

Dear Readers,

I hope the monthly INA-RESPOND Newsletter since its launch in October 2013 has been useful and interesting as we shared with you the highlights of INA-RESPOND Network clinical research study updates. Our thanks go to all the hospitals as network members for their commitment and hard work in particular for the first study (AFIRE study); also our thanks goes to NIHRD, Center 1, Center 2, NIH/NIAID, SSS, and INA-RESPOND Sekretariat for their great collaboration. I wish everybody a Happy New Year 2014 and I look forward to working with you all on the next INA-RESPOND studies. - Dr. Siswanto, Governing Board of INA-RESPOND Network -

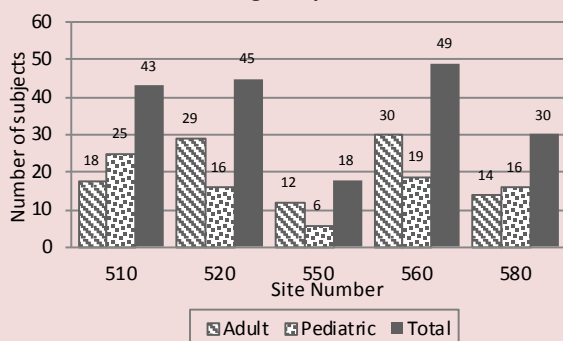
AFIRE STUDY

Site Activation. We would like to congratulate site 570 RS. Dr. Soetomo Surabaya as they begin to screen and enroll participants into this study on January 1.

Enrollment Update. Entering the 24th week of recruitment, INA RESPOND sites have enrolled 185 subjects. Site 560* is now the top recruiter with 49 subjects.

Protocol version 4.0 was submitted on December 16 to NIHRD IRB to be reviewed as well as RS. Dr. Soetomo on December 23. Protocol 4.0 for RS. Cipto Mangunkusumo will be immediately submitted.

Enrollment Progress per 29 Dec 2013



Detailed screening and enrollment progress is available in portal folder: Studies\INA101\Screening progress.pdf or go to the following link:

<https://ina-respond.s-3.com/EdmFile/getfile/797233>

*510 – RS. Hasan Sadikin, Bandung
520 – RS. Sanglah, Denpasar
550 – RS. Wahidin, Makassar
560 – RS. Dr. Kariadi, Semarang
570 – RS. Dr. Soetomo, Surabaya
580 – RS. Dr. Sardjito, Yogyakarta

SEPSIS STUDY

Sepsis study's main objective is to determine the causes of community-acquired sepsis and severe sepsis in adult and pediatric subjects across Southeast Asia. INA-RESPOND foresees the study will start around 3 months after Thailand or Vietnam. Indonesia will recruit 750 subjects within a period of 2 years. The study protocol meeting on January 11, 2014 at NIHRD, Jakarta has been postponed, and a new meeting date in February is to be determined.

TB STUDY

On December 17 at *Badan Penelitian dan Pengembangan Kesehatan (Badan Litbangkes)* / National Institute of Health Research and Development, the second TB meeting was held to discuss the TB protocol which was developed following the output of the first TB meeting on July 10. Several revisions were made to the protocol to further accommodate the needs of the research and inputs from the network members / sites that will conduct the TB study. So far, six hospitals have been confirmed to conduct the study at their sites. These six hospitals are RS. Hasan Sadikin, Bandung, RS. Sanglah, Bali, RS. Persahabatan, Jakarta, RS. Penyakit Infeksi Sulianti Saroso, Jakarta, RSUP. Dr. Kariadi, Semarang, and RS. Dr. Soetomo, Surabaya.

HIV/AIDS STUDY

The first INA-RESPOND HIV/AIDS meeting was held on 18 December 2013 at Lumire Hotel, Jakarta. INA-RESPOND sites' representatives and several invitees from *Komisi Penanggulangan AIDS Nasional (KPAN)* / National AIDS Prevention Commission, World Health Organization (WHO), National Institute of Allergy and Infectious Diseases (NIAID), and The Kirby Institute attended the meeting, which was carried out to inquire about HIV/AIDS research done in Indonesia and the research needed to support and improve the HIV/AIDS treatment which will eventually help reduce the epidemic.

Discussion between dr. Clifford Lane (NIH) and Indonesia Minister of Health, which also happened on December 18 provide considerable research idea. This research intends to model HIV research that is being conducted in Africa, namely PopART – Population Effect of Antiretroviral Therapy to Reduce HIV transmission). HIV/AIDS study in Indonesia will be a randomized community trial with the main goal to observe the impact of prevention combination to reduce HIV incidence. The prevention packages consist of universal household voluntary HIV counseling and testing, linkage of HIV infected individuals to care, and early initiation of antiretroviral therapy (ART) for all those testing HIV-positive. Furthermore, the study would like to pay attention to any non-communicable disease in HIV patient (e.g. diabetes mellitus, cardiovascular disease).

M W W Manuscript Writing Workshop

Manuscript Writing Workshop (MWW) on **January 13-17, 2014** at Lumire Hotel, Jakarta is fast approaching. As preparation of MWW, on December 18 Ms. Lori Dodd from NIH/NIAD provided several authors and mentors a discussion.

We delightedly expect 2 additional participants from each INA RESPOND site to attend this workshop. **The course for additional participants will be compacted into 2 days, January 13-14.** A small fee* will be imposed to all additional participants for refreshment during the course. Please contact your Steering Committee member to sign up.

Let us make the most of this workshop as an opportunity to improve writing capacity for Indonesian researcher.

For questions, email manuscript.inarespond@gmail.com.

*INA-RESPOND will not cover transportation, lodging and meals (B/L/D) for the 2 participants from site. Refreshment fee is Rp. 360.000 per day per person.

