Subject 3. Medical Device Vigilance
VOD lectures
“Introduction to Medical Device Adverse Events”

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in 2020 AHC SCH Medical Device
CoE Pilot Tranining

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JIRA

Introduction of Training

- Training Topics
  - “Introduction to Medical Device Adverse Events”
- Abstract of Topics
  - This section provides an overview of vigilance systems. Within the Vigilance System, the Adverse Event is a key element of global convergence and is outlined in accordance with Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N 54 R8: 2006).
- Introduction of Speaker
  - Mr. Naoki Morooka

Mr. Naoki Morooka is working in SHIMADZU CORPRATION as Senior Manager for RA, QMS and Product Safety, and he is Vice Division Chairman of Regulatory and Safety in JIRA. He is also co sub-champion of Medical Device PWA of APEC. He has long experience in global convergence activities such as GHTF, IMDRF or APEC.

Contents of Presentation

- Outline for Medical Device Vigilance based on GHTF/IMDRF Regulatory Model
- AER(Adverse Event Report)
- FSCA(Field Safety Corrective Action)
- NCAR(National Competent Authority Report)

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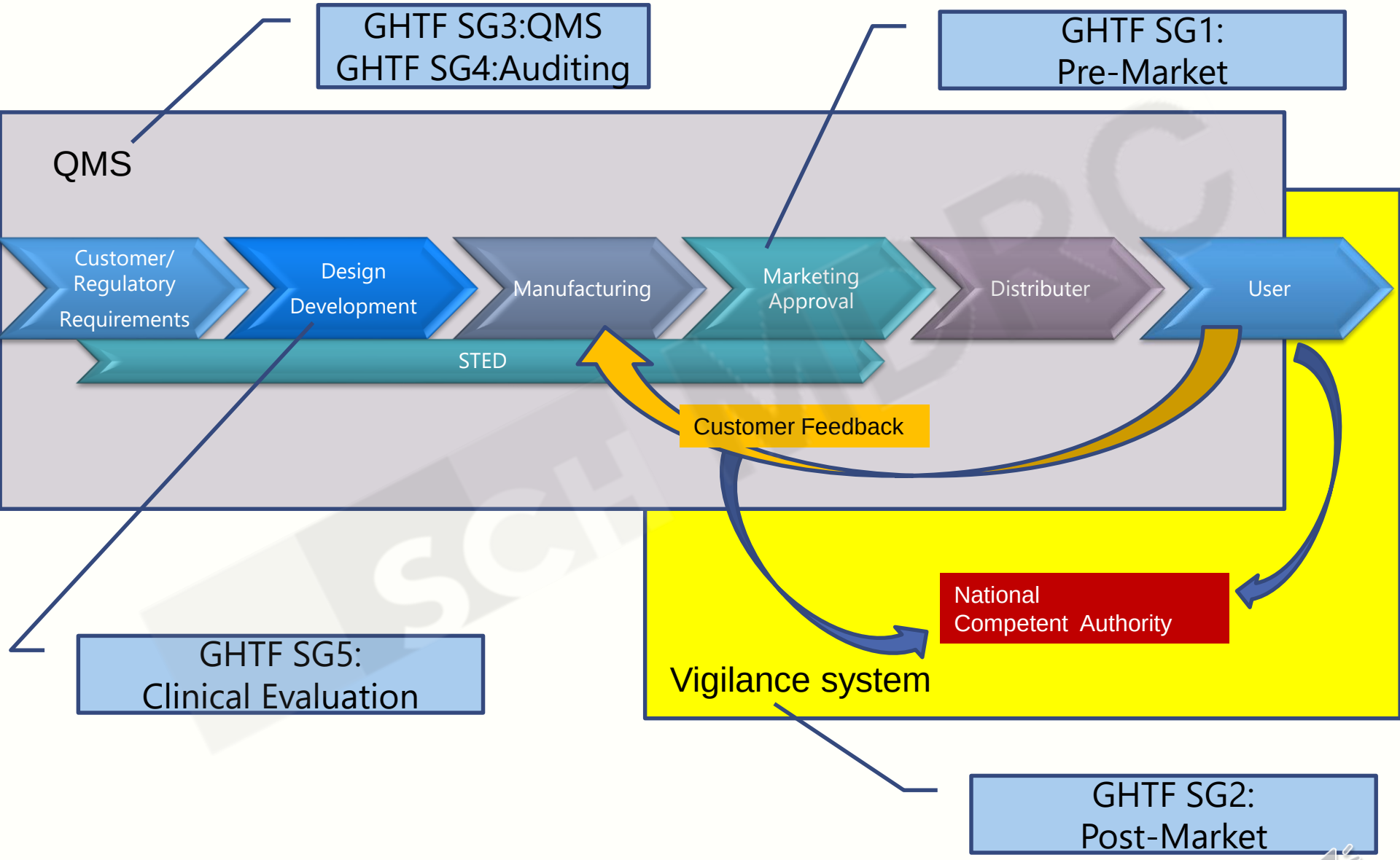
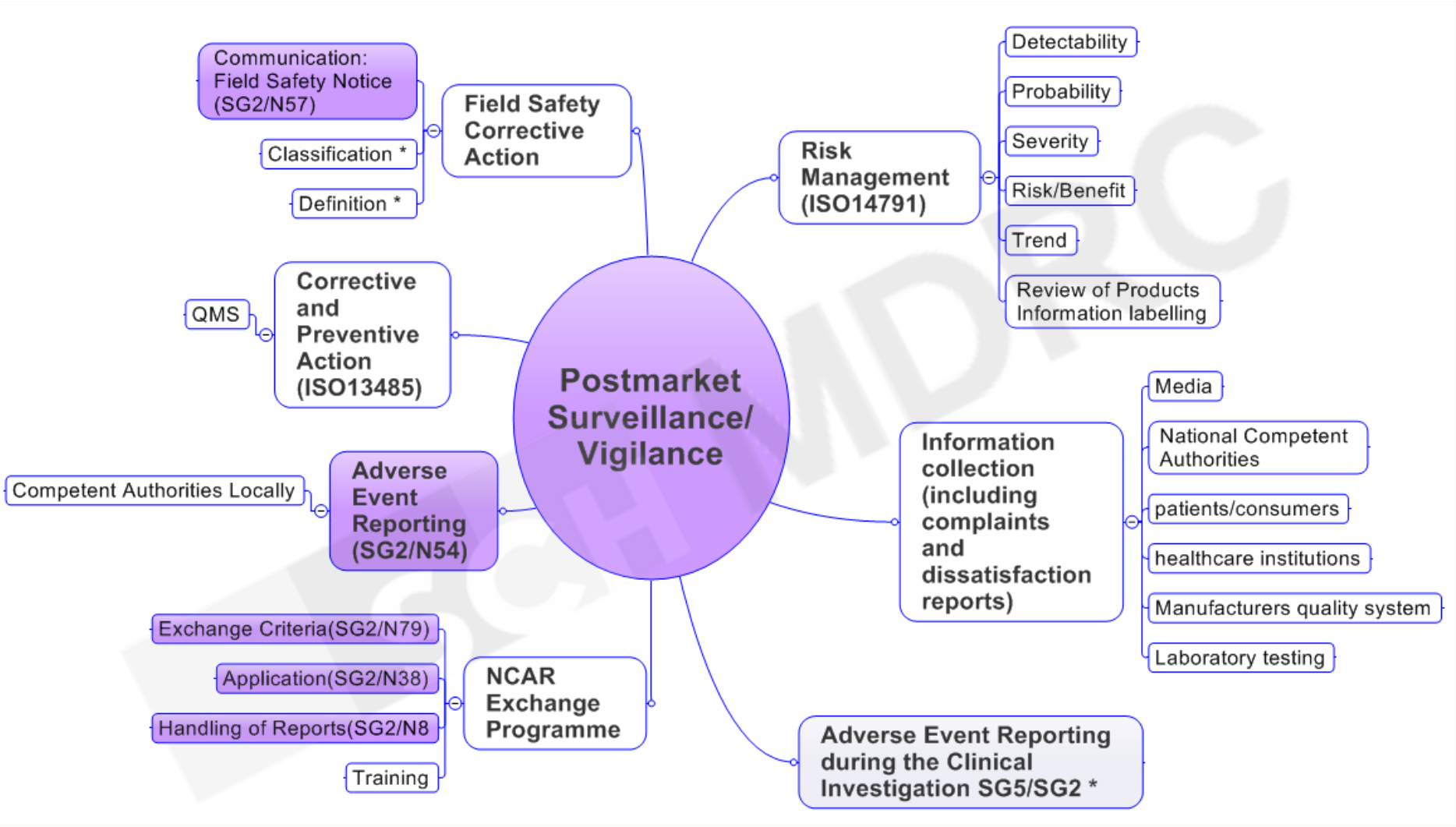
Outline for Medical Device Vigilance based on GHTF/IMDRF Regulatory Model

