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veeda clinical research®

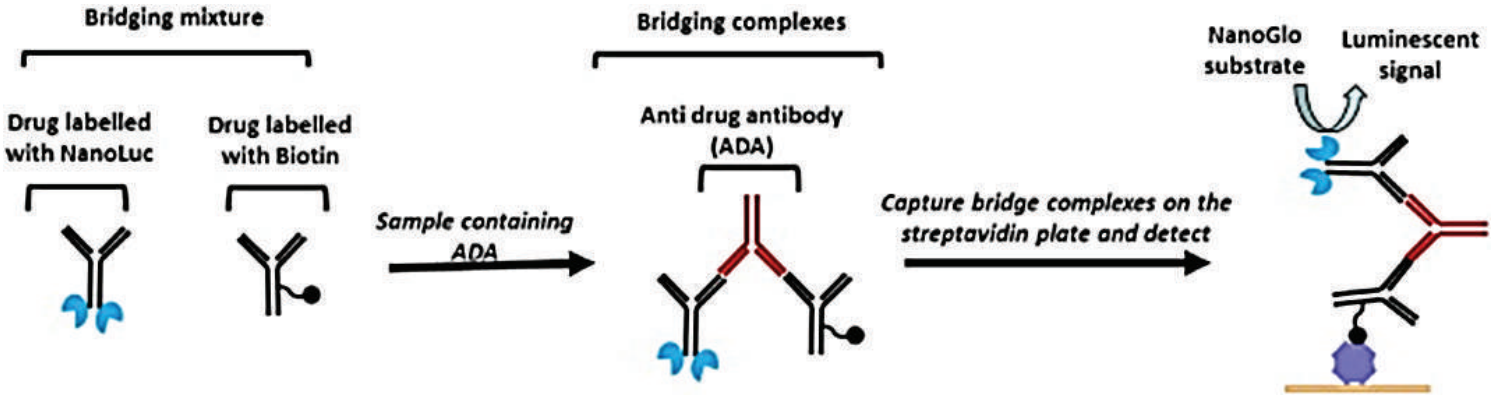
BIONEEDS

Accelerating Biopharma Development: Customized Clinical Bioanalysis Solutions

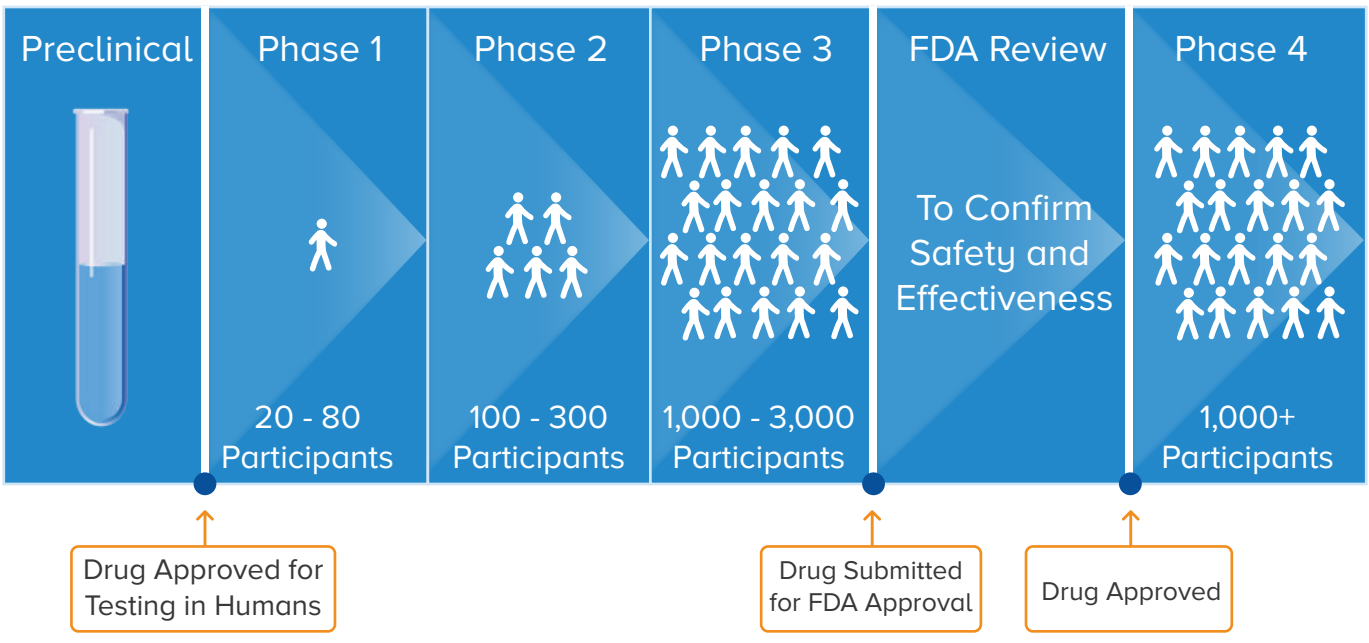
Overview

We are your reliable partner for conducting analyses of clinical samples following GCLP standards

