Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Post-Market Surveillance

A Product Regulator's View

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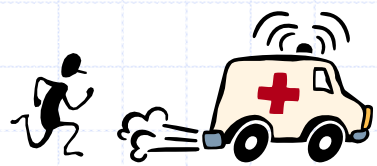
Chair GHTF SG2



Seminar Outline

- Definitions Post-Market Vigilance and Post Market Surveillance
- A little bit of post-market philosophy
  - Tools needed for Post-Market Surveillance
  - Residual risk, risk classification and risk management
- Case Study: Implementation of GHTF SG2 Guidance in Australia
- TGA's Post Market Surveillance Systems

Definitions first...

“Danger! What danger do you foresee?”

Holmes shook his head gravely. “It would cease to be a danger if we could define it,” said he.

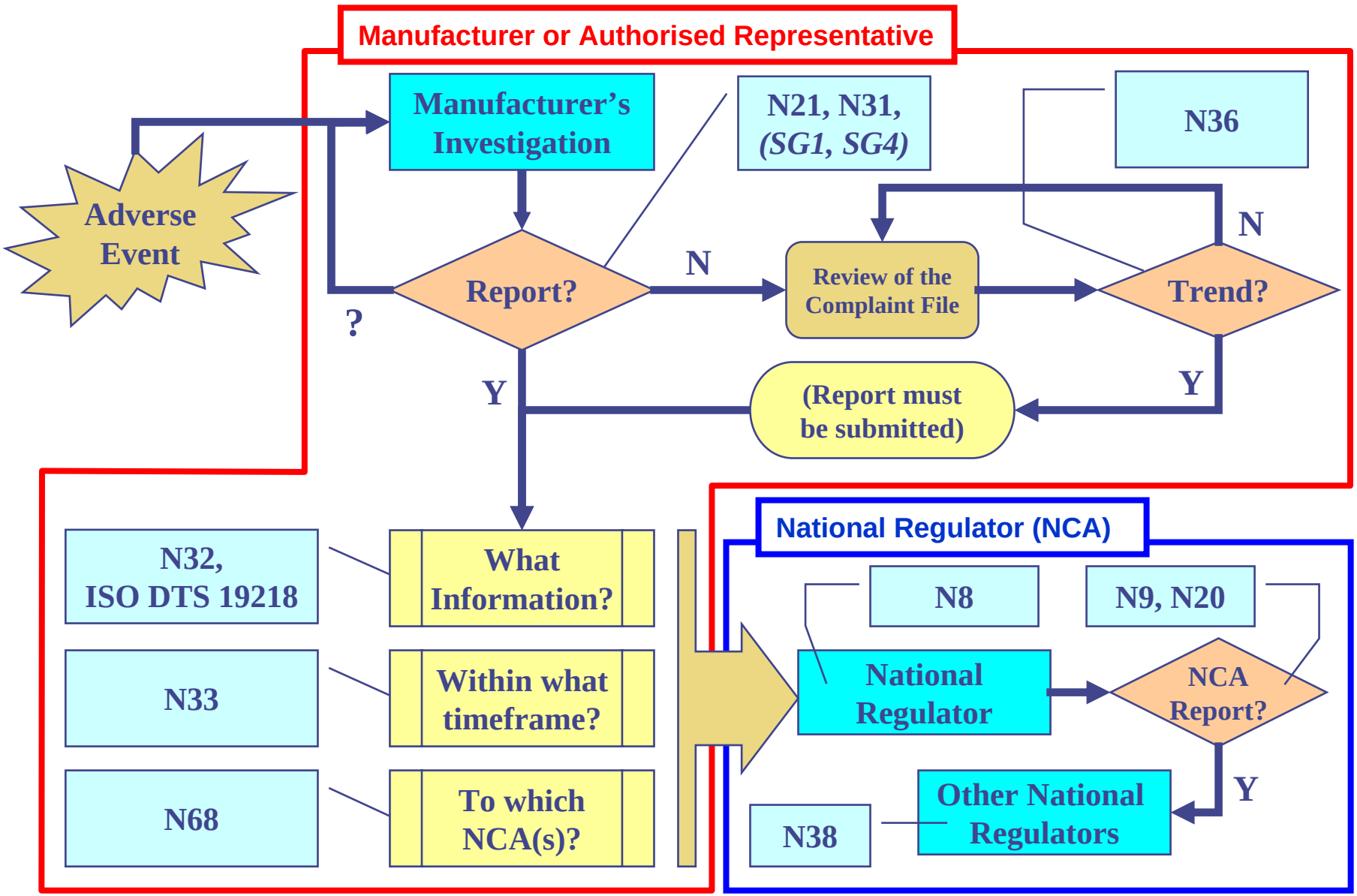
Sir Arthur Conan Doyle, The Adventures of Sherlock Holmes: The Adventure of the Copper Beeches, 1891.

Post-Market Vigilance

- Broadly speaking: (Post-Market) Vigilance is the reporting and investigation of medical device adverse events and incidents. Both the manufacturer and the Regulatory Authority play major roles.

- By its very nature, Vigilance is a REACTIVE activity *(the manufacturer or authority receive reports and REACT to them)* - this is not intended to be a derogatory statement

Map of SG2 Guidance on Vigilance



Post-Market Surveillance: GHTF SG2

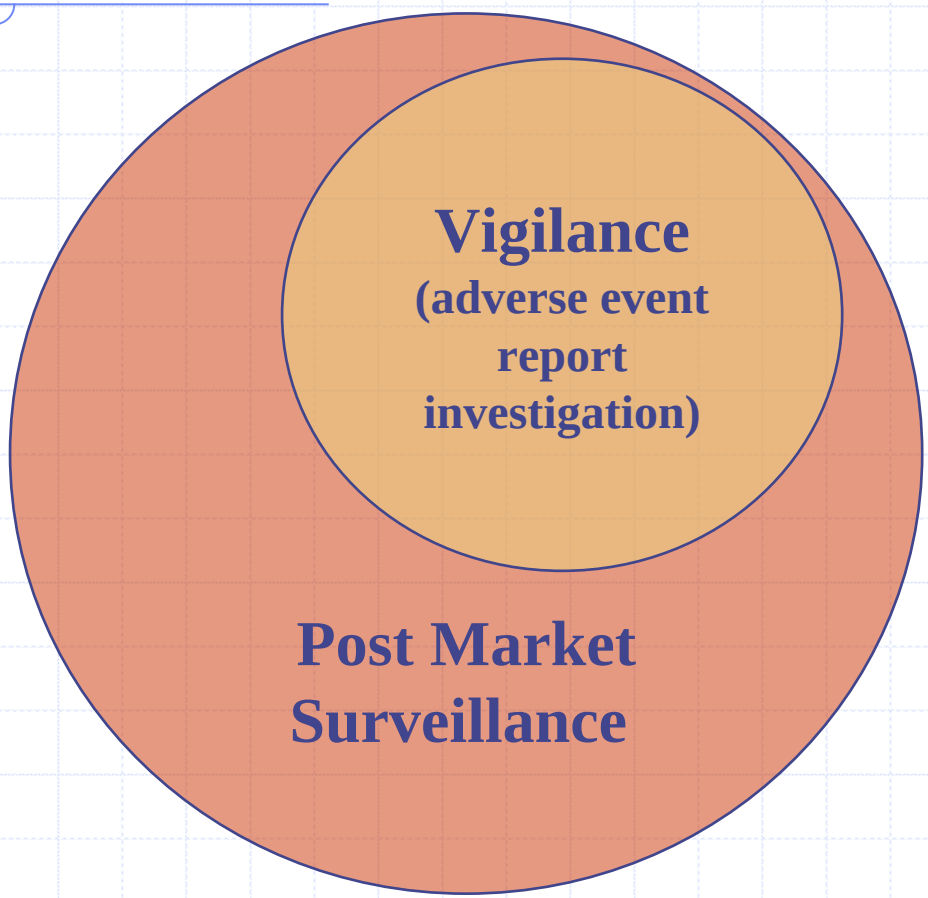
- GHTF SG2 finished VIGILANCE guidance first, and then asked: What's post market surveillance?
- Then suggested a common definition:

