


IMPACC Study Access End-To-End Workflow  
Starting from the ImmPort Shared Data  
Application ([www.immport.org](http://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 [SDY1760](#)
- If you have additional questions after reviewing this document, please contact the ImmPort Help Desk at [ImmPort\\_Helpdesk@import.org](mailto:ImmPort_Helpdesk@import.org)



**IMMPORT**  
BIOINFORMATICS FOR THE FUTURE OF IMMUNOLOGY

User navigates to IMPACC study [SDY1760](#) on the ImmPort Shared Data Application. User clicks the **Download Arrow** next to the Study Accession to download the data.

Facet Charts

Research Focus

Condition or Disease

Assay Methods

Found 1 studies in 101 ms

7 columns selected

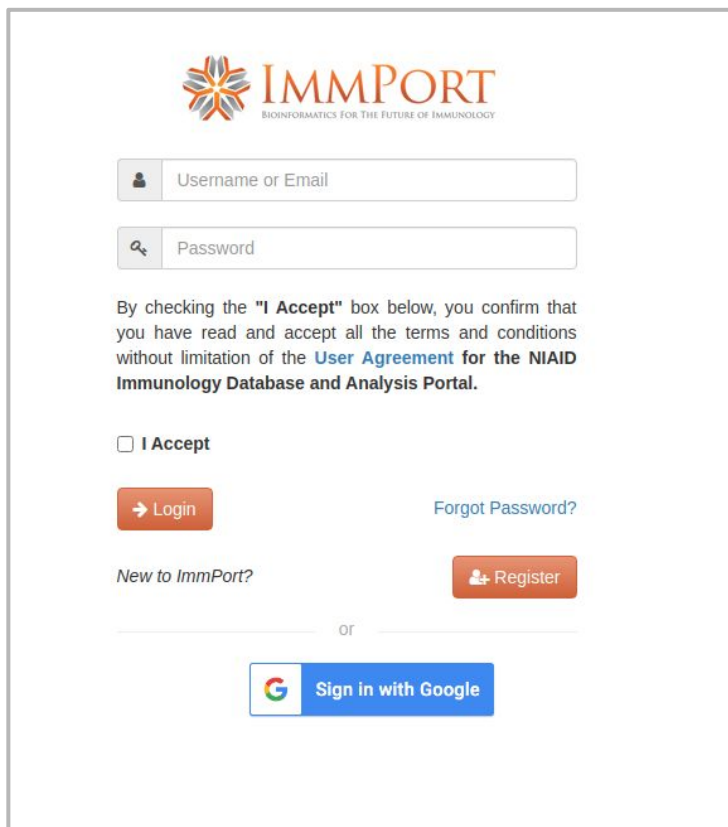
Download All Studies

Cart 3

Export

Study	Title	Pubmed Id	Research Focus	Condition/Disease	Assay Methods	Latest Release Version
<input checked="" type="checkbox"/> + <a href="#">SDY1760</a>	Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized Patients with COVID-19	<a href="#">34376480</a>	Infection Response	COVID-19		DR44

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 left. Below it are two input fields: "Username or Email" and "Password". A paragraph of text follows, starting with "By checking the 'I Accept' box below...". Below the text is a checkbox labeled "I Accept". To the right of the checkbox is a "Forgot Password?" link. Below the checkbox are two buttons: "Login" and "Register". Below the buttons is a "New to ImmPort?" link. At the bottom is a "Sign in with Google" button.



The ImmPort logo is at the top left. Below it are two input fields: "Username or Email" (containing "importimpacc" and "Example") and "Password" (containing "....."). A paragraph of text follows, starting with "By checking the 'I Accept' box below...". Below the text is a checked checkbox labeled "I Accept". To the right of the checkbox is a "Forgot Password?" link. Below the checkbox are two buttons: "Login" and "Register". Below the buttons is a "New to ImmPort?" link. At the bottom is a "Sign in with Google" button. 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". Red circles highlight the "Login" and "Register" buttons.

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.

**i** 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.

**i** SDY1760 is a Controlled Data Set

The download package for SDY1760 will be made available once the **Data Access Request (DAR)** is approved and the signed **NIAID Data Use Agreement (DUA)** is submitted.

[Request Access](#)

Please visit the [NIAID Clinical Trials Repository - AccessClinicalData@NIAID](#) for more information on the DAR and DUA approval process.

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



Core  
Trustworthy  
Data  
Repository



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.

