Evaluating a structured reporting template to increase transparency and reduce review time for healthcare database studies

MODERATOR GUIDE

PRA compliance

Control number and expiration date	OMB control number: 0910-0497 Expiration date: 10/31/2020
Paperwork Reduction Act Statement	According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0497. The time required to complete this portion of the information collection is estimated to be 120 minutes, including time for reviewing the structured reporting template + user guide and participating in a conference call with discussion questions. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.

Agenda for focus groups

	Topics covered	Time allocation [min]
A Welcome and moderator introduction	▪ Purpose of focus group and agenda for the session ▪ How/why participants were chosen ▪ Role of moderator (e.g., time management)	5
B Participant introduction	▪ Names of participants and their organization	10
C Background	▪ Brief review of ISPE-ISPOR joint task force paper ▪ Brief review of structured and reporting template	20
D Structured discussion on benefits, risks, and suggestions for improvement	▪ General impressions, clarity, and usability ▪ Benefits, risks, or challenges ▪ Suggestions for improvement ▪ Likelihood of using/recommending the template ▪ Approach to educating and encouraging adoption	50
E General feedback questions and wrap-up	▪ Other feedback not previously covered	5
Total		**90**

A Welcome and moderator introduction

Moderator instructions

This guide will be used to manage time effectively and ensure coverage of certain topics of conversation. Participants should freely discuss topics presented by the moderator rather than follow the question/answer cadence of an interview. Due to time restrictions, it is possible that not every question will be asked, and it is the moderator's responsibility to decide when to transition to a new topic. Additionally, the moderator will adapt questions, based on the composition of each group and the group's prior responses.

A Welcome and moderator introduction

Moderator introduction script

Hi, my name is [fill in name], and I will be leading our discussion today about a structured protocol and reporting template with design visualization.

I'd like to start by thanking each of you for your participation in this session, which will last 90 minutes. The input from this session will be reported back to FDA in aggregate to help revise and improve the template, but all responses will be anonymized. This session will not be recorded in any form, but I will take notes, as will [fill in name] in the back of the room.

Each of you represents a key stakeholder group with strong experience with database studies. During this session, I will bring up a few topics and allow time for open discussion. There are no right or wrong answers, and I would encourage everyone to share their honest opinions.

To start the conversation, I'll give everyone a chance to introduce themselves. Then, we'll transition to discussing potential challenges of using a template and suggestions for improvement. At the end, I'll leave time for general feedback not covered earlier in the session.

As moderator, I will actively manage the time and make sure that we cover all of our desired topics. This means that I may have to stop an on-going discussion in order to move to a new topic.

B Participant introduction

Participant introduction script

To begin with, can everyone please say their name and the organization they come from?
Wait for everyone to introduce themselves. Allow no more than one minute per participant.
Thank you for those introductions.

C Background

See power point slide deck.

C Structured discussion

Discussion script	In this part of the conversation, we'll focus the discussion on four areas: your general impressions, risks, benefits, suggestions for improvement and thoughts on adoption of a structured reporting template.
Impressions	1) What did you think about the template and user guide, overall? 2) How would you describe the clarity and usability of the template?
Benefits	3) What benefits do you see from developing study protocols or reporting on study implementation using such a template?
Risks	4) What are the main risks or challenges you would foresee in using this template as a researcher or a reviewer?
Suggestions	6) Based on the benefits and risks described earlier, how could this template be improved to better fit your use cases?
Adoption	7) How likely would it be for you to use or recommend using the template to others in the future? 8) What strategies would you suggest to widely educate and encourage adoption of use of a structured protocol and reporting template?

E General feedback and wrap-up

General feedback

1) What other feedback or suggestions for improvement would you like to share?
Save no more than five minutes for this question.

Wrap-up script

Again, I want to thank everyone for taking the time to participate in this session. Your input is incredibly valuable in informing the development of this structured reporting template.