

Beyond Guidance

Formal Meetings and Requests for Information

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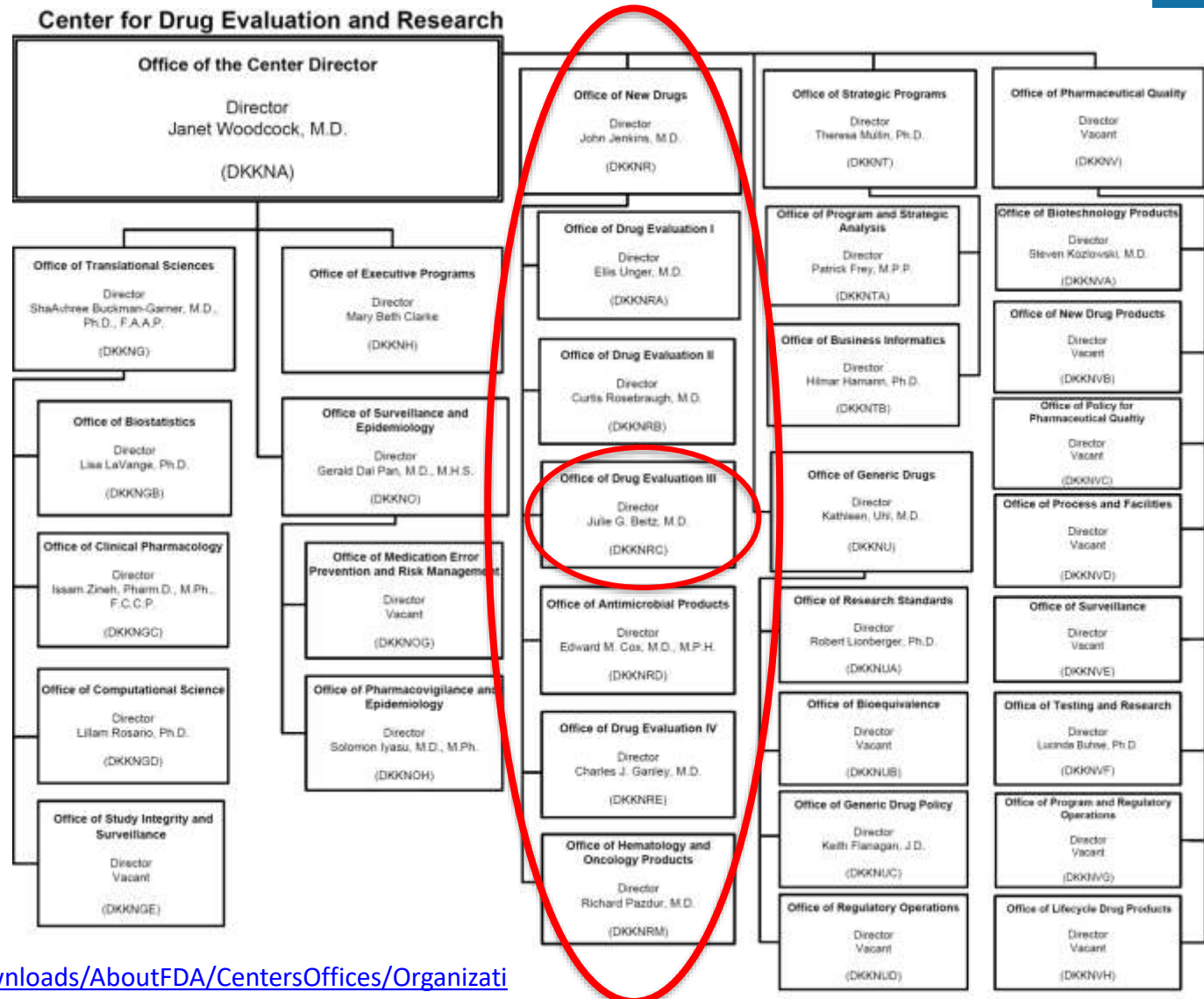
Agenda

