Asymchem Clinical (Clin-nov)

Led by Science
Powered by Technology



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Asymchem Clinical (Clin-nov)

Asymchem
Clinical (Clin-nov)

About Us

We are a global, full service CRO providing customized regulatory and clinical services from early development through post marketing. As a member of AICROs, a global consortium of CROs, we have capacity to provide clinical research services on a global scale.

Asymchem Clinical (Clin-nov) is a wholly-owned subsidiary of Asymchem Group. Together with Asymchem, a world-leading CDMO with over 20 years of experience, we offer End-to-End Service from discovery through commercialization.

Mission

To empower global drug development and advance human health.

Vision

To become a leading CRO in the industry.



Standardized Quality System



10+ Years

500+ Collaborating Trial Sites

500+ Professionals

1200+ Projects

End-to-End Service

From discovery through commercialization



Service Scope

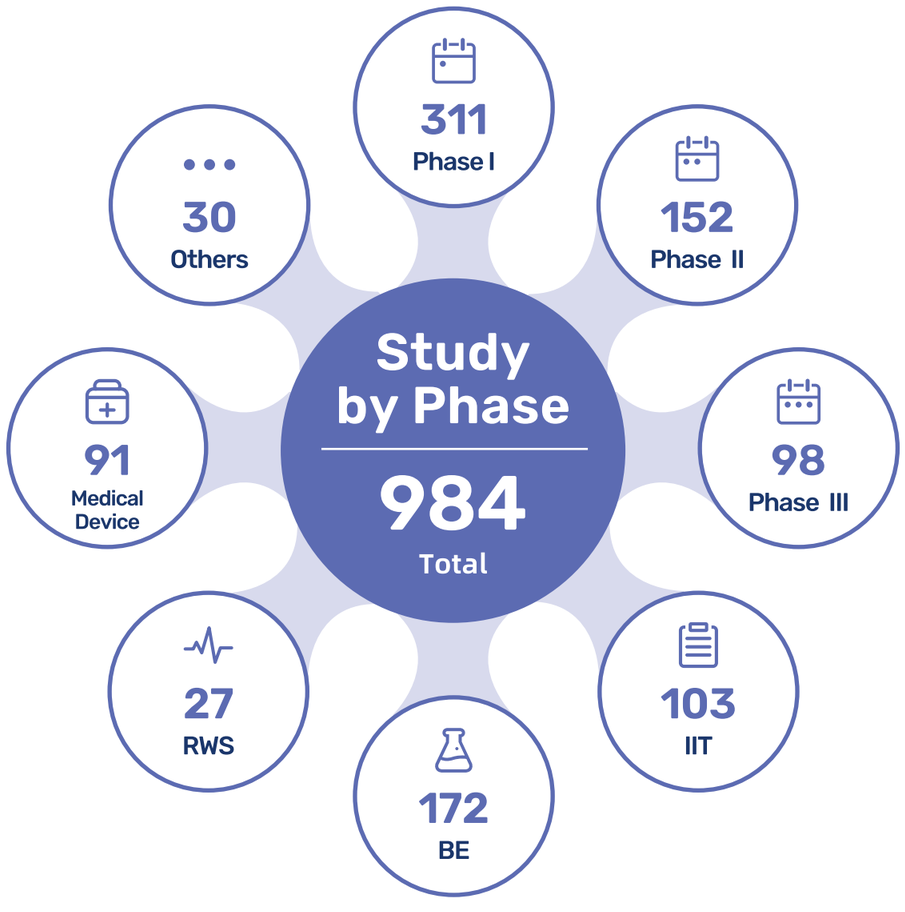
- Early Development Consultation
- Regulatory Consultation & Registration
- Development Strategy & Medical Writing
- Medical Monitoring
- Project Management & Clinical Operations
- Data Management & Biostatistics
- Pharmacovigilance
- Digital Innovation Services
- Clinical Supply Chain
- QA & 3rd-Party Auditing

