Nutrition research @ JCDC

JCDC Overview

360+
clinical projects completed till date

Enrolled **~12,000**
subjects across 14 therapeutic areas

Working with **140+**
clients including **all** Top 10 pharma and several consumer healthcare, nutrition and medical device clients

ISO 9001-2008 Compliant

Inspected by US FDA twice – Zero 483s

IRB accredited by NABH

Awarded Best Research Centre by ISCR

Accredited by AAHRPP: Gold standard of accreditation for Research centers worldwide

 # 2 in India and
 # 7 in Asia to bag this prestigious accreditation

Full Service CRO Capabilities

Study Design and Reg Pathway

Operations Support

Data Management

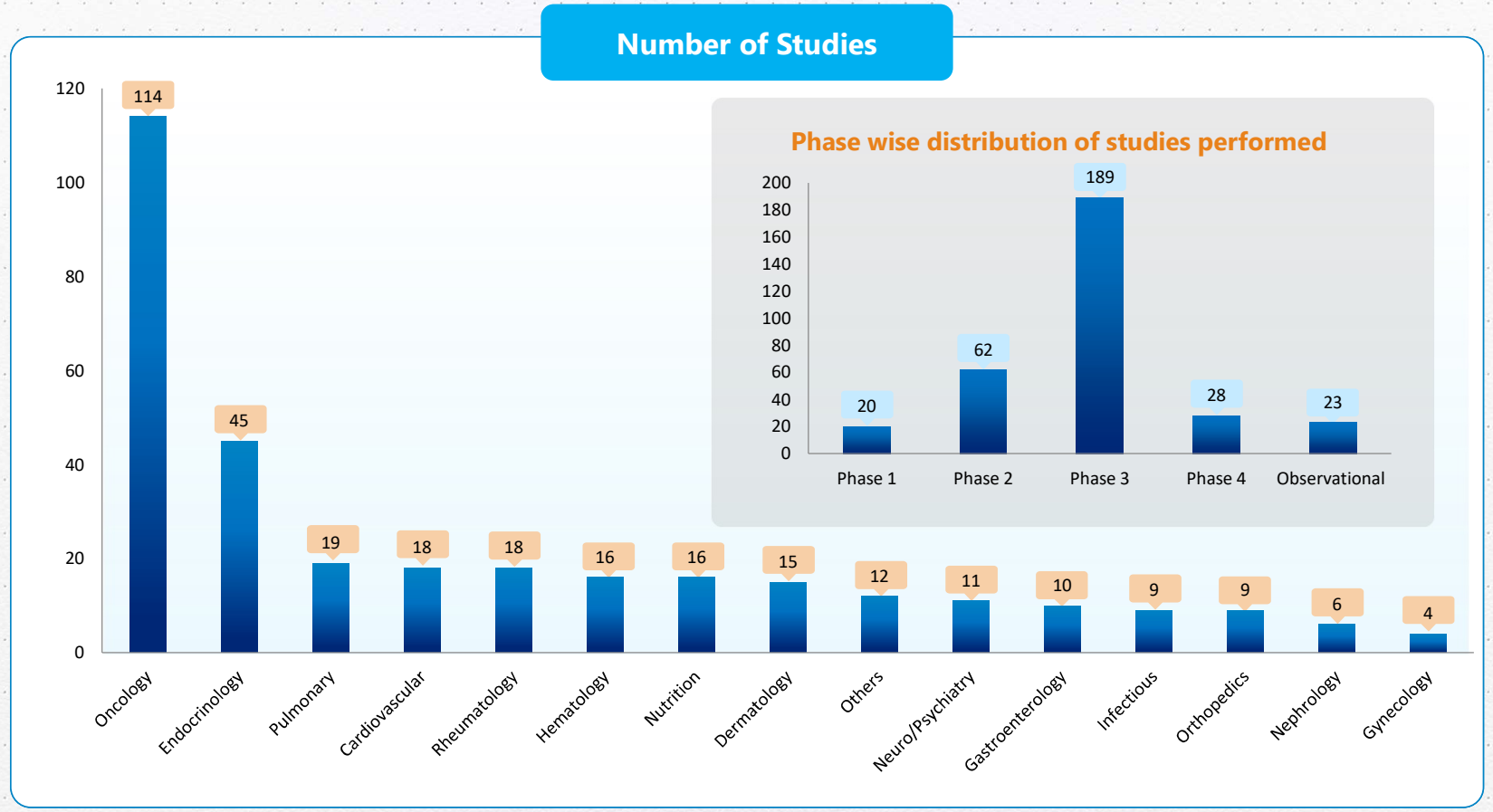
Statistical Analysis

Clinical Writing

Study Design	Operations Support	Data Management	Statistical Analysis	Clinical Writing
Study conceptualization	Site identification	Database design/ develop Data layout;	Statistical Analysis Plan (SAP)	Protocol
Regulatory Pathway Guidance	Subject identification	Data capture	Programming and data analysis	Informed Consent Form (ICF)
Study design, including Statistical design and sample size calculation	Negotiate site Contracts, IRB approvals	Data validation	Statistical study report	Study reports
Protocol synopsis	Site trainings and initiation	Deliver analysis-ready dataset		

JCDC CLINICAL PRECISION

Studies Completed



Customers

Pharma

Nutrition / Consumer

Medical Devices / Others

Medical Writing

Sr. No	Clinical and Regulatory Writing	Scientific Communications
1	ICH GCP compliant Clinical Study reports (CSR'S) and clinical study synopsis	Conference material (abstracts, Posters, Presentations and slide sets)
2	ICF's and CRF's (electronic and paper)	Manuscripts
3	Study protocols including investigator initiated trial protocols	Editorial support (Editing, rewriting, proof reding, ref checks, language corrections)
4	Clinical /non clinical summaries and overviews for domestic and international regulatory authorities	Journal / conference submission
5	Patients safety narratives	Educational material for patients, healthcare professionals and Pharmaceutical industry personnel
6	Patients information including informed consent and patient brochures	Literature reviews
7	Standard operating procedures (SOP'S)Covering all aspects of drug development including the design, conducts and reporting of clinical trials and the outsourcing of sponsor responsibilities to a CRO	Bio Statistical analysis plan in concurrence with well experienced biostatisticians
8	Patent drafting	Feasibility survey reports, disease demographics

