BIONEEDS

Corporate Overview

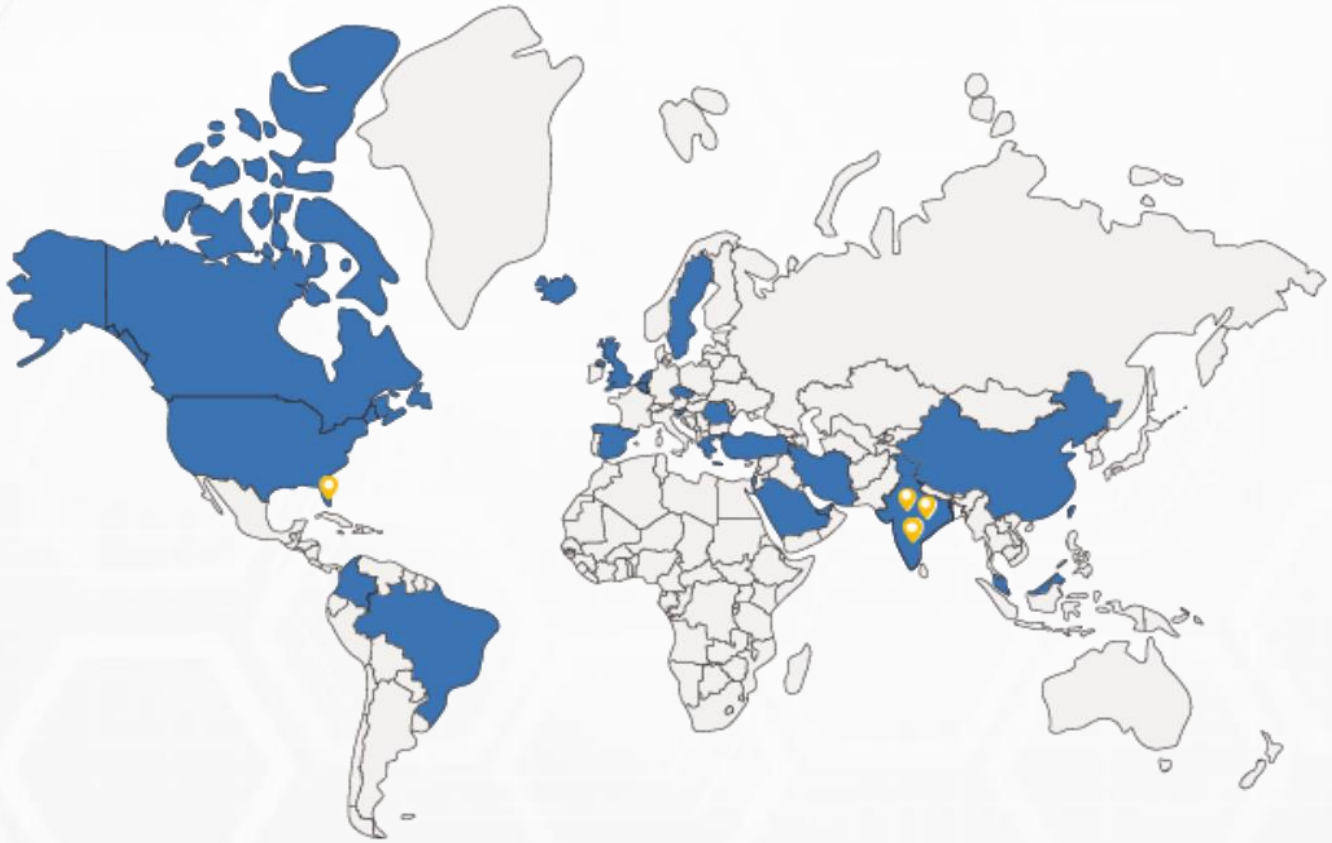
Veeda Group

- Veeda Clinical Research Limited (“Veeda”) together with its subsidiary, Bioneeds India Private Limited (“Bioneeds”), (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 and technology and a deep commitment to quality

- Together, we serve clients globally in the following industries:
  - Pharmaceutical and Biopharmaceutical
  - Agrochemical and Industrial Chemicals
  - Herbal/ Nutraceuticals
  - Medical Devices

Our Global Foot Print



Serving clients across these geographies

Veeda's Team Presence

Corporate Philosophy

Vision

In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs

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

Quality Framework

"Our management is committed to continuous improvement in the effectiveness of our Quality culture, to providing quality research solutions that meet sponsor and regulatory requirements and to protecting the rights, safety and well being of the study volunteers"

- Comprehensive system with more than 350 SOPs
- QC & QA monitoring
- Monthly Quality Review Meetings
- CAPA Management

Focus on implementing policies & nurturing individual behavior to sustain our culture of quality

Balanced Score Cards (BSC) for augmenting corporate strategy

Quantifiable Performance Metrics for all departments

Individual KPI's & KRA's linked to BSC

Continuous process improvement

Regulatory Credentials

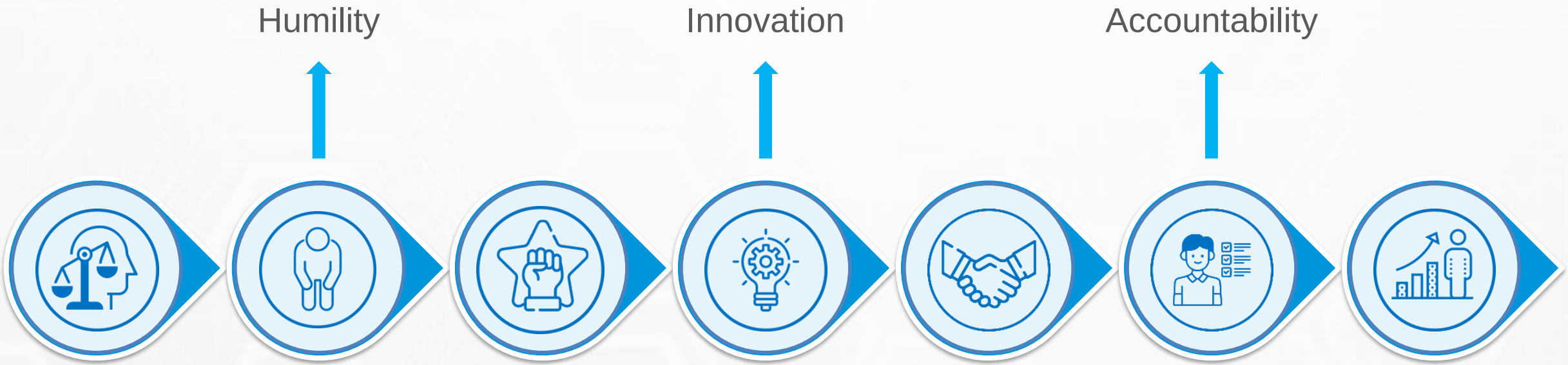
- 98 successful regulatory audits till date
- 15 successful regulatory audits in the last year.

