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VACCINE FORMULATION INSTITUTE

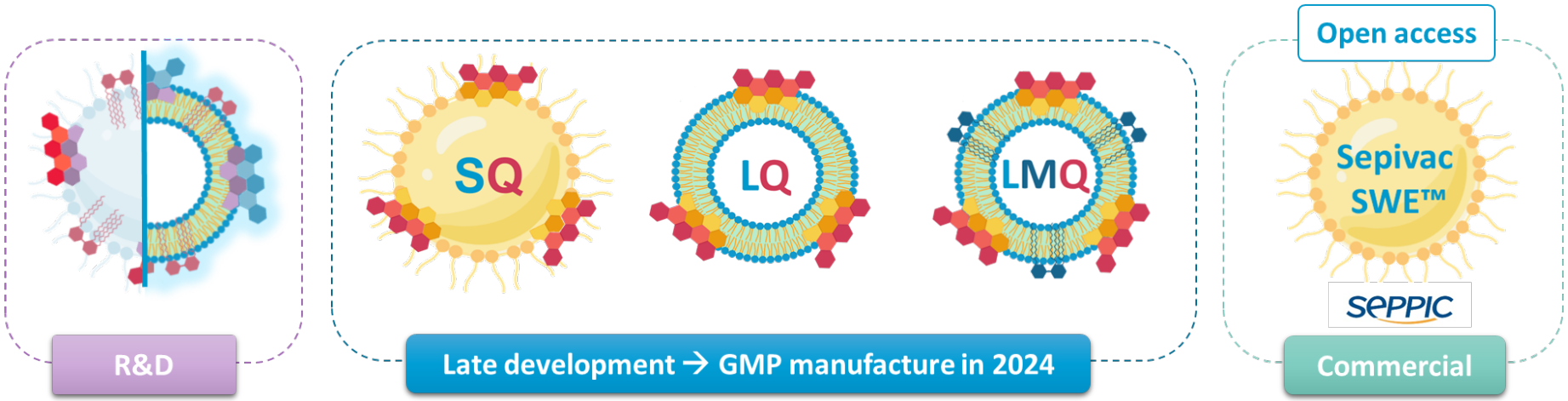
Vaccine adjuvants: needs for a Global Market

GVIRF Webinar - Vaccine Adjuvants for Global Health

September 13th, 2023

The Vaccine Formulation Institute (VFI)

- **Created in 2012** in Switzerland
- **Mission**
  - To develop **clinically-relevant adjuvants** and provide them under **open-access** terms
  - To disseminate **formulation know-how** to vaccine researchers/developers
- **2023**
  - **30 staff**: chemists, formulation experts, immunologists, project managers
  - **2 laboratories** (Geneva and Lausanne)



VFI adjuvant portfolio

- Research, development, commercial
- Session III (Céline Lemoine)

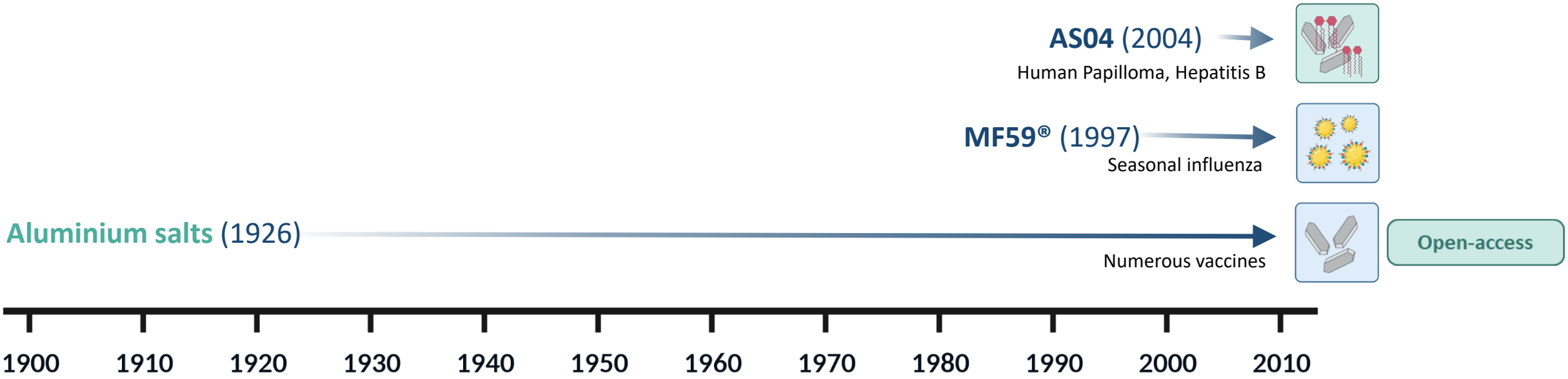
Vaccine adjuvants: needs for a Global Market

- **Adjuvant landscape *before* and *after* H1N1 influenza & COVID-19 pandemics**
- **Current needs and how to improve equitable access and affordability of adjuvanted vaccines**

2009: three adjuvants in approved human vaccines

Situation before H1N1 pandemic (2009)

- Only three adjuvants in approved human vaccines
- Only aluminium salts available under **open-access** terms **(= available without any licensing agreement)**



Pandemic H1N1 (2009) influenza: critical need for more adjuvants

Pandemic specific needs

- Several billion doses of influenza vaccines at affordable price in a short time frame

Wider needs

- Access to GMP adjuvants
- Access to formulation know-how
- Evaluation of adjuvanted vaccines

Challenges

- Aluminium salts not appropriate
- Only few adjuvants available
- Licensing agreements required for dose-sparing adjuvants

Adjuvants and formulation identified as a weak link in vaccine development

Important achievements in the field of vaccine adjuvants

Efficacy demonstrated for different antigen types
Split influenza[1], Parasite-derived (malaria)[2],
Viral glycoprotein (herpes zoster)[3], Viral particles (human papilloma)[4]

Better understanding of
mode of action

Benefits across ages
6-month-old infants to
80+ year-old-adults[3,5]

and vulnerable populations
immuno-compromised
or HIV-positive[6]

Persistent magnitude and quality of immune response
Antibody breadth, cross-reactive T-cells[1]
and increased functionality of antibodies

Dose-sparing
to allow the reduction of
vaccine antigen content

Favorable risk/benefit profile
of adjuvanted vaccines confirmed
by post-marketing studies

