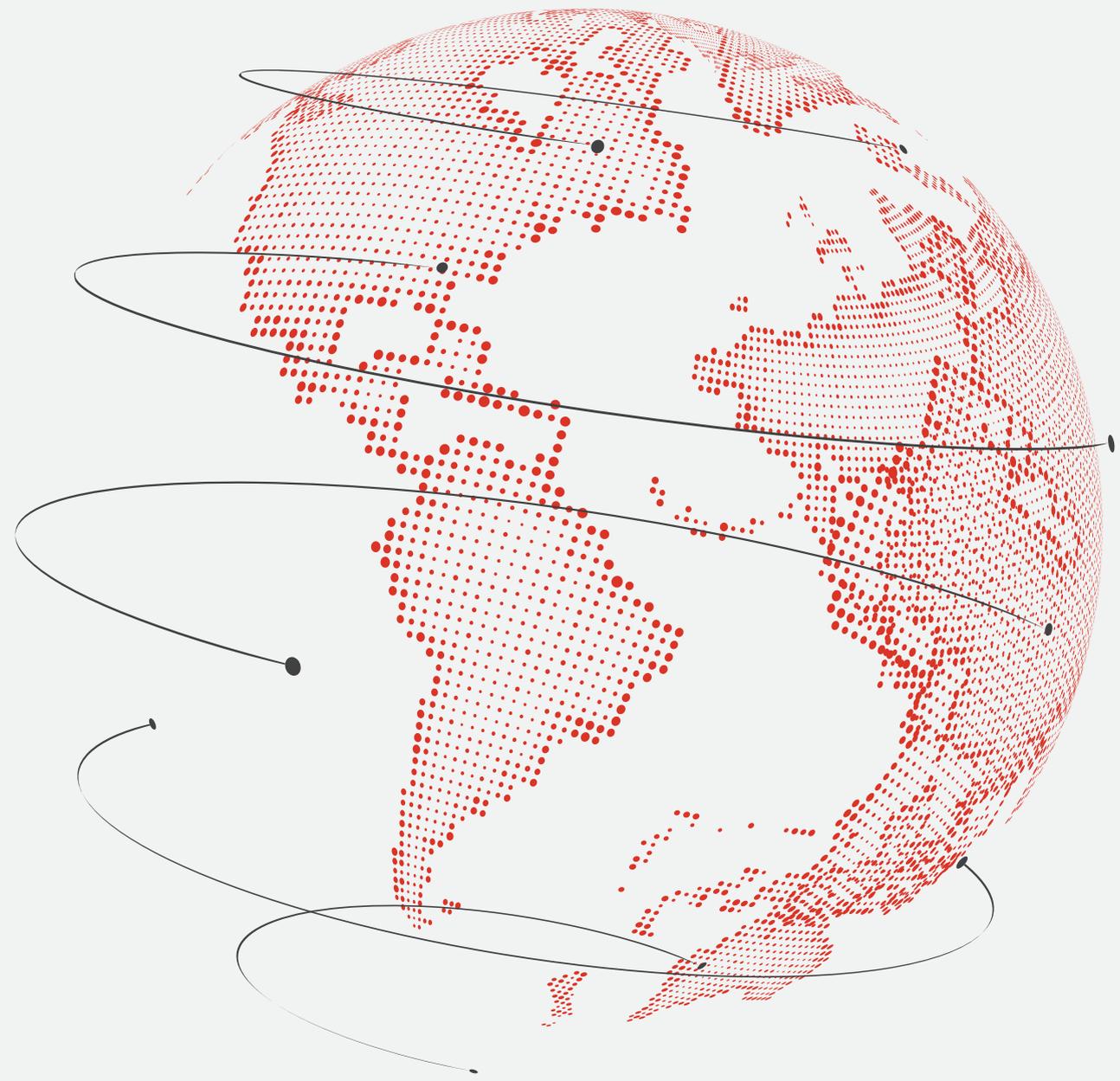


**ADVITY**<sup>®</sup>

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**

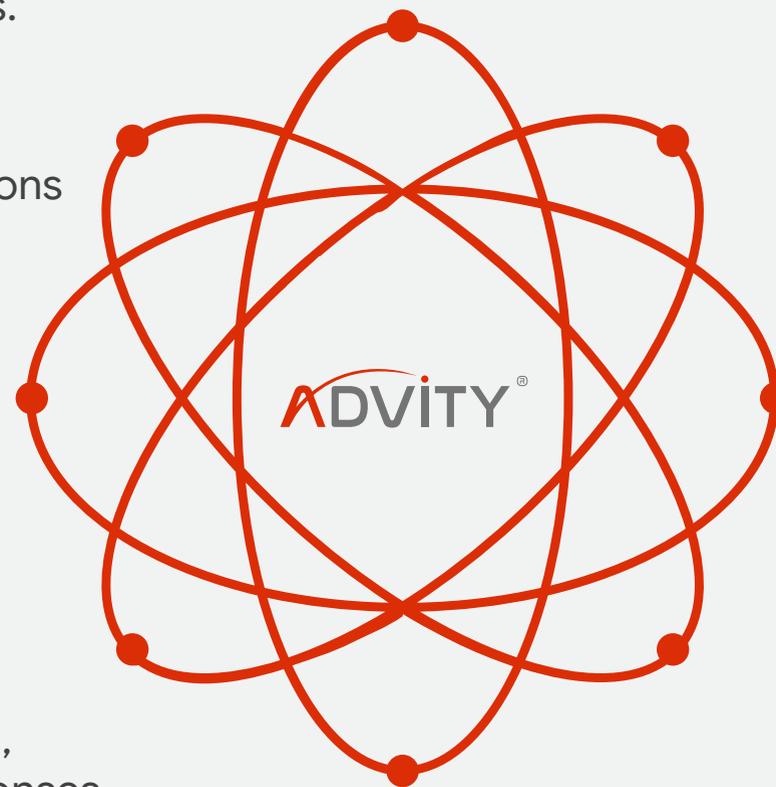
We embracing the technology-driven solutions lead us to more successful and impactful clinical research outcomes.

