PharmaDocs

Clinical Research Ayurveda

Introduction and Service Offering

www.PharmaDocs.in/ClinicalResearch

Agenda Layout

1. Introduction and Service Offering
2. Resources & Capabilities
3. Operations
4. Clinical Data Management with BioStatistics & Programming
5. A Strategic Partner

PharmaDocs Clinical Services

Ancient Science Modern Aspects

Welcome!!

Company Profile

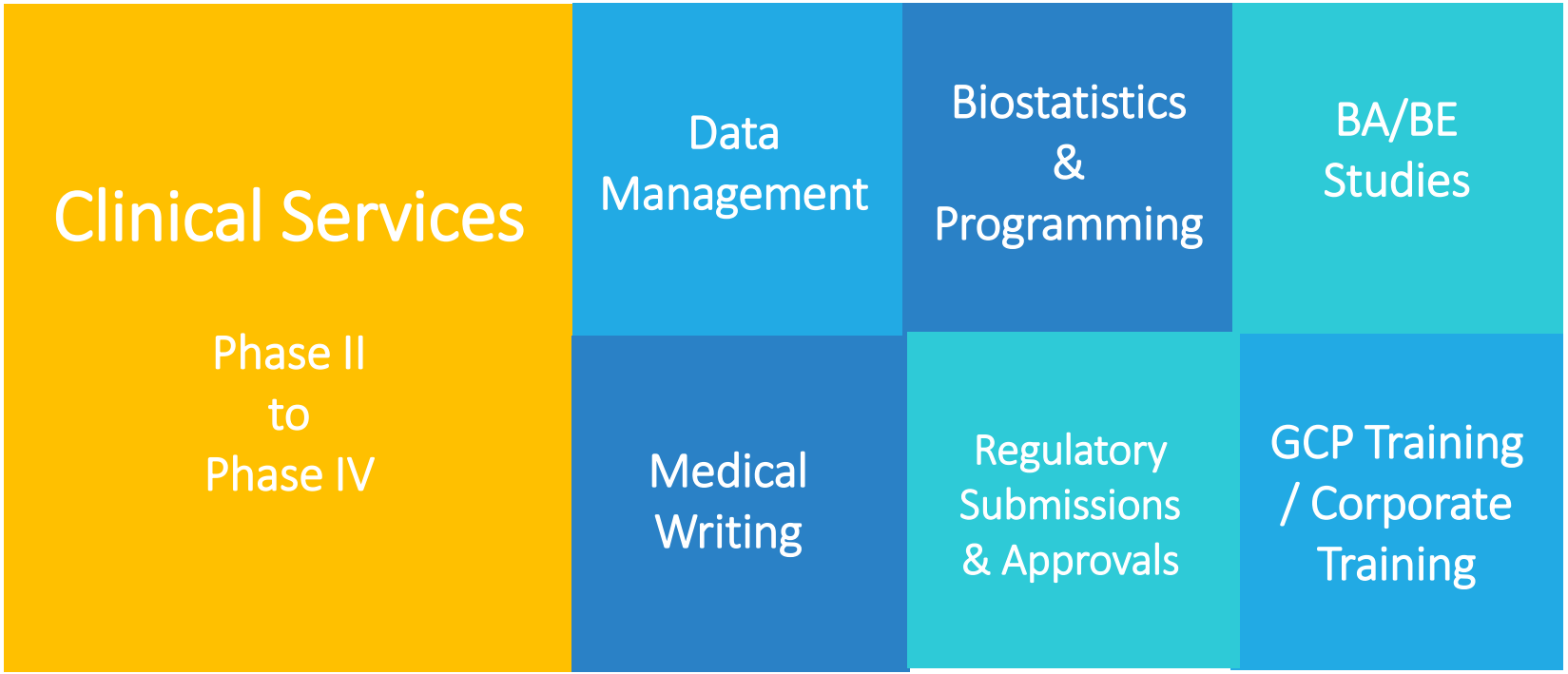
PharmaDocs, is a complete regulatory management company, established in 2017, headquartered in Ahmedabad (INDIA)

With our new vertical of Clinical Research Management, We provide comprehensive Clinical Trial Management, Data Management, and related Clinical Services covering the major therapeutic areas.

Managed by a large team of GCP trained clinical Research professionals with a rich experience of organizing clinical trials for India and Global Pharmaceutical companies and CROs.

We are one of the few companies in India with end to end capabilities in clinical Trials Management esp in Ayurveda & Cosmetic.

