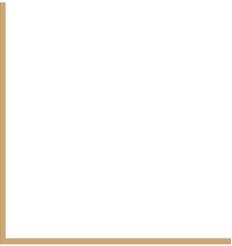




# IMPACC End-To-End Workflow Starting from Publication



# 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](mailto: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](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 The copyright holder for this preprint (which was not certified by peer review) is the author/funder, who has granted medRxiv a license to display the preprint in perpetuity.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](mailto:AccessClinicalData@NIAID) ([https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical\\_trials](https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical_trials)). Please contact [ImmPort\\_Helpdesk@import.org](mailto: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.

The screenshot shows a web browser window with the URL [https://accessclinicaldata.niaid.nih.gov/study-viewer/clinical\\_trials](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", the email address "AccessClinicalData@NIAID", and a "Study Viewer" search icon. A blue banner 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 this, a "Show details" link is visible. A red circle highlights the study title and the "Show details" link. A yellow box highlights the "Show details" link with the text "User clicks on the + icon to expand details". The footer contains the NIH logo, social media links for Facebook, Twitter, LinkedIn, YouTube, and Instagram, and a "Connect with NIAID" section. It also includes "Website Policies & Notices" such as "Freedom of Information Act (FOIA)", "No Fear Act Data", and "Privacy Policy". Finally, it lists "Related Government Websites" including "National Institutes of Health", "Health and Human Services", "USA.gov", and "HHS Responsible Disclosure Form".

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)

User clicks on the + icon to expand details

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

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

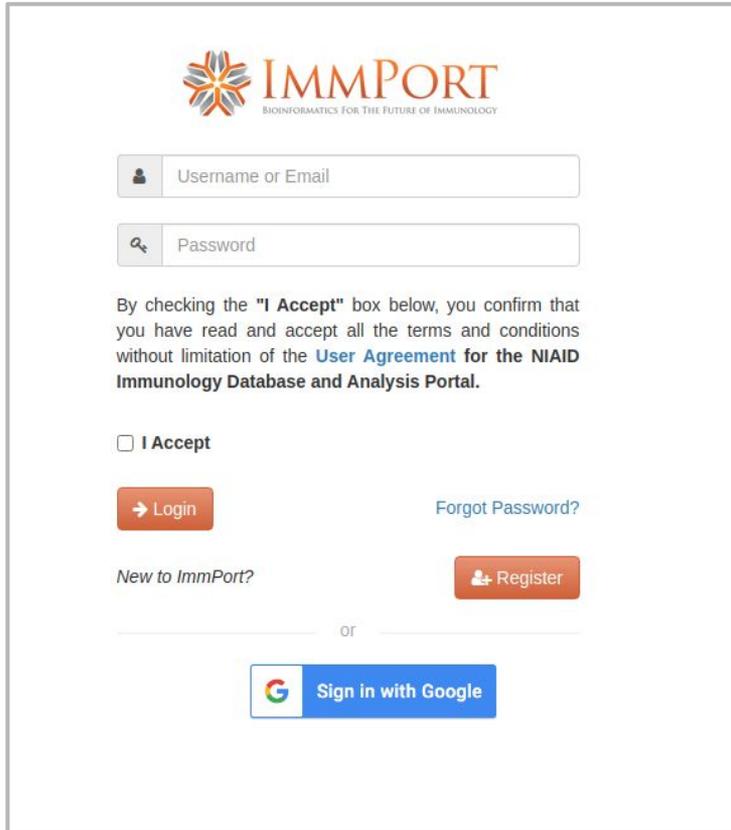
#### Data Access

- 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

**NIH** 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.

Request Access

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

**Confirm** Cancel

NIH National Institute of Allergy and Infectious Diseases AccessClinicalData@NIAID

Contact Support | importimpacc @ | Logout

← Back

### 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.

Data First Available	July 2022
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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 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](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 Requester Information** 2 Research Use

