



Subject: R: Very rare cases of haemorrhage with immune thrombocytopenia, not higher incidence of blood clots is the likely issue with Covid-19 vaccines

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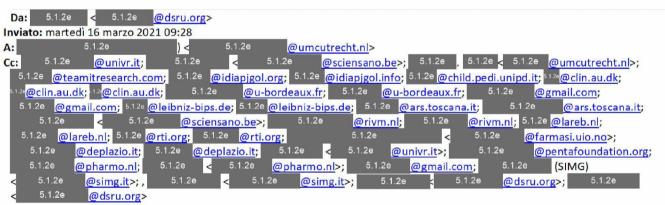
#### Dear colleagues

We are currently facing in our hospital a case of cerebral thrombosis associated to thrombocytopenia and hemorrage in a young patient who received Astrazeneca vaccine two weeks ago. Colleagues from ICU asked us if there is any official protocol to treat these patients. This is really urgent request. If any of you have any information that can be shared I would be really grateful Thanks a lot

Kind regards

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Oggetto: Very rare cases of haemorrhage with immune thrombocytopenia, not higher incidence of blood clots is the likely issue with Covid-19 vaccines

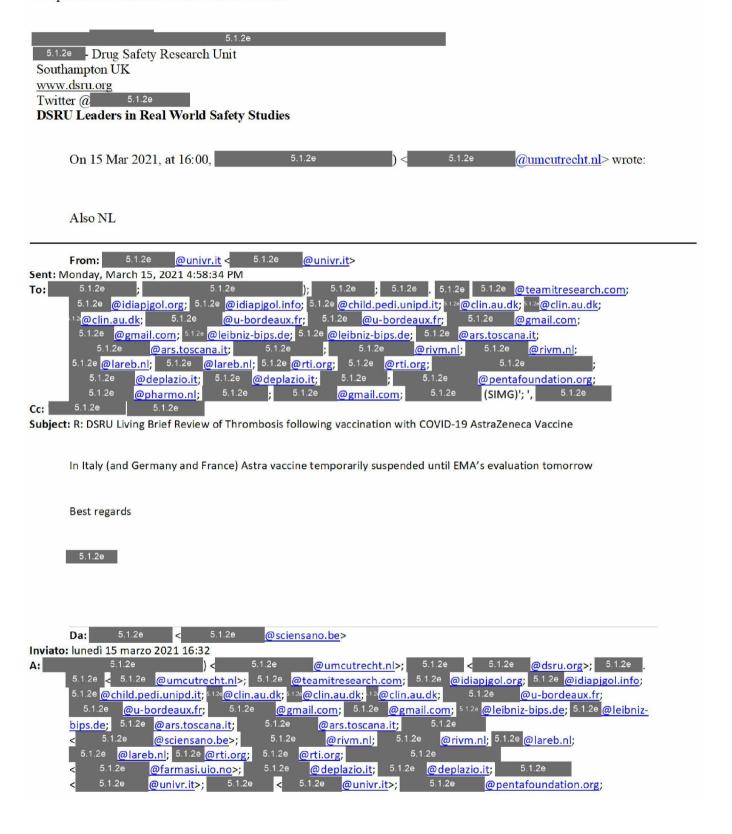
### Dear Friends

The observed incidence of clotting is not higher than the expected. The issue is likely be the opposite; very rare cases of intracranial haemorrhage (ICH) possibly associated with immune thrombocytopenia in relatively young people. The first case of thrombocytopenia with a fatal outcome was reported in the US in January 2021 with the Pfizer vaccine. ICH in young people is commonly caused by hypertension or structural malformations (aneurysms). The use of illicit drugs (with sympathomenatic effects) also contributes to ICH.

We will know whether immune thrombocytopenia is more common with the AstraZeneca vaccine compared to other Covid-19 vaccines. However, spontaneous reporting while good for generating signals, is not the best method to measure

incidence or comparative reporting rates, observational studies are needed for this. Immune thrombocytopenia in young people with Covid-19 vaccines suggest their robust immune response. If confirmed this very rare event will require risk minimisation measures for a selected group of people and further studies.

People need to continue to take Covid vaccines





Oggetto: RE: DSRU Living Brief Review of Thrombosis following vaccination with COVID-19 AstraZeneca Vaccine

### Dear friends,

"Fresh news" (early this afternoon).

