



IMPACC End-To-End Workflow Starting from Publication



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 link provided in the published manuscript
- If you have additional questions after reviewing this document, please contact the ImmPort Help Desk at ImmPort_Helpdesk@immport.org



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User clicks the Access Clinical Data (ACD) link provided in the published manuscript associated with IMPACC study SDY1760

- Publication link to be updated upon formal release. Current release below:
 - <https://www.medrxiv.org/content/10.1101/2022.07.02.22273396v1.full.pdf>
- Data Access Request Link from publication:
 - <https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical-trials>

medRxiv preprint doi: <https://doi.org/10.1101/2022.07.02.22273396>; this version posted July 5, 2022. The copyright holder for this preprint (which was not certified by peer review) is the author/funder, who has granted medRxiv a license to display the preprint in perpetuity. It is made available under a [CC-BY-ND 4.0 International license](#).

The IMPACC Data Sharing Plan is designed to enable the widest dissemination of data, while also protecting the privacy of the participants and the utility of the data by de-identifying and masking potentially sensitive data elements. This approach is fully compliant with the NIH public data sharing policy. The study protocol and clinical dataset are deposited at the Immunology Database and Analysis Portal (ImmPort), a NIAID Division of Allergy, Immunology, and Transplantation-funded data repository, under study accession SDY1760. After publication, it will be available to appropriate academic parties upon request and submission of a suitable study protocol, analysis plan, and signed data use agreement subject to NIAID approval via AccessClinicalData@NIAID (<https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical-trials>). Please contact ImmPort_Helpdesk@immport.org to view data for review purposes. All codes for the analyses and tables generated by this study are available in the [Bitbucket](#) repository.

User is taken to the Access Clinical Data site from the Publication link. The user then clicks on SDY1760 [Show Details](#) link.

The screenshot shows the Access Clinical Data website. The URL in the browser is https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical_trials. The page header includes the NIH logo, the text "National Institute of Allergy and Infectious Diseases", and the text "AccessClinicalData@NIAID". The main content area displays the study title "SDY1760 – Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) - A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized P...". Below the title, there is a "Show details" link. A red oval highlights the study title and the "Show details" link. A yellow box highlights the "Show details" link with an arrow pointing to it. The page footer includes the NIH logo, the text "National Institute of Allergy and Infectious Diseases", and links to "Connect with NIAID", "Website Policies & Notices", and "Related Government Websites".

SDY1760 – Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) - A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized P...

⊕ Show details

Safety and Immunogenicity Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19)

⊕ Show details

Connect with NIAID

Website Policies & Notices

Freedom of Information Act (FOIA)

No Fear Act Data

Privacy Policy

Related Government Websites

National Institutes of Health

Health and Human Services

USA.gov

HHS Responsible Disclosure Form

After expanding details, user is taken to the **Brief Study Description** and then clicks the **Learn More** button.

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 Released August 2022

⊖ Hide details

Learn More

User clicks on Learn More


Brief Study Description

This surveillance study collected detailed clinical, laboratory, and radiographic data in coordination with biologic sampling of blood and respiratory secretions and viral shedding in nasal secretions in order to identify immunophenotypic and genomic features of COVID-19 - related susceptibility and/or progression. The key objectives of the study were to generate data to assist in generating hypotheses for effective host-directed therapeutic interventions, to help to prioritize proposals for such interventions, and/or optimize timing for administration of host-response directed therapeutics.


Data First Available	August 2022
Data Available	Patient-Level Data
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
NCT Number	NCT04378777
Condition	COVID-19

User is presented the SDY1760 Study Detail page. User then clicks on the **Login through IMPORT to Request Access** button.

Contact Support | Login

 National Institute of Allergy and Infectious Diseases

AccessClinicalData@NIAID

 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

Login through IMPORT to Request Access

Please note that researchers are required to log in before requesting access.

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

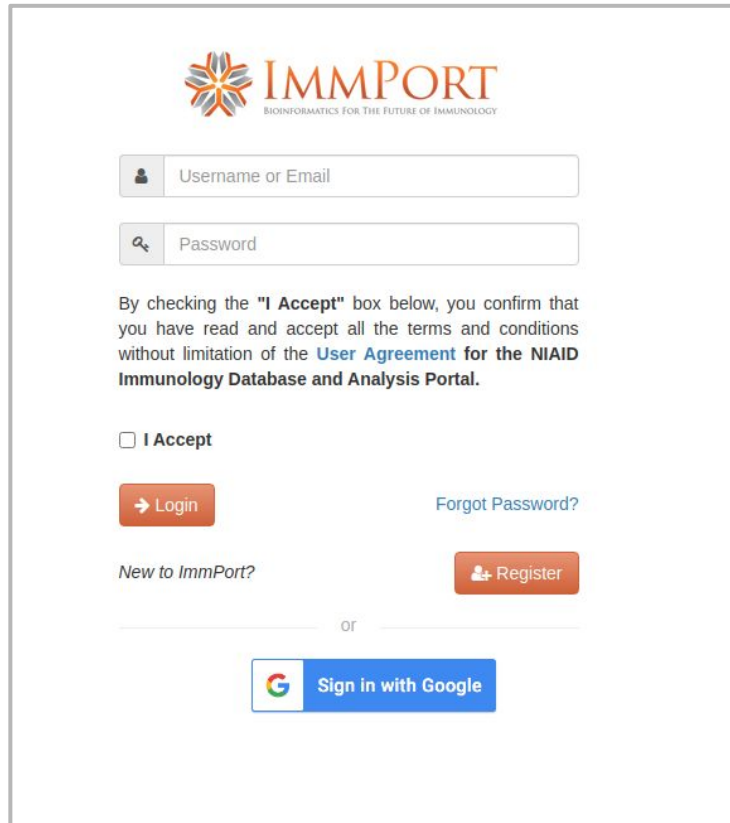
Data Access

[Data Use Agreement \(DUA\)](#)[Data Access Request \(DAR\)](#)

Study Documents

[IMPACC March 2022 Data Use Limitations.pdf \(pdf - 72.02 KB\)](#)

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.



