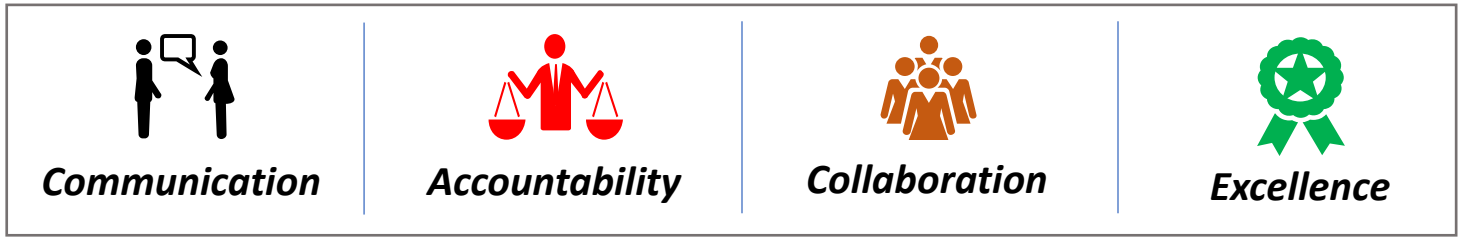
U.S. FOOD & DRUG ADMINISTRATION

Office of Study Integrity and Surveillance (OSIS)



Office of Translational Sciences
Center for Drug Evaluation and Research
U.S. Food and Drug Administration(FDA)

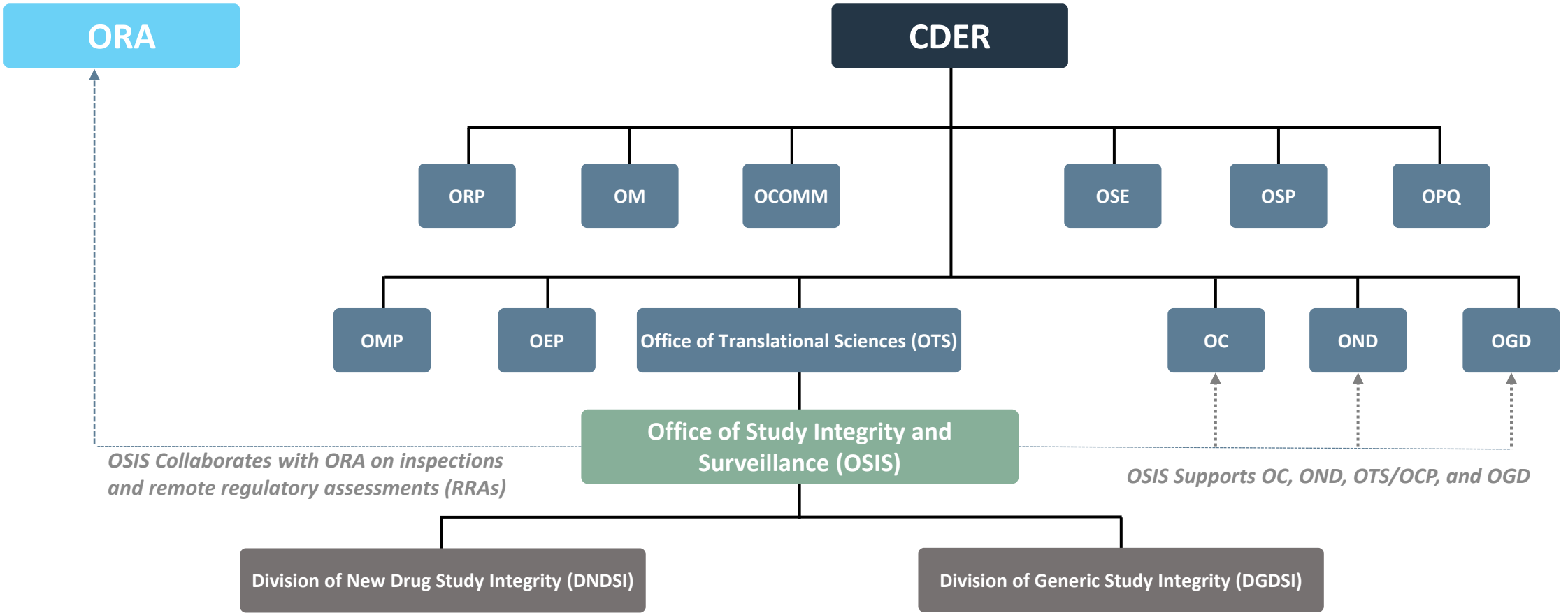
OSIS VISION

OSIS improves the public health by protecting study subjects and promoting properly conducted studies.

