Overview of GHTF SG2 and NCAR

Dr Jorge Garcia –Therapeutic Goods Administration- Chairman GHTF SG2
Dr Philippe Auclair - Abbott Vascular– EUCOMED

Overview of this presentation

- what is post-market surveillance?
- membership…
- what we've done so far…
  - adverse event reporting
  - other postmarket surveillance
  - NCAR
- what we plan to do in the future…

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 (Adverse Event Reporting)

- (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

What we've done so far…

Adverse Event Reporting (AER)

SG2 Guidance
Adverse Event Reporting by Manufacturers

- 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 Guidance

Report Handling & NCAR Program

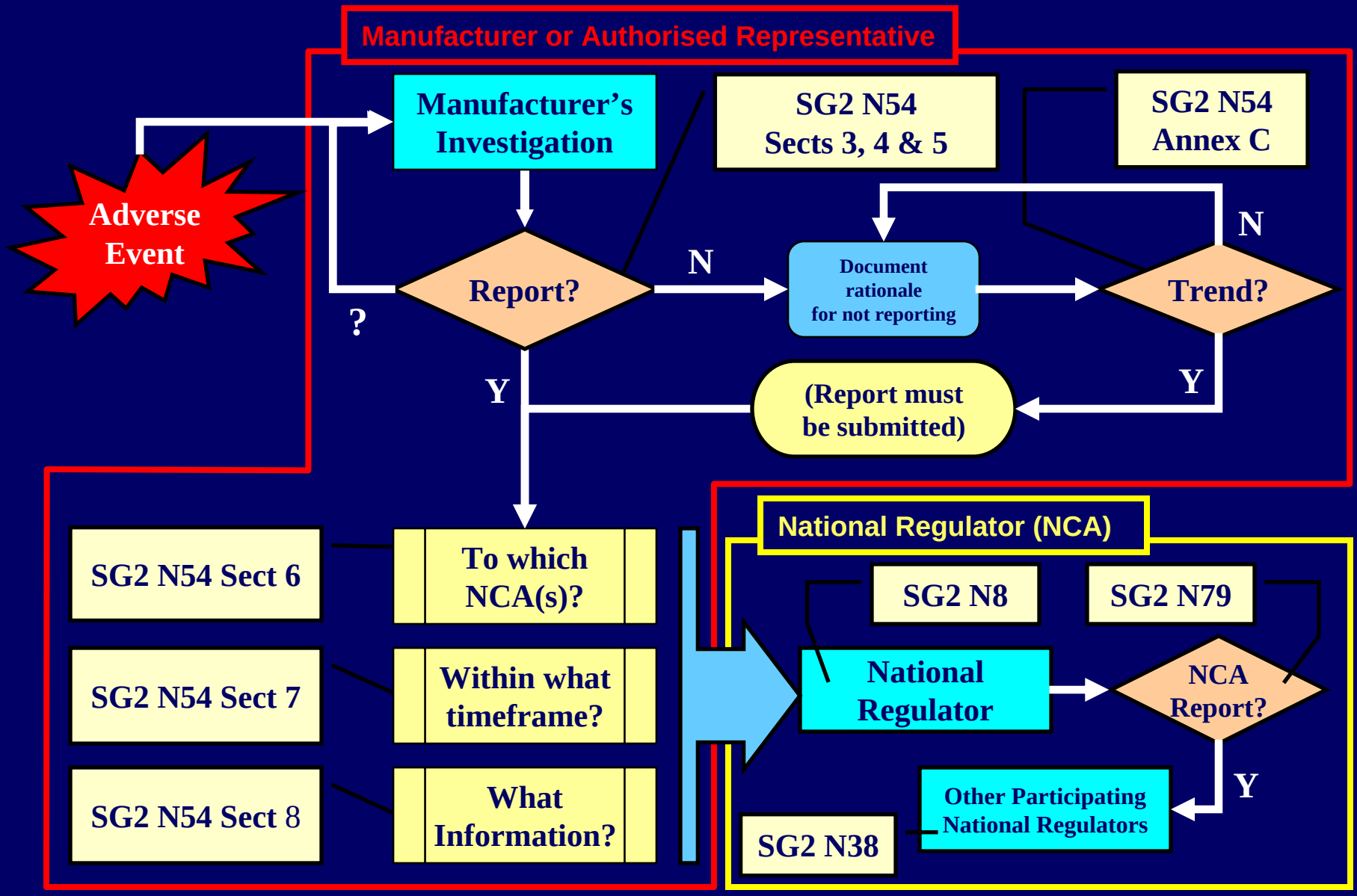
- SG2-N8R4: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
- SG2-N9R11: Global Medical Device Competent Authority Report
- SG2-N20R10: National Competent Authority Report Exchange Criteria
- SG2-N38R14 Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program.

GHTF SG2 N79R8

SG2 Guidance
Other documents & guidance

- SG2-N6R3: Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan
- SG2-N16R5: SG2 Charge & Mission Statement
- SG2-N12R4: Précis
- SG2-N47R4: Review of Current Requirements Regarding Post-market Surveillance
- SG2-N57R8: Content of Field Safety Notice
- SG2-N61R6: PMS Harmonisation Chart

Map of SG2 Guidance on AE Reporting



GHTF SG2 N54 :

