GHTF SG2 Guidance:

Group work output presentation

SG2
Post-market Surveillance & Vigilance

- SG2 is charged with the task of developing harmonized manufacturers' adverse event reporting and other forms of post-market surveillance for countries with existing medical device regulations and those countries in the process of developing medical device reporting regulations.
- Significant elements of post-market surveillance/ vigilance involve information collection and assessment, risk analysis, decision / implementation, and safety information distribution.

Reference: section 9.2 GHTF/AHWG-GRM/N1R13

Post-market Vigilance

Vigilance is the reporting and investigation of adverse events (AE) and incidents. Both the manufacturer and the Regulatory Authority play major roles.

GHTF SG2 now prefers to use the term “Adverse Event Reporting”

Post-Market Surveillance

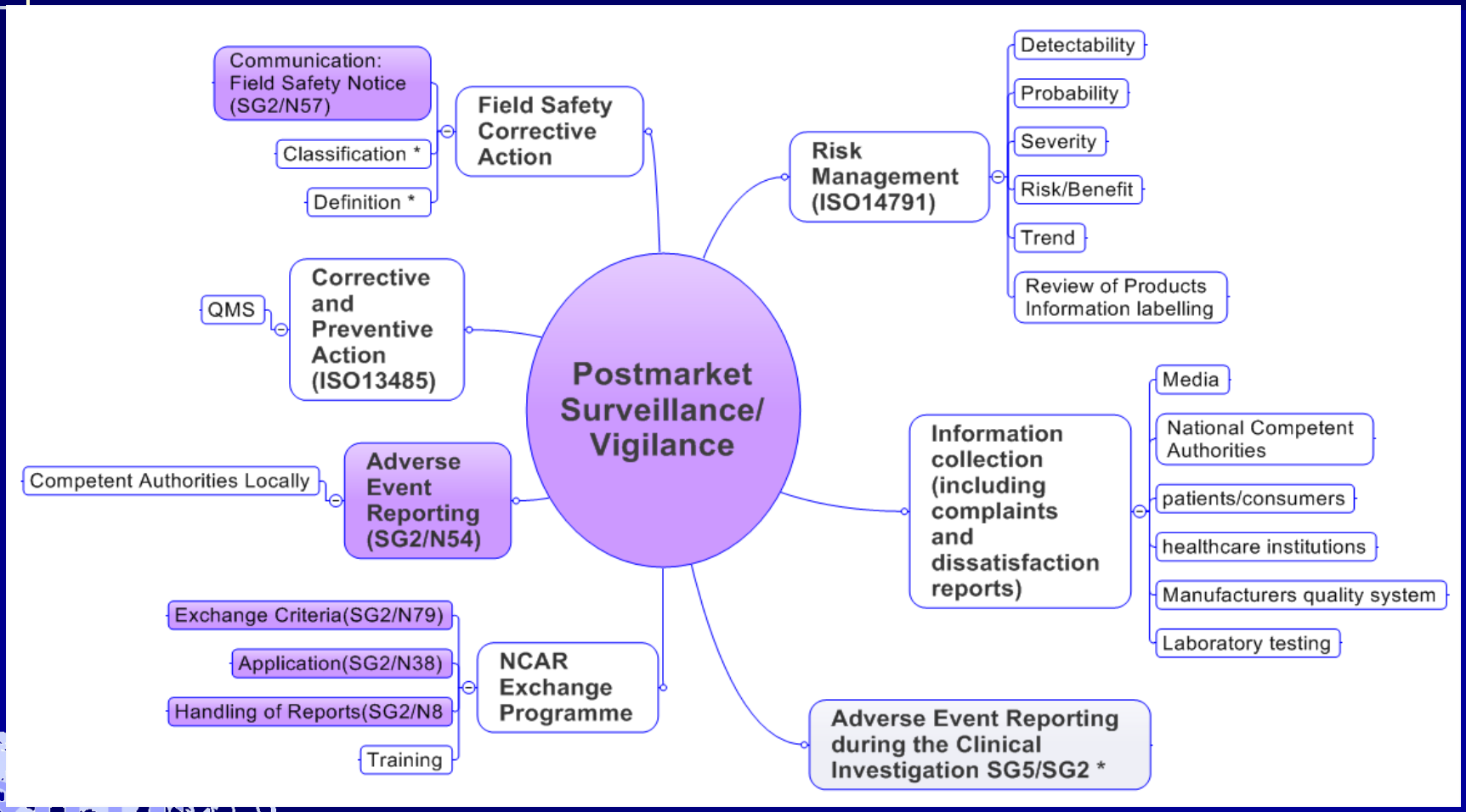
- Post-Market Surveillance is the collection of information on the quality, safety or performance of Medical Devices after they have been placed in the market.
- A balanced Post-Market Surveillance system will contain an appropriate mix of proactive and reactive activities.

Post-market Surveillance & Vigilance

Post-Market Surveillance Information is used for:

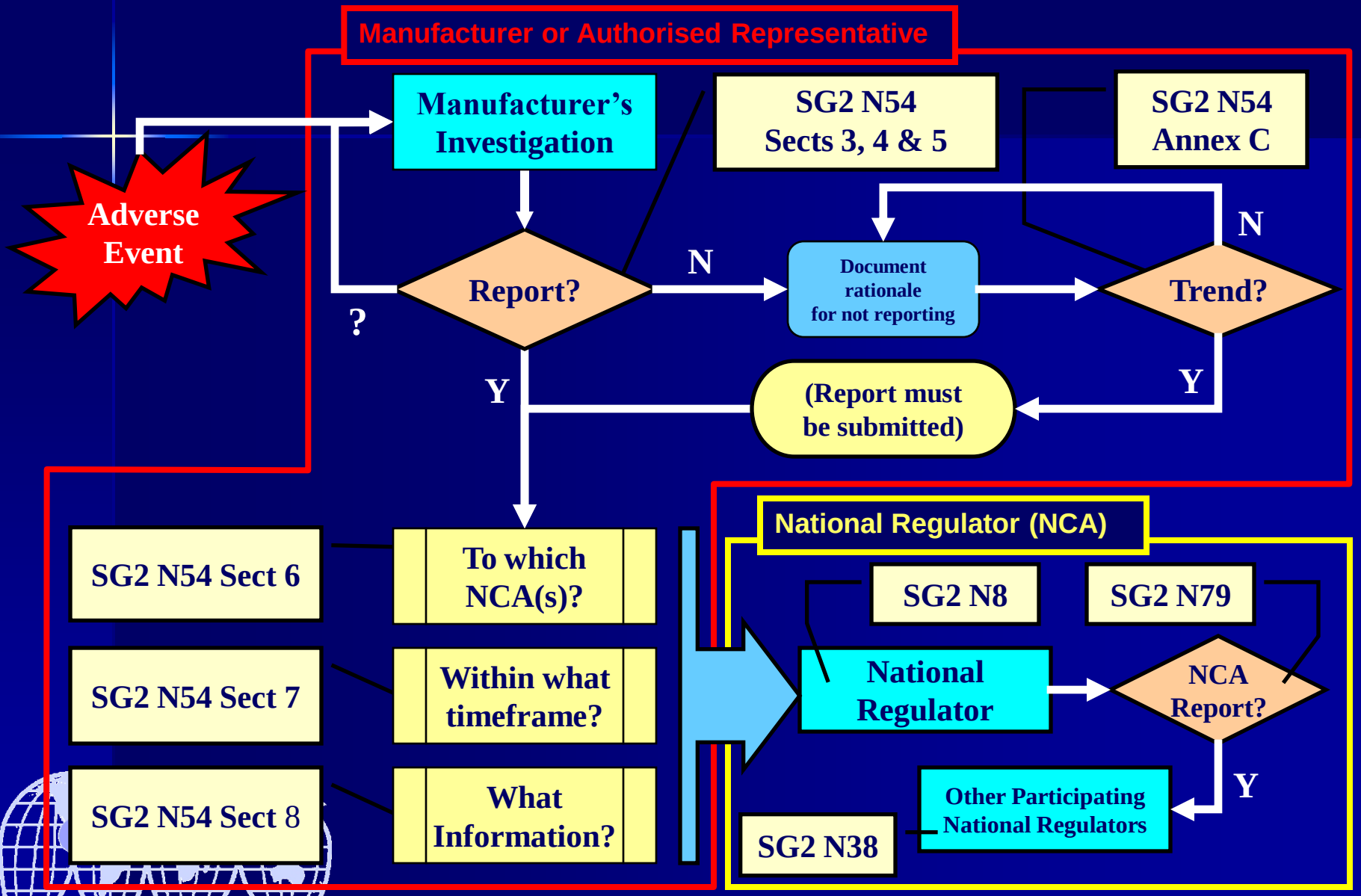
- Injury prevention
- Development of standards
- Regulatory refinement
- Product improvement

Summary: SG2 PMS/Vigilance activities, SG2 Documents & Links to International Standards (*)



(*) section 9.2 GHTF/AHWG-GRM/N1R13

Map of SG2 Guidance on AE Reporting



SG2 Guidance on AE Report Handling & NCAR Exchange Program

- SG2-N8R4 (2009): Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
- SG2-N38R19 (2009): Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program.
- SG2 N79R11 (2009): Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form
- SG2-N57R8 (2006): Medical Devices Post Market Surveillance: Content of Field Safety Notices

GHTF SG2 Guidance:

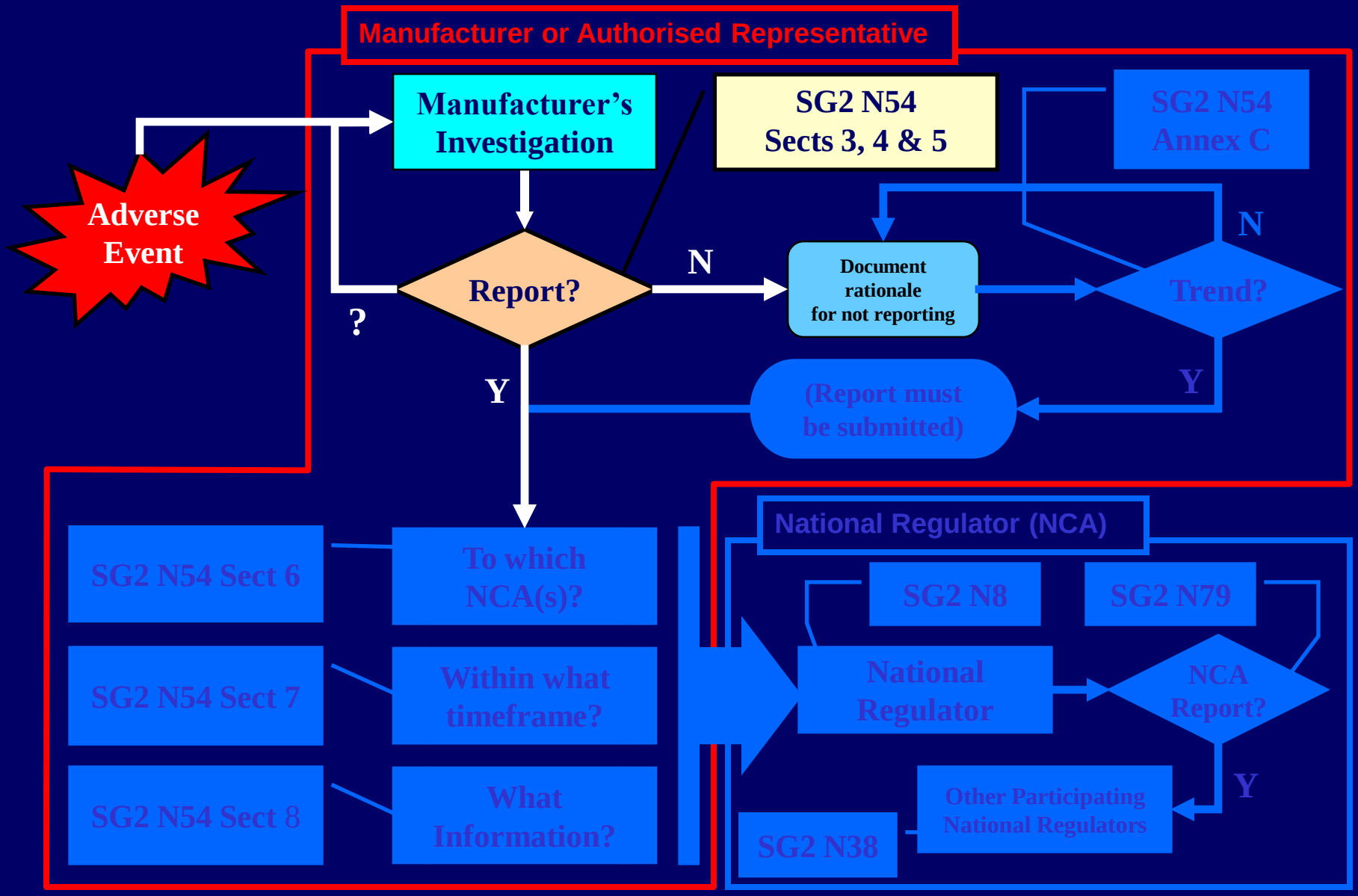
Reporting of Medical Device Adverse Events

Guidance on AE Reporting by Manufacturers - GHTF SG2 N54R8 (2006)

Table of Contents:

Annexes :

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

EVENT

- Malfunction or deterioration
- Inadequate design or manufacture
- Inaccuracy in labeling
- Significant public health concern
- Other information from testing or literature
- A change in trend

ASSOCIATION (WITH THE DEVICE)

- When the association with the device is difficult to establish, the manufacturer must rely on:
  - Opinion from healthcare professional
  - Previous similar events
  - Other information available to the manufacturer
- If there is any doubt, assume that the device was associated with the event.

SERIOUS INJURY

- Life threatening illness or injury
- Permanent (irreversible) impairment of a body function or permanent damage to a body structure
- A condition requiring medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

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 Rule 1

1) Deficiency of a new device found by the user prior to its use

   Deficiencies of devices that would always be detected by the user and where no serious injury has occurred, do not need to be reported

Exemption Rule 1 Example

1) Deficiency of a new device found by the user prior to its use

   Example-

   User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured

Exemption Rule 2

2) Adverse event caused by patient conditions

When the manufacturer has information that the root cause of the adverse event is due to a patient□s condition, the event does not need to be reported. These conditions could be preexisting or occurring during device use

Exemption Rule 2 Example

2) Adverse event caused by patient conditions

Example-
Revision of an orthopedic implant due to loosening caused by the patient developing osteoporosis

Exemption Rule 3

3) Service life or shelf life of the medical device

When the only cause for the adverse event was that the device was used beyond its service life as specified by the manufacturer and the failure mode is not unusual, the adverse event does not need to be reported

Exemption Rule 3 Example

3) Service life of the medical device

Example-

Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explantation of pacemaker required

Exemption Rule 4

4) Malfunction protection operated correctly

   Adverse events which did not lead to serious injury or death, because a design feature protected against a malfunction becoming a hazard, do not need to be reported

Exemption Rule 4 Example

4) Malfunction protection operated correctly

Example-

After a malfunction of an infusion pump it gives an appropriate alarm and stops (in compliance with relevant standards). There was no injury to the patient

Exemption Rule 5

5) Negligible likelihood of occurrence of death or serious injury

Adverse events which could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment do not need to be reported

Exemption Rule 5 Example

5) Negligible likelihood of occurrence of death or serious injury

Example-

Manufacturer of pacemaker released on the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is negligible. No patients experienced adverse health effects

Exemption Rule 6

6) Expected and foreseeable side effects which meet all the following criteria :

- Clearly identify in the manufacturer□s labeling
- Clinically well known and having a certain qualitative and quantitative predictability when used & performed as intended
- Documented in the device master record, with risk assessment prior to occurrence
- Clinically acceptable in terms of patient benefit are not reportable

Exemption Rule 6 Example

6) Expected and foreseeable side effects

Example-

Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labeled side effects

Exemption Rule 7

7) Adverse events described in an advisory notice

AE□s that occur after a manufacturer has issued an advisory notice need not be reported individually if specified in the notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the relevant NCA

Exemption Rule 7 Example

7) Adverse events described in an advisory notice

Example-

Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly recall reports and individual events did not have to be reported

Exemption Rule 8

8) Reporting exemptions granted by NCA

Upon request by the manufacturer and agreement by NCA common and well-documented events may be exempted from reporting or changed to periodic summary reporting

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

GHTF N54 Section 5 & Annex D
Use Errors

- Use Error: Section 5 (N54) + appendix D

  Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator

  Examples-
  - Despite proper instruction and proper design according to manufacturers analysis operator presses wrong button
  - Operator enters incorrect sequence and fails to initiate an action such as infusion

GHTF N54 Section 5 & Annex D
Abnormal Use

- Abnormal Use:

  Act, or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer

  Examples-

  – Use of a medical device in installation prior to completing all initial performance checks as specified by the manufacturer

  – Continued use of a medical device beyond the manufacturers defined planned maintenance interval as a result of user's failure to arrange for maintenance

Use Errors & Abnormal Use

Note - Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted

Use Error - Reportability

- Use errors related to medical devices, which did result in death or serious injury or serious public health threat should be reported by the manufacturer to the National Competent Authority

Use Error - Reportability

- Use errors related to medical devices which did not result in death or serious injury or serious public health concerns, need not be reported by the manufacturer to the national competent authorities.
- Use errors become reportable by the manufacturer to the national competent authorities when a manufacturer:
  - Notes a change in trend that can potentially lead to death or serious injury of public health concern.
  - Initiates corrective action to prevent death or serious injury or serious public health concern.

Abnormal Use - Reportability

- Abnormal use need not to be reported by the manufacturer to the national competent authority under adverse event reporting procedure. Abnormal use should be handled by the healthcare facility and appropriate regulatory authorities
- If manufacturers become aware of instances of abnormal use, they may bring this to the attention or other appropriate organizations and healthcare facility personnel

