

# ANISA

MOVING FORWARD



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Published in  
**October 2012**

Published by:  
**CHILD HEALTH RESEARCH FOUNDATION  
DEPARTMENT OF MICROBIOLOGY  
DHAKA SHISHU HOSPITAL  
BANGLADESH**

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# AETIOLOGY OF NEONATAL INFECTION IN SOUTH ASIA



# ANISA MOVING FORWARD

## The first year of surveillance

The ANISA project has now reached one year of surveillance. The mission was challenging but the team has navigated it successfully with magnificent support from all our affiliates, including the site teams, TAG members, CDC group and BMGF. This publication will briefly sketch out how the ANISA team established and is currently maintaining the population-based surveillance system to detect the aetiology of neonatal sepsis in South Asia.

### NIAGARA, CANADA

20-22 Oct 2011

**2nd**  
investigators  
meeting

Discussion about the challenges of initial implementation at the sites, finding solutions and exploring the ways of improving ANISA further.



**1st**  
investigators  
meeting

**COX'S BAZAR,  
BANGLADESH**

6-7 Dec 2010

Finalization of project structure,  
methodology and implementation  
plan.

**3rd**  
investigators  
meeting

**PHUKET, THAILAND**

23-25 Oct 2011

Mid-project retrospective, first look  
at data from sites, defining  
strategies for further improvement  
and planning for the final year.

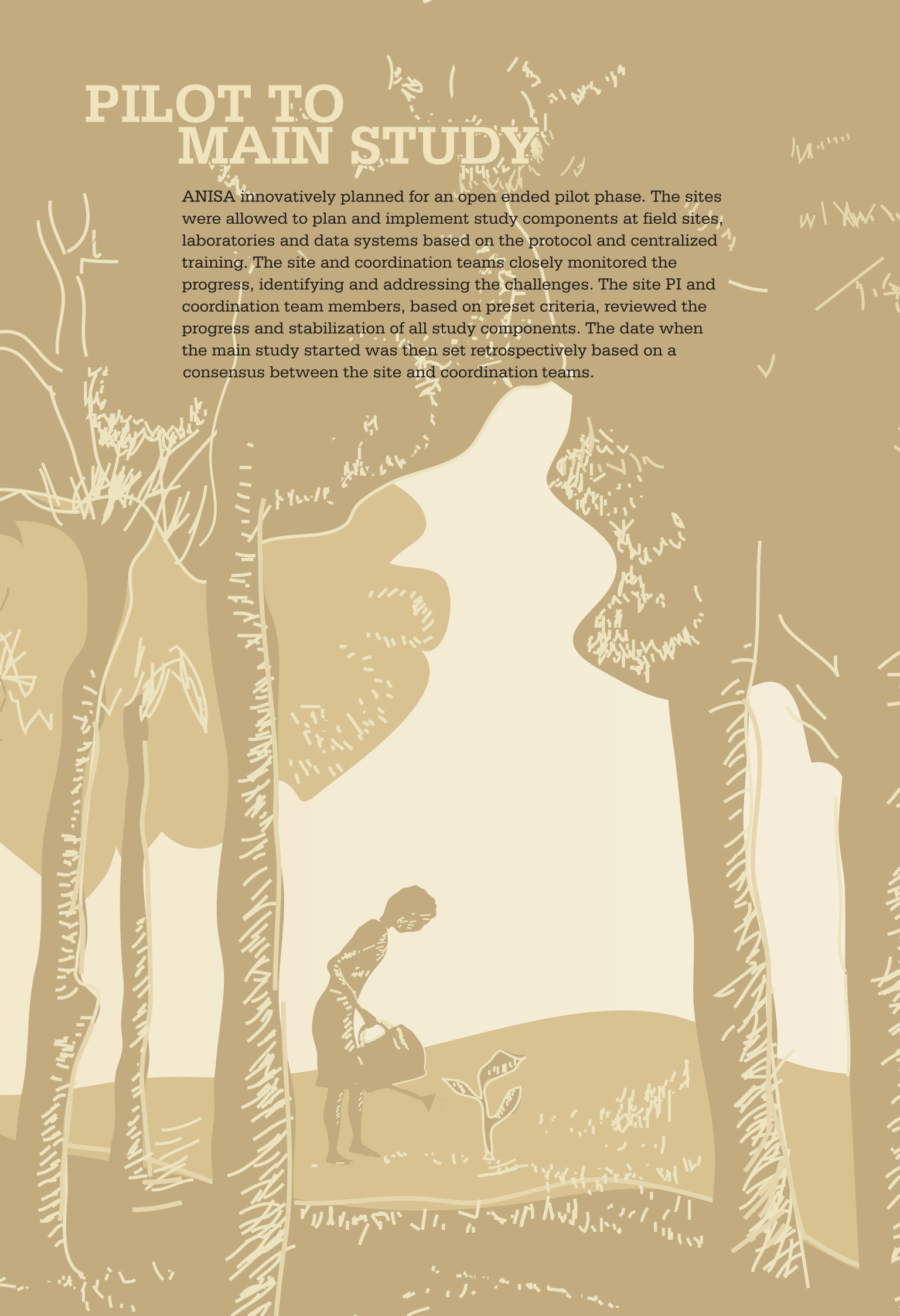
# Tools and steps for implementation of surveillance

