Medical Billing Statement
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Discharge date
Service
REIMBURSE
Currency of payment
Payment method
Payment by ch
Bank name
Branch code (BLZ, AB
BIC/SWIFT code
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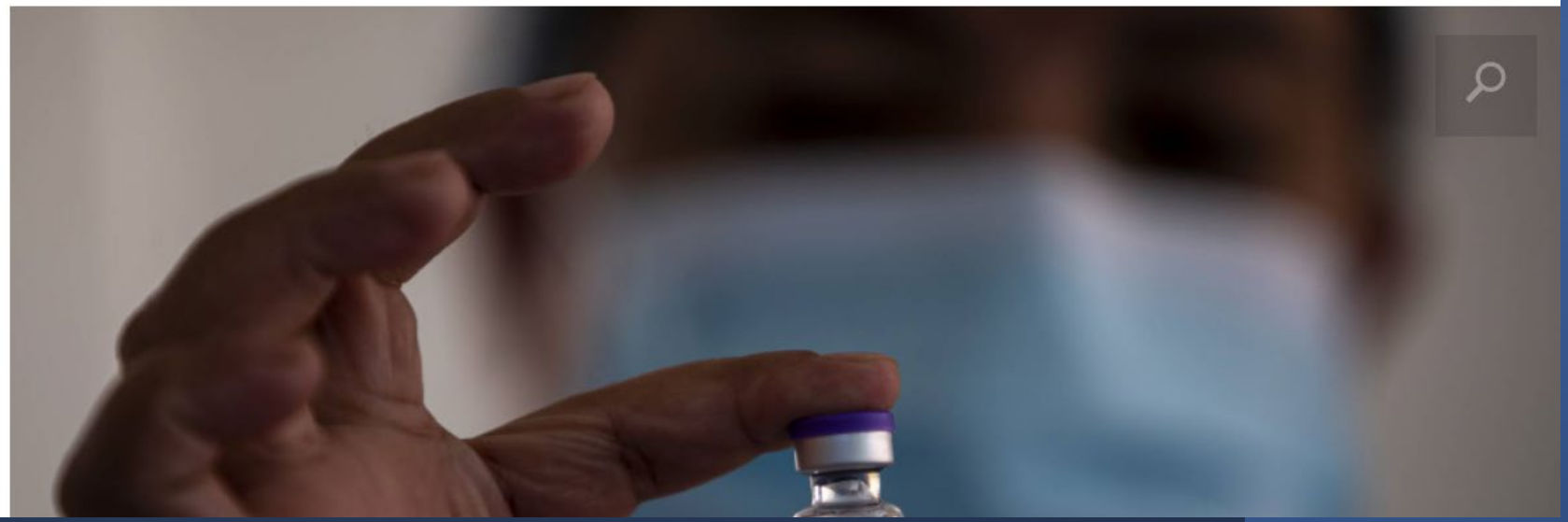
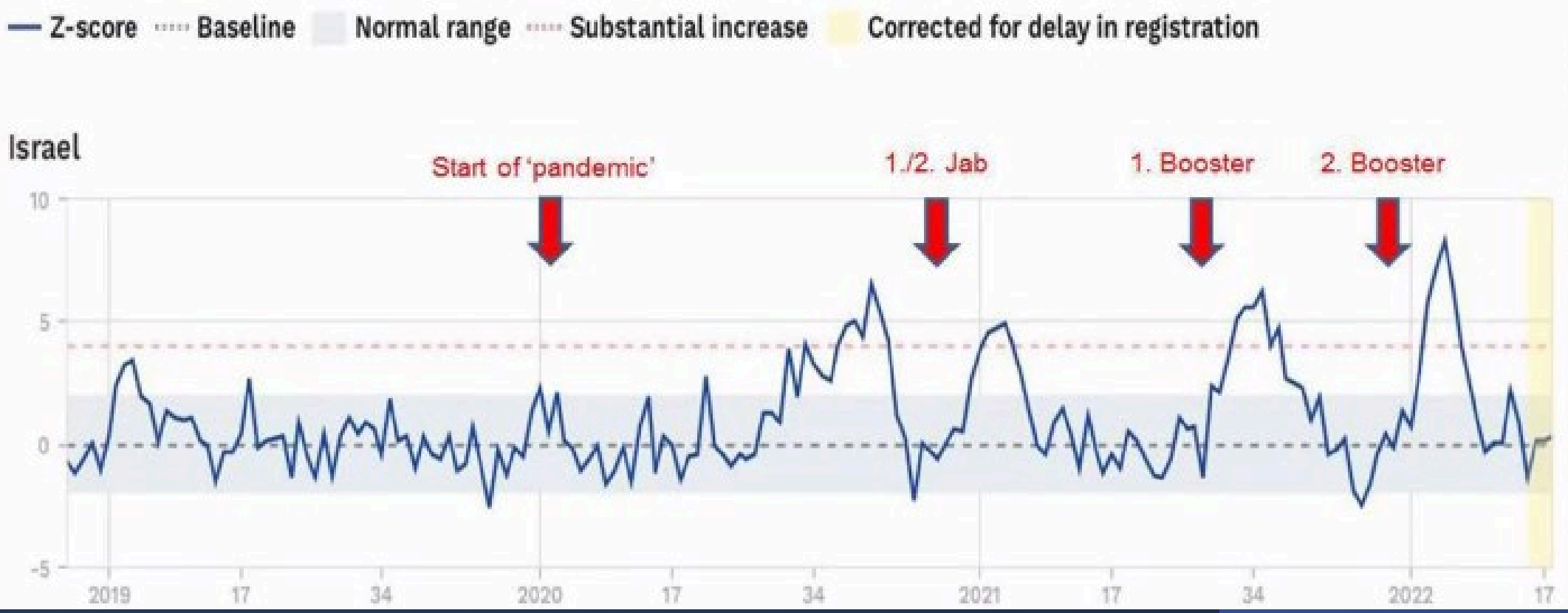
Path Specimen
Med/Surg Private r
Thora Drain
Erythromycin
Pharmacy
medisch

