ADDING
VALUE
WITH
INTEGRITY

ADVITY®

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. 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 5000+ clinical research projects

300+

Extensive track record includes collaboration with 300+ diverse clients

Range of Services

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)

Early Phase Trials – BA/BE, PK/PD, Clinical End Point Studies

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

Our BA/BE Services facility has been successfully inspected and audited by **USFDA & ANVISA**

Team Experience & Expertise

Experience in with execution of

5,000+ Healthy participants & Patient PK studies

which includes BA/BE studies in healthy and patient participants

Team has successfully faced

60+ Global Regulatory audits

(USFDA, EMA, 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

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 facility spread over 42,000 sq. Ft

Our bioanalytical capabilities support the analysis of over 20,000 subject samples annually.

Equipped with high sensitive instruments: API 6500

Clinical capacity having 182 beds spread over 10 clinics and can accommodate 20,000 doses per year.

Large molecule analysis lab - Ligand Binding Assays

Comprehensive Solutions

BA/BE Studies:
On healthy participants
& patients

PK/PD & Clinical End Point studies on
Healthy participants & Patients

Studies on Special Populations: Healthy
female, PMW & elder participants

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

Late Phase Clinical Trials – from Phase IIB to IV

ADVITY provides comprehensive support across Phase IIB to IV and PK/Clinical end point 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 •

Drug Safety Solutions

Our Comprehensive Capabilities

Robust Infrastructure & Core Services

- Advanced E2B R2 and R3 compliant safety database systems
- Comprehensive literature surveillance and monitoring
- ICSR processing and global submissions
- Thorough medical review by qualified professionals

Strategic Safety Management

- Safety reporting and signal detection
- Aggregate report writing and analysis
- Development of Risk Management Plans (RMPs) and handling of REMS products
- LPPV and Deputy LPPV services
- QPPV & Deputy QPPV services for regulatory compliance

Technical Excellence

- Medical Information Call Centre Management (MICC)
- Seamless data migration and system transitions
- Gateway establishment for efficient data transmission
- Development and management of Safety Data Exchange Agreements (SDEAs)

Global Pharmacovigilance Excellence: Worldwide Coverage & Expertise

Extensive QPPV and LPPV network across major markets

Multilingual MICC operations (English, French, German, and Spanish)

Specialized expertise in complex legacy data migrations

Successfully navigated USFDA inspection history

Comprehensive global submission capabilities including FDA, EMA, Health Canada and more

Proven Track Record of Excellence: Our Experience in Numbers

18+
Years
18+ years of specialized pharmacovigilance expertise

1,000+
ANDA
Successfully managed 1,000+ ANDA submissions

500+
MAS
500+ Marketing Authorization Holders globally

30,000+
ICSRs
Processed over 30,000+ ICSRs with precision

10,000+
PADERs
Delivered 10,000+ PADERs to regulatory authorities

3,000+
PBRERs
Produced 3,000+ PBRERs for comprehensive safety analysis

300+
Implemented 300+ Risk Management Plans

1500+
Generated 1,500+ detailed signal reports

1000+
Managed 1,000+ Addendum to Clinical Overview (ACOs)

Regulatory Excellence

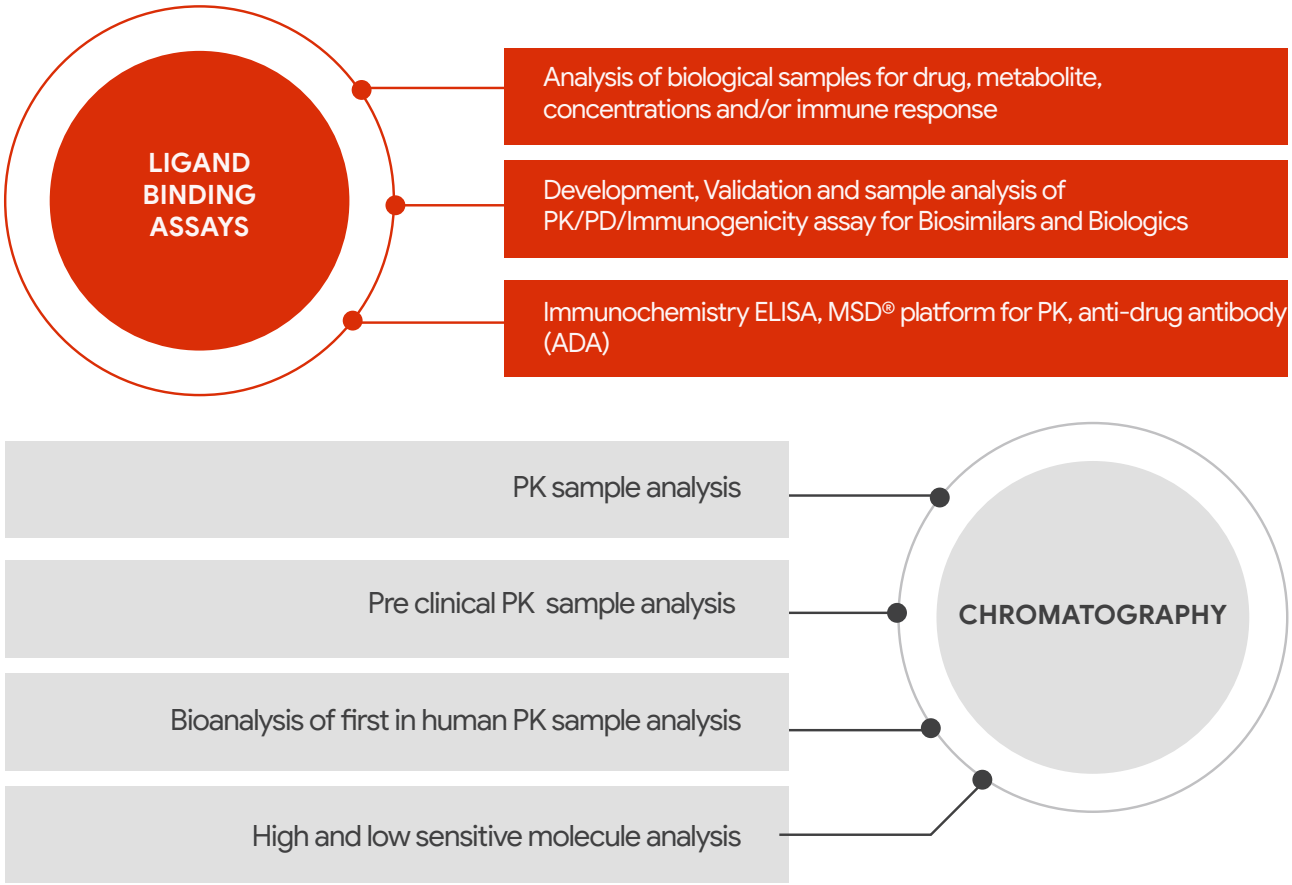
Our team's past expertise is validated through successful handling of multiple regulatory inspections:

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

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.

Agile & 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, Patient IVRS & Analytical activities.

Cost Benefit

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

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