Indonesia’s Clinical Trial Ecosystem: From Potential to Performance

November 2025

From potential to performance: Indonesia's clinical trial ecosystem is entering a phase of accelerated transformation

An untapped regional opportunity	• Southeast Asia (SEA) presents a significant, underleveraged opportunity for clinical research • Despite accounting for **about 8%** of the world's population and disease burden, the region contributes **less than 2%** of global clinical trials, highlighting a major gap between need and activity
Indonesia's scale and historical barriers	• Home to **over 40%** of the region's population, Indonesia offers unmatched scale for patient recruitment. • Its potential has been historically limited by regulatory bottlenecks and infrastructure gaps, which have kept its clinical trial participation among the lowest in SEA
A catalyst for change: structural reforms	• This landscape is now being transformed by decisive structural reforms. The Ministry of Health, through the INA-CRC as national facilitator for clinical research, supports faster regulatory processes by guiding authorities, streamlining procedures, and strengthening quality standards. • This pivotal shift is fostering a pro-investment environment and renewing international engagement.
Future growth and compelling opportunity	• As a result, Indonesia's clinical trials market is poised for rapid expansion, projected to grow to **around 300 local trials** valued **at $1 billion to $1.5 billion** in the medium term. • This momentum creates a compelling opportunity for sponsors and service provider/CROs to engage with a large, cost-competitive, and rapidly maturing market

Note: SEA=Southeast Asia; INA-CRC=Indonesian Clinical Research Consortium; CROs=contract research organizations
Source: L.E.K. research and analysis

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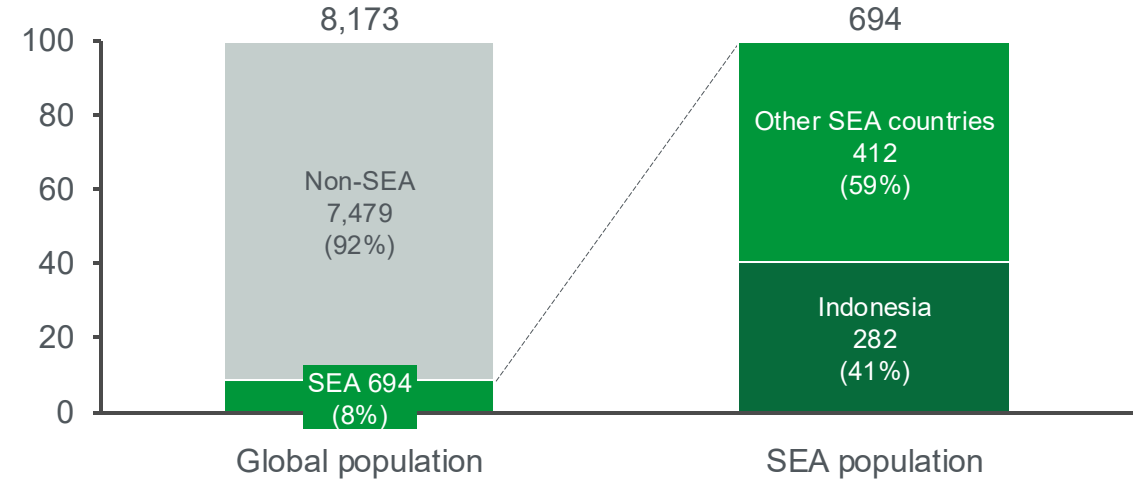
Southeast Asia is home to ~8% of the world's population and ~10% of the global burden of disease; Indonesia represents over 40% of SEA's population — a pivotal market in the region

