Crystal Bio Solutions

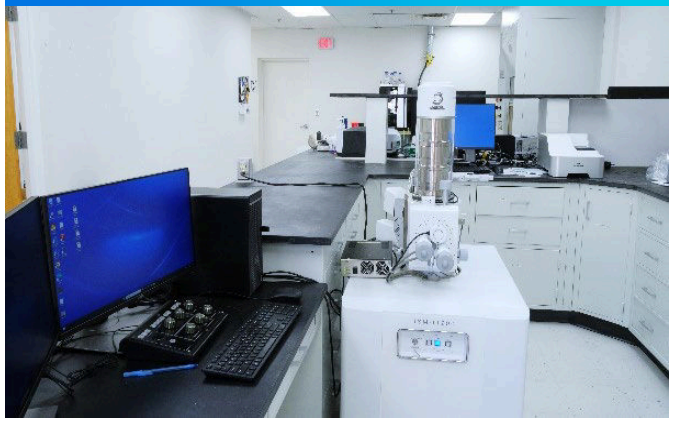
A Member of Crystal Pharmatech

A Premier Provider of Analytical and Bioanalytical Services

About Crystal Bio Solutions

- Crystal Bio Solutions, a wholly owned subsidiary of Crystal Pharmatech Inc., operates the Biologics CMC Analytical Lab in Cranbury, New Jersey, ,and the Bioanalytical and Biomarker GLP Lab in Pleasanton, California.
- The expertise spans a broad range of therapeutic modalities including antibody, bi/multi-specifics, protein, ADC, CGT, mRNA, LNP, nucleotide, vaccine and virus.
- Crystal Bio Solutions is committed to being your trusted partner and providing the highest quality deliverables through sound science and operational excellence.

Cranbury, New Jersey



Pleasanton, California

Core Services

Biologics CMC Analytical Services

- High-resolution Mass Spectrometry
- Product Quality Analysis
- Process Impurity Analysis
- Developability Assessment, Pre-formulation Study for IND Enabling
- Bio-analytics
- Additional Capabilities

Bioanalysis and Biomarker Services

- Immunoassays
- LCMS
- Cell-based Assays
- Flow Cytometry
- ELISpot Assays
- Molecular Biology

Seasoned Leadership Team

Shiaw-Lin (Billy) Wu, Ph.D.

CSO & Head of
the Biologics CMC Analytical Lab

- >30 years of experiences in characterization of complex biologics with various advanced analytical

Meina Liang, Ph.D.

CSO & Head of
the Bioanalytical and Biomarker Lab

- Former AstraZeneca's Global Head of Integrated Bioanalysis
- >30 years of industry experience

Ye Gu, Ph.D

CTO & Head of BD,
Crystal Bio Solutions

- Held pivotal leadership positions in Pharma and Biotech, overseeing process and analytical development and CMC operations
- >16 years in biologics R&D

Competitive Advantages

Comprehensive Expertise Across All Stages of Biologics R&D

We offer a full range of analytical and bioanalytical services, supporting the entire biologics research and development lifecycle, from early-stage discovery through clinical development and commercialization. Our expertise ensures precise data and reliable insights at every phase.

Cutting-Edge Technology and Methodologies

Utilizing state-of-the-art technologies and validated methodologies, we deliver high-quality, accurate results. Our advanced platforms and custom solutions enable detailed characterization and analyses, ensuring regulatory compliance and accelerating time to market.

Tailored, Client-Centric Approach

We take pride in offering personalized service and flexible solutions to meet the unique needs of each client. We collaborate closely with clients to design custom assays and analytical strategies, providing the best outcomes for biologics development.

Proven Track Record of Success

With a reputation for excellence in the industry, We have a history of delivering reliable and timely results to support biologics development. Our team’s deep expertise in analytical and bioanalytical sciences ensures clients receive high-quality data that drives informed decision-making.