1. Mapping and listing of households
2. Development of SOP and translated data forms
3. Establishment of real time data upload
  - i. Programming and refinement of data system, establishment of network
  - ii. Real time registration of enrolled newborns, identification of sepsis cases & simultaneous algorithm based selection of healthy controls
4. Recruitment and training of study staff to facilitate standardized application of project protocol across sites.
5. Establishment of appropriate specimen collection, transportation preservation and tracking procedure.
6. Establishment of standardized microbiological and molecular test procedures.

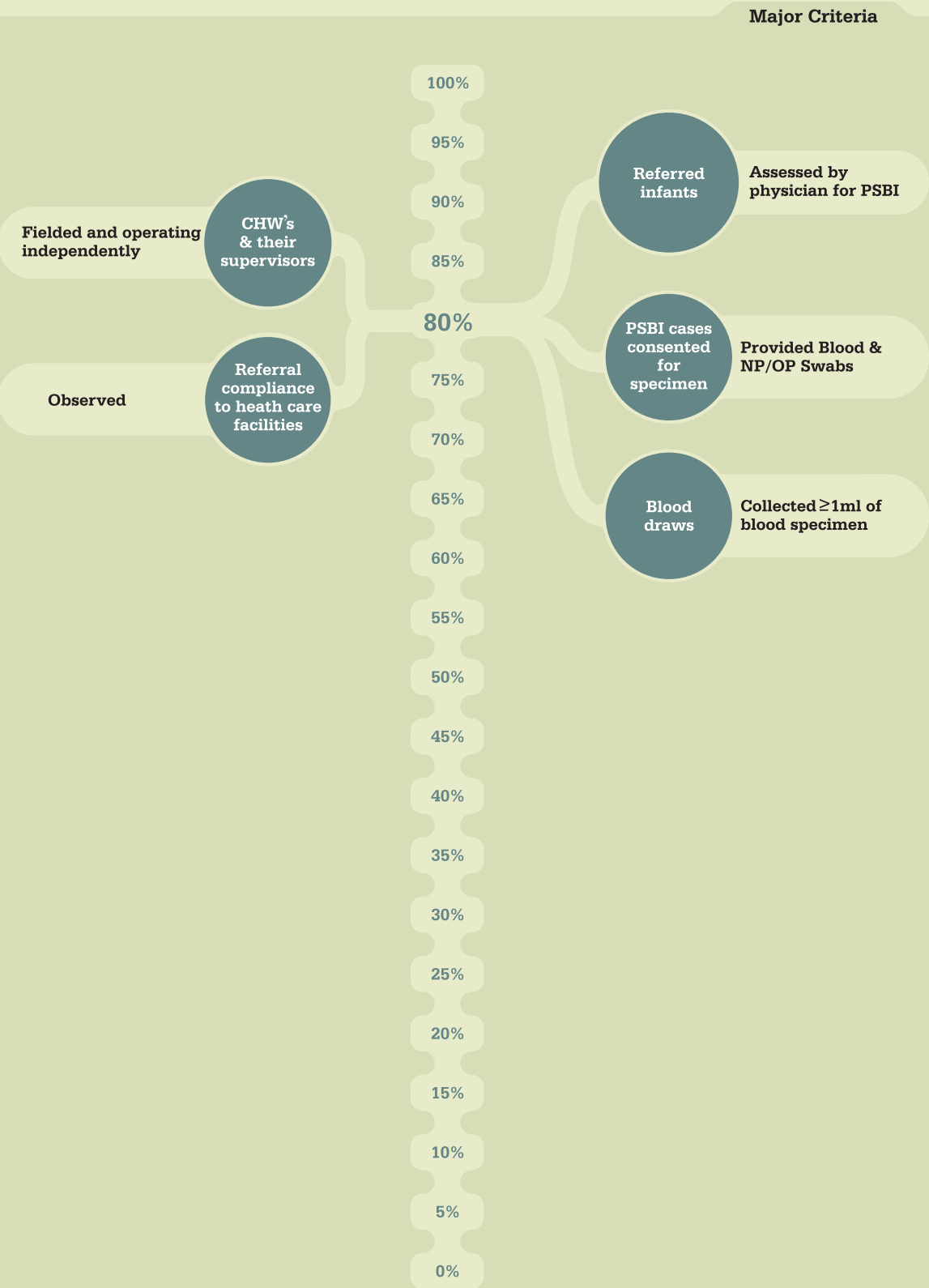


# PILOT TO MAIN STUDY

ANISA innovatively planned for an open ended pilot phase. The sites were allowed to plan and implement study components at field sites, laboratories and data systems based on the protocol and centralized training. The site and coordination teams closely monitored the progress, identifying and addressing the challenges. The site PI and coordination team members, based on preset criteria, reviewed the progress and stabilization of all study components. The date when the main study started was then set retrospectively based on a consensus between the site and coordination teams.



