RAPTIM RESEARCH PVT. LTD.

A CONTRACT RESEARCH ORGANIZATION

Raptim Research Corporate Portfolio

Rapid, as Time Matters

Unlocking Success: Accelerate Your Drug Development Journey with Expertise

July 2024

- 19+ years of legacy in Clinical Research
- Full-Service Independent Global CRO
- Compliant with Global Regulatory Authorities
- ~ 700 highly skilled / expert team
- State of the Art Infrastructure

Our Journey

2005
- **Inception** of Raptim Research, Navi Mumbai

2009
- Successfully cleared first **2 USFDA Inspections**

2010
- Initiated **Clinical Trials Services** (Phase II-IV)

2014
- Crossed 1000 pivotal BE Studies
- Started In-Vitro services

2015
- Analytical capacity increased to 20 LCMS
- ISP – Chile approval

2017
- Analytical capacity increased of 25 LCMS

2018
- Added **125 beds** at Gandhinagar facility
- **UK MHRA Inspection**

2019
- Cleared **3 Unannounced USFDA Inspections**
- Cleared **BfArM, NPRA and HPRA Inspections**

2020
- F2F study through Covid pandemic
- Large Clinical Trials of **900+ patients**
- Cleared **WHO Inspection**

2021
- IVPT Capacity Crossed **240 Cells (Largest in APAC)**
- **Reached~ 350 Beds**: 50 Beds added in Gandhinagar
- Analytical Capacity increased to **36 LCMS**
- Successfully cleared **UK HRA and ANVISA** Inspections

2022
- IVPT Capacity crossed **288 Cells (Largest in APAC)**
- Analytical capacity increased **to 43 LCMS**, Added **ICP-MS**
- **CRED-BIO / LIMS-eCRF** implementation
- Successfully cleared **GCC Inspection**
- Successfully cleared **27th USFDA Inspection** (BE and IVPT)

2023
- Successfully cleared **31st USFDA Inspection** (BE, IVPT and Pt BE studies)
- **5 IVPT studies** received **USFDA approval**
- Crossed **3000+ BE Studies**

2024
- **DCGI Approval** for **12 Bed Phase I facility** in Mumbai
- **Approval for 36 beds for BA/BE studies**
  - Total capacity reaches **390 Beds**
- Analytical capacity increased **to 48 LCMS**
- **GCC Approval** received
- Successfully cleared **32nd USFDA Inspection**
- **WHO audit cleared** for clinical trials without any findings

Global Reach and Local Expertise through Strategic Partners

Aggressively investing in strengthening Global Capabilities and Foot Print

Core Values

- INNOVATIVE
- CLIENT CENTRIC
- QUALITY FOCUSED
- TIME EFFICIENT

Raptim Offices	Global Partners
New Jersey, USA Mumbai, India Gandhinagar, India	USA EU AFME APAC LATAM

Delivering Consistent Customer Delight through E2E One Stop Solutions

Leaders

Dr. Rajen Shah
Director

Ph.D. from the University of Maryland, USA, and Bachelor of Pharmacy, has over 22 years of experience in regulatory affairs and Contract Research Organizations (CROs) in India, with notable contributions to global pharmaceutical companies like Novartis.

Mr. Viraj Shah
Director

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. Milind Bagul
Head, Analytical Services

Dr. Bagul is M.Pharm, and Ph.D in Pharmaceutical Sciences. He has over 19 years of experience in managing Biopharmaceutical Studies and is associated with Raptim for more than 17 years. He is the pillar in developing the In Vitro service portfolio of Raptim.

Dr. Chirag Shah
Head, Clinical Operations

Dr. Chirag is M.Pharm,Ph.D (Clinical Pharmacology) with PGDPM. He has 25+ 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. Hardik Dave
VP, Clinic

