WuXi AppTec's Integrated Drug Development Services

Small Molecule Development

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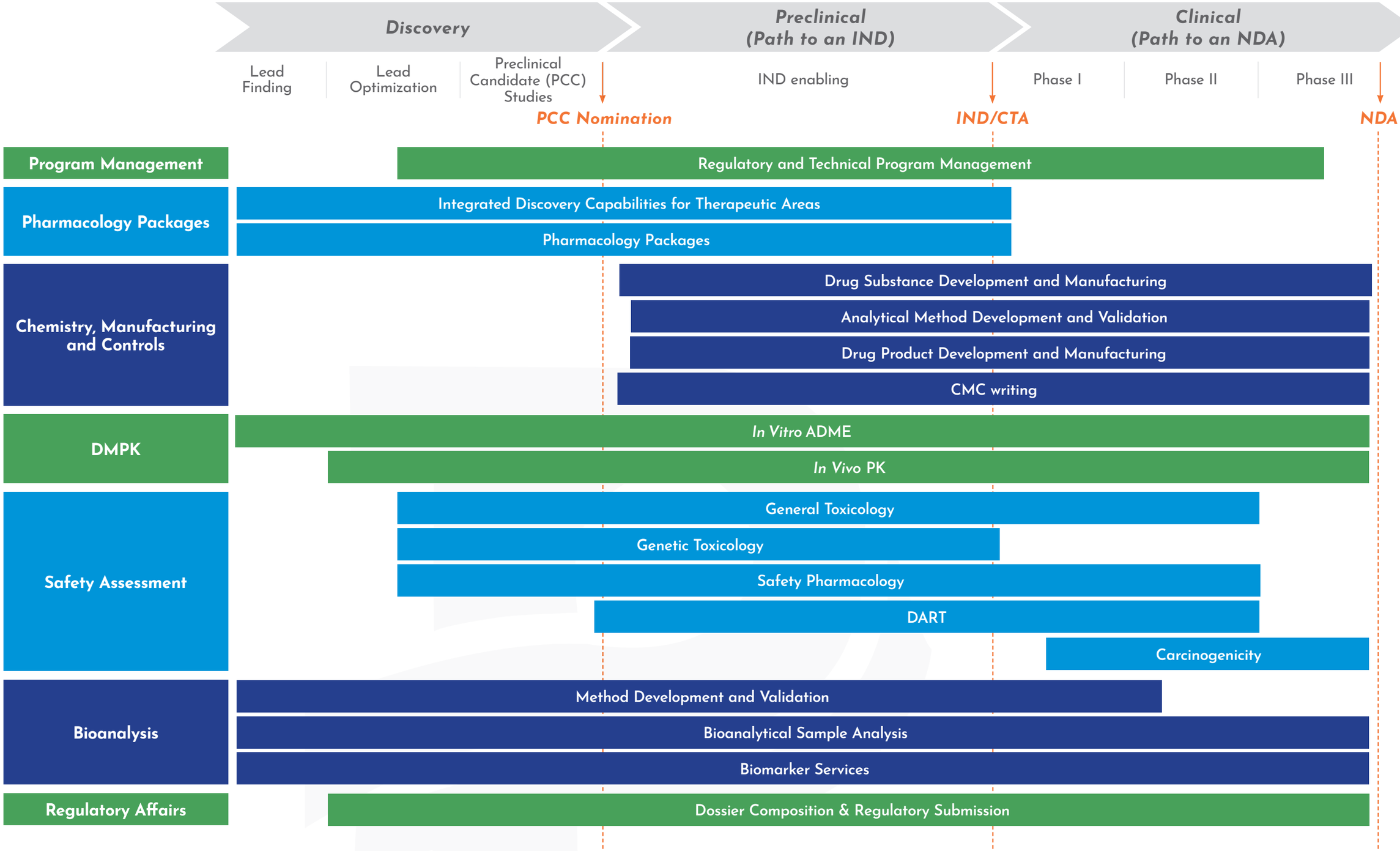
WuXi AppTec

Drug Development Process



Program Management

WuXi AppTec's program management (PM) team provides support for IND program design, from study execution to dossier preparation and submission. The PM team provides information and consultation during the initial project discussion with our Business Development team.

