U.S. FOOD & DRUG ADMINISTRATION

National Center for Toxicological Research (NCTR)

Bioinformatics & Biostatistics

About the Division of Bioinformatics and Biostatistics (DBB)

Division Mission

Develop integrated bioinformatics and biostatistics capability to address increasing needs of FDA product centers in areas such as biomarker development, drug safety, drug repositioning, precision medicine, artificial intelligence (AI), rare diseases, endocrine disruptors, and risk assessment.

Division Branches

Research-to-Review (R2R) Branch: Translates division research for regulatory application.

Bioinformatics Branch: Constructs knowledge bases to provide a data-driven decision-making environment for enhanced safety evaluation and precision medicine.

Biostatistics Branch: Conducts research of statistical methods to analyze toxicological and molecular data as well as data-mining techniques for pattern identification and signal detection

Scientific Computing Branch: Provides IT support to the entire NCTR.

Select DBB Accomplishments in 2021

- Informed drug selection and combination of FDA-approved drugs for COVID-19 treatment using AI.
- Studied drug-induced liver injury (DILI) to support FDA review.
- Developed knowledge base for opioid crisis.
- Performed characterization of different next-generation sequencing technologies for precision medicine.
- Studied clinical implication of non-steroidal anti-inflammatory drugs (NSAIDs) using real-world data and AI.
- Supported regulatory application requested by other FDA centers.
- Awarded FDA intramural research grants for four projects with topics including racial disparities in critical care patients, DILI risk associated with herbal medicine and dietary supplements, and computation strategies and approaches to combat COVID-19.
- Published over 30 research and review articles and one book chapter, many of which will be key milestones in better achieving both NCTR's and FDA's mission.

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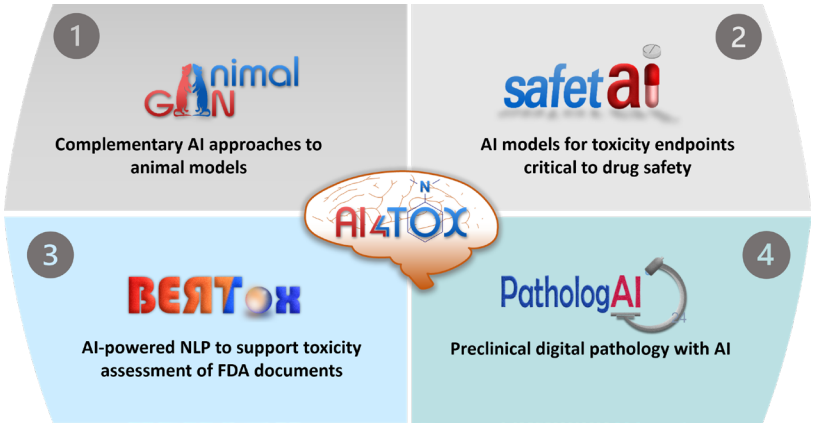
Ongoing DBB Research Projects in 2022

1. Regulatory Applications and Support

- Collaborating with CDER to develop and support:
  - Data Analysis and Search Host (DASH)
  - Safety Policy and Research Team (SPRT)
  - Smart Template System (STS)
  - FDA drug labeling documents (FDALabel)
- Supporting ORA by developing Automated Laboratory Information System (ALIS)
- Collaborating with Center for Tobacco Products to create ASSIST4Tobacco



2. Alternative Methods and Knowledge Bases

Developing the following:

- Advanced DILI prediction models for FDA-regulated products like drugs and supplements.
- Opioid Agonists/Antagonists Knowledgebase (OAK) for better management of opioid-use disorder.
- Molecules with Androgenic Activity Resource (MAAR) open-access platform for assessing the safety profile for chemicals in various food, supplement, or cosmetic products that may affect the endocrine system and cause hormonal disfunction.

3. Precision Medicine and Therapeutics

- Completing the final studies under Sequencing Quality Control Phase 2 (SEQC2), an NCTR-led consortium effort to assess technical performance and application of emerging technologies for safety evaluation and clinical application.

4. Artificial Intelligence and Machine Learning (AI/ML)

- Applying the most advanced AI methods using the AI4Tox program to develop new tools to support FDA regulatory science and strengthen the safety review of FDA-regulated products.
- Conducting research to harness AI in mining FDA documents for relevant information to enhance regulatory operations and applications.
- Assessing the safety profile of prospective drugs in Investigational New Drug (IND) applications to assist FDA reviewers.

5. Real-World Data and Real-World Evidence

- Investigating racial disparities in patients with heart failure admitted to critical care and its subsequent impact on their health.
- Analyzing safety profiles of various prescription NSAIDs to understand the difference in patient sexes (male vs. female) across the U.S. population.

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