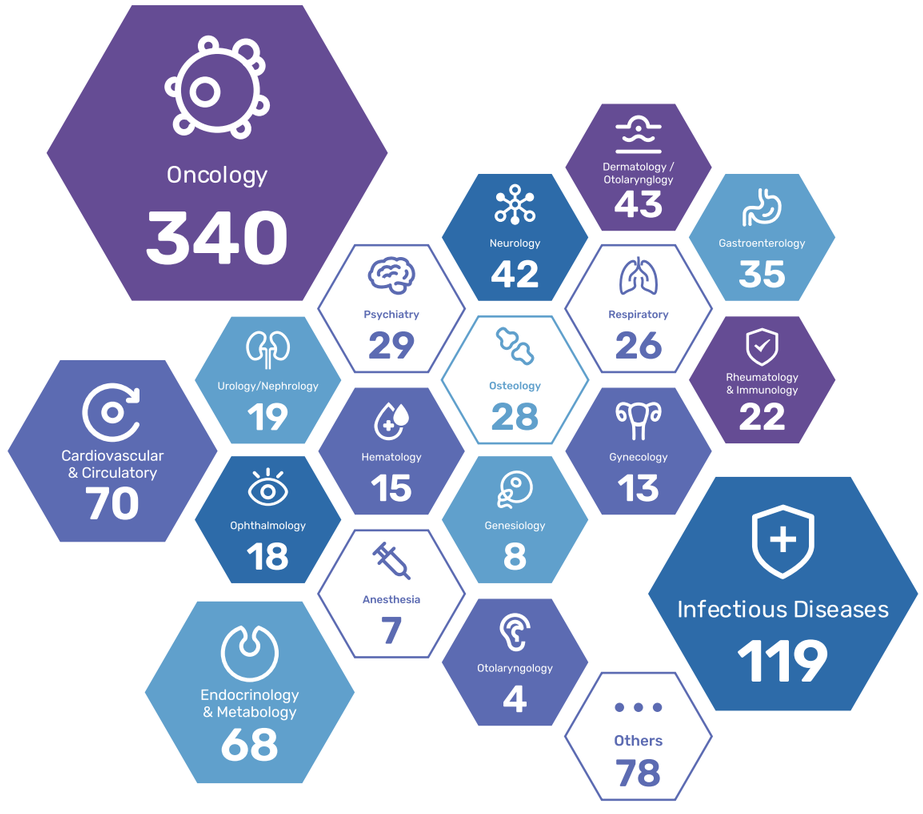
Project Experience

984 Clinical Studies

258 INDs & NDAs

175 CGT Projects

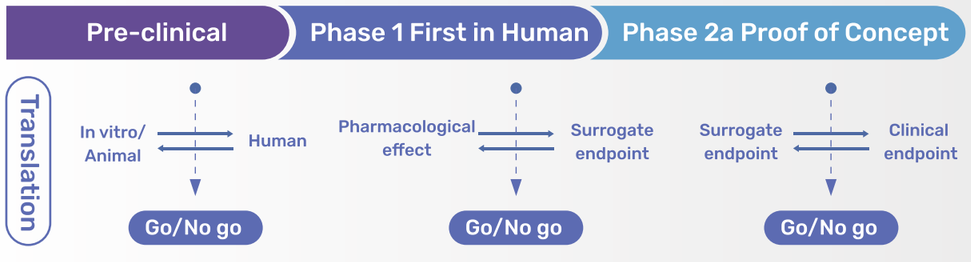




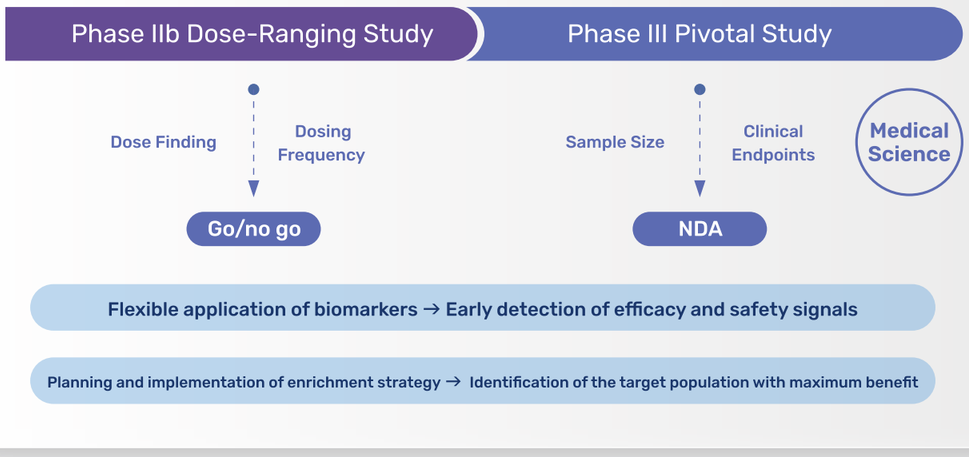
Global Novel Drug Early Development Consulting

Our multidisciplinary team of scientists, with expertise in translational medicine, PK/PD, and biomarkers, bringing basic research with clinical trials. We design customized development strategies and identify optimal patient populations to accelerate the delivery of novel, clinically valuable drugs to patients worldwide.

