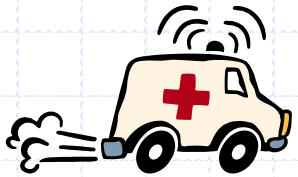
Overview of SG2

SG2 Terms of Reference

- Examine the requirements for the reporting of medical device adverse incidents involving medical devices,
- Recommend ways to harmonize:
  - Reporting requirements of medical device adverse events
  - Post-market surveillance
  - Other forms of vigilance
- Promote dissemination of relevant information

Aim of GHTF SG2

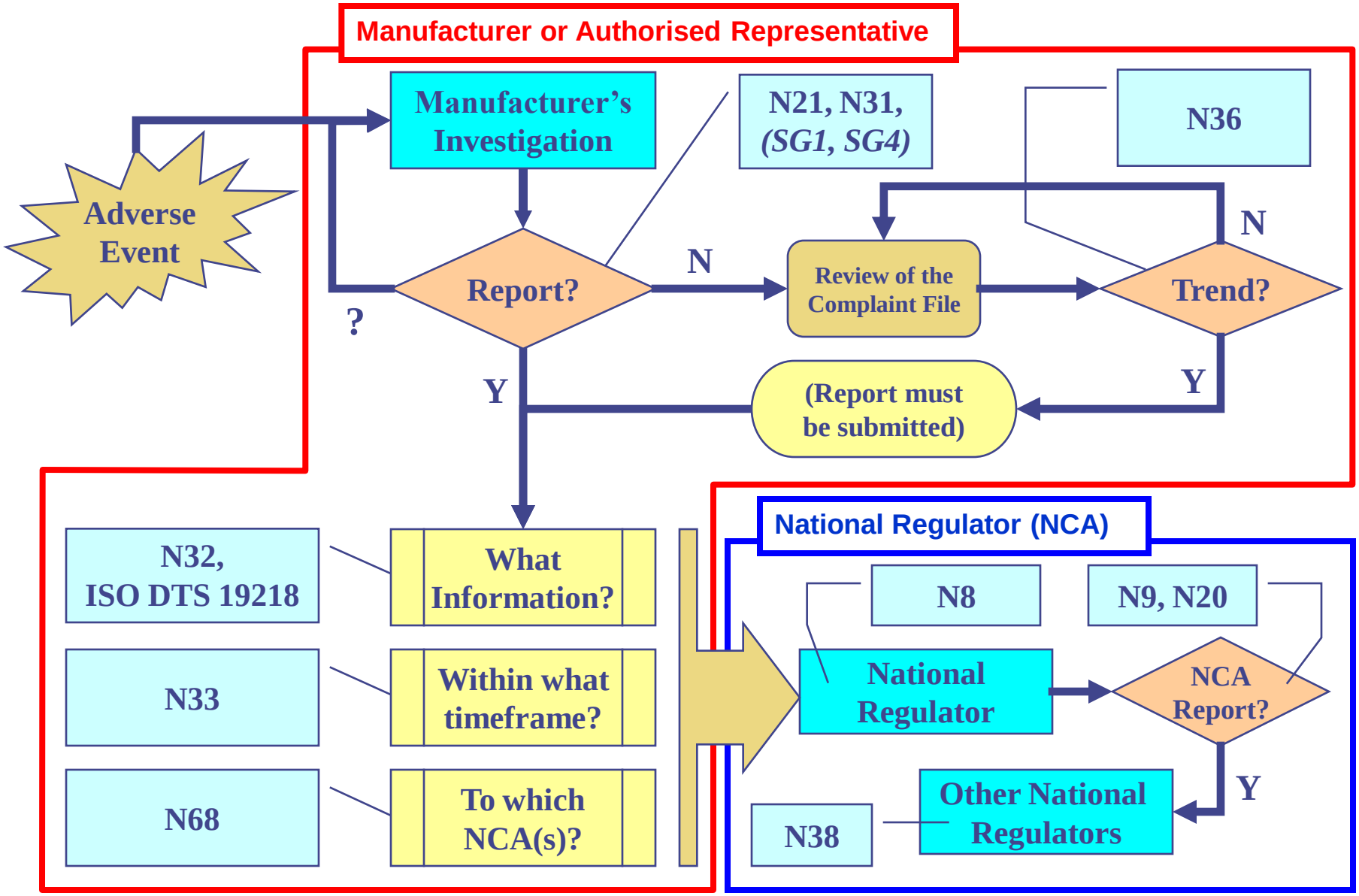
- Improve protection of public health and safety of patients, users and others
- Evaluate reports and disseminate information which may reduce the likelihood of or prevent repetition of adverse events
- Define post market medical device reporting and surveillance requirements and guidelines on an international basis