NOS NIEUWS • BUITENLAND • ECONOMIE • WOENSDAG, 14:33

Pfizer stelt medicijnen beschikbaar aan arme landen, 'hoognodige eerste stap'



EuroMoMo, European mortality monitoring,
aiming to detect and measure excess deaths related to
seasonal influenza, pandemics and other public health threats
www.euromomo.eu



Herman Steigstra
@SteigstraHerman

Portugal twee maal bijna wereldkampioen. Eerst met vrijwel hoogste percentage #vaccination tegen #COVID19. Nu zijn ze vrijwel wereldkampioen in aantal overlijdens aan #covid. Rarara hoe zou dat toch zitten. Het wonder van Portugal werd het genoemd.

portugalresident.com
Covid mortality “going to get worse”, warn specialists - Portugal Resident

25 mei 22 om 08:34 · Twitter for Android

Coronavirus bij kinderen

Stiko beveelt één vaccindosis aan voor alle niet-gevaccineerde vijf- tot elfjarigen

Tot nu toe heeft de Permanente Vaccinatiecommissie een coronavaccinatie voor kinderen tussen de vijf en elf jaar alleen aanbevolen als er risicofactoren zijn. De commissie actualiseert nu haar advies – met het oog op het najaar.

24 mei 2022, 13:31 uur

18:38

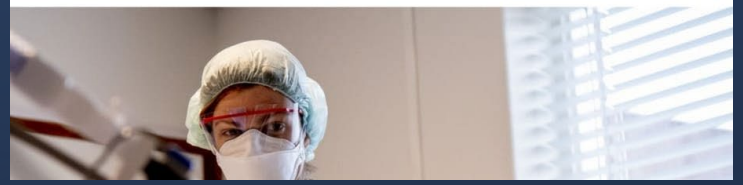
www.bnr.nl

GEZONDHEID

GOMMERS: ZIEKENHUIZEN EN VERZORGINGSTEHUIZEN HEBBEN MENSEN INHUMAAN LATEN STERVEN

BNR Webredactie / Gisteren, 10:27
Update: gisteren, 13:17

IC-arts en voormalig OMT-lid Diederik Gommers zegt dat de ziekenhuizen en verzorgingstehuizen mensen inhumaan hebben laten sterven tijdens de eerste coronagolf. Dat is volgens hem de zwarte bladzijde uit de pandemie. Hij zegt dat in de speciale Pandemie-terugblik van BNR, tegen collega Kees Dorresteijn.



Meer onderzoek naar menstruatiestoornis na coronaprik

Bijwerkingencentrum Lareb gaat opnieuw onderzoeken of menstruatiestoornissen en bloedingen na de menopauze bijwerkingen kunnen zijn van coronavaccins. Eerder onderzoek heeft nog geen afdoende conclusie opgeleverd.

https://www.volkskrant.nl/wete

deVolkskrant

NIEUWS

Vaccinatie verkleint kans op langdurige covidklachten nauwelijks

Wie is ingeënt tegen corona en het virus alsnog krijgt, kan ook het langdurige postcovidsyndroom krijgen. De kans op het syndroom, voorheen 'longcovid', is bij gevaccineerden maar iets kleiner dan bij mensen die níét werden ingeënt.

Maarten Keulemans 25 mei 2022, 17:33

Ambulanceverpleegkundige Roger Schleipen zit al twee jaar thuis nadat hij tijdens zijn werk het coronavirus opliep. Beeld ANP / Roger Dahmen Fotografie

Annals of Internal Medicine®

Original Research | 24 May 2022

A Longitudinal Study of COVID-19 Sequelae and Immunity: Baseline Findings FREE

Michael C. Sneller, MD, C. Jason Liang, PhD, Adriana R. Marques, MD, ... View all authors +

Author, Article and Disclosure Information

https://doi.org/10.7326/M21-4905

Eligible for CME Point-of-Care

Abstract

Background:

A substantial proportion of persons who develop COVID-19 report persistent symptoms after acute illness. Various pathophysiologic mechanisms have been implicated in the pathogenesis of postacute sequelae of SARS-CoV-2 infection (PASC).

