

INA-RESPOND Secretariat

Badan Litbangkes, Kemenkes RI, Building 4, 5th Floor, Jl. Percetakan Negara No. 29, Jakarta, 10560. Phone: +62 21 42879189 Email: INA.Secretariat@ina-respond.net Website: www.ina-respond.net

Newsletter January 2016



In This Issue

- 3 Have you heard of the name Leidos Biomedical Research, Inc.? Who are they and what do they have to do with our network? Find the answer here!
- The Sepsis study (SEA050)
 closed its enrollment on the
 last day of December 2015.
 Let's find out how it is doing
 in this edition.

Diabetes Mellitus and TB: Friends that Should Not Be Together

It's already that time of the year when we celebrate the new year and write down our New Year resolutions! I am sure that some of us write something like eat fewer calories, be slimmer, or get fit for our New Year resolutions.

Different people have different motives as to why they want to eat fewer calories. The most understandable motivation is to lose weight. After all, when we carry extra weight, it places us at a greater risk of a whole range of serious health problems, including heart disease, diabetes, and some other infectious diseases.

With all of the conflicting information out there on what to eat, sometimes it is hard to decide what to do when we want to lose weight.

In this edition, we are going to take a closer look at diabetes and tuberculosis (TB) in relation to healthy eating and healthy lifestyle. You can also find some tips on healthy eating. Enjoy!

Page 5

The 9th World Society of Pediatric Infectious Diseases (WSPID)

INA-RESPOND participated at the 9th WSPID in Rio De Janeiro from 18 – 21 November 2015. Read the report in this edition. Page 8



Save The Date

Wish You New Year 2016!

On 1st January, when the moon sets and the sun rises, the world would wake up to a new dawn. I wish all my friends and co-workers live long and to witness 100 such dawns. Happy New Year! May the New Year fill up days with all things that are nice and bright.

1 January

New Year 2016

31 January

World Leprosy Day

January Birthday

7 Jan	Ms. Wiwik Lestari	Lab Tech Site 560
10 Jan	dr. Umi Solekhah Intansari, SpPK	Co-PI SEA050 Site 43
24 Jan	Mr. M. Alfian	Lab Tech Site 530
25 Jan	dr. I Made Gede Dwi Lingga Utama, Sp.A(K)	INA101 Co-PI Site 520
27 Jan	dr. Ida Safitri, Sp.A(K)	INA101 Co-PI Site 580





Profile: Leidos Biomedical Research, Inc.

By:

Beth Baseler Louis Grue Dr. Jacqueline Perodin

Leidos Biomedical Research, Inc. (Leidos Biomed) develops and applies advanced technologies to help translate research discoveries into treatments for cancer and AIDS. It is a wholly-owned subsidiary of Leidos and is dedicated to a single contract to operate the Frederick National Laboratory for Cancer Research, a Federally Funded Research and Development Center focused on cancer and AIDS research. This is the only national lab within the Department of Health and Human Services.

Leidos Biomed's staff of scientific, technical, and support professionals conducts basic and applied research in cancer and AIDS, operates and manages the federal government's only vaccine manufacturing facilities which includes the Vaccine Pilot Plant (VPP) and the Biopharmaceutical Development Program (BDP), and runs the high-performance Advanced Biomedical Computing Center.

Leidos Biomed's Clinical Monitoring Research Program (CMRP) provides comprehensive, dedicated clinical research support to major programs within the National Institutes of Health (NIH), including the National Cancer Institute (NCI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Center for Advancing Translational Sciences (NCATS), the National Institute of Mental Health (NIMH), the National Institute of Neurological Disorders and Stroke (NINDS), and the Clinical Center (CC). To support the diverse research requirements of the clinical research community, CMRP

provides an integrated range of quality services that are functionally organized within the Clinical Research Directorate. CMRP represents a comprehensive resource for a number of the intramural clinical research programs at NIH.

As a program, CMRP has provided high-quality clinical research support services to meet



Beth Baseler Director Clinical Monitoring Research Program Leidos Biomedical Research, Inc.

Continued



Jacqueline Perodin Clinical Project Manager II Clinical Monitoring Research Program Leidos Biomedical Research, Inc.