  "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

Summary GHTF SG2 documents

- **N 47R4** Review of Current Requirements on Postmarket Surveillance.
  - Approved SC. To be posted on the website
- **N61R4** PMS harmonization chart
  - Presented as a report to SC. Other SG's to consider
- **N57R4** Harmonizing of the Recall and Advisory notices.
  - Endorsed as Final Document in June 2006.

An alternative view of PMS



Post-Market Surveillance Information is used for:

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

Key Ideas 1-3

- Post-Market Surveillance is really a mix of “proactive” and “reactive” activities.
- Post-Market Vigilance is an essential part of Post Market Surveillance.
- A balanced Post-Market Surveillance system will contain an appropriate mix of proactive and reactive activities.

Post-Market Surveillance: Activities

Reference: GHTF SG2 N61R4

Condition of Approval Studies

Review of product - associated clinical trials

Recalls

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

Vigilance

Evaluate and investigate reported device problems and complaints

Audits on Manufacturer

Inspect manufacturer processes and procedures for production and complaints handling

Market Surveys

Market Surveys of Technical and clinical documentation

Laboratory Testing

Testing of product for compliance with standards

Review of Product Claims/Labelling

Labelling includes labels, IFU, promotional material, websites

Enforcement

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

Public Access to Information

Provide public access to information taken and reported to the Agency

Standards Activities

Participate in global and international programs towards standardization and harmonization

Technical File Reviews

Review of Clinical and Technical Information for a specific product

Other Post Market Feedback

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

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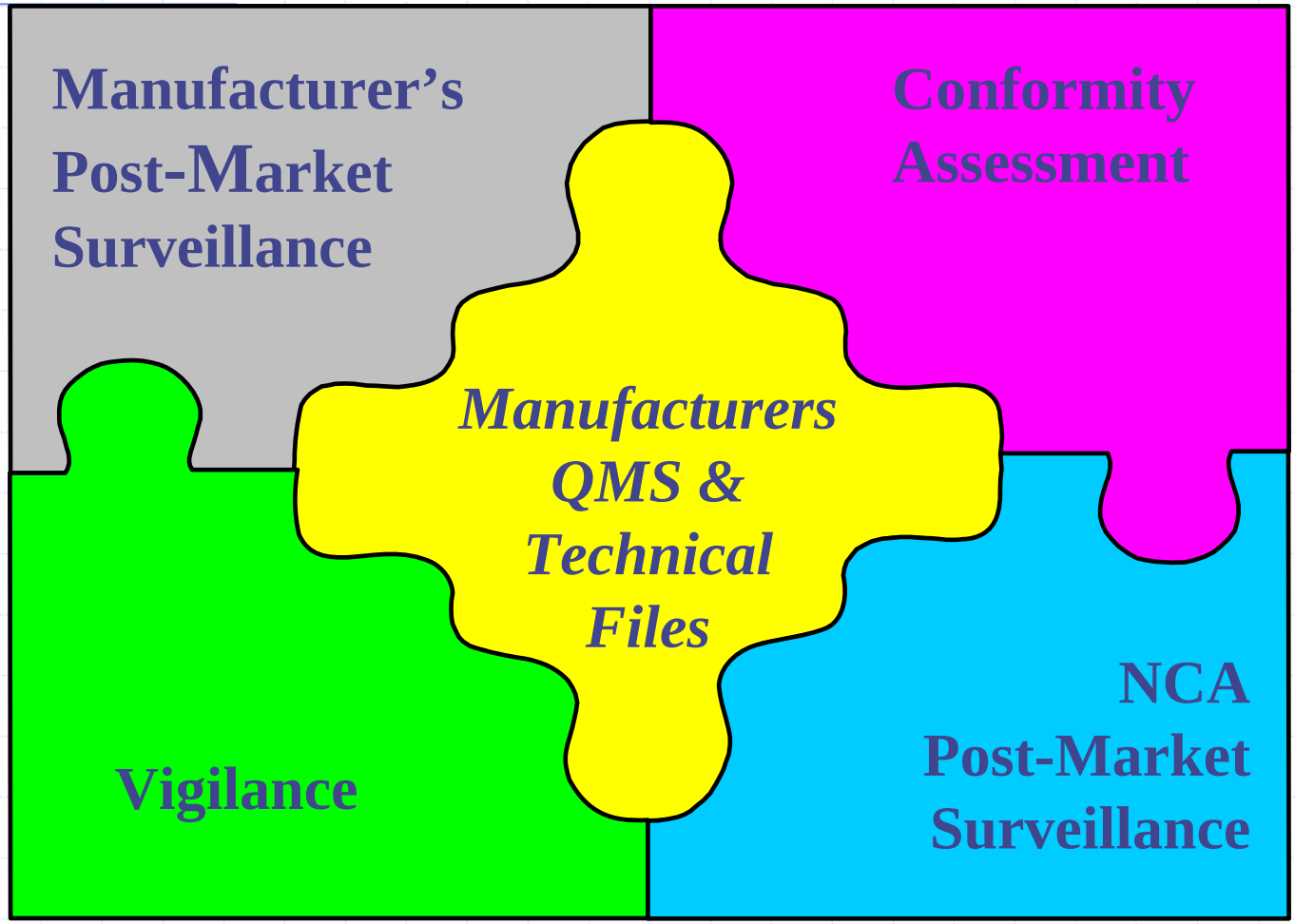
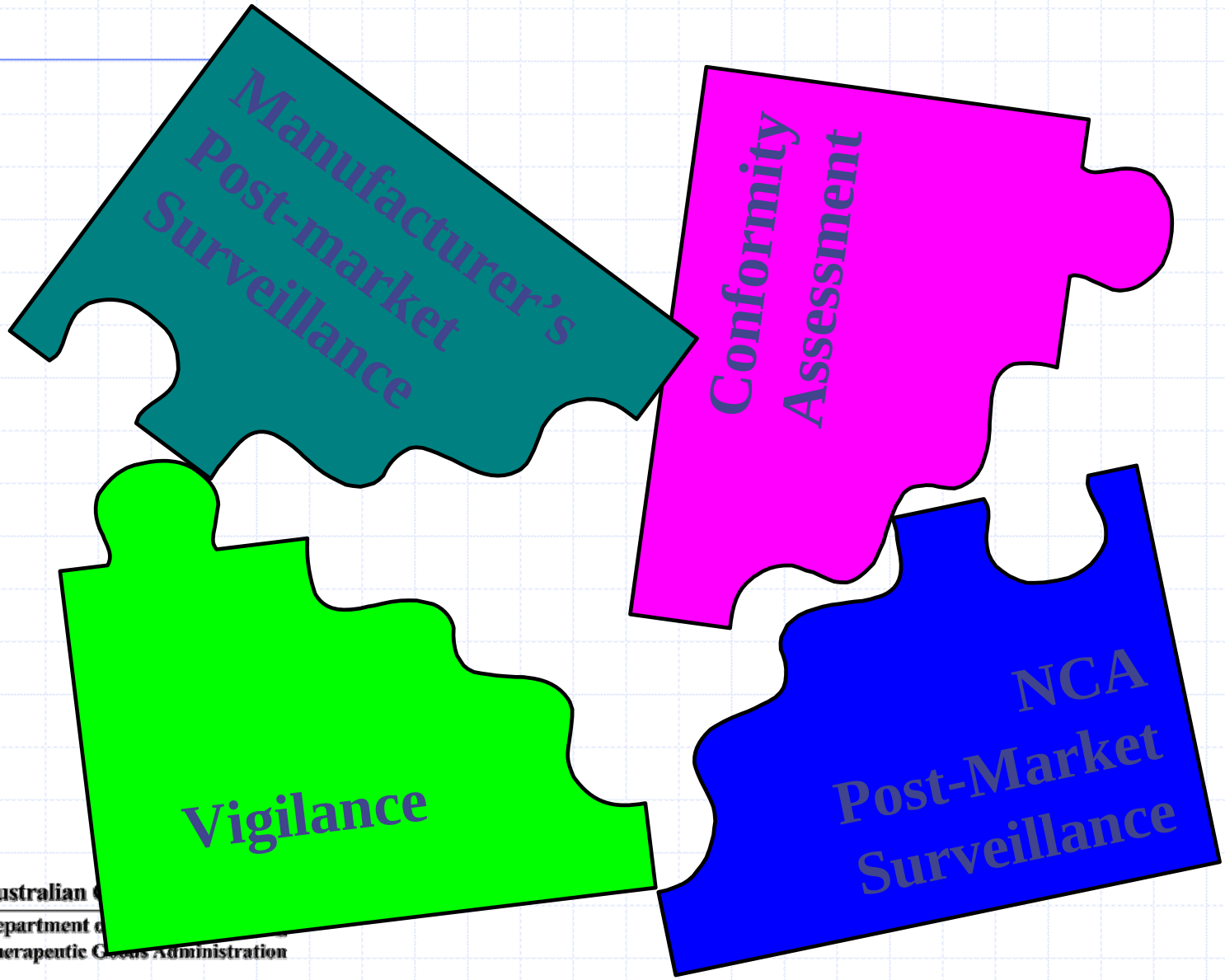
“Pre-Market (Conformity Assessment) is what you do to get ready for Post-Market (Surveillance)”

