



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@import.org



IMMPORT

BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY

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 The copyright holder for this preprint (which was not certified by peer review) is the author/funder, who has granted medRxiv a license to display the preprint in perpetuity.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@import.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.

https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical_trials

Contact Support | Login

NIH National Institute of Allergy and Infectious Diseases **AccessClinicalData@NIAID** Study Viewer

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

Show details

NIH National Institute of Allergy and Infectious Diseases

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

User clicks on the + icon to expand details

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

User clicks on Learn More

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

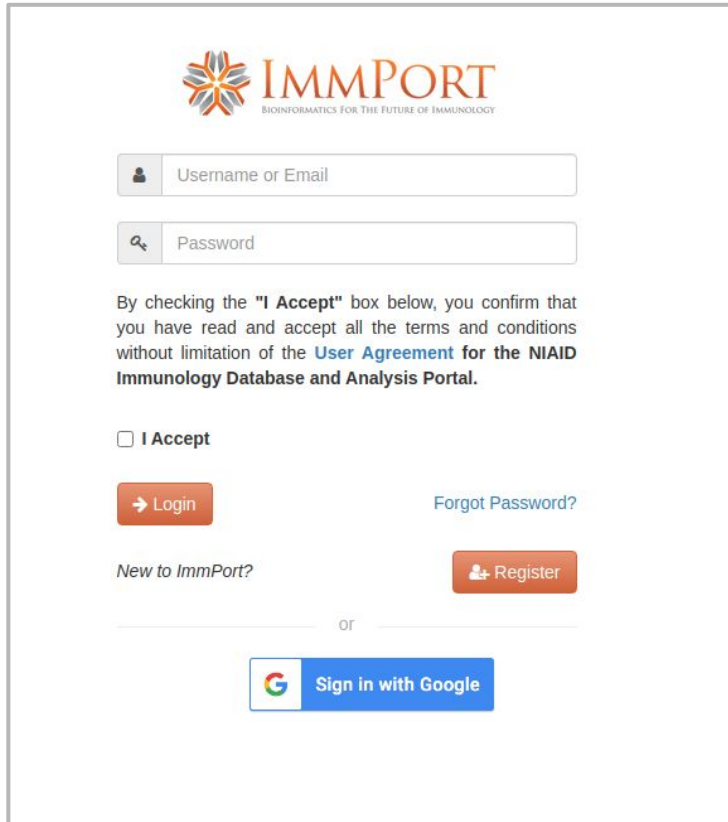
Data Access

- 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 logo is at the top, with the tagline "BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY". Below it are two input fields: "Username or Email" and "Password". A paragraph of text follows: "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](#)." Below this text is a checkbox labeled "I Accept". There are two buttons: "Login" and "Register". A link "Forgot Password?" is also present. At the bottom, there is a "Sign in with Google" button.



This is the same ImmPort login screen as the first image, but with annotations. The "Username or Email" field contains the text "importimpacc" and is highlighted with a yellow box labeled "Example". The "Password" field contains a series of dots. The "I Accept" checkbox is checked. The "Login" button is circled in red. The "Register" button is also circled in red. A yellow callout box with an arrow pointing to the "Register" button contains the text: "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](#)

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

The screenshot shows the NIAID AccessClinicalData portal. At the top, there is a navigation bar with 'Contact Support', 'importimpacc', and 'Logout'. The main header includes the NIH logo and the email 'AccessClinicalData@NIAID'. The page title is 'SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort of Hospitalized Patients with COVID-19 - Dataset Coming Soon'. A 'Request Access' button is visible. A modal dialog box titled 'Request Access' is centered on the screen, containing the text 'You will now be sent to the NIAID Data Access Request Form.' and two buttons: 'Confirm' (circled in red) and 'Cancel'. The background content includes a 'Data Access' section with links for 'Data Use Agreement (DUA)' and 'Data Access Request (DAR)', and a 'Study Documents' section with a PDF document titled 'IMPACC March 2022 Data Use Limitations.pdf (pdf - 72.02 KB)'. A 'Detailed Description' section provides information about the study, and a table lists key study details.



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

- 1a - Requester Information

- 1b - Requester's Institution Signing Official Information

niaidportal.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

 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](mailto: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"/>
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.*

** 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


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"/>	<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"/>
Degree *	Position/Title *	
<input type="text"/>	<input type="text"/>	
Department/Branch *	Institution *	
<input type="text"/>	<input type="text"/>	

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 *
<input type="text"/>	<input type="text"/>	<input type="text"/>
Email Address *	Phone Number *	
<input type="text"/>	<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"/>
Position/Title *	Department/Branch *	Institution *
<input type="text"/>	<input type="text"/>	<input type="text"/>