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

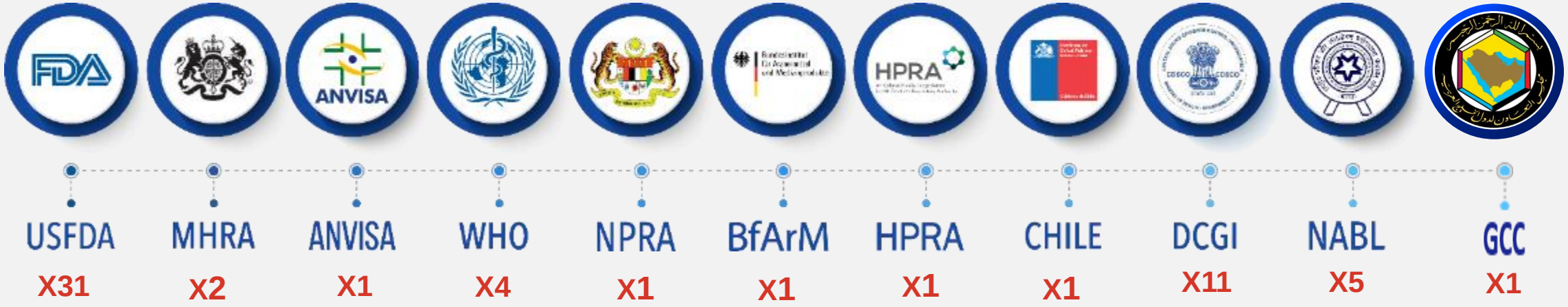
Mrs. Usha Ramakrishnan
Head, QA

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).

Mr. Kashinath Balapalli
AVP, Client Solutions & BD

Kashinath is a Graduate in Pharmaceuticals and Masters in Software Engineering. Has 22+ years of rich CRO leadership experience in client relations, innovative solutions & strategic consultation across Operations, OPEX, Business Development, Sales, and Marketing initiatives

Regulatory Inspections



USFDA inspection Scope

- Clinical and Analytical BE studies
- Patient BE Studies
- Late Phase Trials (Phase I to IV)
- IVRT / IVPT Studies
- In-vitro Binding Studies

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 sites through
- Inspection

Audits Support

- Investigational Sites Audit
- Inspection Readiness Audits
- In-house Audit
- System Audit

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
- Patient PK studies
- Phase II- IV Trials
- Clinical End Point (CEP) / 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 StudiesSkin Adhesion Assay and Vasoconstriction Assay
- BCS Bio Waiver Studies
- In Vitro Feeding Tube Studies

Early Phase Capabilities

- Spread over more than 50,000 sq.ft.
- **390 Beds** in 9 Clinical Units with **~50000+** volunteers database.
  - **218 beds** in Mumbai, Maharashtra
  - **172 beds** in Gandhinagar, Gujarat (Citus)

  Negative pressure area designed for dosing of Inhalation products at Mumbai Facility.
- Separate housing for Male and Female subjects
- Capability to manage multiple studies at a time.
- Well Equipped Emergency Care Units (ECUs)

Bioanalytical Capabilities

48 LC MS/MS	10 HPLC	1 ICP OES	2 ICP MS

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

- 375+ Validated Methods (fg/ml level)
- Developed Sensitive and Complex Methods
- 250+ Well-Trained and Experienced Scientists
- Laboratory Information Management System (LIMS)
- Deep Freezers (-20°C and -70°C) and walk in cold rooms.
- GLP Compliant Lab

Analytical / BABE Expertise

Key Highlights

- Experience in 2500+ Analytical studies
- Capacity to analyse 1.2 million samples / year
- Quick turnaround time for analysis
- Electronic platform for Data Review
- LLOQ up to fg/ml
- Chiral analysis
- Simultaneous analysis of more than 1 analyte
- Metabolite Impact study
- Liposomal drug analyses
- Complex products handling like Vitamins, Hormones and Peptides
- Elemental Analysis from plasma samples

Complex products

- **Inhalation Products:** Salmeterol+ Fluticasone, Budesonide, Salbutamol
- **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, Lidocaine, Estradiol, Fentanyl and Oxybutynin
- **Vitamins**: Phytonodione, Calcitriol, Ergocalciferol
- **Injectables**: Propofol, Fulvestrant Tigecycline, Amphotericin B, Methyl Prednisolone, Cetrorelix

Complex products

- **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, Inserts, etc.
- **Inhalers** – MDI
- **Nasal Sprays**
- **Suppositories**

In-Vitro (IVRT And IVPT) Studies

Raptim Research, a leader in In-Vitro Release Test (IVRT) and In-Vitro Permeation Test (IVPT) studies, analytical method development, provides complete topical product development services utilizing in-vitro/in vivo penetration models and other scientific tools.

