

Seizing the digital opportunities in pharma

Preparing your organization and monetizing the digital technologies

Arthur D Little

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Executive summary

Digitalization in healthcare is booming, and creates unprecedented opportunities to further improve health standards and accessibility. Still, large pharma companies are confronted with the challenge of selecting, funding and developing the right projects among myriad initiatives: What is the right starting point and framework to compete? What to prioritize? How to make digital pervasive in the organization? How to monetize it?

Based on our recent experience, we at Arthur D. Little have developed a pragmatic framework to characterize and evaluate the opportunities, define and prioritize the related initiatives, and ensure that there is a clear business rationale – along with its financial business case – supporting them.

We share below some of the learnings from our recent work with pharmaceutical companies in this area.

Figure 1: From foundation to digitally enabled business models **Business Model Innovation** Patient-centric solutions Real-World Outcomes Digital Capabilities & Consumerization of healthcare Foundation Organization Health apps and lifestyle "smartization" **R&D** Acceleration IT architecture & Target Real-World Evidence infra-structure archetype(s) Precision medicine Translational medicine Data manage-Adaptive (pre) clinical trials Governance ment & **New Commercial Models** standards Skills Multichannel apps & tools Al targeting and caregiver relationship mgt Data safety and AI caregiver decision support Engagement integrity Marketing factories Smart Operations Relevant Collaborative **Digital factory** partners interfaces Batch of one Prescriptive analytics Machine learning

Source: Arthur D. Little

1. Personalized medicine thanks to innovative digital business models

Like in other industries, digital technologies are about to disrupt traditional business models in healthcare. Chronic diseases, in particular, offer increasing opportunities to provide comprehensive therapeutic solutions on top of drugs that offer improved outcomes and superior convenience for patients and caregivers.

While data privacy and regulations remain concerns, increasingly empowered patients are willing to share their medical information to get improved treatments and personalized care. The capture of real-world data by connected devices – in some cases, in real time – is one of the key enablers of innovative therapeutic solutions, paving the way to tailoring treatment to specific needs. The amount of data captured through connected items is exploding and, while the full value of the information is not yet captured or used, several remarkable initiatives are developing: as shown the examples in Figures 2 and 3 demonstrate, pharma companies are collaborating with partners that have strongly developed capabilities with regards to specific technologies, in order to provide new forms of treatments to their patients.

In addition to these transformational initiatives, most players are experimenting with more focused pilots in R&D, commercial and industrial operations.

Figure 2: Sanofi and Verily develop a new business model in diabetes

S onduo

- Sanofi and Verily Life Sciences (an Alphabet company) launched diabetes-focused, joint venture Onduo.
- **\$500m investment** shared equally.
- Onduo's mission is to help people with diabetes live full, healthy lives by developing comprehensive solutions that combine devices, software, medicine, and professional care to enable simple and intelligent disease management.
- Practically, it is expected that the wearable devices will enable patients with type 2 diabetes to monitor physiological parameters and to continuously adapt insulin dosage accordingly and in real-time to optimize the treatment.
- In the future, Onduo will include the type 1 diabetes community and even help to better prevent the onset with high risk people.

Source: Arthur D. Little, Sanofi, Onduo, Bloomberg, press releases

- Enormous benefits can be achieved, as it provides:
 - An invaluable source of real world data as an input for future development & improvement of the treatment
 - Outcome information that can be used to adapt prescription guidelines, pricing and reimbursement
 - A tool for treatment improvement through augmented adherence
- Provided you have the required analytical tools, processes and systems to use them. These require new capabilities, e.g.:
 - Highly accurate sensors and device (99% is not sufficient)
 - Ubiquitous connectivity with guaranteed QoS & low latency
 - Enormous analytical computing power
 - Absolute data security

