H2020-SC1-2019-RTD

Grant Agreement Number 874866

Deliverable N° D1.2

Communication Plan

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

June 2021

Version N° 1

Main Author(s):

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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).

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EC Project Officer	Oana Bodron

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Table of Contents

1. INTRODUCTION 5

2. OBJECTIVES 6

3. INCENTIVE COMMUNICATION PLAN 7

3.1 INTERNAL COMMUNICATION 8

3.2 EXTERNAL COMMUNICATION 8

4. COMMUNICATION TOOLS, CHANNELS AND ACTIVITIES 9

4.1 PROJECT WEBSITE 9

4.2 PROJECT VISUAL IDENTITY 12

4.2.1 INCENTIVE Logo 12

4.2.2 Acknowledgement of Funding 12

4.2.3 INCENTIVE Templates 13

4.3 SCIENTIFIC PUBLICATIONS, COMMUNICATION MATERIALS AND PUBLIC DELIVERABLES 15

4.4 DISSEMINATION MONITORING 16

5. ANNEX 17

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)

List of Figures and Tables

Figure 1. Outline of INCENTIVE Communication Plan. 7

Figure 2. INCENTIVE Webpage 11

Figure 3. The INCENTIVE logo. 12

Figure 4. Acknowledgement of EU and India funding for INCENTIVE. 12

Figure 5. MS Word template for INCENTIVE. 13

Figure 6. PowerPoint Template for INCENTIVE (title slide). 13

Figure 7. Meeting minutes template for INCENTIVE. 14

Figure 8. INCENTIVE deliverables template for submission of EU deliverables. 15

Figure 9. INCENTIVE dissemination tracker template. 16

Table 1. Planned communication activities for INCENTIVE. 9

List of Abbreviations

CA	Consortium Agreement
CDSCO	Central Drugs Standard Control Organization
CERN	Conseil Européen pour la Recherche Nucléaire (European Council for Nuclear Research)
COBRA	Computationally-Optimized Broadly-Reactive Antigens
EMA	European Medicines Agency
EU	European Union
EC	European Commission
GA	Grant Agreement
H2020	Horizon 2020
PMB	Program Management Board
PMO	Project Management Office
SEAB	Scientific and Ethical Advisory Board
WP	Work package

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1. Introduction

This document is the **Deliverable 1.2 Project presentation prepared, website launched and communication plan** developed of **Work Package 1 - Management and Coordination** 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, Govt. of India (project no.BT/IN/EU-INF/16/AP/19-20/11746). The INCENTIVE project started on 01st August 2020 and has a duration span of 60 months. The highly integrated INCENTIVE consortium comprises of 19 institutions representing 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.[1] 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.

The aim of **Task 1.4** is to develop and define specific communication tools to communicate the project and its findings and in accordance, this deliverable outlines a strategic communication plan to raise/create awareness of the project (throughout the projects lifespan), enhance its visibility, and promote its results amongst a wide audience of different stakeholder groups. The communication plan details the key stakeholder groups that will be targeted, and the communication channels and tools that will be employed for efficient engagement and outreach for the project. The plan will also briefly describe the internal communication activities within the consortium. The final and ultimate goal of the project's communication and dissemination activities (including WP-8, **Task 8.3** dissemination and exploitation of results)[2] is to facilitate the transfer of the emerging health benefits to the end-users, as well as the market deployment and exploitation of the technologies investigated within the project.

This deliverable is in compliance/accordance with **Article 38.1** of the project Grant Agreement (GA) and also takes guidance from the H2020 manual on "Communicating EU research and innovation guidance for project participants".[3]

[1] Please refer to Section 5 (Annex) for list of all INCENTIVE project partners.
[2] A detailed dissemination and exploitation plan will be presented in deliverable D8.3 'Development and annual update of INCENTIVE dissemination and exploitation plan' in M60
[3] https://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-guide-comm_en.pdf

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2. Objectives

INCENTIVE'S goal will be achieved by pursing 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 up to proof-of-concept for vaccine efficacy in non-human primates, 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.

The communication tools and strategies have been outlined keeping in mind the importance of disseminating information about the project and promoting its results throughout the project's life and beyond. Regular exchange between the different stakeholders and the consortium will ensure the successful implementation of the project according to the needs of society, whereas increasing the innovation potential. In this context, the communication measures to be implemented have the objectives of promoting the project, its results and societal impact as widely and as effectively as possible to all relevant stakeholders by:

- Development and creation of the project corporate identity image for INCENTIVE,
- Development and regular update of the INCENTIVE project website,
- Regular project internal information exchange and communication for knowledge, data and experience sharing,
- Defining the project's dissemination intents and measures for the project,
- Dissemination and communication of project results to all key stakeholders,
- Stimulating discussion amongst stakeholders of the project findings,
- Stakeholder meeting to increase awareness and to establish a close dialog with the relevant organizations, and
- Facilitating market deployment/exploitation of knowledge, results and deliverables of the project.

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3. INCENTIVE Communication Plan

The project's communication plan outlines the internal communication activities between the members of the consortium and external communication activities targeting the different stakeholder groups (Fig. 1).

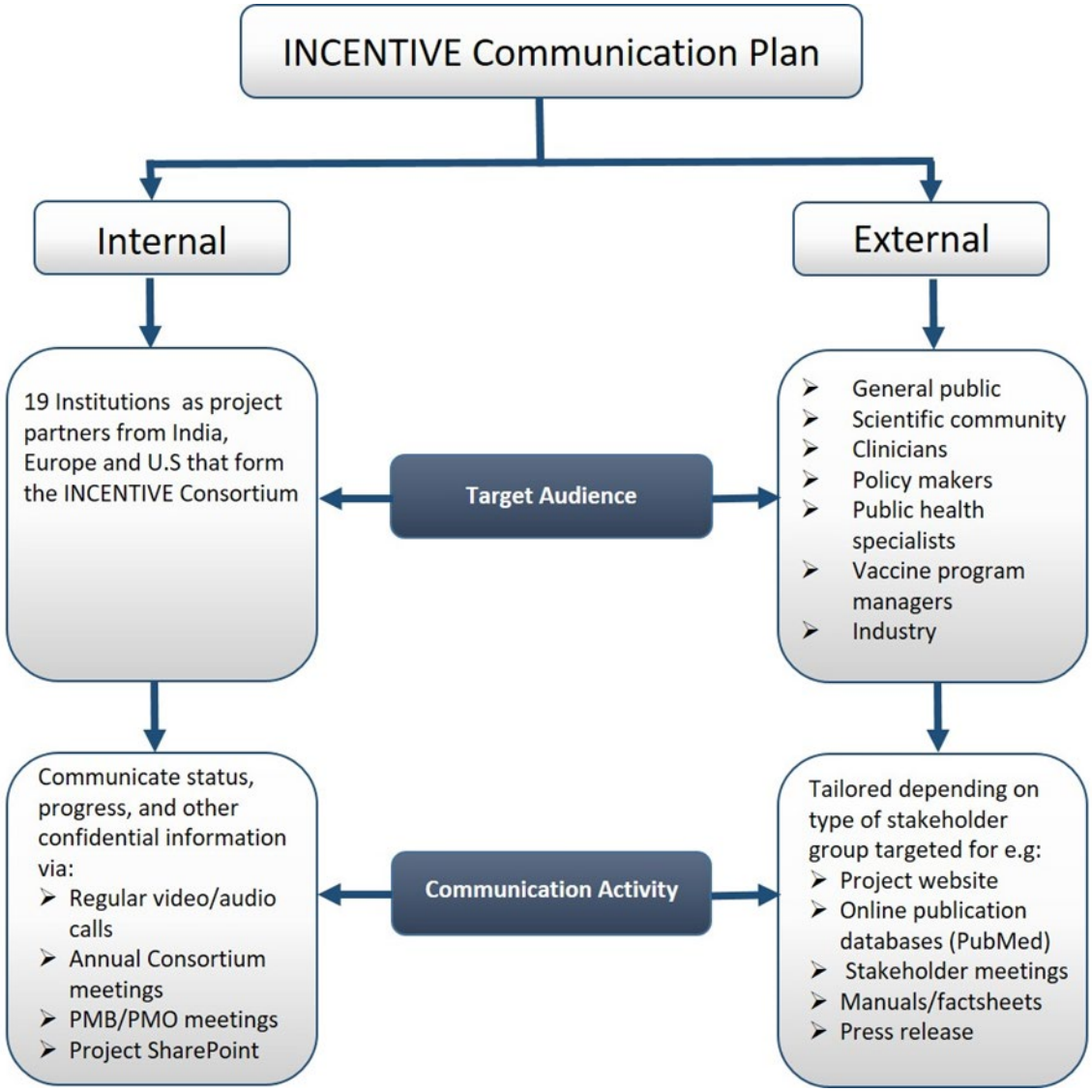

Figure 1. Outline of INCENTIVE Communication Plan.

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3.1 Internal Communication

The internal audience comprises of the 19 partner institutions of the consortium. To ensure success and smooth implementation/execution of the project plan and objectives, internal communication includes:

a. Regular video/audio conference calls to support the different Work Package (WP) collaboration and interactions.
b. Annual consortium meetings (virtual, face-to-face when possible) to ensure overall monitoring of project progress and interaction between all WP partners.
c. Bi-monthly Program Management Board (PMB) meetings and monthly Project Management Office (PMO) meetings to further enable seamless coordination and communication amongst the consortium partners.

Project partners are encouraged to routinely discuss the project results, progress, as well as communicate any hurdles/roadblocks faced during the course of the project. A project SharePoint will also be established through which the project partners can also communicate status, deliverables, milestones, and other confidential information.

Additionally, the Scientific and Ethical Advisory Board (SEAB), a consultative body composed of international interdisciplinary experts shall provide external recommendations and monitor the project to achieve a maximum impact in scientific, technological and health terms, as well as in compliance to the highest ethical standards. They will advise the consortium on the exploitation strategy of the most promising results. They shall have an advisory role in the project and be consulted when relevant to project progress, providing advice on scientific, technological and ethics issues.

3.2 External Communication

To promote the project to an external audience, a tailored strategy will be implemented, which will take into account the specific needs in terms of type, quality and quantity of information to be delivered to the different stakeholders. In addition, to reach all the various stakeholders, different communication strategies will be pursued. The objective is to ensure an effective dissemination of project information and results, to all relevant stakeholders, including the general public. The ultimate goal is to facilitate the transfer of the emerging health benefits to the end-users, as well as the market deployment and exploitation of the technologies investigated within the project. Several communication tools and strategies are being considered to target the different stakeholder groups (Table 1).

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Type of Communication Activity	Target Audience
Communicate project aims and outcomes via project website	Scientists, stakeholders, policy makers and general public
Disseminate the study protocol as publication in an open access journal with coverage in PubMed/MEDLINE	Clinicians, scientists, stakeholders, policy makers and general public
Disseminate clinical study documents according to EMA policy 0070 and EU Regulation 536/2014, and the Indian New Drugs and Clinical Trial Rules by CDSCO	Clinicians
Disseminate project knowledge through peer-reviewed journals	Scientists, policy makers, stakeholders
Communicate project advances and innovations through participation at national, European and international meetings	Scientists (industry and academia)
Stakeholder meeting	Policy makers, public health specialists, vaccine program managers and industry
Promotional literature (e.g. factsheets) with information about the project to be used as a communication tool at scientific events and workshops attended by consortium members	Scientists, policy makers, stakeholders
Social media (e.g. LinkedIn) to announce main activities and/or achievements	General public, scientists (industry and academia), policy makers, stakeholders
Press releases (through appropriate press channels and partner websites) aimed at all mass media	General public

Table 1. Planned communication activities for INCENTIVE.[4]

4. Communication Tools, Channels and Activities

4.1 Project Website

A website for INCENTIVE has been developed (available here: www.incentive-h2020.eu) and will be the main communication channel that provides up-to-date relevant information about the project to a wide audience (see Fig. 2). The INCENTIVE website will also be a tool to promote the project results and activities to all stakeholders. The website displays the following information:

- **Objectives** – Here the main objectives and strategic goals of the INCENTIVE consortium will be

[4] In-person meetings with relevant stakeholder groups will only be organized depending on the COVID-19 pandemic travel regulations.

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displayed.

- **Consortium** – This page will provide a brief description of each project partner and their main project roles along with the respective logo and contact person. Clicking the organization's name will redirect the user to the official website of the project partners.
- **Results** – Publishable project results/reports/public deliverables as well as a link to the INCENTIVE Zenodo community https://zenodo.org/communities/incentive/
- **News** – News related to the project (this page will be frequently updated),
- **Contact information** – Here the visitor can see contact information of the consortium coordinators and the project managers.
- **Impressum**
- **Data privacy statement**

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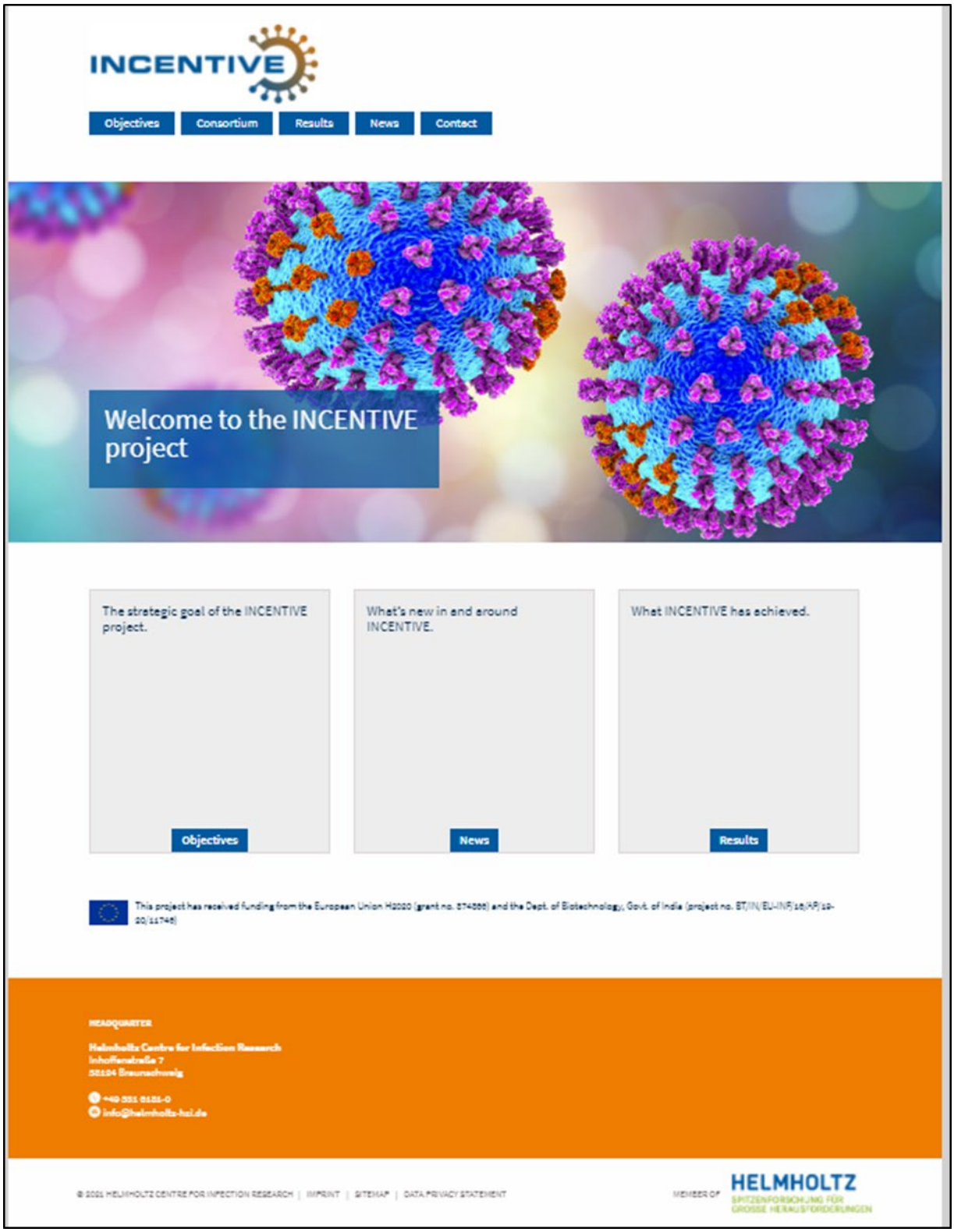

Figure 2. INCENTIVE Webpage

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4.2 Project Visual Identity

4.2.1 INCENTIVE Logo

The INCENTIVE logo displays in a stylized manner the surface structure of the Influenza virus particle (Fig. 2), whereas the colours and their fusion represent the collaboration between the EU/US partners (blue as seen in the respective flags) and the Indian partners (saffron as seen in the Indian flag).