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

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

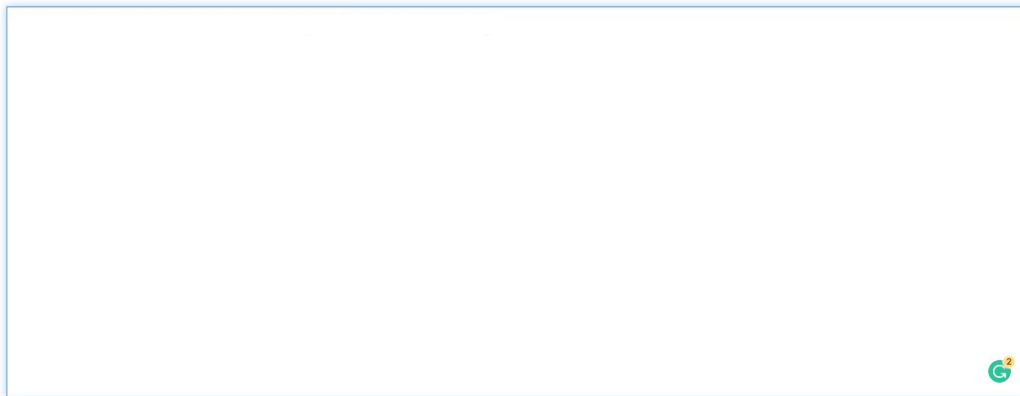
User then has to enter a **Research Use Statement**. Guidelines for what to include in the Research Use Statement are noted. After entering the requested information, the user clicks the **Submit** button.

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) *



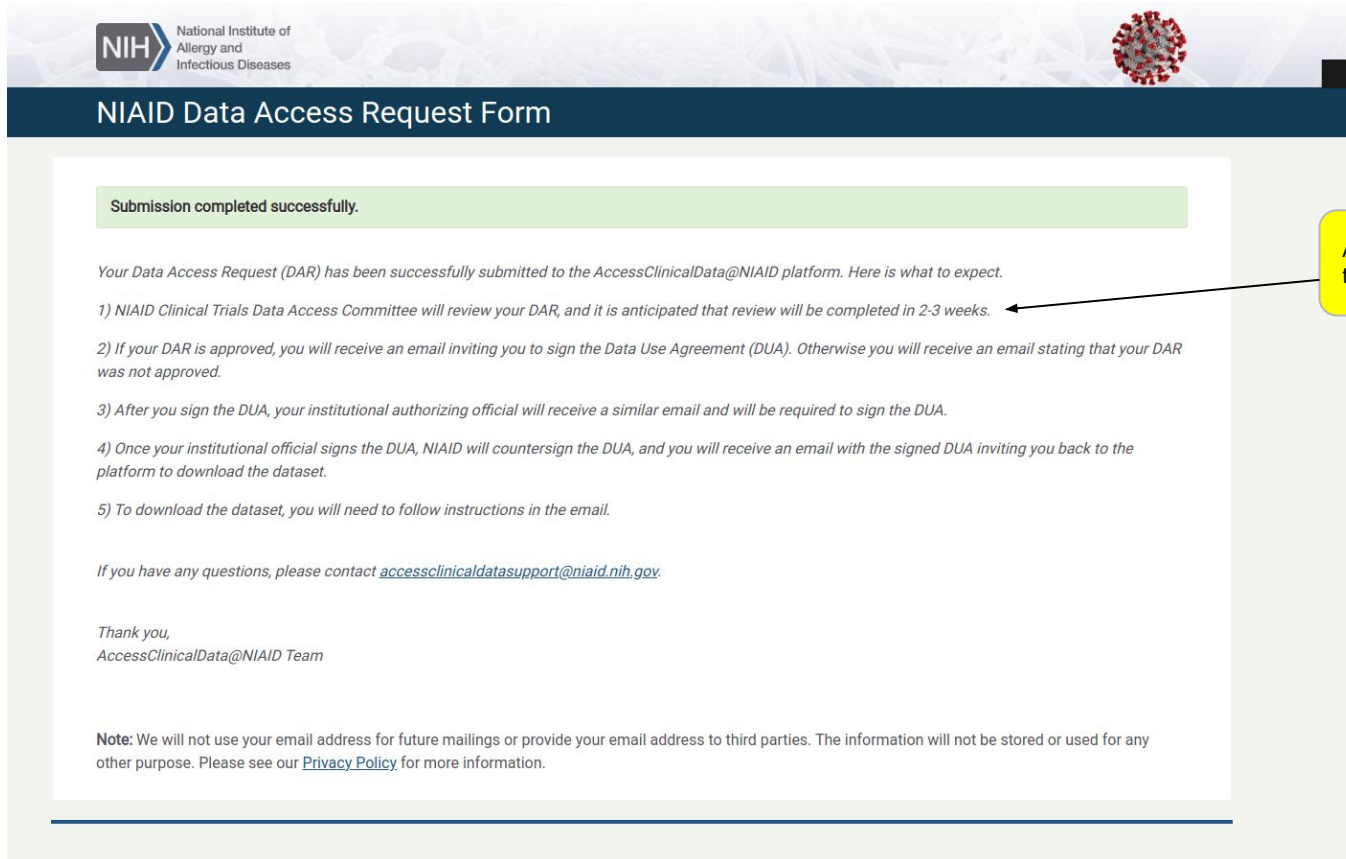
Previous

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.



