Center for Drug Evaluation & Research

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Office of Translational Sciences
NCTR, Science Advisory Board
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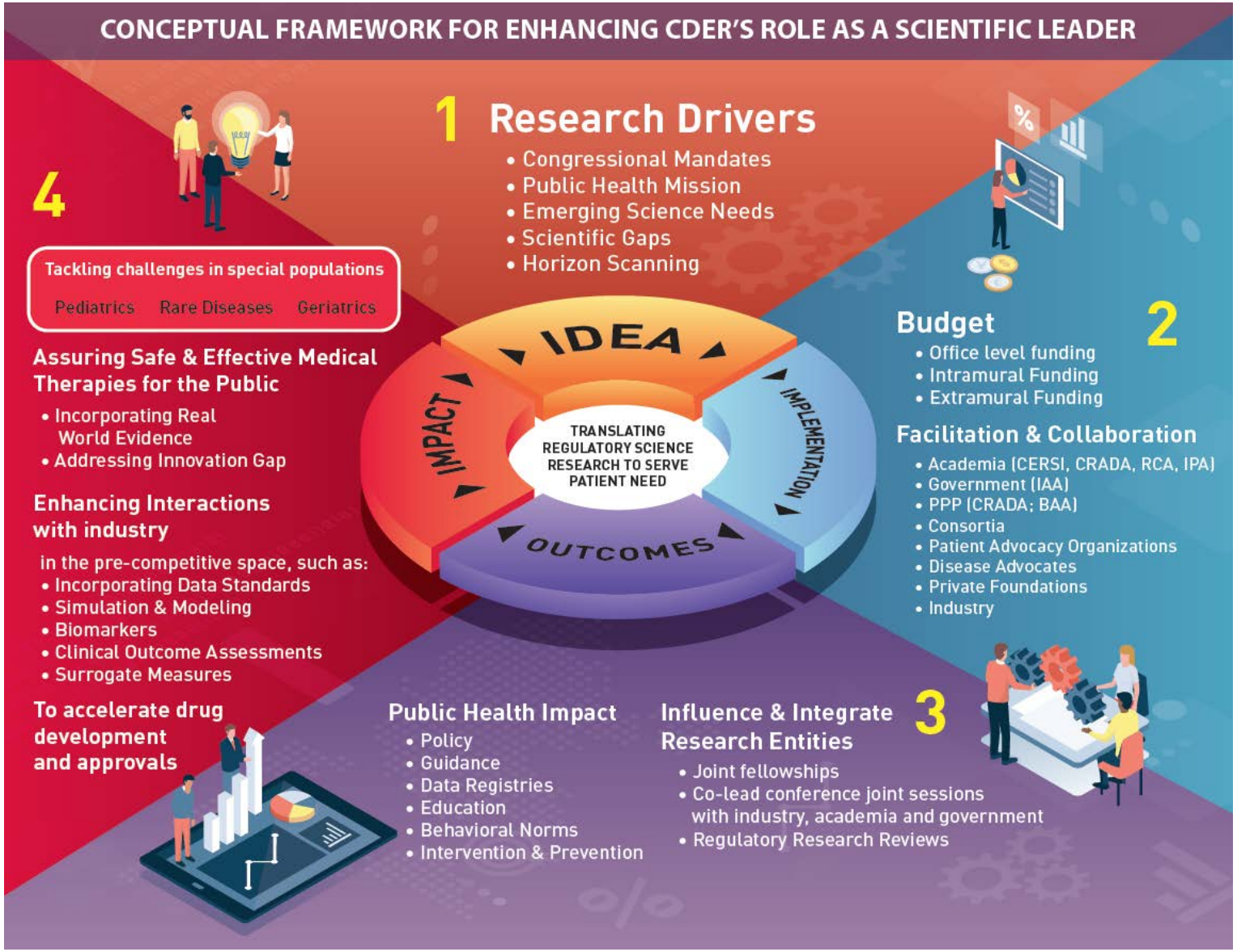
Outline

1. Overview of CDER's Research Governance Council (RGC)
2. RGC 2019-2024 Strategic Plan
3. CDER Intramural Funding
4. Scientific Review Process of NCTR Submissions
5. Regulatory Science Impact of NCTR/CDER Collaborations
6. Questions, Feedback and Suggestions