GHTF Regulatory Model & Role of SG



GHTF Regulatory Model for Post-Market



Ref.: GHTF/AHWG-GRM/N1R13:2011 Regulatory Model

Post Market Vigilance & Surveillance

■ Post-market Vigilance

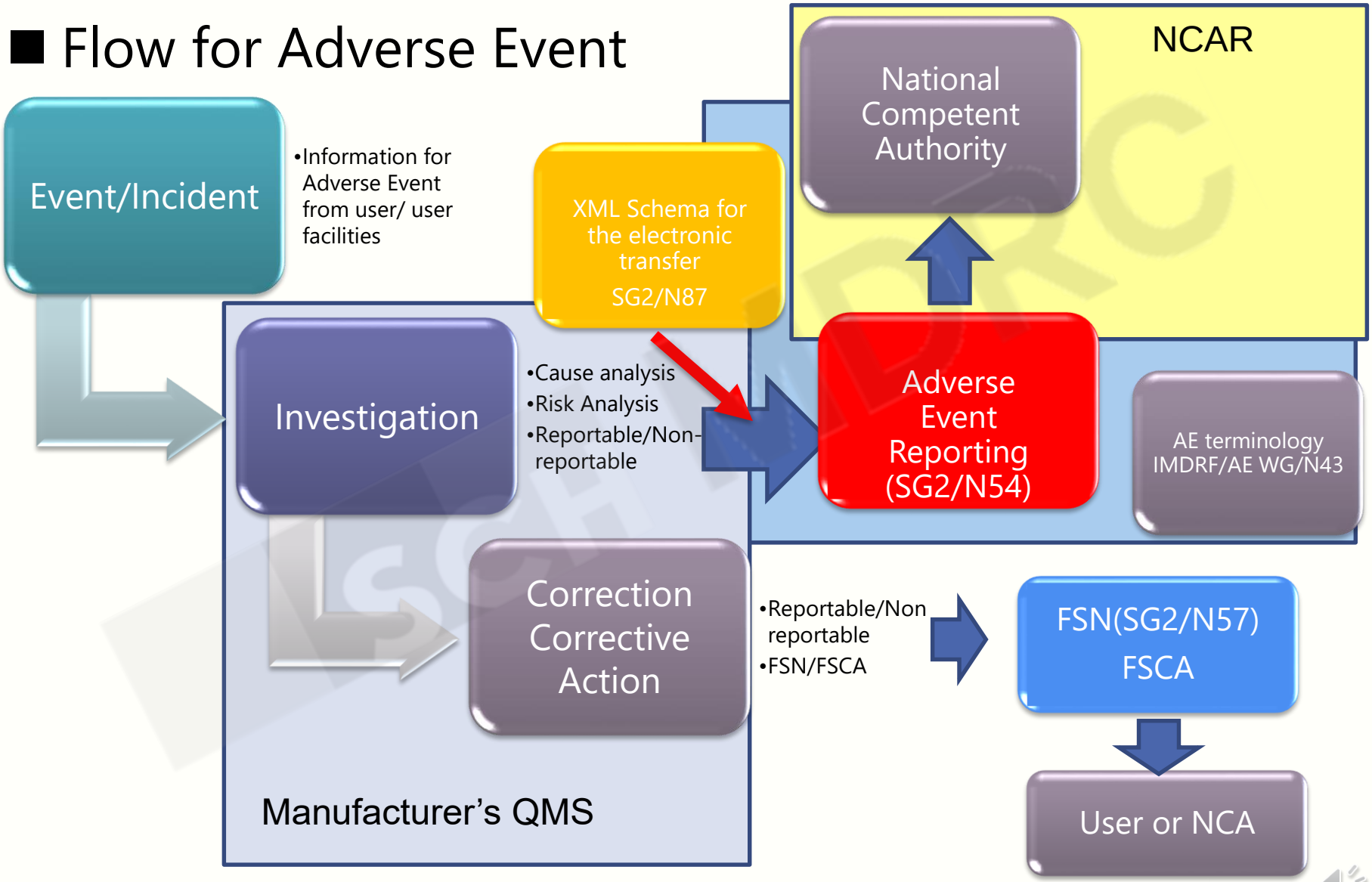
- Vigilance is the reporting and investigation of adverse events (AE) and incidents.
- Both the manufacturer and the Regulatory Authority play major roles.

