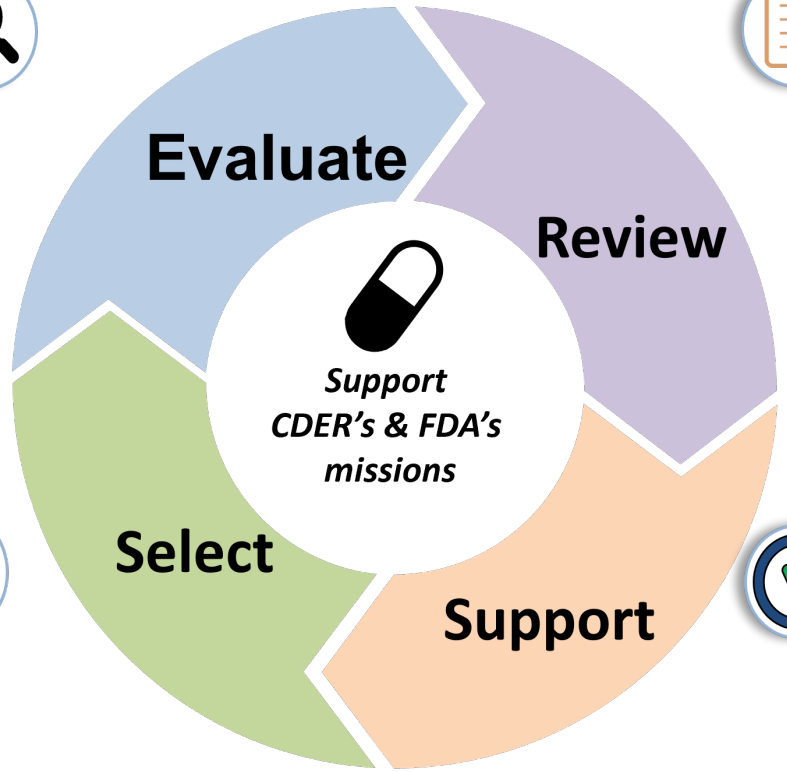
Remote Regulatory Assessment

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

Office of Study Integrity and Surveillance (OSIS)

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



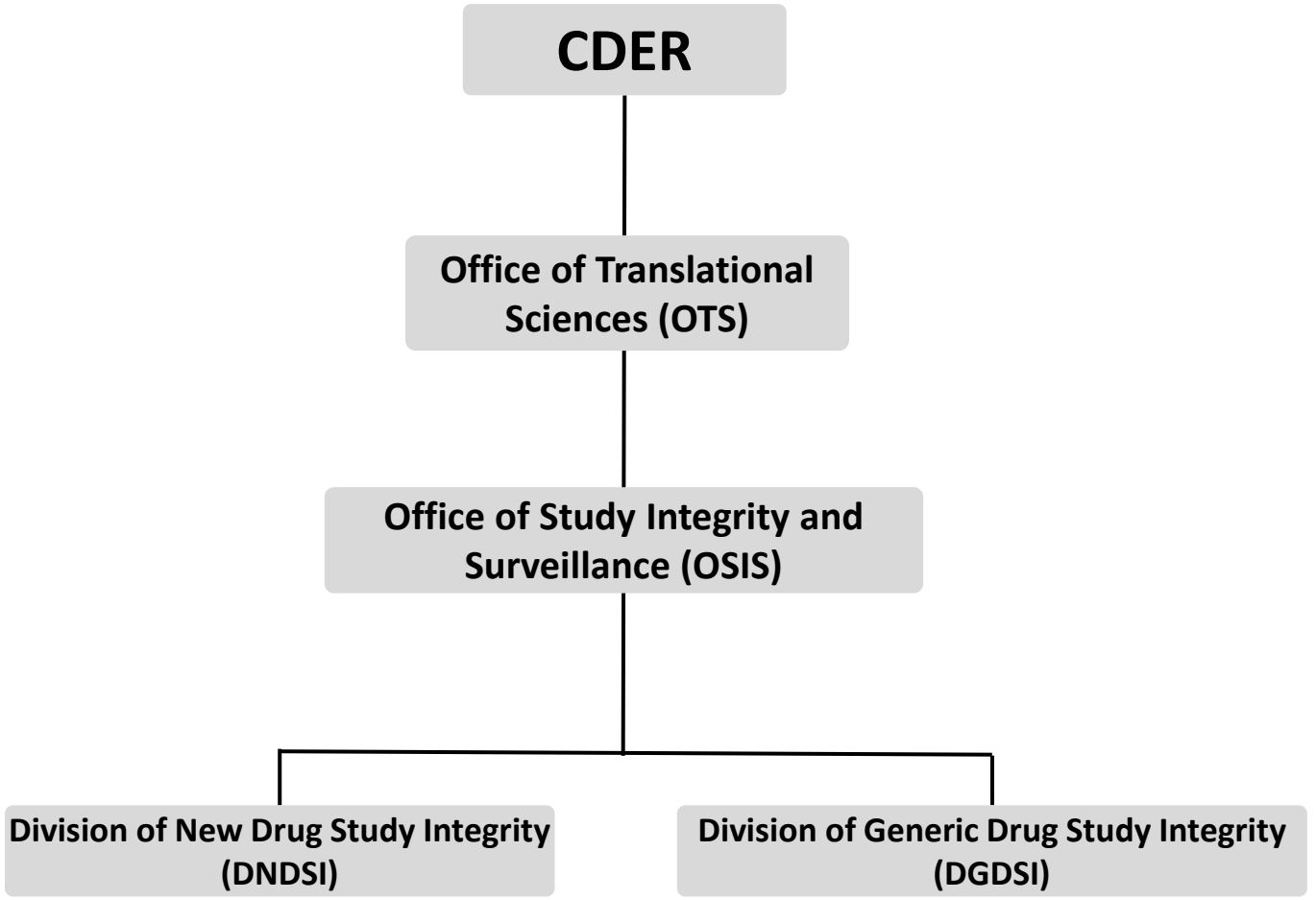
Review the evidence in Establishment Inspection Reports/RRA Reports and generate OSIS Reviews

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 (1)

- 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 (2)

- 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?