

**FDA CDER Risk Communications
Internal and External Focus Groups
Interviewer's Guide
Deloitte OPM Task Orders 2&5**

Draft v6– October 5, 2011

Event Type: Focus Group Interview

Moderator/Interviewer:

Site: _____ Date:

Participant Details (Do Not Use Identifying Information):

Research Purpose: To assist FDA CDER in gaining your perspective on what you believe constitutes the key factors of message effectiveness within FDA's Drug Safety Communications.

Introduction and Ground Rules

Thank you for being here today. We greatly appreciate your willingness to participate in this <group / interview>. My name is _____, and I work for Deloitte Consulting/Global Prairie, an independent research and consulting firm. Today we are doing a project for the Center for Drug Evaluation and Research within the Food and Drug Administration. We have invited you here today to help us gain a better understanding of your perceptions of Drug Safety Communications, commonly referred to as DSCs.

Your opinions are important to us and to FDA. With your help we will recommend ways FDA can improve their DSCs. There are no right or wrong answers here—we're really just looking for your feelings and opinions on the issues that we'll be talking about.

Before we begin, I want to briefly go over a few ground rules for our <group / interview> today:

- We're recording this discussion to help facilitate the research. This helps to make sure we capture everything that's said during the conversation.
- <If Focus Group, include the following>
 - Please keep side conversations to a minimum—let us all hear what you're saying to your neighbor.
 - Please speak one at a time so the recording can clearly pick up what you're saying.
 - We want to hear from all of you, so as moderator I may ask you specifically to respond to a question.
- We will keep what you say confidential, and will not use your name or share this information beyond our research group.
- Also, I don't write FDA DSCs, so don't worry about offending me if you say something critical of the process or products. You really can't hurt my feelings here, and getting your honest opinions and feedback is the whole purpose of the <group / interview> today, so don't feel the need to hold back or pull any punches.

So, with that being said, let's begin...

Ice Breaker

To start off, please introduce yourself and respond briefly to the following question(s):

- What are some sources you go to for medical information?
 - What are some of the reasons you go to that source?
- If a message was sent out to convey drug safety information, what would you expect to see included in that message?

General Thoughts on DSCs

Great, thank you. So, turning specifically to Drug Safety Communications then, please describe to me how familiar you are with DSCs.

<Whether or not the participant(s) is/are familiar with DSCs, lead into general thoughts on purpose and function of DSCs.>

- In your own words, what would you say is the main purpose for FDA to release a DSC?
 - What gives you this impression?

There are a variety of factors that health communications experts view as being an important part of communication effectiveness/success. This might include the message itself, who the target audience is, what language/word choices the messages uses, and/or whether or not there is a multi-media component to the message. What we would like to understand from you, is to what extent these particular variables affect the success of the communication. Before we go through the various elements, I want to address how we define communication success for these research questions. There are multiple ways to look at message success, and it is important for us to differentiate our definitions as we go through our conversation today. For the next set of questions, we have defined message success by focusing on three questions: how wide the message spreads online, how many people or media outlets pick up the message and how long people stay engaged in online discussions about the communication.

- With that idea of success in mind, I am going to share with you a list of items that I would like for you to rank on a scale of 1 to 5, how important you think they are in contributing to message success and why. 1 being the least important and 5 being the most important:
 - Use of multi-media (images, videos, podcasts, etc.)
 - Inclusion of scientific evidence
 - Readability (how important it is for the message to be written in simple language)
 - If the target population is classified as vulnerable (this would include women, children, elderly, etc.)
 - Overall use of the drug, such as usage data
 - Clear call to action

<Once they have written down their responses, allow each person to share what they chose and their reasons for choosing as they did>

- Another component in communication success is effective dissemination. The FDA posts their DSCs to the FDA website upon release. What are your thoughts on how FDA sends out their information?
 - What are some reasons you believe this?

<If Focus Group, allow each person to briefly introduce and share thoughts>

DSC Review Exercise

Now let's take a look at an actual DSC. I have one here that I will share with you. Please take a few minutes to look this over, and then I'll ask you some questions about your thoughts and reactions to the document. Just look up or give me a nod when you're ready.

<Allow participant(s) time to review the DSC.>

OPTIONS FOR DSCs:

Biphosphonates - <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm203891.htm>

Invirase - <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm201221.htm>

Zocor - <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm>

OK, to start off:

- What are your general impressions of the DSC?
 - What gives you this impression?
- What first caught your attention when you began looking the DSC over?
 - What about that grabbed your attention?
- What, if anything, in this DSC do you find interesting?
 - What are some reasons you feel this way?
- How easy do you find it is to read this DSC?
 - Please elaborate on your answer.
 - What portions were difficult to understand?
 - <PROBE: ease of reading, language used (too technical, too much jargon, etc.), format>
- What is your impression of the DSC format and design?

Great, that is helpful information. Now, how about sharing with me your thoughts on what is effective or ineffective in this DCS. Think back to our conversation on defining success and use that to guide your thoughts.

- What do you think the main message of this DSC is?
 - On a scale from 1 to 10 (1 being “poorly” and 10 being “exceptionally”), how well would you say this DSC is doing at conveying its intended message to readers?
 - What are some reasons for your opinion?
- How would you define effectiveness for this DSC? What in this DSC really stands out as effective to you?
 - Feel free to define “effective” as you see fit—what I’m looking for here is “what really works for you in this DSC?”
- OK, and now, what in this DSC stands out as particularly ineffective?
 - What really isn’t working for you here, or what has really missed the mark?
 - What are some reasons you feel this way?

<Be sure to probe for content driven answers>

Essential and Effective Elements of a DSC

So now that we've looked at this DSC and discussed it at some length, I'd like to get your opinion on how DSCs can be improved and made stronger or better in communicating their intended messages. To start out with:

- What do you think could make this DSC more effective?
- What ideas or information in the DSC are most compelling to you?
- Who would you say is the target population?
 - How is that made clear in the communication?

*(Hypothesis driven questions)

- What are your thoughts of how the severity of the disease targeted by the communication affect how many people or sources might be picking up or passing on the message?
- Some severe diseases have smaller patient populations, and some less severe conditions have large patient populations – to what extent do you believe the size of the patient population affects message pick up? Please explain your answer.
- Switching over to the severity of the potential risk that the DSC is describing (for example, “People who take X, may develop bladder cancer”), what are your thoughts on how the severity of the potential disease/condition might affect message pick up?
- DSCs are meant for patient, consumer and health care professional populations. Based on that knowledge and now having a sense of what the DSCs look/read like, do you think that the DSCs do a good job of addressing the potential needs of each of those populations? Please explain your answer.
- In today's media landscape of microblogging and twitter, many people only read the headline and first sentence or two of a communication before deciding to repost or re-tweet it. Based on that idea, explain to me why you think the DSC would or would not be reposted or retweeted.
- Many of the DSCs affect vulnerable populations, including women, children, and the elderly. Do you think a communication that focuses on a vulnerable population would have greater increased online behavior? Why/Why not?

Conclusion

We'd like to thank you again for being here and for contributing to this discussion. We have learned a lot and really appreciate your ideas and insights. Before we conclude, I'd like to ask just one more question:

- Based on what we've discussed today, what one piece of advice would you give FDA to improve the effectiveness of the DSCs that they produce in terms of:
 - The DSC content?
 - How DSCs are presented?

Closing Statement

Well, those are all of the questions I have for you. Thank you very much for your comments. This has been very helpful. Your responses will help us make great recommendations to FDA.