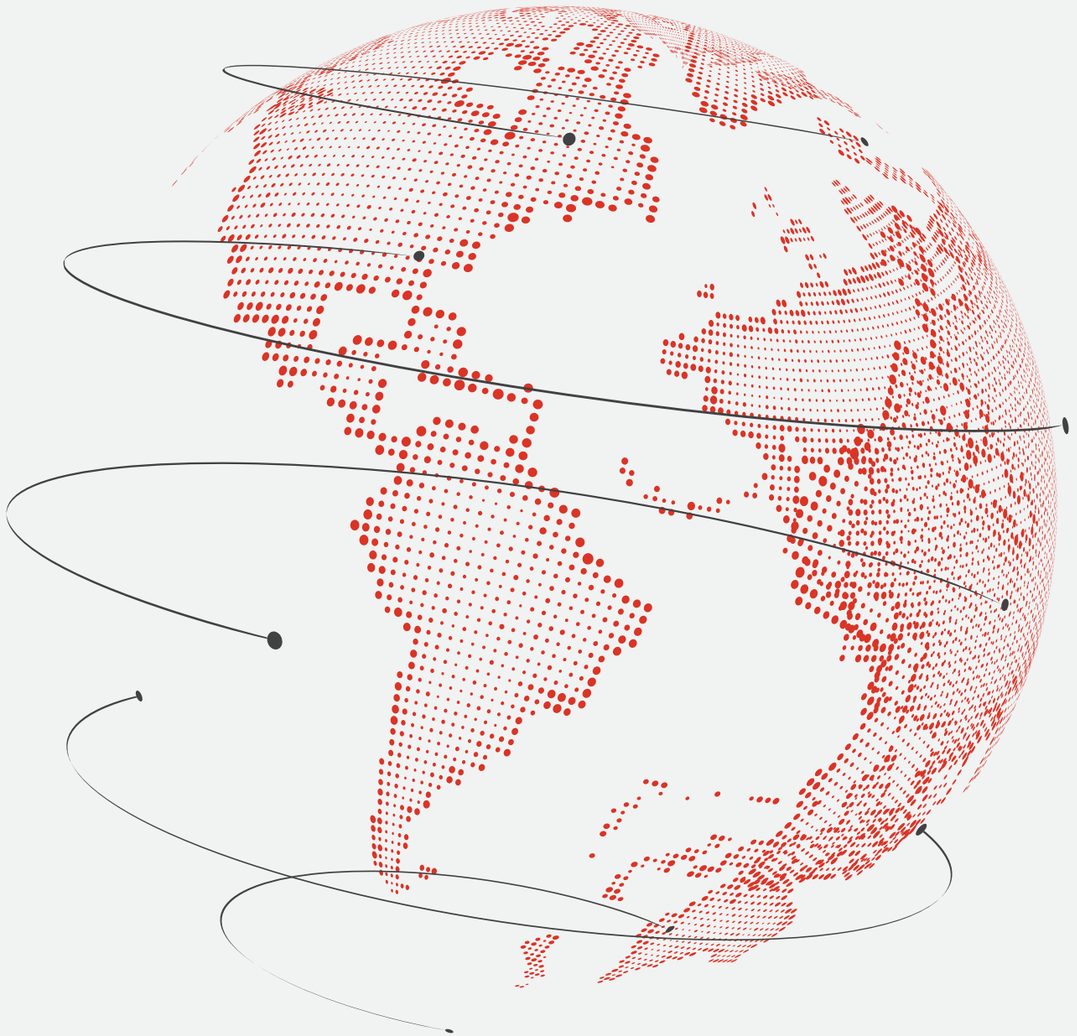
ADVITY®

ADDING
VALUE
WITH
INTEGRITY



Our Saying ... ADDING VALUE WITH INTEGRITY ...

At ADVITY Research, we understand the importance of ADDING VALUE while upholding the highest standards of INTEGRITY.

Partnership Approach

We view ourselves as your strategic partner, tailoring our services to meet your specific needs.

Technology Integration

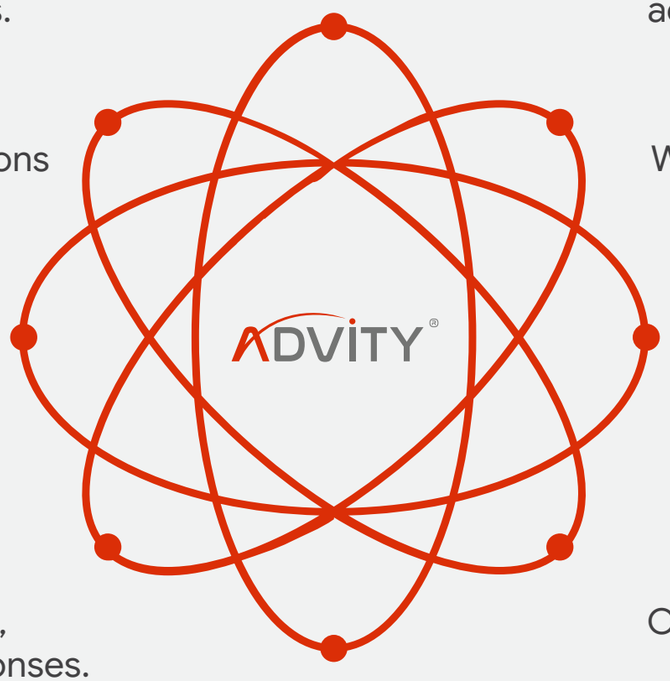
We embracing the technology-driven solutions lead us to more successful and impactful clinical research outcomes.

Scientific Excellence

We uphold the highest scientific standards, employing rigorous methodologies and innovative approaches.

Transparent Communication

We maintain open and clear communication, providing regular updates and prompt responses.