Figure 3. The INCENTIVE logo.

4.2.2 Acknowledgement of Funding

Whenever possible, documents, reports, results, presentations and communication/dissemination activities that refer to the INCENTIVE project will include the EU-Flag logo with the accompanied text as mentioned in the project GA (section 29.4), as well as acknowledge the funding received from the Department of Biotechnology, Govt. of India (Fig. 3).

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Figure 4. Acknowledgement of EU and India funding for INCENTIVE.

4.2.3 INCENTIVE Templates

To ensure a standardised format for internal and external communication that can be used by the INCENTIVE partners, various branding templates were developed displaying the INCENTIVE logo and the respective funding acknowledgements. These templates include those for: i) MS Word documents in general, ii) PowerPoint presentations, iii) meeting minutes and, iv) deliverables for submission to the EU (Fig. 4-7). The templates were distributed amongst the INCENTIVE partners and will be used throughout the project duration to maintain consistency.

Figure 5. MS Word template for INCENTIVE.

Figure 6. PowerPoint Template for INCENTIVE (title slide).

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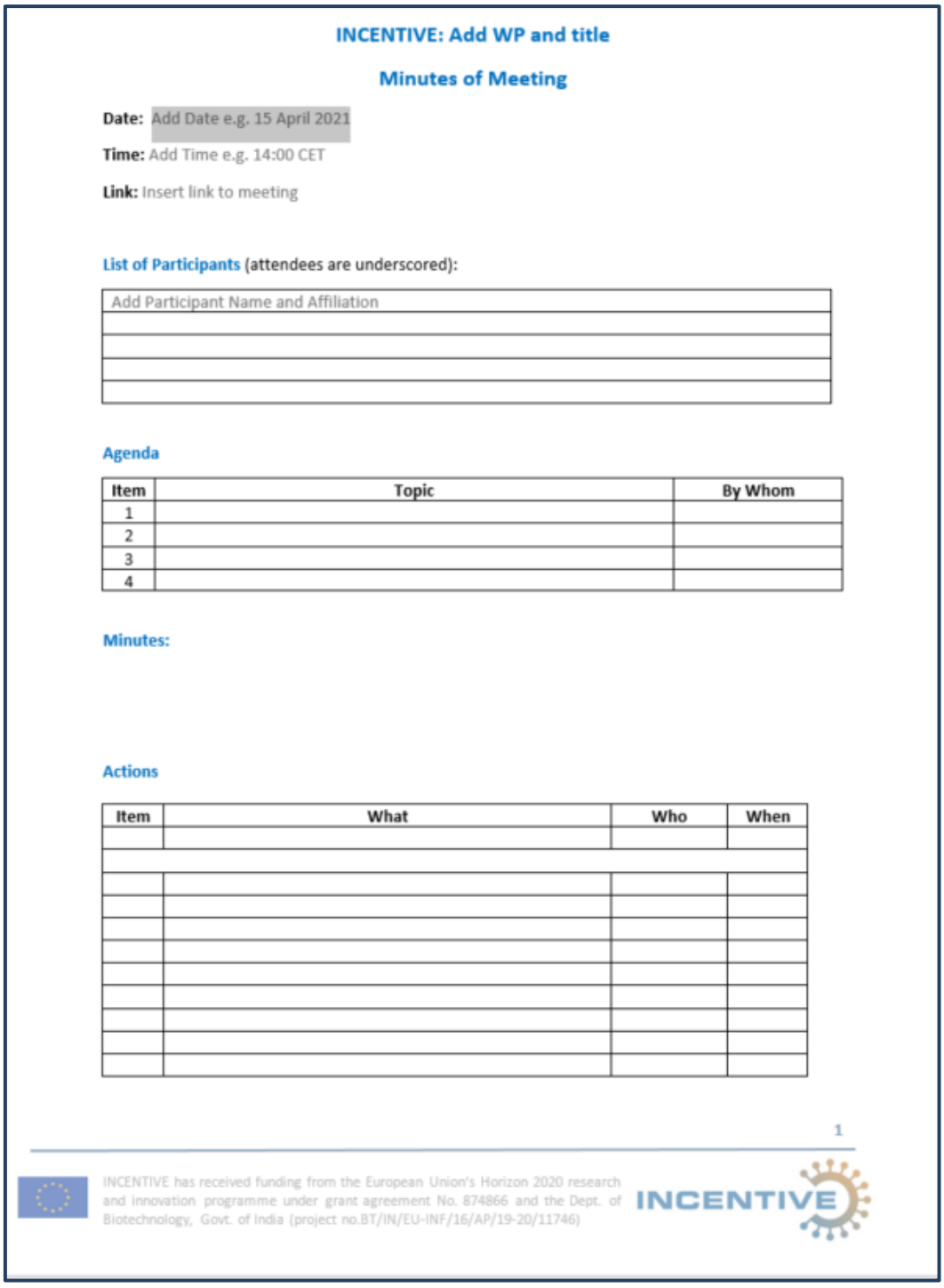

INCENTIVE: Add WP and title

Minutes of Meeting

Date: Add Date e.g. 15 April 2021

Time: Add Time e.g. 14:00 CET

Link: Insert link to meeting

List of Participants (attendees are underscored):

Add Participant Name and Affiliation

Agenda

Item	Topic	By Whom
1		
2		
3		
4		

Minutes:

Actions

Item	What	Who	When

1

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Figure 7. Meeting minutes template for INCENTIVE.

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First name:
Family Name:
Institution:
Country:

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Deliverable D (N°) INCENTIVE – 874866

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

Deliverable title	
Nature of Deliverable (please choose – see Annex 1)	R=Document, report; DEM=Demonstrator, pilot, prototype; DEC=Websites, patent fillings, videos, etc.; OTHER; ETHICS=Ethics requirement
Contractual date of delivery	Project Month N° XX
Actual date of delivery	dd/mm/yyyy
Deliverable number	DX.X
Dissemination Level (please choose, remove other – see Annex 1)	PU = Public CO = Confidential, only for members of the consortium (including the Commission Services)
Status & version	Draft/Final – number of version
WP of the deliverable	WP1-9
Lead Beneficiary	N° of the beneficiary leading the work in this WP
Main Author(s)	Names of PI(s) contributing
Project coordinator (EU, USA) Project coordinator (India)	Prof. Carlos A. Guzmán, HZI, Germany Dr. Amulya Panda, NII, India
EC Project Officer	Oana Bodron

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Figure 8. INCENTIVE deliverables template for submission of EU deliverables.

4.3 Scientific Publications, Communication Materials and Public Deliverables

Sharing, verification and re-use of scientific results produced during the project's lifespan will be mainly achieved by publications in scientific peer-reviewed journals, posters and short communications. The INCENTIVE Consortium recognizes the need to ensure that research publications and data are made widely and publicly available via open access. Thus, the Consortium will follow the regulations laid out in the GA and by the European Commission (EC) for open access to scientific publications and research data in Horizon 2020. The project partners acknowledge the importance of providing immediate availability to the research publications. Therefore, the 'gold' open access route will be followed. Scientific publications will also be available through OpenAIRE, on the project website and archived online in the INCENTIVE Zenodo community (https://zenodo.org/communities/incentive/). Zenodo is an open access catch-all data repository developed under the European OpenAIRE program and supported and hosted by CERN. It enables researchers worldwide and from every scientific discipline

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to upload their datasets, research articles, etc., thereby making data open and findable to the global scientific community. INCENTIVE deliverables that are public will also be made available online via the project website and INCENTIVE Zenodo community. INCENTIVE will also develop a project factsheet (as mentioned in Task 1.4.2 in the Description of Action) that will be circulated amongst the project partners to be eventually used in their dissemination activities.

4.4 Dissemination Monitoring

As stated in **Article 29.1** of the GA, all project partners are obliged to "disseminate" their results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium). Moreover, as also stated in the Consortium Agreement (CA); prior notice of any **planned publication** shall be given to the other Parties at least **45 calendar** days before the publication. Any objection to the planned publication shall be made in accordance with the GA in writing to the European Coordinator and to the Party or Parties proposing the dissemination within **30 calendar days** after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted

All partners have received an INCENTIVE **dissemination tracker** template where all communication /dissemination activities and scientific publications will be recorded and tracked (Fig. 8). Project partners will fill the list that includes details such as type of communication activity, target audience, place of dissemination, estimated size of target audience, etc.

INCENTIVE (874866) - List of Dissemination / Communication activities for 2021

No.	Date of dissemination (completed or planned) dd/mm/yyyy	Type of dissemination (select from drop down list)	Title of dissemination	Author(s)/ Presenter(s)	Participant (institution)	Place of dissemination (journal/title of conference/etc.)	Link to article/ event/ other	Audiences reached - Select multiple from below *Scientific Community; Industry; Civil Society; General Public; Policy Makers; Media; Clinicians; Public Health Specialists; Vaccine Program Managers; Others*	(Estimated) Size of audience	INCENTIVE related?	Estimated costs per activity (in €)
										yes	
		Organisation of a Conference								yes	
		Organisation of a workshop								yes	
		Press release								yes	
		Non-scientific and non-peer review								yes	
		Exhibition								yes	
		Flyers								yes	
		Training								yes	
		Social media								yes	
										yes	
										yes	

Figure 9. INCENTIVE dissemination tracker template.

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5. Annex

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

June 2021

Version 1

Main Author(s):

Upneet Hillebrand, Blair Prochnow and Carlos A. Guzmán – HZI, Germany

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Main Author(s)	Upneet Hillebrand, Blair Prochnow and Carlos Guzmán– HZI, Germany
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EC Project Officer	Oana Bodron

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Introduction

The PowerPoint project presentation provides background information to the INCENTIVE project, its strategic goals and objectives. The project partners may use this presentation to present the project. The presentation will be updated regularly.

Please find below the PPT presentation.

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Indo-European Consortium for Next Generation Influenza Vaccine Innovation

INCENTIVE

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Influenza – a serious global public health threat

- Influenza is a major global health threat with ~650000 annual deaths worldwide.
- Significant progress in understanding of influenza led to multiple vaccines in the past 50 years.
- There is limited progress in improving the breadth and length of vaccine-conferred protection.
- Annual seasonal vaccines also fail to adequately protect the most vulnerable.
- The influenza vaccine problem is primarily a ***human immunology problem.***

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INCENTIVE Project Strategic Goals

- Advance knowledge on mechanisms of poor responsiveness to influenza vaccines (IVs)

- Develop two next-generation universal IVs

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INCENTIVE Objectives

To establish a cornerstone towards the development of next generation influenza vaccines through:

- Comprehensive immunome profiling of responders and non-responders to influenza vaccination in infants, children and elderly.
- Advancement of two next generation universal vaccines: COBRA and APC-Mix.
- Identification of predictive biomarkers of responsiveness to vaccination.
- Health systems and investment analysis and establishment of vaccine preparedness program.

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INCENTIVE Partners

A partnership of 19 institutions from Europe, India and the US, with leading scientists in the fields of influenza, vaccinology, adjuvants, immunology, clinical science, biostatistics and social-economics.

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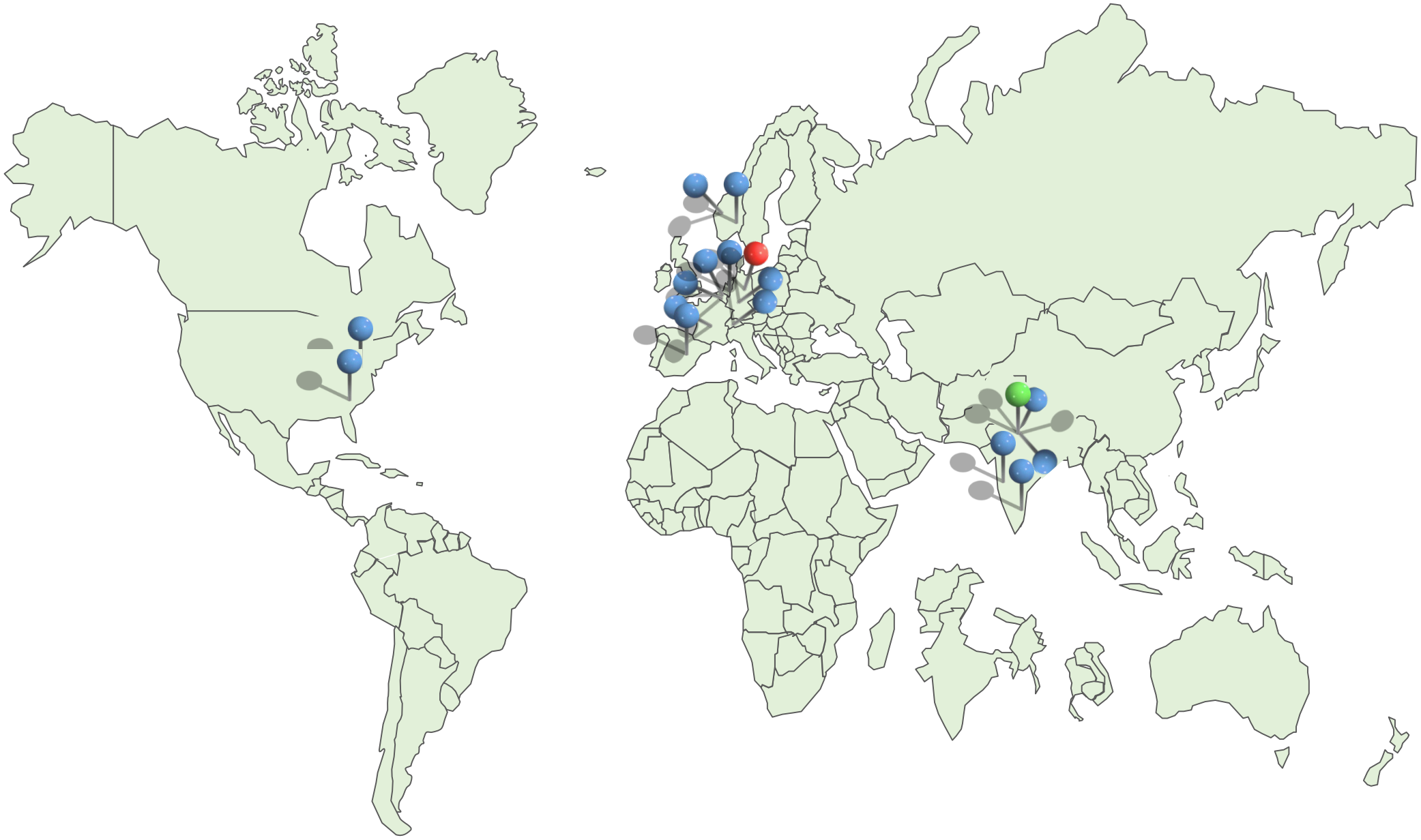
INCENTIVE Partners



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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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INCENTIVE Scientific Program

Phase IV Trial with QIV in vulnerable populations in Europe and India associated with in-depth immune profiling

Advance **NGU COBRA vaccine** to clinical development, with efficacy study using a controlled human challenge model

Preclinical development of an innovative nucleic acid vaccine – **APC-Mix**

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Phase IV QIV Trials

Phase IV clinical trials of current influenza vaccines in vulnerable individuals from Europe and India who are responders and not to vaccination associated with in-depth immune profiling.

