EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The development of COVID-19 vaccines

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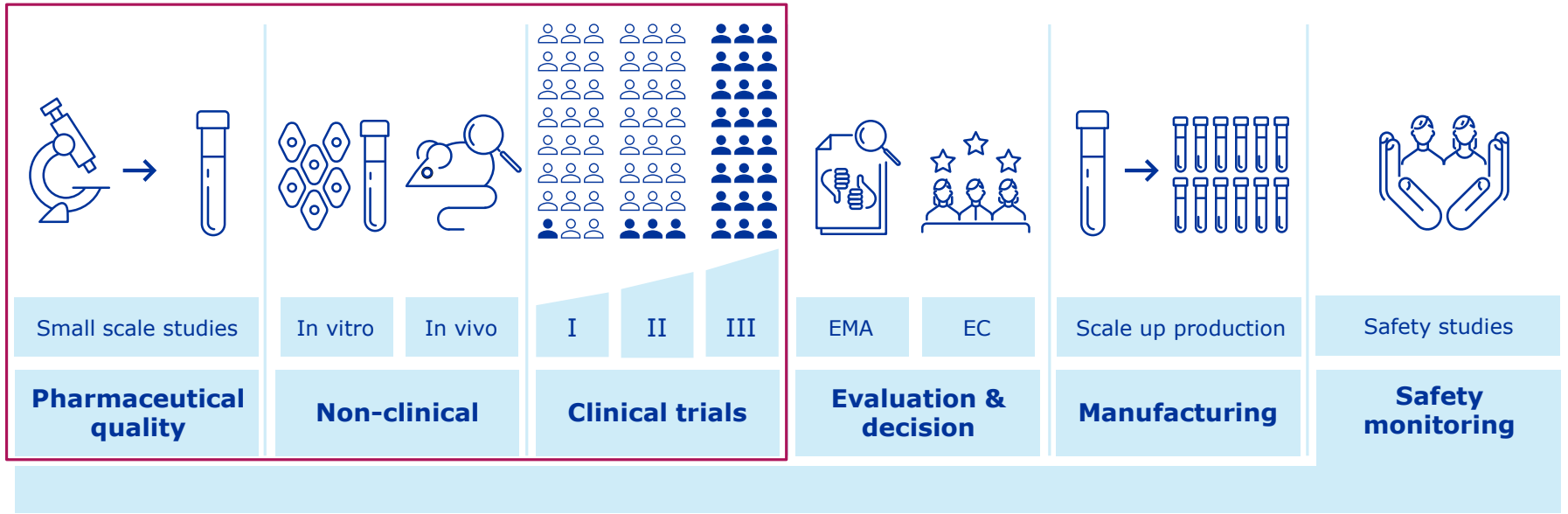
An agency of the European Union

