



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

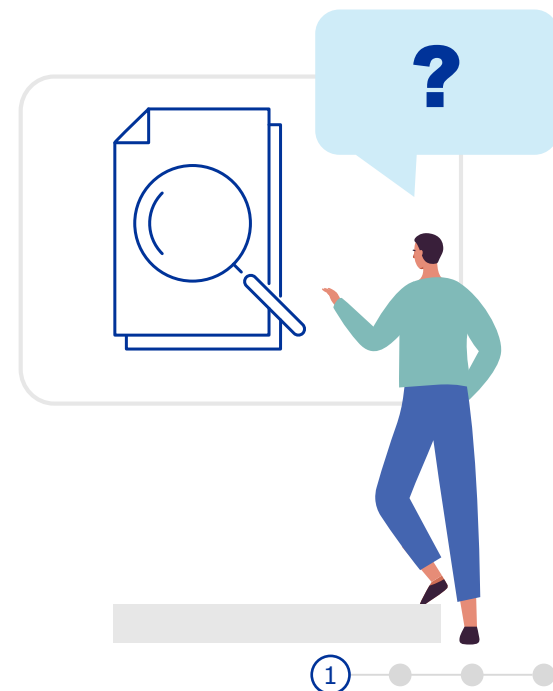


Outline

- 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**






WHAT INFORMATION IS BEING PUBLISHED?

Start of rolling review and applications for marketing authorisation

COVID-19 vaccines in the EU
Status as of 25.03.2021



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 Currently under rolling review	 Marketing authorisation application submitted	 Authorised for use in the European Union
<ul style="list-style-type: none">· NVX-CoV2373 (Novavax CZ AS)· CVnCoV (CureVac AG)· Gam-COVID-Vac (Sputnik V)	<p><i>No marketing authorisation applications currently under evaluation</i></p>	<ul style="list-style-type: none">· Comirnaty· COVID-19 Vaccine Moderna· COVID-19 Vaccine AstraZeneca· COVID-19 Vaccine Janssen

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WHAT INFORMATION IS BEING PUBLISHED?

Publication of clinical data

The screenshot shows the homepage of the Clinical data website. At the top, there is a navigation bar with 'Home', 'Find Clinical Data', and 'About'. The main content area features a large banner with a bar chart and the text 'Online access to clinical data for medicinal products for human use'. Below the banner, there are two columns of text: 'Data on this website' and 'Latest clinical data published'. The 'Latest clinical data published' section lists two entries: COMIRNATY (COVID-19 mRNA vaccine) published on 11 March 2021, and COVID-19 Vaccine Moderna (COVID-19 mRNA vaccine) published on 2 March 2021. On the right side, there is a login section with fields for 'Username' and 'Password', and a 'Login' button. Below the login fields, there is a 'Create EMA account' button.

EUROPEAN MEDICINES AGENCY
Clinical data

Help Login or register

Home Find Clinical Data About

Online access to clinical data for medicinal products for human use

Data on this website
This website contains clinical data published under the European Medicines Agency (EMA) policy on the publication of clinical data. The clinical data have been submitted by pharmaceutical companies to support their marketing applications for human medicines under the centralised procedure and have been assessed by the Committee for Human Medicinal Products (CHMP).

Latest clinical data published
COMIRNATY (COVID-19 mRNA vaccine (nucleoside-modified))
EMA/H/C/005735/0000 published 11 March 2021
COVID-19 Vaccine Moderna (COVID-19 mRNA vaccine (nucleoside-modified))
EMA/H/C/005791/0000 published 2 March 2021

Log in with an EMA account
EMA account holders should log in with their login credentials.
Username
Forgot username
Password
Forgot password
Not sure if you have an EMA account?
 Remember me **Login**
No EMA account?
New users need to create an EMA account to access clinical data on this website. Once you have created an EMA account, please return to this page to log in.
Create EMA account