■ 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.

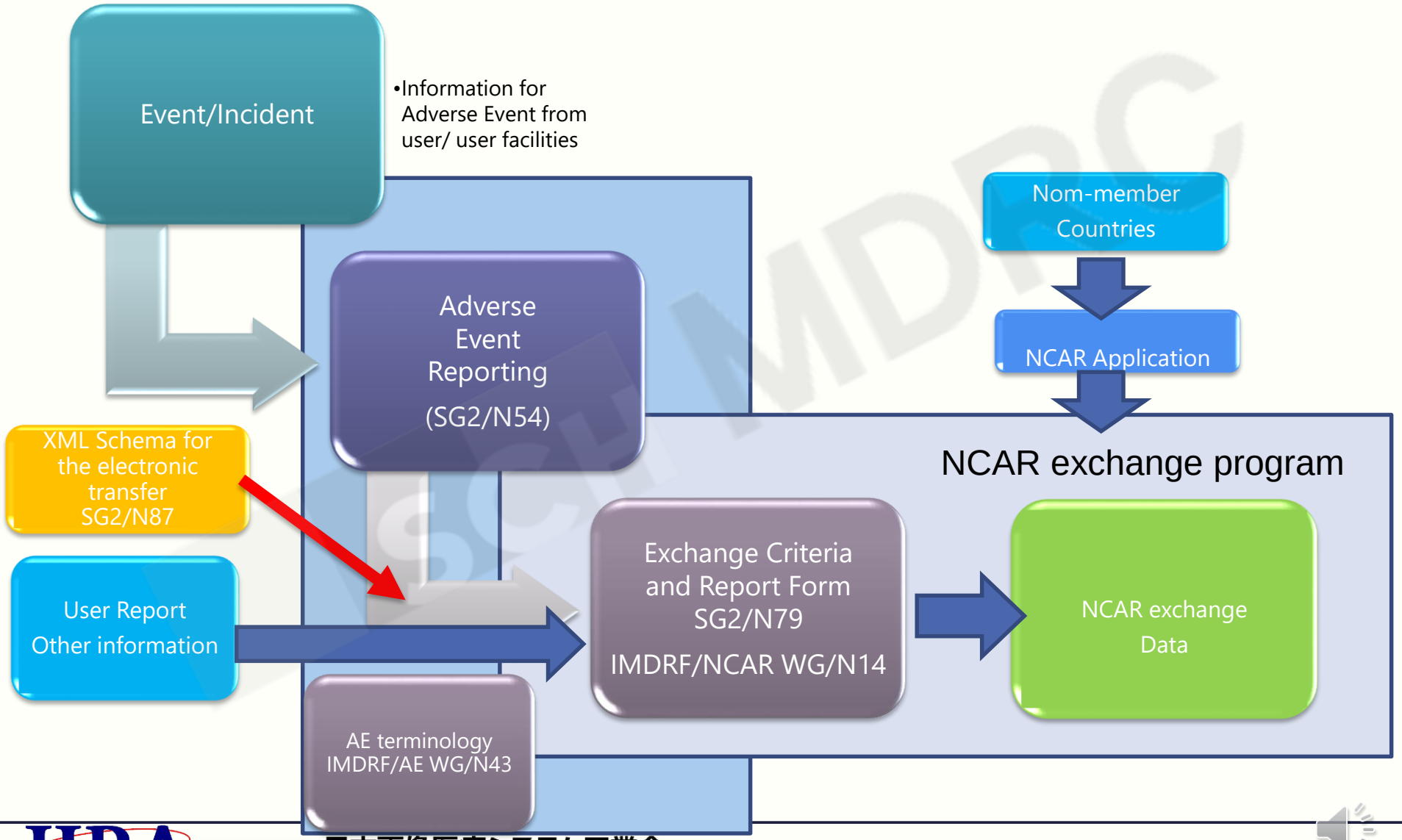
Adverse Event and FSN/FSCA

■ Flow for Adverse Event



NCAR

■ Flow for NCAR



Role in Vigilance & Surveillance

■ Role

	Post-market
National Competent Authority (NCA)	• Establish Adverse Event Report (AER) Requirements (N54) • Establish and maintain national vigilance database • Evaluate AER received • Monitor mfr. Investigation and Field Safety Corrective Actions (FSCA - N57) • Handle information concerning AE reports (N8) • Exchange information through GHTF NCAR system (N79)
Conformity Assessment Body (CAB)	• Assess mfr. Post Market Surveillance (PMS) and vigilance reporting systems during QMS audits • Assess mfr. Field Safety Corrective Action systems during QMS audits
Manufacturer	• Establish and maintain PMS system (part of QMS) • Prepare and submit vigilance reports (N54) • As appropriate, conduct Field Safety Corrective Actions (FSCA - N57)

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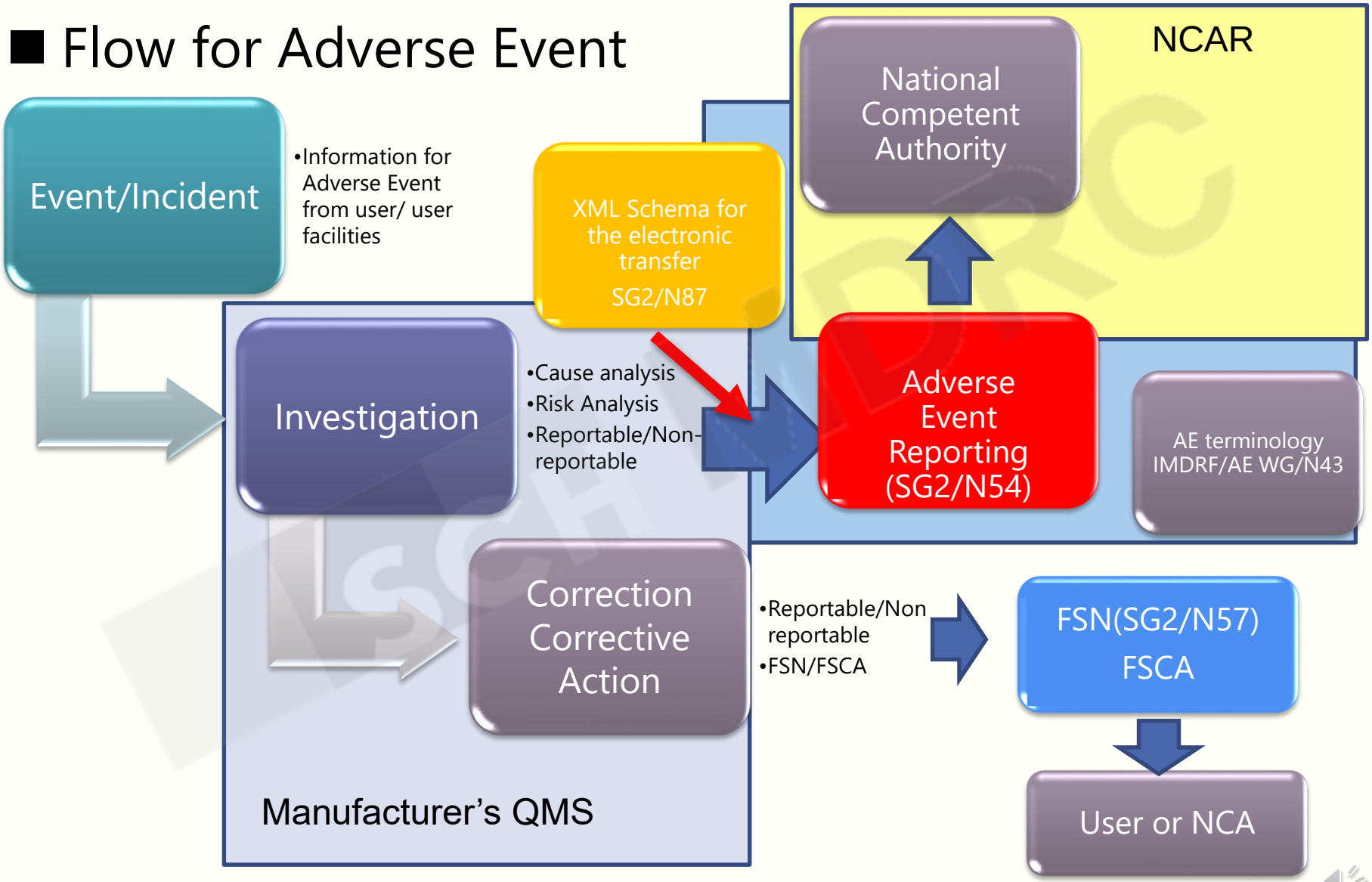
Adverse Event Reporting