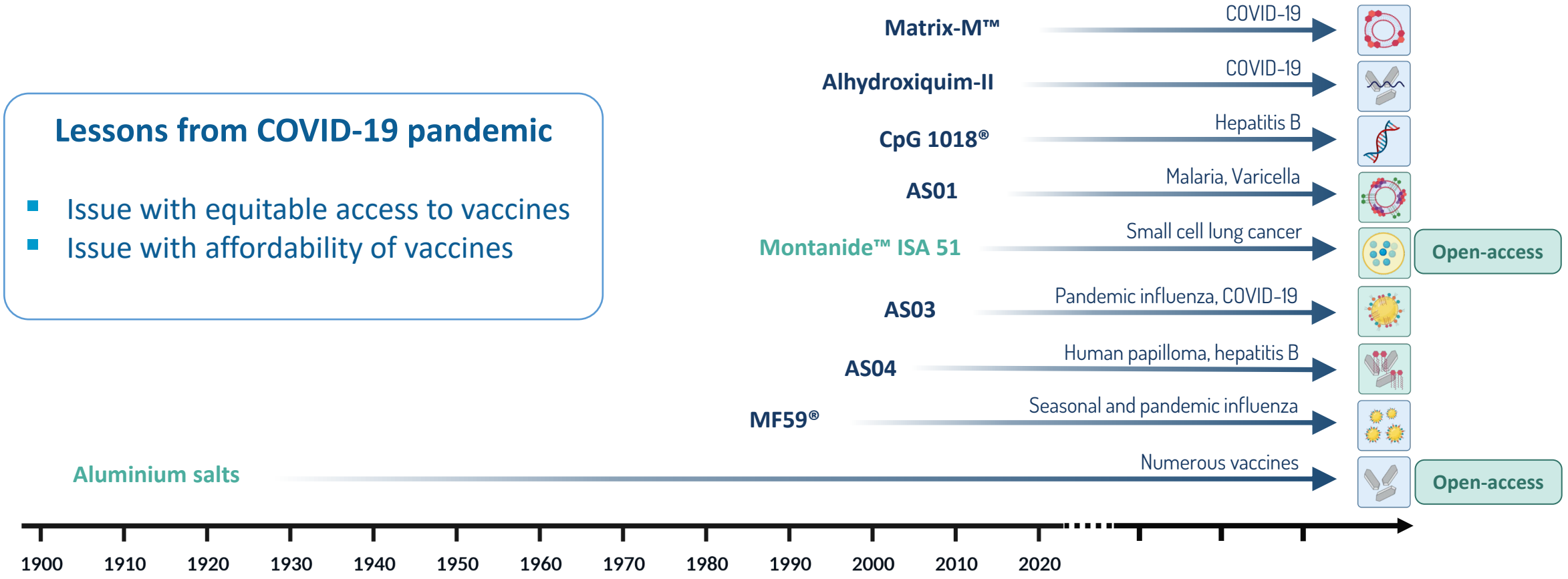
1: Leroux-Roels I, et al. PLoS One. 2008;3:e1665.
2: RTS, S Clinical Trials Partnership. N Engl J Med. 2011;365:1863-1875.
3: Lal H, et al. N Engl J Med. 2015;372:2087-2096
4: Roteli-Martins, et al. Hum Vaccin Immunother. 2012;8:390-397.
5: Knuf M, et al. Hum Vaccin Immunother. 2015;11(2):358-76. 7. Denny L, et al. Vaccine. 2013;31:5745-5753.
6. Denny L, et al. Vaccine. 2013;31:5745-5753.

2023: several adjuvants in approved vaccines

Situation after COVID-19 pandemic (2023)

Lessons from COVID-19 pandemic

- Issue with equitable access to vaccines
- Issue with affordability of vaccines



Vaccine adjuvants: needs for a Global Market

- Adjuvant landscape before and after H1N1 influenza & COVID-19 pandemics
- **Current needs and how to improve equitable access and affordability of adjuvanted vaccines**

A need to develop more adjuvants

There is no single best adjuvant for all antigens

GMP adjuvants

- If adjuvants are not available at GMP: limited interest from vaccine developers
- Very few vaccine developers willing to pay for the initial establishment of GMP adjuvant process
- Potential key role for funders, public-private partnerships

Multiple adjuvant options for different vaccine antigens

- Access to different delivery systems combined with different immunomodulators
- Physico-chemical compatibility depends on a specific adjuvant-antigen combination
- One adjuvant does not fit all vaccine antigens

Testing adjuvants in comparative / H2H studies

- Provides critical information on the class/type of adjuvant required for a given antigen/indication
- Pre-clinical and clinical
- To be ideally performed by a “neutral” laboratory/investigator

A need to leverage expertise in adjuvant preparation, formulation and testing

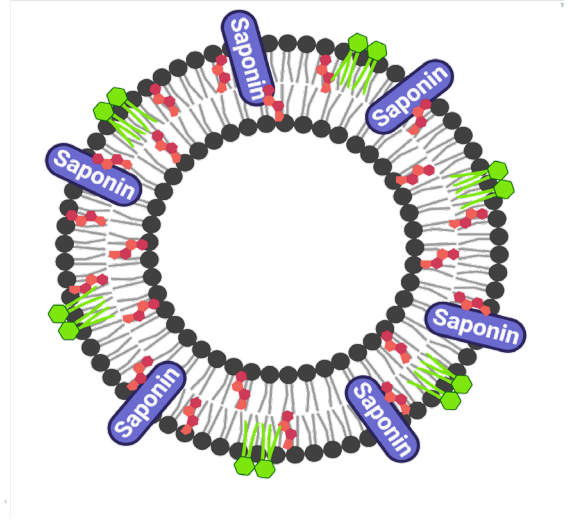
Much more than a matter of simply mixing

1 Composition

- Choice of lipids and immunostimulants
- Ratio of components
- Concentrations
- Lytic activity of saponin

2 Manufacturing

- Processes
- Purification
- Upscaling
- Filtration
- Quality control



3 Formulation/ Stability

- Formulation parameters
- Buffers
- Containers
- Temperatures

4 Immunogenicity/ Tolerability/Protection

- Humoral response
- Cellular response
- Tolerability
- Protective efficacy

A need to develop new adjuvants

Towards the next generation of adjuvanted vaccines


Improved duration of immunity


Thermostable adjuvanted vaccines


Induction of specific immune responses *e.g.* Th-17


Sustainably-sourced adjuvant components


Single-dose adjuvanted vaccines


Mucosal adjuvanted vaccines

For reference: Lykins, Fox et al. Pharmaceutics 2023; 15(7), 1850

A need to decipher Intellectual Property & Freedom-To-Operate

A (big) bag of (big) worms

IP landscape analysis & review of adjuvant FTO

- FTO for each country of component production and final vaccine administration
- FTO on the manufacture, formulation, filtration, QC - as well as combinations of adjuvant with other antigens
- Expertise in formulation and CMC required
- FTO on target antigens
- Beware of dominant IP of broader scope
- Evaluation of vaccine development timeline vs. remaining time of patent life
- Moving target: regular updates required
- Costly and time-consuming

Exemptions to patent protection

- Legal provisions to progress during the final years of a patent term to be ready for rapid market entry
- Knowledge of national patent laws

(*e.g.* research exemptions in US *vs.* EU)