The ImmPort login screen features the logo at the top, followed by input fields for 'Username or Email' and 'Password'. Below these is a paragraph of terms and conditions, an 'I Accept' checkbox, and 'Login' and 'Register' buttons. A 'Forgot Password?' link is also present. At the bottom, there is a 'Sign in with Google' button.

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Username or Email

Password

By checking the "I Accept" box below, you confirm that you have read and accept all the terms and conditions without limitation of the [User Agreement for the NIAID Immunology Database and Analysis Portal](#).

☐ I Accept

→ Login

Forgot Password?

New to ImmPort?

Register

or

Sign in with Google



This version of the ImmPort login screen includes the same elements as the first, but with additional annotations. The 'Login' button is circled in red, and the 'Register' button is also circled in red. A yellow callout box points to the 'Register' button with the text: 'If user does not have an existing ImmPort account, user selects 'Register' to create an account'. A red arrow points from the first screen to this one.

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importimpacc

Example

By checking the "I Accept" box below, you confirm that you have read and accept all the terms and conditions without limitation of the [User Agreement for the NIAID Immunology Database and Analysis Portal](#).

☒ I Accept

→ Login

Forgot Password?

New to ImmPort?

Register


or

Sign in with Google


If user does not have an existing ImmPort account, user selects 'Register' to create an account

User is then taken to the SDY1760 Study Detail page . User then has to click on the **Request Access** button and will be taken to the NIAID Data Access Request Form.

Contact Support | immportimpacc @ | Logout

 National Institute of Allergy and Infectious Diseases

AccessClinicalData@NIAID

 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

[Request Access](#)

Data Access

[Data Use Agreement \(DUA\)](#)
[Data Access Request \(DAR\)](#)

Study Documents

[IMPACC March 2022 Data Use Limitations.pdf \(pdf - 72.02 KB\)](#)

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

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

The screenshot shows the NIAID Data Access Request Form interface. At the top, there is a navigation bar with the NIH logo, the text "National Institute of Allergy and Infectious Diseases", and the email "AccessClinicalData@NIAID". On the right, there are links for "Contact Support", "importimpacc", and "Logout". Below the navigation bar, the main content area displays the study title "SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort" and a subtitle "Patients with COVID-19 - Dataset Coming Soon". A "Request Access" button is visible. A modal window titled "Request Access" is open in the center, showing the message "You will now be sent to the NIAID Data Access Request Form." and two buttons: "Confirm" (highlighted with a red circle) and "Cancel". To the right of the modal, there is a sidebar with sections for "Data Access" (containing links for "Data Use Agreement (DUA)" and "Data Access Request (DAR)") and "Study Documents" (containing a link for "IMPACC March 2022 Data Use Limitations.pdf (pdf - 72.02 KB)").

Request Access

You will now be sent to the [NIAID Data Access Request Form](#).

Confirm Cancel

SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort
Patients with COVID-19 - Dataset Coming Soon

Request Access

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.

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NCT Number	NCT04378777
Condition	COVID-19
Study Type	Observational
Study Start Date	May 1, 2020

Data Access

- Data Use Agreement (DUA)
- Data Access Request (DAR)

Study Documents

- IMPACC March 2022 Data Use Limitations.pdf (pdf - 72.02 KB)

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

niaiddevportal.dynamics365portals.us/en-US/data-use-request/?request_id=b255dfa4-dad7-4996-98eb-78b51d66d77e&resource_id=SDY1760&resource_display_name=SDY1760%20-%20Immunophenotyping%20Assessment%20in%20... Update

NIH National Institute of Allergy and Infectious Diseases

NIAID Data Access Request Form

To access data, a Data Access Request (DAR) is required to be submitted to NIAID by the requestor using this electronic DAR form as part of the request access process found on the Accessclinicaldata@niaid data platform and will be reviewed by the NIAID Clinical Trials Data Access Committee.

Upon approval of the DAR by NIAID and prior to accessing the data set, the primary requestor and their institution official will be notified and required to agree to and sign a NIAID Data Use Agreement (DUA) using DocuSign found on the Accessclinicaldata@niaid data platform that outlines the terms of the use of the data.

If you have any questions about the DAR, please contact accessclinicaldatasupport@niaid.nih.gov.

1 Requester Information

2 Research Use

1a. Requestor

First Name *	Middle Name	Last Name *
<input type="text"/>	<input type="text"/>	<input type="text"/>
Email Address *	Phone Number *	ORCID ID (ORCID Login)
<input type="text"/>	<input type="text" value="Provide a telephone number"/>	<input type="text"/>
Address *		City *
<input type="text"/>		<input type="text"/>
State/Province *	ZIP/Postal Code	Country *
<input type="text"/>	<input type="text"/>	<input type="text" value="v"/>
Degree *	Position/Title *	
<input type="text"/>	<input type="text"/>	
Department/Branch *	Institution *	
<input type="text"/>	<input type="text"/>	

User provides the information requested in **1a - Requestor Information**

NIAID Data Access Request Form

* To access data, a Data Access Request (DAR) is required to be submitted to NIAID by the requestor using this electronic DAR form as part of the request access process found on the Accessclinicaldata@NIAID data platform and will be reviewed by the NIAID Clinical Trials Data Access Committee.

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If you have any questions about the DAR, please contact ✉ accessclinicaldatasupport@niaid.nih.gov.

1 Requestor Information 2 Research Use

1a. Requestor

First Name *

Middle Name

Last Name *

Email Address *

Phone Number *

ORCID ID ([ORCID Login](#))

Address *

City *

State/Province *

ZIP/Postal Code

Country *

Degree *

Position/Title *

Department/Branch *

Institution *

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**

1b. Requestor's Institutional Signing Official

 The Institutional Signing Official is a senior official at an institution who is authorized to enter the institution into a legally binding contract and sign the Data Use Agreement with the requestor who has submitted a Data Access Request to NIAID.

