

Persetujuan Pelaksanaan Uji Klinik (PPUK) Tahun 2019

No	JUDUL PROTOKOL	SPONSOR/ CRO	Center	Peneliti	No.PPUK	Tanggal PPUK
1	<i>Safety and efficacy of early start deferiprone treatment in infants and young children newly diagnosed with transfusion - dependent beta thalassemia (START)</i>	ApoPharma Inc, Canada / IQVIA	Dr. Cipto Mangunkusumo	Dr.dr. Pustika Amalia Wahidiat SpA(K)	B-PN.01.06.3.323.01.19.0040	04-Jan-19
			RS Hasan Sadikin	Dr. dr. Lelalni Reniarti SpA(K), M.Kes	B-PN.01.06.3.323.01.19.0039	04-Jan-19
2	<i>The Evaluation of a standard treatment regimen of anti-tuberculosis drugs for patients with MDR-TB (Stage 2)</i>	<i>The International Union Against Tuberculosis and Lung Disease (Vital Strategies) / PT. IQVIA</i>	RSUP Persahabatan Jakarta	dr. Erlina Burhan, Sp.P (K)	B-PN.01.06.3.321.03.19.1121	19-Mar-19
3	<i>DIA - RAMADAN Observational Study Program Assessing Effectiveness and Tolerability of Gliclazide MR 60 mg in patients with Type 2 Diabetes Fasting During Ramadan</i>	<i>Servier Global Medical Affairs / PT. Servier Indonesia</i>	<ol style="list-style-type: none"> 1. RS Saiful Anwar, Malang 2. RSUD Dr. Soetomo Surabaya 3. RS Fatmawati, Jakarta 4. RS Mitra Kelapa Gading, Jakarta 5. RS Gading Pluit, Jakarta 6. RS Hasan Sadikin, Bandung 7. RS Sardjito, Yogyakarta 8. RS Panti Rapih, Yogyakarta 9. RS Moewardi, Solo 10. RS Zainal Abidin, Aceh 	<ol style="list-style-type: none"> 1. Prof. Dr. dr. Achmad Rudijanto, SpPD-KEMD 2. Prof. Dr. Agung Pranoto, dr., SpPD-KEMD, FINASIM 3. dr. Ida Ayu Khsanti 4. dr. Fatimah Eliana 5. dr. Benny Santosa 6. dr. Nanny Natalia 7. dr. Bowo Pramono 8. dr. FX Suharnadi 9. dr. Eva Nia M. 10. dr. Hendra Zufrie 	B-PN.01.07.3.321.04.19.1356	04-Apr-19
4	Efektivitas Keamanan dan Efek Samping Injeksi Cyclonate yang diproduksi oleh PT. Catur Dakwah Crane Farmasi, Indonesia dibandingkan dengan Injeksi Cyclofem yang diproduksi oleh PT Tunggal Idaman Abadi	PT. Catur Dakwah Crane Farmasi / PT. Pharma Metric Labs	<ol style="list-style-type: none"> 1. RSUP Dr. Kariadi, Semarang 2. RSUP Dr. Sardjito, Yogyakarta 3. Bali Royal Hospital, Bali 4. RSIA Husada Bunda, Malang 	Peneliti Utama : Dr.dr. Syarief Thaufik, SpOG(K) <ol style="list-style-type: none"> 1. dr. Nurvita Nindita, SpOG 2. dr. Shofwal Widad, SpOG(K) 3. dr. Ida Bagus Putra Adnyana, SpOG(K.Fer) 4. Dr. dr. I Wayan Arsana Wiyasa, SpOG(K) dan dr. Anin Indriani, SpOG 	B-PN.01.06.3.321.04.19.1513	22-Apr-19
5	<i>Safety , Tolerability Immunogenicity and Protective Efficacy Against Naturally Transmitted Malaria in Eastern Indonesia of Two Plasmodium falciparum Sporozoite Vaccines Sanaria PfSPZ Vaccine and Sanaria PfSPZ-Cvac : A Randomized Double Blind Placebo Controlled Phase 2 Trial in Healthy Indonesian Adults</i>	Sanaria Inc USA / Eijkman Oxford Clinical Research Unit (EOCRU)	FK Universitas Indonesia	dr. Erni Juwita, SpPD	B-PN.01.06.3.321.05.19.1739	10-Mei-19

