

# H2020-SC1-2019-RTD Grant Agreement Number 874866

# Deliverable N° D4.2

INCENTIVE-QIV: Registration of the clinical trial in the trial registry

# Indo-European Consortium for Next Generation Influenza Vaccine Innovation (INCENTIVE)

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#### List of abbreviations

COBRA Computationally-Optimized Broadly-Reactive Antigens

CTRI Clinical Trial Registry of India
DBT Department of Biotechnology

EUDRA-CT European Union Drug Regulating Authorities Clinical Trials Database

HUS Haukeland University Hospital

NHP Non-Human Primates



#### 1. Introduction

This document is the **Deliverable 4.2 INCENTIVE-QIV:** Registration of the clinical trial in the trial registry of the project **INCENTIVE** (Indo-European Consortium for Next Generation Influenza Vaccine Innovation) funded by the European Union's Horizon 2020 research and innovation programme under Grant Agreement No. 874866 and the Dept. of Biotechnology (DBT), Govt. of India (project no.BT/IN/EU-INF/16/AP/19-20/11746). The INCENTIVE project started on 01<sup>st</sup> August 2020<sup>1</sup> and has a duration span of 60 months. The highly integrated INCENTIVE consortium comprises 19 institutions representing a true partnership between Indian and European/United States of America (US) groups that addresses the global health and economic challenge posed by influenza infections, to reduce the worldwide burden resulting from outbreaks.<sup>2</sup> INCENTIVE's strategic goals are to provide seminal knowledge on the underlying mechanisms of poor responsiveness to influenza vaccines in vulnerable individuals and advance the development of two next generation universal influenza vaccines.

INCENTIVE'S goal will be achieved by pursuing the following specific objectives: 1) address the current knowledge gap by performing comprehensive immunome profiling of responders and non-responders to licensed influenza vaccines in infants, children and elderly in parallel phase IV trials in Europe and India to identify the underlying mechanisms of vaccine responsiveness in different vulnerable populations and ethnical groups; 2) advance the development of two next generation universal influenza vaccines, including an antigen presenting cell-targeted nucleic acid vaccine (APC-MIX) up to proof-of-concept for vaccine efficacy in non-human primates (NHP), and a computationally-derived second generation COBRA (Computationally-Optimized Broadly-Reactive Antigens) vaccine up to clinical development, comprising a phase I trial in Europe, a phase II trial in India and efficacy studies using an influenza controlled human challenge model; 3) identify predictive biomarkers of responsiveness to vaccination to develop new diagnostics; 4) implement comprehensive technology transfer and harmonization activities for immunological analysis and data integration; and 5) perform a health systems and investment analysis, and discrete choice experiments to assess the suitability of the developed technologies for low- and middle-income countries, and to identify potential downstream constraints that might affect uptake by health care systems.

This deliverable 4.2 will confirm that the INCENTIVE QIV studies have been registered at a WHO- or ICMJE-approved registry.

<sup>&</sup>lt;sup>2</sup> Please refer to Annex section 3.1 for list of all INCENTIVE project partners.





<sup>&</sup>lt;sup>1</sup> The Indian grant start date is 29<sup>th</sup> December 2020

#### 2. INCENTIVE-QIV trials

One of the objectives of INCENTIVE is to conduct Phase IV trials in vulnerable populations to identify the underlying mechanisms of vaccine responsiveness. INCENTIVE-QIV is a series of phase IV trials studying response to the licensed Sanofi's quadrivalent Flu seasonal flu vaccine in three vulnerable populations: 1) elderly ≥ 60 years; 2) children 3-8 years; and 3) infants 6 to 7 months. The study will be conducted in parallel in Europe and India in the same sub-population groups with the licensed Sanofi's quadrivalent influenza vaccine. Centers involved in the Phase IV trials are P7 UA in Belgium (QIV-1 Elderly), P5 UiB in Norway (QIV-2 Children), P4 ULB in Belgium (QIV-3 Infants) and P18 GSMC&KEM in India (for all three groups, QIV-1, QIV-2 and QIV-3). This deliverable shows that the INCENTIVE QIV studies, in EU and India, have been registered with the European Union Drug Regulating Authorities Clinical Trials Database (EUDRA-CT) and Clinical Trial Registry of India (CTRI) respectively.

#### 2.1 INCENTIVE-QIV-1-EU (P7 UA, Belgium)

<u>INCENTIVE-QIV-1-EU</u>: This will be a Phase IV vaccine trial conducted at P7 UA in Belgium in 50 healthy participants, 60 years and older, to evaluate the immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra® from Sanofi) administered by the intramuscular route.

INCENTIVE-QIV-1-EU trial has been registered with EUDRA-CT (EudraCT Number: 2021-003307-18). **Link**: https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-003307-18/BE/

Please refer to Annex section 3.2 for the trial registration details at the EU Clinical Trials register.

### 2.2 INCENTIVE-QIV-2-EU (P5 UiB, Norway)

**INCENTIVE-QIV-2-EU**: This will be a Phase IV vaccine trial conducted by P5 UiB at the Clinical Trials Unit of HELSE BERGEN HF - HAUKELAND UNIVERSITY HOSPITAL (HUS) in Norway (HUS is a linked third party and affiliated to UiB) in 50 healthy children, 3-8 years old, to evaluate the immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra®) administered by the intramuscular route.

INCENTIVE-QIV-2-EU trial has been registered with EUDRA-CT. (EudraCT Number: 2021-003804-42) **Link:** https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-003804-42/NO

Please refer to Annex section 3.3 for the trial registration details at the EU Clinical Trials register.







#### 2.3 INCENTIVE-QIV-3-EU (P4 ULB, Belgium)

INCENTIVE-QIV-3-EU: This will be a Phase IV vaccine trial conducted by P4 ULB at CHU Saint-Pierre and Hôpital Erasme in Belgium in 50 infants, aged 6 to 7 months, to evaluate the immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra®) administered by the intramuscular route.

INCENTIVE-QIV-3-EU trial has been registered with EUDRA-CT (EudraCT Number: 2021-003760-27). Link: https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-003760-27/BE

Please refer to Annex section 3.4 for the trial registration details at the EU Clinical Trials register.

#### 2.4 INCENTIVE QIV-1, QIV-2 and QIV-3 (P18 GSMC&KEM, India)

INCENTIVE-QIV-1: This will be a Phase IV vaccine trial to be conducted at P18 GSMC&KEM in India in 100 healthy participants, 60 years or older, to evaluate the immunogenicity, molecular profiling and safety of a marketed Quadrivalent Influenza Vaccine (FluQuadri<sup>TM</sup>) administered by the intramuscular route. In India, FluQuadri™ manufactured by Sanofi India will be used, which is produced according to the same manufacturing procedure as Vaxigrip Tetra® (which is being used for the parallel QIV trials in EU) and composition of influenza strains are the same for both vaccines.

INCENTIVE-QIV-1 trial at P18 GSMC&KEM has been registered at the CTRI (CTRI Number: CTRI/2020/09/027913).

Link: http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=45001&EncHid=&userName=CTRI/2020/09/027913

Please refer to Annex section 3.5 for the trial registration details at the CTRI.

INCENTIVE-QIV-2: This will be a Phase IV vaccine trial to be conducted at P18 GSMC&KEM in India in 100 healthy children, 3-8 years old to evaluate the immunogenicity, molecular profiling and safety of a marketed Quadrivalent Influenza Vaccine (FluQuadri<sup>TM</sup>) administered by the intramuscular route.

INCENTIVE-QIV-2 trial at P18 GSMC&KEM has been registered at the CTRI (CTRI Number: CTRI/2021/10/037159)

Link: http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=58563&EncHid=&userName=CTRI/2021/10/037159





Please refer to Annex section 3.6 for the trial registration details at the CTRI.

<u>INCENTIVE-QIV-3</u>: This will be a Phase IV vaccine trial to be conducted at P18 GSMC&KEM in India in 100 healthy infants, aged 6 to 12 months, to evaluate the immunogenicity, molecular profiling and safety of a marketed Quadrivalent Influenza Vaccine (FluQuadri<sup>TM</sup>) administered by the intramuscular route.

INCENTIVE-QIV-3 trial at P18 GSMC&KEM has been has been registered at the CTRI (CTRI Number: CTRI/2021/10/037161)

Link: http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=58564&EncHid=&userName=CTRI/2021/10/037161

Please refer to Annex section 3.7 for the trial registration details at the CTRI.



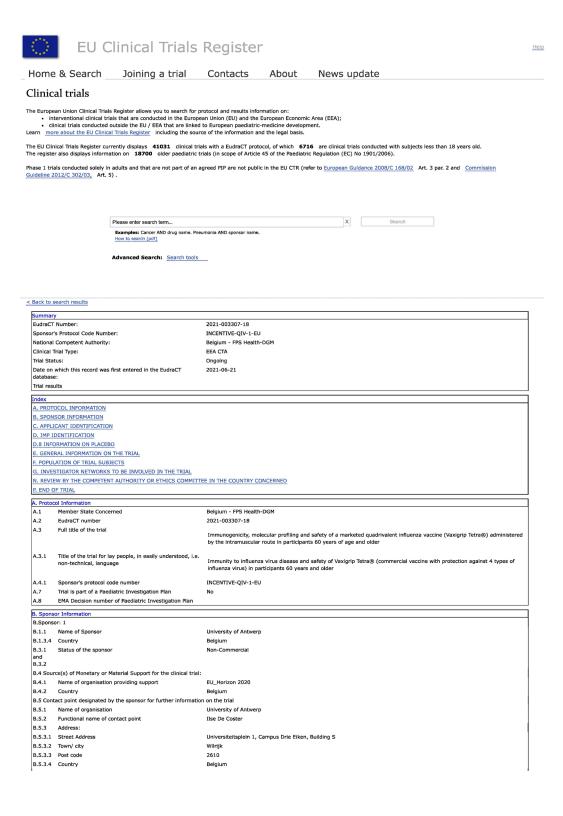
#### 3. Annex

# 3.1 List of INCENTIVE partners

Part Nr.	Institution	Short Name	Country
1 Coord.	Helmholtz Zentrum für Infektionsforschung GmbH	HZI	Germany
2	Public Health Foundation of India	PHFI	India
3	Translational Health Science and Technology Institute	THSTI	India
4	Université Libre de Bruxelles	ULB	Belgium
5	University of Bergen	UiB	Norway
6	University of Oslo	UiO	Norway
7	Universiteit Antwerpen	UA	Belgium
8	Academisch Ziekenhuis Leiden	LUMC	the Netherlands
9	Institut Pasteur	IP	France
10	ASA Spezialenzyme GmbH	ASA	Germany
11	Fundacion Privada Instituto de Salud Global Barcelona	ISGlobal	Spain
12	Bioaster Fondation de Cooperation Scientifique	Bioaster	France
13	University of Georgia Research Foundation, Inc	UGARF	United States
14	Stichting Human Vaccines Project Europe	HVP Stichting	the Netherlands
15	EuroVacc Foundation	EVF	Switzerland
16	Human Vaccine Project, Inc	HVP Inc	United States
17	Indian Institute of Technology Madras	IITM	India
18	Seth GS Medical College & KEM Hospital, Mumbai	GSMC & KEM	India
19 Coord	National Institute of Immunology	NII	India



