



RSNN

Regulatory Science Network Netherlands

COVID-19 observations

Hans GCP Schikan
Special Envoy vaccines

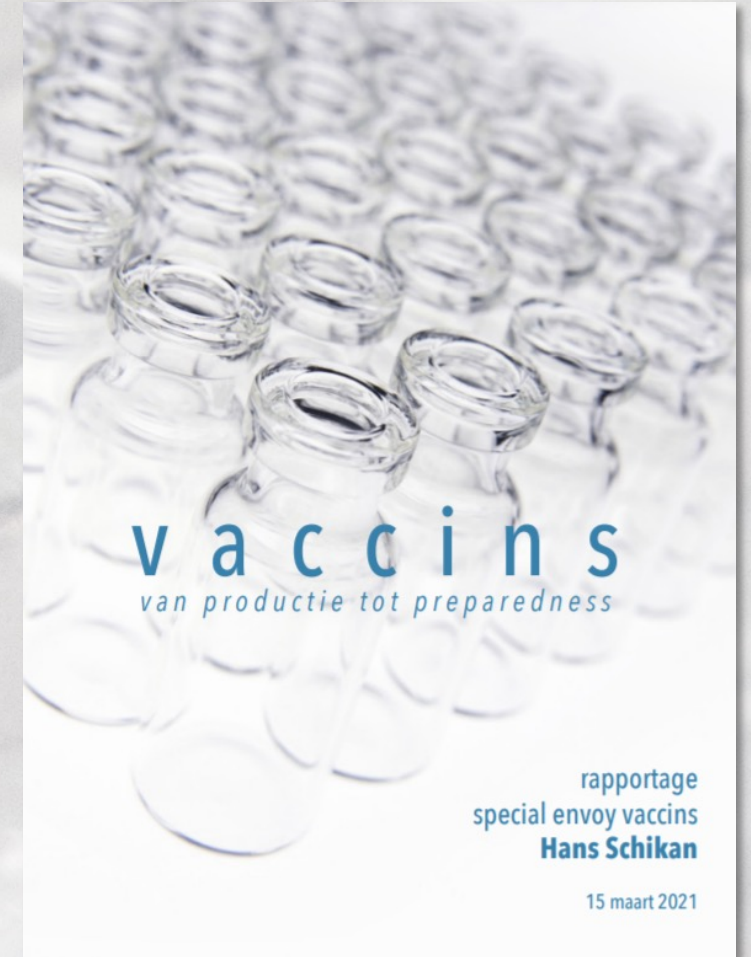
Assignment

In a short time span, provide a closer picture of:

- available **production capacity** in The Netherlands for the scaling up of COVID-19 vaccines manufacturing;
- **when** can this capacity be utilized and what is required;
- **other ways** in which the Dutch government or Dutch companies can contribute to the scaling up of production capacity

What have we done?

- Approximately 80 meetings with 120 people
- Frequent interactions with colleagues in the EU
- Participation in round table conferences
- Desk research
- Report March
- Implementation of Taskforce
- Recommendations to Minister of Health



Major conclusions

- Enough vaccines purchased, approx. 100 mln doses for NL
- Short-term scaling up not possible: can be done on medium to long term
- High global demand for vaccines: 10-14 billion doses (normally 4-5 billion)
- Shortages in supply chains (vials, stoppers, bioreactor bags)
- Possibly consequences for other medicines
- Supply chain is truly global
- Export barriers are harmful

The numbers globally

- 250 million cases
- 5 million deaths
- 7 billion vaccines administered
- 50% vaccinated with 1 dose
- 40% fully vaccinated
- Total anticipated cost 2025: USD 16-35 trillion (12 zero's)

