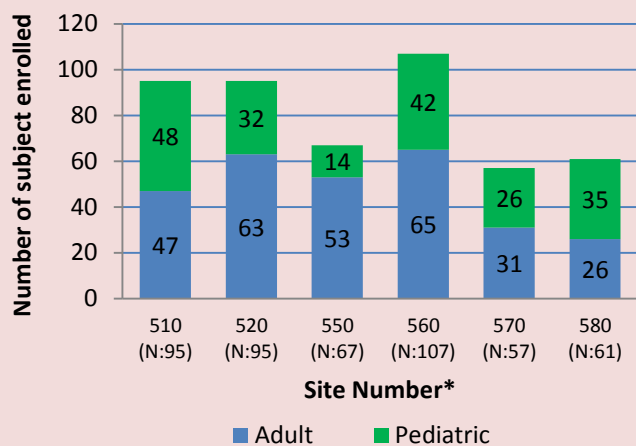


AFIRE STUDY

The Etiology of Acute Febrile Illness Requiring Hospitalization (AFIRE)

For further information on this study please go to:
<http://www.ina-respond.net/afire-study/>

Up to June 29, from 6 active sites, 1,532 patients had been screened, with 482 subjects (285 adults and 197 pediatric) enrolled. Enrollment progress up to June 29 can be seen in the graphic below:



*510 – RSUP dr Hasan Sadikin, Bandung
520 – RSUP Sanglah, Denpasar
550 – RSUP dr Wahidin, Makassar
560 – RSUP dr Kariadi, Semarang
570 – RSUD dr Soetomo, Surabaya
580 – RSUP dr Sardjito, Yogyakarta

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>

Joint Commission International (JCI) inspection – An Experience Worth Sharing

MAKASSAR – Aiming to improve patient safety and quality of health care in the international community, a JCI inspection occurred from June 2-6 at RSUP Dr. Wahidin Sudirohusodo.

One of the inspector's agenda was to assess the ongoing study at the hospital by checking the study document completeness and interviewing some of the study subjects.

The AFIRE research team informed the subject about the JCI inspection and prepared the study documents required by the inspector. The inspector raised some questions related to the study document, and they were successfully answered by the study team as some of them were quite similar to the ones asked by the AFIRE study monitor. The highlight of the inspection was when the inspector interviewed a study subject. Various and unanticipated questions such as "What are the requirements to be enrolled in the study? What do you have to do in this study? Are there any benefits to taking part in this study? Can you withdraw from the study at any time? Does the study give you something for your participation?" were given to the study subjects. The research team members were blown away when the subject claimed that he had received something from the study in exchange for his participation. The subject then explained that he was given a set copy of 7-pages Informed Consent Form to be taken home. The inspector was really satisfied with the study team and the subject.

Having good review, the INA-RESPOND network and AFIRE study have been very famous at the hospital ever since. We are all very proud of the research team members who have dedicated their time and made lots of effort for the success of the AFIRE study.

-UN-



TRIPOD STUDY

JAKARTA – The INA-RESPOND network first TB study is officially named TRIPOD, which stands for Tuberculosis Research of INA-RESPOND on Drug Resistance. On June 11, the network held a TB Meeting to share its most current TB study design. The network's TB core team members and representatives from National TB Program, NIHRD, NIAID, USAID, as well as from the CDC attended the meeting and sounded many valuable suggestions and motions. The network's TB core team has made some revisions to the protocol and the Case Report Form (CRF) draft based on the discussion results. The finalized protocol and CRF will be submitted to NIHRD scientific committee for review this month.

For more information on this study, please go to <http://www.ina-respond.net/tripod-study/>

-NHS-

SEPSIS STUDY

The SEAICRN Governing Board (GB), Executive Committee (EC) and Annual Meetings took place in Bangkok, Thailand from June 15 - 19, 2014. All meetings were a great success. GB members attended a Press Conference on June 16. The Press Release stated that Thailand, Vietnam and Indonesia were to collaborate on major study of sepsis, a deadly medical condition. Members of the GB and EC focused on Strategic Planning, Future Research Priorities, and the Sepsis Study, while attendees of the Annual Meeting shared experiences from the implementation of the Sepsis Study in Thailand and Vietnam, learned about policy implications of epidemiologic and clinical research on infectious diseases, discussed what clinical research is needed for public health in Southeast Asia, shared experience how clinical research can integrate into Ministry of Health, learned about mentoring, and grant opportunities. In this opportunity dr. M. Karyana, the Chair of INA-RESPOND, presented the INA-RESPOND model for work collaboration between Indonesia and the US government. Also, dr. I Made Susila Utama, one of site PIs in AFIRE study, shared his success story from Sanglah Hospital, Bali.

