



# **COMMUNICATION BEST PRACTICES – Interacting with Regulatory Project Managers in the Office of Regulatory Operations**

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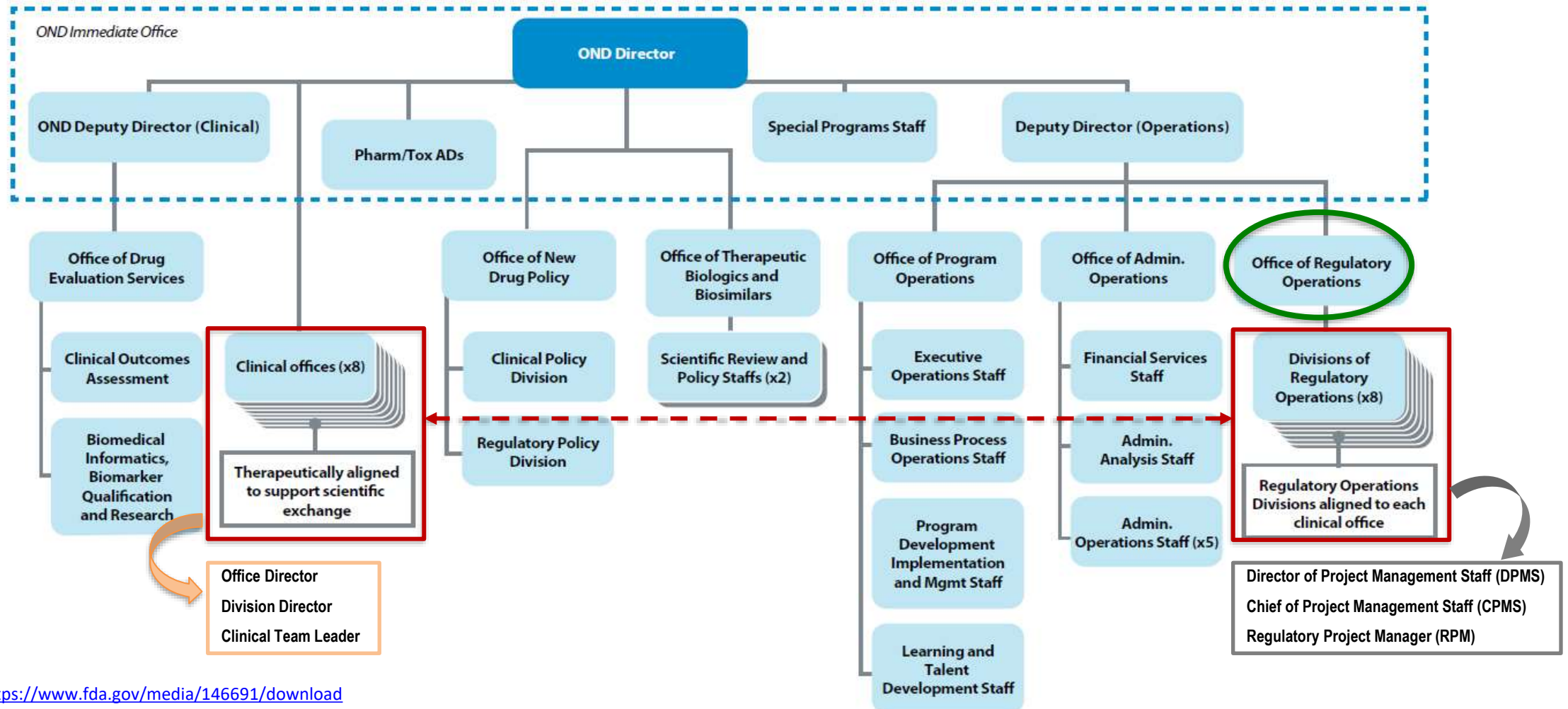
# What can you expect?

