Remote Regulatory Assessment (RRR)

Office of Study Integrity and Surveillance (OSIS)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

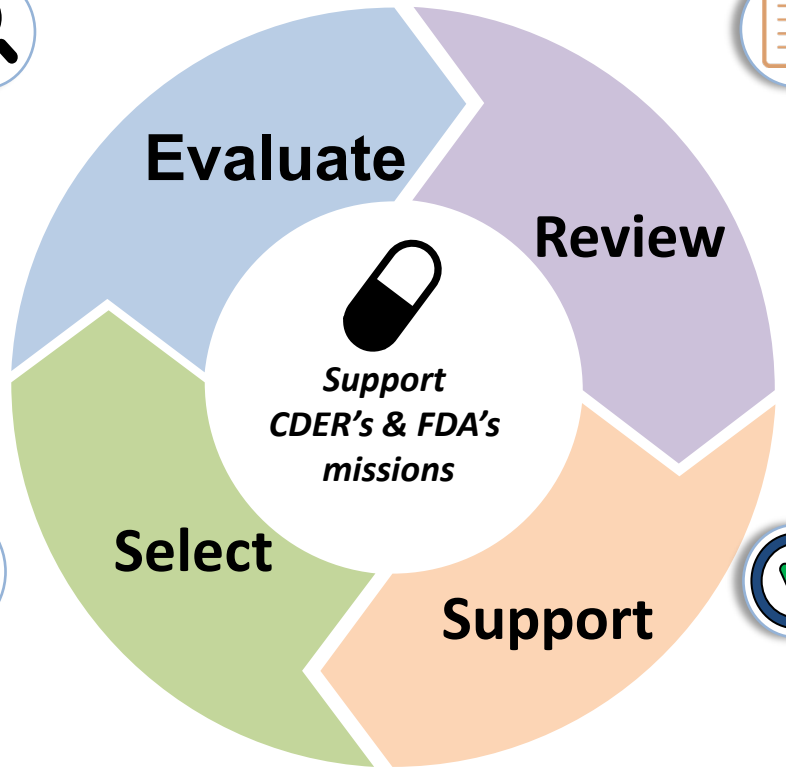
Identification

- You may verify the identification of the FDA attendees using the HHS Employee Directory/Program Support Center (PSC) link below:

http://directory.psc.gov/employee.htm

Office of Study Integrity and Surveillance (OSIS)