***Objectives**: To evaluate and compare the immunogenicity of a commercial QIV vaccine in vulnerable populations*

- In depth analysis of antibodies and their effector functions
- T- and B-cell mediated immunity
- Transcriptome, proteome and metabolome
- Identification of correlates of responsiveness across populations in EU and India

Study Populations

- Elderly ≥ 60 years: 50 in Belgium and 100 in India
- Children 3-8 years: 50 in Norway and 100 in India
- Infants (6 months-old) born to mothers immunized with QIV during pregnancy: 50 in Belgium and 100 in India

***Timeline**:*

- Q1 Year 1 – Q1 Year 2: protocol development and regulatory approval
- Q2 Year 2: Trial initiation

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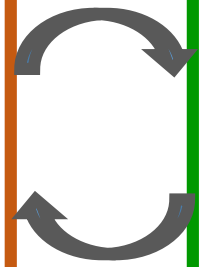
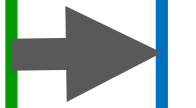
Immune Profiling & Data Integration

- **Unprecedented in-depth immune profiling** across different populations:
  - Functional, HA and NA specific antibodies
  - IgG subclass antibody responses
  - Systems serology
  - T and B cell immunity
  - Functionality of blood
  - Transcriptome, proteome and metabolome



- **Data Warehouse** in Europe and India
  - Repository of ALL data generated from each continent
  - Standardized data curation and storage
- Standardized data format and methodology allow data integration



- Identification of vaccine-specific signatures and biomarkers
- Guide the development of next generation vaccines

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Next Generation Universal COBRA Vaccine Development

- ***COBRA (Computationally-Optimized Broadly-Reactive Antigens) Vaccine***
  - Using computer algorithms and multi-consensus building approach that allows for the incorporation of both major and minor neutralizing epitopes against all strains of influenza regardless of subtype.
  - Designed hemagglutinin (HA) and neuraminidase (NA) antigens that elicit neutralizing antibodies active against circulating influenza viruses from season to season.
  - Demonstrated broad neutralizing (bNAb) activity more protective than native HA in both mouse and ferret models of infection.

- ***c-di-AMP (CDA) Mucosal Adjuvant***
  - Acts as STING agonist inducing expression of type I IFN and TNF, promoting Ab, Th, CTL responses.
  - Self-limited immune activation [Rueckert *et al*. 2017] exclusively at the inductive site.

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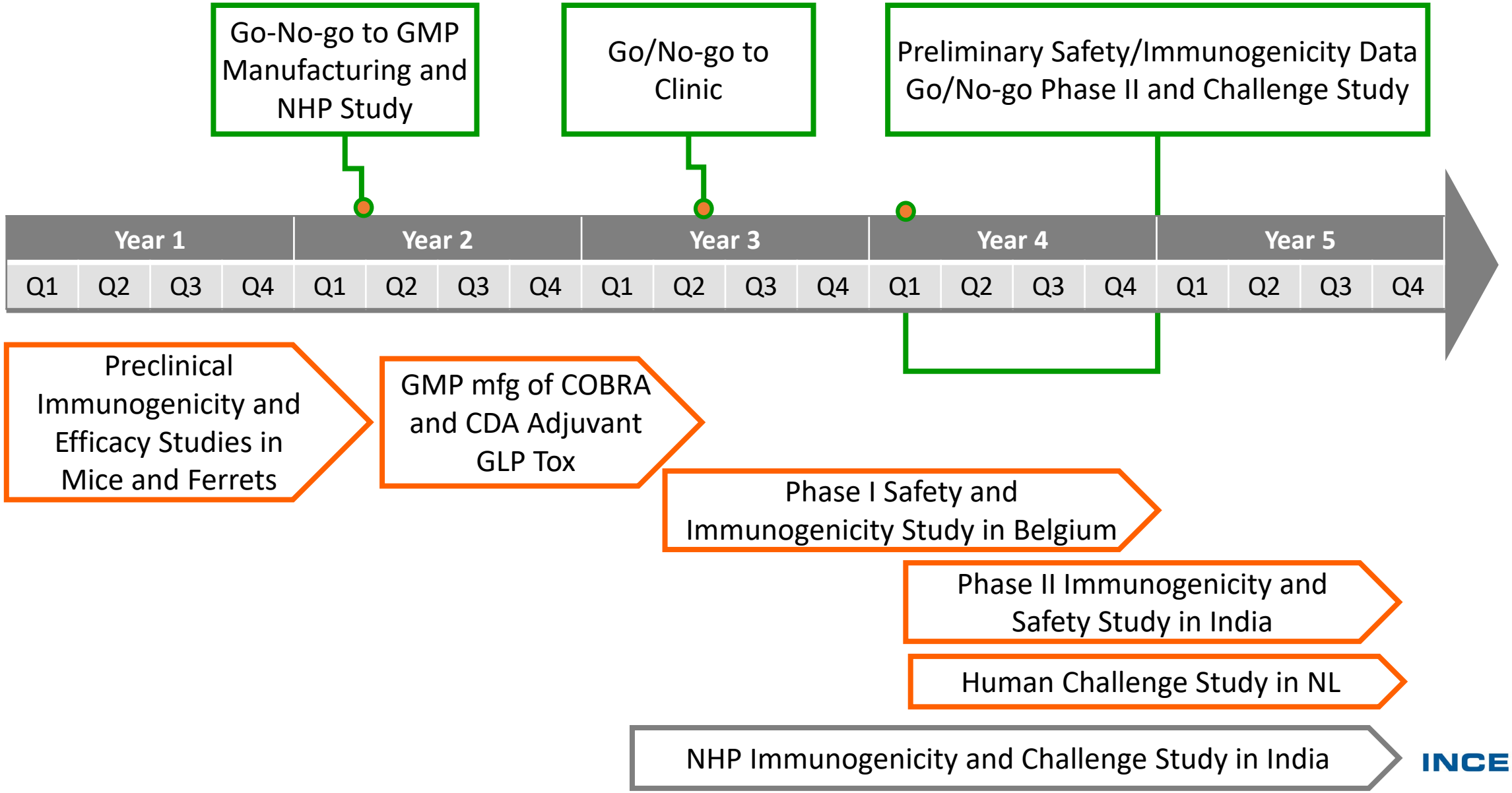
COBRA Development



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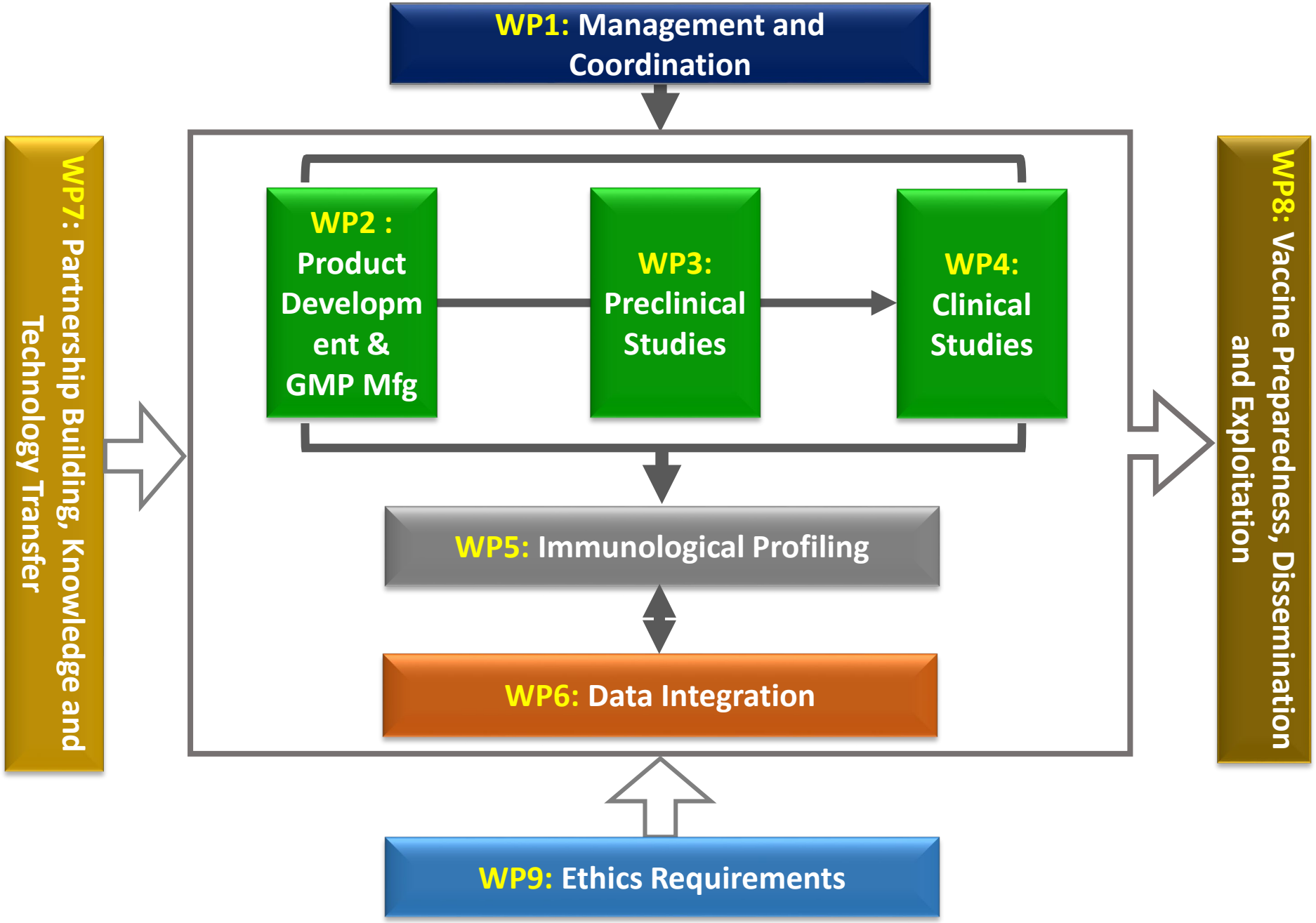

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INCENTIVE WP Leaders

EU/US

Management and Coordination	Product Development and GMP Mfg	Pre-clinical Studies	Clinical Trials	Immune Profiling	Data Integration	Partnership Building, Knowledge and Tech Transfer	Vaccine Preparedness, Dissemination and Exploitation	Ethics Requirements
C.A. Guzmán	A. Cordes	G. Grødeland	P.v.Damme	A.Marchant	W.Koff	C.Dobano	F.v.d.Boom	C.A. Guzmán
								
A. Panda	A. Panda	P. Tailor	N. Gogtay	A. Awasthi	H. Sinha	A. Awasthi	S. Mohan	A. Panda
								

India

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Objectives of the INCENTIVE project per WP

WP	Major objective	Partner's acronym
1	Ensure effective and comprehensive coordination of the project	**P1HZI**, **P19NII**, all partners
2	Development of novel vaccine and adjuvant, and production of GMP-grade material for clinical trials	P1HZI, **P10ASA**, P13UGARF, **P19NII**
3	Preclinical testing of the candidate ***INCENTIVE*** vaccines, and select the appropriate candidate for progression to clinical testing in humans	P1HZI, **P6UiO**, P13UGARF, **P19NII**
4	To conduct phase IV trial with licensed seasonal vaccine in elderly, children and infants in Europe and India; to conduct phase I and II as well as challenge study to evaluate the safety, immunogenicity and efficacy of the novel COBRA vaccine	P4ULB, P5UIB, **P7UA**, P8LUMC, **P18GSMC&KEM**
5	Conduct unprecedented immune profiling of influenza vaccinated subjects across diverse populations to guide the development of next-generation vaccines	P1HZI, **P3TSHTI, P4ULB**, P5UiB, P9IP, P11ISGlobal, P12Bioaster, P13UGARF
6	To develop an innovative approach to manage and analyze immunological data generated from the ***INCENTIVE*** trials	**P16HVP Inc, P17IITM**, all partners
7	Strengthening the partnership between India and European partners through exchanges of the State-of-the-Art technology and methodology in order to ensure harmonization in the conduct of the proposed studies in India and Europe and standardization in the data collection, management and analysis	P1HZI, **P3THSTI**, P4ULB, P5UiB, P7UA, P8LUMC, P9IP, **P11ISGlobal**, P16HVP, P17IITM, P18GSMC&KEM
8	Optimal exploitation of ***INCENTIVE's*** results during and beyond the lifespan of the project, and enhance visibility of the Indo-European research	**P2PHFI, P14HVP Stichting**, all partners