# 3.2 INCENTIVE-QIV-1-EU (P7 UA, Belgium)





B. Sponsor	Information	
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D.1.2 and	TMP Role	Test
D.1.3		
D.2	Status of the IMP to be used in the clinical trial	
D.2.1	IMP to be used in the trial has a marketing authorisation	Yes
D.2.1.1.1	Trade name	Vaxigrip Tetra
D.2.1.1.2	Name of the Marketing Authorisation holder	Sanofi Pasteur Europe
D.2.1.2	Country which granted the Marketing Authorisation	Belglum
D.2.5	The IMP has been designated in this indication as an	No
	orphan drug in the Community	
D.2.5.1	Orphan drug designation number ption of the IMP	
D.3.4	Pharmaceutical form	Solution for injection in pre-filled syringe
D.3.4.1	Specific paediatric formulation	No
D.3.7	Routes of administration for this IMP	Intramuscular use
The second secon	3.10 IMP Identification Details (Active Substances)	Title and south
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRIÓN, INACTIVATED)
	Other descriptive name	A/Guangdong-Maonan/SWL1536/2019 (H1N1)
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	2007/95/04/05/07/24/95/04
	Concentration unit	μg/ml microgram(s)/mililitre
************	Concentration type	not less then
	Concentration number	30
	3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name	A/Hongkong/2671/2019 (H3N2)
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	µg/mi microgram(s)/millilitre
D.3.10.2	Concentration type	not less then
D.3.10.3	Concentration number	30
D.3.8 to D	3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name	B/Washington/02/2019, wild type
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
	Concentration unit	μg/mi microgram(s)/millilitre
	Concentration type	not less then
	Concentration number	30
	3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name	B/Phuket/3073/2013, wild type
D.3.9.4 D.3.10	EV Substance Code	SUB12066MIG
	Strength Concentration unit	realist as large manufal (as illillare
	Concentration unit	µg/mi microgram(s)/millilitre
	Concentration type  Concentration number	not less then 30
	e IMP contains an:	M
	Active substance of chemical origin	No
	Active substance of biological/ biotechnological origin	Yes
2	(other than Advanced Therapy IMP (ATIMP)	
	The IMP is a:	
D.3.11.3	Advanced Therapy IMP (ATIMP)	No
D.3.11.3.1	Somatic cell therapy medicinal product	No
D.3.11.3.2	Gene therapy medical product	No
	Tissue Engineered Product	No
	Combination ATIMP (i.e. one involving a medical device)	No
D.3.11.3.5	Committee on Advanced therapies (CAT) has issued a	No
D.3.11.4	classification for this product  Combination product that includes a device, but does not Involve an Advanced Therapy	No
D.3.11.5	Radiopharmaceutical medicinal product	No
	Immunological medicinal product (such as vaccine,	Yes
	allergen, immune serum)	
D.3.11.7	Plasma derived medicinal product	No
D.3.11.8	Extractive medicinal product	No
D.3.11.9	Recombinant medicinal product	No
	Medicinal product containing genetically modified organisms	No
D.3.11.11	Herbal medicinal product	No
D.3.11.12	Homeopathic medicinal product	No
D.3.11.13	Another type of medicinal product	No
D.8 Inform	ation on Placebo	
	Information on the Trial Il condition or disease under investigation	
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E. General Information on the Trial	
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### Pitropial inclusion orderina    Explain production and production with the below criterina at the dime of erroriment:	E.2.2	Secondary objectives of the trial	Not applicable
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2. The participant is willing to comply with subly proced requirements, including wailability for all scheduled withs of the study.  4. Subjects are healthy or with sead-controlled pre-solution conditions by the optimis of the investigator and the study of the sead of			
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S. Current or previous, laboratory confirmed case of influenza during the past 6 months, based on assumests or metal all in the walkable) at strenging valt.			<ol> <li>Not willing to refrain from physical exercise during 48 hours prior to vaccination</li> <li>History of any influenza vaccine administration during the past 6 months and during study participation.</li> </ol>
6. Household contract with any facility that any biboratory confirmed influence infection during the past & more than prior to succession.  7. Instruct of severe allergic reactions after previous vencinations or hypersensitivity to any study vaccine component of the past of the pas			5. Current or previous, laboratory confirmed case of influenza during the past 6 months, based on anamnesis or medical file
the past & menths prior to waccination.  7. History of several ellipsic residuous steer previous vascinations or hypersensitivity to any study vascine component.  8. Periodes history of Cullian barre Syndrome.  9. Leading the past of			
8. Previous history of Guillain Barre Syndrome.  9. Any confirmed or supported condition with impaired/altered function of immune system (e.g. Immunodefident or autionimum conditions).  10. Faving parts be possible on the product of the substance of the confidency of the confidenc			the past 6 months prior to vaccination.
8. A y confirmed or suspected condition with impaired/altered function of immune system (e.g., immunedeficient or autoimmune cenditions). 10. Reving tested positive for Human Immuno-deficiency Virus (HIV), Hespitis B or hespitis C on the blood tests of the autoimmune cenditions). 11. Reving a tested positive for Human Immuno-deficiency Virus (HIV), Hespitis B or hespitis C on the blood tests of the strength of			
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be >6 months prior to enrollment) or planned administration of any vaccine during study participation.  16. Use of any investigational or on-registered drug or vaccine within 30 days prior to the administration of study vaccines or planned during the study.  17. Hiving received systemic antibloid: treatment within 3 days prior to enrollment.  18. Acute or chronic, clinically significant pulmonary, cardiovescular, metabolic, neurological, hepatic, or renal functional abnormality, as determined by medical history or physical examination if uncontrolled or without appropriate treatment 19. Any other condition that in the opinion of the investigator would jeopardize the safety or rights of the volunteer participation.  E.5. 11 Primary end point(e)  **HAI antibody titres on D0 and D28** Proportion of participants with HAI three ≥ 40 (1/dilution) at D28** Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28** Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D28** Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28** Proportion of high and low responders (HAI			
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HAI antibody three fold increase between D0 and D28 Proportion of participants with Sercoonversion (thre < 10 [1/dilution] et D0 and post-vaccinetion titre ≥ 40 [1/dilution] et D28, or titre ≥ 10 [1/dilution] et D0 and a ≥ 4-fold increase in titre [1/dilution] et D28 Proportion of high and low responders (HAI titres <40 (1/dilution) at D28 Proportion of high and low responders (HAI titres <40 (1/dilution) at D28 Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 Proportion of participants with Sercoonversion (thre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28 Proportion of participants with Sercoonversion (thre < 10 [1/dilution] at D28 Proportion of participants with Sercoonversion (three < 10 [1/dilution] at D28 Proportion of participants with Sercoonversion (three < 10 [1/dilution] at D28 Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28) Proportion of high and low responders (HAI titres <40 (1/dilution) at D28 Proportion of high and low responders (HAI titres <40 (1/dilution) at D28 Proportion of high and low responders (HAI titres <40 (1/dilution) at D28 Proportion of participants with Sercoonversion (three <10 [1/dilution] at D28 Proportion of participants with Sercoonversion (three <10 [1/dilution] at D28 Proportion of participants with Sercoonversion (three <10 [1/dilution] at D28 Proportion of participants with Sercoonversion (three <10 [1/dilution] at D28 Proportion of participants with Sercoonversion (three <10 [1/d	E.5.1	Primary end point(s)	
Proportion of participants with Seroconversion (tirc < 10 [L/dilution] at D0 and post-vaccination titre ≥ 40 [L/dilution] at D28, or titre ≥ 10 [J/dilution] at D28			
E.5.1.1 Timepoint(s) of evaluation of this end point  +AI antibody titres on D0 and D28 - Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 - Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 - Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 - Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28 - Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28 - Proportion of high			
E.5.1.1 Timepoint(s) of evaluation of this end point  - HAI antibody three fold increase between D0 and D28 - Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 - Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 - Proportion of participants with Secretorwersion (thre < 10 [1/dilution] at D28 or titre ≥ 40 [1/dilution] at D28 - Proportion of high and low responders (HAI titres <40 (1/dilution) at D28)  E.5.2 Secondary end point(s)  Not applicable  E.5.2.1 Timepoint(s) of evaluation of this end point  Not applicable  E.6.3 Scope of the trial  E.6.4 Scope of the trial  E.6.5 Prophylaxis - Proportion of high and low responders (HAI titres <40 (1/dilution) at D28)  Proportion of high and low responders (HAI titres <40 (1/dilution) at D28)  Not applicable  Not applicable  Not applicable  No Scope of the trial  E.6.4 Secondary end point(s)  No Secondary end point (proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants with HAI titres <40 (1/dilution) at D28  Proportion of participants			
HAI antibody litres on D0 and D28     Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28     HAI antibody litres fold increase between D0 and D28     Proportion of participants with FAIX titres ≥ 40 (1/dilution) at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28     Proportion of participants with Serconversion (titre < 10 [1/dilution] at D28     Proportion of Participants with Serconversion (titre < 10 [1/dilution] at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of High and low responders (HAI titres < 40 (1/dilution) at D28     Proporti			• Proportion of high and low responders (TAL titres <-0 (1/dilution) at D26)
Proportion of participants with IAIX titres ≥ 40 (1/dilution) at D28     Pla1 an intibody titres fold increase between 0 and D28     Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28     Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilution) at D28     Proportion of high and low responders (HAI titres < 40 (1/dilu	E.5.1.1	Timepoint(s) of evaluation of this end point	HAI antibody titres on D0 and D28
Proportion of participants with Serconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D0 and past-vaccination titre ≥			
E.5.2 Secondary end point(s)  E.5.2. Timepoint(s) of evaluation of this end point  Not applicable  E.6.3 and E.7 Scope of the trial  E.6.4 Scope of the trial  E.6.5.2 Prophylaxis  E.6.3 Therapy  No  No  No  No  No  No  No  No  No  N			
E.5.2 Secondary end point(s) Not applicable  E.5.2.1 Timepoint(s) of evaluation of this end point Not applicable  E.6 and E.7 Scope of the trial  E.6.1 Diagnosis No  E.6.2 Prophylexis Yes  E.6.3 Therapy No  E.6.4 Safety Yes  E.6.5 Efficacy No  E.6.6 Pharmacoidnetic No  E.6.7 Pharmacoidnetic No  E.6.8 Bioequivalence No  E.6.9 Dose response Yes  E.6.9 Dose response Yes			
Not applicable  E.5.2.1 Timepoint(s) of evaluation of this end point  Not applicable  E.6 and E.7 Scope of the trial  E.6 Scope of the trial  E.6.1 Diagnosis No  E.6.2 Prophylaxis Yes  E.6.3 Therapy No  E.6.4 Safety Yes  E.6.5 Efficacy No  E.6.6 Pharmacokinetic No  E.6.7 Pharmacokynamic No  E.6.8 Bioequivalence No  E.6.9 Dose response Yes  E.6.9 Dose response  No  No  No  No  No  No  No  No  No  N			<ul> <li>Proportion of high and low responders (HAI titres &lt;40 (1/dilution) at D28)</li> </ul>
Not applicable  E.5.2.1 Timepoint(s) of evaluation of this end point  Not applicable  E.6 and E.7 Scope of the trial  E.6 Scope of the trial  E.6.1 Diagnosis No  Prophylexis Yes  E.6.2 Prophylexis Yes  E.6.3 Safety Yes  E.6.4 Safety Yes  E.6.5 Efficacy No  Pharmacokinetic No  E.6.6 Pharmacokynamic No  E.6.7 Pharmacokynamic No  E.6.8 Bioequivalence No  E.6.9 Dose response Yes	E.5.2	Secondary end point(s)	
Not applicable			Not applicable
E.6 and E.7 Scope of the trial E.6 Scope of the trial E.6.1 Diagnosis No E.6.2 Prophylexis Yes E.6.3 Therapy No E.6.4 Safety Yes E.6.5 Efficacy No E.6.6 Pharmacokinetic No E.6.7 Pharmacokynamic No E.6.8 Bioequivalence No E.6.9 Dose response Yes	E.5.2.1	Timepoint(s) of evaluation of this end point	Not annifrante
E.6     Scope of the total       E.6.1     Diagnosis     No       E.6.2     Prophylexis     Yes       E.6.3     Therapy     No       E.6.4     Safety     Yes       E.6.5     Efficacy     No       E.6.6     Pharmacokinetic     No       E.6.7     Pharmacodynamic     No       E.6.8     Bioequivalence     No       E.6.9     Dose response     Yes			revs approadule
E.6.1       Diagnosis       No         E.6.2.       Prophylexis       Yes         E.6.3.       Therapy       No         E.6.4.       Safety       Yes         E.6.5.       Efficacy       No         E.6.6.       Pharmacokinetic       No         E.6.7.       Pharmacodynamic       No         E.6.8.       Bloequivalence       No         E.6.9.       Dose response       Yes	100000000000000000000000000000000000000		
E.6.2 Prophylaxis Yes E.6.3 Therapy No E.6.4 Safety Yes E.6.5 Efficacy No E.6.5 Pharmacoldnettic No E.6.7 Pharmacoldnettic No E.6.7 Disequivalence No E.6.9 Dose response Yes	E.6		
E.6.3 Therapy No E.6.4 Safety Yes E.6.5 Efficacy No E.6.5 Pharmacokinetic No E.6.7 Pharmacocymanic No E.6.8 Bloequivalence No E.6.9 Dose response Yes	E.6.1		
E.6.4 Safety Yes E.6.5 Efficacy No E.6.6 Pharmacokinetic No E.6.8 Bloequivalence No E.6.9 Dose response Yes	A 74 TO CO S. NO.		
E.6.5 Efficacy No E.6.5 Pharmacokinetic No E.6.7 Pharmacokynamic No E.6.8 Bloequivalence No E.6.9 Dose response Yes	E.6.4		
E.6.5 Pharmacokinetic No E.6.7 Pharmacokinetic No E.6.8 Bloequivalence No E.6.9 Dose response Yes	E.6.5		
E.6.8 Bloequivalence No E.6.9 Dose response Yes	E.6.6	and the same of	
E.6.9 Dose response Yes	E.6.7	Pharmacodynamic	No
	E.6.8		
E-0.10 Priarmacogenetic NO	E.6.9		
	2.6.10	rnamiacogenetic	nu