The screenshot shows the ImmPort website interface. At the top, there is a navigation bar with 'ImmPort', 'Upload', 'Shared', 'Analysis', and 'Resources'. A search bar is located on the right. Below the navigation bar, there is a blue header with 'Shared Data' and '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, there are quick links for 'COVID-19 studies', 'Influenza studies', 'Respiratory-like illnesses studies', and 'Viral infectious diseases studies'. The main content area is titled 'Data Browser' and describes the ImmPort data browser. A breadcrumb trail shows 'Browse Shared Data > SDY1760'. The main content area displays the title 'Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized Patients with COVID-19' and a brief description. A 'Request Access' button is visible. A confirmation dialog box is overlaid on the page, containing the text: 'Redirecting to NIAID Clinical Trials Repository - AccessClinicalData@NIAID to initiate the Data Access Request.' and a 'Proceed' button circled in red. The footer contains information about sponsors (NIAID, NIH, HHS), logos for 'Nature Scientific Data's Recommended Data Repository Cytometry & Immunology', 'PLOS ONE Recommended Data Repository', and 'CORE TRUST SEAL', and social media links for Facebook and Twitter. It also includes contact information and recommended browsers.

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



The screenshot shows the top navigation bar with 'Contact Support' and 'Login' links. The NIH logo and 'National Institute of Allergy and Infectious Diseases' are on the left, with 'AccessClinicalData@NIAID' in the center. A 'Study Viewer' icon is on the right. Below the navigation, a breadcrumb trail shows '← Back'. The main heading is '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'. A blue button labeled 'Login through IMPORT to Request Access' is circled in red. Below the button is a light blue box with the text: 'Please note that researchers are required to log in before requesting access.' The 'Detailed Description' section follows, providing a summary of the study. On the right side, there are two sections: 'Data Access' with links for 'Data Use Agreement (DUA)' and 'Data Access Request (DAR)', and 'Study Documents' with a link for 'IMPACC March 2022 Data Use Limitations.pdf (pdf - 72.02 KB)'. At the bottom, 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

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.

Contact Support | importimpac | 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 the NIAID Data Access Request form site.

The screenshot shows the NIAID Access Clinical Data portal. At the top, there is a navigation bar with 'Contact Support', 'importimpacc', and 'Logout'. The main header includes the NIH logo and 'AccessClinicalData@NIAID'. A modal dialog 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 page shows a study titled 'SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort of Hospitalized Patients with COVID-19 - Dataset Coming Soon'. Below the title is a 'Request Access' button. The 'Detailed Description' section provides information about the study, including participant details and data collection methods. A table at the bottom lists study metadata.

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

## 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](mailto: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](mailto: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 \*

Email Address \*

Phone Number \*

ORCID ID ([ORCID Login](#))

Address \*

City \*

State/Province \*

ZIP/Postal Code

Country \*

Degree \*

Position/Title \*

Department/Branch \*

Institution \*

# 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](mailto: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](mailto: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 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 ( <a href="#">ORCID Login</a> )
<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

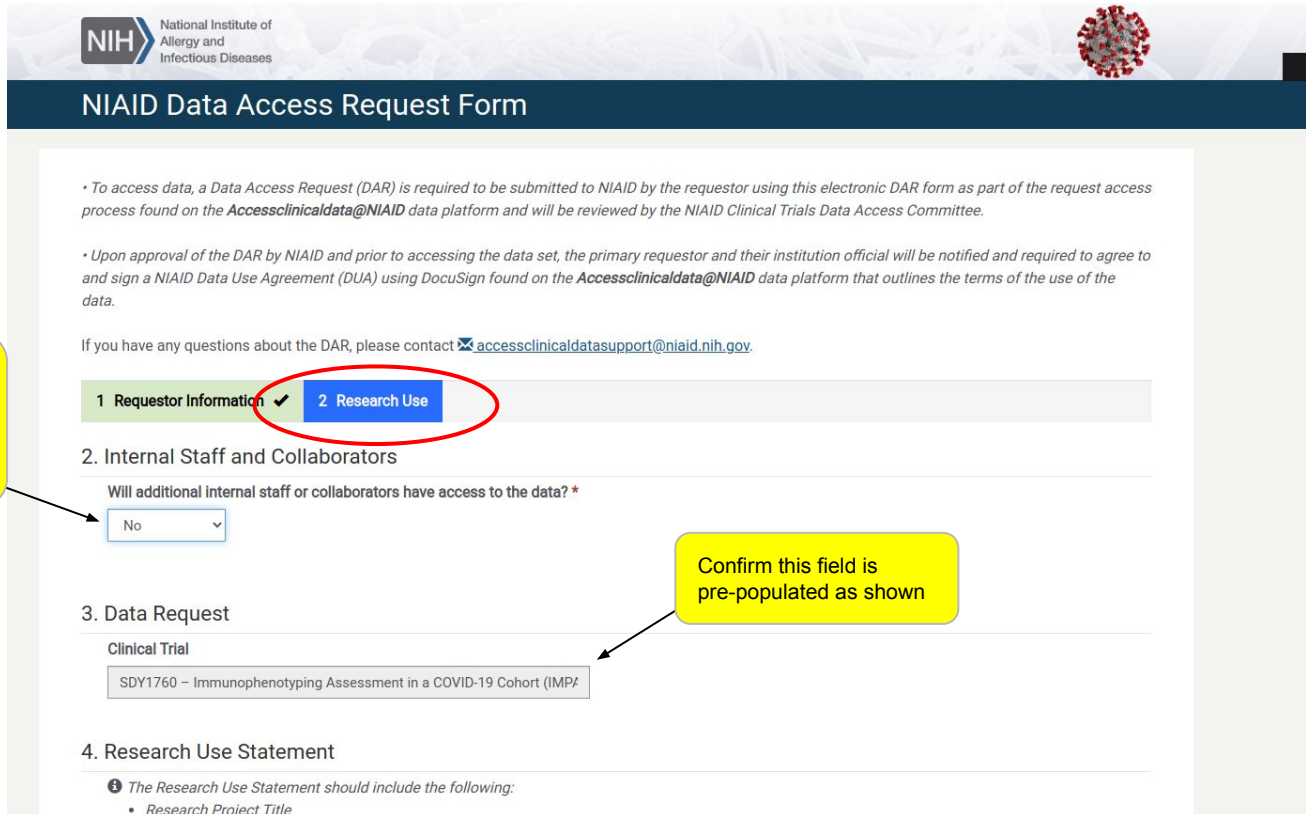
 The Institutional Signing Official is a senior official at an institution who is authorized to enter the institution into a legally binding contract and sign the Data Use Agreement with the requestor who has submitted a Data Access Request to NIAID.

