EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How the safety of the new COVID-19 vaccines will be monitored

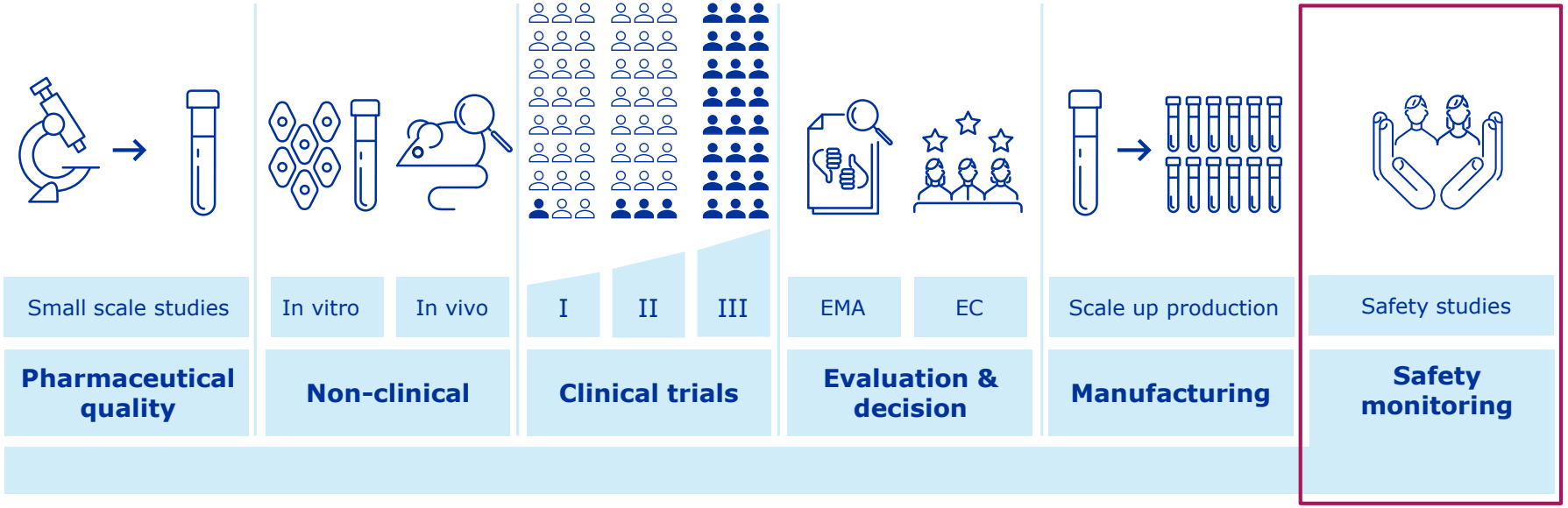
Presented by Sabine Straus on behalf of EMA, as
Chair of Pharmacovigilance Risk Assessment Committee (PRAC)

Outline

1. Why do we need to monitor the safety of medicines after approval?
2. Who does the safety monitoring in the EU?
3. Are there different safety requirements for COVID-19 vaccines?
4. How is safety of vaccines studied from the development stage to use in real life?
5. How will the safety of vaccines continue to be monitored after approval?
6. What studies will be undertaken by regulators in the context of the COVID-19 pandemic?
7. How can I report side effects?
8. How will I know if side effects are caused by the vaccine?
9. Where can I find more information about Comirnaty and Moderna?

Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING

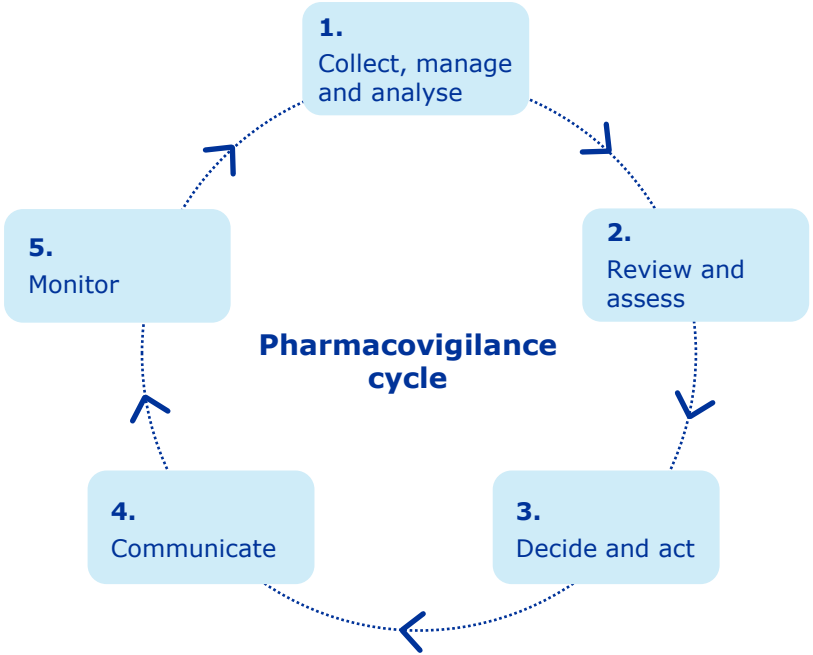


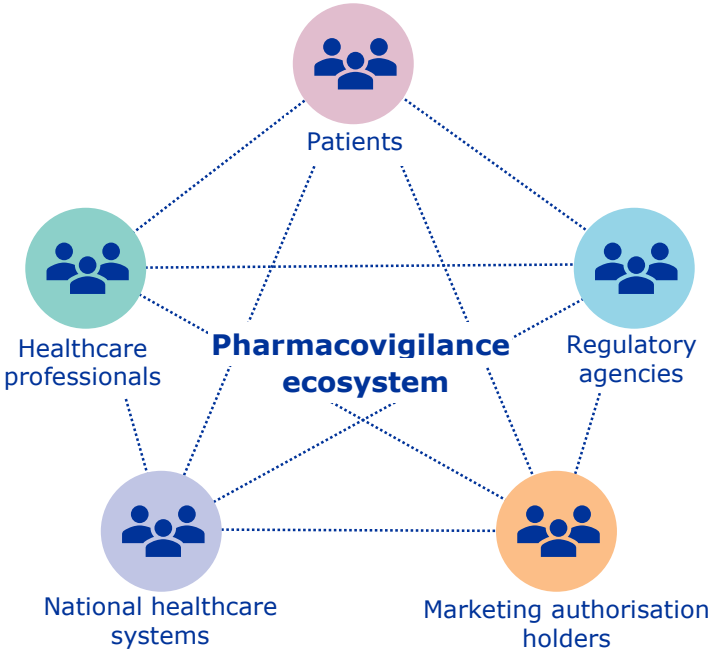
Why do we need to monitor the safety of medicines after approval?

- 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
- Post-marketing **safety monitoring** is important **to identify** any new or changing risk as quickly as possible, and **take action**

Who does the safety monitoring in the EU?

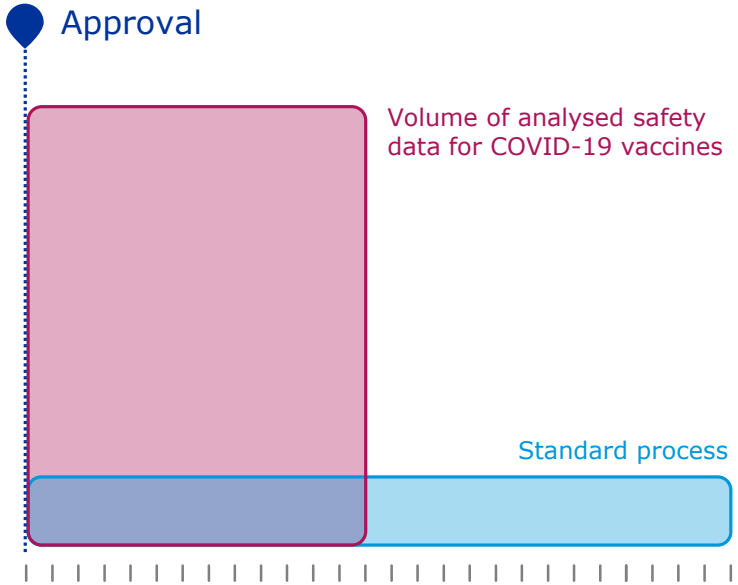
The EU has a comprehensive **safety monitoring** and **risk management** system known as the **EU pharmacovigilance system**



