

## CTMS : Testing CTEP rules

This page last changed on Sep 11, 2008 by [iyerk](#).

### Study

N027D

### Short title

A Phase I Study of CCI-779 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Rule #	Study Phase	IND holder	severity	Hospitalization	Expected	Attribution	Expected behavior	Result
1,3	Phase I Trial	CTEP IND	Grade 3	yes	No	Definite	5 Calendar Day SAE Report	✓
1,3	Phase I Trial	CTEP IND	Grade 3	yes	No	Definite	24 Hour SAE Notification	✓
2	Phase I Trial	CTEP IND	Grade 3	yes	No	Unlikely	CTEP 10 Calendar Day SAE Report	✓
1	Phase I Trial	CTEP IND	Grade 3	no	No	Definite	24 Hour SAE Notification	✓
1	Phase I Trial	CTEP IND	Grade 3	no	No	Probable	5 Calendar Day SAE Report	Error[CAAERS-754]
3	Phase I Trial	CTEP IND	Grade 3	Yes	no	Possible	5 Calendar Day SAE Report	✓
3	Phase I Trial	CTEP IND	Grade 3	Yes	no	Possible	24 Hour SAE Notification	✓
4	Phase I Trial	CTEP IND	Grade 3	Yes	yes	Possible	CTEP 10 Calendar Day SAE Report	✓
4	Phase I Trial	CTEP IND	Grade 3	Yes	yes	Definite	CTEP 10 Calendar Day SAE Report	✓
5	Phase I Trial	CTEP IND	Grade 4	Yes	YES	Possible	5 Calendar Day SAE Report	✓
5	Phase I Trial	CTEP IND	Grade 4	Yes	YES	Possible	24 Hour SAE Notification	✓
5	Phase I Trial	CTEP IND	Grade 5	Yes	YES	Possible	5 Calendar Day SAE Report	✓
5	Phase I Trial	CTEP IND	Grade 5	Yes	YES	Possible	24 Hour SAE Notification	✓
6	Phase I Trial	CTEP IND	Grade 2	Yes	No	Definite	CTEP 10 Calendar Day SAE Report	Error[CAAERS-756]
6	Phase I Trial	CTEP IND	Grade 2	Yes	No	Possible	CTEP 10 Calendar Day SAE Report	Error[CAAERS-757]

Study  
C80405  
Short title  
A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin

Rule #	Study Phase	IND holder	severity	Hospitalization	Expected	Attribution	Action	Result
7	Phase III Trial	CTEP IND	Grade 2	NA	no	definite	CTEP 10 Calendar Day SAE Report	✓
7	Phase III Trial	CTEP IND	Grade 2	yes	no	Possible	CTEP 10 Calendar Day SAE Report	✓
8	Phase III Trial	CTEP IND	Grade 3	yes	no	unrelated	CTEP 10 Calendar Day SAE Report	✓
8	Phase III Trial	CTEP IND	Grade 3	yes	no	Possible	CTEP 10 Calendar Day SAE Report	✓
9	Phase III Trial	CTEP IND	Grade 3	yes	no	definite	CTEP 10 Calendar Day SAE Report	✓
9	Phase III Trial	CTEP IND	Grade 3	no	no	definite	CTEP 10 Calendar Day SAE Report	Error[CAAERS-758]
10	Phase III Trial	CTEP IND	Grade 3	yes	yes	definite	CTEP 10 Calendar Day SAE Report	✓
10	Phase III Trial	CTEP IND	Grade 3	yes	yes	Unlikely	CTEP 10 Calendar Day SAE Report	✓
11	Phase III Trial	CTEP IND	Grade 4	NA	yes	definite	CTEP 10 Calendar Day SAE Report	Error[CAAERS-759]
11	Phase III Trial	CTEP IND	Grade 5	yes	yes	definite	CTEP 10 Calendar Day SAE Report	✓
12	Phase III Trial	CTEP IND	Grade 4	NA	no	unlikely	CTEP 10 Calendar Day SAE Report	Error[CAAERS-760]
12	Phase III Trial	CTEP IND	Grade 5	no	no	unrelated	CTEP 10 Calendar Day SAE Report	Error[CAAERS-761]
13	Phase III Trial	CTEP IND	Grade 4	NA	no	definite	CTEP 10 Calendar Day SAE Report	Error[CAAERS-762]

13	Phase III Trial	CTEP IND	Grade 5	yes	no	probable	5 Calendar Day SAE Report	✓
13	Phase III Trial	CTEP IND	Grade 5	yes	no	probable	24 Hour SAE Notification	✓