The development of a vaccine in times of a (Covid-19) pandemic

Air Freight Conference 2020

Covid-19 Vaccine Distribution

Dr. Peter Bertens

Dutch association Innovative Medicines

The Association Innovative Medicines represents

- 43 innovative pharmaceutical companies
- Members develop innovative medicines and vaccines

Vereniging Innovatieve Geneesmiddelen

Agenda

1. Vaccines research & development at glance

2. United in the search of Covid-19 vaccines

Vaccines research & development at a glance

Dutch association Innovative Medicines

Value of vaccines during history

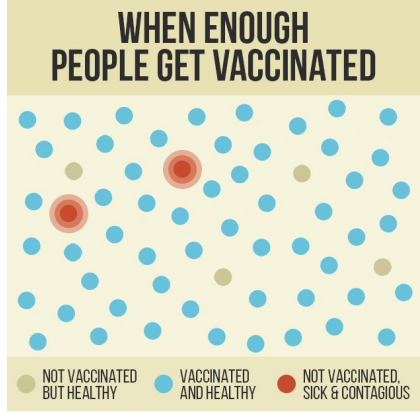
1. Vaccines are one of the greatest medical achievements in history, saving 2-3 million lives globally every year by preventing infectious diseases.

2. Vaccines offer a community-wide protection (it is a social act).

3. Close to 30 diseases today are vaccine-preventable.

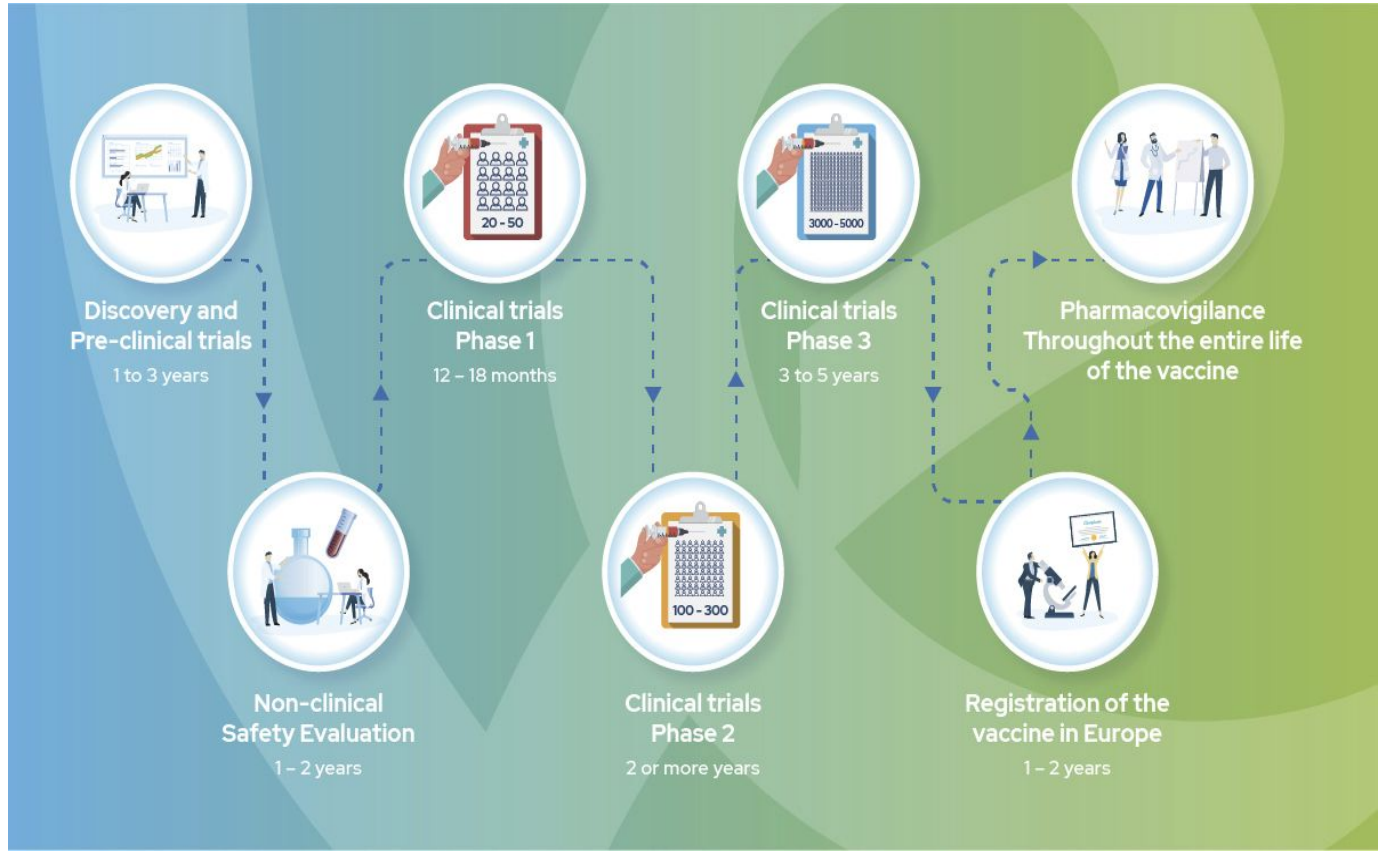
4. Vaccines save and improve lives across the entire life-course (newborns, children, adolescents, pregnant women, adults and older people).

