

GHTF Study Group 2

- **Medical Device Adverse Events: What Information, by When and to Whom to Report**
&
• **The Vigilance Exchange Program**

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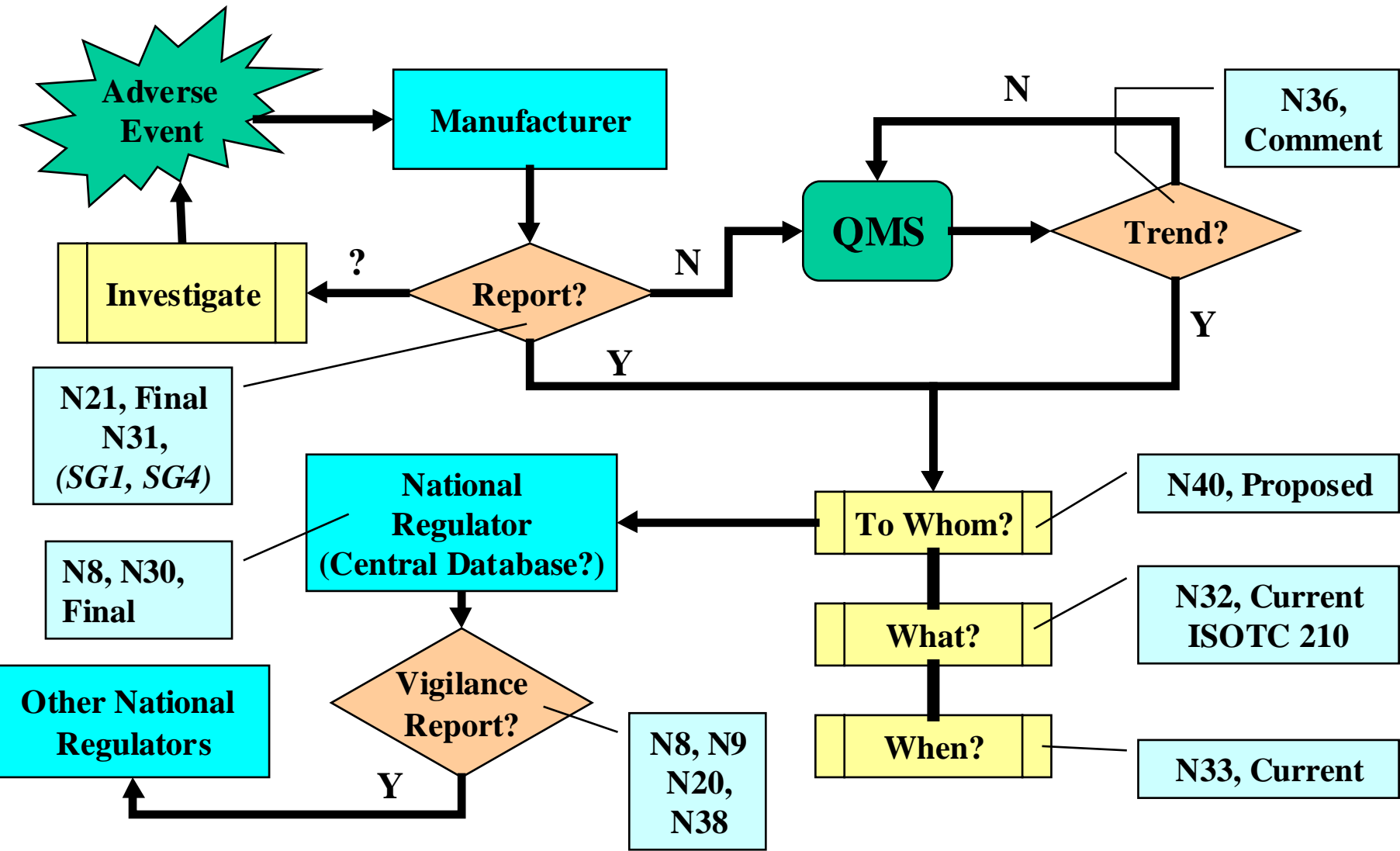
Member, SG2 (representing TGA, Australia)



Presentation Topics

- What Information to Report : SG2 documents N7 (Final) and N32 (Final Draft).
- By When to Report: Progress on SG2 Document N33 (Final Draft).
- To Whom to Report: Progress on SG2 Document N40 R2 (Committee Draft).
- Vigilance Exchange - Criteria, Philosophy, Processes and Experience.





