Manohara Basoor Halasiddappa

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Cupertino, CA USA

DIRECTOR, CLINICAL OPERATIONS

- Pharmaceutical Professional with well-rounded experience (15+ years) at start-up pharmaceutical, Global pharma, and Contract Research Organizations (CRO).
- Broad drug development experience in leading clinical development from First-In-Human Phase I through Phase IV clinical trials with multiple investigational drug products in various indications
- Editorial Board member of United Journal of Clinical Trials and Clinical Research
- Certified peer reviewer – Elsevier and Web of Science Academy
- "Thinking Critically: Interpreting Randomized Clinical Trials" certification by Stanford Medicine, USA
- Expertise: Clinical Program Management, Vendor management, Monitoring &Site Management, Medical Writing, Data Management, Investigational Product Management, Budget, and finance management, KPI's, Metrics, Audit preparation & Inspection readiness, Root cause analysis, CAPA, Recruitment and retention strategies, Study document management, etc.

THERAPEUTIC EXPERIENCE

- Oncology: Gastric Cancer (GC), Colorectal (CRC), Adenoid Cystic Carcinoma (ACC), Hepatocellular Carcinoma (HCC), Sarcomas, Ovarian Cancer and NSCLC
- Chronic Infectious Disease: Hepatitis C, Hepatitis B
- Immunology: Rheumatoid Arthritis, Psoriatic Arthritis
- Cardiovascular: Myocardial Infarction
- Dermatology: Active Psoriasis, Skin Infections & Skin and structural infections
- Musculoskeletal: Low Back Pain
- Neurology: Post Herpetic Neuralgia
- Other: Diabetic Neuropathic Pain, Biologics, Recombinant Monoclonal Antibodies etc.

PROFESSIONAL EXPERIENCE

AlgokBio,USA
Director, Clinical Operations - Consultant — *May 21- Current*

Elevar Therapeutics, South San Francisco, CA
Director, Clinical Operations — *Aug 18- Apr 21*
Senior Global Project Manager — *Nov 17– Aug 18*

Responsible for creating operational strategy and providing direction and oversight of oncology clinical development programs including budgets, resources, plans and timelines. Management responsibility for clinical operations staff, as well as external contract research organizations and other vendors.

Abbvie, North Chicago, IL
Clinical Study Manager — *Oct 15 – Nov 17*
Clinical Study Management Associate III — *Mar 13 – Oct 15*

Responsible for the oversight and strategic direction of clinical development programs in Infectious Diseases (e.g., start-up, multiple vendor management, enrollment, patient data, patient samples, timeline, departmental budget, and protocol amendments) to ensure milestones are met and aligned with corporate goals.

Pharmaceutical Product Development (PPD)

Senior Clinical Research Associate Level II — *Apr 11-Dec 12*
Senior Clinical Research Associate Level I — *Jul 10-Apr 11*

Clinigene International Limited (BIOCON Company) Bangalore, India

Senior Clinical Research Associate — *Jul 2009-Jul 2010*
Clinical Research Associate — *Jan 2006-Jul 2009*

EDUCATION AND CERTIFICATIONS

Project Management for Professionals Certification
Northwestern University School of Professional Studies, Chicago

Certification Clinical Research Associate, ACRP
Academy of Clinical Research Professionals

Post Graduate Diploma in Clinical Research
Institute of Clinical Research in India (ICRI) affiliated to Cranfield University (UK), Bangalore, India

Bachelor of Dental Surgery (BDS)
Rajiv Gandhi University of Health Sciences (RGUHS), Bangalore, Karnataka, India

MEMBERSHIP AND ASSOCIATIONS

Drug Information Association (DIA)
Association of Clinical Research Professionals (ACRP)
Society of Clinical Research Associates (SOCRA)-Member ID: 48983
The Society for Clinical Trials-Member ID: 19147
Institute of Clinical Research (UK),
American Association for the Advancement of Science (AAAS)

CLINICAL TRIALS -RECENT

- A Phase 1, open-label, 3-arm, parallel, fixed sequence study to investigate the effect of coadministration of CYP3A4 and CYP2D6 inhibitors and increased gastric pH on the pharmacokinetics, safety, and tolerability of XXX in healthy subjects.
- A phase 1, open-label study of the absorption, metabolism, and excretion of [14C]- XXX following a single oral dose in healthy male subjects.

- A Phase 1, Open-label, Nonrandomized, Single-dose Study to Investigate the Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Varying Degrees of Hepatic Impairment Compared to Subjects with Normal Hepatic Function.
- A Phase I/IIa Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of XXX in Combination with Paclitaxel in Advanced Gastric or Gastroesophageal Junction Cancer.
- Phase I/II Open-label Study to Evaluate the Safety, Tolerability and Efficacy of XXX or TAS-102 as monotherapies and XXX and TAS-102 as Combination Therapy in Subjects with Refractory Metastatic Colorectal Cancer
- A Single-Center, Randomized, Open-Label, Two-Sequence, Two-Period, Crossover Study to Evaluate the Pharmacokinetic Properties of Two Different Formulations of XXX Tablets in Healthy Subjects
- A Pharmacokinetic Interaction Study Between XXX and Cytochrome P450 Enzymes (CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A) Substrates
- A Phase 2 Open-Label, Multicenter, Study to Evaluate the Efficacy and Safety of XXX in Subjects with Recurrent or Metastatic Adenoid Cystic Carcinoma of all anatomic sites of origin.
- A Prospective, Randomized, Double-Blinded, Placebo-Controlled, Multinational, Multicenter, Parallel-group, Phase III Study to Evaluate the Efficacy and Safety of XXX plus Best Supportive Care (BSC) compared to Placebo plus BSC in Patients with Advanced or Metastatic Gastric Cancer (GC)
- A Randomized, Open-Label, International, Multi-Center, Phase 3 Clinical Study of PD-1 Antibody SHR-1210 Plus XXX Versus Sorafenib as First-Line Therapy in Patients with Advanced Hepatocellular Carcinoma (HCC) Who Have Not Previously Received Systemic Therapy