

The Accelerated Development of Vaccine beNefit-risk Collaboration in Europe (ADVANCE)

PROGRESS AND CHALLENGES OF WP1 DEVELOPMENT OF BEST PRACTICE AND CODE OF CONDUCT

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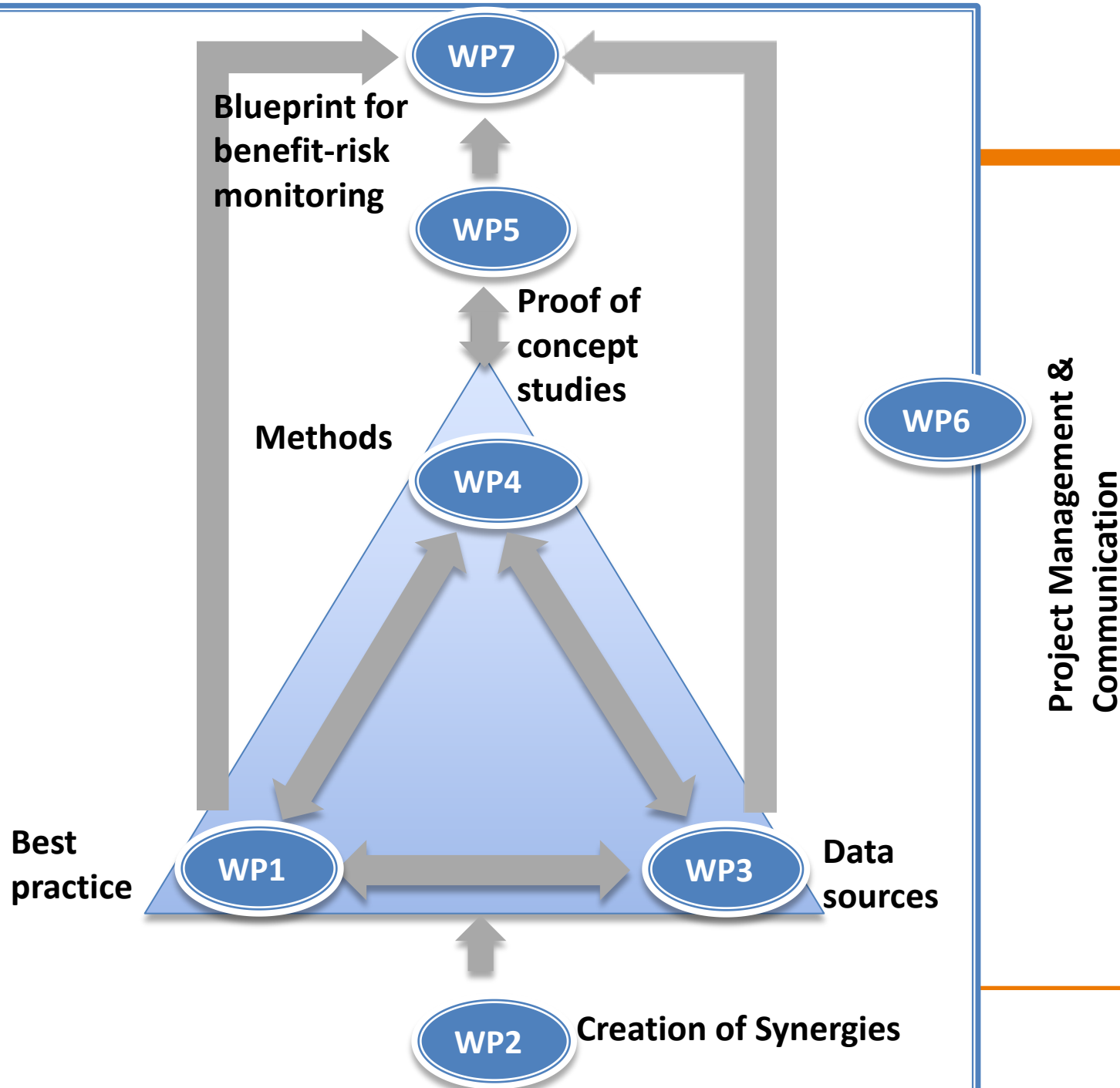
PCWP
November 26, 2014

