

GHTF SG2:

National Competent Authority Report Program



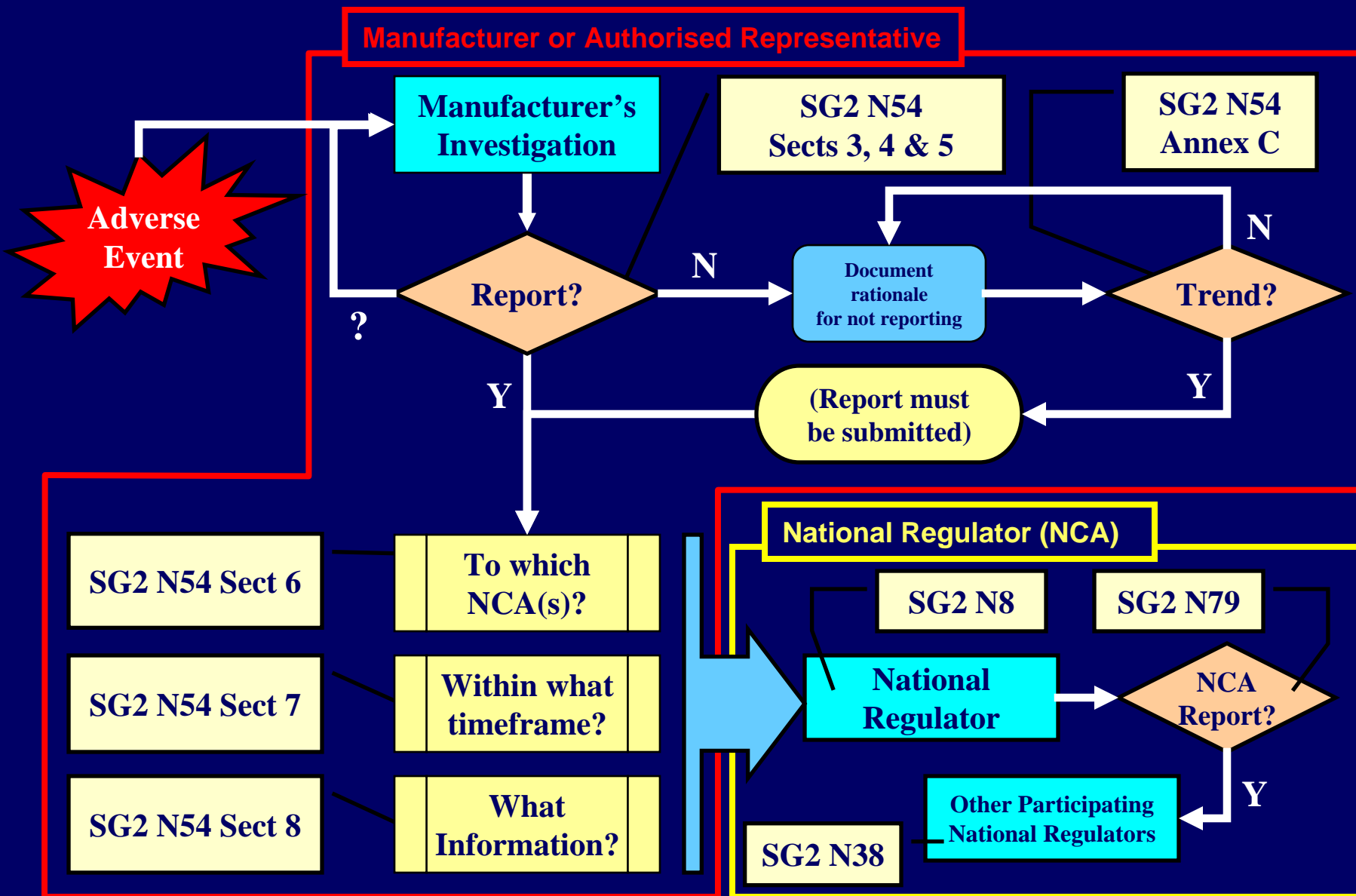
Ekkehard Stösslein – BfArM Germany

Jorge Garcia – TGA

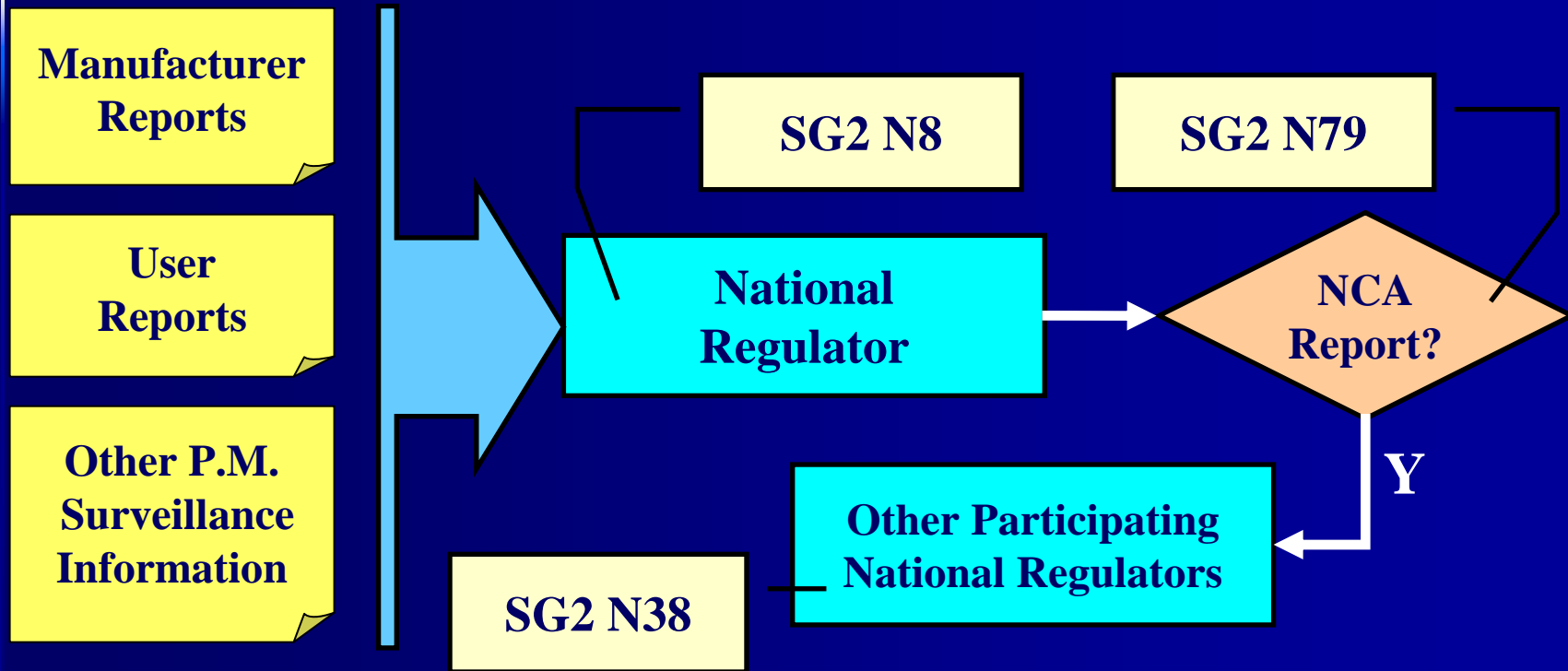
Mark Segstro – Health Canada

Deborah Yoder – FDA

Map of SG2 Guidance on AE Reporting



Handling Adverse Event Reports: NCA Systems



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

- 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



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.”