Raptim Provide different types of In-vitro services to demonstrate Bioequivalence

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

- 11+ fully automated Franz diffusion cells system with 288+ cells from Logan and Hanson - **LARGEST IN ASIA**
- In-vitro test with Human Cadaver skin and other types of synthetic membranes

In-Vitro Binding Studies

- To compare the extent and rate of binding affinity between Test and Reference formulations where assay should be performed with Min. 12 replicates at various pH conditions
- Equilibrium Binding studies with and without Acid Pre-treatment
- Developed in-vitro nail permeation technique for anti-onychomycosis drugs

In-Vitro Feeding Tube Studies

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

BCS Bio-waiver Studies

- Established Caco-2 permeability method using 20 model drugs

Service Portfolio for Biologics & Biosimilars

Early Phase Capabilities

Pre-Clinical Comparability	Clinical Comparability	Manufacturing & Marketing
Bio-analytical services • Pharmacokinetics • Immunogenicity • Pharmacodynamics	Phase I ,Phase II and III • Pharmacokinetics • Immunogenicity • Pharmacodynamics	• Post- marketing surveillance • Immunogenicity

Few Examples

Monoclonal antibodies
- Pertuzumab
- Pembrolizumab
- Tocilizumab

Hormones
- hCG
- EPO
- hGH

Complex generics
- Heparin
- LMWH

Clinical Trials Business Unit: 50+* experts and Growing

Collective Experience

270+ Clinical Trials across 14+ Therapeutic Areas

Leadership Team

25+ years in Drug Discovery and Global Clinical Trials (I-IV)

Head Clinical Trials

19+ years of Clinical Trials and team management experience

Late Phase Capabilities

- **Project Manager (5):** 12+ years of experience in Clinical Trials and 6+ years of exclusively as Project Managers
- **Clinical Team Leads (1):** Experience of 9+ years in Team Management
- **CRAs/Sr CRAs (14):** Experience of 3+ years in Site Monitoring, Site Management
- **Medical Team/ Feasibility Team (3):** M.D. with 20+ years in Clinical Research
- **In-house CRA/CTAs (3)**
- **Medical Writing(2):** PhD with more than 15 years of experience
- **QA – CT (5)**
- **Data Management:** 10+ Team members with experience ranging from 2-16 Years
- **Biostatistics:** 5+ Team members including Programmers 3-25 Years

*: Clinical Trial Team Only
We have our strategic vendor partners in Data Management with a team of 12+ resources and PV partner with 50+ resources, including whom, our team strength to support Late phase trials crosses 100

Clinical Trial Services: Flexible partnership models to choose from

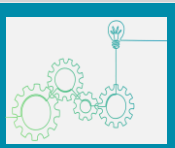
Clinical Trial Operations	Medical Monitoring	Regulatory	PV Operations	Clinical Data Management	Biostatistics, Statistical Programming & Clinical Data Standardization	Medical Writing
• Clinical Program Management • Feasibility, Site Selection and Activation • Patient Recruitment • Site Management and Clinical Monitoring • RBM, CM / RM and adaptive monitoring	• Consulting • Therapeutic area expertise • Medical Monitoring • Trend Analysis • Eligibility / Deviations • Data Review	• Regulatory Submissions and approval • Dossier Compilation and Publishing	**PV, DM and Biostats as FSP models** • ICSR Receipt • Case Processing • Medical Safety • Medical Review • EU QPPV • Local QPPV for EU and GCC • MICC	• **Database Design** - **Oomnia® EDC,** INFORM, RAVE, Medrio, OpenClinica • **Data Co-ordination** - Data Cleaning & Query Resolution - Medical Coding - SAE Reconciliation	• **Biostatistics** - Creation of SAP - Sample Size Calculation, Randomization • **Statistical Programming** - Generation of TLFs, Interim Analysis, DMC, IB • **Clinical Data Standardization (SDTM, ADaM)** - Data Conversion Services - Generation of Define.xml	• Protocol, ICF, IB, CSR,s • Periodic Safety Reports • Manuscript & Publication support • Patient Safety Narratives • Literature search

BA / BE studies, BE PK and BE CE Studies, Biosimilars, Non Interventional Studies

Expertise across 14+ Therapy Areas, Global operations and 'Critical to Quality' and Safety across all functions

