are an issue across all of pharma, digital “is an area where the talent war is really tremendous,” said GSK’s Wood.

Part of what makes digital recruiting so challenging is that pharmas are competing with other well-funded sectors such as tech. They also face a scarcity of people who are “bilingual” — well versed in both data science and biomedical research — in part because that talent is highly sought after by the growing crop of well-funded start-ups at the intersection of tech and biotech.

Branson credits CSO and President of R&D Hal Barron, who came to GSK from the Verily Life Sciences LLC unit of Alphabet Inc. (NASDAQ:GOOG), for knowing what machine learning teams would require and building the group.

He highlighted the hiring of VPs Steve Crossan, formerly of DeepMind, and Shane Lewin, formerly of Microsoft Corp. (NASDAQ:MSFT), and senior director Jeremy England, formerly a physics professor at Massachusetts Institute of Technology.

Other factors helping GSK recruit its digital workforce include the GSK.ai Fellowship Programme, and the opening of GSK’s AI hub in London last year, Branson said.

Khan, who has built a team of about 100 people, said the majority of them were “developed” to be bilingual internally. About half of the team are women, and she thinks representation on digital teams is a critical step to avoid baking bias into the products they create. “To create a diverse team is not by accident. We need to do that, not just speak about it.”

She also thinks about organizational structure from a recruitment and retention point of view.

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Najat Khan, J&J

“Every time you build capability, you need to gather a critical mass of people, give them autonomy and make sure their voices are heard, because they’re going to be outnumbered,” Khan said. “What we did is we centralized, so we have one Janssen R&D data science team. It helped us draw in good talent because they knew we were serious about it. It’s not two people in a therapeutic area somewhere.”

Rall thinks the recruitment picture has improved during the pandemic. In addition to remote work making it possible to bring in talent from anywhere, enthusiasm has grown.

“We did a survey among tech practitioners, and they believed that with COVID, the day of digital in pharma and healthcare has arrived,” he said. “There’s now a shared understanding of the importance of what we do and the impact you can have.”

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### NEWSROOM

news@biocentury.com

### SAN CARLOS, CA

+1 650-595-5333; Fax: +1 650-595-5589

### CHICAGO

+1 312-755-0798; Fax: +1 650-595-5589

### WASHINGTON, DC

+1 202-462-9582; Fax: +1 202-667-2922

### UNITED KINGDOM

+44 (0)1865-512184; Fax: +1 650-595-5589

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