

Title: The Reporting recommendations Intended for pharmaceutical risk Minimization Evaluation Studies: Standards for Reporting of Implementation Studies Extension (RIMES-SE).

Journal: Drug Safety

Authors: Smith MY, Morrato EH, Mora N, Nguyen V, Pinnock H, Winterstein AG

Corresponding Author: Meredith Y Smith, Evidera Inc., tantmieux57@gmail.com

Supplementary File 2. RIMES-SE eDELPHI: Round 2 Survey

Start of Block: Default Question Block

Q1

Welcome to Round 2 of our eDelphi initiative!

As you may recall from Round 1, our goal is to develop a quality reporting checklist for risk minimization evaluation studies that will be an extension of the **Standards for Reporting of Implementation studies (StaRI)**. Our new reporting checklist will be entitled the **Reporting recommendations Intended for pharmaceutical risk Minimization Evaluation Studies (RIMES) statement-StaRI Extension (the RIMES-SE)**. This new checklist is intended to facilitate comprehensive, standardized reporting of risk minimization evaluation studies to permit synthesis of the research literature and, ultimately, to advance the science by providing greater understanding of what types of programs work most effectively for whom and under what conditions.

We are pleased to inform you that approximately two-thirds of the items from Round 1 achieved a high level of consensus. The goal of this second eDelphi round is to gain consensus on the remaining set of items – those for which there was low consensus. We defined “low consensus” as follows: less than 80% of respondents assigned the item a ranking score of 7, 8, 9, or 10 on scales of “Importance” (higher score meaning more important) or “Understandability” (higher score meaning more understandable).

In Round 1, you were asked to rate 49 items. In contrast, in Round 2, you will be asked to rate only **19** items in terms of their **1) importance** and **2) understandability**. All of these items have been modified in response to Round 1 comments. To assist you in this exercise, the median, mean, standard deviation, and frequency distribution of the Round 1 ratings for each item are provided for your reference.

We strongly encourage you to complete this second round of the eDelphi exercise as it enables us to achieve high quality expert consensus. If you wish to participate in Round 2, please click YES in the box below to proceed. This survey should take only about **10 minutes to complete**. All information collected will be kept confidential. Results will be presented in a collated manner and will not be linked to any individual respondent.

You can begin the survey and stop and come back to it to finish it at a later point if you need to. Please note, **we kindly request your response by August 17th** (midnight, Eastern Time) as we will be presenting and discussing preliminary findings in a special interest group (SIG)

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meeting at the upcoming International Conference on Pharmacoepidemiology in late August 2023.

☐ Yes, I agree to participate (1)

☐ No, I decline to participate (2)

Skip To: Q2 If Welcome to Round 2 of our eDelphi initiative! As you may recall from Round 1, our goal is to deve... = Yes, I agree to participate

Skip To: End of Survey If Welcome to Round 2 of our eDelphi initiative! As you may recall from Round 1, our goal is to deve... = No, I decline to participate

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Q2 Before we begin, could you please identify your area of expertise (check all that apply):

☐

Implementation Science/Knowledge Translation (1)

☐

Pharmacoepidemiology (2)

☐

Pharmacovigilance/Drug Safety (3)

☐

Other (4) _____

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Q3 What sector(s) have you worked in? (check all that apply):

☐

Government/Regulator (1)

☐

Academia (2)

☐

Industry (3)

☐

Research Consultancy (4)

☐

Other (5) _____

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Q4 The following item relates to the *Title* of the study.

Q5 ITEM 1. Identification as a risk minimization evaluation study, and description of the targeted safety risk, medicinal product, target population, geographical location, and description of study methodology in title or keywords. *Example: A mixed methods evaluation of the HIV PreP risk minimization program to reduce the risk of HIV infection in adolescent girls and young women in Nairobi, Kenya.*

The median, mean, standard deviation, and frequency distributions for importance and understandability from Round 1 are provided for your reference.

Importance					
Ranking	Frequency	Percent	Median	Mean	SD
6	1	6.67	9.0	8.6	1.4
7	3	20.00			
8	3	20.00			
9	2	13.33			
10	6	40.00			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
3	1	7.69	9.0	7.8	2.2
5	1	7.69			
6	2	15.38			
8	2	15.38			
9	4	30.77			
10	3	23.08			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

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Q6 Are there any comments you would like to add?

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Q7 The following item relates to the *Abstract* of the study.

Q8 ITEM 2. Identification as a risk minimization evaluation study, description of risk minimization program including its goal(s) and theoretical basis (if known), how it was implemented and by whom, the target population, evaluation methods, and the key process and health outcomes.