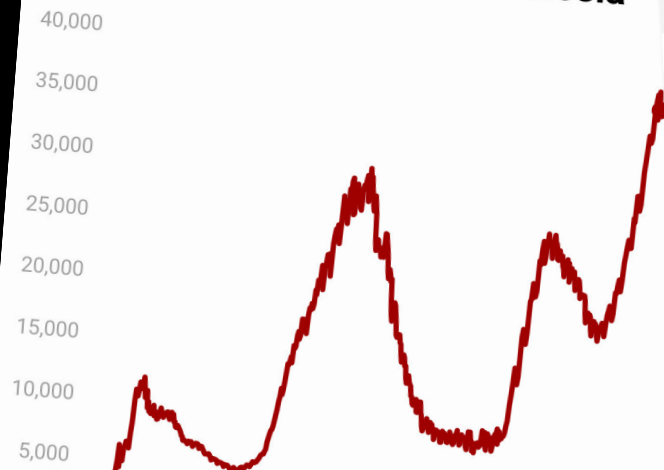
LIVE UPDATES

COVID-19 live updates: Unvaccinated Americans continue to drive infection, death rates

People who aren't fully vaccinated are 6.1 times more likely to test positive.

By Morgan Winsor and Emily Shapiro
October 26, 2021, 4:26 PM ET

New Coronavirus Cases in Russia



The Facebook Papers Trending News Coronavirus pan

Ukraine registers record daily number of COVID-19 deaths

By YURAS KARMANAU today

Contribute

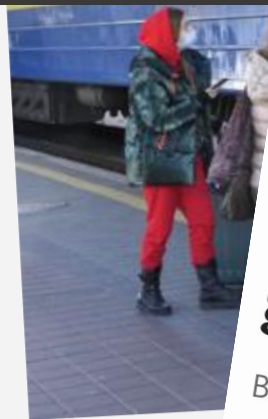
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News > Health

Covid news - live: UK sees highest daily death toll since March as Plan C discussed in government

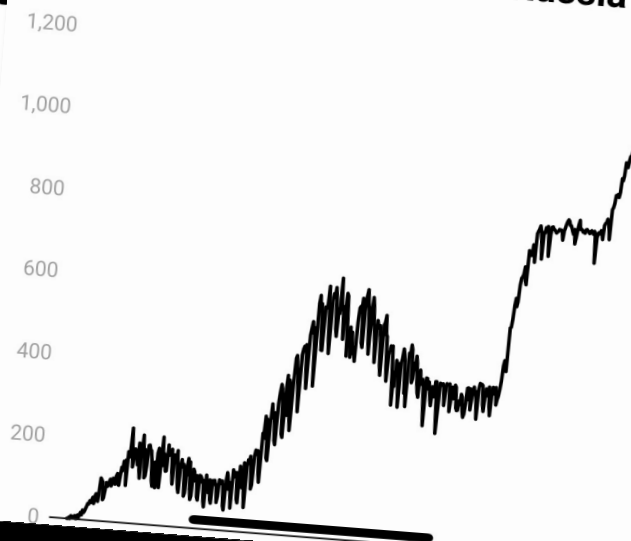
Biggest death total since UK was coming down from winter spike

Liam James | 24 minutes ago



KYIV, Ukra

New Coronavirus Deaths in Russia



Home / World / China Puts Cit

China Puts City Of 4 Millic Under Lockdown Due To Spike In Covid Cases

Residents have been told not to leave hom except in emergencies, as China pushes I into lockdown due to six new cases repor the city and 29 new cases reported over the nation.

it ain't over yet...



🕒 positive news on covid-19



COVID-19: Ed Sheeran tests positive for coronavirus - but says he will gig from home

The artist has apologised to fans for pulling out of his in-person commitments so that he can self-isolate and follow government guidelines.

🕒 Sunday 24 October 2021 18:10, UK



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Coronavirus live: European Medical Agency approves Moderna booster;

NEWS UPDATE
BOOSTERS APPROVED

PM VS PREMIER

REUTERS

October 24, 2021 5:28 AM CEST Last Updated 4 days ago

Asia Pacific

Melbourne to ease more COVID curbs as 80% vaccination rate nears

2 minute read



FINANCIAL TIMES

SIGN IN

BioNTech

BioNTech strikes deal to open Africa's first mRNA manufacturing plant

Agreement with Rwanda and Senegal is a big step in company's plans to produce Covid jabs on the continent



