



Vayam Research Solutions Limited

Next to Zodiac Party plot, B/h Shaligram Lake view
Opp. AUDA Garden, B/h Vaishnodevi Temple,
Khoraj
Ahmedabad, Gujarat

Clinical Research delivered with passion

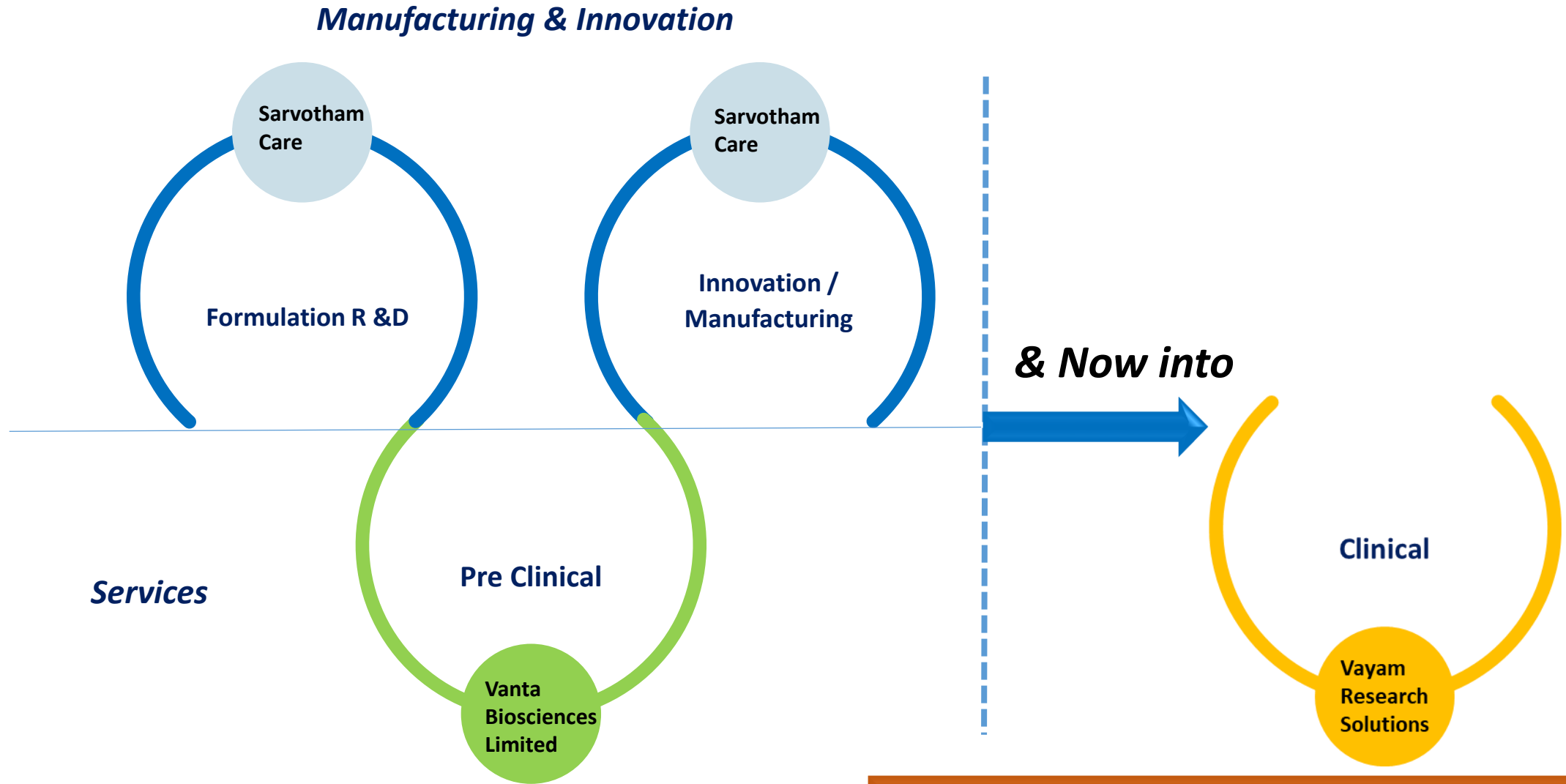


Vayam Research Solutions Limited..... *Is an Initiative of*



SARVOTHAM

Nurturing human health & enriching the quality of life has been the founding mandate of **Sarvotham** since inception (In 1996). Following this vision, **Sarvotham** today has grown from a small batch manufacturing unit to a **recognized Research-oriented Organization that touches every living person's lives.**





Vayam Research Solutions **has imbibed**



From



SARVOTHAM

- Engaging in Conscious Research
- Adhering to stringent regulatory requirements with consistent Quality
- Recognizing the need to constantly improvise

Quality. Consistency. Customer focus. Commitment. Trust.

