

Appendix A

FDA External Focus Group Moderator's Guide

Introduction

(5 Minutes)

Hello. Thank you all for coming today.

My name is _____ and I will be the moderator for the session today. I would also like to introduce _____ who will be taking some notes and helping me during the session today. We are here on behalf of the FDA's Office of External Affairs in their efforts to improve service delivery.

Purpose of the Group

The purpose of this session is for us to talk about your experiences with the FDA.gov website.

Role of the Moderator

My role as moderator will be to direct the flow of the discussion and keep us on track. I need to make sure we get through all the topics in the next hour. In order to do so and to make sure everyone has a chance to contribute to the discussion, I have a few guidelines for the session.

Guidelines for the Session

Confidentiality. Anything that is said in this discussion will be strictly confidential. Nobody's name will be associated with any opinions included in the report. So, please feel free to express your opinions.

Frank opinions on the topics under discussion. We asked you to come today because what you have to say is important. We want to know exactly how you feel on the topics under discussion. It's important that I hear from each of you. Some of you may not feel comfortable talking at first, but as the discussion progresses, I may call on some of you directly to get feedback from everyone.

You may comment on the opinion of others. We do not expect that everyone here will agree or disagree on a given issue or point of view. We ask, however, that you respect each other's opinions, and respond to each other in a respectful manner. Remember, there are no right or wrong answers.

Audio taping. This session is being recorded to have an accurate record of what was said, so it will be easier for us to write our report. I want to assure you again, the report will not mention you by name.

Speak loudly enough to be heard by everyone. It is important that everyone hears what you have to say and for us it is especially important that the tape recorders pick up what you say. So please speak loudly and clearly.

Talking over each other. When the discussion starts to get exciting, you may want to say what you are thinking without waiting for someone else to finish. That is exactly when we want to ensure that we hear everyone. So, I'm asking that you talk one-at-a time, and avoid side conversations so I don't miss any of what you are saying.

Warm-up Exercise

(5 minutes)

I'd like to start by having us get to know a little bit about each other. Could you please briefly tell us: **[Go around the table]**

- Your first name; and
- Your occupation.

Project Introduction

(5 minutes)

Let's begin our discussion with a little project background. Based on an analysis of site data, the FDA found the majority of their site visitors fall into five audience groups, and we are holding sessions with members of each group to refine our knowledge of the target audiences (meaning, you), the content and tasks for which you are coming, and the information architecture challenges you are encountering.

Opening

Please tell me how often you use the FDA.gov website, and when you last visited. **[Go around the table]**

Target Audience

(10 minutes)

Now, let's talk about the target audience.

[Begin writing NOTES on easel or whiteboard or shared document]

Who do you think makes up this audience?

3.1a Let's tally up what we already have attending our session.

3.1b What other groups might also belong?

How well does this audience label fit you?

Content & Tasks

(10 Minutes)

Now let's talk about what you came to the website to do. You may have been looking for information, or trying to accomplish a task (like filling out a form). **[do NOT read the following lists out loud]**

What kinds of information are you looking for?

		[mark per mention]	[take a poll]
4.1a	What's New		
4.1b	Guidance Documents		
4.1c	Video		
4.1d	Regulations		
4.1e	Warning Letters		
4.1f	Device Information		
4.1g	Device Approval (Process)		
4.1h	Databases		
4.1i	Recalls		
4.1j	Safety Information		
4.1k	Alerts		
4.1l	Drug Information		
4.1m	Drug Approval (Process)		
4.1n	Federal Register Notices		
4.1o	Presentations		
4.1p	FOIA		
4.1q	Contact Information		
4.1r	Other [list]		

Are there any tasks you have tried to accomplish on the website?

	[mark per mention]	[take a poll]
4.2a Use MAUDE		
4.2b Use Medwatch		
4.2c File a Complaint		
4.2d Sign Up for Alerts		
4.2e Other [list]		

Can you rank any of these in order of importance to you?

[paper-based, can be done at end]

- 4.3a Please write down those items you needed in order of importance to you.
- 4.3b Beside each item, indicate how many times in the last year you looked for that item.

Information Architecture

(10 Minutes)

Next, I would like to talk about the Information Architecture of the site. Information Architecture (or IA) is how you define the structure, organization, navigation, labeling and indexing of a website. Good IA helps a site make sense to its end users, enables them to more easily find their way through it, and builds a site that can accommodate future growth.

Have you encountered any problems when searching for information or performing tasks on the website? It's okay to say "no."

5.1a If "yes," what were they?

		[mark per mention]	[take a poll]
5.1a	Need to improve search		
5.1b	Difficulty locating information in general		
5.1c	Too many levels/layers		
5.1d	Difficulty locating Guidance Documents		
5.1e	Information is scattered		
5.1f	Resorting to search		
5.1g	Difficulty locating the right database		
5.1h	Difficulty reporting events		
5.1j	Database usability		
5.1n	Other [list]		

Can you name any specific items with which you had difficulty?

5.2a Were you ultimately successful? How did you get there?

5.2b If not, what did you do when you couldn't accomplish your goal?

Can you rank any of these in order of most applicable to you?

[paper-based, can be done at end]

5.3a Please write down those issues you feel are most applicable to you, in the order that reflects their relative impact on your usage of the website.

Desires

(10 Minutes)

Now, let's talk a little bit about what you think could make your experience of the FDA.gov website better. This section is about brainstorming beyond just addressing the challenges brought up earlier.

Name some features or functionality that you would like to see implemented on the website.

		[mark per mention]	[take a poll]
6.1a	Improved search		
6.1 b	Provide FAQs		
6.1c	Provide a guide to FDA.gov		
6.1 d	Add natural language queries		
6.1e	Consolidate related information		
6.1f	Other [list]		

What other websites do you know of that have features you like?

6.2a Please name the site(s) and their feature(s).

Wrap-Up

(5 minutes)

What other comments or observations would you like to add about the FDA.gov website?

Those are all of the questions I have for this session. You have been very helpful. Thank you very much for coming and helping us with this project.

[If asked about what happens to this data] We plan to start incorporating any changes at the end of the third quarter or the beginning of the fourth quarter, depending on the complexity.