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Managing Conflicts of Interest and Promoting Successful Public-Private Partnerships in Food and Agricultural Research

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A Transparent, Actionable Framework for Food and Nutrition Research
Public-Private Partnerships

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Disclosures: New era of transparency

- I have no current affiliations and funding sources related to the subject on which I will speak today.
 - Disclosure
 - Divestiture
 - Recusal
- Office of Government Ethics posts annual financial disclosures of Schedule C employees
- Stock Act of 2012 requires Schedule C and Senior Executive Service to publicly file report of transactions above \$1000 involving stocks, bonds and some securities.



Administration of Barack Obama, 2011

Memorandum on Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses

October 28, 2011

Memorandum for the Heads of Executive Departments and Agencies

Subject: Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses

(c) I encourage agencies with Federal laboratories and other research facilities to engage in public-private partnerships in those technical areas of importance to the agency's mission



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Ethics of Public Private Partnerships

- US Government is active promoter of public-private partnerships for research and technology transfer and continues to evolve new ways of working
- US Government has well-developed requirements for managing employee conflict of interest:
 - public disclosure of financial investments,
 - divestiture of holdings presenting conflict of interest
 - recusal from decisions when divestiture is not possible
- Transparency of public-private partnerships is required through annual reports
- Underlying principle is to promote the “public good”



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Post Government Employment Activities

- The U.S. government recognizes that career and political appointee employees leave for private employment
- Minimum one year cooling off period for all employees, two years for very senior employees
- Lifetime ban on future communications or representation on specific contracts, grants or lawsuits over which you had official responsibility.
- Even without direct official responsibility you may have a bar for up to two years.
- The ethics system is strong but permits experience to be of value in the public and private sectors

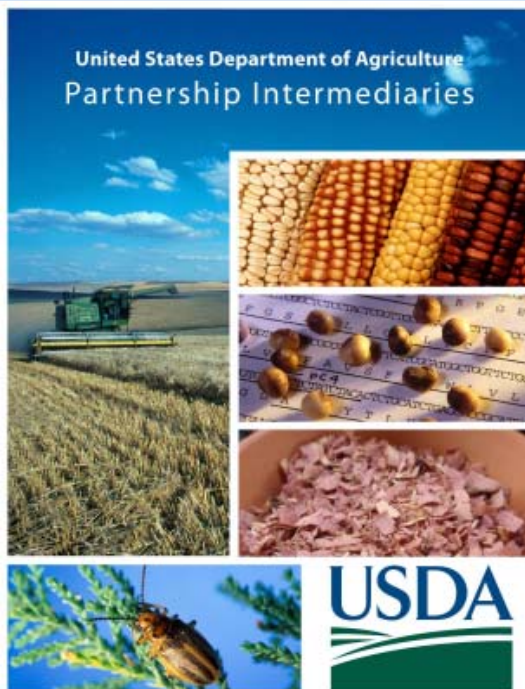


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Many mechanisms for partnering also address IP issues...