Evaluate sites using inspections/RRAs to ensure the integrity of study data



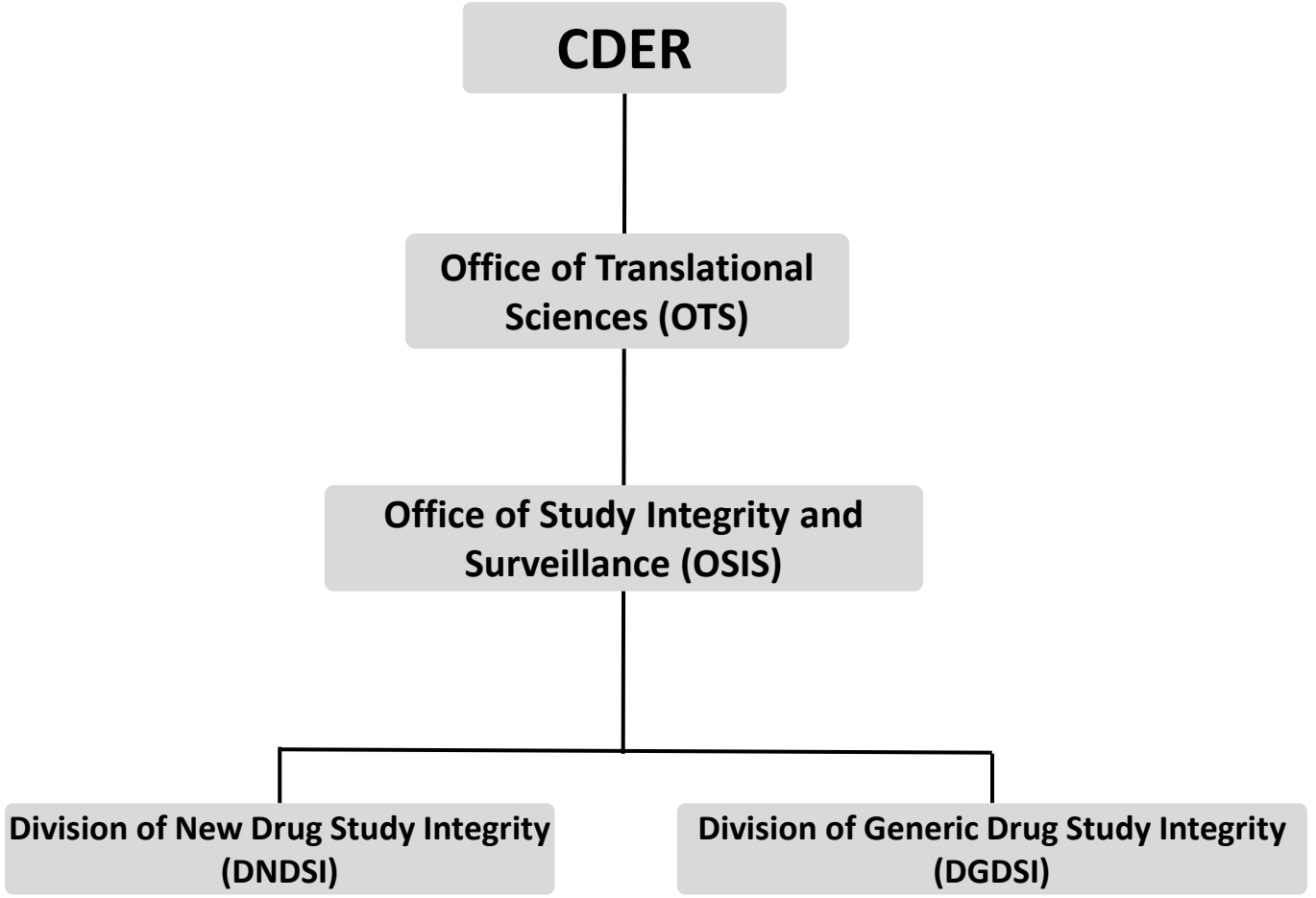
Review the evidence in Establishment Inspection Reports/RRA Reports and generate OSIS Reviews

Select sites for inspections/RRAs through risk-based surveillance evaluation

Support CDER review divisions by providing data reliability recommendations and compliance evaluations

https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-study-integrity-and-surveillance

Organization Chart



Remote Regulatory Assessment (RRA)

- We are conducting this RRA because data from one or more studies conducted at your site were submitted to the FDA
- RRAs are not inspections, but they support FDA's review of marketing applications. However, the format of an RRA is comparable to the format of an inspection.
- An RRA usually lasts one week, but could be shorter or longer depending on staff availability, data complexity and/or findings

What to Expect during an RRA

- We have reviewed the records you provided via the FDA Cloud File Sharing system (box.com), and will meet with site staff over the next few days
- We will review various aspects of the studies and your facility, through the following activities:
  - Viewing source records and documentation
  - Touring specific areas of the facility
  - Visualizing electronic systems
  - Interviewing relevant staff
- Any findings will be discussed during interactions and close-out meetings

What to Expect during an RRA …continued

- Recording of the opening meeting or any subsequent meeting is not allowed.
- Form FDA 483 will not be issued, but any RRA Observations will be shared in writing and discussed at the close-out meeting.
- An establishment inspection report (EIR) will not be issued, but you will receive a copy of the RRA Report after the conclusion of the RRA.
- If you don't receive the RRA report within 6 months, please email us at the following: CDER-OSIS-BEQ@fda.hhs.gov OR CDER-OSIS-GLP@fda.hhs.gov.

Feedback

- Your feedback is important to us
- We appreciate any constructive comments you can provide to help us improve the RRA process. Please send comments to the following: CDER-OSIS-BEQ@fda.hhs.gov or CDER-OSIS-GLP@fda.hhs.gov.

Any Questions?