EIMPRIS
ENGAGING IMMUNO-PROTECTION INTERVENTION STUDY

Date: July 11, 2022

To: All EIMPRIS Team Members

From: MediMergent Project Team

Memo: Credentials, Labs, and Frequent Questions

This memo provides updates to three major areas of the study: (1) Program Platform Credentials, (2) Lab testing procedures, and (3) Frequently Asked Questions. Please read this Memo carefully and reach out to us with any questions you may have at eimpris@eimpris.com or **800-757-7345.**

As more sites are coming online with the study and more patients are being enrolled, there are new updates to share with you.

Credentials to access the Program Platform

1. Credentials to access the Program Platform, including the Dashboard, have been issued for the staff at your site who will be managing your patients. These users should have received an email from Bryan James with the information necessary to access the Platform. If you believe you should have access to the Program Platform and have not received your credentials, please reach out directly to Bryan at bjames@medimergent.com or call our hotline at 800-757-7345. Please refer to the information provided under FAQ #4 in this Memo for additional instructions on the credentialing process. Please note that if your site's regulatory documents and online training have not been completed, credentials may be delayed.

Lab Tests:

1. **Labeling:** All sites are instructed to affix a label to all vials used for the collection and shipment of all lab samples. This includes samples for LabCorp, PPD and Isoplexis. Each label should include the Patient ID number and the date collected. You were sent both small and large labels in the box of supplies containing all the lab vials to be used for Isoplexis samples plus the COVID home kits and the patient appointment cards to remind your study participants of their monthly surveys, office visits, blood draws, etc. Further, these "**general purpose**" labels should also be affixed to the syringes used for drug administration and placed on the box that contained the Evusheld in order to maintain inventory control and document which box contained drug for a specific patient.

2. **Isoplexis**: As many sites are reaching the Day 30 labs, please be reminded that the Isoplexis lab is temperature sensitive. As such, the lab should only be drawn and sent **Monday** – **Thursday** as the cold pack may not have the longevity to maintain temperature integrity over any weekend. DO NOT DRAW THE ISOPLEXIS SAMPLES

ON FRIDAYS. The video outlining this process has been updated and is available under the RESOURCES tab on the EIMPRIS Provider Training site (provider.eimpris.com). Sites are also reminded to take this into consideration when scheduling appointments for follow up visits.

Frequently Asked Questions (FAQs):

1. **Question**: If a patient is on daily oral therapy for cancer treatment can he/she enroll in EIMPRIS and receive Evusheld?

   Answer: Yes. The protocol requirement for waiting until "after the day" of cancer treatment does not apply to daily oral therapy.

2. **Question**: Can you draw patient's blood at baseline visit, have the patient complete the baseline survey but administer drug on the following day?

   Answer: Yes, but the drug MUST be administered on the following day.

3. **Question:** What do I do if the Patient tests positive for COVID at the baseline visit?

   Answer: If the patient tests positive by rapid test, the patient must complete an RT-PCR test. If the RT-PCR test is positive, the patient is disqualified from study participation. If the RT-PCR test is negative the patient may proceed to the baseline visit.

4. **Question**: Please explain who gets credentials so they can access the study platform?
   Answer: Please read the following **Guidelines for Issuing User Credentials for Study Sites**

Purpose and Intent:

The purpose of this document is to outline the process for the issuance and maintenance of **credentials** that will enable users to access the MediMergent study platform including the Clinical Trials Management Dashboard.

It is the intent of this process to judiciously issue credentials to appropriate and active users as well as to sever the credentials quickly to individuals no longer involved in the study.

Initial Credentials:

Issuing of credentials to appropriate users will be based on several metrics. Potential users need to: (1) have successfully completed the on-line video-based training program; (2) ensure that all regulatory documents have been submitted to MediMergent; (3) name is listed on the Delegation of Responsibility Form; (4) site has received approval from Advarra; (5)

demonstrate active participation in the management of the study patients. Credentials will not be issued until all these metrics have been satisfied.

At the conclusion of the live training/review session, at which users will review the requirements of the study and workflow, attendees will be asked to self-identify who should have access to the study platform based on their role in patient access and management. The User's name, address, phone number, fax number, email address and name of investigator(s) will be collected to allow profiles to be constructed for the study site.

Maintenance:

To maintain the integrity of the study platform, users' access will be monitored. Monthly reports will be generated showing the number of logins of a user. Sites will be contacted to address users who have not logged in within the last 30 days (or who had never logged in). The objective is to ensure that users who no longer work on the EIMPRIS program or at the site do not have access to the study platform. These users will have their credentials terminated. This will also identify potential new users who need credentials to access the platform. Such access will require compliance to the above metrics.

That brings this update to a close. Thank you for commitment to the EIMPRIS Study. Please let us know what we can do to help make EIMPRIS successful for you and your patients.

Feel free to reach out to us any time at eimpris@eimpris.com or **800-757-7345.**