The Research Loop at CDER



CDER'S RESEARCH GOVERNANCE COUNCIL

GOAL
Establish CDER as a Scientific Leader and Partner

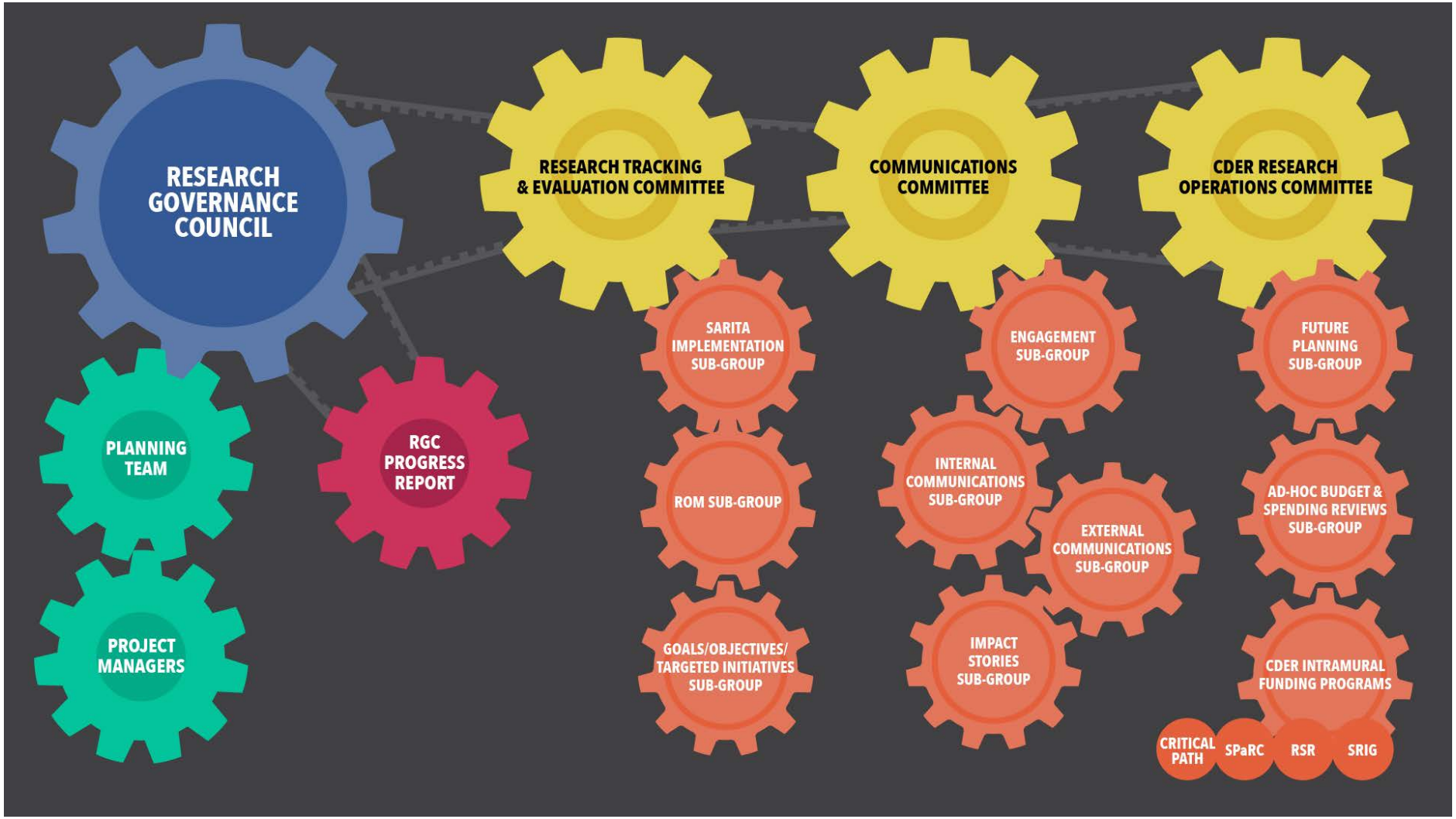
MISSION
Enhance CDER's Research capabilities and impact by fosterin awareness of and optimizin regulatory research activities

STRATEGIC PLAN
A roadmap for regulatory science research

VISION
Be the Benchmark for the governance of mission driven research

SYNERGY & IMPACT
Identifying opportunities for engagement between regulatory and translational science research

