

# NPAC INDIA<sup>®</sup>

## Study Newsletter

ISSUE #2

APRIL 14<sup>TH</sup> 2025



### A Word from the Principal Investigator

Dear NPAC India Study Team,

It gives me great pleasure to connect with you all through the second issue of our NPAC India Study Newsletter. As you all know this study represents our shared commitment to improving the lives of pregnant women with cardio-vascular diseases in India.



Every milestone we achieve is a testament to your dedication and teamwork. Your hard work, from patient enrollment to careful data entry and follow-ups, is shaping the future of maternal cardiac care. I truly appreciate your efforts and encourage you to keep striving for excellence.



Let's continue this journey with the same enthusiasm and dedication. Together, we are making a difference!

Warm regards,

**Dr. G. Justin Paul**

*In this newsletter you can expect:*

Investigators 's Meeting Highlights

New Site Announcements

Site monitoring updates

ICMR Review Visit

Performance & Data Updates

Upcoming Plans & Reminders

# UPDATES ON THE STUDY

## 1st Quarter Investigator's Meeting - 30<sup>th</sup> January 2025 :

- **Members Present:** 166 members attended the meeting (110 Site Investigators, 43 PTS-I, 7 NPAC HQ members, 6 Core Investigators)
- **Study enrollment:** Current enrollment status across all sites was reviewed and discussed. Importance of consecutive and complete enrollment was stressed upon.
- **Online Data entry:** Investigators were requested to enter data in real time, without delay.
- **Primary Composite Outcomes:** The currently observed primary outcome rate is 8%. This is less than half of the anticipated outcome (18%) rate. This can affect the power of the study. Some sites with very high enrollment have reported very few study outcomes, suggesting possible gaps in documenting outcomes. Accurate outcome documentation is vital to validate the study hypothesis and assess intervention impact. Hence investigators are requested to be vigilant and capture every single study outcome.
- **Postnatal Follow up:** Most study outcomes occur in the postnatal period, as per earlier data. Hence complete postnatal follow up is critical to maintain data integrity and support the study's objectives. If the patient is unable to come in person, telephonic follow up is accepted for 6 months postnatal follow up. Multiple telephonic calls, postcard reminders and home visits, may be undertaken for follow up. Kindly coordinate with the NPAC headquarters to facilitate follow-up of patients who have relocated to other states.
- Site-specific operational challenges were identified and addressed.

## Appreciation Awards for October 2024 to March 2025:

Special Appreciation awards for the PTS-1 was presented based on a structured evaluation, each Zone Coordinator ranked their respective PTS using the following criteria: Punctuality, Timely Communication, Coordination, Quality of Work, Workload Management, Overall Involvement.

*Congratulations to the top-performing  
PTS for their dedication and  
excellence!*



**Mr. Goga Anil-** Guntur Medical College, Guntur  
**Mr. Mohammad Ismail Soban-** HIMS, Hassan  
**Ms. Adithi Mishra -** GSVM Medical College, Kanpur  
**Ms. Poorvi Verma -** AIIMS, Jodhpur  
**Mr. Suman Hazra -** Burdwan Medical College, Burdwan  
**Ms. Kangakana Kalita-** Gauhati Medical College, Guwahati  
**Ms. Debatta Pattanaik-** SCB Medical College, Cuttack  
**Ms. Gargi Tyagi-** AIIMS, Rishikesh

## Setting the Standard for Patient Tracking:

**Andhra Medical College** is appreciated for *ensuring 100% follow-up* for all enrolled patients—going as far as *conducting a home visit* for a missed case. This proactive effort by *PTS-1 Mr. Madhu Narayana Rao Kottaki* reflects exemplary dedication to patient care and data integrity. We encourage all sites to strive for similar excellence.

## Innovative Site-Level Outreach Initiatives:

**Christian Medical College, Vellore** has created *NPAC awareness pamphlets* and designed *NPAC stickers* to be affixed on Echo reports, helping supervisors and PTS staff easily *identify enrolled pregnant women* with cardiac conditions.

**PI- Dr. Sowmya Sathyendra (Obstetric Medicine)**

**AIIMS, Jodhpur** has a *dedicated phone number* for the NPAC Study and distributes *visiting cards and pamphlets to nearby hospitals* encouraging referrals and boosting patient enrollment.

**PI- Dr. Surender Deora (Cardiology)**

These thoughtful initiatives reflect the dedication of both sites to strengthen the study's visibility and impact.

## ANNOUNCEMENT!

**We're happy to welcome six new non-funded sites to the NPAC India Study Team!**

- All India Institute of Medical Sciences, Bathinda
- All India Institute of Medical Sciences, Bhubaneswar
- Institute of Medical Sciences, Banaras Hindu University, Varanasi
- Institute of post graduate medical education and research, Kolkata
- Rajendra Institute of Medical Sciences, Ranchi
- U N Mehta Institute of Cardiology and Research Center, Ahmedabad

## Site Monitoring Visits

Site Monitoring Visits (SMVs) were conducted at **GOA, BMC, IPG, and KMC** with objectives of strengthening engagement with headquarters, understanding site-specific needs, evaluating performance, and ensuring adherence to the study protocol. These visits played a critical role in reinforcing site involvement, improving data quality, and supporting the effective implementation of the NPAC India Study.

