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

# IMPACC Study SDY1760 Access Instructions

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



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



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

Experimental Sector Secto	Immportimpace     Example
By checking the "I Accept" box below, you confirm that you have read and accept all the terms and conditions without limitation of the User Agreement for the NIAID Immunology Database and Analysis Portal.	By checking the <b>"I Accept"</b> 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. If user does not have an existing ImmPort account,
□ I Accept      Forgot Password?  New to ImmPort?      Legister	✓ I Accept → Login New to ImmPort? Forgot Password? ▲ Register
G Sign in with Google	or Sign in with Google

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.

the basic	w 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 c study metadata, protocol(s) and study files. Learn more Data quick links: COVID-19 studies) (Influenza studies) (Respiratory-like illnesses studies) (Viral infectious diseases studies)	dof ×
🕷 Data B	Browser 😧	
	a browser allows users to download ImmPort data by individual file, directory, or study. The data browser uses a software tool called Aspera Connect to tra rt to users. Here are the 🗗 Instructions to install Aspera Connect on your browser.	ansfer files
# Browse	e Shared Data > SDY1760	
Title	Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospit Patients with COVID-19	alized
Brief Description	This is a prospective observational cohort of adult participants hospitalized with known or presumptive COVID-19.	
The download	50 is a Controlled Data Set ad package for SDY1760 will be made available once the Data Access Request (DAR) is approved and the signed NIAID Data Use Agreement (DUA) is at Access the HIAID Clinical Trials Repository - AccessClinicalData@NIAID for more information on the DAR and DUA approval process.	s submitted.
National Insti	by: tiltule of Allergy and Infectious Diseases (NIAID) tiltules of Health (NIH) Human Services (HHS)	

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

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.

🔆 ImmPort 🛛 🎇 Upload 🔻 🏡 Shared 🎡 Analysis 🤮 Resources	Search www.immport.org Q Data + About +
😸 Shared Data	Data Catalogs Data Model Help • Welcome immportimpacc •
A new online wizard is now available to register a study within ImmPo the basic study metadata, protocol(s) and study files. Learn more . Shared Data quick links: COVID-19 studies Influenza studies Respirat	vrt. The wizard is a web based tool that will guide you through the initial upload of any-like linesses studies (Viral Infectious diseases studies)
🕷 Data Browser 🥹	
ImmPort data browser allows users to download ImmPort data by individual file, di from ImmPort to users. Here are the C Instructions to install Aspera Connect on y	rectory, or study. The data browser uses a software tool called Aspera Connect to transfer files our browser.
# Browse Shared Data > SDY1760	
Title Immunophenotyping Assessment in a COVID-19 Cohort (IMPAC Patients with COVID-19	C) A Prospective Cohort Study to Assess Longitudinal Immune Responses in Hospitalized
Brief This is a Confirmation Description	×
SDY1760 is a Contro     SDY1760 is a Contro     The download package fo	y - AccessClinicalData@NIAID to initiate the Data Access Request.  Y Proceed ef (DUA) is submitted.
C Request Access	
Please visit the NIAID Clinical Trials Repository - AccessClinicalData@NIAID for n	are 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)	Repository Recommended TRUST Data Twitter
Contact Us   Privacy Policy   Disclaimer   Accessibility   HHS Vulnerability Disclosure	Recommended Browsers: Chrome, Firefox, Safari v7+, Internet Explorer v11+

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

		Contact Support   Login
National Institute of Allergy and Infectious Diseases	AccessClinicalData@NIAID	کر Study Viewe
	ophenotyping Assessment in a COVID-19 Cohort (IMPACC) - A Prospective Cohort S <del>D-19 -</del> Dataset Coming Soon	
ogin through IMMPORT to	Request Access	Data Access
Please note that researc	chers are required to log in before requesting access.	Data Access Request (DAR)
ess upon enrollment. Partic itilatory support requiremen inges that occurred through spital through Day 28, unles hin 24 and 96 hours of care	rvational cohort surveillance study of approximately 1100 adult participants hospitalized with COVID-19. Detailed information was coll icipants had longitudinal assessments of clinical status, and pertinent clinical data (including clinical laboratory values, radiographic f nets, complications, etc.) was recorded. In parallel, the study conducted serial biologic sampling for detailed immuophenotyping to p ghout the course of infection. The biologic samples collected for this observational study included blood, nasal swabs, and endotrache ess discharged earlier. If a participant required an escalation to Intensive Care Unit (ICU)-level care, either within or outside of a dedicat re escalation. Convalescent questionnaires and biologic samples were collected at 3-month intervals up to Month 12 after discharge, prior to Day 28, attempts were made to collect additional scheduled assessments through Day 28 on an outpatient basis, if feasible.	findings, medication use, oxygen and provide a comprehensive picture of immune eael aspirates. Participants were followed in ated ICU, additional samples were collected
Data First Available	July 2022	
Data Available	Patient-Level Data	
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)	
NCT Number	NCT04378777	
	COVID-19	
Condition	COVID-19	

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.