# Criteria of Graduation

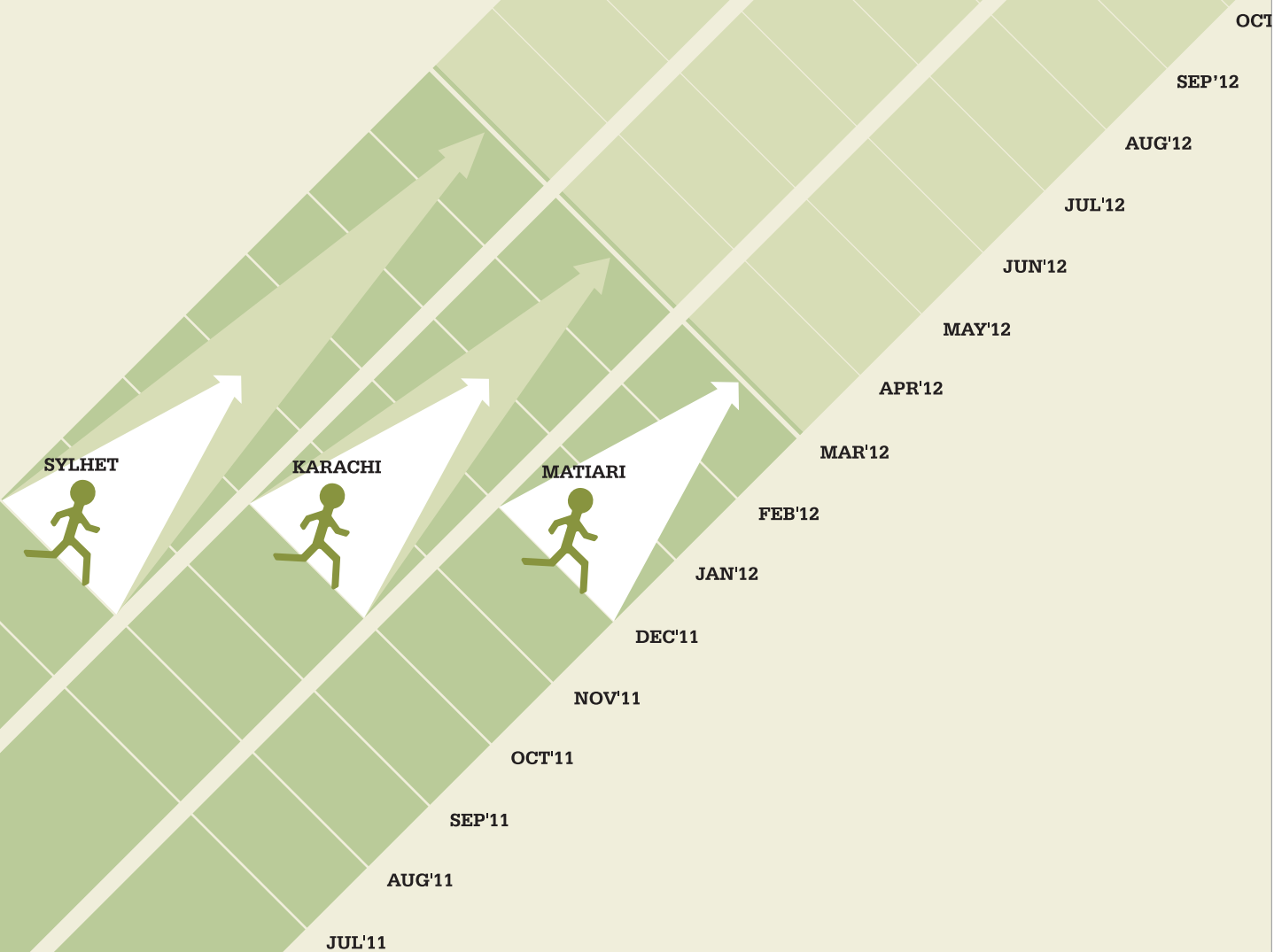


## Other Criteria

1. Successful blood cultures accomplished and results reported to treating physicians at real-time.
2. Data collections on ANISA data forms and subsequent management is working well.
3. The lists of detected bacteria are shared with the coordination centre periodically.
4. Healthy controls are assigned using the automated selection algorithm.