While the dedication and hard work of the site teams were duly acknowledged and appreciated, several key challenges were noted:

1. Incomplete documentation of outcomes
2. Difficulties in ensuring timely follow-up
3. The need for stronger interdepartmental coordination
4. Incomplete or inconsistent data entry

Pro actively addressing these areas will be crucial for enhancing site performance and safeguarding the overall integrity of the study.

19TH MARCH 2025



INSTITUTE OF POST GRADUATE MEDICAL  
EDUCATION AND RESEARCH, KOLKATA



GOA MEDICAL COLLEGE

13TH MARCH 2025

13TH MARCH 2025



BENGALURU MEDICAL COLLEGE

19TH MARCH 2025



KOLKATA MEDICAL COLLEGE

## ICMR Site Review meeting at the Central Coordinating Site - Madras Medical College (MMC)

MARCH 25TH 2025



The following ICMR members visited the Central Coordinating Site - **Madras Medical College** on **March 25-26, 2025**.

- **Dr. Beena Joshi** - Scientist G, NIRRH, Mumbai
- **Dr. Amarjeet Singh** - Ex HOD Comm. Medicine - PGI
- **Dr. Khushwant Singh** - ICMR Consultant, Division of Implementation Research
- **Dr. Saurabh Sharma** - Scientist D Delivery Research Division, ICMR

The visit focused on reviewing **patient enrollment, outcomes, site-wise challenges, and future timelines**. Discussions also included key administrative aspects of the study. The team also visited nearby collaborating sites — IOG, Egmore and KGH Hospitals — to review infrastructure and facilities, ensuring readiness and support for ongoing study activities.

MARCH 26TH 2025





# STUDY ENROLLMENT UPDATES (AS OF MARCH 31ST)

## Site Enrollment :

As of March 31st, a total of **2,189 patients** have been enrolled across all participating sites.

**More than 50 enrollment** - VMM, AND, GBP, GSV, KEM, GMK, CGM, GRH, BMC, MMC, TMC

**41-50 enrollment** -GAU, SGP, JIP

**31-40 enrollment** - PGH, SIK, NIM, SCB, PJN, GOA, GAP, CMV

**21-30 enrollment** - RNT, AJP, SPM, SMS, CML, STN, BMW, GMC, ARP, ARK, KGM, ANP, AKC, ATR, HIM, AMC, UNM

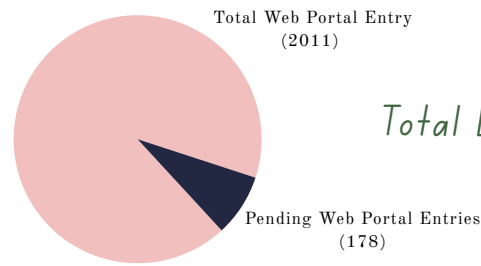
**11-20 enrollment-** DMC, SGH, APN, MKC, KMC, MGM, AIC, BHU, IPG

**Below 10 enrollment** -CIH, JNW, ABO

A **special appreciation** to sites that have crossed **50 enrollments within 8 months** of study for their outstanding efforts.

We also acknowledge the **continued commitment of all other participating sites** for their proactive steps in enhancing patient screening and enrollment.

The newly added non funded sites - ABO, BHU, UNM and IPG has initiated enrollment process at their sites. The sites ABN and RIM will start enrolling participants shortly.



*Total Enrolment: 2189*

## NPAC Web Portal Entry.

Since the launch of the NPAC Web Portal on November 1st, 2024, it has made significant strides, **with 2,011 patient records successfully entered** as of March 31st, 2025.

This reflects the commendable efforts of our dedicated participating sites across India. Currently, only **8.1%** of enrolled patient data remains to be updated — a gap we're confident can be bridged with continued focus and collaboration.

Achieving 100% online data entry remains a key study objective, enabling real-time monitoring, enhancing data accuracy, and driving efficient study outcomes.

Let's continue this momentum and work together toward complete and timely data capture.

## Upcoming Events/Reminders

- We are actively gathering responses for the **Care Process Questionnaire** to assess the infrastructure and available facilities across all participating sites. A heartfelt thank you to all the sites that have responded with such enthusiasm
- A gentle nudge to sites yet to submit the Utilization Certificate—let's get it done!

### **MARK YOUR CALENDARS!**

We are pleased to inform you that the **In-Person Investigator's Meeting of the NPAC India Study** is scheduled to be held on:

**May 23rd & 24th, 2025 at New Delhi.**

*Your presence is highly valuable as we review the study's progress, discuss key updates, and plan the way forward together.*

*Thank you for continuous cooperation and support*

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

National Coordinating Center

Cardiovascular Research Unit, First Floor, Institute of Cardiology,  
Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai.  
Website: <https://www.npacindia.in>; Email: [npacindia2023@gmail.com](mailto:npacindia2023@gmail.com) Ph: 9884073616