

# BIRAC CTN - Diabetology

# Newsletter

Quarterly Newsletter : 05 (Mar 2022- May 2022)

## **Introduction**

The Clinical Trial Network for Hospital Based Trial in Diabetology constitutes Multi Centric Diabetic Registry across 7 sites in India which is functional from past 1 year. About 9500 participants across India have been enrolled for this study. This registry will collect details of patients with Type 1 and Type 2 Diabetes mellitus and generate real-time data from patients with diverse cultural and linguistic representations. This will help us to accurately gauge the trend pertaining to diabetes management within the country as well as to study the patterns followed by diabetic patients. The SOP, Protocol and Data Management system are in place to ensure uniformity across all the sites. High quality of data is guaranteed through quality management activities at site level and 1% of data examination by the lead site on monthly basis.

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# JOURNEY SO FAR

Events held : From March 1<sup>st</sup> 2021 to May 31<sup>st</sup> 2022

## Diabetes Registry

Data collection is progressing at all the sites in CTN- Diabetology Network. Data collected till 31<sup>st</sup> December 2021 has been considered for Interim report preparation and analysis where, 4,626 patients were found eligible for the study from all the sites in the network. Among them 3,271 (70.7%) patients are willing to be contacted in future for Clinical Trials and 3,957 (85.5%) patients agreed to share their details with Indian Biologic Manufactures for planning future Clinical Trials. The First interim report has been submitted to BIRAC on 16th March 2022. All the sites have notified the Interim report to their respective Ethics Committee. During the PMC meeting held on 21st April 2022, the Principal Investigator of each site in the network presented the progress of their respective sites and milestones achieved. The Interim report was also discussed in detail and recommendations were given.

- ♦ BIRAC Steering Committee Meeting held on 13th April 2022
- ♦ PMC meeting held on 21st April 2022
- ♦ BIRAC PI & PM Monthly Meeting held on 4th May 2022

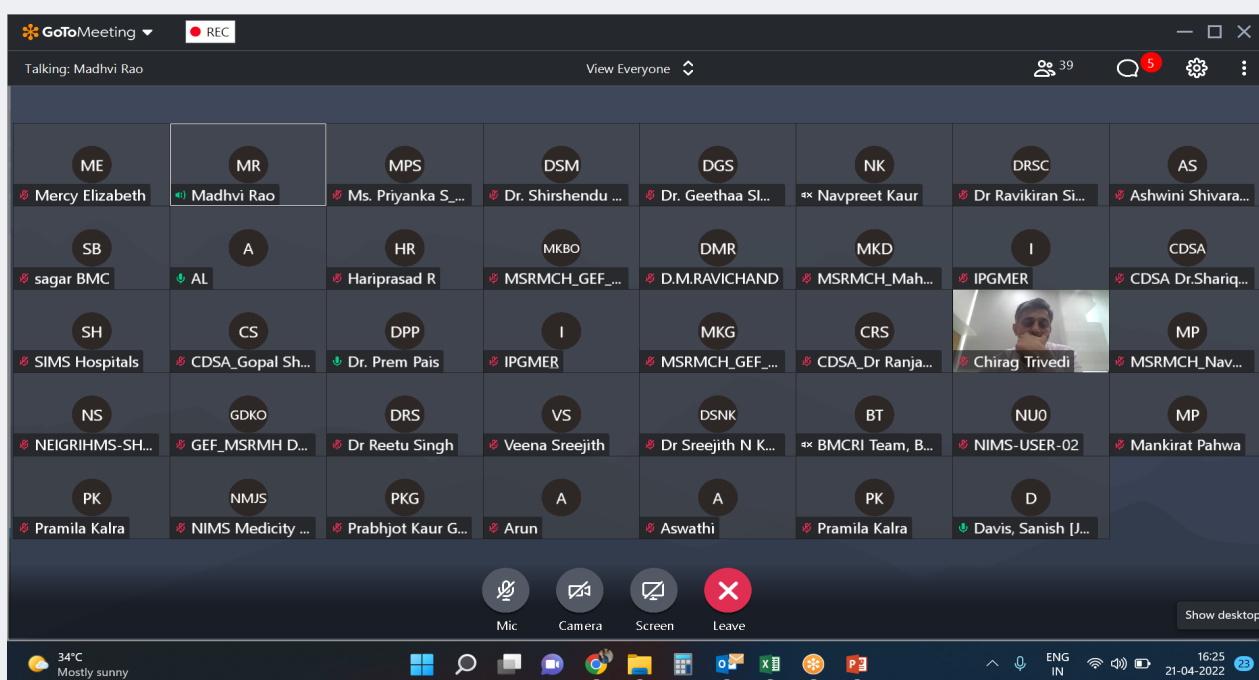
## **RECENT EVENTS**

### **Recommendations from PMC Meeting held on April 21<sup>st</sup>**

- ⇒ The CTN Diabetology network to develop a common slide set and pamphlet for patient awareness program.
- ⇒ An independent auditor for checking site readiness is not required, instead the sites can have a common checklist to assess the same. However, the committee suggested to have an auditor for auditing the registry process.
- ⇒ The sites should approach government funding bodies like ICMR, NIH and can do more outreach activities through forums like Indian Society for Clinical Research (ISCR). Sites can do clinical trials investigator - initiated studies or academic trials in partnership mode with other specializations within the institute for sustainability.
- ⇒ For publication and sharing the Registry report with pharmaceutical companies, the report should present at least 5000 patients to get meaningful data and detailed analysis, hence the interim report has to be revised.