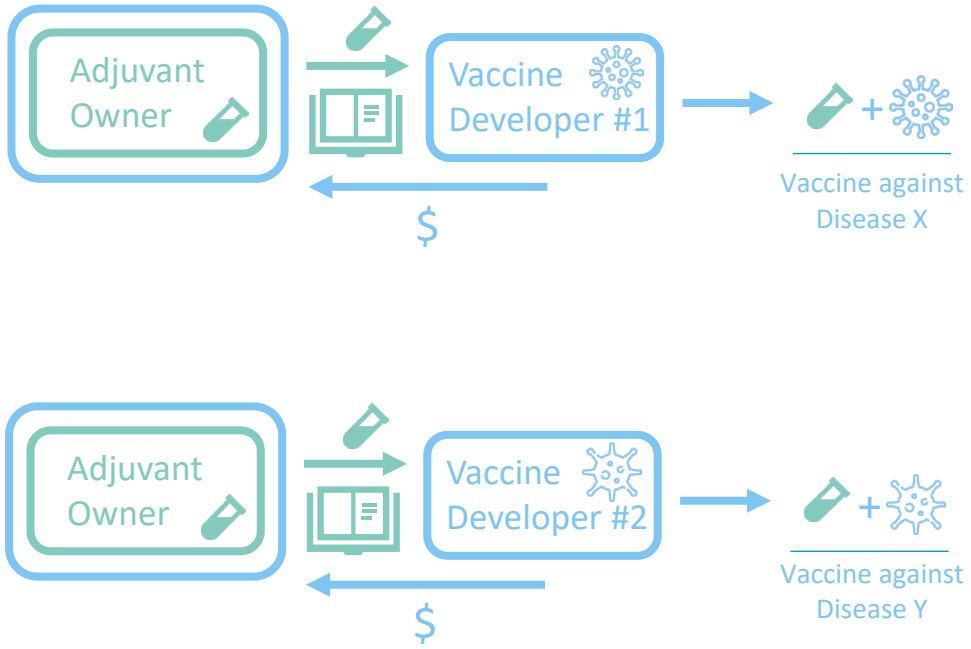
Negotiation with patent owner

- Often lengthy and complicated

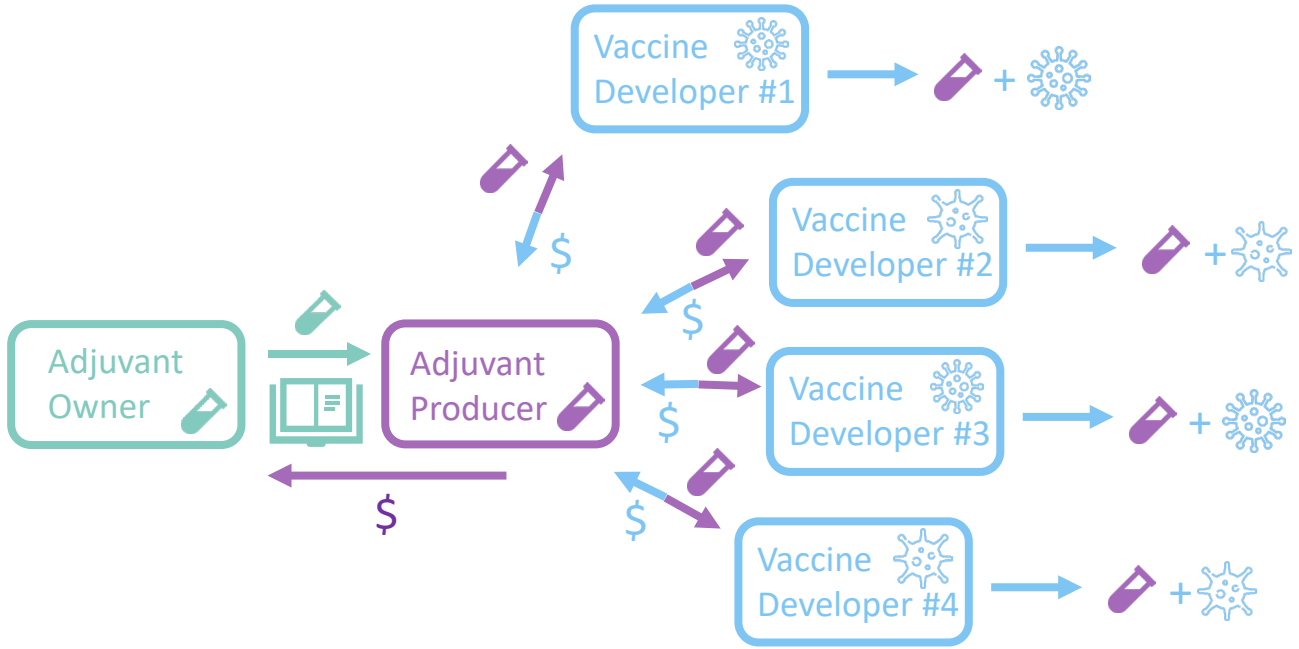
A need to implement alternative business models

Thinking out of the usual box

Classical Outlicensing model



Open-access model



Aluminium salts - Croda
Sepivac SWE™ - Seppic

Conclusions

- **Develop more adjuvants**
  - Use the simplest adjuvant when possible
- **Leverage expertise in adjuvant preparation, formulation and testing**
  - Innovate on raw materials and processes
- **Better understand FTO/IP**
  - Identify barriers and opportunities
- **Implement business models compatible with Global Health challenges**
  - Open-access / large volumes (reduction of costs)

Increased global capacity

More equitable access

More affordable vaccines

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Adjuvants for Pandemic Preparedness

Daniel Fullen, Senior Manager Office of Technology,

CEPI

13th September 2023

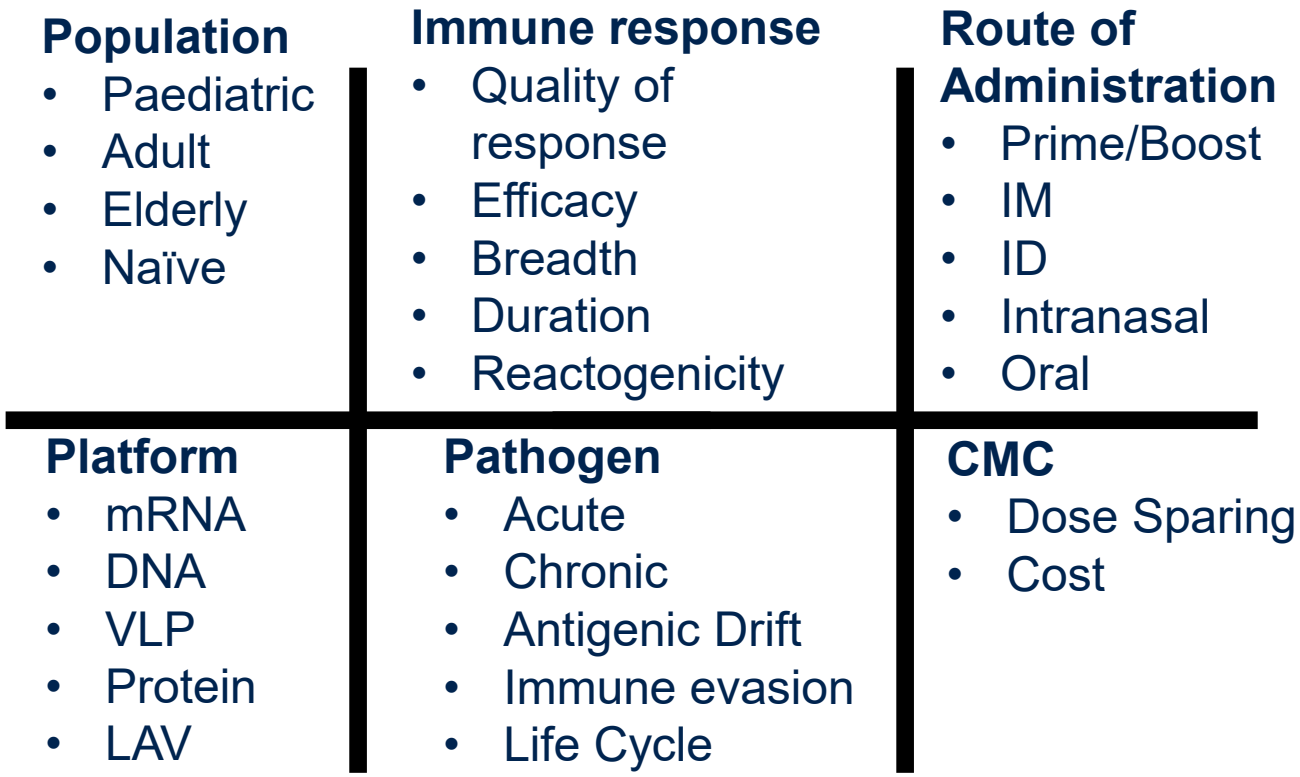
Introduction

- What makes the Optimal adjuvant?
- Requirements of an Adjuvant for Pandemic Preparedness?
- How to we ensure that adjuvants are where there are when we need them?
  - Stockpiling
  - Geo-diversified production

What Makes the Optimal Adjuvant?

