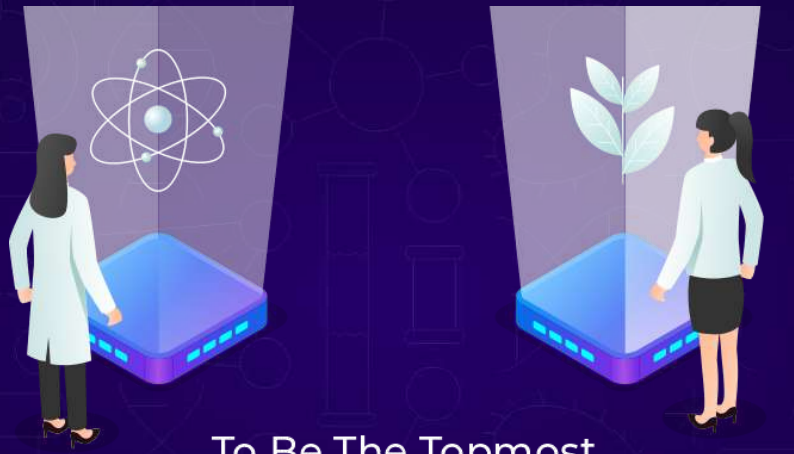
SPINOS

LIFE SCIENCE AND RESEARCH PRIVATE LIMITED

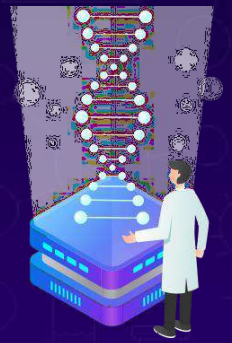
- Quality in Research

VISION



To Be The Topmost
Trusted Regulatory Compliant Clinical
Research Organization

MISSION



Touch base with at least 50 International Pharmaceutical Companies by 2028

Obtain UKMHRA/EMEA/GCC regulatory approvals in next five years of time

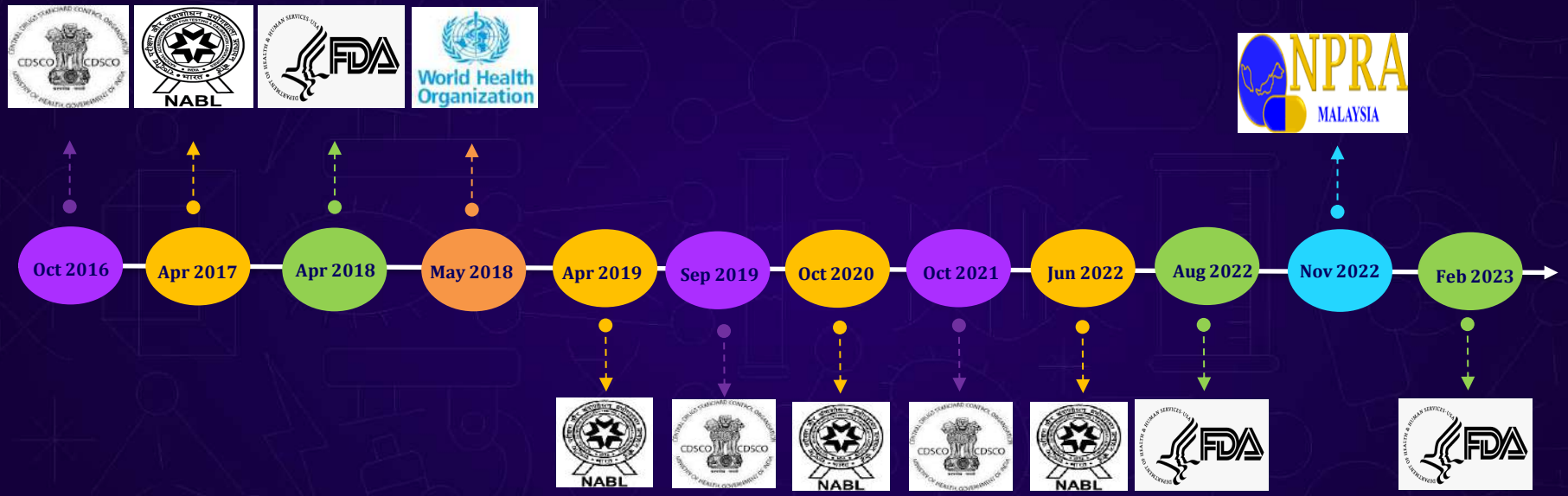
Exceed customer expectation in terms of quality and timeline.