First Name *

Middle Name

Last Name *

Email Address *

Phone Number *

Address *

City *

State/Province *

ZIP/Postal Code

Country *

Position/Title *

Department/Branch *

Institution *

Save & Continue

Note: We will not use your email address for future mailings or provide your address to third parties. The information will not be stored or used for any other purpose. Please see our [Privacy Policy](#) for more information.

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

The screenshot shows the NIAID Data Access Request Form. At the top, the NIH logo and the text 'National Institute of Allergy and Infectious Diseases' are visible. A red coronavirus icon is in the top right corner. The title 'NIAID Data Access Request Form' is centered in a dark blue header. Below the header, there are two paragraphs of text explaining the DAR process. A link for questions is provided. The form is divided into four steps: 1. Requestor Information (checked), 2. Research Use (highlighted with a red circle), 3. Data Request, and 4. Research Use Statement. In step 2, there is a question 'Will additional internal staff or collaborators have access to the data?' with a dropdown menu showing 'No'. In step 3, the 'Clinical Trial' field is pre-populated with 'SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC)'. In step 4, there is a note that the Research Use Statement should include the Research Project Title.

NIH National Institute of Allergy and Infectious Diseases

NIAID Data Access Request Form

• To access data, a Data Access Request (DAR) is required to be submitted to NIAID by the requestor using this electronic DAR form as part of the request access process found on the [Accessclinicaldata@NIAID](#) data platform and will be reviewed by the NIAID Clinical Trials Data Access Committee.

• Upon approval of the DAR by NIAID and prior to accessing the data set, the primary requestor and their institution official will be notified and required to agree to and sign a NIAID Data Use Agreement (DUA) using DocuSign found on the [Accessclinicaldata@NIAID](#) data platform that outlines the terms of the use of the data.

If you have any questions about the DAR, please contact accessclinicaldatasupport@niaid.nih.gov.

1 Requestor Information ✓ 2 Research Use

2. Internal Staff and Collaborators

Will additional internal staff or collaborators have access to the data? *

No

3. Data Request

Clinical Trial

SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC)

4. Research Use Statement

The Research Use Statement should include the following:

- Research Project Title

If desired, user can select additional staff that would like access to the data by changing this field to 'Yes'

Confirm this field is pre-populated as shown

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.

4. Research Use Statement

 The Research Use Statement should include the following:

- Research Project Title
- Objectives of the proposed research project
- Study design
- Describe the role of collaborators, if appropriate
- Describe how requested dataset is consistent with the objectives of the proposed research project
- Describe how the proposed research project is consistent with data use limitations for the requested data set, if appropriate
- Analysis plan with methods

Research Use Statement (Limit to 3500 characters) *




Previous

Submit


User will click Submit
after entering their
Research Use
Statement

Guidelines for what to
include in the
Research Use
Statement are noted
here

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



National Institute of
Allergy and
Infectious Diseases



NIAID Data Access Request Form

Submission completed successfully.

Your Data Access Request (DAR) has been successfully submitted to the AccessClinicalData@NIAID platform. Here is what to expect.

- 1) NIAID Clinical Trials Data Access Committee will review your DAR, and it is anticipated that review will be completed in 2-3 weeks.
- 2) If your DAR is approved, you will receive an email inviting you to sign the Data Use Agreement (DUA). Otherwise you will receive an email stating that your DAR was not approved.
- 3) After you sign the DUA, your institutional authorizing official will receive a similar email and will be required to sign the DUA.
- 4) Once your institutional official signs the DUA, NIAID will countersign the DUA, and you will receive an email with the signed DUA inviting you back to the platform to download the dataset.
- 5) To download the dataset, you will need to follow instructions in the email.

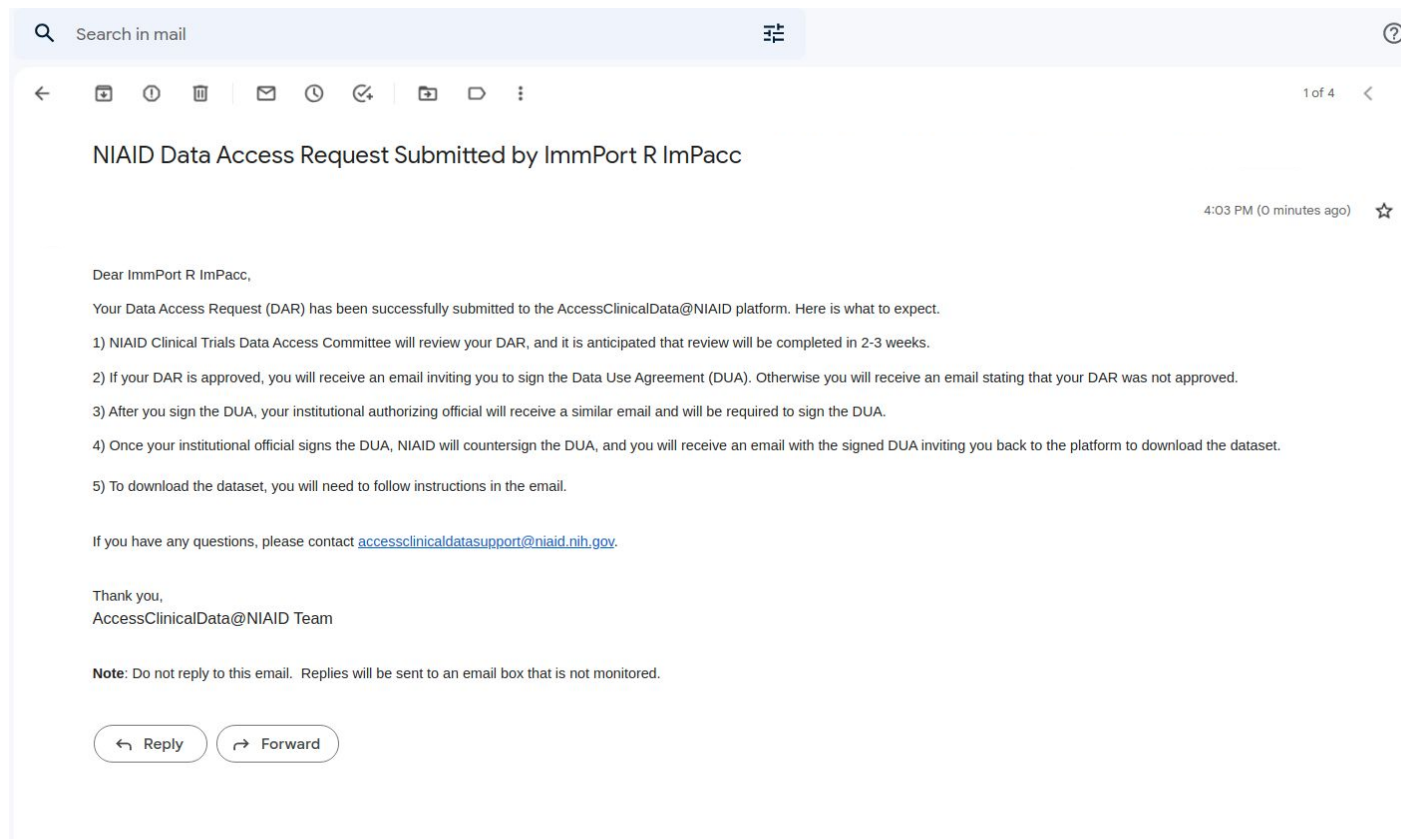
If you have any questions, please contact accessclinicaldatasupport@niaid.nih.gov.

