

# BIRAC CTN - Diabetology

# Newsletter

Quarterly Newsletter : 09 (Mar 2023 - May 2023)

## **Introduction**

The Clinical Trial Network (CTN) for Hospital Based Trial in Diabetology is under Biotechnology Industry Research Assistance Council (BIRAC) set up by NBM, Department of Biotechnology (DBT), Government of India. BIRAC is an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

CTN is a collaboration of geographically diverse organization aimed towards the transformation of diabetes care through innovation. The network nearing to complete its 3 years of project duration and as end result all the site have improvised their infrastructure and research facilities to take up clinical trials. The team is well trained in ICH GCP and all other applicable regulatory guidelines. The network facilitates in making meaningful large scale clinical trials possible through powerful partnership of seven hospitals across India.

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# JOURNEY SO FAR

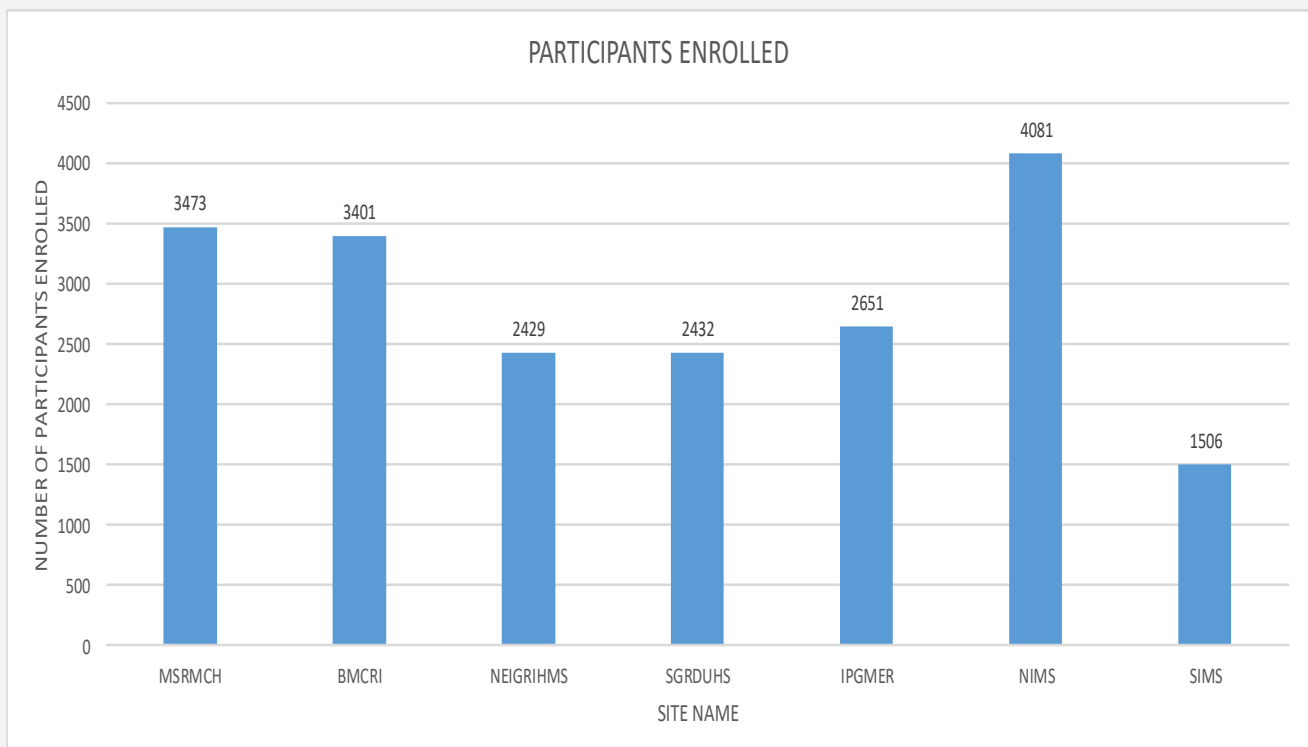
Events held : From 1<sup>st</sup> Mar 2023 to 31<sup>st</sup> May 2023

## Diabetes Registry

The Hospital Based Multi Centric Diabetes Registry developed as part of the project has enrolled approximately 20,000 participants over a period of 2 years. It will serve as a database from which interested individuals may be identified and enlisted for upcoming research initiatives and clinical trials. The healthcare planners, researchers, and government officials will benefit from this diabetes registry in developing primary and secondary preventive initiatives that might minimize the rising healthcare burden because of diabetes.

## Registry Recruitment status

A total of 19,973 participants across India have been enrolled for the study from 15th April 2021 to 30th April 2023.



# RECENT EVENTS

## Recommendations from “Project Monitoring Committee Meeting 08<sup>th</sup> February 2023” received on 13<sup>th</sup> April 2023

Committee applauded the network for work carried out so far and for developing the Diabetes Registry with huge number i.e., 15,000 and recommended to showcase this to attract sponsors.