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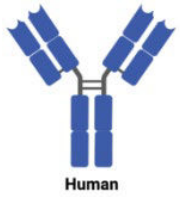
Biologics CMC Analytical Services

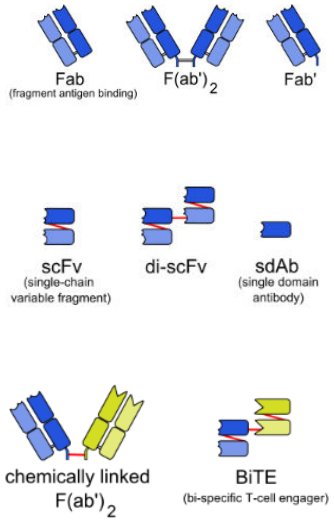
Providing advanced Biologics Analytical Services, facilitating the progression of your biologics from discovery to the clinic

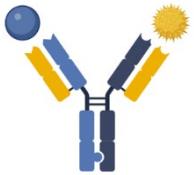
Biologics CMC Analytical Services

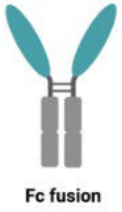
Biologics CMC Analytical Lab, operates a cutting-edge 5,300 sq.ft lab in New Jersey. We provide **advanced analytical services** for biotech and pharma companies developing biologics. Our expertise spans a broad range of therapeutic modalities including antibodies, bi/multi-specifics, proteins, ADCs, mRNA, LNP, and nucleotides, supporting projects from discovery to the clinic.

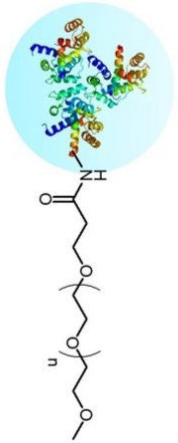
Monoclonal Antibodies	Antibody Fragments	Bispecific Antibody	Fusion Protein	PEGylated Protein	Antibody Drug Conjugate	Other Proteins and Peptides	DNA, RNA LNP











Cytokines

Growth factors

Enzymes

Polypeptides

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Phase-Appropriate Analytical Strategies in Biologics Development

Biologics Discovery

- **High throughput screening**
- **Candidate specific analysis: initial developability and risk assessment**
  - Candidate characterization
  - Accelerated stability
  - Forced degradation
  - Function evaluation
  - Serum stability
- **Additional tests:**
  - Reagent QC
  - De novo sequencing
  - Epitope mapping
  - Immunogenicity assessment

Preclinical Development

- **Lead candidate analysis including comprehensive developability assessment for IND enabling**
  - In-depth characterization
  - In-process analytical
  - Stability assessments
  - Pre-formulation / formulation
  - Bioassay development
  - Pharmacokinetics
  - Immunogenicity
  - PD, biomarker verification, dose response
- **Release method development /Tech Transfer**
- **Additional tests to support:**
  - Clone selection
  - Cell line stability

Clinical Development

- **Clinical molecule analysis for BLA submission**
  - Extensive characterization
  - Comparability analysis
    Real-time/ accelerated stability
    Serum stability
  - Gap analysis
    Biotransformation/ *in vivo*
    CQA
  - Clinical PK/PD, ADA

Launch and Beyond

- **Post-marketing commitment analysis**
  - ADA monitoring
  - Failed lot characterization as needed
  - Lot release method refinement as needed

Advanced Biologics Analytical Services

We understand the importance of meeting your demanding project deadlines with **excellence, speed, and flexibility**. Our team of subject matter experts is strategically positioned in both NJ and Boston, ensuring **local access** for your projects.

High-resolution Mass Spectrometry

- **CMC**: Experts in BLA filings for drugs at biophysical/chemical section using LC-MS under regulatory guideline for drug approval with several large pharma
- **Preclinica**l: Experts in candidate characterization, accelerated stability, serum stability and in-vivo CQA analysis to assure drug candidate selection in pre-clinical stage
- **Clinical**: Extensive experience in gap analysis of CMC issues related to clinical development

Process Impurity Analysis

- Capable of utilizing both analytical and bio-analytical tools to address residual chemical, formulation components stability, bacterial/virus, or protein-related compounds for safety concerns, with rational selection of reliable assays under regulatory guideline as going forward

Bio-analytics

- High-sensitivity, high-accuracy quantitative analysis to support bioactivity, PK/PD, bio-contaminants, safety testing

Developability Assessment, Pre-formulation Study for IND Enabling

- Strategic designing and generating work package utilizing analytical and biophysical tools to study accelerated and stressed stability of lead candidate for risk assessment

Product Quality Analysis

- Rationally combined both analytical with various biophysical/chemical tools and bio-analytical with various bioassay tools for structure and structure-function characterization

