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Platform protocol templates: An innovative upcoming tool for comparability assessment and process validation

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Talking points

1. CEPI 2.0 and the 100-day mission
2. Initiative – project description
3. Prior-knowledge - notes on the European regulatory landscape evolution

CEPI 2.0 and the 100-day mission

CEPI: An innovative global partnership

VISION

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

Epidemic diseases affect us all.
They do not respect borders.

Vaccines are one of our most powerful tools in the fight to outsmart epidemics.
The development of vaccines can help save lives, protect societies and restabilise economies.

MISSION

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

The need for speed

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.

Intentional preparedness to assist with faster decision making and deployment would have:

- saved many of the millions of lives lost so far to COVID-19
- prevented trillions of dollars of economic damage
- limited or possibly prevented the emergence of the challenging variants we see today

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CEPI's 100-DAY MISSION: REGULATORY INITIATIVES

It is about accelerating all aspects of product development and identifying opportunities for early deployment

Prepare, Develop, Deploy are essential for future outbreaks

Partnering with regulatory authorities worldwide and other key stakeholders to capitalise on lessons learnt and embed regulatory innovation

Enable maximal use of platform data and pre-approved documentation

Evaluate product development pathways for any acceleration / streamlining

Identify circumstances to accelerate development and deployment based on anticipated benefit risk

Harmonise outbreak ready pathways and maximize speed of review and regulatory reliance to enable rapid regional and global roll-out

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Project description

INITIATIVE'S OBJECTIVE

Build CMC platform protocol templates that are "pre-approved"/pre-agreed by worldwide regulators

- Ready-to-use guiding tool based on agreed baseline and understanding
- Two areas: 1) comparability and 2) manufacturing process validation/PPQ
- Use for vaccine products in pandemic/emergency situations
- Keyword is PLATFORM – prior knowledge
- Content will build on COVID-19 lessons and other scientific and regulatory tools
- Templates to be
  - Disease-agnostic
  - Product-agnostic
  - Publicly available, i.e. "open source"

SCIENCE RISK-BASED APPROACH

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting Report: Workshop with stakeholders on support to quality development in early access approaches (i.e. PRIME, Breakthrough Therapies)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2022
EMA/CHMP/BWP/QWP/IWG/694114/2019
Committee for Human Medicinal Products (CHMP)

Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need

Contains Nonbinding Recommendations

Emergency Use Authorization for Vaccines to Prevent COVID-19

Guidance for Industry

Document issued on March 31, 2022.

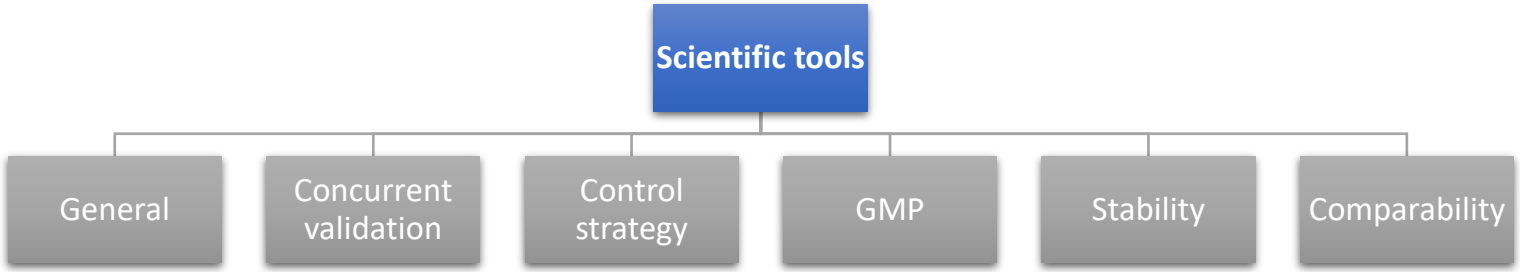
This document supersedes the guidance of the same title issued on May 25, 2021.

