DRUG REGULATORY AUTHORITY OF PAKISTAN

Ministry of National Health Services,
Regulations and Coordination

Pakistan Clinical Research Industry

Investment Opportunity Pitchbook

Gateway to South Asia, China Collaboration, and Global Clinical Development

- Large Patient Population
- Growing Clinical Research Market
- China–Pakistan Collaboration
- Evolving Regulatory Excellence
- Gateway to South Asia & Beyond

B2B INVESTMENT FORUM

Pakistan – China Partnership for Health Innovation and Growth

PREPARED FOR

Drug Regulatory Authority of Pakistan (DRAP)

COLLABORATE. INNOVATE. IMPACT.

Advancing Global Health Together

IMPORTANT NOTICE

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Please read before reviewing the material that follows

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NAVIGATION

Contents

Five sections, from the country opportunity to actionable next steps

Section structure reflects the flow from country opportunity to actionable next steps

Executive summary

Three themes define the investment case for Pakistan's clinical research sector

Attractive investment destination

- A market of more than 250 million people with a large, treatment-naive patient base.
- Disease burden aligns closely with the therapeutic priorities of international sponsors.
- A regulatory system aligned with WHO and ICH standards and steadily digitalizing.

Clinical research growth opportunity

- Competitive clinical development costs, enabling sponsors to achieve 30–50% operational savings compared with many traditional research markets.
- 70+ international studies successfully conducted across multiple therapeutic areas.
- Pakistan participates today at modest scale; early-phase capacity is the principal constraint to close.

China-Pakistan collaboration platform

- China holds an estimated one-fifth to one-third of the global development pipeline and approved roughly 230 innovative drugs over 2021 to 2025.
- Nineteen studies sponsored by twelve Chinese companies have already been delivered in Pakistan.
- Senior government endorsement supports technology transfer and local production of advanced medicines.

Source: Clinical Research Industry Landscape (DRAP, 2026); Clinical Research Sector Response to the Chinese Mission (DRAP, 2026)

Why Pakistan

Ten structural advantages, consolidated as the single reference for the country case

JCI / ISO accreditation present

Well-established, internationally accredited centers

Treatment-naive pool

Low prior exposure improves recruitment and signal detection

Young workforce

Median age in the low 20s; expanding healthcare labor pool

Cost advantage

Lower per-patient and site costs improve trial economics for large pivotal programs

International standards

Practice aligned with global GCP and quality norms

ICH / WHO alignment

CTD adopted; requirements mapped to ICH and WHO

Strategic location

At the junction of South, Central, and West Asia

CPEC connectivity

Economic corridor links the two markets directly

Global CRO presence

IQVIA and TigerMed already operate in or around the market.

Disease-burden alignment

Hepatitis, infectious-disease and metabolic burden maps onto China's strongest pipeline categories

Population and demographic descriptors are structural context. Source: Clinical Research Industry Landscape (DRAP, 2026)

Pakistan clinical trial ecosystem

The institutions that host and support international studies

DRAP

National regulator; Bio-Study Rules 2017 under the DRAP Act 2012

Ethics / NBC

Ethics review via the Clinical Studies Committee and bioethics oversight

Major hospitals

Tertiary-care and academic trial sites across the country

33 Registered CROs

Thirty-three DRAP-registered Clinical Research Organizations

Laboratories

Bioanalytical and central-lab capacity

Logistics

Sample transport, import and cold-chain handling

Insurance

Trial indemnity and subject coverage

Universities

Investigator training and academic research

CRO count per DRAP registration. Source: Clinical Research Industry Landscape (DRAP, 2026)

DRAP-licensed contract research organizations

Pakistan's registered CRO base spans international names, academic institutions, and a growing local sector

