

# BIRAC CTN - Diabetology

# Newsletter

Quarterly Newsletter : 11 (September 2023 - November 2023)

## Introduction

The Biotechnology Industry Research Assistance Council (BIRAC), established by NBM, the Department of Biotechnology (DBT), Government of India, is home to the Clinical Trial Network (CTN) for Hospital Based Trial in Diabetology. BIRAC serves as an interface agency, empowering emerging biotech companies to engage in innovative and strategic research while addressing demands for product development that are pertinent to the country.

The Multi Centric Diabetes Registry with seven hospitals across India has been operational for more than two years. As of November 30<sup>th</sup>, 2023, 24,840 people from various sites within the CTN Diabetology were enrolled in this registry. Information on patients with Type 1 and Type 2 Diabetes mellitus is being gathered by this registry.

Our research teams across multiple centers delve into discovering the key trends and emerging patterns in diabetes in India through innovative approaches to identifying risk factors. We're committed to advancing diabetes knowledge collectively.

Explore the success stories of our network, where researchers and healthcare professionals from seven centers came together to tackle diabetes challenges and learn about the impact of these joint efforts on patient care of diabetes and its outcomes through the series of our newsletter.

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# JOURNEY SO FAR

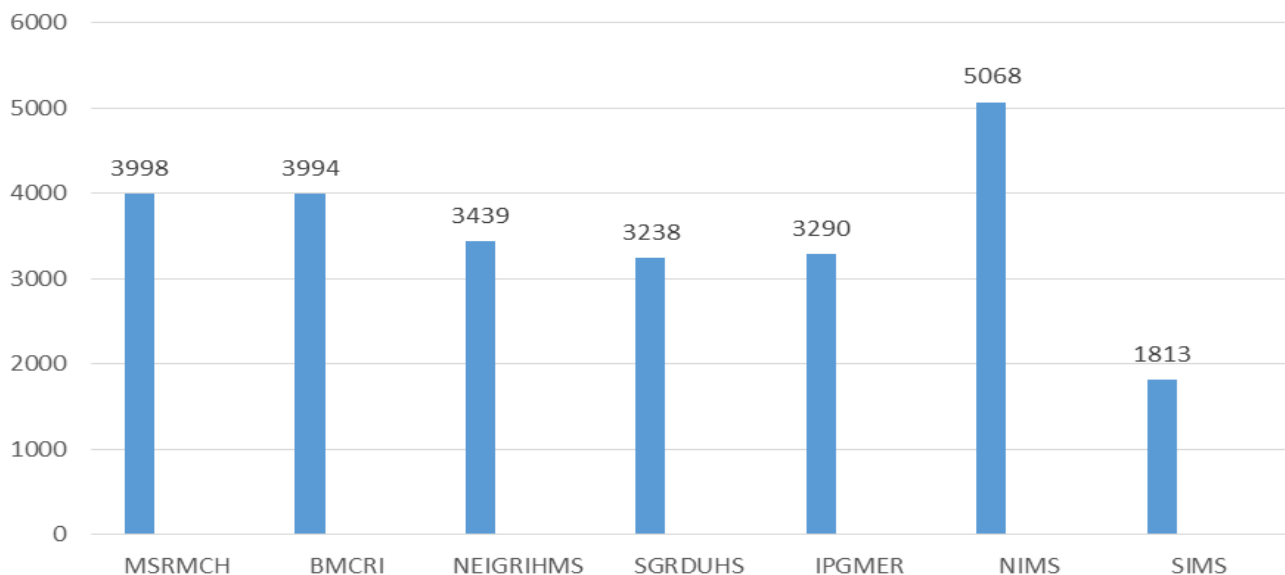
Events held : From 1<sup>st</sup> Sept 2023 to 30<sup>th</sup> Nov 2023

