



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Safety monitoring of COVID-19 vaccines

Dr. Peter Arlett
Head of Data Analytics and Methods, EMA

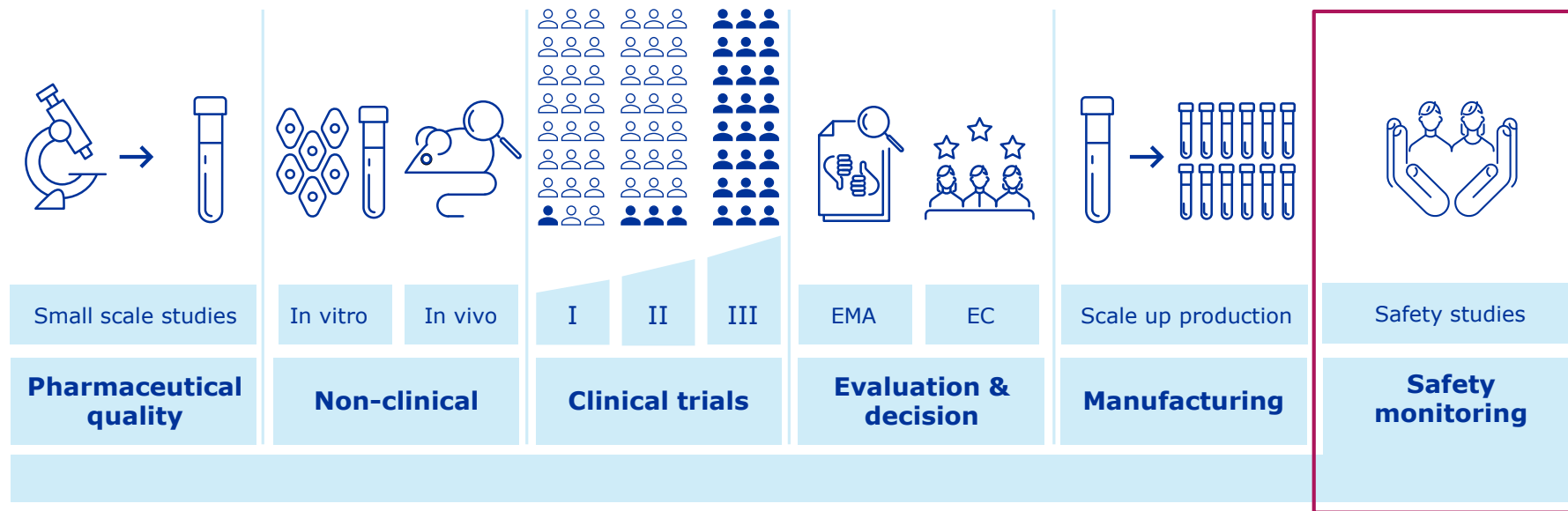
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Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING



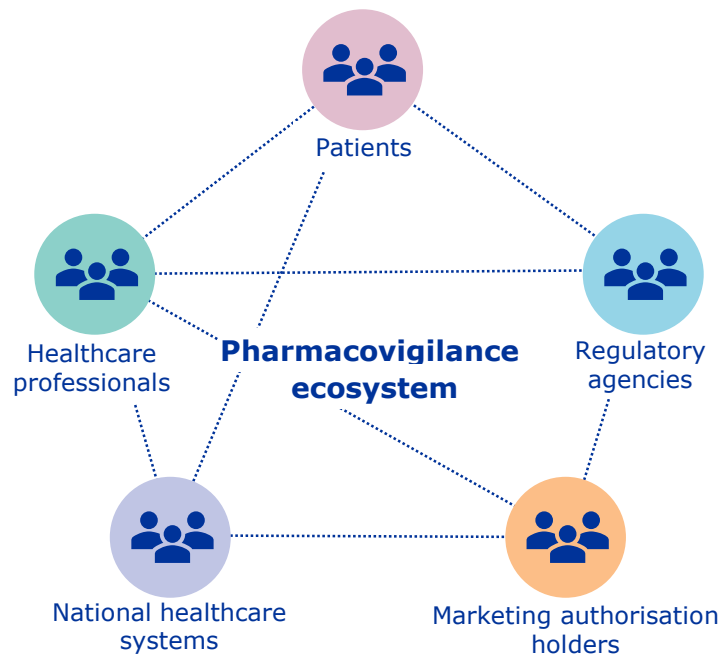
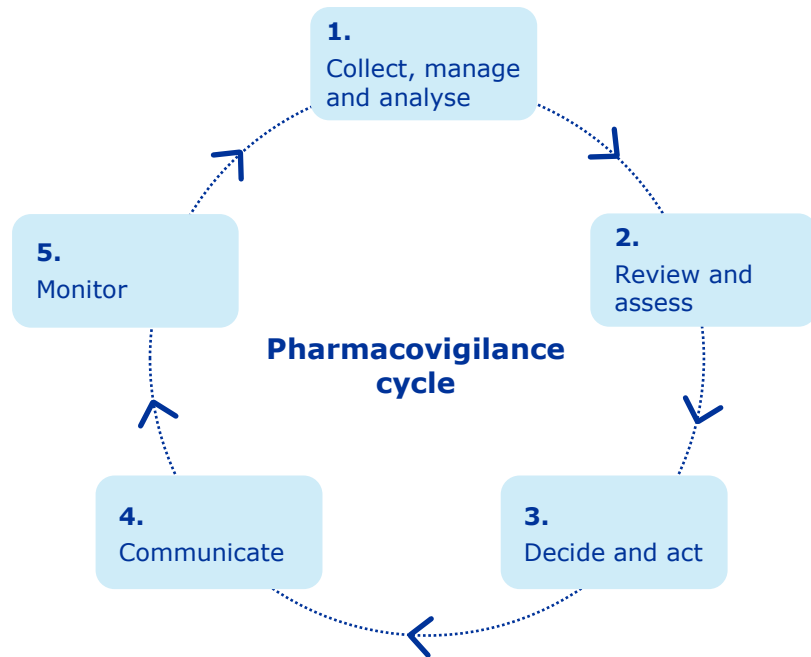
Why do we need to monitor the safety of medicines?