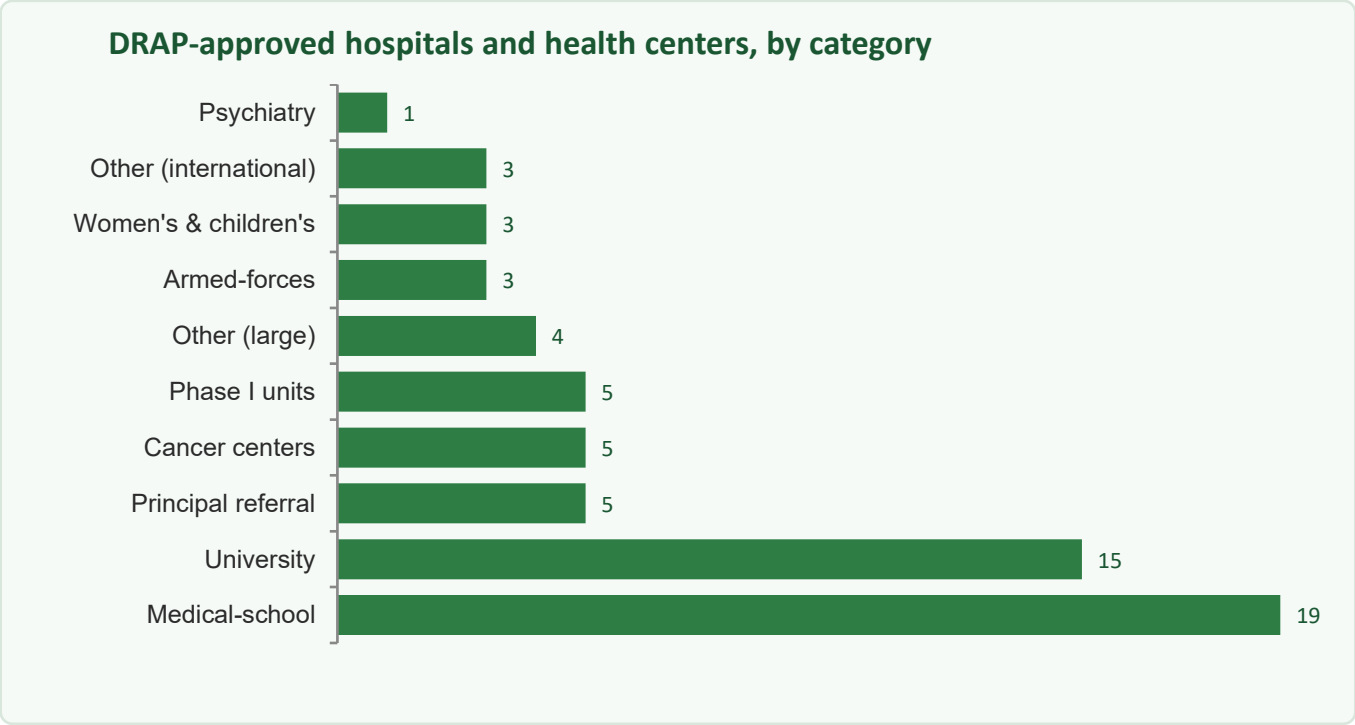
29
Licensed CROs on the DRAP register (Jun 2025)

3
International CRO names licensed locally

7
Cities with a licensed CRO presence

DRAP-approved clinical trial site network

53 approved hospitals and centers across 11 categories



Site capabilities and expertise

Early-phase ready
Dedicated Phase I units; first-in-human and PK sampling experience

Fast ethics review
Monthly ethics review; committee turnaround typically within a few weeks

Globally recognized KOLs
Foreign-trained consultants; members of international societies

Audit-grade quality
Sites prepared for international sponsor audits and inspections

Valid-license CROs shown; register also lists expired entries. Source: DRAP published register of approved CROs, 26 Jun 2025

Market Size and Growth Opportunity

Opportunity Snapshot

Parameter	Value
Opportunity Type	Clinical Research & Clinical Trial Delivery Hub
Target Investors	Pharmaceutical Companies, CROs, Biotech Firms, Healthcare Investors
Market Focus	Phase II–IV Clinical Trials, Vaccines, Oncology, Hepatology, Metabolic Diseases
Population Base	250+ Million
Existing Track Record	70+ International Studies
Chinese Sponsors Engaged	12 Sponsors / 19 Studies
Registered CROs	33
Approved Trial Sites	53
Strategic Objective	Position Pakistan as South Asia's preferred clinical research destination

Structural advantages

- **A. Large treatment-naïve patient pool**
- **B. 30–50% lower trial execution costs**
- **C. Fast patient recruitment**
- **D. Government-backed regulatory modernization**
- **E. China-Pakistan collaboration platform**
- **F. Gateway to South Asia, Central Asia and Middle East**

Valid-license CROs shown; register also lists expired entries. Source: DRAP published register of approved CROs, 26 Jun 2025

Clinical Research Investment Opportunity

Market Size and Growth

Global Market

Metric	Value
Global Clinical Research Market (2025)	~USD 85 Billion
Expected Market (2030)	~USD 130 Billion
CAGR	~9%

