INA RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

Clinical trial databases are a crucial investment in clinical research

Part 1 – Opening, Clinical Data Management and INA-RESPOND overview

PIT PETRI 2018

B-IDeaS

1st Annual Scientific Meeting of the
Indonesian Society of Tropical and Infectious Disease
in conjunction with
The 7th Annual Bandung Infectious Disease Symposium
Harnessing innovative strategies tocontrol and manage infectious diseases
October 12th-14th 2018 | El Royale Hotel, Bandung

Speakers: M.Duvenhage
K. Laras
S. Erari
12 Oct 2018

Introductions

Kanti Laras

Senior Data Manager at INA-RESPOND.

Michael Duvenhage

Clinical Trials Data Operations Manager at the National Institute of Allergy and Infectious Diseases. He is supporting data management operations for emerging infectious and re-emerging diseases and other infectious diseases.

Silvera Erari

Data Manager at INA-RESPOND

Agenda

	Topic	Time - Presenter
Part 1	Opening Clinical Data Management - Where do we fit into the Protocol Life cycle INA-RESPOND Data Management - Overview of Capacity	13.00 – 13.20 - Kanti Laras
Part 2	Design and Development of Case Report Forms (CRFs) CRF Example and Exercise	13.20 – 14.10 – M. Duvenhage 14.10 – 14.25 – Silvera Erari
	Coffee break	14.25 – 14. 35
Part 3	Database Development Considerations RedCAP demo	14.35 – 15.05 – Kanti Laras 15.05 – 15.25 –M. Duvenhage & Silvera Erari
Part 4	The "Life" of a Data Manager - Project Manager for the Database	15.25 – 16.10 - M. Duvenhage
Part 5	Hitting the bullseye - How to successfully close the Database	16.10 – 16.40 – Kanti Laras

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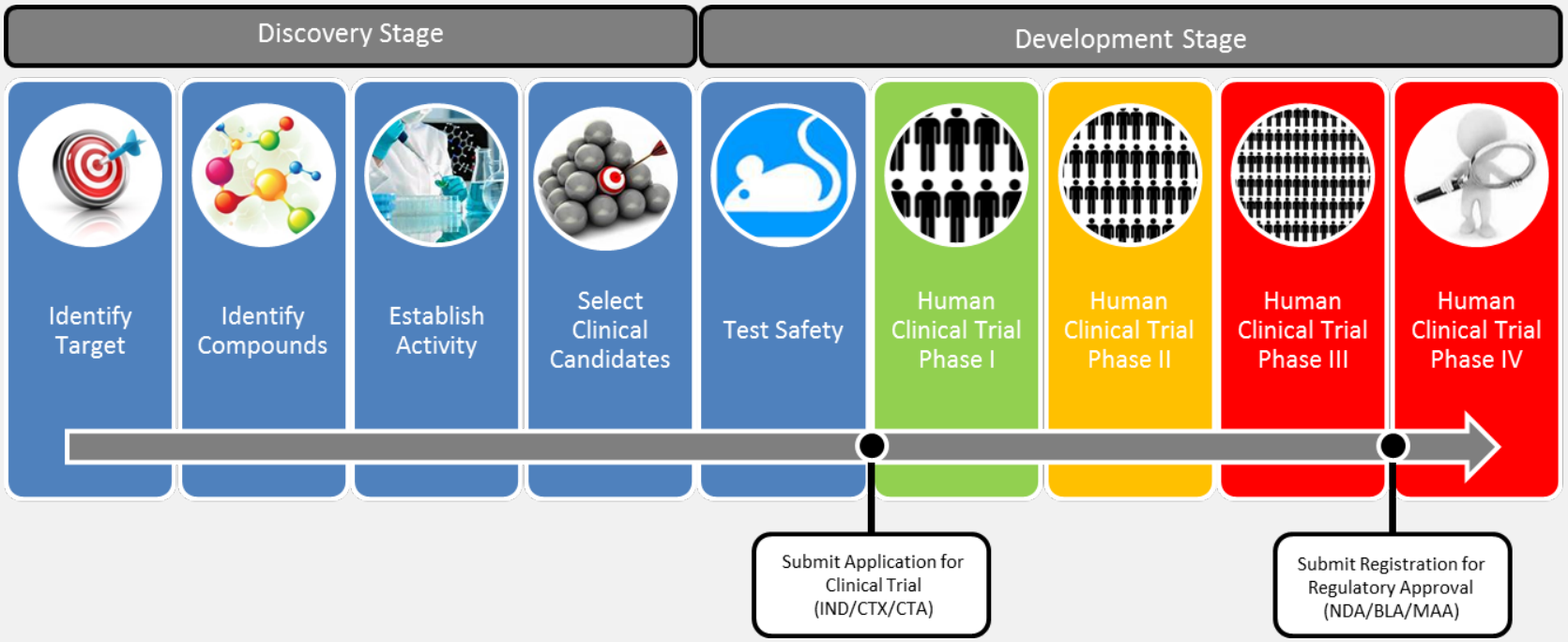
Clinical Data Management - Where do we fit into the Protocol Life cycle