Accelerated Timeline to expedite your molecule to IND

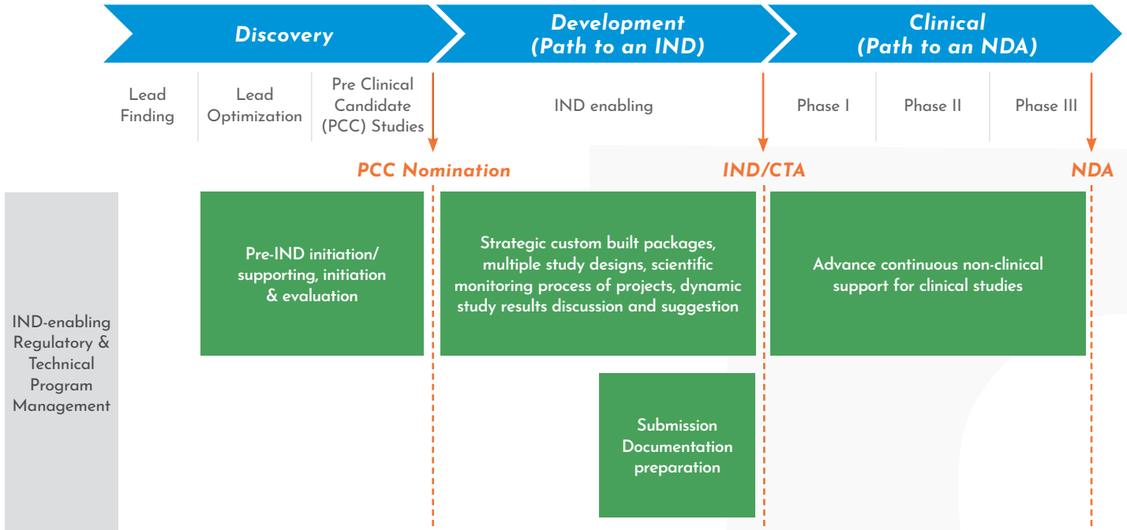
Dual Filing in U.S. and China to increase asset value

Truly Integrated Platform consolidating all tasks within one organization

Flexible Approach ranging from a la carte to IND package

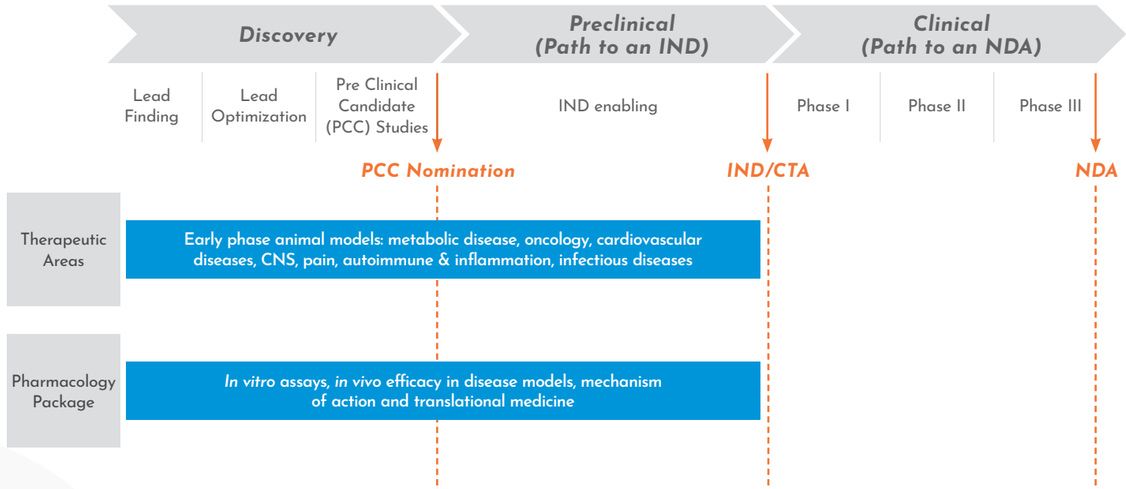
High Quality experienced team of experts and state-of-the-art facility to ensure compliance with global regulatory agencies

Cross Functional Program Management



Pharmacology

WuXi AppTec's full-service pharmacology department provides validated discovery assays, including *in vitro* assays (HTS, SAR screening support, compound selectivity and early safety profiling, and cancer cell panel profiling) and *in vivo* disease models in cardiovascular, CNS, respiratory, metabolic, and infectious diseases.