The Universe of Device Associated Adverse Events

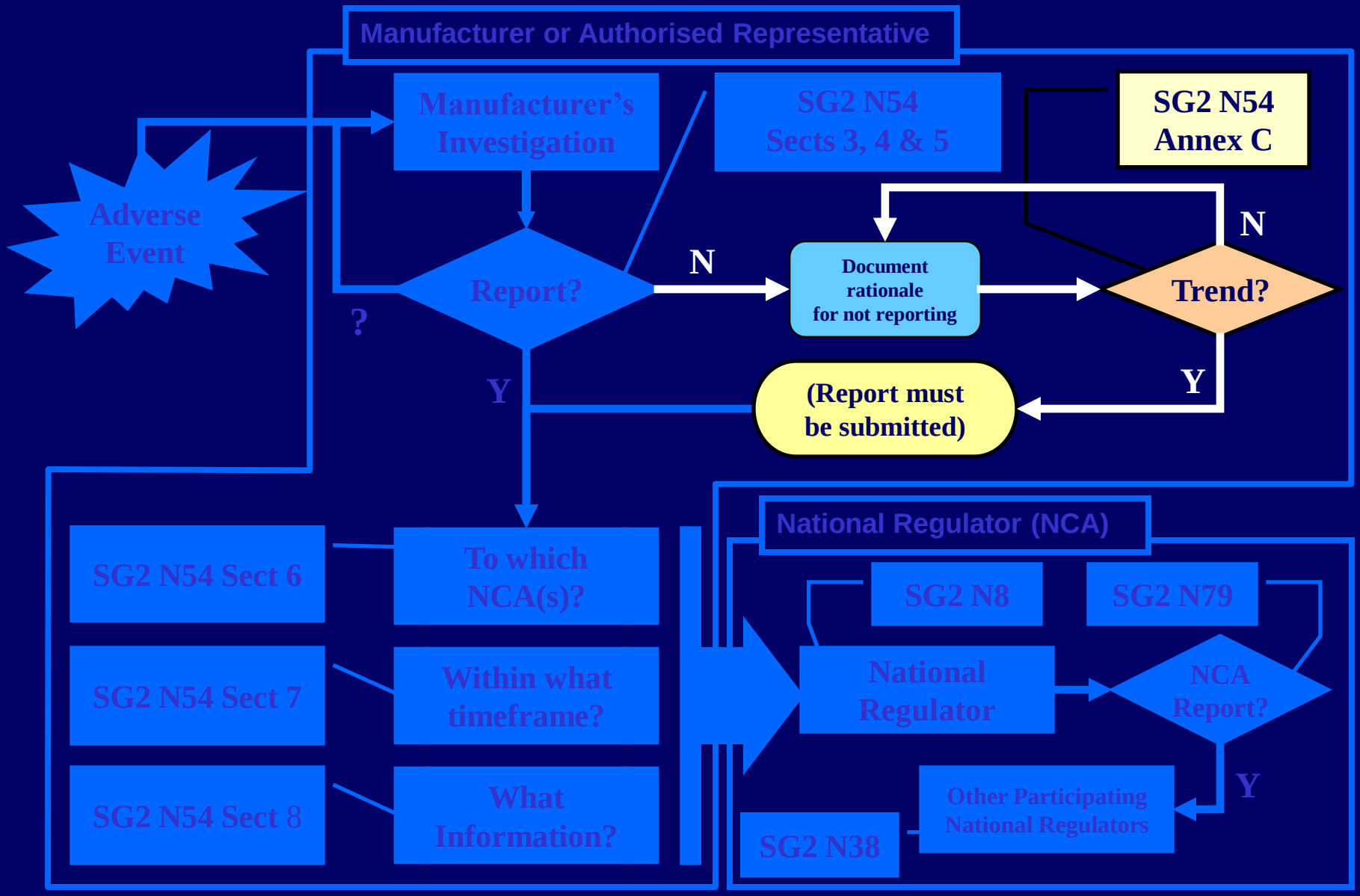
R=Report
NR*= No Report*

= Death

= Serious Injury

= Malfunction /could have resulted SI

Trends

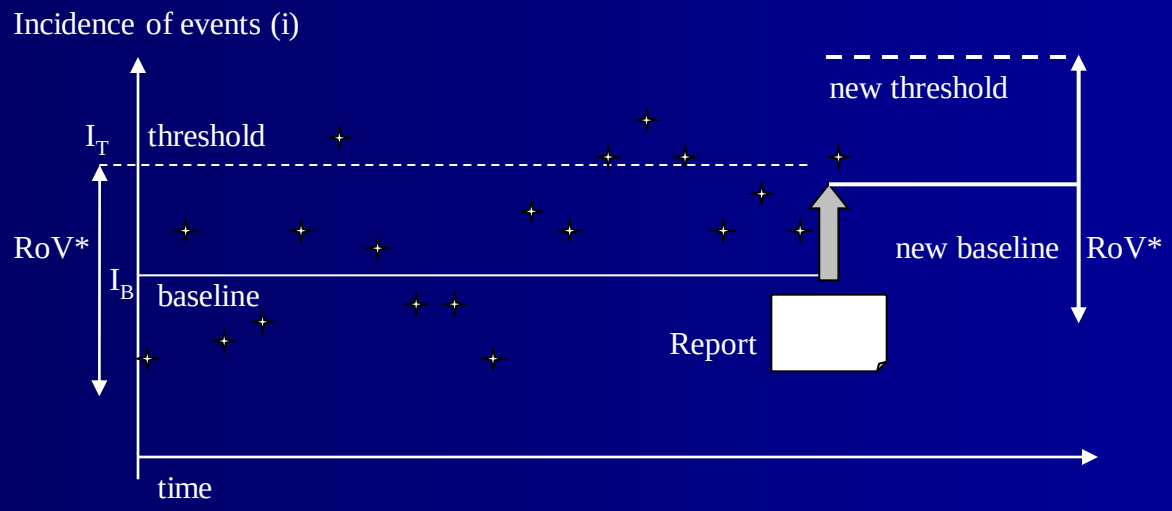

Manufacturer or Authorised Representative
Manufacturer's Investigation
SG2 N54 Sects 3, 4 & 5
SG2 N54 Annex C
Adverse Event
Report?
N
Document rationale for not reporting
Trend?
N
Y
(Report must be submitted)
Y
?
SG2 N54 Sect 6
To which NCA(s)?
SG2 N54 Sect 7
Within what timeframe?
SG2 N54 Sect 8
What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

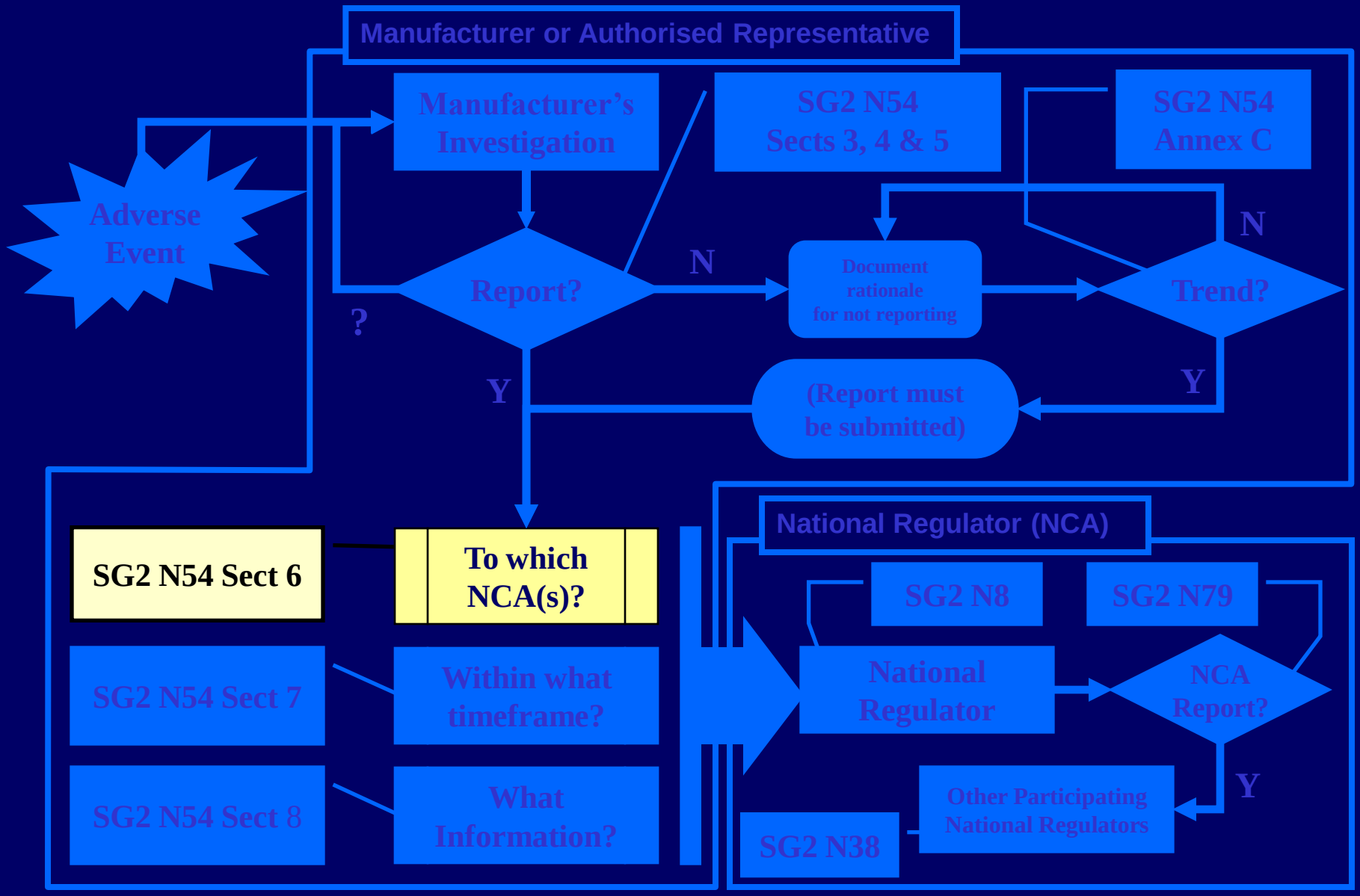
AE Trend Reporting

- Example of an upward shift in trend



* normal Range of Variance

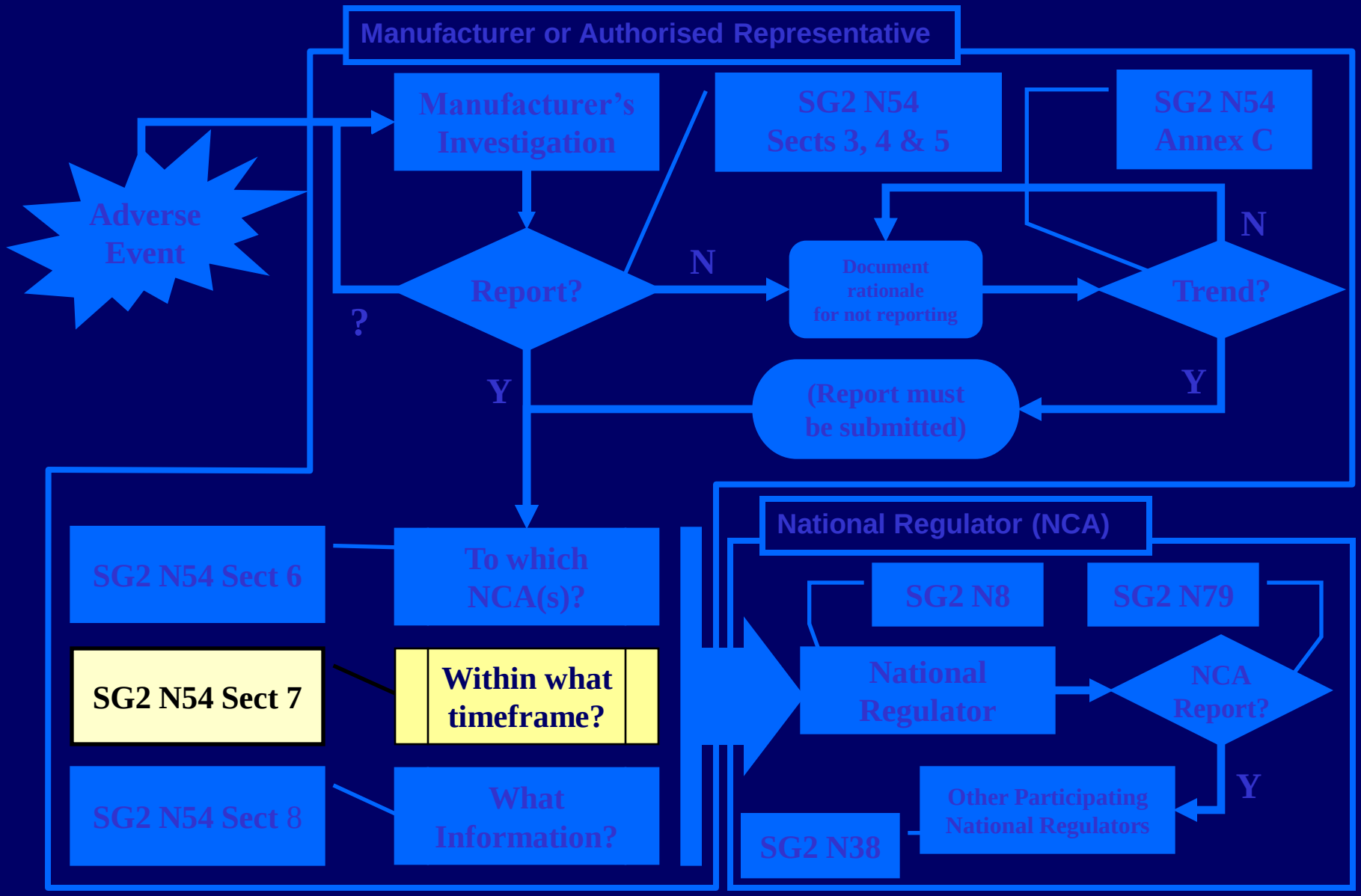
To Which NCAs to Report?