Objective:

To characterize medical sequelae and persistent symptoms after recovery from COVID-19 in a cohort of disease survivors and controls.

Maarten van den Berg @mr_Smith_Econ · 3 u

Uitgebreide studie: longcovid lijkt psychosomatisch.

Geen verschillen in uitgebreide set "markers" tussen groep die covid doormaakte en controlegroep.

> **Adam W Gaffney** @awgaffney · 21 u
>
> An important new study is out. Baseline findings from the NIH's longitudinal, intramural Long COVID study — perhaps the most detailed, controlled, comprehensive investigation of multiple health metrics in this setting thus far conducted — were just published in @AnnalsIM
>
> A🧵
> 1/
>
> Deze collectie weergeven

2 6

Augustus 2021 in Ede. Hulpdiensten zijn bezig met de reanimatie van een 33-jarige bij een pompstation. Vergeefs: de man is al overleden. © AS Media

Ambulancepersoneel ziet niks geks aan hartfilmpje, een uur later is 33-jarige toch dood

EDE - Een oplettende pompbediende vindt het maar raar: ongeveer een uur nadat ambulancepersoneel een 33-jarige man bij het tankstation heeft onderzocht en hem in orde heeft bevonden, zit hij nog steeds in zijn auto. Hij vraagt ambulancepersoneel dat toevallig langs rijdt om nog eens te kijken. De afloop: de man bleek te zijn overleden.

Eric Reijnen Rutten 25-05-22, 12:19 **Laatste update:** 13:03

1 REACTIE

Het vindt allemaal plaats op dinsdag 17 augustus 2021 bij een benzinestation aan de Dr. W. Dreeslaan in Ede. Even voor kwart over acht 's avonds belt de man zelf vanuit zijn auto 112.

The CEO of Moderna Stéphane Bancel is seen in this video frame grab as he speaks during an interview with AFP on Nov. 17, 2020. (Ivan Couronne/AFP via Getty Images)

PREMIUM **VACCINES & SAFETY**

Moderna 'Throwing 30 Million Doses in the Garbage,' CEO Says

By Katabella Roberts | May 25, 2022 Updated: May 25, 2022

A A Print

The CEO of pharmaceutical and biotechnology company Moderna, Stéphane Bancel, said the company is having to "throw away" millions of doses of COVID-19 vaccines because "nobody wants them."

Bancel made the comments during an appearance at the World Economic Forum on Monday, while noting his concerns over the lack of people getting vaccinated and waning immunity among those who have had the shots but declined to get boosters.

6-1200x764...

Finally we have evidence, how Pfizer came to calculate a 95% vaccine efficacy! **Real efficacy is likely only 19%**, with a very bad side effect profile of up to 0.8% severe side effects, as reported by German Hospital Study Charité!

As we know from the published Pfizer studies, the vaccine arm *(those who received the actual vaccine vs. the placebo)* suffered from **+12.1% and +36.1% more systemic Adverse Events** (side-effects) than the placebo group. These side effects, are indistinguishable from COVID19 in most cases!

Table 14. Study C4591001 Safety Overview- Ages 16 years and older

Participants Experiencing at Least One:	BNT162b2 n/N (%)	Placebo n/N (%)
Immediate unsolicited AE Within 30 minutes after vaccination[a]		
Dose #1	78/18801 (0.4)	66/18785 (0.4)
Dose #2	52/18494 (0.3)	39/18470 (0.2)
Solicited injection site reaction within 7 days[b]		
Dose #1	3216/4093 (78.6)	525/4090 (12.8)
Dose #2	2748/3758 (73.1)	396/3749 (10.6)
Solicited systemic AE within 7 days[b]		
Dose #1	2421/4093 (59.1)	1922/4090 (47.0)
Dose #2	2627/3758 (69.9)	1267/3749 (33.8)
From Dose 1 through 1 month after Dose 2[a]		
Unsolicited non-serious AE	5071/18801 (27.0)	2356/18785 (12.5)
SAE	103/18801 (0.5)	81/18785 (0.4)
From Dose 1 through cutoff date (safety population)		
SAE	124/18801 (0.7)	101/18785 (0.5)
From Dose 1 through cutoff date (all-enrolled)[c]		
Withdrawal due AEs	37/21621 (0.6)	30/21631 (0.5)
SAE	126/21621 (0.6)	111/21631 (0.5)
Deaths	2/21621 (0.0)	4/21631 (0.0)

Jackanapes Junction

Is Subject #12312982 the Key to Proving Pfizer Vaccine Trial Fraud?