Population

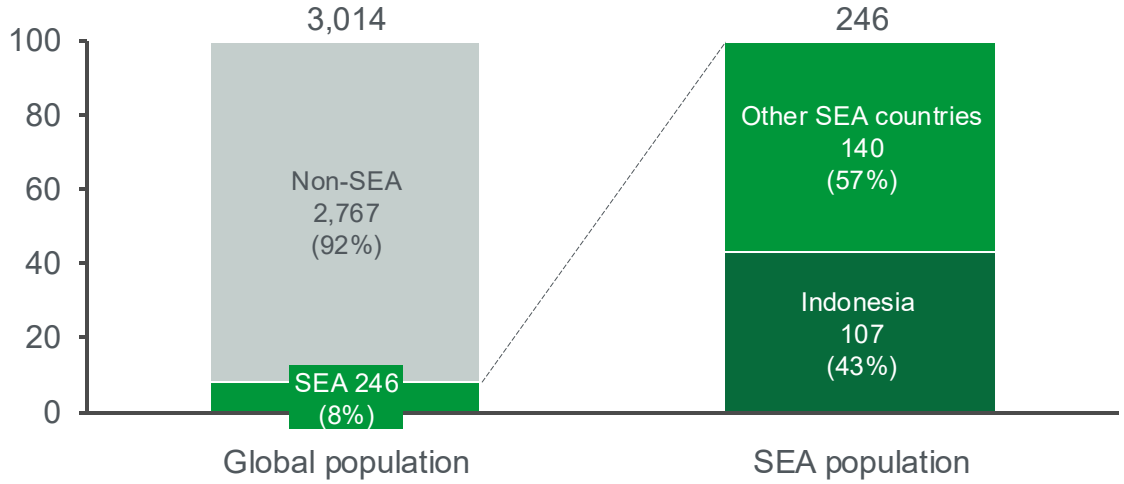
Population by region (2025F)
Millions of people



- SEA accounts for **~10% of the global population**
- Indonesia accounts for **nearly half** of SEA's population

Disease burden

Disease burden by region (2020-21)
Millions of DALY



- Disease burden shows a similar pattern, while SEA accounts for **~10% of global disease burden** and Indonesia constitutes **40%-45% within SEA**

Note: SEA=Southeast Asia; DALY=disability-adjusted life year
Source: IASMED; Citeline; World Bank; United Nations; WHO; L.E.K. research and analysis

In addition to Southeast Asia's sizable and diverse population, cost advantages and improving healthcare infrastructure provide strong fundamentals and potential for global clinical trials

SEA's strong fundamentals for global clinical trials

Diverse population

SEA provides high ethnoracial diversity, including **East Asian, South Asian, Malay and Indigenous populations**, supporting more representative clinical evidence and facilitating multi-region regulatory submissions

Low clinical trial execution costs

Clinical trial execution costs in SEA are significantly lower than those in China and the U.S., offering **attractive operational efficiency** for global sponsors

Improving healthcare infrastructure

Developed hubs such as **Singapore** offer internationally recognized **regulatory frameworks and globally benchmarked clinical infrastructure**, serving as strategic anchors for global biopharma conducting trials across the SEA region

Clinical trial execution costs of an SEA country, China and the U.S.

2022	Indonesia	China	United States
Average wage per year (USD)	~13,760	~16,500	~64,900
Average inpatient cost per day* (USD)	~100	~170	~640

Conducting trials in SEA is typically ~80% cheaper than in the U.S. and 20%-40% cheaper than in China

Note: SEA=Southeast Asia
*The costs refer to the actual average amount paid per hospital day, after insurance or subsidies
Source: World bank; OECD; WHO; Health Action International; L.E.K. research and analysis

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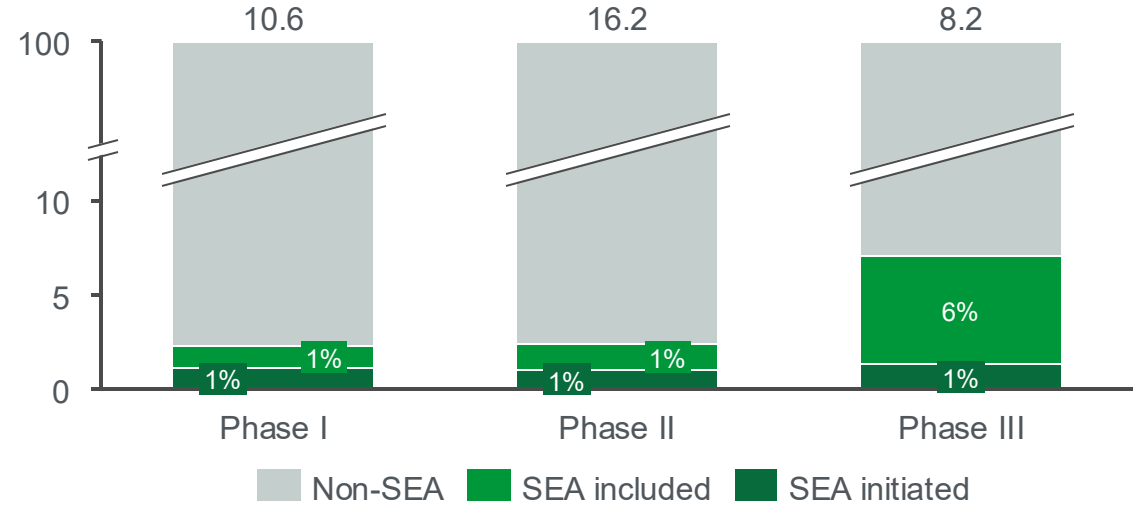
Despite this SEA's participation in global clinical trials remains limited; Indonesia, in particular, has lagged behind regional peers in trial activity

