CEPI

Drug Delivery Innovations for CEPI's 100 Days Mission

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#100DaysMission

Contents

CEPI: A global partnership to tackle epidemics and pandemics

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

CEPI's 100 Days Mission: The need for speed, innovative technologies

If the world had developed a coronavirus vaccine within 100 days, the first injections might have been given in April 2020, when there were **just**

2.3 million

cases of COVID-19 rather than on the 8th December, when

more than 68 million

people had already been infected with the disease.

#100DaysMission

Which innovative technologies do we need?

- Consultations with internal and external experts, as well as critical path analysis, resulted in prioritized innovation areas to invest in to reach our speed, scale and access goals

Speed:
- Platform optimization and standardization
- Cell-free manufacturing
- Synthetic DNA templates
- Transient transfection
- Adjuvant library / stockpiles
- Rapid IPC and release testing

Scale:
- Standardized, optimized processes, ready for scale-up / tech transfer / validation
- High-yielding expression systems
- Infrastructure readiness (facilities, supply chain, workforce, etc.)
- Modular / flexible / scalable / continuous manufacturing systems
- Scale-down models, digital twin, AI
- Tech transfer support, logistics support
- Dose reduction

Access:
- Alternative raw materials for e.g. LNPs
- New / stockpiled adjuvants
- Easy (self-)administration (e.g. oral, nasal, intradermal)
- Thermostability
- Reduced cost of goods

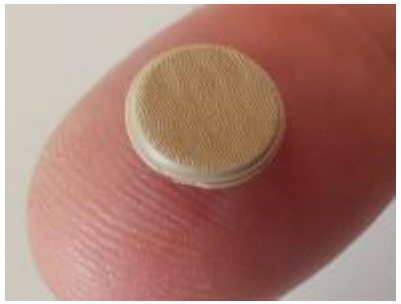
- Included in three Calls for Proposals: Thermostability (Jan ‘22 – Jan ‘23), Speed (May – Dec ‘23) and Scale/Access (Oct ‘23 – Feb ‘24), additional CfPs / Focus Areas may be added to address remaining gaps

Drug delivery innovations (thermostability and alternative presentations) are crucial for CEPI's 100 Days Mission, in making epidemic and pandemic vaccines equitably accessible.

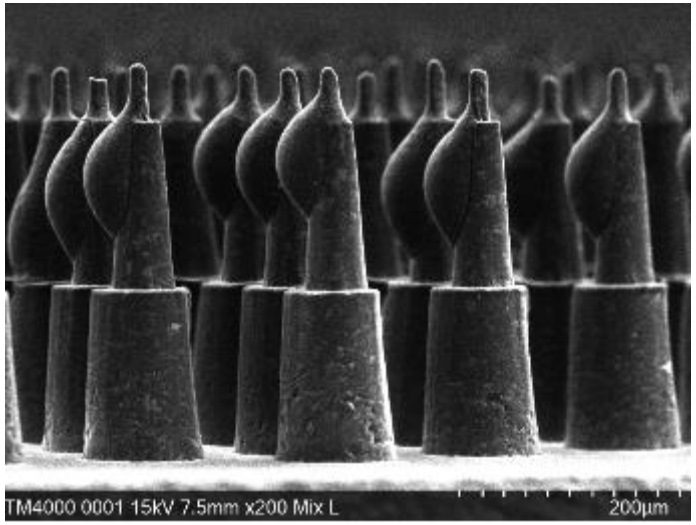
Vaxxas – Microarray Patches for mRNA stabilization and delivery

What	• High-density microarray patch platform for thermostabilization and intradermal delivery of mRNA-based vaccines • Formulation and process development to dry mRNA-LNPs (and other carriers) on microneedles, to achieve 2-8°C stability
Why	• Thermostability, no/less need for cold chain (12 months at 40°C achieved for protein-based vaccines) • Ease of distribution and delivery, possibly self-administration