SG2 Achievements

- Compared participating countries regulatory systems to determine a baseline for harmonization
- Developed guidance for manufacturer reporting of adverse events
- Developed an international system for exchange of high risk reports between competent authorities
- Ten Final Documents on Website

"Map" of SG2 Guidance



SG2 Publications

- **Vigilance (Adverse Event reporting by manufacturers to NCAs)**
  - SG2-N8R4: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
  - SG2-N21R8: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative
  - SG2/N31R8: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative
  - SG2/N32R5: Universal Data Set for Manufacturer Adverse Event Reports
  - SG2-N36R7: Manufacturer's Trend Reporting of Adverse
  - SG2-N33R11: Timing of Adverse Event Reports
  - SG2-N68R3: Who Should Adverse Event Reports be Sent To?

SG2 Publications (cont'd)

- **National Competent Authority Reports (Vigilance Exchange)**
  - SG2-N9R11: Global Medical Device Competent Authority Report
  - SG2-N20R10: National Competent Authority Report Exchange Criteria
  - SG2-N38R14 Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program.
- **Information**
  - SG2-N6R3: Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan
  - SG2-N16R5: SG2 Charge & Mission Statement

Postmarket Surveillance

Summary of documents

- **N 47.R4** Review of Current Requirements on Postmarket Surveillance.
  - Approved SC. To be posted on the website
- **N61R4** PMS harmonization chart
  - Presented as a report to SC. Other SG's to consider
- **N57R4**. Harmonizing of the Recall and Advisory notices.
  - Definition of terms. target date is 2005/Q3 as a PD

Harmonisation Chart (N.61)

Post Market Surveillance Activity	Short Description	Harmonisation Useful?	In what areas?	Recommendation on how to progress
Laboratory Testing	Testing of product for compliance with standards	no		Sharing of corrective action taken covered by NCAR (SG2-N20). Standards against which tests are done developed by ISO
Market Surveys on Information	Market Surveys of Technical and clinical documentation	no		Results of surveys may be shared using NCARs.
Audits of Manufacturer Facilities	Inspect manufacturer processes and procedures for production and complaints handling	yes	auditing reports and techniques	addressed by SG4
Technical File Reviews	Review of Clinical and Technical Information for a specific product	no		Standards for technical files are addressed by SG1. Result of review may be shared using an NCAR
Review of Product Claims/Labeling	Labeling includes labels, IFU, promotional materials, websites	no		

GHTF

Post Market Surveillance Activity	Short Description	Harmonisation Useful?	In what areas?	Recommendation on how to progress
Condition of Approval Studies, PMS Studies, re-evaluation re-examination schemes	Review of product - associated clinical trials	yes	Common format for submitting report	Could be addressed by SG5
Recalls	Order, Monitor, and Classify product recalls, and disseminate written communications to appropriate recipients	yes	what to report in a recall, information given to affected users	N57 will address this.
Enforcement	Prohibit distribution of violative products via regulatory processes such as injunction, product seizure, import detention, etc.	no		Enforcement per se does not need to be harmonised. Safety related measures taken are addressed shared by NCAR.
Vigilance/AE Monitoring	Evaluate and investigate reported device problems and complaints	yes		Addressed by SG2-N54
Public Access to Information	Provide public access to information taken and reported to the Agency	no		Related to legislation normally out of control of NCAs
Standards Activities	Participate in global and international programs towards standardization and harmonization	no		Other groups are responsible.
Other Post-Market feedback	Information on device performance in post-market phase.	yes	What is the minimum requirement for a "systematic review of experience gained …" (ISO 13485)	This is related to QS. Could be addressed by SG3

Conclusion

The SG2 review of areas of post-market surveillance where there is a potential value in harmonization resulted in the identification of a number of areas where harmonization is recommended

However there is only one area where SG2 feels it is within their mandate to pursue harmonization. That is in the category of recalls including what to report in a recall and what information should be given to users

This topic is currently being developed based on an approved work item by the GHTF Steering Committee and is covered by document SG2-N57 target date is 2005/Q3 as a PD

SG2 Workplan

Workplan

Work Item	Reference (SG2)	Current Status – Next steps	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	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	2005/Q4 (as PD)
NCAR Exchange (consolidation of N9 and N20).	N79R5 (PD)	Present to SC as PD Ask for shortened comment period	2005/Q4 (as PD)
Precis	N12R11	Update as per discussions in Gaithersburg Sep 2005	2006/Q2 (final draft)
Status of Implementation of SG2 Documents	N73R6	Update as necessary	Ongoing
NCAR Statistics	N76R2	Update periodically –	Ongoing -R3 to be sent out Jan 2006
An XML Schema for the electronic transfer of AE data…..	N87R1	Developed in accordance with discussion in Gaithersburg Sep 2005	2006/Q1 (as New Draft)