Technical Brief: Regulation of COVID-19 Vaccines

Synopsis from the August 2020 – February 2021 COVAX RAG meetings

14 April 2021

World Health Organization



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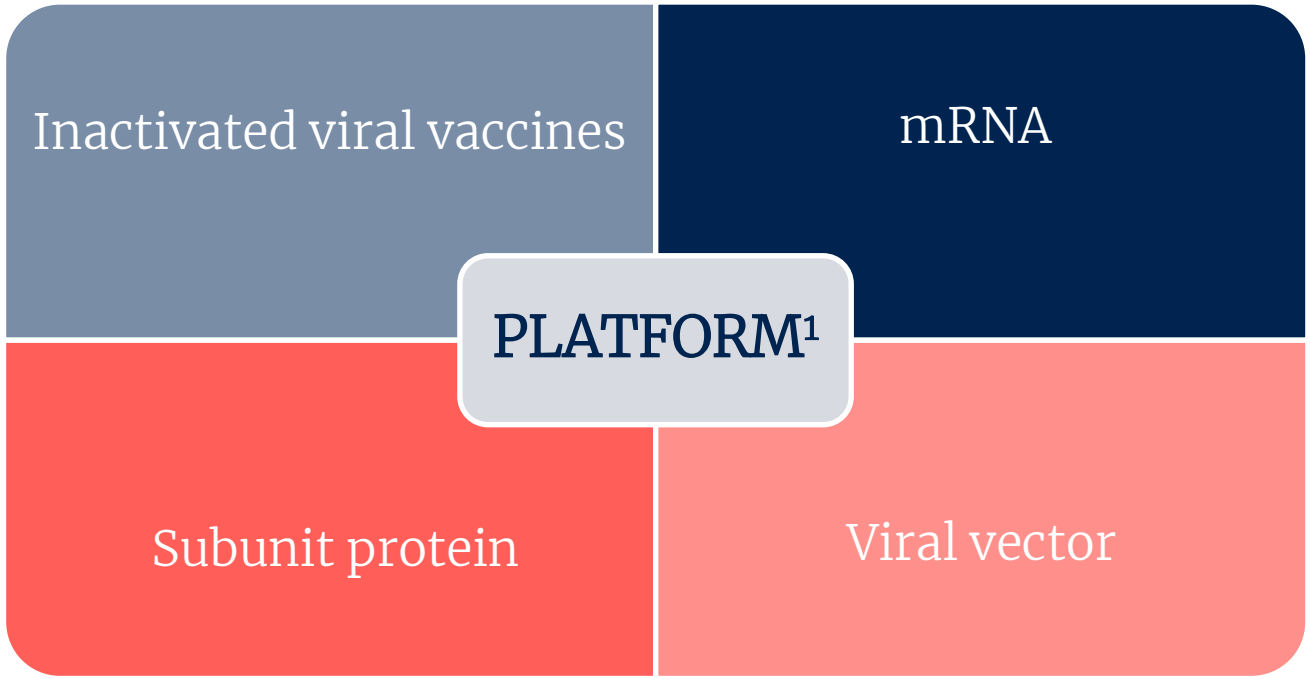
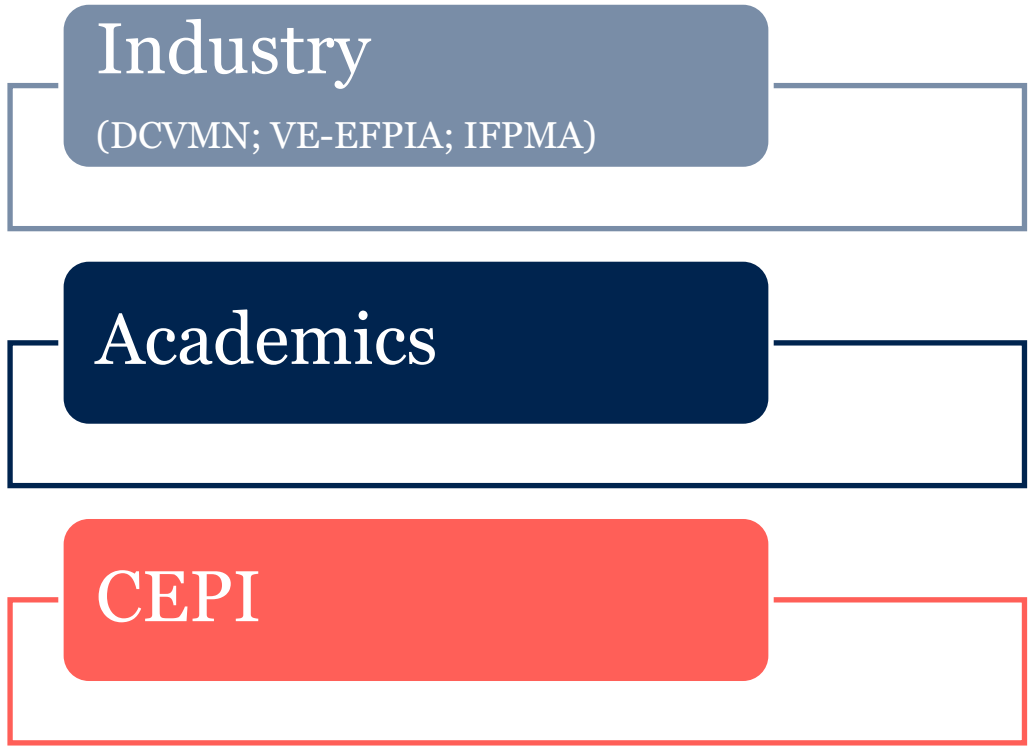
VACCINE PLATFORM TEHCNOLOGIES SELECTED