SAN DIEGO SCIENTISTS WORK ON A VACCINE AGAINST ALL CORONAVIRUSES

Vaccine / October 25, 2021 / 1 Min read

RS. MERS. COVID-19. Coronaviruses used all three dis

Advisory com
Pfizer Covid va

NEWS

CORONAVIRUS
FDA advisory panel OKs Pfizer vaccine for children 5 to 11

The move, if the FDA signs off on it, would expand eligibility to 28 million kids in the U.S

SCIENCE | CORONAVIRUS COVERAGE

How a village in India reached 100% vaccination in the face of misinformation and hesitancy

The techniques used in the village of Janefal could now be a model for

Unprecedented collaboration

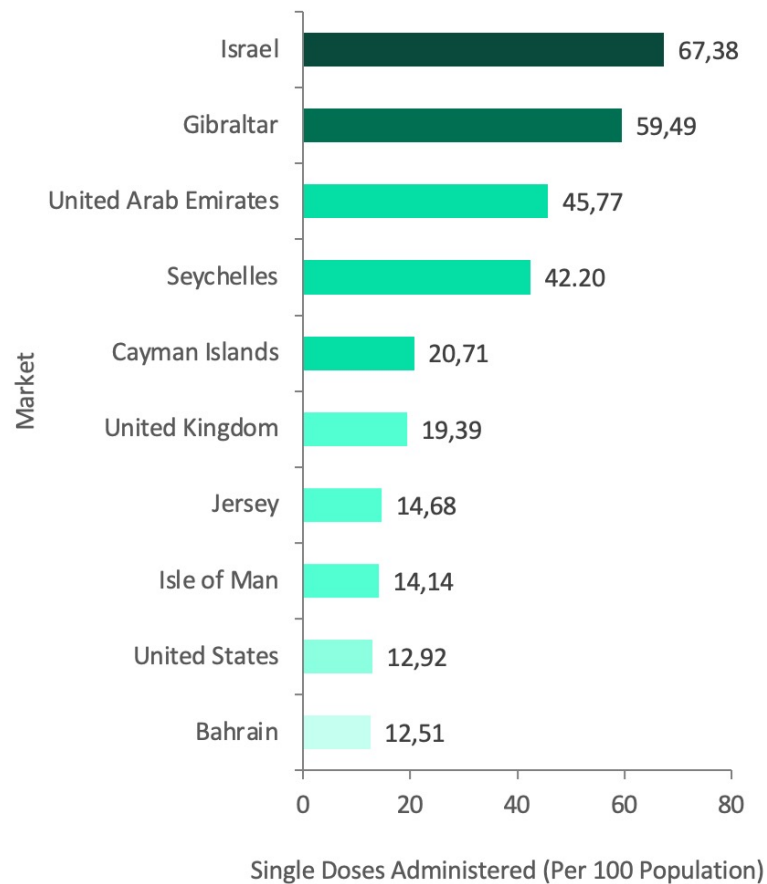
private-
private

public-
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public-
private

sense of urgency

Top 10 Countries/Regions, COVID-19 Vaccine Single Doses Administered Per 100 Population
as of 9 February, 2021



Regulatory
innovation



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AstraZeneca vaccine: EU regulator 'firmly convinced' benefits outweigh risks

16 March



Corona

Vaccinationerna med Astra Zenecas vaccin kan fortsätta för personer som är 65 år och äldre

Astra Zenecas vaccin rekommenderas till personer under 65 år

Prikken met AstraZeneca voor mensen van 60 jaar en ouder gaat door

Nieuwsbericht | 08-04-2021 | 20:06

België geeft AstraZeneca-vaccin voorlopig niet aan 55-plussers: "Vaccinatiestrategie op langere termijn herbekijken"

België gaat het coronavaccin van AstraZeneca toelaten voor mensen ouder dan 55 jaar

Volksgezondheid
HOME > NIEUWS > BINNENLAND

AstraZeneca maand lang enkel voor 55-plussers in België
op de zeer laag aantal bloedplaatjes.
vooral gezien bij mensen onder de 60 jaar.
minister het vaccineren met AstraZeneca van mensen.
het prikken door.

mensen vanaf 60 jaar, geboren in 1960 of eerder, kunnen veilig een prik met AstraZeneca blijven krijgen. Mensen onder de 60 jaar ontvangen een ander vaccin. Minister Hugo de Jonge (VWS) volgt hiermee het advies van de DGS. Die stelt dat het risico op gezondheidsschade als het risico op een bloedplaatjesgebrek vele malen groter is dan het risico op een ernstige bijwerking met een ander vaccin.