Technology Transfer Mechanisms



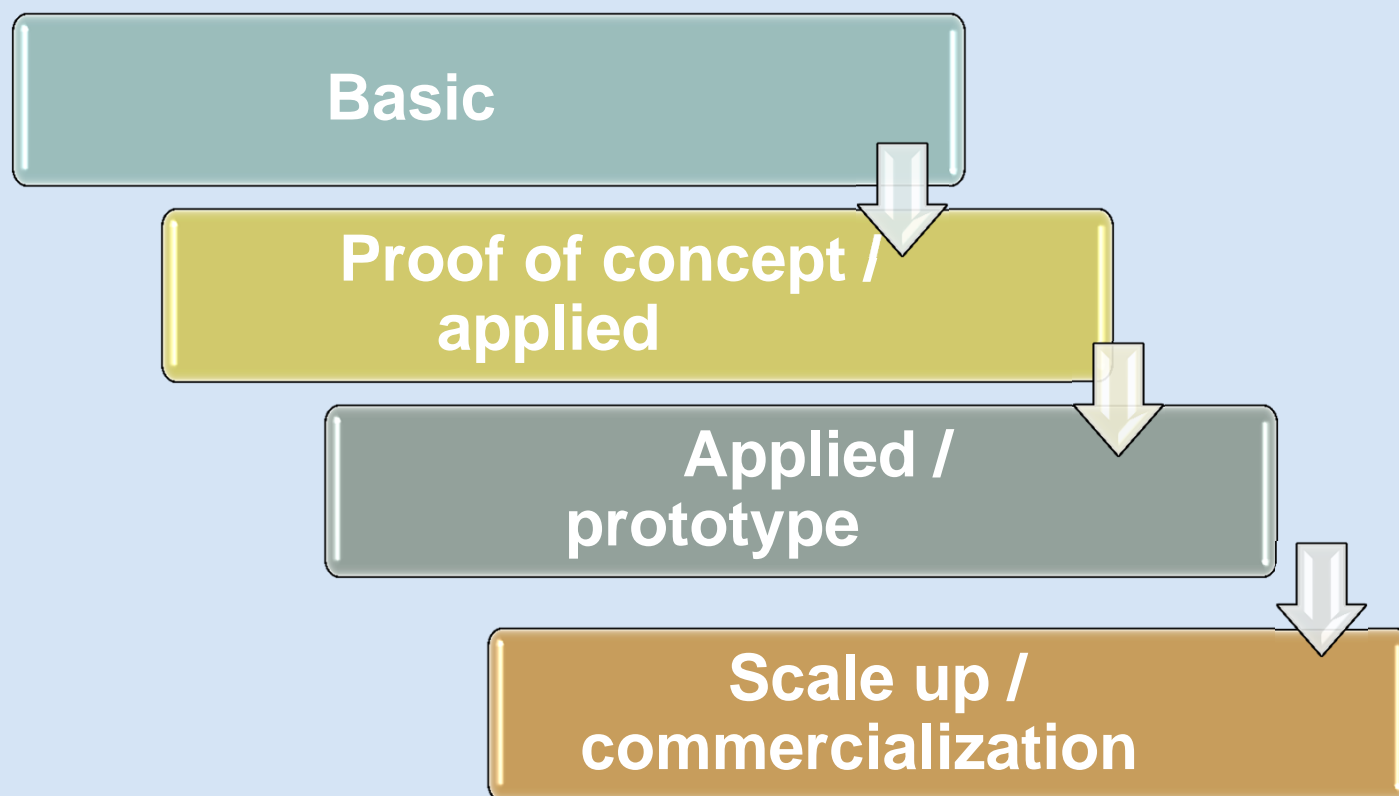
- Patent License Agreement (PLA)
- Cooperative Research and Development Agreement (CRADA)
- Trust Fund Cooperative Agreements (TFCA)
- Reimbursable Cooperative Agreements (RCA)
- Non-Assistance Cooperative Agreements
- Agreements with Other Federal Agencies (Interagency Agreements)
- Material Transfer Agreements (MTA)
- Material Transfer Research Agreements (new)
- Enhanced Use Lease Authority (EUL)



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The continuum of research and development ...



Where does “precompetitive” end?



