Überblick Impfmöglichkeiten bei COVID 19

Webinar „Impfungen und pulmonale impfpräventable Erkrankungen“
10.5.2021

Grafik: https://www.slidemembers.com/

Monika Redlberger-Fritz
Zentrum für Virologie
Medizinische Universität Wien

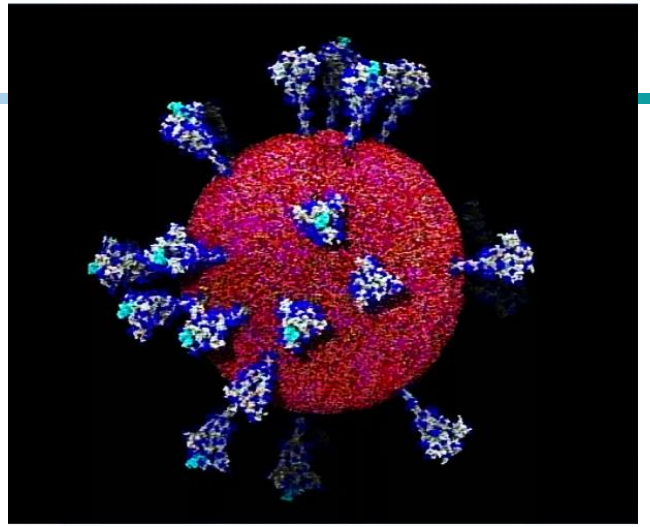
ZENTRUM FÜR VIROLOGIE
MEDIZINISCHE UNIVERSITÄT WIEN

SARS CoV 2

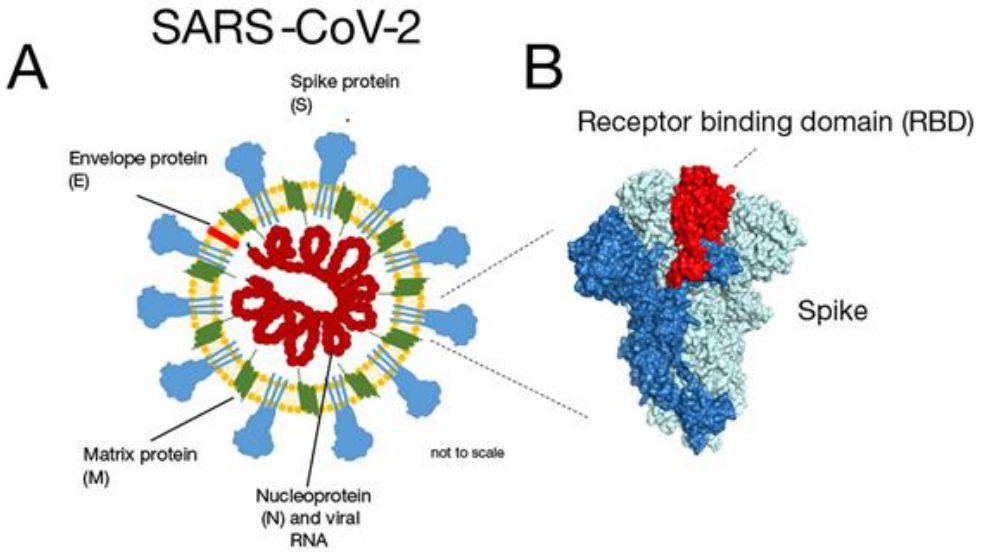
- membranumhüllte RNA-Viren
- Virionen ca. 80-140 nm

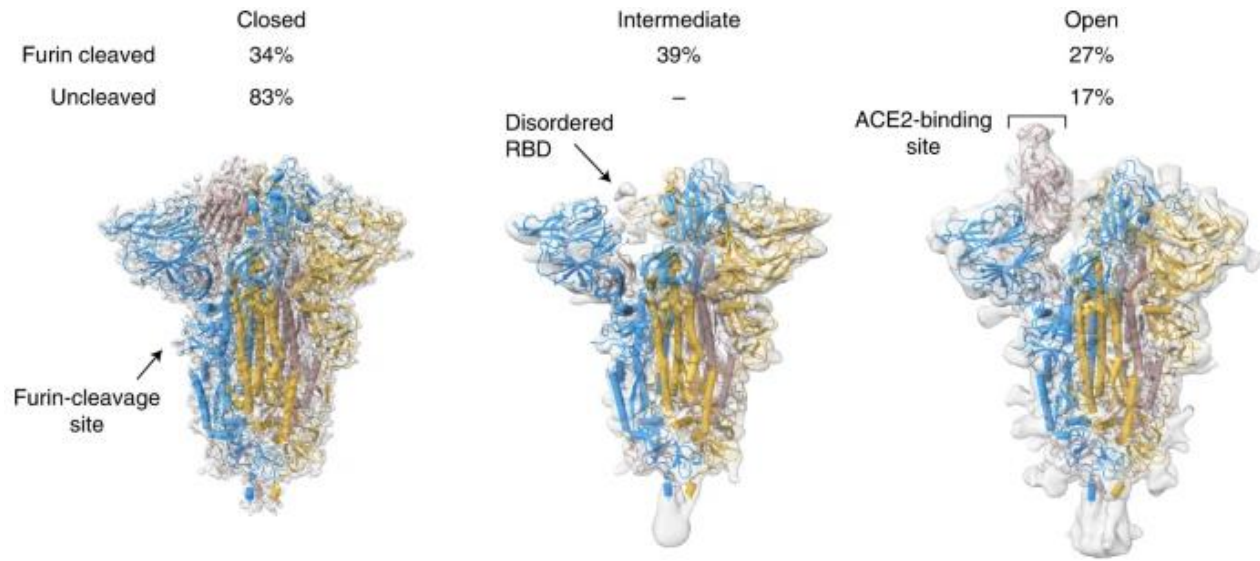
- einzelsträngiges RNA-Genom rund 30 kb größte bekannte Genom aller RNA-Viren
- Besitzen einen proofreading Mechanismus (ggs. zu anderen RNA Viren)

- Oberflächenprotein S Protein hoch immunogen



An atom-by-atom model of the coronavirus.
Lorenzo Casalino and Abigail Dommer, Amaro Lab, U.C. San Diego

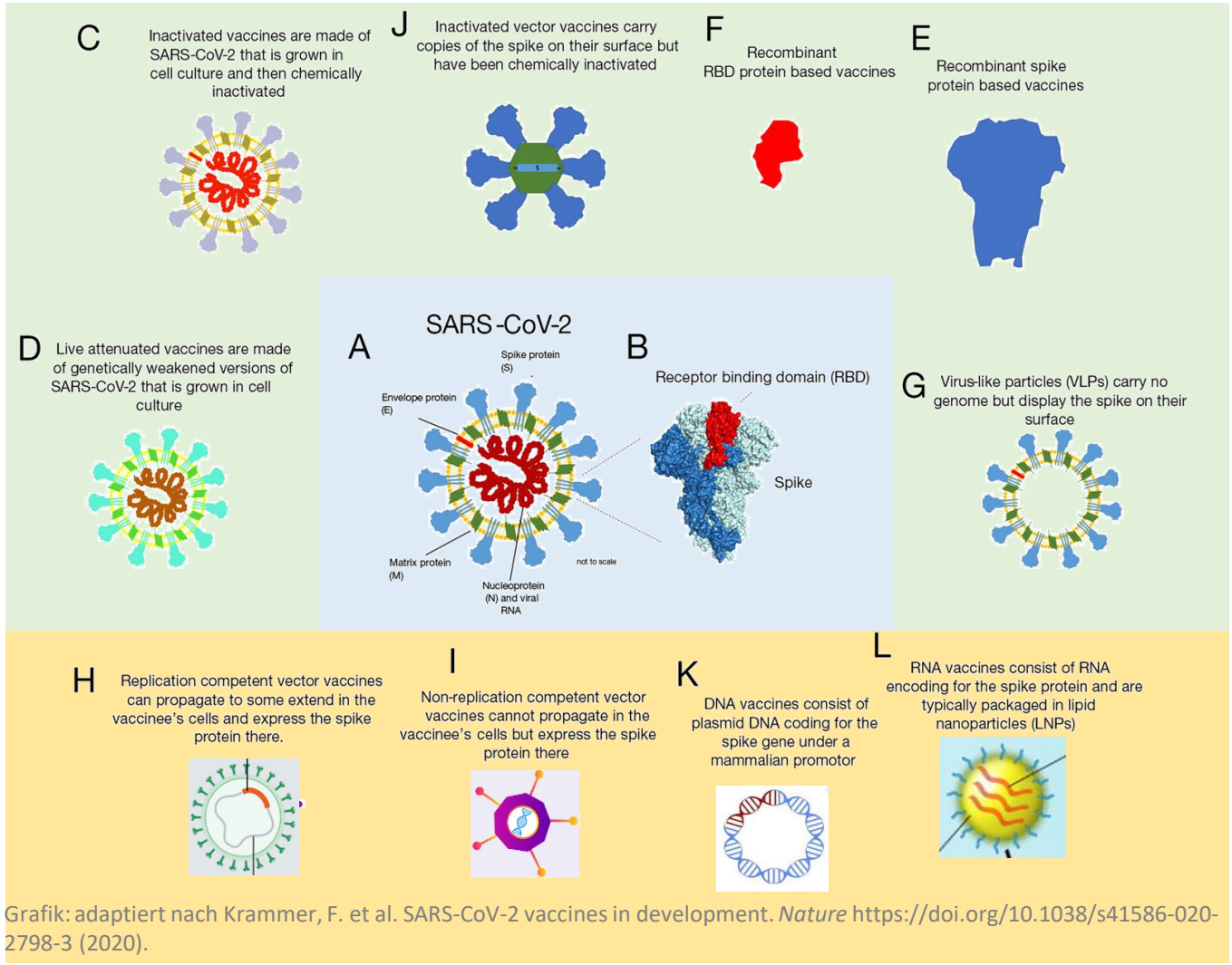




Wrobel et al. Nat Struct Mol Biol 27, 763–767 (2020). https://doi.org/10.1038/s41594-020-0468-7