Clinical Research delivered with passion



Vayam Research Solutions **New Facility with Team of Experts**



- State-of-the art Infrastructure
- Situated in Ahmedabad – A Hub of CRO's
- Vast & **Experienced** professionals / Team
- Fully compliant with ICH GCP, WHO, FDA, MHRA guidance
- **Expertise** in wide therapeutic categories/ segment
- + 4,000 active study participants.
- **Excellent** Project Turn around time



- BA / BE Studies (Healthy Subjects)
- PK-PD Studies (In Healthy & Patients)
- Proof of Concept Studies (PoC)
- Special Patient Population
- Drug- Drug Interaction Studies
- Food- Drug Interaction Studies
- Irritation, Sensitization, Adhesion Studies
- Late Phase Clinical Trials (Phase 2, 3, 4)
- Bioanalytical
- Pharmacokinetics & Biostatistics
- Medical Writing
- Project Management
- Clinical end point BE studies
- Protocol to Report



➤ **Biostatistics & Medical Writing**

- Sample Size and power
- Medical writing and literature search
- Randomisation
- Statistical plan (SAP)
- Interim Analysis
- Statistical Report
- Regulatory services

- Late Phase Clinical Trials (Phase 2, 3, 4)
- Bioanalytical
- Pharmacokinetics & Biostatistics
- Medical Writing
- Project Management
- Clinical end point BE studies
- Protocol to Report
- Pre Clinical - Toxicology



Where Expertise meets your Expectations



CPU Entrance



Subject Screening



Subject Housing



Subject Dosing

- 15000 Sq. ft area
- Capacity for 140 beds (70 beds to start with)
- Subject Screening area
- Subject Housing area
- Subject Dosing area
- Dedicated state of art ICU with cardiac monitoring
- Capacity to handle +200 dosings/month



Subject dining



Subject Recreation



2 Bed ICU



Dedicated Pharmacy

- Subject Dining Area
- Subject recreation area
- Dedicated Pharmacy
- World class infrastructure to support clinical activities
- Accredited by India (DCGI)
- Tie up with CAP-NABL accredited central lab



Therapeutics Segments

- Antibiotic / Antimicrobial
- Antidepressant
- Antiepileptic
- Antiretroviral
- Hormonal Preparations
- Hypoglycaemic Agents
- Lipid Lowering Agents
- Muscle Relaxants
- NSAIDs
- Oral Contraceptives
- Psychotropic agents
- Nutraceuticals
- Cosmeceuticals

Formulations



All Oral Dosage forms



Liquid Orals



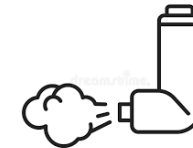
Parentrals



Transdermal Patches



Creams / Ointments



Inhalers / Nasal Sprays



- Total ~ 7500 Sq. ft
- 02 LCMS/MS (API 4500). Infrastructure built to accommodate 18 LCMS/MS
- Vast **experienced** team – Experience on validation of +250 bioanalytical methods in different matrixes.
- Handled complex Liposomal Method Development, Validation & Bioanalysis
- **Expertise** in Quantitive analysis of parent Drugs & their metabolites in a variety of Biological matrices
- SPE/LLE/protein precipitation methods.

Analyst software version 1.7.2



Collaborations with more than
85 potential Clinical Sites

Access to more than
90 Principal Investigators

Patient Population PK Studies



Segments: Oncology, Cardiology, GI,
Orthopaedic, Ophthalmology, Endocrinology,
Metabolism, Topical

CE Point studies





Statistical inputs to study protocol

Randomization

Interim Analysis

PK & Statistical report



Statistical Analysis Plan

Sample Size & Power Calculation

SAS Programming & Validation

Latest Version of SAS & WinNolin





- a) Nutraceutical / Natural health products, dietary supplements Research.
- b) Cosmetic clinical research.
- c) Baby care and Mother care product's research
- d) Home care products research
- e) OTC products research
- f) Patch Testing [PIPT | HRIPT | CIPT]
- g) In vitro and Ex-vivo testing



These studies/services are provided in collaboration with our channel domain specialist partner.





