

INCLUSÃO DOS IMUNIZANTES CONTRA O SARS CoV-2 NO PNI

CAIO ROBERTO SALVINO

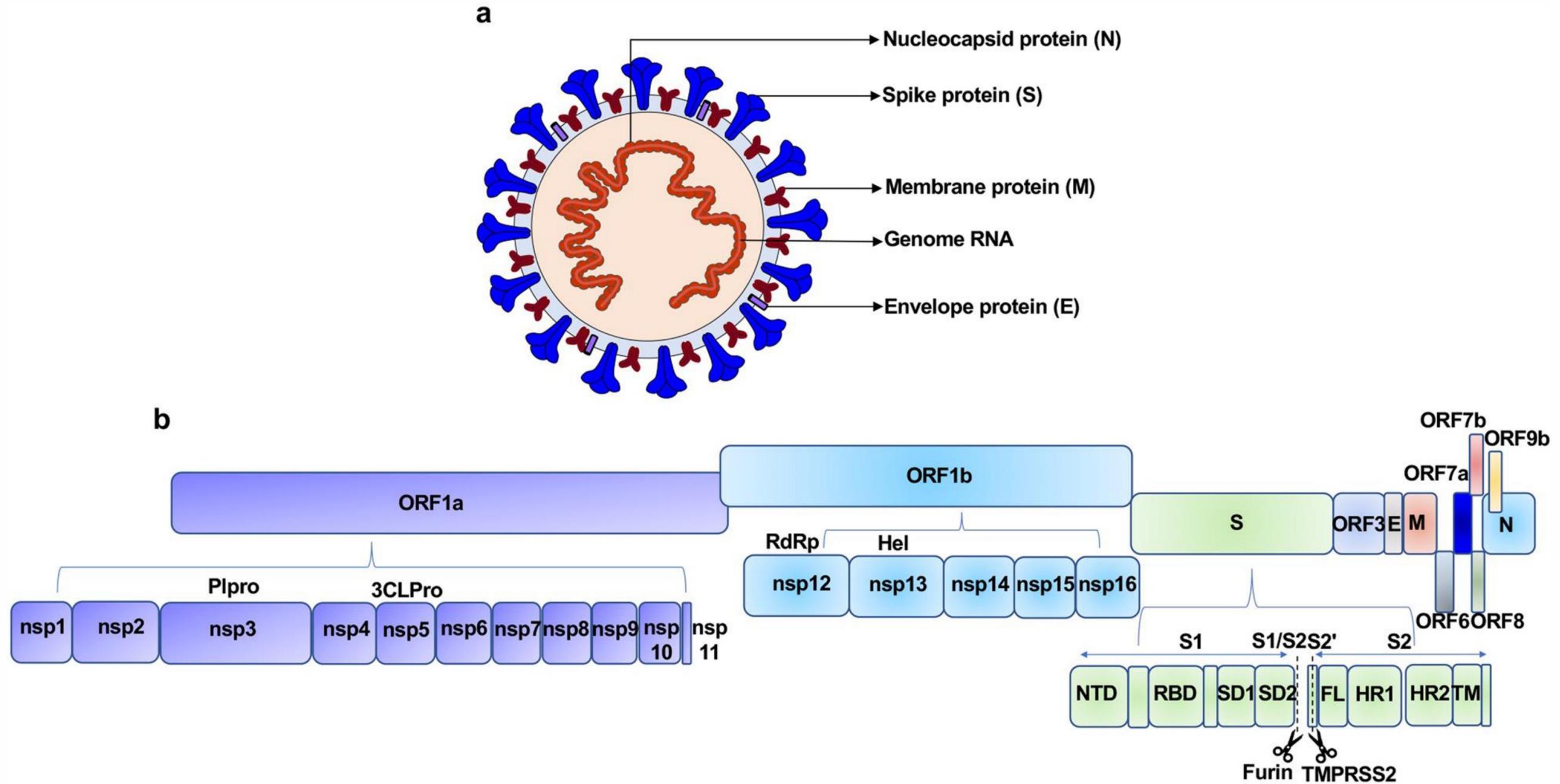
CONFLITOS DE INTERESSES

- Declaro não haver conflitos de interesses de minha parte.
- Declaro não ser contrário ao uso de vacinas constantes no PNI
- Declaro não concordar que o imunizante de mRNA seja uma vacina no conceito clássico

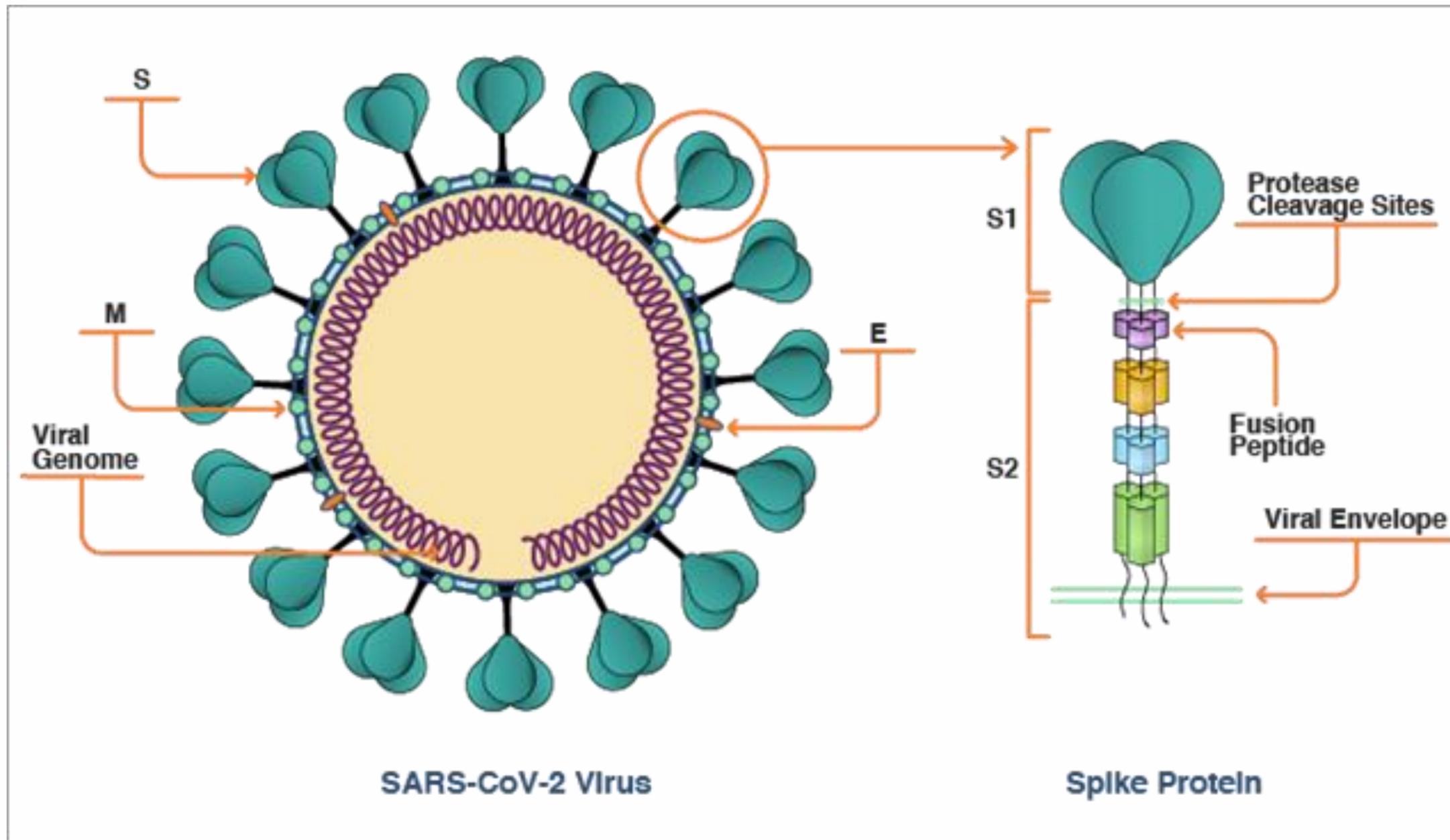
SEQUÊNCIA DA APRESENTAÇÃO

1. O vírus SARS CoV-2
2. mRNA imunizante monovalente e mRNA imunizante bivalente
3. GenomaHCoV Fiocruz - Dashboard
4. Monitoramento de resposta imunológica apenas baseado na atividade de anticorpos neutralizantes – verdades paralelas
5. Gráficos e Dados
 - a. Curva de casos de c-19 Brasil
 - b. Curva de imunização contra c-19 Brasil
 - c. Sobreposição e comparação Brasil/EUA
 - d. Dados UNICEF
 - e. Dados Portal Transparência Registro Civil
 - f. Dados MS
6. Estudo de Hong Kong
7. Estudo Cleveland Clinic
8. Considerações finais

I. O VÍRUS SARS CoV-2



I . O VÍRUS SARS CoV-2 – PROTEÍNA SPIKE



2. MRNA COMPOSIÇÕES IMUNIZANTES*



Comirnaty®
vacina covid-19

I - IDENTIFICAÇÃO DO MEDICAMENTO

Nome comercial: Comirnaty®
Nome genérico: vacina covid-19

APRESENTAÇÕES

Comirnaty® (diluir antes de usar) para idades acima de 12 anos 30 mcg/dose: cada frasco contém 0,45 mL de suspensão injetável concentrada (6 doses/frasco) em embalagens com 195 frascos com tampa roxa.

Comirnaty® (diluir antes de usar) para crianças de 5 a 11 anos de idade (ou seja, 5 a menos de 12 anos de idade) 10 mcg/dose: cada frasco contém 1,3 mL de suspensão injetável concentrada (10 doses/frasco) em embalagens com 10 frascos com tampa laranja.

Comirnaty® (diluir antes de usar) para idades entre 6 meses e menos de 5 anos 3 mcg/dose: cada frasco contém 0,4 mL de suspensão injetável concentrada (10 doses/frasco) em embalagens com 10 frascos com tampa de cor vinho.

VIA DE ADMINISTRAÇÃO: USO INTRAMUSCULAR

USO ADULTO E PEDIÁTRICO (A PARTIR DE 6 MESES DE IDADE)

COMPOSIÇÃO

Comirnaty® (diluir antes de usar) para pessoas com 12 anos de idade ou mais, tampa roxa:

Cada dose da vacina diluída (0,3 mL) contém:

vacina covid-19*30 mcg
Excipientes** q.s.p.

*Comirnaty® é composto de RNA mensageiro (mRNA) de cadeia simples, embebido em nanopartículas lipídicas, com estrutura 5-cap altamente purificado, produzido usando transcrição *in vitro* sem células a partir dos modelos de DNA correspondentes, codificando a proteína S (spike) do coronavírus 2 vírus da síndrome respiratória aguda grave (SARS-CoV-2) (Original).

**Excipientes: di-hexildecanoato de di-hexilaminobutanol, ditetradecilmetoxipolietilenoglicolacetamida, levoalfosfatidilcolina distearoila, colesterol, sacarose, cloreto de sódio, cloreto de potássio, fosfato de sódio

VIA DE ADMINISTRAÇÃO: USO INTRAMUSCULAR



USO ADULTO E PEDIÁTRICO (A PARTIR DE 6 MESES DE IDADE)

COMPOSIÇÃO

Comirnaty® (diluir antes de usar) para pessoas com 12 anos de idade ou mais, tampa roxa:

Cada dose da vacina diluída (0,3 mL) contém:

vacina covid-19*30 mcg
Excipientes** q.s.p.

*Comirnaty® é composto de RNA mensageiro (mRNA) de cadeia simples, embebido em nanopartículas lipídicas, com estrutura 5-cap altamente purificado, produzido usando transcrição *in vitro* sem células a partir dos modelos de DNA correspondentes, codificando a proteína S (spike) do coronavírus 2 vírus da síndrome respiratória aguda grave (SARS-CoV-2) (Original).



“(...) proteína S (spike) do (...) ORIGINAL”

chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.pfizer.com.br/files/Comirnaty_Profissional_de_Saude_54.pdf



2. MRNA COMPOSIÇÕES IMUNIZANTES*



Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5)
vacina covid-19 bivalente

I - IDENTIFICAÇÃO DO MEDICAMENTO

Nome comercial: Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5)

Nome genérico: vacina covid-19 bivalente

APRESENTAÇÕES

Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5) (não diluir) 15/15 mcg por dose para pessoas com 12 anos de idade ou mais: cada frasco contém uma dose de 0,3 mL de suspensão injetável diluída (dose única) em embalagens com 10 frascos com tampa cinza.

VIA DE ADMINISTRAÇÃO: USO INTRAMUSCULAR

USO ADULTO E PEDIÁTRICO (A PARTIR DE 12 ANOS DE IDADE)

COMPOSIÇÃO

Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5) para pessoas com 12 anos de idade ou mais, tampa cinza:

Cada dose da vacina (15/15 mcg) contém:

vacina covid-19 cepa Original* 15 mcg

vacina covid-19 cepa Ômicron BA.4/BA.5* 15 mcg

*Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5) é composto de RNA mensageiro (mRNA) de cadeia simples, com estrutura 5-cap altamente purificado, produzido usando transcrição *in vitro* sem células a partir de modelos de DNA correspondentes, codificando a proteína S (spike) do coronavírus 2 da síndrome respiratória aguda grave (SARS-CoV-2) (Original e Ômicron BA.4/BA.5).

VIA DE ADMINISTRAÇÃO: USO INTRAMUSCULAR



USO ADULTO E PEDIÁTRICO (A PARTIR DE 12 ANOS DE IDADE)

COMPOSIÇÃO

Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5) para pessoas com 12 anos de idade ou mais, tampa cinza:

Cada dose da vacina (15/15 mcg) contém:

vacina covid-19 cepa Original* 15 mcg

vacina covid-19 cepa Ômicron BA.4/BA.5* 15 mcg

*Comirnaty® Bivalente (Original + Ômicron BA.4/BA.5) é composto de RNA mensageiro (mRNA) de cadeia simples, com estrutura 5-cap altamente purificado, produzido usando transcrição *in vitro* sem células a partir dos modelos de DNA correspondentes, codificando a proteína S (spike) do coronavírus 2 da síndrome respiratória aguda grave (SARS-CoV-2) (Original e Ômicron BA.4/BA.5).