CDER RGC


RESEARCH GOVERNANCE COUNCIL
RESEARCH TRACKING & EVALUATION COMMITTEE
COMMUNICATIONS COMMITTEE
CDER RESEARCH OPERATIONS COMMITTEE
PLANNING TEAM
PROJECT MANAGERS
RGC PROGRESS REPORT
SARITA IMPLEMENTATION SUB-GROUP
ROM SUB-GROUP
GOALS/OBJECTIVES/ TARGETED INITIATIVES SUB-GROUP
ENGAGEMENT SUB-GROUP
INTERNAL COMMUNICATIONS SUB-GROUP
EXTERNAL COMMUNICATIONS SUB-GROUP
IMPACT STORIES SUB-GROUP
FUTURE PLANNING SUB-GROUP
AD-HOC BUDGET & SPENDING REVIEWS SUB-GROUP
CDER INTRAMURAL FUNDING PROGRAMS
CRITICAL PATH
SPaRC
RSR
SRIG

RESEARCH GOALS AND OBJECTIVES

CDER Research Governance Council (RGC) established CDER research goals and objectives.

This research goals/objectives framework was developed to encompass all CDER research activities.

It will serve as an anchor for all research-related activities, enabling CDER to identify, organize, and summarize all research activities related to a particular goal and objective.

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

ROADMAP TO ENHANCE REGULATORY SCIENCE CAPABILITIES AT CDER

Optimize

As CDER's executive board for oversight of research, the RGC governs research activity as a recommending body. We ensure budgeting and spending linkage to CDER research goals and objectives, and communicate the impact of CDER research throughout the agency.

Influence

The RGC facilitates engagement in CDER research activities through process development and improvement. We recommend ways to recognize collaborative activities, and we coordinate CDER's response to research-related policy.

Serve

We plan to develop, launch, and maintain an online "hub" for all research information. This "hub" will be a central location for CDER staff to find a comprehensive list of research-related information, as well as to submit requests to the RGC.

Engagement and Collaboration

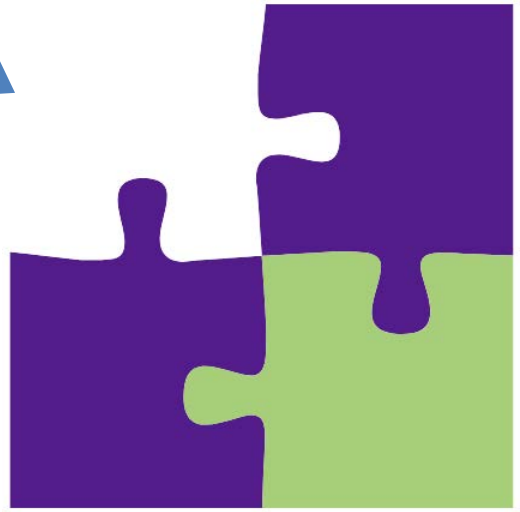
The RGC aims to define and develop a mechanism to identify cross-office research activity. We enable sharing of research activity, best practices, and research outcomes. Increasing research-related training and activities to further develop our research professionals.