Experience gained with routine vaccines and H1N1 pandemic

- EU capacity for collecting vaccine exposure, safety and effectiveness data is limited:
 - Difficulty to initiate and conduct studies
 - Interactions between multiple stakeholders (regulators, public health agencies, academia, industry) – lack of confidence
 - Disharmonised communications
 - Funding issues – contractual issues -perceived conflicts of interest
- Multinational collaborations are possible
 - Lessons learnt from European consortia in vaccine effectiveness (I-MOVE) and safety (VAESCO)

To build a B/R vaccine monitoring system:

- Efficient and sustainable
- Rapid and integrated
- Clear governance rules
- Meeting the common interest of all main stakeholders



OBJECTIVE OF WP1

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.

The best practice guidance should:

- include **governance principles, code of conduct, minimum quality requirements** and **communication principles**
- be **practical** (eg. funding aspects, interaction between involved stakeholders)
- be **agreed** by all stakeholders (i.e. large consultation needed)
- be **sustainable** (eg. funding mechanisms, training)
- be **tested** in real-life situations
- take into account **different situations and different needs and requirements** of involved stakeholders for a given study.

- **Regulatory authorities:**
 - EMA, MHRA, AIFA, ANMS
- **Public health agencies:**
 - ASLCR, WIV-ISP, SSI, RIVM, NCE, FISABIO, THL
- **Academia:**
 - EMC, UNIBAS, Surrey, OU, LSHTM, KI, AUH-AS, UTA, RCGP, ICL
- **SME/CRO:**
 - P95, Synapse, Pedianet
- **Industry:**
 - GSK, SP, Novartis, SP MSD, Crucell, Pfizer, Takeda

Four working groups

- Code of conduct
- Quality control and assurance
- Governance models
- Communication strategy

WP1 Workshops

- 13 November 2013
- 13-14 November 2014

Representatives from PCWP (2014: Jose Drabwell, Marco Greco)

Objective

To identify/develop components of a code of conduct

Key element is consensus among all stakeholders

Starting from review of existing guidance (22) and literature review

Access to data

Confidentiality

Conflicts of interest

Development of study protocol

Ownership of results

Publications and communications

Research contracts

Roles and responsibilities

Scientific Independence

Study conduct

Transparency

Writing of study report

Timeline: first draft in March 2014

Challenges

- definitions of terms and concepts
- balance between requirements and need for consensus
- impact on research contracts and legal aspects
- formalisation of agreement



Objective

To propose minimum requirements for quality standards to provide confidence in the validity of results and support a mutual understanding of quality control and assurance.

Challenges

- Most organisations already have procedures in place and use guidance
- Large variability of documents being used as reference
- National accreditations exist
- Need to ensure and communicate that the same minimum criteria are applied.

Objective

To perform a **landscape analysis** of existing models of multi-stakeholder initiatives for the framework (including public-public, private-private and public-private interactions (PP)) and describe **operational models** with different scenarios for PP interactions.

Challenges

- Definition of generic functions and activities
- Differentiation between funding mechanisms and governance model