Additional Capabilities

- Versatile with flexible adoption of existing methods to address different modalities such as ADC with novel conjugated combinations, mRNA & LNP
- Strong troubleshooting skills in resolving challenging analytical issues and addressing complex modalities

Broad Applications of High-Resolution Mass Spec

In-depth characterization

- PTMs
- S-S scrambling
- Sequence variant
- Impurities such as HCP

Intact molecular weight analysis

- HMW species / Native MS
- LMW species
- Glycoprofiling
- High-level PTMs

Serum stability, Biotransformation

- *In vitro* or *in vivo degradation*

PK/PD

- Quantitative bioanalysis
- ADA study
- Dose response analysis
- Biodistribution

Target and Biomarker verification

- Proteomics
- Protein and isoform identification

mAbs *de novo* sequencing

- HMW species / Native MS
- LMW species
- Glycoprofiling
- High-level PTMs

Hydrogen-deuterium exchange (HDX) MS

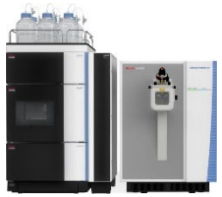
- Epitope mapping
- High-order structure

MHC-associated Peptide Proteomics (MAPPS) assay

- Immunogenicity assessment

** Advanced LC-MS techniques and phase-appropriate applications across the entire process of biologics R&D*

Analytical Instruments



Orbitrap LC-MS

Agilent 1260/1290 Infinity II Bio-inert

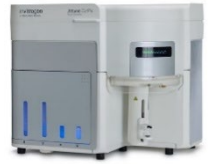
Sciex CE-SDS

Maurice icIEF

Shimadzu FTIR with ATR

Shimadzu UV-Vis

RT-PCR



Flow cytometer

Octet RED96e

DLS

TA Nano-DSC

Beckman SV-AUC

Chirascan V100

Varioskan plate reader

Plate Washer

Microscope

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Bioanalysis and Biomarker Services

Bioanalysis and Biomarker Services that Support Every Drug Development Phase

Bioanalysis & Biomarkers

With more than 100 years of combined industry experience of our leadership team and GLP compliant laboratories, we are ready for all your current and emerging bioanalytical needs.

- ☐ **Immunoassays**
- ☐ **LCMS**
- ☐ **Cell-based Assays**
- ☐ **Flow Cytometry**
- ☐ **ELISpot Assays**
- ☐ **Molecular Biology**

Pharmacokinetics (PK)

- Immunoassay; ECL
- LC-MS/MS for ADC
- In vitro ADME
- GLP nonclinical & clinical sample analyses

Immunogenicity (ADA)

- Anti-drug Antibody
- Neutralizing Antibody
- Immunogenicity Assessment
- Integrated Summary of Immunogenicity (ISI) for BLA

Pharmacodynamics (PD)

- Receptor Occupancy
- ADCC, complement system, Cytokine release
- Inflammation-related biomarker/tumor marker
- Signal pathway/transcription factors/physiological activity of cells
- Screening biomarker

Informed Bioanalysis of Biomarkers

We perform in-house GLP and GcLP sample analysis with optimized methods targeted to your compound needs. To ensure that biomarkers are decision-making for drug development, we deliver not only method and data, but also strategy and data interpretation in collaboration with our clinical research and PKPD modeling teams.

Comprehensive Immunogenicity Assessment to Support Drug Approval

Customized Assay Development

Several Steps Ahead

Global Bioanalysis and Biomarkers Services

Discovery & Preclinical	IND	Clinical Development (Phase I, II & III)	NDA/BLA	Post-marketing

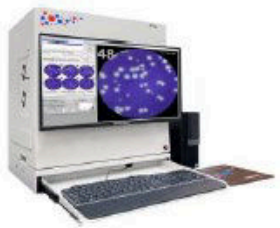
Discovery & Preclinical Strategy	PK	ADA	NAb	Cytokine release risk assessment	Biomarkers (PD, safety, CDx)	Discovery and regulated (GLP, GCP, CLIA)	Regulatory interaction, e.g.- ISI in 2.7.2.4 & 2.7.1