70+

Protocols, CRFs/ & ICFs Developed

45+

Manuscripts written

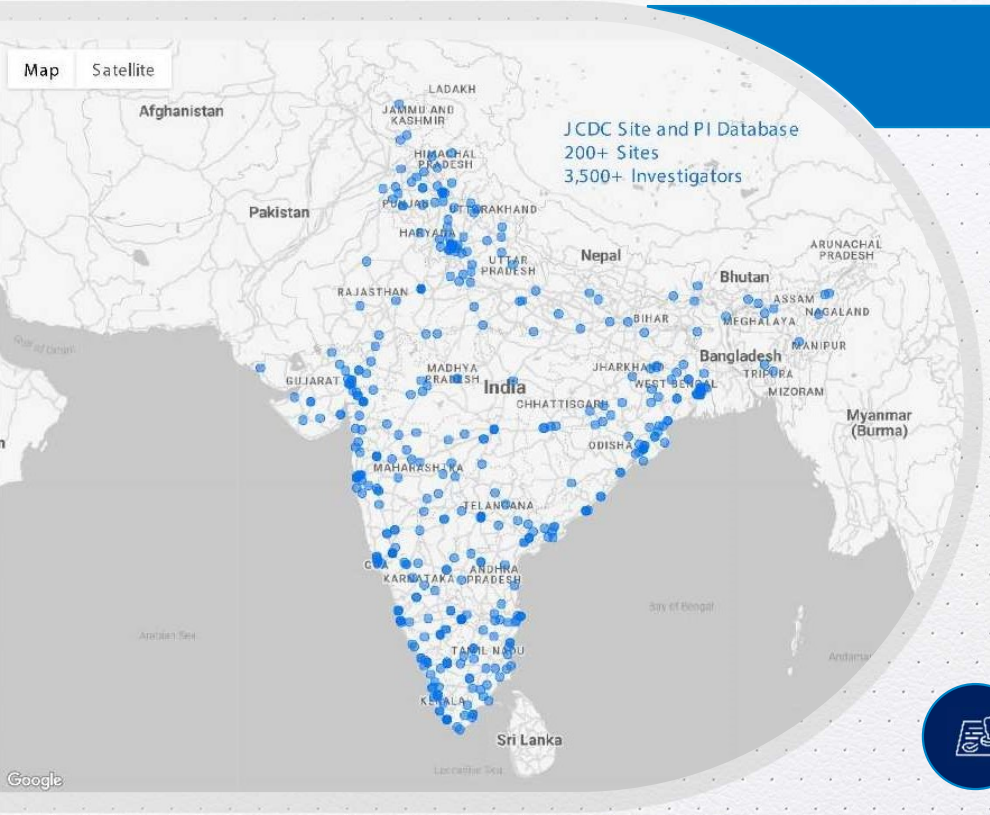
Medical Writing SLAs

Sr. No	Activity	Turnaround Time
1	Concept Note/ Protocol Synopsis	3-4 business days
2	Protocol	10-12 business days from approval of Synopsis
3	Case Record From	8 business days from approval of Protocol
4	Informed Consent From	4 business days from approval of Protocol

JCDC CLINICAL PRECISION

Site Selection process

TRIAL OPTIMA
(RE)SEARCH REDEFINED



Database of over 500+ sites and 3,500 investigators in India

Our database for each site covers **52 data points,** including the studies done in the past, Indication & Phase of study, infrastructure at site etc.

Our sites are **across India** and **cover all major therapeutic areas**

Once the study is kicked off, we identify the initial sites from our database and conduct **study-specific site feasibilities** to filter the top sites.

Site Qualification Visits are then done for the selected sites to arrive at the final sites for Sponsor approval

* In addition to our database of sites in India we also work with partners in the **USA, Europe and Asia for Global Studies**

