

# BIRAC CTN - Diabetology

# Newsletter

Quarterly Newsletter : 03 (Sep - Nov) 2021

## INTRODUCTION

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BIRAC Diabetology CTN across all 7 centers in India is functioning well. All the sites are harmonized in terms of SOP, Protocol and Data Management system. Considering the fact that the target population at each site will be different, therefore implementing uniform program will not be practical. Hence it was decided to conduct the Patient awareness program conducted independently at individual sites in the network. The intent of the program is to bring awareness about Diabetes mellitus & its complications among people and to emphasize the need to take part in Clinical Research.

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# JOURNEY SO FAR

Events held : From September 1<sup>st</sup> to November 30<sup>th</sup>

## Diabetes Registry

All the sites of BIRAC CTN Diabetology have started collecting data from the patients who are known case of Diabetes Mellitus as per ADA Guidelines. SOP for the Registry has been finalized after taking inputs from all the sites and circulated among all sites. The training of the Registry SOP has been completed at all the sites. First Interim report of the Registry will be submitted by mid of January, Data entered in the Indian CST software till 31<sup>st</sup> December 2021 will be considered for the analysis and report preparation.

### Enrollment status at each site

Patient enrolled till 30<sup>th</sup> Nov 2021/ No of Patients data entered on Indian CST software

MSR: 693/659

SSKM: 240/202

BMC: 297 /285

NIMS: 757/720

NEIGRIHMS: 430/421

SIMS: 559/534

SGRDUHS: 392/387

## Registry software

Data entry portal for the Registry has been finalized by Indian CST. The major backlog of data entry in Indian CST software was completed by all the sites and moving forward, it will be an ongoing process.

## **Quality Management Activities**

In accordance with the protocol, Standard Operating Procedure and the Quality Management Plan, the Quality Management Activities are being conducted by the lead site for all the collaborating sites. The purpose of this Quality Management Activity is to verify the compliance with the protocol, verifies data accuracy and completeness, ensures protection of rights of the participants and adhere to the Good Clinical Practice Standards along with the regulatory requirements. This activity is commenced in the month of September 2021 and is a continuous process in which the site master file (once in six months), 1% of Data Collection Form (Every month) is reviewed and reports for the same is generated and shared by the lead site.

## **Patient Awareness Program**

As part of our third Objective, “To make the sites ready for clinical trial conduct”, Patient awareness program is being conducted across the sites in CTN Diabetology. The mode of conducting the awareness program is decided by the individual sites according to their requirement and need. The Patient Awareness program is conducted at three sites.

1. The lead site GEF MSRMCH Bangalore has conducted Focus group discussion and distributed pamphlets about trial awareness on 15<sup>th</sup> November 2021.
2. SGRDUHS, Amritsar site has conducted a Focus group discussion for the diabetes patients on 26<sup>th</sup> Nov 2021.
3. NIMS, Trivandrum conducted awareness class, on 14<sup>th</sup> November

# Photographs of Patient Awareness Program conducted at different sites

**Focus group discussion and Distributing pamphlets on the occasion of World Diabetes day at Gokula Education Foundation, M S Ramaiah Medical College and Hospitals, Bangalore**





# Photographs of Patient Awareness Program conducted at different sites

Focus group discussion for the diabetes patients at Sri Guru  
Ram Das University Of Health Sciences, Amritsar





# Photographs of Patient Awareness Program conducted at different sites

**Awareness Class at Diabetes Care Center, Noorul Islam Institute  
of Medical Science and Research Foundation Trivandrum**



## RECENT EVENTS

BIRAC - Diabetology CTN Project Managers Monthly meeting was held on 1<sup>st</sup> Sep, 7<sup>th</sup> Oct 2021 and PM & PI sync up meeting was held on 10<sup>th</sup> November 2021

### PMC - Meeting

Third Project Monitoring Committee (PMC) meeting organized by BIRAC was held on 30<sup>th</sup> September, 2021. The recommendation from experts includes;