Adverse Event and FSN/FSCA

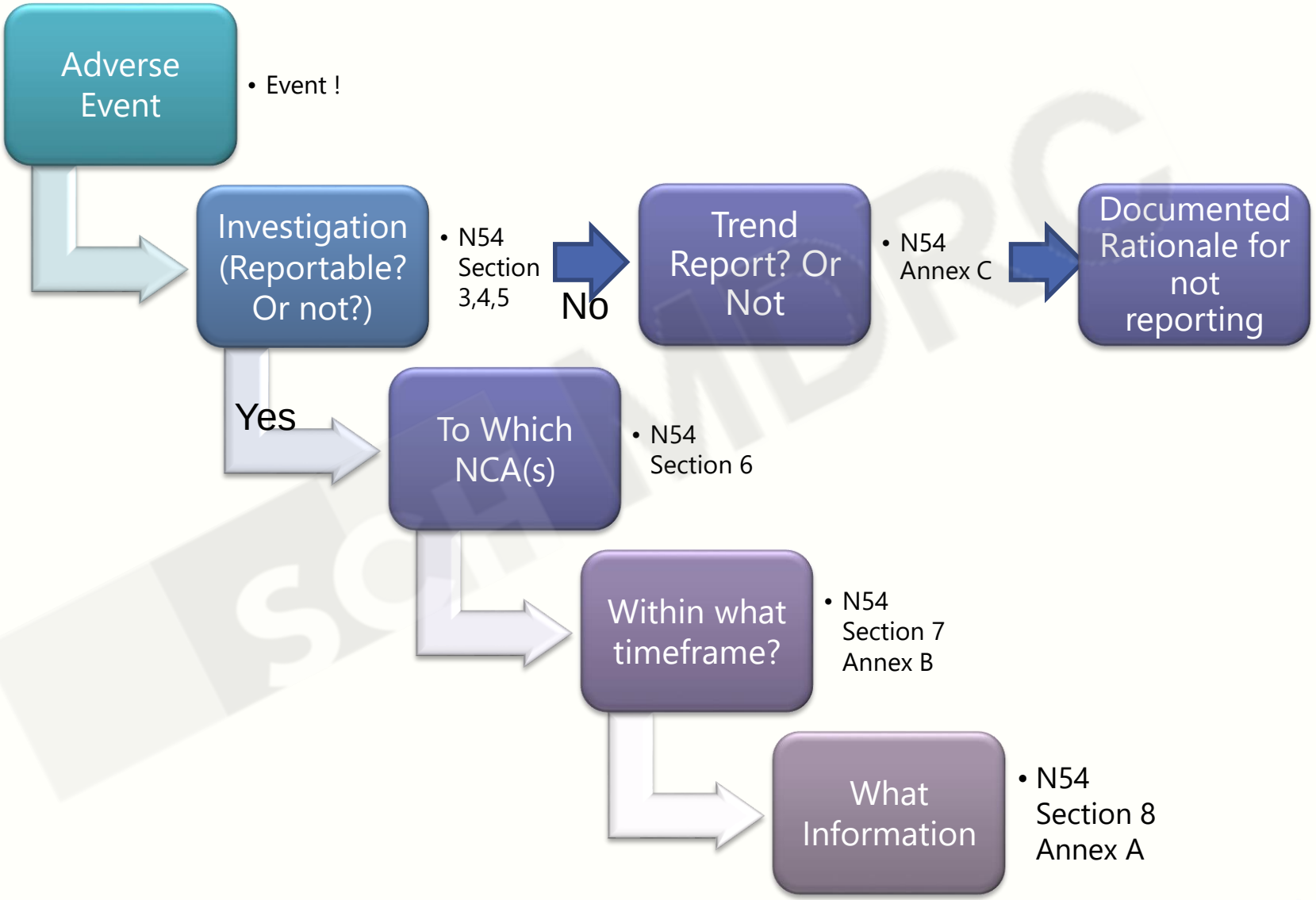
■ Flow for Adverse Event



AE Reporting - GHTF/SG2/N54R8

- 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

AE Reporting - GHTF/SG2/N54R8



AE Reporting Criteria

- Reporting Criteria (Section 3)
  - 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

AE Reporting Exemption

- Exemption (Section 4.1-4.8)
  - Deficiency of a new device found by the user prior to its use
  - Adverse event caused by patient conditions
  - Service life or shelf life of the medical device
  - Malfunction protection operated correctly
  - Negligible likelihood of occurrence of death or serious injury
  - Expected and foreseeable side effects
  - Adverse events described in an advisory notice
  - Reporting exemptions granted by NCA
- Other Considerations (Section 4)
  - 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

Consideration Use Error/Abnormal Use

- Use Errors (Section 5+ Annex D)
  - 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.
- Abnormal Use (Section 5 + Annex D)
  - 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.

Who should report?

To Whom To Report (Section 6)

- 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

AE Reporting Timing

■ Reporting Timeframes

- Immediately (not later than 10 elapsed calendar days)
  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
- not later than 30-elapsed calendar days
  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
  - ✓ 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

AE Report Contents

■ Report Data Set (Section 8 and Annex A)