- Overview of CDER
- Review Team Dynamics
- *Formal* Meetings with CDER and Tips for success
- CDER Requests for Information and Tips for responding

Quick Overview of CDER

- Structures
 - Organizational Structure
 - Review Division Structure
 - Regulatory Structure
 - Review Team Structure

Organizational Structure



Structures: OND Review Divisions

Signatory

- Division Director
- Deputy Director
- Deputy Director for Safety
- Associate Director

Medical Teams

- Medical Team Leader
- Medical Reviewer

Nonclinical Teams

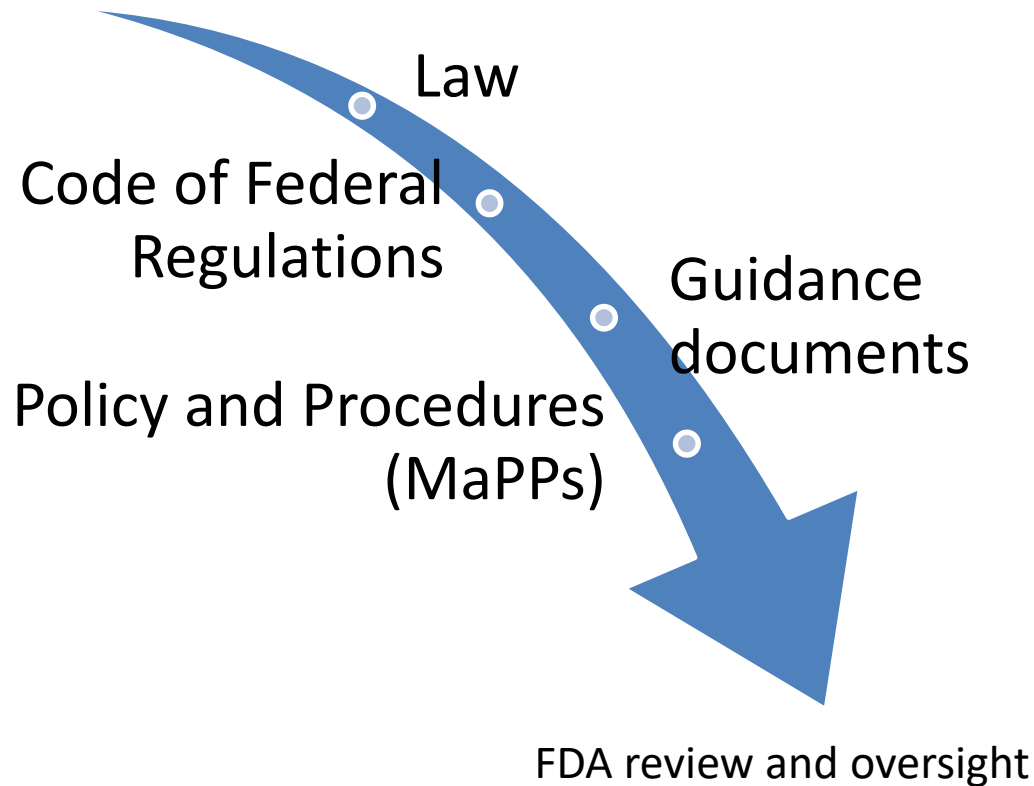
- Nonclinical Team Leader
- Nonclinical Reviewer

Project Mgmt

- Chief, Project Management Staff
- Regulatory Project Managers

Structure: Regulatory

Public Health need



Structures: Review Teams



Regulatory Project Manager (RPM) = BSN, MSN, PhD, PharmD, RPh, MS, MPH, BS



Medical Team Leader (TL)= MD, PhD, MPH

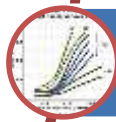
- “Cross Discipline Team Leader”