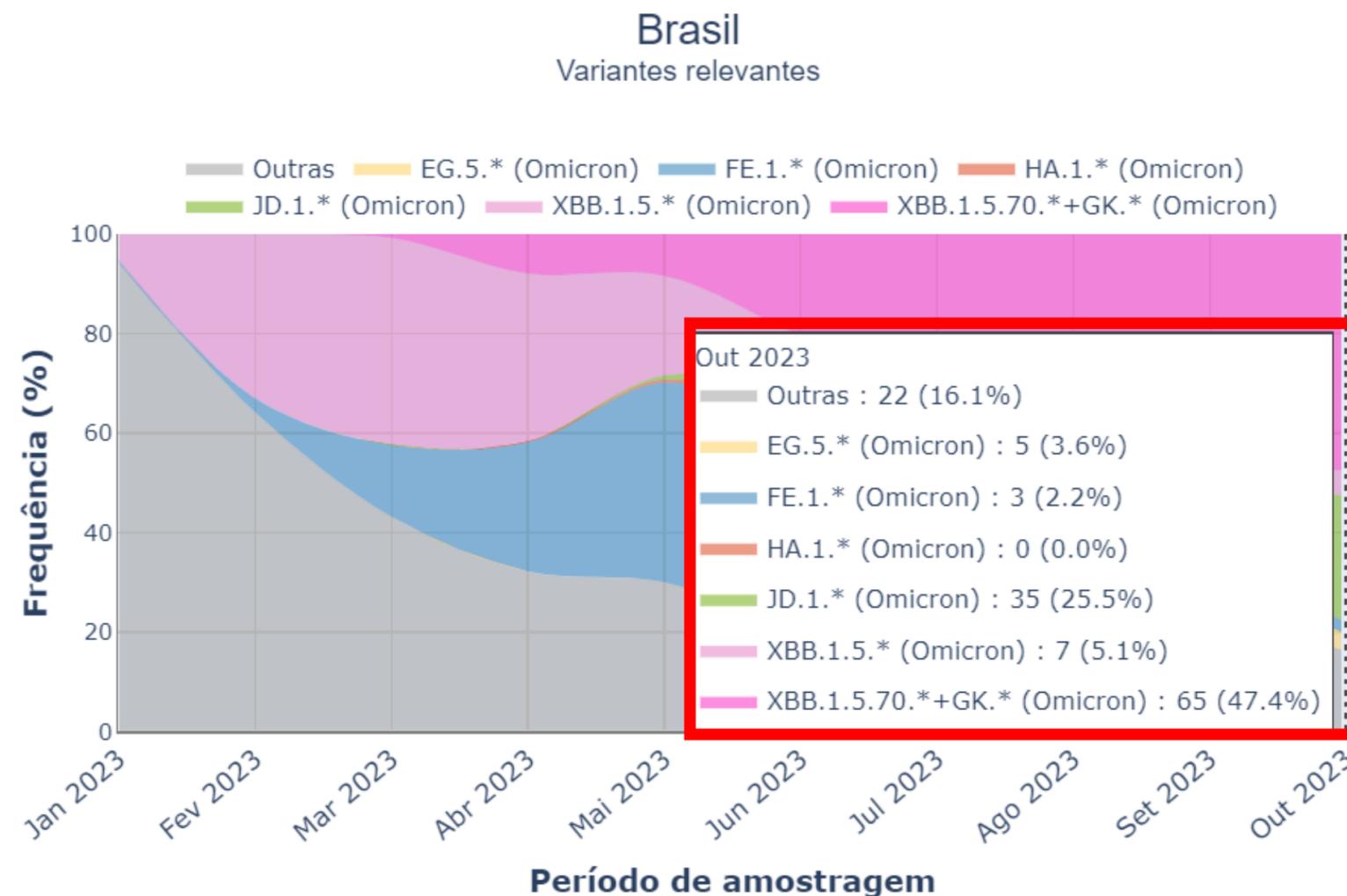
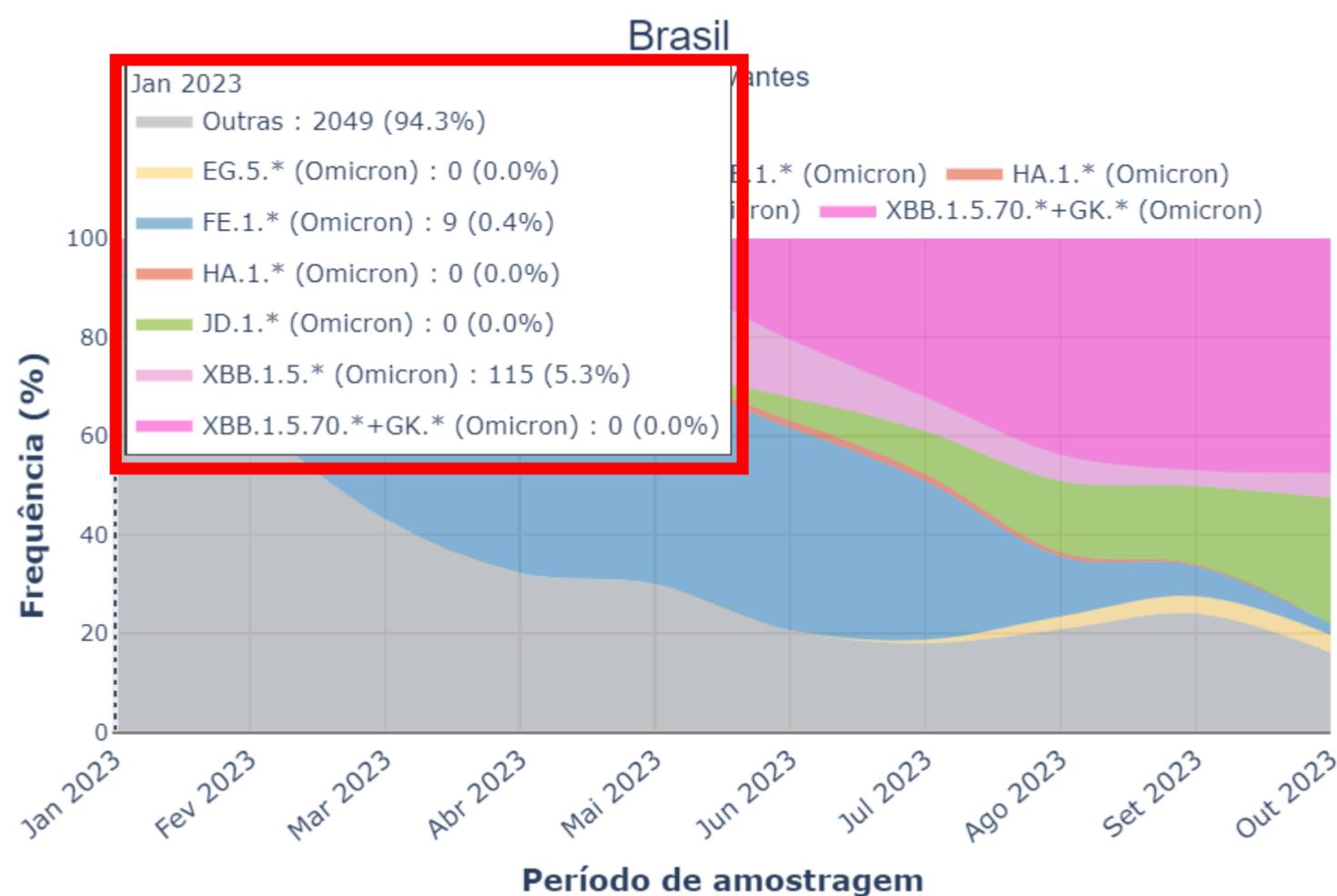
“(...) proteína S (spike) do (...) ORIGINAL E Ômicron BA.4 /BA.5”

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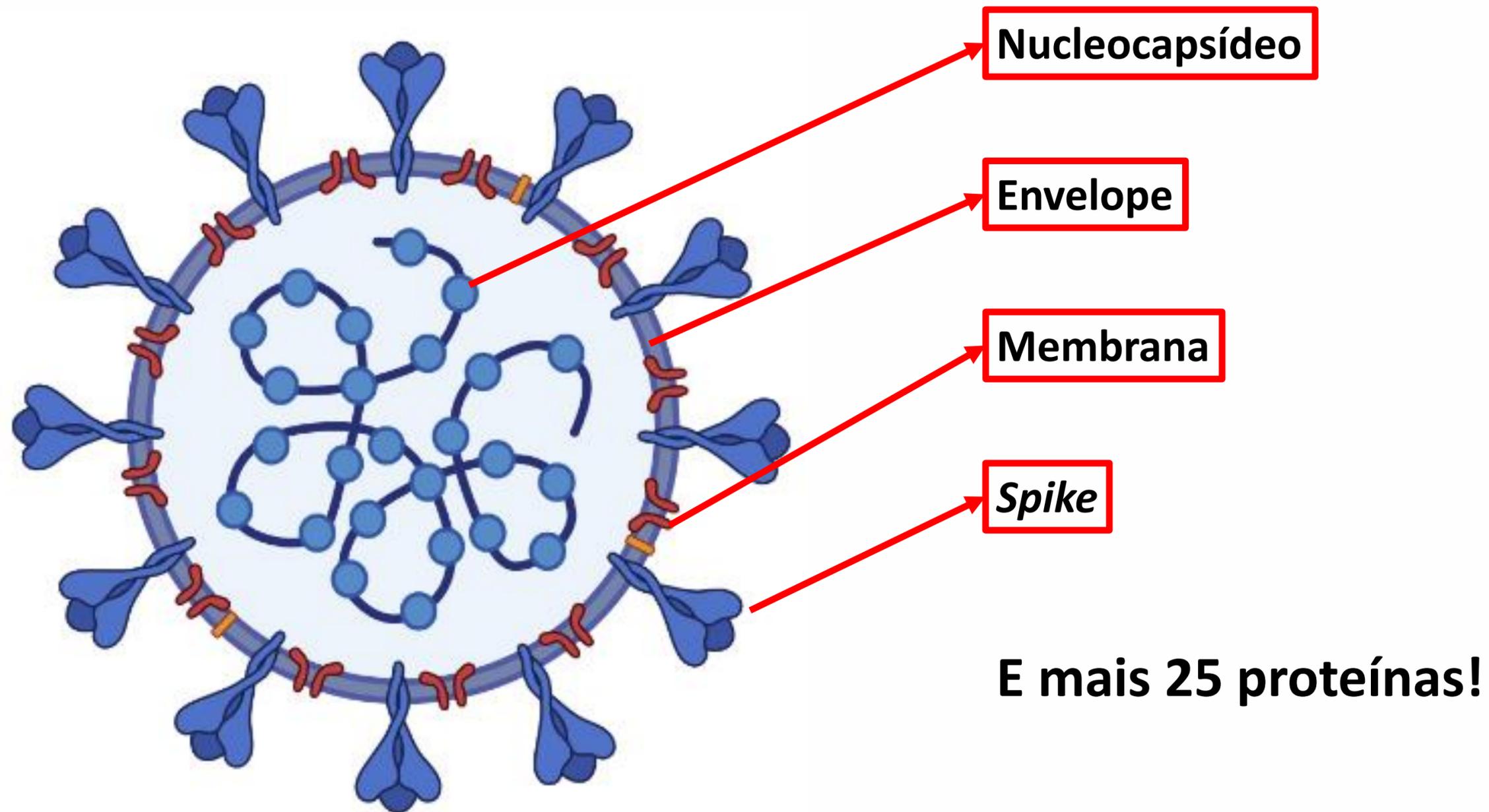
extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.pfizer.com.br/files/Comirnaty_Bivalente_BA4_BA5_Profissional_de_Saude_12.pdf

