VEEDA GROUP

Integrated, Tech-Driven, Global CRO

Table Of Contents

- Group Overview
- Preclinical Capabilities
- Early Phase Capabilities
- Bioanalytical Research
- Clinical Trial Capabilities
- Biopharma Capabilities

Veeda Group Overview

Veeda: Vision and Mission

Vision

Become the premier Global development partner for advancement of Oncology assets through Science, Technology and Real World Data

Mission

To be the pre-eminent independent Indian contract research organization, with **Global Execution** capabilities, distinguished by the breadth of our services and by excellence in the quality of our: Scientific and Regulatory knowledge; Research design, execution and insights; and Client Centricity

Full-Service Independent Global CRO

Our Values: Foundations of Our Commitment

Uniquely Positioned for Comprehensive Drug Development

BIONEEDS + Veeda Clinical & Biopharma + heads = Veeda Group

Discovery → End-to-End Services Under Veeda Group → Market

115+ Regulatory Audits

500+ Global Active Clients

22,000+ GLP Pre-Clinical Studies

150+ Clinical Trials

4,900+ Healthy Volunteer studies

20+ Biopharma Studies

Data and Tech Driven CRO

- **Clinical** – Accelerating study completion with real-time data, streamlined Case Report Form (CRF) management, automated tracking, and seamless Clinical Data Interchange Standards Consortium (CDISC)/Study Data Tabulation Model (SDTM) mapping.
- **Bioanalytical** – Leveraging advanced technologies like Laboratory Information Management System (LIMS) and Electronic Laboratory Notebook (ELN).

In-house developed platforms

- **Electronic Data Capture (EDC)** - EDC platform for Clinical Trials.
- **Study Management System** – Tracking of studies including Management Information System (MIS), Enterprise Data Layer, etc.
- **Artificial Intelligence (AI) Implementation** – Proof of Concept (POC)/Prototypes of various Generative Artificial Intelligence (GenAI)-based applications. Exploration of external partnerships.

7 ongoing technology projects that will save ~50% of paper and ~20% of time and effort

Strategic Security Solutions for a Resilient Future

Network & Email Protection

- **VPN for Remote Working**: Secure remote access with firewall protection
- **VAPT (EPC Manage Engine, Nessus)**: Regular vulnerability testing
- **Email Security:** Phishing filters and campaign tests

Endpoint & Perimeter Security

- **Anti-virus Software for Endpoints**: Protects individual devices against malware and viruses
- **Web Security (Firewall)**: Monitors and controls internet traffic

Data & Backup Protection

- **Zerto**: Real-time backup for critical servers
- **Veeam**: Daily backups for server redundancy
- **Acronis**: Hourly backups for LCMSMS systems

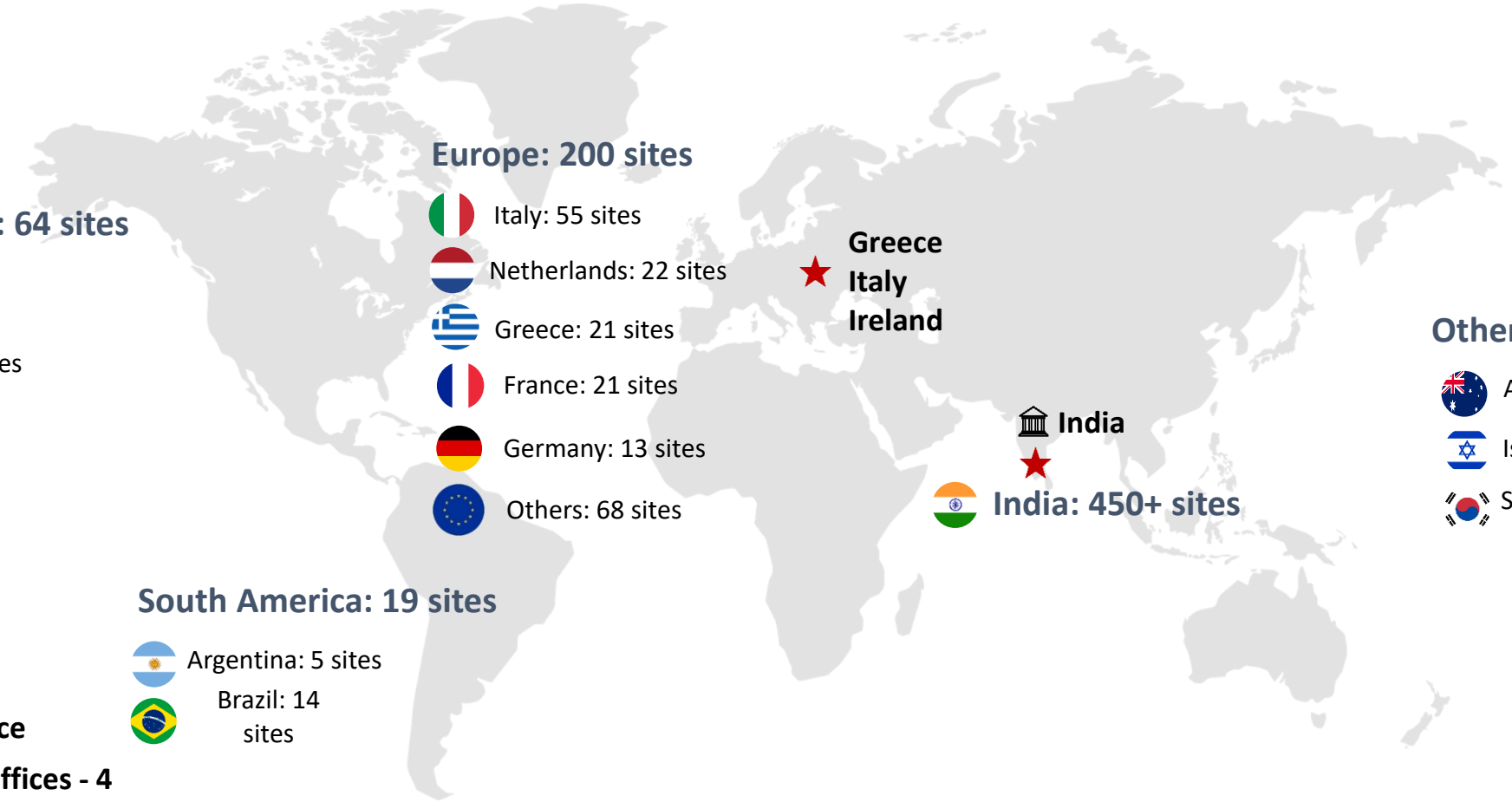
Device & Application Security

- **Device Compliance - Microsoft Intune**: Ensures that all devices comply with security policies
- **MDM (EPC Manage Engine)**: Secures mobile devices
- **Patch Deployment (Manage Engine)**: Automatic updates to secure devices from vulnerabilities