Clinical Reviewer = MD, PhD, MPH, PharmD



Nonclinical Reviewer = PhD



Clinical Pharmacology Reviewer = PhD, PharmD

- Pharmacometrics, Pharmacogenomics



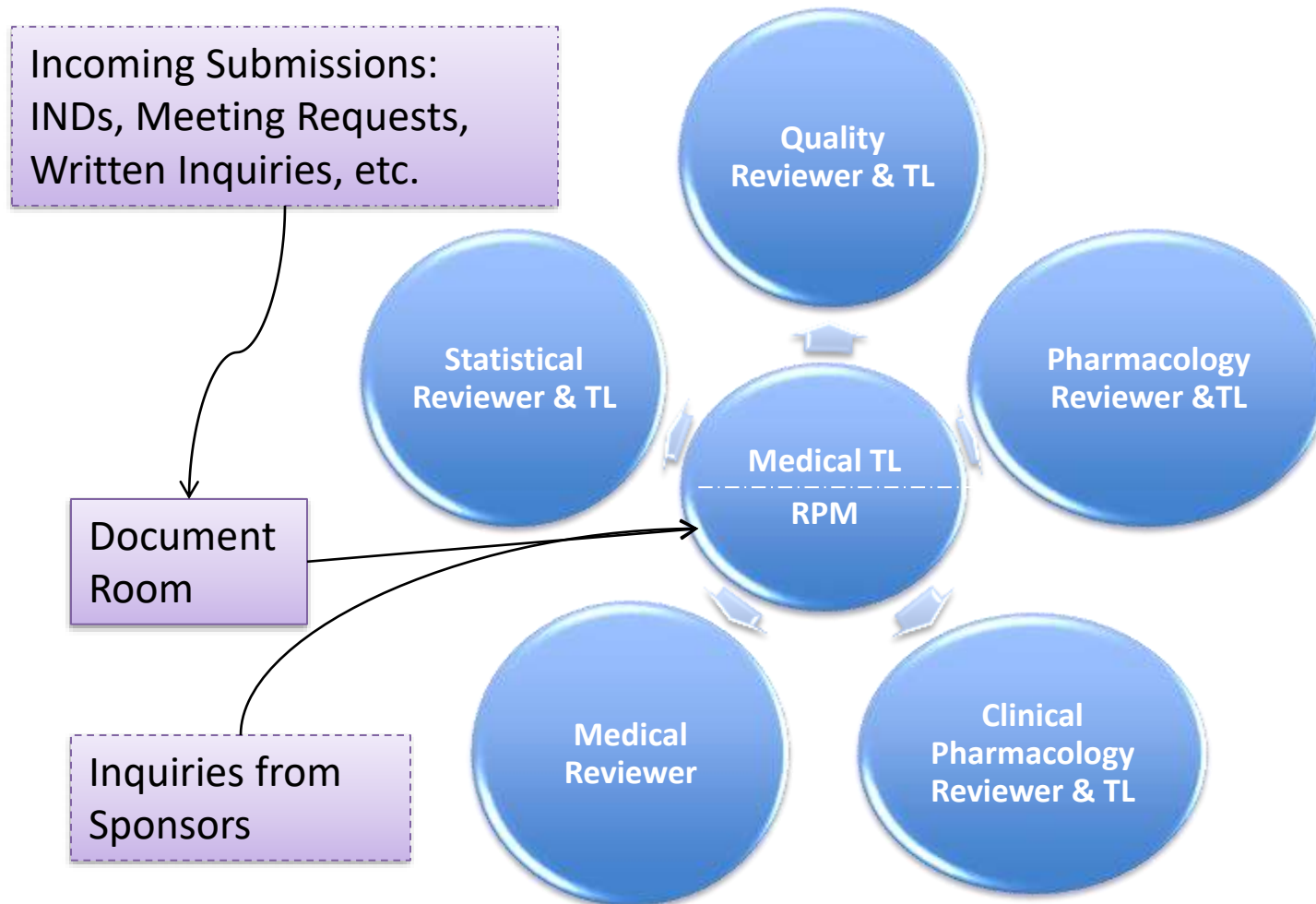
Biostatistics Reviewer = PhD



