



DRIVE

Development of Robust
and Innovative Vaccine
Effectiveness

Declaration of Interest

Name _____ Hector S. Izurieta, MD. MPH_

Affiliation ___Immediate Office, OBE/CBER/FDA

Role in DRIVE: Independent Scientific Committee member

Conflict of interest (COI) means a professional or personal interest that may influence one's judgment regarding a project. Sources of COI include (but are not limited to) commercial interest, professional interest, personal relationships, academic competition and beliefs.

Transparency is of utmost importance in DRIVE. The purpose of this form is to identify potential COI in DRIVE's expert committees. As even perceptions of COI are important, all interests that may lead to potential conflicts must be declared.

Each committee member is responsible for the accuracy and completeness of the submitted information as well as updating in case of change. In the name of transparency, the forms may be made available on DRIVE's website and disclosed in study reports and publications.

☒ I have no conflict of interest to report during the past 36 months*

☐ I have the following potential conflict(s) of interest to report during the past 36 months*

Receipt of grant / research support:

Receipt of honoraria / consultation fees:

Board memberships:

Shares / patents:

Travel / accommodation not included above:

Personal / familial relationships:

Other (please specify):

Signature _____

Date _____

02/06/2018

ADVISORY AGREEMENT

between

Consortium Members as listed in Appendix 1

- hereinafter jointly referred to as "**Consortium**" -

and

Hector S. Izurieta, MD, MPH

- hereinafter referred to as "**Advisor**" -

WHEREAS,

- (A) The Consortium has been formed under the Innovative Medicines Initiative 2 ("IMI") for the purpose of establishing the project called "***Development of Robust and Innovative Vaccine Effectiveness - DRIVE***" (IMI Grant Agreement No. 777363) (the "**Action**"). It consists of the participants listed in Appendix 1 hereto (collectively the "**Participants**"), including FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA COMUNITAT VALENCIANA - FISABIO acting as the "Coordinator". The Participants are parties to an IMI Consortium Agreement for "*Development of Robust and Innovative Vaccine Effectiveness - DRIVE*" effective as of 1st July 2017 (the "**Consortium Agreement**").
- (B) Subject to the Consortium Agreement, an **Independent Scientific Committee (ISC)** is established to endorse the relevant scientific deliverables of the project as identified in the Annex 1 of the Grant Agreement.
- (C) Advisor, who is employed by the FDA (Food and Drug Administration, HHS, U.S.), has extensive experience, scientific prominence and leadership in the field of Influenza vaccines/vaccine effectiveness relating to the Action.
- (D) The Consortium is interested to have the Advisor to be part of the Independent Scientific Committee (ISC).
- (E) Each Participant has authorized the Coordinator to execute this Advisory Agreement on its behalf, except for GSK Biologicals SA, which will act as co-signatory to this Agreement.

Therefore, it is agreed as follows:

1. SUBJECT MATTER OF THE AGREEMENT

Advisor shall provide consultative and advisory services to the Consortium according to the terms and conditions of the Consortium Agreement and this Agreement as set forth below (hereinafter referred to as the "**Services**");

- 2.3 The payment of the daily subsistence allowance shall be made by wire transfer on the bank account of which the Advisor is the direct beneficiary. This account shall be located in the Advisor country of residence.

Advisor acknowledges and agrees that the amounts paid will be reported to the members of the Consortium as well as the country to which the amount is paid.

- 2.4 Advisor shall be responsible for all other taxes payable on account of payments made hereunder.
- 2.5 Advisor agrees that the Consortium (by stating Advisor's private information) may store, process and publish any payments made by the Consortium under this Agreement, if such disclosure is required by statutory or internal regulation or any binding Code of Conduct.

3. CONFIDENTIALITY, ARCHIVING, DATA PROTECTION

- 3.1 Advisor undertakes to hold in strict confidence any information, in particular but not limited to scientific, technical or commercial information relating to the business, products or research of the Consortium, which becomes known to Advisor during the course of this collaboration, together with any information regarding the Action and all results of the cooperation with the Consortium, to use such information and results only for the purposes of this Agreement, and not to disclose such information or results to any other employees/collaborators of the institution or any third party without a prior written consent of the Consortium.

The foregoing restrictions on use and disclosure will not apply to any of such information which: (a) at the time of receipt by Advisor is available to the public; or (b) becomes public knowledge other than by an act or omission on the part of Advisor; or (c) which Advisor can prove was known to Advisor before the date of its disclosure to Advisor by the Consortium; or (d) is legally acquired by Advisor from a third party not bound to Consortium or any of its Participants by any express or implied obligation of secrecy, or (e) Advisor can prove was developed independently by him/her without reference to or use of the information.