US FDA	→	49*	ANSM	→	1
MHRA	→	4	AGES	→	5*
ANVISA	→	8	MCC	→	1
WHO	→	6	DCGI	→	19
NPRA Malaysia	→	5			

*FDA : 25 AUDITS FOR PATIENT BASED STUDIES
24 AUDITS FOR HEALTHY SUBJECTS STUDIES

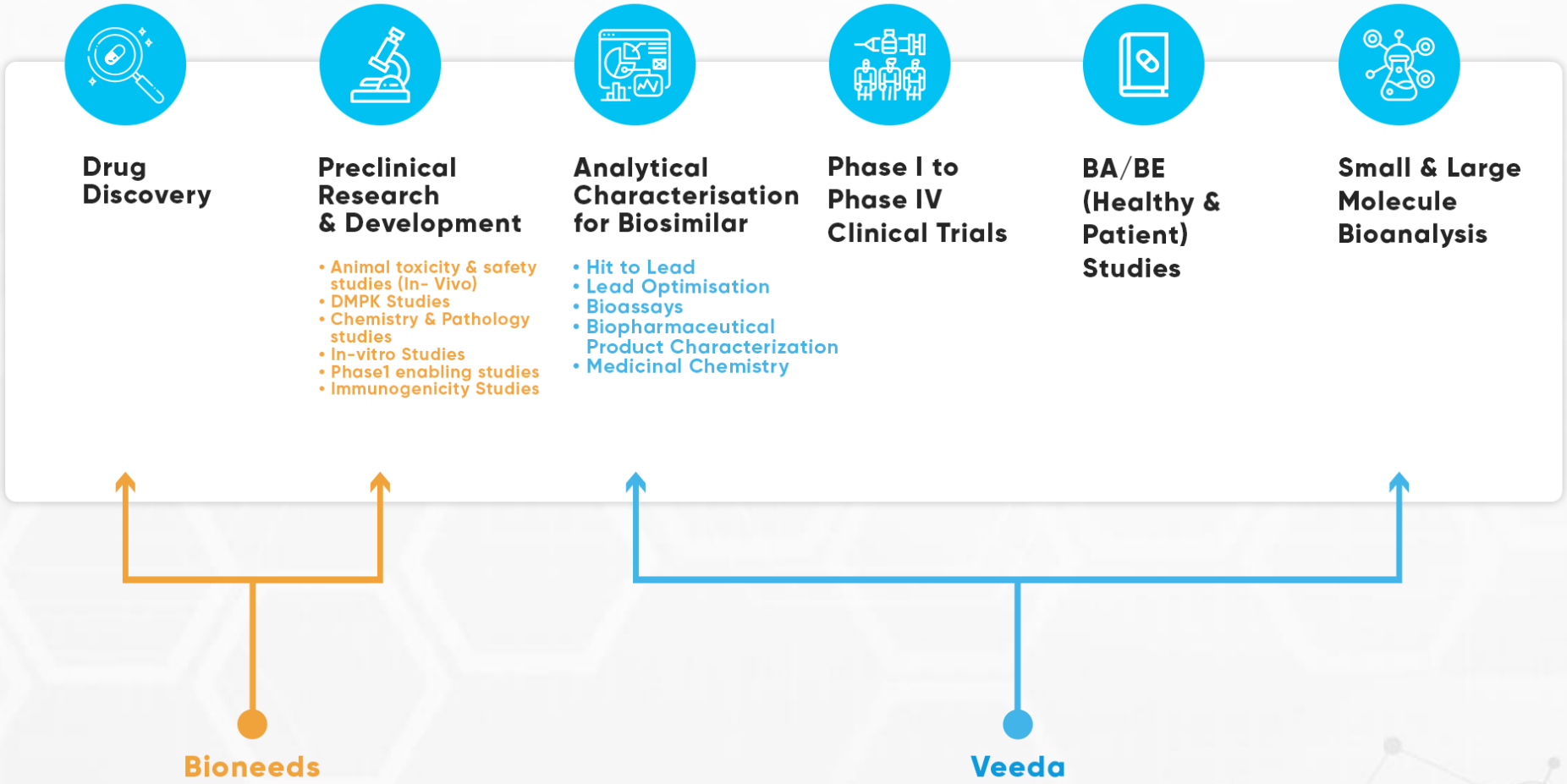
AGES : 2 AUDIT FOR PATIENT BASED STUDIES
3 AUDITS FOR HEALTHY SUBJECTS STUDIES

Our Values

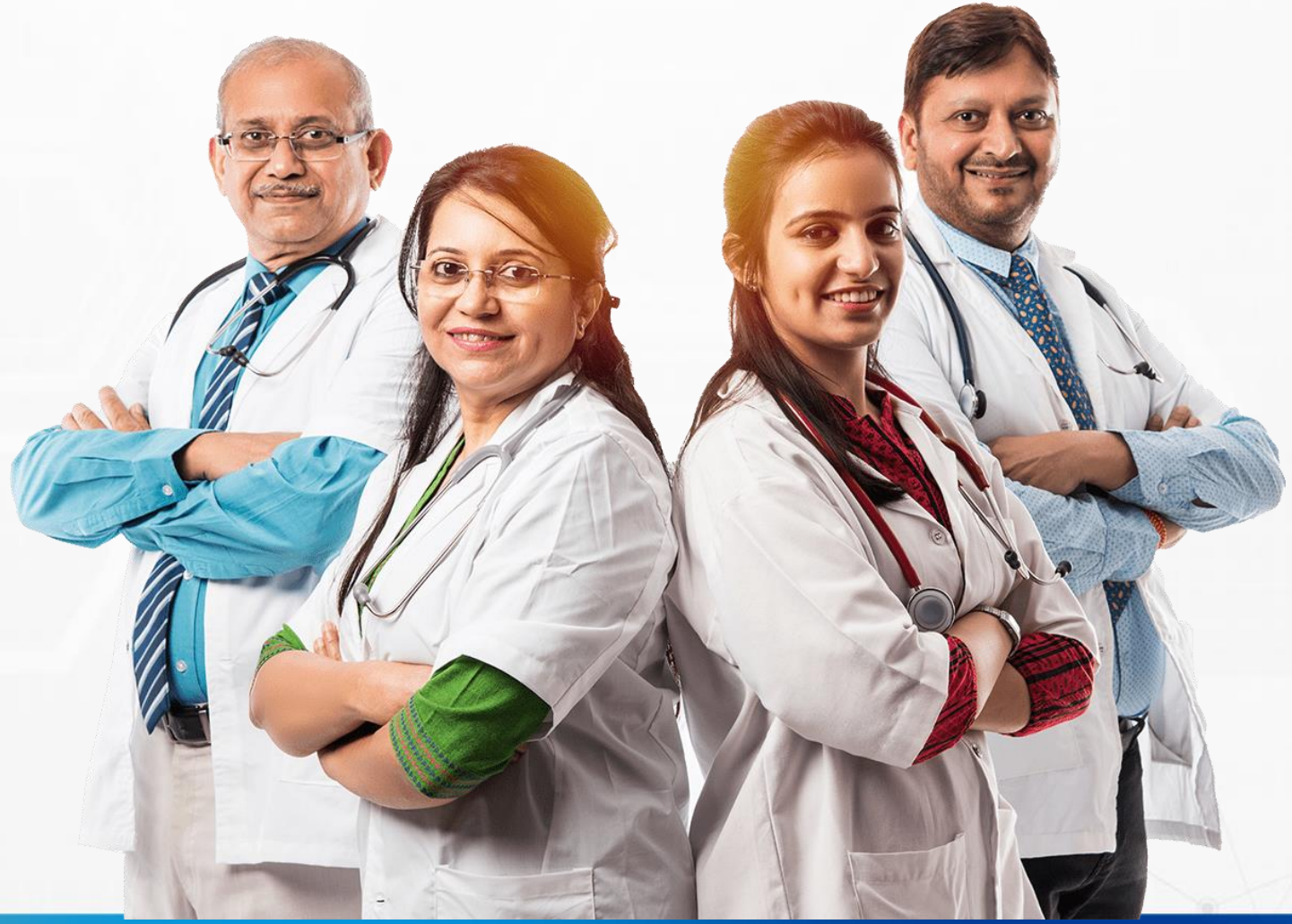

Humility
Innovation
Accountability
Integrity
Excellence
Collaboration
Nurturing
Individual Growth

Drug Development Services Overview

Your Drug Development Journey



Early to Late Phase Clinical Trials



Partners in creating a healthier tomorrow

Infrastructure

- **VEDANT**
  Clinical,
  Bio-analytical facility
- **SATYAMEV CORPORATE PARK**
  Corporate office
- **SHIVALIK**
  Dedicated Clinical facility
- **MEHSANA**
  Clinical and
  Screening facility
- **SKYLAR**
  Common screening facility for both Shivalik and Vedant
- **INSIGNIA**
  Dedicated
  Bio-analytical facility
- **ARCHIVES**
  Internal archival area in each facility.
  Separate long term archival facility at Changodar and Unjha

