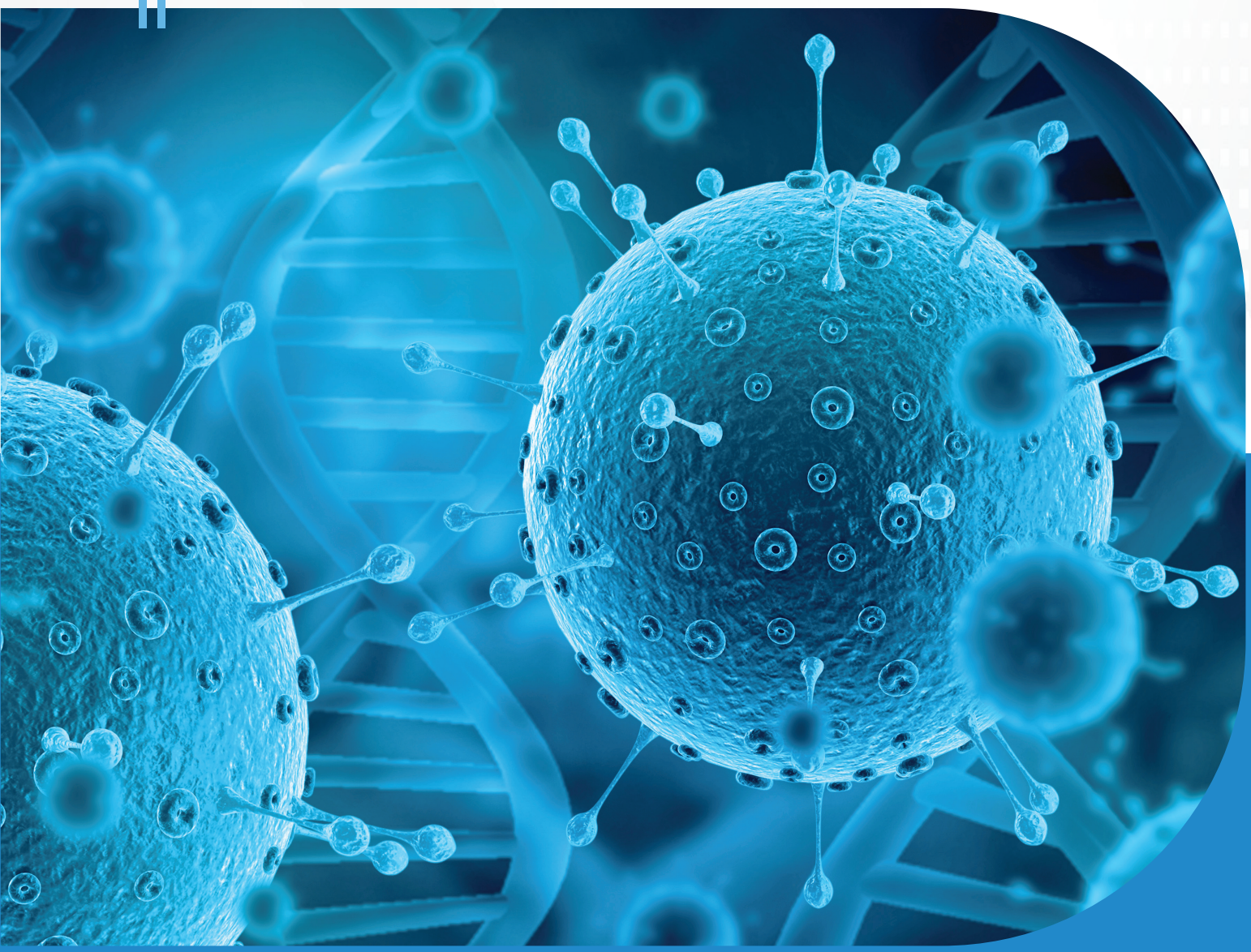
veeda clinical research | BIONEEDS | Ingenuity BioSciences



Vaccine Development Solutions

Our services are supported by our Integrated Clinical & Laboratory experience and expertise to meet your development needs across the entire Vaccine Development life cycle

