CEPI Adjuvant Library: PATH

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The origins of CEPI

A global partnership

Vision

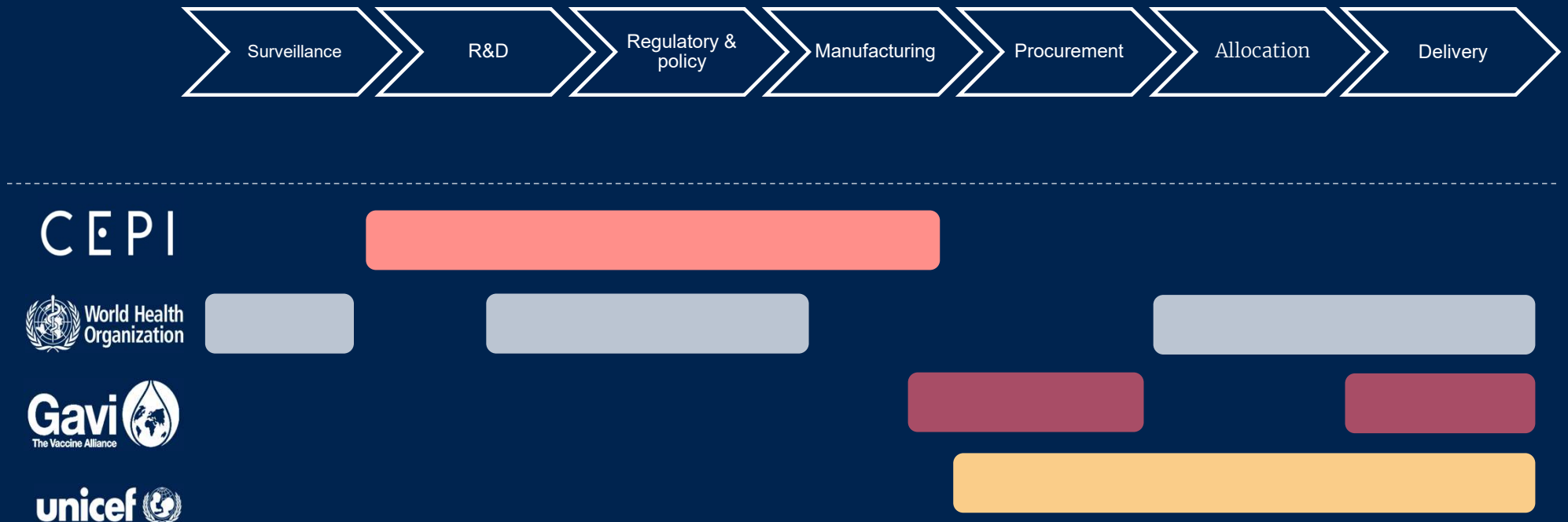
A world in which epidemics and pandemics are no longer a threat to humanity.

Mission

To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

CEPI's unique and complementary role in the ecosystem

Connector, funder, source of global expertise, taking a whole-systems approach to pandemic preparedness



Note: Vaccine development pathway is non-linear and not serial – parallel activities & feedback are continuous up and down value chain

