Center for Drug Evaluation & Research

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Outline

1. Overview of CDER's Research Governance Council (RGC)
2. RGC's Progress to Date
3. 2019-2024 Strategic Plan
4. Research Portfolio Oversight: Benefits & Recap
5. Scientific Review Process of NCTR Submissions
6. Regulatory Science Impact of NCTR/CDER Collaborations
7. Questions, Feedback and Suggestions

CDER'S RESEARCH GOVERNANCE COUNCIL

The RGC Charter (March 2017)

Oversee Central Research Functions

- Set Goals, Objective & Priorities
- Track Research Investments
- Develop Research Outcomes Metrics
- Conduct Research Project & Portfolio Evaluations
- Review Scientific Interactions with Non-CDER FDA Centers and Offices
- Provide General Oversight of CDER-wide Research Programs and Policies

CDER Research Goals

1. Develop and improve scientific approaches that aid in developing new drugs or evaluating their pre-market safety and efficacy

2. Develop and improve scientific approaches to enhance the safety of marketed drugs

3. Improve product manufacturing, testing, and surveillance to help ensure the availability of high-quality drugs

4. Develop and improve methods for comparing products to facilitate the development and review of generic drugs and biosimilars

5. Maintain scientific readiness to address emerging public health threats, enable regulatory integration of emerging technologies, and facilitate stakeholder adoption of novel approaches to drug development

- Defining goals, objectives, and priorities (Dec. 2017)
- In time for FY19 Budget request data call to offices (early Jan. 2018)

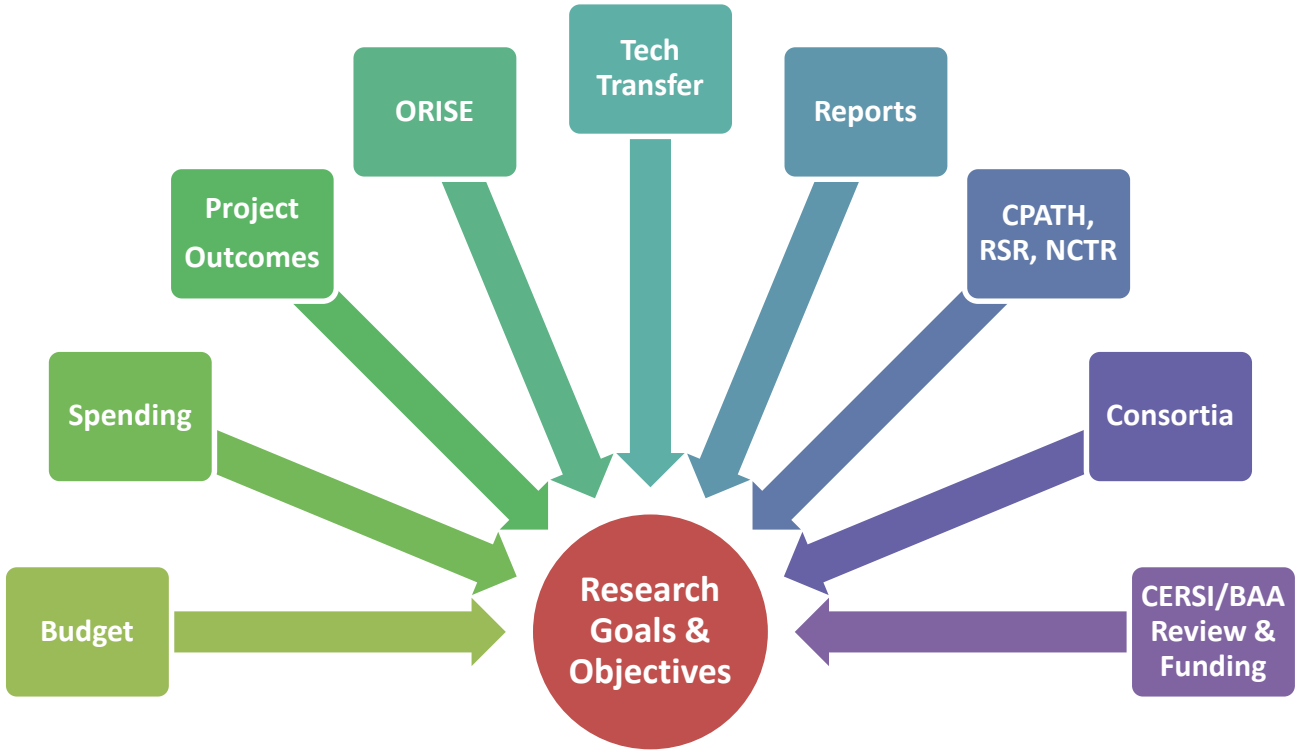
- Developing processes to track:
  - research-related budget requests (Jan. 2018) *and*
  - research spending (Oct. 2018) by research goal, objective, and priority