Louis Grue Clinical Project Manager III Clinical Monitoring Research Program Leidos Biomedical Research, Inc.



Josh Ensor Sr. Subcontracts Administrator Leidos Biomedical Research, Inc.

the expanding and new challenges faced by NIH researchers. CMRP has recognized the numerous barriers to conducting clinical research, not only domestically, but particularly in an international setting. The successful completion of our mission directly benefits the missions of NCI, NIAID, and other institutes, and has contributed to improving the overall standards of public health globally. The repertoire of support services provided to clinical researchers throughout the world has expanded dramatically over the last 14 years, assisting researchers in providing the highest-quality clinical research that is compliant with applicable regulations and guidelines, and maintaining data integrity, with the overall goal of protecting human subjects. CMRP has supported the goal of increasing the capability of international locations to participate and partner in clinical research and has assisted in the critical development of clinical trial networks across the world.

CMRP provides high-quality programmatic and clinical trials management, regulatory, pharmacovigilance, protocol development and navigation, and project/program management services to support to an extensive variety of high-profile NCI and NIAID initiatives and domestic and international studies. For additional information on the projects supported by Leidos Biomed's CMRP: <u>http://cmrp.ncifcrf.gov/CMRP/Def</u> <u>ault.aspx</u>

Leidos Biomedical Research has extensive experience working with NIAID in the implementation of international and domestic research collaborations. As the prime contractor, Leidos will subcontract with: Prodia the CRO, an Indonesian based company to provide research support; SSS to provide data management; and PTG to provide staffing for the network secretariat in an effort to promote greater autonomy and independence in day-to-day functioning. The goal of this new infrastructure is to better meet the needs of the INA-RESPOND Network and move towards its self-sustainability.

Beth Baseler Louis Grue Dr. Jacqueline Perodin

Leidos Biomed will manage the subcontracts that are supporting the

INA-RESPOND Network:

- Prodia the CRO (Prodia)
- Social & Scientific Systems, Inc. (SSS)
- PT Ganesha Aggies Jaya (PTG) Staffing Agency



World Diabetes Day 2015 has been transformed into World Diabetes Campaign, which is a 365-day celebration. The transformation has been made to remind us that diabetes has become an inseparable part of our daily lifestyle. The campaign focuses on healthy eating as a key factor in the fight against diabetes mellitus (DM) and act as a cornerstone of global health and sustainable development.

Healthy eating can prevent the onset of type 2 DM and is an important part of the effective management of all types of diabetes to help avoid complications. Therefore, this campaign is not only intended for healthy people but also for people who are suffering from diabetes and its complications.

Many studies in both developed and developing countries show that DM associates with an increased risk of TB, regardless of study design and population. This relationship was a well-known fact in the past, but it was easily forgotten when treatment for both diseases were widely available. As type 2 DM has become a current global problem and TB is highly endemic, doctors are giving more attention to the association between DM and TB. In addition, the complexity of TB treatment and development of multidrug resistant TB (MDR-TB) have increased physicians' alertness.

DM seems to have negative effects on the outcome of TB treatment. Consequently, the mortality rate increases and the length of TB treatment is taking longer. These conditions add

(continued)

Diabetes Mellitus and TB: Friends that Should Not Be Together

By Dr. Aly Diana

TAKE ACTION:

PROVIDERS

MAKE DIABETES PREVENTION A PRIORITY; DOING MASS SCREENING, INCREASING POLICY ON CUT SUGAR LEVEL ON PACKAGED FOODS AND BEVERAGES.

EVERYONE

START HEALTHY EATING. STOP DRINKING SWEETENED BEVERAGES AND START EATING MORE VEGETABLES AND FRUITS. DO MORE PHYSICAL ACTIVITIES.



bigger burden on patients (and their families), physicians, health facilities, and government. Therefore, it is important to increase public awareness on this issue and also on how to minimize the risks.