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E. General Information on the Trial
E.6.11 Pharmaconeness's
E.6.13 Others
E.6.13.1 Other scope of the trial description
           Human pharmacology (Phase I)
E.7.1
E.7.1.2 Bioequivalence study
 E.7.1.3 Other
E.7.1.3.1 Other trial type description
 E.7.2 Therapeutic exploratory (Phase II)
 E.7.4
        Therapeutic use (Phase IV)
E.8 Design of the trial
E.8.1
E.8.1.1 Randomised
E.8.1.3 Single blind
 E.8.1.4 Double blind
E.8.1.5
E.8.1.6 Cross over
E.8.2
           Comparator of controlled trial
 E.8.2.1 Other medicinal product(s)
 E.8.2.2 Placebo
 E.8.2.3 Other
 E.8.4
           The trial involves multiple sites in the Member State concerned
 E.8.5
           The trial involves multiple Member States
E.8.6 Trial involving sites outside the EEA
E.8.6.1 Trial being conducted both within and outside the EEA
 E.8.6.2 Trial being conducted completely outside of the EEA
 E.8.7
           Trial has a data monitoring committee
          Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial end of trial is last visit of last subject
 F.R.9 Initial estimate of the duration of the trial
E.8.9.1 In the Member State concerned years
 E.8.9.1 In the Member State concerned months
E.8.9.1 In the Member State concerned days
F. Population of Trial Subjects
F.1.1 Trial has subjects under 18
 F.1.1.1 In Utero
 F.1.1.2 Pretarm newborn infants (up to gestational age < 37 weeks)
 F.1.1.4 Infants and toddlers (28 days-23 months)
 F.1.1.5 Children (2-11years)
 F.1.1.6 Adolescents (12-17 years)
 F.1.2 Adults (18-64 years)
                                                                       Yes
 F.1.2.1 Number of subjects for this age range:
 F13
          Elderly (>=65 years)
                                                                       25
F.1.3.1 Number of subjects for this age range:
 F.2.1
       Female
Male
                                                                       Yes
 F.3 Group of trial subjects
 F.3.1
          Healthy volunteers
                                                                       Yes
 F.3.2
 F.3.3
           Specific vulnerable populations
          Women of childbearing potential not using contraception
 F.3.3.2 Women of child-bearing potential using contraception
 F.3.3.3 Pregnant women
 F.3.3.4 Nursing women
 F.3.3.5 Emergency situation
 F.3.3.6 Subjects Incapable of giving consent personally
 E3.3.7 Others
 F.4 Planned number of subjects to be included
        For a multinational trial
F.4.2
 F.4.2.2 In the whole clinical trial
           Plans for treatment or care after the subject has ended
the participation in the trial (if it is different from the
expected normal treatment of that condition)
G. Investigator Networks to be involved in the Trial
N. Review by the Competent Authority or Ethics Committee in the country concerned
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N. Review by the Competent Authority or Ethics Committee in the country concerned
N. Competent Authority Decision Authorised
N. Date of Competent Authority Decision 2021-07-12
N. Ethics Committee Opinion of the trial application Favourable
Opinion
N. Date of Ethics Committee Opinion
N. Date of Ethics Committee Opinion

For support, visit the EMA Service Desk., log in using your EMA account and open a ticket specifying "EU CTR" in your request.

If you do not have an account, please visit the EMA Account management page page click on "Create an EMA account" and follow the instructions.

Ongoing

The status of studies in GB is no longer updated from 1.1.2021
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI
EU Clinical Thisis Register Service Desk: https://servicedesk.ema.europa.eu
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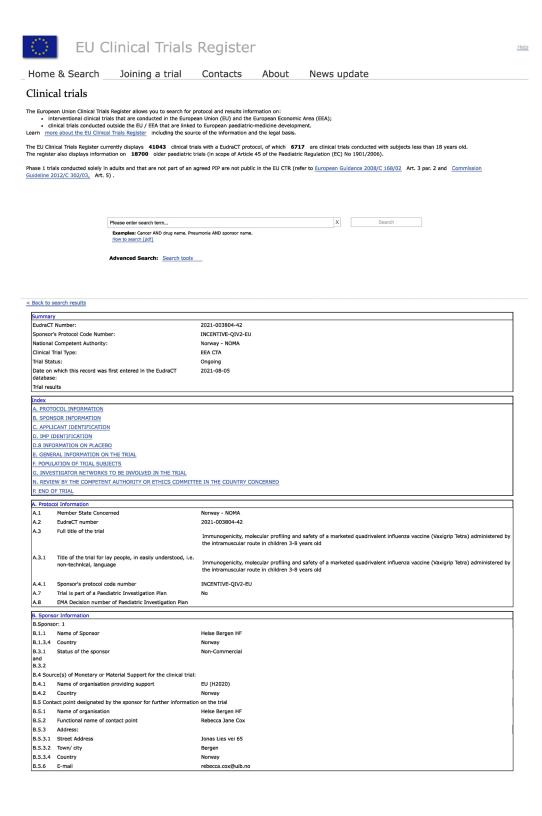


End of Trial Status





# 3.3 INCENTIVE-QIV-2-EU (P5 UiB, Norway)







D. IMP Ide	ntification	
D.IMP: 1		
D.1.2 and	IMP Role	Test
D.1.3		
D.2	Status of the IMP to be used in the clinical trial	
D.2.1	IMP to be used in the trial has a marketing authorisation	Yes
D.2.1.1.1	Trade name	Vaxigriptetra
D.2.1.1.2	Name of the Marketing Authorisation holder	Sanofi Pasteur Europe
D.2.1.2	Country which granted the Marketing Authorisation	Norway
D.2.5	The IMP has been designated in this indication as an orphan drug in the Community	No
D.2.5.1	Orphan drug designation number	
D.3 Descri	ption of the IMP	
D.3.4	Pharmaceutical form	Suspension for injection in pre-filled syringe
D.3.4.1	Specific paediatric formulation	No
D.3.7	Routes of administration for this IMP	Intramuscular use
D.3.11 The	IMP contains an:	
D.3.11.1	Active substance of chemical origin	Yes
D.3.11.2	Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP)	No
	The IMP is a:	
D.3.11.3	Advanced Therapy IMP (ATIMP)	No
D.3.11.3.1	Somatic cell therapy medicinal product	No
D.3.11.3.2	Gene therapy medical product	No
D.3.11.3.3	Tissue Engineered Product	No
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device)	No
D.3.11.3.5	Committee on Advanced theraples (CAT) has issued a classification for this product	No
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy	: No
D.3.11.5	Radiopharmaceutical medicinal product	No
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)	Yes
D.3.11.7	Plasma derived medicinal product	No
D.3.11.8	Extractive medicinal product	No
D.3.11.9	Recombinant medicinal product	No
D.3.11.10	Medicinal product containing genetically modified organisms	No
D.3.11.11	Herbal medicinal product	No
D.3.11.12	Homeopathic medicinal product	No
D.3.11.13	Another type of medicinal product	No

#### D.8 Information on Placebo

al Information on the Trial	
cal condition or disease under investigation	
Medical condition(s) being investigated	Immune response to infuenza vaccine in young children
Medical condition in easily understood language	Immune response to influenza vaccine in young children
Therapeutic area	Body processes [G] - Immune system processes [G12]
Classification	
Condition being studied is a rare disease	No
ctive of the trial	
Main objective of the trial	• To measure the level of the immune response (HAI titres) after two intramuscular doses of the quadrivalent inactivated influenza vaccine (Vaxigrip Tetra) in mainly healthy children aged 3-8 years old.
Secondary objectives of the trial	Exploratory objectives
	To measure the levels, avidity, biophysical characteristics and functionality of influenza-specific antibodies induced by the vaccine  * To measure the functional programming of peripheral blood immune cells (transcriptome and phenotype), the plasma proteome and metabolome before and after vaccination
Trial contains a sub-study	No
Principal inclusion criteria	<ol> <li>Healthy children or children with well-controlled pre-existing medical conditions (as concluded from the medical history with a stable regimen for at least 2 weeks prior to study entry, physical examination, and clinical judgment) age range ≥ 3 and ≤ 8 years old.</li> <li>Signed informed consent from parents/guardiens.</li> <li>Parents/guardians able to understand and comply with the study protocol requirements, including availability for all scheduled visits of the study.</li> </ol>
	cal condition or disease under investigation Medical condition(s) being investigated  Medical condition in easily understood language  Therapeutic area Classification Condition being studied is a rare disease ctive of the trial  Main objective of the trial  Secondary objectives of the trial



