Commentary: Femida Gwadry-Sridhar

Asia drives trials, but its data must travel too

Within the space of one week in March 2026, two of the world's largest pharmaceutical companies committed nearly one billion dollars to South Korea's biotech ecosystem. Roche pledged $484 million on 3 March while Eli Lilly and Co followed six days later with $500 million[1,2]. Both signed memoranda of understanding with the South Korean government, both cited an intent to attract global clinical trials, and both pointed to Korea's clinical pipeline, which is ranked third in the world, as the strategic rationale. A similar pattern is unfolding across the region: AstraZeneca Plc, Merck & Co Inc, and others have staked positions in Korean, Chinese and Australian biotech regions in recent years.

The signal is unmistakable. Global pharma has concluded that Asia is not a peripheral clinical market. It is a primary one.

But investment and infrastructure are not the same thing. The gap between them – specifically, the gap between generating clinical data in Asia and generating clinical data that the US Food and Drug Administration and the European Medicines Agency and global payers will accept, without requiring costly replication – is the defining challenge facing the region's biopharma ambitions.

A recent example is China-based Akeso Biopharma's biologics application to the FDA for the approval of ivonescimab, a bispecific antibody targeting PD-1 and VEGF for non-small cell lung cancer. In the HARMONi-2 trial, conducted entirely in China, the antibody reduced the risk of progression-free survival events by 49% compared with pembrolizumab[3], a result that, if it holds, would represent one of the most significant advances in immuno-oncology in years. The FDA accepted the biologics licence application in January 2026, with a target action date of November 2026.

Yet the scrutiny the application faces is precisely the scrutiny that any China-only dataset faces: can data generated in a single geography, in a predominantly Han Chinese population, in a healthcare system with distinct standard-of-care practices, support an approval claim in the United States? The question is not rhetorical. It is the operational question that every Asian biotech with global ambitions must answer before it runs its first patient.

BeiGene, now BeOne Medicines Ltd, responded by building the answer into its operating model. Its path to becoming the first Chinese company to gain FDA approval for an oncology drug (zanubrutinib, 2019) required running 100% in-house clinical operations across more than 45 countries to ensure data consistency at scale. The lesson was not that Chinese data is inherently less credible. It was that credibility requires infrastructure investment, not just trial volume.

The regulatory mechanics underlying the credibility gap are worth understanding, precisely because they are so often conflated with the gap itself.

ICH E17, the guideline on multi-regional clinical trials adopted in 2017, establishes the preferred framework for trials designed to support global registration. Its adoption in principle, however, is not the same as its implementation in practice. Consistent application of standards set by the Clinical Data Interchange Standards Consortium (CDISC), required by the FDA and adopted by China's National Medical Products Administration (NMPA) in 2020, remains uneven across the network of clinical sites operating in the region. Even where CDISC adoption is mandated at the regulatory level, individual trial sites may collect data in proprietary formats that require manual mapping before a submission package can be assembled. This is a process that, when discovered late, can delay a regulatory filing by months.

Beyond data standards, HL7 FHIR, the emerging interoperability standard for electronic health records, is only beginning to reach Asian trial infrastructure. And patient-reported outcome instruments validated in Western populations often have not been re-validated in the languages and cultural contexts of Asian trials, raising questions about measurement equivalence that regulators are increasingly unwilling to set aside.

The cumulative consequence is not that Asian trial data is poor. It is that harmonising it for multi-regional regulatory review adds, by industry estimates, an average of 12 to 18 months to the post-collection timeline. In a competitive environment where speed to proof of concept is a primary driver of value creation, that lag is not a technical detail. It is a strategic liability.

Natural history studies as a foundation

This is where the architecture of natural history studies becomes critical, and where the current wave of pharma investment in Asian clinical infrastructure has an opportunity to do something more durable than attract trials.