The next Annual Meeting will take place in Indonesia from June 2 – 5, 2015. Save the date! -NJ-



Indonesian delegates at SEAICRN Annual Meeting in Bangkok, Thailand

From left to right: dr Sri Idaiani, dr Sudirman Katu, Prof. Mansyur Arif, dr. M. Karyana, dr. Abu Tholib Aman, dr. I Made Susila Utama, Ms. Yanti Triswan, dr. Armaji KS, Ms. Sonia Kusumawardani

HIV STUDY



HIV study is getting closer and more real in its implementation. Please welcome the name for this HIV study, **Indonesia PASTI BISA** which stands for **Indonesia** Prevention of HIV-AIDS Transmission by Increasing Testing and Prompt ART. This study will focus in answering the research question: "Does early administration of ART decrease the incidence of new HIV infections?". Accordingly, the study is designed to compare early treatment of ART regardless of CD4 count (arm1) against standard therapy (arm2). Both arms will receive the same intervention package and community engagement program. Treatment arm will be randomly allocated on cluster/district level. However, this is not a small feat to accomplish as a lot of considerations such as mobility within the cluster, level of disease prevalence, infrastructure of the district need to be taken into account especially since we would like to start this study by 2015.

-AP-



SCIENTIFIC CORNER

Malaria in Indonesia: Problem in Elimination

dr. Armedy Ronny Hasugian, M.Biomed., Prof. Dr. Emiliana Tjitra, M.Sc., PhD

Malaria control is one of the main goals in Millennium Development Goals (MDG). World population at risk of malaria infection is approximately 1.2 billion, and 37% of that number lives in Southeast Asia including Indonesia. In Indonesia, 17% of its population lives in high endemic areas, mostly from eastern region, namely Papua, West Papua, East Nusa Tenggara, Maluku and North Maluku. Considering the high occurrences of malaria cases, Indonesia is committed to eliminate malaria by 2030.

Clinical manifestations of malaria vary from asymptomatic to severe malaria. Headache, nausea, vomiting, fatigue, and other symptoms followed by fever, chills, and perspiration appear frequently. Blood tests often show thrombocytopenia, anemia, and eosinophilia. All of these are commonly observed symptoms in infectious diseases that may lead to misdiagnosis, especially in travelers. Misdiagnoses in turn will result in mistreatment, increasing number of severe malaria case and its spread to non-endemic area (i.e. Sukabumi and Jakarta, Indonesia).

For malaria diagnosis, Giemsa microscopy is still considered as the gold standard. However, there is limited resource, especially in remote and endemic areas, that can perform this test. Rapid Diagnosis Test (RDT) is chosen as a strategy to overcome this situation, but it is not to replace Giemsa microscopy. RDT is easy to use but raises more concern due to its sensitivity, specificity, number of false positive and negative result, temperature, and cost. This approach may increase both under and over diagnosis, which in turn may induce treatment failure of Artemisinin Combination Therapy (ACT).

Treatment failure is defined as occurrence of any asexual parasitemia after completing antimalarial and avowed as recrudescence, reinfection or relapse (only for *P. vivax* and *P. ovale*). Aside from diagnosis problems, poor adherence, drug resistance, and inadequate drugs are also related with treatment failure. ACT is a standard antimalarial that consists of artemisinin derivative and other drugs which have different mechanism. Most of antimalarial still have good efficacy which meet WHO policies. However, resistance of ACT partner drug (i.e. amodiaquine, piperazine) has been reported. Recently, artemisinin derivative resistance for *P. falciparum* was reported in the border of Thailand and Myanmar.

Indonesia has lots of homework to reach the malaria elimination target by 2030. Surveillance of incidence and prevalence of malaria cases, surveillance and monitoring of drug resistance of antimalarial therapy, training for Giemsa microscopy, development of new diagnostic tools and drug resistance detection kits are strategic to eliminate malaria. Research and endorsements is essential in helping government eliminates malaria in Indonesia.

