

# **T**uberculosis **R**esearch of **INA-RESPOND** on **D**rug-resistant **(TRIPOD)**

JS Luwansa, April 30<sup>th</sup> 2015

# Background (1)

## The burden of tuberculosis in 2013 (estimation)

### Globally

- 9.0 million new TB cases (13% TB-HIV)
  - 1.5 million deaths (360 000 TB-HIV)
- 480,000 new MDR-TB cases
  - 210,000 deaths from MDR-TB

### Indonesia

- Prevalence: 680,000 cases
- Incidence: 460,000 cases (rank 5<sup>th</sup>)
- Mortality: 64,000 cases

Source: WHO Global Tuberculosis Report 2014



# Background(2)

## Proportion of MDR-TB cases in Indonesia

	<b>Papua, 2004</b>	<b>Central Java, 2006</b>	<b>Makassar, 2007</b>
Of new TB cases	2%	1.8%	4.1%
Of previously treated TB cases	-	17.1%	19.2%

# Background (3)

## Our main goal

***To provide valid data which are beneficial for the government to better prepare a national program in controlling this disease***

TRIPOD is INA-RESPOND's first TB study, focused on questions specific to improve diagnosis and treatment of TB in Indonesia

TRIPOD closely observe a large number of various TB patients from many centers prospectively



# Study Objectives

## Primary Objective

- To estimate the proportion of MDR TB of new and previously treated cases

## Secondary Objectives

- To estimate the proportion of cured, completed, failed, died and lost to follow up and treatment outcomes in drug susceptible & drug resistant cases

# Study Objectives (2)

## Secondary Objectives (continued)

- **To evaluate the association of treatment success (cured or completed) with the following data.**
  - Demographics (age, sex)
  - TB contact history
  - Smoking habit
  - Treatment seeking behavior
  - **Comorbidities (HIV, Diabetes Mellitus)**
  - Primary or secondary drug resistance
  - Symptoms
  - Cavity in the lung
  - Nutritional status
  - Treatment regimens
  - Compliance
  - Number of bacteria by AFB test
  - TB strains (e.g., Beijing)



# Study Objectives (3)

## Secondary Objectives (continued)

- Comparison of clinically defined TB against laboratory confirmed TB for accuracy of diagnosis.
- Comparison between AFB and X-pert as TB diagnostic tests against culture result.
- Estimation of Rif susceptibility result sensitivity and specificity in X-pert against Rif susceptibility result in DST.



# Study Sites

- 1. Persahabatan Hospital (Jakarta)**
- 2. Dr. Soetomo Hospital (Surabaya)**
- 3. Dr. Hasan Sadikin Hospital (Bandung)**
- 4. Dr. Kariadi Hospital (Semarang)**
- 5. Sanglah Hospital (Bali)**
- 6. Prof. Dr. Sulianti Saroso Hospital (Jakarta)**
- 7. Dr. Sardjito Hospital (Yogyakarta)**



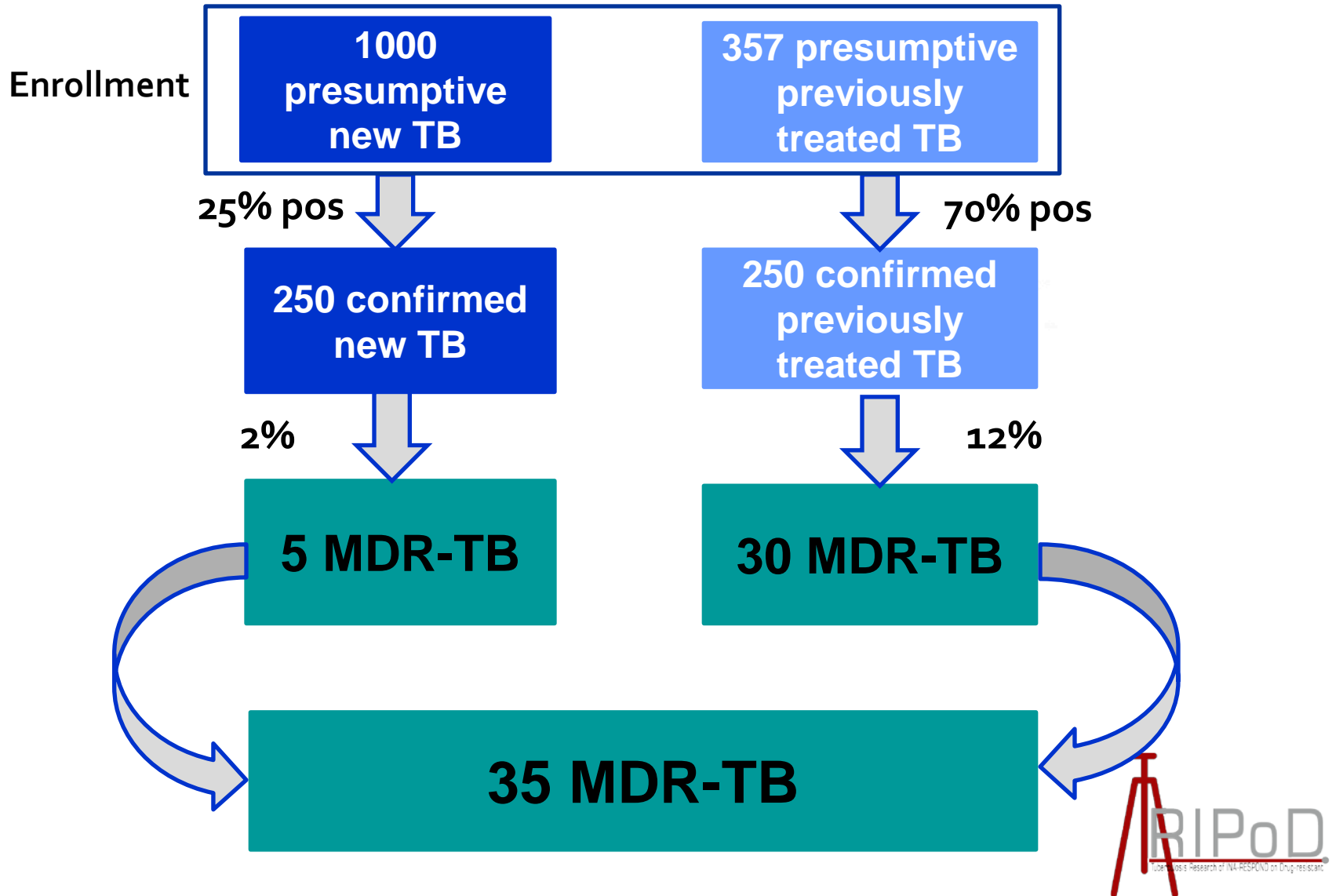
# Study Design

**This study is a prospective observational cohort study of new and previously treated TB patients.**

**Patients will be treated as per standard of care according to national TB treatment guidelines and each study site policy.**



# Sample Size Estimation



# Study Duration

**Accrual/Enrollment period: 2 years**

**Follow Up period: up to 2 years**

- Drug susceptible TB patients: until end of treatment
- MDR TB patients: until end of treatment / max 24 months

**▶ ▶ ▶ Total study duration: up to 4 years**



# Specimen Collection

- ***M.tb* Isolate from sputum**
- **Blood:**
  - serum,
  - plasma,
  - buffy coat
- **Urine**



**“Every breath  
counts  
Stop TB NOW!”**

**Thank You**  
**#supportTRIPOD**



**INA-RESPOND**