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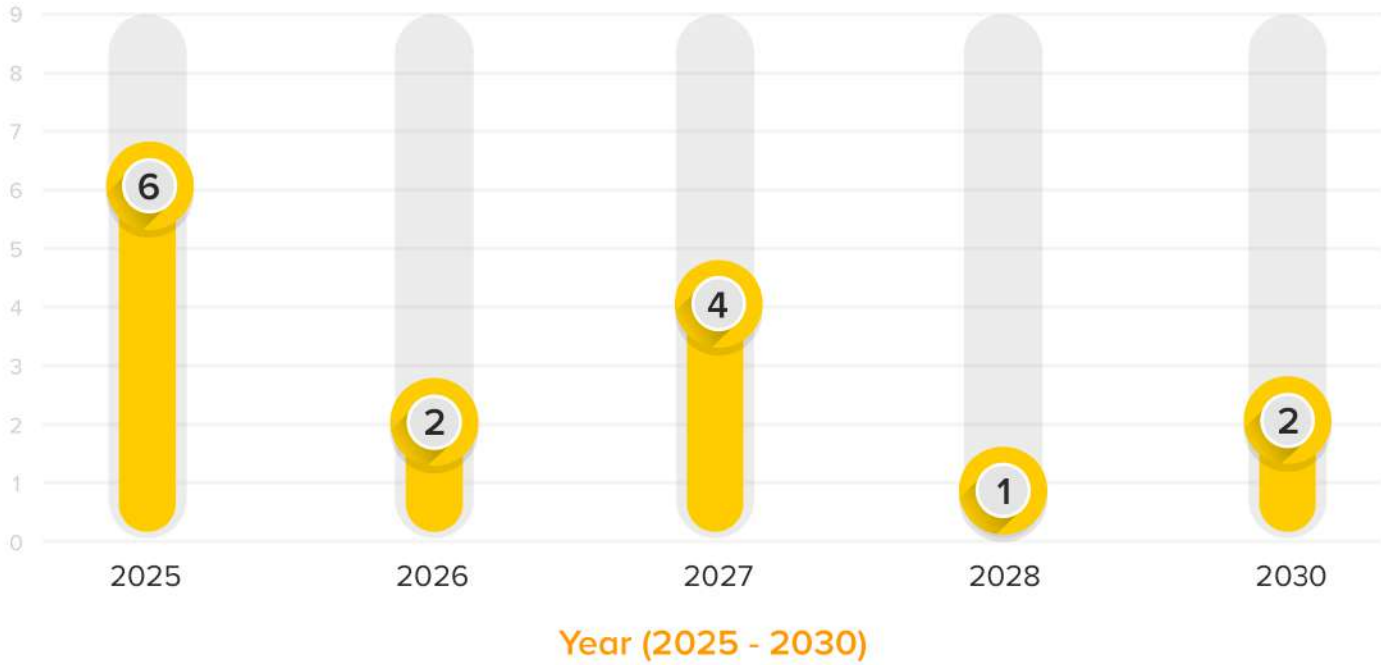
Supporting end to end development of

Oncology Large Molecule

treatments coming off patent in the next few years

We are now supporting you through all the stages in a drug development continuum

Oncology Large Molecule Treatments coming off patent in next few years



Major Oncology Drugs falling off the patent cliff in next few years. Which one is on your watch list?

Oncology Drug	Therapeutic Indication	Year of Patent Expiry
Rituximab	Non-Hodgkin's Lymphoma Chronic Lymphocytic Leukaemia	2025
Bevacizumab	Colorectal, Cervical, NSCLC, Renal and Ovarian Cancer	2025
Pertuzumab	Breast Cancer	2025
Ipilimumab	Unresectable Malignant Pleural Mesothelioma	2025
Ramucirumab	Advanced gastric or Gastro-Esophageal junction Adenocarcinoma	2026
Daratumumab	Multiple Myeloma	2027
Pembrolizumab	Melanoma, Lung cancer, Head and Neck cancer, Hodgkin Lymphoma, stomach cancer, cervical cancer, and certain types of breast cancer	2028
Atezolizumab	Hepatocellular Carcinoma	2030
Durvalumab	Stage III non-small cell lung cancer	2030

Fast-track your cancer therapy with Veeda Group

BIOLOGICS (mAbs, vaccine, RNA therapeutics)

DRUG DISCOVERY & CHEMISTRY

Biopharmaceutical Product Characterization, Critical Reagent Generation and Validation, Phenotypic Approaches, Binding kinetics, Antibody Library Discovery, Discovery Pharmacology Studies (in vitro and in vivo), Cell Therapy Studies, Bioactivity and Potency testing (in vitro/in vivo), Cell-based Assays, Screening Biomarker services, Cell banking & Cell line generation/ characterization, Product Release Testing, Polyclonal and Monoclonal Antibody (development, characterization, production, and purification), Lot release testing, Detection and Quantification of Residual HCD.