- Extensive experience in **drug development and regulatory interaction** across multiple therapeutic areas
- Track record in **design of bioanalysis and biomarker strategy,** successfully supporting drug approval
- Expertise in **broad drug modalities,** e.g., small molecule, mAb, fusion protein, enzyme, peptide, ADC, cell and gene therapy, oligonucleotide, vaccine, etc..
- Expansive understanding of **Integrated summary of Immunogenicity (ISI)**
- Specialized central laboratory services
- Strong knowledge in **Compliance** and experience in **regulatory inspections**

Laboratory Capabilities


MSD S600


Cytek flow cytometry


ELISpot


LCMS/Sciex 7500+


ELISA


ddPCR


qPCR (ABI Q7)

Multiplex


CytoFlex

※ Immunoassays

- ELISA, MSD, Gyrolab, Luminex, SPX
- Multiplex & Ultra-sensitive
- Ab, protein, oligonucleotide
- Biomarker, cytokines, novel drug delivery

※ Cell-based Assays

- Synergy, multifunction reader
- Nab, biomarker

※ LCMS

- Sciex 7500+, HRMS, TOF
- ADC, peptide, oligonucleotide and SM, metabolomics, proteomics

※ Molecular Biology

- qPCR, ddPCR, NGS, Nanostring
- Cell and gene therapy, vaccine, ModRNA
- Gene editing, biomarker