5. Vaccines are helping to combat antimicrobial resistance.



How are vaccines being developed?

- Safety is paramount.
- Vaccine clinical trials must demonstrate both:
  - that a vaccine is safe
  - that it is effective in preventing disease.
- Before a vaccine is licensed and brought to market it undergoes a long and rigorous period of research followed by many years of post-approval surveillance.
- On average, it takes between 10 to 15 years to research and develop a vaccine.



Clinical trials – key steps in ensuring vaccine's safety, effectiveness and

Clinical trials Phase 1

12 – 18 months

The candidate vaccine is tested in a small number of healthy individuals (typically 20-50) to determine whether it is safe and can generate an immune response in humans.

Clinical trials Phase 2

2 or more years

The candidate vaccine is administered to a larger group of individuals (typically 100-500) to further confirm its safety and immunogenicity. This phase explores in detail the optimal dose and might provide initial evidence of the vaccine's ability to protect against the target infection.

Clinical trials Phase 3

3 to 5 years

The most promising vaccine candidate is tested in thousands of individuals (typically 3,000 to 5,000) to collect conclusive evidence of its ability to protect against the target infection. Additional information is collected on its safety and potential for causing rare side effect, not seen in smaller studies.

And phase IV trials after market authorisation

Pharmacovigilance

Throughout the entire life of the vaccine

Pharmacovigilance activities take place to carry on a strict safety supervision of the vaccines already introduced to the market. It detects, assesses, understands, prevents and communicates any reported side effects following immunisation, or immunisation-related issues.

United in the search of Covid-19 vaccines

Dutch association
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Fast and collaborative response to the pandemic