Thank you,
AccessClinicalData@NIAID Team

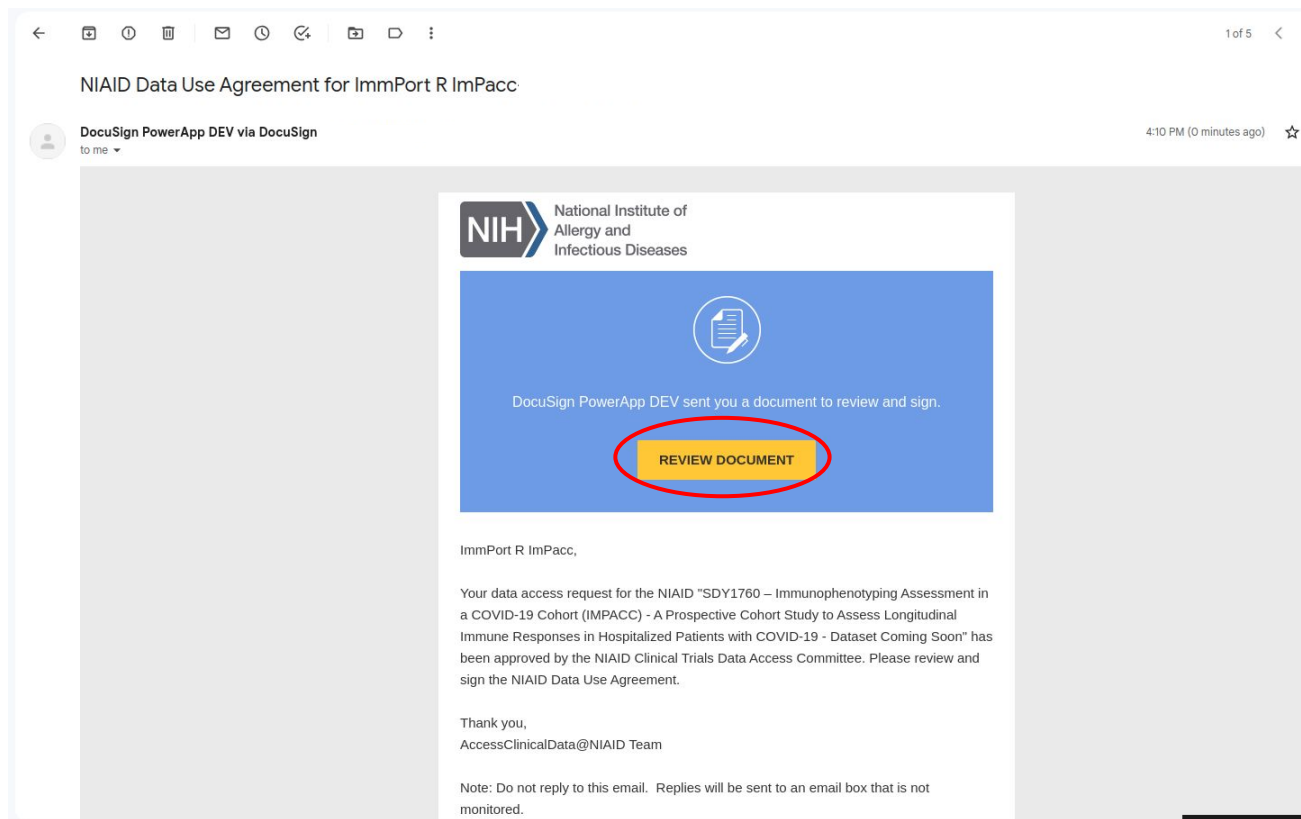
Note: We will not use your email address for future mailings or provide your email address to third parties. The information will not be stored or used for any other purpose. Please see our [Privacy Policy](#) for more information.

Anticipated
timeline for review

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 11).



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

demo.docusign.net/signing/?ti=a8f163a8561143c38b0b19cd228d98b4

Please Review & Act on These Documents

NIH National Institute of Allergy and Infectious Diseases
Powered by DocuSign

ImmPort R ImPacc,
View data access request for the NIAID ImmPort R ImPacc R Project Access Request for COVID-19 Data ImPacc R
[View More](#)

Please review the documents below.