## Diabetes Registry

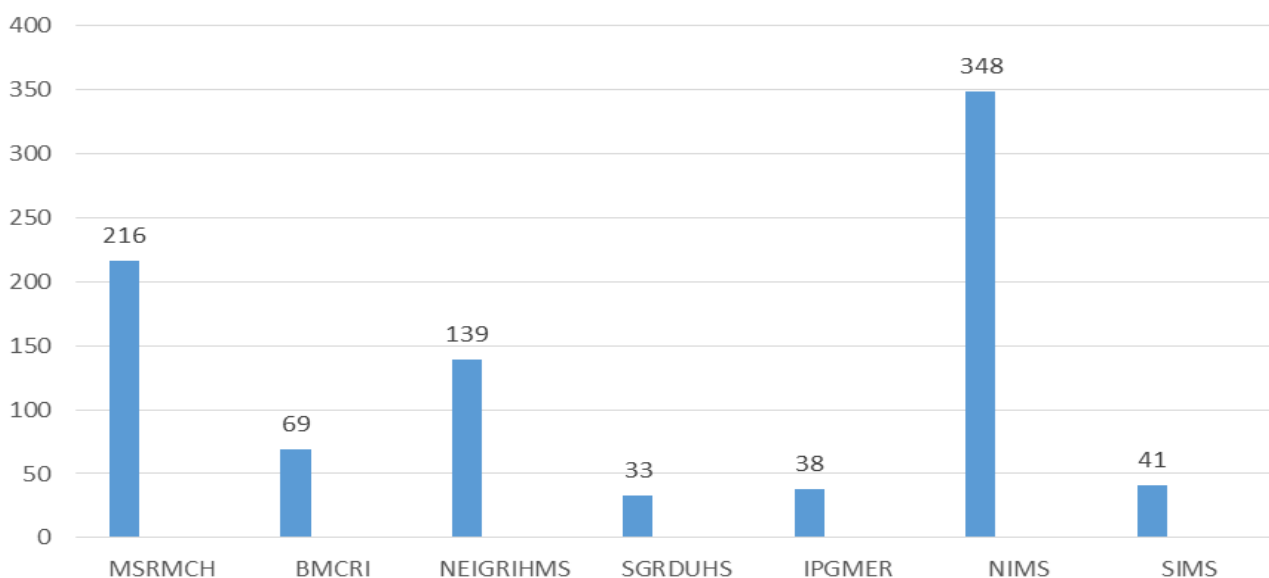
The Hospital Based Multi Centric Diabetes Registry has captured baseline data of 24,840 participants and follow up data of 884 participants as of 30<sup>th</sup> November 2023

### Registry Recruitment status

#### BASELINE DATA COLLECTED AS OF 30<sup>th</sup> NOV 2023



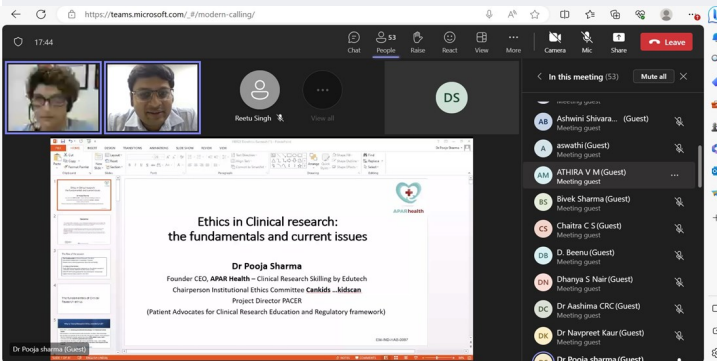
#### FOLLOW UP DATA COLLECTED AS OF 30<sup>th</sup> NOV 2023



# RECENT EVENTS

## Pfizer-Capability building session hosted by MS Ramaiah medical college and hospitals

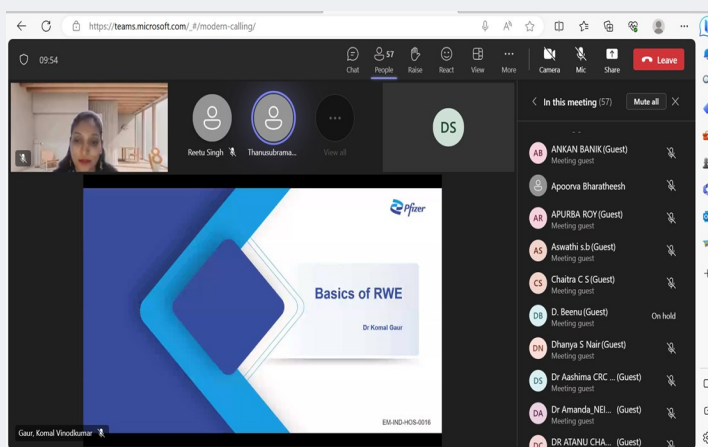
### First Educational Webinar: “Ethics in Clinical research: The foundation and current issues” on 20<sup>th</sup> Sept 2023