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

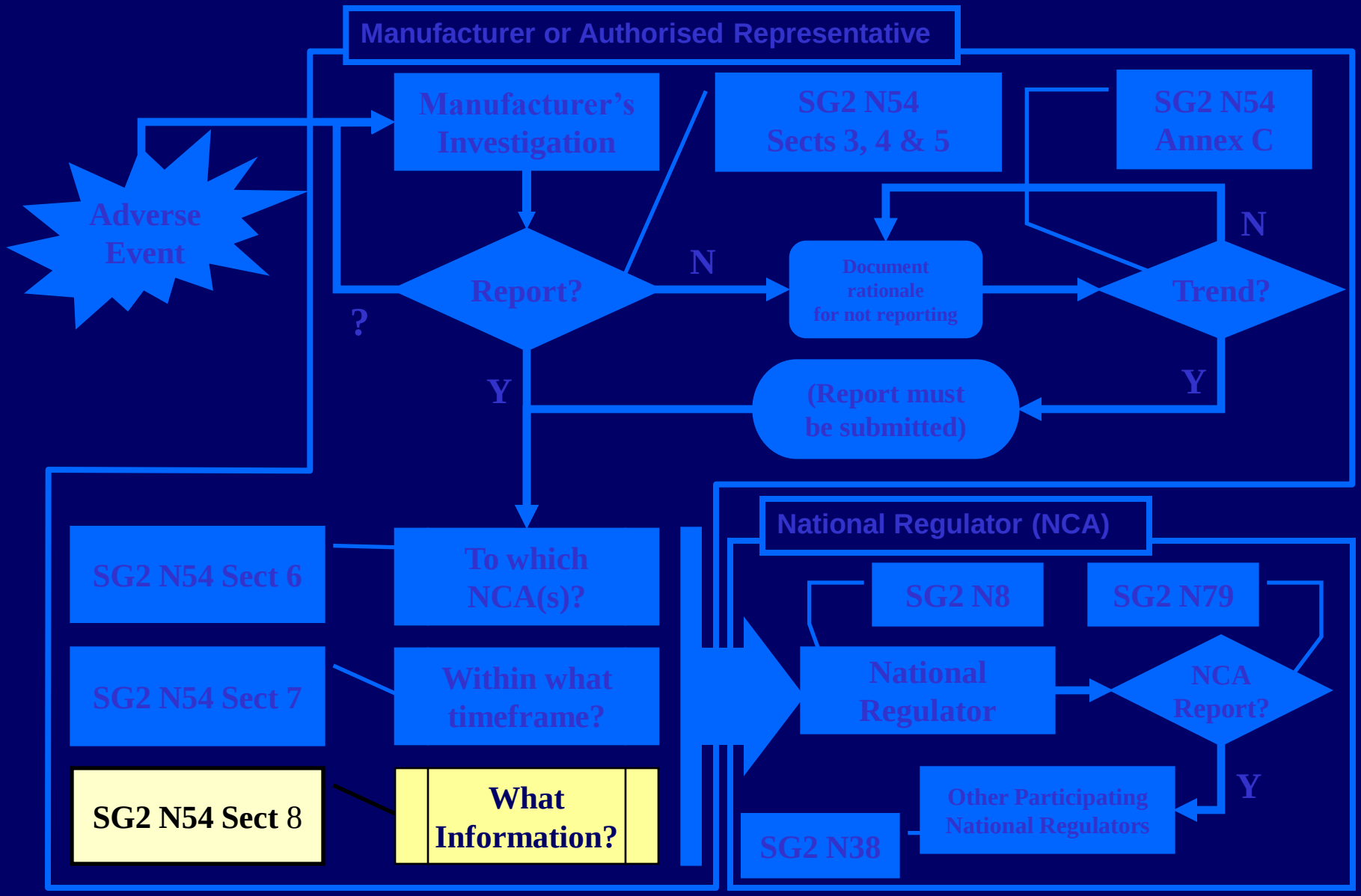
Reporting Timeframes

- **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

- **<u>Unanticipated:</u>** 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

Case study:

Implementation of SG2 Adverse Event Reporting Guidance in Australia

Changes Required

- The way that **YOU** and your agency thinks about regulation.
- Then change:
  - The Law
  - The Regulations (legal instruments)
  - National guidelines
  - Administrative practice

People to Convince

- Yourself
- Your colleagues and your superiors
- Peak advisory bodies (medical associations, hospital associations etc)
- Politicians (and the public)
- Local industry (?)

Basic Reporting Criteria, Exemptions 1-3

N54 Part	Description	Status in Australia
Sections 3.1-3.3	Definition of reportable event, basic reporting criteria	Implemented in the law S41FN, S41MP, examples and plain English definition in TGA Guidance 11
Exemptions		
Section 4.1	Deficiency of a New Device Found by the User Prior to its Use	Implemented, but TGA Guidance says "always instead of "normally".
Section 4.2	Adverse Event Caused by Patient Conditions	Implemented in TGA Guidance
Section 4.3	Service Life of the Medical Device	Implemented in TGA Guidance

Exemptions 4-8

N54 Part	Description	Status in AU
Section 4.4	Protection Against a Fault Functioned Correctly	Implemented in TGA Guidance
Section 4.5	Remote Likelihood of Occurrence of Death or Serious Injury	Implemented in TGA Guidance
Section 4.6	Expected and Foreseeable Side Effects	Implemented in TGA Guidance
Section 4.7	Adverse Events Described in an Advisory Notice	Implemented in TGA Guidance
Section 4.8	Reporting Exemptions Granted by NCA	Implemented in TGA Guidance

Other Sections

SG2 Doc	Description	Status
Section 5	Use Error Exemptions	Not implemented, user errors are reportable in Australia - this is explicit
Section 8	Universal Dataset	Implemented in TGA Guidance, minor local variations: ARTG#, ARTG Manufacturer#
Section 7	Timing for Adverse Event Reports	Implemented in the Medical Devices Regulations: Difference - "Immediate Reports" in 2 calendar days. "Death and Serious Injury Reports" in 10 Calendar Days
Annex C	Trending of Adverse Event Reports	Implemented, trending mentioned in TGA Guidance

Conclusions:

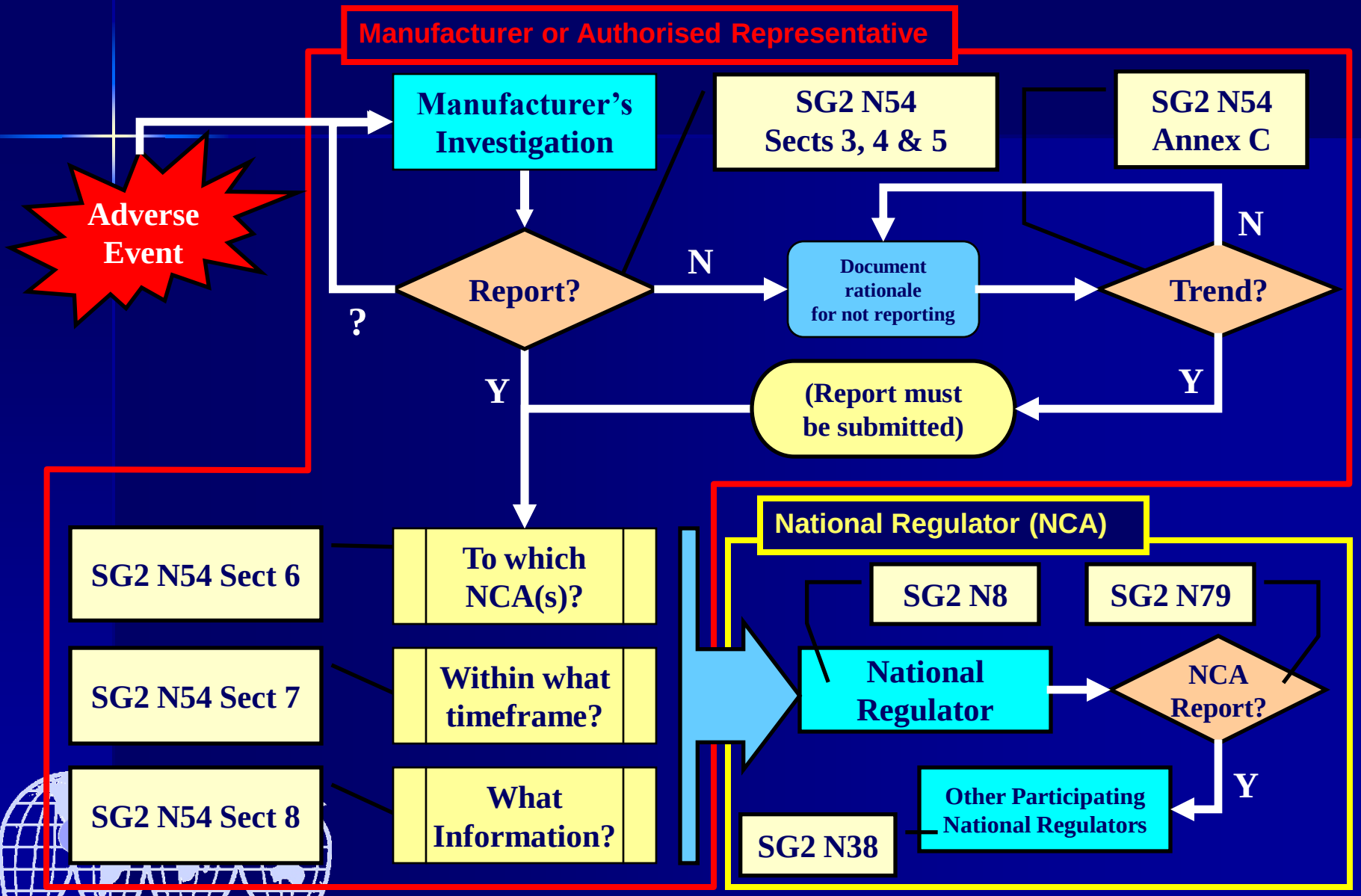
- Was it easy?.....NO
- Was it hard work?.....YES

- Was it worth the trouble?.....YES!