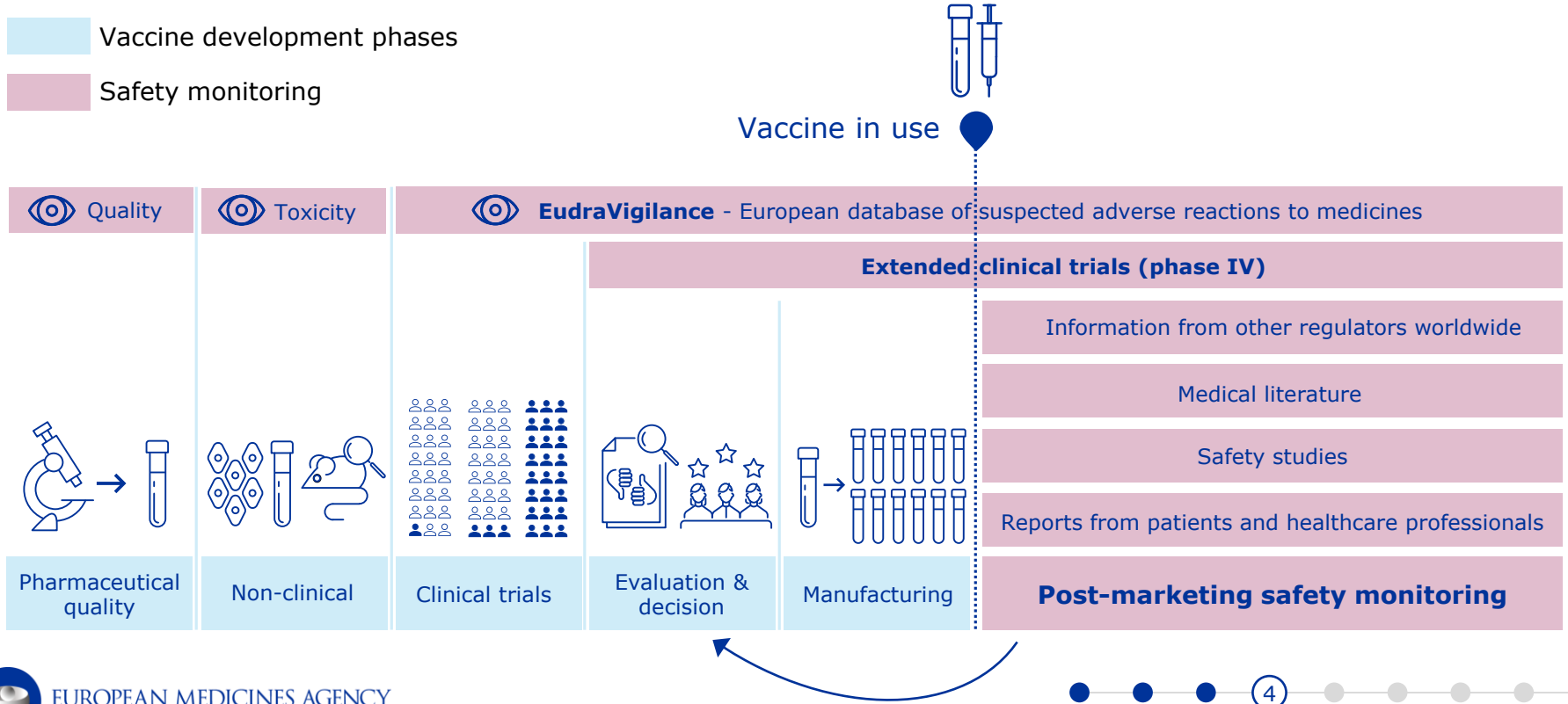


Are there different safety requirements for COVID-19 vaccines?

- 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 will the safety of vaccines continue to be monitored after approval?

Safety monitoring after approval is needed to detect any new or changing side effects. This includes:

- **Intensive analysis** of reports of suspected side effects from patients and healthcare professionals (also referred to as spontaneous reporting collected in EudraVigilance, the European database of suspected side effects)
- **Post-authorisation safety studies** conducted by the vaccines' manufacturers, as required by regulators
- **Additional studies** performed in Europe on the safety of vaccines when used in real life (also referred to as observational studies)
- **International collaboration** on COVID-19 vaccine monitoring

Risk management plan (RMP)

- Specifically developed for each approved vaccine, following EU guidelines
- Contains important information about the vaccine's safety, how to collect further information and how to minimise any risks
- Continually updated as more information becomes available

What studies will be undertaken by regulators in the context of the COVID-19 pandemic?

