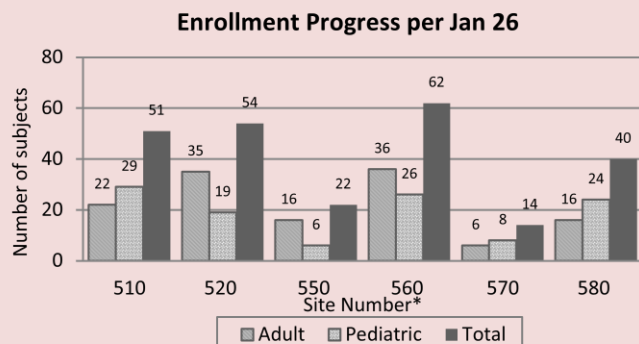


AFIRE STUDY

24 weeks after the start of the AFIRE study, a total number of 240 subjects have been enrolled by the 6 active sites; with site 560 being the highest subject recruiter. Below are the details of the enrollment per January 26:



More 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 – RSUP. Hasan Sadikin, Bandung 520 – RSUP. Sanglah, Denpasar
550 – RSUP. Wahidin, Makassar 560 – RSUP. Dr. Kariadi, Semarang
570 – RSUD. Dr. Soetomo, Surabaya 580 – RSUP. Dr. Sardjito, Yogyakarta

DOCUMENT UPDATES. AFIRE Protocol version 4.0 dated 27 Nov 2013 was approved by RS Soetomo IRB, NIHRD IRB, and FKUI/RSCM IRB on January 7, 9, and 13 respectively. Other related documents and forms are under revision and soon to be imposed.

AFIRE STUDY REVIEW POINT IN NETWORK STEERING COMMITTEE (NSC) MEETING ON JANUARY 9-10.

SAE reporting. NIHRD IRB is currently discussing the need for sites to report all SAEs occurring in AFIRE study. During this time, sites are expected to report all SAEs regardless of their relation to the study procedures.

BPJS scheme. The BPJS scheme, which took effect on Jan 1, has raised concerns from Steering Committee (SC) members and sites as it may affect recruitment number and study lab budget. We will wait and monitor to see if the BPJS implementation affects subject recruitment rate. Moreover, SC members also express their commitment to negotiate the lab exam fee with the hospitals in regards to the BPJS practice.

Interim analysis. An interim analysis will be conducted once CRFs from 200 subjects (100 adults and 100 pediatric) are registered in OpenClinica, a clinical research software for electronic data capture. Up to Jan 28, CRFs from 79 subjects had been entered into OpenClinica.

TB STUDY

Steering Committee member and experts decided to add X-Ray besides 2 clinical symptoms as inclusion criteria for TB study. This discussion point has resulted in some changes in study plan.

Blood, urine, and sputum samples are planned to be taken and carried on to the hospital's laboratory. Nevertheless, specimen management outside the hospital laboratory is still possible.

Gladly, all sites are interested in joining this study. Site selection will be determined by taking into account the site performance and sample size requirements. The network is planning to have small meetings at site hospitals to socialize this study once all participating sites are identified.

HIV/AIDS STUDY

The Steering Committee members have given their full support to the HIV/AIDS community trial study. A PopART (Population Effect of Antiretroviral Therapy) research model is planned to be applied in our INA-RESPOND HIV/AIDS study. This research will be vast and will need a great amount of effort to make the study successful, which make it very exciting for our growing network.

A collaboration with the KPA (AIDS Prevention Committee) and Centre for Disease Control and Prevention (P2PL) will have to be established for this study to work well. Moreover, the HIV/AIDS study needs to involve and engage the District Health Centre (*Dinas Kesehatan*). It is believed that the massive scale of this study and collaboration will further strengthen the INA-RESPOND network.

