



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/EMA/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

THERAPEUTICS EXPERTISE

Oncology.

Anti-diabetic.

Anti-viral.

Anti – malarial.

Anti-depreasant

Anti-inflammatory.

Anti-tubercular.

Oral Contraceptives.

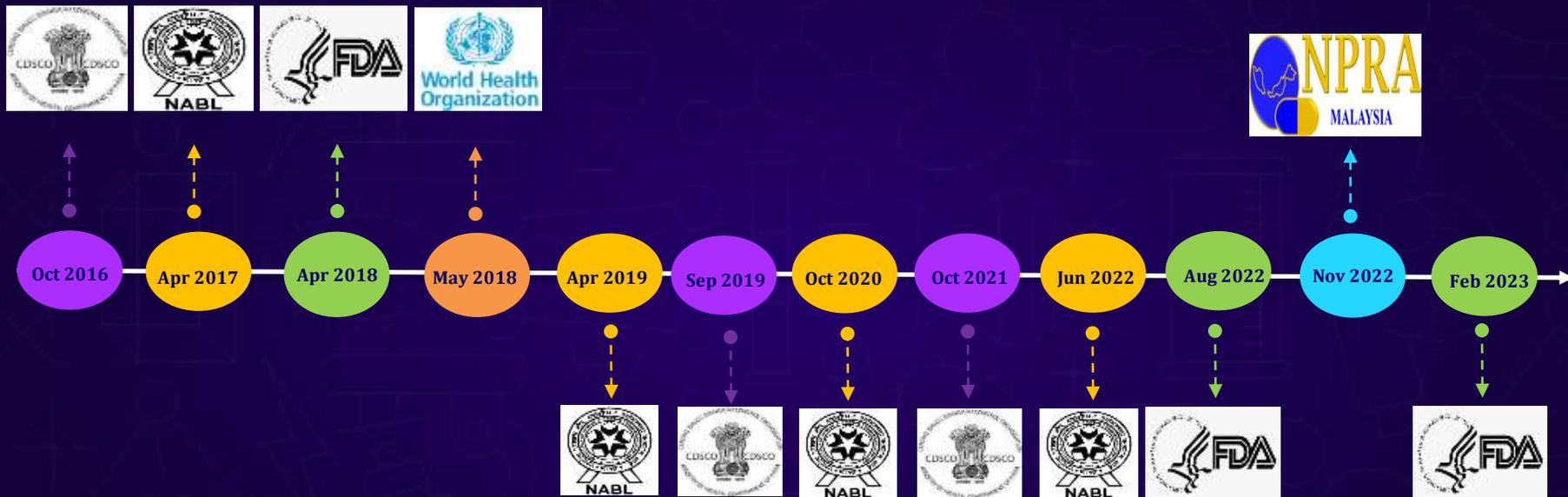
Hormones.

Nutraceuticals.

Biosimilars.