China's Clinical Development Scale

Metric	Value
Global Pipeline Share	20–33%
Innovative Drugs Approved (2021-25)	~230
Clinical Trials Registered (2024)	~4,900

Pakistan's Untapped Opportunity

Current Share of Global Clinical Trial Market: **<0.5%**

Target Share by 2030: **1–2%**

Potential Annual Clinical Research Revenue: **USD 300–500 Million**

What is driving demand

- Rising Chinese innovation pipeline
- Increasing pressure to diversify trial geographies
- Cost containment requirements
- Strong disease burden alignment

Valid-license CROs shown; register also lists expired entries. Source: DRAP published register of approved CROs, 26 Jun 2025

Investor Facilitation Ecosystem; Economic Case for Clinical Research Investment

Key Stakeholders Supporting investment

Illustrative Annual Economic Impact

Assuming:

- 50 additional multinational trials annually
- Average spend USD 2–5 Million per trial

USD 100–250 Million

Potential annual inflow

5,000–10,000

Potential direct and indirect jobs

Long-Term Outcome

Clinical research becomes a healthcare export sector.

Economic impact channels

Channel	Impact
Foreign Direct Investment	Sponsor spending
Hospital Revenue	Trial procedures
CRO Revenue	Trial management
Laboratory Services	Testing & diagnostics
Employment	Research workforce
Investigator Development	Human capital
Technology Transfer	Capability enhancement
Export Services	International trial delivery

Key stakeholders

- **SIFC** Investor facilitation
- **BOI** Investment promotion
- **Ministry of NHSR&C** Policy support
- **DRAP** Regulatory approvals & oversight
- **Universities & Hospitals** Trial delivery
- **CRO Network** Operational execution

Valid-license CROs shown; register also lists expired entries. Source: DRAP published register of approved CROs, 26 Jun 2025

Regulatory and Investment Incentives

Existing Advantages

- ✓ WHO-aligned regulatory framework
- ✓ ICH-compliant dossier standards
- ✓ CTD adopted
- ✓ Dedicated Clinical Trial Rules
- ✓ Digital transformation underway

Comparative Positioning

Initiative	Impact
Priority Review Pathway	Faster approvals
Reliance Mechanism	Reduced duplication
Single Window Facilitation	Simplified engagement
Electronic Submission	Increased transparency
Dedicated Investor Support Desk	Reduced onboarding time

Proposed Competitive Measures

Factor	Pakistan	Regional Competitors
Trial Cost	**Low**	Medium-High
Recruitment Speed	**High**	Medium
Treatment-Naïve Population	**High**	Medium
Regulatory Modernization	**Improving**	Mature

Risk Assessment

Risk	Assessment	Mitigation
Limited Early Phase Capacity	Medium	Develop Phase I Units
Investigator Concentration	Medium	Expand training programs
Regulatory Processing Time	Medium	Priority review pathway
Competition from Regional Markets	Medium	Cost and recruitment advantage
Data Quality Concerns	Low	GCP compliance and audits
Sponsor Awareness	Medium	International promotion campaigns

Strategic Message

High recruitment efficiency at substantially lower operational cost.

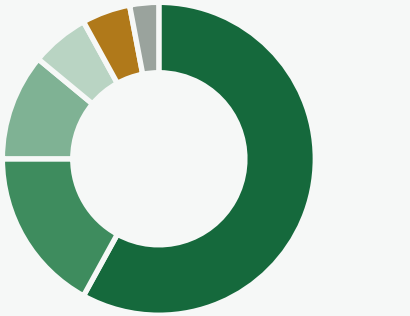
Pakistan presents a lower-cost, high-recruitment, high-growth clinical research destination with manageable risks and strong government support.

Valid-license CROs shown; register also lists expired entries. Source: DRAP published register of approved CROs, 26 Jun 2025

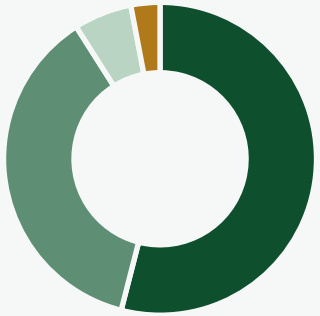
Pakistan's broader trial landscape

Ten-year IQVIA view of 330 studies: industry-funded, drug-led, and quality-assured