- Determining how CDER will evaluate research programs against research goals and objectives (Oct. 2018)
- In time for initiation of FY19 research programs and projects

- Facilitating updates to the CDER Science Projects Database *and*
- Developing a uniform project initiation process (Spring 2018)
- In time for research **project** data collection during FY19

- Communicating the work of the RGC, raising awareness of CDER research and resources, and generating ideas for telling CDER's research story (ongoing)

Using the CDER Research Goals & Objectives Framework…..



…..to Link CDER Research Activities

RGC Strategic Plan 2019-2024

VISION

Be the benchmark for governance of mission-driven research.

MISSION

Enhance CDER's research capabilities and impact by fostering awareness of and optimizing regulatory research activities and investments.

OPTIMIZE

Research Activities through Effective Stewardship

INFLUENCE

Processes and Policies that impact Research

SERVE

Be the Information Hub for CDER Research

Foster a Community of

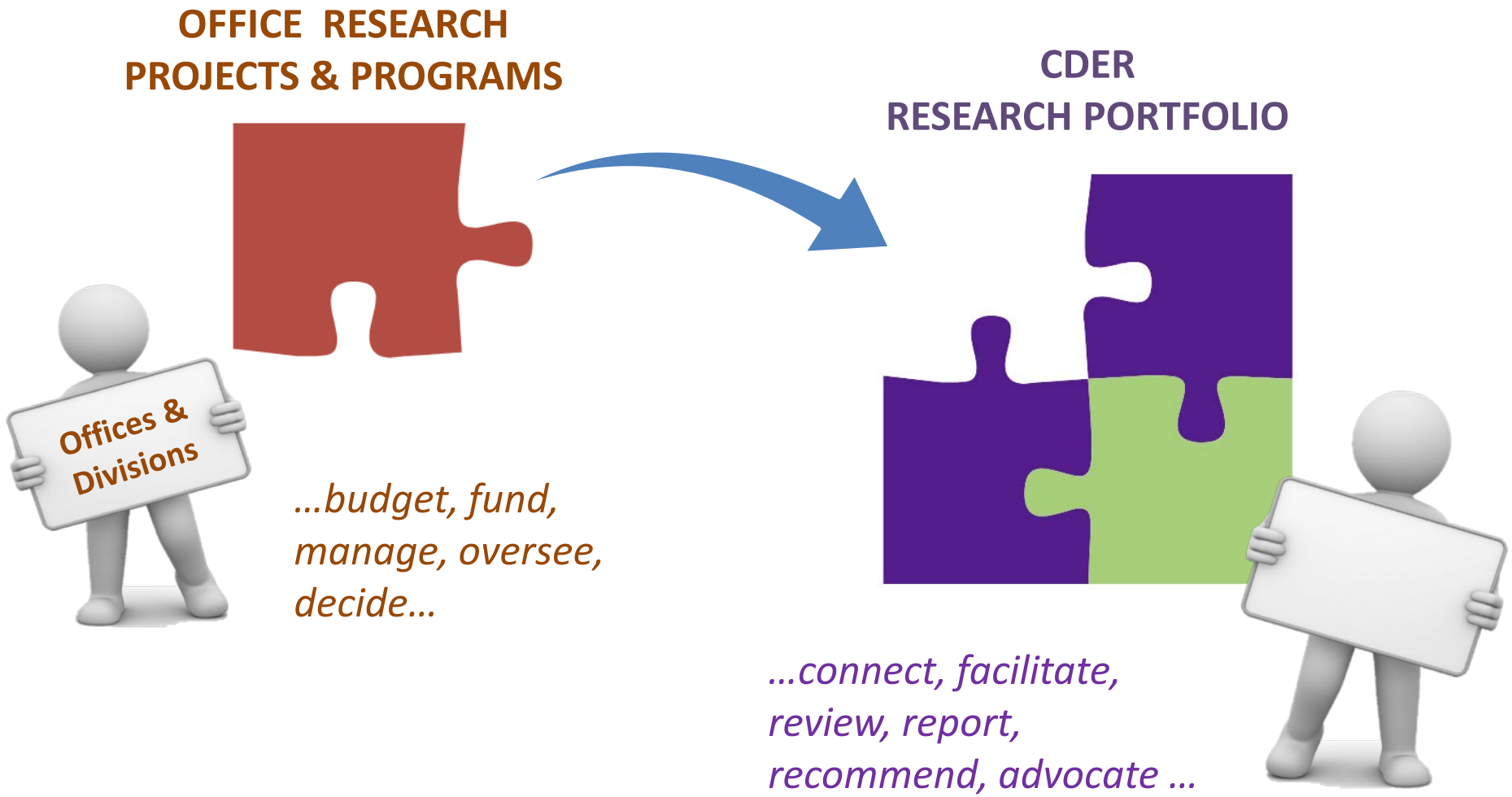
ENGAGEMENT & COLLABORATION

for CDER Research

Benefits of Research Portfolio Oversight

- In-depth review of CDER research investment portfolio is a priority for the Executive Committee.
- Identify, prioritize, and recommend funding of any significant gaps not currently addressed.
- Foster communication amongst communities working on specific goal/objectives across all project types.
- Identify and cultivate areas for collaboration and coordination, and resolve areas of duplication.