## **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

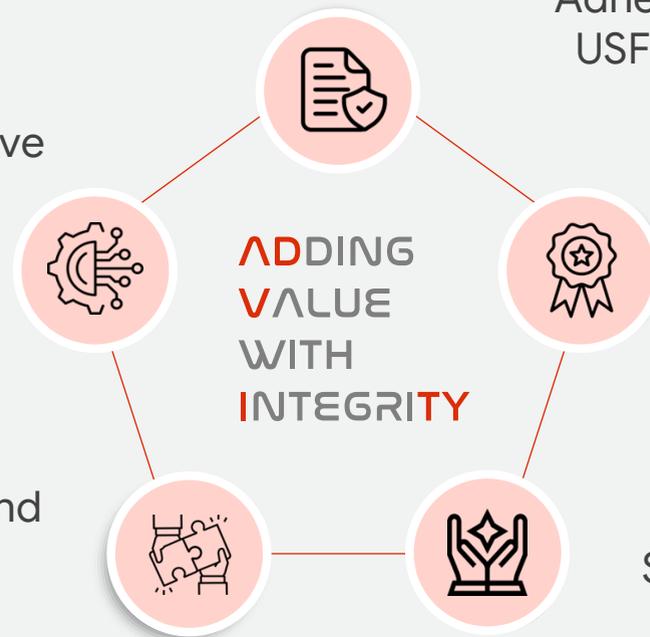
At ADVITY RESEARCH, we are dedicated to "ADDING VALUE WITH INTEGRITY" in all our clinical research endeavors. Our Quality Policy focuses on:

