

2014-
2017



[NCTR STRATEGIC PLAN]

U.S. Department of Health and Human Services(HHS)/Food and Drug Administration

Vision

The U.S. Food and Drug Administration National Center for Toxicological Research (NCTR) is a global resource for collaboration providing consultation, training, and innovative scientific solutions in support of FDA's mission to improve public health.

Mission

NCTR conducts scientific research to develop and support innovative tools and evaluation of approaches that FDA uses to protect and promote individual and public health.

STRATEGIC GOALS

To accomplish its mission, NCTR has established three strategic goals to ensure the conduct of innovative regulatory-science research vital to FDA. Regulatory Science—the science of developing and establishing tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated products—is the foundation of decision-making at FDA.

Goal 1: Advance scientific approaches and tools required to support public health

Goal 1 identifies specific objectives that align with the priorities outlined in FDA's Advancing Regulatory Science Plan. This goal illustrates the importance of maintaining a strong basic-science core; one that provides NCTR the flexibility to address ever-changing research needs.

Goal 2: Promote global interactions in regulatory science research

Goal 2 defines initiatives that promote NCTR's global activities dedicated to building and strengthening the product safety net around the world.

Goal 3: Improve administrative management and develop new communication materials and methods to support HHS/FDA science goals

NCTR:

- *Provides interdisciplinary toxicology research solutions and consultations for FDA.*
 - *Uses multidisciplinary research teams to develop novel translational research approaches that translate animal studies to humans for safety-assessment.*
 - *Engages in collaborations vital to developing sound regulatory policy.*
 - *Promotes the international standardization of regulatory science through participation and leadership in the annual Global Summit on Regulatory Science.*
 - *Provides and encourages multidisciplinary workforce development.*
 - *Fosters national and international collaborations with scientists from government, academia, and industry.*
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Goal 3 focuses on recruiting and retaining highly qualified scientists and staff, improving business processes, and extending the reach of NCTR's internal and external communications.

Goal 1: **Advance scientific approaches and tools required to support public health**

NCTR conducts research that develops and investigates innovative tools to promote efficient regulatory processes and individualized public-health decisions. Research topics represent a full range of FDA's product portfolio including foods, cosmetics, dietary supplements, human and animal drugs, tobacco products, and medical devices. Study designs are peer-reviewed by experts from FDA, academia, and/or industry. The research designs are customized for each project ranging from comprehensive toxicology assessments to key data-gap questions identified by regulatory centers. Research projects are planned whenever possible that allow the translation of animal study results into human clinical data. Some of the emerging technologies used at NCTR include nanotechnology, genomics, proteomics, metabolomics, bio-imaging, and computational modeling.

The NCTR research environment is fully integrative in nature and NCTR is dedicated to conducting research vital to regulatory decisions and the regulatory decision-making processes. Furthermore, NCTR provides a

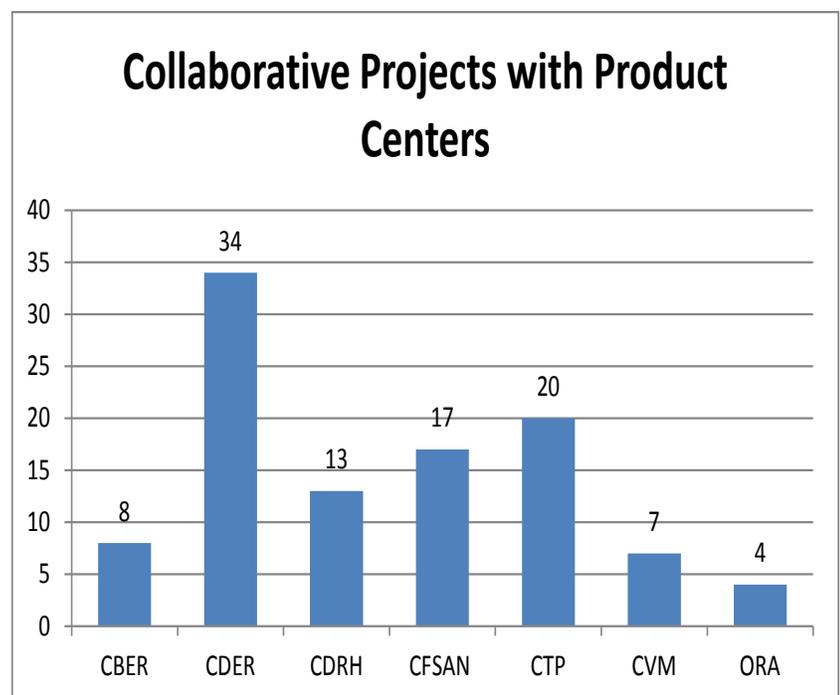
NCTR partners with a number of organizations, including:

- *FDA Regulatory Centers*
 - *National Cancer Institute*
 - *National Institutes of Health*
 - *National Toxicology Program*
 - *SmartTots*
 - *State of Arkansas (via Memorandum of Understanding)*
 - *Toxicology Excellence for Risk Assessment*
 - *Arkansas University System*
 - *Arkansas Children's Hospital*
 - *University of Illinois*
 - *University of Miami*
 - *Wayne State University*
 - *Baylor University*
 - *University of Texas Health Science Center*
 - *Hamner Institute*
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unique environment within FDA where regulators, academicians, and regulated industry can interact and discuss solutions and advance studies that promote improved public health.