Exploratory Development Phase



Confirmatory Development Phase





Customized Clinical Pharmacology Plan

- Use M & S to guide clinical drug development, optimize or exempt clinical trials and accelerate the new drug development process
- Provide compliant and practical overall strategy for clinical pharmacology in new drug development

Strategy Development

- Clinical Pharmacology Program (CPP)
- FIH dose prediction/effective human dose prediction/dose escalation design
- Ethnic sensitivity analysis
- Global development bridging strategies
- Special population study strategies and dose adjustment solutions

M & S Platforms

- PopPK model
- Pop PK-PD model
- E-R analysis, PK-PD model
- PBPK model
- Food effect prediction
- Dosing strategies and recommendations, such as prediction of different dosing frequencies, RP2D, dose optimization schemes, etc.

Clinical Research

- Early exploratory clinical studies (SAD/MAD/POC)
- Dose optimization strategies for pivotal clinical studies
- FE/DDI/MB/Bridging studies
- Special populations (e.g., hepatic/renal insufficiency, obesity/pediatrics)
- BE (special formulation, inequivalence cause analysis and solution)

Medical Strategy Development, Medical Writing, and Monitoring

Our Medical Science team is composed of 100% clinicians, with over 36% holding a doctoral degree (PhD or MD), covering a broad spectrum of therapeutic areas. With extensive clinical experience, strong scientific acumen, and proven expertise in clinical project execution, we are dedicated to designing clinical development strategies and clinical study protocols for sponsors, while providing high-quality medical monitoring services.

Early Development Strategy

- Tailor-made global clinical development strategy to plan the drug development path systematically.

Clinical Pharmacology

- Feasible strategies for clinical pharmacology study on new drugs, assisting the medical team in new drug development.
- Improved quantitive pharmacology platforms, quality technical services, and delivery capabilities enable us to provide customized clinical/quantitative pharmacology services.
- Using MIDD to direct clinical pharmacology studies across various populations and formulate dosage selection strategies at different study phases.

Medical Monitoring

- Provide Protocol review, team training, medical consulting, safety and efficacy data review, professional medical monitoring, strict quality management.
- Ensure data accuracy, reliability and integrity, timely identification of risk signals and effective risk control measures to ensure subject safety.

Medical Writing

- IB, Protocol, CDP, ICF, 2.5 Clinical Overview, 2.7 Clinical Summary, CSR, etc.

Regulatory Consultation & Registration

Our regulatory team members are well-versed in the regulatory requirements for innovative drugs in China, the United States, Australia, and the European Union. We have extensive hands-on experience with submissions including ODD, PIND, EOP1, EOP2 and NDA. With deep insight into the differences between Chinese and US review standards, we integrate development considerations at each stage of the innovative drug lifecycle to formulate tailored regulatory strategies that ensure compliance while significantly improving development efficiency.

200+
Innovative drugs

10+ years
Professional team

PRC+SC+SAB
World-class scientific expertise

Chemicals	Biologics	Cellular & Gene Therapy Products	Multi-Regional Clinical Trials
IND and NDA filing services for chemicals e.g., innovative small molecules, chemical macromolecules, peptides, etc.	IND and NDA filing services for biologics e.g., innovative McAb, vaccines, recombinant proteins, oncolytic viruses, bacteria	IND filing services for nearly 100 cell & gene therapy companies in China e.g., stem cells (MSC, IPSC), immune cells, gene therapy products (in vivo, in vitro), etc.	Filling services for international multicenter clinical trials e.g., the United States, Australia, Canada, Bulgaria, Germany, France, Netherlands, Switzerland, Belgium, South Korea

Clinical Operations
Project Management and Monitoring

Our expertise spans infectious diseases, oncology, endocrinology, and autoimmune disorders, with project operations covering through early-phase to early-phase to post-marketing and real-world studies. Our PM core team, each with more than 10 years experience and extensive experience in inspections by national and provincial regulatory authorities, contributed to the approval of China's first small-molecule anti-COVID-19 drug.



CRA: 7 regional teams covering 80% of China's provincial capitals.

PM: Average industry experience exceeds 10 years.

01. Close Cooperation with Sites

Site

- Partnership with 500+ clinical trial institutions
- 80+ Phase I research centers with accelerated study start-up capability
- Comprehensive cooperation with national and provincial cancer hospitals and infectious disease hospitals

02. Leading Study Start-Up Capability

SSU

- SSU: 2.9 months (median)
  Fastest SSU: 19 business days
- CRAs: Distributed across 80% of the provincial capital cities in China
- CRM: 8 years of industry experience on average