### 1a. Requestor

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

**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) 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**

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

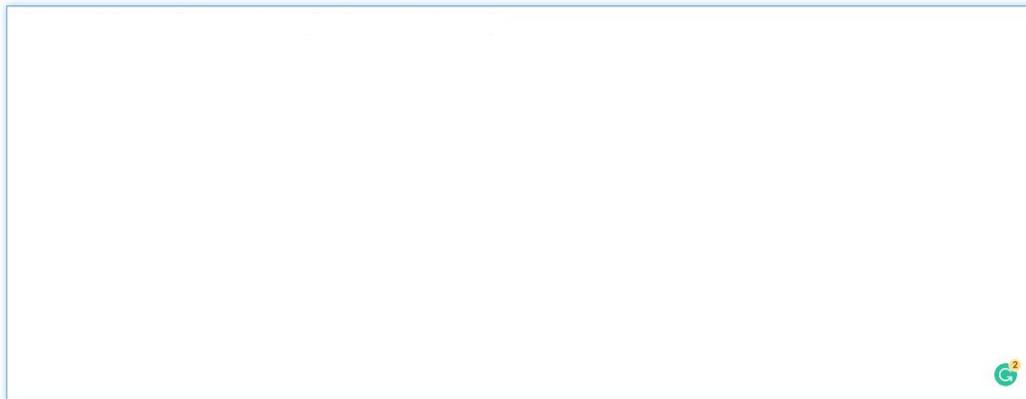
User then has to enter a **Research Use Statement**. Guidelines for what to include in the Research Use Statement are noted. After entering the requested information, the user clicks the **Submit** button.