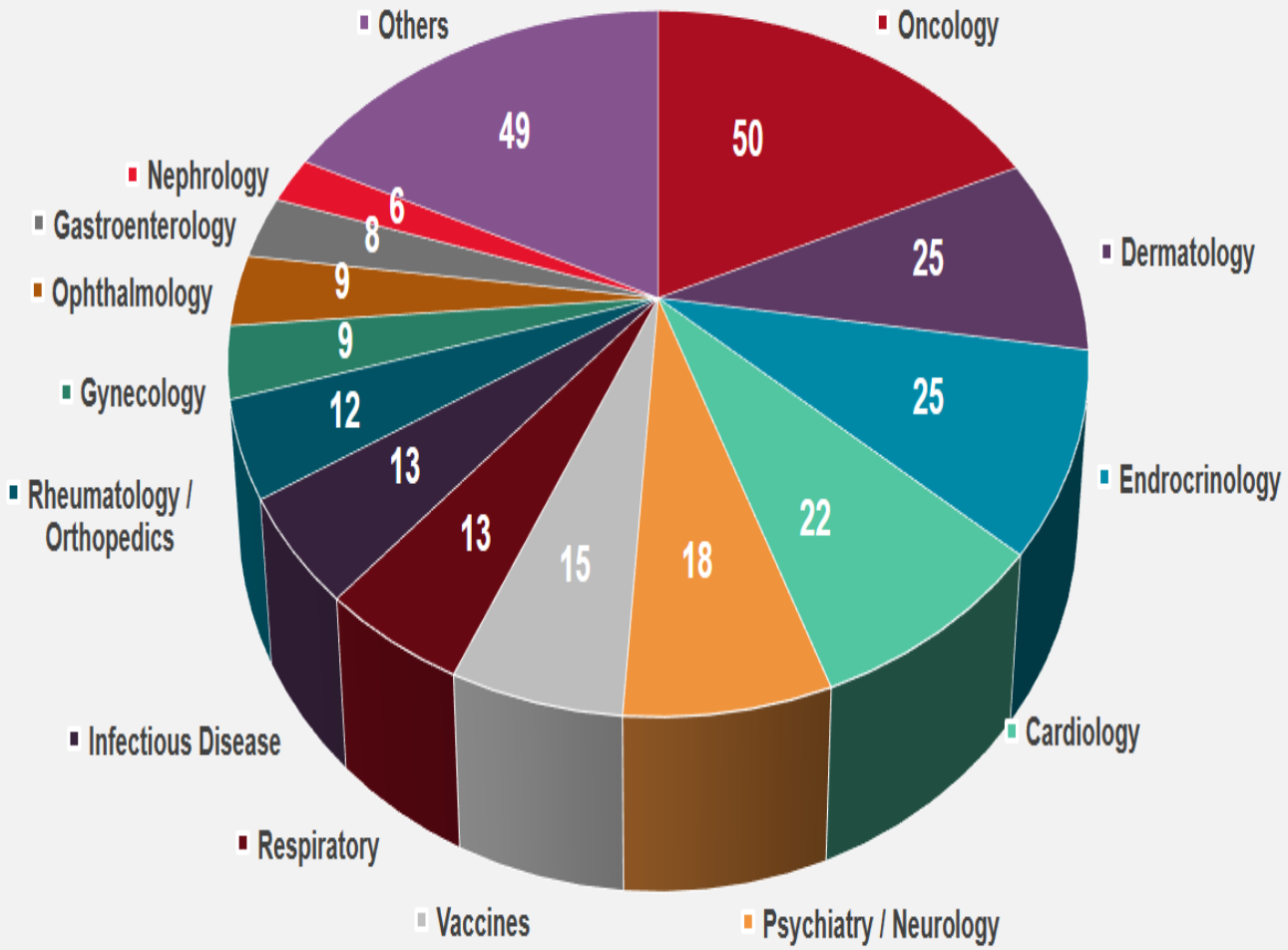
Proprietary Tech tools / Integration (rSDV + EDC) for "real time" data visibility, analytics and outcomes-based models

Versatile / Plug & Play Tech Infrastructure: CTMS  **rSDV**  **EDC**  **eTMF** 

IWRS  **ePRO** 

Global Trials	Globally Harmonized	Run Better	Run Different
New Markets / Products / TAs, Adaptive Design / Virtual Trials	Processes, Technology and People	Optimized Operations – Productivity, Quality and Cost	Realize benchmark outcomes - Cycle Time, Quality, Compliance

Rich Clinical Trials Experience: 270+ Trials, 14+ TAs and Growing…



*Others: Clinical Trials on * Mutation, Otolaryngology & Vaccines Studies*

Completed 24+ Clinical Trials for Major Regulatory Authorities

Rich and Deep Experience across 15+ Therapeutic Areas

Recruited ~15000+ Patients

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

Clinical Trials Status: Ongoing Trials

Study Name	Indication	Type of Study	No. of Patients/Sites	Study Stage	Scope Of Work
Sunitinib	Advanced RCC	Patient based PK	15/6	Study Closed	End to End
Pazopanib	Advanced RCC	Patient based PK	56/15	Site closeout done	End to End
Nitazoxanide	Diarrhea by Giardia Lamblia	Clinical Endpoint	390/15	Study Closed	End to End
Cephalexin	URTI & SSTI	Phase- IV	230/06	CSR finalized	End to End
Foracort	COPD	Observational Study	250/20	Study Closed	End to End
Bosentan	PAH	PMS	150/06	Recruitment completed	End to End
Tofacitinib	Atopic dermatitis	Phase III	184/14	MA is received	End to End
Clozapine	Schizophrenia	Patient based PK	48/06	Study Closed	End to End