Clinical Bioanalysis department at Biopharma Division of Veeda offers comprehensive bioanalytical solutions to support early to late-stage clinical trials. We offer services to perform Pharmacokinetics, Pharmacodynamics, immunogenicity testing, vaccine sciences and biomarker assays for the development of biotherapeutics with Good Clinical Laboratory Practice (GCLP) compliance. We ensure that our clients receive reliable and accurate results while adhering to rigorous quality standards. GCLP encompasses a set of guidelines that combine the principles of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), ensuring the integrity and reliability of data generated in bioanalytical laboratories. Our laboratories are equipped with state-of-the-art instrumentation and technology to ensure accurate and reliable analysis of biological samples.



Clinical Trials



PK/PD Assessments and Immunogenicity Testing

Veeda offer services for method development, validation, and sample analysis using state-of-the-art LC-MS/MS and Ligand Binding Assay platforms (ELISA and ECL) for bioanalysis of biologics, meeting the needs of clients involved in drug development and regulatory submissions utilizing robust, sensitive, specific and reproducible methods.

Biosimilars

1

Pharmacokinetics

- Quantify Free/Bound/Total drug concentrations
- Incurred Sample Reanalysis
- Statistical Report Preparation

2

Pharmacodynamics

- Serum Biomarker Levels
- Cytokine Responses

3

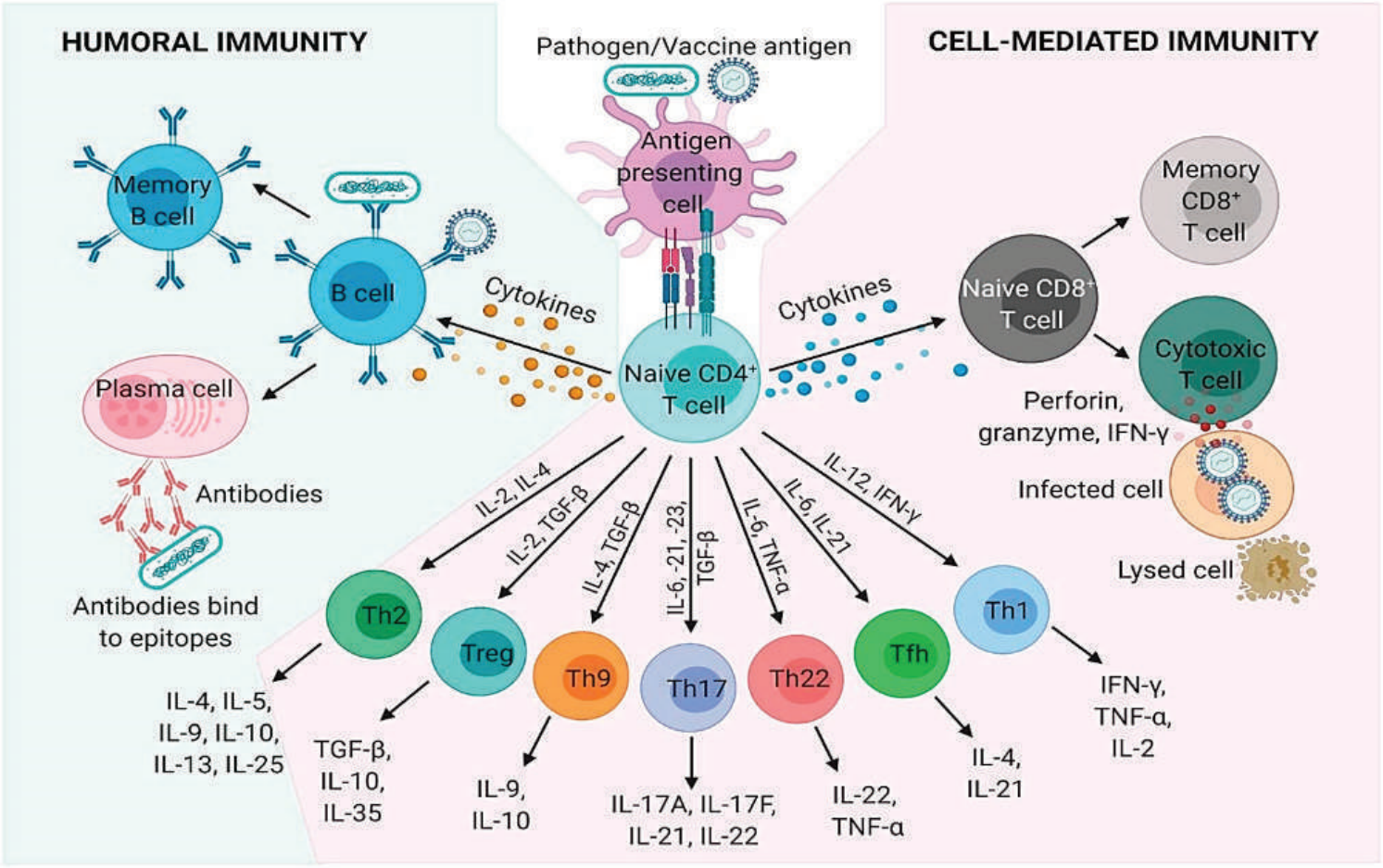
Immunogenicity

- Analysis of Anti-drug antibodies (ADAs) using Tier based approach
  - Screening
  - Confirmatory
  - Titer
- Neutralizing Antibody (NAb) Assays – Cell-based/ Competitive Ligand Binding

Vaccine Immunogenicity Services

We collaborate with your team to expedite the launch of transformative vaccines Our extensive range of capabilities ensures robust and innovative immuno-analytical methods, yielding precise, high-quality, and rapid results for bacterial and viral vaccine immunogenicity testing.

Veeda assists in achieving the highest scientific standards for your program, prioritizing focus on understanding the cell-mediated immunological response for vaccine candidates.



Humoral Immunity

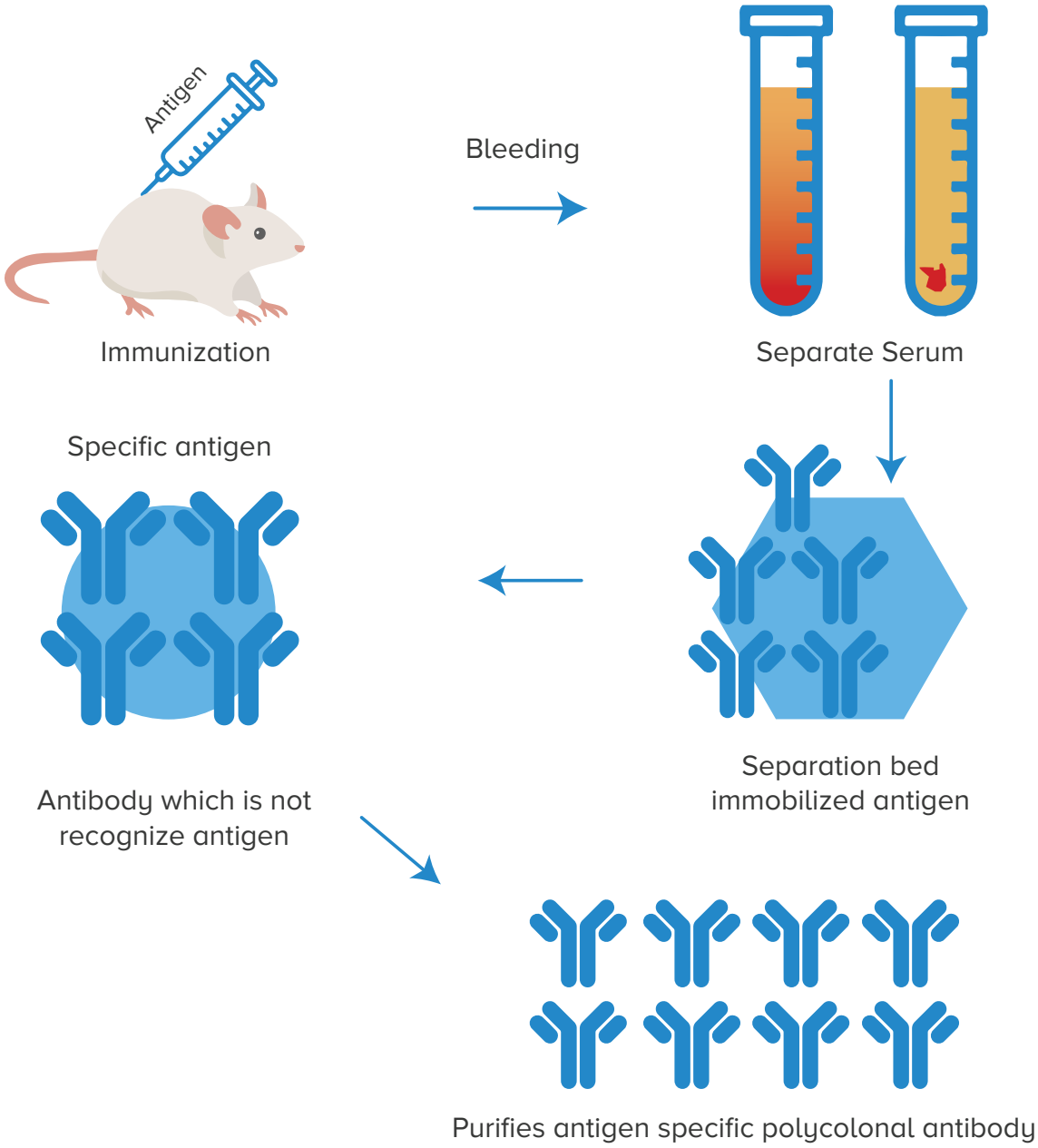
- Estimation of serum IgG titers/concentrations (GMT/GMC levels)
- Seroprotection and Seroconversion (GMFR) estimations for assessing vaccine immune responses
- Functional Antibody Assays for Bacterial and Viral antigens (SNT/SBA/PRNT etc.)