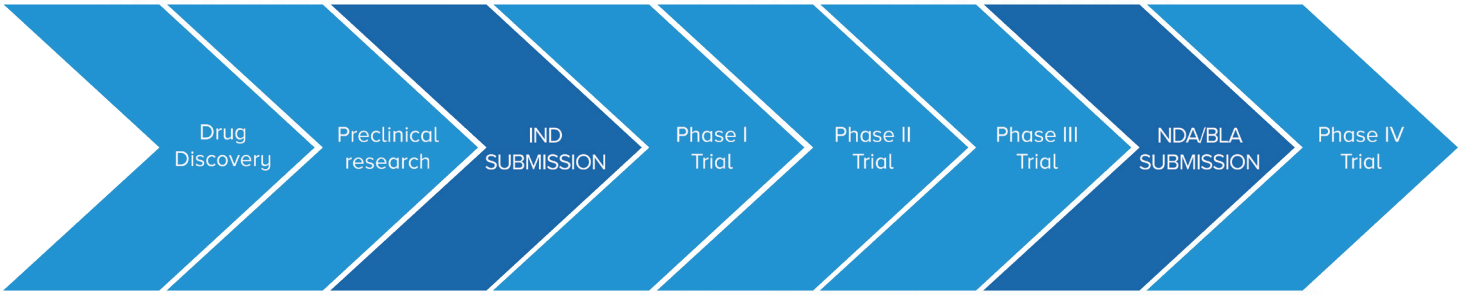
Veeda Clinical Research Limited together with its subsidiary, Bioneeds India Private Limited, and its joint venture, Ingenuity Biosciences Private Limited, (together referred to as the "Veeda Group") offers a comprehensive portfolio of clinical, preclinical and bio/analytical services to support innovator, biosimilar and generic drug development programs of our global clientele.

We are an independent, institutional investors owned, board governed and professionally managed contract research group offering scientific leadership, global quality management systems and long term operational and financial stability through a continuing investment in our people, processes, systems, infrastructure, technology and a deep commitment to quality.

Together, we serve clients globally in the following industries:

- **Pharmaceutical and Biopharmaceutical**
- **Herbal/Nutraceuticals**
- **Agrochemical and Industrial Chemicals**
- **Medical Devices**

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



Accelerate the development of your Vaccine Candidate from Concept through Commercialization with Veeda Group

- Preclinical Research
- Conducting Feasibility & Site Set up activity
- Trial Design and Execution
- Site Monitoring and Safety Monitoring
- Project Management
- Bioanalytical Services
- Volunteer Recruitment
- Regulatory Guidance

Assisting you at every stage of Vaccine Clinical Assay Development across a wide range of Diseases and Pathogens

Development	Optimization	Qualification	Validation	Life-cycle management
• Discovery • List of Critical Reagents	• Pre-clinical Development • Design of Experiments	• Phase 1/2a • Evaluate assay performance for intended purpose	• Phase 2b/3 • Formal approval by CBER	• Monitor assay trending • Trending of the assay
Development report	**Assay strategy**	**Qualification results and validation plan**	**Validation report**	Opportunity for CBER interactions

Assay Experience
ELISA - Antibody Titer and Antigen Detection
Neutralizing Antibody Detection and Titer
Type-specific Micro Neutralization
Vector-specific Quantitative PCR (qPCR)
Pseudovirus Neutralization Assay
Hemagglutination Agglutination (HAI)
Multiplex Antibody Assay
Viral Neutralization Assay
IgG/IgM/NS1 ELISA
Serotype-specific Neutralization (multiple platforms)
Serotype-specific Quantitative RT-PCR

Disease/Pathogen Experience
Adenovirus
Anthrax
Human Papilloma Virus (HPV)
Influenza
Shingles
Pneumococcal
Zica
SARS-COV-2
Dengue Virus

Providing high-quality Vaccine Laboratory Services - Our experts can assist you in determining the best path to develop your potential Vaccine Candidate

Lab services to support Vaccine Safety and Efficacy Studies

Risk Assessment Assays

- Cytokine Storm Detection
- Immune Fingerprinting Assays - Intelli.b™

Characterization

- Bioassays for Vaccine Characterization
- Vaccine Antigen Detection
- Host Cell Protein

Biomarker Assays

- Multiple Cytokine and Chemokine Panels

Immune Response Assays

- Antibody Titer, Antibody Characterization
- Neutralizing Antibody Assays PNA and PRNT
- Cell-Mediated Immunity
- Enumeration of Antigen-specific Cellular Response

Molecular Assays

- Viral Load
- Genotyping
- Gene Expression
- Host-Cell DNA

Validation of Immunogenicity Assays to support Vaccine Clinical Trials with Aegyris™

The powerful statistical engine allows for the robust calculation of assay cut points i.e. screening, confirmatory, and titer.

