

ETCTN Agent Ordering Information Sheet

1. Introduction

The Cancer Therapy Evaluation Program's (CTEP) Pharmaceutical Management Branch (PMB) handles the pharmaceutical support for clinical trials sponsored by CTEP, including those conducted within the ETCTN. Amongst other tasks, the PMB:

- Provides pharmaceutical information about CTEP Investigational New Drug (IND) agents;
- Manages the registration of study personnel participating in CTEP clinical trials and maintains all registration records. Refer to [PMB Person Registration](#) and [NCI Registration and Credential Repository](#) for additional information;
- Provides access to IND agent Investigator Brochures for NCI-sponsored clinical trials. Refer to [PMB Investigator Brochure](#) for additional information; and
- Authorizes and distributes all CTEP-sponsored IND agents to eligible investigators.

Active CTEP-registered investigators, and investigator-designated shipping designees and ordering designees can submit agent requests through the PMB, CTEP Inventory Management System: [AURORA](#). Access to AURORA requires the establishment and maintenance of an active CTEP Identity and Access Management (IAM) account ([Identity and Access Management](#)) with a linked ID.me account (the latter required immediately for new CTEP-IAM accounts, and by July 1, 2023 for all users) as well an *active* person registration status. For questions about drug orders, transfers, returns, or accountability, call (240) 276-6575 Monday through Friday between 8:30 am and 4:30 pm (ET) or email PMBAfterHours@mail.nih.gov at any time.

For more information on the PMB, visit the [PMB](#) webpage.

2. Use of PMB, CTEP Inventory Management System: AURORA

2.1 Access

Access the PMB, CTEP Inventory Management System [AURORA](#).

The following requirements must be met before ordering agent in AURORA:

- The ordering investigator must be registered with PMB and have an *active* CTEP-IAM account with a linked ID.me account (the latter required immediately for new CTEP-IAM accounts, and by July 1, 2023 for all users) as well as an *active* person registration status; and
- If an *ordering designee* or *shipping designee* (i.e., a non-physician staff member authorized on the investigator's Agent Shipment Form to order and receive agent) is placing an order on behalf of an investigator, they too must have an *active* person registration status, and a CTEP-IAM account with a linked ID.me account (the latter required immediately for new CTEP-IAM accounts, and by July 1, 2023 for all users).

2.2 Submitting a Drug Request

- The ordering investigator must be claimed on an ETCTN grantee [i.e., Lead Academic Organization (LAO)] roster and must have an *active* person registration status.
- The grantee organization (LAO) must be listed as the lead or participating organization on the protocol cover page for the study for which the investigator is ordering agent.
- The participating institution under the lead or participating organization must have an active site registration status.

3. Questions and Support

For questions related to PMB and the AURORA application, please contact PMB.

- PMB Contact Information: (240) 276-6575; pmbafterhours@mail.nih.gov