SEA's share of global trials

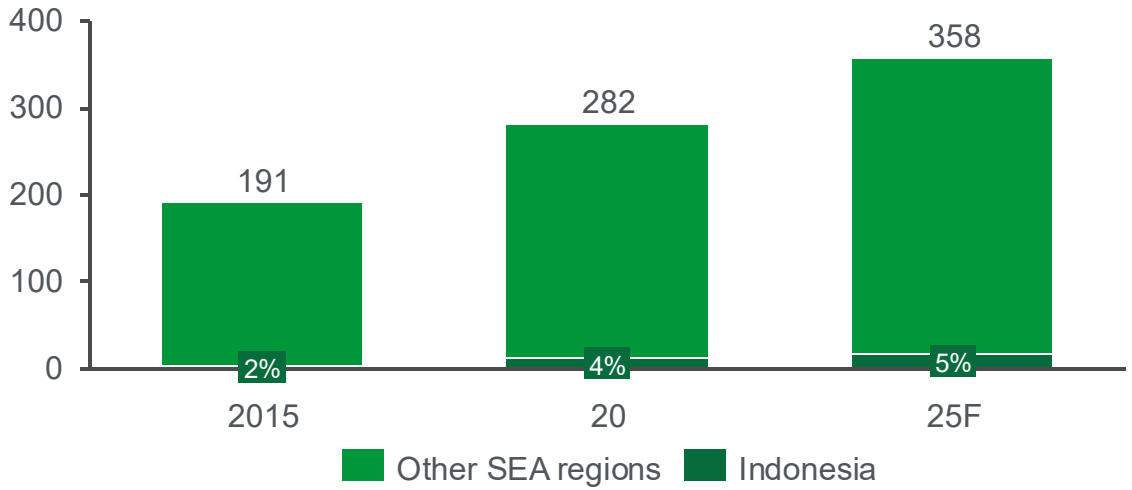
Ongoing clinical trials in SEA and non-SEA regions by phase (Until July 2025)
Millions of units



- SEA accounts for only **~7%** of global ongoing phase III clinical trials
- SEA's share in early-stage trials is even smaller, which is only **~2%** of global trials

Indonesia's share of SEA trials

Clinical trials initiated in Indonesia and other SEA regions (2015-2025F)
Number of units



- Despite its large population, Indonesia accounts for only **~5%** of trials initiated in SEA
- Indonesia's clinical trial development has **lagged behind** other SEA regions

Source: Citeline; IASMED; L.E.K. research and analysis

Indonesia's clinical trial ecosystem has been constrained by structural challenges: underdeveloped trial infrastructure, biosample export regulations, talent gap and operational complexities

01 – Immature clinical research infrastructure

- High-performing sites are predominantly concentrated in major urban centers, resulting in limited coverage and uneven research capacity across regions.
- Only 10% of CRUs meet readiness thresholds; majority fall below basic capability levels

04 – Operational complexities

- Regulatory requirements and timelines of Indonesia's study start-up are unclear
- Indonesia does follow GCP (CUKB), but implementation has been uneven across hospitals, with site SOPs, ethics review and contracts historically decentralized

02 – Restrictive regulations

- Biosample exports are tightly controlled, with lengthy, multilayered approval processes
- Mandatory MTAs and government oversight drive operational delays and cross-border execution risk