Ethical conduct

We prioritize participant safety and well-being, strictly adhering to ethical guidelines and regulations.

Quality Assurance

We ensure reliable and accurate data through robust quality control measures.

Regulatory Compliance

We navigate complex regulatory landscapes to ensure full compliance with global requirements.

Experienced Professionals

Our skilled team brings expertise and valuable insights to your trials.

Quality Policy

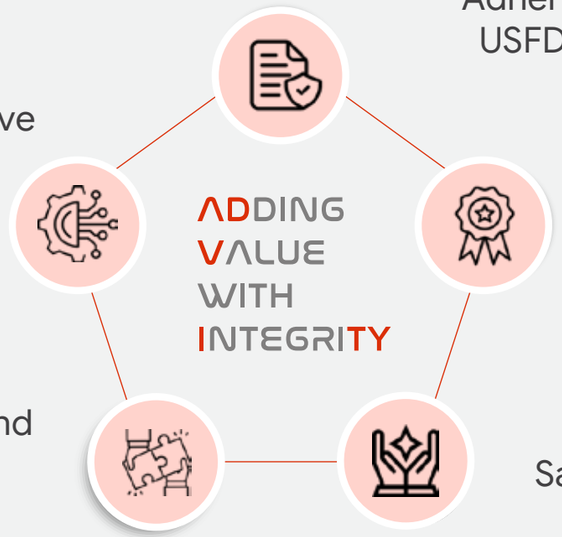
At ADVITY RESEARCH, we are dedicated to "ADDING VALUE WITH INTEGRITY" in all our clinical research endeavors.
Our Quality Policy focuses on:

Encouraging Innovation:

Cultivating an innovative environment to improve clinical research processes.

Fostering Collaboration:

Working closely with sponsors, investigators, and patients to foster transparency and trust.



Ensuring Compliance:

Adhering to regulatory requirements set by ANVISA, USFDA, EMA, and other relevant bodies to maintain integrity in compliance.

Promoting Excellence:

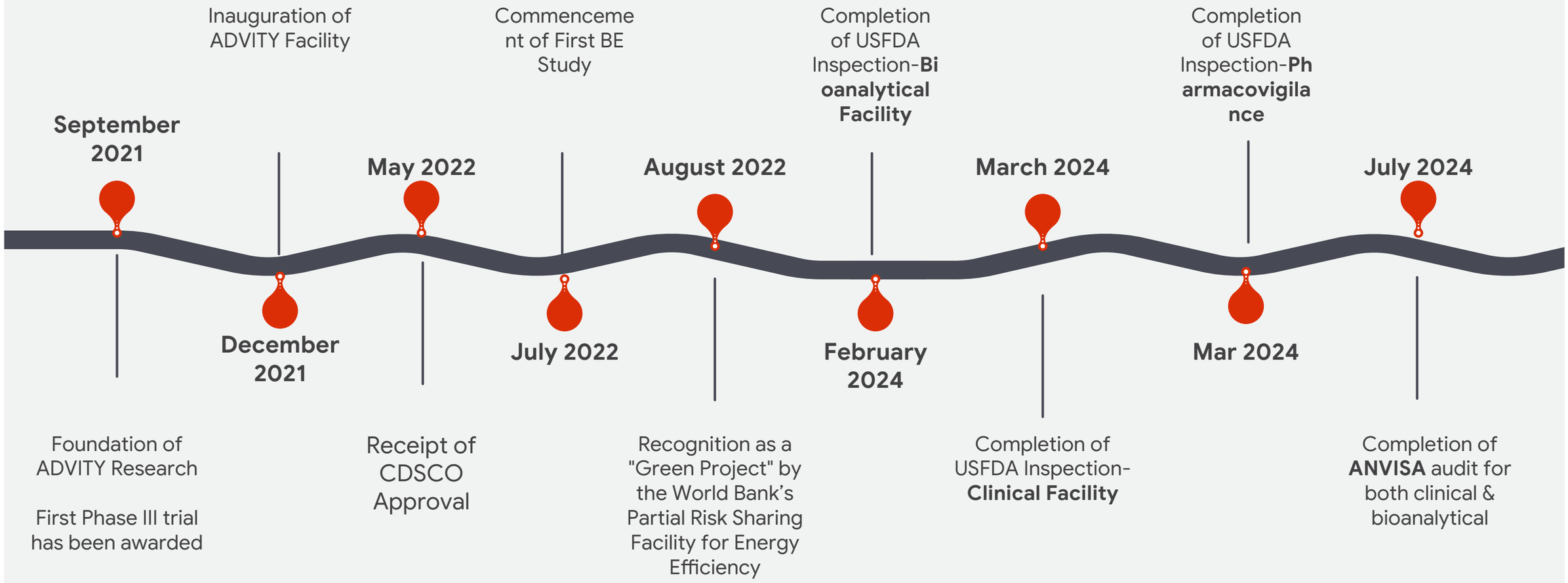
Continuously enhancing our Quality Management System (QMS) and upholding data integrity to excel in our research efforts.

Prioritizing Patient Safety:

Safeguarding the rights and well-being of study participants/clinical trial participants through unwavering commitment to safety.

This policy undergoes regular review to ensure its alignment with our operations, meeting the needs of clients & regulatory authorities.