The Session offered an excellent opportunity to delve into the following key areas:

1. Principles of Ethics
2. The Roles of Stakeholders in Upholding Ethics
3. Patient-Centric Ethics

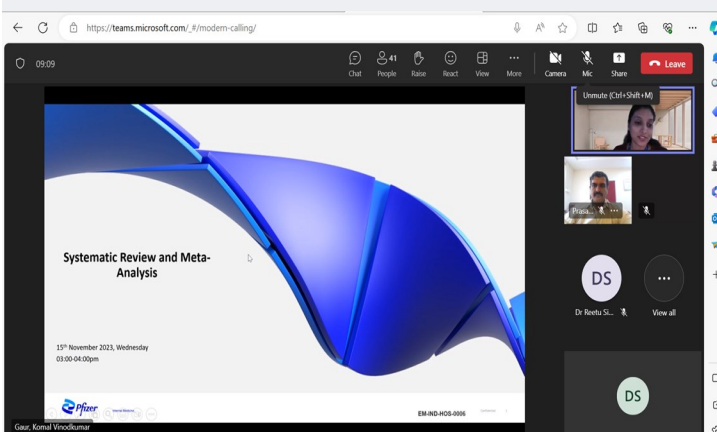
### Second Educational Webinar: “Real World Evidence– Unravelling the Essentials” on 18<sup>th</sup> Oct 2023



An in-depth investigation of Real World Evidence (RWE) and Real World Data (RWD), with a focus on related subjects such as:

1. Differentiating RWE and RWD
2. Application of Real World Evidence
3. Type of Real World Evidence Studies
4. Real World Evidence in the Indian

### Third Educational Webinar: “Systematic Review and Metanalysis” on 15<sup>th</sup> Nov 2023



The theory session on systematic review and meta-analysis typically covered

1. The foundational principles
2. Methodologies
3. Applications of these research approaches.

# RECENT EVENTS

## 63<sup>rd</sup> Annual Conference of National Academy of Medical Sciences– NAMSCON 2023 06<sup>th</sup> - 07<sup>th</sup> October 2023



Dr Pramila Kalra received the best oral presentation award on abstract titled “ **Hospital Based Multicentric Diabetes Registry from India** ”at NAMSCON 2023 conference held at M S Ramaiah Medical College, Bangalore.



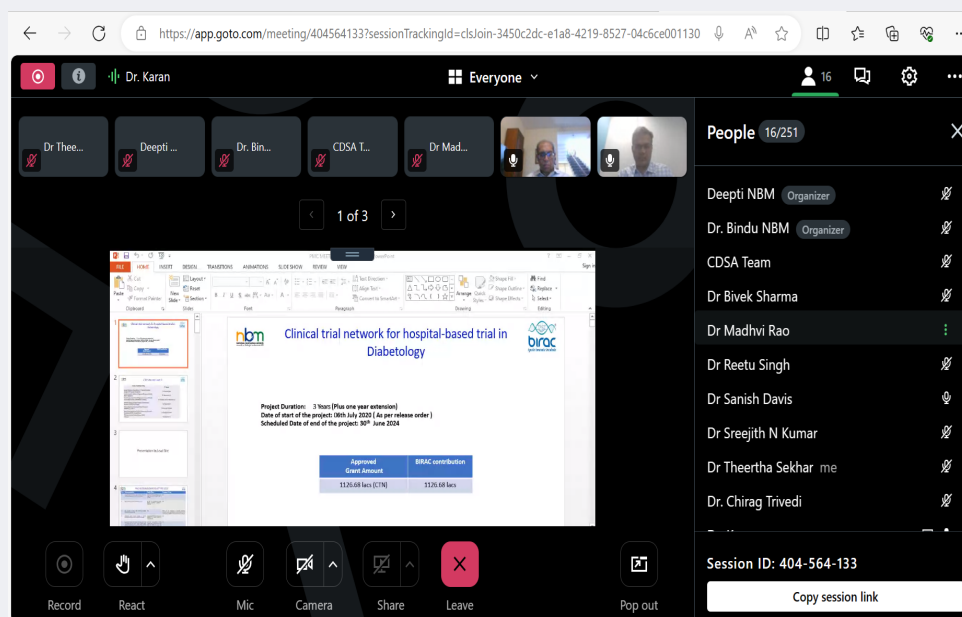


# RECENT EVENTS

## CAG Audit at M S Ramaiah Medical College and Hospitals Bangalore 30<sup>th</sup> October 2023



## 06<sup>th</sup> PMC Meeting 31<sup>st</sup> October 2023



# RECENT EVENTS

## Patient Awareness Program for Diabetes Patients 27<sup>th</sup> October 2023 Conducted at M S Ramaiah Medical College and Hospitals, Bangalore