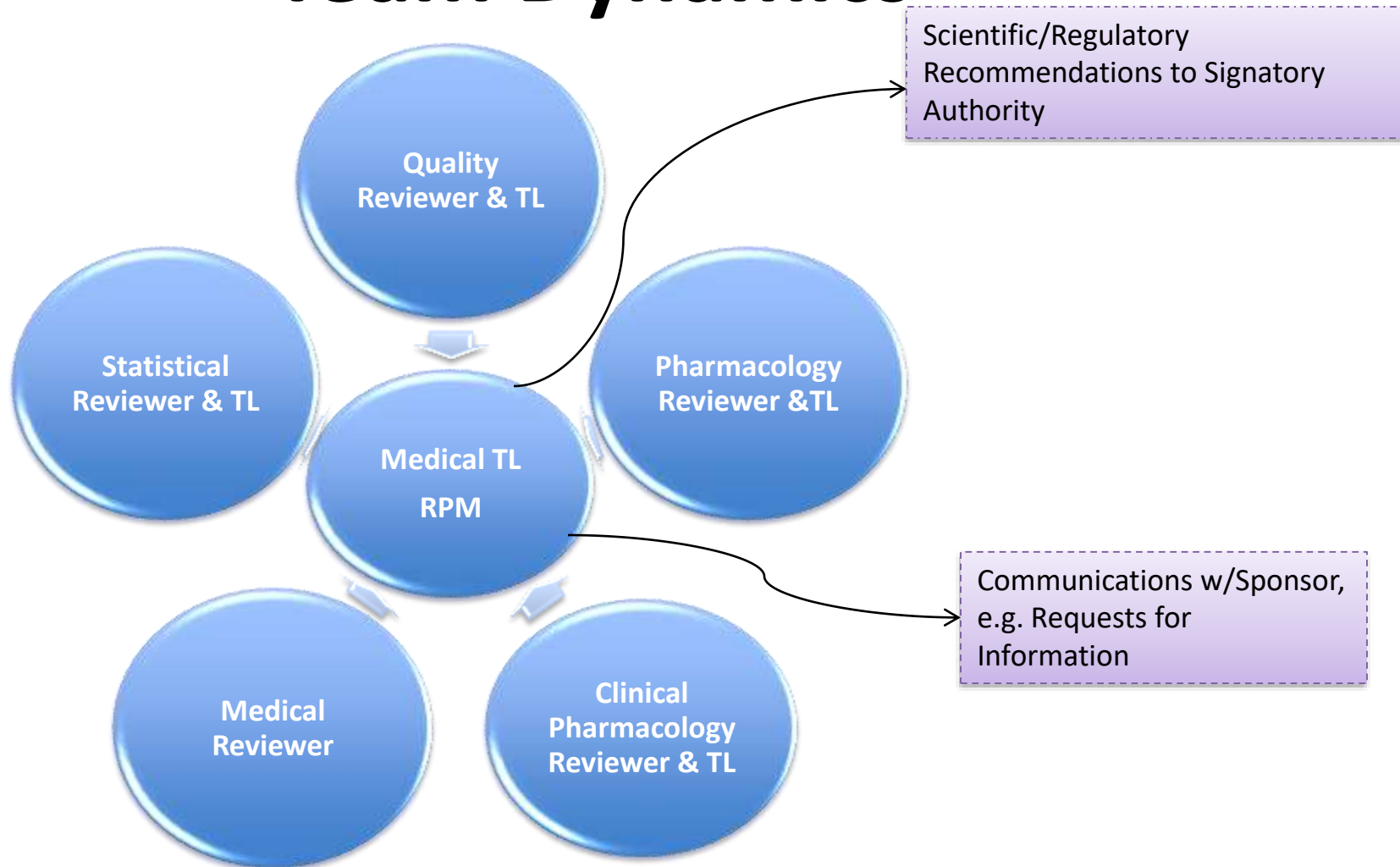
Quality Reviewer = MS, PhD

- Drug Substance, Drug Product, Micro, Immunogenicity, Others

Team Dynamics



Team Dynamics





Division Contacts

Office of Drug Evaluation I (ODE I)

