# **COVID-19 tyrimai ir skiepijimas:** ką būtina žinoti?

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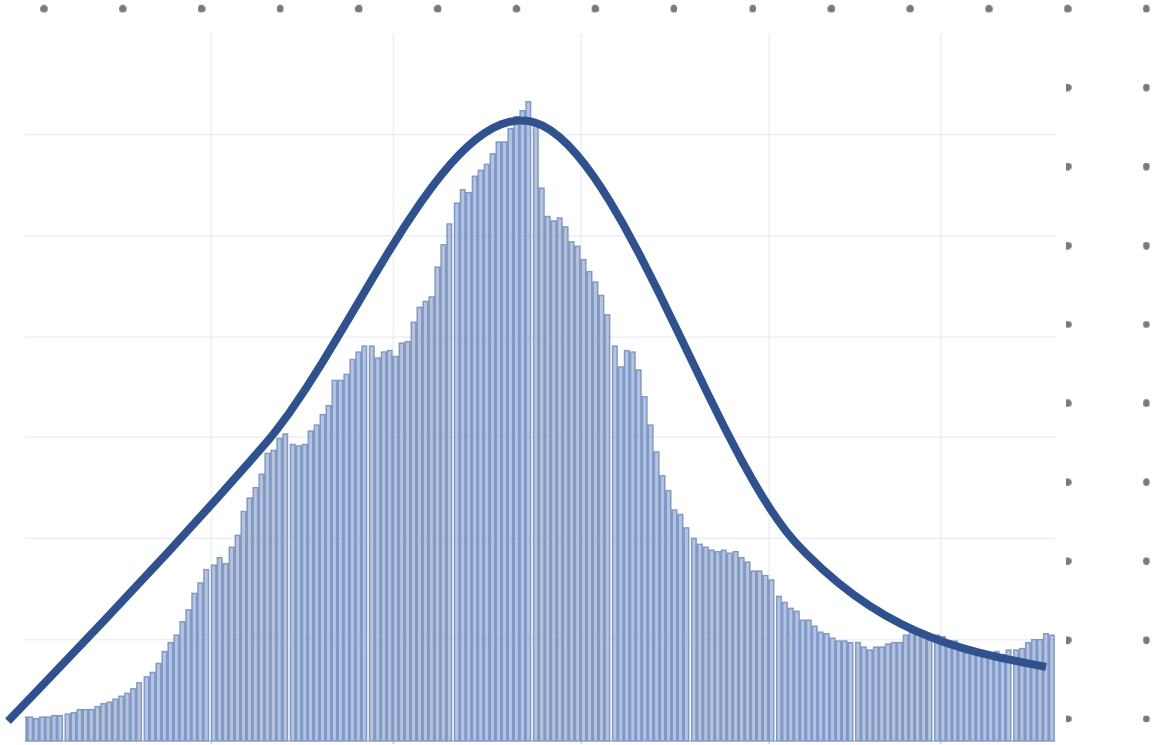
# 01

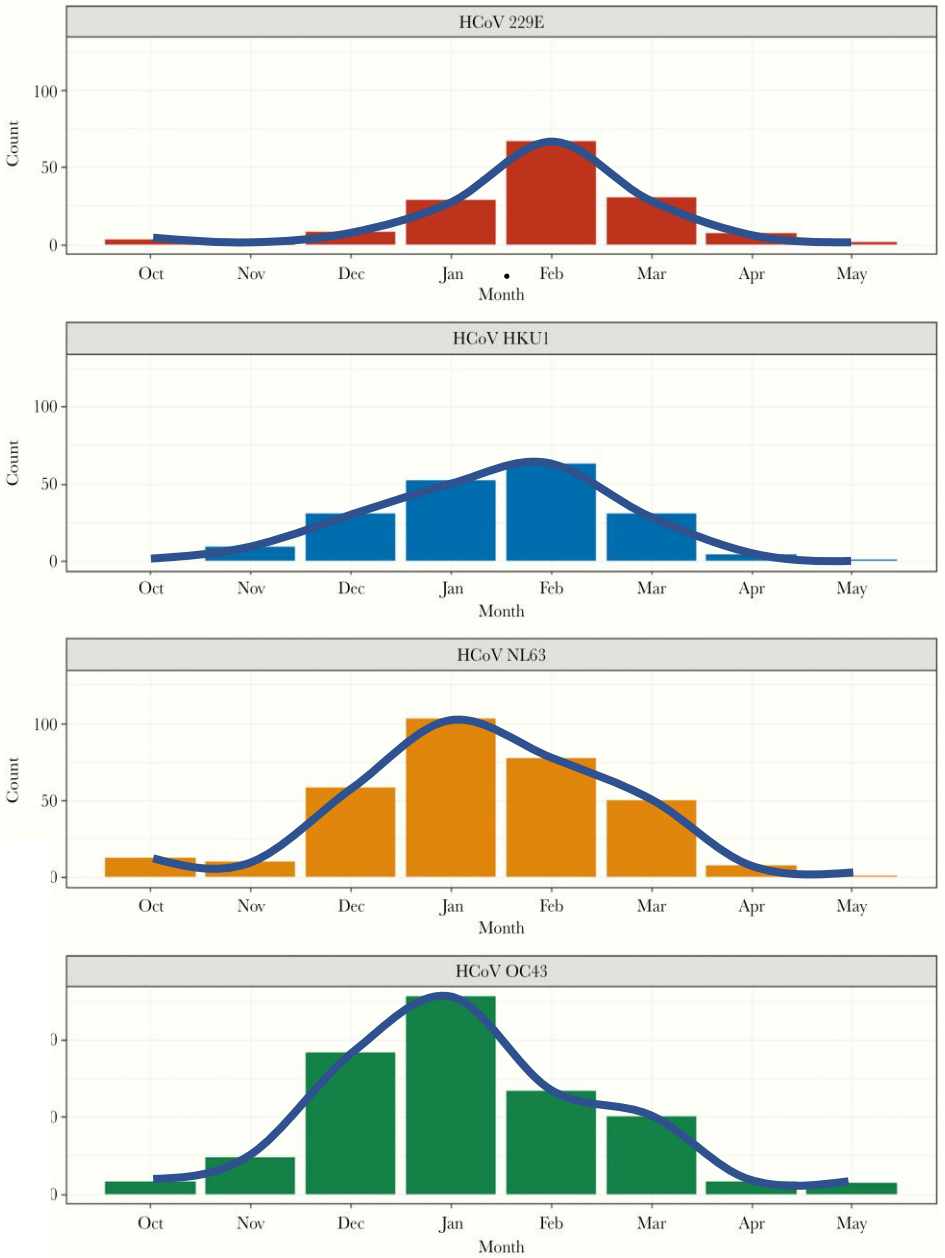
# Kaip išgyvenome **metus**?