Zero-Downtime Backup & Disaster Recovery High Compliance Security Standards (GDPR & ISMS)

Presence Across 26 Geographies Globally

Access to Sites in 26 Countries along with Offices in 9 Countries



North America: 64 sites

- USA: 51 sites
- Canada: 13 sites

Europe: 200 sites

- Italy: 55 sites
- Netherlands: 22 sites
- Greece: 21 sites
- France: 21 sites
- Germany: 13 sites
- Others: 68 sites

Greece
Italy
Ireland

India

India: 450+ sites

Others: 23 sites

- Australia: 10 sites
- Israel: 6 sites
- South Korea: 7 sites

South America: 19 sites

- Argentina: 5 sites
- Brazil: 14 sites

Registered Head Office

Operational Onsite Offices - 4

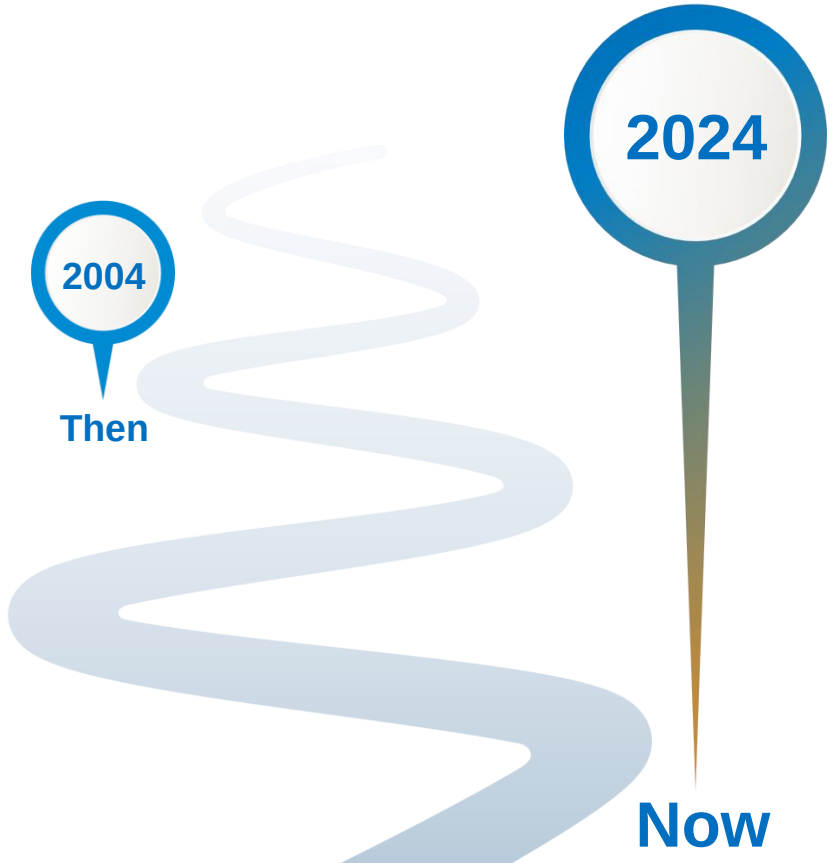
Other Registered Offices - 5

Progression towards an Integrated Contract Research Organization

Early Phase
Phase I

Generics/Biosimilar
Healthy Volunteer Studies
Patient Based Studies

Bioanalytical
Small Molecule



Preclinical
Discovery Services
Chemistry
Bioanalysis
Toxicology

Early Phase
Phase I
Phase II

Mid Phase
Phase III
PV/ RWE

Generics/Biosimilar
Healthy Volunteer Studies
Patient Based Studies

Bioanalytical
Small Molecule
Biologics
Biosimilars

Expanding Horizons: From Generics to Innovative Therapies

Environmental, Social and Governance (ESG)

Eco-Conscious Facility Management

Efficient air quality and waste management protocols for energy conservation

E-waste management.

Partner with certified vendors to ensure responsible disposal of electronic waste

Automated Threat Detection

Leveraging Trend Micro XDR to detect anomalous behaviors to identify complex, multi-layered attacks.

SFC: Safeguarding the Environment

Replacing LC with SFC to minimize the use of toxic organic solvents

LHS: Minimizing Plastic Waste

Reducing plastic waste by using 30% fewer pipette tips per batch

LES: Digitalization for Sustainability

60% reduction in paper-based logbooks

Corporate Social Responsibility (CSR): Uplifting Lives, One Step at a Time

10+
Institutes

- Primary-secondary school, colleges and technical institutes
- Sponsoring for vocational and technical training