JCDC CLINICAL PRECISION

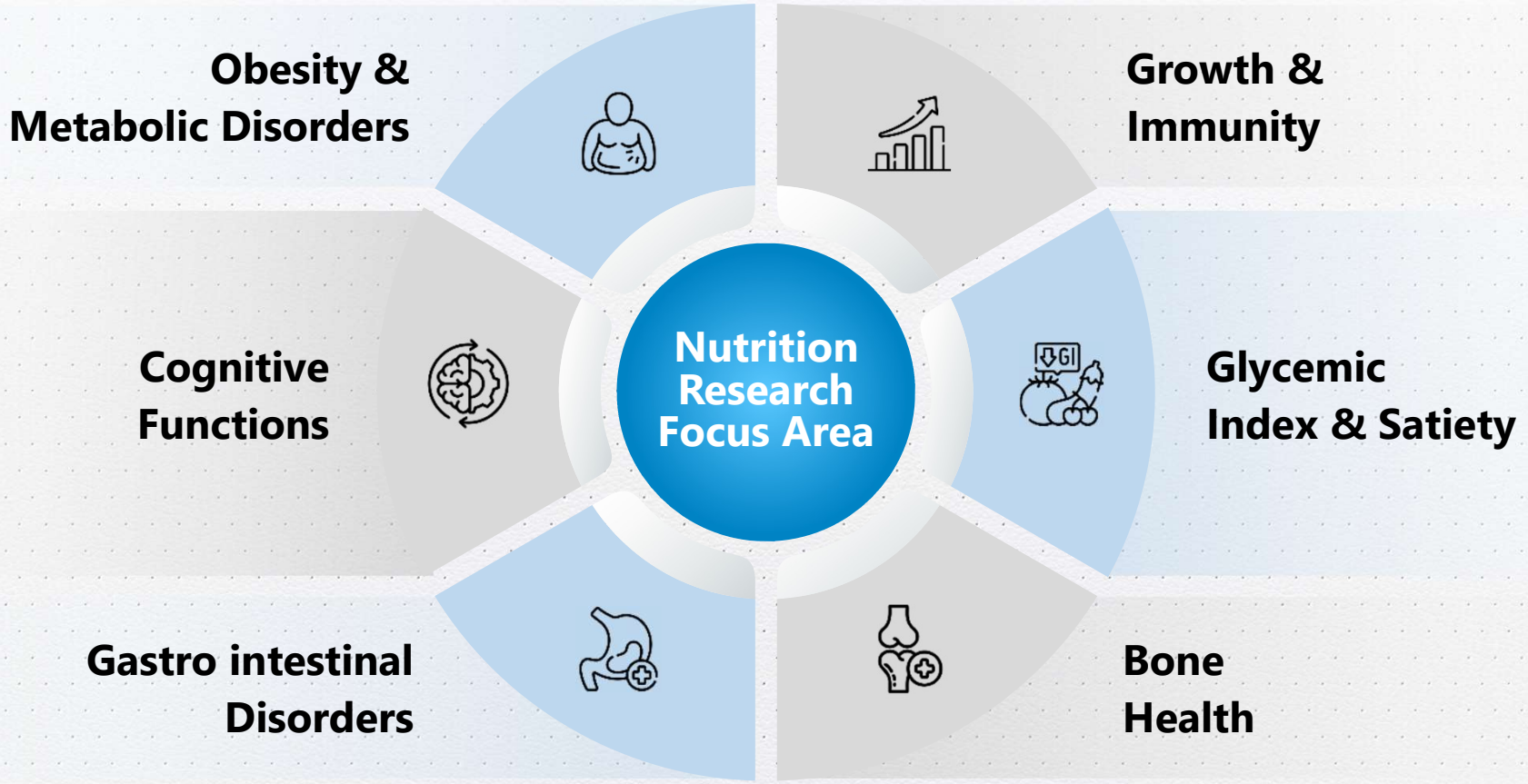
Nutrition Clinical Studies

JCDC provides end to end trial management for Nutritional products which includes product claims or Exploratory research

Our Experience is in a range of products that include

- Health drinks
- Sports drinks
- Dietary Supplements
- Probiotics
- Nutraceuticals
- Food Ingredients

Areas of Expertise



Studies done till date

Product	Patient Population	Study Objective
Carbohydrate Supplement	Healthy Volunteers	To calculate Glycemic Index
Dietary Fiber	Healthy Volunteers	Measure Blood Glucose Response & Satiety Response
Probiotic Tablets	Healthy Volunteers	To determine the effect of Partial Meal Replacement Product with added sugar on satiety ratings in overweight and obese subjects.

Immunity

Product	Patient Population	Study Objective
Fortified Malt based food	Children (~950 children screened)	To measure the impact of fortified malt based food on immunity outcomes in school children
Health Drink	Toddlers	To study the impact of Oral Nutritional Supplementation on growth in children

Studies done till date

Product	Patient Population	Study Objective
Beverage Powder	Children (~400 children screened)	To test the Impact of a beverage powder fortified with multiple micronutrients (MMN) on cognitive variables after 4 months of intervention.
Energy Drink	Healthy Adults	To evaluate the effectiveness of an energy drink on Mental alertness and Fatigue.

Product	Patient Population	Study Objective
Carbohydrate Drink	Developmental athletes of 12 to 15 years of age	To test the efficacy of a carbohydrate drink on speed, agility and power

Studies done till date

Product	Patient Population	Study Objective
Probiotic Formulation	Patients with Gastric Disorders (90 patients)	To evaluate the efficacy and safety of two probiotic formulations in subjects with functional intestinal gas symptoms
Dietary Fiber	GERD Patients	To determine the effect of a dietary fiber in patients with gastroesophageal reflux disease (GERD).