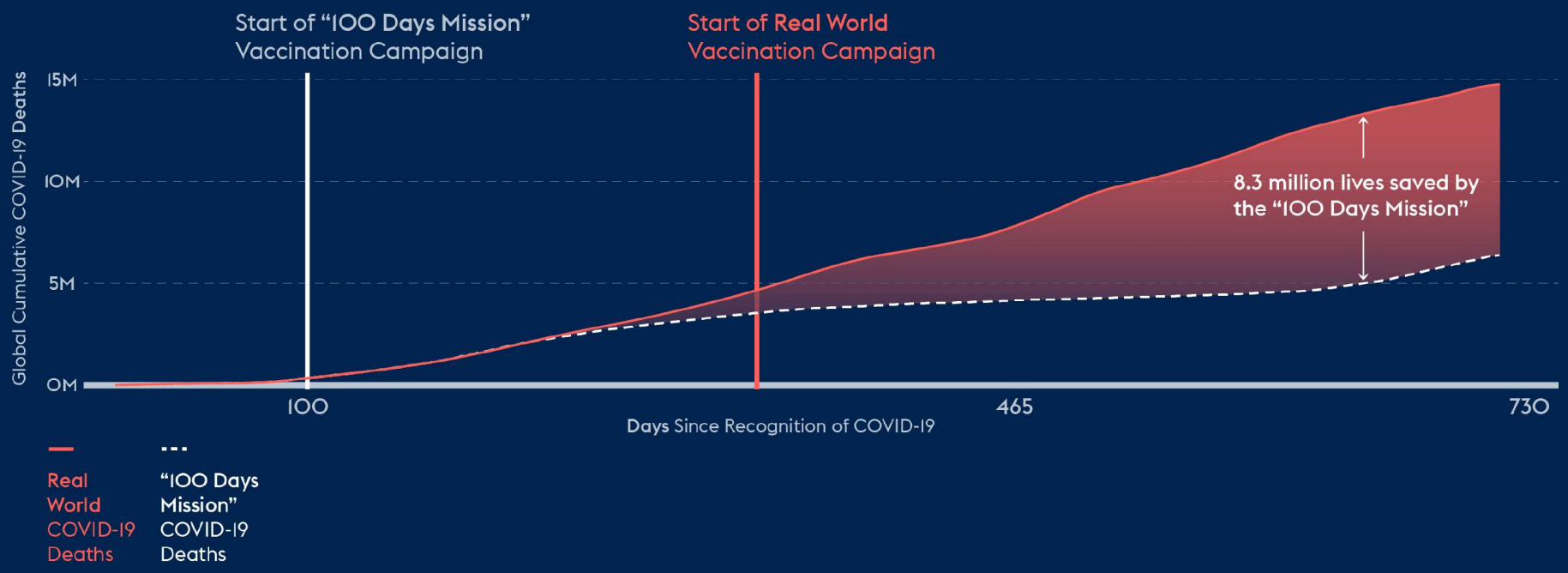
CEPI's 100 Days Mission

Coupled with improved surveillance, and swift use of non-pharmaceutical interventions, a vaccine in 100 days could defuse the threat of a new pathogen with pandemic potential.

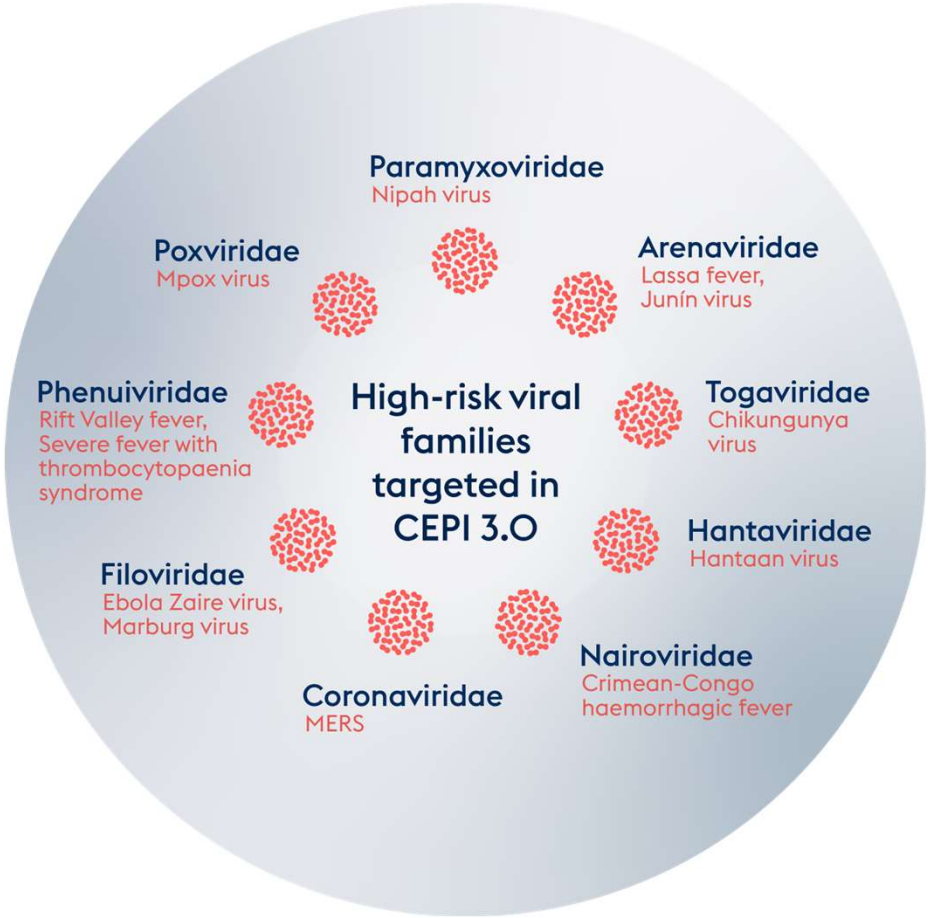
Definition:
'Vaccines should be ready for initial authorisation and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when appropriate.'

