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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

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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 01st August 2020[1] 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.[2] 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.

[1] The Indian grant start date is 29th December 2020

[2] Please refer to Annex section 3.1 for list of all INCENTIVE project partners.

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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)

INCENTIVE-QIV-1-EU: 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.

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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™) 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™) 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

INCENTIVE has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 874866 and the Dept. of Biotechnology, Govt. of India (project no.BT/IN/EU-INF/16/AP/19-20/11746)

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

INCENTIVE-QIV-3: 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^{TM}) 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.

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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

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

EU Clinical Trials Register

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Clinical trials

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn more about the EU Clinical Trials Register including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays **41031** clinical trials with a EudraCT protocol, of which **6716** are clinical trials conducted with subjects less than 18 years old.
The register also displays information on **18700** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

Phase 1 trials conducted solely in adults and that are not part of an agreed PIP are not public in the EU CTR (refer to European Guidance 2008/C 168/02 Art. 3 par. 2 and Commission Guideline 2012/C 302/03, Art. 5) .

Please enter search term... X Search

Examples: Cancer AND drug name. Pneumonia AND sponsor name.
How to search [pdf]

Advanced Search: Search tools

< Back to search results

Summary	
EudraCT Number:	2021-003307-18
Sponsor's Protocol Code Number:	INCENTIVE-QIV-1-EU
National Competent Authority:	Belgium - FPS Health-DGM
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2021-06-21
Trial results	

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P. END OF TRIAL

A. Protocol Information		
A.1	Member State Concerned	Belgium - FPS Health-DGM
A.2	EudraCT number	2021-003307-18
A.3	Full title of the trial	Immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra®) administered by the intramuscular route in participants 60 years of age and older
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language	Immunity to influenza virus disease and safety of Vaxigrip Tetra® (commercial vaccine with protection against 4 types of influenza virus) in participants 60 years and older
A.4.1	Sponsor's protocol code number	INCENTIVE-QIV-1-EU
A.7	Trial is part of a Paediatric Investigation Plan	No
A.8	EMA Decision number of Paediatric Investigation Plan	

B. Sponsor Information		
B.Sponsor: 1		
B.1.1	Name of Sponsor	University of Antwerp
B.1.3.4	Country	Belgium
B.3.1 and B.3.2	Status of the sponsor	Non-Commercial
B.4 Source(s) of Monetary or Material Support for the clinical trial:		
B.4.1	Name of organisation providing support	EU_Horizon 2020
B.4.2	Country	Belgium
B.5 Contact point designated by the sponsor for further information on the trial		
B.5.1	Name of organisation	University of Antwerp
B.5.2	Functional name of contact point	Ilse De Coster
B.5.3	Address:	
B.5.3.1	Street Address	Universiteitsplein 1, Campus Drie Eiken, Building S
B.5.3.2	Town/ city	Wilrijk
B.5.3.3	Post code	2610
B.5.3.4	Country	Belgium

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B. Sponsor Information		
B.5.4	Telephone number	+3232652676
B.5.5	Fax number	+3232652404
B.5.6	E-mail	lise.decoster@uantwerpen.be

D. IMP Identification		
D.IMP: 1		
D.1.2 and D.1.3	IMP Role	Test
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	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	
D.3 Description 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
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/SWL1536/2019 (H1N1)
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	µg/ml 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/Hongkong/2671/2019 (H3N2)
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	µg/ml 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	
D.3.10.1	Concentration unit	µg/ml 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/Phuket/3073/2013, wild type
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	µg/ml microgram(s)/millilitre
D.3.10.2	Concentration type	not less then
D.3.10.3	Concentration number	30
D.3.11 The IMP contains an:		
D.3.11.1	Active substance of chemical origin	No
D.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
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 therapies (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