The screenshot shows the NIAID Data Access Request Form submission confirmation page. At the top left is the NIH logo with the text "National Institute of Allergy and Infectious Diseases". At the top right is a red and white virus-like icon. Below the header is a dark blue bar with the text "NIAID Data Access Request Form". The main content area is white and contains a green success message, a list of five steps, contact information, and a note. A yellow callout box on the right points to the first step of the list.

NIH 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.

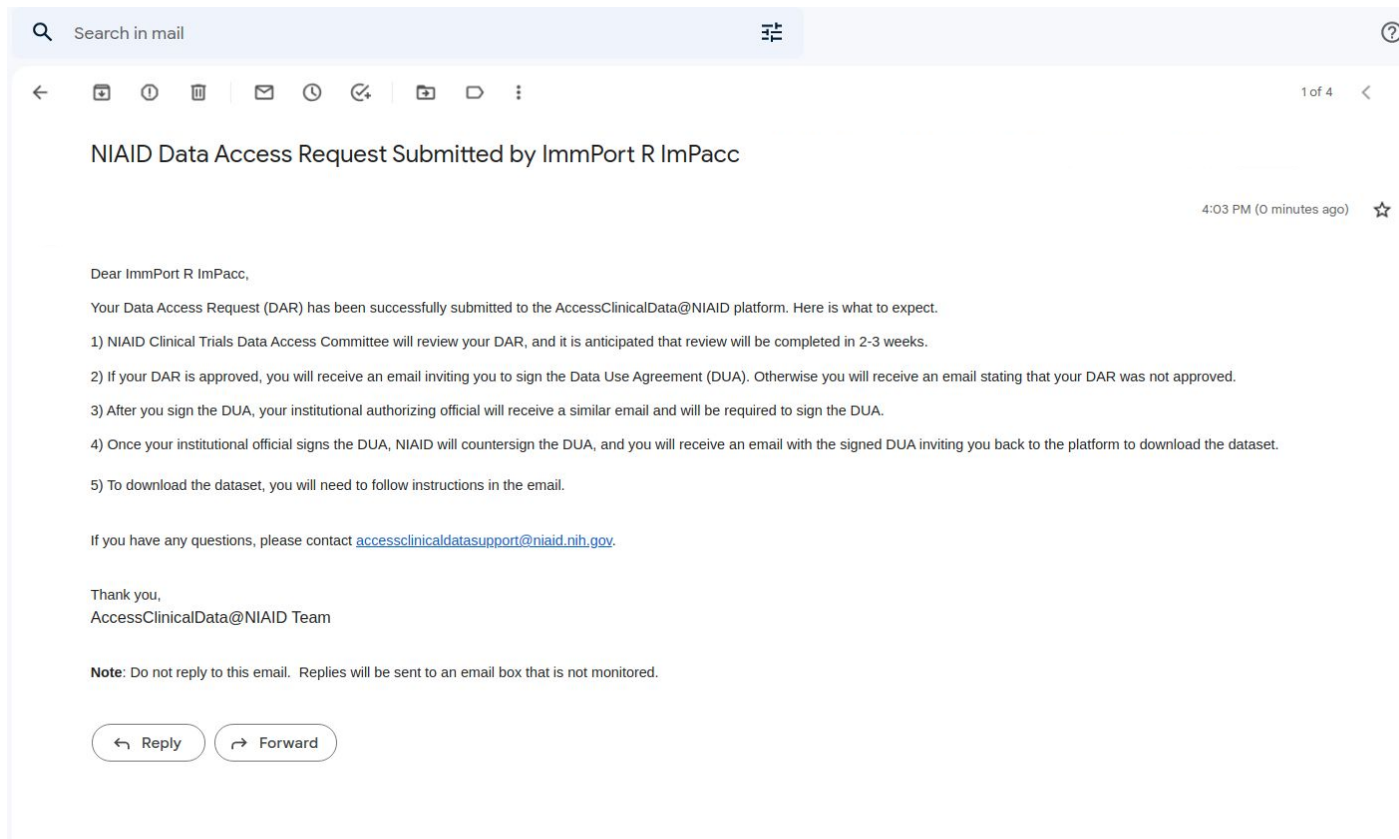
If you have any questions, please contact accessclinicaldatasupport@niaid.nih.gov.

