

Study Group 2 Workplan

Document Timetable

Work Item	Reference (SG2)	Current Status – Next steps	Who	Prior ity	Target for Completion Of Work Item
Application Requirements for Participation in National Competent Authority Report Exchange	N38R14 (PD)	Awaiting comments – comment period closes October 7	KD/JG	1	2005/Q1 (as Final)
Post-market Surveillance	N47R4 (WD)	Send to SC: consider as final and publish on website	PA/JG/KD	1	2004/Q4 (as final)
Global Guidance for Adverse Event Reporting (formerly known as Consolidated N21)	N54R4.2 (WD)	Revision of sections 1-4 in progress	HI/CW/PA/TS/HS/LK	1	2005/Q3 (as PD)
Harmonizing of the content of Recall and Advisory notices	N57R2 (WD)	Definitions of terms to be developed.	ES/PA	2	2005/Q3 (as PD)
PMS harmonisation chart	N61R3.1	To be updated based on discussion in Canada 09/04	KD	1	2005/Q1
National requirements on to whom adverse event reports must be submitted	N68R2 (WD)	Status document according to SC request. New draft to be created based on discussions.	JG	1	2005/Q1 (as PD)
NCAR Exchange (consolidation of N9 and N20).	N79R0	Received proposal for changes from Japan	TS/SM	2	2005/Q3 (as PD)
Precis	N12R9	Modify text update bullets	SS	3	2005/Q1 (new draft)
Status of Implementation of SG2 Documents	N73R3	Update as necessary	KD/JG	3	Ongoing
Definition and Classification of Recalls	N75	NWI rejected by SG2	N/A	N/A	N/A
NCAR Statistics	N62R2	Update periodically	KD	3	Ongoing
Overview of SG2 guidance (slides)	N80R1	Modify based on discussion in Canada 09/04	JG	3	2005/Q1
Harmonized format for electronic reporting of AEs	N72R1	Proposed NWI under consideration within SG2. Proposal to be refined.	TS/LK	3	2005/Q2 (as Proposed WI)