2020
ACCESS PROJECT

Set up a European infrastructure for vaccine monitoring

- Gather background information on key adverse events
- Establish an EU network of data sources
- Develop template protocols for vaccine coverage, effectiveness, and safety studies

2020/2021
BRIDGING STUDY

Additional early safety monitoring to complement spontaneous reporting systems

- Primary data collection using an app-based application to gather incidence rates of adverse events
- Complemented by secondary analysis of healthcare data for rapid signal assessment
- In priority groups, for one year, in at least 5 EU Member States

2021/2022
FUTURE STUDIES

Additional EMA-funded safety studies

- Active surveillance, building on the Bridging study
- Additional studies for rapid evaluation of any potential safety signals

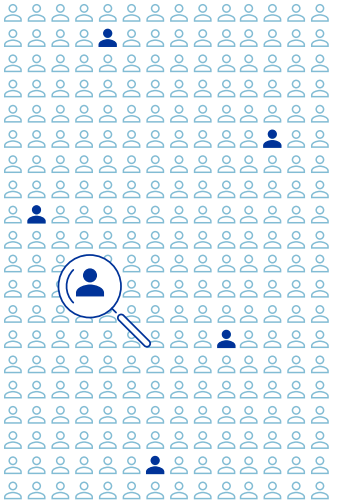
How can I report side effects?

- **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
  - As vaccines are biologicals released in batches, the batch number is important for reporting purposes

http://www.adrreports.eu/

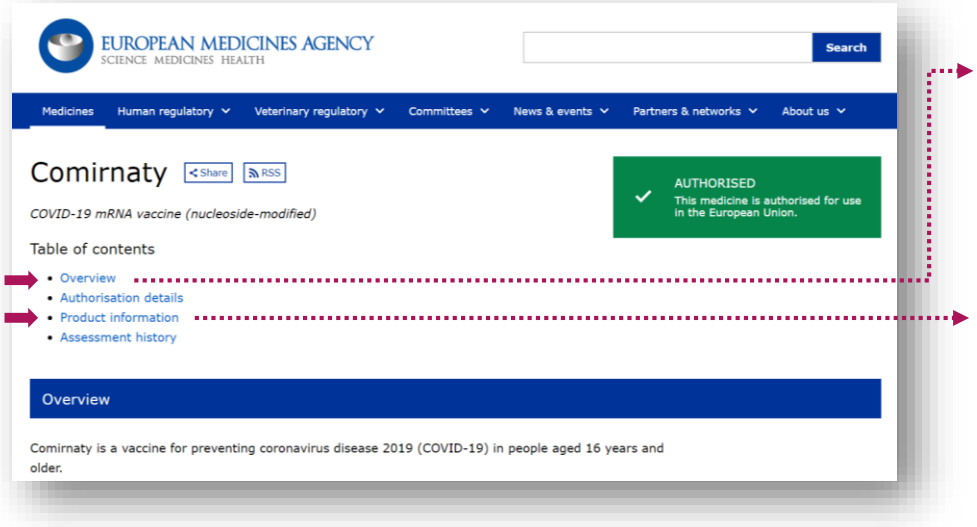
How will I know if side effects are caused by the vaccine?

- **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
    - For example, a very small number of severe allergic reactions (anaphylaxis) have occurred in vaccination campaigns outside the EU an this new information was assessed and reflected in the package leaflet



Where can I find more information about Comirnaty?

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty



- Medicine overview addressing questions and answers in lay language; available in all EU languages
- Risk management plan (RMP)

- Recommendations and precautions to be followed by
  - healthcare professionals (summary of product characteristics) and
  - patients (package leaflet)

  for the safe and effective use of each approved vaccine; available in all EU languages

Where can I find more information about COVID-19 Vaccine Moderna?

https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-moderna

- Medicine overview addressing questions and answers in lay language
- Risk management plan (RMP)
- Product information with recommendations and precautions to be followed by
  - healthcare professionals (summary of product characteristics) and
  - patients (package leaflet)

  for the safe and effective use of each approved vaccine; available in all EU languages

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**