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



The screenshot shows the NIAID Data Access Request Form. At the top left is the NIH logo and 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 title 'NIAID Data Access Request Form'. The main content area has a light beige background. It contains two paragraphs of text explaining the DAR process. Below the text is a contact email: 'accessclinicaldatasupport@niaid.nih.gov'. There are two tabs: '1 Requestor Information' (checked) and '2 Research Use' (highlighted with a red circle). Under '2 Research Use', there is a section '2. Internal Staff and Collaborators' with a question 'Will additional internal staff or collaborators have access to the data? \*' and a dropdown menu set to 'No'. Below that is a section '3. Data Request' with a text input field containing 'SDY1760 - Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC)'. At the bottom is a section '4. Research Use Statement' with a note that the 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](mailto:accessclinicaldata@niaid.nih.gov) 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](mailto:accessclinicaldata@niaid.nih.gov) 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 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

**i** 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.

**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.

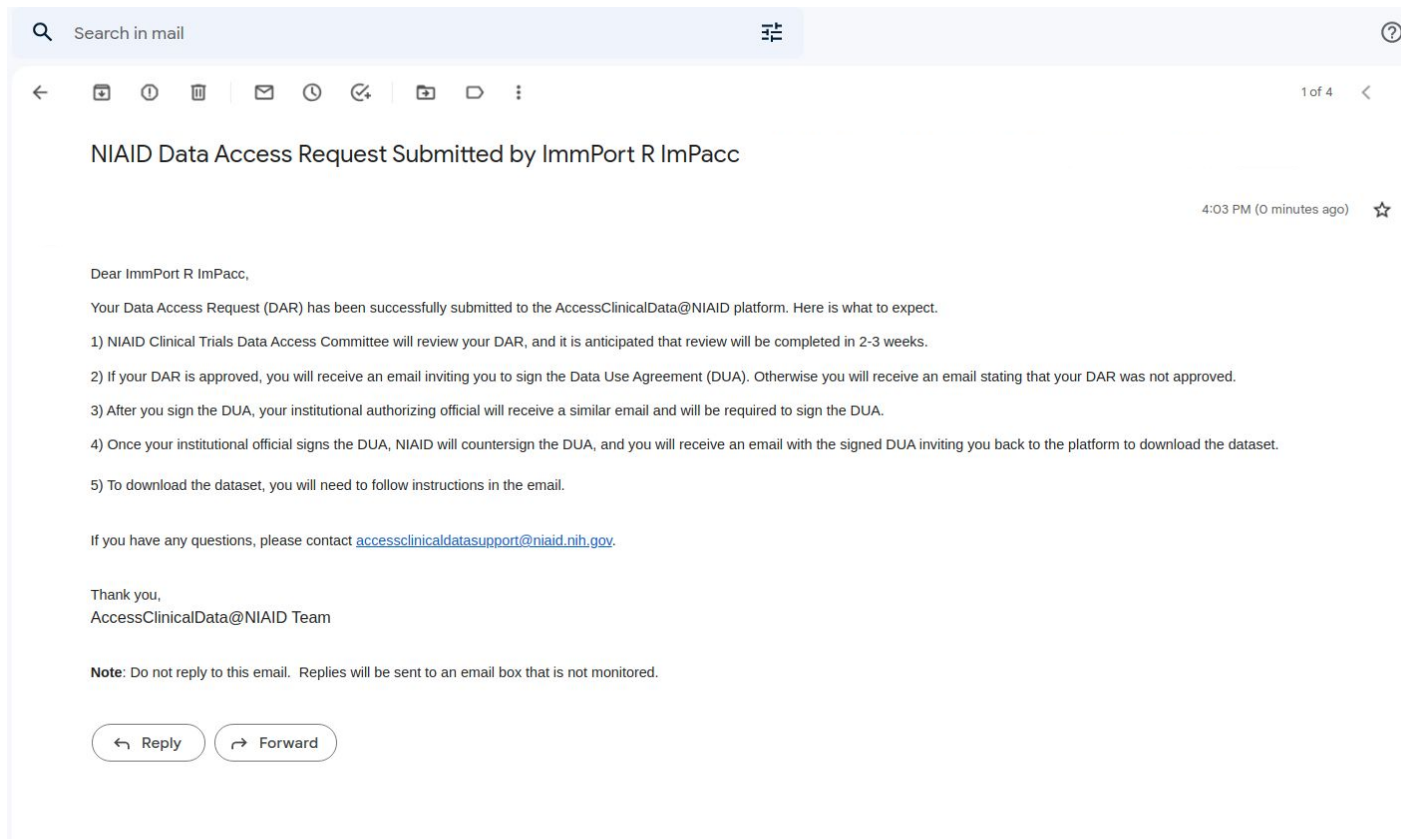
If you have any questions, please contact [accessclinicaldatasupport@niaid.nih.gov](mailto:accessclinicaldatasupport@niaid.nih.gov).