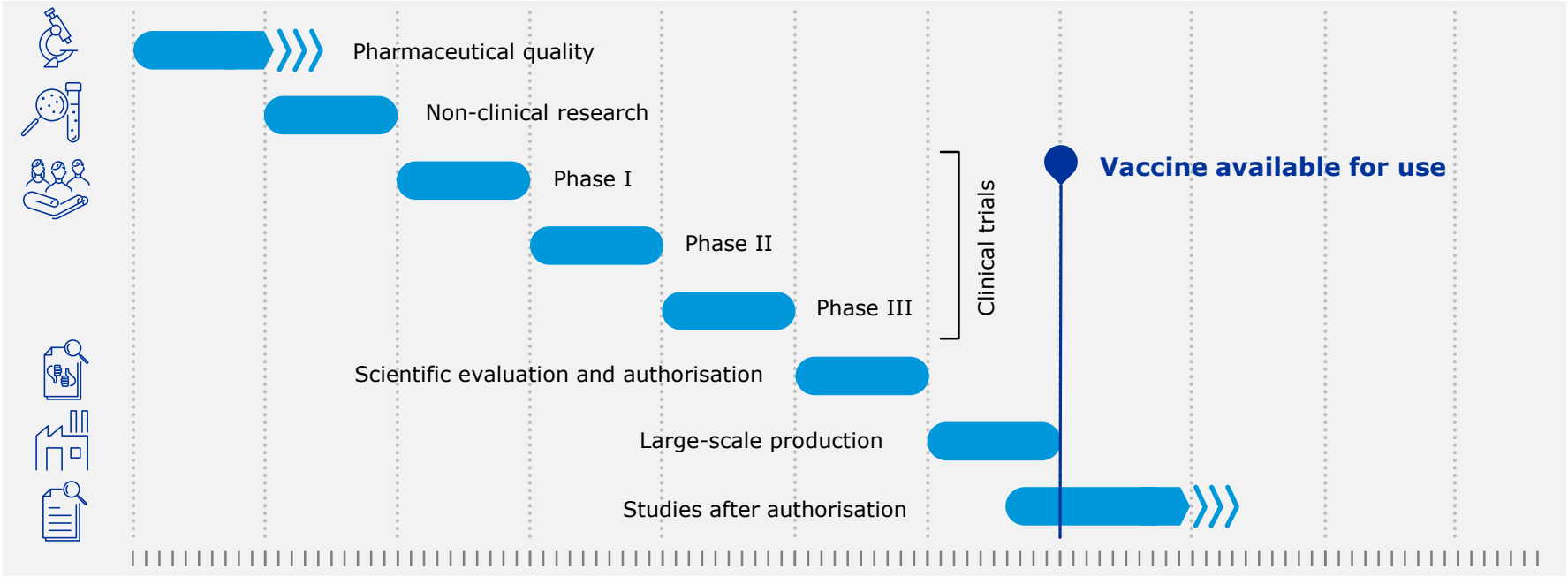
Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING



STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Indicative timeline



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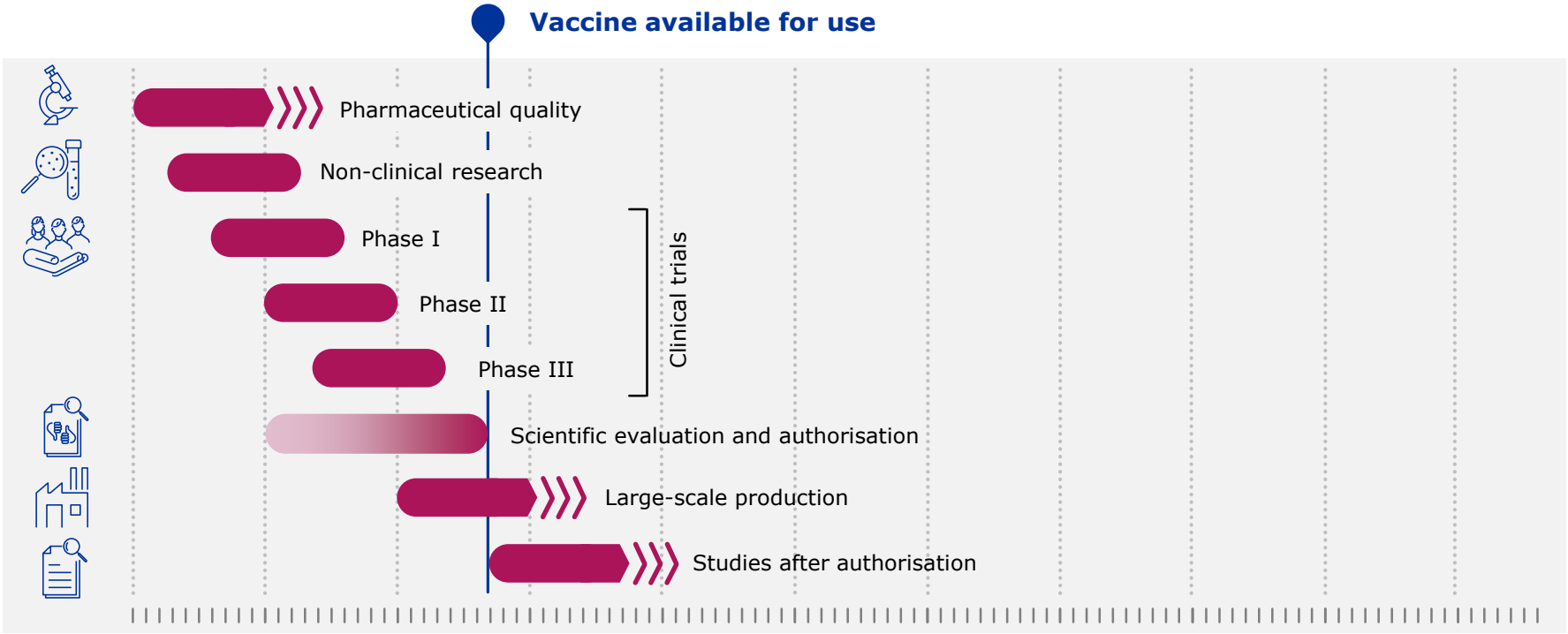
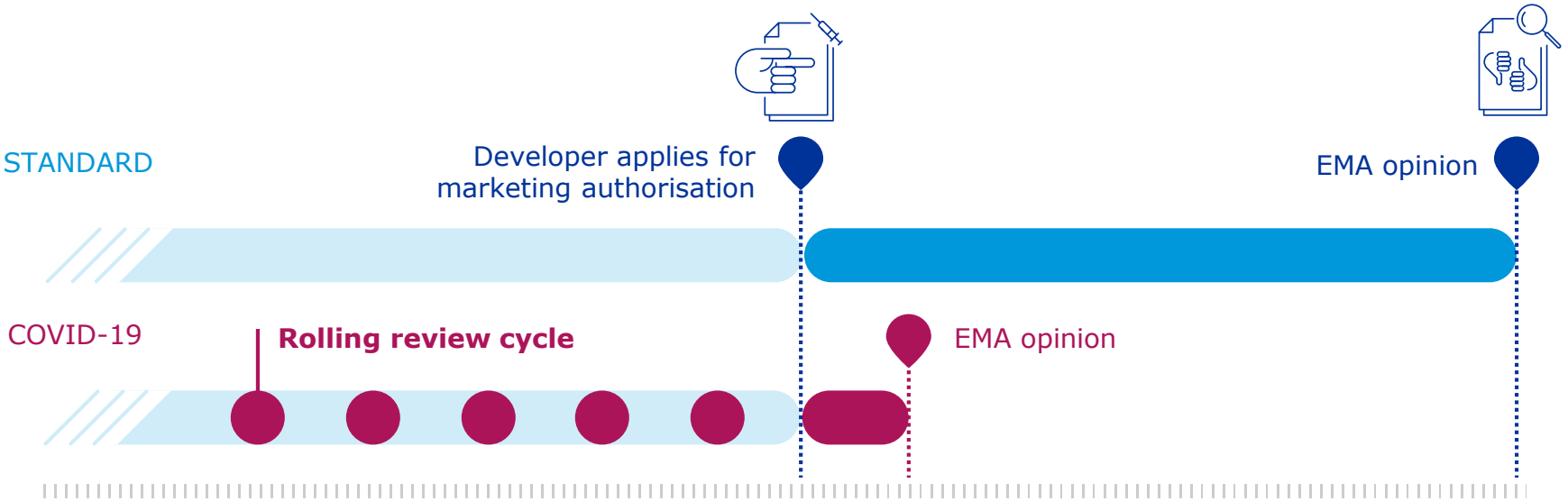


Rolling review

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

- 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



STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Regulatory standards

COVID-19 vaccines must be approved according to the **same standards** that apply to all medicines in the EU

