



Tuberculosis Research of **INA-RESPOND** on **Drug-resistant (INA-102)**



TRIPOD STUDY TEAM

Background

- To provide valid data which are beneficial for the government to better prepare a national program in controlling this disease, it is important to closely observe a large number of various TB patients from many centers prospectively
- This study is INA-RESPOND's first study of TB, which may be followed by other studies focused on questions specific to improving diagnosis and treatment of TB in Indonesia

Objectives

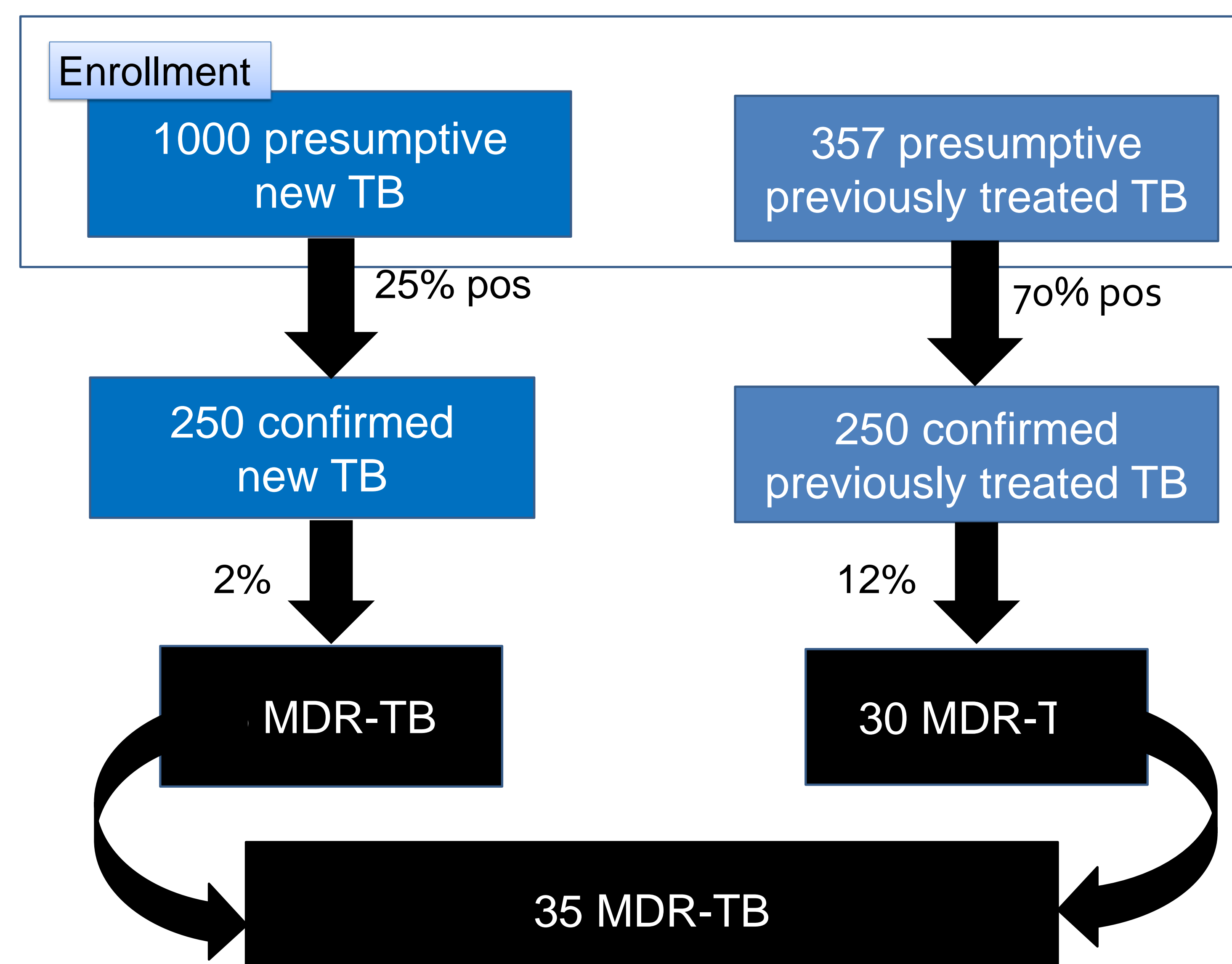
Primary Objectives

- 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 as treatment outcomes in drug susceptible & drug resistant cases
- To evaluate the association of treatment success with the following: demographic, TB contact history, smoking habit, treatment seeking, comorbidities (HIV, DM), primary drug resistance, symptoms, lung cavity, nutrition status, treatment regimens, compliance, number of bacteria, TB strains (Beijing)
- Comparison of clinically defined TB vs laboratory confirmed TB for accuracy of diagnosis.
- Comparison between AFB and Xpert as TB diagnostic tests vs culture result.
- Estimation of Rif susceptibility result sens and spec in Xpert vs Rif susceptibility result in DST.