## 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:

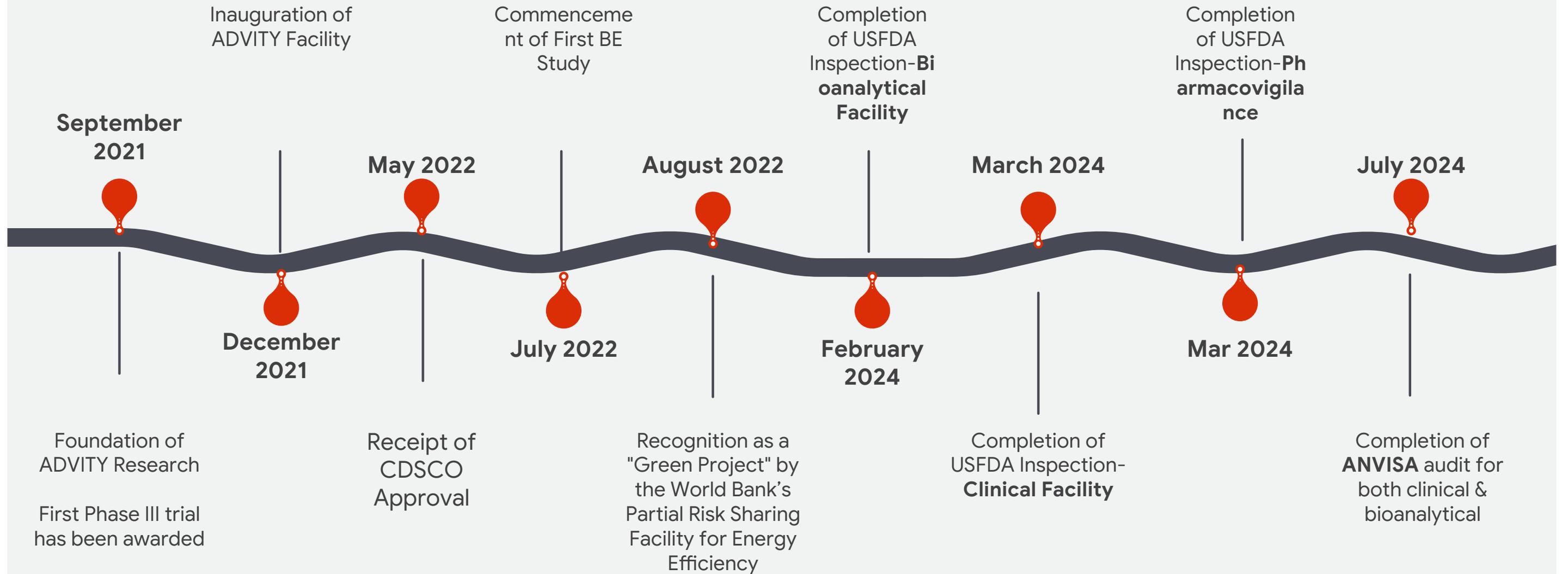
Continuously enhancing our Quality Management System (QMS) and upholding data integrity to excel in our research efforts.