03 – Talent gap

- High uncertainties exist related to the availability of local researchers, levels of expertise and specific skill sets
- There is an urgent need for stronger domestic capacity building to address growing gaps in the healthcare and research workforce

Source: L.E.K. research and analysis

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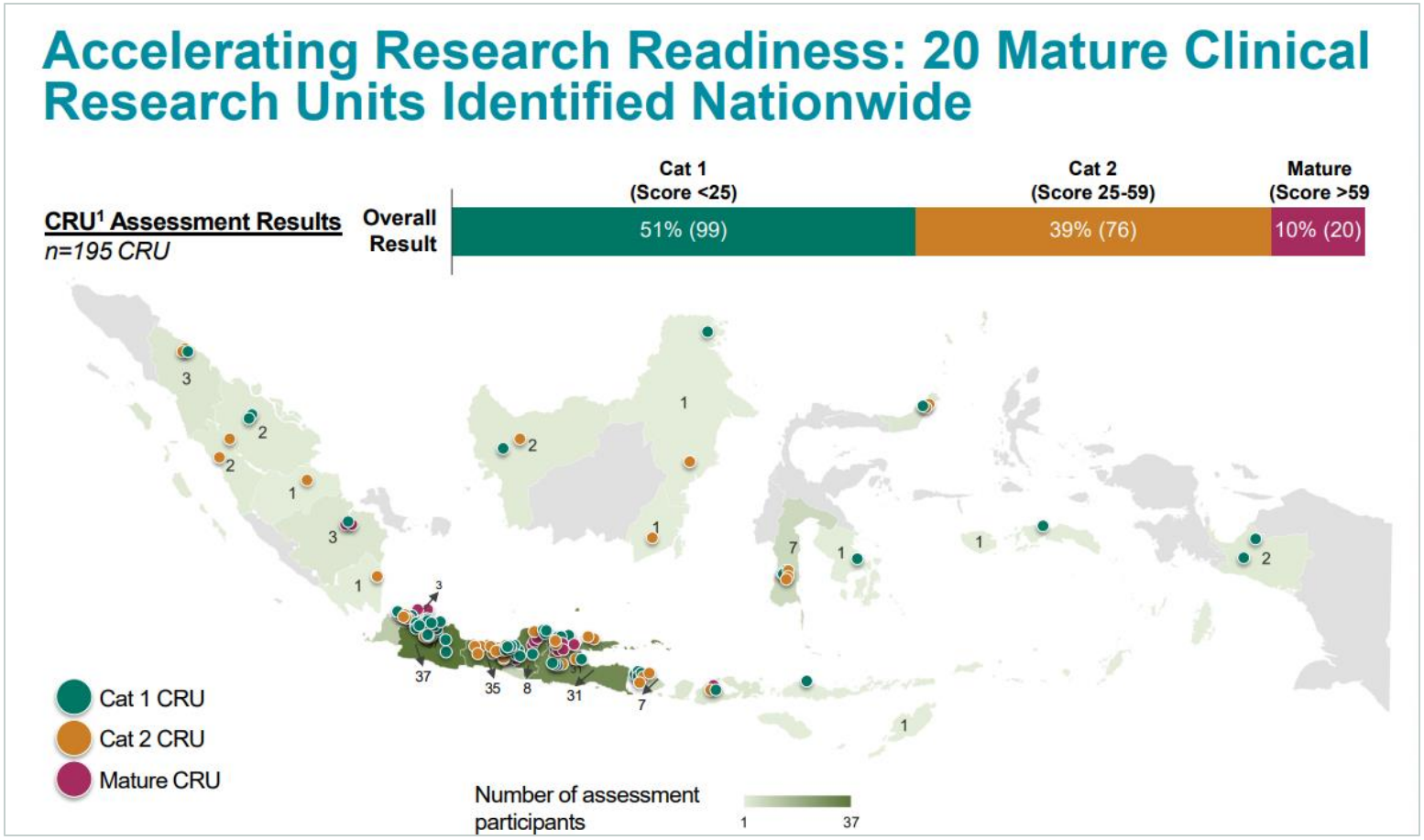
Limited clinical trial development in Indonesia is primarily driven by low maturity of research infrastructure, with only 10% of CRUs meeting readiness standards and most clustered in major cities