STANDARD

COVID-19

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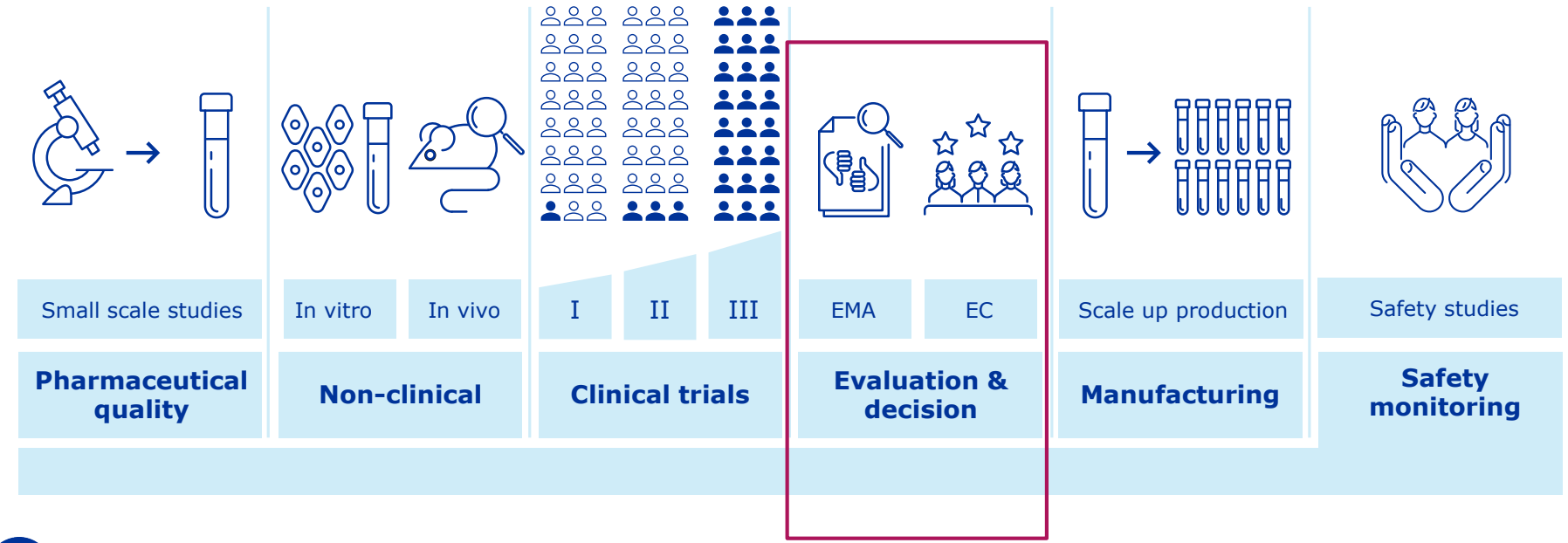

Conditional Marketing Authorisation

- Medicines that address unmet medical needs
- The benefit of immediate availability of the medicine outweighs the risks
- Medicines intended for
  - treating, preventing or diagnosing seriously debilitating or life-threatening diseases
  - public health emergencies
- Other data must be provided by the company, after approval (e.g. long-term safety 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**

