

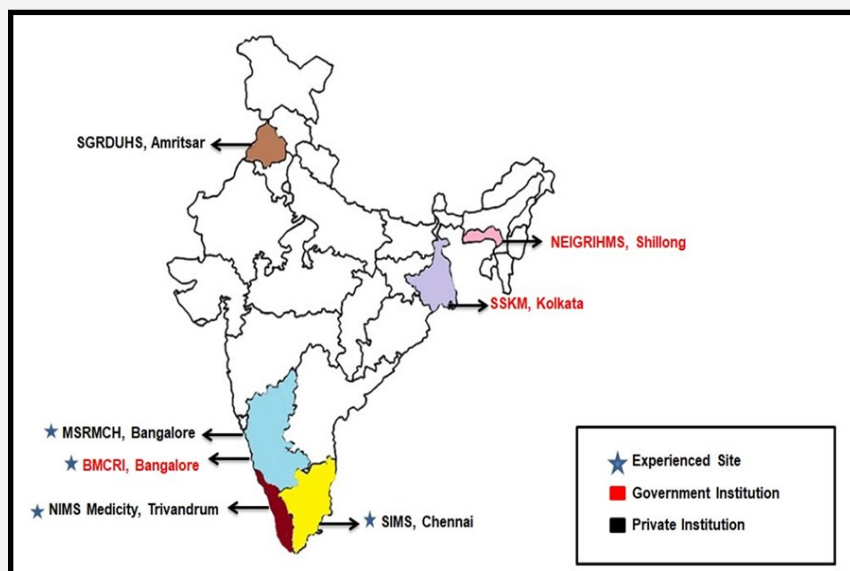
BIRAC CTN - Diabetology

Newsletter

Quarterly Newsletter : 10 (Jun 2023 - Aug 2023)

Introduction

The Clinical Trial Network (CTN) for Hospital Based Trial in Diabetology, a network of 7 hospitals across India has been established in terms of research facilities and are now open for new trials in Diabetology as a network.



The sites are approaching pharmaceutical industries for Clinical Trials in Diabetology in Network Mode

Content

Introduction
Page 1

Journey so far
Page 2

Recent Events
Pages 3-14

Future plans, Upcoming Events
Page 14

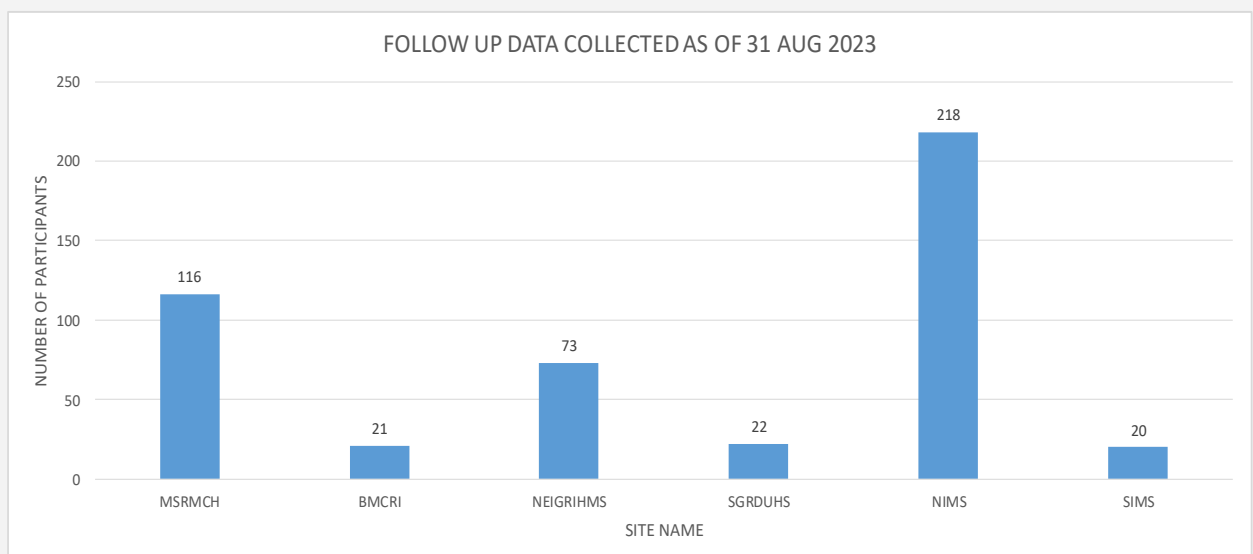
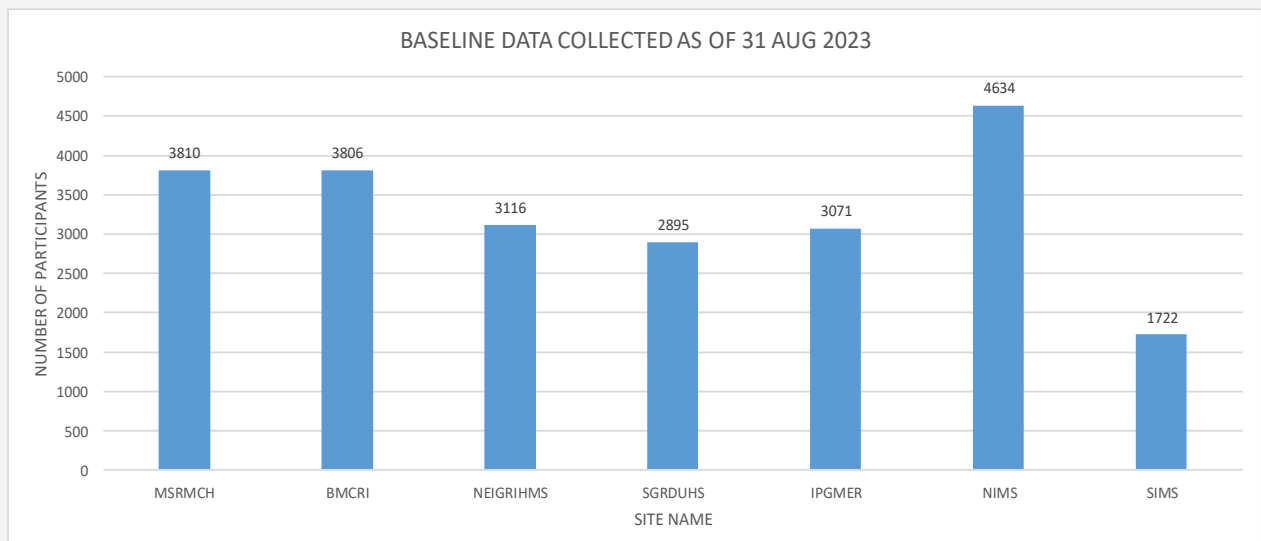
JOURNEY SO FAR

