INA RESPOND
INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

SEA050 SEPSIS STUDY

An Observational Study of the Causes, Management, and Outcomes of Community-acquired Sepsis and Severe Sepsis in Southeast Asia

Study type

Observational study

In collaboration with

SEAICRN (South East Asia Infectious Disease Clinical Research Network)

Principal Investigator

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STUDY OBJECTIVES

Primary Objective

To determine the causes of community-acquired sepsis and severe sepsis in adult and pediatric subjects across Southeast Asia

Secondary Objectives

- To define the current acute management and gaps of current practice as defined by the surviving sepsis campaign
- To define the clinical outcomes
- To identify risk factors associated with sepsis or severe sepsis

Secondary Objectives (2)

- To determine the extent of antimicrobial resistance in organism & the association between antimicrobial resistance and mortality → database required
- To evaluate the accuracy of selected rapid diagnostic tests (RDTs) → Future Study

STUDY ENDPOINTS

Endpoints

Primary endpoint

- The etiology of community-acquired sepsis and severe sepsis expressed in percentages of enrolled subjects

Endpoints (2)

Secondary Endpoints

- Adequate management of community-acquired sepsis
- Outcome of community-acquired sepsis and severe sepsis
- Risk factors associated with sepsis or severe sepsis

Endpoints (3)

Secondary Endpoints

- Prevalence of antimicrobial resistance and its association with appropriate empirical therapy and outcomes → database required
- Sensitivities and specifities of selected RDT's in determining the causes of community-acquired sepsis and severe sepsis → future study

STUDY DESIGN

Study Design

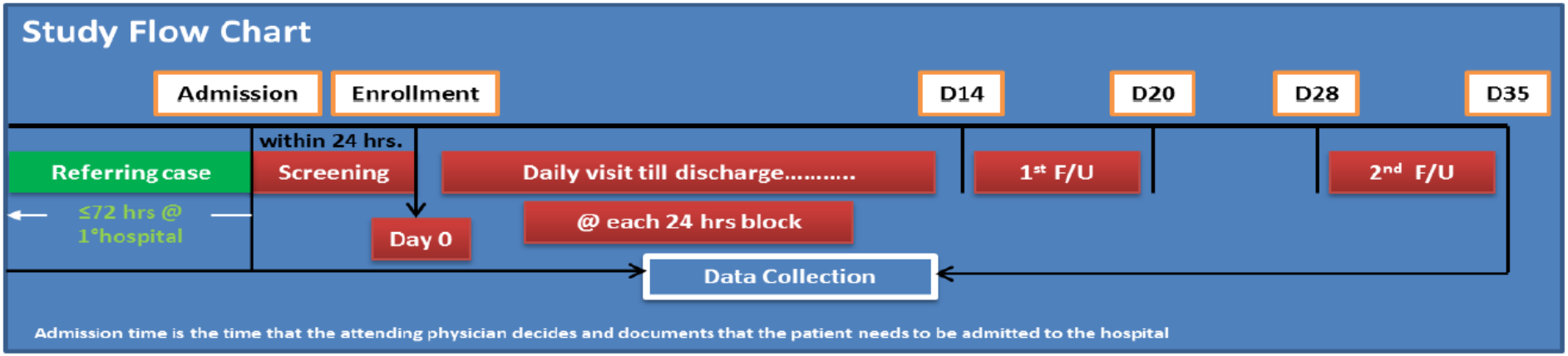
Observational Study to identify

- Etiology
- Management
- Outcome

Researcher will not be involved in the management care and treatment of study patients

Clinical Flow

Study Flow Chart



Admission time is the time that the attending physician decides and documents that the patient needs to be admitted to the hospital

Screening

Potential Subjects:**
- Confirmed infection by any methods.
- Clinical diagnosis of any specific diseases.
- Suspected having both infectious/non-infectious diseases.
- Referral subjects admitted < 24 hrs. and not hospitalized at other hospital > 72 hrs

Complete subject screening & enrollment log and assign screening number.