#### 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) \*



A large, empty rectangular text input field with a light blue border. In the bottom right corner of the field, there is a small green circular icon with a white 'G' and a small orange square with a white '2' next to it.

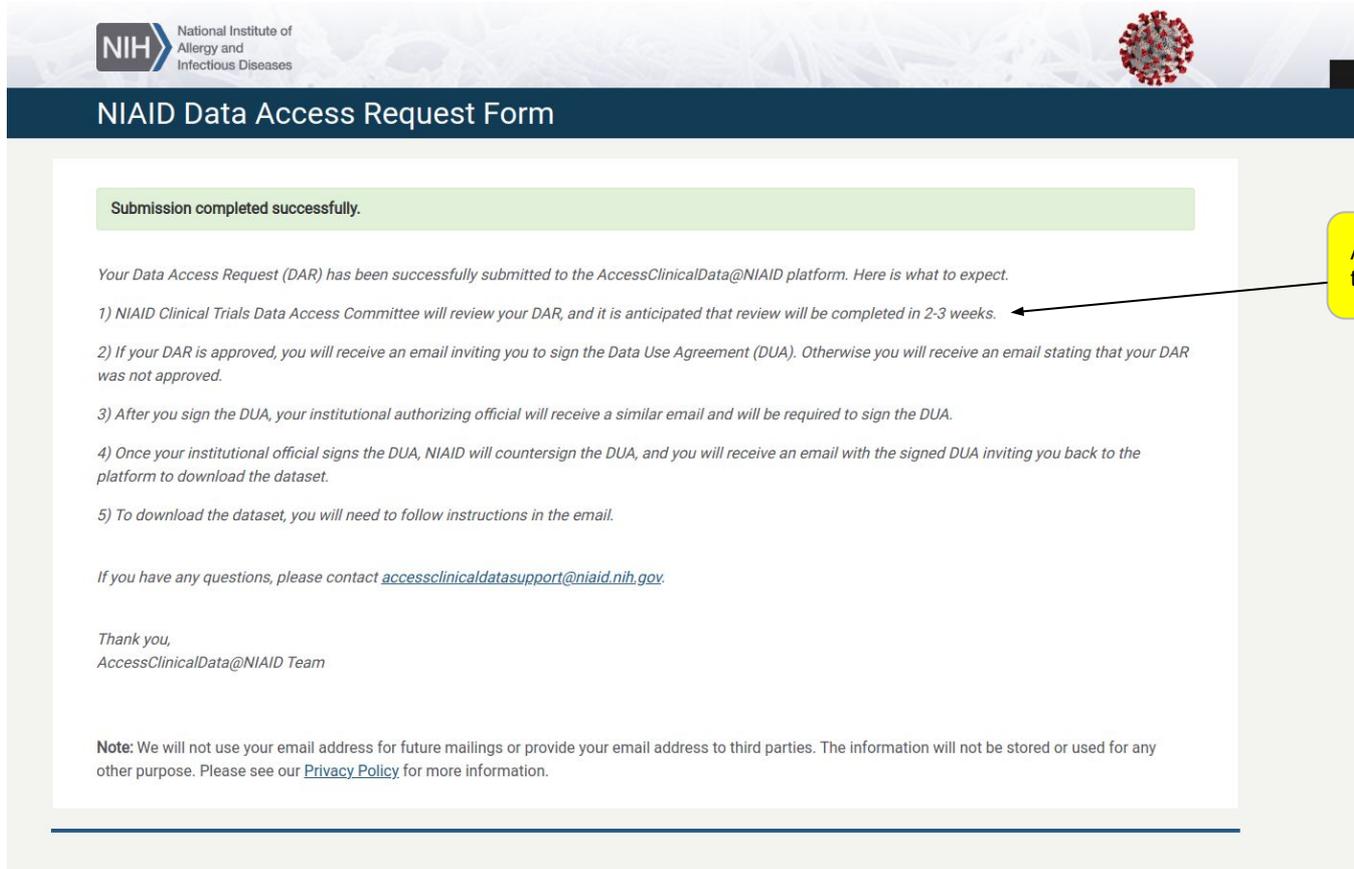
Guidelines for what to include in the Research Use Statement are noted here