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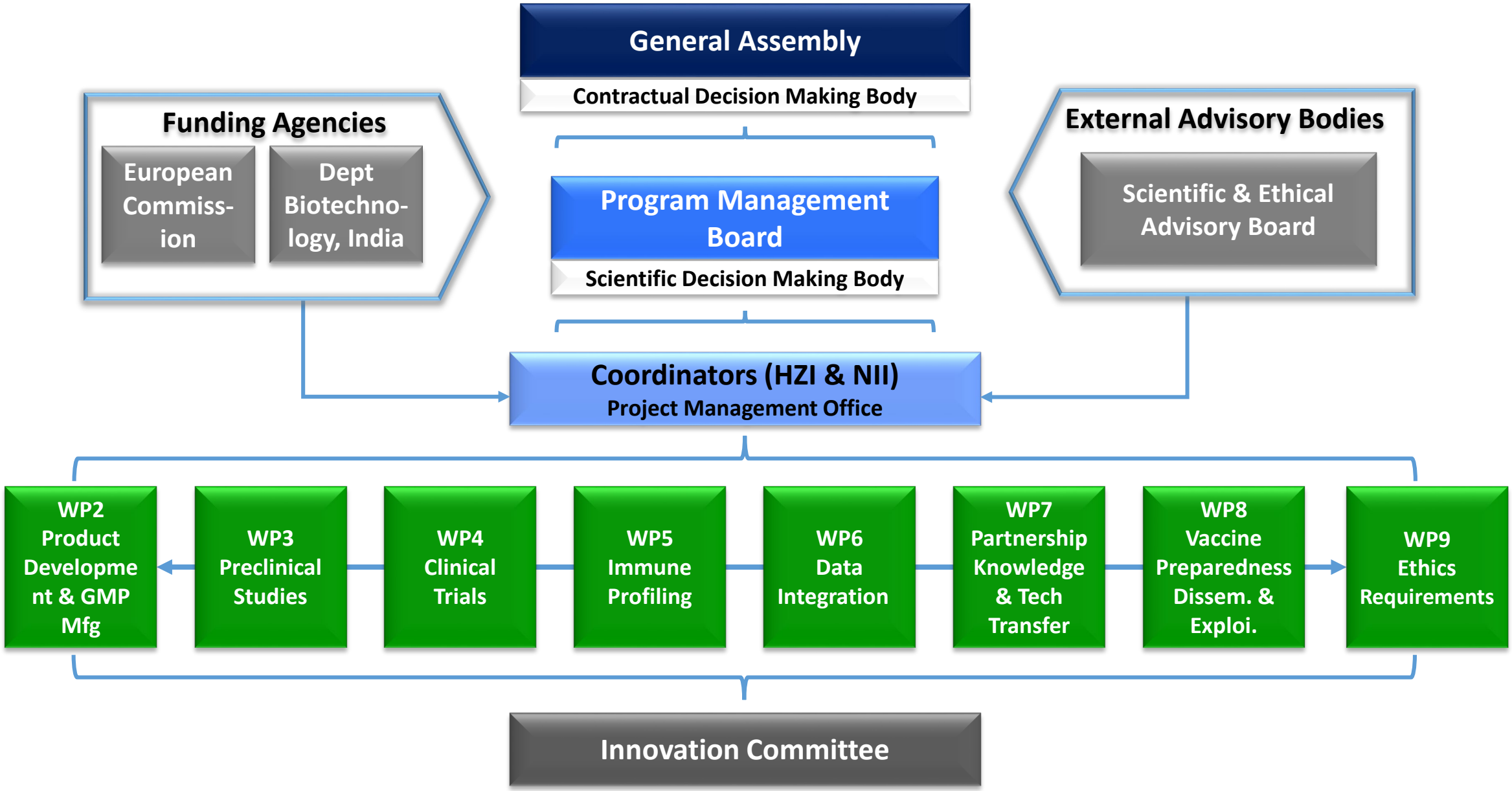
INCENTIVE Management Structure



Timing of INCENTIVE WPs and tasks

INCENTIVE

Work packages / Tasks	YEAR 1												YEAR 2												YEAR 3												YEAR 4												YEAR 5											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60
WP1 Management and coordination (months 1-60)																																																												
1.1: Strategic steering (HZI, NII)																																																											
1.2: Project monitoring and internal communication (HZI, EVF)																																																											
1.3: Administration and financial management (HZI, NII)																																																											
1.4: Communication activities (HZI, NII, HVP Stichting)																																																											
WP2 Product development and GMP manufacturing (months 1-60)																																																											
2.1: GMP manufacturing of next generation universal COBRA vaccine (NII)																																																											
2.2: Development and GMP manufacturing of adjuvant CDA (ASA)																																																											
2.3: Short-term stability study of the antigen and adjuvant formulation (ASA)																																																											
WP3 Preclinical validation of the safety, immunogenicity, and efficacy of the experimental vaccines (months 1-60)																																																											
3.1: Evaluate the immunogen. of COBRA-based vaccine formulations in mice (HZI)																																																											
3.2: Evaluate the efficacy of the most promising COBRA vaccine formulations in mice (HZI)																																																											
3.3: Test COBRA vaccine immunogen. and efficacy in ferrets (UGARF)																																																											
3.4: Perform toxicological testing (GLP) of a candidate vaccine (NII)																																																											
3.5: Evaluate the immunog. and efficacy of APC-MIX vaccine in mice (UiO)																																																											
3.6: Evaluate the immunog. and efficacy of COBRA and APC-MIX vaccine in NHPs (NII)																																																											
WP4 Conduct of clinical trials (months 1-60)																																																											
4.1: Selection of CRO to support the conduct of the INCENTIVE trials (HZI, GSMC&KEM)																																																											
4.2: Scientific advice meeting with regulatory body Belgium for COBRA-1 (UA)																																																											
4.3: Trial management logistics (ULB, UiB, UA, LUMC, GSMC&KEM)																																																											
4.4: Clinical trial application to ethics committee and national competent authorities (UA)																																																											
4.5: Clinical trial preparation (ULB, UiB, UA, LUMC, GSMC&KEM)																																																											
4.6: Phase IV clinical trials of commercially available QIV (UA)																																																											
4.7: Phase I clinical trial of the experimental COBRA vaccine (UA)																																																											
4.8: Phase II clinical trial of the experimental COBRA vaccine (GSMC&KEM)																																																											
4.9: Pilot challenge trial with experimental COBRA vaccine (LUMC)																																																											
WP5 Immune profiling (months 1-60)																																																											
5.1: Prepare viruses and recombinant antigens for influenza-specific immune profiling (UGARF)																																																											
5.2: Quantify IgG levels and avidity against most relevant influenza strains (UiB, TSHTI)																																																											
5.3: Quantify IgG subclasses and assess their role in influenza immunity (ISGlobal, TSHTI)																																																											
5.4: Perform systems serology analysis of influenza antibodies (ULB)																																																											
5.5: Profile T and B cell immunity at baseline and post-immunization (HZI)																																																											
5.6: Profile functionality of peripheral blood immune cells at baseline (IP, TSHTI)																																																											
5.7: Profile peripheral blood transcriptome, proteome and metabolome (Bioaster)																																																											
WP6 Data management and data integration (months 6-60)																																																											
6.1 Establishment of a data warehouse in Europe and in India (IITM, HVP Inc, HVP Stichting)																																																											
6.2 Data analysis and integration of INCENTIVE-QIV phase IV study (Europe and India) (HVP Inc, IITM)																																																											
6.3 Data analysis and integration of the trials with COBRA vaccine (HVP Inc, NII)																																																											
6.4 Data integration methods for datasets from all clinical trials (HVP Inc, IITM)																																																											
WP7 Partnership building, knowledge, technology transfer (months 1-36)																																																											
7.1: Exchanges between scientists for streamlining clinical trials (GSMC&KEM, UA)																																																											
7.2: Exchanges between Indian and European scientists on immunological assays (TSHTI, ULB)																																																											
7.3: Standardization of sample storage, data management and data integration tools (HVP Inc, IITM)																																																											
WP8 Vaccine preparedness, dissemination and exploitation (months 1-60)																																																											
8.1: Prepare manufacturing scale-up and other enabling activities for licensure of vaccine (PHFI)																																																											
8.2: Prepare for the distribution and uptake of already licensed vaccine(s) (PHFI)																																																											
8.3: Dissemination and exploitation of results (HZI, HVP Stichting, EVF)																																																											
8.4: Intellectual property management (HZI)																																																											
WP9 Ethics requirements (months 1-60)																																																											

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INCENTIVE - Dissemination

- Establishment of a project corporate identity image for INCENTIVE.
- Establishment and further development of an external website.
- Development and implementation of a communication plan.
- Regular project internal information exchange for knowledge, data and experience sharing.
- Wide dissemination of project results and for awareness creation, *e.g*. press releases, social media.
- Stakeholder meeting to increase awareness and establish a close dialog with relevant organizations.

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INCENTIVE - Exploitation

- Implementation of proactive IP rights strategy for protection and targeted exploitation of results.
- Generation of well-defined Target Vaccine Product Profile (TPP) to ensure swift movement in the clinical pipeline of novel vaccine candidates.
- Establishment of an Innovation Committee to maximize impact and optimal exploitation of data.
- Close interaction with the relevant regulatory authorities with the goal of rapid market authorization of the candidate vaccine after a successful phase II clinical trial.
- Optimal measures to provide open access to publications and data resulting from the project.

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Expected Outcomes

- Phase IV clinical trials in Europe and India to address current knowledge gaps in the field of underlying mechanisms of responsiveness to influenza vaccines in vulnerable individuals.

- Preclinical studies and a first-in-human phase 1 clinical trial in Europe and a phase 2 study in India, as well as efficacy studies using a controlled human challenge model of a Next Generation COBRA-derived innovative universal vaccine candidate.

- Tailoring of immune responses to vaccination by using an innovative mucosal adjuvant (c-di-AMP).

- Preclinical development of an innovative nucleic acid vaccine (APC-Mix).

- Identification of biomarkers for responsiveness to vaccination to develop new diagnostics.

- Health systems and investment analysis.

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INCENTIVE has the long term goal of contributing towards the reduction of the worldwide burden resulting from disease outbreaks, as well as fostering preparedness of the international community not only for seasonal influenza, but also future epidemics and pandemics…

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INCENTIVE – Horizon2020

Indo-European Consortium for Next Generation Influenza Vaccine Innovation

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H2020-SC1-2019-RTD

Grant Agreement Number 874866

Deliverable N°: D1.2

A PowerPoint presentation of the INCENTIVE project website

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

June 2021

Version 1

Main Author(s):

Blair Prochnow and Upneet Hillebrand – HZI, Germany

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

Deliverable title	**Project presentation prepared, website launched and communication plan developed**
Nature of Deliverable	**DEC=** Websites, patent fillings, videos etc.
Contractual date of delivery	Project Month N°11
Actual date of delivery	29/06/2021
Deliverable number	D1.2
Dissemination Level	**PU** = Public
Status & version	Final – version 1
WP of the deliverable	WP1
Lead Beneficiary	N° 1 - HZI
Main Author(s)	Blair Prochnow, Upneet Hillebrand (HZI, Germany) with input from Consortium members
Project coordinator (EU, USA) **Project coordinator (India)**	Prof. Carlos A. Guzmán, HZI, Germany Dr. Amulya Panda, NII, India
EC Project Officer	Oana Bodron

Table of Contents

1. INTRODUCTION 3

2. RESULTS 4

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)

1. Introduction

A website for INCENTIVE has been developed (available here: www.incentive-h2020.eu) and will be the main communication channel that provides up-to-date relevant information about the project to a wide audience. The INCENTIVE website will be updated regularly. The website displays the following information:

- **Objectives** – Here the main objectives and strategic goals of the INCENTIVE consortium will be displayed.
- **Consortium** – This page will provide a brief description of each project partner and their main project roles along with the respective logo and contact person. Clicking the organization's name will redirect the user to the official website of the project partners.
- **Results** – Publishable project results/reports/public deliverables as well as a link to the INCENTIVE Zenodo community https://zenodo.org/communities/incentive/
- **News** – News related to the project (this page will be frequently updated),
- **Contact** – Here the visitor can see contact information of the consortium coordinators and the project managers.
- **Impressum**
- **Data privacy statement**

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2. Results

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Objectives | Consortium | Results | News | Contact

INCENTIVE > Objectives

Objectives

The main strategic goal of the INCENTIVE project is to establish a cornerstone toward the development of next generation influenza vaccines to reduce the worldwide burden resulting from disease outbreaks.

© Adobe Stock / Leigh Prather

The highly integrated INCENTIVE consortium represents 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. 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 is achieved by pursing the following specific objectives: 1) address the current knowledge gap by performing comprehensive immunome profiling of responders and nonresponders 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 vaccines, including an antigen presenting cell-targeted nucleic acid vaccine up to proof-of-concept for vaccine efficacy in non-human primates, 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.

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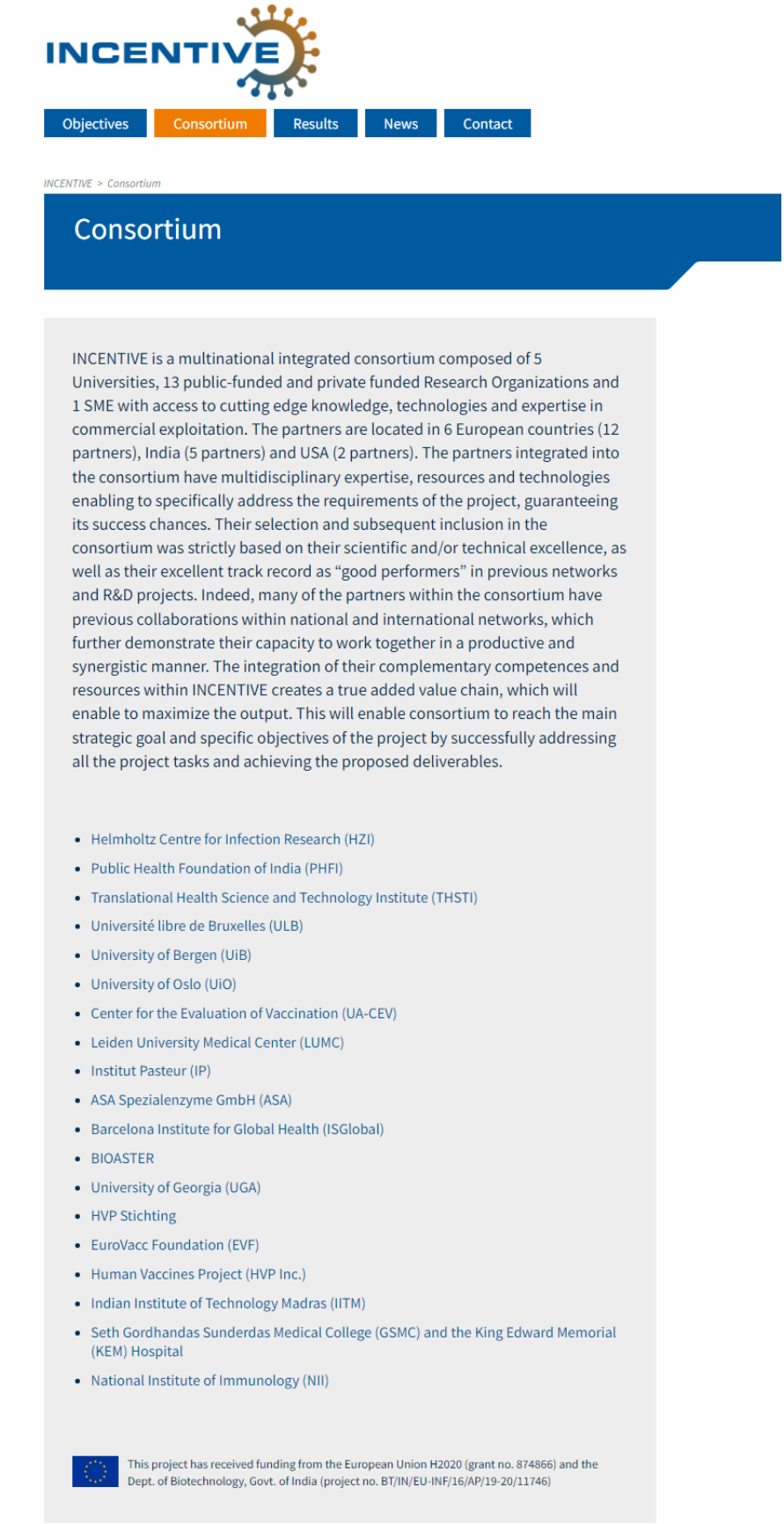

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Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium

Consortium

INCENTIVE is a multinational integrated consortium composed of 5 Universities, 13 public-funded and private funded Research Organizations and 1 SME with access to cutting edge knowledge, technologies and expertise in commercial exploitation. The partners are located in 6 European countries (12 partners), India (5 partners) and USA (2 partners). The partners integrated into the consortium have multidisciplinary expertise, resources and technologies enabling to specifically address the requirements of the project, guaranteeing its success chances. Their selection and subsequent inclusion in the consortium was strictly based on their scientific and/or technical excellence, as well as their excellent track record as "good performers" in previous networks and R&D projects. Indeed, many of the partners within the consortium have previous collaborations within national and international networks, which further demonstrate their capacity to work together in a productive and synergistic manner. The integration of their complementary competences and resources within INCENTIVE creates a true added value chain, which will enable to maximize the output. This will enable consortium to reach the main strategic goal and specific objectives of the project by successfully addressing all the project tasks and achieving the proposed deliverables.