Events held : From 1st June 2023 to 31st August 2023

Diabetes Registry

The Hospital Based Multi Centric Diabetes Registry has captured baseline data of 23054 participants and follow up data of 470 participants as of 31st Aug 2023.

Registry Recruitment status



RECENT EVENTS

SAG Committee Meeting

4th July 2023



BIRAC Meeting in continuation to

SAG Committee Meeting

19th July 2023

The points discussed:

- Ongoing Studies in Endocrinology Department - Network Mode
- Publications and Presentations
- Planned Investigator Initiated Study In Network Mode
- Challenges at sites in getting clinical trials
- Future sustainability plan

RECENT EVENTS

ICLINSYMPOSIA 2023

28th July 2023

Conducted at M S Ramaiah Medical College and Hospitals

M S Ramaiah Medical College and Hospitals hosted “ICLINSYMPOSIA 2023” titled “Empowering Clinical Research” in collaboration with Infoclin consultancy and ISCR. All collaborating site within CTN Diabetology was part of the program.



RECENT EVENTS

ICLINSYMPOsia 2023

28th July 2023

Conducted at M S Ramaiah Medical College and Hospitals



RECENT EVENTS

ICLINSYMPOSIA 2023

28th July 2023

Conducted at M S Ramaiah Medical College and Hospitals

Dr. Saurendra Das, Director of Medical Affairs, Hazlo Consultancy. He has over 25 years research experience in managing all phases of global and domestic clinical research projects of innovative healthcare products and cutting-edge technology medical devices. He has been involved in setting up 8 major healthcare and research organizations across India. He has successfully trained more than 10,000 investigators, physicians, dentists, CRC's & CRAs', other stakeholders including lab and pharmacy personnel and ethics committee members. He was in charge of the 4 sites which became the first clinical trial sites in India to be inspected by US FDA and of 4 sites which were inspected by EMA. He is into Digital health and digitization of clinical trial management.



Innovate In India i3 Mission

- National Biopharma Mission under BIRAC, DBT
- CHOORD (Consortia of Hospitals in Onco, Ophthal, Rheumat, Diabet)

Gokula Education Foundation Diabetology Network (7 sites)



Dr. Saurendra Das
ICLINSYMPOSIA - 2023

Dr. Saurendra Das, was one of the speaker for ICLINSYMPOSIA. During his session he briefed about BIRAC_CTN Diabetology and the importance of such networks for the clinical research industry.

RECENT EVENTS

Accomplishment

A. ONGOING STUDIES IN ENDOCRINOLOGY DEPARTMENT - NETWORK MODE

I. MSRMCH, BANGALORE & IPGMER, SSKM HOSPITAL, KOLKATA

Study Title	Sponsor
A Randomized, Controlled, Multicenter Study to Evaluate the Safety and Efficacy of Paltusotine in Subjects with Non-pharmacologically Treated Acromegaly	Crinetics Pharmaceutical

II. BMCRI, BANGALORE & IPGMER, SSKM HOSPITAL, KOLKATA

Study Title	Sponsor
A Master Protocol to Investigate the Efficacy and Safety of XX Once weekly in Participants with Type 2 Diabetes Mellitus who have Obesity or Overweight: A Randomized, Double-Blind, Placebo-Controlled Trial(TRIUMPH-2)	Eli Lilly

B. FEASIBILITY IN NETWORK MODE

I. SGRDUHS, Amritsar & NIMS Medicity, Trivandrum

Study Title	Sponsor
A Prospective, Interventional, Multicenter, Post-marketing Clinical Study of An-sulin 30/70 Injection 100 IU/ml {Insulin Human (rDNA) 30/70 100 Injection} in the treatment of Diabetes Mellitus (DM)	Square Pharmaceuticals Ltd.