- 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

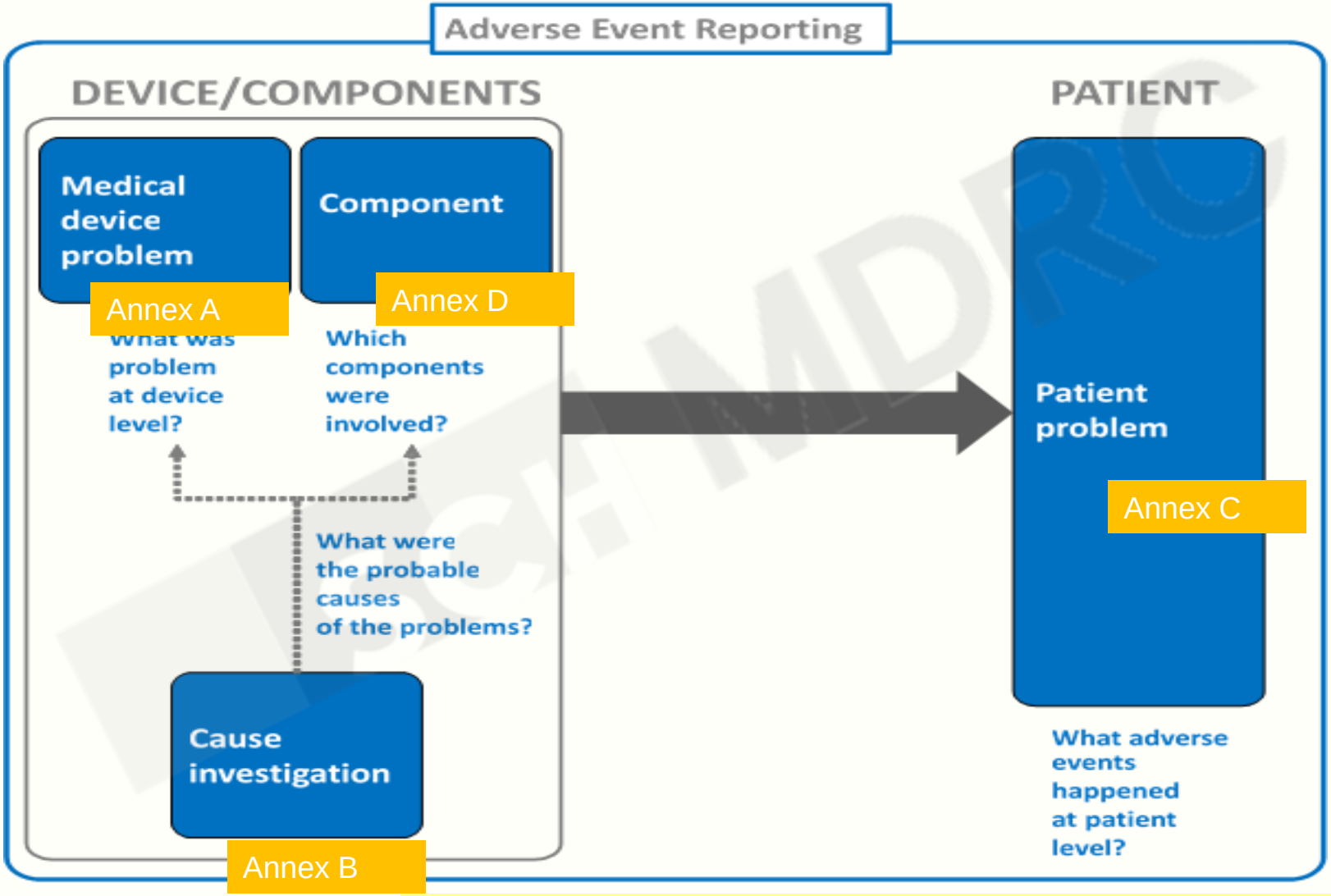
AE Terminology and Coding

■ AE Terminology and Coding (IMDRF/AET WG N43)

- Development of a harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics (IVDs).
- Benefits;
  - ✓ Improved accuracy of capturing and reporting of medical device related adverse events,
  - ✓ Reduced ambiguity, hence increased effectiveness of the evaluation process, and
  - ✓ Better usability, in contrast to narrative text;

AE Terminology and Coding

■ Construction of AET WG N43



IMDRF/AET WG/N43 AE terms, Temininology structure and Codes, Maintenance

AE Terminology and Coding