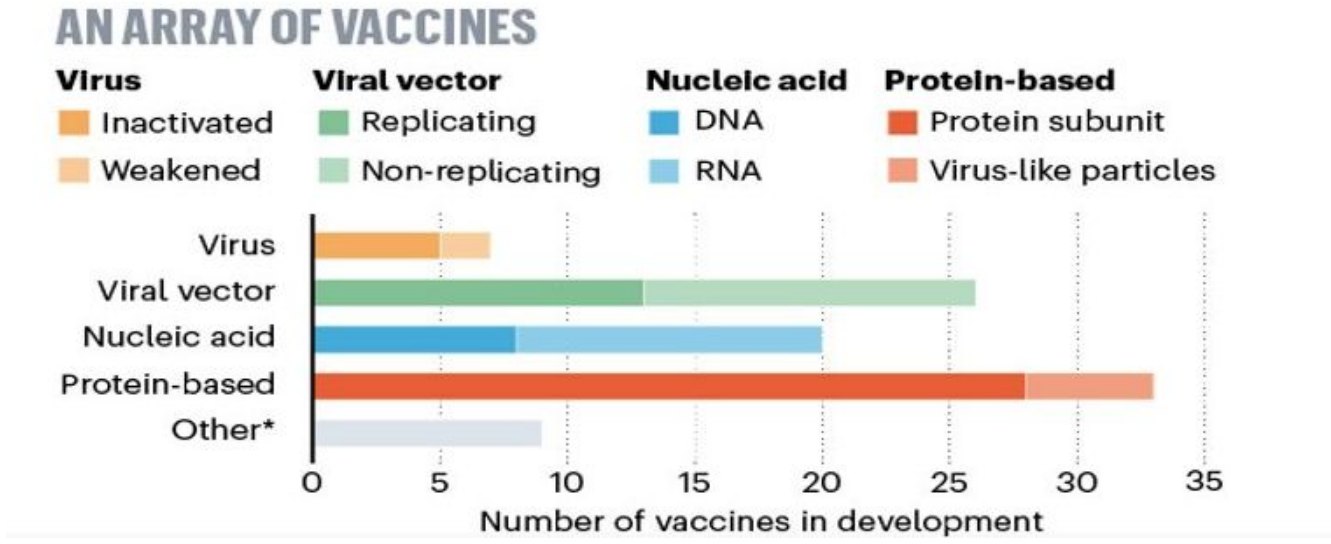
Since the beginning of the COVID-19 pandemic, the industry has been working around the clock to search for Covid-19 vaccines – creating multiple partnerships and collaborations.

There are at least 194 confirmed vaccine projects in development globally (2020/12/14)

- With 73 in clinical trials
- And 16 in Phase III
- 5 vaccines in early or limited use
- 2 vaccines for approved for full use
- (1 vaccine abandoned after trials)

Multiple development platforms for Covid-19 vaccines

- All vaccines aim to expose the body to an antigen that won't cause disease but will induce an immune response that can block or kill the virus when a person meets it.
- There are at least 5 types being tried against the coronavirus, and they rely on different viruses or viral parts.
- Under review by EMA (2020/12/14):
  - 2 nucleic acid vaccines
  - 2 viral vectors



COVID-19 clinical studies –efficacy and safety

Measuring Covid-19 vaccines' benefit

- Prevention of symptomatic disease as main measure of benefit
  - Less disease with symptoms in people given vaccine compared to placebo

- Other benefits likely uncertain at approval and only clearer after the vaccine is used:
  - Long term protection
  - Prevention of infection (asymptomatic cases)
  - Prevention of virus transmission in the community -needs specific studies post-approval

Efficacy levels

Studies designed to show efficacy of 50% or more

50% efficacy means the vaccine prevents half of the cases of symptomatic COVID-19 compared with placebo

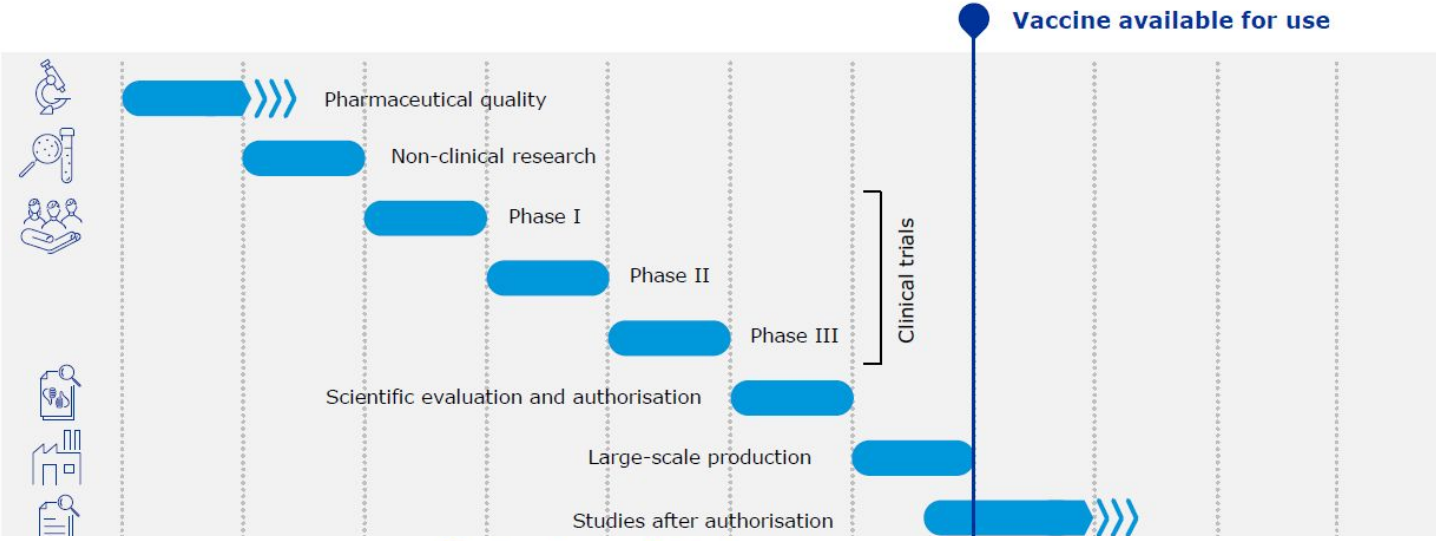
90% efficacy means the vaccine prevents nine out of 10 cases of symptomatic COVID-19 compared with placebo