CONTINUE OTHER ACTIONS ▾

Consent to use data repository, Access clinical data repository, approved and managed by NIAID, the DUA is between the NIAID, a component of the National Institutes of Health (NIH), and Peraton ("Accessing Institution"), on behalf of ImmPort R ImPacc ("Approved User"), and will become effective on the date of the last signature below to this DUA.

NIAID has established this data platform for securely storing and sharing controlled-access human clinical trials data from NIAID supported clinical trials for COVID-19 and other infectious diseases for research purposes and has been built to protect participant privacy and data security. De-identified individual participant-level data from clinical trials will be made available to Approved Users only through controlled-access, and Accessing Institution must agree to the terms of data access and permitted uses of the data and execute this DUA as established with signatures from Approved User, Accessing Institution, and NIAID, prior to access to the approved dataset. Failure to comply with the terms of this agreement at any time may result in revocation of data access.

TERMS OF ACCESS

1. Definitions

- (a) **Accessclinicaldata@NIAID** is a NIAID managed cloud-based data repository to store, share, and access clinical trials data from NIAID sponsored clinical trials for research purposes.
- (b) **Accessing Institution** is the institution, entity, or organization that will be signatory of this agreement and the responsible party for the conduct of its User(s) approved to access Data under this agreement.
- (c) **Approved User** is an individual who has submitted a Data Access Request that has been reviewed and approved and authorized by NIAID to access the specific clinical trial dataset(s).
- (d) **Data** are the specific clinical trial dataset(s) available for access by the research community and are de-identified data, which is individual participant-level data that is health information collected for the clinical trial that has been stripped of all protected health identifiers as defined by HIPAA that can be used to identify the participant.
- (e) **Data Access Request (DAR)** is a NIAID document that the requestor is required to complete and submit to NIAID for review and approval prior to accessing clinical data in the NIAID Clinical Trials Data Repository, Accessclinicaldata@NIAID. Attachment A provides a blank DAR form.
- (f) **Data Use Agreement (DUA)** is this NIAID agreement that Approved User and Accessing Institution agree to and sign that outlines the terms of data use for the dataset approved and authorized by NIAID. This DUA will also be signed by an authorized NIAID official.
- (g) **Research Project** is the research project described in the Research Use Statement of the DAR and approved by NIAID.

User reviews and clicks on **Start**

Please review the documents below.

FINISH OTHER ACTIONS ▾

DocuSign Envelope ID: 3BD2FBAE-80C1-49C0-8899-D9D0C371EF9A

DEMONSTRATION DOCUMENT ONLY
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999 3rd Ave, Suite 1700 • Seattle • Washington 98104 • (206) 219-0200
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START

National Institute of Allergy and Infectious Diseases Data Use Agreement NIAID Clinical Trials Data Repository

National Institute of Allergy and Infectious Diseases (NIAID) Data Use Agreement (DUA) outlines the terms of use for controlled-access dataset(s) from NIAID supported clinical trials maintained in the NIAID Clinical Trials Data Repository, Accessclinicaldata@NIAID, supported and managed by NIAID. This DUA is between the NIAID, a component of the National Institutes of Health (NIH), and Peraton ("Accessing Institution"), on behalf of ImmPort R ImPacc ("Approved User"), and will become effective on the date of the last signature below to this DUA.

NIAID has established this data platform for securely storing and sharing controlled-access human clinical trials data from NIAID supported clinical trials for COVID-19 and other infectious diseases for research purposes and has been built to protect participant privacy and data security. De-identified individual participant-level data from clinical trials will be made available to Approved Users only through controlled-access, and Accessing Institution must agree to the terms of data access and permitted uses of the data and execute this DUA as established with signatures from Approved User, Accessing Institution, and NIAID, prior to access to the approved dataset. Failure to comply with the terms of this agreement at any time may result in revocation of data access.

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- (f) **Data Use Agreement (DUA)** is this NIAID agreement that Approved User and Accessing

User signs the document

Select the sign field to create and add your signature.

FINISH **OTHER ACTIONS ▾**

Peraton
ImmPort R ImPacc

Data Use Agreement
Page 5 of 9

NIAID Data Use Agreement For - ImmPort R ImPacc-2022-08-01T20:10:10.0996521Z 5 of 9

DocuSign Envelope ID: 3BD2F8AE-8CC1-49C0-8899-D9D0C371EF9A

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www.docusign.com

Signature Page

Required - Sign Here

DECLARATION OF APPROVED USER:

SIGN

Sign
↓

ImmPort R ImPacc

8/1/2022

Date

FOR **ACCESSING INSTITUTION):**

Date

Mailing Address for Notices:

Email:

Tel:

User clicks **Finish**

demo.docusign.net/Signing/7ti=a9f163a8561143c38b0b19cd228d98b4

Incognito

Done! Select Finish to send the completed document.

FINISH

OTHER ACTIONS ▾

Peraton

ImmPort R ImPacc

Data Use Agreement

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NIAID Data Use Agreement For - ImmPort R ImPacc-2022-08-01T20:10:10.0996521Z5 of 9

DocuSign Envelope ID: 3BD2F8AE-8CC1-49C0-8899-D6D0C371EF9A

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www.docusign.com

Signature Page

Required - Signature Applied

ACKNOWLEDGEMENT OF APPROVED USER:

ImmPort R ImPacc

8/1/2022

ImmPort R ImPacc

Date

FOR

ACCESSING INSTITUTION):