PRECLINICAL DEVELOPMENT

Safety pharmacology & Toxicology studies, immunogenicity testing, Immunoassays (Multiplexing Assays), Preclinical Bioanalytical services, Translational Biomarker services, Early phase HCP assay, Viral Safety studies (BSL3), Stability Testing Studies (DLS (Dynamic light scattering)), and Impurity Testing services.

Biosimilars (follow on biologics)

ANALYTICAL CHARACTERIZATION

Cell line and Process development, Primary Amino Acid Structure Determination (Amino Acid sequencing, peptide mapping, disulfide linkage characterization, protein glycosylation analysis.), Higher Order Protein Structures Evaluation, Aggregation, Confirmation Enzymatic Post Translational Modification (PTM), Target Binding, Evaluation of Purity, and Measurement of function and potency through different assays (In vitro, Bioassays, ADCC, Cell-based, Immunogenicity and biomarkers)

PRECLINICAL DEVELOPMENT

Primary PD, PK, safety pharmacology, single-dose toxicity, repeat-dose toxicity, toxicokinetics (TK), local tolerance, and immunogenicity studies (as a part of repeat dose toxicity studies) in animal models.

Strong Capability and Proven Expertise in Bringing your Biosimilar Drugs First to Market

- Immunogenicity Studies
- Study Design and Execution of PK & PD comparative study (Phase 1 studies), and Phase 3 clinical comparability trials (efficacy and safety) in healthy and patient population for Biosimilars
- Project Management
- Volunteer Recruitment
- Conducting Feasibility & Site Set up activity
- Site Monitoring and Safety Monitoring
- Clinical Pharmacology Services
  - Medical Writing
  - Investigator Brochures
  - Clinical Trial Protocol
  - Informed Consent Forms
  - Clinical Study Reports (CSRs)
  - Biostatistics
  - Clinical Data Management
- Pharmacy & Bioanalytical Services
- Regulatory Guidance

Effective Services for Bio-Comparability and Functionality Testing of Biosimilars- Ingenuity BioSciences

Bio-comparability Testing Solutions

Wide range of Bio-comparability testing solutions so that you can test your biosimilar early in the development process and minimize the risk of failure during late phases of the drug development.

Bioassay Solutions

Evaluate functionality of your biosimilar using cell-based assay based on the drug's mechanism of actions such as cell proliferation, cell viability, cell signaling, receptor activation, and ligand binding assays to measure various downstream proteins

Antibody Functionality Testing

Evaluate antibody function utilizing following assays: ADCC assays, CDC assays, Fc Receptor binding assays (i.e, FcγRI (CD64), FcγRII(CD32a), FcγRIII(CD16a), and FcRn etc.) and C1q binding assays.

Veeda's Experience with Biosimilars (Our Ongoing Studies)

Molecule Name	Short description of the study
Filgrastim	Two-Part Study Evaluating the Pharmacokinetics, Pharmacodynamics, Safety and Immunogenicity study
Omalizumab	Randomized, double blind, two-arm, parallel group, single dose comparative PK, PD, and Immunogenicity study
Recombinant FSH	Single Dose, Crossover, Bioequivalence Study in adult female volunteers
Pegfilgrastim	Two-part Crossover Study Evaluating the Pharmacokinetics (PK), Pharmacodynamics (PD), Safety, and Immunogenicity study

Our Team's Cumulative Experience with other Large Molecules

Molecule Name		
Filgrastim	Romiplostim	Teriparatide
Erythropoetin	Ranibizumab	H1N1 Vaccine
Denosumab	Pegfilgrastim	Covid Vaccine
FSH	Tocilizumab	

Validated PK/ADA Methods List for Oncology Biosimilars

PK METHODS	ADA METHODS
Alemtuzumab	Alemtuzumab
Bevacizumab	Bevacizumab
Cetuximab	Cetuximab
Denosumab	Denosumab
Gemtuzumab ozogamicin	Gemtuzumab
Ibritumomab	Ibritumomab
Ipilimumab	Nivolumab
Nivolumab	Obinutuzumab
Obinutuzumab	Ofatumumab
Ofatumumab	Panitumumab
Panitumumab	Pegfilgrastim
Pegfilgrastim	Pembrolizumab
Pembrolizumab	Pertuzumab
Pertuzumab	Tositumomab
Trastuzumab	Trastuzumab

Helping you navigate through your study with our strong Bioanalytical Expertise

Our Bioanalytical Services include **Feasibility, Method Development and Method Validation.** We recently **developed and validated** below large molecules as per current **EMEA guidance** using commercially available kits by **ELISA technique**

Insulin Aspart & C-peptide	Filgrastim	Denosumab	Teriparatide	Romiplostim

State-of-the-art Clinical Research Facilities to Support Your Biosimilar Research and Development

Veeda Group has state-of-the-art Biosimilar laboratory Bioequivalence study center co-located with Insignia site of Veeda Clinical Research

Critical Instruments & Monitoring

- BD FACSLyricTM Flow cytometer
- Shimadzu Nexera UHPLC and HPLC
- Q Exactive Orbitrap Mass Spectrometer -LC-MS/MS
- ICP-MS
- 2D Electrophoresis- BioRad
- Microplate Reader and Washer
- Plate Readers Softmax Pro and Biotek
- Real time PCR- Thermo Fisher
- Bioreactors (5 lts)
- Ekta Purification system
- Gas Chromatography
- BOD Incubator
- Stability Chambers