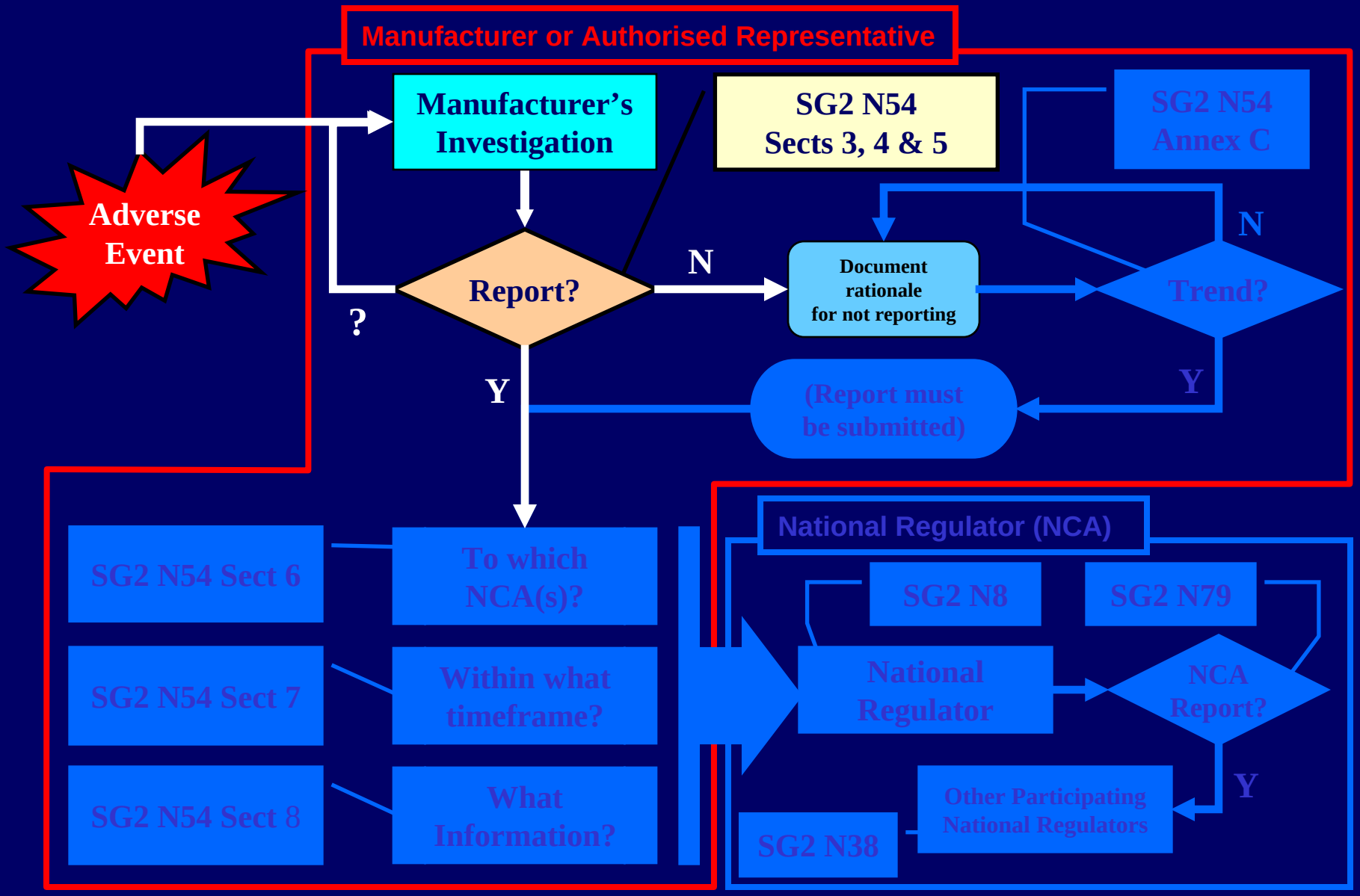
Table of Contents

- Section 1 Scope
- Section 2 Definitions
- Section 3 Adverse Event Reporting Guidance
- Section 4 Exemptions
- Section 5 Use error
- Section 6 To Whom to Report
- Section 7 Reporting Timeframes
- Section 8 Report Data Set

Annexes :

- A. Universal data set
- B. Timing of AE report
- C. Trends
- D. Use error

Reporting Criteria and Exemptions



GHTF N54 Section 3.0
Three Basic Reporting Criteria

- An EVENT must have occurred

AND

- The manufacturers device was ASSOCIATED with the event

AND

- The event led to the death or SERIOUS INJURY of a patient user or other person, OR might lead to death or serious injury if the event re-occurs

GHTF N54 Section 4.1- 4.8
Exemption Rules

Whenever any one of the following exemption rules is met, the adverse event does not need to be reported to a NCA by the manufacturer

Exemption Rules

1) Deficiency of a new device found by the user prior to its use
2) Adverse event caused by patient conditions
3) Service life or shelf life of the medical device
4) Malfunction protection operated correctly
5) Negligible likelihood of occurrence of death or serious injury
6) Expected and foreseeable side effects
7) Adverse events described in an advisory notice
8) Reporting exemptions granted by NCA

