| Table 15: FDA Collaborations - FY 2010 = 243 | | | | | NIH Funding = $151,974,128 | | | |
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| **Collaboration Title and Link** | **Collaboration Type with Various Additional Links** | **Brief Description of Collaboration** | **HHS Participating Agencies** | **HHS Strategic Priority Alignment** | **NIH Participating Institutes/Centers/ Office of the Director** ***(Activity Submitting Office(s) Bolded)*** | **NIH Strategic Priority Alignment** | **Year Collaboration Originated** | **NIH Funding Contribution in FY 2010** |
| 3rd and 4th Annual CounterACT Network Research Symposium | Meeting/Workshop | Counter ACT is the division at NIH whose mandate is to develop medical countermeasures designed to protect the populace against chemical agents. At the meeting funded PI's presented their research and are provided guidance regarding next steps and recommendations. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | NHLBI/NIAID/ NIAMS/**NICHD**/ NIEHS/NINDS | High-throughput Technology. Translational Research. | 2007 | 0 |
| Accelerating Therapies for Rare Diseases Workshop | Meeting/Workshop | The 3-day workshop focused on FDA's regulatory requirements and the clinical trial issues that are especially relevant to rare disease and orphan products research. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. | **NINDS**/OD | High-throughput Technology. Translational Research. Regulatory Science. | 2010 | 0 |
| Adolescent Health Work Group for Healthy People 2020 | Committee/Workgroup | This ongoing workshop addresses adolescent health - a continued Healthy People 2020 topic. The committee identifies opportunities that could be implemented with existing resources, and new ideas requiring additional resources. Currently, the focus is on three current near-term priorities: (1) Enrolling eligible adolescents in Medicaid and the Children's Health Insurance Program; (2) Preventing and addressing mental disorders and promoting mental wellness in adolescents; and (3) Engaging youth. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ OS/SAMHSA | Social/Behavior Research. | **NICHD**/NIMH | Health Care Reform: Behavioral Science. | Unknown | 0 |
| Adolescent Health Working Group | Committee/Workgroup | Interagency working group established in January 2010 within the Office of the Assistant Secretary for Health as a forum for HHS agencies to share updates on adolescent health activities and address cross-cutting issues. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ IHS/SAMHSA | Social/Behavior Research. | **NIDA**/NIMH | Health Care Reform: Behavioral Science. | 2010 | 0 |
| Adolescents in HIV Biomedical Prevention Clinical Trials | Meeting/Workshop | The purpose of this meeting was to examine and discuss the desirability and timing of as well as barriers to enrollment of adolescents in the HIV Biomedical Prevention Clinical Trials. Participants included representatives from academia, industry, HIV-affected communities, and various branches of the United States government and offered an expanse of expertise covering the medical, behavioral, ethical, legal and regulatory ramifications of including or not including adolescents in biomedical prevention trials. The deliberations from this consultation formed the foundation for the special July 2010 adolescent supplement in the Journal of Acquired Immune Deficiency Syndromes (JAIDS) entitled "Inclusion of Adolescents and Young Adults in Biomedical HIV Prevention Research." | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Fast-track innovation planning and regulatory review, and Innovative Biomedical Methodologies. HIV/AIDS. Social/Behavior Research. | NIAID/**NICHD**/ NIDA/NIMH/OD | Health Care Reform: Behavioral Science and Health Disparities. | 2009 | 0 |
| Advancing Regulatory Science through Novel Research and Science-Based Technologies | Research Initiative | NIH and FDA began interagency partnership to foster regulatory science, a specialized and inter-disciplinary area of biomedical research that serves to generate new knowledge and tools for assessing experimental therapies, preventatives, and diagnostics. A key goal of this new Regulatory Science program is to accelerate the development and use of new tools, standards and approaches to efficiently develop products and to more effectively evaluate product safety, efficacy and quality. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | NINDS/**OD** | Regulatory Science. | 2009 | 0 |

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| Advancing Regulatory Science through Novel Research and Science-Based Technologies (U01) [RFA-RM-10-006] | Research Initiative | This regulatory science initiative aims to foster the development, evaluation and availability of new or improved tools, methods, standards, and applied science that support a better understanding and improved evaluation of product safety, quality, effectiveness, and manufacturing throughout the product life cycle. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Patient-centered Research, and Translate basic science into new therapies. Global Health: Innovative Biomedical Methodologies and Innovative Biomedical Technologies. Health Care Quality/Patient Safety. | NIDDK/NINDS/**OD** | Health Care Reform: Health Information Technology, Patient Safety. High-throughput Technology. Translational Research. Regulatory Science. | 2010 | 2,900,000 |
| Advising on human papillomavirus (HPV) tests | OTHER: Consulting | National Cancer Institute (NCI) scientists advised the FDA on testing for human papillomavirus (HPV) infection. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies | **NCI** | NONE | 2008 | 0 |
| Advisory Committee on HIV and STD Prevention and Treatment | Committee/Workgroup | Chartered committee to advise CDC and HRSA on HIV and Sexually Transmitted Diseases (STD) programs. | AHRQ/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Global Health: Infectious Diseases. HIV/AIDS. | **OD** | NONE | 2003 | 0 |
| Affordable and Accessible Hearing Health Care for Adults with Mild to Moderate Hearing Loss August 25-27, 2009 | Meeting/Workshop | According to Healthy People 2010, only 16 to 17 percent of adults between the ages of 20 and 69 with hearing impairment have used hearing aids, and only 25 to 29 percent of adults ages 70 and over with hearing impairment have used them. Hearing health researchers cite multiple reasons for the gulf that exists between those who need and those who have hearing aids, with cost as an important factor. Since a hearing aid's lifespan is only 4-5 years, a hearing aid wearer could spend tens of thousands of dollars on aids over his or her lifetime. In August 2009, this issue was explored during a working group sponsored by the NIDCD. The goal of the meeting was to develop a research agenda that could help increase the accessibility and affordability of hearing health care for adults with mild to moderate hearing loss. | FDA/HRSA | Accelerate Discovery to Improve Patient Care: Specific category priorities not reported. Global Health: Specific category priorities not reported. | **NIDCD** | Empowering Biomedical Research Community: Specifics not reported. Health Care Reform: Specifics not reported. | 2009 | 0 |
| AIDSinfo | OTHER: Web site | Trans-HHS Coordinating Committee for a web site of Federal prevention and treatment guidelines and HIV/AIDS clinical trial information; includes a Spanish-language complementary Web site (infoSIDA). | CDC/CMS/FDA/ HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | NIAID/**NLM**/OD | Health Care Reform: Health Information Technology. | 2002 | 0 |
| AIDSinfo/InfoSIDA | Information Clearinghouse | These English- and Spanish-language websites assist in the dissemination of the Public Health Service Treatment Guidelines. | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | **NLM** | Health Care Reform: Health Disparities. | 2002 | 500,000 |
| Alzheimer's Disease Neuroimaging Initiative | Research Initiative | To develop biomarkers of Alzheimer's Disease in elderly subjects. A major goal of the study has been to establish and validate MRI and PET images, cerebral spinal fluid, and blood biomarkers as predictors of the disease. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Innovative Biomedical Technologies. | **NIA**/NIBIB | Translational Research. | 2004 | 14,507,139 |

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| Animal Welfare and Scientific Research Symposium | Meeting/Workshop | Modeled after the first symposium on Animal Welfare and Scientific Research (AWSR) in 1984, NIH co-sponsored a two day symposium October 2010 to recognize the achievements of two and a half decades of biomedical research conducted under the U.S. Government Principles and Public Health Service Policy on the Humane Care and Use of Laboratory Animals, and the Animal Welfare Act and Regulations. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | NCI/NEI//NHGRI/ NHLBI/NIA/ NIAAA/NIAID/ NIAMS/NICHD/ NIDA/NIMH/**OD** | Translational Research. | 2010 | 30,000 |
| Annual Tribal Budget Consultations | Meeting/Workshop | In compliance with Executive Order 13175, the Secretary of HHS convened Annual Tribal Budget Consultation sessions in 8 of 10 HHS regions. Tribal Affairs, Office of Intergovernmental Affairs coordinated and executed the sessions. Accordingly, each Federal agency must have an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. While HHS and a number of its operating divisions have established a consultation process, the NIH has not established such a process. NICHD participated in the Denver session held in HHS Region 8. | ACF/AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/OSG/ SAMHSA | NONE | **NICHD** | Empowering Biomedical Research Community: Workforce Diversity. Health Care Reform: Health Disparities. | 2000 | 0 |
| Anti-Infective Drugs Advisory Committee | Committee/Workgroup | Committee provides expertise in the evaluation of evidence submitted by pharmaceutical companies to the FDA for drug approval. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NIAID** | Regulatory Science. | 2007 | 0 |
| Antiretroviral Pregnancy Registry | Committee/Workgroup | This is a registry of use of antiretroviral drugs in pregnancy that is sponsored by the various pharmaceutical companies and has a Committee of external experts and government staff from NIH, CDC and FDA. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | **NICHD** | NONE | 1989 | 0 |
| Antisense Oligonucleotide (AON) Therapies in Neuromuscular Diseases | Meeting/Workshop | This workshop will allow neuromuscular disease stakeholders to present updates in the field, develop, and promote regulatory sciences and exchange information on issues relevant to AONs. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, Translate basic science into new therapies. | NIAMS/NICHD/ **NINDS**/NHLBI | Translational Research. Regulatory Science. | 2010 | 0 |
| Assay Development Working Group Meetings | Committee/Workgroup | Invitational work group convened to discuss issues critical to the development of an assay into a robust test that can be used for clinical decision making. Discussions included use cases and approaches to safe harbors for marker development in clinical research. | CMS/FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NCI** | Translational Research. Regulatory Science. | 2009 | 0 |
| Assessment of validities for analytical protocols & prototypes for various dietary supplements (AOAC) | Research Initiative | The AOAC provides methods of analysis for which performance characteristics have been determined and tested. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Innovative Biomedical Technologies. | **OD** | Regulatory Science. | 2004 | 146,489 |

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| Asthma Outcomes Workshop | Meeting/Workshop | The NHLBI participated in a workshop, attended by federal agency representatives and asthma clinical researchers, to establish standard definitions and data collection methodologies for validated outcome measures in asthma clinical research. Standard definitions and methods would facilitate comparisons across asthma research studies and clinical trials. A secondary objective of the workshop was to identify promising outcome measures for asthma clinical research and discuss the status of their development and validation. | AHRQ/CDC/ CMS/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, and Patient-centered Research. Health Care Quality/Patient Safety. Social/Behavior Research. | **NHLBI**/NIA/ NIAID/NICHD/ NIEHS/NIMHD/NINR | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, and Health Disparities. Translational Research. | Unknown | 62,500 |
| Autism Coordinating Committee | Committee/Workgroup | The Interagency Autism Coordinating Committee (IACC) is a Federal advisory committee that coordinates all efforts within the Department of Health and Human Services (HHS) concerning autism spectrum disorder (ASD). Through its inclusion of both Federal and public members, the IACC helps to ensure that a wide range of ideas and perspectives are represented and discussed in a public forum. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Health Care Quality/Patient Safety. Pharmacogenomics. Social/Behavior Research. | NICHD/NIDCD/ NIEHS/NIMH/ NINDS/**NINR**/OD | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Disparities, and Patient Safety. Translational Research. | 2006 | 0 |
| Autoimmune Disease Coordinating Committee | Committee/Workgroup | The purpose of the ADCC is to increase collaboration and facilitate coordination of research among NIH Institutes, Centers, and Offices; other federal agencies; and private organizations and patient advocacy groups with an interest in autoimmune diseases. | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Pharmacogenomics. Social/Behavior Research. | CSR/FIC/NCCAM/NCI/ NCRR/NEI/ NHGRI/NHLBI/ NIA/NIAAA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDA/NIDCD/ NIDCR/NIDDK/ NIEHS/NIGMS/ NIMH/NINDS/**NINR** | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, and Health Disparities. High-throughput Technology. Translational Research. | 2002 | 0 |
| Bench-to-Bedside (B2B) Program | Research Initiative | An intramural Bench-to-Bedside Program was established in 1999 to integrate the work of basic and clinical scientists on the NIH campus and to foster collaborations across institutes. Since the program's beginning, more than 500 principal and associate investigators have collaborated on 176 funded projects. The Clinical Center has coordinated the program for the past 12 years. Funding for the program is provided by ICs, the Food & Drug Administration, the NIH Office of Behavioral and Social Sciences Research, the Office of AIDS Research, the Office of Rare Diseases Research, the Office of Research on Women's Health, the National Center on Minority Health and Health Disparities, the National Center for Research Resources and represents a total investment of approximately $40M. The program expanded in 2006 to encourage partnerships between intramural and extramural investigators. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Global Health: Infectious Diseases and Non-Infectious Diseases. HIV/AIDS. Nutrition/Obesity. Pain Research. Pharmacogenomics. Social/Behavior Research. | **CC**/CIT/NCI/ NCRR/NEI/NHLBI/ NHGRI/NIAAA/ NIAID/NIAMS/ NICHD/NIDA/ NIDCD/NIDCR/ NIDDK/NIEHS/ NIGMS/NIMH/ NINDS/NINR/NLM/OD | Health Care Reform: Behavioral Science and Health Disparities. Translational Research. | 2009 | 109,750 |

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| Best Pharmaceuticals for Children Act | Research Initiative | The Best Pharmaceuticals for Children Act (BPCA) Program is a major activity for the Obstetric and Pediatric Pharmacology Branch (OPPB), a component of the Center for Research for Mothers and Children at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). OPPB is responsible for developing and supporting a comprehensive national research and training effort to increase the knowledge base for understanding how to appropriately treat disease during pregnancy, infancy, and childhood using pharmaceuticals that are appropriately tested within their target populations. NICHD activities related to BPCA are intended to improve pediatric drug therapeutics through preclinical and clinical testing that lead to drug labeling changes. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health. Pharmacogenomics. | NHLBI/**NICHD**/ NIMH/OD | Health Care Reform: Patient Safety. Regulatory Science. | 2002 | 18,000,300 |
| Biannual Animal Welfare Meeting | Meeting/Workshop | The participating agencies share a common concern for the care and welfare of laboratory animals used in research and testing. Each agency, operating under its own authority, has specific responsibilities for fostering proper animal care and welfare. The biannual meetings set forth a framework for reciprocal cooperation which assists each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. The biannual meetings maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals. | FDA | NONE | **OD** | NONE | 1990 | 0 |
| Biomarkers Consortium Workshop on Qualification and Validation of Circulating Tumor Cell (CTC) Assays | Meeting/Workshop | Workshop to outline the path to qualification of biomarkers by the FDA for clinical use. Focused on the emerging science around enumeration of circulating tumor cells and their interrogation as "liquid biopsies" of tumors, as well as how to compare different platforms for measuring Circulating Tumor Cells (CTCs). | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies and Translate basic science into new therapies. | **NCI** | Translational Research. Regulatory Science. | 2010 | 0 |
| Blood Product Advisory Committee | Committee/Workgroup | The committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Global Health: Infectious Diseases and Non-Infectious Diseases. Health Care Quality/Patient Safety. HIV/AIDS. | **NHLBI** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Patient Safety. | 2006 | 0 |
| Brazil-US Working Group on Public Health (WGPH) | Committee/Workgroup | This committee formed under the US-Brazil Joint Commission on Scientific and Technological Cooperation focuses on collaboration and joint research in HIV/AIDS, neglected tropical diseases, TB, malaria, and non-transmissible chronic disease. | FDA/OS | Global Health: Infectious Diseases. | **NIAID** | Empowering Biomedical Research Community: Global Health. | 2007 | 0 |
| caBIG® Integrative Cancer Research Nanotechnology Working Group | Committee/Workgroup | The goal of this working group is to develop nanotechnology standards and guide the application of these standards in the caNanoLab nanotechnology resource. This includes developing standards for data sharing as well as standardizing terminology in nanomedicine (ontology). | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies and Translate basic science into new therapies. | **NCI**/NIBIB | Translational Research. Regulatory Science. | 2007 | 0 |
| caNanoLab | Database | caNanoLab is a data sharing portal designed to facilitate information sharing in the biomedical nanotechnology research community to expedite and validate the use of nanotechnology in biomedicine. caNanoLab provides support for the annotation of nanomaterials with characterizations resulting from physico-chemical and in vitro assays and the sharing of these characterizations and associated nanotechnology protocols in a secure fashion. | FDA | Accelerate Discovery to Improve Patient Care: Innovative biomedical technologies and Translate basic science into new therapies. | **NCI**/NIBIB/NIEHS | Health Care Reform: Patient Safety. Translational Research. Regulatory Science. | 2007 | 220,000 |