The immunogenicity module includes the evaluation of the following assay parameters as per Immunogenicity Method Validation Guidance:

- **Documentation - Validation plan & Report**
- **Screening Cut Point**
- **Confirmatory Cut Point**
- **Titer Cut point**
- **Precision and Acceptance Criteria**
- **Sensitivity**
- **Hook Effect**
- **Selectivity**
- **Specificity**
- **Stability**
- **Summary Precision**

Our vast Global Regulatory Experience with USFDA, EMA, Health Canada, MHRA, ANVISA, WHO, NPRA Malaysia, ANSM, AGES, MCC, and DCGI helps in successfully guiding sponsors through the ever-evolving Regulatory Landscape

Supporting you throughout the application and regulatory review phases of the Vaccine Clinical Studies in India

Initial application submission	Initial review by the regulatory agency within 1-1.5 months, if any query is found, it needs to be raised in the online portal	SEC body discussion and approval, if any query is raised, then a response /clarification has to be submitted	Meeting & discussion with the SEC body to present the proposal (Once in a month for each therapy/ indication)	Once the SEC body approves the protocol, final approval is received within 10-15 days. The overall approval timeline takes around 3-3.5 months

Our Infrastructural Capabilities can help you advance your next Vaccine Development Project

PBMC	PCR	Flow Cytometry	ELISpot	Kits and Depots
Washed and prepared cells for functional analysis at clinical site	Amplification of viral components (i.e., RNA levels)	Population functional analysis of immune response post administration	Cell-mediated immunity for vaccine specific immune response monitoring	Global kit supply and clinical trial material transport

Our Clinical Sites Network aims to optimize Vaccine Trial Timeframes

No. of Sites in the Database	No. of Sites in Active Touch Base	No. of Sites Presently Working
112	28	7

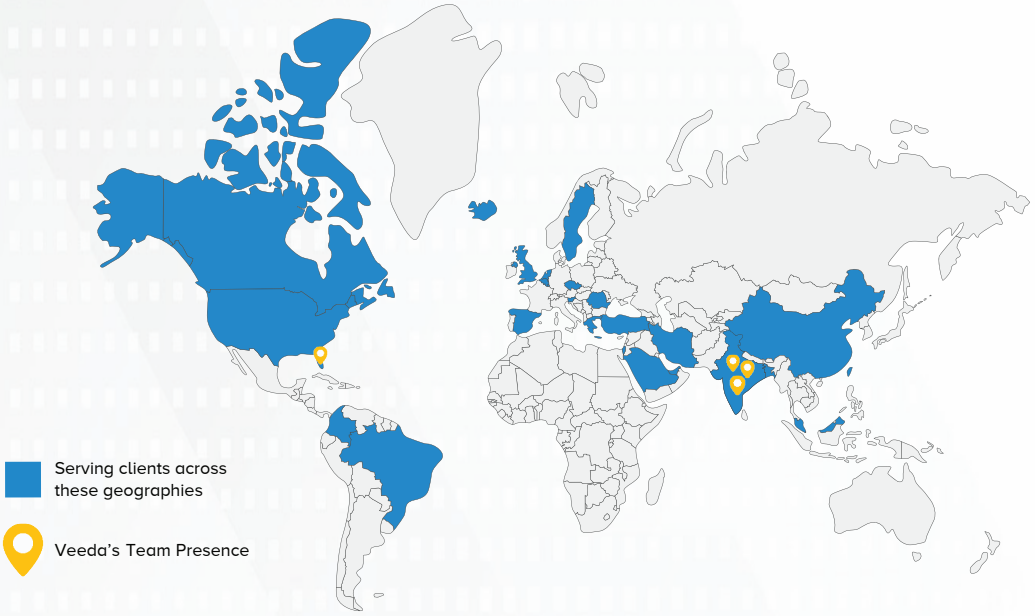
India has emerged as a testing ground for several Global Vaccine Candidates

Live attenuated Influenza A (H1N1) Virus Vaccine	MMR Vaccine
Polysialylated Erythropoietin	Powdered Measles Vaccine
Rotavirus Vaccine	PsA-TT Conjugate Vaccine
Rubella Vaccine	Repoitin
10-valent Pneumococcal Conjugate Vaccine	Inactivated Salk Polio Vaccine (Adsorbed)
BCG Vaccine	RMAb
DTP/ Hib Vaccine	RMab: Human IgG1 monoclonal antibody
DTP-HB-Hib	Typhoid Conjugate Vaccine (Bivalent)
DTwP-HB+Hib	Yellow Fever Vaccine
Edmonston-Zagreb (E-Z) strain attenuated Measles Vaccine	Purified Vero Rabies Vaccine
Live attenuated Influenza Virus Vaccine	Purified Vero Rabies Vaccine + Human Rabies Immune Globulin (HRIG)
Live attenuated Seasonal trivalent Influenza Virus Vaccine	Purified Vero Rabies Vaccine + Human Rabies Immune Globulin (HRIG)
H. Influenzae Type B Vaccine	Vero Cell Rabies Vaccine (PVRV)
Human Serum Albumin - Free Repoitin	
Influenza Vaccine (whole virion, inactivated) 10 mcg	
Influenza Vaccine	
Influenza Vaccine (whole virion, Inactivated) A/H1N1 (Pandemic) (15 mcg)	