- To increase familiarity with the Office of Regulatory Operations (ORO) in the Office of New Drugs (OND)
- To reinforce that the ORO Regulatory Project Manager (RPM) is the primary point of contact for applications managed by the OND
- To learn a few strategies that may improve interactions with ORO RPMs

# Meet ORO

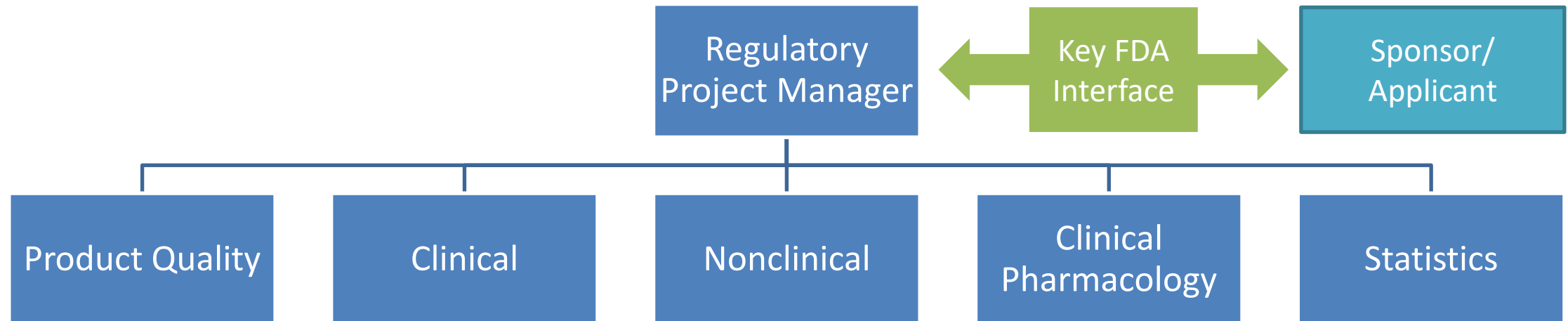


## High-Level OND Organizational Chart



# Who should I contact in OND?

- **ORO RPM is the primary point of contact for investigational, new drug, and biologics applications (INDs, NDAs, BLAs) managed by OND.**



# Who should I contact in ORO?



- ORO RPMs, CPMSs, and DPMSs are aligned with OND clinical divisions and offices
  1. Contact the CPMS or DPMS – for name of assigned ORO RPM and jurisdiction confirmation
    - [OND Office and Division Contact Information](https://www.fda.gov/media/78312/download)  
(<https://www.fda.gov/media/78312/download>)
  2. To identify the OND clinical review division that would manage your application
    - Use OND clinical offices' web pages to research  
<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs>

# What information is important to include?

- FIRST and LAST NAME from COMPANY
  - If you are working on behalf of a different company
- Application type and number AND submission date
- Reason for contacting the RPM
  - New issue/query or follow up
- Is response time sensitive (or not)?
- Preferred method of response

# What can I do to improve communications with the ORO RPM?



- Develop a good working relationship
- Cover letters
  - Prominently state “Feedback Request” and “response requested by” if requesting feedback
  - Include your and an alternate contact information (phone #, secure email)
- Provide and update planned submission dates
- Ensure availability after sending submissions with short goal dates
- Inform RPM when others contact FDA leaders directly



# What communication resources would you recommend?



- [Best Practices for Communication Between IND Sponsors and FDA Drug Development](#)
- [Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry](#)
- [Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry](#)
- [Good Review Practice: Good Review Management Principles and Practices for Effective IND Development and Review](#)



# Challenge Questions

1. The Office of Regulatory Operations is a newly formed office within the Office of New Drugs.
  - a. True
  - b. False

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  - a. True
  - b. False

# Challenge Questions

2. If I have a question about the review status of my IND, I should contact the \_\_\_\_\_.
- a. Director of the clinical division reviewing my IND
  - b. FDA Commissioner
  - c. Regulatory Project Manager assigned to my application
  - d. CDER's Division of Information Disclosure Staff

# Challenge Questions

3. All of the below items except \_\_\_\_\_ are helpful pieces of information to provide the Regulatory Project Manager during communications.
- a. Application type and number
  - b. My first and last name and name of company I represent
  - c. My phone number and secure email address
  - d. Reason for inquiry
  - e. A description of my company's organizational structure

# Thank you!

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