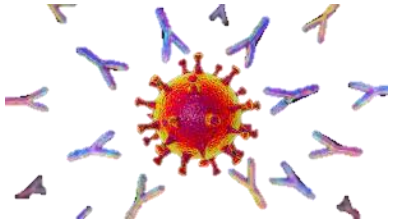
Impfstoffarten

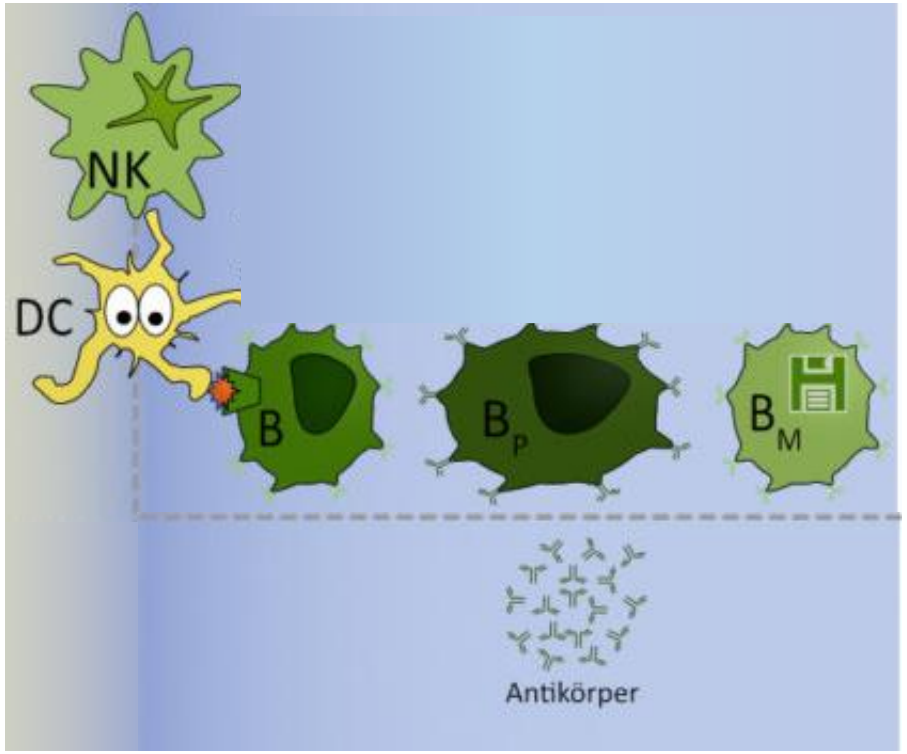
Impfstoffplattformen



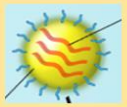
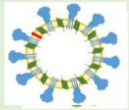
Grafik: adaptiert nach Krammer, F. et al. SARS-CoV-2 vaccines in development. *Nature* https://doi.org/10.1038/s41586-020-2798-3 (2020).

Immunsystem

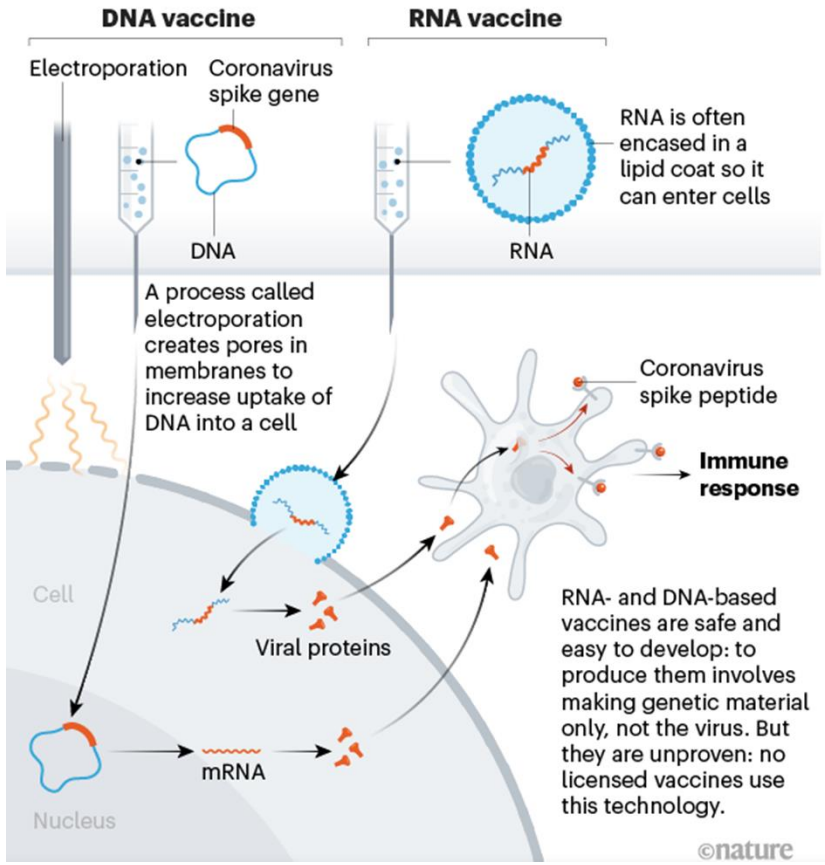




Impfstoffentwicklung – Plattformen

Platform	inactivated	RNA	DNA	non-repl. viral vector	replicating viral vector	Protein subunit	Virus like particle VLP
							

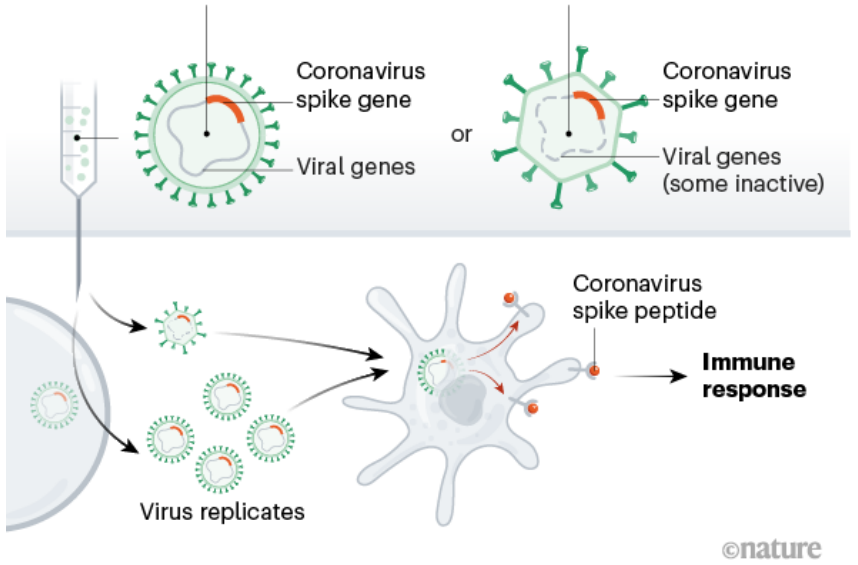
NUCLEIC-ACID VACCINES



VIRAL-VECTOR VACCINES

Replicating viral vector (such as weakened measles)
The newly approved Ebola vaccine is an example of a viral-vector vaccine that replicates within cells. Such vaccines tend to be safe and provoke a strong immune response. Existing immunity to the vector could blunt the vaccine's effectiveness, however.

Non-replicating viral vector (such as adenovirus)
No licensed vaccines use this method, but they have a long history in gene therapy. Booster shots can be needed to induce long-lasting immunity. US-based drug giant Johnson & Johnson is working on this approach.



Impfstoffentwicklung – Plattformen

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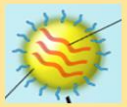
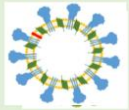
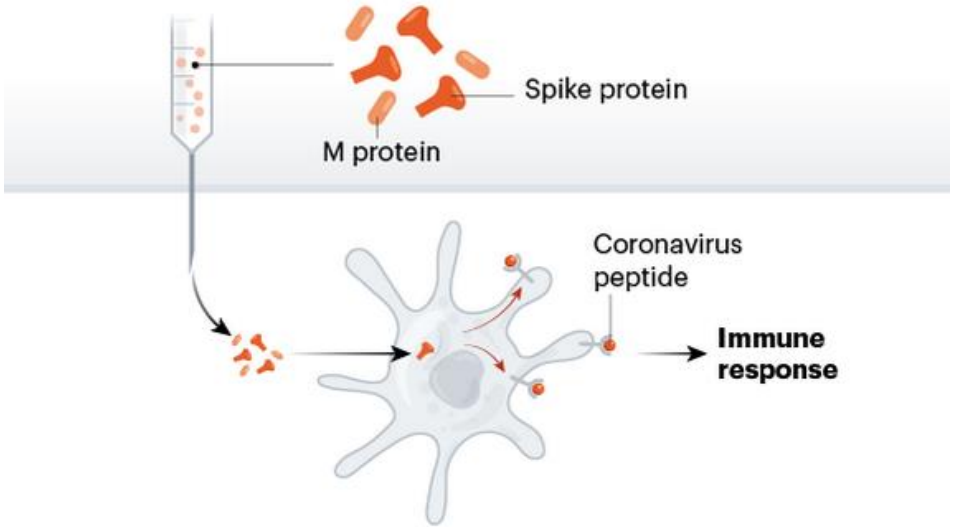
							

PROTEIN-BASED VACCINES

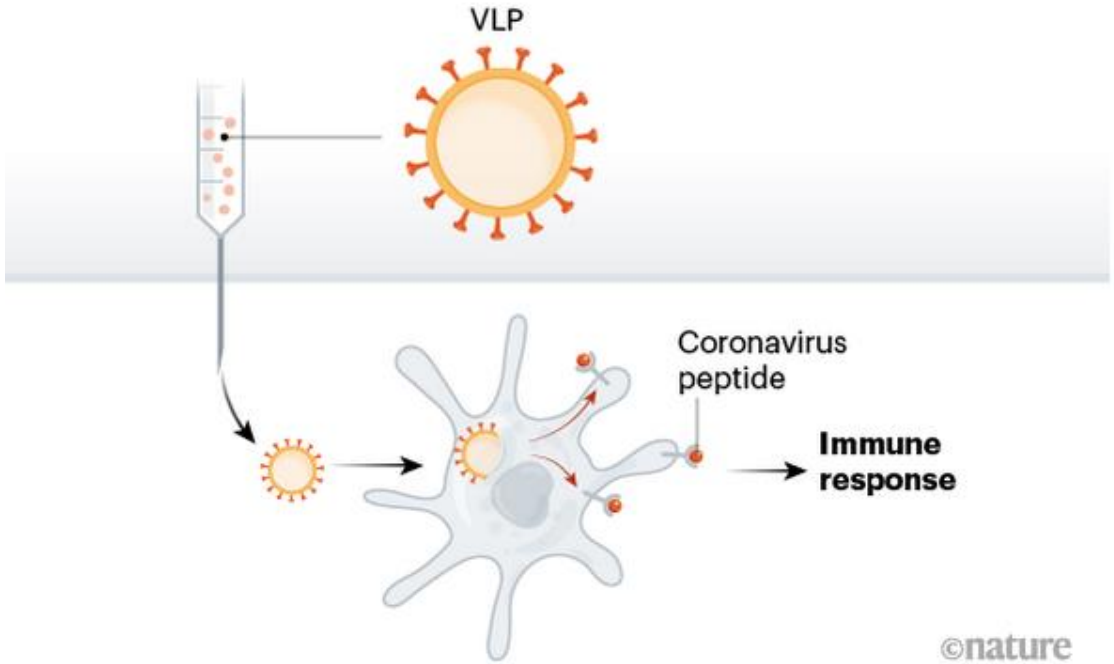
Protein subunits

Twenty-eight teams are working on vaccines with viral protein subunits — most are focusing on the virus's spike protein or a key part of it called the receptor binding domain. Similar vaccines against the SARS virus protected monkeys against infection but haven't been tested in people. To work, these vaccines might require adjuvants — immune-stimulating molecules delivered alongside the vaccine — as well as multiple doses.