FACILITATING RESEARCH
CDER INTRAMURAL FUNDING PROGRAMS

CDER INTRAMURAL FUNDING PROGRAMS

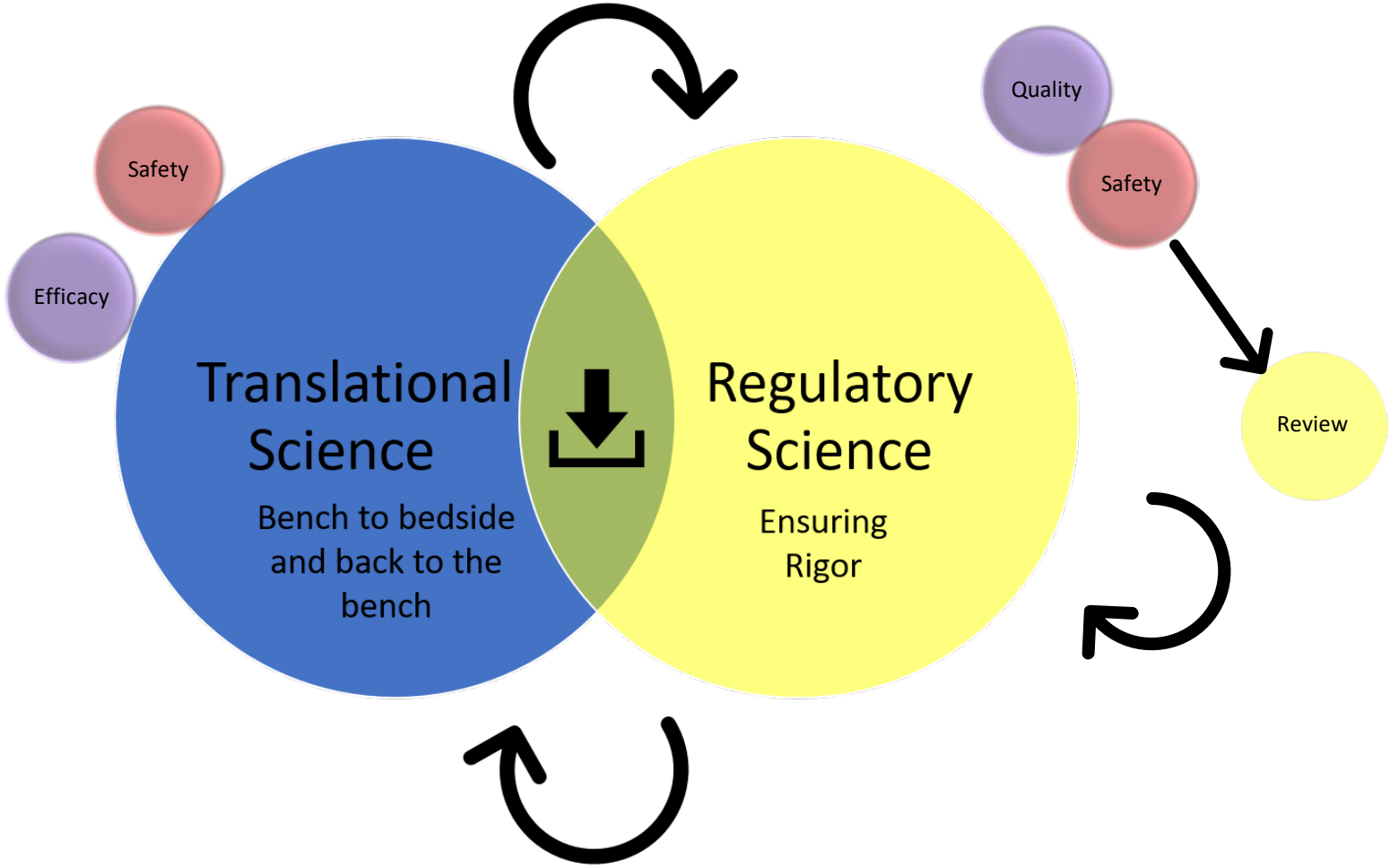
…seeks to address the gaps in CDER research and strongly encourages collaborative proposals that address those needs

CDER RESEARCH PORTFOLIO



*…is comprised of research programs funded at the Office and agency level and complemented by intramural funding programs that **complete** the repertoire of mission critical regulatory research questions being addressed*

The Synergy between Translational and Regulatory Science



CDER Intramural Funding Programs

CDER CRITICAL PATH

Identify and modernize the science via which FDA regulated products are developed, evaluated and manufactured

