Integrated Assessment Process: ORO Regulatory Project Management Perspective

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Current Overview of the Integrated Assessment

- During the Pre-NDA/BLA phase
  - Items may be identified as “potential” review issues and discussed during the Pre-NDA/BLA meeting
  - “Potential” review issues will be tracked using the review issues tracker
  - The Division may seek additional information or analysis to “potentially” address the identified issue either pre-NDA/BLA or in the marketing application

- Once the marketing application is submitted
  - The Integrated Assessment is currently being used for NMEs and original BLAs
  - Divisions are still using the 21st Century review process with the Integrated Assessment Process
  - If the marketing application is specifically utilizing the Integrated Review, the unique aspects of the Integrated Review will be merged with the 21st Century review timelines
Example of Merging 21st Century and Integrated Review

Meetings and Milestones of the Integrated Review for Marketing Applications

- **Pre-NDA/BLA Sponsor Meeting**
  - Application submission

- **Benefit-Risk Scoping Meeting**

- **Filing Meeting**

- **Midcycle Meeting**

- **Late-Cycle Meeting**

- **Wrap-Up Meeting**

- **Advisory Committee Meeting**

1. **Review month**
2. **PDUFA clock starts**

**Early identification of review issues at the pre-NDA/BLA phase**

**Issue-based meetings with earlier involvement of Office/Division leadership (i.e., Benefit-Risk Scoping and JAM)**

**The Review Issue List allows transparent, systematic tracking of issues by teams through the review**

1. Benefit-Risk Scoping Meeting can be held in conjunction with the Filing Meeting as the default; provided 90 minutes is allowed for both meetings.
2. JAMs (Joint Assessment Meetings) are shown for illustrative purposes only – timing and number should be tailored for the needs of the application.
Review Milestone Meetings

Internal Meetings:
• Filing meeting
• Benefit/Risk scoping meeting - NEW
• Wrap-up meeting
• Sprinkled in the review timeline are Joint Assessment Meetings (JAM) - NEW
  • No set number of JAM meetings that a Division must hold – depends on the review issues identified
  • Very structured meetings with specific agenda topics identified by the Review Issues Tracker
  • After a JAM Meeting – the RPM may send the Applicant information requests

External Meetings:
• Mid-Cycle
  • Mid-cycle communication
• Late-Cycle meeting
  • Late-cycle communications
What’s new with the Integrated Review for the RPM

- The RPM and CDTL are working as co-leaders to guide the team through the review process
- The RPM/CDTL as co-leaders ensure reviewers update the Review Issues Tracker to help identify agenda items for the upcoming JAM Meetings
- The RPM is writing the Regulatory History portion of the Integrated Review document
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