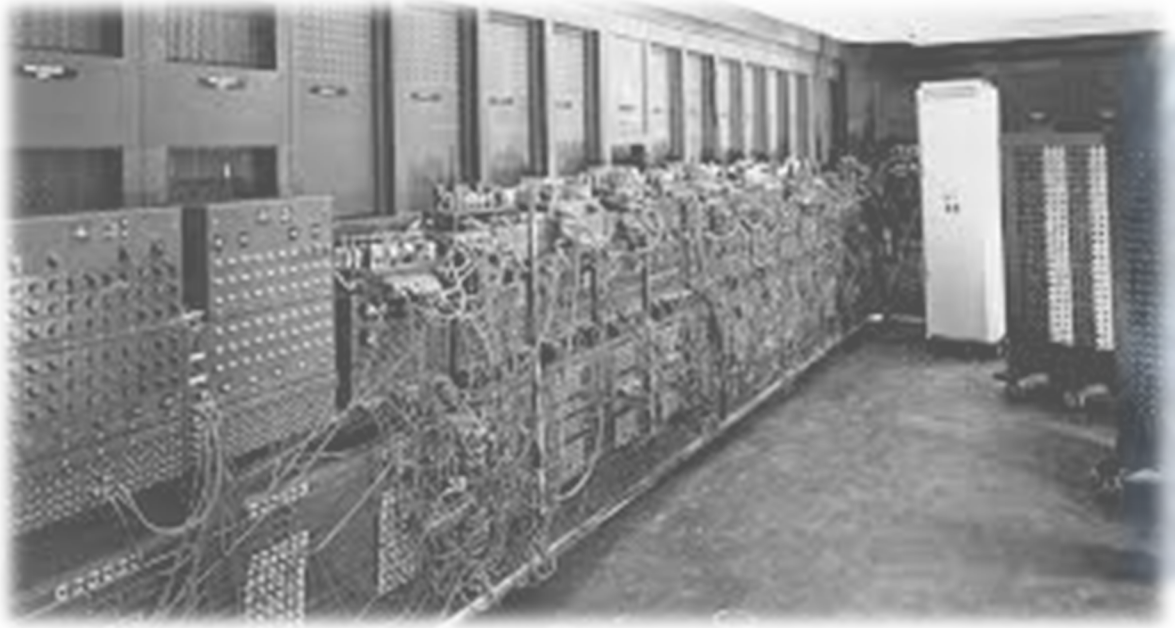
U.S. FOOD & DRUG ADMINISTRATION

Adoption of Mission Driven Innovations



Denny Skiles

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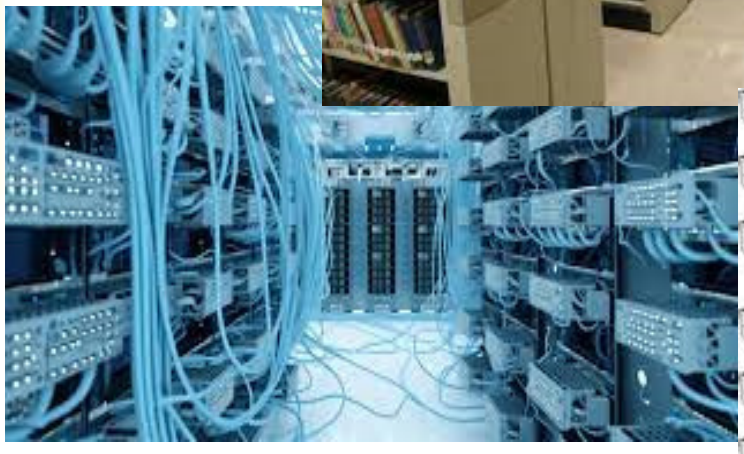
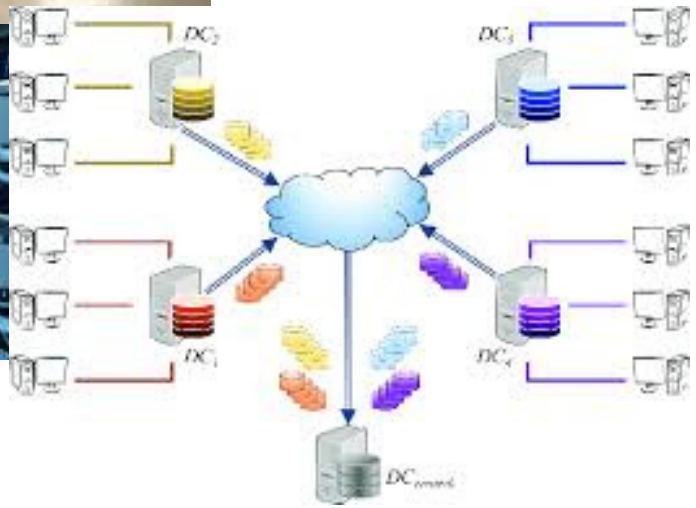
Why Innovate?

