



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Safety monitoring of COVID-19 vaccines

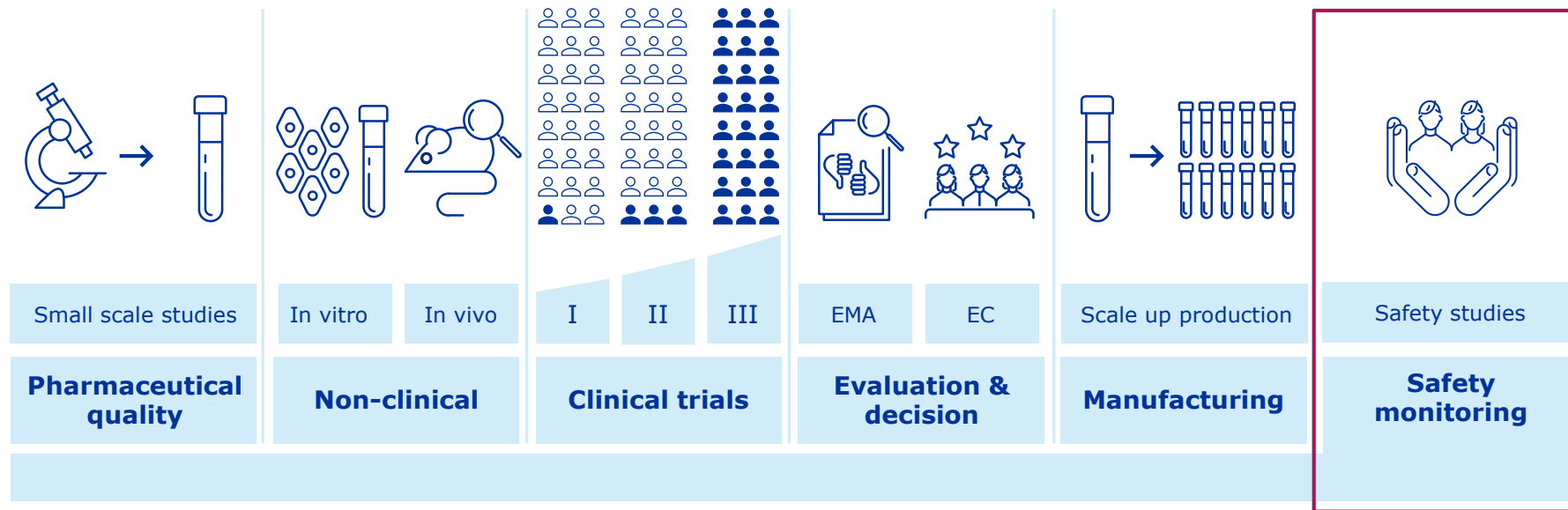
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Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING



