U.S. FOOD & DRUG ADMINISTRATION

NEW DRUGS REGULATORY PROGRAM MODERNIZATION

Impact Narrative Update 2023

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I. EXECUTIVE SUMMARY

The U.S. Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research's (CDER, the Center) mission is to protect and promote public health by helping to ensure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients. CDER achieves its mission for new drug products and original therapeutic biological products through the New Drugs Regulatory Program (NDRP, the program), which is designed to stay ahead of the fields it regulates to achieve its public health mission. To continuously improve regulatory science and review, CDER embarked upon an initiative to modernize the NDRP in early 2017.

In the early stages, the program identified six strategic objectives to shape a multi-year journey to modernize the program, including structural changes, process transformations, and improvements in talent management. These strategic objectives were:

SCIENTIFIC LEADERSHIP
INTEGRATED ASSESSMENT
OPERATIONAL EXCELLENCE
BENEFIT-RISK MONITORING
MANAGING TALENT
KNOWLEDGE MANAGEMENT

Guided by these strategic objectives, the program formed interdisciplinary workstreams to identify areas for improvement, develop recommendations, design detailed changes, and drive implementation. The workstreams have focused on the following:

- OND Reorganization
- Integrated Assessment of Marketing Applications
- Postmarket Safety
- Investigational New Drug (IND) Review Management
- Advisory Committees
- Assessing Talent and Talent Development & Management
- Knowledge Management

To ensure the impact and success of these workstreams, implementation follows a set of guiding principles for mobilizing stakeholders and creating shared expectations of progress. The collaborative approach is supported by a central organizing body with subject matter experts to drive implementation, a governance body with frequent check points to create accountability, a network of senior leaders to champion implementation, and ambassadors to expand the impact and embed change in the organization. Implementation is phase-based to enable an iterative test-and-learn approach, allow for ambitious timelines with built in flexibility to revise as conditions change, support coordination with interdependent efforts and organizations, and regularly track progress.

Since the initial 2020 Impact Narrative, the NDRP has reorganized the primary super-offices within CDER charged with its daily work. The restructuring resulted in the establishment of offices that better coordinate interconnected disease areas and divisions, each with a more defined and concentrated expertise. The aim was to increase leadership in proportion to the workload by expanding the number of divisions and offices, thereby mitigating bottlenecks. The focus on well-aligned offices and disease-specific divisions was intended to elevate expertise at both the leadership and divisional levels and afford leaders more time to invest in developing colleagues, while reaffirming the commitment to strengthening program operations and the science behind drug evaluation. CDER will continue to evaluate the full impact of the reorganization on an ongoing basis.

Implementation is phase-based to enable an iterative test-and-learn approach, allow for ambitious timelines with built in flexibility to revise as conditions change, support coordination with interdependent efforts and organizations, and regularly track progress.

Working to complement the reorganization, and in varying stages of implementation, the other workstreams have also demonstrated a positive impact on the NDRP.

The Integrated Assessment of Marketing Applications (IAMA) workstream created, refined, and expanded the use of the Integrated Review Template (IRT) and process to include all new molecular entities (NMEs) and original biologics license applications (BLAs). As part of this effort, the workstream developed and implemented the Collaborative Authoring Tool (CAT) to help standardize and streamline the marketing application process. The IAMA workstream has finalized its assessment/review tools. The process and template became mandatory for all NMEs and original BLAs starting in October 2023 (with the exception of the Office of Oncologic Disease (OOD), which has the option to use either IAMA process/template or the Assessment Aide). As a result of these activities, there are now more integrated assessments: articulating the key issues and providing an interdisciplinary perspective on those issues, with reduced redundancy and greater focus. This improves readability of the reviews and ultimately drives increases in understanding and collaboration.

The Postmarket Safety workstream developed an Integrated Safety Assessment (ISA) template for use in Newly Identified Safety Signal (NISS) evaluations, created and stood up all 9 planned Drug Safety Teams (DSTs), piloted a new process for pharmacovigilance strategies (PVS) that documents an internal post-approval plan for coordinated monitoring of safety information to enhance postmarketing drug safety surveillance for a drug or drug class, and developed

a postmarket safety curriculum for those in the space trying to learn more about key postmarket safety issues. These efforts have focused on improving collaboration on safety-related issues, increasing operational transparency on postmarket safety activities, enhancing approaches to identification and management of potential risks/safety signals, and improving professional development. While the Postmarket Safety workstream has made great strides, it is also currently reimagining its DST strategy to ensure that it provides the most value to all stakeholders in the process and that it standardizes certain applicable processes while also remaining flexible enough to tailor to the needs of certain DST operational requirements.

The IND workstream has successfully implemented new templates and processes for reviews across all OND prescription review divisions and aligned divisions in the Office of Translational Sciences, including transitioning 30-Day Safety Assessments into an automated workflow system (Nexus) to enhance efficiency, collaboration, and standardization of processes.

The Advisory Committee workstream continues to streamline processes and provide tools and resources to improve AC meetings so that there is consistent, efficient and high-quality AC preparation and consistent high quality AC meetings that provide well-informed and clear expert advice to FDA.

To further enhance productivity and value of the regulatory review process, the Talent and Knowledge Management workstreams continue to design and implement a robust applicant screening and talent development process, as well as enhance the overarching approach to managing knowledge through modern technology, analytics, and data governance tools.

These are just a few highlights of the last few years of the NDRP modernization. As progress across the workstreams continues, the iterative and phased approach allows for improvements developed by the workstreams to be applied quickly and visibly.

Collectively, the workstreams are advancing NDRP's ability to deliver on the six strategic objectives and offer opportunities for those interested to get involved in shaping the future of the program. This report, the New Drugs Regulatory Program Modernization – Impact Narrative Update (2023), provides a comprehensive look at the continued strategic objectives and achieved impact (including data points, where applicable) of the program modernization's progress, as well as on continued efforts toward reaching program goals. The report also illustrates how the progress and the contributions to-date further NDRP's ability to achieve its mission by staying ahead of the rapid growth and evolutions of drug development, review, and surveillance activity, the increasing complexity of innovative therapies under development, and the expanding public engagement in FDA activity.

NDRP's program contributions to-date further FDA's ability to achieve its mission by staying ahead of the rapid growth and evolutions of drug development, review, and surveillance activity, the increasing complexity of innovative therapies under development, and the expanding public engagement in FDA activity.