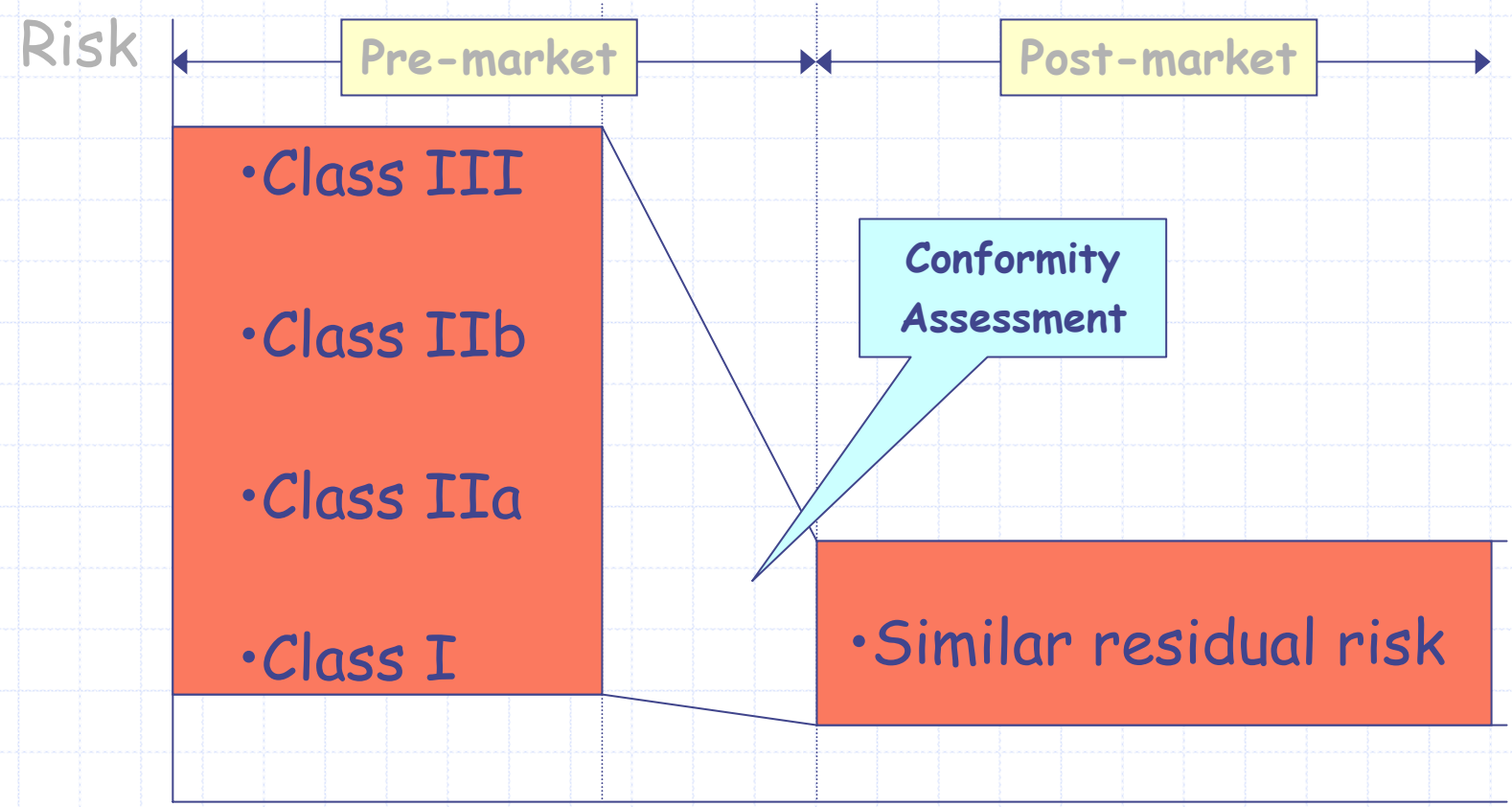
- Jorge Garcia

Tools needed for PMS

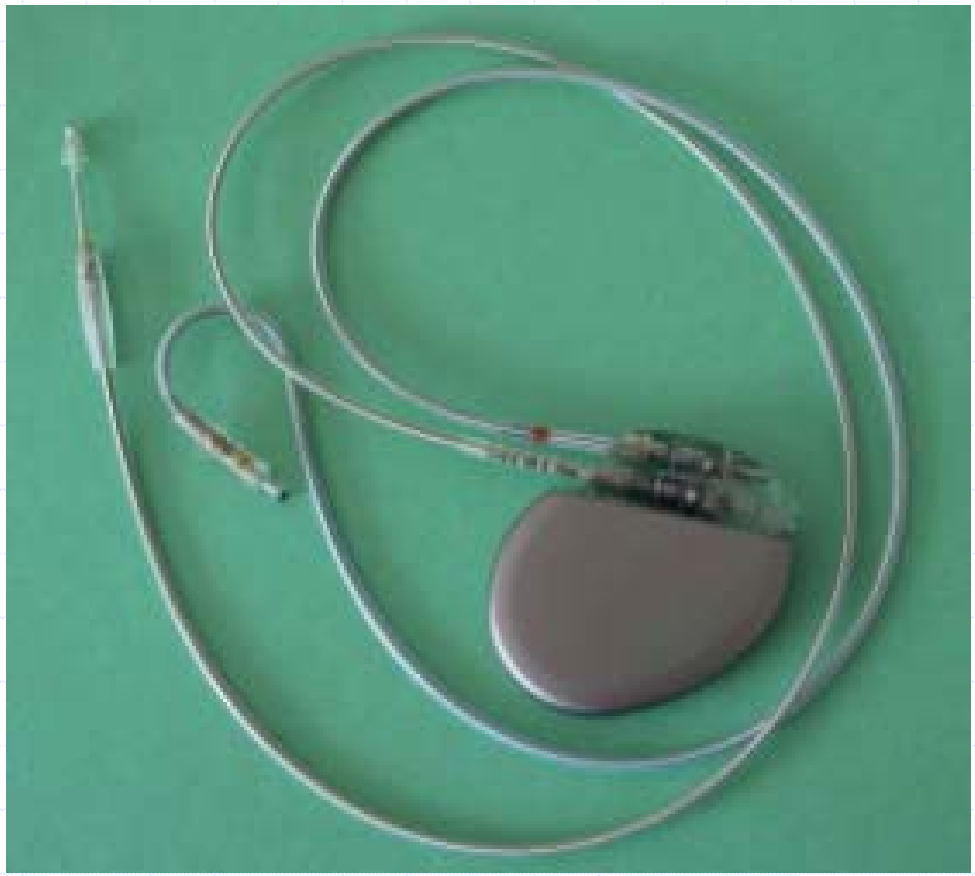



Manufacturer's Post-market Surveillance
Conformity Assessment
Vigilance
NCA Post-Market Surveillance

Residual Risk...

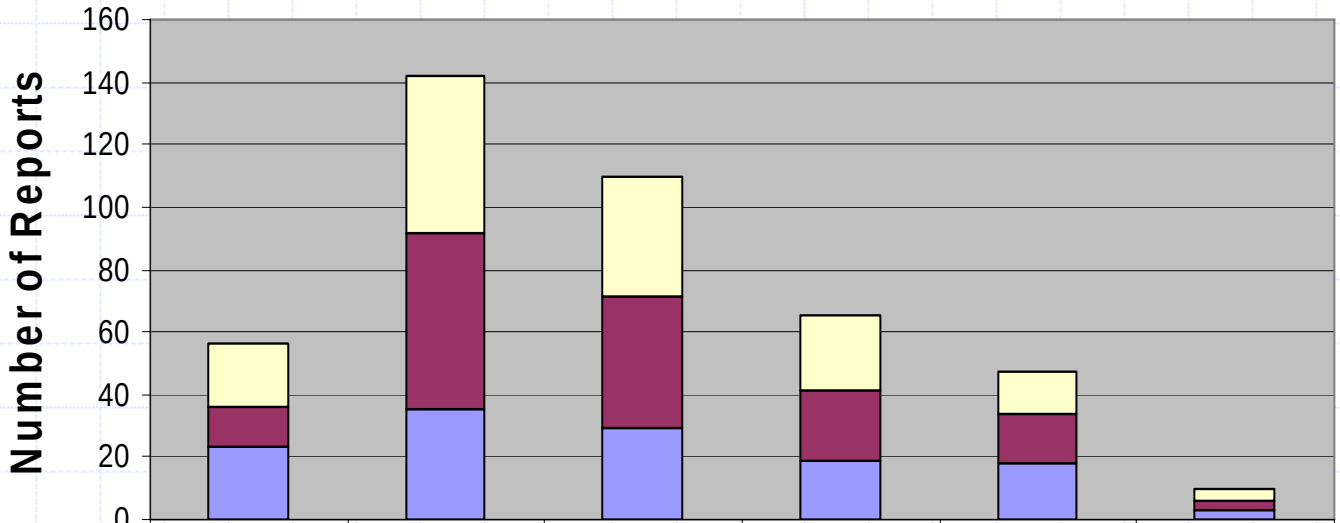


Residual Risk...



Residual Risk...

Number of Incident Reports by EU Class



	I	IIA	IIB	III	AIMD	IVD
Qtr 1 2005	20	50	39	24	13	4
Qtr 4 2004	13	57	42	22	16	3
Qtr 3 2004	23	35	29	19	18	3

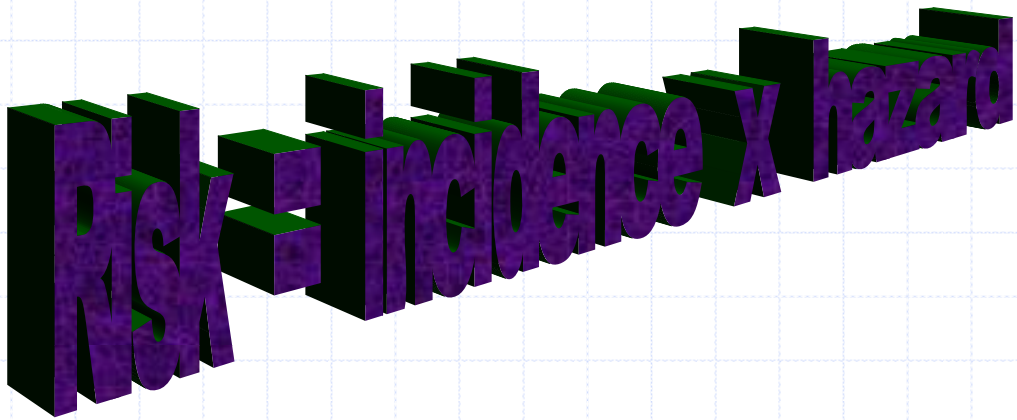
Key Ideas 4-5

- The medical device manufacturer's Quality Management System (QMS) and Technical File are key tools in Post-Market Surveillance.