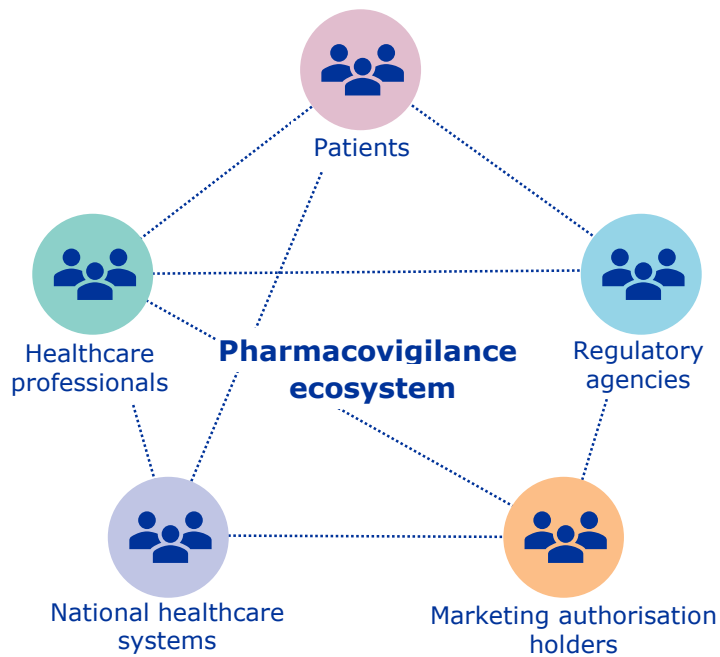
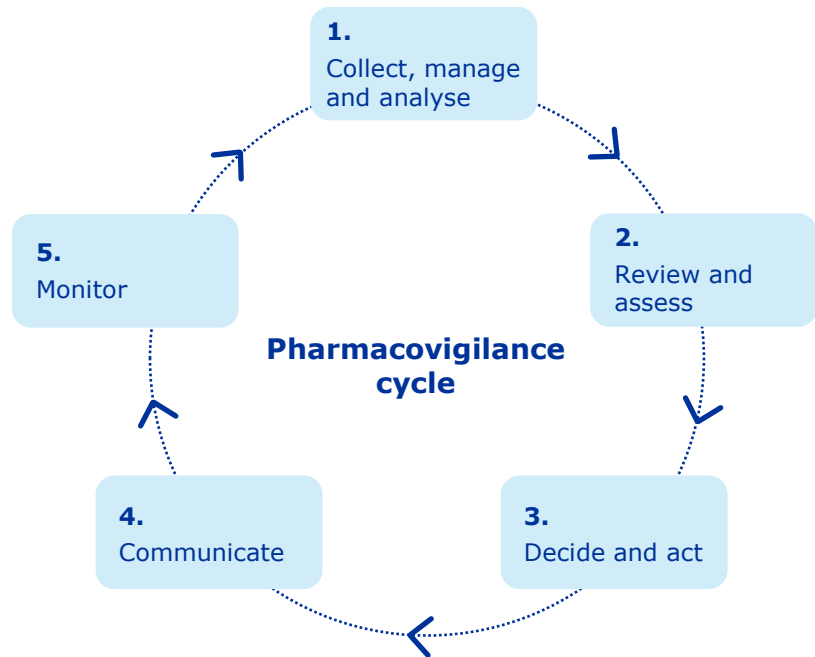
Why do we need to monitor the safety of medicines?

- All medicines, including vaccines, have **benefits and risks**
- **At the time of approval:** evidence comes mainly from controlled, randomised clinical trials
- **After approval:** medicines will be used in real conditions by a far larger population
- **We monitor safety to identify** any new or changing risk as quickly as possible, and **take action**



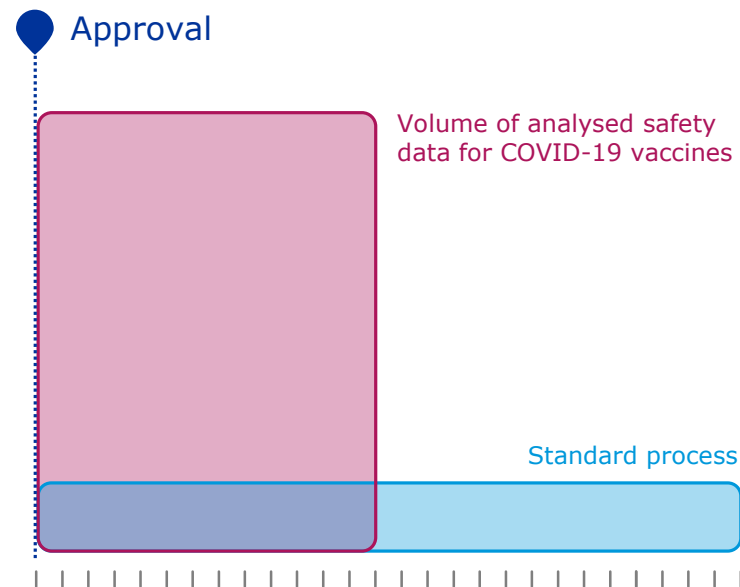
Who does the safety monitoring in the EU?