Some of us may wonder about the friendship between DM and TB. Apparently, DM directly impairs the innate and adaptive immune response necessary to counter the proliferation of TB. Hence, DM patients are more likely to get TB than nondiabetic people. In terms of affecting outcome of TB treatment, some studies show that pharmacologic interactions between TB medication (rifampicin) and diabetic medication (sulfonylureas); and decreased absorption of rifampicin by patients with DM give bad impact on treatment of both diseases. Furthermore,

> More than 80% of people with diabetes live in low & middleincome countries.

tuberculosis might induce glucose intolerance and worsen glycemic control in people with DM.

Indonesia, a country with the third highest number of patients with TB and the fourth highest number of people with DM, should pay more attention on these diseases. Suggestions have been made to reduce fatalities and morbidities, which include: 1) screening people with TB for DM; 2) screening people with DM for TB, particularly in settings with high TB prevalence; and 3) ensuring high quality diabetes and TB management.

High quality diabetes management is not only about medication. It is also about healthy eating! Healthy eating for 365 days in a year will provide a better answer for both diseases. It reduces risks for developing TB and worsening TB outcome. Most of the times, however, physicians are busy calculating/ adjusting the dose of medication and making sure that patients are compliant in taking the drugs. Patients are busy with remembering when to take their medication and dealing with the side effects. Somehow, both sides forget that DM management means combining both medication and healthy eating.

Actually, recommendations of healthy eating for patients with TB/DM and general population are the same. So, what are they?

- Choose water, unsweetened coffee or tea INSTEAD OF fruit juice, soda, and other sugar-sweetened beverages
- Eat at least three servings of vegetables every day, including green leafy vegetables
- 3. Eat up to three servings of fresh fruit every day
- Choose nuts, fresh fruits, or unsweetened yogurt for snack
- Choose lean cuts of white meat, poultry, or seafood INSTEAD OF processed meat or red meat
- If you like bread, choose peanut butter INSTEAD OF chocolate spread or jam
- Choose brown rice (unpolished) and wholegrain bread INSTEAD OF white rice or white bread
- Choose unsaturated fats (olive oil, canola oil, corn oil, or sunflower oil) INSTEAD OF saturated fats (butter, animal fat, coconut oil, or palm oil). More importantly, you have to

use the fats only once and avoid deep-fried.

 Eat the same amount of carbohydrate each day; spaced evenly throughout the day.

Basically, we need to eat fresh food, lean white meat, at least 5 portions/ servings of fruits and vegetables, high fiber diet, and unsweetened beverages. To maintain appropriate blood glucose level and maximize the effectiveness of drug therapy, we need a consistent carbohydrate intake, which is divided evenly into 3-5 meals per day. Too high or too low carbohydrate intake may harm the body, so please consult with your doctor to get a good estimate of the amount of carbohydrate you need a day.

In addition, to upgrade healthy eating into healthy lifestyles, we have to do regular physical activities. Jogging, running, or swimming for 30-60 minutes every day are some good examples of physical activities. Nevertheless, you can add other simple activities, such as: parking your car a little farther from your office so you will walk more, taking stairs instead of the elevator, and playing with your children.

For some of you, the information here may not be novel. However, the message is very clear: **we** need to act today to change the world tomorrow. Healthy eating (or healthy lifestyles) will reduce the risk of developing type 2 DM and will help patients with DM and TB to achieve better outcomes. Let's start now!

References:

Alisjahbana B, et al. The effect of type 2 diabetes mellitus on the presentation and treatment response of pulmonary tuberculosis. *Clin Infect Dis 2007*; 45: 428-35.

Baghael P, et al. Diabetes mellitus and tuberculosis facts and controversies. *Journal of Diabetes & Metabolic Disorders* 2013; 12: 58.

http://www.jdmdonline.com/content/1 2/1/58

Dobler CC, Flack JR, Marks GB. Risk of tuberculosis among people with diabetes mellitus: an Australian nationwide cohort study. *British Medical Journal Open* 2012.

Dooley K and Chaisson RE. Tuberculosis and diabetes mellitus: convergence of two epidemics. *Lancet Infect Dis* 2009; 9(12): 737-46.

Dooley KE, et al. Impact of diabetes mellitus on treatment outcomes of patients with active tuberculosis. *Am J Trop Med Hyg* 2009; 80(4): 534-9.

