

# Overview of OND Research

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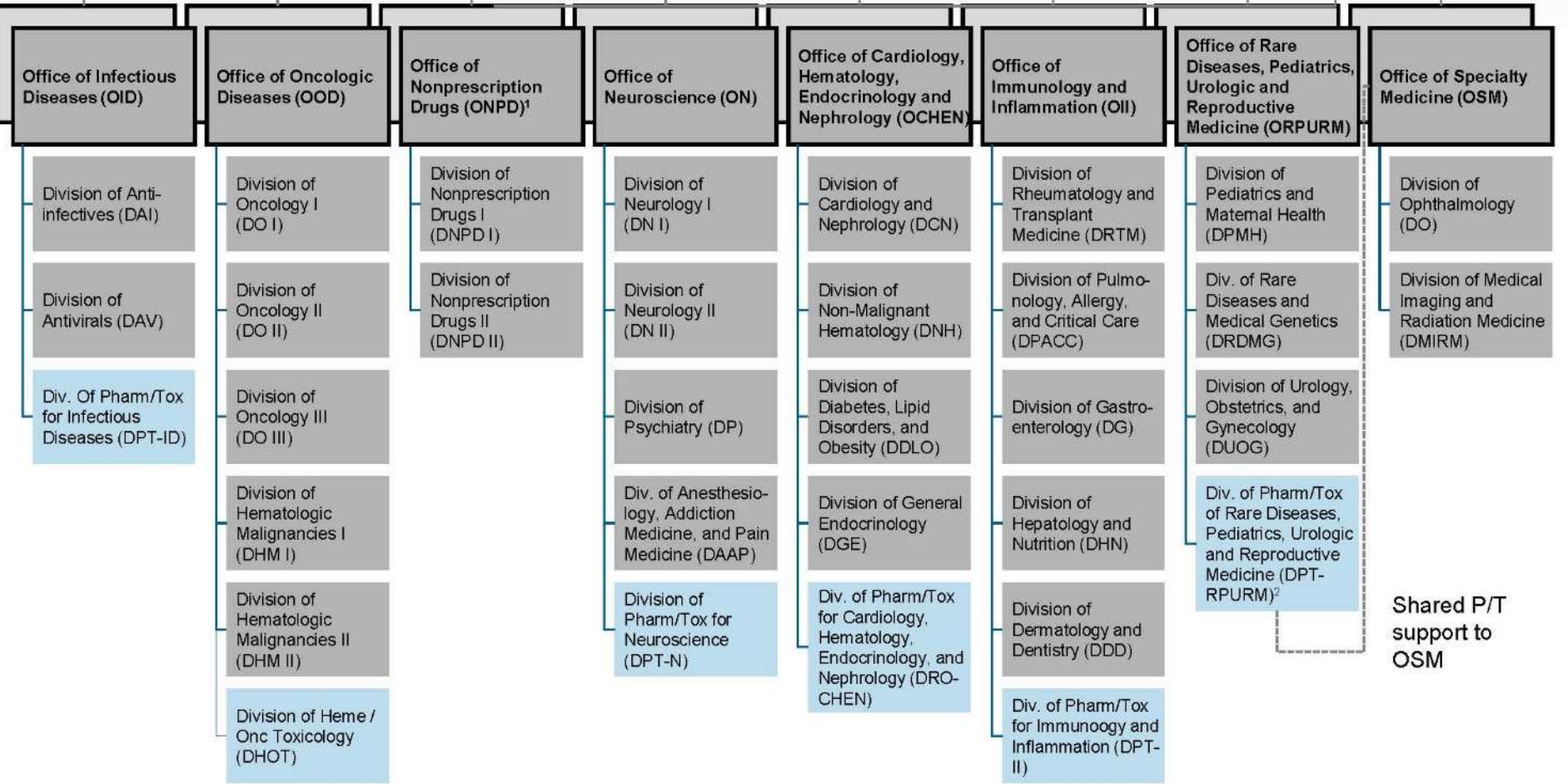
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(DBIRBD)  
CDER | US FDA