Thank you,  
AccessClinicalData@NIAID Team

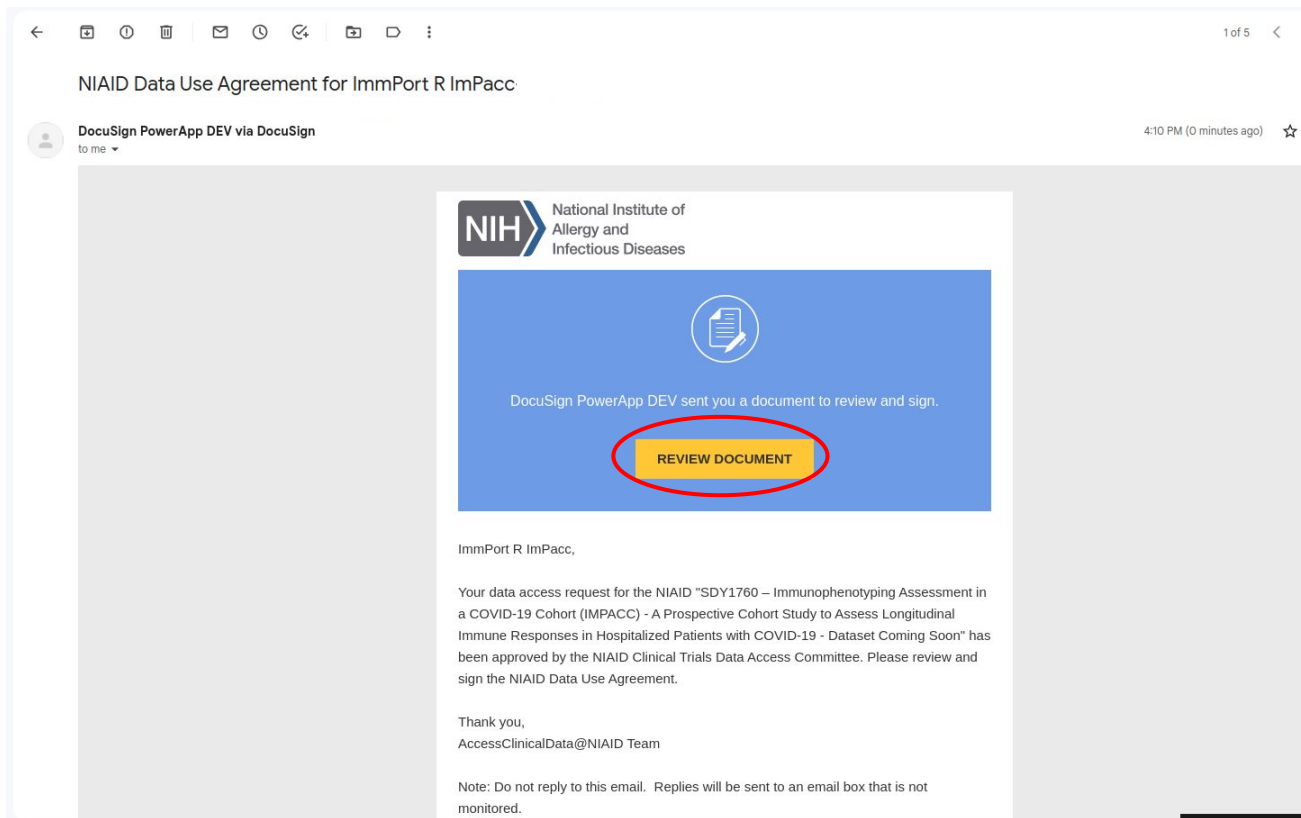
**Note:** We will not use your email address for future mailings or provide your email address to third parties. The information will not be stored or used for any other purpose. Please see our [Privacy Policy](#) for more information.

