

NEWSLETTER

Quarterly Newsletter : 13 (March 2024 - May 2024)

Introduction

The Biotechnology Industry Research Assistance Council (BIRAC), established by NBM under the Department of Biotechnology (DBT), Government of India, hosts the Clinical Trial Network (CTN) for Hospital-Based Trials in Diabetology. BIRAC acts as a facilitator, empowering burgeoning biotech firms to partake in forward-thinking and strategic research endeavours, all the while meeting the country's pertinent demands for product development.

For over three years, the Multi-Centred Diabetic Registry is a component of the Clinical Trial Network for Hospital-Based Trials in Diabetology, involving seven hospitals throughout India. As of December 31, 2023, a total of 25279 participants were enrolled in this study, from different sites within the CTN Diabetology.

Through creative methods of identifying risk factors, our research teams are exploring the identification of important trends and emerging patterns in diabetes within India. We have a strong commitment to working together in collectively advancing our knowledge of diabetes. Discover the achievements of our network, where researchers and medical professionals from seven centers collaborated to address challenges in diabetes, through our newsletter series.

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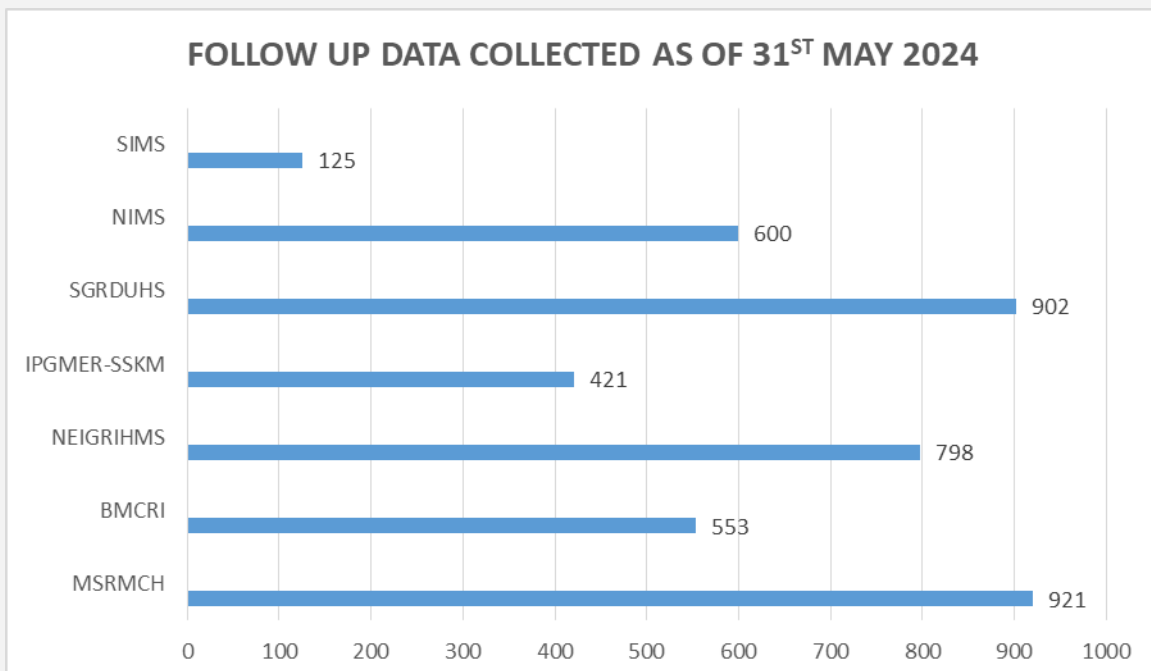
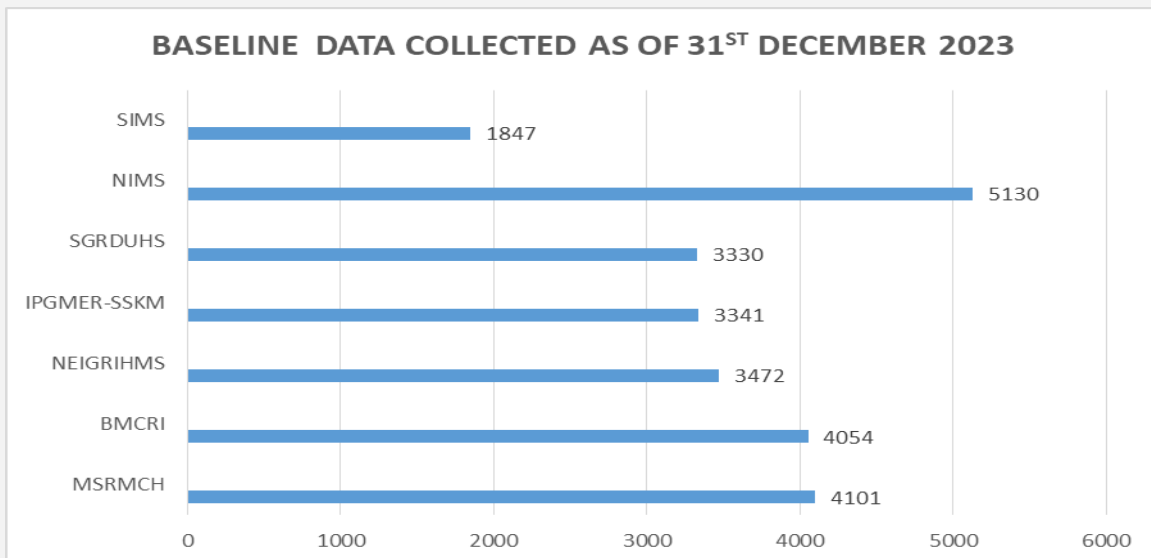
JOURNEY SO FAR

