

**Guidance: Minimum requirements for shipping frozen muscle biopsies  
for clinical trials**

- The sponsor should provide a kit containing proformas and materials for packaging the biopsy prior to shipment.
- Requests for biopsy shipment should be made from the sponsor to the lead clinical trial co-ordinator responsible for the study who will communicate directly with the laboratory where the samples are stored.
- The trial co-ordinator will be responsible for ensuring all paperwork is collated to meet the sponsor's requirements as outlined in the study protocol. Particular attention should be paid to ensure the current version of the study protocol guidelines are followed as in long running studies these can change.
- The trial co-ordinator should ensure local customs requirements are met and dates for collection or delivery do not clash with a public holiday or weekend unless specific arrangements are made.
- Only use a courier who can guarantee dry ice top up of packages at key points in transit and makes use of 'Temp tales' to record temperature of the biopsy during shipment.
- The courier should supply all packaging for transit of the frozen biopsy and ensure it is labelled appropriately and meets all current UN standards.
- Ensure packages are tracked on a regular basis from collection to delivery.
- Timely communication with the sending and receiving laboratories prior to shipment is essential.