- **Risk classification** (I, IIa, IIb, III, AIMD) has little meaning or relevance in Post-Market Surveillance

Key Idea 6

- A good understanding of **risk assessment** and **risk management** is an **essential** element for success in Post-Market Surveillance.



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Implementation of GHTF SG2 Guidance in Australia

GHTF SG2 N21R8

Section	Description	Status
1.1-1.3	Definition of reportable event	Implemented in the law S41FN, S41MP, examples and plain English definition in TGA Guidance 11
Reporting Exemption Rules		
2.1	Deficiency of a New Device Found by the User Prior to its Use	Implemented, but TGA Guidance says "always instead of "normally".
2.2	Adverse Event Caused by Patient Conditions	Implemented in TGA Guidance
2.3	Service Life of the Medical Device	Implemented in TGA Guidance
2.4	Protection Against a Fault Functioned Correctly	Implemented in TGA Guidance
2.5	Remote Likelihood of Occurrence of Death or Serious Injury	Implemented in TGA Guidance
2.6	Expected and Foreseeable Side Effects	Implemented in TGA Guidance
2.7	Adverse Events Described in an Advisory Notice	Implemented in TGA Guidance
2.8	Reporting Exemptions Granted by NCA	Implemented in TGA Guidance

Other GHTF SG2 Documents

Doc #	Description	Status
N31	Use Error	Not implemented, user errors are reportable in Australia - this is explicit
N32	Universal Dataset	Implemented in TGA Guidance, minor local variations: ARTG#, ARTG Manufacturer#
N33	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
N36	Trending of Adverse Event Reports	Implemented, trending mentioned in TGA Guidance
NCA Reporting		
N9	NCAR Form	In Use
N20	NCAR Exchange Criteria	In Use, Full Participation

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TGA Regulatory Authority

- Authority to ask questions (penalties for providing false or misleading information).
- Authority to seize product & inspect premises.
- Authority to cancel/suspend the product.
- Authority to mandate a recall.
- Obligation (by the manufacturer & sponsor) to gather and report certain information

- Act references: S29, 30, 31 - S41FN, S41MP

Australian Manufacturer & Sponsor obligations:

- Records to be kept and made available on request that demonstrate compliance with Essential Principles.
- Establish and maintain a post-market surveillance, reporting and corrective action system for problems and complaints - (no matter how minor) - associated with the device. Make information obtained using this system available upon request

TGA Post-Market Surveillance

- TGA Conducts
  - post-market testing of certain types of products.
  - “product surveys” to check for compliance with information requirements and for meeting essential principles. (NB: sponsor is required to provide information on request)
  - post-market (follow-up) QMS audits.
- and encourages user reporting to both the sponsor and the TGA.

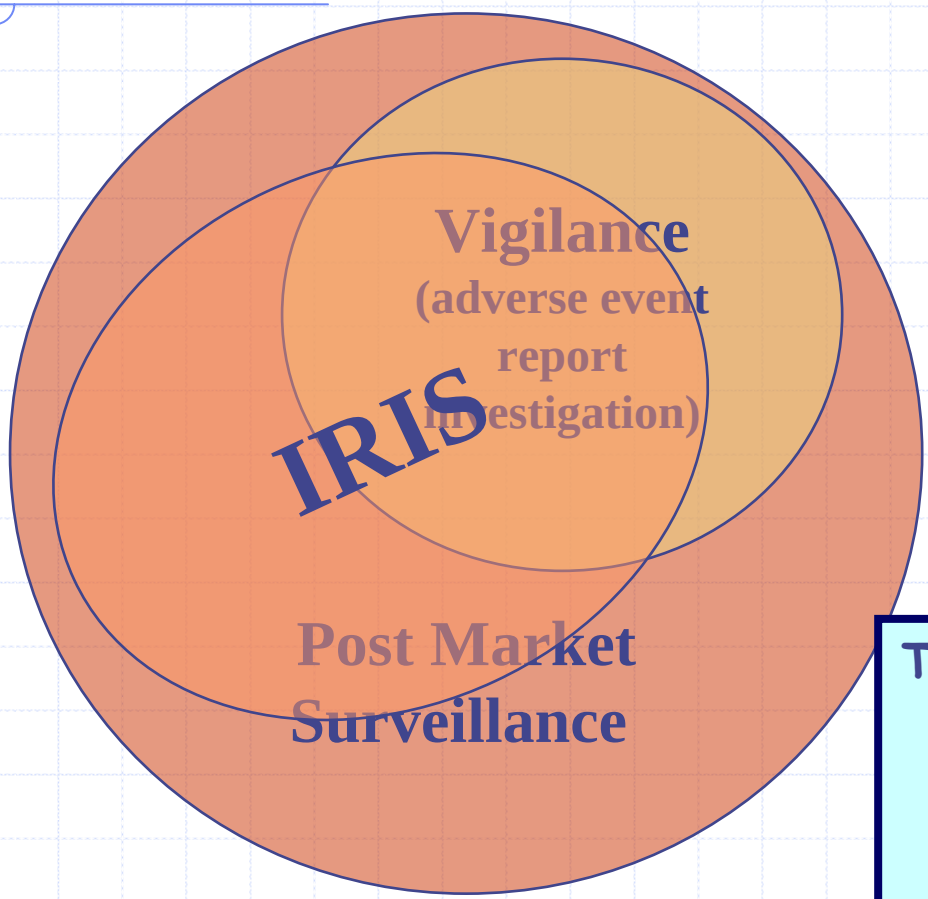
TGA Medical Device Testing Plan

- A focus on complaint samples, testing of new technologies (in particular biological origin), maintenance of accreditation.
- Post-market testing ”projects” justified and prioritised in terms of hazard, incidence and immediate relevance.
- In 2004 TGAL:
  - Carried out tests on 262 medical device samples. 95 samples failed testing. Most samples were received with a complaint.

TGA Vigilance: IRIS

- (Medical Device) **I**ncident **R**eport **I**nvestigation **S**cheme.
- The IRIS:
  - Collects, and where necessary investigates Adverse Events reports from sponsors, other regulatory agencies and medical device users.
  - Disseminates information and/or oversees corrective actions (eg recalls) taken as a result of adverse event report investigations.
  - Exchanges vigilance information with other regulatory agencies in accordance with various MRA and GHTF agreements.