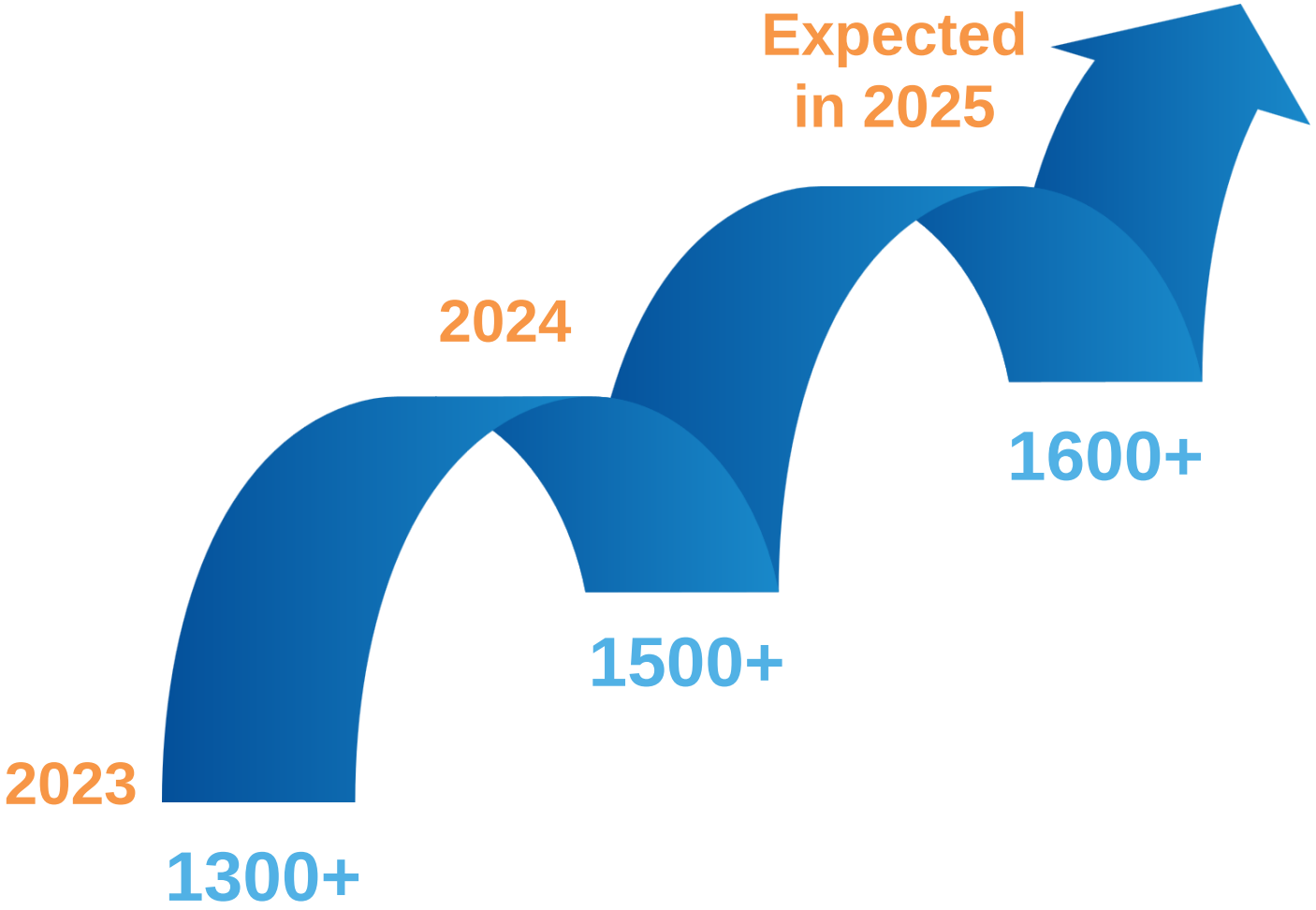
4000+
Students

- Bridging literacy gaps in small towns
- Empowering women and marginalized communities

1200+
Health Beneficiaries

- Supporting children with special medical needs
- Training and employment of individuals with intellectual disabilities

Growing Employee Strength



Culture of Diversity & Inclusion

- Ph.D.s - **70+**
- MBBS - **20+**
- M.Pharm - **300+**
- M.D. - **4**
- Over **30%** of female employees
- Employees from **12** different countries

Our Leadership Team: Pillars of Veeda Group

Dr. Mahesh Bhalgat
Group CEO, Veeda Group

Strategic Business Units

Dr. Venu Madhav
Chief Operating Officer, Healthy Volunteer

Dr. Sanjib Banerjee
Chief Operating Officer, Biopharma

Mr. James Brook
Chief Operating Officer, Clinical Trial

Ms. Sapna YR
Chief Operating Officer & Chief Business Officer, Pre-clinical & Toxicology

