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DIA 2021 GLOBAL ANNUAL MEETING | VIRTUAL JUNE 27-JULY 1

Integrated Assessment of Marketing Applications

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NDRP Modernization: Strategic Objectives

Objectives	Guiding principles for modernizing the NDRP
Scientific Leadership	Grow our scientific expertise and clarify pathways to regulatory approval.
Integrated Assessment	Critically, collaboratively and consistently assess whether information in submissions meets legal and regulatory requirements. • We will take a new approach to document our assessments, developing a more integrated, inter-disciplinary document to foster collaboration and reduce redundant information. • Our assessments will be rigorous, clinically relevant, focus on the key issues, and incorporate the patient perspective.
Benefit-Risk Monitoring	Systematically monitor the balance of benefits and risks of approved drugs pre- and post-approval to effectively protect the American public.
Managing Talent	Attract, develop, and retain outstanding people.
Operational Excellence	Standardize workflow, business processes, roles, and responsibilities to improve operational efficiency and enable our scientists to focus on science.
Knowledge Management	Facilitate the identification, capture, distribution and effective use of institutional knowledge.

Why was there a need for a new Integrated Assessment of Marketing Applications?

The Agency identified challenges with the prior process & template

- Discipline-specific reviews lead to redundant work and desire for additional clarity on rationale of interdisciplinary review issues
- Reviews centered by disciplines rather than interdisciplinary collaboration on review issues
- Reviewers asked for support to spend more time on critical thinking instead of editing or other programming tasks
- A need for better knowledge management

Feedback from External Stakeholders

New Drugs Regulatory Program Modernization: Implementation of the Integrated Assessment of Marketing Applications and Integrated Review Documentation Virtual Workshop

October 30, 2020

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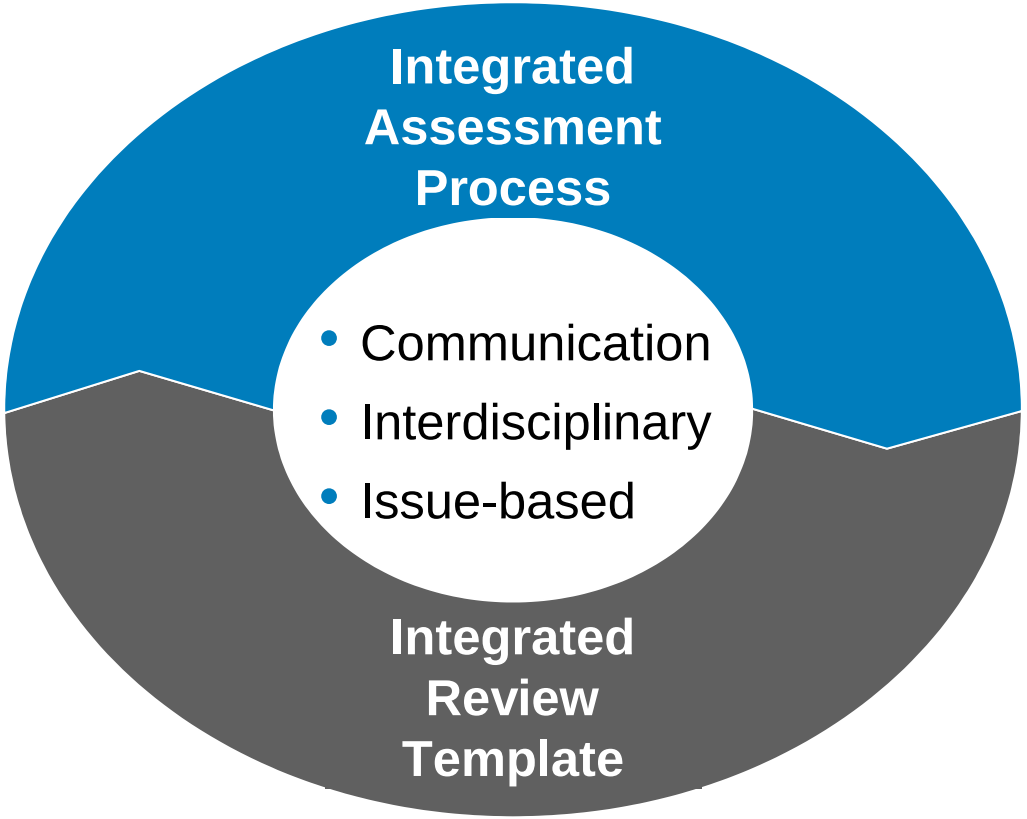
The new process and template address the identified challenges

New Integrated Assessment of Marketing Applications



Key issues are generally comprised of issues that inform or characterize our **assessment of benefit and risk**.

