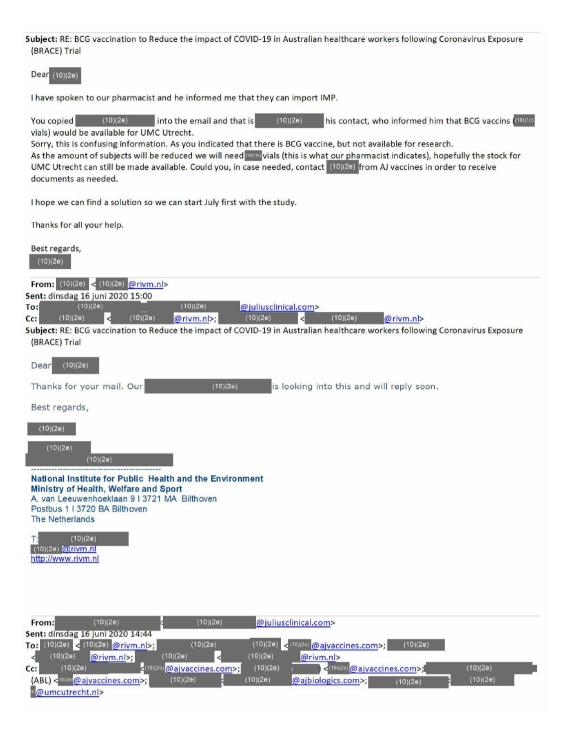
From: (10)(2e) [(10)(2e) @rivm.ni]
Sent: Thur 8/20/2020 11:49:30 AM Subject: FW: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure
(BRACE) Trial Received: Thur 8/20/2020 11:49:31 AM
FYI, zo te zien zijn er wel kosten voor UMC. Gr
From: (10)(2e) < (10)(2e) @rivm.nl>
Sent: maandag 22 juni 2020 15:12 To: (10)(2e) (10)(2e) @juliusclinical.com>; (10)(2e) @umcutrecht.nl'
(10)(2e) @umcutrecht.nl> Cc: (10)(2e) < (10)(2e) @rivm.nl>
Subject: RE: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure (BRACE) Trial
Beste (10)(2e)
Ja, dat klopt. Er zijn verder geen bijkomende kosten en wij brengen geen BTW in rekening.
Hartelijke groet,
(10)(2e)
From: (10)(2e) (10)(2e) @juliusclinical.com> Sent: maandag 22 juni 2020 12:36 To: (10)(2e) < (10)(2e) @rivm.nl>; (10)(2e) @umcutrecht.nl' < (10)(2e) @umcutrecht.nl' < (10)(2e) @umcutrecht.nl' < (10)(2e) @umcutrecht.nl > Subject: RE: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure (BRACE) Trial
Beste (10)(2e)
lk wil graag de prijs nogmaals controleren.
Klopt het dat 1 doos van vivie vials (BCG poeder en oplosmiddel) (10)(1c) kost? Zijn er nog bijkomende kosten? Is dit excl BTW? Dank voor je antwoord.
Met vriendelijke groet, (10)(2e)
From: \(\(\text{10} \text{\gamma} \) (10)(2e) \\ Sent: donderdag 18 juni 2020 11:12 \\ To: \(\text{10} \text{\gamma} \) < \(\text{10} \text{\gamma} \) (10)(2e) \(\text{\gamma} \) (10)(2
Beste (10)(2e)
Aangezien we nog niet goed kunnen inschatten hoeveel participanten in Nederland worden gerecruiteerd zou ik graag voor de vials gaan.
Wat is het proces wat gevolgd moet worden? Hoe werkt het met de kosten?

Ik werk nog niet zolang voor de studie binnen het UMCU en weet niet goed waar ik tegenaan kan gaan lopen. Graag een overleg, zodat het proces voor mij duidelijk is en ik de tijdslijnen duidelijk heb. Heb je vandaag of morgen tijd om te bellen? Mijn nummer is (10)(2e)
Er is een CA goedkeuring aanwezig van de CCMO.
Groet, (10)(2e)
From: (10)(2e) < (10)(2e) @rivm.nl> Sent: dinsdag 16 juni 2020 18:01 To: (10)(2e) @umcutrecht.nl> Cc: (10)(2e) @umcutrecht.nl> Cc: (10)(2e) @ (10)(2e) @rivm.nl> Subject: RE: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure (BRACE) Trial
Beste (10)(2e) en (10)(2e)
Zoals afgelopen vrijdag met (10)(2e) besproken, hebben wij (10)(1e) vials BCG-vaccin (in (10)(1e)) uit onze voorraad gereserveerd voor het onderzoek van het UMCU. Dit is een aantal maanden geleden al gedaan op verzoek van (10)(2e)
Begrijp ik uit onderstaande mail goed dat er van deze <mark>dogte</mark> vials nu nog maar <mark>dogte)</mark> nodig zijn? In dat geval zijn ze beschikbaar en kunnen wij ze uitleveren aan het UMCU.
Mocht ik het niet goed begrijpen en mocht het zo zijn dat deze (10(10) vials nog bovenop de (10(10) gereserveerde vials komen, dan wordt het lastiger.
Kunnen jullie me laten weten hoeveel vials er in totaal nodig zijn?
Alvast bedankt!
Hartelijke groet,
(10)(2e)
(10)(2e) (10)(2e)
Dienst Vaccinvoorziening en Preventieprogramma's (RIVM-DVP) Rijksinstituut voor Volksgezondheid en Milieu A. van Leeuwenhoeklaan 9 3721 MA Bilthoven kamer (10)(2e) postbak (10)(2e) Postbus 1 3720 BA Bilthoven
T: (10)(2e) M: (10)(2e) E: (10)(2e) @rivm.nl http://www.rivm.nl/dvplogistiek
(10)(2e)
From: (10)(2e) < (10)(2e) @juliusclinical.com> Sent: dinsdag 16 juni 2020 16:58 To: (10)(2e) @rivm.n > (10)(2e) @rivm.n > (10)(2e) (10)(2e) @rivm.n >



