

DATA UJI KLINIK OBAT 2016

No	JUDUL PROTOKOL	SPONSOR/ CRO	OBAT UJI		FASE	CENTER	PENELITI	PERSETUJUAN PELAKSANAAN UJI KLINIK	
			NAMA OBAT / ZAT AKTIF	PRODUSEN				Nomor	Tanggal
1	<i>A multicenter, randomized, double-blind Phase III trial to evaluate efficacy and safety of BI695502 plus chemotherapy versus Avastin plus chemotherapy in patients with advanced nonsquamous Non-Small Cell Lung Cancer</i>	Boehringer Ingelheim International /PT. Quintiles	BI695502 / Bevacizumab	Boehringer Ingelheim Pharma GmbH & Co KG	III	Dr. Kariadi Hospital Semarang / Bagian Penyakit Dalam Subdivisi Hematologi Oncologi Medik, FK Undip	Prof. Dr. Catharina Soeharti, Ph.D, SpPD, KHOM	PN.01.06.313.3.06.16.3008	16 Juni 2016
						RSUD Dr. Soetomo, Lab/SMF Penyakit Paru, Surabaya	Dr. Laksmi Wulandari, dr., SpP(K) FCCP		
						RSUP Sardjito (Instalasi Kanker Terpadu Tulip), Yogyakarta	Dr. Kartika Widayati, SpPD, KHOM		
						RSUD Moewardi, SMF/Bagian Paru, Solo	Dr. Ana Rima SpP(K) Onk		
						RS Persahabatan, Jakarta	Dr. Elisna Syahrudin, PhD, Sp.P (K)		
2	<i>Immunogenicity and Safety Profile of Primary Dose of bivalent OPV (bOPV Bio Farma) Given Simultaneously with Pentabio® and Inactivated Poliovirus Vaccine (IPV) at the 4<sup>th</sup> visit in Indonesia Infants</i>	PT. Biofarma	bOPV / Bivalent Oral Poliomyelitis Vaccine Type 1 & 3	PT. Bio Farma (Persero)	III	Departement of Child Health, School of Medicine, Padjadjaran University, Bandung	Prof. Dr. Kusnandi Rusmil, dr., Sp.A(K), MM.	PN.01.06.313.3.06.16.3095	21 Juni 2016
3	<i>A Randomized, Open-Label, Active-controlled, Multi-Center, Phase III Study to Evaluate the Efficacy, Safety and Immunogenicity of Leucostim® versus Neupogen® in Breast Cancer Patients Receiving Myelosuppressive Chemotherapy.</i>	Dong-A ST Co., Ltd	Leucostim / Recombinant filgrastim (rhG-CSF)	Dong-A ST Co., Ltd	III	RSUP Hasan Sadikin - Bandung	Dr. Trinugroho Heri Fadjar, Sp.PD, KHOM	B-PN.01.06.313.3.11.16.8965	28 Oktober 2016
						RSUP Dr. Sardjito - Yogyakarta	Dr. Johan Kurnianda, Sp.PD, KHOM	B-PN.01.06.313.3.11.16.8967	28 Oktober 2016
						RSUD Dr. Soetomo Surabaya	Prof. Dr. Ami Ashariati, SpPD, KHOM	B-PN.01.06.313.3.03.17.01315	20 Maret 2017
						RSPAD Gatot Subroto - Jakarta	Dr. Nyoto Widyo Astoro, SpPD, KHOM	B-PN.01.06.313.3.11.16.8966	28 Oktober 2016
4	<i>Uji Klinik Random "Randomized Clinical Trial" Kontrasepsi Implant Sinoplast versus Indoplast</i>	PT. Catur Dakwah Crane Farmasi	Sinoplast / Levonorgestrel	PT. Catur Dakwah Crane Farmasi	III	Pusat Kesehatan Reproduksi FK UGM, Jogjakarta	Prof. dr. Siswanto Agus Wilopo, S.U, M.Sc. Sc.D	B-PN.01.06.313.3.12.16.9772	19 Desember 2016
						Departemen Obstetri Ginekologi FK Universitas Sumatera Utara (USU) - Medan	Prof. dr. Delfi Lutan, Msc., SpOG(K)		
						Departemen Obstetri Ginekologi FK Universitas Hasanuddin (UNHAS)- Makassar	Dr. Retno Budiati, SpOG		
5	<i>Non-interventional study describing patients perception on anticoagulant treatment and treatment convenience when treated with Pradaxa® or Vitamin K Antagonist for Stroke Prophylaxis in Atrial Fibrillation</i>	PT. Boehringer Ingelheim Indonesia	-	-	IV	RS. Harapan Kita	Dr. Dicky Hanafy, SpJP(K), FIHA	PN.01.06.313.10.16.2215	10 Oktober 2016