II. BACKGROUND AND CONTEXT

The U.S. Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research's (CDER, the Center) mission is to protect and promote public health by helping to ensure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients. CDER achieves its mission for new drug products and original therapeutic biological products through the New Drugs Regulatory Program (NDRP, the program). Central to achieving its public health mission is ensuring CDER's NDRP stays in the front of the fields it regulates, through the continued improvement of approaches to regulatory science and review. Consistent with that imperative, in early 2017, CDER embarked on an initiative to modernize the NDRP. The impetus to modernize came about in response to several changes in the external environment and the opportunity to seize on the existing success of the program, including:

- Rapid and sustained growth in the volume of drug development activity, including more targeted drugs, increasing focus on orphan and breakthrough therapies;
- Increased complexity of innovative therapies under development (e.g., combination products, innovative delivery platforms, tumor agnostic treatments in oncology, rare diseases);
- Evolution in drug development, review, and surveillance activity driven by greater availability of observational and other "real world" data;
- Increased public engagement in FDA activity, including heightened patient involvement in drug development and elevated external scrutiny of FDA review decisions;
- Persistent budget constraints in which resources do not grow to match increases in workload, coupled with sustained performance expectations captured in user fee commitments; and
- A chronic talent shortage in which understaffed offices and divisions find themselves competing with industry to attract, develop, and retain talent.

The implications of these external factors are profound for CDER and the program. Specifically:

- A continued increase in review workload without corresponding increases in resources necessitates an emphasis on making day to day work more efficient through process simplification and technology-enablement.
- Pace and scope of therapeutic innovation requires deeper subject matter expertise, evolution in regulatory policy and guidance, introduction of new analytical techniques, and a tighter structural alignment between the Office of New Drugs' (OND's) internal organization and the fields it regulates.
- Complexity of new innovations in applications for approval requires an interdisciplinary approach to new drug reviews, bringing novel capabilities and techniques to bear in a more consistent way across the development pipeline, as well as improvements in how the NDRP communicates regulatory decisions and their underlying rationale.
- Increasingly diverse data sources and rare disease programs present both a challenge and an opportunity for the program, specifically to determine how to apply flexibility most appropriately to leverage these data sources for review and surveillance activity.
- Sustained competition for talent and OND's position as a knowledge-driven organization creates a need for renewed focus on how OND attracts and manages talent while fostering a world-class working environment.

III. INITIAL DIAGNOSTIC AND DESIGN PHASES

To address some of the challenges above and in furtherance of modernizing the NDRP, CDER launched a rigorous diagnostic phase, soliciting extensive input from internal stakeholders to understand existing strengths and pain points and to identify opportunity areas and potential pathways forward. The diagnostic approach involved internal focus groups, expert interviews, program-wide listening sessions, internal document reviews, surveys, and review and analysis of internal and external data.

Following the initial Diagnostic Phase, the Design Phase focused on executing against the diagnostic's recommendations and a core set of strategic objectives. After extensive deliberation and refinement of the insights, CDER leadership established six core strategic objectives for the modernized program. They include:

1. **Scientific Leadership:** Grow our scientific expertise and clarify pathways to regulatory approval.
2. **Integrated Assessment:** Critically, collaboratively, and consistently assess whether information in drug applications meets legal and regulatory requirements.
3. **Operational Excellence:** Standardize workflows, business processes, roles, and responsibilities to improve operational efficiency and enable our scientists to focus on science.
4. **Benefit-Risk Monitoring:** Systematically monitor the balance of benefits and risks of approved drugs pre- and post-approval to effectively protect the American public.
5. **Managing Talent:** Attract, develop, and retain outstanding people.
6. **Knowledge Management:** Facilitate the identification, capture, distribution, and effective use of institutional knowledge.

Guided by these strategic objectives, the program formed modernization workstreams to address challenging issues and opportunity areas identified during the diagnostic phase. For each of the following areas, one or more interdisciplinary working groups were established to conduct a targeted assessment, develop recommended changes, conduct detailed design of the changes, and drive implementation. The workstreams and their associated objectives include:

A. OND Reorganization, and Corresponding Changes to Office of Pharmaceutical Quality and Office of Translational Sciences

- Refresh the alignment of scientific expertise to therapeutic areas to enable more targeted and deeper understanding of therapeutic areas and enable increased scientific leadership and patient engagement;
- Better manage staff workloads and enable a more balanced leadership span of control;
- Establish a policy office within OND to drive clarity in precedent, consistency in review decisions, and improve external engagement on important policy issues; and
- Enhance career paths.

B. Integrated Assessment of Marketing Applications

- Enhanced scientifically rigorous discipline-specific assessments through interdisciplinary collaboration/discussion;
- Promote efficient, issue-focused assessment supported by new roles;
- Enhance communication within the review team and with external stakeholders;
- Clear articulation of the basis for regulatory decisions; and
- Increase support for review teams, including through clinical data scientists, medical editors, on-demand resources, trainings, ambassadors and peer support, and seamless workflow management.

C. Postmarket Safety

- Enhance the current construct for collaborative, interdisciplinary scientific safety expertise by assigned portfolio of drugs and facilitate efficient sharing of information about safety issues from all CDER offices with scientific safety responsibilities;
- Develop and implement product-specific, post-approval surveillance plans for certain products that dynamically document pharmacovigilance and risk management activities necessary to identify and characterize product risk;
- Develop and implement a standard process for consistent review and documentation of periodic safety reports;
- Develop and implement a standard format and process to manage a Newly Identified Safety Signal (NISS) evaluation in a single, cohesive, and interdisciplinary document; and
- Create a venue for high-priority, cross-cutting safety issues that require Center-wide coordination or guidance.

D. Investigational New Drug (IND) Review Management

- Create templates that are issue-based and enable future knowledge management for IND reviews;
- Implement procedures that standardize the review process and clearly define roles and responsibilities, and improve the ability to provide high-quality feedback to sponsors in a timely manner; and
- Develop an approach to categorize incoming protocols and amendments, and identify those that should follow a high-priority process.

E. Assessing Talent and Talent Development & Management

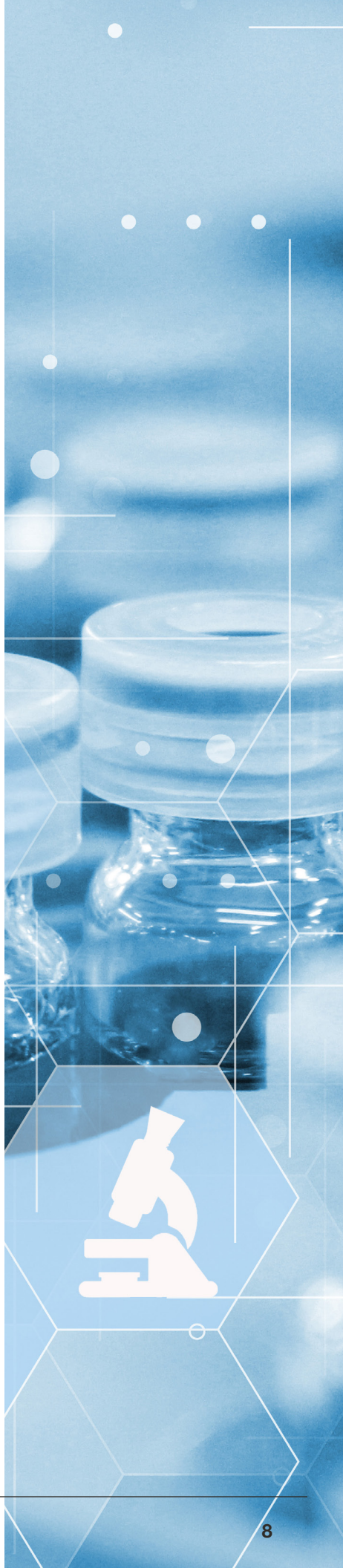
- Establish a new robust applicant screening and interviewing process, incorporating competencies, which targets recruitment of new pharmacology and toxicology (pharm/tox) and clinical reviewers;
- Design a new approach to onboard, develop and evaluate first year clinical reviewers focused on core competencies and incorporating regular feedback; and
- Develop an OND competency model to serve as the foundation for a new approach to managing talent.