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

The screenshot shows the 'Clinical data available' page. The navigation bar is the same as the home page. The main content area has a breadcrumb trail: 'Clinical Data Publication > About > Clinical data available'. Below the breadcrumb, there is a section titled 'Clinical data available' with a list of links: 'Annual report - policy implementation', 'Data protection notice', 'Terms of Use', 'Contact Us', and 'Cookie policy'. To the right of these links, there is a section titled 'Clinical data available' with a list of bullet points: 'Scope of the clinical data publication policy', 'Information published', 'Redaction of information', and 'Timelines for Publication'. Below this list, there is a section titled 'Scope of the clinical data publication policy' with a paragraph of text: 'This website contains clinical data published under the European Medicines Agency's (EMA) policy on the publication of clinical data. Clinical data are defined as clinical reports and individual patient data (IPD). EMA will implement the policy in two phases. Phase 1 concerns the publication of clinical reports submitted to the Agency as shown in the table below, regardless of the outcome of the regulatory procedure. It entered into force on 1 January 2015.'

EUROPEAN MEDICINES AGENCY
Clinical data

Help Login or register

Home Find Clinical Data About

Clinical Data Publication > About > Clinical data available

Clinical data available

- Annual report - policy implementation
- Data protection notice
- Terms of Use
- Contact Us
- Cookie policy

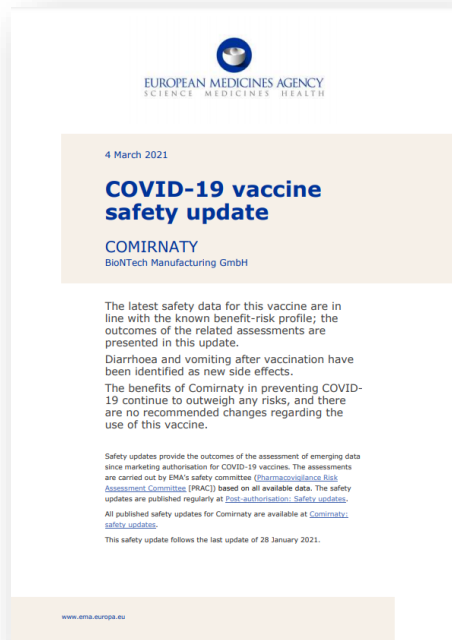
Clinical data available

- Scope of the clinical data publication policy
- Information published
- Redaction of information
- Timelines for Publication

Scope of the clinical data publication policy
This website contains clinical data published under the European Medicines Agency's (EMA) policy on the publication of clinical data.
Clinical data are defined as **clinical reports and individual patient data (IPD)**.
EMA will implement the policy in two phases.
Phase 1 concerns the publication of **clinical reports submitted to the Agency** as shown in the table below, regardless of the outcome of the regulatory procedure. It entered into force on 1 January 2015.

WHAT INFORMATION IS BEING PUBLISHED?

Safety updates on vaccines



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**



HOW ARE WE COMMUNICATING?