E. General Information on the Trial
E.1 Medical condition or disease under investigation

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E. General Information on the Trial		
E.1.1	Medical condition(s) being investigated	Influenza
E.1.1.1	Medical condition in easily understood language	flu
E.1.1.2	Therapeutic area	Diseases [C] - Virus Diseases [C02]
MedDRA Classification		
E.1.3	Condition being studied is a rare disease	No
E.2 Objective of the trial		
E.2.1	Main objective of the trial	To measure the level of immune response [HAI-haemagglutinin Antibody Inhibition titres] of a single intramuscular dose of the quadrivalent inactivated influenza vaccine (Vaxigrip Tetra®) in healthy participants aged 60 years and above
E.2.2	Secondary objectives of the trial	Not applicable
E.2.3	Trial contains a sub-study	No
E.3	Principal inclusion criteria	Eligible participants must meet all of the below criteria at the time of enrolment: 1. Male or female of non-child bearing potential 60 years and above at the time of study 2. Provide written informed consent. 3. The participant is willing to comply with study protocol requirements, including availability for all scheduled visits of the study. 4. Subjects are healthy or with well-controlled pre-existing medical conditions by the opinion of the investigator
E.4	Principal exclusion criteria	Participants meeting any of the below criteria at the time of enrolment will be ineligible to participate in the trial: 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-evaluated 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. Not willing to refrain from physical exercise during 48 hours prior to vaccination 4. History of any influenza vaccine administration during the past 6 months and during study participation. 5. Current or previous, laboratory confirmed case of influenza during the past 6 months, based on anamnesis or medical file (if available) at screening visit 6. Household contact with and/or intimate exposure to an individual with any laboratory confirmed influenza infection during the past 6 months prior to vaccination. 7. History of severe allergic reactions after previous vaccinations or hypersensitivity to any study vaccine component 8. Previous history of Guillain Barre Syndrome. 9. Any confirmed or suspected condition with impaired/altered function of immune system (e.g. immunodeficient or autoimmune conditions). 10. Having tested positive for Human Immuno-deficiency Virus (HIV), Hepatitis B or Hepatitis C on the blood tests of the screening visit 11. Having any bleeding disorder which is considered as a contraindication to intramuscular injection or blood draw according to the opinion of the investigator 12. 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 prednisone, or equivalent, ≥ 0.5 mg/kg per day. Inhaled, intranasal and topical steroids are allowed. 13. Neoplastic disease or any hematologic malignancy (except localized skin 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 years). 14. Administration 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.; 15. 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) or planned administration of any vaccine during study participation. 16. 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. 17. Having received systemic antibiotic treatment within 3 days prior to enrolment. 18. Acute or chronic, clinically significant pulmonary, cardiovascular, 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 participating in the study or make it unlikely that the participant could complete the protocol.
E.5 End points		
E.5.1	Primary end point(s)	• HAI antibody titres on D0 and D28 • Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 • HAI antibody titres fold increase between D0 and D28 • Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28, or titre ≥ 10 [1/dilution] at D0 and a ≥ 4-fold increase in titre [1/dilution] at D28 • Proportion of high and low responders (HAI titres <40 (1/dilution) at D28)
E.5.1.1	Timepoint(s) of evaluation of this end point	• HAI antibody titres on D0 and D28 • Proportion of participants with HAI titres ≥ 40 (1/dilution) at D28 • HAI antibody titres fold increase between D0 and D28 • Proportion of participants with Seroconversion (titre < 10 [1/dilution] at D0 and post-vaccination titre ≥ 40 [1/dilution] at D28, or titre ≥ 10 [1/dilution] at D0 and a ≥ 4-fold increase in titre [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 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	Pharmacodynamic	No
E.6.8	Bioequivalence	No
E.6.9	Dose response	Yes
E.6.10	Pharmacogenetic	No

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E. General Information on the Trial		
E.6.11	Pharmacogenomic	No
E.6.12	Pharmacoeconomic	No
E.6.13	Others	Yes
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
E.7.1.2	Bioequivalence study	No
E.7.1.3	Other	No
E.7.1.3.1	Other trial type description	
E.7.2	Therapeutic exploratory (Phase II)	No
E.7.3	Therapeutic confirmatory (Phase III)	No
E.7.4	Therapeutic use (Phase IV)	Yes
E.8 Design of the trial		
E.8.1	Controlled	No
E.8.1.1	Randomised	No
E.8.1.2	Open	Yes
E.8.1.3	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	
E.8.2.1	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 concerned	Yes
E.8.4	The trial involves multiple sites in the Member State concerned	No
E.8.5	The trial involves multiple Member States	No
E.8.6 Trial involving sites outside the EEA		
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	No
E.8.8	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
E.8.9 Initial estimate of the duration of the trial		
E.8.9.1	In the Member State concerned years	0
E.8.9.1	In the Member State concerned months	3
E.8.9.1	In the Member State concerned days	

