Office of Regulatory Affairs (ORA) Data Exchange (DX)

Coffee Talk with
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The Partnership for Food Protection (PFP) Information Technology Workgroup (IT WG) recently had an opportunity to catch-up with Robyn Randolph for a Coffee Talk about the ORA DX.

Hello, Robyn! Tell us about yourself, your job role, and your involvement with the ORA DX program.

In my role as Senior Specialist in APHL's Food Safety program, I work to support Human and Animal Food (HAF) laboratories across the country in a variety of ways; including improving data defensibility, assisting in the development of best practices and quality-related resources, and supporting laboratories involved in the various Laboratory Flexible Funding Model (LFFM) tracks. I also serve as staff liaison to APHL's HAF Committee, and project manager for the PFP Laboratory Science Workgroup. Through both groups, I have been working with FDA and the PFP IT WG to support laboratories involved in the ORA DX program.

Based on your role as Senior Specialist for APHL, PM for the PFP Lab Science WG, and DX stakeholder, share your thoughts on some of the benefits for state labs looking to participate with the ORA DX.

I think that the ORA DX program is a fantastic opportunity for increased sharing and collaboration between food safety regulatory partners in real time. The multitude of ways to share data through the DX platform (Office of Regulatory Affairs Partners Portal (ORAPP), Enhanced DX Client, or System-to-System), allows states to determine the best way to work with the system, based on their unique needs/situations. For laboratories going the System-to-System route, time spent on upfront system integration development and testing is decreased and frees analysts from hours of manual data entry.

What challenges has APHL heard from laboratories participating in ORA DX?

APHL has been working closely with HAF Committee members and others participating in ORA DX to help identify challenges and communicate them with FDA partners. The common challenges for laboratories, which includes Firm Establishment Identifier (FEI) numbers and lot size data fields, boil down to identifying the critical data that FDA needs to be submitted in ORA DX versus what information would be "nice to know" if eventual traceback is needed.

Laboratories are submitting data for hundreds of samples, and the time commitment for both laboratories and state regulatory partners to collect and upload the metadata can be a huge hinderance. Many laboratories are suffering burnout and understaffing, and this time commitment can be untenable. I think it is important to find that balance between what data is critical for timely follow-up and what would be nice to know for trending or risk assessment.

The laboratories have also expressed gratitude towards the ORA DX team for their willingness to listen to the states, hear their concerns, and work towards solutions that benefit both parties as well as protect public health.

Share your insight on how state lab experience can be improved during the ORA DX onboarding process, including support provided by FDA.

Some laboratories have experienced issues during the ORA DX onboarding process due to state IT infrastructure or the structure of their organization (e.g., IT is not co-located with the laboratory, interaction is not consistent). Some laboratorians are learning a new language during the onboarding process, and it can be difficult to understand next steps in the process even with FDA assistance. It may be helpful to form user groups with laboratories based on the Laboratory Information Management System (LIMS) so challenges, solutions, and lessons learned can be shared. Continued onboarding support from FDA will be crucial for laboratories entering the ORA DX.

In your opinion, what are the biggest challenges facing the long-term success and sustainability of state laboratory participation with ORA DX? And what advice do you have for improvement?

Some laboratories have expressed concerns about continued financial support for ORA DX participation. While laboratories opting into the ORAPP upload pathway can use new features released in updated versions automatically, those using System-to-System typically need to adjust their LIMS system in order for those schema changes to apply. Without continued financial support, it will be difficult to make those changes and be able to fully utilize ORA DX.

Has APHL been involved in other integrated data reporting initiatives between states and FDA or other federal agencies? What lessons learned or successes have you seen from those initiatives that could be applied to ORA DX?

APHL has long been involved in assisting states and federal partners with data sharing efforts. APHL collaborates with Center for Disease Control (CDC), public health laboratories and public health agencies to develop viable options for electronic transmission of laboratory test data and vital epidemiological information.

To facilitate many of the Data Exchange projects, APHL supports the APHL Informatics Messaging Services (AIMS), which is a secure, cloud-based platform that accelerates the implementation of health messaging by providing shared services to aid in the visualization, interoperability, security, and hosting of electronic data. More than 200 public health and clinical laboratories, federal organizations, and medical providers use AIMS to transport, translate, validate, and host their electronic data, ensuring that the right information gets into the right hands quickly to inform decision making and surveillance.

AIMS has developed a technical assistance model to guide and support public health laboratories, public health agencies and other data exchange partners. With the tools and expertise offered through APHL, public health laboratories and agencies can understand, navigate, and implement electronic data exchange using simple, effective, standards-based methods. Laboratorians, subject matter experts (SMEs) staff and IT administrators benefit from an unprecedented knowledge transfer and gain valuable technical capability and expertise. This approach also liberates a laboratory or agency's staff resources from time-consuming reporting obligations as soon as possible.

To learn more about APHL's Informatics technical assistance projects and the AIMS Platform, please visit the APHL website.

How does APHL support the FDA's Lab Flexible Funding Model (LFFM)?

APHL engages with state and federal partners to further and support LFFM efforts, as well as strengthen laboratory data defensibility through continuous quality improvements and strong laboratory quality management systems. APHL utilizes the knowledge and experience from accredited laboratories to compile lessons learned, accreditation strategies, success stories and other resources to assist other laboratories looking to become ISO/IEC 17025 accredited. APHL also manages an Accreditation Process Consultant, who provides direct technical assistance to non-FDA funded HAF testing laboratories working towards this accreditation – five laboratories have achieved it with our consultant's assistance.

APHL also facilitates information sharing between and among state and federal partners. APHL plans and co-hosts both the annual GenomeTrakr and LFFM Cooperative Agreement Program (CAP) Grantee meetings, which offer LFFM grantees the opportunity to connect with peers and partners on successes, challenges, and lessons learned. APHL supports other training opportunities for LFFM laboratories, such as in person and virtual workshops and webinars.

Are there particular capabilities or enhancements you would like to see within ORA DX?

I would like to see the continued conversations between state and federal partners on the challenges states are facing in ORA DX participation. I would like to see solutions to challenges posed (e.g., FEI numbers, lot size, Program Assignment Codes (PACs)) that are efficient for state participants but still provide FDA with enough metadata to follow up with a sample if follow-up is necessary.

How do you see APHL being involved in the ORA DX in the future?

APHL would like to continue assisting state laboratories as they onboard and continue their participation in ORA DX. We can assist states with data modernization and interoperability, utilizing APHL Informatics staff to provide states with technical assistance. APHL can also continue determining gaps, limitations, and/or barriers that may exist in state laboratory IT infrastructures that prevent full integration in ORA DX.

The PFP IT WG would like to thank Robyn for her support of the ORA DX program and the PFP. We look forward to continued collaboration with Robyn and expanding the ORA DX program. For questions or information about the ORA DX or the PFP IT WG, contact us at appsdesk@fda.hhs.gov.