# RECENT EVENTS

**World Diabetes Day Program and Patient Awareness Program for Diabetes Patients on 14<sup>th</sup>, 15<sup>th</sup> November 2023**  
**Conducted at SGRDUHS, Amritsar**



## RECENT EVENTS

**Patient Awareness Program for Diabetes Patients on 14<sup>th</sup> November 2023, Conducted at NEIGRIHMS, Shillong**





# RECENT EVENTS

## World Diabetes Day and Patient Awareness Program for Diabetes on 14<sup>th</sup> November 2023 conducted at SIMS Hospital, Chennai





# RECENT EVENTS

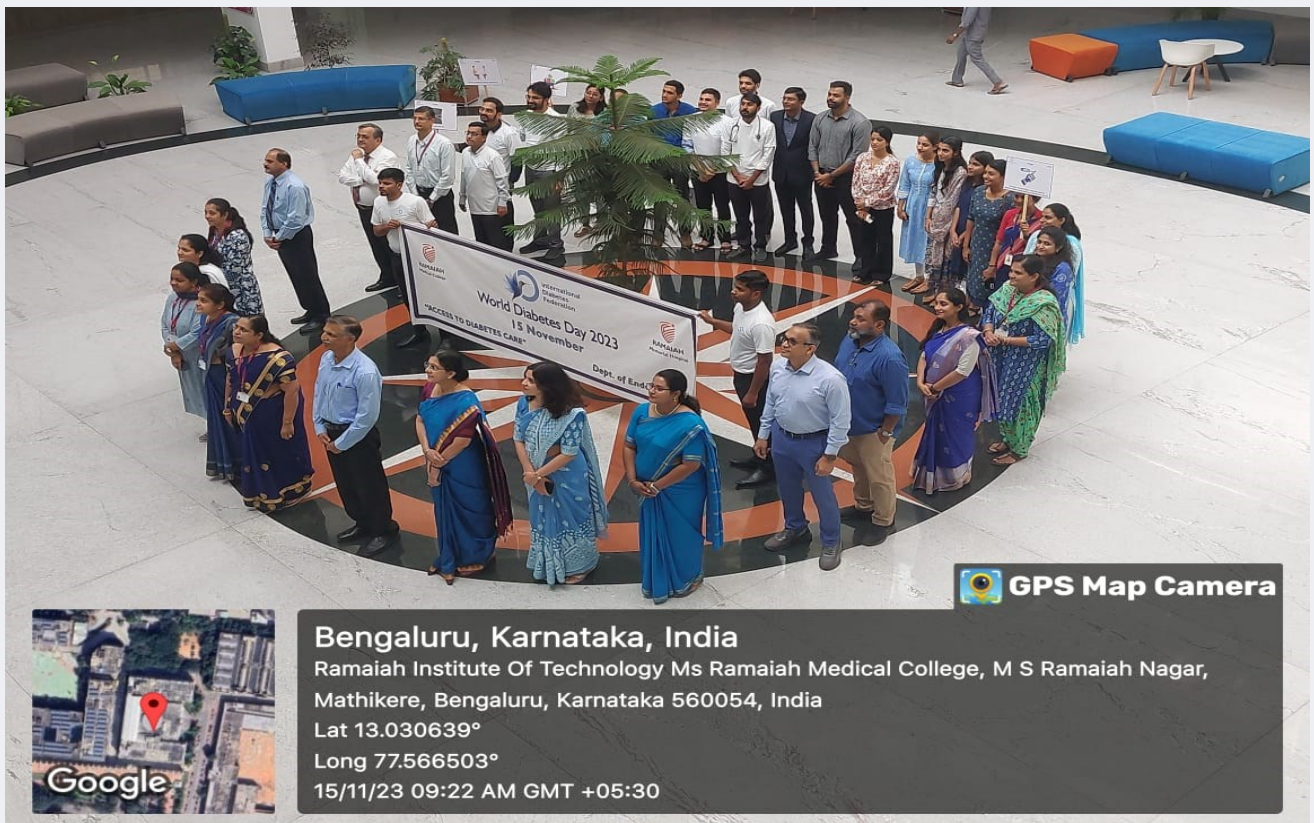
## World Diabetes Day and Patient Awareness Program for Diabetes Patients 14<sup>th</sup> November 2023 Conducted at NIMS Hospital, Trivandrum