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FNIH: Role and Function

- Create innovative public-private biomedical partnerships that complement NIH priorities and advance the public health
- Partner with corporations, foundations, academia, federal agencies, and philanthropic individuals
- Work with all NIH Institutes and Centers to support research, training and other types of programs
- Serve as a neutral forum for partners to collaborate
- Facilitate communication; ensure all partners' voices are heard
- Structure flexible donor relationships, multiple shapes/sizes
- Directly solicit contributions, steward & manage donor funds
- Manage grants, contracts, and projects, oversee & conduct research





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Funding & Partnership Models

1. Raise funds from private donors and partners to expand ongoing NIH activities (NIH-managed)
 - NIH intramural and extramural research programs
 - Fellowships and other training programs
 - Lectures, awards, etc.
 - Patient and family support activities
 - Follow all NIH rules; FNIH coordinates the partnership
2. Develop or support activities that take advantage of NIH expertise but are not led by NIH (FNIH-managed)
 - Biomarkers Consortium projects (BC)
 - Grand Challenges in Global Health
 - Observational Medical Outcomes Partnership
 - Other tailored opportunities
 - Can be more flexible; FNIH manages the program and coordinates the partnership





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Foundation for Food and Agricultural Research: History

- Established by 2014 Farm Bill
- New, private, non-profit Foundation to foster research, innovation, and public-private partnerships important to America's agricultural
- Congress provided \$200 million for the Foundation, matched by mandatory non-federal funds
- Will consult with USDA on research activities:
 - plant and animal health
 - production and products
 - food safety, nutrition and health
 - renewable energy, natural resources and the environment
 - agricultural and food security
 - agriculture systems and technology
 - agricultural economics and rural communities





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Foundation for Food and Agricultural Research: Current Status

- Foundation incorporated – July 17, 2014
- Board members named – July 23, 2014
- First Board meeting by phone, by-laws adopted, officers elected – August 7, 2014
- Funds transferred into FFAR account





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June 2011: ATIP members established the ATIP Foundation Leveraging the Assets of Partnership Intermediaries of ARS





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Focus – Seven Critical Metrics

1. Expedite the transition of USDA technologies from USDA labs into the commercial sector.
2. Increase the use of agriculture technology discoveries that meet the needs of emerging markets.
3. Seek funding for research, training, and product development to support the technology needs of the Agriculture industry and efforts to commercialize new technologies.
4. Develop industry access to utilize USDA/ARS research and research facilities consistent with USDA mission & priorities.
5. Create sustainable communities by promoting regional innovative clusters, based on USDA research outcomes.
6. Host regional events co-sponsored with USDA/ARS, showcasing technologies available for licensing, and/or Forums for delivering solutions to ag sector.
7. Provide for the development of the skilled workers needed to sustain the growth of the industry.





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ILSI Research Foundation – Public Private Partnerships

- ILSI Research Foundation – 501(c)(3)
- Primary business is to develop scientific knowledge in public interest and make it widely available.
- May enter into agreements granting sponsor ownership of patents, copyrights, etc. – but work must be in public interest and substantially all results must be published at earliest date possible without jeopardizing patent/copyright rights.





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ILSI Research Foundation – Public Private Partnerships

- Able to accept funding from corporations, foundations and government agencies for specific work.
- Operates with transparency and attention to declarations of interest.
- ILSI Research Foundation Board of Trustees is the governing body.