It depends…….

Adjuvants are context specific:



Squalene Emulsion adjuvants appear most effective for acute infections

Target	Platform	1st	2nd	3rd	4th	5th	6th	Developer	Ref:
COVID	RBD–NP	AS03	CpG-Alum	Alum	O/W 1849101	AS37	-	SK Biosciences	Arunachalam et al 2021
COVID	CoVLP	AS03	CpG-Alum	-	-	-	-	Medicago	Pillet et al 2022
COVID	S-Trimer	AS03	CpG-Alum	-	-	-	-	Clover	Richmond et al 2022
COVID	RBD-Fc, RBD S-Trimer	Manganese nanoparticle	MF59	Alum	PBS	-	-	Fudan University	Zhang et al 2022
COVID	Prefusion Spike	AS03	AF03	-	-	-	-	Sanofi, GSK	Goepfert et al 2021 De Rosa et al 2022
MERS	RBD-Fc	MF59	mPLA-SM	ISA51	Alum	Freund's	-	NY Blood Centre	Zhang et al 2016
MERS	Molecular Clamp	SQ	SMQ	LMQ	LQ	SWE	Alum	U. Queensland	O'Donnell et al 2022
Influenza	Meta analysis	AS03	MF59	-	-	-	-	U. New South Wales	Hauser et al 2019
Influenza	Protein	MF59	GLA-SE	IC31	CAF1	Alum	-	Statens Serum Institut	Knudsen et al 2016
Influenza	Protein	AS03	MF59	-	-	-	-	Sanofi	Jackson et al 2015
Influenza	Stalk	AS03	AS01	-	-	-	-	GSK	Folschweiller et al 2022
Influenza	Molecular Clamp	ALF55	Addavax	Alum	AdQS21	QS21	-	U. Queensland	Isaacs et al 2021
RSV	Molecular Clamp	Alum	AdQS21	ALF55	Addavax	QS21	-	U. Queensland	Isaacs et al 2021
PRRSV	Protein	ISA28	SWE	SWE+TLRa	skiSE+TLRa	-	-	Xeolas	Vreman et al 2021

Liposomal Adjuvants appear most effective for chronic infections

Target	Platform	1st	2nd	3rd	4th	Developer	Ref:
HBV	Protein	AS01	AS03	AS04	Alum	GSK	Burny et al 2017
HBV	Protein	AS01	AS03	AS04	Alum	GSK	Budroni et al 2021
HBV	Protein	AS04	Alum	-	-	GSK	Levie et at 2009, Tong et al 2005, Kundi et al 2007
HBV	Protein	AS01	AS02	CpG	-	GSK	Vandepapeliere et al 2008
HPV	VLP	AS01	AS02	AS04	-	GSK	van Damme et al 2014
HPV	VLP	AS04	Alum	-	-	PHE	Reed et al, 2018; Godi et al 2015
VZV	Protein	AS01	AS04	AS03	-	GSK	Fochesato et al 2016
HIV	Protein	ALFQ	ALF	-	-	WRAIR	Beck et al 2015

Requirements of an Adjuvant for Pandemic Preparedness

Immune Response

- Induces a Th2 Response
- Support a broad immune response

Suitable of a wide population (young and old)

Adaptable

- Ability to be used with a range of vaccine platforms
- Bedside mixing

CMC

- Cheap
- As few components as possible
- Abundant raw materials from sustainable sources
- Ability to be produced at scale
- Ability to produce in different territories
- Not limited by IP restrictions
- Halal

Tested Clinically

Dose Sparing Potential

Stable (especially if used for stockpiling)
Tolerant of Temperature fluctuations

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Squalene Based Emulsion Adjuvants

e.g. AS03, MF59, SWE, SE, CAS-1, BFA03

- Established Safety Profile
- Stability
- Clinically Tested
- Broad Immune response
- Broad Compatibility
- Adjuvant Platform
- Bedside Mixing
- Potential for Dose Sparing

Alum Adjuvants

e.g. Aluminium Hydroxide, Aluminium Phosphate, Aluminium oxyhydroxide

- Established Safety Profile
- Stability
- Clinically Tested
- Broad Regulatory approval
- Th2 biased Response
- Broad Compatibility
- Adjuvant Platform
- Bedside Mixing

How do we ensure where these adjuvants are when we need them?

- Export Restrictions
- Advance Purchase agreements
- Stockpiling
- Delayed Sharing
- Bilateral agreements

POLITICS

UK and EU vaccine dispute deepens as Brussels considers new export controls

PUBLISHED MON, MAR 22 2021·8:31 AM EDT | UPDATED MON, MAR 22 2021·10:03 AM EDT

India Cuts Back on Vaccine Exports as Infections Surge at Home

A major supplier of the AstraZeneca vaccine, India is now circling the wagons and restricting exports. The impact is beginning to be felt worldwide, particularly in poorer countries.

Science & technology | A vaxxing problem

American export controls threaten to hinder global vaccine production

The world's biggest vaccine-maker says it will feel the pinch in a month

Healthcare & Pharmaceuticals

EU to extend COVID-19 vaccine export controls as AstraZeneca shipment blocked -sources

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India hopes U.S. will soon ease ban on vaccine material exports - sources

By **Neha Arora**, **Rupam Jain** and **Rupam Jain**

April 19, 2021 5:08 PM GMT+1 · Updated 2 years ago

Sustainability of Supply: Adjuvant Stockpiles

Generally, more suitable for outbreak rather than pandemic scenarios

Virtual Stockpile: Pre-purchased material that can be manufactured/released on demand to where it is needed.

Pros: No cost/storage/liability issues
No Expiry of material (rolling stockpile)
Cons: May be vulnerable to host nation export controls
May be vulnerable to supply shortages of raw materials/manufacturing capacity

Physical Stockpile

Pros: Potential to be stored at a range on locations to minimise issues of vaccine nationalism
Cons: Cost of Storage, Maintenance and managing expiry of product
Liability issues, QA/QC release
Ideally to be stored in countries with a small population and close to formulation sites
Typically, dependent on existing licenced vaccines for scale up

Use of an existing IP constrained adjuvant may create dependencies

Sustainability of Supply: Raw Material Stockpiles

Pros:

- Raw materials can often be stored for longer periods of time and do not have to be QA/QC released to the same standard a licenced final product.
- Diversity of Adjuvant production

Cons:

- Longer Lead time for Adjuvant production
- Require Proximity to Adjuvant/Vaccine Production Sites
- Ideally Regional Centres would store raw material be in countries will smaller population, to limit the impact of any potential vaccine nationalism.

