



RAPTIM RESEARCH PVT. LTD.

A CONTRACT RESEARCH  
ORGANIZATION

# RAPTIM RESEARCH

Rapid, as Time matters

An Independent and Internationally Accredited CRO

# Overview

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- Key Highlights
- Our Journey
- Leaders
- Core Team
- Core Values
- Our Presence
- Service Profile
- Regulatory Inspections
- Quality Assurance
- Clinical Trials Segment
- In-Vitro segment
- Experience in Dermatology
- The Raptim Edge

# Key Highlights



16 years of  
legacy in Clinical  
Research



Full-Service  
Independent  
Global CRO



Compliant with  
Global Regulatory  
Authorities



More than 500  
highly skilled  
employees



State of the Art  
Infrastructure

# Our Journey

- |             |   |   |             |   |  |
|-------------|---|---|-------------|---|--|
| <b>2005</b> | ● | Inception of Raptim Research, Navi Mumbai   | <b>2018</b> | ● | Added <b>125 beds</b> at Gandhinagar facility  |
| <b>2009</b> | ● | Successfully cleared first <b>2 USFDA Inspections</b>   | <b>2019</b> | ● | Successfully completed <b>3 Unannounced USFDA Audits</b>   |
| <b>2010</b> | ● | Initiated <b>Clinical Trials Services</b> (Phase II-IV)   | <b>2020</b> | ● | <ul style="list-style-type: none"> <li>○ Successfully completed F2F study during the initial days of Covid pandemic</li> <li>○ Successfully completed large <b>Clinical Trials of 900+ patients</b></li> </ul>   |
| <b>2014</b> | ● | <ul style="list-style-type: none"> <li>○ Reached the mark of <b>1000 pivotal BE Studies</b></li> <li>○ Started In-Vitro services</li> </ul> | <b>2021</b> | ● | <ul style="list-style-type: none"> <li>○ In-Vitro Department reached <b>240+ cells</b> (Biggest in APAC)</li> <li>○ Another <b>50 beds</b> added to the Gandhinagar facility, A total bed strength of <b>350</b></li> <li>○ Added 11 LCMS to a total of 36 LCMS</li> </ul> |
| <b>2015</b> | ● | Added 15 more LCMS to 20 LCMS   |             |   |  |
| <b>2017</b> | ● | Installed 5 more LCMS to 25 LCMS  |             |   |  |



# Leaders



**Dr. Rajen Shah**

Director

Dr. Rajen Shah is a Ph.D. from the University of Maryland (US), and a Bachelor in Pharmacy.

He has worked in the research group of Global Pharmaceutical companies like Novartis in US and Basel for more than 14 years and has more than 22 years of Regulatory and CRO experience in India.



**Mr. Viraj Shah**

Director

Mr. Viraj Shah is a post-graduate in Business Administration from the University of Richmond, US.

He has 25+ years of experience in Global Equity Finance and Management in USA and UK, and 16+ years of experience in the CRO industry.



# Core Team



**Dr. Chirag Shah**

Head, Clinical Operations

Dr. Chirag is M.Pharm, Ph.D (Clinical Pharmacology) with PGDPM. He has 22+ years of experience in Clinical Development (Phase I-IV), Global Project Management, Regulatory, Setting up new department, M & A, and Business Strategy in Pharma, Biotech and CRO Industry.



**Dr. Milind Bagul**

Head, Analytical Services

Dr. Bagul is M.Pharm, and Ph.D in Pharmaceutical Sciences. He has over 15 years of experience in managing Biopharmaceutical Studies and is associated with Raptim for more than 12 years. He is the pillar in developing the In Vitro service portfolio of Raptim.



**Mrs. Usha Ramakrishnan**

Head, Quality Assurance

Mrs. Ramakrishnan is Bachelor of Pharmacy and Diploma in Industrial and Analytical Chemistry. She has extensive experience of about 33 years in Quality Assurance with various pharmaceutical companies and Contract Research Organizations (CROs).



**Dr. Hardik Dave**

Head, Clinic

Dr. Dave is a Medical Doctor and has served as a Clinical Investigator for Bioequivalence and Clinical Studies for more than 20 years.