Milestones achieved as on Date



Board of Directors

	 **Dr. Rajendra Prasad** Managing Director & CEO	 **Ravi Kumar G** Executive Director & CFO	 **Vasudev Sureddy** Executive Director & COO	 **Kalyan Reddy** Director Clinical	 **Sunil Sirigiri** Director Bioanalytical
Responsibilities	• Oversee the strategic direction of organization • Monitor company performance • Maintain accountability with the board • Quality Management	• Financial Controller • Corporate functions	• Designing & implementation of business operations • Business Development • Overseeing operations of the company and the work of executives	• Clinical Operations	• Bioanalytical operations
Reporting Teams	• Board • All functional & non functional heads • QA • Compliance department • IT	• HR • Finance • Accounts • Purchase • IPR • Admin	• All functional heads • Business development team	• Clinical team – BA/BE & Clinical trial team	• Bioanalytical team

Aligned & Driven Leadership

Dr. Rajendra Prasad M
Managing Director & CEO

Raja Agnihotri
Chief Strategy Officer

Rama Raju
Chief Compliance officer

Ravi Kumar G
Executive Director & CFO

Dr. Rajendra Prasad M
Managing Director & CEO

Gopikrishna K
Head QA

Kalyan Reddy
Director Clinical

Sarva Raidu
GM Pharmacovigilance

Sunil Sirigiri
Director Bioanalytical

Dileep Kumar
Sr. Manager BD & PM

Range of Services

Drug Development Cycle

Target Discovery, Lead Identification – **Preclinical** – **PHASE-I** – **PHASE-II** – **PHASE-III** – **Post Marketing**

Healthy Participants & Patient PK studies	**Regulatory Writing**: (Protocols & Related Documents, Aggregate Reports, RMPs, Clinical & Non Clinical overviews
Clinical End Point & DDI Trials	**Clinical Trial Management:** From Phase IIB to IV (Execution & Monitoring)
Clinical Trial: QA/QC Monitoring Services	
Biometrics: (PK & Statistical Analysis, Clinical Data Management)	
Bioanalytical Support: (Small & Large Molecule Analysis)	
Glucose Clamping Studies	**Drug Safety/Pharmacovigilance** Support (Clinical Vigilance & Post-marketing Vigilance)

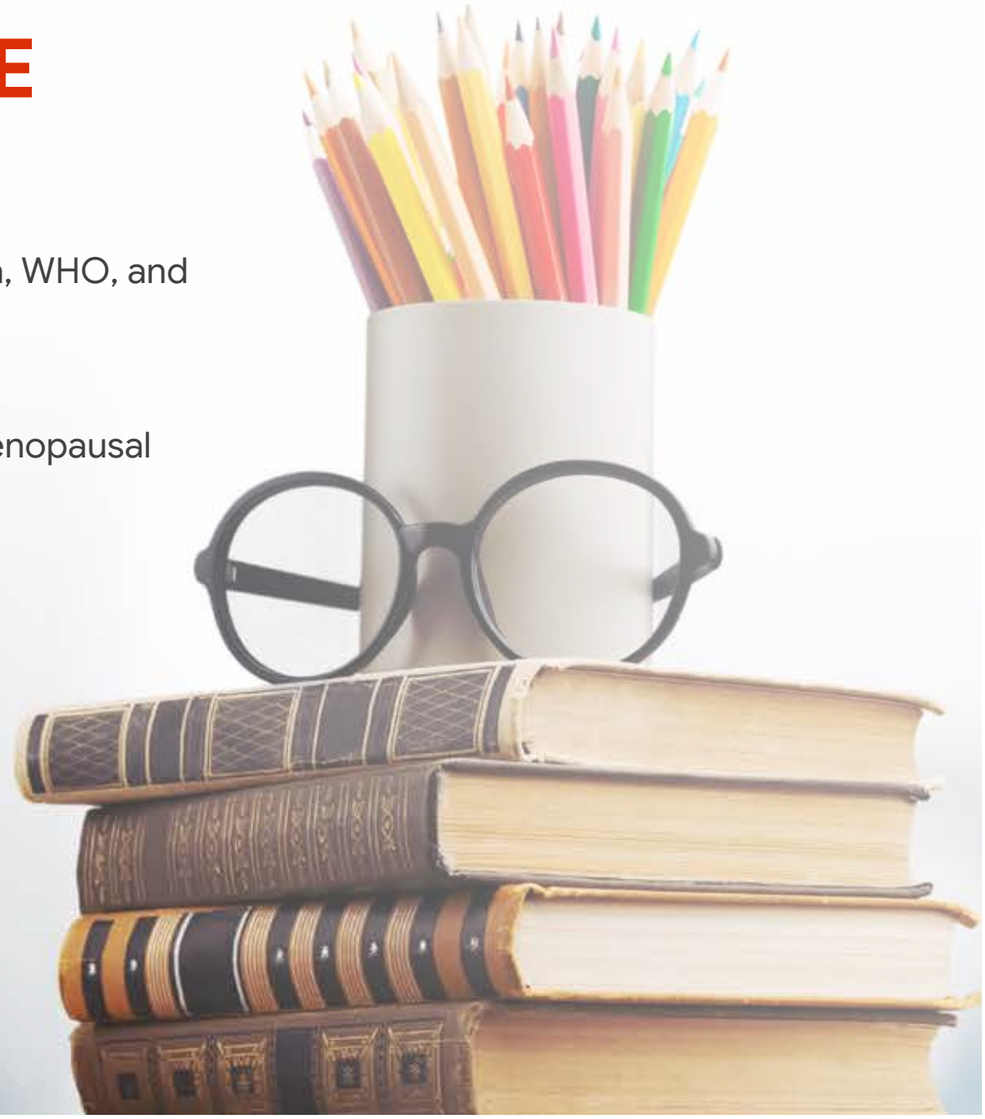
BIOAVAILABILITY & BIOEQUIVALENCE SERVICES

At ADVITY, our Bio Studies portfolio includes BA/BE Studies, Phase I Studies (conducted in healthy volunteers and special population) and PK / PD & Patient Studies (conducted in special populations).