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
<i>Prerequisites</i>		
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
<i>A commitment to:</i>		
Confidentiality	No	Yes
Full Participation	No	Yes
Single Contact Point	Yes	Yes
Must be NCA	No	Yes



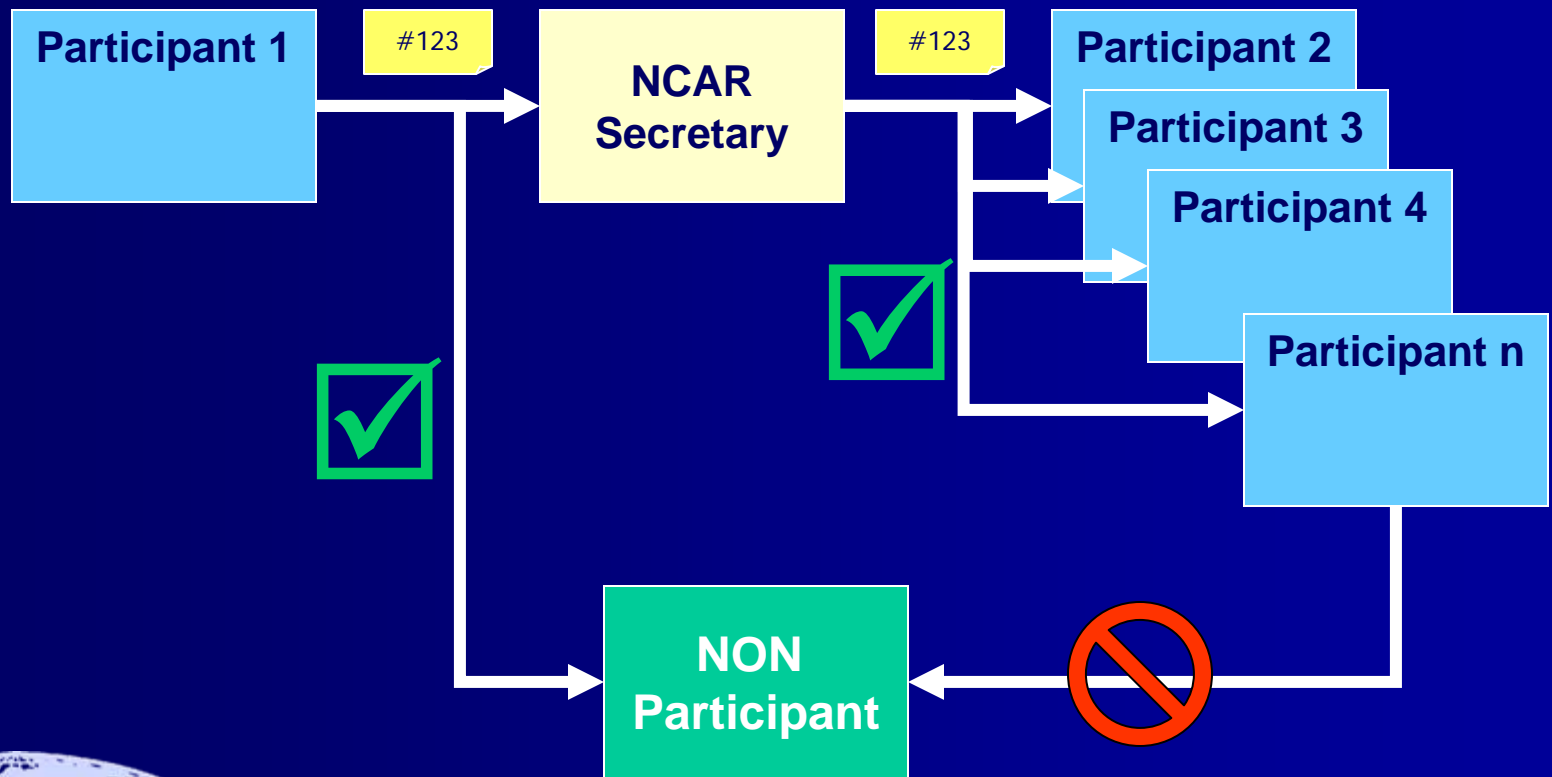
Participation: Important Commitments

- 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



SG2 - Final Documents - Microsoft Internet Explorer

Address: <http://www.ghtf.org/sg2/final.html>

Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

Home > Study Group 2 (SG2) > Final Documents

SG2 - Final Documents

Title	Description	Posted Date	Size	Comments To
SG2-N54R8:2006 PDF Word	Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices	18 December 2006	37 pages	Jorge Garcia
SG2-N57R8:2006 PDF Word	Medical Devices Post Market Surveillance: Content of Field Safety Notices	31 August 2006	6 pages	
SG2-N79R8:2006 PDF Word	Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form	31 August 2006	13 pages	
SG2/N47R4:2005 PDF Word	Review of Current Requirements on Postmarket Surveillance	01 February, 2006	10 pages	
SG2/N68R3:2005 PDF Word	Summary of Current Requirements for Where to Send Adverse Event Reports	01 February, 2006	5 pages	
SG2/N38R15 PDF Word	Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program	08 August, 2005	9 pages	
SG2/N31R8 PDF	Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their	22 December, 2003	11 pages, 62.14Kb	



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., DE-BfArM-2008-10-08-030



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 from #6)

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 must 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