**Pirmieji atvejai:**

- Įvežtinis – 2020 vasario 28
- Vietinis – 2020 kovo 18
- Mirtis – 2020 kovo 21
- Pirmoji vakcina – 2020 gruodžio 27


**Kasdieniai infekcijos atvejai. Šaltinis**: Valstybės duomenų valdysenos IS



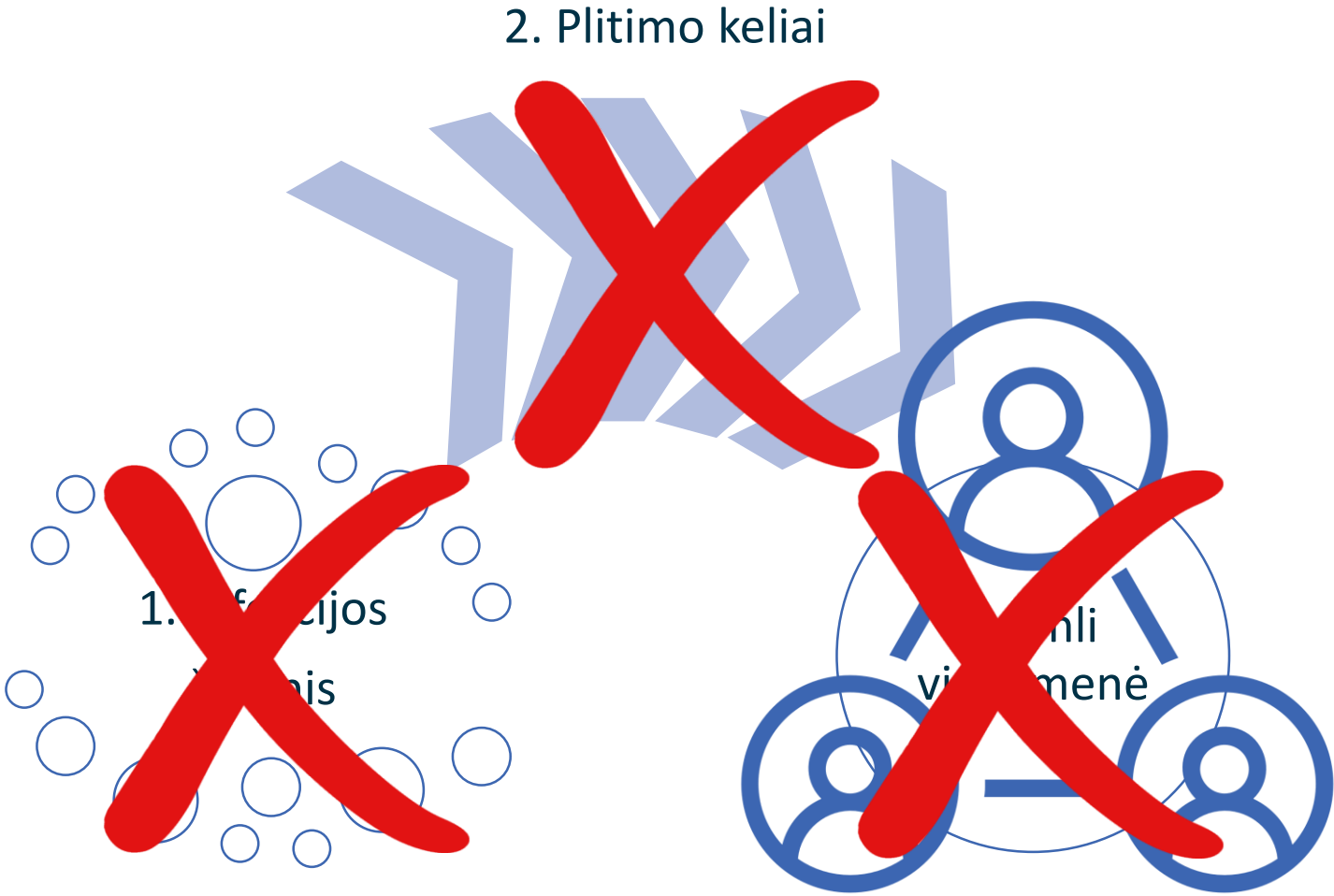



- **Sezoninis svyravimas**
- Plitimas vasarą, besimptomės formos
- Lapkritį didėja sezoninis aktyvumas
- Judėjimo apribojimas sumažino užkrėtimus, bet paveikė visuomenę

