Digital's transformative power across R&D: Keeping pace with stakeholder expectations
The healthcare industry continues to experience massive change driven by both external and internal factors, which combined, present opportunity for deep reflection and radical business model transformation.

External demographic and economic pressures consist of an aging global population; rise of chronic disease; changing customer expectations including patients, payers and providers; increased patient involvement; and amplified regulatory scrutiny. Companies are challenged by the need to understand, prioritize and leverage the growing opportunities made available by technology proliferation and capabilities.
Against this background, the pharmaceutical and biotechnology industry continues to define and redefine how to meet the requirements of the world around it. As identified in newly released Accenture research, internally, Research & Development (R&D) organizations within pharmaceutical companies are considering important strategic imperatives necessary for enabling future success.¹ These consist of how R&D functions will:

- **Pivot to the patient**—transforming R&D models to be more patient outcome focused.
- **Advance to the next generation of R&D operating models**—facilitating cost reductions to improve productivity.
- **Drive scientific and operational excellence**—advancing faster time to market from first in human to approval.

To take action, the industry is beginning to shift from volume-based models to a value-based approach, which means companies must focus on delivering outcomes-based health and therapy management services.² R&D organizations have an opportunity to leverage the power of the digital age to help achieve business imperatives (see sidebar). Truly digital business models are information intensive, technology enabled and disruptive while focusing on creating an exceptional customer experience and amplifying internal performance.

With forever changed and increasing customer expectations and the dramatic adoption of digital solutions by customers and companies, we believe it is essential for R&D organizations to expedite a more holistic embrace of digital or risk being outdone by their competition. Many analyses (including Accenture’s⁴) within and outside the pharmaceutical industry have measured the value that digital transformation creates in terms of profitability, revenue and customer experience.

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**What is "the digital age"?**
We define it as one in which technologies are capable of collecting, synthesizing, analyzing and communicating information to and/or from individuals and systems. We believe the industry is at an inflection point for digital disruption in R&D. Digital is changing our lives. People’s habits, behaviors and expectations are perpetually evolving as new devices, platforms and applications emerge. Four of the five top global brands (e.g., Google, Apple) are digital businesses.³

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According to Accenture research, in the next three years, 82% of companies expect to be a digital business.³
R&D's primary stakeholders—patients, providers, payers, regulators and employees—have already begun to embrace digital. Patients use online forums and social networks to discuss conditions and treatments; providers trade YouTube™ videos to demonstrate and share medical techniques. Payers and regulators have invested millions in analytics to assess the value of treatments and procedures. R&D employees are embracing virtual work environments and collaborations through the use of mobile and cloud based technology. R&D stakeholders are accustomed to living in a digital world where instant access to information and improved interactions are standard. They expect the same experiences during their interactions with pharmaceutical and biotechnology companies.

However, many R&D organizations lag behind their stakeholders’ expectations in adopting digital.

None of the typical reasons for delay—hesitancy to adopt new technologies, risk adverse cultures, and the uncertainty of regulations and perception of health authorities—should prevent R&D organizations from embracing digital. One of the great aspects of the digital age is that it appears to be maturing in an evolutionary manner—occurring on a continuum yet following a recognized path evident in other sectors.

This Point of View explores what digital R&D is and how R&D organizations can close the gap to harnessing its transformational power. What follows addresses three key questions:

1. Digital can help drive value in R&D: What value?
2. Digital is already transforming R&D: Are you ready?
3. Digital R&D transformation is happening: How do you get there?
Digital can help drive value in R&D: What value?

Digital capabilities can be applied across three major industry imperatives that we believe are enablers to R&D's future success.

- **Pivot to the patient.** Digital capabilities create patient connection and engagement.

  Applications of digital solutions and services help generate and document a holistic, shareable picture of patient health and improve understanding of the patient journey and disease areas.

- **Better understand diseases and shape R&D product programs.**

  Using real-world evidence to study existing therapies and the corresponding impacts on patient lives in order to uncover unmet medical and personal needs which can inform a product’s target product profile.

- **Enhance the patient experience.**

  Connecting patients, caregivers and advocates within their communities leveraging digital capabilities and multi-channel access (e.g., apps, wearables, social media) to understand changing habits, behaviors and expectations to inform the design of a clinical trial, and/or patient services.

- **Improve patient outcomes.**

  Understanding, incorporating, and testing digital solutions and services during the drug development process and assisting clinicians with collecting the appropriate data to better understand a disease and complementing therapies, increase the efficaciousness and effectiveness of products, as well as patient adherence to product use and compliance with procedures for better health outcomes.

