IMPACC Study Access End-To-End Workflow Starting from the ImmPort Shared Data Application (www.immport.org)

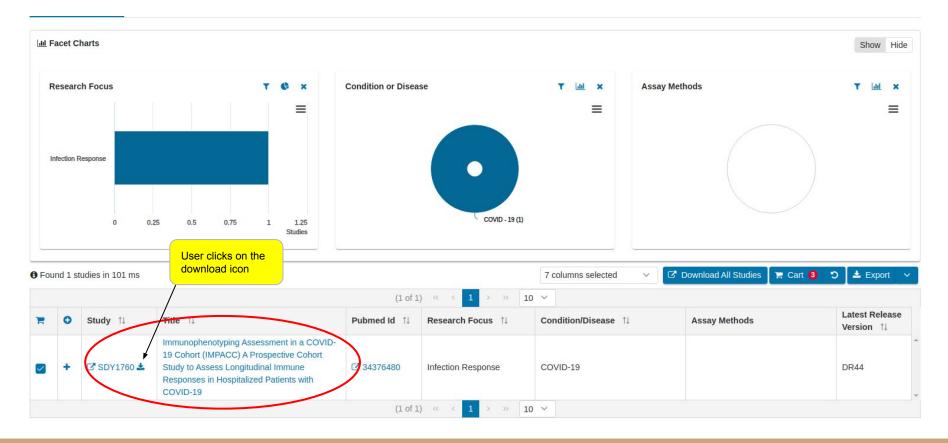
IMPACC Study SDY1760 Access Instructions

- Data associated with the Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) study SDY1760 requires additional registration steps for access
- The IMPACC data are limited to use for COVID-19/SARS-CoV-2 basic and clinical research
- This document provides a step by step guide for accessing the data when starting from the ImmPort study accession <u>SDY1760</u>
- If you have additional questions after reviewing this document, please contact the ImmPort Help Desk at ImmPort_Helpdesk@immport.org





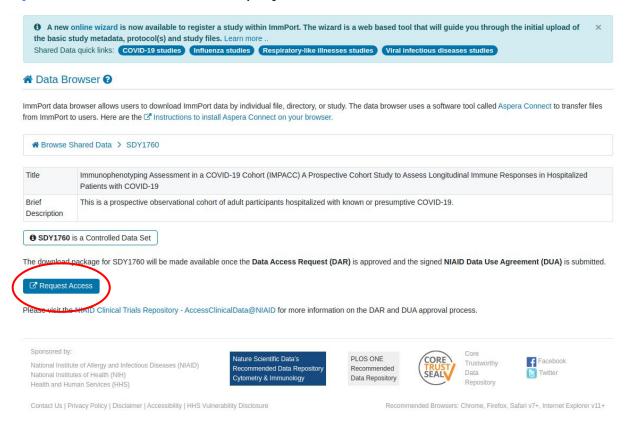
User navigates to IMPACC study <u>SDY1760</u> on the ImmPort Shared Data Application. User clicks the <u>Download Arrow</u> next to the Study Accession to download the data.



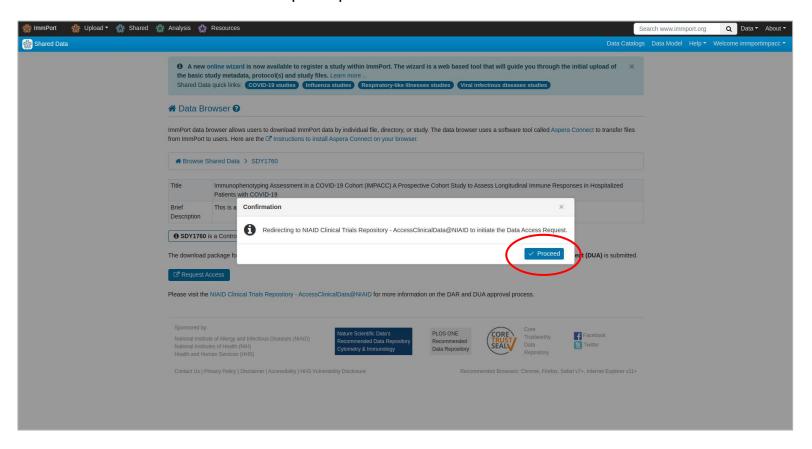
User is presented with the ImmPort Login screen. User logs in with their existing ImmPort credentials, or registers for an account if they are a first time user.