Cell-mediated Immunity

- Cytokine Release
- T-cell, B-cell and immune cell characterization
- Detection of functional T-cell responses
- Detection of B-cell mediated immune responses
- Multiplexing Assays

Critical Reagent Generation and Qualification

Critical reagents are the crucial components of Ligand Binding Assays whose unique characteristics are important for assay performance and repeatability, and therefore, require extensive characterization and documentation. Their unique characteristics, such as specificity, affinity, stability, and purity, are vital for the accurate measurement of target analytes in biological samples.



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Generation → Affinity Purification → Biotinylation Ruthenylation → Qualification & Optimization

Experience and Expertise

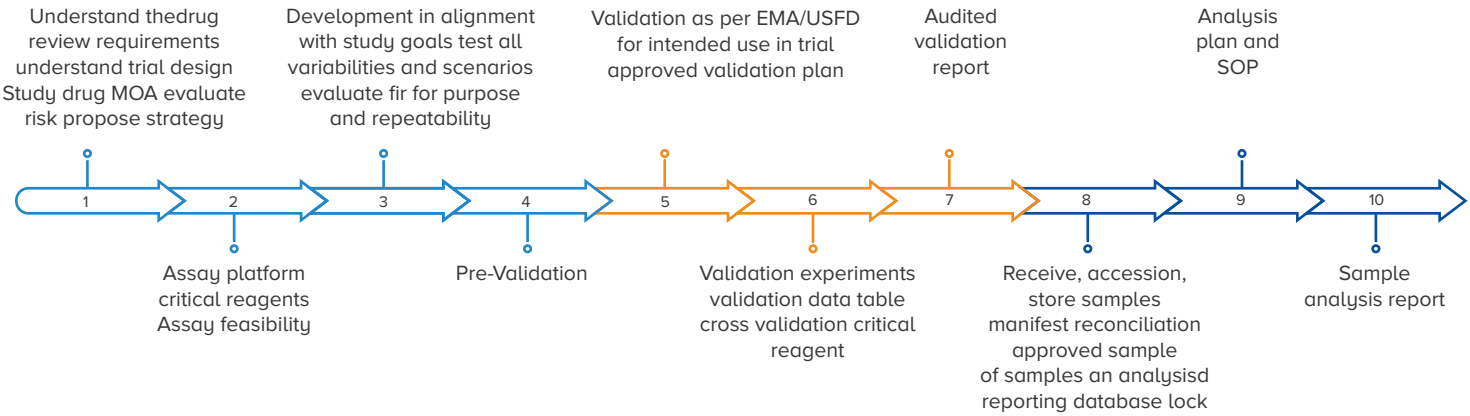
Highly trained scientists with significant experience in large molecule bioanalysis for a wide range of biotherapeutic modalities.