Get ready for a ~12-year trip!



Only 5 in 5,000 drugs that enter preclinical testing stage progress to human testing.

Tufts Center for the Study of Drug Development (CSDD) pegs the cost of developing a prescription drug that gains market approval at **$2.6 billion.**

What is Clinical Data Management

- **Clinical Data Management** (CDM) is involved in all aspects of processing the clinical data, working with a range of computer application database systems to support collection, cleaning and management of subjects or trial data.

- **CDM** is ***the collection, integration, and validation*** of clinical trial data

- End result for the **CDM**:
  - ✓ A study database - ***accurate, secure, reliable and ready for analysis***.
  - ✓ Timeline from data collection to analysis

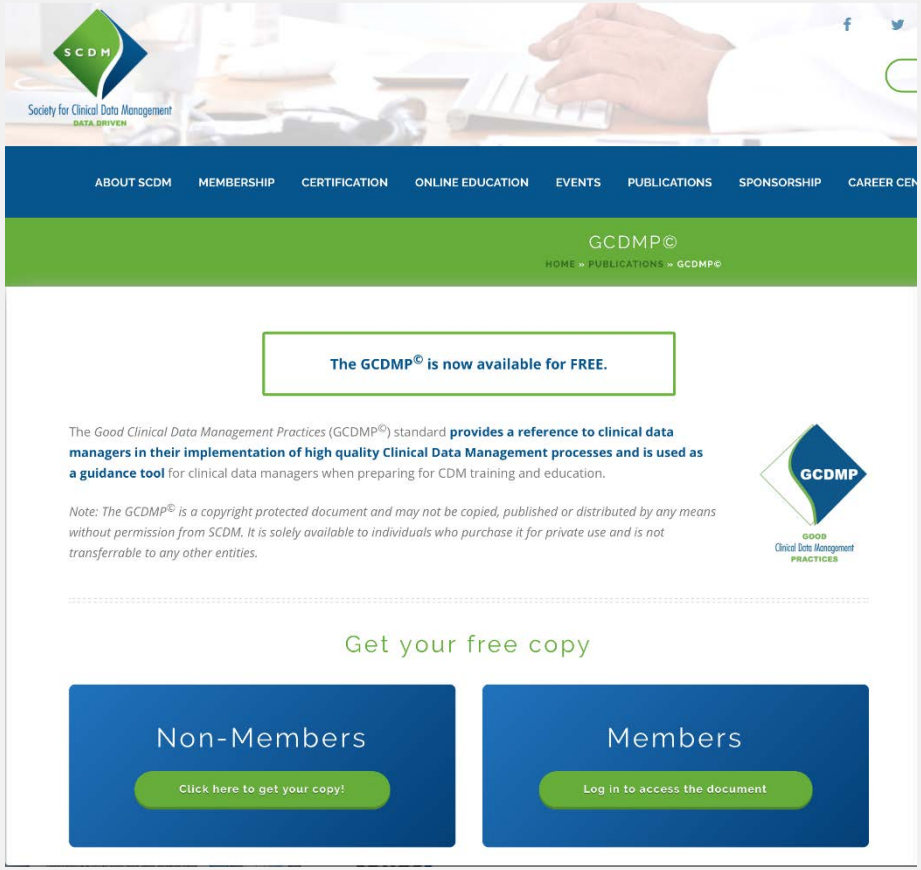
- Good CDM - delivery of the quality data on-time and within the trial budget

Benefits of Good Clinical Data Management practices

- Efficient Data Management leads to less costly drug development process
- Faster data generation and availability their off
- Allows for accurate, real-time (or at least near-time) view of clinical trial status
- Robust quality control and data validation procedures
- Aggregation of data and dissemination via approved platform/process