Spread across 16 clinics

Shivalik

170 Beds +

7 Special care beds +

12 Intensively monitored beds to conduct Phase I study

Vedant

226 Beds +

6 Special care beds +

18 Intensively monitored beds to conduct Phase I study

Mehsana

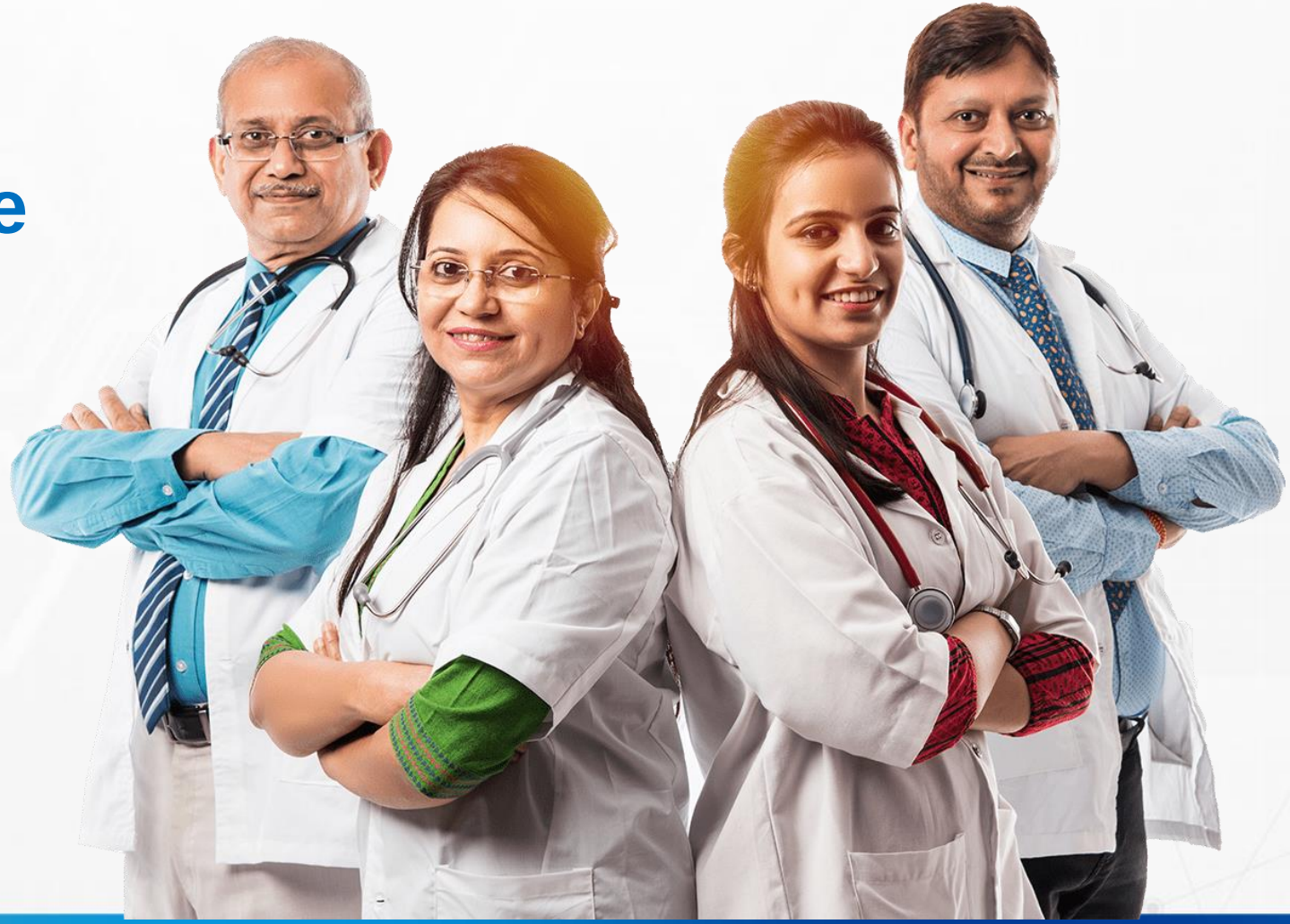
162 Beds +

7 Special care beds

Clinical Trials Overview

Clinical Trial Services

Clinical Trials Experience And Capabilities



Diverse Therapeutic Areas Of Expertise

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- Cardiology
- Rheumatology
- Dermatology
- Ophthalmology
- Gynecology
- Gastroenterology
- ENT
- Oncology
- Psychiatry
- Respiratory
- Endocrinology

Our Patient Trials Capabilities

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

THERAPEUTIC EXPERTISE

- **Oncology**
- **Psychiatry**
- **Infectious disease**
- **Ophthalmology**
- **Rheumatology**

50+ Patient bioequivalence studies

4,400+ Patients

500+ Sites

10 Phase Trials

900+ Investigator Database

16+ Ongoing Studies

- 3 Phase I/II/IIa studies
- 11 Patient PK studies
- 2 Clinical end point studies

Anti-COVID-19 vaccine SARS-Cov-2 infection in Healthy subjects– 1600 subjects

Successfully completed 25 USFDA inspections across sites without 483 observations.

Successfully Completed EMA inspections across 02 sites.

Team Experience - Biosimilar

Study Molecule	Indication	Phase	No. of patients
Rituximab	Non-Hodgkin's lymphoma	Phase-III	100
Bevacizumab	All approved indications of bevacizumab	Phase-IV	268
Bevacizumab	NSCLS patients	Phase III	129
Bevacizumab v/s Avastin	NSCLC	Phase III	594
Cetuximab	Small Cell Carcinoma, Head and Neck	Phase III	129
Denosumab	Solid tumors with bone metastasis	Phase III	150
Trastuzumab	MBC	Phase III	500
Trastuzumab	MBC and gastric cancer	Phase-IV	200
Trastuzumab	HER2- Overexpressing Metastatic Breast Cancer patients	Phase III	120

Deep Expertise Across Multiple Therapeutic Areas

Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Anti-Retroviral	HIV	Patient PK	Nevirapine 400 mg prolonged release tablet	USFDA	48	4	Completed
Gastroenterology	Chronic idiopathic constipation	Clinical end point	Linaclotide 145 mcg capsule	MENA	450	15	Ongoing
Haematology	Iron Deficiency	Patient PK	Ferric carboxymaltose 1000 mg solution for injection/infusion (50mg iron/ml)	EMA	120	10	Completed
	Iron Deficiency	Patient PK	Ferric carboxymaltose solution for injection/infusion (50 mg iron/mL)	EMA	150	15	Ongoing
	Iron Deficiency	Patient PK	Ferric carboxymaltose solution for injection/infusion (50 mg iron/mL)	EMA	120	15	Ongoing
	Iron Deficiency	Patient PK	Ferric carboxymaltose solution for injection/infusion (50 mg iron/mL)	USFDA	110	8	Ongoing
	Sickle cell anemia	Patient PK	Hydroxy urea capsules 500 mg	USFDA	36	4	Completed

Deep Expertise Across Multiple Therapeutic

Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Oncology	Acute Myeloid Leukemia	Patient PK	Azacitidine 300 mg	EMA	60	15	Ongoing
	Advanced ovarian cancer and/or metastatic breast cancer patients	Patient PK	Liposomal Doxorubicin Injection	EMA	94	20	Completed
	Advanced ovarian cancer and/or metastatic breast cancer patient	Patient PK	Liposomal Doxorubicin Injection	EMA	58	15	Completed
	Advanced ovarian cancer or metastatic breast cancer	Patient PK	Liposomal Doxorubicin Injection	EMA	65	14	Completed
	Advanced ovarian cancer or metastatic breast cancer	Patient PK	Liposomal Doxorubicin Injection	EMA	79	18	Completed
	Advanced ovarian cancer or metastatic breast cancer	Patient PK	Liposomal Doxorubicin Injection	EMA	75	15	Completed
	Ovarian Cancer	Patient PK	Liposomal Doxorubicin Injection	USFDA	103	21	Completed
	Ovarian Cancer	Patient PK	Liposomal Doxorubicin Injection	USFDA	66	14	Completed
	Ovarian Cancer	Patient PK	Liposomal Doxorubicin Injection	USFDA	51	15	Completed
	Advanced renal cell carcinoma	Patient PK	Everolimus 10 mg tablet	USFDA	30	25	Completed

Deep Expertise Across Multiple Therapeutic

Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Oncology	Chonical myeloid Leukemia/ Gastrointestinal Stromal Tumor	Patient PK	Imatinib mesylate 400 mg tablet	USFDA	40	4	Completed
	Chonical myeloid Leukemia/ Gastrointestinal Stromal Tumor	Patient PK	Imatinib mesylate 400 mg tablet	USFDA	34	4	Completed
	Chonical myeloid Leukemia/ Gastrointestinal Stromal Tumor	Patient PK	Imatinib mesylate 400 mg tablet	USFDA	32	6	Completed
	Chonical myeloid Leukemia/ Gastrointestinal Stromal Tumor	Patient PK	Imatinib mesylate 400 mg tablet	EMA	37	13	Completed
	Chonical myeloid Leukemia/ Gastrointestinal Stromal Tumor	Patient PK	Imatinib mesylate 400 mg tablet	USFDA	32	13	Completed
	Breast cancer and Colorectal cancer	Patient PK	Capecitabine	USFDA	70	9	Completed
	Breast cancer and Colorectal cancer	Patient PK	Capecitabine	USFDA	39	6	Completed
	Breast cancer and Colorectal cancer	Patient PK	Capecitabine	EU	54	11	Completed
	Breast cancer and Colorectal cancer	Patient PK	Capecitabine	USFDA	45	10	Completed