Capabilities at a Glance:

- More than **340 global collaborators** including 14 partners from the top 20 pharmaceutical companies
- **4 locations**, including **360 scientists** working on *in vitro* and *in vivo* biology in Shanghai, **9 scientists** on assay development/transfer, SAR screening support and HTS in Plainsboro, New Jersey, **19 scientists** in our pharmacology team in Suzhou, and 40 scientists in Qidong.
- **CAP-certified FACS**, as well as pathology services and a molecular testing laboratory for clinical virology
- A total of **~400 biologists**, offering plate-based screening, and pharmacology services under FTE or FFS models
- **More than 30 Ph.D.**, trained in US & Canada, 10 with >15 years R&D experience
- **43,000 ft²** of Biology labs and AAALAC-accredited animal facility
- **50,000+ ft²** of new small animal facility is under construction at Qidong, Jiangsu

Chemistry, Manufacturing, and Controls (CMC)

STA Pharmaceutical Co., Ltd., a WuXi AppTec company (WuXi STA), can support efficient, flexible, and high-quality solutions for small molecule development, from preclinical to commercial lifecycle management for both drug substance and drug product. We are experienced in authoring CMC sections be filed in both the US and China.

Capabilities at a Glance:

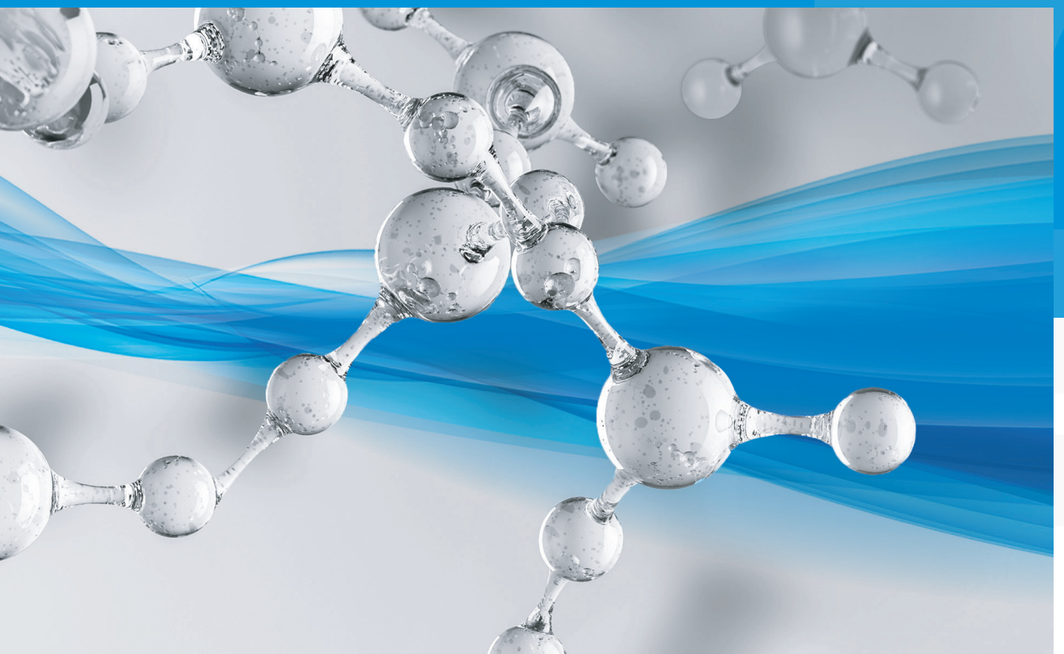
Speed

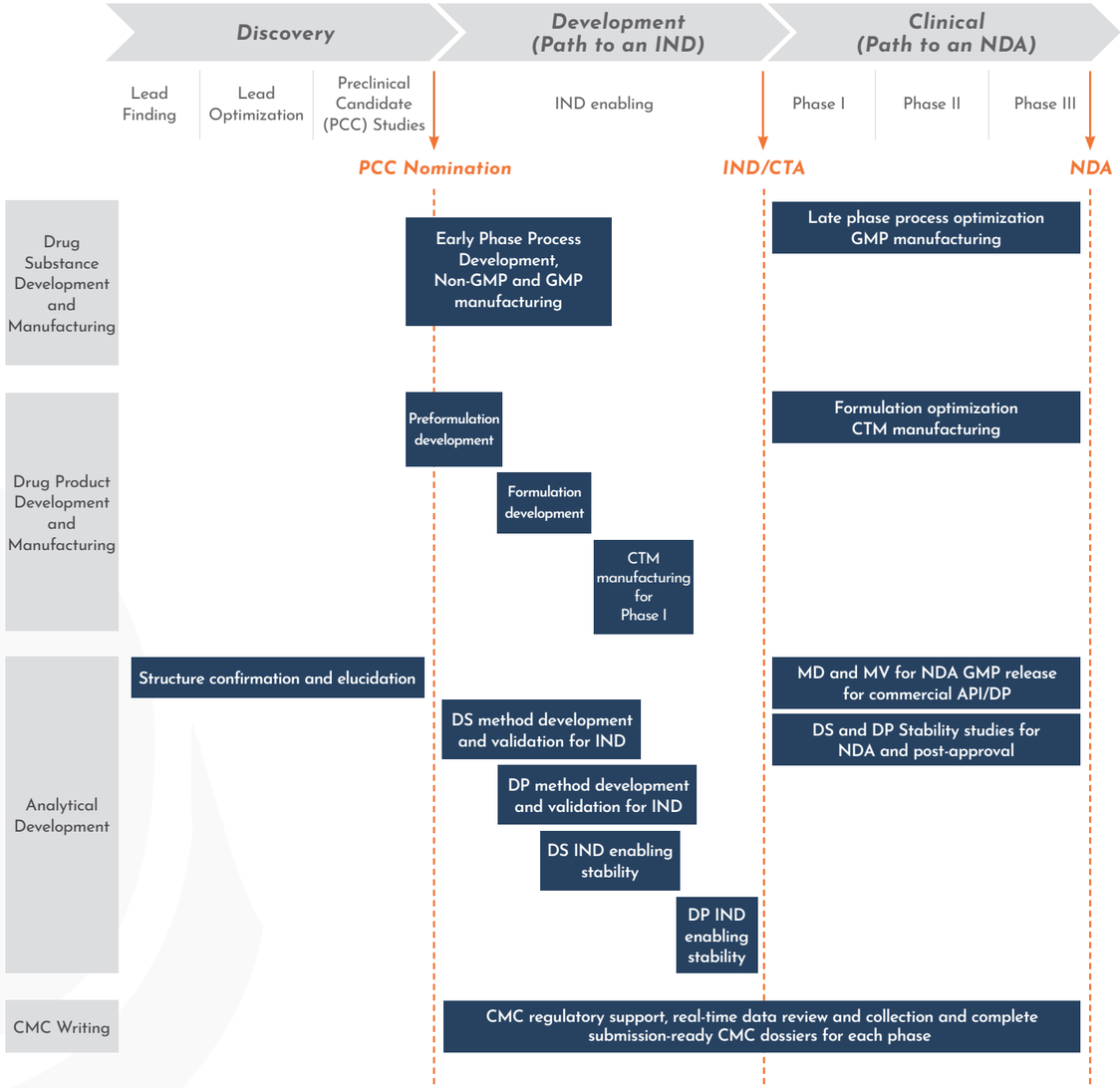
- **Drug Substance: 2** weeks/step for 1st GMP API batch (Process R&D + Manufacturing)
- **Drug Product: 8-12** weeks for developability assessment & IND formulation
- **Analytical: 4-8** weeks DS & DP analytical method development and validation

Expertise

- Supported **250+** successful IND Programs
- Supported **1,300+** new molecules in 2020
- Product approved in **90+** countries

Quality: Unified quality system across all sites, approved by all major regulatory agencies