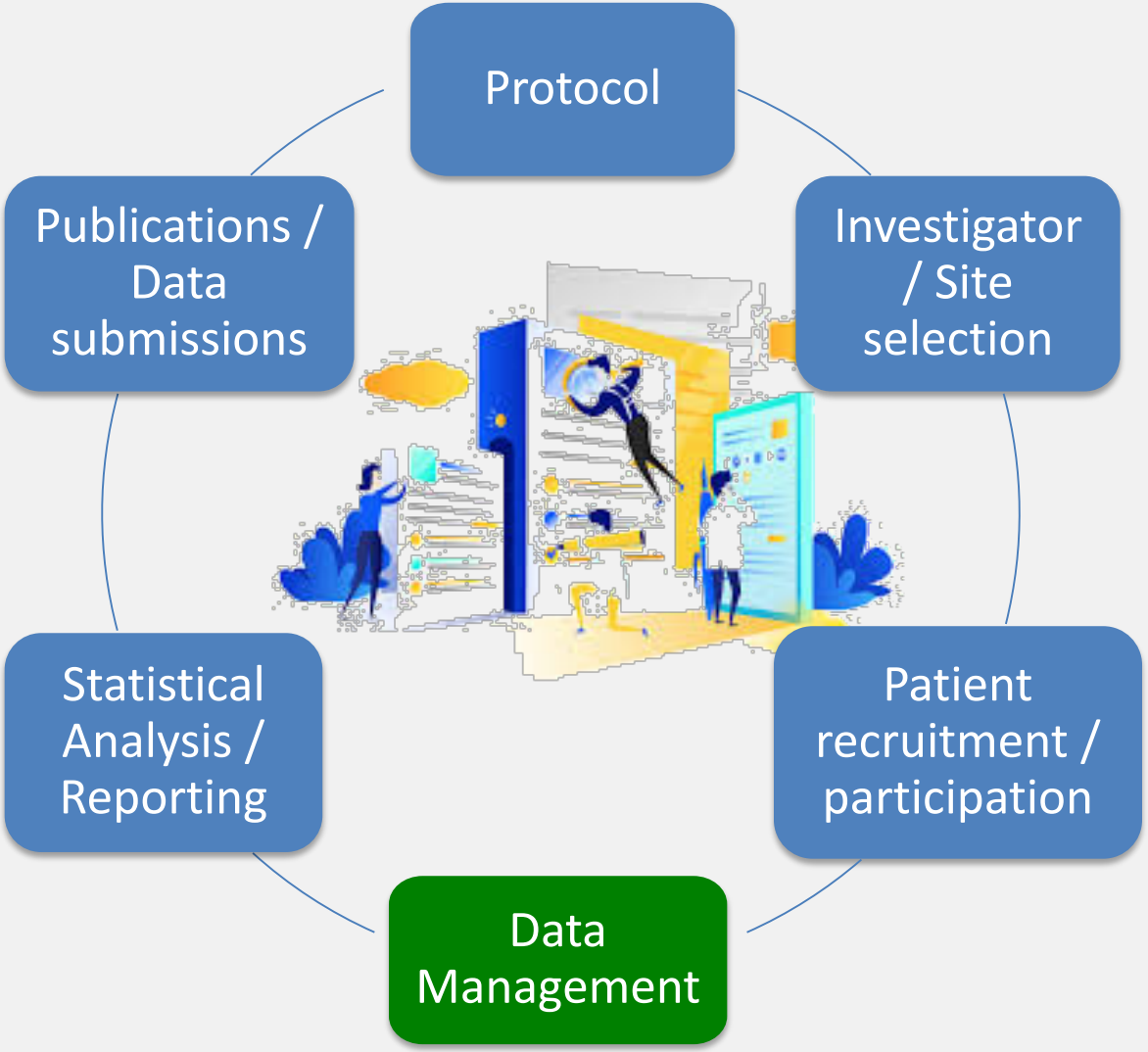
Standard

- **Society of Clinical Data Management (SCDM) – Good Clinical Data Management Practices (GCDMP)**
  - Initially published in Sep 2000; various revisions thereafter
  - GCDMP provides guidance on accepted practices in Clinical Data Management



http://scdm.org/publications/gcdmp/

Clinical Trial Workflow – where does DM fit in



Key Team Members & Responsibilities

Role	Responsibilities
Data Manager	Oversight of entire DM Project / Communication with Clinical project team
Database Programmer	Setup of Database screens, edit checks
Medical Coding	Coding of Adverse Events / Medications
Clinical Data Coordinator	Review of data / discrepancy review and management
Data Entry Associate	Perform data entry (from CRF into database)