## 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

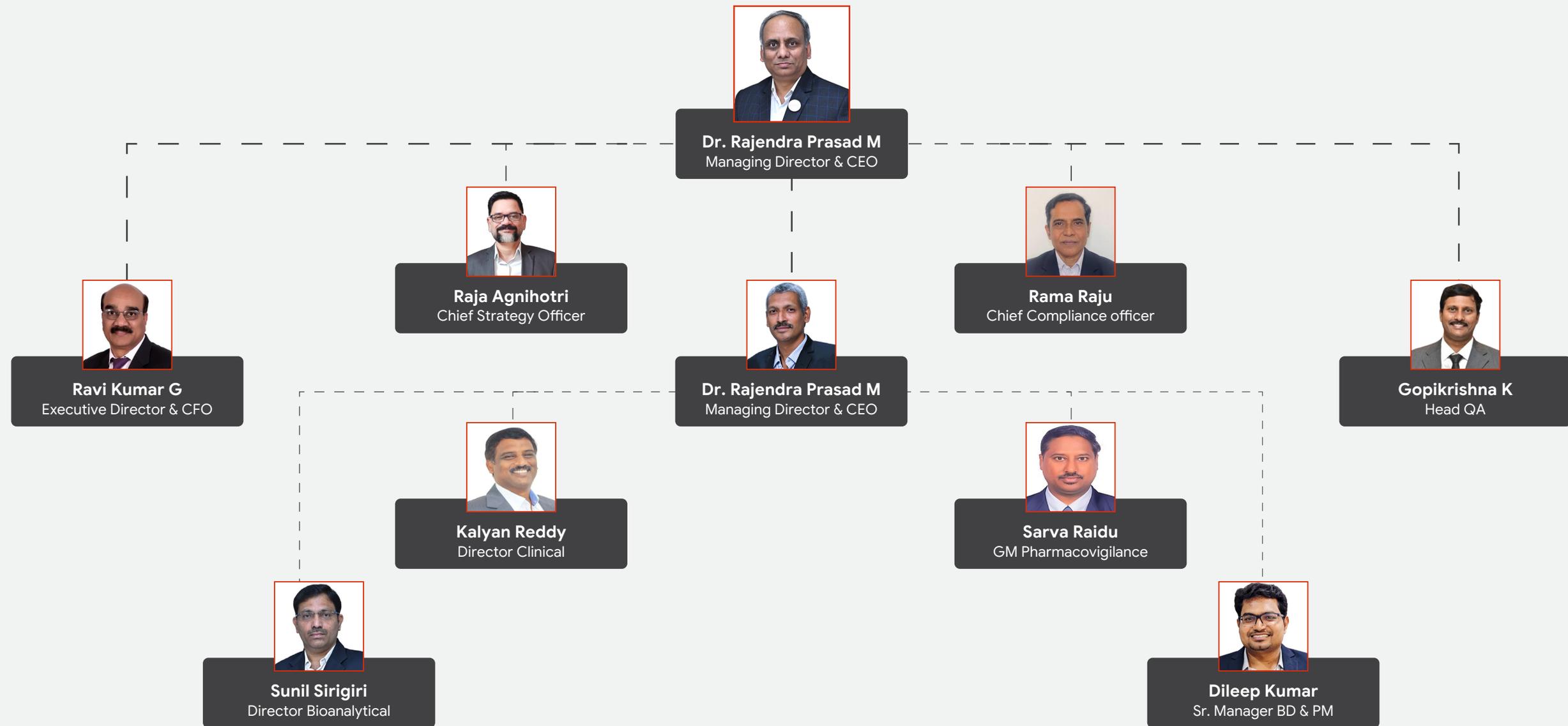
- HR
- Finance
- Accounts
- Purchase
- IPR
- Admin