- Helmholtz Centre for Infection Research (HZI)
- Public Health Foundation of India (PHFI)
- Translational Health Science and Technology Institute (THSTI)
- Université libre de Bruxelles (ULB)
- University of Bergen (UiB)
- University of Oslo (UiO)
- Center for the Evaluation of Vaccination (UA-CEV)
- Leiden University Medical Center (LUMC)
- Institut Pasteur (IP)
- ASA Spezialenzyme GmbH (ASA)
- Barcelona Institute for Global Health (ISGlobal)
- BIOASTER
- University of Georgia (UGA)
- HVP Stichting
- EuroVacc Foundation (EVF)
- Human Vaccines Project (HVP Inc.)
- Indian Institute of Technology Madras (IITM)
- Seth Gordhandas Sunderdas Medical College (GSMC) and the King Edward Memorial (KEM) Hospital
- National Institute of Immunology (NII)

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Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Helmholtz Centre for Infection Research (HZI)

Helmholtz Centre for Infection Research (HZI)

HELMHOLTZ ZENTRUM FÜR INFEKTIONSFORSCHUNG

The Helmholtz Centre for Infection Research (HZI) in Braunschweig is a publicly funded research centre with more than 800 employees and an annual budget of approximately 90 million Euros as well as an additional approximately 19 million Euros of external funds from national and international support programmes, and industry. The focus of its activities lies in the field of infection. The mission of the HZI is to rise to the societal challenges of infectious diseases by investigating their fundamental pathogenesis mechanisms, with the aim of deriving innovative approaches for their prevention, diagnosis and therapy. The HZI is also member of the German Centre for Infection Research (35 research institutions located at seven sites), with the managing office being located at the HZI campus.

Main roles in project

The HZI will be responsible for the overall coordination of the project. The HZI will also contribute to the scientific tasks by providing expertise and technologies in the fields of vaccinology, immunology and adjuvants. More specifically, the HZI will evaluate the safety, immunogenicity and protective efficacy of the experimental vaccine candidates against influenza in a preclinical setting in the model organism mouse. Furthermore, it will contribute to the evaluation of the immunogenicity of the vaccines, in terms of adaptive immune responses, in the phase I and IV clinical trials. The results gained from these comprehensive assessments together with correlation-analyses will allow a deep insight into phenotypic and functional immunological changes induced by the vaccine candidate, as well as the identification of putative biomarkers of responsiveness to vaccination.

Contact: Prof. Carlos A. Guzmán

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INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Public Health Foundation of India (PHFI)

Public Health Foundation of India (PHFI)

KNOWLEDGE TO ACTION phfi | PUBLIC HEALTH FOUNDATION OF INDIA

The Public Health Foundation of India (PHFI) is a public private initiative that has collaboratively evolved through consultations with multiple constituencies including Indian and international academia, state and central governments, multi & bi-lateral agencies and civil society groups. PHFI is a response to redress the limited institutional capacity in India for strengthening training, research and policy development in the area of Public Health. Structured as an independent foundation, PHFI adopts a broad, integrative approach to public health, tailoring its endeavours to Indian conditions and bearing relevance to countries facing similar challenges and concerns. The PHFI focuses on broad dimensions of public health that encompass promotive, preventive and therapeutic services, many of which are frequently lost sight of in policy planning as well as in popular understanding. PHFI recognizes the fact that meeting the shortfall of health professionals is imperative to a sustained and holistic response to the public health concerns in the country which in turn requires health care to be addressed not only from the scientific perspective of what works, but also from the social perspective of, who needs it the most.

Main roles in project

PHFI will lead work directed at incorporating the new influenza vaccine within the current public health system in India. Specifically, this will include two objectives: (i) Estimation of the theoretical demand for a new influenza vaccine, and (ii) Optimization/maximization of the efficiency and effectiveness of a stratified vaccination program. For the first objective, PHFI will assess the influenza disease burden and conduct a needs assessment. For accomplishing the second objective, PHFI will conduct a gap analysis of the current national immunization program for the incorporation of the new influenza vaccine. Furthermore, PHFI will also identify the potential enablers, barriers and challenges for the acceptance and community mobilization of the new influenza vaccine among the targeted beneficiaries. Any possible regulatory issues in the incorporation of the new influenza vaccine into the current national immunization program will also be identified. This will inform the process of development and implementation of a capacity-building program for the current health workforce to incorporate the new influenza vaccine. PHFI will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Dr. Sailesh Mohan

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Translational Health Science and Technology Institute (THSTI)

Translational Health Science and Technology Institute (THSTI)

thsti
ट्रांसलेशनल स्वास्थ्य विज्ञान एवं प्रौद्योगिकी संस्थान

The Translational Health Science and Technology Institute (THSTI), at the NCR-Biotech Science Cluster, Faridabad, is an autonomous institution of the Department of Biotechnology, Ministry of Science and Technology, Government of India. The institution was established in 2009 to facilitate the development, optimization and evaluation of technologies for public health. THSTI's Mission is to integrate the fields of medicine, science, engineering and technology into translational knowledge. THSTI aims to make the resulting biomedical innovations accessible to public health, to improve the health of the most disadvantaged people in India and throughout the world. THSTI is a collective of physicians and scientists who work to improve health in India by creation of new knowledge for innovation, development of innovative solutions based on existing knowledge, and new strategies for implementation of existing solutions. THSTI complements the discovery, design and development of interventions by building rigorous research capacity through high quality training

The immunobiology laboratory of the Translational Research Laboratory was established in 2012. The laboratory primarily carries out translational research in understanding the immunological basis of autoimmune and infectious diseases. In addition, the laboratory has successfully developed cellular assays that are critical in evaluating the immunogenicity of vaccines and vaccine candidates.

Main roles in project

THSTI will contribute to the evaluation of antibody and T cell responses induced following influenza vaccine immunization in clinical trial vaccines. THSTI will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Dr. Amit Awasthi

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)

INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Université libre de Bruxelles (ULB)

Université libre de Bruxelles (ULB)

ULB UNIVERSITÉ LIBRE DE BRUXELLES

Founded in 1834, Université libre de Bruxelles (ULB) has a long tradition of excellence in Research with four scientific Nobel Prizes, two Nobel Peace Prizes, one Fields Medal, three Wolf Prizes and two Marie Curie Excellence Awards. It is one of the largest and best Research Universities in Belgium, with a student population of 35,000 and with almost 2,000 PhD in progress distributed among 22 Doctoral schools. ULB has considerable experience with European funding programmes, being involved in more than 280 projects financed by both the 7th European Framework Programme and Horizon 2020, including 41 ERC grants and 83 MSCA grants.

Main roles in project

The Université libre de Bruxelles will coordinate the project's immune profiling in collaboration with TSHTI and will apply systems serology approach to characterize influenza vaccine responses. Furthermore, ULB will be responsible for conducting the proposed phase IV trial in infants. ULB will guide harmonization of clinical sample collection, storage and shipment, as well as work in close collaboration with the leaders of data management and data integration to ensure excellent data formatting, management and transfer for optimal data integration and analysis.ULB will actively participate in the transfer of technologies from the laboratories of immune profiling partners to the laboratory of THSTI. ULB will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Prof. Arnaud Marchant

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > University of Bergen (UiB)

University of Bergen (UiB)

UNIVERSITY OF BERGEN

The University of Bergen (UiB) is a modern research driven university with 16900 students and 3700 staff. The university comprises 7 faculties spanning 54 departments, institutes and interdisciplinary research centres. UiB is the most cited university in Norway. The Influenza Centre is situated in a state-of-the-art laboratory building, at the University of Bergen and Haukeland University Hospital with the vision of reducing the global burden of influenza illness through being an international leader in development of new and improved influenza vaccines. The Centre specializes in preclinical (immunogenicity and protective efficacy) studies and human clinical phase I-IV trials of new influenza vaccines under good clinical practice (GCP).

Main roles in project

The key competence of the Influenza Centre at the University of Bergen is human clinical trials of influenza and COVID-19 vaccines focusing on immunology particularly B- and T-cells. The University of Bergen will be responsible for conducting the proposed phase IV trial in young children and serological evaluation of vaccine responses. We will also be involved in technology transfer of serological assays to India.

Contacts: Prof. Rebecca Jane Cox and Prof. Karl Albert Brokstad

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > University of Oslo (UiO)

University of Oslo (UiO)

UNIVERSITY OF OSLO

The University of Oslo (UiO) was founded in 1811, and is Norway's largest public institution of research and higher education with 28 000 students and 6 600 employees. UiO is a classical university with excellent research in a broad range of academic fields. Its current strategic focus is on interdisciplinary research, particularly in the fields of energy and life sciences. With five Nobel Prize winners, UiO has a strong track record of pioneering research and scientific discovery. The UiO Faculty of Medicine has scientific employees within three institutes: Clinical Medicine, Basic Medical Sciences, and Health and Society. The Faculty has an extensive EU project portfolio with more than 50 awarded projects and 7 ERC awardees. The Faculty runs its second Marie Curie COFUND postdoctoral program, and has been awarded four National Centres of Excellence (two past, two ongoing). These Centres have a strategic focus on interdisciplinary research in the field of life sciences.

Main roles in project

INCENTIVE UiO partners Gunnveig Grødeland and Bjarne Bogen are located in the Department of Immunology and Transfusion Medicine, at the Institute of Clinical Medicine at the Faculty of Medicine, with access to state of the art laboratories and animal facilities. The Department is also intimately linked with the Oslo University Hospital, which is the largest hospital in Northern Europe. For INCENTIVE, we will contribute to development of novel vaccine formats that can offer broad protection against a variety of influenza subtypes. More specifically, we will use a mixture of influenza antigens for induction of immune responses towards conserved epitopes. To ensure vaccine efficacy, the antigens in the vaccine mixture will be targeted specifically to the most relevant receptors expressed on antigen presenting cells.

Contact: Dr. Gunnveig Grødeland

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Center for the Evaluation of Vaccination (UA-CEV)

Center for the Evaluation of Vaccination (UA-CEV)

Centre for the Evaluation of Vaccination
Vaccine & Infectious Disease Institute
University of Antwerp

The Center for the Evaluation of Vaccination (UA-CEV) of the University of Antwerp, headed by Prof. Pierre Van Damme, was founded in 1994. It has until present conducted more than 450 vaccine trials (phase 1-4) with a variety of vaccines and in all age groups. Furthermore, CEV has conducted more than 60 policy research projects related to vaccination. It has published more than 500 peer reviewed papers. The Center has been recognised by the World Health Organization as a WHO Collaborating Center for the control and prevention of viral hepatitis and more recently for the control and prevention of infectious diseases. CEV provides state-of-the-art infrastructure for the conduct of vaccine studies. The research mission of CEV is to improve knowledge on all aspects of vaccination (including education) and to support vaccination policy making.

Main roles in project

The Center will be responsible for the conduct of a first in man trial to establish the safety and immune profile of the experimental COBRA vaccine. In addition, the Center will participate in the conduct of a phase IV trial to test the seasonal flu vaccine in vulnerable patients (elderly). CEV will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Prof. Pierre Van Damme

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Leiden University Medical Center (LUMC)

Leiden University Medical Center (LUMC)

LUMC Leiden University Medical Center

The Leiden University Medical Center (LUMC) is a modern university medical centre for research, education and patient care with a high quality clinical profile and a strong scientific orientation. Its unique research practice, ranging from pure fundamental medical research to applied clinical research, places LUMC among the world top. This enables LUMC to offer patient care and education that is in line with the latest international insights and standards – and helps it to improve medicine and healthcare both internally and externally.

Within the LUMC, the Controlled Human Infections Centre (CHIC), headed by Prof. Meta Roestenberg, is taking the lead on developing and exploiting human challenge trials for the development of novel vaccines and medicine for public health. Inpatient clinical trials of the CHIC are performed in collaboration with the Center for Human Drug Research (CHDR), where single-room beds are available for challenge studies. CHDR is located opposite the LUMC facility and former LUMC spin-out, which specializes in innovative early-stage clinical drug research.

Main roles in project

LUMC will be responsible for establishing the influenza controlled human infection model with new viral strains provided by the NIH (USA). Subsequently, LUMC will test the preliminary efficacy of the selected COBRA vaccine candidate in healthy Dutch adults in a phase I challenge trial. The LUMC can build on the experience from the CHIC (located within LUMC) and the CHDR (located opposite the LUMC) with which it collaborates closely.

Contact: Prof. Meta Roestenberg

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Institut Pasteur (IP)

Institut Pasteur (IP)

INSTITUT PASTEUR

The Institut Pasteur (IP) is an internationally renowned centre for biomedical research with a network of 33 institutes worldwide. Institut Pasteur operates in four main areas: scientific and medical research, public health and health monitoring, teaching, business development and technology transfer. The Institut Pasteur is a global leader in infectious diseases, microbiology, and immunology with the goal to expand our knowledge of living organisms in a bid to lay the foundation for new prevention strategies and novel therapeutics. Since its inception, 10 scientists have been awarded the Nobel Prize for Medicine, and play a major role in activities that directly benefit patients.