The impact of the 100 Days Mission on COVID-19

Cumulative COVID-19 deaths through 2021



Integrated viral family approach to vaccine development



*High-risk viral families and example pathogens within each family

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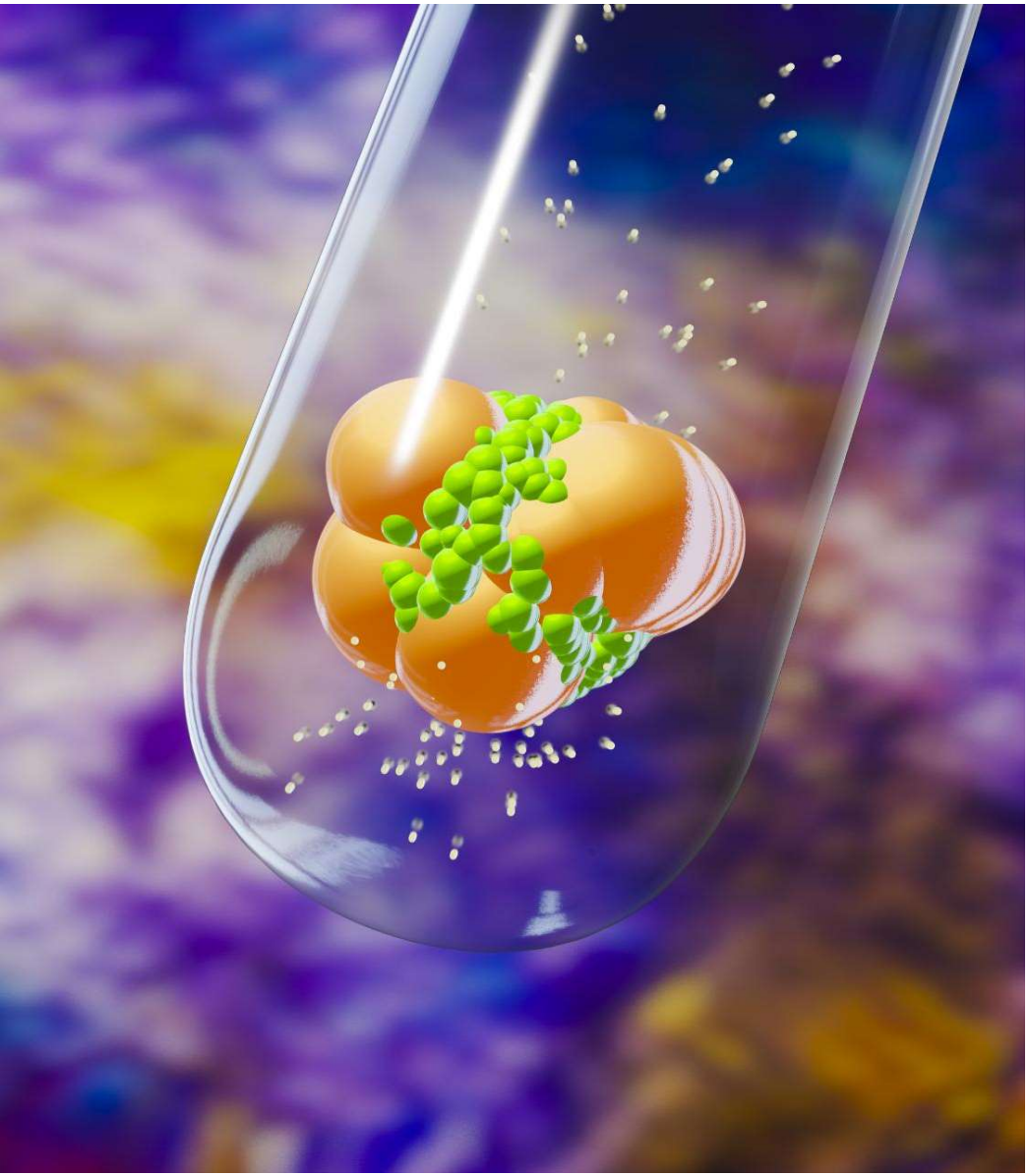
Adjuvant Recap



Adjuvant Recap:

Enhanced Immune Response

Adjuvants boost the effectiveness of vaccines by stimulating stronger or more tailored humoral and cellular immune responses.

Increased Duration of Immune Response

Adjuvants help vaccines provide durable immunity, reducing the need for frequent booster doses.