Our Services



Clinical Trial Management Services

Clinical Trial Operation

- Clinical Trial Monitoring –BABE and Late Phase
- Site auditing of BA/BE, patient PK studies & late phase clinical trials
- Auditing study document
- Bioanalytical Monitoring
- 3rd party vendors audits (including Clinical laboratories, CROs, Drug depots, Phase I Units, BA/BE units, Translators and ECs)
- For cause audits (including root cause analysis and Corrective and Preventive actions (CAPA) program), Process audits
- Management of audit programs
- Medical Monitoring
- Preparing the sites for Pre-inspection audits

Resources & Capacity

- 20 Bedded Multispecialty Hospital
- 4 bedded fully equipped ICU
- Round the clock staff available
- In house Ambulance available
- In house Pharmacy
- Institutional Ethics Committee
- Trained staff for conducting clinical trials
  Dedicated study coordinators
- Archival area
- IMP dispensing area
- Separate Conference room
  20 deep freezer
  2-8 degree refrigerator
  Centrifuge
  All other required equipment's needed for the conduct of the clinical trials and all equipment are calibrated.
- Specialty doctor for conducting indication specific trials like Ayurveda, oncology, dermatology

Site Introduction

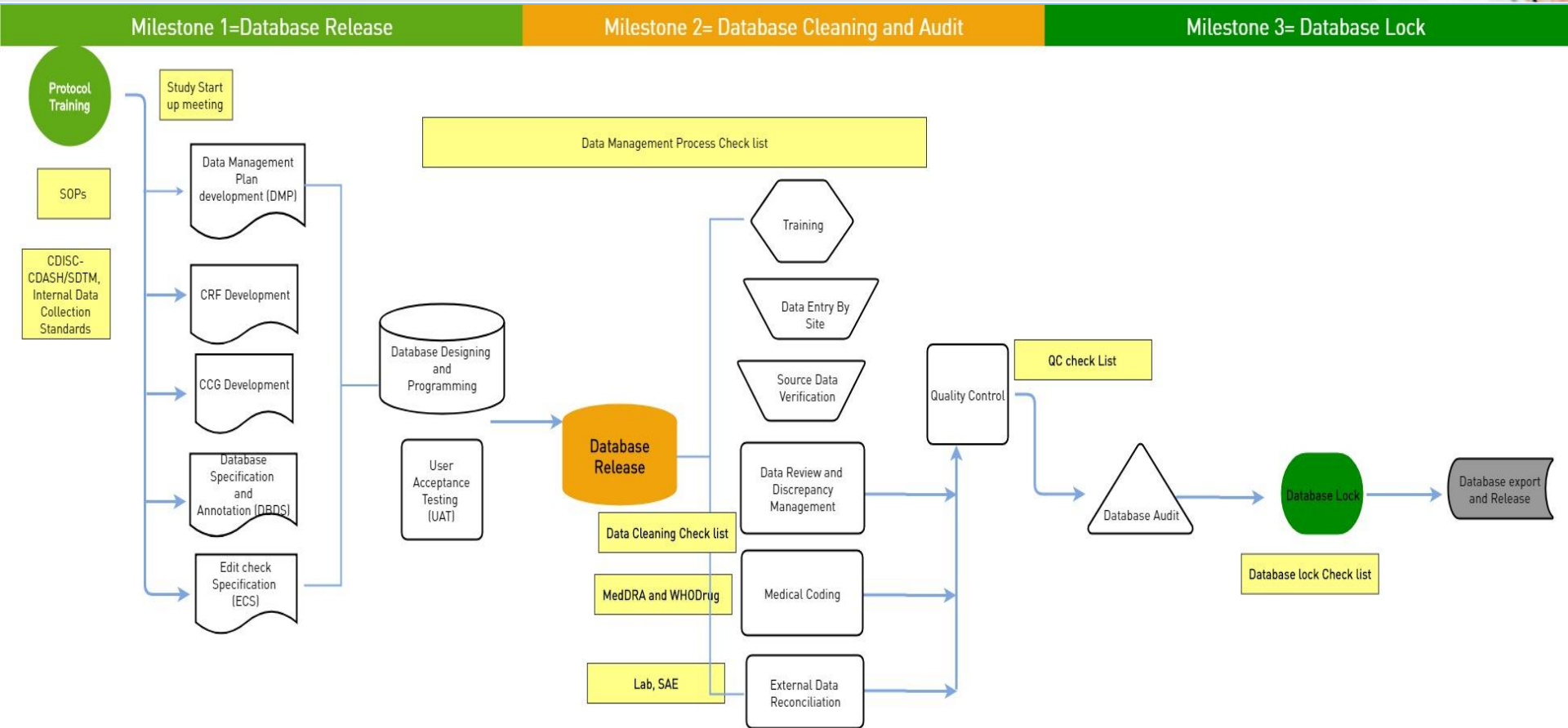
- Our Hospital is located in heart of the city i.e. satellite area and hospital is fully equipped with all the facilities like TMT, 2D ECHO, ECG facility, Blood Collection center, Consultation rooms, Administ rative area, ample waiting area, in house pharmacy, NICU, ICU, Special rooms, Deluxe rooms , Pantry area, Institutional Ethics Committee.
- Round the clock staff
- 4 Bedded ICU facility and all ICU are fully equipped with facility like Ventilators, Multi para monitors, Defibrillator, Pulse Oxymeter, Central oxygen line, Central Compressor, Nebuliser, Infusion Pumps, Syringe Pumps, Portable 2D ECHO, ECG Machines.
- 24*7 Trained, experienced medical, para medical staff, Medical Officers, round the clock MD Physician, MD Paediatric and other doctors are available.
- Have In house ambulance with 24*7 driver facility and Ambulance is having the entire basic requirement like oxygen, Ambu bag, emergency medicines, cardiac medicine kit etc.
- Site is having DCGI and OHRP registered Institutional Ethics Committee for review and approval of Phase-I, BA/BE, Phase-II to Phase-IV, Epidemiology studies, Academic Studies etc.

