



IMDRF 이상사례용어(AE)

실무그룹 업무 현황

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I. 실무그룹 개요

IMDRF AE WG(이상사례용어 실무그룹) 주요 업무

- **(업무1)** IMDRF 의료기기 이상사례보고 용어 및 코드 연례 현행화
 - 용어·코드 변경 요청 받아(~매년 9.1) 분석(9~11월) 후, MedDRA 맵핑을 거쳐(~11월) IMDRF 웹사이트에 업데이트 게시(익년 3.1~7)
 - * 의장: Liling Liew(싱가포르)
- **(업무2)** 규제당국 간 이상사례보고 정보 교환을 위한 공통 항목 마련
 - 국가별 이상사례 보고 양식 등을 기반으로 공통 항목 및 요구사항 마련 중
 - * 의장: Nancy Pressly(미국) & Robin Seidel(독일)

I. 실무그룹 개요

Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes

IMDRF Code: IMDRF/AE WG/N43 Published date: 20 April 2020 Status: Final

IMDRF code: IMDRF/AE WG/N43FINAL:2020 (Edition 4) Published date: 20 April 2020

Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes
[PDF \(1.22 mb\)](#) [DOCX \(279.8 kb\)](#)

IMDRF code: IMDRF/AE WG/N43 FINAL:2022 Updated Annexes (Release 2022) Published date: 8 March 2022

[Annex A: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Medical Device Problem](#) [JSON \(164.89 kb\)](#) [XLSX \(52.73 kb\)](#)

[Annex B: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Type of Investigation](#) [JSON \(12.73 kb\)](#) [XLSX \(14.1 kb\)](#)

[Annex C: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Investigation Findings](#) [JSON \(49.2 kb\)](#) [XLSX \(24.94 kb\)](#)

[Annex D: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Investigation Conclusion](#) [JSON \(15.39 kb\)](#) [XLSX \(15.77 kb\)](#)

[Annex E: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Health Effects - Clinical Signs and Symptoms or Conditions](#)
[JSON \(364.01 kb\)](#) [XLSX \(179.15 kb\)](#)

[Annex F: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Health Effects - Health Impact](#)
[JSON \(20.41 kb\)](#) [XLSX \(17.27 kb\)](#)

[Annex G: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Medical Device Component](#)
[JSON \(84.56 kb\)](#) [XLSX \(34.61 kb\)](#)

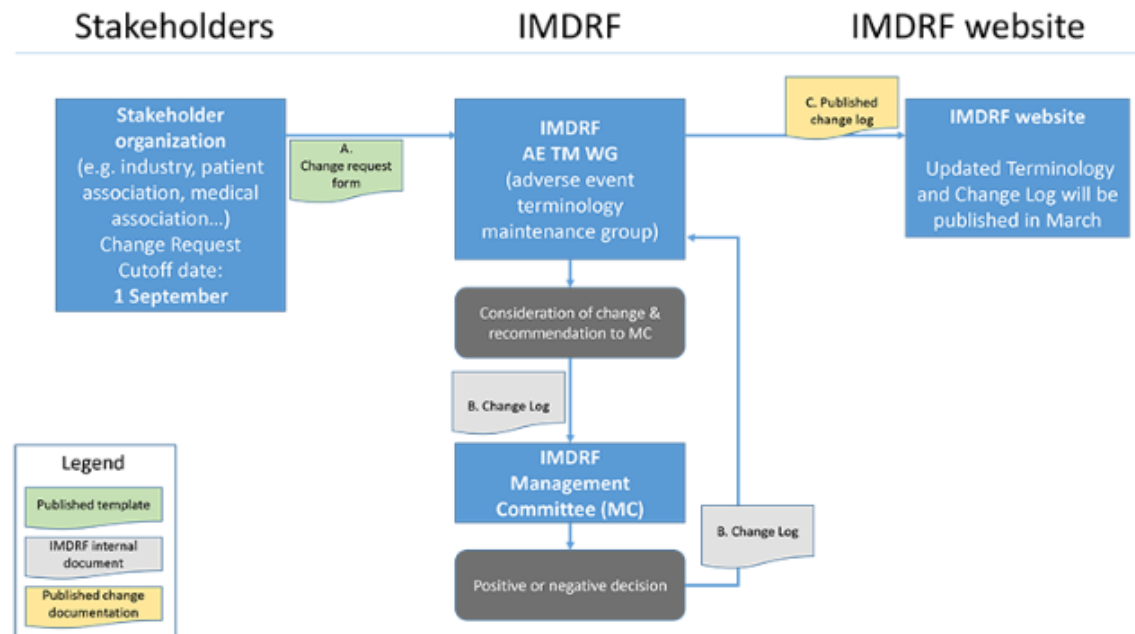
[Appendix B: IMDRF terminologies for categorized Adverse Event Reporting \(AER\) - Change Log](#) [XLSX \(92.7 kb\)](#)