Virus-like particles

Empty virus shells mimic the coronavirus structure, but aren't infectious because they lack genetic material. Five teams are working on 'virus-like particle' (VLP) vaccines, which can trigger a strong immune response, but can be difficult to manufacture.



WHO - Novel Coronavirus Landscape Stand 30.4.2021

World Health Organization

R&DBlueprint
Powering research to prevent epidemics

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

Freitag, 30. April 2021

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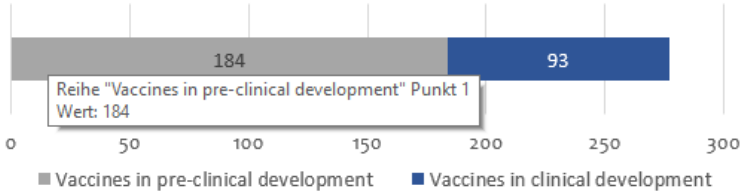
Summary Information on Vaccine Products in Clinical Development

1. - Number of vaccines in clinical development 93

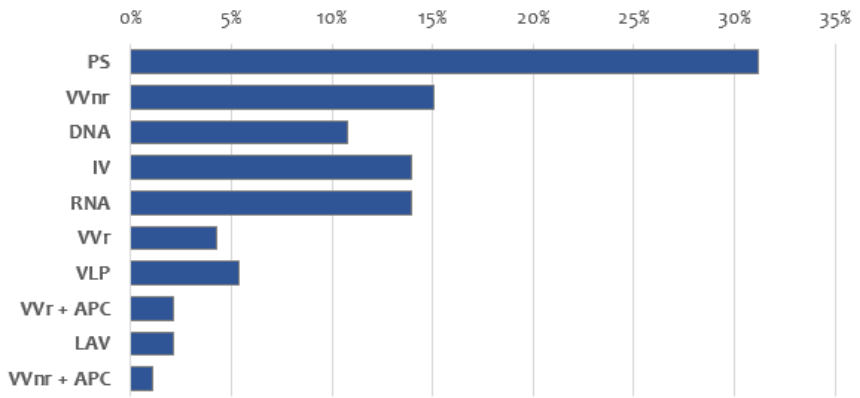
2. - Number of vaccines in pre-clinical development 184



3. - Candidates in clinical phase

Filter: All — Select phase of development (default is all)

Platform		Candidate vaccines (no. and %)	
PS	Protein subunit	29	31%
VVnr	Viral Vector (non-replicating)	14	15%
DNA	DNA	10	11%
IV	Inactivated Virus	13	14%
RNA	RNA	13	14%
VVr	Viral Vector (replicating)	4	4%
VLP	Virus Like Particle	5	5%
VVr + APC	VVr + Antigen Presenting Cell	2	2%
LAV	Live Attenuated Virus	2	2%
VVnr + APC	VVnr + Antigen Presenting Cell	1	1%
		93	



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

COVID-19-Impfstoffe in EU zugelassen

Comirnaty
BioNTech/Pfizer

2 Teilimpfungen

mRNA

COVID 19 Vaccine
Moderna

2 Teilimpfungen

mRNA

Vaxzevria
Astra Zeneca

2 Teilimpfungen

Schimpansen-
Adenovektor

Janssen COVID 19
Johnson&Johnson

1 Teilimpfung

Adeno-26-Vektor

Empfehlungen

Impfung nach Infektion:

medizinisch nicht notwendig, aber bei Impfstoffknappheit bitte um 6 Monate verschieben

Bei Personen, bei denen eine Infektion durch PCR oder neutralisierende Antikörper gegen SARS-CoV-2 gesichert wurde (Neutralisationstests/entsprechende NT-Korrelate)), ist eine einmalige Impfung ausreichend (off label). Dies entspricht immunologisch gesehen einer Boosterung.

Impfabstände / Überschreitung von Impfabständen

ACHTUNG: Auf Grund der momentanen epidemiologischen Situation in der Pandemie wird empfohlen, die Impfintervalle bei den beiden verfügbaren mRNA-Impfstoffen auszudehnen: Die Zweitimpfung soll in der 6. Woche nach erfolgter Erstimpfung stattfinden. Ab dem 22. Tag nach der 1. Dosis ist bei allen verfügbaren Impfstoffen mit Beginn einer gewissen Schutzwirkung zu rechnen.

Impfstoff	Dosen pro Vial	Empfohlenes Intervall (mögliches Intervall) und Anzahl notwendiger Dosen	mL pro Dosis	Rekonstitution
Comirnaty BioNTech/Pfizer, mRNA-Impfstoff	6	6 Wochen (19-42 Tage), 2 Dosen	0,3 mL	1,8 mL NaCl (0,9%)/Vial
COVID-19 Vaccine Moderna, mRNA-Impfstoff	10	6 Wochen (21-42 Tage), 2 Dosen	0,5 mL	Keine
COVID-19 Vaccine AstraZeneca Vektorimpfstoff	10	11-12 Wochen (28 bis 84 Tage) 2 Dosen	0,5 mL	Keine
COVID-19 Vaccine Janssen Vektorimpfstoff	5	1 Dosis	0,5 mL	Keine

VITT Vaccine-induced Immune Thrombotic Thrombocytopenia

Auftreten von Thrombosen im Zusammenhang mit einer COVID-19 - Impfung

Vaccine-Induced Immune Thrombotic Thrombocytopenia (**VITT**)

Empfehlungen zur Diagnostik und Therapie (Stand: 12.4.2021), auf Anregung des österreichischen nationalen Impfgremiums

Verfasser: S. Eichinger, P.A. Kyrle, I. Pabinger, P. Quehenberger (in alphabetischer Reihenfolge); Klinische Abteilung für Hämatologie und Hämostaseologie und Klinisches Institut für Labormedizin, Medizinische Universität Wien

Auftreten: 5 – 20 Tage nach Impfung

- Kopfschmerzen, Schwindel, Übelkeit/Erbrechen, Sehstörungen, Lähmungserscheinungen (Vd.auf Hirnvenenthrombose/Insult)
- Schmerzen im Abdomen, Übelkeit/Erbrechen (Vd. Auf abdominelle Thrombose)
- Kurzatmigkeit, Thoraxschmerz (Vd. auf Lungenembolie)
- Schmerzen, Schwellung in einem Bein/Arm (Vd. auf Bein/Armvenenthrombose)
- Schmerzen, Kältegefühl in einer Extremität (Vd. auf arterielle Thrombose)

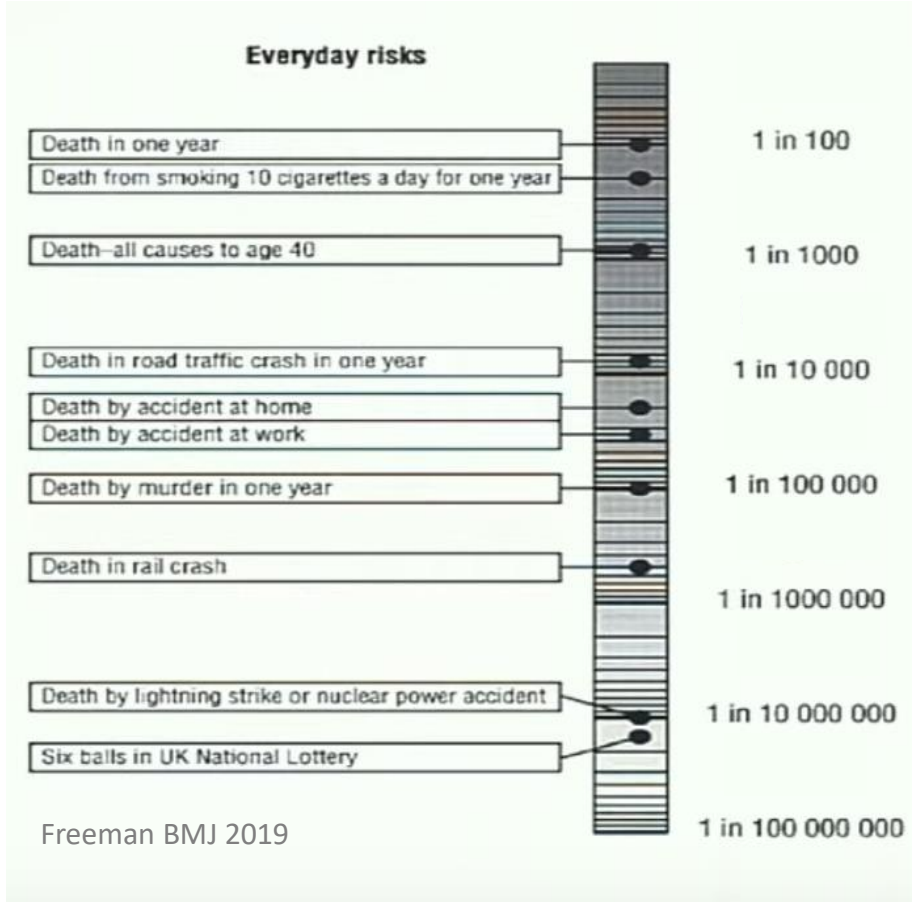
Wahrscheinlichkeit nach Erstimpfung: 1:100.000
9 CVST bei 10 Millionen Zweitimpfungen mit AZ

Wahrscheinlichkeit einer CSVT nach COVID19: 39 pro 1.000.000

Table 2: Some Risks for Average Americans Annually and Over a Lifetime

Risk	Annual	Lifetime
You will die of heart disease.	1:340	1:3
You will die of cancer.	1:500	1:5
You will die in an automobile accident.	1:5,000	1:45
You will be murdered.	1:11,000	1:93
You will die from AIDS.	1:11,000	1:97
You will die in an airplane crash.	1:250,000	1:4,000

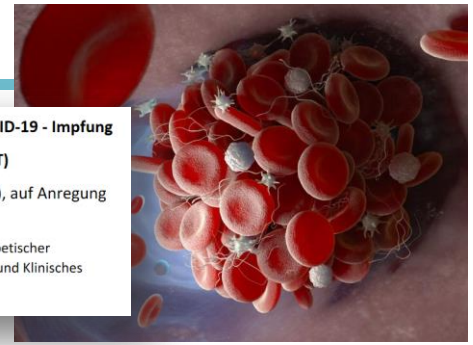
Adapted from L. Laudan, *The Book of Risks: Fascinating Facts about the Chances We Take Every Day*, 1994.