- Annex A: Medical Device Problem
  - Based on FDA/NCI terms and ISO/TS 19218 terms
  - 3 level hierarchical coding structure
  - Consist of IMDRF codes, terms and definitions
- Annex B: Cause Investigation
  - Based on FDA/NCI terms and ISO/TS 19218 terms
  - Consist of IMDRF codes, terms and definitions
  - 3 sections
    - ✓Section1: Type of Investigation (1 level)
    - ✓Section2: Investigation Findings (3 levels)
    - ✓Section3: Investigation Conclusion (2 levels)
- Annex C(Patient Problem), D(Component); under discussion

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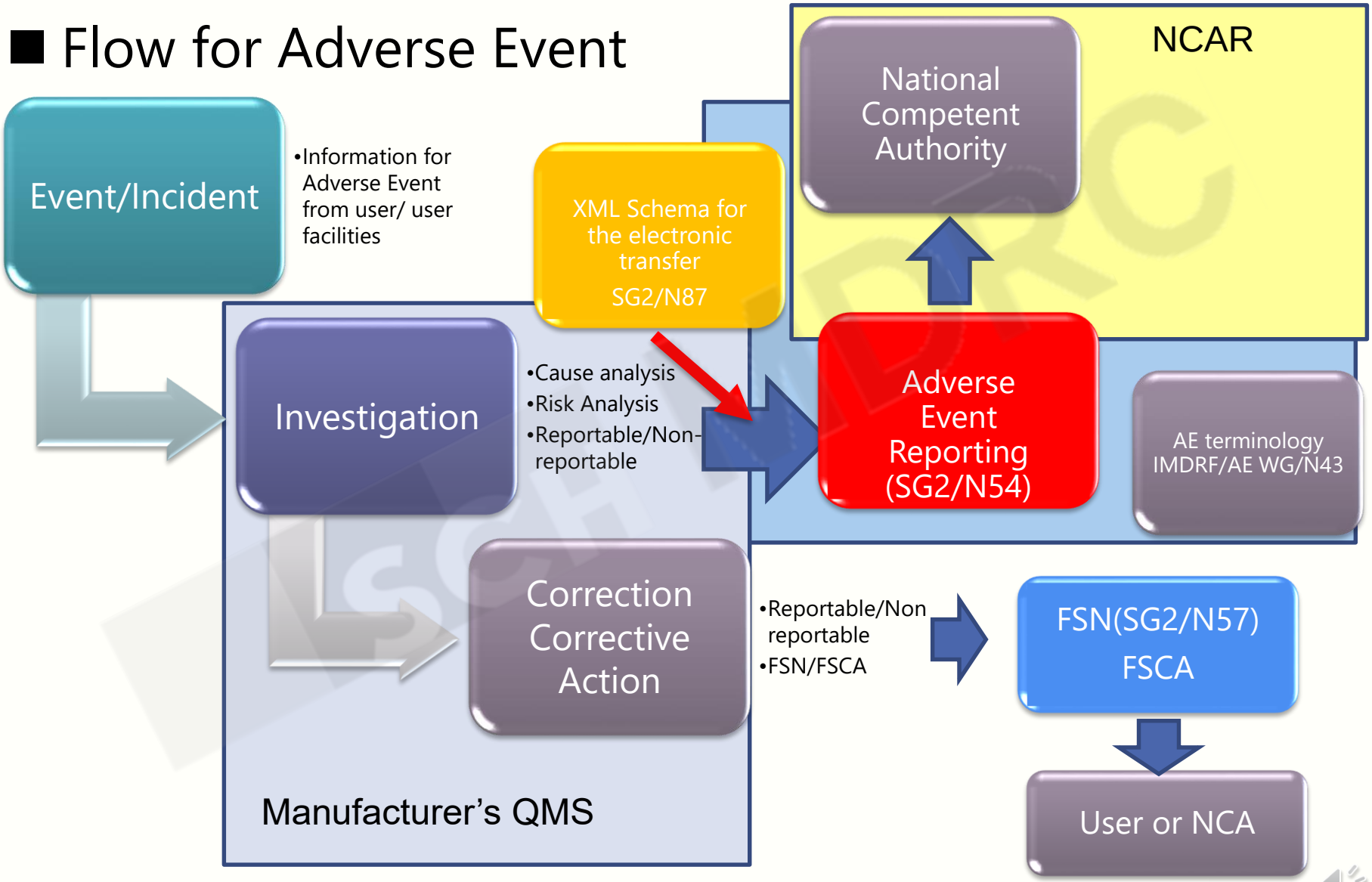
Field Safety Corrective Action