TGA Vigilance: IRIS



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- Regulatory refinement
- Product improvement

TGA's Incident Report Investigation Scheme (IRIS) is a large part of Vigilance and contributes significantly to Post-Market Market Surveillance

TGA Vigilance: Mandatory Reports

- Sponsors must report the details of events associated with their device(s) that have resulted or could have resulted in serious injury or death. (ref TG Act S41MP)
- Guidance allows certain exemptions from reporting. (ref TGA MD Guidance #11)
- Guidance stipulates the information that constitutes a complete report. (ref TGA MD Guidance # 11)

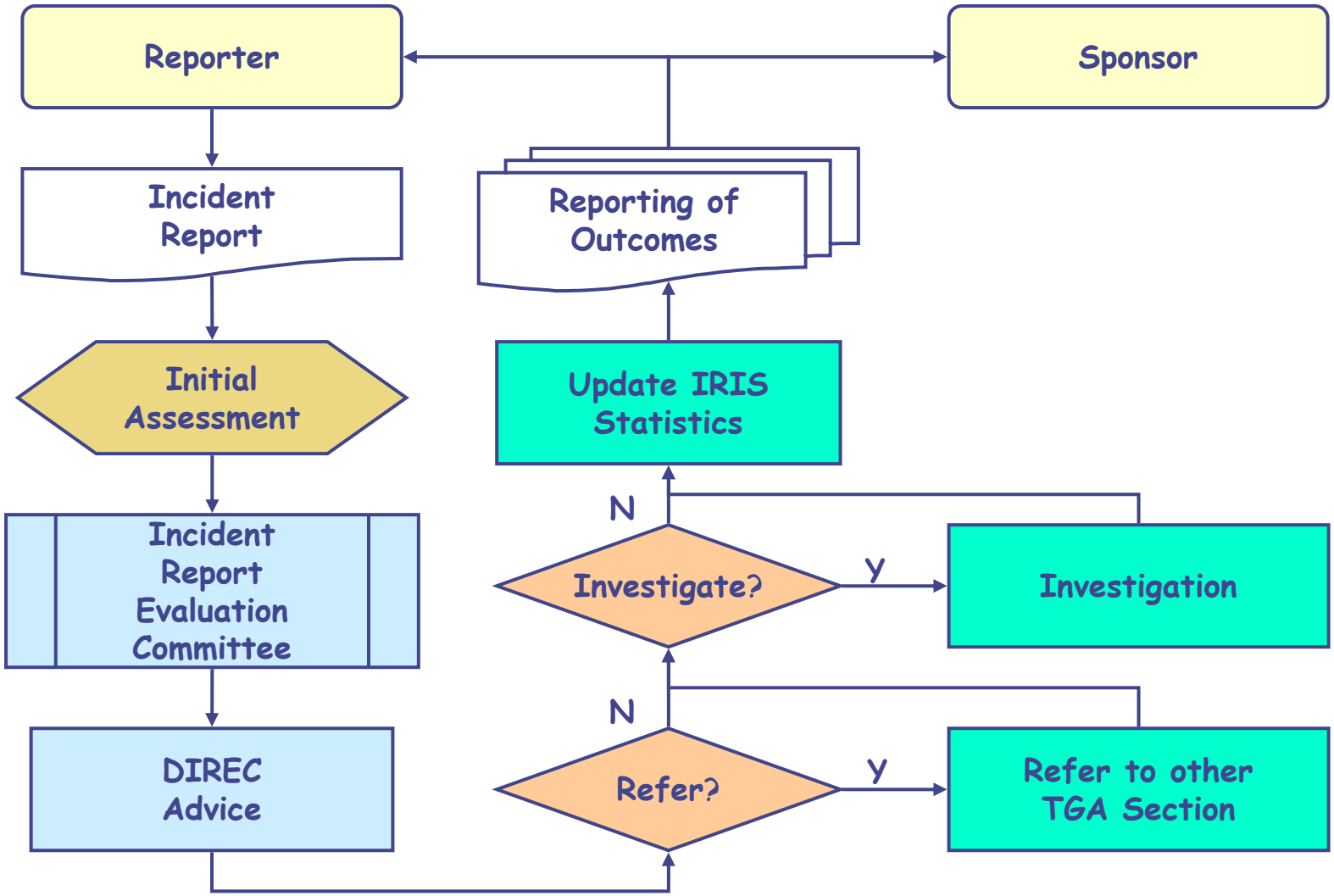
TGA Vigilance: Mandatory Reports

- AE Reporting timeframes**...**
  - Within **two days** of becoming aware of an issue of serious public health threat or concern that will require prompt action to reduce the hazard.
  - Within **ten days** of becoming aware of a death or serious injury.
  - Within **thirty days** of becoming aware of an event that might have led to serious injury or death.
  - (ref Medical Devices Regulations)

