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Worries And Hopes For Health Care Delivery In 2024

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Industry experts from Norstella, whose data and technologies support decision making from R&D through to market access, shared their worries going into 2024.

From less tolerance for failure as pressure mounts on pipelines to ongoing consequences of regulatory changes, such as the introduction of US Inflation Reduction Act, life sciences companies will face a number of challenges in the coming year. Precisely *how* health care systems deliver novel medicines is also high on the list of concerns.

Industry experts from across the wider Norstella business shared their predictions going into 2024.

Ashley Schwalje, senior director of Clinical Solution Consulting at *Citeline*, told *In Vivo* she was expecting less tolerance for clinical trials that are not producing results. "Every trial is of increased importance," she noted. Big pharmas are approaching a lengthy patent cliff, where best-selling brands will face heavy generic competition. This is driving a "fail fast mentality," Schwalje said.

The longer that investment remains at suppressed levels, the more attritional the industry will be. "This is not necessarily a bad thing," said Daniel Chancellor, thought leadership and consulting director at *Evaluate*, noting that few drugs that enter clinical trials eventually gain approval. "Concentration of investment around fewer companies, platforms and assets that are more differentiated is better for long-term innovation. Nevertheless, picking the winners from the losers at early stages of R&D is as much luck as calculated risk. While an overfunded industry during 2020-2021 undoubtedly created some bloat, we are now seeing an overcorrection and that risks some ideas going underfunded."

At the individual biotech level, a clear vision is required on how to create value for the end customer, whether that is patients, potential partners or investors. “Pharma is unequivocal in looking for assets that are first-in-class or best-in-class, with a measurable patient impact, so adopting a development roadmap with this shared mindset is essential,” said Chancellor. In the absence of this, raising capital will be a challenge considering the huge number of other companies vying for investment, he noted. “This must also occur alongside careful consideration of costs and alternative means of funding such as partnerships.”

At the same time, industry is also witnessing innovation outpace the rate of health care delivery system evolution, experts from *The Dedham Group* warned. “Without recognition of insufficiencies and openness to change across payer and provider channels, novel testing and treatment options will continue to face limitations reaching patients,” said James Pisano and Jen Klarer, both partners at the specialty consulting firm.

The Dedham Group highlight three key challenges in 2024 for access to medicines in the US:

1. Sustained, Insufficient CMS Reimbursement: Provider sites are increasingly strained by insufficient government reimbursement, limiting patient access to appropriate care. CMS reimbursement is also slow to change and lacks recognition of its inability to adequately accommodate novel treatment options.

2. Constraints In Offering Novel Treatments: Provider sites are struggling to evolve treatment capabilities at a pace which matches novel product releases (e.g., psychiatrist observation for psychedelics, inpatient bed availability for patient-specific treatment with cell-based therapies).

3. Slow, Inconsistent Payer Coverage Of Genetic Testing: As opportunities for personalized medicine evolve, payers are unable to develop clear, comprehensive, and consistent coverage policies for novel patient identification techniques, even when targeted treatment options are available.

Amidst these challenges, “some provider sites and payers are staying ahead of the curve with increased resource allocation and forward-looking consideration of needs to enable access to emerging innovation,” Pisano and Klarer noted. Also, biopharma companies “are increasingly allocating resources toward market access to anticipate patient access challenges and develop stakeholder education plans, resources and patient services to address needs,” they added.

New Tech And Patient Goals

On a brighter note, industry spectators are watching a few important trends as we head into 2024, particularly the greater use of artificial intelligence to speed up decision-making.

Also, with a renewed focus on health equity after the worldwide COVID-19 pandemic, experts expect that there will be a stronger emphasis on diversity in health care in the coming years. Looking at clinical trials specifically, Schwalje said, "Rubber will meet the road on diversity in 2024." Final guidance on DEI in clinical trials is expected from the US Food and Drug Administration in 2024 or the early part of 2025. "Pharma companies will tap deeper into real-world data to understand patient behaviors and social determinants of health to craft clinical trials that fit the needs of patients and create omnichannel, more personalized patient engagement strategies," she noted.

"Clinical trial diversity is part of a bigger picture related to health equity – this will become a major part of the conversation," Schwalje predicts.

Alongside a focus on diversity and inclusion, Schwalje expects an increased emphasis on clinical trial patient experience in 2024. Some companies have already made waves in this area. *Moderna, Inc.*, as an example, has a team dedicated to site and patient experiences.

AI tools will play their part in helping biopharma companies reach the right patients. Companies are starting to use AI to augment decision making and make smarter, more refined decisions related to:

- Building more precise, measured patient cohorts/segments;
- Designing clinical trial protocols with greater confidence; and
- Selecting the best sites and investigators (based on more sophisticated data models).

Despite the increased use of AI, other digital tools are falling out of favor. Schwalje expects the interest in decentralized clinical trials to "die down" in 2024. Virtual trials were ramped up in the midst of COVID, but the need for DCTs has calmed as the world moves on from the pandemic.

AI is spilling into other areas of health care, such as managed care. "Payers experience significant infrastructure challenges so one might imagine them to be slower adopters to technological innovation," said Dinesh Kabaleeswaran, senior vice president of consulting & advisory services at *MMIT*. He noted that events across other industries had encouraged payers "to have conversations within their organizations on the applications of ChatGPT and AI to their day-to-day activities."

Innovation At A Cost

"Increasing R&D costs, while great for bringing new therapies to the market, also pass on a percentage of these costs to patients through payers imposing higher premiums and stricter

restrictions in access," Kabaleeswaran warned. "As costs tend to increase, we should not lose sight of the most important stakeholder in the industry – the patient."

The introduction of the Inflation Reduction Act in the US will also have an impact on the cost of innovation. "What assets will be cut because companies cannot afford the R&D investments?" asked Citeline's Schwalje. According to a 2023 survey by PhRMA of its member companies, 78% of respondents expect to cancel early-stage pipeline projects that no longer make sense given the short timelines before medicines could be subject to government price setting.

Experts from *Panalgo* also highlighted the IRA as a critical issue in 2024, noting that "CMS is becoming the *de facto* US health technology agency."

Chancellor noted that pharma has so far been powerless to shape the IRA. Although, with numerous challenges in play it will be interesting to see whether any legal arguments hold water. "Regardless of outcome, R&D and commercial decisions taken today must reflect the reality that the pricing environment in the US is getting tougher, and the IRA may just be the tip of the iceberg."

Each new high-cost drug launch puts strains on budgets and can lead to increased premiums. In 2024, the conversation must shift towards value for money. "This will play out in real-time considering the eye-wateringly high revenue forecasts for the GLP-1 class," Chancellor gave as an example. Looking just at *Novo Nordisk A/S*'s glucagon-like peptide 1 agonist Wegovy (semaglutide), approved for the treatment of diabetes and obesity, the drug is expected to see worldwide sales of around $8.6bn in 2024.