Workforce Readiness: Cultures, Tools and Skills Needed by Organizations and Employees to Drive Innovation in Drug Development

Despite significant investment in pharmaceutical research and development (R&D), productivity is sinking to a new low. A recent report suggested that the costs of developing and securing regulatory approval for a new, innovative drug has grown to $2.18 billion (1). At the same time, return on investment in R&D at the top 12 pharmaceutical companies is the lowest it has been in a decade: just 1.9% (1). This cycle of escalating R&D costs layered onto lackluster output in new drug approvals and falling ROI is unsustainable for the industry.

To spur conversation about these challenges and potential solutions, *Pharmaceutical Executive*, in collaboration with Parexel, brought together senior leaders in the industry in a roundtable discussion about how innovative approaches to drug development might increase efficiency and boost productivity in R&D. Much of the discussion sprouted from the key findings of a recent report from The Economist Intelligence Unit (EIU), commissioned by Parexel.

In this work, the EIU gathered and interpreted data on the effect of innovation in clinical trials against specific success metrics, including likelihood of launch and market access. It identified inadequate workforce readiness as a major challenge to innovation in the pharmaceutical industry (2). Stemming from this, participants in the *Pharm Exec* roundtable considered issues such as the **current workforce**, including gaps in skills and training as well as standardization of clinical trial roles; **challenges in data science** and how they relate to workforce readiness issues; **addressing skill gaps** through data standardization and AI; and **driving forces** to implement change, including making pharma company cultures more appealing.

The following captures the highlights of this roundtable discussion with these leading experts and the solutions they offer to address the current gaps in workforce readiness:

Participants in the roundtable discussion were:
- Julian Upton (Moderator) - *Pharmaceutical Executive*, European Editor
- Shona Fraser - Johnson & Johnson, UK Clinical R&D Director
- Liam Good - Tecrea Limited, Director
- Alberto Grignolo - Parexel, Corporate Vice President; DIA *Global Forum*, Editor-in-Chief
- Barbara Lopez Kunz - DIA, Global Chief Executive

- Jim Kremidas - Association of Clinical Research Professionals, Executive Director
- Mishal Patel - AstraZeneca, Senior Director and Head of Health Informatics
- Joseph Scheeren - DIA, Board Chairman; C-Path Institute, CEO
- Paul Simms - eyeforpharma, Chairman
- Albert Siu - Parexel, Corporate Vice President, Learning & Development
- Paul Strouts - Hays Life Sciences, Global MD
- Colin Terry - Deloitte, Partner, Life Sciences R&D
- Michael Thomas - A.T. Kearney, Partner

JULIAN UPTON (*Pharmaceutical Executive*): Alberto Grignolo will provide a backdrop to our discussions.
ALBERTO GRIGNOLO (Parexel): The Economist Intelligence Unit (EIU) looked at approximately 24,000 clinical trials completed between 2012 and 2017 and published a report *The Innovation Imperative: The Future of Drug Development* in June 2018.

Parexel commissioned the report because we were concerned that the cost of drug development continues to increase and is becoming unsustainable. If this pace continues, it will cost more than $20 billion to develop a new drug just 25 years from now. The industry faces several other challenges as well: time to market still takes about 12 years, the failure rate of drug candidates is extremely high, health systems are concerned with the cost of drugs, and companies are hard-pressed to bring affordable drugs to market.

The EIU research objectives were to:
- Look for hard evidence of the role of four specific innovations in drug development (adaptive designs; patient-centric trials; precision medicine trials; RWD trials)

- Identify any barriers that might exist to the adoption of innovation;
- Look for ways to improve efficiency, productivity, sustainability; and
- Seek stakeholders call to action.

Several metrics were used by EIU to assess the impact of these four innovations. Specifically, researchers looked at enrollment time in clinical studies, normalized across the examined trials to be the time it took to recruit 100 participants. Researchers also looked at the likelihood of launch as well as reimbursement and affordability after drugs have gained regulatory approval and are launched.

