GOG FOUNDATION PORTAL MANUAL

Version 1.1



GOG FOUNDATION PORTAL MANUAL



CONTENTS

Introduction	2
Portal access	3
For new users requiring access	3
For existing GOG Foundation Portal users	3
Interactive Response Technology (IRT)	4
Screening a new patient	4
Enrolling a patient	5
Reporting a screen failure	5
Additional resources	6
GOG Roster Form & Help	6



INTRODUCTION

What is the GOG Foundation Portal?

The GOG Foundation portal is the growing home for content and tools necessary to support the GOG Foundation participants and research program. The portal can be reached by any web browser at <u>https://partners.gog.org</u>.

What will I be using it for?

Initially, the primary purpose of the portal is to help manage the screening and enrollment of patients onto GOG-3026. Additional functionality will be developed and made available over time.

How can I contact GOG?

You can contact GOG via email or phone. For urgent issues, a phone call is recommended. For questions related specifically to the portal, or IRT system, please use the contact details below. Otherwise please visit the <u>Contact Us</u> page on the portal for up-to-date contact information.

Regulatory Support Email: gogregulatory@gog.org Roster Support Email: gogregulatory@gog.org Protocol Support Email: gogregulatory@gog.org Website Support Email: support@gog.org

Note: You should receive emails from the GOG Foundation account management and IRT systems. If you do not receive these messages, please check your **Junk/Clutter** folder for emails from <u>no-reply@gog.org</u>. Please contact GOG Support (<u>support@gog.org</u>) if you are still unable to find any messages from these systems.



PORTAL ACCESS

FOR NEW USERS REQUIRING ACCESS

Method 1: Added to GOG Foundation Roster

- · When added to the GOG Foundation roster, you will automatically have an account created for you.
- You will receive an invitation to your email with a link to complete the account creation process. The link in this email is valid for 30 days from the time you receive it.
- You will be prompted to provide a username and password. The password should be a minimum of 6 characters, and MUST include at least one of each of the following: uppercase, lowercase, number, and special character.
- Once completed, a confirmation screen will be displayed. At this point, you can now login to the portal.

Note: To add staff to the GOG Foundation roster, please send a completed **GOG Foundation Site Roster Update Form** to GOG Roster Support at <u>gogregulatory@gog.org</u>.

FOR EXISTING GOG FOUNDATION PORTAL USERS

Steps:

- Select the "Log In" link in the upper-right.
- Enter your previously created username and password.
- In the event that you forget your password, please click on "Forgot your password?".
- Enter the email for your account.
- Upon submission, you will receive an email with a link to reset your password. The link in this email is valid for 30 days from the time you receive it.

Note: If you have forgotten your username please contact GOG Support for further assistance.

Note: Your username and password are for only you alone. Further, no GOG staff has access to your credentials. The self-service password reset functionality must be used in the event you have forgotten your password.



INTERACTIVE RESPONSE TECHNOLOGY (IRT)

SCREENING A NEW PATIENT

Steps:

- Select "IRT" from the top menu.
- Select "Screen New Patient".
- Select the Site, Study, and Investigator for the patient, then press "Continue".
- Enter **Screening Date** and patient demographic details following any system prompts for required fields or other data validation.
- Select "Create" to initialize the screening case in the IRT system and receive a Patient Study Id.

Note: If you do not see an expected Study or Treating Investigator during screening, please contact GOG Roster Support (gogregulatory@gog.org) for further assistance.

GOG FOUNDATION PORTAL MANUAL



ENROLLING A PATIENT

Steps:

- Select "IRT" from the top menu.
- Navigate to your "Screened Patients" list.
- Select patient from list by clicking "Enroll/Screen Fail"
- Review provided details to confirm the correct patient is selected.
- Click the radio button indicating that you have confirmed the patient details and that the patient meets eligibility criteria. *Note*: Inclusion & Exclusion criteria details are captured in Medidata Rave.
- Select "Enroll Patient".
- A confirmation screen and notification will be provided to the registrar with some patient details, and the assigned treatment arm.

Note: Some studies may have additional screening requirements, and associated steps within the IRT system. Please consult the study protocol for specifics.

Note: If the "Enroll/Screen Fail" option is not available for an expected patient, and the corresponding **Patient Status** is "Screen – Successful", please contact GOG Support for further assistance.

REPORTING A SCREEN FAILURE

Steps:

- Select "IRT" from the top menu.
- Navigate to your "Screened Patients" list.
- · Select patient from list by clicking "Enroll/Screen Fail"
- Review provided details to confirm the correct patient is selected.
- Click the radio button indicating that the confirmed patient is not eligible, or has elected to not participate on the study.
- Provide the primary Screen Failure Reason from the dropdown list.
- Select "Screen Fail Patient".
- A confirmation notification will be sent to the registrar.

Note: For studies with a safety/reservation component, screen failures can also be reported while still with a **Patient Status** of "In Screening", or "Backup". Timely reporting of patient screen failures helps to ensure limited enrollment slots are available to interested patients and investigators.



ADDITIONAL RESOURCES

GOG ROSTER FORM & HELP

Current GOG Foundation Roster forms and instructions can be found at <u>https://partners.gog.org/Home/Help/</u>.