H2020-SC1-2019-RTD

Grant Agreement Number 874866

Deliverable N° D 4.6

INCENTIVE-QIV-1, 2, 3 (EU) and QIV-1 (India): Study results posted in the study registry

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

March 2025

Version N° 1

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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)

Project ref. no.	874866 — INCENTIVE H2020-SC1-2019-RTD
Project title	Indo-European Consortium for Next Generation Influenza Vaccine Innovation

Deliverable title	**INCENTIVE-QIV-1, 2, 3 (EU) and QIV-1 (India): Study results posted in the study registry**
Nature of Deliverable	**R=Document, report**
Contractual date of delivery	Project Month N° 53
Actual date of delivery	10th March 2025
Deliverable number	D4.6
Dissemination Level	**PU = Public**
Status & version	Final – version 1
WP of the deliverable	WP 4
Lead Beneficiary	N° 7 – UA
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List of abbreviations

CSR	Clinical Study Report
CTRI	Clinical Trial Registry India
DBT	Department of Biotechnology
EU	European Union
H2020	Horizon 2020
EUDRA-CT	European Union Drug Regulating Authorities Clinical Trials Database
HUS	Haukeland University Hospital

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1. Introduction

This document is the Deliverable D4.6 **INCENTIVE-QIV-1, 2, 3 (EU) and QIV-1 (India): Study results posted in the study registry** of **Work Package 4** 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 66 months. The highly integrated INCENTIVE consortium comprises 19 institutions representing a true partnership between Indian and European/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.

This deliverable **D4.6** will show that for QIV 1, 2 and 3 trials (EU) as well as for QIV-1 (India) the safety and preliminary immunogenicity results have been posted on the respective study registry.

2. INCENTIVE-QIV trials

The main objective of the INCENTIVE QIV trials is to improve our understanding of protective immunity against influenza and to identify predictors and potential determinants of vaccine responsiveness by performing Phase IV clinical trials using a quadrivalent influenza vaccine (QIV). Immune profiling of influenza vaccinated subjects will be performed across age groups and across diverse populations in India and Europe.

INCENTIVE-QIV trials is a series of phase IV trials studying response to a licensed vaccine in three vulnerable populations: 1) QIV-1 Elderly; 2) QIV-2 Children; 3) QIV-3 Infants conducted in parallel in Europe and India with the licensed Sanofi's Quadrivalent influenza vaccine. Centres involved in the

[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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Phase IV trials are **P7 UA** in Belgium (QIV-1 Elderly), **P6 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). Currently, QIV-1, QIV-2 and QIV-3 (EU) as well as QIV-1 (India) have been completed.

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

INCENTIVE-QIV-1-EU: This is 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 the marketed QIV Vaxigrip Tetra® from Sanofi administered by the intramuscular route.

Study results for INCENTIVE-QIV-1-EU have been duly posted. The Clinical Study Report (CSR) was submitted to https://cespportal.hma.eu on 20th Dec 2024.

Please find below the submission confirmation.

HMA Common European Submission Portal
Heads of Medicines Agencies

Upload Time (UTC +1)	Delivery File Id	Deliveries Complete	Size	Status
20/12/2024 14:47:58	2230999	1 of 1	2.33 MB	Complete

Agency	Delivery Time
BE	20/12/2024 13:50:26

CESP Submission ID: 2230999
Company Name: Universiteit Antwerpen
First Name: Leen
Last Name: Suykens
Contact Number:
Email: leen.suykens@uantwerpen.be
Department Type: Human Medicines
Procedure Type: National
Submission Type: Other eSubmission Type
Technically Validated: false
Agency Reference Numbers:
Procedure Number: NA
Regulatory Activity ID: G0020
Agency Activity Reference ID: Clinical Trial
Sub Activity ID: H005
Sub Activity Detail: Closing Documents
Products:
- Agency: BE MAANo: NA Product Name: NA

Comments: Submission of CSR of 2021-003307-18 trial (INCENTIVE-QIV-1)
Filename: 2021-003307-18.zip
File Size: 2.33 MB
Zip Software: WinZip

Receipt Created By: c6916-suykensl Tue Jan 07 2025 11:39:12 GMT+0100 (Midden-Europese standaardtijd)

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

INCENTIVE-QIV-2-EU: This is 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 the marketed QIV Vaxigrip Tetra® administered by the intramuscular route.

The CSR for INCENTIVE-QIV-2-EU was submitted by email to the Medicines agency on 18th Dec 2024. Please see below a screenshot of the email confirmation.

From: Rebecca Jane Cox Brokstad
Date: Wednesday, 18 December 2024 at 16:33
To: post@dmp.no post@dmp.no

Subject: Clinical Study Report INCENTIVE EudraCT 2021-003804-42

Clinical Study Report

Title: Immunogenicity, molecular profiling and safety of a marketed quadrivalent influenza vaccine (Vaxigrip Tetra) administered by the intramuscular route in children 3-8 years old

Sponsor´s protocol identifying number INCENTIVE-QIV2-EU Version 2 Phase IV study

EudraCT 2021-003804-42

This email contains the clinical study report from the trial of the primary and secondary endpoints with conventional serlogy.

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

INCENTIVE-QIV-3-EU: This is a Phase IV vaccine trial conducted by **P4 ULB** at CHU Saint-Pierre and Hôpital Erasme in Belgium in 50 infants, aged 6 to 8 months, to evaluate the immunogenicity, molecular profiling and safety of the marketed QIV Vaxigrip Tetra® administered by the intramuscular route.

The CSR for INCENTIVE-QIV-3-EU have been posted on EudraCT on 24th Dec 2024. Please find below the submission confirmation.

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Your page

Clinical trials that appear in the list below are those that are posted or finalised and assigned to you.

Filter by EudraCT number:

Filter | Show latest versions only | Clear filtering options

Posted and finalised results

EudraCT number	Version	Sponsor name	Friendly description	Posted/finalised date	Status	Options
2021-003760-27	1		QIV-3 CSR	24-Dec-2024	Posted	Edit | View | Manage assigned users

View draft results

Post results - success

Data for this version of the results of the clinical trial have been posted to EudraCT

This version of the results will be made public within the next 15 days, in accordance with the European Commission guideline [2012/C 302/03]. During this period you will be able to cancel the posting of this version of the results to enable further editing.

IMPORTANT:

Result-related data will be made public if, in addition to European Commission guideline, at least one of the protocol-related records for this trial has also been made public in the EU clinical trials register.

See the table below for more information.

CTA Member state name/Third country file	EU clinical trials register publication status
CTA: Belgium - FPS Health-DGM	published

Contact the national competent authority in the relevant member state if you have questions about the publication status of the clinical trial applications for this trial.

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

INCENTIVE-QIV-1: This is 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 the marketed QIV FluQuadri™ administered by the intramuscular route. In India, FluQuadri™ manufactured by Sanofi India was used, which is produced according to the same manufacturing procedure as Vaxigrip Tetra® (which is being used for the parallel QIV trials in EU), being the same influenza strains used for both vaccines.

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The results for INCENTIVE-QIV-1 (India) have been posted on the CTRI (Clinical Trial Registry India). Please find here the link:

https://ctri.nic.in/Clinicaltrials/pmaindet2.php?EncHid=NDUwMDE=&Enc=&userName=INCENTIVE%20QIV%201.

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3. Annexes

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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