**Lietuva – 7 dienų vidurkiai.**
**Šaltinis**: Valstybės duomenų valdysenos IS

**Journal of Infectious Diseases**, Vol. 222, 1, 2020, p. 9–16, https://doi.org/10.1093/infdis/jiaa161

# 02
# Kaip **suvaldyti** epideminį procesą?




** ypač aktualu ruošiantis pokarantininiam grįžimui į darbą*

# Plitimo keliai

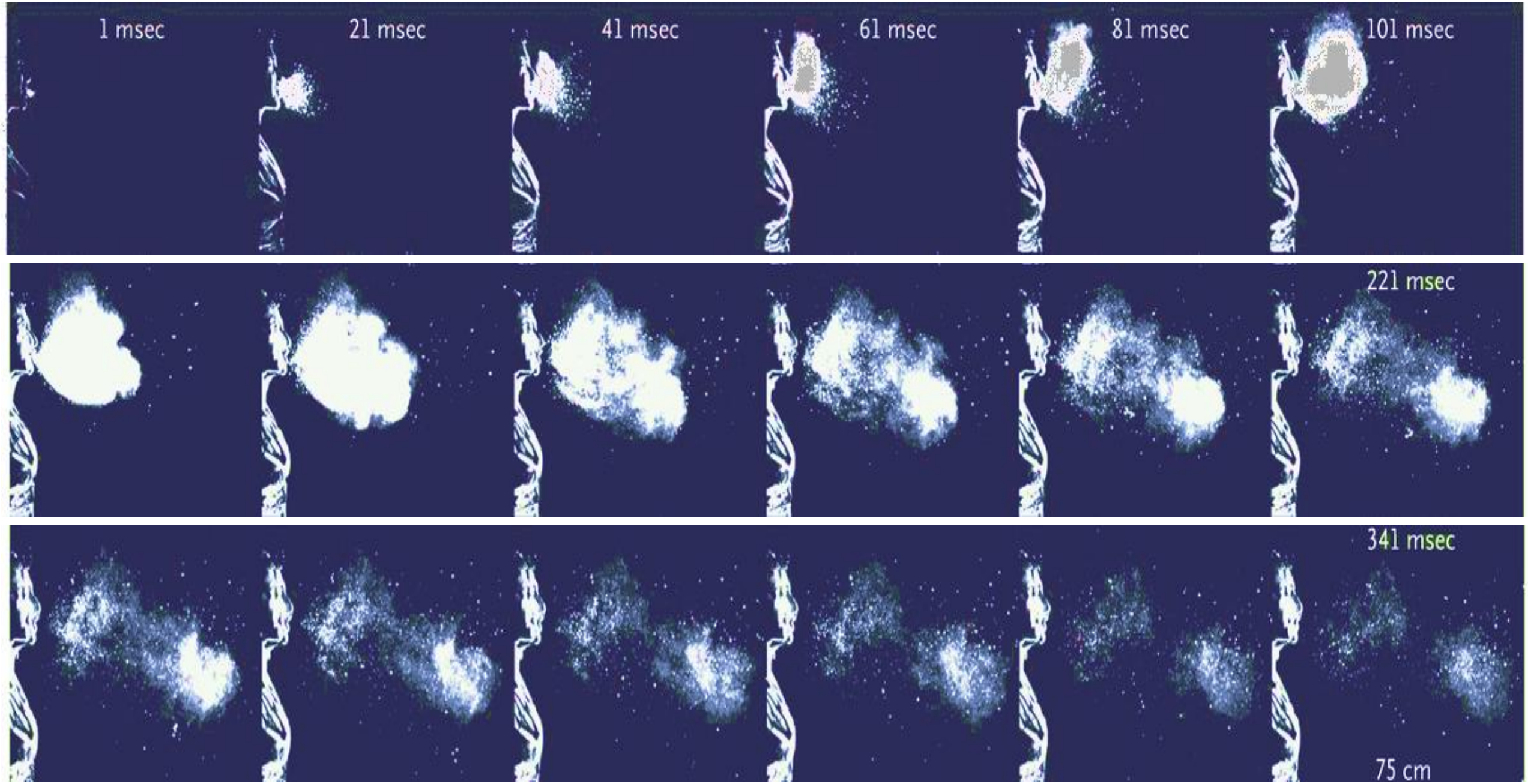
- **Aplinkoje SARS-CoV-2 išsilaiko gana ilgai:**
  - **Aerozoliuose** – iki **3 val.**
  - **Ant kartono** – iki **24 val.**
  - **Ant plastiko, nerūdijančio plieno** paviršių – iki **2-3 d.**, mažėjančiomis koncentracijomis