CDER RSR

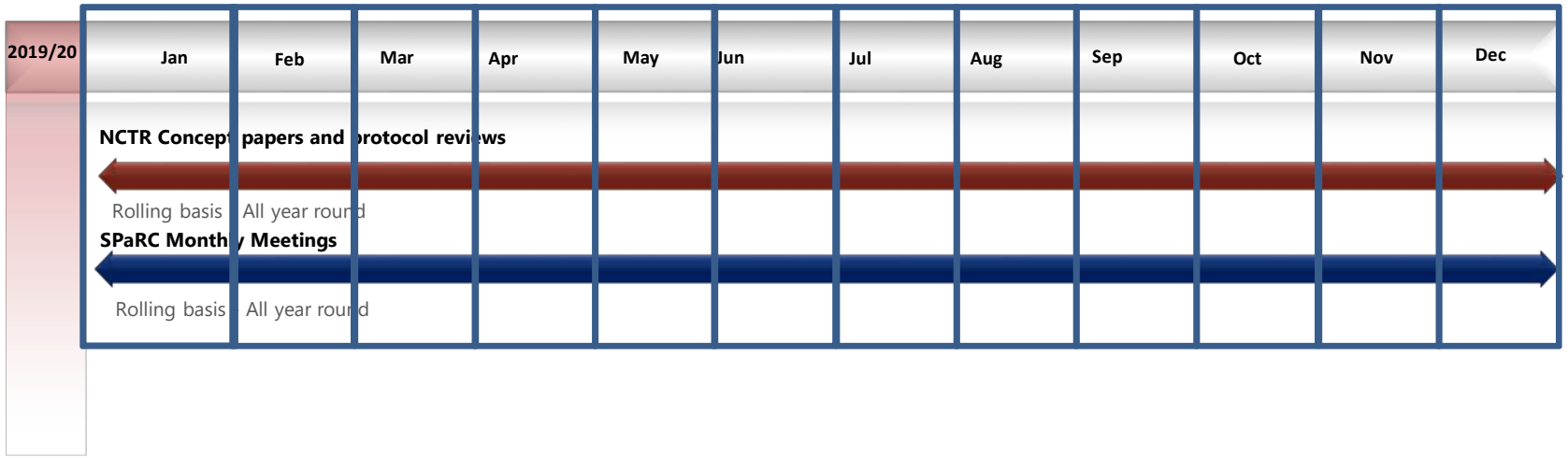
Identify novel approaches that propose to enhance the review process for drug applications.

CDER SRIG

Identify research projects that propose to fill gaps in current safety research efforts.

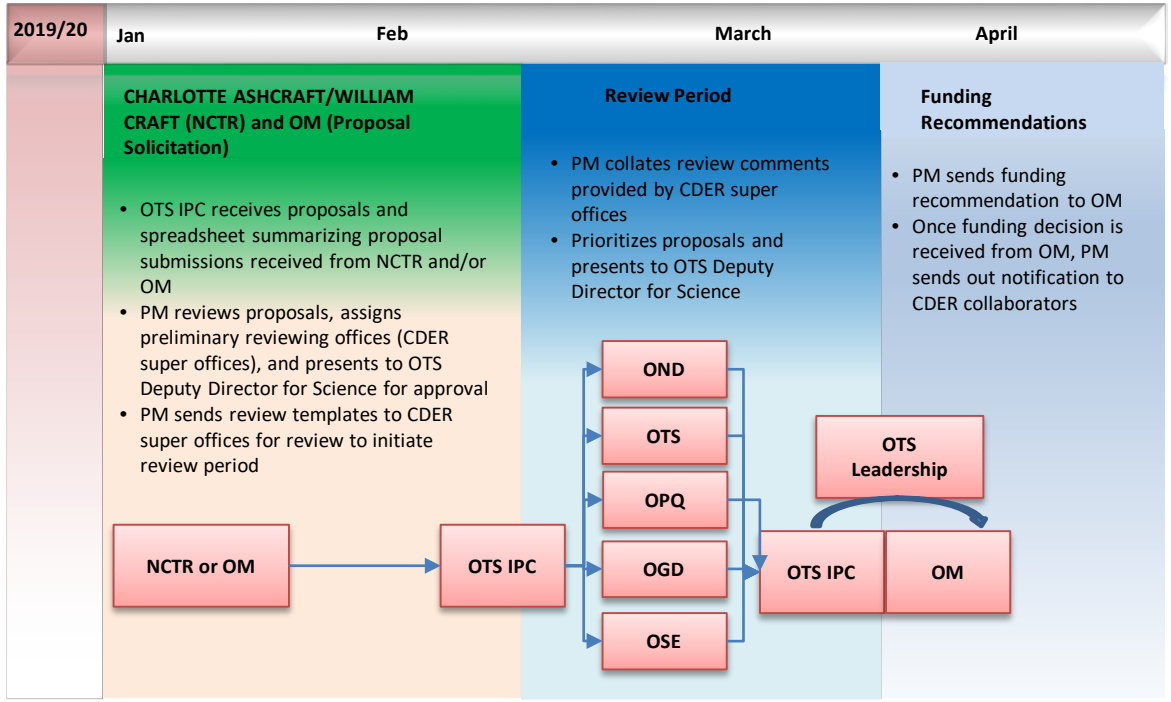
SCIENTIFIC REVIEW PROCESS OF NCTR SUBMISSIONS