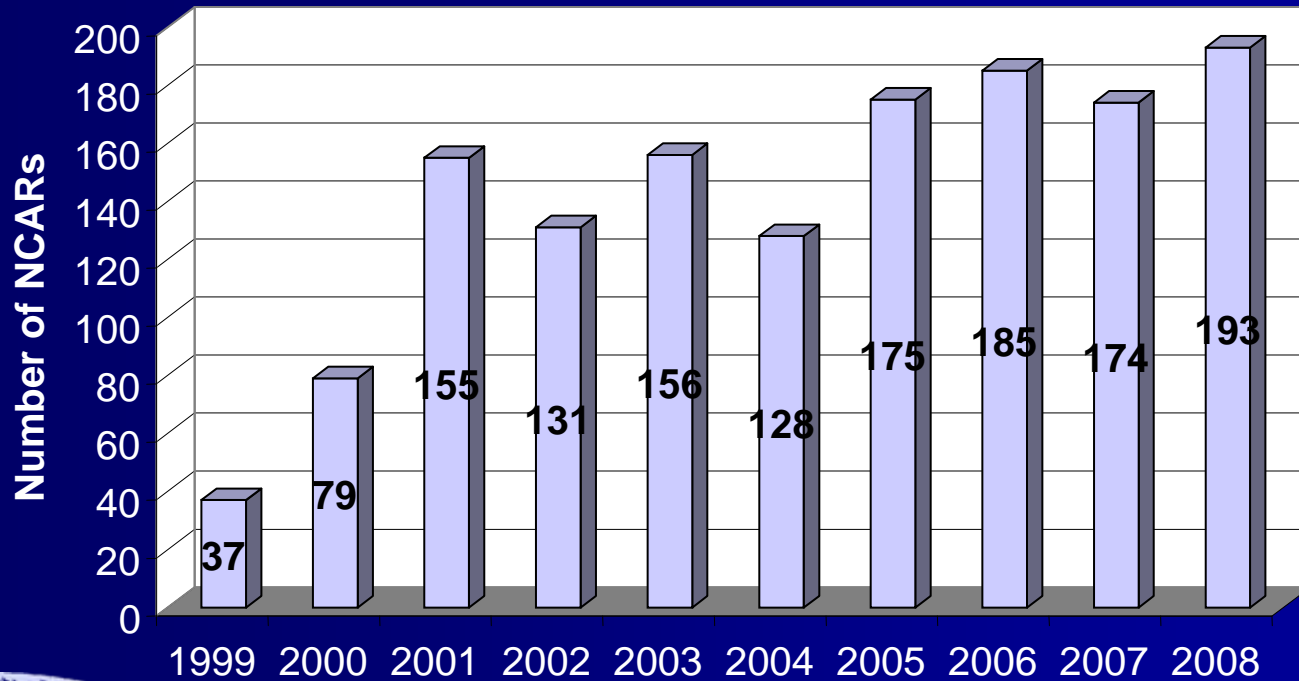


NCAR Exchange Program - Statistics



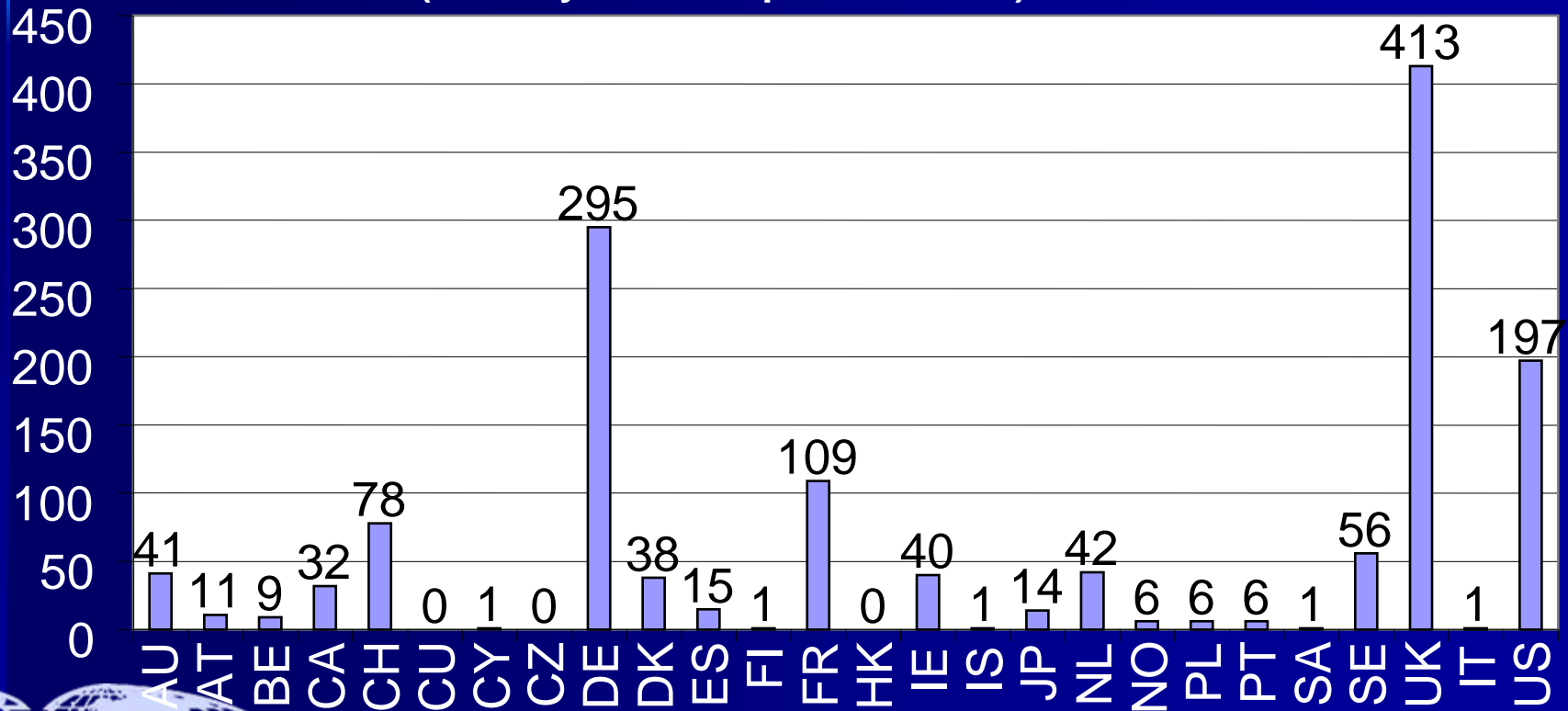
NCAR Exchange Program - Statistics

NCARs Exchanged (total = 1,413)



NCAR Exchange Program - Statistics

Countries that send NCARS (January 1999 - September 2008)



NCAR Exchange Program - Statistics

- Cardiovascular – 290 NCARs (20.5 %)
- General Hospital – 213 NCARs (15.1%)
- Orthopaedics – 120 NCARs (8.3 %)
- General/Plastic Surgery – 110 NCARs (8.0 %)
- Radiology – 97 NCARs (7 %)
- Anaesthesia – 92 NCARs (6.5 %)



Thanks for Your Attention!

Questions??