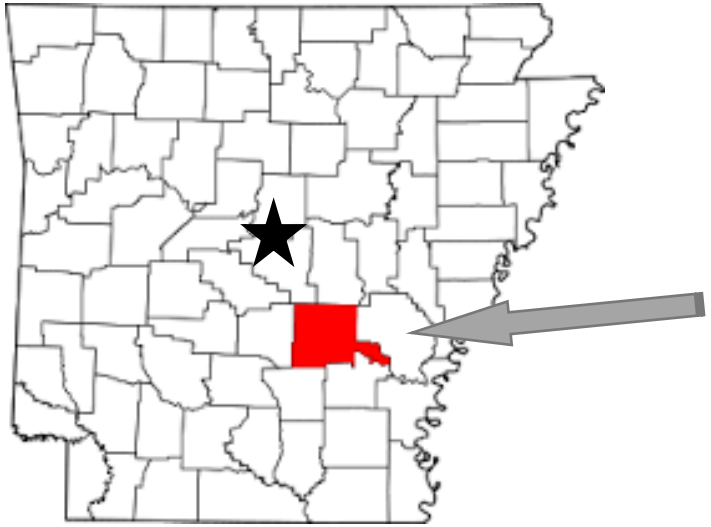


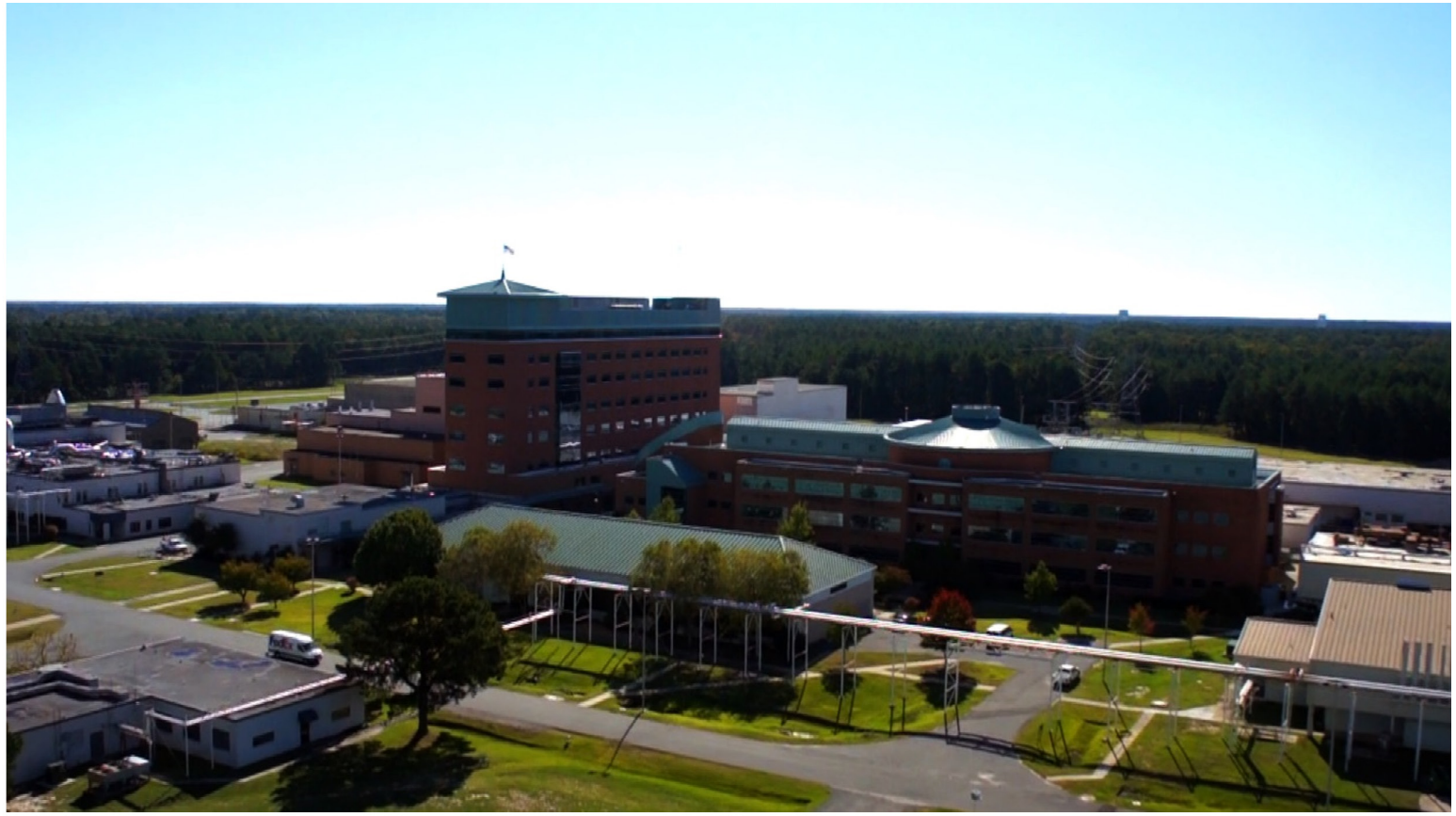


Innovation

- What is it?
  - a new or changed entity realizing or redistributing *value.*
- How do we inspire it?
  - create an environment conducive to creativity.
  - demonstrating curiosity, autonomy, risk-taking, creativity, and collaboration in our work.

National Center for Toxicological Research (NCTR)

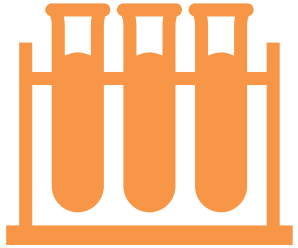




Jefferson, Arkansas

Research at NCTR