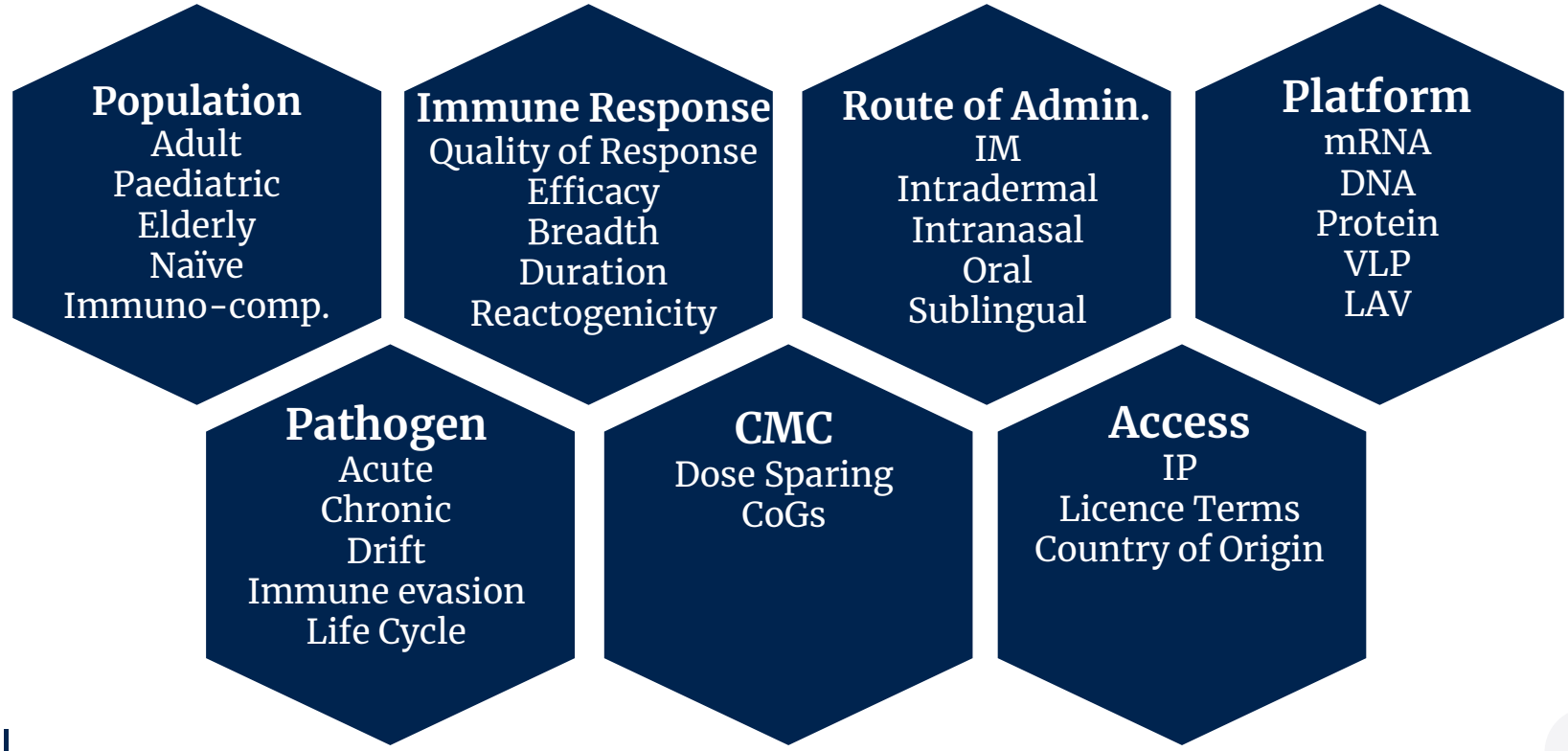
Dose Sparing

Adjuvants allow for reduced antigen amounts in each dose, making vaccines more resource-efficient.

What Makes the Optimal Adjuvant?

It depends……..

Adjuvants are context specific:



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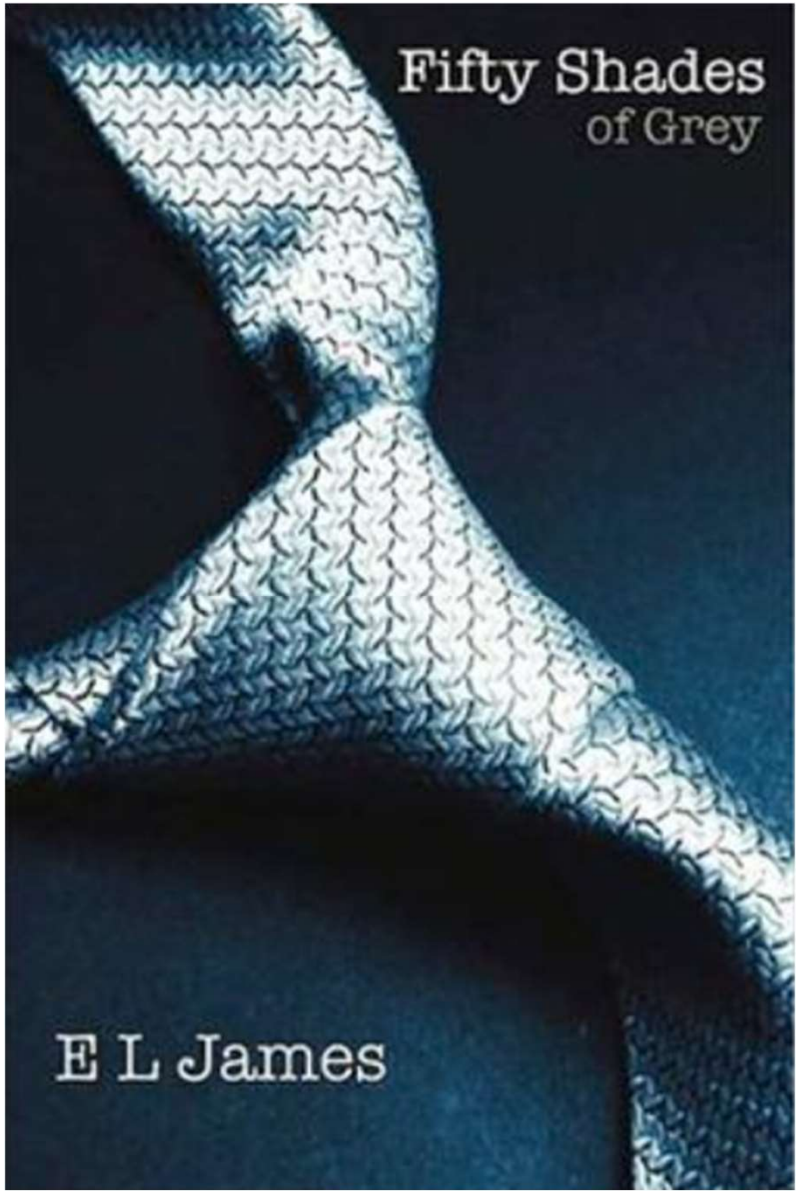
The Regulatory Grey Zone

