Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

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DRUG DEVELOPMENT WORKFORCE IN THE AGE OF DIGITAL TRANSFORMATION

The Fourth Industrial Revolution[i] is here, and it is transforming the drug development enterprise. The unprecedented and simultaneous maturing of a wide variety of data-management solutions and breakthrough technologies[ii] has increased the biopharmaceutical industry's ability to collect and store large, ever-growing quantities of clinical[iii] and patient-generated health data (PGHD)[iv]. These data, when paired with powerful analytics, hold great promise in better informing and supporting stakeholders throughout the drug development process, in advancing public health, and in delivering new treatments and cures to waiting patients around the world.

On December 4, 2019, the Tufts Center for the Study of Drug Development (Tufts CSDD), with support by a grant from Pfizer, Inc., facilitated a first-of-its-kind Senior Leadership Roundtable in New York City to discuss the current state of the drug development workforce as it enters the digital era. Sixty executives from pharmaceutical and biotechnology companies, technology-solutions companies, professional trade organizations, and academia participated in the roundtable. Participant functional expertise included clinical, clinical operations, data management, regulatory affairs, human resources, digital technology, and R&D strategy.

Experts discussed the current state and preparedness of the drug development workforce, challenges and opportunities presented by the digital transformation era, new and emerging critical skills and competencies required, changes in talent recruitment and retention practices, and the reshaping of corporate mindsets and cultures to become digitally proficient organizations.

This White Paper, which provides key findings from the roundtable, is intended to inform and stimulate discussion, as the various components of the drug development pipeline lead the vanguard in the Fourth Industrial Revolution.

Executive Summary

The Tufts Center for the Study of Drug Development (Tufts CSDD) convened a roundtable on December 4, 2019 with sixty executives from pharmaceutical and biotechnology companies, technology-solutions companies, professional trade organizations, and academic institutions to discuss the current state of the drug development workforce as it enters the digital era. Insights were generated and shared through discussion on the following topics:

- **Challenges the drug development industry is expected to face as it adapts to the digital era**
- **Key trends shaping the industry's future workforce**
- **Skills and competencies that will be most valued by the industry**
- **Changing and new roles expected to emerge during this digital era**
- **What industry can do to meet human resource needs**
- **Practical steps organizations can take to advance existing staff and attract new talent**
- **What Human Resource functions can do to support digital transformation**
- **What organizations can do to shape corporate mindset, behavior, and culture**

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1. The Evolution of Data Sources and Usage Supporting the Drug Development Process

Over the past forty years, the sources and usage of data supporting the drug development process have evolved substantially. Between 1980 and 2000, industry focused primarily on gathering scientific data which used retrospective, insular data sets that were small and had limited accessibility and utility. Since the turn of the millennium, industry has embraced gathering scientific and operating data to inform scientific questions and executional feasibility. This approach relies on more accessible and comparative data permitting interim review and adjustment. The enterprise continues to evolve toward patient-centered data that requires open, flexible operating models supported by a high volume of structured and unstructured data, as well as powerful prospective and predictive analytics including those supported by machine learning and artificial intelligence. In the coming years, clinical development is expected to become increasingly decentralized, customized, and predictive. Figure 1 maps this transformation.

Figure 1: Speed of transformation of data and analytics usage in drug development

	1980–2000	2000–2025?	Post-2025?
Primary mission	Great science	Feasible and great science	Patient-engaged science
Clinical trial orientation	Key Opinion Leadership (KOL)	Investigative site	Patients and patient data
Operating focus	Insular	Comparative and competitive	Open
Operating approach	Reactive	Responsive	Customized and predictive
Decision support	Basic and lagging	Risk-based, root cause and benchmarking oriented	Advanced analytics, leading
Data accessibility	Limited accessibility	Improving accessibility	High cross-platform accessibility
Data value	Retrospective, appraisal-based	Anticipatory, pre-approved, adaptive	Continuous, flexible learning

As biopharmaceutical research transforms into a more data-rich operating environment, drug development professionals need to be equipped with the skills to distill actionable knowledge from vast clinical and patient-generated health data sets. It is in the industry's immediate interest to take the steps necessary to transform infrastructure and operating models, and to develop workforce data-science capabilities.