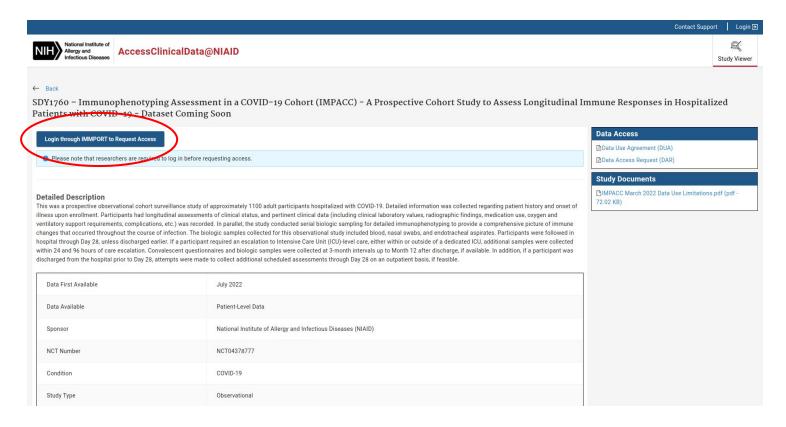
User is presented the download screen for study SDY1760. Since the user does not have access to the data, a **Request Access** button is displayed to the user.



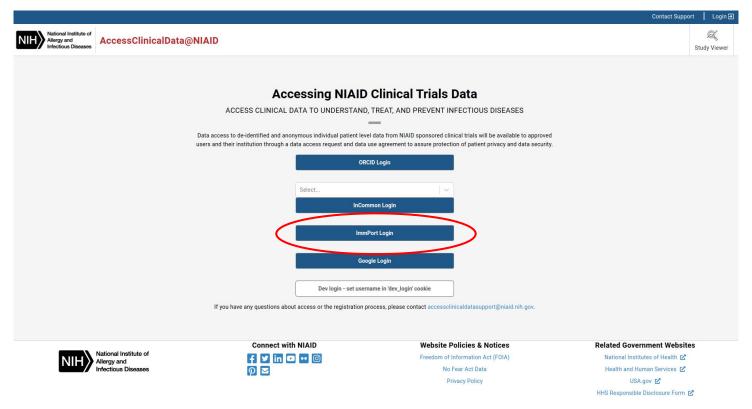
After clicking on the Request Access button, the user is asked to proceed to the Access Clinical Data site to initiate the Data Access Request process. User clicks on the **Proceed** button.



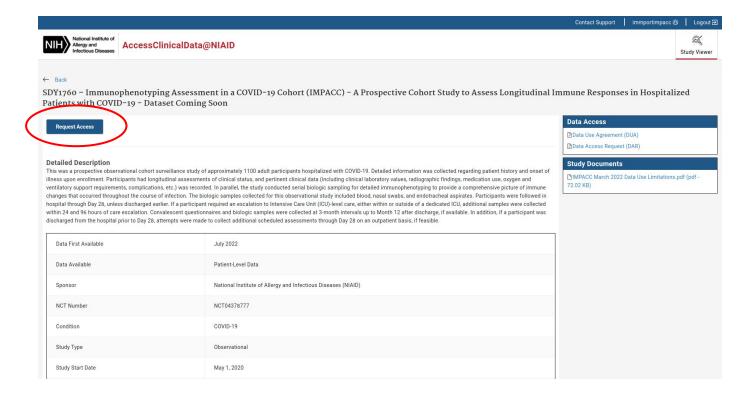
User is taken to the Access Clinical Data site. The user then clicks on the **Login through IMMPORT to Request Access** button.