Intervention type



Funder type



Why sponsors choose Pakistan

Treatment-naive depth

Among the highest-recruiting countries for many indications

Enrollment ahead of plan

Consistently hits targets ahead of schedule, often exceeding them

Audit-grade data

Average of just 1% major findings in third-party audits

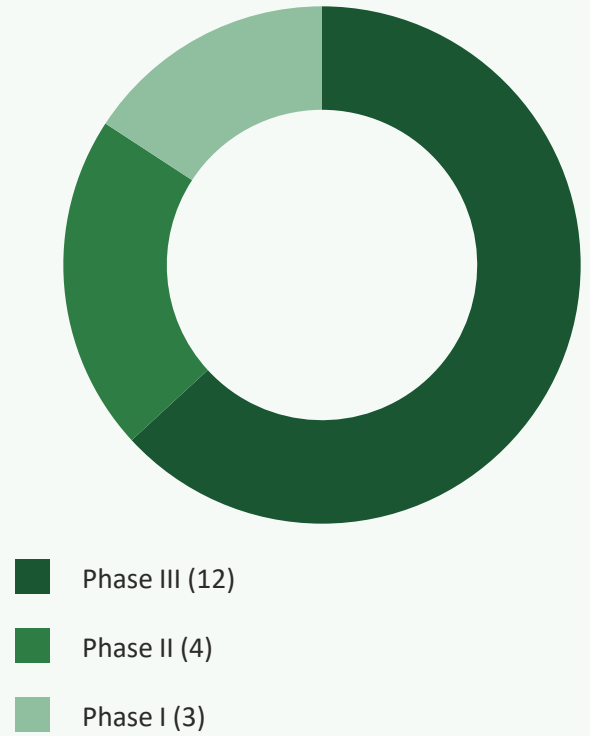
Read-across for Chinese sponsors. Over the past decade oncology, hepatitis and cardiovascular disease have drawn international sponsors to Pakistan, the same categories where Chinese pipelines are deepest.

Source: IQVIA, Southeast Asia and Pakistan Overview: The Emerging Hub for Clinical Trial Scale-Up (2024-25).

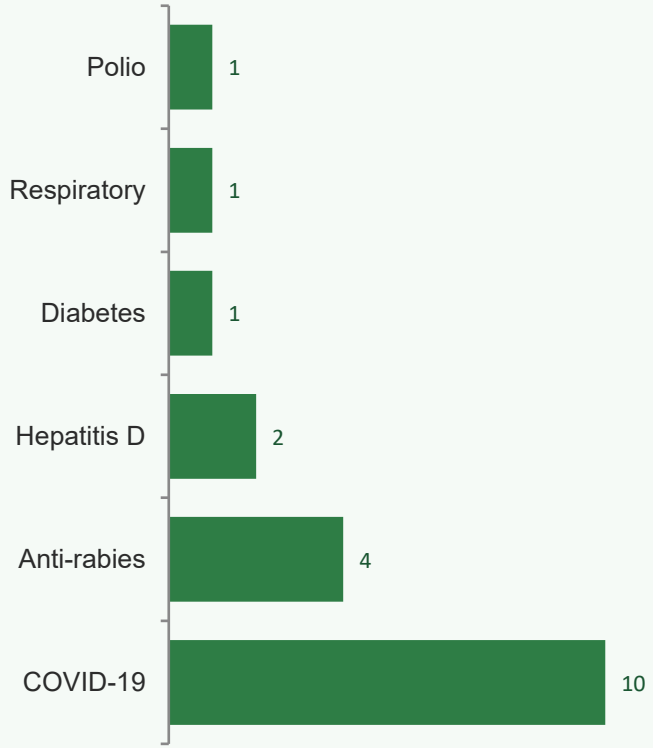
Pakistan's clinical trial track record

Chinese-sponsored activity is late-phase and vaccine-led, a strong baseline to build on

Phase distribution (n=19)



