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Sharing Data Through the FDA Expertise and Research Portal

Ben Hope, Deputy Director, FDA Library, Office of Digital Transformation (ODT)

Alexis Norris, Chair, FDA Omics Working Group and Bioinformatician, Center for Veterinary Medicine (CVM)

FDA Expertise and Research Portal

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Search the repository | FDA Staff | All

FDA Expertise and Research Portal

The FDA Expertise and Research Portal preserves and provides access to the research, expertise, and creative output of the FDA's staff.

FDA Profiles | Output | FDA Organizations

Our Researchers

JASON GORMAN

Principal Investigator

MAYUMI F MILLER

Veterinary Research Branch

ZHICHAO LIU

Principal Investigator

What is the Portal and why did we build it?

The Portal is a centralized, automated tool for finding FDA experts and linking to their research and data to support knowledge sharing and collaboration.

The FDA lacks a comprehensive, centralized, and automated source of researcher profiles and expertise data representing the collective research output across the Centers. Profiles are stored in multiple locations, manually created, and are often out-of-date or incomplete. FDA publications, data, and additional scientific and research outputs are similarly dispersed and not easily searchable.

How does the Portal align with the FDA IT Strategy?

The Portal directly aligns with the new FDA IT strategic goals:

1. Create a Shared OneFDA Ecosystem
2. Strengthen IT Infrastructure
3. Modernize Enterprise Services and Capabilities
4. Share Data for Mission Outcomes
5. Adopt AI and Mission-Driven Innovations
6. Cultivate Talent and Leadership

How does it work?

- Based on a commercial off-the-shelf (COTS) solution called **Esploro**, the Portal uses artificial intelligence (AI) to harvest data from trusted internal and external sources.
- Users can edit their profiles as needed, but they no longer need to update their research outputs manually.
- Persistent digital identifiers, such as the Open Researcher and Contributor ID (**ORCID**) and Digital Object Identifier (**DOI**) are used to increase data quality and share data with other systems.
- Planned integrations with systems like **openFDA** will connect researchers and publications to datasets, code, and additional scientific and research outputs.

How does the FDA benefit?

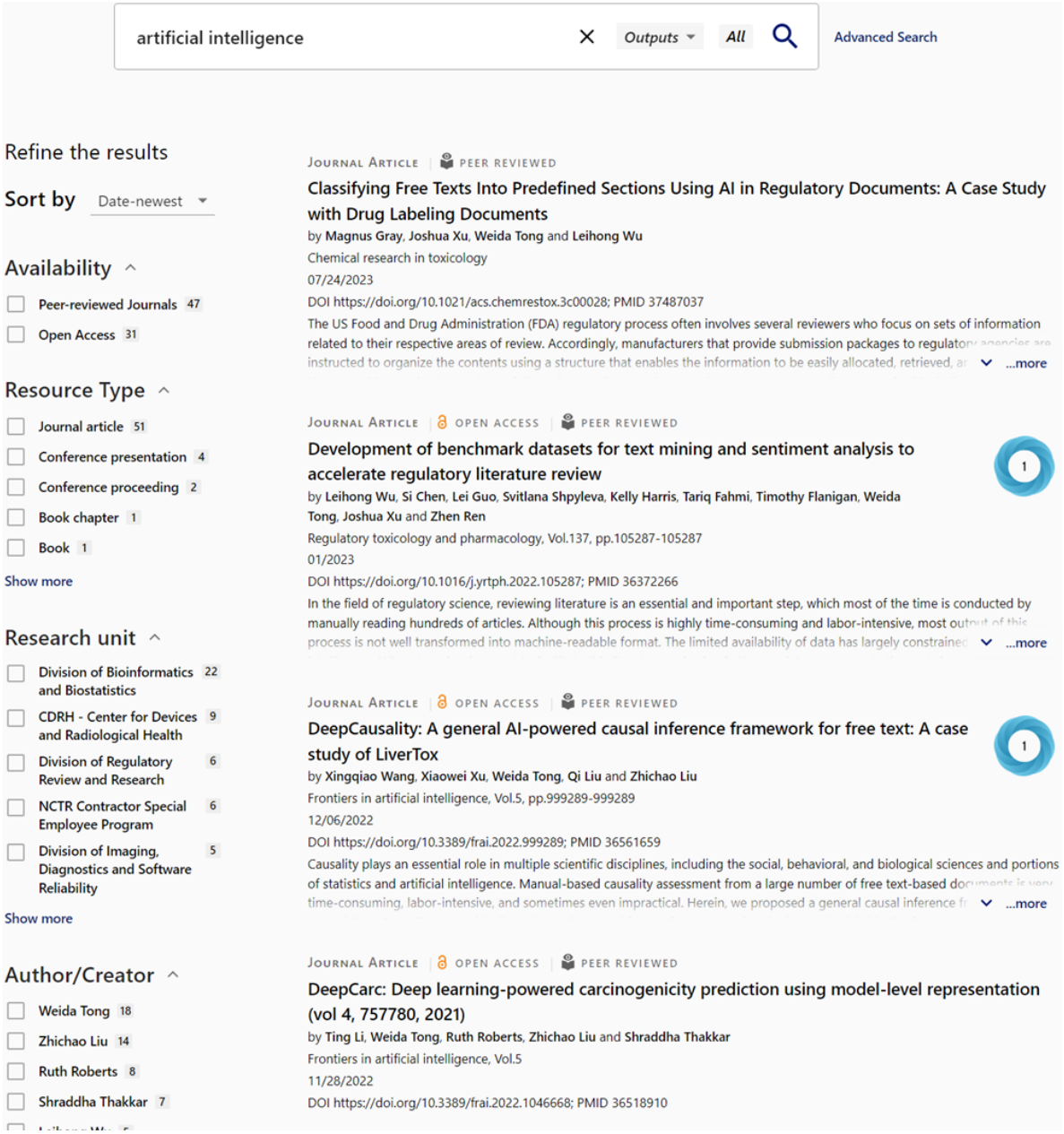
- AI harvesting from trusted internal and external sources helps minimize the data entry burden on FDA researchers.
- FDA staff has access to expertise across the Centers and to external collaborators.
- FDA has a searchable catalog of research and scientific assets.
- Data transparency enables compliance with federal requirements and laws, such as Open Science, HR 4174, and M-13-13.

