EASEE-PRO Guide for CRAs Participating in EAQ152 – COMET

Introduction

This document outlines the steps necessary for you and your patients to enroll in the COMET (COMMunication and Education in Tumor Profiling) study and gain online access to the EASEE-PRO system. EASEE-PRO is the web-based system that patients will use to participate in the self-guided genetic education module and enter their patient-reported outcomes (PRO) data. The instructions are divided into three sections:

- Enrollment Instructions (All Sites) ........................................................................................................... 1
- EASEE-PRO Patient Account Creation Instructions (All Sites) ................................................................. 2
- Instructions for Sites Providing Optional On-site Connectivity ............................................................... 2

A separate instructional handout for you to provide to patients is available on the ECOG-ACRIN website (http://ecog-acrin.org/clinical-trials/eaq152-educational-materials) and the CTSU website.

Enrollment Instructions (All Sites)

Before you can utilize the EASEE-PRO system, you must consent and register your patient to the COMET (EAQ152) study using CTEP’s OPEN registration system. We recommend that you consent the patient to COMET at the same time as consent for tumor profiling. Be aware, however, that the COMET consent form(s) must be separate and distinct from that of any tumor profiling consent(s).

1. If the patient is receiving tumor profiling as part of a clinical study, consent and register the patient to that study first.
   a. Make note of the study subject ID, as it will be requested during the COMET registration process.

2. Consent the patient to the COMET (EAQ152) study, log into OPEN, and register them to COMET
   a. Be sure to enter the email of the contact CRA at your site responsible for this participant
   b. Be sure to enter the study subject ID in the checklist, if applicable.
   c. Be sure to enter the participant’s email address
      NOTE: Only participants with an email address and internet access may participate in the COMET randomized control trial (Step 1)
   d. Make a note of the COMET subject ID (returned by OPEN); you will need this to access participant information in EASEE-PRO and RAVE.

3. You have a user account in EASEE-PRO, which you may use to view your patient’s information
   a. Go to https://pride.stat.brown.edu/CRA-Login
   b. Enter your CTSU (IAM) login credentials

4. Make a copy of the “Instructions for Patients Participating in the COMET Trial” at the end of this document and provide it to the participant
EASEE-PRO Patient Account Creation Instructions (All Sites)

Upon successful consent, registration, and randomization through OPEN, the participant will automatically be registered in EASEE-PRO. Instruct the patient that:

1. Their email address is their username
2. They will receive an auto-generated email with a secure activation link at the email address entered during the registration process. Note that it may take up to 15 minutes after registration for the email to propagate through all the systems and reach the patient.
3. Once the patient activates their account, they will need to verify their contact information before they can access the COMET study tools.
4. They must activate their account and complete the initial survey as soon as possible because it must be done before they receive their tumor genetic testing results.

Instructions for Sites Providing Optional On-site Connectivity

In the COMET trial, it is optional for sites to provide a guest area with on-site connectivity so study participants can access the intervention and complete their surveys. EASEE-PRO is compatible with most web-enabled devices (computer, tablet, smartphone, etc.) and browsers (Internet Explorer, Chrome, Safari, etc.). While patients are required to have their own connectivity to participate in COMET, some sites may choose to provide on-site connectivity as a matter of convenience for the patient and/or to provide additional assistance for the baseline survey. The following steps describe how to log into your account and provide on-site access for the participant to complete the baseline survey online:

1. Set up the participant in a guest area on a computer with internet access.
2. Log in to your EASEE-PRO account and select your patient’s profile.
   a. Go to https://pride.stat.brown.edu
   b. Select “CRA login” tab from the navigation bar.
c. Enter your CTSU (IAM) credentials

![CTSU(IAM)-SSO Users:](image)


d. Select ‘COMET’ from the list of studies to which you have access

e. Select the patient’s subject ID from the list of subject IDs at your site

3. For a new patient, provide them with access to the dashboard that appears on the screen. The dashboard for a new patient will only have one survey available: the “T0 – Baseline” survey. Instruct the patient to:

a. Find the T0-Baseline survey and select “Start Survey”

![Dashboard with T0-Baseline survey selected](image)

b. At the end of the survey, click the link *Return to My Home Page* to return to the dashboard

Notes:

- After completing the T0-Baseline survey, Arm B participants will have no more surveys and are done. They should go home and look for an email to activate their account.

- After completing the T0-Baseline survey, Arm A participants will have a new survey, *Educational Materials*. This survey is the introduction to the self-guided genetic education module. The participant may view this now, or they can go home, activate their account, and view this later.

- The self-guided genetic education module is encapsulated within the *Educational Materials* survey. Once an Arm A participant has completed the *Educational Materials* survey or any participant is three (3) months past the receipt of their genetic testing, the *Educational Materials* will appear in the Educational Materials section.