Thank you,
AccessClinicalData@NIAID Team

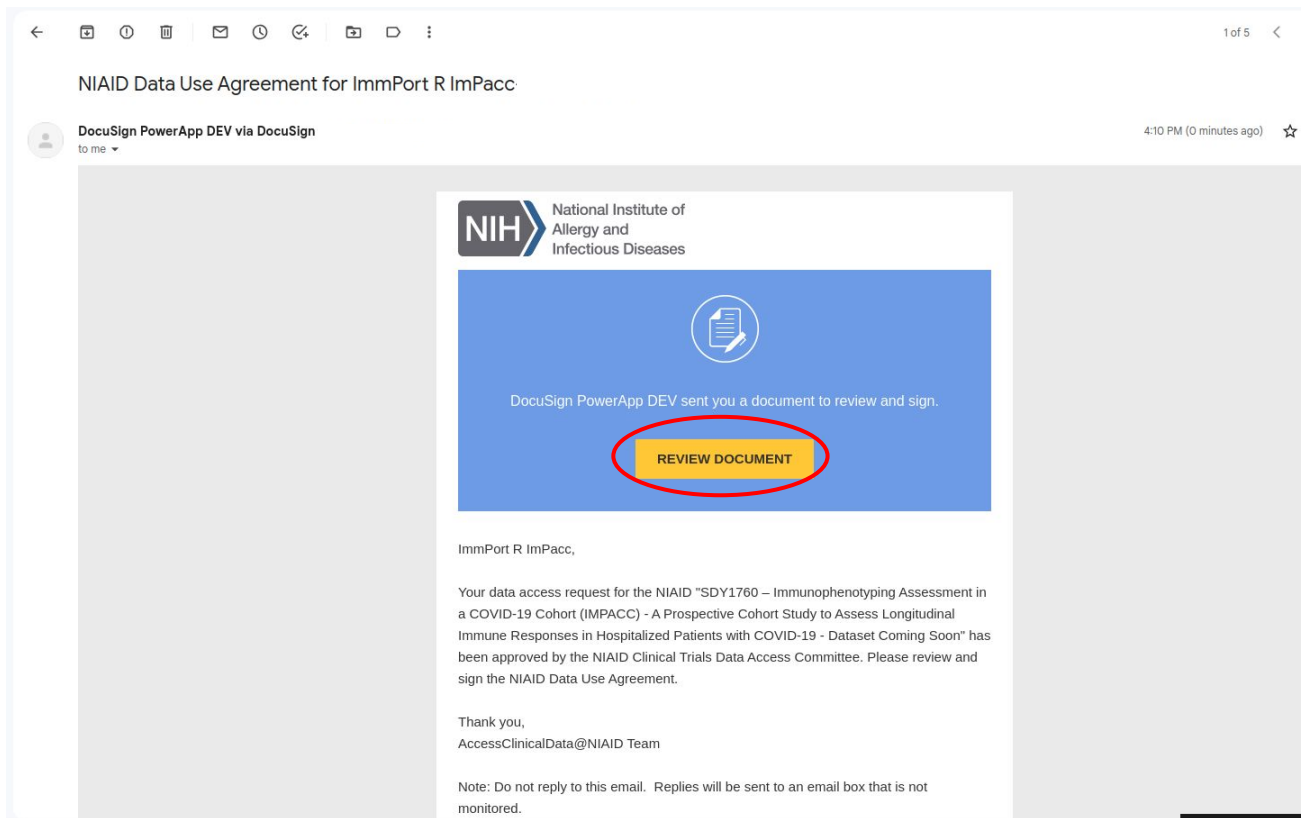
Note: We will not use your email address for future mailings or provide your email address to third parties. The information will not be stored or used for any other purpose. Please see our [Privacy Policy](#) for more information.

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 More

Please review the documents below.

CONTINUE OTHER ACTIONS ▾

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: 3BD2F8AE-8CC1-49C0-8899-D9D0C371EF9A

DEMONSTRATION DOCUMENT ONLY
PROVIDED BY DOCUSIGN ONLINE SIGNING SERVICE
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www.docuSign.com

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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- 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-8CC1-49C0-8899-09D0C371EF9A

DEMONSTRATION DOCUMENT ONLY
PROVIDED BY DOCUSIGN ONLINE SIGNING SERVICE
999 3rd Ave, Suite 1700 • Seattle • Washington 98104 • (206) 219-0200
www.docusign.com

Signature Page

Required - Sign Here

DECLARATION OF APPROVED USER:

SIGN 

8/1/2022

ImmPort R ImPacc Date

FOR ACCESSING INSTITUTION):

_____ Date

Mailing Address for Notices:

Email:

Tel:

User clicks Finish

The screenshot shows a web browser window with the address bar displaying `demo.docusign.net/Signing/?ti=a8f163a8561143c38b0b19cd228d98b4`. The browser's address bar includes navigation icons and the text "Incognito".

At the top of the page, a blue banner contains the text "Done! Select Finish to send the completed document." on the left and a yellow "FINISH" button on the right, followed by "OTHER ACTIONS ▾".

Below the banner is a toolbar with icons for search, zoom, download, print, refresh, and close.

The main content area displays a document titled "Peraton Data Use Agreement" with "ImmPort R ImPacc" as the sender and "Page 5 of 9" as the page number. Below this, the document ID "NIAID Data Use Agreement For - ImmPort R ImPacc-2022-08-01T20:10:10.0996521Z" and "5 of 9" are shown.