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| CBER Flow Cytometry Facility | Research Initiative | The Center for Biologics Evaluation (CBER) and FDA will provide support to the NICHD for ongoing research utilizing the CBER Flow Cytometry Facility. | FDA | NONE | **NICHD** | NONE | 2010 | 4,000 |
| Centers for Medicare & Medicaid Services (CMS) - National Institutes of Health (NIH) Interagency Coordinating Committee | Committee/Workgroup | The mission of the Centers for Medicare & Medicaid Services (CMS) - National Institutes of Health (NIH) Interagency Coordinating Committee, is to facilitate interactions between CMS and NIH on topics of mutual interest to both agencies. Through semiannual meetings, or more frequently if needed, and through regular communications, the committee links CMS and NIH officials to discuss ways that NIH research can help inform policy decisions of CMS, to keep CMS appraised of NIH's plans of upcoming clinical trials, and to discuss how CMS data can be utilized by NIH researchers. | AHRQ/CMS/FDA | Accelerate Discovery to Improve Patient Care: Specific category priorities not reported. Health Care Quality/Patient Safety. | NCI/**NCRR**/NEI/ **NHLBI**/NIA/NIDDK | NONE | 2004 | 0 |
| Chronic Fatigue Syndrome Advisory Committee (CFSAC) | Committee/Workgroup | The Chronic Fatigue Syndrome Advisory Committee (CFSAC) provides advice and recommendations to the Secretary of Health and Human Services via the Assistant Secretary for Health of the U.S. Department of Health and Human Services on issues related to chronic fatigue syndrome (CFS). These include: 1) factors affecting access and care for persons with CFS; 2) the science and definition of CFS; and 3) broader public health, clinical, research and educational issues related to CFS. | AHRQ/CDC/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Pain Research. | NCCAM/NCRR/ NCI/NHLBI/NIA/ NIAAA/NIAID/ NIAMS/NICHD/ NIDCR/NIDDK/ NIEHS/NIGMS/ NIMH/NINDS/ NINR/**OD** | Translational Research. | 2003 | 0 |
| Circulating Tumor Cells (CTCs): Emerging Technologies for Detection, Diagnosis and Treatment | Meeting/Workshop | Presented several technologies under development for assessing the number and molecular biology of CTCs. Regulatory issues were also discussed. Meeting reviewed the results of work with CTCs to that time. Organized by Cancer Biomarkers Research Program, DCP, Cancer Diagnosis Program , DCTD and SBIR, and OD NCI. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Translate basic science into new therapies. | **NCI** | Translational Research. Regulatory Science. | 2009 | 0 |
| CLIA Workshop | Committee/Workgroup | Held in conjunction with Spring 2009 Interventional Drug Steering Committee meeting. The purpose was to educate clinicians who participate in biomarker development and early phase clinical trials on the need for performance of assays in CLIA-certified laboratories when the results of those assays are used for clinical decision-making. | CMS/FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. Health Care Quality/Patient Safety. | **NCI** | Translational Research. Regulatory Science. | 2009 | 0 |
| Clinical and Translational Science Awards (CTSA) Industry Forum | Meeting/Workshop | Workshop focused on issues of intellectual property (IP) as an issue for the CTSA participants to perform clinical research by developing collaborative relationships with industry. Parallel tracks were presented with use cases that addressed multiple aspects of managing IP to get markers and treatments across the "valley of death." | CDC/FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. Health Care Quality/Patient Safety. | **NCI**/NCRR | Empowering Biomedical Research Community: Training. Translational Research. Regulatory Science. | 2010 | 0 |
| Clinical Data Acquisition Standards Harmonization (CDASH) initiative led by Clinical Data Interchange Standards Consortium (CDISC) | Committee/Workgroup | Harmonization efforts to standardize elements for data capture. | FDA | NONE | **NCI** | NONE | 2006 | 0 |
| Clinical Investigator Interagency Working Group for the Development of Antiviral Influenza Therapeutics | Committee/Workgroup | Objective: To discuss a range of issues relevant to the development of antiviral drugs for the treatment of influenza. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NIAID** | Translational Research. | 2009 | 0 |
| Clinical Proteomic Technologies for Cancer (CPTC) | OTHER: Consulting | Collaboration between FDA and NCI to accelerate proteomics technology development and application in clinical settings. FDA and NCI intend to collaborate in areas involving proteomics, such as sample collection, preparation, storage, and processing; bioinformatics and data analysis; discovery and validation of biomarkers; and surrogate biomarkers of cancer development and drug response, including standardization among technology platforms and assay standards development. | FDA | Innovative biomedical technologies | **NCI** | Translational Research. Regulatory Science. | 2008 | 0 |

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| Computational Toxicology for NIH Medications Discovery | Research Initiative | Through an Inter-Agency Agreement, the FDA provides structure-activity relationship-based toxicity predictions for compounds that are under evaluation in the NIDA Addiction Treatment Discovery Program. On a limited basis, other NIH ICs may utilize this resource by working through NIDA. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NIDA** | Translational Research. | 2002 | 100,000 |
| Conducting Comprehensive Toxicological Assessments | Research Initiative | The purpose of this Agreement is to conduct, at FDA/NCTR, comprehensive toxicological assessments on FDA priority chemicals/agents nominated to the National Toxicology Program. Studies can include range finding sub-chronic and chronic, compound-specific mechanistic studies, and consideration of the use of alternate test systems. This combination of studies is designed to facilitate the interpretation of study results in support of comprehensive quantitative human health risk assessments. The primary goal of this program is to develop a comprehensive scientific data base that can be utilized to reduce the uncertainty in risk assessment/risk benefit analysis for specific chemicals with high FDA impact. | FDA | NONE | **NIEHS** | NONE | Unknown | 14,700,000 |
| Coordinating Committee on Women's Health (CCWH) | Committee/Workgroup | The Coordinating Committee on Women's Health (CCWH) advises the Assistant Secretary for Health on current and planned activities across HHS that safeguard and improve the physical and mental health of women and girls. | ACF/AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/OSG/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. Nutrition/Obesity. Pain Research. Social/Behavior Research. Tobacco Prevention and/or Control. | **OD** | Empowering Biomedical Research Community: Budgets and Workforce Diversity. Health Care Reform: Behavioral Science, Health Information Technology, and Health Disparities. Translational Research. | 1990 | 0 |
| Council on Emergency Medical Care | Committee/Workgroup | Provides strategic and operational support to the HHS Emergency Care Coordinating Committee (ECCC) through policy-level guidance and interdepartmental and interagency collaboration for ongoing and future Federal efforts that address daily emergency medical care issues in the US. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. Health Care Quality/Patient Safety. | NCRR//NHLBI/ NICHD/NIGMS/ NIMH/**NINDS** | Health Care Reform: Patient Safety. | 2008 | 0 |
| Countermeasures Against Chemical Threats (CounterACT) Research Network Annual Symposium | Meeting/Workshop | This workshop was organized by NINDS as part of the Countermeasures Against Chemical Threats (CounterACT) Research Network, a group formed to conduct basic, translational, and clinical research aimed at the discovery and/or identification of better therapeutic and diagnostic medical countermeasures against chemical threat agents. The 3-day meeting allowed researchers to share information, encouraged collaboration, and enabled NIH staff to evaluate the group's progress on themes such as nerve agents, seizure detection technology, cyanide, and sulfur mustard. | CDC/FDA/OS | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. | NEI/NIAID/ NIAMS/NICHD/ NIEHS/NIGMS/**NINDS** | High-throughput Technology. Translational Research. | 2006 | 255,404 |
| DailyMed | OTHER: Content services | DailyMed provides high quality information about marketed drugs, including FDA labels (package inserts). The Web site provides health information providers and the public with a standard, comprehensive, up-to-date, look-up and download resource of medication content and labeling as found in medication package inserts. NLM provides this DailyMed a public service, free of advertising. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Global Health: Strategic Initiative. Health Care Quality/Patient Safety. | **NLM** | Health Care Reform: Health Information Technology and Patient Safety. | 2005 | 0 |

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| Data Mining on FDA's 510K Documents for Laboratory Tests | Research Initiative | U.S. Food and Drug Administration (FDA) provides a large corpus of text about decision summaries on the applications for in vitro diagnostic (laboratory) products. This corpus of text contains valuable information about the nature of laboratory testing devices and test products such as analyte and specimen names that are tested, unit of measures, and analyze detection limits of the presented devices and products. The goal is to recognize and extract this information algorithmically from the FDA's 510 thousdand doucments, and have it placed into the Logical Observation Identifers Names and Codes (LOINC) database manually. | FDA | NONE | **NLM** | Health Care Reform: Health Information Technology. | 2009 | 0 |
| Demand Reduction Interagency Working Groups | Committee/Workgroup | To encourage greater cross-talk and Agency participation in developing the National Drug Control Strategy, ONDCP reconstituted its demand reduction workgroups focusing on prevention, emerging threats, healthcare delivery, justice systems, military veterans and their families, and performance and accountability measures. NIDA staff have participated in all of these working groups. | CDC/FDA/HRSA/ OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Early Childhood Health/Development. Pain Research. | NIAAA/**NIDA** | NONE | 2009 | 0 |
| Determination of the safety for various dietary supplements | Research Initiative | Conduct evidence-based reviews of the efficacy and safety of dietary supplements | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | **OD** | Health Care Reform: Patient Safety. Regulatory Science. | 2004 | 74,500 |
| Development of In-Vitro Assays to Assess the Potency of Botulinum Neurotoxin Type A | Research Initiative | This Funding Opportunity Announcement (FOA) encourages Small Business Innovation Research (SBIR) grant applications from small business concerns (SBCs) that propose to develop new non-animal-based assays to assess the potency of botulinum neurotoxin type A (BoNT/A) in a Good Manufacturing Practice (GMP) commercial environment. (STTR [R41/R42]) [PA-09-178], (SBIR [R43/R44]) [PA-09-179] | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Innovative Biomedical Technologies | NIAID/**NINDS** | Translational Research. Regulatory Science. | 2010 | 0 |
| Development of Standards of Care Regulations for Sanctuary Chimpanzees Committee | Committee/Workgroup | Development of Standards of Care Regulations for Sanctuary Chimpanzees. | ATSDR/FDA | NONE | **NCRR**/OD | NONE | 2002 | 0 |
| Diabetes Mellitus Interagency Coordinating Committee (DMICC) | Committee/Workgroup | The DMICC facilitates cooperation, communication, and collaboration on diabetes among these government entities. DMICC meetings, held several times a year, help members identify emerging issues and opportunities and develop ways in which different government components can work together and build upon each other's expertise and resources. This approach helps ensure that federal diabetes activities are coordinated and not duplicated, as well as stimulates collaborations where appropriate. | AHRQ/CDC/ CMS/FDA/ HRSA/IHS/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Nutrition/Obesity. Pharmacogenomics. Social/Behavior Research. | CSR/NCCAM/ NCRR/NEI/ NHLBI/NHGRI/ NIA/NIAAA/ NIAID/NIBIB/ NICHD/NIDA/ NIDCD/NIDCR/ NIDDK/NIEHS/ NIGMS/NIMH/ NIMHD/NINDS/ **NINR**/NLM/OD | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, and Health Disparities. Translational Research. High-throughput Technology. | 1974 | 0 |
| Dietary Supplements Federal Workgroup | Committee/Workgroup | The ODS Federal Workgroup meets quarterly to review Guidelines for Dietary Supplements (botanics, probiotics/prebiotics; vitamins) reference standards. Collaborative initiatives, state of the science topics, conferences, and workshop are also discussed. | AHRQ/CDC/FDA/ HRSA/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Global Health: Strategic Initiative. Health Care Quality/Patient Safety. Nutrition/Obesity. | **NCCAM**/NCI/ NCRR/NHLBI/ NIDDK/NIEHS | Health Care Reform: Patient Safety. Regulatory Science. | 2008 | 0 |

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| Dietary Supplements Ingredient Database (DSID) | Database | The database provides statistical estimates—based on chemical analysis—of the nutrient content of selected ingredients in dietary supplements, compared with label-reported ingredient levels. Currently the DSID provides estimated levels of 18 vitamin and mineral ingredients derived from analytical data for 115 representative unspecified adult multivitamin/multimineral supplements (MVMs). Additional dietary supplement ingredients will be included in future releases of the database. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | NCI/**OD** | Health Care Reform: Health Information Technology. Regulatory Science. | 2002 | 1,400,000 |
| Diet-induced hypomethylation in preneoplastic liver | Research Initiative | Research to examine the activity of epigenetic mechanisms as factors that predetermine individual susceptibility to development of hepatocellular carcinoma and to investigate dietary manipulations that may impact these events during preneoplasia. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NCI** | Translational Research. | 2004 | 80,000 |
| Domestic Scheduling to Control New Drugs of Abuse, with NIDA-Funded Testing Conducted in Support of DEA Scheduling Recommendations to the FDA | Research Initiative | HHS depends upon NIDA contracts to generate the in vitro and animal behavioral data that are required to support the domestic scheduling of new street drugs. The long-standing agreement is that DEA provides the drugs (or the funds to cover drug synthesis) to NIDA, and NIDA covers the cost of pharmacological testing. | FDA/OS | NONE | **NIDA** | NONE | Unknown | 400,000 |
| Dominantly Inherited Alzheimer's Network (DIAN): International network for the identification, evaluation, and follow up of families with early onset dominantly inherited Alzheimer's Disease | Research Initiative | To set up an international network consisting of a consortium of scientific investigators that will have the responsibility to identify, recruit, evaluate, and follow-up individuals from families with early onset dominantly inherited Alzheimer's disease [i.e., families with the amyloid precursor protein (APP), presenilin 1 (PS1), and presenilin 2 (PS2) mutations or duplications or others still to be discovered]. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Innovative Biomedical Methodologies. | **NIA** | Translational Research. | 2008 | 3,119,594 |
| Effective Health Care Program Issue Exploration Forum on Developmental Disabilities and Cerebral Palsy | Meeting/Workshop | The Agency for Healthcare Research and Quality's (AHRQ) Effective Health Care (EHC) Program hosted an Issue Exploration Forum on Developmental Disabilities with a focus on Cerebral Palsy on Tuesday, October 26, 2010. This Forum presented an opportunity to provide input to the EHC Program on future research related clinical and decision dilemmas for cerebral palsy. Participants assisted with identifying and prioritizing potential research topics to address key evidence gaps in the current state of the research. Series of meetings to draft report on future research directives for cerebral palsy. | AHRQ/FDA/HRSA | Early Childhood Health/Development. Social/Behavior Research. | CC/**NICHD**/NINDS | NONE | 2010 | 0 |
| Emergency Medical Services for Children | Committee/Workgroup | The Federal EMSC Program is designed to ensure that all children and adolescents, no matter where they live, attend school, or travel, receive appropriate care in a health emergency. | AHRQ/AoA/CDC/ FDA/HRSA/IHS/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Social/Behavior Research. | NHLBI/NIAAA/ NIAID/NIBIB/ NICHD/NIDA/ NIGMS/NIMH/ **NINDS/NINR** | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, Health Disparities, and Patient Safety. Translational Research. | 2003 | 0 |
| Endocrinologic and Metabolic Drugs Advisory Committee | Committee/Workgroup | Committee provides expertise in the evaluation of evidence submitted by pharmaceutical companies to the FDA for drug approval. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NIAID** | Regulatory Science. | 2003 | 0 |
| Enhancing Peer Review Initiative | Committee/Workgroup | NIH and agency partnership stakeholders worked in collaboration to integrate all OPDIVs into the Enhancing Peer Review effort; including individual meetings with AHRQ to integrate the initiative into their FOAs and issue a Guide Notice. | AHRQ/CDC/FDA | NONE | **OD** | NONE | 2009 | 0 |

