Modernizing the New Drug Regulatory Program in FDA/CDER

November 7, 2018

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Disclaimer

The views and opinions presented here represent those of the speakers and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.
Agenda

- FDA is Modernizing Drug Review Process
- OCS Supports Regulatory Review Decisions by:
  - Enabling access to validated and usable standardized study data
  - Providing tools and systems to support analysis
  - Delivering targeted services that create efficiencies and effectiveness
FDA IS MODERNIZING DRUG REVIEW PROCESS
FDA Proposes Modernization to Support New Drug Development

• Aim is to “maintain and advance FDA’s global leadership, and better support our deeply committed staff”\(^1\)

• Focus on drug development and collaborations needed to ensure that the development and assessment of novel candidate drugs have appropriate input from external scientists, expert physicians, and patient communities

\(^1\) Janet Woodcock, M.D., Director of the FDA’s Center for Drug Evaluation and Research
Posted on June 4, 2018 by FDA Voice
Proposed Changes to CDER’s New Drug Regulatory Program

Proposal Includes

- Changes in regulatory and review process
- Organizational restructuring
- Strengthening of support structures
  - Personnel
  - Information Technology

Janet Woodcock, M.D., Director of the FDA’s Center for Drug Evaluation and Research
Posted on June 4, 2018 by FDA Voice
Highlights of the Proposal to Modernize New Drug Review

• **Recruiting** the best and brightest individuals from many disciplines
• Enhancing focus on **multidisciplinary teams**
• Prioritizing **operational excellence**
• Improving **knowledge management**
• Emphasizing the importance of **safety** across a drug’s lifecycle
• Incorporating the **patient voice**
Modernization to Support New Drug Development

• CDER/FDA system is effective and we can always improve
  – CDER approved 46 novel drugs in 2017
  – 100% reviewed on time – fulfilling Prescription Drug User Fee Act

• Both science and technology are rapidly changing and we need to keep up

• Aim is to generate efficiencies so CDER/FDA can build stronger external collaboration capabilities and enhanced support for the scientific, clinical, and technological innovation

Janet Woodcock, M.D., Director of the FDA’s Center for Drug Evaluation and Research
Posted on June 4, 2018 by FDA Voice
OFFICE OF COMPUTATIONAL SCIENCE SUPPORTS REGULATORY REVIEW AND THE NEW DRUG MODERNIZATION
Where We Are

Graphic is for demonstration purposes only and does not depict all FDA offices.
Where We Are:
CDER Review Offices

- Office of Generic Drugs
- Office of Surveillance and Epidemiology
- Office of Translational Sciences
- Office of New Drugs
- Office of Pharmaceutical Quality
- Office of Compliance
- Center for Drug Evaluation and Research
- Office of Computational Science

Graphic is for demonstration purposes only and does not depict all FDA offices.
Who We Are

**Our Vision**
Drive the modernization of CDER’s scientific review process through the implementation of tools, services, and training to enable reviewers to apply their expertise to information.

**Our Mission**
To provide CDER reviewers innovative and reliable solutions that improve and strengthen the scientific review process by integrating data, tools, and training.
OCS Provides Access to Standardized Data, Services, and Technologies to Support Regulatory Review
FDA REQUIRES ELECTRONIC STANDARDIZED STUDY DATA
FDA Requires Standardized Electronic Submissions and Study Data

**eCTD Guidance**
Binding Guidance – Requires that content be submitted to the Agency electronically in the format specified in the guidance.

**eStudy Guidance**
Binding Guidance—Requires that studies are compliant with the standards outlined in the FDA Data Standards Catalog

**Data Standards Catalog**
Lists supported and/or required standards.

**Tech Conformance Guide**
How to submit standardized study data

**FDA binding guidance and deadlines for electronic submissions**

**FDA binding guidance and deadlines for submission of standardized study data**

List what data standards are supported and required by FDA in electronic submissions

**Describes how industry should submit standardized study data in NDAs, BLAs, INDs and ANDAs**
FDA Requires Standardized Electronic Submissions and Study Data

**eCTD Guidance**
Binding Guidance – Requires that content be submitted to the Agency electronically in the format specified in the guidance.