- All functional heads
- Business development team

- Clinical team – BA/BE & Clinical trial team

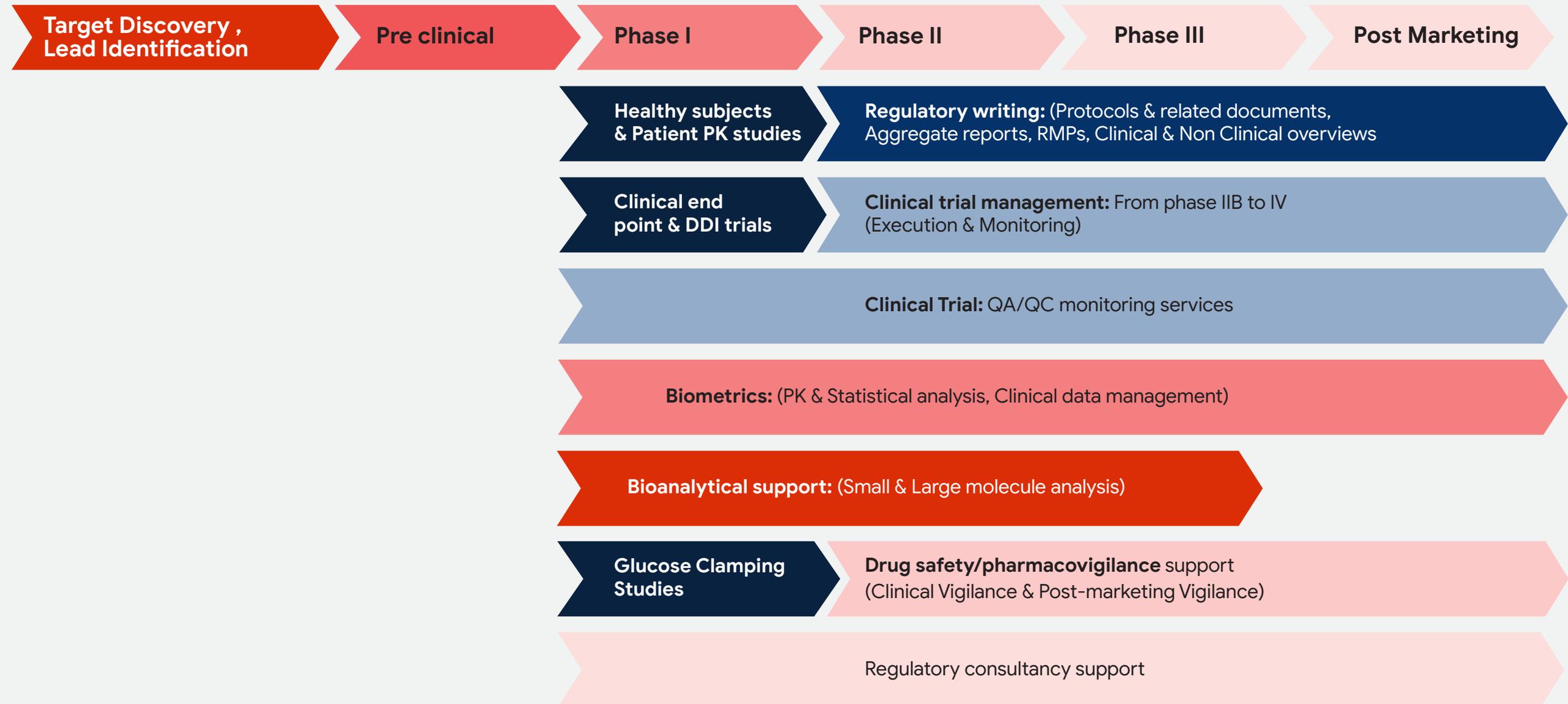
- Bioanalytical team

# Aligned & Driven Leadership



# Range of Services

Drug Development Cycle





## **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<sup>+</sup>**

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

**60<sup>+</sup>**

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<sup>+</sup>**

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

**200<sup>+</sup>**

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

**3500<sup>+</sup>**

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



Derma Studies –  
Skin Patches



Pre-clinical PK  
sample analysis



PK/PD & Clinical end point studies  
on healthy subjects & patients



Extensive cardiac  
monitoring studies



Pharmacokinetic &  
Biopharmaceutics



Studies on special populations:  
Healthy female, PMW & elder subjects



Palatability  
evaluation studies



Statistical analysis and  
Population BA/BE analysis



Proof-of-concept  
studies (PK Studies)



Medical writing services:  
Protocol development, ICD, ICF  
and Clinical study reports



Data Management &  
CDISC services



Glucose  
Clamping studies



Bioanalytical services: For  
small & large molecule analysis  
and elemental analysis

# 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



Archivals 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

A close-up photograph of a person's hand holding a grey medical device. The device has a black strap with the text 'INDEX mus' and a white arrow pointing to the left. The person is wearing a blue shirt and a blue sock. The background is dark and out of focus.

