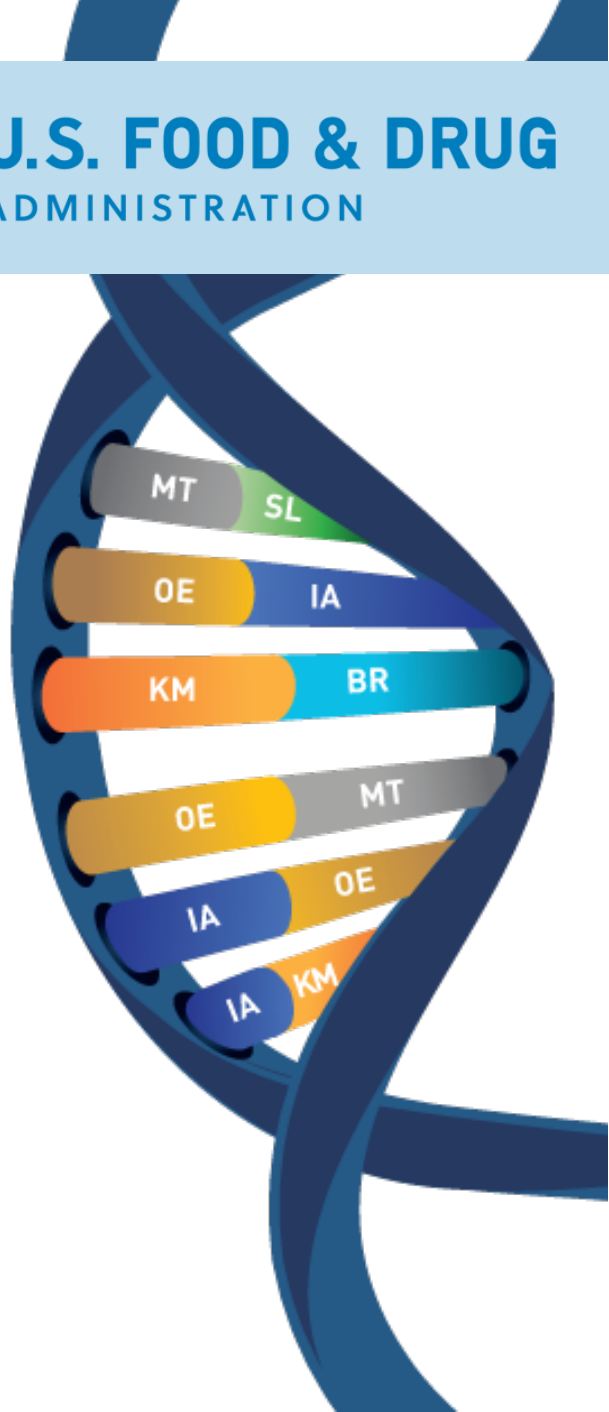
U.S. FOOD & DRUG ADMINISTRATION



New Drugs Regulatory Program Modernization

FDLI Update – April 2019

New Drugs Regulatory Program Modernization

Objectives	Guiding principles for modernizing the new drugs regulatory program
Scientific Leadership	**We will grow our scientific expertise and clarify pathways to regulatory approval.** • Expanding the armamentarium to address unmet medical needs is an important part of our public health mission. • Towards that end, we will proactively collaborate with academic medical scientists and patient/disease advocates, evaluate scientific gaps, and strategically foster drug development.
Integrated Assessment	**We will critically, collaboratively and consistently assess whether information in submissions meets statutory and regulatory requirements.** • We will take a new approach to document our assessments, developing a more integrated, cross-disciplinary document to foster collaboration and reduce redundant information. • Our assessments will be rigorous, risk-based, and clinically relevant; focus on the key issues; and incorporate the patient perspective.
Benefit-Risk Monitoring	**We will establish a unified post-market safety surveillance framework.** • To effectively protect the American public, we will systematically monitor the benefits and risks of approved drugs across their lifecycles.
Managing Talent	**We will attract, develop, and retain outstanding people.** • We will use 21st Century Cures Act authorities to recruit and retain technical, scientific and professional experts, and eliminate our backlog of vacant positions.
Operational Excellence	**We will have a dedicated focus on operational excellence.** • We will enhance our ability to address OND's large volume workload through greater process standardization and better defined roles and responsibilities. • This will improve operational efficiency and enable our scientists to focus on science, not ancillary tasks.
Knowledge Management	**We will facilitate knowledge management.** • Vast and diverse information is submitted to and generated by the New Drugs Regulatory Program. • We will make it easy for our staff to find and use scientific and regulatory precedents. • This will reduce manual work time, increase the speed and efficiency of submission assessment, and increase the consistency and predictability of regulatory decision-making.

The New Drugs Regulatory Program has 6 active initiatives

Integrated Review for Marketing Applications	Developing a streamlined interdisciplinary review process and template to support the new integrated review for assessing NDA/BLAs
IND Review Management	Streamlining the IND scientific review processes for managing IND applications, beginning with 30-Day Safety Reviews and Protocols
Post-Market Safety Management	Creating a standardized, consistent, and effective approach to post-market drug safety
Assessing Talent	Developing an effective and consistent process for hiring, onboarding, developing and evaluating new Clinical and Pharm/Tox reviewers
Reorganization and Transition Management	Planning, coordinating, and implementing modernization and organization changes at the future Office and Division levels across the New Drugs Program
Administrative Operations	Optimize administrative and clerical staff roles, structure, and functions to enhance customer focus and employee engagement

Integrated Review of Marketing Applications

- Effort attempts to design a streamlined issue-based integrated review process and template that reduces silo reviews, by
  - Creating **a template and a process** that are issue-based, foster interdisciplinary collaboration, reduce redundancy and low-value work, and enable better knowledge management
  - Developing a **tracking tool** to be utilized from pre-NDA through end of review cycle, allowing for systematic tracking of review issues for the entire review team
  - Adding **new roles** to allow reviewers to focus on the science and regulatory aspects of the application: (1) Clinical Data Scientists to support safety analysis and (2) Medical Editors to provide editing and formatting services
  - Incorporating **purposeful scoping working meetings** with early involvement of leadership to discuss known benefit and risk issues; and **joint assessment meetings** focused on specific review issues

Currently in Phased Implementation. All divisions to begin using the new process and template in 2020.

IND Review Management

- Effort attempts to address variable practices across divisions and reduce redundant documentation practices
- Creating templates that are **issue-based**, foster **interdisciplinary collaboration**, **reduce redundancy** and low-value work, and enable better **knowledge management**
- Establishing procedures that **standardize** the review process, clearly **define roles and responsibilities** and improve our ability to provide **high-quality feedback** to sponsors in a **timely manner**
- Developing a risk based approach to **categorize** incoming protocols and amendments and identify the protocols that should follow a **higher priority process** to review more expeditiously

Anticipate beginning implementation this summer

Post-Market Safety Management

Create a **standardized** post-market drug safety framework that will include:

- **Cross-disciplinary, collaborative, science-focused** assessments
- Clear **roles, responsibilities,** and **governance**
- IT-enabled processes to enhance **knowledge management** and fit-for-purpose **analytic tools** to promote optimal evaluations
- **Policies and processes** (i.e., via SOPs, charters, templates) that support this framework

Anticipate beginning implementation this fall