3. GENOMAHCoV FIOCRUZ – DASHBOARD*

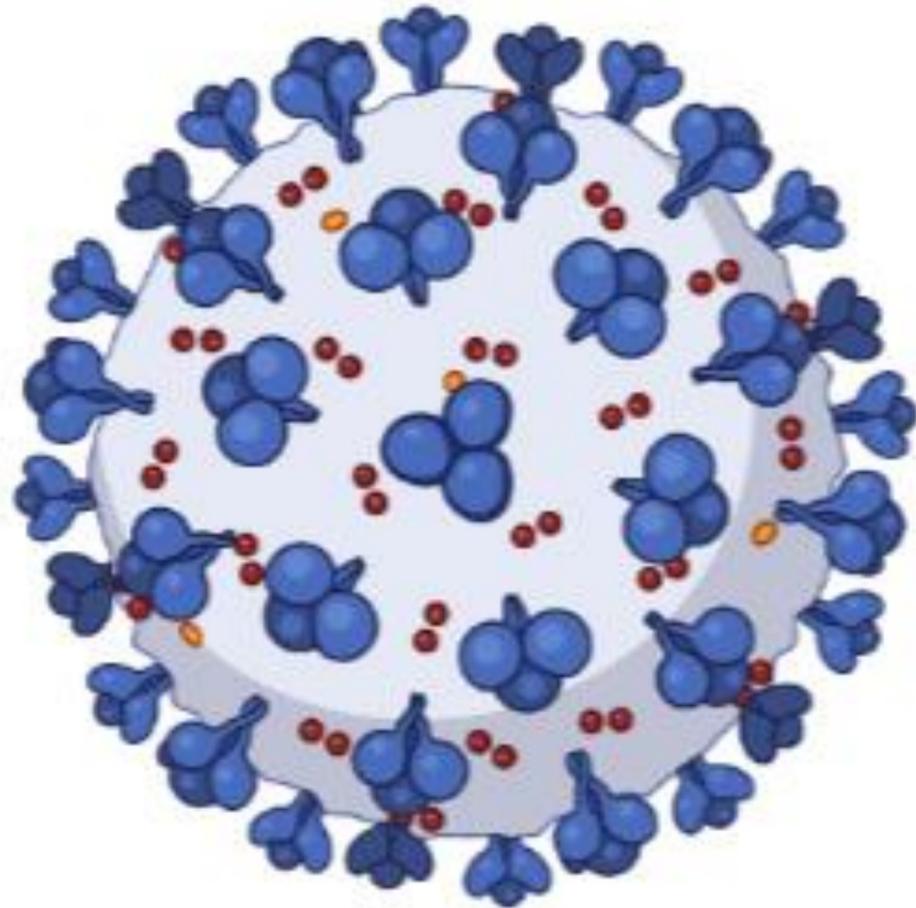
*Atualizado em 06/11/2023



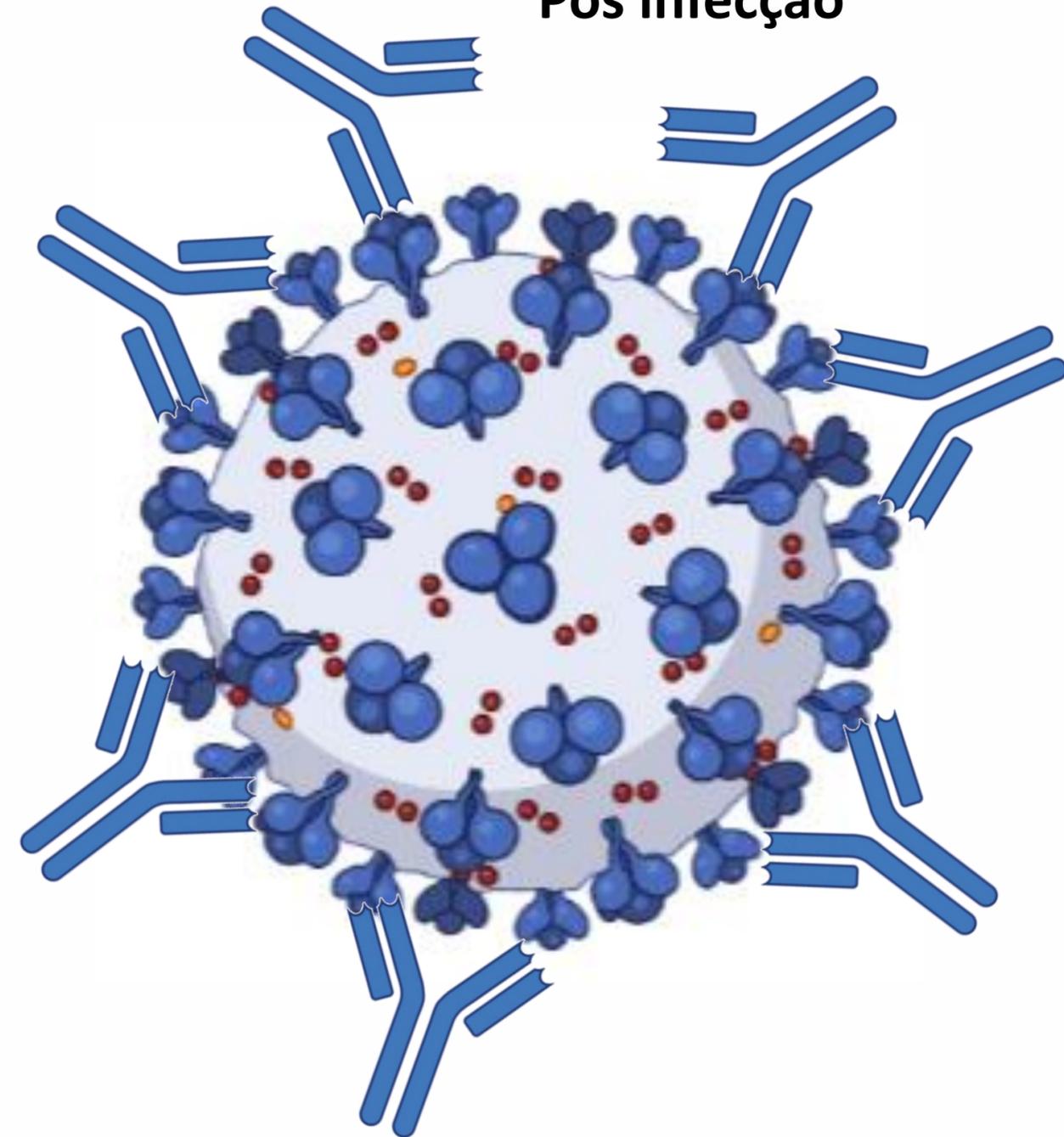
4. MONITORAMENTO POR NAB



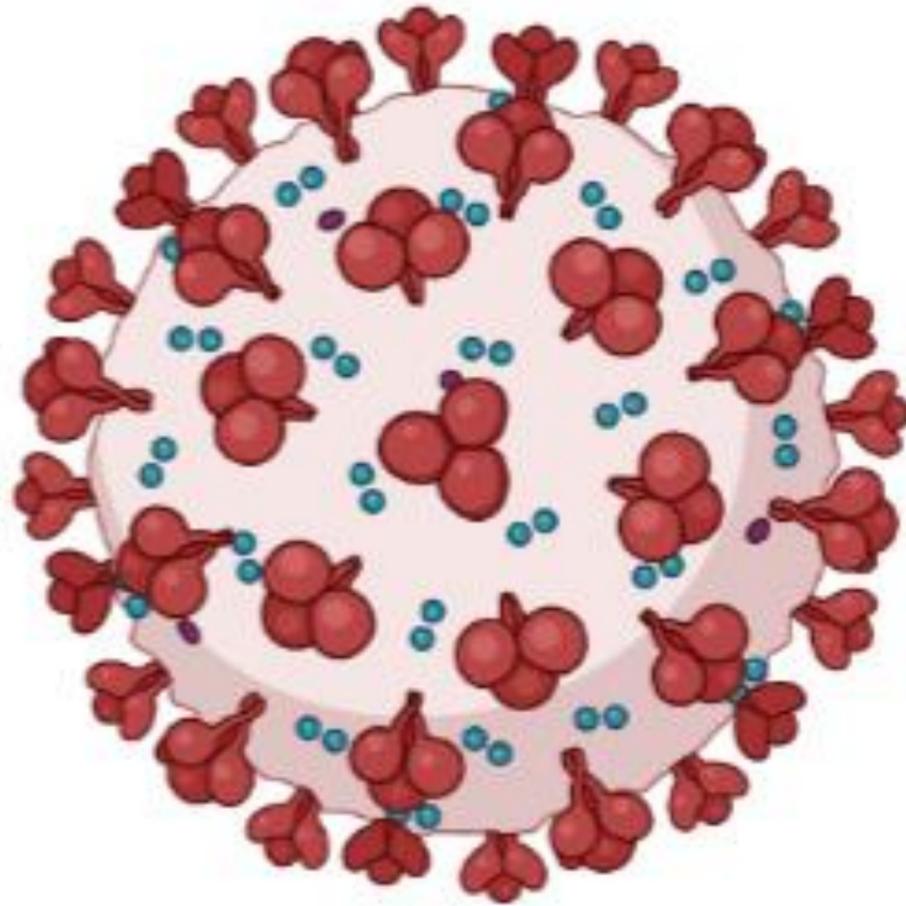
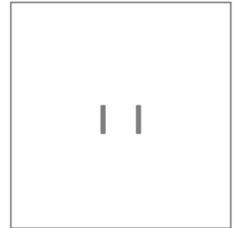
**Anticorpos anti RBD
SARS CoV-2 Wuhan
Pós infecção**



