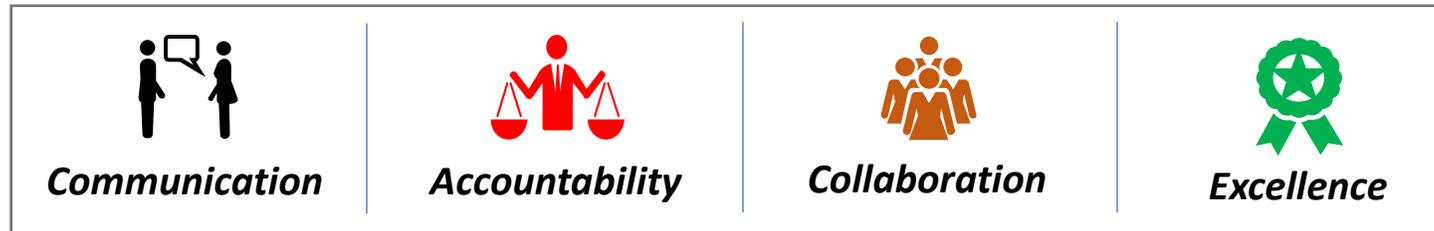


# Office of Study Integrity and Surveillance (OSIS)



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



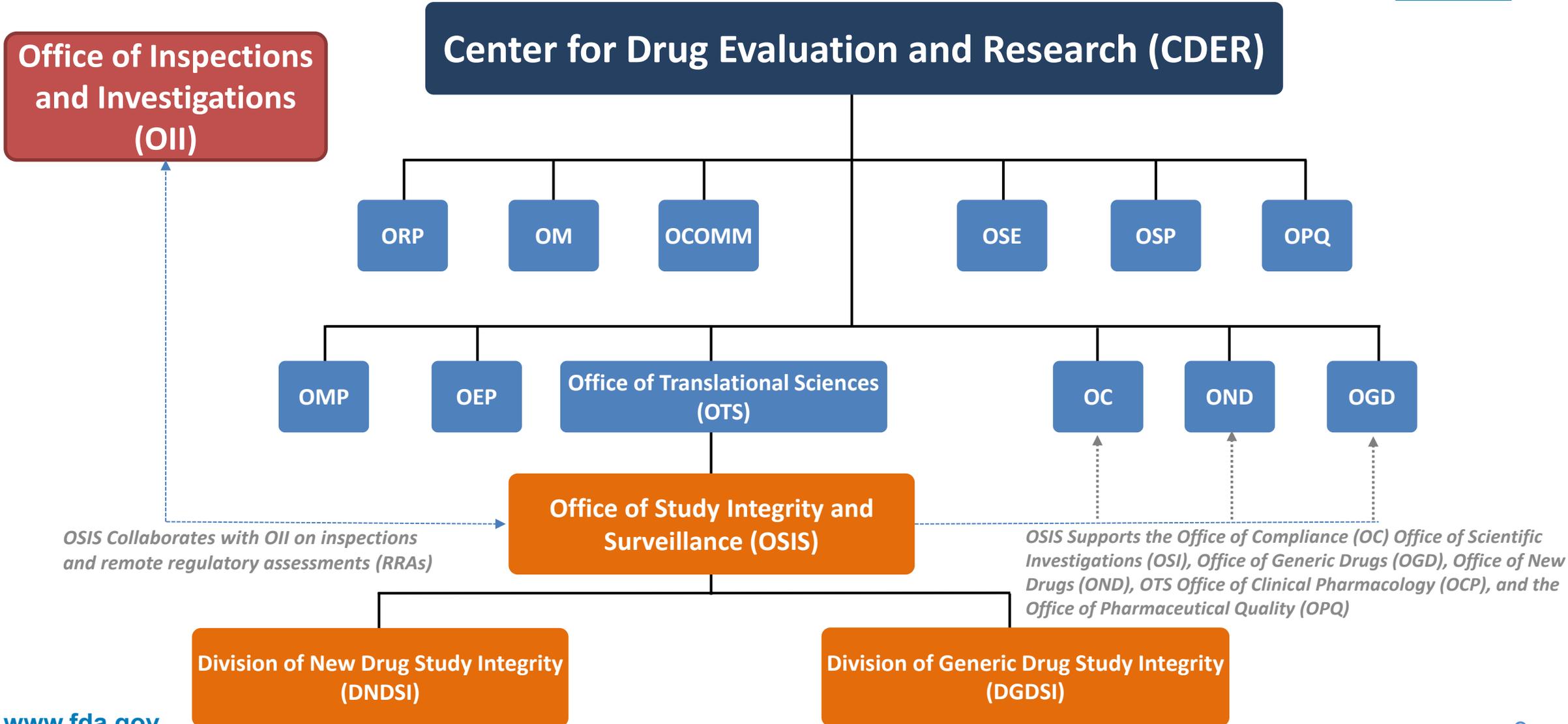
### **OSIS Vision**

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

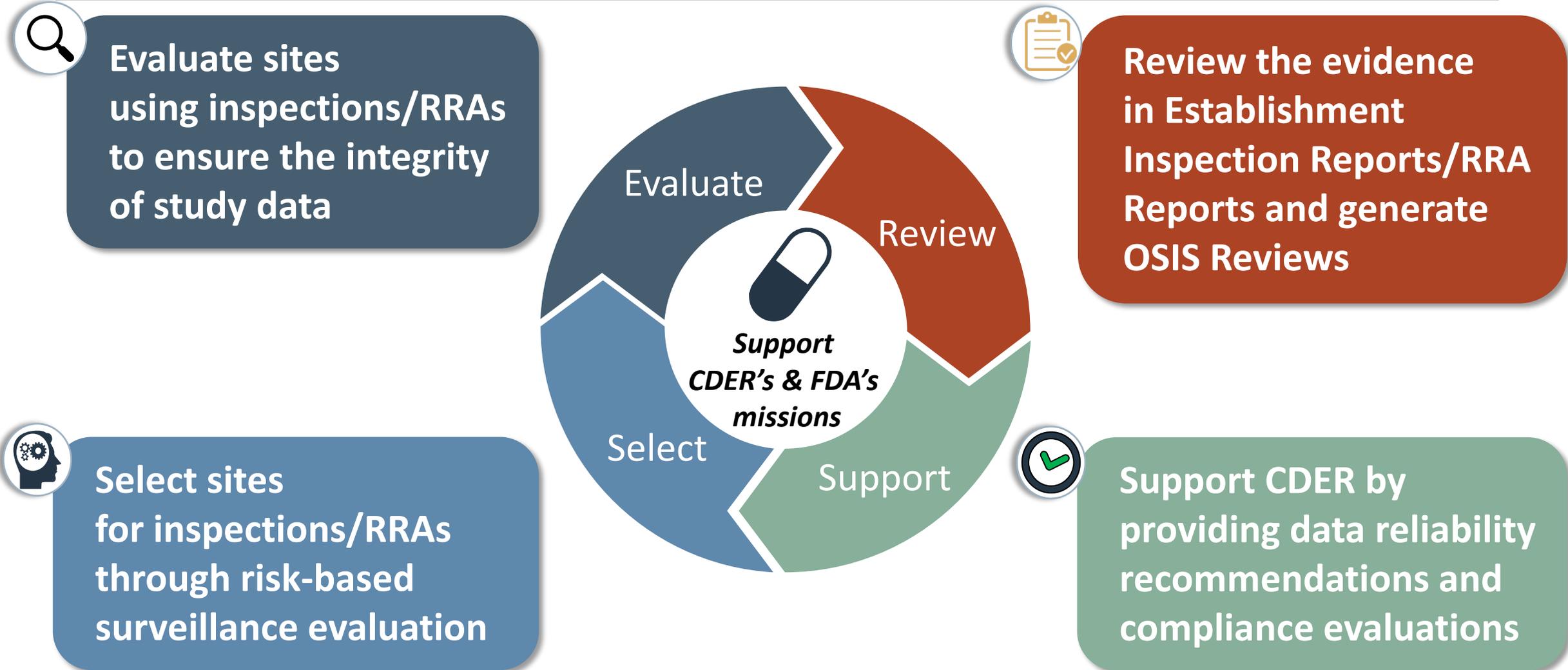
### **OSIS Mission**

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 (Good Laboratory Practices (GLP)), and Animal Rule (AR) studies.

# Center for Drug Evaluation and Research



# OSIS Mission: **Select**, **Evaluate**, **Review**, **Support**



# Select

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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

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## Evaluate sites to ensure quality and integrity of studies

- Assign and Conduct inspections/RRAs in collaboration with Office of Inspections and Investigations (OII)
- 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 RRA Reports 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

# INTERESTED IN WORKING FOR FDA/OSIS CONSIDER SENDING YOUR RESUME

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