



GHTE

**Study Group 2
Post-market Surveillance**

Status Report – October 2007

Dr Jorge Garcia
Therapeutic Goods Administration
Chairman, GHTE SG2

Overview of this Report

- ◆ our role ...
- ◆ membership...
- ◆ what we've done so far...
- ◆ what we plan to do in the near future...
- ◆ reflections on harmonisation...



Our Role: Terms of Reference...

- ◆ To examine the requirements for post-market surveillance and for the reporting of adverse incidents involving medical devices on an international basis and to recommend ways of harmonizing those requirements.
- ◆ To provide a forum for discussion on global harmonization of adverse event reporting and post-market surveillance, and
- ◆ To promote the dissemination of relevant information related to medical device post-market surveillance



Our Role: Vision...

A globally harmonized medical device adverse event reporting and pos-market surveillance process that provides the highest level of protection of the health and safety of patients, users and others.



Membership...

Regulatory Agencies

USA/Canada

- ◆ **Brady, Mary**, [FDA]
- ◆ **Segstro, Mark**, [Health Canada]

Europe

- ◆ **Demade, Isabelle**, [EC]
- ◆ **Antunes, Miguel**, [INFARMED]
- ◆ **Stösslein, Ekkehard**, [BfArM]

Japan/Australia

- ◆ **Eno, Hideo**, [MHLW]
- ◆ **Ishii, Kensuke**, [PMDA]
- ◆ **Garcia, Jorge**, [TGA]

Industry Associations

USA/Canada

- ◆ **Khosravi, Ben**, [AdvaMed]
- ◆ **Kroger, Larry**, [MITA/NEMA]
- ◆ **Stitz, Klaus**, [MEDEC]

Europe

- ◆ **Auclair, Philippe**, [EUCOMED]
- ◆ **Wallroth, Carl**, [EUROM VI]

Japan Australia

- ◆ **Ishikawa, Hiroshi**, [JFMDA]
- ◆ **Arima, Takehiko**, [JFMDA]
- ◆





Post-market Surveillance

- ◆ "The **pro-active** collection of information on quality, safety or performance of Medical Devices after they have been placed in the market" –
Reference : GHTF SG2 N47R4
- ◆ A balanced Post-Market Surveillance system will contain an appropriate mix of proactive and reactive activities.

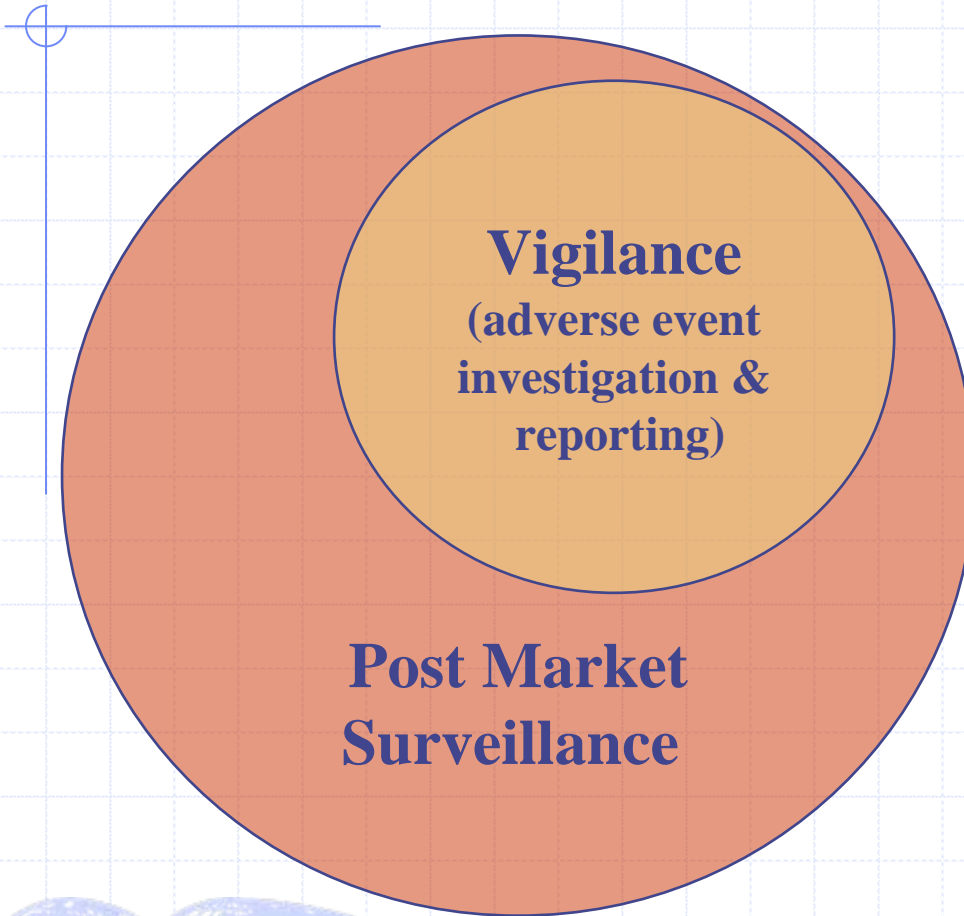


Post-market Vigilance

- ◆ (Broadly speaking) Vigilance is the reporting and investigation of adverse events and incidents. Both the manufacturer and the Regulatory Authority play major roles.
- ◆ SG2 now prefers to use the term “Adverse Event Reporting”