Digital transformation is moving at a rapid pace, and has shifted from adopting specific technologies to the broader project of rapidly establishing and embracing new operating models and adopting new solutions that take full advantage of what data can offer. Drug development stands to benefit greatly from increased exchange of knowledge and improved best practices for collecting, organizing, storing, sharing, exchanging, analyzing, interpreting, and communicating data. Such a transformation requires a high degree of adaptability at the levels of individuals, organizations, and the entire industry.

2. What Challenges Will the Industry Face as It Adapts to the Digital Era?

The need for overarching data strategies and governance frameworks

The volume of diverse scientific and operating data requires organizations to prioritize, clarify, and coordinate strategies for how data will be used to support development decisions. Biopharmaceutical companies are also seeking clarity from regulatory agencies to ensure the validity and regulatory compliance of data sources and to determine what constitutes meaningful and useful evidence to support agency decisions. Guidelines for data ownership, data privacy and security, data integration, data sourcing, and use of real-world data remain unclear.

Competition with technology sector for workforce talent

The emergence of hybrid roles will drive competition between drug development companies and technology companies in recruiting top data-science and artificial-intelligence talent. The biopharmaceutical industry must tap into the technology sector to recruit cohorts of data scientists and others with expertise in areas such as project management, systems engineering, and computer science. As competition for talent intensifies, biopharmaceutical companies must factor the expectations of digital natives who demand flexibility, opportunity, upward mobility, and the opportunity to do work they find meaningful.

Increasing cost of data management

Managing and coordinating sources of data and containing the growing costs of data management are driving the adoption of unified data platforms. Employees will require constant retraining to ensure up-to-the-minute proficiency in the rapidly changing features of such unified data platforms and skills. Such upskilling in technological updates will increase workforce training and development costs. New features and upgrades in a platform, as well as the development and adoption of new platforms that offer enhanced functions, mean that what was not possible six months ago has now become both possible and

a competitive advantage; and if companies are not agile in systems deployment and training, the development lifecycle will remain long, become obsolete, and as a result considerably delay the industry's progress along the transformation continuum.

3. What Are the Key Trends Shaping the Industry's Future Workforce?

Rapid changes in the job market

Dramatic job destruction and job creation will characterize the job market of the near future, and digital innovation is expected to have a sweeping impact on all involved in healthcare, including patients, payers, and drug developers. Technological developments, most especially the automation of repetitive and rote tasks, are expected to allow individuals to focus on meaningful work. Wages are expected to increase for STEM occupations, and these jobs will have high employment multiplier effects.

Growing demand for individuals with blended backgrounds and expanded skill sets

Drug development organizations must find individuals not only with depth of experience and expertise, but also with breadth. Science and engineering skills, for example, are most highly valued when complemented by a background in business management. Similarly, expertise in computer and data science is becoming more attractive to biopharmaceutical companies, particularly when paired with hands-on engineering experience. Regardless of the combination, however, strong communication, management skills, strategic thinking, agility, and an ability to work in diverse teams will continue to be indispensable characteristics for the drug development professional of today and tomorrow. In traditional legacy operating models, such combinations of skill sets have not always been prioritized in the hiring process and therefore are the exception rather than the rule. New human-resource planning, strategy, and execution are required to foster the right environment for new cadres of hires with breadth and depth of talent and skill sets to flourish.

Increasing need for clinical-research and clinical-care convergence

As drug development seeks access to patients and patient data, existing infrastructure within clinical care represents a viable and sustainable source for data. Health and lifestyle data drawn from patients' personal and mobile devices will also become increasingly common. Partnerships between drug developers, health-data aggregators, health systems, and online health communities will become far more commonplace. To succeed, the workforce will need to become more adept at integrating, managing and analyzing data from these historically unused and under-leveraged sources.

4. What Skills and Competencies Will Be Valued by the Industry?

The industry's nascent patient-centric approach is requiring a different type of professional: one who can easily adapt to the conditions described above. Figure 2 details the desired competencies in drug development professionals.

