EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Transparency and publication of clinical data for COVID-19 vaccines

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An agency of the European Union

Outline

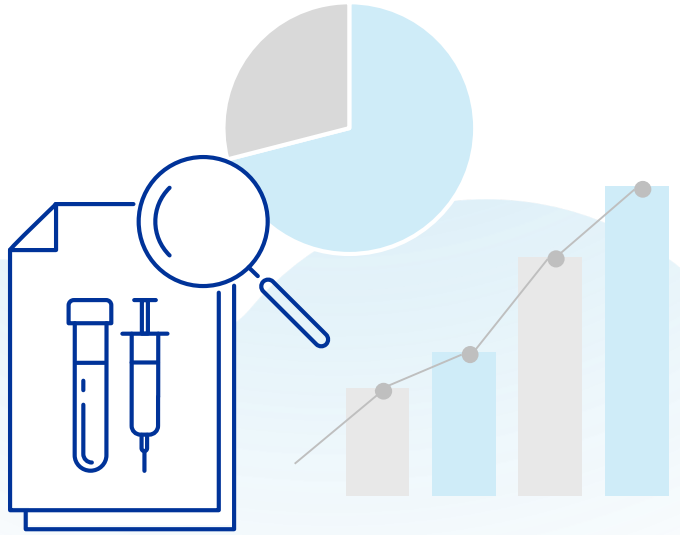
1. Transparency, communication and engagement
2. What information is being published?
3. How are we communicating?
4. Engagement and collaboration

Transparency, communication and engagement

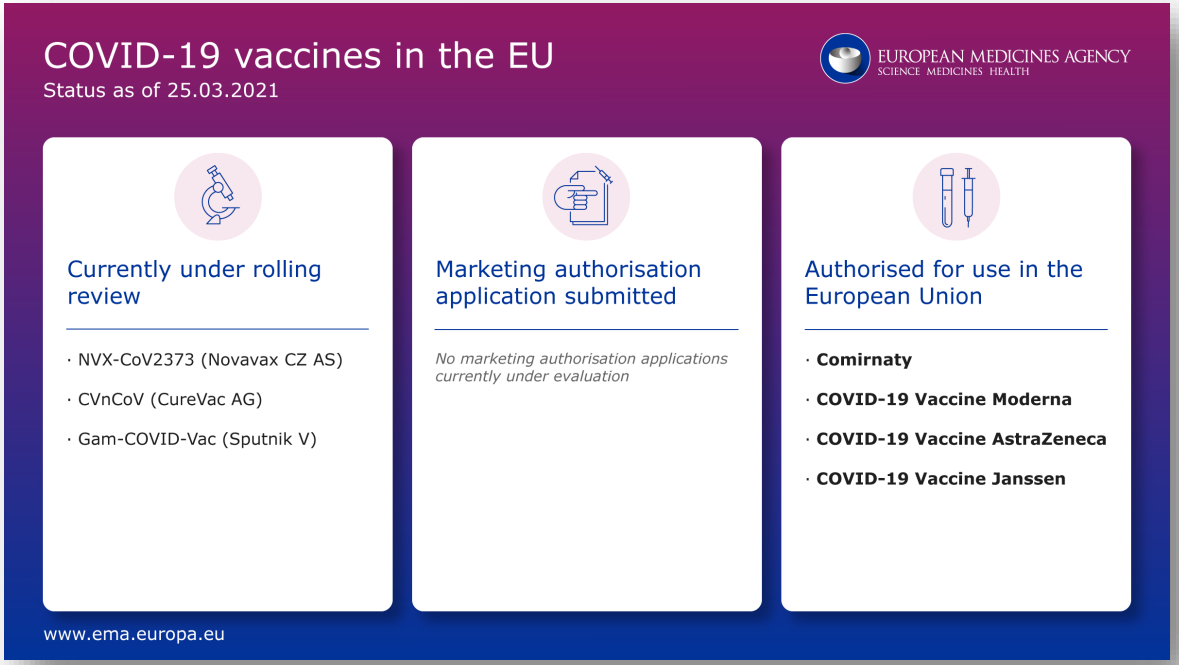
- **Extraordinary measures** have been put in place to enhance the level of transparency for COVID-19 medicines
- We are working with stakeholders to **communicate better**, put the data into context and explain the science in plain language
- The public needs to be able to **access data** and understand the rationale behind important decisions on vaccines
- **Engagement** remains crucial:
    - actively listening to the public and our stakeholders
    - involving them in our activities

What information is being published ?