Panelists, pictured left to right are: (front row) Alberto Grignolo, Shona Fraser, Liam Good, Albert Siu, Paul Strouts, Paul Simms; (back row) Julian Upton, Colin Terry, Mishal Patel, Michael Thomas, Joseph Scheeren

Let's look at some key top-level findings.

- All four innovative trial types reduced the time to enroll 100 patients.
- The likelihood of launch was 10–21% higher for drugs that used these innovative trial models than drugs that did not.
- Drugs tested with innovative trial designs were also more likely to be reimbursed.

However, the adoption rates of these types of innovations were very low: 0.6% for adaptive trial designs, 5.2% for patient-centric trials, 13.7% for precision medicine trials, and 0.3% for real-world data trials.

The EIU speculated upon several factors that could enable the adoption of these innovations:

1. **Workforce readiness** to manage health data in a novel and more automated way
2. **Collaborative partnerships** in the global ecosystem of drug development that need to be more diverse and more unconventional, in some cases with competitors working together
3. **Early stakeholder involvement**, including regulators, payers and the patients themselves.
4. **Advanced data analytics**, health data sciences and related activities and disciplines that will only expand and play a far more significant role in drug development. Some believe there is a gap in data analytics skills today and a wide range of competencies in this regard.

In summary, all four clinical trial innovations were shown to benefit drug developers in terms of trial efficiency, likelihood of launch and likelihood of reimbursement. But to be beneficial to developers, the innovation ecosystem needs a talent pipeline and the ability to access and utilize vast amounts of data from diverse sources. So, the question is: who should be involved in creating the workforce of tomorrow?

CURRENT WORKFORCE READINESS: IDENTIFYING THE SKILLS GAPS

UPTON: With that backdrop from Alberto, let's get everyone's perspectives on the kinds of skills gaps or issues that need addressing with regard to the workforce.

BARBARA LOPEZ KUNZ (DIA): The evolution from individual component data to the entire digitization of healthcare creates enormous opportunity. We have an immense amount of information that has driven, and was central to, the development of many current therapies and cures. Assuming that the world continues to develop good data scientists, through advancements in university curricula and ongoing education programs by organizations like DIA and others, it is critical to get a whole system in place so we can harvest the data and use it to develop the next therapies. If we can do this, such a dataset—well-designed and supported by the right workforce capabilities—will create new horizons in healthcare.

PAUL STROUTS (Hays Life Sciences): One problem is a lack of leadership skills in the pharmaceutical sector. A recent LinkedIn report identifies a 40% gap in project management skills in the sector right now. There is definitely a lack of medical technology skills, and a recent Deloitte report lists a 15% gap in product research skills and a 30% gap in product development skills. Lastly, with so much disruption in the life sciences sector at the moment, many smaller biotech companies are emerging and require nimble commercial teams. That's lacking in the life sciences business.

COLIN TERRY (Deloitte): Return on investment for every R&D dollar declines every year. Still, leaders are essentially running a historical model of a linear development process with no urgency to make changes.

We also don't see an enterprise mindset anywhere. Some pharma companies have study teams that are trying to fight the status quo by finding tools that help. However, these tools are not being embraced at the corporate level, so penetration rates of some of the innovative study methods are low and everybody comes to it by exception rather than as a rule. In addition, there are counter-incentives to project teams where adopting new technologies may compromise their timelines or costs.

The third point is that the future of work has shifted. We are moving into a "co-bot" world where operational teams are working with robots or advanced automation technologies. This environment needs smart people who understand data, process standardization and aren't threatened by the potential for improved productivity.

SHONA FRASER (Johnson & Johnson): We are talking about workforce readiness, but maybe the workforce should break the model rather than trade on the model.

In pharma, we are adding to the amount of data and I'm not sure that analyzing all of it is the way forward. Within J&J, we've discussed using BOTS (robotics) to pull data from different systems to prepare clinical research associates (CRAs) to go to site. The CRAs, the data managers, run our studies and need to understand the basics of the science; they are our ambassadors. If you're not going to change the system, you have to automate it so that when CRAs go to site, they are prepared.