Events held : From 1st March 2024 to 31st May 2024

Diabetes Registry

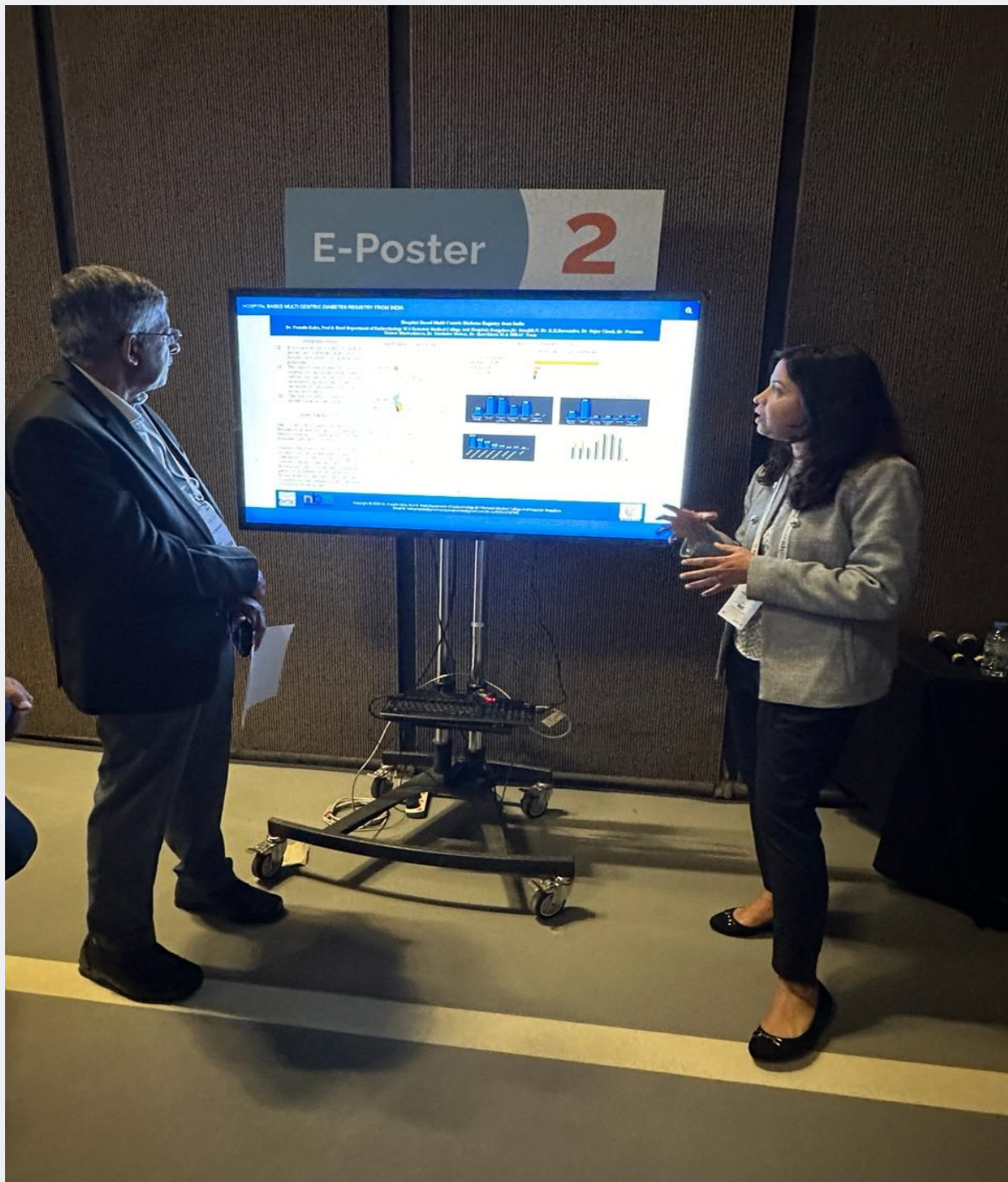
The Hospital Based Multi Centric Diabetes Registry has captured baseline data of 25,279 participants as of 31st December 2023 and follow up data of 4320 participants as of 31st May 2024.