Post-market Surveillance



Post-Market Surveillance
Information is used for:
Injury prevention
Development of standards
Regulatory refinement
Product improvement



The logo for GHTE (Global Health Threats Education) features the acronym 'GHTE' in a bold, blue, serif font. The letters are superimposed on two overlapping, light blue wireframe globes. The background of the slide is a light blue grid with a thin blue line and a small circle in the upper left corner.

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What we've done so far...

Adverse Event Reporting (AER)

SG2 Publications on AER

◆ 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?



GHTF SG2 N54R8

SG2 Publications on AER (2)

GHTF SG2 N79R8

◆ 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



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What we've done so far...

Post-Market Surveillance

Post-market Surveillance: Activities

Reference: GHTF SG2 N61R4

Condition of Approval Studies

Review of product - associated clinical trials

Market Surveys

Market Surveys of Technical and clinical documentation

Enforcement

Prohibit distribution via regulatory processes such as injunction, product seizure, import detention, etc.

Technical File Reviews

Review of Clinical and Technical Information for a specific product

Recalls

Order, Monitor, and Classify product recalls, and disseminate written communications to appropriate recipients

Laboratory Testing

Testing of product for compliance with standards

Public Access to Information

Provide public access to information taken and reported to the Agency

Vigilance

Evaluate and investigate reported device problems and complaints

Audits on Manufacturer

Inspect manufacturer processes and procedures for production and complaints handling

Review of Product Claims/Labeling

Labelling includes labels, IFU, promotional material, websites

Standards Activities

Participate in global and international programs towards standardization and harmonization

Other Post Market Feedback

Information on device performance in post-market phase (...ISO 13485)



Summary of PMS Documents

- ◆ GHTF SG2 N47R5 Review of Current Requirements on Postmarket Surveillance.
- ◆ GHTF SG2 N61R5 PMS Harmonization Chart
- ◆ GHTF SG2 N57R8 Harmonising the Content of Field Safety Notices.





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What we're planning to do...

Work Plan

Work Item	Reference (SG2)	Current Status – Next steps	Target for Completion Of Work Item
Update NCAR documents	N79R8, N38R14	Changes to statements about expectations in relation to confidentiality of reports	2008/Q1
Precis	N12R11	Document to become a report on achievements of SG2	2007/Q4 (final draft)
Status of Implementation of SG2 Documents	N73R8	Update as necessary	Ongoing
NCAR Statistics	N76R5	Update periodically	Ongoing
Overview of SG2 guidance	N80R7	Update as necessary	2007/Q4
An XML Schema for the electronic transfer of AE data	N87R7	Pilot program – and consider comments received on PD	2008/Q2 (as Final)
Electronic reporting pilot program protocol	N100R1	Develop e-forms, enroll participants, amend N100	2007/Q3 as next draft



Monitoring & Improvement Phase:

◆ Maintenance of NCAR

- Development and maintenance of training materials - Handling of new applications for membership/Training - Review of performance

◆ Monitoring of the performance of SG2 Guidance

- Report on the implementation - Review and update documents

◆ Improvement of reporting and exchange mechanisms

- Electronic reporting - Passive database

◆ Take on new work items as identified by developments in products and regulations.

- IVDs - combination products - software devices – nanotechnology - Public access to information

◆ Training on SG2 Guidance





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Reflections on harmonisation...

Implementation of SG2 Documents

- ◆ SG2's key documents are:
 - N8, N38, N54, N57, N79
- ◆ N38 does not require "implementation"
- ◆ N8, N57 and N79 have been fully implemented by all founding members.
- ◆ That leaves GHTF-SG2-N54R8: SG2's "keystone" document.



GHTF SG2 N54R8 Section		AU	CA	EU	JP	US
3.0	Definition of reportable event					
4.1	Deficiency of a New Device Found by the User Prior to its Use					
4.2	Adverse Event Caused by Patient Conditions					
4.3	Service Life of the Medical Device					
4.4	Protection Against a Fault Functioned Correctly					
4.5	Remote Likelihood of Occurrence of Death or Serious Injury					
4.6	Expected and Foreseeable Side Effects					
4.7	Adverse Events Described in an Advisory Notice					
4.8	Reporting Exemptions Granted by NCA					
5.0	Use Error					
6.0	To Whom to Report					
7.0	Timing for Adverse Event Reports					
8.0	Universal Dataset					
Legend:		Lt Green Implemented		Lt Yellow Partly Implemented		Orange Not Implemented

Impediments for Implementation

- ◆ Impetus
- ◆ Culture
- ◆ Language
- ◆ Resources
- ◆ Politics
- ◆ Fundamental disagreement