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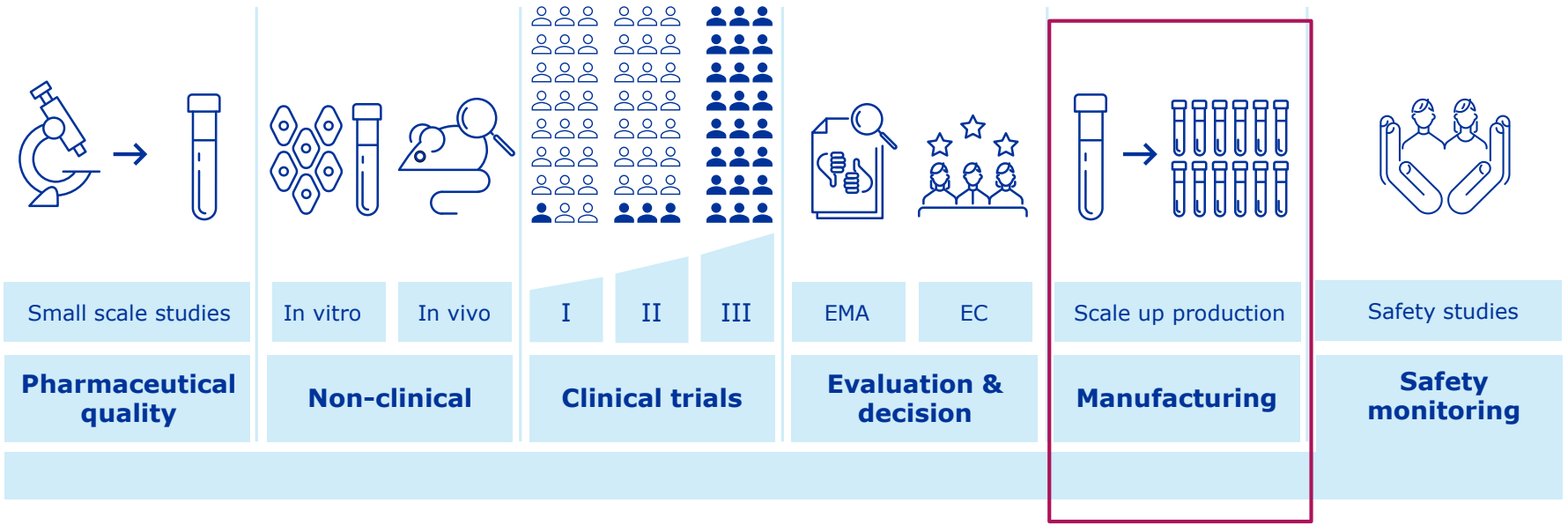

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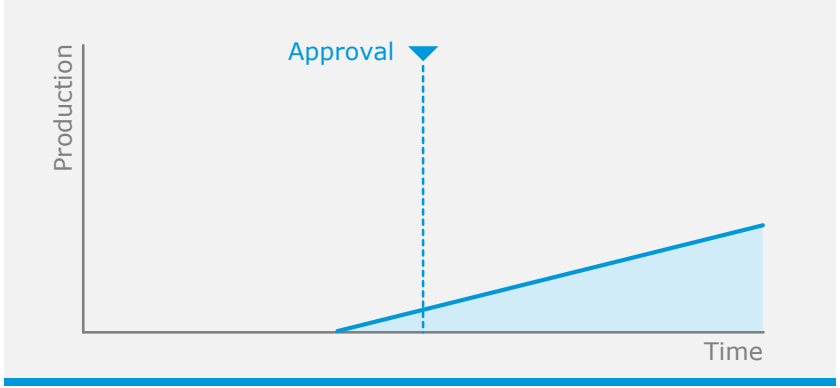
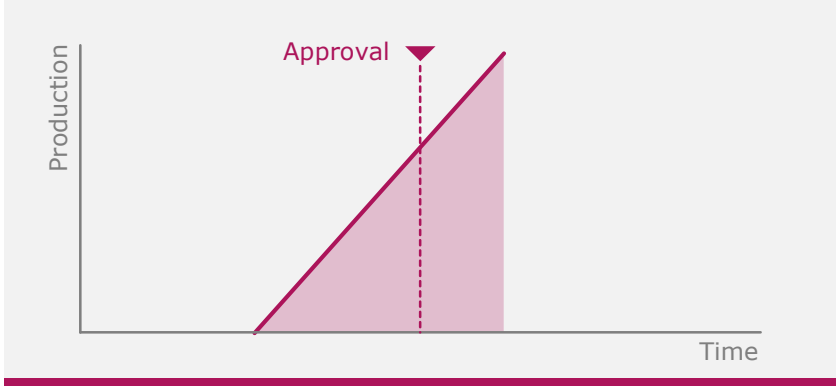
Manufacturing