- **Excipient classification:** Adjuvants are formally classified as excipients, yet they have a **direct biological effect** on the immune response
- **Biological product component:** Unlike inert excipients, adjuvants are **functionally part of the biological product** — the vaccine would not perform without them.
  - EMA: “Excipient classification with active-like expectations”
  - FDA**: “**Component of the licensed biologic”
- **No standalone pathway:** Adjuvants **cannot be licensed in isolation** — they are only evaluated as part of a final vaccine product
- **Context dependency:** The same adjuvant can behave differently depending on antigen, platform, and route of administration — further complicating universal classification



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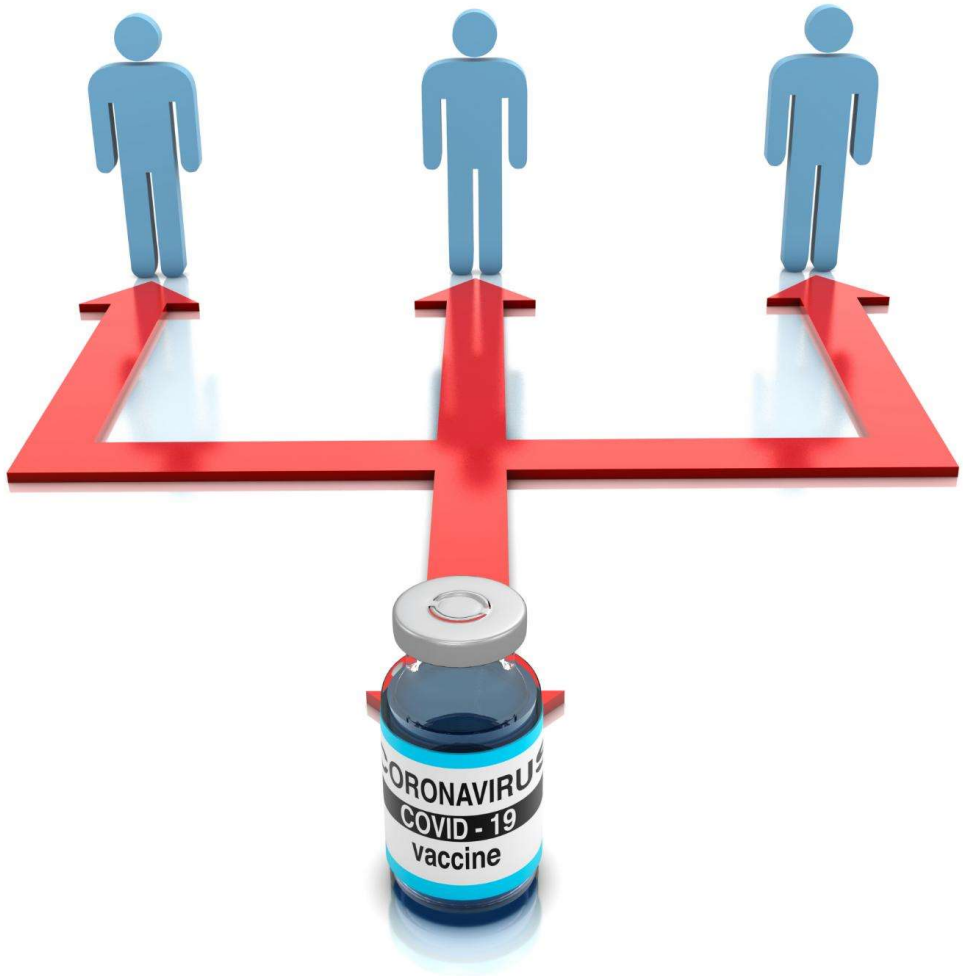
The Adjuvant Problem

The Adjuvant Problem

- Adjuvants used in licensed vaccines are in **high demand but difficult to license**
- It is not clear **which adjuvant to choose** for a particular vaccine candidate
- Supply issues and export bans during pandemics can result in **scarcity**, particularly impacting the Global South
- If access to an adjuvant is withdrawn mid development the vaccine developer will have to **start back at the beginning** (Non-clinical GLP tox)



China's Clover ends COVID-19 vaccine partnership with GSK

By **Reuters**

February 1, 2021 1:18 PM GMT · Updated February 1, 2021

GSK, Innovax end HPV vaccine deal

July 24, 2024

Novavax storms back with $1.2B Sanofi deal

By Lee Landenberger May 10, 2024

PROPUBLICA

How a Big Pharma Company Stalled a Potentially Lifesaving Vaccine in Pursuit of Bigger Profits

Sanofi swoops on Dynavax with $2.5bn takeover deal

BIOTECH

Pfizer pens $530M deal to use Novavax's vaccine adjuvant tech on 2 programs

By **James Waldron** · Jan 20, 2026 10:40am

CEPI Adjuvant Library

CEPI-MHRA Adjuvant Library Repository

Adjuvants received by MHRA:

• Allergy Therapeutics	UK
• CHA Vaccine Institute	Korea
• MaxVax (3 adjuvants)	China
• Clover	China
• GHDDI	China
• Glycovax	Canada
• Jiansgu Recbio (2 adjuvants)	China
• Panacea	India
• Parr Biotec (2 adjuvants)	China
• Sumitomo	Japan
• Shionogi	Japan
• SSI (2 adjuvants)	Denmark
• *AAHI (6 adjuvants)*	US
• *Croda (2 adjuvants)*	Denmark/UK

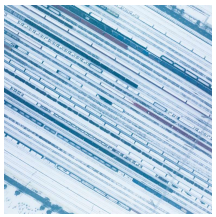
CEPI Adjuvant Library Benefits: Vaccine Developers

Improved Access to Adjuvants

The library offers vaccine developers a wide selection of adjuvants, facilitating innovation and broader research possibilities.