Adverse Event and FSN/FSCA

■ Flow for Adverse Event



FSCA&FSN

■ FSCA (Field Safety Corrective Action)

- A field safety corrective action (FSCA) is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device.
- This may include:
  - ✓ the return of a medical device to the manufacturer
  - ✓ device modification ;
  - ✓ device exchange;
  - ✓ device destruction;
  - ✓ advice given by manufacturer regarding the use of the device
- Device modifications may include:
  - ✓ retrofit in accordance with the modification or design change;
  - ✓ permanent or temporary changes to the labelling or IFU;
  - ✓ software upgrades including those carried out be remote access;
  - ✓ modification to the clinical management of patients to address a risk of serious injury or death related.

FSCA&FSN

- FSN (Field Safety Notice)(GHTF/SG2/N57/8)
  A communication sent out by a manufacturer or its representative to the device users in relation to a Field Safety Corrective Action.
  - A clear title like “Urgent Safety Notice”
  - Intended recipient of the notice.
  - Concise description of subject device, model/batch/serial number
  - Explaining the reasons for the FSCA, including description of the problem
  - Description of the hazards
  - The recommended action(s)
  - Where appropriate, include time frames by which the action(s) should be taken by the manufacturer and user.
  - Designated contact point

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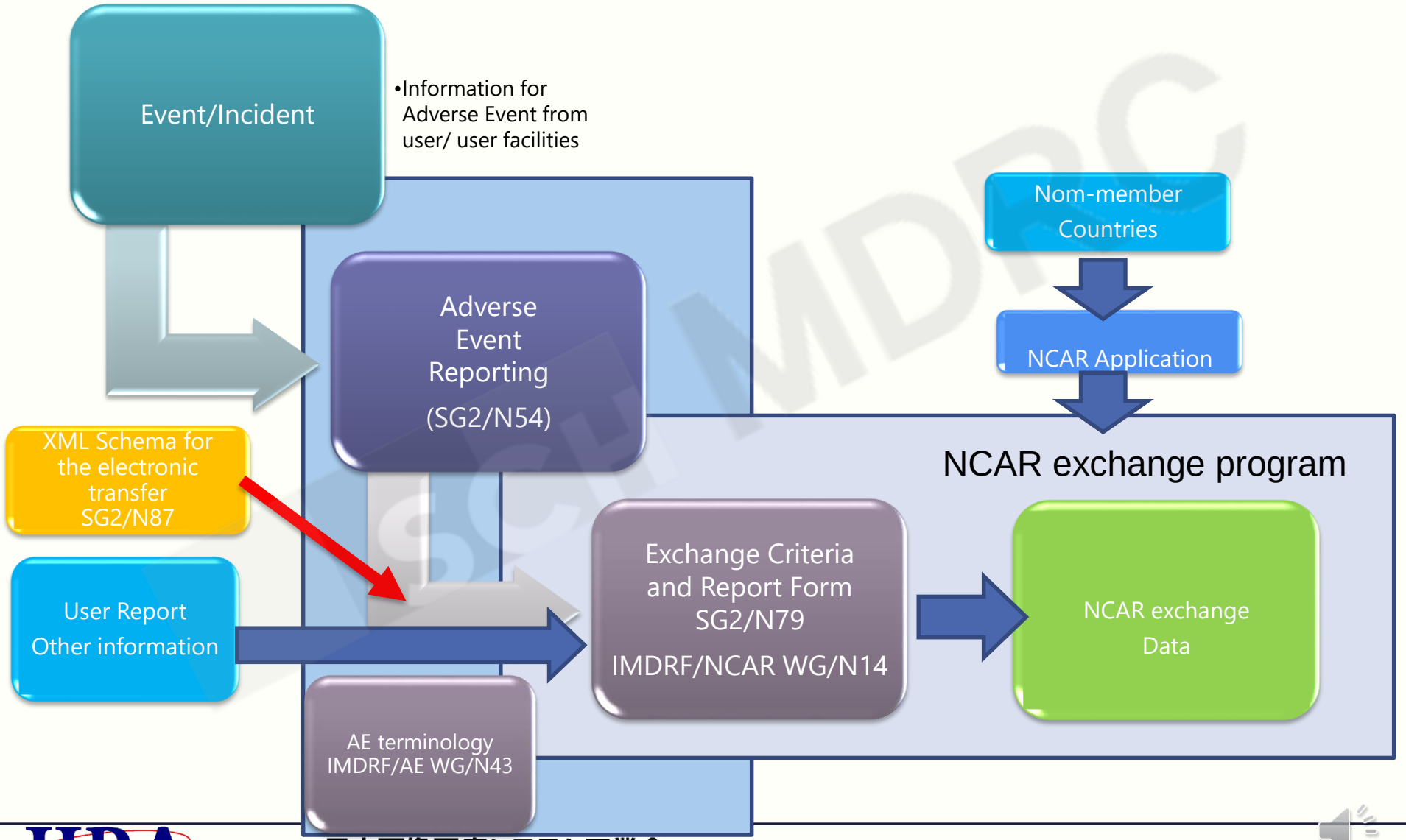
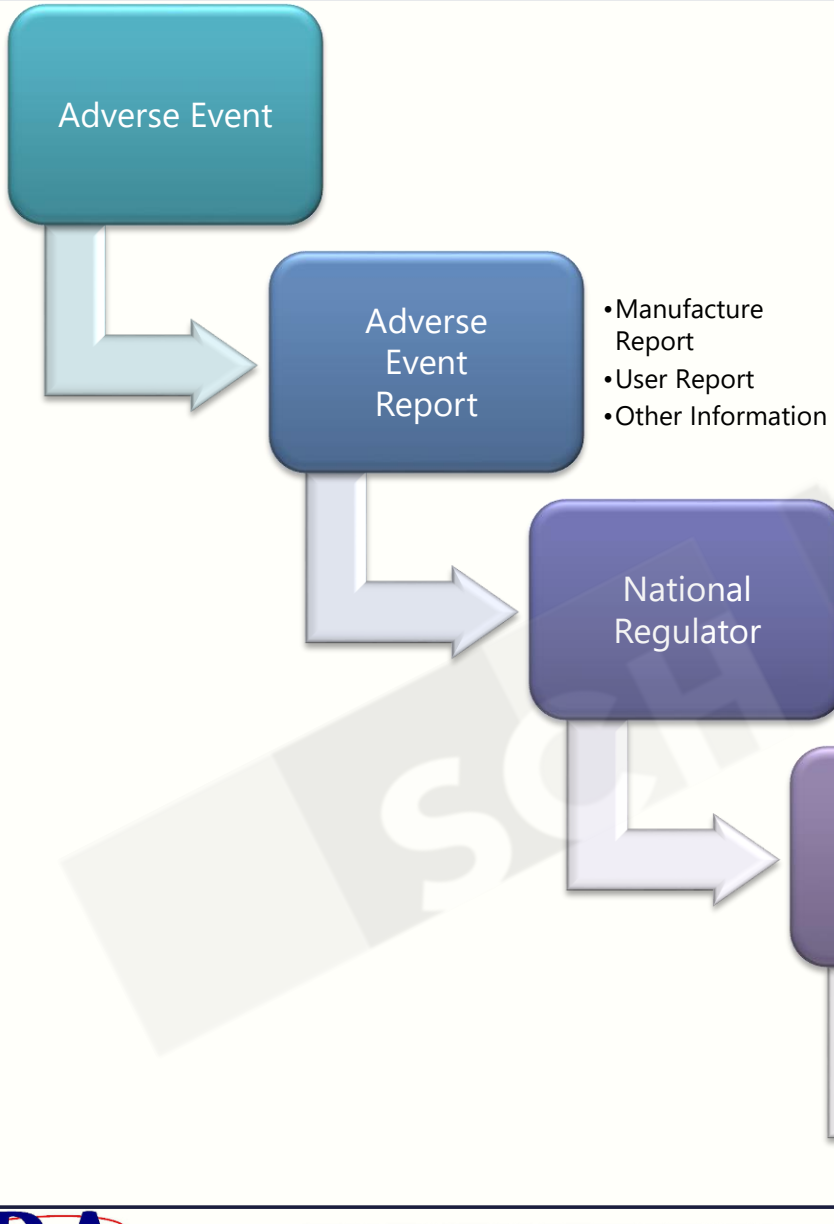
NCAR

NCAR

■ Flow for NCAR



NCAR



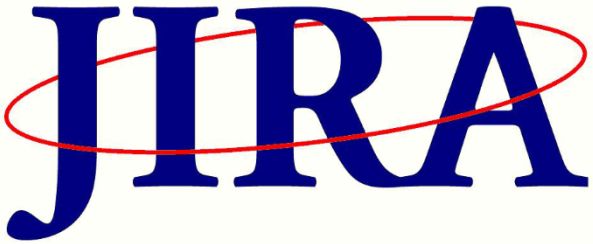
GHTF/SG2/N79
IMDRF NCAR WG/N14

• N54 Section 8 Annex A

Summary of Section

- Key elements of Medical Device Vigilance
  - AER & AET

- AER
  - Harmonized Reporting Criteria
  - Timeline
    - ✓Immediately (not later than 10 elapsed calendar days)
    - ✓or not later than 30-elapsed calendar days.
- AET
  - Good communication tool for AER between Manufacturer and Regulatory Authorities.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