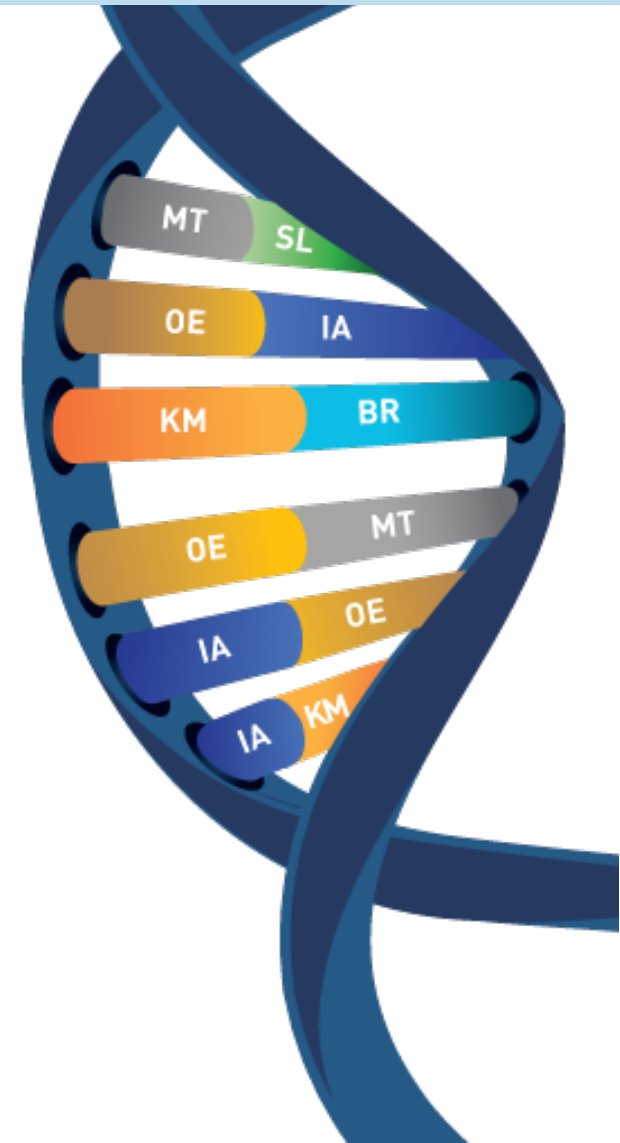


# New Drugs Regulatory Program Modernization

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 21<sup>st</sup> 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**