# E. General Information on the Trial 1) Acute illness, at the time of study vaccine administration (once acute illness is resolved, participants will be re-revaluated for eligibility). 2) Recorded fever (for eligibility purpose defined as a body temperature greater than 37.5°C) within 3 days priovacche administration (once fever/acute illness is resolved, participants will be re-evaluated for eligibility by the Investigator). 3) Current or previous, laboratory confirmed case of influenza during the past 6 months, based on anamnesis or medical record (if available) at screening visit. 4) Household contact with and/or intimate exposure to an individual with any laboratory confirmed influenza infection during the past 6 months prior to vaccination. 5) History of severe allergic reactions after previous vaccinations or hypersensitivity to any study vaccine components (ovalbumin, egg proteins), neomycin, formaldehyde or octoxynol-9. 6) Previous history of Guillain Barré Syndrome. 7) Any confirmed or suspected condition with impaired/altered function of immune system (e.g. immunodeficient or autoimmune conditions). 7) Any confirmed or suspected condition with impaired/actered function or immune agraem (e.g. autoimmune conditions). 8) Having any bleeding disorder which is considered as a contraindication to intramuscular injection or blood draw according to the opinion of the investigator 9) Chronic administration (defined as more than 14 days) of immunosuppressant or other immune-modifying drugs within three months prior to the study vaccination or planned use throughout the study period. (For corticosteroids, this means predisione, or equivalent, 2. or mg/kg per day. Inhaled, Intransas and topical steroids are allowed. 10) Neoplastic disease or any hematologic malignancy (except localized sidn or prostate cancer that is stable at the time of vaccination in the absence of therapy and subjects who have a history of neoplastic disease and have been disease-free for >5 wars). alnistration of blood, blood products and/or plasma derivatives or any parenteral immunoglobulin preparation in the past 3 months or planned use throughout the study period. 12) Administration of any vaccine within 28 days prior to enrolment in the study or planned administration of any vaccine during study participation. during study participation. 13) Use of any investigational or non-registered drug or vaccine within 30 days prior to the administration of study vaccines or planned during the study. 14) Having received systemic antibiotic treatment within 3 days prior to enrolment. 15) Acute or chronic, clinically significant pulmonary, cardiovascular, matabolic, neurological, hepatic, or renal functional abnormality, as determined by medical history or physical examination if uncontrolled or without spropriate treatment 16) Any other condition that in the opinion of the investigator would jeopardize the safety or rights of the volunteer participating in the study or make it unlikely that the perticipant could complete the protocol. For the second vaccine dose the exclusion criteria are: 1) Previous Influenza vaccination before study start, as these children only require one vaccination. 2) Acute Illness, at the time of study vaccine administration (once acute Illness is resolved, participants will be re-revaluated for study vaccine. 2) Addite liness, at the time of study vectorie administration (once actue liness is resolved, participants will be re-revalual for eligibility). 3) Recorded fever (for eligibility purpose defined as a body temperature greater than 37.5°C) within 3 days prior to study vectorie administration (once fever/acute liness is resolved, participants will be re-evaluated for eligibility by the investigator). investigator, All History of severe allergic reactions after previous vaccinations or hypersensitivity to any study vaccine comp (ovalibumin, egg proteins), neomycin, formaldehyde or octoxynol-9. E.5.1 Primary end point(s) HAI antibody titres on D0 and D58 Proportion of participents with HAI titres ≥ 40 at D58 HAI antibody titres fold increase between D0 and D58 Proportion of participants with Sercooversion (titre < 10 at D0 and post-vaccination titre ≥ 40 at D30 (one dose) or D58 (two dose), or titre ≥ 10 at D0 and a ≥ 4-fold increase in titre</li> E.5.1.1 Timepoint(s) of evaluation of this end point day 58 after first vaccination dose (for two doses) / day 30 (for one dose) E.5.2 Secondary end point(s) Exploratory endpoints A. Neutralizing antibody titres will be measured for each vaccine strain with the microneutralization (MN) assay. The analyses will be performed on blood samples obtained on D0, D30 and D58. - Detectable NN (NN antibody titre on D0, D30 and D58 - Detectable NN (NN antibody titre ≥ 10 at D0, D30, D58 - Proportion of participants with MN antibody thres ≥ 20, ≥ 40, ≥ 40, ≥ 80) at D30, D58 - Froincividual NN antibody titre (biol-increase D30 and D58 post-vaccination relative to D0 - Fold-increase in MN antibody titre [D58/D0] or [D30/D0] ≥ 2 and ≥ 4 b. Anti-Haemagglutinin (HA) and Neuraminidase (NA) antib ody titres to vaccine strain and antibody avidity. 0. AnD-naemaggiutum (rA) and neuraminosas (rA) antibody circes to vaccine strain and anti-individual HA and NA antibody titres on D, D30 and D58 • Detectable HA and NA antibody titre $\geq$ 10 at D0, D30 and D58 • Proportion of participants with HA and NA antibody titres $\geq$ 20, $\geq$ 40, $\geq$ 80 at D30 and D58 • Individual HA and NA antibody titre aribo (D58/ D0) (D30/ D0) • Fold-increase in HA and NA antibody titre [nost/pre] $\geq$ 2 and $\geq$ 4 at D30 and D58 • Avidity index of HA and NA antibody at D0, D30 and D58 c. Level (mean fluorescence intensity) and avidity (avidity index) of influenza-specific antibody (sotypes at D0, D30 and D58 d. Level of influenza-specific antibody isotypes triggering Fc-dependent effector functions (proportion of activated cells, phagocytic score or mean fluorescence intensity) at D0, D30 and D50, D30 and D58 e. Proportions of influenza-specific peripheral blood T cells with effector or regulatory phenotypes at D0, D30 and D58 f. Proportions of peripheral blood 8 cells with effector or regulatory phenotypes at D0, D30 and D58 g. Proportions influenza-specific [og Fc expressing individual glycans at D0, D30 and D58 h. Level of binding (mean fluorescence intensity) of Fc receptors and complement by influenza-specific antibodies at D0, D30 and D58 I. Level of cytokines (pg/mi) and mRNA (arbitrary units) induced by microbial products in an ex vivo whole blood assay at j. Number (n per microliter) and proportions of immune cell subsets in peripheral blood at D0. k. Level of expression of peripheral blood cell mRNA, plasma metabolites and plasma proteins (arbitrary units) at D0 and D3. E.5.2.1 Timepoint(s) of evaluation of this end point Scope of the trial Diagnosis E.6.1 E.6.3 Therapy Safety F.6.5 Efficacy E.6.6 Pharmacokinetic E.6.8 Bioequivalence





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E. General Information on the Trial
E.6.9 Dose response
          Pharmacogenetic
E.6.11
                                                                    No
No
E.6.12 Pharmacoeconomic
          Trial type and phase
         Human pharmacology (Phase I)
E.7.1.1 First administration to humans
E.7.1.2 Bioequivalence study
E.7.1.3 Other
E.7.1.3.1 Other trial type description
 E.7.2 Therapeutic exploratory (Phase II)
E.7.3
        Therapeutic confirmatory (Phase III)
                                                                    No
                                                                    Yes
          Therapeutic use (Phase IV)
E.8 Design of the trial
E.B.1 Controlled
E.8.1.1 Randomised
E.8.1.2 Open
                                                                    Yes
E.8.1.3 Single blind
F.S.1.4 Double blind
                                                                    No
No
E.8.1.5 Parallel group
E.8.1.6 Cross over
                                                                    No
No
E.8.1.7 Other
E.8.2.1 Other medicinal product(s)
E.8.2.2 Placebo
E.8.2.3 Other
E.8.3
          The trial involves single site in the Member State
E.8.5
         The trial involves multiple Member States
E.8.6 Trial involving sites outside the EEA
E.8.6.1 Trial being conducted both within and outside the EEA
E.8.6.2 Trial being conducted completely outside of the EEA
          Trial has a data monitoring committee
          Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial LVLS
 E.8.9 Initial estimate of the duration of the trial
E.B.9.1 In the Member State concerned years
E.B.9.1 In the Member State concerned months
E.8.9.1 In the Member State concerned days
E.8.9.2 In all countries concerned by the trial years
F. Population of Trial Subjects
F.1 Age Range
F.1.1 Trial has subjects under 18
E1.1
         Number of subjects for this age range:
                                                                    50
F.1.1.1 In Utero
F.1.1.3 Newborns (0-27 days)
         Infants and toddlers (28 days-23 months)
F.1.1.5 Children (2-11years)
F.1.1.5.1 Number of subjects for this age range:
 F.1.1.6 Adolescents (12-17 years)
F.1.2 Adults (18-64 years)
                                                                    No
          Elderly (>=65 years)
F.2 Gender
         Female
                                                                    Yes
F.2.1
 F.2.2
F.3 Group of trial subjects
F.3.2
          Patients
                                                                    Yes
          Specific vulnerable populations
F.3.3
F.3.3.1 Women of childbearing potential not using contra
          Women of child-bearing potential using contraception
F.3.3.2
 F.3.3.3
F.3.3.4 Nursing women
         Emergency situati
E3.3.6
         Subjects incapable of giving consent personally
F.3.3.7 Others
F.4.1
          In the member state
G. Investigator Networks to be involved in the Trial
N. Review by the Competent Authority or Ethics Committee in the country concerned
N. Competent Authority Parketon
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Date of Competent Authority Decision 2021-10-01





For support, visit the EMA Service Desk., log in using your EMA account and open a ticket specifying "EU CTR" in your request.

If you do not have an account, please visit the EMA Account management page page click on "Create an EMA account" and follow the instructions.