Figure 2: Competencies of digital-era drug development professionals

Complex reasoning, critical thinking, and data-driven decision-making	Skill at understanding big data and acquiring secondhand knowledge. This requires an understanding of interfaces, infrastructure, and algorithms.
Curiosity	Genuine interest in mining, cleaning, and analyzing data, and skill at quickly discerning patterns and questioning assumptions.
Communication and emotional intelligence	Ability to share, connect, and build relationships with peers and collaborators in different cultural and functional settings, oftentimes using digital communities.
Agility	Willingess to quickly learn new software packages, tools, and methodologies through self-training and group training with the goal of using technology to aid in improving individual and team workflow efficiencies.
Novel and adaptive thinking	Capacity to continuously adapt to and foresee changes in the way drug development is conducted.
Transdisciplinarity	Ability to understand concepts across multiple disciplines and work across the various workflow functions that make up the bench-to-bedside process.

5. What Roles Are Expected to Emerge?

In the near term, as the impact of digital transformation becomes evident, drug development organizations must retain flexibility to act nimbly and redeploy or reconfigure the workforce. The following roles are expected to gain greater currency in coming years:

- **Data scientists** will mine, clean, and analyze and find patterns in large data settings using advanced analytics.
- **AI systems trainers** will be responsible for training colleagues in the use and inner workings of complex AI algorithms.
- **Sustainers** will be responsible for ensuring that AI systems operate as designed and in the way in which they are intended to operate.
- **Translators** will convert data into findings and AI algorithms into actionable items.

- **Patient and provider navigators** will work with providers and patients in granting them a more active role in drug development.
- **Technology navigators** will provide technology support to clinical-research associates and the staff involved in the execution of clinical trials.

6. What Can the Industry Do to Meet Human-Resource Needs?

Develop a set of digital-thinking principles for drug development

Developing a set of digital-thinking principles for drug development is urgent. These principles must have a particular focus on workflow, understood as the sequence of research, development, manufacturing, and administrative processes that constitute the drug development pipeline from initiation to completion. Additionally, a harmonized understanding of the concept of "digital drug development professional" must be developed. To achieve this, a thorough industry-wide "Comprehensive Needs Assessment" must take place.

Develop dynamic corporate cultures

At the organizational level, senior management must continue to focus on building dynamic cultures and developing feedback loops within and across teams. Intra-company community building is perceived as an important part of digital transformation.

Motivate with higher purpose

It is also of great importance to focus on attracting and motivating today's workforce with higher-purpose objectives, emphasizing the industry's mission to save lives and benefit society. A higher purpose that staff members find personally meaningful will encourage outsiders to join the industry and galvanize employees to develop new skills and adapt to changing conditions.

Proactively train and develop its workforce

Taking a proactive approach in the training of existing staff and incoming recruits is encouraged. Specifically, offering individualized mentorships and training programs geared to individual needs are proven to deliver value, particularly when they address deploying and implementing new technologies, methodologies, or applications. Staff can be trained through both bottom-up and top-down training methodologies. These include in-house experiential training, simulation programs, hackathons, coding camps, and other off-campus training programs. Creating an environment that fosters and rewards constant self-learning is of paramount importance.

Workforce training should not end here, however. A continuous learning environment in which progress and small wins are measured and communicated must be developed. Teams can achieve great success by innovatively capturing progress and routinely celebrating success stories within their teams and throughout the organization. Examples of key performance indicators to champion include the number of new data-science–related training programs deployed by an organization, participation in and outcomes

from the deployment of such programs, number of data-science fellows and/or interns recruited, number of training programs aimed at increasing quantitative and computational skills, trainee-reported self-efficacy in quantitative and computational skills, degree attainment, and disciplinary diversity of staff.

7. What Practical Steps Can Organizations Take to Advance Existing Staff and Attract New Talent?

First**, industry leadership must model desired behaviors**. It is important that staff are able to take calculated risks and operate outside comfort zones, but this behavior must first be modeled by managers in order to develop high levels of psychological safety.[v]

Second, **organizations must be agile**. Digital transformation will likely exacerbate already-high employee turnover rates. To thrive, the industry must integrate recruitment processes more tightly with corporate cultures to accelerate decision-making. This approach will allow for shorter timelines and ensure the ramp-up period for new recruits, which will, in turn, facilitate faster recruitment and onboarding. Such an approach will require ongoing colleague development to retain staff.

Third, **organizations must develop experiential and individualized training programs**, as well as community engagement programs such as innovation challenges, contests, hackathons, and crowdsourcing. Organizations benefit greatly when employees are provided with spaces to come together to develop solutions to problems in which they and their peers are most personally invested.