Effective Clinical Data Managers

Task	Competencies
Understanding – protocol, documentation, SOPs, regulations, roles and responsibilities	Attention to detail; organisational skills e.g. understand instructions
Execution of tasks – discrepancy management, data review, User Acceptance Testing (UAT), data locking	Attention to detail; personal organisation e.g. deliver on time, planning; software skills
Effective communication – with study team, monitors, study data manager	Good written and verbal communication skills; influence; interpersonal skills
Issue identification	Attention to detail; problem solving; tenacious
Process improvement identification	Attention to detail; strategic thinking; displays initiative

Responsibilities of Clinical Data Management through out study process

Protocol Design

Start up phase

- CRF design & development ⟷ quality check
- DM-related documents development *
- Database design ⟷ quality check
- Edit checks ⟷ quality check
- Database activated ⟷ quality check

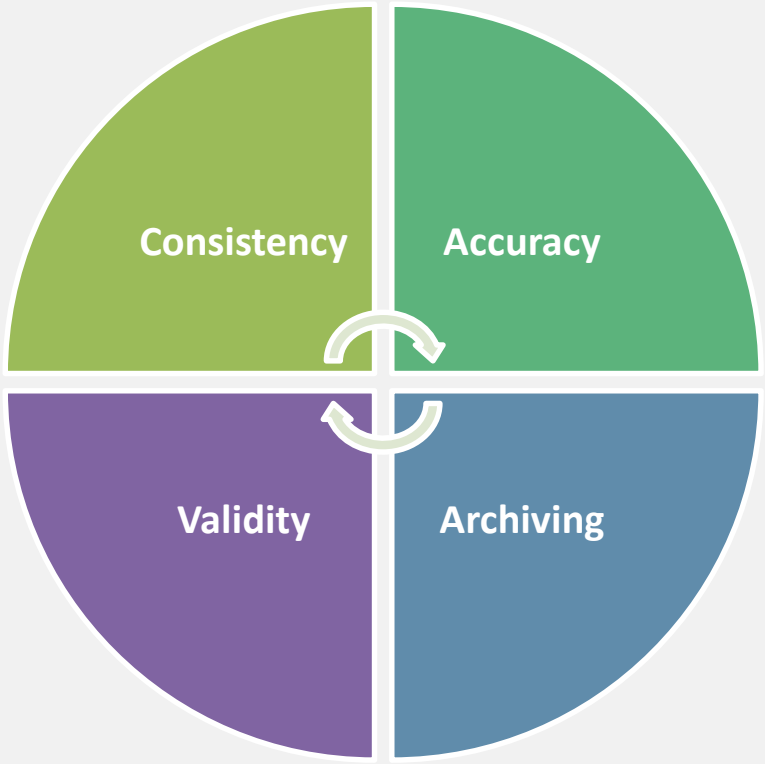
Conduct phase

- Data collection, entry, & tracking
- Data validation/cleaning
- Medical coding
- Data transfer
- Discrepancy management
- Data review (Ongoing QC)
- SAE reconciliation
- Database updates (if any)

Close out phase

- SAE reconciliation
- Database lock
- Database transfer
- Database QC
- Electronic Archival
- Database unlock and re-lock

Mission of CDM



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INA-RESPOND Data Management

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Overview of Capacity

DM related documents

- Case Report Form (CRF)
- Annotated CRF
- Source Document Worksheet
- CRF Completion Guideline
- Data Management Plan
- Data Entry Guideline
- Self Evident Correction
- Data Clarification Plan
- Edit Specific Document
- Data QA Plan

