



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU's regulatory process for evaluation and approval of vaccines

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An agency of the European Union

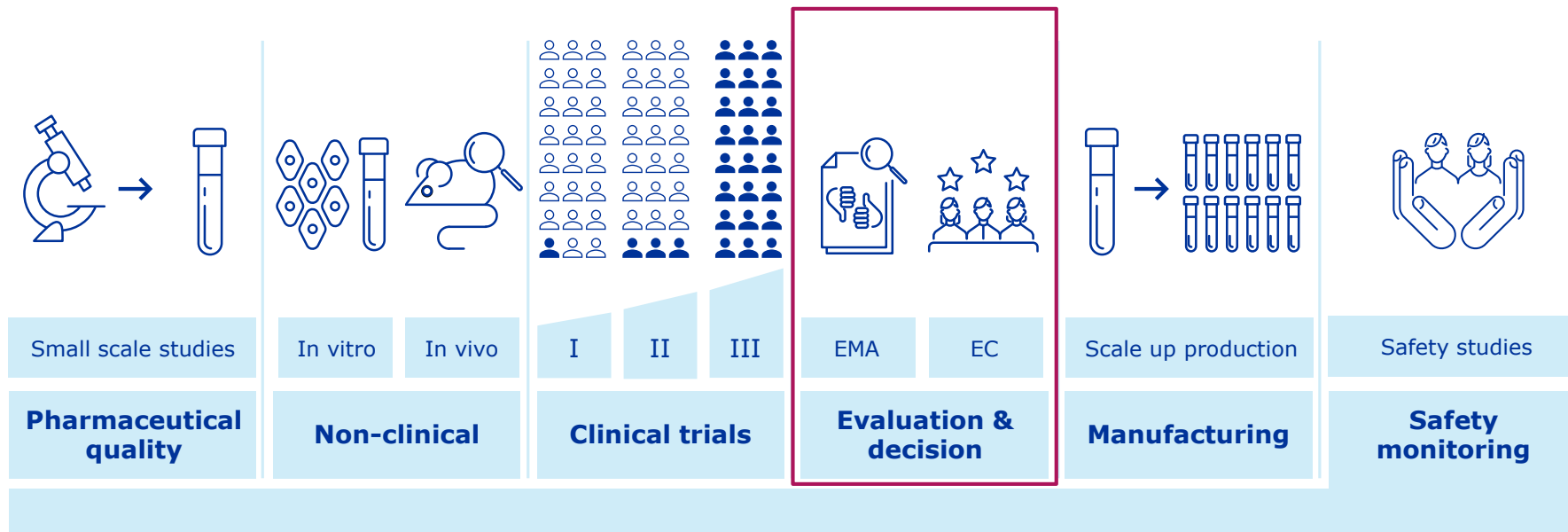


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Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING



Benefit-risk evaluation by scientific experts

- Vaccines only approved after demonstration that their overall **benefits outweigh their risks**
- Safety is paramount
- Because vaccine is given to healthy people, less risks can be accepted

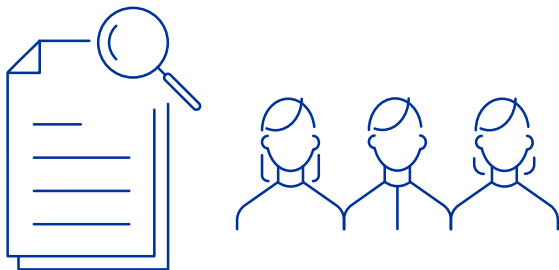


Vaccines benefits in protecting people



Side effects or potential risks

EMA's scientific experts



Evaluation by **EMA's expert scientific committees on human medicines:**

- **CHMP** (all aspects of medicines' evaluation)
- **PRAC** (safety and risk minimisation)

Unprecedented pooling of expertise in Europe to **reduce timelines**

Multidisciplinary **COVID-19 Task Force (ETF), key experts**

- From European medicines regulatory agencies
- Fast and coordinated response to the pandemic

Rapid approval processes in the EU

Early support for vaccine developers:

EMA provides scientific advice and a dedicated Task Force (COVID-ETF)