NCTR strives to develop cross-center collaboration and to include scientists from other FDA Centers on all major research projects. These partnerships also may involve expertise with investigators and programs outside FDA to leverage the advantage of wide perspectives into regulatory considerations.

Of 197 active projects in 2014, NCTR collaborates with at least one Product Center on 103 of those.



Nanotechnology

Collaborations:

The NCTR/ORA

Nanotechnology Core Facility (NanoCore) is supporting collaborative efforts within and outside FDA.

FDA and the State of Arkansas entered into a Memorandum of Understanding (MOU).

Through the MOU a research effort by a consortium of the five Arkansas research universities and NCTR focuses on the synthesis, detection and toxicity of graphene, a carbon-rich nanoscale material. In FY14 the consortium, with contributions from the NanoCore completed the first year of the consortium and has provided FDA with comprehensive data on the synthesis and detection of graphene. The NanoCore also is collaborating with other U.S. government agencies and university researchers. NCTR provides analytical support to projects that will inform the FDA and other U.S. government agencies on the toxicity and safety of nanotechnology-based materials.

Objectives and Supporting Strategies for Goal 1

Objective 1.1: Integrated product assessment

To protect patients and consumers, FDA must apply the best available science to its regulatory activities and promote innovation that addresses unmet medical and public health needs. New and evolving areas of science, like nanotechnology and bioinformatics, are promising novel approaches for improving our health while demanding new ways to evaluate the safety and effectiveness of these products.

Strategies for Implementation:

- Conduct *in vitro* and *in vivo* toxicological assessments* to identify biomarkers, quantify toxicities, and establish dose-response information for chemicals of interest to FDA.
- Develop and implement approaches to link chemical structures to a wide range of information about product safety, disease targets, and toxicity mechanisms.
- Evaluate the accuracy with which cell-based assays correctly predict potential human risk.

**Compounds being evaluated in 2014 and beyond include, but are not limited to: Furan, Glycidamide, Bisphenol A (BPA), Melamine with cyanuric acid, Retinyl palmitate, Usnic acid, Usnea lichen, Aloe vera, Triclosan, Nanoscale silver, Oxybenzone.*

***Estrogenic Activity
Database for Assessing
Potential Endocrine
Activity:***

NCTR scientists, in collaboration with FDA's Center for Drug Evaluation and Research, FDA's Center for Food Safety and Nutrition, U.S. Environmental Protection Agency, National Institute of Environmental Health Sciences, Texas A&M University, and Chang'an University (China) have developed the publicly available [Estrogenic Activity Database \(EADB\)](#) of in vitro and in vivo estrogenic activity data for a diverse set of over 8,000 chemicals, including drugs, food additives, and environmental chemicals. The EADB enables the user to search and evaluate the estrogenic activity of chemicals of interest as well as create models to predict the estrogenic activity of chemicals for which that data is not available. Estrogenic chemicals can interfere with the body's normal estrogen signaling pathways and can have adverse effects.

- Develop the infrastructure and research expertise in the area of nanotechnology to better understand and regulate consumer products containing nanomaterials.
- Evaluate quantitative imaging and other advanced approaches for identifying new biomarkers and predictors of efficacy and safety.
- Integrate system-biology approaches into assessments of foodborne pathogens and chemical contaminants in FDA-regulated products that improve risk assessments.

Objective 1.2: Advance regulatory science through new tools and approaches

The advancement of regulatory science is fundamental to FDA's core mission of protecting and promoting the public health. Rapid advances in research are changing not only the way medical treatments are delivered, but also how the FDA must respond to potentially new and complex technologies. NCTR remains committed to helping FDA remain one step ahead of these changes. We do this through active research intramurally and collaboratively with external partners as well as continuous efforts at horizon scanning.

Strategies for Implementation:

- Identify and investigate new and improved biomarkers for safety and efficacy.
- Develop new tools to better characterize and standardize measurements that have typically relied on subjective interpretation.

- Develop a bioinformatics infrastructure to apply the most recent data to the areas of systems biology, food safety, genomics, pharmacogenomics, predictive toxicology, neurological function, and translational bio-imaging.
- Use the bioinformatics infrastructure and conduct pilot studies in support of the electronic regulatory submission (e-submission) process.
- Develop rapid, sensitive, and cost-effective methods for the identification, quantification, and molecular characterization of potential microbial and chemical contaminants in human food, animal feed, and other FDA-regulated products.

Objective 1.3: Approaches for promoting individualized health and identifying susceptible subpopulations

NCTR will continue to support the Advancing Regulatory Science Plan to improve product development and patient outcomes through research into personalized medicine. Although overall some significant progress has been made in tailoring treatments to individual patients, translating new discoveries into the safe and effective use of medical products remains a challenge. With their significant experience and expertise, scientists at NCTR are uniquely positioned to develop, evaluate and facilitate the translation of basic science into real world applications.