# Core Values



INNOVATIVE



CLIENT CENTRIC



QUALITY FOCUSED



TIME EFFICIENT

# Our Presence

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Navi Mumbai  
Maharashtra, India

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Operations Facility



Gandhinagar  
Gujarat, India

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Operations Facility



Skillman  
New Jersey, USA

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Marketing Facility



# Service Profile

## Full Service CRO

### Early Phase

#### End-to End Service

- Expertise in conducting PK/PD studies
- Food effect / Drug – Drug Interaction studies
- Proof of Concept studies
- Biosimilar and Large molecules
- Glucose Clamp Studies
- 505(b)2 Studies

### Late Phase

#### End-to End Service

- Phase II- IV Trials
- Clinical End Point Studies
- Real World Evidence (RWE) Studies
- Post Marketing Surveillance (PMS) Studies

### Clinical Data Management

#### Complete Data Management

- Preparation of DMP
- Query Management
- Medical Coding, SAE Data
- Reconciliation
- Database Lock and Export to SAS

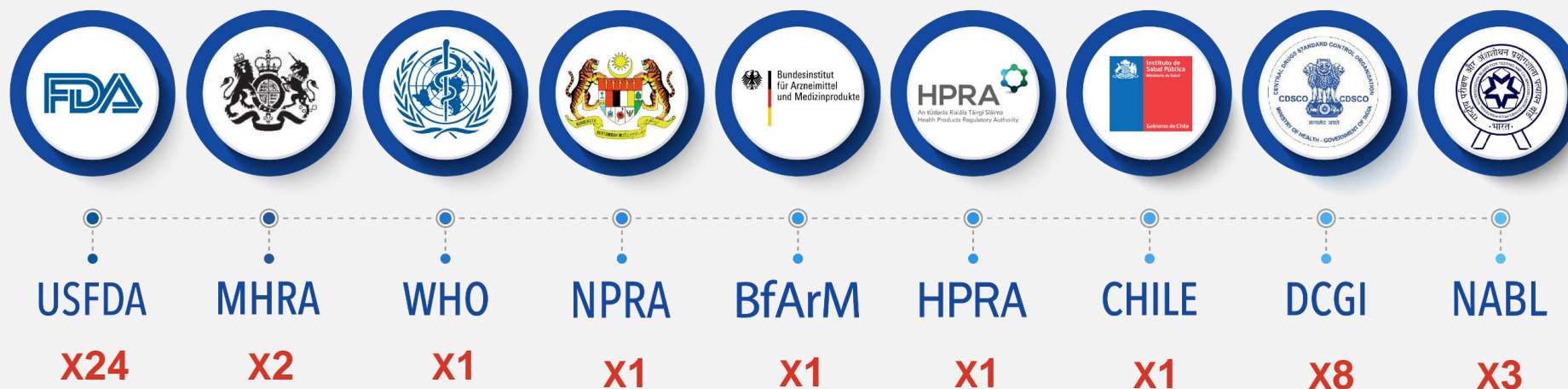
### Biostatistics & Medical Writing

- Sample Size and Power Calculation
- Statistical Analysis Plan (SAP)
- SAS Programming and Validation
- Medical writing and literature search
- CDISC Dataset

### In-Vitro Segment

- In Vitro Release Test (IVRT) & In Vitro Permeability Test (IVPT)
- In Vitro Binding Studies
- BCS Bio Waiver Studies
- In Vitro Feeding Tube Studies
- Nail Permeation Studies

# Regulatory Inspections



USFDA inspection at 8 Multicentric Sites

# Quality Assurance

## Compliance

- Protocol
- Standard Operating Procedures
- Regulatory Guidance



## Process

- Routine Review of SOPS
- Compliance to Process
- Quality Review System



## Query Management

- Regulatory Query
- Sponsor Query
- Support Investigational site during Inspection



## Audit

- Investigational Site Audit
- In-house Audit
- System Audit



# Early Phase Capabilities

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- Spread over more than 50,000 sq.ft.
- ~**350 Beds** in 6 Clinical Units
  - **170 beds** in Mumbai, Maharashtra
  - **172 beds** in Gandhinagar, Gujarat
- Negative pressure area designed for dosing of Inhalation products
- Separate housing for Male and Female subjects
- Capability to manage multiple studies at a time
- Well equipped Emergency Care Units (ECUs)

