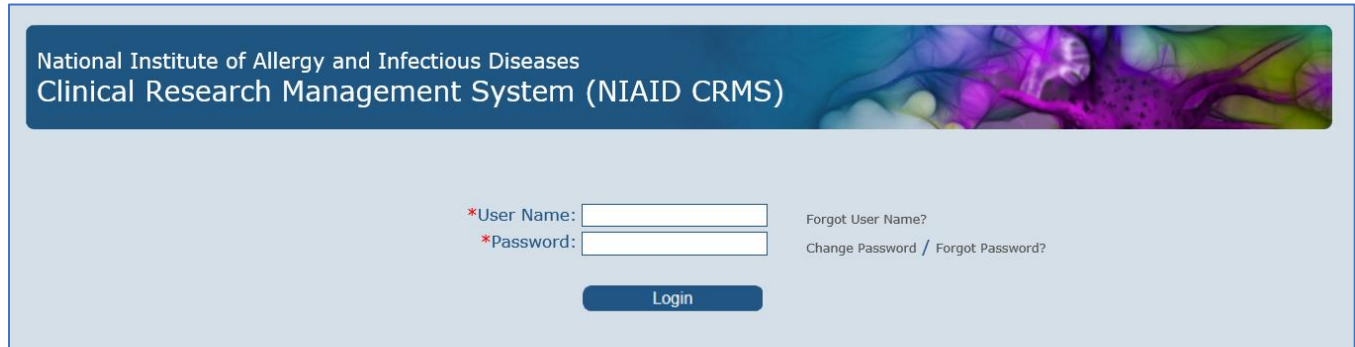


Study Chairs, Co-chairs and Vice Chairs User Guide to Access Investigator's Brochures through NIAID Clinical Research Management System (NIAID CRMS)

A. Locating the Investigator's Brochure (IB) on the IB interface

After receiving an email notification regarding an IB distribution, please follow the steps below to access the IB:

- Click on <https://ncrms.niaid.nih.gov> to access the NIAID CRMS.
- Log into the NIAID Clinical Research Management System (NIAID CRMS) using your login and password.
- If you do not have access to DAERS please contact NCRMS at (240) 778-2517 or CRMSSupport@niaid.nih.gov.



National Institute of Allergy and Infectious Diseases
Clinical Research Management System (NIAID CRMS)

*User Name: Forgot User Name?
*Password: Change Password / Forgot Password?

Login

- Click on the **Investigator's Brochure** link on the tool bar.



B. Acknowledging Receipt of the IB

- Under the **IB Notification** section, view the IB notification(s).

Investigator's Brochure RSC

The table below lists IB notifications distributed by DAIDS Regulatory Support Center. Notifications have to be acknowledged prior to accessing the IB documents. Please click on the "Acknowledge/Decline" button in order to provide your final decision. Your decision cannot be changed.

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Acknowledge or Decline...	19-Sep-2024	Test IB Document	Modification Document (01-Sep-2018)	Zidovudine

- Click the **Acknowledge** or **Decline** button.

- Read the **IB Receipt Confirmation and Confidentiality Agreement** that appears in the pop-up window.

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

Please review the receipt confirmation and confidentiality agreement. Once reviewed, please select one of the options below (**Acknowledge** or **Decline**) and submit your final decision. Your decision cannot be changed.

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

+			
Distributed to:	[Study Chair/Co-Chair/Vice Chair]		
Distributed By:	DAIDS RSC Safety Information Center (RIC)	Distributed on:	DD-MMM-YYYY
RIC Email:	RIC@tech-res.com	RIC Telephone:	1-301-897-1708
RE:	[Notification title created by RSC]	RIC Fax:	1-301-897-1710
Investigator's Brochure (IB) Included in this Notification/Distribution		Study Product associated with the IB	
[Display Name of IB Documents (s)]		[Study Product Selected for Distribution]	

As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to **Study Chairs, Co-chairs and Vice Chairs** participating in DAIDS-sponsored protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-chairs and Vice Chairs are responsible for acknowledging receipt of IBs sent to them. IBs contain third-party, proprietary and confidential information and may be disclosed or reproduced only for the purpose of conducting DAIDS-funded studies.

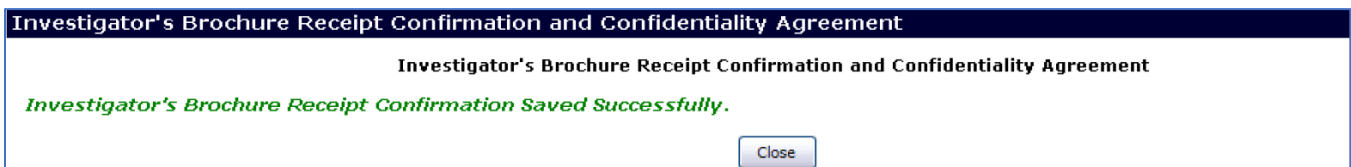
All copies of IBs must be retained as essential documents in accordance with the ICH Guidance E6, federal regulations and the DAIDS Policy on Record Retention. DAIDS strongly urges Study Chairs, Co-chairs and Vice Chairs to establish and maintain a system for the use and secure storage of the documents.