JIM KREMIDAS (Association of Clinical Research Professionals): There is little consistency in performance, particularly at the site level. FDA's guidance on principal investigators (PIs) says they must be trained to qualify, but it doesn't provide additional details. So, there is a huge variability in PIs' ability to conduct clinical research.

Likewise, there are no guidelines or educational requirements for study coordinators. Some coordinators are very good, but others are inadequately prepared for the role. Again, industry faces a lack of consistency and alignment on competencies for individuals implementing protocols at the site level.

Moreover, data shows the competencies of CRAs are diminishing. In our certification programs for CRAs, we are seeing consistently poorer performance over time in terms of their ability to display the competencies required for the role.

MICHAEL THOMAS (A.T. Kearney): Last year, we conducted a review of Alzheimer's and Parkinson's research teams in the UK. The skills gap they all mentioned was *data sciences*. Outside the US, and possibly even in the US, demand for these skills (raw data sciences, data mining algorithm development and data analytics in conjunction with biological knowledge) currently far outweighs supply.

The issue is even more pressing for big pharma. Will a young data scientist want to go to a big pharma research lab or to an academic institute or academic spin-out or start-up? The placement officer for Stanford graduates told us their graduates mainly want to work in start-ups based in London. That's what excites them in their career. We need to think about big pharma and CRO workforce shortages in Europe, how we invest in building them up, and how we create attractive jobs. Otherwise, young talent will naturally migrate to the more exciting, dynamic and flatter environment offered by start-ups. New company formation in healthcare and biotech is rising at twice the rate of R&D expenditure, so it gives you a sense of just where the jobs are really being created right now.

ALBERT SIU (Parexel): I want to tie up a few points that have been brought to the table. First, do we have a good return on the investment made in workforce development? Most companies cannot tell how much training costs them and unless organizations are clear on their costs of training, investment in areas of skills gaps won't happen and thus we will continue to compound the issue of inadequacy in workforce development, because we lack accountability in managing training costs.

Second, when we talk about training, we should talk about a framework that can transcend training topics and give us insight into what needs to be trained. The most basic component of a training framework is the "foundational element." For example, we hire a lot of CRAs with diverse scientific backgrounds. Some may be nurses. Others may be biologists or chemists. For each of those disciplines we look for those that have a strong "foundational knowledge," as this "foundational" content is taught at universities, and not within a company. Companies like ours must create "context" whereby those foundational elements can be leveraged. "Contextual" content is sometimes called "industry knowledge," such as by teaching our new hires about drug development, regulatory requirements, clinical monitoring, project management, data management, and real-world data as well as "soft skills" to deal with people issues, through which they can be effective in their role. The next aspect of training is the "practice" component. Just knowing facts doesn't mean that one can take care of a real-life situation, so we put a lot of emphasis on the "practice" element. The last part is "credentialing and certification." Given the needed skills to advance innovations in drug development are multidisciplinary, we need different educational bodies to validate knowledge gained and skills acquired. The credentialing efforts must be multidisciplinary. The framework described here, the foundational, contextual, practice and credentialing elements are generic in nature, but I believe they can give us commonality to approach addressing the workforce development skill gaps.

KREMIDAS: We pulled together a cross-functional group of sponsors, regulatory, CROs, sites, and developed a framework for CRAs and CRCs. We are also introducing one for PIs.

It's a starting point, but the industry must agree on a framework for what it means to be a clinical researcher and the skills and competencies needed. Better data and AI may offer amazing solutions for our industry, but if we don't get the basic building blocks right, it will be very difficult to get into more sophisticated activities.

MISHAL PATEL (AstraZeneca): There were similar efforts in the UK. Within the National Health Service (NHS), the Scientific Training Program is intended to make the workforce ready to understand bioinformatics, informatics and computer science. After proving the competencies in this three-year program, one can gain certification to become a clinical researcher.

The challenge is that we tend to concentrate most on technical competencies and less on the soft skills. Newer data scientists will get a problem and just go with it without asking the *what*, *why* and *when*. We invest a lot of time in building their soft skills.