Prospectively designed natural history studies establish the evidentiary infrastructure before any intervention begins.[4] They are the foundation on which external control arms stand. In the Asian context, this function takes on particular urgency. Consider a rare-disease biotech in Seoul that initiates a prospective natural history study alongside its Phase 1 programme, collecting CDISC-compliant endpoints, validated Korean-language patient-reported outcomes, and longitudinal biomarker data from day one. When that company later seeks FDA review, its external control arm is already built to regulatory standards. No twelve-month remediation would be required. The alternative, which is retrospective chart data assembled after the fact with inconsistent measures and missing outcomes, is precisely the evidentiary gap that stalls regulatory submissions and erodes acquirer confidence.

A natural history study designed to FDA and EMA standards from the outset, with pre-specified endpoints using

standards for real-world data which can be transformed into CDISC-compliant data collection, validated patient-reported outcomes, and contractual data access provisions[5,6], produces data that travels by design rather than by remediation. This is not an incremental improvement on the current model. It is a different model.

A case involving the Belgian biotech, EsoBiotec SA, is a constructive example. The company dosed its first patient in a cell therapy trial in China in January 2025. AstraZeneca, which was vetting prospective acquisitions, announced a bid for the company within three months. What made the dataset attractive to the acquirer was not the speed of the investigator initiated trial alone. It was the fact that the data was designed, from the start, to answer the right question in a form that could be evaluated.

Lilly's Gateway Labs in Korea, to be built in collaboration with Samsung Biologics and designed to house up to thirty companies, is an incubation platform[7]. Roche's MOU explicitly targets building "an ecosystem for global clinical trials." These are the right instincts. The question is whether the infrastructure being built includes the data layer.

Korea already demonstrates what is possible. Seoul ranked first globally among cities for industry-sponsored clinical trial activity every year from 2017 to 2023, according to KoNECT's analysis of ClinicalTrials.gov data[8]. Trial startup timelines in Korea range from 112 days from the clinical trial application package to first site initiation visit, to 152 days to full enrolment, against a global top-15 average of 224 days[9,10]. Its regulatory track record is equally striking: between 2008 and 2019, the FDA's Center for Drug Evaluation and Research conducted 39 inspections of Korean clinical trial sites, all of which resulted in no official action indicated[10]. The data quality potential is there. The question is whether it is being systematically designed into trials at the point of protocol development, or treated as a downstream compliance exercise.

China's trajectory points in the right direction. The NMPA's ICH membership, its adoption of CDISC standards, and the maturation of its contract research organisation ecosystem meaningfully changed what is possible. But the ivonescimab FDA review is live evidence that adoption at the regulatory level has not yet become operational at the trial execution level. The gap between standard adopted and standard consistently applied, at scale, across a network of sites, is where the work remains.

Australia offers a different model worth noting. Its 43.5% refundable R&D tax rebate and five to seven week clinical trial notification scheme, with no investigational new drug equivalent required, have made it the strongest first-in-human destination in the region. Thirty years of FDA and EMA data acceptance give it a credibility baseline that other Asian trial destinations are still building toward. The structural lesson is that regulatory credibility counts, and that it was built, in Australia's case, on decades of data harmonisation, not volume alone.

The opportunity ahead

The billion dollars committed to Korea in a single week represents confidence in Asian clinical infrastructure at a scale that was not imaginable a decade ago. That confidence is warranted. The scientific capability is there. The patient populations are there. The regulatory frameworks are converging.

What remains is to make data quality a design principle rather than a compliance function. Natural history studies, when designed to travel from day one, are among the most effective mechanisms for doing that. They are the scaffolding on which the next generation of Asian clinical infrastructure should be built – and the mechanism by which the fastest data becomes, also, the most credible.

The companies and investors now committing to Asian clinical infrastructure have an opportunity to build this into their operating models from the start. The cost of doing so is front-loaded. The cost of not doing so is paid later, in the 12 to 18 months of harmonisation delay, in the FDA scrutiny that China-only datasets still face, and in the partnership opportunities that stalled because acquirers could not evaluate the data to their own regulatory standards.

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