**FDA binding guidance and deadlines for electronic submissions**
- **May 5th, 2016:** NDAs, ANDAs, BLAs, DMFs
- **Dec 17, 2017:** Commercial INDs

**eStudy Guidance**
Binding Guidance—Requires that studies are compliant with the standards outlined in the FDA Data Standards Catalog

**FDA binding guidance and deadlines for submission of standardized study data**
- **Dec 17, 2016:** NDAs, ANDAs, BLAs, DMFs
- **Dec 17, 2017:** Commercial INDs

[https://www.fda.gov/forindustry/datastandards/default.htm](https://www.fda.gov/forindustry/datastandards/default.htm)
FDA Accepts Study Data using the Standards, Formats, and Terminologies Described in the FDA Data Standards Catalog

The FDA Data Standards Catalog lists what data standards are supported and required by FDA in electronic submissions. The catalog is available at [www.fda.gov](http://www.fda.gov).

<table>
<thead>
<tr>
<th>Data Exchange Standard</th>
<th>Exchange Format</th>
<th>Standards Development Organization (SDO)</th>
<th>Supported Version</th>
<th>Supported Implementation Guide Version</th>
<th>FDA Center(s)</th>
<th>Date Support Begins (MM/DD/YYYY)</th>
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<tr>
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<td>Clinical Data Interchange Standards Consortium (CDISC)</td>
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<tr>
<td>Define</td>
<td>XML</td>
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<td>2.0</td>
<td>N/A</td>
<td>CDER, CBER</td>
<td>08/07/2013</td>
</tr>
</tbody>
</table>
TCG provides technical specifications and general considerations on how to submit standardized electronic study data.

Describes how industry should submit standardized study data in NDAs, BLAs, INDs and ANDAs.
Submission of Standardized Clinical Study Data: 51% of Original NDAs and efficacy supplement submissions contained SDTM data (FY18)
Submission of Standardized Nonclinical Study Data is Increasing

The types of studies included Repeat-Dose Toxicity, Single-Dose Toxicity, and Carcinogenicity. FDA has received 130 submissions with SEND data during FY17 thru beginning of FY19.
Validation Activities help ensure study data are compliant, useful, and will support meaningful review

• Validation activities occur at different times
  – Submission receipt
  – Beginning of the regulatory review
The FDA may refuse to file (RTF) for NDAs and BLAs, or refuse to receive (RTR) for ANDAs, an electronic submission that does not have study data in conformance to the required standards specified in the FDA Data Standards Catalog.

FDA published “Technical Rejection Criteria for Study Data” to specify the criteria for validation.


Deadlines:
Dec 17, 2016: NDAs, ANDAs, BLAs, DMFs
Dec 17, 2017: Commercial INDs
FDA Assessed Rate of Compliance for Requirement to Submit Standardized Study Data

• Conformance to requirement was assessed in sample of study data
  – Received between 12/18/2016 to 3/31/2018 for NDA, BLA, and ANDA Submissions
  – Received between 12/18/2017 to 3/31/2018 for Commercial IND Submissions

• Technical Rejection Criteria used to validate conformance
  – Two high-level errors
    • 1734 – A Trial Summary (TS.xpt) dataset must be present (supplies study start date and determines if standardized, electronic format is required)
    • 1736 – Demographics Domain (DM.xpt) and Define.xml or ADSL and Define.xml must be present for each qualifying study
  – Two medium-level errors
    • 1735 – Correct STF file must be used
    • 1737 – Only one dataset should be submitted as New
Less than 70% study data in sample were received with non-critical errors

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>NDA</th>
<th>ANDA</th>
<th>BLA</th>
<th>Comm. IND</th>
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<td>Total Number of Submissions</td>
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<td>24,837</td>
<td>38,346</td>
<td>7,601</td>
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<td>Total Number of Submissions with Study Data</td>
<td>3,221</td>
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<td>Total Number Submissions with Critical Errors</td>
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<td>Error 1734 (Absence of TS.xpt dataset)</td>
<td>968</td>
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<td>506</td>
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<td>Error 1736 * (Absence of DM.xpt and Define.xml or ADSL and Define.xml Demographics)</td>
<td>84</td>
<td>14</td>
<td>63</td>
<td>1</td>
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<tr>
<td>Error Rate (% among submissions with Study Data)</td>
<td>32.04%</td>
<td>26.82%</td>
<td>38.11%</td>
<td>29.18%</td>
<td>23.30%</td>
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</table>

* Error 1736 validation is not performed if a study has Error 1734

- NDA, BLA, and ANDA submissions received from 12/18/2016 to 3/31/2018
- Commercial IND submissions received from 12/18/2017 to 3/31/2018
Only ~ 50% study data in original NDAs were received with non-critical errors

