



NEWSLETTER

BIRAC CTN - DIABETOLOGY

Issue 1 | June 2021

Greetings From Bengaluru Gokula Education Foundation..!

We are happy to present first newsletter of the BIRAC CTN - Diabetology.

SITES WITH NAMES OF PI AND PM

Site Name	Principal Investigator	Project Manager
Gokula Education Foundation_ M.S. Ramaiah Medical College and Hospitals, Bengaluru	Dr. Mala Dharmalingam	Dr Reetu Singh
Victoria Hospital (Bangalore Medical College), Bengaluru	Dr. K.R. Raveendra	Mr Hariprasad R
North Eastern Indira Gandhi Regional Institute Of Health And Medical Sciences, Shillong	Dr. Prasanta Kumar Bhattacharya	Ms Melinda Nongbet Sohleng
Sri Guru Ram Das University Of Health Sciences, Amritsar	Dr. Gurinder Mohan	Dr Richa Thaman

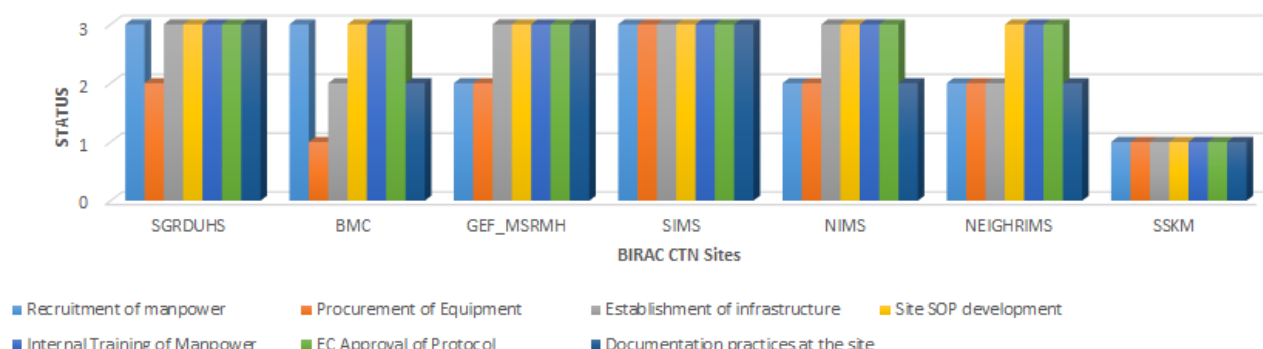
Institute Of Post Graduate Education And Research, SSKM Hospital, Kolkata	Dr. Sujoy Ghosh	_____
Noorul Islam Institute of Medical Science and Research Foundation (NIMS Medicity), Trivandrum	Dr. Sreejith. N. Kumar	Ms Jasmin Sheejas
Sri Ramaswamy Memorial (SRM) Institute for Medical Sciences Chennai	Dr. Ravi Kiran M	Dr Vedantha Srinivas J

CAPACITY BUILDING

SOP Harmonization	Completed by all sites except SSKM, Kolkata
Development of Training modules & Training of manpower on GCP	Amritsar has taken the lead. Three half day workshop was conducted by CDSA, on 27-4-2021, 04-5- 2021 & 11-5-2021. GCP training completed for all site in the CTN -Diabetology including Ethics Committee member.
Gap Analysis	Gap analysis was done by lead site, and the necessary action is taken at respected site level.

Site activities update chart

Completed - 3
Partially completed -2
Incomplete -1



Sites and Responsibilities		REGISTRY PROTOCOL	
Registry	GEF_MSRMCH, Bengaluru	Protocol for Hospital based Multi Centric Diabetes Registry	Common protocol for all the sites in the network has been prepared along with Informed Consent form, Data Collection form and Statistical Analysis Plan.
SOP	SRM, Chennai		
Training	SGRDUHS, Amritsar		
CTRI REGISTRATION The protocol has been registered under CTRI on 15-04-2021 and have received approval for same. CTRI registration number for this protocol is CTRI/2021/04/032847. As per CTRI It is mandatory to update the status of the study in every 6 months.		Tool validation	Experts from different part of country have validated data collection form
		EC-DHR Registration status	Sites registered with DHR: <ul style="list-style-type: none"> • GEF_MSRMCH (Bengaluru), • NIMS Medicity (Trivandrum) • SIMS (Chennai) • NEIGRIHMS (Shillong) Sites yet to register with DHR : <ul style="list-style-type: none"> • SSKM (Kolkata) • SGRDUHS (Amritsar) Site registertion rejected with DHR: <ul style="list-style-type: none"> • BMC (Bengaluru)
		Protocol-EC approval status	All sites have received EC approval for protocol except SSKM Kolkata.
		Pilot run	To check the feasibility of the study GEF_MSRMCH Be have kick started pilot run on 23/04/2021 with a sample size of 30.

SOFTWARE FOR REGISTRY

A common vendor (ICST) is identified by network for developing software for this registry.

Key Dates

- Scientific Advisory Group meeting will be held on 02-06-2021
- PM Sync up meeting will be held on 09-06-2021.
- Steering committee meeting will be held on 14-07-2021.
- PI & PM Sync up meeting will be held on 04-08-2021

Announcements

- BIRAC clinical trial network will be releasing a Newsletter once in every 3 months to keep updated on events

Photographs of online GCP training for Clinical Trial Network Diabetology organized by CDSA in collaboration with NBM

