

NPAC India Study Newsletter



17 December 2024 ♦

A WORD FROM THE PRINCIPAL INVESTIGATOR

Dear NPAC India Family,

Greetings to all of you. Happy to communicate with you all through the inaugural edition of the National Pregnancy and Cardiac Disease of India Study (NPAC INDIA STUDY) Newsletter!

It is so exciting to know how far we have forward together during in this, brief period.

Thank you so much for being a part of the NPAC- India family to come alongside with us for this noble work. We would like to express our heartfelt gratitude each and every one of you, for your amazing support and participation in the study.

The study is invariably going to expand our understanding and widen our knowledge in the field of pregnancy and cardiovascular disease.

With your support we can achieve our ultimate goal of improving maternal and fetal outcomes in pregnant women with heart disease, thereby helping to lower maternal mortality in our nation.

We will periodically send status updates, opportunities, reminders and special announcements pertaining to the trial through the subsequent newsletters. Looking forward for a closer and more efficient collaboration with you all.

**Yours truly,
G Justin Paul**

In this newsletter
you can expect:

*Updates on the
study*

*Funds and Project
technical support
details*

*Online web portal
and CRF details*

*Participant
Enrolment status*

*Planning updates-
timelines*

ABOUT THE STUDY

The NPAC-India study, funded by the Indian Council of Medical Research (ICMR), officially commenced on June 1st, 2024. Participant enrollment for the study began on July 1st, 2024.

UPDATES ON THE STUDY

Project Technical Support -1 Appointment & training:

As of now, 44 sites have successfully appointed the Project Technical Support-1. To ensure effective contribution to the study, the Central Coordinating team has been providing regular training sessions to all appointed PTS

CRF booklets:

The case report forms (CRFs) for the NPAC study were dispatched to all participating sites via courier on October 28, 2024.

Sites requiring additional CRF booklets for data entry can utilize the allocated funds under the contingency head to print more copies. We will provide the CRF print file to these sites that enable clearer reprints.

Data Management and Verification Process:

- To facilitate data management and verification, each participating site has been assigned a study-specific Gmail account. The Google Drive folder for all sites is arranged uniformly and its managed by the site investigators. Drive is used for online source data verification process.
- We've created a dedicated WhatsApp group for each participating site, connecting members, including Investigators (Cardiology and OBG), Research staff, PTS involved in patient care and follow-up. This group facilitates local coordination within and between departments.

FUNDS

The sanctioned funds for the first year of the NPAC-India study have been disbursed to all participating sites in two instalments.

Online data entry portal:

Our web portal www.npacindia.in is ready for data entry.

Logins:

We have provided a total of 5 logins for the Web Portal for each of the participating sites:

- 3 logins will be for Data entry- one for Cardiology department, one for Obstetrics department and one for PTS of each site
- 2 logins will be for Admin Logins - for diagnosis and outcome Data verification and approval, one for the Cardiology investigator and one for the Obstetrics investigator of each participating site.

Tips: We have sent the login credentials to the designated email addresses provided by each site. We kindly request that you initiate online data entry promptly upon receiving the notification from our Central Coordinating team. To ensure accurate and chronological records, please start data entry with the first enrolled patient at your site and proceed sequentially to the most recent.

Note: Following the launch of the NPAC application, we kindly request that all investigators ensure that data from previously enrolled patients is accurately updated in the web portal.

Participant Enrolment status

Enrollment update as of October 2024

As of October 2024, 1,000 participants have been enrolled in the study across 48 participating sites. We extend our sincere gratitude to all investigators and site staff for your tireless efforts.

To ensure data integrity, we kindly request that you:

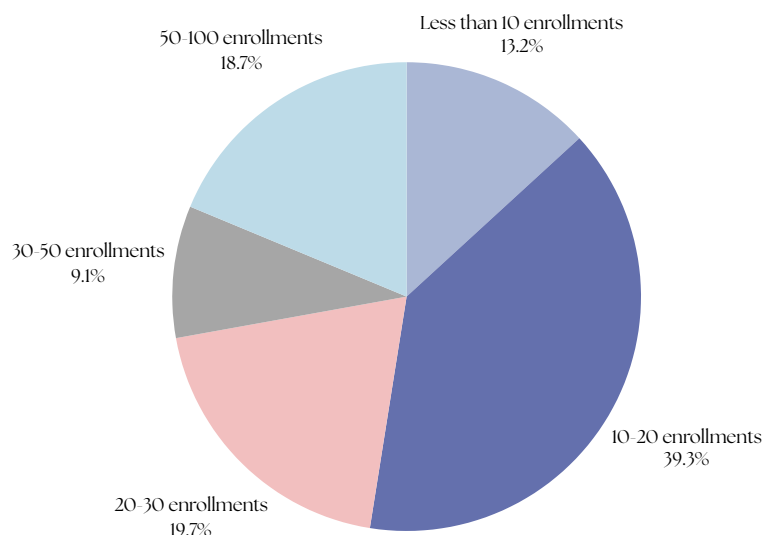
- Regularly update the CRF booklet with patient information to avoid missing data.
- Ensure that lead investigators from OBGYN and Cardio departments sign in the designated areas of the CRF form.

