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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



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Example of Merging 21st Century and Integrated Review

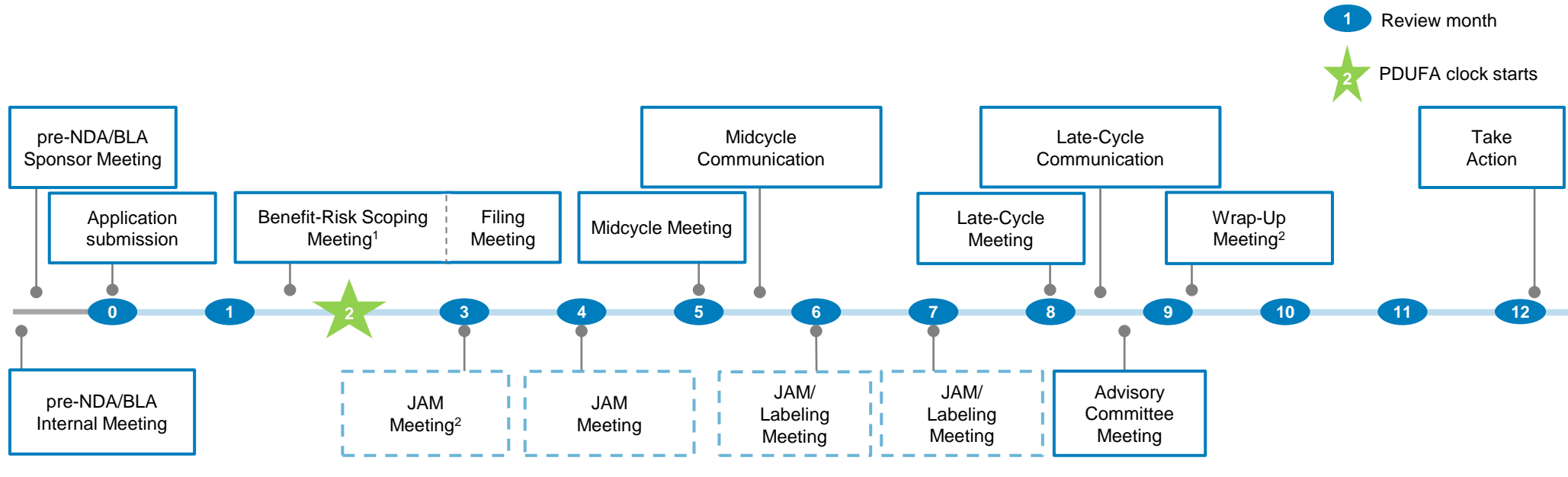


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Meetings and Milestones of the Integrated Review for Marketing Applications



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



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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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