Few Studies Currently being executed

Study Name	Indication	Type of Study	No. of Patients/Sites	Study Stage	Scope Of Work
Flora-6 (Oregovomab)	Ovarian Cancer	Phase- II	88/14	Recruitment Completed	End to End
Adalimumab	Ankylosing spondylitis (AS)	Phase IV	200/8	Recruitment Completed	End to End
Olaparib	Ovarian Cancer/Breast Cancer	Patient based PK	24/6 (Pivotal study will be followed after this	Recruitment Completed	End to End
Biosimilar	Systemic Lupous Eryhtomus	Phase III	200/08	Recruitment	End to End
NCE Phase II	Prostate Cancer	Phase II	40/15	Regulatory Submission	End to End
Novel Formulation (500 (b)2	Atopic Dermatitis	Phase II a	12/2	Completed	End to End
VG	COPD	Phase IV	200/5	Completed	End to End
VGF	Asthma	Phase IV	200/5	Completed	End to End

Our Clinical Data Services Offers Flexible Engagement Models that can be Delivered Globally

Clinical Data Management

Database Design
Oomnia® EDC, InForm, Rave, Medrio, OCRDC, e-case link DSG

Data Coordination
Document Creation | eCRF Testing
Edit Check Testing

Data Coordination
- Data Entry / Quality Control
- Discrepancy Management
- Medical Coding
- External Reconciliation

Data Coordination
- Data Base Lock Support
- Data Base Archival

Biostatistics & Statistical Programming

- Biostatistical consulting
- Sample size calculations
- Generate randomization schedules
- Creation of SAP

- ADaM Dataset – Specifications, Creation, Validation
- TLFs – Creation, Validation
- SAP – Creation
- PK/PD Analysis

- Unblinding randomization codes
- ADaM Datasets – Creation, Validation
- TLFs – Creation, Validation
- Creation of SAP • PK/PD Analysis

Clinical Data Standardization

SDTM
- Conversion
- Generation of Define.XML

ADaM
- Conversion
- Generation of Define.XML

Medical Writing

Quality by Design (QbD) approach to provide all clinical trial documentation for successful regulatory submissions

- CSR, Clinical Summary and Clinical overview documents for eCTD submissions leveraging client preferred Reg platform
- Manuscript and Publication Support

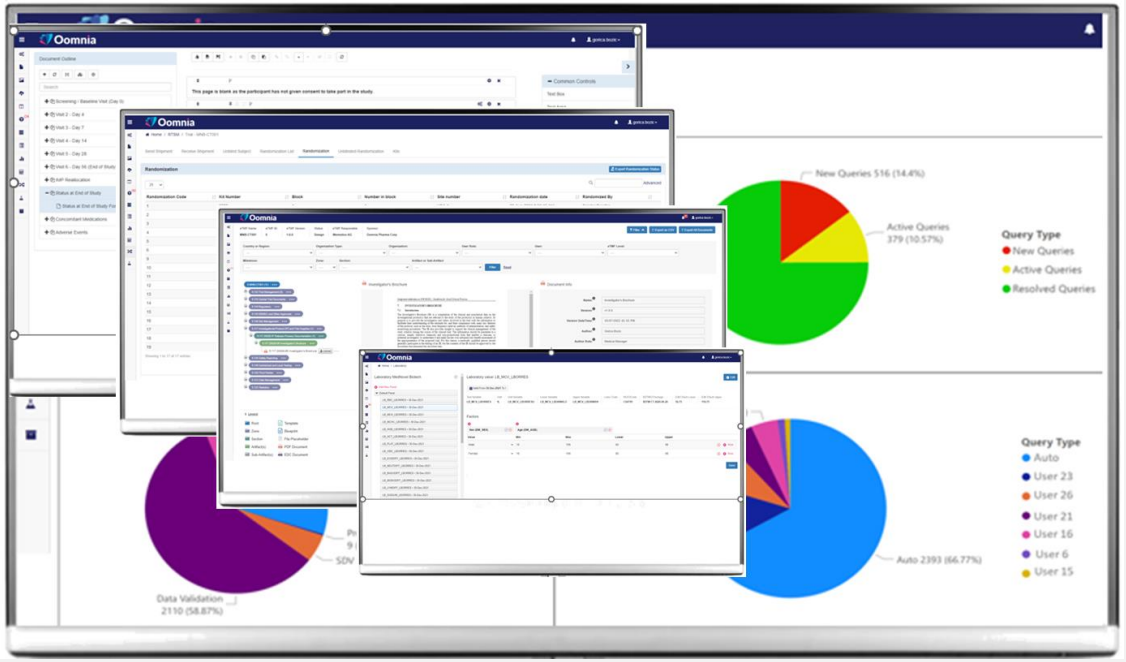
- Patient Safety Narratives
- Web Synopsis
- Literature search submissions