Central Functional Units

Mr. Nirmal Bhatia
Chief Finance Officer

Dr. Pranav Dalal
Chief Technology Officer

Mr. Ajay Tandon
Chief Strategy Officer

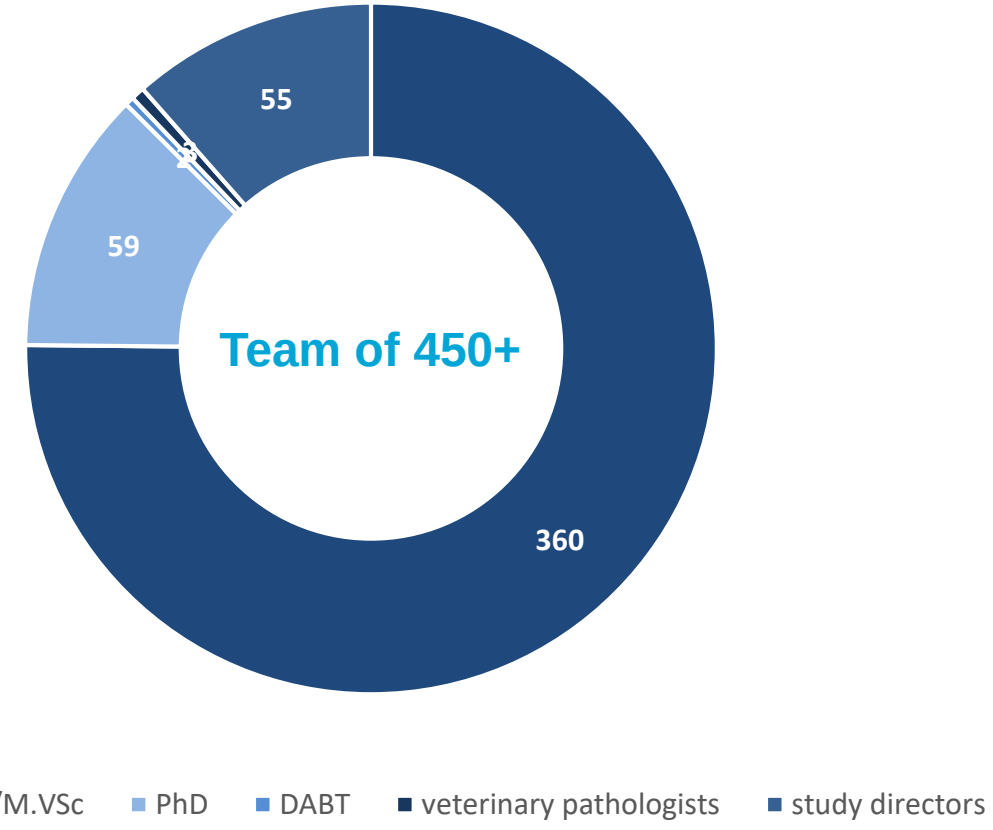
Ms. Amee Kanuga
Chief Quality Officer

Mr. Manmohansinh Chauhan
Chief Human Resource Officer

Exploring Preclinical Capabilities: A Foundation for Success

Bioneeds: Delivering World-Class Preclinical Solutions

- **15 years** in Integrated Discovery, Development, and Regulatory Services, Bangalore
- Services for Pharma, Biopharma, Medical Devices, Agro/Industrial Chemicals
- **300+** impurity qualification studies; **22,000+** GLP studies
- Expertise in NCEs, generics, biosimilars, biologics, vaccines



Building Credibility and Trust

Accreditations & Certifications

- GLP certified & **USFDA audited** test facility
- Accredited by AAALAC & **OLAW for laboratory animal care**
- ISO 17025 accredited by the NABL
- Registered - Committee for Control and Supervision of Experiments on Animals, Ministry of environment, forests, and climate change, GOI

Infrastructure

- Labs Supporting In vivo pharmacology, pharmacokinetics, toxicology, genetox, DART, ERA, analytical & bioanalytical (TK) assessment.
- 250,000 sq. ft. facility.
- State-of-the-Art Inhalation Facility & In Vitro Cell Culture and Microbiology Labs
- Synthetic chemistry and analytical labs.

One of the Largest Vivarium in the Country with 115 animal rooms

Preclinical & Chemistry Services

Generics Preclinical

- **Impurity qualification**
- ANDA/NDA, 505(B)2 toxicity studies
- Analytical & Bioanalytical MD & MV
- Biodistribution studies: complex injectable like FCM, Liposomal products etc.

Innovators (NCE/Small molecules)

- IND enabling studies
- Standalone PK studies
- **Inhalation Toxicity**
- Mutagenicity
- DMPK

Biopharma Preclinical

- **Safety / Toxicity with Immunogenicity assessment**
- Custom HCP assay dev., mAbs, pAbs generation
- Biological assays

Synthetic, Chemistry Services

- Medicinal chemistry, **Custom Synthesis**, Process R&D and scale up
- Impurity Synthesis & **Agrochemical**

Serving 410+ global clients, across big pharma, biotech, and research institutions

Laying the Groundwork for Early-Stage Drug Development

Best-in-class Infrastructure: Driving Credibility and Efficiencies

Clinical & Bioanalytical Facility 1
Vedant

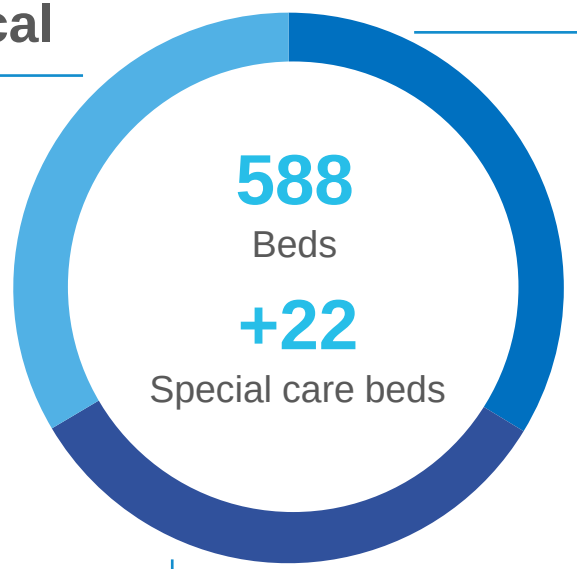
Corporate Office & Bioanalytical Facility 2
Satyamev Corporate Office

Common Screening Facility
Skylar for both Shivalik and Vedant

Dedicated Clinical Facility 2
Shivalik

Clinical Facility 3
Mehsana, - dedicated Screening facility

Spread across 16 clinics



Dedicated Clinical Facility 2

170 Beds +
7 Special care beds +
12 Intensively monitored beds to conduct Phase I study

Clinical & Bioanalytical Facility 1

226 Beds +
8 Special care beds +
18 Intensively monitored beds to conduct Phase I study

Clinical Facility 3

162 Beds +
7 Special care beds

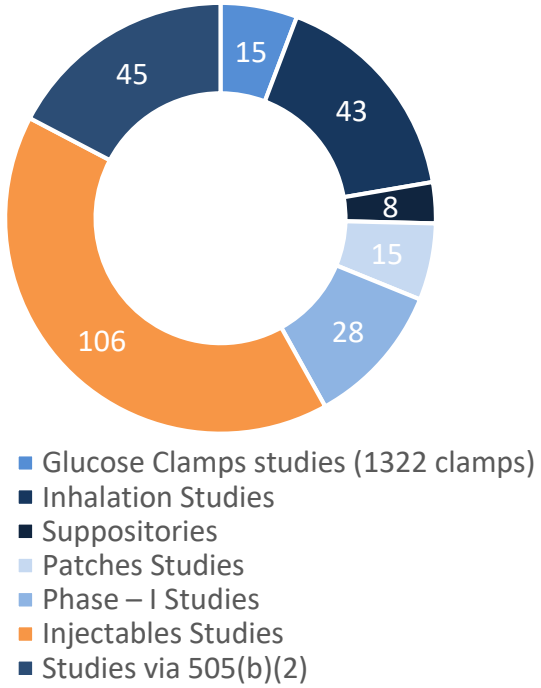
Largest Phase I Unit in the Country

Leadership in Healthy Volunteer Bioequivalence Studies

Two Decade of Extensive Experience in Healthy Volunteer Studies

- **5000+** Healthy Volunteer Studies
- **230+** Complex Clinical Studies

Effectively Moving Up The 'Complexity Curve'