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| Evaluation of growth and cardiovascular function in male rhesus monkeys (macaca mulatta) chronically exposed to methylphenidate hydrochloride (MPH) | Research Initiative | This IAA is a supplement to a prior IAA between NICHD and FDA that addresses the increasing documentation of drugs causing acute and delayed onset of cardiomyopathy. Specifically, the coupling of fatal arrhythmias in children receiving methylphenidate with the findings of evidence of dose related mitochondrial damage from the same drug warrants further investigation. | FDA | Early Childhood Health/Development. Health Care Quality/Patient Safety. | **NICHD** | Health Care Reform: Patient Safety. | 2010 | 529,244 |
| Evaluation of Patient Reported Outcomes Following LASIK Surgery. | Research Initiative | This will be a prospective, questionnaire-based study conducted by the U.S. Navy Refractive Surgery Center San Diego in collaboration with the U.S. Food and Drug Administration's Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices. The primary purpose is to quantify the satisfaction and health related quality of life of 500 active duty patients over a period of six months following state-of-the-art laser in situ keratomileusis (LASIK). The questionnaire to be used will be a new instrument which, once validated in this study, might be employed in future clinical studies that include civilian refractive surgery centers in the U.S. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. | **NEI** | Health Care Reform: Patient Safety. | 2009 | 54,089 |
| Evidence based Review - Probiotic Safety | OTHER: Evidence based review initiative | In 2008, the ODS, NCCAM and FDA/CFSAN initiated a systematic review through the AHRQ to evaluate the evidence for safety of probiotics. The collaboration has consisted of intellectual exchange of knowledge expertise and appropriate guidance during monthly teleconferences. | AHRQ/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Global Health: Strategic Initiative. Health Care Quality/Patient Safety. | **NCCAM**/OD | Health Care Reform: Patient Safety. Regulatory Science. | 2008 | 42,000 |
| Family Smoking Prevention and Tobacco Control Act National Longitudinal Study | OTHER: Research resource | This longitudinal study aims to evaluate the behavioral and health impact of the 2009 Family Smoking Prevention and Tobacco Control Act, which gives the FDA authority to regulate tobacco products. | CDC/FDA | Tobacco Prevention and/or Control. | NCI/NHLBI/ NICHD/**NIDA**/NIEHS/ OD | Regulatory Science. | 2010 | 0 |
| FDA Workshop: Issues in the Design of Clinical Trials of Aerosolized Antimicrobials for the Treatment of Cystic Fibrosis | Meeting/Workshop | The purpose of the workshop was to discuss the scientific data addressing key issues in the optimal design of clinical trials to evaluate aerosolized antimicrobials for the treatment of patients with cystic fibrosis. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research and Translate basic science into new therapies. | **NHLBI** | Translational Research. Regulatory Science. | Unknown | 0 |
| Federal Collaboration on Health Disparities Research (FCHDR) | Committee/Workgroup | The FCHDR is sponsored by the Office of Minority Health, Assistant Secretary for Health, Office of the Secretary, HHS. The FCHDR was established to increase effective and efficient communications across federal agencies. The current participants are ACF, CDC, DOE, DOT, DVA, EPA, HRSA, HUD, IHS, NIH, NIDRR, NSF, OS/OMH/DHHS, and SAMHSA. | ACF/AoA/AHRQ/ CDC/FDA/HRSA/ IHS/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Fast-track innovation planning and regulatory review, and Patient-centered Research. Early Childhood Health/Development. Health Care Quality/Patient Safety. HIV/AIDS. Nutrition/Obesity. Social/Behavior Research. Tobacco Prevention and/or Control. | NCI/NHLBI/NIAID/ NICHD/NIDA/ **NIMH**/NIMHD/NINR | Empowering Biomedical Research Community: Workforce Diversity. Health Care Reform: Behavioral Science, Health Information Technology, Health Research Economics, and Health Disparities. | 2006 | 0 |

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| Federal HIV/AIDS Web Council (AIDS.gov) | Committee/Workgroup | A trans-agency planning group that manages the activities for AIDS.gov, a web site designed to provide access to Federal HIV/AIDS information through a variety of new media channels, and supports the use of new media tools by Federal and community partners to improve domestic HIV programs serving minority and other communities most at-risk for, or living with, HIV. | CDC/CMS/FDA/ HRSA/IHS/OS/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | NCI/NIAID/NIDA/NLM/ **OD** | NONE | 2006 | 0 |
| Federal Interagency Working Group on Vitamin D | Committee/Workgroup | Workgroup supports research on the importance of vitamin D for health. For instance, the ENG Branch funds research on safe and effective levels of vitamin D intake for newborn infants and for women during pregnancy and lactation, with a particular focus on health disparities in the prevalence and impact of vitamin D deficiency in the United States. | AHRQ/CDC/FDA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Nutrition/Obesity. | **NEI** | NONE | Unknown | 0 |
| Federal Liaison Group on Asthma (FLGA) | Committee/Workgroup | The FLGA is committed to achieving and maintaining effective coordination that respects the unique contributions of individual agencies, facilitates exchange of information to avoid duplication, enables identification of opportunities for collaboration, and ensures that consistent messages about asthma are developed and disseminated. Much coordination of federal asthma activities already exists, and plans for expansion are under way. The FLGA will continue to explore current and planned asthma activities in greater depth in each of the five goal areas and seek new opportunities for interagency coordination and collaboration. | ACF/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Social/Behavior Research. Tobacco Prevention and/or Control. | NHLBI/NIAID/ NIEHS/NIMH/ **NINR**/NLM | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, and Health Disparities. Translational Research. | 2003 | 0 |
| Federal mHealth Collaborative | Committee/Workgroup | Federal working group of agencies interested in mHealth technology and its potential for enhancing health care | AHRQ/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. Health Care Quality/Patient Safety. Social/Behavior Research. | NHLBI/NIDA/**OD** | Health Care Reform: Health Information Technology. | 2010 | 0 |
| Federal Partners in the Gulf Long-Term Follow-up (GuLF) Study Working Group | Committee/Workgroup | The Federal Partners in the Gulf Long-Term Follow-up (GuLF) Study Working Group is an interagency group of Federal agencies responding to potential health effects of the Deepwater Horizon oil spill disaster. The working group was convened to provide input on the design and conduct of the Gulf Long-Term Follow-up (GuLF) study, a longitudinal study of oil spill clean-up workers led by the National Institute of Environmental Health Sciences with support from the NIH Common Fund, NIH OD and BP. Working group members share ideas on ways to maximize interagency efficiency and effectiveness by working collaboratively on areas of common interest and sharing data and samples collected by their agencies, they identify data collection needs that could be met by the GuLF study rather than duplicate surveys to the same population, and they identify agency resources that could be brought together to improve the GuLF study. Scientific oversight for the study is provided by the National Academy of Science's Institute of Medicine. | ACF/ATSDR/ CDC/CMS/FDA/ HRSA/OS/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Social/Behavior Research. | CIT/NHGRI/ NIEHS/NIMH/NLM/**OD** | Health Care Reform: Behavioral Science and Health Disparities. Translational Research. | 2010 | 1,000,000 |

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| Federal Partners Senior Workgroup for Mental Health Transformation | Committee/Workgroup | The workgroup is the direct result of President's Bush's New Freedom Initiative, which included 10 proposals designed to "tear down the barriers that face Americans with disabilities," This workgroup provides a forum for brainstorming ideas for improving the nation's mental health. Initiatives are collated, coordinated, streamlined and presented to the interagency steering committee for further discussion and possible implementation. | ACF/AoA/AHRQ/ CDC/CMS/FDA/ HRSA/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. | **NIDA**/NIMH | Health Care Reform: Health Information Technology, Health Research Economics, and Health Disparities. | 2008 | 0 |
| Federal Working Group on Bone Diseases | Committee/Workgroup | Serves to develop and foster collaborative activities among the government agencies in bone diseases. | AHRQ/CDC/CMS/ FDA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Global Health: Non-Infectious Diseases. | NCCAM/**NCI/** NCR/NIA/NIAAA/ **NIAMS**/NIBIB/ NICHD/**NIDCR/** NIDDK/NIEHS/NINR | Empowering Biomedical Research Community: Global Health. Health Care Reform: Comparative Effectiveness Research and Patient Safety. Translational Research. | 1993 | 0 |
| Federal Working Group on Dietary Supplements | Committee/Workgroup | Interagency committee organized by the NIH Office of Dietary Supplements as a communication forum for those agencies with an interest in dietary supplement research. | AHRQ/CDC/FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | CSR/FIC/NCCAM/NCI/ NHLBI/NIA/ NIAAA/NIAMS/ NICHD/NIDA/ NIDCD/NIDDK/ **NIEHS**/NIGMS/ NIMH/NINDS/OD | Health Care Reform: Patient Safety. | 2005 | 0 |
| Fetal Pulse Oximetry Trial (FOX) | Research Initiative | This randomized clinical trial tested the hypothesis that the use of fetal pulse oximetry, used in addition to conventional electronic fetal heart rate monitoring, reduces the rate of cesarean delivery. | FDA | NONE | **NICHD**/OD | NONE | 2001 | 0 |
| FIREBIRD (Federal Investigator Registry of Biomedical Information Research Data) | Information Clearinghouse | An agreement has been reached by the FDA and the NCI to manage and share information about clinical investigators using the Federal Investigator Registry of Biomedical Information Research Data, or FIREBIRD, system. Drug makers are encouraged to also submit information about investigators electronically to the new registry. FIREBIRD is the first module of an expected suite of software programs that will compose a system called the Clinical Research Information Exchange (CRIX). CRIX is intended to support the biomedical and biopharmaceutical research community by streamlining the document and data exchange process. The resulting reduction of paperwork is expected to increase the efficiency and lower the cost of conducting clinical trials. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. | **NCI** | Health Care Reform: Health Information Technology. | 2004 | 1,429,546 |
| Food Allergy Guideline Coordinating Committee | Committee/Workgroup | The NIAID Food Allergy Guideline Coordinating Committee oversees the process of guidelines development, to provide advice to NIAID throughout the process, to review the guidelines draft(s), and to disseminate the final version of the guidelines. Coordinating Committee members are professional organizations, advocacy groups, and Federal agencies who appoint one or more representatives to serve on the committee. Each organization, group, or agency holds a single voting position on the committee. | AHRQ/CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Patient-centered Research, and Translate basic science into new therapies. Health Care Quality/Patient Safety. Nutrition/Obesity. | NHLBI/NIDDK/**NINR** | Health Care Reform: Patient Safety. Translational Research. | 2008 | 0 |
| Food and Drug Administration Amendments Act (FDAAA) ClinicalTrials.gov Working Group | Committee/Workgroup | Collaborative effort between various NIH OD offices and FDA to implement the Food and Drug Administration Amendments Act of 2007 (FDAAA) | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | CC/NLM/**OD** | Health Care Reform: Patient Safety. | 2007 | 0 |

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| Function of HIV-1 capsid protein in virus assembly and early postentry events | Research Initiative | This research has been focused on the role of the HIV-1 capsid protein (CA) in early post-entry events, a stage in the infectious process that is still not completely understood. The results obtained thus far indicate that the linker region of CA is essential for proper CA structure and function and contributes to modulation of core stability. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. Global Health: Infectious Diseases. | **NICHD** | Empowering Biomedical Research Community: Global Health. | 2006 | 0 |
| Glaucoma Clinical Trial Design and Endpoints Symposium: Measures of Structural Change and Visual Function | Meeting/Workshop | Conference aims were to develop definitions and standards for describing structural changes in the glaucomatous optic nerve and functional changes in vision, as criteria for approval of new glaucoma therapeutics in clinical trials. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review and Translate basic science into new therapies. | **NEI** | Translational Research. | 2009 | 575 |
| Global Health Initiative (GHI) Research Committee | Committee/Workgroup | The GHI Research Committee, of which Francis Collins is the Chair, was formed to facilitate the integration, synergy, and strategic alignment of USG research and technical guidance in support of reaching the GHI's targets through identifying and implementing evidence-based interventions. The GHI Research Committee's purpose is to advance the utilization and application of existing knowledge and integrated coordinated USG research to support GHI Principle #7, "Research and Innovation", in the implementation and advancement of the GHI's strategic goals. | CDC/FDA/HRSA/ OS | HIV/AIDS. Social/Behavior Research. | **FIC**/NIAID/NICHD/OD | Empowering Biomedical Research Community: Global Health. | 2010 | 0 |
| Glycomics/Glycoscience Needs | Meeting/Workshop | Meeting held in March 16, 2010, on the NIH Campus with NIST, the FDA, and other NIH Institutes to discuss the field of glycomics and how to work together to meet the needs/challenges for this emerging field. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. | NCI/NHLBI/NIAID/ NIDCR/**NIGMS**/NCRR | High-throughput Technology. | 2010 | 0 |
| Glycosciences Research Day | Meeting/Workshop | The NIH Glycobiology Interest Group, with support from other NIH institutes and departments, and the FDA holds a one-day event to explore Glycosciences in an effort to promote collaborative communication and interaction among intramural laboratories. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review and Innovative Biomedical Methodologies. | **NIGMS** | NONE | 2008 | 0 |
| Guide to Grants and Contracts | Information Clearinghouse | The NIH Guide to Grants and Contracts is the official publication for NIH medical and behavioral grant policies, guidelines and funding opportunities, and is used by other HHS Agencies to disseminate FOAs to its 50,000 subscribers. | AHRQ/CDC/FDA | Accelerate Discovery to Improve Patient Care: Specific category priorities not reported | CIT/CSR/**OD** | Empowering Biomedical Research Community: Specifics not reported. | 2007 | 0 |
| Guidelines for Prevention and Treatment of HIV Related Opportunistic Infections in Adults and Adolescents | OTHER: Professional education to inform health care providers and patients about optimal standard of care | In 1987, CCMD recognized the need for national guidelines on HIV management. The initial guideline focused on prevention and treatment of pneumocystis pneumonia. This was followed by guidelines on mycobacterium avium and then on all opportunistic infections. In 1995 both CDC and the Infectious Diseases Society of America were brought in as partners. Since then these guidelines have been revised many times, widely disseminated in print and on the web, and are the global standard for care. These have been funded by OAR. | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | **CC** | Translational Research. | 1987 | 0 |
| Guidelines for Prevention of Mother to Child HIV Transmission; Guidelines for Pediatric Antiretroviral Treatment; Guidelines for Adult Antiretroviral Treatment; Guidelines for Prevention and Treatment of Opportunistic Infections in Adults; Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Exposed and Infected Children | Committee/Workgroup | These are separate Working Groups for development of U.S. guidelines related to HIV infection an its treatment. These Working Groups are composed of external experts in the various areas covered as well as federal agency representatives, including CDC, HRSA, and FDA. | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Infectious Diseases. HIV/AIDS. | **NICHD**/NIAID | NONE | 1998 | 0 |

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| Gulf Oil Spill Interagency Coordination for issues involving toxicology, health effects, and research | Committee/Workgroup | Facilitate information exchange and coordination among federal agencies with regards to understanding the toxicity and health effects associated with the Gulf oil spill exposures among workers and affected communities. | ATSDR/CDC/ CMS/FDA/ HRSA/OS/OSG/ SAMHSA | NONE | NCR/**NIEHS**/ NIMH/NLM | NONE | 2010 | 0 |
| Health Literacy Work Group | Committee/Workgroup | This work group meets several times a year and works to promote health literacy within the government for the benefit of the general population. | AoA/AHRQ/CDC/ FDA | Early Childhood Health/Development. | NCI/NEI/NHLBI/ NHGRI/**NICHD/** NIDCR/NIDA/NLM | Health Care Reform: Health Disparities. | 2007 | 0 |
| Health Resources and Services Administration Interagency Working Group on Hematopoietic Stem Cell Transplantation | Committee/Workgroup | The working group advises the DHHS Secretary and the HRSA Administrator on the activities of the C. W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program. | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Health Care Quality/Patient Safety. | **NHLBI** | Health Care Reform: Patient Safety. | 2006 | 0 |
| Healthy People 2010/2020 | Committee/Workgroup | Healthy People 2010 provides a framework for prevention for the Nation. It is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats. | ACF/AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | NCI/NEI/NHLBI/ NIAAA/NIAID/ **NIAMS/**NICHD/ NIDA/NIDCD/ NIDCR/NIDDK/ NIEHS/NIMH/ NINDS/OD | Empowering Biomedical Research Community: Specific category priorities not reported. Health Care Reform: Health Information Technology. Translational Research. | 2000 | 0 |
| Healthy People 2020 | Committee/Workgroup | Healthy People provides science-based, 10-year national objectives for promoting health and preventing disease. Since 1979, Healthy People has set and monitored national health objectives to meet a broad range of health needs, encourage collaborations across sectors, guide individuals toward making informed health decisions, and measure the impact of our prevention activity. Currently, Healthy People 2010 is leading the way to achieve increased quality and years of healthy life and the elimination of health disparities. Healthy People 2020 is currently assessing the objectives of the past decade, measuring the impact of its prevention activity, and developing new 10-year targets. | AHRQ/ATSDR/ CDC/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Patient-centered Research. Social/Behavior Research. | NCI/NEI/NHLBI/ NIA/NIAAA/ NIAID/NIAMS/ **NICHD**/NIDA/ **NIDCD**/NIDCR/ NIDDK/NIEHS/ NIGMS/NIMH/ NIMHD/NINDS/ NINR/NLM/OD | Empowering Biomedical Research Community: Specific category priorities not reported. Health Care Reform: Health Disparities. High-throughput Technology. Translational Research | 2008 | 0 |
| Healthy People 2020 - Blood Diseases, Disorders, and Safety | Committee/Workgroup | The purpose of this agreement is to support development and implementation of survey questions and measures to assess progress made toward the achievement of the Healthy People 2020 national objectives for blood diseases/disorders and safety. | CDC/FDA/HRSA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, and Patient-centered Research. Health Care Quality/Patient Safety. Social/Behavior Research. | **NHLBI** | Empowering Biomedical Research Community: Training. Health Care Reform: Comparative Effectiveness Research, Behavioral Science, and Health Disparities. | 2009 | 0 |
| HHS Behavioral Health Coordinating Committee | Committee/Workgroup | This is an HHS-wide committee to coordinate and collaborate on behavioral health issues. NIMH and the ASPA are co-leads of the subcommittee for communications. | ACF/AoA/AHRQ/ CDC/CMS/FDA/ HRSA/IHS/OS/ OSG/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Social/Behavior Research. | NIAAA/NIDA/**NIMH** | Health Care Reform: Behavioral Science. | Unknown | 0 |
| HHS Biovigilance Committee | Committee/Workgroup | Develop systems for reporting adverse events resulting from blood transfusion or donation. | CDC/CMS/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. | **CC/**NHLBI | Health Care Reform: Health Information Technology and Patient Safety. Regulatory Science. | Unknown | 0 |