N32 R3.2: Universal Report Format (Final, for comment)

- Early on, SG2 developed a minimum data set document - SG2 N7. This document represents the bare minimum amount of information required by GHTF Competent Authorities about Medical Device Adverse Events.
 - Discussion of SG2 N7 led to the development of SG2 N32 R3.2: Universal Manufacturer Report Format. This document provides guidance on what information must be submitted in an AE report.
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N32 R3.2: Universal Report Format

- General considerations:
 - Date formats (DD MMM YYYY), age and timeframes to specify units, electronic addresses preferred, each field must be completed, information identifying the Health Care Facility or the User is considered optional in certain NCA systems - Privacy Statement.
- Administrative Information
 - Report Control Number(s), Report Type, Date Report, Date of the Event, Type of Event, Mfr. Awareness Date, Date of next report (if applicable), Reporter Contact details, identity of other NCA's contacted..



N32 R3.2: Universal Report Format (2)

- Clinical Event Information
 - Event description narrative, number of patients involved, number of devices involved.
- HealthCare Facility Information
 - Event facility name, contact details and contact person.
- Device Information (as many times as required)
 - Mfr. Name & Contact, User Type, Usage of Device (single use?), Device Code & type (eg GMDNS), Brand Name, Model #, Catalogue #, Device identifiers (serial #, batch #, software version #, etc.), Device Disposition



N32 R3.2: Universal Report Format (3)

- Device approval information
 - Regulatory/Competent Authority, Notified Body or other, NB ID number, Document approval number.
- Results of Manufacturer's Investigation
 - Manufacturers device analysis results, Remedial action/corrective action/preventive action. Similar events? (Y/ N). Comments. Disclaimer
- Patient Information
 - Age, gender, weight, corrective action taken, patient outcome.



N33 R10: Timing of AE Reports (Final, for comment)

- Each medical device manufacturer or its authorised representative should submit reports of adverse events as soon as possible after becoming aware of that reportable event has occurred, but in no case after more than 30 calendar days have elapsed
- A much shorter time frame (2-10 days) is suggested for the reporting unanticipated deaths or issues where there is “considerable public health risk or concern, where there may be a need for prompt remedial action”.



N40 R2: “To Whom to Report” (Committee Draft)