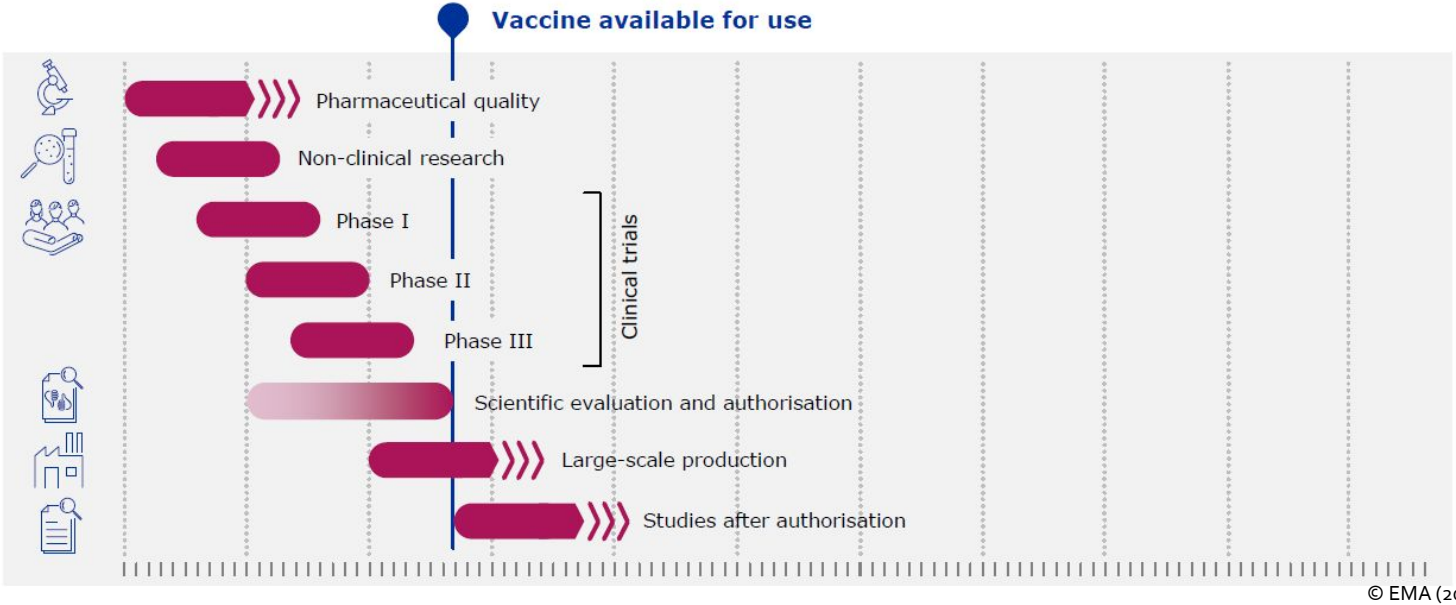
COVID-19 clinical studies –efficacy and safety

