

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.

| 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 | <input type="checkbox"/> Yes (Amendment Number: Click or tap here to enter text.) <input type="checkbox"/> No |

| Engagement with the TAP Pilot | | |
|-------------------------------|------------------------------|----------------------------------|
| Prompt | Answer | Observer Notes |
| Did all intended participants | <input type="checkbox"/> Yes | Click or tap here to enter text. |

| | | |
|---|---|----------------------------------|
| join the meeting? | <input type="checkbox"/> No | |
| 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. |

| 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? | <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 feedback received? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Click or tap here to enter text. |
| 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 | Click or tap here to enter text. |

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|---|---|----------------------------------|
| | <input type="checkbox"/> N/A | |
| 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. |