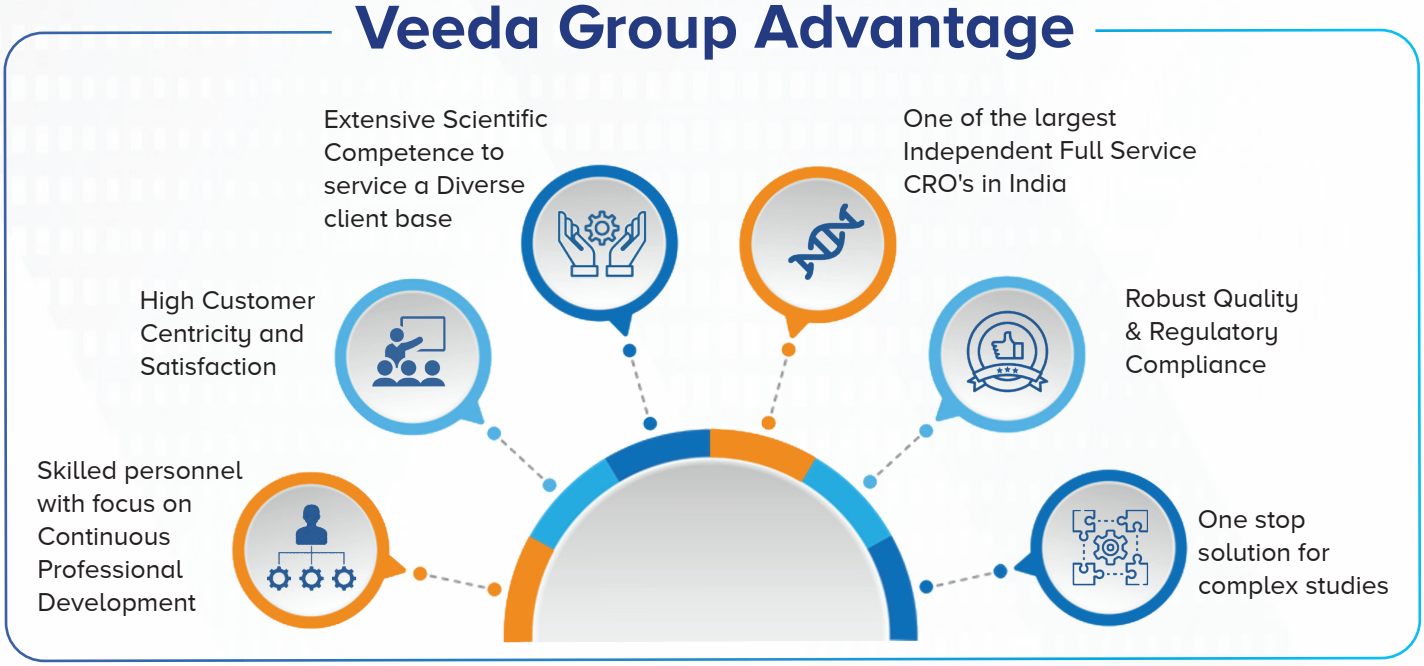
We assist our clients in navigating the path to developing New Treatments and Vaccines by leveraging our experience in Vaccine Studies

Vaccine Studies	Short Description	Study Status
COVID-19 Study (IgG Titer, ELISPOT & FACS Assays)	• Open-label bridging study followed by a double-blind Phase II/III study of AKS-452 (a second-generation protein sub-unit vaccine against COVID-19) • IgG Titer Clinical studies involve the measurement of human anti-SP/RBD IgG titers in human serum samples • The enzyme-linked immunospot ELISPOT assay is a highly sensitive immunoassay that measures the frequency of cytokine-secreting cells at the single-cell with PBMC isolation & culturing • The FACS test is an effective way to identify and measure a wide range of immune responses for a vaccine candidate • Study specific cell population analysis, cell proliferation, cell death analysis, Cell Surface marker analysis, Bead-based Multiplexed assays • No of Subjects: 100 (Bridging) 1500 (Phase II/III study)	Ongoing
Polio Vaccine Study	• Open-Label Phase 1 Clinical Study for Evaluation of Safety and Immunogenicity of Sabin-based Inactivated Polio Vaccine in Healthy Adult Human Male Subjects • No. of subjects- 24	Completed

Our Global Footprint



Veeda Group Advantage



To know more about our Vaccine Development Capabilities, write to us at:

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