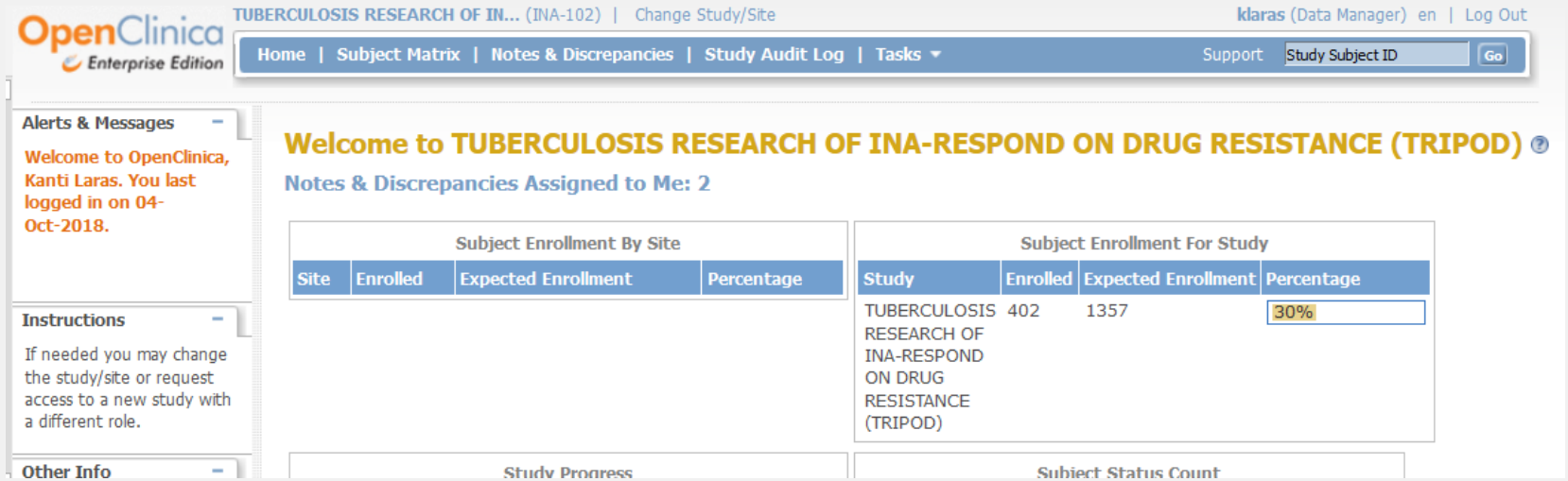
All documents are :

✓ Reviewed and approved by share holders, e.g Protocol PI, DM, Litbangkes/NIH, INA-RESPOND Chairman.