						RS. Abdi Waluyo	Salim Haris, MD, FICA		10 Oktober 2016
						RS. Bina Waluya	DR. dr. M. Munawar, SpJP (K), FIHA, FESC, FACC		10 Oktober 2016
						RS Siloam Karawaci	Dr.dr. Antonia Anna Lukiyo, SpJP		10 Oktober 2016
6	<i>Evaluasi Manfaat / Efektivitas Pharmalene B Gel Dengan Produk Originator Epiduo Gel Terhadap Acne Vulgaris Dengan Menggunakan Alat</i>	PT. Genero Pharmaceuticals	Pharmalene B Gel / Adepeleone 0.1 % / Benzoiil peroksida 2.5 %	PT. Genero Pharmaceuticals	III	PT. Assetra Inno Medikos	Dr. rer. Nat. Anna S. Ranti, Apt	B-PN.01.06.313.3.12.16.9681	15 Desember 2016

7	<i>"Community Based Safety Study of 2-drug (Diothylcarbamazine and Albendazole) versus 3-drug (Ivermectin, Diothylcarbamazine and Albendazole) Therapy for Lymphatic Filariasis in Indonesia"</i>	Washington University School of Medicine, USA	Ivermectin	Merck Sharp Dohme B.V. The Netherlands	III	Departemen Parasitologi / Universitas Indonesia	Prof. Dr.dra. Taniawati Supali	B-PN.01.06.313.3.10.16.4846	5 Oktober 2016
8	<i>Uji Klinik Faso 3, acak, tersamar ganda membandingkan efikasi dan kemanan gel ekstrak plasenta + neomycin pada luka pasceoperasi sectio caesarea dibandingkan dengan kelompok plasebo</i>	PT. Kalbe Farma	Bioplacenton	PT. Kalbe Farma	III	SMF Obstetri dan Ginekologi RSUP Persahabatan	dr. Lucky Savitry Widayakusuma, SpOG(k)	B-PN.01.06.313.3.08.16.4320	31 Agustus 2016
9	<i>Two-month Regimens Using Novel Combinations to Augment Treatment Effectiveness for Drug-sensitive Tuberculosis</i>	University College London / PT. INC Research Indonesia	Truncate-TB	FDC Rifampisin 150 mg + INH 75 mg + Pyrazinamid 400 mg + Etambutol 275 mg, Rifampicin, Clofazimine, Rifapentine, Isoniazid, Pyrazinamide, Levofloxacin, Bedaquiline, Etambutol, Pyridoxine, Linezolid	III	Universitas padjajaran, Bandung	Dr. Rovina Ruslami	B-PN.01.06.313.3.07.17.3169	4 Juli 2017
						Fakultas Kedokteran/Univ. Indonesia	Dr. Erlina Burhan	B-PN.01.06.313.3.04.17.1793	18 April 2017
						Universitas Hasanuddin, Makassar	Dr. Irawaty Djaharuddin	B-PN.01.06.313.3.04.17.1792	17 April 2017
						Rumah Sakit Dr. Soetomo	Dr. Tutik Kusmiati	B-PN.01.06.313.3.04.17.1791	18 April 2017
10	<i>The Clinical Comparison of rHu-EPO produced by North China Pharmaceutical Group Corp. Genetech Biotechnology Co. Ltd. (GerEPO, a biosimilar) with that produced by Janssen-Cilag (EPREX, the innovator) in Chronic Kidney Disease (CKD) anemia : a confirmatory study in Indonesian Population</i>	PT. Darya-Varia Laboratoria Tbk / PT. Elana Biotechnologies, Indonesia	Renogen (Erythropoietin alfa)	North China Pharmaceutical Group Corp. Genetech Biotechnology Co. Ltd	III	Renal Hypertension Division, Dept. of internal medicine Dr. Cipto Mangunkusumo Hospital	Prof. Dr. dr. Partindungan Siregar, SpPd-KGH	B-PN.01.06.313.3.12.16.9540	7 Desember 2016
11	<i>An Opened, Randomized, Comparative Study of Efficacy And Safety of 0,5 Mg Lynestrenol Tablet Produced by PT Triyasa Nagamas Farma Versus The Reference Product (Erluton®; PT Sydna Farma Indonesia) in Women of Childbearing Age</i>	PT. Triyasa Nagamas Farma / PT. Equilab Internasional	Linestrenol	PT. Triyasa Nagamas Farma	III	PT. Equilab International	Peneliti Utama : Dr. Danang Agung Yunaidi, Peneliti Pendamping : Dr. Retih Sofia Ika putri dan Dr. Niken Arjar Wulan	PN.01.06.313.12.16.2834	6 Desember 2016
