

MEMS[®] TrackCap[™] Worksheet

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	<p>The MEMS[®] TrackCap[™] Worksheet is designed to capture MEMS cap events (opening of the medication vial) that should not be counted toward the number of doses taken by the patient. The first and last use of the cap as well as each medication refill should be recorded on the Worksheet so that these events will not be counted as doses taken.</p> <p>Once a start time is recorded and the cap is dispensed to the patient it should not be opened by clinical center personnel except to switch vials at the time that a refill is provided.</p> <p>The MEMS cap for each study medication should be assigned to the patient at the Baseline visit. Refills of study medications should be completed at Treatment weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, and 44. At this time, the cap should be removed from the empty vial and placed on the new vial.</p>
PATIENT ID	Record the patient's ID number.
CAP SERIAL NUMBER	<p><u>Original</u>: Record the serial number for the MEMS caps assigned to each study medication.</p> <p><u>Replacement</u>: If during the study, a replacement MEMS cap is needed for either ribavirin, interferon, or both, record the serial number for the replacement MEMS cap assigned to each study medication and the date and time of first use. Once a replacement cap has been assigned, do not use the original cap again for this or any other patient in the trial.</p> <p>GENERAL INSTRUCTIONS:</p> <p>At the specified protocol time points, record the date (month/day/year) and military time (hour:minutes) that the MEMS cap was placed on the refill vial of ribavirin and interferon.</p> <p>SPECIFIC INSTRUCTIONS:</p> <p><u>Date entered</u>: This field is to be completed at the time of data entry. Complete the date (month/day/year) that the record is entered.</p> <p><u>CC #1</u>: This line is to be completed, if at any time the <i>Coordinator</i> opens the MEMS cap at a time other than to provide a drug refill. Do not record information for times that the patient opened the cap and did not take the medication.</p> <p><u>CC #2</u>: This line is to be completed, if at any time the <i>Coordinator</i> opens the MEMS cap at a time other than to provide a drug refill. Do not record information for times that the patient opened the cap and did not take the medication.</p>