The Story of Augusto Roux

Josh Guetzkow
May 22

143 27

Subject # 12312982 in Pfizer study C4591001 is Augusto Roux, a 35-year old lawyer from Buenos Aires, Argentina who volunteered for Pfizer's stage 3 trial

PREMIUM HEALTH VIEWPOINTS

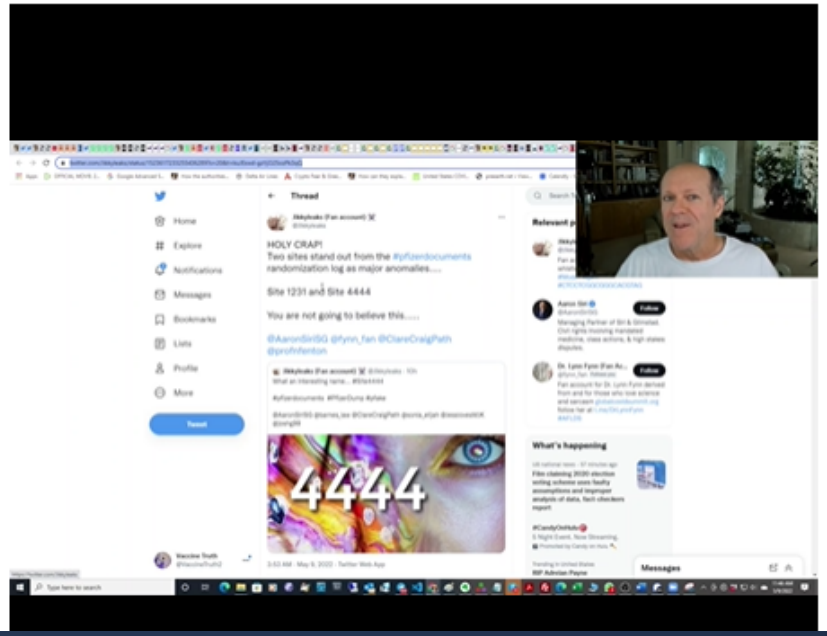
Did Pfizer Commit Huge Fraud in Its COVID Vaccine Research?

BY JOSEPH MERCOLA TIME MAY 17, 2022 PRINT

0:00 21:51

1×

It's becoming more and more apparent as to why Pfizer tried – albeit unsuccessfully – to withhold their COVID jab trial data for 75 years. Now, with the release of the data, internet sleuths are uncovering problems suggestive of fraud and manipulation, including the suspicious site 4444.



RECOMBINANT POXVIRUS BASED VACCINE AGAINST SARS-CoV-2 VIRUS

Abstract

The invention relates in various aspects to a recombinant poxvirus comprising a nucleic acid encoding a SARS-CoV-2 virus protein, methods for producing such viruses and the use of such viruses. The recombinant poxviruses are well suited, among others, as protective virus vaccines against SARS-CoV-2 virus.

Images (28)

Classifications

V · T · E	Skin infections, symptoms and signs related to viruses			[hide]
DNA virus	*Herpesviridae*	*Alpha.*	HSV	Herpes simplex · Herpetic whitlow · Herpes gladiatorum · Herpes simplex keratitis · Herpetic sycosis · Neonatal herpes simplex · Herpes genitalis · Herpes labialis · Eczema herpeticum · Herpetiform esophagitis
			B virus	B virus infection
			VZV	Chickenpox · Herpes zoster · Herpes zoster oticus · Ophthalmic zoster · Disseminated herpes zoster · Zoster-associated pain · Modified varicella-like syndrome
		Beta.		*Human herpesvirus 6*/*Roseolovirus* (Exanthema subitum · Roseola vaccinia) · Cytomegalic inclusion disease
		Gamma.		KSHV (Kaposi's sarcoma)
	Poxviridae	*Ortho.*		Variola (Smallpox · Alastrim) · **MoxV** (Monkeypox) · CPXV (Cowpox) · VV (Vaccinia · Generalized vaccinia · Eczema vaccinatum · Progressive vaccinia) · Buffalopox
		Para.		Farmyard pox: Milker's nodule · Bovine papular stomatitis · Pseudocowpox · Orf · Sealpox
		Other		Yatapoxvirus: Tanapox · Yaba monkey tumor virus · MCV (Molluscum contagiosum)
	Papillomaviridae	HPV		Wart/plantar wart · Heck's disease · Genital wart (giant) · Laryngeal papillomatosis · Butcher's wart · Bowenoid papulosis · Epidermodysplasia verruciformis · Verruca plana · Pigmented wart · Verrucae palmares et plantares
		BPV (Equine sarcoid)		
	Parvoviridae	*Parvovirus B19* (Erythema infectiosum · Reticulocytopenia · Papular purpuric gloves and socks syndrome)		
	Polyomaviridae	*Merkel cell polyomavirus* (Merkel cell carcinoma)		
RNA virus	*Paramyxoviridae*	MeV (Measles)		
	Togaviridae	*Rubella virus* (Rubella · Congenital rubella syndrome ("German measles")) · Alphavirus infection · Chikungunya fever		
	Picornaviridae	CAV (Hand, foot, and mouth disease · Herpangina) · FMDV (Foot-and-mouth disease) · Boston exanthem disease		
Ungrouped	Asymmetric periflexural exanthem of childhood · Post-vaccination follicular eruption · Lipschütz ulcer · Eruptive pseudoangiomatosis · Viral-associated trichodysplasia · Gianotti–Crosti syndrome			
Taxon identifiers	Wikidata: Q6900886 · Wikispecies: Monkeypox virus · EoL: 540224 · IRMNG: 11460289 · NCBI: 10244			