F. Knowledge Management

- Prioritize, develop and implement use cases to improve structured capture, retrieval and utility of information needed to support informed and efficient regulatory decision-making, and accountability;
- Refresh strategic roadmap to guide continued development and implementation of priority use cases through new or improved workflows, analytics and information management solutions;
- Promote established program knowledge management governance processes and continually monitor and refine strategy and program data domains and facilitate broader CDER coordination and integration of knowledge management initiatives; and
- Foster culture of collaboration through enhancing data transparency and shareability.

G. Advisory Committee

- Clarify the policies that determine the need for an advisory committee meeting;
- Streamline and clarify the processes to recruit and retain advisory committee meeting experts; and
- Provide tools and resources to improve the process and development of content before and during an advisory committee meeting.



NDRP Modernization Phase 2: Crosswalk

Directly Addresses
Indirectly Addresses
Does Not Address

Workstream	Objectives	Scientific Leadership	Integrated Assessment	Operational Excellence	Benefit-Risk Monitoring	Managing Talent	Knowledge Management
1	OND Recoganization	●	◆	●	◆	◆	◆
2	Integrated Assessment of Marketing Apps	●	●	●	●	◆	◆
3	Postmarket Safety	●	●	◆	●	◆	◆
4	IND Review Management	◆	●	●	◆	⬢	◆
5	Assessing Talent/ Talent Develop- ment and Management	⬢	⬢	⬢	●	⬢	⬢
6	Knowledge Management	◆	◆	◆	⬢	●	⬢
7	Advisory Committee	●	●	●	⬢	●	⬢

IV. IMPLEMENTATION

After workstreams conclude their design phase, each working group established an implementation plan to operationalize the changes outlined in the program modernization. The implementation phase of the program modernization began across most workstreams in 2019 and was informed by a set of guiding principles:

- **Implement in a phase-based manner to enable iterative test-and-learn:** Implementation was phased for each workstream—focusing on a few divisions, gathering feedback from those involved, making refinements based on the feedback, and then rolling out to the next tranche of divisions. This approach facilitates continuous improvement while managing risk.
- **Establish a central organizing body with Subject Matter Experts (SMEs) to drive implementation:** The Special Programs Staff (initially called the New Drugs Transition Team) in OND serves as a coordinating body to drive the implementation in conjunction with SMEs for each workstream.
- **Stand up a governance body with frequent check points to drive implementation:** An NDRP Steering Committee was initially established to provide oversight, review progress, and address any bottlenecks that may exist. In 2020, an NDRP Council was established for the continued governance and improvement of the program following the "sunsetting" of the NDRP Steering Committee. In 2021, the NDRP Council was disbanded in favor of regular Executive Sponsor meetings and bi-monthly cross-workstream meetings to continue making progress and reporting on status.
- **Activate a network of senior leaders representing a broad cross section of the organization to support implementation:** Executive Sponsors were identified for each workstream, and Transition Leads were established for each office, division, and function. Their roles include communication of changes as part of the modernization, gathering of feedback, and supporting change management initiatives.
- **Leverage ambassadors to expand the impact and embed change in the organization:** Early adopters serve as ambassadors and change agents to scale implementation across additional divisions in future phases of implementation and serve as conduits for rapid dissemination of information and collection of feedback.
- **Set ambitious timelines but build in flexibility to revise them as conditions change:** Each workstream established an implementation roadmap with milestones. While the timeline for implementation is ambitious,

there is flexibility to update the roadmap based on internal and external factors (e.g., Congressional approval of the re-org package, internal learnings on the workstream). The implementation roadmap was shared freely with the entire organization to promote awareness and create excitement.

- **Coordinate with interdependent efforts and organizations:** In recognition that there are other efforts to modernize the agency, the Special Programs Staff and workstreams coordinated closely with interdependent initiatives and organizations to achieve our strategic objectives.
- **Track progress of implementation:** For each modernization workstream, the NDRP defined key activities, outputs, and outcomes for implementation and impact, and both workstream and CDER leaders review these regularly to ensure implementation is on track and achieving the desired impact.

The NDRP has completed the implementation of initiatives for IND 30-Day Safety Assessments, Integrated Assessment of Marketing Applications, and the reorganization of OND and corresponding changes to OPQ and OTS. The NDRP continues to work through implementation initiatives in IND Protocol and Amendment Assessments, Postmarket Safety, Talent, Knowledge Management, and Advisory Committees to the present day.

V. ACHIEVED AND ANTICIPATED IMPACT

As mentioned previously, early in the program modernization, CDER and OND leadership articulated a concrete set of strategic objectives to guide the modernization and form the basis for an assessment of program impact. These six strategic objectives have served and continue to serve as a 'North Star' for the program, providing a consistent language and framework for determining progress and impact. What follows is an overview of the specific outcomes toward which the program modernization is aiming within each strategic objective, an overview of metrics and other indicators of progress toward the objectives, and a summary of accomplishments to date as well as continued plans for future progress.

A. Scientific Leadership

The scientific leadership objective elevates FDA's ambition around shaping the drug development ecosystem for the benefit of public health.

Objective:

Grow our scientific expertise and clarify pathways to regulatory approval.

Outcomes:

The long-term outcomes for this objective include expansion of drug development to indications/patient populations with unmet needs which should in time lead to the availability of more approved products with favorable benefit-risk profiles that will increase options for patients, increase industry competition, address existing unmet patient needs, and may reduce costs overall. In the short- to medium- term, outcomes associated with this strategic objective will focus on innovations in trial design (e.g., novel endpoints), sustained progress in regulatory policy for product development and increased recognition of FDA's leadership position through references and citations in the regulatory and scientific community.