DGS recomenda utilização da vacina de AstraZeneca acima dos 60 anos



The NEW ENGLAND
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Coronavirus (Covid-19)

A collection of articles and other resources on the Coronavirus (Covid-19) outbreak, including clinical reports, management guidelines, and commentary.

CORONAVIRUS (COVID-19)

[VACCINE RESOURCES](#) [VACCINE FAQ](#)

All Journal content related to the Covid-19 pandemic is freely available.

COVID-19 RESOURCE CENTRE

COVID-19 content collection

The *Lancet* family of journals publishes the latest COVID-19 related content across epidemiology, treatments, vaccines and much more. Here you can explore COVID-19 content published across all *Lancet* journals and [content types](#). All of our COVID-19 content is free to access.



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ADVANCE PURCHASE AGREEMENT ("APA") FOR THE PRODUCTION, PURCHASE AND SUPPLY OF A COVID-19 VACCINE IN THE EUROPEAN UNION

This Advance Purchase Agreement (this "**Agreement**") for the production, purchase and supply of the ChAdOx1 nCov-19 vaccine ("**Vaccine**") in the European Union (the "**EU**") is entered into as of 27 August 2020 (the "**Effective Date**"), by the following parties:

- the European Commission having a business address of rue de la Loi 200, 1049 Brussels (Belgium) (the "**Commission**" or "**Contracting Authority**") acting on behalf and in the name of the member states of the European Union (each a "**Member State**").

- and AstraZeneca AB, a party incorporated in Sweden having a business address of KVARNBERGAG 16, 151 85 SÖDERTÄLJE ("**AstraZeneca**", the "**contractor**").

The Commission, the Participating Member States and AstraZeneca may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, by Decision C(2020) 4192 final of 18 June 2020, the Commission approved the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States ("**the Decision**"). This agreement is based on **Article 4**, paragraph 5, point (b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union¹ ("**the ESI Regulation**") which provides that the Commission may grant emergency support in the form of procurement on behalf of the Member States based on an agreement between the Commission and Member States. In order to implement such action, the Commission has offered to run a single central procurement procedure on behalf of Member States, with a view to signing EU-level advanced purchase agreements with various vaccine manufacturers.

WHEREAS, according to Article 4 of the agreement between the Commission and the Member States, as annexed to the Decision, where the Commission intends to conclude an APA containing an obligation to acquire Vaccine Doses, it shall inform the Member States of such intention and the detailed terms. In case a Member State does not agree with the conclusion of an APA containing an obligation to acquire Vaccine Doses or its terms, it has the right to opt out by explicit notification to the Commission within five working days after the Commission has communicated its intention to conclude the APA. All Member States not having opted out within the period of five (5) working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf and become thus by operation of law Participating Member States.

WHEREAS, the present APA contains obligations to acquire Vaccine Doses.

¹ OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID- 19 outbreak, OJ L 117, 15.4.2020, p. 3.



New models of risk sharing

Increased appreciation for Pharma



Marketing

Pharma's reputation rehab: A whopping two-thirds of Americans now offer a thumbs-up, Harris Poll finds

by Beth Snyder Bulik | Feb 19, 2021 10:05am



American consumers have changed their tune on pharma in the past year, with the vast majority now giving the industry good marks. (Getty Images)