Working Collaboratively to Optimize CDER Research

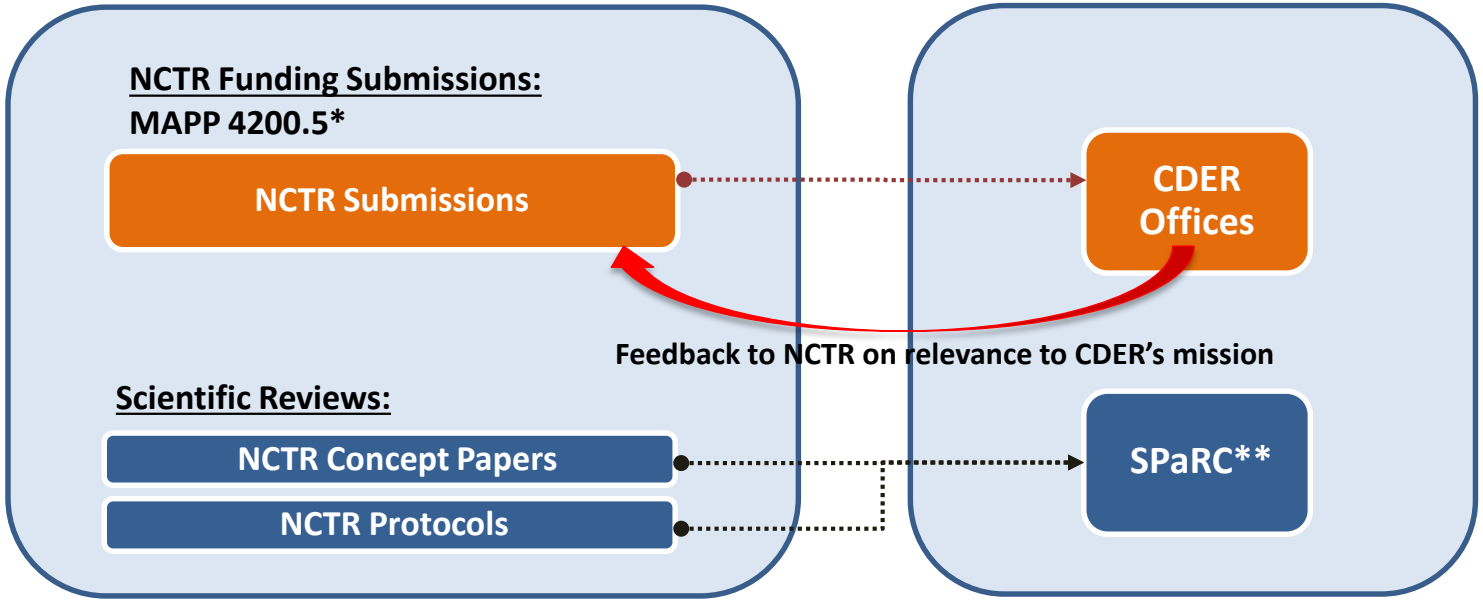


Summary

- All CDER projects (intramural, extramural, consortia, etc.) are linked to goal/objective/priority beginning with FY17 updates
- Outcome measures were collected for FY17 and FY18
- Five-year strategic plan was developed
- Data will allow the RGC to:
  - Develop reports on CDER's aggregate progress related to each goal/objective/priority.
  - Assess aggregate progress across all project types related to goal/objective/priority.
  - Develop a reporting format(s) for future research activities.

SCIENTIFIC REVIEW PROCESS OF NCTR SUBMISSIONS

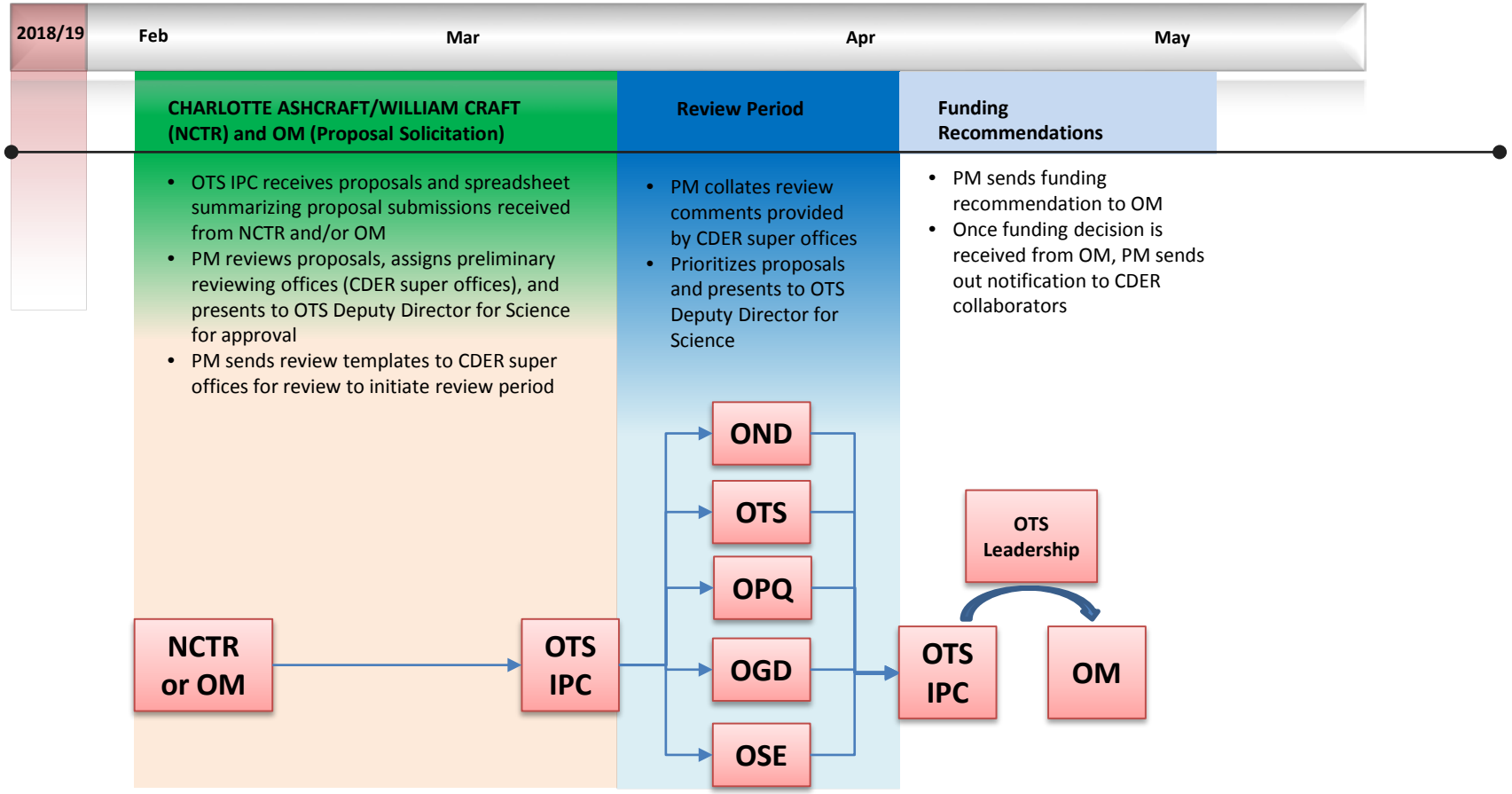
NCTR Funding Submissions and Scientific Reviews by CDER