F. Population of Trial Subjects		
F.1 Age Range		
F.1.1	Trial has subjects under 18	No
F.1.1.1	In Utero	No
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	No
F.1.1.3	Newborns (0-27 days)	No
F.1.1.4	Infants and toddlers (28 days-23 months)	No
F.1.1.5	Children (2-11years)	No
F.1.1.6	Adolescents (12-17 years)	No
F.1.2	Adults (18-64 years)	Yes
F.1.2.1	Number of subjects for this age range:	25
F.1.3	Elderly (>=65 years)	Yes
F.1.3.1	Number of subjects for this age range:	25
F.2 Gender		
F.2.1	Female	Yes
F.2.2	Male	Yes
F.3 Group of trial subjects		
F.3.1	Healthy volunteers	Yes
F.3.2	Patients	No
F.3.3	Specific vulnerable populations	No
F.3.3.1	Women of childbearing potential not using contraception	No
F.3.3.2	Women of child-bearing potential using contraception	No
F.3.3.3	Pregnant women	No
F.3.3.4	Nursing women	No
F.3.3.5	Emergency situation	No
F.3.3.6	Subjects incapable of giving consent personally	No
F.3.3.7	Others	No
F.4 Planned number of subjects to be included		
F.4.1	In the member state	50
F.4.2	For a multinational trial	
F.4.2.2	In the whole clinical trial	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)	None

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

P. End of Trial		
P.	End of Trial Status	Ongoing

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INCENTIVE

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

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Clinical trials

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Phase 1 trials conducted solely in adults and that are not part of an agreed PIP are not public in the EU CTR (refer to European Guidance 2008/C 168/02 Art. 3 par. 2 and Commission Guideline 2012/C 302/03, Art. 5) .

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Summary	
EudraCT Number:	2021-003804-42
Sponsor's Protocol Code Number:	INCENTIVE-QIV2-EU
National Competent Authority:	Norway - NOMA
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2021-08-05
Trial results	

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P. END OF TRIAL

A. Protocol Information		
A.1	Member State Concerned	Norway - NOMA
A.2	EudraCT number	2021-003804-42
A.3	Full title of the trial	Immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra) administered by the intramuscular route in children 3-8 years old
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language	Immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra) administered by the intramuscular route in children 3-8 years old
A.4.1	Sponsor's protocol code number	INCENTIVE-QIV2-EU
A.7	Trial is part of a Paediatric Investigation Plan	No
A.8	EMA Decision number of Paediatric Investigation Plan	

B. Sponsor Information		
B.Sponsor: 1		
B.1.1	Name of Sponsor	Helse Bergen HF
B.1.3.4	Country	Norway
B.3.1 and B.3.2	Status of the sponsor	Non-Commercial
B.4 Source(s) of Monetary or Material Support for the clinical trial:		
B.4.1	Name of organisation providing support	EU (H2020)
B.4.2	Country	Norway
B.5 Contact point designated by the sponsor for further information on the trial		
B.5.1	Name of organisation	Helse Bergen HF
B.5.2	Functional name of contact point	Rebecca Jane Cox
B.5.3	Address:	
B.5.3.1	Street Address	Jonas Lies vei 65
B.5.3.2	Town/ city	Bergen
B.5.3.4	Country	Norway
B.5.6	E-mail	rebecca.cox@uib.no

INCENTIVE has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 874866 and the Dept. of Biotechnology, Govt. of India (project no.BT/IN/EU-INF/16/AP/19-20/11746)