Realm:	*Varidnaviria*
Kingdom:	*Bamfordvirae*
Phylum:	*Nucleocytoviricota*
Class:	*Pokkesviricetes*
Order:	*Chitovirales*
Family:	*Poxviridae*
Genus:	*Orthopoxvirus*
Species:	***Monkeypox virus***

Reservoir [edit]

Monkeypox is carried by animals including primates. It was first identified by Preben von Magnus in Copenhagen, Denmark in 1958 in crab-eating macaque monkeys (*Macaca fascicularis*) being used as laboratory animals.[6] The 2003 outbreak in the United States was traced to prairie dogs infected from an imported Gambian pouched rat.

Monkeypox virus causes the disease in both primates and in other animals. The virus is mainly found in tropical rainforest regions of central and West Africa.

Transmission [edit]

The virus can spread both from animal to human and from human to human. Infection from animal to human can occur via an animal bite or by direct contact with an infected animal's bodily fluids. The virus can spread from human to human by both droplet respiration and contact with fomites (touchable surfaces) from an infected person's bodily fluids. The incubation period is between 10 and 14 days. Prodromal symptoms include swelling of lymph nodes, muscle pain, headache, fever, prior to the emergence of the rash.[7]

Epidemiology [edit]

Further information: Monkeypox § Epidemiology

The virus is mainly found in the tropical forests of Central Africa and West Africa. It was first discovered in monkeys in 1958, and in humans in 1970. Between 1970 and 1986, over 400 cases in humans were reported. Small viral outbreaks with a death rate in the range of 10% and a secondary human to human infection rate of about the same amount occur routinely in equatorial Central and West Africa.[8] The primary route of infection is thought to be contact with the infected animals or their bodily fluids.[8] The first reported outbreak outside Africa occurred in 2003 in the Midwestern United States in Illinois, Indiana, and Wisconsin, with one occurrence in New Jersey. No deaths occurred.

A map of the spread of the monkeypox virus globally.

Eerste patiënt geïnjecteerd met kankerdodend virus

DOOR JEANNETTE KRAS

23 MEI, 2022 // 12:09

Voor het eerst is een patiënt geïnjecteerd met een experimenteel kankerdodend virus. De weg is nog lang, maar uiteindelijk moet het op de markt komen als succesvolle methode om kanker te bestrijden.

Het middel, CF33-hNIS genoemd, is een oncolytisch virus, een genetisch gemodificeerd pokkenvirus, ontworpen om kankercellen te infecteren en te doden, terwijl de gezonde cellen gespaard worden.

ck
TV News Sport Meinung Politik Wirtschaft People Green
Auf Basis der mRNA-Technik
Biontech und Pfizer entwickeln Impfstoff gegen Gürtelrose
Das deutsche Pharmaunternehmen Biontech und sein US-Partner Pfizer wollen gemeinsam einen Impfstoff gegen Gürtelrose entwickeln. Es soll das erste derartige Vakzin auf Basis der mRNA-Technik werden, die auch bereits bei dem Corona-Impfstoff angewendet wurde.

Gabor Erdosi 🧩📄📊🧭
@gerdosi

What a coincidence
“The binding epitope on S harbors a sequence motif unique to SARS-CoV-2 (not present in other SARS-related coronaviruses), which is highly similar in both sequence and structure to the bacterial superantigen staphylococcal enterotoxin B”
pnas.org/content/117/41…

produced by the bacterium *Staphylococcus aureus* . It is a common contributor to food poisoning in humans. The bacteria grow and produce toxins in unrefrigerated meats, dairy, and bakery products. Typically, food poisoning due to SEB occurs in clusters because of a common food source (in settings such as a church picnic or passengers on an airliner eating the same contaminated food).

What are the symptoms and health effects of SEB exposure?

Symptoms of SEB exposure are similar to that of the flu. They can include sudden onset of fever, chills, headache, sore throat and muscle pain.