# Graduation of sites into main study



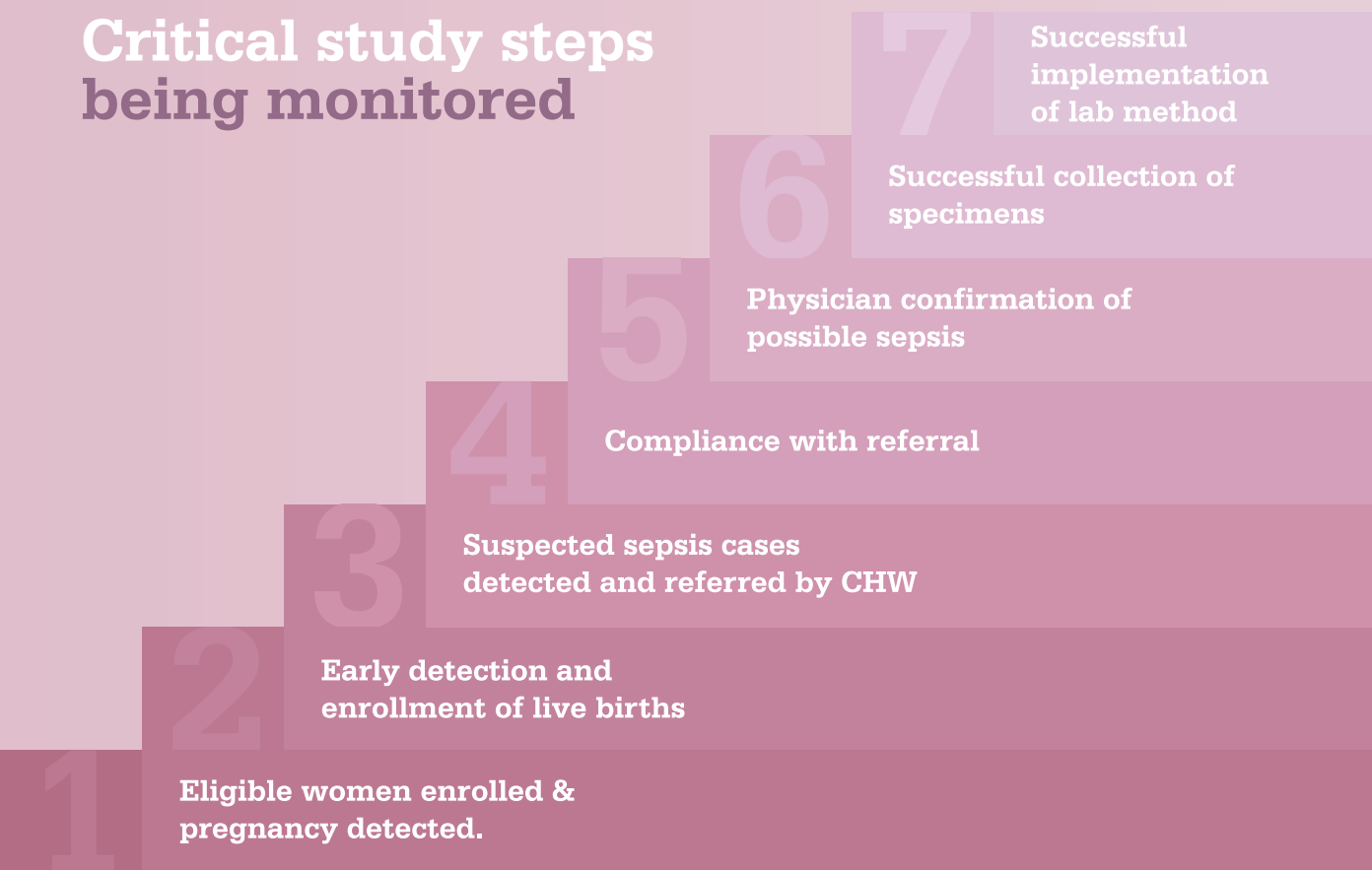
# Monitoring

Being a multi-country and multi-site project, ANISA has inherent complexities that deserve constant monitoring. ANISA, in addition to conventional monitoring visits, has built a robust system for real time monitoring by the PIs at the sites and the distant coordination team. The monitoring tools are built in the data management, and mobile texting system. All these help to detect any deviation from the protocol at real time.