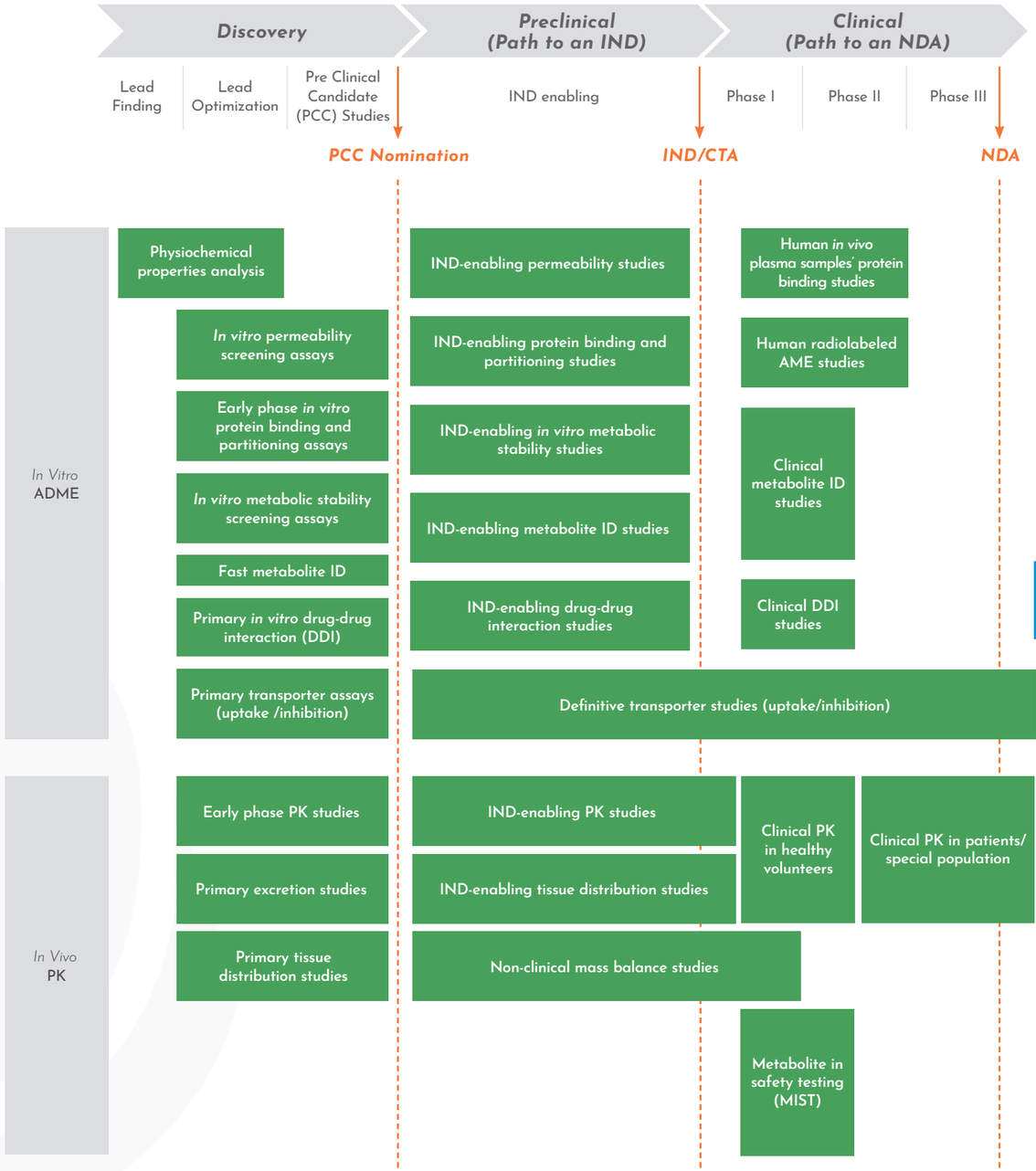
CDMO services provided by WuXi AppTec subsidiary STA Pharmaceutical

DMPK

WuXi AppTec offers a true end-to-end platform of discovery through clinical Drug Metabolism and Pharmacokinetic (DMPK) services that provides comprehensive *in vitro and in vivo* Absorption, Distribution, Metabolism and Excretion (ADME) solutions that are needed during the drug development journey.