Our BA/BE Studies Services – Fully Compliant with International Regulatory Requirements

Key Highlights as on Date – BA/BE

- **Biostudies:** Completed approximately 60 biostudies within 2 years.
- **Regulatory Markets:** Conducted studies for USFDA, EU, Health Canada, WHO, and ROW markets.
- **Audits:** Successfully completed USFDA and ANVISA audits.
- **Study Subjects:** Conducted studies on normal healthy subjects, postmenopausal women, and healthy female subjects.
- **Special Studies:**
  - ⋆ Completed two transdermal skin patch studies,
  - ⋆ One vaginal insert study,
  - ⋆ Amphotericin B clinical study and 05 more studies on injection dosage forms,
  - ⋆ Biologic: Completed, Liraglutide & Rituximab for the India market.
- **Glucose Clamping Studies:** Completed two insulin BE studies for the Indian market.



Team Experience & Expertise

5,000+

Experience in with execution of more than 5000 + **PK Studies** which includes BA/BE studies in healthy and patient subjects

60+

Team has successfully faced more than **Global Regulatory audits**. (USFDA, EMEA, UKMHRA, ANVISA, GCC, TGA, Canada, MCC, NPRA, TGA, MOH Turkey) in their prior experience

800+

Hands on experience with 800+ **analytical methods** which including complex, low sensitive molecules (Pg/mL) and NCEs

200+

Working experience with more than 200+ **pharma and biotech** companies located across the globe, including large pharmaceuticals

3500+

Experience in execution of more than 3500+ clamps and a well established **Glucose clamping facility** with an experience in execution of more than

Team has experience in handling various **Complex Dosage forms**, Studies with Special population, Various routes of administration, Long washout and prolong housing studies

Comprehensive Services

- BA/BE Studies:
  On healthy subjects & patients
- PK/PD & Clinical end point studies
  on healthy subjects & patients
- Studies on special populations:
  Healthy female, PMW & elder subjects
- Proof-of-concept
  studies (PK Studies)
- Glucose
  Clamping studies
- Derma Studies –
  Skin Patches
- Extensive cardiac
  monitoring studies
- Palatability
  evaluation studies
- Medical writing services:
  Protocol development, ICD, ICF
  and Clinical study reports
- Bioanalytical services: For
  small & large molecule analysis
  and elemental analysis
- Pre-clinical PK
  sample analysis
- Pharmacokinetic &
  Biopharmaceutics
- Statistical analysis and
  Population BA/BE analysis
- Data Management &
  CDISC services

Infrastructure

State-of-the-art BA/BE facility spread over 28,000 sq.ft.

Well connected to all major parts of the city

94 beds spared over 04 clinical wards

05 ICU beds

Collaborated with the Tertiary Care Hospital (150 bedded super specialty hospital) for handling emergency situations

Associated with NABL accredited clinical path labs

Pharmacy area: Humidity chamber and Cold chamber

A comprehensive emergency in house response infrastructure in place

- 07 LC-MS/MS are on board.
- 5: API 4500 & 02: API 6500
- Capacity to accommodate 11 LC-MS/MS

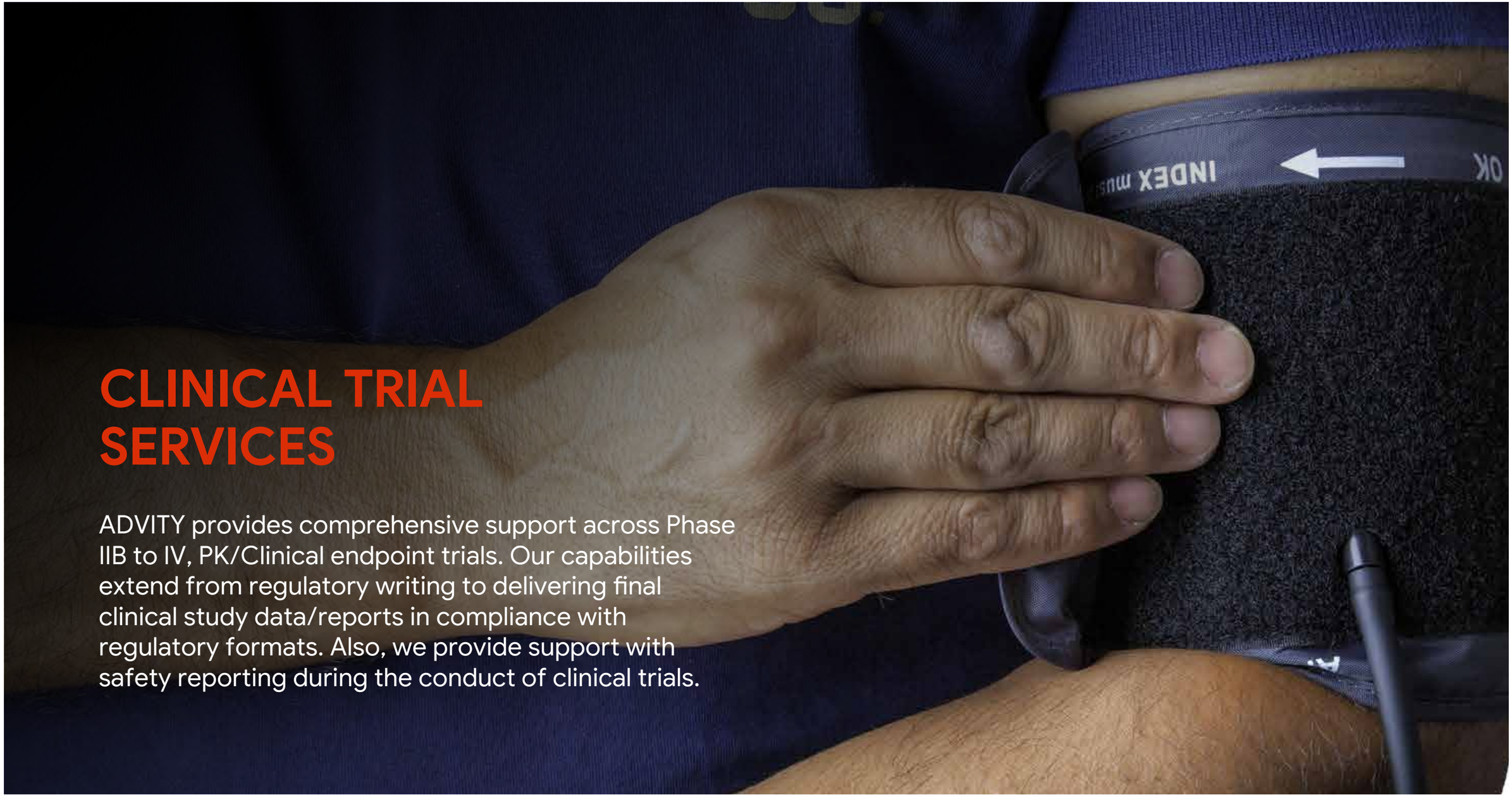
Provision for large molecule analysis (Ligand binding assays) using ELISA