D. IMP Identification		
D.IMP: 1		
D.1.2 and D.1.3	IMP Role	Test
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 Description 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 therapies (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

E. General Information on the Trial		
E.1 Medical condition or disease under investigation		
E.1.1	Medical condition(s) being investigated	Immune response to infuenza vaccine in young children
E.1.1.1	Medical condition in easily understood language	Immune response to infuenza vaccine in young children
E.1.1.2	Therapeutic area	Body processes [G] - Immune system processes [G12]
MedDRA Classification		
E.1.3	Condition being studied is a rare disease	No
E.2 Objective of the trial		
E.2.1	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.
E.2.2	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
E.2.3	Trial contains a sub-study	No
E.3	Principal inclusion criteria	1) 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. 2) Signed informed consent from parents/guardians. 3) Parents/guardians able to understand and comply with the study protocol requirements, including availability for all scheduled visits of the study.

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E. General Information on the Trial		
E.4	Principal exclusion criteria	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 prior to study vaccine 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). 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 prednisone, or equivalent, ≥ 0.5 mg/kg per day. Inhaled, intranasal and topical steroids are allowed. 10) Neoplastic disease or any hematologic malignancy (except localized skin 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 years). 11) Administration 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. 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, metabolic, neurological, hepatic, or renal functional abnormality, as determined by medical history or physical examination if uncontrolled or without appropriate 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 participant 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 eligibility). 3) 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, participants will be re-evaluated for eligibility by the investigator). 4) History of severe allergic reactions after previous vaccinations or hypersensitivity to any study vaccine components (ovalbumin, egg proteins), neomycin, formaldehyde or octoxynol-9.
E.5 End points		
E.5.1	Primary end point(s)	• HAI antibody titres on D0 and D58 • Proportion of participants with HAI titres ≥ 40 at D58 • HAI antibody titres fold increase between D0 and D58 Proportion of participants with Seroconversion (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
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. • Individual MN antibody titre on D0, D30 and D58 • Detectable MN (MN antibody titre ≥ 10 at D0, D30, D58 • Proportion of participants with MN antibody titres ≥ 20, ≥ 40, ≥ 80) at D30, D58 • Individual MN antibody titre fold-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) antibody titres to vaccine strain and antibody avidity. • Individual HA and NA antibody titres on D0, D30 and D58 • Detectable HA and NA antibody titre ≥ 10 at D0, D30 and D58 • Proportion of participants with HA and NA antibody titres ≥ 20, ≥ 40, ≥ 80 at D30 and D58 • Individual HA and NA antibody titre ratio (D58/ D0) (D30/ D0) • Fold-increase in HA and NA antibody titre [post/pre] ≥ 2 and ≥ 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 isotypes 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 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 B cells with effector or regulatory phenotypes at D0, D30 and D58 g. Proportions influenza-specific IgG 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/ml) and mRNA (arbitrary units) induced by microbial products in an ex vivo whole blood assay at D0. 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	Day 30, Day 58 post vaccination
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	No
E.6.6	Pharmacokinetic	No
E.6.7	Pharmacodynamic	No
E.6.8	Bioequivalence	No

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E. General Information on the Trial		
E.6.9	Dose response	No
E.6.10	Pharmacogenetic	No
E.6.11	Pharmacogenomic	No
E.6.12	Pharmacoeconomic	No
E.6.13	Others	No
E.7	Trial type and phase	
E.7.1	Human pharmacology (Phase I)	No
E.7.1.1	First administration to humans	No
E.7.1.2	Bioequivalence study	No
E.7.1.3	Other	No
E.7.1.3.1	Other trial type description	
E.7.2	Therapeutic exploratory (Phase II)	No
E.7.3	Therapeutic confirmatory (Phase III)	No
E.7.4	Therapeutic use (Phase IV)	Yes
E.8 Design of the trial		
E.8.1	Controlled	No
E.8.1.1	Randomised	No
E.8.1.2	Open	Yes
E.8.1.3	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	
E.8.2.1	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 concerned	Yes
E.8.4	The trial involves multiple sites in the Member State concerned	No
E.8.5	The trial involves multiple Member States	No
E.8.6 Trial involving sites outside the EEA		
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	No
E.8.8	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.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	
E.8.9.2	In all countries concerned by the trial years	2

