



U.S. Department of Health and Human Services  
U.S. Food and Drug Administration

# **NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR) JEFFERSON, ARKANSAS**

## **OVERVIEW**





# NCTR—A Unique FDA Resource

Established in January 1971 by Executive Order as a non-regulatory national resource owned and managed by the FDA.





# What Makes NCTR Unique?

Only FDA Center located outside the D.C. area—  
in Arkansas!





# What Makes NCTR Unique?

Only FDA Center solely dedicated to research and training, and providing quantitative toxicology data to support FDA regulatory decisions.





# Regulatory Science at NCTR

## Examines risks posed by regulatory products

- Characterizes risk from exposure to pharmaceuticals (e.g., [anesthetic exposure in children](#))
- Develops *de novo* experimental data to conduct risk assessments in humans or animals (e.g., [melamine](#)).
- Reduces risk of regulated products (e.g., [the Center for Tobacco Products inhalation laboratory](#))
- Develops background risk profiles for generally recognized as safe (GRAS) pharmaceuticals (e.g., [sunscreen components](#))



# Regulatory Science at NCTR

**Develops and evaluates emerging science and technology**

- Bio-imaging—preclinical translational biomarkers (microPET, MRI, CT)
- Bioinformatics and biostatistics—the “big data problem” best practices
- *In vitro* human tissue/organ models
- Detection of bacteria, yeast, prions, etc., in regulated products
- Computational, *In silico* modeling for identifying potential risk



# Regulatory Science at NCTR

## Science and technology (cont.)

- Induced-pluripotent human stem cells characterizing pre-clinical risk
- Intestinal microflora and host interactions—the microbiome
- Nanotoxicology in regulated products (NanoCore facility)
- Omics (genomics, epigenetics, metabolomics, proteomics)
- Biomarker identification for precision medicine protocols



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# Regulatory Science at NCTR

## Education and training

- Intramural training programs
- Extramural training programs
- International outreach



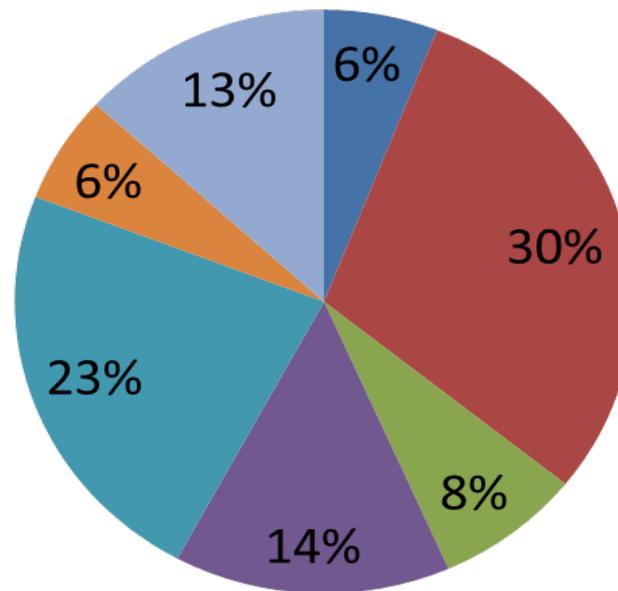


# What Makes NCTR Unique?

## Collaborative Projects with Product Centers

■ CBER ■ CDER ■ CDRH ■ CFSAN ■ CTP ■ CVM ■ ORA

Provides toxicology and research data to all FDA Product Centers





# What Makes NCTR Unique?

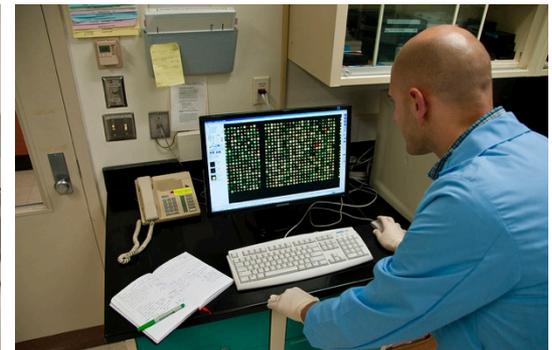
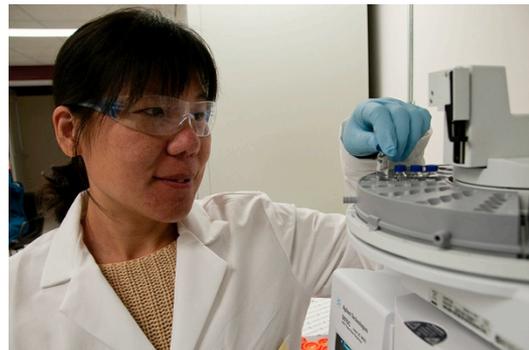
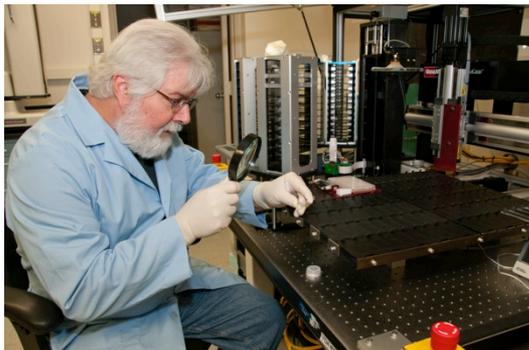
- FDA-owned facility maximizes flexibility and rapid adaptability of research space
- Multidisciplinary research and scientific staff
- High employee retention rate
- Low production costs





# NCTR Resources in Profile

- 132 laboratories
- 8 specialty laboratories
- 542 personnel
- 200 research studies





# Scientific Collaborations—External

- **National Toxicology Program (IAA)\***
- **University of Illinois\***
- University of Arkansas (MOU)
- Harvard University
- University of Miami
- Wayne State University
- Baylor University
- Stanford University
- University of Texas Health Sciences Center
- Duke University
- St. Jude Research Hospital
- Huntington Medical Research Institute

***\*Funding received. Remaining are intellectual collaborations.***



# Additional Information About NCTR

- FDA Website: [www.fda.gov/NCTR](http://www.fda.gov/NCTR)
- NCTR Strategic Plan: [www.fda.gov/NCTRStrategicPlan](http://www.fda.gov/NCTRStrategicPlan)
- NCTR Annual Report:  
[www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/ResearchAccomplishmentsPlans/default.htm](http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/ResearchAccomplishmentsPlans/default.htm)