Vision: Conduct scientific research to provide reliable data for FDA's decision-making and develop innovative tools and approaches that support FDA's public health mission.



NCTR has 6 research divisions with focus areas:

Artificial Intelligence and Machine Learning (AL/ML)

Biomarker Identification

Bio-Imaging

Nanotechnology

Molecular Toxicology

One Health

Perinatal and Maternal Health Research

Precision Medicine

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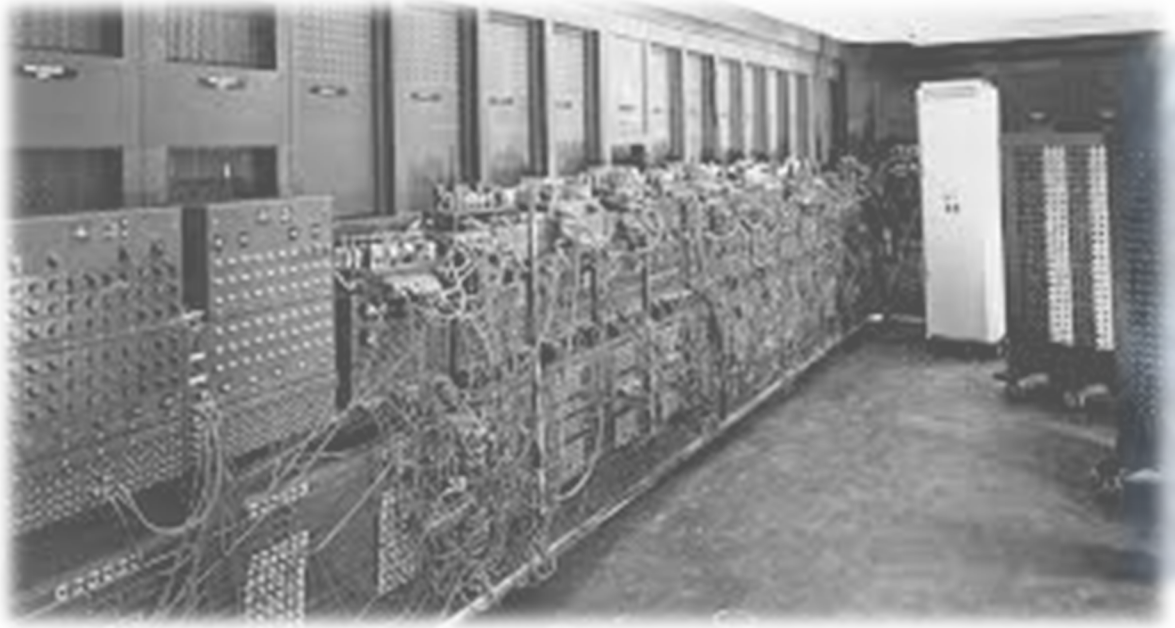

