

# ORA DATA EXCHANGE (DX) PROGRAM OVERVIEW

## ORA DX SUMMARY

The Office of Regulatory Affairs (ORA) DX program is an initiative of the Partnership for Food Protection Information Technology Workgroup (PFP IT WG). It seeks to unify food safety data sharing and contribute to the public health goal of a safer food supply. It enables secure data exchange between FDA and regulatory partners to:

 Improve Data Sharing Efficiency

 Increase Collaboration

 Reduce Dual Data Entry

 Increase Data Standardization

### DATA SHARING AREAS

3 areas of ORA DX data sharing include:  
Inventory, Inspection, and Sample

### PARTICIPATION

49 states and 2 US territories are onboarded for  
at least one ORA DX capability

## ORA DX SYSTEMS

### ORA Partners Portal (ORAPP)

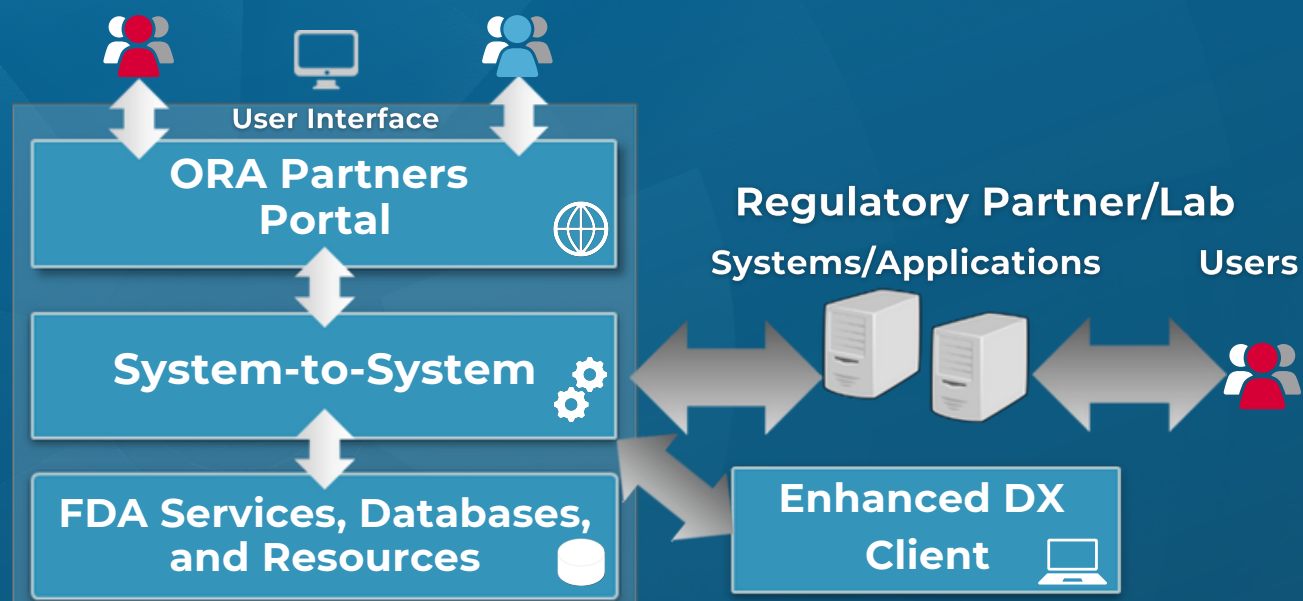
Web portal with user interface where regulatory partners and FDA users can submit and receive data

### \*System-to-System (S2S)

Web services that connect state and FDA systems to enable electronic data exchange

\*Includes Enhanced DX Client which supports sample data sharing

Regulatory Partner/Lab & FDA Users



## REGULATORY PARTNER ONBOARDING

➤ FDA and regulatory partner work together on steps for S2S and ORAPP onboarding

➤ High-level guidance by FDA for data mapping, testing, production rollout and ongoing maintenance

For more information on the ORA DX Program or PFP IT WG, please contact us at [appsdesk@fda.hhs.gov](mailto:appsdesk@fda.hhs.gov).

### S2S ONBOARDING PROCESS

- 1 Partner Expresses Interest
- 2 FDA Meets with Partner & Integration Files Provided
- 3 Partner IT Development
- 4 S2S Integration in Production

### ORAPP ONBOARDING PROCESS

- 1 Partner Requests ORAPP Access
- 2 Access Approved by FDA
- 3 ORAPP Access Established and Credentials Sent