Studies by therapeutic area



Trial management model

Sponsor-direct management with local CROs

9 studies 47%

Leading Multinational CRO managed

5 studies 26%

Local CRO managed

5 studies 26%

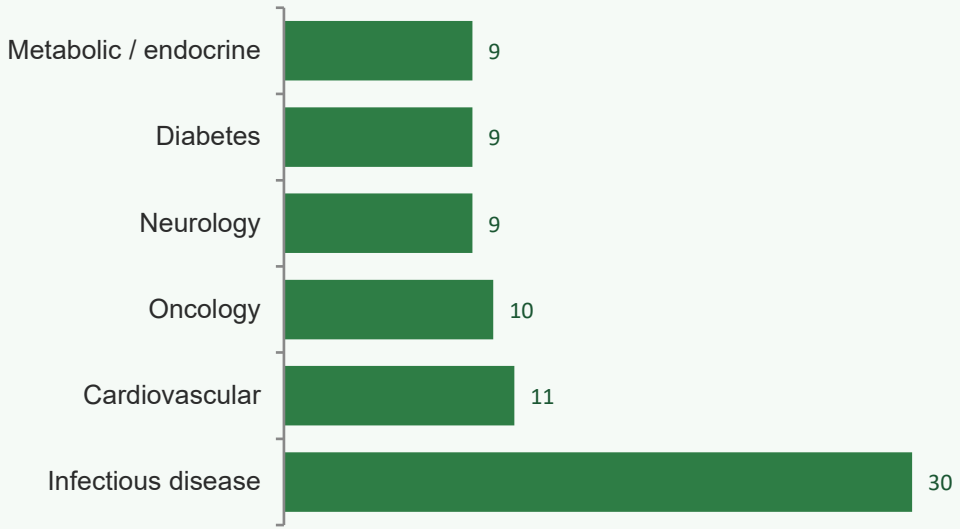
Almost half of studies ran under direct sponsor management, indicating confidence in direct operations and a clear opening for expanded CRO partnership.

Phase III represents about 63% of activity; CRO arrangement is indicative. Source: project dataset; DRAP (2026)

Disease burden aligns with sponsor demand

Pakistan's epidemiology maps onto the deepest pipeline categories

Leading therapeutic areas in Pakistani studies



Top cancers by share of total cases: breast (21%), lip/oral (13%), colorectal, liver and lung each in single digits.

Selected high-value indications, burden in Pakistan

Indication	Prevalence / burden in Pakistan
Viral hepatitis (HBV/HDV)	~16.6% of HBV patients carry Delta; an estimated 1M+ affected
MASH / NASH	~10% to 20% of the general population, 40% to 60% of those with NAFLD
Asthma	10% to 18% in children, 6% to 12% in adults
Diabetes	One of the highest national prevalence rates globally
Oncology	Rising incidence; breast cancer the leading single type

Viral hepatitis combines a large, poorly-addressed burden with a near-absence of approved therapy, the clearest point of alignment with China's pipeline.

Burden figures are approximate; ranges per published epidemiology. Source: PubMed (2005, 2018); Polaris Observatory (2024); WHO EMHJ (2024)

Clinical research delivery model

Capabilities are organized by category, not by individual organization

Global CROs

End-to-end trial delivery, monitoring and data analysis; bridge sponsors to local sites

Full-service, multi-country

Regional CROs

Site management, regulatory and operational support across South and Central Asia

Operational depth

Local CROs

In-country monitoring, regulatory liaison and direct site management

Market knowledge

Academic research organizations

Investigator-initiated research, protocol development and training exchange

Scientific depth

Site management organizations

Coordinated multi-site delivery, recruitment and quality oversight

Recruitment scale

Thirty-three CROs are DRAP-registered. The categories above describe the capability mix available to international sponsors without reference to individual firms.

Categories describe ecosystem capability. Source: Clinical Research Industry Landscape (DRAP, 2026)

Appetite and readiness to collaborate

Readiness is evidenced by delivered activity, government commitment, and an established regulatory base

19

studies already delivered

by twelve sponsors, 63% at Phase III

2017

Bio-Study Rules in force

under the DRAP Act 2012; CTD adopted

Jan 2026

ministerial endorsement

Federal Minister for Health convened DRAP and partners

Ready now

- Pivotal Phase III vaccine and infectious-disease delivery
- Tertiary-care and academic hospitals for Phase II and III work
- Registered CROs already supporting international sponsors
- WHO and ICH-aligned regulatory framework and licensing

Gaps to close with collaboration

- Investigator pool concentrated in a few centers
- Limited early-phase (Phase I) and complex-trial infrastructure
- Bioequivalence and bioavailability capacity still maturing

Gap assessment reflects strategic judgment. Source: Clinical Research Sector Response to the Chinese Mission (DRAP, 2026)

Counterpart-matching structure

Each Pakistani need mapped to a counterpart type and an initial instrument

Pakistani need	Chinese counterpart	Initial instrument
Late-phase trial delivery	Vaccine and infectious-disease sponsors plus a global CRO	Site feasibility and master service agreement
Local production of biologics	Innovative sponsors, including hepatology	Technology-transfer and licensing memorandum
BE/BA capacity	Bioequivalence centers and bioanalytical labs	Joint center development and method transfer
Investigator depth	Academic and university hospitals	Training and research exchange agreement

Instruments are proposed starting points for partner matching, not commitments.