Date

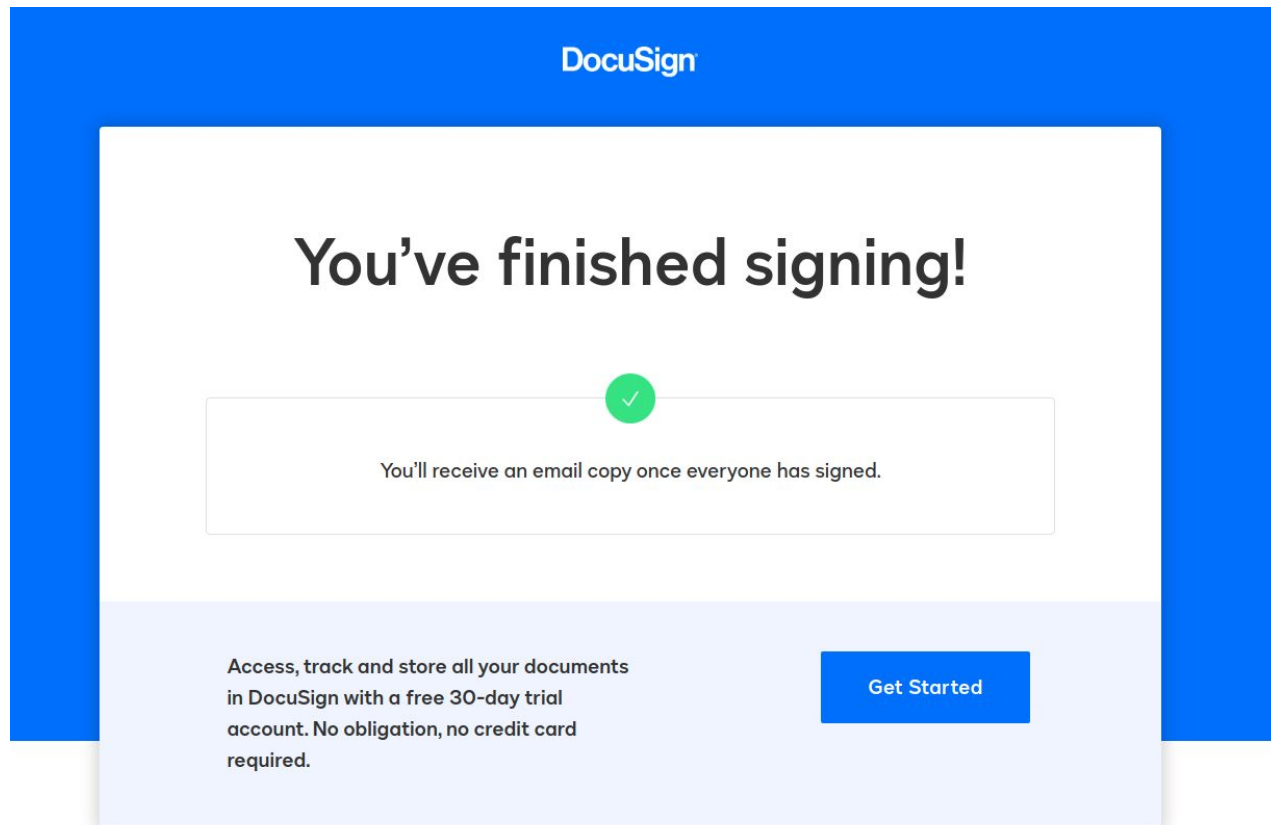
Mailing Address for Notices:

Ready to Finish?

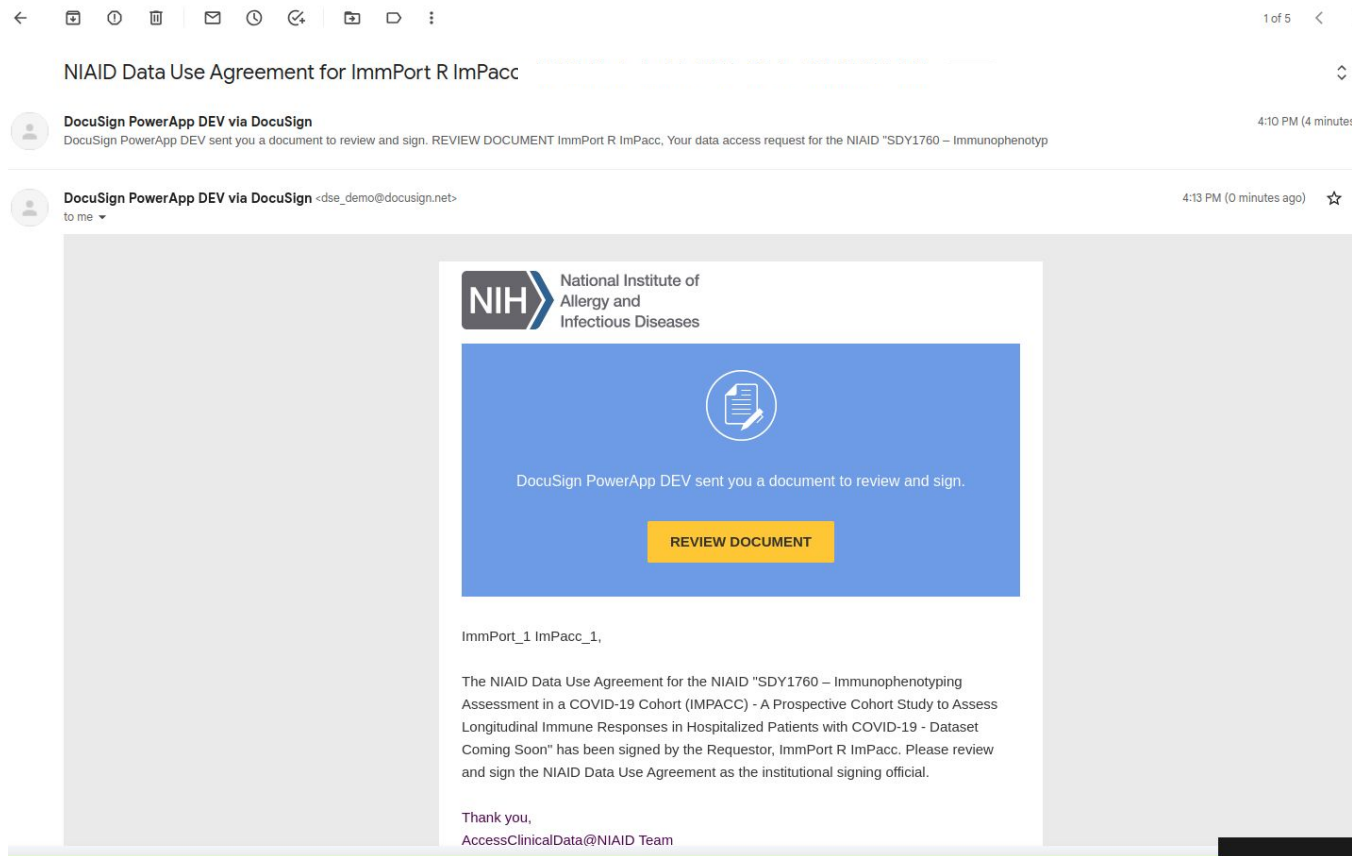
You've completed the required fields. Review your work, then select **FINISH**.