The median, mean, standard deviation, and frequency distributions for importance and understandability from Round 1 are provided for your reference.

Importance					
Ranking	Frequency	Percent	Median	Mean	SD
7	2	13.33	9.0	8.8	1.1
8	4	26.67			
9	4	26.67			
10	5	33.33			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
3	1	8.33	7.0	7.3	2.2
5	1	8.33			
6	2	16.67			
7	3	25.00			
8	1	8.33			
9	1	8.33			
10	3	25.00			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	☐
Understandability (2)	☐									☐	☐

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Q9 Are there any comments you would like to add?

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Q10 The following 2 items relate to the *Introduction* of the study.

Q11 ITEM 4a. The scientific background and rationale for the risk minimization program being implemented (including any theory, model or framework used, any evidence about its effectiveness (e.g., pilot studies) and how it is expected to achieve its effects). Report "None used" if no theory, model or framework used or report "Information not available" if any of the above information is unknown. Example: *The eculizamab risk minimization program featured education for healthcare professionals on the risk of meningococcal infection, the different types of anti-meningitis vaccines available, and the importance of ensuring that patients were vaccinated prior to use of eculizamab. The program was based on the Theory of Reasoned Action which posits that knowledge is a necessary pre-condition for taking action (i.e., achieving the desired risk minimization behavior change). The risk minimization program was piloted in the phase 3 clinical trial program.*

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
3	1	6.67	7.0	7.1	2.3
4	1	6.67			
5	2	13.33			
6	2	13.33			
7	3	20.00			
8	1	6.67			
9	1	6.67			
10	4	26.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
4	1	8.33	8.0	7.8	2.2
5	1	8.33			
6	2	16.67			
7	1	8.33			
8	2	16.67			
10	5	41.67			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q12 ITEM 4b. The scientific rationale for the implementation strategy/ies (including any underpinning theory, model or framework, how it is expected to achieve its effects, and any pilot work). Report "None used" if no theory, model or framework used or report "Information not available" if any of the above information is not known. (Note:

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“Implementation strategy” refers to, for example, site training on how to implement the risk minimization program and how to implement it; or the requirement for local country sponsor affiliate offices to develop ‘local implementation plans’ and to monitor the implementation process).

The median, mean, standard deviation, and frequency distributions for importance and understandability from Round 1 are provided for your reference.

Importance					
Ranking	Frequency	Percent	Median	Mean	SD
3	1	6.67	8.0	8.0	2.0
5	1	6.67			
6	1	6.67			
7	1	6.67			
8	4	26.67			
9	3	20.00			
10	4	26.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	8.33	8.5	8.1	2.0
6	3	25.00			
7	1	8.33			
8	1	8.33			
9	1	8.33			
10	5	41.67			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐								☐		☐
Understandability (2)	☐								☐		☐

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Q13 Are there any comments you would like to add?

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Q14 The following item relates to the *Aims and Objectives* of the study.

Q15 ITEM 5. The aims of the evaluation study, differentiating between the risk minimization (“intervention”) objectives and the program implementation objectives.

Example: The study evaluation objectives for the HIV PrEP risk minimization program were to determine whether the program was implemented fully (i.e., 1) all targeted specialists received the risk minimization educational materials (‘reach’); and 2) all targeted healthcare settings implemented the program fully (‘adoption’); what impacts it had on healthcare professionals’ behaviors (i.e., 3) all patients prescribed PrEP to be screened monthly for HIV infection); and on patient health outcomes (i.e., 4) the monthly incidence of HIV infection among PrEP patients was less than 5%).

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	6.67	9.0	8.3	1.8
6	3	20.00			
8	3	20.00			
9	3	20.00			
10	5	33.33			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	8.33	9.0	7.8	2.6
5	2	16.67			
6	1	8.33			
8	1	8.33			
9	3	25.00			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q16 Are there any comments you would like to add?

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Q17 The following 5 items relate to the *Methods: Description* section.

Q18 **ITEM 6. The goals/objectives of the risk minimization evaluation study (including any hypotheses), design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards), date of implementation of risk minimization program, and any changes to evaluation (or "assessment") plan, with reasons.** *Example: We hypothesized that, as a result of distributing a brochure, 80% of physicians who prescribed [drug name] would correctly identify the three key steps involved in screening patients for low blood pressure prior to initiating [drug name] therapy.*

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
6	1	6.67	9.0	8.9	1.2
7	1	6.67			
8	3	20.00			
9	4	26.67			
10	6	40.00			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
6	4	33.33	7.0	7.6	1.6
7	3	25.00			
8	2	16.67			
10	3	25.00			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	☐
Understandability (2)	☐									☐	☐

Q19 ITEM 7. The broader context in which the risk minimization program (the “intervention”) was implemented. (Consider healthcare regulations, other relevant policies, social, economic or political factors that might influence implementation).
Example: The revised REMS program for Mifeprax was implemented following the US Supreme Court decision to reverse Roe v. Wade.