References: 1.WHO. Health and Millenium Development Goals. Geneva2005 2.Riset Kesehatan Dasar 2013. Jakarta: Balitbangkes, Kementerian Kesehatan RI; 2013 3. Eryando T, Susanna D, Pratiwi D, Nugraha F. Imported malaria cases in Sukabumi District-West Java Indonesia, in 2012. Malaria journal. 4. Lederman ER et al. Imported malaria in Jakarta, Indonesia: passive surveillance of returned travelers and military members postdeployment. Journal of travel medicine. 2006 5. González A et al. Severe imported malaria in adults: retrospective study of 20 cases. The American journal of tropical medicine and hygiene. 2009 6. Bell D, Wongsrichanalai C, Barnwell JW. Ensuring quality and access for malaria diagnosis: how can it be achieved? Nature reviews Microbiology. 2006 7. WHO. Malaria Rapid Diagnostic Tests: An Implementation Guide. Geneva2013 8. Mouatcho JC, Goldring JP. Malaria rapid diagnostic tests: challenges and prospects. Journal of medical microbiology. 2013 9. Imwong M et al. Relapses of Plasmodium vivax infection usually result from activation of heterologous hypnozoites. The Journal of infectious diseases. 2007 10. Liu DQ. Surveillance of antimalarial drug resistance in China in the 1980s-1990s. Infectious diseases of poverty. 2014 11. Dondorp AM et al. Artemisinin resistance in Plasmodium falciparum malaria. The New England journal of medicine. 2009



G C P FORUM / CFR 21 part 11: Electronic Records

Code of Federal Regulations (CFR) is the official and complete text of US Federal Government regulations that provides a comprehensive and convenient reference. It provides technical, operational, and legal details that make the law works on a day-to-day level. It is good to be familiar with these regulations because research conducted or supported by the US federal government must adhere to these federal regulations.

There are 50 titles of CFR, representing broad areas. Title 21 Part 11 specifically talks about electronic records. How a system should be set to ensure that electronic records, electronic signatures and handwritten signatures executed to electronic records are trustworthy, reliable and generally equivalent to paper records and handwritten signatures executed on paper. When we choose to use records in electronic format in place of paper format, part 11 would apply. On the other hand, when computers are used to generate paper printouts of electronic records, and we rely on that paper records for regulatory activities, this part 11 does not apply.

An example on implementation of part 11 principle is in the use of identification codes/ passwords when accessing electronic documents (e.g. INA-RESPOND portal). The combination of ID and password should maintain uniqueness in a way that no two individuals have the same combination of identification code and password. The identification code and password issuance are also periodically updated. These principles are all have been in place for our INA-RESPOND portal.

To better understand about 21 CFR part 11, you can go to:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

-SK-



Manuscript Writing Workshop

We are delighted to see a couple of Manuscript Writing Workshop (MWW) participants have submitted their manuscripts. We believe this will encourage other participant to hasten the manuscript submission. Here is the progress:

Author	Abstract Title	Status
Ni Made Dewi Dian Sukmawati	Preliminary Study for the Herbal Topical Repellent of Piper betle and Patchoulli oil mixture in gel forms against Aedes aegypti.	Submitted to International Scholarly Research Notices journal
Mutiara Widawati	Assessing Risk For Severe Manifestation Of Dengue Virus Infection: Role Of Enzyme Metalloproteinase 9.	Submitted to Biotropia journal
Tri Wibawa	Cyclosporine A Decreases the Fluconazole Minimum Inhibitory Concentration of C. albicans Clinical Isolates.	Submitted to Mycoses journal

-AP-

INA RESPOND SQUAD

Site 550 – RS Dr. Wahidin Sudirohusodo, Makassar

If you have met the Wahidin hospital team before, well... You may want to get to know them more. Almost all of them have cute nicknames and they study really hard. Let's start with **dr. Ninny Meutia, Sp.A**, the Site PI, who is popularly known as dr. Unil. She is a very friendly and loving person whose heart easily breaks when she sees sick children. Becoming site PI in one of INA-RESPOND studies is like a dream comes true for her as she loves doing research.

dr. Risna Halim Sp.PD, a.k.a. dr. Mima, (co-PI) is on her way to finishing her PhD research on HIV-TB. Between her busy practice and research, she likes to go shopping, travelling and eating chocolate.

dr. Nurhayana Sennang Sp.PK (co-PI) is a very friendly person. Her personality is like a magnet, that when you chat with her although only for a while you will feel like you've known each other for years. She is studying Malaria for her doctoral degree.

This world cup season is something that **dr. Fatmawaty Ahmad** (RA) has been looking forward to as she loves soccer. She is rooting for Brazil to win the world cup this year. Other than the world cup, she is a fan of Inter Milan. Chimo is her nickname.

dr. Patricia Tauran/ Patty/ Monic (RA) is a Clinical Pathology resident. She is a sporty doctor who enjoys marathon, just like **Prof. Dr. Mansyur Arif, PhD, Sp.PK (K)** (NSC Member) who is a badminton athlete in the campus.