The document content includes a "DocuSign Envelope ID: 3BD2F8AE-8CC1-49C0-8899-D6D0C371EF9A" and a red "DEMONSTRATION DOCUMENT ONLY" notice. The main section is titled "Signature Page" and contains the following text:

Required - Signature Applied
ACKNOWLEDGEMENT OF APPROVED USER:
Documented by: ImmPort R ImPacc 8/1/2022
ImmPort R ImPacc Date

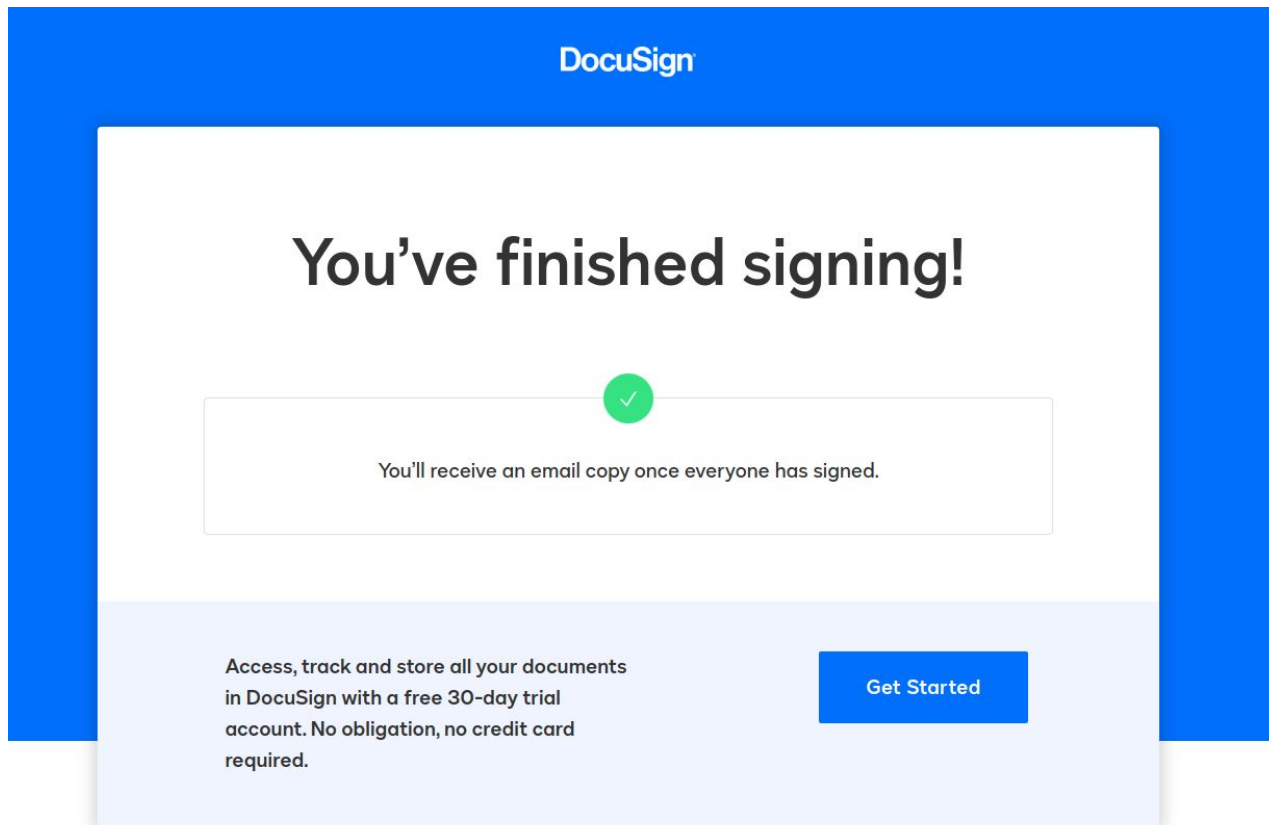
FOR ACCESSING INSTITUTION):

Date

Mailing Address for Notices:

At the bottom of the page, a blue banner contains the text "Ready to Finish?" and "You've completed the required fields. Review your work, then select FINISH." A yellow "FINISH" button is circled in red.

User has finished signing the document

A screenshot of a DocuSign completion screen. The page has a blue header with the DocuSign logo. The main content area is white and features the text "You've finished signing!" in a large, bold font. Below this text is a green checkmark icon. A white box contains the text "You'll receive an email copy once everyone has signed." At the bottom of the page, there is a light blue footer area with promotional text and a blue "Get Started" button.

DocuSign

You've finished signing!