| Table 15: FDA Collaborations - FY 2010 = 243 | | | | | NIH Funding = $151,974,128 | | | |
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| HHS Blood, Organ, and Tissue Safety Committee (BOTSEC) | Committee/Workgroup | Advises Asst. Secretary on issues related to blood safety and availability and scientific and policy issues regarding blood safety and organ transplantation. | CDC/CMS/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Health Care Quality/Patient Safety. HIV/AIDS. | **CC**/NHLBI | Health Care Reform: Patient Safety. Regulatory Science. | 1997 | 0 |
| HHS Data Council | Committee/Workgroup | Coordinates all health and human services data collection and analysis activities of the Department of Health and Human Services, including an integrated data collection strategy, coordination of health data standards and health and human services and privacy policy activities. | AHRQ/CDC/ CMS/FDA/ HRSA/IHS/OS/ SAMHSA | NONE | **NIA**/NIMH | NONE | 2005 | 0 |
| HHS Health Literacy Working Group | Committee/Workgroup | This Workgroup is comprised of various HHS agencies that work towards meeting the Department's prevention goals and to accomplish the Healthy People 2010 Objective: Improve the health literacy of persons with inadequate or marginal literacy skills | ACF/AoA/AHRQ/ CDC/CMS/FDA/ HRSA/IHS/OS/ OSG | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Health Care Quality/Patient Safety. | NCI/**NEI**/NLM/OD | Health Care Reform: Health Disparities. | 2006 | 0 |
| HHS HIV/AIDS Management Team | Committee/Workgroup | Representatives of HHS agencies coordinate HIV/AIDS research across HHS. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ IHS/OS/OSG/ SAMHSA | HIV/AIDS. | CC/CSR/FIC/ NCCAM/NCI/ NCRR/NEI/ NHLBI/NHGRI/ NIA/NIAAA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDA/NIDCD/ NIDCR/NIDDK/ NIEHS/NIGMS/ NIMH/NIMHD/ NINDS/NINR/NLM/**OD** | NONE | 1982 | 0 |
| HHS National Strategy Group | Committee/Workgroup | OAR participates in the HHS Leadership Group to develop the HHS operational plan for the President's National HIV/AIDS Strategy. | ACF/AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/OSG/ SAMHSA | HIV/AIDS. | NIAID/**OD** | Health Care Reform: Health Disparities. | 2010 | 0 |
| HHS Outreach and Messaging Working Group, part of the HHS Steering Committee for the Prevention of Healthcare-Associated Infections | Committee/Workgroup | This working group is developing and implementing several promotional activities to raise awareness and improve behaviors to reduce healthcare-associated infections (HAI). Activities include dissemination of HAI prevention information at nation-wide conferences/events during 2010, development of an HAI website to provide information and resources and development of a web-based training program on HAI prevention and include launch of a media campaign on prevention of HAI in October 2010. | AHRQ/CDC/ CMS/FDA/IHS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Health Care Quality/Patient Safety. | **CC**/NIAID/OD | Health Care Reform: Patient Safety. | 2008 | 0 |
| ICARE: Interagency Collaborative to Advance Research in Epilepsy | Committee/Workgroup | The purpose of this group, which is led by the National Institute of Neurological Disorders and Stroke, is to increase communication among institutes and agencies sponsoring epilepsy-related research and explore opportunities for increased coordination. | CDC/FDA | NONE | NCRR/NHLBI/ **NIA**/NIAAA/ NIAMS/NIBIB/ NICHD/NIDA/ NIGMS/NIMH/ NINDS/NINR | NONE | 2003 | 0 |

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| ICARE: Interagency Collaborative to Advance Research in Epilepsy | Committee/Workgroup | ICARE: Interagency Collaborative to Advance Research in Epilepsy is an expansion of the Interagency Epilepsy Group to include broader representation across NIH and other agencies, as well as members from the research and patient advocacy communities. The committee's primary focus will be on biomedical research. Future annual meetings will provide a forum for sharing information about ongoing and planned epilepsy research activities, highlighting advances and discussing needs and opportunities, and promoting increased collaboration toward common research goals. | AHRQ/CDC/FDA/ HRSA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Global Health: Non-Infectious Diseases and Strategic Initiative. Pharmacogenomics. Social/Behavior Research. | FIC/NCRR/ NHGRI/NHLBI/ NIA/NIAAA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDA/NIGMS/ NIMH/**NINDS**/NINR | Empowering Biomedical Research Community: Global Health. Health Care Reform: Comparative Effectiveness Research and Behavioral Science. High-throughput Technology. Translational Research. | 2010 | 23,100 |
| Image-guided Interventional Therapeutics | Research Initiative | This collaboration will lead to safer and more effective treatment planning and performance of image-guided interventions and therapeutic drug delivery. The results of all of these studies of image guided interventions and related technologies and the models used to study them will have a direct impact on the effectiveness and consistency of the FDA CDRH's preclinical review of device applications while meeting the primary research goal of optimizing image guided interventions and pre-clinical modeling of those interventions. Regulatory science and translational therapeutics have overlapping goals when it comes to drugs + devices combination therapies. | FDA | NONE | **CC**/NCI/NIAID/NIBIB | Translational Research. | 2004 | 100,000 |
| Imaging Database Resource Initiative (IDRI) | Database | Public resource of CT and X-ray images of the lung for the purpose of testing methods for detection and classification of lung cancer. The resource is an extension of the LIDC database supported by the FNIH. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies and Patient-centered Research. | **NCI/**NIBIB | Translational Research. Regulatory Science. | 2004 | 0 |
| Improving Technical Standards and Molecular Tools for Probiotics Research and Development | Research Initiative | In 2008, the USDA Agricultural Service initiated a Memorandum of Understanding (MOU) with NCCAM to exchange expertise in technology development and partner research initiatives to advance the field of probiotic biology and role in human health. The MOU consists of a five year plan defining common mission goals; expected benefits from the exchange of research expertise and resources; and demonstration projects based on NIH/NCCAM funded U01 cooperative agreements. The long-term goal of the MOU is to develop trans-agency networked initiatives. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public/Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Global Health: Strategic Initiative. Health Care Quality/Patient Safety. Nutrition/Obesity. | **NCCAM** | Health Care Reform: Patient Safety. High-throughput Technology. Regulatory Science. | 2008 | 100,000 |

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| Inter-Agency Agreement for Technology Transfer | OTHER: Technology transfer | The NIH Office of Technology Transfer (OTT) oversees patent prosecution, markets inventions, executes and monitors licensing agreements, and administers royalties for the FDA Intramural Research Program. NIH and FDA share a common interest in assuring that those employee inventions which pertain to the public health and conform to patent policy, are patented, marketed and commercialized responsibly. These patenting and licensing activities contribute to maximizing the public's investment in Federal health research. | FDA | Alternate Discovery to Improve Patient Care: Disseminate health information to the public. Global Health: Strategic Initiative. | NIAID/**OD** | NONE | 1988 | 0 |
| Interagency Animal Management Committee | Committee/Workgroup | Reviews experimental protocols for use of federally funded chimpanzees. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Translate basic science into new therapies. Global Health: Infectious Diseases. HIV/AIDS. | NCRR/NHLBI/**OD** | NONE | 1987 | 0 |
| Inter-Agency Animal Models Committees (IAMC) | Committee/Workgroup | Reviews requests for use of chimpanzees in research projects funded by NIH. | CDC/FDA | Global Health: Infectious Diseases. | **NCRR**/OD | Empowering Biomedical Research Community: Specifics not reported. | 2009 | 0 |
| Interagency Chemical Hazards Working Group | Committee/Workgroup | Working group on chemical hazards led by the Office of Science and Technology Policy (OSTP). | CDC/FDA/OS | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | **NINDS** | High-throughput Technology. Translational Research. | 2007 | 0 |
| Interagency Collaboration on Identification of In Vitro and Omics Biomarkers for Liver Toxicity | Research Initiative | This grant will provide approximately 300 compounds related to liver toxicity for testing at the NIH Chemical Genomics Center (NCGC) in a group of liver toxicity-related assays. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | **NHGRI** | High-throughput Technology. Translational Research. Regulatory Science. | 2009 | 0 |
| Interagency Collaborative to Advance Research in Epilepsy (ICARE) | Committee/Workgroup | This working group aims to help to increase communication and coordination among Institutes and agencies that support epilepsy-related research. Group members also collaborate with epilepsy researchers and voluntary organizations on scientific workshops. | AHRQ/CDC/FDA/ HRSA | NONE | FIC/NCRR/ NHLBI/NHGRI/ NIA/**NIAAA/** NIAMS/NIBIB/ NICHD/NIDA/ NIGMS/NIMH/ NINDS/NINR/OD | NONE | 2003 | 0 |
| Inter-Agency Committee on Drug Control (ICDC) | Committee/Workgroup | This committee facilitates communication between USG agencies involved in the drug control process. | FDA/OS/SAMHSA | NONE | **NIDA** | NONE | 1981 | 0 |
| Interagency Committee on Emergency Medical Services for Children Research (ICER) | Committee/Workgroup | ICER is a federal collaborative effort begun in the mid-1990's to improve the quality and quantity of Emergency Medical Services for Children (EMSC) research, to foster collaboration between federal agencies in highlighting EMSC research topics during development of research agendas, and to reduce barriers to the production of high quality EMSC research. | AHRQ/CDC/FDA/ HRSA/OS/ SAMHSA | Early Childhood Health/Development. Health Care Quality/Patient Safety. Social/Behavior Research. | NHLBI/NIAID/ NIAMS/**NICHD/** NIDCR/NIGMS/ **NIMH**/NINR | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, and Patient Safety. | 1998 | 0 |
| Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) | Committee/Workgroup | To establish criteria for validation of testing methods to reduce, refine, or replace animals in toxicity testing. | FDA | NONE | **NCI**/NIEHS/NLM/OD | NONE | 1994 | 0 |

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| Inter-agency Council on Biomedical Imaging in Oncology (ICBIO) | Committee/Workgroup | Organized by the Cancer Imaging Program of DCTD, ICBIO is a confidential informational meeting for entities, usually small companies, planning product development in cancer. The Interagency Council on Biomedical Imaging (ICBIO) in Oncology brings together technology developers and representatives from the National Cancer Institute (NCI), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) to expedite the process of bringing new products to market, to provide advice from a multi-agency perspective on the spectrum of scientific, regulatory, and reimbursement issues related to developing imaging devices or technology. | AHRQ/CMD/FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, and Innovative Biomedical Technologies. | **NCI** | Translational Research. Regulatory Science. | 1999 | 0 |
| Interagency Modeling and Analysis Group | Committee/Workgroup | The Interagency Modeling and Analysis Group (IMAG) is comprised of program directors from nine government agencies in the U.S. and Canada, including the National Institutes of Health (NIH), the National Science Foundation (NSF), Department of Energy (DOE), Department of Defense (DOD), the United States Department of Agriculture (USDA), the Canadian federal research network for Mathematics of Information Technology and Complex Systems (MITACS), the National Aeronautics and Space Administration (NASA), the United States Department of Veterans Administration (USDVA), and the Food and Drug Administration (FDA). The purpose of IMAG is to bring together program officers who have a shared interest in supporting modeling and analysis methods in biomedical, biological and behavioral systems. IMAG has promoted and supported a wide variety of modeling over the past six years, notably the multi-scale modeling (MSM) initiative, which was originally a multi-agency FOA and continued on by different IMAG agencies through separate FOAs. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. Nutrition/Obesity. Social/Behavior Research. | CSR/FIC/NCI/ NCRR/NHGRI/ NHLBI/NHGRI/ NIA/NIAID/ NIAMS/**NIBIB**/ NICHD/NIDA/ NIDCD/NIEHS/ NIGMS/NIMH/ NINDS/NLM/OD | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, and Health Information Technology. High-throughput Technology. Translational Research. | 2003 | 5,000 |
| Interagency Oncology Task Force (IOTF) | Committee/Workgroup | The IOTF is a multi-party interagency effort to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications. The goal of the IOTF is to leverage the experience and capabilities of NCI and FDA for streamlining and accelerating the development of diagnostic, preventive and therapeutic interventions. Collaborative working groups have included biomarkers, biospecimens, clinical trial design, biologics, imaging, informatics, proteomics, nanotechnology, and interagency training. | CMS/FDA/HRSA/ OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Social/Behavior Research. | **NCI** | Empowering Biomedical Research Community: Training. Translational Research. Regulatory Science. | 2003 | 200,000 |
| Interagency Subcommittee on Disability Statistics (ISDS) | Committee/Workgroup | A Government-wide group, the Federal Interagency Subcommittee on Disability Statistics (ISDS), meets monthly to discuss the issues related to identifying people with disabilities and coordinate research in this area. | ACF/AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/OSG/ SAMHSA | Accelerate Discovery to Improve Patient Care: Specific category priorities not reported. Global Health: Specific category priorities not reported. | **NIDCD** | Empowering Biomedical Research Community: Specific category priorities not reported. Health Care Reform: Specific category priorities not reported. Translational Research. | 1996 | 0 |
| Inter-Agency Working Group in Preparation for the Annual U. N. Commission on Narcotic Drugs Meeting | Committee/Workgroup | This committee, lead by the Department of State, is responsible for preparing the U.S. Delegation to the annual meeting of the U.N. Commission on Narcotic Drugs. International drug scheduling issues are a major focus. | FDA/OS/SAMHSA | NONE | **NIDA** | NONE | Unknown | 0 |

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| Interagency Working Group on Blood Safety and Availability | Committee/Workgroup | The working group explores the role of federal and private entities in developing and supporting a national biovigilance system for blood safety/availability. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Global Health: Infectious Diseases and Non-Infectious Diseases. Health Care Quality/Patient Safety. HIV/AIDS. | **NHLBI** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Patient Safety. | 2006 | 0 |
| Interagency Working Group on Human Stem Cell Transplantation | Committee/Workgroup | The working group provides a forum for the participating agencies to share information about their current activities in human stem cell transplantation. | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Innovative Biomedical Technologies. | **NCI**/NHLBI/NIAID | Empowering Biomedical Research Community: Budgets, Training, Peer Review, and Workforce Diversity. Health Care Reform: Comparative Effectiveness Research, Health Information Technology, Health Research Economics, Health Disparities, and Patient Safety. Regulatory Science. | 1998 | 0 |
| Interagency Working Group to Develop White House National HIV/AIDS Strategy | Committee/Workgroup | OAR participates in the Leadership Group to develop the President's National HIV/AIDS Strategy and Implementation Plan. | ACF/AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/OSG/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | NCI/NIAID/NIDA/NIMH/ **OD** | Health Care Reform: Health Disparities. | 2009 | 0 |
| Interdepartmental Committee on Behavioral Health/Subcommittee on Alcohol Policy/Underage Drinking | Committee/Workgroup | The purpose of this subcommittee is to use policy and other interventions to reduce alcohol use. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Health Care Quality/Patient Safety. Social/Behavior Research. | **NIAAA**/NIDA/NIMH | Health Care Reform: Behavioral Science, Health Research Economics, and Health Disparities. Translational Research. | Unknown | 0 |
| INTERMACS - Interagency Registry for Mechanically Assisted Circulatory Support | Disease Registry | INTERMACS is a national registry for patients who are receiving mechanical circulatory support device therapy to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung, and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists, and industry representatives, in conjunction with the University of Alabama at Birmingham (UAB) and the United Network for Organ Sharing (UNOS). | CMS/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies, and Patient-centered Research. | **NHLBI** | Regulatory Science. | 2005 | 1,487,293 |
| Janus | Database | Janus is a study data repository component of a common, standards-based infrastructure that is being jointly developed by the FDA and the NCI to support the exchange of clinical research data. This collaborative effort between FDA and NCI has been ongoing, and we are now entering Phase 3. FDA and NCI will explore and evaluate uploading of standard data and their required transport layers into the Janus architecture. FDA intends to store all standardized clinical study data submissions in the NCI Janus data warehouse as part of this phase of Janus development. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. | **NCI** | Health Care Reform: Health Information Technology. | 2005 | 0 |
| Joint Fellowship Program | Training Initiative | The objective of the NCI-FDA fellowships is to train a cadre of scientists in research and research-related regulatory review, policies, and regulations so that they develop a skill set that bridge the two disparate processes. Fellows will learn to build awareness of regulatory requirements into the early stages of the medical product development process and develop strategies to improve planning throughout research and regulatory review. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NCI** | Empowering Biomedical Research Community: Training. | 2005 | 701,957 |

