Noriyuki Takai — CEO, EPS Corporation

Patients in Japan deserve the same access to innovative treatments that patients in other markets have. Accelerating that access is what drives us

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Noriyuki Takai, CEO of EPS Corporation, outlines the CRO's mission to help address Japan's drug lag and drug loss by supporting faster access to innovative medicines. He highlights EPS's end-to-end clinical development capabilities, strong site network and dedicated support for overseas biotechs through EPS BIOPATH. EPS is also developing strategic regional partnerships, using AI to improve trial efficiency, and developing talent, with Takai hoping to help position Japan as a key destination for early-phase and regional clinical research.

To begin, could you introduce EPS Corporation and its core mission?

Our corporate philosophy is contributing to the development of the healthcare industry through the creation of value-added solutions. In practice, that means addressing two of the most urgent challenges in the Japanese market: drug lag and drug loss. Japan has a well-documented issue with patients not having timely access to innovative treatments that are already available in other markets, and as the leading contract research organisation in Japan, we feel a genuine social responsibility to help solve that problem. It is not simply a commercial mandate – it is a mission.

Our track record reflects the depth of that commitment. To date we have supported more than 1,000 companies, achieved over 20,000 patient enrolments in the past decade, and have been involved in approximately 85 percent of pharmaceutical approvals in Japan. That level of engagement across the market gives us a perspective and a network that few organisations can

match. We are well positioned to act as a long-term partner for overseas biopharma companies, accompanying them through the full journey from clinical development through to successful market entry and commercialisation.

Underpinning all of this is our people. We invest heavily in talent development from a long-term perspective, and the deep expertise and strong teamwork our teams bring is what enables us to consistently deliver high levels of service to our clients.

You have been with EPS for 23 years and became CEO last year. What are your priorities in this role, and what has that long institutional experience given you?

I joined EPS 23 years ago and have held many different roles across that time – clinical monitoring, quality management, business development, corporate planning, and from 2019, leading our global business operations. That breadth of experience across the organisation gives me a deep understanding of how EPS works and what it stands for, which I think is a genuine asset in the CEO role.

My most immediate priority is increasing awareness and recognition of the EPS brand globally. Japan has serious challenges around drug lag and drug loss, and resolving those challenges is both a business priority and a moral one – patients in Japan deserve the same access to innovative treatments that patients in other markets have. Accelerating that access is what drives us.

At the same time, we are focused on delivering on our philosophy, which is centred on two things: our deep commitment to getting new treatment options to patients who are waiting for them, and our belief in the development of our people as the foundation that makes everything else possible.

Western companies often perceive Japan as a particularly complex market. How does EPS help them navigate it?

Japan is often perceived as a complicated country for entry, but in reality it is one of the most predictable and scientifically rigorous markets in the world when supported by an experienced regional partner. With EPS, a company gains access to a total solution spanning everything from clinical trial management through to new drug application submission and post-marketing surveillance. We can support the entire journey from clinical development through to commercialisation.

What differentiates EPS is our ability to combine CRO expertise, site management capabilities, regulatory knowledge and local market access support within a single integrated platform. A particularly important strength within our group is our site management organisation network, which covers more than 70% of clinical sites in Japan and gives us a strong, well-established presence across the country. That translates into something very specific that sponsors value greatly: Feasibility assessment and predictable patient enrolment.. When we commit to a patient enrolment target on a given schedule, we deliver it. That level of predictability in a clinical trial environment is genuinely valuable, and it is one of the reasons Japan – with the right partner – is actually a highly efficient market in which to conduct a clinical trial.

EPS has introduced two distinct service concepts to support different client needs. Can you walk us through Trial Gate and EPS BIOPATH?

Trial Gate is our one-stop solution concept for clinical operations. Rather than a sponsor company trying to manage all the different functions, processes, and steps involved in conducting a clinical study – which is genuinely complex and demanding – EPS operates as a single gate through which everything flows. We handle all operational functions on the sponsor's behalf, from start to finish. This reduces complexity and management burden dramatically for our clients.

Beyond the operational dimension, Trial Gate also functions as a gateway in a broader geographic sense: bridging between overseas markets and Japan*, and between Japan and the rest of Asia*. Japan's regulatory framework creates real opportunities here, because data generated and approved in Japan can be used as reference data for regulatory submissions in other countries under the Reference Country Program. That means a Japan approval can serve as a stepping stone for broader regional market entry, and we help sponsors understand and navigate that pathway.

EPS BIOPATH is a newer service brand we have developed specifically for overseas biotech companies. Biotechs entering Japan often face a distinct set of barriers: limited familiarity with the Japanese regulatory framework, language challenges, and financial constraints that make it difficult to justify the investment in building Japan expertise internally. EPS BIOPATH is a hands-on consulting service that provides integrated support from early development all the way through regulatory submission and commercialisation, with the explicit goal of making successful Japanese market entry feasible for companies that would otherwise struggle to get there on their own. Given that biotechs are now the primary source of innovative pipeline globally, being able to support them as a dedicated service offering is a natural and important extension of what EPS does.

