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Scrip Asks... What Does 2025 Hold For Biopharma? Part 5: Clinical Trials Trends

Data Science Transforms Data Gathering

06 Feb 2025 • By Eleanor Malone

A revolution is underway. Technology offers the possibility to transform multiple aspects of the traditional gold standard of drug development: the randomized controlled trial. Sharing their insights with Scrip, 30 thought leaders consider how the clinical trial landscape will evolve in 2025.

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"By 2025, clinical trials will undergo transformative advancements, driven by innovation, patient-centricity, and regulatory evolution." So said **Scott Schliebner**, vice president and global head, drug development consulting, at contract research organization Novotech.

"Looking toward 2025 and beyond, enhanced collaboration and efficiency will drive significant transformation in the design of clinical trials," commented **Kelly Ragins,** senior vice president and head of development operations at Genmab. "This includes utilizing centralized electronic medical records and digital tools to reduce costs, streamlining data flow, and reduce the burden on clinical trial sites. Equally important to data access is fostering partnerships beyond individual organizations and promoting collective efforts among industry leaders, advocacy groups, and policymakers to reshape clinical research. By collaborating better and embracing technology, we enable clinical trials to be more equitable and efficient, improving patient experience and outcomes, while meaningfully advancing scientific discovery."

Scrip Asks:
What Does 2025 Hold For Biopharma?

A broad survey of the industry's expectations for the year to come

At the turn of each year, Scrip invites industry leaders, investors, experts and other stakeholders to share their expectations for the year ahead. With responses from hundreds of professionals, Scrip Asks... What Does 2025 Hold For Biopharma? provides an exceptional insight, both broad and deep, into the biopharma universe's collective crystal ball.

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- The State Of The Biopharma Industry Heading Into 2025
- The Funding Environment, M&A And Partnering
- Impacts Of Political Change In US And Beyond
- Artificial Intelligence And Data Science
- Clinical Trials Trends
- Therapeutic Area Advances

Schliebner's and Ragins's views were broadly reflected by other industry leaders who shared with *Scrip* their perspectives on the outlook for the evolution of clinical trials over the coming year. Combining advances in remote monitoring with improvements in predicting trial success and identifying patients to recruit, this is an area undergoing significant modernization.

With artificial intelligence and data science underpinning the revolution, it is not simply a question of drug developers being able to generate better data: there is also the opportunity to derive far more insights from the data, in turn enhancing both trial efficiency and patient outcomes.

"Artificial intelligence will manage 50% of trial data tasks, reducing timelines by 20% and enhancing precision. Real-world evidence (RWE) will ensure inclusivity, with over 85% of pharmaceutical companies leveraging it for diverse trial designs," Schliebner predicted, adding that "adaptive trial methodologies and biomarker-driven approaches will dominate, streamlining drug development and improving outcomes."

He concluded: "These advancements will shape a future where trials are faster, more inclusive, and precision-driven, ultimately accelerating the development of innovative therapies and improving global healthcare outcomes."

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Patient Engagement

"Everyone has the right to be included in clinical research," said **Kate Owen**, head of global development at Johnson & Johnson Innovative Medicine. "Heading into 2025, we're at a critical turning point in the industry – with the world watching – where we can truly shift the standards of access, participation and inclusivity."

For Owen, "thanks to AI-powered strategies and FDA-driven policies, we've never been more capable of doubling down on health equity."

Iddo Peleg, CEO of clinical trial software provider Yonalink, took a similar view. "In 2025, clinical trials will become more patient-centric, leveraging real-time patient data and feedback to increase efficiency and accessibility," he said. "Geographical and demographic barriers to trial participation remain a critical issue and technologies will increasingly address these challenges."


Iddo Peleg

Nevertheless, Peleg saw a need for more than just technology solutions. "Decentralized clinical trials (DCTs) have not fully solved the issue of trial accessibility, creating a need for a shift to more robust models such as satellite sites – local medical centers and clinics that serve as accessible hubs for patient trial participation," he said. "By combining decentralized elements with these community-based sites, trials will be able to extend their reach and become more inclusive, improving enrollment and retention, creating more robust and equitable trials, and ultimately therapeutics that have been tested on a wider population."

