ADVITY®

ADDING VALUE WITH INTEGRITY

ADVITY Research is an Independent Clinical Research Organization that possesses all the essential attributes and capabilities required of a CRO.

We are a dedicated team united by a unified vision that we deliver clinical research services infused with our firm commitment to ADDING VALUE WITH INTEGRITY. This dedication distinguishes us in a competitive industry landscape.

OUR TEAM CREDENTIALS

150 Years

Boasts 150 years of combined experience in clinical research

800+

Developed 800+ analytical methods for multiple regulatory markets

5000+

Successfully delivered on nearly 5000+ clinical research projects

300+

Extensive track record includes collaboration with nearly 300+ diverse clients

RANGE OF SERVICES

Target discovery, lead identification
Preclinical

Phase I

Phase II

Phase III

Post Marketing

Healthy subjects & 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)

Regulatory consultancy support

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.

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.

EXTENSION TO YOUR TEAM

Our team serves as an extension of your clinical program, sharing your commitment and values.

CLINICAL SITE NETWORK

80 Autoimmune	35 Cardiology	15 Dermatology	50 Endocrinology	30 Haematology	20 Infectious
40 Mental Health	25 Neurology	35 Oncology	50 Ophthalmology	25 Respiratory	35 Women's Health

SCOPE OF SERVICES

Regulatory writing & Consultancy

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

Clinical Site Management

Study start up & Feasibility •
Patient recruitment •

Clinical Trial Monitoring

- QC monitoring services
- QA monitoring services

Clinical Project Management

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

Biometrics (Full Digital)

- Clinical Data Management
- PK and Statistical analysis & CDISC

Drug Safety Services

Post marketing safety services •
Clinical vigilance •

PHARMACOVIGILANCE SERVICES

Our pharmacovigilance team supports post-marketing safety surveillance and clinical trial across the globe. As patient safety is 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.

TEAM

ADVITY PV TEAM

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

TEAM EXPERIENCE IN DELIVERABLES

- 16+ Experience
- Handled
  - 700+ ANDAs
  - 450+ MAs
- Processed
  - 15,000+ ICSRs
- Prepared
  - 8000+ PADERs
  - 1000+ PBRERs/PSURs
  - 300+ ACOs
  - 200+ RMPs
  - 1000+ Signal reports
  - 300+ SDEAs

REGULATORY AUDIT EXPERIENCE

FDA	HEALTH CANADA	ANVISA	ANSM	CBG MEB
EUROPEAN MEDICINES AGENCY	AIFA	MHRA	MALTA MEDICINES AUTHORITY	INFARMED

SCOPE OF 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

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

TEAM EXPERIENCE & EXPERTISE

Experience in with execution of more than

5,000+ Healthy subjects & Patient PK studies

which includes BA/BE studies in healthy and patient subjects

Team has successfully faced more than

60+ Global Regulatory audits

(USFDA, EMEA, UKMHRA, ANVISA, GCC, TGA, Canada, MCC, NPRA, TGA, MOH Turkey) in their prior experience

Hands on experience with

800+ Analytical Methods

which including complex, low sensitive molecules (pg/mL) and NCEs

Working experience with

300+ Pharma, Biotech companies

located across the globe, including large pharmaceuticals

A well established Glucose clamping facility with an experience in execution of more than

2,000+ Clamps

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

INFRASTRUCTURE

- State-of-the-art BA/BE facility spread over 28,000 sq.ft.
- Well connected to all major parts of the city.

- Clinical capacity can accommodate 12,000 doses per year
- A comprehensive emergency in-house response infrastructure in place
- Associated with NABL accredited clinical path labs
- Associated with tertiary care hospitals (100 bedded superspecialist) to accommodate the emergency handling