No Fear Act Data Privacy Policy

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Health and Human Services 🗹

USA.gov 🗹

HHS Responsible Disclosure Form 🗹

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

Allergy and Infectious Diseases	ccessClinicalData@NIAID			C Study Viewe
	enotyping Assessment in a COVID-19 Cohort (II 9 - Dataset Coming Soon	MPACC) - A Prospective Cohort Study to Assess Longitudinal Im	mune Responses in Hospita	lized
Request Access			Data Access Data Use Agreement (DUA) Data Access Request (DAR)	
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Data First Available	July 2022			
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Data Available Sponsor	Patient-Level Data National Institute of Allergy and Infectiou	s Diseases (NIAID)		
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Data Available Sponsor	National Institute of Allergy and Infectiou	s Diseases (NIAID)		
Data Available Sponsor NCT Number	National Institute of Allergy and Infectiou NCT04378777	s Diseases (NIAID)		

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

		Contact Support	immportimpacc @	Logout Đ
National Institute of Allergy and Infectious Diseases	<u>@NIAID</u>			Q
← Back SDY1760 - Immunophenotyping Assessm Patients with COVID-19 - Dataset Coming Request Access		Data Access	(DUA)	:d
illness upon enrollment. Participants had longitudinal assessmen ventilatory support requirements, complications, etc.) was record changes that occurred throughout the course of infection. The bic hospital through Day 28, unless discharged earlier. If a participant within 24 and 96 hours of care escalation. Convalescent question	approximately 1100 adult participants hospitalized with COVID-19. Detailed information was collected regarding patient history and onset of ts of clinical status, and pertinent clinical data (including clinical laboratory values, radiographic findings, medication use, oxygen and ed. In parallel, the study conducted serial biologic sampling for detailed immunophenotyping to provide a comprehensive picture of immune logic samples collected for this observational study included blood, nasal swabs, and endotracheal aspirates. Participants were followed in required an escalation to intensive Care Unit (UC)I-evel care, either within or outside of a dedicated ICU, additional samples were collected naires and biologic samples were collected at 3-month intervals up to Month 12 after discharge, if available. In addition, if a participant was to collect additional scheduled assessments through Day 28 on an outpatient basis, if feasible.	Data Access Reques  Study Documents  MMPACC March 2022 72.02 KB)		f (pdf -
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 Acces	s Request F	orm		
process found on the <b>Accessclinica</b> • Upon approval of the DAR by NIAIL and sign a NIAID Data Use Agreeme data.	Idata@NIAID data platf and prior to accessing nt (DUA) using DocuSig	form and will be reviewed by the NIAID Cl g the data set, the primary requestor and	linical Trials their institu AID data pla	is electronic DAR form as part of the request access Is Data Access Committee. ution official will be notified and required to agree to atform that outlines the terms of the use of the
1 Requestor Information       2 R         1a. Requestor	esearch Use			
First Name *	N	/iddle Name		Last Name *
Email Address *	P	Phone Number *		ORCID ID (ORCID Login)
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Degree *		Position/Title *		
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Department/Branch *	Ir	nstitution *		

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

	DAR) is required to be submitted to NIAID by the red NIAID data platform and will be reviewed by the NI.	questor using this electronic DAR form as part of the request AID Clinical Trials Data Access Committee.
		r and their institution official will be notified and required to a @ <b>NIAID</b> data platform that outlines the terms of the use of th
If you have any questions about the DAR, pl	ease contact 🔀 <u>accessclinicaldatasupport@niaid.</u>	<u>nih.gov</u> .
1 Requestor Information 2 Researc	h Use	
1a. Requestor		
➤ First Name *	Middle Name	Last Name *
I		
Email Address *	Phone Number *	ORCID ID (ORCID Login)
Address *		City *
Address * State/Province *	ZIP/Postal Code	City *
	ZIP/Postal Code	
	ZIP/Postal Code Position/Title *	

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**

First Name *	Middle Name	Last Name *
Email Address *	Phone Number *	
Address *		City *
State/Province *	ZIP/Postal Code	Country *
Position/Title *	Department/Branch *	Institution *

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



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

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

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

- 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

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Analysis plan with methods

#### Research Use Statement (Limit to 3500 characters) \*



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

NIAID Da	ta Access Request Form	
Submission cor	npleted successfully.	Anticipated
Your Data Access	Request (DAR) has been successfully submitted to the AccessClinicalData@NIAID platform. Here is what to expect.	timeline for re
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 a was not approved	pproved, you will receive an email inviting you to sign the Data Use Agreement (DUA). Otherwise you will receive an email stating that your DAR	
3) After you sign t	he DUA, your institutional authorizing official will receive a similar email and will be required to sign the DUA.	
4) Once your insti platform to down	tutional official signs the DUA, NIAID will countersign the DUA, and you will receive an email with the signed DUA inviting you back to the load the dataset.	
5) To download th	e dataset, you will need to follow instructions in the email.	
lf you have any qu	vestions, please contact <u>accessclinicaldatasupport@niaid.nih.gov</u> .	
Thank you, AccessClinicalDa	ta@NIAID Team	
Note: Wo 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	

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).

