Oncology Patient Enrollment Network Funding Screen User Guide

1. Background

The National Clinical Trials Network (NCTN) trials follows National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP) per case management funding principles for cancer treatment and advanced imaging trials. NCI's Division of Cancer Prevention (DCP) NCI Community Oncology Research Program (NCORP) Research Base grant provides funding for quality-of-life endpoints, cancer control, and cancer prevention studies to non-NCORP sites. All screenshots in this document are from the Oncology Patient Enrollment Network (OPEN), https://open.ctsu.org/open/home.open

Funding for trial activities falls under one of the following categories:

- Screening for Intervention
- Base Intervention (may also include subset funding in some trials)
- Advanced Imaging
- Biospecimen Collection
- Shipment of CTEP Investigational New Drug (IND) Oral Agents to Patients – funding for shipping agents to patients
- Special Precision Medicine Initiative (PMI) Lead Funding (funding for precision medicine treatment trials, paid by the lead group for the screening trial)
- Special – funding for complex or rare disease trials which is paid by the lead group
- Special Credit Group (CG) – funding for complex or rare disease trials which is paid by the credited group
- Subset Funding – Funding for Base Intervention is tiered and distributed at different steps within a protocol
- Subset - High Performance Funding – Funding is tiered and distributed at different steps within a protocol
- Quality of Life (NCI DCP's NCORP grant covers this funding)
- Non-NCI/Division of Cancer Treatment and Diagnosis (DCTD) Funding (e.g., Industry)

NCI per case management funds are provided to all sites enrolling subjects onto NCTN and NCORP trials via one of three NCI funding mechanisms:

1) NCTN Group Grants

2) NCTN Lead Academic Participating Site (LAPS) Grant

3) DCP NCORP Grant

Non-NCI funding obtained by the Network Groups to supplement trial support is dispersed to all of the three categories of sites by the Lead Protocol Organization (LPO). All non-NCI funding is available to any site that meets the specific requirement of the study and is tracked by the LPO; therefore, no CTSU or Oncology Patient Enrollment Network (OPEN) steps are needed to trigger these funds unless otherwise specified.

Studies with approved additional NCI funding will require the entry of completion dates in the OPEN Funding Screen at the time of subject completion. Completion dates will be required for all mandatory requests, mandatory events, optional, and conditional funding types. Completion dates are not required for Screening for Intervention, Base Intervention and Subset Funding.

Mandatory Funding – This funding is provided to all sites participating on a study. Subject enrollment itself serves as the trigger for this funding type. No additional data entry in OPEN is required.

Mandatory Request and Mandatory Event – This funding is provided for trials requiring sites to ask a subject to participate in an optional study or trials that require specific data or biospecimen collection at a specific event (e.g., recurrence). The entry of completion dates is required in the OPEN funding screen at the time of subject completion or the date a specimen was sent.

Conditional Funding Types – This funding is provided to sites once a certain condition or parameter is met (e.g., completed a mandatory biospecimen collection at month 12). The entry of completion dates is required in the OPEN funding screen at the time of subject completion or the date a specimen was sent.

Optional Funding Types – This funding is provided if sites complete an optional component of the study. The entry of completion dates is required in the OPEN funding screen at the time of subject completion or the date a biospecimen was sent.

2. Instructions for Accessing the Oncology Patient Enrollment Network Funding Screen

The below instructions provide steps for accessing the OPEN Funding screen as well as information regarding the screen functionalities.

