# FROM IDEAS TO POLICIES:
## The Process of INA-RESPOND Study

INA RESPOND
INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

**What is the process to develop a high quality and beneficial Protocol ?**

**IDEAS** from Indonesian Researchers

**NSC Reviews and Approves**
- GB endorses NSC's decisions
- Investigator selection

**Protocol Development**
Study Protocol, Manual Of Procedures, Informed Consent Form, Case Report Form, Database are prepared by a Protocol Core Team, Protocol PI, Co-PI and Investigators.

**Protocol Submission**
Submitted to :
- SCIENTIFIC COMMITEE
- The EC and BPOM

## ETHICAL CLEARANCE AND APPROVAL

**What preparation activities are conducted before the approved protocol is applied at site ?**

**APPROVED PROTOCOL**

**INVESTIGATOR MEETING**
To ensure site team members across sites have common understanding.

**SITE VISITS**
SPV
SIV
Site Preparation Visit -
To prepare the site team, necessary documents, supplies, and equipment.
Site Initiation Visit -
To ensure the readiness of the sites.

**SITE ACTIVATION**
Site can be activated after obtaining approval from Protocol PIs, NIH & NIHRD, and NSC Chair.

**The real journey begins. How does a research produce something?**


- Inform progress of the study.
- Discuss and recommend if any alteration is needed.
- Gather information for preliminary publication.

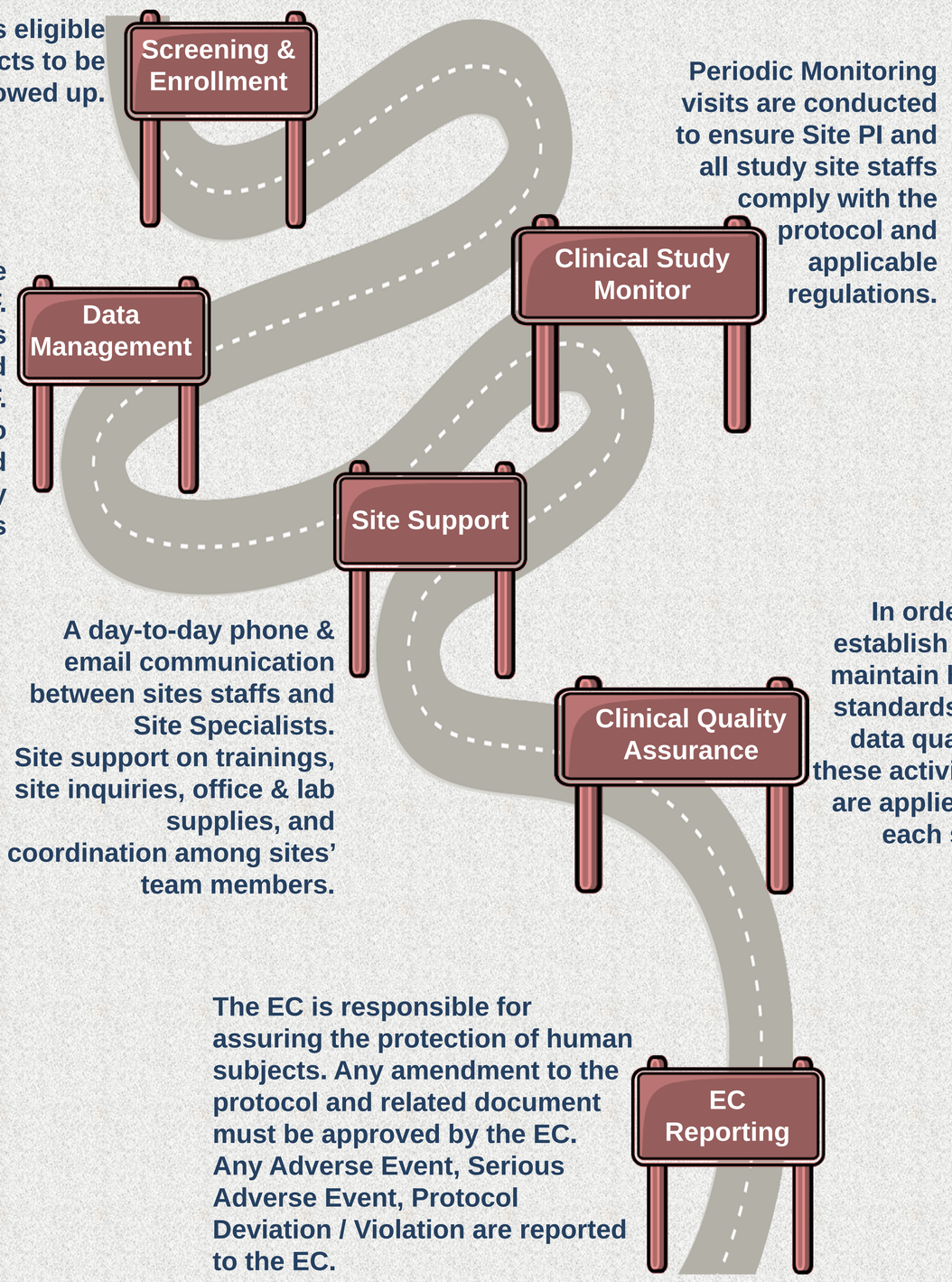
**PUBLICATION**
Secretariat processes the publication (submission, review, revision, re-submission)

- NSC reviews and approves
- GB endorses

**MANUSCRIPT PUBLISHED**

**INPUTS FOR PUBLIC HEALTH POLICIES & IDEAS FOR FUTURE STUDIES**

**What is going on behind the scene?**




RA identifies eligible subjects to be enrolled and followed up.

Periodic Monitoring visits are conducted to ensure Site PI and all study site staffs comply with the protocol and applicable regulations.

RAs complete SDW and CRF. DM checks completeness and accuracy of CRF. DM enters data to database and resolves any discrepencies

A day-to-day phone & email communication between sites staffs and Site Specialists. Site support on trainings, site inquiries, office & lab supplies, and coordination among sites' team members.

In order to establish and maintain high standards for data quality, these activities are applied at each site.

The EC is responsible for assuring the protection of human subjects. Any amendment to the protocol and related document must be approved by the EC. Any Adverse Event, Serious Adverse Event, Protocol Deviation / Violation are reported to the EC.

**GLOSSARY**

CRF : Case Report Form
DM : Data Manager
EC : Ethical Committee
GB : Governing Board
NSC : Network Steering Committee
PI : Principal Investigator
RA : Research Assistant
SDW : Source Document Worksheet
SPV : Site Preparation Visit
SIV : Site Initiation Visit


Partners

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