- To develop new ideas to create patient awareness and to strategize and strengthen the network.
- Register the network in international forums
- PIs to form a forum with institutional higher authority to promote CTN Collaborate with academic centers to conduct investigator-initiated trials to sustain the network
- Registry data should be analyzed therapy wise as well as disease wise. The teams should follow CDSCO website on regular basis for details about ongoing trials/approvals and reach out to those sponsors.
- Committee recommended to have a minimum 3 month follow up to the last recruited patient. The patients follow up should be categorized as 3, 6 months and 1 year in the report and analysis.
- Committee recommended to promote the network with some patient success stories in clinical trials
- Recommended to the network to submit a concrete next three months plan to get clinical trials and to sustain the network by 15<sup>th</sup> April to PMC Committee.
- Committee recommended to update clinical trial network details in individual site’s websites to promote it.
- Committee noted that parents were reluctant to give details for Type I DM patients and recommended to include this challenge in future publication.

# RECENT EVENTS

## Summary of Protocol Version 2

The hospital based multi centric diabetes registry was initially aimed to collect the patient data at one point of time (Cross sectional). After the PMC and SAG committee meeting it was suggested to include follow up to acquire in-depth knowledge of positive and negative correlation of diabetes and its management over a period of time. Protocol version 2 is developed as part of implementing the recommendation from the committee.

- The study is revised as a hospital based, prospective longitudinal study. This is an observational study which will be conducted without any intervention.
- The follow up of participants will be done after a minimum period of 3 months from the date of enrollment., apart from this no additional mandatory follow-up visits, nor interventions will be conducted.
- The DCF for Follow up visit will collect longitudinal prospective data on the following; Survival status, hospitalization, anthropometry, complications, associated risk factors, laboratory investigation, concomitant medications.
- The statistical analysis plan as per protocol version 2 has incorporated data analysis like; correlation analysis; Chi-Square test to assess the relationship type of diabetes and the prone age group, to assess the relationship between type of diabetes and gender, to assess the association between duration of disease versus complications after classifying duration of disease; paired t-test will be employed in order to detect the significant difference between the baseline and end-line HbA1c values; Proportion test will be used to examine the significant difference between participant with and without the family history of diabetes.

# **RECENT EVENTS**

## **Accomplishment**

### **I. ACTIVITIES DONE IN NETWORK MODE**

#### **A. Clinical Trial— MSRMCH, Bangalore and IPGMER, SSKM Hospital, Kolkata**

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

#### **B. Streamlining the individual contacts of the sites by connecting with the pharmaceutical company and working for the network sustainability**

The site are in discussion with the Medical Managers of companies like Parexel, Pfizer, Merck’s, Sanofi Healthcare India Private Limited, IQVIA, Pharmaze India Private Limited, ICBio Clinical Research Private Limited and CBCC Global Research in getting clinical trial in network mode.

### **II. FEASIBILITY IN NETWORK MODE**

#### **A. MSRMCH, Bangalore and SGRDUHS, Amritsar**

Randomized, double—blind, placebo controlled, parallel- group phase 3 study to evaluate the efficacy, safety, and tolerability of SAR440340 (anti-IL, 33mAb) in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) from Sanofi

#### **B. SGRDUHS, Amritsar and NIMS Medicity, Trivandrum**

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

# RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at  
NIMS Medicity, Trivandrum on 14<sup>th</sup> March 2023**



# RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at  
BMCRI, Bangalore on 9<sup>th</sup> April 2023**



# RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at  
M S Ramaiah Medical College Hospital on 17<sup>th</sup> April 2023**





# RECENT EVENTS

## Patient Awareness Program for Diabetes Patients Conducted at BMCRI, Bangalore on 19<sup>th</sup> April 2023



# RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at SGRDUHS, Amritsar on 1<sup>st</sup> May 2023**



# RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at  
NEIGRIHMS, Shillong on 19<sup>th</sup> & 20<sup>th</sup> May 2023**



# RECENT EVENTS

**Indian Diabetes Education Association Indian Medical Association AMS 17th Annual “Diabetes Update” conducted on 21<sup>st</sup> May 2023 conducted at NIMS Medicity, Trivandrum**



# RECENT EVENTS

## Meeting updates from 1st March 2023 - 31st May 2023



## Future plans

- ⇒ Conduct of virtual quality management activity for all sites by Lead site.
- ⇒ Training on Protocol Version 2.0, Amended Registry SOP, Indian CST software planned on 7<sup>th</sup> June 2023 along with PM Monthly meeting .
- ⇒ Preparation of third interim registry report.

## Upcoming events

- ⇒ BIRAC - Diabetology CTN PM Monthly meeting for the month of June 2023 will be held on 7<sup>th</sup> June 2023 @ 2:30 pm via WebEx