Additional symptoms are specific to the way that SEB enters the body. If the toxin comes into contact with the eyes, irritation, redness and facial swelling may occur. People who have ingested (swallowed) SEB typically experience symptoms common to food poisoning, including nausea, vomiting, and diarrhea. If SEB is inhaled into the lungs, symptoms include a dry cough, shortness of breath, and chest pain. In severe cases, there may

December 13th 2020

National Library of Medicine
National Center for Biotechnology Information

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Journal List > J Virol > v.89(20); 2015 Oct 15 > PMC4580173

AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Virology®

J Virol. 2015 Oct 15; 89(20): 10489–10499.
Published online 2015 Aug 5. doi: 10.1128/JVI.00304-15

PMCID: PMC4580173
PMID: 26246580

Evasion of the Innate Immune Type I Interferon System by Monkeypox Virus

William D. Arndt,[a,b,*] Samantha Cotsmire,[b] Kelly Trainor,[a,b,*] Heather Harrington,[a,b] Kevin Hauns,[a,b,*] Karen V. Kibler,[b] Trung P. Huynh,[a,b] and Bertram L. Jacobs[a,b]

G. McFadden, Editor

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4580173/

▸ Author information ▸ Article notes ▸ Copyright and License information Disclaimer

EXCLUSIVE

EXC: The Infamous Wuhan Lab Recently Assembled Monkeypox Strains Using Methods Flagged For Creating 'Contagious Pathogens'.

ARE WE HERE BECAUSE OF CHINA'S EXPERIMENTS AGAIN?

START

Blick

NIEUWS

"In een mum van tijd"

Roche heeft PCR-tests ontwikkeld om het apenpokkenvirus te detecteren

Het farmaceutisch bedrijf Roche heeft PCR-tests ontwikkeld om het apenpokkenvirus op te sporen, dat inmiddels in tal van landen is aangetroffen. Samen met dochteronderneming TIB Molbiol zijn drie verschillende testkits gemaakt.

Gepubliceerd: 25/05/2022 om 19:04 | Bijgewerkt: 25/05/2022 om 19:13

5

View PDF

KeAi
CHINESE ROOTS
GLOBAL IMPACT

Virologica Sinica
Available online 28 February 2022
In Press, Corrected Proof

Research Article

Efficient assembly of a large fragment of monkeypox virus genome as a qPCR template using dual-selection based transformation-associated recombination

Lei Yang [a, b], Lingqian Tian [a, b], Leshan Li [a, b], Qiuhong Liu [a, b], Xiang Guo [a, b], Yuan Zhou [a], Rongjuan Pei [a], Xinwen Chen [a] ✉, Yun Wang [a] ✉

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https://doi.org/10.1016/j.virs.2022.02.009

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https://www.sciencedirect.com/science/article/pii/S1995820X22000414

EUROPESE UNIE

HET EUROPEES PARLEMENT **DE RAAD**

Brussel, 16 december 2021
(OR. en)

2021/0323 (COD) **PE-CONS 79/21**

PHARM 205
SAN 694
MI 873
COMPET 855
CODEC 1514

WETGEVINGSBESLUITEN EN ANDERE INSTRUMENTEN

Betreft:	VERORDENING VAN HET EUROPEES PARLEMENT EN DE RAAD tot wijziging van Verordening (EU) 2017/746 wat betreft overgangsbepalingen voor bepaalde medische hulpmiddelen voor in-vitrodiagnostiek en de uitgestelde toepassing van de voorwaarden voor intern vervaardigde hulpmiddelen

BIJLAGE VIII

CLASSIFICATIEREGELS

1. UITVOERINGSBEPALINGEN

1.1. Het beoogde doeleind van de hulpmiddelen is bepalend voor de toepassing van de classificatieregels.

1.2. Indien het betrokken hulpmiddel is bestemd om in combinatie met een ander hulpmiddel te worden gebruikt, zijn de classificatieregels op elk van deze hulpmiddelen afzonderlijk van toepassing.

1.3. Toebehoren van een medisch hulpmiddel voor in-vitrodiagnostiek worden op zich volgens de classificatieregels ingedeeld, los van het hulpmiddel waarmee zij worden gebruikt.

1.4. Software die een hulpmiddel bestuurt of het gebruik ervan beïnvloedt, valt in dezelfde klasse als het hulpmiddel.

Software die onafhankelijk is van alle andere hulpmiddelen wordt op zich volgens de classificatieregels ingedeeld.

1.5. Kalibratoren die zijn bestemd om met een hulpmiddel te worden gebruikt, worden in dezelfde klasse als het hulpmiddel ingedeeld.

1.6. Controlemateriaal waaraan kwantitatieve of kwalitatieve waarden zijn toegekend en dat is bestemd voor een specifiek analyt of meerdere analyten, wordt in dezelfde klasse als het hulpmiddel ingedeeld.

1.7. De fabrikant neemt voor de vaststelling van de passende classificatie voor het hulpmiddel alle classificatie- en uitvoeringsregels in aanmerking.

1.8. Indien de fabrikant voor een hulpmiddel meerdere beoogde doeleinden opgeeft, en het hulpmiddel daardoor in meer dan een klasse valt, wordt het in de hogere klasse ingedeeld.

1.9. Indien verscheidene classificatieregels van toepassing zijn op hetzelfde hulpmiddel, is die regel van toepassing waardoor het hulpmiddel in de hogere klasse terechtkomt.