**Inaktyvavimas**:

**Paviršiai → Alkoholio (~70$^0$) dezinfektantai**

**Uždaros patalpos → HEPA filtrai** ventiliacinėse sistemose

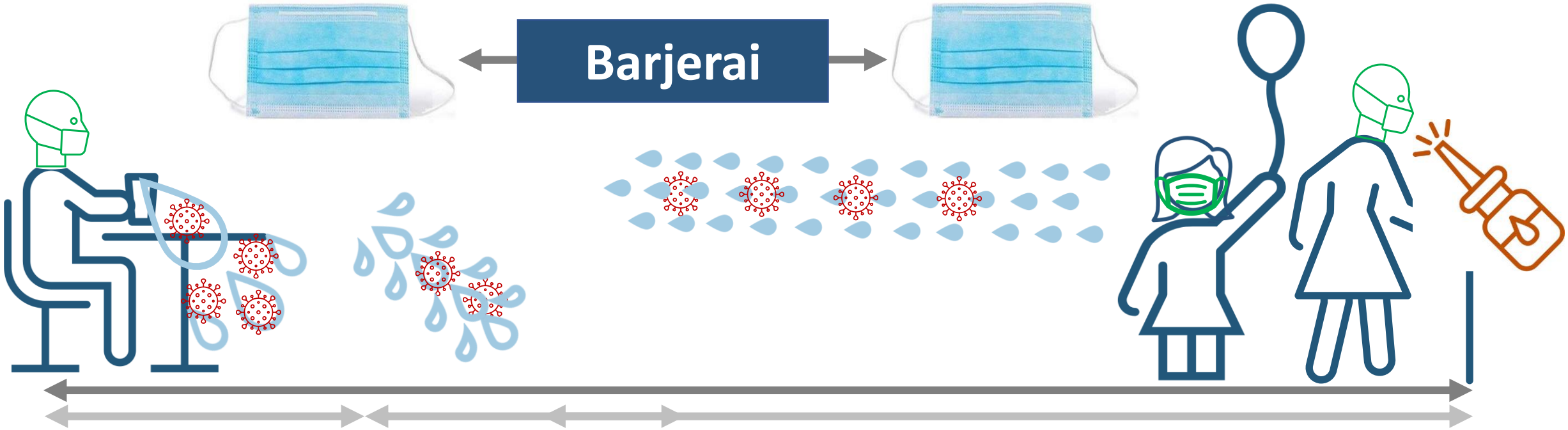
**Audiniai → skalbimas 90$^0$C** su įprastais detergentais




Bourouiba L. N Engl J Med 2016;375:e15.

The NEW ENGLAND JOURNAL of MEDICINE

# Apytikriai infekuojančių lašelių plitimo atstumai




**Iki 1 metro**
Dideli užkrečiami lašeliai

**Iki 2 metrų**
Maži užkrečiami lašeliai

**1.5 iki 48 metrų**
Užkrečiančios dalelės lašeliuose

**Dezinfektantai**

**Ventiliacija**

# 03 Barjerinė profilaktika?

Kaukės, respiratoriai, skydeliai

Nosiaryklės gleivinės drėkinimas

Barjeriniai nosies purškalai

- Biologiškai aktyvūs (pvz. su antivirusine medžiaga *iota-carrageenan*)

**Vokietijos ligoninių higienos draugija** gydytojams, dirbantiems su COVID-19 pacientais, rekomenduoja **barjerinius antivirusinius nosies purškalus, kurių sudėtyje yra medicininio jota-karagenino**.

## Preparatai Europoje


## Moksliniai tyrimai

**Iota-carrageenan neutralizes SARS-CoV-2 and inhibits viral replication in vitro**

PLOS ONE

Martina Morokutti-Kurz, Maria Fröba, Philipp Graf, Maximilian Große, Andreas Grassauer, Janina Auth, Ulrich Schubert, Eva Prieschl-Grassauer

**Iota-carrageenan and Xylitol inhibit SARS-CoV-2 in cell culture**

Shruti Bansal, Colleen B. Jonsson, Shannon L. Taylor, Juan Manuel Figueroa, Andrea Vanesa Dugour, Carlos Palacios, Julio César Vega

**doi:** https://doi.org/10.1101/2020.08.19.225854

bioRχiv
THE PREPRINT SERVER FOR BIOLOGY

**Iota-carrageenan as an antiviral treatment for the common cold**

Eccles, Ronald 2020. Iota-carrageenan as an antiviral treatment for the common cold. *The Open Virology Journal* 14 (9) , pp. 9-15. 10.2174/1874357902014010009

**La eficacia del spray nasal con carragenina para la prevención del COVID-19 ha dado resultados positivos** (IIT; CARR-COV-02, NCT04521322)

CONICET Fundación Pablo Cassará
ICT - MILSTEIN

**IŠVADA**:

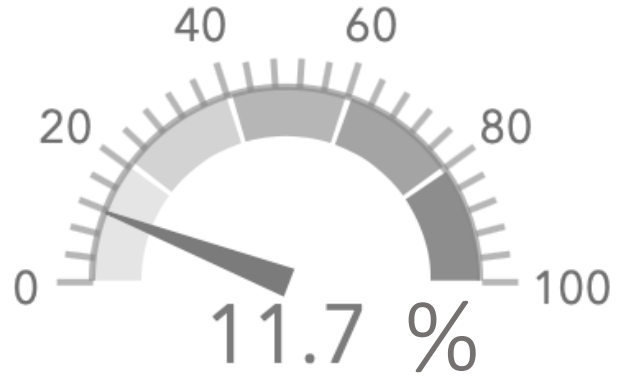
Iki pasiekiant **pandemiją galinčio stabdyti visuomenės imuniteto lygio**, saugų gyvenimą gali sąlygoti **racionaliai taikomi socialinio atstumo ir bendravimo laiko apribojimai,** bei **tinkamas barjerinių priemonių naudojimas**

