



## Broken Vials No. 007

The TICH-3 drug treatment packs contain glass vials that hold the trial drug. If one or more of these vials break or are found broken upon opening, please follow the guidance below, and for advice please contact the coordinating centre.

In all instances we would ask that you:

- Follow the relevant bullet points marked below in **bold**.
- Update your accountability, inventory and disposal logs accordingly and any other local documentation as required.
- Dispose of all broken vials locally and without delay, following WPD008 (Destruction of IMP) and your local procedures for destruction of pharmaceutical waste

**Broken prior to randomisation** (e.g. upon receipt in pharmacy, or transfer from pharmacy to ward etc.), please inform the Nottingham coordinating centre and dispose of the pack(s) in accordance with WPD008 (Destruction of IMP).

**Broken after randomisation, but before treatment**, please disregard this pack and use the next lowest treatment pack ID that is available at your centre.

**Broken during treatment** (i.e. Bolus given but infusion vial breaks), please continue to administer as much drug as possible and then enter a protocol violation for 'participant does not receive all of the randomised treatment as per protocol'.

The Nottingham coordinating centre will:

- ❖ Apply the data corrections to the randomisation record, if required.
- ❖ Update and mark the broken vials as 'disabled' on the database.