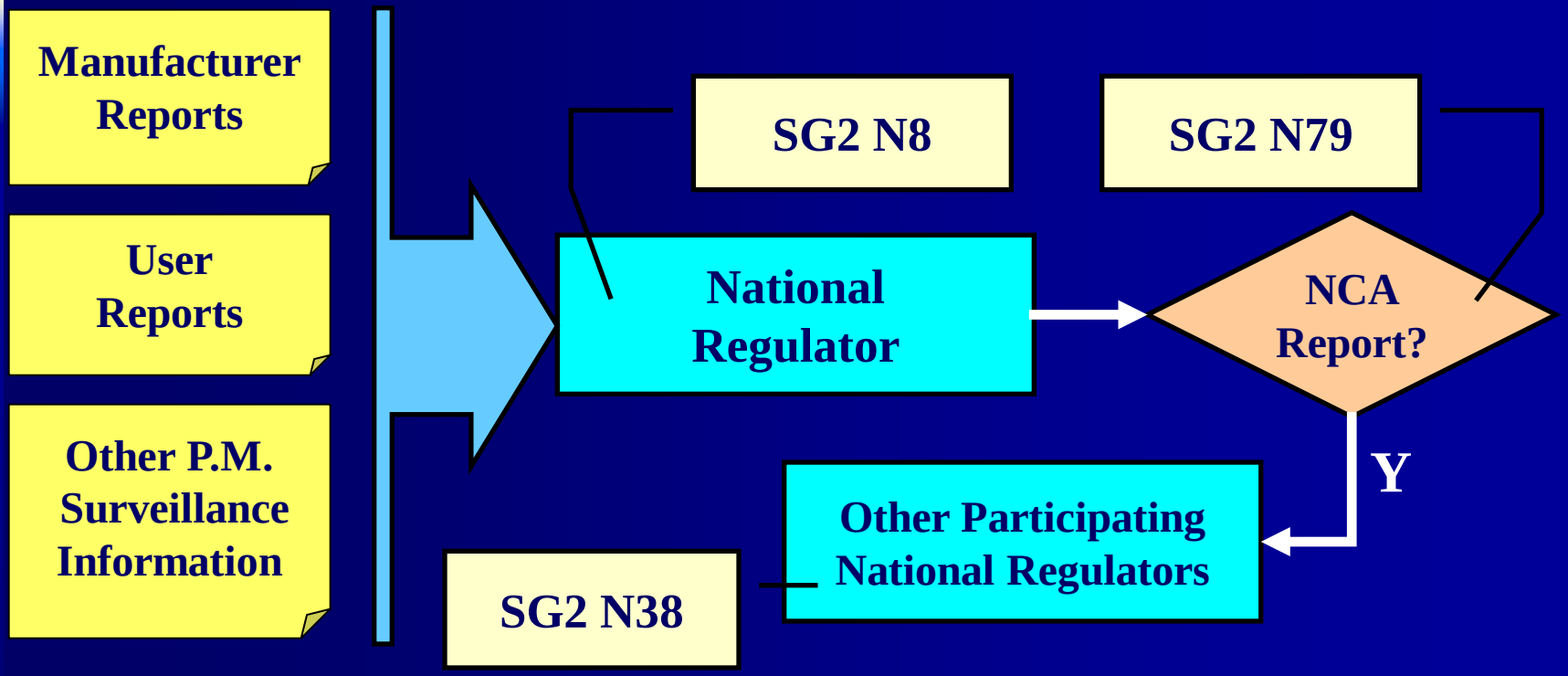
GHTF SG2:

National Competent Authority Report Program

Map of SG2 Guidance on AE Reporting



Handling Adverse Event Reports: NCA Systems



Handling Adverse Event 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."

Handling Adverse Event Reports:
Risk Assessment

RISK = Incidence x Hazard

- A hazardous event that occurs infrequently constitutes a LOW RISK
- An event that occurs often but has few or no safety implications constitutes a LOW RISK

Handling Adverse Event Reports:
Risk Assessment for public servants

- There may be other factors that affect the outcome of risk assessment.
- These may be local or global considerations.

RISK = Incidence x Hazard x Public Concern

Handling Adverse Event Reports:
Risk versus Benefit

- Australian road **“TOLL”**
  - 14,400,000 registered vehicles
  - 600,000 reported crashes (4.16%)
  - 200,000 reported injuries (1.38%)
  - 22,000 serious injuries (0.15%)
  - 1600 deaths (0.01%)

Handling Adverse Event Reports:
Risk versus Benefit

- What “toll” is the public willing to pay for the benefit of using:
  - Pacemakers? - Heart valves?
  - Hip implants? - Catheters?
- Does the “risk taker” benefit from taking the risk?

Handling Adverse Event Reports:
Risk Assessment

- There is no “silver bullet”
- Every ISSUE should receive individual risk assessment
- When difficult, seek help:
  - Medical experts
  - Other regulators
  - Manufacturer

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

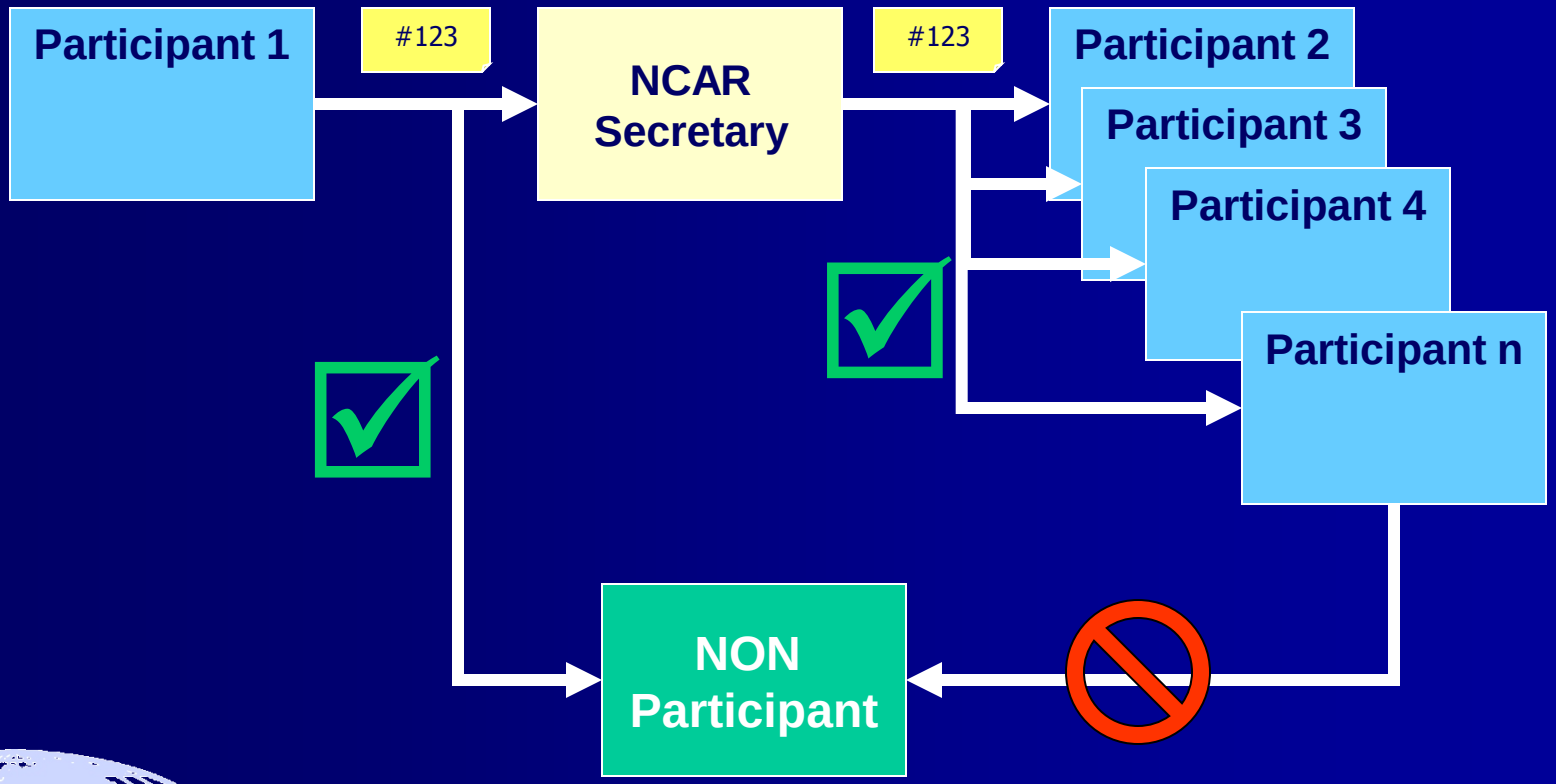
Participation:
Commitments

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



Submitting a Report:

Criteria for Reporting & Form

NCAR Criteria & Reporting Form

- Most of the information provided during this session is available in document N79R8:2006 at www.ghtf.org/sg2/final

Getting started

An NCAR tells other regulators about device issues that they do not already know about

There are 10 criteria *to consider* before generating an NCAR

NOTE: Criteria considerations can clarify that no NCAR is needed

1. Consider : Seriousness not serious = no NCAR

Seriousness is determined by:

- A technical or clinical assessment
- The actual or potential impact to patients and users
- The difficulty in recognizing the issues and how to prevent or mitigate them

2. Consider : Unexpectedness by itself = no NCAR

Unexpected because of:

- a lack of historical information; rare
- an increase in frequency of occurrence
- a change in the situation in which it's occurring
- a change in the outcome

3. Consider: Vulnerable Pop.

Is any special population at increased risk for adverse events?