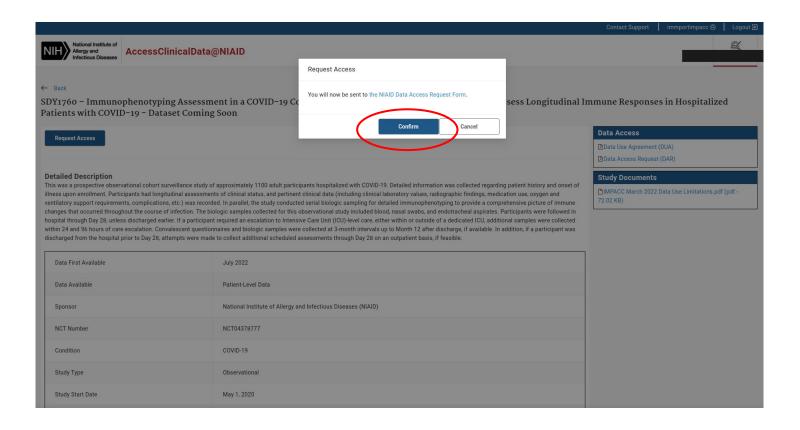
User is taken to the Access Clinical Data Login site. The user then clicks the **ImmPort Login** button. Since the user has already logged in to the ImmPort Data Browser and since single-sign on is enabled, the user gets logged in without having to re-enter their ImmPort credentials.



User then clicks on the **Request Access** button and will be taken to the NIAID Data Access Request form site.

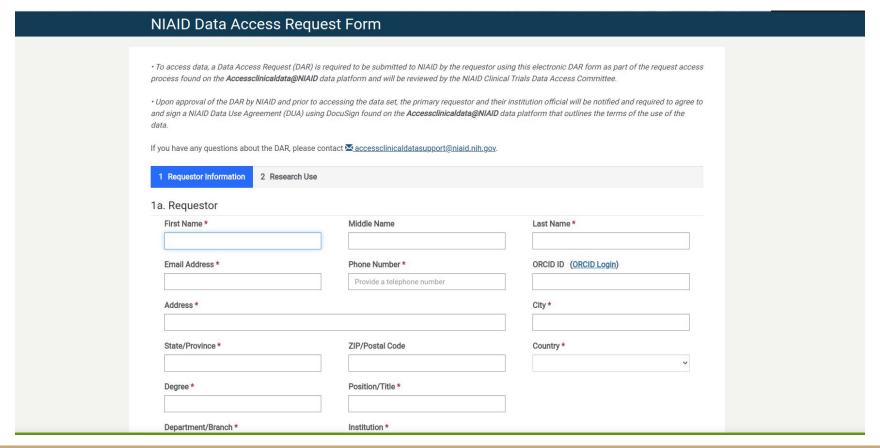


User clicks on the **Confirm** button to go to the NIAID Data Access Request form site.



User is presented the Data Access Form. There are two parts on the first page

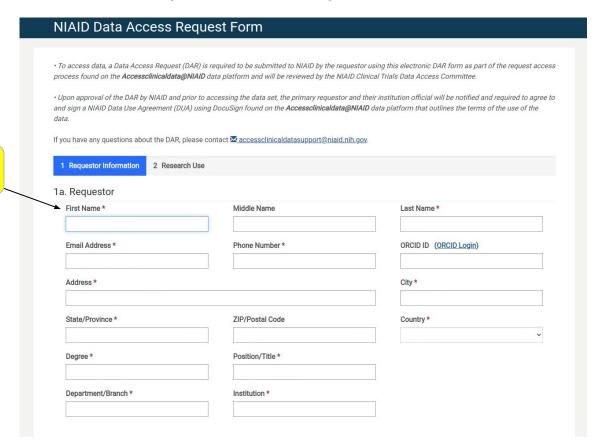
- 1a Requester Information
- 1b Requester's Institution Signing Official Information