NCTR Concept Paper and Protocol Reviews
A timeline

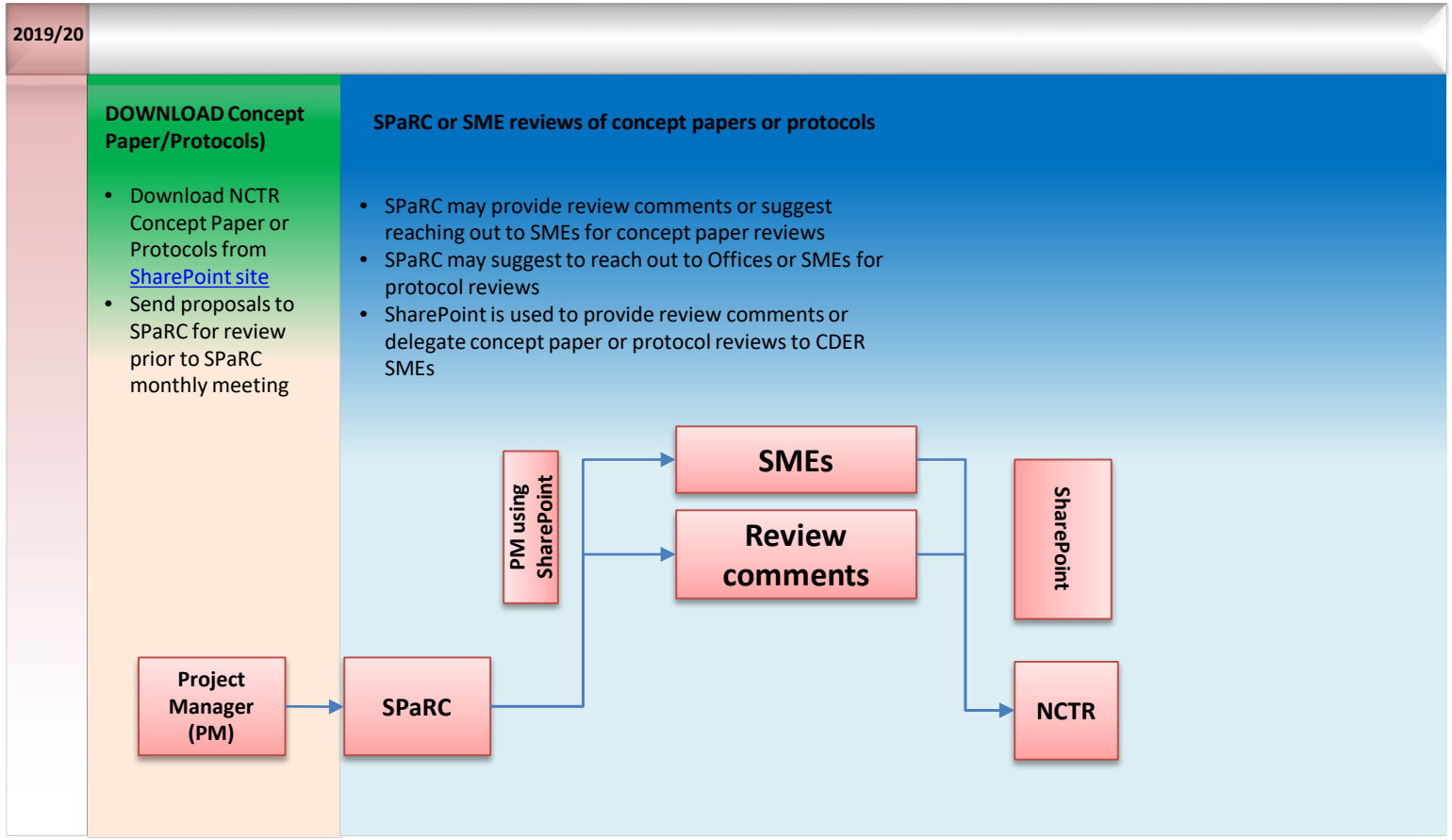


POC: Sandra Matson (NCTR)
SharePoint support: Kieu Pham (CDER/OTS)