A comprehensive emergency in house response infrastructure in place

Archrivals area

IT: SonicWall (Fire wall), Dell server with RAID-5 Configuration, NAS storage with RAID-5 Configuration, Kaspersky Antivirus

SAS Ver 9.4 fully validated



CLINICAL TRIAL SERVICES

ADVITY provides comprehensive support across Phase IIB to IV, PK/Clinical endpoint trials. Our capabilities extend from regulatory writing to delivering final clinical study data/reports in compliance with regulatory formats. Also, we provide support with safety reporting during the conduct of clinical trials.

Clinical Trial Services at ADVITY

Extension

The clinical development team at ADVITY serve as an extension of your clinical program, sharing your commitment and values

Quality

Our rapid engagement and strategic thinking ensure more efficient start-up times and superior quality data across all phases of clinical trials (phase I to IV)

Integrity

We instill the motto "ADDING VALUE WITH INTEGRITY" as part of our daily routine, to emphasize our commitment to ethical clinical research

Scope of Services

Clinical Site Management

- Study start up & Feasibility
- Patient recruitment

Clinical Project Management

- Trial, Site, Patient Management, CTMS
- In-house & On-site Monitoring Management

Regulatory writing & Consultancy

- Protocol & related documents
- Clinical study reports
- Safety Aggregate reports
- Consultancy support

Drug Safety Services

- Post marketing safety services
- Clinical vigilance

Clinical Trial Monitoring

- QC monitoring services
- QA monitoring services

Biometrics (Full Digital)

- Clinical Data Management
- PK and Statistical analysis & CDISC

Project completed/ under progress

Phase III

One Phase III trial completed (Nutraceutical product).

120 subjects

Therapeutic segment: Osteoarthritis

One Phase III trial is currently in progress.

Therapeutic segment: Endocrinology

Recruitment has been completed with 240 subjects across 15 sites in India. Treatment phase is ongoing, with a study completion in April 2025.

Patient PK study

One patient PK study is currently in progress

Therapeutic segment: anti-psychotic

Sample size is 42.

Regulatory & EC approvals in place

IMP receipt & distribution in process

Planned study completion by Dec 2024

Under FSP model

Support provided one of Patient PK study for 100% QC monitoring of study activities

Therapeutic segment: anti-psychotic

Sample size: 320 and study has conducted across 13 sites across India

Status completed

Biologics/Biosimilars

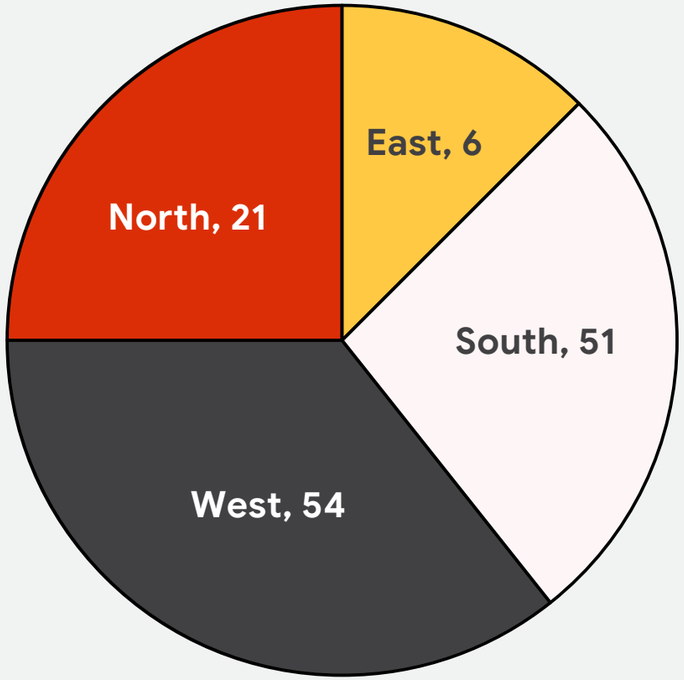
Executed 03 Phase I studies in metabolic & endocrinology

Two insulin products (ASPART & Glargine) and Liraglutide

PK sample estimation in Rituximab Phase III study which also covers immunogenicity.

Clinical Sites database

Zones



- Feasibility assessments from various sponsors have been received for all the therapeutic segments mentioned above.

Therapeutic Segment

Autoimmune: 31	Ophthalmology: 31	Oncology: 17
Endocrinology: 15	Genitourinary: 2	Antipsychotic: 16
Dermatology: 5	Others*: 38	

- CDAs with the clinical investigators have also been signed for all the segments and zones listed.

