



## **MEMORANDUM #6**

**Date:** August 08, 2022

**To:** All EIMPRIS team members

**From:** MediMergent Project Team

**RE: Protocol Amended 08Jul2022 and 21Jul2022, Updated ICF, Laboratory Reference Manual V1.0 dated 04Aug2022 and SARS-CoV-2 at home test kit expiry**

Hello EIMPRIS Team Members,

You should have received Advarra IRB approval for the amended protocol (amendment 02 dated 08Jul2022 and 21Jul2022) and for the updated ICF (updated ICF dated 22Jul2022). The ESR 22-21698 protocol has been amended along with updating the ICF which reflects the protocol amendment 02 additional procedures.

The amended protocol (dated 08Jul2022 and 21Jul2022) has the following changes:

- Increasing the dose of Evusheld to 600 mg every 6 months (added a second dose of AZD7442 at 6 months)
- Increasing the number of RBD-IgG antibody blood draws to 6 including a 9-month and 12-month blood draw
- Added a T-Cell sample at Day 210
- Added an extra patient survey taken the day after the second dose of AZD7442
- Elimination of the exclusion criteria that states: “AZD7442 IM or IV administration on the same day as the patient receives any IM or IV cancer treatment” so patients may receive study treatment on the same day as their cancer treatment.

Please note that your Advarra IRB approval for the amendment documents the 08Jul2022 protocol date and not the 21Jul2022 date, however, the Advarra approval covers both dates, and all changes are reflected in the amended protocol. We are working with Advarra to correct this.

Attached please find the amended protocol along with a form entitled “Read and Confirm Training Document”. This needs to be completed by your staff once they have reviewed the amended protocol document. Once signed, please upload this to your EIMPRIS regulatory

portal. The amended signature page for the PI's signature will follow once the IRB has corrected their cover sheet.

You should have received the ESR 22-21698 study Laboratory Reference Manual sent out Friday 05Aug2022 under separate cover (Memorandum #5).

Also as requested in Memorandum #5, if you haven't already done so, please review your SARS-CoV-2 at home test kit supply and let us know how many kits you have left and the expiry of your supply. It is important to ensure you have supplies that are not expired and that patients are also using kits that are not expired. The ESR 22-21698 lab manual has information on kits with extended expiry (see the letter at the back of the Laboratory Reference Manual).

Feel free to reach out to us any time at [eimpris@eimpris.com](mailto:eimpris@eimpris.com) or **800-757-7345** if you have any questions. We are here to support you.