



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on ADVANCE project Follow-up of EMA Workshop of 13 November 2013 Dr Peter Arlett





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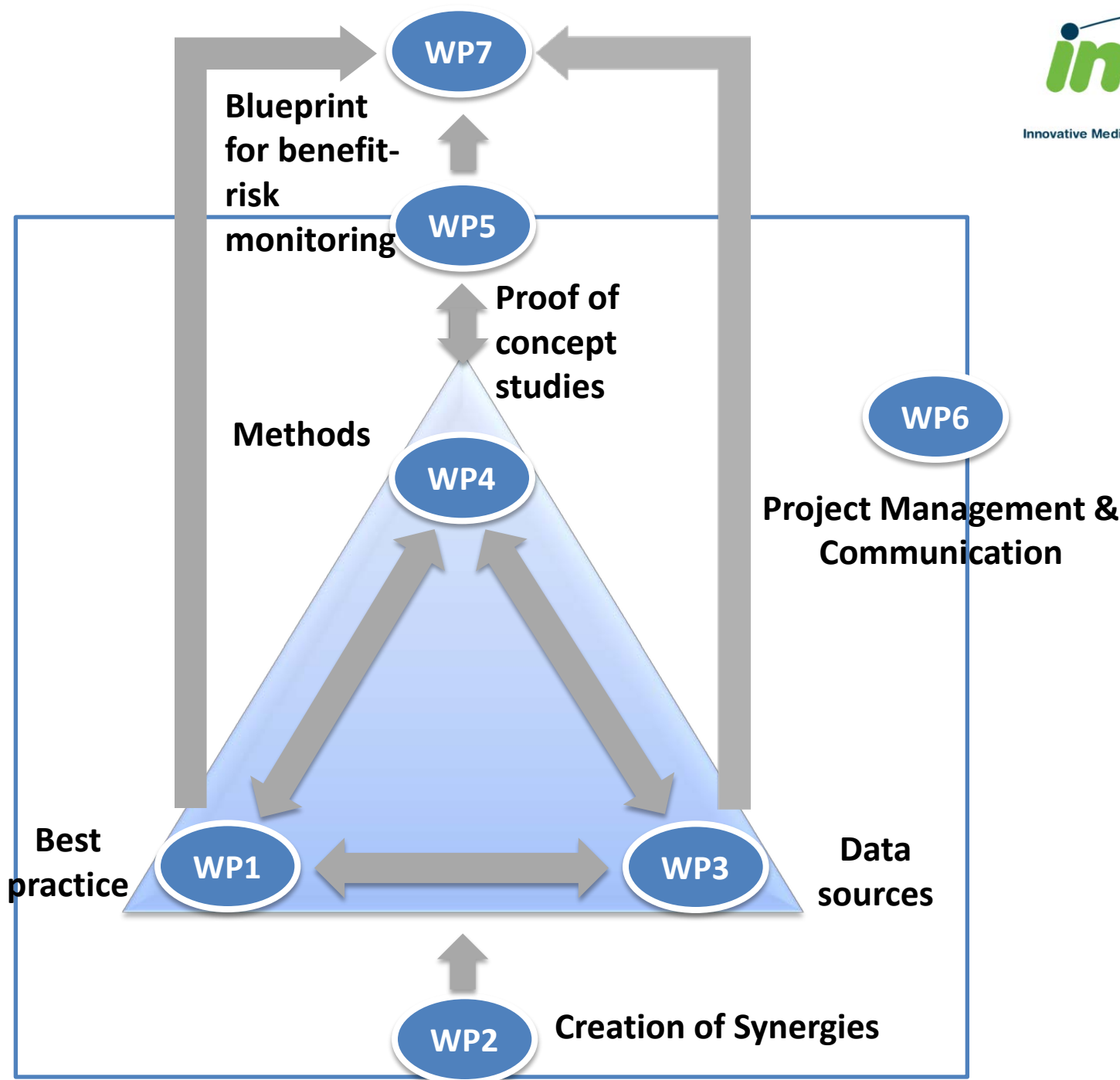


Aim

Long-term vision:

- The ADVANCE vision is focused on “timely and best evidence on vaccine benefits and risks”.
- The mission is to establish a Blueprint for a validated and tested best practice framework that could rapidly provide robust data on vaccine benefits and risks to support accelerated decision making.

ADVANCE PROJECT WORKPLAN





Main objective of WP1 (co-lead by EMA)

To develop and test a **best practice guidance** for the initiation, conduct and reporting of studies on the benefits and risks of vaccines in Europe



Guiding principles

The best practice model should:

- include governance rules, code of conduct and communication strategy
- be practical (e.g.. interactions between concerned stakeholders)
- be agreed by all stakeholders
- be sustainable (e.g.. training)
- be tested in real-life situations
- take into account different situations and different needs and requirements of concerned stakeholders for a given study.