Freeman BMJ 2019

https://www.oegho.at/aktuelles/aktuelles/news-detail/empfehlungen-zur-diagnostik-und-therapie-astra-zeneca-impfung-209/

VITT Vaccine-induced Immune Thrombotic Thrombocytopenia



Auftreten von Thrombosen im Zusammenhang mit einer COVID-19 - Impfung

Vaccine-**I**nduced Immune Thrombotic **T**hrombocytopenia (**VITT)**

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Hintergrund

- Sehr selten
- Vermehrt (aber nicht ausschließlich) Frauen (< 60 Jahre) betroffen
- Tritt zwischen 5 und 20Tagen nach der Impfung auf
- PatientInnen mit früheren Thrombosen und/oder Thrombophilie nicht häufiger betroffen

Anmerkung: Grippeähnliche Symptome während der ersten 2 Tage nach der Impfung sind häufig und für VIPIT nicht typisch.

Pathomechanismus

- Antikörperbildung gegen Plättchenfaktor 4 (PF 4); Immunkomplexe aktivieren über den Fc-Rezeptor die Thrombozyten; Mechanismus ähnlich der heparininduzierten Thrombozytopenie (HIT), aber ohne vorherige Heparinexposition.
- Massive Aktivierung der Thrombozyten führt zur Aktivierung der plasmatischen Gerinnung mit Zeichen der Verbrauchskoagulopathie (Thrombozytopenie, hohes D-Dimer, vermindertes Fibrinogen)

https://www.oegho.at/aktuelles/aktuelles/news-detail/empfehlungen-zur-diagnostik-und-therapie-astra-zeneca-impfung-209/

Astra Zeneca – prime boost interval

Bessere VE bei längerem Impfintervall
Empfehlung zwischen 1. und 2. Impfung: 12 Wochen

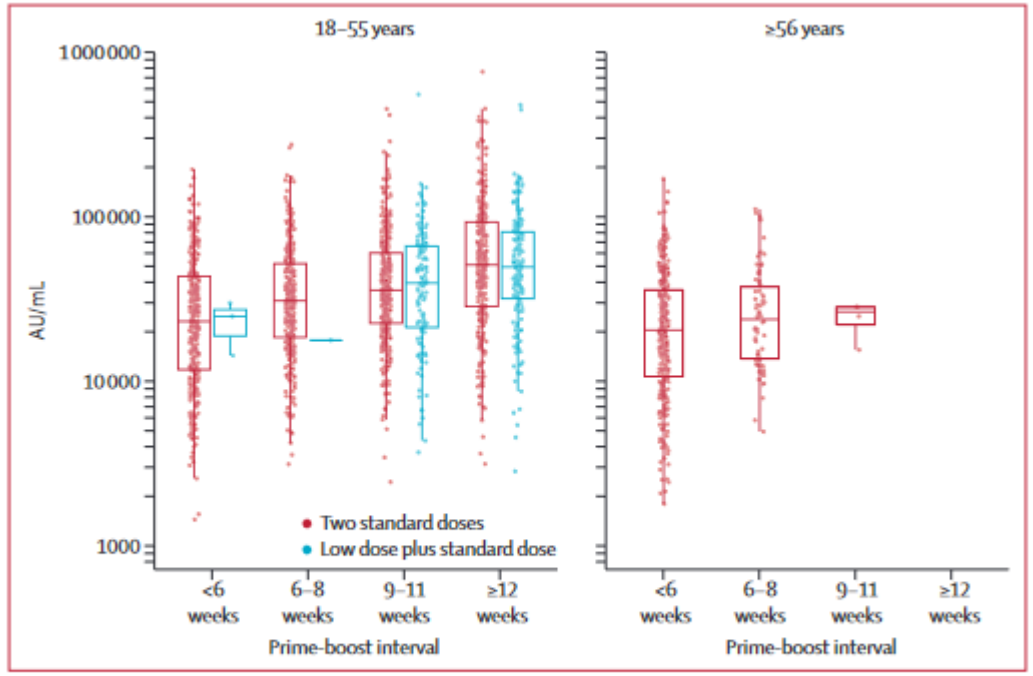


Figure 3: **Anti-SARS-CoV-2 spike IgG responses by multiplex immunoassay at 28 days after the second dose in participants receiving two standard doses or low dose plus standard dose, by prime-boost interval (n=3337)**

Voysey M. et al , Lancet, Vol 397 March 6, 2021

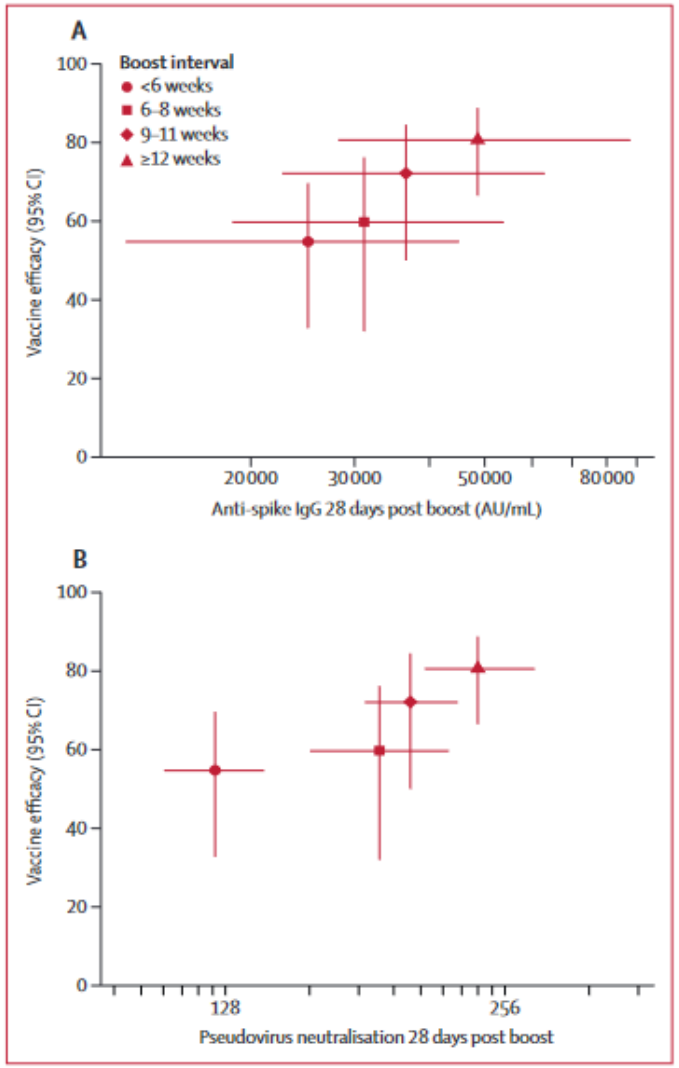


Figure 4: **Relationship between binding and neutralising antibody 28 days after second dose, and vaccine efficacy against primary symptomatic COVID-19**

Janssen / Johnson & Johnson

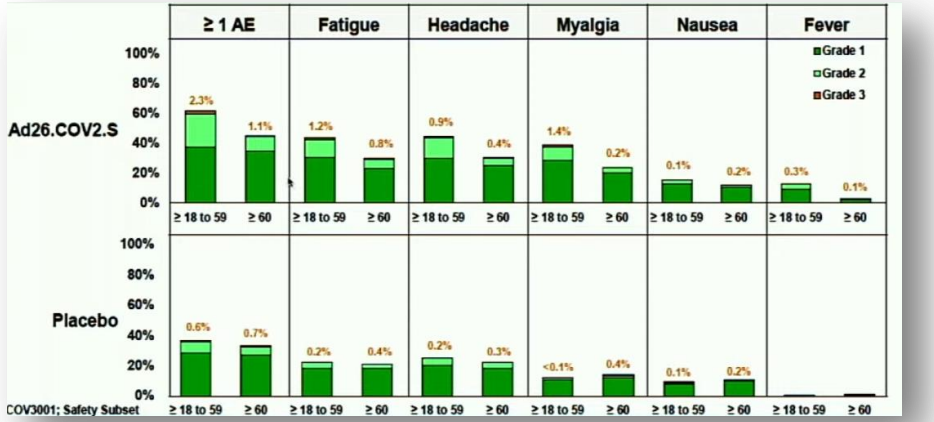
Adenovirus 26 Vektorimpfstoff

Seroprävalenz: global: 5-18%
Afrika: 43-67%

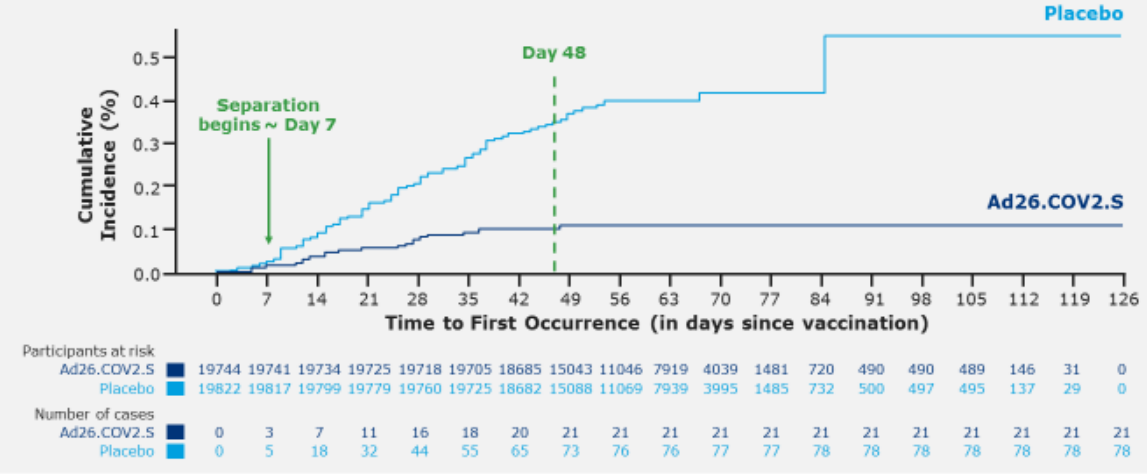
Zulassungsstudien: ca. 44.000 Teilnehmer

Vergleichbar mit allen anderen Adenovirus basierten Impfstoffen,

1 malige Gabe !!