There are three specific goals associated with the scientific leadership strategic objective:

1. *Develop and execute against a strategic/defined policy agenda (refreshed annually) to address substantive issues in drug development both domestically and internationally;*
2. *Deepen scientific expertise to enhance regulatory decision-making and support career development of staff; and*
3. *Reduce the time, cost, and risk associated with drug development to create therapeutic options for patients, increase competition, and expand access.*

Report on progress:

The reorganization of OND was completed in 2019-20 to therapeutically align offices and divisions to enable scientific leadership—with six former product offices being reorganized into eight therapeutically aligned offices and a new Office of Drug Evaluation Sciences (ODES) being established. The talent management workstream is working towards more strategic recruitment of top talent for science offices and review divisions, which will deepen scientific expertise across OND. Moreover, OND has developed an approach to assessing the need for scientific leadership to foster drug development across therapeutic areas and anticipates that each division will develop and execute against a strategic policy agenda to proactively address substantive issues in drug development and patient access to medicines in areas of unmet medical need. To date, several divisions have already begun this process—examples include the FDA Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis.[1]

These activities have led to favorable outcomes in furthering scientific leadership and improving public health. In 2021 and 2022, FDA finalized 20 and 23 disease-specific guidance documents, respectively, bringing that total to 136 such documents since December 2017. In 2021, OND presented at 594 speaking engagements to demonstrate leadership in its strategic priorities. In 2022, OND presented at an additional 437 speaking engagements.

The following are some specific examples of how OND and CDER have provided scientific leadership to improve drug development and regulatory processes in furtherance of improving outcomes:

- **CDER-wide Scientific Leadership:** CDER offices provide scientific leadership to facilitate product development in areas of unmet medical need, including the approval of novel therapies and drug products as well as the advancement of drug development tools and programs. Beyond their role in novel drug approvals, CDER Offices have been critical partners to the drug development industry and the medical community by writing guidances for sponsors on product development, contributing to regulatory policies for drug development, and facilitating workshops and outreach activities.

[1] https://www.fda.gov/news-events/public-health-focus/accelerating-access-critical-therapies-als-act-act-als

These activities aim to help to reduce the time, cost, and risk associated with drug development and lead to more therapeutic options for patients, increase industry competition, and expand access. NDRP has aided these activities by first reorganizing those offices as mentioned previously. Since that time, NDRP regulatory activities have modernized, standardized, centralized, and streamlined the way that CDER receives applications, conducts drug reviews and approvals, and provides its scientific leadership and advice to fulfill unmet needs and improve public health outcomes.

As a prime example, in 2021, CDER offices continued to work jointly with partners within and outside of FDA to expand upon the shared understanding of COVID-19, further develop effective COVID-19 therapies, and promote the safety of products used to treat or prevent the infection These collaborations also ensured that CDER provided timely advice on COVID-19 to sponsors, standardized regulatory actions across CDER, and modified trial designs to best evaluate potential therapies within the current standard of care treatment paradigm. The OND review teams also worked closely with internal and external stakeholders to address drug shortages of products to treat COVID-19, including tocilizumab and baricitinib.

NDRP regulatory activities have modernized, standardized, centralized, and streamlined the way that CDER receives applications, conducts drug reviews and approvals, and provides its scientific leadership and advice to fulfill unmet needs and improve public health outcomes.

For additional information on each of the OND Offices' accomplishments and successes in coordination with other CDER super-offices, please see the OND Annual Reports for 2020, 2021, 2022, and 2023. Additionally, the CDER "New Drug Therapy Approvals" report provides a detailed listing and discussion of all the new drugs that OND, working with offices across CDER, have approved.

- **Initiative Highlight - OND Science Strategies.** In 2020, NDRP launched an exploratory Science Strategies pilot program to develop and execute strategic plans to address substantive issues in drug development, one of the goals of scientific leadership. The program enables divisions to systematically assess unmet medical needs (e.g., disease prevalence, disease burden, treatment burden); evaluate the state of clinical development (e.g., pipeline activity); and identify challenges and barriers to drug development. After assessing an unmet medical need and diagnosing drug development barriers, divisions can develop multi-year, disease-specific science strategies (strategic plans) to address the identified barriers.

  As of 2021, OND's Division of Dermatology and Dentistry (DDD) and Division of Clinical Outcome Assessments (DCOA) are implementing science strategies to assess and overcome barriers to drug development in areas of unmet need. Beginning in 2020 and continuing in 2021, staff from DDD and DCOA collaborated with experts from the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) to create a non-healing chronic wound science strategy to identify barriers to product development in this disease area. Staff from these divisions and Centers undertook a landscape analysis to identify unmet medical needs in this disease area and recognized the notable lack of innovative products to treat non-healing chronic wounds.

  The NDRP continues to explore how to expand the Science Strategies approach developed by OND to other therapeutic areas.

- **Advisory Committees:** By convening Advisory Committee meetings, FDA provides scientific leadership through facilitated discussion and input from medical experts, industry, patients, caregivers, and the public on topics/issues of particular importance to public health. To support these committees in their mission of providing the highest level of scientific advice and expertise, the NDRP Advisory Committee (AC) workstream has worked since 2019 to promote efficient and excellent AC meetings that provide well-informed, clear, and consistent expert advice. The AC workstream started by focusing on three areas of the AC planning process where clear and streamlined policies, processes, and resources would be helpful for FDA staff. These include clarifying when an AC meeting is appropriate, finding ways to streamline the process for recruiting and retaining relevant experts on committees, and developing accessible resources for FDA review teams to improve the development of high-quality FDA meeting materials and day-of execution.

  The workstream is developing a range of resources, including:

  - A tool containing a series of questions to assist review teams in determining whether an advisory committee meeting is appropriate. In CDER, decisions about whether to go to an advisory committee are made by the clinical division and office leadership within OND and with input from CDER leadership, when appropriate.
  - An educational reference guide and technology/knowledge management platforms for CDER staff, and learning modules for advisory committee experts, to enhance recruitment and retention of excellent advisory committee experts.
  - A template to help staff efficiently produce a streamlined advisory committee briefing document that focuses on the most pertinent information, while helping ensure a well-informed discussion of the issues.

  Internally, the percentage of review team staff who felt completely prepared for AC meetings has increased over time, from around 50% in 2021 and 2022, to 71% in 2023. The Advisory Committee Team's commitment to continuous improvement is reflected in these results and is an encouraging sign of progress in the workstream.

  The AC Workstream also sends a survey to AC members after an AC meeting for feedback on their experience preparing for and participating in the meeting. The external survey gathers feedback on FDA meeting materials, including voting and discussion questions, the briefing document, and slide presentations, as well as FDA's responses to AC member questions. This survey also includes a section for feedback from the AC Chair on how prepared they felt to lead the meeting and suggestions for improvement. AC members have generally provided positive feedback on their AC meeting experiences while also providing valuable suggestions for improvements and planning enhancements. This feedback will shape the workstream's future work. To learn more about the AC Workstream, please visit the NDRP Advisory Committee FDA webpage.

To support Advisory Committees in their mission of providing the highest level of scientific advice and expertise, the AC Workstream started by focusing on three areas of the AC planning process where clear and streamlined policies, processes, and resources would be helpful for FDA staff. The percentage of FDA review team staff who felt completely prepared for AC meetings has increased over time, from around 50% in 2021 and 2022, to 71% in 2023.

B. Integrated Assessment

The integrated assessment strategic objective aims for a more consistent, efficient team-based, and issue-focused assessment process and output.

Objective:

Critically, collaboratively, and consistently assess whether information in drug applications meets legal and regulatory requirements.