Goals for Integrated Assessment of Marketing Applications

Scientifically rigorous discipline-specific assessments enhanced by interdisciplinary collaboration/discussion

Efficient, issue-focused assessment supported by new roles

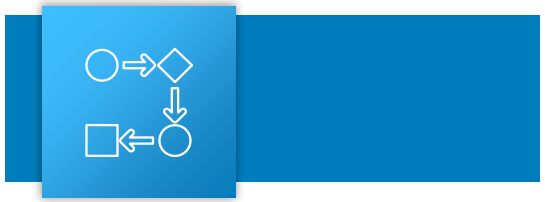
Enhanced communication within the review team and with external stakeholders

Clear articulation of the basis for regulatory decisions

Increased support for review teams, including clinical data scientists, medical editors, on-demand resources, trainings, ambassadors and peer support, and seamless workflow management

Overview of New Components of the Integrated Assessment

Integrated Assessment Components



New **process** to enable **early identification of review issues** and **interdisciplinary collaboration**

New **template** to enable **issue-based** and **inter-disciplinary** review documentation

New roles: **Clinical Data Scientist** and **Medical Editor** to enable **more time** for critical thinking

FDA is Actively Addressing Many of the Concerns Raised

Potential Concerns	
Themes	**FDA Actions**
Potential for **"groupthink"**	**FDA further defined guidelines for documentation of scientific differences of opinion within the process and template to provide clarity on avenues for discussion and documentation:** • Detailed discussion of different perspectives during issue-based interdisciplinary Joint Assessment Meetings (JAMs) • Different perspectives are embraced (aligned or not aligned) • All perspectives are clearly documented in the Executive Summary, Review Issues Section, Appendices, and/or discipline-specific sections within the IRT
Potential **loss of detailed data** and information	**Additional detailed information is available in the discipline-specific appendices, which include:** • Supportive documents, assessments, and analyses • Documents, assessments, and analyses of import to key facts, data, or conclusions of the review

FDA is Actively Addressing Many of the Concerns Raised

Potential Concerns	
Themes	**FDA Actions**
Potential loss of insight into **regulatory process**	**Intent behind the Integrated Review Template is to:** • Provide a standalone regulatory history section that summarizes the regulatory history of the drug product, including key regulatory decisions made throughout drug development • Provide further insight and clarity into the regulatory process through an interdisciplinary lens
Decreased navigability	**FDA improved navigability of the Integrated Review:** • The Integrated Review will retain hyperlinks • The Integrated Review will retain bookmarking functionality
Potential **decreased usability** for patients and other non-technical audiences	**FDA produces Drug Trials Snapshots for all approved NMEs:** • Non-technical document that describes the decision in layman's terms • Ensures transparency, clarity, readability, and usability for patients and other non-technical audiences

FDA Continues to Evaluate and Enhance Identified Benefits

Benefits	
Themes	**FDA Actions**
Improves **clarity** of the review document	**Reviewers also agree that Integrated Review documents provide more clarity, as they focus on key review issues.** **FDA intends to continue soliciting and evaluating feedback from the public to evaluate clarity of the review document.**
Improves **usability**	**Senior FDA subject matter experts continue to evaluate completed Integrated Review documents for usability.** **FDA intends to continue soliciting and evaluating feedback from the public to evaluate the usability of the Integrated Review documents.**
Drives a more **holistic assessment** by reviewers	**Senior FDA subject matter experts continue to evaluate completed Integrated Review documents for comprehensiveness.** **FDA intends to continue soliciting and evaluating feedback from the public.**

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