Fourth, biopharmaceutical **leaders must visit and engage with companies outside of the industry** to understand how other sectors (such as financial services, telecommunications, or computing) are approaching workforce development and consumers, as well as hire and engage with consultants with experience in digital transformation.

Fifth, **organizations must factor the "extended workforce" into their growth and training strategies** and make a habit of the following practices: (1) understanding the role and capabilities of the CRO; (2) understanding the needs of users (that is, the hands-on implementers of protocols); (3) defining the roles of the CRAs, etc., as well as the roles of those involved in the digital transformation process (e.g. trainers, translators, sustainers, navigators); (4) developing materials to train healthcare providers in data science-related clinical applications; and (5) attending conferences outside the drug development industry to gain insight into how other industries are adapting to technological change.

Finally, biopharmaceutical organizations should **develop partnerships with universities** in the form of data-science training programs, rotational internship programs, and fellowships. These programs are effective in providing introductions to the industry and organization, as students are a gateway to their peers when they return to their respective institutions.

8. What Can Human Resources Do to Support Digital Transformation?

Human-resources departments play a crucial role in supporting the industry's digital transformation. Therefore, it is recommended that HR staff take the following actions:

1. **Develop guidelines for hiring** by identifying the competencies and educational requirements of each new position. To narrow down the ideal characteristics of a prospective recruit, the process should be part of a partnership between HR and the manager hiring a new employee, and it should include a conversation focused around values, behaviors, and cultural fit.

2. **Develop simplified high-level job descriptions focused equally on behavioral characteristics and on specific job roles**. Because roles are likely to change dramatically and frequently in coming years, high flexibility and dynamism are in high demand. Accordingly, job descriptions can be modeled after those for technology companies, and should also communicate the industry's and organization's greater purpose to prospective hires.

3. HR functions at biopharmaceutical companies must **develop recruitment campaigns that highlight what prospective talent most cares about**. Millennials will soon make up the majority of the workforce and the competencies desired by the biopharma industry are most likely to be found in this group. Accordingly, the factors that matter most to potential recruits as they evaluate companies to work for generally include purpose, fun, agility and the potential for rapid professional advancement.

4. **Develop interactive digital media** that engage the public, experts, and non-experts while creating online and offline communities, as these groups can attract talent and better establish these organizations within the digital and real-world spheres.

5. **Develop communication campaigns that make use of consistent messaging** targeting colleges, high schools, and middle schools to increase awareness of career opportunities in the industry.

6. HR functions will need **to expand sources for identifying talent**. They must be more resourceful and broader in scope to find talent excluded by traditional recruitment pools such as agencies and universities. Human Resource functions play a crucial role in supporting the industry's digital transformation.

9. What Can Organizations Do to Shape Corporate Mindset, Behavior, and Culture?

Measure and communicate outcomes

It is imperative to measure and communicate outcomes associated with implementing digital transformation initiatives. Companies must become accustomed to assessing the state of their processes before and after rolling out such initiatives. Tangible achievements can be shown by periodically assessing the process of collecting, cleaning, and analyzing data across departments within the organization. This can be done with benchmarking tools and operational excellence metrics such as cycle-time reductions. Organizations must be able to **demonstrate the positive impact of those initiatives on revenue** and customize the communication of these achievements to different internal audiences.

Hire individuals aligned with the mission and culture of the organization

To guarantee that new hires are well aligned with company culture and values, organizations must focus on developing and expanding unconventional hiring arrangements. Tiered approaches are a type of unconventional hiring arrangement that yields positive results for biopharmaceutical organizations. In these arrangements, individuals work contractually for a "trial period," and then, if they are found to be a good fit, are brought in as full-time employees.