OUR SERVICES

- Bioavailability / Bioequivalence Studies
- CLINICAL TRIAL (Phase I to Phase IV)
- Real World Evidence Data collection & Registry Studies
- NUTRACEUTICAL TRIALS
- PROOF OF CONCEPT STUDIES
- MEDICAL DEVICE TRIALS

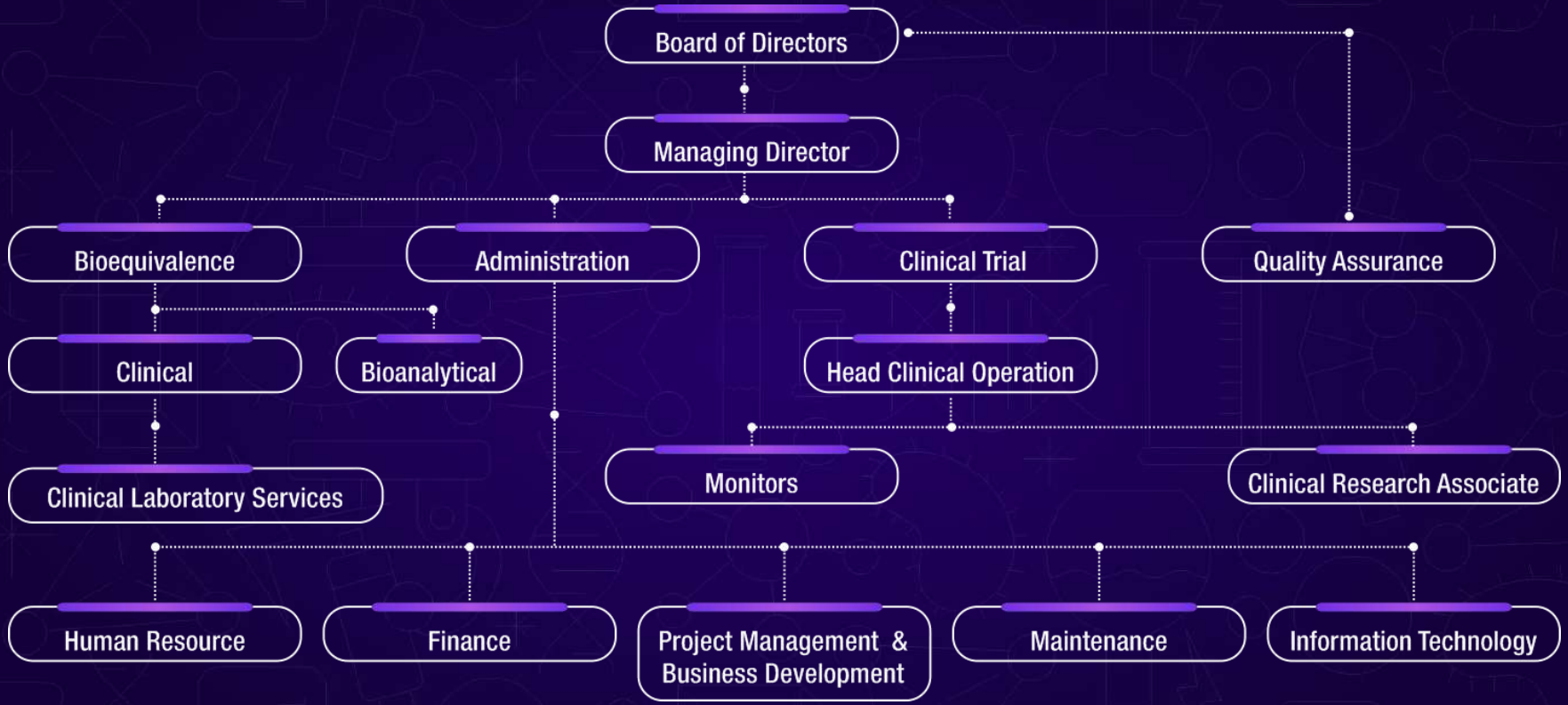


REGULATORY STATUS



Renewal Audits

ORGANOGRAM


Board of Directors
Managing Director
Bioequivalence
Administration
Clinical Trial
Quality Assurance
Clinical
Bioanalytical
Head Clinical Operation
Clinical Laboratory Services
Monitors
Clinical Research Associate
Human Resource
Finance
Project Management & Business Development
Maintenance
Information Technology

INFRASTRUCTURE

Construction Area

44000 square feet with air conditioned facility for BA/BE studies.

Clinical Facility

- 100 beds capacity divided in 8 clinical processing units.
- OVIS software to identify cross participation of volunteers.
- Strong volunteer database of around 10,000 including male and female.
- Inhouse Digital X-Ray facilities.

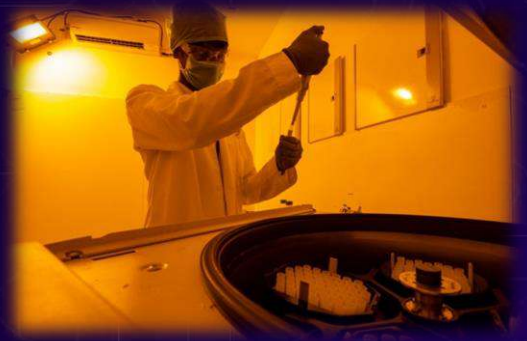
Clinical Laboratory Services

- NABL accredited clinical laboratory services.
- Seamless data transfer through LIMS software.

Quality Assurance

- Inhouse Quality Assurance department.
- Robust Quality systems with continuous audits facilitates improvements.
- Data integrity is ensured through well written data governance policies.

INFRASTRUCTURE



Bioanalytical Facility

- 3 LC-MS/MS which includes API 5500, API 4000, and Shimadzu 8045.
- Seamless data transfer through software platform.

Information Technology

- Well equipped with 3 dedicated servers.