Team Experience

Molecule	TA	Type of study	No. of studies done	Market
Temozolomide	Oncology	Patient BE	1	US
Imatinib	Oncology	Patient BE	4	US
Sunitinib	Oncology	Patient BE	3	US/EU
Melphalan	Oncology	Patient BE	2	US
Methotrexate	Oncology	Patient BE	2	US
Capecitabine	Oncology	Patient BE	3	US
Everolimus	Oncology	Patient BE	1	US
Adalimumab	Autoimmune	Phase III	1	EU
EsloMet	Cardiology	Phase IV	1	India
Rabies Vaccine	Vaccine	Phase IV	1	India
Insulin	Endocrinology	Phase III	1	India
Clozapine	Schizophrenia	Patient BE	2	US
Palmitoylethanolamide	Pain (Nutraceutical)	Phase III	1	India
Capecitabine	Oncology	Patient BE	1	EU
BIOCHAPERONE PDGF-BB	Diabetic foot ulcers	Phase III	1	EU
Quetiapine	Mental health	Patient BE	2	US/EU
Lenalidomide	Autoimmune	CEP	1	EU
Pazopanib	Oncology	Patient BE	1	US/EU

Molecule	TA	Type of study	No. of studies done	Market
Daunorubicin	Oncology	Patient BE	1	US/EU
Molnupiravir	Infectious	Patient BE	1	US/EU
Nevirapine	Infectious	Patient BE	1	US/EU
Amphotericin B	Infectious	Patient BE	1	US/EU
Stents	Cardiology	Phase III	11	ROW/DC
Denosumabin	Oncology	Patient BE	1	GI
Entecavir	Infectious	Patient BE	1	US/EU
	Autoimmune		1	US/EU
Estrogen Cream	Women health	Patient BE	1	US/EU
Rifaximin IBS	Infectious	Patient BE	1	US/EU

PHARMACOVIGILANCE SERVICES

Our pharmacovigilance team support post-marketing safety surveillance and clinical trial and across the globe. As patient safety as the critical component, our quality focus aligns us to collaborate with Pharma and Biotech companies to provide both standalone and integrated services throughout the lifecycle of a product.

Capabilities – in a Glance

Comprehensive Services

PV System setup & Integration

- PV Database : Setting up and hosting of database & management
- Migration of cases
- Legacy Data Migration
- SDEA (Co-licensing, Third party Manufacturer/Distributor, Piggy back ..etc)
- PSMF
- Support with third parties and Channel Partners
- **PV** consulting involving SOP development, quality systems and strategic consulting
- **System Audits**

Expedited & Periodic Safety Reporting

- End to end ICSR case processing including electronic transmission
- Dedicated clinical trials team with experience processing cases from early dose determination studies to advance phase 3 clinical trials
- Integrated PV and Medical information (MI) response centers
- Medical review case assessment
- Global literature monitoring
- Aggregate report preparation and compilation (PSURs, PBRERs, PADERs, CASRs, DSURs etc)

Safety Surveillance & Risk management activities

- End-to-end signal management activities
- Routine risk monitoring activities
- Preparation and review of RMP,
- MAH oversight and support including training, SME review and gap analysis of Risk Management Measures

Capacities & Achievements as on date

USFDA	Process, System, Database, Team were audited by USFDA. Audit successful with no observation
MICC	As of now, average handling more than 1,000 calls/month
2500+	ICSR cases have been processed as on date
20+	Our PV services is audited by more than 20 companies with product range from generics to Complex generics
500	500 cases can be handled with the current capacity.
REG.	Handling pharmacovigilance activities to products marketed in Australia, Health Canada, and other Global markets beyond the US and EU.
200	Safety and aggregate reports (PADERS/PSURs) developed as on date
TEAM	Team consists of over 40 professionals, and we are continuously expanding by adding more professionals.
MICC	Medical information call centre, Handling MICC for EU region in English, French , Germany & Spain languages .
Other	Executing timebound case migration of high volume

Team Experience

TEAM @ ADVITY

- Experienced
- Reliable
- Agile & Adaptable
- Know the Challenges

TEAM EXPERIENCE IN DELIVERABLES

- 16+ Experience
- 800+ ANDAs handled
- 450+ MAs handled
- 30000+ ISCRs processed
- 8000+ PADERs
- 1000+ PBRERs/PSURs
- 300+ ACOs
- 200+ RMPs
- 1000+ Signal reports
- 300+ SDEAs

REGULATORY EXPERIENCE

U.S. FOOD & DRUG ADMINISTRATION · CBG MEB · Infarmed · Health Canada · AIFA · ANVISA · European Medicines Agency · MHRA · ansm · Medicines Authority

BIOANALYTICAL SERVICES

ADVITY provides quality services for pharmacokinetic, immunogenicity, and large molecule analysis, leveraging a diverse array of platforms for both small and large molecule analysis. Our bioanalytical procedures adhere to GLP requirements, and we foster cross-functional team collaboration to ensure the swift analysis of time-critical samples.