Shift behaviors and develop a collaborative corporate culture

Collaborative work cultures are those in which transparency, seamless communication, agility, and calculated risk-taking are encouraged and supported, and can facilitate the successful deployment of digital transformation initiatives. For this reason, leaders and managers must prioritize communication with staff at every level of the organization and share best practices across functional departments. Leaders and managers must also communicate openly with their staff about the pace of implementation of strategic initiatives and the possibility that some initiatives might fail. Teams and individuals must be provided with the space and leadership support to take calculated risks and employ breakthrough thinking. Agility develops when individuals feel empowered to learn, take action, and communicate their impact to others. For this reason, digital transformation initiatives that focus on implementing incremental changes are found to be most effective. Incremental changes facilitate the use of recognition and reward systems, which encourage individuals to self-train, train others, and deliver results. Individuals are motivated by their ability to communicate about a problem they have solved and their impact on the bottom line. In sum, when individuals feel psychologically safe and teams focus on smaller goals, realize quick wins, and communicate seamlessly, they achieve greater cycle-time reductions.

Adjust to the global nature of drug development

Organizational cultures are an essential factor in business transformation processes, and critical to the success of any digital transformation strategy. As the world has become more interconnected, and as biopharmaceutical development is global in nature, companies are encouraged to recognize the value of maintaining a diverse workforce. Having an understanding of the cultural nuances surrounding the management of data across world regions will determine the success of biopharma companies and the

industry as a whole. People react differently to various data-management protocols and regulations, and privacy needs vary from region to region; companies must be prepared to address that. A diverse workforce that brings a wide variety of experiences, talents, thinking styles, and approaches to problem solving will be ideally positioned to develop creative solutions resulting from cultural challenges inherent in a company's global presence.

10. Conclusions

In this roundtable, pharmaceutical, biopharmaceutical, and technology company senior executives discussed digital transformation and the ways in which the drug development enterprise must adapt to meet the rapidly changing digital landscape and ensure that the life sciences sector continues to thrive. The discussion was candid, thoughtful, timely and critical. The shared learnings from this roundtable are invaluable and represent just the beginning of an ongoing conversation.

The rapid pace and broad scope of digital transformation requires individual companies, and the industry as a whole, to be adaptable, resourceful, curious, agile and open. Senior leadership and HR will be instrumental in guiding organizations through this transformation and in establishing and executing strategies, policies, and procedures.

11. Next Steps

This White Paper is intended to stimulate discussion and help spur new strategies and responses. It is the authors' hope that the biopharmaceutical industry will continue to convene roundtables and discussion forums to guide the enterprise as it navigates this challenging digital transformation.

12. Endnotes

[i] The Brookings Institution defines the Fourth Industrial Revolution as one that is "characterized by the fusion of the digital, biological, and physical worlds, as well as the growing utilization of new technologies, such as artificial intelligence, cloud computing, robotics, 3D printing, the Internet of Things, and advanced wireless technologies."

[ii] Recent breakthrough technologies include genomics, smartphones, nanotechnology, robotics, and wearable sensors.

[iii] The University of Washington Health Sciences Library defines clinical data as "information that is collected during the course of ongoing patient care or as part of a formal clinical trial program." It lists six major types of clinical data: electronic health records, administrative data, claims data, patient/disease registries, health surveys, and clinical-trials data.

[iv] The United States National Coordinator for Healthcare Information Technology defines patient-generated health data (PGHD) as "health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern. PGHD include, but are not limited to, health history, treatment history, biometric data, symptoms, [and] lifestyle choices."

[v] In the book "Trust and Distrust in Organizations" (Kramer and Cook, 2004, p. 241), psychological safety is defined as describing "individuals' perceptions about the consequences of interpersonal risks in their work environment. It consists of taken-for-granted beliefs about how others will respond when one puts oneself on the line, such as by asking a question, seeking feedback, reporting a mistake, or proposing a new idea."

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The **Tufts Center for the Study of Drug Development** (Tufts CSDD) is an independent, academic, non-profit research center at Tufts University School of Medicine in Boston, Massachusetts. Our mission is to provide data-driven analysis and strategic insight to help drug developers, regulators, and policy makers improve the quality, efficiency, and productivity of pharmaceutical R&D.

Established in 1976, Tufts CSDD conducts scholarly analyses addressing the economic, scientific, political, and legal factors that affect the development and regulation of human therapeutics. For over four decades, Tufts CSDD has been a prominent and influential voice in national and international debates on issues pertaining to biomedical innovation and the development of drugs and biologics. In addition, the Center hosts symposia, workshops, courses, and public forums on related topics, and publishes the *Tufts CSDD Impact Report*, a bimonthly newsletter providing analysis and insight to critical drug development issues.

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