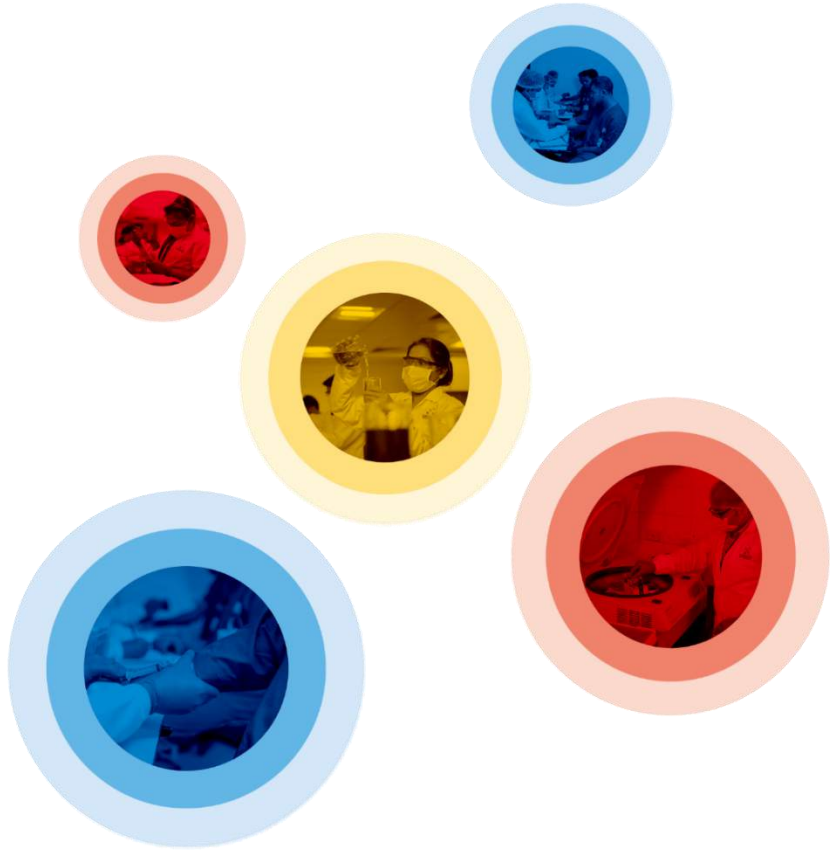
Global Clinical Development Partner

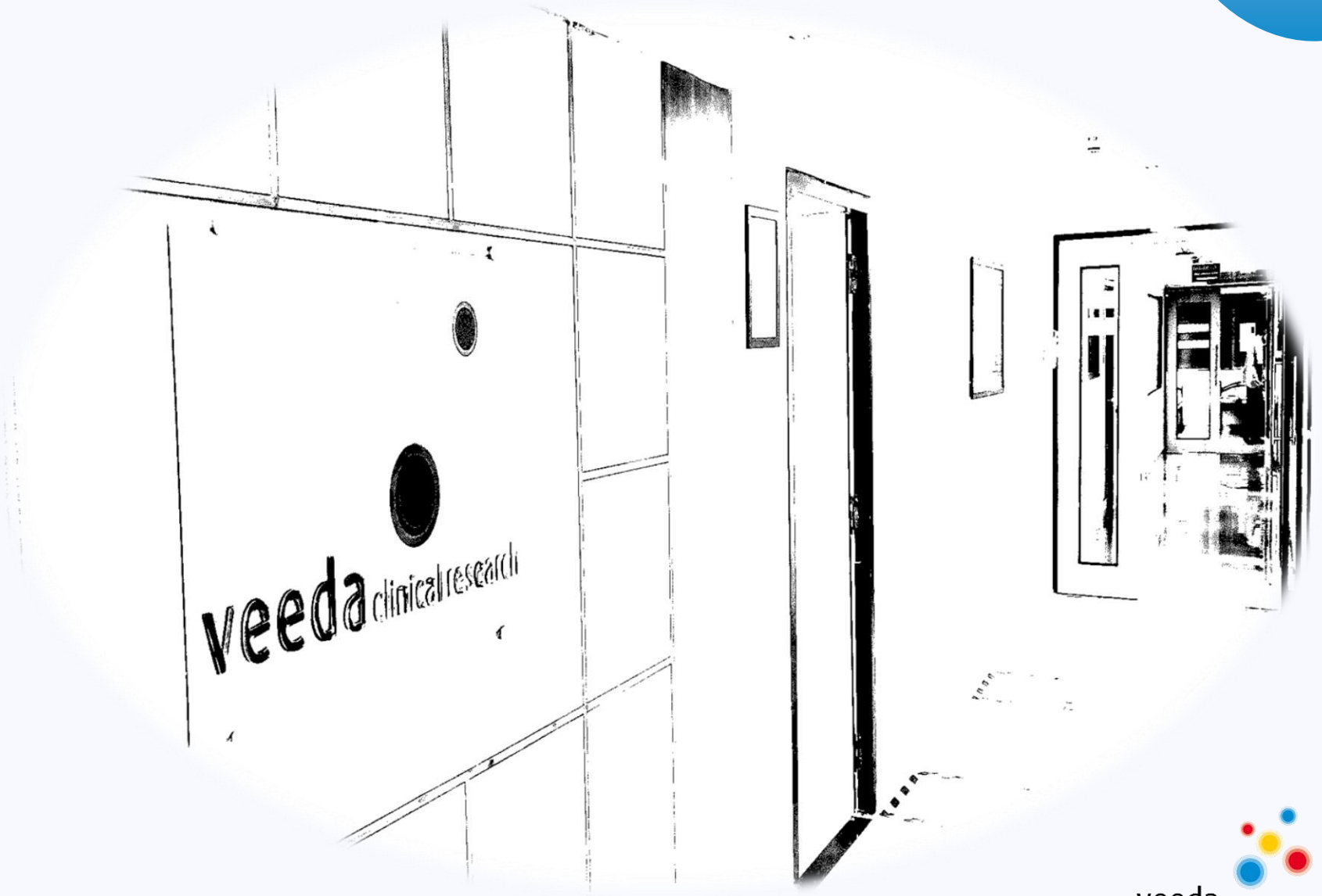
Providing Quality Clinical Research Solutions



veeda clinical research®

Flow of Presentation

- Who we are
- Experience
- Capabilities
- Infrastructure
- Services & Process



Who we are

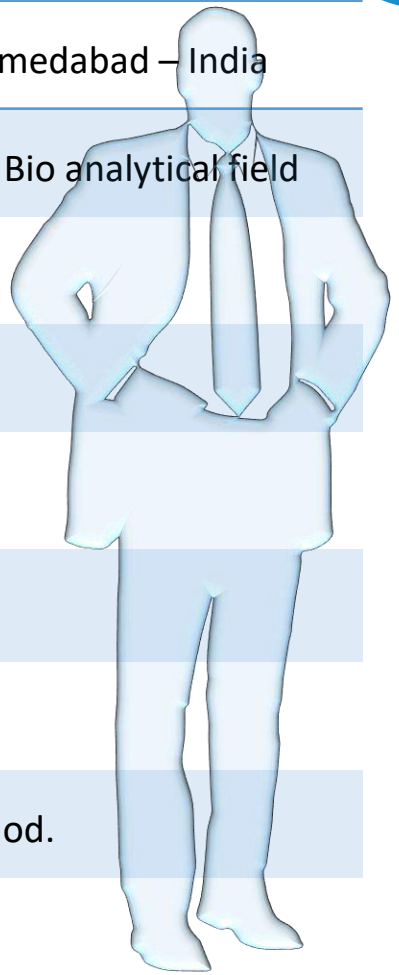
We are one of the largest Independent CRO in India. The name represents our firm belief in scientific knowledge and technical expertise to provide quality clinical research solutions in India & across the world. We are innovators with a foresight because of which we were the first ones at many instances to embrace new advancements and technologies with a vision to deliver enhanced CRO solutions on time. We strongly believe in scientific excellence through teamwork and this has led us to become the safest and the most competent partner for the Pharmaceutical World.

We place a firm emphasis on our scientific knowledge and our past experience to plan the conduct of each clinical trial in advance. This enables us to provide quality results on time in each trial. We also follow a stringent quality check to assure no statistical errors in our final result.

