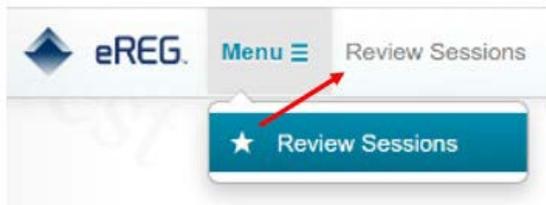


eREG Monitor Guide

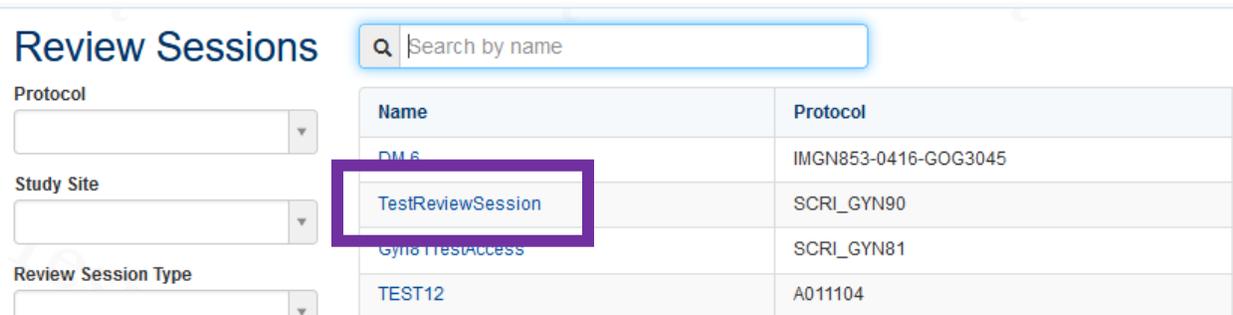
- You should have received an email with your Username and a Temporary Password. **Please note that the link to activate your account is only valid for 24 hours.**
- Your access to the system and to protocol as well as subject documents will only be valid for the dates requested. If you need to extend your visit, please reach out to your Data Specialist.

Reviewing Protocol and Subject Documents

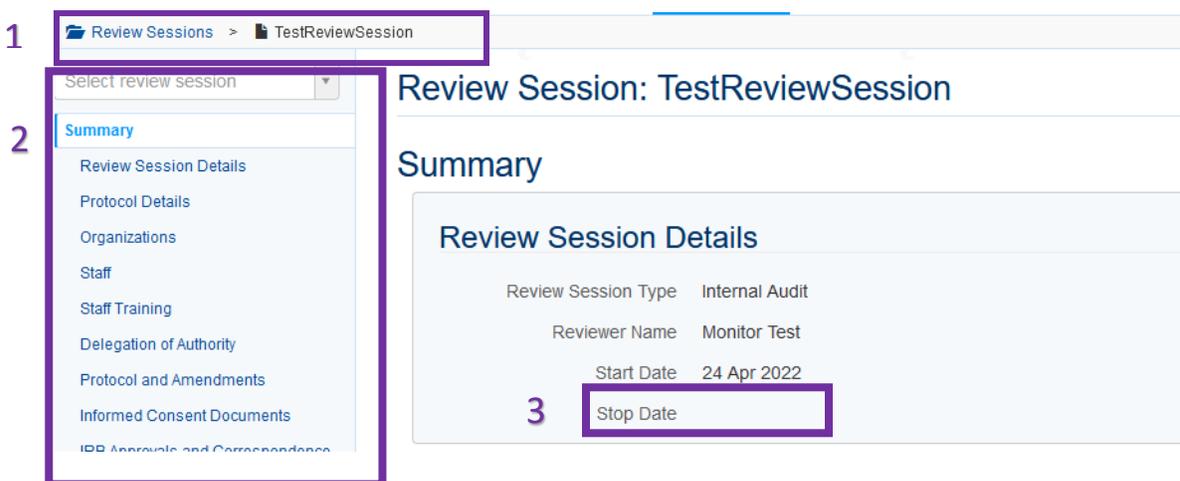
- From the Menu, choose Review Sessions to start your monitoring visit.



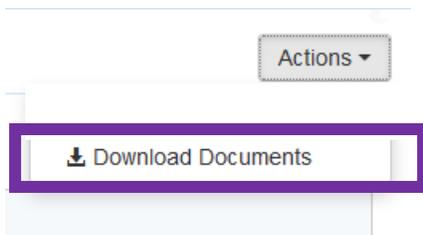
- Click on the name of the applicable Review Session to access the protocol information and documents.



- The Review Session will open and you will see a Summary of the visit.



1. The Breadcrumbs trail on the Top navigation bar will help you navigate back to your list of Review Sessions.
 2. The Menu on the Left Navigation Bar will help you navigate between different Binder Sections.
 - i. The Study Documents are organized by the sections listed on the left side of the screen.
 - ii. The IB signature pages, protocol signature pages, and other miscellaneous documents are found under the other documents tab.
 3. The Stop Date will list the last day you will no longer have access to review these documents. It should correspond with the last day of your scheduled visit.
- To Download all available documents, Click on the Actions Dropdown, then click Download Documents. This will generate a zip file containing the documents for your review.



- **You will not be able to download, or print Subject Documents.** You will only be able to view those documents in the system.
- To navigate through the different sections, click on a section to review the associated study documents.



Protocol and Amendments

IRB-approved Protocol

| Document Name | Effective Date ↓ |
|------------------------------------|------------------|
| GYN_96_Protocol_Amd_2_20210503.pdf | 03 May 2021 |

IRB-approved Protocol Clarification Letter

| Document Name | Effective D |
|---|-------------|
| GYN_96_PCL_Carbo-Dosing_20210611.pdf | 11 Jun 202 |
| GYN_96_PCL_Change_of_Address_20210510.pdf | 10 May 202 |
| GYN_96_PCL_Protocol_Memo_-_Exclusion_9_20210107.pdf | 07 Jan 202 |
| GYN_96_Protocol_Clarification_Letter_20200807.pdf | 07 Aug 202 |

1. Click on the  icon to review the individual documents. Electronic signatures will be at the end of the document if not placed in the signature section.
2. Signature Status will indicate if the document was Wet Signed, Electronically Signed, still Needs Electronic Signature, or the signature was not applicable. Wet Signed may include

documents that have wet ink signatures or that were signed in a different system (e.g. Adobe Sign or SIGNiX)

3. Please note: The IB signature pages, protocol signature pages, and other miscellaneous documents are found under the other documents tab.

- **Return to Home Page**

- From anywhere in the application, click the eREG logo in the upper-left corner to return to the homepage.

If you have any difficulties locating a study document, please reach out to the Regulatory Specialist assigned to the study.