Technical Information Report

AAMI TIR50: 2014/(R)2017

Post-market surveillance of use error management





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Post-market surveillance of use error management

Approved 10 March 2014 and reaffirmed 6 December 2017 by **AAMI**

Abstract: This document will address the issue of use error detection for medical devices from clinical,

manufacturer, and regulatory perspective regarding human factors assessment. The goal is to provide guidance on how clinicians and manufacturers can best collect and leverage post-market

use error data to improve product safety and usability.

Keywords: human factors, usability, hospital, clinical

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Contents

7 Process flow high level introduction			Page		
Purpose	Glo	ssary of equivalent standards	V		
1 Purpose	Со	mmittee representation	vi		
2 Scope 1 2.1 Stakeholder entities (not all inclusive) 1 2.2 Reporting entities (not all inclusive) 1 3 Terms and definitions 2 4 How to use this document 3 5 Background 3 5.1 Manufacturer's perspective 3 5.2 Clinical perspective 4 6.3 Lay users perspective 5 6.4 Regulatory focus on use error post-market surveillance 5 7 Process recommendations for manufacturers 6 7.1 Process flow high level introduction 6 7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports") 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 20 8.4 Evaluate experience to determine root cause 22 8.5 Reporting to manufa	Fo	reword	viii		
2 Scope 1 2.1 Stakeholder entities (not all inclusive) 1 2.2 Reporting entities (not all inclusive) 1 3 Terms and definitions 2 4 How to use this document 3 5 Background 3 5.1 Manufacturer's perspective 3 5.2 Clinical perspective 4 6.3 Lay users perspective 5 6.4 Regulatory focus on use error post-market surveillance 5 7 Process recommendations for manufacturers 6 7.1 Process flow high level introduction 6 7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports") 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 20 8.4 Evaluate experience to determine root cause 22 8.5 Reporting to manufa	1	Purpose	1		
2.1 Stakeholder entities (not all inclusive)	2	·			
2.2 Reporting entities (not all inclusive). 1 3 Terms and definitions. 2 4 How to use this document. 3 5 Background. 3 5.1 Manufacturer's perspective. 4 5.2 Clinical perspective. 4 5.3 Lay users perspective. 5 6 Regulatory focus on use error post-market surveillance. 5 7 Process recommendations for manufacturers. 6 7.1 Process flow high level introduction. 6 7.1.1 Deployment. 8 7.1.2 Valid use event reports received (inputs for "reports"). 11 7.1.2 Valid use event reports received (inputs for "reports"). 11 7.1.3 Triage. 12 7.1.4 Analysis. 14 7.1.5 Monitor and trend. 15 7.1.6 Motion and trend. 15 7.2.1 Data trending. 18 7.2.2 Recommendations for how and when to take action. 18 8 Process recommendations for clinical users. 19 8.1 Process flow high-level introduction. 19 8.2 Use error event. 20 8.3 Immediate impact on user/patient. 20 8.4 Evaluate experience to determine root c					
4 How to use this document 3 5 Background 3 5.1 Manufacturer's perspective 4 5.2 Clinical perspective 4 6. Regulatory focus on use error post-market surveillance 5 7 Process recommendations for manufacturers 6 7.1 Process flow high level introduction 6 7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports") 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.1.6 Action 17 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 <					
5 Background	3	Terms and definitions	2		
5 Background	4	How to use this document	3		
5.1 Manufacturer's perspective					
5.2 Clinical perspective 4 5.3 Lay users perspective 5 6 Regulatory focus on use error post-market surveillance 5 7 Process recommendations for manufacturers 6 7.1 Process flow high level introduction 6 7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports") 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.1.6 Action 15 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 8.4 Evaluate experience to determine root cause 20 8.5 Reporting to manufacturer 24 8.6 Organization activities 24 8.6.1 General training on use error 24 8.6.2 Develop an understanding of the value of reporting close calls 24 8.6.3 Address the blame game 25 8.6.4 How post-market surveillance use error management drives value in clinical environments 25	J	•			
5.3 Lay users perspective					
7 Process recommendations for manufacturers					
7.1 Process flow high level introduction. 6 7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports"). 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.1.6 Action 17 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 8.3 Immediate impact on user/patient 20 8.4 Evaluate experience to determine root cause 22 8.4.1 Monitor, trend and report to patient safety bodies 24 8.5 Reporting to manufacturer 24 8.6.1 General training on use error 24 8.6.2 Develop an understanding of the value of reporting close calls 24 8.6.3 Address the blame game 25 8.6.4 How post-market surveillance use error management drives value in clinical environments 25 8.6.5 Develop use error and close call reporting process for clinical orga	6	Regulatory focus on use error post-market surveillance	5		