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>
> Iddo Peleg, Yonalink

Dipal Doshi, CEO of Entrada Therapeutics, which has early clinical programs in Duchenne muscular dystrophy, noted: "In recent years, there has been a much-welcomed shift toward prioritizing the patient and care partner experience in clinical trials."


Faye Feller

He predicted that "throughout 2025, we'll see an increased use of study protocols that are directly informed by feedback from patients and advocates. As an industry, we're making progress in our efforts to listen, learn and subsequently design clinical trials based on the needs of patients, including those who are currently underrepresented and underserved. Whether it be selecting multi-lingual study sites or minimizing geographical burdens, it is critical that all patients feel supported and empowered to participate. As we progress into 2025, I hope that the industry continues to act on the input from patients and care partners so that together we can achieve better outcomes."

Part of listening to patient feedback involves understanding what really matters to them in terms of medical intervention and outcomes.

"I believe we will see a continued to push to involve patients earlier in the clinical development process," commented **Faye Feller**, executive vice president, chief medical officer at blood cancer drug developer Geron. "As new mechanisms and delivery systems are being studied, it is vitally important to incorporate patient insights into how treatments are delivered and what endpoints matter. We saw this firsthand with our newly approved treatment for certain patients with lower-risk MDS [myelodysplastic syndrome], where red blood cell transfusion independence was a key endpoint because dependence on transfusions is a significant driver of patient burden that impacts a patient's quality of life."

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>
> Faye Feller, Geron

"For 2025, I hope to see stronger collaboration efforts between clinical-development stage biotechs and patient advocacy organizations," said **Carlos Quezada-Ruiz**, senior vice president, therapeutic area head, ophthalmology, at genetic medicine developer 4DMT, which has clinical programs in ophthalmology, cystic fibrosis and Fabry disease cardiomyopathy.

fibrosis and Fabry disease cardiomyopathy.

"Stronger partnerships between these two key stakeholders will result in better, more patient-centric development programs and higher participation in trials; potentially resulting in overall faster recruitment timelines, broader population inclusion, and higher retention rates," said Quezada-Ruiz. "Additionally, this collaboration may help our field develop therapies that better address patients' real-world needs and priorities, like reducing the burden of treatment as well as the disease itself, ultimately improving quality of life. This is particularly relevant to people living with severe retinal diseases that can cause severe irreversible vision loss like those with neovascular age-related macular degeneration (wet AMD)."

"In 2025, people will see clinical trials as part of a more dynamic healthcare experience, instead of a one-off transaction as in the past," predicted Medidata's vice president of patient engagement, **Alicia Staley**.

"The industry will embrace the different stakeholders including patients and sites that come together to create a rich collaborative framework for better trial experiences. Patients will be involved much earlier in all aspects of a clinical trial experience, including protocol design and development. We may even get to a point where patient research collaboratives can assess whether trial outcomes are as beneficial to patients as pharmaceutical companies believe them to be," she outlined.

Staley predicted: "Funding and research will also come from areas we've never seen before, as non-profit organizations work to fund specific research functions to support better patient engagement. There will also be an increased focus on building energy and enthusiasm for clinical research in patient communities in new ways."

J&J's Owen concluded: "Patient-centricity is not just critical for participants – it's critical for science. I'm optimistic we'll see continued innovation around this important responsibility in the future."

Back To Top

Remote Monitoring


Gianluca Pirozzi

"In 2025, we will see digital technologies playing an even more influential role in clinical data collection and measurement, potentially accelerating the delivery of life-changing therapies," predicted **Gianluca Pirozzi**, senior vice president, head of development and safety at Alexion, AstraZeneca Rare Disease. "For example, employing wearables to collect data on a daily basis from trial participants could enhance analysis of endpoints as compared to single time point collection. These tools could greatly enrich clinical datasets and make it possible to reduce the size of a study, which could be transformative for clinical trials in rare diseases, where populations are small and dispersed. Further, expanded use of remote monitoring tools could help facilitate enrollment in rural and remote areas by reducing the need to travel to a clinical site, thereby contributing to more diverse trial populations. The use of sophisticated AI tools promises to help researchers interpret these vast datasets more quickly and accurately, enabling them to generate meaningful insights and regulatory submissions sooner."