1 – Nomenclature according to NIH terminology for vaccines types

COLLABORATORS

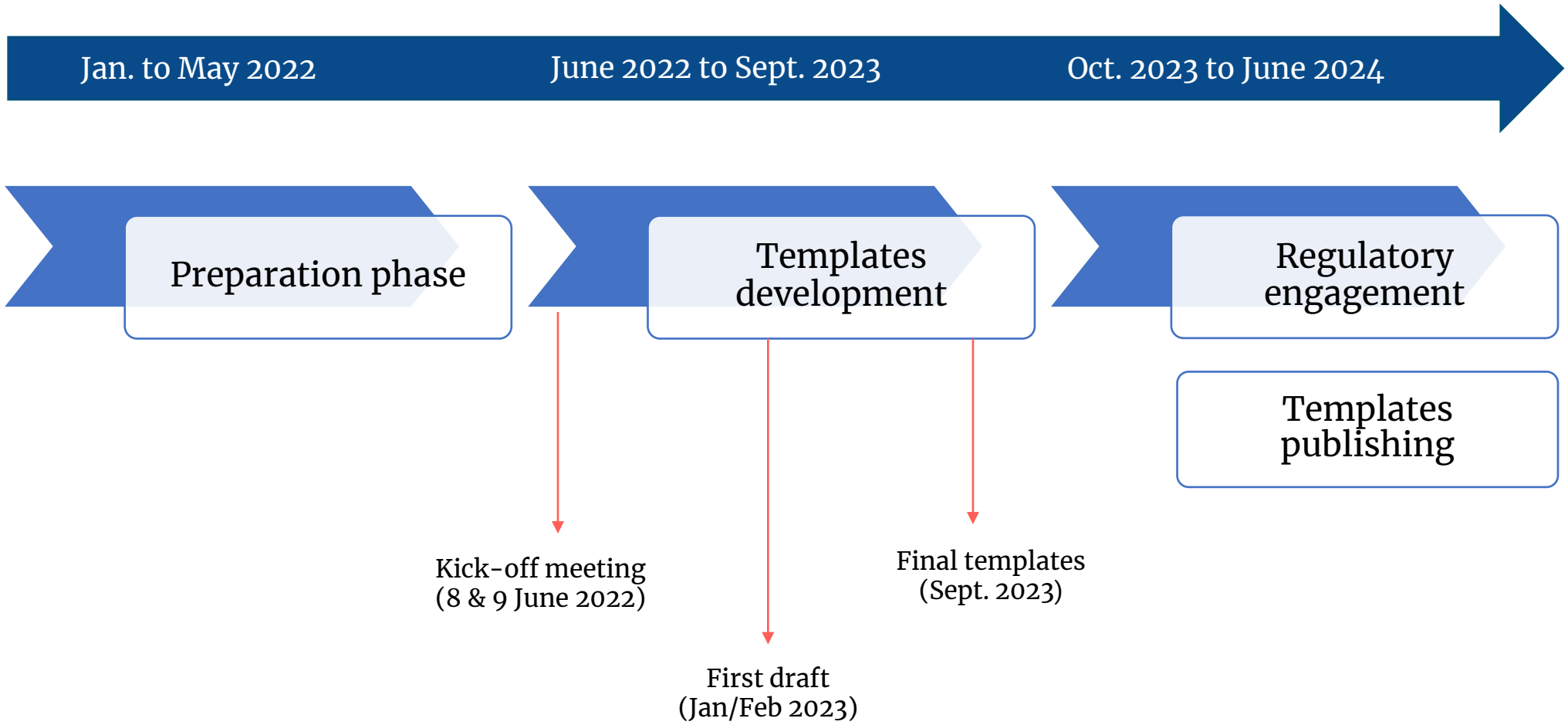
Industry
Astra Zeneca (AZ)
Bio Farma
Biological E
Bio-Manguinhos / Fiocruz
BioVac
CanSinoBIO
CureVac
GlaxoSmithKline (GSK)
Innovative Biotech Nigeria
Instituto Butantan
Institut Pasteur Dakar
Johnson & Johnson – Janssen
Merck Sharp and Dohme (MSD)
Quantoom Biosciences
Sanofi
Seqirus
Sinergium Biotech
Touchlight
Walvax