Previous

Submit

User will click Submit after entering their Research Use Statement

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 has a light green bar at the top that says "Submission completed successfully." Below this is a paragraph of text: "Your Data Access Request (DAR) has been successfully submitted to the AccessClinicalData@NIAID platform. Here is what to expect." This is followed by a numbered list of five steps. A yellow callout box on the right side of the page points to the first step with the text "Anticipated timeline for review". At the bottom of the page is a "Note" section.

**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.

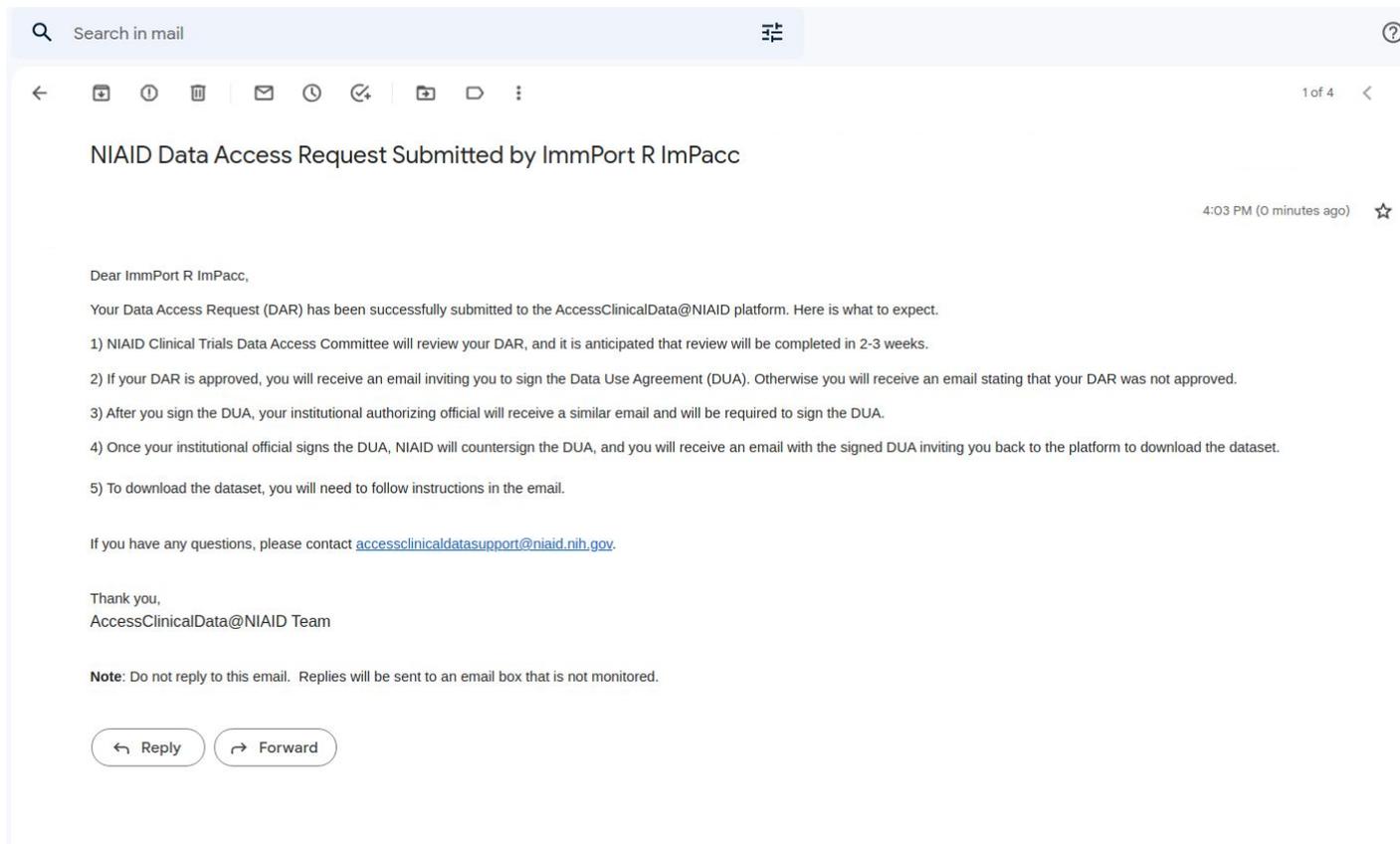
If you have any questions, please contact [accessclinicaldatasupport@niaid.nih.gov](mailto:accessclinicaldatasupport@niaid.nih.gov).

