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ASIA EDITION

Asia should help design global clinical trials, Not simply enroll in them

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The next phase of global clinical development requires moving Asia upstream, from recruitment to trial strategy



Clinical research has become increasingly global, yet an important distinction remains between conducting clinical trials globally and designing them globally.

Too often, Asia enters clinical-development discussions after major decisions have been made. Protocols are established, endpoints selected, eligibility criteria finalised, and regional teams are subsequently asked to activate sites and recruit patients.

This approach overlooks an important opportunity. Asia should not simply provide patients, investigators, and enrollment capacity for strategies developed elsewhere. Its scientific, clinical, regulatory, and patient perspectives should help shape those strategies from the beginning.

Representation should be considered a clinical-development design variable, not merely an enrollment metric.

Asia Is Not One Population

Asia encompasses considerable diversity in ancestry, disease epidemiology, healthcare infrastructure, treatment practices, and regulatory environments.

Japan is not India, and India is not China. Even within individual countries, meaningful differences exist across populations and healthcare systems.

The scientific question therefore extends beyond whether sufficient Asian patients participated in a trial.

Researchers must consider which populations will ultimately receive a treatment, whether intrinsic or extrinsic factors could influence therapeutic outcomes, and whether the available evidence adequately addresses those considerations.

ICH E5 provides an established framework for evaluating ethnic factors when determining whether clinical data can be extrapolated across regions. These include genetic and physiological characteristics alongside environmental, cultural, and medical-practice differences.

Geographic representation must serve a scientific purpose rather than become a numerical exercise.

Representation Begins Before Recruitment

Clinical-trial diversity is frequently discussed during recruitment. However, many decisions influencing participation have already been finalized by that stage.

Eligibility criteria, diagnostic requirements, visit schedules, endpoints, and technology requirements can unintentionally restrict participation across different populations.

A diagnostic procedure routinely available in one country may be inaccessible in another. Similarly, demanding visit schedules or digital assessments may create barriers involving transportation, language, connectivity, or differences in clinical practice.

Recruitment initiatives alone cannot resolve these challenges.

Meaningful representation requires incorporating regional considerations during protocol development and early feasibility assessments.

The FDA has emphasised trial-design approaches and eligibility practices intended to broaden participation and better reflect populations likely to receive approved treatments.

Instead of asking how to recruit more representative populations, organisations should ask how to design trials capable of generating relevant evidence for those populations.

Generalisability, Not Numerical Quotas

Improving representation does not mean every clinical trial should mirror population demographics.

Scientifically appropriate enrollment depends on disease prevalence, biological characteristics, therapeutic mechanisms, treatment practices, and specific research objectives.

ICH E17 recognizes these complexities in multiregional clinical-trial design. Regional sample allocation should consider scientific and operational factors, including the ability to evaluate treatment-effect consistency across participating regions.

The objective is not maximising enrollment from particular geographies. It is generating reliable, interpretable, and generalizable clinical evidence.

Depending on the therapeutic context, this may require greater regional participation, pharmacokinetic assessments, pharmacogenomic investigations, or appropriately designed bridging studies.

Regional differences should be evaluated prospectively when scientifically relevant, rather than addressed only after development decisions have been finalised.

Local Investigators as Strategic Partners

Regional investigators possess valuable clinical knowledge, yet their involvement often begins after protocols have largely been established.

Their understanding of patient characteristics, referral pathways, diagnostic availability, and healthcare infrastructure can identify challenges that might otherwise emerge during trial execution.

Early engagement allows investigators to influence protocol feasibility, patient accessibility, and operational planning.

Patients and patient advocates provide equally important perspectives. Research examining enrollment among Asian and other underrepresented populations has identified barriers involving language, cultural considerations, communication practices, and family participation.

Incorporating these perspectives during protocol development can reduce avoidable participation barriers without compromising scientific rigor.

Local investigators and patients should therefore contribute more than operational support. Their insights should inform clinical-development strategy.

From Regional Execution to Global Co-Design

Achieving meaningful regional participation requires changes in clinical-development governance.

Global programmes should create structured opportunities for regional clinical, regulatory, statistical, operational, and patient perspectives to influence decisions before protocols are finalized.

Practical approaches include regional representation on protocol-design committees, earlier feasibility assessments, evaluation of population-specific factors, and scientifically justified sample allocation.

Existing regulatory frameworks support this approach.

ICH E5 addresses ethnic factors and the acceptability of foreign clinical data, while ICH E17 provides principles for multiregional trial design, including regional variability and treatment-effect consistency.

European and Japanese regulatory frameworks also address considerations relevant to international clinical development.

A 2026 review in Clinical Therapeutics examined differences in regulatory approaches to clinical-trial representation across major regions.

Collecting data internationally does not automatically make clinical evidence globally applicable. Its relevance depends on how regional characteristics and population differences are incorporated into scientific strategy.

Technology Is an Amplifier, Not a Substitute

Digital technologies increasingly connect global clinical trials, enabling coordinated execution and efficient data collection.

However, differences in digital literacy, connectivity, device availability, language, and clinical workflows can influence participation across regions.

Technology strategies must reflect local healthcare realities rather than assume standardized digital approaches will work equally well everywhere.

Technology can strengthen global clinical development, but it cannot compensate for limitations embedded in trial design.

The Opportunity for Asia

Asia's opportunity extends beyond increasing clinical-trial volume or accelerating recruitment.

Its investigators, healthcare systems, regulators, patient populations, and development leaders can contribute directly to the scientific decisions shaping global clinical research.

This does not mean every regional difference is clinically meaningful or every study requires proportional representation.

Instead, the objective is to design integrated global-development programs that appropriately consider regional characteristics while maintaining scientific consistency.

Progress should be measured not only by countries activated or patients enrolled, but also by how effectively regional perspectives influence clinical-development decisions.

For years, the industry has focused on bringing more of the world into clinical trials.

The next priority should be bringing more of the world's scientific, clinical, regulatory, and patient perspectives into designing those trials.

The future of clinical research should not simply involve conducting more trials globally. It should involve designing trials more globally.

And Asia should help design them.

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