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Original Submission</th>
<th>Efficacy Supplement</th>
<th>Rolling Submission</th>
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<tr>
<td>Total Number of Submissions with Study Data</td>
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<tr>
<td>Total Number Submissions with Critical Errors</td>
<td>302</td>
<td>74</td>
<td>28</td>
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<td>Error 1734 (Absence of TS.xpt dataset)</td>
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<tr>
<td>Error Rate (% among submissions with Study Data)</td>
<td>26.82%</td>
<td>52.11%</td>
<td>30.43%</td>
<td>40.00%</td>
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- NDA, BLA, and ANDA submissions received from 12/18/2016 to 3/31/2018
- Commercial IND submissions received from 12/18/2017 to 3/31/2018
About 80% nonclinical study data in sample were received with non-critical errors

<table>
<thead>
<tr>
<th>Total Number of Submissions with xpt files</th>
<th>All</th>
<th>NDA</th>
<th>BLA</th>
<th>Comm. IND</th>
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<tr>
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<td>2,509</td>
<td>1,486</td>
<td>591</td>
<td>432</td>
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<td>Original Submissions with m4 Study Data</td>
<td>59</td>
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<td>3</td>
<td>44</td>
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<tr>
<td>Original Submissions with 1734 Error (Absence of TS.xpt dataset)</td>
<td>10</td>
<td>3</td>
<td>1</td>
<td>6</td>
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<tr>
<td>Original Submissions with 1736 Error (Absence of DM.xpt and Define.xml or ADSL and Define.xml Demographics)</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Original Submissions with Critical Error (1734/1736)</td>
<td>11</td>
<td>3</td>
<td>1</td>
<td>7</td>
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<tr>
<td>Critical Errors Rate for m4 Study Data</td>
<td>18.64%</td>
<td>25.00%</td>
<td>33.33%</td>
<td>15.94%</td>
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</tbody>
</table>

- NDA, BLA, and ANDA submissions received from 12/18/2016 to 8/31/2018
- Commercial IND submissions received from 12/18/2017 to 8/31/2018
Assessment Findings

• If FDA applied published technical rejection criteria to assess compliance to the
  requirement to submit standardized study data,
  • only ~3/4 of applications would pass validation
  • ~1/4 of applications would report high error
  • Identified errors are easily identified and correctable.
• To date, FDA has not rejected any submission containing errors as reflected in this
  analysis.
• FDA plans to use technical rejection criteria to identify applications that are not
  fulfilling the requirement.

TIP
To avoid validation errors, it is important for sponsors and applicants to understand the requirements specified in guidance and recommendations for submitting study data in the Study Data Technical Conformance Guide.
Validation Activities help ensure study data are compliant, useful, and will support meaningful review

• Validation activities occur at different times
  – Submission receipt
  – Beginning of the regulatory review
Validation Activities at Beginning of the Regulatory Review

• After an application has been successfully submitted, OCS provides data quality assessments
• OCS uses FDA Validator
  • To assess data quality
  • Conformance to the standard
  • Reviewability
  • To create reports for quality assessments and services
OCS SERVICES
OCS SERVICES
Benefits of JumpStart Service

**Purpose**

1. Assess and report on whether data is fit for purpose
   - Quality
   - Tool loading ability
   - Analysis ability

2. Load data into tools for reviewer use and run automated analyses that are universal or common (e.g., demographics, simple AE)

3. Provide analyses to highlight areas that may need a focus for review

**Benefits**

1. Understand data, analyses that can be performed, and identify potential information requests for the sponsor

2. Improves the efficiency of review by setting up tools and performing common analyses, which provides time to focus on more complex analyses

3. Points to a possible direction for deeper analysis
JumpStart Services Support Clinical Safety Review

![Bar chart showing NDA and BLA applications from 2017 to 2019](image_url)
OCS Provides Data Quality Assessments for Clinical Data

• OCS provides Data Fitness assessments as part of the JumpStart Services
  – Completed 43 JumpStart services FY 2018 that included a Data Fitness Assessment
  – Expected to complete up to 120 Data Fitness assessments in FY 2019