Thank you,  
AccessClinicalData@NIAID Team

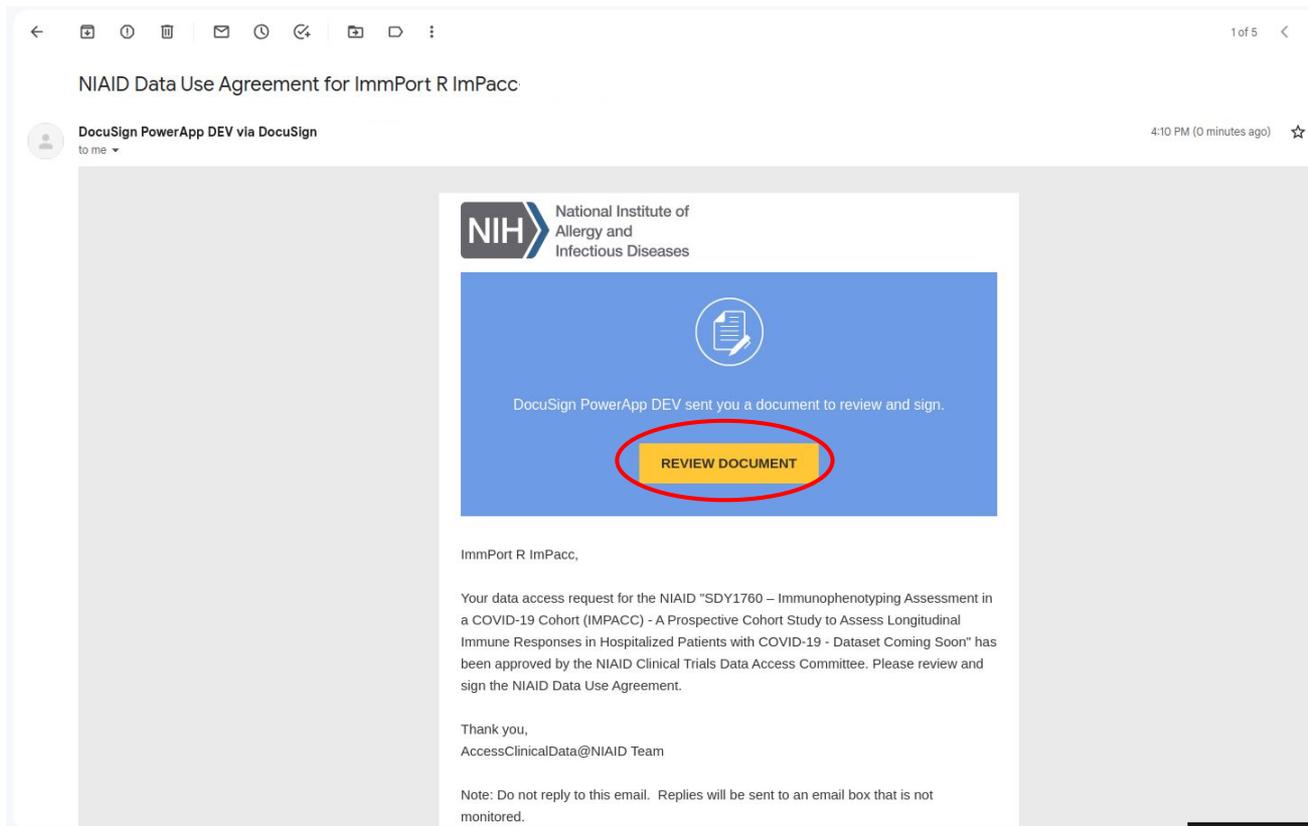
**Note:** We will not use your email address for future mailings or provide your email address to third parties. The information will not be stored or used for any other purpose. Please see our [Privacy Policy](#) for more information.

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

- (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.
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- (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](mailto:Accessclinicaldata@NIAID). Attachment A provides a blank DAR form.
- (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-8CC1-49C0-8899-09D0C371EF9A

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 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 Data Use Agreement" with the subtitle "ImmPort R ImPacc" and "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 "DEMONSTRATION DOCUMENT ONLY" notice. The main section is titled "Signature Page" and contains the following text:

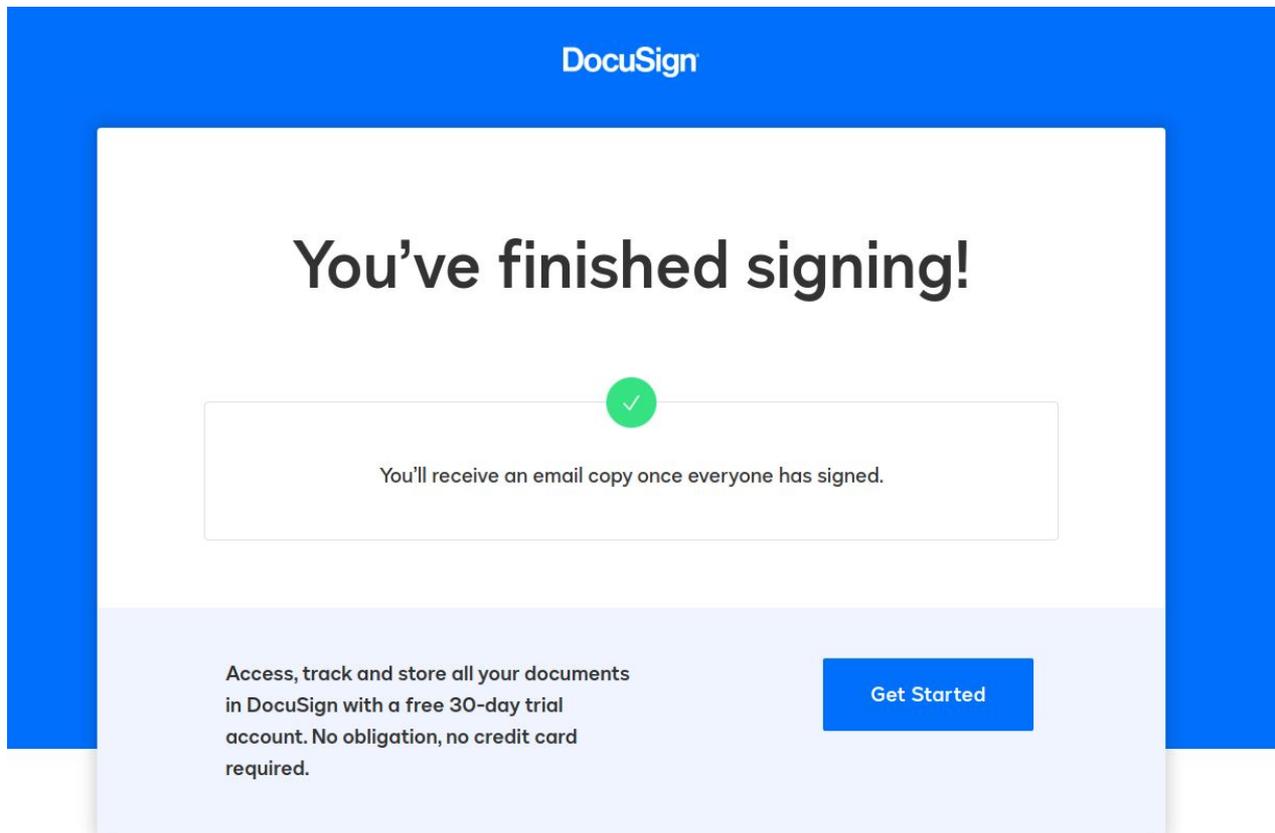
Required - Signature Applied  
ACKNOWLEDGEMENT OF APPROVED USER:  
Signed by: ImmPort R ImPacc 8/1/2022  
ImmPort R ImPacc Date

FOR ACCESSING INSTITUTION):  
\_\_\_\_\_  
Date

Mailing Address for Notices:  
\_\_\_\_\_

At the bottom of the page, a blue footer 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!