# 04
# Kiek **dar liko**?

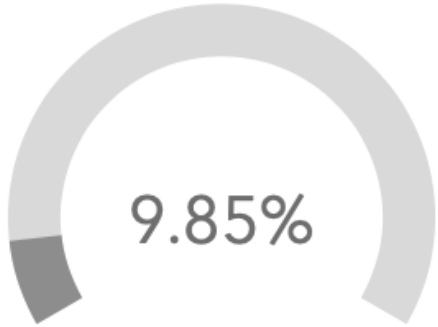
Netrumpas kelias iki visuomenės imuniteto:

- Tik EVA (EMA) registruotos vakcinos
- Skiepijant siekiama asmens apsaugos ir visuomenės imuniteto formavimo
- **Tikslas: 60-70%** visuomenės imuniteto lygis leistų grįžti į (beveik) įprastą gyvenimą

## Galimai imunizuoti (persirgę) gyventojai

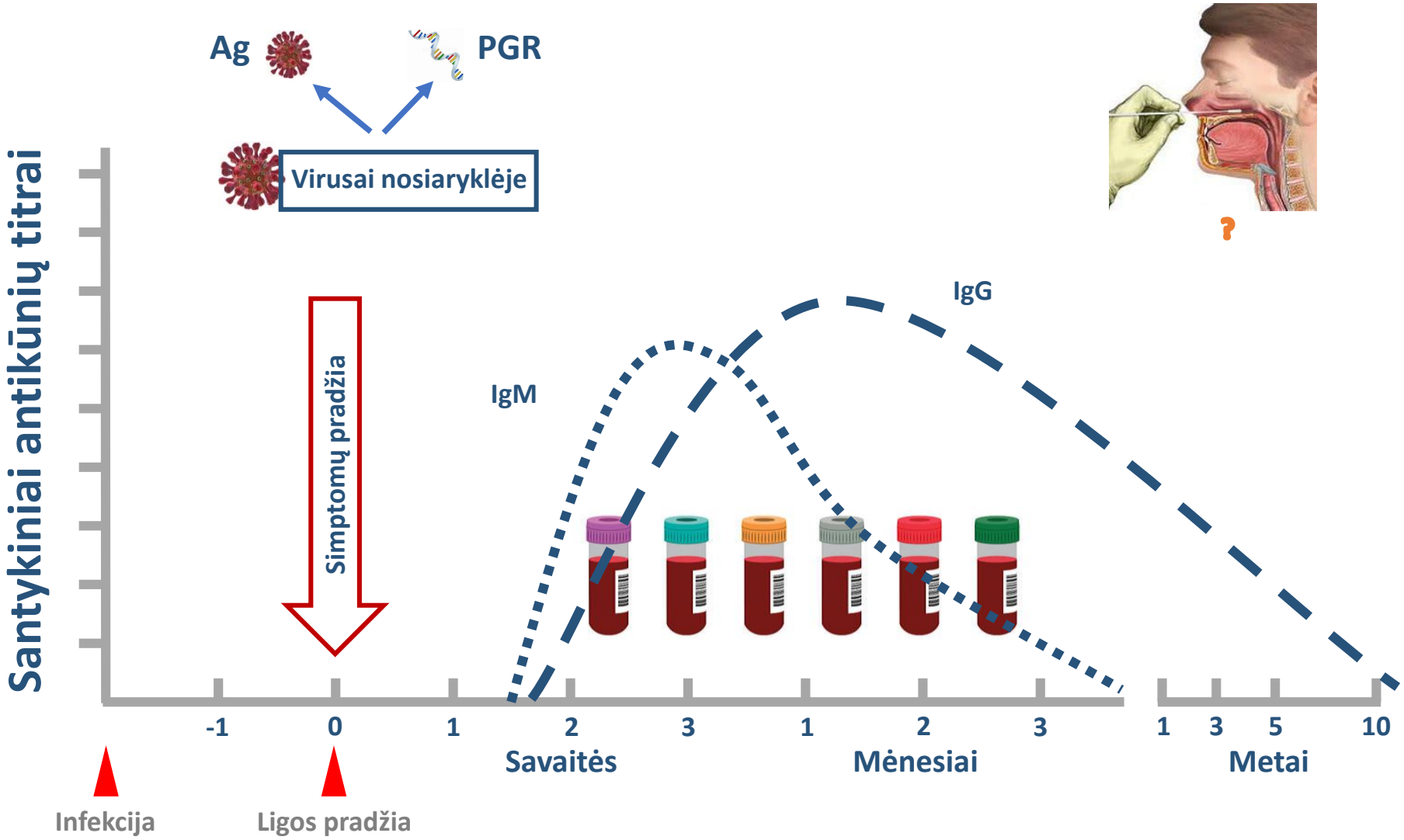



## Gyventojų vakcinavimas

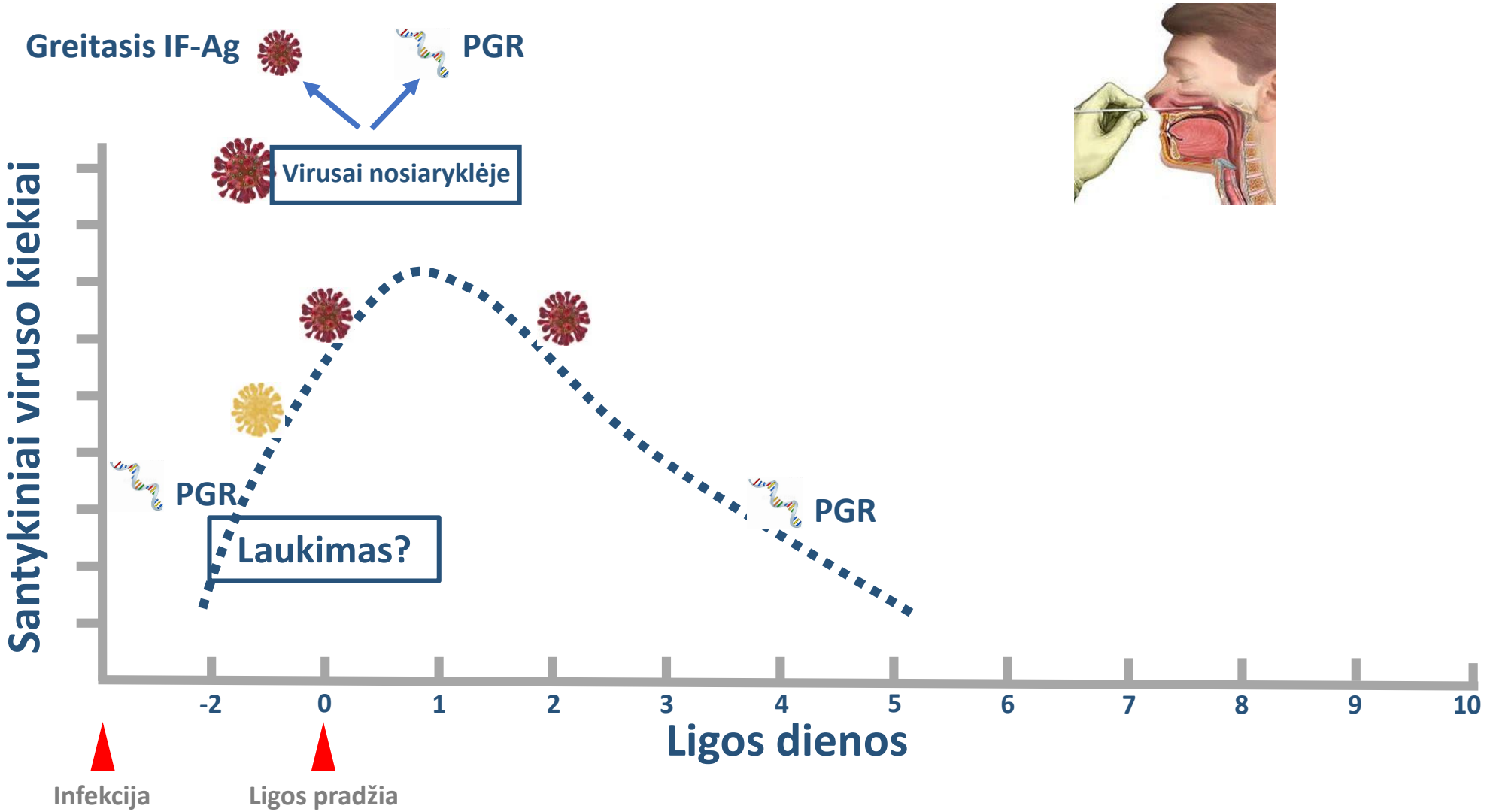



**Šaltinis**: Valstybės duomenų valdysenos IS
Kovo 20 d. duomenys

# Infekcija ir imunitetas

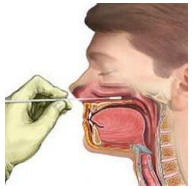


# Virusai nosiaryklėje ir testai



# Kaupinių metodas

## Įprastas PGR tyrimas

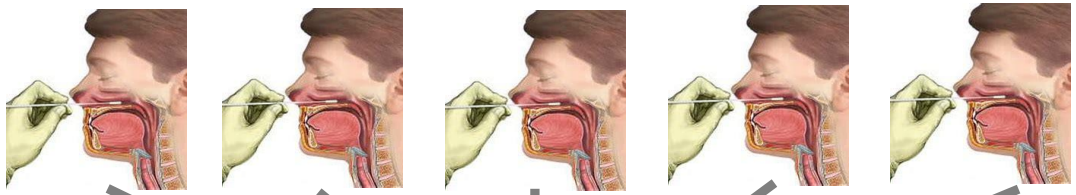


Laboratorija

Atsakymas

Visi bandiniai pakartojami individualiai