- Medicines that have received **EMA advice** during their development
- Committee **meeting highlights**, minutes and agendas
- Start of rolling review and applications for marketing authorisation
- **Product information** (all EU languages)
- An overview of the vaccine and why it is approved - in plain language (all EU languages)
- European Public **Assessment Report**
- Full **Risk Management Plan**
- **Clinical data** supporting marketing authorisation
- Changes post-authorisation and regular **safety updates**



Start of rolling review and applications for marketing authorisation



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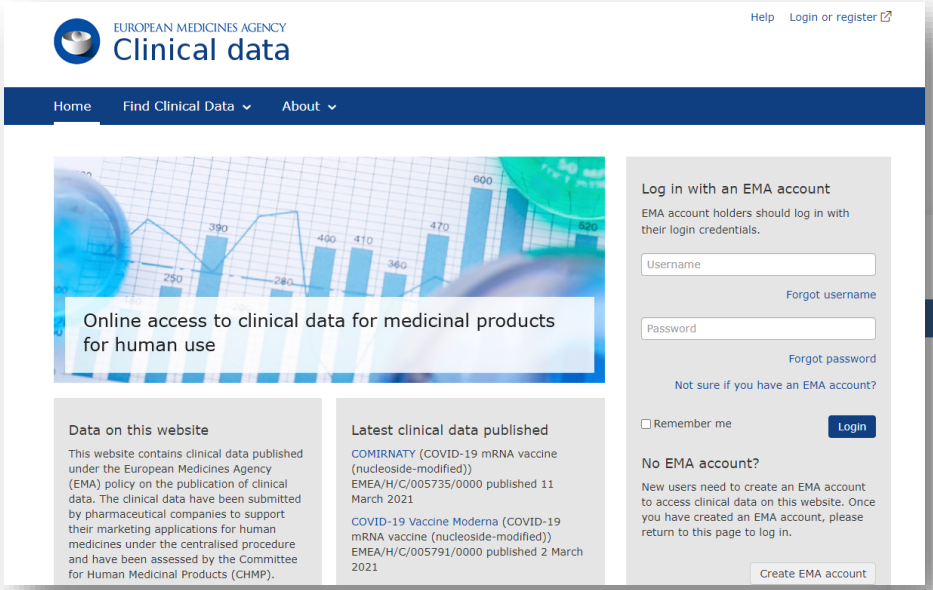
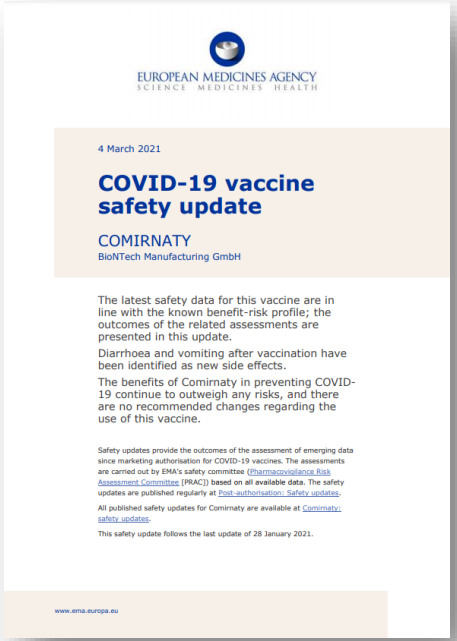
WHAT INFORMATION IS BEING PUBLISHED?

Publication of clinical data



https://clinicaldata.ema.europa.eu/web/cdp/home

Safety updates on vaccines



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 March 2021

COVID-19 vaccine safety update

COMIRNATY
BioNTech Manufacturing GmbH

The latest safety data for this vaccine are in line with the known benefit-risk profile; the outcomes of the related assessments are presented in this update.

Diarrhoea and vomiting after vaccination have been identified as new side effects.

The benefits of Comirnaty in preventing COVID-19 continue to outweigh any risks, and there are no recommended changes regarding the use of this vaccine.

Safety updates provide the outcomes of the assessment of emerging data since marketing authorisation for COVID-19 vaccines. The assessments are carried out by EMA's safety committee (Pharmacovigilance Risk Assessment Committee (PRAC)) **based on all available data.** The safety updates are published regularly at Post-authorisation: Safety updates.

All published safety updates for Comirnaty are available at Comirnaty: safety updates.

This safety update follows the last update of 28 January 2021.