03. Distinctive Project Experience

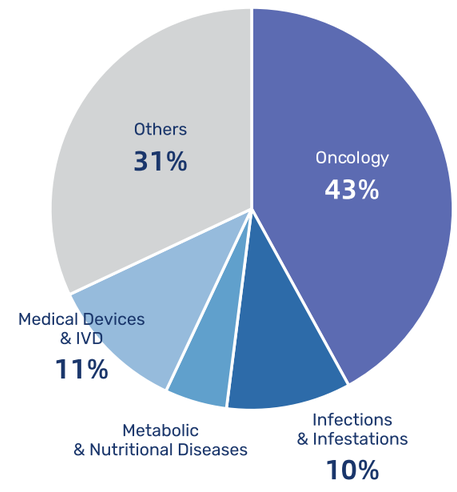
TAs

- CGT: A dedicated Cell & Gene Therapy Team with accumulated project management experience in 10+ cell therapies, such as MSC, IPSC, CAR-T, and gene therapy, etc.
- Infectious Disease: Experienced in HIV/HBV-related trials (initially treated patients, treated patients, drug-resistant patients, etc.)
- Specific Populations: Rapid enrollment of patients with hepatic/renal insufficiency
- Rare Diseases: Good communication with patients

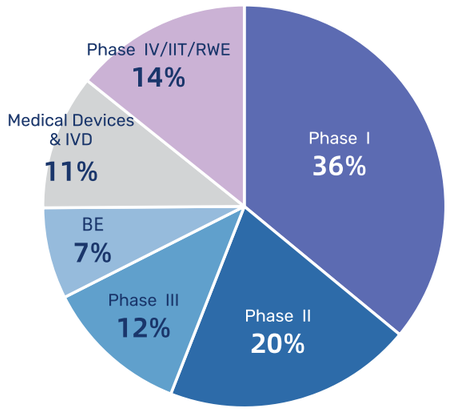
Data Management & Biostatistics

We deliver compliant, professional, and timely data management and biostatistical programming services that meet international standards. Our core team, with expertise from global pharma and CROs, is stable and highly skilled. With **100+** professionals, we have served **100+** innovative biopharma clients and executed **600+** projects. As China's first CDISC corporate member, we bring proven CDISC experience and rigorous SOPs to every engagement.

Therapeutic Areas



Therapeutic Areas



60+	150+	150+	20+
Rave EDC/RTSM	eCollect/eBalance	CIMS EDC/CRS	Clinflash EDC/IRT

Pharmacovigilance

Our PV team is proficient in global and domestic regulatory requirements, with working languages in Chinese, English, and Japanese. We have completed 600+ projects for 150+ global clients, spanning oncology, infectious diseases, rheumatology, immunology, and endocrinology.



Advantages

- A professional team of PV physicians with clinical backgrounds and practice experience, along with drug safety experts.
- Extensive experience across the full drug lifecycle, from early-phase clinical trials to post-marketing surveillance.
- In-depth knowledge of domestic and international PV regulations and best practices, with real-time awareness of the latest requirements to ensure compliance.
- Multilingual capabilities (Chinese, English, Japanese) to support therapeutic areas such as oncology multi-regional projects.

Professional Services, Intelligent Databases, and Automated Technologies

	Safety Aggregated Reports DSUR, PSUR, PBRER, Other Safety Update Reports.		**Safety System Service** Database setup and maintenance, Argus, Empirica, and other database.
Case Management Data entry, medical review, Customized narrative writing, Analysis of similar events, company comments, submission.		**Safety Data Service** Safety data migration, electronic transmission.	

Digital Innovation Services

As a strategic partner to leading global brands, we deliver localized, ecosystem-based solutions powered by AI. We tailor our services to diverse business scenarios, optimizing workflows and resource allocation to drive intelligent transformation, improve clinical research efficiency and quality, and accelerate drug market launch.

Independent IT Compliance Ensures Program Success

Offer both SaaS and on-premise deployment options

Compatible with all mainstream models

AI-Powered Enablement Across All Clinical Trial Business Units



Global Partners

ORACLE UiPath Microsoft LabVantage

Quality Assurance

Committed to quality and compliance in every clinical study. We aim for 100% project acceptance and delivery, offering end-to-end, high-standard quality assurance with an independent, professional approach.



Advantages

Standardized Quality Management System

- We maintain a quality management system that covers all business processes and has been continuously certified to ISO 9001 for nine consecutive years.

Rigorous Process Control

- Our QA team performs project-specific QA activities. We strictly adhere to all applicable laws, regulations, and protocol requirements, while closely monitoring quality risks.
- We provide objective and impartial evaluations of trial processes, and strictly follow CAPA management principles for all audit findings, ensuring timely corrective actions and re-verification within agreed timelines.

High-Quality Delivery

- Our past projects have undergone **70+** inspections by regulatory authorities, all of which were successfully passed with no critical findings.

One-stop Clinical Supply Chain Service

Comprehensive clinical supply chain services, fully addressing diverse customized needs.



4-5 weeks from DP manufacturing to initial IMP site shipment delivery,
1-3 weeks shorter than average industry timeline.



20+ countries with warehouses locations.



100+ countries covered by our distribution services.



1-3 business days for shipment delivery across China.



5-10 business days for shipment delivery around the world.