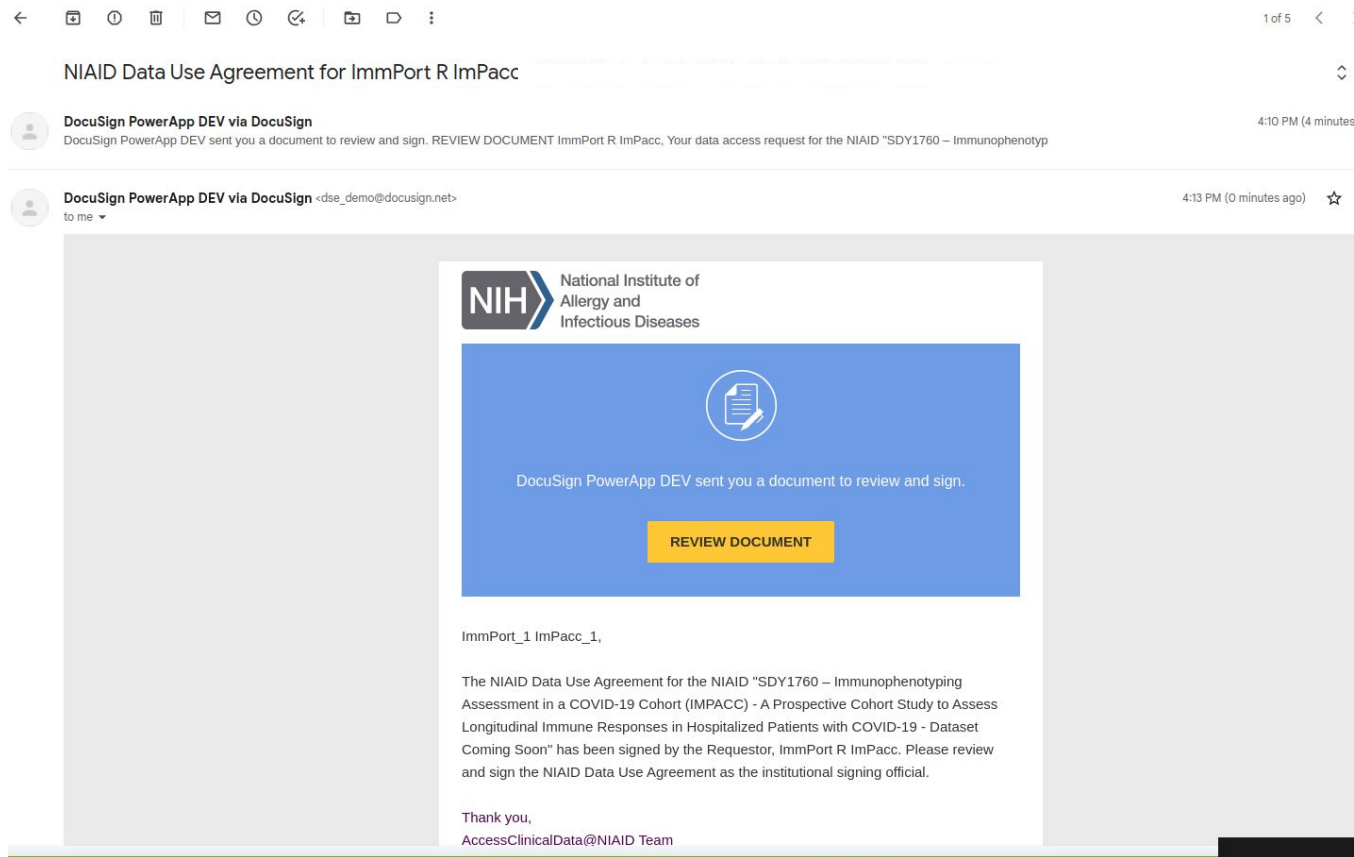
✓

You'll receive an email copy once everyone has signed.

