RAPTIM RESEARCH PVT. LTD.

A CONTRACT RESEARCH ORGANIZATION

RAPTIM RESEARCH

Rapid, as Time matters

An Independent and Internationally Accredited CRO

Overview

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

Key Highlights

17 years of legacy in Clinical Research

Full-Service Independent Global CRO

Compliant with Global Regulatory Authorities

More than 570 highly skilled employees

State of the Art Infrastructure

Our journey started in 2005 And today…

27 successful audits by USFDA (for both Late Phase & Early Phase)

Clinical trials of 900+ patients completed and approved by USFDA

Total capacity of 342 beds

43 LCMS installed

240+ cells (biggest in APAC) in In-Vitro segment

CRED-Bio system implemented for early phase

28 BCS studies submitted/completed

11 Binding studies submitted/completed

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

Navi Mumbai
Maharashtra, India

Operations Facility

Gandhinagar Gujarat,
India

Operations Facility

Skillman
New Jersey, USA

Marketing Facility

Service Profile

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

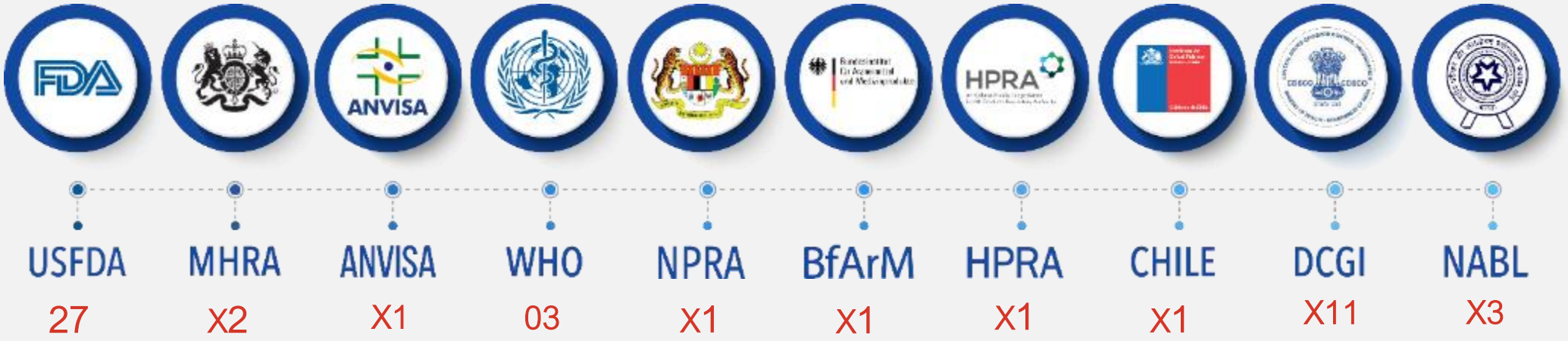
Biostatistics & Medical Writing

- 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 9 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

Technological Adaptation

With electronic tools we have improved

- Data Integrity
- Cycle Times
- Risk Management
- Cost
- Patient Recruitment

Technological Adaptation

Some of the tools implemented at Raptim are

- CTMS
- eTMF
- rSDV
- CRED-Bio

Implementation of Complete Electronic Documentation System (CREDs-Bio)

Data Integrity By Design

Increased efficiency with Accuracy and Quality

Appreciation by Regulatory Agencies for

- Data integrity
- Ease of operation
- Quick search of data
- Availability of full audit trail
- 21CFR Part 11 Compliant

CREDs-Bio Key Advantages

Volunteer & Screening

- Complete tracking of volunteer database and screening records

Pathology

- Instrument to CRED-Bio Interface
- Reports generated electronically

Clinical

- Subjects and samples barcoding to avoid mix-ups
- eCRFs : Ease of search and review
- C-DISC is generated automatically and error free

Sample Management

- Ease in sample movement and tracking
- Easy overview of number of samples (project wise and deep freezer wise)

SDMS Print & LIMS (Analytical)

- Captures activity of sample preparation, data analysis and printing of all raw data
- Electronic sample preparation records
- Unique barcodes for samples avoids sample mix-ups and ensures data integrity
- Software performs the calculations and batch/experiment acceptance
- Electronic data review and e-signature
- Interfacing with analyst software for exporting of acquisition batches and
- importing of result data
- One center for all study data for easy review
- No manual intervention and thus error free
- Seamless data movement from Analyst software to CRED-Bio software without manual intervention Concentration data capturing from the
- CRED-Bio software to SAS program assuring data integrity