F. Population of Trial Subjects		
F.1 Age Range		
F.1.1	Trial has subjects under 18	Yes
F.1.1	Number of subjects for this age range:	50
F.1.1.1	In Utero	No
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	No
F.1.1.3	Newborns (0-27 days)	No
F.1.1.4	Infants and toddlers (28 days-23 months)	No
F.1.1.5	Children (2-11years)	Yes
F.1.1.5.1	Number of subjects for this age range:	50
F.1.1.6	Adolescents (12-17 years)	No
F.1.2	Adults (18-64 years)	No
F.1.3	Elderly (>=65 years)	No
F.2 Gender		
F.2.1	Female	Yes
F.2.2	Male	Yes
F.3 Group of trial subjects		
F.3.1	Healthy volunteers	Yes
F.3.2	Patients	Yes
F.3.3	Specific vulnerable populations	No
F.3.3.1	Women of childbearing potential not using contraception	No
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F.3.3.3	Pregnant women	No
F.3.3.4	Nursing women	No
F.3.3.5	Emergency situation	No
F.3.3.6	Subjects incapable of giving consent personally	No
F.3.3.7	Others	No
F.4 Planned number of subjects to be included		
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)	None

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 Decision	Authorised
N.	Date of Competent Authority Decision	2021-10-01

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N. Review by the Competent Authority or Ethics Committee in the country concerned		
N.	Ethics Committee Opinion of the trial application	Favourable
N.	Ethics Committee Opinion: Reason(s) for unfavourable opinion	
N.	Date of Ethics Committee Opinion	2021-10-04

P. End of Trial		
P.	End of Trial Status	Ongoing

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INCENTIVE

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

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Clinical trials

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Examples: Cancer AND drug name. Pneumonia AND sponsor name.
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Summary	
EudraCT Number:	2021-003760-27
Sponsor's Protocol Code Number:	INCENTIVE-QIV-3-EU
National Competent Authority:	Belgium - FPS Health-DGM
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2021-07-30
Trial results	

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P. END OF TRIAL

A. Protocol Information		
A.1	Member State Concerned	Belgium - FPS Health-DGM
A.2	EudraCT number	2021-003760-27
A.3	Full title of the trial	INCENTIVE-QIV-3-EU: Immunogenicity, molecular profiling of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra®) administered by the intramuscular route in participants aged 6 to 7 months
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language	Study of the immune response to influenza vaccine in children aged 6 to 7 months. Etude de la réponse immunitaire au vaccin de la grippe chez des enfants de 6 à 7 mois.
A.3.2	Name or abbreviated title of the trial where available	INCENTIVE-QIV-3-EU
A.4.1	Sponsor's protocol code number	INCENTIVE-QIV-3-EU
A.7	Trial is part of a Paediatric Investigation Plan	No
A.8	EMA Decision number of Paediatric Investigation Plan	

B. Sponsor Information		
B.Sponsor: 1		
B.1.1	Name of Sponsor	Université Libre de Bruxelles
B.1.3.4	Country	Belgium
B.3.1 and B.3.2	Status of the sponsor	Non-Commercial
B.4 Source(s) of Monetary or Material Support for the clinical trial:		
B.4.1	Name of organisation providing support	European Union
B.4.2	Country	Belgium
B.5 Contact point designated by the sponsor for further information on the trial		
B.5.1	Name of organisation	CHU Saint Pierre
B.5.2	Functional name of contact point	Dr Tessa Goetghebuer
B.5.3	Address:	
B.5.3.1	Street Address	Rue Haute, 322

INCENTIVE has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 874866 and the Dept. of Biotechnology, Govt. of India (project no.BT/IN/EU-INF/16/AP/19-20/11746)