## Kaupinių PGR tyrimas



Laboratorija

Atsakymas

Teigiamas

Atsakymas

Neigiamas

Atsakymas visiems

# Šiuolaikinių vakcinų kūrimo etapai

1) **Teoriniai pagrindai, mikrobiologijos imunologijos žinios**
2) **Vakcinos kūrimo platforma**
3) **Ikiklinikiniai tyrimai**
4) **Klinikiniai tyrimai:**
   - I fazė – dešimtys savanorių
   - II fazė – šimtai/tūkstančiai savanorių
   - III fazė – dešimtys tūkstančių savanorių
5) **Vakcinos registravimas**
6) **Vakcinos stebėjimas po registravimo – nepageidaujamų reiškinių registravimo sistemos**

# PSO informacija apie COVID-19 vakcinas

World Health Organization

R&DBlueprint
Powering research to prevent epidemics

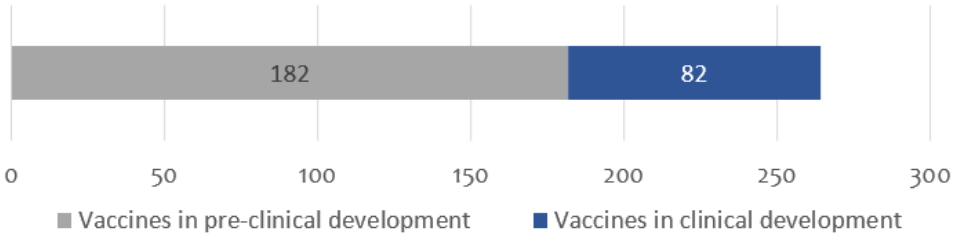
## COVID-19 - Landscape of novel coronavirus candidate vaccine development worldwide