Study Start-up **Study Conduct** **Study Start-up**

Data Management Service Portfolio: Oomnia EDC

E2E Clinical Data Management | **Database Set-up and EDC support** | **Discrepancy Management** | **Medical Coding using MedDRA and WHODrug** | **Data Entry- Excel / Software**

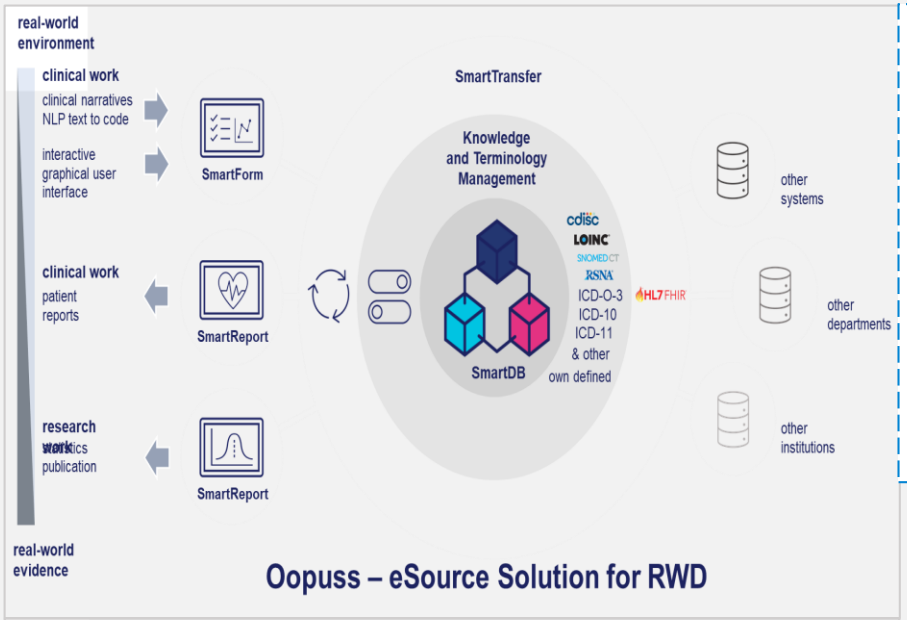
Enter data once. Create templates. Monitor across clinical trials. One system for all your work



- No vendor lock-Data exportable in any format at any time
- Very competitive pricing per Oomnia module
- Cloud-based solution (MS Azure) with server location per client's choice

- **Your information at fingertips:**
- Real time analysis-ready clinical data through out the trial period
- Integrated / mapped with CDISC, MedDRA and WHODD
- Built in Thesaurus incl. LOINC, SNOMED CT, RSNA, ICD-O-3, ICD 10
- Proven high quality of 99.99% of final data sets that is further reusable.
- Highly efficient Real Time Query Management by button click
- Own templates library for future studies, including Complex checks, dependencies & email notifications with Drag & Drop functionalities
- Quick & Easy set up / fully adjustable CTMS tools per clients/studies
- Manage multiple documents separately like SAE, Protocol deviation
- Fully Integrated with RTSM, eConsent, ePRO, and Local lab modules
- ePRO and e-Consent configurable per patient's language/all languages
- eTMF
- Audit trail in UTC- Need for global/multinational trials/sites
- Users audit log and 2FA for secure user management