Below is the enrollment breakdown from our member sites:

- **50-100 enrollments:** GRH, CGM
- **30-50 enrollments:** GBP, KEM
- **20-30 enrollments:** RNT, TMC, AND, VMM, SIK, GAU
- **10-20 enrollments:** BMC, ATR, HIM, GMC, STN, GSV, ANP, BMW, GOA, SPM, SMS, ARP, NIM, GMK, ARK, PGH, CML, PJN, SGP, AMC
- **10 enrollments:** JIP, NHL, KMC, SGH, JNW, CIH, MGM, CMV, AJP, APN, AIC, DMC, SCB, MKC, GAP, KGM, AKC

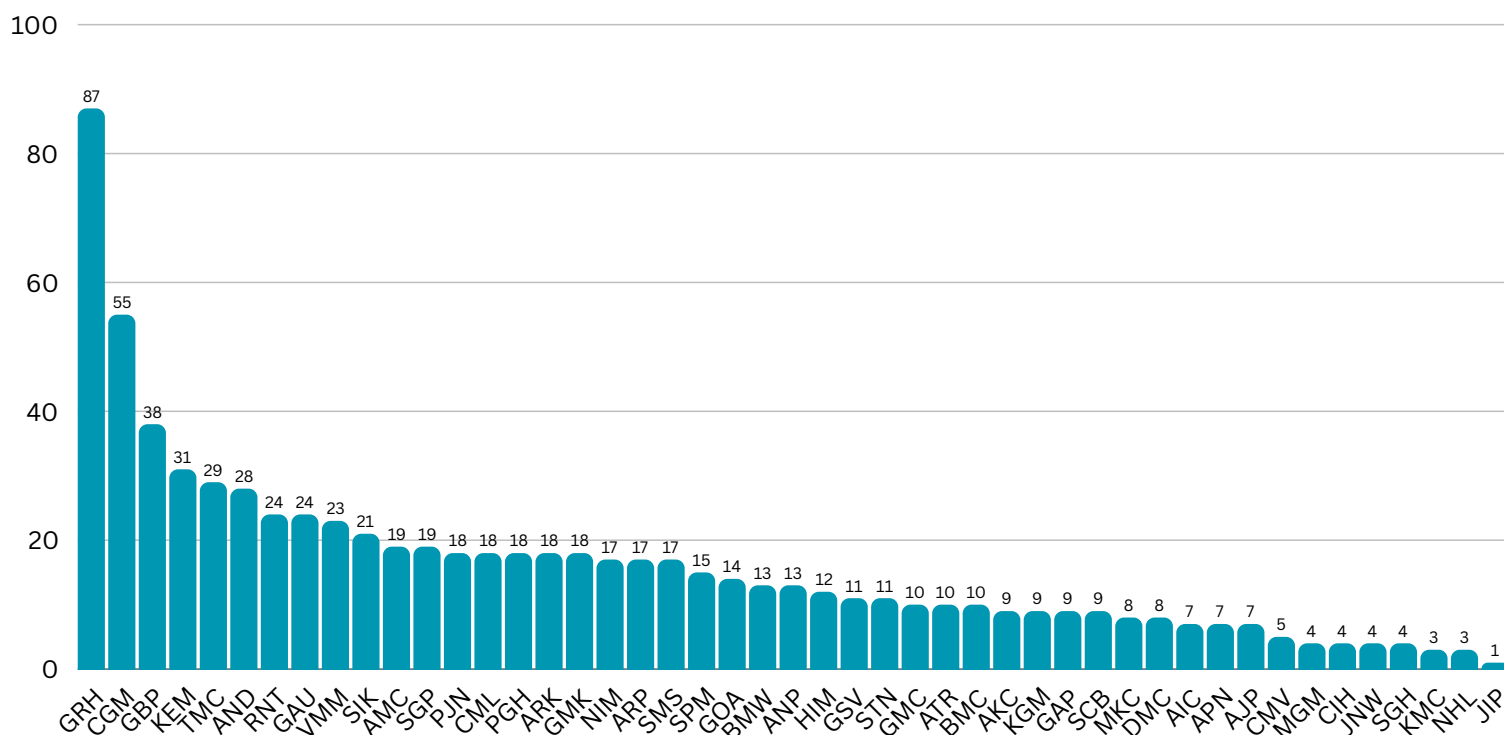
THE FOLLOWING SITES ARE YET TO START ENROLLMENT:

- PATNA MEDICAL COLLEGE
- OSMANIA MEDICAL COLLEGE



SINCERE APPRECIATION TO THE SITES FOR THEIR OUTSTANDING PERFORMANCE IN ENROLLING MORE THAN 20 PARTICIPANTS IN JUST FOUR MONTHS.

■ Number of enrollment



PLANNING UPDATE-TIMELINES

As we reach the five-month milestone of the NPAC-India study, which commenced on June 1, 2024, and four months into participant enrolment starting July 1, 2024, we urge you to intensify patient recruitment efforts.

With only seven months remaining to complete the first 12 months of the study, we kindly request that you enroll all eligible patients registered at your institution.

Note: Request for Enhanced Enrollment Efforts

Important Reminder: Cluster Randomization Phase Requirement

As a reminder, to be considered for inclusion in the cluster randomization phase, each site must demonstrate the ability to enroll a minimum of 60 patients per year. We kindly request that all sites intensify their enrollment efforts to meet this requirement.

Strategies to Enhance Patient Enrollment:

To support improved referral rates, we suggest organizing cardio-obstetric awareness programs and camps. These initiatives can help increase referrals from neighboring medical officers and hospitals. If you require assistance in enhancing patient enrollment, please do not hesitate to contact us. We are committed to providing support to ensure the success of the NPAC study.

Thank you for continuous cooperation and support

IN CASE OF ANY QUERIES PLEASE GET IN TOUCH WITH THE NPAC CENTRAL HEAD QUARTERS, CHENNAI.

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