Geodiversity of Manufacturing

- Support the development of adjuvant (and vaccine) manufacturing capacity in more territories to enable independence of production.
- Tech transfer adjuvant technologies for broader production base
- Formulate adjuvants at regional centres would help smooth the demand for supply when there is an urgent global need and help limit the effects of vaccine nationalism.
- Warm base: Produce adjuvants as sites where they would be useful in peace time (e.g., Influenza, Malaria, HIV). Ability to switch production for a pandemic.
- Localised production of Raw materials:
  - Squalene
  - QS-21
  - MPL

Localised Production of Raw Materials

- The availability of raw materials has a direct impact on the ability to produce adjuvants and the scarcity of a finite resource will have a direct impact on the cost of supply.
- By enabling the production of raw materials in a sustainable way would ensure continuity of supply and will also have the potential to reduce the cost of goods.
- If more organisations that can produce a material, this will further secure global supplies and further reduce cost of the material.

Summary

- We probably already have the adjuvants required for the next pandemic
- However, need to have the ability to be able to supply them to where and when they are needed
- There is a real need to expand the production and capacity
- If we can expand production capabilities of adjuvants and raw materials, we can reduce the dependence and burden on HICs
- Greater Independence and agency required for the Global South to be better prepared for the next pandemic.

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Empowering Public Health:

Strengthening Capacity for Global Supply, Accessibility and Affordability for Adjuvants and Formulations

Dexiang Chen, CEO
Maxvax, China
GVIRF Webinar, Sep 13, 2023

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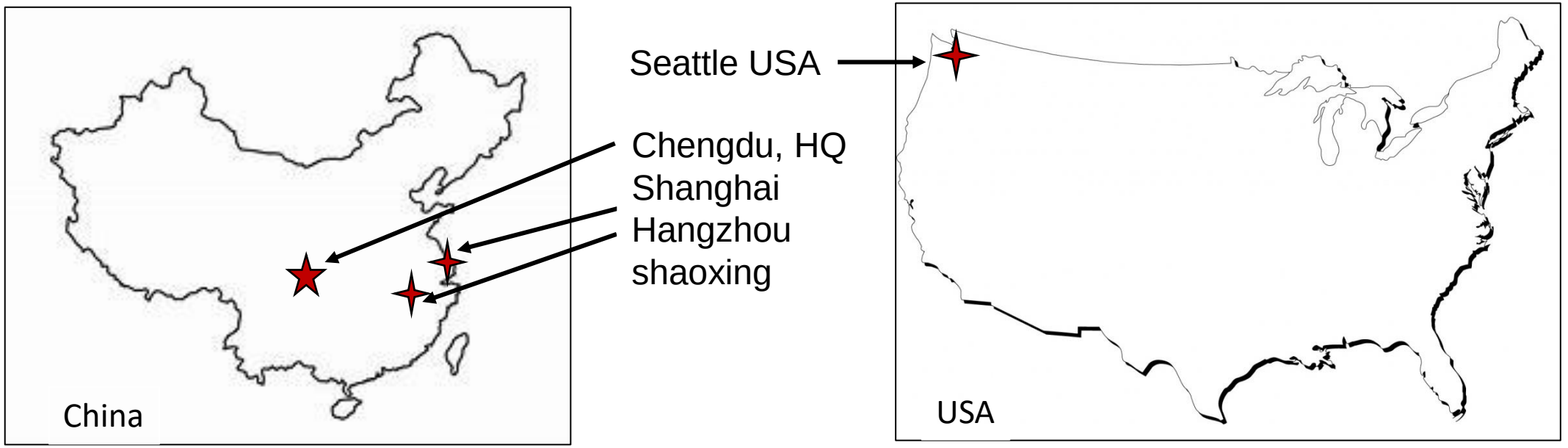
Maxvax introduction

Adjuvant platform

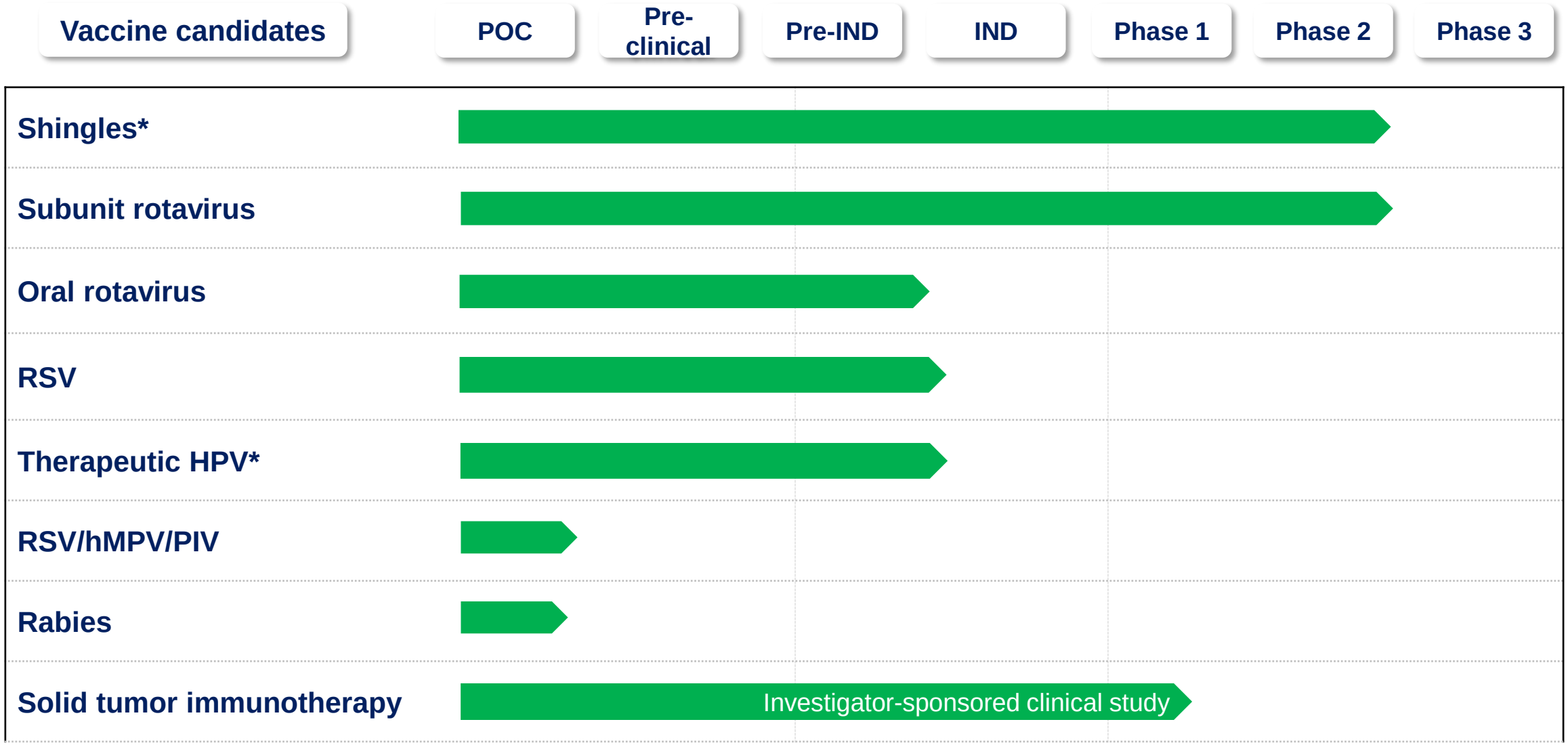
Partnering opportunities

Maxvax Biotechnology

- A clinical stage vaccine company incorporated in 2016 with operations in multiple sites in China and in Seattle USA.
- Technology platform - novel adjuvants.
- >300 employees.