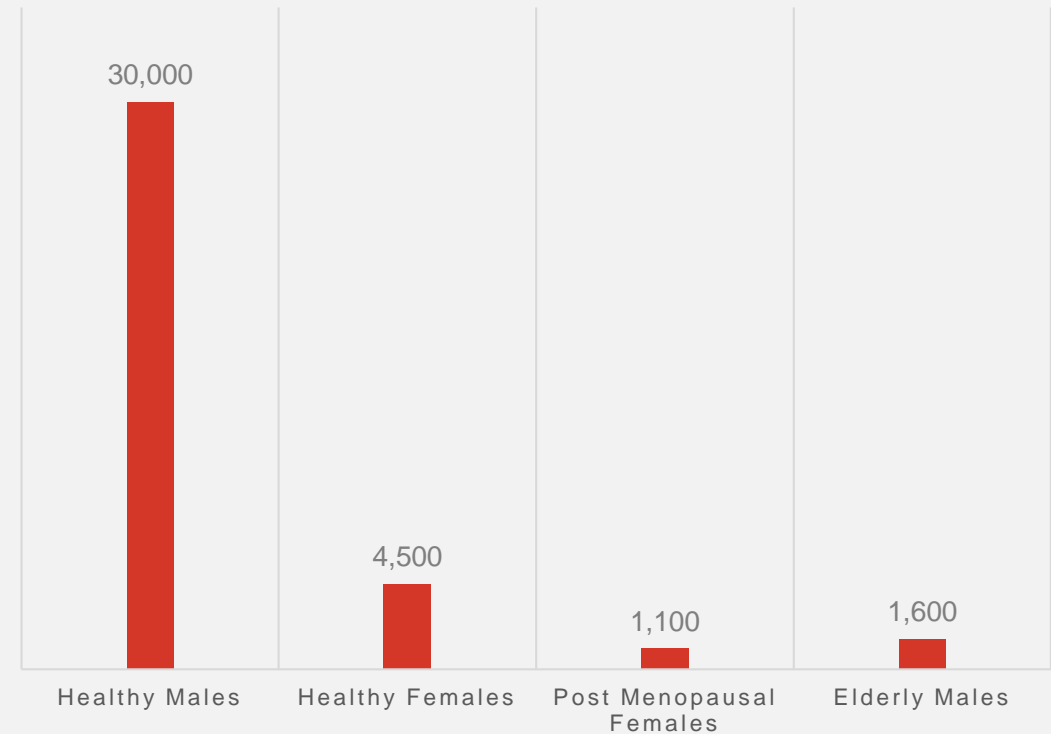
# Volunteer Database

**35,000+**

Volunteer Database

## Measures at Screening

- Double verification during OVIS check
- Encouraging volunteers to report with dual identity proof







# Bioanalytical Capabilities

**36 LC MS/MS**

**3 HPLC**

**2 ICP**

**1 ICP MS**

**LC MS/MS: API 6500/5500/4500/4000/3500/2000**



250+ Validated Methods



Developed Sensitive and Complex Methods



50+ Well-Trained and Experienced Scientists



Laboratory Information Management System (LIMS)



Deep Freezers (-20°C and -70°C)



GLP Compliant Lab



# Expertise & Experience

## Formulations

- Oral Solids, Capsules, Tablets, Soft gels, Granules, ODT, Lozenges, Modified Release Dosage Forms
- Liquid Orals
- Parenteral
- Transdermal patches
- Topical: Gel, Cream, Lotion
- Vaginal Cream, Ring and Inserts
- Inhalers - MDI
- Nasal Sprays
- Suppository