Clinical Data Management

Clinical Data Management Activities

- Clinical Data Management Plan
- Case Report Form Development (pCRF/ eCRF)
- CRF Completion Guideline development
- CDISC-CDASH/ SDTM Compliant Database Designing
- Edit Check preparation and Implementation
- User Acceptance Testing (UAT)
- Data Entry
- Discrepancy Management and Data Cleaning
- Self-Evident Corrections
- Protocol Deviation identification and Handling
- Medical Coding –MedDRA, WHO Drug
- External Data Reconciliation –Lab, SAE etc.
- Trend Analysis and Preventive Actions
- Quality Control on each data handling steps-Driven through QC checklist
- Quality Assurance Audit
- Study Progress report and metrics
- Database Lock

Clincal Data Management



Biostatistics and Programming

Statistical Services

- Statistical Analysis Plan (SAP) development
- Statistical Analysis
- Statistical Programming and mock shells development
- Input on Study Design and sample size calculation
- Development and review of Tables, Listings, Graphs (TLGs)
- Statistical Report and input on Clinical Study Report (CSR)
- Interim analysis and support to Data and Safety Monitoring Boards (DSMBs)
- Ad-hoc programming for support of Statistics, Clinical Operations, Data Management and Regulatory functions
- Support Interim analysis, Data Monitoring Committee meetings, Database lock related activities and regulatory submissions activities

Medical Writing

- Study Protocol
- Clinical Study Reports
- Standard Operating Procedures (SOPs)
- Literature reviews
- Conference Materials
- Manuscripts
- Editorial support
- Product website content
- Journal/conference submission
- Educational material for patients, healthcare professionals and pharmaceutical industry personnel
- Medical marketing reviews and reports
- Publication planning

Regulatory Submissions & Approvals

- Regulatory submissions for Clinical Trailsand follow ups
- Communication management with Authorities
- Post regulatory compliance
- Dossier Compilation as per Asean Common Technical Dossier (ACTD) Common Technical Dossier (CTD) Drug Master File
- Drafts Data BMR, MFR, Process Validation, Stability Study Reports
- Compilation of Periodic Safety Update Reports (PSUR)

Auditing and Compliance

GCP/GLP Compliant Audits

- Understanding in details client expectation
- Sharing a detail scope of audit agenda
- Understanding the systems & capabilities of the Site/CRO for qualification
- Bio-analytical, Immunogenicity & Clinical Lab identification & qualification
- Cross confirmation of the systems as per the applicable regulatory norms
- Going in depth reviewing the documents for any nonconformity
- Providing feedback to our clients in form of detail reports
- Guiding our clients with solutions in order to overcome any issues observed as part of the audit