- Large number of adults expected (above 30,000)
- Ideally one quarter of all participants above 65 years of age
- Some people with underlying diseases at risk of severe COVID-19
- Some studies include adolescents above 16 years of age
  - Younger children to be studied after analysing data in adults and adolescents
- Some minorities represented
- Follow-up data for at least the6 weeks after last dose of vaccine
  - Most side effects occur within 4-6 weeks of having a dose
- Trials to last for at least 1 year: longer-term protection & side effects

- COVID-19 vaccines must be approved according to the same standards that apply to all medicines in the EU
  - Industry will only submit COVID-19 vaccines for approval after demonstrating safety and efficacy data through phase 3 clinical studies that are designed and conducted to meet the requirements of expert regulatory authorities such as the EMA

COVID-19 vaccine development is compressed in time





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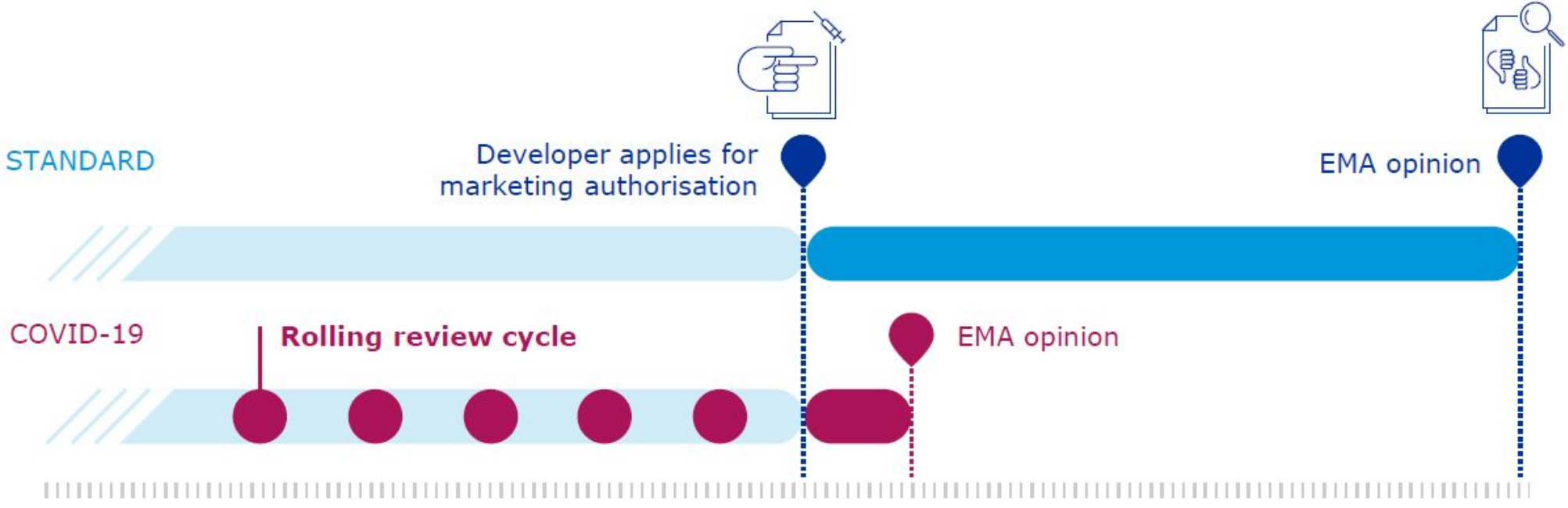
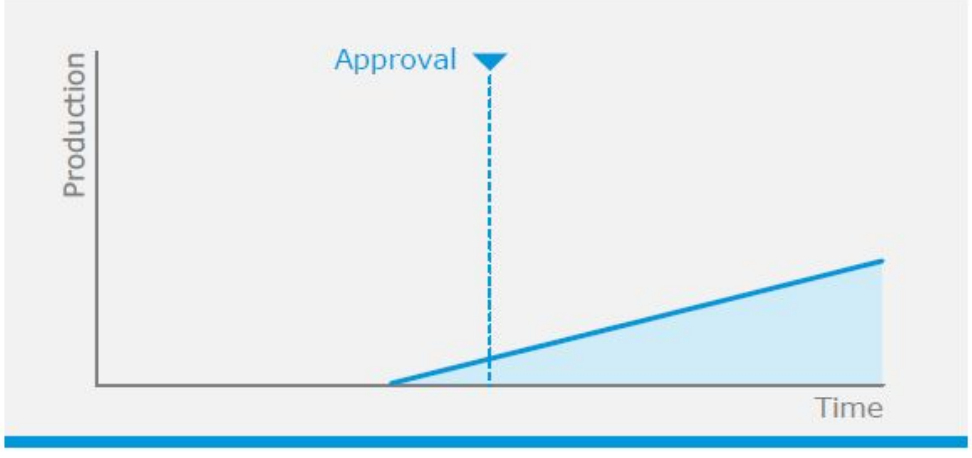
EMA Rolling Review: Evaluate data as soon as available