Deep Expertise Across Multiple Therapeutic Areas

Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Oncology	Advanced prostatic cancer	Patient PK	Leuprolide Acetate 30 mg intramuscular injection for Depot Suspension	USFDA	32	10	Completed
	Advanced prostatic cancer	Patient PK	Leuprolide Acetate 30 mg intramuscular injection for Depot Suspension	USFDA	30	15	Ongoing
	Ovarian cancer and Metastatic breast cancer	Patient PK	Olaparib 150 mg tablets	USFDA	70	19	Completed
	Patient with solid tumors	Patient PK	Docetaxel Injection 80 mg/4 mL	USFDA & China NMPA	46	5	Completed
	Small cell lung cancers	Patient PK	Etoposide 50 mg capsules	USFDA	24	8	Completed
	Multiple Myeloma	Patient PK	Bortezomib for Injection 3.5 mg/vial	USFDA	44	19	Completed
	Metastatic Breast Cancer (MBC)	Patient PK	Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial	USFDA	76	15	Completed
	Metastatic Breast Cancer (MBC)	Patient PK	Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial	USFDA	32	16	Completed
	Metastatic Breast Cancer (MBC)	Patient PK	Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial	USFDA	24	17	Ongoing
	Metastatic Breast Cancer (MBC)	Patient PK	Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial	USFDA	50	17	Ongoing

Deep Expertise Across Multiple Therapeutic Areas

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Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Psychiatry	Schizophrenia	Patient PK	Clozapine tablets 100 mg	USFDA	12	1	Completed
			Clozapine tablets 100 mg	USFDA	28	2	Completed
			Paliperidone Palmitate (3-month) Extended Release Injectable Suspension for intramuscular use 546 mg (350 mg Paliperidone)	EMA	284	14	Ongoing
			Paliperidone Palmitate extended-release injectable suspension 156 mg	USFDA	170	15	Ongoing
			Paliperidone Palmitate extended-release injectable suspension 156 mg (1month)	EMA	108	8	Ongoing
			Paliperidone prolonged Release 9 mg tablets	EMA	75	5	Completed
			Paliperidone Palmitate extended-release injectable suspension 156 mg (1month)	USFDA	110	12	Ongoing
			Quetiapine 600mg tablets	EMA	52	3	Completed
			Quetiapine Fumarate Prolonged Release Tablet 400 mg	EMA	64	10	Completed
			Risperidone 25mg injection	EMA	108	7	Completed

Deep Expertise Across Multiple Therapeutic Areas

Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Ophthalmology	Open angle glaucoma or ocular hypertension	Clinical end point	Brimonidine tartrate 2 mg/ml & Timolol 5 mg/ml preservative-free eye drops solution	EMA	196	12	Completed
			Brinzolamide 10 mg/ml + Brimonidine tartrate 2 mg/ml eye drops suspension	EMA	208	12	Completed
			Brinzolamide 10mg/ml & Brimonidine tartrate 2 mg/ml eye drops suspension	EMA	204	14	Ongoing
Rheumatology	Mild to severe psoriasis or rheumatoid arthritis (RA)	Patient PK	Methotrexate Tablets 2.5 mg	USFDA	55	4	Completed
	Rheumatoid Arthritis	Patient PK	Methotrexate Tablets 2.5 mg	USFDA	48	3	Completed

Deep Expertise Across Multiple Therapeutic Areas

Therapeutic Area	Indication	Type of Study	Intervention Name	Submission	Sample Size	Sites	Current Status
Gynecology	Assisted Reproductive Technology (ART) treatment program	Clinical end point	Progesterone	USFDA	360	12	Ongoing

Phase Study Experience

Type of Study	Therapeutic Area	Indication	Submission	Number of subjects
Phase I	Oncology	Colon or pancreatic cancer	DCGI	45
Phase II	Oncology	Relapsed Advanced Tumors and classical Hodgkin Lymphoma (cHL)	USFDA	130
	Infectious disease	SARS- CoV-2 Infection	DCGI	60
	Infectious disease	COVID-19	USFDA	112
	Antiretro viral	HIV positive patients	DCGI	30
	Infectious disease	Covid -19 Vaccine	DCGI	1600
	Respiratory	Asthma /COPD	USFDA	25+ 30
	Infectious disease	HIV positive patients	DCGI	18
	Autoimmune skin diseases	Atopic dermatitis, Psoriasis (Ongoing)	POC for USFDA	Up to 30 patients in each indication

Team Experience in Clinical Trials

Sr. No.	Area	Indication	Regulatory Submissions
1	Psychiatry	Major Depressive Disorder, Schizophrenia, Bipolar disorder, Bipolar I depression	USFDA, EMA and DCGI
2	Medical Devices	CAD, Arrhythmia, Heart failure, Uncontrolled hypertensions,	USFDA & DCGI
3	Cardiology	Hypertension, Ischemic cardiomyopathy, CVD, ACS	USFDA, EMA and DCGI
4	Endocrinology	DM-I, DM-II, Diabetic nephropathy	USFDA, EMA and DCGI
5	Oncology	Advanced Ovarian Cancer, Metastatic breast cancer, Renal Cell Carcinoma, Multiple Myeloma, Colorectal Cancer, Solid Tumors / Lymphoma, NSCLC, Cervix Cancer,	USFDA, EMA, ENVISA and DCGI
6	Respiratory	Asthma, COPD	USFDA & DCGI
7	Dermatology	Atopic dermatisis, Oral lichen planus, Dermatomycoses	DCGI
8	Nephrology	CKD, Urinary tract infection and pyelonephritis	USFDA & DCGI
9	Gastroenterology	Arsenic Poisoning, GERD, Constipation, Ulcerative Colitis	USFDA & DCGI
10	Infectious diseases	Bacterial Infection, Skin Infection, Hepatitis B Infection	USFDA & DCGI
11	Ophthalmology	Chronic Open Angle Glaucoma, Ocular Hypertension	USFDA & DCGI
12	Neurology	Epilepsy, Seizures	DCGI
13	Vaccine	Rabies, Leishmaniasis & serious fungal infections	DCGI
14	Orthopaedic	Psoriasis and Rheumatoid Arthritis& Osteoporosis	USFDA & DCGI

Veeda's Investigator & Site Database

Therapeutic Area	Investigators Database	No. of sites Veeda worked with
Oncology	352 Oncologist	120 sites
Psychiatry	40 Psychiatrists	40 sites
Orthopedics and Rhuematology	69 Rheumatologists	4 sites
Infectious Disease	56 MD Physicians	54 sites
Dermatology	67 Dermatologist	40 sites
Cardiology	50 Cardiologist	6 sites
Opthalmology	108 Ophthalmologists	107 sites
Urologist	115 Urologist	48 sites
Physician	81 MD Physician	50sites
Neurologist	40 Neurologist	13 Sites
Surgeons	19 MS Surgeons	20 sites
Pulmonology	42 Pulmonologists	32 sites
Gastroenterology	57 Gastroenterologists	47 sites
Endocrinology	100 Endocrinologist	9 sites
Hematology	68 Hematologists	68 sites
ENT	89 ENT	5 sites
Gynaecology-Obs	28 Gynaecologist	6 sites

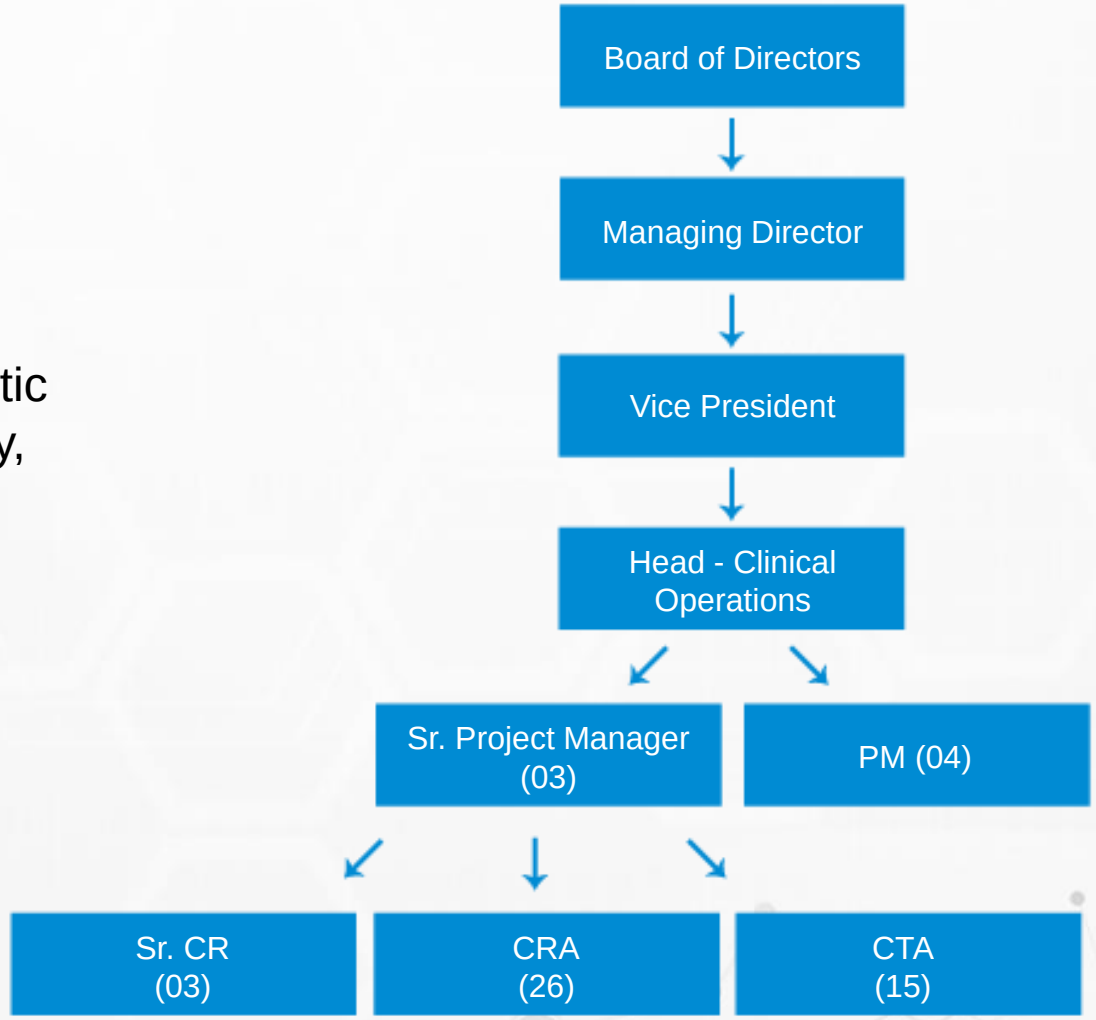
Database of more than 1300+ Investigators, Veeda team has worked with more than 600+ Clinical Research Investigators.