The Lab technicians are experienced and very dedicated to their work. **Ms. Dewi Sriyanti** has worked for 14 years at the hospital. Early this year she was honored as the Employee of the Year. This is a great achievement because besides working in the hospital, she is also completing her diploma of languages. **Ms. Ennycke Sary**, usually called Ai, is doing her Master degree in Microbiology while working hand in hand with Dewi and the RAs handling the AFIRE study specimen.

Next time you meet the team you can ask these friendly people how they got their nicknames or how they juggle between research, academic, practice, and family.

-SK-



Prof. Dr. Mansyur Arif, PhD, Sp.PK (K)



dr. Nurhayana Sennang, M.Kes, Sp.PK, DMM (K)



From left to right: Ms. Dewi Sriyanti, dr. Patricia Tauran, dr. Ninny Meutia, Sp.A, dr. Risna Halim Sp.PD, dr. Fatmawaty Ahmad, Ms. Ennycke Sary

WORD FINDER

How much do you know about infectious disease?

We challenge you to find 15 possible disease terminologies in this word finder!

Please email your answer to INA.Secretariat@s-3.com by 26 July 2014, 12 pm WIB for a chance to win a souvenir.



X	B	C	K	Q	P	Y	A	G	C	L	L	Q	P	H	F	X	Z
C	C	R	S	Q	F	I	L	A	R	I	A	S	I	S	E	Z	Y
A	S	L	S	I	S	O	C	I	M	O	G	Y	Z	L	O	N	X
N	I	E	A	V	R	K	L	S	K	S	Y	I	P	A	N	A	B
D	S	P	L	B	C	D	E	N	G	U	E	M	T	V	S	J	H
I	A	T	L	O	G	N	G	C	U	K	I	D	X	P	I	Q	S
D	I	O	E	Q	E	J	I	S	X	S	S	H	S	N	S	H	I
I	D	S	B	I	G	C	K	T	S	H	I	K	I	E	O	T	S
A	R	P	U	K	Y	F	W	E	E	O	S	P	T	U	C	H	O
S	A	I	R	D	J	H	P	P	H	B	O	C	I	M	Y	J	C
I	I	R	E	X	T	R	A	C	I	T	L	J	G	O	M	F	Y
S	G	O	D	Y	E	T	Y	H	S	X	U	Y	N	N	O	I	M
T	Q	S	V	H	I	D	D	E	H	J	C	M	A	I	N	Y	O
F	J	I	K	T	K	V	I	R	K	L	R	Q	L	A	I	X	T
U	Q	S	I	G	B	B	A	M	V	Z	E	K	O	E	T	S	S
M	L	S	Y	Z	A	X	G	W	N	C	B	I	H	E	C	I	A
O	R	D	L	C	Y	O	H	D	S	G	U	F	C	K	A	F	L
M	N	N	S	Q	P	H	H	P	H	C	T	F	A	H	H	X	B

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

- 08 July – dr Fadila Zitria (RA Site 540)
- 11 July – Dwi Sri Winarti (LT site 580)
- 12 July - Evi Hindawati (LT Site 540)
- 13 July – dr Suratno Lulut Ratnoglik (RA Site 530)
- 31 July – Prof. Dr. Pratiwi Sudarmono, PhD (SC Member)
- 31 July – dr Yuli Mawarti (RA Site 580)



Congratulations to dr Indri Hapsari (site 560) for her baby girl born on June 10.

We bid **Farewell** to Mr. Christian Yoder, MPH, RN (NIH/NIAID) after his undeterred support for INA-RESPOND. As you are heading forward for the newer opportunity, we wish you all the best in your future endeavors. And we **Welcome** to Ms. Susan Vogel, RN, BSN (NIH/NIAID), who for now will take on Christian's role. Please accept our warm welcome and we look forward to working with you.

We would like to express our deepest **Condolences** to Prof. Dr. Tuti Merati, SpPD-KPTI (SC member site 520) and family for the loss of beloved husband and father on June 26. Our hearts go out to you in your time of sorrow.

INA-RESPOND Newsletter

Advisor : dr. M. Karyana, dr. Herman Kosasih
 Editor in Chief : dr. Anandika Pawitri
 Language Editor : Dedy Hidayat S., S.Kom.
 Editorial Board : Sonia Kusumawardani, S.Si., Apt, dr. Nurhayati , dr. Nugroho Harry Susanto, Nasreen Jahed, MPH
 Thanks to : INA-RESPOND Network and Partners
 Disclaimer : **All Copyright and trademark are recognized**

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