| Who? | What? | Details? |
|---------------------|--|--|
| | Establishment of Verily & GSK JV Galvani Bioelectronics to advance in bio-electronic medicines | Modulating electrical signals in peripheral nerves using miniature, implanted devices aiming at disease control and reversal Initial focus: clinical proof of principle in inflammatory, metabolic & endocrine disorders (development of miniaturized, precise devices) |
| verily Unovartis | Collaboration to develop next generation contact lenses | The main product is a contact lens capable of measuring glucose levels in the tear film, collecting that data, and transmitting it to a cloud- or smartphone-based connection Other products: near- & far-sighted accommodating contact lens, and intraocular lens implanted in the eye to clear up cataracts |
| GECKO HEALTH | Gecko Health Innovations acquisition by TEVA to bring patient-centered respiratory disease management solution | Cloud-based solution connecting patients and caregivers through remote monitoring and real-time adherence tools Solution: comprises hardware device which attaches to most metered-dose inhalers as well as a software program which synchronizes and stores data through an app-based user interface |
| | Collaboration on next generation Breezhaler inhaler device to treat Chronic obstructive pulmonary disease (COPD) | Improved inhaler wirelessly sends the data to the patient's smartphone and a Novartis COPD mobile application and cloud The solution enables patients and healthcare providers to monitor their COPD in near real time |

Figure 3: Several major initiatives combining digital technologies and traditional pharma will change the treatment paradigm

Source: Arthur D. Little, healthegy, TEVA, Novartis, Verily, press releases

2. A drastic acceleration of R&D

Digital technologies such as cognitive computing and connected devices are revolutionizing R&D in pharma, dramatically impacting the speed and economics of the process. For example, the availability of data on an individual's genotype, environment or lifestyle, combined with advanced technologies such as genomics and other "-omics", data analytics and improved modeling, allow for faster discovery of drugs, as well as better prediction of the efficacy and safety of different treatment alternatives for specific patients. This is sometimes referred to as "precision medicine".

The Baylor College of Medicine, for example, managed to find 20–30 potential tumor- suppressor candidates in a few days, compared to one every few years, by using cognitive computing to execute labor-intensive modification and cross-correlation activities.

Cross-domain discovery can lead to the identification of drug candidates within an existing portfolio in a matter of days instead of months or years – e.g., Novartis used Amazon Web Services to virtually screen 10 million compounds for a common cancer target, resulting in three successfully identified compounds. The project ran for nine hours and cost ~4,000 USD, compared to 39 years of research and 40 million USD for the traditional computational chemistry approach.

Through mobile solutions, the recruiting of more – or more appropriate – candidates for clinical trials also becomes

significantly easier and cheaper, e.g., instead of paying 10,000 USD for a few hundred patients, through apps such as ResearchKit, pharma companies can work with thousands of participants at a fraction of the ,cost. In addition, the mobile solutions are much more patient centric than the classic approach.

R&D no longer stops at the door of the lab where clinical trials take place: "translational medicine", or "bench-to-bedside", bridges academic research with information from clinical science and community practices. Novartis and Merck, for example, have already set up a Translational Medicine Research center that enables them to bridge their phase I research with phases II and III. Early proof-of-concept studies that support early drugdiscovery pipeline decisions will help avoid expensive later-stage failures, thus further decreasing development costs.

Analytics that incorporate real-world evidence and data also allows for the adaptation of parameters for clinical trials, including dosage, subject population and sample size. Implementing digitally enabled "adaptive (pre-) clinical trials" will result in overall cost reduction, increased transparency, increased approval rates, and ultimately better, faster and more targeted care, thanks to quicker identification of the drugs that have therapeutic effects on specific patient populations.

| Who? | What? | Details? |
|--------------------------------|--|---|
| Roche | Roche invests in Blueprint's medicine platform to speed up development, discovery & commercialization of molecules targeting kinases | Blueprint uses genomic profiling to match compounds from a library of kinase inhibitors with the cancers they are best suited to treat, to craft precision therapies Blueprint makes use of a high-capacity computing infrastructure that can store very large genomic databases, but also rapidly analyze the data, using algorithms to analyze human tumor sequences. |
| Pfizer Watson Health | Pfizer is working with IBM's Watson around immuno-oncology, to faster identify new drug targets and support patient selection strategies | IBM's Watson incorporates technologies such as cloud, machine learning, natural language processing, and other cognitive reasoning technologies, which allow it to read, understand and analyze large amounts of data through the application of algorithms IBM Watson Health is used by a variety of HC players in drug discovery and precision medicine, matching treatments with patients |
| verily | Longitudinal study using wearable sensors, machine algorithms and computational techniques to discover the most relevant factors influencing severity and evolution of MS | Verily, Biogen and Brigham and Women's Hospital collaborate in an effort to discover why multiple sclerosis (MS) progresses so differently among individuals and how care can be improved Data will be collected in lab based and clinical tests as well as through the use of wearable devices outside of the lab |

Figure 4: Illustrative examples of technologies accelerating R&D

Source: Arthur D. Little, IBM Watson Health, Verily, Blueprint medicine

3. Superior patient and provider convenience to boost commercial performance

The increased diversification in the way patients, caregivers and other stakeholders in the health care sector engage with each other in the digital space requires pharma companies to further develop and nurture their multichannel competences, as this creates an invaluable source of information for them.