Outcomes:

The long-term outcomes for this objective include consistent development of highly integrated, thoroughly documented, and clearly communicated issue-focused regulatory decisions, in addition to strengthened alignment across the multi-disciplinary team on the rationale underpinning pre- and post-approval decisions from drug development programs. In the short- to medium-term, outcomes associated with this strategic objective include building out operations that are more efficient and interdisciplinary in nature; earlier leadership engagement in review issue identification and resolution; increased focus on clear, collaborative, and issue-based writing; and more comprehensive scientific, issue-based, integrated communication to sponsors and external stakeholders.

There are two specific goals associated with the integrated assessment strategic objective:

1. *Foster a paradigm shift in the application decision-making process to include transitioning to a consistent, team-based, issue-focused assessment process and documentation; and*
2. *Establish and consistently integrate new disciplines to enhance the assessment process, including clinical data scientists, medical editors, epidemiologists, and others.*

Report on progress:

Over the last few years, the NDRP has developed and refined more standardized and collaborative assessment processes and documentation for IND 30-day safety assessments, IND protocol and protocol amendment assessments, assessments of new molecular entity New Drug Applications (NDAs), original Biologics License Applications (BLAs), Efficacy Supplements, and Newly Identified Safety Signals (NISS). All of the activities below have been designed and accomplished in furtherance of the goal of critically, collaboratively, and consistently assessing whether information in drug applications meets legal and regulatory requirements.

1. IND Workstream

Over the past 4 years, the Investigational New Drug (IND) Review Management workstream has worked to streamline the IND review process and develop review templates for 30-day IND reviews and clinical and clinical pharmacology protocols and protocol amendments. This included improving the timeliness of reviews of high-priority protocols and protocol amendments (those particularly critical for drug development programs, such as phase 3 trial protocols), developing structured data elements to facilitate knowledge management, enhancing consistency in review of trial protocols and amendments, and reducing redundancy in IND review work.

The IND Workstream developed and refined issue-based review templates that streamline the review, prompt reviewers to comment on the various critical aspects of protocols and protocol amendments, and incorporate standard data capture to enable future knowledge management capabilities.

Since 2020, the IND Workstream has:

- Designed and implemented policies and procedures focused on guiding review teams on prioritizing incoming protocols and protocol amendments, standardizing their review processes, and clearly defining each team members' roles and responsibilities.
- Transitioned IND 30-Day safety reviews into an automated workflow system (Nexus) to enhance efficiency, collaboration, and standardization of processes.
- Developed and refined issue-based review templates that streamline the review, prompt reviewers to comment on the various critical aspects of protocols and protocol amendments, and incorporate standard data capture to enable future knowledge management capabilities.

Feedback from reviewers and RPMs who have used the new IND protocols and amendments process and templates has generally been positive. Reviewers specifically noted favorable experiences as it relates to standardization of processes and ease of use of the review templates:

- Increased consistency across reviews
- Readers and reviewers know where to look for specific information
- Improved organization and comprehensiveness of templates
- Easy and efficient documentation of findings

Their feedback also highlighted areas that still required improvement, including:

- The template's inflexibility or unsuitability for certain types of reviews, such as pediatric reviews
- Formatting issues in the template that inconvenienced reviewers
- Clearance issues and decisional bottlenecks that hindered some staff from meeting process milestones
- Limited adoption by some staff due to lack of awareness

The IND workstream has since modified the templates to improve their flexibility and suitability for certain types of reviews and fixed formatting issues that were identified. Additionally, the IND workstream has recently expanded their communication efforts to help boost familiarity and access to the IND protocols and amendments resource site.

The IND workstream plans on gathering and addressing user feedback in the next year, and it is committed to help transition this process into the NEXUS IT solution.

Between July 25, 2022, when the 2.0 version of the IND 30-day safety review workflow and the new Supporting Document Review common workflow were launched in a subset of OND Divisions (Phase 1), and July 31, 2023, with all OND Divisions (and a few additional offices such as the Office of Clinical Pharmacology, the Office of Biostatistics, and the Office of Pharmaceutical Quality) included in the implementation, there were:

- 1,235 IND 30-Day workflows created in Nexus
- Approximately 2/3 (865) IND 30-Day workflows completed in Nexus
- 3,172 Supporting Document Review workflows (optional) created in Nexus
- Many (780) Supporting Document Review workflows (optional) completed in Nexus

Based on user feedback, the team has made improvements and enhancements to 30-day INDs in Nexus. There are now multiple stakeholder interest groups for users to provide feedback, including:

- Enhanced formatting capabilities for review documents
- Increased visibility into the progress of a review across the review team
- Reduced administrative burden when communicating with sponsors (e.g., auto populating letters)
- Improved knowledge management capabilities

These continuous enhancements assist in creating a collaborative, transparent, and efficient IND 30-day safety review workflow and Supporting Document Review common workflow.

2. Integrated Assessment of Marketing Applications Workstream

Over the past four years, the IAMA process has made significant progress in achieving its core objectives. The IAMA Implementation Workstream worked to collect feedback from both internal and external stakeholders, to help drive improvements to the overall process and template. This feedback was collected by reviewing surveys, submission forms, focus group takeaways, and interview responses.

Feedback from stakeholders included suggestions surrounding:

- Process and template improvements
- IT challenges
- Helpful resources

This feedback was reviewed by implementation staff, and changes were made to ensure a streamlined review process and template for all teams. Since its phased implementation, the IAMA process has made significant progress in innovating new drug reviews. In October 2023, use of the IAMA process and template will be mandatory for all original NME and BLA applications (with the exception of the Office of Oncologic Disease, which will be required to use either the IAMA process and template or the Assessment Aide for all Original BLA and NME applications).

Since 2019, the IAMA Implementation Workstream has:

- Created and updated the Integrated Review Template (IRT) to include an issue-based and interdisciplinary review process that enables early identification of review issues, early leadership involvement, and encourages collaboration.
- Utilized the Clinical Data Scientist (CDS) and Medical Editor (ME) roles to ensure consistent, high-quality data analysis and improved clarity and cohesiveness of final review products.
- Enhanced clarity of the final regulatory decision documentation and underlying rationale to better inform industry, healthcare providers, patients, and other stakeholders of FDA's thinking and appropriately guide sponsors' drug development pipeline.

The IAMA Workstream created and updated the Integrated Review Template (IRT) to include an issue-based and interdisciplinary review process which enhanced clarity of the final regulatory decision documentation and underlying rationale to better inform industry, healthcare providers, patients, and other stakeholders of FDA's thinking and appropriately guide sponsors' drug development pipeline.

- Implemented new technology platforms such as the Collaborative Authoring Tool (CAT) which modularizes sections of the IRT, to mitigate IT challenges faced by review staff when filling in the template.