Team experience ensure maximum level of expertise and quality standards to support our clients at any stage of clinical development.

- Multi-domain Biologics
- Hormones
- Insulins
- Proteins
- Peptides
- Biosimilars
- Vaccines
- PEGylated Proteins
- Monoclonal Antibodies

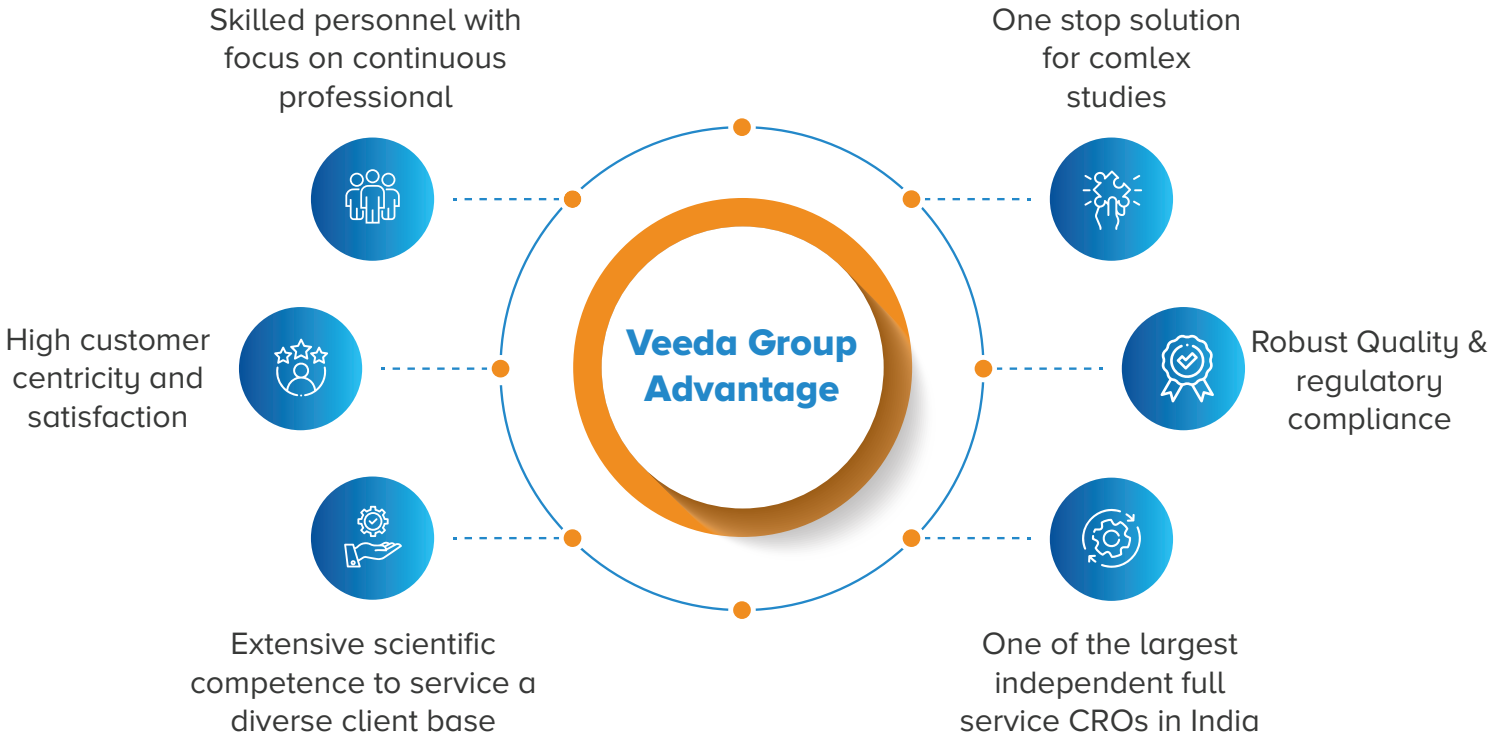
Global Quality Standards

Veeda Clinical Bioanalysis team is supported at all the stages of analyses by a robust quality management system aimed at achieving the highest attainable quality data through accountability and traceability required for regulatory submissions. The Quality team is well versed with GCLP/GLP and regulatory guidelines from EMEA/FDA/ICH.



1 to 4	Transfer / development
5 to 7	Method validation
8 to 10	Sample analysis

State-of-the-art Technology



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Partners in creating a healthier tomorrow