Division of Neurology Products (DNP)	301-796-2250
Division of Psychiatry Products (DPP)	301-796-2260
Division of Cardiovascular and Renal Products (DCRP)	301-796-2240

Office of Drug Evaluation II (ODE II)

Division of Metabolic and Endocrine Products (DMEP)	301-796-2290
Division of Pulmonary, Allergy and Rheumatology Products (DPARP)	301-796-2300
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)	301-796-2280

Office of Drug Evaluation III (ODE III)

Division of Gastroenterology and Inborn Errors Products (DGIEP)	301-796-2120
Division of Bone, Urologic, and Reproductive Products (DBRUP)	301-796-2130
Division of Dermatology and Dental Products (DDDP)	301-796-2110



Division Contacts

Office of Drug Evaluation IV (ODE IV)

Division of Nonprescription Drug Products (DNDP)	301-796-2080
Division of Medical Imaging Products (DMIP)	301-796-2050
Division of Pediatric and Maternal Health (DPMH)	301-796-2141

Office of Antimicrobial Products (OAP)

Division of Anti-Infective Products (DAIP)	301-796-1400
Division of Anti-Viral Products (DAVP)	301-796-1500
Division of Transplant and Ophthalmology Products (DTOP)	301-796-1600

Division Contacts

Office of Hematology Oncology Products (OHOP)

Division of Oncology Products I (DOP1) 301-796-2330
Breast, Gynecologic, Genitourinary, Supportive care (non-hematologic)

Division of Oncology Products II (DOP2) 301-796-2320
*Gastrointestinal, Lung/Head & Neck, Neuro-oncology/Rare cancers/
Pediatric Solid Tumor, Melanoma/Sarcoma*

Division of Hematology Products (DHP) 301-796-7550
*Benign hematology, Hematologic malignancies, Hematology support,
Pediatric Hematology*

Division of Hematology Oncology Toxicology (DHOT) 301-796-2340
Nonclinical Review Division for Hematology/Oncology Products



Locations

Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

OND Review Divisions – Building 22



Locations – *for submissions*

Food and Drug Administration

Center for Drug Evaluation and Research

Central Document Room

(Therapeutic Biologics Document Room)

5901-B Ammendale Road

Beltsville, MD 20705-1266

What are Formal Meetings?

Any meeting requested by a sponsor or applicant following the [Guidance for Industry – Formal Meetings Between the FDA and Sponsor or Applicants of PDUFA Products.](#)

Relate to the development and review of drug or biological products regulated by the CDER or CBER

Types of Meetings

Type	A	B	C
Meeting Response: Grant/Deny	14 days	21 days	21 days
Held no later than	30 days	60 days	75 days
Briefing package	With meeting request	1 month	1 month
Description, Comments	Dispute resolution, Clinical holds, Special Protocol Assessment (SPA), Post action meeting (3 months post-action)	preIND [¥] , EOP1, EOP2, Pre NDA/BLA, REMS* or PMRs**	Any other than type A or B Can be granted as written response only (WRO)

*Risk Evaluation and Mitigation Strategy

** Post Marketing Requirements

[¥] can be granted as WRO

How to Request a Meeting

- Written correspondence to the application (e.g. IND, NDA, BLA)
- If no application, the request should be submitted to the CDER Division Director with copy to the Division's Chief, Project Management Staff (CPMS)
 - Consult CDER Org Chart for which Division to send the Meeting Request to
 - As indicated in the Guidance for Industry, it is recommended to contact the Division informally before submitting any request
 - Refer to Guidance regarding recommendations for content and organization of the Meeting Request
- **List of Questions is essential and critical!**

