AHWP

Review of Safety Alert Dissemination System (SADS)

Review of the

Safety Alert Dissemination System

(SADS)

AHWP Work Group 2 (WG2)
Post-market Surveillance and Vigilance

1

Objective

Regulatory authorities and manufacturers work together to improve the protection to the public by reducing the likelihood of repeated adverse events.

2

Targets

- To provide an efficient platform for the sharing of non-confidential medical device safety information among regulatory authorities for the better protection of the public

- To merge with GHTF National Competent Authority Report (NCAR) Exchange Program for the global sharing of medical device safety information
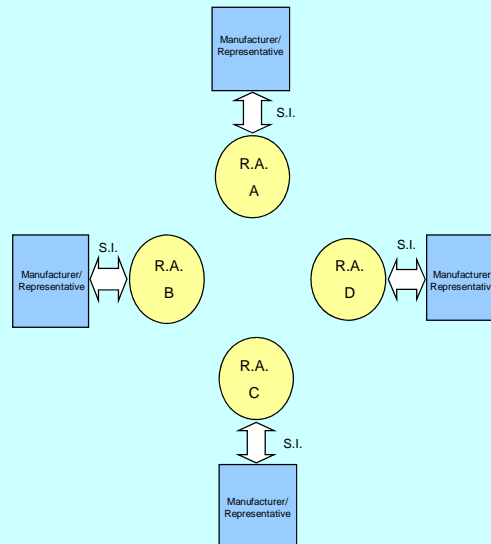
3

SADS vs NCAR

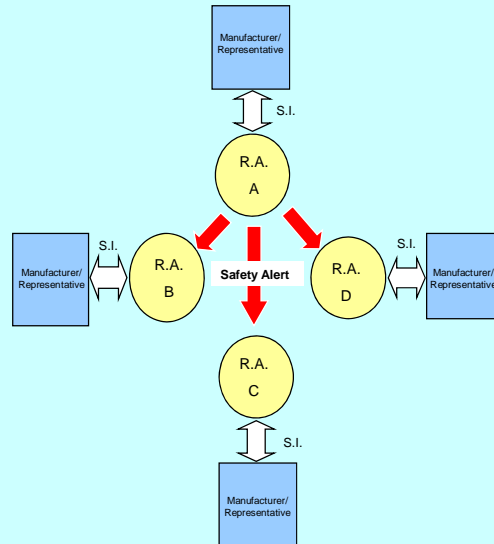|	SADS	NCAR (Associate)	NCAR (Full)
Participants	Regulatory Authorities	Regulatory Authorities + Related Parties	Regulatory Authorities
Safety Information	Non-confidential + Investigatory	Non-confidential	Non-confidential + Confidential
Secretary	Originating Party	TGA	TGA
Requirement	AHWP Member + Training	Training	Training + Reporting System
Contact Point	2 (Primary + Alternate)	1	1
Admin Charge	No	Possible	Possible

Progress

- ◆ 7 Participants
  - ▪ Hong Kong
  - ▪ Indonesia
  - ▪ Malaysia
  - ▪ Philippines
  - ▪ Singapore
  - ▪ Saudi Arabia
  - ▪ Thailand
- ◆ 2 Cases disseminated

Communication between RA and Manufacturer

Dissemination of Safety Alerts

Requirements for Joining SADS

- AHWP member;
- Nominate a representative and an alternate representative; and
- At least one of the representatives has attended relevant training or not more than 10% of WG02 members disagree.

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What Next?

- Participation
- Review and fine-tune SADS
- Collaborate with GHTF NCAR Exchange Program to work towards one harmonized system