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
0	1	6.67	9.0	8.5	2.5
7	1	6.67			
8	3	20.00			
9	4	26.67			
10	6	40.00			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
6	1	8.33	8.5	8.6	1.3
7	1	8.33			
8	4	33.33			
9	2	16.67			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	☐
Understandability (2)	☐									☐	☐

Q20 ITEM 8. The characteristics of the targeted healthcare sites for the evaluation (type, location, and eligibility criteria).

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
0	1	6.67	8.0	7.5	2.6
5	1	6.67			
6	2	13.33			
7	2	13.33			
8	3	20.00			
9	3	20.00			
10	3	20.00			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
6	2	18.18	9.0	8.5	1.6
7	1	9.09			
8	1	9.09			
9	3	27.27			
10	4	36.36			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q21 ITEM 9a. A description of the risk minimization program, including the risk minimization tool(s) and whether any stakeholders were involved in program and or tool development (Key content/messages in any educational material recommended to be included in online supplementary materials or appendix). *Example: The risk minimization program consisted of educating healthcare professionals. The specific risk minimization tools, which were developed based on focus group input from healthcare professionals, included a*

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Dear Healthcare Professional letter and a Benefit-Risk Counseling tool for physicians.

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
0	1	6.67	9.0	8.5	2.6
6	1	6.67			
8	1	6.67			
9	7	46.67			
10	5	33.33			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
6	1	9.09	9.0	8.5	1.4
7	2	18.18			
8	2	18.18			
9	2	18.18			
10	4	36.36			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q22 ITEM 9b. A description of the risk minimization program implementation and dissemination strategies. If the implementation and/or dissemination strategies are unknown, report "Unknown." *Example: The implementation strategy for the risk minimization program involved healthcare site-specific training programs for healthcare professionals (HCPs) regarding how to use the risk minimization tools. A letter was also sent to all HCPs describing the risk minimization program and the tools and informing the HCPs about how to access a dedicated website where electronic versions of the tools were available for downloading.*

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
0	1	6.67	9.0	7.8	2.7
5	1	6.67			
6	2	13.33			
8	3	20.00			
9	4	26.67			
10	4	26.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	9.09	8.0	8.0	1.7
6	1	9.09			
7	2	18.18			
8	3	27.27			
9	1	9.09			
10	3	27.27			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q23 Are there any comments you would like to add?

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Q24 The following 4 items relate to the *Methods: Evaluation* section.

Q25 ITEM 10. Describe the outcome measures of the risk minimization program evaluation study (including knowledge-, behavior- and patient health-related), how they were selected and assessed, and the sources of data and methods of measurement, and what were the pre-determined thresholds of success. If not assessed or not pre-specified, report such (e.g., "Not assessed"). *Example: The primary effectiveness outcome of the risk minimization evaluation study was the cumulative annual incidence of patients using clozapine who developed agranulocytosis. The (pre-determined) acceptable threshold was set at .05% or lower based on clinician input and discussions with the regulatory authority.*

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
7	1	6.67	10.0	9.3	0.96
8	2	13.33			
9	4	26.67			
10	8	53.33			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	9.09	8.0	8.1	2.3
7	1	9.09			
8	5	45.45			
10	4	36.36			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐								☐		☐
Understandability (2)	☐								☐		☐

Q26 ITEM 11. Describe the process measures prespecified as a goal of the evaluation study (Note: these are considered “implementation outcomes” and include: degree of program reach, adoption, and the fidelity with which the program was implemented) and how they were selected and assessed. If not assessed or unknown, report such (e.g., "Not assessed", or "Unknown").

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
7	1	6.67	9.0	9.1	1.0
8	3	20.00			
9	4	26.67			
10	7	46.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	8.33	8.0	7.4	2.3
5	1	8.33			
6	1	8.33			
7	2	16.67			
8	3	25.00			
9	2	16.67			
10	2	16.67			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐								☐		
Understandability (2)	☐								☐		

Q27 ITEM 12. Description of program burden (for example, any extra time, personnel, skills, equipment required by site to implement the risk minimization program).

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Journal: Drug Safety

Authors: Smith MY, Morrato EH, Mora N, Nguyen V, Pinnock H, Winterstein AG

Corresponding Author: Meredith Y Smith, Evidera Inc., tantmieux57@gmail.com

The median, mean, standard deviation, and frequency distributions for importance and understandability from Round 1 are provided for your reference.