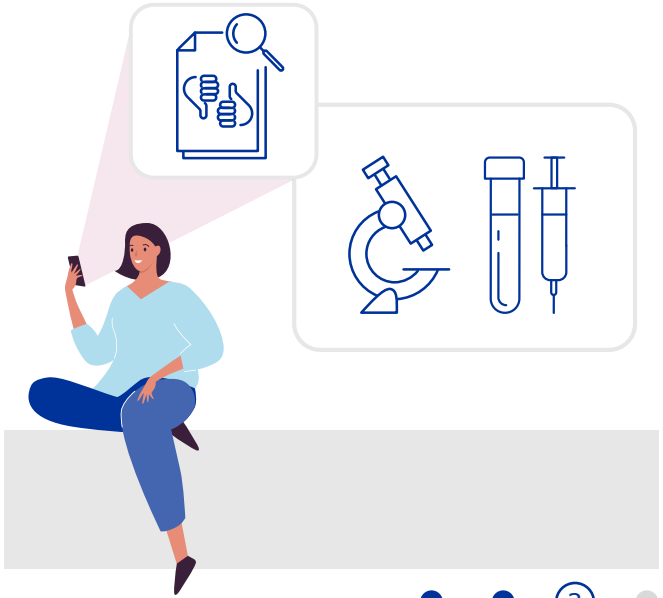
www.ema.europa.eu

Published monthly for each authorised vaccine, they include information regarding:

1. Updates on safety of the vaccine:
   - Assessed side effects;
   - Suspected side effects;
   - Side effects subject to further investigation
2. Other information about the vaccine
3. Overall information on how safety is monitored:
   - Collecting case reports of suspected side effects
   - Planned and ongoing studies

How are we communicating ?

- **New information** on development & approval of COVID-19 vaccines – specifically targeting the general public
- **Responding to queries** from members of the public and media
- **Press, public meetings & social media** on key developments
- **Media interviews** with experts
- Providing content for **European Vaccination Information Portal** and supporting the European Commission
- EMA/Member States' **safety communications**

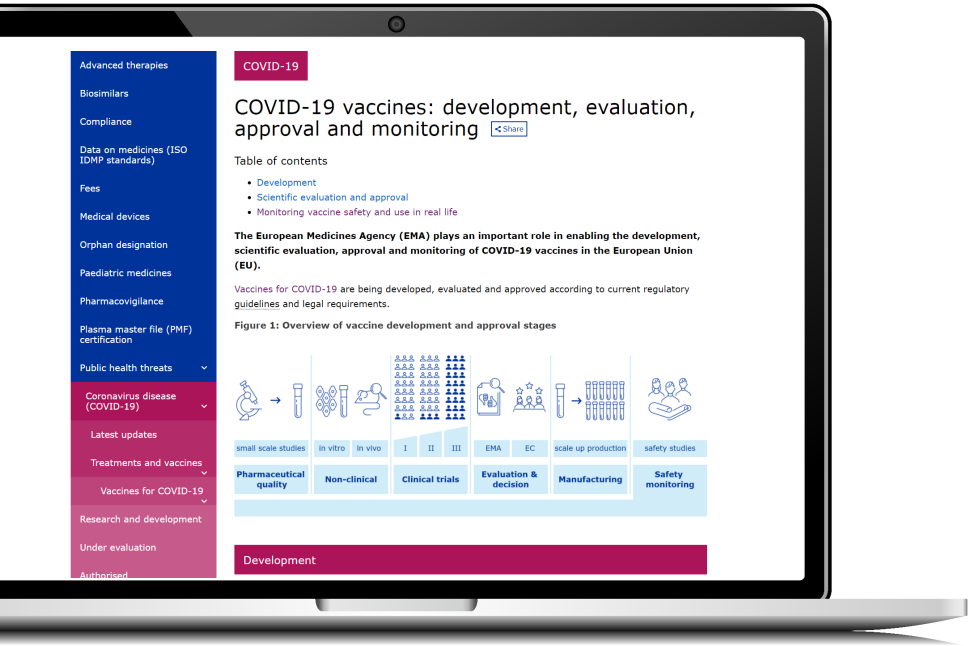


Information materials on COVID-19 vaccines: key facts

Published √

- Questions and answers format
- General public
- Addresses commonly received questions