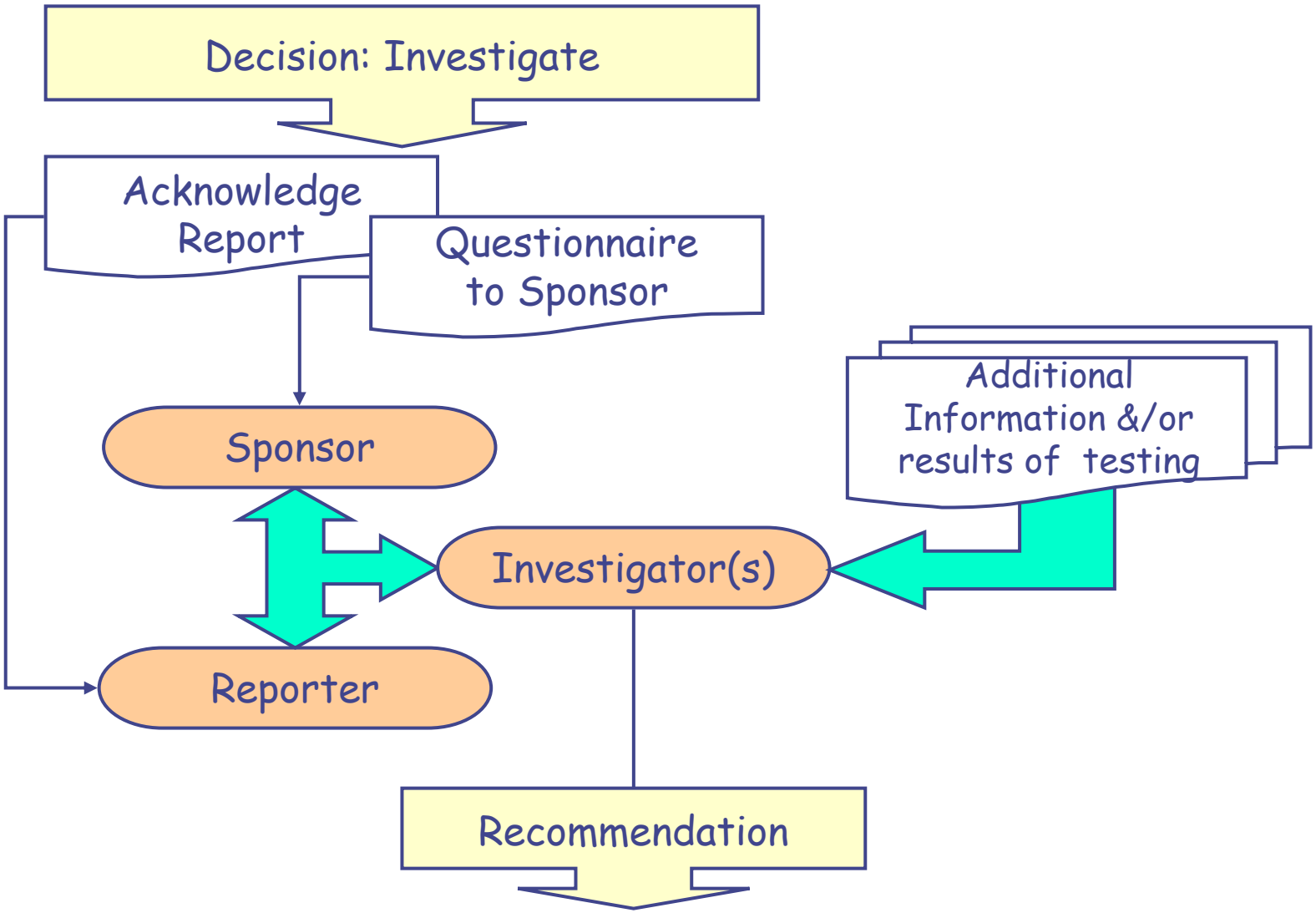
TGA Vigilance: User Reports

- Reporting is voluntary. Device users and others are ***encouraged*** to report both:
  - Medical Device Adverse Events. Events associated with the use of a medical device, that has led, or could have led to serious injury or death.
  - Difficulties and Malfunctions. Events or other information regarding to the quality safety and performance of medical devices.