Real-world data (RWD) on treatment effectiveness, adherence, side effects and individual patient responses can also be used to adapt and improve therapies, position drugs more accurately, target specific patients and recommend amendments to prescription guidelines. For example, Roche acquired the digital diabetes management platform company mySugr.com in June 2017: an app and associated services provide a solution to help diabetics track their blood sugar, medications, activity levels and automated data via a variety of connected devices. With more than 1 million loyal users registered with mySugr, this acquisition is is expected to provide Roche with access to a vast amount of valuable data, which will be used to meet needs and improve quality of life.

Roche has also developed a smartphone-based continuousmonitoring system for Parkinson's disease fluctuation. The app measures disease and symptom severity during daily routines set for the patients.

RWD will be increasingly used to support the decision-making processes of care providers (and patients for consumer brands), while digital tools and data analytics will also allow companies to better understand prescribing behaviors. For example, sales representatives who use digital tools have performed up to 30 percent better than their peers, with increases of customer loyalty of up to 10 percent. Using analytics to target specific caregivers with the most relevant products has, in some cases, led to top-line improvements of 10 percent. Novartis rolled out a digital, multi-channel social campaign tailored to attract younger MS patients, and to encourage community feeling and information sharing; this has led to an increase of 28 percent in sales over one year, reaching 2.48 billion USD.

Figure 5: Case study Novartis

| Case Study - Novartis saves 250 hour per rep per year by enabling a consultative, insight-driven, two-way dialogue with HCPs | |
|--|---|
| Context | Historically, pharma relied on a "Share of Voice" model: reps paid visits to doctors visits following a script, leaving behind prints However, this model lost traction as generics rose, payers and providers gained purchasing power & formulary lists were put in place Moreover, some doctors were opting out of the one-way in-person visitation model |
| Business capabilities | Novartis aimed to enable its field force to engage doctors in a consultative two-way dialogue via a multiple channels thanks to, e.g.,: Videoconferencing across multiple locations Accessing and sharing the latest information and practices Gathering information on customers and tailoring the approach to the needs of the customer's patients Carrying the entire product portfolio and all underlying details |
| IT enablers | Digital customer interaction platform to track HCP info & preferences Analytics to understand HCPs & tailor contact approach/messages Non-linear navigation through cloud-accessible content in all product domains, e.g., expert opinions, clinical pathways, research papers on side effects and off-label use requests Mobile devices to access content anywhere |
| Source: Arthur D. Little | |

4. Operations as a driver for competitive edge

The digital transformation has changed the rules of the game across sectors, significantly altering the customer journey. In an era of hyper-connectivity, the customer now has myriad options to research and buy the products and services he or she needs, 24/7.

A strong increase in operational complexity and a growing focus on improving operational efficiency in order to preserve patient safety, while keeping operating costs under control, is driven by:

- The increasing share of targeted treatments addressing narrow populations of patients
- The increasing technological complexity of products (biologics, suspensions, combos)
- Ever-increasing regulatory requirements (e.g., serialization)
- Multiplication of the roads to market

Industry 4.0 digital technologies enable more accurate planning (e.g., patterns, predictions, prescription analytics), more reliable and cost-efficient operations, and more sophisticated service models.

The related initiatives provide fast payback, e.g., working-capital reductions of up to 30 percent become possible thanks to

dynamic forecasting and inventory allocation based on advanced analytics and more comprehensive, centralized and correct data sets. Improvements in response time to changes in market demand by 25 percent, as well increased product availability by 10 percent, are additional examples of very tangible benefits to the digital supply chain. Analytics in production can lead to 30–40 percent downtime reduction thanks to predictive maintenance and automatic corrective actions, which are driven by actionable metrics coming from machine-to-machine communication, data integration and analytics.