Subject: RE: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure (BRACE) Trial
Dear (10)(2e)
Do you know when you are able to say if we=UMC Utrecht can use the stock at the RIVM? In case of yes, can we have a call to see what you need in order to release BCG to UMC Utrecht? I hope it will. It will tremendous help us speed up the study.
Thanks a lot for your kind help.
(10)(2e) (10)(2e) (10)(2e)
From: (10)(2e) < (10)(2e) @rivm.nl> Sent: dinsdag 16 juni 2020 10:47 To: (10)(2e) (10)(2e) @rivm.nl> (10)(2e) (10)(2e) @rivm.nl>; (10)(2e) @rivm.nl>; (10)(2e) @rivm.nl> Cc: (10)(2e) @rivm.nl> Cc: (10)(2e) @rivm.nl> (10)(2e) @rivm.nl>; (10)(2e) @rivm.nl> (ABL) < (10)(2e) @rivm.nl> (10)(2e) @rivm.nl> (ABL) < (10)(2e) @rivm.nl> (10)(2e) @rivm.nl> (ABL) < (10)(2e) @rivm.nl> (ABL) < (10)(2e) @rivm.nl> Subject: RE: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure
(BRACE) Trial
Dear (10)(2e) We are still checking if we can supply our Academic Hospital in Utrecht directly from our stock. Supply to (10)(2a) will not be feasible – we are not allowed to export a non-registered product. Best regards,
(10)(2e)
From: (10)(2e) (10)(2e) @ajvaccines.com> Sent: maandag 15 juni 2020 15:58 To: (10)(2e) (10)(2e) @juliusclinical.com>; (10)(2e) @rivm.nl>; (10)(2e) @rivm.nl>; (10)(2e) @ajvaccines.com>; (10)(2e) @rivm.nl> Cc: (10)(2e) (10)(2e) @ajvaccines.com>; (10)(2e) @ajvacci
Dear (10)(2e) and (10)(2e) Thanks for the talk today (10)(2e) Please used this email confidential. A seen this collaboration of several global sites has involved The Netherlands and (10)(2e)

Would it be possible for you to provide/sell approx vials for used in the Netherlands and (10)(20) for this shared setup?

as mentioned (10)(2e) is in charge of (10)(2e) if needed.

Best regards



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Just to be clear the route of the products are essential to the way the request is handled not the payment,
If products have to ship to The Netherlands and/or (19)23), it Either has to be products with marketing authorisation for the country,
or we have to do a special permit for it if we sell our standard English version.

Aside the work we have to do internally you also need to seek approval by the local authorities, which also normally is associated with a cost. I have heard something like 1500 Eur from other countries. I don't know how it is for the Netherlands. If the product is shipped to Australia, it would be the Australian rues that count.

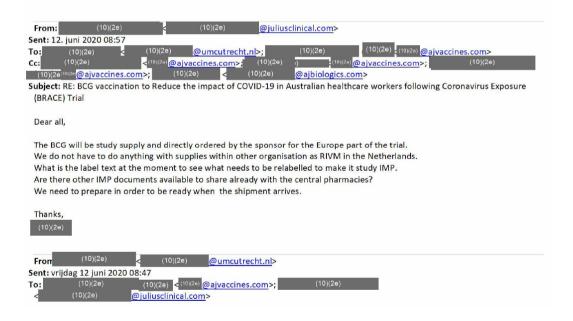
That is the reason for me asking how many vials you would need to be shipped to the Netherlands and how many to Due to the relatively high cost and workload in the process for a few vials, I would guess it might be more effective to get products already on stoc in the Netherlands.

Please let me know if you prefer a call? Then I would be happy to set up a call Best



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Is this a potential problem at the local level? The product has to be distributed directly from the sponsor site as in your email below?

Thank you very much in advance.

Best regards,







(10)(2e) | Julius Centrum voor Gezondheidswetenschappen en Eerstelijns Geneeskunde | Universitair Medisch Centrum Utrecht Huispostnummer Str. (10)(2e) | Postbus 85500 | 3508 GA UTRECHT



Please do let me know if you would require Tuberculin PPD as well .

Best Regards,

(10)(2e)



Subject: Re: BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure (BRACE) Trial

Hi (10)(2e)

With the changing epidemiology of COVID-19 and different rates between countries, we are now planning on recruiting participants in the Netherlands and (10)(2a) starting some time next month.

How soon would you be able to ship wow vials (out boxes) direct to our collaborators in Utrecht who are co-coordinating the new sites? Also can you please let me know the cost for this given the use is for our COVID-19 trial in healthcare workers.

With thanks and best wishes

The Royal Children's Hospital Melbourne

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