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 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

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  
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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](mailto: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.

#### TERMS OF ACCESS

##### 1. Definitions

- 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.
- 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.
- 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).
- 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.
- 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](mailto:Accessclinicaldata@NIAID). Attachment A provides a blank DAR form.
- 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  
EDGEMENT OF APPROVED USER:

**SIGN**

8/1/2022  
Date

ImmPort R ImPacc

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 and "OTHER ACTIONS" dropdown on the right.

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 ImmPort R ImPacc" and "Data Use Agreement Page 5 of 9". Below the document title, it shows "NIAID Data Use Agreement For - ImmPort R ImPacc-2022-08-01T20:10:10.0996521Z" and "5 of 9".

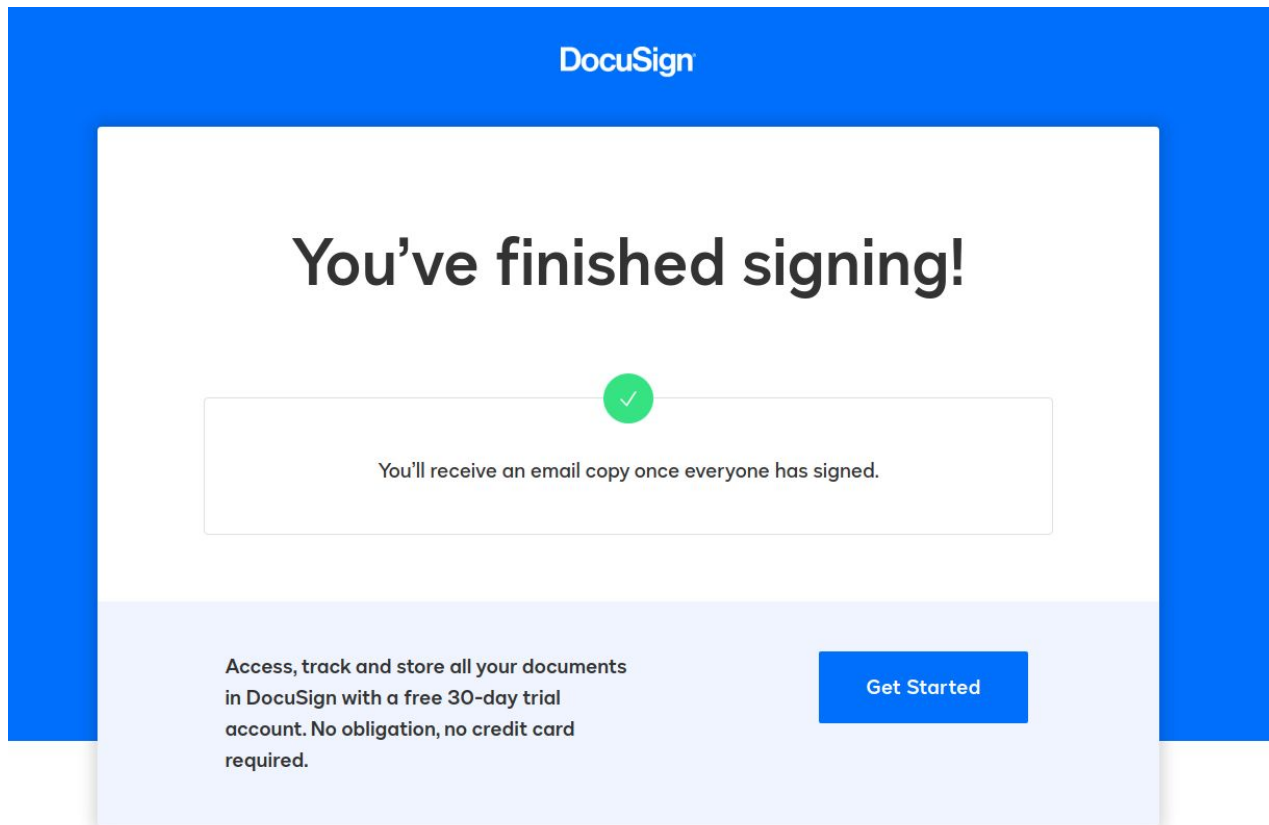
The document content includes a DocuSign Envelope ID: 3BD2F8AE-8CC1-49C0-8899-D6D0C371EF9A and a red notice: "DEMONSTRATION DOCUMENT ONLY PROVIDED BY DOCUSIGN ONLINE SIGNING SERVICE 999 3rd Ave, Suite 1700 • Seattle • Washington 98104 • (206) 219-0200 www.docusign.com".