B. Sponsor Information		
B.5.3.2	Town/ city	Bruxelles
B.5.3.3	Post code	1000
B.5.3.4	Country	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 Identification		
D.IMP: 1		
D.1.2 and D.1.3	IMP Role	Test
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
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	
D.3 Description 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	
D.3.10.1	Concentration unit	µg/ml 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/Hongkong/2671/2019(H3N2)
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	µg/ml 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/Washington/02/2019, wild type
D.3.9.4	EV Substance Code	SUB12066MIG
D.3.10	Strength	
D.3.10.1	Concentration unit	µg/ml 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	
D.3.10.1	Concentration unit	µg/ml microgram(s)/millilitre
D.3.10.2	Concentration type	not less then
D.3.10.3	Concentration number	30
D.3.11 The IMP contains an:		
D.3.11.1	Active substance of chemical origin	No
D.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
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 therapies (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

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E. General Information on the Trial		
E.1 Medical condition or disease under investigation		
E.1.1	Medical condition(s) being investigated	Prophylaxis of Influenza (Northern Hemispher 2021-2022 season) in Children aged 6-7 months
E.1.1.1	Medical condition in easily understood language	Prophylaxis of Influenza (Northern Hemispher 2021-2022 season) in Children aged 6-7 months
E.1.1.2	Therapeutic area	Diseases [C] - Virus Diseases [C02]
MedDRA Classification		
E.1.3	Condition being studied is a rare disease	No
E.2 Objective of the trial		
E.2.1	Main objective of the trial	Immunogenicity - To measure the level of immune response [HAI-haemagglutinin 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
E.4	Principal 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-evaluated 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 file (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 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 vaccination or planned use throughout the study period. (For corticosteroids, this means prednisone, or equivalent, ≥ 0.5 mg/kg per day. Inhaled, intranasal and topical steroids are allowed. 11. Neoplastic disease or any hematologic malignancy (except localized skin 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 years). 12. Administration 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.; 13. Administration of any vaccine within 28 days prior to enrolment in the study or planned administration of any vaccine during study participation. 14. 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. 15. Having received systemic antibiotic treatment within 3 days prior to enrolment. 16. Acute or chronic, clinically significant pulmonary, cardiovascular, metabolic, neurological, hepatic, or renal functional abnormality, as determined by medical history or physical examination if uncontrolled or without appropriate treatment 17. 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.
E.5 End points		
E.5.1	Primary end point(s)	• 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)
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	Pharmacogenomic	No
E.6.12	Pharmacoeconomic	No
E.6.13	Others	Yes

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E. General 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
E.7.1.2	Bioequivalence study	No
E.7.1.3	Other	No
E.7.1.3.1	Other trial type description	
E.7.2	Therapeutic exploratory (Phase II)	No
E.7.3	Therapeutic confirmatory (Phase III)	No
E.7.4	Therapeutic use (Phase IV)	Yes
E.8 Design of the trial		
E.8.1	Controlled	No
E.8.1.1	Randomised	No
E.8.1.2	Open	Yes
E.8.1.3	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	
E.8.2.1	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 concerned	No
E.8.4	The trial involves multiple sites in the Member State concerned	Yes
E.8.4.1	Number of sites anticipated in Member State concerned	2
E.8.5	The trial involves multiple Member States	No
E.8.6 Trial involving sites outside the EEA		
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 end of the trial and justification where it is not the last visit of the last subject undergoing the trial	LSLV
E.8.9 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	6
E.8.9.1	In the Member State concerned days	

F. Population of Trial Subjects		
F.1 Age Range		
F.1.1	Trial has subjects under 18	Yes
F.1.1	Number of subjects for this age range:	50
F.1.1.1	In Utero	No
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	No
F.1.1.3	Newborns (0-27 days)	No
F.1.1.4	Infants and toddlers (28 days-23 months)	Yes
F.1.1.4.1	Number of subjects for this age range:	50
F.1.1.5	Children (2-11years)	No
F.1.1.6	Adolescents (12-17 years)	No
F.1.2	Adults (18-64 years)	No
F.1.3	Elderly (>=65 years)	No
F.2 Gender		
F.2.1	Female	Yes
F.2.2	Male	Yes
F.3 Group of trial subjects		
F.3.1	Healthy volunteers	Yes
F.3.2	Patients	No
F.3.3	Specific vulnerable populations	Yes
F.3.3.1	Women of childbearing potential not using contraception	No
F.3.3.2	Women of child-bearing potential using contraception	No
F.3.3.3	Pregnant women	No
F.3.3.4	Nursing women	No
F.3.3.5	Emergency situation	No
F.3.3.6	Subjects incapable of giving consent personally	Yes
F.3.3.6.1	Details of subjects incapable of giving consent	Consent will be given by parents
F.3.3.7	Others	No
F.4 Planned number of subjects to be included		
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. Review by the Competent Authority or Ethics Committee in the country concerned		
N.	Competent Authority Decision	Authorised

