LAMBDA
Research Accelerated

Novum
PHARMACEUTICAL RESEARCH SERVICES

Global Full-service CRO

LOOKING FOR A CRO WITH END-TO-END BA/BE EXPERTISE?

Partner with a Globally Trusted CRO from **India** with **25 Years of Legacy** for Scale, Speed, and Compliance

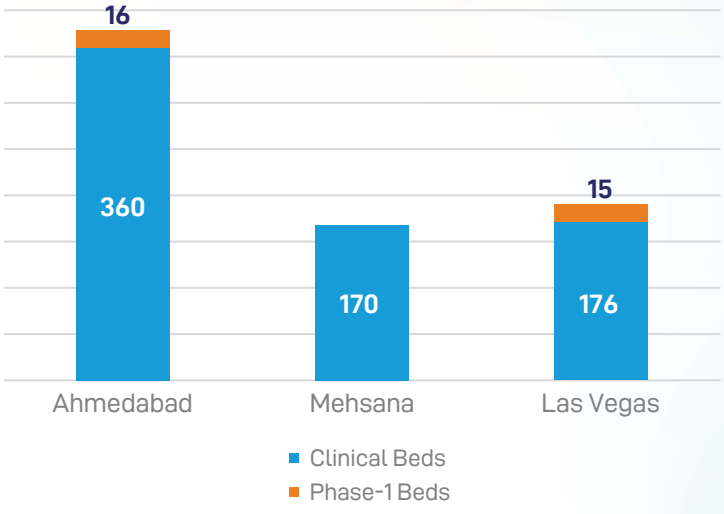
- **7500+ BA/BE** Studies completed
- End-to-end execution: **Feasibility to Reporting**
- **Inspected** by USFDA, EMA, WHO, MHRA, ANVISA, AGES & others.
- **Diverse Volunteer Database -** Healthy, Elderly, PM & Surgically Sterile Females
- Expertise in **Complex Generics & Biosimilars**

BA/BE EXPERTISE ACROSS HEALTHY VOLUNTEERS AND PATIENT POPULATIONS

EXPERIENCE ACROSS DIVERSE DOSAGE FORMS

- All Oral Dosage Forms
- Injectables
- Inhalation Products
- Topical Products
- Nasal Sprays
- Transdermal Products
- Vaginal Products
- Ointments & Creams
- Suppositories
- Rectal Products

700+ BEDS GLOBALLY



EXTENSIVE & DIVERSE VOLUNTEER DATABASE

- Healthy Volunteers (Males & Females)
- PM & Surgically Sterile Females
- Elderly

PHASE-1 EXTENSIVE CAPABILITIES

- Single-Dose & Multiple-Dose Studies (Fed/Fasted)
- Comparative Pharmacokinetic (PK) Studies
- PK/PD Proof-of-Concept Studies
- Food Effect Studies
- Drug-Food and Drug-Drug Interaction Studies
- Drug-device Combination Studies
- Bridging Studies for Global Submissions
- First-in-Human and Early Phase Studies
- Controlled Substance Studies
- FDA-qualified for Schedule II–V
- Mixed Population Studies
- Biosimilar Clinical Pharmacology Studies
- Human Factor Studies
- Self-Administration Studies

EXECUTED 40+ PHASE-1 STUDIES

ADVANCED INFRASTRUCTURE AND OPERATIONAL SUPPORT

- First in the industry to implement IRIS-based subject registration system
- End-to-End Management of Investigational Products
- 24/7 medical coverage supported by advanced ICU facilities
- Real-time clinical data capture across all phases
- Integrated Safety and Bioanalytical Laboratory with automated Sample Management System
- Proven experience in mixed population studies
- Negative pressure inhalation chambers at Las Vegas Clinic for respiratory drug studies
- FDA-qualified to conduct studies involving Schedule II–V products

CENTRAL CLINICAL LAB

COMPREHENSIVE SERVICES FOR ALL PHASES OF CLINICAL TRIAL TESTING

ADVANCED BIOANALYTICAL EXPERTISE

METHOD DEVELOPMENT, VALIDATION AND SAMPLE ANALYSIS

1500+ VALIDATED METHODS

PEPTIDES EXPERIENCE

Proven Track Record in Early-Phase Peptide Studies Supporting FDA & EU Submissions

- **Glucagon**
- **Octreotide**
- **Somatropin**
- **Leuprolide**
- **Semaglutide**
- **Leuprolide**
- **Semaglutide**

PROVEN REGULATORY TRACK RECORD

The logos of regulatory authorities are displayed solely for informational purposes and do not constitute endorsement or certification beyond the scope of authorized inspections and approvals.

Why Lambda?

- Digitalization of in-process activities (Central Lab, Clinical, Bioanalytical) for faster report generation.
- Bar-coded sample labeling for seamless digital scanning and tracking.
- Expertise in First-in-Human studies with global hybrid execution for global clients
- Proven leadership in biosimilars, oncology, dermatology, neuropsychiatry, and respiratory studies.
- State-of-the-art infrastructure with over 700 beds, 45+ LC MS/MS, and extensive global facilities in Ahmedabad & Mehsana (India), Las Vegas (USA), and Toronto (Canada).
- Trusted Experience: Conducted 7,500+ studies over 25 years, inspected by USFDA, EMA, MHRA, ANVISA, and NPRA Malaysia.

Connect with us to explore how we can accelerate your clinical trials.

BD@lambda-cro.com