

**PELAKSANAAN INSPEKSI UJI KLINIK
TAHUN 2016**

No	JUDUL PROTOKOL	CENTER / PENELITI	SPONSOR / CRO	VAKSIN / OBAT	PELAKSANAAN INSPEKSI
1	<i>A Prospective, Randomized, Multicenter, Open Label Phase III Study of Active Specific Immunotherapy with Racotumomab Plus Best Support Treatment Versus Best Support Treatment in Patients With Advanced Non Small Cell Lung Cancer</i>	RSUD Dr Soetomo Surabaya / Dr. dr.Laksmi Wulandari, Sp.P(K)	Innogene Kalbiotech Pte Ltd Indonesia/ PT. Pharma Metric Labs	Obat	Februari 2016
2	Uji Klinik Perbandingan Pil KB Novadiol 28 dan Microgynon di Indonesia	Bagian Kebidanan FK Universitas Sam Ratulangi, Manado/ Prof. dr. Eddy Suparman, SpOG(K)	PT. Catur Dakwah	Obat	Maret 2016
3	Uji Klinik Perbandingan Pil KB Novadiol 28 dan Microgynon di Indonesia	Bagian Obstetri Dinekologi FK UNDIP/RSUP Dr Kariadi Semarang/ Dr. dr. Syarif Thaufik Hidayat, SpOG(K)	PT. Catur Dakwah	Obat	Apr-16
4	<i>A Randomized, Open Label, Multi-Centre Study To Evaluate Patient Preference With Subcutaneous Administration of Rituximab Versus Intravenous Rituximab in Previously Untreated Patients with CD20+ Diffuse Large B-Cell Lymphoma or CD20+ Follicular Non-Hodgkin's Lymphoma Grades 1, 2 or 3A</i>	Divisi Onkologi Hematologi, Departemen Ilmu Penyakit Dalam, RSUP dr. Hasan Sadikin/ Fakultas Kedokteran Universitas Padjadjaran, Bandung/ Dr. Rachmat S. Sumantri, dr., SpPD-KHOM	PT. Roche Indonesia	Obat	Apr-16
5	Uji Klinik Perbandingan Efektifitas, Keamanan dan Penerimaan Kontrasepsi yang Mengandung Lynestrenol (Nexton® dan Exluton®) untuk Wanita Menyusui di Indonesia	RSAB Rika Amelia, Palembang / Dr. dr. H. Heryadi manan, SpOG	PT. Harsen Indonesia	Obat	Mei 2016
6	<i>A 20-week study comparing patient-adjusted versus physician-adjusted titration of BIAsp 30 combined with metformin in type 2 diabetes patients uncontrolled on NPH insulin</i>	SMF Ilmu Penyakit Dalam, RSUD Dr. Syaiful Anwar, Malang/Prof. Dr. Djoko Wahono Soeatmadji, SpPD KEMD	PT. Novo Nordisk	Obat	Agustus 2016

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7	Uji Klinik Secara Random : Studi Perbandingan Kontrasepsi Susuk KB Satu Batang Monoplant® dengan Susuk Dua Batang Indoplant® di Lima Center Penelitian	Klinik PKBI Semarang / dr. Julian Dewantiningrum, SpOG Field site RS Nasional Diponegoro Semarang	PT. Triyasa Nagamas Farma	Obat	Agustus 2016
8	Studi klinik acak, open label, multisenter, untuk membandingkan immunogenisitas Ezelin dan Lantus® pada pasien Diabetes Melitus tipe 2 dewasa	Departemen Penyakit Dalam Direktorat Kesehatan Angkatan Darat RSPAD Gatot Soebroto, Jakarta / dr. Susie Setyowati, SpPD, KEMD.	PT. Kalbe Farma	Obat	Agustus 2016
9	Uji Klinik Secara Random : Studi Perbandingan Kontrasepsi Susuk KB Satu Batang Monoplant® dengan Susuk Dua Batang Indoplant® di Lima Center Penelitian	Bagian Kebidanan FK Universitas Airlangga/RSU Dr. Soetomo, Surabaya / dr. Hendy Hendarto, Sp.OG(K)	PT. Triyasa Nagamas Farma	Obat	Sep-16
10	"Asian Sudden Cardiac Death in Heart Failure (ASIAN-HF) Prospective Observational Study"	Rumah Sakit Khusus Jantung Binawaluya Jakarta/Dr. Muhammad Munawar, SpJP, PhD	PT. Quintiles Indonesia	Obat	Sep-16
11	Uji Klinik Secara Random : Studi Perbandingan Kontrasepsi Susuk KB Satu Batang Monoplant® dengan Susuk Dua Batang Indoplant® di Lima Center Penelitian	RSAB Prof. Dr. HM. Farid, Makassar / dr. Retno Budiarti Farid, Sp.OG	PT. Triyasa Nagamas Farma	Obat	Nov-16
12	Uji Klinik Secara Random : Studi Perbandingan Kontrasepsi Susuk KB Satu Batang Monoplant® dengan Susuk Dua Batang Indoplant® di Lima Center Penelitian	dr. Heriyadi Manan, Sp.OG (RSAB Rika Amelia, Palembang)	PT. Triyasa Nagamas Farma	Obat	Desember 2016

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13	Studi klinik acak, open label, multisenter, untuk membandingkan immunogenisitas Ezelin dan Lantus® pada pasien Diabetes Melitus tipe 2 dewasa	RSUPN Dr. Cipto Mangunkusumo, Jakarta/ dr. Tri Juli Edi Tarigan, Sp.PD, K-EMD, FINASIM	PT. Kalbe Farma	Obat	Desember 2016