RECENT EVENTS

Accomplishment

B. FEASIBILITY IN NETWORK MODE

II. MSRMCH, Bangalore & IPGMER, SSKM Hospital, Kolkata

Study Title	Sponsor
The cardiovascular safety of cagrilintide 2.4 mg s.c. in combination with obesity and established cardiovascular disease	Novonordisk
Efficacy and safety of early initiation of oral semaglutide 50 mg and 25 mg once daily versus empagliflozin 25 mg once daily and versus metformin 2 g in treatment native patients with newly diagnosed type 2 diabetes and overweight or obesity	Novonordisk

Plan for Sustainability

- Approaching pharmaceutical industries for Clinical Trials in Diabetology in Network Mode
- Strengthening the social presence of the CTN Diabetology Network
- Diabetes Research India – Diabetology Clinical Trial Network (Website)
- Shared Investigators Platform, Cognizant
- Registering the Sites in the CTN under India-International platforms, Clinical Networks and authorized Organisations
- Novonordisk Study – Cardiometabolic Disorders

RECENT EVENTS

World Prediabetes Day Awareness Programme at M S Ramaiah Medical College Hospital on 16th August 2023



RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at
M S Ramaiah Medical College Hospital on
12th June 2023 and 18th August 2023**



RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at
SIMS Hospital, Chennai on
24th July 2023 and 2nd August 2023**



**Patient Awareness Program for Diabetes Patients &
Fibro Scan for Obesity Patients Conducted at
BMCRI, Bangalore on 9th August 2023**



RECENT EVENTS

Patient Awareness Program for Diabetes Patients Conducted at SGRDUHS, Amritsar on 22nd August 2023



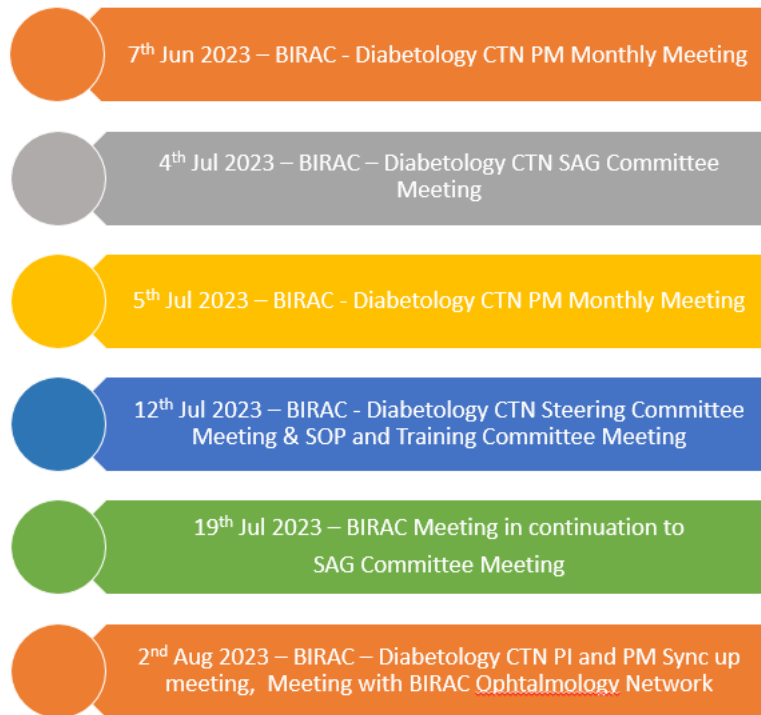
RECENT EVENTS

Patient Awareness Program for Diabetes Patients Conducted at IPGMER, Kolkata on 23rd August 2023



RECENT EVENTS

**Meeting updates from
1st June 2023 - 31st August 2023**

- 
- 7th Jun 2023 – BIRAC - Diabetology CTN PM Monthly Meeting
 - 4th Jul 2023 – BIRAC – Diabetology CTN SAG Committee Meeting
 - 5th Jul 2023 – BIRAC - Diabetology CTN PM Monthly Meeting
 - 12th Jul 2023 – BIRAC - Diabetology CTN Steering Committee Meeting & SOP and Training Committee Meeting
 - 19th Jul 2023 – BIRAC Meeting in continuation to SAG Committee Meeting
 - 2nd Aug 2023 – BIRAC – Diabetology CTN PI and PM Sync up meeting, Meeting with BIRAC Ophthalmology Network

Future plans

- ⇒ Conduct of virtual quality management activity for baseline data (3%) and follow up data (3%) for all sites by Lead site
- ⇒ Preparation of third interim registry report

Upcoming events

- ⇒ BIRAC - Diabetology CTN PM Monthly meeting for the month of Sept 2023 will be held on 6th Sept 2023 @ 2:30 pm via Microsoft Teams