OND Research: Seeking Collaborators, Funding Opportunities Available! – November 6, 2020

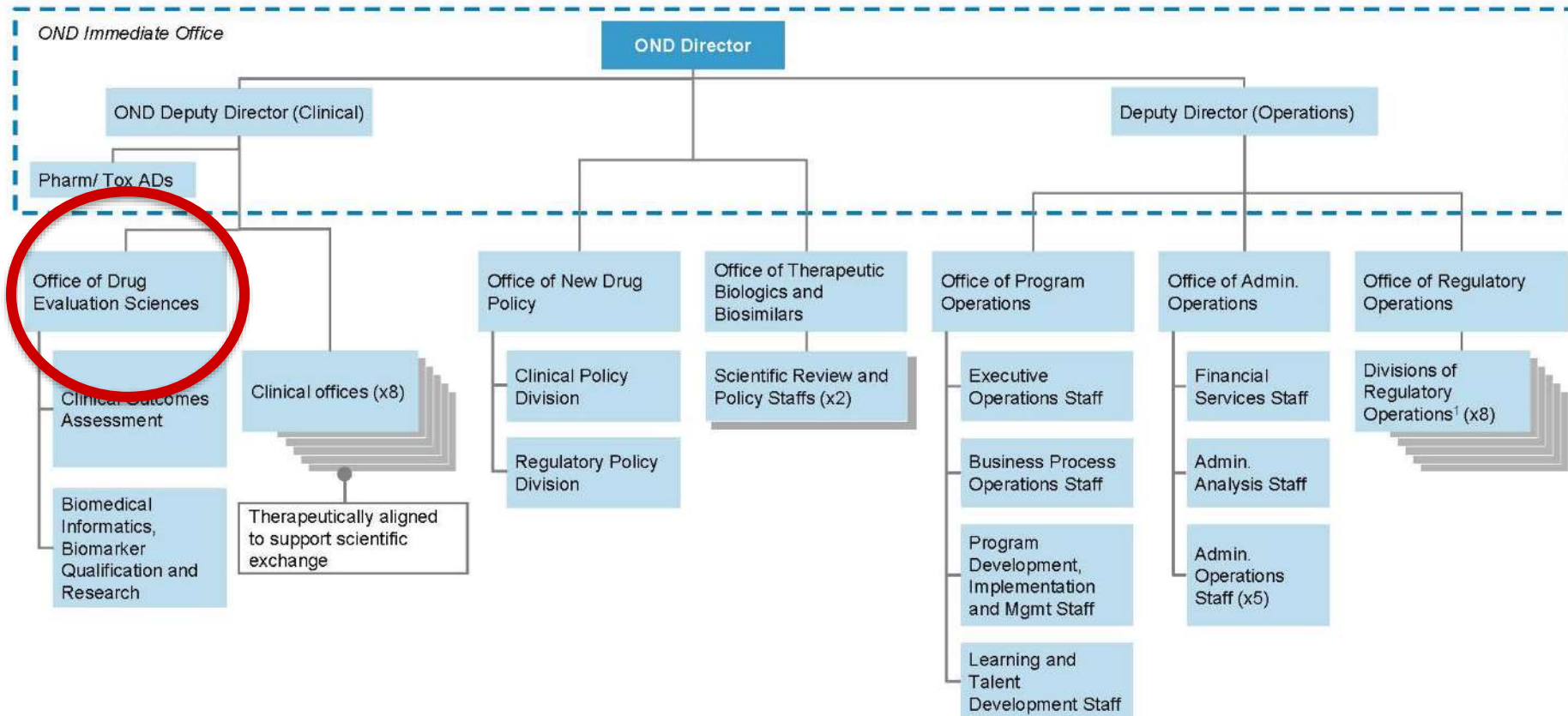
# Office of New Drugs (OND) Review Divisions

Office of Regulatory  
Operation: Divisions of  
Regulatory Operations



Shared P/T  
support to  
OSM

# OND Support Offices





# What is the OND Research Program (OND-RP)?

**Launched in October 2018**

## **Mission:**

Provide education, support, infrastructure, and oversight to foster RSR in OND.