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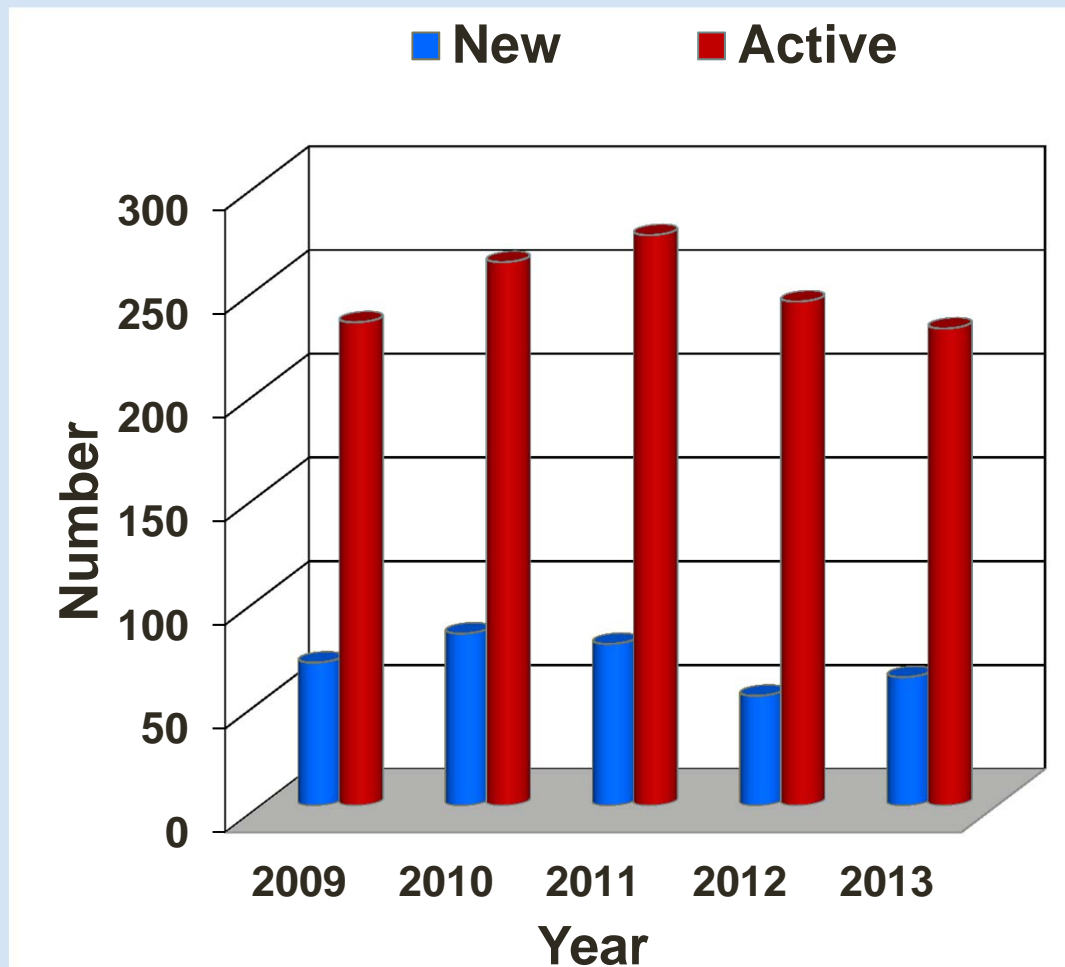
Thank you!



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Number of New and Active CRADAs FY 2009-2014