Proprietary RWE Tool: High Quality, Quicker and Lower Cost

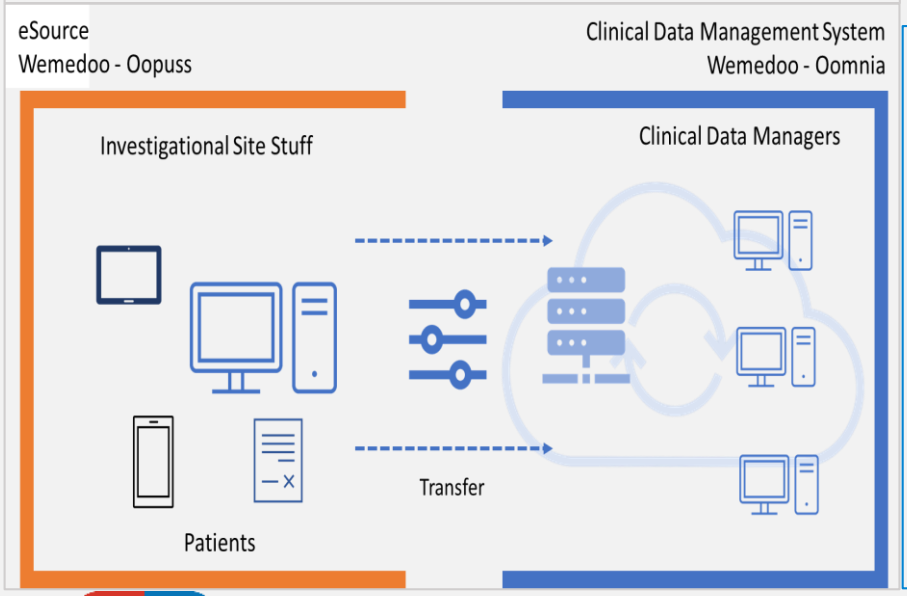


Oopus eSource

- Forms. layout, features, & usability are similar in Oopus & Oomnia EDC (CRFs)
  - Additional fields can be added for investigator's notes
- Investigators **enter the data directly** onto the Oopus forms
- Save and lock the document after entry
- Maintain patient profile
- **Site-wise deployment** of forms

Oomnia EDC

- Oopus data fields **sync** with corresponding Oomnia EDC data fields
- Data dropped on Oomnia EDC fields with in-built **interconnect functionality**



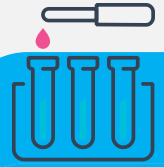
Key Benefits

- Easy deployment at multiple sites and Easy accessibility to sites staff
- **Reduces time, effort and maintain the data integrity**
- **No** data entry/SDV required on sync fields/ pages→ **~60-70%** reduced efforts
- **Eliminates** transcription error and its queries → Saves time and efforts → Cost
- **Real-time data management, reduces queries, higher quality data, Lower cost**
- Can select the fields for sync and fields for manual entry
- Allow query management on dropped data
- **Faster database lock**
- Cost-effective, highly compliant and efficient
- Collection and transfer of data in electronic format from external vendors (e.g.: laboratory results, imaging, ECG, randomization, drug accountability)

Biostatistics and Programming Services

Study Start-Up

- Randomization
- (e)CRF Review
- SAP
- TLF - Mockshells



Study Conduct

- Dataset Specifications Documents
- Extract SAS datasets
- Programming for Analysis Data sets
- Programming for Reports (TFL)
- Validation (Datasets, TFL)
- Draft Run
- Stat Review
- Client Review

Locked Database

Study Closure

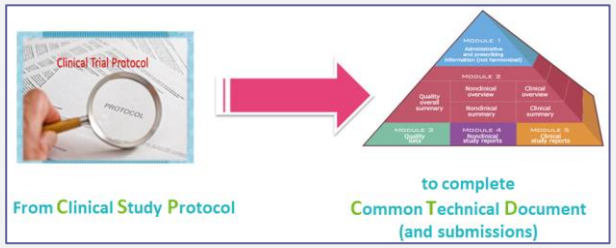
- Top line Reports
- Statistical Reports(TLFs)/SAR for CSR
- Final Review
- Ad-hoc analysis

Client Activities | Raptim Activities

Medical Writing Services

Clinical / Safety Writing

- Clinical Study Outline - RACT
- Clinical Study Protocol (QbD)
- Synopsis and Amendments
- Patient Information Sheet
- Informed Consent Form and Patient Brochure
- Investigator's Brochure
- Investigator review materials
- CRF Out Flow
- Inputs SAP/Monitoring Manual
- Clinical Study Report (CSR)
- CSR synopsis for public disclosure
- Patient Narratives, Appendices, Publishing, Basic results, Lay summaries, Redaction