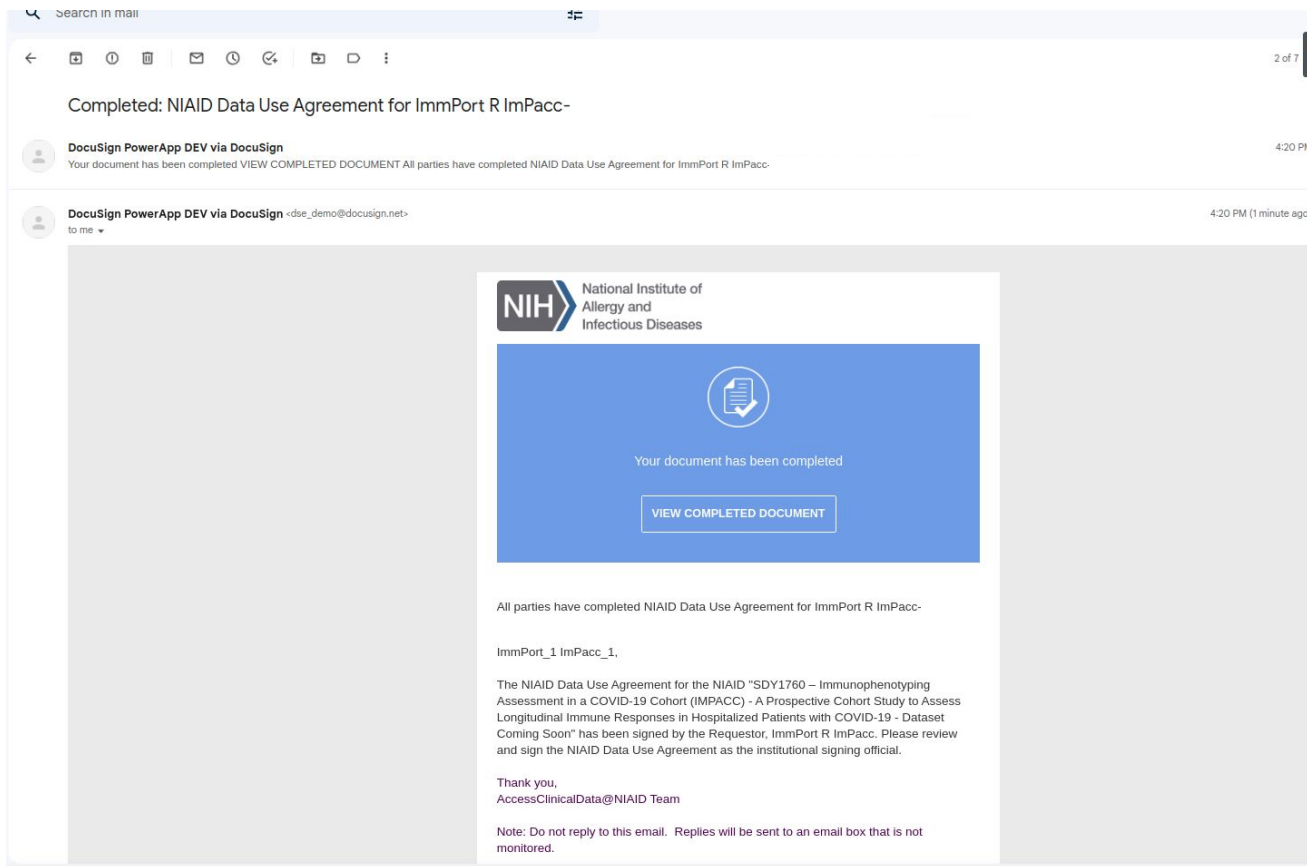
Access, track and store all your documents in DocuSign with a free 30-day trial account. No obligation, no credit card required.

Get Started

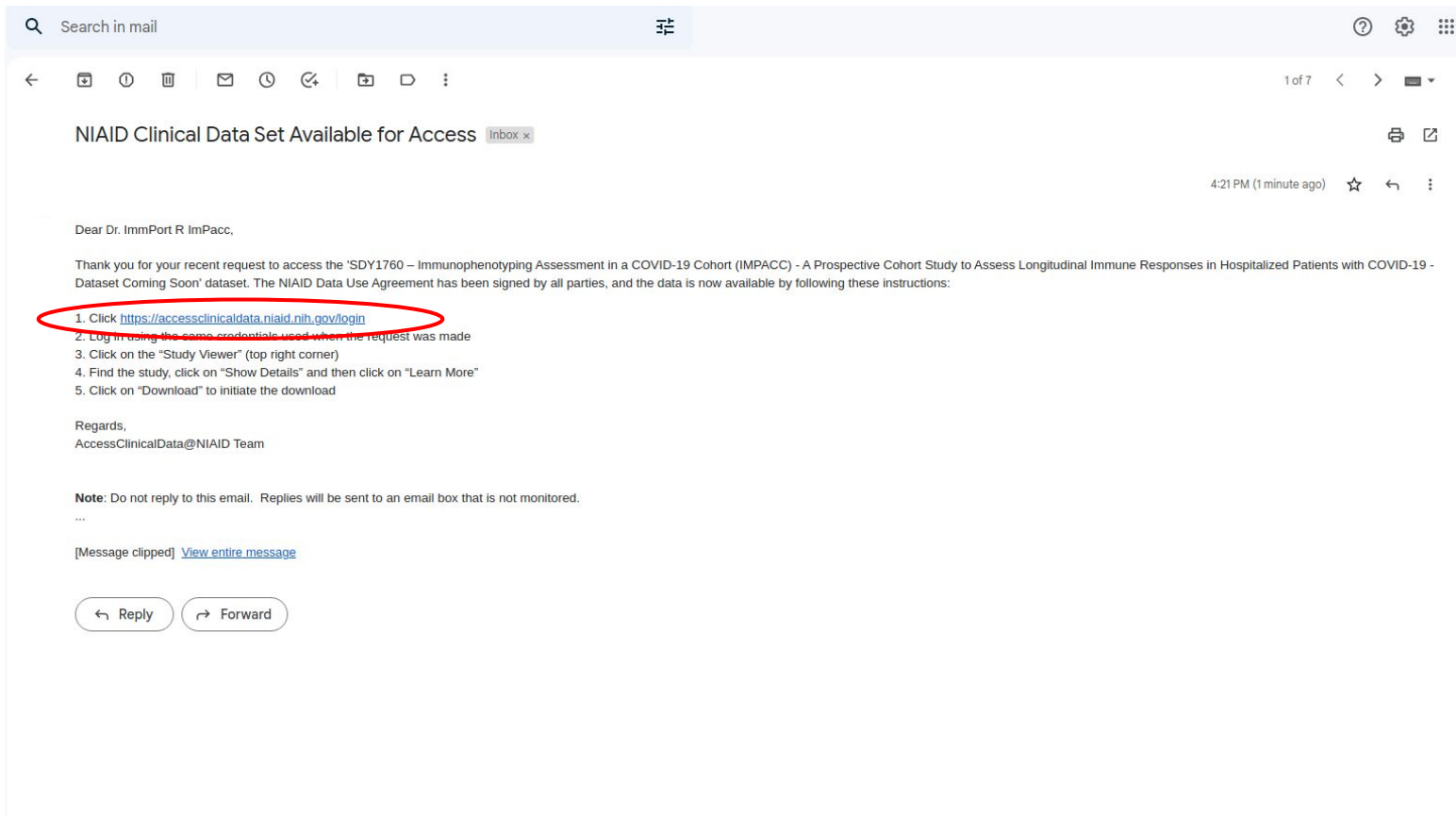
Next, the user's Institution Signing Official will receive an email directing them to review and sign the Data Use Agreement via DocuSign. The email is sent to the address that was entered on form **1b - Requester's Institution Signing Official Information** (slide 12).



