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•••The next chapter of Clinical Trials is about the evidence we generate for Indian patients in Indian settings•

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The pharmaceutical industry is undergoing a significant shift from standalone clinical trials to integrated evidence generation across the product lifecycle. As regulatory expectations, real-world data requirements, and AI-driven insights reshape healthcare decision-making, organisations are increasingly looking for partners that can support evidence generation from development through commercialization and beyond. Against this backdrop, Mumbai-based SIRO Clintech is evolving from a traditional Clinical Research Organisation (CRO) to a Lifecycle Evidence Partner, enabling pharmaceutical companies to generate, connect, and maximise evidence throughout the product journey. In a detailed conversation with BioSpectrum, Dr Gautam Daftary (Founder and Chairman) and Karan Daftary (Managing Director), SIRO Clintech shares details about the company's growth plans.



SIRO Clintech is repositioning itself from a traditional CRO to a Lifecycle Evidence Partner. What specific gaps in the current pharmaceutical ecosystem prompted this transformation?

Dr Gautam Daftary- The traditional CRO model was built for a different era. Sponsors hired us to execute discrete projects: a Phase III trial here, a publication there, a PMS (post marketing surveillance) programme after the product launch. We delivered each piece competently in isolation. What we watched unfold over two decades is that data and insights generated within one project rarely informed the next. A trial would close, the dataset would lock away, and a year later the same molecule would face a guideline body, a payor, or a prescriber community asking exactly the questions that dataset could have answered.

The second gap is uniquely Indian. We have built, over three decades, the operational and scientific capability to run trials to global standards. What we have not built at industry scale is the connective tissue between trial data, real-world evidence, post-approval programmes, and publication output that turns a molecule's clinical story into prescriber confidence and guideline alignment. Sponsors increasingly need a partner who treats evidence as a continuum rather than a sequence of transactions.

What are the major plans in store for FY 26-27? Please share the details.

Karan Daftary- FY 26-27 has four explicit workstreams under our Lifecycle Evidence Partner architecture. First, deepening Development Clinical Trials capability, particularly in metabolic, hepatic, and respiratory portfolios, where Indian sponsors are increasingly running pivotal Phase III programmes. Second, scaling Post-Approval Clinical Programmes, including a structured offering that mines historical Clinical Study Reports to surface publication-ready evidence sponsors didn't realise they already owned. Third, expanding Real-World Evidence generation tied to Indian prescriber and patient populations, where unmet need is significant. Fourth, our differentiator: Evidence Platforms and Intelligence, the technology layer delivered through SIROai, which gives sponsors structured access to patient conversations and discussions about the drug on social media – we call that patient voice, investigator intelligence and centralised reading capability.

One question Indian CROs rarely get asked, and one worth answering directly: how much does a CRO invest in R&D? The easy assumption is that buying a few off-the-shelf SaaS tools amounts to a technology strategy. That assumption is wrong- In our case, SIROai is the outcome of more than five years of foundational platform development. The wider technology organisation SIROai sits within, also runs an ISO 13485-certified diagnostics AI business, which speaks to the engineering and governance depth behind our broader platform work. That level of sustained R&D investment is uncommon in the Indian CRO landscape. SIROai will be one of the principal drivers and enablers of the lifecycle model we are building over FY 26-27 and beyond.

We expect meaningful growth this year, driven less by trial-volume expansion and more by sponsors consolidating multiple evidence workstreams with a single partner.

What are the current challenges and opportunities facing the Indian CRO market?

Karan Daftary- The Indian CRO market is in a more interesting position than it gets credit for. The challenge is real. Margin compression on traditional trial execution, sponsor consolidation, and a global perception that India is a low-cost site rather than a strategic evidence partner. Cost-arbitrage models are running out of room. The economics no longer work for anyone competing only on price.

Indian pharma is moving from generics to specialty and innovator molecules at scale. Indian sponsors are increasingly publishing in global journals, presenting at international congresses, and seeking guideline inclusion for their assets. That requires a different kind of CRO partner: one with publication capability, real-world evidence infrastructure, regulatory depth, and analytical platforms to mine existing trial data

The CROs who will define the next decade in India aren't competing on per-patient cost. They are competing on evidence yield per dataset. A single well-designed Phase III, run with the right architecture, can generate ten to twenty publications, multiple post-approval extensions, and a real-world evidence programme that shapes guidelines for years. That is the conversation Indian sponsors want to have now. The CRO of the next decade will be defined by something different: how it embeds technology inside its own workflows, governed by the quality systems sponsors require, drawing on the operational and scientific expertise its people have built up over years. SIROai is our technology platform and is our enabler for the lifecycle model and is we are already partnering with some of our pharma sponsors to help them harness their existing trial data

Real-world evidence (RWE) is increasingly influencing regulatory and commercial decisions. How can pharmaceutical companies better leverage RWE to improve patient outcomes and product adoption?

Karan Daftary- The first shift is to stop treating RWE as a regulatory checkbox or a post-launch afterthought. Companies getting genuine value from RWE in India design the evidence question upstream, often before launch and sometimes before Phase III readout, and then build the data infrastructure to answer it longitudinally. That changes everything about how the programme is scoped.

The second shift is recognising that India's RWE opportunity is not the Western HEOR-and-payor model. Indian medical affairs teams aren't building dossiers for HTA bodies. They are building prescriber confidence, shaping treatment guidelines, and equipping field teams with locally relevant evidence. The buyer is medical affairs, the currency is clinical insight, and the deliverable is content that lands with Indian prescribers: adherence patterns, sub-population responses, real-world tolerability, comparator context in actual Indian practice.

