# 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* *PRAStaff@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!*

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| **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 (*Definition: An amendment is a requested and documented interaction with FDA or non-FDA stakeholders*) | [ ]  Yes (Amendment Number: Click or tap here to enter text.)[ ]  No |

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| **Participation and Engagement with the TAP Pilot** |
| Prompt | Answer | Observer Notes |
| Did all intended participants join the meeting? | [ ]  Yes[ ]  No | Click or tap here to enter text. |
| Did participants introduce themselves when relevant? | [ ]  Yes[ ]  No | Click or tap here to enter text. |
| Were the goals or objectives of the meeting outlined from the beginning of the meeting? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |

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| **Collaboration** |
| Prompt | Answer | Observer Notes |
| Did all team members participate in the discussion? | [ ]  Yes[ ]  No | Click or tap here to enter text. |
| Did team members ask questions? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |
| Did attendees suggest options or opinions that differed from those around them? | [ ]  Yes[ ]  No | Click or tap here to enter text. |
| Did participants seem comfortable engaging in the discussion? | [ ]  Yes[ ]  No | Click or tap here to enter text. |

| **Quantity and Quality of Interaction** |
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| Prompt | Answer | Observer Notes |
| What type(s) of feedback were sought during the teleconference? | [ ]  General Strategy[ ]  Commercialization[ ]  Device Development Plan[ ]  Regulatory Requirements[ ]  Stakeholder Engagement Plan [ ]  Other  | Click or tap here to enter text. |
| Was the feedback provided by the team constructive and actionable? (*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)* | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |
| Were participants receptive to the feedback received? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |
| Were there agreements or resolutions reached during the teleconference? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |

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| **Program Submission Activities and Their Timeliness** |
| Prompt | Answer | Observer Notes |
| Did the teleconference start on time? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |
| Did the teleconference end with clearly outlined next steps? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |
| Was the teleconference documented in minutes? | [ ]  Yes[ ]  No[ ]  N/A | Click or tap here to enter text. |