



Innovative Medicines Initiative

Zoonoses anticipation and preparedness initiative

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Merial



efpia*

Need for public-private collaboration



- Providing effective control tools against zoonotic diseases a few months after the occurrence of first cases is today not achievable in practice if we contemplate a true GMP scale.
- Such a goal requires the combination of scientific and technological breakthroughs.
- These breakthroughs will be designed, tested and validated through a close collaboration between:
 - Academia / SMEs: new ideas, scientific knowledge, technological innovations
 - Large companies: validation of QA and QC processes, validation of new processes and short timelines under true GMP industrial scale conditions



Objectives of the full project



Overall objective: Definition of fast-track manufacturing processes for providing biological control tools (vaccines and/or antibodies) against (re-) emerging viral diseases with pandemic potential

Specific objectives:

- **Ultra-fast screening processes** for identifying key protective immunogen(s) and corresponding neutralizing proteins (antibodies or antibody-like proteins)



Objectives of the full project



- **Validated GMP processes for:**
 - Manufacturing system(s) enabling surge capacity and short QC release for neutralizing reagent (antibody or antibody-like proteins)
 - Vaccine manufacturing system(s) enabling surge capacity and short / immediate, fully *in vitro*, QC batch release assays
- **Pre-approved regulatory process:** allowing fast track review for vaccines, antibodies, (and antivirals) in the context of a new zoonosis (based on current model developed for human influenza vaccine).



Pre-competitive nature



- The ZAPI project is not focused on specific commercial products.
- The ZAPI project aims to design new manufacturing processes (up to large scales) for delivering neutralizing reagents and vaccines against zoonotic diseases.
- These new R&D and manufacturing processes should be usable both for animal and human health needs in the context of infectious diseases.