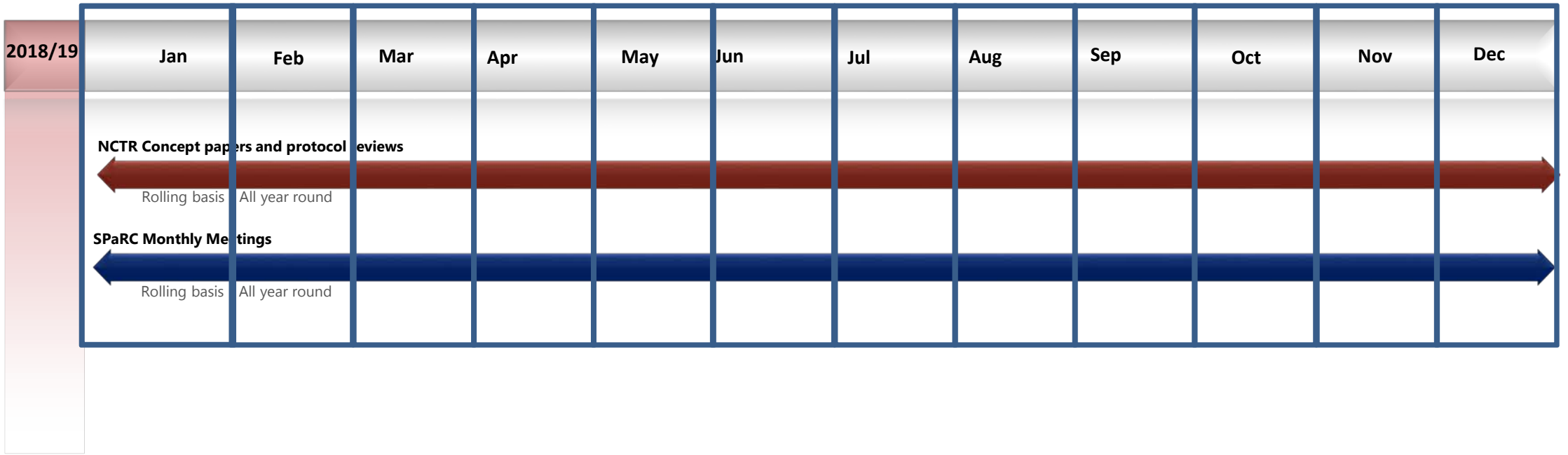
**CDER's Science Prioritization and Review Committee (SPaRC)

*MAPP 4200.5 Link: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm477146.pdf