Darragh Duffy leads the Translational Immunology Lab within the Immunology Department that aims to better understand inter-individual differences in immune responses, and apply these discoveries to relevant clinical questions. They use cellular mechanistic models, population immunology cohorts, and experimental clinical studies in infection and autoimmunity and work closely with clinicians to help develop new patient management systems. This laboratory has also played a leading role in the establishment of the LabEx Milieu Intérieur project, which has provided an initial assessment of healthy donor reference values for microbe-induced cytokines and chemokines and quantified the major genetic and intrinsic contributors to immune response variability. This laboratory is now focused on the deconvolution of the healthy immune response, and applying these approaches for a better understanding of perturbed immune responses in infection, autoimmunity and variable responses to immunotherapy and vaccination.

Main roles in project

Our main task will be to implement standardized immune monitoring strategies to deeply characterize baseline immune responses and test the hypothesis that induced immune responses prior to vaccination can be used to model and ultimately predict vaccine responsiveness.

Contact: Dr. Darragh Duffy

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > ASA Spezialenzyme GmbH (ASA)

ASA Spezialenzyme GmbH (ASA)

The business activities of ASA Spezialenzyme GmbH (ASA) are the development and production of enzymes, microbial mixed cultures and other biotechnological products. The product range covers the fields of application food and feed processing, pharmaceutical enzymes organic synthesis, analytics, biosensors, bioenergy, textile industry and paper industry. Furthermore, ASA is offering services as contract research and contract manufacturing. Since the foundation in the year 1991, several research projects were carried out in the area of enzymatic conversion of ingredients for food applications, pharmaceutical purposes and renewable raw materials resulting in new marketable products.

Main roles in project

ASA will develop stable liquid adjuvant formulations. For this purpose a sterile filling process has to be implemented and validated. Furthermore, a product specification has to be compiled consisting of analytical techiques according to GMP. The stability of the resulting formulation will be evaluated by long term trials at different storage temperatures. Finally, ASA will be responsible for the production and filling of GMP-grade c-di-AMP to be used in the GLP-tox studies, animal trials and human challenge studies. ASA will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Dr. Arno Cordes

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Barcelona Institute for Global Health (ISGlobal)

Barcelona Institute for Global Health (ISGlobal)

ISGlobal Barcelona Institute for Global Health

The Barcelona Institute for Global Health (ISGlobal) is the fruit of an innovative alliance between the "la Caixa" Foundation, academic institutions and government bodies to contribute to the efforts undertaken by the international community to address the challenges in global health.

ISGlobal is a consolidated hub of excellence in research that has grown out of work first started in the world of health care by the Hospital Clínic and the Parc de Salut MAR and in the academic sphere by the University of Barcelona and Pompeu Fabra University. The pivotal mechanism of its work model is the transfer of knowledge generated by scientific research to practice, a task undertaken by the institute's Education and Policy and Global Development departments. Its ultimate goal is to help close the gaps in health disparities between and within different regions of the world.

Main roles in project

Carlota Dobaño is a Research Professor (Vaccinology Module) and head of the *Malaria* Immunology Group at ISGlobal. Her group aims at in-depth immune profiling of influenza-vaccinated subjects across diverse European and Indian populations to guide the development of next-generation vaccines. The group aims at understanding the antibody response to influenza antigens in the vaccine trials of European cohorts. Her group is also leading the work package -Partnership building, knowledge, technology transfer- aimed at coordinating technology transfer and standardisation to strengthening the partnership between European and Indian partners.

Elisa Sicuri is Assistant Research Professor at ISGlobal. Her specific task involves eliciting preferences for influenza vaccines and vaccinations with the aim of exploring a theoretical demand in Europe and India. To do so, a discrete choice experiment (DCE) will be performed in India among trial participants and among a sub-sample of a large general population cohort. In Europe, selected key questions will be asked to trial participants with the additional aim of eliciting potential trade-offs between influenza and COVID-19 vaccines. The same selected questions will be asked in India aiming for a pooled analysis.

Contacts: Prof. Carlota Dobaño and Prof. Elisa Sicuri

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > BIOASTER

BIOASTER

BIOASTER MICROBIOLOGY TECHNOLOGY INSTITUTE

Created in 2012, following the French initiative of Technology Research Institutes, BIOASTER is a non-for-profit foundation developing a unique technological and innovative model to support the latest challenges in microbiology. In particular, BIOASTER uses and develops high value technological innovations that accelerate development of medical solutions for populations and personalized medicine. The aim of BIOASTER is to bring together academic, industry and its capacities and specific knowledge to develop and execute high impact collaborative projects requiring industry compatible innovative technologies.

Key figures:

4 fields of expertise:

- antimicrobials, diagnostics, microbiota, vaccines
- BSL2 & BSL3 laboratories in Lyon and Paris
- 100+ employees, including 80% of scientific experts, 17 nationalities
- 250+ research contracts, involving 93 private partners, 54 public partners.

Main roles in project

BIOASTER will be in charge of generating whole blood transcriptome profiles at baseline and at an early time point after influenza immunization on all subjects enrolled in clinical cohorts in Europe and India. Exploratory plasma proteome and metabolome profiling will be initially performed at baseline on subsets of high and low responders from each clinical cohort.

Contact: Laurent Beloeil

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > University of Georgia (UGA)

University of Georgia (UGA)

UNIVERSITY OF GEORGIA

The University of Georgia (UGA) is the oldest state-chartered institution of higher education in the United States. Spanning more than 750 acres on its main campus alone and employing almost 3,000 faculty members, UGA provides educational and research services to almost 35,000 individuals, including over 8,000 doctoral and professional students. With an annual budget in excess of $1.4 billion, annual externally sponsored research expenditures in excess of $200 million, and NIH awards totaling more than $60 million annually, UGA's 17 colleges offer doctoral degrees in 96 areas spanning the liberal arts and humanities; business; journalism; public affairs; law, education, and social work; and include science-based colleges for veterinary medicine, ecology (the first stand-alone college of its type in the world), public health, pharmacy, engineering, and agriculture. The first cohort of medical students was admitted in 2010 to the Augusta University/UGA Medical Partnership, sharing the site of the former Navy Supply Corps School with UGA's College of Public Health in Athens, GA.

The University of Georgia Research Foundation, Inc. (UGARF) performs two primary functions in support of the research enterprise at the University of Georgia. UGARF is the named party to sponsored research agreements for projects to be performed at UGA. UGARF also owns the patents and other intellectual property developed at UGA. Through Innovation Gateway, UGARF protects, markets, and licenses its intellectual property portfolio throughout Georgia and the U.S. and across the globe. Funds acquired by UGARF are reinvested in the UGA research enterprise.

Main roles in project

UGARF will 1) design recombinant HA and NA vaccine antigen candidates, 2) produce the vaccine sequences for the preclinical validation in mice and ferrets of immunogenicity and the efficacy studies against different strains of influenza virus, 3) be responsible for the validation studies in ferrets, 4) transfer the critical technology for the production of the recombinant HA and NA antigens to the CRO selected for GMP manufacturing and 5) provide antigens for the immune monitoring following vaccination.

Contact: Prof. Ted Ross

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > HVP Stichting

HVP Stichting

HUMAN VACCINES PROJECT

The HVP Stichting aims to contribute to the acceleration of the development of vaccines and immunotherapies to prevent and treat important diseases. The contribution of HVP Stichting focuses in particular, but not exclusively, on outreach, advocacy, fundraising and bringing together European research organizations and companies in order to shape and strengthen the European contribution to the global research program. The foundation aims to achieve its goal by:

- Establishing a network of leading European centres for human immunology and vaccination and connect them to the global Human Vaccines Project Inc.
- Generating public sector, private sector and philanthropic financial support.

Main roles in project

HVP Stichting will assess the feasibility and suitability of developed technologies to be implemented in national vaccination programs by organizing expert / stakeholder meetings in Europe. We will also deliver a European Dissemination and Exploitation Plan outlining the plans to further utilize the project's results. Furthermore, HVP Stichting will contribute to the management and coordination of the consortium as a work package leader.

Contact: Dr. Frans van den Boom

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > EuroVacc Foundation (EVF)

EuroVacc Foundation (EVF)

EUROVACC FOUNDATION

The EuroVacc Foundation (EVF), created in 2002, is a non-profit organization dedicated to develop vaccines against infectious diseases and to promote worldwide accessibility to these vaccines. EVF's core activity is to facilitate the development of vaccine candidates through early clinical trials, to enable early identification of the promising vaccine candidates and eliminate candidates unlikely to succeed in the clinic, with the ultimate goal to reduce the development risks and accelerate the advancement of the promising candidates to large clinical trials.

Main roles in project

EVF will provide scientific project management support to the project coordinator, with the focus on clinical trial and product development related activities.

Contact: Dr. Song Ding

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Human Vaccines Project (HVP Inc.)

Human Vaccines Project (HVP Inc.)

HUMAN VACCINES PROJECT

The Human Vaccines Project (HVP Inc.) is a global non-profit comprised of leading stakeholders from academia, industry, and government institutions who work together to accelerate the development of vaccines and immunotherapies against major global diseases and cancer by decoding the human immune system. Operating under a consortium model, the HVP network consists of leading university and academic research centres that serve as scientific hubs. These hubs work collaboratively to investigate the underlying mechanisms responsible for differences in vaccine responsiveness and vaccine efficacy in populations around the world.

The scientific activities of the HVP network include, (i) conducting multicentre international vaccine clinical trials aimed at elucidating the underlying immune mechanisms responsible for vaccine protection following a single-dose, (ii) using a systems immunology approach and the integration of data across multiple datasets to identify host signatures prior to immunization that correlate with subsequent measurements of vaccine efficacy, (iii) conducting a comprehensive systems analysis of host factors, including prior influenza exposures, that influence protective immune responsiveness to a quadrivalent seasonal influenza vaccine, and (iv) developing novel bioinformatic tools to allow for enhanced machine learning and artificial intelligence approaches to elucidate a more comprehensive understanding of the human immune system.

Main roles in project

HVP Inc. will collaborate to establish the central data warehouses in Europe and in India. We will conduct the data analysis and integration for the phase IV trials of seasonal influenza vaccines in vulnerable populations (Europe) COBRA vaccine trials, as well as for the phase I trial and the Human Challenge Study (Europe). We will also ensure that all required immune response and meta data generated from these trials is deposited into the Europe data warehouse. We will then conduct data integration and a comprehensive immune biomarker analysis for biomarker identification. HVP Inc. will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Dr. Wayne C. Koff

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)

INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Indian Institute of Technology Madras (IITM)

Indian Institute of Technology Madras (IITM)

Established in 1956, the Indian Institute of Technology Madras (IITM), an Institute of Eminence, is known both nationally and internationally for excellence in technical education, basic and applied research, innovation, entrepreneurship and industrial consultancy. IIT Madras has been the top-ranked engineering university in India for the past 5 years. The Centre for Integrative Biology and Systems medicinE (IBSE) at IIT Madras is a vibrant interdisciplinary group comprising faculty and students from Biotechnology, Computer Science and Chemical Engineering departments. By applying tools from various engineering domains, we investigate exciting biological questions emerging from the massive amounts of biological and clinical data being currently generated. Our broad areas of research have application to the bioprocess and pharma industries, medicine and healthcare. IBSE is also an integral part of the Robert Bosch Centre for Data Science and Artificial Intelligence (RBCDSAI) at IIT Madras. RBCDSAI comprises faculty from several departments across the Institute, with research in various areas of data science and artificial intelligence. RBCDSAI is pre-eminent interdisciplinary research centre for Data Science and AI in India with the largest network analytics, deep reinforcement learning, and the most active natural language processing and deep learning groups.

Main roles in project

IITM will establish and manage the data warehouse in India for all data generated in India with harmonised and standardised data curation and analysis methods across India and EU. We will perform integrated analysis of immunological data generated from the INCENTIVE-QIV trials and from the 3 trials on the COBRA vaccines in different populations in India. We will retrieve all the required immune response, conventional and systems serology, T, and B and immune cell analyses, and metadata generated including transcriptome, proteome, and metabolome data for in-depth immunological and integrated statistical analysis to identify immune biomarkers of responders versus non-responders to inform future vaccine design and to establish immunogenicity profile of COBRA vaccines for the Indian population. IITM will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Prof. Himanshu Sinha

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > Seth Gordhandas Sunderdas Medical College (GSMC) and the King Edward Memorial (KEM) Hospital

Seth Gordhandas Sunderdas Medical College (GSMC) and the King Edward Memorial (KEM) Hospital

Founded in 1926, the Seth Gordhandas Sunderdas Medical College (GSMC) and the King Edward Memorial (KEM) Hospital are amongst the foremost teaching and medical care providing institutions in India. The medical college (school) provides training to about 2000 students in undergraduate, postgraduate and super-speciality medical courses; in undergraduate and postgraduate physical and occupational therapy; and Masters and PhD courses in various allied specialties. A nursing school is also maintained by these institutions. With about 390 staff physicians and 550 resident doctors, the 1800 bedded hospital treats about 1.8 million out-patients and 85,000 in-patients annually and provides both basic care and advanced treatment facilities in all fields of medicine and surgery. Funded mainly by the Municipal Corporation of Greater Mumbai, these institutions render yeomen service – virtually free of cost – mostly to the underprivileged sections of the society.

Main roles in project

We will conduct phase IV clinical research studies using an already marketed quadrivalent influenza vaccine (QIV) in elderly (QIV-1 study) and in infants/children (QIV-2 study). At a later stage, once the phase I trial of COBRA vaccine is completed in Europe, we will be conducting the phase II COBRA vaccine study in India. The biological samples collected during these studies will be used by our laboratory partners within the consortium to compare the immune profiling between the QIV and COBRA vaccine. GSMC & KEM will also contribute to the management and coordination of the consortium as a work package leader.

Contact: Dr. Nithya Gogtay

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Consortium > National Institute of Immunology (NII)

National Institute of Immunology (NII)

National Institute of Immunology

The National Institute of Immunology (NII) is committed to advanced research addressing the basic mechanisms involved in the body's defence to identify modalities for manipulation of the immune system to provide protection against diseases and understand mechanisms that can be used to target disease processes for intervention. The institute's research thrust areas under immunology and related disciplines cluster in four main themes, namely, infection and immunity, molecular design, gene regulation and reproduction and development, where cutting edge research in modern biology is being carried out.

Main roles in project:

NII will contribute to the management and coordination of the consortium as the Indian Scientific Lead. This will be further supported by the NII Primate Research Centre (PRC), administrative section, accounts section and legal support. We at NII will take the lead and oversee the GMP manufacturing of the COBRA vaccine, oversee the GLP toxicity study of the COBRA vaccine and conduct immunogenicity and challenge studies in NHP with the COBRA and APC-MIX vaccines.

Contact: Dr. Prafullakumar Tailor

This project has received funding from the European Union H2020 (grant no. 874866) and the Dept. of Biotechnology, Govt. of India (project no. BT/IN/EU-INF/16/AP/19-20/11746)

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INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > News

News

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INCENTIVE Kick-off Meeting (24th March, 2020)
The INCENTIVE consortium conducted its online kick-off meeting on March 24th, 2020. This meeting was an opportunity for all partners to get to know each other better and the agenda included introductory presentations of project related topics and work packages.