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No	JUDUL PROTOKOL	CENTER / PENELITI	SPONSOR / CRO	VAKSIN / OBAT	PELAKSANAAN INSPEKSI
1	<i>"Safety and Immunogenicity of Vi-DT Typhoid Conjugate Vaccine (Bio Farma) in Adults and Children (Phase I)"</i>	Departemen of Child Health, School of Medicine, University of Indonesia, Jakarta / Bernie Endyami, dr, SpA(K), MPH	PT. Bio Farma (Persero), Bandung	Vaksin	Februari 2017
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 4th visit in Indonesia Infants</i>	Departemen of Child Health, School of Medicine, Padjadjaran University, Bandung / Prof. Dr. Kusnandi Rusmil, dr., Sp.A(K), MM	PT. Bio Farma (Persero), Bandung	Vaksin	Maret 2017
3	<i>Tranexamic acid for the treatment of significant traumatic brain injure : an international randomized, double blind placebo controlled trial (CRASH 3)</i>	RS Sekar Kamulyan, Kuningan / Dr. Antonius Kumiawan Sp.B FINAC,FICS	London School of Hygiene and Tropical Medicine London UK	Obat	Apr-17
4	<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>	RSPAD Gatot Soebroto, Jakarta / Dr. Nyoto Widyo Astoro, Sp.PD, KHOM	Dong-A ST Co.Ltd, Republic of Korea / PT. Prodia Diacro Laboratories	Obat	Juli 2017
5	<i>"Uji klinik fase 3, acak, tersamar ganda, membandingkan efikasi dan keamanan gel ekstrak plasenta + neomycin pada luka pascaoperasi sectio caesarea dibandingkan dengan ketompok plasebo" (Bioplacenton Gel)</i>	SMF Obstetri dan Ginekologi RSUP Persahabatan / dr. Lucky Savitry Widyakusuma, SpOG(K)	PT. Kalbe Farma, Tbk / PT. Pharma Metric Labs	Obat	Juli 2017
6	<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 (Exluton[®], PT Sydna Farma Indonesia) in Women of Childbearing Age+</i>	PT Equilab International dan field site : Klinik Al-Barokah, Cibinong / dr. Danang Agung Yunaidi	PT. Triyasa Nagamas Farma /	Obat	Oktober 2017

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No	JUDUL PROTOKOL	CENTER / PENELITI	SPONSOR / CRO	VAKSIN / OBAT	PELAKSANAAN INSPEKSI
7	<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 (a maintenance phase study) in Indonesian population"</i>	Renal Hypertension Division, Dept. Of Internal Medicine Dr. Cipto Mangunkusumo Hospital / Prof. Dr. dr. Partindungan Siregar, SpPD-KGH	PT. Etana Biotechnologies, Indonesia	Obat	Nov-17
8	<i>"A Two-Cohort, Open-Label, Multicenter, Study of Trastuzumab Emtansine (T-DM1) in HER2 Positive Locally Advanced or Metastatic Breast Cancer Patients Who Have Received Prior Anti-HER2 and Chemotherapy-Based Treatment" (Studi Kamilla)</i>	RS MRCCC Siloam, Jakarta / Dr. dr. Andika Rachman, SpPD-KHOM	PT. Roche Indonesia	Obat	Nov-17
9	Uji Klinik Random "Randomized Clinical Trial Kontrasepsi Implant Sinoplant Versus Indoplant"	Bagian Obstetri Ginekologi RS Dr. Sardjito, Yogyakarta / dr. Lutfi, SpOG(K) peneliti utama : Prof. Djaswadi Dasuki, MD, MPH, Ph.D, SpOG(K)	PT. Catur Dakwah Crane Farmasi	Obat	Desember 2017
10	<i>"A randomized double-blind placebo-controlled trial for the evaluation of a polycap, low dose aspirin and vitamin D supplementation in primary prevention – The International Polycap Study 3 (TIPS 3)"</i>	Pusat Jantung Nasional Harapan Kita / Dr. dr. Anwar Santoso, SpJP(K), FIHA	PT. Cadila Pharma, India / PT. Prodia DiaCro	Obat	Desember 2017

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No	JUDUL PROTOKOL	CENTER / PENELITI	SPONSOR / CRO	VAKSIN / OBAT	WAKTU PERENCANAAN
1	<i>"Safety and Immunogenicity of Rotavirus (Bio Farma) Vaccine in Adults, Children and Neonates (Phase I)"</i>	Pediatric Research Office, Gadjah Mada University, Yogyakarta / Dr. Jarir At Thobari, PhD dan Dr. Kristy Iskandar, SpA., MSc	PT. Biofarma, Bandung	Vaksin	Februari 2018
2	<i>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</i>	Rs. Cipto Mangunkusumo /Dr.dr. Aida Tantri, SpAn (K)	PT. Innokeys	Obat	Februari 2018
3	Uji Klinik Random "Randomized Clinical Trial" Kontrasepsi Implant Sinoplast versus Inoplast	Departemen Obstetri Ginekologi FK Universitas Sumatera Utara (USU) - Medan / Prof. dr. Delfi Lutan, Msc., SpOG(K)	PT.Catur Dakwah Crane Farmasi	Obat	Apr-18
4	<i>"Phase 3 study of SFPP in knee Osteoarthritis : a randomized controlled study using diclofenac gel as the comparator"</i>	RS Islam Pondok Kopi, Jakarta Timur / Dr. Tanggo Meiriza, Sp.PD-KR	Taisho Pharmaceutical Co. Ltd. Jepang / PT. Prodia Diacro Lab	Obat	Apr-18