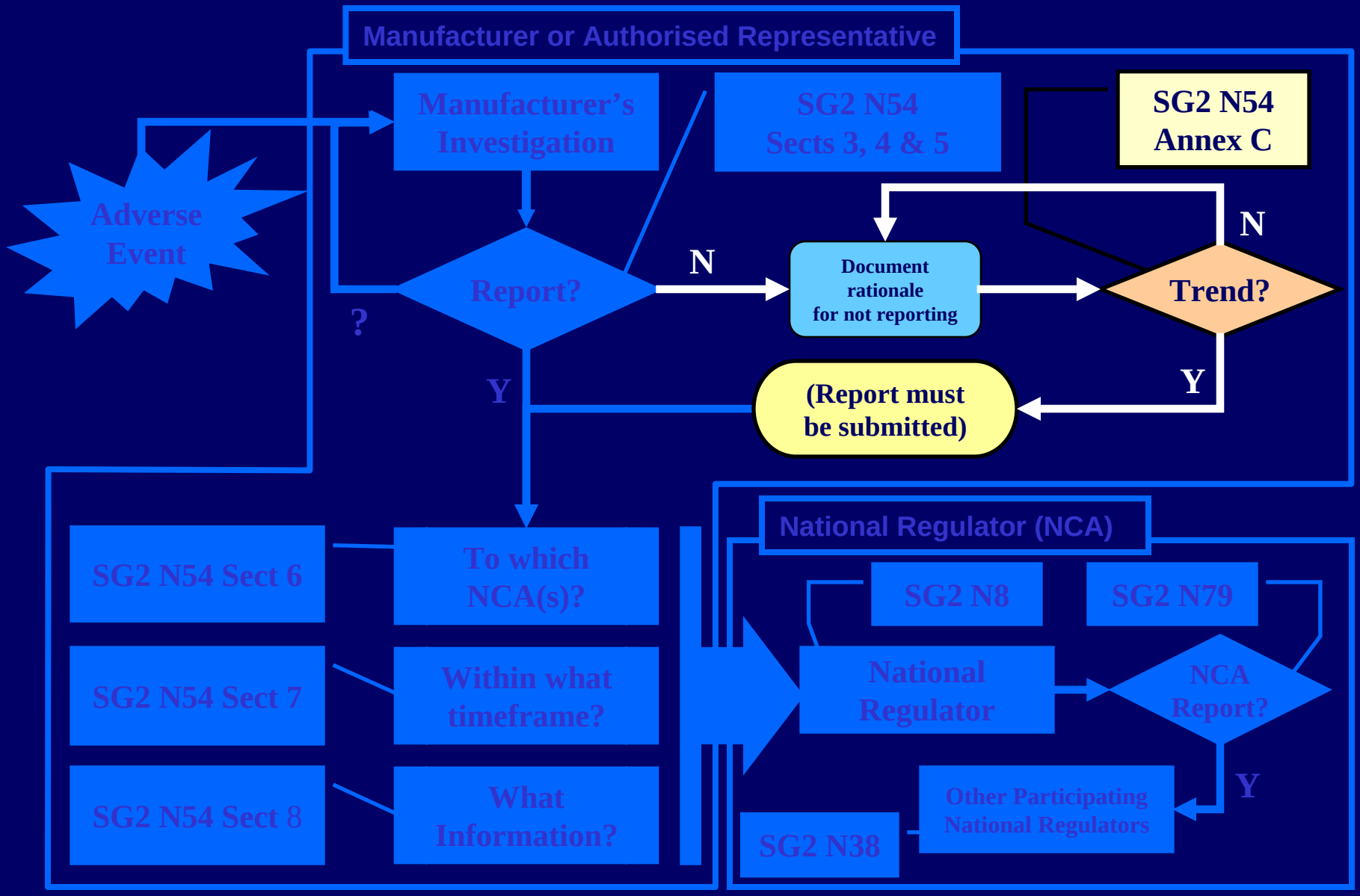
GHTF N54 Section 4
Other considerations

- If a NCA requires reporting a specific type of event due to a significant public health concern, the exemptions are no longer applicable
- Adverse events which are subject to an exemption become reportable to the NCA if a change in trend (usually an increase in frequency) or pattern is identified

Reporting of Use Errors and Abnormal Use

R=Report
NR*= No Report*

Trends

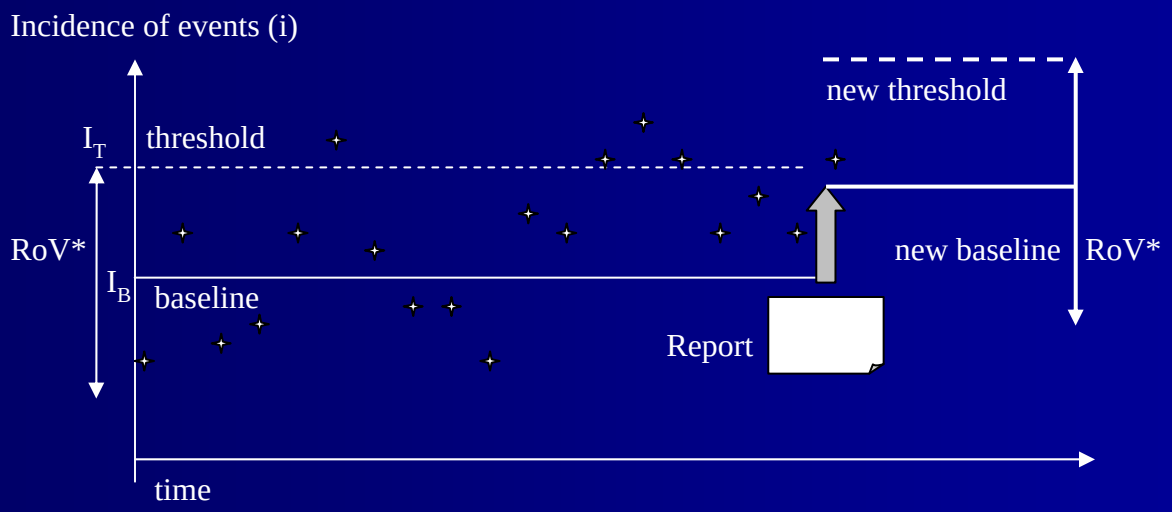

Manufacturer or Authorised Representative
Manufacturer's Investigation
SG2 N54 Sects 3, 4 & 5
SG2 N54 Annex C
Adverse Event
Report?
N
Document rationale for not reporting
Trend?
N
Y
(Report must be submitted)
?
Y
SG2 N54 Sect 6
To which NCA(s)?
SG2 N54 Sect 7
Within what timeframe?
SG2 N54 Sect 8
What Information?
National Regulator (NCA)
SG2 N8
SG2 N79
National Regulator
NCA Report?
Y
Other Participating National Regulators
SG2 N38