Information materials on COVID-19 vaccines: key facts

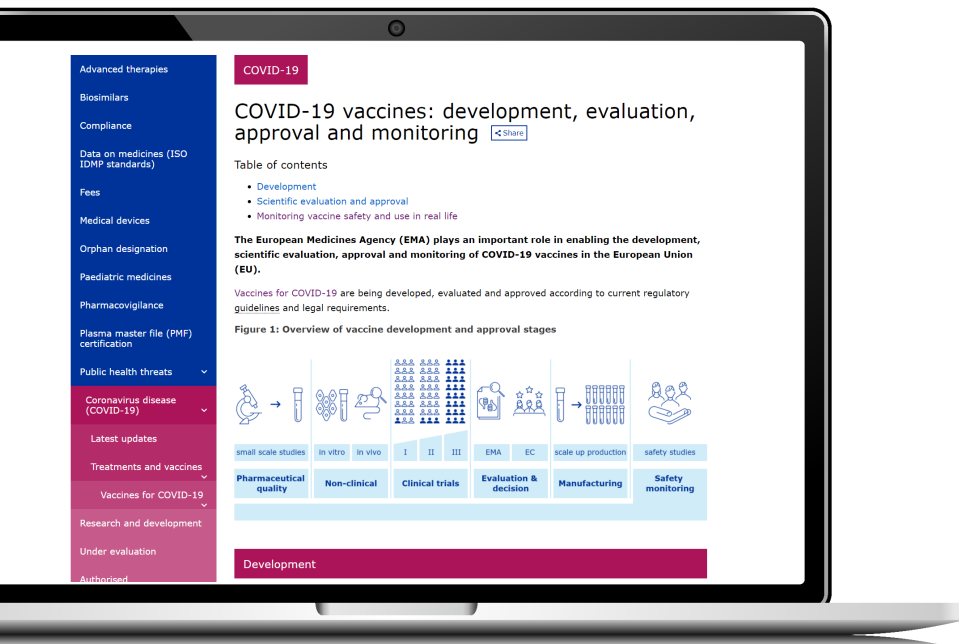


Published ✓

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

HOW ARE WE COMMUNICATING?

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



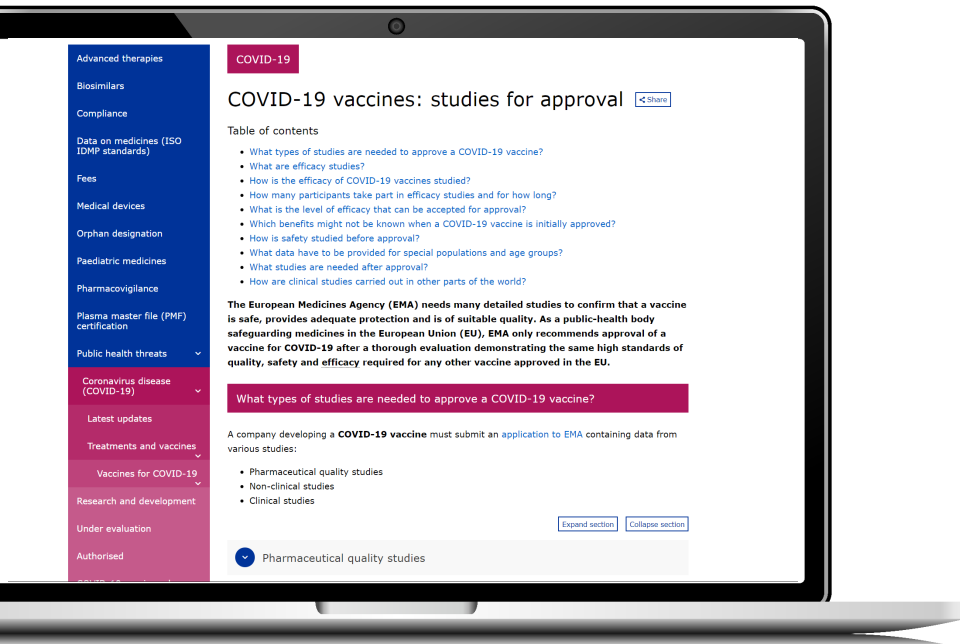
The screenshot displays the EMA website interface. On the left is a navigation menu with categories like 'Advanced therapies', 'Biosimilars', 'Compliance', 'Data on medicines (ISO IDMP standards)', 'Fees', 'Medical devices', 'Orphan designation', 'Paediatric medicines', 'Pharmacovigilance', 'Plasma master file (PMF) certification', 'Public health threats', 'Coronavirus disease (COVID-19)', 'Latest updates', 'Treatments and vaccines', 'Vaccines for COVID-19', 'Research and development', 'Under evaluation', and 'Authorized'. The main content area is titled 'COVID-19' and features the heading 'COVID-19 vaccines: development, evaluation, approval and monitoring' with a 'Share' button. Below this is a 'Table of contents' section listing 'Development', 'Scientific evaluation and approval', and 'Monitoring vaccine safety and use in real life'. A paragraph states: 'The European Medicines Agency (EMA) plays an important role in enabling the development, scientific evaluation, approval and monitoring of COVID-19 vaccines in the European Union (EU)'. Another paragraph notes: 'Vaccines for COVID-19 are being developed, evaluated and approved according to current regulatory guidelines and legal requirements.' A caption reads: 'Figure 1: Overview of vaccine development and approval stages'. The figure is a horizontal flowchart with icons and labels: 'small scale studies', 'in vitro', 'in vivo', 'I', 'II', 'III', 'EMA', 'EC', 'scale up production', and 'safety studies'. Below the flowchart is a table with two rows: 'Pharmaceutical quality' and 'Safety monitoring', with columns corresponding to the stages above. The 'Development' stage is highlighted in a pink bar at the bottom of the figure.

