Tigermed

Regulatory Pathways for Clinical Trials in China

A Guideline for Initiating Clinical Trials in China

May 2026

Regulatory Pathways
for Clinical Trials in China

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Things You Need to Know before initiating **Clinical Trials in China:**

1. What's the regulatory pathway for clinical trials in China?
2. What's the difference between IND, IIT and NBT?
3. How is the timeline for each pathway?
4. Key considerations of clinical operation for each pathway?
5. How to Choose, IIT or IND?

What's the Regulatory Pathway for Clinical Trial in China?

A New Dual-Track System with State Council Order No.818

IND (Investigational New Drug)

Sponsor: Legal entity

Approval: CDE, NMPA ➔ EC

Regulated by **NMPA**

国家药品监督管理局
National Medical Products Administration

Traditional NMPA Product Registration Track

IIT (Investigator-Initiated Trial)

Investigators

Approval: Academic commitment + EC ➔ filing in NHC

Clinical Trial for New Biomedical Technology

Sponsor: Chinese legal entity

Approval: Academic commitment + EC ➔ filing in NHC

Regulated by **NHC**

中华人民共和国国家卫生健康委员会
National Health Commission of the People's Republic of China

IIT and NBT Tracks under NHC

A New “Technology Translation” Fast Track for **NBT**

State Order **No.818** introduces a second and fast pathway for **NBT**

Which Therapies Qualify for the NBT Fast Track?

The new pathway applies to a clearly defined set of innovative technologies, including those that utilize:

- Personalized cell therapies and gene editing
- Brain-computer interfaces
- Xenotransplantation
- Stem cell therapy, CAR-T, and assisted reproductive technology

What Global Biopharma Can Benefit from the NBT Fast Track?

- **Faster Time-to-Market**: allowing a quicker route to commercializing advance therapies in China.
- **Lower Regulatory Burden**: potentially offering a more streamlined set of regulatory requirements.
- **New Deal Opportunities**: opens up novel licensing and partnership possibilities.
- **Viable Path for Hospital-Based Clinic**: establishes a compliant path for therapies traditionally developed and administered in a hospital setting

Definition of **New Biomedical Technology (NBT)**

China State Council Order No. 818

—— the Regulations on the Administration of Clinical Research and Clinical Translation Application of New Biomedical Technologies
Release Date: October 10, 2025
Effective Date: May 1,2026

Official Definition

> It refers to the medical professional methods and measures that are based on biological principles, act on the cellular and molecular levels of the human body, and have not yet been applied clinically in China, for the purposes of judging health status, preventing or treating diseases, or promoting health.

Clinical Research on New Biomedical Technologies
(1) Directly performing operations on the human body;
(2) Performing operations on ex vivo cells, tissues, organs, etc., followed by implantation or infusion into the human body;
(3) Performing operations on human germ cells, zygotes, or embryos, followed by implantation into the human body to facilitate their development;
(4) Other methods as specified by the National Health Commission of the State Council.

Definition of **New Biomedical Technology (NBT)**

China State Council Order No. 818

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Release Date: October 10, 2025
Effective Date: May 1,2026

Different Stage, Different Scope

> Broad Scope for Clinical Trials
> Narrowed Scope for Clinical Translation

For Clinical Trials
- Guidance List for Filing of Clinical Research on New Biomedical Technologies”
- No drug with the same MOA targeting the same indication has been approved for marketing in China

For Transformation application
- Highly personalized, and no drug with the same MOA has been approved for marketing in China, nor has a confirmatory clinical trial been initiated for such drugs; OR
- Intended for the treatment of rare diseases listed in the *Rare Diseases Catalog*, and no drug with the same MOA targeting the same indication has been approved for marketing in China, nor has a confirmatory clinical trial been initiated for such drugs.

Definition of **Investigator-Initiated Trial (IIT)**

Official Definition

> IIT refers to activities conducted by medical and health institutions that take humans as research subjects, are not aimed at product registration, and study the etiology, diagnosis, treatment, rehabilitation, prognosis, prevention, control, and health maintenance of diseases.

—— *Notice on Printing and Distributing the Measures for the Administration of IITs (Sep 18, 2024)*

Issued By

- National Health Commission (NHC)
- National Administration of Medical Products (NAMTC)
- National Administration of Disease Control (NADC)

What Therapy Technologies Qualify for **NBT Clinical Trial**?

