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How to deliver new vaccines under very short timelines: The ZAPI project

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www.zapi-imi.eu

Non-competitive nature

- The ZAPI project is not focused on specific commercial products.

- The ZAPI project aims to design **new manufacturing large scale capability processes** for neutralizing reagents and vaccines against zoonotic diseases.

- These new R&D and manufacturing processes should be usable both for animal and human health needs

1st One Health IMI project

The need to anticipate the future… and preparedness activities

- It is always better to anticipate the risks..
- Major bio-threats are known (OIE list + (new arthropod-borne diseases) + WHO initiatives…
- However, experience and recent history show that some events are unpredictable…. And we actually face the “unexpected” more and more.

Global needs for new vaccines

- **VACCINE PRODUCT « BY DESIGN »:**
  - **Selection of protective immunogens**
  - **Adjuvants, Immuno-modulators**
  - **Delivery systems**

Global needs for new vaccines

- **TECHNOLOGIES**
  - Many advantages to use recombinant technologies as solutions for industrial bottlenecks:
    - **No handling of pathogens**
    - **Large manufacturing capacity**
    - **Less biological variability for the final product**
    - **Easier QC testing for batch release**

Challenges for delivering emergency vaccines

Technical constraints….

- **Timelines** (very short by definition = a few months…)
- **Manufacturing capacity** (with secured supply chains for raw materials = source of many bottlenecks)
- **Reliable processes / fully *in vitro* QC tools**

Challenges for delivering emergency vaccines

Technical constraints (2)….

- Contained ABSL-3, ABSL-3+, ABSL-4 animal facilities for testing vaccines …
- Stockpiling storage:
  - Vaccine stability, facilities for vaccine storage → will drive the selection of technical solutions
- If “immediate use” (implies efficient “surge capacity”):
  - No need for long term stability (and for stockpiling ?)

Challenges for delivering emergency vaccines

Technical constraints (3)….

- Manufacturing capacities (with secured supply chains for raw materials) (“capacity” can be a very complex figure):
  - Minimum number of doses
  - Dose of antigen (linked to adjuvant, delivery route)
  - Key equipment for the process
  - Manufacturing average cycle time (reliability of process, batch release success rate…)
  - Stability (shelf life)

"New thinking" as part of the preparedness

- Need to work with an "Industrial mindset" rather than a "scientific mindset". At the end of the day, one delivers a ***product***, not an experimental vaccine…

- Better preparedness if vaccine solutions are based on the "re-use" of existing (proven) manufacturing technologies.

“New thinking” as part of the preparedness

- Viruses are perceived today as technically achievable for this objective.
- 3 viral models are used in the ZAPI project:
  - Rift Valley Fever Virus
  - Schmallenberg Virus
  - MERS-CoV
- Key progress in bioinformatics and new expression systems enable now the implementation of efficient subunit vaccine solutions

Conclusions (1)

- **For « expected events », the best approach is to stockpile (« no delay » between identification and implementation of field vaccination)**
  - **However, this is associated with costs, technical issues, and uncertainties…**

- **For « unexpected events », all timelines become highly critical:**

  - **Identification of pathogen / immunogen is key**

  - **« Quality by Design » of the optimal vaccine for « instant » manufacturing capacities**

Conclusions (2)

Necessity to innovate for designing subunit vaccines fit to robust and « high yield » expression systems / processes:

- **Effectively achieving delivery of a product with existing GMP facilities**
- **Ensuring surge manufacturing capacity**

Timelines are critical for well-adapted responses:

- **Select solutions enabling a short cycle time for production:**
  - **Rapid antigen production with high « volumetric yields »**
  - **Fast Quality Control (*in vitro*) for batch release**

Conclusions (3)

We are in a global « One World / One Health »

- Anyone (domestic animals, people) can or will be exposed to new (re-)emerging diseases.
- The « reduction to effective field use » is too slow if we follow the « old ways ».

It is time for a change and for action :

- Need to « act » the preparedness through large collaborations
- Demonstration of the key industrial steps through prototype projects such as ZAPI

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Thank you for your attention

ZAPI

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20 Partners in ZAPI consortium

EFPIA partners :

- Merial — EFPIA coordinator
- Boehringer Ingelheim Animal Health — EFPIA partner
- AstraZeneca / Medimmune — EFPIA partner

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