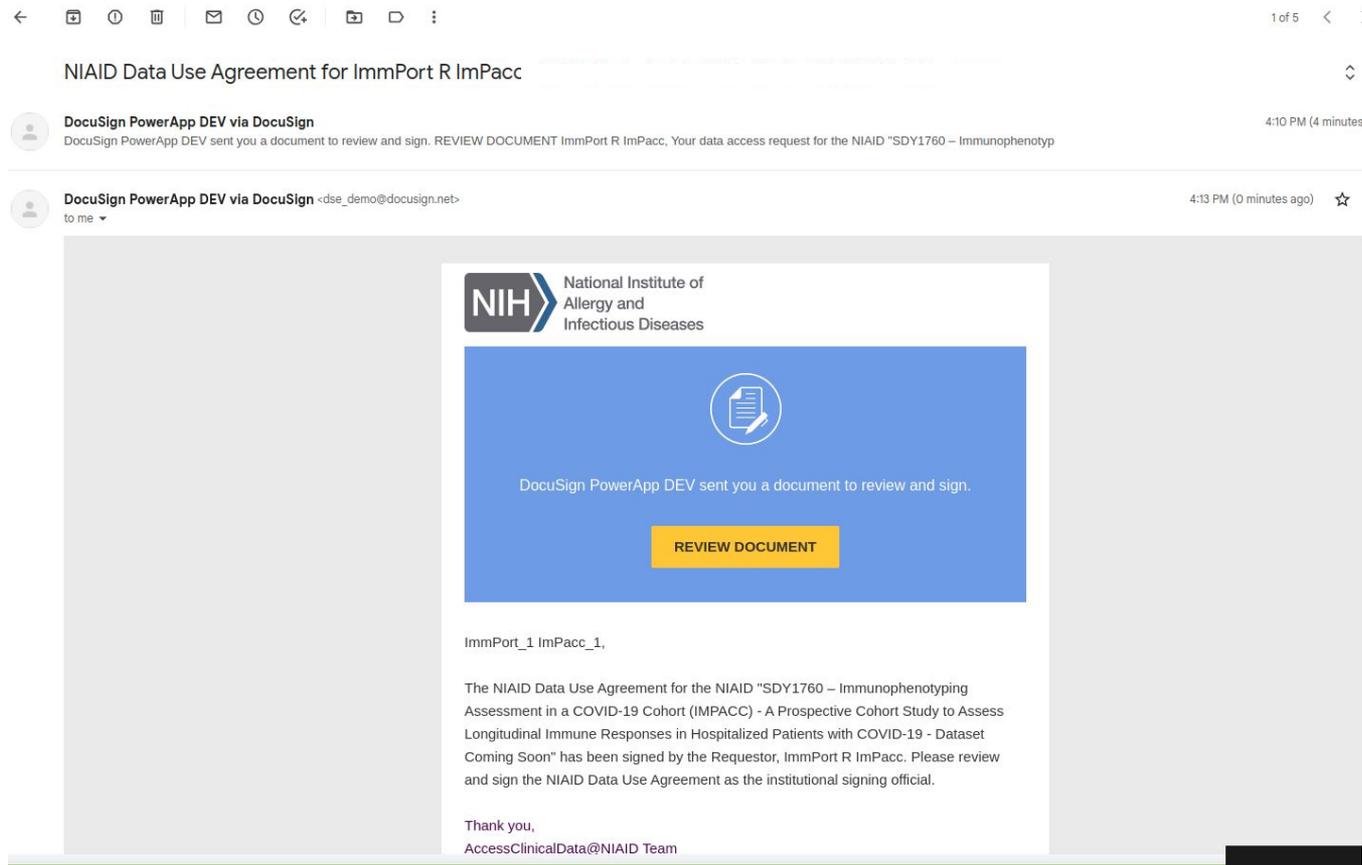
✓

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

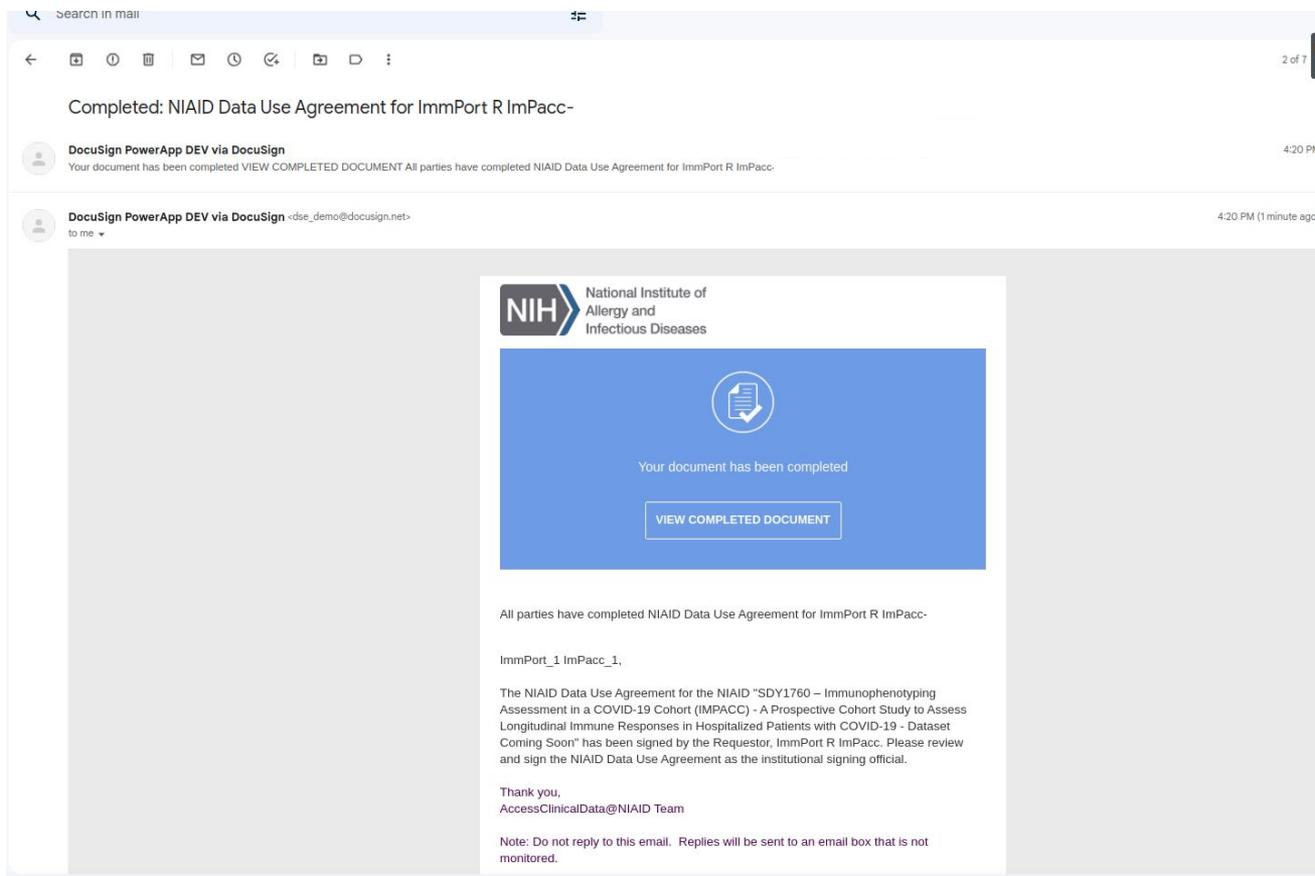
Access, track and store all your documents in DocuSign with a free 30-day trial account. No obligation, no credit card required.

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.

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, delete, reply, and other actions. The email title 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 for a 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. A list of five instructions follows, with the first instruction, "1. Click <https://accessclinicaldata.niaid.nih.gov/login>", circled in red. The email ends with "Regards, AccessClinicalData@NIAID Team" and a note: "Note: Do not reply to this email. Replies will be sent to an email box that is not monitored." 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**

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](#)

### 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 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 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 brief 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 the data files, with a 'Download' button circled in red. The table has columns for Name, Size, and Last Modified. The footer includes sponsorship by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), and Health and Human Services (HHS), along with logos for Nature Scientific Data's Recommended Data Repository, PLOS ONE Recommended Data Repository, CORE TRUST SEAL, and social media links for Facebook and Twitter. Contact Us, Privacy Policy, Disclaimer, Accessibility, and HHS Vulnerability Disclosure links are also present, along with recommended browser information.

ImmPort Upload Shared Analysis Resources

Shared Data

Launching IBM Aspera Connect...

Search www.immport.org Data About

Data Catalogs Data Model Help Welcome immportimpacc

**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

<input type="checkbox"/>	Name <sup>1</sup>	Size <sup>↑↓</sup>	Last Modified <sup>↑↓</sup>
<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 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+