International Diabetes Federation. Be a part of the World Diabetes Day 2015 campaign. 2015.

Jeon CY and Murray MB. Diabetes mellitus increases the risk of active tuberculosis: A systematic review of 13 observational studies. *PLoS Medicine* 2008; 5(7): e152: 1092-101.

Whitney E and Rolfes SR. Understanding Nutrition 12e. Wadsworth Cengage Learning. Belmont, USA 2011.

World Health Organization. Tuberculosis & diabetes: Collaborative framework for care and control of tuberculosis and diabetes. WHO – The Stop TB Department 2011.

Start Loving Yourself; Start Healthy Eating Today

Aly Diana, dr., M.Kes, MPH (nutr.) Manuscript Writing and Publication Specialist, INA-RESPOND. Lecturer, Dept. of Medical Nutrition, Faculty of Medicine, Universitas Padjadjaran, Bandung.



9th World Society of Pediatric Infectious Diseases Congress

By Dwiyanti Puspitasari, Ninny Meutia Pelupessy

On 18-21 November 2015 the 9th World Society of Pediatric Infectious Diseases (WSPID) Congress was held in Rio De Janeiro. The Congress is a meeting forum for more than 1,500 pediatricians and specialists from all countries in the world to share some of the latest developments and updates in the treatment and prevention of infectious disease in children. There were 5 participants present from Indonesia (4 pediatricians and 1 general practitioner).

INA-RESPOND participated in the event by sending its representatives from the AFIRE pediatrics team to present two posters titled 'Clinical and Etiological Diagnoses of Febrile Illness in Pediatrics in Indonesia', presented by Dr. Dwiyanti Puspitasari, SpA (K) (Co-PI from site 570); and 'Dengue and Salmonella infections in Indonesian Children', presented by Dr. Ninny Meutia Pelupessy, SpA (PI from site 550).

Dr. Damayanti, SpA got a chance to present her poster on the first day. There were some questions and appreciation given by participants from Indonesia and other countries; One of them was for our multicenter study on the causes of fever. This appreciation was given because before the AFIRE study, there had not been any comprehensive data in Indonesia for fever. Some participants from the USA stated that a more detailed clinical discussion on the topic would be interesting to follow. Last but not least, there was a comment saying that the existing conditions (diseases that had been diagnosed) were similar to those in many other Southeast Asian countries.

The 2nd poster was presented on the last day of the congress. This time we received advice from one of the participants who said that the data obtained from the research's results (clinical signs and symptoms) is the clinical diagnosis strength that can be used by clinical practitioners when accurate supporting diagnostic tools are not available.



Dr. Dwiyanti Puspitasari (right) and dr. Ninny Meutia Pelupessy (left)

The 9th WSPID Congress discussed a lot about dengue vaccines, those that were ready or still in the pipeline, as well as updates on pnemoni, tuberculosis, CMV, HIV and emerging disease in children. In addition, we also have the opportunity to build relationships with pediatric infections experts from our neighboring countries: Singapore, Thailand, etc. as well as introducing INA-RESPOND study group.

Finally, our experience to Brazil would not happen without the support from all INA-RESPOND team. We would like to give our thanks to Dr. M. Karyana, who responded to the initial plan to participate in the 9th WSPID; Dr. Herman Kosasih and Dr. Patricia Tauran, who were key to the creation and development of AFIRE abstracts and posters; Ms. Yayu Nuzulurrahmah, who helped with the preparation of trip documents to Brazil; Study Coordinators, PIs and Co-PIs, and Laboratory Technician at eight sites that helped us in data and specimens collection; the INA-RESPOND Secretariat staff, who helped with the data analysis and the poster preparation; the patients involved in the study activities; and the hospitals and universities, which supported this study. Hopefully, other INA-RESPOND studies are going well and succeed, thus making our country's name more famous in the world health community.