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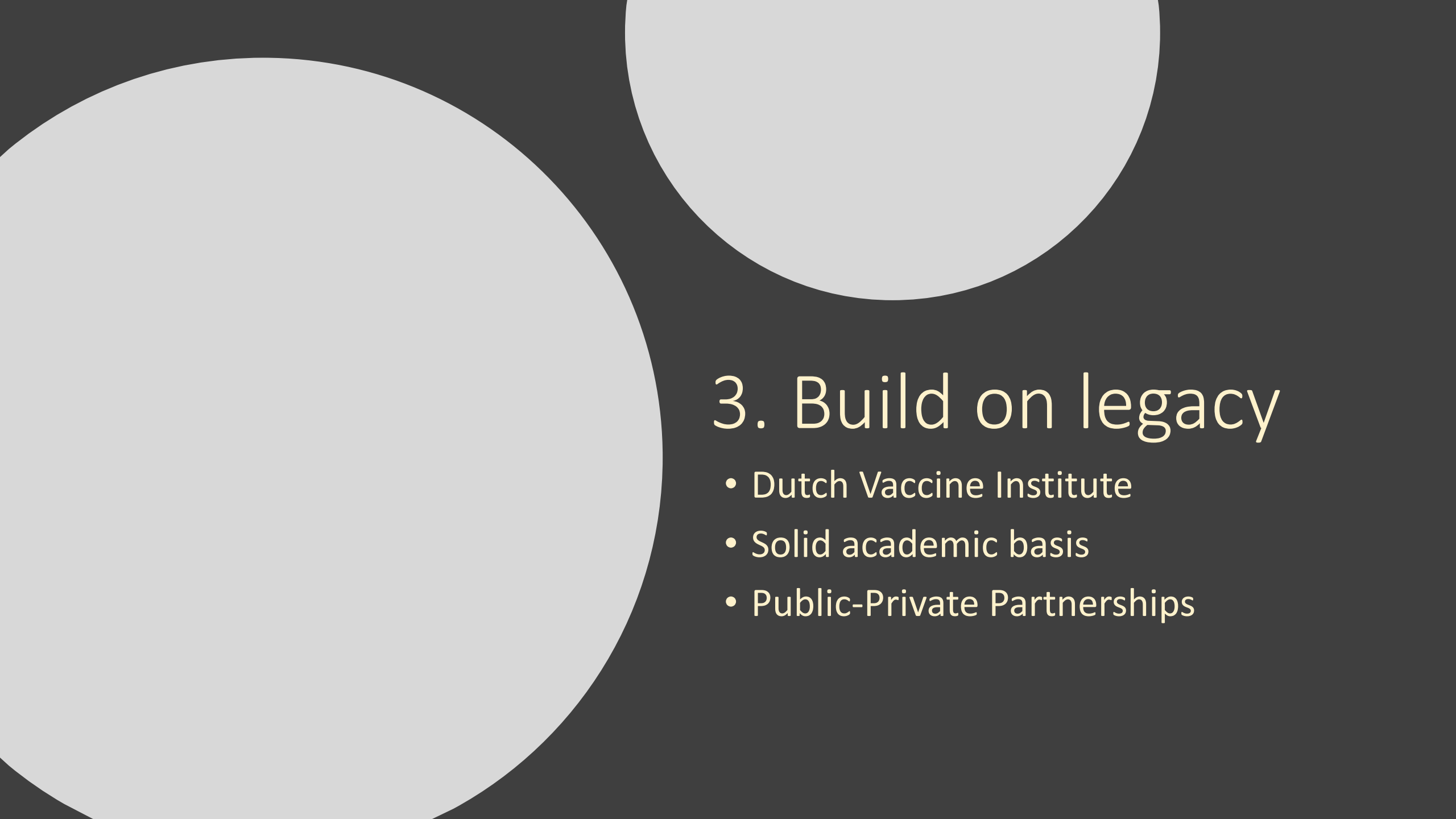
RECOMMENDATIONS

1. Engage the private sector early

- Complementarity
- Part of the solution
- Mutual respect

2. Bridge healthcare and industrial policy

- USA, UK, Germany, France, Denmark
- Support LMIC's



3. Build on legacy

- Dutch Vaccine Institute
- Solid academic basis
- Public-Private Partnerships

4. Invest timely in Plan B

- Entire supply chain
- More tech transfer personnel
- Advance Purchase Agreements
- Vaccines and therapeutics
- Pandemic Preparedness Plan

5. Cherish the positive side effects

- Collaboration
- Sense of urgency
- Risk sharing
- Regulatory harmonisation