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Gianluca Pirozzi, Alexion, AstraZeneca

"I predict that we'll see a significant adoption of digital biomarkers by pharma companies in clinical trials [in 2025], as they seek to enhance precision and personalization in drug development," said **Chris Benko**, CEO of Koneska, a company that specializes in remote clinical trials and digital biomarkers. "Digital biomarkers offer real-time data insights, allowing for more accurate assessments of disease progression and treatment efficacy. This trend will be driven by advancements in wearable technology and the integration of mobile health platforms, enabling continuous monitoring of patients outside traditional clinical settings."

Benko identified another trend in this area – in which companies look beyond the silo of their own individual trial for data gathering.

He said Koneska was "already seeing growing interest in data syndication as a way to pool and analyze data from multiple sources, providing a comprehensive view of patient outcomes across different trials. We recently signed Merck and Regeneron as partners in our data syndication efforts in Parkinson's disease. By enabling data sharing between research organizations, this approach will help to accelerate drug development, reduce redundancy, and improve the efficiency of clinical trials. In 2025, we'll see data syndication become more widely adopted to facilitate collaboration and drive the development of new biomarkers and treatments."

Mikesh Udani, CEO of University of Oxford spinout company Albus Health, which has developed technology to monitor breathing patterns during sleep, said: "The ability to reliably collect objective real-world evidence will transform pharmaceutical drug development and approval in 2025."

Homing in on his company's specialism, he added: "The industry is increasingly focused on sleep monitoring and objective endpoints – recognizing the impact that nighttime symptoms and poor sleep have on a patient's quality of life, yet we've lacked reliable ways to capture this data. The game-changer will be measuring this accurately and objectively over long periods in all demographics, but without burdening the patients. We're already seeing this transformation in respiratory trials, where we can track symptom resolution daily for 12 months even in challenging populations like children. Most disease areas, including neurology and obesity, will soon follow."

Robert Metcalf is group vice president for clinical design, delivery and analytics, China and Japan medical, for Eli Lilly & Co. "The modernization of clinical trial research is essential to improving patients' lives in powerful new ways," he said. "This includes leveraging community-based clinics/imaging/labs as

well as telemedicine, remote monitoring of trial participants, and other novel clinical research methods that make it easier for patients to participate in clinical studies in the first place. Crucially, all of this can be done while maintaining the highest standards for quality, patient safety and data integrity."

Back To Top

Artificial Intelligence, Data Analytics And Digital Technology

"Clinical trials remain the most resource-intensive stage of drug development, but innovation is accelerating change," said **Suzanne Caruso**, general manager clinical and regulatory at pharma industry solutions and consulting provider and *Scrip*'s parent company, Norstella. "AI is redefining how trials are designed and executed – enhancing patient recruitment by identifying eligible participants faster, optimizing site selection through real-world data insights, and enabling real-time data analysis to detect issues early, reduce protocol deviations, and improve decision-making. By integrating predictive analytics and automation, we have a clear path to faster, more cost-effective trials that improve both patient outcomes and the likelihood of success."

Emmanuel Frenehard

"Artificial intelligence is already having a significant impact on various aspects of clinical trials – from recruitment to the use of virtual patients – and this trend is likely to continue into 2025 and beyond," commented Sanofi's chief digital officer, **Emmanuel Frenehard**. "For example, as part of Sanofi's ongoing partnership with OpenAI and Formation Bio, we recently launched Muse, an advanced AI-powered tool developed to accelerate and improve drug development by optimizing patient recruitment for clinical trials.