Leaders in Injectable Research: Including 18 Long-Acting Formulations

Largest Volunteer database In India 89,000+

Strong Regulatory Credentials

Successful Inspections Across all Pre-Clinical, Clinical and Bioanalytical Facilities

- **56** – USFDA
- **17** – ANVISA
- **10** – NGCMA
- **4** – UK-MHRA
- **24** – CDSCO
- **4** – NPRA
- **6** – NABL
- **6** – WHO
- **4** – AGES(EMA)
- **5** – AAALAC
- **11** – Others

Till 2023 **129 Inspections**

+

Last 1 year **18 Inspections**

=

Total 147 Inspections

Phase I Trial Expertise

19 Unique sponsors associated for phase I studies across the globe

1000 Volunteers enrolled for phase I studies in last 3 years

- Multiple Ascending Dose Studies
- First In Human Studies
- Glucose Clamp Studies
- Novel Generics 505(b)2 Studies
- Proof Of Concept Studies
- Drug-drug Interaction Studies
- Food Effect Studies
- Age And Gender Effect Studies
- Single Ascending Dose Studies

Advanced Bioanalytical Expertise: Driving Success in Clinical Programs

Laboratory Infrastructure: Promoting Scientific Excellence

1. LC-MS/MS, ICP-OES, ICP-MS, LHS & LIMS machines
2. BSL class-2 lab for Infectious Samples
3. Deep Freezers and Cold Room for Plasma Samples
4. Pharma Refrigerators, Walk-In & Humidity Chambers

- **Uniquely Positioned to rapidly advance NCE development using SFC-MS/MS**
- **Capable of Processing 1,20,000 samples per month**

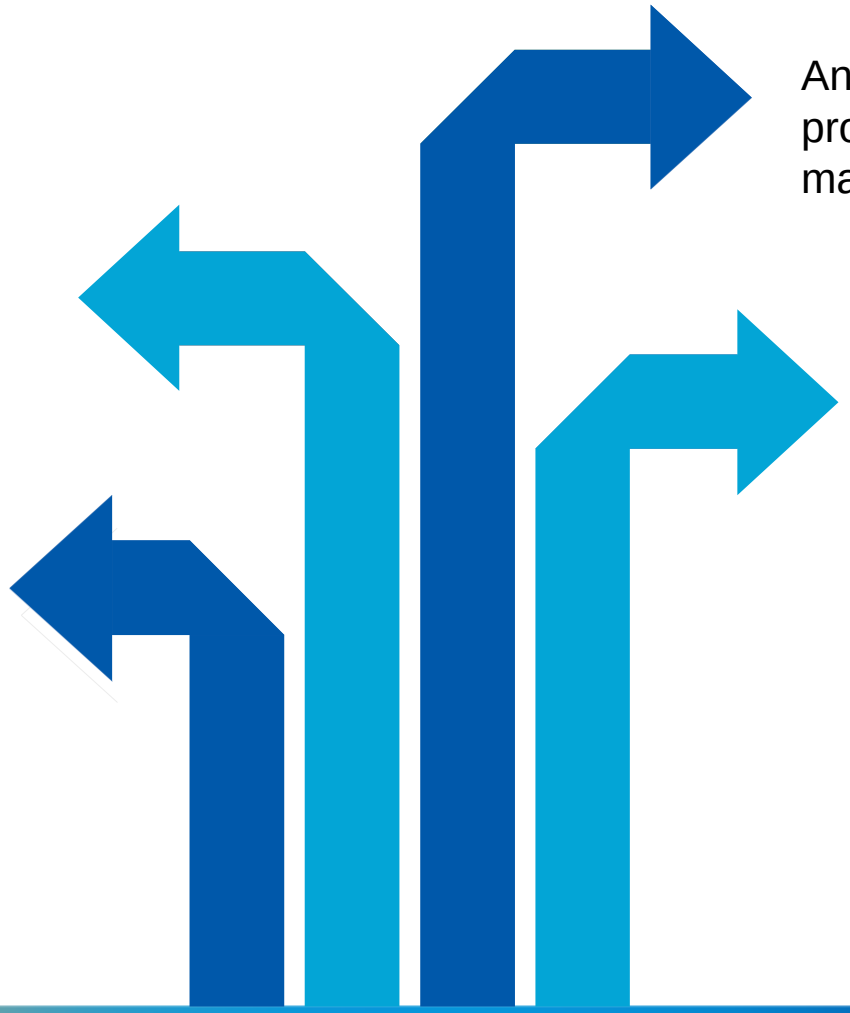
Timeliness & Technical Expertise

Analytical techniques like protein binding and rare matrix

Complex molecule method development <3weeks

>240 Trained and competent scientific team to handle regulated bioanalysis.

Sample analysis, within 5 days to support FIH study for NCE dose escalation studies.



Bioanalytical Experience

Over **1,250+** bioanalytical methods with an average runtime of under **5 minutes,** covering diverse categories.