INA-RESPOND Study Updates

By dr. Anandika Pawitri,

dr. Nurhayati,

Ms. Novitasari

Site Number – Name	Date 1 st enrollment	Number screened patients	Number of Enrolled Subjects (adult/child)
510 - RSUP dr Hasan Sadikin	04 Sep 2013	374	238 (132 / 106)
520 – RSUP Sanglah	18 Jul 2013	1188	184 (135 / 49)
530 – RSUPN dr Cipto Mangunkusumo	27 Nov 2014	264	43 (28 / 15)
540 – RSPI Prof dr <u>Sulianti Saroso</u>	08 Dec 2015	179	53 (13 / 40)
550 – RSUP dr <u>Wahidin</u>	16 Oct 2013	323	141 (105 / 36)
560 – RSUP dr <u>Kariadi</u>	19 Aug 2013	606	233 (124 / 109)
570 – RSUD dr <u>Soetomo</u>	03 Jan 2014	554	193 (115 / 78)
580 – RSUP dr <u>Sardiito</u>	26 Aug 2013	795	143 (56 / 87)
Total		5293	1.228 (708 / 520)

Description of Monthly Enrollment progress can be seen in the figure below :



Detailed screening and enrollment progress is available in portal folder: Studies\INA101\Screening progress.pdf or go to the following link: <u>https://ina-respond.s-3.com/EdmFile/getfile/797233</u>

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

AFIRE Study (INA101) Updates

Since July 2013, the study has screened 4,293 patients. 1,228 subjects have been enrolled (708 adults and 520 children). Site 510 is December's top recruiter with 238 subjects recruited.

Screening and enrollment progress at each site is available in table 1. Screening and enrollment progress at each site.

The enrollment progress at all sites has been decreasing since June 2015. The implementation of the Indonesian health insurance regulation (BPJS) affects subject's recruitment rate at all sites.

Sepsis Study (SEA050) Updates

It's a wrap! The recruitment process for 3 sites in Indonesia finished on 31 December 2015. Overall RSUPN Cipto Mangunkusumo, Jakarta; RSUP Wahidin Sudirohusodo and RS Universitas Hasanuddin, Makassar; and RSUP Sardjito, Yogyakarta have recruited 82 subjects for this study.

It's been a tough process in the past year from initiation to end of recruitment process. Each site has different challenges: overlapping recruitment with AFIRE study, changes of regulation, lengthy IRB and administration process, immediate turnover of RA, and other problems. However, we had fun too! The site team manages to overcome the challenges with excellent effort. A lot of experience in this study made the team solid!

	Site 41 – RS dr. Cipto Mangunkusumo		Site 42 – RS dr. Wahidin Sudirohusodo & RS Universitas Hasanuddin		Site 43 – RS Sardjito					
Number of	Adult	: 132	Adult	: 92	Adult	: 166				
Screened	Pediatric	: 78	Pediatric	: 38	Pediatric	: 113				
Patients	Total	: 210	Total	: 130	Total	: 279				
Number of	Adult	: 17	Adult	: 24	Adult	: 25				
Enrolled	Pediatric	: 6	Pediatric	: 4	Pediatric	: 6				
Patients	Total	: 23	Total	: 28	Total	: 31				
Enrollment	Adult	: 15	Adult	: 25	Adult	: 20				
Expectation	Pediatric	: 15	Pediatric	: 25	Pediatric	: 20				
Number of	Day 151		Day 312		Day 256					
days after	(activation date:		(activation date:		(activation date:					
enrollment	6 August 2015)		26 February 2015)		23 April 2015)					
Sereening and Encollment Dragrage										

up to 31 December 2015



INA-RESPOND Newsletter

Advisors Art & Language Columnists

Thanks to Disclaimer

: dr. M. Karyana, M.Kes, dr. Herman Kosasih

: Dedy Hidayat S, S.Kom, Dona Arlinda, MD : dr. Anandika Pawitri, dr. Nurhayati, Ms. Novitasari, dr. Aly

Diana, dr. Dwiyanti Puspitasari, dr. Ninny Meutia Pelupessy, Beth Baseler, Dr. Jacqueline Perodin, Louis Grue.

- : INA-RESPOND Network and Partners
- : 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 <u>INA.Secretariat@ina-respond.net</u>

INA-RESPOND Newsletter 2016