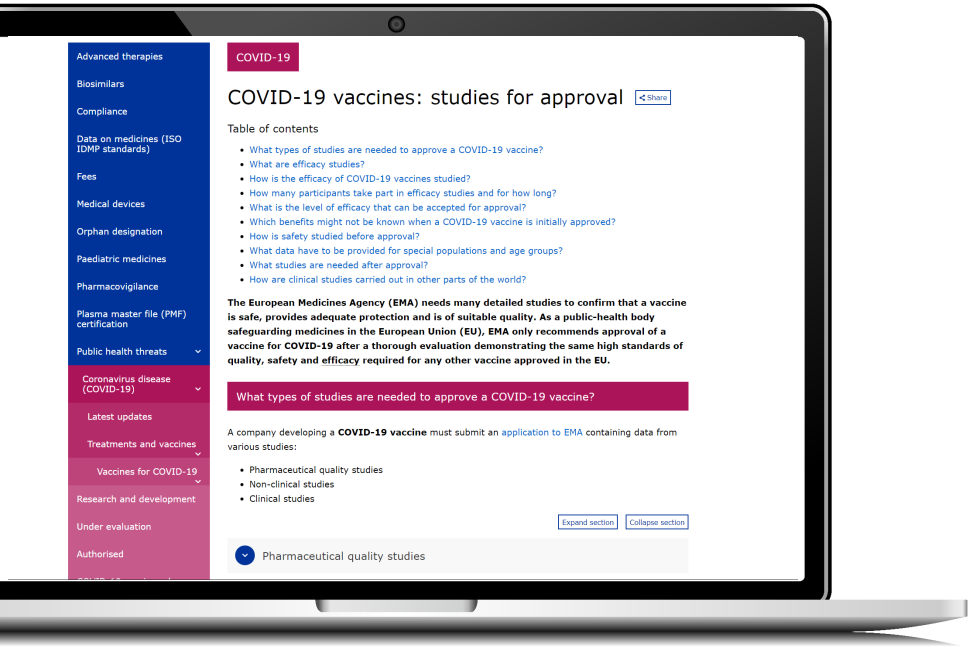
Information materials on COVID-19 vaccines: development, evaluation, approval and monitoring



Published ✓

- More detailed information on how COVID-19 vaccines are developed, evaluated, approved and monitored post-marketing
- Professional audiences and general public
- Addresses commonly received questions
- Graphics to illustrate concepts

Information materials on COVID-19 vaccines: studies for approval



Published ✓

- Information on studies needed to approve a COVID-19 vaccine
  - Quality (manufacturing, shelf life, storage)
  - Safety (before and after approval)
  - Efficacy (benefit of the medicine)
- Professional audiences and general public

Engagement and collaboration

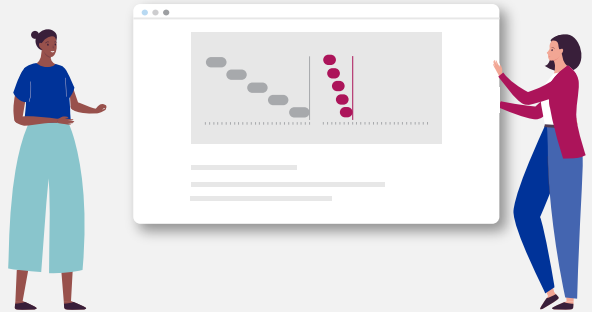
Who are we working with?

- Engaging with **patients and healthcare professionals** in EMA's pandemic task force, regular meetings, user testing information materials
- **Working together** with European Commission, ECDC, national medicines regulators
- Listening to **public concerns** on vaccines, to understand what people want/need to know and try to explain the science

EMA public meetings

11 December 2020

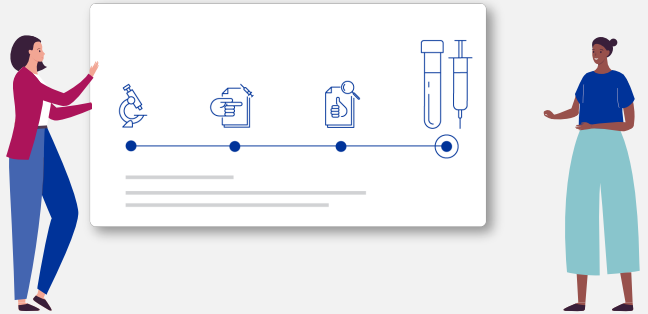
BROADCAST LIVE



Inform the public and stakeholders about EU regulatory process for approval of COVID-19 vaccines and EMA's role in their development, evaluation and approval

8 January 2021

BROADCAST LIVE



Explain the basis for the approval and use of new vaccines, how their safety will be monitored and their roll-out at national level

Listen to the public and stakeholder groups on their needs, expectations and any concerns, so that these can be considered in the relevant regulatory processes.

Latest updates on EMA's corporate website:

COVID-19 pandemic

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