Eligibility Criteria on Interim CRF:
Review medical records for clinical diagnosis and **routine** lab results

See protocol for details

Determining Eligibility

Eligible

Consent

Consent Process:*
≥ 30 days – < 7 yrs old: Parent ICF
7 – < 13 yrs old: Assent + Parent ICF
13 – < 18 yrs old: Assent/Adult ICF + Parent ICF
≥ 18 yrs old: Adult ICF

* Depends on local regulations

Ineligible

Refuse to consent

Enrollment
Complete :
- Subject screening & enrollment log and assign enrollment number
- Subject identification & contact information log
- Subject follow-up visit log

Complete CRF:
SCR

Screening Failure
Complete the reasons subject not be enroll into the study on the screening log.
Complete CRF:
SCR

** Infection must be the primary cause of illness leading to hospitalization

Diagnostic to be performed

- **Following standard of care of the hospital**
- **For research purpose:**
  - Test to be performed in every cases (100% of subjects): Blood culture, rapid diagnostic test
  - Test to be performed in Blood culture Negative cases (±90% of subjects: PCR RNA 16s
  - Test to be performed based on syndrome:
    - CNS panel
    - Respiratory panel
    - Diarrheal panel
    - Non-specific organ involvement

STUDY POPULATION

Inclusion and Exclusion Criteria

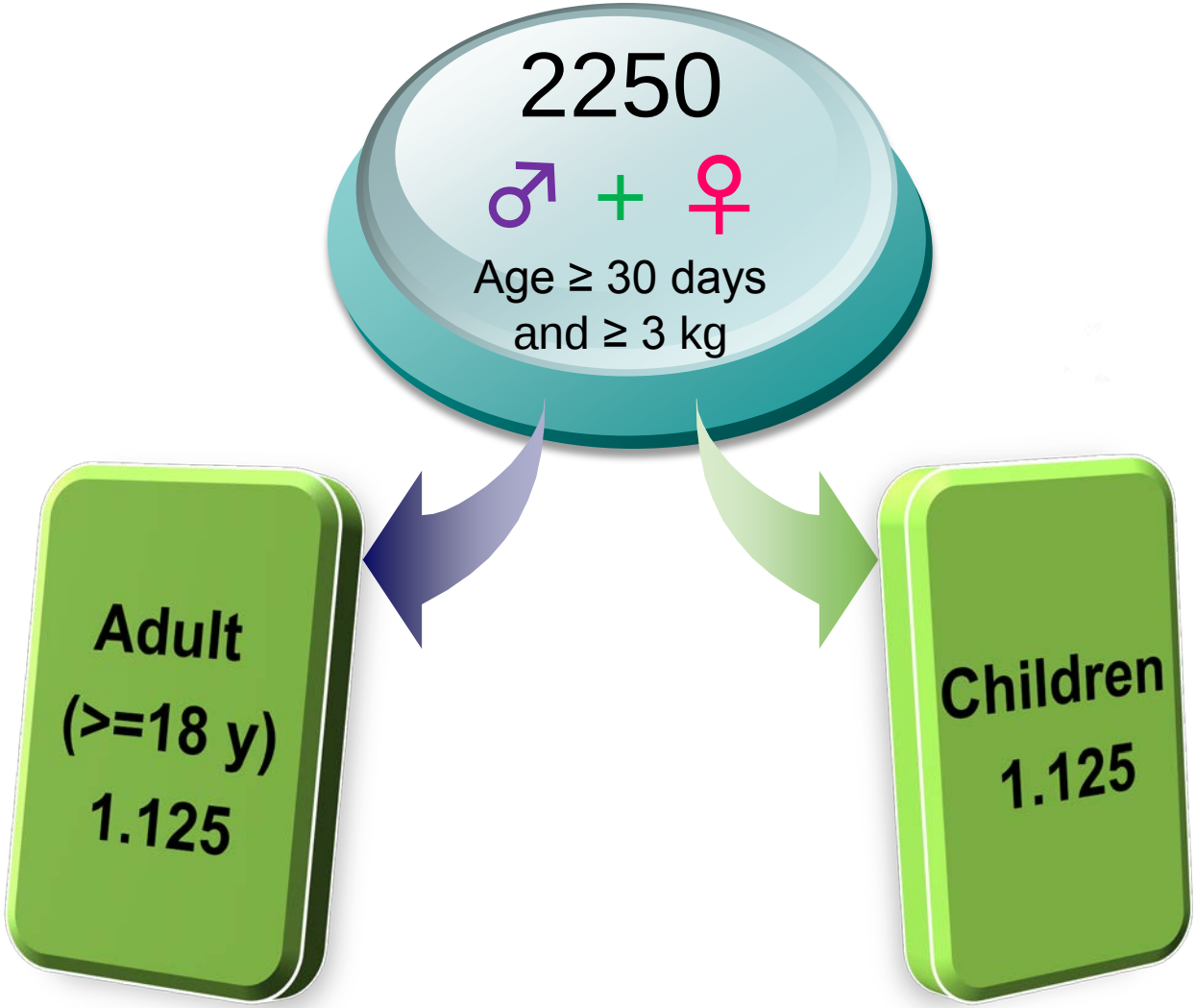
Inclusion criteria

1. **Age ≥ 30 days old and weighing at least 3 kg or more on the day of enrollment into the study**
2. **Required hospitalization as decided by the attending physician**
3. **Documented by attending physician that an infection is the primary cause of illness leading to hospitalization**
4. **Presence of SIRS**
5. **Informed consent has been obtained**