SEPSIS STUDY

Sepsis study is one of the studies conducted by the Southeast Asia Infectious Disease Clinical Research Network (SEAICRN), a collaborative partnership of hospitals and research institutions in Indonesia, Thailand, and Vietnam. Recently, Dr. Direk Limmathurostsakul, Mahidol Oxford - Bangkok, has been named the new Director of SEAICRN. As the Director of SEAICRN, he will provide leadership to the network and be accountable to the SEAICRN Governing Board.

Dr. Direk will be traveling to Yogyakarta to give lectures and talk about Sepsis study in Indonesia. A sepsis meeting is also planned to be held at NIHRD, Jakarta during Dr. Direk's visit to Indonesia – date to be determined.

M

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Manuscript Writing Workshop

The **First Manuscript Writing Workshop (MWW)** by **INA-RESPOND** was held on January 13-17, 2014 at Hotel Lumire, Jakarta. In his opening remarks, NIHRD Directorate General, DR. Dr. Trihono, MSc, encouraged all authors who attended this workshop to complete their paper until it is published.

The MWW was attended by 41 participants from Jakarta, Bandung, Jogjakarta, Surabaya, Bali, and Makassar. Authors were mentored by a lot of experts from Indonesia and NIH: **Prof. Dr. Suharto, SpPD-KPTI, Prof. Dr. Mansyur Arif, SpPK, dr. Helmia Farida, dr. Bachti Alisjahbana, PhD, SpPD-KPTI, Prof. Dr. Ketut Tuti Merati, SpPD-KPTI, Dr. Abu Tholib Aman, Msc, PhD, SpMK, Prof. dr. Emiliana Tjitra, MSc, PhD, Prof. Inge Sutanto, Dr. Gina Samaan, dr. Michael A. Polis, dr. Michael Fay, Dr. Lori Dodd, Dr. Martha Nason, Dr. Nancy Touchette, Dr. Anand Joshi, and dr. Agus Salim.**

During the first two days of the workshop, participants received useful materials on how to improve their writing skills. Afterwards, authors received a 3-day-intensive one-on-one writing session. Good news comes from one author, **dr. Masri Sembiring Maha**, who will soon be the first author of this workshop to publish his paper - **The First Identification of ECSA Chikungunya Virus in Indonesia.**

In order for the mentors and authors of MWW to be able to stay in touch and help one another, a Facebook group was set up: **Manuscript Writing Workshop 2014.** Please find and join us!



"The workshop was simply superb; it was mind-changing and far from boring. The time provided by the committee was sufficient and effective. Every author has an opportunity to consult their work with his/ her mentor intensively, so we know what to do next." Dr. Hera (Author – Jogjakarta)



"Advancing biomedical research that promotes public health depends on effective writing that clearly describes the study undertaken and accurately conveys results and conclusions. The recent manuscript writing workshop signified one of many productive collaborations between INA-RESPOND and the US NIH/NIAID. By the end of the five-day workshop, all authors made considerable progress on their manuscripts and some even produced drafts nearly suitable for submission to international journals. I was especially impressed at the dedication demonstrated by authors and faculty. The week was intense and demanding, but especially rewarding. It was also good to develop a sense of the great potential of infectious disease research in Indonesia." Lori Dodd (Biostatistician – NIH)



"The topics presented in the manuscript writing workshop were very interesting and mind-broadening. We were taught how to construct a decent article worth publishing by qualified mentors. I believe that this workshop would benefit a lot of people if it is conducted regularly. Thanks to the committee that have organized this event." Dr Armedy (Author – NIHRD)



"When I attended a similar workshop in 2011, I was convinced that I had a great and almost final draft –thinking that it would only need a final touch from English native speakers to make my draft perfect. However, it was only published 17 months later after a long process including retesting a number of specimens. I learned that writing is complicated and involves a lot of preparations. Having that said, the lecturers in this Manuscript Writing Workshop managed to provide us with many tips on how to start writing correctly and effectively while maintaining a fun and creative atmosphere. So, LET'S START writing!" Dr. Herman Kosasih (Scientific Lead – INA-RESPOND)

NSC MEETING



Network Steering Committee (NSC) meeting on January 9-10 was attended by all Steering Committee (SC) members, including from *Universitas Indonesia*, RSPI Sulianti Saroso, Centre 1 NIHRD, NIAID/NIH representatives, and SSS representatives. The meeting agenda discussed the following items: AFIRE Study Updates, Interim Analysis, Sites Challenges, Performance and Evaluation, INA-RESPOND Future Studies (TB, Sepsis, and HIV), INA-RESPOND Annual Evaluation, Manuscript Writing Workshop and Meeting Plans for 2014.