- Cloud data back-up.

Archival Facilities

- In-house archival facility with fireproof compactors.

Emergency Facilities

- Round the clock power back-up.
- In-house ambulance services.
- In-house ICU facility with 4 beds.

Our few success stories on Nutraceutical Trials…

Curcumin – we have validated method for Total Curcumin, Free Curcumin, Demethoxy curcumin and Bisdemethoxy curcumin in K_2EDTA human plasma.

Method is validated with the CC range of 0.3501 ng/ml to 500.1401 ng/ml for Free Curcumin, 5.3660 to1065.1840 ng/mL for Demethoxy Curcumin and 5.2340 to 1038.8780 ng/mL for Bisemethoxy Curcumin.

For Total Curcumin using hydrolysis method by conjugating the curcumin as Curcumin glucuronide and Curcumin sulfatase and validated with CC range 0.4480 to 71.8820ng/mL.

Caffeine – a comparative oral bioavailability study was successfully completed for caffeine molecule in healthy volunteers.

- Method is validated in LC-MS/MS using K_2EDTA human plasma with the CC range of 100.2678 to 6099.7949 ng/mL.
- Results of this study showed that SR-Caffeine formulation provided a continuous release of caffeine in the plasma for an extended period of time.

Vitamin C (L-ascorbic acid) – Vitamin C Sustained Release capsules have shown significantly increased plasma vitamin C levels compared to Placebo. This study shows Superior Bioavailability of Vitamin C compared to Placebo.

A highly sensitive and a challenging molecule to be validated using LC–MS/MS method in K_2EDTA human plasma.

- Method is validated with the CC range of 100.6188 to 19583.4541 ng/mL.