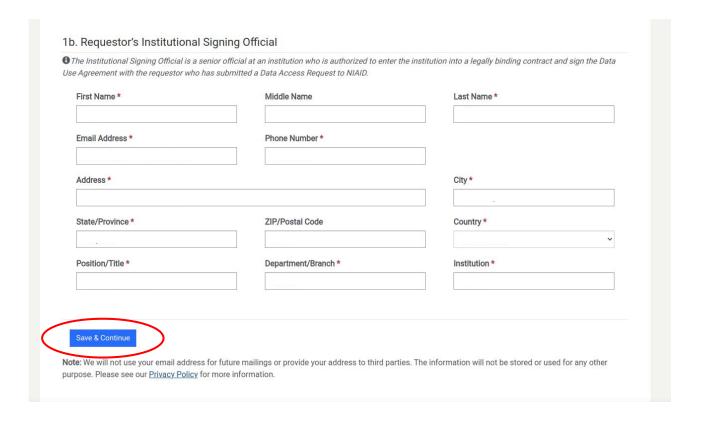
User provides the information requested in 1a - Requestor Information

Required fields are

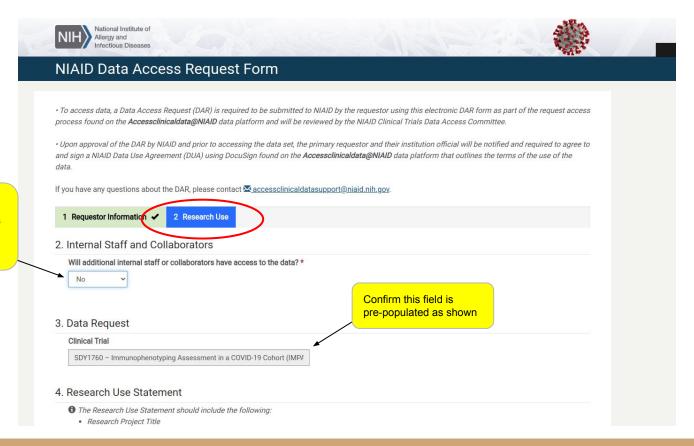
noted with an asterisk



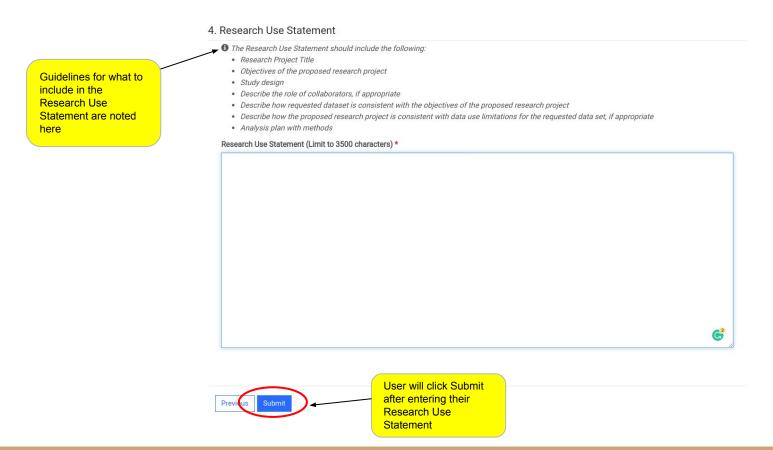
User provides the information requested in 1b - Requester's Institution Signing Official Information and then clicks Save & Continue



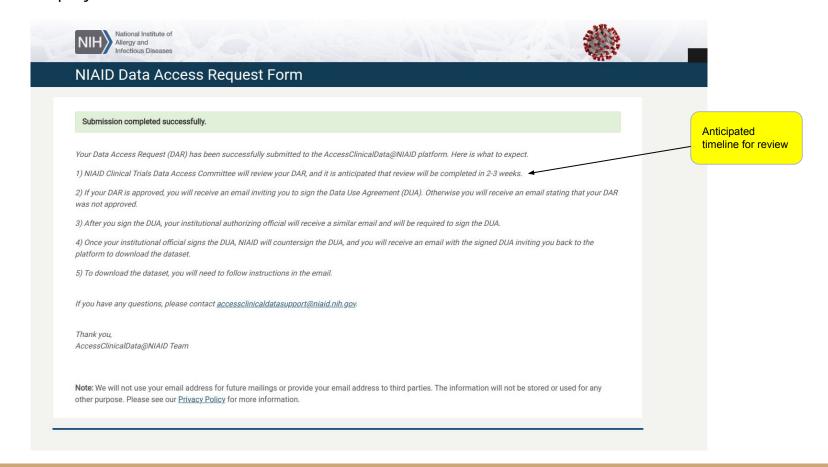
User is sent to the second page of the form, **Research Use**. User can add additional staff that needs access to the data if desired. Confirm the **Data Request** field is pre-populated with the IMPACC study accession SDY1760