Training

- Automatic tracking, documentation and evaluation of training related activities

Successfully Completed F2F BE Study

No. of Subjects
100 Subjects

Scope
Regulatory, Screening and Clinical Services

Study location
Raptim Gandhinagar

Total Duration
14 Days

- First CRO to work during COVID with Restrictions, Ambiguity and Challenges.
- Achieved the desired recruitment target during the peak COVID period.

Outcome

Product is approved by FDA

Early Phase Capabilities

- Spread over more than 50,000 sq.ft.
- ~342 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)

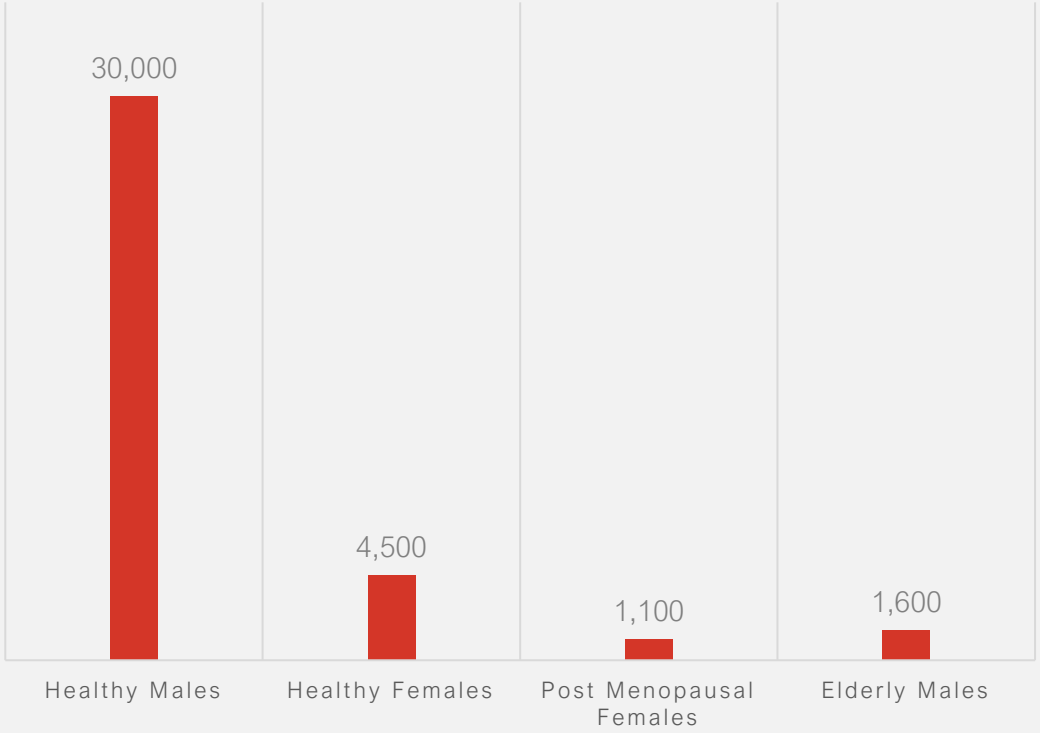
Volunteer Database

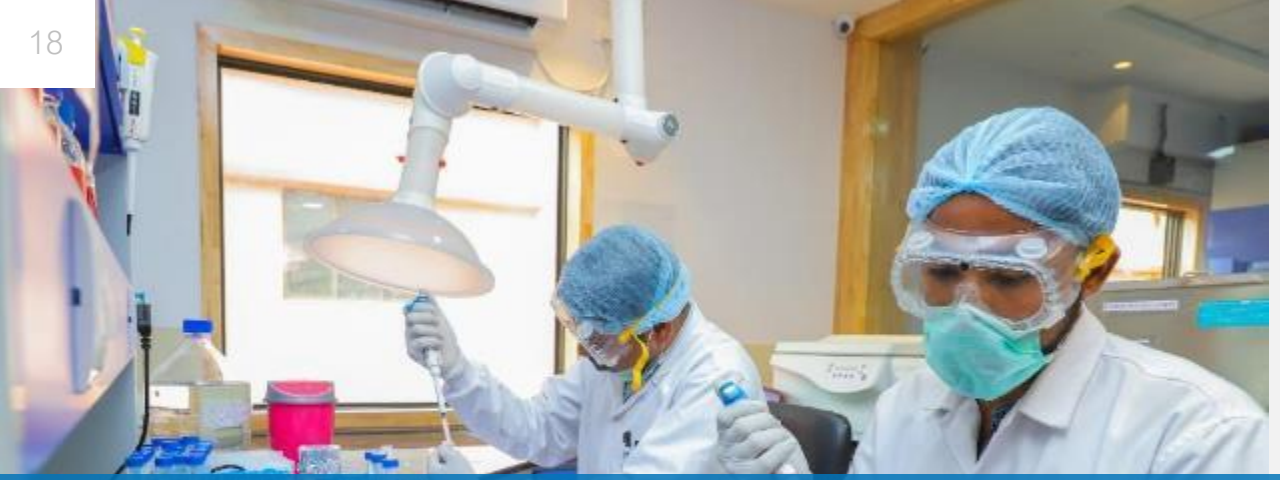
35,000+

Volunteer Database

Measures at Screening

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





Bioanalytical Capabilities

43 LCMS/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

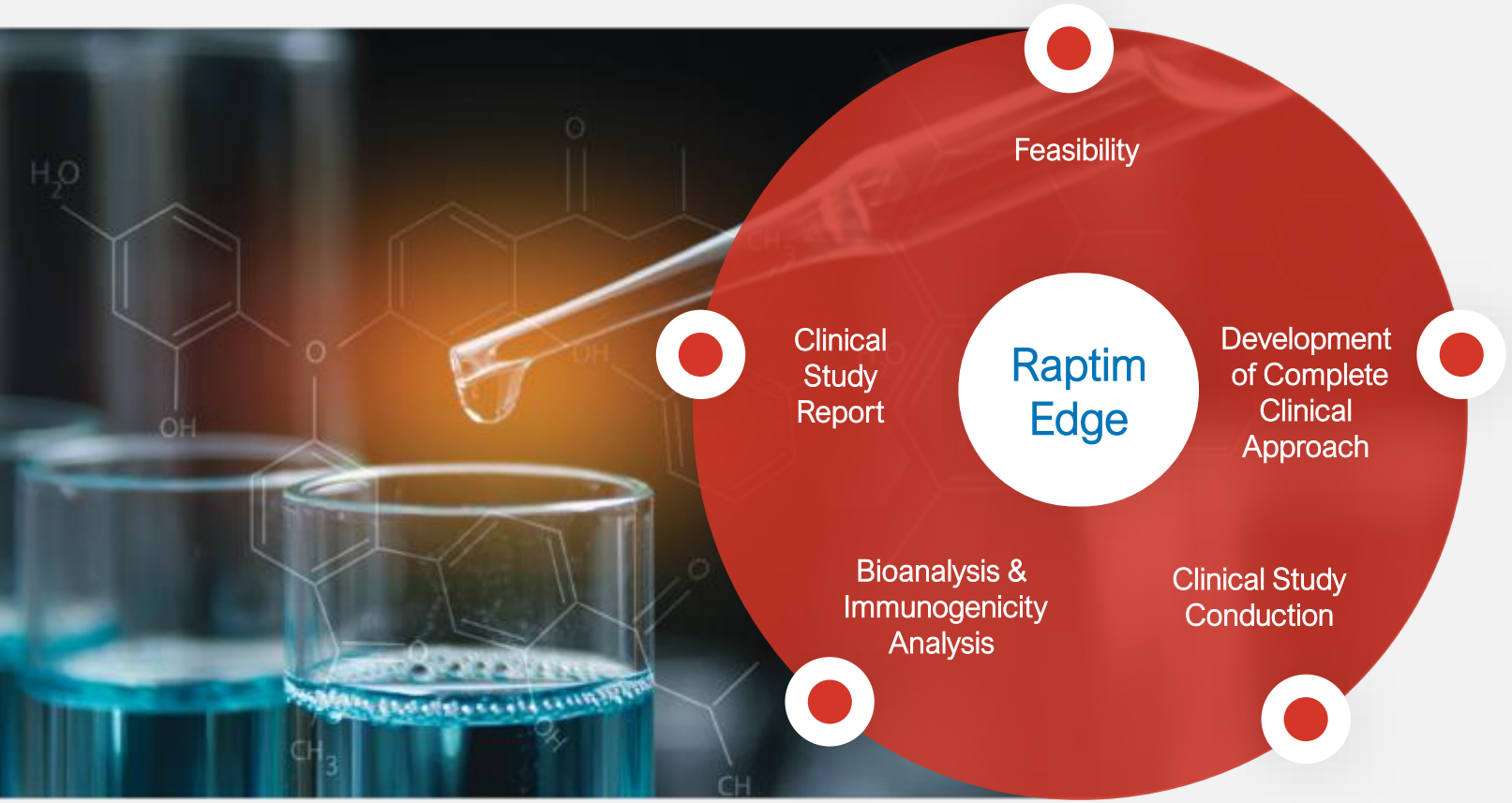
- Oral Solids, Capsules, Tablets, Soft gels, Granules, ODT, Lozenges, Modified Release Dosage Forms
- Liquid Orals
- Parenteral
- Transdermal patches
- Topical: Gel, Cream, Lotion
- Vaginal Cream, Ring and Inserts
- Inhalers - MDI
- Nasal Sprays
- Suppository

