

Science Board: Science Projects Subcommittee

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Subcommittee Members

- David R. Parkinson, M.D.
- 3 other potential members currently being vetted with a range of scientific expertise

Charge to the Subcommittee

Review of each Center's projects within the FDA-designated Scientific Priority Areas, in order to assess the quality of each proposal, and its relevance to the regulatory mission of the Agency

Agency Science Priority Areas

- Rapid Detection
- Adverse Event Detection and Analysis
- Biomarkers
- Clinical Trial Design and Analysis
- Microbial Ecology and Contamination Mitigation Strategies
- Manufacturing Science
- Personalized Medicine and Nutrition

FDA Priority Areas and Projects Arranged by Center
(12/08)

CBER

Rapid Detection

- Proactive Identification, assessment, monitoring of and response to Top Priority Pathogen Threats to Blood and Tissue Supply
- Development of standards, reagents and assays to facilitate rapid response to emerging pathogens that threaten the blood and tissue supply
- Harness new science for pathogen detection to enhance prevention and response to emerging and unknown threats and to improve product quality through in-process testing and process analytic technologies

FDA Priority Areas and Projects Arranged by Center
(12/08)

CBER (continued)

Adverse Event Detection and Analysis

- Enhanced analytic capability: Develop tools to more quickly and reliably identify adverse events caused by administration of biologics

Biomarkers

- Build and apply genomics and personalized medicine to biologics safety
- Development and use of improved preclinical models to predict the safety and efficacy of cellular therapies and tissue engineered products

FDA Priority Areas and Projects Arranged by Center
(12/08)

CDER

Adverse Event Detection and Analysis

- Analysis of Drug Adverse Events Utilizing a Distributed Network

Biomarkers

- Genetic Basis of Drug Adverse Events

FDA Priority Areas and Projects Arranged by Center
(12/08)

CDRH

Rapid Detection

- Assuring the Safety of Ophthalmic Medical Devices
- New Approaches to Analyzing Chemical Contamination at Medical Device Surfaces

Adverse Event Detection and Analysis

- Adverse Event Detection, Analysis and Action: Utilizing Quantitative Analysis Techniques on Post Market Data

FDA Priority Areas and Projects Arranged by Center
(12/08)

CDRH - continued

Biomarkers

- Personalized Medicine Diagnostics Development, Review and Safety
- Computational Endpoints for Cardiovascular Device Evaluations

Clinical Trial Design and Analysis

- Clinical Trial Design and Analysis Methods to Address Barriers to Medical Device Development for Underserved Populations
- Improving Clinical Trials for Imaging Devices

FDA Priority Areas and Projects Arranged by Center
(12/08)

CFSAN

Rapid Detection

- High Throughput Technology for Identification and Characterization of Microorganisms: Field trial of IBIS Biosensor
- Rapid identification of food pathogens using high-throughput detection methods that target single-nucleotide polymorphisms (SNPs).

Microbial Ecology and Contamination Mitigation Strategies

- Ecology and Control of Salmonella on Tomatoes

Manufacturing Science

- High pressure processing as a new technology for producing safe shelf-stable foods

FDA Priority Areas and Projects Arranged by Center
(12/08)

CVM

Rapid Detection

- Simultaneous Detection and Identification of Multiple Foodborne Bacterial Pathogens Isolated from Animals and Foods by Bioplex Technology and Microarray.
- Development of Rapid Immunochemical Tests for the Detection of Banned Proteins in Animal Feed and Feed Ingredients
- Development of Next Generation Regulatory Methods

FDA Priority Areas and Projects Arranged by Center
(12/08)

CVM - continued

Adverse Event Detection and Analysis

- Data Mining and Analyses of Adverse Drug Events (ADEs)
- Impact of *Solanum elaeagnifolium* (Silverleaf Nightshade) in Ivermectin Toxicity in Horses: Rabbit Model to Determine Mechanism of Enhanced Toxicity of Ivermectin
- *Solanum elaeagnifolium*/Ivermectin Interaction (A proposed joint project between the Texas Veterinary Diagnostic Laboratory and the Center for Veterinary Medicine)

FDA Priority Areas and Projects Arranged by Center
(12/08)

CVM - continued

Manufacturing Science

- Researching New Manufacturing Technologies and Processes for Animal Drugs and Medicated Feeds. (*series of projects*)
- Study on the Impact of Nano-materials in Aquaculture

FDA Priority Areas and Projects Arranged by Center
(12/08)

NCTR

Rapid Detection

- Development of Strategic Technologies for Detection and Identification of Contaminants

Biomarkers

- Bio-Imaging: New Approaches for Safety Assessment and Toxicology.
- Nanotechnology.
- Systems Biology
- Biomarkers

Personalized Medicine and Nutrition

- Personalized Medicine and Nutrition

FDA Priority Areas and Projects Arranged by Center (12/08)

ORA

Rapid Detection

- Enhanced Preventive Analytical Capabilities
- Expansion of Forensic Chemistry Center capacity through the addition of capabilities within the ORA Laboratory Network
- Development of High Throughput Microbiology laboratories
- Science Leveraging/Collaborations
- Development of the next generation Mobile Testing Platforms (MTPs) to assist during food outbreaks in areas throughout the United States
- Expansion of FERN Chemistry and Radiological Cooperative Agreements