Rational Adjuvant Selection

Developers can choose the most effective adjuvants based on preclinical and disease-specific data rather than just access and availability.



Preclinical Data

The adjuvant library provides preclinical data and disease specific challenge data to vaccine developers, enabling assessment of vaccine candidates during early research stages.

Competitive and Cost-effective

Increased market competition between adjuvants potentially reduces the overall cost of goods for vaccines.

Benefits for Adjuvant Developers

Increasing Developer Visibility

The library raises the profile of lesser-known adjuvant developers, connecting them more effectively with vaccine producers.

Preclinical Data

By offering valuable preclinical and challenge data, the library builds trust and credibility for adjuvant developers in the scientific community.

Enhances Adjuvant Development

The library supports adjuvant progression down the developmental pathway, further derisking them and making them more attractive for the vaccine market.

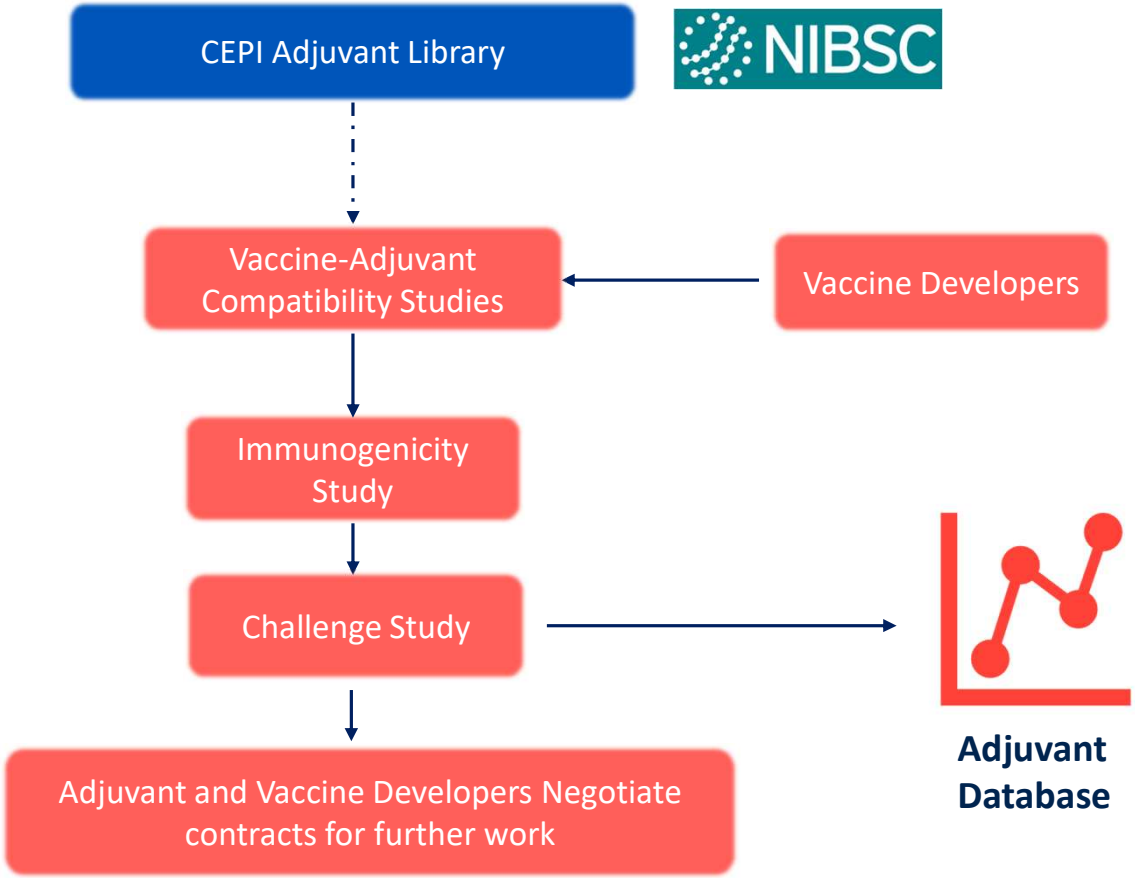
Adjuvant Portfolio and stage of development