Meeting Briefing Package

- In order to facilitate a productive discussion or exchange of information a meeting package should be provided:
 - At the time of submission of a Type A Meeting Request
 - At least 4 weeks before the formal meeting for a Type B or C Meeting Request
- Should contain summary information and any supplementary information needed to develop responses to the questions raised
- Questions should be clear and not dramatically changed from the initial request

Tips for Select Meeting Briefing Documents

EoP2 Meeting

- Summaries of Phase 1 and Phase 2 investigations
- Summary information on plans for Phase 3 trials
- Specific draft protocols or select details for Phase 3 trials
 - Choice of comparator
 - Definition and time point for assessment of primary endpoint
 - Statistical analysis approach and criterion for success and failures of the primary efficacy and secondary endpoints
 - Size of the safety database
- Plans for Pediatric Studies to address PREA
- Plans for REMS
- Plans for additional non-clinical studies (if required)

Tips for Select Meeting Briefing Documents

Pre-submission Meeting (Pre-NDA/BLA)

- Summary of the data from completed pivotal trials
- Proposed Indication
- Manufacturing information on the products used in the studies and product intended for distribution, if different
- Discussion on Requests for Priority Review, Information on Fast Track, Breakthrough, or Orphan designation, if applicable
- Pediatric Study Plan Review
- Proposed format and content of the submission
- Timeline for submission



Tips for Select Meeting Briefing Documents

Pre-submission Meeting (Pre-NDA/BLA)

- PDUFA V Program (NME and BLA) –
 - Include a proposal for the content of a complete application
 - Any minor components to be submitted within 30 days

Conduct of the Meeting

- THIS IS YOUR MEETING
- Take the lead
 - Make sure that your questions have been addressed
 - Summarize key discussion points, agreements, and action items

Meetings Best Practices

- Face to face meetings are not the only way to obtain feedback and advice
- Schedule meetings to discuss specific issues
- Do not schedule meeting to obtain pre-review of data
- “What ifs” or hypothetical situations are difficult to address
- The Agency will provide guidance/comments on your proposals
- Utilize guidance documents to the fullest

Meetings Best Practices

- Communicate clearly with the RPM
- Work with RPM to determine mutually agreed upon time/day for the meeting
- Update RPM on changes in attendees
- Discuss with RPM how many copies of the briefing package are needed
- Organize the briefing package with tabs
- Submit focused questions
 - Do not add new topics or questions to original agenda
 - Avoid open ended questions
- Electronic submission vs. paper