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| Lesbians, Gay, Bisexuals, and Transgender (LGBT) Coordinating Committee | Committee/Workgroup | This committee includes senior representatives from each operating division to ensure coordination of and inclusion for LGBT populations throughout the Department's activities. | ACF/AoA/AHRQ/ CDC/CMS/FDA/ HRSA/IHS/OS/ SAMHSA | NONE | **NICHD**/OD | NONE | 2010 | 0 |
| Lung Image Database Consortium (LIDC) | Database | Public database of CT images of the lung designed to evaluate software methods for detection and classification of cancer. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies and Patient-centered Research. | **NCI** | Translational Research. Regulatory Science. | 2000 | 0 |
| Lupus Federal Working Group | Committee/Workgroup | The Lupus Federal Working Group, established on behalf of the HHS Secretary by the NIH, facilitates collaboration among NIH components, other Federal agencies, voluntary and professional organizations, and industry groups with an interest in lupus. | AHRQ/CDC/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Specific category priorities not reported. | NCCAM/NEI/ NHLBI/NIAID/ **NIAMS/**NICHD/ NIDCR/NIDDK/ NIMHD/NINDS/OD | Empowering Biomedical Research Community: Specific category priorities not reported. Health Care Reform: Specific category priorities not reported. Translational Research. | 2003 | 0 |
| M2010 Microbicides: Building Bridges in HIV Prevention | Meeting/Workshop | Co-sponsor and member of Scientific Program Committee for this international microbicides scientific conference, which is held every 2 years. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Patient-centered Research. Global Health: Infectious Diseases. HIV/AIDS. Social/Behavior Research. | NCI/NIAID/NICHD/NIDA / NIMH/**OD** | Empowering Biomedical Research Community: /Global Health/Health Care Reform: /Behavioral Science/Translational Research/Regulatory Science | 2009 | 0 |
| Memorandum of Understanding (MOU) between the FDA/Center for Biologics Evaluation and Research (FDA/CBER) and NIH/NINDS | OTHER: Memorandum of Understanding | This MOU provides a mechanism for addressing cross-cutting issues related to therapy development for neurological disorders, from bench science to clinical trials and FDA approval and licensure. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | **NINDS** | Translational Research. Regulatory Science. | 2002 | 0 |
| Methylphenidate in Male Rhesus Monkeys | Research Initiative | The purpose of this IAA is to utilize a structure approach to evaluate the safety of this frequently used stimulant in a developing animal model in accordance with FDA protocol E0728701. The information from these experiences will enhance our ability to conduct a safety assessment of methylphenidate in humans. | FDA | Early Childhood Health/Development. Health Care Quality/Patient Safety. | **NICHD** | Health Care Reform: Patient Safety. | 2008 | 529,224 |

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| mHealth | Committee/Workgroup | The Public Private Partnership (PPP) program is coordinating the mHealth Summit (Nov 8-10, 2010, DC Convention Center) with FNIH and other partners; has convened a meeting with and plans another with Federal stakeholders in the mHealth arena (HHS agencies as well as DoD, FCC, OSTP, VA, and others) and will hold another such mFederal partners meeting at the Summit; and has convened an NIH-wide, inter-Institute Interest Group on mHealth which has involved other agency representatives as invited guests. Furthermore, the PPP program is working with the Indian Health Service and a private partner to establish a partnership to conduct a feasibility study regarding the use of mobile devices in healthcare on the reservation. | AHRQ/CDC/ CMS/FDA/HRSA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Global Health: Infectious Diseases and Non-Infectious Diseases. Global Health: Strategic Initiative. Health Care Quality/Patient Safety. HIV/AIDS. Nutrition/Obesity. Social/Behavior Research. Tobacco Prevention and/or Control. | FIC/NCI/NCRR/ NHLBI/NHGRI/ IA/NIBIB/NICHD/ NIDA/NIDDK/ NIMCHD/NINDS/ NLM/**OD** | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, Health Research Economics, Health Disparities, and Patient Safety. Translational Research. Regulatory Science. | 2009 | 0 |
| Microbial Project Interagency Working Group | Committee/Workgroup | Continuing coordination of agency interests in microbial genomics. | CDC/FDA | NONE | **NIGMS** | NONE | Unknown | 0 |
| Multi-Agency Tissue Engineering Science (MATES) Interagency Working Group | Committee/Workgroup | The MATES provides a forum for federal agencies involved in tissue science and engineering to stay informed of each other's activities and coordinate research efforts. | CMS/FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Technologies and Translate basic science into new therapies. | **NHLBI**/NIAMS/ **NIBIB**/NICHD/ **NIDCD**/NIDCR/OD | Empowering Biomedical Research Community: Training. High-throughput Technology. Translational Research. Regulatory Science. | 2000 | 10,508,987 |
| Muscular Dystrophy Coordinating Committee (MDCC) | Committee/Workgroup | Coordinate activities across NIH and with other Federal health programs and activities relevant to the various forms of muscular dystrophy. | ACF/CDC/FDA/ HRSA | Accelerate Discovery to Improve Patient Care: Patient-centered Research and Translate basic science into new therapies. Early Childhood Health/Development. Global Health: Strategic Initiative. Social/Behavior Research. | NHLBI/**NIAMS/** NICHD/**NINDS** | Empowering Biomedical Research Community: Training. High-throughput Technology. Translational Research. | 2001 | 0 |
| Nanotechnology Characterization Laboratory | Research Initiative | The Nanotechnology Characterization Laboratory (NCL) performs and standardizes the preclinical characterization of nanomaterials intended for cancer therapeutics and diagnostics developed by researchers from academia, government, and industry. The NCL serves as a national resource and knowledge base for cancer researchers and facilitates the development and translation of nanoscale particles and devices for clinical applications. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies and Translate basic science into new therapies. | **NCI** | Empowering Biomedical Research Community: Training. Translational Research. Regulatory Science. | 2004 | 3,300,000 |

| Table 15: FDA Collaborations - FY 2010 = 243 | | | | | NIH Funding = $151,974,128 | | | |
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| National Asthma Education and Prevention Program Federal Liaison Group on Asthma (FLGA) | Committee/Workgroup | The Federal Liaison Group on Asthma is a subcommittee of the National Asthma Education and Prevention Program that is charged with addressing ways to strengthen and improve the coordination of asthma-related activities across agencies of the Federal Government. The group provides a forum for federal agencies with major interest in asthma to exchange ideas and explore collaborative activities. | AHRQ/ATSDR/ CDC/CMS/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Patient-centered research. Global Health: Non-Infectious Diseases. Health Care Quality/Patient Safety. Social/Behavior Research. | NIA/**NHLBI/** NIAID/NICHD/ NIEHS/NINR/NIMHD | Empowering Biomedical Research Community: Global Health. Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, and Health Disparities. Translational Research. | 1998 | 0 |
| National Asthma Education and Prevention Program/National Asthma Control Initiative | Committee/Workgroup | The National Asthma Education and Prevention Program (NAEPP) seeks to enhance the quality of life for patients with asthma and decrease asthma-related morbidity and mortality by improving asthma awareness, diagnosis, and treatment. The National Asthma Control Initiative (NACI) is a national effort to facilitate implementation of the NAEPP Expert Panel Report-3 Asthma Guidelines implementation panel report. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Early Childhood Health/Development. Health Care Quality/Patient Safety. Social/Behavior Research. Tobacco Prevention and/or Control. | **NHLBI**/NIAID/NIEHS | Health Care Reform: Comparative Effectiveness Research, Behavioral Science, and Health Disparities. | 1998 | 1,650 |
| National Committee on Vital and Health Statistics | Committee/Workgroup | Monitoring and coordination of health-related statistics. | ACF/AoA/AHRQ/ CDC/FDA/HRSA/ IHS/OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Fast-track innovation planning and regulatory review. Health Care Quality/Patient Safety. | CIT/**NCI/**NIMHD | Health Care Reform: Health Information Technology and Health Disparities. | 2008 | 0 |
| National Food and Nutrient Analysis Program (NFNAP) | Database | Provides basic information about the nutrient content of highly consumed foods and supplements in the U.S. | CDC/FDA | Nutrition/Obesity. | **NCI**/NEI/NHLBI/NIA/ **NICHD**/NIDDK/OD | Health Care Reform: Behavioral Science and Health Disparities. | 2005 | 450,000 |
| National Health and Nutrition Examination Survey (NHANES) | Health Survey | A program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations. | ACF/CDC/FDA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Nutrition/Obesity. | **NIA/NCI**/NHLBI/ NIDDK/**OD** | Health Care Reform: Behavioral Science and Health Information Technology. | 1999 | 2,020,000 |
| National Healthcare Quality/Disparities Report Interest Working Group | Committee/Workgroup | The Working Group, led and coordinated by AHRQ, reviews healthcare and research data for selected diseases and health conditions, develops appropriate performance measures, and reports annually on the quality of health care received by Americans as well as data on health related disparities. | AoA/AHRQ/ ATSDR/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Health Care Quality/Patient Safety. | **NCI/**NHLBI/NIAID/ NICHD/NIDDK/ NIEHS/NIMH/NIMHD | Health Care Reform: Comparative Effectiveness Research, Health Information Technology, and Patient Safety. | 2003 | 0 |

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| National Robotics Initiative | Research Initiative | The Office of Science and Technology Policy (OSTP) is creating a "National Robotics Initiative" to promote research in a variety of robot-related topics. NIH has been asked to join as a major civilian aspect of this coordinated inter-agency plan which will incorporate agencies from the Departments of Defense, Education, Health and Human Services, and Commerce. The National Center for Medical Rehabilitation Research would like to issue a Program Announcement focusing on the human/machine interaction aspect of incorporating robots into the healthcare and rehabilitation system, with particular emphasis on the needs of people with disabilities. The goal is not to develop robotic technologies, but to understand the human factors required for successful integration. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies and Patient-centered Research. Social/Behavior Research. | NIBIB/**NICHD**/NINDS | Translational Research. | 2009 | 0 |
| National Science Advisory Board for Biosecurity (NSABB) | Committee/Workgroup | NSABB advises USG on oversight of dual use life sciences research. | CDC/FDA/OS | NONE | NIAID/**OD** | NONE | 2004 | 450,000 |
| National Toxicology Program Executive Committee | Committee/Workgroup | Policy oversight to NTP Director. | ATSDR/CDC/FDA | NONE | **NCI**/NIEHS/OD | NONE | 1994 | 0 |
| National Toxicology Program Interagency Committee for Chemical Evaluation and Coordination (ICCEC) | Committee/Workgroup | Interagency committee that provides formal review of the study nominations for the NTP testing program. | ATSDR/CDC/FDA | NONE | NCI/**NIEHS** | Regulatory Science. | 1978 | 0 |
| National Toxicology Program Interagency Review Group (ISRG) for the Report on Carcinogens (RoC) | Committee/Workgroup | Scientific Review Group for the RoC that makes a recommendation for listing status for candidate substances in the RoC. | ATSDR/CDC/FDA | Global Health: Non-Infectious Diseases. | NCI/**NIEHS** | Empowering Biomedical Research Community: Global Health | 1990 | 0 |
| National Women's Health Week | Public Education Campaign | This is a weeklong health observance to empower women to make their health a top priority and encourages women to take simple steps for a longer, healthier, and happier life. This nationwide initiative is collaboration between federal departments, agencies, state and local governments and the general public. | ACF/AoA/AHRQ/ CDC/CMS/FDA/ HRSA/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. Nutrition/Obesity. Pain Research. Tobacco Prevention and/or Control. | CC/CIT/CSR/FIC/ NCCAM/NCI/ NCRR/NEI/ NHLBI/NHGRI/ NIA/NIAAA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDA/NIDCD/ NIDCR/NIDDK/ NIEHS/NIGMS/ NIMH/NIMHD/ NINDS/NINR/NLM/**OD** | Health Care Reform: Behavioral Science and Health Disparities. Translational Research. | 2005 | 13,343 |
| NEI/FDA Endpoints Symposium: Use of Patient-reported Outcomes in Medical Product Development | Meeting/Workshop | Conference to determine how vision-related patient-reported outcomes might be used to improve medical product labeling in ophthalmology. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. | **NEI** | Regulatory Science. | 2008 | 0 |
| Network for Translational Research (NTR): Optical Imaging in Multimodality Platforms | Research Initiative | NTR is a U54 research network. The goals are to develop and validate the next generation of imaging platforms that address the cancer problem. The network structure is designed to develop a consensus on their validation with an overall aim to accelerate the FDA approval of these imaging platforms. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies. | **NCI** | Translational Research. Regulatory Science. | 2009 | 4,800,000 |
| Neural Interfaces Conference | Meeting/Workshop | The Neural Interfaces research community consists of investigators, supported by grants or contracts, who are working in areas that include functional neuromuscular/electrical stimulation, auditory prosthesis, cortical prosthesis, neuromodulation, microelectrode array technology, brain computer/machine interfaces and other related areas. This conference was held in June of 2010. NIH Program Officers reviewed abstracts. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Innovative Biomedical Technologies. | CSR/NEI/NIA/ NIBIB/**NICHD**/ NIDCD/NINDS/OD | NONE | 2006 | 1 |

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| New Drug Application - Domestic Scheduling of New Medications | OTHER: Consultation | Consultative Assistance to the FDA regarding the filing of a New Drug Application by a pharmaceutical company, the FDA prepares an "8-factor analysis" of abuse liability and prepares a draft scheduling recommendation. NIDA reviews the draft documents and provides advice regarding potential revisions. | FDA | NONE | **NIDA** | NONE | Unknown | 0 |
| New York Academy of Science (NYAS) Probiotic Foods and Supplements: the Science and Regulations of Labeling | Meeting/Workshop | The aim of the symposium, held on June 12, 2010, was to facilitate the exchange of ideas regarding labeling and substantiation of claims for probiotics and to discuss ways to translate and communicate research results in a trustful way to the consumer and health professionals. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. | **NCCAM**/OD | High-throughput Technology. Regulatory Science. | 2009 | 5,000 |
| NIH Recombinant DNA Advisory Committee | Committee/Workgroup | NIH RAC advises NIH on the safe and ethical conduct of basic and clinical recombinant DNA research. | CDC/FDA/OS | NONE | NCI/NHGRI/NIAID/ NIMH/**OD** | Translational Research. | 1975 | 700,000 |
| NIH State-of-the-Science Conference: Diagnosis and Management of Ductal Carcinoma In Situ (DCIS) | Meeting/Workshop | NIH State-of-the-Science Conference provides a written statement on a controversial medical topic prepared by an independent panel of health professionals free from conflicts of interest on the basis of the results of a systematic literature review, presentations by experts in the field, and public comments and questions. With the increasing prevalence of DCIS of the breast and our current inability to determine those women with DCIS at high risk for invasive breast cancer, the purpose of the conference was to critically evaluate the available data on diagnosis and management. The panel concluded that much remains unknown in this area, but strong consideration should be given to remove the anxiety-producing term "carcinoma" from the description of DCIS. The primary question for future research should focus on the accurate identification of patient subsets diagnosed with DCIS who may be managed with less intervention. | AHRQ/CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Health Care Quality/Patient Safety. | NCI/**OD** | Health Care Reform: Comparative Effectiveness Research and Health Disparities. | 2007 | 0 |
| NIH-FDA Leadership Council | Committee/Workgroup | The Joint Leadership Council will work together to help ensure that regulatory considerations form an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process. Such collaboration and integration will advance the development of new products for the treatment, diagnosis and prevention of common and rare diseases and enhance the safety, quality, and efficiency of the clinical research and medical product approval enterprise. The formation of the Leadership Council represents a commitment on the part of both agencies to forge a new partnership and to leverage the strengths of each agency toward this common goal. | FDA | NONE | NHLBI/NIAID/ NIDDK/NIGMS/ NIMH/NINDS/**OD** | Regulatory Science. | 2010 | 0 |
| Nutrition Coordinating Committee (NCC) | Committee/Workgroup | Nutrition Coordinating Committee (NCC) operates as an NIH-wide forum to review, stimulate, and encourage the support of nutrition research and training to better define the role of nutrition in the promotion and maintenance of health and in the prevention and treatment of disease. The NCC also plays a key role in the development of nutrition research policy at the NIH. | AHRQ/CDC/FDA/ HRSA/IHS/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Early Childhood Health/Development. Nutrition/Obesity. Social/Behavior Research. | CC/CIT/CSR/FIC/ NCCAM/NCI/**NEI/** NHLBI/NHGRI/ NIA/NIAAA/ NIAID/NIAMS/ NICHD/NIDA/ NIDCD/NIDCR/ NIDDK/NIEHS/ NIGMS/NIMH/ NINDS/**NINR**/OD | Empowering Biomedical Research Community: Training. Health Care Reform: Behavioral Science. Translational Research. | 1999 | 0 |