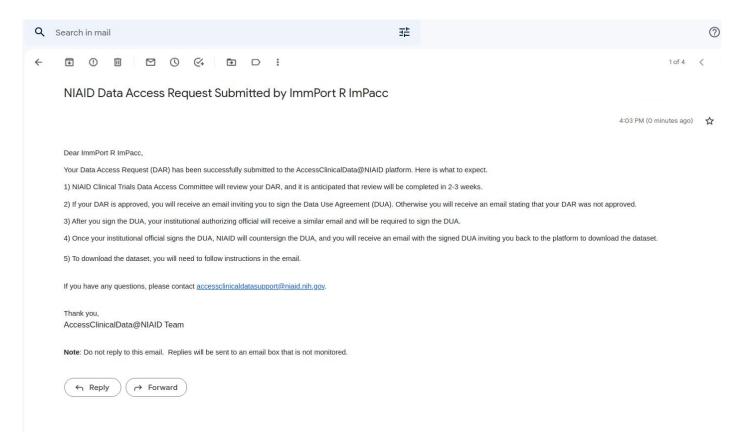
If desired, user can select additional staff that would like access to the data by changing this field to 'Yes' User then has to enter a **Research Use Statement**. Guidelines for what to include in the Research Use Statement are noted. After entering the requested information, the user clicks the **Submit** button.



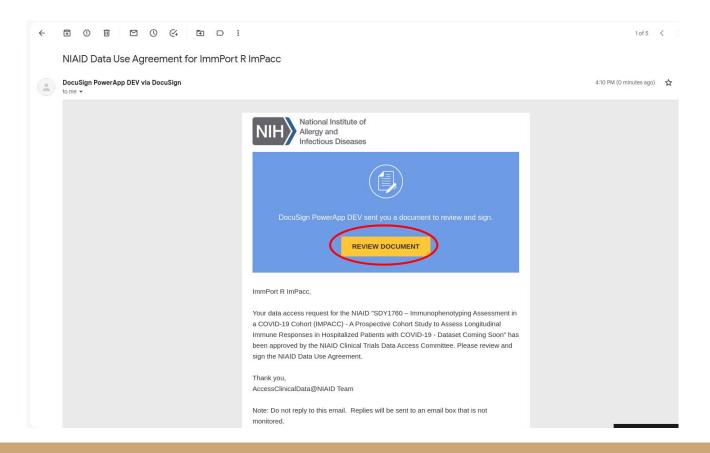
User data access request is submitted successfully and expected approval timelines, as well as next steps, are displayed.



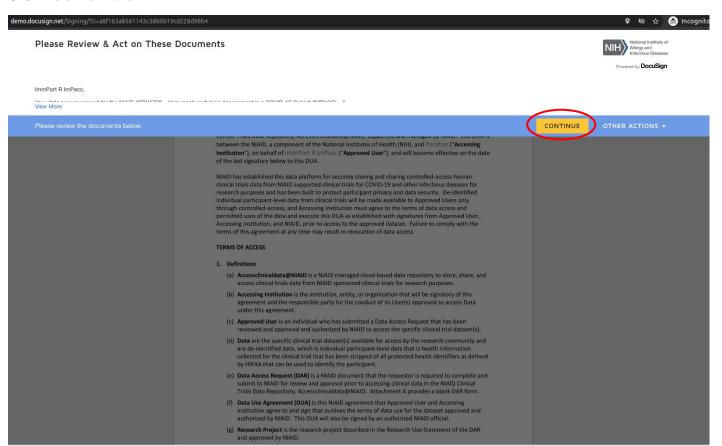
User also receives an email that the Data Access Request has been received. This notification will go to the email address that was provided on **1a** - **Requestor Information** (slide 12).