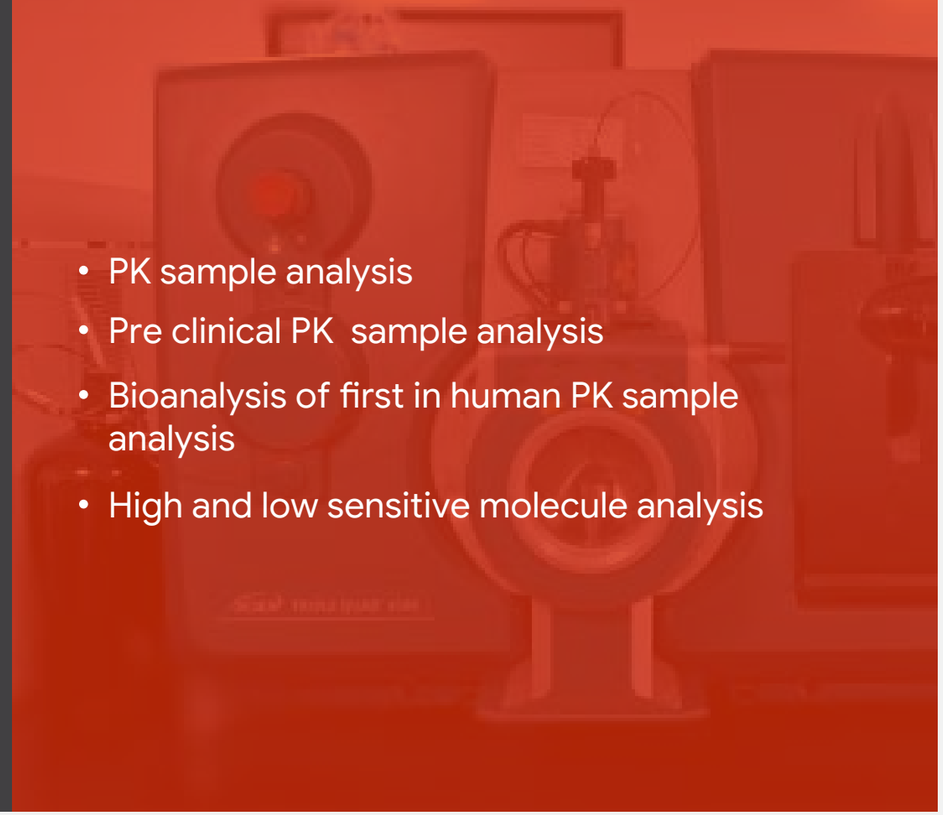
PK/PD Analysis

Ligand Binding Assays

Analysis of biological samples for drug, metabolite, concentrations and/or immune response

- Development, Validation and sample analysis of PK/PD/Immunogenicity assay for Biosimilars and Biologics
- Immunochemistry ELISA, MSD® platform for PK, anti-drug antibody (ADA)

Chromatography



- PK sample analysis
- Pre clinical PK sample analysis
- Bioanalysis of first in human PK sample analysis
- High and low sensitive molecule analysis

Ligand Binding Assays – Challenges Accepted

Team also having experience in MSD SQ 120, Spectra Max M5

Ligand Binding Assays: **Pharmacokinetic & Immunogenicity** Assays on ELISA...

Our team comprises individuals with over 15 years of experience in method development and validation of complex large molecule for various regulatory markets

Proficiency in PK, quantification of biological drugs, and ADA assessment.

We consistently invest in resources such as new technologies and instruments to stay abreast of ongoing market demands.

We have a comprehensive grasp of regulatory prerequisites and a track record of method development aligned with FDA, EMA, and ICH standards.

Ligand Binding Assays – Team Experience

Monoclonal antibodies: Adalimumab, Rituximab*, Infliximab, Pembrolizumab, Tocilizumab, Pertuzumab, Denosumab, Ranibizumab, Trastuzumab

Interleukins: IL-2, IL-7, IL-11, IL-15 etc.

Liraglutide*

Insulin: Glargine & Aspart (Insulin & C peptide)*

GCSF/Filgrastim

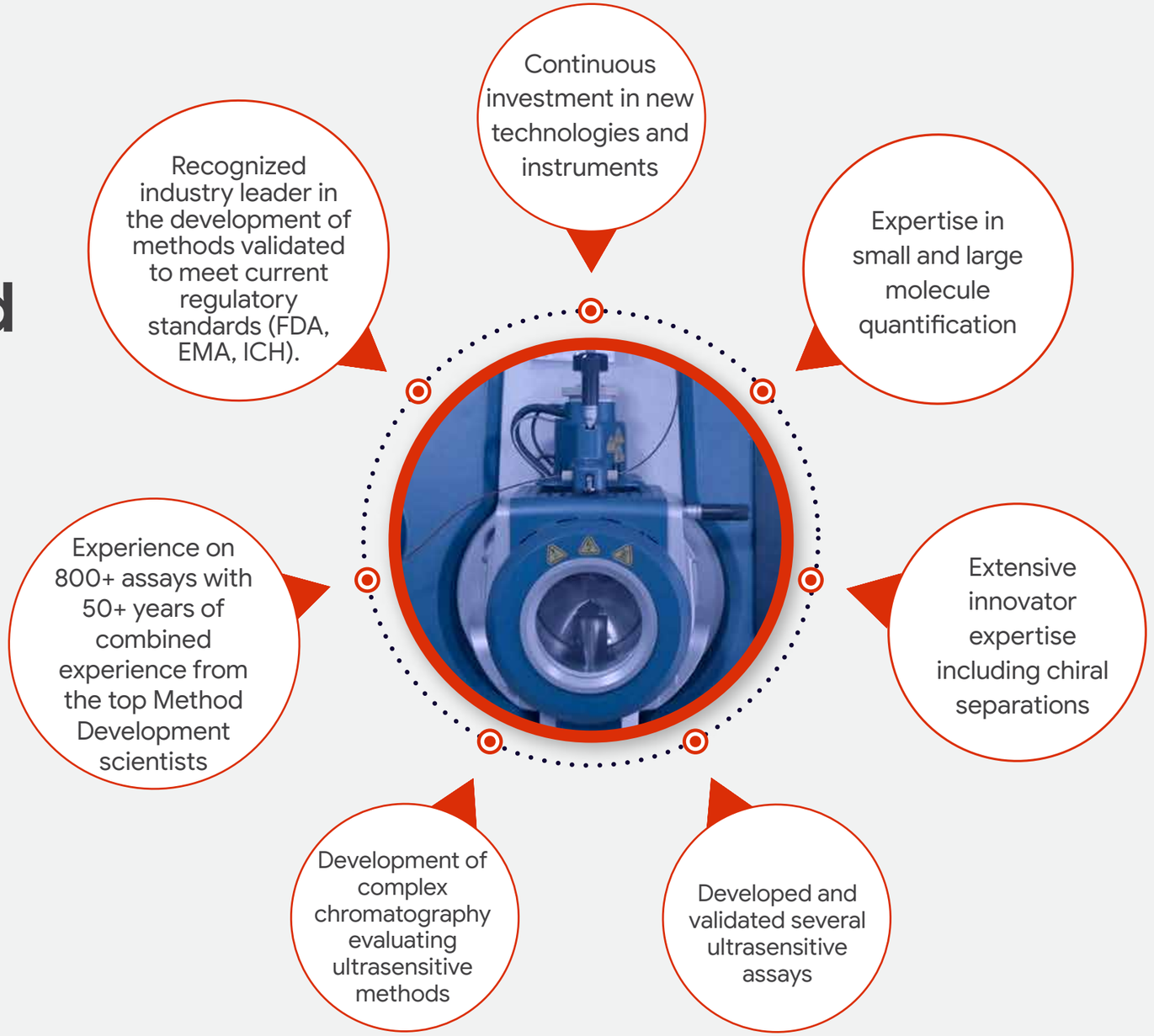
PEGylated molecules: PEG IL-2, PEG IL-7, PEG IL-15, PEG-Filgrastim