How would the Public benefit?

- The Portal would be publicly accessible and would provide free and immediate access to FDA peer-reviewed publications.
- Faster access to expertise internally would contribute to better regulatory, scientific, and research decisions.
- Data approved for public access would be more readily searchable and accessible with openFDA integration.
- Additional research and scientific outputs would be available to the public.

Sharing Data – Expertise

- Expertise can be searched by keyword and refined using filters.
- Collaborators can be identified more readily.



Sharing Data – Expertise

Alexis Norris

Bioinformatician, CVM

Genomics | Bioinformatics | Computer Programming | Computational Biology | Genetics | Animal Genetics or Breeding | Transgenic Animals | Genome Editing | precisionFDA | High Performance Computing | Cloud Computing | Omics | Transcriptomics

Expertise

Bioinformatics reviewer (CVM) and current Chair of FDA Omics Working Group. Experience with bioinformatics analysis of data generated to characterize genome edited animals. Data is typically next generation sequencing (NGS) -- Illumina, Nanopore, PacBio. Analysis is primarily focused on variant calling, de novo genome assembly, and gene expression.

Links

- FDA Omics Working Group
- GitLab (FDA)
- Google Scholar Publications
- LinkedIN

Organizational Affiliations

Division of Animal Bioengineering and Cellular Therapies, Office of New Animal Drug Evaluation, CVM - Center for Veterinary Medicine, FDA

Sharing Data – Publications

Alexis Norris

Overview | Output

Highlights (1)

All assets (35)

Publication (32)

Posted Content (2)

Conference/Event (1)

+ ADD WORK EXPORT ALL

JOURNAL ARTICLE | OPEN ACCESS | PEER REVIEWED

Template plasmid integration in germline genome-edited cattle

by Alexis L Norris, Stella S Lee, Kevin J Greenlees, Daniel A Tadesse, Mayumi F Miller and Heather A Lombardi

Published 02/2020

Nature biotechnology, 38, 2, 163 - 164

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Sharing Data – Datasets

Benefits to FDA staff (user perspective)

- Find people (internal subject matter experts)
  - Research: potential collaborations
  - Review: potential consults
- Find communities (e.g., working groups)
- Find datasets
  - Leverage existing datasets to answer regulatory questions as they arise
- Find software/tools
  - Especially those that already exist internally (e.g., FDA GitLab)

Benefits to FDA staff (user perspective)

- Transparency to scientific community and external stakeholders (e.g., industry, trade groups, consumer advocacy groups)
  - Awareness of publications
  - Encourage reuse of FDA-generated datasets
  - Sharing FDA-developed tools/code

Looking ahead

- Integrations with internal and external trusted systems
- Collaborations with FDA Centers, publishers, and vendors
- Additional outputs minted with DOIs
- Open Science compliance
- Reporting and Analytics

Questions?