Services offered – Site Network

- Sites across all major cities
- More than 150 active sites currently
- CRAs based in > 4 cities.
- 17 sites audited by regulatory agencies

Clinical Project Team Experience

11+ Years of Average Experience in multiple therapeutic areas such as Oncology, Ophthalmology, Dermatology, Infectious Diseases and many more.



Team Training

Site & Study Management

- Coordination with Sponsor/CRO
- Electronic Management of Research Participants
- Feasibility
- Managing Resources
- Operational Plans
- Study Closeouts

Research Operations

- Contracts And Agreements
- FDA Submissions
- Institutional Regulatory Policies & Procedures
- International Regulatory Documentation
- Investigational Products
- Monitoring and Audits
- Participant Level Documentation
- Participant Retention
- Recruitment
- Screening
- SOPs
- Study Visits
- Team Meetings
- Specimen Management
- Study Level Documentation

Scientific Concepts

- Funding Proposal Development
- Literature Reviews
- Protocol Development
- Research Design
- Scholarly Works

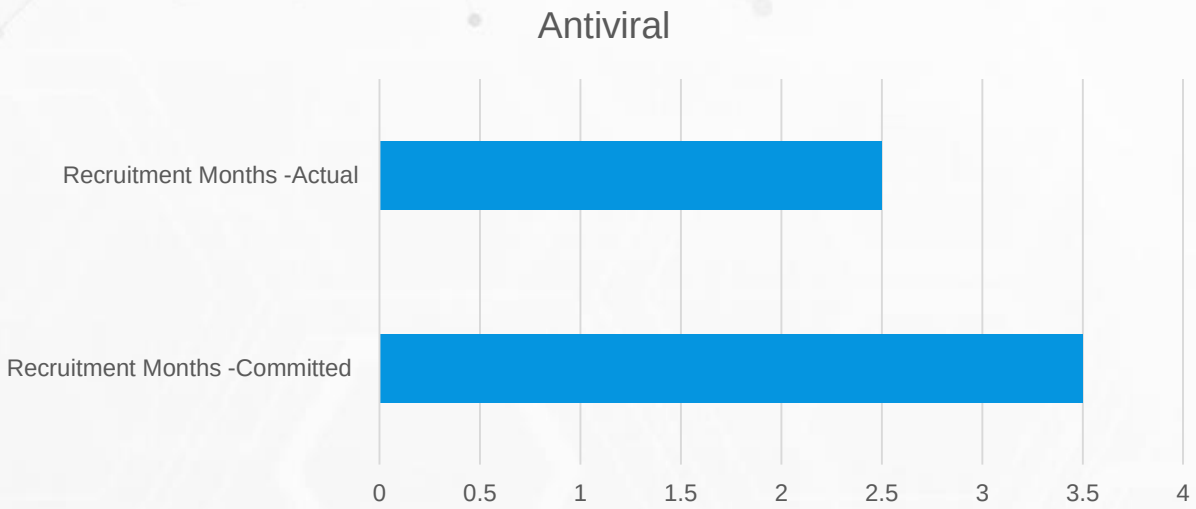
Safety And Ethics

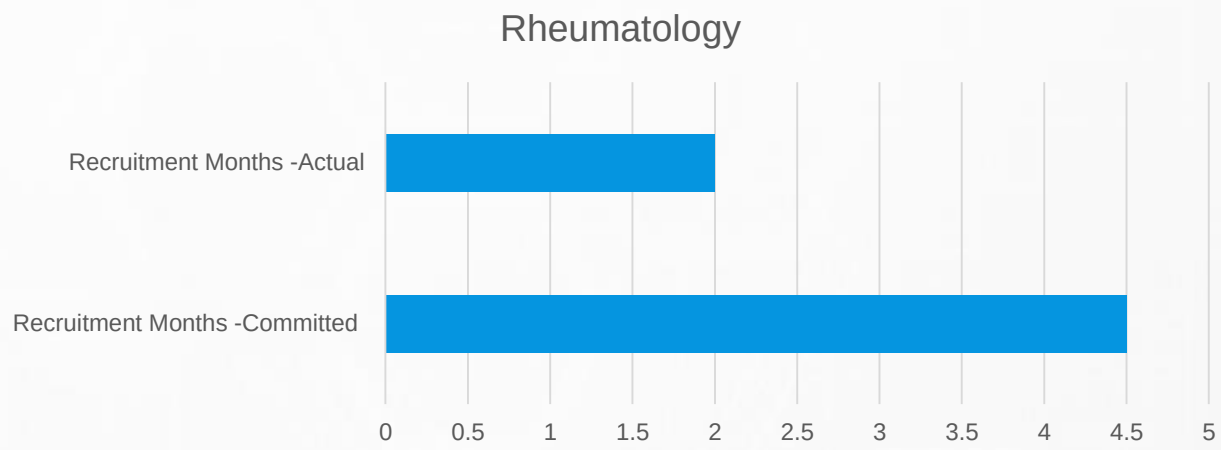
- Adverse Events
- Consent Procedure
- Development of Informed Consent Doc & Plan
- Navigating the Ethics Review Process (IRB)
- Sponsor/Regulatory Reporting

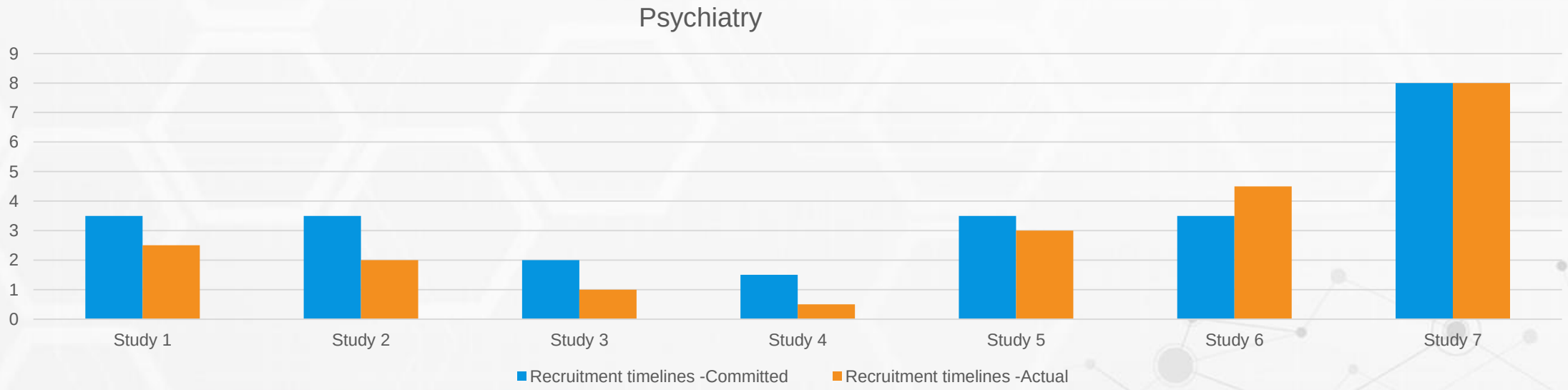
Data

Data Collection and Entry
Data Quality Assurance
Data Security and Provenance
Mapping Data Flow
Technology Use and Innovation