Biomarkers like sCD25

methods developed at ADVITY

- Enoxaparin
- Etanercept
- Erythropoietin (EPO)
- FSH, LH, PTH
- Streptokinase (SK)

Chromatography- Challenges Accepted



Chromatography- Capabilities

- Chiral Molecules
- Geometric isomers
- Positional isomers
- Enzyme Hydrolysis
- Nutrients(E.g. Vitamins)
- Protein bound drug (unbound & Total)
- Hormones
- Liposomal Drugs
- Molecules required derivatization
- High sensitive molecules
- Metabolite & Impact study

Ligand Binding Assays – Team Experience

Monoclonal antibodies: Adalimumab, Rituximab*, Infliximab, Pembrolizumab, Tocilizumab, Pertuzumab, Denosumab, Ranibizumab, Trastuzumab

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Biomarkers like sCD25

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- FSH, LH, PTH
- Streptokinase (SK)

Glucose Clamping Studies

Requirement

“Regulatory agencies require Pharmacokinetic and pharmacodynamic data on time-action profiles for new or biosimilar insulin preparations, using the glucose clamp procedure”

Why ADVITY !

- A state-of-the-art Glucose clamping unit
- CLAMP SCIENTISTS with more than 15 years experience in handling glucose clamping studies
- Clear understanding of the study procedures and challenges associated with the execution of glucose clamp studies for different insulin formulations
- Expertise, capabilities, and infrastructure in the areas of Bioanalytical, PK and statistical analysis

Glucose Clamping Studies

Study Design & Protocol Development	Regulatory Affairs	Clinical conduct (Clamp execution)	Bioanalytical	Data Management & Biostatistics
• ADVITY team of highly experienced clinical experts have longstanding expertise in developing protocols and related documents for glucose clamping studies. • Insights in study design and PK & Stat aspects of the protocols	• ADVITY Regulatory Affairs Team provides project management for in collation of documents, submission, and representation of the client at meetings with regulatory agencies. • Regulatory documents compilation • Regulatory application filing	• Experienced expert Physicians who specially trained for the clamping studies • In-house expertise in design and conduct of clamp Qualified, 21CFR Part11 Compliant analyzer with redundancy • Constant safety monitoring of subjects during the conduct of the study • State-of-the-art facility can accommodate studies lasting more than one week with 24/7 medical support.	• Validated methods for estimation of Insulin /analogs /metabolites • Robust analytical procedures • Estimation of Insulin and C-peptide using ELISA • Experienced analytical scientists • Analytical platforms like Ligand binding assays, chromatographic assays	• An understanding of key technical considerations for rigorous data analysis (Pharmacokinetic considerations, • statistical considerations especially for differentiating exogenous Insulin from endogenous) • Regulatory compliance report generation in a quick turn around time

Glucose Clamping Studies

In our team, we have first-generation glucose clamp scientists with over 15 years of experience in conducting various glucose clamping studies for multiple insulin formulations.

Analytical scientists with experience and robust methods and infrastructure to estimate insulin and C-peptide levels

Insulin Glargine 40 IU/mL
Insulin Regular Human 100 IU/mL
Insulin Isophane Human 100 IU/mL
Biphasic Isophane Insulin 30/70 IU/mL

Dedicated work force (Medical monitors, CRAs, Nurses and Phlebotomists) for execution of glucose clamping studies

Experience in handling glucose clamping studies for the multiple insulin formulations (long acting to ultra short acting)

Vision 2028


Expansion of the bioanalytical facility to provide comprehensive support for large molecule analysis
Technology & Innovation: Leveraging AI, blockchain, and digital solutions
BA/BE Facility expansion to accommodate another 9000 doses per year. Also provision for accommodating specialty dosage forms
Vision 2028
Full fledged in house biometric department
Decentralized Clinical Trials implementation
Full operational segment specific of the Scientific Advisory Board
Strengthen further in segments like: Endocrinology, Oncology, Women's health Immunology, Mental health, Biosimilars & Respiratory to accommodate complex Clinical trials

Thank you!

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