Maxvax's vaccine pipeline



*US and China program

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Maxvax introduction

Adjuvant platform

Partnering opportunities

Why Maxvax works on novel vaccine adjuvants?

- **Accessibility:** Adjuvants are not a “one size fits all” for different types of vaccines; Maxvax has a library of adjuvant molecules and formulations that can be tailored for different vaccines.

- **Quality and scale**: Most vaccine manufacturers do not have the capacity or ability to scale up adjuvant manufacturing for commercialization; Maxvax has the facilities and necessary tools in place to “fast track” the development of novel adjuvants for clinical trials and commercialization.

- **Affordability:** Vaccine manufacturers often rely on third parties for adjuvants, which can be costly; Maxvax produces all its adjuvant molecules and formulations in-house at low cost.

- **Sustainability and supply security**: Many commonly used adjuvant molecules are derived from non-sustainable natural resources (animals or plants). Maxvax has developed synthetic processes for making many adjuvant molecules.

Maxvax's approach: build an in-house adjuvant platform

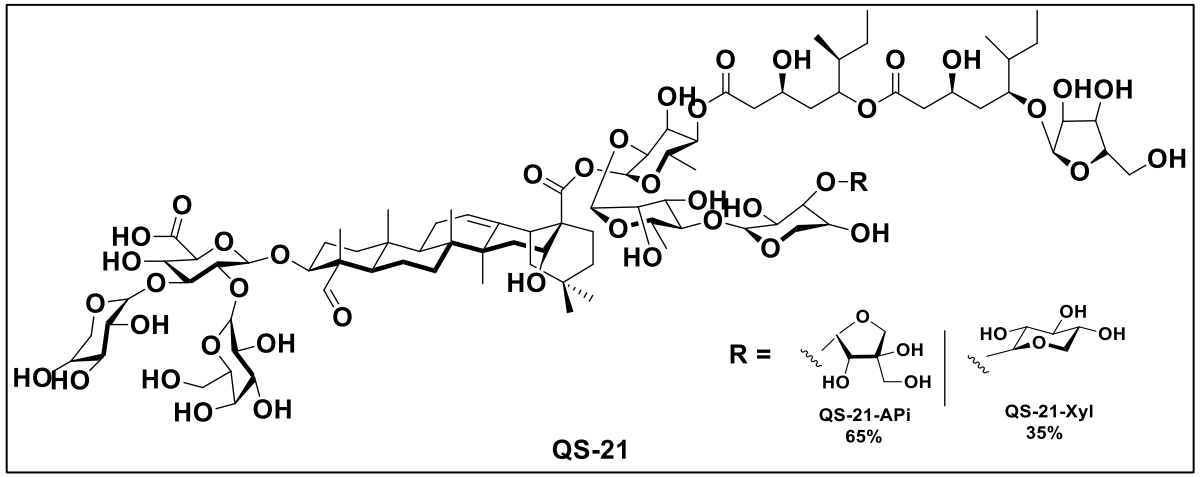
- Goal is to become "self-sufficient" and make it available for partners interested in adjuvants and formulations.
- Focus on improving the quality, access and affordability of advanced adjuvants.
- In-house capabilities:
  - Expertise in chemical synthesis of adjuvants-glycolipids and nucleic acids based.
  - R&D and industrial plants available to produce adjuvants and formulations.
- Adjuvants produced at Maxvax:
  - >20 research-grade adjuvant molecules, covering common classes.
  - IND-ready GMP grade materials:
    - Four adjuvant molecules.
    - Three delivery systems: Aluminum, oil-in-water emulsions, and liposomes.
    - Four combination adjuvants: delivery systems containing one or more molecular adjuvants.

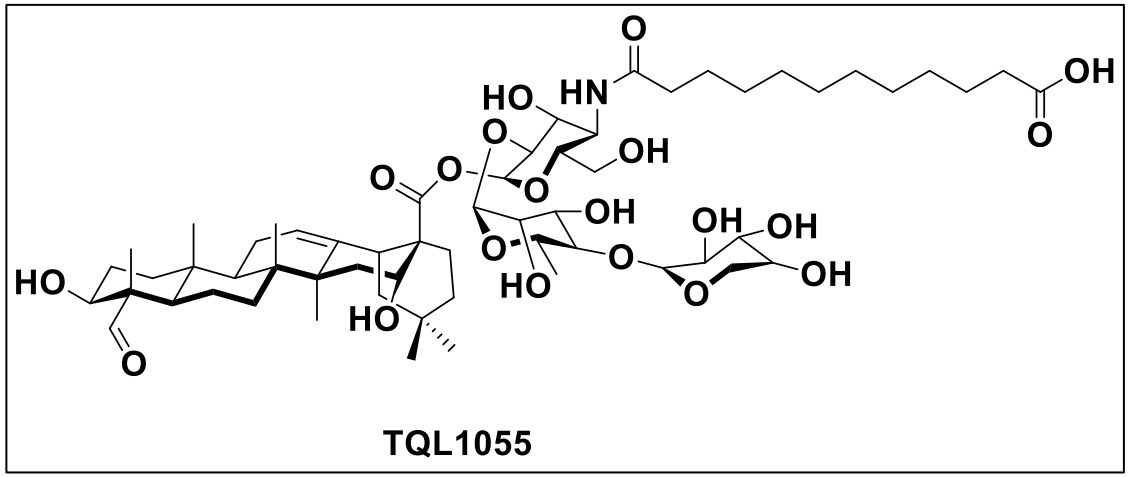
Classes of adjuvant molecules and development status

Adjuvant classes	Method of production	Current batch size	Quality
QS-21	Purified and synthetic	50 g (purified)	GMP
Poly (I:C)	Synthetic	1000 g	
MPL	Synthetic	200 g	
CpG	Synthetic	10g*	
Lipids for liposomes	Synthetic	1000 g	
TLR-7/8 agonists	Synthetic	5 g*	GLP
iNKT class	Synthetic	2 g*	

* Currently at pilot scale and can be scaled up to industrial scale in 6-12 months.