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



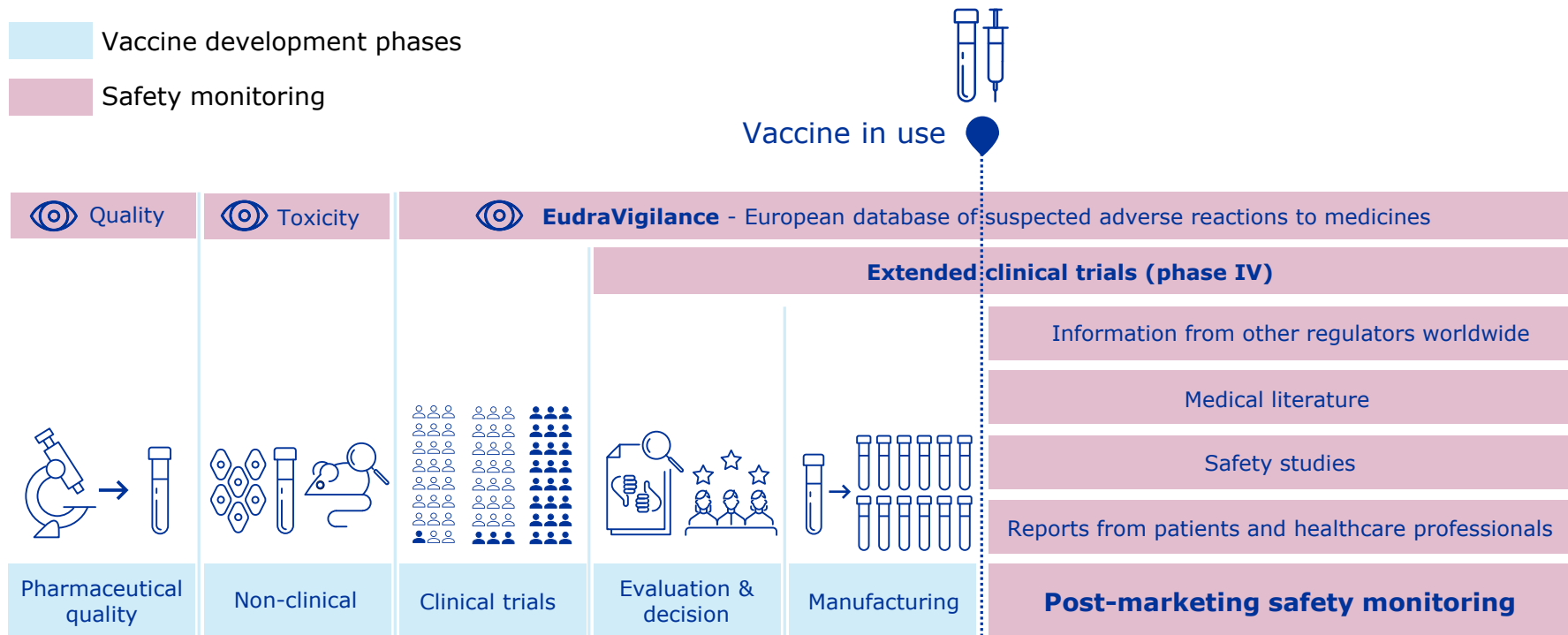
Are there different safety requirements for COVID-19 vaccines?

- The core safety requirements are the **same as** for any other vaccine in the EU
- Vaccines are **only approved if** overall benefits outweigh their risks
- COVID-19 vaccines to be used in millions of EU citizens in a short time;
 - Due to large number of vaccinated people we need to ensure safety monitoring **reacts quickly**
- **Additional resources** are being mobilised to closely monitor safety and assess new information

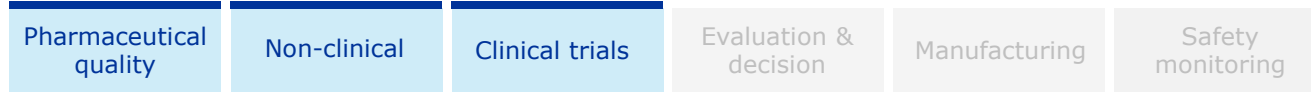


How is safety of vaccines studied from the development stage to use in real life?

- Vaccine development phases
- Safety monitoring

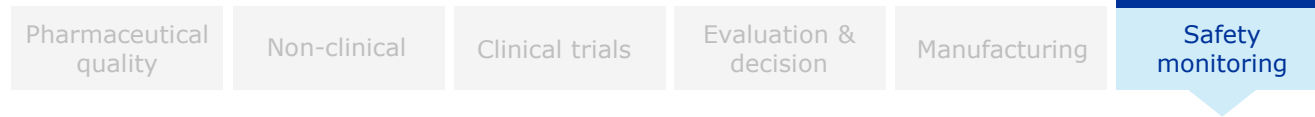


How is the safety of vaccines studied before approval?