1) To enter additional funding for a subject, click on the history tab and search for the Patient ID (PID) associated with the enrollment. Any enrollments with additional funding will have a dollar sign $ icon next to the protocol number. See Figure 1: History Screen.
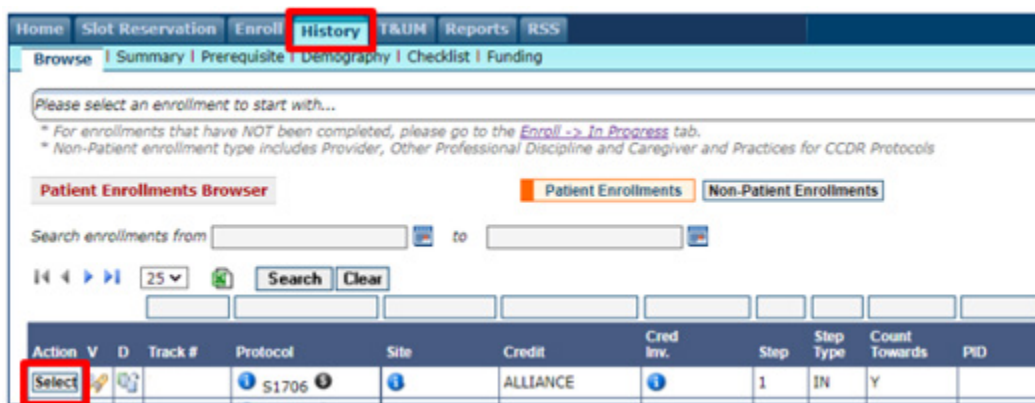

Figure 1: History Screen

2) Click on *Select* next to the subject enrollment with the required PID. The summary screen will be displayed. See Figure 2: Summary Screen.
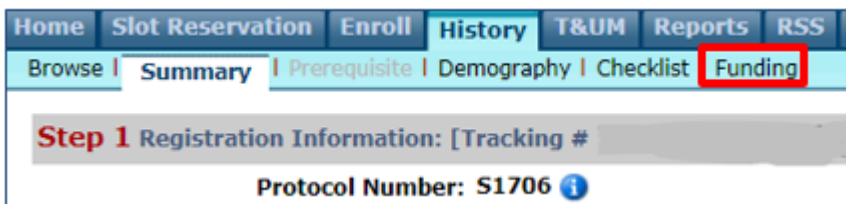

Figure 2: Summary Screen

3) Click on the Funding subtab at the top of the screen (Figure 2: Summary Screen).

4) The enrollment data will be displayed at the top and a funding table will be populated with each of the funding types available. See Figure 3: Funding Screen.

5) Enter the date the funding was completed by clicking on the textbox to enter the date in MM/DD/YYYY format or click on the calendar icon to select a date. (Note: the Date Completed cannot be before 01-Mar-2014).
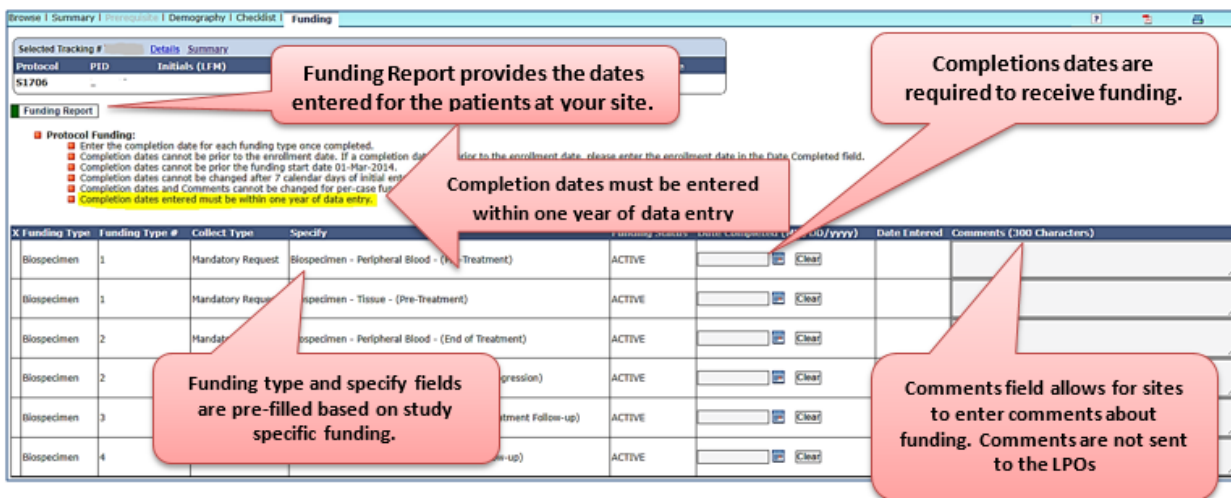