- **Only 10% of assessed clinical research units meet maturity criteria**, with the majority falling into lower readiness categories
- Mature CRUs are **highly concentrated in major urban centers**, particularly in and around Jakarta, indicating regional infrastructure disparities

Note: CRUs=Clinical Research Units; Cat=category
Source: IASMED; L.E.K. research and analysis

Stringent biosample export restrictions and material transfer process in Indonesia create high operational friction, significantly hindering clinical development and cross-border research execution

Indonesia MTA and biosample export restriction

Biosample export restrictions and mandatory material transfer agreement
(Initial policy: 2009/Legal codification: 2023)

- Indonesia's Law No.17 **prohibits biosample exports** unless local testing is unavailable, foreign testing is essential or quality assurance is required
- Government Regulation No. 28 **mandates MoH approval** and a **formal MTA** for all sample exports
- The MTA requirement has been in place since MoH Decree No. 657, and applies to both physical and digital transfers of biospecimens

Clinical sample export process

Dimension	Indonesia	China	United States
Export permission framework	**Permitted** export under strict exemptions	Generally permitted; export of human genetic materials subject to registration	Fully permitted; no national-level restrictions
Central government involvement	Mandatory MoH approval for **all** biosample transfers	Required **only for sensitive categories** (e.g., HGR)	**Not required**; governed by institutional review
MTA	Legally required and subject to MoH approval and processing	Required for regulated samples; Otherwise, contractual best practice	Common contractual instrument; not regulated by law
Operational impact on trials	High friction: multitier approval, **6-10 week** lead time	Moderate friction: compliance manageable, **1-2 week** cycle	Low friction: streamlined, decentralized, typically **<1 week**

Compared to China and the U.S., Indonesia's MTA and biosample export restriction policies make it more difficult to participate in global clinical trials, due to **higher regulatory friction** and **longer approval timelines**

Highly regulated | Moderately regulated | Lowly regulated

Note: MTA=material transfer agreement; MoH=Ministry of Health; HGR=human genetic resources
Source: Indonesia MoH, China NMPA, U.S. NIH, FDA, L.E.K. research and analysis

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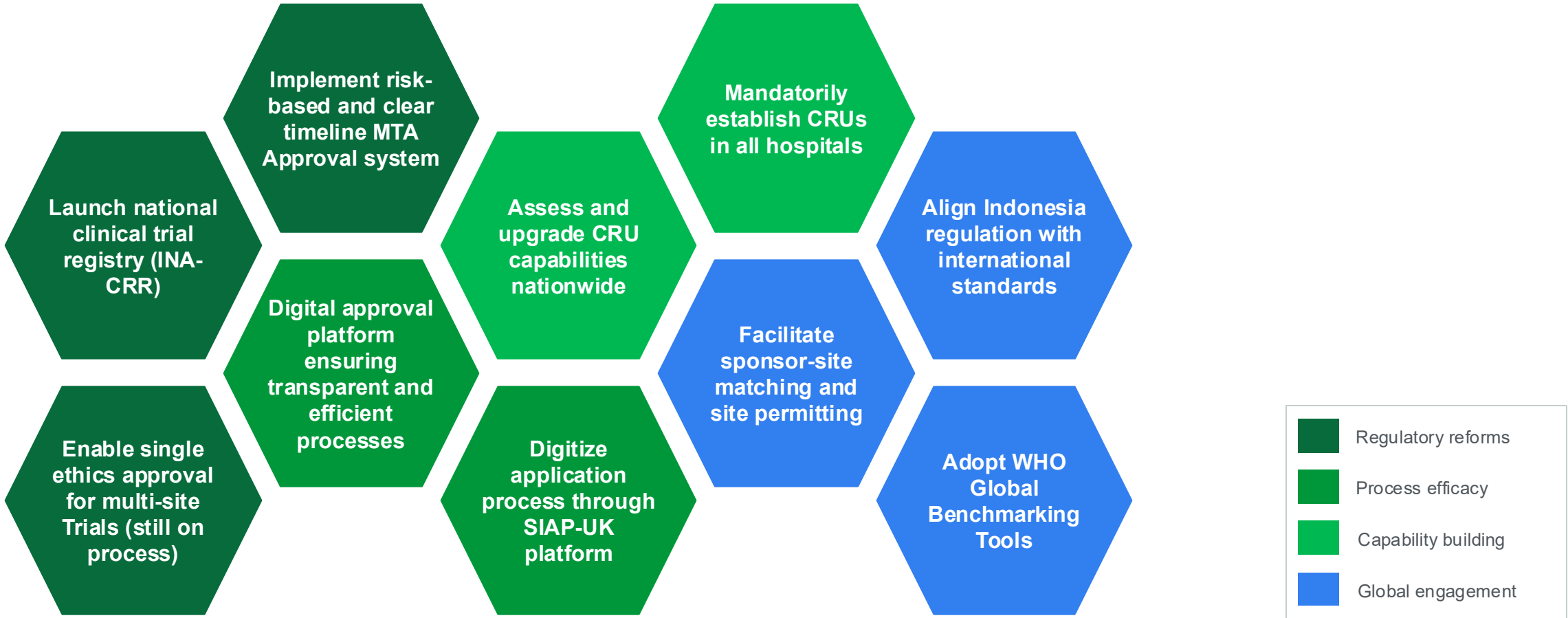
However, targeted reforms driven by Indonesia's MoH are reshaping the clinical research landscape; the initiatives focus on regulatory reforms, process efficiency, capability building and global engagement