OSIS MISSION

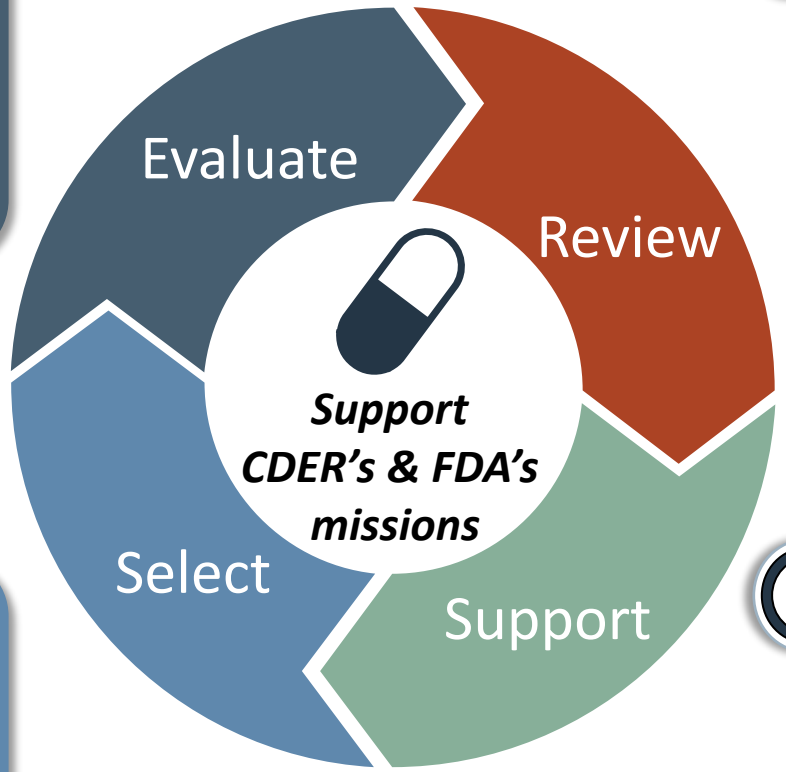
OSIS promotes the public health by ensuring the welfare of study subjects and by verifying the quality, study integrity and regulatory compliance of bioavailability/bioequivalence (BA/BE), nonclinical (GLP), and animal rule (AR) studies.

Organization Chart



OSIS Mission: Select, Evaluate, Review, Support

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 by providing data reliability recommendations and compliance evaluations

Select

Select sites for inspection/RRA using surveillance intelligence to generate site assessments

- Perform risk-based assessment and identify sites that conduct pharmacokinetic (PK), bioavailability/ bioequivalence (BA/BE), Good Laboratory Practice (GLP), and Animal Rule (AR) studies for inspection or RRA.

Evaluate

Evaluate sites to ensure quality and integrity of studies

- Assign and Conduct inspections/RRAs in collaboration with Office of Regulatory Affairs (ORA)
- Investigate allegations/complaints of regulatory non-compliance

Review

Review inspections/RRAs by analyzing Establishment Inspection Reports and Remote Regulatory Assessment Reports to generate OSIS Reviews

- Review Establishment Inspection Reports (EIRs) and RRARs and determine regulatory and scientific impact
- Develop and refine strategies to improve inspection planning, execution, evaluation

Support

Support CDER with data reliability recommendations and compliance evaluations

- Make recommendations to CDER review divisions to support regulatory review and approval decisions
- Collaborate on regulatory actions/enforcement with Office of Scientific Investigations (OSI)
- Collaborate with international regulatory agencies by sharing data, and conducting joint inspections, observed inspections, and training