Updated position in Belgium regarding AstraZeneca Vaccine (Superior Health Council): vaccination is maintained with Astra7eneca vaccine

Press, in French: https://www.rtbf.be/info/dossier/epidemie-de-coronavirus/detail vaccin-astrazeneca-le-conseilsuperieur-de-la-sante-maintient-sa-position-sur-la-poursuite-de-la-vaccination-en-belgique?id=10719815 Sorry, communication in English is not yet available on the Superior Health Council website.

#### Additional info:

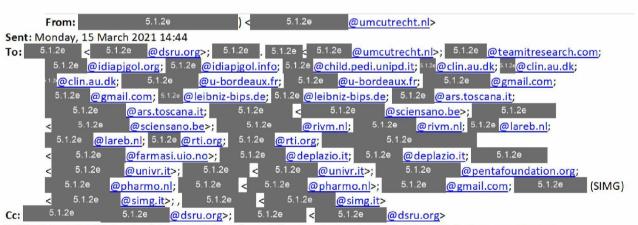
Recent message from belgian Federal agency for medicines and health products:

"In Belgium, as of 8 March 2021, 94,063 doses of AstraZeneca's COVID-19 vaccine have been administered. So far, no cases of thromboembolic events have been reported in Belgium with this vaccine. In addition, no deaths have been reported in Belgium with AstraZeneca's COVID-19 vaccine. A total of 1,707 adverse event reports have been received in Belgium for AstraZeneca's COVID-19 vaccine. More than 95% of the serious cases concern expected reactions due to reactogenicity (fever, fatigue, pain)".

# Regards,



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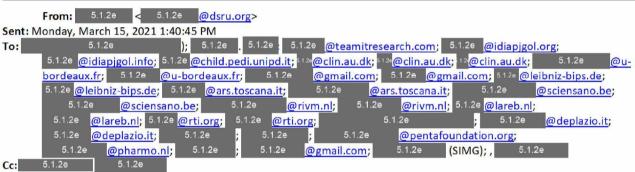
Subject: Re: DSRU Living Brief Review of Thrombosis following vaccination with COVID-19 AstraZeneca Vaccine

Dear 5.1.2e thank you very much for this, the current situation with differences of news between EMA and national regulators creates doubts and uncertainties.

As you may have noticed there are several new items also about NL and 6 cases reported from Norway and Denmark with both ITP and PE/DVT.

The current situation is very unfortunate, as it will have major impact on vaccine confidence esp. since AstraZeneca is so far the only one that is shipped to lower and middle income countries.

Best regards, 5.1.2e



Subject: DSRU Living Brief Review of Thrombosis following vaccination with COVID-19 AstraZeneca Vaccine

# Dear Friends

Attached is our brief but detailed living review of these events, which includes an overview of the Causality Assessment methods. These are the introductory paragraphs.

DSRU Living Brief Review of Thrombosis following vaccination with COVID-19 AstraZeneca Vaccine.

We agree with MHRA and EMA that people should continue to be vaccinated with the Oxford/AstraZeneca vaccines and other authorised vaccines per their country's vaccination programme.

In early-March 2021, it was reported that thromboembolic events had been reported shortly following vaccination with a specific batch of the Oxford/AstraZeneca COVID-19 vaccine (batch ABV5300). This batch was distributed to 17 countries throughout Europe, constituting one million doses. At this time, there had been two deaths reported related to coagulation conditions following vaccination. No regulatory authority in the world has attributed causality with the Oxford/AstraZeneca vaccine of the reported events of increased coagulation. This signal is being evaluated by regulatory agencies and the scientific community worldwide. The difference is that some European regulatory authorities decided to suspend the use of this batch of the vaccine while a full investigation is ongoing (e.g. Denmark, Austria, Iceland and Norway), while other agencies such as the UK MHRA and the European Medicine Agency

decided that the lack of causal association indicates that vaccination with Oxford/AstraZeneca vaccine should continue.

The <u>DSRU Global Observatory</u> has been set up to collate outputs regarding current or high-profile drug safety issues from several regulatory authorities. There are a number of broad similarities between national medicines regulators across the world, however there are also important differences in how each agency operates. A long-standing important issue is why different national regulatory authorities can reach different decisions. In response we are regularly publishing 'living' Pharmacovigilance Evidence Reviews on the Global Observatory's webpage, which will be updated when new relevant information becomes available. One such Pharmacovigilance Evidence Review concerns the recent thromboembolic events observed following COVID-19 Vaccine AstraZeneca.

Best wishes

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5.1.2e - Drug Safety Research Unit

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**DSRU Leaders in Real World Safety Studies** 

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