Veeda Clinical Research Organization boasts of well-designed, world class, custom-built and regulatory compliant clinical research infrastructure to facilitate conduct of quality research. It is spread over a total floor area of approximately 1,46,000 sq.ft., divided to cover the Clinical Units (88,000 sq.ft. approximately), Bio analytical Laboratory area (38,000 sq.ft. approximately) and other supporting infrastructure.

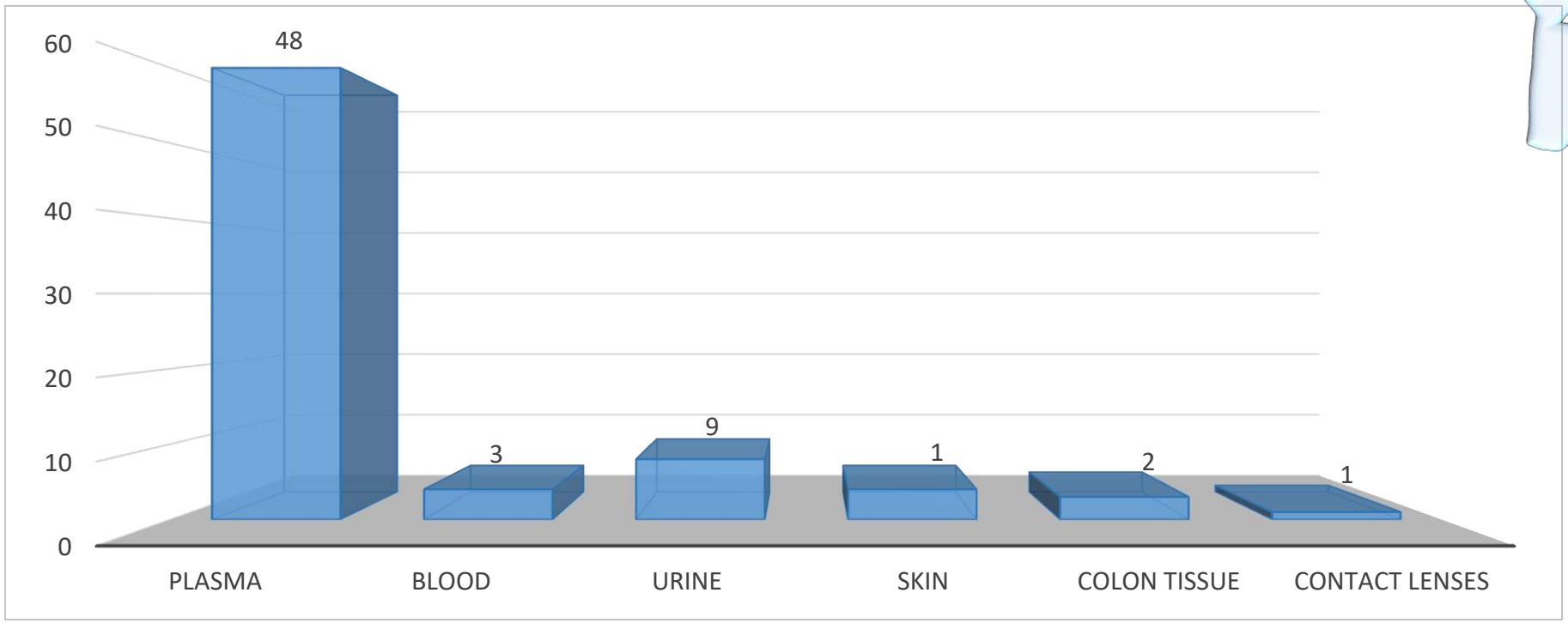
Experience

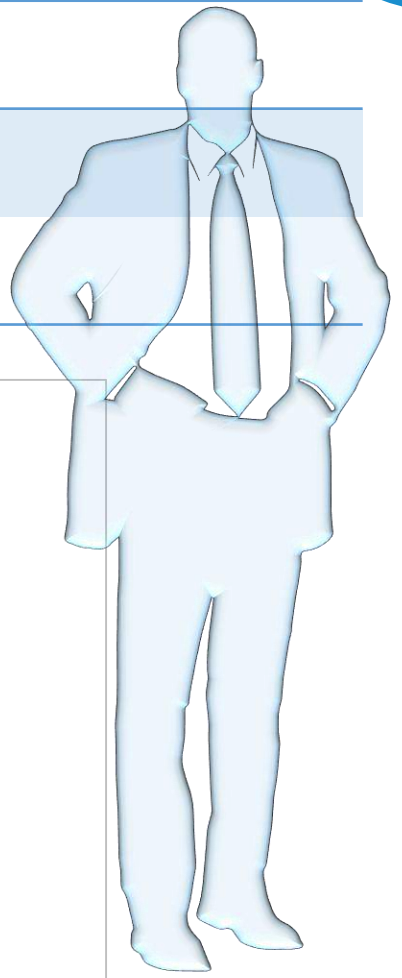
- Veeda is clinical research partner to leading Pharma companies including large MNCs across the globe, Located in Ahmedabad – India
- All scientist(> 200) have Science/Pharma post graduate and senior persons have more than 15 years of experience in Bio analytical field
- More than 40 studies ongoing (from multisite globally, approx.20000 samples per year)
- Bio similar Studies(3 studies PK and immunogenicity)
- Sample management (receipt, logging in LIMS for reconciliation).
- Safety analysis (sample receipt to analysis within 5 days)
- Sponsor specific reports with e-CTD
- Done multi center study which involved more than 35 sites, estimation of 10 analytes involving 4 bio-analytical method.
- 64 methods developed and validated for NCEs



Experience

- Exploratory studies, e.g. skin tissues , plasma protein binding experiment, chiral impurity estimation in the sample