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| Patient-Reported Outcomes Measurement Information System (PROMIS) | Research Initiative | The Patient-Reported Outcomes Measurement Information System (PROMIS) is a network of NIH-funded primary research sites and coordinating centers working collaboratively to develop a series of dynamic tools to reliably and validly measure patient-reported outcomes (PROs). PROMIS provides an opportunity to improve healthcare outcomes by giving decision makers hard data on how healthcare effects what patients are able to do and how they feel. The FDA has been invited to contribute to the scientific steering committee meetings as an interested partner. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. | NCCAM/NCI/ NHLBI/NIAID/ NIAMS/**NICHD**/ NIDA/NIDDK/ NIGMS/NIMH/ NINDS/OD | Health Care Reform: Behavioral Science. | 2004 | 481,774 |
| Patient-Reported Outcomes Measurement Information System (PROMIS) Item Response Theory (IRT) Assessment Center Training | Meeting/Workshop | PROMIS is creating a psychometrically-robust computer adaptive testing (CAT) system, based on item response theory (IRT), to administer these items. In addition, it is developing a web-based system to give clinical researchers access to the item banks and the CAT system. | AHRQ/FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. | NCI/NEI/NHLBI/ NHGRI/NIAID/ NICHD/NIDDK/ NIGMS/**OD** | Health Care Reform: Behavioral Science and Health Information Technology. | 2010 | 0 |
| Pediatric Advisory Committee (PAC) to the FDA | Committee/Workgroup | NIMH staff served as advisors to FDA and voting members in this committee which reviewed the efficacy and safety of psychotropic medications in children and adolescents. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. Early Childhood Health/Development. | **NIMH** | Health Care Reform: Patient Safety. | 1999 | 0 |
| Pediatric Formulations Platform | Committee/Workgroup | This IAA is a collaboration between NICHD and the Center for Drug Evaluation and Research, FDA. The purpose is to create an open-source, publicly available oral pediatric formulations platform. This platform will designate specific formulation technologies, given the molecular and chemical properties of the drug and specific desired properties of the dosage form. The ideal pediatric dosage form would be an orally dissolvable solid; tasteless; in an appropriate dose amount that would be appropriate for infants; contain minimal amounts of safe excipients; stable in light, humidity, and heat; and have the necessary release characteristics, as applicable. | FDA | Early Childhood Health/Development. Health Care Quality/Patient Safety. | **NICHD** | Health Care Reform: Patient Safety. | 2010 | 325,000 |
| Peripheral and Central Nervous System Drugs Advisory Committee | Committee/Workgroup | Ad hoc member. August 11 2009, to consider an NDA for I-123 Ioflupane to detect loss of functional nigrostriatal dopaminergic neurons by SPECT imaging. | FDA | NONE | **CC** | NONE | 2009 | 0 |
| Personal Motion Technologies for Healthy Independent Living | Meeting/Workshop | Support the development and translation of high-impact home-based technology systems for health. This includes viable integrated systems using standards and common platforms for diagnosis, monitoring, screening, and intervention as well as studies to prove the effectiveness/efficacy of personal health technologies for people with disabilities, aging adults, and people with chronic disease. | CMS/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies, Innovative Biomedical Technologies and Patient-centered Research. Health Care Quality/Patient Safety. | NCRR/NIA/NIBIB/ **NICHD**/NINDS/OD | Health Care Reform: Comparative Effectiveness Research, Health Information Technology, and Patient Safety. | 2010 | 5,000 |
| Phenylketonuria (PKU) | Meeting/Workshop | A two-day scientific conference on PKU and other forms of hyperphenylalaninemia is planned to take place within the next 12-18 months. NIH last published screening and management guidelines for PKU as the result of a Consensus Conference held in October 2000. Developments since that time regarding PKU and treatment strategies have made it time to revisit those guidelines. NIH established five Working Groups to generate and address specific questions related to: 1) Diet Control and Management; 2) Pharmacologic Interventions; 3) PKU and Pregnancy; 4) Long-Term Cognitive Outcomes and Follow-up; and 5) Molecular Testing, New Technologies, and Epidemiologic Considerations. | AHRQ/CDC/FDA/ HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Early Childhood Health/Development. Global Health: Non-Infectious Diseases. Nutrition/Obesity. Social/Behavior Research. | NHGRI/NICHD/ NIDDK/NINDS/ NINR/**OD** | Health Care Reform: Behavioral Science and Patient Safety. Regulatory Science. | Unknown | 0 |

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| Photography and Image Processing of Prescription Solid Dosage Form Medications and Hosting of a Database of Substances in Medicinal Products | Database | This project aims to create and expand a database interface to provide public access to FDA unique ingredient identifiers (UNIIs) in medicinal products and substances. The interface allows exchange between government and industry for phases of clinical developments. As part of the project, NLM will assist in conducting a comprehensive scientific literature review, developing a compilation of results in a searchable table format and preparing a written summary and interpretation of results. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Innovative Biomedical Technologies. | **NLM** | Health Care Reform: Health Information Technology. | 2009 | 0 |
| Pillbox - creation of digital images of solid dosage form medications | Database | Pillbox is a collaboration between NLM and FDA to enhance patient safety through the linking of digital images of prescription solid dosage form medications to the Structured Product Labeling (SPL) files and the substance information of those pharmaceuticals. NLM will use these images to create a resource for identification of pharmaceuticals through a search system. Work is ongoing to create digital images and develop imaging standards. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Health Care Quality/Patient Safety. | **NLM** | Health Care Reform: Patient Safety. | 2009 | 0 |
| Pilot Validation Study of Computer Administration of Vision Targeted Quality of Life Instruments | Research Initiative | Study to test and compare computerized and paper versions of eye questionnaires. Questionnaires are used in medicine to gain a better understanding of how a disease can impact a person's quality of life. Computerized versions of such questionnaires are often as good as or better than paper versions, but there has been no direct comparison of the two. This study may help in the development of eye questionnaires used to understand symptoms and monitor patients in clinical trials. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered research. Social/Behavior Research. | **NEI** | Health Care Reform: Behavioral Science. | 2008 | 28,745 |
| Pregnancy and Contraception in Microbicide Clinical Development | Meeting/Workshop | Workshop to examine and provide data management solutions to the issues of potential pregnancies in HIV research. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Patient-centered Research. Global Health: Infectious Diseases. HIV/AIDS. Social/Behavior Research. | NIAID/NICHD/ NIMH/**OD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Behavioral Science. Translational Research. | 2008 | 0 |
| Presentation of the Patient Reported Outcomes Measurement Information System (PROMIS) | Meeting/Workshop | The PROMIS investigators along with NIH staff met with FDA staff to provide background information and an update on PROMIS. In addition, there was a discussion about item response theory and the possible use of PROMIS items as secondary endpoints in FDA research. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research and Translate basic science into new therapies. Health Care Quality/Patient Safety. Social/Behavior Research. | NIAMS/**OD** | Health Care Reform: Behavioral Science and Health Information Technology. Translational Research. | 2009 | 0 |
| Procurement of biotechnology services, including amino acid sequence analysis | Research Initiative | The purpose of this IAA is for NICHD to provide funding to the Center for Biologics Evaluation (CBER), Food and Drug Administration (FDA) to purchase various biotechnology services, including amino acid sequence analysis. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. Early Childhood Health/Development. | **NICHD** | NONE | 2009 | 1,000 |
| Procurement of biotechnology services, including GFP cell sorting and analysis | Research Initiative | The purpose of this agreement is to provide funding from the NICHD to the FDA to purchase various biotechnology services, including GFP cell sorting and analysis. FDA will administer this funding and will keep the NICHD informed of the results through the delivery of data reports. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. Early Childhood Health/Development. | **NICHD** | NONE | 2009 | 975 |

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| Prognostic and Predictive Immunologic Biomarkers in Cancer | Meeting/Workshop | Held in conjunction with the annual meeting of the International Society of Biological Therapy for Cancer in October 2009. The workshop focused on development of biomarkers for use in clinical immunotherapy research and trials. This workshop involved FDA and NCI who provided advice on the paths to clearance as well as approval for markers used to monitor immunotherapy. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NCI** | Translational Research. | 2009 | 0 |
| Project Involving Ethical and Regulatory Issues | Meeting/Workshop | Conference on ethical and regulatory issues in global pediatric clinical trials that will involve regulators, ethicists, and investigators from approximately 30 countries to discuss the ethical design and conduct of pediatric research in the international setting. | FDA | Early Childhood Health/Development. Global Health: Non-Infectious Diseases. Health Care Quality/Patient Safety. | **NICHD** | Empowering Biomedical Research Community: Global Health. | 2009 | 0 |
| Public Health Dimensions of Epilepsy | OTHER: Study and report by the Institute of Medicine (IOM) | The Institute of Medicine will convene an ad hoc committee to recommend priorities in public health, healthcare and human services, and health literacy and public awareness for the epilepsies and to propose strategies to address these priorities. | ACF/CDC/FDA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Early Childhood Health/Development. | NIA/NICHD/NIMH/ **NINDS** | Health Care Reform: Comparative Effectiveness Research, Health Research Economics, and Patient Safety. | 2010 | 0 |
| Public Health Emergency Management Countermeasures Enterprise | Committee/Workgroup | The NICHD representative is a regular member of the chemical working group and provides PRN assistance to the Infectious Disease and Radiation Working Groups. These groups determine medical countermeasures (MCM) requirements, reviews available and up and coming MCMs, makes advanced R&D study recommendations, funds recommended studies, funds some of the MCMs for the strategic national stockpile. The NICHD representative provides pediatric/OB input regarding MCM gaps, study needs, prioritization. | ACF/CDC/FDA/ OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, and Innovative Biomedical Technologies. Global Health: Non-Infectious Diseases and Strategic Initiative. | NIAID/NIAMS/ **NICHD**/NINDS/NLM | High-throughput Technology. Translational Research. | 2008 | 0 |
| Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Chemical Integrated Product Development Team (IPT) | Committee/Workgroup | The HHS Public Health Emergency Medical Countermeasures Enterprise (HHS PHEMCE) leads the mission to develop and acquire medical countermeasures that will improve public health emergency preparedness as well as prevent and mitigate the adverse health consequences associated with chemical, biological, radiological and nuclear (CBRN), and naturally occurring threats. | CDC/FDA/OS | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | NIAID/**NINDS** | Translational Research. Regulatory Science. | 2007 | 0 |
| Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Chemical Requirements Working Group | Committee/Workgroup | The HHS Public Health Emergency Medical Countermeasures Enterprise (HHS PHEMCE) leads the mission to develop and acquire medical countermeasures that will improve public health emergency preparedness as well as prevent and mitigate the adverse health consequences associated with chemical, biological, radiological and nuclear (CBRN), and naturally occurring threats. | CDC/FDA/OS | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | NIAID/NICHD/ NIEHS/**NINDS** | Translational Research. Regulatory Science. | 2007 | 0 |

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| Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Product Development Tools Working Group | Committee/Workgroup | The HHS Public Health Emergency Medical Countermeasures Enterprise (HHS PHEMCE) leads the mission to develop and acquire medical countermeasures that will improve public health emergency preparedness as well as prevent and mitigate the adverse health consequences associated with chemical, biological, radiological and nuclear (CBRN), and naturally occurring threats. | CDC/FDA/OS | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | NIAID/NICHD/**NINDS** | Translational Research. Regulatory Science. | 2007 | 0 |
| Quality Review of ClinicalTrials.gov | Database | ClinicalTrials.gov is an NLM-operated database of summary protocol and results information from publicly and privately funded clinical research. As of October 2010, the database included over 96,000 studies conducted in 174 countries with over 2,300 summary results. NLM is collaborating with FDA and other parts of NIH to implement the statutory requirements of the Food and Drug Administration Amendments Act of 2007 and working together on a project with CTTI (Clinical Trials Transformation Initiative) to create a ClinicalTrials.gov Analysis Data Set. NLM and AHRQ are collaborating on conducting quality reviews (e.g., evaluate for internal consistency, meaningful entries, formatting) of summary results information. | AHRQ/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | CC/NCCAM/NCI/ NCRR/NEI/ NHGRI/NHLBI/ NIA/NIAAA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDA/NIDCD/ NIDCR/NIDDK/ NIEHS/NIGMS/ NIMH/NIMHD/ NINDS/NINR/**NLM**/OD | Empowering Biomedical Research Community: Peer Review. Health Care Reform: Comparative Effectiveness Research. Translational Research. | 2000 | 0 |
| Rabbit Study | Research Initiative | NEI is conducting rabbit studies in support of FDA Toxic Anterior Segment Syndrome (TASS) project. TASS is an acute sterile postoperative inflammation of the anterior segment believed to be caused by toxic non-infectious substances. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review. Health Care Quality/Patient Safety. | **NEI** | Health Care Reform: Patient Safety. | 2009 | 0 |
| Reciprocal Educational and Training Partnerships between FDA/CDER and the NIH Clinical Center | Training Initiative | This activity is sponsored by the Clinical Pharmacology Program, Office of Clinical Research Training and Medical Education (OCRTME) at the NIH Clinical Center and it consists of elective rotations at the Office of Clinical Pharmacology (OCP) - FDA/CDER for NIH staff with a primary focus on clinical fellows and research fellows who expressed an interest in learning more about FDA regulatory sciences applicable to drug development research. Rotating fellows are mentored by FDA staff on the required elements of an Investigational New Drug (IND) application and the key elements of the FDA review process from a regulatory perspective. This program also established a mechanism for FDA scientific reviewers at the OCP to rotate at the NIH Clinical Center and to interact with members of a clinical research team, thus acquiring a better perspective on clinical research protocol implementation and the requirements of an Institutional Review Board (IRB) at the NIH. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. | **CC**/NCI/NIAID | Empowering Biomedical Research Community: Training. Translational Research. Regulatory Science. | 2007 | 0 |
| Reducing Barriers to Mobile Technology Usage in Behavioral and Social Sciences Research | Meeting/Workshop | Meeting designed to identify and address barriers to mobile health (mHealth) research. The meeting brought together experts from the research, public and private sectors to address the barriers in this area. Enhancing utilization of mobile technology should have a significant public health impact. | AHRQ/FDA/ HRSA/OS | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review and Innovative Biomedical Technologies. Social/Behavior Research. | NCI/NHLBI/**OD** | Health Care Reform: Behavioral Science and Health Information Technology. | 2010 | 17,638 |

| Table 15: FDA Collaborations - FY 2010 = 243 | | | | | NIH Funding = $151,974,128 | | | |
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| Reference Image Database to Evaluate Response to Therapy (RIDER) | Database | Public Resource that is web accessible that contains longitudinal and repeat phantom and patient images for a range of imaging modalities and organ systems. The purpose is to test software tools for the measurement of response to therapy. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. Patient-centered Research. | **NCI**/NIBIB | Translational Research. Regulatory Science. | 2004 | 0 |
| Report on Carcinogens | Committee/Workgroup | Report issued to the HHS Secretary every 2 years. | ATSDR/CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | **NCI**/NIEHS | NONE | 1994 | 0 |
| Research Challenges in Central Nervous System (CNS) Manifestations of Inborn Errors of Metabolism Workshop | Meeting/Workshop | Jointly sponsored by the National Institute of Health's Office Rare Diseases Research and the National Institute of Neurological Disorders and Stroke and the Food and Drug Administration's Center for Drug Evaluation and Research, Division of Gastroenterology Products, the goal of this workshop was to bring together those involved in research and investigational treatments for central nervous system aspects of inborn errors of metabolism and to discuss ways to translate these therapies to clinical trials and beyond. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Non-Infectious Diseases. | NINDS/**OD** | Empowering Biomedical Research Community: Training and Global Health. Translational Research. Regulatory Science. | 2008 | 74,203 |
| Research on the Comparative Management of Uterine Fibroid Disease | Committee/Workgroup | The primary purpose of the project is to develop a protocol to study the clinical effectiveness and/or comparative effectiveness of uterine fibroid diagnosis, management, care coordination and treatment, and to disseminate the findings. | AHRQ/CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. | NCCAM/**NICHD**/ NIEHS/OD | Empowering Biomedical Research Community: Specific category priorities not reported. Health Care Reform: Comparative Effectiveness Research and Health Disparities. | 2009 | 0 |
| Role of TGF-beta signaling in head and neck squamous cell carcinoma | Research Initiative | Our collaborative efforts are focused on delineating precise molecular mechanisms that contribute to the initiation and progression of head and neck squamous cell carcinoma (HNSCC), with a special emphasis on TGF-β and PI3K/Akt signaling pathways as targets for developing therapeutic approaches. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Fast-track innovation planning and regulatory review, and Innovative Biomedical Technologies. Global Health: Non-Infectious Diseases. | NIDCD/**NIDCR** | Empowering Biomedical Research Community: Training. Health Care Reform: Comparative Effectiveness Research. Translational Research. | 2008 | 0 |
| RuSH (Registry and Surveillance System in Hemoglobinopathies) | Research Initiative | RuSH is a system to collect information on people living with hemoglobinopathies (sickle cell disease and thalassemia) in six states. | CDC/FDA/HRSA/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, and Patient-centered Research. Health Care Quality/Patient Safety. Social/Behavior Research. | **NHLBI** | Empowering Biomedical Research Community: Training. Health Care Reform: Behavioral Science and Health Disparities. | 2007 | 4,913,679 |
| RxNorm | OTHER: Content Services | RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary. | FDA | Global Health: Strategic Initiative. Health Care Quality/Patient Safety. | **NLM** | Health Care Reform: Health Information Technology and Patient Safety. | 2005 | 0 |