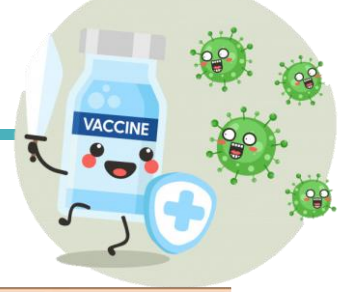
Time to first occurrence of severe/critical COVID-19 demonstrates early onset of protection



COV3001; Full analysis set. Baseline seronegative. Confirmed: positive PCR centrally confirmed COVID-19 cases
VRBPAC - Ad26.COV2.S Sponsor Briefing document. Available at: https://www.fda.gov/media/146219/download. Accessed March 2021.

janssen | Johnson&Johnson 37

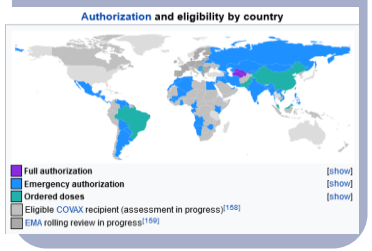
COVID-19-Impfstoffe – kommend?



Sputnik

Adenovektor 5/26

Zul. beantragt



Sputnik V (in Zulassung)

Replikationsdefizienter Adenovirus Vektor

Erstimpfung: Ad26 Vektor
Zweitimpfung: Ad5 Vektor

Dadurch wird Problem der impfinduzierten Vektorimmunität umgangen

	Total cases	Vaccine group	Placebo group	Vaccine efficacy (95% CI)	p value
First COVID-19 occurrence from 21 days after dose 1 (day of dose 2)*					
Overall	78	16/14 964 (0·1%)	62/4902 (1·3%)	91·6% (85·6–95·2)	<0·0001
Age group (years)					
18–30	5	1/1596 (0·1%)	4/521 (0·8%)	91·9% (51·2–99·3)	0·0146
31–40	17	4/3848 (0·1%)	13/1259 (1·0%)	90·0% (71·1–96·5)	<0·0001
41–50	19	4/4399 (0·1%)	15/1443 (1·0%)	91·3% (73·7–96·9)	<0·0001
51–60	27	5/3510 (0·1%)	22/1146 (1·9%)	92·7% (81·1–97·0)	<0·0001
>60	10	2/1611 (0·1%)	8/533 (1·5%)	91·8% (67·1–98·3)	0·0004
Sex					
Female	32	9/5821 (0·2%)	23/1887 (1·2%)	87·5% (73·4–94·2)	<0·0001
Male	46	7/9143 (0·1%)	39/3015 (1·3%)	94·2% (87·2–97·4)	<0·0001
Moderate or severe cases	20	0/14 964	20/4902 (0·4%)	100% (94·4–100·0)	<0·0001
First COVID-19 occurrence after dose 1†					
Any time after dose 1	175	79/16 427 (0·5%)	96/5435 (1·8%)	73·1% (63·7–80·1)	<0·0001
From 14 days after dose 1	109	30/14 999 (0·2%)	79/4950 (1·6%)	87·6% (81·1–91·8)	<0·0001
First COVID-19 occurrence after dose 2 (28 days after dose 1)*					
All	60	13/14 094 (0·1%)	47/4601 (1·0%)	91·1% (83·8–95·1)	<0·0001

ta are n/N (%), unless otherwise stated. *Includes those who received both doses. †Includes participants who

Logunuv et al, Lancet 2021

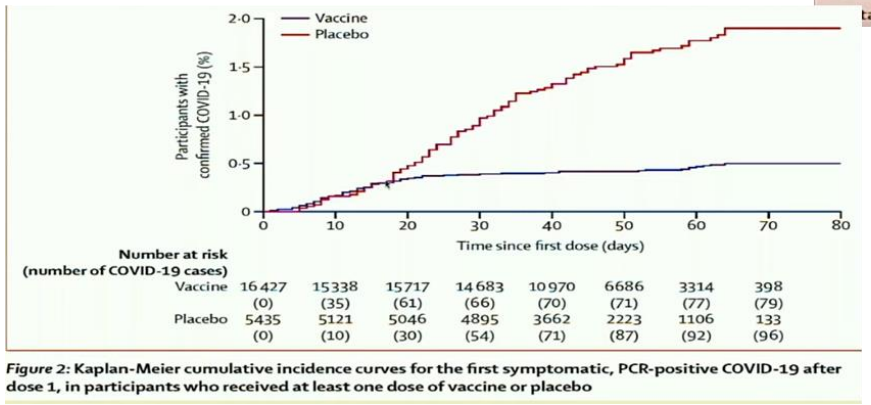
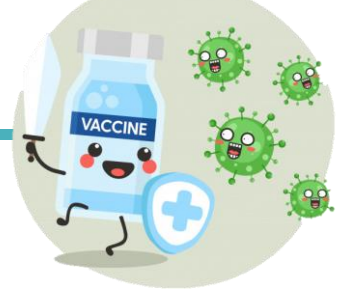


Figure 2: Kaplan-Meier cumulative incidence curves for the first symptomatic, PCR-positive COVID-19 after dose 1, in participants who received at least one dose of vaccine or placebo

COVID-19-Impfstoffe – kommend?



Sputnik

Adenovektor 5/26

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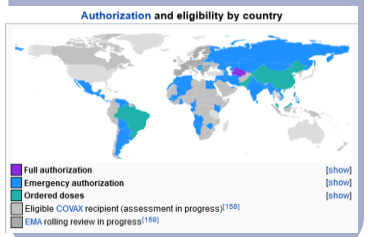
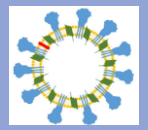




Novavax

Protein Subunit, VLP

M1 Adjuvans

im Rolling Review

Pressemitteilung

89,3% Wirksamkeit

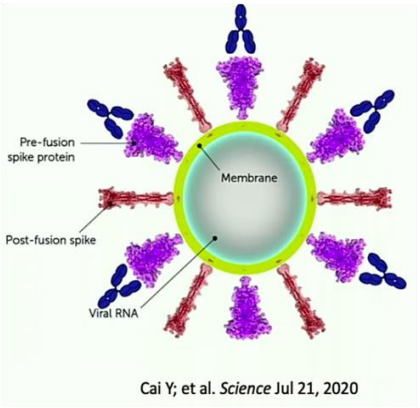
Novavax

Rekombinante Nanopartikel Vakkzine = Subunit Vaccine

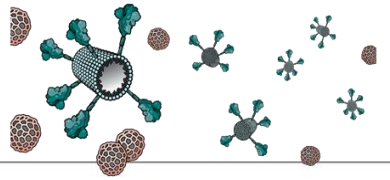
Produziert in Insektenzellen
27nm Nanopartikel, Matrix M Adjuvant

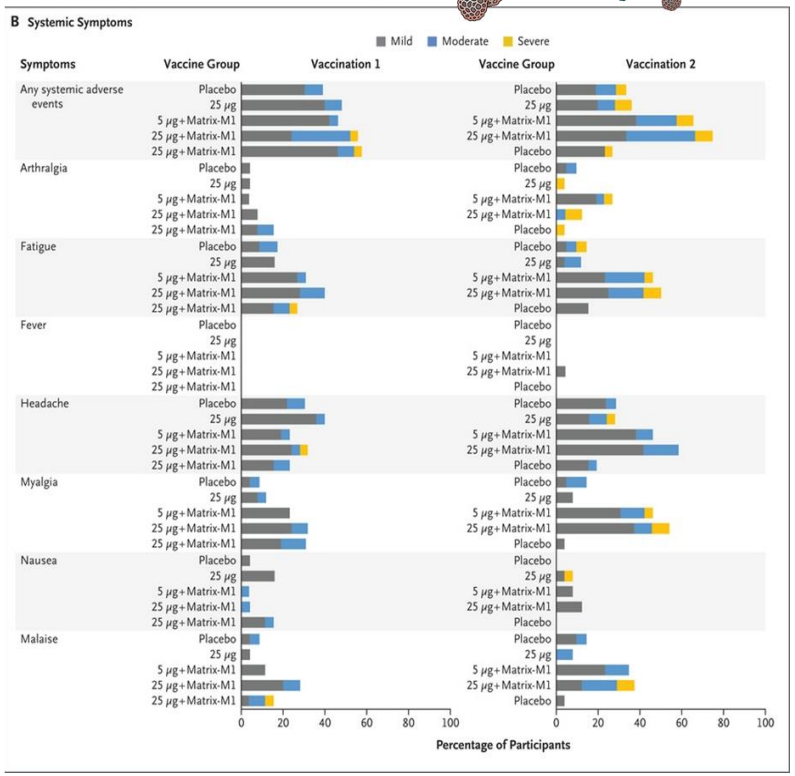
Mutationen eingebaut um die Präfusionsform zu stabilisieren

VE: ca. 95%
Gegen SA-Variante 60%

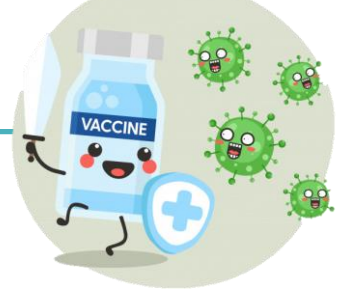


Cai Y; et al. *Science* Jul 21, 2020





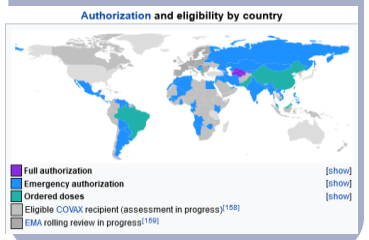
COVID-19-Impfstoffe – kommend?