AE Trend Reporting

- Adverse events specifically exempted from reporting become reportable if there is a change in trend (usually an increase in frequency) or pattern is identified
- The SG2 document on trend reporting describes the criteria for identifying a significant increase in the rate of adverse events
- Not a handbook of statistical techniques
- Provides guidance to assist manufacturers to perform trending

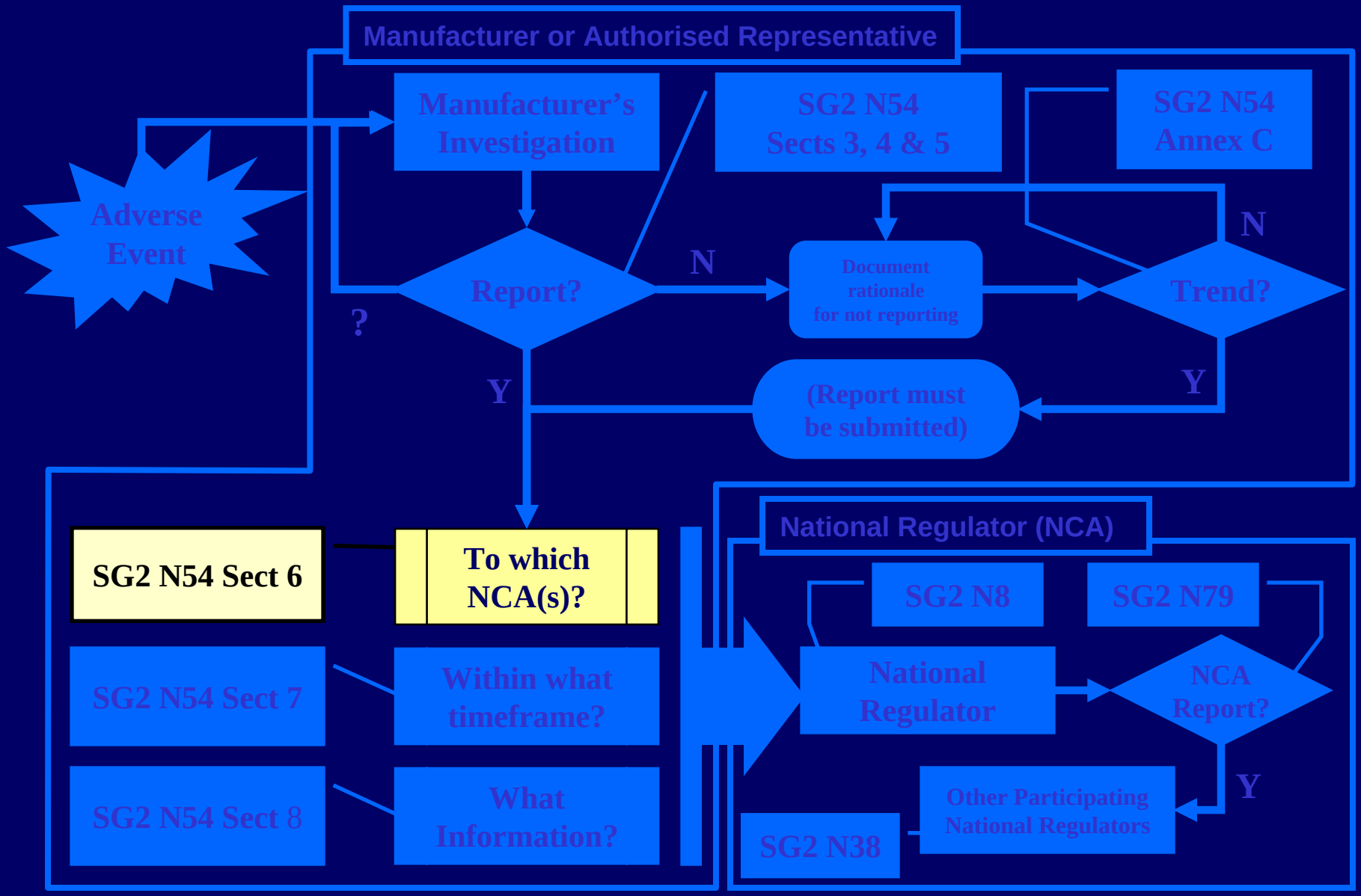
AE Trend Reporting

- Example of an upward shift in trend



* normal Range of Variance

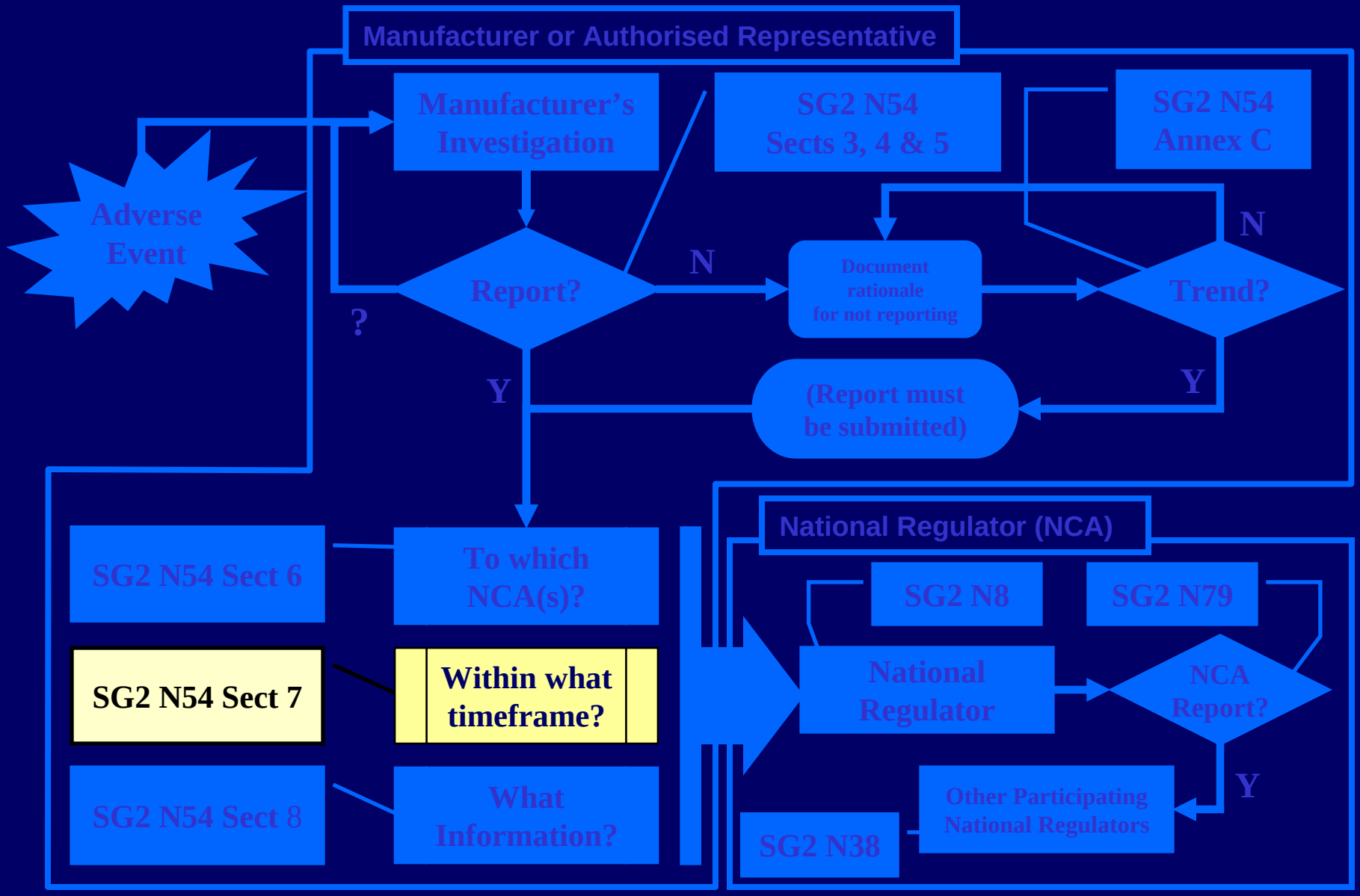
To Which NCAs to Report?



GHTF N54 Section 6
To Whom to Report

- Adverse Events must be reported to a National Competent Authority (NCA) according to applicable requirements in each jurisdiction. NCAs should provide a contact point to manufacturer from reporting
- SG2 considered several options that might resolve this situation, including the establishment of a global database for submission of adverse event reports

Within What Timeframe?



GHTF N54 Section 7 & Annex B
Reporting Timeframes

- Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported immediately by the manufacturer
- All other reportable events must be reported as soon as possible by the manufacturer, but not later than 30-elapsed calendar days following the date of awareness of the event