## 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



## 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)



## Extension

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



## 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

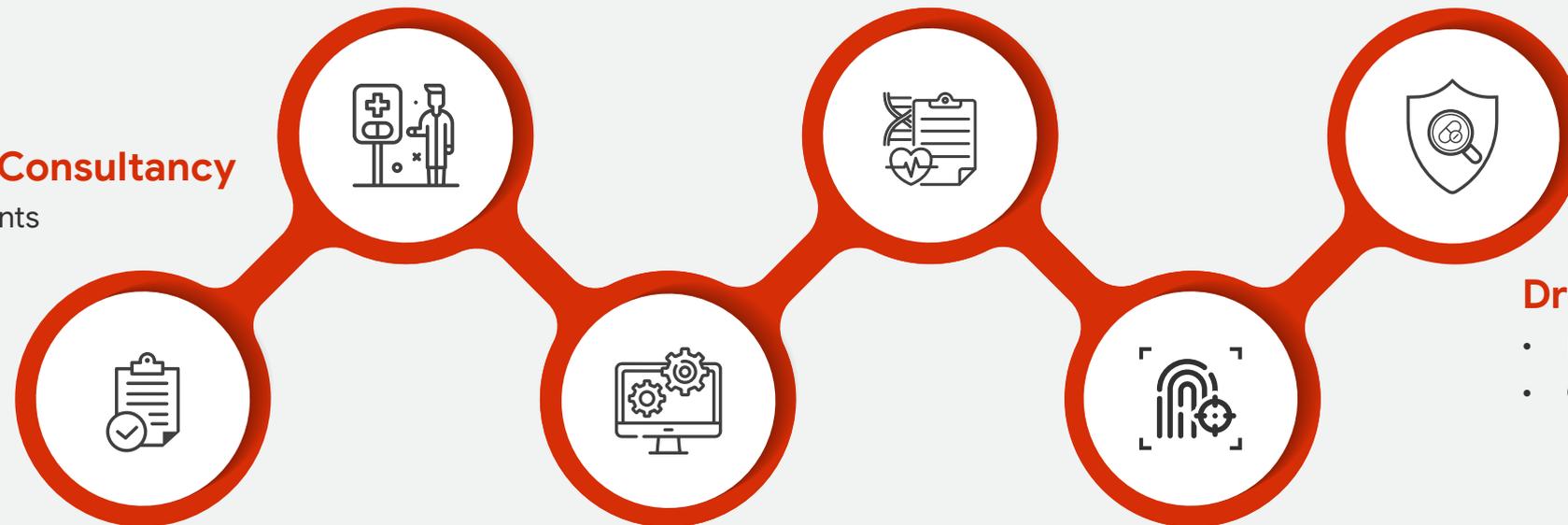
- Post marketing safety services
- Clinical vigilance