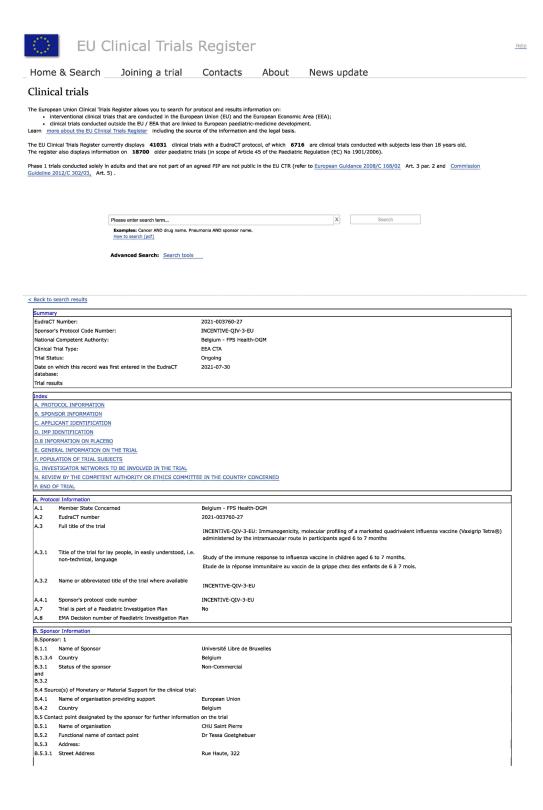
The status of studies in GB is no longer updated from 1.1.2021
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI
EU Clinical This Register Service Desk: <a href="https://servicedesk.ema.europa.eu">https://servicedesk.ema.europa.eu</a>
European Medicines Agency © 1995-2021 | Domenico Scariattilaan 6, 1083 HS Amsterdam, The Netherlands







# 3.4 INCENTIVE-QIV-3-EU (P4 ULB, Belgium)







B. Sponsor	Information	
B.5.3.2		Bruxelles
B.5.3.3	De Carlos de Car	1000
B.5.3.4		Belgium
B.5.4	Telephone number	+3225354369
B.5.5	Fax number	+3225354171
B.5.6	E-mail	tessa.goetghebuer@stpierre-bru.be
D. IMP Ide	ntification	
D.IMP: 1		
D.1.2 and	IMP Role	Test
D.1.3		
D.2	Status of the IMP to be used in the clinical trial	
D.2.1	IMP to be used in the trial has a marketing authorisation	DOD HIS HE WAY DOD
	Trade name	Vaxigrip Tetra®
	Name of the Marketing Authorisation holder	Sanofi
D.2.1.2	Country which granted the Marketing Authorisation	Belgium
D.2.5	The IMP has been designated in this indication as an orphan drug in the Community	No
D.2.5.1	Orphan drug designation number	
	ption of the IMP	
D.3.1	Product name	Quadrivalent Influenza Vaccine(split-virion, inactivated)
D.3.4	Pharmaceutical form	Suspension for injection in pre-filled syringe
D.3.4.1	Specific paediatric formulation	No
D.3.7	Routes of administration for this IMP	Intramuscular use
D.3.8 to D	.3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name	A/Guangdong-Maonan/SWL136/2019(H1N1)
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
	Concentration unit	µg/mi microgram(s)/millilitre
D.3.10.2		not less then
TENORGE CONTRACTOR	Concentration number	30
	3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name  EV Substance Code	A/Hongkong/2671/2019(H3N2) SUB12066MIG
D.3.9.4		SUB12000MIG
D.3.10	Strength Concentration unit	µg/mi microgram(s)/millilitre
	Concentration type	not less then
	Concentration number	30
	3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name	A/Washington/02/2019, wild type
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	μg/mi microgram(s)/millilitre
D.3.10.2	Concentration type	not less then
D.3.10.3	Concentration number	30
D.3.8 to D	.3.10 IMP Identification Details (Active Substances)	
D.3.8	INN - Proposed INN	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)
D.3.9.3	Other descriptive name	A/Phuket/3073/2013, wild type
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
	Concentration unit	μg/ml microgram(s)/millilitre
	Concentration type	not less then
reconsupportunity.	Concentration number	30
	e IMP contains an:	No
	Active substance of chemical origin	No Voe
0.3.11.2	Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP)	Yes
	The IMP is a:	
D.3.11.3	Advanced Therapy IMP (ATIMP)	No
17.40012.6/20m00.00.0000.	Somatic cell therapy medicinal product	No
D.3.11.3.2	Gene therapy medical product	No
D.3.11.3.3	Tissue Engineered Product	No
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device)	No
D.3.11.3.5	Committee on Advanced therapies (CAT) has issued a	No
	classification for this product	
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy	I NO
D.3.11.5	Radiopharmaceutical medicinal product	Na
D.3.11.6	Immunological medicinal product (such as vaccine,	Yes
	allergen, Irnmune serum)	page 14
D.3.11.7	Plasma derived medicinal product	No
D.3.11.8		No
D.3.11.9	Recombinant medicinal product	No
D.3.11.10	Medicinal product containing genetically modified	No
	organisms	
	Herbal medicinal product	No.
2773	Another type of medicinal product	No.
	Another type of medicinal product	,no
D.8 Inform	ation on Placebo	





TOTAL	al Information on the Trial	
E.1.1	cal condition or disease under investigation  Medical condition(s) being investigated	
		Prophylaxis of Influenza (Northern Hemispher 2021-2022 season) in Children aged 6-7 months
	Medical condition in easily understood language	Prophylaxis of Influenza (Northern Hernispher 2021-2022 season) in Children aged 6-7 months
	Therapeutic area Classification	Diseases [C] - Virus Diseases [C02]
E.1.3	Condition being studied is a rare disease	No
E.2 Obje	ctive of the trial	
E.2.1	Main objective of the trial	Immunogenicity - To measure the level of immune response [HAI-heamagglutinin Antibody Inhibition titres] of 2 Intramuscular doses of the quadrivalent inactivated influenza vaccine (Vaxigrip Tetra®) in healthy participants aged 6 to 7 months
E.2.2	Secondary objectives of the trial	To measure the levels, avidity, biophysical characteristics and functionality of influenza-specific antibodies induced by the vaccine To measure the functional programming of peripheral blood immune cells (transcriptome and phenotype), the plasma proteome and metabolome before and after vaccination
E.2.3	Trial contains a sub-study	No
E.3	Principal inclusion criteria	Male or female infants born at ≥ 36 weeks of gestation and aged 6 to 7 months  Provide written informed consent from parents.  The parents are willing to comply with study protocol requirements, including availability for all scheduled visits of the study.  Subjects are healthy or with well-controlled pre-existing medical conditions by the opinion of the investigator
E4	Principal exclusion criteria	1. Acute liness, at the time of study vaccine administration (once acute iliness is resolved, if appropriate, as per investigator assassment, participant will be re-revaluated for eligibility).  2. Recorded fever (for eligibility purpose defined as a body temperature greater than 37.5°C) within 3 days prior to study vacche administration (once fever/acute iliness is resolved, if appropriate, as per investigator assessment, participant will be re-evaluated for eligibility.  3. Current or previous, laboratory confirmed case of influenza during the past 6 months, based on anamnesis or medical file (if available) at screening visit  4. House-hold contact with analyor intimate exposure to an individual with any laboratory confirmed influenza infection during the past 6 months prior to vaccination.  5. History of severe allergic reactions after previous vaccinations or hypersensitivity to any study vaccine component  6. Previous history of Guillain Barre Syndrome.  7. Any confirmed or suspected condition with impaired/altered function of immune system (e.g. immunodeficient or autoimmune conditions).  8. Having tested positive for Human Immuno-deficiency Virus (HIV), Hepatitis B or Hepatitis C  9. Having any bleeding disorder which is considered as a contraindication to intramuscular injection or blood draw according to the opinion of the investigator  10. Chronic administration (defined as more than 14 days) of immunosuppressant or other immune-modifying drugs within three months prior to the study veccination or planned use throughout the study period. (For corticosteroids, this means prediscion, or equivalent, 2.0.5 mg/kg per day. Inhielad, intransasi and topical steroids are allowed.  11. Neoplastic disease or any hematologic malignancy (except localized akin or prostate cancer that is stable at the time of vaccination in the absence or therapy and subjects who have a history of neoplastic disease and have been disease-free for 25 years).  12. Administration of blood, blood products and/or plasme derivatives or an
E.5 End E.5.1	points Primary end point(s)	<ul> <li>HAI antibody titres on D0 and D58</li> <li>Proportion of participants with HAI titres ≥ 40 (1/dilution) at D58</li> <li>HAI antibody titres fold increase between D0 and D58</li> <li>Proportion of participants with Seroconversion (titre &lt; 10 [1/dilution] at D0 and post-veccination titre ≥ 40 [1/dilution] at D58, or titre ≥ 10 [1/dilution] at D6 and a ≥ 4-fold increase in titre [1/dilution] at D58</li> <li>Proportion of high and low responders (HAI titres &lt; 40 (1/dilution) at D58)</li> </ul>
E.5.1.1	Timepoint(s) of evaluation of this end point	D3 and D58
E.5.2	Secondary end point(s)	Not applicable
E.5.2.1	Timepoint(s) of evaluation of this end point	Not applicable
E.6 and	E.7 Scope of the trial	
E.6	Scope of the trial	
E.6.1	Diagnosis	No
E.6.2	Prophylaxis	Yes
E.6.3	Therapy	No
E.6.4	Safety	No
E.6.5	Efficacy	Yes
E.6.6	Pharmacokinetic	No
E.6.7	Pharmacodynamic	No
E.6.8	Bioequivalence	No
E.6.9	Dose response	No
E.6.10	Pharmacogenetic	No
E.6.11	Pharmacogeriomic	No
E.6.12	Pharmacoeconomic	No
E.6.13	Others	Yes