- Successfully audited by US-FDA, MHRA, ANVISA, NPRA
- Supported around 64 NCE molecule in different Biological Matrices for 6 different sponsors





Infrastructure

- Bio analytical Laboratory area (38,000 sq.ft. approximately).
- 46 LCMSMS machines to cater the sample size up to 0.1 million per month.
- 20 high end machines(TQ5500/QTRAP5500,SH8050,SH8060) to handle the sensitivity of 1 pg/mL.
- One micro plate reader for ELISA based assays of large molecules (Bio similar).
- Two ICP OES machines for elemental assays e.g. Iron sucrose, Lithium, Potassium, Magnesium, Zinc etc.
- Watson LIMS support for Sample Management.
- 45 Deep freezers with capacity to store approx. 1.1million samples(plasma, blood, urine) at -80°C.
- 1 Walking type chambers with overall capacity to store 2,50,000 samples at -20°C.
- 7 Pharmaceutical refrigerators having storage capacity of 5800 Liter at 2-8°C.

Infrastructure

- Archival: Four Archival facility at different location having archival capacity of more than 0.1million files.

- Team of qualified and experienced researchers (>200) with experience in method development, validation and regulated bio analysis for a wide range of chemically diverse drug molecules (NCEs, complex molecules, vitamins, isomers, enantiomers, geometric isomers, amino acids etc.)