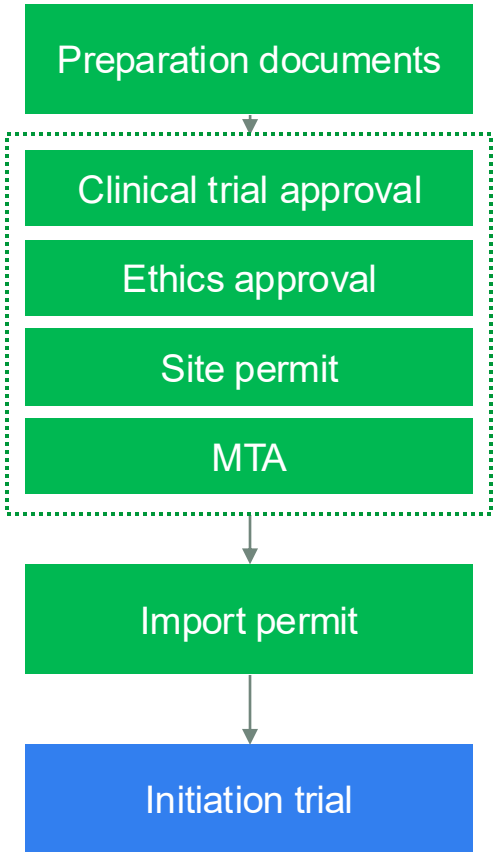
Key initiatives to develop Indonesian clinical trials



Source: IASMED, L.E.K. research and analysis

To overcome operational friction, INA-CRC was introduced to streamline fragmented approvals, accelerating trial start-up through coordinated and risk-tiered review pathways