Qualified and Experienced QA Team

Well Established SOPs and Processes

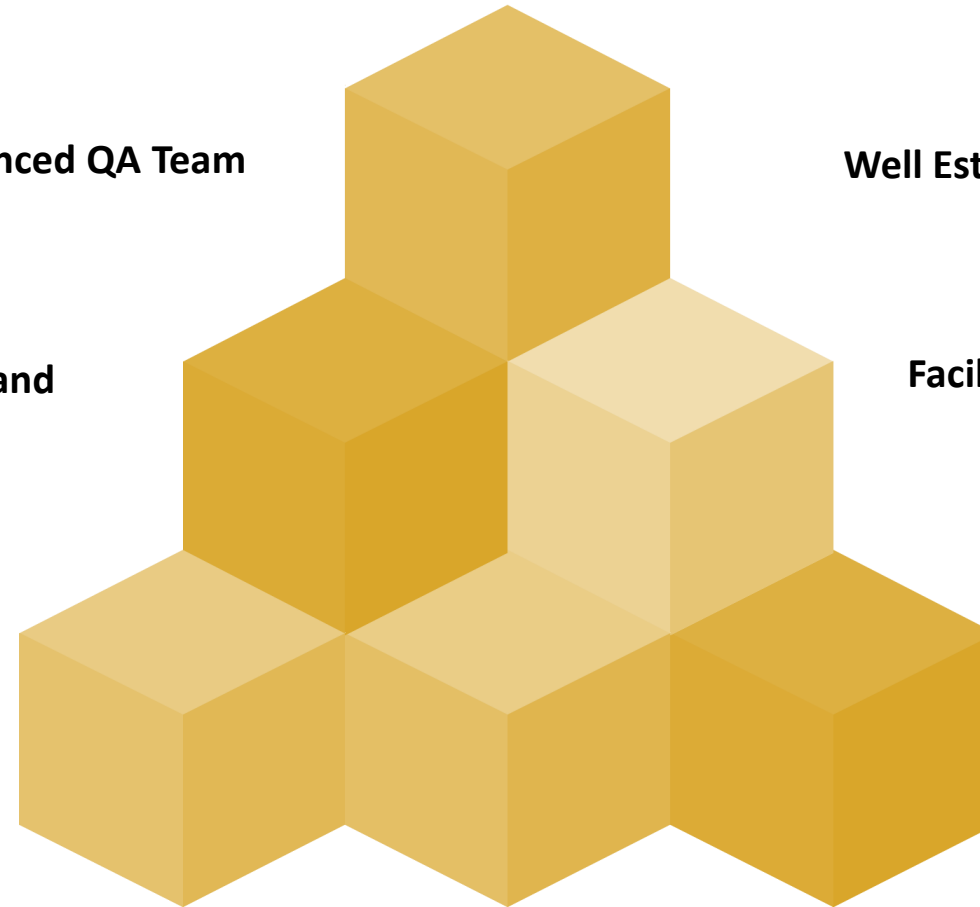
Regular update to Management and Update on Quality

Facility, Process and Study Based Audits

Regular Trainings and Evaluations

Qualification of instruments, supplies, vendors and test sites

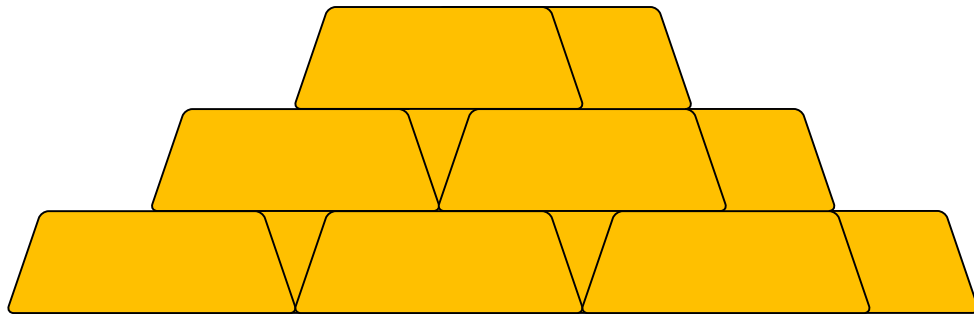
All QA systems are compliant with applicable local and international regulations.





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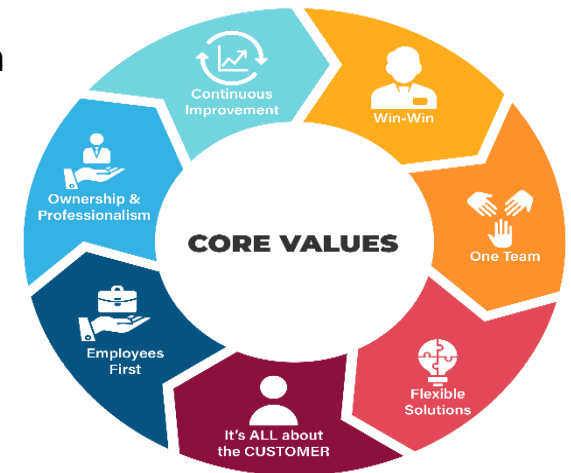
Value Based Leadership : Our vision outlines the value that provides us the foundation to perform as a reliable service provider and as individual employees who continue to put the needs of the sponsors and regulators we serve first.