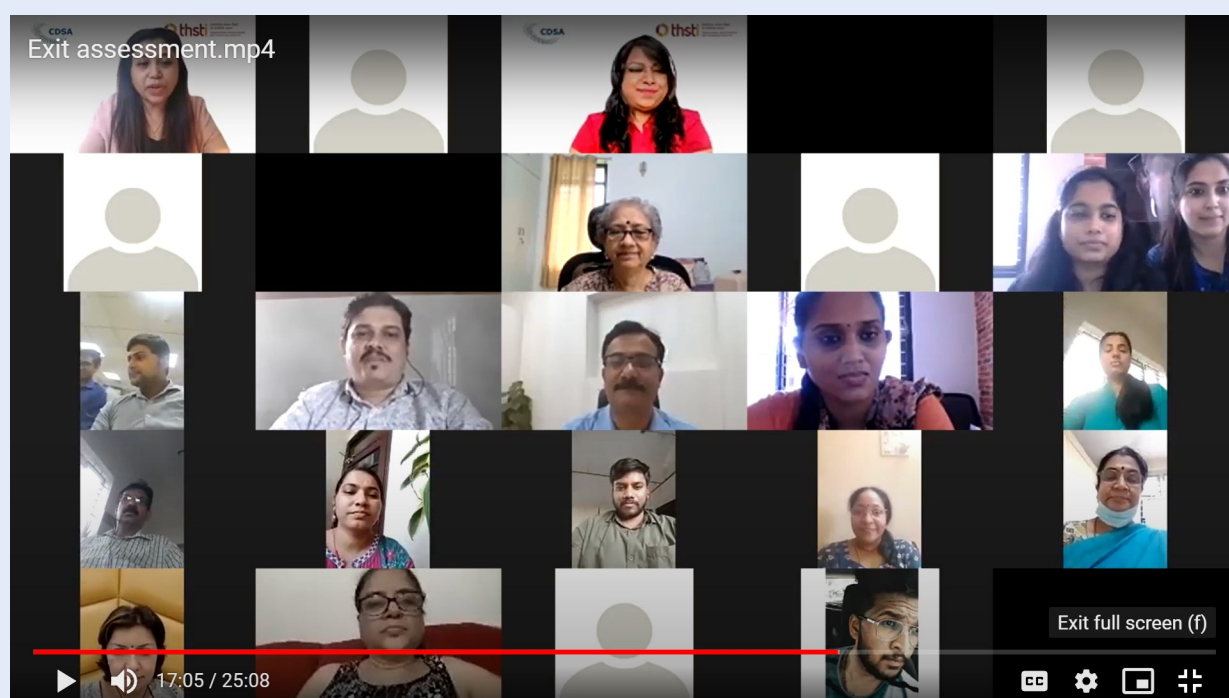
- ♦ Timeline for completion of data entry and in the Online portal to avoid too much of backlog - **Completed**
- ♦ Data management plan on data entry, validation and analysis should be in compliance with SOP, and keep uniformity across sites - **In place**
- ♦ To include more centers from different areas of India in future to spread the network and to get NABL accreditation or MoU with NABL accredited lab in all the sites - **Noted**

BIRAC CTN Diabetology- Steering committee and SOP & Training Committee meeting held on 21<sup>st</sup> Oct 2021. There were an update on change of designation, The Principal Investigator of Lead site, Dr. Mala Dharmalingam has been superannuated from the institution therefore, Co-I Dr. Pramila Kalra has been appointed as the PI & the same has been approved by BIRAC.

## BIO-ETHICS training by CDSA

CDSA in collaboration with NBM organized an online training program on Bioethics/ethical considerations. Training was for Investigators, research staff, Ethics Committee members and secretariat. The trainings were conducted on August 27, September 03, September 17, 2021.

The objective of the training was to keep participants abreast of introduction to research Ethics code of conduct, Ethics, guidelines, law, international guidelines, etc. All the sites in the CTN Diabetology actively participated in the training.



## FUTURE PLANS

- ⇒ Preparation of first interim Report

## UPCOMING EVENTS

- ⇒ BIRAC - Diabetology CTN PM Monthly meeting on 1st Dec 2021 @ 2.30 via WebEx.
- ⇒ Quality Management activity for all sites by Lead site tentatively scheduled on 22nd Dec 2021.