

To: (10)(2e) <(10)(2e)@rivm.nl>
From: (10)(2e)
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 (10)(2e)

From: (10)(2e) <(10)(2e)@rivm.nl>
Sent: maandag 22 juni 2020 15:12
To: (10)(2e) <(10)(2e)@juliusclinical.com>; (10)(2e) <(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) <(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)

Ik wil graag de prijs nogmaals controleren.

Klopt het dat 1 doos van 10x10 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: (10)(2e)
Sent: donderdag 18 juni 2020 11:12
To: (10)(2e) <(10)(2e)@rivm.nl>; (10)(2e) <(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)

Aangezien we nog niet goed kunnen inschatten hoeveel participanten in Nederland worden gerecruteerd zou ik graag voor de (10)(1c) 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) <(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) en (10)(2e)

Zoals afgelopen vrijdag met (10)(2e) besproken, hebben wij (10)(1c) vials BCG-vaccin (in (10)(1c)) uit onze voorraad gereserveerd voor het onderzoek van het UMCU. Dit is een aantal maanden geleden al gedaan op verzoek van (10)(2e) (10)(2e)

Begrijp ik uit onderstaande mail goed dat er van deze (10)(1c) vials nu nog maar (10)(1c) 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)(1c) vials nog bovenop de (10)(1c) 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) <(10)(2e)@rivm.nl>
Cc: (10)(2e) <(10)(2e)@rivm.nl>; (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

Dear (10)(2e)

I have spoken to our pharmacist and he informed me that they can import IMP.

You copied (10)(2e) into the email and that is (10)(2e) his contact, who informed him that BCG vaccins (10)(1e) vials) would be available for UMC Utrecht.

Sorry, this is confusing information. As you indicated that there is BCG vaccine, but not available for research.

As the amount of subjects will be reduced we will need (10)(1e) vials (this is what our pharmacist indicates), hopefully the stock for UMC Utrecht can still be made available. Could you, in case needed, contact (10)(2e) from AJ vaccines in order to receive documents as needed.

I hope we can find a solution so we can start July first with the study.

Thanks for all your help.

Best regards,

(10)(2e)

From: (10)(2e) <(10)(2e) @rivm.nl>

Sent: dinsdag 16 juni 2020 15:00

To: (10)(2e) (10)(2e) @juliusclinical.com>

Cc: (10)(2e) <(10)(2e) @rivm.nl>; (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

Dear (10)(2e)

Thanks for your mail. Our (10)(2e) is looking into this and will reply soon.

Best regards,

(10)(2e)

(10)(2e)

(10)(2e)

National Institute for Public Health and the Environment

Ministry of Health, Welfare and Sport

A. van Leeuwenhoeklaan 9 | 3721 MA Bilthoven

Postbus 1 | 3720 BA Bilthoven

The Netherlands

T: (10)(2e)

(10)(2e) @rivm.nl

<http://www.rivm.nl>

From: (10)(2e) <(10)(2e) @juliusclinical.com>

Sent: dinsdag 16 juni 2020 14:44

To: (10)(2e) <(10)(2e) @rivm.nl>; (10)(2e) (10)(2e) <(10)(2e) @ajvaccines.com>; (10)(2e)

<(10)(2e) @rivm.nl>; (10)(2e) <(10)(2e) @rivm.nl>

Cc: (10)(2e) <(10)(2e) @ajvaccines.com>; (10)(2e) <(10)(2e) @ajvaccines.com>; (10)(2e)

(ABL) <(10)(2e) @ajvaccines.com>; (10)(2e) <(10)(2e) @ajbiologics.com>; (10)(2e) (10)(2e)

@umcutrecht.nl>

A seen this collaboration of several global sites has involved The Netherlands and (10)(2a)

Would it be possible for you to provide/sell approx (10)(1c) vials for used in the Netherlands and (10)(2a) for this shared setup?