Source: Clinical Research Sector Response to the Chinese Mission (DRAP, 2026), Section 5.1

Priority therapeutic areas

Five areas where Pakistan's burden aligns with China's pipeline strength, in order of fit

Therapeutic area	Pakistan rationale	Alignment with China
Viral hepatitis (HBV & Delta)	Over one million Pakistanis live with Delta; ~16.6% of HBV patients carry HDV	Deep Chinese hepatology pipeline
Infectious disease & vaccines	Established delivery record across COVID-19, rabies and polio	Strong vaccine sponsors and prior collaboration
Oncology	Rising cancer incidence and limited access to innovative therapy	China's single largest trial and pipeline category
Metabolic & endocrine disease	Very large diabetic population and high cardiometabolic burden	Expanding Chinese metabolic and cardiovascular portfolios
Rare & immunological disease	Largely unmet need with little local trial activity	Fast-growing biologics, cell and gene-therapy pipeline

Clearest point of alignment: viral hepatitis combines a large, poorly-addressed disease burden with a near-absence of approved therapy.

Burden figures approximate. Source: PubMed; Polaris Observatory (2024); WHO EMHJ (2024); DRAP (2026)

Regulatory facilitation and incentives

What is already in force, and the near-term reforms proposed to lift competitiveness

Current | already in force

Defined review procedure

First-in, first-out basis; initial scrutiny within 30 working days and shortcoming letters within 5 working days, under published SOPs.

International alignment

DRAP requirements aligned with WHO and ICH standards, reducing the adaptation burden for sponsors already operating to those norms.

Regulatory evolution

WHO and ICH alignment, CTD adoption, and ongoing digitalization.

Regulatory dimension comparison

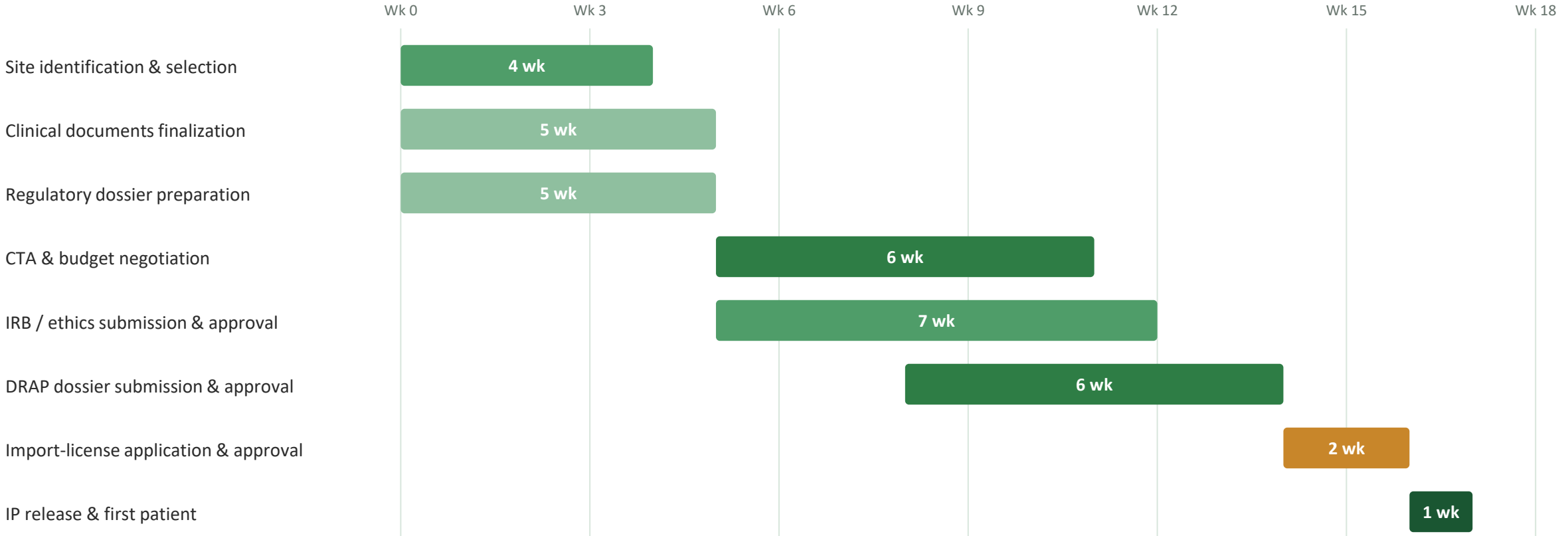
Dimension	China	US	EU	Pakistan
Standard review	60 wd	30 d	~60 d	**30 wd initial**
Expedited track	30 d	Fast Track	PRIME	**Proposed**
CTD adoption	Yes	Yes	Yes	**Yes**
Reliance pathway	Established	Yes	Yes	**Proposed**
Digitalization	Advanced	Advanced	Advanced	**Improving**