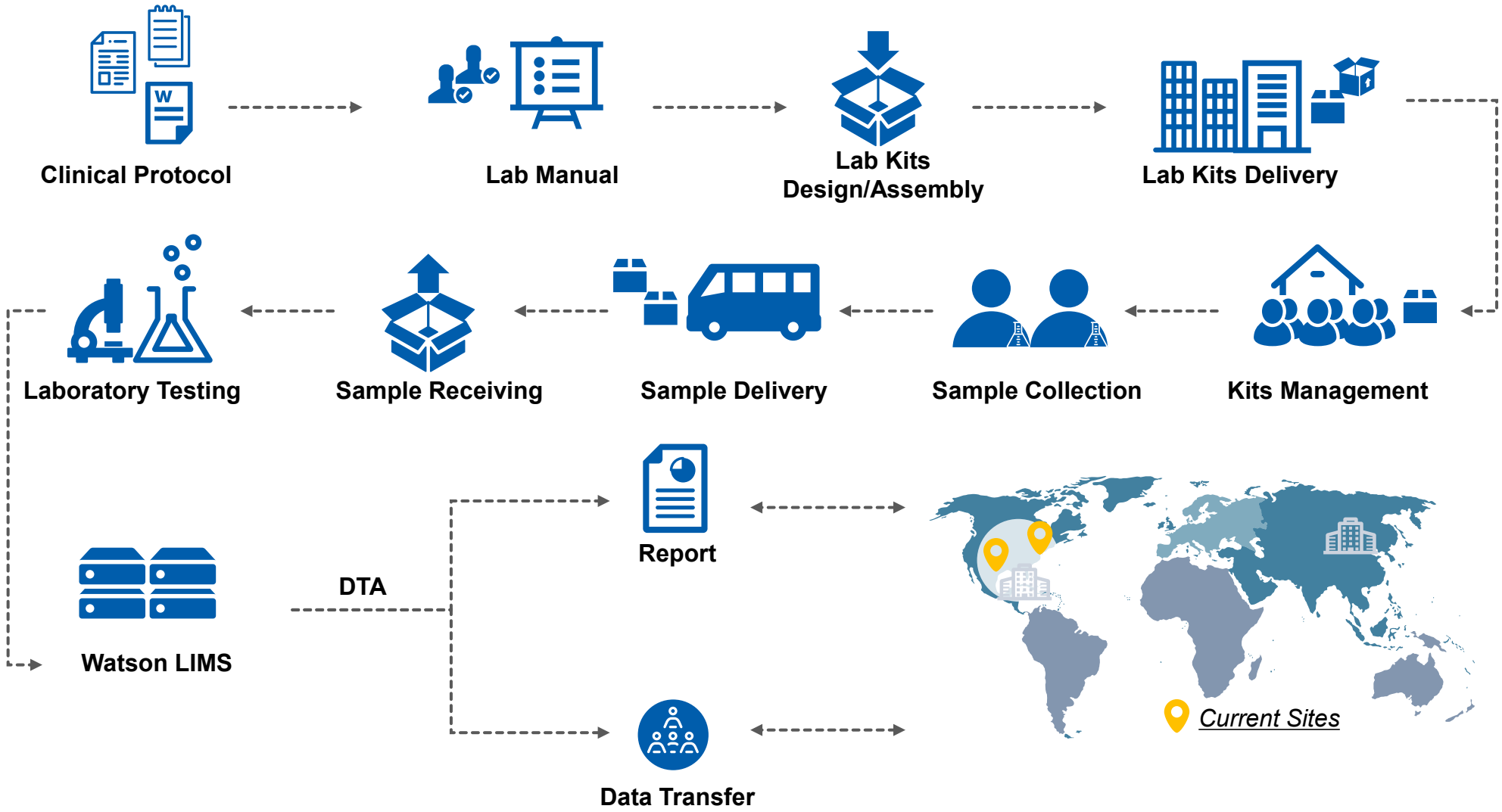
※ Flow Cytometry

- Cell therapy
- Biomarker, eg RO, immunophenotyping

※ ELISpot

- Cellular immune response
- Vaccine, biomarker

Central Lab Services



Notes: The central laboratory services on this page refer to the upstream and downstream centralized laboratory services around bioanalysis, excluding clinical examination and pathology for the time being.

Global Regulatory Submissions

With highly experienced regulatory experts in the United States, Europe, and China, we are an extension of your regulatory team. Let us streamline your product development with cutting-edge regulatory strategies, author your important regulatory documents, and manage interactions with regulators for a smooth development process.

IND/CTA Preparation

Enable Marching to IND/ CTA Milestones

- Gap analysis / feasibility analysis
- Due diligence/license-in assessment of data quality
- Fastest market registration strategy of compliance in the us, CN and EU
- Strategies cut out for the clinical development in the us, CN and EU.
- Scientific Advisory (SA) background information
- Pre-IND meeting preparation and communication

IND/CTA

Facilitate Products Entering the Clinical Trial

- Drafting, publishing and submitting IND/CTA in the US, CN and EU
- CMC, nonclinical and clinical support complying the US, CN and EU requirements
- EOP1/EOP2 briefing material preparation
- Assist with regulatory agency meeting preparation and presentations

NDA/BLA

Bring Products to Success

- Quality control and management of registration documents
- Pre-BLA/Pre-NDA/NDA/BLA/MAA preparation and submission
- CTD/eCTD format document preparation and submission in the US, CN and EU
- Bilingual support for the US, CN and EU filing
- Regulatory agency negotiation
- 200+ successful cases

Quality Management System

SOP System Development & Management

- General/QA SOPs
- Function specific SOPs
- English & Chinese versions

Global Company Policies

- Data Protection & Privacy
- Confidentiality & Personal Information
- Ethical Responsibility
- Employee Handbook

Audit Management

Internal, external & vendor audits

- Virtual & onsite audits
- Written responses
- Successfully completed 20+ vendor qualification audits
- Leading biopharma & MNC

Development & Management of Controlled Documents

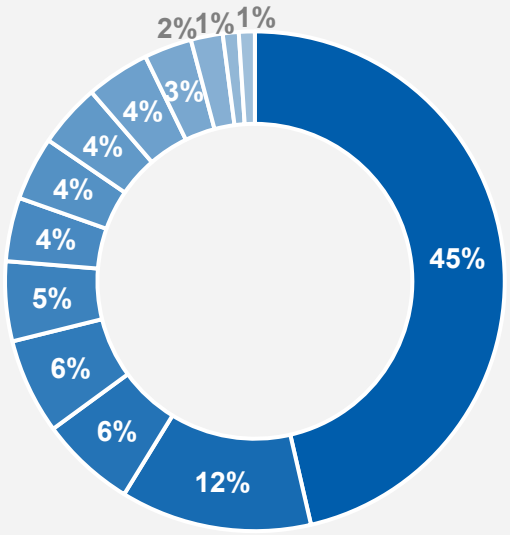
- Forms & templates
- Working practices
- Quality control related documents

Management of Training Records

- Personal and Group Training
- Electronic Archival & Retention
- Annual Updates of CVs and Job Descriptions