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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
N.	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 Trials Register Service Desk: https://servicedesk.ema.europa.eu

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA

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INCENTIVE

3.5 INCENTIVE QIV-1 (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, 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

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

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

Details Contact Person (Scientific Query)

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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	Phone	07904286189
	Fax	
	Email	jpraj.m07@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Department of Biotechnology (DBT), R. No. 706, Block-2, CGO Complex Lodhi Road, New Delhi-110 003

Primary Sponsor

Primary Sponsor Details	
Name	Seth GSMC and KEM Hospital
Address	Acharya Donde Marg, Parel, Mumbai-400012
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Nithya Gogtay	Department of Clinical Pharmacology, 1st floor New Building	Seth GS Medical College & KEM Hospital, Acharye Donde Marg, Parel Mumbai MAHARASHTRA	9820495836 njgogtay@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Insitutional Ethics Committee I	Approved	04/08/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy human volunteers of age 60 years and above

Intervention / Comparator Agent

Type	Name	Details
Intervention	FluQuadri arm	single dose of Intramuscular injection of quadrivalent influenza vaccine (Fluquadri) in the deltoid muscle (arm)
Comparator Agent	Not applicable	Not applicable - its a single arm study

Inclusion Criteria

Inclusion Criteria	
Age From	60.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Male or female of no child bearing potential 60 years and above at the time of study vaccine administration. 2. Provide written informed consent. 3. The participant is willing to comply with study protocol requirements, including availability for all scheduled visits of the study. 4. Healthy, as determined by medical history and clinical assessment of the investigator.

Exclusion Criteria

Exclusion Criteria	
Details	

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Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Haemagglutinin Antibody Inhibition (HAI) antibody titres	Day 28

Secondary Outcome

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	Phase 4
Date of First Enrollment (India)	01/12/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable

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Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Nil
Brief Summary	Preamble In June 2019, the European Union [EU] along with the Department of Biotechnology [DBT], Govt of India put out a call for proposals called HORIZON 2020. This was a joint call for the development of better and novel vaccine for influenza [flu] vaccines. We were approached by the National Institute of Immunology [NII] to collaborate on this project where they would develop the novel vaccine. This novel vaccine would be developed using something called the Computationally Optimized, broadly reactive antigen [COBRA] technology which exists in Europe. Eventually, the vaccine developed using the COBRA technique would need to be with an existing flu vaccine and the immune profiling seen with the existing flu vaccine. Since the existing flu vaccines are given once a year, their immune profiling would be different from the COBRA vaccine where the immune profiling is likely to show more long-term immune protection. This project has been sanctioned both by EU and DBT and is called INCENTIVE. We will be seeking HMSC approval AFTER IEC approval for this study. The actual study: The present study is the first study in the INCENTIVE and is planned as a Phase IV study. It will test in an open label study a marketed quadrivalent vaccine called FluQuadri™. This is marketed by Sanofi. The study will be done in n = 100 elderly participants aged more than 60 years who are otherwise healthy. Well controlled hypertensives and diabetics will be included. This is a group where the complications of flu [both morbidity and mortality] are maximally relevant and therefore the vaccine recommended particularly in developed countries as part of their national program. There is no similar recommendation in India. This is also the group where an adequate immune response may or may not be mounted. A similar study will also be done in Belgium. The vaccine will be given on Day 0. They will be discharged on the same day after approximately an hour after the injection. Subsequently, they will be asked to follow up on Days 3, 7 and 28. Geometric mean titres of the antibodies will be estimated before and after vaccination. Similarly, the immune profiling will include use of peripheral blood mononuclear cells [PBMC] for a transcriptome analysis. The results of the transcriptome analysis with FluQuadri™ will be compared down the line with the novel COBRA vaccine to see the difference in immune profiling that will inform how better the newly developed COBRA vaccine is.