12	<i>Studi 200894 : A double-blind, double-dummy, randomized, parallel group, placebo-controlled superiority study to evaluate the efficacy and safety of tafenoquine (SB-252263, WR238605) co-administered with dihydroartemisinin-piperaquine (DHA-PQP) for the radical cure of Plasmodium vivax malaria</i>	PT. Glaxo Smith Kline / PT. Quintiles Indonesia	Tafenoquine	PT. Glaxo Smith Kline	III	Department of Parasitology FKUI	Prof. Dr. dr. Ingo Sutanto, Mphil, SpPark	B-PN.01.06.313.3.10.17.5298	17 Oktober 2017

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1	A Phase IV Interventional Safety, Efficacy and Quality of Life Study of ELIGARD® in Prostate Cancer Patients in Asia (ELIGANT)	Astellas Pharma Singapore Pte Ltd / PT. Quintiles Indonesia	ELIGARD®	Astellas Pharma Singapore Pte Ltd	IV	RS Cipto Mangunkusumo, Jakarta	Prof. dr. Rainy Umbas, Sp.U(K)	B-PN.01.06.313.3.05.17.2214	15 Mei 2017
2	A Prospective, randomized, double-blind study assessing the efficacy of intravenous (IV) ibuprofen versus IV Acetaminophen for the treatment of pain following orthopaedic low extremity surgery	Innokeys Pte Ltd	Intrafen / Ibuprofen	Mefar Ilac Sanayi A.S	III	RS Cipto Mangunkusumo, Jakarta	Dr.dr. Aida Tantri, SpAn (K)	B.PN.01.06.313.3.08.17.4149	15 Agustus 2017
3	Studi klinik acak, open-label, multisenter untuk membandingkan imunogenisitas Ezelin dan Lantus® pada pasien diabetes melitus tipe 2 dewasa	PT. Kalbe Farma	Ezelin / Insulin glargine 100 unit/ml	Gan & Lee Pharmaceuticals	III	RS. Pelni	dr. Tri Juli Edi Tarigan, Sp.PD, K-EMD, FINASIM	B-PN.01.06.313.3.02.17.0922	22 Februari 2017
4	A Randomized double blind placebo controlled trial of adjunctive dexamethasone for the treatment of HIV-infected adults with tuberculous meningitis	University of Oxford	Dexamethasone	Pharbaso Central Pharmaceutical Joint Stock Company No.1 (injeksi), Agimexpharm Pharmaceutical Joint Stock Company (tablet)	III	RS Cipto Mangunkusumo, Jakarta	dr. Darma Imran Sp.S (K)	B.PN.01.06.3.08.17.3791	1 Agustus 2017
5	Protectivity and Safety of Quadrivalent Influenza HA Vaccine in Indonesian Population (Bridging Study)	PT. Biofarma	Vaksin Influenza Quadrivalent	PT. Biofarma	III	Departemen Ilmu Kesehatan Anak RSUP Hasan Sadikin Bandung RS. Moewardi, Surakarta	Dr. Meita Dhamayati, dr., Sp.A(K), M.Kes Dr. Rovina Ruslami	B-PN.01.06.313.3.10.17.5300 B-PN.01.06.313.3.07.17.3169	17 Oktober 2017 4 Juli 2017
6	Two-month Regimens Using Novel Combinations to Augment Treatment Effectiveness for Drug-sensitive Tuberculosis	University College London / PT. INC Research Indonesia	Truncate-TB	FDC Rifampisin 150 mg + INH 75 mg + Pyrazinamid 400 mg + Etambutol 275 mg, Rifampicin, Clofazimine, Rifapentine, Isoniazid, Pyrazinamide, Levofloxacin, Bedaquiline, Etambutol, Pyridoxine, Linezolid	III	RS. Saiful Anwar Malang	Dr. Erlina Burhan	B-PN.01.06.313.3.08.17.4147	15 Agustus 2017