By leveraging advanced AI capabilities, we can not only enhance recruitment efficiency but also potentially bring new treatments to patients faster. Our ambition at Sanofi is to become the first pharma company powered by AI at scale, and through this lens, the future of AI-enabled clinical trials holds significant potential."

By leveraging advanced AI capabilities, we can not only enhance recruitment efficiency but also potentially bring new treatments to patients faster.

Emmanuel Frenehard, Sanofi

"Investors remain focused on clinical-stage assets which means it is ever more important for those running clinical stage trials to make them as efficient and effective as possible," pointed out **Mairi Dillon**, associate director, Science Ecosystem, at London, UK-based property management firm Canary Wharf Group. "In 2025, I think we will therefore see an even greater reliance on technology, including AI, in this field to speed up and improve studies." However, Dillon also underlined the fundamental importance of a favorable environment for clinical trials as a precondition. "In the UK, tech alone cannot overcome the barriers to fully capitalize upon the NHS and the sheer volume of patients and data it serves," she said. "As the industry continues to focus on delivering the recommendations of the Lord O'Shaughnessy review [which was commissioned by the UK government in 2023 to address challenges in conducting commercial clinical trials in the UK], I am hopeful that in 2025 we will see these barriers removed."

Jay Ferro, chief information, technology and product officer for healthcare research and technology company Clario, also flagged the opportunities for improved speed and efficiency. "In 2025, I'm excited about the rise of real-time analytics in clinical trials. Real-time data collection and analysis across diverse sources will revolutionize decision-making, enabling swift adaptability and better outcomes for sponsors and patients. This agility is transformative, particularly when the mission is to deliver life-saving treatments," he said.

"I also anticipate we'll see a regulatory evolution for digital tools," Ferro continued. "Regulatory agencies will adopt more agile frameworks to keep pace with the integration of AI, wearable technology, and digital endpoints in clinical trials. This alignment will help streamline approvals, enabling life-saving therapies to reach patients faster while maintaining rigorous standards for safety and efficacy."

"AI and machine learning will significantly impact clinical trials in 2025 and beyond, addressing core challenges like rising costs, slow recruitment, and the need for precision medicine," said **Raviv Pryluk**, CEO of PhaseV, which develops technology for trial design, management and analysis. "While oncology has led AI adoption, its influence is expanding to immunology, neurodegenerative diseases, and rare conditions through predictive modeling and retrospective analysis. The FDA's Complex Innovative Trial Design program is supporting adaptive, data-driven trials, while the industry pushes for more ethical, patient-centered designs. As the focus shifts toward transparency and away from 'black box' models, AI solutions grounded in clinical and statistical rigor will become essential for modern drug development. In 2025, AI will drive the next generation of clinical trials, contributing to smarter designs, more efficient execution, and improved outcomes for patients worldwide."

Raviv Pryluk

As the focus shifts toward transparency and away from 'black box' models, AI solutions grounded in clinical and statistical rigor will become essential for modern drug development.

Raviv Pryluk, PhaseV

Addressing the question of transparency and trustworthiness, Novotech's **Schliebner** predicted that: "Blockchain will safeguard data integrity, enabling secure, auditable clinical trial processes."

Back To Top

Measuring Outcomes

There is hope that 2025 will see continued advances in the measurement of outcomes in clinical trials.

"Some diseases, like hereditary angioedema (HAE), rely on patient-reported outcomes (PROs) to assess the efficacy of novel therapeutics in clinical studies," noted **Peng Lu**, chief medical officer of Dutch biotech Pharvaris, which is developing a treatment for the condition. "Continued improvement in electronic PROs to ease the burden on study participants may result in more accurate data collection, supporting rigorous evaluation of investigational drug efficacy and safety.


Peng Lu

"In 2025, we anticipate study sponsors to conform to a core outcome set (COS) across various study designs, such as the COS recommended for HAE clinical studies by the panel of experts participating in the AURORA project. Homogenizing the use of specific outcomes and outcome measures for clinical studies will support clinical guidelines development and future indirect comparisons among interventions," Lu went on.