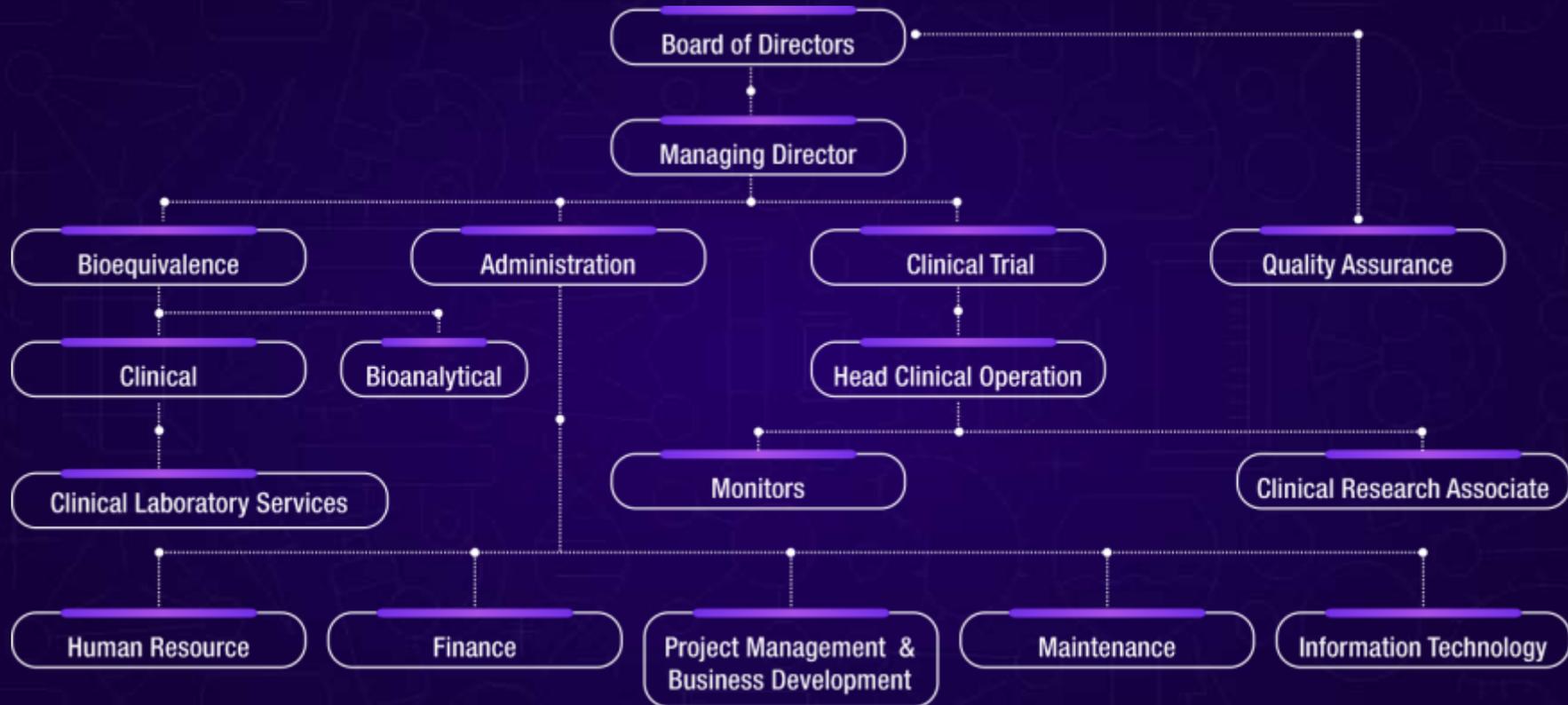


REGULATORY STATUS



Renewal Audits

ORGANOGRAM



OUR CREW

Principal Investigator
Dr. Gokul



Medical Officer
Dr. Santhosh



Quality Manager
Mrs. S. Revathi



Managing Director

Mrs. R. Abiraamasundari

Manager - Clinical
Mr. John Merlin Y S



Consultant Pathologist
Dr. S. Aravinth



Senior Manager - Bioanalytical
Mr. Vijaya Krishnan



Lab Director
Dr. R. D. Puvitha



Manager - Quality Assurance
Mr. Immanuel Manicaraj J



Project Manager
**Mrs. Latha &
Vignesh Kumar P. Ph.D.,**



HR Manager
Mrs. Rupa K P



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.