Registry Recruitment status



RECENT EVENTS

Dr. Pramila Kalra Presented on HOSPITAL BASED MULTI CENTRIC DIABETES REGISTRY FROM INDIA at the 21st International Congress of Endocrinology, 1st-3rd March 2024, Dubai, UAE



RECENT EVENTS

ACTIVITIES IN NETWORK MODE

Novonordisk Cardio-metabolic Disorders Education Module on 13th March 2024

Meeting now | Microsoft Teams | Cardio-Metabolic Disorder Educa... | 02:02:52

Stay in the know. Turn on desktop notifications. Turn on

Chat People Raise React View More Camera Mic Share Leave

Your microphone is muted.

Sujoy Ghosh (Unverified)

Participants

Share invite

In this meeting (26)

- DS Dr. Theertha Sekhar
- AP Antara Patra (Unverified)
- APHZ (Anupa... (Unverified)
- APZR (Abishek ... (Unverified)
- BSGI (Bharani S... (Unverified)
- BSYZ@novono... (Unverified)
- DQJH (Dhruv J... (Unverified)

Type here to search

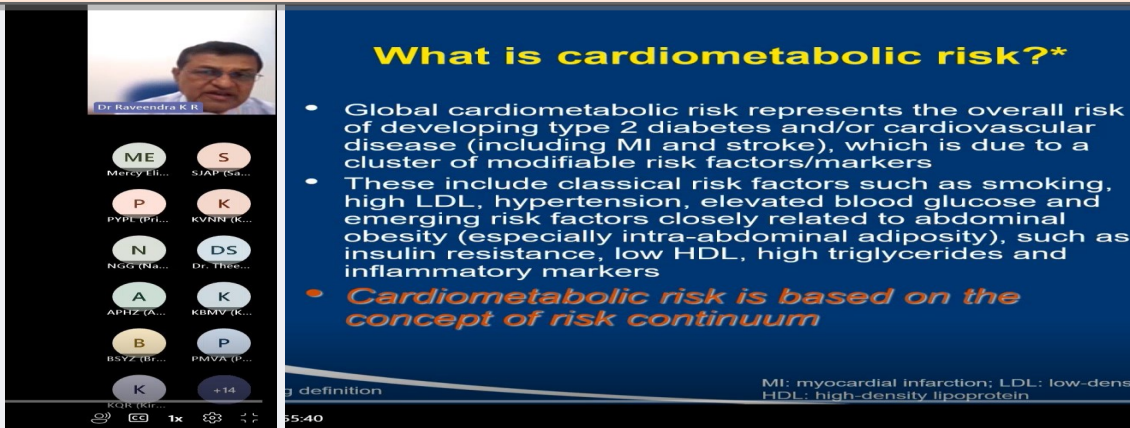
15:02 14-03-2024

Dr. Sujoy Gosh conducted a class on Lifestyle Modification and Pharmacological Management (practical aspects and newer therapies). Adverse reactions to all classes of anti-diabetic drugs and their management and followed by clinical posting in the endocrinology outpatient department of M S Ramaiah Memorial Hospital.