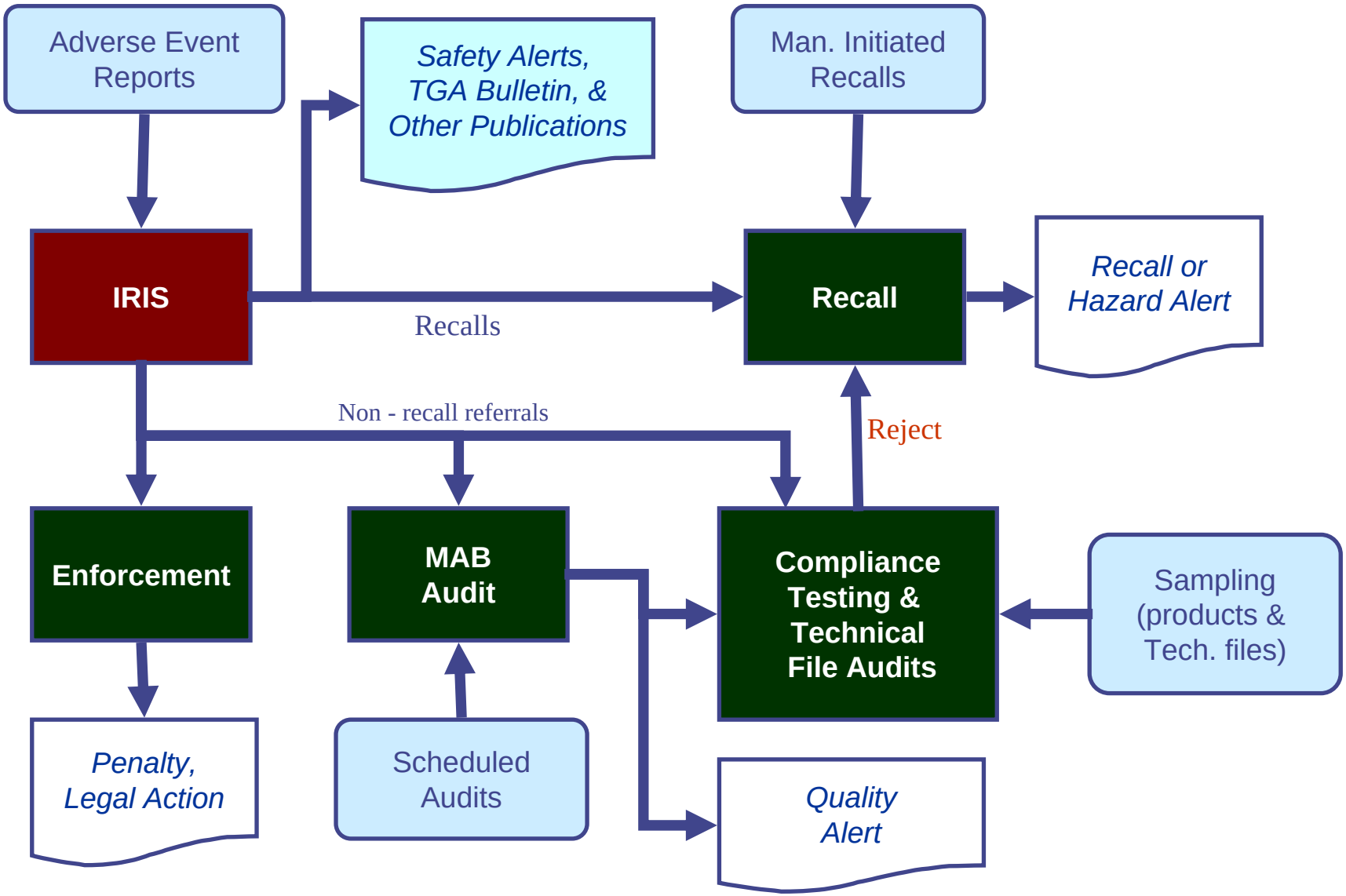
The IRIS process



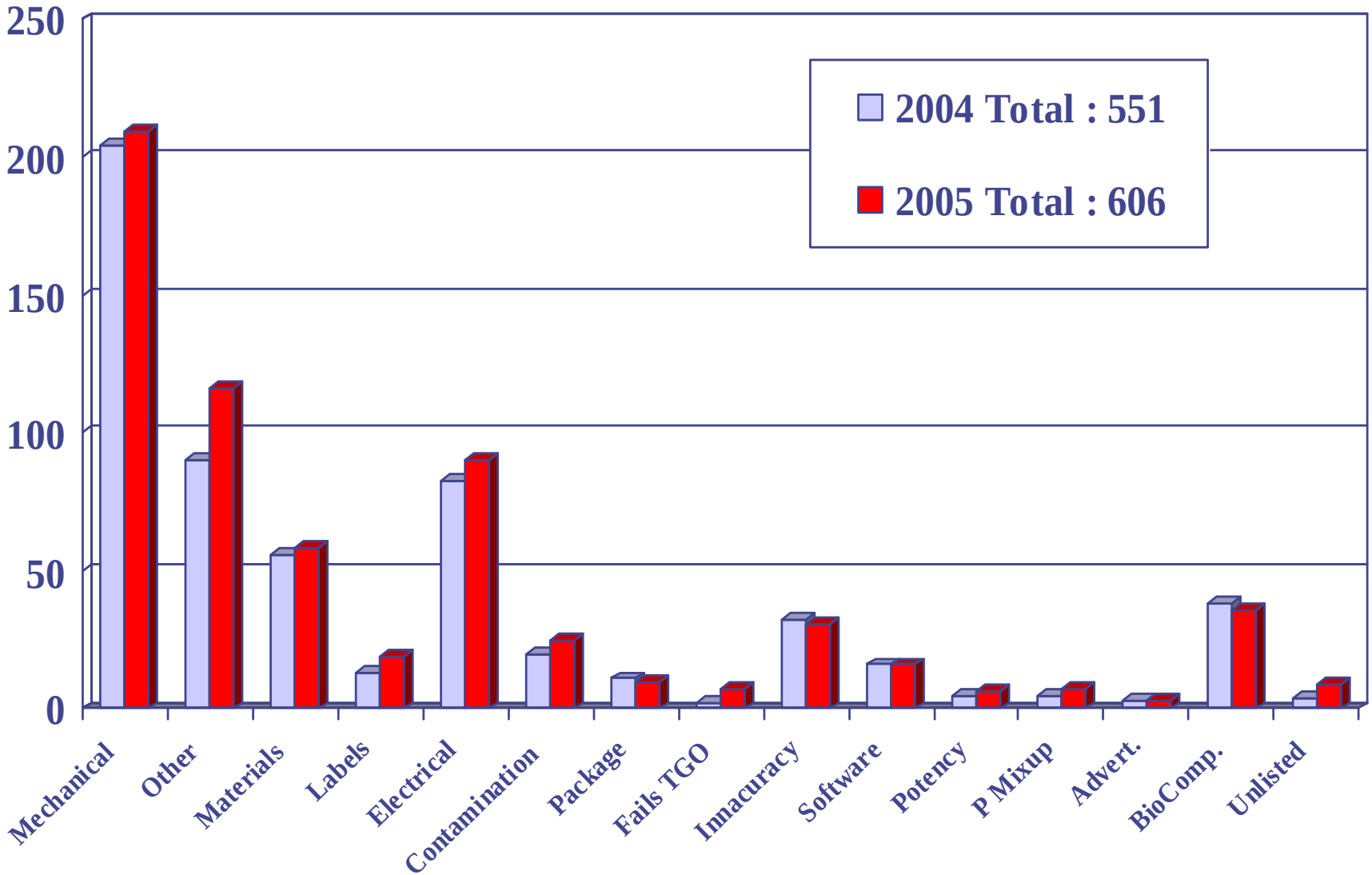
The investigation process