- Please make the appropriate selection regarding your participation in the study.
- **Select** whether you are participating by **Confirming that you will be participating in the study** or not participating in the study by **Confirming that you will NOT be participating in the study** then **submit to save** your selection.

I hereby confirm that I will be participating in the study(ies) that use the drugs listed above and I acknowledge receipt of this Notification/Distribution from DAIDS. I understand that selecting this option will allow me to access the IBs included in this Notification/Distribution, which I hereby agree to keep confidential per the terms stated above, to which I am legally bound.

I hereby confirm that I will NOT be participating in the study(ies) that use the drugs listed above and I DECLINE to access the IBs and IB documents included in this distribution.

- The image below provides a view of the IB Receipt Confirmation Agreement selection saved successfully.



- * **Please note that your selection is final and cannot be changed.**
- * **Please note that the submit button may take a few seconds to update and only needs to be clicked once.**
- * **If you incorrectly decline access, you will need to email the RIC (RIC@tech-res.com) to request access, which will cause a delay in your IB access.**
- * **Saving and Printing options will be available after the confirmation window is closed.**

C. Saving and Printing the IB Receipt Confirmation

- You will be able to access the signed confirmation under the Acknowledgement Status by clicking on either “**Acknowledged**” or “**Decline**” on the left side under the IB Notification section. This confirmation can then be saved or printed for your records.

Investigator's Brochure RSC

he table below lists IB notifications distributed by DAIDS Regulatory Support Center. Notifications have to be acknowledged prior to accessing the IB documents. Please click on the "Acknowledge/Decline" button in order to provide your final decision. Your decision cannot be changed.

inter product/brand/other name → Pending Notifications (n=0) All Notifications

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Acknowledged (15-Sep-2024)	Sep-2024	Test IB Document	Modification Document (01-Sep-2018)	Zidovudine

- The image below provides a view of the IB Receipt Confirmation Agreement selection once opened to print or save.

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

Distributed to:	Study Chair, A5403		
Distributed By:	DAIDS RSC Safety Information Center (RIC)	Distributed on:	15-Aug-2024
RIC Email:	RIC@tech-res.com	RIC Telephone:	1-301-897-1708
RE:	Test IB - OSM PQ	RIC Fax:	1-301-897-1710

Investigator's Brochure (IB) Included in this Notification/Distribution	Study Product associated with the IB
IB_Zidovudine_Test document (06-Aug-2024)	Zidovudine

As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to Study Chairs, Co-Chairs and Vice Chairs participating in DAIDS-sponsored protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-Chairs and Vice Chairs are responsible for acknowledging receipt of IBs sent to them. IBs contain third-party, proprietary and confidential information and may be disclosed or reproduced only for the purpose of conducting DAIDS-funded studies.

All copies of IBs must be retained as essential documents in accordance with the ICH Guidance E6, federal regulations and the DAIDS Policy on Record Retention. DAIDS strongly urges Study Chairs, Co-Chairs and Vice Chairs to establish and maintain a system for the use and secure storage of the documents.

I hereby confirm that I will be participating in the study(ies) that use the drugs listed above and I acknowledge receipt of this Notification/Distribution from DAIDS. I understand that selecting this option will allow me to access the IBs included in this Notification/Distribution, which I hereby agree to keep confidential per the terms stated above, to which I am legally bound.




Name: Jordan Lake **Date:** 15-Aug-2024

- You will be able to print or save your Declined confirmation by clicking on “Declined” to open the document.

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Declined (31-Aug-2018)	30-Aug-2018	IB QA Test 1	Maraviroc - IB Test (01-Aug-2018) Maraviroc - IB SOC - Test (01-Aug-2018)	Maraviroc

D. Saving and Printing the IB

- You will be able to access the IB document(s) by clicking on the PDF icon or IB date hyperlink under IB Notification section.

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Acknowledged (31-Aug-2018)	31-Aug-2018	Updated Investigator's Brochure for Maraviroc	Maraviroc dated October 2017 (01-Oct-2017)   Maraviroc Summary of Changes dated October 2017 (01-Oct-2017) 	Maraviroc


- You will not be able to click or access the IB(s) if you choose not to participate in the study. You will also not be able to save or print the IB for your records. The IB(s) can only be saved or printed for your records after you choose to participate in the study.

E. Where to Get Help

- If you have additional questions regarding IBs please contact RIC at RIC@tech-res.com or by selecting RSC on the navigation menu.

EAE Search **RSC**

The table below lists IB notifications distributed by DAIDS Regulatory Support Center. Notifications have to be acknowledged prior to accessing the IB documents. Please click on the "Acknowledge/Decline" button in order to provide your final decision. Your decision cannot be changed.

Enter product/brand/other name Pending Notifications (n=1) All Notifications 

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
<input type="button" value="Acknowledge or Decline"/>	19-Sep-2024	Test IB Document	Modification Document (01-Sep-2018)	Zidovudine