Clinical trial application process

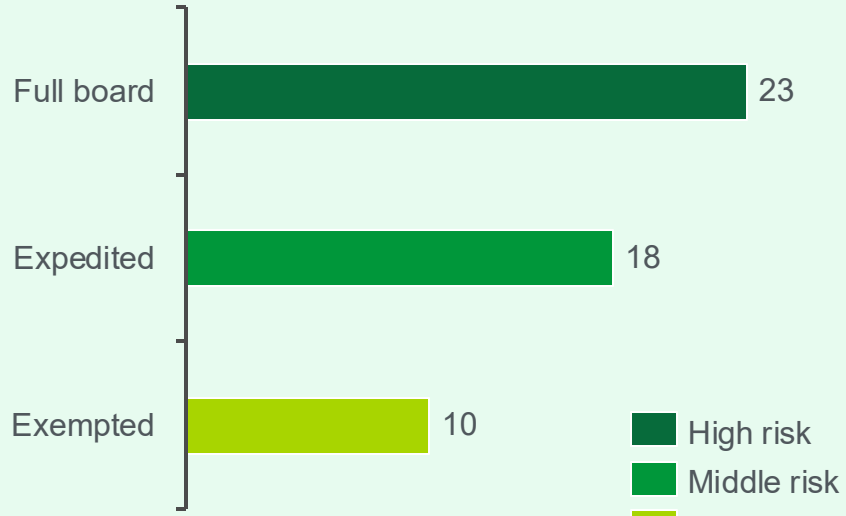


Original duration	Reform action	New duration
2-3 months	• **Standardize** document preparation by unified templates and guidance	2 months
4-5 months	• Process ethics, site, MTA and trial approvals under INA-CRC **parallelly** • **Shorten MTA** turnaround	1-3 months
3-4 months	• **Centralize approval processes** under INA-CRC	1-2 months

INA-CRC was appointed as the end-to-end coordinator for clinical trials, reducing the start-up timeline **from 9-12 months to 4-7 months**

INA-CRC replaced the one-size-fits-all MTA review process with a risk-based, tiered system, reducing approval timelines **from 6-10 weeks to 2-5 weeks**

MTA application processing times median (2025)
Working days



*Data were collected *as of August 2025*

Note: INA-CRC=Indonesia Clinical Research Center; MTA=material transfer agreement
Source: IASMED; L.E.K. research and analysis

INA-CRC is also focusing on setting up and professionalizing CRUs and harmonizing operating standards across hospitals

INA-CRC's key initiatives for CRU capacity development in hospitals

Build CRU workforce capability

- **Run national training** related to clinical trials, including GCP, protocol development, research management, etc.
- Require **GCP certification** for principal investigators to lead clinical trials

Establish research career pathways

- **Define roles, responsibilities and competencies** inside CRU (e.g., management/administration vs. research implementers)
- **Create a career ladder** for hospital-based research staff and link progression to qualifications and experience

Standardize CRU operating quality

- Establish function-specific **policies and SOPs** in CRU to enhance interdepartments coordination
- Embed **quality standards into hospital routines** to ensure consistent outputs across all hospitals
- **Accelerate CRU capacity-building** through mentorship

Source: Indonesia MoH; IASMED; L.E.K. interviews, research and analysis

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Beyond policy reform, local CROs and associations are actively enabling clinical development in Indonesia by strengthening regulatory support, trial operations and research infrastructure partnerships

Case study: Prodia

A leading CRO and SMO, leveraging its **robust local network and research resources** to support global trial

Site network and CRU building	• Established a dedicated SMO division to scale its trial site footprint • Collaborates with major hospitals to co-develop CRUs
Talent development	• Offers structured GCP training programs to research staff across Indonesia • Built local research capacity aligned with global trial requirements
Local trial feasibility	• Leverages its SMO network to help overseas sponsors identify suitable trial sites • Provides tailored support on local regulatory guidance, site feasibility assessment and KOL engagement

Prodia's partnership

Prodia collaborated with INA-CRC to help establish CRUs in multiple Indonesian hospitals, and it provided GCP training and site management support via IASMED

Case study: Equilab International

A leading CRO offering **one-stop localized clinical trial services** for global sponsors

Regulatory localization	• Serves as the local regulatory lead, navigating BPOM submissions • Expedites trial approvals through close alignment with Indonesian authorities
Import and sample transfers	• Provides end-to-end support across import licensing, MTA coordination and ethics approvals • Streamlines sample and drug logistics
Domestic trial execution	• Operates a fully equipped central laboratory and clinical trial facility in Indonesia • Supports overseas sponsors in local trial implementation

Equilab's partnership

BetterLife Pharma collaborated with Equilab in regulatory and trial services of Phase II clinical trial of AP-003, which was relocated from Australia to Indonesia

Case study: IASMED

An independent association to support the development and implementation of high-quality clinical trials in Indonesia

GCP/CUKB trainings	• Conducted a series of training programs for newly established CRUs and a series of courses and workshops of Applied GCP for hospitals and academic institutions, in cooperation with Indonesia MoH and INA-CRC
Site capacity building	• Improves the clinical trial ecosystem by increasing the number of qualified sites
Scientific seminar	• Hosts scientific seminars about clinical research to advance clinical trials in Indonesia