- 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**



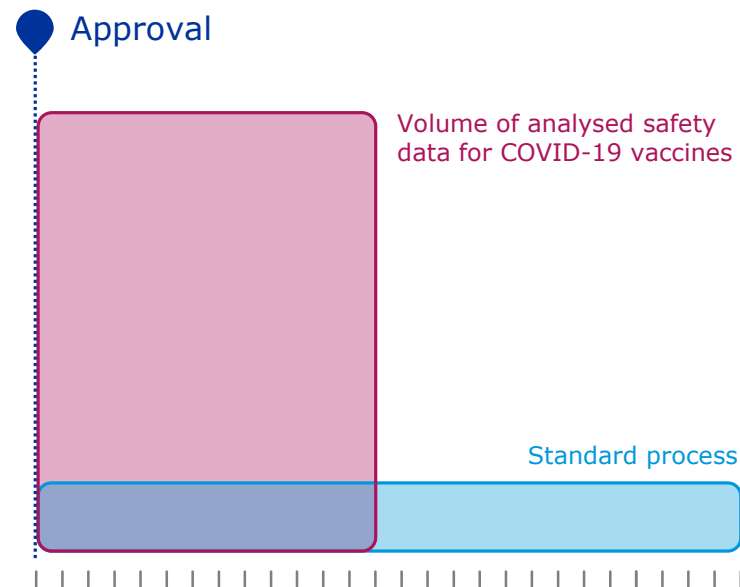
Who does the safety monitoring in the EU?