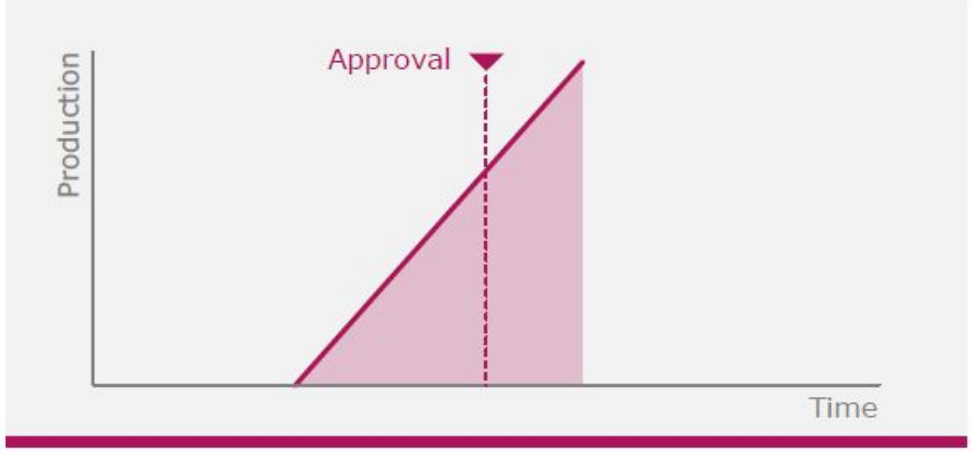
COVID-19 vaccine development is supported by early, continuous dialogue between developers and a dedicated group of regulatory experts EMA COVID-19 Task Force

Companies are expanding manufacturing and production capacity to ensure efficient vaccine deployment

STANDARD



COVID-19



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Conclusions

- Vaccines are one of the greatest medical achievements in history
- Before a vaccine is licensed and brought to market it undergoes a long and rigorous period of research followed by many years of post-approval surveillance, demonstrating
  - that a vaccine is safe
  - that it is effective in preventing disease
- On average, it takes between 10 to 15 years to research and develop a vaccine.

- The industry has been working around the clock to search for Covid-19 vaccines
  - Diverse pipeline of experimental fvaccines
- COVID-19 vaccine development is compressed in time
- COVID-19 vaccine development is supported by early, continuous dialogue between developers and the EMA; rolling review: acceleration of market authorisation process
- Companies are already manufacturing the experimental vaccines, to ensure fast and efficient vaccine deployment

Thank you

Address

Association Innovative Medicines
Prinses Beatrixlaan 548-550
2595 BM Den Haag
The Netherlands
T + 31 70 313 22 22
E info@innovatievegeneesmiddelen.nl

Online

www.innovatievegeneesmiddelen.nl
www.wewordenbeter.nl
@wewordenbeter

Dutch association
Innovative
Medicines