Third, draw on patient voice systematically. Most sponsors still treat patient experience as qualitative colour. Structured patient voice intelligence, gathered at scale, longitudinally, and integrated with clinical data, answers questions sponsors don't yet know they should be asking. We treat patient voice and investigator intelligence as evidence streams in their own right, on the same footing as clinical data, and feed them back into the publication and medical affairs engine.

There is a fourth dimension to this that doesn't always sit neatly under the RWE label, but increasingly belongs in the conversation. Social media has been one of the most empowering shifts for the Indian citizen, giving every patient and caregiver a voice they did not have a decade ago. It has also produced an environment where content travels on virality rather than on scientific accuracy. Some of what circulates around major therapeutic categories has no evidence base. The governance question that sits over those platforms is properly the domain of policy-makers and regulators. But pharma companies in India face a practical, immediate question: what is being said about their molecules, their categories, their indications, and how do they respond with accurate, evidence-grounded information? That question is one we can help answer directly.

Our social and digital listening infrastructure, paired with AI-based classification tools, gives Indian sponsors the ability to monitor public conversations at scale, distinguish credible content from misinformation, and generate the evidence-based response their medical affairs teams need. It is real-world signal capture applied to a question pharma companies have historically had to handle on instinct.

From building clinical research capabilities in India to now advocating for integrated evidence generation, what do you see as the next major chapter in India's contribution to global healthcare innovation?

Dr Gautam Daftary- The first chapter was capability. When we started, the question global sponsors asked about India was whether trials could be run here to international standards. That question is settled. India runs pivotal programmes for the world's largest pharmaceutical companies, and Indian sponsors run programmes that compete head-on with global molecules. The infrastructure exists, the scientific community exists, and the regulatory framework has matured considerably.

The next chapter, in my view, is about the evidence we generate for Indian patients in Indian settings. The first chapter answered the question of whether molecules can be tested in Indian populations to international standards. We proved that they can. The next chapter answers a fundamentally different question. How do those molecules actually perform in real Indian clinical practice, with Indian patients, on Indian care pathways, with the comorbidity profiles and prescribing patterns and adherence realities that an Indian physician actually sees? That is what real-world evidence actually means. Evidence for India, not evidence from India.

Consider the scale of that need. India has over a hundred million people living with prediabetes, large populations with non-alcoholic fatty liver disease, distinctive hepatitis profiles, oncology patterns that present quite differently from Western cohorts, and patient cohorts on multi-drug treatment combinations that look nothing like the clean homogeneity of trial protocols. Indian physicians have been making prescribing decisions for those patients using evidence generated elsewhere, for cohorts that are not theirs, in healthcare systems that are not theirs. The next chapter is about generating the evidence here, for them, in the conditions in which they actually practice. When that evidence subsequently informs global guideline conversations, and it will, that follows naturally. The design priority is the Indian patient and the Indian prescriber.

That is the shift we are trying to lead from SIRO Clintech. Indian medicines, evaluated in Indian conditions, with evidence that reaches Indian patients first. It is a meaningfully different ambition from the trials-done-in-India era, and it is the chapter that justifies the Lifecycle Evidence Partner repositioning.

How do you envision the growth of clinical research and clinical trials in India? Are there any major expectations from the government?

Dr Gautam Daftary- Over the last decade, Indian regulation has matured category by category in a way that has tracked how the industry itself has accumulated experience. The New Drugs and Clinical Trials Rules 2019 created a more predictable, codified framework in place of what had previously been a more interpretation-heavy regime. The biosimilar guidelines, revised in 2016 and progressively aligned with WHO and global standards, were shaped by India's own decade of experience as a biosimilar manufacturing hub. The Pharmacovigilance Programme of India has grown from inception into a structured national reporting system. Subject Expert Committee processes have become more transparent and more consistent year on year. Across categories, the pattern that emerges is one of a regulator translating sectoral experience into the rule framework as that experience accumulates.

The biosimilar example is the one I find most instructive. India was one of the first countries to build a domestic biosimilar industry at meaningful scale. The regulatory framework evolved as the experience accumulated. The outcome is that Indian patients have access to biological therapies at a fraction of innovator-market pricing within the safety standards the framework codified. Looking across categories, the pattern is consistent. As a therapeutic area matures, the regulatory framework moves in step with it, addressing access, pricing structure and safety architecture together rather than in isolation. That pattern, in my reading, is the most useful frame for thinking about where things go next.

The same cycle appears to be approaching in several of the areas where experience is currently accumulating. Real-world evidence is one of them. India is generating real-world data at scale, through pharmacovigilance, through post-marketing surveillance, through investigator-initiated research, and increasingly through digital health platforms. A formal RWE framework of the kind the FDA has been building is not yet in place here. When one does take shape, it will draw on the Indian-specific evidence work being done today. Health Technology Assessment (HTA) is another. HTA in has been operational under the Department of Health Research in India since 2017, and the conversation that appears to be developing is how formal HTA frameworks integrate, over time, with pricing, reimbursement and access decisions. Cell and gene therapy is a third area where the science is moving rapidly and the regulatory architecture sits at an earlier stage of the same cycle.

My expectation from government, then, is less of a list of specific asks and more a reading of where the trajectory is heading. Each step in this maturation cycle, taken in step with sectoral experience, has historically produced outcomes that align both industry and patient interests. I see RWE frameworks, HTA frameworks, pharmacovigilance evolution and the emerging digital health infrastructure all converging into a more integrated regulatory ecosystem over the next several years. That convergence in my view will be an important thread that will help shape future Indian healthcare policy direction.

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