



## Data Monitoring Committee (DMC): Internal Data Compliance Policy

All Northwestern University (NU) investigators that initiate Phase I, II, or III interventional trials monitored by the Lurie Cancer Center DMC, and all investigators who enroll subjects on these trials, must be familiar with and comply with all data submission requirements specified by each individual protocol. This policy applies only to NU interventional investigator-initiated trials (IITs) that fall under the purview of the Lurie Cancer Center Data and Safety Monitoring Plan and have been determined to require high intensity monitoring by the Scientific Review Committee (SRC). This policy does not apply to non-interventional studies, studies that fall under an alternate monitoring system, or studies initiated by other institutions.

The DMC monitors data submission for all NU IITs. DMC data submission timelines are outlined below.

### Phase I Trials, On-Study and Toxicity Data

On-study and toxicity data must be submitted no later than one week after a subject is registered and no later than one week after a subject completes each cycle, respectively. Failure to submit on-study and toxicity data at these time points will result in immediate and automatic suspension of accrual. The PI will be notified of accrual suspension for either of these reasons. If a PI believes that there are extenuating circumstances as to why on-study or toxicity data cannot be submitted within the respective time frames, he or she is responsible for contacting the study's Quality Assurance Monitor (QAM) immediately.

### Phase I, All Other Data and Pilot Trials

Excluding on-study and toxicity data, all other data for phase I trials, and all data for pilot trials must be submitted within 30 days of the due date as defined by the protocol. Failure to submit the required data by the due date will result in suspension of accrual. The PI will not be notified separately of accrual suspension for this reason.

### Phase II & III Trials

Data must be received within 90 days. Data submitted 90 days past the due date (as the due date is defined by the protocol) are considered to be severely delinquent. The DMC may suspend subject accrual for the trial for which data are considered severely delinquent. The DMC will provide the PI with written notification of a suspension and will outline all the requirements the PI must fulfill to reinstate accrual privileges, or follow-up with any additional questions or requests for information.

In addition to the compliance policy detailed above, if local sites use the NU IRB as the IRB of record, they must also follow [the adverse event reporting requirements established by the NU IRB](#).

If accrual privileges have been suspended, they may only be reinstated once all required data is satisfactorily submitted, and DMC members have voted to reinstate accrual privileges for the trial. The DMC will send written notification when accrual privileges have been reinstated.

If the DMC determines that a PI's data is severely delinquent, the committee may also rule that the PI will not be permitted to submit a new trial for SRC approval until all outstanding data has been submitted.

**As the Principal Investigator of [NU Trial Number] at Northwestern University, I acknowledge that I have reviewed and understand the Data Monitoring Committee's Data Compliance Policy.**

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PI Signature

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Date

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PI Name [Printed]