During the meeting, dr. Jaya and dr. Tyas, two research assistants from Site 520 (RS Sanglah-Denpasar), shared their experiences. At the end of their presentation a Site Award was handed by Dr. Siswanto and Dr. Lane to Site 520 for their significant efforts on the AFIRE study during 2013. The network believes that this yearly award will provide good motivation for each site in managing the research as well as they can. In respect of this, RA meeting was proposed as a forum to accommodate further needs of learning.

At the end of the meeting, the SC members identified a few things that the network needs to work on to reach its goal such as conducting integrated Good Clinical Laboratory Practice (GCLP) and training for new sites joining the INA-RESPOND network.

The next NSC meeting will be held in May in Jakarta (date to be confirmed).

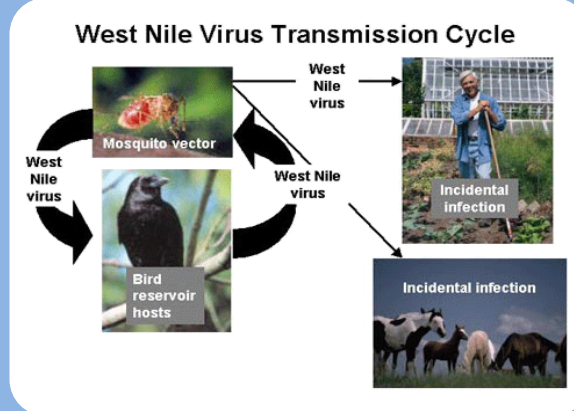
Scientific Corner

WEST NILE VIRUS DOCUMENTED IN INDONESIA: HOW SERIOUS IS IT?

The name West Nile Virus (WNV) comes from the area around the Nile River in Uganda, where the virus was first identified in 1937. Now WNV has an extensive geographical spread throughout Africa, Middle East, Southern Europe, Russia, Western Asia, Australia and the US. Moreover, a recent study has discovered its existence in Indonesia. The lineage 2 of WNV found in Indonesia is similar to the one that caused an outbreak in Eastern and Southern Europe. Consequently, further surveillance and research on WNV in Indonesia is required.

The WNV belongs to the Flaviviridae family and can be designated into 5 lineages. The transmission of the virus to humans is mainly through the bite of *Culex* mosquitoes. Most human infections are mild, but severe illness occurs in 1% of the cases. If the virus crosses the blood-brain barrier, it may cause encephalitis. Severe cases and large outbreaks have typically been associated with lineage 1 viruses and thus are considered to be more virulent than the lineage 2 strains. However, lineage 2 viruses caused an epidemic in Europe in 2008 and were also fatal, suggesting an increase in their virulence.

A study by Myint et al in Bandung, Indonesia in 2013 looked into 157 blood specimens from febrile non-dengue patients and found 1 positive sample for WNV lineage 2. Sequencing analysis revealed similarity with the first WNV strain isolated from Uganda. This sample was taken from a 15-year-old boy admitted for systemic febrile illness with epistaxis, gastrointestinal symptoms, elevated serum transaminases, leucopenia, and thrombocytopenia. No neurological



symptoms were reported and the patient was discharged with full recovery.

Although the case in Bandung was not severe, cases such as encephalitis caused by WNV lineage 2 have been found in other countries. As the etiologies of encephalitis cases in Indonesia are often undiagnosed, the discovery of WNV in Indonesia leads us wondering whether WNV may be one of the causes. A large WNV surveillance and research regarding this issue should be conducted to provide clearer picture of WNV in Indonesia.