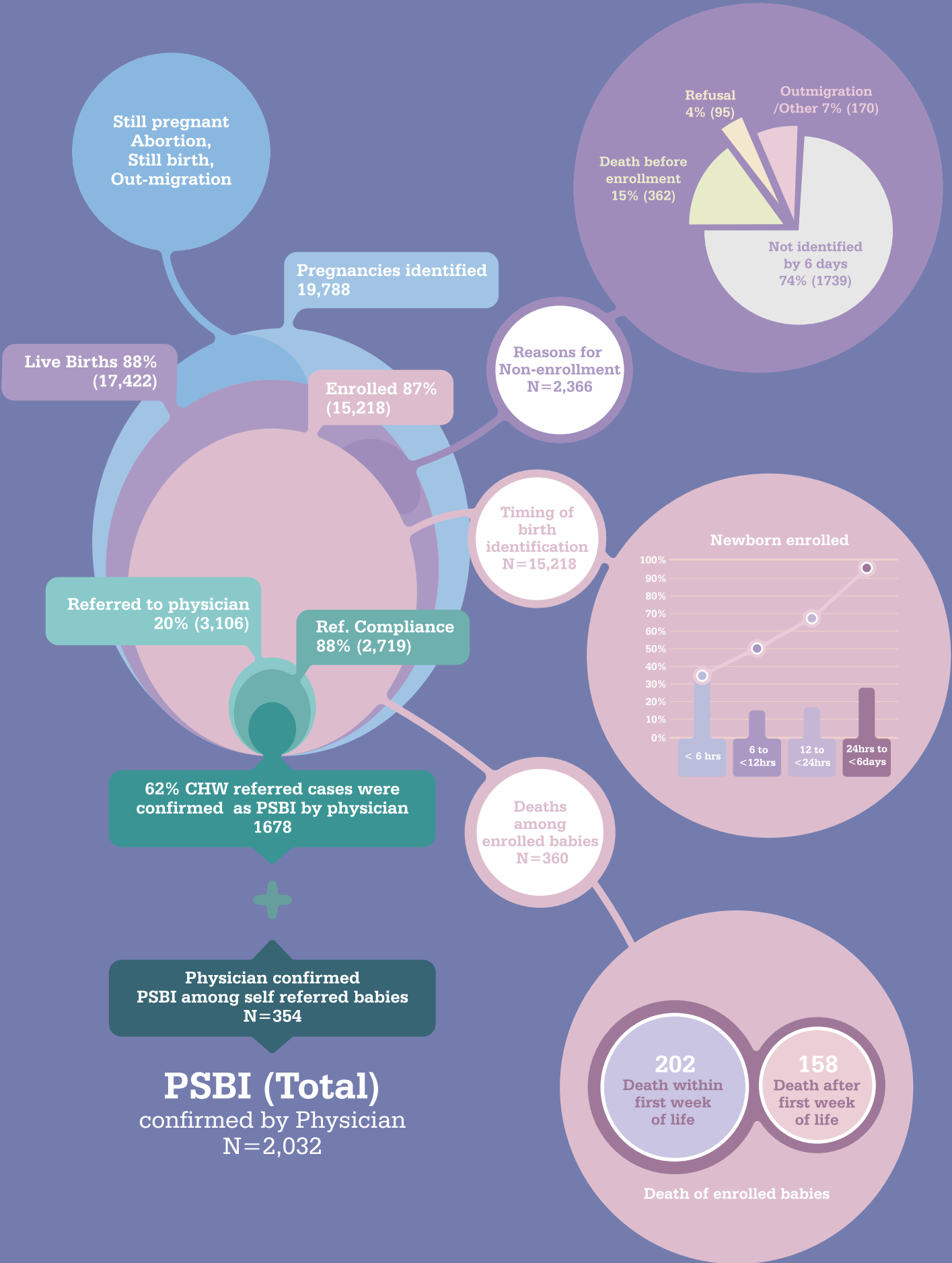
A matrix has been developed based on multiple critical indexes to weigh the performance of each site against the target and the threshold required to achieve the study objectives.