7	Tranexamid Acid For The Treatment of Significant Traumatic Brain Injury : An International Randomized, Double Blind Placebo Controlled Trial	London School of Hygiene and Tropical Medicine London UK	Cyklokapron injection 100 mg/ml atau Placebo / Tranexamic Acid atau Sodium Chloride 0.9% injection	PFIZER (previously Pharmacia Ltd), Kent, UK (Cyklokapron) / South Devon Healthcare NHS Foundation Trust, UK (Placebo)	III	RS Atmajaya RS Tarakan	dr.Rr. Josephine Retno W, Sp.S, M.Kes Wismaji Sadewo, MD Phd	B-PN.01.06.313.3.09.17.4481 B-PN.01.06.313.3.09.17.4482	11 September 2017 11 September 2017
8	"Studi Farmakokinetik Inapant Susuk Satu Batang 150 mg yang diproduksi oleh PT. Catur Dakwah Crane Farmasi, Indonesia dibandingkan dengan Sino-Implant (II) Susuk Dua Batang 2 x 75 mg (150 mg) yang diproduksi oleh Shanghai Dahua Pharmaceuticals Co., Ltd., China"	PT. Catur Dakwah / PT. Pharma Metriclabs	INAPLANT	PT. Catur Dakwah	III	Rumah Sakit Ibu dan Anak (RSIA) Kendangsari Surabaya	Prof. DR. dr. Budi Santoso, Sp. OG (K)	B-PN.01.06.313.3.03.18.00898	5 Maret 2018

9	Phase 3 study of SFPP in knee Osteoarthritis : a randomized controlled study using diclofenac gel as the comparator	Taisho Pharmaceutical Co. Ltd. Jepang	S-Flurbiprofen Plaster (SFPP)	Tokuhon Corporation, Jepang	III	1. RSUPN Dr. Cipto Mangunkusumo, Jakarta Satelite site : - RSUD Tarakan -RSUD Budi Asih - RS Hermina Kemayoran	Peneliti Utama : Dr. Bambang Setyohadi, Sp.PD-KR Peneliti Center : 1. Dr. Sumaryono Sp.PD-KR Satelit site: - Dr. Nuriak Sp.PD / RSUD Tarakan, Jakarta Pusat - Dr. Ehamida, Sp.PD / RSUD Budi Asih, Jakarta Timur - Dr. Anna Sp.PD / RS Hermina Kemayoran, Jakarta Utara	B-PN.01.06.313.3.12.17.6223	8 Desember 2017
						2. RS Islam Pondok Kopi, Jakarta Timur	Dr. Tanggo Meiriza, Sp.PD-KR	B-PN.01.06.313.3.12.17.6224	8 Desember 2017
						3. RS Siloam Karawaci, Banten	Dr. Sandra Sinthya Langow, Sp.PD-KR	B-PN.01.06.313.3.12.17.6225	8 Desember 2017
						4. RS Anna Medika, Bekasi	Dr. Ika Wulan Yuliani Sp.PD-KR	B-PN.01.06.313.3.12.17.6226	9 Desember 2017
						5. RSUP Dr. Hasan Sadikin, Bandung	Dr. Rachmat Gunadi, Sp.PD-KR	B-PN.01.06.313.3.12.17.6227	10 Desember 2017
						6. RSUD Al Ihsan, Bandung	Dr. Laniyati Hamijoyo, Sp.PD-KR., M.Kes.	B-PN.01.06.313.3.12.17.6229	11 Desember 2017
						7. Klinik Perisai Husada, Bandung	Dr. Andri Reza Rahmadi, Sp.PD-KR., M.Kes.	B-PN.01.06.313.3.12.17.6228	12 Desember 2017
10	Non Interventional Study on the Safety and Efficacy of Micafungin for Prevention and Treatment of Fungal Infections in Paediatric Patients in Asia/ Oceania – ERADICATE Study	PT. Astellas Pharma Singapore Pte Ltd	Mycamine / Micafungin Sodium	-	IV	Dr. Soetomo General Hospital, Surabaya	Leny Kartina, SpA(K)	B-PN.01.06.313.3.11.17.5926	20 November 2017

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			NAMA OBAT / ZAT AKTIF	PRODUSEN				Nomor	Tanggal
1	Treatment of Thrombocytopenia with oseltamivir in avute dengue virus infection (TOTO Trial) : A Randomized, placebo controlled, multicenter trial	Quirijn de mast M.D, PHd / Radboud university medical center	Oseltamivir	PT. Indofarma	II	1. RS Nasional Diponegoro	Setyo G. Pramudo Sppd	B-PN.01.06.313.3.01.18.00198	12 Januari 2018
						2. RSUD Krmr Wongosonegoro	dr. Pujo Hendrianto SpPD		
						3. RSU William Booth	dr. Setyo G. Pramudo, Sp.PD		