## **Vision:**

Transform OND into a leading hub for collaborative regulatory science research (RSR).



# What is Regulatory Science Research (RSR)?

*The type of research conducted at FDA is called RSR*

## RSR Basics

- Unique to the Agency
- Targeted - addresses specific knowledge gaps
- Time and resource limited
- Outcomes - high regulatory applicability

## For OND:

Used to develop tools or approaches to assess new drug safety and efficacy

# Overview of OND RSR Topics

**Data mining applications (INDs & NDAs) and real world evidence (electronic health records, registries) to:**

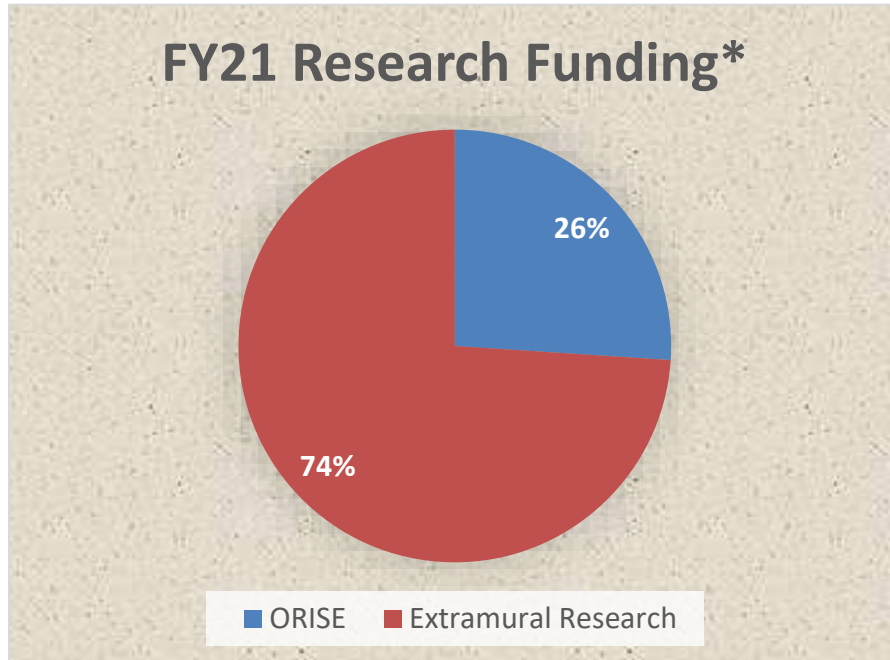
1. Make data-driven decisions about drug evaluation policies

# Overview of OND RSR Topics

**Data mining applications (INDs & NDAs) and real world evidence (electronic health records, registries) to:**

2. Create tools to streamline evaluation of drug safety and efficacy

# How Does OND Use RSR Funding?



**Total Commitment: \$9.6 million**

ORISE: \$2.5 million

Extramural Research: \$7.1 million

*\*Does not include 21<sup>st</sup> Century Cures DDT Grants Program*



# OND Has Research Fellowships Available!



## ORISE Program

- Around 40 fellows
- College students currently enrolled
- Recent graduates (5 years or less)

# OND Has Collaborative RSR Opportunities Available!



## Extramural Research

- Combatting Antibiotic Resistant Bacteria (CARB) Program
- 21<sup>st</sup> Century Cures Drug Development Tools Grant Program

# Resources

- [OND Home Page](#)
- [CDER Regulatory Science in Action](#)
- [CDER Science and Research](#)
- [Scientific Internships and Fellowships at FDA](#)



*OND is actively growing our RSR portfolio... Join us on our path to success!*