Academics
Imperial College London
(Process System Engineering)

King's College London
(Department of Engineering)

TIMELINES



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REGULATORY ENGAGEMENT AND PUBLISHING

- **Advocacy engagement plan** under development
  - worldwide (collaborators present in 5 continents)
  - consultations with agencies, e.g. via scientific advice
  - socialization at global forums and organisations such as ICMRA, WHO, PAHO
  - consultation via COVAX Regulatory Advisory Group (RAG) chaired by CEPI & WHO (https://epi.tghn.org/covax-overview/regulatory-advisory-group/)
- **Templates' publishing**
  - available to all developers ("open source") – location to be developed
  - in journals, white paper, etc.

Prior-knowledge

Notes on the European regulatory landscape evolution

Prior-knowledge in the EU

- **2012 -2014: the concept of "prior-knowledge" starts to appear in EMA PV guidelines as supportive information**
  - Guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission (EMA/CHMP/BWP/187338/2014)
  - Guideline on process validation for finished products – information and data to be provided in regulatory submissions (EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1,Corr1)
- **2017 -2018: dedicated workshops with Industry and regulators about prior-knowledge**
  - Joint BWP/QWP workshop with stakeholders in relation to prior knowledge and its use in regulatory applications (EMEA/CHMP/BWP/187162/2018)
  - Workshop with stakeholders on support to Quality development in early access approaches (i.e. PRIME, Breakthrough Therapies) (EMEA/CHMP/BWP/812924/2018)
- **2022: EMA Toolbox guideline – prior-knowledge as enabler**
  - Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need (EMEA/CHMP/BWP/QWP/IWG/694114/2019)

ICH Q11 (2012)
Platform Manufacturing Definition

ICH Q8 (2009)
ICH Q9 (2005)
ICH Q10 (2008)

ICH Q12 (2019)

ICH Draft Q13 (2021)

ICH Draft Q14 (2022)
ICH Draft Q2R2 (2022)

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THANKS TO

- CEPI – the Regulatory Affairs division and the Manufacturing & Supply Chain division
- Steering Committee of the CMC platform protocol templates initiative
  - Adrian Azhari (DCVMN)
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  - ShouBai Chao (CanSinoBIO)
  - Prof. Harris Makatsoris (King‘s College London)
  - Mic McGoldrick (IFPMA)
  - Vincent Loh (CEPI RA CMC)
  - Maria Papathanasiou (Imperial College London)
  - Diane Wilkinson (Vaccines Europe/EFPIA)
- All Initiative‘s Collaborators