Product	Patient Population	Study Objective
Nano-Curcumin	Cancer Patients	To determine the efficacy of Nano Curcumin Nutritional Supplement in management of pain, fatigue and thrombocytopenia attenuation after Chemotherapy

Facilities

Dedicated Space

- 4 offices across 10,000 sq ft
- Main office within Jehangir Hospital premises
- Research ward devoted for trial patients

Drug Storage

- Temperature and humidity controlled drug storage with automated continuous temp monitoring
- Refrigeration & Freezer storage (2-4 Deg, - 80 Deg, Cryopreservation

Instruments Nutrition Research

- DEXA Scanner
- PQCT
- Jumping Mech
- Jamar – Hand Dynamometer
- Skinfold Thickness Calipers
- 12 Lead ECG
- Cooling Centrifuge

Accredited IRB

- Accredited and highly experienced IRB
- IRB registered with CDSCO
- Meetings conducted every month
- Institutional as well as Central IRB capabilities

Niche Lab

- Niche cell biology, molecular biology and microbiology research lab
- Digitized and catalogued bio bank

Food Preparation & Analysis

- Access to food Analysis Labs
- Experience working with food databases
- Access to Hygienic Kitchens

Differentiators

Rich Cross Functional Experience across the Continuum

Strong Technology Focus

Customized services as per Sponsor's needs

Global mindset, Local adaptation

The key differentiator is **JCDC's** strong culture of values of ethics, reliability and quality

Leadership Team

Executive Leadership

Sir Jehangir H.C. Jehangir

Chairman Jehangir Hospital
Leading from
the front for over 40 yrs

Dr. Uma Divate

MD, Medicine, Co-Founder Director.
Passionate clinician, researcher for 45 years

Pathik Divate

Co-founder and CEO
CA and MBA (US) with 25+ years experience

Cowas Jehangir

Trustee at Jehangir Hosp
BBA from Univ of
San Diego with
15+ years experience

Geeta Divate

Director Finance & Legal
CA with 20+ years exp in finance, legal, auditing, systems & management

Scientific Leadership

Dharmendra Ved

Chief Operating Officer
Seasoned CR professional with 30+ years experience in Clinical Operations, Regulatory and quality

Dr. Ravindra Ghooi

Chief Scientific Advisor
PhD with over 45 years experience in Pharmaceutical Industry and Clinical Research

Dr. Anuradha Khadilkar

KOL in Nutrition
MD Pediatrics with 30 +years experience in Basic Research, over 110
indexed publications

Dr. Neil Sankar

Global Medical Advisor
Med Oncologist with 30+ years of experience in Drug Dev Strategy, Medical Oversight, Clinical strategic support

Mr. Tariq Ahmed

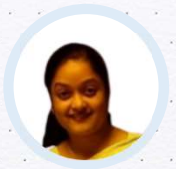
Director Business Development
30+ Years experience in Global Pharma and CROs
Led global, regional and local clinical teams across the US, EMEA and APAC.

JCDC CLINICAL PRECISION

Execution Team

Ms. Neelambari Bhosale

Head Clinical Operations
21+ years of experience in Site Project Management and Quality Assurance.



Ms. Aditi Bose

Head Data Management
18+years experience in CDM handling end to end CDM work,

Dr. Arati Ranade Ph.D

Head Medical & Regulatory Writing
18+years experience including. Assistant Professor, at, Sinhgad College of Pharmacy.

Ms. Nisha Sujan

Senior Manager Digital Health
18+years experience including. Quality Assurance, team management in clinical research.

Dr. Milind Patole Ph.D.

Lab Director
40+ years experience in Wet lab in research.
PhD in Biochemistry with over100+ papers published

THANK YOU

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