## Clinical Trial Monitoring

- QC monitoring services
- QA monitoring services

## Biometrics (Full Digital)

- Clinical Data Management
- PK and Statistical analysis & CDISC

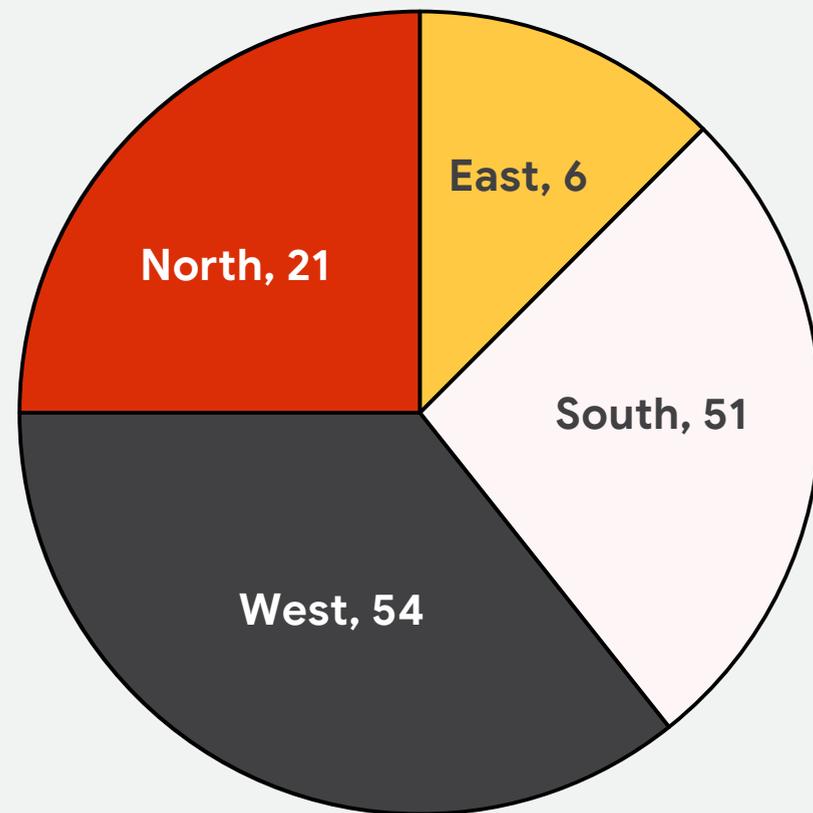


# Project completed/ under progress

Phase III	Patient PK study	Under FSP model	Biologics/Biosimilars
<p>One Phase III trial completed (Nutraceutical product).</p> <p>120 subjects</p> <p>Therapeutic segment: Osteoarthritis</p>	<p>One patient PK study is currently in progress</p>	<p>Support provided one of Patient PK study for 100% QC monitoring of study activities</p>	<p>Executed 03 Phase I studies in metabolic &amp; endocrinology</p>
<p>One Phase III trial is currently in progress.</p>	<p>Therapeutic segment: anti-psychotic</p>	<p>Therapeutic segment: anti-psychotic</p>	<p>Two insulin products (ASPART &amp; Glargine) and Liraglutide</p>
<p>Therapeutic segment: Endocrinology</p>	<p>Sample size is 42.</p>	<p>Sample size: 320 and study has conducted across 13 sites across India</p>	<p>PK sample estimation in Rituximab Phase III study which also covers immunogenicity.</p>
<p>Recruitment has been completed with 240 subjects across 15 sites in India. Treatment phase is ongoing, with a study completion in April 2025.</p>	<p>Regulatory &amp; EC approvals in place</p>	<p>Status completed</p>	
	<p>IMP receipt &amp; distribution in process</p>		
	<p>Planned study completion by Dec 2024</p>		