Sample Size Estimation

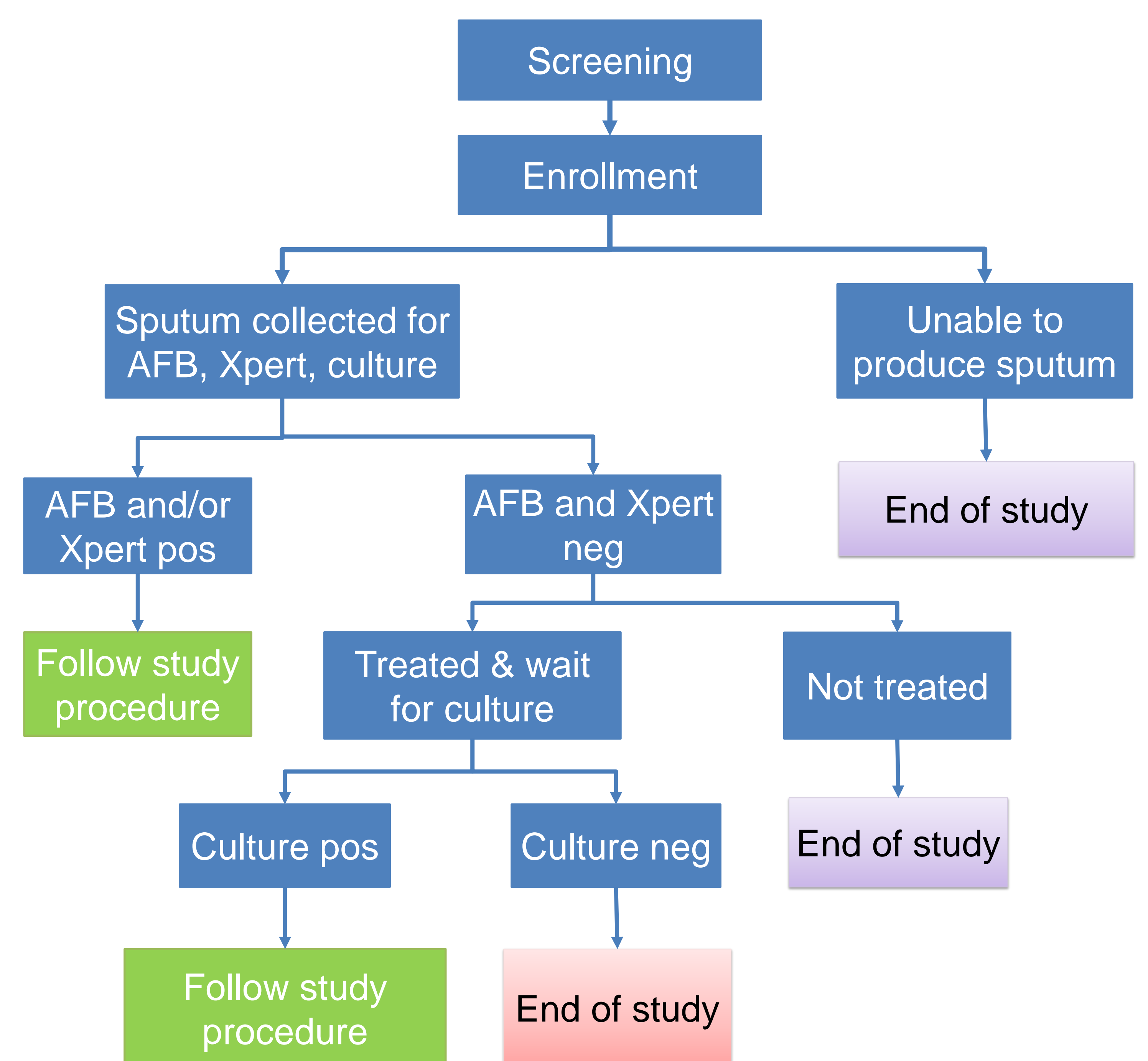


Eligibility Criteria

Patients (with or without TB treatment history) who meet the following criteria:

- Patients suspected of having pulmonary TB
- Cough \geq 2 weeks
- At least 1 other TB clinical symptoms
- Suggestive pulmonary TB chest X-ray results
- Denies having TB treatment in the last 2 months
- Age \geq 18 years old
- Willing to be treated/evaluated at study site
- Willing to have specimens stored
- No liver or chronic kidney disease or pregnancy or severe psychiatric illness that might interfere with study compliance

Study Procedures



Study Hospitals

- RSUP Persahabatan/FK UI (Jakarta)
- RSUD Dr Soetomo/FK UA (Surabaya)
- RSUP Dr Hasan Sadikin/FK Unpad (Bandung)
- RSUP Dr Kariadi/FK Undip (Semarang)
- RSUP Sanglah/FK Udayana (Bali)
- RSUP Sulianti Saroso (Jakarta)
- RSUP Dr Sardjito/FK UGM (Yogyakarta)