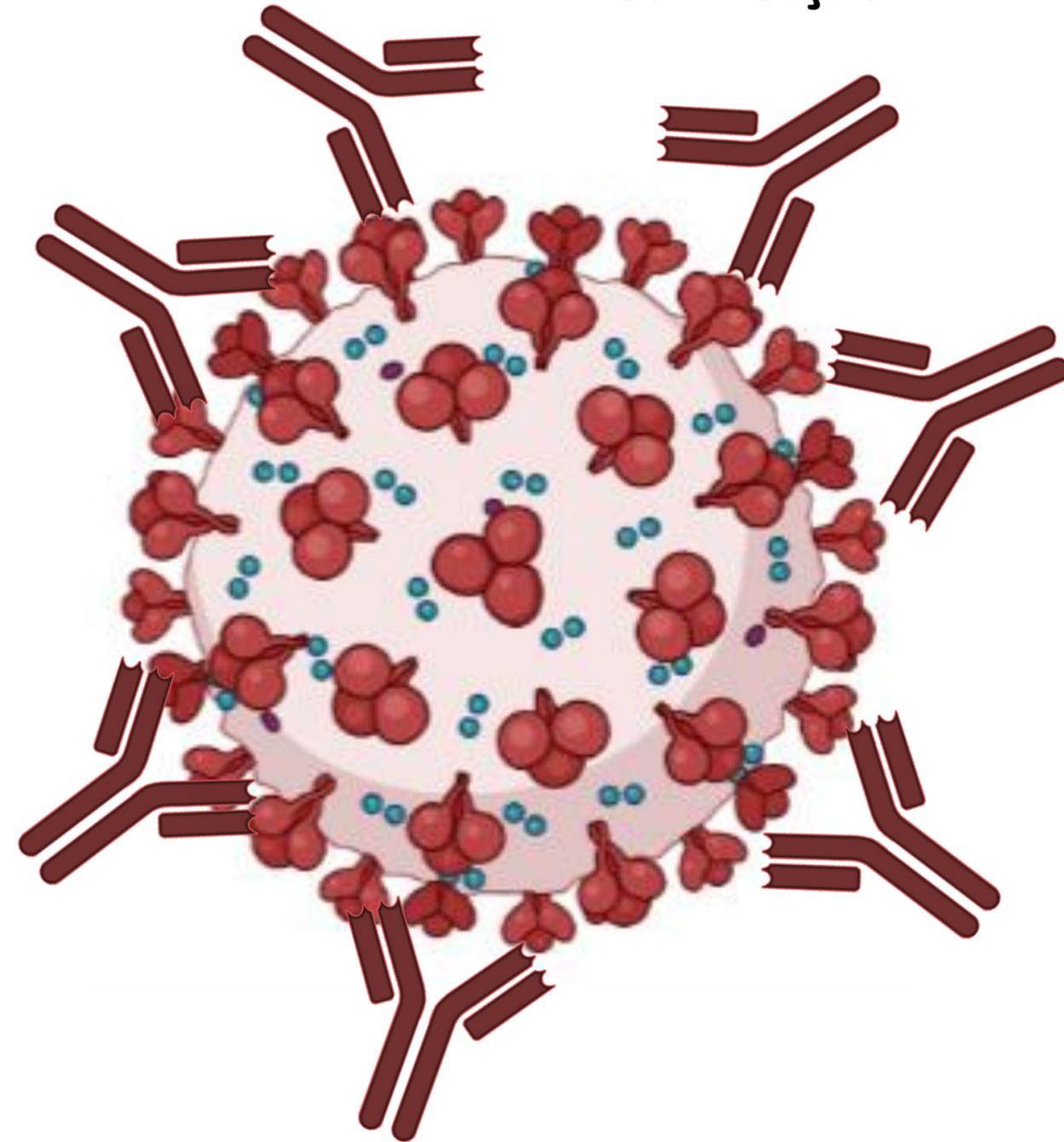
**Infecção por
SARS CoV-2 Wuhan**

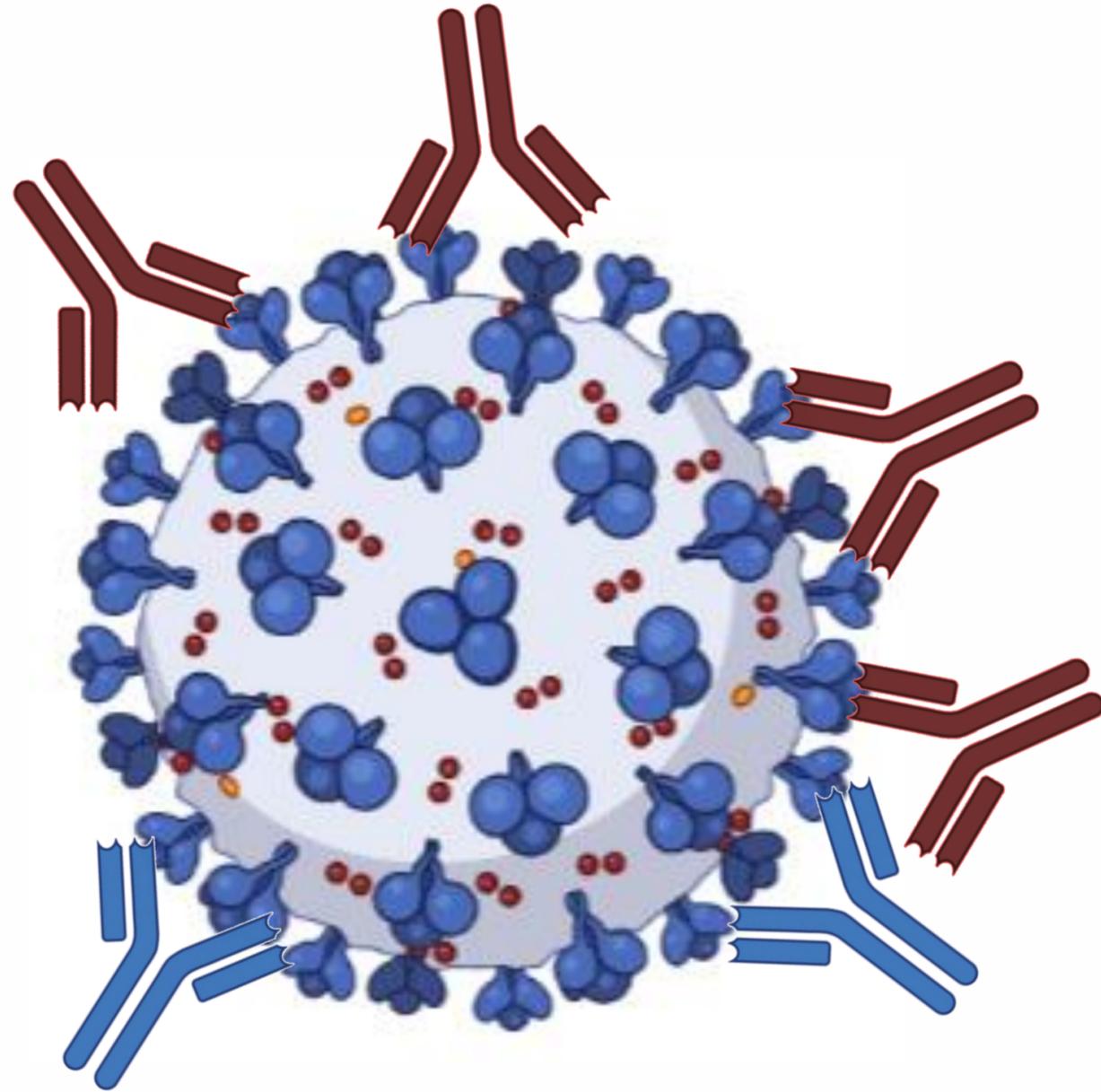


**Anticorpos anti RBD
SARS CoV-2 Omicron BA.1
Pós infecção**

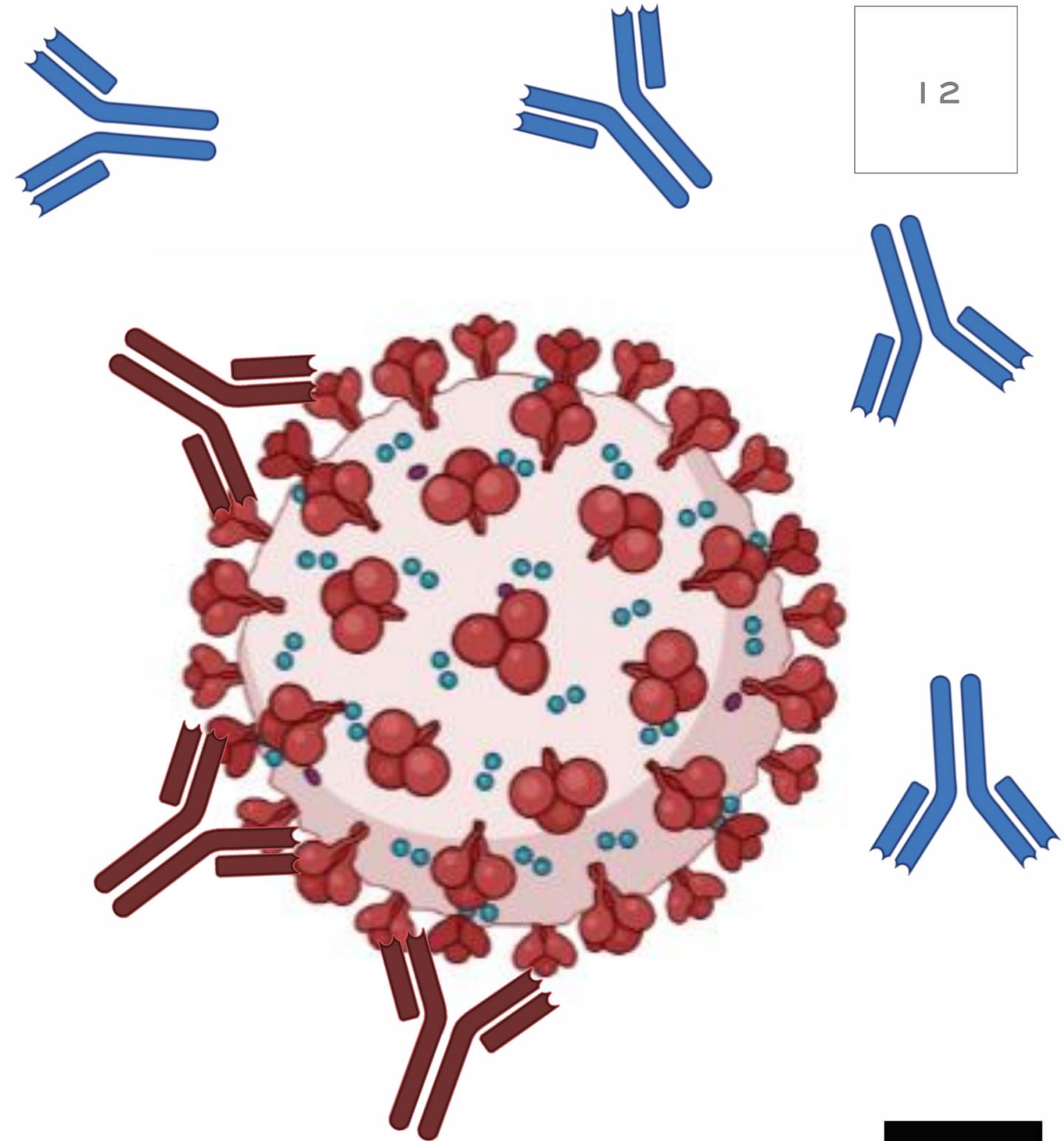


**Infecção por
SARS CoV-2 Omicron BA.1**





SARS CoC-2 Wuhan



SARS CoC-2 omicron

12



Nanopartícula lipídica
Contendo mRNA → codifica spike
SARS CoV-2 Wuhan

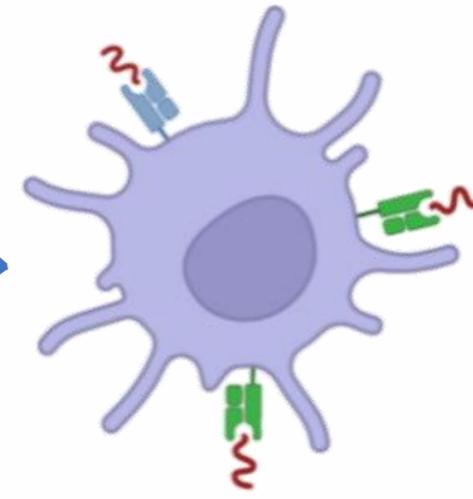
INJEÇÃO



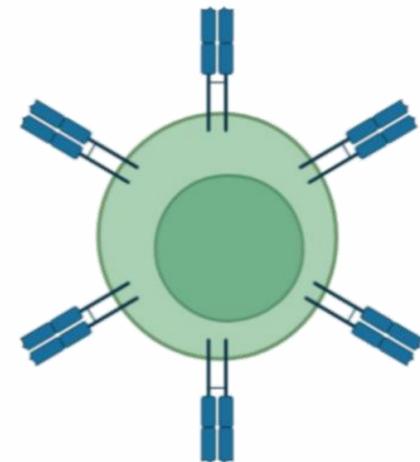
SPIKE

Célula humana
produz Spike

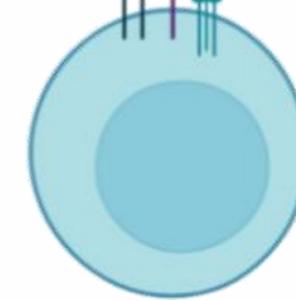
Célula Dendrítica



Linfócito T CD8+



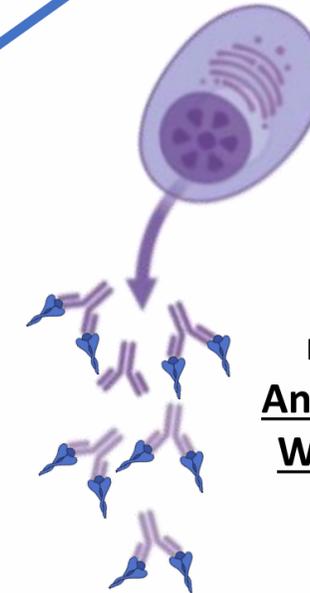
Linfócito T CD4+



Linfócito B

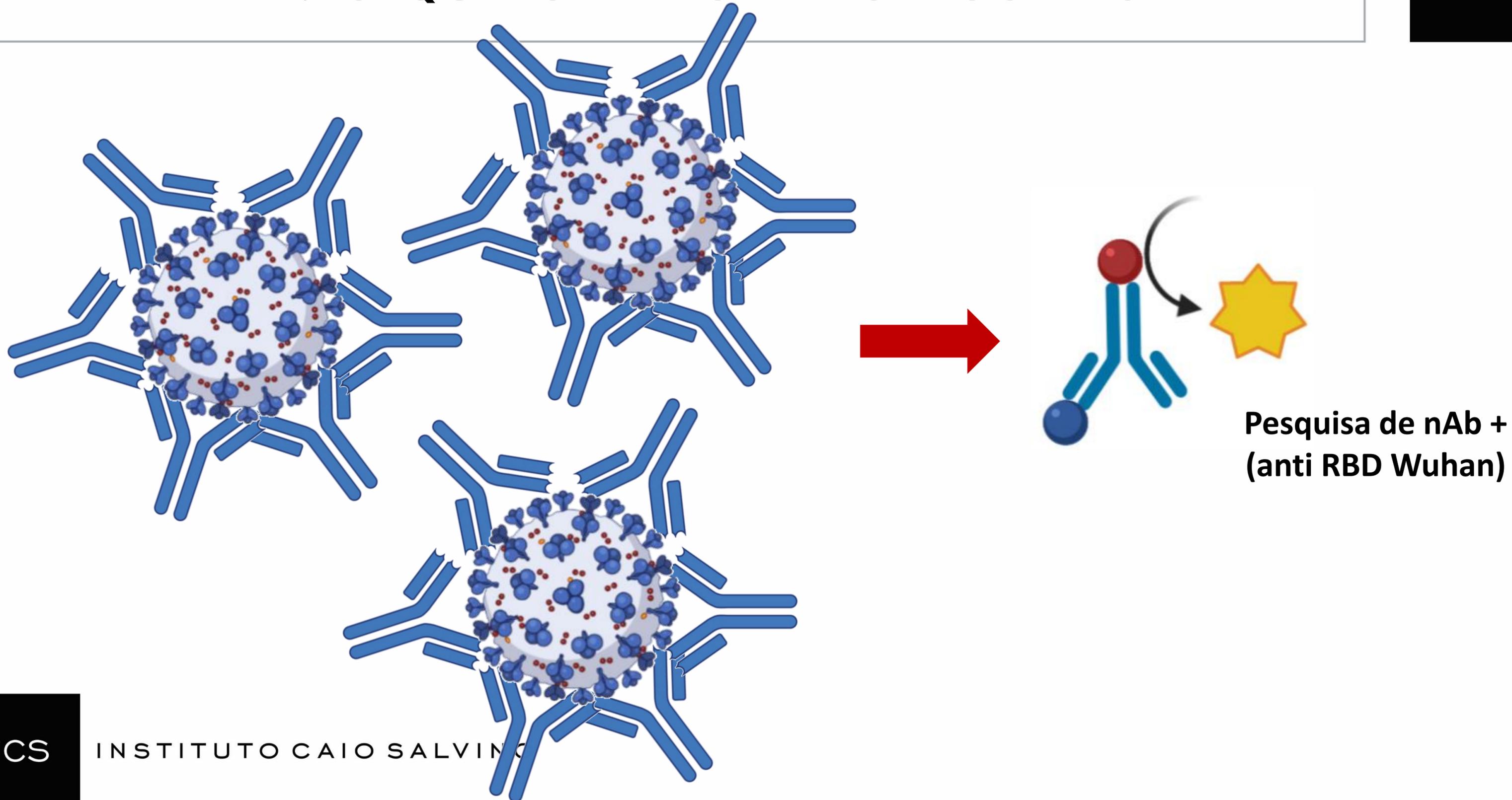


Plasmocito

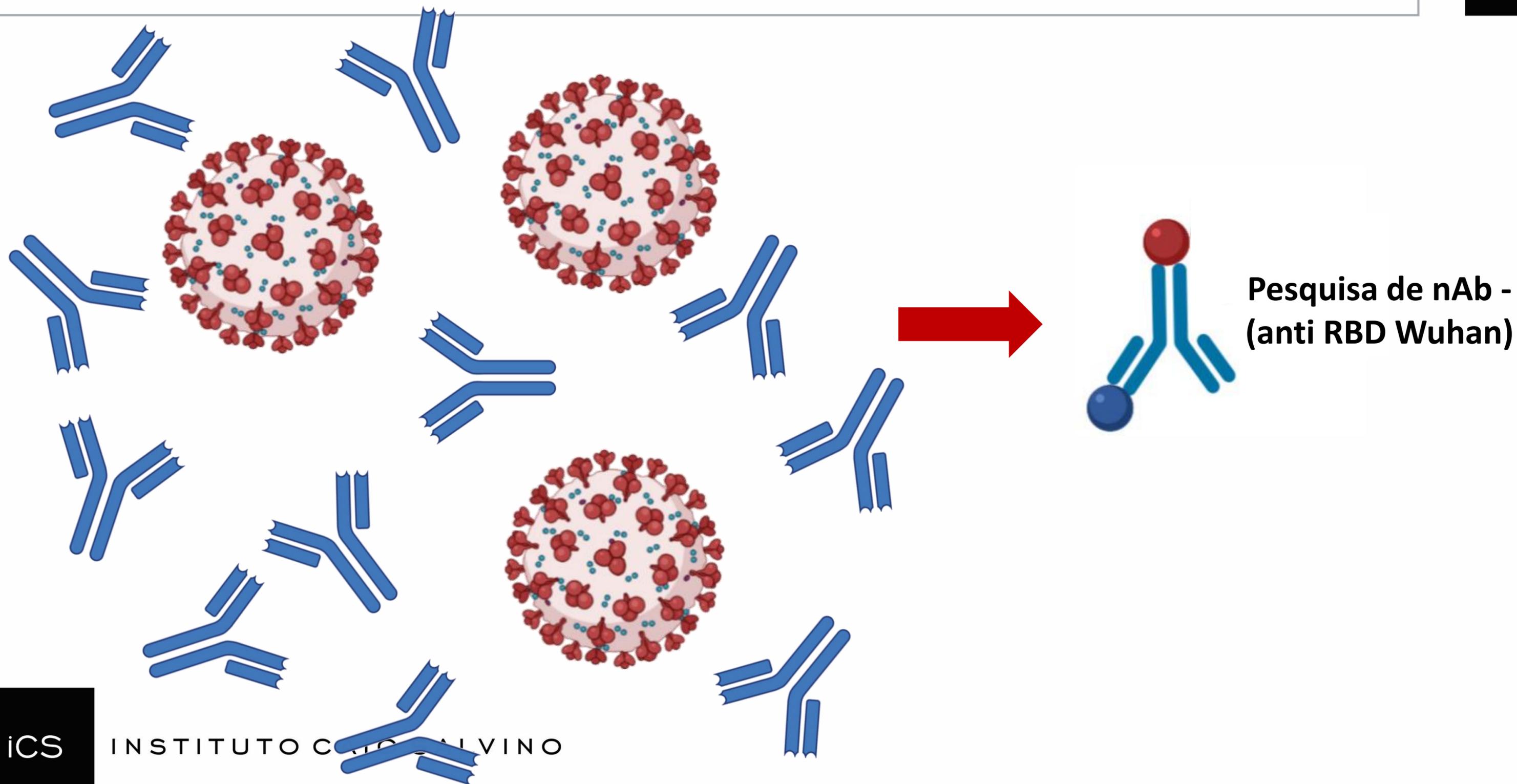


nAb
Anti RBD
Wuhan

VERDADE I : O QUE SE PROVA NO PÓS VACINA



VERDADE 2: PÓS VACINA E INFECÇÃO OMICRON



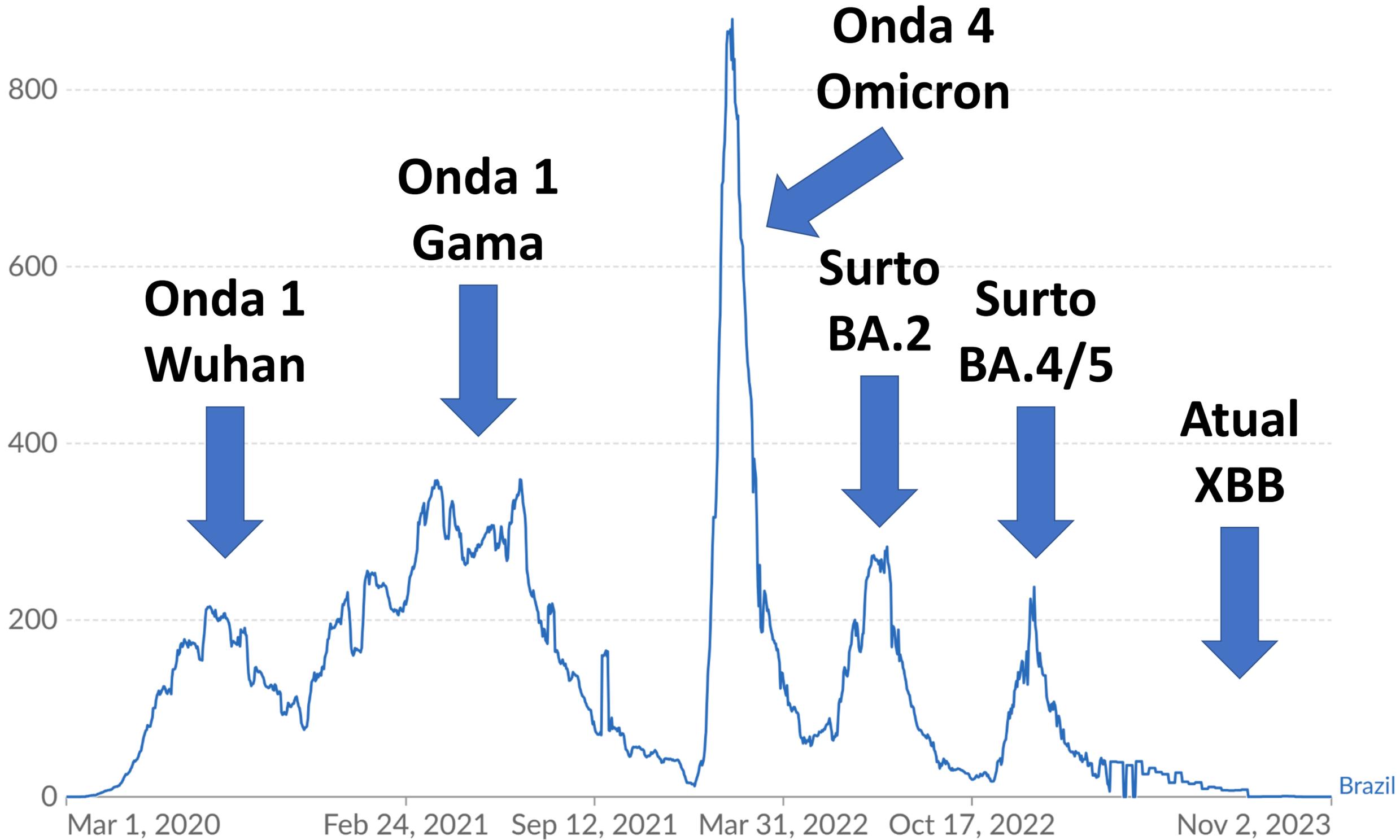
1. Vacinas provocam produção de nAb anti-RBD cepa ancestral;
2. A presença destes Ab demonstrada pelos atuais kits → organismo produzindo anticorpos obsoletos → **VERDADE 1**
3. Estes nAb não neutralizam Omicron (nem suas subvariantes e sublinhagens) → **VERDADE 2**
4. nAb anti RBD spike Wuhan → não comprova imunidade contra Omicron em todas as suas subvariantes, sublinhagens e recombinantes
 - Prova **APENAS** que o organismo produziu anticorpos neutralizantes contra spike original (ou contra spike BA.4/BA.5 no caso da bivalente → não é o caso da versão usada em crianças < 12 anos)

GRÁFICOS E DADOS

BRASIL E MUNDO

Daily new confirmed COVID-19 cases per million people

7-day rolling average. Due to limited testing, the number of confirmed cases is lower than the true number of infections.