NCTR/CDER Intercenter Projects

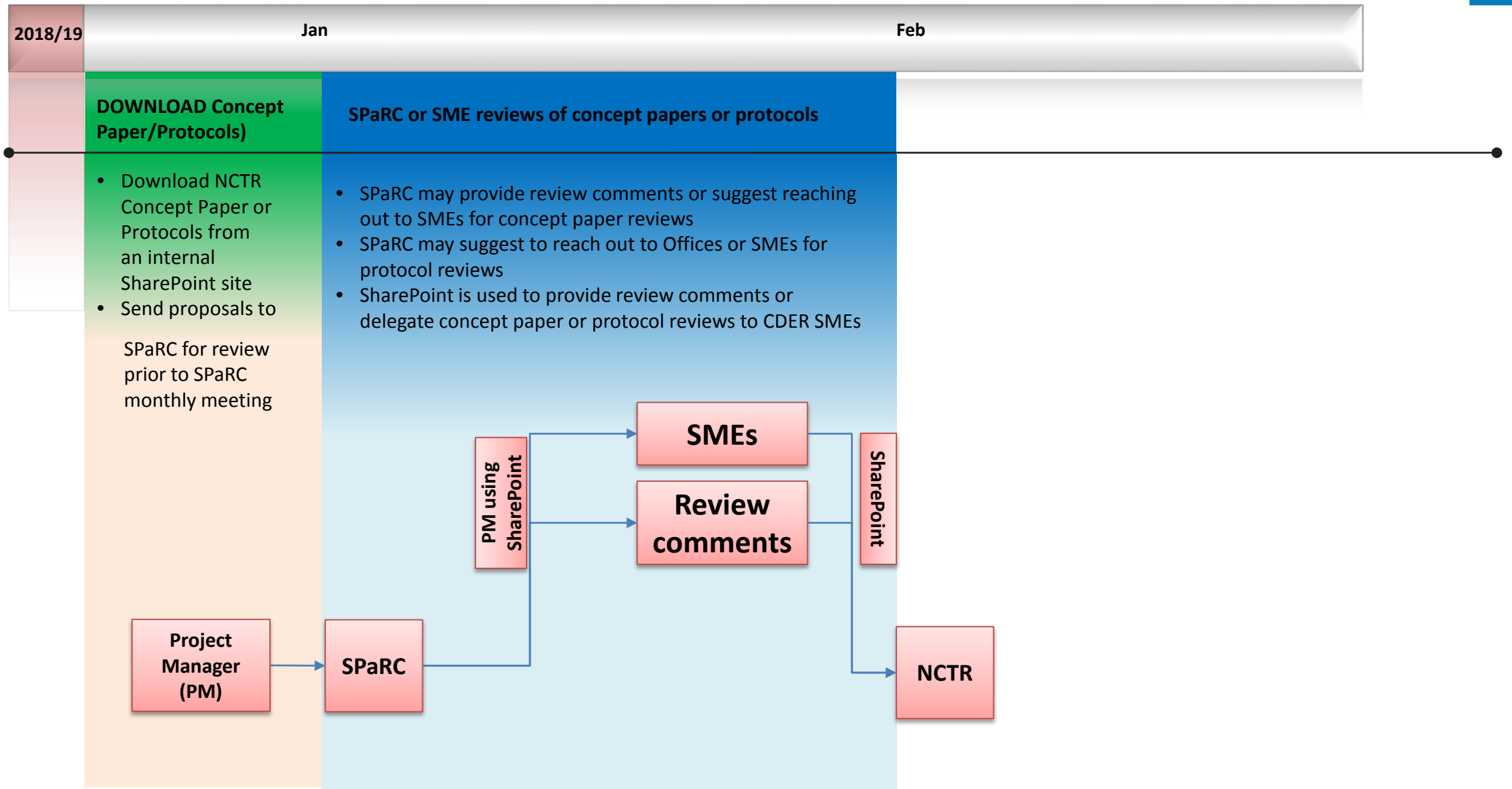


NCTR Concept Paper and Protocol Reviews



POC: Krystina Fahey (NCTR)
SharePoint support: Kieu Pham (CDER/OTS)