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| Sabbatical in Clinical Research Management Program | Training Initiative | Experienced investigators come to the NIH to learn about management of a clinical research enterprise, including topics such as planning and budget development, protocol writing and tracking and scientific review. Sabbaticals are self-directed, meaning that the participant chooses from a list of electives and helps determine how much time to spend studying each topic. The electives are offered by leaders at the NIH and other HHS agencies with the NIH Clinical Center being the most heavily involved. | FDA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | **CC**/FIC/NCRR/ NEI/NIAID/NLM/OD | Empowering Biomedical Research Community: Training. | 2009 | 72,740 |
| Safe Medication Use as an Essential Component of Wellness Among People with Mental Health Problems | Meeting/Workshop | This webinar training series was developed by FDA and SAMHSA for both professionals and consumers relating to atypical antipsychotics, health complications and polypharmacy, and the safe uses of, and preventable harm from, medications. | FDA/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. Health Care Quality/Patient Safety. Nutrition/Obesity. | **CC** | Empowering Biomedical Research Community: Training. Health Care Reform: Patient Safety. | 2010 | 0 |
| Safety Reporting Portal | OTHER: Policy innovation | Development of a portal to streamline the process of reporting pre- and post-market safety data to the FDA and NIH and to serve as a prototype for a federal-wide system. The Portal is an important policy innovation and major step forward in the effort to eliminate unnecessary complexities and inefficiencies associated with the current system of reporting adverse events. The Portal uses a harmonized set of terms, the Basal Adverse Event Report, to provide a single, web-based interface for standardized electronic reporting of adverse events and unanticipated problems to NIH and FDA and also enables the transmission of reports to local oversight bodies such as IRBs and DSMBs. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review. | **OD** | Health Care Reform: Patient Safety. Translational Research. | 2008 | 3,873,386 |
| Sale of IT Services for Operating Division (OPDIV) | OTHER: Service Agreement | CIT receives funding from each OPDIV to pay for IT services provided either through Interagency Agreements (IAA) or monthly recurring invoicing using the CIT billing system and Inter-governmental Payment and Collection System (IPAC). | ACF/AoA/AHRQ/ CDC/CMS/FDA/ HRSA/IHS/OS/ SAMHSA | NONE | **CIT** | NONE | Unknown | 0 |
| Scientific Advisory Committee on Alternative Toxicological Methods (SACTM) | Committee/Workgroup | To establish criteria for validation of testing methods to reduce, refine, or replace animals in toxicity testing. | ATSDR/CDC/FDA | NONE | **NCI**/NIEHS/NLM/OD | NONE | 1994 | 0 |
| Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) | Committee/Workgroup | During FY 2009 and FY 2010, SACGHS advised the Secretary of Health and Human Services on issues associated with development and use of genetic technologies. Topics delineated in its charter included the integration of genetic and genomic technologies into health care and public health; the clinical, public health, ethical, economic, legal, and societal implications of these technologies; gaps in research and data collection; the impact of patent policy and licensing practices on their accessibility and availability; and how genetic and genomic technologies are used in other settings such as education, employment, insurance, and law. | ACF/AHRQ/CDC/ CMS/FDA/HRSA/ OS | Health Care Quality/Patient Safety. Pharmacogenomics. | NHGRI/**OD** | Translational Research. | 2002 | 500,000 |
| Secretary's Committee on Blood Safety and Availability (BSAC) | Committee/Workgroup | Oversees national status of blood safety and availability, investigates problems and proposes action. | CDC/FDA/CMS/ OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Patient-centered Research. Health Care Quality/Patient Safety. HIV/AIDS. | **CC**/NHLBI | Health Care Reform: Patient Safety. | Unknown | 0 |

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| SNOMED (Systematized Nomenclature of Medicine) International and Support Services | OTHER: Support Services | This activity provides support for SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms), a systematically organized computer processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, microorganisms, pharmaceuticals etc. It allows a consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps organizing the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research. | AHRQ/CDC/ CMS/FDA/HRSA/ IHS/OS/SAMHSA | Global Health: Strategic Initiative. Health Care Quality/Patient Safety. | **NLM** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Health Information Technology and Patient Safety. | 2003 | 6,010,000 |
| Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health | Research Initiative | The SCOR programs are large Center Programs (P50) that consist of 11 Centers that conduct interdisciplinary research focused on health issues that affect women and examine sex/gender contributions to health and disease. The currently funded SCORs are interdepartmental, intercollegiate, interinstitutional and focus on sex differences in pregnancy, substance abuse, reproductive health, urinary tract, and pain. The SCOR mechanism promotes collaborative research among scientists with varied expertise in order to achieve research objectives that are less likely to occur through other grant mechanisms. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Patient-centered Research, and Translate basic science into new therapies. Pain Research. Social/Behavior Research. | NIAMS/NICHD/ NIDDK/NIMH/**OD** | Health Care Reform: Behavioral Science. Translational Research. | 2002 | 8,825,901 |
| Standing Committee on Use of Emerging Science for Environmental Health Decisions of the National Academy of Sciences | Committee/Workgroup | The standing committee will examine, explore, and consider issues on the use of emerging science for environmental health decisions. For this process, it will provide a public venue for communication among government, industry, environmental groups, and the academic community about scientific advances in methods and approaches that can be used in the identification, quantification, and control of environmental impacts on human health. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Innovative Biomedical Technologies. Pharmacogenomics. | NICHD/**NIEHS** | High-throughput Technology. Translational Research. Regulatory Science. | Unknown | 550,000 |
| Stem Cell Workshop | Committee/Workgroup | Representative from different institutes with interest in developing stem cell based therapies and representatives from the FDA have been meeting to organize a workshop on the current state of the art of stem cell therapies, and how to navigate the path from translational research, through the FDA, and into clinical reality. The workshop will be held in the spring of 2011. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. | NCI/NHLBI/ NIAMS/NIBIB/ **NIDCR**/NINDS | Translational Research. Regulatory Science. | 2010 | 0 |
| Studies on viral and host factors in transfusion-transmitted infections | Research Initiative | This ongoing research collaboration is exploring virus and host factor interactions relevant to disease. Initial studies focused on HIV, and they have been expanded to a variety of other transfusion-transmitted infectious agents to characterize molecular mechanisms and explore potential translational applications. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NIDCR** | Translational Research. | 1990 | 10,000 |
| Subcommittee on Nanoscale Science, Engineering, and Technology | Committee/Workgroup | This subcommittee of the National Science and Technology Council's Committee on Technology is responsible for coordinating the National Nanotechnology Initiative (NNI). The NNI was established in 2001 to coordinate federal research and development in nanotechnology by providing a vision of the long-term benefits and opportunities offered by nanotechnology and acting as a locus for communication, cooperation, and collaboration between federal agencies involved in nanotechnology research and development. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. | **NCI**/NHGRI/NIBIB | NONE | 2001 | 0 |

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| Subpopulations and Intermediate Outcome Measures in Chronic Obstructive Pulmonary Disease (COPD) | Research Initiative | SPIROMICS (SubPopulations and Intermediate Outcome Measures In Chronic Obstructive Pulmonary Disease Study) is an observational study of COPD that seeks to identify practical intermediate outcome measures and mechanistically homogeneous subgroups of patients with the disease. The study was developed in cooperation with the FDA and will be implemented with industrial partners. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered research. | **NHLBI** | NONE | 2006 | 27,960,468 |
| Summer Institute in Maternal-Fetal Pharmacology | Meeting/Workshop | This course provides training for clinical and non-clinical scientists who are considering academic careers in studying therapeutics during pregnancy, the perinatal period, and lactation. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Patient-centered Research, and Translate basic science into new therapies. | **NICHD** | Empowering Biomedical Research Community: Training. | 2006 | 0 |
| Support of Meeting Organized by Govt. Agencies and the Society of Toxicology (Developmental Basis of Adult Disease) | Meeting/Workshop | An international conference focused on the role of environmental exposures in the developmental basis of disease paradigm will provide an opportunity to review the current literature, to identify research opportunities, gaps and challenges, and to integrate basic and applied research. | FDA | Early Childhood Health/Development. | **NIEHS** | NONE | 2009 | 0 |
| Symposium on Bringing Gender Home: Implementing Gender Responsive HIV/AIDS Programming for U. S. Women and Girls | Meeting/Workshop | Co-sponsor of symposium on the issues of HIV research and programming for women and girls; and to identify and address roles and behaviors that increase risk for contracting and transmitting STDs, including HIV/AIDS. | CDC/FDA/HRSA/ SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Fast-track innovation planning and regulatory review, and Patient-centered Research. Health Care Quality/Patient Safety. HIV/AIDS. Social/Behavior Research. | NIAID/NICHD/ NIDA/NIMH/NINR/**OD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Behavioral Science, Health Information Technology, Health Disparities, and Patient Safety. Translational Research. | 2009 | 37,384 |
| Telemedicine & Advanced Technology Research Center (TATRC) Spinal Cord Injury Product Line Review | Committee/Workgroup | TATRC invites the opinions, guidance and review expertise of staff from several government departments including HHS for the evaluation of supported research in several medical areas including Spinal Cord Injury. Goals of TATRC include the development of advanced technologies in areas such as: health informatics; medical imaging; mobile computing and remote monitoring, as well as simulation and training. TATRC serves the interests of the Army, Navy, and Air Force and is a "thought leader in areas such as the use of virtual reality tools, biomaterials and hospital-of-the-future concepts." | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Translate basic science into new therapies. | **NICHD**/NINDS | Health Care Reform: Comparative Effectiveness Research and Health Disparities. High-throughput Technology. Translational Research. | 2008 | 0 |

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| Ten years post PKU Consensus Conference: State of the Science | Committee/Workgroup | The purpose of this collaboration is to have a scientific discussion to address management of phenylketonuria (PKU) in light of recent research findings. Screening and management guidelines for PKU were last published as the result of a Consensus Conference held in October 2000, and there have been new developments since that time. This new discussion will consider the state of the science in the areas of diet control and management; pharmacologic interventions; PKU and pregnancy; long-term cognitive outcomes and follow-up; and molecular testing, new technologies, and epidemiologic considerations. We are convening working groups to generate and address specific questions related to these topics. In parallel, an AHRQ Evidence-based Practice Committee is independently evaluating the use of newly available pharmaceutical interventions relative to dietary interventions for PKU, with the NIH as a partner in this process. We plan to host a conference in late 2011 (or early 2012) after the AHRQ review process, to discuss the conclusions and recommendations of the working groups. | AHRQ/CDC/FDA/ HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Global Health: Non-Infectious Diseases. Nutrition/Obesity. Pharmacogenomics. | NHGRI/**NICHD**/ NIDDK/NINDS/ NINR/OD | Empowering Biomedical Research Community: Global Health. Health Care Reform: Health Research Economics. Translational Research. | 2009 | 0 |
| Terminology Resources | OTHER: Memorandum of Understanding | In 2004, the FDA and the National Cancer Institute (NCI) signed a Memorandum of Understanding (MOU) whereby NCI agreed to provide terminology development and maintenance services to all FDA Centers. Under this MOU, CDRH's Office of Surveillance and Biometrics (OSB) convened a cross-Center workgroup and collaborated with staff at NCI Enterprise Vocabulary Service (EVS) to streamline the Patient and Device Problem Codes and integrate them into the NCI Thesaurus and Meta-Thesaurus. | FDA | NONE | **NCI** | NONE | 2004 | 0 |
| Text 4 Baby Program Evaluation Technical Advisory Group | Committee/Workgroup | Formal program evaluation of the Text 4 Baby initiative, which provides health info to pregnant women and young mothers via text message. | CDC/FDA/HRSA/ OS/SAMHSA | Early Childhood Health/Development. | **NICHD** | Health Care Reform: Health Information Technology. | 2010 | 250,000 |
| The Application of Computation Intelligence in Medical Device Study: Developing a Composite Index Approach to Predicting Individual Patient Success Outcomes after Intervetebral Disc Replace | Research Initiative | In this project, the Scientific Computing Section will: 1) Select optimal computational intelligence approaches to identify factors associated with the patient outcomes and to develop a patient composite index that can effectively predict the patient clinical success outcome after receiving the artificial inter-vertebral disc replacement system.; 2) Test the created composite index with a different dataset than the one used to develop the composite index model and compare the results of this approach with the conventional statistical analysis method.; 3) Upon successful development and testing of the composite index based system, provide a descriptive system design outline and prototype (non-production) system that could be used to develop a production system that could be used by FDA reviewers and orthopedic surgeons to identify individual patients who are more likely to benefit from the inter-vertebral disc implantation. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies. | **CC** | Health Care Reform: Comparative Effectiveness Research. | 2010 | 100,000 |
| The Ethics and Regulation of Marketing Junk Food to Children | OTHER: Conceptual papers | This project involves reviewing the known risks associated with "junk food" marketing campaigns that are directed at young children; summarizing US-based regulations related to these marketing practices; reviewing/critiquing the literature on the ethics of these marketing practices and the ethics of regulating such practices; and developing an alternate ethical framework, grounded in public health ethics, in support of more stringent regulation of these marketing practices. | FDA | NONE | **CC** | NONE | 2010 | 0 |