Ashwagandha – Succesfully completed oral bioavailablity study of Ashwagandha by analysing 4 withanolides in single method. Method was validated in LC-MS/MS using K_2EDTA human plasma with the CC range of

Withanoside IV – 0.1504 – 20.0796 ng/ml.

Withanolide A – 0.1505 – 20.0948 ng/ml.

Withaferin A – 0.1543 – 20.5980 ng/ml.

12-Deoxywithastramonolide – 0.1499 – 20.0070 ng/ml.

- Results of this study showed that the test product had better bioavailability in comparison with the reference product.

Capsaicin– Completed a bioavailability study of Capsicum capsules in healthy volunteers. Analysed Capsaicin as primary analyte in K_2EDTA human plasma over the concentration range of 0.0452 to 10.0851 ng/mL.

- Results of this study showed that the test product had bioavailability in comparison with the reference product.

Melatonin – a comparative oral bioavailability study was successfully completed.

- Method is validated in LC-MS/MS using K_2EDTA human plasma with the CC range of 201.3000 to 200629.9000 pg/mL.
- Results of this study showed that the test product has better bioavailability than the reference product.

Omega 3 Fatty acid– Completed a bioavailability study of Omega 3 fatty acid. Test product Omega 3 powder was dispersed in orange juice. EPA and DHA (Both acids and esters) were analyzed and reported.

Vitamin D3 (Cholecalciferol) – a highly sensitive and a challenging molecule for which comparative oral bioavailability study was successfully completed in healthy volunteers.

- Method is validated in LC-MS/MS using human serum with the CC range of 0.5115 to 100.1054 ng/mL.

Coenzyme Q10 – 120 mg/4mL nano emulsion – A bioavailability study of Coenzyme Q10 has been conducted in healthy volunteers

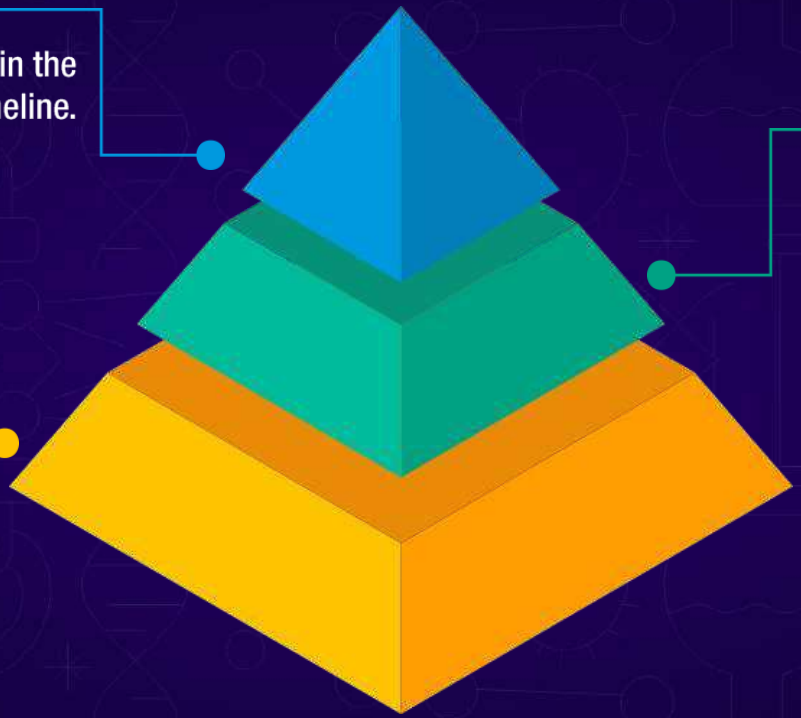
- Method is validated in LC-MS/MS using human plasma with the CC range of 23.4580 to 8006.8480 ng/mL.

UNIQUE SELLING POINT

Delivering the projects in the committed timeline.

Quality and Data integrity is proven through two consecutive successful USFDA inspection with NIL 483

100 years of combined expert team in conducting Phase I to Phase IV studies, oncology trials, IITS, MMSS, PMSSS and therapeutic equivalent studies



OUR CLIENTS

REACH OUT US

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THANK YOU!