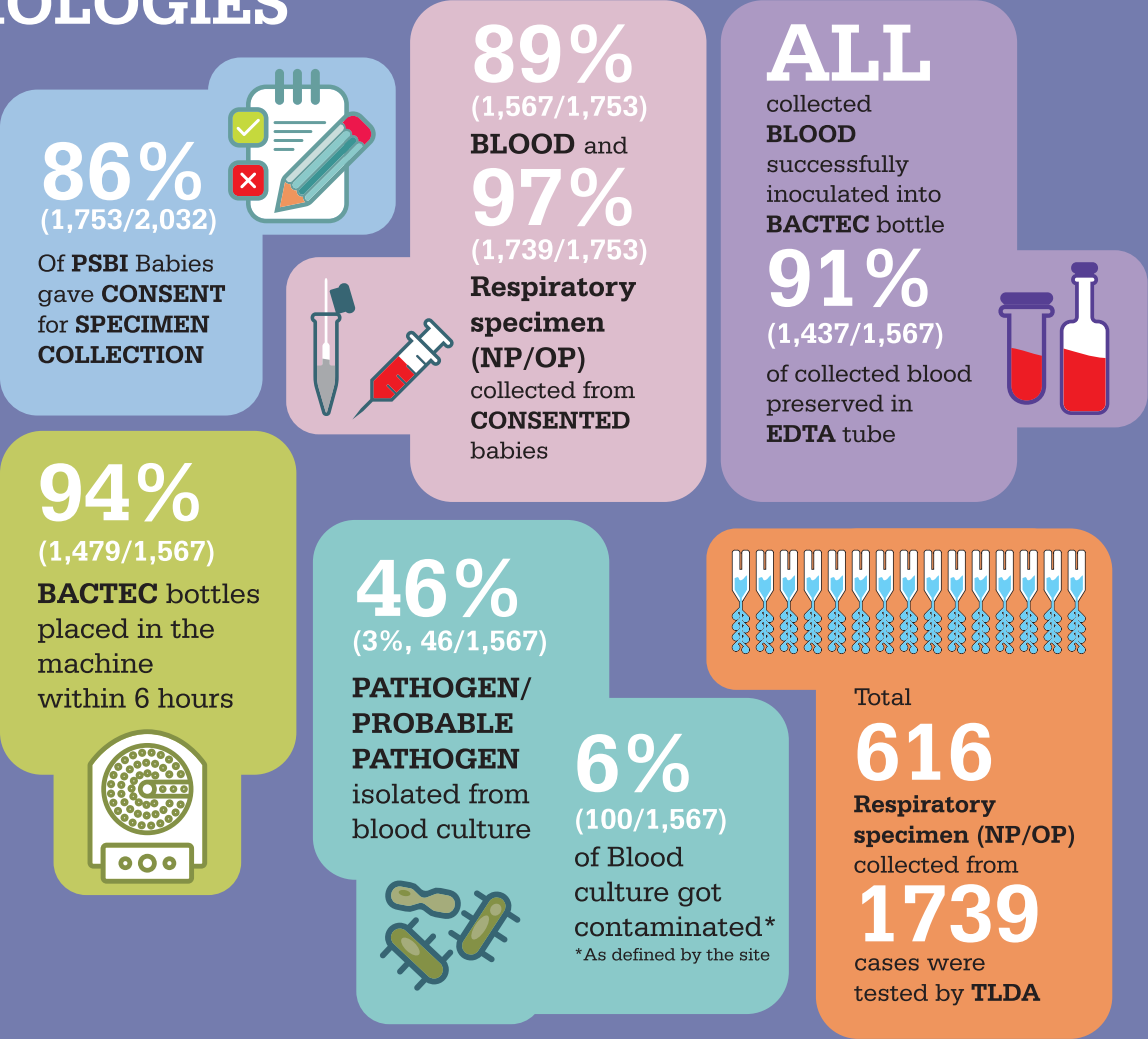
# Critical study steps being monitored



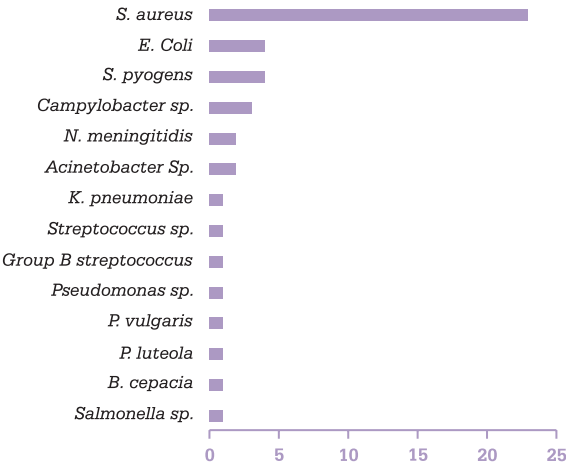
# CASES



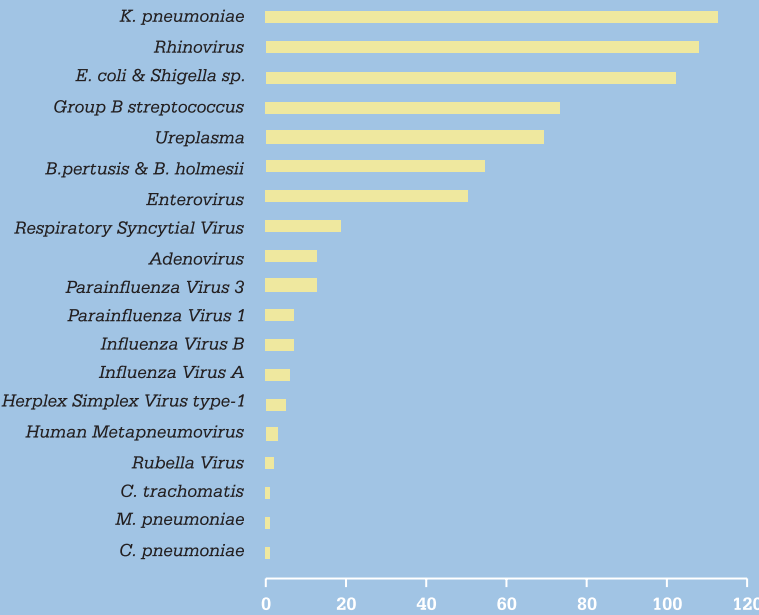
# AETIOLOGIES



Pathogen /Probable pathogen isolated from Blood Culture (N=46)



Organisms detected by TAC from Respiratory specimen (N=616)



- Successful bi-monthly  
pregnancy surveillance

- Newborn enrollment targets  
reached.