Gene Therapy

1.Viral Vector-Based Gene Therapy Technologies
2.Non-Viral Vector-Based Gene Therapy Technologies
3.Virus-Like Vector-Based Gene Therapy Technologies
4.Vector-Free Gene Therapy Technologies

Tissue and Organ Therapy

1.Tissue Engineering Technologies
2.Xenotransplantation Technologies

Brain-Computer Interface (BCI)

1. Invasive Brain-Computer Interface Technologies
2. Non-Invasive Brain-Computer Interface Technologies

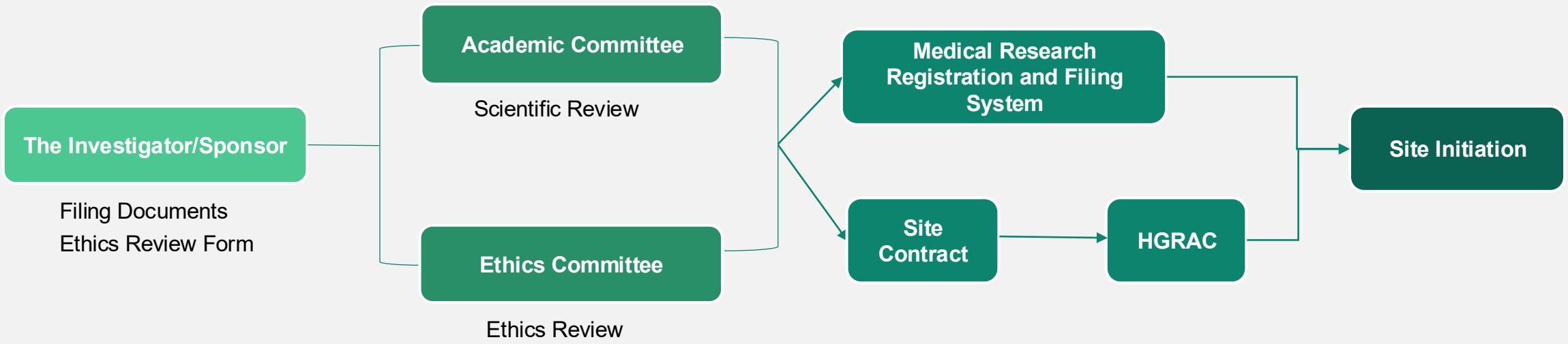
Cell and Derivative Biotherapy

1.Pluripotent Stem Cell Therapy Technologies
2.Tissue Stem Cell Therapy Technologies
3.Somatic Cell Therapy Technologies
4.Cell Component and Derivative Biotherapy Technologies
5.Antigen-Specific Immune Cell Activation Technologies
6.Germ Cell / Embryo-Based New Technologies

Microbiological Therapy

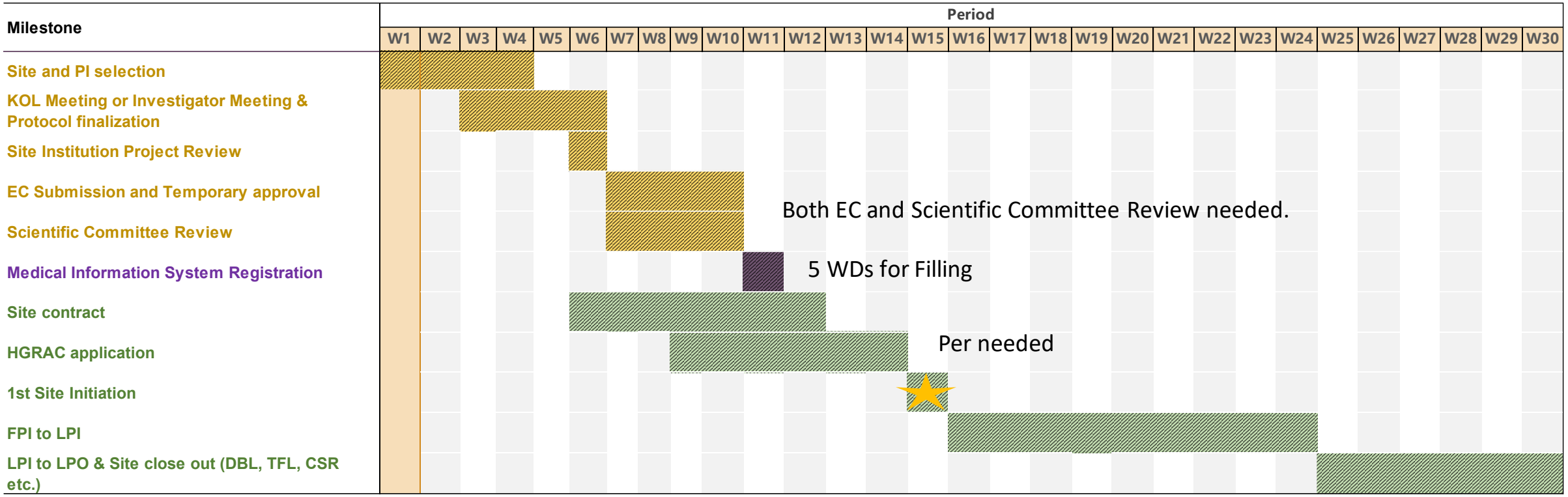
1. Oncolytic Microbial Therapy Technologies
2. Phage Therapy Technologies
3. Microbiota Transplantation Technologies

