

CRS Leaders and CRS Coordinators 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 **EAE Reporting Module** icon.



- If you have full access to DAERS, you will find the **IB Notification section** at the lower left side of your home page.

The screenshot shows the DAERS home page with several sections:

- EAE Report Status:** Pending (2), Ready for Final Review (0), Submitted to RSC (247).
- Alerts:** No matching Alerts for EAE Reports were found.
- Investigator's Brochure (IB):** This section is circled in red. It contains a table of IB notifications and an "Acknowledge or Decline" button for each row.
- Questions from RSC Safety Office:** A table with columns: EAE Number, Protocol ID, PID, Open Questions, Days Open. One row is visible for EAE Number 2017-109925.
- Unstable EAE Outcomes:** A section for providing updates with stable outcomes, with a message: "No matching EAEs with Unstable Outcomes were found."

- The image below provides a closer view of the IB Notification section.

This is a close-up of the IB Notification section. It includes a search bar and a table with the following data:

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

- If you only have access to IBs in DAERS, the IB Notification section will appear after you select the EAE Reporting Module icon.

This screenshot shows the IB Notification section for a user with limited access. The table contains the following data:

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Acknowledge or Decline...	30-Aug-2018	IB QA Test 3	Maraviroc - IB Test (01-Aug-2018)	Maraviroc
Declined (30-Aug-2018)	30-Aug-2018	IB QA Test 2	Maraviroc - IB SOC - Test (01-Aug-2018) Maraviroc - IB Test (01-Aug-2018) Maraviroc - IB SOC - Test (01-Aug-2018)	Maraviroc
Acknowledged (30-Aug-2018)	30-Aug-2018	IB QA Test 1	Maraviroc - IB Test (01-Aug-2018) View Maraviroc - IB SOC - Test (01-Aug-2018) View	Maraviroc

B. Acknowledging Receipt of the IB

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

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=4) All Notifications

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
<input data-bbox="175 548 315 569" type="button" value="Acknowledge or Decline..."/>	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
<input data-bbox="175 621 315 642" type="button" value="Acknowledge or Decline..."/>	30-Aug-2018	IB QA Test 1	Maraviroc - IB Test (01-Aug-2018) Maraviroc - IB SOC - Test (01-Aug-2018)	Maraviroc

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

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=4) All Notifications

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
<input data-bbox="175 957 315 978" type="button" value="Acknowledge or Decline..."/>	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
<input data-bbox="175 1031 315 1052" type="button" value="Acknowledge or Decline..."/>	30-Aug-2018	IB QA Test 1	Maraviroc - IB Test (01-Aug-2018) Maraviroc - IB SOC - Test (01-Aug-2018)	Maraviroc

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

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

X

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: Site(s) 5121

Distributed By: DAIDS RSC Safety Information Center (RIC)

Distributed on: 06-Dec-2018

RIC Email: RIC@tech-res.com

RIC Telephone: 1-301-897-1708

RE: Updated Investigator's Brochure for Dolutegravir (GSK1349572)

RIC Fax: 1-301-897-1710

Investigator's Brochure (IB) Included in this Notification/Distribution	Study Product associated with the IB
GSK1342572 (Dolutegravir) dated November 2018 (15-Nov-2018); Summary of Changes dated November 2018 (15-Nov-2018)	GSK1349572 (Dolutegravir)

As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to CRS Leaders / CRS Coordinators participating in DAIDS-sponsored protocols. CRS Leaders / CRS Coordinators are required to forward this safety information to their Institutional Review Boards (IRBs)/Ethics Committees (ECs). Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, CRS Leaders / CRS Coordinators 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.

It is the CRS Leader's responsibility to copy and distribute IBs to study personnel such as site employees, consultants, pharmacists, investigators or contractors to whom it is necessary to disclose IBs for the purpose of conducting DAIDS-funded studies. Any person who is given access to an IB shall be informed of the requirement to maintain its confidentiality. Site staff shall protect the IB by using the same degree of care, but no less than a reasonable degree of care, as they use to protect their own information. The requirement to maintain the confidentiality of an IB shall apply in whatever format the IB is transmitted (e.g., as a written document, memorandum, report, correspondence, CD-ROM or other electronic transmission).

The IB, along with this Investigator's Brochure Receipt Confirmation and Confidentiality Agreement, must be retained for verification at the time of monitoring. 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. Compliance monitors will verify that all IBs are maintained in secured locations to protect confidentiality. DAIDS strongly urges CRS Leaders / CRS Coordinators 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 your site will be participating in the study** or not participating in the study by **Confirming that your site 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.

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

Investigator's Brochure Receipt Confirmation 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.

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

- 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:	Site(s) 5121		
Distributed By:	DAIDS RSC Safety Information Center (RIC)	Distributed on:	06-Dec-2018
RIC Email:	RIC@tech-res.com	RIC Telephone:	1-301-897-1708
RE:	Updated Investigator's Brochure for Dolutegravir (GSK1349572)	RIC Fax:	1-301-897-1710

Investigator's Brochure (IB) Included in this Notification/Distribution	Study Product associated with the IB
GSK1342572 (Dolutegravir) dated November 2018 (15-Nov-2018); Summary of Changes dated November 2018 (15-Nov-2018)	GSK1349572 (Dolutegravir)

As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to CRS Leaders / CRS Coordinators participating in DAIDS-sponsored protocols. CRS Leaders / CRS Coordinators are required to forward this safety information to their Institutional Review Boards (IRBs)/Ethics Committees (ECs). Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, CRS Leaders / CRS Coordinators 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.

It is the CRS Leader's responsibility to copy and distribute IBs to study personnel such as site employees, consultants, pharmacists, investigators or contractors to whom it is necessary to disclose IBs for the purpose of conducting DAIDS-funded studies. Any person who is given access to an IB shall be informed of the requirement to maintain its confidentiality. Site staff shall protect the IB by using the same degree of care, but no less than a reasonable degree of care, as they use to protect their own information. The requirement to maintain the confidentiality of an IB shall apply in whatever format the IB is transmitted (e.g., as a written document, memorandum, report, correspondence, CD-ROM or other electronic transmission).

The IB, along with this Investigator's Brochure Receipt Confirmation and Confidentiality Agreement, must be retained for verification at the time of monitoring. 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. Compliance monitors will verify that all IBs are maintained in secured locations to protect confidentiality. DAIDS strongly urges CRS Leaders / CRS Coordinators 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.

- 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.



The screenshot shows a web interface for the DAIDS Regulatory Support Center. At the top, there is a navigation menu with 'EAE', 'Search', 'Person', 'EAE Notification Recipient:', and 'RSC' (circled in red). Below the menu is a table of IB notifications. The table has columns for Acknowledgement Status, Distributed by RSC on, IB Notification Email, IB Document (Version Date), and Product(s). The first row shows 'Acknowledged (31-Aug-2018)' with a date of '31-Aug-2018' and an email 'Updated Investigator's Brochure for Maraviroc'. The second row shows 'Acknowledged (31-Aug-2018)' with a date of '30-Aug-2018' and an email 'IB QA Test 1'. Both rows have 'Maraviroc' listed as the product. The table also includes buttons for 'Acknowledge or Decline...' and a search bar.