> **Homogenizing the use of specific outcomes and outcome measures for clinical studies will support clinical guidelines development and future indirect comparisons among interventions**
>
> Peng Lu, Pharvaris

"Additionally, 2025 will yield improved biomarker identification and validation – advancing disease diagnosis and therapeutic evaluation, which could improve diagnosis of HAE and other bradykinin-mediated diseases. This will support the development of effective and tolerable novel therapies for treatment of these diseases," she said.

Joseph Tucker, CEO of neuropsychiatric therapeutic developer Enveric, also emphasized the importance of defining appropriate outcomes and measuring them effectively. "The psychedelic space has generated immense interest, but in 2024 we learned, as many suspected, that the FDA is going to look at the 'shroomboom' with a skeptical eye. Questions around the placebo effect and functional unblinding for these therapies that manifest profound experiences for trial subjects will continue to present high hurdles," he warned.

"Companies with hallucination-inducing agents will be retooling their trials, but the research into neuroplastogens that don't generate hallucinations are expected to accelerate with the goal of providing clear evidence of measurable neurophysiological impacts. Additionally, brainwave biomarkers are keying us into specific molecular mechanisms and pathways, generating a new paradigm for clinical trial success in mental health. We believe that as this science takes off in the clinical trial setting, we could be opening new avenues for the treatment of key mental health disorders like treatment-resistant depression, anxiety and PTSD."

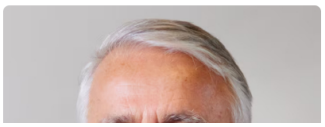
Back To Top

Improving Efficiency

"The biopharma industry continues to face significant challenges, with 85% of trials failing to meet recruitment timelines and dropout rates reaching as high as 20%. This drives up the costs of trials and delays the development of potentially life-saving treatments for patients," said **Erik Buntinx**, CEO and global coordinating principal investigator at Belgium-based contract research organization Anima Research.

"We need to professionalize the way in which we run clinical trials, putting them in centers that are fully experienced in clinical trial delivery rather than prioritizing centers because of their therapeutic expertise. Bringing patients more directly into the clinical trial process, through more engaging and more personalized recruitment approaches, will have better results, driving improved clinical trial delivery times and retention rates. I hope this is a trend that the industry will begin to adopt."

"Clinical trials are evolving and adopting technology to recruit, retain and engage patients at an increasing rate," said **James West**, managing director in London for investment bank Lincoln International. "The pace of designing and running a trial has long been seen as a pain point for pharma, which can result in large sums of money to run a trial, and potentially not reach the endpoint, or complete it. In addition, the increasing complexity of clinical trials requires business models and technology to adapt. Key factors driving change include: dispersed global patient groups, ultra-rare diseases with small patient populations, and novel therapeutics. These all increase the workload on the gold standard method, the RCT [randomized controlled trial], and to solve this inefficiency, new organisations are applying large datasets to model the success or failure of a trial before it starts. These future insights into drug development could lead to significant time, resource and patient outcomes."



J&J's **Owen** also emphasized the need to make smart use of data to improve efficiency. "As we shape the post-pandemic research environment, I foresee that country and site optimization will remain a top priority for industry in 2025," she said. "The paradigm of sponsor and site engagement has shifted in recent years, and it's essential that R&D organizations lean further on data to drive


Paul Peter Tak

R&D organizations lean further on data to drive decision-making. Greater efficiencies ultimately lead to greater – and quicker – patient impact."

"2025 will mark an important evolution in the use of high density of data Phase Ib/IIa clinical trials to inform early go/no go decisions," predicted **Paul Peter Tak**, CEO of cancer viral immunotherapy developer Candel Therapeutics. "This approach is based on the concept of experimental medicine and can be applied across different disease areas. The trials are rich in biomarker data while also capturing the patient experience in the best way possible. The integrated data package allows biopharmaceutical companies to make informed decisions about whether to continue investing in the development of a particular drug or to stop the development process before the initiation of large, adequately powered, late-stage clinical trials."