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| The Federal TB Task Force | Committee/Workgroup | The Federal Tuberculosis (TB) Task Force is a coalition composed of the federal agencies and organizations involved in U.S. TB control efforts. Established in 1991, it facilitates coordination of activities between federal agencies. It was created by the Director of the Center for Disease Control and Prevention (CDC) to address the outbreaks of multidrug-resistant (MDR) TB occurring during 1985-1992 surge in TB cases. | AHRQ/CDC/CMS/ FDA/HRSA/IHS/ OS/SAMHSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Fast-track innovation planning and regulatory review, and Patient-centered Research. Global Health: Infectious Diseases. HIV/AIDS. | **FIC/NHBLI/** NIAAA/NIAID/NIDA | Empowering Biomedical Research Community: Global Health. Health Care Reform: Health Disparities. Regulatory Science. | 1991 | 0 |
| The Foundation for the NIH Biomarkers Consortium | Committee/Workgroup | he Biomarkers Consortium develops, validates, and qualifies biological markers (biomarkers) to speed the development of medicines and therapies for detection, prevention, diagnosis, and treatment of disease and improve patient care. The NIH Public Private Partnership Program coordinates NIH participation in the sponsored Biomarkers Foundation for the National Institutes of Health (FNIH) consortium. The consortium is an umbrella which encompasses research projects, ongoing working groups, as well as occasional workshops and conferences. | CMS/FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies, Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | NCI/NHLBI/NIA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDDK/NIMH/ **NINDS/OD** | Health Care Reform: Health Disparities. High-throughput Technology. Translational Research. Regulatory Science. | 2006 | 0 |
| The Genetic and Rare Diseases Information Center | Information Clearinghouse | Genetic and Rare Diseases Information Center (GARD), is a collaborative effort of two agencies of the National Institutes of Health, the Office of Rare Diseases Research (ORDR) and the National Human Genome Research Institute (NHGRI) to provide patients, their families, healthcare providers, researchers, and the general public with access to free, current, and reliable information in English and Spanish about rare and/or genetic diseases. GARD has works with the FDA/Office of Zorphan Products Development, CDC, HRSA, AHRQ and others to provide comprehensive information to persons with rare diseases and the public. | AHRQ/CDC/FDA/ HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | NHGRI/**OD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Health Information Technology. | 2002 | 593,405 |
| The Health Consequences of Smoking and Involuntary Exposure to Tobacco Smoke: An Update – Workgroup on Mathematical and Statistical Modeling on the Population Impact of Smoking | Committee/Workgroup | The workgroup was convened to share relevant information and begin formulating writing plans for the 2011 update to the Surgeon General's Report, the Health Consequences of Smoking and Involuntary Exposure to Tobacco Smoke. | CDC/FDA/OSG | Tobacco Prevention and/or Control. | NCI/NIGMS/**OD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Behavioral Science. Regulatory Science. | 2010 | 0 |
| The Pediatric Heart Network-- Marfan Trial | Research Initiative | The Pediatric Heart Network is a collaboration of clinical sites and a data coordinating center that conducts research studies in children with congenital or acquired heart disease. The FDA's Office of Orphan Products Development is providing financial support for the Marfan Trial, one of the studies being conducted in the network. | FDA | Accelerate Discovery to Improve Patient Care: Patient-centered Research. Early Childhood Health/Development. Health Care Quality/Patient Safety. | **NHLBI** | Translational Research. | 2006 | 7,471,016 |
| The Pharmacology Research Associate (PRAT) Program | Training Initiative | Funding provided for the support of PRAT Associate as a first year fellow in the laboratory at the Food and Drug Administration (FDA). | FDA | NONE | **NIGMS** | Empowering Biomedical Research Community: Training. | 1965 | 56,935 |
| The Research Challenges in CNS Manifestations of Inborn Errors of Metabolism Workshop | Meeting/Workshop | This workshop will bring together those involved in research and investigational treatments for central nervous system aspects of inborn errors of metabolism, and to discuss ways to translate these therapies to clinical trials and beyond. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. | **NINDS**/OD | Translational Research. Regulatory Science. | 2010 | 0 |

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| The Science of Sex and Gender in Human Health | OTHER: Educational training course for physicians | This is a Web-based course that offers a basic scientific understanding of the major physiological differences between the sexes; their influence on illness and health outcomes; and their implications for policy, medical research, and health care. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. | **OD** | Empowering Biomedical Research Community: Training. | 2006 | 150,209 |
| The Science of Small Clinical Trials | Meeting/Workshop | The Science of Small Clinical Trials, a course created jointly by the FDA's Office of Orphan Products Development (OOPD) and NIH's Office of Rare Diseases Research, (ORDR), dealt with issues arising in the design and analysis of clinical trials based on small study populations. While small clinical trials are a necessity in the context of rare diseases, being able to conduct small trials with scientific rigor is of increasing importance in other contexts, particularly as genomic science begins to provide opportunities for individualized pharmacology. 1,300 persons attended the course either in person or via Web streaming and completed the test leading to a certificate. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, and Patient-centered Research. Global Health: Infectious Diseases and Non-Infectious Diseases. | **OD** | Empowering Biomedical Research Community: Training, Peer Review, and Global Health. Regulatory Science. | 2009 | 14,000 |
| The Trans-NIH Rare Diseases Working Group | Committee/Workgroup | The Trans-NIH Rare Diseases Working Group was established in 2004. The working group assists ORDR to carry out its mission by working towards a set of goals that build on partnerships ORDR has developed with NIH Institutes, Centers, and Offices, HHS agencies, and other organizations that address issues in rare diseases research such as identifying research opportunities and advances in rare diseases research; promoting coordination and cooperation in joint research efforts among the NIH ICs and Offices and the research entities they support. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Early Childhood Health/Development. Global Health: Infectious Diseases, Non-Infectious Diseases, and Strategic Initiative. Health Care Quality/Patient Safety. Pain Research. Pharmacogenomics. Social/Behavior Research. | CC/FIC/NCCAM/NCI/ NCCR/NEI/ NHLBI/NHGRI/ NIA/NIAAA/ NIAID/NIAMS/ NIBIB/NICHD/ NIDA/NIDCD/ NIDCR/NIDDK/ NIEHS/NIGMS/ NIMH/NIMHD/ NINDS/NINR/NLM/**OD** | Empowering Biomedical Research Community: Training, Peer Review, and Global Health. Health Care Reform: Comparative Effectiveness Research, Behavioral Science, Health Information Technology, Health Research Economics, Health Disparities, and Patient Safety. High-throughput Technology. Translational Research. Regulatory Science. | 2004 | 0 |
| Therapeutics for Rare and Neglected Diseases (TRND)/FDA Working Group | Committee/Workgroup | A group of Therapeutics for Rare and Neglected Diseases (TRND) staff and FDA staff from the Center for Drug Evaluation and Research (CDER) meet on a semi-monthly basis to discuss pilot projects for the TRND program. The purpose of this working group is to discuss the scientific progress on each project toward the eventual goal of an Investigational New Drug Application for each project. Results of experiments are discussed, and TRND staff takes the feedback of FDA/CDER staff into consideration when developing future project plans. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Translate basic science into new therapies. Global Health: Infectious Diseases and Non-Infectious Diseases. | **NHGR**I/OD | Empowering Biomedical Research Community: Global Health. Translational Research. | 2009 | 0 |
| TNF-alpha induced REL interactions with p63/p73in head and neck cancer | Research Initiative | NIDCD Head and Neck Surgery Branch and FDA CDER Monoclonal Antibody group collaborated to define novel interactions between REL and p63/p73 family transcription factors in head and neck cancer. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NIDCD** | NONE | 2003 | 100,000 |

| Table 15: FDA Collaborations - FY 2010 = 243 | | | | NIH Funding = $151,974,128 | | | | |
|---|---|---|---|---|---|---|---|---|
| **Collaboration Title and Link** | **Collaboration Type with Various Additional Links** | **Brief Description of Collaboration** | **HHS Participating Agencies** | **HHS Strategic Priority Alignment** | **NIH Participating Institutes/Centers/ Office of the Director** ***(Activity Submitting Office(s) Bolded)*** | **NIH Strategic Priority Alignment** | **Year Collaboration Originated** | **NIH Funding Contribution in FY 2010** |
| Tobacco and Tobacco Smoke Constituent Review and Assessment | Database | This project is to compile, review, summarize and interpret the scientific literature on constituents of tobacco and tobacco smoke in order to provide recommendations to the Commissioner of the FDA to implement the Family Smoking Prevention and Tobacco Control Act. | FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Fast-track innovation planning and regulatory review. Tobacco Prevention and/or Control. | **NLM** | Regulatory Science. | 2010 | 0 |
| Tobacco Control Strategic Planning Committee | Committee/Workgroup | This committee, led by the Department of Health and Human Services, helped to develop the HHS Tobacco Control Strategic Action Plan. | CDC/FDA/HRSA/ OS/SAMHSA | Tobacco Prevention and/or Control. | NCI/**NIDA** | Translational Research. | 2010 | 0 |
| Tox21 Collaboration | Research Initiative | The Toxicology in the 21st Century project, or Tox21, is a collaborative effort that began in 2006 with the NIH Chemical Genomics Center (NCGC), the National Toxicology Program (NTP) based at the National Institute of Environmental Health Sciences (NIEHS), and the Environmental Protection Agency. The ambitious initiative was designed to predict the toxicity of chemicals on human health and the environment. This is accomplished by developing in vitro assays for more predictive, mechanistically-based methods than those used with current animal testing. On July 19th, 2010, the U.S. Food and Drug Administration (FDA) joined this ground-breaking collaboration. The FDA will bring human toxicity data into the project, along with other expertise, to improve upon current chemical testing methods. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Translate basic science into new therapies. | **NHGRI**/NIEHS | High-throughput Technology. Translational Research. Regulatory Science. | 2006 | 4,000,000 |
| Trans-Federal Policy Coordination for Adverse Event Reporting in Clinical Research | Committee/Workgroup | Propose specific means for promoting harmonized and streamlined federal requirements for reporting, analyzing, and communicating adverse events in clinical research. | AHRQ/FDA | NONE | **NCI** | NONE | Unknown | 0 |
| Trans-HHS Taskforce on Harmonization of Ethical and Legal Policies Related to the Use of Human Specimens and Data in Research (HELPS) | Committee/Workgroup | Data (HELPS) explores ways of harmonizing federal regulations and policies related to research involving human specimens and data. HELPS is chaired by NIH/OBA. | AHRQ/CDC/FDA/ OS | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review and Translate basic science into new therapies. | **OD** | Health Care Reform: Health Information Technology. High-throughput Technology. | Unknown | 0 |
| Translational Research Potential for Hyperpolarized C13 Techniques for cancer and Other Diseases | Meeting/Workshop | A trans-NIH workshop held in May 2010 to develop a report on the potential role of hyperpolarized C`3 MRI for cancer and other diseases. | FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies and Innovative Biomedical Technologies. | **NCI**/NCRR/ NHLBI/NIBIB/NIDDK | Translational Research. | 2009 | 0 |
| Trans-NIH Nanotechnology Task Force: National Nanotechnology Initiative (NNI) call for trans-agency Signature Initiatives | Committee/Workgroup | In response to NNI's call for Signature Initiatives, the NIH Nanotechnology Task Force (NIDCR and NIBIB representatives) together with FDA and other Federal Agencies (NIST, NSF, and DoD) have generated a draft of the Initiative entitled "Nano-Regenerative Medicine". The overarching goals of this Initiative are to develop robust and efficient platforms for standardization, fabrication, GMP manufacturing, and regulatory approval of nanotechnology-based products that will lead to new paradigms in low-cost therapies targeting regeneration of a range of tissues in the human body affected by disease and injury. On July 24, 2009, the draft of the Initiative was submitted for review to the Office of Science and Technology Policy through NNI. In 2010, a trans-Federal Agency Working Group was formed to continue the development of this Initiative. | FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Global Health: Strategic Initiative. | NIBIB/**NIDCR**/NHLBI | Empowering Biomedical Research Community: Training. High-throughput Technology. Translational Research. Regulatory Science. | 2001 | 0 |

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| Trans-NIH Plan for HIV-Related Research | Committee/Workgroup | Authorized by section 2353 of the Public Health Service Act, this annual collaborative planning process establishes scientific priorities for all NIH AIDS research. Broad input is solicited from scientists from NIH, other government agencies, and non-governmental organizations, as well as community representatives and other experts from the United States and abroad. | CDC/FDA/OS | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, Patient-centered Research, and Translate basic science into new therapies. Global Health: Infectious Diseases and Strategic Initiative. HIV/AIDS. Social/Behavior Research. | CC/CSR/FIC/ NCCAM/NCI/ NCRR/NEI/NHLBI/ NHGRI/NIA/ NIAAA/NIAID/ NIAMS/NIBIB/ NICHD/NIDA/ NIDCD/NIDCR/ NIDDK/NIEHS/ NIGMS/NIMH/ NIMHD/NINDS/ NINR/NLM/**OD** | Empowering Biomedical Research Community: Training and Global Health. Health Care Reform: Behavioral Science and Health Disparities. Translational Research. | 1994 | 0 |
| U. S. Government Interagency Working Group on Nanotechnology Environmental, and Health Implications (NEHI), of the Nanoscale Science, Engineering, and Technology Subcommittee (NSET) of the National Science and Technology Council (NSTC) | Committee/Workgroup | The NSET Subcommittee and NEHI Working Group provide leadership in establishing the national nanotechnology environmental, health, and safety research agenda and in communicating data and information related to environmental and health aspects of nanotechnology between National Nanotechnology Initiative (NNI) agencies and with the public. NNI activities support the development of new tools and methods required for the research that will enable risk analysis and assist in regulatory decision-making. NNI agencies engage and interact with regional, state, and local groups, educational institutions, industry-supported groups, and non-governmental organizations to enhance the impact and value of NNI efforts and to provide a collaborative approach. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public and Fast-track innovation planning and regulatory review. | **NCI**/NHGRI/NIBIB/ NIEHS | Health Care Reform: Patient Safety. Regulatory Science. | 2005 | 0 |
| U. S. Government Microbicides Coordinating Committee | Committee/Workgroup | NIH/OAR administers and chairs a committee of representatives from each of the U.S. Government agencies involved in microbicides research. The committee provides coordination and collaboration of U.S. Government microbicide research activities. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Fast-track innovation planning and regulatory review, Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Patient-centered Research. Global Health: Infectious Diseases and Strategic Initiative. HIV/AIDS. Social/Behavior Research. | FIC/NCI/NIAID/ NICHD/NIDA/ NIMH/NINR/**OD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Behavioral Science. Translational Research. | 2001 | 0 |
| U. S.-Japan Cooperative Medical Science Program (CMSP) | Committee/Workgroup | This is a bilateral program with Japan. Various HHS agencies were invited to participate in various events (e.g., conferences). | CDC/FDA/OS | Global Health: Specific category priorities not reported. | **NIAID** | Empowering Biomedical Research Community: Global Health. | 1965 | 0 |
| Unified Medical Language System Metathesaurus (UMLS) | OTHER: Data Services | NLM's Unified Medical Language System (UMLS®) facilitates the development of computer systems that behave as if they understand the meaning of the language of biomedicine and health. To that end, NLM produces and distributes the UMLS Knowledge Sources (databases) and associated software tools (programs) for use by system developers in building or enhancing electronic information systems that create, process, retrieve, integrate, and/or aggregate biomedical and health data and information, as well as in informatics research. By design, the UMLS Knowledge Sources are multi-purpose. | AHRQ/CDC/ CMS/FDA | Global Health: Strategic Initiative. Health Care Quality/Patient Safety. | **NLM** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Comparative Effectiveness Research and Health Information Technology. | 1990 | 0 |

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| US-Japanese Meeting: Immunotherapy Markers in Oncology: Progress and Challenges | Meeting/Workshop | Goals of conference were to 1) enhance collaboration and cross-fertilization of ideas and approaches among the U.S. and Japanese community; 2) provide opportunities to cross-evaluate and compare immunotherapy practice in the U.S. and Japan; 3) provide seeds for a collaborative network that would eventually represent a consortium working in this field; and 4) bring together the community to address international regulatory challenges in developing cell products for immune-based therapy that will improve the efficiency of developing protocols that are acceptable to the FDA. | FDA | Accelerate Discovery to Improve Patient Care: Translate basic science into new therapies. | **NCI** | Translational Research. Regulatory Science. | 2009 | 0 |
| Viral Panel Project: Characterization of HIV diversity for the evaluation of test performance using viral panels | Research Initiative | The purpose of this interagency agreement is to characterize emerging HIV strains from blood donors and patients and determine viral tropisms based upon co-receptor usage of strains. | FDA | HIV/AIDS. | **NIAID** | Empowering Biomedical Research Community: Global Health. | 2009 | 0 |
| Working Groups to Develop Federal HIV/AIDS Prevention and Treatment Guidelines | Committee/Workgroup | The U.S. Department of Health and Human Services issues Federal guideline documents for the prevention and medical management of HIV infection and issues surrounding HIV infection. The guidelines are written, reviewed, and updated by Working Groups of HIV experts, including physicians, pharmacists, researchers, and HIV treatment advocates. These Working Groups function under the auspices of the NIH Office of AIDS Research Advisory Council (OARAC). | CDC/FDA/HRSA | Accelerate Discovery to Improve Patient Care: Disseminate health information to the public. HIV/AIDS. | CC/NIAID/NICHD/ NIMH/NLM/**OD** | NONE | 2005 | 489,985 |
| Workshop on Ethics and Regulatory Issues in Global Pediatric Trials | Meeting/Workshop | This workgroup will examine the challenging ethical and regulatory issues in global pediatric clinical trials. It will provide a forum for the mutual exchange of views and discussion among key international stakeholders in the design and conduct of pediatric clinical trials. | FDA | NONE | **NICHD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Health Disparities. | 2009 | 0 |
| Workshop on Safety Studies for Microbicides Research | Meeting/Workshop | Workshop to discuss parameters for determining safety of microbicide products. | CDC/FDA | Accelerate Discovery to Improve Patient Care: Innovative Biomedical Methodologies, Innovative Biomedical Technologies, and Patient-centered Research. Global Health: Infectious Diseases. HIV/AIDS. Social/Behavior Research. | FIC/NCI/NIAID/ NICHD/NIMH/**OD** | Empowering Biomedical Research Community: Global Health. Health Care Reform: Behavioral Science. Translational Research | 2009 | 0 |