Good C&D - hypoxia agreement  
on cases of sepsis.

- Early birth registration

- Good referral compliance

- Timely identification of forgotten  
cases of PSEI

- Good number of successful  
blood collections

- Good community relations

All Excellent ANISA achievements  
of ANISA will be ruined  
if blood cultures get contaminated



# Communication

To maintain the study quality during the planning and implementation phases, the ANISA management team ensures regular communication between the ANISA team members across the world. An attempt is continually made to keep everyone abreast of new progress, challenges and/or achievements and to bolster relations with the teams at the sites. Establishment of this communications from this developing country was a real challenge. However, ANISA managed to establish global conference calls from Dhaka via Cisco's WebEx system. Due to the global distribution of partners, call timing is also a challenge. Often, ANISA-CDC members are taking the calls at 5.00 am and in the say way the Dhaka team is taking it at 9.00 pm. Small group calls are happening even at midnight. Nevertheless, consideration and dedication of the entire ANISA team is making it possible to arrange the calls with challenging times at either end.

The management team in Dhaka is convening around 16 conference calls per month with different collaborators which includes the site teams, ANISA coordination team, the CDC, ANISA TAG and BMGF



# New Sites

## Welcome to ANISA Family

Due to unforeseen logistical challenges, the original proposed site in India at Shivgarh in Uttar Pradesh was discontinued and this created a challenge for the ANISA project. Without an Indian site, it would lack data from the largest and most populous country in the sub-continent, which may lessen the impact of the study findings on both Indian and global policy makers. In order to redress this issue, the ANISA team embarked on a search for suitable Indian sites. Two sites with desirable characteristics have been identified, Vellore and Odisha.

### VELLORE

#### SITE DESCRIPTION

Site PI  
**Dr. Pinaki Panigrahi**

Population at ANISA site  
**237,600**

Birth Rate/1000 year  
**21.4**

Neonatal Mortality  
Rate/1000 year  
**43**

Facility-based deliveries  
**80%**

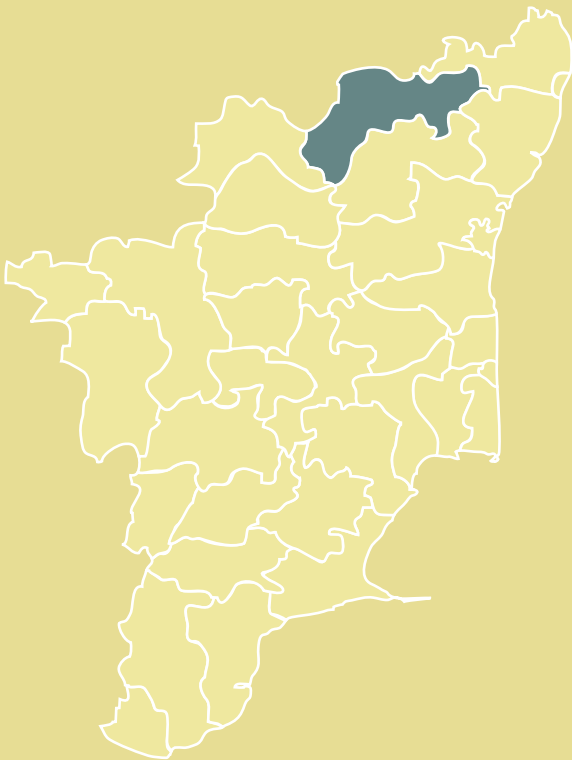
Available ANISA  
Newborns per year  
**4500**