Purified QS-21 (GMP) and its synthetic analogue (GLP)

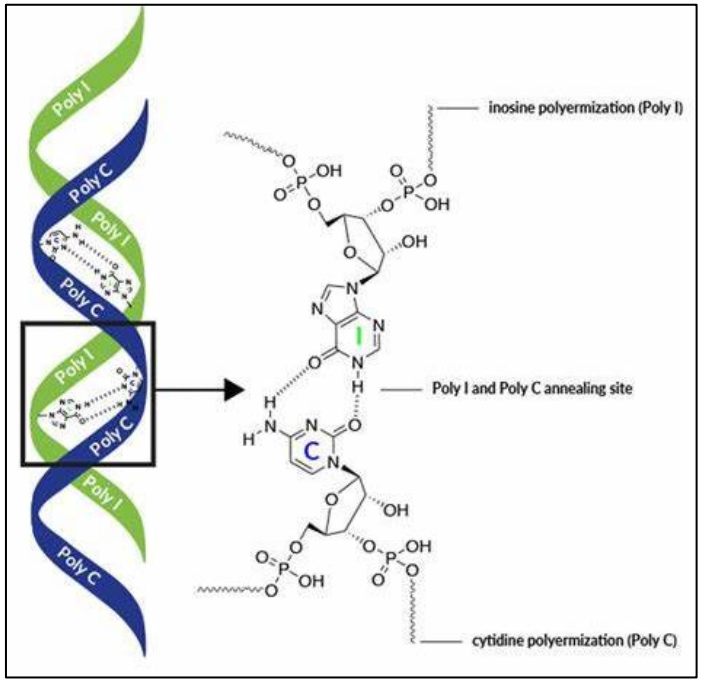




1. **Purified from plant extract:**
   - ① Used in a vaccine in phase II study.
   - ② 50 g (GMP) batch size equivalent to 1 million doses.

2. **Synthetic QS-21 analogue:**
   - ① Research material available （GLP）
   - ② GMP material anticipated 2024.

Poly (I:C) made under GMP compliance



Molecular structure of poly (I:C)

Background：

- TLR-3 ligand stimulating Th1 responses.
- API in a licensed drug for treating shingles and chronic hepatitis B in China.

Maxvax's project:

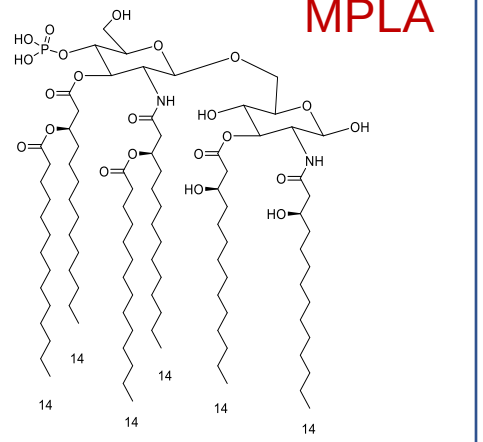
- Optimal molecular weight, stability, and low endotoxin.
- Batch size: 1 kg (GMP) equivalent to 2 million doses.
- Used in a vaccine candidate in Phase II studies.

Synthetic TLR-4 agonists made under GMP compliance

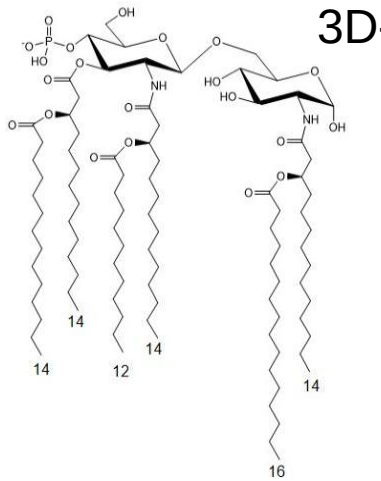
1. Maxvax's project:
   - Four synthetic MPL molecules have been made (see structures below) for research use.
   - GMP MPLA is made at a 200 g batch size. IND planned for China in 2023. Plan to file DMF in US and China.
2. Comparison of MPL production technologies:

Technology	compositions	Batch size	Batch-to-batch consistency
Fermentation and purification	Mixture	10s g	Difficulty to control
Synthetic	Single molecule	200 g (4 million doses)	Easier to control and scale-up

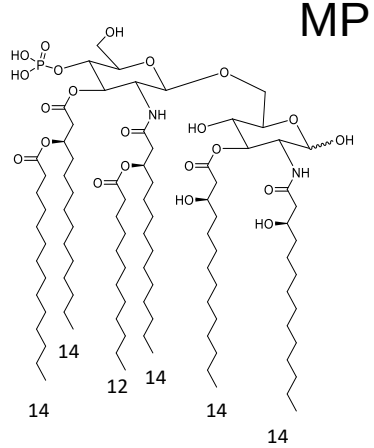
MPLA



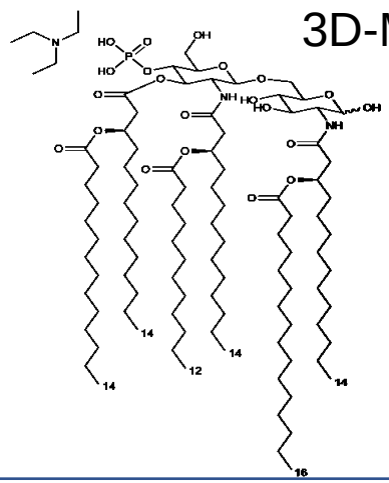
3D-MPL



MPL-12



3D-MPLA



Synthetic TLR-9 agonists made under GMP compliance

Background:

- CpG oligo is an adjuvant component in licensed vaccines against hepatitis B and COVID-19.
- Some of the CpG oligo IP is off patent.

Maxvax's program:

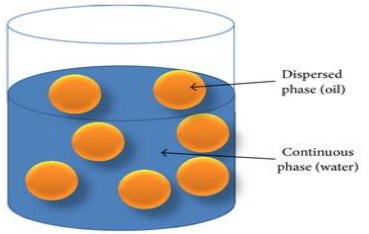
- Two synthetic CpG oligos (Sequences 1018 and 7909) have been made under GMP compliance for R&D use.
- Current scale is at 10 g batch size and can be scaled up to kg batch size in 6 months.
- Annual capacity (planned) is 200 kg (100 million doses).

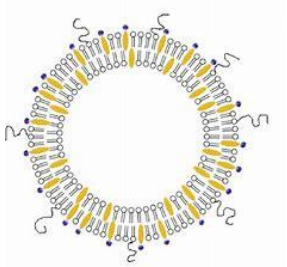
CpG ODN 1018: **5' -TGA CTG TGA ACG TTC GAG ATG A -3'**

CpG OND 7909 (or 2006): **5'-TCG TCG TTT TGT CGT TTT GTC GTT-3 '**

Delivery systems made under GMP compliance

Delivery systems	Current batch size (commercial scale)	equivalent to vaccine dose	Quality
Aluminum hydroxide	500 liters	2.5 million doses	GMP
Oil-in-water emulsions	120 liters	0.5 million doses	
Liposomes	300 liters	1.2 million doses	





Combination adjuvants (adjuvant molecule+ delivery system) made under GMP compliance

Formulation codes	Immuno-profile promoted by these formulations	Development status (of applied vaccines)
MA130A (oil-in-water emulsion+1 adjuvant)	Antibodies	Pre-clinical
MA103 (liposome + 1 adjuvant)	Antibodies, $CD4^+$ T cells	IND
MA105 (liposome + 2 adjuvants)	Antibodies, $CD4^+$ T cells ($CD8^+$ T cells?)	Phase II
AYK103 (liposome + 2 adjuvants)	M1, $CD4^+$, $CD8^+$ T cells	Investigator-sponsored clinical study (Solid tumors)

Maxvax facilities

Vaccine R&D center-Chengdu

- 70K SF, part is GMP
- pilot plants (CHO, *E. coli* and viral vaccines)
- Producing adjuvant formulations and vaccines for Phase I & II vaccine studies.