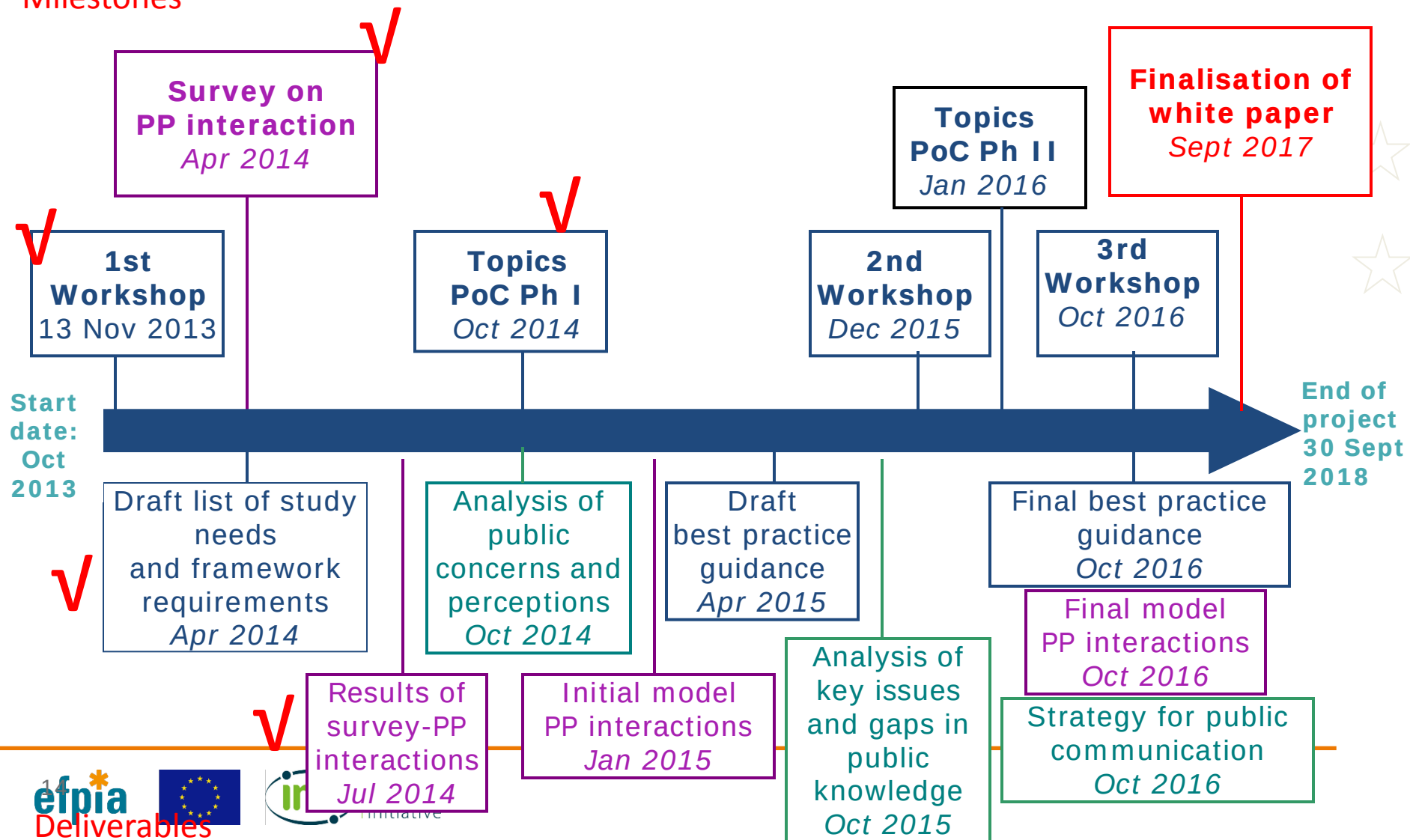
Objective

To provide recommendations on **effective communication strategies for disseminating study results and evaluations** on the benefits and risks of vaccines for supporting stakeholders in making informed decisions.

Includes:

- planned proactive communication as well preparedness for communicating on emerging needs;
- addressing concerns and information needs of the public (including vaccinees(-to-be), carers, healthcare professionals, vaccination policy makers)
- mitigating media crises.

Milestones



Three topics selected for first wave:

- HPV vaccines
- Influenza vaccines
- Pertussis vaccines

First study: Pertussis

- To estimate burden of pertussis disease and identification of outbreaks over time.
- To estimate pertussis vaccination coverage and schedule compliance in various populations and countries, and various combinations.
- To estimate pertussis vaccine effectiveness
- To assess the risk for established safety outcomes

Thank you !