



# CLARITY NEWS

Welcome to CLARITY News. Thanks to your participation, we have collected valuable information that has helped us answer important research questions relating to COVID-19 infection and vaccine response. In this newsletter, we would like to share the impact of your contributions to the CLARITY study, and how we are continuing to use this valuable information to answer other important research questions beyond COVID-19 relating to specific treatments we use in IBD.

## Your participation has helped...



Inform government policy in the UK and globally relating to COVID-19 vaccinations in patients with IBD



Test the use of a finger prick blood-testing kit, including for monitoring of drug levels

## IMPACT of CLARITY IBD



Pioneer the use of digital and direct communication with patients in research studies

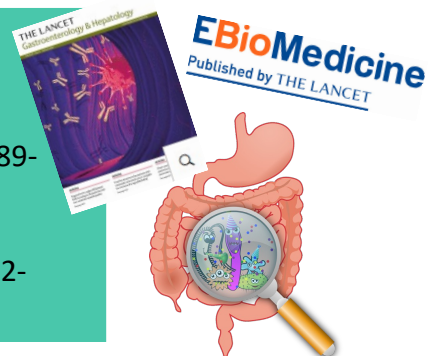
# Effects of COVID-19 vaccine antibodies against different COVID-19 variants and the influence of gut microbiome

Further study results have recently been published in two journals:

*The Lancet Gastroenterology & Hepatology:*

[https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(22\)00389-2/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(22)00389-2/fulltext)

*eBioMedicine:* [https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964\(22\)00612-0/fulltext](https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(22)00612-0/fulltext)



## What did we investigate?

In collaboration with researchers at the Division of Digestive Diseases at Imperial College London, we investigated:

- 1. Neutralising antibody responses following a 3<sup>rd</sup> dose of vaccine to different SARS-CoV-2 variants** (wild-type original variant vs. BA.1 and BA.4/5 Omicron variants) in 871 infliximab- and 417 vedolizumab-treated participants who did not have prior COVID-19 infection.
- 2. The gut microbiome of infliximab-treated participants with IBD undergoing vaccination:** the gut bacteria in stool samples from 43 infliximab-treated participants were studied and compared to the COVID-19 vaccine antibody responses in these participants

## What did the results show?

- After a third dose of SARS-CoV-2 vaccine, patients with IBD treated with infliximab had lower neutralising antibody titres against wild-type SARS-CoV-2, BA.1 and BA.4/5 subvariants when compared to patients treated with vedolizumab. Lower neutralising antibody levels against BA.4/5 was also associated with a shorter time to breakthrough COVID-19 infection.
- COVID-19 infections in CLARITY participants remain mild, and hospitalisations uncommon.
- An individual's gut microbiota may affect antibody response to the SARS-CoV-2 vaccine.

## What does this mean for me?

- 1. Vaccines continue to protect against severe illness, hospitalisations and death in infliximab and vedolizumab-treated patients with inflammatory bowel disease.**
- 2. Infliximab (and other anti-TNFs, including adalimumab) are associated with attenuated antibody responses to wild-type, BA.1 and BA.4/5 Omicron subvariants.**
- 3. Spring booster COVID-19 vaccination programmes are underway and you will be contacted by the NHS or your GP if you are eligible.**

## Ongoing projects

We continue to analyse all the information that we have collected from CLARITY participants. We aim to better understand the impact of specific treatments on COVID-19 infection and vaccination and to address important questions beyond COVID-19:

1. The impact on drug levels and IBD disease activity of switching from intravenous (IV) infliximab/vedolizumab to subcutaneous (SC) preparations during the pandemic (CLARITY-SWITCH)
2. Strategies to improve the vaccine response in patients treated with infliximab
  - Do drug levels at the time of vaccine impact your vaccine response?
  - Do vitamin D levels influence vaccine response?



## Update for our participants in Scotland: How we handle your data

The last patient visit of the CLARITY IBD study was end of June 2022. We are continuing to investigate the impact of immunosuppressive and biologic drugs on COVID-19 vaccine response. Subject to the necessary approvals from Public Health Scotland (PHS) for which our application is currently being processed, we will continue to link the CLARITY study data with COVID-19 testing and vaccination information held by PHS. We will do this using your name, date of birth and CHI number. The study team at the Royal Devon and Exeter Hospital and this government body already hold these data, but the matching process will allow us to securely link the testing and vaccination data with the correct participant in the CLARITY IBD study.

We will destroy your personal identifiable information which enables us to link the study data to you, no later than the end of December 2023. Following this process of anonymisation the CLARITY data will be kept for an additional 4 years before being destroyed. Data will be destroyed safely in accordance with the GDPR and the Data Protection Act 2018, as set out under The Royal Devon University Healthcare NHS Foundation Trust's Data Sharing Framework Contract. This process was approved by an ethical committee that reviewed this study.

If you have any concerns about the use of your data in this way, or would like to withdraw from the study, please contact the CLARITY IBD email: [rdetr.clarityibd@nhs.net](mailto:rdetr.clarityibd@nhs.net)

## Update for all participants: How we handle your data

We had originally planned to anonymise all data from the CLARITY IBD study at the end of June 2023. However, we have faced substantial delays in obtaining data from UK government agencies. We are therefore delaying anonymisation until the end of December 2023.



Once again, from the CLARITY IBD team,  
thank you for participating in the study!

If you have a question, please email us at  
[rde-tr.clarityibd@nhs.net](mailto:rde-tr.clarityibd@nhs.net)