Innovative Medicines Initiative

Immunosafety of Vaccines

New Biomarkers associated with adverse events (early inflammation and autoimmune disease)

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Need for public-private collaboration 1

The goal of this project is the harmonization, standardization and optimization of both reporting and grading as well as

the prediction of early and late adverse events following vaccination through the discovery and validation of new biomarkers.

Need for public-private collaboration 2

- This will provide guidelines and guidance for the vaccine community to assess the safety of new vaccines that will be accepted by the public, manufacturers and regulators.
- The project is also aimed to support the collection and organization of comprehensive data to better understand the aetiology of autoimmune diseases and their possible link with previous events including infections and vaccination.

For this a strict collaboration between vaccine companies and academic partners will be of extreme importance.

Objectives of the full project

The three main objectives of the project are the following:

1.The characterization of early inflammation induced by vaccines currently on the market and the identification and validation of biomarkers of early inflammation and allergic responses

2.The identification and validation of early biomarkers of autoimmunity and their use to help identifying population at risk of developing autoimmunity

3.The analysis of the incidence and epidemiology of autoimmune disease in the general population and the link to genetic background or previous events in the life of patients, including severe effects such as anaphylactic shock.

Expected impact on the R&D process

The scope of the project is to modify the vaccine development process as follows:

- Creating awareness in the industry and academia on the immunosafety of molecules impacting the immune system (e.g., antigens, adjuvants, etc.)
- Establishing a common language on the vaccine immuno-safety problems
- Having an impact on the way to develop and to evaluate new vaccines
- Addressing the problem of immuno-safety of vaccines much earlier than before (before first clinical trials)

Suggested architecture of the project 1

- **Major goal: Identification of biomarkers of early inflammation**
- **Major goal: Identification and validation of biomarkers of autoimmunity**
- **Major goal: Incidence and epidemiology of early reactions and autoimmune diseases in the general population**

Suggested architecture of the project 2

- WP1 Definition of biomarkers of vaccine induced inflammation
- WP2 Establishment of reliable in vivo animal models or in vitro models predicting early inflammation, autoimmune diseases and allergy
- WP3 Definition of early biomarkers of autoimmunity to predict potential risk of revealing chronic disorders at time of vaccination
- WP4 Understanding of the frequency of more common autoimmune diseases in the general population
- WP5 Creation of a large databases of samples from recipients of current vaccines, innovative tools and adequate IT/Knowledge management structure
- WP6 Preparation of new general guidelines approved by Regulatory Authorities to evaluate the immuno-safety of vaccines.

Expected contributions of the applicants 1

The Applicant consortium is expected to address all areas outlined in the Call, taking into account synergies with the EFPIA participants.

New innovative approaches on the way to evaluate the immunosafety of vaccines are expected from the Applicant Consortium.

Expected contributions of the applicants 2

The Consortium should bring together experts not only in vaccinology but also in the clinical and preclinical identification and assessment of biomarkers for inflammatory diseases and autoimmunity.

The Consortium should have demonstrable experience in conducting pan-European clinical trials, establishing and maintaining biobanks, sample and data management, bioinformatics and mathematical modeling.

Expected contributions of the applicants 3

Regulatory authorities (FDA/EMEA) should be closely associated to the project as well as experts in infectivology and cohorts of patients suffering from autoimmune diseases.

Expected (in kind) contributions of EFPIA members 1

Vaccines

•Make available to the public consortium marketed vaccines

Preclinical

•Share relevant animal models or in vitro model used in the companies to evaluate immunosafety of vaccines

•Harmonize and standardize preclinical tests used to evaluate the safety of vaccines

Clinical

•Make available bio samples from internal bio banks (sera, cells ….)

• Provide support and expertise in data management and biostatistics

•Standardize immunoassays used to evaluate the safety of vaccines (evaluation of cytokines, inflammatory proteins ……) and transfer to public consortium

Expected (in kind) contributions of EFPIA members 2

General

- General immunological and toxicological expertise's regarding inflammation
- Know how in statistical analysis of genomic and pre clinical or clinical study data
- Know how in bioinformatics - Know how in sample and data management

Key deliverables of full project 1

1. Innovative biomarkers and assessment methods to accurately describe vaccine induced inflammation

2. Validation of acceptable type/level of inflammation after administration of vaccine

3. Validation of new and reliable in vivo (animal models) or in vitro (cell culture) models predicting early inflammation and potential exacerbations of latent autoimmunity induced by vaccines