1.10. Elk van de classificatieregels geldt voor eerstelijnsassays, bevestigingsassays en aanvullende assays.

Were fears about asymptomatic Covid spread overblown? Infected people without symptoms are TWO-THIRDS less likely to pass virus on, study finds

- Scientists analysed data from over 28,000 Covid infections from 42 countries
- Cases were from towards the start of the pandemic in April 2020 up to July 2021
- They found asymptomatic people were less-likely to spread the virus to others
- Brits were urged in the pandemic to 'act like you've got it' and obey lockdowns

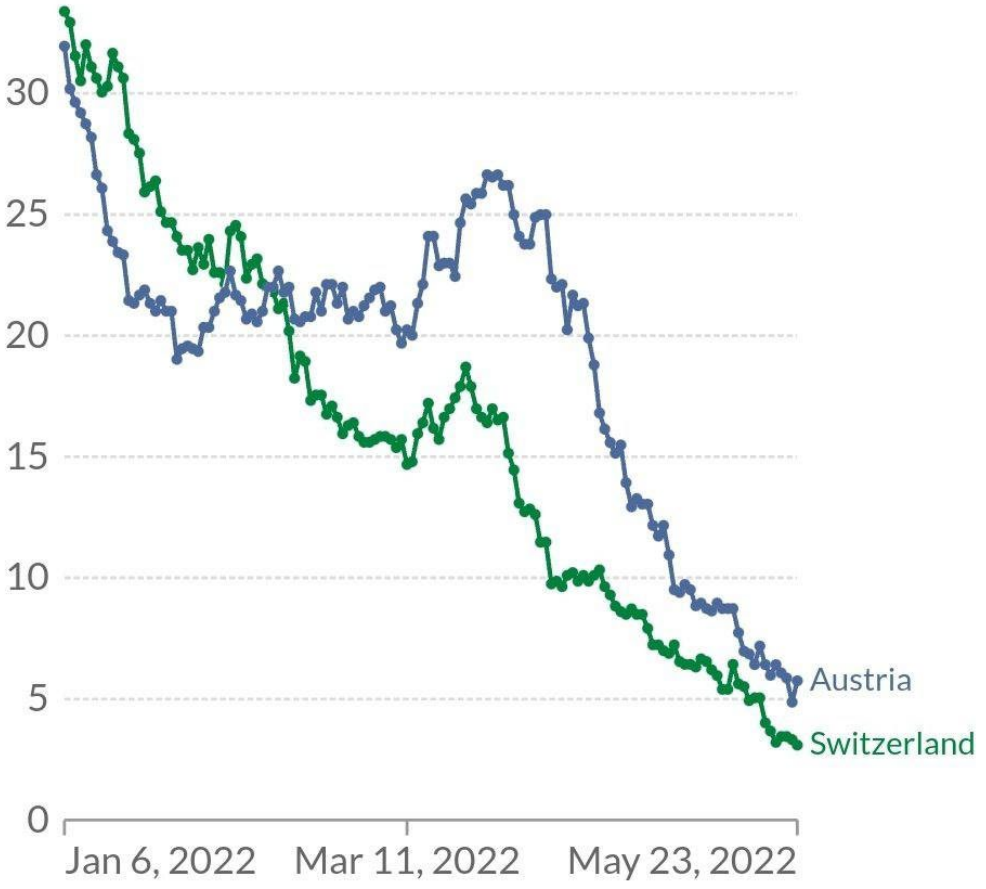
By JOHN ELY SENIOR HEALTH REPORTER FOR MAILONLINE

PUBLISHED: 19:00 BST, 26 May 2022 | **UPDATED:** 19:02 BST, 26 May 2022

Number of COVID-19 patients in intensive care (ICU) per million people

Our World in Data

LINEAR | LOG



Aan: [redacted]; Boer, dhr. prof. dr. T. de; Boersma, dhr. prof. dr. ir. H.; Bouvy, dhr. prof. dr. M.L.; "Dekkers, dhr. O.M."; Deneer, mw. V.H.M.; Graeff, dhr. prof. dr. P.A. de; Guchelaar, dhr. H.J.; Nieuwkoop, dhr. C. van; Russel, dhr. Prof. Dr. F.G.M.; Rob R. Marum van; Janneke J. Belo; Bosch, mw. dr. A.M.; [redacted]@amc.uva.nl; Rensen, mw. J.M.L. van; "Kersting, Sabina"; "Nurmohamed, M.T. (Mike)"; Sonke, dr. G.S.