wd = working days; d = calendar days. Pakistan figure is the published initial-scrutiny window.

Proposed measures are recommendations requiring endorsement, not existing entitlements. Source: DRAP (2026), Section 4.2; published SOPs

Study start-up timeline

From business initiation to first patient in roughly 18 weeks, with parallel DRAP and ethics review



~18 weeks
Business initiation to site initiation

Parallel review
DRAP and ethics submitted in parallel

~9 weeks
Ethics committee review window

3 to 5 days
IP release once licensed

Illustrative start-up sequence; actual timelines vary by study. Source: DRAP Guidelines (2024); IQVIA Overview (2024-25)

China-Pakistan clinical research collaboration

A portfolio of delivered programs across multiple therapeutic areas

2020

Vaccines

COVID-19 pivotal Phase III programs placed at Pakistani sites

2021

Infectious disease

Anti-rabies and respiratory programs broaden the relationship

2023

Viral hepatitis

Hepatology programs enter the pipeline as burden alignment is recognized

2024

Metabolic disease

Diabetes and cardiometabolic studies extend therapeutic scope

2026

Biologics & beyond

Government endorses technology transfer and local production of advanced medicines

Vaccines | **Infectious disease** | **Metabolic disease** | **Biologics** | **Oncology** | **Emerging areas**

Timeline and portfolio are illustrative of the collaboration's evolution. Source: project dataset; DRAP (2026)

Economic impact of clinical trials

Eight channels through which trial investment flows into the economy

Hospital revenue

Per-patient and procedure income to trial sites

Employment

Coordinators, monitors, data and lab roles

Investigator development

GCP training and research-career pathways

Laboratory revenue

Central-lab, bioanalytical and imaging work

Tax revenue

Corporate, payroll and service taxation

Logistics industry

Sample transport, import and cold-chain

Insurance industry

Trial indemnity and subject coverage

Foreign direct investment

Sponsor and CRO capital into local capacity

Qualitative framework; channel-level values are program-specific. Source: Clinical Research Industry Landscape (DRAP, 2026)

Investment opportunities

Eight entry points across the clinical research value chain

CRO expansion

Scale monitoring, data and regulatory capacity in-country

Site management orgs

Professionalize and network trial sites

Central laboratories

Bioanalytical, sample-management and imaging hubs

Biostatistics centers

Statistical analysis and study-design capability

Data management centers

EDC, data-management and pharmacovigilance services

Phase I units

Early-phase and complex-trial infrastructure

Technology transfer

Inbound know-how for biologics and innovative therapy

Local manufacturing

Fill-finish and biologics production capacity

Source: Clinical Research Industry Landscape (DRAP, 2026); Clinical Research Sector Response (DRAP, 2026)

SWOT analysis

Pakistan as a destination for international clinical research

Strengths

- Track record of nineteen Chinese-sponsored studies
- Large, treatment-naive patient populations
- WHO and ICH-aligned framework; CTD adopted
- Senior government endorsement of collaboration

Weaknesses

- Investigator base concentrated in a few centers
- Limited early-phase and BE/BA infrastructure
- Regulatory timelines continue to evolve through ongoing digitalization and process optimization initiatives
- Fragmented site data for partner matching

Opportunities

- Priority-review and reliance pathways to shorten review
- Technology transfer and local manufacturing
- Multi-area collaboration portfolio to scale
- Regional health-sector investment momentum

Threats

- Regional competition for the same programs
- Reputational risk if quality or oversight slips
- Currency and operating-cost volatility
- Loss of momentum if engagement is deferred