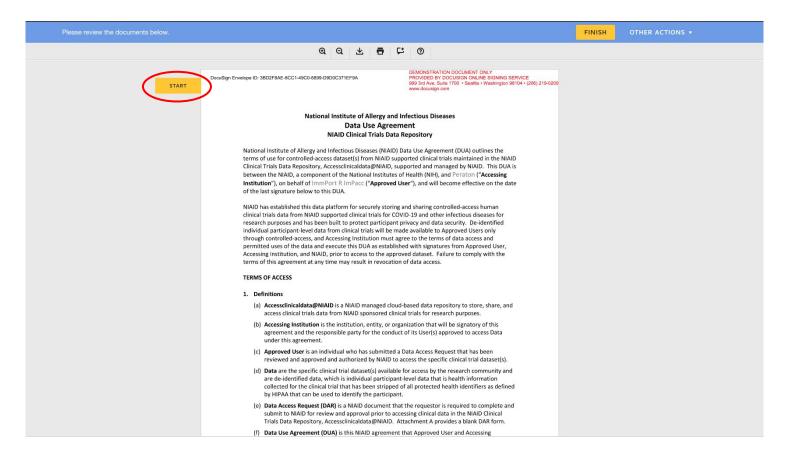
Upon approval of the Data Access Request, the user then receives an email with the Data Use Agreement (DUA) which they will sign via a DocuSign document. To start the process, user clicks on the **Review Document** button.