2025 will mark an important evolution in the use of high density of data Phase Ib/IIa clinical trials to inform early go/no go decisions.

Paul Peter Tak, Candel Therapeutics

Lisa Ricciardi, CEO of Cognition Therapeutics, took a similar view, citing the area in which her company is operating as an example of how trials could be designed more precisely using better data. "Neurodegenerative diseases like Alzheimer's disease, dementia with Lewy bodies, and Parkinson's disease are seeing major diagnostic advances with biomarkers. These changes are enabling precision-medicine approaches that allow drug companies to target the right patients for the right trial. The result? Faster enrollment and more efficient clinical trials given appropriate patient selection. We believe accurate biomarker biology will allow for more and better candidates to achieve success in Phase III."

It is not just a question of being more precise in trials in humans, but also of considering new ways of conducting preclinical research. "My prediction is we'll see more companies leveraging human cells and tissues for drug discovery and development," said Vivodyne CEO **Andrei Georgescu**. "This trend reflects a deeper understanding of how these biological systems respond to new therapies in ways that animal models cannot fully replicate. Human cells and tissues provide more accurate and relevant data, enabling more precise predictions of drug efficacy and safety. At Vivodyne, we're harnessing this approach to develop novel therapies that better mimic human biology. By using human-derived systems, we can identify potential drug candidates that are more likely to succeed in clinical trials. As more companies recognize the value of integrating human cells and tissues into their research processes, this trend will become standard practice, accelerating the development of new treatments and improving patient outcomes. In 2025, I expect to see a broader adoption of this methodology, driving more personalized and effective therapies to market."

Back To Top

Novel Trial Design

Several executives flagged up the increasingly nuanced ways in which trials are being designed.

"The march of progress in medicine creates challenges in the design of clinical trials for innovative therapeutics," commented **Pravin Dugel**, CEO of Ocular Therapeutix, which is developing therapeutics for retinal diseases, including age-related macular degeneration. "As more treatments become available, exposure to placebo or sham procedures becomes increasingly less acceptable. Furthermore, the sheer range in modalities, dosing and routes of administration can confound blinding or masking of active comparators against an experimental treatment arm. For example, in certain retinal diseases, innovative therapies designed to reduce treatment burden and increase therapeutic durability are challenging to study without sham injections given current standards of care that require much more frequent dosing. Fortunately, the solution to such barriers lies in adaptation and cooperation between researchers and regulators. Special Protocol Assessments and collaborative approaches between sponsors and agencies are going to become increasingly critical to untangle complexities in trial design, while also mitigating regulatory risks by enhancing certainty and agreement on the adequacy and acceptability of clinical trial designs and endpoints."


Pravin Dugel

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Pravin Dugel, Ocular Therapeutix

Mark Mallon, CEO at George Medicines, thought that: "As biopharma looks toward 2025, the industry's approach to clinical trials will likely accelerate beyond traditional methodologies. While randomized controlled trials have long been the gold standard, and the importance of randomization remains, more therapeutic areas are beginning to explore pragmatic trial designs that capture real-world implementation challenges.

"Hypertension research in resource-constrained settings exemplifies this critical shift," he continued. "Traditionally, clinical trials relied on artificial head-to-head comparisons that provided limited insights for physicians. Now, studies are capturing broader treatment implementation challenges, including medication adherence, systemic healthcare constraints, and comprehensive patient outcomes.

"This evolution represents a fundamental move away from narrowly defined efficacy measurements. As our understanding of treatment complexity improves, more clinical research will likely incorporate context-aware designs that provide nuanced insights into medical interventions across diverse global settings, ultimately leading to more meaningful and translatable research outcomes."