- Dedicated team for functional role,

Sample preparation: Trained analyst

Sample handling: custodian team

Sample management(re-conciliation): Watson LIMS team

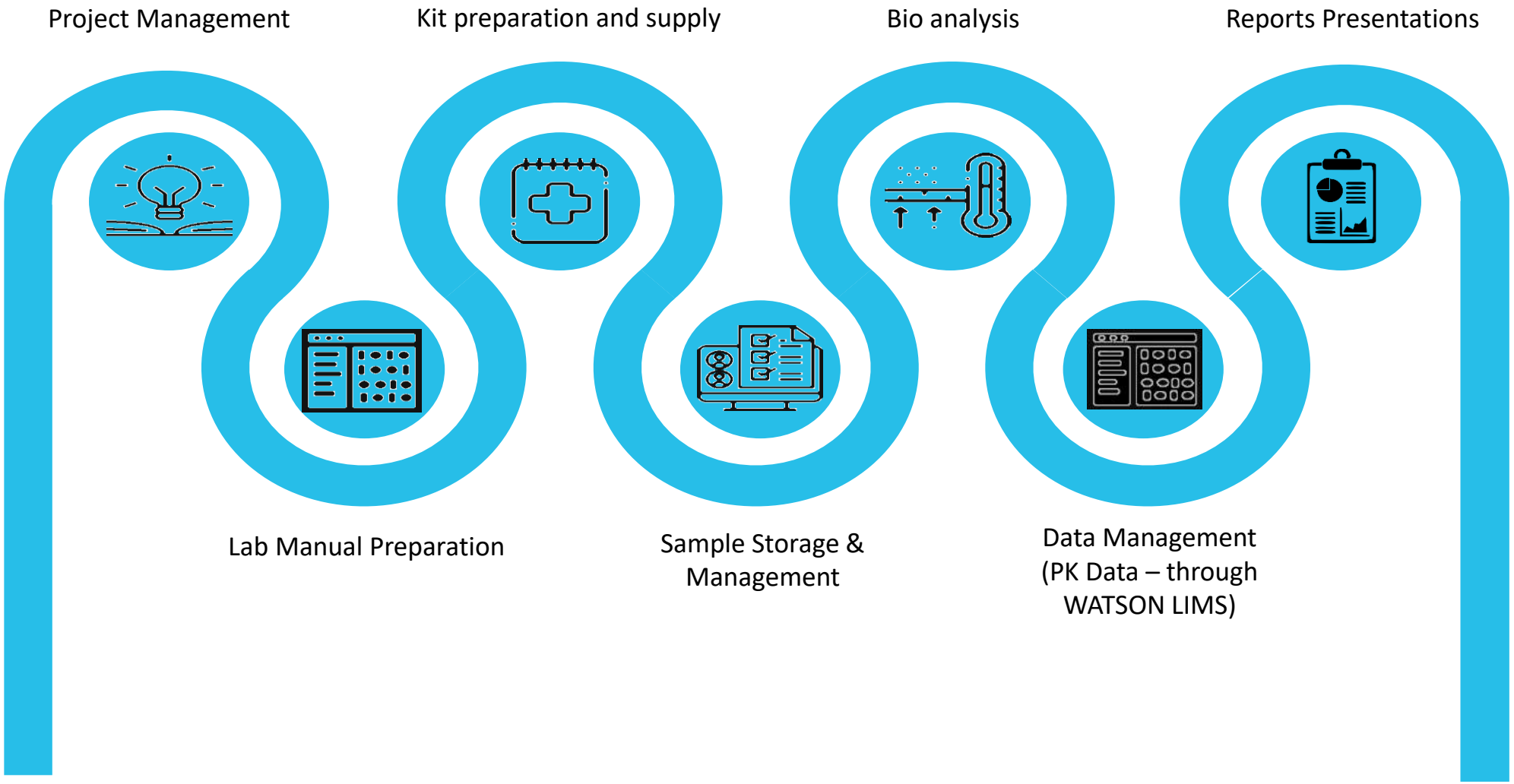
Report preparation(Sponsor specific requirement) : Report writer team

QC check(100%raw data review) : Bio analytical Quality Monitoring team

Capabilities

- 65 Complex Method(i.e. Endogenous molecule, Hormones, steroids, Amino acids, inhalation formulation, element Bio analysis, Immunogenicity, Large molecules/ELISA.
- 990 Validated Methods are available(generics/NCE/PD/immunogenicity).
- Capability to develop methods with lowest quantification level-up to 0.1 pg
- Central labs for Phase II / Phase III studies
- Tissue distribution studies
- Multiple analysis in single injection(up to 20 analytes per injection)
- More than 3000(BA/BE) studies completed with Incurred sample re-producibility >98.0%
- Our Bio analytical lab have vast molecule experience for different NCEs and have 64 methods, the turnaround time for safety analysis reporting is less than 4 days from sample receipt for faster decisions for dose escalation studies.

Services & Process



Services & Process

- We can offer all services including project management, lab manual preparation, Kit preparation and supply, sample storage management, Analyte testing(bio analysis), report preparation for multi site studies (BA-BE studies).
- Protocol Preparation and resolution to sponsor and regulatory Queries by dedicated Project management team.
- Lab manual Preparation- Preparation of lab manual which includes sample collection procedure and sample handling condition.
- Kit preparation and supply by dedicated team with effective communication
- PK samples handling by trained custodian team(Labeling/Storage temperature/light condition)
- PK sample reconciliation(Watson LIMS support by trained team)
- Analysis with respect to current regulatory requirements(trained analyst)
- Sponsor specific reports with e-CTD(trained and dedicated report writing team)

Thank You

For any further assistance kindly write to us at info@veedacr.com
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Partners in creating
a healthier tomorrow