FDA's Review and Requests for Information

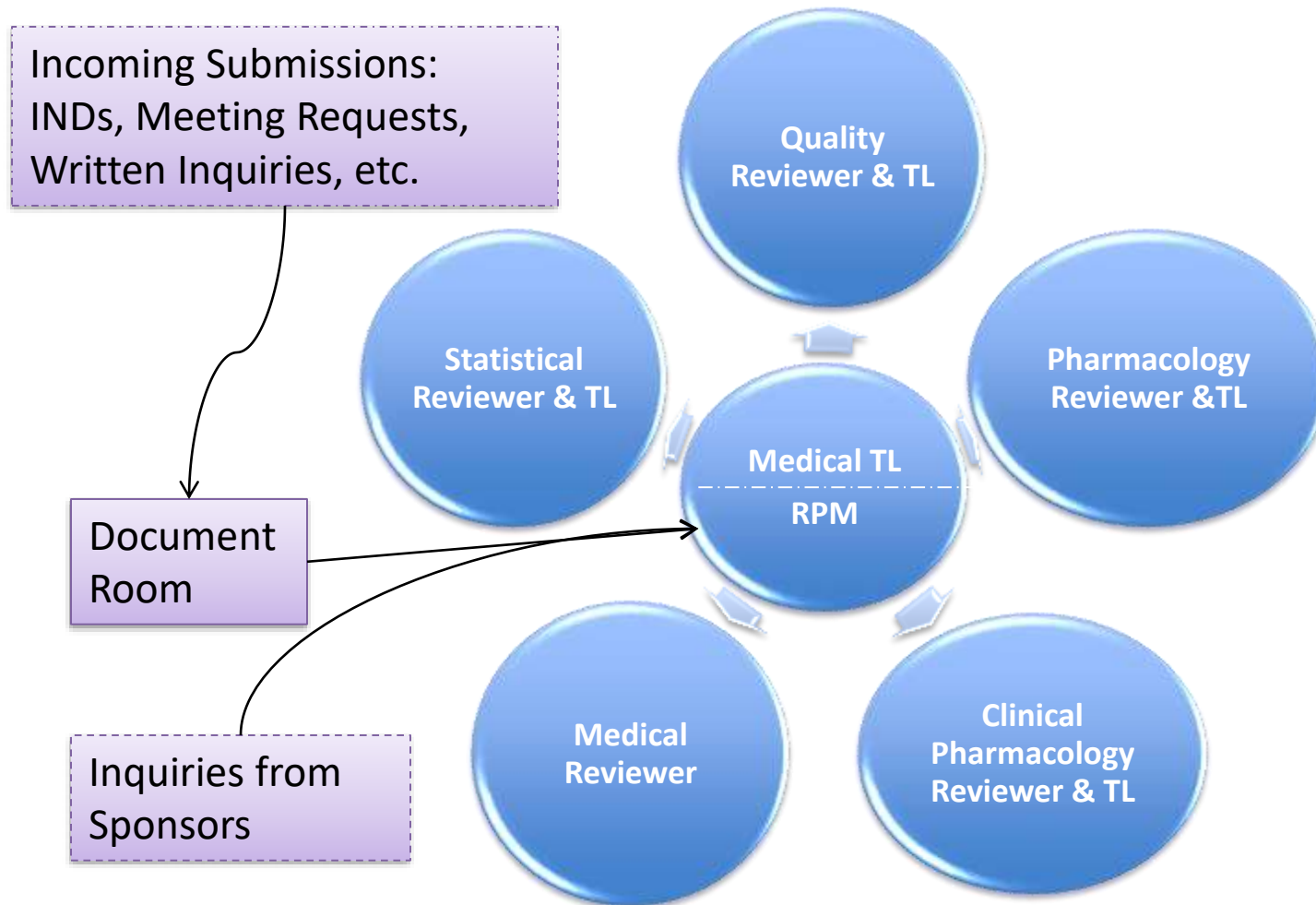
- What happens once a submission is in the hands of the RPM?
- How does CDER manage applications and submissions?
- Requests for Additional Information and Tips for Responding

FDA's Good Review Management Practices



- Good Review Management Practices – “GRuMPy” Guidance,
- Good Review Practice MAPPs for Effective IND Development and Review,
- CDER's 21st Century Desk Reference Guide,
- Best Practices for Communication Guidance,
- and more.

Team Dynamics



Information Requests

- Investigational New Drug applications:
 - See MAPP 6030.9 for review policy and procedures
 - Requests for Information can be prompted or unprompted
- For pre-decisional applications:
 - See 21st Century Desk Reference Guide
 - Information requests are encouraged throughout the review process and not bundled or sent at specific time points
- RPM is your point of contact for information requests

Tips for Responding to Information Requests



- Acknowledge Receipt
- Make sure you fully understand the review team's information request
 - This means, ask for clarification if needed before responding to avoid re-work or failing to adequately address all requests
- Understand the review team's timeline for the request(s)
 - If a timeline is not provided, propose one or inquire for one
 - Respond promptly
- When responding utilize cross-referencing
 - Reference specific requests contained in an overall information request
 - Group responses by discipline
 - Utilize hyperlinks to facilitate review



Resources

- www.fda.gov
- www.fda.gov/drugs
- www.fda.gov/BiologicsBloodVaccines
- www.fda.gov/cder/guidance
- <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm>
- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM218757.pdf>
- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM349907.pdf>
- <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079748.pdf>
- <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm475586.pdf>

Questions?



Please complete the session survey:

surveymonkey.com/r/DRG-D1S7

Closing Thoughts...



Thank You!