Guiding principles

- Identification of key characteristics that a governance model should fulfill eg independance, transparency, flexibility, etc.
- Identification of parameters linked to each characteristic, i.e. what do we mean by « conflict of interest », « independence », « transparency », « flexibility » etc.
- Mapping of existing governance structures: private-public, public-public, others
- Proposal for possible governance structures (eg study leadership, review, data access, ...)
- Review of communication issues and gaps



WP1. Milestones and deliverables (from Full Project Proposal)

Milestones

Survey of
partners on
PP interaction
Apr 2014

1st
Workshop
13 Nov 2013

Topics
PoC Ph I
Oct 2014

Topics
PoC Ph II
Jan 2016

Finalisation of
white paper
Sept 2017

2nd
Workshop
Dec 2015

3rd
Workshop
Oct 2016

Start
date:
Oct
2013

End of
project
30 Sept
2018

Draft list of study
needs
and framework
requirements
Apr 2014

Analysis of
public
concerns and
perceptions
Oct 2014

Draft
best practice
guidance
Apr 2015

Final best practice
guidance
Oct 2016

Results of
survey-PP
interactions
Jul 2014

Initial model
PP interactions
Jan 2015

Analysis of
key issues
and gaps in
public
knowledge
Oct 2015

Final model
PP interactions
Oct 2016

Strategy for public
communication
Oct 2016

Deliverables



**FEED-BACK FROM
EMA WORKSHOP OF ADVANCE WP1
13 November 2013**



OBJECTIVES

- to present the work programme and WP1 activities
- to discuss and confront the needs and perceived challenges and barriers expressed by stakeholders regarding a future system for benefit-risk monitoring of vaccines

Stakeholders represented:

- ✓ public health authorities
- ✓ regulatory authorities
- ✓ patients
- ✓ health care professionals
- ✓ academic institutions
- ✓ industry



OBJECTIVES

Each stakeholder group asked to address four topics:

- Main needs and expectations from a vaccine B-R monitoring system
- Most important perceived challenges and barriers in a system based on public-private partnership
- Priorities for topics for proof-of-concept studies
- “Ideal” framework for a vaccine B-R monitoring system



PATIENTS' VIEWS

- PCWP represented by Lina Buzermanie and Wim Wientjens
- Written contribution received from Hildrun Sundseth



PATIENTS' VIEWS

Needs and expectations

- to consider the impact of vaccinations on people's quality of life
- to address communication aspects
- to show that benefits of vaccines outweigh their risks
- evidence-based benefit/risk analysis in order to counter-act emotional reactions on vaccine-related risks
- transparency and clarity: often protocols are not available to the public, or they are written in scientific language which is challenging to understand



PATIENTS' VIEWS

Challenges and barriers

- industry-sponsored studies often generate scepticism among patients and will always be criticised (to some extent, same comment as regards academic studies)
- vaccination coverage and trust in the general population is low; people will have to understand how herd immunity works and how vaccination can help to protect vulnerable population groups before we can expect the public to understand the benefit of vaccination
- no problem with industry funding of studies, but this should be done within a private/public partnership/regulator approach to be in the best interest of public health.



PATIENTS' VIEWS

Priorities for topics for proof of concepts studies

- allergies caused by vaccines is an important topic
- population based approach including pregnant women
- studies in high-risk groups (e.g. diabetes)

“Ideal model” for a framework

- collaborative approach involving regulators



HEALTH CARE PROFESSIONALS' VIEWS

Could not attend due to professional activities - comments in writing from Dr. JP Baeyens and Constance Colin (Standing Committee of European Doctors)

- Total transparency to guarantee for non-biased research
- Communication of high quality, up-to-date, evidence-based information is vital component in increasing vaccine uptake
- Very old frail co-morbid persons is a special group in greater need and with low response rate to vaccines
- Source of funding not a problem in order to provide urgent results
- Research on vaccinations to be embedded in a framework for cooperation in order to avoid duplication



MAIN TOPICS OF THE DISCUSSION

- Choice of outcomes for vaccine B/R studies, e.g. effectiveness, safety, quality of life, impact on public health, data for HTA
- Recognition of the validity and reliability of industry studies
- Trust between stakeholders (definition of “trust”?)
- Definition, use and control of quality standards for observational studies
- Accessibility of data sources for vaccine studies
- Transparency (what does it mean in practice?)
- Confluence of needs and expectations across stakeholders’ groups
- Large diversity of topics proposed for POCs (besides influenza)
- Need to identify attributes of “ideal” models proposed



Next steps

- **Dec. 2013:** Minutes and presentations to be circulated
- **Feb. 2014:** Survey of stakeholders about (non-)successful models of projects with public-public and public-private interactions
- **Apr. 2014:** Draft list of study needs and framework requirements
- **Next workshop due in Q4 2015**
 - o Sub-group meetings before that date.



Expected roles of PCWP and HCPWG

To verify that the needs, expectations and concerns from patients and health care professionals are adequately taken into account in the best practice guidance

- Comments on the Minutes of the workshop
- Participation in survey on possible models for vaccine B/R monitoring framework (Feb 2014)
- Participation in sub-groups on a voluntary basis, e.g. communication strategy, transparency, code of conduct
- Comments on elements, drafts and final version of best practice guidance (starting in Apr 2014)
- Participation in 2nd workshop



Questions?