Strategies for Implementation:

- Identify individual or panels of biomarkers and biometrical methods to aid in the quantification of an individual's risks and benefits.
- Analyze candidate gene and genomic architecture contributing to phenotypic differences in responses to drug treatments among individuals of diverse ethnic groups or in animal models using multiple strains of animals.
- Implement computational approaches and advanced computer technologies to evaluate human-health outcomes and improve the safety and efficacy of FDA-regulated products.

Global Summit on Regulatory Science:

NCTR established a series of annual Global Summits on Regulatory Science (GSRS) that bring together an international body for discussion of innovative technologies and partnerships to enhance translation of basic science into regulatory applications within the global context.

The conference provides a platform where regulators, policy makers, and bench scientists from various countries can exchange views on how to develop, apply, and implement innovative methodologies into regulatory assessments in their respective countries, as well as harmonizing strategy via global collaboration.

To engage the global community to address regulatory-science research and training needs, GSRS is held in different countries on an annual basis. Learn more about the 2014 Global Summit at:

<http://www.fda.gov/GlobalSummit2014>

Goal 2: **Promote global interactions in regulatory science research**

NCTR will support global-outreach programs and engage the global community to address regulatory-science research and training needs.

Objectives and Supporting Strategies for Goal 2

Objective 2.1: Promote global scientific interactions

This will enable NCTR to stay on the forefront of research critical to the FDA mission in the international community.

Strategies for Implementation:

- Establish national and international collaborations and promote innovation among government, industry, and academic partners.
- Support FDA's regulatory science activities by providing technical expertise in the interpretation of data, the development and harmonization of guidelines, and by participating in national and international scientific work-groups and advisory panels.
- Train international researchers to increase a two-way flow of information and talent related to research with widely applicable skills.
- Promote cross-disciplinary regulatory-science training and research to address gaps and challenges posed by novel products and technologies.

Goal 3: **Develop new communication materials and methods to support HHS/FDA science goals and improve administrative management**

NCTR's ability to efficiently and effectively support its scientific mission depends on ensuring, workforce expertise, effective communications, and financial responsibility. NCTR will recruit talented scientists, develop staff, assess financial business processes, evaluate current costs, and use a broad range of communication tools to increase the visibility of NCTR's scientific research and other accomplishments to a broader audience.

Objectives and Supporting Strategies for Goal 3

Objective 3.1: Develop best practices to recruit and retain a talented workforce, and implement business processes that ensure program integrity

In support of FDA's Strategic Priorities, a key component of NCTR's ability to respond to scientific challenges is its ability to attract and retain a talented and diverse workforce. Additionally, NCTR will maintain a culture of continual business process improvement.

Strategies for Implementation:

- Explore and utilize contract options to maximize research objectives.
- Provide professional development and training for staff and foster a culture of continuous improvement.
- Clearly link performance goals of research projects to public-health outcomes.
- Ensure transparency and communication of business processes across NCTR.
- Find opportunities to meet the sustainability goals of HHS; reducing energy consumption, and reducing costs of operations.

Objective 3.2: Develop strategies to better communicate who NCTR is and what we do

To provide clear information about how to use products to promote health or reduce harm, NCTR seeks to inform the research community about NCTR's capabilities and accomplishments.

Strategies for Implementation:

- Evaluate and improve the effectiveness of NCTR communication delivery methods.
- Identify and communicate the characteristics, impact, and value of NCTR divisions and programs.
- Individualize key messages and communication methods based on target audiences.
- Identify new platforms that can carry NCTR's message forward.
- Participate in reviewer/research meetings at FDA regulatory centers.

Appendix A: NCTR – FDA – Advancing Regulatory Science (ARS) Crosswalk

| NCTR Goal | NCTR Objective | FDA Goal | FDA Goal | FDA Goal | ARS Priority | ARS Priority | ARS Priority | ARS Priority |
|----------------------------------|---|-------------------|----------------|--|------------------------|---|--|---------------------|
| | | Enhance Oversight | Improve Access | Organizational Excellence and Accountability | Modernizing Toxicology | Evaluate Innovative Emerging Technologies | Development of Medical Countermeasures | Personalized Health |
| 1. Advance Scientific Approaches | Integrated Product Assessment | ✓ | | | ✓ | ✓ | ✓ | ✓ |
| 1. Advance Scientific Approaches | New Approaches | | ✓ | | ✓ | ✓ | ✓ | ✓ |
| 1. Advance Scientific Approaches | Personalized Medicine | | ✓ | | ✓ | ✓ | ✓ | ✓ |
| 2. Promote Global Interactions | Promote Global Interactions | ✓ | ✓ | | ✓ | ✓ | | |
| 3. Improve Administration Tools | Implement Business Processes for Program Integrity and Recruitment Strategy | | | ✓ | | | | |
| 3. Improve Administration Tools | Develop Communication Strategies | | | ✓ | | | | |

Appendix B: Strategic Goal Crosswalk: (NCTR – FDA –HHS)