Daily COVID-19 vaccine doses administered

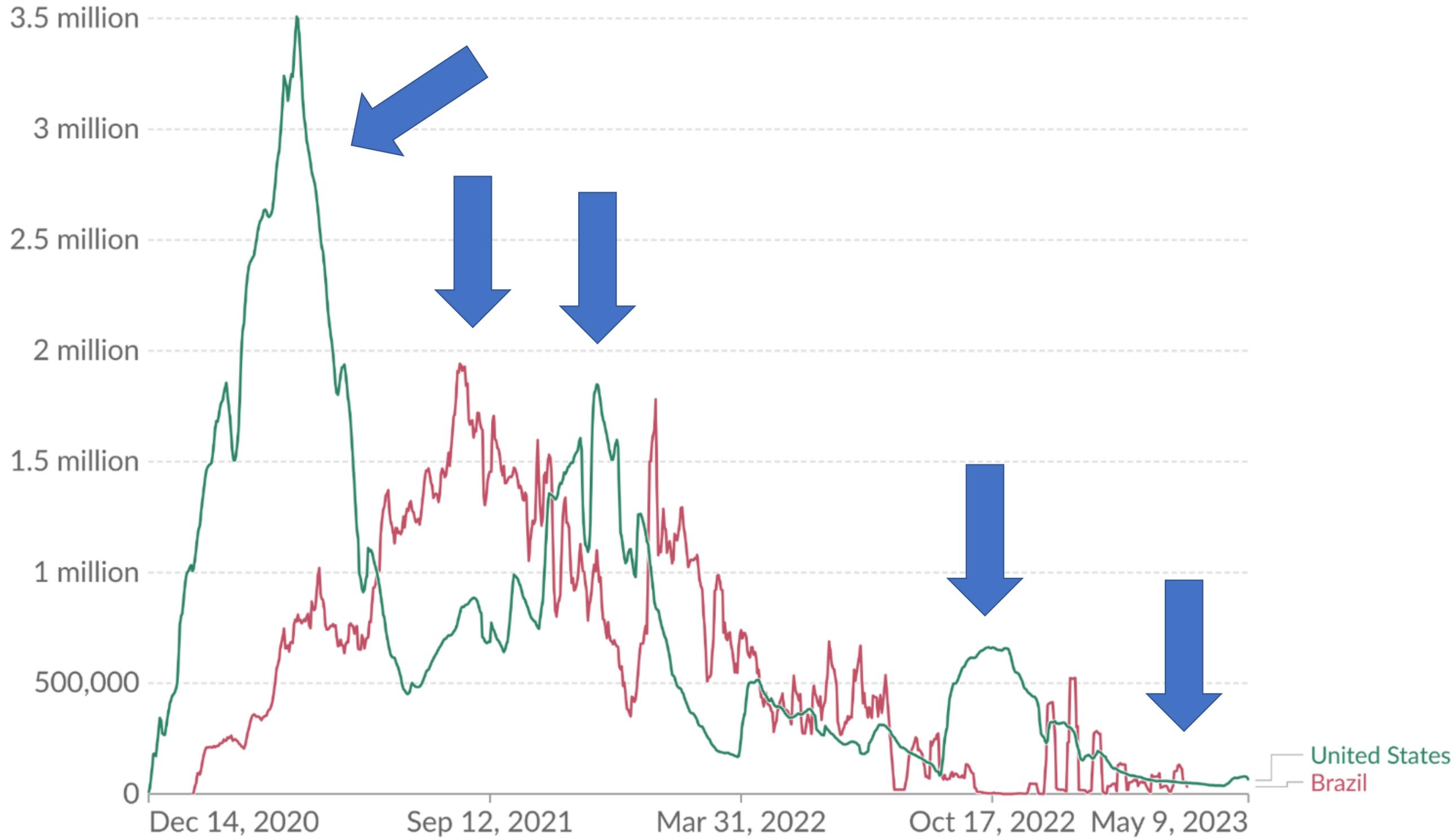
7-day rolling average. All doses, including boosters, are counted individually.





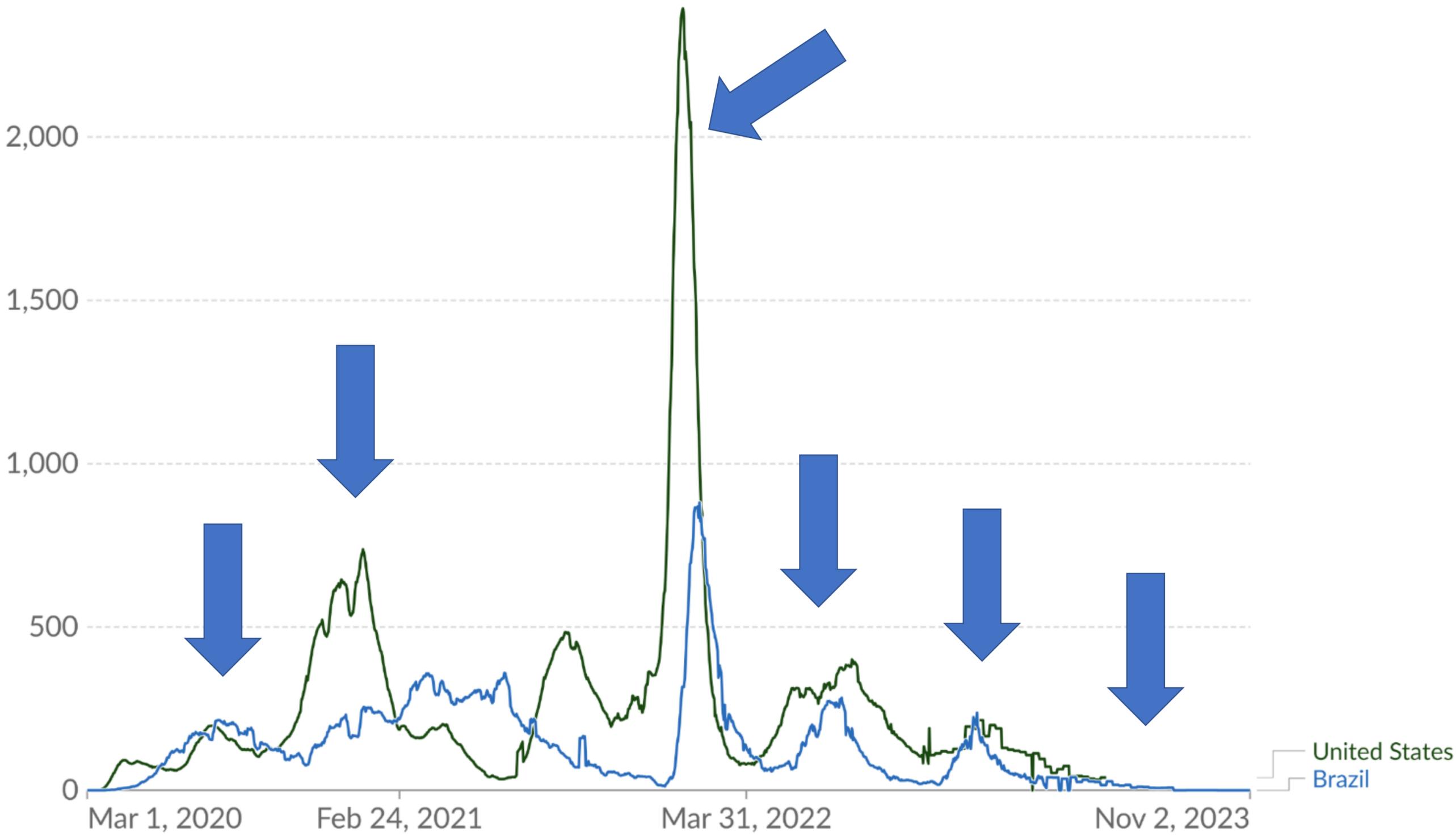
Daily COVID-19 vaccine doses administered

7-day rolling average. All doses, including boosters, are counted individually.



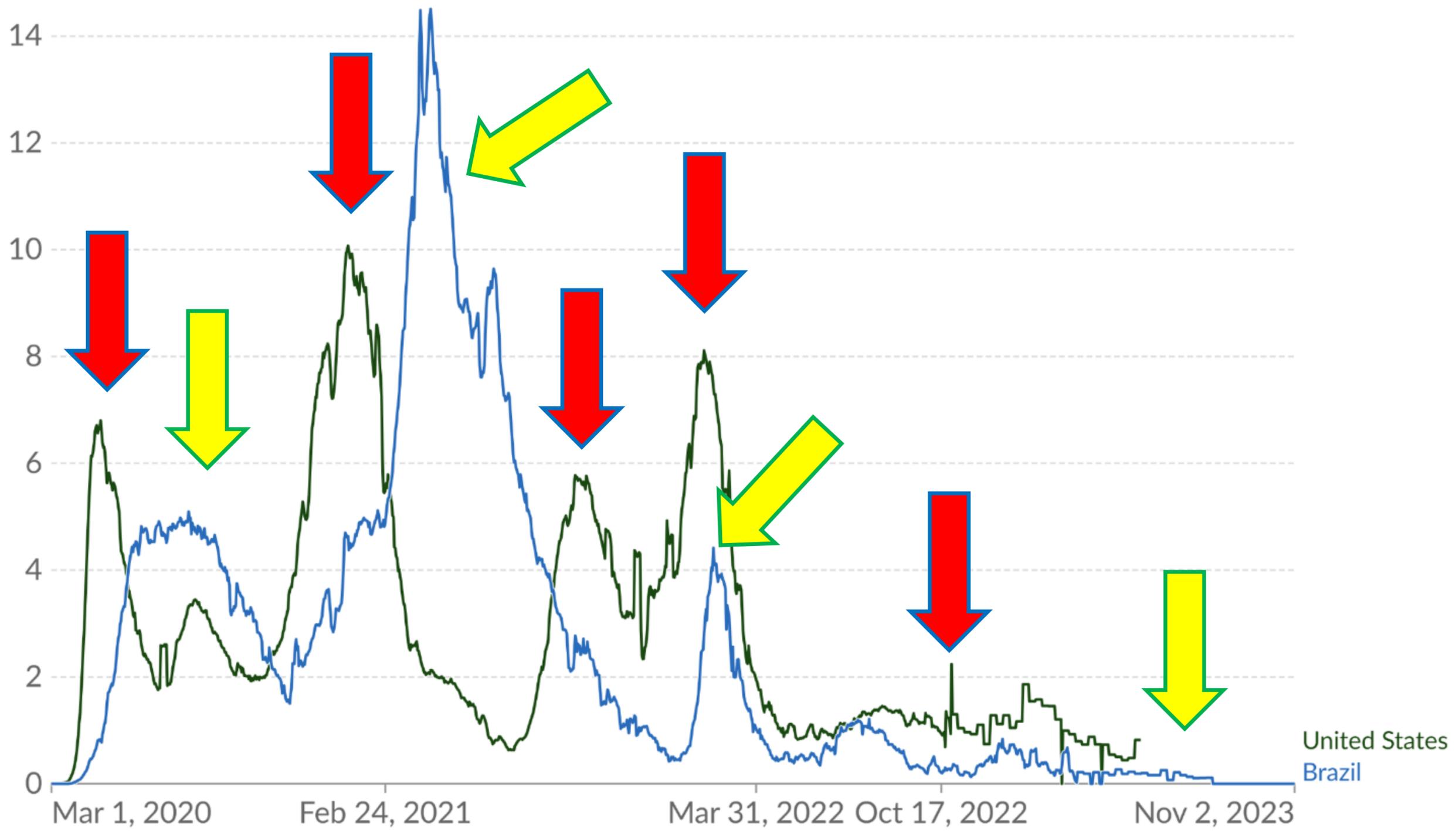
Daily new confirmed COVID-19 cases per million people

7-day rolling average. Due to limited testing, the number of confirmed cases is lower than the true number of infections.



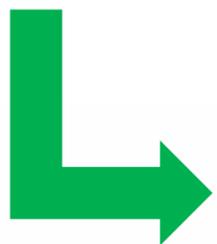
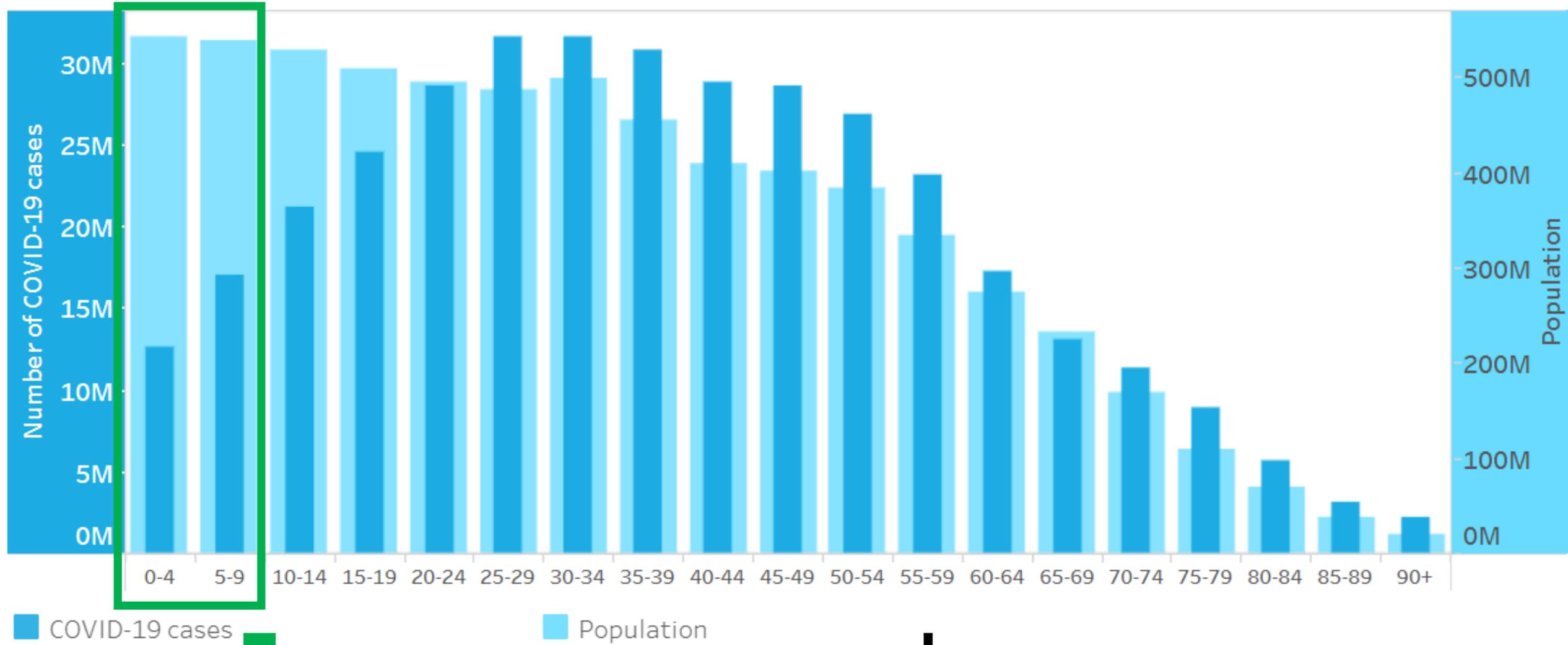
Daily new confirmed COVID-19 deaths per million people

7-day rolling average. Due to varying protocols and challenges in the attribution of the cause of death, the number of confirmed deaths may not accurately represent the true number of deaths caused by COVID-19.