EPS has a footprint across the Asia Pacific region. How do you support clients looking to run regional trials beyond Japan, and what is your view on regulatory harmonisation across the region?

Our approach in Asia is built on strategic partnerships rather than trying to replicate our Japan model across every market ourselves. We have strategic partners for regional clinical operation that provide comprehensive services across Asia and Pacific region. Within our own group we have EPS International Korea, EPS International China, and SMO services in Taiwan. Where our own capabilities end, our partners' capabilities begin.

This partnership model is deliberate. Regional CROs have accumulated deep knowledge of local sites, investigators, and regulatory cultures that is very difficult to replicate from a centralised structure. Global CROs managing from headquarters sometimes struggle to fully engage with regional regulatory nuances, and for a clinical trial to run smoothly that local knowledge is critical. By partnering with organisations that have that expertise embedded in each region, we can offer clients a genuinely effective regional solution.

On harmonisation: I believe Japan can play a first-mover role in building the communication and collaboration frameworks that will eventually allow Asia Pacific regulatory authorities to work more closely together. The National Cancer Center Japan and PMDA are already leading individual initiatives in that direction. Once those communication channels are established and more countries join the alliance, the region as a whole will be in a much stronger position to support clinical development efficiently and consistently. We see that as an important long-term direction.

Japan's regulations around phase 1 trial participation have been evolving. Where are you seeing the most demand across clinical development phases, and which therapeutic areas are attracting the greatest investment?

Historically, overseas companies would conduct phase 1 studies in the United States or Europe and only engage Japan at a later stage, typically phase 3. That pattern is changing. The PMDA has issued new regulatory guidelines specifically enabling assessment of Japanese patient safety and efficacy within phase I studies, and that is opening a pathway for earlier Japan entry. We actively encourage overseas companies to consider Japan from the early stages of development. Japan has high enrolment potential and high-quality investigator sites across virtually all therapeutic

indications, and the regulatory data generated here has significant downstream value for regional submissions.

In terms of therapeutic areas, oncology remains the primary driver of demand. But Japan also has specific and well-developed regulatory frameworks for regenerative medicine, advanced therapies, and new modalities, which is an increasingly important area of investment.

How is EPS integrating AI and digital technologies into its operations, and what capabilities and talent are needed to support that transformation?

AI and digital transformation are central to EPS's strategy for improving clinical trial efficiency, and the most important metric we focus on is overall development timeline reduction. We have implemented AI-driven initiatives across a range of standard document preparation processes – data management planning, medical writing, and related functions. However, the single most impactful lever for timeline acceleration is patient recruitment, and that is where AI combined with our accumulated site knowledge is producing the most tangible results. We are already seeing examples where AI-enhanced site intelligence is enabling more efficient patient enrolment and contributing to on-schedule trial delivery.

On the technology side, we have developed several proprietary systems, including a pharmacovigilance system for EPS-supported studies in Japan and a gateway submission system to support regulatory submissions to the PMDA.

Talent is genuinely the most important and the most challenging dimension of this. Our teams need expertise across a very wide range of functions – clinical research monitors, project managers, data scientists, AI specialists. Our approach is to recruit strong new graduates and invest heavily in training and development internally, building from entry-level capability through to genuine domain expertise over time. We are also attracting experienced professionals from the pharmaceutical industry and from academic institutions. With approximately 4,000 employees in our CRO business and 8,000 across the EPS group, maintaining the quality and depth of that talent pool is one of my most important responsibilities as CEO.

As you look ahead, where do you see the greatest opportunities for EPS?

EPS is accelerating on two fronts simultaneously: deepening and broadening our services for domestic Japanese companies, and strengthening our support for global companies entering Japan and Japanese companies expanding into overseas markets. Both directions are growing in importance.

Japan has a genuine and urgent need to solve its drug lag and drug loss challenges. The patients who are waiting for access to treatments already available elsewhere are the reason this work matters. Every initiative we drive – from earlier phase engagement with overseas companies, to regulatory guidance, to AI-driven efficiency improvements – is ultimately in service of getting new treatments to those patients faster.

Our ambition is not only to support clinical development in Japan, but to position Japan as a strategic gateway to Asia.

As Japan’s regulatory decisions are increasingly recognized and leveraged across a growing number of Asian countries, successful development in Japan can become a foundation for broader regional expansion.

We want Japan to be one of the first countries global innovators consider when bringing transformative therapies to patients.

Ultimately, our success will be measured by how quickly those innovations reach the people who need them.

That is what EPS is for, and it is what will guide our priorities going forward.

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