1020 + 20 Generics + Pharmacodynamics/ Immunogenicity

110 Complex Generics

111 NCEs

Analytical Capabilities

- Method development with quantification down to 0.1 pg/mL.
- Multi-molecule analysis in a single injection
- Central Bioanalytical Lab for global Phase II/III trials
- Advanced Microsampling Methods like VAMS and Capillary micro sampling
- Peptide and Protein analysis by LC-MSMS

ISR acceptance > 97%

Precision and Compliance in Clinical Trials: From Design to Delivery

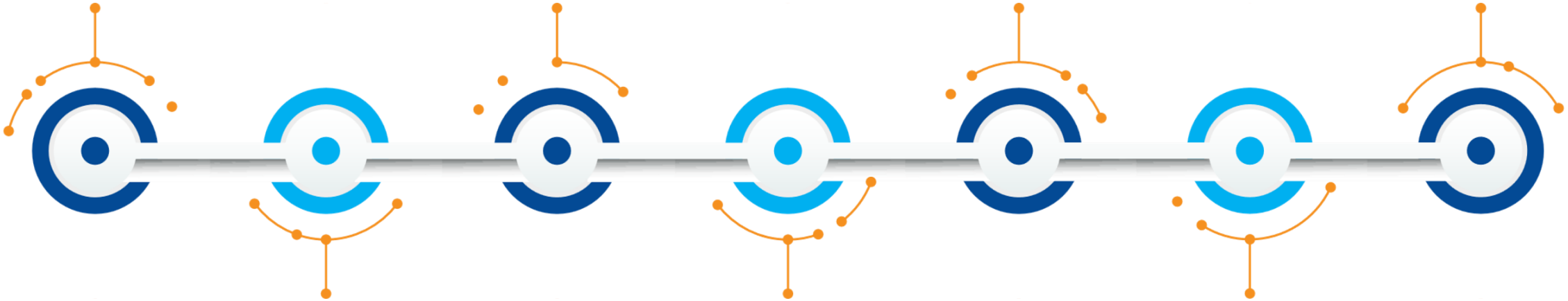
Late Phase Global Clinical Trial Capabilities

Medical Writing
- Protocol, ICF, IB, Study Report etc.

Regulatory Services
Application processing
Technical presentation
-Liasioning

Pharmacy and Laboratory services including PK and Immunogenicity analysis capabilities

Safety
Database and Pharmacovigilance



Conducting Feasibility & Site Set up activity

Site Monitoring, Logistics and Project Management, &Safety Monitoring,

Electronic Clinical Trial management, Biostatistics including eCRF capabilities

Driving Clinical Excellence

Our in-depth experience, capabilities and experienced project team enables us to deliver high-quality and timely outcomes for your clinical studies.

55+ Patient bioequivalence studies

10,000+ Patients

750+ Sites

20+ Ongoing Phase I-IV Trials

1800+ Investigator Database

14 Ongoing Studies
- 12 Bioequivalence Studies
- 1 Clinical end point studies
- 1 Patient PK Studies

- **Leading CRO supporting the fight against multiple myeloma**
- **Expert in psychiatry trials**
- **Conducting the 2nd largest multiple myeloma study**
- **Leader in plasma cell disorders**

Successfully completed 27 USFDA inspections across sites without 483 observations.

Successfully Completed EMA inspections across 02 sites.

A Legacy of Success: Phase Trials Across Various Indications

Successfully Completed 75 Phase Trials:

40+ Oncology trials for the treatment of indications like bladder cancer, lung cancer, breast cancer, multiple myeloma

Phase Trial Success Across a Vast **Range of Therapeutic Areas**:

- Oncology
- Hematology
- Cardiology
- Dermatology
- Endocrinology
- Gastroenterology
- Infection
- Rheumatology

In-house Electronic Data Capture (EDC) Platform

Overview

- 21 CFR Part 11 compliant
- Very quick set up. CRF to go Live: 2-10 days!

Reports

- Real time reporting with TIBCO Jaspersoft integration

Modules

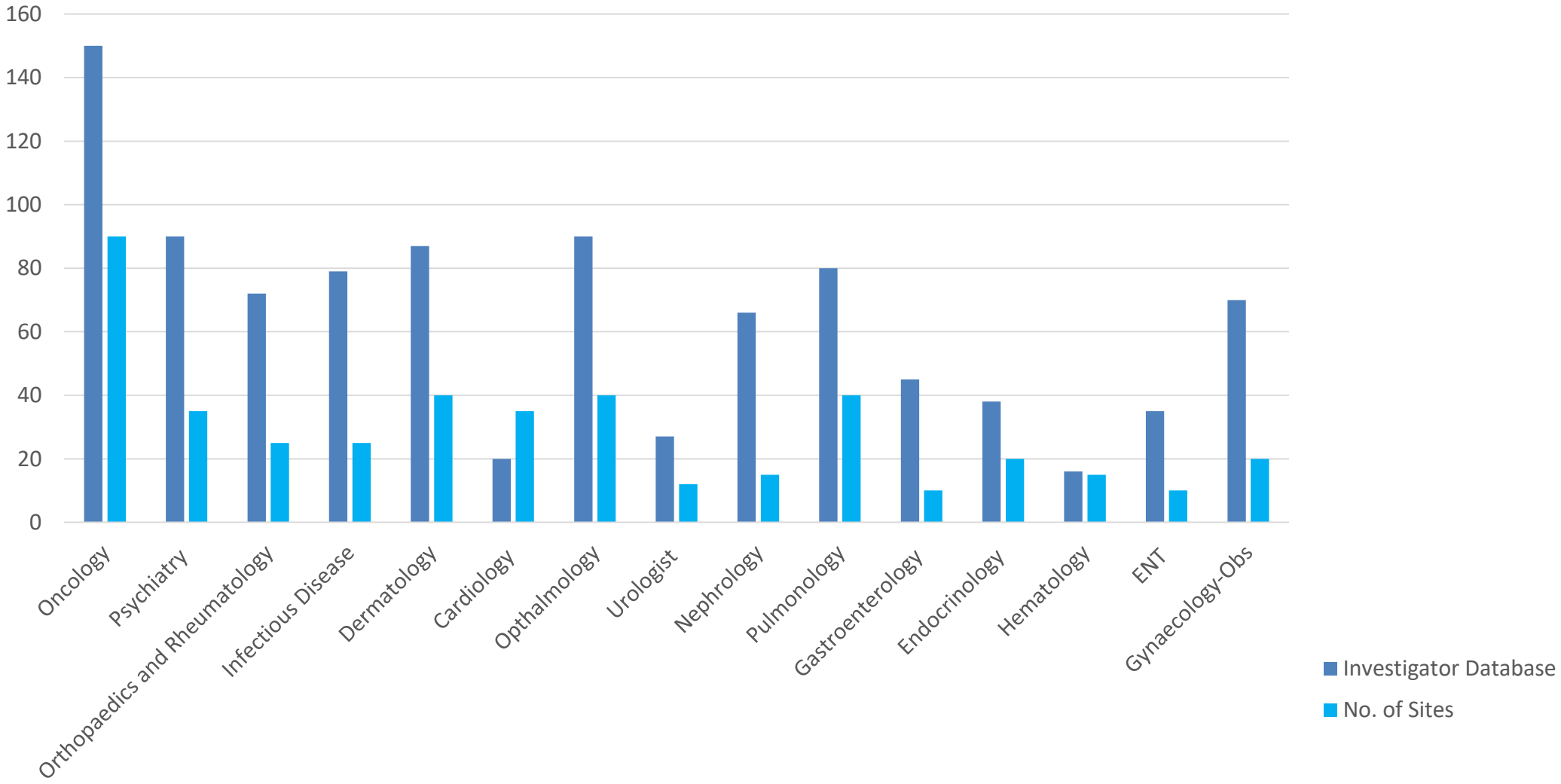
- IWRS – Fully customizable to each project, Integrated with Medidata Rave*
- SAE – Real time automated pdf sharing via email
- Medical Review – Eligibility/PD review and approval within the platform