# RECENT EVENTS

## World Diabetes Day Program on 15<sup>th</sup> November 2023 Conducted at M S Ramaiah Medical College and Hospitals, Bangalore



# RECENT EVENTS

## Accomplishment

### Ongoing Academic studies in Endocrinology Department- Network Mode

To study the effect of patient education on Knowledge Attitude and Practice (KAP) of Diabetic foot care among Type 2 Diabetic Mellitus patients.

### Ongoing Clinical Trials in Endocrinology Department –Network Mode

#### I. MSRMCH, Bangalore& IPGMER, SSKM Hospital, Kolkata

Sl. No	Study Title	Sponsor
1	A Randomized, controlled, Multi-center study to Evaluate the study and Efficacy of Paltusotine in Subject with Non –Pharmacologically Treated Acromegaly	Crinetics Pharmaceuticals
2	A Phase 3, Randomized, Double – Blind study to Investigate the Efficacy and safety of once Daily Oral LY3502970 Compared with Placebo in Adult Participant with TYPE 2 Diabetes and Inadequate Glycemic Control with Diet and Exercise Alone	Eli Lilly
3	The cardiovascular safety of cargrilintide 2.4 mg s.c in combination with obesity and established cardiovascular disease	Novo Nordisk
4	A 40– week study comparing the efficacy and safety of once lcosema and daily Insulin Glargine100	Novo Nordisk



# RECENT EVENTS

## Accomplishment

### Ongoing Clinical Trials in Endocrinology Department –Network Mode

#### II. BMCRI, Bangalore & IPGMER, SSKM Hospital, Kolkata

Sl. No	Study Title	Sponsor
1	LY3437943 Once weekly in participant with Type 2 Diabetes and Obesity or overweight patient	Eli Lilly

### Feasibility In Network Mode

#### I. SGRDUHS, Amritsar & NIMS Medicity, Trivandrum

Sl. No	Study Title	Sponsor
1	A Prospective, Interventional, Multicenter, Post marketing Clinical study of Ansulin 30/70 Injection 100 IU/ml {Insulin Human (rDNA) 30/70 100Injection} in the treatment of Diabetes Mellitus (DM)	Square Pharmaceuticals Ltd.

# RECENT EVENTS

## Accomplishment

### Feasibility In Network Mode

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

Sl. No	Study Title	Sponsor
1	Efficacy and safety of early initiation of oral semaglutide 50 mg and 25 mg once daily dose versus empagliflozin 25 mg once daily and versus metformin 2g in treatment native patient with newly diagnosed type 2 diabetes and over weight or obesity	Novo Nordisk
2	Fixed ratio combination of Glargine and lixisenatide in adult patient with Type 2 Diabetes	Sanofi





# RECENT EVENTS

**Meeting updates from  
1<sup>st</sup> September 2023 - 30<sup>th</sup> November 2023**

- 06th Sept 2023-BIRAC CTN PM Monthly Meeting
- 13 Sept 2023-BIRAC CTN Technical Advisory Group Meeting
- 04 Oct 2023-BIRAC CTN PM Monthly Meeting
- 18 Oct 2023 -BIRAC CTN Steering Committee Meeting &SOP and Training Committee Meeting
- 31 Oct 2023-BIRAC CTN PMC Meeting
- 08 Nov 2023-BIRAC CTN PI &PM Sync up Meeting

## Future plans

- To start study on “Assessment of KAP about periodontal disease among diabetic patients: A Hospital Based Multi-Centric Study”

## Upcoming events

- “Global Bio India 2023” at New Delhi from 4<sup>th</sup> to 6<sup>th</sup> December 2023.
- Education Module Cardiac Metabolic Disorder-Novonordisk will be starting from the month of December 2023
- PM Monthly meeting on 6<sup>th</sup> December 2023 at 2:30 pm via Microsoft teams