NYU Langone Health | Perlmutter Cancer Center

Clinical Trials Office

Perlmutter Cancer Center Medical Events Form

Please email this medical event form and all relevant attachments (medical history, con med, AE tracker forms and all other applicable documents) to the data manager within **24 hours** of event notification

NYU Trial ID #: _____

Principal Investigator:

_____

Report Updates:

(•) Initial
( ) Follow-up # ____

Begin Amending

Event Type:

☐ Serious Adverse Event
☐ Event of Special Interest
☐ Reportable Event

Trial Type: ☐ Industry-sponsored ☐ Cooperative Group
☐ **IIT – email NYUPCCsafetyreports@nyumc.org within 24 hours of event notification**

Subject Information:			
Initials:	**Subject ID #**	**Sex:** ☐ Female ☐ Male	**Date of Birth:**
Ht: _____ ☐ cms ☐ in. **Wt:** _____ ☐ kgs ☐ lbs	**Date Informed Consent Obtained:**	**ICF Version Date:**	

Seriousness Criteria or Reportable Reason	
☐ Death / Date of Death:	☐ Congenital Anomaly
☐ Life-threatening	☐ Required Intervention
☐ Hospitalization-Initial or Prolonged	☐ Medically Important Condition/Reportable Event
☐ Disability	☐ Other:

Adverse Event Information: ☐ **CTCAE 4.03** ☐ **CTCAE 5.0** ☐ **N/A (Reportable event)**			
Event Description:		Grade:	Date of Event Notification:
Event Start Date:	Event End Date:	☐ Hospitalized at NYULH or Outside hospital:	DM to request records? ☐ Yes ☐ No
Outcome of Event: ☐ Unresolved/Ongoing ☐ Resolved with sequelae ☐ Resolved without sequelae ☐ Fatal			

Study Treatment Information

Drug	Dose	Route of Adminis.	Freq.	Start Date of Treatment	Date of Last Treatment	Relationship^	Action Taken*
						Choose One	Choose One
						Choose One	Choose One
						Choose One	Choose One
						Choose One	Choose One
						Choose One	Choose One
						Choose One	Choose One

Did the event abate when treatment was discontinued? ☐ Yes ☐ No ☐ N/A

Contributing cause if unrelated or unlikely related: _____

Date of reduction/discontinuation: _____ New Dose: _____ Reason for reduced/discontinuation: _____

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Narrative Description of Event:

Narrative continues to next page? ◯ Yes ◯ No

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Continuation of Narrative Description of Event:

Tracked changes to the form:

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Relevant Information: ☐ No relevant information as of this report, await follow-up report		
Assessments ☐ Not Applicable (eg. Labs, scans, procedures):	Date	Results
☐ See attached		

Relevant Medical History ☐ Not Applicable (Pre-existing/ concurrent conditions):	Start Date	Stop Date or Ongoing
☐ See attached		

Medications used to treat event ☐ Not Applicable

Drug	Dose	Route of admin.	Frequency	Start Date	Indication

Concomitant Medication: please attach the subject's study concomitant medication log.

Attach all relevant emails, logs and source documentation for this event.

Is this event ***immediately*** reportable (within 5 days) to the IRB based on the below criteria:

☑ Unexpected; ☑ Related to the research study; ☑ Harmful to the subject (including confidentiality)

☑ Yes ☐ No

If the answer to the above question is "Yes", notify the regulatory specialist.

Principal/Sub-Investigator: _____
Print Name Signature Date

RN/CRC: _____
Print Name Signature Date

Draft email to PCCReports | How to add a signature