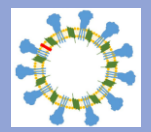


Sputnik

Adenovektor 5/26

Zul. beantragt





Novavax

Protein Subunit, VLP

M1 Adjuvans

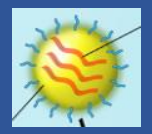
im Rolling Review

Pressemitteilung

89,3% Wirksamkeit

CureVac

the RNA people®

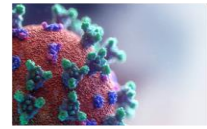


CureVac

mRNA

Seit 12.2.2021 im Rolling Review

Curevac



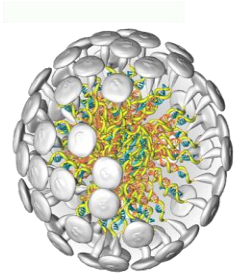
mRNA Impfung

Phase 2b/3 Studie im Dezember 2020 gestartet

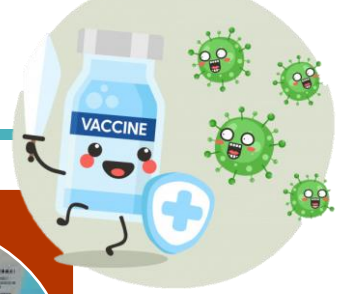
Insgesamt 35.000 Teilnehmer in Europa und Lateinamerika

CUREVAC

the RNA people®



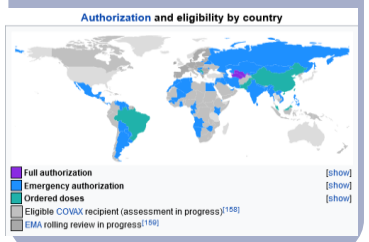
COVID-19-Impfstoffe – kommend?



Sputnik

Adenovektor 5/26

Zul. beantragt



Novavax

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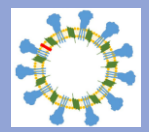
im Rolling Review

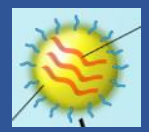
Pressemitteilung 89,3% Wirksamkeit



CureVac

mRNA

Seit 12.2.2021 im Rolling Review

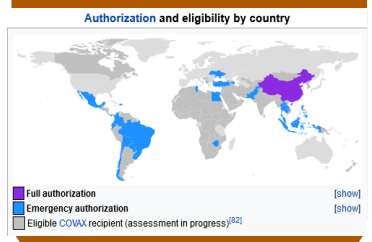


Sinovac

Totimpfstoff

Mitte Januar, Brasilien Effektivität 50%

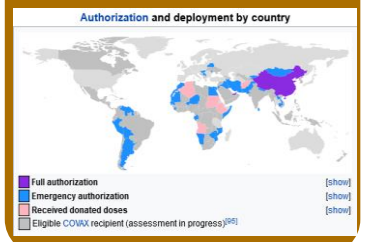
keine PhIII Studien



Sinopharm

Totimpfstoff

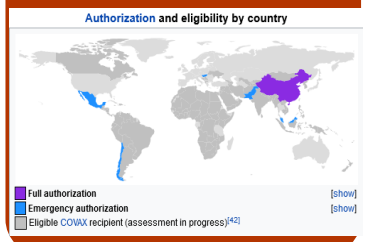
Seit 30.12.2020 in China zugelassen



CanSino

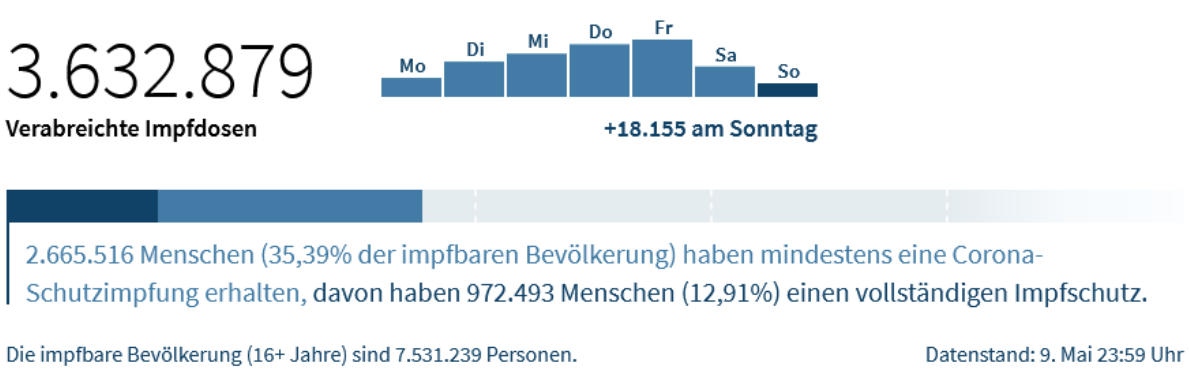
Ad5 Vektor

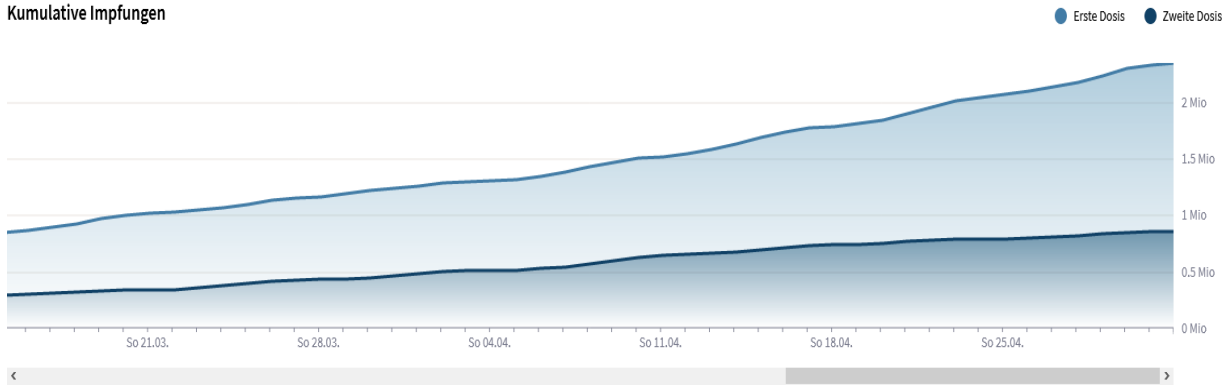
In China seit 25.6.2020 an Militär ohne PhIII Studie verwendet



Überblick über die in Österreich zugelassenen Impfstoffe:

Impfstoff	Firma	Plattform	Anzahl gelieferter Dosen (Stand 2.5.2021)
Comirnaty	BioNTech/Pfizer	mRNA Impfstoff	3.043.755
Covid-19 Vaccine	Moderna	mRNA Impfstoff	511.200
Vaxzevria	Astra Zeneca	Schimpansen Adenovektor	1.138.400
Covid-19 Vaccine	Janssen/ Johnson&Johnson	Adeno 26 Vektor	46.800





Daten: info.gesundheitsministerium.at Stand 09.05.2021

Bundesministerium Soziales, Gesundheit, Pflege und Konsumentenschutz

Österreichische Sozialversicherung

Antigendrift - Escapemutation - Variantenentstehung

Antigendrift: z.B. Influenza

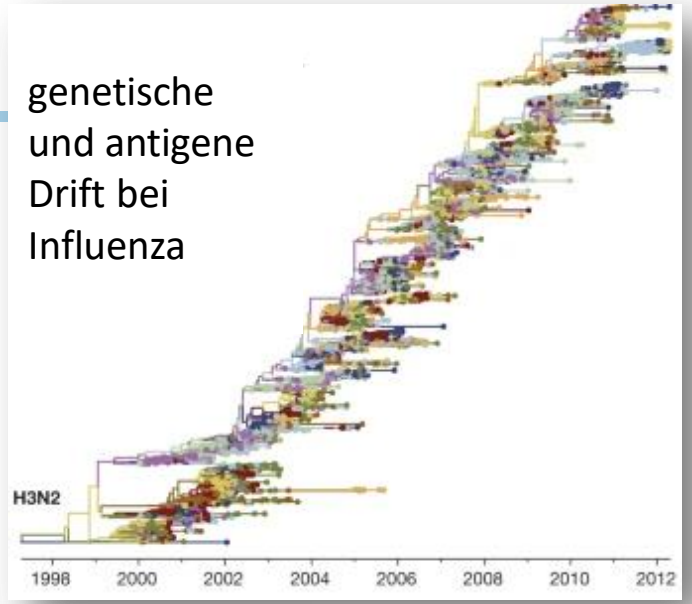
Mutationen führen ständig zu kleinen Änderungen bis die Summe der Veränderungen einen sprunghafte Änderung der antigenen Eigenschaften bewirken → Änderung der antigenen Eigenschaften durch Vorhandensein präformierter AK→ positiver Selektionsdruck

positive Selektion durch immunologischen Druck beeinflusst

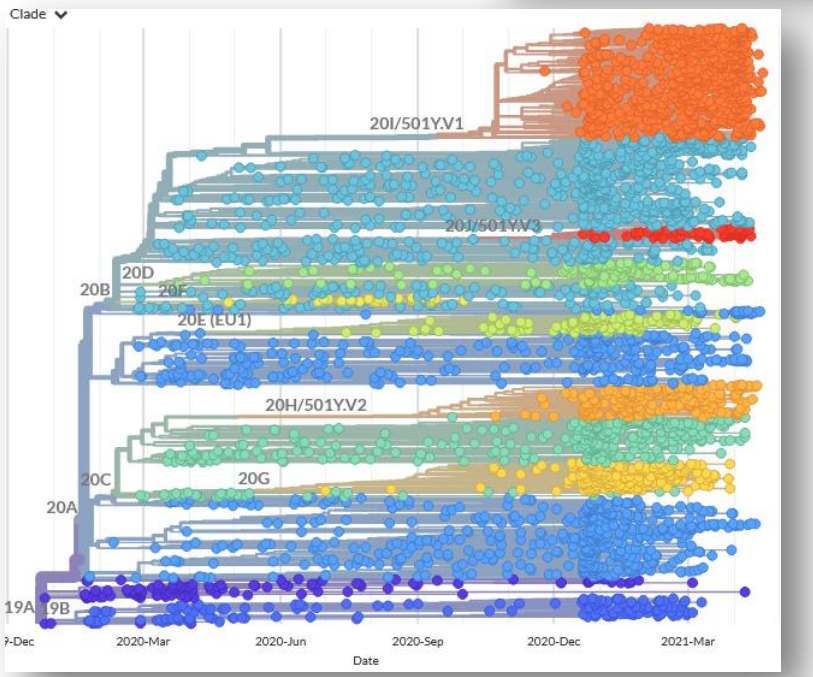
Escapemutation:

Escapemutanten werden von präformierten AK (z.B. nach einer Impfung) schlechter gebunden → Selektionsvorteil durch zufällige Mutation

Variantenentstehung bei SARS CoV 2: Mutationen durch fehlerhafte Replikation → Mutationen an Prädilektionsstellen führen zu erhöhter Fitness der Viren!!!



genetische und antigene Drift bei Influenza



Phylogenetische Entwicklung des SARS-CoV-2

Bedford et al, Nature 523, 217–220 (2015). https://doi.org/10.1038/nature14460
and https://nextstrain.org/ncov/global