Expected infants with  
PBSI (10%)  
**450**

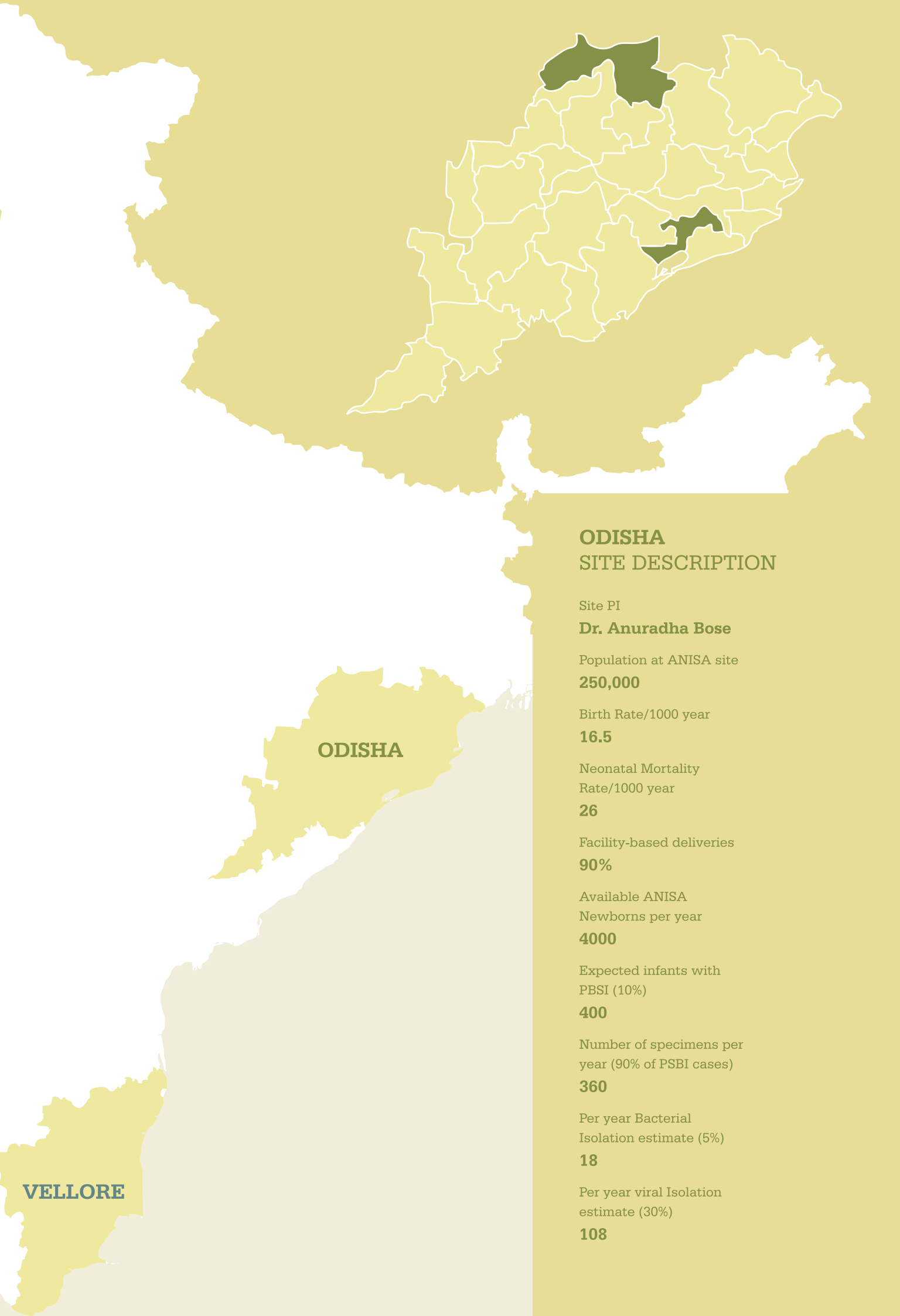
Number of specimens per  
year (80% of PSBI cases)  
**360**

Per year Bacterial  
Isolation estimate (5%)  
**21**

Per year viral Isolation  
estimate (30%)  
**110**







## ODISHA SITE DESCRIPTION

Site PI  
**Dr. Anuradha Bose**

Population at ANISA site  
**250,000**

Birth Rate/1000 year  
**16.5**

Neonatal Mortality  
Rate/1000 year  
**26**

Facility-based deliveries  
**90%**

Available ANISA  
Newborns per year  
**4000**

Expected infants with  
PBSI (10%)  
**400**

Number of specimens per  
year (90% of PSBI cases)  
**360**

Per year Bacterial  
Isolation estimate (5%)  
**18**

Per year viral Isolation  
estimate (30%)  
**108**

# Aetiology of Puerperal Sepsis

## A supplement to ANISA

Population based studies are pertinent to understanding the true burden of any disease. However, established sites with the capacity to identify numerator along with known denominators are few, specially in South Asia. Further, maintenance of these sites and implementation of disease surveillance is expensive and time consuming. Therefore, exploration of possibilities to introduce additional studies on any ongoing study is desirable to make the rational use of the team's effort and the invested resources. ANISA is no exception, it explored the possibility of introducing other relevant studies using the same infrastructures, study design and logistics, specially when all the MWRAs in the study sites are enrolled and followed up for ANISA main study.

ANISA, in collaboration with Prof. Linda Bartlett of Johns Hopkins University developed a proposal to find aetiology of post partum infection of enrolled mothers. This supplement aims to capture the PP sepsis cases using the customized clinical algorithm derived from the formative research done in the same community. Endometrial swabs will be collected and processed for aetiologies using the ANISA facilities.



ROAD  
MAP