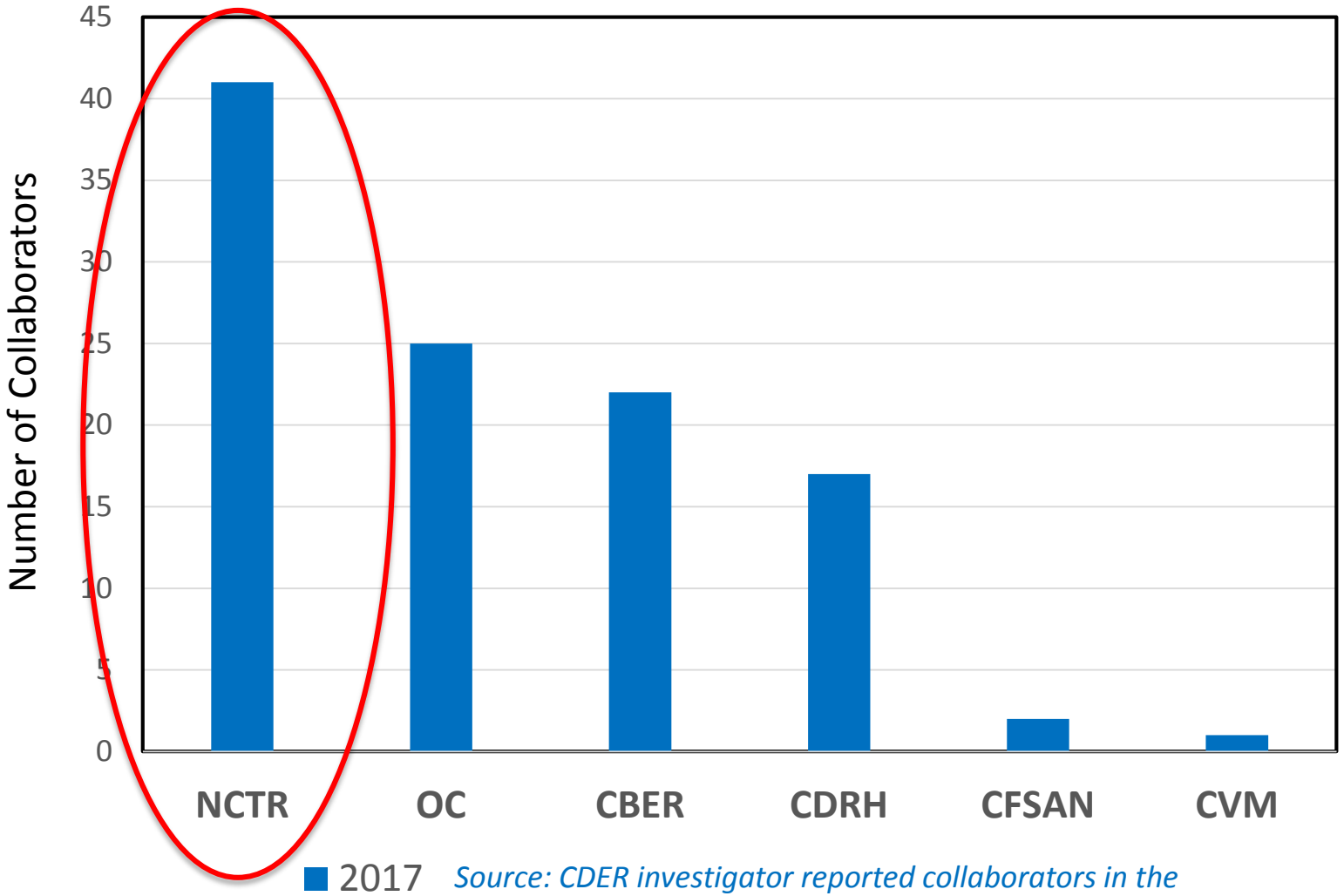
NCTR Concept Paper and Protocol Reviews



Impact of NCTR/CDER Collaborations on Review Tools and Projects

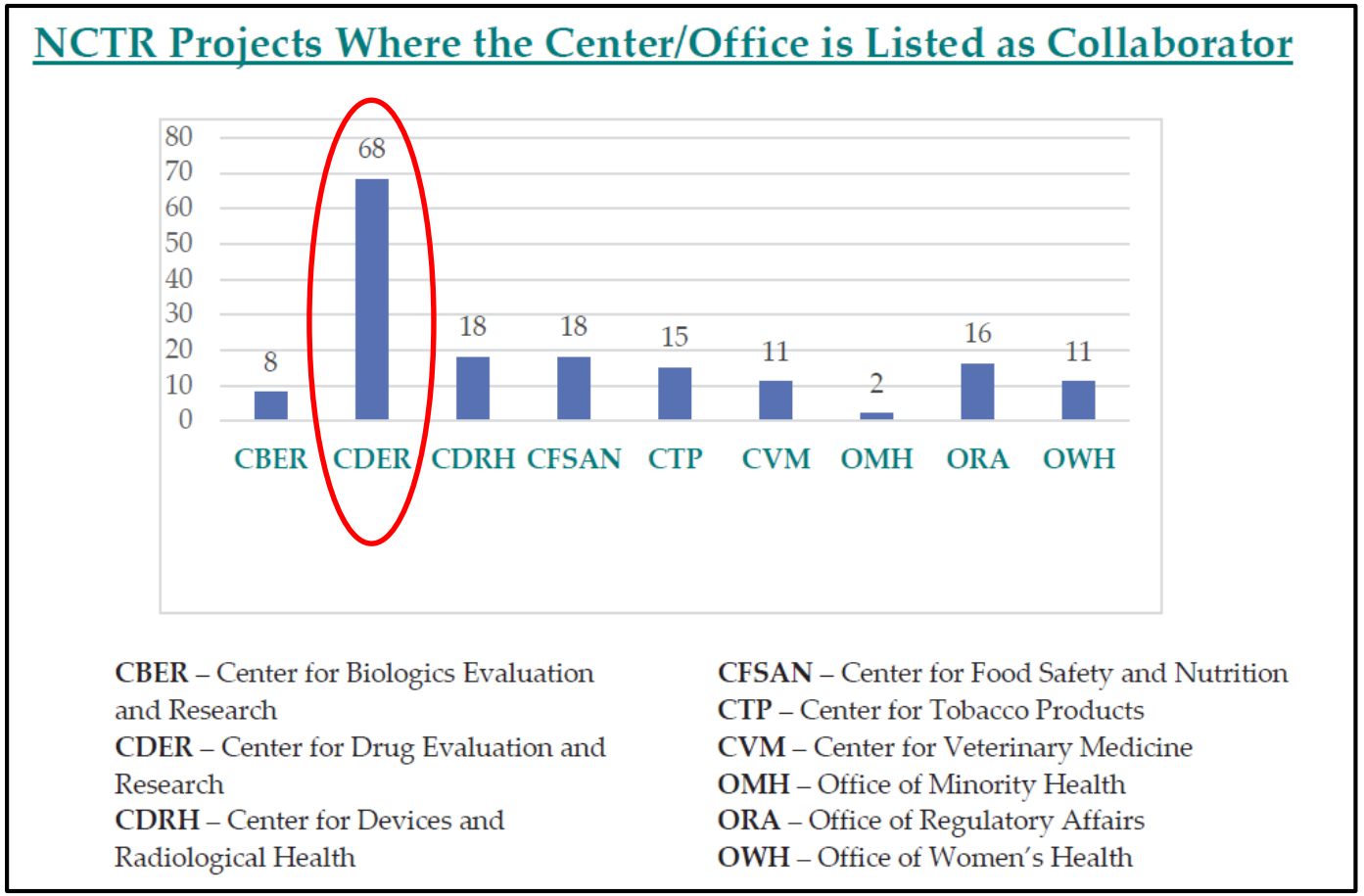
- Informatics:
  - FDA label provides customizable search capabilities of >100,000 approved labels using structured product labeling (SPL). CDER medical officers, pharmacologists, chemists, and toxicologists use this tool during labeling reviews.
  - The Investigational New Drug (IND) Smart Template System supports CDER reviewers during IND reviews. It standardizes input of data into a structured template and provides access to historical data through a dashboard. Fully searchable database used to inform regulatory review and decision-making activities.
- Toxicity Studies (two examples):
  - Better understanding of opioid exposure and effect on the developing fetal brain and nervous system by looking at exposure outcomes in hiPSC/hESC lines and mouse/rat NSCs. May contribute to more precise recommendations regarding the safety of opioid use in pregnancy.