Strategic assessment. Source: Clinical Research Sector Response to the Chinese Mission (DRAP, 2026), Section 5.2

Strategic roadmap 2026 to 2030

Sequenced so early wins on approval transparency build sponsor confidence

Short term

0 to 12 months

Regulatory

Publish approval-timeline charter; retain sector in B2B framework

Partnerships

Convene working groups; stand up coordination desk

Infrastructure

Compile verified national site, investigator and ethics register

Training

GCP refresher and certification at priority tertiary sites

Medium term

1 to 3 years

Regulatory

Pilot expedited channel and recognized reliance review

Partnerships

Sign CRO and academic MoUs; pilot reliance pathways

China investment

Reliance and data-acceptance MoU; partner matching at scale

Digitalization

Single-window facilitation desk with status tracking

Long term

3 to 5 years

Capability

National early-phase unit network; upgraded BE/BA centers

Localization

Local biologics manufacturing and technology-transfer uptake

Standing

WHO maturity-level benchmarking; regional research hub

Expansion

Scale to oncology and metabolic-disease programs

Phased proposal. Source: Clinical Research Sector Response to the Chinese Mission (DRAP, 2026), Section 5.3

The investment case

Six reasons to act now

First-mover advantage

Early partners shape relationships and the regulatory dialogue before the market scales

Large untapped market

250M+ population and high disease burden, with trial participation still at modest scale

China partnership platform

Established sponsor relationships, an active pipeline, and senior political backing

Government support

Ministerial endorsement plus proposed priority-review, reliance and single-window measures

Return potential

Cost-efficient delivery in high-prevalence indications supports attractive program economics

Regional leadership

Potential to anchor a South-Asia clinical research and innovation hub

Source: Clinical Research Industry Landscape (DRAP, 2026); Clinical Research Sector Response (DRAP, 2026)

Strategic recommendations

Actionable next steps by stakeholder group

Chinese pharma

Extend pivotal Phase III programs to Pakistani sites and pursue technology-transfer partnerships in priority areas

CROs

Expand in-country monitoring, data and regulatory capacity; build SMO and central-lab partnerships

Biotech firms

Target high-burden indications where Pakistani burden and Chinese pipelines align

Hospitals

Invest in GCP-trained investigators, ethics throughput and early-phase capability to qualify for pivotal work

Government

Adopt the priority-review track, reliance pathways and single-window desk; publish a verified site directory

Investors

Back CRO, SMO, central-lab and BE/BA capacity, and technology-transfer ventures with sponsor anchor demand

Source: Clinical Research Industry Landscape (DRAP, 2026); Clinical Research Sector Response (DRAP, 2026)

APPENDIX A

Detailed data tables

Supporting datasets referenced throughout the pitchbook

A.1 China clinical trial registration

Year	Registered trials	Class 1 share
2021	3,358	-
2022	3,410	-
2023	4,300	-
2024	4,900	68.3%
2025e	5,050	-

A.2 Chinese-sponsored studies in Pakistan

Metric	Value
Total studies	19
Sponsor companies	12
Phase III share	~63%
Therapeutic areas	COVID-19, rabies, hepatitis D, others

A.3 China innovative-drug output

Metric	Value	Period
Innovative drugs approved	~230	2021 to 2025
Domestic share of approvals	80%+	2021 to 2025
IND applications accepted	3,073	2024
Global pipeline share	20% to 33%	2025

Methodology: Pakistan trial counts from the project dataset; China-level figures from official CDE reporting and independent trackers, with divergent values reported rather than blended. Burden figures from peer-reviewed and WHO-affiliated literature. Estimates and projections are labelled as such.

Inclusion criteria vary between years; figures are approximate. Source: project dataset; CDE 2024 Annual Report

Resources and regulatory links

Reference resources for prospective investors and partners

Drug Regulatory Authority of Pakistan

Official clinical trial portal and oversight framework

DRAP Clinical Trials Portal

National Bioethics Committee

Ethics oversight and committee registration

NBC Official Website

Registered clinical trial sites

DRAP-verified directory of approved sites

Approved Site Directory

Registered hospitals

Tertiary-care and academic trial centers

DRAP e-Services Portal

Registered CROs

Thirty-three DRAP-registered organizations

CRO Register

Government regulatory resources

Guidelines, application forms and SOPs

Regulatory Guidelines

Links are reference labels to official DRAP and government resources. Source: DRAP (2026)