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...

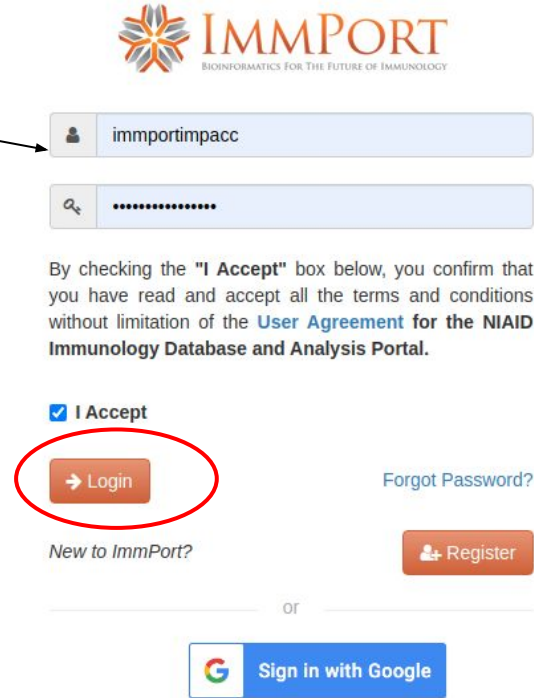
InCommon Login


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.



 **IMMPORT**
BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY

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

User clicks the **Download** button

[Contact Support](#) | [impportimpacc](#) | [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

[Download](#)

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

The screenshot shows the ImmPort Data Browser interface. At the top, there is a navigation bar with 'ImmPort', 'Upload', 'Shared', 'Analysis', and 'Resources'. A search bar contains 'www.immport.org'. A secondary bar includes 'Data Catalogs', 'Data Model', 'Help', and 'Welcome immportimpacc'. A notification banner at the top states: '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 ...'. Below this, 'Shared Data quick links' include 'COVID-19 studies', 'Influenza studies', 'Respiratory-like illnesses studies', and 'Viral Infectious diseases studies'. The main heading is 'Data Browser'. A paragraph explains that the browser allows users to download data by individual file, directory, or study, using Aspera Connect. A breadcrumb trail shows 'Browse Shared Data > SDY1760'. The study details include: 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.' A badge indicates 'SDY1760 is a Controlled Data Set'. A table lists files for download, with a 'Download' button circled in red. The table has columns for Name, Size, and Last Modified. The files are: Protocols (1 file), 13.70 KB, May 5, 2022 8:20 AM; ResultFiles (0 files), 0.00 bytes, Mar 29, 2022 16:01 PM; StudyFiles (1 file), 211.00 bytes, Aug 1, 2022 14:27 PM. The footer contains sponsor information (NIAID, NIH, HHS), logos for Nature Scientific Data's Recommended Data Repository, PLOS ONE Recommended Data Repository, and CORE TRUST SEAL, along with social media links for Facebook and Twitter. Recommended browsers are listed as Chrome, Firefox, Safari v7+, and Internet Explorer v11+.

ImmPort Upload Shared Analysis Resources

Search www.immport.org Data About

Shared Data

Launching IBM Aspera Connect...

Data Catalogs Data Model Help 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
Protocols (1 files)	13.70 KB	May 5, 2022 8:20 AM
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StudyFiles (1 files)	211.00 bytes	Aug 1, 2022 14:27 PM

Showing 1 to 3 of 3 records

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

Nature Scientific Data's Recommended Data Repository
Cytometry & Immunology

PLOS ONE Recommended Data Repository

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Core Trustworthy Data Repository

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