• Created Core DataFit reports to expand reach
  – CoreDF Reports contain, on average, 68% of Data Fitness findings presented to reviewers during the JumpStart Service
  – Delivered 35 CoreDF Reports to reviewers, including desk-side services, across 13 reviewer divisions
  – Plan to deliver in FY 2019 to all Original NDAs and BLAs
  – Future: All Applications and Submissions with study data

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Data Fitness Assessments for Clinical Study Data

- SDRG/Define File
- Supplemental Dataset Info
- Controlled Terminology
- Deaths
- Missing Data
- CDER Common Issues
- Duplicates
- Term Matching
- Standard Units
- Safety Population
- Race/Ethnicity
Core DF Assessments for Clinical Study Data

<table>
<thead>
<tr>
<th>Standards / Dictionaries</th>
<th>Findings</th>
</tr>
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<tbody>
<tr>
<td>SDTM-IG 3.1.2</td>
<td><strong>Adverse Events</strong></td>
</tr>
<tr>
<td>SDTM-CT 2017-09-29</td>
<td>36 (92.3%) of serious adverse events are not flagged as serious</td>
</tr>
<tr>
<td>MedDRA 8.0</td>
<td>473 (39.7%) of events are missing end time point</td>
</tr>
<tr>
<td></td>
<td>230 (19.3%) of adverse events are potential duplicates</td>
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</table>

<table>
<thead>
<tr>
<th>Disposition</th>
<th>No significant findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplemental Info</td>
<td>No significant findings</td>
</tr>
<tr>
<td>Terminology</td>
<td>No significant findings</td>
</tr>
<tr>
<td>Laboratory</td>
<td>2,041 (3.5%) of observations are missing Reference Range Upper Limit in Standard Units (LBSTNRH)</td>
</tr>
<tr>
<td></td>
<td>318 (0.6%) of Standard Units (LBSTRES) are missing when Standard Results (LBSTREC) are provided</td>
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<table>
<thead>
<tr>
<th>Vital Signs</th>
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<tbody>
<tr>
<td>Demographics</td>
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<tr>
<td>Exposure</td>
<td>No significant findings</td>
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<tr>
<td>Other</td>
<td>EPOCH variable was not provided</td>
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Pilot: Use of Clinical Data Specialist Role within Regulatory Review

Challenge:
- There are time limitations to analyze and review submission data
- Clinical reviewers are skilled medical therapists, not data scientists

Approach:
- OCS piloted using CDS to assist clinical reviewers with
  - data quality assessments
  - Safety analysis support throughout lifecycle of review

Results:
- CDS provides data management, data integration, and analysis support while clinical reviewer focuses on clinical meaning and implications
- CDS role develops algorithms to address specific safety concern that can then be re-used providing consistency when evaluating this type of safety concern
- OCS develops reusable analysis and code focused on specific therapeutic areas and/or clinical outcomes of interest to improve the efficiency of clinical review
Benefits of KickStart Service

**KickStart Service**

1. Interpret data quality checks and load data into Janus Nonclinical
2. Assist with data exploration in Janus Nonclinical
3. Support and training for working with review tools and SEND standardized data
4. Support Review Team communications about the SEND data to the applicant

**Benefits for You**

1. Understanding of SEND data and which analyses can be performed
2. Improved review by providing possible directions for in-depth exploration
3. Learn how to automatically create tables and graphs for your review
4. Resolution to questions about the SEND submission
KickStart Services Support Nonclinical Review

**Useable SEND**
- **2017**: 8 Useable, 4 Unusable
- **2018**: 83 Useable, 5 Unusable
- **2019**: 30 Useable, 5 Unusable

**KickStart Services***
- **2017**: 1 IND, 16 NDA/BLA
- **2018**: 4 IND, 4 NDA/BLA
- **2019**: 4 IND, 1 NDA/BLA

*Application must meet the following criteria:
- Study loaded into Janus Nonclinical
- Reviewer submits service request form
- Reviewer has not received a KickStart service
OCS Provides Data Quality Assessments for Nonclinical Data

• OCS provides Data Fitness assessments as part of the KickStart Service
  – Performs data quality checks for conformance and usability
  – Loads into analytical environment

• Plan to automated Data Quality Reports for SEND data
ANALYTICS AND SYSTEMS
OCS Analysis Toolbox

Offers a catalog of analytical tools or scripts that inform, facilitate, and support the review of study data

Simple Analyses
- Scripts or macros comprising small programs or a series of programs
- Analyses that answer a simple question or perform a simple function, such as showing population counts by arm variables and population flags