> "Instead of workforce readiness, maybe it's about employer readiness, about the environment you bring people into."
>
> —Liam Good, Tecrea Limited

DEVELOPING JOB KILLS TO ADDRESS DATA SCIENCE CHALLENGES

JULIAN UPTON: That raises the question of data and what to do about it. Is it about getting people in? Is it about training people earlier? Is it about re-thinking the whole issue of data science?

PAUL SIMMS (eyeforpharma): When you work for a technology company, you have a large responsibility for redefining what that company does. When you work for a pharma company, you're iterating and, at best, improving an existing process. This is not attractive and must be addressed before we start talking about whether the training is adequate.

LIAM GOOD (Tecrea Limited): Instead of workforce readiness, maybe it's about employer readiness, about the environment you bring people into.

At Royal Veterinary College, we are involved in training and talk about "day skills." Before graduation, students need to have a check mark on several skills. This only works if you have an agreed list of what work skills are required. I think that might be something for the industry to work on and agree upon which these skills are needed.

JOSEPH SCHEEREN (DIA, C-Path Institute): I once worked for a company that brought in university students; every two months, they worked in a different department and built an informal network. Today, companies are less willing to do that because it costs money and requires mentoring time. However, such programs could be very beneficial in bringing people on board and giving them a feel of what the industry is about. Image-building for the industry is tremendously important for making it more attractive.

UPTON: If we talk about solutions, is recruiting people from other industries to tackle the problem with data optimization a solution, even short-term?

TERRY: Being competitive—and hunting for talent or people to create solutions—is an industry problem, not a company problem. If we all got to the same standard quicker, it would save everybody cost in trying to repetitiously agree to things that we talked about, whether it is data standards or a utility of

different people. There is a risk that key talent simply chooses another industry entirely—like consumer technology—rather than bring their skills to life science challenges and opportunities.

FRASER: It is an employer issue to sort out. They can look at ways to bring in talented individuals using apprenticeships, for instance. These programs are attractive to students who are intelligent, but don't necessarily want to go to university, or who don't want to leave universities in debt because all the funding for apprenticeships comes from employers (e.g., big pharma companies). But, finding the framework to create that situation is a joint industry issue; one company approaching one university to start up an apprenticeship program is inefficient and slow.

SIU: In the United States, at the end of the Clinton administration, I was on a government effort called the *Al Gore Commission for the 21st Century Skills*. That was a public–private partnership effort to identify the needed skills for the 21st Century jobs and examined how the Federal, State and City governments can partner with industries to prepare workers that can thrive in the 21st Century jobs. A series of ideas were proposed, which involved the creation of internships, faculty exchanges with companies and special training programs, with special funding to be channeled from the Federal government to states and municipalities so that universities and, in particular, community colleges can be supported with special programs to augment job skill development. Eventually, this piece of work, together with other public policy debates, culminated in the creation of the "Workforce Development Act" that has since been certified and re-certified for federal funding to be channeled to states and municipalities for job development and job creation purposes. This sort of public-private policy debates and conversations are needed if we are to advance drug development and to take advantage of the innovative approaches to reduce cost while improving productivity in clinical development.

STANDARDIZATION OF DATA AND TRAINING ELEVATES CLINICAL TRIALS

UPTON: The report mentioned data siloes. What are your thoughts about data standardization and what is being done or what can be done?

SCHEEREN: There are two major topics. One is privacy. Patients must provide authorization to use their data. Second, there is general agreement that anonymized data can be pulled together, but there are problems with randomized datasets when they clearly come from different worlds. Even simple differences in date formats can present a challenge. Standards from ISO or another group like CDISC could help.

One of the beauties of having data standardized is that you can more easily pull it together, conduct analysis and uncover

information not found in individual datasets. If industry reached a more harmonized way of reporting information, it would help the real-world data and real-world evidence we are trying to gather.

KREMIDAS: Yes, industry could do a better job of utilizing data and defining standards. The healthcare industry extends well beyond clinical research, and various electronic medical record systems use different methodologies, compounding the problems.

Also, it's not just the data that isn't standardized; again, we really need some standardization among study coordinators and PIs.