Figure 3: Funding Screen

6) Click on save after the dates have been entered. Multiple dates may be entered at one time, or you may return later to enter additional dates.   **Save**

7) A confirmation screen will be displayed. Completion dates cannot be changed **after 7 days of initial entry**. **Sites must enter dates in OPEN within one year of the completion date of the test or specimen.**

8) A funding report is available to assist sites with tracking the funding dates entered in the OPEN funding screen. The report provides sites with a snapshot of the completed and outstanding funding components required for subjects enrolled in trials at their site.

9) Click on the dollar sign icon 🪙 for any subject enrollment and the report will open in a separate browser (Figure 4: Dollar Icon) or from the Funding screen, click on the Funding Report Funding Report link. You may search for funding by selected dates. The funding data may be downloaded to an Excel spreadsheet. In addition, the Funding Report can include data for one or more sites, for multiple entries separate sites with commas. See Figure 5: Funding Report.
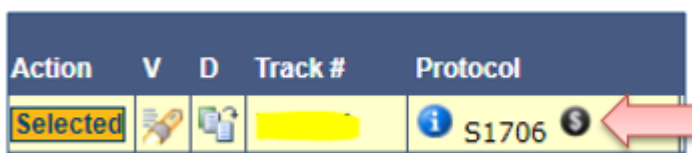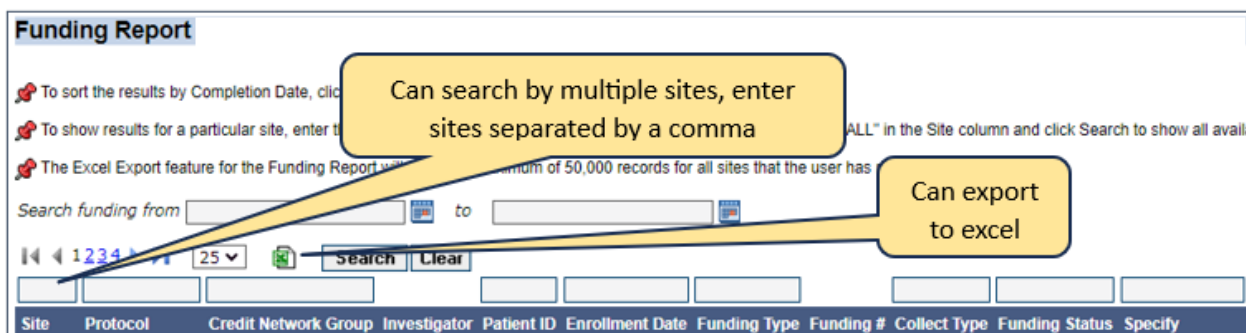

Figure 4: Dollar Icon

Figure 5: Funding Report

3. Oral Agent Funding Table

A separate funding table for the shipment of oral agents is available in OPEN to allow users to add funding lines as needed per patient for those protocols with oral agent funding. This will streamline the process for adding funding entries and reduce the number of entries needed for a protocol.

A funding type is included in the list of funding values in OPEN for 'Shipment of CTEP IND Oral Agent to Patient'. The values for 'Funding Type, specify' are:

- Refrigerated Agent
- Non-Refrigerated Agent

The agent name will be entered in the Specify details field in the Funding Screen within OPEN.

Under the Funding tab in OPEN, two sub tabs will appear when there is oral agent funding, as illustrated in Figure 6 and Figure 7. The subtabs are:

- Standard Funding
- Oral Agent Funding

If there is no oral agent funding for the protocol, then OPEN will only display the 'standard funding' subtab.