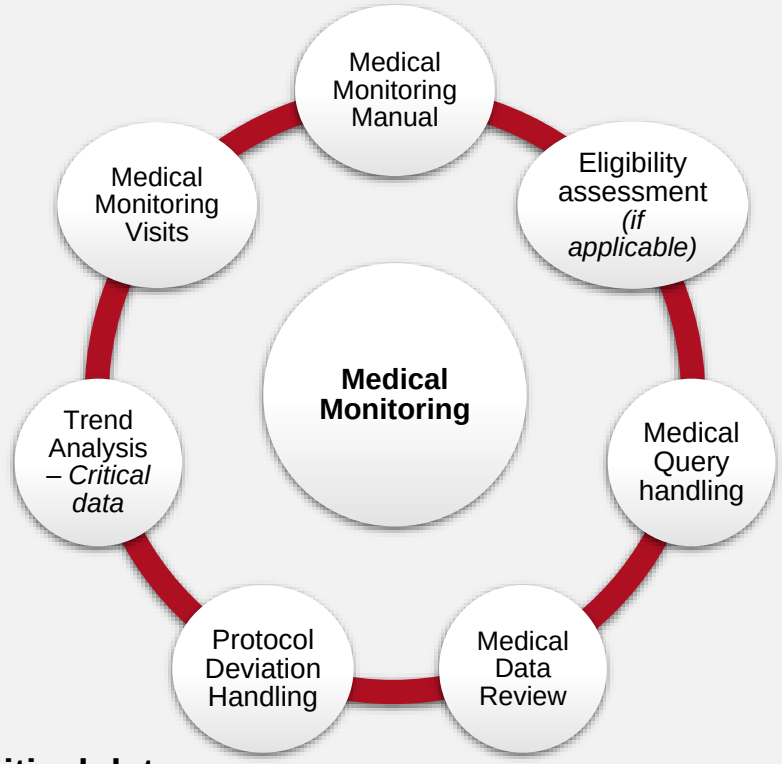
Technical / Reg Writing

- CTD Summary Module 2, 3, 4, 5 and M2 summaries
- M2 Summaries: 2.3/4/5/6, 2.7.3 and 2.7.4
- Compile and Submit eCTD
- Literature Based Submission
- Safety narratives
- Aggregate Reports
- RMP / REMS
- Web Synopsis
- CERs and CEPs, IFUs, CE Mark
- Integrated Summaries of Safety & Efficacy (ISS / ISE)
- CPSR, Toxicology Reports
- COs, NCOs, etc.

Scientific / Publications

- Manuscripts
- Abstracts
- Articles
- Posters
- Research Articles
- Review Articles
- Posters / Publications writing
- Therapeutic Expert Reports
- Expert Summary Reports
- Medical Rationale Reports
- MOM support
- KOL Support
- Web Synopsis
- Web / Social Media content
- Ad hoc writing services

Medical Monitoring Services



Activities before trial initiation

- Familiarization on protocol
- Review of trial documents (CRF, SAP, feasibility)
- Preparation of Medical Lead Plan (MLP)
- Project Team Training (Medical / Therapeutic Area)
- Preparation of MLP Study related documents

Activities during trial conduct

- Medical Advice/ oversight
- Medical Query handling (Project team and Site)
- Protocol Deviation Handling
- Medical Data Review
- Medical Monitoring Meeting
- Medical report

Activities at end of study

- ML reviews the Statistical Analysis Report (SAR)
- CSR review before finalisation

Critical data

- Safety data – Compliance, missing data, outliers, Vitals/Physical Examination, Lab Data, Injection site, AEs/ADRs/SAE/ protocol significant, prohibited concomitant medications etc.
- Efficacy – Compliance, missing data, outliers
- Protocol Deviation analysis – Major/Minor.
- Potential patients/Screen Failure analysis
- Discontinuation/Withdrawals analysis

- **Trend Analysis across,**
- Study Level
- Site Level
- Subject Level

Raptim USPs for your studies success

- **Full Service CRO**
- **Experienced Team**
- **Proactive and Flexible**

Carving a niche in the Industry

Rich Experience / Network in multiple Therapy Areas

Global Coverage with Extensive Pan Asia Network

Central EC I Local Resources I Simple CRF design I rSDV & eDC I Proprietary RWE tool (eSource Linkage)

Excellent team of managers pool ready to kick start your studies

Flawless remote monitoring plan for efficiency and cost optimization

End to End Support from Protocol to CSR + Reg support

Proactive and Transparent Governance for timely steering of progress to success

Q & A? Next Steps…

Thank you

Join Hands With Us!

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