FRASER: It is also about knowing what data you want to collect and why you want to collect it. Then, you can standardize it. When a clinical trial protocol is being designed, it generally involves the medical organization and the commercial organization coming together. At that point, the medics may not have much training on adaptive designs or new ways of working, so they tend to pursue traditional ways of running clinical research with head-to-head trials. Training is critical to changing the design of the whole program. I think if you are looking at workforce skills, it is not just the data scientists and the standards. It is the people who are designing programs. Perhaps, medical school doesn't set them up for the pharmaceutical industry.

HOW LEADERSHIP AFFECTS ORGANIZATIONAL CHANGE

UPTON: In terms of embedding the culture, does it come from the top down? If genuine culture change is needed, is it the CEO? Do we need a chief transformation officer or a chief cultural officer?

SCHEEREN: The CEO can change the culture quite significantly. We have seen that within the Bayer organization with the lead values brought in by the CEO: leadership, integrity, flexibility and efficiency. If a decision was being made that was not in line with one of those values, people were talking about it.

KREMIDAS: While it always takes strong leadership from the top to create an environment, it also takes people at the grass roots. One of the most difficult things is identifying the leaders in lower positions in the organization. They can help drive change within the troops. Finding people who are willing to accept change and developing them into the leaders is a key element for any organizational change in management and culture to be successful.

ARTIFICIAL INTELLIGENCE (AI): A SOLUTION TO WORKFORCE SKILLS GAPS?

UPTON: How might AI help to solve some of these workforce-readiness problems? Is it effecting real change in organizations yet?

FRASER: It has started. We are looking at automating some minor processes so that people don't have to spend their time doing administrative tasks.

TERRY: I think there's a couple of things to consider, including educating people about what's an automation opportunity, what's a machine-learning opportunity, or what's a cognitive

opportunity. Then, the individuals and teams can quickly identify the opportunities for an enterprise team to drive rather than at the moment, where we have enterprise teams looking for opportunities but not understanding the context of the business needs.

SCHEEREN: It's a no-brainer that AI and automation will affect the way we operate. For example, operational aspects of the regulatory activities will be automated quite significantly. Will that lead to workforce reduction? I think it will mean a shift in the use of people within the workforce and it will make their work more intelligent and more interesting. Another aspect is regulatory intelligence. If you have a machine that can extract information into a digestible format, it would be a great advantage.

STROUTS: It seems that it's about willingness to change. Some companies are so slow in getting to the next point of the process internally. We're talking about AI here and you have to foster that; you have to really want to make the change.

GRIGNOLO: Many of you have mentioned a lack of sense of urgency within the pharmaceutical industry, especially large companies. What will make the pharmaceutical industry engage in transformative change?

TERRY: It will be something that hits hard in the wallet. For instance, if European drug pricing was implemented in America. In our report a couple of years ago, we looked at what NICE pricing would do to our numbers and essentially it gives everybody a haircut of 15% because a lot of sales projections are US-based. That would give everybody a wake-up call that we need to engage in transformative change.

Second, if a FAANG (Facebook, Amazon, Apple, Netflix or Google) company entered the market at scale, it would definitely light a fire under the industry. If the data locked up in American payers suddenly became available to the world, that would represent a very different place and challenge the incumbents.

THOMAS: When 60% of your new filings are by companies that have never filed before, that's no longer a wake-up call; it's several wake-up calls [for large pharma]. We are reaching a point where 70% of industry-driven R&D expenditure accounted is accounted for big pharma, basically driving only a quarter of the portfolio.

INCREASING THE ADOPTION OF INNOVATIVE CLINICAL TRIAL DESIGN

GRIGNOLO: Why are the four innovative designs or approaches adopted so infrequently, as I mentioned earlier? And, in relation to workforce readiness, what solutions can this group think about that could be captured as a call to action to increase the adoption of innovations?

THOMAS: The straightforward answer is incentives. As long as the primary measure of R&D reward is time-to-regulatory filing, clinical trial methods won't change. There is still an overwhelming culture of "get this product through its first regulatory approval" and the whole reward model largely hinges on that. In addition to personal incentives, it's also about how the capital markets will view you.