While R&D organizations have evolved patient centricity strategies, there is opportunity to do more. Rebalancing traditional vs. digital activities within a patient engagement strategy provides a pathway for companies to understand and deliver an improved patient experience, while integrating perspectives from caregivers and advocates to provide more seamless and holistic care.
Advance to the next generation of operating models. Digital capabilities create a digitally empowered workforce.

A digitally empowered workforce generates the opportunity to operate differently, with improved productivity both within and across functions of an R&D organization. Digital workforce solutions facilitate faster evolution of roles and responsibilities and help with greater collaboration across functions which can speed time to market.

- **Change the traditional way of thinking and operating.** Identifying and leveraging digital solutions and services (e.g., virtual reality and thermal reading eyewear within the lab, gamification techniques across clinical groups, multi-channel interactive communication across functions) within the workforce to challenge the traditional way of thinking and operating.

- **Enhance the employee experience.** Understanding more broadly organizational needs and expectations of the employee to design an experience focused on improving how work gets done and improving employee engagement.

- **Embed digital savviness in your organization.** Identifying the appropriate talent across R&D functions to facilitate the collaboration, innovation, agility and flexibility needed to operate in a digital business model and balance the level of innovation and traditional thinking to help drive stakeholder and functional alignment.

Effective implementation of a digitally empowered business model requires a shift from the traditional analog mindset to an innovative and strategic approach to operations and decision making across the R&D value chain (e.g., early development, clinical, data management, regulatory, PV, medical). While automation and artificial intelligence can remove the burden of low value activities and help an organization’s resources to advance on the digital adoption curve, to upskill and focus elsewhere—understanding where the organization is and wants to be—in terms of people, process, technology, governance, and organizational structure and can guide development of digital initiatives that improve workforce management and organizational productivity.
Digital capabilities make it possible for companies to aggregate and synthesize data that have not traditionally been combined. Synthesizing historical data, internal data (e.g., clinical trial data, operational data), and external data (e.g., electronic medical records, claims data) empowers R&D organizations to generate insights to inform R&D activities and decisions.

- **Improve scientific decisions earlier in the R&D processes.** Empowering early research with genomic data, identifying unmet medical requirements, and predicting early on in the lifecycle which products would be successful and remain competitive in the long-term.

- **Shift the R&D way of working to an informed and predictive approach.** Equipping cross-functional operations with a more informed and predictive approach, one that combines benchmarking and statistical models to determine acceptable relevant performance deviations based upon pre-defined outcomes, as well as actions that create value for the organization.

With the appropriate capabilities and understanding of current data, companies can deploy analytics to improve both the scientific understanding of their products and the effectiveness of their operations across R&D functions. Realizing the true value of internal and external data, in combination with analytics tools is one of the largest benefits of embracing digital for R&D. However, to work towards success, R&D organizations must interact with patients and stakeholders differently and change internal operations to generate, collect and consume the data and unlock the insights digital can transform.
Digital is already transforming R&D: Are you ready?
Early digital adopters are leveraging pilots in clinical trials and/or submitting new products for regulatory approval with a digital companion. However, we believe there is opportunity to move beyond disconnected pilots and isolated initiatives to embrace digital and realize all the value it has to offer. Recent Accenture research indicates despite the shared industry belief that digital can sharpen the focus on patients and improve outcomes, with an understanding of the clear impact digital has had in transforming other sectors, there appears to be an even split in the rate of adoption of digital (see figure 1 below). Responses indicate 55% of R&D executives confirm their companies are adopting digital, 42% characterize their companies as exploring digital and 3% are “waiting and seeing” how digital is deployed before ramping up internal capabilities.1

In order to increase impact from digital capabilities aligned to the industry imperatives, organizations ought to identify a holistic set of cross-functional services and solutions which can be applied to all activities within the value chain, from scientific collaboration internally and externally, to the transition from in vitro to in vivo, to phase I through phase III clinical trials and initial product submissions, to ongoing safety monitoring, and product maintenance, and key opinion leader (KOL) and health authority interactions through various channels and partnership methods.

In order to assess your organization’s readiness toward adoption of digital capabilities, we recommend asking the functional and technology leadership teams the following questions to understand what the organization has versus does not have:

- Current state: What is your digital footprint today?
- Future state: Have you defined it?
- Alignment: Is your organization onboard with it?
- Path forward: Do you have a plan to achieve it?