If yes, can you define it? Such as:

- Age related – pediatric, geriatric
- Immune status – pregnancy, illness

4. Consider: Preventability

Can the issue be prevented or minimized?

Do you have recommendations for preventing or minimizing the issue?

5. Consider: Public Percept.

Sometimes the public perception* of an issue makes it appear “serious”

*All NCARs should be perceived as or considered “serious”

6. Consider: Risks & Benefits

Do established risks and benefits related to the device address the issue?

Are there well recognized and established standards of practice related to the use of the device?

Are there alternative devices available for use?

7. Consider: Lack of Data

Do you have scientific data on long term effects?

Do you have baseline data for comparison?

Is there national or international consensus on the issues and their resolution?

8. Consider: Repeated issues

- Has this issue been identified before?
- What new information do you have to share?
- How will a new NCAR change what is already being done?

9. Consider: Written notifications already exist

No NCAR is needed when the issue is already well published and publicly available.

An NCAR might be appropriate when you get new information that is not otherwise publicly available.

The new information should be clearly described and easily found.

10. Consider: How will the NCAR help?

When the manufacturer's efforts are sufficient = no NCAR

When you have no new information about the issue = no NCAR

When you have identified a new serious device issue, or have additional information of regulatory significance = send NCAR

The final decision is yours

Ultimately each regulator decides if and when to send an NCAR.

Too many NCARs = loss of attention

Too few NCARs = loss of information

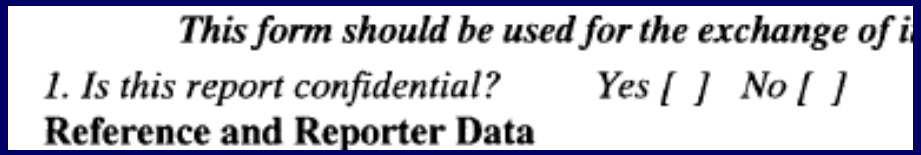
About the NCAR document

An NCAR is for exchange of information between NCAR participants only, and should not be made public.

The NCAR format provides for consistency and familiarity with reported information.

Use “NA” in boxes where data is not applicable

1. Is this report confidential?


This form should be used for the exchange of i

1. Is this report confidential? *Yes [ ] No [ ]*

Reference and Reporter Data

Check Yes [x] only when the NCAR has information that is not already public.

If the NCAR includes both public and confidential information, clearly identify what information is considered confidential.

2. The permanent NCAR Reference

2. NCA report ref. no.:

Assigned by the originating regulator:

- Always begin with your 2 letter ISO* Country code (*see ISO 3166)
- Add –YYYY-MM-DD- for the year, month and day
- Last is the 3 digit sequence number; start each new year with 001

E.g., US-2007-10-08-030

Additional Ref #s

3. Local NCA reference no.:	4. Related NCA report nos.: (if any)	5. Manufacturer Ref/Recall no.:

3. Local NCA # = national tracking #
4. Related NCAR # = list of any NCARs sent on the same issue
5. Mfr Ref/Recall No = internal tracking # relating to corrective action or recall

Reporter Data

6. Sent by: (Name and Organization)	7. Contact person: (if different fr
8. Tel:	9. Fax:	10. E-mail:

6. Sent by = who sent the NCAR
7. Contact person = who will answer any questions, if not #6.
8 – 10. Telephone, Fax, and E-mail information = how to reach the person who can answer any questions about the NCAR

Device Data

11. Generic name/ kind of device:	12. Nomenclature id:	13. No.:

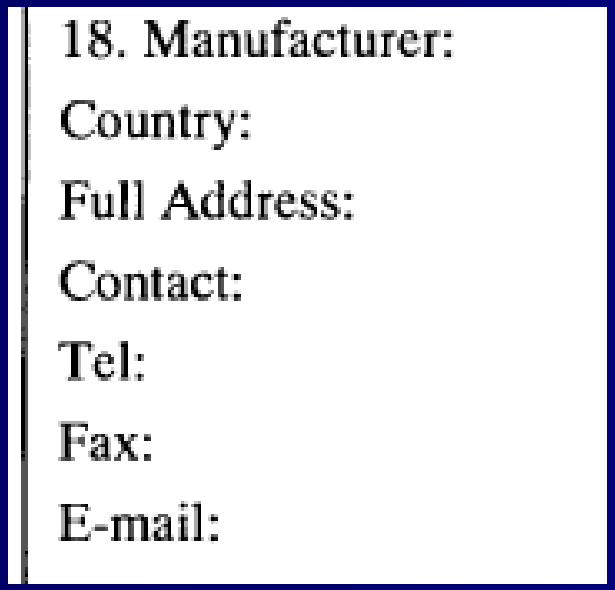
11. Generic name/ kind of device = a general & short device descriptor ; e.g., defibrillator; wheelchair; suture
12. Nomenclature id = the name of the coding system you use, if any
13. No. - the specific code number for the subject device, if any

More Device Data

14. Trade Name and Model:	15. Software version:	16. Serial no.:	17. Lot/batch no.:

14. Trade Name & Model* = common product identifiers. **Note: 25c. also asks for other trade names used*
15. Software version – e.g., FreeWare V2.1
16. Serial No.: & 17. Lot/batch No.: = unique product identifiers

18. Manufacturer Info.


18. Manufacturer:
Country:
Full Address:
Contact:
Tel:
Fax:
E-mail:

Informs:

- who made the device,
- where the device was made, and
- a contact at the manufacturer

19. Authorized Rep. Info.

Optional: Use only when contact information is different from 18.

19. Authorized rep (if different from 18):

Country:

Full Address:

Contact:

Tel:

Fax:

E-mail:

20. CAB/Notified Body no.

CAB = conformity assessment body

Conformity assessment includes testing, inspection and certification of products, processes and persons.

Notified bodies carry out the tasks pertaining to the conformity assessment procedures

21. Device approval status & Risk Class

21a. Device approval status = the device was or was not approved for marketing

21b. Risk Class* = the device is classified as a low, medium or high risk.

**Risk Class is not globally harmonized at this time. Generally, the higher the risk- the higher the risk class #.*

22. Action Taken

Action taken identifies what the NCA or the MFR has done.

- Check all boxes that apply.
- Use the “other” option as needed, and include a brief description

7. Action taken:
[ ] None
[ ] Safeguard Action
[ ] Field Safety Corrective Action
[ ] Other (specify)

Event Data

23a. Background and reason for this report = Description of what the device issues are and what impact they have on patients or users

23b. Investigation complete? Y or N -

Confirms if the investigation about the reported issue is complete or not

More Event Data

24a. Conclusions = the findings of the device investigation. Attach any documents and include web addresses when possible

24b. Have the manufacturer's actions been made public? Y or N

24c. Tells if you will coordinate the investigation - Y or N

Recommendations & global information

25a. Recommendations = what you want recipients to do with the information

25b. Known to be in the Market… = a list of countries where device is known to be marketed

25c. Also marketed as = list names different from #14.

Report distribution

NCAR Secretariat: MDV@hc-sc.gc.ca

26a. Mark all that apply.

This report is being distributed to:
[ ] The NCAR Secretariat for further distribution to FULL NCAR PARTICIPANTS.
[ ] The NCAR Secretariat for further distribution to ALL NCAR PARTICIPANTS.
[ ] EEA states, EC, and EFTA
[ ] The following targeted NCAs:
[ ] The manufacturer / authorized rep.:

26b. Complete only when your NCAR #s are not sequential

26b. The last GHTF-NCAR distributed by this NCA was (>>>>

NCAR Program:

Procedures and Statistics

NCAR Exchange Program - Procedures

- NCA Report number format: CC-YYYY-MM-DD-###, where:
  - CC is the 2-letter ISO code for the NCA
  - YYYY-MM-DD is the year-month-day
  - ### is the sequential numeric identifier for the report

NCAR Exchange Program - Procedures

- Submit to NCAR Secretariat (NCAR-Sec) at GHTF.NCAR@tga.gov.au
- Prefer N79 form, MS-Word (.doc) format
- NCAR-Sec reviews report:
  - NCA Report Number correct?
  - Previously submitted? Other errors?

NCAR Exchange Program - Procedures

- 2 mailing lists:
  - NCARs originating in Europe
  - NCARs originating in AU, CA, HK, JP, US
- Forwarded with filename:
  CC-YYYY-MM-DD-###_Company-Name_Device-Name.doc

NCAR Exchange Program - Procedures

- NCARs may be:
  - For your information
  - For your action
    - Recalls, Corrective Actions
    - Safety Alerts
    - Confidential requests from an NCA for information concerning an investigation