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

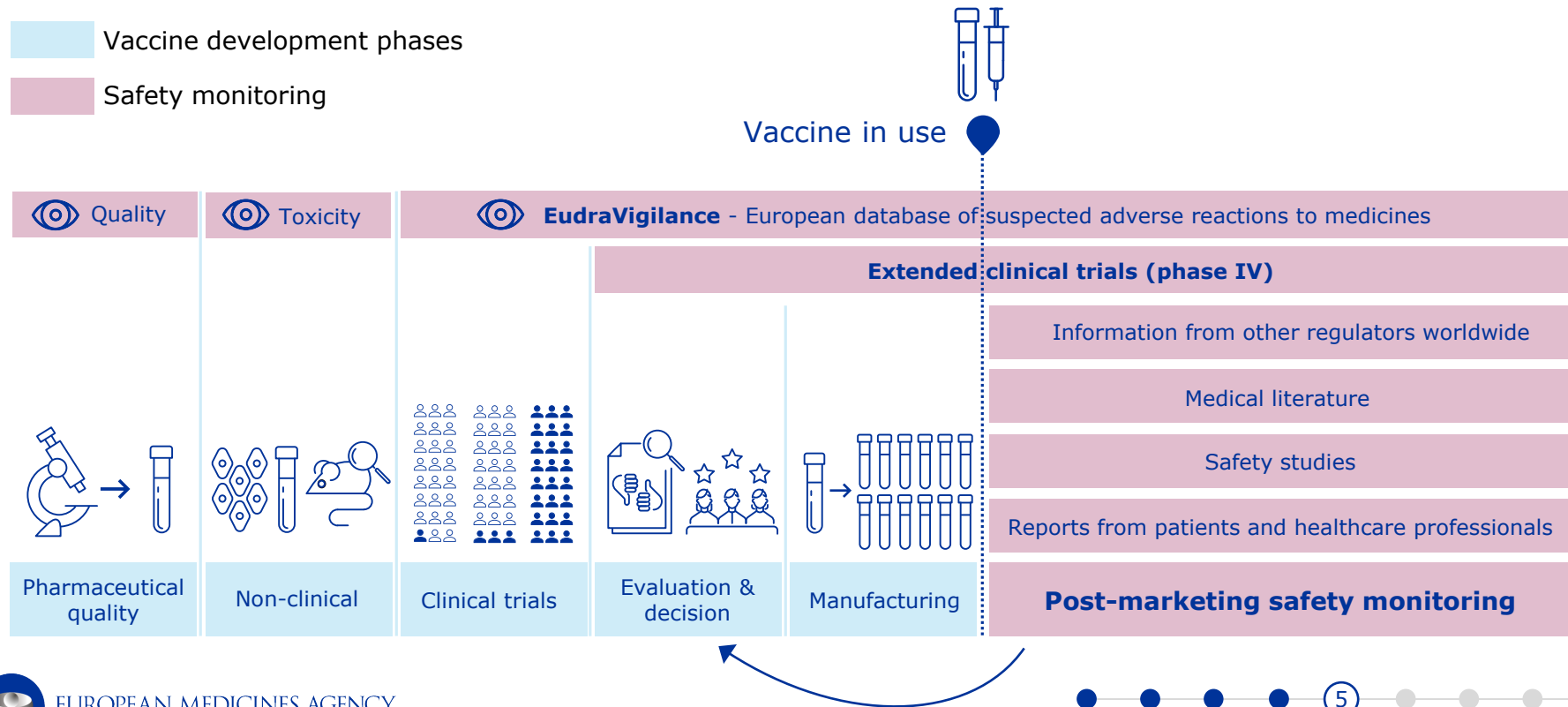


Are there different safety requirements for COVID-19 vaccines?

- 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?

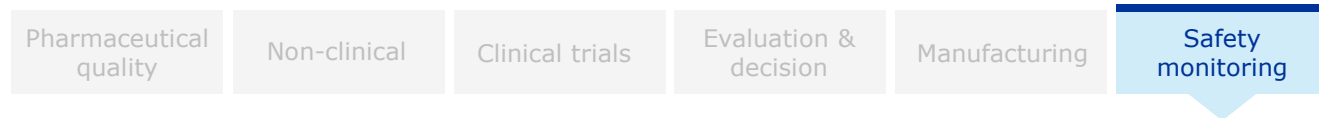


How is the safety of vaccines studied before approval?



- 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

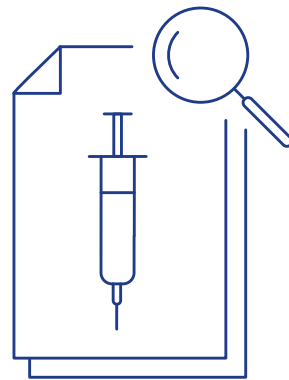
Why and how is the safety monitored after approval?



- 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

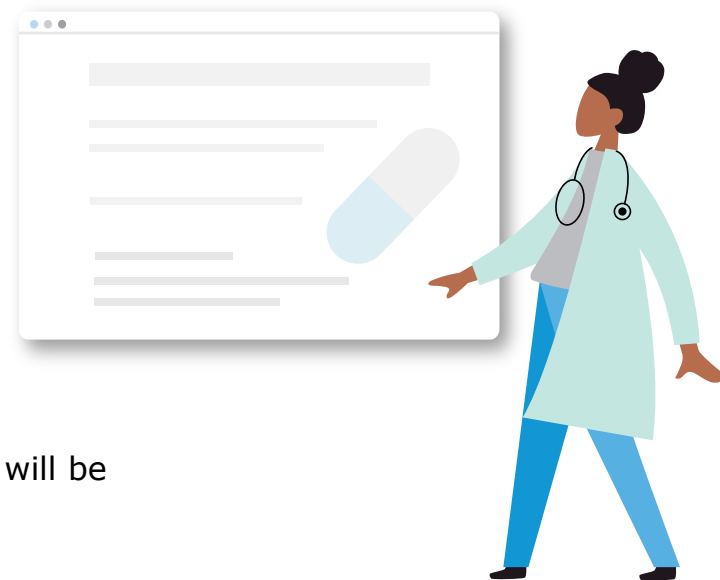
How will we know if side effects are caused by the vaccine?

- **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**