INCENTIVE Zenodo Community
On March 27th, 2021 the project established a Zenodo Community for providing open access to the project's results.
https://zenodo.org/communities/incentive/

INCENTIVE Annual Consortium Meeting (12th May, 2021)
The virtual annual consortium meeting took place on May 12th, 2021. The agenda included an overview of the results obtained so far by the project partners as well as discussion of plans for the next 6-12 months. Three members of the INCENTIVE Scientific and Ethical Advisory board (SEAB), namely Prof. N. K. Ganguly, Dr. B. Sesikeran and Prof. David Smith, also attended this virtual meeting.

INCENTIVE Scientific and Ethical Advisory Board
The Scientific and Ethical Advisory Board (SEAB) is a consultative body composed of international interdisciplinary experts whose role is to provide external review and monitoring on the conduct the project to achieve a maximum impact in scientific, technological and health terms, as well as in compliance to the highest ethical standard. Find here the current members of the INCENTIVE SEAB.

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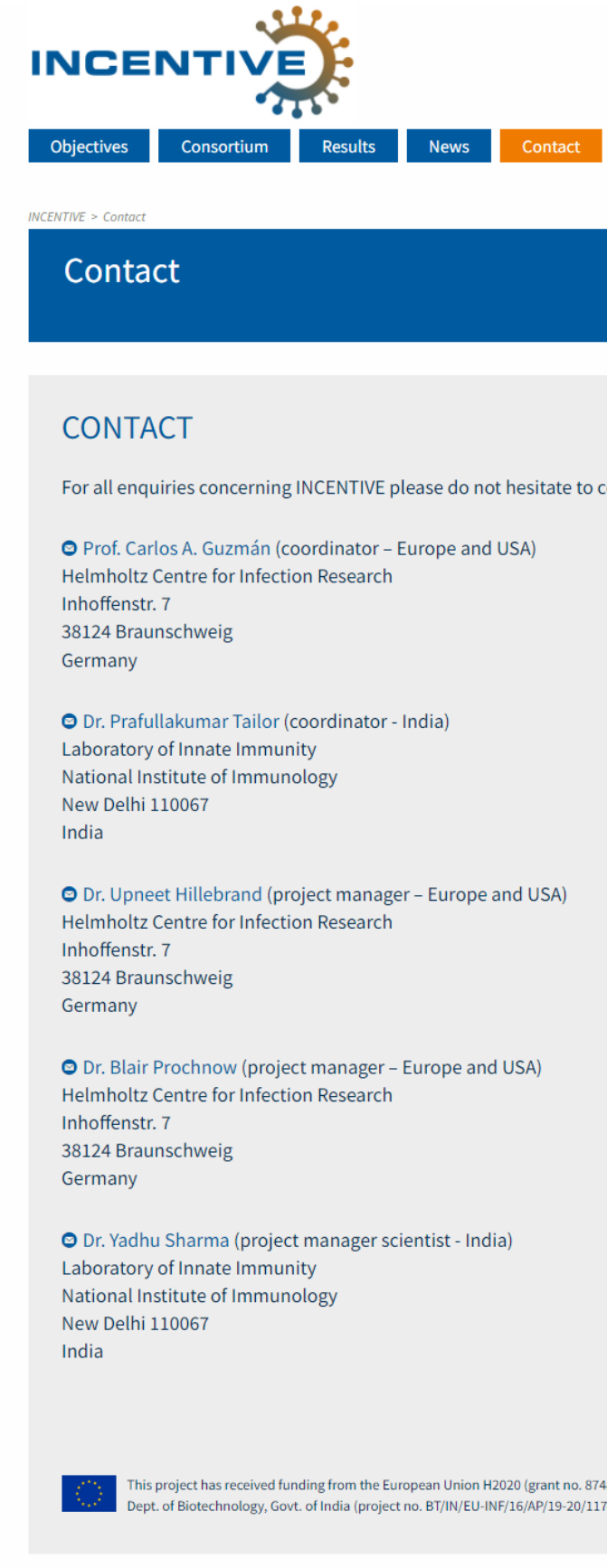

INCENTIVE

Objectives Consortium Results News Contact

INCENTIVE > Contact

Contact

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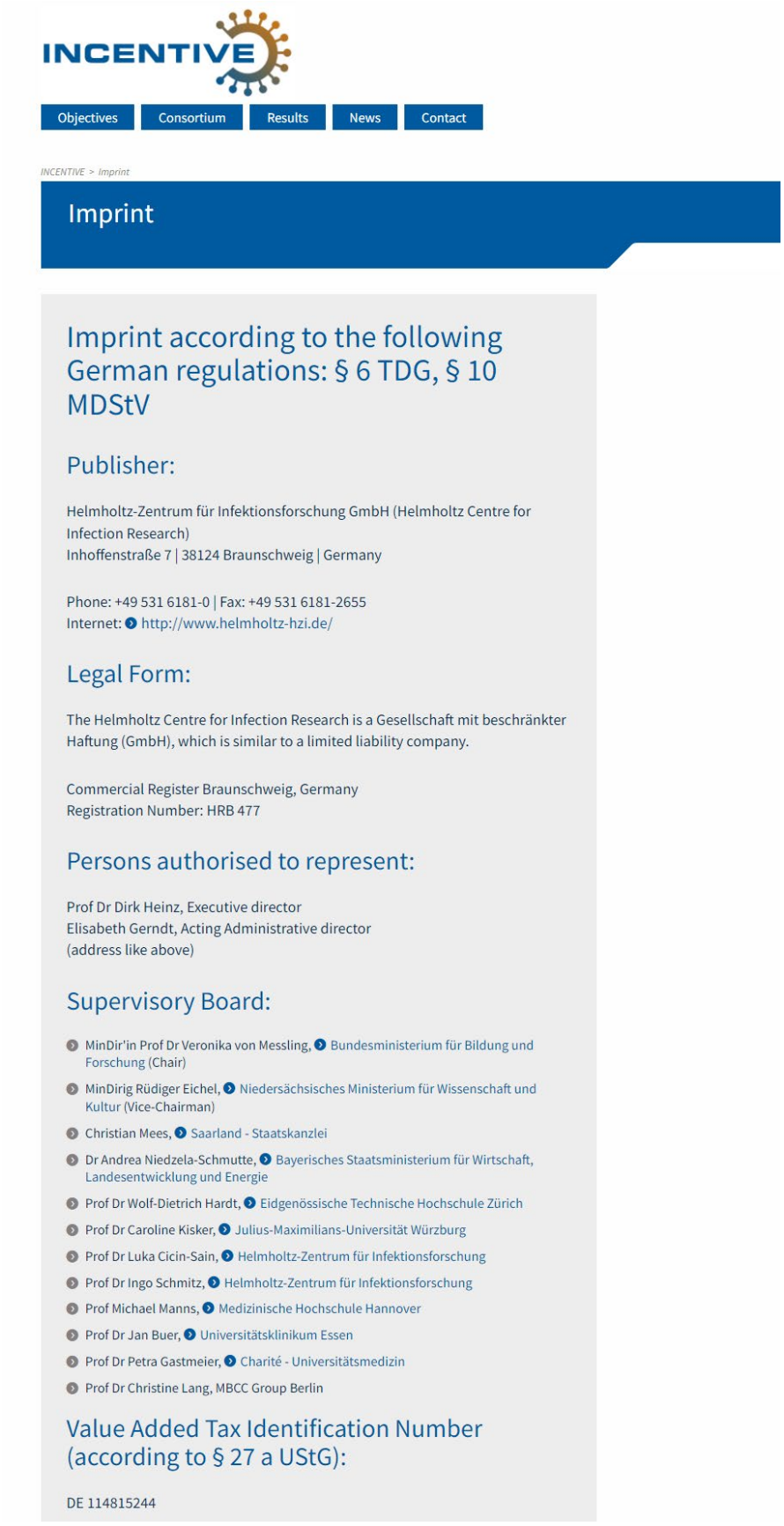

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Objectives | Consortium | Results | News | Contact

INCENTIVE > Imprint

Imprint

Imprint according to the following German regulations: § 6 TDG, § 10 MDStV

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Helmholtz-Zentrum für Infektionsforschung GmbH (Helmholtz Centre for Infection Research)
Inhoffenstraße 7 | 38124 Braunschweig | Germany

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Internet: http://www.helmholtz-hzi.de/

Legal Form:

The Helmholtz Centre for Infection Research is a Gesellschaft mit beschränkter Haftung (GmbH), which is similar to a limited liability company.

Commercial Register Braunschweig, Germany
Registration Number: HRB 477

Persons authorised to represent:

Prof Dr Dirk Heinz, Executive director
Elisabeth Gerndt, Acting Administrative director
(address like above)

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- MinDirig Rüdiger Eichel, Niedersächsisches Ministerium für Wissenschaft und Kultur (Vice-Chairman)
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Value Added Tax Identification Number (according to § 27 a UStG):

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Phone: +49 531 6181-0 | Fax: +49 531 6181-1499

Corporate Governance:

The Helmholtz Centre for Infection Research GmbH submits to the "Public Corporate Governance Code (PCGC)" of the federal government according to the memorandum of association. The Code recommends that the management and the supervisory board reports on the Company's corporate governance (Corporate Governance Report) on an annual basis.

The report refers to the PCGK as constituted on 30th of June 2009. Management and Supervisory Board declare that the recommendations of the Code are being complied essentially and will, deviations are explained in the respective report.

The Management Board and Supervisory Board declare that the Federal Public Corporate Governance Code as amended on 30 June 2009 has been complied with with reasonable deviations from the prescribed recommendations.

- PCGK-Report 2011
- PCGK-Report 2012
- PCGK-Report 2013
- PCGK-Report 2014
- PCGK-Report 2015
- PCGK-Bericht 2016
- PCGK-Bericht 2017

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The data in this imprint is exclusively intended for getting in contact with us regarding content and legal issues. Any use of this data for advertisement is strictly prohibited.

Implementation Partner:

- Bitmotion GmbH, Hanover. Bitmotion is TYPO3 Agency Business Partner and TYPO3 Association GOLD Member.

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INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Sitemap

Sitemap

- Objectives
- Consortium
  - Helmholtz Centre for Infection Research (HZI)
  - Public Health Foundation of India (PHFI)
  - Translational Health Science and Technology Institute (THSTI)
  - Université libre de Bruxelles (ULB)
  - University of Bergen (UiB)
  - University of Oslo (UiO)
  - Center for the Evaluation of Vaccination (UA-CEV)
  - Leiden University Medical Center (LUMC)
  - Institut Pasteur (IP)
  - ASA Spezialenzyme GmbH (ASA)
  - Barcelona Institute for Global Health (ISGlobal)
  - BIOASTER
  - University of Georgia (UGA)
  - HVP Stichting
  - EuroVacc Foundation (EVF)
  - Human Vaccines Project (HVP Inc.)
  - Indian Institute of Technology Madras (IITM)
  - Seth Gordhandas Sunderdas Medical College (GSMC) and the King Edward Memorial (KEM) Hospital
  - National Institute of Immunology (NII)
- Results
- News
- Contact

HEADQUARTER

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info@helmholtz-hzi.de

© 2022 HELMHOLTZ CENTRE FOR INFECTION RESEARCH | IMPRINT | SITEMAP | DATA PRIVACY STATEMENT

MEMBER OF HELMHOLTZ SPITZENFORSCHUNG FÜR GROSSE HERAUSFORDERUNGEN

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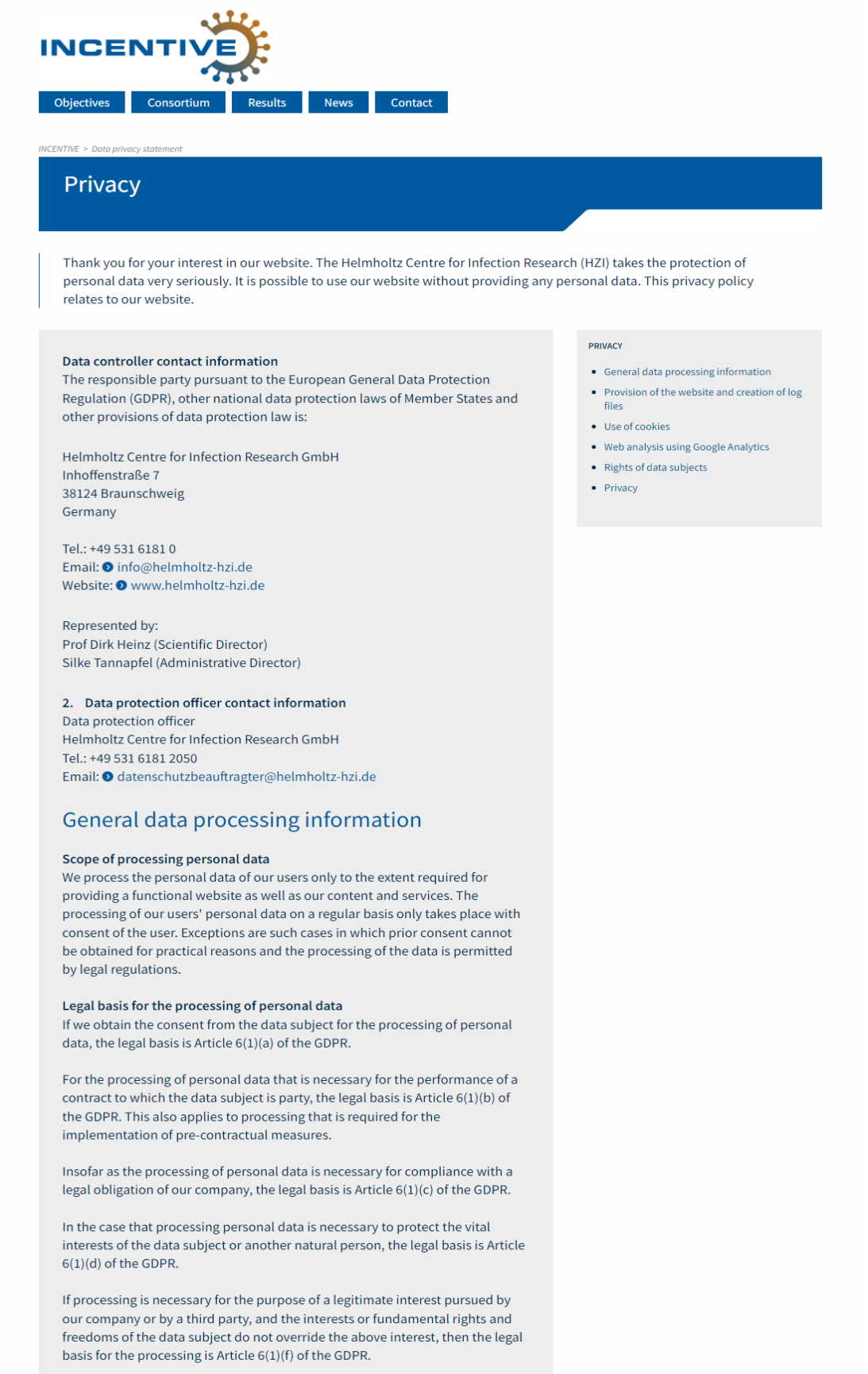

INCENTIVE

Objectives | Consortium | Results | News | Contact

INCENTIVE > Data privacy statement

Privacy

Thank you for your interest in our website. The Helmholtz Centre for Infection Research (HZI) takes the protection of personal data very seriously. It is possible to use our website without providing any personal data. This privacy policy relates to our website.