RECENT EVENTS

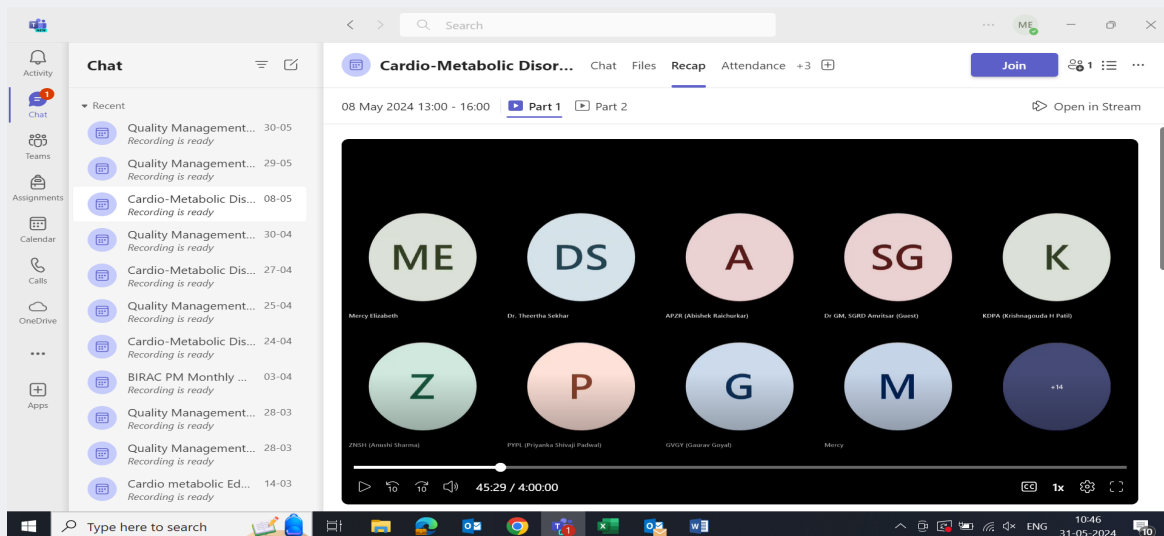
ACTIVITIES IN NETWORK MODE

Novo Nordisk Cardio-metabolic Disorders Education Module on 10th April 2024



Dr. Raveendra addressed participants on normal and abnormal physiology, acute chest pain: signs and symptoms, risk factor assessment, diagnosis, and monitoring of clinical cardiovascular disorders and followed by clinical posting in the endocrinology outpatient department of M S Ramaiah Memorial Hospital

Novo Nordisk Cardio metabolic disorder Education Module on 8th May 2024



Dr. Gurinder Mohan covered the topic of acute and chronic complications of cardiovascular disease. Managing the consequences of cardiovascular diseases, Hypertension control in primary and tertiary care Vascular diseases and diabetes complications and followed by clinical posting in the endocrinology outpatient department of M S Ramaiah Memorial Hospital

RECENT EVENTS

PATIENT AWARENESS PROGRAM FOR DIABETES MELLITUS CONDUCTED AT NEIGRIHMS, SHILLONG, FROM 1st April 2024 to 30th April 2024



Patient awareness programs were held from April 1st until April 30th. Diabetes patients who visited the General Medicine department's outpatient department (OPD) were given a pamphlet outlining the importance of participating in clinical trials and diabetes, and Medical Officer Dr. Barilangki Bamon explained the subjects to each participant and their attendants. 45 patients were given the leaflets, which were accessible in Hindi, Khasi, and English.



RECENT EVENTS

NIMS ,Trivandrum conducted 18th Annual Diabetes Update on 12th May 2024, in association with Indian Medical Association (IMA), Dr Sreejith N Kumar leads as the Organizing Chairman of the program



RECENT EVENTS

**Patient Awareness Program for Diabetes Patients on
15th May 2024, conducted at
MS Ramaiah Medical College and Hospital Bangalore**



RECENT EVENTS

Diabetes Education and Clinical Trials Awareness Program was conducted at SGRDUHS, Amritsar on Clinical Trials Day on 20th May 2024



RECENT EVENTS

ACTIVITIES IN NETWORK MODE

The screenshot shows a Zoom meeting in progress. The main content is a slide titled "Schedules" with the following table:

Schedule no.	Topic
I	General Principles and Practices for Clinical Trial
II	Requirements and Guidelines for permission to import or manufacture of new drug for sale or to undertake clinical trial
III	Conduct of Clinical Trial
IV	Requirements and Guidelines for conduct of bioavailability and bioequivalence study of new drugs or investigational new drugs
V	Post market assessment
VI	Fee payable for license, permission and registration certificate
VII	Formulae to determine the quantum of compensation in the cases of clinical trial related injury and death
VIII	Application for registration/renewal of ethics committee relating to clinical trial or bioavailability and bioequivalence study or biomedical health research

On the right side, there is a "Participants (67)" list with names and icons. The names visible include ARYA, Kiran, Punitha, Dr. Sreelakshmi PR, Gayathri, Dr. Iovling aarthi maria, Ashwini Shivaram BMCRI, Melvin George, Karthik Palani, Sr, Dr. SINDHUJA K, and Seethalakshmi.

The event hosted by SIMS, Chennai held in a hybrid mode, seamlessly integrated virtual and in person participation on 18th May 2024

The screenshot shows a Zoom meeting with a video of Aswin Kumar. Below the video is a slide titled "STAKEHOLDERS" with three columns:

- INTERNAL- CORE TEAM**
 - Clinical operations
 - Clinical sciences
 - Biostatistics
 - Medical affairs
 - Data management
 - Pharmacokinetics
 - Clinical supply
- OTHER R&D FUNCTIONS**
 - Non-clinical
 - Drug safety
 - Regulatory strategy
 - Project management
 - Formulations/CMC
 - Intellectual property
 - Publishing
- EXTERNAL**
 - Patients/Clinical Participants
 - Investigators/KCO
 - Trial Site Staff/RD
 - Ethics Committee
 - Agencies
 - Payers

The screenshot shows a Zoom meeting interface with a recording notification: "This meeting is being recorded...". Below this is a name tag for "Karthik Palani". The main content is a slide titled "ICH E3 - Clinical Study Report Structure" with a list of sections:



1. TITLE PAGE
2. SYNOPSIS
3. TABLE OF CONTENTS FOR THE INDIVIDUAL CLINICAL STUDY REPORT
4. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS
5. ETHICS
6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE
7. INTRODUCTION
8. STUDY OBJECTIVES
9. INVESTIGATIONAL PLAN
10. STUDY PATIENTS
11. EFFICACY EVALUATION
12. SAFETY EVALUATION
13. DISCUSSION AND OVERALL CONCLUSIONS
14. TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT
15. REFERENCE LIST
16. APPENDICES

At the bottom, there is a note: "We will create the tables according to the SAP and Mockhell. Those main tables will go into the body of the report if you".

RECENT EVENTS

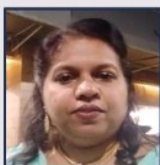
ACTIVITIES IN NETWORK MODE

Indian Society for Clinical Research (ISCR) conducted a virtual program on “Informed Consent in Clinical Trials” on 25th May 2024

are viewing Kishma Vinod's screen   View Opti

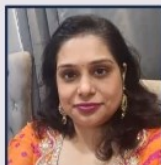


Introduction to Speakers



Kishma Vinod

Senior manager –
Clinical research &
Pharmacovigilance
Bharat Serums and
Vaccines Ltd.
12 years in CR including
Medical writing



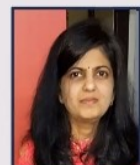
Smruti Limaye

Medical Writer
Zydus Life Sciences
14 years of
experience in
Medical Writing field



Jai Tilak-Jain

Associate Director,
Medical Writing
Syneos Health
17 years of experience
in Medical Publications
and Regulatory
Medical Writing



Jyoti Adnani

Expert Scientific
Writer
GSK -GCC
20 years experience
in medical writing
and safety writing

The views and opinions expressed in the presentation are those of the speaker and do not necessarily reflect the official policy or position of the individual organizations

RECENT EVENTS

Meeting updates from 1st March 2024 - 31st May 2024



Future plans

- Submission of Manuscript for the study titled: To Study the Effect of Patient Education on Knowledge Attitude and Practice (KAP) of diabetic foot care among type 2 Diabetic Mellitus Patients
- Submission of Manuscript for the 4th Interim Diabetes Registry Report

Upcoming events

- Continuation of Education module on cardiac metabolic disorder
- PM Monthly meeting on 5th June 2024 at 2:30 pm via Microsoft teams