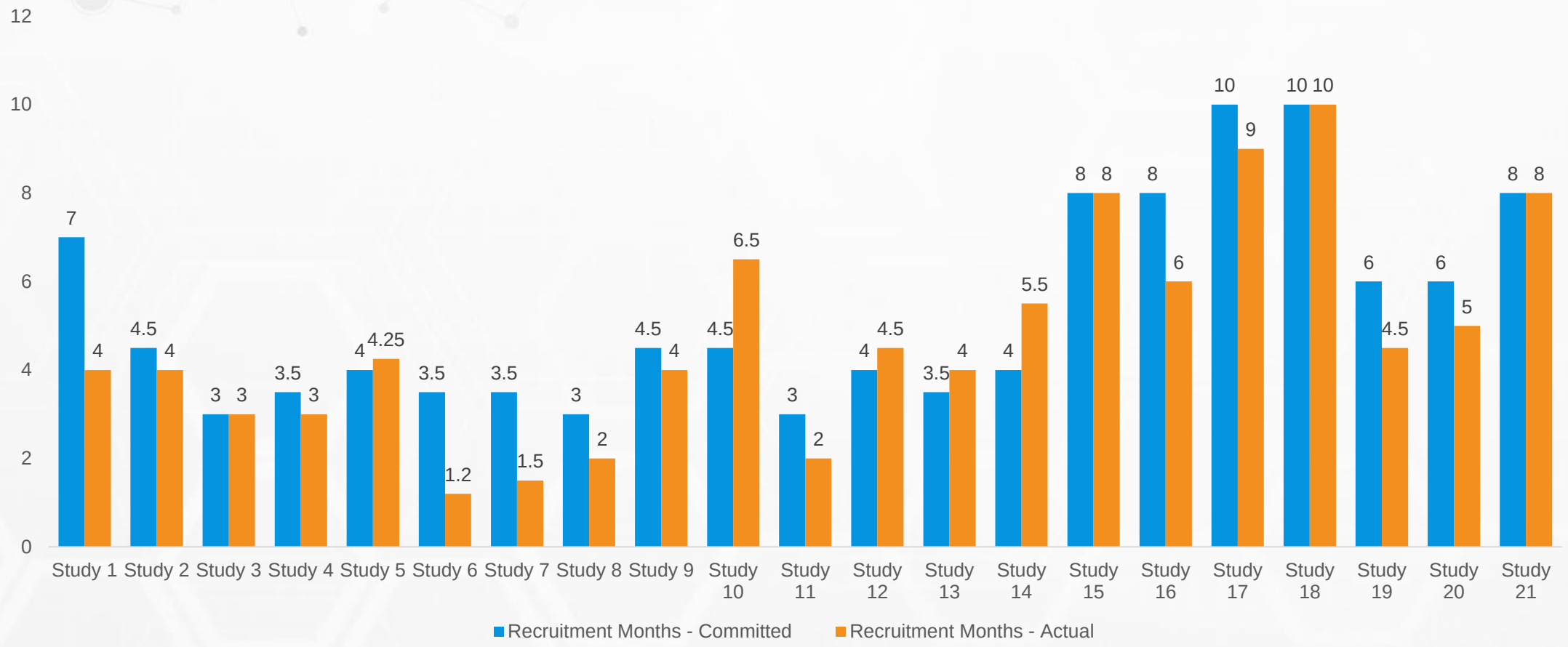
Meeting Recruitment Timelines







Meeting Recruitment Timelines



Average dropout rate of 7% across all completed Clinical Endpoint, Patient PK, Interventional and Phase II studies.

Pre-Study Activities - Project Plans

Project Management Plan	Communication Plan	Risk Management Plan (Identified Risk & Mitigation)	Bio Analysis Plan	PK sample handling Plan
Data Management Plan & Data Validation Plan (Data entry and system Validation) • Edit check Plan (Checking Edits in CRFs)	Lab Data Transfer Plan	Investigational Product Plan & IMP Manual	Medical Monitoring Plan – MMP	Safety Management Plan
	Site Monitoring Plan	Quality Plan	Working Instructions and Site Operations Manual for sites	

- Our project team ensures development of comprehensive project plans to successfully manage triple constraints of projects – cost, time and resources.

Monitoring

Study Startup

- **Regional CRA team ,located near our network sites**
- Experience with PK study designs
- Study specific training
- **COVID mitigations**
- Option for 2 step SIV
- Site training and recruitment plan discussion at SIV

Site Management

- Regular calls with site staff
- **Discuss screening, enrollment and retention status**
- Site compliance with data entry and query resolution
- EDC review for consistency and missing values
- Site staff training & problem solving as needed

Increased Quality Advantage

Interim Monitoring

- **Remote visits for COVID mitigations**
- Monitoring timing and duration are flexible to meet site/study needs
- Data quality
- PK sample quality
- Protocol deviations
- Risk management

Risk Management

- **Early identification of potential risks**
- Risk mitigation plan
- Root Cause Analysis on critical issues
- Issue Escalation

Recruitment Strategies

Patient level

- Pre-identification of patients
- Work with site team for pre-identified patient database
- Pre set recruitment targets for sites

Recruitment tools for awareness

- Email/Newsletter to sites
- Motivate sites to boost Screening of subjects
- Awareness & benefits
- Compassionate treatment cycles

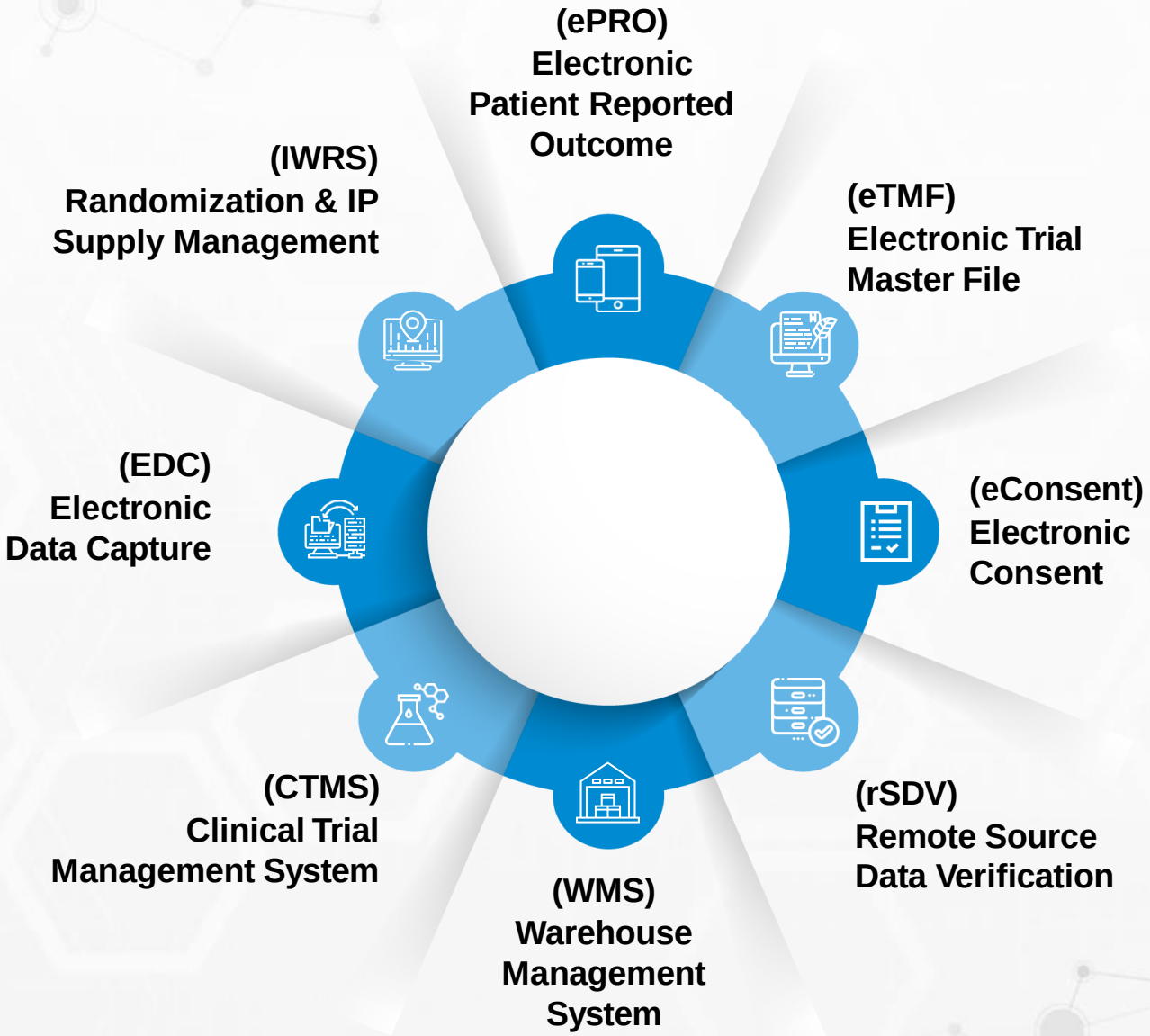
Site Staff

- Training sites Do not cut, crush, or chew the tablets.
- Encourage site for Patient Retention.
- Engage sites/PI for regular recruitment discussions.
- Quality Control measures at site.