	I Information on the Trial	
E.6.13.1	Other scope of the trial description	Immunogenicity Molecular profiling
E.7	Trial type and phase	
E.7.1	Human pharmacology (Phase I)	No
E.7.1.1	First administration to humans	No
.7.1.2	Bioequivalence study	No
E.7.1.3	Other	No
	Other trial type description	Ti.
E.7.2 E.7.3	Therapeutic exploratory (Phase II)	No No
E.7.4	Therapeutic confirmatory (Phase III) Therapeutic use (Phase IV)	No Yes
	in of the trial	TCS
E.8.1	Controlled	No
E.8.1.1	Randomised	No
E.8.1.2		Yes
	Single blind	No
E.8.1.4	Double blind	No
E.8.1.5	Parallel group	No
E.8.1.6	Cross over	No
E.8.1.7	Other	No
E.8.2	Comparator of controlled trial	
	Other medicinal product(s)	No
E.8.2.2	Placebo	No
E.8.2.3	Other	No
E.8.3	The trial involves single site in the Member State	No
E.8.4	concerned The trial involves multiple sites in the Member State	Yes
E.8.4.1	Number of cities anticipated in Member State concerned	2
E.8.4.1 E.8.5	Number of sites anticipated in Member State concerned The trial involves multiple Member States	Z No
	I Involving sites outside the EEA	130
E.8.6.1	Trial being conducted both within and outside the EEA	No
E.8.6.2	Trial being conducted completely outside of the EEA	No
E.8.7	Trial has a data monitoring committee	Yes
E.8.8	Definition of the and of the trial and fuelification where it	
	is not the last visit of the last subject undergoing the trial	LSLV
E.8.9 Init	ial estimate of the duration of the trial	
	In the Member State concerned years	
	In the Member State concerned months	6
	In the Member State concerned days	
E.8.9.1		
E.8.9.1 F. Populat	ion of Trial Subjects	
E.B.9.1 F. Populat F.1 Age R	ion of Trial Subjects	Yes
E.8.9.1 F. Populat F.1 Age R F.1.1	ion of Trial Subjects ange	Yes 50
E.8.9.1 F. Populat F.1 Age R F.1.1 F.1.1	ion of Tifial Subjects ange Trial has subjects under 18	
E.8.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1	ion of Tital Subjects ange Tital has subjects under 18 Number of subjects for this age range:	50
E.8.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.1 F.1.1.2	ion of THal Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks)	50 No
E.8.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.1 F.1.1.2	ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days)	50 No No
E.8.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4	ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Pretarm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months)	50 No No
E.8.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1	ion of THal Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utaro Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range:	50 No No
E.B.9.1 F. Populat F.1 Age F F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5	ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years)	50 No No Yes 50 No
E.B.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6	ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Number of subjects for this age range: Children (2-11/years) Adolescents (12-17 years)	50 No No No Ses Ses No No No No No No No No
E.B.9.1 F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6 F.1.1.6	Ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Pretarm newborn infants (up to gestational age < 37 weeks) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adults (18-64 years)	50 No No No So No No No No No No No
E.B.9.1 E. Populat E. Populat E.1 Age R E.1.1 E.1.1 E.1.1.2 E.1.1.3 E.1.1.4 E.1.1.4.1 E.1.1.5 E.1.1.5 E.1.1.6 E.1.2 E.1.1.6 E.1.2 E.1.3	Ion of THal Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adults (18-64 years) Adults (18-64 years) Elderly (>=65 years)	50 No No No Ses Ses No No No No No No No No
E.B.9.1  F. Populat F.1 Age F F.1.1 F.1.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6 F.1.2 F.1.3 F.2 F.1.3 F.3 F.3 F.4	ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utaro Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adults (18-64 years) Elderly (>=85 years) er	50 No No No Yes 50 No No No No No No
E.B.9.1  F. Populat F.1 Age F F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6 F.1.2 F.1.3 F.2 Gende F.2.1	ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (2-17 years) Adults (18-64 years) Elderly (>=65 years) er Female	50 No No No So No No No No No No No
E.B.9.1 F. Populat F.1 Age F F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6 F.1.2 F.1.3 F.2 Gende F.2.1	ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utaro Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adults (18-64 years) Elderly (>=85 years) er	50 No No No Yes 50 No No No No No No
E.B.9.1  F. Populat F.1 Age R F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4 F.1.1.5 F.1.1.6 F.1.2 F.1.3 F.2 Gende F.2.1 F.2.2 F.3 Group	ion of Trial Subjects ange Trial has subjects under 18 Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adults (18-64 years) Elderty (>-65 years) er Female Male of trial subjects	50 No No No See
E.8.9.1  F. Populat F.1 Age F F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6 F.1.2 F.1.3 F.	ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Childran (2-11years) Adults (18-64 years) Elderly (>-65 years) er Female Male Male Of trial subjects Healthy volunteers	50 No No No Yes Yes Yes
E.8.9.1  F. Populat F.1 Age F F.1.1 F.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4.1 F.1.1.5 F.1.1.6 F.1.2 F.1.1.6 F.1.2 F.1.1.6 F.1.1 F.1.1.6 F.1.1 F.1.1 F.1.1 F.1 F.1 F.1 F.1 F.1 F	Ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adolescents (12-17 years) Elderly (2-85 years) er Female Male Of trial subjects Healthy volunteers Patients	50 No No No No Yes S0 No
E.8.9.1  F. Populat F. 1 Age R F.1.1 F.1.1 F.1.1.1 F.1.1.2 F.1.1.3 F.1.1.4 F.1.1.4 F.1.1.5 F.1.1.5 F.1.1.5 F.1.2 F.1.3 F.2 Gend F.2.1 F.3 Group F.3.1 F.3 Group F.3.2 F.3.3	ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adolescents (18-64 years) Elderty (>=65 years) er Female Male of trial subjects Healthy volunteers Patients Specific vulnerable populations	50 No No No Yes Yes Yes
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E.8.9.1  F. Populati F. Populati F. P. Populati F. P.	ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utaro Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adolescents (12-17 years) Elderly (>-85 years) er Female Male of trial subjects Healthy volunteers Patients Specific vulnerable populations Women of child-bearing potential using contraception Women of child-bearing potential using contraception Pregnant women	50 No No No No So So No
E.8.9.1  F. Populat E.1 Age R E.1 Age R E.1 Age R E.1.1 E.1.1 E.1.1 E.1.1.2 E.1.1.3 E.1.1.4 E.1.1.5 E.1.1.5 E.1.1.5 E.1.1.6 E.1.2 E.1.1.6 E.1.2 E.1.3 E.2 Gend E.2.1 E.3.3 E.3.3 E.3.3.3 E.3.3 E.3 E	ion of Thial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utero Pretarm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Childran (2-11years) Adolescents (12-17 years) Adults (18-64 years) Elderly (>=65 years) er Female Male of trial subjects Healthy volunteers Patients Specific vulnerable populations Women of child-bearing potential using contraception Women of child-bearing potential using contraception Pregnant women Nursing women	50 No No No No Yes Yes Yes No
E.8.9.1  F. Populat  F. Populat  F. 1 Age F  F. 1.1  F. 1.1  F. 1.1  F. 1.1  F. 1.1.2  F. 1.1.3  F. 1.1.4  F. 1.1.5  F. 1.1.5  F. 1.1.6  F. 1.2  F. 1.1.6  F. 1.2  F. 1.1.6  F. 2.2  F. 3.1  F. 3.2  F. 3.3	ion of Trial Subjects ange Trial has subjects under 18 Number of subjects for this age range: In Utaro Preterm newborn infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddiers (28 days-23 months) Number of subjects for this age range: Children (2-11years) Adolescents (12-17 years) Adolescents (12-17 years) Elderly (>-85 years) er Female Male of trial subjects Healthy volunteers Patients Specific vulnerable populations Women of child-bearing potential using contraception Women of child-bearing potential using contraception Pregnant women	50 No No No No State

F.4.1	In the member state	50	
F.5	Plans for treatment or care after the subject has ended the participation in the trial (if it is different from the expected normal treatment of that condition)	Not applicable	
	G. Investigator Networks to be involved in the Trial G.4 Investigator Network to be involved in the Trial: 1		
N. Carlotte, M. Carlotte, S. Mariette, and F. Carlotte,			





Cons

F.3.3.6.1 Details of subjects incapable of giving consent

F.4 Planned number of subjects to be included

F.3.3.7 Others

N. Review by the Competent Authority or Ethics Committee in the country concerned

N. Date of Competent Authority Decision 2021-08-12

N. Ethics Committee Opinion of the trial application Favourable opinion

N. Date of Ethics Committee Opinion: Reason(s) for unfavourable opinion

N. Date of Ethics Committee Opinion 2021-09-21

P. End of Trial

P. End of Trial Status Ongoing

For support, visit the EMA Service Desk., log in using your EMA account and open a ticket specifying "EU CTR" in your request. If you do not have an account, please visit the EMA Account management page page click on "Create an EMA account" and follow the instructions.

The status of studies in GB is no longer updated from 1.1.2021
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI
EU Clinical Trishs Register Service Desk: <a href="https://servicedesk.ema.europa.eu">https://servicedesk.ema.europa.eu</a>
European Medicines Agency © 1995-2021 | Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands







# 3.5 INCENTIVE QIV-1 (P18 GSMC&KEM, India)

Secondary ID

CLINICAL TRIALS REGISTRY - INDIA ICMR - National Institute of Medical Statistics



**PDF of Trial** CTRI Website URL - http://ctri.nic.in

#### Clinical Trial Details (PDF Generation Date :- Thu, 29 Apr 2021 10:16:08 GMT)

CTRI Number	CTRI/2020/09/027913 [Registered on: 18/09/2020] - Trial Registered Prospectively
Last Modified On	10/09/2020
Post Graduate Thesis	No
Type of Trial	PMS
Type of Study	Vaccine
Study Design	Single Arm Trial
Public Title of Study	Immunity against Influenza virus disease and safety of FluQuadri (marketed vaccine with protection against 4 types of influenza virus) in participants 60 years of age and older
Scientific Title of Study	Immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (FluQuadriTM) administered by the intramuscular route in participants 60 years of age and older

Study Secondary IDs if Any

**Details of Principal** Investigator or overall **Trial Coordinator** (multi-center study)

INL INL				
Details of Principal Investigator				
Name	Dr Nithya Gogtay			
Designation	Professor			
Affiliation	Seth GSMC & KEM Hospital			
Address	Dept. of Clinical Pharmacology 1st Floor, New Building Seth GSMC & KEM Hospital Parel.  Mumbai  MAHARASHTRA 400012 India			
Phone	9820495836			
Fax				
Email	njgogtay@hotmail.com			

Identifier

**Details Contact** Person (Scientific Query)

Eman	ngoga genoman.com		
Details Contact Person (Scientific Query)			
Name	Jeffrey Pradeep Raj		
Designation	Senior Resident		
Affiliation	Seth GSMC & KEM Hospital		
Address	Dept. of Clinical Pharmacology 1st Floor, New Building Seth GSMC & KEM Hospital Parel. Mumbai MAHARASHTRA 400012 India		
Phone	07904286189		
Fax			
Email	jpraj.m07@gmail.com		

Details Contact Person (Public Query)

Details Contact Person (Public Query)				
Name Jeffrey Pradeep Raj				
Designation Senior Resident				
Affiliation Seth GSMC & KEM Hospital				
Address	Dept. of Clinical Pharmacology 1st Floor, New Building Seth GSMC & KEM Hospital Parel.  MAHARASHTRA			
	400012 India			

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CLINICAL TRIALS REGISTRY - INDIA





#### PDF of Trial

CTRI Website URL - http://ctri.nic.in

	Laurence	la	7004000400			1	
	Phone	- 0	7904286189				
	Fax		rai m07@amail a				
	Email	P:	oraj.m07@gmail.co				
Source of Monetary or Material Support			urce of Monetary	•			
matorial Capport	> Department of Biotechnology (DBT), R. No. 706, Block-2, CGO Complex Lodhi Road, New Delhi-110 003				x Lodhi Road, New		
Primary Sponsor			Primary Spo	nsor Details			
	Name Seth GSMC and KE			EM Hospital	M Hospital		
	Address Acharya Donde Ma			rg, Parel, Mumbai-400012			
	Type of Sponsor Government medical college						
Details of Secondary	Name			Address			
Sponsor	NIL NIL						
Countries of	List of Countries						
Recruitment	India						
Sites of Study	Name of Principal Investigator	Name	of Site	Site Address		Phone/Fax/Email	
	Dr Nithya Gogtay		tment of Clinical	Seth GS Medica	al	9820495836	
			nacology, 1st floor Building	College & KEM Hospital, Achar		nigogtov@hotmoil.com	
		ivew c	sullurig	Donde Marg, Pa		njgogtay@hotmail.com	
				Mumbai			
				MAHARASHTR	'A		
Details of Ethics Committee	Name of Committee	Approval Status		Date of Approval		Is Independent Ethics Committee?	
	Insitutional Ethics Approved Committee I		04/08/2020		No		
Regulatory Clearance	Status			Date			
Status from DCGI	Not Applicable			No Date Specified			
Health Condition /	Health Type			Condition			
Problems Studied	Healthy Human Volunteers			Healthy human volunteers of age 60 years and above			
Intervention /	Туре		Name	labove	Details		
Comparator Agent	Intervention		FluQuadri arm			dose of Intramuscular	
				inje		ection of quadrivalent	
						za vaccine (Fluquadri) in	
	Comparator Agent		Not applicable			toid muscle (arm) plicable - its a single arm	
	Comparator Agent		140t applicable		study		
Inclusion Criteria	Inclusion Criteria						
	Age From 60		60.00 Year(s)				
	-		99.00 Year(s)				
	Gender		Both				
			Male or female of no child bearing potential 60 years and above at the time of study vaccine administration. Study vaccine administration. Verovide written				
			informed consent. study protocol requirements, including availability for all scheduled			ability for all scheduled	
		sits of the study. br/> 4. Healthy, as determined by medical history and clinical assessment of the investigator.					
Exclusion Criteria		ļa	40 K 10	404 W A3	Aiguiol.		
Exclusion Citiena	Exclusion Criteria  Details						
	Details						