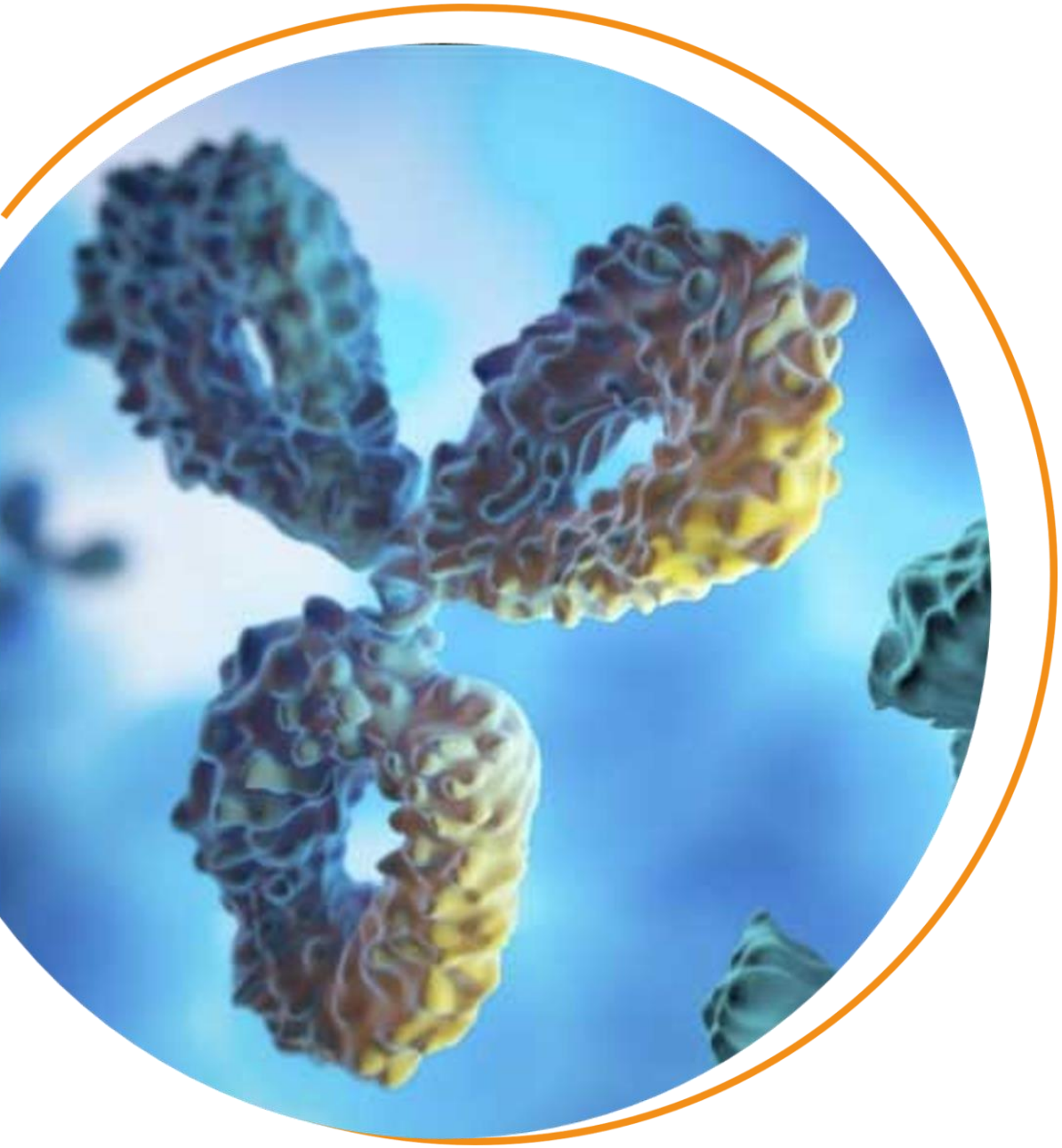
*Veeda Group is a Medidata partner

Why EDC?