✓ Stored in the Trial/Study Master File with a limited access

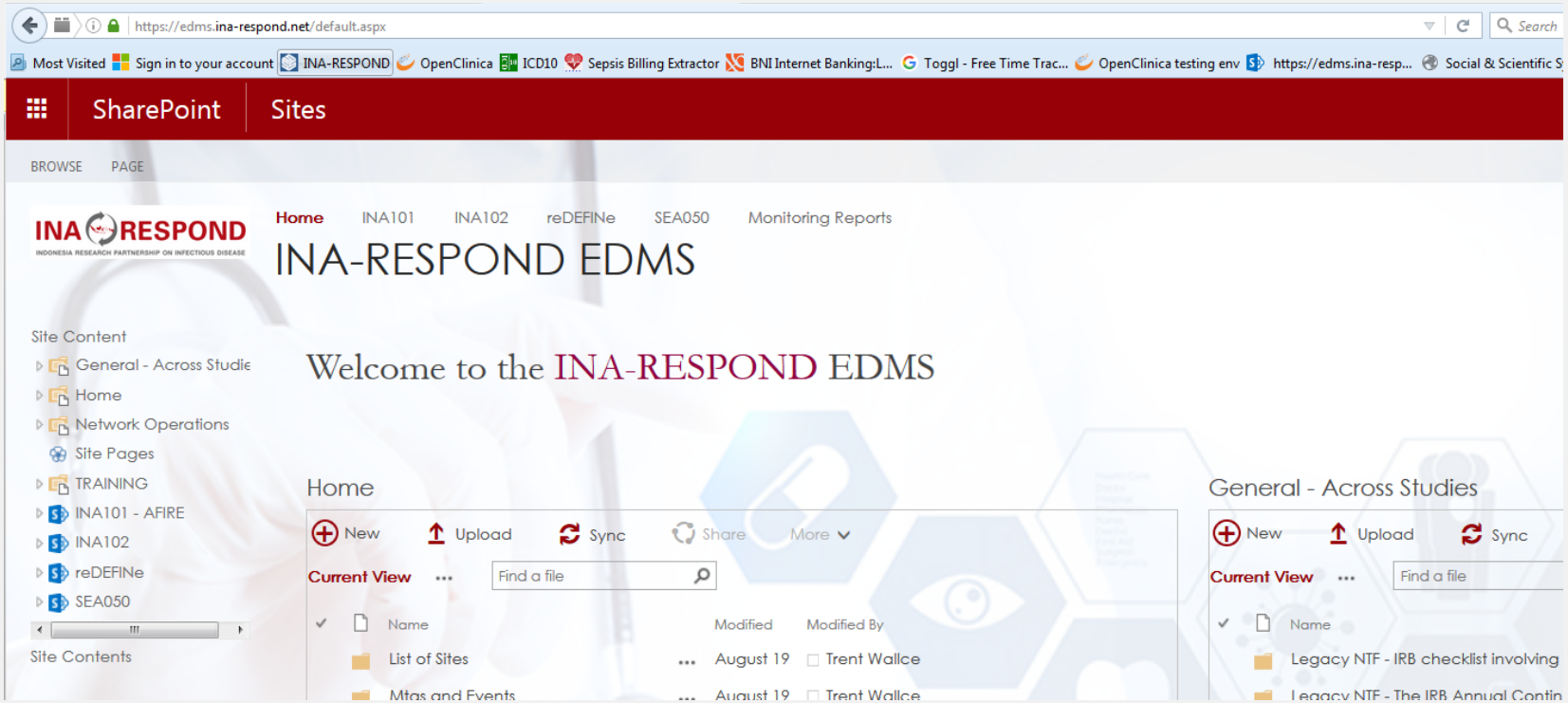
Database Study

- OpenClinica Enterprise v3.13



- RedCAP
- Access to the database is limited, controlled, documented and based on each person's roles
- Data is stored in the Lintas Artha servers (Jakarta & Bandung), with a back-up at Litbangkes
- The server location must be followed these criteria: physically secured, 24 hours, at 2 different location (minimum distance 50 km)

Study Document Management



- Access is limited, controlled, documented and based on each person's roles

SOPs Data Management

1	Good Documentation Practices
2	Study Trial Master File
3	Electronic Signatures
4	Data Management Plan
5	Case Report Form Design and Approval
6	Annotated Case Report Forms
7	Study Database Configuration and Testing
8	Study Database Access and Control
9	Data Clarification Process
10	Pre-Entry Review and Data Entry
11	Study Database Change Requests
12	Programmed Edit Checks
13	Serious Adverse Event Reconciliation
14	Study Database Quality Control
15	Study Database Lock and Unlock
16	Case Report Form Receipt and Handling
17	Statistical Program Development, Testing, and Control
18	Statistical Programming Practice
19	Data Transfer
20	Medical Coding
21	Statistical Analysis Plan
22	Project Database Functional Testing

23	Statistical Program Release Notification (SPRN)
24	External User E-Signature Agreement
25	Coding Specifications
26	INA-RESPOND Staff Member Signature Record
27	Records Management File Cabinet Access Log
28	eTMF Access Authorization Form
29	TMF Specifications
30	Project Database Peer Review
31	Self-Evident Correction Document
32	Edit Specifications Document (ESD)
33	Program Requirements and Validation Plan (PRVP)
34	Data Quality Control Plan (DQCP)
35	Data Entry Guidelines (DEG)
36	Data Clarification Plan (DCP)
37	Audit of Critical Fields
38	Audit of Random Sample of Subjects
39	Case Report Form Completion Guidelines
40	Data Transfer Specification
41	Release Authorization
42	Statistical Analysis Plan
43	Edit Check Verification Log
44	Data Transfer Log
45	SAE Reconciliation Discrepancy Log

INA-RESPOND's Studies

- 8 hospitals
- Paper CRF, CRF was scanned & uploaded to portal
- Double data entry at INA-RESPOND Secretariat

INA101 (AFIRE)
locked

- 3 hospitals in Indonesia, Vietnam, Thailand
- E-CRF
- Single data entry
- Separate database for Indonesian data

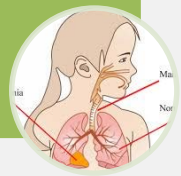
SEA050 (Sepsis)
locked

- 7 hospitals
- Paper CRF, CRF was scanned & uploaded to portal
- Double data entry at INA-RESPOND Secretariat

INA102 (TRIPOD)
ongoing

- 3 hospitals
- Paper CRF, CRF was scanned & uploaded to portal
- Double data entry at INA-RESPOND Secretariat

INA201 (PePPes)
ongoing



- 20 hospitals
- Paper CRF
- Double data entry at hospital & INA-RESPOND Secretariat

INA104
(ProActive)
ongoing

- E-CRF using RedCAP in the mobile devices

INA105
(Schistosomiasis)
Start up

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Questions