Site Monitoring

- Monthly Visit during Recruitment phase
- Periodic visit during Followup phase.
- Remote SDV on need basis.

Access to eClinical Platforms



CTMS

Centralized Database:

- One consolidated, centralized database for your trial data
- Facilitates collaboration and favors proactive management
- Make time-critical decisions and resolve issues promptly

Site and Subject Management:

- Track study progress from start-up through enrollment
- Integrated calendar helps track subject visits and milestones
- Standardize CRA Trip Reports
- Track Open Issues, Protocol Deviations, and site communication

Finance Management

- Define, manage and track Trial Budget
- Define and manage CTAs with Sites
- Automate Investigator payment based on pre-agreed milestones
- Integrate required workflow in invoice generation and payment

Project Reporting

- Project Status & Progress Reports
- GANTT Chart
- Create and Customize Reports with filters on Projects, Tasks, Priorities, Status and Users

eTMF & Doc. Management

- DIA Reference Model Compliant
- Standardized eTMF TOC and Site ISF
- Store and organize Project Documents
- Version Control
- Manage Complete Life Cycle of Documents

Comprehensive Solution

- Integrated IMP Tracking module
- Integrated eTMF and Doc. Mgt Module
- Integrated Safety Management Module
- Enable integration with EDC/IWRS

CTMS –Value adds

Performance Improvement Levers	Realized Value
Faster Clinical Trials	Gain up to 25% resource efficiency in Trial Planning and execution resulting in: • Manage end-to-end trial process from one centralized database • Quickly identify and replace low-recruiting sites • Gain Real-time insight in bottlenecks encountered and remediate • Process Automation and Workflow enabled processes increases collaboration and productivity
Improved Finance Management	Save up to 20% cost in conducting a clinical trial: • Gain Site Monitoring efficiencies with reduced efforts in writing trip reports • Save on CRA Travel costs, IMP Shipping Costs, IMP Wastage, and Printing Cost • Automated PI payment process ensures site is paid based on their performance • Define Study Budget; Track Actuals against Budget
Site Monitoring Efficiencies	• Monitor Subject enrollment against goals. • Complete targeted Subject enrollment at a faster rate. • Workflow enabled Site Monitoring Reports. • Automated Investigator Payment reconciliation • Automated IMP Reconciliation • Investigator/Site Issue Management
Audit Ready	• Real-time tracking of Trial Master File • Shortened Clinical Trial Time • Better GCP Compliance

Electronic Data Capture

Capture, manage and report clinical trial data securely:

- Web-based and mobile-enabled
- Capture data faster and more accurately
- Online validation at the point of data entry
- Streamline monitoring visits
- Integrated Query Management
- Integrate medical dictionary (MedDRA, WHO..)
- Automated alerts/ notifications
- 21 CFR Part 11 compliant, maintains complete audit trail

Clinical Data Management

Study Setup

- Data Management Plan
- Database Design
- Data Management Guidelines
- CDISC Compliance

Data Review

- CRF Data Review
- DCF
- Lab Data Review
- Medical Coding

Data Processing

- Data Management Plan
- Database Design
- Data Management Guidelines
- CDISC Compliance

Electronic File Management

- Data Transfer to Sponsor
- Study Document Management

Remote Source - Data Verification (rSDV)

Connects Sponsors / CROs to Sites for:
- Remote Access
- Remote Monitoring
- Source Data Review/Verification

Purpose-built system includes capabilities:
- View documents
- Share comments
- Assign tasks and review response

Compliant with Regulatory requirements:
- 21 CFR Part 11
- HIPAA

Cloud Based
- High Security
- Scalable
- Role-based access to data

rSDV - Key Features

Deploy as a standalone portal or integrated with Octalsoft eClinical Platform

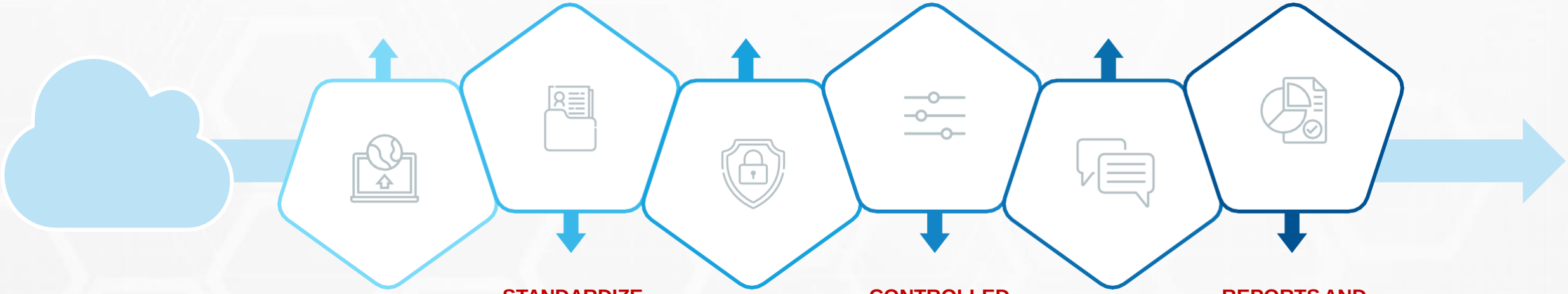
FLEXIBLE DEPLOYMENT OPTIONS

Upload scanned and redacted documents. Site Administrator retains control of their documents

UPLOAD DOCUMENTS SECURELY

Configurable document review workflow along with integrated collaborate feedback mechanism

DOCUMENT REVIEW WORKFLOW



STANDARDIZE DOCUMENT FOLDERS

Standardize Document Folder structure across sites enabling easy access and review of source documents

CONTROLLED DOCUMENT ACCESS

Permission based controls to limit document visibility and functional capabilities

REPORTS AND DASHBOARDS

Management reports and dashboards provide insight into real-time progress at site

Quality Compliance

Study specific Quality Management Plan

PM review issue escalations

Ongoing Protocol Deviation Analysis

Proactive Quality and Compliance Control

- ✓ **Sponsor** and CRO Processes, aligned
- ✓ Detailed ***Quality Management Plan***

CRA Resource:

- ✓ GCP Trained CRAs
- ✓ Study specific training for CRAs
- ✓ Mandatory **protocol training** with knowledge assessment
- ✓ **Accompanied site visit** by PM, as needed
- ✓ TMF review

Site Education:

- ✓ **GCP** training
- ✓ **Protocol** training during IM, SIV
- ✓ Ongoing training at IMVs
- ✓ Tools, aids provided

Executive Profiles

Dr. Kiran Marthak,

M.D. F.C.C.P. T.D.D. Director- Medical and Regulatory Affairs

- Post graduate in Internal Medicine and fellow of Faculty of Pharmacology University of London, UK. Fellow of Faculty of Pharmacology University of London, U.K. Fellow of American College of Clinical Pharmacology. Chairman of ISBEC- Ethics Committee
- Over 40+ years of experience in the clinical research and pharmaceuitcal industry. Managed more than 25 Phase-1 studies, Expertise in dealing with Drug Discovery and Development, expertise in International Regulatory affairs mainly related to Drug Discovery programs.
- Will provide insights to the study team for patient safety and regulatory acitivies.

Mr. Sivakumar Vaidyanathan,

Chief Operating Officer, Clinical Trials

- Has professional experience of more than 20 years in clinical research with significant exposure of working closely with CROs and Pharmaceutical Industry.
- He was associated with Biocon Biologics India Limited, Glenmark Pharmaceuticals, Novartis, Jubilant Clinsys, and Torrent Pharmaceuticals Limited.
- Will manage teams in Clinical Operations, Medical affairs and pharmacovigilance.

Dr. Rakesh Patel,

MBBS, M.D., Associate Vice President, Project management, Clinical Operations

- Physician with specialization in Clinical Pharmacology (MBBS, MD- Pharmacology) with over 18+ years of experience in the field of Clinical Operations of early and late phase clinical trials
- Will manage teams in Project management, Clinical Operations department.