Integrity :

- Committed to conduct our business with individual and organizational Integrity
- Compliance with Local and International laws
- Treat everyone fairly, honestly and courteously
- Act with integrity and professionalism
- Patient safety is paramount for Vayam

Responsibility : We hold ourselves accountable for our actions:
Take personal responsibility in everything that we do and we lead by example
Treat our Organization's reputation as our own
Committed to a culture of shared responsibility that promotes high performance





Management

Vast Experience in the Industry
High commitment
Quality Oriented

Scientific Team

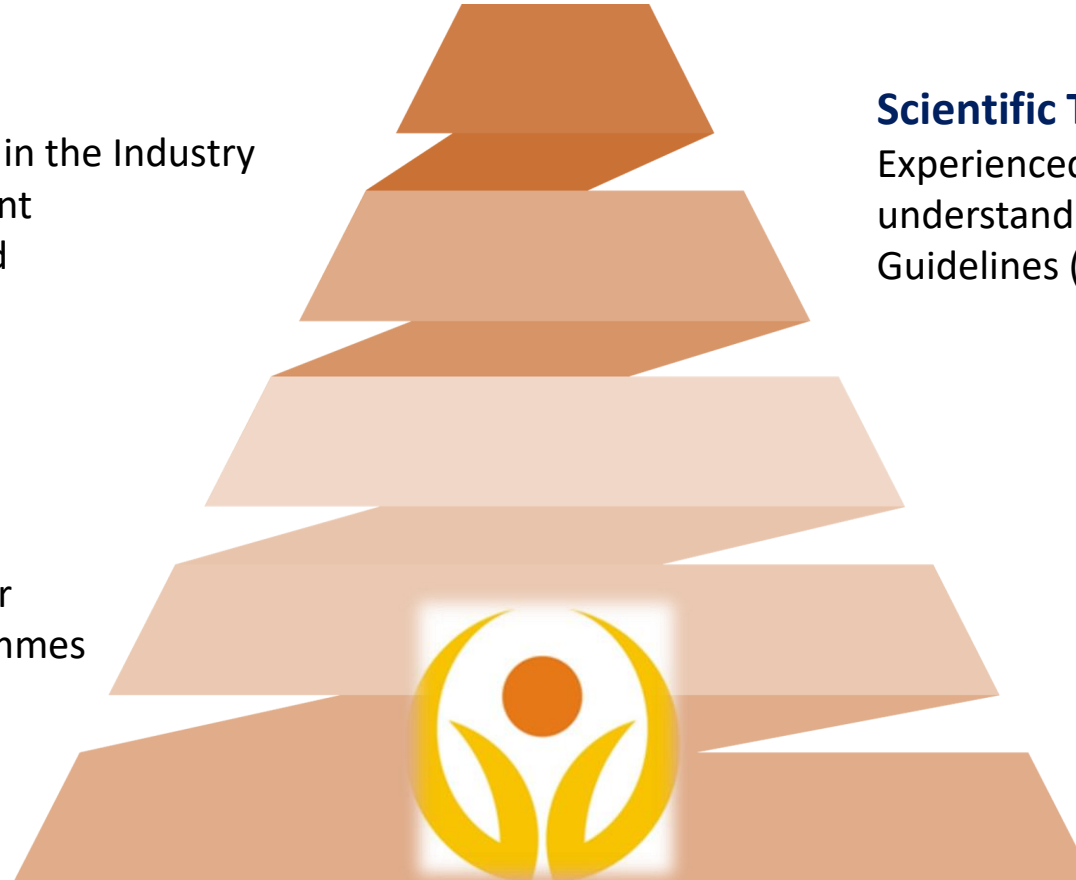
Experienced scientific team with excellent understanding of governing regulations/ Guidelines (Domestic & International)

Infrastructure

State of the art facility for
Clinical Research Programmes

Compliance

Reputation for high quality and compliance including **strict confidentiality and data integrity**



Complete service/solution provider with highly experienced research professionals & excellent infrastructure



Vayam Research Solutions Limited

Management Team at Vayam



Dopesh Raja – Managing Director



Dr. Yati Chugh – CEO
30+ Yr of experience in clinical research



Sudhir Pai - Director



P. Prasad Rao – VP, BD
30+ Yr experience in Pharma Industry



Ketel Prajapati – Manager Bioanalytical
18+ Yr experience in BA research



E. Sriram – Head Quality
18+ Yr experience

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Thank You

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