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	NIAID Data Access Request Submitted by ImmPort R ImPacc	2	
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	Dear ImmPort R ImPacc,		
	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	vill 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 (DU,	A). 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 re	equired to sign the DUA.	
	4) Once your institutional official signs the DUA, NIAID will countersign the DUA, and you will receive a	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: Do not reply to this email. Replies will be sent to an email box that is not monitored.		
	← Reply → Forward		

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.

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	NIAID Data Use Agreement for ImmPort F	R ImPacc		
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		Note: Do not reply to this email. Replies will be sent to an email box that is not monitored.		

#### User clicks on Continue

demo.docusign.net/Signing/?ti=a8f163a8561143c38b0b19cd228d98b4 💡 🔌 🚖 🚓 Incognit Please Review & Act on These Documents National Institute of Allergy and Infectious Disease Powered by DocuSign ImmPort R ImPacc. Value data anoma to a second for the NUMP RODV(1700) Incompany and a second second second (NUPACO). View More CONTINUE 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, Access/clinical/data@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



## User signs the document

Select the sign field to create and add your sign	ature.	FINISH	OTHER ACTIONS -
	@ @ ¥ ➡ ¢ 0		
	Peraton Data Use Agreement ImmPort R ImPacc Page 5 of 9		
	NIAID Data Use Agreement For - ImmPort R ImPacc-2022-08-01T20:10:10.0996521Z 5 of 9		
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SIGN	Signature Page		
	FOR ACCESSING INSTITUTION):		
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	Mailing Address for Notices:		
	Email: Tel;		

#### User clicks Finish

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	Signature Page	8/1/2022 Date	
	FOR ACCESSING INSTITUTION):		
	Mailing Address for Notices:	Date	
	Ready to Finish? You've completed the required fields. Review your work, then selec	: FINISH	

#### User has finished signing the document



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

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	NIAID Data Use Agreement for ImmPort R ImPacc		\$
-	DocuSign PowerApp DEV via DocuSign DocuSign PowerApp DEV sent you a document to review and sign. REVIEW DOCUMENT ImmPort R ImPacc, Your data access request for the	4:10 PM (4)	minutes
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	Import_1 ImPacc_1,         The NIAID Data Use Agreement for the NIAID "SDY1760 - Im Assessment in a COVID-19 Cohort (IMPACC) - A Prospective Longitudinal Immune Responses in Hospitalized Patients with Coming Soon" has been signed by the Requestor, ImmPort R and sign the NIAID Data Use Agreement as the institutional sign the NIAID Data Us	munophenotyping Cohort Study to Assess COVID-19 - Dataset ImPacc. Please review	
	AccessClinicalData@NIAID Team		

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.

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		1 of 7	< >		•
NIAID Clinical Data Set Available for Access	X×			\$	ß
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Dear Dr. ImmPort R ImPacc,					
	ing Assessment in a COVID-19 Cohort (IMPACC) - A Prospective Cohort Study to ned by all parties, and the data is now available by following these instructions:	o Assess Longitudinal Immune Responses in Hospitalized Patient	s with CC	OVID-1	19 -

Click <u>https://accessclinicaldata.niaid.nih.gov/login</u>
 C. Log in onig the cases codestials used when the request was made
 Click on the "Study Viewer" (top right comer)
 Find the study, click on "Show Details" and then click on "Learn More"
 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

C accessclinicaldata.niaid.nih.gov/login	🖈 😸 Incognito 🛛 Update 🔅
	Contact Support   Login 🗗
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



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.



#### User clicks the **Download** button

National Institute of Allergy and Infectious Diseases

#### ← 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

#### **Detailed Description**

Download C

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 perturbidinat 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 a 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)

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Study Viewer

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

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hared Data	G	Launching IBM Aspera Connect		Data Catalogs Data Model	Help - Welcome immportimpacc -
the basic s	study metadata, protocol(s) and study		will guide you through the initial us diseases studies	lupload of X	
😭 Data Br	rowser 😢				
		Port data by individual file, directory, or study. The data browser uses install Aspera Connect on your browser.	a software tool called Aspera Conne	ect to transfer files	
A Browse S	Shared Data > SDY1760				
Title	Immunophenotyping Assessment in Patients with COVID-19	a COVID-19 Cohort (IMPACC) A Prospective Cohort Study to Assess	Longitudinal Immune Responses in	n Hospitalized	
Brief Description	This is a prospective observational c	ohort of adult participants hospitalized with known or presumptive CC	VID-19.		
• SDY1760	is a Controlled Data Set				
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	: ute of Allergy and Infectious Diseases (NIAID) utes of Health (NIH)	Recommended Data Repository Recommended	Core Trustworthy Data	acebook	

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Health and Human Services (HHS)

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