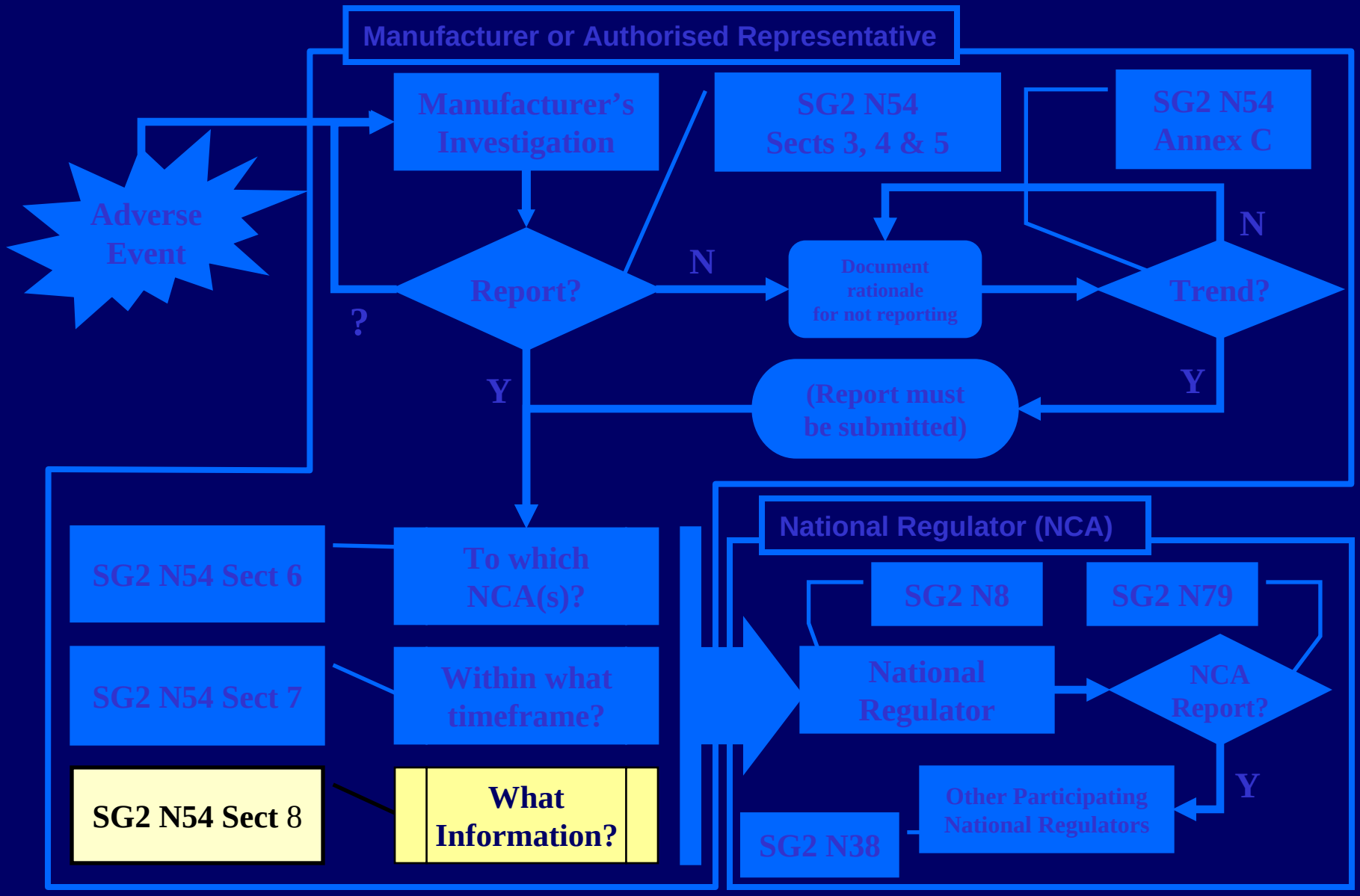
Reporting Timeframes

- Immediately: For purposes of adverse event reporting, immediately means as soon as possible, but not later than 10 elapsed calendar days following the date of awareness of the event
- Serious public heath threat: Any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action

Reporting Timeframes

- Unanticipated: A death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level

What Information (Dataset)?



Report Data Set

- Event information: Dates, Reporter details, Healthcare facility details, Patient details, Event type and description, Notified CA's, Resolution description
- Device Information: Manufacturer, Generic device group, Disposition, Results of analysis, Corrective action taken.
- Other: Comments, Notified Body details, CAs notified of Corrective action

What we've done so far…

Post-Market Surveillance

Post-market Surveillance Activities

Reference: GHTF SG2 N61R4

Market Surveys

Market Surveys of Technical and clinical documentation

Public Access to Information

Provide public access to information taken and reported to the Agency

Vigilance

Evaluate and investigate reported device problems and complaints

Recalls

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

Enforcement

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

Laboratory Testing

Testing of product for compliance with standards

Review of Product Claims / Labelling

Labelling includes labels, IFU, promotional material, websites

Technical File Reviews

Review of Clinical and Technical Information for a specific product

Condition of Approval Studies

Review of product - associated clinical trials

Standards Activities

Participate in global and international programs towards standardization and harmonization

Audits on Manufacturer

Inspect manufacturer processes and procedures for production and complaints handling