What's the Pathway for Initiating **IIT/NBT Trial** in China?



- Timelines and required documentation vary depending on each Research Institution's specific requirements.
- Grade A hospital/PI (with a senior professional title)
- Well suited for:
  - First-in-human exploration Autologous
  - Highly personalized CGT
  - Academic–industry collaboration at top-tier hospitals

Timeline for IIT Implementation Process



- Full-process supervision by the National Health Commission (NHC)
- NHC may conduct risk assessments and suspend studies if necessary

What's the Process for China IND Application?

Pre-IND
(Not Mandatory)

60 Working Days

Pre-IND Necessity Assessment
- Product maturity
- Relevant guidelines
- Overseas registration status
- Development needs

IND: Regular 60 WDs

or

IND: Accelerated 30 WDs

30 Working Days IND-Innovative drugs

Eligibility Criteria

1. Nationally supported key innovative drugs.
2. Innovative drugs and TCMs for pediatric use or rare disease treatment
3. Globally developed drugs in phase I or II stage OR phase III MRCT that assigns China physician as leading PI or co-PI.

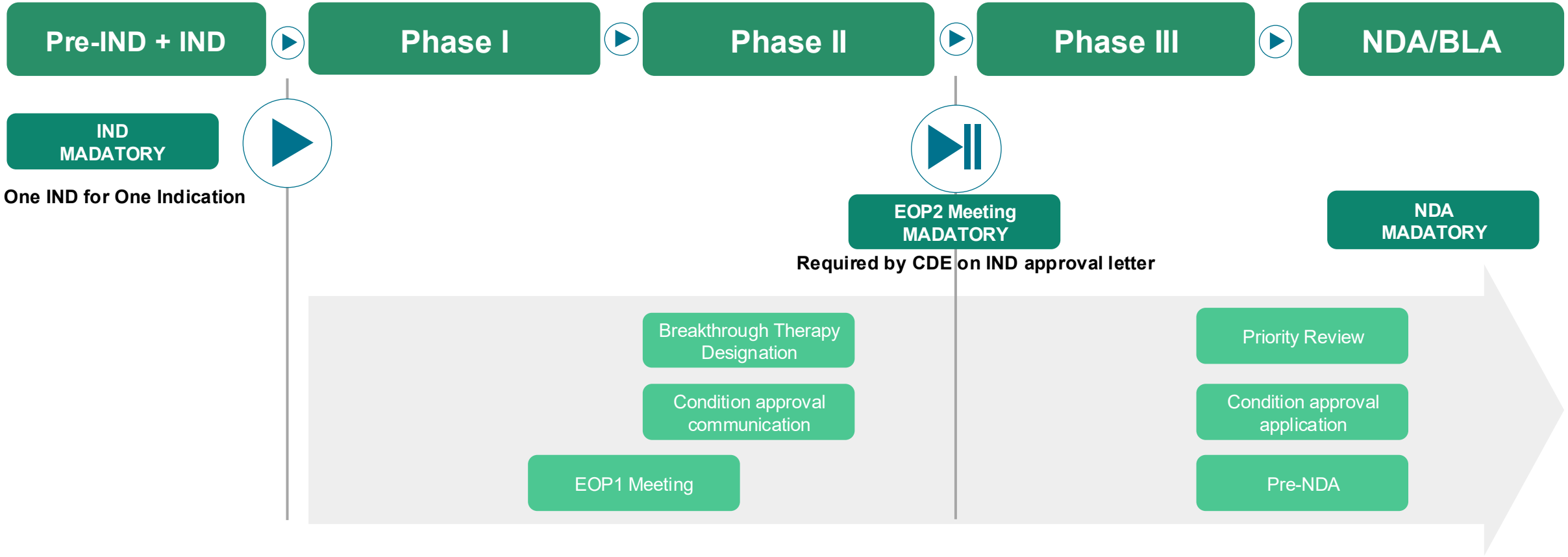
30-day IND specific dossiers:

- Protocol and RMP with PI signature
- Evidence: EC is under review
- Evidence: Contract with leading sit is under review
- Commitment: initiate clinical trials within 12 weeks of approval

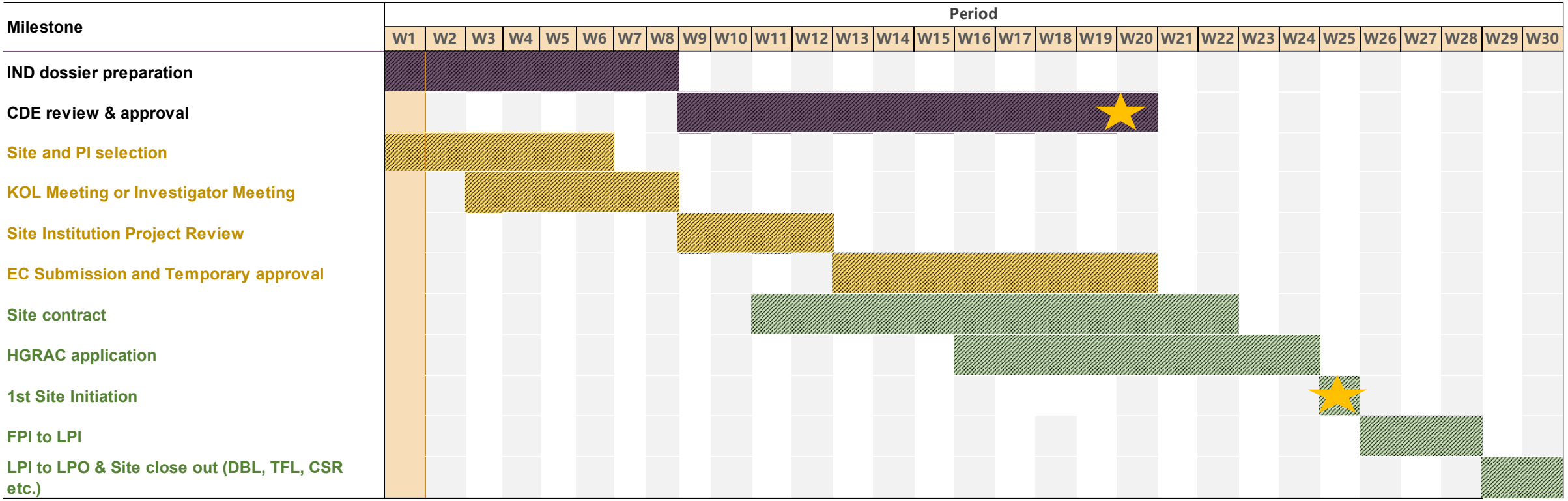
20 cases

We have supported 20 success approvals since **IND 30-WD pathway available** in Sep 2025