Rolling review

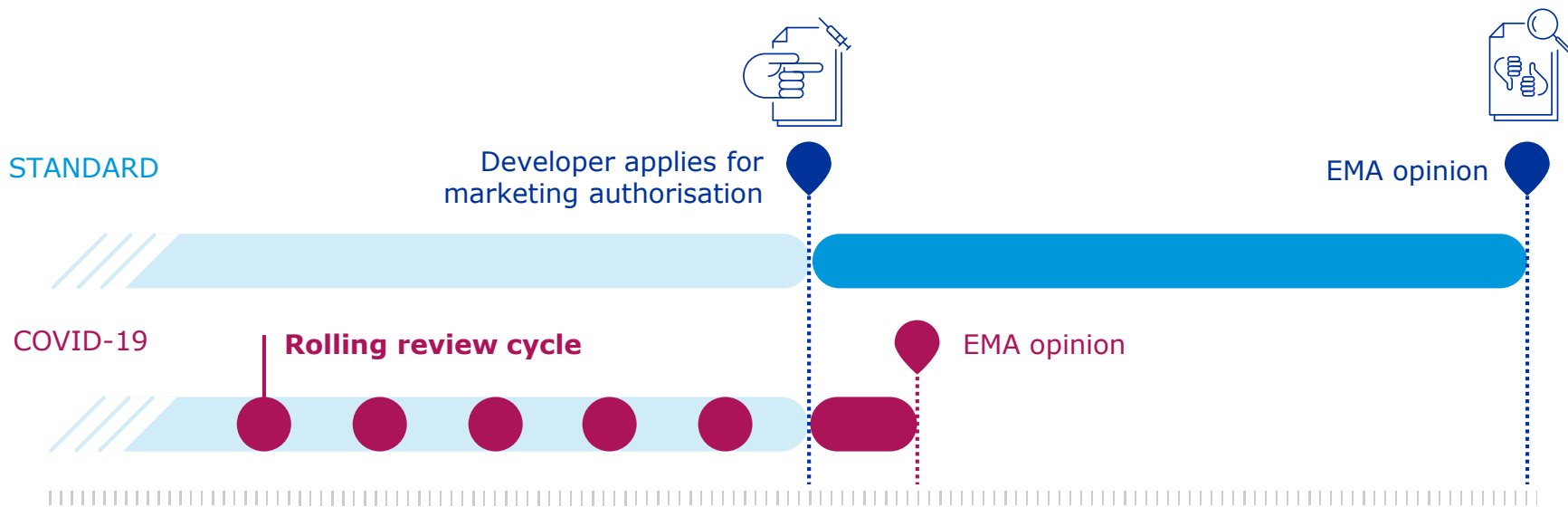
EVALUATE DATA AS SOON AS AVAILABLE



- In public health emergency - EMA can **evaluate data** for a promising medicine **as soon as available**
- **Several** rolling review **cycles** can be done as data continue to emerge
- Once all **Quality, Safety and Efficacy** data are ready, the company can formally apply for marketing authorisation application to EMA

Rolling review

- Research & development
- Standard EMA evaluation
- EMA evaluation with rolling review



Conditional Marketing Authorisation



Approval for medicines to be used in **public health emergencies**:

- As soon as data available show that benefits outweigh the risks
- **Other data** must be provided by the company, **after approval** (e.g. long-term protection data)

Conditional Marketing Authorisation

WHY CONDITIONAL APPROVAL IS THE MOST APPROPRIATE TOOL IN THE EU?

- **Formal approval** of a medicine across the EU: **all member states benefit** from the joint scientific assessment and approval
- It has **all safeguards and controls** in place to ensure high level of protection to citizens during a mass vaccination campaign:
 - A robust **monitoring plan** for managing **safety**
 - Clear **legal framework** for evaluation of **emerging efficacy data**
 - **Manufacturing** controls including **batch controls** for vaccines
 - Full **prescribing information** and **package leaflet** with defined conditions for storage and use of the vaccine
 - A **plan** for **use** of the vaccine **in children**
 - **Additional studies or other data** ('conditions') that the company is **legally obliged** to provide with defined **timelines**

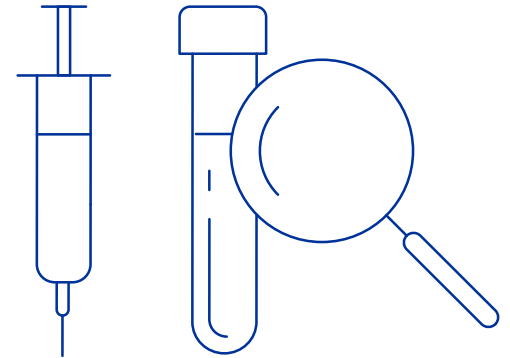
Quality check before releasing vaccines to the market

Before approval, **stringent quality testing:**

- Batches **must meet** the **specifications** approved by EMA

After approval, **each batch of COVID-19 vaccine approved via EMA will be tested:**

- **Before** vaccines are used in **immunisation** programmes
- Independently done by an **official medicines control laboratory**



Conclusions

- **An important role** – EU citizens rely on the EMA's evaluation
- **Protect European population** and support EU citizens' confidence in the vaccines
- **Stringent** scientific **evaluation** by EMA on quality, safety and efficacy
- Unprecedented **pooling of EU expertise**
- **Rolling review** of data as it becomes available, to enable fast **approval**
- **Conditional marketing authorisation** provides strong safeguards
- **Independent quality check** before vaccinations start
- Public health emergency: some **data** will emerge **post-approval**