The "Signature Page" section 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 highlighted with a red circle.

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 text about a free 30-day trial and a blue "Get Started" button.

DocuSign

# You've finished signing!

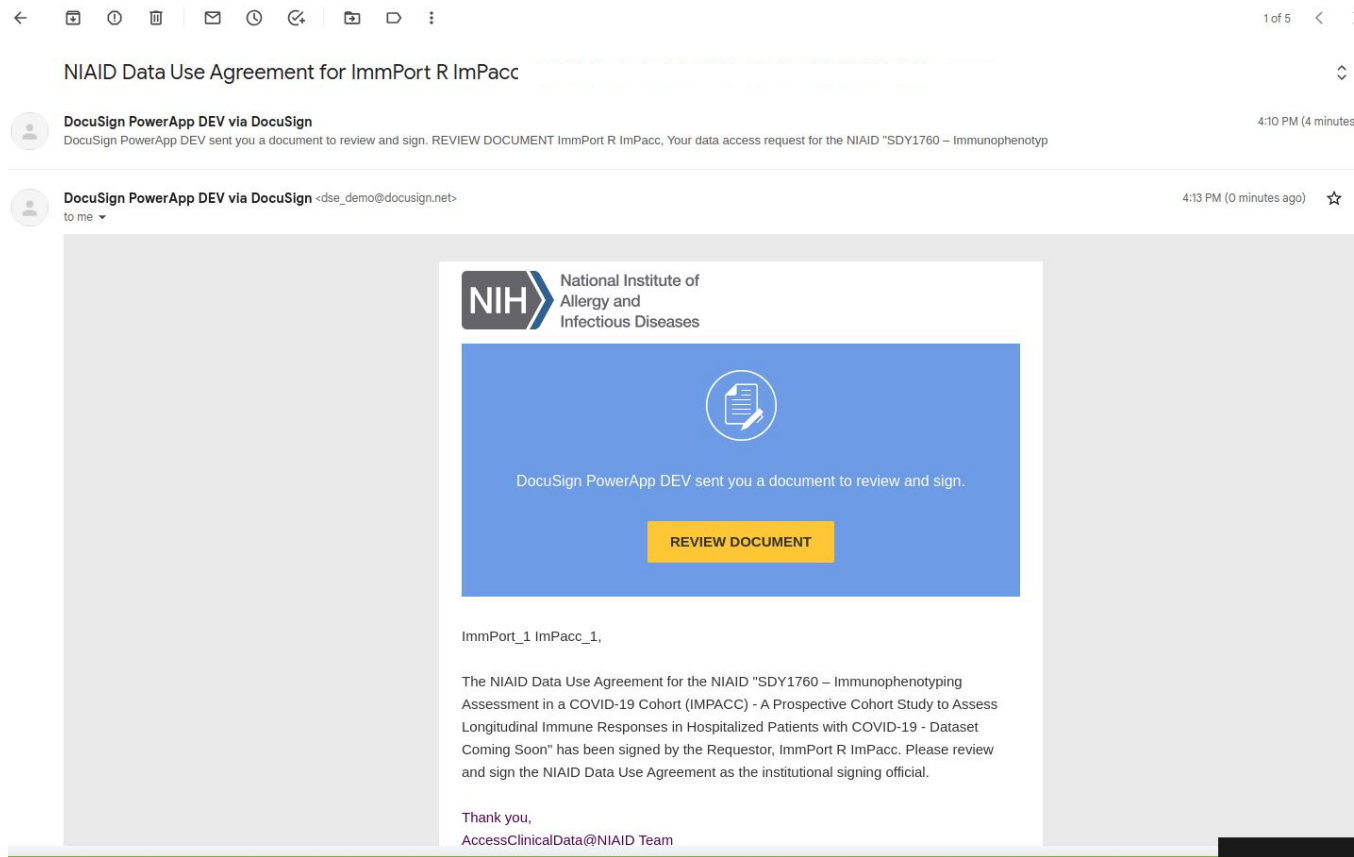


You'll receive an email copy once everyone has signed.