Cc: Hurts, dhr. drs. H.R.; Loekemeijer, mw. Drs. P.A.; [redacted]

Onderwerp: gemandateerde Collegevergadering van 11 augustus geannuleerd

Datum: donderdag 29 juli 2021 14:33:20

Bijlagen: image001.png
image002.gif

Geachte Collegeleden,
Omdat voor de gemandateerde **Collegevergadering van 11 augustus** slechts één agendapunt is aangeleverd, is besloten om deze **vergadering te annuleren**.
Het openstaande agendapunt ([redacted]) betreft een [redacted]

- [redacted]
- [redacted]

Met vriendelijke groet,
[redacted]
[redacted] College ter Beoordeling van Geneesmiddelen
CBG MEB - logo NL - RGB e-mail

Agenda - CAT agenda of the 6-8 October 2021 meeting (PDF/333.95 KB)

Draft

First published: 08/10/2021
Last updated: 29/11/2021
EMA/CAT/526882/2021

Agenda - CAT agenda of the 8-10 September 2021 meeting (PDF/347.27 KB)

Draft

First published: 07/09/2021
EMA/CAT/468912/2021

Agenda - CAT agenda of the 14-16 July 2021 meeting (PDF/392.54 KB)

Draft

First published: 15/07/2021
EMA/CAT/396514/2021

Agenda - CAT agenda of the 16-18 June 2021 meeting (PDF/382.59 KB)

First published: 16/06/2021
EMA/342564/2021

Agenda - CAT agenda of the 10-12 May 2021 meeting (PDF/336.27 KB)

First published: 11/05/2021
EMA/CAT/268790/2021

Agenda - CAT agenda of the 14-16 April 2021 meeting (PDF/338.39 KB)

First published: 14/04/2021
EMA/CAT/212367/2021

https://www.ema.europa.eu/en/committees/cat/cat-agendas-minutes-reports

4.1. Next deadline for submission of new requests is 29 July 2021. These will appear in the CAT Written Procedure of August 2021.New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Autologous population of selected renal cells (SRC)

Intended for the treatment of chronic kidney disease (CKD)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous adipose mesenchymal stem cells (MSCs)

Indicated for cartilage defects of degenerative origin and for the treatment of osteoarthritis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Allogeneic natural killer cells armed with anti-CD20 monoclonal antibody

Intended for the treatment of B-Cell Non-Hodgkin lymphoma

Scope: ATMP scientific recommendation

Action: for adoption

https://www.ema.europa.eu/en/documents/agenda/agenda-cat-agenda-14-16-july-2021-meeting_en.pdf

4. Scientific Recommendation on Classification of ATMPs

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

Next deadline for submission of new requests is 26 August 2021. These will appear in the CAT Agenda 08-10 September 2021.

Timetable:

-Start of the procedure:	13.08.2021
-EMA Coordinator's draft report:	27.08.2021
-CAT Coordinator's comments:	01.09.2021
-Revised scientific recommendation:	03.09.2021
-CAT's discussion of scientific recommendation:	10.09.2021

https://www.ema.europa.eu/en/documents/minutes/minutes-cat-written-procedure-11-13-august-2021_en.pdf

Agenda - CAT agenda of the 18-20 January 2017 meeting (PDF/324.76 KB)

Draft

First published: 19/01/2017
Last updated: 19/01/2017
EMA/CAT/39859/2016

Minutes

Minutes of the CAT meeting 8-10 December 2021 (PDF/420.38 KB)

Adopted

First published: 24/03/2022
EMA/CAT/752469/2021

Minutes of the CAT meeting 6-8 October 2021 (PDF/362.76 KB)

Adopted

First published: 14/01/2022
EMA/CAT/574435/2021

Minutes of the CAT meeting 8-10 September 2021 (PDF/372.45 KB)

Adopted

First published: 14/01/2022
EMA/CAT/515396/2021

Minutes of the CAT written procedure 11-13 August 2021 (PDF/302.38 KB)

Adopted

https://www.ema.europa.eu/en/committees/cat/cat-agendas-minutes-reports

7.3.3. Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances

EMA: Veronika Jekerle (on behalf of the drafting group)

Scope: feedback on the status of the NAS reflection paper

Action: for information

EMA provided detailed information on status of the reflection since it was discussed at the CAT in July 2021. The document underwent regulatory and legal scrutiny by both EMA regulatory and legal affairs offices, and by the Commission. This was a necessary step with regards to the regulatory nature of the NAS status. EMA informed CAT members that the European Commission shared EMA's view that this is an important document in view of its regulatory implications, which go beyond purely scientific assessment. All documents and comments received are made available to the BWP-CAT drafting group and to all CAT and BWP members.

This topic was included in the agenda on specific request from CAT members to be informed on the grounds for delays in the finalisation of this CAT 2021 work plan topic. During the preparation of the December CAT agenda, EMA considered that this topic was not mature enough to bring back to the CAT: the BWP-CAT drafting group has to review all the comments and finalise the draft reflection paper. It was considered more

appropriate to present the revised draft reflection paper to CAT for discussion and adoption early 2022, once finalised by the drafting Group.

The European Commission representative summarised the legal issues that they have identified during the review.

The CAT chair thanked EMA for the information provided and asked for a more proactive communication to CAT on CAT work plan topics and legal/regulatory considerations relevant to ATMPs.

As the comments from the external consultation will have to be reviewed in 2022, it was agreed to include the NAS reflection paper in the CAT work plan for 2022 (see 7.6.2).