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Challenges

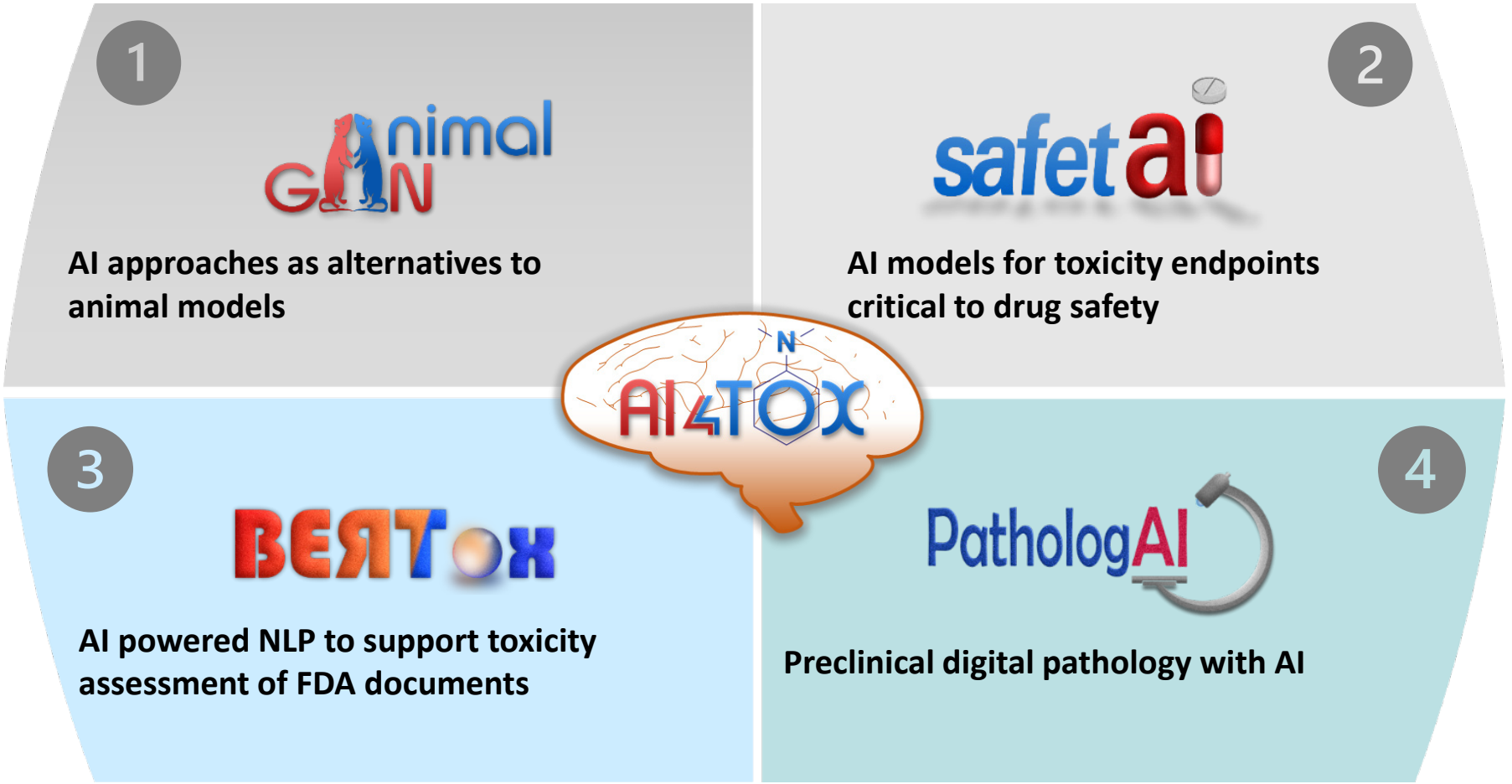
How long does it take to find information?