Other Post Market Feedback

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

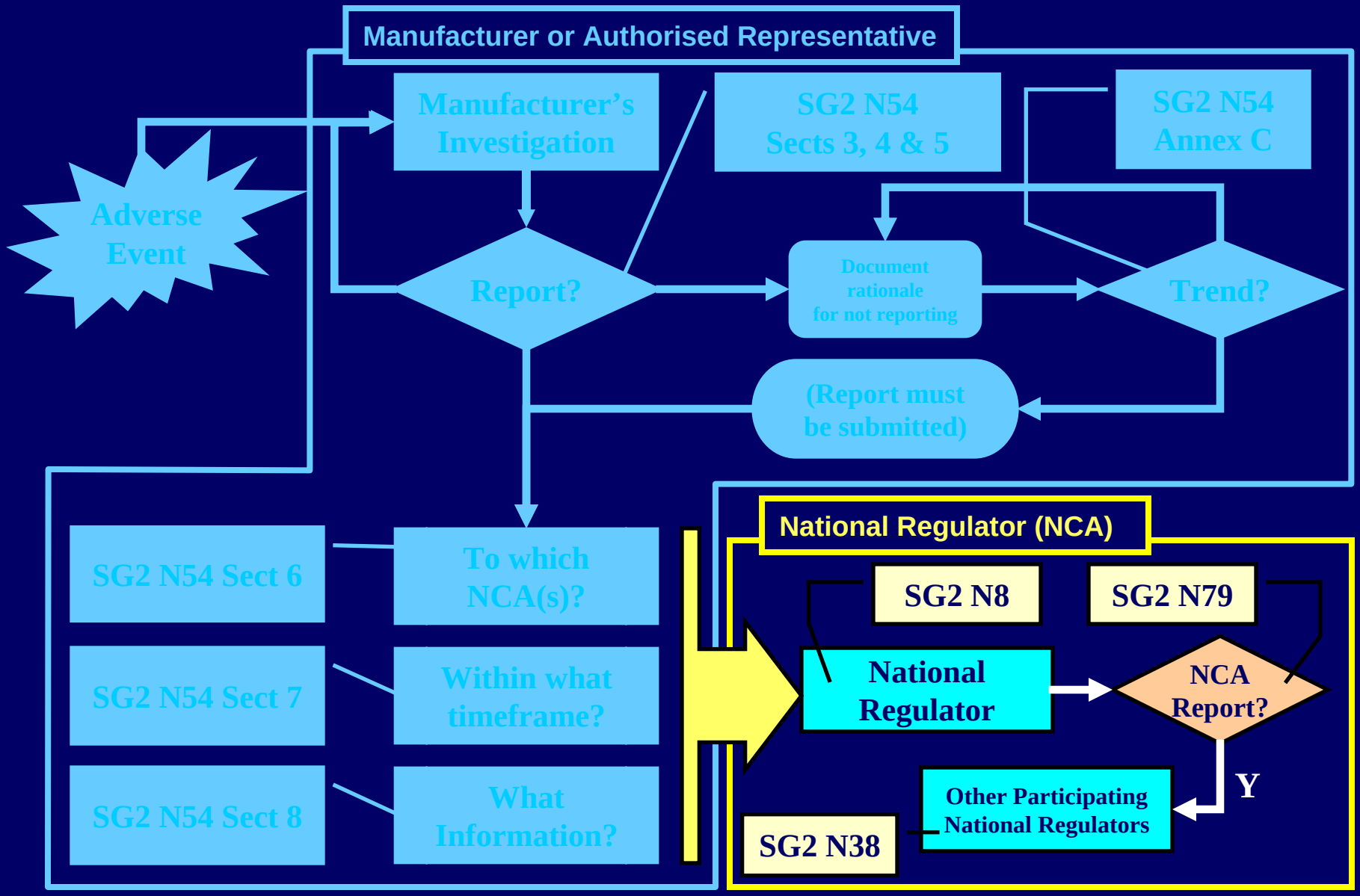
Summary of PMS Documents

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

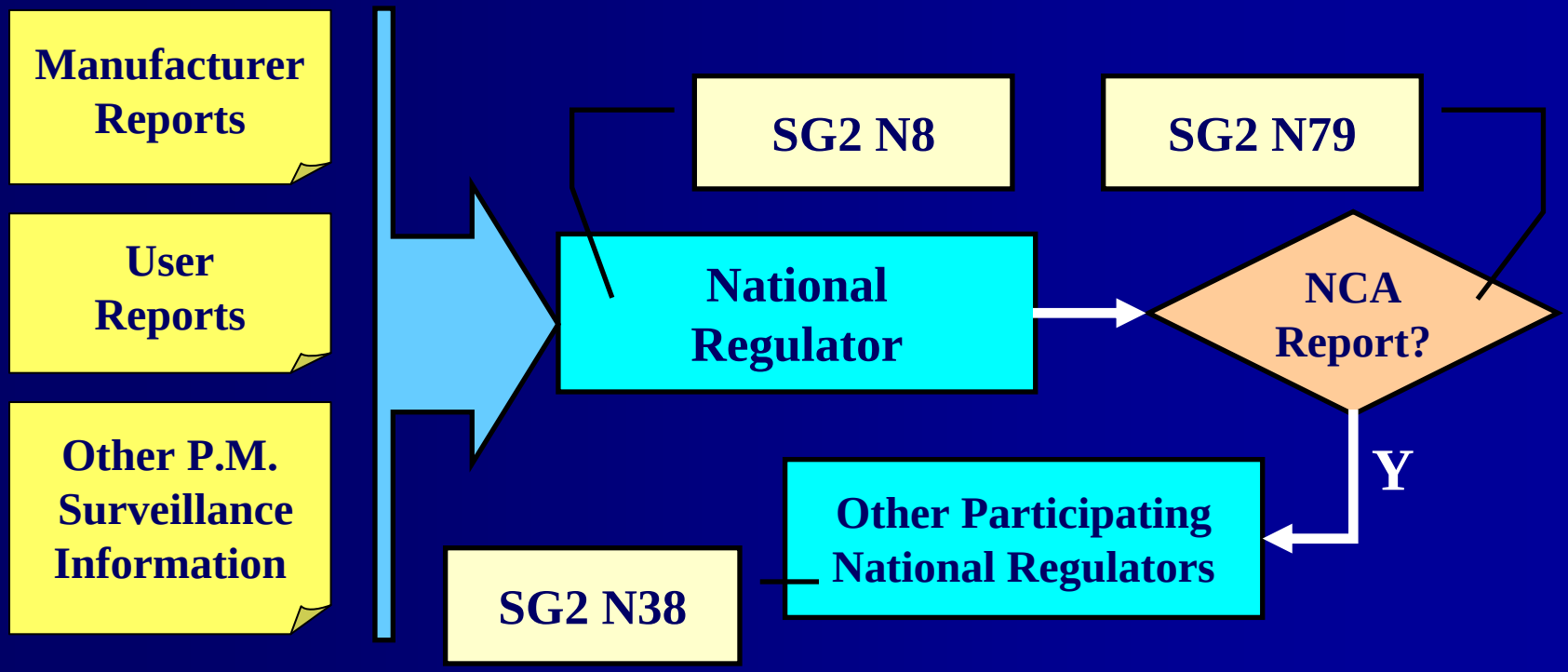
What we've done so far…

National Competent Authority Report Program

Map of SG2 Guidance on AE Reporting



Handling Adverse Event Reports:
NCA Systems



NCA Reports

- Are:
  - Reports that contain important information about an issue relating to a medical device that is or may be of great public health consequence.
- Are NOT:
  - SOLELY about Recalls or Safety Alerts
  - About individual adverse events
- May:
  - Contain information about issues that have not been completely resolved and which is therefore CONFIDENTIAL

Handling of Reports: Confidence

"A good reporting culture … can only be achieved through *confidence between all parties concerned*. The question will always remain; what happens to data handed into the system? Can everybody along the line be trusted? Will the information be properly treated? As important as confidential and discrete handling and treatment of data, will be the way conclusions are drawn. What information is to be released and used, and how will this be done."