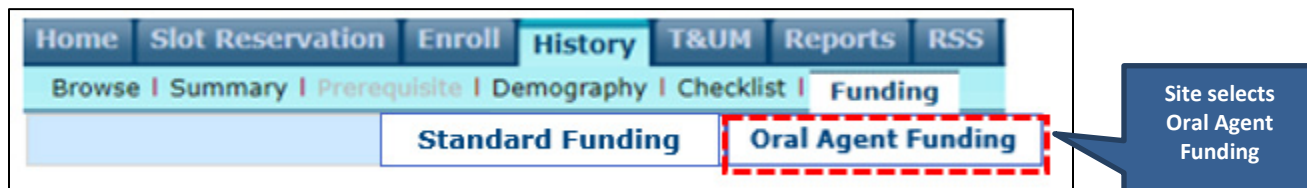Sites will be allowed to add rows for each oral agent funding type as needed, as shown in Figure 8.

Figure 6: Oral Agent Funding Subtab

Figure 7: Oral Agent Funding for New Table

Figure 8: Adding Additional Funding Row

OPEN Funding Reports (which can be accessed by clicking on Reports module and Funding tab) also display oral agent funding information when available.

4. Automatic Population (EA1151)

OPEN has the ability to prepopulate per-case funding data from Rave into OPEN (for protocols that are configured for this feature). The feature will remove the need to duplicate data entry in OPEN and Rave. The per-case funding data fields will be read-only in the Funding subtab for those protocol's enrollments.

Currently, only protocol EA1151 uses the automatic population feature. Sites will not enter funding dates in OPEN for EA1151; the fields will be read-only. Based on the data entered in Rave, the dates will be prepopulated in OPEN once they are verified by the LPO.

Questions should be directed to the CTSU Help Desk at ctsucontact@westat.com.

5. Funding Screen Validations

The OPEN Funding Screen contains the following data validations:

1) Completion dates cannot be prior to the enrollment date.

2) Completion dates cannot be prior to 01-Mar-2014.

3) Completion dates cannot be changed after seven calendar days of initial entry.

4) Completion dates and comments cannot be changed for per-case funding items that have an INACTIVE Funding Status.

5) Completion dates must be entered in OPEN within one year of the completion date of the test or specimen.

Revision History

#	Date	By	Description
1	26-FEB-2014	Lucille Patrichuk	Created initial version.
2	22-APR-2015	Lucille Patrichuk	Added description for Mandatory Event and Mandatory Request, and the Funding Report. Updated the screenshot for the Funding screen.
3	07-DEC-2015	Lucille Patrichuk	Updated the screenshot of the Funding screen to show the new Comments field.
4	12-JUL-2016	Mark Stauffer	Updated the document to include the CTSU styles. Updated the screenshot for the Funding screen to describe the logic for displaying funding items.
5	20-JUL-2017	Mark Stauffer	Upgraded the document to the latest CTSU template. Updated the screenshots to incorporate OPEN 7.8 changes.
6	08-DEC-2017	Thomas Healand, Mark Stauffer	TH 04-DEC-2017: Added the OPEN 8.1 changes (automatic population feature). MS 07-DEC-2017: Reviewed changes. MS 08-DEC-2017: Revised the document.
7	10-APR-2020	Lela Makbul	10-APR-2020: Updated Figure 5 with new screenshot and added details regarding new feature in Funding report. 29-APR-2020: Updated Figure 5 with a newer screenshot per updated Jira requirement. 18-MAY-2020: Addressed feedback provided by AET.
8	20-AUG-2020	Lela Makbul, Mark Stauffer	02-Aug-2020 LM: Added the OPEN 2020.3.0 changes. 04-Aug-2020 MS: Added a validation section. 07-Aug-2020 LM: Updated the validation section. 20-Aug-2020 MS: Reviewed the document.
9	22-FEB-2022	Lucille Patrichuk	Updated screenshots and made minor changes.
10	13-APR-2023	Lela Makbul	Created Section 3 – Oral Agent Funding table.
11	03-APR-2024	Lucille Patrichuk	Updated Sections 1, 2, and 5.