How do we seek out new sources of information?

How do we best use our research time?

- searching for information or evaluating the most relevant information?

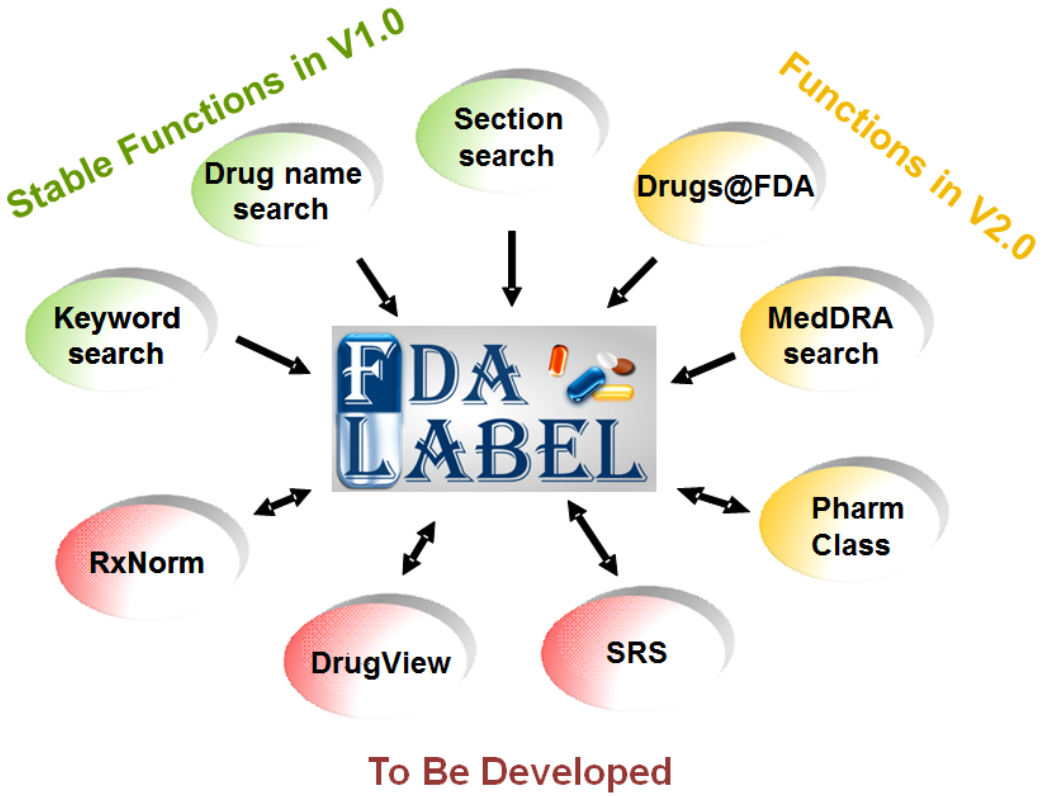
AI for Toxicology (AI4TOX) Program at NCTR



https://www.fda.gov/about-fda/nctr-research-focus-areas/artificial-intelligence

FDALabel

Office of Computational Science, Office of New Drugs (OND) Labeling Development Team (LDT), Office of Generic Drugs (OGD), Office of Surveillance and Epidemiology (OSE)