# RECENT EVENTS

## Project Monitoring Committee Meeting on 21<sup>st</sup> April 2022



# RECENT EVENTS

On– Site SDV at M S Ramaiah Medical College and Hospitals by BIRAC on 17<sup>th</sup> and 18<sup>th</sup> May 2022



# RECENT EVENTS

On - Site SDV & Monitoring Visit at Victoria Hospital, Bangalore Medical College and Research Institute by BIRAC on 19<sup>th</sup>, 20<sup>th</sup> and 21<sup>st</sup> May 2022



# RECENT EVENTS

**Patient Awareness Program for Diabetes Patients Conducted at BMC on 21<sup>st</sup> March 2022**

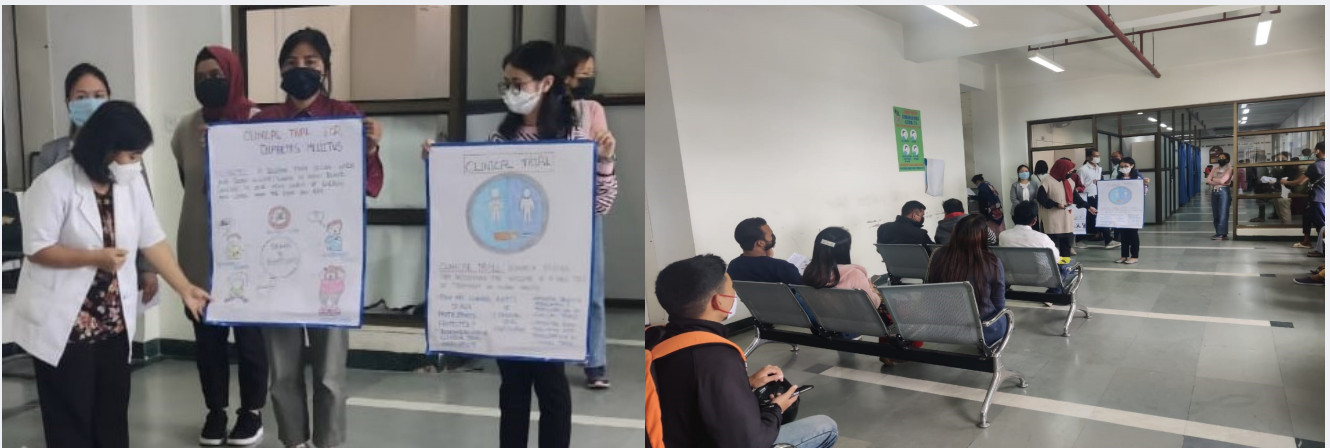


**Patient Awareness Program for Diabetes Patient Conducted at SGRDUHS on 6<sup>th</sup> May 2022 and 20<sup>th</sup> May 2022 ( as part of International Clinical Trial Day 2022)**



# RECENT EVENTS

**Patient Awareness Program** for diabetes patients Conducted at **NEIGRI-HMS** on 20<sup>th</sup> May 2022 as part of International Clinical Trial Day 2022



**Patient Awareness Program** for diabetes patients Conducted at **M S Ramaiah Memorial Hospital** on 21<sup>st</sup> March 2022 and 20<sup>th</sup> May 2022 ( as part of International Clinical Trial Day 2022)



# RECENT EVENTS

**Basic Life Support Training** was conducted for all the staff's at **NIMS** on 2<sup>nd</sup> March 2022



**Basic Life Support Training** was conducted for all the staff's at **NEIGRI-HMS** on 9<sup>th</sup> March 2022



# RECENT EVENTS

**Basic Life Support Training** was conducted for all the staff's at SSKM on 8<sup>th</sup> May 2022



## Future plans

- ⇒ Investigator Meet proposed to be conducted on 23<sup>rd</sup> & 24<sup>th</sup> of July 2022
- ⇒ To conduct On-site Quality Management activity for all sites by Lead site
- ⇒ Submission of Revised Registry Report to BIRAC by 10th June 2022

## Upcoming events

- ⇒ BIRAC - Diabetology CTN PM Monthly meeting for the month of June 2022 will be held on 1<sup>st</sup> June 2022 @ 2.30 pm via WebEx.
- ⇒ BIRAC - Diabetology CTN SAG Meeting will be held on 17<sup>th</sup> June 2022