- Seamless Integration with other systems
- Supports Real-Time Data Capture
- Automates deviation tracking and CDISC/SDTM mapping
- Offers a reusable eCRF library, reducing design time
- Enhances study speed and reduces costs

Veeda's Investigator & Sites Database





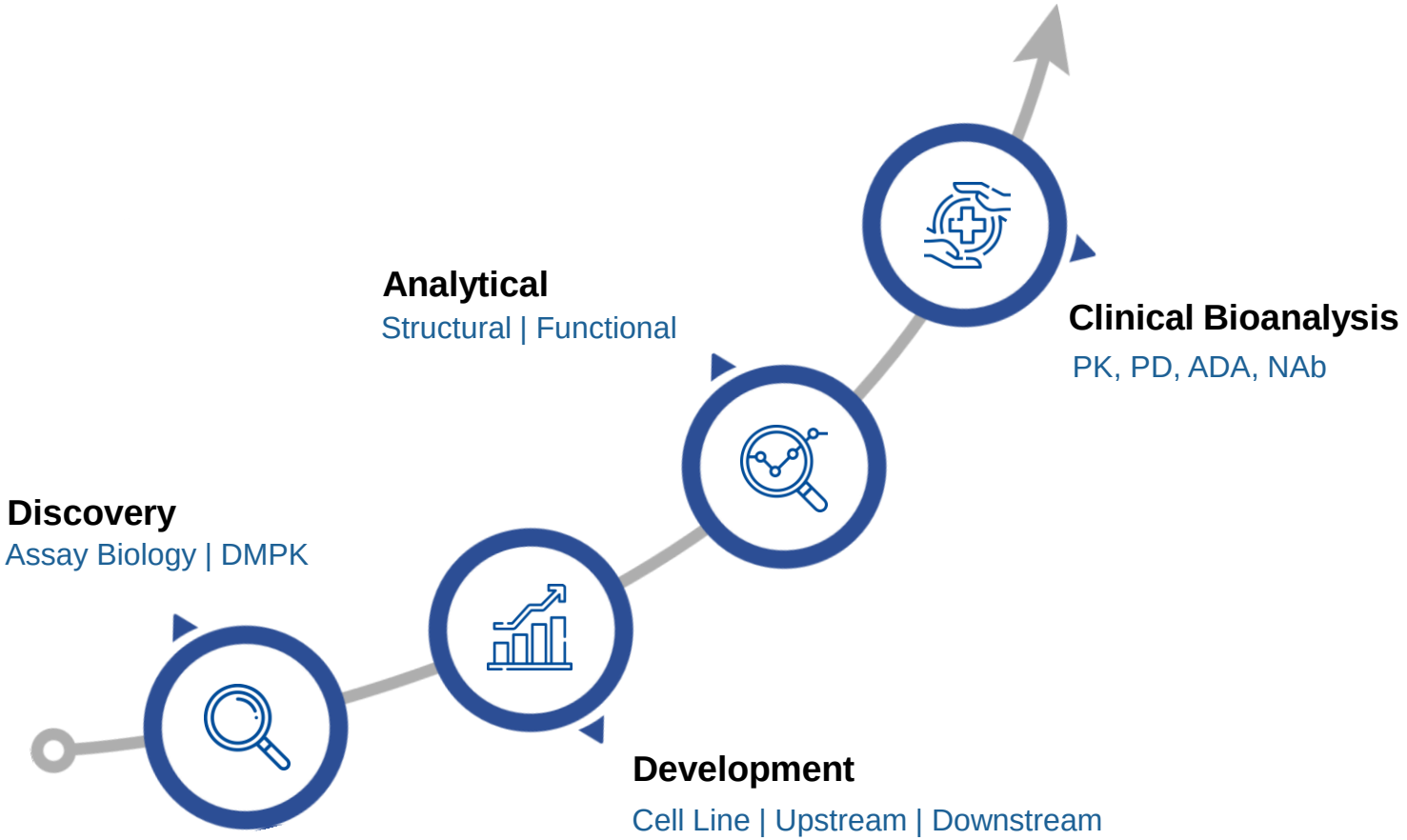
Biopharma Capabilities: Advancing Novel Biologics & Biosimilars Together

Biopharma Infrastructure

- Contract Research and Development Organization (CRDO)
- Launched in 2023
- ~50,000 square feet campus in Bangalore, India
- DCGI and DSIR approved facility

- ~60 People Team, >60% Technical Staff, **10+ PHD**
- State-of-the-art Facility with Innovative Technologies
- Team of 30+ scientists with expertise in Biosimilars, Therapeutic Proteins, Biologics and Vaccines

One-Stop Solution for Novel Therapeutics



NCE | NBE | Biosimilars | Vaccines Development & Characterization

ADC, mAbs (bispecific, Ab Fragments), Fusions/ Conjugated Proteins, Biopolymers, Oligos, Protac

Biopharma Lab:

Non-clinical and Clinical analysis

Exclusive Access to ZIP CHIP Technology

Accelerates analysis, cutting LC-MS/MS times and ensuring product consistency through detailed charge variant examination

GLP 1 Development

Specialized services in intact mass, peptide mapping, and glycopeptide analysis

Veeda Biopharma Analytical Expertise

Product Characterization

- Expertise in complex biopharmaceuticals
- Expertise in glycosylated, fusion proteins, ADCs & vaccines
- State-of-the-art High Resolution Mass Spectrometry (2024 model) with Complementary Techniques: Transmission MS & Trapping MS

Higher Order Structure (HOS)

- Exclusive FFF-MALS services in India
- Precision-driven analysis tailored for complex molecules
- Innovative ZIPCHIP collaboration enhancing precision in charge variant characterization
- Global-standard specialized instrumentation to support HOS

Analytical CMC

- Fully automated workflows for efficiency and accuracy
- N-glycan analysis: fully automated & rapid processing (expedited to 3-4 days from 3-4 weeks)
- Plethora of analytical testing to support process-product CQA and QTPP
- Structural and functional assessment for stage-appropriate analytical feedback (FPC and FIO)
- In-house process-specific HCP kit development capability

Thank You

Partners in creating

a healthier tomorrow

For any further assistance kindly write to us at info@veedacr.com or visit us at www.veedacr.com