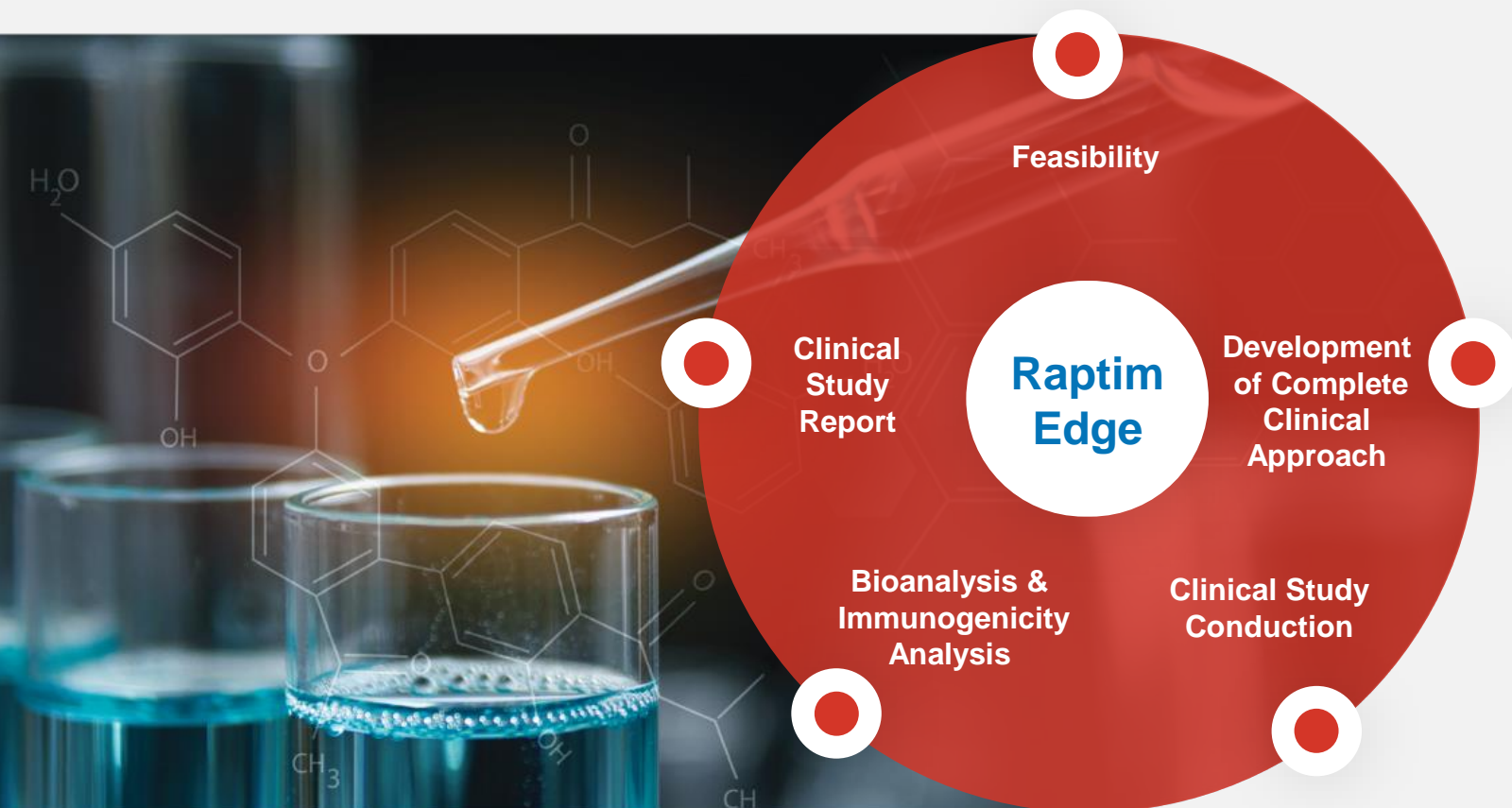
## List of Complex Studies

- **Inhalation Products:** Salmeterol+ Fluticasone, Budesonide, Salbutamol, Glycopyrrolate, Beclomethasone MDI, Ipratropium Bromide MDI, Levalbuterol HFA Aerosol
- **Narcotics and Psychotropic Substances:** Morphine, Buprenorphine and Naloxone, Methylphenidate, Dexmethylphenidate and Pseudoephedrine products
- **Hormonal Products:** Fulvestrant Injection, Progesterone, Ethinyl Estradiol and Etonorgestral Vaginal Ring (Nuvaring), Levothyroxine & Dienogest
- **Transdermal System:** Buprenorphine and Naloxone, Nicotine, Estradiol, Fentanyl and Oxybutynin
- **Vitamins:** Phytonadione, Calcitriol, Ergocalciferol



# Biosimilars & Large Molecules

Your Trusted Partner in the course of development of Biosimilars



- Collaboration with NABH accredited Hospitals for conduction of complex studies
- Expert and Experienced Team
- Panel of KOLs for scientific advice
- Validated methods for Teriparatide and Insulin Glargine (metabolites M1 and M2) from human plasma
- Method under development:
  - Semaglutide
  - Liraglutide
  - Octreotide
  - Adalimumab

# Glucose Clamp Studies



## ➤ Infrastructure

- YSI analyzer
- Automated (computer algorithm directed) glucose infusion rate adjustment program
- Heated Hand Box – To keep Cannula Patent

## ➤ Experience

- Completed 300+ Clamps
- In-depth knowledge and scientific base of clamping technique
- Phases of Glucose Clamp:
  - Scientific discussion at SEC committee meeting
  - 30 minute stabilization with monitoring commenced
  - Baseline blood glucose levels, Clamp Value, Algorithm
  - Insulin administration
  - 5 / 10 minute blood sugars and Glucose Infusion Rate adjustment
  - Samplings for PK