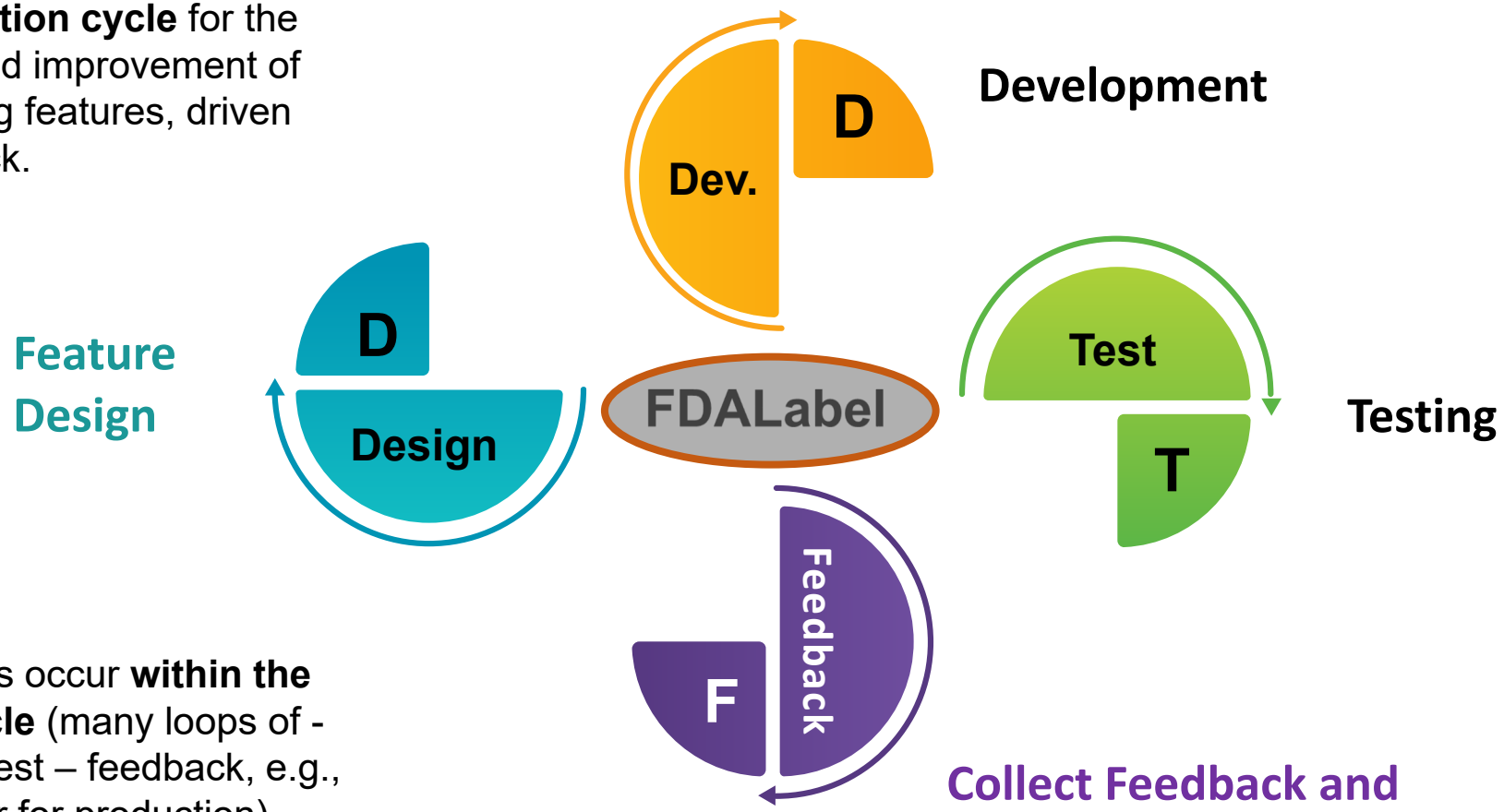


- A web-based database for managing, querying and organizing drug labeling and other product labeling
  - User-friendly interface that searches against the entire text of drug labeling
- Actively used by CDER reviewers
- Used also by researchers from the public
- Integrated with other FDA resources such as Drugs@FDA, OrangeBook, and PurpleBook
- Weekly update (currently with >140,000 labeling)

Please check out FDALabel **on Amazon Cloud**: https://nctr-crs.fda.gov/fdalabel/ui/search

How is FDALabel Developed?

Annual production cycle for the development and improvement of new and existing features, driven by user feedback.