Companies are **expanding** manufacturing and production **capacity** to ensure efficient vaccine deployment

STANDARD



COVID-19



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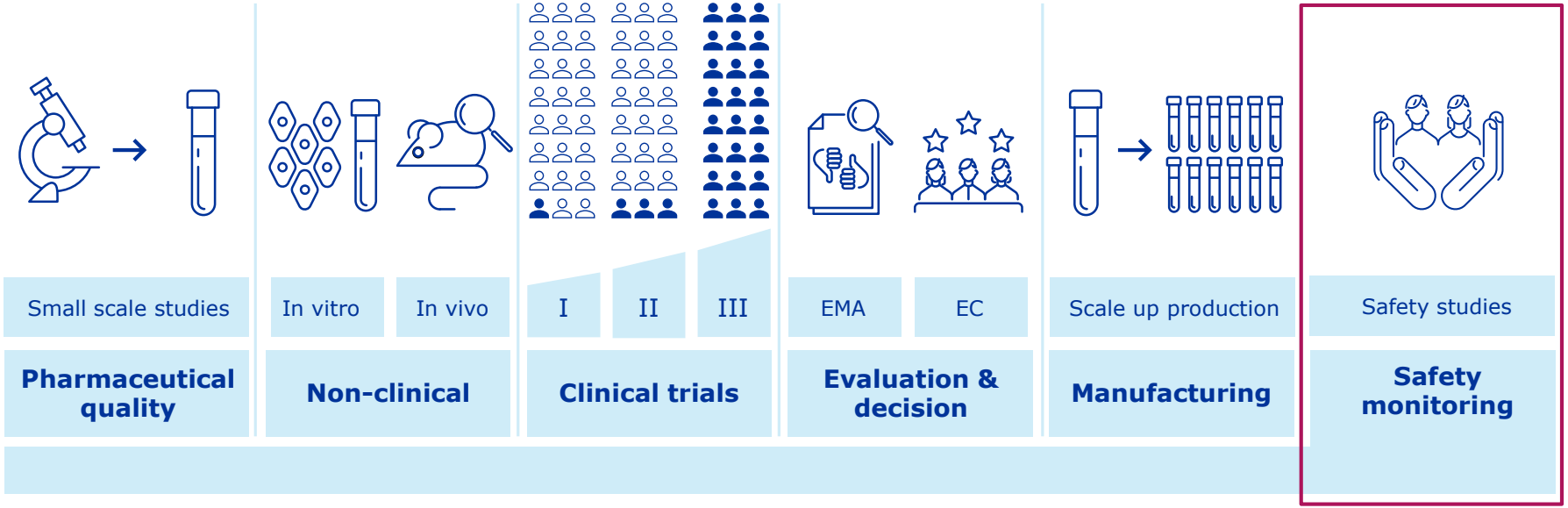
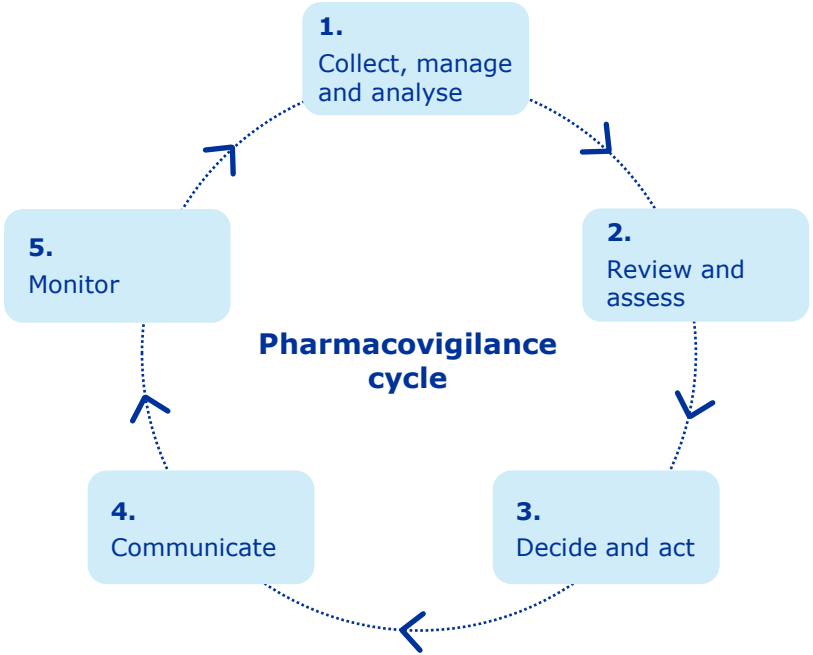
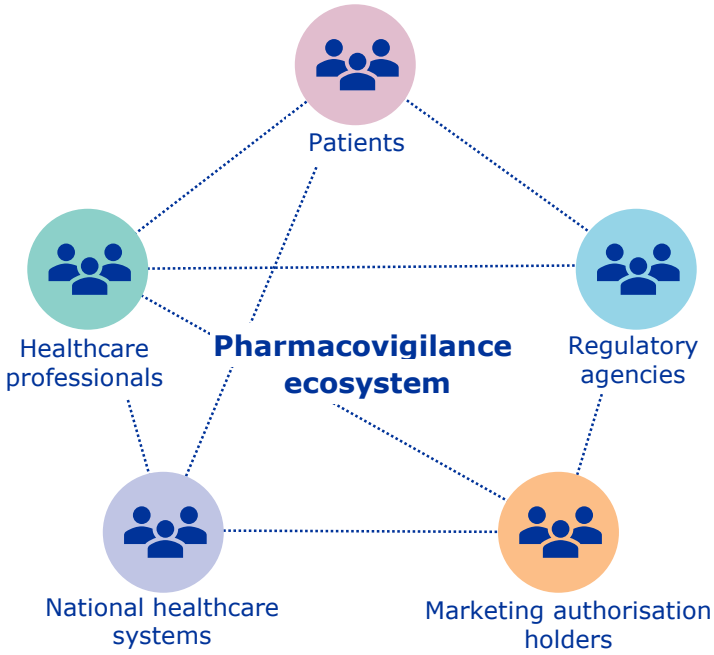