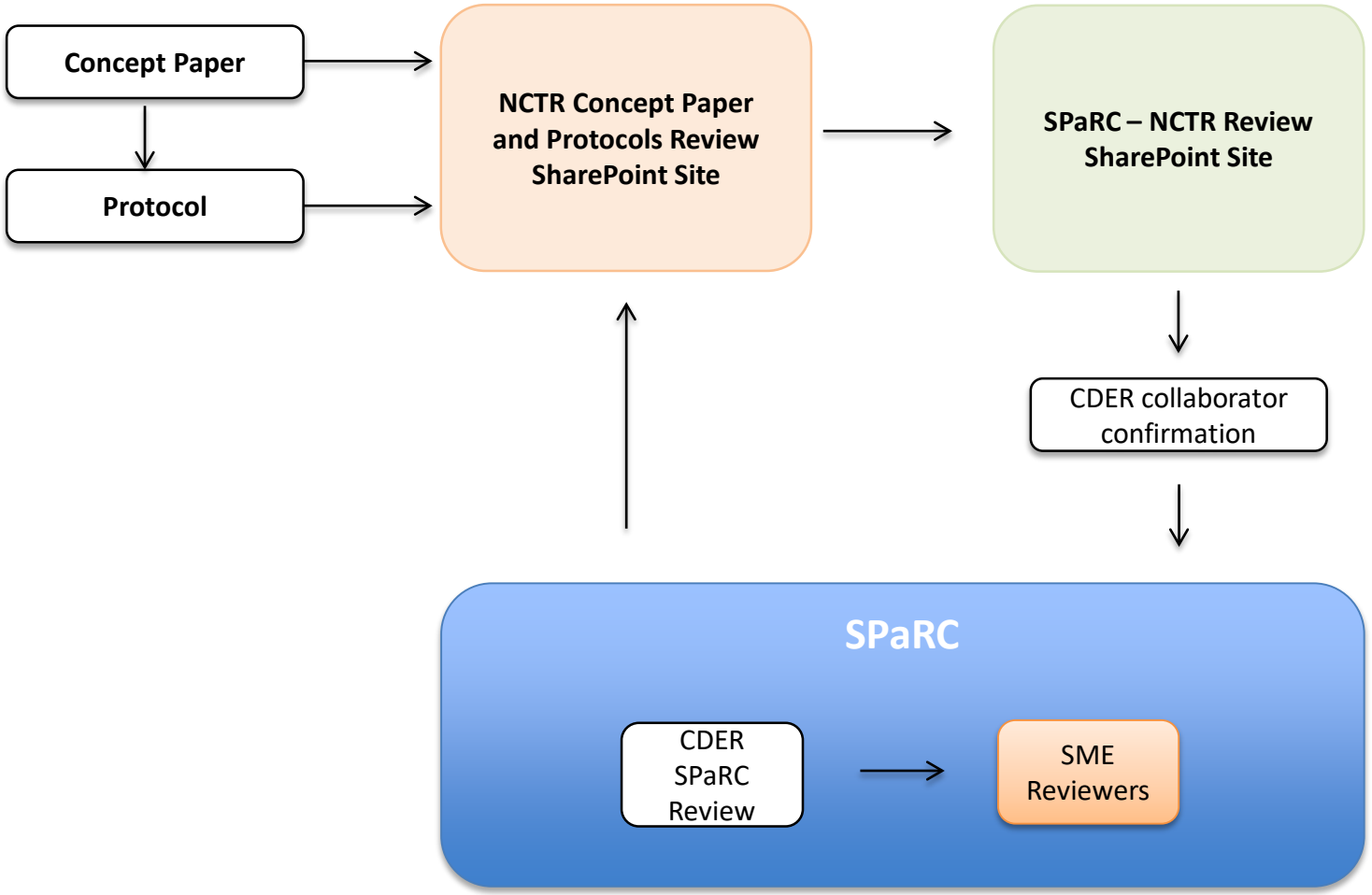
NCTR/CDER Intercenter Projects



NCTR Concept Paper and Protocol Reviews



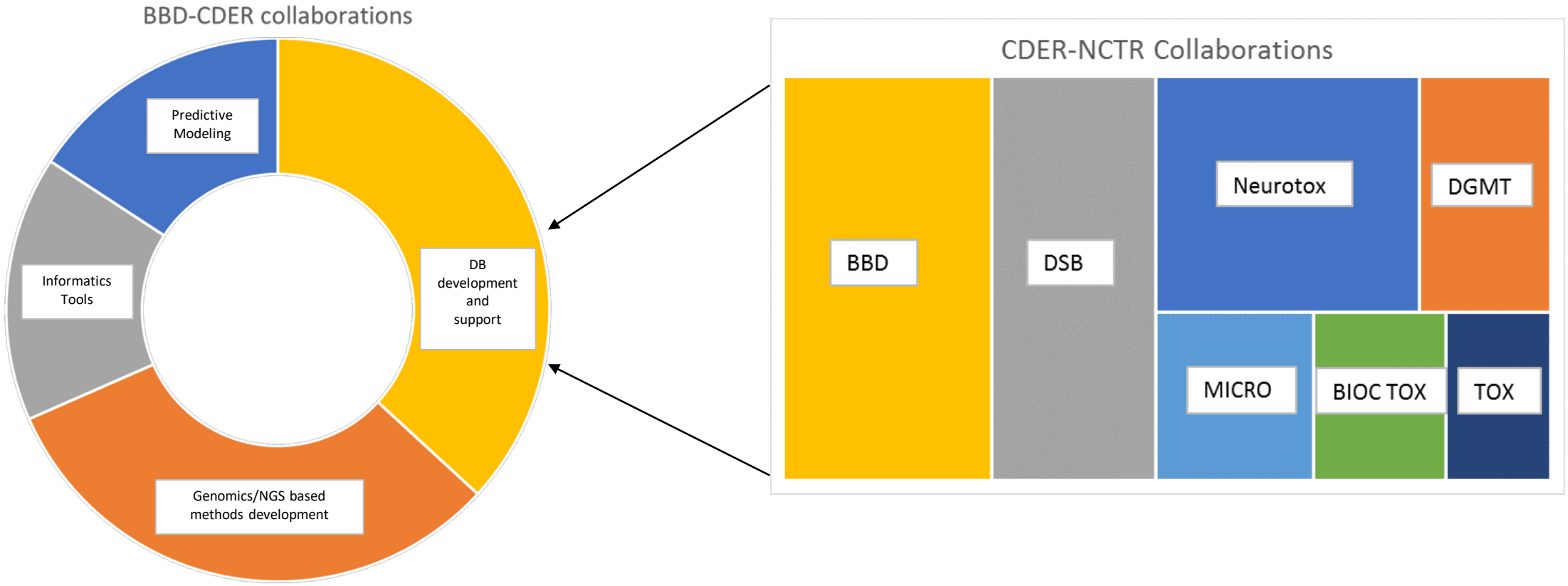
NCTR Concept Paper And Protocol Review



Impact of NCTR/CDER Collaborations on Review Tools and Projects

- Informatics:
  - FDALabel 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-NCTR Collaborations 2018 - A snapshot



NCTR/CDER Expertise Exchange

- Development and evaluation of predictive models for the management of risk of drug-induced liver injury (DILI) in the Investigational New Drug (IND) phase (BBD)
- Development of an integrated network of physiologically based pharmacokinetic (PBPK) models in rhesus monkeys and humans across life-stages for predicting drug dosimetry in pregnant women for the anti-influenza drug oseltamivir (BIOCHEM TOX)
- Validating the rat Pig-a assay for regulatory use: Determining the molecular basis of mutants detected in the rat Pig-a gene mutation assay (DGMT)
- Systems biology approach to discover biomarkers in biofluids for drug induced liver injury to determine individual susceptibility, severity, adaptation and regeneration: using acetaminophen as a proof-of-concept (DSB)
- Nonclinical modeling and risk assessment of FDA-regulated drug-nanocrystals(MICRO)
- Assessment of Gaseous Anesthetics in the Developing Nonhuman Primate (NEURO TOX)

Looking Ahead

- CDER-SPaRC would benefit greatly from NCTR participation in scientific review and prioritization
- Afford an opportunity for NCTR to offer an alternative perspective as part of the gap analysis for regulatory science research needs
- Afford NCTR a platform to showcase their research models, methods and tools to the CDER Scientific community on a regular basis
- Afford a greater exposure to NCTR PIs to CDER researchers with similar research interests
- Greater collaboration with harmonization of multiple platforms

QUESTIONS, FEEDBACK & SUGGESTIONS


FDA
U.S. FOOD & DRUG
ADMINISTRATION