Importance					
Ranking	Frequency	Percent	Median	Mean	SD
5	3	20.00	8.0	7.3	1.7
6	2	13.33			
7	2	13.33			
8	5	33.33			
9	1	6.67			
10	2	13.33			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
5	2	16.67	7.5	7.7	2.0
6	2	16.67			
7	2	16.67			
8	2	16.67			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q28 ITEM 15. Any a priori sub-group analyses (e.g., between different sites, or different clinical or demographic populations). *Example: We planned to assess level of self-reported adherence to using 2 forms of birth control among 3 subgroups of patients using isotretinoin: 1) adolescent females of child-bearing potential (FCBP); 2) FCBP aged 20-30; and 3) FCBP aged 31+).*

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	6.67	8.0	8.1	1.6
6	2	13.33			
7	2	13.33			
8	4	26.67			
9	2	13.33			
10	4	26.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	8.33	8.5	7.9	2.4
6	2	16.67			
7	1	8.33			
8	2	16.67			
9	2	16.67			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q29 Are there any comments you would like to add?

Page Break

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Q30 The following 5 items relate to the *Results* section.

Q31 ITEM 16. Proportion recruited and characteristics (if appropriate) of the recipient population for the risk minimization evaluation study including a table showing baseline characteristics of study sample or population and settings (e.g., demographic, clinical, social, setting type, number, and locations).

The median, mean, standard deviation, and frequency distributions for importance and understandability from Round 1 are provided for your reference.

Importance					
Ranking	Frequency	Percent	Median	Mean	SD
7	2	13.33	8.0	8.8	1.2
8	6	40.00			
10	7	46.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
6	1	8.33	8.5	8.8	1.3
8	5	41.67			
9	1	8.33			
10	5	41.67			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

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Q32 ITEM 17a. Primary and other outcome(s) of the risk minimization evaluation study (if assessed), including precision of assessment and whether the primary outcome met a pre-specified success threshold. If pre-specified success threshold is unknown, report “Unknown.”

The median, mean, standard deviation, and frequency distributions for importance and understandability from Round 1 are provided for your reference.

Importance					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	6.67	9.0	8.9	1.4
7	1	6.67			
8	2	13.33			
9	5	33.33			
10	6	40.00			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	8.33	7.5	7.4	2.5
5	1	8.33			
6	2	16.67			
7	2	16.67			
8	2	16.67			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q33 ITEM 17b. Process indicators (“implementation outcomes”) associated with program implementation (e.g., Numbers of healthcare professionals trained; number of

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educational materials delivered; assessments of barriers and facilitators to program implementation). If not assessed, report "Not assessed."

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	6.67	9.0	8.7	1.4
7	1	6.67			
8	4	26.67			
9	3	20.00			
10	6	40.00			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	8.33	8.0	8.1	2.3
6	1	8.33			
8	5	41.67			
9	1	8.33			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q34 ITEM 20. Degree of fidelity involved in delivering the risk minimization program intervention elements (e.g., elements to assure safe use per FDA guidance, or the specific additional risk minimization measures per EMA guidance). If the degree of fidelity involved in delivering the elements of the program is unknown or was unmeasured, report "Unknown or Unmeasured."

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
4	1	6.67	8.0	7.5	1.6
5	1	6.67			
6	1	6.67			
7	2	13.33			
8	7	46.67			
9	2	13.33			
10	1	6.67			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
2	1	8.33	7.0	6.8	2.6
4	2	16.67			
6	3	25.00			
8	2	16.67			
9	2	16.67			
10	2	16.67			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐									☐	
Understandability (2)	☐									☐	

Q35 ITEM 22. Results of other analyses performed (for example, important, pre-defined subgroup analyses, sensitivity analyses) and evaluation of important harms and unintended effect(s) of the risk minimization intervention.

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Importance					
Ranking	Frequency	Percent	Median	Mean	SD
7	4	28.57	8.0	8.5	1.3
8	4	28.57			
9	1	7.14			
10	5	35.71			

Understandability					
Ranking	Frequency	Percent	Median	Mean	SD
5	1	8.33	8.0	7.9	1.9
6	3	25.00			
7	1	8.33			
8	2	16.67			
9	1	8.33			
10	4	33.33			

	0 (0=Lowest) (1)	1 (2)	2 (3)	3 (4)	4 (5)	5 (6)	6 (7)	7 (8)	8 (9)	9 (10)	10 (10=Highest) (11)
Importance (1)	☐								☐		☐
Understandability (2)	☐								☐		☐

Q36 Are there any comments you would like to add?

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