Mimic	Preclinical	GMP	Phase I	Phase II	Phase III	Licenced
Lipo + QS-21		MA103 Maxvax	GLA-LSQ AAHI		MA105 Maxvax; BFA01 Recbio	
Sq. Emulsion + Vit E		MA130 Maxvax	CAS-1 Clover	SE AAHI		A-910823 Shionogi; BFA03 Recbio
Alum +TLR4				GLA-Alum AAHI		
Alum						Alhydrogel Croda; Adjuphos Croda
CpG			CpG Parr Bio; CpG + Alum Parr Bio			
Squalene Emulsion						EmulsiPan Panacea
Other		A225-CL GHDDI; 3M-052-SE AAHI; SLA Archaeosomes Glycovax	SA-2 Sumitomo; CAF01 SSI	GLA-SE AAHI; SLA-SE AAHI; CAF09b SSI; Lipo-pam CHA Vaccine Institute		MCT Allergy Therapeutics

Canada, China, Denmark, India, Japan, Korea, UK, USA

Alum, CpG, Liposome, Emulsion

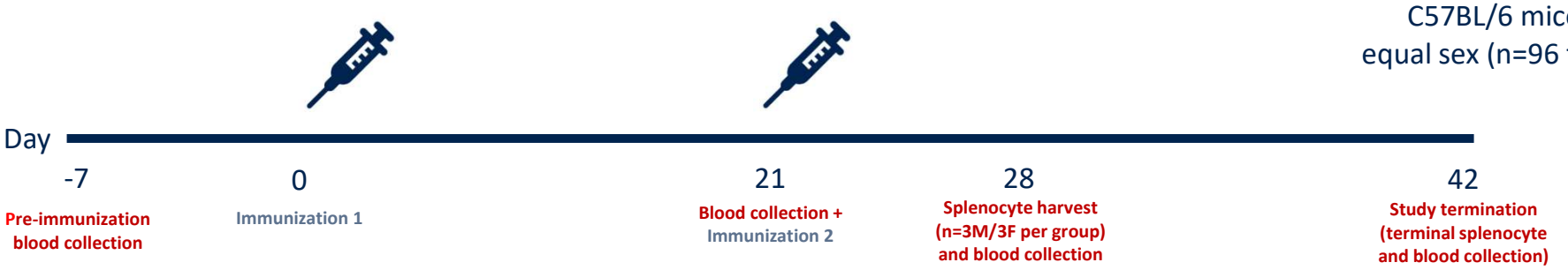
Adjuvant Library



Study 1: Mouse Immunogenicity Screening Study

Up to five (5) adjuvants will be tested in combination with a vaccine candidate from the CEPI portfolio (*to be determined*) in a preclinical immunogenicity screening study as follows:

C57BL/6 mice,
equal sex (n=96 total)



Study Group[c]							
Adjuvant 1[a]	Adjuvant 2[a]	Adjuvant 3[a]	Adjuvant 4[a]	Adjuvant 5[a]	Current Adjuvant Control	AddaSO3 Ref Adjuvant	Antigen Only Control[b]
6M/6F	6M/6F	6M/6F	6M/6F	6M/6F	6M/6F	6M/6F	6M/6F

[a]Adjuvant concentration to be determined; presumably highest tolerable concentration
[b]Antigen and adjuvant only groups will not be immunized with vaccine candidate
Total n per group = 12 (6 male [M], 6 female [F]); this represents the minimum number required per sex for acceptable statistical power

Deliverable: Down-selection of two (2) adjuvants for ensuing challenge/efficacy study (Study 2)

Study 2: Proof of Principle Challenge/Efficacy Study

Two (2) down-selected adjuvants will be tested in combination with a vaccine candidate from the CEPI portfolio in an appropriate disease-specific challenge model as follows:



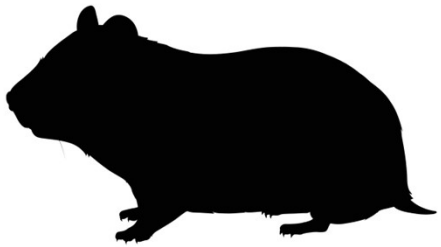
[*14 Day Post-Challenge Period*]

Day

-7	0	21	28	42	56
Pre-immunization blood collection	Immunization 1	Blood collection + Immunization 2	Splenocyte harvest (n=3M/3F per group) and blood collection	Pre-challenge blood collection and challenge	Post-challenge biosampling, clinical observations, and measurements

Study Group[c]				
Adjuvant 1[a]	Adjuvant 2[a]	Current Adjuvant Control	AddaSO3 Ref Adjuvant	Antigen Only Control[b]
6M/6F*	6M/6F	6M/6F	6M/6F	6M/6F