Adjuvant R&D center-Shanghai

- 18K SF; operational since 2022
- Adjuvant R&D center

Industrial vaccine manufacturing plant-Shanghai

- 120K SF, GMP commercial plants
- Producing adjuvant formulations and vaccines at commercial scale.

Industrial adjuvant production plant-Shaoxin

- 30K SF, GMP
- Producing adjuvant raw materials

CONTENTS

Maxvax introduction

Adjuvant platform

Partnering opportunities

Partnering opportunities

- Materials and data package are available for research and product development
  - ① Research-grade adjuvant molecules
  - ② GMP-grade adjuvant molecules
  - ③ GMP-grade adjuvant formulations

Thank you for your attention!

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成都迈科康生物科技有限公司
Maxvax Biotechnology LLC

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Lead Innovation

WHAT ARE THE MAIN OBSTACLES AND POTENTIAL SOLUTIONS FOR KNOWLEDGE SHARING ON ADJUVANTS?

DR V. KRISHNA MOHAN

• POTENTIAL OBSTACLES FOR KNOWLEDGE SHARING

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- Proprietary information leading to incomplete knowledge transfer
- Adjuvant characterization in the final product will be even more complex, and the complexity depends on the type of antigen.
- Requirement of modifications in the ‘know-how’ due to complexities involved in scaling up from R&D to large-scale manufacturing.
- GMP Facility Readiness, especially in a pandemic.
- Mandatory requirement of extensive characterization of adjuvant and vaccine, to ensure the safety of the vaccine, making it delay in vaccine development. This extensive characterization may not be available at the R&D stage of development.
- Requirement of Pharmacokinetics/absorption, distribution, metabolism, and excretion studies
- Understanding the mechanism of action of adjuvants with various antigens
- Selection of appropriate adjuvant for the target antigen.

• POTENTIAL SOLUTIONS FOR KNOWLEDGE SHARING

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- Mutual Collaboration with consent, having a clear objective of its usage between the partners, focusing on a WIN-WIN approach for both parties

- Working on new adjuvants, specifically, safe, effective, and in the market, with a slight modification.

THANK YOU

National Institute of Allergy and Infectious Diseases

Bill & Melinda Gates foundation

World Health Organization

GVIRF Webinar
Vaccine Adjuvants for Global Health
September 13th, 2023 09:00-12:30 EDT

Session I: Global Demand for Vaccine Adjuvants

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122 YEARS OF INSTITUTO BUTANTAN

We at Instituto Butantan work tirelessly at the **service of life**

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PRODUCTION OF **SERA AND VACCINES**

100%
80 million

of the **FLU VACCINES** distributed to the Brazilian public health system (SUS)

- ✓ One of the Largest producers of immunobiologicals in Latin America.
- ✓ TIV-IB: Vaccine prequalification by WHO in 2021.
- ✓ Capacity to produce 120 million doses of Influenza Vaccine.
- ✓ PAHO and UNICEF supplier

Production of IB160, a squelene based oil in water emulsion adjuvant: Phase 1 studies with influenza A/H7N9

Preparedness for a pandemic influenza A/H7N9

PLOS ONE

RESEARCH ARTICLE

Preparedness against pandemic influenza: Production of an oil-in-water emulsion adjuvant in Brazil

Milena Apetito Akamatsu[1]*, Vitor Anselmo Sakihara[1], Bianca Pereira Carvalho[1], Aline de Paiva Abrantes[1], Maria A. Sakauchi Takano[1], Eduardo Alfredo Adami[2], Fernando Seiji Yonehara[3], Patrícia dos Santos Carneiro[3], Stefanni Rico[4], Alessandra Schanoski[4], Maurício Meros[5], Adrian Simpson[6], Tony Phan[6], Christopher B. Fox[6], Paulo Lee Ho[1]*

1 Divisão BioIndustrial, Serviço de Bacteriologia, Instituto Butantan, São Paulo, Brazil, **2** Divisão BioIndustrial, Laboratório de Influenza, Instituto Butantan, São Paulo, Brazil, **3** Controle de Qualidade, Instituto Butantan, São Paulo, Brazil, **4** Laboratório de Bacteriologia, Instituto Butantan, São Paulo, Brazil, **5** Divisão BioIndustrial, Instituto Butantan, São Paulo, Brazil, **6** Infectious Disease Research Institute, Seattle, Washington, United States of America

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PLOS ONE

RESEARCH ARTICLE

Dose-sparing effect of two adjuvant formulations with a pandemic influenza A/H7N9 vaccine: A randomized, double-blind, placebo-controlled, phase 1 clinical trial

Tazio Vanni[1], Beatriz C. Thomé[1], Erin Sparrow[2], Martin Friede[2], Christopher B. Fox[3], Anna Marie Beckmann[3], Chuong Huynh[4], Gabriella Mondini[1], Daniela H. Silveira[1], Juliana Y. K. Viscondi[1], Patrícia Emilia Braga[1], Anderson da Silva[1], Maria da Graça Salomão[1], Roberta O. Piorelli[1], Joane P. Santos[1], Vera Lúcia Gattás[1], Maria Beatriz B. Lucchesi[1], Mayra M. M. de Oliveira[1], Marcelo E. Koike[1], Esper G. Kallas[5], Lucia M. A. Campos[6], Eduardo B. Coelho[7], Marilda A. M. Siqueira[8], Cristiana C. Garcia[8], Milene Dias Miranda[8], Terezinha M. Paiva[9], Maria do Carmo S. T. Timenetsky[9], Eduardo A. Adami[1], Milena A. Akamatsu[1], Paulo Lee Ho[1], Alexander R. Precioso[1,6]*

1 Instituto Butantan, São Paulo, Brazil, **2** World Health Organization, Geneva, Switzerland, **3** Infectious Disease Research Institute, Seattle, WA, United States of America, **4** Biomedical Advanced Research and Development Authority, Washington, DC, United States of America, **5** Clinics Hospital of the School of Medicine of University of São Paulo, São Paulo, Brazil, **6** Child Institute of the Clinics Hospital of the School of Medicine of University of São Paulo, São Paulo, Brazil, **7** Clinics Hospital of the Medical School of Ribeirão Preto of the University of São Paulo, Ribeirão Preto, Brazil, **8** Oswaldo Cruz Foundation, Rio de Janeiro, Brazil, **9** Adolfo Lutz Institute, São Paulo, Brazil

Check for updates

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IB160: - Industrial Production Planned to Start in April 2024
- 100 Million doses/year

QUESTION BY THE AUDIENCE

Is it better to look for newer adjuvant systems or modify the currently available ones to increase productivity and availability?

- Depends…case by case evaluation

- producer of well established adjuvant with volume capability for the market
- producer of well established adjuvant with no volume capability for the market
- antigen for vaccine development (humoral - correlates of protection)
- antigen for vaccine development (cellular and humoral - correlates of protection)

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THANK YOU!

FOR TAKING THE TIME AND
TRUSTING OUR WORK