Canadian Cancer Trials Group

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Guidance for Shipment of Oral Investigational Agents to Participants in Clinical Trials Sponsored by the Canadian Cancer Trials Group

As sponsor, the Canadian Cancer Trials Group (CCTG) is responsible for the oversight of the investigational medicinal product(s) (IMPs) used in its clinical trials.

Effective September 27, 2023 CCTG will permit oral investigational agents stored at ambient temperatures to be shipped from the centre's pharmacy directly to participants as per the parameters outlined below.

Parameters for Direct to Participant Shipment of Oral Investigational Agents	
Regulations	• All applicable regulations (e.g., National, Provincial and Local) must be followed when shipping oral investigational agents to participants
Local SOPs	• Local institutional Standard Operating Procedures (SOPs) must be in place and include procedures to inform the participant of when the agent is shipped, confirming delivery to the participant and maintenance of all records for each shipment.
Which agents	• Oral agents stored at an ambient (15 - 30°C) temperature
When permitted	• Only if circumstances prevent the participant from being seen at the centre and if determined necessary by the investigator that it is in the best interest for continuity of patient care. • It is not a replacement for protocol required in-person study visits and assessments.
Authorization	• Trial specific authorization not required
Quantity	• In accordance with the requirements of the protocol • Not to exceed what is required for the patient until the next protocol-defined in-person study visit.
Confidentiality	• Must be protected during shipment. Outer packing should not include identifiable information such as health card numbers, clinical trial information or medication names.
Dispensation	• Recommended first time dispensing performed in-person • Agent Risk Management Plan (if applicable) is followed • Counselling is documented in the participant's medical file
Documentation	• All shipment records must be retained per applicable regulations (e.g., FDR C.05.12(3)(e)) • Process documented in participant's study record

Please refer to *CCTG Instructions for Shipping Oral Investigational Agents Directly to Participants (Appendix 1)* for detailed instructions on the steps to be taken when shipping oral agents to participants.

While shipment costs will not be routinely reimbursed, please contact CCTG with any questions, as funding may be available for participants where oral shipment can facilitate access to the clinical trial.

For questions concerning Direct to Participant Shipments please contact IMP@ctg.queensu.ca.

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Appendix 1: CCTG Instructions for Shipping Oral Investigational Agents Directly to Participants

1. Any institutional, local, and national guidelines for the shipping of drug must be adhered to.
2. Select and use an appropriately qualified shipping containers based on the storage requirements of the drug. Supportive documents of the shipping container system used should be retained. The shipping container system must maintain the specific storage temperature range, as outlined on the medication's label, for a pre-determined timeframe that covers the transit time from time of packaging and shipment until receipt by the participant.
3. Package IMP in qualified shipping container in such a way to ensure safe and undamaged conditions upon arrival to the participant. If applicable, trial specific patient drug administration diary should be included in the shipment.
4. Create address label for participant. Confirm with the participant that someone will be at the address to receive the protocol therapy.
5. Ensure the Agent's Risk Management Plan (if applicable) is followed, and that counselling is documented in the participant's medical file
6. Use discreet packaging to maintain confidentiality that does not include identifiable information such as health card numbers, clinical trial information, or medication names.
7. Prior to sealing the container and applying the label, perform a secondary check by someone not involved in the packing to confirm the correct amount / kit numbers have been packed and the address label is correct.
8. Use same day or overnight courier and require confirmation of receipt by the participant. Documentation of date and time of shipment, date and time of receipt, and recipient of the shipment kept in the trial site file.
9. The dispensing pharmacy must document on the Drug Accountability Log the amount and kit numbers (if applicable) of drug being sent to participant.
10. Once received, the participant should confirm with the site that the agent is in good condition and received within the qualification period. This should be documented in the participant's medical file or study DAL (if applicable).
11. If the participant does not receive the agent within the defined period a) inform the participant that the received agent cannot be used, b) dispense a replacement shipment, c) recover the impacted agent and 4) document the incident in the participant's medical file and study DAL (if applicable).
12. Retain all shipping records in the trial site file.
13. Instruct participants to return patient diary, if applicable, and unused protocol therapy to the pharmacy at their next on-site visit to ensure safe drug destruction as well as compliance.
14. Document participant returns on the drug accountability log and destroy as per drug destruction processes outlined in the protocol.