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:** Phytonodione, 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

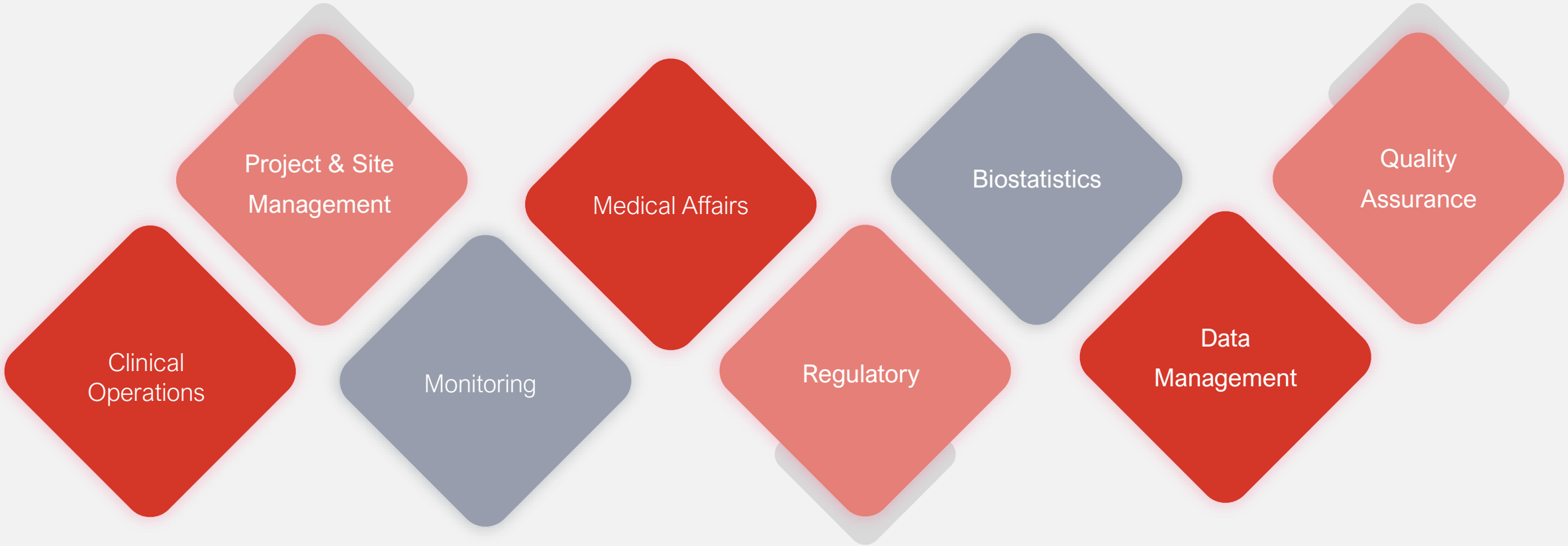
- YSI analyzer
- Automated (computer algorithm directed) glucose infusion rate adjustment program
- Heated Hand Box – To keep Cannula Patent