Scientific Corner

The Discovery of Dengue Virus (DENV)-5: What Does it Mean?

Jane Cardosa is a famous virologist, previously working at the Universiti Malaysia Sarawak. Through surveillance network, she collected serum specimens during the dengue outbreak in 2007. One of the severe cases, which was originally labelled as "DENV-4", later turned out not to respond to DENV-4 diagnostic tests. Nikos Vasilakis, a virologist at the University of Texas Medical Branch in Galveston, sequenced its entire genome and found that it is phylogenetically distinct from the other four types. Vasilakis et al. then determined that monkey and human antibodies produced against the new type differ significantly from those resulting from the four previously known dengue viruses. As the virus replicates well when it was injected into monkeys that were previously infected with types 1, 2, and 3, but replicated poorly in monkeys that had recovered from type 4, it indicates that the monkeys' immune system saw similarities in the two.

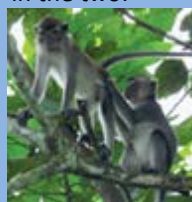


Figure 1. Macaque as DENV-5 host

This discovery was announced during a dengue conference in Bangkok on the October 25, just a year after the report of the failure of tetravalent dengue vaccine to provide protection to DENV-2 infections.

A full protection is important since subsequent dengue infections are associated with severe illness. Concern about dengue virus evolution and emergence was brought up by Duane Gubler. Contrary to this, Thomas Scott said that we did not need another complication in controlling dengue. Moreover, in an international seminar which was held in Yogyakarta last November, Scott Halstead, a dengue guru, advised us not to worry too much as this virus had probably been circulating in Malaysian and Indonesian jungles among macaques for many years and had only been linked to one outbreak in humans. Facetiously, as a productive writer, he is more worried that many dengue textbooks should now be revised to include this novel serotype in their description regarding dengue viruses. In line with the opinion of Plianbangchang, the Regional Director WHO SEARO, we should remember that vaccine will complement, not replace, the efforts to contain dengue through mosquito control and public awareness.

Sources: "Researchers identify fifth dengue subtype" Lisa Schnirring, CIDRAP. <http://www.cidrap.umn.edu/news-perspective/2013/10/researchers-identify-fifth-dengue-subtype>
Normile D. Surprising New Dengue Virus Throws a Spanner in Disease Control Efforts. *Science* 25 October 2013: 342 (6157), 415. [DOI:10.1126/science.342.6157.415]
International Dengue Seminar, Yogyakarta, November 27, 2013



SITE AWARD



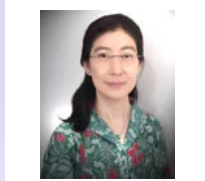
The INA-RESPOND Secretariat would like to thank all research team members at sites who have dedicated their time and have been contributing a lot to the success of the AFIRE study. In the spirit of honoring site research teams' dedication and efforts, we are pleased to

announce **Site 520** as the winner of the Site Award 2014. Congratulations!

2 site research team members from site 520 are invited to attend the upcoming NSC meeting in Jakarta on January 9-10. Kindly submit the 2 names to the INA-RESPOND Secretariat office by January 3 to be processed. For more information, please contact INA101SiteSupport@s-3.com or at **(021) 4287 9189**.

The DMS is located at INA-RESPOND Secretariat, NIHRD, Jakarta, Indonesia. The Clinical Data Management activities include, but are not limited to: Case Report Form (CRF) design, study base set-up and development, edit specifications, data flow and tracking, data entry, data validation management process, database quality control, database finalization, data transfer, and status reports.

The Coordinator of Data Management (CoDM) has primary responsibility to coordinate and oversee all Clinical Data Management activities (CDM) activities in ensuring key milestone are met and INA-RESPOND deliverables are provided on schedule. Additionally, the CoDM oversees the development, approval, and maintenance of study-related documentation. In conducting its activities, the CoDM supervises the Lead Data Manager and Project Assistants. The Operating Support and Statisticians support CDM as needed.



Delima
Coordinator of
Data Management



Kanti Laras
Lead Data
Manager



Eni Yuwarni
Project Assistant



Agnita Triyoga
Project Assistant



Dedy Hidayat
Project Assistant

QUIZ!

What is Your Diagnosis?

An immunocompetent 35-year-old male was admitted to hospital after experiencing fever and myalgia. The doctor diagnosed him with respiratory distress and shock. He was treated with inotropic and broad-spectrum antibiotics with piperacillin /tazobactam. Later he developed skin rash, conjunctival suffusion, and subconjunctival hemorrhage.

What is his diagnosis?

Hint: There was a heavy rainfall a month before the symptoms appear

Please email your answer to INA.Secretariat@s-3.com by 28 Jan 2014, 12pm WIB for a chance to win a souvenir.



ARDS appearance



Conjunctival suffusion
with subconjunctival
hemorrhage

Best Wishes for INA101 team members celebrating their birthday in January:

- o 1 Jan – **Budi Hartati** (Site 530)
- o 7 Jan – **Wiwik Lestari** (Site 560)
- o 9 Jan – **Sonia Kusumawardani** (INA-RESPOND Secretariat)
- o 25 Jan – **I Made Gede Dwi Lingga Utama, Sp.A(K)** (Site 520)
- o 27 Jan – **dr Ida Safitri, Sp.A(K)** (Site 580)



Upcoming Events

January 2014 : 9-10 – NSC Meeting; 13-17 – Manuscript Writing Workshop

We would like to hear from you. Go ahead and send us your scientific articles, team profile, or feedback about the newsletter to INA.Secretariat@s-3.com

What is Your Diagnosis Quiz is taken from: Chien-Yu Lin, Han-Chang Chiu, and Chun-Ming Lee. Downloaded from <http://www.ejournals.org/content/18/1/187.html>