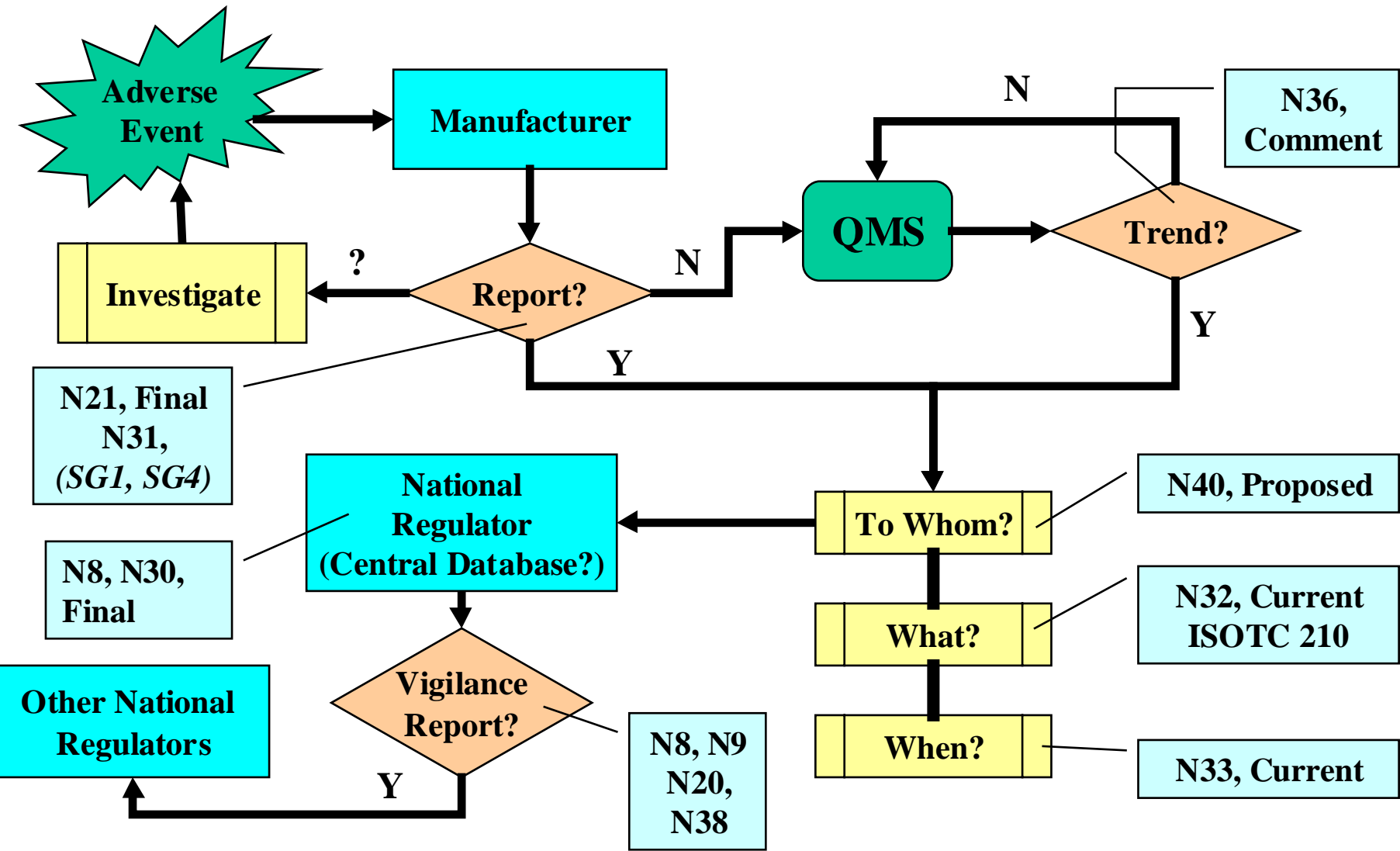
- **Present thinking**: That a database should be commissioned for manufacturers to submit AE reports from all countries (GHTF lead?).
 - NCA’s would direct manufacturers or their authorised representatives to submit N21 reportable events as stipulated by N32 and N30 directly into this database.
 - NCA’s subscribing to this database would be able to access adverse event reports that occurred within all jurisdictions - A “global” database of reportable events.
 - The burden of reporting, and of receiving reports would be minimised.
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N40 R2: “To Whom to Report” (2)

- Until the the database is commissioned, manufacturers or their authorised representatives should only be required to report an AE to the NCA of the country in which the AE occurred†.
 - †For implants, where implantation took place
 - (not presently the case in all jurisdictions) - Minimises reporting burden and replication of effort.
 - Regardless of the existence of the database, corrective actions should be reported directly to all NCAs of nations where the product is distributed.
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N9R11 & N20R10: NCA Reports

- Also known as Vigilance Exchange
- Information is exchanged actively. Notion of “passive exchange” not yet in operation.
- GHTF SG2 N9R11 is filled in and sent to Vigilance Secretariat (VS, currently Canada). VS catalogs the item and sends on to participating NCAs.



NCA Reporting - (2)

- If the investigation is complete, the decision to exchange information is made with regards to the following considerations:
 - Seriousness
 - Unexpectedness
 - High Frequency (Preventability)
(can useful recommendations be made?)
 - Public Concern/Outrage
 - Benefit/Risk
 - State of the art? Alternatives?
 - Population Vulnerable
(pediatric/elderly)
 - Lack of Scientific Data
(especially long term effects)
 - Class I recall or equivalent, or written notifications by the NCA to the public (hospitals, physicians, etc.)
 - Repeated problems
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NCA Reporting - (3)

- If the investigation is not complete but a decision has been made to take action or action is likely, the public health threat or concern must be assessed and if high, a report should be sent.
- If the investigation is complete and no action is required, then the report should not be exchanged.
- In each case, the manufacturer must be consulted.



NCA Reporting: +/-

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- NCA's get advanced and "inside information" of major issues.
- Benefit of knowing the reasoning about other NCA's actions on major issues - better decisions.
- Closer collaboration between NCA's

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- NCA's and Manufacturers concerned about release of confidential information.
- Manufacturers concerned about the possibility of "overreaction" by large numbers of NCAs
- **New member NCA's should make certain commitments and submit to training (N38 - Draft).**