SIMMS: I agree. Opportunity cost is important and there is far too much romanticization in R&D of trying to hold on to what could be a big project when the signs are it is anything but. I call it being more comfortable with failure. Biotech companies certainly are; they'll put through a lot more projects than pharma does.

FRASER: Going back to the four points on design, I disagree with the metrics that were represented. If I look at my portfolio, these innovations are in most of the studies. What you have to imagine is that patient-centricity should be in all of our trials. Adaptive design and patient-centric trials are life. Why are they not employed? In J&J, we do employ them. We work with patient groups. That's part of our normal business. In the UK alone, we have contracts with different patient participation groups. We contact them, speak to them, and involved them in our discussions. Patients are central to everything we do.

Moving into precision medicine is important. If you are looking for particular molecular screenings or for a patient with a genetic mutation, it is very difficult to find those patients within the systems we have in the UK. Every doctor owns their patient's data. Pharma has pockets of information on patients that they screen. There's no joint way of doing precision-genetic testing across the world. There's not a large biobank with all that information that we can readily use, so every patient must be screened and that takes a long time. There is a very good chance the patient will relapse during that period and is no longer available for that trial. If you had a biobank that worked, you would simply pull and use the patient data.

PATEL: I agree. Regarding real-world trials, most of our trials have elements of most of the innovations you mentioned, but we don't tend to just back one of them. When you look at real-world data, having a visual comparator arm would be one of the biggest breakthroughs we could probably push and that is what we are trying to do. At the moment, we use real-world data to select patients, physicians, and sites. What needs to happen is to understand where the gaps are and apply data science, AI, to help us bridge those gaps, and that's challenging.

THE PATHWAY FORWARD

A clear message coming out of this roundtable discussion is that cutting-edge drug development strategies must rekindle R&D productivity in the industry. Getting to this point, however, is impossible if the existing and future workforce is unprepared for such innovation. Thus, companies must focus on closing gaps in workforce readiness such as by removing cultural barriers (including making the company culture more appealing to young, talented workers interested in pharma), addressing preconceived notions about innovation, and breaking down organizational and data silos.

The need for trained data scientists who understand drug development, for instance, becomes especially critical as data management becomes more unconventional with the evolution of clinical trial strategies. "People who understand a little bit more about the end-to-end drug process, through mentoring and other internal activities, are actually some of the most valuable people in the industry. They don't happen by accident. We have to grow them," said Terry, noting that there is a shortage of these individuals going into the industry today.

Closing this gap in workforce preparedness is vital to the future of the industry and requires, as Fraser suggested, collaborative efforts (such as with apprenticeships through universities) and face-to-face hands-on training as opposed to web-based, virtual training.

Overall, collaborative partnerships in the global ecosystem of drug development likely need to become more diverse and less conventional. As Grignolo stated, "This may make for strange bedfellows, as we look at it today, but 10 years from now, we may find that these bedfellows absolutely belong together." Such collaboration may even take the form of data-sharing, data prioritization, alternative data sources, and predictive analytics, though industry needs to first come together for data standardization.

Meanwhile, Kremidas stated, "The most urgent issue is alignment on competencies for clinical research." He explained that while some work must be done to define clinical roles, industry is missing a huge opportunity to increase efficiency by jointly agreeing on some common functions and definitions for these roles.

Another call to action from panelists was to continue to focus on patient centricity during clinical research as innovation advances this area. "Of the three main stakeholders (regulators, payers, and patients), only one has been top of mind for the last years: the regulators. The payers and the patients are now absolutely top of mind and will become even more so in the coming years," Grignolo pointed out.

"You won't have clinical research if you don't have patients," Fraser agreed. "The pharmaceutical industry needs to change how it's perceived based on bringing the patient voice along with it."

The workforce size and capabilities will become a critical bottleneck if the issues raised in this roundtable are not addressed and the workforce is not ready to leverage these innovations in development and clinical trials. Siu concluded that the way to bring the pharma industry forward is to reconsider how it develops its workforce and cultivate its talent pipeline of future employees. "The innovations and the unique skills required to drive it must come from a broader network of partnership efforts than what exists today," he stated.

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