Pharmacovigilance

- Narrative Writing of Case Report and safety Monitoring visits
- Verification of Case Information and case lock
- Periodic, annual and aggregate report writing
- Patient data Management
- Ongoing data capture
- Capturing patient reported outcome
- Post marketing surveillance services

Site Management

Pre- Trial

- Identifying sites & PIs
- Preparation of Essentialdocuments
- Vendor service management
- Regulatory submission & approval.
- Obtain import/export licenses
- IEC / IRB submission & approval
- Create source document template
- Prepare site for SIV
- Pre-screening, in case of chronic disease trial

During the trial

- Assist in the ICF process, screening & enrollment
- Coordinate subject for follow up visits
- Manage drug accountability, distribution & logistics
- Coordinate Central Lab logistics & sample flow
- Coordinate Monitoring &Audit visits
- Subject reimbursements
- Maintain and update Trial Master File
- Coordinate SAE reporting on time

Post Trial

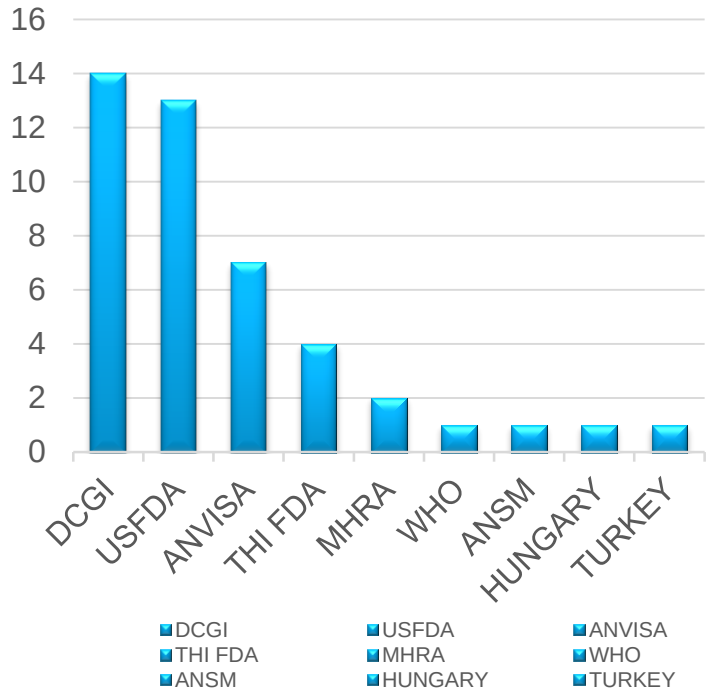
- Coordinate close out visit
- Resolve data queries
- Archival at site


