

DATA UJI KLINIK VAKSIN 2018

NO	PROTOKOL UJI KLINIK VAKSIN	SPONSOR/CRO	VAKSIN		FASE	CENTER	PENELITI	PERSETUJUAN PELAKSANAAN UJI KLINIK	
			NAMA VAKSIN	PRODUSEN				NOMOR	TANGGAL
1	<i>Immunogenicity and Safety Profile of Primary Dose of bivalent OPV (bOPV Bio Fama) Given Simultaneously with Pentabio® and Inactivated Poliovirus Vaccine (IPV) at the 4<sup>th</sup> visit in Indonesia Infants</i>	PT Biofama	bOPV	PT Biofama	III	Departement of Child Health, School of Medicine, Padjadjaran University, Bandung	Prof. Dr. Kusnandi Rusmā, dr., SpA(K), MM.	PN.01.06.313.3.06.16.3095	21 Juni 2016
2	<i>Safety and Immunogenicity of Vi-DT Typhoid Conjugate Vaccine (Bio Fama) in Adults and Children (Phase I)</i>	PT Biofama	Typhoid	PT Biofama	I	Departemen of Child Health, School of Medicine, University of Indonesia, Jakarta	Bemie Endyami, dr, SpA(K), MPH	PN.01.06.313.3.03.17.1449	27 Maret 2017

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2017	1	<i>"Reactogenicity and Protectivity Following Measles-Rubella (MR) Routine Immunization in Indonesian Infants and Children"</i>	PT Biofarma	MR vaccine	Serum Institute of India PVT.,	IV	Department of Child Health Dr. Soetomo Hospital / Medicine Faculty Airlangga University	Dr. dr. Dominicus Husada, SpA (K)	B-PN.01.06.313.3.10.17.5133	4 Oktober 2017
	2	<i>"Protectivity and Safety of Quadrivalent Influenza HA Vaccine in Indonesian Population (Bridging Study)"</i>	PT Biofarma	Vaksin Influenza Quadrivalent	PT. Bio Farma	III	Departemen Ilmu Kesehatan Anak RSUP Hasan Sadikin Bandung	Dr. Meita Dhamayati, dr., Sp.A(K), M.Kes	PN.01.06.313.09.17.2073	31 Agustus 2017
	3	<i>Safety and Immunogenicity of Rotavirus (Bio Farma) Vaccine in Adults, Children and Neonates (Phase I)</i>	PT Biofarma	MCRI-RV3-BB-003 / Vaksin Rotavirus	PT. Bio Farma	I	Pediatric Research Office, Gadjah Mada University, Yogyakarta	Dr. Jarir Al Thobari, PhD dan Dr. Kristy Iskandar, SpA., MSc	B-PN.01.06.313.3.04.18.01367	2 April 2018

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				NAMA VAKSIN	PRODUSEN					
2018	1	<i>"Safety and immunogenicity of Vi-DT Typhoid Conjugate vaccine (Bio Farma) in Indonesian adults-adolescents, children and Infants (Phase II)"</i>	PT. Biofarma	Typhoid	PT. Biofarma	II	Departemen Ilmu Anak FK UI / field site : 1. Puskesmas Jatinegara 2. Puskesmas Senen	Bemie Endyami Medise, dr. Sp.A(K), MPH	B-PN.01.06.323.3.05.18.2344	23 Mei 2018