NCAR
Hazards Associated with Reporting

- Public release of CONFIDENTIAL information
- Inappropriate release of information
- Misinterpretation of the issue
- Over-reaction to an issue
- Under-reaction to an issue

Participation:
Pre-requisites

Participant Level	Associate	Full
Type of Information Sought by Participant	Public	Confidential
Prerequisites		
Possible Admin. Charge	Yes	Yes
Working Reporting System	No	Yes
Training	Yes #	Yes *

Training regarding GHTF N9 and N20 only. * Full Training

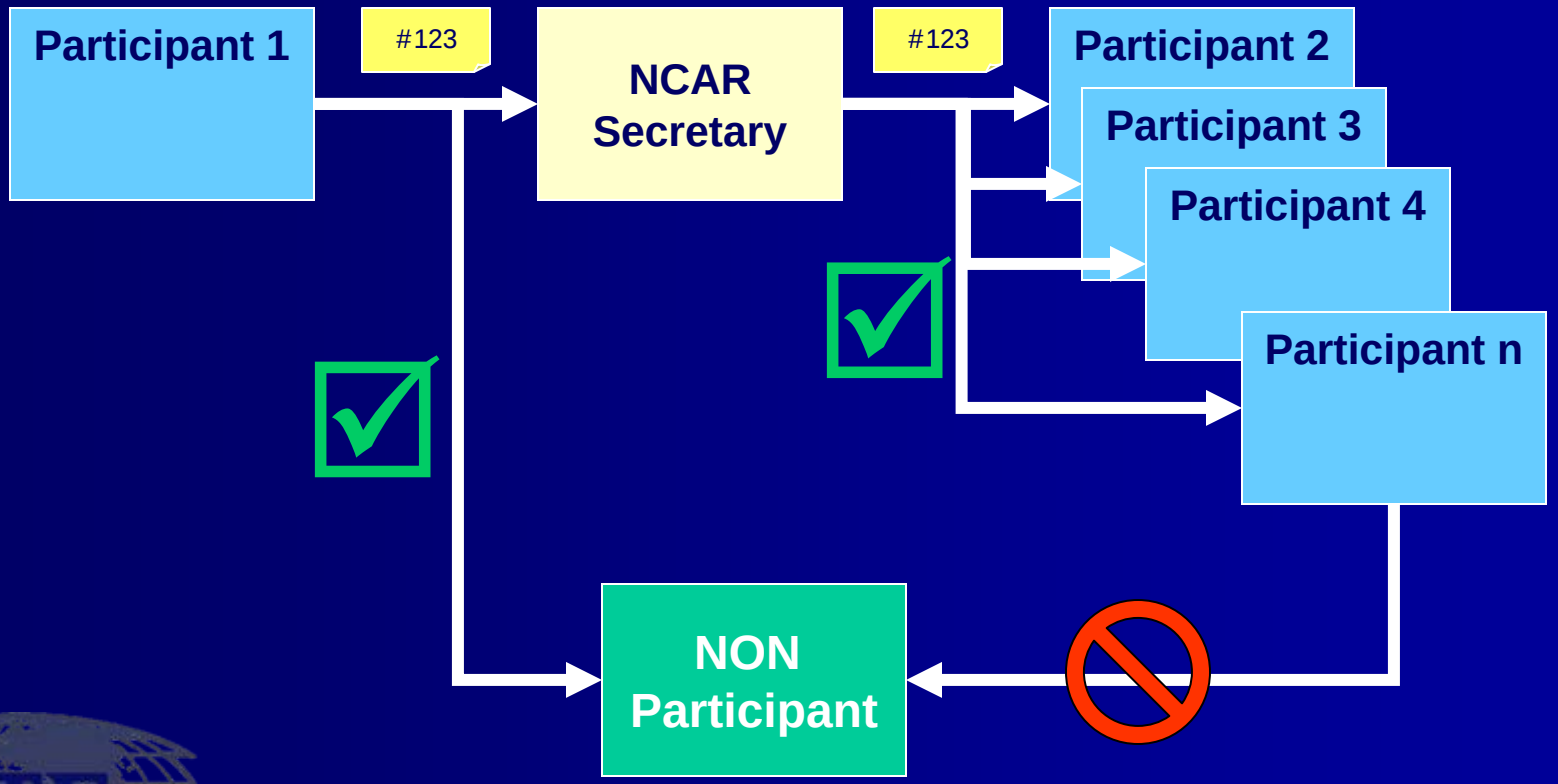
Participation:
Commitments

Participant Level	Associate	Full
Type of Information Sought by Participant	Public	Confidential
A commitment to:		
Confidentiality	No	Yes
Full Participation	No	Yes
Single Contact Point	Yes	Yes
Must be NCA	No	Yes

Participation:
Important Commitments

- Must treat reports labelled “Confidential” **STRICTLY CONFIDENTIAL**
- Must use form N79:
  - Ensures complete information
  - Prevents duplication
  - Protects sender
- Must not “send on” reports to non-participants.

Participation:
Sending to non participants



What we're planning to do…

Active/New Work Items

- Pilot on Electronic Reporting – N87
- New work item on the definition and classification of “Recalls” and associated actions
- New work item on the definition of the term “Adverse Event”

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

After that we'll "put our feet up"