6	<i>Short intervention and measurement of PK of LinEzolid in TB Meningitis (SIMPLE)</i>	<i>Radboud University Medical Center, Nijmegen, Belanda</i>	Pusat Studi Penyakit Infeksi, Fakultas Kedokteran Universitas Padjajaran – RSUP Dr. Hasan Sadikin, Bandung	dr. Ahmad Rizal Ganiem, Sp.S(K), Ph.D	B-PN.01.06.3.321.05.19.1979	28-Mei-19
7	<i>A Dose Escalation Evaluation of Safety and Tolerability and Pharmacokinetics of Adrecizumab - a Humanized Monoclonal Antibody against Adrenomedullin (ADM) in patients with acute heart failure requiring Hospitalization (Adrecizumab Dose Escalation Safety and Tolerability Evaluation (ADESTE))</i>	<i>Great Network Italy/PT. Prodia Diacro Laboratories</i>	RS Saiful Anwar Malang	Dr. M. Saifur Rohman, SpJP(K), Ph.D	B-PN.01.06.3.321.07.19.2414	08-Jul-19
8	<i>Phase 3 study of SFPP in knee Osteoarthritis : a randomized controlled study using diclofenac gel as the comparator</i>	Taisho Pharmaceutical Co. Ltd. Jepang / PT. Prodia Diacro Laboratories	1. RSUD Dr. Soetomo, Surabaya	Dr. Yuliasih, SpPD-KR	B-PN.01.06.3.321.06.19.2033	10-Jun-19
			2. RS TNI AU Soemitro, Surabaya	Dr. Lita Diah Rahmawati, SpPd-KR	B-PN.01.06.3.321.06.19.2034	
			3. RSUD Dr. Saiful Anwar, Malang	Dr. Cesarius Singgih Wahono, SpPD-KR	B-PN.01.06.3.321.06.19.2035	
			4. Klinik Reumatologi dan Alergi, Malang	Prof. Handono Kalim, SpPD-KR	B-PN.01.06.3.321.06.19.2036	
9	<i>Protectivity and safety following Recombinant Hepatitis B Vaccine with Different Source of Hepatitis B Bulk Compared to Hepatitis B (Bio Farma) Vaccine in Indonesia Population</i>	PT. Biofarma, Bandung	Fakultas Kedokteran Univ Diponegoro , Semarang	Dr. Yetty Movieta Nancy Sp.AK	B-PN.01.06.3.32.321.07.19.2543	18-Jul-19

10	<i>A phase IIIb randomised open label trial to complete dolutegravir with pharmacokinetic enhanced darunavir versus dolutegravir with pre-determined nucleosides versus recommended standard of care antiretroviral regimens in patients with HIV -1 infection who have failed recommended first line therapy</i>	University of New South Wales, Australia / INA-RESPOND	1.RS Cipto Mangunkusumo Jakarta 2.RS Soetomo 3.RS Wahidin Makassar 4.RS Sardjito	1. Dr. dr. Evy Yuniastuti, Sp.PD-KAI FINASIM 2.Prof. dr. Usman Hadi, PhD., Sp.PD-KPTI 3. dr. Sudirman Katu, Sp.PD-KPTI 4. Dr. Yanri Wijayanti Subronto, Ph.D., Sp.PD-KPTI, FINASIM	B-RG.01.06.3.32.321.08.19.2939-2942	12-Agu-19
11	<i>Pharmacodynamic Equivalence of Ovine Enoxaparin to Porcine Enoxaparin (Lovenox®) in Healthy Volunteers</i>	PT. Metiska Farma	PT. Pharma Metric Labs, Jakarta	Prof. Arini Setiawati, PhD	B-RG.01.06.3.32.321.08.19.3029	19-Agu-19
12	<i>Immunogenicity & Safety of Bio Farma's Measles-Rubella (MR) Vaccine in Indonesian Infants (Bridging Study)</i>	PT. Biofarma, Bandung	Departemen Kesehatan Anak RSUD Dr. Soetomo / Fakultas Kedokteran Universitas Airlangga, Surabaya	Dr. dr. Dominicus Husada, SpA(K)	B-RG.01.06.3.32.321.08.19.3034	19-Agu-19
13	<i>Non Interventional study on effectiveness and safety of fixed dose combination of netupitant and palonosetron (NEPA) in chemotherapy - induced nausea and vomiting (CINV) patients receiving moderately (MEC) OR highly emetogenic chemotherapy (HEC) (AKY18-ID-401)</i>	Mundipharma Laboratories GmbH / PT. Prodia Diacro Laboratories	RS Kanker Dharmais	Dr.dr.Hilman Tadjoeidin, SpPD-KHOM	B-RG.01.06.3.32.321.08.19.3035	19-Agu-19
14	<i>Safety and preliminary of Immunogenicity Following Recombinant Hepatitis B (BioFarma) Vaccine in Adults & Children</i>	PT Biofarma , Bandung	RSUP Dr. Hasan Sadikin, Bandung	Prof. Dr. Kusnandi Rusmil, dr., Sp.A(K), MM	RG.01.06.321.11.19.4609	18-Nov-19
15	Studi Klinis untuk mengevaluasi Keamanan dan Efikasi dari Epodion pada Pasien PGK(Penyakit Ginjal Kronis) : Uji Klinis Label Terbuka, Teracak, Komparasi Obat Aktif, Desain Paralel dan Multi Sentral	Daewoong Pharmaceutical, Co., Ltd. / PT. Equilab International	RSPAD Gatot Subroto	dr. Jonny Sp.PD-KGH,M.Kes, MM	RG.01.06.321.11.19.4610	18-Nov-19
16	<i>Efficacy and Safety of PEG 3350 for Treatment of Chronic Constipation</i>	PT. Meiji Indonesia Pharmaceutical Industries	Divisi Gastroenterologi Departemen Ilmu Penyakit Dalam RS Cipto Mangunkusumo, Jakarta	Prof. Dr, dr. Murdani Abdullah, SpPD-KGEH	RG.01.06.321.11.19.4753	28-Nov-19

17	<i>The Efficacy, Safety, and Immunogenicity Study Comparing an insulin Glargine Biosimilar Sansulin Log-G With Its Reference Lantus in patients with Type 2 Diabetes Melitus</i>	PT. Sanbe Farma	1.RS Pelni 2.RS Islam Jakarta Pondok Kopi 3. RSUD Pasar Rebo	1.dr. Tri Juli Edi Tarigan, SpPD-KEMD 2.dr. Khomimah, SpPD-KEMD 3. dr. Teddy Ervano, SpPD	RG.01.06.321.12.19.5074	20-Des-19
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