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

Best regards

(10)(2e)
(10)(2e)

M (10)(2e) | E (10)(2e)@ajvaccines.com | F (10)(2e)
A Artillerivej 5, 2300 Kbh S, Denmark | W ajvaccines.com



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From: (10)(2e) <(10)(2e)@juliusclinical.com>

Sent: 15. juni 2020 14:00

To: (10)(2e) (10)(2e) (10)(2e)@ajvaccines.com (10)(2e) (10)(2e)@umcutrecht.nl>

Cc: (10)(2e) (10)(2e)@ajvaccines.com (10)(2e) (10)(2e)@ajvaccines.com (10)(2e)

(10)(2e) (10)(2e)@ajvaccines.com (10)(2e) (10)(2e)@ajbiologics.com>

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

Dear (10)(2e)

Thank you for your email.

In order to proceed I would like to have a call. If you can set-up a call either today from 15:00 – 16:00 or tomorrow afternoon, that will be great.

I attached the EudraCT request I made for the Dutch authorities. This was approved.

An Equal form is made for the (10)(2e) authority.

If there are omissions we can discuss this as well.

Thanks,

(10)(2e)

From: (10)(2e) <(10)(2e)@ajvaccines.com>

Sent: maandag 15 juni 2020 12:41

To: (10)(2e) (10)(2e)@juliusclinical.com (10)(2e) (10)(2e)

@umcutrecht.nl>

Cc: (10)(2e) (10)(2e)@ajvaccines.com (10)(2e) (10)(2e)@ajvaccines.com (10)(2e)

(10)(2e) (10)(2e)@ajvaccines.com (10)(2e) (10)(2e)@ajbiologics.com>

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

Dear (10)(2e)

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 (10)(2e), 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 rules 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 (10)(2a).
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 stock in the Netherlands.

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

(10)(2e)
(10)(2e)

M (10)(2e) | E (10)(2e)@ajvaccines.com | F (10)(2e)
A Artillerivej 5, 2300 Kbh S, Denmark | W ajvaccines.com



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From: (10)(2e) <(10)(2e)@juliusclinical.com>

Sent: 12. juni 2020 08:57

To: (10)(2e) <(10)(2e)@umcutrecht.nl>; (10)(2e) <(10)(2e)@ajvaccines.com>
Cc: (10)(2e) <(10)(2e)@ajvaccines.com>; (10)(2e) <(10)(2e)@ajvaccines.com>; (10)(2e) <(10)(2e)@ajvaccines.com>;
(10)(2e) <(10)(2e)@ajvaccines.com>; (10)(2e) <(10)(2e)@ajbiologics.com>

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

Dear all,

The BCG will be study supply and directly ordered by the sponsor for the Europe part of the trial.
We do not have to do anything with supplies within other organisation as RIVM in the Netherlands.
What is the label text at the moment to see what needs to be relabelled to make it study IMP.
Are there other IMP documents available to share already with the central pharmacies?
We need to prepare in order to be ready when the shipment arrives.

Thanks,

(10)(2e)

From: (10)(2e) <(10)(2e)@umcutrecht.nl>

Sent: vrijdag 12 juni 2020 08:47

To: (10)(2e) <(10)(2e)@ajvaccines.com>; (10)(2e) <(10)(2e)@juliusclinical.com>

On behalf of the UMC Utrecht in the role of sponsor Europe for the BRACE study (10)(2e) I have prepared the submission to the (10)(2a) competent authority (10)(2a) for local approval (I currently work in UMC Utrecht (10)(2e) and I will get some extra request regarding product information at the local level, as you mention it is registered also in (10)(2a). However, they point out that it still appears in their list of products with shortage of supply (10)(2g).

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)(2e) starting some time next month.

How soon would you be able to ship (10)(2e) vials (10)(2e) 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

(10)(2e)

(10)(2e)

(10)(2e)

The Royal Children's Hospital Melbourne

3 West Clinical Offices | 50 Flemington Road | Parkville | 3052 | VIC | Australia

T (10)(2e) | F (10)(2e) | P (10)(2e)
E (10)(2e) @rch.org.au | W [University of Melbourne](#), [RCH](#), [MCRI](#)

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