

Protocol Deviation/Violation Logs

Screening & Recruitment

- Eligibility violations
- Deviations in labs (i.e., randomized someone that had labs out of range)

Study Medications

- Errors in dispensing study drug
- Deviations in following dosing protocol (examples listed below)
 - Not discontinuing medications when protocol/Clinical Care Guidelines indicate this should be done
 - Not following dose reduction strategy as it is written in MM manual

Intervention Delivery

- Deviations in MM or CBI procedures (examples listed below)
 - Not following dose reduction strategy as outlined in the protocol and MM manual
 - Therapy via the phone
 - Uncertified clinicians delivering treatment
 - Clinician/therapist collecting baseline data for patients that they later treat during the study
 - Patient in treatment/on study medications when they should have been discontinued

SAE Reporting

- Events not reported within specified time frame
- Significant errors or incomplete SAE forms