# Clinical Sites database

## Zones



## Therapeutic Segment



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

- 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





## 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



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



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

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



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



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

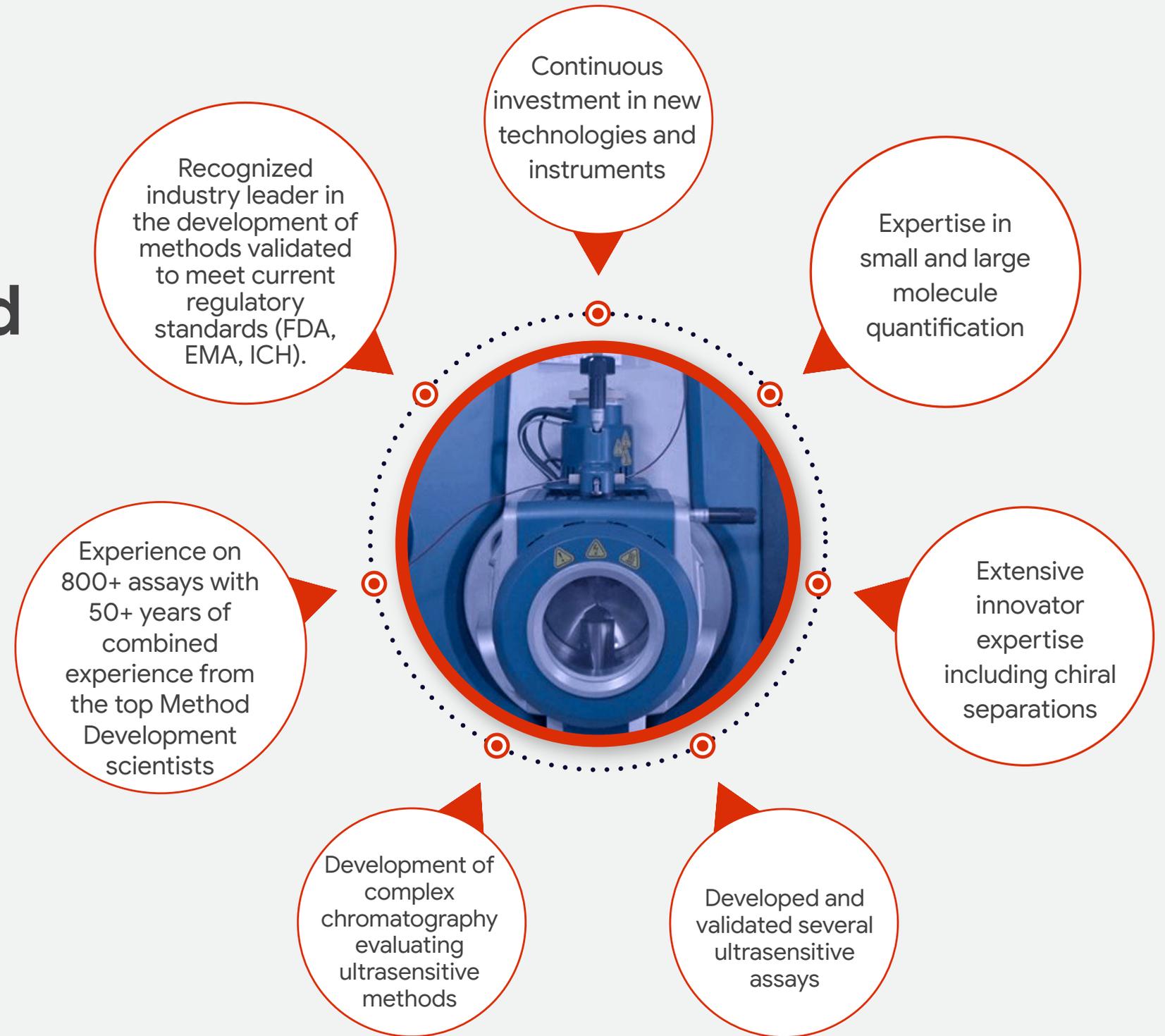
PEGylated molecules: PEG IL-2, PEG IL-7, PEG IL-15, PEG-Filgrastim

Biomarkers like sCD25

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

methods developed at ADVITY

# Chromatography- Challenges Accepted



# Chromatography- Capabilities

 <p><b>Chiral Molecules</b></p>	<p><b>Geometric isomers</b></p> 	 <p><b>Positional isomers</b></p>
 <p><b>Enzyme Hydrolysis</b></p>	<p><b>Nutrients(E.g. Vitamins)</b></p> 	 <p><b>Protein bound drug (unbound &amp; Total)</b></p>
 <p><b>Hormones</b></p>	<p><b>Liposomal Drugs</b></p> 	 <p><b>Molecules required derivatization</b></p>
 <p><b>High sensitive molecules</b></p>	<p><b>Metabolite &amp; Impact study</b></p> 	

# 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

- Enoxaparin
- Etanercept
- Erythropoietin (EPO)
- 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

- 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

## Regulatory Affairs

- 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

## Clinical conduct (Clamp execution)

- 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.

## Bioanalytical

- 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

## Data Management & Biostatistics

- 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



*Thank  
you!*

[www.advityresearch.com](http://www.advityresearch.com)