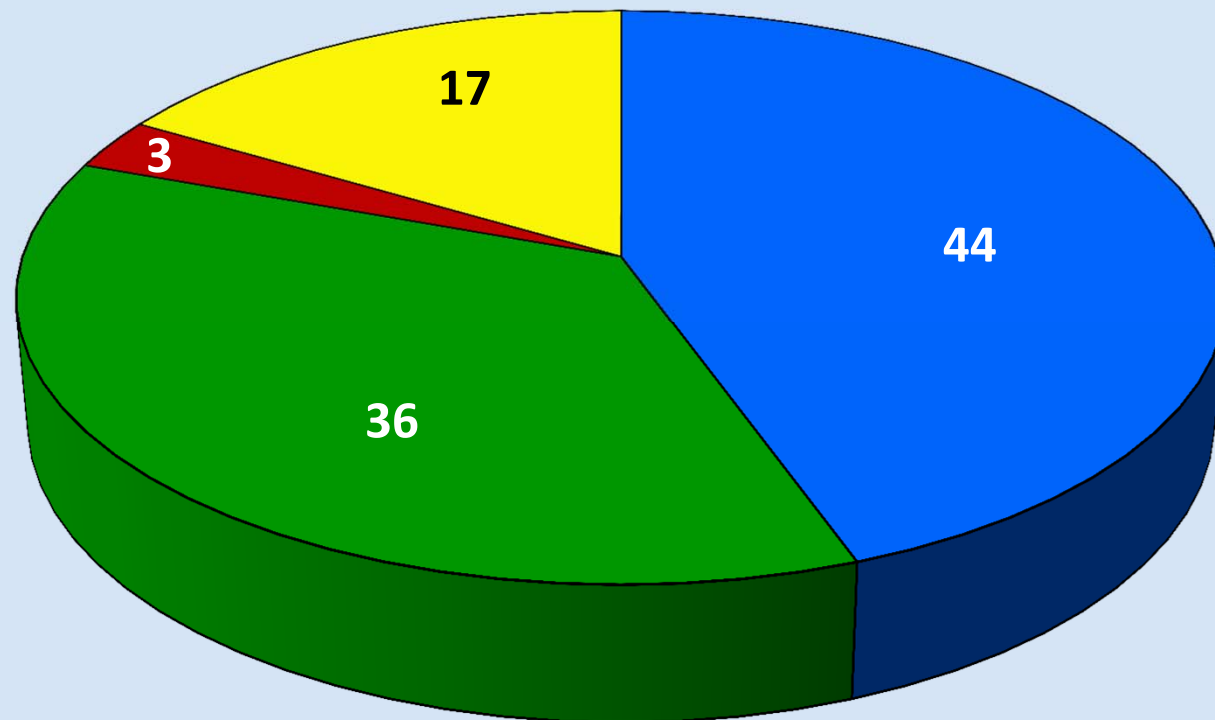


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Percentage of total new licenses executed in FY 2013 by business type.