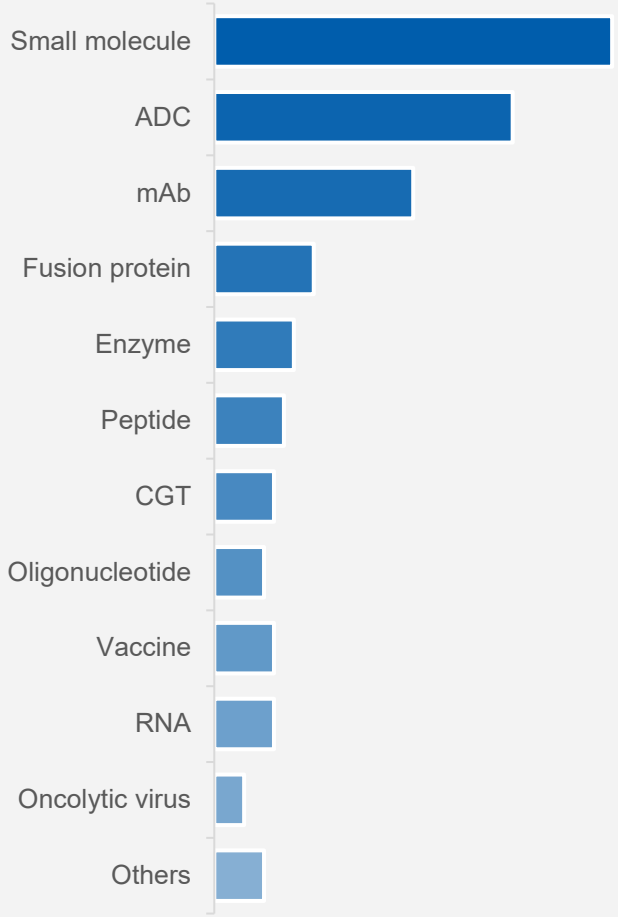
Project Experience

Indications

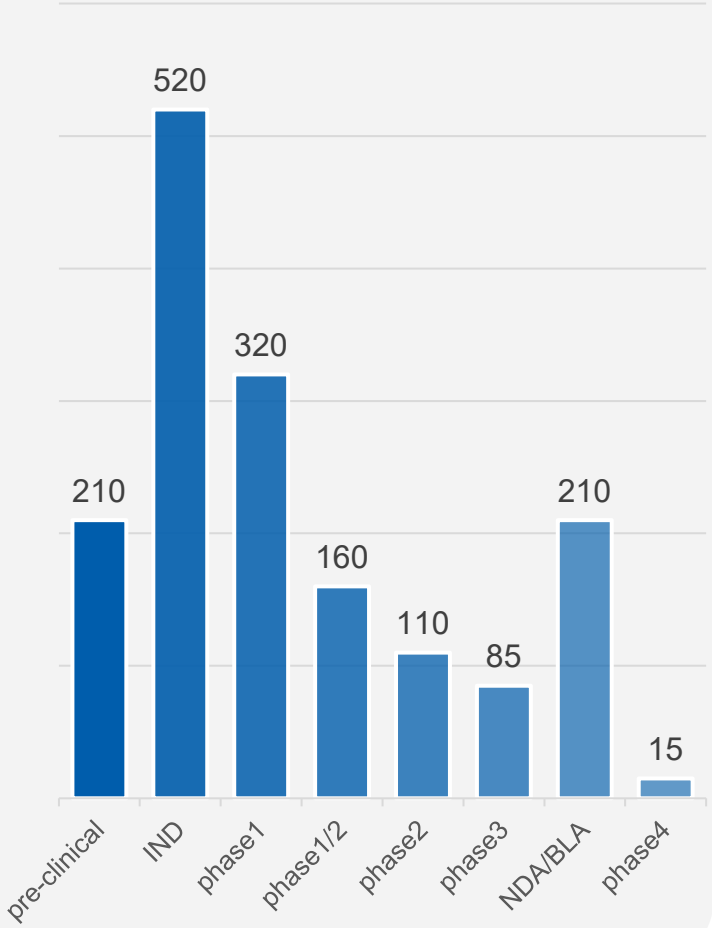


- Oncology
- Immunology
- Respiratory
- Endocrinel
- Rheumatology
- CNS
- Cardio
- Infectious disease
- Hematology
- Analgesic anesthesia
- Digestive
- Gynaecology
- Others

Modalities



Project experience



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Contact us

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