STANDARD TIME ZONES OF THE WORLD
EXPERIENCE

Experience

Regulatory Inspection

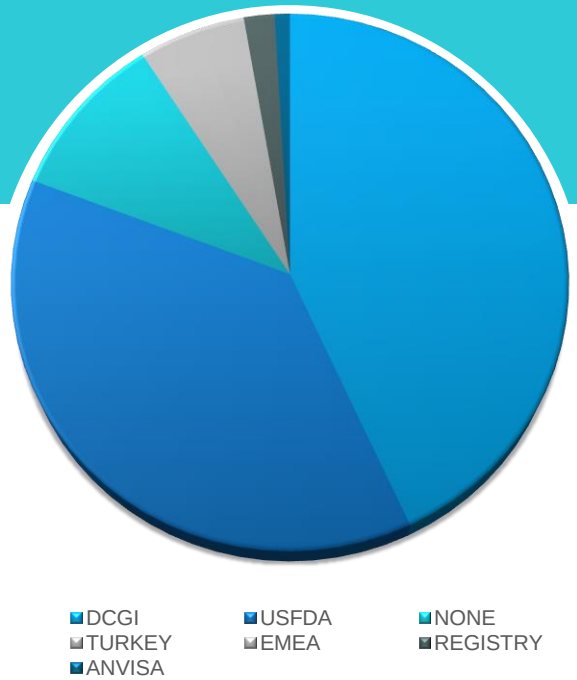
DCGI	14
USFDA	13
ANVISA	7
THI FDA	4
MHRA	2
WHO	1
ANSM	1
HUNGARY	1
TURKEY	1



Experience

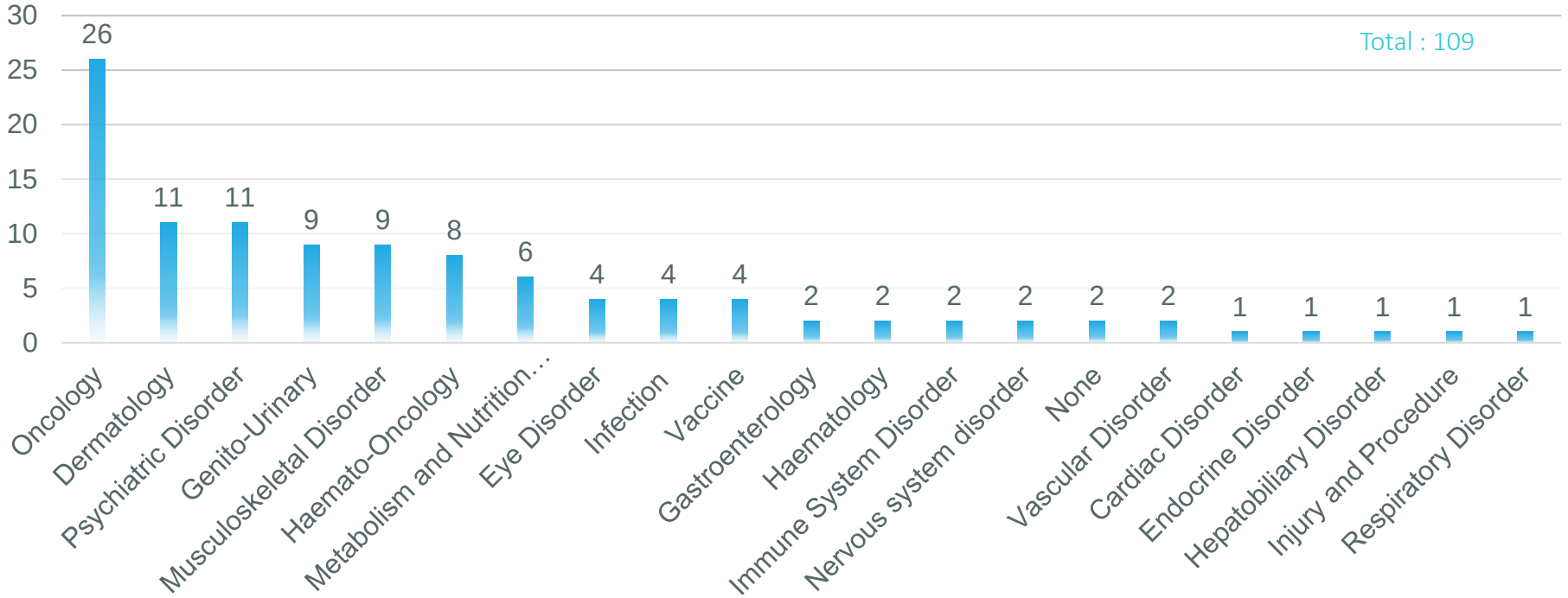
Regulatory Submission

DCGI	43
USFDA	41
NONE	11
TURKEY	4
EMEA	3
REGISTRY	2
ANVISA	1



Experience

Therapeutic Area



Advantage & Customer Benefits

Quality Research for better market acceptance

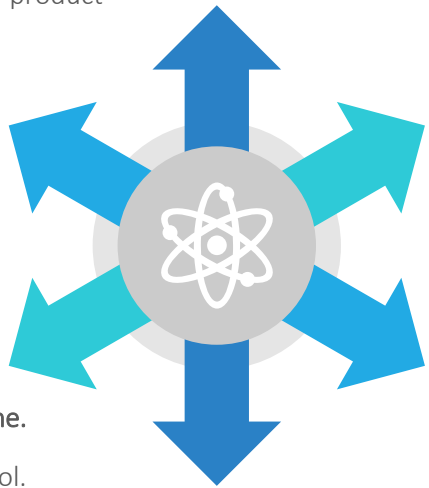
Clean and Consistent high quality data on-time
Endo to End service Provider for all your product

Independent Patient Database & Patient Recruitment System.

Successful Patient Enrollment Results
Effective Standard Operating Procedures

Unmatched quality, Effective Cost & reduced timeline.

Centralized Quality Control.



Rapid Budget and Contract Turnaround

Single Point For All Negotiations & Queries

State-of-the-art Facilities and Equipment

Full-time, Trained, and Experienced Staff
Qualified and Specialized Investigators

Consistent trial Conduction & Documentation

Ultimately to lead our clients to meet all their project timelines within time and within budget

PharmaDocs Management Services

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Thank you

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