

Study Group 2 Workplan

Document Timetable

Work Item	Reference (SG2)	Current Status – Next steps	Who	Prior ity	Target for Completion Of Work Item
Global Guidance for Adverse Event Reporting (formerly known as Consolidated N21)	N54R6(PD)	Present to SC as PD Ask for shortened comment period	JG	1	2005/Q4 (as PD)
Harmonizing of the content of Field Safety Corrective Notifications	N57R5 (PD)	Present to SC as PD Ask for shortened comment period	JG	2	2005/Q4 (as PD)
NCAR Exchange (consolidation of N9 and N20).	N79R5 (PD)	Present to SC as PD Ask for shortened comment period	JG	2	2005/Q4 (as PD)
Precis	N12R11	Update as per discussions in Gaithersburg Sep 2005	JG/MWB	3	2006/Q2 (final draft)
Status of Implementation of SG2 Documents	N73R6	Update as necessary	LK	3	Ongoing
NCAR Statistics	N76R2	Update periodically –	MS	3	Ongoing - R3 to be sent out Jan 2006
Overview of SG2 guidance (slides)	N80R6	Modified based on Sydney and Milwaukee discussions 06/2005. Completed – Put on website	JG	3	2005/Q4
An XML Schema for the electronic transfer of AE data.....	N87R1	Developed in accordance with discussion in Gaithersburg Sep 2005	TS/LK	3	2006/Q1 (as New Draft)