Report on Progress:

The IAMA process is beginning to be used widely across CDER.
As of June 2023:

- 83 total Integrated Reviews have been completed
- 25 applications are ongoing

Based on internal evaluation from review teams, the following positive feedback has been observed:

- Centralization of resources in the IRT has improved visibility and cohesiveness of the decision and the scientific reasoning
- CAT improved ease of use over previous integrated reviews
- Reduced redundancy of processes and decision discussions

Their feedback also highlighted areas that still required improvement, including:

- A need for online resources and how-to guides to assist with completing the IRT
- A lack of clarity surrounding due dates for different IRT deliverables

Based on this feedback, the IAMA workstream created template and process how-to guides, as well as additional online resources to assist with completing the Integrated Review. This included developing a timeline for writing the Integrated Review. The IAMA workstream addressed the feedback above and successfully went into full implementation in October 2023.

3. Postmarket Safety Workstream

The workstream developed an Integrated Safety Assessment (ISA) template and clearance process for NISS evaluations, which allow for a team-based, rather than a consult-driven, approach to the safety review.

The ISA is the preferred template for NISS evaluation and serves as a single document for integrating data across all CDER offices and divisions. The template eliminates redundant content that was written in separate discipline reviews and captures a single integrated discussion of the signal, safety analysis, and recommendations. In 2022, the Workstream released live and on-demand training within CDER to support use of the ISA. In addition, key periodic messaging is conveyed to promote further uptake of the ISA template for NISS evaluations. CDER is continuing to monitor for increased usage of the ISA template in these evaluations and making strides toward encouraging that increased usage.

C. Operational Excellence

The work of the program is knowledge-intensive and involves a multitude of engagements across functions and disciplines from across several offices. The operations of the new drugs regulatory program benefits from disciplined management approaches and strong enabling technology. Optimizing core regulatory workflow is critical to enabling other strategic objectives (e.g., scientific leadership, talent management) because it creates time and space to invest in activity beyond day-to-day activity.

Objective:

Standardize workflow, business processes, roles, and responsibilities to improve operational efficiency and enable our scientists to focus on science.

Outcomes:

The long-term outcomes are FDA operations that lead to increased scientific leadership and prompt and impactful internal advancement of public health. Short- to medium- term outcomes relate to reducing time on ancillary tasks outside of specific roles and responsibilities, increasing time spent on targeted, value-adding activities, and increased staff collaboration with external parties and national regulatory authorities on areas of regulatory and scientific advancement.

There are two specific goals associated with the operational excellence strategic objective:

1. *Implement program-wide standardized core processes for end-to-end drug development and application review across all relevant disciplines, enabled by workflow, knowledge, and content management systems; and*
2. *Establish a quality management system that fosters the use of quality standards and metrics and robust business process management and facilitates strong quality controls, accountability, and continuous improvement.*

Report on progress:

NDRP's ambition is that enhancing consistency of our core processes and responsibilities across the organization will allow staff to more efficiently focus on activities that provide the greatest added value

Multiple workstreams have and are continuing to develop efficiencies across the NDRP, working to achieve the strategic objectives of standardizing workflows, business processes, roles, and responsibilities to improve operational efficiency and enable our scientists to focus on science.

Since 2020, the IAMA workstream has worked to improve processes and efficiency by seeking a more centralized, standardized, and collaborative methodology for submission and review of marketing applications – thus allowing the scientists to focus on the science of these applications instead of the process. Some key examples of operational efficiencies gained within IAMA include:

- Utilized feedback from internal and external stakeholders to modify the IAMA process and template, to ensure any issues were identified and addressed
- Implemented new technology platforms such as the Collaborative Authoring Tool (CAT), which modularizes sections of the IRT to mitigate IT challenges faced by review staff when filling in the template
- Communicated the agency-wide change and initiatives to internal and external stakeholders via various communications channels (e.g., town halls, listening sessions, one-on-one team trainings, newsletters, ambassadors, and facilitator's meetings)
- Developed training and onboarding/coaching sessions to ensure a seamless transition to using the IAMA process and template
- Developed and implemented IAMA and CAT user guides, on-demand trainings, and other helpful resources to help facilitate the transition to the new process and template

Additionally, and similarly to IAMA above, the IND workstream has further defined and standardized processes to eliminate redundant activities – again with the goal of allowing the scientists to focus on the science. Some key examples of operational efficiencies gained within IND include:

- Developed issue-based review templates that streamline the review process and drive future knowledge management efforts
- Improved FDA's ability to provide high-quality IND feedback to sponsors in a timely manner

Finally, in furtherance of Operational Excellence, the NDRP has employed a Program Evaluations team to operate across workstreams with the goal of surveying and providing data-driven improvement suggestions. The Program Evaluation team employs such tools as surveys, observation tools, focus groups and/or interview guides to schedule, prepare, and collect data and other observations. Simultaneously, the team analyzes and synthesizes qualitative and quantitative data captured in focus groups, interviews, and surveys.

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D. Benefit-Risk Monitoring

The benefit-risk monitoring strategic objective aims to enhance FDA's ability to actively manage the benefit-risk profile of regulated therapies through strengthened approaches to identifying and evaluating risks across their lifecycle.

Objective:

Systematically monitor the balance of benefits and risks of approved drugs pre- and post-approval to effectively protect the American public.

Outcomes:

In the long term, this strategic objective aims to ensure a positive impact on patient health by increasing the availability of timely, reliable benefit-risk information to inform treatment decisions and support safe use. In the short- to medium-term, the aim of this objective is to ensure efficient and effective multi-disciplinary collaboration on safety-related issues, increase operational transparency on postmarket safety activities, and enhance approaches to identification and management of potential risks/safety signals.

There is one specific goal associated with this strategic objective:

1. Contribute to advancing the overall CDER vision for integrated, multi-disciplinary benefit risk monitoring across the product lifecycle.

Report on progress:

Postmarket safety initiatives have allowed CDER to make significant progress toward the realization of proactive safety monitoring across high-risk areas. Important team structures, processes, and roles have been created, evaluated, and updated at the FDA driven by both the Postmarket Safety Workstream and CDER's Drug Safety Operations (DSO) staff.

The expectation from the Design Phase was to develop an infrastructure for collaborative, interdisciplinary scientific safety expertise by assigned portfolio of drugs and to facilitate efficient sharing of information about safety issues from across CDER with scientific safety responsibilities. Those expectations specifically included:

- Develop and implement product-specific, post-approval surveillance plans for certain products that dynamically document pharmacovigilance and risk management activities necessary to identify and characterize product risk;
- Develop and implement a standard process for consistent review and documentation of periodic safety reports (PSR);
- Develop and implement a standard format and process to manage NISS evaluation in a single, cohesive, and interdisciplinary document; and
- Create a venue for high-priority, cross-cutting safety issues that require Center-wide coordination or guidance.

The activities of the past few years described below have been instrumental in furthering the strategic objective of systematically monitoring the balance of benefits and risks of drugs pre- and post-approval to effectively protect the American public.