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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
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 3 and 8 years
Scientific Title of Study	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	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Dr Nithya Gogtay
Designation	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	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	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

INCENTIVE has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 874866 and the Dept. of Biotechnology, Govt. of India (project no.BT/IN/EU-INF/16/AP/19-20/11746)

	Phone	7904286189
	Fax	
	Email	jpraj.m07@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Department of Biotechnology, R. No. 706, Block-2, CGO Complex Lodhi Road, New Delhi-110 003

Primary Sponsor

Primary Sponsor Details	
Name	Seth GS Medical College KEM Hospital
Address	Acharye Donde Marg Parel Mumbai - 400012
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Nithya Gogtay	Seth GS Medical College &KEM Hospital	Department of Clinical Pharmacology Room No: 201 1st floor New building Seth GS Medical College and KEM hospital Parel Mumbai MAHARASHTRA	9820495836 njgogtay@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee I of Seth GS Medical College & KEM Hospital	Approved	27/09/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy as determined by laboratory tests and medical history

Intervention / Comparator Agent

Type	Name	Details
Intervention	Fluquadri Vaccine (Quadrivalent influenza vaccine)	Two doses of Intramuscular injection of quadrivalent influenza vaccine (Fluquadri) approximately one month apart (28 - 32 days)
Comparator Agent	Nil	It is a single arm study

Inclusion Criteria

Inclusion Criteria	
Age From	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, physical examination and clinical judgement) age range ?3 and ?9 years old on the day of the study 2. Written, informed consent from

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		parents/guardians. 3. Oral assent for 7-8 years of aged children. 4. Parents/Guardians able to understand and comply with the study protocol requirements, including availability for all scheduled visits of the study.

Exclusion Criteria

Exclusion Criteria	
Details	

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

Primary Outcome

Outcome	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)	Day 0 and Day 58

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
a. 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	Phase 4
Date of First Enrollment (India)	01/11/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Will be published in a peer reviewed journal of national/ international importance
Brief Summary	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 Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Nithya Gogtay
Designation	Professor & Head
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
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific 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 Mumbai MAHARASHTRA 400012 India
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Email	jpraj.m07@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Jeffrey Pradeep Raj
Designation	Senior Resident
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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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	Phone	7904286189
	Fax	
	Email	jpraj.m07@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Department of Biotechnology, R. No. 706, Block-2, CGO Complex Lodhi Road, New Delhi-110 003

Primary Sponsor

Primary Sponsor 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 Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Nithya Gogtay	Seth GS Medical College &KEM Hospital	Department of Clinical Pharmacology Room No: 201 1st floor New building Seth GS Medical College and KEM hospital Parel Mumbai MAHARASHTRA	9820495836 njgogtay@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee I of Seth GS Medical College & KEM Hospital	Approved	27/09/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy infants of age between 6 and 12 months

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	Nil	It is a single arm study
Intervention	Fluquadri Vaccine (Quadrivalent influenza vaccine)	Two doses of Intramuscular injection of quadrivalent influenza vaccine (Fluquadri) approximately one month apart (28 - 32 days)

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 2. Written, informed consent from parents/guardians. 3. Parents/Guardians able to understand

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	and comply with the study protocol requirements, including availability for all scheduled visits of the study.

Exclusion Criteria

Exclusion Criteria	
Details	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	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 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
Anti-Haemagglutinin (HA) and Neuraminidase (NA) antibody titres to vaccine strain and antibody avidity.	Day 0 and Day 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)	Day 0 and Day 58

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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 (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 4
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Date of First Enrollment (Global)	No Date Specified
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Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Results will be published in a peer reviewed journal of national/ international importance
Brief Summary	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 6-12 months 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 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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