4. Harmonization of guidelines to identify and record early clinical symptoms after vaccination

Key deliverables of full project 2

5. Early biomarkers of autoimmunity and allergy “qualified for use” to predict potential risk of revealing chronic disorders at time of vaccination

6. Identification of early biomarkers of potentially at risk individuals which could allow adopting a more personalized vaccination strategy

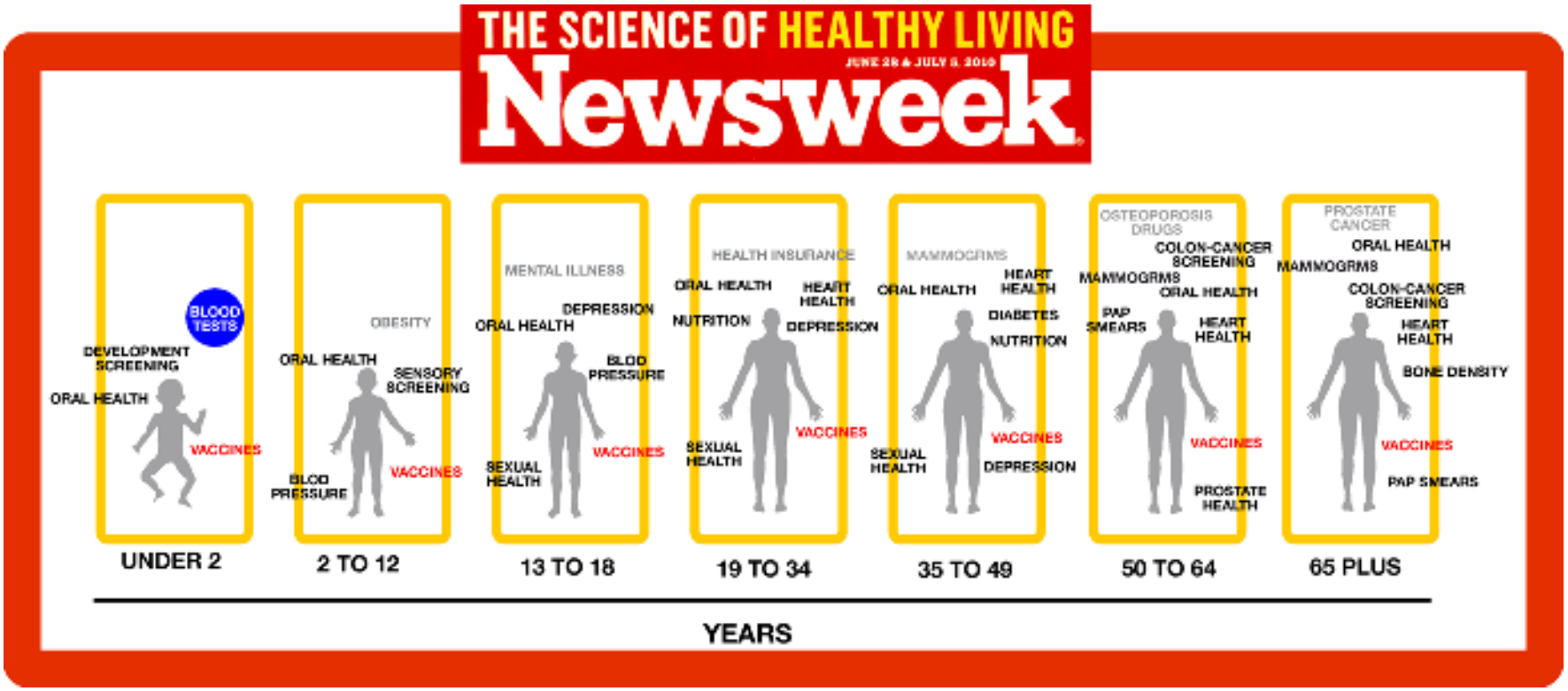
7. Large databases of samples from recipients of current vaccines, innovative tools and adequate IT/Knowledge management structure allowing to determine the link between occurrence of autoimmune and allergic disorders and new biomarkers/historical events in the general population that will serve as a baseline for future vaccines

Key deliverables of full project 3

7. A better understanding of the frequency of more common autoimmune diseases (namely those claimed to be revealed/exacerbated by vaccines) in the general population

8. New general guidelines approved by Regulatory Authorities to evaluate the immuno-safety of vaccines

Vaccines are for all ages.
Let’s make them safetier than ever !



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