# Late Phase Capabilities

Expertise



Experience



Execution

Project & Site  
Management

Medical Affairs

Biostatistics

Quality  
Assurance

Clinical  
Operations

Monitoring

Regulatory

Data  
Management



# Late Phase Experience

**Completed 15+  
Clinical Trials for  
USFDA, Canada  
and DCGI**

**Various  
Therapeutic  
Indications**

**Recruited ~1500  
Patients**

- **Phase II-IV Trials  
Clinical End Point  
Studies**
- **Real World  
Evidence (RWE)  
Studies**
- **Post Marketing  
Surveillance (PMS)  
Studies**

# Setting Trends during the Pandemic

**Recruited  
1,000 Patients**  
for Clinical  
Trials!



Transformed Culture of Digitalization ( CTMS, eTMF, ePRO & rSDV)



Implemented Hybrid Monitoring (i.e Remote and/or Central monitoring)



Real Time Data Collection



Continuous Risk Assessment and Oversight



Remote QA Audit

# In-Vitro Segment

## ➤ In-Vitro Release Stress (IVRT) & In-Vitro Permeation Test (IVPT) Studies

- 11 fully automated Franz diffusion cells system with 192 cells from Logan and Hanson
- In-vitro test with Human Cadaver skin and other types of synthetic membranes

## ➤ BCS Bio-waiver Studies

- Established Caco-2 permeability method using 20 model drugs

## ➤ Nail Permeation Studies

- Access to Cadaver Nails
- Developed in-vitro nail permeation technique for anti-onychomycosis drugs

## ➤ In-Vitro Feeding Tube Studies

- Comparative recovery testing
- Particle size distribution study
- Comparative acid resistance stability testing
- Sedimentation volume testing
- Activities to be captured with DSLR camera

## ➤ In-Vitro Binding Studies

- To compare the extent and rate of binding affinity between Test and Reference formulations where assay to be performed with minimum 12 replicates at various pH conditions
- Includes Equilibrium Binding Study with and Without Acid Pretreatment

# A Leader in IVRT & IVPT Studies

- Superior scientific experience in method development and validation of In-vitro studies for topical formulations
- In-depth expertise in operating Franz Cell instruments with synthetic and tissue membranes including human skin
- Able to rectify challenges of the most complex In-vitro release testing
- Data interpretation and regulatory submission for approval of SUPAC-related changes
- Able to meet strict timelines in a cost-effective manner without compromising on quality

## IVRT STUDIES

Acyclovir Ointment  
Diclofenac Gel  
Lidocaine Gel  
Dapsone Gel 5% and 7.5%  
Nystatin Cream and Onitment

## IVPT STUDIES

Tacrolimus  
Rivastigmin Patch  
Penciclovir Cream  
Acyclovir Cream  
Doxepin Cream

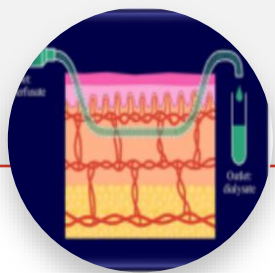


# Experience in Dermatology



## Tape Stripping

- Miconazole nitrate Gel, Cream and Ointment
- Tacrolimus Gel
- Betamethasone Gel
- Adapalene Gel
- Clindamycin Gel



## Dermal Micro Dialysis

- Diclofenac Gel
- Heparin Solution
- Tretinoin Gel



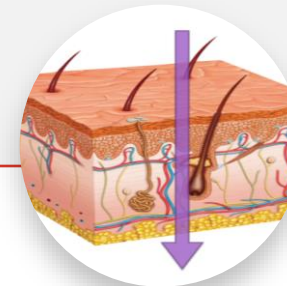
## Pharmacokinetic Studies-Systemically Acting Formulations

- Buprenorphine Patches
- Nicotine Patches
- Rotigotine Patches
- Fentanyl Transdermal Patches
- Oxybutynin Transdermal Patches / Gel



## In-Vitro Release Testing (IVRT) Studies

- Acyclovir Ointment
- Lidocaine Ointment
- Diclofenac Gel
- Nystatin Cream
- Triamcinolone Cream
- Nystatin + Triamcinolone Ointment and Cream
- Cyclosporine Ophthalmic Emulsion



## In-Vitro Permeation (IVPT) Studies

- Acyclovir Cream
- Doxepine Cream
- Dapsone Gel
- Adapalene and Clindamycin Gel
- Tacrolimus Gel



## Carving a niche in the Industry

- Full Service CRO
- Experienced Team
- Flexible

# The Raptim Edge

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# Join Hands With Us!

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