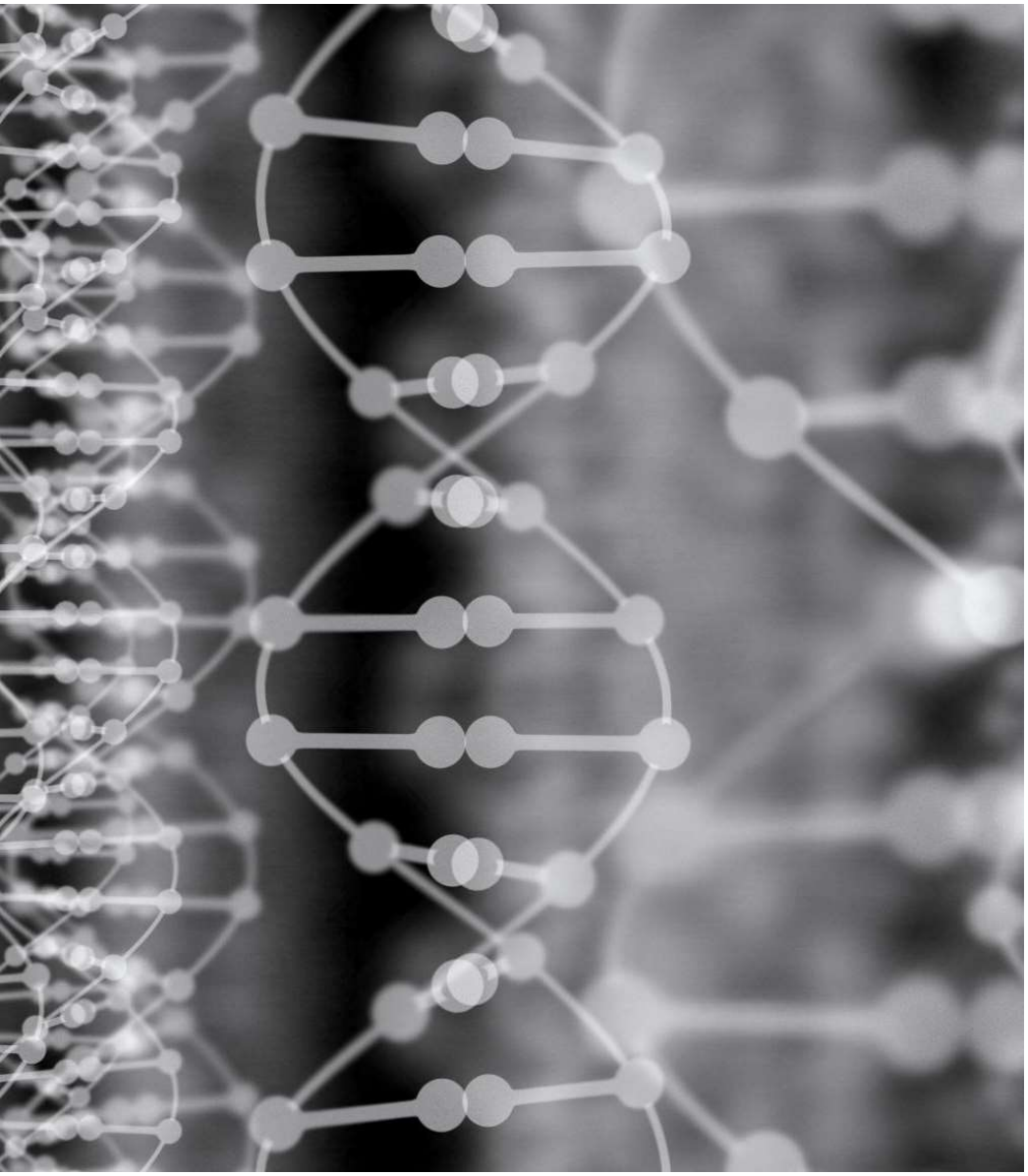
[a]Adjuvant selection and concentration based on results from Study 1
[b]Antigen only groups will not be immunized with vaccine candidate
Total n per group = 12 (6 male [M], 6 female [F]); this represents the minimum number required per sex for acceptable statistical power. Adjuvant 1- and Adjuvant 2-only controls may be added to assess the effect of adjuvant alone on efficacy.



Golden Syrian Hamster, equal sex (n=60 total)
A/BSL-2 or equivalent pre-challenge
A/BSL-3 or equivalent post-challenge

*SARS-CoV-2 challenge assumed

Deliverable: Down-selection of one (1) adjuvant for further development



Creating an adjuvant database to inform adjuvant selection

Data Analysis

Enable analysis of data from Adjuvant Library studies and valuable insights for vaccine R&D.

Cross-Study Comparison

Enable comparison of adjuvants across studies, with the potential to identify shortlist adjuvant candidates for vaccines.

AI-Driven Pandemic Preparedness

The database has the potential to support the CEPI AI Pandemic Preparedness Engine and help to optimise adjuvant selection

Vaccine Studies

- Nipah
- SARS-CoV-1
- SARS-CoV-2
- H5N1
- MERS
- Mpox

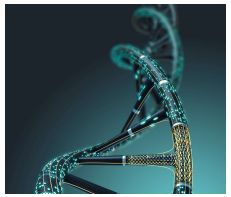
Where next?

Mucosal Adjuvants

Introduce adjuvant into the library that can be mucosally administered and/or elicit a mucosal response

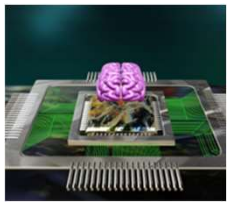
AI Assisted Adjuvant Selection

Support for accelerated adjuvant selection based on disease target, antigen design, vaccine platform and desired immune response



RNA Adjuvants

Library of LNPs and RNA specific adjuvants



Integrating Advanced Technologies

Comparative studies with new and emerging technologies i.e. Organ on a chip, in silico selection etc.

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Questions

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