Executive Profiles

Dr. Hiren Mehta,

Vice President – Clinical Affairs

- Ph.D. in clinical Pharmacology and comes with a rich experience and deep knowledge of pharmacology and scientific affairs functions with over 19 years of experience in managing clinical pharmacology functions, medical and scientific affairs & writing, pharmacokinetics, pharmacodynamics (PK/PD) data analysis-reporting and regulatory compliance.
- He is an expert in Drug Development and Clinical Research with significant experience in top pharmaceutical and contract research organizations.
- Will provide leadership to the team of Biostatistician, Data Management, Pharmacokinetics and Feasibility, Medical and Report Writing, Regulatory Affairs and Quality Control of Clinical Affairs

Mr. Paresh Patel,

Head – Pharmacokinetics & Feasibility

- Has ~13 years of rich experience in CRO as well Pharma industry in the Clinical Research field for various studies of different types of complex dosage forms like Lyophilized dosage form, Transdermal Patch, Topical dosage form, Nasal/Oral Inhalation dosage form, Long-acting depot injection, Solution for I.V bolus/infusion injection, Synthetic as well as r-DNA recombinant drug products apart from Oral dosage form and studies in healthy subjects as well patient population.
- He is specialized in pharmacokinetics/pharmacodynamics (PK/PD) data analysis, creative study design, and regulatory compliance through scientific advice and query responses.
- Will provide leadership to the team of Pharmacokinetics and Feasibility, Biostatisticians, Data Management, Medical and Report Writing, Regulatory Affairs and Quality Control of Clinical Affairs.

Dr. Kamlesh Patel,

Head – Biostatistics, PBD

- Doctorate in Statistics ,experienced Biostatistician and statistical programmer. Hands on experience in MIXED Model, Multivariate/Multinomial analysis, NLMIXED ,NLIN and Modelling, Simulations and Bootstrap analysis, Sample size calculation and simulations, Two-stage designs, Designs of Experiments in Clinical Trials, SAS Programming for Statistical Analysis, Survival Analysis ,Design and analysis of Bioequivalence & Bioavailability Studies, Pharmacokinetic analysis using WinNonlin/Pharsight, Clinical Trials Protocol & Study Report, Data Management ,Cancer Registry, Cancer Epidemiology, Incidence and Survival in Population Based Cancer Registry, Coding System ICD-9 & ICD-O, Early detection of Cancer and Health Education Programme, Community Survey Designs and Analysis

Executive Profiles

Dr. Ashutosh Jani,

Ph.D. (Pharmacology), Head- Clinical Operations

- Pharmacy Professional with Doctorate in Pharmacology and over 17 years of experience in the field of Clinical Research
- Will provide Strategic and Managerial Oversight for all Clinical Operations functions and organize and Implement Operational Strategies for Clinical Operations.

Dr. Ravi Alamchandani,

M.D., GM- Medical Affairs & PV

- MD Pharmacology (Gold Medalist) with over 9 years of experience in the field of Medical Affairs and Safety Reporting. His experience includes working in Hospital, Pharmaceutical companies and Contract Research Organizations.
- Has been involved in and managed teams involved in medical monitoring, medical writing and safety reporting activities of Phase I-IV clinical studies, organizing DSMB meets for NCES wherein he has acted as local medical monitor. He has been a Medical Advisor for new product development and involved in developing medical rationales for new formulations.
- Will provide Strategic and Managerial Oversight for all Medical Monitoring & Medical Writing activities.

Recognitions

Recognitions

Celebrating
19 YEARS
of excellence in Clinical Research

2004

2017

Organization	Award Category
Praxis Media	National Excellence Award
AI Global	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
	Best Clinical Research- India
	Mark of Excellence
FROST & SULLIVAN	Indian Clinical Research company of the year

2018

Organization	Award Category
ASSOCHAM INDIA	Best Clinical Research Organization - India
Health & Wellness	Clinical Trial Company of the Year
ECONOMIC GROWTH FOUNDATION	Bharat Udhyog Ratan Award in Clinical Research

2019

Organization	Award Category
	Best Quality Clinical Research Organization in India
	Best Quality Clinical Research Organization in India
	Indian Clinical Research company of the year

2020

Organization	Award Category
BioSpectrum	Top CLRO Company
Praxis Media	Best Quality Clinical Research Services in India

2022

Organization	Award Category
SHIMADZU Excellence in Science & SPINCO BRINGING TECHNOLOGY, ENABLING SCIENCE.	MS Excellence in BABE Services, Largest Indian CRO

Veeda Group Advantage

Extensive Scientific Competence to service a Diverse client base

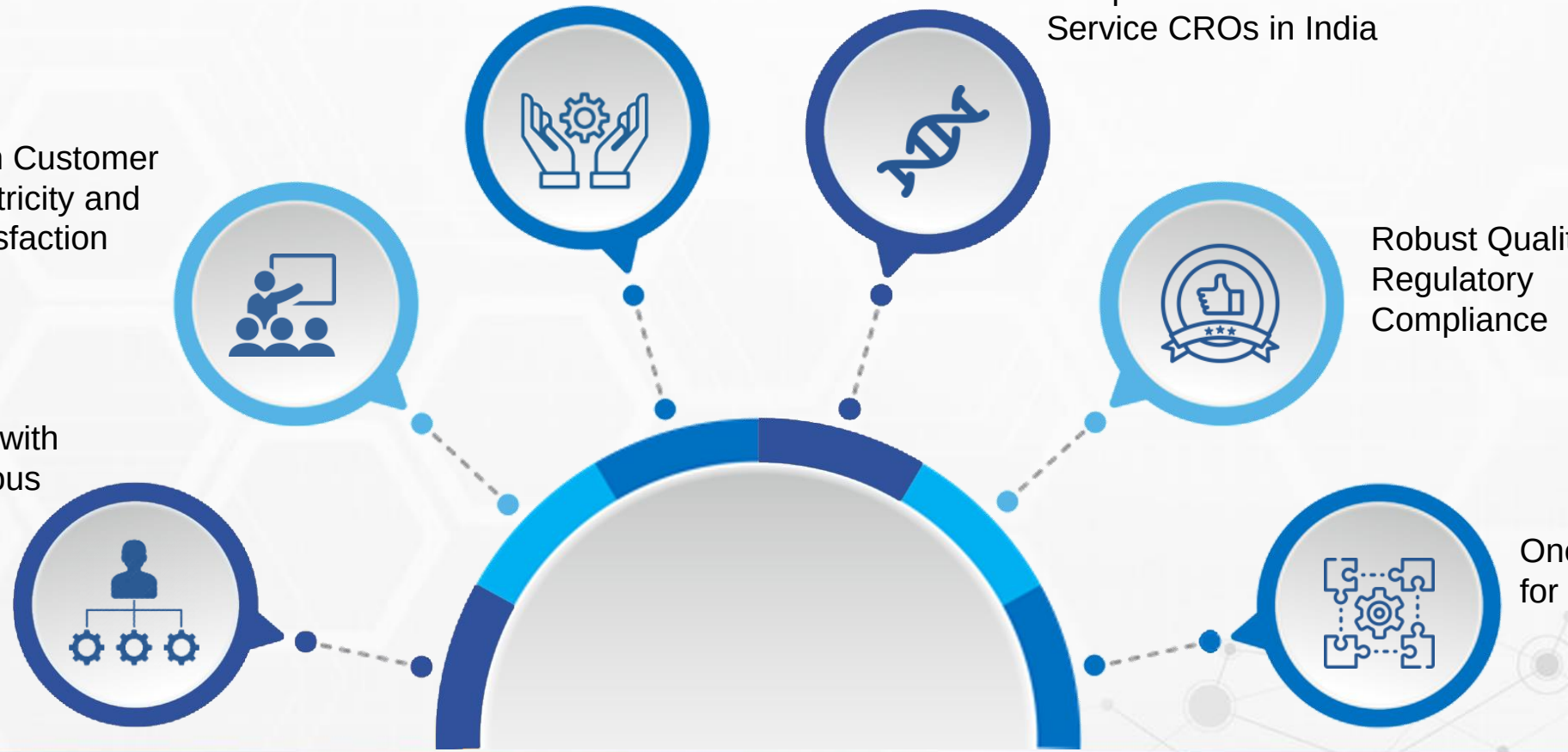
One of the largest Independent Full Service CROs in India

High Customer Centricity and Satisfaction

Robust Quality & Regulatory Compliance

Skilled personnel with focus on Continuous Professional Development

One stop solution for complex studies



Thank You

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a healthier tomorrow

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