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

Large molecule analysis lab

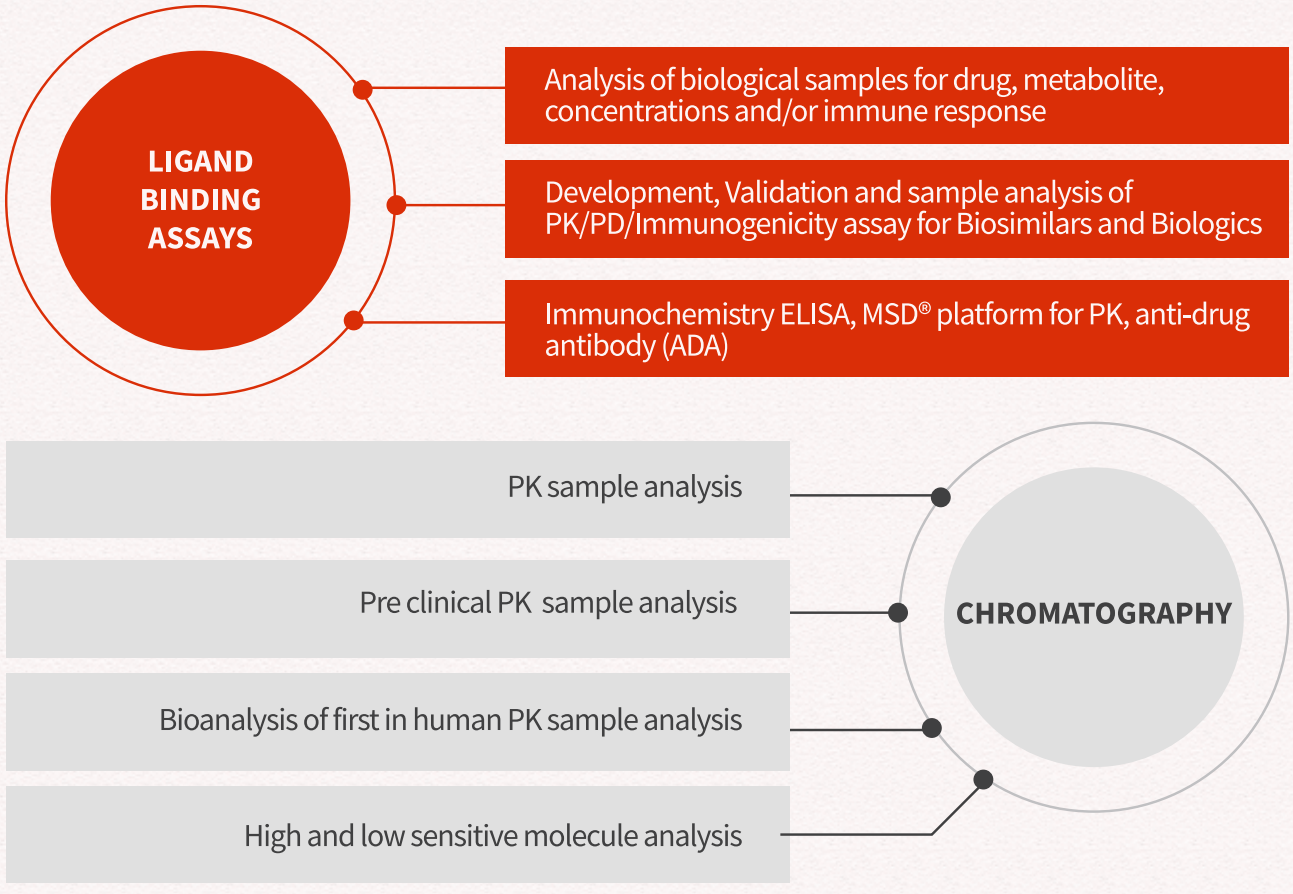
COMPREHENSIVE SOLUTIONS

- 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)
- Bioanalysis of first in human studies
- Pharmacokinetic & Biopharmaceutics
- Statistical analysis and Population BA/BE analysis
- 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
- Glucose Clamping studies
- Pre-clinical PK sample analysis
- Data Management & CDISC services

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



GLUCOSE CLAMPING STUDIES

ADVITY features a team of first-generation scientists with in-depth knowledge of various facets of clamping studies. Our team brings extensive experience with diverse clamp designs. We are committed to meticulously planning studies to meet timelines and ensure regulatory compliance.

REQUIREMENT :

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

SERVICES

- Study Design & Protocol Development
- Regulatory Affairs
- Clinical conduct (Clamp execution)
- Bioanalytical
- Data Management & Biostatistics

TEAM EXPERIENCE & EXPERTISE

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.

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

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

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

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

DIFFERENTIATORS

Know the Challenges

Extensive experience in clinical research, we possess a comprehensive understanding of the drug development process.

Best People to the Trials

Team is a combination of in-depth therapeutic knowledge with a passion for clinical research.

Agility & Responsive

Team is agile and adapts quickly, able to pivot and change course.

Flexible in Business Approach

Ready with resources to cater for the ever expanding requirement(s) of clients.

Technology Integration

Automation (online) of activities EDC, Data capturing, Patient IVRS & Analytical activities.

Cost Benefit

Our cost control mechanisms guarantee a positive cost-benefit without compromising the quality of data and compliance.

ADVITY®

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