Who does the safety monitoring in the EU?

The EU has a comprehensive **safety monitoring** and **risk management** system known as the **EU pharmacovigilance system**





Why and how is the safety monitored after approval?

- Detection of previously unrecognised or changing side effects to **optimise safe and effective use**
- **Intensive analysis** of reports of suspected side effects from patients and healthcare professionals
- Manufacturers obliged to conduct **safety studies** (as part of the **conditional marketing authorisation)**
- **Additional studies** will be performed in Europe on the safety of vaccines when used in real life
- **International collaboration** on COVID-19 vaccine monitoring

COVID-19 vaccination in patients with cancer

- Patients with cancer requiring active therapy and immunocompromised patients were excluded from pivotal trials
- Around 4% of patients included in the Pfizer pivotal trial had a prior history of malignancy (https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf)
- Although these people may not respond as well to the vaccine, no particular safety concerns are anticipated
- The benefit-risk ratio for patients with cancer is positive and they may be at higher risk from COVID-19

Conclusions

- **Same types of studies** as for other medicines - timelines **shortened**
- Expected benefits at time of initial approval:
  - Demonstrated **reduction in** COVID-19 **disease**
  - Some **uncertainties: long term protection** and **community transmission**
  - Use of facemask, hand hygiene, physical distance **remain important**
- **High** regulatory **standards** for Quality, Safety and Efficacy
- A strong EU pharmacovigilance system is in place; **safety will not be compromised**
- **Unprecedented** steps are being taken to monitor safety in practice, to be transparent and to take action immediately
- COVID-19 vaccine safety will be **stronger with your participation**