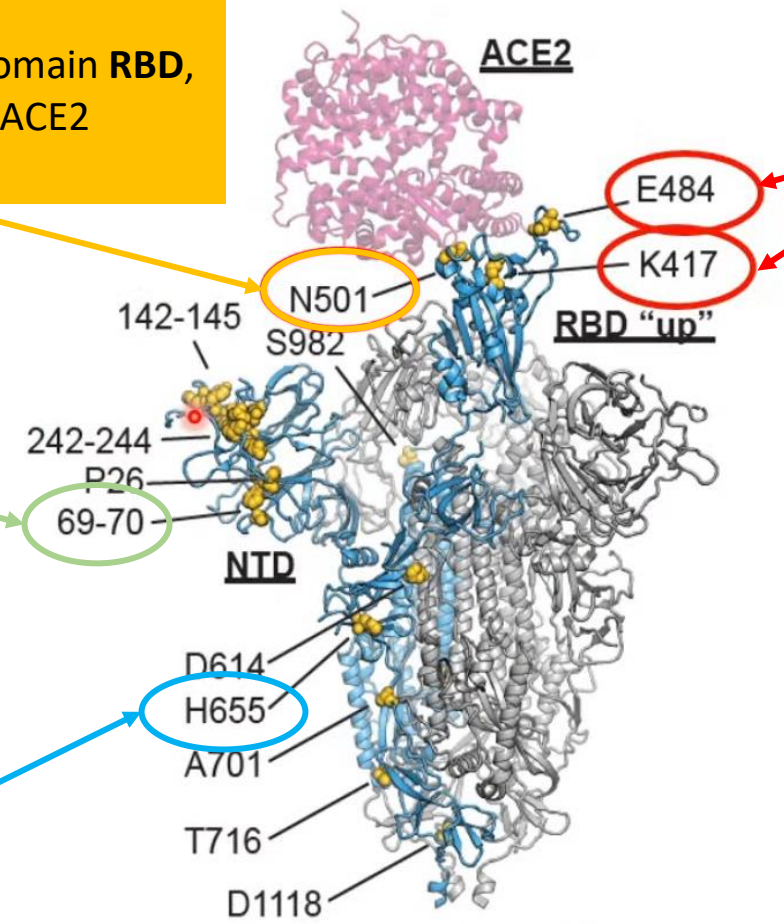
Variantenentstehung bei SARS CoV 2

Mutationen durch fehlerhafte Replikation → Mutationen an Prädilektionsstellen führen zu erhöhter Fitness der Viren!!!

N501Y:
Receptor Binding Domain **RBD**,
bessere Affinität zu ACE2
↑ viral entry

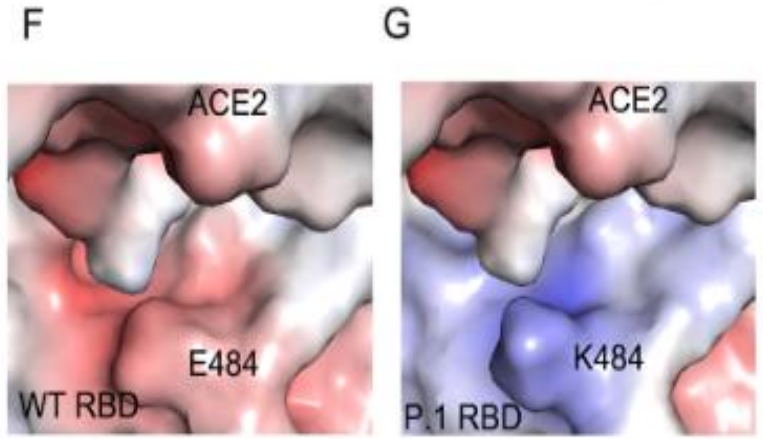
del 69/70:
AK Bindungsstelle,
für AK Bdg 6 AA nötig,
Noch viele weitere AK-Bindungsstellen am S- Protein

D614G, P618H, usw:
Furin Cleavage site
bessere Aktivierung von TMPRSS 2 → ↑ viral entry



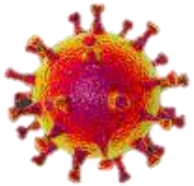
Adaptiert von Goran Bajic

E484K und K417T/N:
Receptor Binding Motif **RBM,**
Bessere Affinität zu ACE 2
↑ viral entry

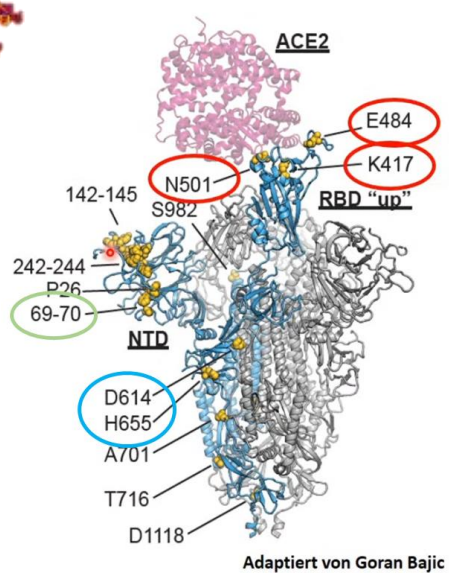


Wanwisa Dejnirattisai et al. bioRxiv preprint https://doi.org/10.1101/2021.03.12.435194doi:

Auswirkungen der SARS CoV 2 Mutationen



Virus

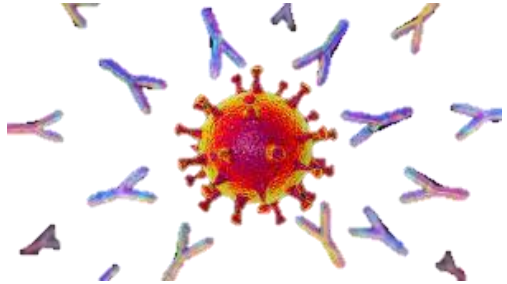


Folgen von ↑ viral entry:

- ↑ virale Replikation
- ↑ virale Infektion (Nachbarzellen)
- ↑ virale Produktion
- ↑ Viruslast

→ **Bessere Virustransmission**

Immunsystem



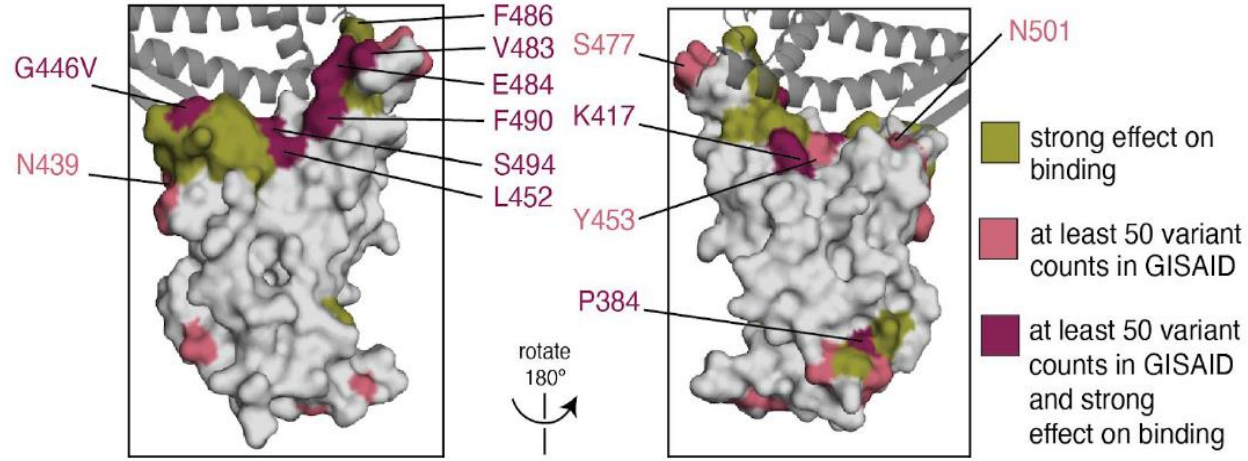
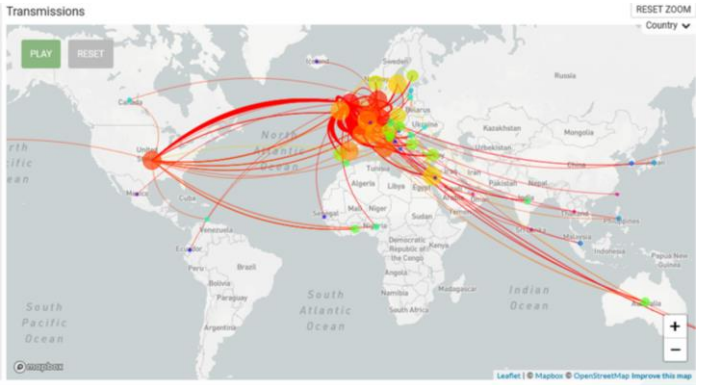


Figure 6. Frequencies of mutations that affect serum antibody binding among circulating SARS-CoV-2

bioRxiv preprint doi: https://doi.org/10.1101/2020.12.31.425021;

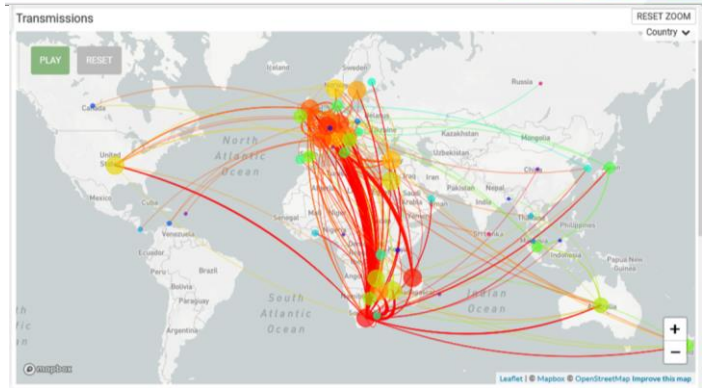
→ **Escape mutation**

Virusvarianten – Mutationen



Britische Variante: B.1.1.7:

Del 69/70 N501Y



Südafrikanische Variante: B.1.351:

N501Y E484K K417N

Brasilianische Variante: P 1

N501Y E484K K417T

Indische Variante: B.1.617:

E484Q L452R

Mutationen und Wirksamkeit der Impfungen

Wanwisa Dejnirattisai et al. bioRxiv preprint https://doi.org/10.1101/2021.03.12.435194doi:

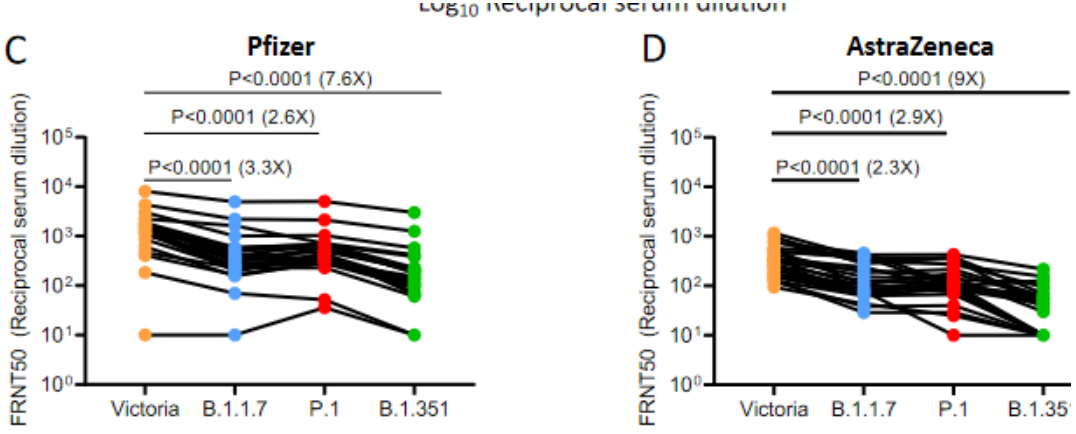


Table 1. Summary Results on SARS-CoV-2 Vaccine Trial Efficacy and Viral Neutralization of the B.1.1.7, P.1, and 501Y.V2 Variants, as Compared with Preexisting Variants.*

Vaccine (Company)	Preexisting Variants			Neutralization by Pseudovirion or Live Viral Plaque Assay			Efficacy in Settings with 501Y.V2 Variant
	Sample Size	Efficacy in Preventing Clinical Covid-19	Efficacy in Preventing Severe Covid-19	B.1.1.7 Variant	P.1 Variant	501Y.V2 Variant	
	no.	*% (no. of events with vaccine vs. placebo)*					%
Ad26.COV2.S (Johnson & Johnson)	43,783	66 (NA)	85 (NA)	NA	NA	NA	57†, 85‡
BNT162b2 (Pfizer)	34,922	95 (8 vs. 162)	90 (1 vs. 9)	Decrease by 2×	Decrease by 6.7×	Decrease by ≤6.5×	NA
mRNA-1273 (Moderna)	28,207	94 (11 vs. 185)	100 (0 vs. 30)	Decrease by 1.8×	Decrease by 4.5×	Decrease by ≤8.6×	NA
Sputnik V (Gamaleya)	19,866	92 (16 vs. 62)	100 (0 vs. 20)	NA	NA	NA	NA
AZD1222 (AstraZeneca)	17,177	67 (84 vs. 248)	100 (0 vs. 3)	NA	NA	Decrease by ≤86× to complete immune escape	22§
NVX-CoV2373 (Novavax)	15,000	89 (6 vs. 56)	100 (0 vs. 1)	Decrease by 1.8×	NA	NA	49§
CoronaVac (Sinovac)¶							
Brazil	12,396	51 (NA)	100 (NA)	NA	NA	NA	NA
Turkey	7,371	91 (3 vs. 26)	NA	NA	NA	NA	NA
BBIBP-CorV (Sinopharm)	NA	79 (NA)	NA	NA	NA	Decrease by 1.6×	NA

* Data were available up to March 18, 2021. The definitions of mild, moderate, and severe coronavirus disease 2019 (Covid-19) vary across the vaccine trials. A list of references associated with these vaccines is provided in the Supplementary Appendix, available with the full text of this letter at NEJM.org. NA denotes not available, and SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.
† Shown is the efficacy of the vaccine, as compared with placebo, against moderate-to-severe Covid-19.
‡ Shown is efficacy of the vaccine, as compared with placebo, against severe Covid-19 and hospitalization.
§ Shown is efficacy of the vaccine, as compared with placebo, against symptomatic Covid-19.
¶ Data are shown separately for the trial sites in Brazil and Turkey.

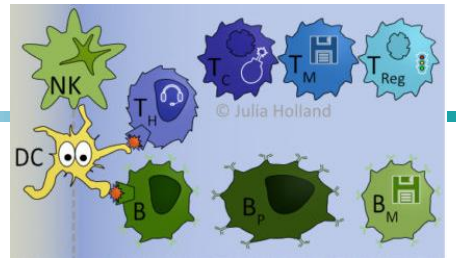
Oliveira et al, NEJM 2021

Antikörper Antwort:

Britische Variante (del 69-70, N501Y): keinen großen Einfluss auf Vaccine Efficacy (VE)

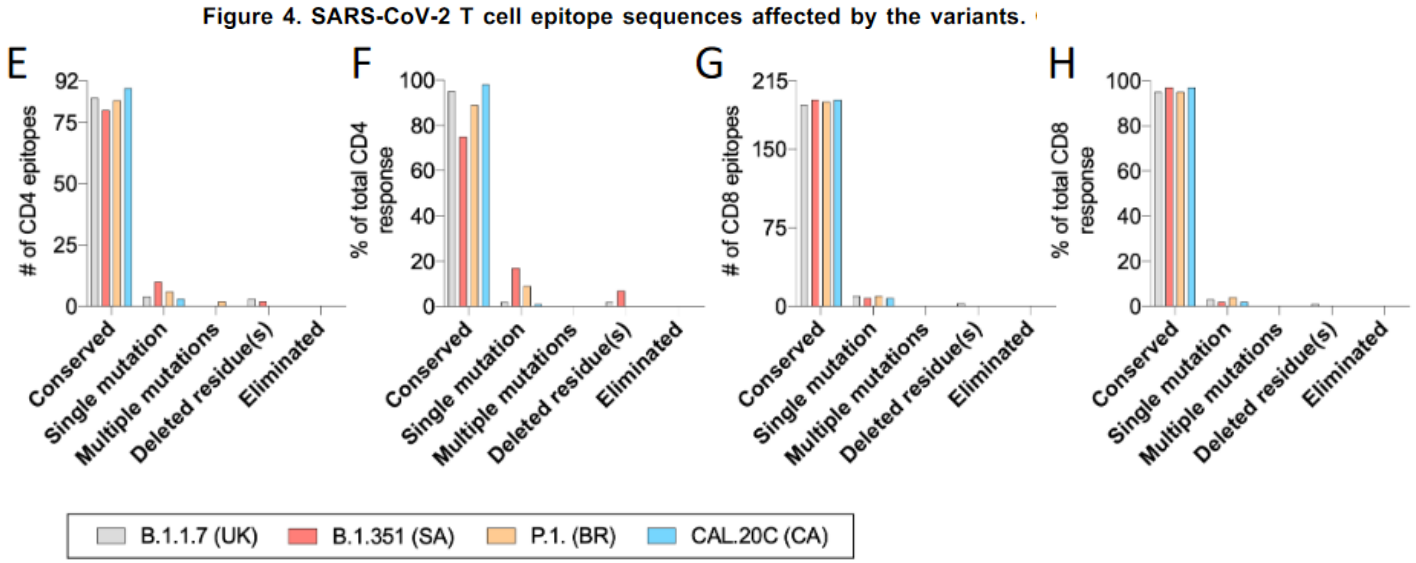
SA-Variante (N501Y, E484K, K417N) + brasilianische Variante (N501Y, E484K,K417T):
(moderater) Einfluss auf VE ausgehend vom ursprünglichen AK Spiegel

Mutationen und Wirksamkeit der Impfungen

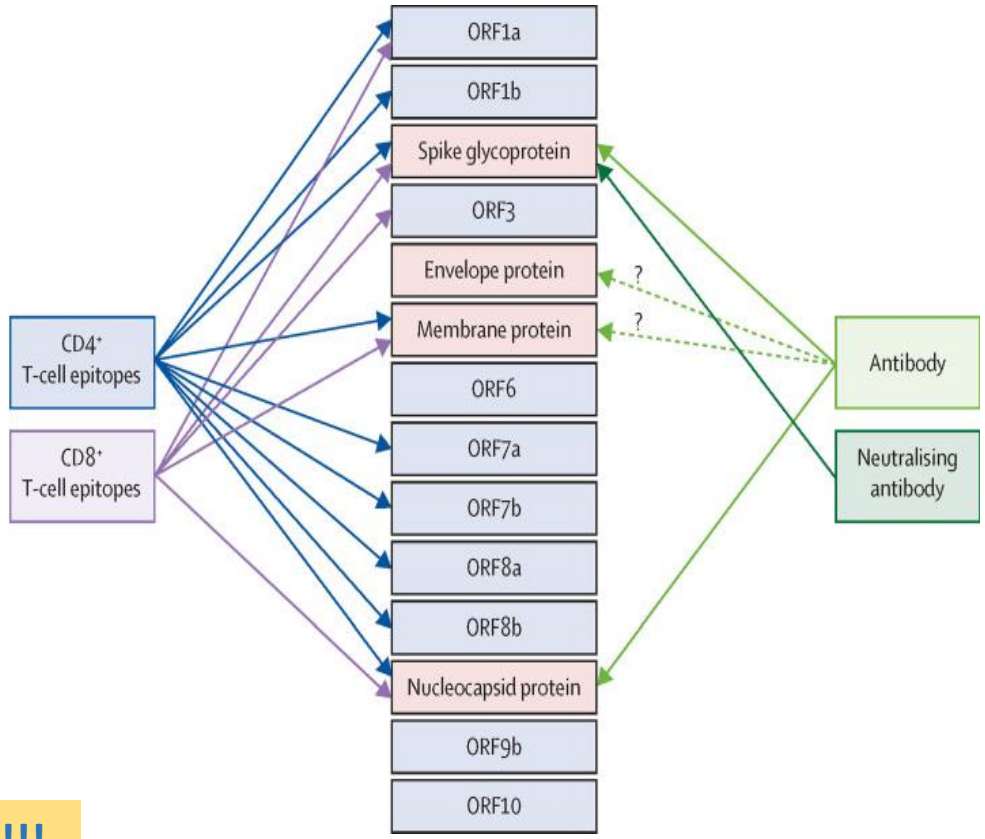


In vitro Austestungen …. Nur die halbe Wahrheit

T-Zell Antwort



Tarke et al, bioRxiv preprint https://doi.org/10.1101/2021.02.27.433180



Poland et al, Lancet. 2020 14-20 November; 396(10262): 1595–1606.

→ Real world Data über tatsächliche Feldeffektivität dringend benötigt !!!

Danke für die Aufmerksamkeit !