Jennifer Litton

"In 2025, we anticipate significant changes in the structure of clinical trials, particularly in cancer care," said **Jennifer Litton**, vice president of clinical research at the University of Texas MD Anderson Cancer Center. "Trials will increasingly leverage genomic and protein-level data to better pinpoint participants, incorporating deep correlative science. This approach will accelerate advancements in immunotherapy, antibody-drug conjugates, and AI-driven, possibly less toxic targeted therapies. Additionally, we expect progress in addressing rare tumors and uncommon subsets of more prevalent cancers through these tailored trials. Simultaneously, there will be a shift toward larger, streamlined trials focused on meaningful endpoints, reducing unnecessary complexities. These studies will likely minimize in-person patient visits and integrate technologies to gather real-time data directly from patients, making trials more efficient and patient-centric."

Trials will increasingly leverage genomic and protein-level data to better pinpoint participants, incorporating deep correlative science. This approach will accelerate advancements in immunotherapy, antibody-drug conjugates, and AI-driven, possibly less toxic targeted therapies.

Jennifer Litton, University of Texas MD Anderson Cancer Center

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Novotech's **Schliebner**, agreed that "hybrid trial models, combining decentralized and traditional approaches, will enhance accessibility and patient engagement."

Francis Burrows, chief scientific officer at Kura Oncology, commented: "Combination therapy has become the standard cancer treatment, which requires combination clinical trials to find new approaches and better serve patients. Typically, these studies include a novel, clinical-stage asset in combination with an approved therapy. But as we further understand and design drugs at the mechanistic level, the more we will see novel drug-novel drug combination trials. We've already seen some oncology trials in which both drug candidates are not FDA approved as monotherapies yet are being evaluated in combination trials. I expect 2025 will bring an uptick in this trend across both small and large organizations."

Back To Top

Global Trials

"The ongoing discussion of 'drug loss – drug lag' in Japan is finally making it to Western boardrooms and we expect the Japanese market to become more attractive to Western biopharmas," declared **Helen Chen**, Shanghai-based Asia healthcare sector head at strategy consultancy L.E.K. Consulting. "Many innovative Western pharmaceuticals have not been brought to Japan to benefit Japanese patients in a timely manner (the lag), or at all (the loss). Among the reasons, the smaller biotechs which make up the innovation ecosystem and contribute 65% of drug approvals in the US tend not to have the capacity or capability to concurrently develop their asset in multiple markets, let alone such a different regulatory regime as Japan's.

"The Japanese government has started to implement measures to turn this around. This includes a December 2023 provision allowing Japanese sites to be included in global multi-center Phase III trials without prior Phase I Japanese patient data, and simplified institutional review board processes. As Japan is already a signatory to the ICH [the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use], these and other measures to streamline clinical development and registration have the potential to change the trajectory of the products available in Japan. The last time such a major transformation happened was probably China's regulatory overhaul in 2017, and that was a catalyst to Western pharma and financial sponsor investment in the country."

Back To Top

Commercial Viability

"Going into 2025, we continue to see biotech facing fundamental business model challenges as clinical end-markets become ever more crowded, former blockbusters are coming off patent, and new true game changers are rare," warned **Max Baumann**, head of execution at healthcare consultancy Treehill Partners.

"Historically, biotech had developed new drugs up to initial clinical evidence for the assets then to be taken further by large pharma, but with the global top 10 players now valued above $3tn in [combined] market cap, what should these buy in order for it to even matter? These dynamics are as key for early-stage drug developers to consider as they craft use-of-proceeds strategies for the money they raise from investors, as they are for large pharma in their portfolio management strategies placing sizeable 'bets' on commercial areas to win in 10 or more years down the line."

We expect continued focus on optimizing the development journeys of assets to achieve not only

an approval-enabling endpoint but to qualify for commercial success.

Max Baumann, Treehill Partners

As a result of these challenges, Baumann foresaw a greater focus in the development process on commercial outcomes: "We expect continued focus on optimizing the development journeys of assets to achieve not only an approval-enabling endpoint but to qualify for commercial success, whilst still no new universe of mid-sized commercial-stage players is forming who would have the risk appetite and pockets to fund late-stage trials in areas where large pharma has grown out of."

Back To Top

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