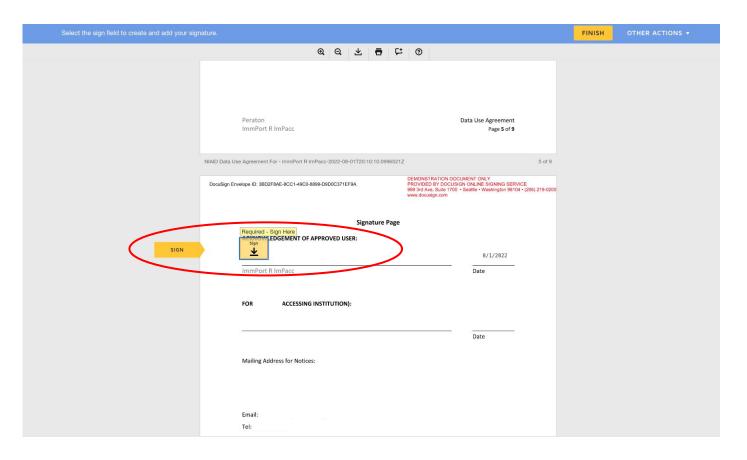
User clicks on **Continue**



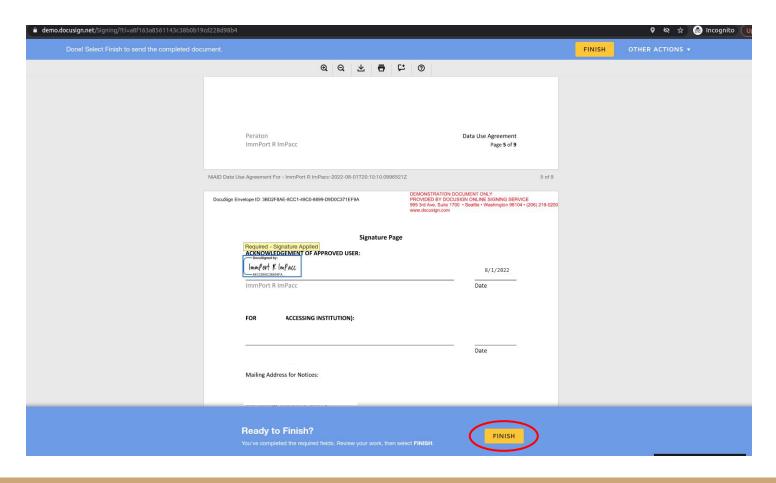
User reviews and clicks on **Start**



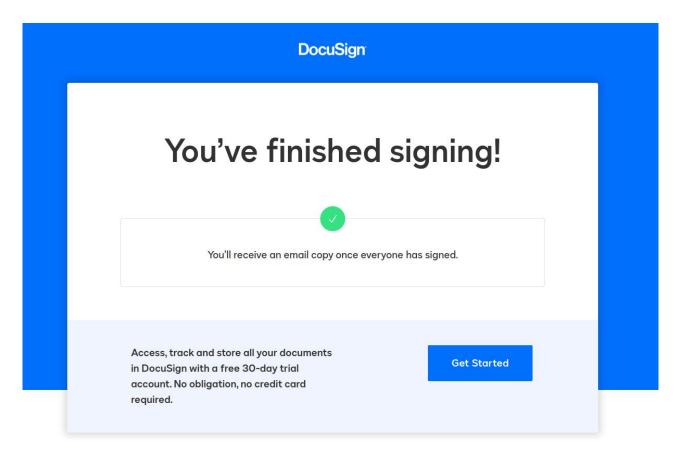
User signs the document



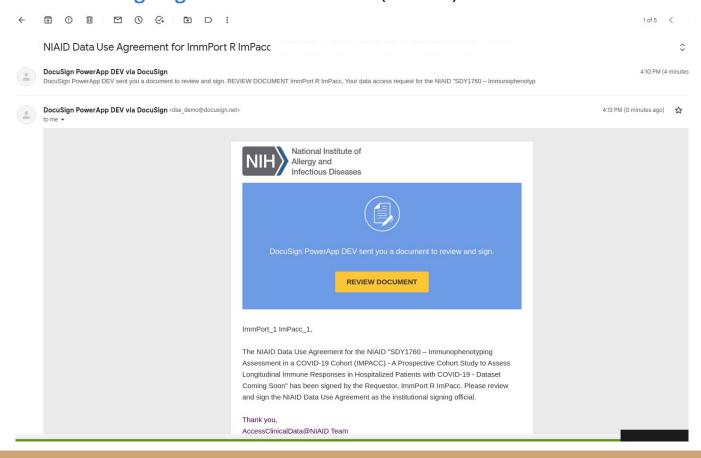
User clicks Finish



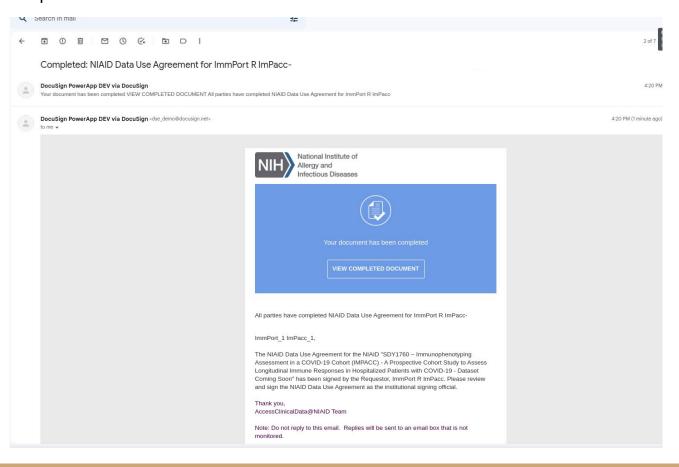
User has finished signing the document



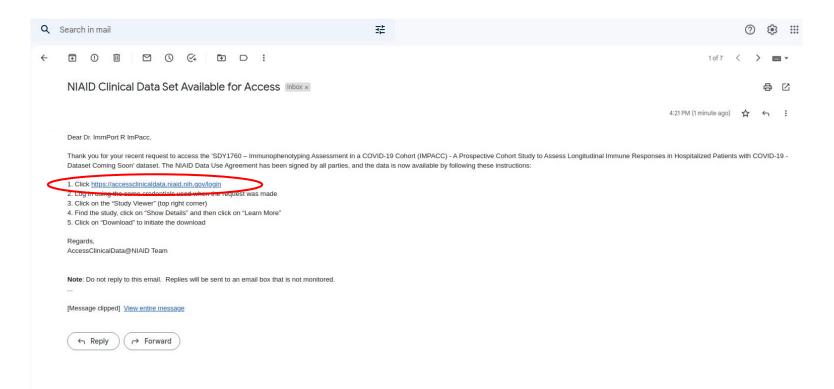
Next, the user's Institution Signing Official will receive an email directing them to review and sign the Data Use Agreement via DocuSign. The email is sent to the address that was entered on form 1b - Requester's Institution Signing Official Information (slide 13).