**Tuesday, March 16, 2021**

*DISCLAIMER: These landscape documents have been prepared by the World Health Organization (WHO) for information purposes only concerning the 2019-2020 pandemic of the novel coronavirus. Inclusion of any particular product or entity in any of these landscape documents does not constitute, and shall not be deemed or construed as, any approval or endorsement by WHO of such product or entity (or any of its businesses or activities). While WHO takes reasonable steps to verify the accuracy of the information presented in these landscape documents, WHO does not make any (and hereby disclaims all) representations and warranties regarding the accuracy, completeness, fitness for a particular purpose (including any of the aforementioned purposes), quality, safety, efficacy, merchantability and/or non-infringement of any information provided in these landscape documents and/or of any of the products referenced therein. WHO also disclaims any and all liability or responsibility whatsoever for any death, disability, injury, suffering, loss, damage or other prejudice of any kind that may arise from or in connection with the procurement, distribution or use of any product included in any of these landscape documents.*

### Summary Information on Vaccine Products in Clinical Development

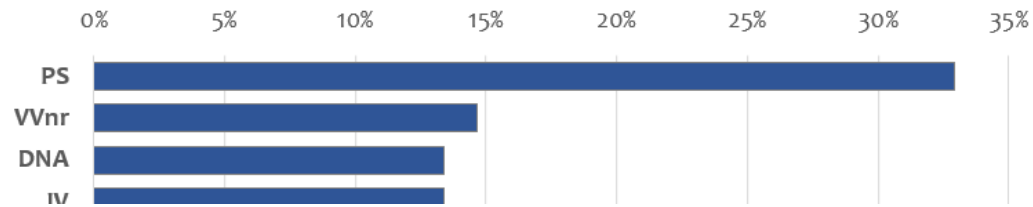
| | |
|---|---|
| 1. - Number of vaccines in clinical development | 82 |
| 2. - Number of vaccines in pre-clinical development | 182 |




### 3. - Candidates in clinical phase

| Filter | All | Select phase of development (default is all) |
|---|---|---|

| Platform | | Candidate vaccines (no. and %) | |
|---|---|---|---|
| PS | Protein subunit | 27 | 33% |
| VVnr | Viral Vector (non-replicating) | 12 | 15% |




https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

# Vakcinų prieš COVID-19 registravimas PSO 2021-01-20 duomenimis

| | Manufacturer | Name of Vaccine | NRA of Record | Platform | EOI accepted | Pre-submission meeting held | Dossier accepted for review* | Status of assessment** | Anticipated decision date*** |
|---|---|---|---|---|---|---|---|---|---|
| 1. | Pfizer BioNTech | BNT162b2/COMIRNATY (INN tozinameran) | EMA | Nucleoside modified mNRA | ✓ | ✓ | ✓ | Finalized | 31/12/20 |
| 2. | Zhifei Longcom, China | Recombinant Novel Coronavirus Vaccine (CHO Cell) | NMPA | Recombinant protein subunit | Not accepted Product in Phase I/II | | | | |
| 3. | IMBCAMS, China | SARS-CoV-2 Vaccine, Inactivated (Vero Cell) | NMPA | Inactivated | Not accepted, still under development | | | | |
| 4. | AstraZeneca / University of Oxford | AZD1222 | Core – EMA Non-COVAX | recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein | ✓ | ✓ | ✓ | In progress Core data Non-Covax.<br><br>Covax data to be reviewed as EMA post approval change | Earliest by EMA End of Jan-Feb 2021 (non- Covax)<br><br>Additional nodes in March/ April for Covax |
| 5. | SK BIO AstraZeneca / University of Oxford | AZD1222 | MFDS KOREA | = | ✓ | ✓ | Tentative 18 and 29 Jan 2021 (CMC for SK Bio) | Core data (non-Covax) in progress | Earliest 2nd half Feb 2021 |
| 6. | janssen Infectious Diseases & Vaccines | Ad26.COV2.S | EMA | recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein | ✓ | ✓ | Rolling data to EMA: Dec, Feb, Apr (critical data), May ✓ | Not yet started.<br><br>Use abridged procedure relying on EMA | Earliest May – June 2021 |
| 7. | Sinopharm / BIBP[2] | SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) | NMPA | Inactivated, produced in Vero cells | ✓ | ✓ | End of Dec 2020 | In progress | Earliest March |
| 8. | sinovac | SARS-CoV-2 Vaccine (Vero Cell), Inactivated | NMPA | Inactivated, produced in Vero cells | ✓ | ✓ | 13Jan2021 (under screening) | | Earliest March |
| 9. | The Gamaleya National Center | Sputnik V | Russian NRA | Human Adenovirus Vector-based Covid-19 vaccine | Additional information submitted – under assessment | ✓ | 22Jan2021 discussion on content and format | | |
| 10. | Vector State Research Centre of Virology and Biotechnology | EpiVacCorona | Russian NRA | Peptide antigen | Letter received not EOI | | | | |
| 11. | 康希诺生物 CanSinoBIO | Ad5-nCoV | | Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) | Additional information requested | 26Jan 2021 | | | |
| 12. | moderna | mRNA-1273 | EMA | mNRA-based vaccine encapsulated in lipid nanoparticle (LNP) | Expected in Feb 2021 | | | | Estimated end of Feb 2021 |
| 13. | Serum Institute of India | Covishield (ChAdOx1_nCoV-19) | DCGI | recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2 | ✓ | 08Jan 2021 | 13 Jan (Under screening) | | Mid Feb 2021 |
| 14. | Sinopharm / WIBP[1] | | NMPA | No pre-submission meeting yet | | | | | |
| 15. | NOVAVAX | | EMA | No pre-submission meeting yet | | | | | |