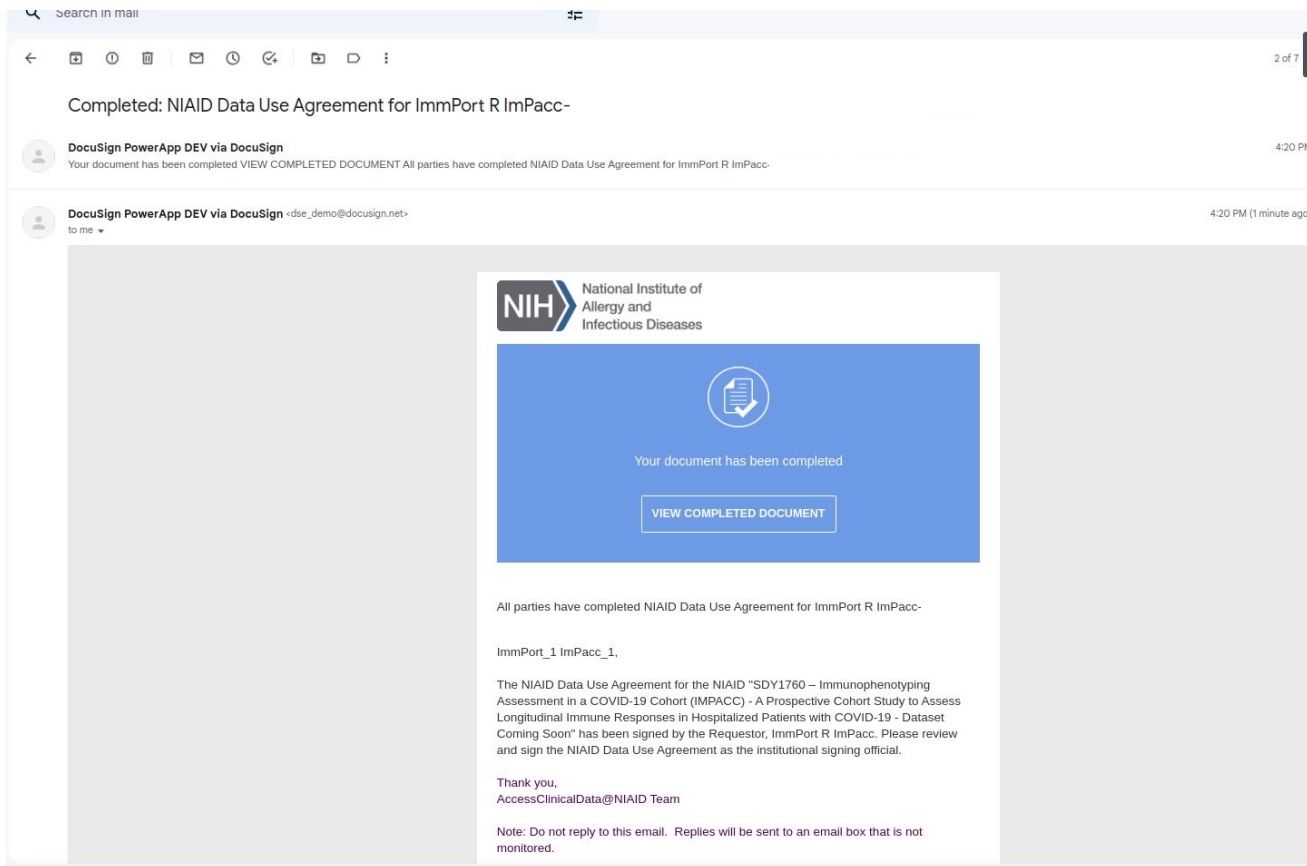
Access, track and store all your documents in DocuSign with a free 30-day trial account. No obligation, no credit card required.