Aluminium applicator



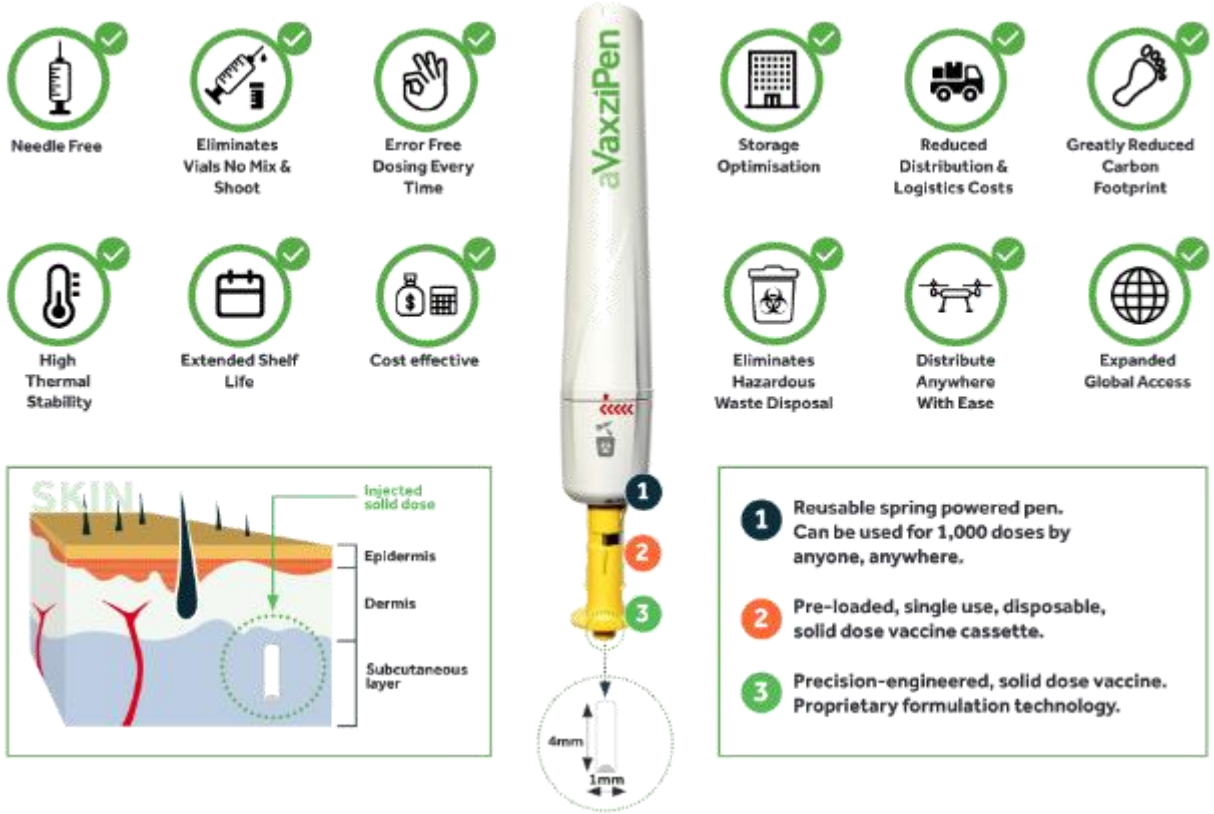
Vaccine-coated HD-MAP



Vaccine-coated microprojections on HD-MAP

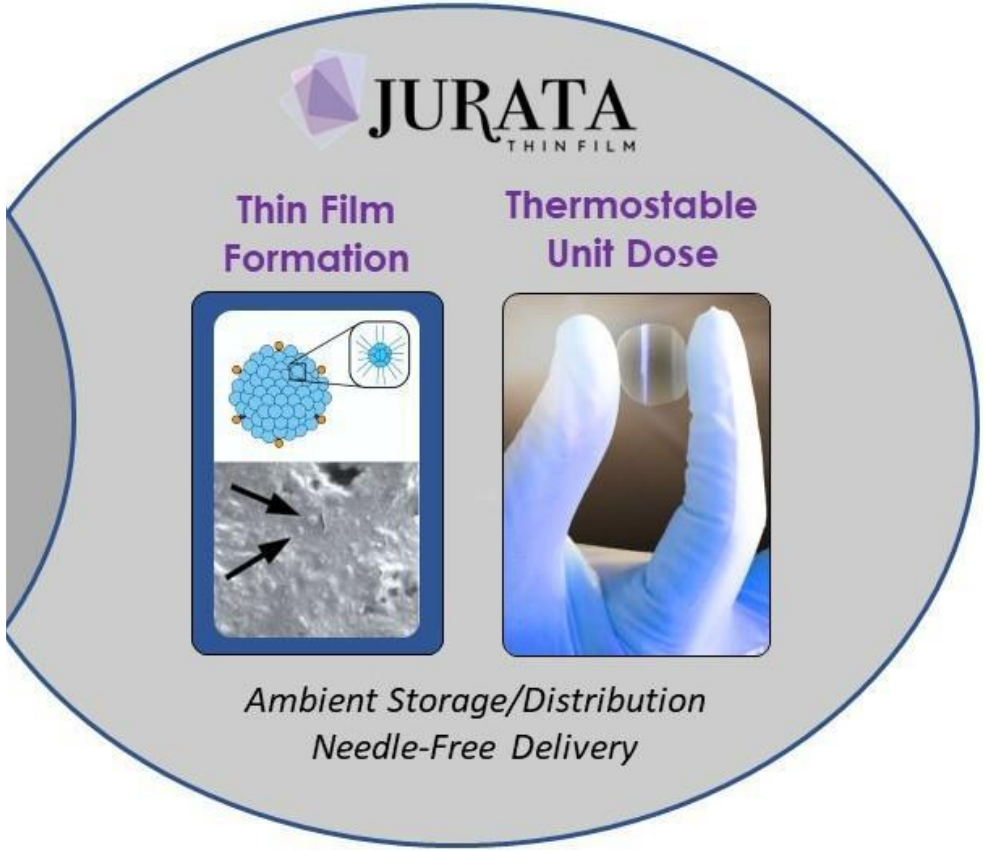
aVaxziPen – Thermally stable, needle-free, solid dose vaccines

What	• Solid dosage form with high thermostability, easy distribution and delivery, and needle-free administration • Formulation and process development to achieve stability targets • For mRNA- and protein-based vaccines
Why	• Significant stability improvement: mRNA at 2-8°C and protein at 40°C • Light and robust presentation for shipment and storage, easy needle-free administration



Jurata – Formulation Development of Room Temperature-Stable mRNA LNP Vaccines

What	• Thermostable thin film formulation for mRNA-LNPs, for sublingual, buccal or intramuscular administration • Formulation and process development to achieve stability targets
Why	• Enhanced thermostability for mRNA-based vaccines, through drying in proprietary film matrix • Ease of distribution of thin, light, stable presentation • Ease of administration via needle-free sublingual/buccal route, or standard intramuscular delivery after reconstitution



Regulatory readiness for 100 Days mission

- ❖ CMC Regulatory Templates
  - CEPI, industry and academics collaborate and develop CMC protocol templates for comparability and process validation.
  - Consultation with global health authorities to gain feedback and endorsement.
- ❖ Masterfile Approach
  - Demonstrate the use of master files to result in a more agile regulatory review mechanism.
  - Integrate three key elements:
    - Platform technology master file - fitting well with CMC but also include clinical and non-clinical
    - Pathogen-orientated master file (preferred clinical option)
    - Product specific data
- ❖ Well developed assays and a regulatory strategy. Ensuring the regional/national release laboratories have the capability to perform the assays and acquire reliable release data.

Participate in CEPI's 100 Days mission

CEPI CfP: Innovative manufacturing technologies to improve vaccine scalability and equitable access

- Technologies that accelerate and support scale-up, scale-out and technology transfer, to make vaccines available at the right commercial **scale** in response to an outbreak
- Technologies that can reduce **cost of goods**
- Technologies that facilitate **equitable access**, distribution and delivery in all regions, especially the Global South
- Focus Area 3 of Vaccines & Biologics Innovations Initiative, is published and **open for applications until 12 Feb 2024**