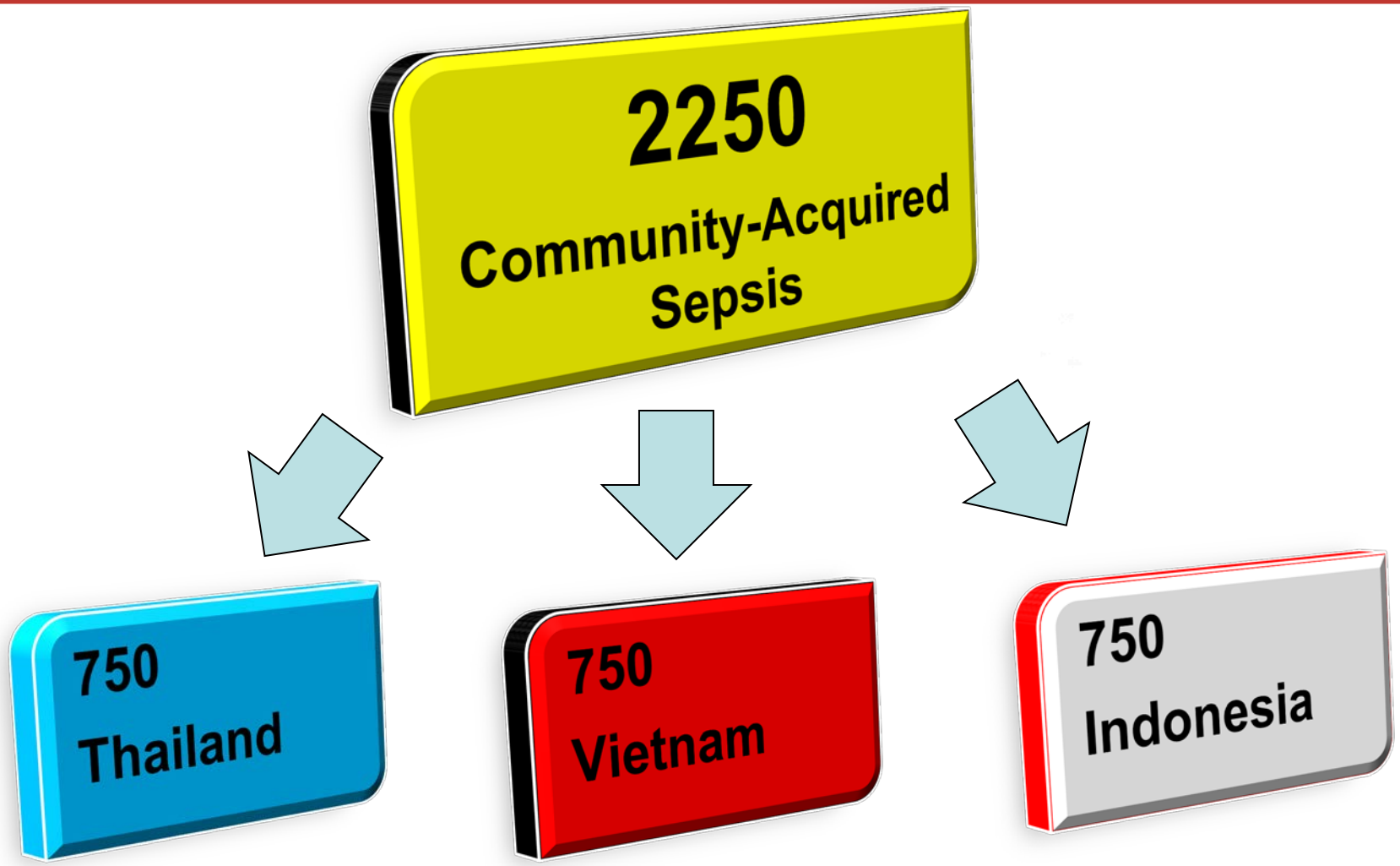
Exclusion criteria

1. **Admitted to the study site hospital for this current episode >24 hours before enrollment**
2. **Hospitalized for this current episode > 72 hours at another primary/referring hospital**
3. **Prior to this current episode, the subject was admitted to any hospital within the last 30 days**
4. **Underlying pre-existing condition is though to have led or contributed to this sepsis episode**
5. **Hospital acquired infection is associated with the cause of sepsis**
6. **Enrolled into this study or another sepsis study before**

Study Population



Sample Size


2250
Community-Acquired Sepsis
750
Thailand
750
Vietnam
750
Indonesia

Study Sites and Populations

Indonesia		
Jakarta	**Makassar**	**Jogjakarta**
University of Indonesia/RS Dr. Cipto Mangunkusumo, (Adults 125, Pediatrics 125)	University of Hassanudin/RS Dr. Wahidin Sudirohusodo (Adults 125, Pediatrics 125)	University of Gadjah Mada/RS Dr. Sardjito, (Adults 125, Pediatrics 125)

Accrual Period

Start

Up to 2 Years

The enrollment period will be completed in December 2015

Study Duration

Total Length of time that subjects will be in the study is 28 to 35 days

SITE ACTIVITIES UPDATES

Data was taken until 20 April

Site Activation Status

	Site	Activation Status
41	RSUPN dr Cipto Mangunkusumo, Jakarta	Ethical approval has not been obtained
42	RSUP dr Wahidin Sudirohusodo, Makassar	Activation date: 24 February 2015 Start to enroll subject: 26 February 2015
43	RSUP dr Sardjito, Yogyakarta	Activation date: 21 April 2015 Start to enroll subject: 23 April 2015

Screening and Enrollment Progress

*Data was taken until 27 April 2015

	RS dr Wahidin Sudirohudo 42	RS Sardjito 43
Number of screened patients	Adult: 14 Pediatric: 16 **Total: 30**	Adult: 8 Pediatric: 2 **Total: 10**
Number of enrolled patients	Adult: 4 Pediatric: 1 **Total: 5**	Adult: 2 Pediatric: 0 **Total: 2**
Enrollment expectation	Adult: 125 Pediatric: 125	Adult: 125 Pediatric: 125
No. of day after enrollment	Day 60	Day 4


Thank You!