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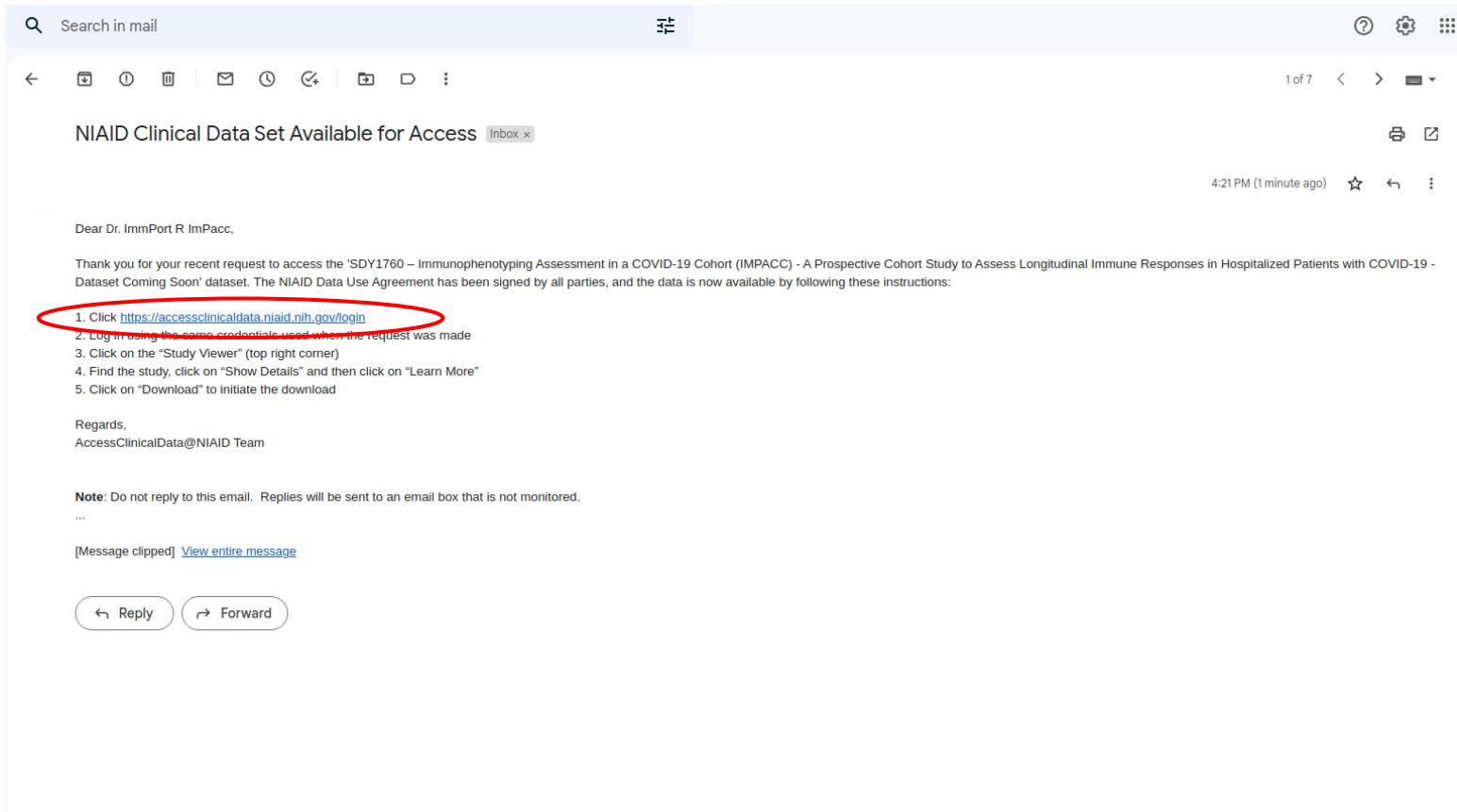
Next, the user's Institution Signing Official will receive an email directing them to review and sign the Data Use Agreement via DocuSign. The email is sent to the address that was entered on form **1b - Requester's Institution Signing Official Information** (slide 13).



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.



The screenshot shows an email client interface. At the top, there is a search bar with the text "Search in mail" and a filter icon. Below the search bar is a navigation bar with icons for back, forward, trash, mail, clock, reply, share, and a menu icon. On the right side of the navigation bar, it says "1 of 7" and has navigation arrows. The email subject is "NIAID Clinical Data Set Available for Access" with an "Inbox x" tag. The email content starts with "Dear Dr. ImmPort R ImPacc," followed by a thank you message. A list of five instructions is provided, with the first instruction circled in red. The email ends with "Regards, AccessClinicalData@NIAID Team" and a note about not replying to this email. At the bottom, there are "Reply" and "Forward" buttons.

Search in mail

1 of 7

NIAID Clinical Data Set Available for Access Inbox x

4:21 PM (1 minute ago) ☆ ↶ ⋮

Dear Dr. ImmPort R ImPacc,

Thank you for your recent request to access the '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' dataset. The NIAID Data Use Agreement has been signed by all parties, and the data is now available by following these instructions:

1. Click <https://accessclinicaldata.niaid.nih.gov/login>
2. Log in using the same credentials used when the request was made
3. Click on the "Study Viewer" (top right corner)
4. Find the study, click on "Show Details" and then click on "Learn More"
5. Click on "Download" to initiate the download

Regards,  
AccessClinicalData@NIAID Team

**Note:** Do not reply to this email. Replies will be sent to an email box that is not monitored.  
...

[Message clipped] [View entire message](#)

↶ Reply   ↷ Forward

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](mailto:accessclinicaldatasupport@niaid.nih.gov).

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

---



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



# User clicks the **Download** button

[← 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

[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.

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, there are quick links for 'COVID-19 studies', 'Influenza studies', 'Respiratory-like illnesses studies', and 'Viral infectious diseases studies'. The main heading is 'Data Browser'. A text block explains that the browser uses Aspera Connect for file transfers. The breadcrumb path is 'Browse Shared Data > SDY1760'. The study title is 'Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized Patients with COVID-19'. The description is '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 with columns for Name, Size, and Last Modified. The 'Download' button is circled in red. The footer includes sponsor information (NIH, HHS), logos for Nature Scientific Data's Recommended Data Repository, PLOS ONE, and CORE TRUST SEAL, and social media links for Facebook and Twitter. It also provides contact information and recommended browsers.

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 ↑↓
<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

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

CORE  
TRUST  
SEAL

Core  
Trustworthy  
Data  
Repository

Facebook  
Twitter

Contact Us | Privacy Policy | Disclaimer | Accessibility | HHS Vulnerability Disclosure

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