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CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics



#### PDF of Trial

CTRI Website URL - http://ctri.nic.in

Method of Generating Random Sequence Method of Concealment Blinding/Masking Primary Outcome Not Applicable

Not Applicable

Open Label

Secondary Outcome

Outcome Timepoints

Haemagglutinin Antibody Inhibition (HAI)
antibody titres

Day 28

antibody titres	
Outcome	Timepoints
Safety: Occurrence of any adverse event (AE) – solicited AEs, unsolicited AEs and Serious AEs as well as effects on safety blood laboratory values. These measures relate to the safety and tolerability of the quadrivalent inactivated influenza vaccine (FluQuadriTM)	Day 7
Individual HAI titres ratio D28/D0, Proportion of participants with titres ? 40 (1/dilution), Proportion of participants with Seroconversion (titre 10 [1/dilution] and post-vaccination titre ? 40 [1/dilution], or titre ? 10 [1/dilution] and a ? 4-fold increase in titre [1/dilution]	day 0 and day 28
Neutralising antibody titres, Anti-N1 and -N2 titres, Detectable ELLA (ELLA Ab titre? 10 [1/dilution]), Proportions of influenza-specific IgG subclasses, Proportions of influenza-specific peripheral blood T cells, Proportions of peripheral blood B cells with effector or regulatory phenotypes	Day 0 and Day 28
Proportions influenza-specific IgG Fc expressing individual glycans, Level of binding (mean fluorescence intensity) of Fc receptors and complement by influenza-specific antibodies, Cell activation (proportion of cells expressing markers of activation and phagocytic score) by influenza specific antibodies	Day 0 and Day 28
Level of cytokines (pg/ml) and mRNA (arbitrary units) induced by microbial products in peripheral blood, Number (n per microliter) and proportions of immune cell subsets in peripheral blood, Level of expression of mRNA, metabolites and proteins (arbitrary units) in peripheral blood	Day 0 and Day 28

Target Sample Size

Total Sample Size=100 Sample Size from India=100

Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials

Phase of Trial
Date of First
Enrollment (India)
Date of First
Enrollment (Global)

Phase 4 01/12/2020

Estimated Duration of Trial

No Date Specified

Recruitment Status of Trial (Global)

Years=1 Months=0 Days=0

Not Applicable

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CLINICAL TRIALS REGISTRY - INDIA
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# PDF of Trial CTRI Website URL - http://ctri.nic.in

Recruitment Status of Trial (India) Publication Details Brief Summary

Not Yet Recruiting
Nil
Prozebi
NAME TO USE IT OFFICE AS TO A PROPERTY OF THE ADMINISTRATE OF THE
The chairbut

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# 3.6 INCENTIVE QIV-2 (P18 GSMC&KEM, India)

CLINICAL TRIALS REGISTRY - INDIA ICMR - National Institute of Medical Statistics



**PDF** of Trial CTRI Website URL - http://ctri.nic.in

#### Clinical Trial Details (PDF Generation Date :- Thu, 07 Oct 2021 09:08:14 GMT)

CTRI Number	CTRI/2021/10/037159 [Registered on: 07/10/2021] - Trial Registered Prospectively
Last Modified On	04/10/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Single Arm Trial
	Immunity against Influenza virus disease and safety of FluQuadri (marketed vaccine with protection against 4 types of influenza virus) in children of age between 3 and 8 years
	Immunogenicity, molecular profiling and safety of a marketed Quadrivalent Influenza Vaccine (FluQuadri TM ) administered by the intramuscular route in children 3-8 years old

Secondary IDs if Any

Secondary ID ldentifier NIL

**Details of Principal** Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator				
Name Dr Nithya Gogtay				
Designation	n Professor & Head			
Affiliation	Seth GSMC & KEM Hospital			
Address	Room No. 201 1st floor New Building Seth GS Medical College & KEM Hospital Parel 1st Floor, New Building Mumbai MAHARASHTRA 400012 India			
Phone	9820495836			
Fax				
Email	njgogtay@hotmail.com			

**Details Contact** Person (Scientific Query)

Details Contact Person (Scientific Query)			
Name	Dr Jeffrey Pradeep Raj		
Designation	esignation Senior Resident		
Affiliation	Seth GS Medical College & KEM Hospital		
Address	Room No. 201 1st floor New Building Seth GS Medical College & KEM Hospital Parel Mumbai MAHARASHTRA 400012 India		
Phone	7904286189		
Fax			
Email	jpraj.m07@gmail.com		

**Details Contact** Person (Public Query)

Details Contact Person (Public Query)				
Name Dr Jeffrey Pradeep Raj				
Designation	esignation Senior Resident			
Affiliation	Seth GS Medical College & KEM Hospital			
Address	Room No. 201 1st floor New Building Seth GS Medical College & KEM Hospital Parel  MAHARASHTRA  400012 India			

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CLINICAL TRIALS REGISTRY - INDIA





#### PDF of Trial

CTRI Website URL - http://ctri.nic.in

	Phone	Į-	7904	1286189			1	
	Fax			1200100				
	Email							
Source of Monetary or	Source of Monetary or Material Support							
Material Support	> Department of Biotechnology, R. No. 706, Block-2, CGO Complex Lodhi Road, New Delhi-110 003							
Primary Sponsor				Primary Spo	nsor Details			
	Name Seth GS Medical College KEM Hospital Address Acharye Donde Marg Parel Mumbai - 400012							
					2			
	Type of Sponsor Government medical college							
Details of Secondary	Name				Address			
Sponsor	NIL				NIL			
Countries of	List of Countries							
Recruitment	India							
Sites of Study	Name of Principal Investigator	Name of Site		Site	Site Address		Phone/Fax/Email	
	Dr Nithya Gogtay			Medical	Department of Clinical		9820495836	
		College &KEM Hospital		KEM Hospital	Pharmacology Room No: 201 1st floor New building Seth GS Medical College and KEM hospital Parel Mumbai MAHARASHTRA		njgogtay@hotmail.com	
Details of Ethics Committee	Name of Committee	hics Approved f Seth GS		l Status	Date of Approval		Is Independent Ethics	
	Institutional Ethics Committee I of Seth GS Medical College & KEM Hospital				27/09/2021		No	
Regulatory Clearance	Status			Date				
Status from DCGI	Not Applicable No Date Specified							
Health Condition /	Health Type				Condition			
Problems Studied	Healthy Human Volunteers				Healthy as determined by laboratory tests and medical history			
Intervention /	Туре		Name			Details		
Comparator Agent Intervention			Fluquadri Vaccir influenza vaccin		influenza vaccine		n of quadrivalent a vaccine (Fluquadri) mately one month apart	
	Comparator Agent			Nil It is a		It is a si	ngle arm study	
Inclusion Criteria				Inclusion	n Criteria			
	Age From 3			3.00 Year(s)				
	Age To 8.00 Year(s)							
	Gender Both							
	Details  1. Healthy children or children with well controlled pre-existing medical conditions (as concluded from the medical history, physi examination and clinical judgement) age range ?3 and ?9 years on the day of the study br/> 2. Written, informed consent from				nedical history, physical ge ?3 and ?9 years old			
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CLINICAL TRIALS REGISTRY - INDIA





#### **PDF of Trial** CTRI Website URL - http://ctri.nic.in

parents/guardians.<br/>
3. Oral assent for 7-8 years of aged children. <br/>br/> 4. Parents/Guardians able to understand and comply

**Exclusion Criteria** 

Method of Generating Random Sequence Method of Concealment Blinding/Masking **Primary Outcome** 

with the study protocol requirements, including availability for all scheduled visits of the study.<br/>

Details Not Applicable

Not Applicable

Not Applicable

Outcome Timepoints Haemagglutinin Antibody Inhibition (HAI) Day 0 and Day 58 antibody titres on D0 and D58; Proportion of participants with HAI titres ? 40 (1/dilution) at D58; HAI antibody titres fold increase between D0 and D58; Proportion of participants with Seroconversion (titre 10 [1/dilution] at D0 and post-vaccination titre ? 40 [1/dilution] at D58, or titre ? 10 [1/dilution] at D0 and a ? 4-fold increase in titre [1/dilution] at D58; Proportion of high and low responders (HAI titres 40 (1/dilution) at D58)

**Exclusion Criteria** 

#### Secondary Outcome

Outcome	Timepoints
Number of AEs and SAEs reported until D58	Days 0, 3, 7, 28 and 58 or any time during the study period
Neutralizing Ab titres will be measured for each vaccine strain with the microneutralization (MN) assay.	Days 0, 30 and 58
b. Anti-Haemagglutinin (HA) and Neuraminidase (NA) antibody titres to vaccine strain and antibody avidity.	Days 0 and 58
Level (mean fluorescence intensity) and avidity (avidity index) of influenza-specific antibody isotypes. Level of influenza-specific antibody isotypes triggering Fc-dependent effector functions (proportion of activated cells, phagocytic score or mean fluorescence intensity)	Days 0 and 58
Proportions of influenza-specific peripheral blood T cells with effector or regulatory phenotypes; Proportions of peripheral blood B cells with effector or regulatory phenotypes; Proportion's influenza-specific IgG Fc expressing individual glycans; Level of binding (mean fluorescence intensity) of Fc receptors and complement by influenza-specific antibodies.	Days 0 and 58
Level of cytokines (pg/ml) and mRNA (arbitrary units) induced by microbial products in an ex vivo whole blood assay; Number (n per microliter) and proportions of immune cell subsets in peripheral blood	Day 0 only
k. Level of expression of peripheral blood cell mRNA, plasma metabolites and plasma proteins (arbitrary units)	Days 0 and 3

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CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics



PDF of Trial CTRI Website URL - http://ctri.nic.in

**Target Sample Size** 

Total Sample Size=100

Sample Size from India=100

Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials

Phase of Trial Date of First Enrollment (India)

Phase 4 01/11/2021

Date of First Enrollment (Global) No Date Specified

**Estimated Duration of** Trial

Years=1 Months=0

Recruitment Status of Trial (Global)

Days=0

Recruitment Status of Trial (India)

Not Applicable

**Publication Details** 

**Brief Summary** 

Not Yet Recruiting

Will be published in a peer reviewed journal of national/international importance

The current study will be an open label study, with the quadrivalent vaccine FluQuadri™ marketed by Sanofi Pasteur. In this study, healthy young children aged 3-8 years old will be enrolled, 50 in Norway and 100 in India. The current recommendations of the Indian Academy of Pediatrics recommend influenza vaccination in all children over the age of 6 months annually and the vaccination of the children in this study is in line with the current Indian guidelines.