1. Drug Safety Operations

- The Drug Risk Management Board (DRMB) was established as a cross-CDER governance board responsible for facilitating/coordinating decisions around major marketed-product safety issues across all relevant stakeholders, providing clear and consistent guidance enabling an appropriate response to major safety issues, and transparently communicating decisions and resulting actions across the Center and to other stakeholders as appropriate.
- The manual of policy and procedures (MAPP) for NISS was finalized and published on April 30, 2020. The MAPP outlines a new, more streamlined signal review process, with clear criteria for which signals should be tracked and a requirement to notify sponsors within 30 days of opening a full evaluation. The MAPP addresses the postmarket safety work across CDER super-offices including the Office of Pharmaceutical Quality and the Office of Compliance. The application of the MAPP within each office is being outlined in corresponding office-level SOPs.

2. Postmarket Safety Workstream

- As of 2023, all 9 planned DSTs are active. These cross-Office teams are accountable for managing postmarket safety for a defined portfolio of drug products.
- Consistent with the NISS MAPP, CDER staff within the DST determine whether safety signals warrant evaluation and, if so, stand up NISS teams with relevant discipline representation.
- After three years of experience with DSTs and based on evaluations of the DST program, the workstream is currently undergoing refinements to the DST framework to facilitate greater collaboration across CDER and reduce process redundancy in documentation. This reimagining of the DST strategy and associated implementation came in late 2023/early 2024 through executive leadership feedback sessions and review/approval through the DRMB.

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- The new PVS process for developing an internal post-approval plan for coordinated monitoring of safety information to enhance postmarket drug safety surveillance for a drug or drug class was piloted and its policies and procedures drafted. PVS will enhance the efficiency of postmarket safety surveillance and promote cross-discipline team alignment on postmarket safety activities.
- The Cross-Discipline Safety Advisor (CDSA) role has been created within OSE to integrate OSE data streams, and to lead development and management of pharmacovigilance strategies. Three full time OSE CDSAs have played a critical role in developing, refining, and implementing the PM Safety programs for DSTs, PVS, and ISA.
- In coordination with the review of the DST framework as mentioned above, the Safety Clinical Analyst (SCA) role is in development within OND to aid inter- and intra-office safety evaluation and communication. The desired impact is to use these SCAs as the touchpoint for centralizing and standardizing DST processes to make them more effective and less individualized. This should help facilitate the reimagined DST strategy and process and drive further adoption across DST participants.

The Postmarket Safety Workstream developed the "Essentials of Postmarket Drug Safety Curriculum" to support staff capabilities, advance understanding of postmarket safety science within CDER, enhance cross-office knowledge, and foster collaboration across multi-disciplinary teams.

Additionally, in order to enhance learning and development opportunities specifically within the Postmarket Safety realm, the "Essentials of Postmarket Drug Safety Curriculum" was developed to support OND and OSE staff's capabilities. The curriculum's trainings seek to advance understanding of postmarket safety science within CDER, enhance cross-office knowledge, and foster collaboration across multi-disciplinary teams. Subject matter experts and learning specialists throughout OND and OSE were enlisted to develop training materials to provide learners with a repository of important postmarket safety topics.

The Essentials of Postmarket Drug Safety curriculum initially launched in 2022 with nine learning modules of on-demand training materials. Users across CDER have been able to explore the curriculum's learning modules independently of each other, thereby empowering them to access relevant materials at their own pace and discretion. The Pharmacoepidemiology and Postmarket Safety Policies and Processes trainings have been of particular use to safety staff, accumulating hundreds of views. The curriculum has since continued to expand its diverse selection of resources through content updates on a rolling basis.

E. Managing Talent

Building and maintaining a strong, energized workforce is central to a robust NDRP. It is imperative to develop colleagues from their initial onboarding, engage them in meaningful work, and consistently build new capability.

Objective:

Attract, develop, and retain outstanding people.

Outcomes:

In the long-term, the program strives to develop and maintain an exceptional reputation for recruiting, developing, and retaining top talent and scientific leaders. Short- to medium- term outcomes relate to successful recruitment of top talent from new sources, reductions in unwanted attrition and increased retention of top talent, and an enthusiastic and satisfied employee atmosphere.

There are four specific goals associated with the managing talent strategic objective:

1. *Implement new approaches to enhance how the NDRP attracts, recruits, and retains the next generation of leaders for the program;*
2. *Revamp our approach to professional development and performance management by incorporating competencies and training with routine annual succession planning (including development plans for each staff member and identification of successors for critical roles);*
3. *Set expectations for team leads and managers to engage in regular and ongoing developmental feedback; and*
4. *Implement a consistent approach to gathering performance input and evaluating performance*.

Report on progress:

Important progress in hiring and retention facilitated by OND operations helped OND manage increasing workload and public health priorities. OND operations also oversaw the implementation of 5 new PDUFA VII commitments/programs intended to benefit public health by enabling earlier patient access to important treatments, increasing feedback opportunities for new drug development programs, and improving consistency and predictability of the review process.

Over 2021-2022, more than 150 leaders were trained in systematic onboarding to establish critical first-year practices including continuous feedback on skill development, orientation mentoring, and building support networks for faster time to productivity and increased job satisfaction for new staff. In addition, to help maintain OND's internationally recognized standard of excellence for drug review and regulation, OND operations delivered 63 internal staff training courses for the equivalent of 8,500+ attendees, to strengthen staff's scientific, regulatory, operational, and leadership skills and abilities.

F. Knowledge Management

Comprehensive knowledge management is one of the key assets for OND's data-rich, knowledge-intensive New Drug Regulatory Program (NDRP). To foster and promote knowledge management, CDER has implemented an infrastructure to adequately support and continuously enrich and grow its knowledge management capabilities, communications, and outreach practices. Modernization efforts will continue to focus on building and improving access to institutional knowledge to support informed decision-making and accountability across its organizations through consistent, efficient, and effective capture, storage, and sharing of relevant information, situational awareness, precedents, and lessons learned.

The Knowledge Management workstream was established in May 2020 to support the standardization of high-impact data elements and identify locations within the program review processes where the standardized information could be captured. The Knowledge Management workstream continues to serve as both a strategic and tactical body to oversee NDRP knowledge management and data governance efforts.

The Knowledge Management workstream works in close partnership with other governance groups across the enterprise to align on the most impactful activities for prototyping and implementation and to further the impact and efficiency of knowledge management efforts.

Objective:

Facilitate the identification, capture, distribution, and effective use of institutional knowledge.

Outcomes:

The NDRP Knowledge Management (KM) workstream is an integral governance body and partner in CDER-wide modernization and innovation efforts working towards instituting comprehensive knowledge and information management capabilities across the organization. The efforts are focused on fostering sharing and learning culture across the organization and external partners and supporting business and program innovation by monitoring emerging needs and technical capabilities to enable continuous modernization of existing regulatory processes and programs.

The KM workstream outcomes include enabling greater consistency of data capture and integration of knowledge across the program through data governance, standardized and structured review templates, workflow enabled processes and information technology tools.