■ Universities ■ Small Businesses
■ Start-ups ■ Other



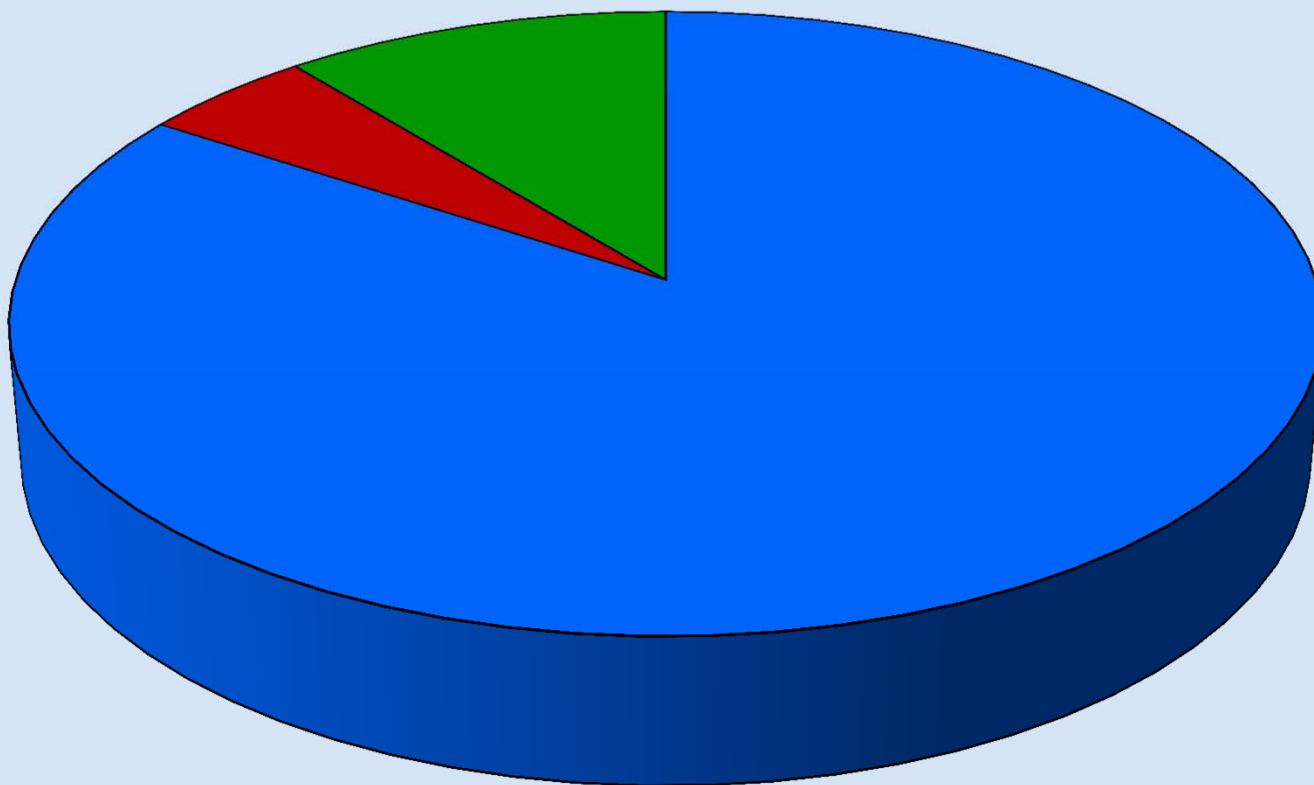


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Number of Tech Transfer Agreements by Type in FY 2014

■ MTAs (84%) ■ CRADAs (5%) ■ MTRAs (11%)