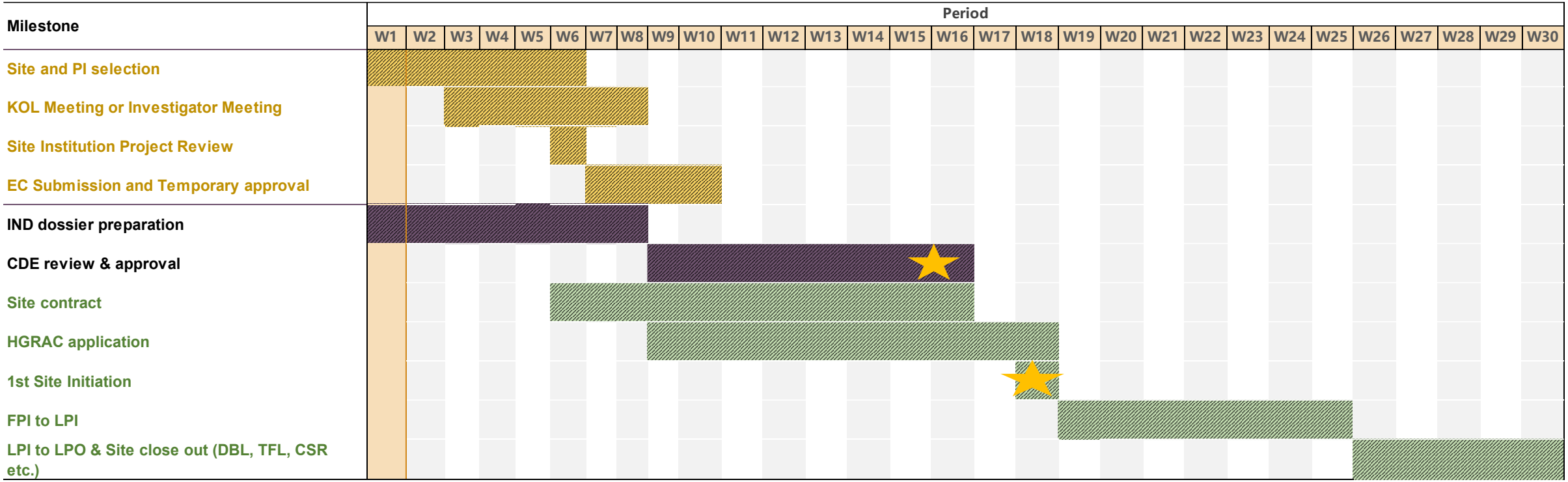
You Just Need One IND Approval for Phase I-III



Timeline Assumption-60-Day Review Pathway



Timeline Assumption-30-Day Review Pathway



What's the Difference in Regulatory? **NMPA vs NHC**

	Regulated by NMPA (National Medical Product Administration)	**Regulated by NHC** (National Health Committee)	
Pathways	**IND**	**IIT**	**NBT**
Sponsor & manufacturing site	• Manufactured in China: Local entity required • Manufactured overseas: Local registration agent required	Investigator Manufactured in China	A Chinese entity Manufacturing site unknow yet
Clinical Trial Pathway	IND Approval from CDE EC approval	EC Approval NHC: Filing	EC Approval NHC: Filing
CMC/Non-clinical data	CTD dossiers Full CMC & non-clinical studies	IB Flexible requirements for study content	IB New policy – Requirements pending clarification
Study Population	Healthy population or patient	Patient	Patient
Study type	Phase I-III	Early phase clinical trial Post Marketing/NIS clinical trial	Early phase clinical trial Multi-center independent validation clinical study
Commercial Pathway	CDE: NDA/BLA	/	NHC: Clinical Translational Application

NHC: National Health Commission
NMPA: National Medical Products Administration
CDE: Center for Drug Evaluation, is affiliated with NMPA

