Press Release

10 March 2015

To improve the toolbox available to evaluate seasonal flu vaccines, European public and private research institutions are joining together in FLUCOP, a 13,9M€ project funded by the Innovative Medicines Initiative (IMI)

On the 1st of March 2015, the IMI collaborative research project FLUCOP, for the Standardization and Development of Assays for Assessment of Influenza Vaccine Correlates of Protection, started. FLUCOP will provide the seasonal influenza vaccine community with improved or new tools to evaluate the vaccine's ability to raise an immune response, allowing the comparability of clinical data across laboratories, and paving the way for establishing improved and/or novel correlates of protection, i.e. measurable parameters that a vaccinated person is protected against subsequent infections or disease. The harmonisation of laboratory tests will ultimately contribute to increase the transparency of the results and therefore the trust of the public in seasonal flu vaccination programmes.

"I am truly honored to be part of such an important international study group" says Prof. Susanna Esposito, Pediatric Highly Intensive Care Unit Director, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan. "The identification of new correlates of protection for influenza vaccines will be crucial for future research on influenza vaccination in pediatric age and for the development of a universal influenza vaccine. Therefore, we expect great results from participating Italian groups and from the team of pediatricians under my leadership at the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico in Milan".

FLUCOP is a public private consortium of twenty-two partners involving experts from six vaccine manufacturers from Europe, small and medium sized European enterprises, major academic institutions, European public health governmental institutions, and European non-governmental organisations. The project will include consultation with partners from regulatory agencies - a mechanism ensuring that the regulatory aspects of the standardisation efforts are addressed and duly considered.

"This is an unprecedented collaboration between European vaccine manufacturers, first rate academic institutions, regulatory and public health agencies" says Patricia Londono-Hayes, EFPIA coordinator of FLUCOP and Senior Director, Research and Development Initiatives in Europe at Sanofi Pasteur in Lyon, France. "The short term impact will be that results of clinical trials are more stringently comparable even if run not concomitantly and in different geographic areas or using different influenza vaccines. The long term impact will be the evolution of the regulatory guidance and ultimately the practices of the vaccine industry, not only in Europe but at global level. To achieve these goals we have built a consortium of twenty-two partner institutions, sharing expertise and experience in order to address the technical and scientific challenges and ensure reliable and accurate criteria for the assessment of the immunogenicity of seasonal flu vaccines".

From existing efficacy criteria to better assessment tools for seasonal flu vaccines

The human influenza virus is the causative agent of one of the most important infectious diseases in the world, causing frequent (seasonal) epidemics as well as pandemics, both of which cause significant morbidity and mortality worldwide. Influenza virus infects all age groups but children and adults over the age of 65 are most at risk of severe morbidity and mortality. Vaccination is recommended for these age groups. Vaccination remains the most effective method to control seasonal infections and the most important strategy to prepare for a possible pandemic. Despite the development and licensure of influenza vaccines along with clinical evidence of their ability to

protect against influenza, the potential correlates of protection induced by these vaccines are still not fully elucidated.
The availability of a tool-box of standardised, validated assays for human influenza vaccines, agreed and used by key parties in the private and in the public sector will have tremendous impact on the Research and Development process globally, and will pave the way for future investigation and definition of correlates of protection for these vaccines.

Facts about FLUCOP:

Starting date: 1 March 2015
End date: 28 February 2020
Total cost: € 13.9 M
IMI contribution: € 6.1 M
EFPIA Coordinator: Patricia Londono-Hayes, Sanofi-Pasteur
Managing Entity Coordinator: Donata Medaglini, Sclavo Vaccines Association and University of Siena
Scientific Coordinator: Emanuele Montomoli, University of Siena
Partners: 22 from 8 countries

Participants

Sanofi-Pasteur – EFPIA Coordinator	(France)
Sclavo Vaccines Association – Managing Coordinator	(Italy)
University of Siena -Scientific Coordinator	(Italy)
Department of Health -MHRA	(United Kingdom)
Paul Ehrlich Institute	(Germany)
European Vaccine Initiative	(Germany)
Erasmus Medical Center	(The Netherlands)
University of Bergen	(Norway)
University of Ghent	(Belgium)
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico	(Italy)
The Chancellor Masters and Scholars of the University of Oxford	(United Kingdom)
QUINTEN	(France)
Biomedical Primate Research Centre	(The Netherlands)
Istituto Superiore di Sanità	(Italy)
University of Surrey	(United Kingdom)
Research Institute for Wildlife Health in Europe, ARTEMIS	(The Netherlands)
European Medicines Agency	(United Kingdom)
Novartis Vaccines	(Switzerland)
GlaxoSmithKline	(United Kingdom)
Crucell, Janssen	(The Netherlands)
Abbott	(The Netherlands)
AstraZeneca	(United Kingdom)

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Partner Section