

Supplementary information for the article:

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Supplementary Tables

Supplementary Table 1: Trial Scheme - Schedule of events for each participant

Study Activities	Study Day (# days from D1)					
	S1/D1* (D1 +4)	D1 to D5	D8 (+/- 1)	D9 to D21	D22 (+/- 1)	D91 (+/- 7)
Information process and written informed consent	X					
Collect baseline demographic data	X					
Collect/review medical history	X					
Perform general physical examination	X					
Perform vital signs & targeted physical examination (symptom based & reactogenicity only)	X*		X			
Perform urine pregnancy check (women of childbearing potential)	X*					
Check/confirm inclusion/exclusion criteria	X*					
Randomization	X					
Collect serum for influenza serology (pre-vaccination for Day 1)	X				X	
Administer one dose of study product (vaccine or placebo)	X					
Observe for 30 Minutes; record and manage immediate reactions	X					
Instruct participant on use of Memory Aid	X					
Participant records solicited reactogenicity and unsolicited AEs and any SAEs in Memory Aid	X	X				
Clinical staff reviews interim AEs/SAEs with participant; records in CRF			X		X	SAE only
Report SAEs to Sponsor, IRBs and regulatory authorities	X	X	X	X	X	X
Participant completion of study						X
*If Day 1 is conducted on a different day from S1, eligibility must be confirmed again on Day of Injection (D1); including Targeted physical examination (PE); inclusion/exclusion; urine pregnancy test.						

Supplementary Table 2: Details of Ethics committee/Institutional Review Board Overseeing the study.

Investigator	Local IRB/Reference Number/Date
WHO	WHO ERC Protocol ID: ERC.0002816 Meeting Date: 15/09/2016
Dr. Goran Stevanovic	Clinical Center Of Serbia Ethics Committee, Ref. Number: 168/16 – B Date: 22 Sep 2016
Prof. Dr. Milos Stojlljkovic/Dr. Aleksandar Obradovic	Ethics Committee of Special Gynecology Hospital with Maternity “Jevremova Ref. Number: 301/2016 Date: 17 Oct 2016
Dr Dragan Petrovic	Institute of Health Care of Ministry of Internal Affairs Ethics Committee Ref. Number:2/2016 18 th of October 2016
Dr Snezana Ristic	Student Health Center Ethics Committee Ref. Number: 4075 Dated: 23 Sep 2016
Prof. Dr. Branislava Milenkovic	Clinical Center of Serbia Ethics Committee Ref. Number: 168/16 – A Date: 22 Sep 2016
Dr Danilo Mitrovic	Republic of Serbia General Hospital “Vrsac”, Vrsac Ethics Committee Ref. Number: 01-988 Dated: 08 Sep 2016
Prof. Dr. Olgica Gajovic	Clinical Center of Kragujevac Ref. Number: 01-11477 Date: 08 Sep 2016, BELGRADE
Prof. Dr. Sinisa Sevic	Expert Collegium of Clinic for Infectious Diseases Ref. Number: 15-202 29 AUG 2016