Data controller contact information
The responsible party pursuant to the European General Data Protection Regulation (GDPR), other national data protection laws of Member States and other provisions of data protection law is:

Helmholtz Centre for Infection Research GmbH
Inhoffenstraße 7
38124 Braunschweig
Germany

Tel.: +49 531 6181 0
Email: info@helmholtz-hzi.de
Website: www.helmholtz-hzi.de

Represented by:
Prof Dirk Heinz (Scientific Director)
Silke Tannapfel (Administrative Director)

2. Data protection officer contact information
Data protection officer
Helmholtz Centre for Infection Research GmbH
Tel.: +49 531 6181 2050
Email: datenschutzbeauftragter@helmholtz-hzi.de

PRIVACY

- General data processing information
- Provision of the website and creation of log files
- Use of cookies
- Web analysis using Google Analytics
- Rights of data subjects
- Privacy

General data processing information

Scope of processing personal data
We process the personal data of our users only to the extent required for providing a functional website as well as our content and services. The processing of our users' personal data on a regular basis only takes place with consent of the user. Exceptions are such cases in which prior consent cannot be obtained for practical reasons and the processing of the data is permitted by legal regulations.

Legal basis for the processing of personal data
If we obtain the consent from the data subject for the processing of personal data, the legal basis is Article 6(1)(a) of the GDPR.

For the processing of personal data that is necessary for the performance of a contract to which the data subject is party, the legal basis is Article 6(1)(b) of the GDPR. This also applies to processing that is required for the implementation of pre-contractual measures.

Insofar as the processing of personal data is necessary for compliance with a legal obligation of our company, the legal basis is Article 6(1)(c) of the GDPR.

In the case that processing personal data is necessary to protect the vital interests of the data subject or another natural person, the legal basis is Article 6(1)(d) of the GDPR.

If processing is necessary for the purpose of a legitimate interest pursued by our company or by a third party, and the interests or fundamental rights and freedoms of the data subject do not override the above interest, then the legal basis for the processing is Article 6(1)(f) of the GDPR.

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Data erasure and storage period
The personal data of the data subject is erased or blocked as soon as the purpose of the storage no longer applies. Storage beyond this point may take place if it is required by European or national legislation through Union regulations, laws or other directives with which the controller must comply. The data is also blocked or erased when a storage period prescribed by the aforementioned standards expires, unless further storage of the data is necessary for conclusion or performance of a contract.

Provision of the website and creation of log files

Description and scope of data processing
Upon each visit to our website, our system automatically collects data and information from the system of the visiting computer. The following data is collected:

1. Information about the browser type and version
2. The operating system of the user
3. The Internet service provider of the user
4. The IP address of the user
5. Date and time of access
6. Websites from which the user's system accesses our website
7. Websites accessed by the user's system through our website

The data is also stored in the log files of our system. This data is not stored together with other personal data of the user.

Legal basis for data processing
The legal basis for the temporary storage of the data and log files is Article 6(1) (f) of the GDPR (legitimate interest).

Purpose of data processing
The temporary storage of the IP address by the system is necessary to enable delivery of the website to the user's PC. The IP address of the user must remain stored for the duration of the session.
Storage in the log files is necessary to ensure the functionality of the website. This data is also used to optimise the website and to ensure the security of our information technology systems. The data is not evaluated for marketing purposes in this context.

These purposes also constitute our legitimate interest in data processing pursuant to Article 6(1)(f) of the GDPR.

Storage period
Data is deleted as soon as it is no longer required for achieving the purpose for which it was collected. In the case of data collection for provision of the website, this is done when the respective session ends.

If the data is stored in log files, this is done after seven days at the latest. Extended storage is possible. In this case, the IP addresses of the users are erased or modified so that these cannot be assigned to the client that accessed the site.

Objection and removal option
Collection of the data for provision of the website and the storage of data in log files is mandatory for the operation of the website. Therefore, the user does not have the option of objecting.

Use of cookies

Description and scope of data processing
Our website uses cookies. Cookies are text files that are stored in the Internet browser or by the Internet browser on the user's computer system. If a user accesses a website, a cookie can be stored on the user's operating system. This cookie contains a characteristic string of characters that allows for the clear identification of the browser when the website is accessed again.

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We use cookies to make our website more user-friendly. Some elements of our website require the accessing browser to continue to be identified after switching to another page.

The following data is stored in and transmitted by the cookies:

1. Language settings
2. Login information

We also use cookies on our website that enable us to analyse users' surfing behaviour.

The user data collected in this manner is anonymised through technological measures. This ensures that it is no longer possible to assign the data to the user who accessed the site. The data is not stored together with any other personal data of the users.

When visiting our website, users are informed about the use of cookies for analytical purposes and their consent is obtained for the processing of the personal data used in this context. This also includes a reference to this privacy policy.

Legal basis for data processing
The legal basis for the processing of personal data using cookies that are technically necessary is Article 6(1)(f) of the GDPR (legitimate interest).

The legal basis for the processing of personal data using cookies for analytical purposes is the consent of the user pursuant to Article 6(1)(a) of the GDPR.

Purpose of data processing
The purpose of using technically necessary cookies is to simplify the use of websites for users. Some functions of our website cannot be offered without the use of cookies. For these functions, it is necessary that the browser is recognised even after switching pages.

We require cookies for the following applications:

1. Adopting language settings

The user data collected by the technically necessary cookies is not used to create user profiles. The analysis cookies are used for the purpose of improving the quality of our website and its contents. The analysis cookies provide information about how the website is used, allowing us to continually optimise our site.

These purposes also constitute our legitimate interest in processing the personal data pursuant to Article 6(1)(f) of the GDPR.

Storage period, objection and removal option
Cookies are stored on the user's computer and transmitted from there to our website. This means that you, as the user, also have full control over the use of cookies. You can deactivate or restrict the transmission of cookies by changing the settings in your Internet browser. Previously stored cookies can be deleted at any time. This can also take place automatically. If cookies are deactivated for our website, it is possible that the full functionality of the website may not be available.

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Web analysis using Google Analytics

Description and scope of data processing
We use Google Analytics to analyse use of our website. The resulting data is used to optimise our website and advertising activities.

Google Analytics is a web analytics service operated and provided by Google Inc. (1600 Amphitheatre Parkway, Mountain View, CA 94043, United States). Google processes data on website usage on our behalf and is contractually bound to take measures to ensure the confidentiality of the processed data.

During your visit to our website the following data, inter alia, is recorded:

1. Pages visited
2. Your behaviour while viewing these pages (for example, clicks, scrolling, length of visit)
3. Your general location (country and city)
4. Your IP address (in shortened form, meaning that no direct assignment is possible)
5. Technical information, such as browser, Internet provider, end device and screen resolution
6. Source of your visit (i.e. the website or advertising medium through which you accessed our website)

This data is transferred to a Google server in the USA. Google complies with the privacy provisions of the EU-US Privacy Shield.

Legal basis for data processing
The legal basis for the processing of the data is Article 6(1)(f) of the GDPR (legitimate interest).

Purpose of data processing
Processing users' personal data enables us to analyse the surfing behaviour of our visitors, and evaluating the data we acquire enables us to gather information regarding the use of the individual components of our website. This helps us to continually improve our website and its user-friendliness. These purposes also constitute our legitimate interest in processing the data pursuant to Article 6(1)(f) of the GDPR. Anonymising the IP address sufficiently takes into account the users' interest in the protection of their personal data.

Storage period
Google Analytics stores cookies in your Internet browser for a period of two years after your last visit. These cookies contain a randomly generated user ID that can be used to recognise you on future visits to the website.

The recorded data is stored together with this randomly generated user ID, which enables the evaluation of anonymous user profiles. This user-related data is automatically deleted after 14 months. Other data remains stored indefinitely in an aggregated form.

Opting out of Google Analytics
If you do not agree with your data being collected, you can prevent this by installing the Google Analytics opt-out browser add-on.

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Rights of data subjects

If your personal data is processed, you are a data subject according to the GDPR, and you have the following rights in relation to the controller:

1. Right to access

You may request confirmation from us as to whether or not your personal data is being processed by us. If that is the case, you can ask the controller for the following information:

1. the purposes for which the personal data is processed;
2. the categories of personal data that are being processed;
3. the recipients or categories of recipients to whom the personal data has been or will be disclosed;
4. the envisaged period for which the personal data will be stored, or, if specific information cannot be provided in this regard, the criteria used to determine that period;
5. the existence of the right to request from the controller rectification or erasure of your personal data, the right to restriction of processing of personal data by the controller or the right to object to such processing;
6. the existence of a right to lodge a complaint with a supervisory authority;
7. any available information as to the source of the data, if the personal data is not collected from the data subject;
8. the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) of the GDPR and, at least in those cases, meaningful information about the logic involved, as well as the significance and envisaged consequences of such processing for the data subject.
9. whether your personal data is transferred to a third country or to an international organisation. Where this is the case, you have the right to be informed of the appropriate safeguards pursuant to Article 46 of the GDPR relating to the transfer.

This right of access may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

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2. Right to rectification

You have the right to obtain from the controller the rectification and/or completion of inaccurate or incomplete personal data concerning you. The controller must carry out the rectification without delay.

With regard to data processing for scientific, historical or statistical research purposes:

Your right to rectification may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

3. Right to restriction of processing

You have the right to obtain from the controller restriction of processing where one of the following applies:

1. if you contest the accuracy of your personal data, for a period enabling the controller to verify the accuracy of the personal data;
2. the processing is unlawful and you oppose the erasure of the personal data and request the restriction of its use instead;
3. the controller no longer needs the personal data for the purposes of the processing, but it is required by you for the establishment, exercise or defence of legal claims; or
4. if you have objected to processing pursuant to Article 21(1) of the GDPR pending the verification whether the legitimate grounds of the controller override yours.

Where processing of your personal data has been restricted, such data shall, with the exception of storage, only be processed with your consent or for the establishment, exercise or defence of legal claims or for the protection of the rights of another natural or legal person or for reasons of important public interest of the Union or of a Member State.

If you have obtained restriction of processing pursuant to the above conditions, you shall be informed by the controller before the restriction of processing is lifted.

With regard to data processing for scientific, historical or statistical research purposes:

Your right to restriction of processing may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

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4. Right to erasure

Erasure obligation

You have the right to obtain from the controller the erasure of your personal data without undue delay and the controller has the obligation to erase this data without undue delay where one of the following grounds applies:

1. Your personal data is no longer necessary in relation to the purposes for which it was collected or otherwise processed.
2. You withdraw the consent on which the processing is based pursuant to Article 6(1)(a) or Article 9(2)(a) of the GDPR, and where there is no other legal ground for the processing.
3. You object to the processing pursuant to Article 21(1) of the GDPR and there are no overriding legitimate grounds for the processing, or you object to the processing pursuant to Article 21(2) of the GDPR.
4. The personal data has been unlawfully processed.
5. Your personal data has to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject.
6. Your personal data has been collected in relation to the offer of information society services referred to in Article 8(1) of the GDPR.

Information to third parties

Where the controller has made your personal data public and is obliged pursuant to Article 17(1) of the GDPR to erase the personal data, the controller, taking account of available technology and the cost of implementation, shall take reasonable steps, including technical measures, to inform controllers which are processing the personal data that you as the data subject have requested the erasure by such controllers of any links to, or copy or replication of, those personal data.

Exceptions

The right to erasure shall not apply to the extent that processing is necessary

1. for exercising the right of freedom of expression and information;
2. for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
3. for reasons of public interest in the area of public health in accordance with Article 9(2)(h) and (i) as well as Article 9(3) of the GDPR;
4. for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) of the GDPR in so far as the right referred to in paragraph a) is likely to render impossible or seriously impair the achievement of the objectives of that processing; or
5. for the establishment, exercise or defence of legal claims.

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5. Right to information

If you have exercised the right to rectification, erasure or restriction of processing towards the controller, the controller shall communicate this rectification or erasure of personal data or restriction of processing to each recipient to whom the personal data has been disclosed, unless this proves impossible or involves disproportionate effort.

You have the right to be informed by the controller about those recipients.

6. Right to data portability

You have the right to receive your personal data that you have provided to a controller in a structured, commonly used and machine-readable format. You also have the right to transmit those data to another controller without hindrance from the controller to which the personal data has been provided, where

1. the processing is based on consent pursuant to Article 6(1)(a) or Article 9(2)(a) of the GDPR
2. the processing is carried out by automated means.

In exercising this right, you have the right to have your personal data transmitted directly from one controller to another, where technically feasible. This shall not adversely affect the rights and freedoms of others. The right to data portability shall not apply to the processing of personal data necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

7. Right to object

You have the right to object, on grounds relating to your particular situation, at any time to processing of your personal data based on Article 6(1)(e) or (f) of the GDPR, including profiling based on those provisions.

The controller shall no longer process your personal data, unless the controller demonstrates compelling legitimate grounds for the processing that override your interests, rights and freedoms or for the establishment, exercise or defence of legal claims.

Where your personal data is processed for direct marketing purposes, you have the right to object at any time to processing of your personal data for such marketing, which includes profiling to the extent that it is related to such direct marketing.

If you object to processing for direct marketing purposes, your personal data will no longer be processed for these purposes.

In the context of the use of information society services, and notwithstanding Directive 2002/58/EC, you may exercise your right to object by automated means using technical specifications.

With regard to data processing for scientific, historical or statistical research purposes:
You have the right to object, on grounds relating to your particular situation, to processing of your personal data for scientific or historical research purposes or statistical purposes pursuant to Article 89(1) of the GDPR.

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This right to object may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

8. Right to withdraw the data protection declaration of consent

You have the right to withdraw your data protection declaration of consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.

9. Automated individual decision-making, including profiling

You have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning you or similarly significantly affects you. This shall not apply if the decision

1. is necessary for entering into, or performance of, a contract between the you and the controller,
2. is authorised by Union or Member State law to which the controller is subject and these laws contain suitable measures to safeguard your rights and freedoms and legitimate interests, or
3. is based on your explicit consent.

However, these decisions shall not be based on special categories of personal data referred to in Article 9(1) of the GDPR, unless Article 9(2)(a) or (g) applies and suitable measures to safeguard your rights and freedoms and legitimate interests are in place. In the cases referred to in points (1) and (3), the controller shall implement suitable measures to safeguard your rights and freedoms and legitimate interests, at least the right to obtain human intervention on the part of the controller, to express your point of view and to contest the decision.

10. Right to lodge a complaint with a supervisory authority

Without prejudice to any other administrative or judicial remedy, you have the right to lodge a complaint with a supervisory authority, in particular in the Member State of your residence, place of work or place of the alleged infringement if you consider that the processing of your personal data infringes the GDPR.

The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy pursuant to Article 78 of the GDPR.

The competent supervisory authority of the HZI is:
The Federal Commissioner for Data Protection and Freedom of Information
Husarenstraße 30
53117 Bonn, Germany
Tel.: +49 228 997799-0

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