The specific goals to support the knowledge management strategic objective outcomes are:

1. *Continued strategic and tactical oversight of NDRP knowledge management and data governance initiatives through established NDRP Knowledge Management workstream and partnerships with CDER governance groups*
2. *Continuous assessment and alignment of KM strategy with overarching CDER IT development plan and refinement, prioritization, development and implementation of knowledge management use cases and data standardization based on current and emerging organization and enterprise needs*

Report on progress:

Building on the initial portfolio of use cases developed in 2020, respective ideation, prioritization, and business requirements gathering, the Knowledge Management workstream has made significant progress towards realizing a number of priority use cases to enhance regulatory review in the identified priority areas for staff across the organization. These include standardization and structured capture of key data elements, development, and implementation of analytic tools for inter- and cross-program analysis, program metrics reports, and exploration of proof-of-concept use cases and novel technologies for maximum integration and utility of structured information in the review processes.

To streamline standardization and structured capture of information in core-enabling business processes across the product lifecycle, the Knowledge Management workstream is directly engaged in pre-marketing, marketing, and post-marketing program developments to assure that critical information is structured and prospectively captured as part of newly developed digitized business processes and platforms.

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With respect to standardization and structured capture of key data elements, the workstream is currently working on enabling expanded systematization and searchability of verbatim indications using mapping to the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) ontology to capture terms beyond indication target/underlying disease and include mapping to indication secondary conditions, symptoms, and procedures, where applicable. This information will enable OND staff to more easily identify institutional knowledge and incorporate historical lessons learned. Looking ahead, the updated indication mapping to SNOMED CT ontology reference data capability will be part of submission forms and respective review processes for enhanced entry and fidelity of SNOMED CT indication mapping. The workstream is working closely with the new workflow platform development team to align data capture requirements with the future vision of the premarket and marketing

application workflow capabilities. The workstream is also utilizing machine learning and AI-based large language model methodology to map retrospective indications to SNOMED CT for applications received prior to its May 2018 implementation. This would provide SNOMED CT indication mapping, respective data linkage, and search capabilities across all applications.

The workstream worked closely with OND Policy to develop a mechanism to capture Substantial Evidence of Effectiveness (SEE) structured language in reviews: one of the key statutory requirements for obtaining marketing approvals. Following a successful yearlong SEE pilot initiated in August 2022, OND is currently integrating SEE structured data capture in the Marketing Application templates (e.g., Integrated Review Template (IRT) and Assessment Aid), and respective review processes/workflows. Standardized SEE capture will enable consistency in capturing the approach by which the SEE standard was demonstrated across programs and aid in review activities with similar frameworks to guide decision-making in novel situations.

In the anticipation of a final ICH M11 Clinical electronic Structured Harmonized Protocol (CeSHarP) standard submission template , the workstream is proactively exploring requirements and technical capabilities to streamline ingestion and integration of the CeSHarP submission structured content into protocols and amendments review templates, processes, and workflow(s). The initial work includes identification of key protocol and amendment data elements for prototyping direct data ingestion capabilities in the review process.

To date, the workstream has also prioritized and supported development of a number of NDRP analytical dashboards to enable critical information search capabilities and reporting on program specific metrics using enhanced data analytics and visualization capabilities. The dashboards include:

- A comprehensive Safety Metrics Dashboard to systematically centralize insights across all safety programs, namely post-marketing requirements and commitments, drug safety and safety-related labeling changes, periodic safety reports, newly identified safety signals, and drug safety communications. In addition to supporting programs and management review, reviewers can also explore individual applications and navigate to the corresponding safety programs to identify drug safety issues requiring mitigative actions.
- To support core clinical and non-clinical review data analytics needs, the workstream supported development of a one-stop-shop for interactive clinical trials and non-clinical studies information databases. The respective databases enable comprehensive linking and searchability of relevant clinical and non-clinical information to support review activities throughout the product lifecycle.
- To further improve on transparency, traceability, and continuity of communications with sponsor, the workstream has led the development of the Information Request (IR) focused dashboard. The IR dashboard provides capabilities to search and filter information requests and corresponding applicant responses within and across programs. Further development involves integration of the dashboard with the review workflows and building expanded lifecycle tracking and searching capabilities for IRs.

- Additional dashboard capabilities developed to date also include analytics focused on tracking Application and Meeting Goals and Rare Disease workload.

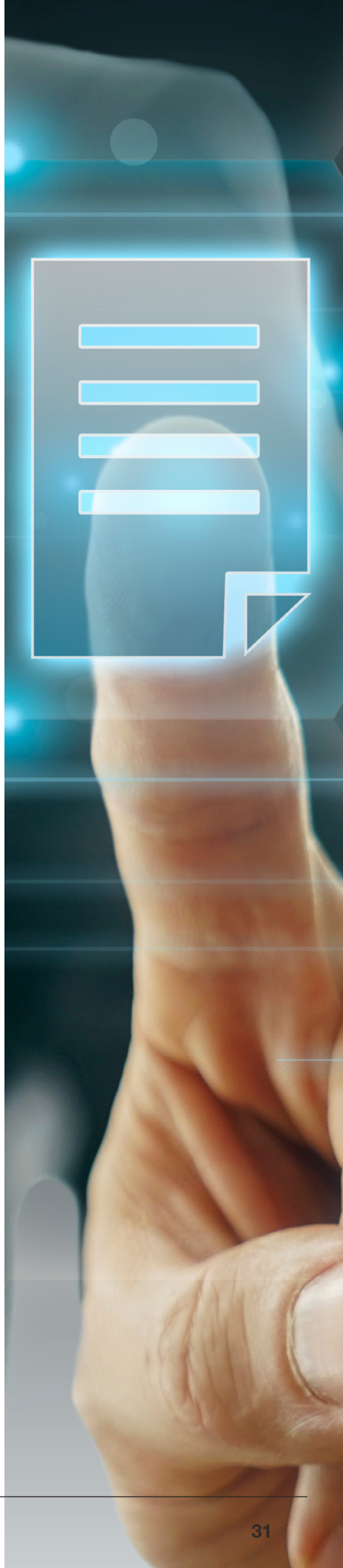
The next steps for all developed dashboards include enhancements based on user input and their integration in the review workflows for seamless access to relevant product lifecycle information.

Finally, the workstream is continuously exploring and assessing emerging and innovative technologies and trends for solutioning the portfolio of use cases and realizing benefits of new approaches for internal capabilities developments to best address institutional knowledge management needs.

VI. CONCLUSION

The NDRP has made great strides in its modernization journey over the last few years. Advances in reviews, assessment, process standardization, information sharing, and the development of technical tools has helped to improve communication, collaboration, efficiency, decision-making, and transparency. In turn, these improvement and modernization efforts have all led to FDA continuing to be the gold standard in drug regulatory scientific leadership and making further strides to work with industry, government, and the general public to improve public health outcomes.

This report serves as an update to the NDRP's modernization efforts, outlining the strides mentioned above from 2020-2023, as well as work still to be accomplished and areas for improvement. As CDER continues to evolve and develop alongside the scientific field, program leadership anticipates publishing additional periodic updates to this report to highlight progress and indicate new areas of focus for the future.



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