NCAR Exchange Program - Procedures

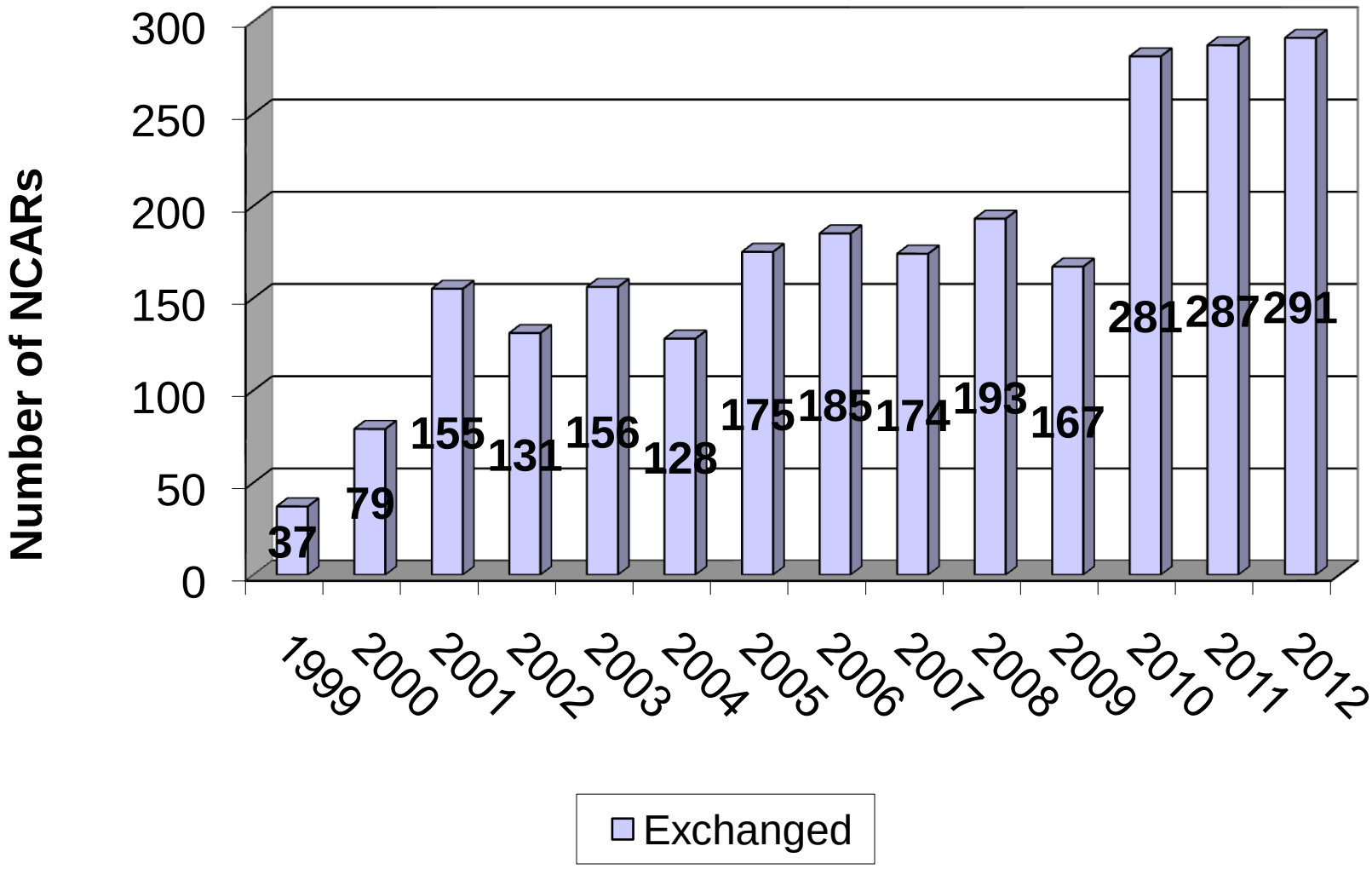
- You may not:
  - Release the information outside your NCA
  - Publish the information on the internet
  - Contact the company for info, if NCAR confidential

NCAR Exchange Program - Procedures

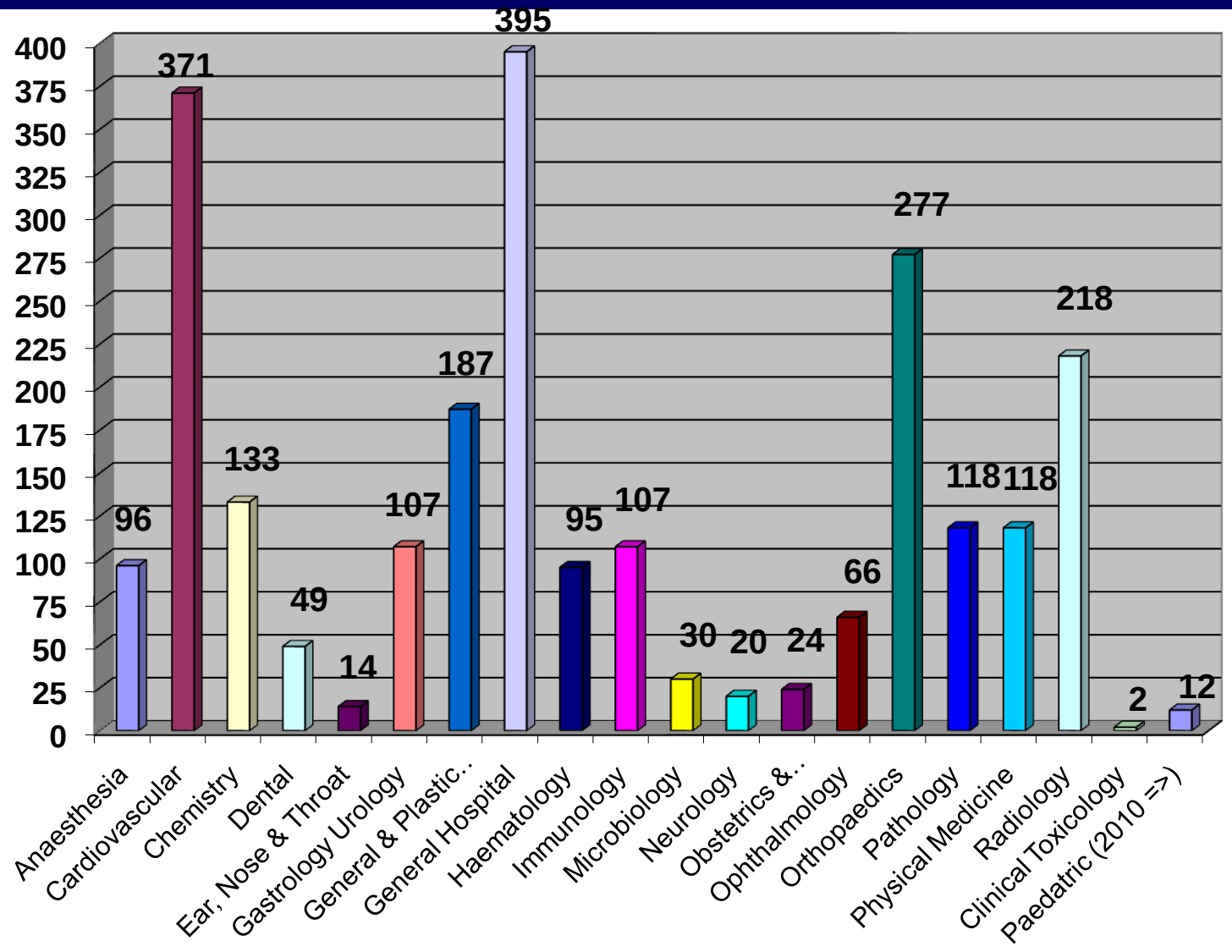
- Important notes:
  - Single point of contact for NCA
  - Responsibilities
  - Field 1, Confidentiality
  - Extent of device distribution

NCAR Performance/ Statistics to end September 2012.

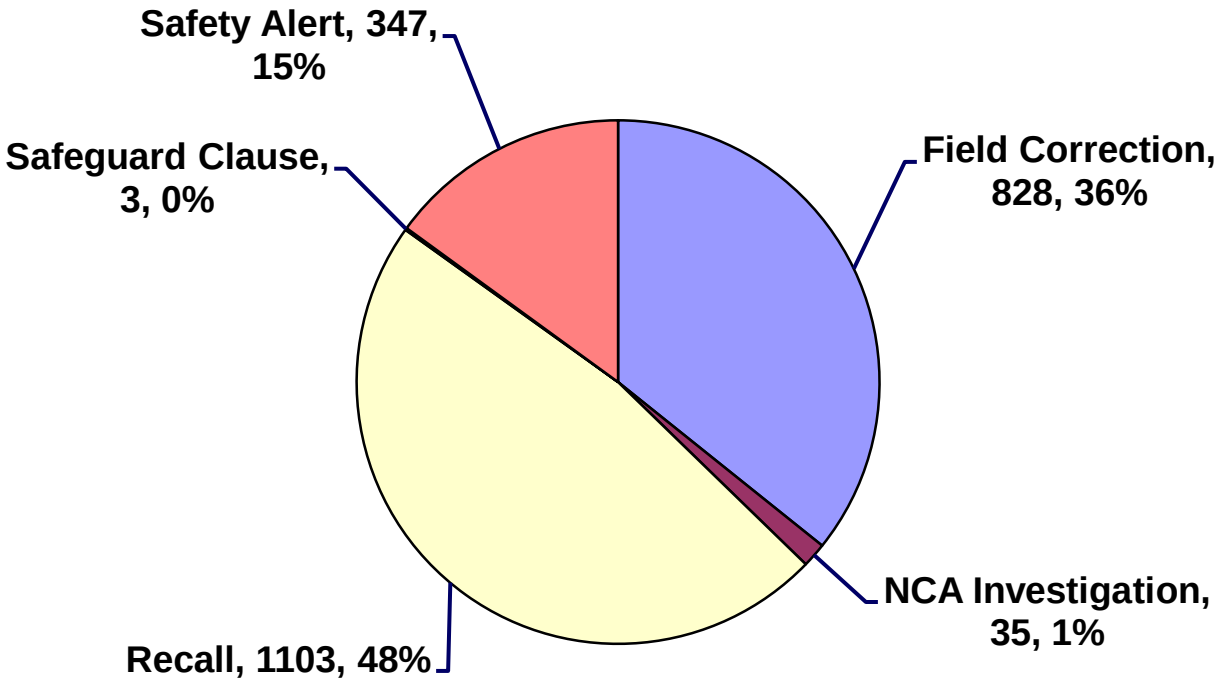
NCARs Exchanged (total = 2,439)