Capabilities at a Glance:

- Physicochemical properties analysis
- *In vitro* permeability assays
- *In vitro* protein binding and partitioning assays
- *In vitro* stability assays
- *In vitro* drug-drug interaction assays
- *In vivo* mass balance
- *In vivo* PK
- *In vivo* tissue distribution
- Metabolite identification and quantification



Safety Assessment

WuXi AppTec's full-service toxicology department adheres to the highest quality standards and will accelerate your program to the next level of development.

Our team of experts have performed more than 11,000 safety assessment studies and completed over 700 IND and NDA packages in our expanded facility of 1,000,000 ft^2 with 500+ animal rooms.

Capabilities at a Glance:

General Toxicity

- Acute toxicity study
- Repeat dose toxicity study at – 7-day, 14-day, 28-day, 13-week, 26-week, and 39-week
- Species: Mouse, rat, dog, monkey, rabbit,and mini-pig
- Administration route: oral, injection (iv, ip, sc), dermal, ocular, etc.

Carcinogenicity

- 104-week carcinogenicity study in rats or mice
- 26-week carcinogenicity study in transgenic mice (RasH2)

Special Toxicity

- Local irritation (skin, vessel, and eyes)
- Sensitization (ASA and PCA)
- Hemolysis (*in vitro*)
- *In vitro* phototoxicity study
- Ocular toxicity study

Developmental and Reproductive Toxicology (DART)

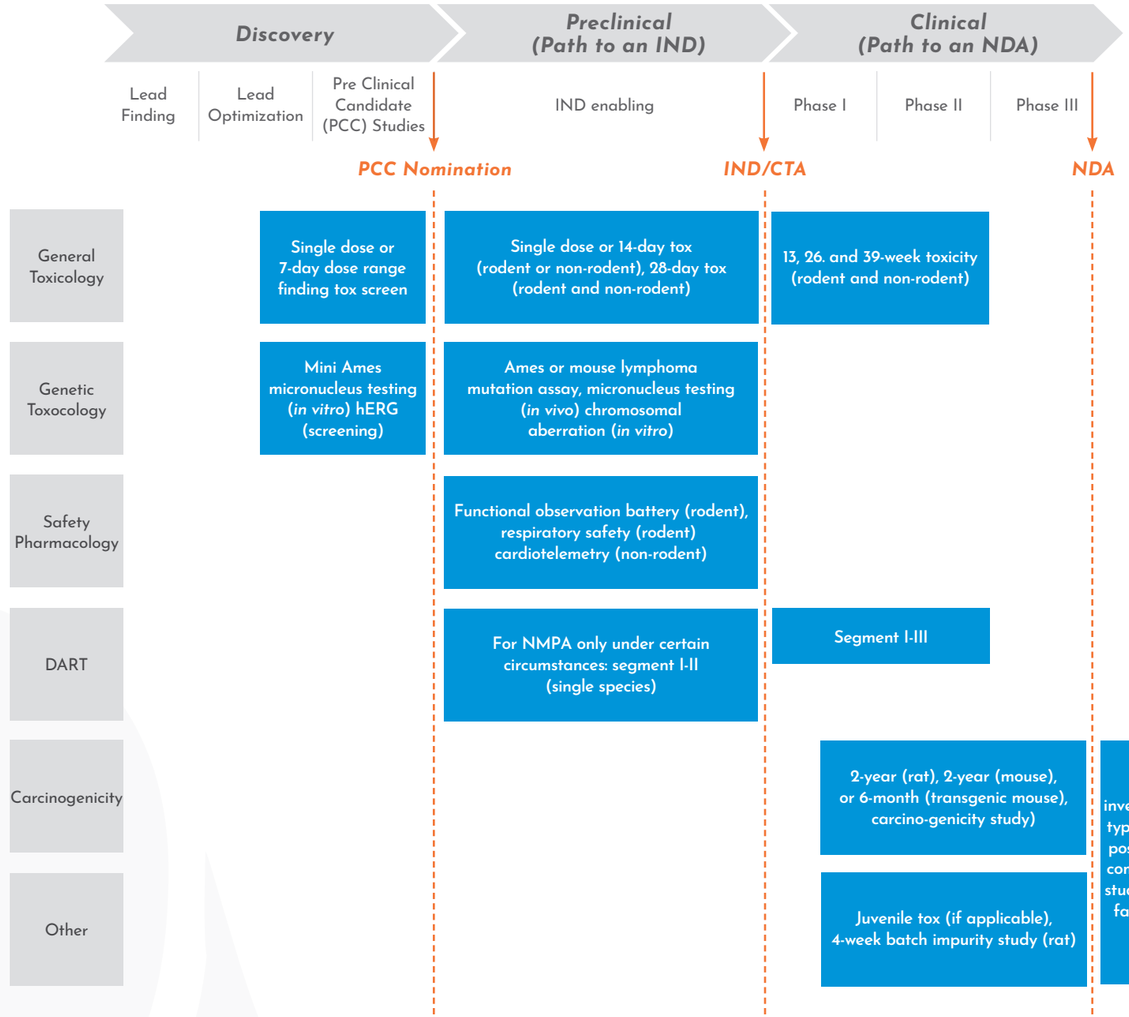
- Seg I fertility and early embryonic development to implantation (mouse and rat)
- Seg II embryo-fetal development (rat and rabbit)
- Seg III pre-and postnatal development (mouse and rat)
- Juvenile toxicity study (mouse and rat)