  - More comprehensive characterization of an induced pluripotent stem cell-derived human cardiomyocytes (iPSC-hCM) model. May provide practical modeling solutions for use in drug-induced proarrhythmia risk assessments.

CDER Collaborations Across FDA Centers FY2017 Data Call*



Source: CDER investigator reported collaborators in the CDER Science Projects Database

NCTR Collaborations Across FDA Centers 2016-2017



Source: NCTR Annual Report 2016-2017

NCTR/CDER Expertise Exchange

- Topic modeling analysis of research projects in the CDER Science Projects database (Dr. Joshua Xu/Dr. Weida Tong team)
- Topic modeling analysis of FDA-NIH co-authored publications (Dr. Joshua Xu/Dr. Weida Tong team)
- Member of the Drug Induced Liver Injury (DILI) Scientific Interest team (led by Dr. Minjun Chen)
- Systematic Genotyping and Annotation of Pharmacogenetic Variations Using Next-Generation Sequencing (NGS) Data with Dr. Baitang Ning
- Opioid agonists/antagonists knowledgebase (Oak) to assist review and development of abuse-deterrent drugs for pain management and opioid addiction treatment with Dr. Huixiao Hong
- Computational drug repositioning for rare diseases with Dr. Zhichao Liu

QUESTIONS, FEEDBACK & SUGGESTIONS


FDA
U.S. FOOD & DRUG
ADMINISTRATION