For several years now, MIT and Novartis have been collaborating to reduce Novartis' OPEX and CAPEX by an estimated 25–60 percent through implementing continuous manufacturing, which is enabled by digital technologies with lowered throughput time (10 days) compared to optimized batch production (~100–150 days). They have formed a 10-year partnership in which Novartis has invested 65 million USD. GSK and Johnson and Johnson have also invested in the continuous manufacturing technology. The advantages have not gone unnoticed by the FDA either, which has – since the first approval in 2015 – become an active supporter of the transition from batch to continuous manufacturing.

Level of Maturity

5. How to prepare your organization

While there is generally a wide consensus on the long-term ambition to make digital a pervasive business capability in the organization, interrogations subsist on the way to organize the required transformation.

Traditional IT departments are clear stakeholders, but face the challenge of seeing a major part of their budgets and resources allocated to maintenance, versus investing in new applications and systems. Engaging in efficient ways with their business counterparts is another frequent challenge. On the other hand, leaving the initiative to the business alone brings along a number of inefficiencies and risks. In practice, we have observed varying philosophies of approach across industries, which can be summarized by three archetypes:

A. The IT department leads the digital transformation

This situation is frequently observed, mostly with the appointment of a special representative reporting to the CIO and creating liaisons with the business owners. This typically evolves over time towards a portfolio of projects led individually from within the business units.

This structure offers the benefits of being easily implementable (evolution of pre-existing structure) and pragmatic (adequate IT infrastructure and capabilities are prerequisites – see below), with a good degree of agility, since the individual projects are independent of each other and typically funded by the business. This is often the situation for companies that start exploring digital but are still in their infancy on the digital journey. In

Figure 6: Organizational archetypes

| Model | IT department leads digital | A "Chief Digital Officer" reporting to | Digital transformation is led by the |
|------------------|---|--|---|
| transfor | transformation | the board leads the transformation | business units |
| Specifics | Frequently observed Combined often along with a special representative reporting to the CIO Evolves towards a portfolio of projects led by the business units | Adopted by several large pharmacos. Either "institutionalized" as a perennial position, or Task force to evaluate options, plan digital transformation | Each BU / segment appoints champions to lead specific initiatives Typically in the form of separated business projects |
| Value | Easily implementable (evolution of pre-existing structure) Pragmatic (adequate IT infrastructure and capabilities are pre-requisites) and Agile: projects independent from each other, funded by the business | Favorable setting to consider and evaluate (major) strategic initiatives Board-level sponsorship sends a strong signal and creates momentum Ensures a focus on business objectives and results | Brings the ultimate pervasiveness of digital into the business Enables real / breakthrough business model innovation |
| Risks | Proliferation of tactical projects Competition for resources Inefficient X-functional collaboration Limited knowledge sharing Over-investment per lack of standards | Requires a solid foundational set of technological capabilities From infrastructure to analytics | Requires solid maturity and familiarity with the operationalization of digital technologies |
| When Best Fit | Companies starting to explore but still in their infancy in the digital journey | For companies who have experimented and enhanced their digital maturity | MT/LT objective for organizations having successfully developed digitally enabled business models |

Source: Arthur D. Little

the longer term, however, it also brings a number of risks: of proliferation of tactical projects, competition for resources, inefficient cross-functional collaboration, limited knowledge sharing, and over-investment due to lack of standards.

B. A "chief digital officer" reporting to the board leads the transformation

This approach has been adopted by several large pharmacos. Practically, it either is "institutionalized" as a perennial position, or can take the format of a task force with a specific objective of evaluating opportunities and planning the digital transformation. This sometimes appears as a small group of "evangelists" who promote digital technologies across the organization, support experiments with digital initiatives, and encourage a climate in which it feels safe to experiment and fail. Both options have the value of creating a favorable setting to consider and evaluate (major) strategic initiatives. The board-level sponsorship sends a strong signal to the rest of the organization and creates momentum among the teams. It also ensures a focus on business objectives and results. However, it requires a solid foundational set of technological capabilities, from infrastructure to analytics, making it more appropriate for companies that have already experimented and enhanced their digital maturity. For example, Novartis sent a strong message in August 2017 by announcing the creation of the role of a digital officer with the remit to lead the digital transformation. The company has embarked on this to improve the way it uses data in drug discovery and development, engages with patients, doctors and other stakeholders, and automates business processes.