In this study, the influenza vaccine will be administered as a two dose regimen on Days 0 [0.25 ml] and 30 [0.25 ml] with a post-vaccination observation period of 30 minutes. Subsequently, the children will come for follow up on Days 3 or , Day 30 for the second dose and the last follow up will be on Day 58. Titres of influenza specific antibodies will be measured [conventional serology]. Along with this specific tests will be performed - system serology, T and B cell responses and omics - transcriptome analysis, metabolomics, proteomics on the blood samples collected. The bulk of the work will be done at the THSTI, Faridabad. As stated earlier, the identification of common or unique determinants of vaccine responses with omics, serology and T and B cell responses will provide the essential guidance to the development of universal influenza vaccine protecting diverse populations.

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# 3.7 INCENTIVE QIV-3 (P18 GSMC&KEM, India)

CLINICAL TRIALS REGISTRY - INDIA ICMR - National Institute of Medical Statistics





PDF of Trial
CTRI Website URL - http://ctri.nic.in

#### Clinical Trial Details (PDF Generation Date :- Thu, 07 Oct 2021 09:15:44 GMT)

CTRI Number	CTRI/2021/10/037161 [Registered on: 07/10/2021] - Trial Registered Prospectively					
Last Modified On	04/10/2021					
Post Graduate Thesis	No					
Type of Trial	Interventional					
Type of Study	Vaccine					
Study Design	Single Arm Trial					
Public Title of Study	Immunity against Influenza virus disease and safety of FluQuadri (marketed vaccine with protection against 4 types of influenza virus) in children of age between 6 and 12 months					
Scientific Title of Study	Immunogenicity, molecular profiling and safety of a marketed Quadrivalent Influenza Vaccine (FluQuadriTM) administered by the intramuscular route in infants aged 6- 12 months					
Secondary IDs if Any	Secondary ID Identifier					
	NIL	NIL				
Details of Principal		Details of Principal Investigator				
Investigator or overall	Name	Dr Nithya Gogtay				
Trial Coordinator (multi-center study)	Designation	Professor & Head				
(main-contor diady)	Affiliation	Seth GS Medical College and KEM Hospital				
	Address	Room No 201 Dept. of Clinical Pharmacology 1st floor New Building Seth GS Medical College and KEM Hospital Parel Mumbai MAHARASHTRA 400012 India				
	Phone	9820495836				
	Fax					
	Email	njgogtay@hotmail.com				
Details Contact	Details Contact Person (Scientific Query)					
Person (Scientific	Name	Dr Jeffrey Pradeep Raj				
Query)	Designation	Senior Resident				
	Affiliation	Seth GS Medical College and KEM Hospital				
	Address	Room No 201 Dept. of Clinical Pharmacology 1st floor New Building Seth GS Medical College and KEM Hospital Parel Mumbai MAHARASHTRA 400012 India				
	Phone	7904286189				
	Fax					
	Email	jpraj.m07@gmail.com				
Details Contact	Details Contact Person (Public Query)					
Person (Public Query)	Name	Dr Jeffrey Pradeep Raj				
	Designation	Senior Resident				
	Affiliation	Seth GS Medical College and KEM Hospital				
	Address	Room No 201 Dept. of Clinical Pharmacology 1st floor New Building Seth GS Medical College and KEM Hospital Parel				
		MAHARASHTRA 400012 India				

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CLINICAL TRIALS REGISTRY - INDIA





# PDF of Trial CTRI Website URL - http://ctri.nic.in

	I - • massered	r_				,	
	Phone	7	904286189				
	Fax		: 0.7.6 :!!				
EN 62.52 N	Email	P.	jpraj.m07@gmail.com				
Source of Monetary or Material Support			urce of Monetary		•		
material Support	> Department of Biotechnology, R. No. 706, Block-2, CGO Complex Lodhi Road, New Delhi-110 003				Road, New Delhi-110		
Primary Sponsor			Primary Spo	nsor Details			
	Name Seth GS Medical College and KEM Hospital						
	Address Acharya Donde Marg Parel Mumbai 400012						
	Type of Sponsor Government medical college						
Details of Secondary	Name Address						
Sponsor	NIL			NIL			
Countries of	List of Countries						
Recruitment	India						
Sites of Study	Name of Principal	Name	of Site	Site Address		Phone/Fax/Email	
•	Investigator			7 Hugi 030			
	Dr Nithya Gogtay		SS Medical	Department of Clinical Pharmacology Room No: 201 1st floor New building Seth GS Medical College and KEM hospital Parel		9820495836	
		Colleg	e & KEM Hospital			nigogtov@hotmail.com	
						njgogtay@hotmail.com	
				Mumbai MAHARASHTRA			
Details of Ethics	Name of Committee	Approval Status		Date of Approval		Is Independent Ethics	
Committee	Traine of Committee	Approved SS		Date of Approval		Committee?	
	Institutional Ethics			27/09/2021		No	
	Committee I of Seth GS Medical College & KEM						
	Hospital						
Regulatory Clearance	Status			Date			
Status from DCGI	Not Applicable			No Date Specified			
Health Condition /	Health Type		Condition				
Problems Studied	Healthy Human Voluntee		Healthy infants of age between 6 and 12 months				
Intervention /	Туре		Name Details				
Comparator Agent	Comparator Agent		Nil		It is a single arm study		
	Intervention		Fluquadri Vacci	ne (Quadrivalent		Two doses of Intramuscular	
						n of quadrivalent	
						za vaccine (Fluquadri) imately one month apart	
					(28 - 32)		
Inclusion Criteria	Inclusion Criteria						
	Age From 6.00 Month(s)						
	Age To 12.00 Month(s)						
	Gender	Both					
	Details	1. Healthy children or children with well controlled pre-existing					
			medical conditions (as concluded from the medical history, physical examination and clinical judgement) age range 6 months – 12 months the day of the study by/s> 2. Written, informed consent from				
		1850					
			parents/guardians. 3. Parents/Guardians able to understand				
	l	Į.					

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CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics



#### **PDF** of Trial

CTRI Website URL - http://ctri.nic.in

			e study protocol requirements, including		
Exclusion Criteria	availability for all scheduled visits of the study.  Exclusion Criteria				
EACIDSION CITIENTS	Details	Exclusion Criteria  1. Acute illness, at the time of study vaccine administration (once acute illness is resolved, if appropriate, as per investigator assessment, participant will be re-revaluated for eligibility).  2. Recorded fever (for eligibility purpose defined as a body temperature greater than 37.5°C) within 3 days prior to study vaccine administration (once fever/acute illness is resolved, if appropriate, as per investigator assessment, participant will be re-evaluated for eligibility.  3. Current or previous, laboratory confirmed case of influenza during the past 6 months, based on anamnesis or medical records (if available) at screening visit.  4. Administration of any vaccine within 28 days prior to enrolment in the study (except for influenza vaccine which should be >6 months prior to enrollment in the study) or planned administration of any vaccine during study participation  5. Use of any investigational or non-registered drug or vaccine within 30 days prior to the administration of study vaccines or planned during the study  6. 16. Any other condition that in the opinion of the investigator would jeopardize the safety or rights of the volunteer participating in the study or make it unlikely that the participant could complete the protocol			
Method of Generating Random Sequence	Not Applicable				
Method of Concealment	Not Applicable				
Blinding/Masking	Not Applicable				
Primary Outcome	Outcome	í	Timepoints		
	Haemagglutinin Antibody Inhibition (HAI) antibody titres on D0 and D58; Proportion of participants with HAI titres? 40 (1/dilution) at D58; HAI antibody titres fold increase between D0 and D58; Proportion of participants with Seroconversion (titre 10 [1/dilution] at D0 and post-vaccination titre? 40 [1/dilution] at D58, or titre? 10 [1/dilution] at D0 and a? 4-fold increase in titre [1/dilution] at D58; Proportion of high and low responders (HAI titres 40 (1/dilution) at D58)		Baseline and Day 58		
Secondary Outcome	Outcome		Timepoints		
	Number of AEs and SAEs rep	ported until D58	Days 0, 3, 7, 28 and 58 or any time during the study period		
	Neutralizing Ab titres will be measured for each vaccine strain with the microneutralization (MN) assay  Anti-Haemagglutinin (HA) and Neuraminidase (NA) antibody titres to vaccine strain and antibody avidity.  Level (mean fluorescence intensity) and avidity (avidity index) of influenza-specific antibody isotypes. Level of influenza-specific antibody isotypes triggering Fc-dependent effector functions (proportion of activated cells, phagocytic score or mean fluorescence intensity)		Days 0, 30 and 58  Day 0 and Day 58		
			Day 0 and Day 58		

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CLINICAL TRIALS REGISTRY - INDIA



#### **PDF of Trial** CTRI Website URL - http://ctri.nic.in

Proportions of influenza-specific peripheral blood T cells with effector or regulatory phenotypes; Proportions of peripheral blood B cells with effector or regulatory phenotypes; Proportion's influenza-specific IgG Fc expressing individual glycans; Level of binding (mean fluorescence intensity) of Fc receptors and complement by influenza-specific antibodies.	Day 0 and Day 58
Level of cytokines (pg/ml) and mRNA (arbitrary units) induced by microbial products in an ex vivo whole blood assay; Number (n per microliter) and proportions of immune cell subsets in peripheral blood	Day 0 only
Level of expression of peripheral blood cell mRNA, plasma metabolites and plasma proteins (arbitrary units)	Day 0 and Day 3

Target Sample Size

Total Sample Size=100

Sample Size from India=100

Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials

Phase of Trial Date of First Enrollment (India)

Date of First Enrollment (Global)

**Estimated Duration of** 

Recruitment Status of Trial (Global) Recruitment Status of

Trial (India) **Publication Details** 

**Brief Summary** 

Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials

Phase 4 01/11/2021

No Date Specified

Years=1 Months=0 Days=0

Not Applicable

Not Yet Recruiting

Results will be published in a peer reviewed journal of national/ international importance

In this study, the influenza vaccine will be administered as a two dose regimen on Days 0 [0.25 ml] and 30 [0.25 ml] with a postvaccination observation period of 30 minutes. Subsequently, the infants will come for follow up on Days 3 or Day 7, Day 30 for the second dose and the last follow up will be on Day 58. Titres of influenza specific antibodies will be measured [conventional serology]. Along with this specific tests will be performed - system serology, T and B cell responses and omics transcriptome analysis, metabolomics, proteomics on the blood samples collected. The bulk of the work will be done at the THSTI, Faridabad. As stated earlier, the identification of common or unique determinants of vaccine responses with omics, serology and T and B cell responses will provide the essential guidance to the development of universal influenza vaccine protecting diverse populations.

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