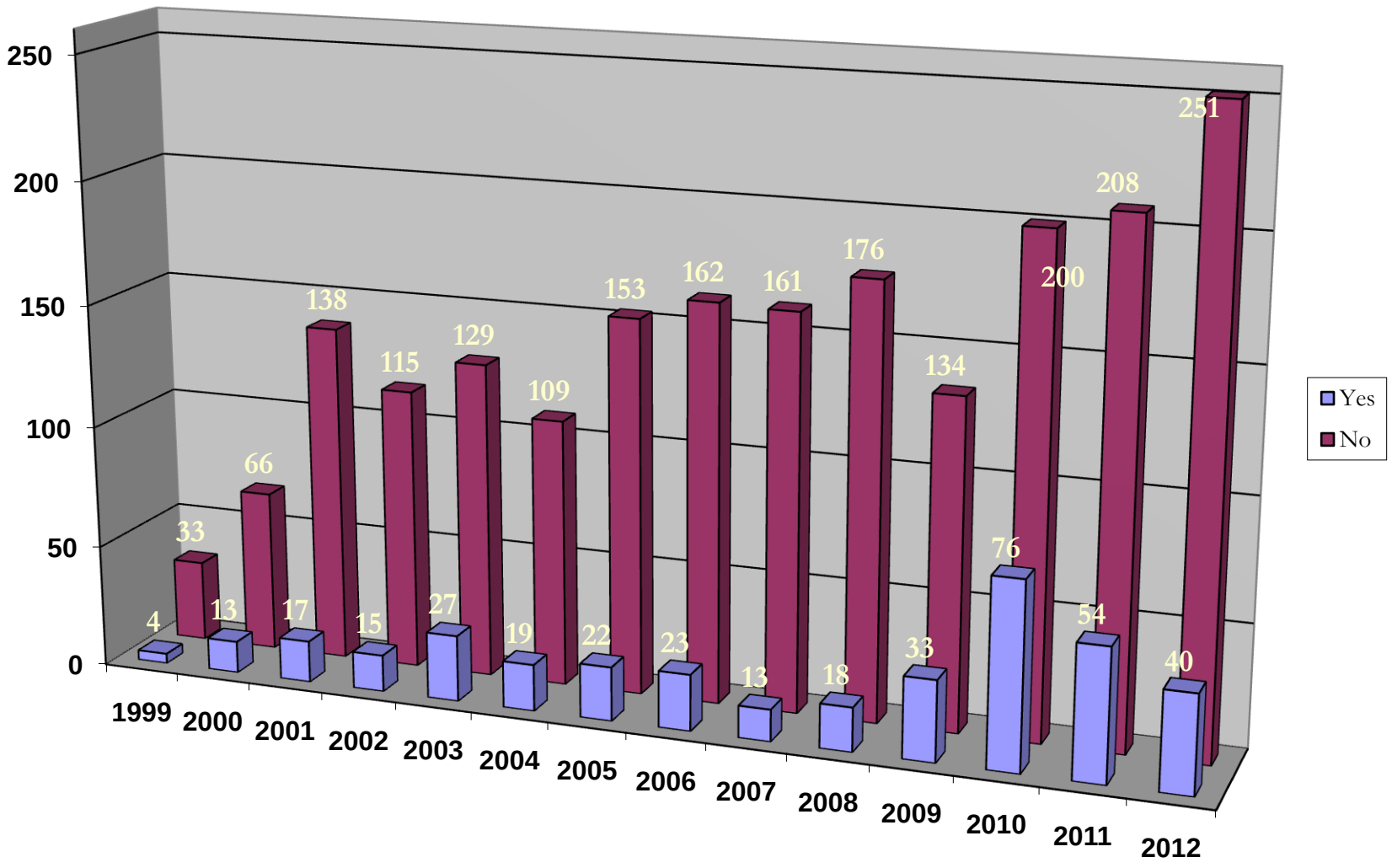
Numbers of NCARs Represented by Device Sectors



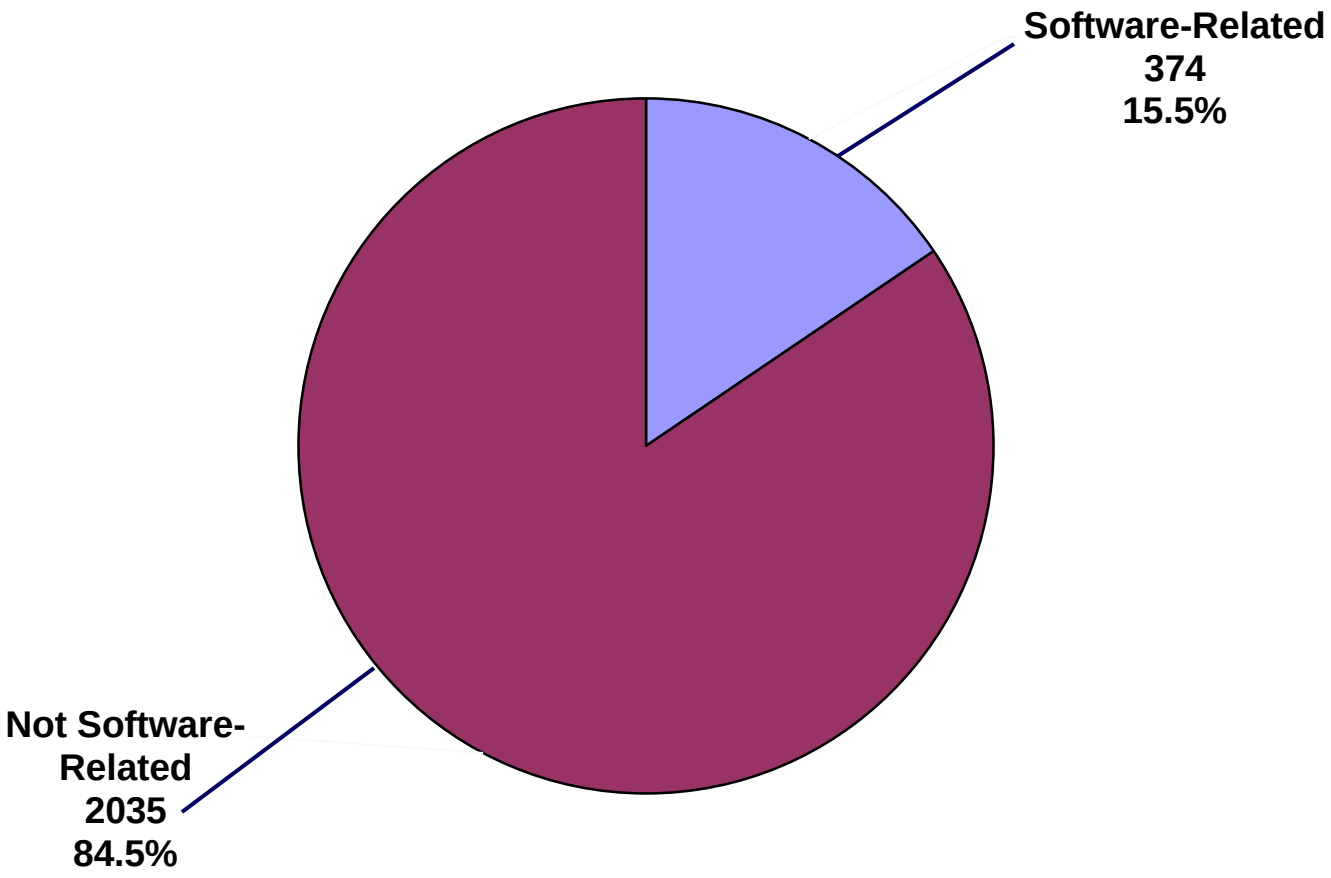
Total Number of NCARs Represented by Actions Taken



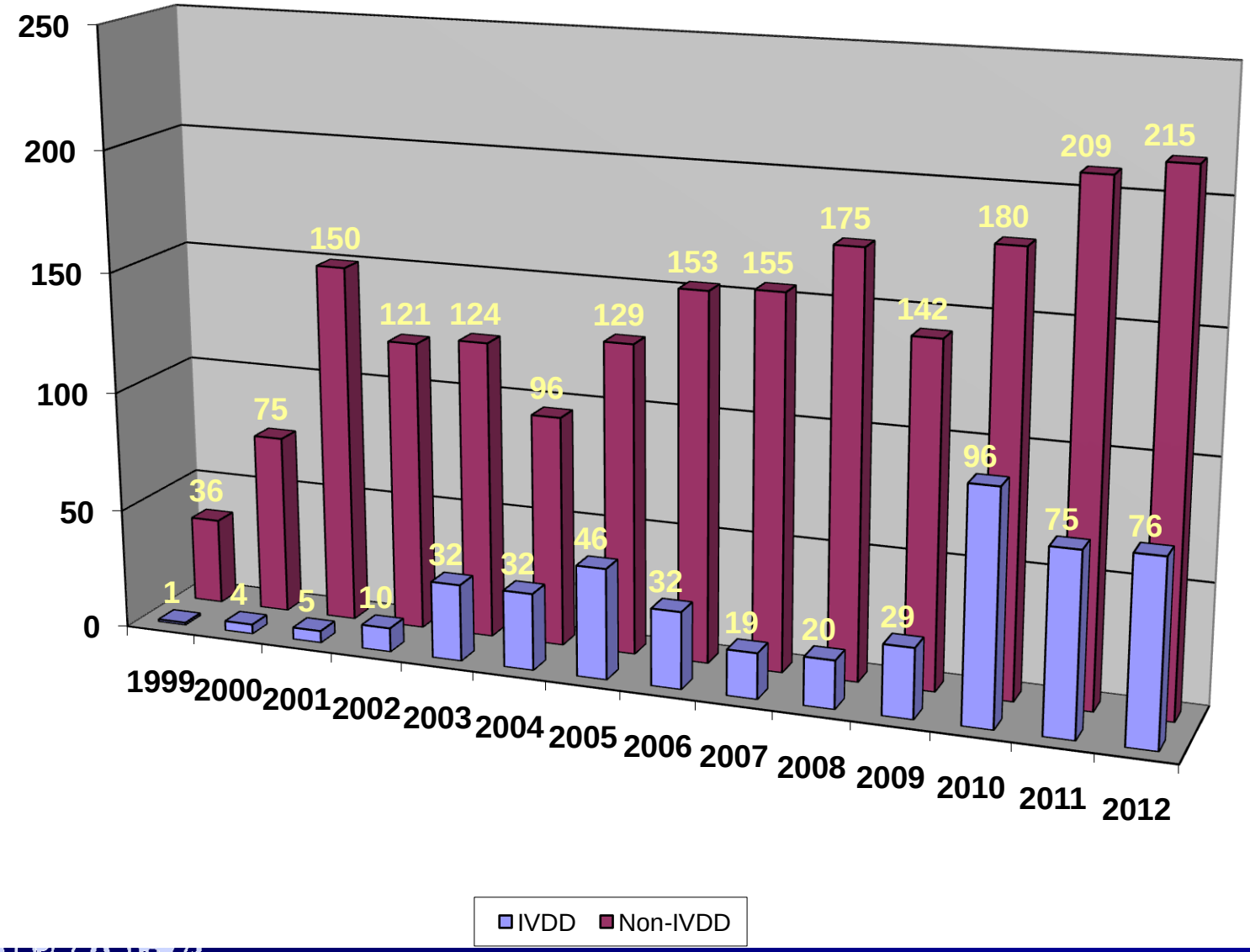
NCARs with Software-Related Corrective Actions



NCARs with Software-Related Corrective Actions



Numbers of NCARs that are related to IVDDs



Number of NCARs that are related to IVDDs