

Observational Meeting Form

All Meeting Types

Paperwork Reduction Act Statement:

OMB Control No. **0910-NEW**

Expiration date:

*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-NEW**. There is no time required to complete this information collection, since this data collection will consist of passive observations of existing or scheduled meetings. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.*

Opening Script (optional):

*Hello everyone. My name is **[NAME]**, and I am with Eagle Hill Consulting. FDA contracted with the management consulting firm Eagle Hill Consulting to conduct an assessment on the TAP Pilot, which includes passive observations of meetings. During this session, I will be observing and taking notes on engagement, collaboration, quality, and program submission activities.*

I want to note that this a non-intrusive observation, meaning my role is to watch and take notes without interfering with your usual activities. All observations made today will remain confidential. Any notes taken will be used solely for the assessment, and no personal identifiers will be included in any reports or discussions. Your participation is voluntary. If you have any questions or concerns during the observation, please feel free to let me know, but otherwise, I will remain in the background. Thank you!

Teleconference Details	
Date of Meeting	Click or tap to enter a date.
Meeting Start Time	Click or tap here to enter text.
Meeting End Time	Click or tap here to enter text.
Meeting Duration (in minutes)	Click or tap here to enter text.
Sponsor Name (i.e., company name)	Click or tap here to enter text.
Device Name	Click or tap here to enter text.
List of Other Organizations Present	Click or tap here to enter text.

List of Names, roles, and organization of meeting attendees	Click or tap here to enter text.
Observer Name	Click or tap here to enter text.
Amendment (<i>Definition: An amendment is a requested and documented interaction with FDA or non-FDA stakeholders</i>)	<input type="checkbox"/> Yes (Amendment Number: Click or tap here to enter text.) <input type="checkbox"/> No

Participation and Engagement with the TAP Pilot		
Prompt	Answer	Observer Notes
Did all intended participants join the meeting?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or tap here to enter text.
Did participants introduce themselves when relevant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or tap here to enter text.
Were the goals or objectives of the meeting outlined from the beginning of the meeting?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.

Collaboration		
Prompt	Answer	Observer Notes
Did all team members participate in the discussion?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or tap here to enter text.
Did team members ask questions?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.
Did attendees suggest options or opinions that differed from those around them?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or tap here to enter text.

Did participants seem comfortable engaging in the discussion?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or tap here to enter text.
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Quantity and Quality of Interaction		
Prompt	Answer	Observer Notes
What type(s) of feedback were sought during the teleconference?	<input type="checkbox"/> General Strategy <input type="checkbox"/> Commercialization <input type="checkbox"/> Device Development Plan <input type="checkbox"/> Regulatory Requirements <input type="checkbox"/> Stakeholder Engagement Plan <input type="checkbox"/> Other	Click or tap here to enter text.
Was the feedback provided by the team constructive and actionable? <i>(Constructive and actional feedback aims to improve outcomes by focusing on specific areas for development with clear, specific, and supportive suggestions and steps that can be taken. Criteria includes specific, objective, balanced, direct, timely, respectful and outcome-oriented feedback)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.
Were participants receptive to the	<input type="checkbox"/> Yes	Click or tap here to enter text.

Quantity and Quality of Interaction		
Prompt	Answer	Observer Notes
feedback received?	<input type="checkbox"/> No <input type="checkbox"/> N/A	
Were there agreements or resolutions reached during the teleconference?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.

Program Submission Activities and Their Timeliness		
Prompt	Answer	Observer Notes
Did the teleconference start on time?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.
Did the teleconference end with clearly outlined next steps?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.
Was the teleconference documented in minutes?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Click or tap here to enter text.