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



Late Phase Experience

Completed 18+ Clinical Trials for USFDA, Canada and DCGI

Various Therapeutic Indications

Recruited ~2000 Patients

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

Continuous Upgradation & Trend Setting

- 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

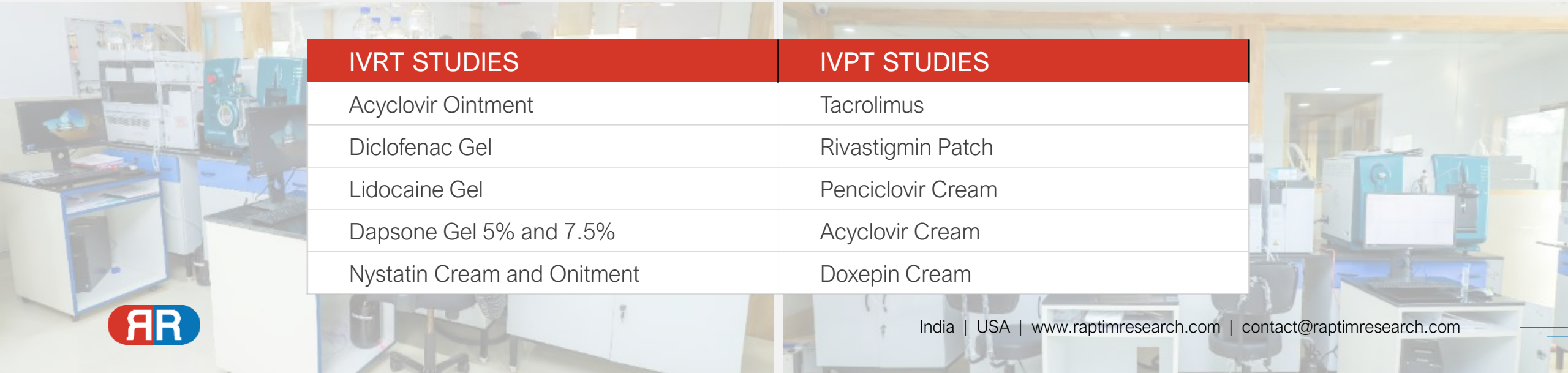
- Comparative recovery testing
- Particle size distribution study
- Comparative acid resistance stability testing
- Sedimentation volume testing
- Activities to be captured with DSLR camera

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

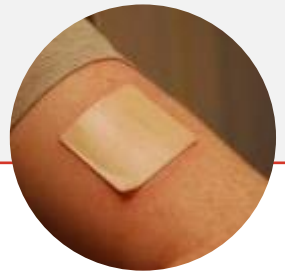
A Leader in IVRT & IVPT Studies

- 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



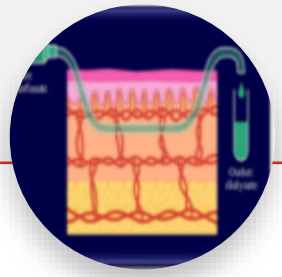
IVRT STUDIES	IVPT STUDIES
Acyclovir Ointment	Tacrolimus
Diclofenac Gel	Rivastigmin Patch
Lidocaine Gel	Penciclovir Cream
Dapsone Gel 5% and 7.5%	Acyclovir Cream
Nystatin Cream and Onitment	Doxepin Cream

Experience in Dermatology



Tape Stripping

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



Dermal Micro Dialysis

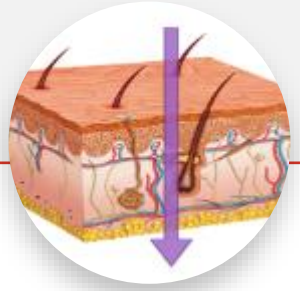
- Diclofenac Gel
- Heparin Solution
- Tretinoin Gel

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
- Triamecinolone Cream
- Nystatin + Triamecinolone Ointment and Cream
- Cyclosporine Opthalmic Emulsion



In-Vitro Permeation (IVPT) Studies

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

The Raptim Edge

Carving a niche in the Industry

- Full Service CRO
- Experienced Team
- Flexible

Join Hands With Us!

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