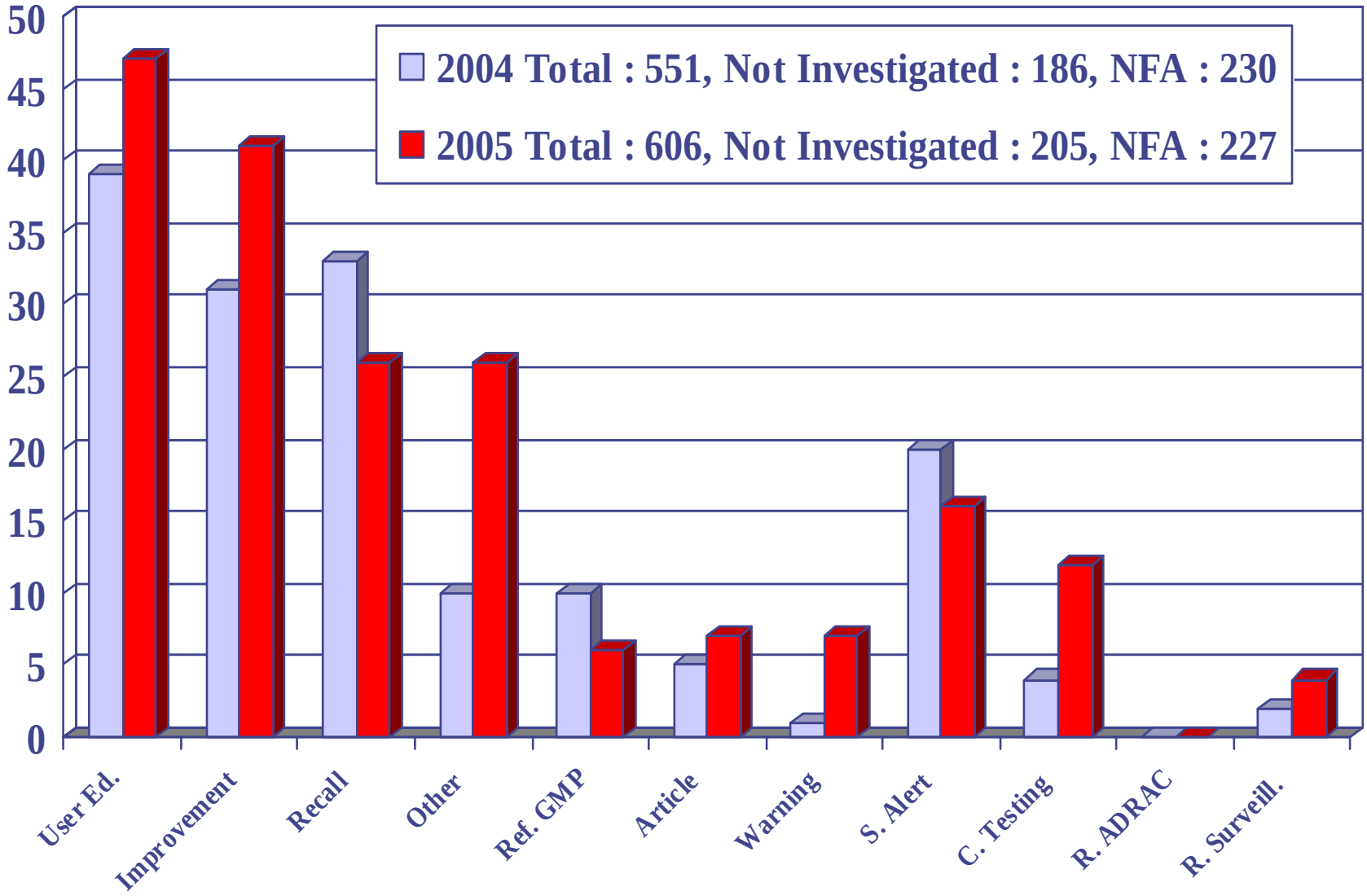
TGA's PMS Systems



Type of Reports Received



Result of Investigations

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