This process of asking important questions across the imperatives can help R&D organizations communicate the opportunities and threats digital might pose to the business and to what degree. It can also help organizations get a better view of where each opportunity and threat is coming from and the strategy and actions needed to build competitive advantage in a quickly evolving digital business environment.

Figure 1: Industry at a crossroads: The rise of digital in the outcome-driven R&D organization

55% of R&D executives confirm their companies are adopting digital

42% characterize their companies as exploring digital

3% are “waiting and seeing” how digital is deployed before ramping up internal capabilities

Some R&D organizations appear "digital" yet few have built the necessary capabilities discussed here to realize digital’s potential value. To do that, companies should take the following actions:

- Assess the current digital footprint within your R&D organization and across the enterprise.
- Create the “art of the possible” future state inspired by examples within and outside the industry.
- Seek to understand stakeholder needs and expectations to shape optimal experiences across therapeutic areas and R&D functions.
- Align on the appropriate vision, strategy and prioritization for organizational buy in.
- Build a roadmap to seek to achieve the desired future state, inclusive of timelines, resources, and budget.
Once R&D organizations move toward a "digital" way of working by implementing a set of capabilities, solutions, or services or at least improving priority processes such as clinical trials (see Figure 2), aligned to a holistic digital strategy, they will not return to the traditional approach.

The time to digitally transform pharma R&D is now. Accenture research shows companies that invest aggressively in building digital capabilities can boost profits.⁵

Digital transformations outside the constraint of today’s ways of working should even further reduce development costs; however, R&D organizations should first begin to improve within today’s environment considering the full R&D value chain and available opportunities.

Digital can play an important role in helping R&D organizations overcome today’s challenges, realize the value of each industry imperative and make significant progress toward the industry’s overarching, fundamental mission: to better understand specific disease states, and create products and services that improve patient experiences and long-term outcomes.

Defining and implementing a digital strategy to transform your current ways of working will help getting the right products—better products, targeted to the appropriate customer segment and condition, with outcomes in mind—to market faster.

**Figure 2: Clinical Trial Digital Study (Illustrative)**

<table>
<thead>
<tr>
<th>Digital Methods</th>
<th>Study Design/ Pre-study</th>
<th>Study Start-up</th>
<th>Study Conduct</th>
<th>Study Closeout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real-world evidence in design of protocols and modeling expected outcomes</td>
<td>Social platform for patient recruitment and ongoing trial awareness</td>
<td>Digital tools for screening, consent and cohort randomization</td>
<td>Electronic supply chain management</td>
<td>Automated data analysis and filing for regulatory review</td>
</tr>
<tr>
<td>Adaptive trial design</td>
<td>Site and patient identification using analytics</td>
<td>Optimized site start-up leveraging digital platforms</td>
<td>eLabels for optimized drug authorization, shipment and reconciliation</td>
<td>Automated generation of TFD&amp;Gs (Tables, Listings, Figures and Graphs)</td>
</tr>
<tr>
<td>Patient articulated outcomes in product and program design</td>
<td>Social platform for patient recruitment and ongoing trial awareness</td>
<td>Digital tools for screening, consent and cohort randomization</td>
<td>Electronic supply chain management</td>
<td>Automated data analysis and filing for regulatory review</td>
</tr>
<tr>
<td>Predictive analysis and risk identification; improved protocol design</td>
<td>Faster site patient identification and enrollment</td>
<td>Faster site start-up; increased patient understanding &amp; compliance</td>
<td>Transparent, efficient, and cost effective delivery</td>
<td>Digital tools to thank patients and provide results/data</td>
</tr>
<tr>
<td>Faster site patient identification and enrollment</td>
<td>Faster site start-up; increased patient understanding &amp; compliance</td>
<td>Real time data access, monitoring, control; improved patient experience</td>
<td>Early detection of data trends; decreased early withdrawals</td>
<td>Improved speed to market</td>
</tr>
<tr>
<td>Transparent, efficient, and cost effective delivery</td>
<td>Real time data access, monitoring, control; improved patient experience</td>
<td>Early detection of data trends; decreased early withdrawals</td>
<td>Improved speed of database lock</td>
<td>Improved patient understanding and compassionate care</td>
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Source: Accenture Digital
Contact Us

Nicole Faust Cohen
Managing Director – Life Sciences
nicole.f.cohen@accenture.com

Kevin K. Julian
Managing Director – Accelerated R&D Life Sciences
kevin.k.julian@accenture.com

Ian C. Shafer
Managing Director – Life Sciences
ian.c.shafer@accenture.com

Katie M. Strasser
Manager – Life Sciences
katie.strasser@accenture.com

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