IASMED's partnership

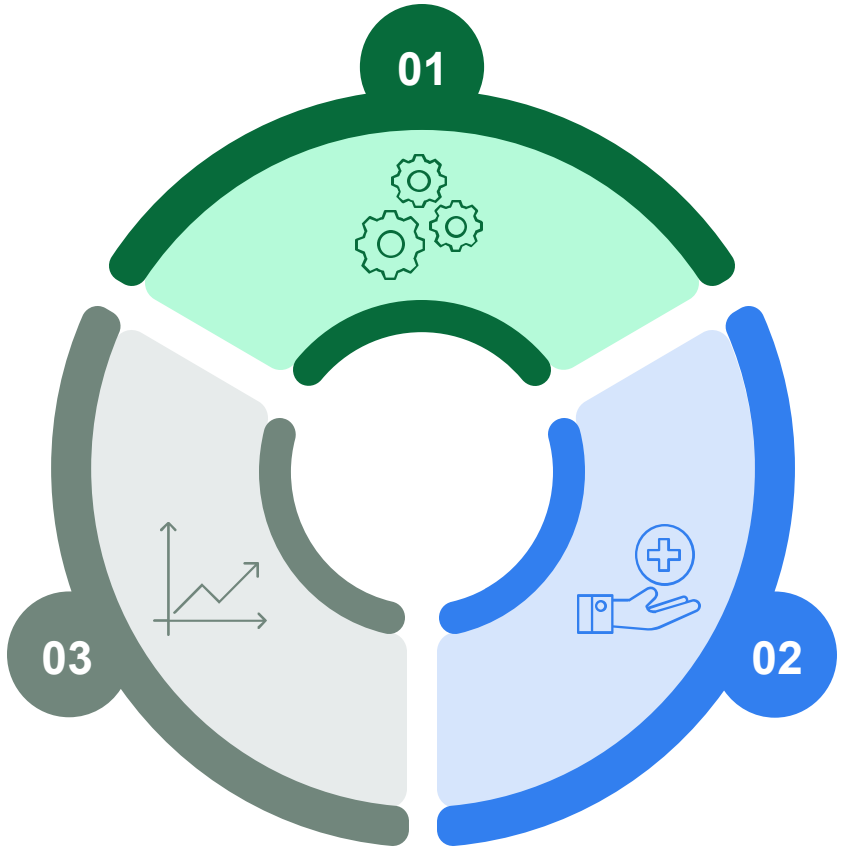
Collaborates with the BPOM and the MoH to build a medicine and vaccine development ecosystem through regulatory reform and alignment with international standards

Note: CROs=contract research organizations; IASMED=The Indonesian Association for the Study of Medicinals;SMO=site management organization; GCP=Good Clinical Practice; CUKB=Cara Uji Klinik yang baik; KOL=key opinion leader; INA-CRC=Indonesia Clinical Research Center; BPOM=Indonesian Food and Drug Agency (Badan Pengawas Obat dan Makanan); MTA=material transfer agreement; MoH=Ministry of Health
Source: Official site and public release; L.E.K. research and analysis

By 2030, trials initiated in Indonesia are expected to reach ~300 per year, with the market valued at $1 billion to $1.5 billion, giving patients earlier access to new therapies and boosting investment

Clinical trial market outlook

- **Approximately 300 trials** initiated in Indonesia per year by 2030:
  - INA-CRC aims to certify **~100 researchers** with GCP and **~3 CRUs** with GCP per year over the next five years
  - A national single-review system for multicenter studies is expected to be built in three months
- Indonesia's clinical trial market could **reach $1 billion to $1.5 billion** by 2030, driven by the increase in trials initiated



Economic benefits

- Increased trial activities will **attract investment** from sponsors and CROs and **create skilled jobs**
- Strengthen hospital research capacity and foster deeper global partnerships, **generating long-term productivity gains**

Patient benefits

- GCP-trained teams and standardized CRU quality processes **strengthen protections for trial participants**
- Expanded clinical trials will give Indonesian patients **earlier access to innovative therapies** and raise the quality of care

Source: L.E.K. interviews, research and analysis

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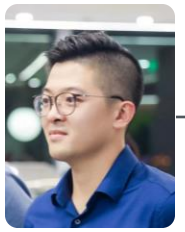

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