[Release Notes: IMDRF terminologies for categorized Adverse Event Reporting \(AER\)](#) [TXT \(1.82 kb\)](#)

I. 실무그룹 개요

IMDRF Adverse Event Terminology Maintenance

- The terms in the Annexes of the final version of the guideline document are maintained by the AE Working Group (AE WG) in accordance with the "[Maintenance of IMDRF AE Terminologies](#)" (IMDRF/AE WG/N44)FINAL:2020).
- The terminology is always open for Change Requests. The process is outlined in the figure below. **The cutoff date for inclusion in the next release is 1 September.** The Change Requests will then be reviewed by IMDRF, and the updated terminology and outcome of Change Requests will be published in March.



- Proposal of addition/modification/deletion of the terms must be submitted to AE WG by either **National Competent Authorities** or **Stakeholder Organizations**, using the Change Request form. **No proposal from an individual will be accepted.**
- Please use the most recent Change Request form below:

[Appendices A & B: Change Request Form and Change Log - XLSX \(16kb\)](#)

- Please send the completed form to: HSA_MDC@hsa.gov.sg

I. 실무그룹 개요

Meetings

- Apr 23 & May 28, 2015
1st & 2nd Teleconferences
 - June 4 and 5, 2015
1st Face to Face meeting,
Silver Spring, US
 - Jun 18, Jul 9, Aug 6, Oct 8, &
Dec 9, 2015, and Mar 1, 2016
3rd to 8th Teleconferences
 - April 12-15, 2016
2nd Face to Face meeting,
Tokyo, Japan
 - May 24, Jun 17, Jul 14, Aug 26
and Nov 4, 2016,
9th - 13th Teleconferences
 - Dec 13-16, 2016
3rd Face to Face meeting,
Tokyo, Japan
 - Feb 2, Feb 8, Apr 5, 2017
14th - 16th Teleconferences
 - June 13 – 16, 2017
4th Face to Face meeting,
Ispra, Italy
 - Jul 6, Oct 11, 2017
17th, 18th Teleconferences
 - Nov 28-Dec 1 2017
5th Face to Face meeting,
Moscow, Russia
 - Feb 19, 2018
19th Teleconference
 - April 16-20, 2018
6th Face to Face meeting,
Canberra, Australia
 - Oct 25 & Nov 21, 2019
20th & 21st Teleconferences
 - Nov 26-30, 2019
7th Face to Face meeting,
Singapore
 - Feb 22, 2019
22nd Teleconference
 - March 26-29 2019
8th Face to Face meeting,
Brasilia, Brazil
 - Apr 24, May 22, Jun 18, Oct 23, 2019
23rd - 26th Teleconferences
 - November 4-7, 2019
9th Face to Face Meeting, Geneva, Switzerland
 - Dec 17, 2019, Apr 7, May 13,
Jun 9, 2020
27th- 30th Teleconferences
 - Oct 29 & Nov 10, 2020
31st & 32nd Teleconferences
Maintenance
 - Feb 16, Apr 27, May 11, May 25,
Jun 8, Jun 22, Jul 6, Jul 20, 2021
33rd – 40th Teleconferences
 - Sept 28, Oct 5, 12, 19, 26, 28,
Nov 2, 9, 16, 2021
41st – 49th Teleconferences
Maintenance
 - Feb 16, Mar 29, Apr 26, May 17, June
7, June 28, Aug 30 2022
50th – 56th Teleconferences
- *NWIE was discussed in red meetings

II. 실무그룹 주요 논의사항

- “규제당국 간 이상사례보고 정보 교환을 위한 공통항목 마련”을 위한 논의**
- 국가별 보고받는 이상사례 관련 정보 항목을 기반으로, 해당 항목 정보를 요구하는 의미 및 운용 사례 등에 대한 규제당국 별 경험 및 의견 공유
 - 실무그룹 업무의 궁극적인 목표인 규제당국 간 정보 교환을 위하여 기반 마련 필요(정보활용 동의 등)

III. 실무그룹 주요 추진사항





Thank you



식품의약품안전처