* Dossier Submission dates: more than one date is possible because of the rolling submission. Dossier is accepted for submission after screening of received submission
** Status of assessment: 1. Under screening; 2. Under assessment; 3. Waiting responses from the applicant. 4. Risk-benefit decision 5. Final decision made
*** Anticipated decision date: this is only an estimate because it depends on when all the data is submitted under rolling submission and when all the responses to the assessors' questions are submitted.
1. Wuhan Institute of Biological Products Co Ltd
2. Beijing Bio-Institute of Biological Products Co-Ltd

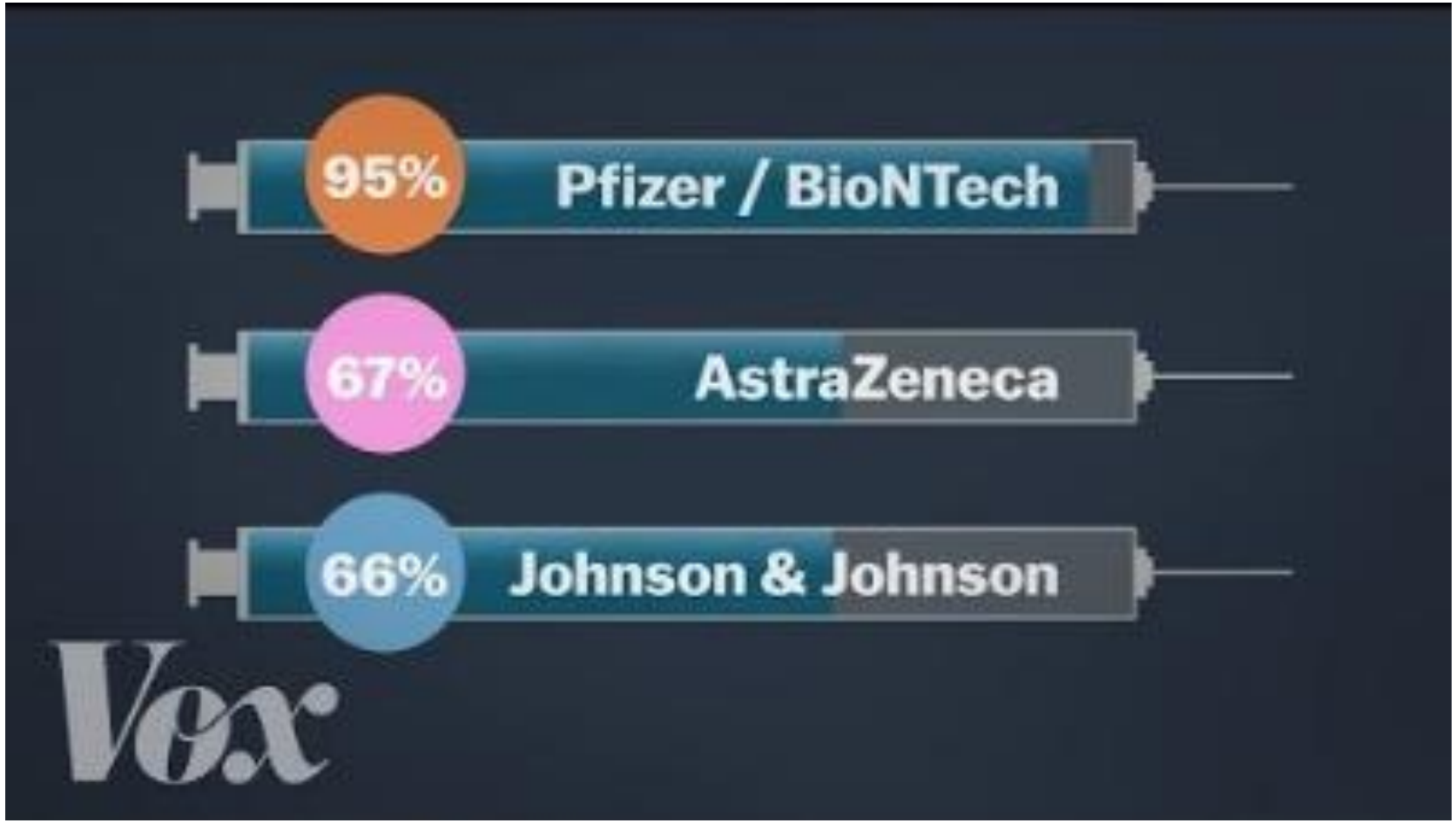
Status_COVID_VAX_20Jan2021_v2.pdf (who.int)

# Dėkui už dėmesį.

# Ar turite klausimų?

vytautas.usonis@mf.vu.lt
http://vytautas.usonis.lt

# Vox: Kodėl negalima lyginti vakcinų




https://youtu.be/K3odScka55A