Safety pharmacology

- Central nervous system (mouse and rat)
- Respiratory (mouse, rat, dog, and monkey)
- Cardiovascular (dog and monkey)
- hERG (*in vitro*)

Genetic Toxicity

- Ames (*in vitro*)
- Micronucleus (*in vitro* or *in vivo*)
- Chromosome abbreviation (*in vitro*)
- Mouse lymphoma assay (*in vitro*)
- Comet assay (*in vitro*)



Bioanalysis

WuXi AppTec's bioanalytical team works closely with you to design a fit-for-purpose solution to accelerate your program. Our diverse range of bioanalytical services support discovery, preclinical and clinical phases of development. The bioanalytical strategies are designed to establish and execute the right assays for successful regulatory submission - Investigational New Drug (IND), New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)

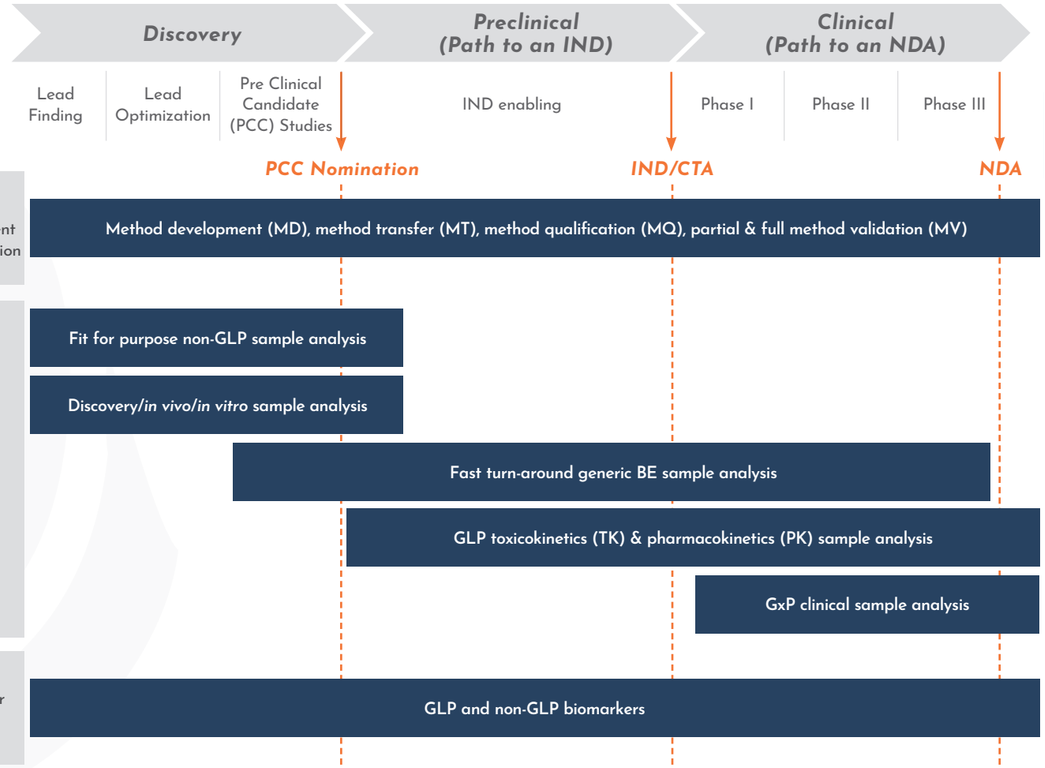
Capabilities at a Glance:

Key Highlights

- Over 200 validated non-proprietary methods
- Over 40 validated new methods for proprietary/innovator molecules each year
- State-of-the-art LC-MS/MS platforms with HPLC and UPLC capabilities
- Over 500,000 sample analysis capacity per year
- Automated high throughput capable systems including Janus® and CyBio®-SELMA
- 21 CFR Part 11 compliant validated systems; Analyst®, MassLynx™, Watson LIMS™

State-of-the-Art Instrumentation to Rapidly Deliver High-Quality Scientific Results

- 70+ LC-MS/MS instruments globally
- SCIEX API Triple Quad™ 4000/5000/5500/6500/6500+ LC-MS/MS
- Waters Xevo® TQ-S LC-MS/MS
- Waters UPLC®/Shimadzu HPLC/Agilent HPLC/Shimadzu UPLC
- Fully automatic LC method scouting system
- PerkinElmer Janus® liquid handling system
- TomTec® liquid handling system

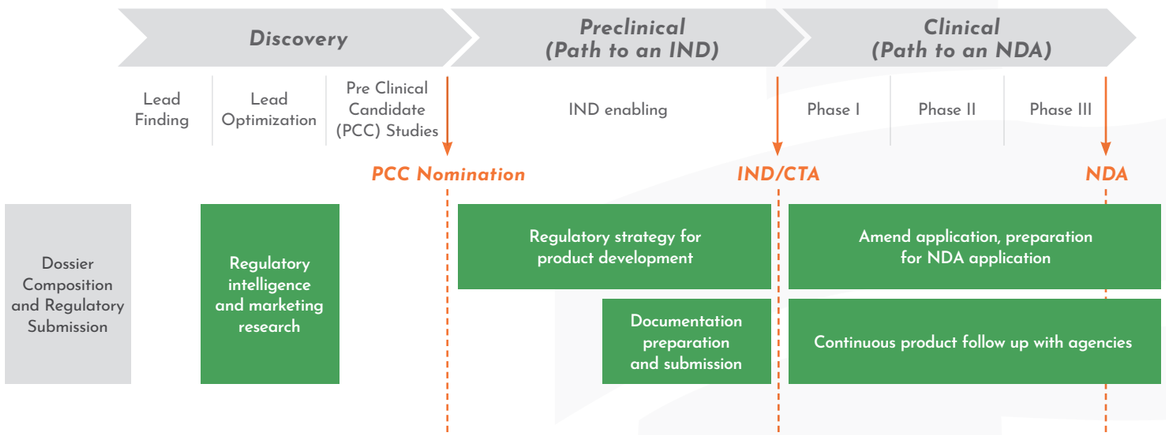


Regulatory Affairs

WuXi AppTec's regulatory team provides you a complete package of services to support global regulatory submission by incorporating internal expertise and partnering with external consultation networks. Our one-stop service can make your global filling convenient, efficient, and cost-effective across the U.S. Food and Drug Administration (FDA), National Medical Products Administration (NMPA), and the European Medicines Agency (EMA).

Capabilities at a Glance:

- Regulatory consultation, project feasibility assessment, product registration strategy, and planning
- Gap analysis based on available dossier information
- Dossier composition
- Communication meetings with different regulatory agencies
- Electronic Common Technical Document (eCTD) submission
- Coordination of on-site inspection
- National Institute for Food and Drug Control (NIFDC) testing progress follow-ups in China
- Annual reports and subsequent supplement submissions
- Other assistance in product registration



Contact Us to Learn More

labtesting.wuxiapptec.com

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