- 3.2 Furthermore, Advisor may disclose such information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that Advisor shall give reasonable advance notice to the Consortium and on request, shall cooperate with the Consortium to seek a protective order or other appropriate remedy. The Advisor shall cooperate with the Consortium in seeking an appropriate relief or remedy and use his/her reasonable efforts to secure confidential treatment of any such information that will be disclosed.
- 3.3 Information shall not be deemed to be or have become public knowledge merely because any part of such information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.
- 3.4 Advisor agrees to duly preserve all information and documentation provided to Advisor and to ensure that no third parties gain access thereto. Any documentation provided must be returned to the Consortium at Consortium's request during the term of this Agreement, and shall be returned to the Consortium, without being asked, upon the termination of this Agreement.
- 3.5 This confidentiality and non-use obligation shall remain in effect for five (5) years after the Consortium Agreement expires or is terminated.

5.3 The terms set forth in Sections 3 and 6.1 shall survive any termination or expiration of this Agreement.

6. MISCELLANEOUS

6.1 Advisor shall not use any name, logos or trade names or product trademarks owned by a member of the Consortium, IMI or the Consortium as such in any public announcement, press release or other public document without prior written consent of the Consortium and/or the member of the Consortium that owns the name, logos or trade names or product trademarks.

6.2 Advisor shall be deemed for all purposes to be an independent contractor. Advisor shall not have the authority to enter into agreements or make any representations on behalf of or otherwise bind the Consortium.

6.3 This Agreement contains the entire agreement between the Advisor and the Consortium. Any amendments to this Agreement shall be made in writing. If any provision of this Agreement is or becomes invalid or unenforceable, this shall not affect the remaining provisions hereof. The parties shall in this case replace the invalid or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid or unenforceable provision.

6.4 Each Participant is intended to be a third party beneficiary with the ability to enforce the terms of the Agreement in its own name and as if it was a party to this Agreement.

6.5 This Agreement shall be construed, controlled and interpreted by the laws of Belgium, regardless of its conflict of laws provisions. Exclusive place of jurisdiction shall be Brussels.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in 3 copies in their own name and in case of Coordinator in addition in the name and on behalf of the Participants as their duly authorized representatives.

FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA COMUNITAT VALENCIANA - FISABIO [Coordinator]

Name: Hector S. Izurieta, MD, MPH

Name: _____

Function: Senior Epidemiologist, Immediate Office

Function: _____

Place: Silver Spring, MD, USA

Place: _____

Date: February 8, 2018

Date: _____

Signed: _____

Acknowledged and agreed by

GLAXOSMITHKLINE BIOLOGICALS SA

Appendix 1: Consortium Members

1. FUNDACION PARA EL FOMENTO DE LA INVESTIGACION SANITARIA Y BIOMEDICA DE LA COMUNITAT VALENCIANA (FISABIO), established in CALLE MICER MASCO 31, VALENCIA 46010, Spain
2. INSTITUT DE RECHERCHE POUR LE DEVELOPPEMENT (IRD), established in BOULEVARD DE DUNKERQUE 44 CS 90009, MARSEILLE 13572, France
3. P95 CVBA (P95), established in KONING LEOPOLD III LAAN 1, HERVELEE 3001, Belgium
4. UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI), established in Piazza San Marco 4, Florence 50121, Italy
5. SYNAPSE RESEARCH MANAGEMENT PARTNERS SL (SYNAPSE), established in CALLE DIPUTACION 237 PLANTA AT PUERTA 3, BARCELONA 08007, Spain
6. TERVEYDEN JA HYVINVOINNIN LAITOS (THL), established in MANNERHEIMINTIE 166, HELSINKI 00271, Finland
7. ISTITUTO SUPERIORE DI SANITA (ISS), established in Viale Regina Elena 299, ROME 00161, Italy
8. UNIVERSITY OF SURREY (SURREY), established in Stag Hill, GUILDFORD GU2 7XH, United Kingdom
9. CONFEDERATION OF MENINGITIS ORGANISATIONS LTD (COMO), established in NEWMINSTER HOUSE BALDWIN STREET, BRISTOL BS1 1LT, United Kingdom
10. UNIVERSITE LYON 1 CLAUDE BERNARD (UCBL), established in BOULEVARD DU 11 NOVEMBRE 1918 NUM43, VILLEURBANNE CEDEX 69622, France
11. ASSOCIATION INTERNATIONALE DE STANDARDISATION BIOLOGIQUE POUR L'EUROPE (IABS-EU) (IABS-EU), established in BOULEVARD VIVIER MERLE 10-12 WORLD TRADE CENTER TOUR OXYGENE, LYON 69393, France
12. SANOFI PASTEUR SA (SP), established in Avenue Pont Pasteur, 2, LYON 69007, France
13. ABBOTT BIOLOGICALS BV (ABBV), established in C.J. VAN HOUTENLAAN 36, WEESP 1381 CP, Netherlands
14. SEQIRUS UK LIMITED (SEQIRUS), established in POINT 29 MARKET STREET, MAIDENHEAD SL6 8AA, United Kingdom
15. GLAXOSMITHKLINE BIOLOGICALS (GSK Bio), established in Rue de l'Institut 89, Rixensart 1330, Belgium