Complex Analyses
- “Guided” macros for more complex analyses
- Tool interfaces that facilitate dataset and parameter selection, such as selection of subgroups, filters, variables, and calculations, to produce the desired outputs
OCS Analysis Toolbox

AE Temporal Tool
Longitudinal analysis of adverse events through Kaplan-Meier and Mean Cumulative Function

Demographic Tool
Performs demographic subgroup analysis through a web app

Hepatotoxicity Tool
Examine drug-induced liver injury through composite visualization

Napoleon's March
Longitudinal visualization of disposition categories

AE Temporal Characterization Tool:
conducts time to first event and time to recurrent event analysis for safety endpoints of interest

Demographic Tool:
provides targeted descriptive statistics and safety endpoint analysis for demographic subgroups

Hepatotoxicity Tool:
designed to complement standard Hy’s Law analysis by providing drug induced liver injury analysis for subjects with underlying liver injury

Napoleon's March:
designed to analyze subject study disposition longitudinally

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Adverse Event Temporal Characterization Tool

Kaplan Meier (KM) Estimator:
- used to estimate survival function from lifetime data
- allows estimation of survival over time
- analyze any event of interest

Mean Cumulative Function (MCF):
- analysis of recurrent event data, where each population unit can be described by a cumulative history function for the cumulative number of events
- staircase function depicts the cumulative number of recurrences of an event

R Markdown generates HTML report that can be shared, keeping all the interactivity of the output but without the need of R or the source data!
Hepatotoxicity Tool

Use Case:
Subjects with elevated liver enzyme test results at baseline (e.g., subjects with Chronic Hepatitis C)

Solution:
Composite visualization that includes pre-treatment and on-treatment prevalence of:
• ALT and BILI in terms of Hy’s Law candidate laboratory Upper Limit Normal thresholds
• magnitude of these elevations normalized by respective baseline test results

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Kidney Function Tool

- Provides tool to assess the impact of a drug on kidney function (i.e., renal impairment)

- Analysis Components:
  - Provides clinical reviewers with information on:
    - Development of marked abnormality in serum creatinine
    - Shifts in estimated glomerular filtration rate (eGFR)
    - Changes in albumin/creatinine ratio
    - Shifts in albuminuria (e.g., normal to microalbuminuria)
Safety Assessments and Signal Detection
Drug Induced Liver Injury (DILI) Research

Challenge:

- There are no tools to identify DILI in subjects with liver disease who exhibit baseline pre treatment liver test values that exceed normal limits. A rise in liver test values above normal limits predicts fatal DILI when accompanied by liver dysfunction (Hy’s law).
- In patients with liver disease, a rise in liver test values over baseline while on treatment can represent liver disease progression or DILI.

Approach:

- Compared the variability in liver test markers in clinical trials of healthy volunteers to patients with liver disease
- Developed a hepatotoxicity tool to visualize the change in liver tests from baseline and complement current DILI screening with Hy’s Law analyses.

Results:

- The Hepatotoxicity Tool complements Hy’s law analysis with a visualization of the change over baseline test values
- Provides reviewers a screening tool for DILI in treatment trials for liver disease

Machine Learning

Challenge:
- Adverse event data includes text that provides context.
- Manual review of text is limiting and time-consuming.

Approach:
- Test automated/semi-automated processing of text data using statistical, machine learning, and linguistic techniques
- Generate structured data from unstructured, then apply modeling techniques

Results:
- Uncovered relationships between these drugs and hepatic failure
- Offered information on drug combinations related to hepatic failure
- Clarified factors that can predict a greater degree of hepatic failure from serious events (death) versus less serious (treatable) events
- Assisted with rating the impact of using these drugs on patients

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RESEARCH COLLABORATIONS
Current Collaborations: PhUSE

- Data Transparency
- Optimizing the Use of Data Standards
- PhUSE Working Groups
- Standard Analyses and Code Sharing
- Educating for the Future
- Nonclinical Topics
- Emerging Trends and Technologies

OCS collaborates with Pharmaceutical Users Software Exchange (PhUSE) in the Computational Science Symposium (CSS) and associated working groups.
Modernization to Support New Drug Review

• Recruiting the best and brightest individuals from many disciplines
• Enhancing our focus on multidisciplinary teams
• Prioritizing operational excellence
• Improving knowledge management
• Emphasizing the importance of safety across a drug’s lifecycle
• Incorporating the patient voice

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