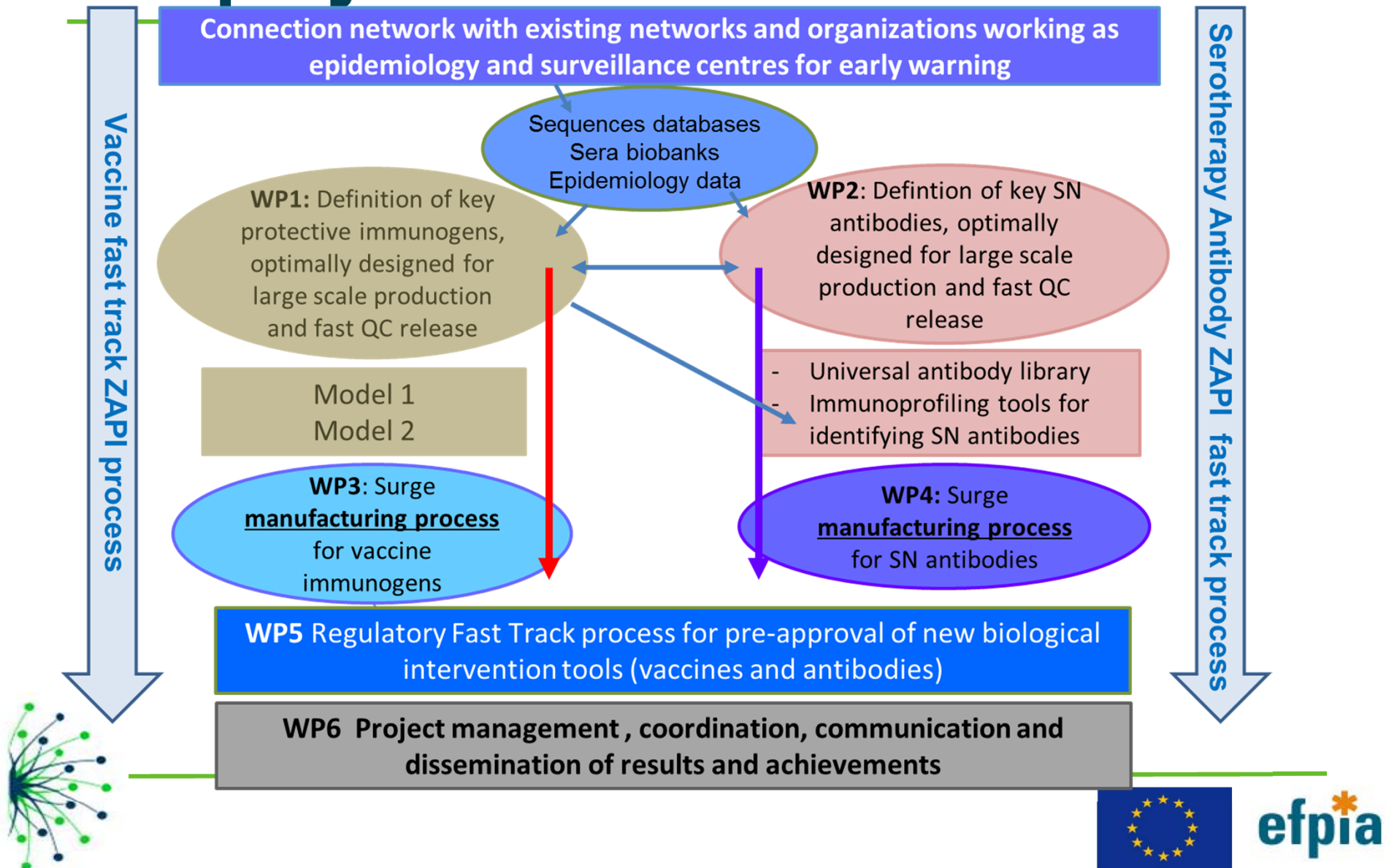
Expected impact on the R&D process



- Increase the accuracy of bioinformatics predictive softwares
- Define HTS systems for detecting neutralizing antibodies or protein scaffolds
- Validate new approaches for implementing true “Quality by Design” (QbD) for neutralizing antibodies/reagents
- Validate new approaches for implementing true “QbD” for vaccine immunogens
- Validate QbD for achieving full *in vitro* QC batch release tests
- Decrease very significantly the R&D process timelines for vaccines and neutralizing reagents



Suggested architecture of the project



Vaccine fast track ZAPI process

Serotherapy Antibody ZAPI fast track process

Connection network with existing networks and organizations working as epidemiology and surveillance centres for early warning

Sequences databases
Sera biobanks
Epidemiology data

WP1: Definition of key protective immunogens, optimally designed for large scale production and fast QC release

Model 1
Model 2

WP3: Surge manufacturing process for vaccine immunogens

WP2: Defintion of key SN antibodies, optimally designed for large scale production and fast QC release

- Universal antibody library
- Immunoprofiling tools for identifying SN antibodies

WP4: Surge manufacturing process for SN antibodies

WP5 Regulatory Fast Track process for pre-approval of new biological intervention tools (vaccines and antibodies)

WP6 Project management, coordination, communication and dissemination of results and achievements



Expected contributions of the applicants



State-of-the-art scientific and technical expertise for zoonotic diseases

- Immunology, microbiology, antibody neutralization and immunoprofiling assay technologies
- in silico* immunogen design, interactive database development and operation
- innovative expression systems able to support the objectives of the project

Capability and capacity to design new universal tools:

- In silico* design of candidate immunogens for expression as subunits or VLPs in recombinant systems
- Design universal libraries for antibody molecules from multi-species origin
- Design HTS techniques for neutralization assays
- Provide basic knowledge for immunoprofiling assays



Expected (in kind) contributions of EFPIA members



- Perform comparative immunological studies in target species for validating the design and selection of vaccine immunogens.
- Implement HTS technologies for screening key antibody reagents out of universal antibody libraries.
- Validate options for new QC release techniques and validate selected QC techniques.
- Validate overall timelines for ZAPI approaches.
- Validate industrial scale manufacturing options defined by ZAPI (testing in actual industrial conditions).



What's in it for you?



- **Academic researchers**
 - New patents, new publications, new technologies for developing new scientific knowledge, new research agreements with large companies
- **SMEs**
 - Validation of proprietary technologies, new patents, research service agreements, increased visibility for collaborations with large companies
- **Animal health stakeholders** (farmers, veterinarians, veterinary public health authorities)
 - Rapid access to effective tools for avoiding economical losses, and for blocking spread of infectious diseases to people, better animal welfare
- **General public and Public Health authorities**
 - Rapid access to effective tools against infectious diseases, effective tools accessible to poor countries due to speed of development and surge manufacturing capacity, no use of animals for batch QC release of products



Key deliverables of the full project



- Quality by Design process of expression constructs for surge capacity manufacturing
- GMP process able to deliver highly defined vaccine antigens/neutralizing antibodies in a very short cycle time
- Universal antibody libraries combining immunoglobulin genes from multiple species
- High throughput screening technologies for identifying neutralizing antibodies or protein scaffolds
- Pre-approved regulatory and political process allowing fast track review for biological control tools (vaccines, antibodies)
- **All above deliverables will be modeled on a few known high risk agents to test and validate the practical applicability of new systems and advance specific programs.**



Questions?



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