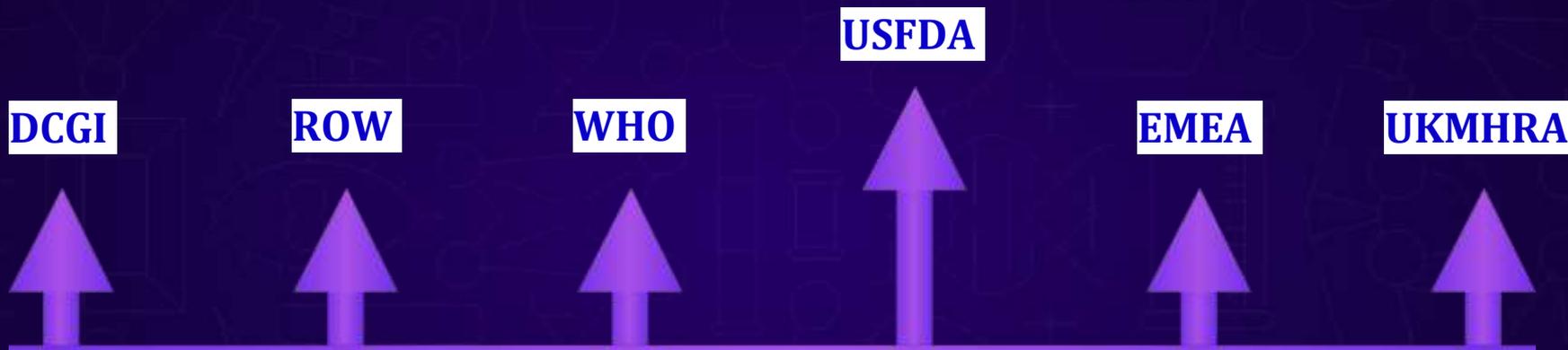
Archival Facilities

- ❖ 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.

OVERVIEW OF BA/BE STUDIES



TOTAL NO. OF STUDIES : 311

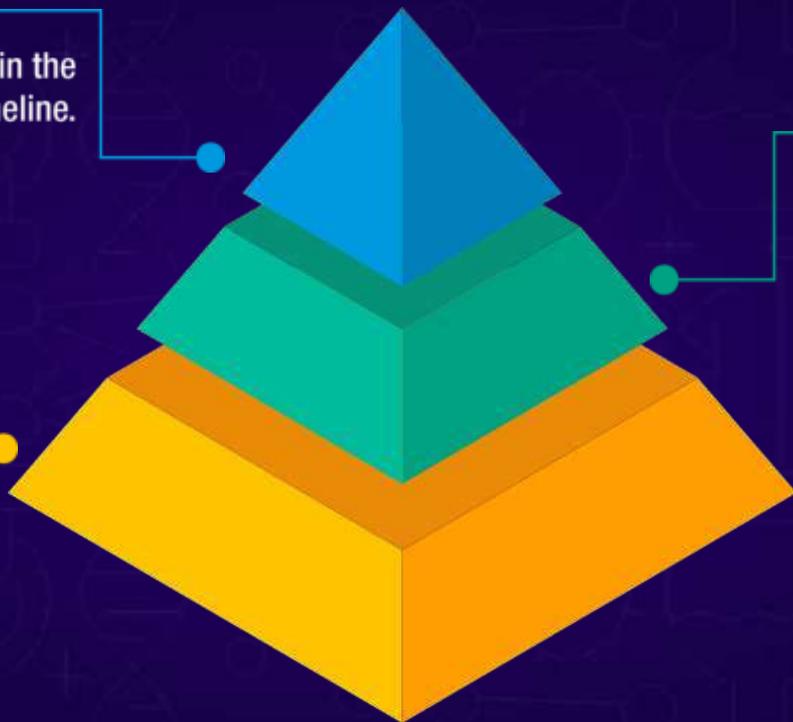


UNIQUE SELLING POINT

Delivering the projects in the committed timeline.

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

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



UNIQUE SELLING POINT

Timeline for BA/BE pilot study with 12 subjects cross over study with 24 Hrs. housing & 03 days wash out

CLINICAL - Lit. Survey, Protocol preparation and approval.

BA - Procurement of standards.

WEEK 1

CLINICAL - P-II - check-in to washout.
BA - Method Validation.

WEEK 3

Report Compilation

WEEK 5

WEEK 2

Clinical - Ethics committee approval.

P-I - check-in to washout.

BA - Method Development.

Sample transfer & analysis

WEEK 4

WEEK 6

Draft report sharing

Total time line to complete the project is 45 days

UNIQUE SELLING POINT



QUALITY



**TIMELY
DELIVERY**



**DATA
INTEGRITY**



**COST
EFFECTIVE**



**GOOD
OUTPUT**

OUR CLIENTS



REACH OUT US



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