COVID-19 cases and population by 5-year age groups (in numbers) in 105 countries

Select year



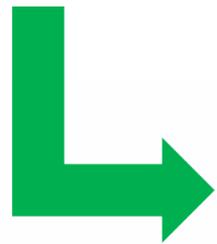
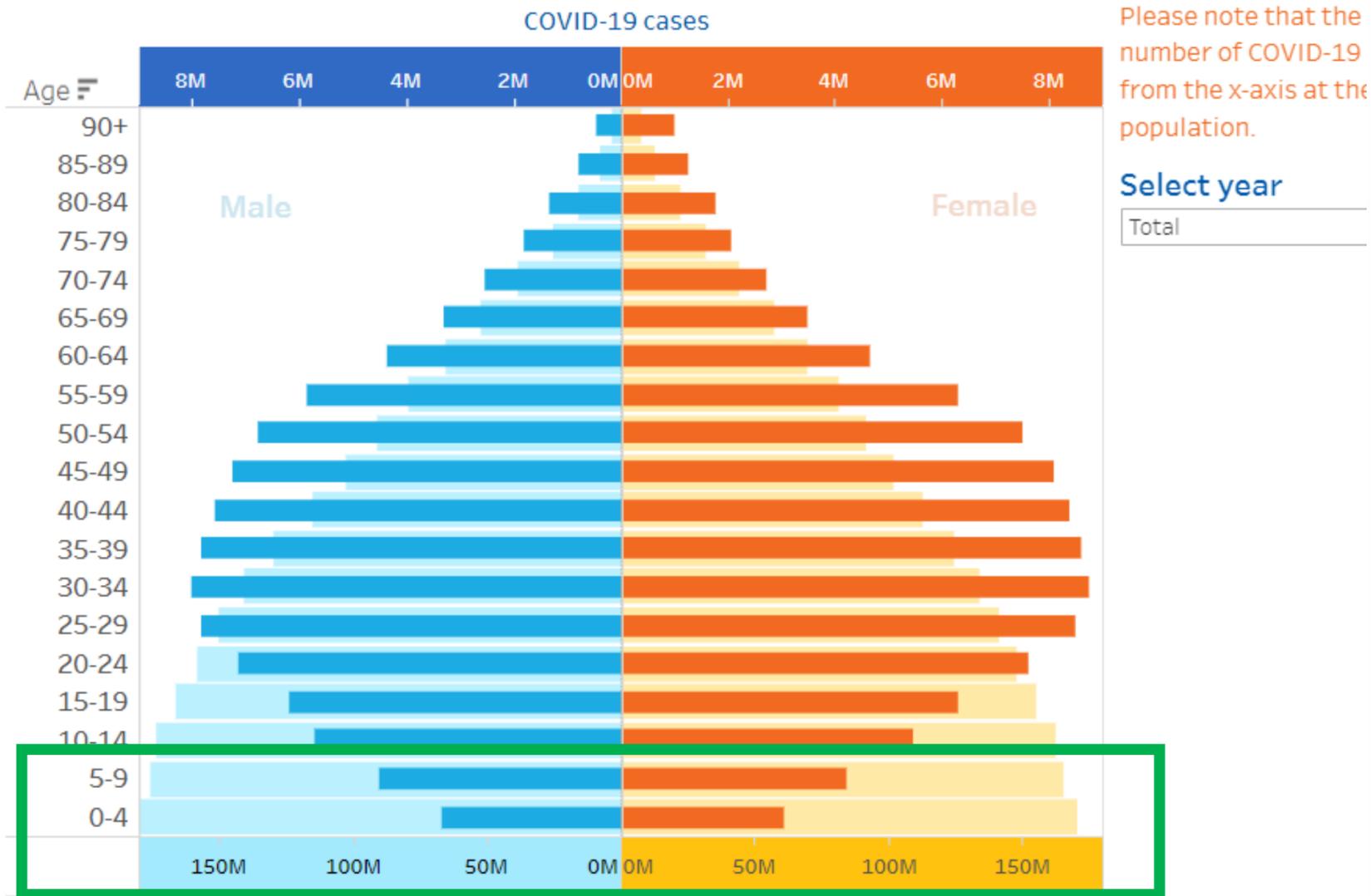
0 – 4 anos:
543.338.189
8,4%

0 – 4 anos:
12.584.255
3,4%

5 – 9 anos:
537.893.382
8,3%

5 – 9 anos:
17,032,844
4,64%

COVID-19 cases and population by 5-year age groups and sex (in numbers) in 70 countries



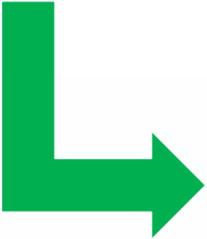
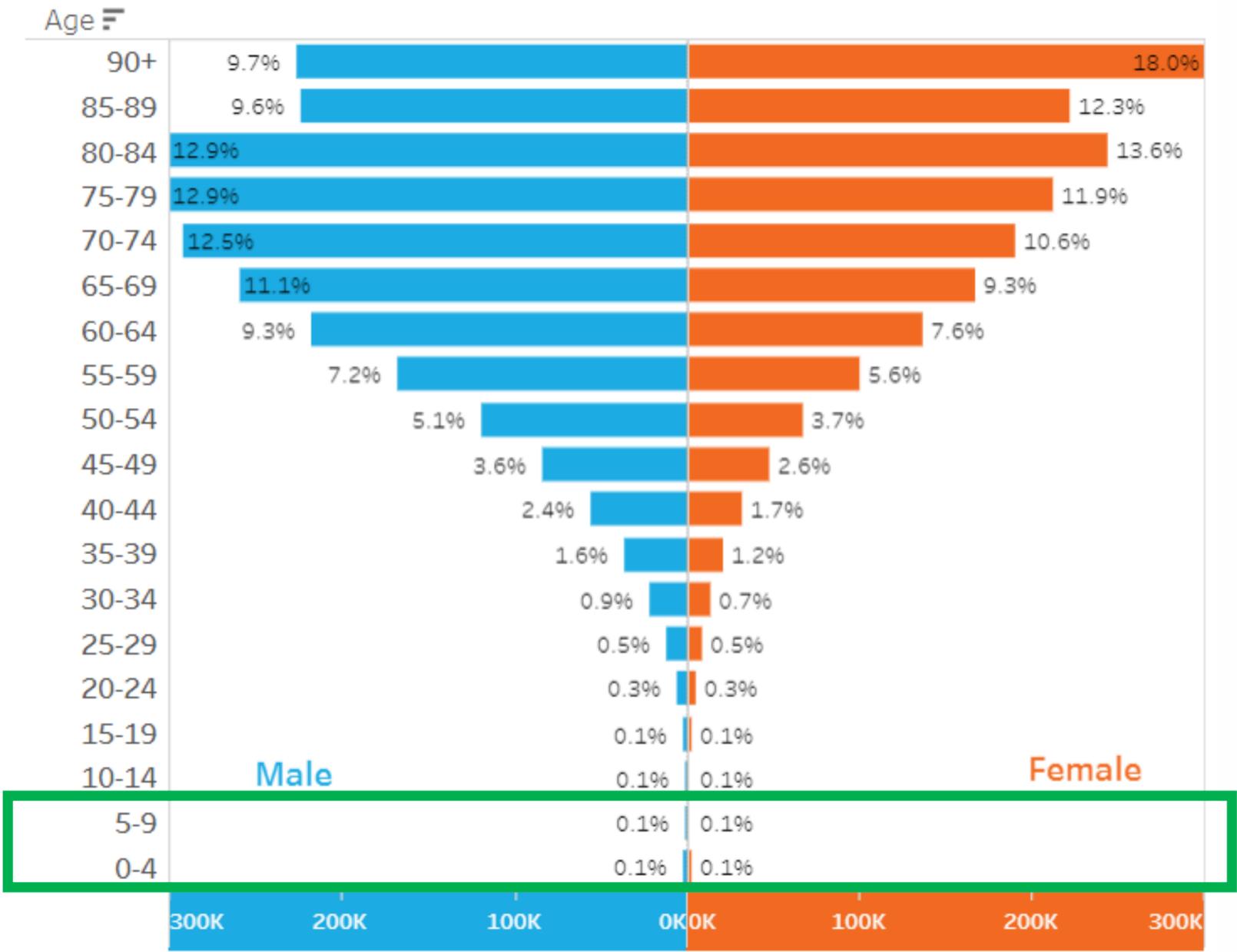
0 – 4 anos:
351.496.526
9,5%

0 – 4 anos:
3,35%

5 – 9 anos:
341.247,319
9,2%

5 – 9 anos:
4,65%

COVID-19 deaths by 5-year age groups and sex (in numbers) in 72 countries



0 – 4 anos:
351.496.526
9,5%

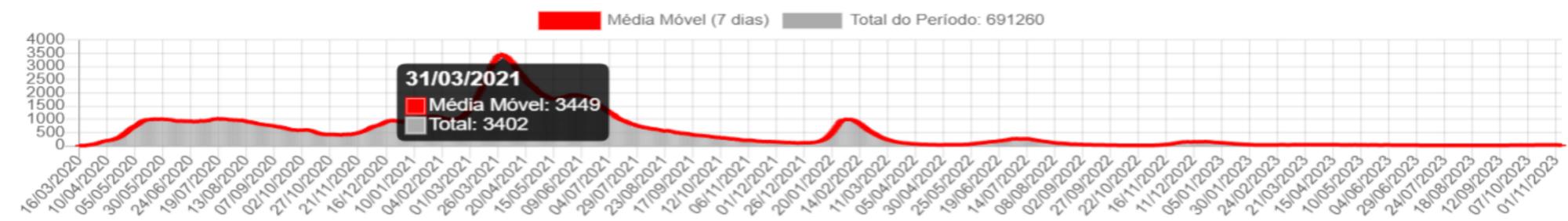
0 – 4 anos:
3,35%

5 – 9 anos:
341.247,319
9,2%

5 – 9 anos:
4,65%

Período ²

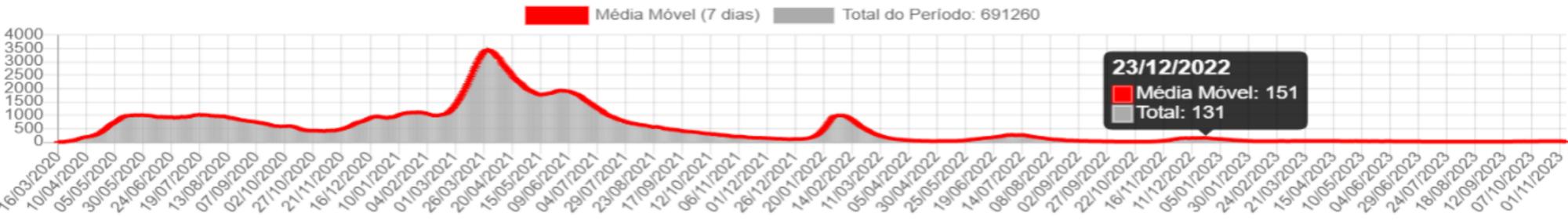
16/Março/2020  até 08/Novembro/2023 



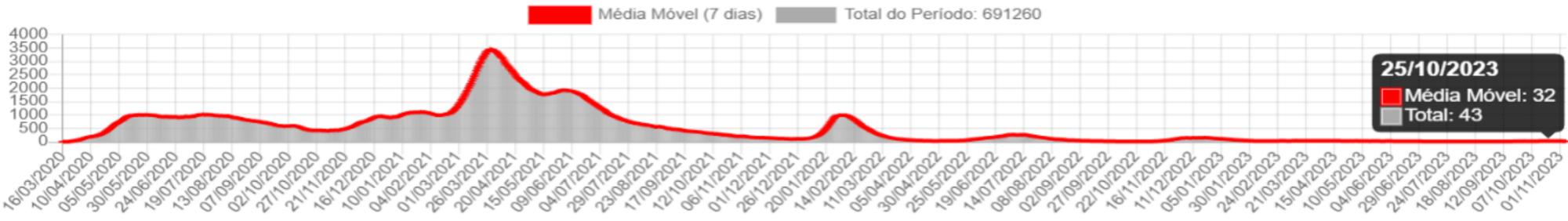
Fonte: Central de Informações do Registro Civil - CRC Nacional



Fonte: Central de Informações do Registro Civil - CRC Nacional



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Fonte: Central de Informações do Registro Civil - CRC Nacional

Estado

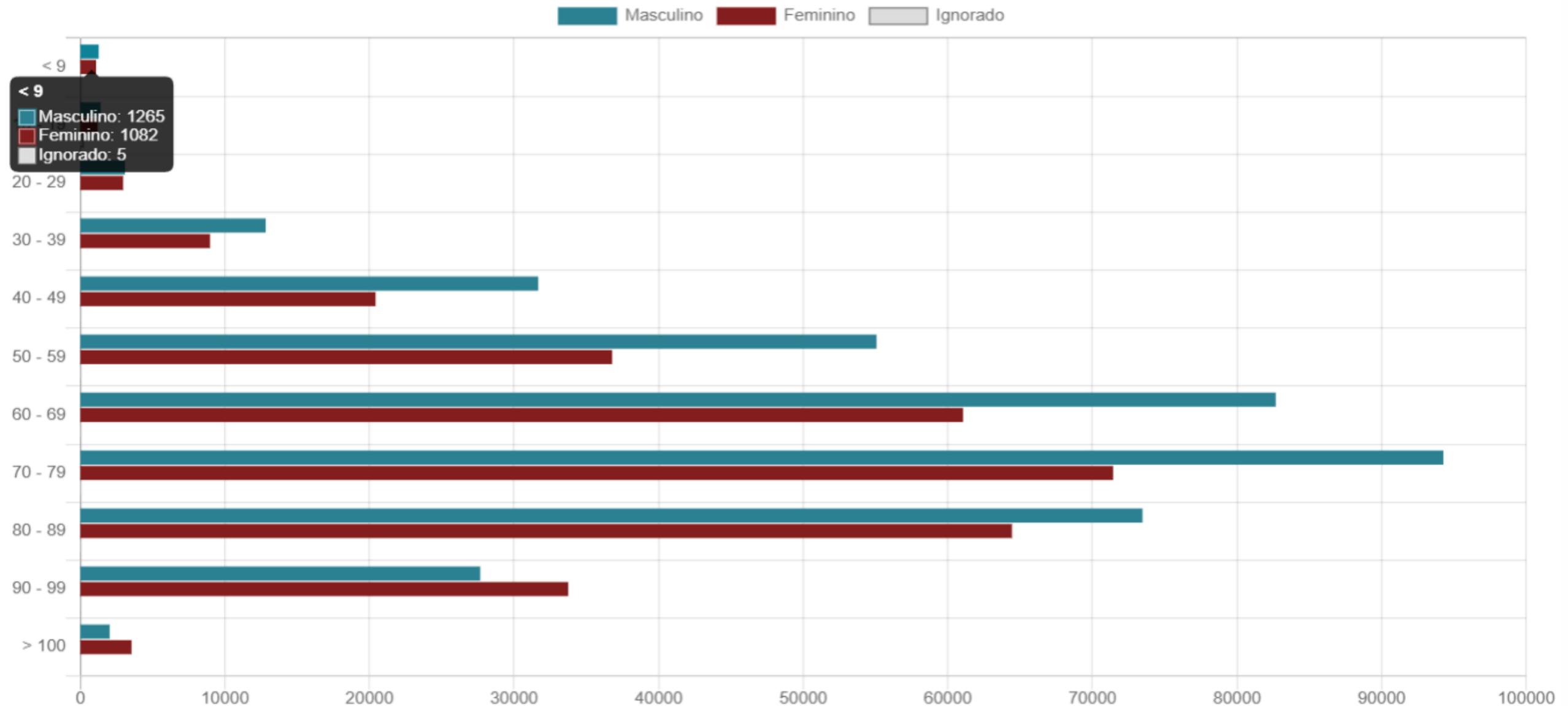
Todos

Data de

Óbito Registro

Período ²

16/Março/2020 até 08/Novembro/2023



Fonte: Central de Informações do Registro Civil - CRC Nacional

COVID-19 NO BRASIL

Dados até 04/11/2023



29

Região UF Município Reg.Metropolitana/Interior Ano Semana

BRASIL

01/01/2023 a 04/11/2023

População
210.147.125

Painel de acompanhamento diário: 20/02/2020 a 03/03/2023

Nota Informativa

CASOS

Casos novos notificados na semana

44.412

Casos Acumulados

37.994.356

Incidência covid-19 (100 mil hab)

791,39

ÓBITOS

Óbitos novos notificados na semana

178

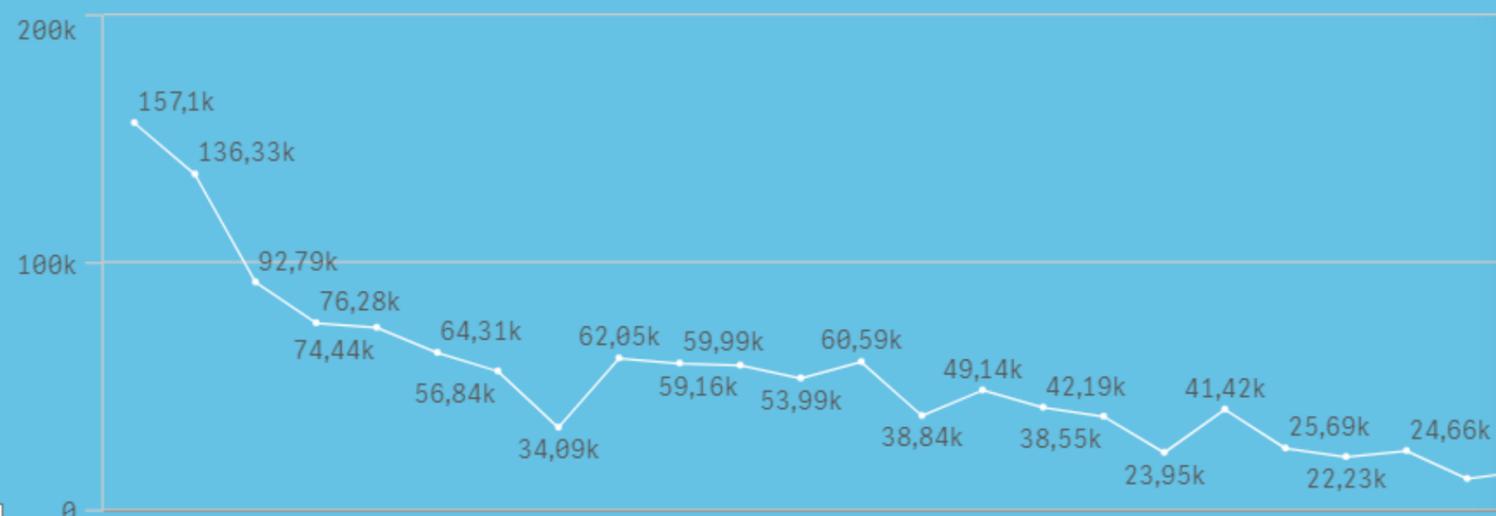
Óbitos Acumulados

706.986

Taxa mortalidade (100 mil hab)