C. Digital transformation is led by the business units

Theoretically, this model brings the ultimate pervasiveness of digital into the business. However, it requires solid maturity and familiarity with the operationalization of digital technologies, which has not yet been achieved in the pharmaceutical industry: it is, rather, a medium- to long-term objective into which organizations can evolve after having successfully experimented and developed one or several digitally enabled business models.

6. Recommendation to executives: a call to action

Digital health is a reality: many initiatives may not yet have delivered tangible results for patients, but one should expect to see radical changes very soon in the way drugs are being developed, produced and marketed. The patient's therapeutic journey is about to be transformed in terms of efficiency, convenience and affordability. A number of transformational initiatives is on the way, essentially in the form of partnerships with technology companies. The digital-health market is expected to keep growing at a pace of 20–30 percent annually in the years to come. Hence, to stay in the race, it is urgent for pharmacos to develop foundational capabilities and transition out of the "old" organizational archetypes:

1. Build a solid "digital foundation" with a set of relevant capabilities

While this may seem obvious, a large number of companies are trapped dealing with a complex and poorly connected

Figure 7: Start by building a solid digital foundation

Digital foundation

legacy application landscape, and struggling to catch up with infrastructure challenges such as cloud migration. Some have managed to develop islands of sophisticated analytical and data-processing capabilities, while others are experimenting with targeted (R&D) pilots with tech companies, but none have developed comprehensive sets of technological and human resources that can provide the required capabilities. Notwithstanding the constraints mentioned above, a good place to start (to accelerate) is the development of foundational capabilities, which we can split into four main categories: supporting infrastructure, whether cloud, micro-services or other; data management and advanced analytics platforms with data scientists and applications that support advanced analytics capabilities; data integrity and safety; and collaborative platforms that allow connections across functions, partners, and suppliers, and ultimately with patients; and A clear advantage of this approach is that this is where IT typically has strong legitimacy; hence, a fast ramp-up in close collaboration with the

| IT architecture & infrastructure | Provision of the required on-premise and cloud infrastructure Integration of information, processes and applications, hosted both internally and externally Alignment of application landscape – E.g. cloud-ready vs. non-cloud-ready applications Scalable, easy to use and versatile data integration platforms – E.g. micro-services | |
|----------------------------------|--|--|
| Data management & standards | Common policies and standards for data collection, storage, processing, integration and curation Digitalization of data capture, wherever possible, structured master data and data sets Cognitive tools for collection of external and / or unstructured data Applications that support advanced analytics capabilities Data scientists | |
| Data safety & integrity | Secured shared platforms and processes for internal and external collaboration Easy to use data integration platforms Policies on preferred tools and proper usage Clear data ownership and access | |
| Collaborative interfaces | Open systems for external partnerships opportunities Virtual meeting environments Seamless collaboration systems in meeting rooms | |

Source: Arthur D. Little

business is possible. The ultimate objective of building a solid IT foundation is to make the technology versatile, safe, ubiquitous and accessible across the company.

2. Engage and experiment with partners

The majority of initiatives a currently run "from inside," yet the most transformational ones take the form of strategic partnerships. (See examples above.) Provided your company has the corresponding level of ambition, we recommend also systematically exploring opportunities to engage with partners that have the relevant digital capabilities and the right cultural DNA to help transform your company. These partners could be well-established companies that are interested in entering into a joint venture, but also start-ups, scale-ups, governmental organizations, educational institutions, suppliers or even competitors.

The right partners will have deep understanding of the real potential of the new technology they are working with. Not only are these initiatives more transformational in terms of business model innovation, but they also provide access to (and create a home for) specific expertise and skills that may prove lengthy, costly or even just impossible to develop in-house. It is much faster and cheaper to bring this capability into the company via partnerships than through own training and recruitment. Ultimately, such partnerships prove to be important assets in the war for digital talent. Strategic partnerships are, if not a starting point, a key building block in the development of digitally enabled competitive advantages.

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Arthur D. Little

Arthur D. Little has been at the forefront of innovation since 1886. We are an acknowledged thought leader in linking strategy, innovation and transformation in technology-intensive and converging industries. We navigate our clients through changing business ecosystems to uncover new growth opportunities. We enable our clients to build innovation capabilities and transform their organizations.

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