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

HOW ARE WE COMMUNICATING?

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

European Commission

English

Search

Home > Live, work, travel in the EU > Coronavirus response > Safe COVID-19 vaccines for Europeans

Safe COVID-19 vaccines for Europeans

The European Commission has secured up to 2.6 billion doses of COVID-19 vaccines so far and negotiations are underway for additional doses. Vaccine deliveries to EU countries have increased steadily and vaccination is gathering pace. The Commission is also working with industry to step up vaccine manufacturing capacity.

At the same time it has started work to tackle new variants, aiming to rapidly develop and produce effective vaccines against these variants on a large scale. The HERA Incubator will help respond to this threat.

The EU is committed to ensuring that safe vaccines reach all corners of the world. The Commission and EU countries have pledged over €2.2 billion to COVAX, the global initiative aimed at ensuring equitable access to COVID-19 vaccines, and are supporting vaccination campaigns in partner countries.

PAGE CONTENTS

- Figures on vaccination
- Highlights
- Information about vaccination in the EU
- Securing doses of future vaccines

Figures on vaccination

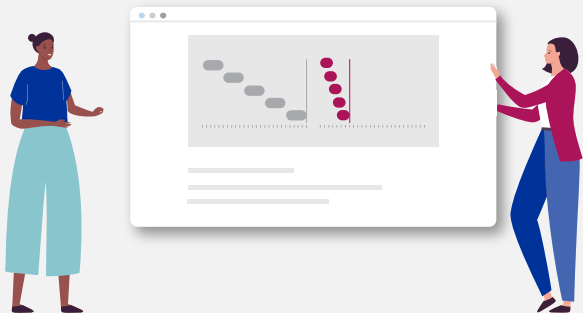
 60.7 million doses delivered in the EU	 43.1 million doses administered in the EU
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ENGAGEMENT AND COLLABORATION

EMA public meetings

11 December 2020

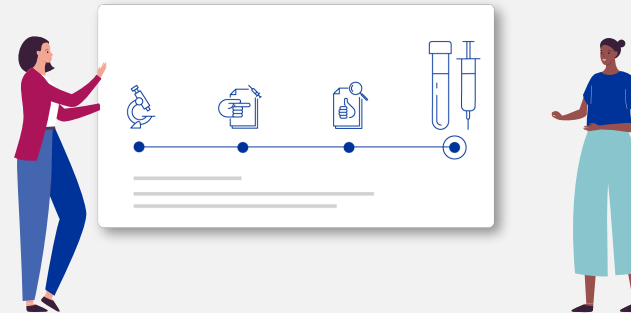
BROADCAST LIVE



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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 [European Medicines Agency](https://www.linkedin.com/company/european-medicines-agency)

Your feedback is welcome

[slido.com #T488](https://www.slido.com/join-public/488)



The screenshot displays the EMA website's COVID-19 pandemic page. At the top, the EMA logo and navigation menu are visible. The main heading is "COVID-19 pandemic" in large white text on a dark blue background. Below this, there is a search bar and a "Search" button. A navigation menu includes "Medicines", "Human regulatory", "Veterinary regulatory", "Committees", "News & events", "Partners & networks", and "About us". A prominent "All info here >" button is located below the heading. To the right, a "QUICK LINKS" section lists "Latest updates", "Vaccines", "Treatments", and "Guidance for developers and companies", each with a right-pointing arrow. The main content area features a large image of a person's arm being injected with a vaccine, overlaid with a timeline of icons representing research, development, and approval. Below the image, the text reads "COVID-19 | VACCINES" and "Fourth COVID-19 vaccine authorised in the EU". A sub-headline states: "The European Commission has granted a conditional marketing authorisation for COVID-19 Vaccine Janssen following EMA's recommendation". On the right side of the page, there are three news highlights: "Management Board: Highlights of March 2021 meeting", "PRAC highlights March 2021", and "Fourth COVID-19 vaccine authorised in the EU".