6,25

Casos novos por semana epidemiológica de notificação



Óbitos novos por semana epidemiológica de notificação



Article

SARS-CoV-2 Omicron variant replication in human bronchus and lung ex vivo

<https://doi.org/10.1038/s41586-022-04479-6>

Received: 13 January 2022

Accepted: 27 January 2022

Published online: 1 February 2022

 Check for updates

Kenrie P. Y. Hui^{1,2}, John C. W. Ho¹, Man-chun Cheung¹, Ka-chun Ng¹, Rachel H. H. Ching¹, Ka-ling Lal¹, Tonla Tong Kam¹, Haogao Gu¹, Ko-Yung Sit³, Michael K. Y. Hsin³, Timmy W. K. Au³, Leo L. M. Poon^{1,2}, Malik Peiris^{1,2}, John M. Nicholls⁴ & Michael C. W. Chan^{1,2}✉

The emergence of SARS-CoV-2 variants of concern with progressively increased transmissibility between humans is a threat to global public health. The Omicron variant of SARS-CoV-2 also evades immunity from natural infection or vaccines¹, but it is unclear whether its exceptional transmissibility is due to immune evasion or intrinsic virological properties. Here we compared the replication competence and cellular tropism of the wild-type virus and the D614G, Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2) and Omicron (B.1.1.529) variants in ex vivo explant cultures of human bronchi and lungs. We also evaluated the dependence on TMPRSS2 and cathepsins for infection. We show that Omicron replicates faster than all other SARS-CoV-2 variants studied in the bronchi but less efficiently in the lung parenchyma. All variants of concern have similar cellular tropism compared to the wild type. Omicron is more dependent on cathepsins than the other variants of concern tested, suggesting that the Omicron variant enters cells through a different route compared with the other variants. The lower replication competence of Omicron in the human lungs may explain the reduced severity of Omicron that is now being reported in epidemiological studies, although determinants of severity are multifactorial. These findings provide important biological correlates to previous epidemiological observations.

- “Nossos resultados sugerem que a variante Omicron tem uma competência de replicação substancial (aumento de mais de 70 vezes) e significativamente maior nos brônquios humanos em comparação com os vírus WT e Delta”
- “A variante Omicron possui 37 substituições de aminoácidos na proteína spike, 15 das quais estão no domínio de ligação ao receptor. A infecção pelo Omicron depende da ECA2 e a ligação do pico do Omicron à ECA2 é melhorada em comparação com a do vírus WT”

Article

SARS-CoV-2 Omicron variant replication in human bronchus and lung ex vivo

<https://doi.org/10.1038/s41586-022-04479-6>

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The emergence of SARS-CoV-2 variants of concern with progressively increased transmissibility between humans is a threat to global public health. The Omicron variant of SARS-CoV-2 also evades immunity from natural infection or vaccines¹, but it is unclear whether its exceptional transmissibility is due to immune evasion or intrinsic virological properties. Here we compared the replication competence and cellular tropism of the wild-type virus and the D614G, Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2) and Omicron (B.1.1.529) variants in ex vivo explant cultures of human bronchi and lungs. We also evaluated the dependence on TMPRSS2 and cathepsins for infection. We show that Omicron replicates faster than all other SARS-CoV-2 variants studied in the bronchi but less efficiently in the lung parenchyma. All variants of concern have similar cellular tropism compared to the wild type. Omicron is more dependent on cathepsins than the other variants of concern tested, suggesting that the Omicron variant enters cells through a different route compared with the other variants. The lower replication competence of Omicron in the human lungs may explain the reduced severity of Omicron that is now being reported in epidemiological studies, although determinants of severity are multifactorial. These findings provide important biological correlates to previous epidemiological observations.

- “Nossos dados mostrando que a **variante Omicron tem menor competência de replicação viral nos pulmões em comparação com os brônquios** são de particular interesse. Esta diferença também é **confirmada pelos estudos imunohistoquímicos** que mostram menos células infectadas por vírus em culturas de explantes de pulmão humano ex vivo.
- **Estas observações podem sugerir que Omicron pode ter reduzido a gravidade clínica,** mas tais interpretações precisam de ser qualificadas porque a **gravidade da doença da COVID-19 é determinada não apenas pela replicação do vírus, mas também por respostas imunitárias inatas desreguladas.**”

Open Forum Infectious Diseases

MAJOR ARTICLE



Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine

Nabin K. Shrestha,^{1,•} Patrick C. Burke,² Amy S. Nowacki,^{3,•} James F. Simon,⁴ Amanda Hagen,⁵ and Steven M. Gordon¹

¹Department of Infectious Diseases, Cleveland Clinic, Cleveland, Ohio, USA, ²Infection Prevention, Cleveland Clinic, Cleveland, Ohio, USA, ³Quantitative Health Sciences, Cleveland Clinic, Cleveland, Ohio, USA, ⁴Enterprise Business Intelligence, Cleveland Clinic, Cleveland, Ohio, USA, and ⁵Occupational Health, Cleveland Clinic, Cleveland, Ohio, USA

Background. The purpose of this study was to evaluate whether a bivalent coronavirus disease 2019 (COVID-19) vaccine protects against COVID-19.

Methods. The study included employees of Cleveland Clinic in employment when the bivalent COVID-19 vaccine first became available. Cumulative incidence of COVID-19 over the following 26 weeks was examined. Protection provided by vaccination (analyzed as a time-dependent covariate) was evaluated using Cox proportional hazards regression, with change in dominant circulating lineages over time accounted for by time-dependent coefficients. The analysis was adjusted for the pandemic phase when the last prior COVID-19 episode occurred and the number of prior vaccine doses.

Results. Among 51 017 employees, COVID-19 occurred in 4424 (8.7%) during the study. In multivariable analysis, the bivalent-vaccinated state was associated with lower risk of COVID-19 during the BA.4/5-dominant (hazard ratio, 0.71 [95% confidence interval, .63–.79]) and the BQ-dominant (0.80 [.69–.94]) phases, but decreased risk was not found during the XBB-dominant phase (0.96 [.82–.1.12]). The estimated vaccine effectiveness was 29% (95% confidence interval, 21%–37%), 20% (6%–31%), and 4% (–12% to 18%), during the BA.4/5-, BQ-, and XBB-dominant phases, respectively. The risk of COVID-19 also increased with time since the most recent prior COVID-19 episode and with the number of vaccine doses previously received.

Conclusions. The bivalent COVID-19 vaccine given to working-aged adults afforded modest protection overall against COVID-19 while the BA.4/5 lineages were the dominant circulating strains, afforded less protection when the BQ lineages were dominant, and effectiveness was not demonstrated when the XBB lineages were dominant.

Keywords. COVID-19; SARS-CoV-2; bivalent vaccine; effectiveness; vaccines.

- “A eficácia estimada da vacina foi de 29%, 20% e 4%, durante as fases dominantes BA.4/5, BQ e XBB, respectivamente..”

*Revisado por pares

<https://academic.oup.com/ofid/article/10/6/ofad209/7131292>

Open Forum Infectious Diseases

MAJOR ARTICLE



Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine

Nabin K. Shrestha,^{1,•} Patrick C. Burke,² Amy S. Nowacki,^{3,•} James F. Simon,⁴ Amanda Hagen,⁵ and Steven M. Gordon¹

¹Department of Infectious Diseases, Cleveland Clinic, Cleveland, Ohio, USA, ²Infection Prevention, Cleveland Clinic, Cleveland, Ohio, USA, ³Quantitative Health Sciences, Cleveland Clinic, Cleveland, Ohio, USA, ⁴Enterprise Business Intelligence, Cleveland Clinic, Cleveland, Ohio, USA, and ⁵Occupational Health, Cleveland Clinic, Cleveland, Ohio, USA

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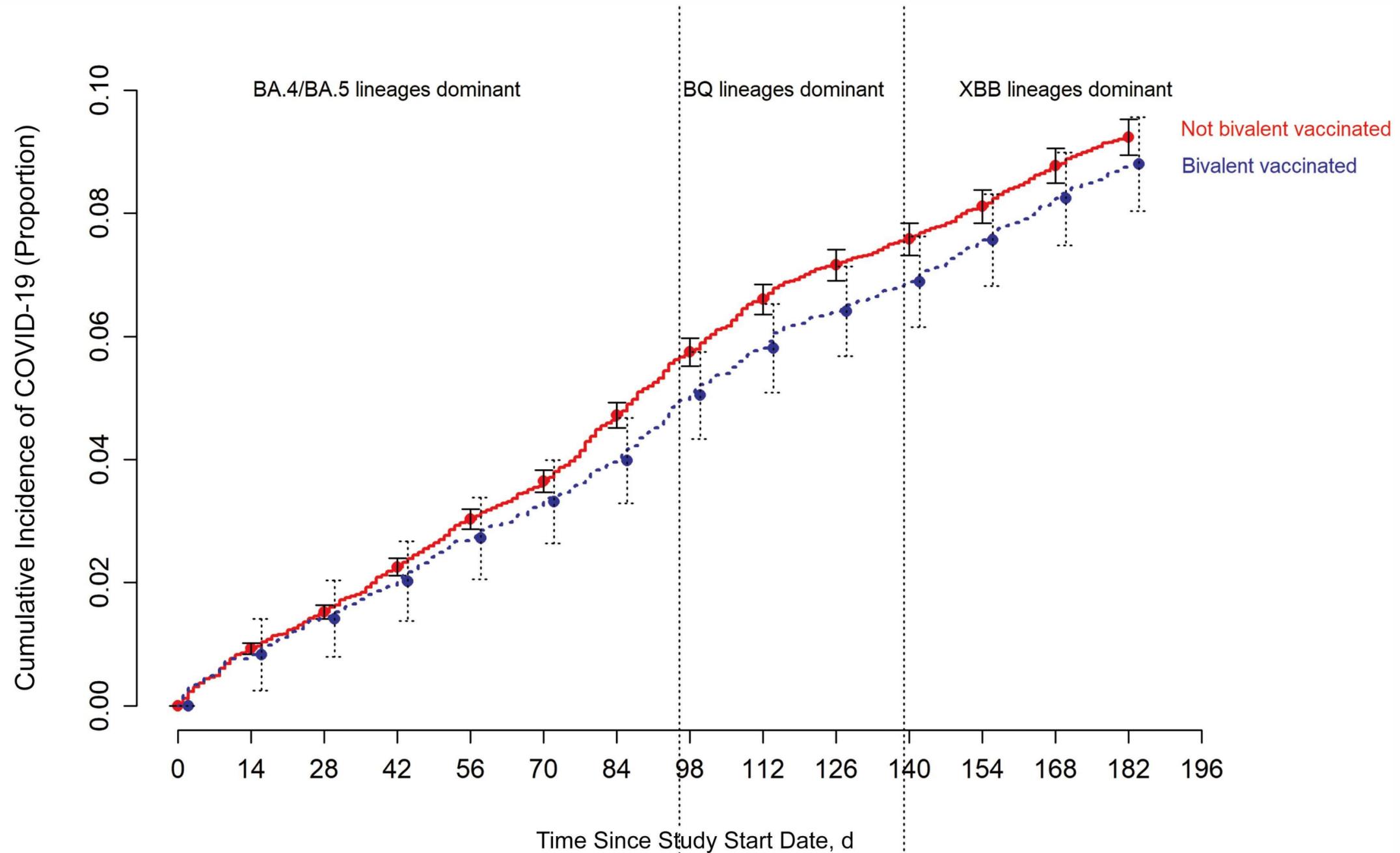
Conclusions. The bivalent COVID-19 vaccine given to working-aged adults afforded modest protection overall against COVID-19 while the BA.4/5 lineages were the dominant circulating strains, afforded less protection when the BQ lineages were dominant, and effectiveness was not demonstrated when the XBB lineages were dominant.

Keywords. COVID-19; SARS-CoV-2; bivalent vaccine; effectiveness; vaccines.

- “Em conclusão, este estudo encontrou um **efeito protetor geral modesto da vacina bivalente** contra a COVID-19 **enquanto as estirpes circulantes estavam representadas na vacina** e uma **proteção inferior quando as estirpes circulantes já não estavam representadas**. Um **efeito protetor significativo não foi encontrado quando as linhagens XBB eram dominantes**. A descoberta inesperada de **aumento do risco com o aumento do número de doses anteriores** da vacina contra a COVID-19 **necessita de mais estudos.**”

*Revisado por pares

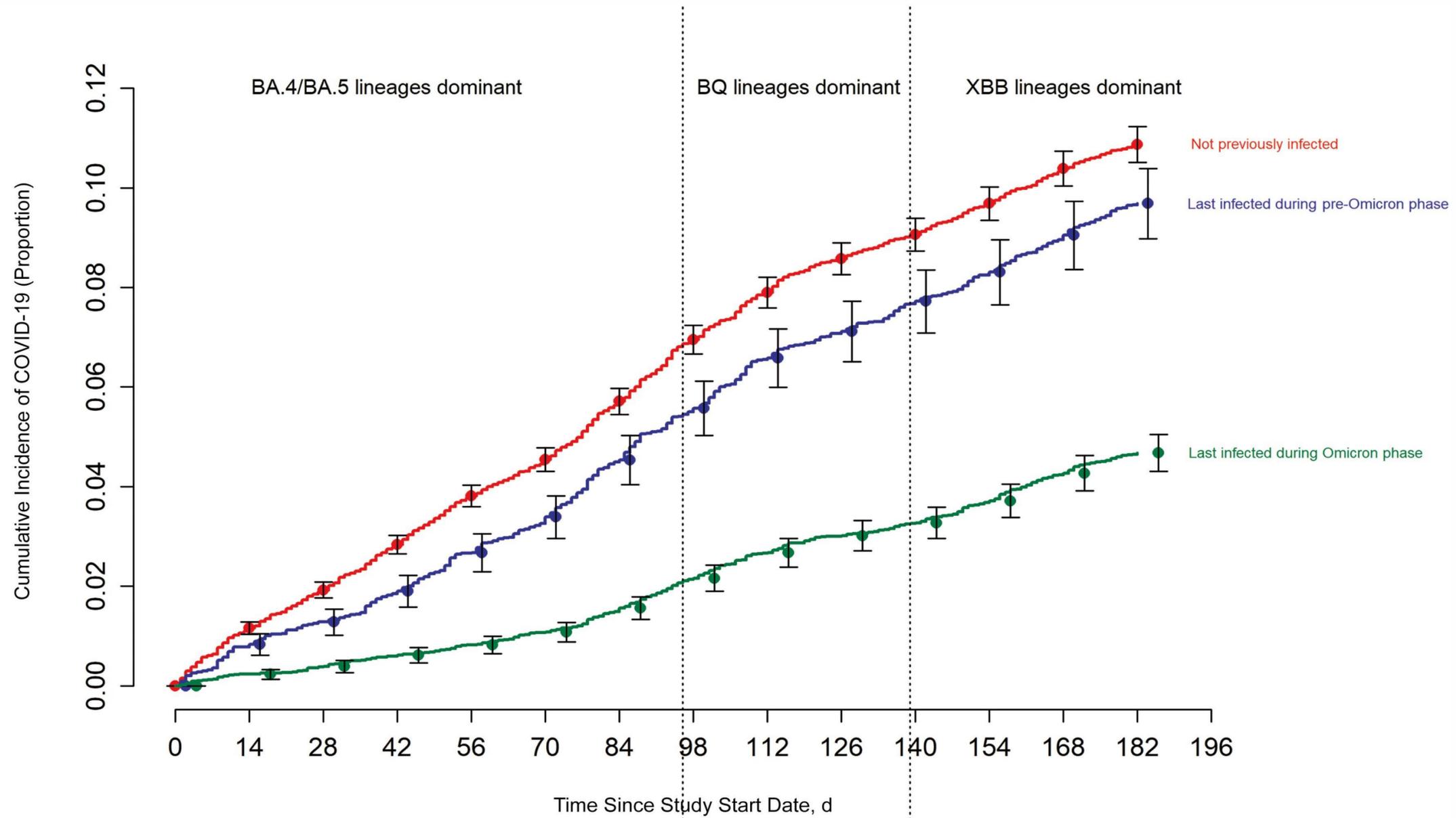
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Nos. at risk:

___ Not bivalent vaccinated	46 005	43 535	41 167	39 288	37 638	36 921	36 264	35 404	34 595	33 838	33 278	32 745	32 237	31 784
---- Bivalent vaccinated	499	2835	5265	7417	9155	10 071	10 565	11 041	11 160	11 364	11 496	11 525	11 543	11 530

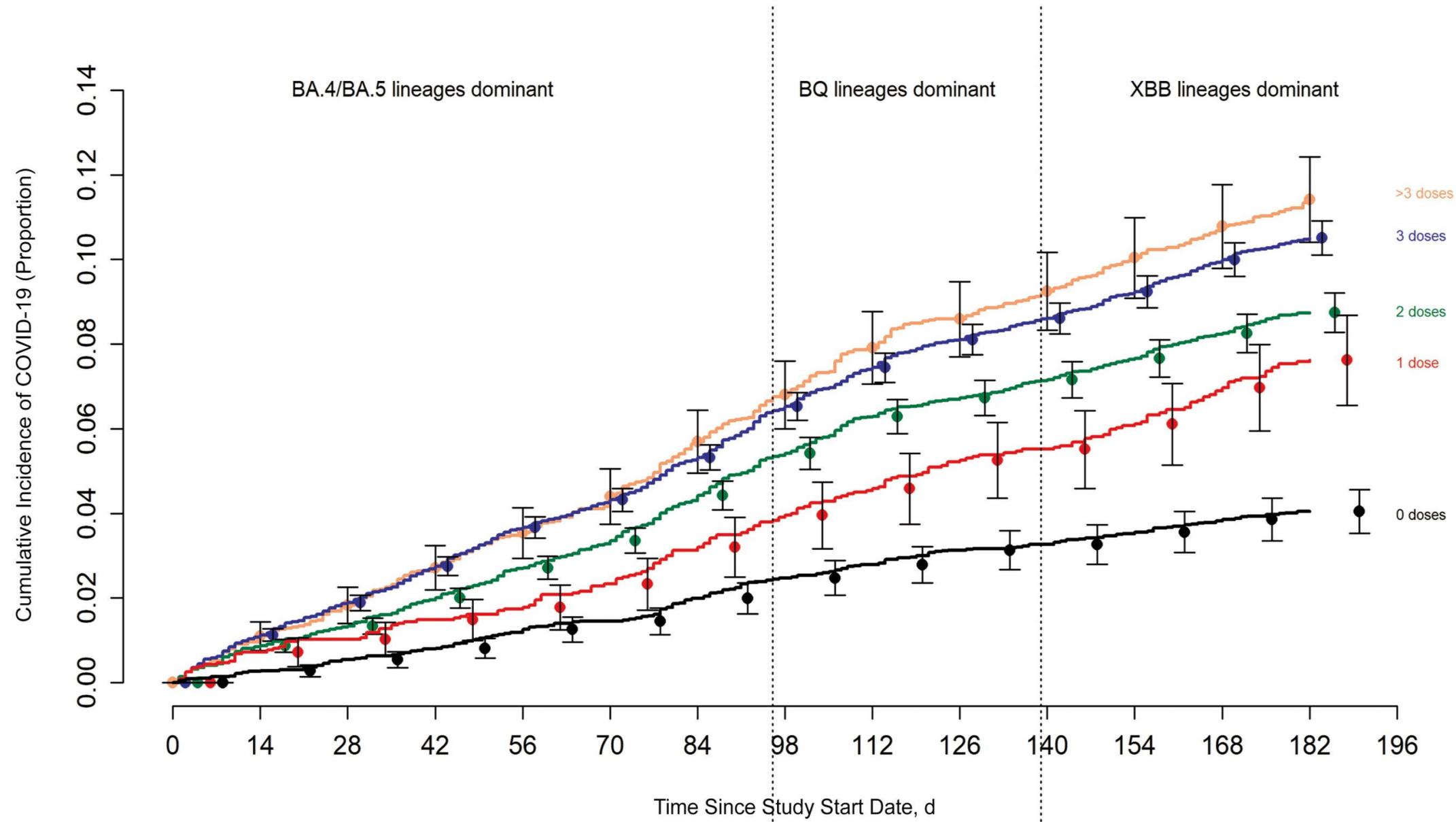




Nos. at risk:

Last infected during Omicron phase	9204	9667	10 252	11 019	11 719	12 355	12 825	13 045	12 918	12 821	12 743	12 630	12 511	12 399
Last infected during pre-Omicron phase	6969	6894	6824	6760	6674	6600	6479	6380	6279	6206	6137	6071	5999	5925
Not previously infected	30 331	29 809	29 356	28 926	28 400	28 037	27 525	27 020	26 558	26 175	25 894	25 569	25 270	24 990



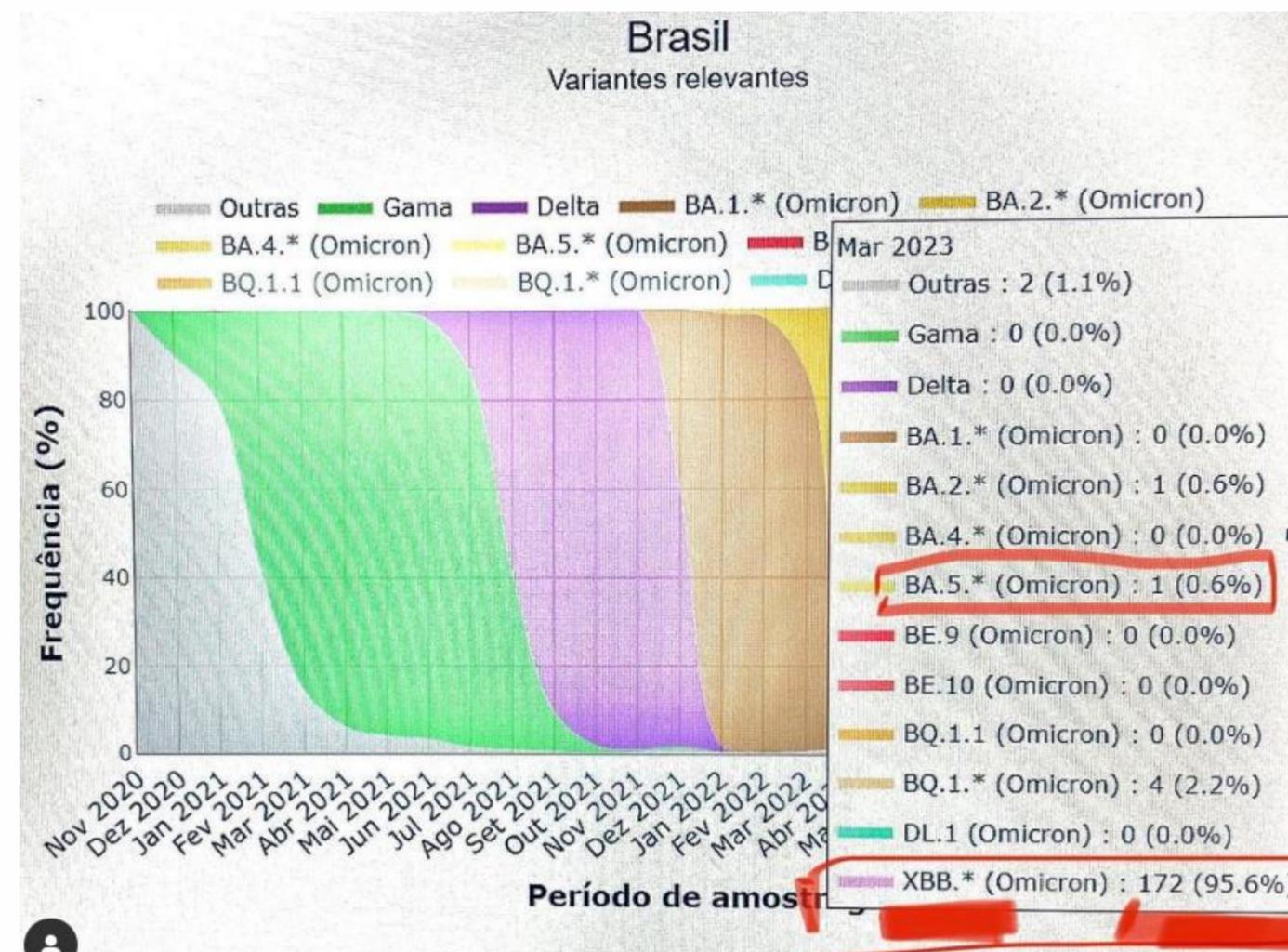


Nos. at risk:

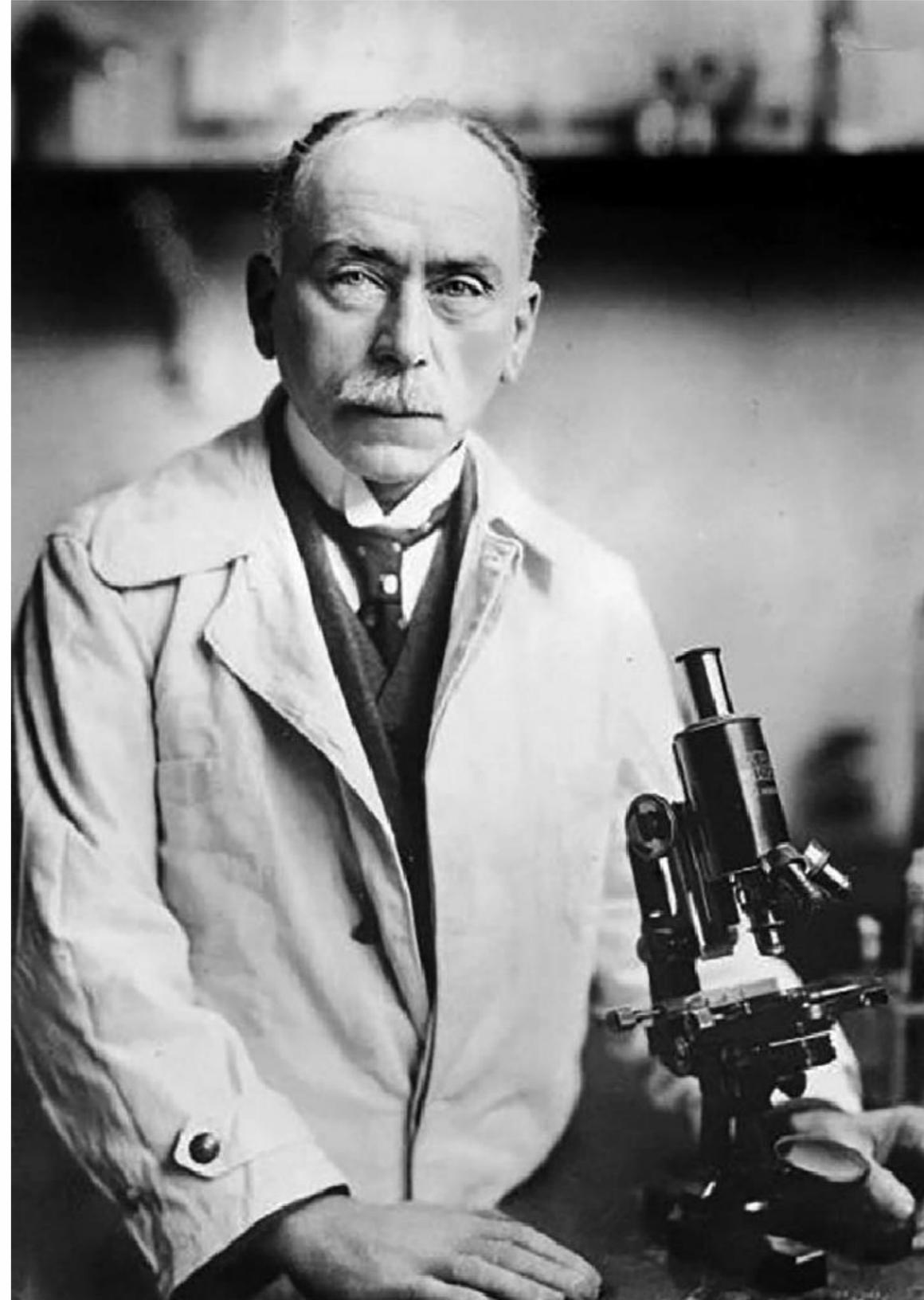
0 doses	5738	5683	5626	5593	5528	5506	5449	5406	5333	5260	5208	5156	5108	5067
1 dose	2350	2340	2333	2328	2334	2328	2322	2299	2268	2236	2214	2187	2157	2127
2 doses	13 784	13 693	13 684	13 758	13 757	13 787	13 714	13 569	13 351	13 200	13 059	12 907	12 751	12 597
3 doses	20 998	21 024	21 158	21 368	21 509	21 696	21 702	21 555	21 257	21 020	20 841	20 613	20 396	20 187
>3 doses	3634	3630	3631	3658	3665	3675	3642	3616	3546	3486	3452	3407	3368	3336



- Imunizante monovalente: mRNA proteína spike SARS CoV-2 original
 - Não houve demonstração de eficácia
 - Não circula desde fim de 2020
 - Lembrete: esse é o mRNA do imunizante Comirnaty® autorizado para crianças a partir de 6 meses
- Imunizante bivalente: mRNA proteína spike SARS CoV-2 BA.4 e BA.5
 - Eficácia de 29%
 - Não predomina desde dezembro de 2022
- Predomínio HOJE acarreta eficácia da bivalente em < 4% (estudo CC) e ausência de eficácia da monovalente;
- Ainda há a proteção humoral e celular nasal SUPERIOR em crianças em relação a adultos, mas esse não é o tema da apresentação.
- Diagnóstico laboratorial tem como padrão ouro o RT-PCR, que traz consigo a necessidade de interpretação do CT para avaliação da viabilidade viral (carga viral efetiva)
- Teste rápido de Ag → qualitativo e passivo de erros



<https://www.genomahcov.fiocruz.br/dashboard-pt/>



Jules Bordet
1870- 1961



**QUE A CIÊNCIA E A VERDADE SEJAM SEMPRE PARCEIRAS
E ANDEM DE MÃOS DADAS. A BUSCA DA VERDADE, SENDO
A BASE DA CIÊNCIA, A DESCOBERTA CIENTÍFICA, A
CONSAGRAÇÃO DA UMA VERDADE.
UMA SEM A OUTRA, ABSOLUTAMENTE INEXISTE.
(CAIO SALVINO – 2023)**

MUITO OBRIGADO PELA OPORTUNIDADE