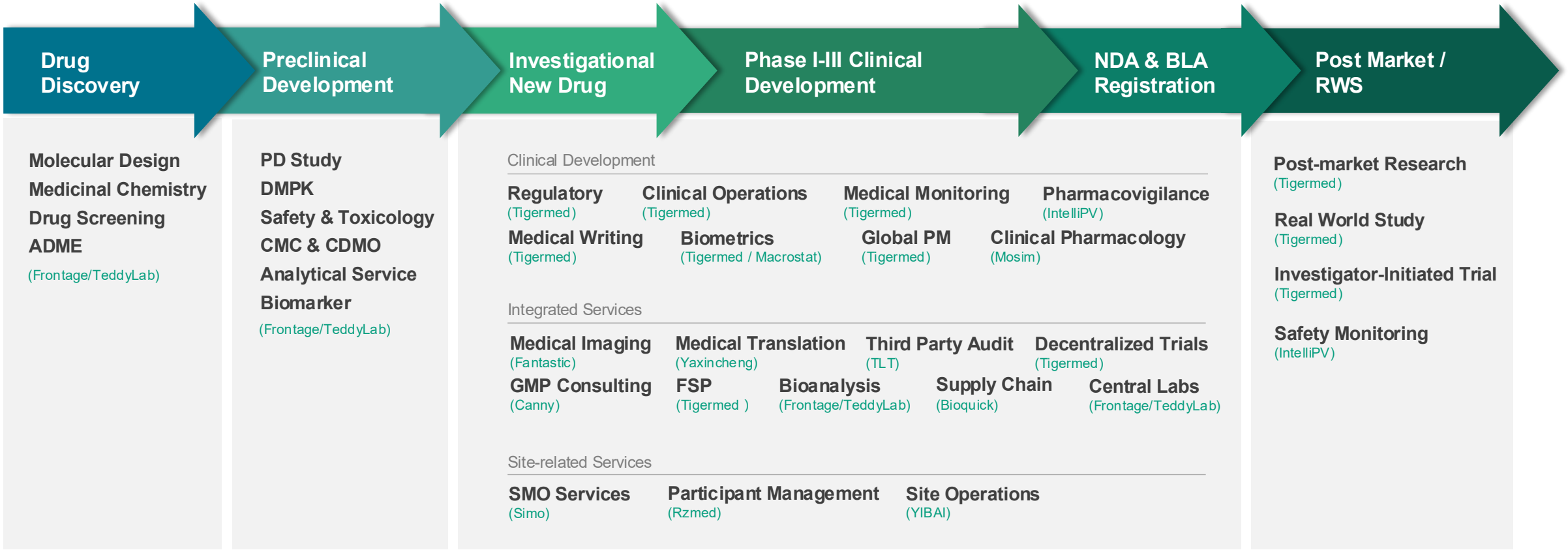
Key Clinical Operations Implications: **IIT vs IST**

Clinical Operation Aspects	IIT (Investigator-Initiated Trial)/NBT	IND/IST (Industry-Sponsored Trial)
Regulatory Positioning	Academic / investigator-driven research initiated/clinical translation purpose	Sponsor-driven registration-oriented clinical development
Regulatory Review Timeline	5 WDs for Dossier Filling, no Technical review.	30 / 60 WDs
SSU Timeline	3 to 4 Months	5 to 7 Months
Subject Population	Patients only; healthy volunteers are not permitted	Healthy volunteers or patients allowed, depending on phase
Drug Supply & Importation	Importation may be challenging; requires clinical trial approval notification, Manufacture should be in China	Importation permitted upon IND clinical trial approval
Sponsor	Should have a substantive entity in China	Manufacturing in China requires a substantive local sponsor entity; overseas manufacturing allows greater flexibility.
Data Role in Global Development	Exploratory / supportive; regulatory acceptance assessed case-by-case	Fully acceptable for NDA/BLA and global regulatory submissions
Cost Structure	Investigator fees may appear lower; overall cost depends on operational intensity	Higher upfront regulatory cost; clearer budgeting across phases
Lifecycle Coverage	Clinical Transformation Application or IND application supportive dossier	One IND can cover Phase 1–3 within the same indication

Our Practical Guidance:
When to Choose the Path: IIT vs IND?

IIT/NBT		IND
• The therapy is autologous or highly personalized • Hospital-prepared or bedside manufacturing model • Limited feasibility for early industrial standardization	Product	• Therapy is standardized or industrializable • Manufacturing, CMC, and comparability can be defined early • Intended to become a registrational drug product
• Primary goal is first-in-human exploration or proof-of-concept • Speed and capital efficiency outweigh long-term asset value • Early clinical signal generation to inform next-step strategy	Purpose	• Supports MRCTs • Designed for global development and submissions (FDA/EMA/NMPA) • Value creation through licensing, partnership, or commercialization
• Chinese patients represent a small or standalone exploratory cohort • Data used mainly for internal decision-making, not global registration • Clinical translation application	China Role	• Requires upfront alignment on global endpoints and development plan • Subject to formal regulatory review and approval • Harmonized expectations with international health authorities

We Are Here to Support from Discovery to Clinical



End-to-End Service Offerings for Drug R&D

Names in (GREEN) represent subsidiary companies or joint ventures that provide corresponding services

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