FINISH

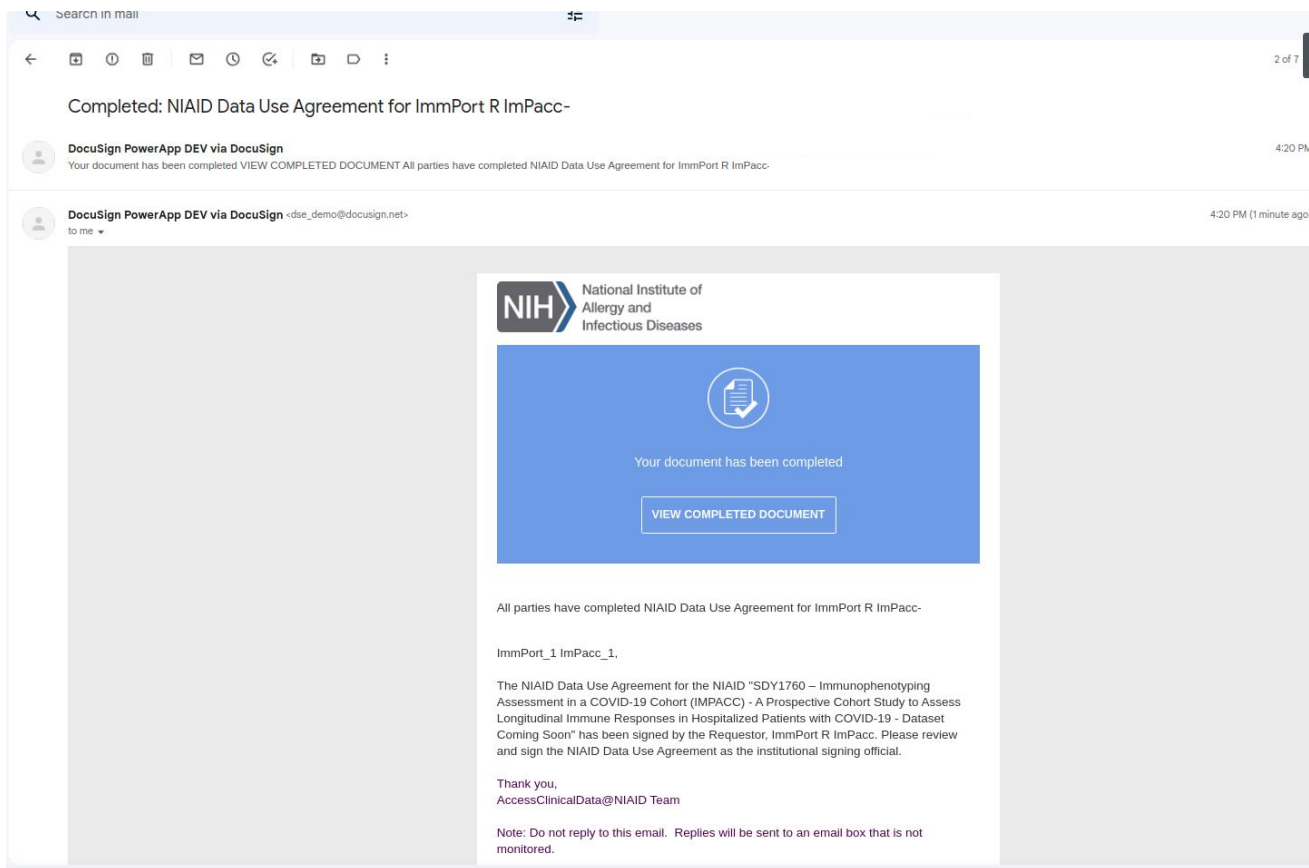
User has finished signing the document



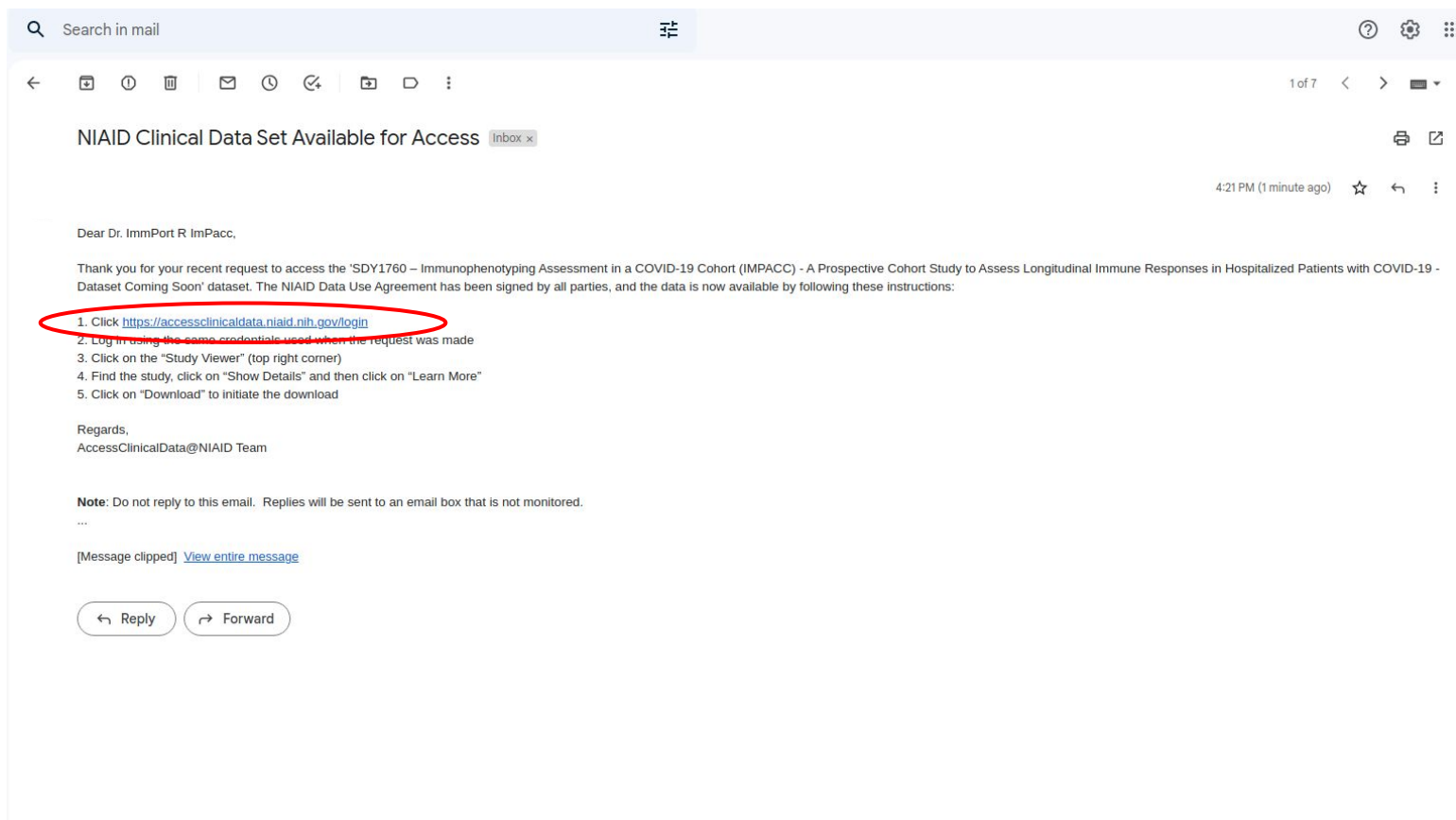
Next, the user's Institution Signing Official will receive an email directing them to review and sign the Data Use Agreement via DocuSign. The email is sent to the address that was entered on form **1b - Requester's Institution Signing Official Information** (slide 12).



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**

accessclinicaldata.niaid.nih.gov/login

Incognito Update

Contact Support | Login

National Institute of Allergy and Infectious Diseases

AccessClinicalData@NIAID

Study Viewer

Accessing NIAID Clinical Trials Data

ACCESS CLINICAL DATA TO UNDERSTAND, TREAT, AND PREVENT INFECTIOUS DISEASES

Data access to de-identified and anonymous individual patient level data from NIAID sponsored clinical trials will be available to approved users and their institution through a data access request and data use agreement to assure protection of patient privacy and data security.

ORCID Login

Select...


InCommon Login


ImmPort Login


If you have any questions about access or the registration process, please contact accessclinicaldatasupport@niaid.nih.gov.

User enters their ImmPort credentials and clicks **Login**

Example of login-
User needs to
enter their own
credentials.









By checking the "**I Accept**" box below, you confirm that you have read and accept all the terms and conditions without limitation of the [User Agreement for the NIAID Immunology Database and Analysis Portal](#).


☒ **I Accept**



[Forgot Password?](#)


New to ImmPort? 

OR


 [Sign in with Google](#)

User clicks the **Download** button

Contact Support | immportimpacc @ | Logout

 National Institute of Allergy and Infectious Diseases

AccessClinicalData@NIAID

 Study Viewer

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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