Source: Myint KS et al. Short Report: West Nile Virus Documented in Indonesia from Acute Febrile Illness Specimens. 2014.

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

- 2 Feb – **dr. Indri Hapsari Putri** (Site 560)
- 7 Feb – **Anandika Pawitri** (INA-RESPOND Secretariat)
- 28 Feb – **dr. Khie Chen, SpPD-KPTI** (Co-PI site 530)



INA-RESPOND Squad

Site 510 – RS Hasan Sadikin, Bandung

So who are their members? Let's meet them!

Site PI: Dr. Bachti Alisjahbana, PhD, SpPD-KPTI

Co-PI: dr. Anggraini Alam, SpA(K), Prof. DR. dr. Ida Parwati, SpPK(K), PhD

RA : dr. Linda Choerunissa and dr. Heny Yuniarti
(soon to be replaced by dr Sindy Siahaan)

Lab technician: Hofiya Djauhari, Msi, Ernawati



dr Heny and dr Linda



Dr Sindy

A glimpse into this wonderful team; site 510 research team is led by **dr. Bachti**, who is described as a very active and passionate person when it comes to conducting research. For this very reason, 24 hours a day are not enough for him. Besides his passion in research, his heart also goes to kayaking, a popular water sport!

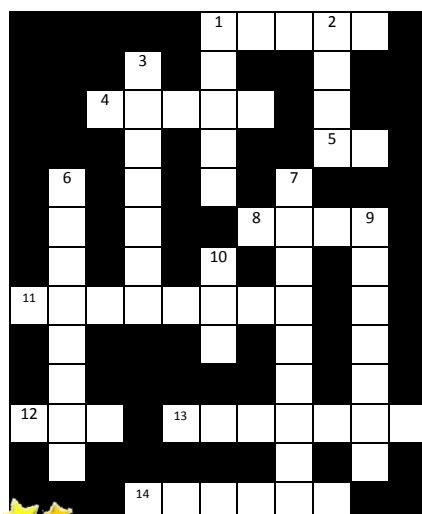
As site 510 front liners, we have dedicated research assistants: **dr. Heny, dr. Linda, and dr. Sindy**. Dr. Heny, who is expecting a baby soon, will be replaced by dr. Sindy, who is currently being trained for the AFIRE study. We also have dr. Linda, a Soedirman University graduate, who loves travelling and making culinary trips.

"Talent wins games, but teamwork and intelligence wins championships." – Michael Jordan-



Site 510 Team
University of Padjajaran/RS Dr. Hasan Sadikin

QUIZ!



Across

1. One of the sponsor for AFIRE study
4. Across/6 Down. An individual authorized under law to consent, on behalf of a prospective subject
5. A responsible leader for the conduct of a clinical trial at a trial site
8. The opposite of impartial witness
- 11 Across/7 Down. Any change from protocol that has a major impact on the subject's rights, safety or well-being, and/or data integrity
12. Any untoward medical occurrence that is life-threatening
13. Before getting this clearance, site must not screen subjects
14. the process whereby children may agree to participate in clinical trials

Down

1. One of the sponsor for AFIRE study
- 2/9. This AFIRE site is located in the 'island of gods'
3. The ... Report, issued in 1978, explains 3 fundamental principles in research involving human subjects
10. A document where a subject confirms in writing his/her willingness to participate in a trial.

Please email your answer to INA.Secretariat@s-3.com by Feb 26, 12 pm WIB for a chance to win a souvenir.



From three correct answers received by the INA-RESPOND Secretariat, the prize of January Quiz goes to dr. Indri Hapsari Putri from site 560, Semarang. Congratulations! A souvenir will be sent to you within 2 weeks.

Upcoming Events

February: 27-28 TB laboratory meeting; HIV, Sepsis

INA-RESPOND Newsletter

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