7.1 Process flow high level introduction. 6 7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports"). 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.1.6 Action 17 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 8.3 Immediate impact on user/patient 20 8.4 Evaluate experience to determine root cause 22 8.4.1 Monitor, trend and report to patient safety bodies 24 8.5 Reporting to manufacturer 24 8.6.1 General training on use error 24 8.6.2 Develop an understanding of the value of reporting close calls 24 8.6.3 Address the blame game 25 8.6.4 How post-market surveillance use error management drives value in clinical environments 25 8.6.5 Develop use error and close call reporting process for clinical orga	7	Process recommendations for manufacturers	6		
7.1.1 Deployment 8 7.1.2 Valid use event reports received (inputs for "reports") 11 7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.1.6 Action 17 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 8.3 Immediate impact on user/patient 20 8.4 Evaluate experience to determine root cause 22 8.4.1 Monitor, trend and report to patient safety bodies 24 8.5 Reporting to manufacturer 24 8.6 Organization activities 24 8.6 Organization activities 24 8.6.2 Develop an understanding of the value of reporting close calls 24 8.6.3 Address the blame					
7.1.2 Valid use event reports received (inputs for "reports")					
7.1.3 Triage 12 7.1.4 Analysis 14 7.1.5 Monitor and trend 15 7.1.6 Action 17 7.2 How post-market surveillance use error management drives value for your company 18 7.2.1 Data trending 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 8.3 Immediate impact on user/patient 20 8.4 Evaluate experience to determine root cause 22 8.4.1 Monitor, trend and report to patient safety bodies 24 8.5 Reporting to manufacturer 24 8.6 Organization activities 24 8.6.1 General training on use error 24 8.6.2 Develop an understanding of the value of reporting close calls 24 8.6.3 Address the blame game 25 8.6.4 How post-market surveillance use error management drives value in clinical environments 25					
7.1.4 Analysis					
7.1.6 Action					
7.1.6 Action					
7.2.1 Data trending 7.2.2 Recommendations for how and when to take action 18 7.2.2 Recommendations for how and when to take action 18 8 Process recommendations for clinical users 19 8.1 Process flow high-level introduction 19 8.2 Use error event 20 8.3 Immediate impact on user/patient 20 8.4 Evaluate experience to determine root cause 22 8.4.1 Monitor, trend and report to patient safety bodies 24 8.5 Reporting to manufacturer 24 8.6 Organization activities 24 8.6.1 General training on use error 24 8.6.2 Develop an understanding of the value of reporting close calls 24 8.6.3 Address the blame game 25 8.6.4 How post-market surveillance use error management drives value in clinical environments 25 8.6.5 Develop use error and close call reporting process for clinical organizational environments 25 8.6.6 User dissatisfaction 26 8.6.7 Utilize internal resources to identify use error events 26 8.6.8 Proactive assessment 26 8.6.9 Scalability 27 Annexes A Example questions for collecting use error or close call data 28 Connecting use error to customer complaints 33					
7.2.2 Recommendations for how and when to take action		7.2 How post-market surveillance use error management drives value for your company	18		
8 Process recommendations for clinical users			18		
8.1 Process flow high-level introduction		7.2.2 Recommendations for how and when to take action	18		
8.2 Use error event	8	Process recommendations for clinical users			
8.3 Immediate impact on user/patient					
8.4 Evaluate experience to determine root cause		8.2 Use error event	20		
8.4.1 Monitor, trend and report to patient safety bodies					
8.5 Reporting to manufacturer					
8.6 Organization activities					
8.6.1 General training on use error					
8.6.2 Develop an understanding of the value of reporting close calls					
8.6.3 Address the blame game		8.6.1 General training on use error.	24		
8.6.4 How post-market surveillance use error management drives value in clinical environments					
8.6.5 Develop use error and close call reporting process for clinical organizational environments		9.6.4 How post market augusillane use error management drives value in disignal environments	25		
8.6.6 User dissatisfaction		9.6.5 Develop use error and close call reporting process for clinical organizational environments	25		
8.6.7 Utilize internal resources to identify use error events 26 8.6.8 Proactive assessment 26 8.6.9 Scalability 27 Annexes A Example questions for collecting use error or close call data 28 B Connecting use error to customer complaints 33					
8.6.8 Proactive assessment					
8.6.9 Scalability					
Annexes A Example questions for collecting use error or close call data					
B Connecting use error to customer complaints	An	-	····· - ·		
B Connecting use error to customer complaints	Α	Example questions for collecting use error or close call data	28		
	В	Connecting use error to customer complaints	33		
		·			

Tables

Table 1 — Potential use error complaint scenarios	
Table B.1 — Tie use error to customer complaints	34
Figures	
Figure 1 — Process overview flow chart on post-market surveillance of use error for manufacturers	7
Figure 2 — Deployment flow chart	8
Figure 3 — Triage flow chart	13
Figure 4 — Analysis flow chart	14
Figure 5 — Monitor and trend flow chart	16
Figure 6 — Action process flowchart	17
Figure 7 — Process overview flow chart on post-market surveillance of use error for clinical users	19
Figure 8 — Mitigate impact on user/patient	21
Figure 9 — Evaluate experience to determine root cause	22
Figure 10 — Sources of information	26