 [Data Use Agreement \(DUA\)](#)

 [Data Access Request \(DAR\)](#)

Study Documents

 [IMPACC 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.

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Data Model

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Welcome immportimpacc

A new online wizard is now available to register a study within ImmPort. The wizard is a web based tool that will guide you through the initial upload of the basic study metadata, protocol(s) and study files. [Learn more ...](#)

Shared Data quick links: [COVID-19 studies](#) [Influenza studies](#) [Respiratory-like illnesses studies](#) [Viral infectious diseases studies](#)

Data Browser

ImmPort data browser allows users to download ImmPort data by individual file, directory, or study. The data browser uses a software tool called [Aspera Connect](#) to transfer files from ImmPort to users. Here are the [Instructions to install Aspera Connect on your browser](#).

[Browse Shared Data](#) > SDY1760

Title	Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized Patients with COVID-19
Brief Description	This is a prospective observational cohort of adult participants hospitalized with known or presumptive COVID-19.

SDY1760 is a Controlled Data Set

	Name	Size	Last Modified
<input type="checkbox"/>	Protocols (1 files)	13.70 KB	May 5, 2022 8:20 AM
<input type="checkbox"/>	ResultFiles (0 files)	0.00 bytes	Mar 29, 2022 16:01 PM
<input type="checkbox"/>	StudyFiles (1 files)	211.00 bytes	Aug 1, 2022 14:27 PM

Showing 1 to 3 of 3 records

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National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
Health and Human Services (HHS)

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Cytometry & Immunology

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Recommended Browsers: Chrome, Firefox, Safari v7+, Internet Explorer v11+