Additional cycles occur **within the production cycle** (many loops of - development - test – feedback, e.g., 4 times this year for production)

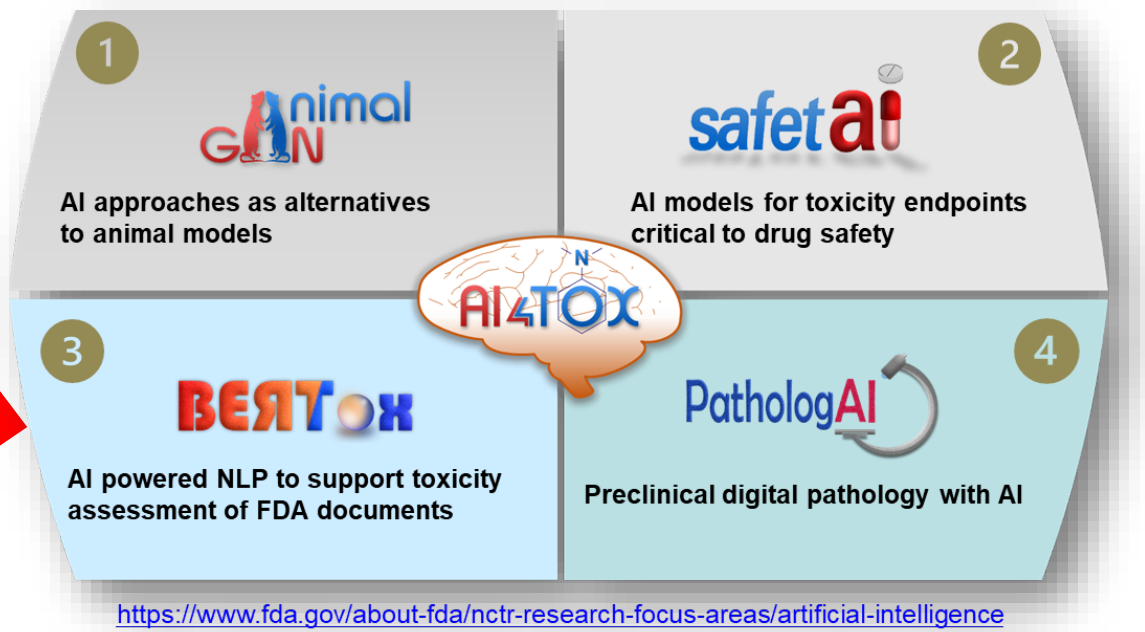
Why FDALabel?

- FDA Drug labeling is one of the important documents to support the review and study adverse events of drugs
  - We initially developed a pilot to support our study of drug induced liver injury (DILI)
- Challenges presented by drug labeling data including
  - Rapid growth of drug labeling data
  - Major format change in 2006, many sections and subsections
  - Complex relationship between drug products
- Need a flexible, powerful, and fast tool to manage and search over the entire text or specific sections with the awareness of relationships
  - Timely updating and repeated use with complex queries
  - Create and save customized queries for sharing and later viewing
  - Flexible combination of various search options

Next Step: AI for FDALabel

- RxBERT with improved functionalities for FDALabel
  - Developed based on the most advanced AI for Natural Language Processing (NLP) algorithm, called BERT (developed by Google).
  - Customized domain-specific BERT model that was trained using human prescription drug labeling documents.
  - Provides a Google-like searches in FDALabel.
  - Enhances text search and improves adverse events recognition

RxBERT is a part of BERTox initiative



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Collaboration with CDER

>10 yrs in collaboration

- **DASH** (Data Analysis Search Host) to record a drug's lifecycle of IND → NDA or BLA (CDER/OTS)
- **Smart Template System** to enable the automated capture of findings during the review process (MOU with CDER/OCS)
- **FDALabel** to facilitate review application of drug labeling documents (Led by NCTR/OSC, MOU with CDER/OCS)

Other projects

- CDER/OND - Develop a DASH-like system to support FDA Safety Policy Research Team (SPRT)
- CDER/OCS – Develop SafetAI initiative to support 30-day drug safety review
- CDER/OCP - Organize findings from biosimilar submissions to support biosimilarity assessment
- CDER/OSE - AI4PharmcoVig, an AI model for document screening, classification, and processing to enhance pharmacovigilance
- …

Collaboration with FDA Centers

ORA

- **ALIS**: Automated Laboratory Information System to manage laboratory date generated during the ORA review process (completed last year)

CTP

- **ASSIST4Tobacco:** An Artificial Intelligence (AI)-based information retrieval system (completed the first phase of the project)

For additional information, you may email ODTVendorEngagement@fda.hhs.gov