- Safety starts with ensuring vaccines are of **good quality**: studies demonstrate their purity
- Testing used to ensure that **each batch** of vaccine is of good quality
- Vaccines undergo non-clinical studies to **exclude toxicity**
- Vaccines are being studied in some of the **largest clinical trials** seen by EMA, involving tens of thousands of individuals
- **Rigorous safety monitoring** of clinical trials allows to estimate the frequency of more common side effects
- **Safety follow up** of volunteers for at least six weeks and extended clinical trials will pick up any longer-term effects

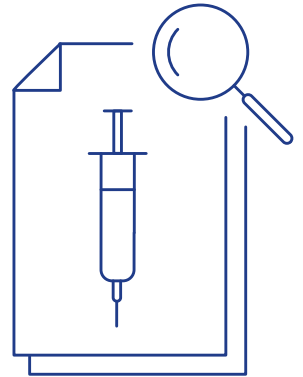
Why and how is the safety monitored after approval?



- 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**
- **Additional studies** will be performed in Europe on the safety of vaccines when used in real life
- **International collaboration** on COVID-19 vaccine monitoring

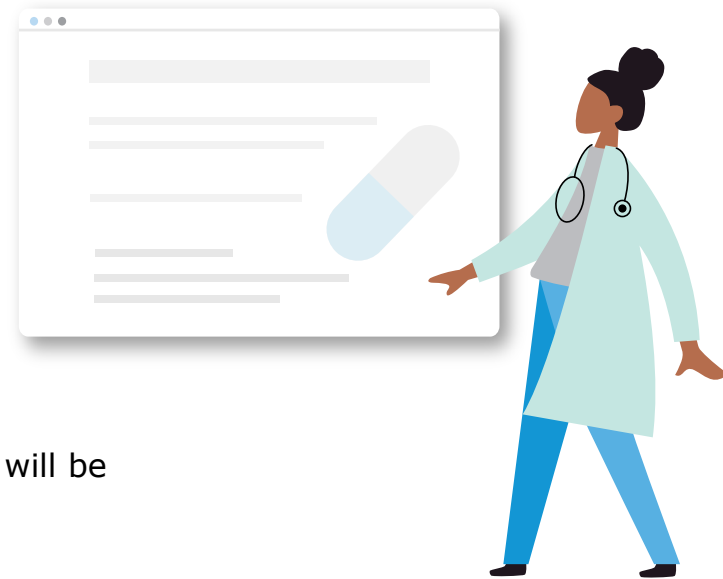
How will we know if side effects are caused by the vaccine?

- **Established analysis techniques** are in place to assess whether a side effect is likely to be caused by the vaccine
- Since millions of people will be getting the vaccine in a short time, many of them will develop illnesses for other reasons in close proximity to vaccination
- If these occur just after vaccination, they may be reported as suspected adverse reactions to the vaccine, when the **association** was just **due to chance**
- If analysis concludes that a **new** side effect is caused by a vaccine, it is included in the package leaflet



Informing the public of suspected and confirmed side effects

- Committed to **transparency** and keeping patients and healthcare professionals fully **informed** to make their choices, for example:
 - Public access to **EudraVigilance** in place since 2012 through www.adrreports.eu
 - Publication of data from reports of suspected side effects to vaccines will be **updated weekly**
 - Regular public COVID-19 vaccines **safety updates**
 - Publish **risk management plans (RMPs)** for COVID-19 vaccines
 - Established side effects will be **included in the package leaflet**
- Network of **national medicines agencies** and of **stakeholders** will be strong channels for communication



You can report side effects yourself

- **Reporting** suspected **side effects** following vaccination is critical
- **Anyone can report** a suspected side effect to their national authority or the vaccine manufacturer
- All reports are sent to **EudraVigilance, the European database** of suspected side effects where
 - the data are analysed to detect new side effects
 - and anonymised data are made public for all to review
- **Please report** suspected side effects

<http://www.adrreports.eu/>



Conclusions

- **Vaccines are a key pillar** of public health and have been proven to **prevent serious diseases**
- No medicine is 100% safe so like any other medicines, vaccines can have side effects
- The majority are mild, and even rare, serious side effects must be balanced against the prevention of severe or even fatal disease like COVID-19
- 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
- Use of facemask, hand hygiene, physical distance **remain important**
- COVID-19 vaccine safety will be **stronger with your participation**
- **Please report suspected side effects**