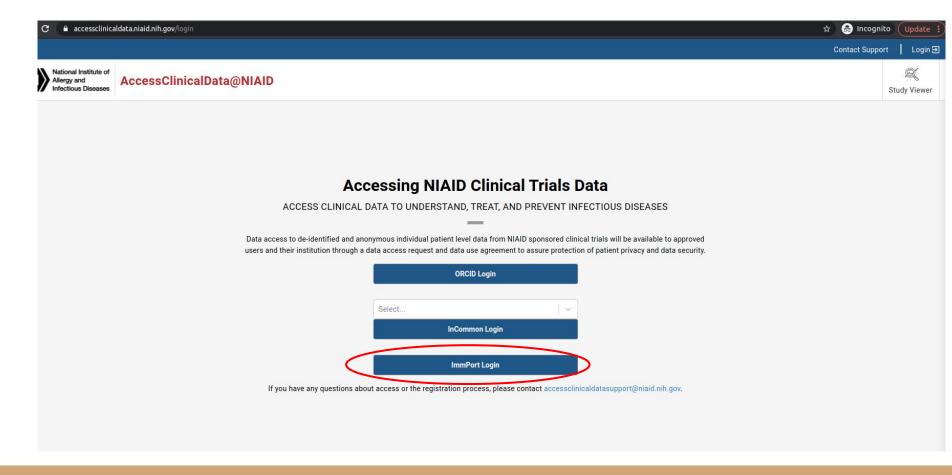
After the user's Institution Signing Official signs the DUA, the user then receives an email that all parties have completed the DUA.



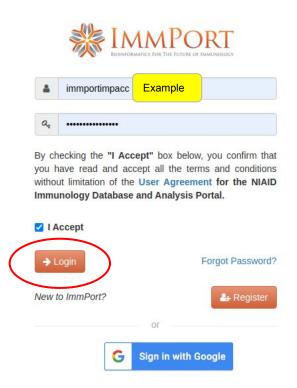
User then receives an email with the **Download Link** to the study. User clicks on the download link.



After clicking the download link, user is presented the login screen. User clicks on the ImmPort Login



User enters their ImmPort credentials and clicks Login



User clicks the **Download** button

AccessClinicalData@NIAID

Contact Support immportimpace @

Logout 3

0 Study Viewer

← Back

SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) - A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized Patients with COVID-19 - Dataset Coming Soon

Download ☑*

Detailed Description

This was a prospective observational cohort surveillance study of approximately 1100 adult participants hospitalized with COVID-19. Detailed information was collected regarding patient history and onset of illness upon enrollment. Participants had longitudinal assessments of clinical status, and pertinent clinical data (including clinical laboratory values, radiographic findings, medication use, oxygen and ventilatory support requirements, complications, etc.) was recorded. In parallel, the study conducted serial biologic sampling for detailed immunophenotyping to provide a comprehensive picture of immune changes that occurred throughout the course of infection. The biologic samples collected for this observational study included blood, nasal swabs, and endotracheal aspirates. Participants were followed in hospital through Day 28, unless discharged earlier. If a participant required an escalation to Intensive Care Unit (ICU)-level care, either within or outside of a dedicated ICU, additional samples were collected within 24 and 96 hours of care escalation. Convalescent questionnaires and biologic samples were collected at 3-month intervals up to Month 12 after discharge, if available. In addition, if a participant was discharged from the hospital prior to Day 28, attempts were made to collect additional scheduled assessments through Day 28 on an outpatient basis, if feasible.

Data First Available	July 2022
Data Available	Patient-Level Data
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
NCT Number	NCT04378777
Condition	COVID-19
Study Type	Observational
Study Start Date	May 1, 2020

Data Access

Pata Use Agreement (DUA) AData Access Request (DAR)

Study Documents

MPACC March 2022 Data Use Limitations.pdf (pdf 72.02 KB)

User is redirected to the ImmPort Data Browser and can now **Download** the data for SDY1760.