Other Infrastructure Capabilities:

49 LC-MS/MS machines, 2ICP-OES, Watson LIMS, 40 Deep freezers of -80°C (1 M samples capacity) and 11 Deep freezers of -20°C (0.15 M samples capacity) 3 Walking Type Stability Chambers, 4 Pharmaceutical Refrigerators, and 4 Humidity Chambers

LC MS Capabilities

1

Q Exactive Orbitrap Mass Spectrometer

Make: Thermo Fisher Scientific Inc
Model: Q Exactive Basic

2

UHPLC – Front End

Make: Shimadzu Corporation
Model: Shimadzu Nexera

3

Software components

Xcalibur 4.0.27.19 (Thermo Fisher Scientific Inc.)
Biopharma Finder 2.0 Data Analysis Software

Ingenuity's Use of Innovative technologies in development of Biosimilars:

mAbY™: Recombinant antibody platform

Aegyris™: Laboratory Informatics Solutions

Intelli.b™: Biosimilar Characterization Solutions

Veeda Clinical Research's Central Bioanalytical Lab Experience

- Handling Multicentric Complex Studies
- Sample management, method development, method validation and analysis of NCEs
- Sponsor specific reports with e-CTD for NCE Molecules
- Experience in Exploratory studies, e.g. skin tissues, plasma protein binding experiment, chiral impurity estimation in the sample

Why Choose Veeda Group for your next Oncology Biosimilar Study?

- Veeda is one of the largest Independent Full Service CROs in India with presence in both, pre-clinical and clinical trials domain
- Extensive Scientific Competence to service a diverse client base
- High Customer Centricity and Satisfaction
- Skilled personnel with focus on Continuous Professional Development
- Robust Quality & Regulatory Compliance
- State of the Art Infrastructure for handling complex studies
- Experience of handling studies for different dosage forms (solid, semisolid, suspension, injectables, inhalation, topical drugs etc.)
- With Bioneeds we offer a wide range of pre-clinical services complimented by our early phase clinical services to innovator pharmaceutical companies in order to provide them with comprehensive drug development support
- With Ingenuity Biosciences we are providing regulatory, laboratory and clinical developmental services in biosimilars and our team comprises of scientists with in-depth knowledge of bioassay method development and sample analysis, clinical trial management, and global regulatory requirements
- Ongoing investments to provide technology driven CRO solutions and enhance operating efficiencies and compliance management
- We have successfully completed several regulatory inspections by some of the most stringent regulatory authorities worldwide such as, among others, USFDA, UK-MHRA, WHO, ANVISA, DCGI and EMA so far

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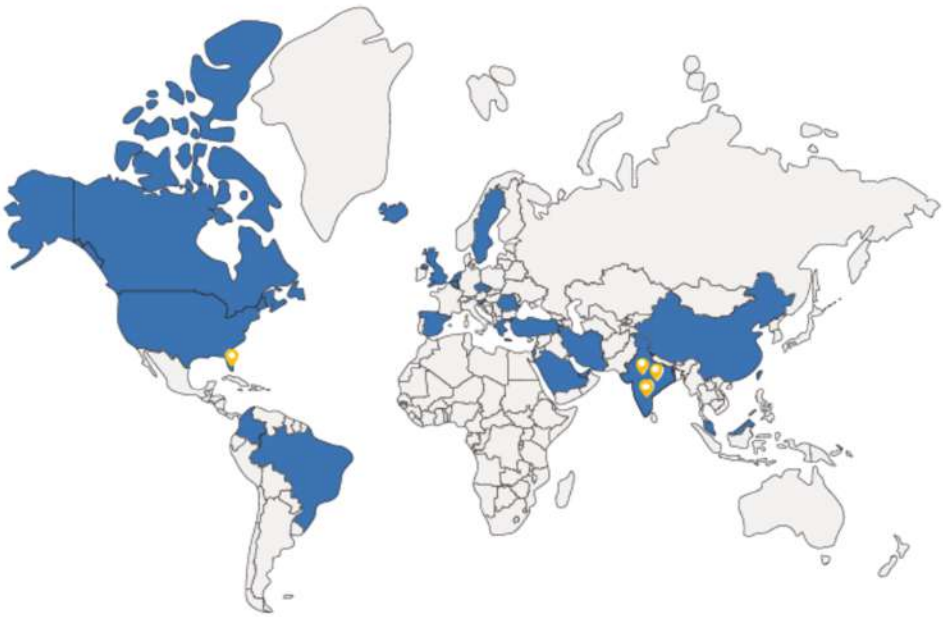
Our Global Foot Print



Serving clients across these geographies

Veeda's Team Presence

To know more about
our expertise in Large Molecule Oncology Trials, mail us at
info@veedacr.com

Partners in creating a healthier tomorrow

+91 79 6777 3000

www.veedacr.com