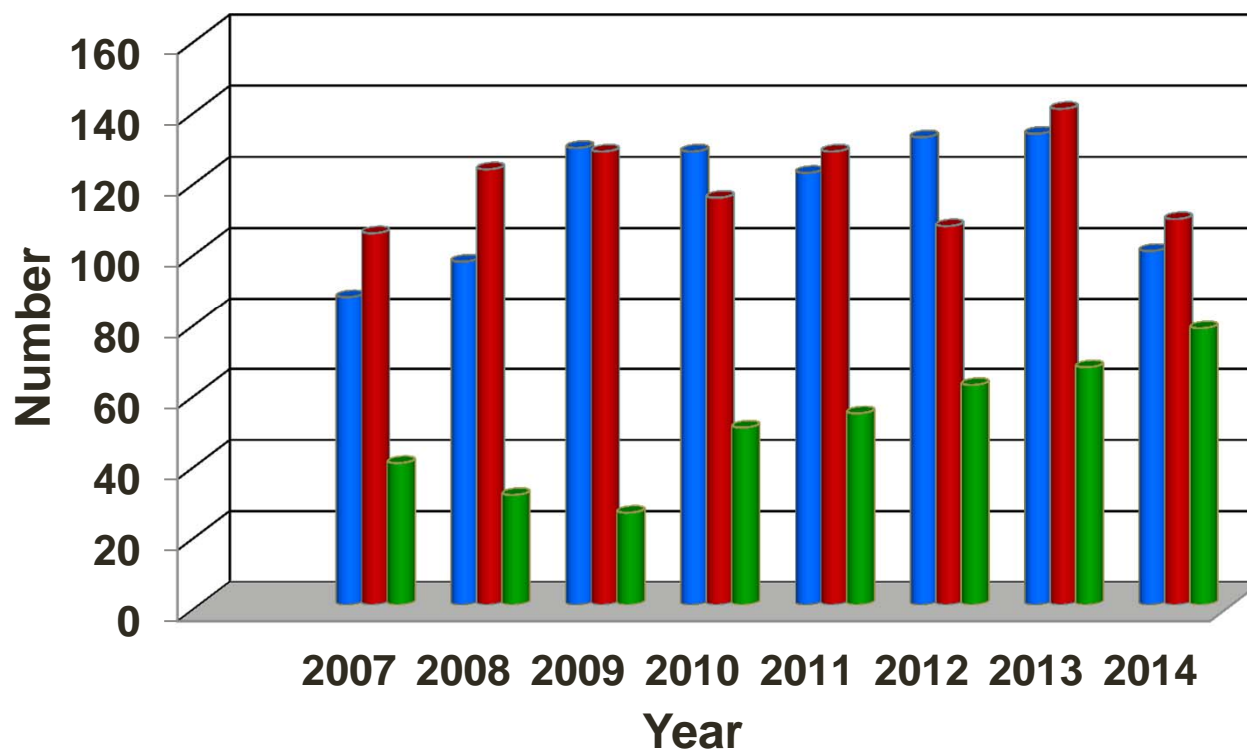


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Number of invention disclosures, patent applications filed and patents issued FY 2009-2014

■ Invention Disclosures ■ Patents Filed ■ Patents Issued



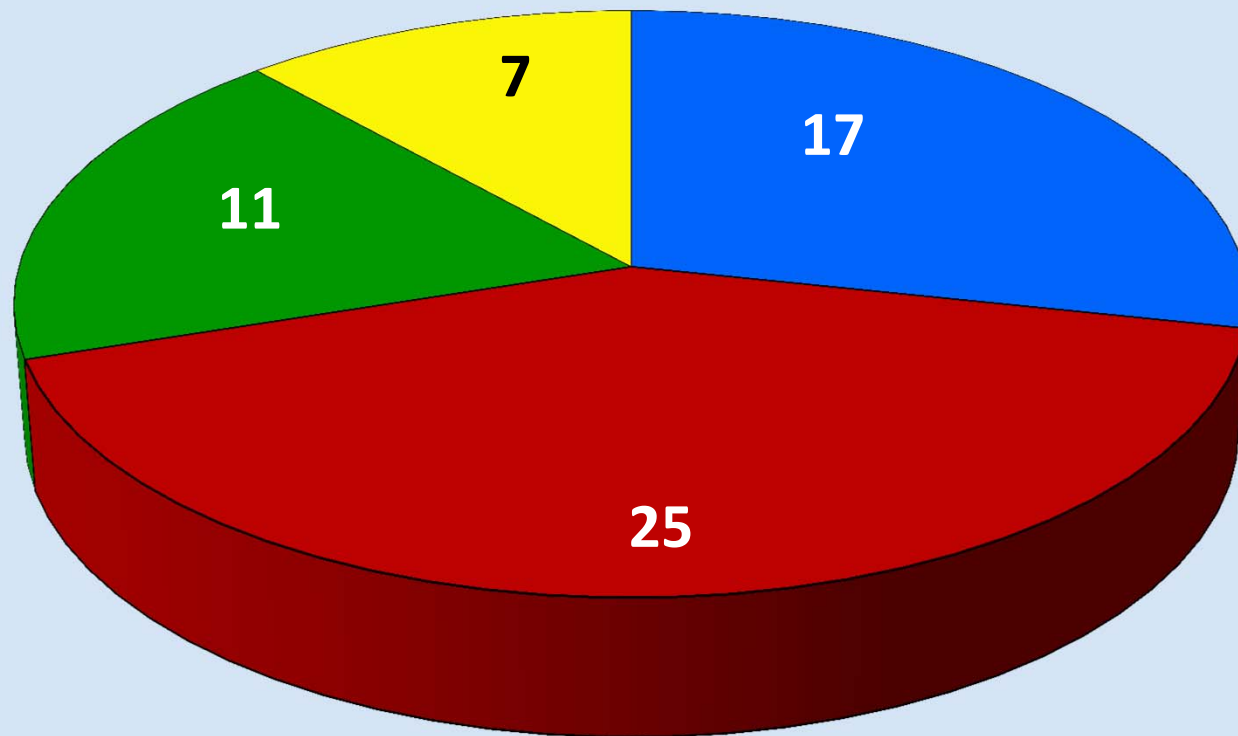


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Number of patents issued in FY 2013 by scientific discipline

- Life Science
- Chemical
- Mechanical & Measurements
- Plant Patents



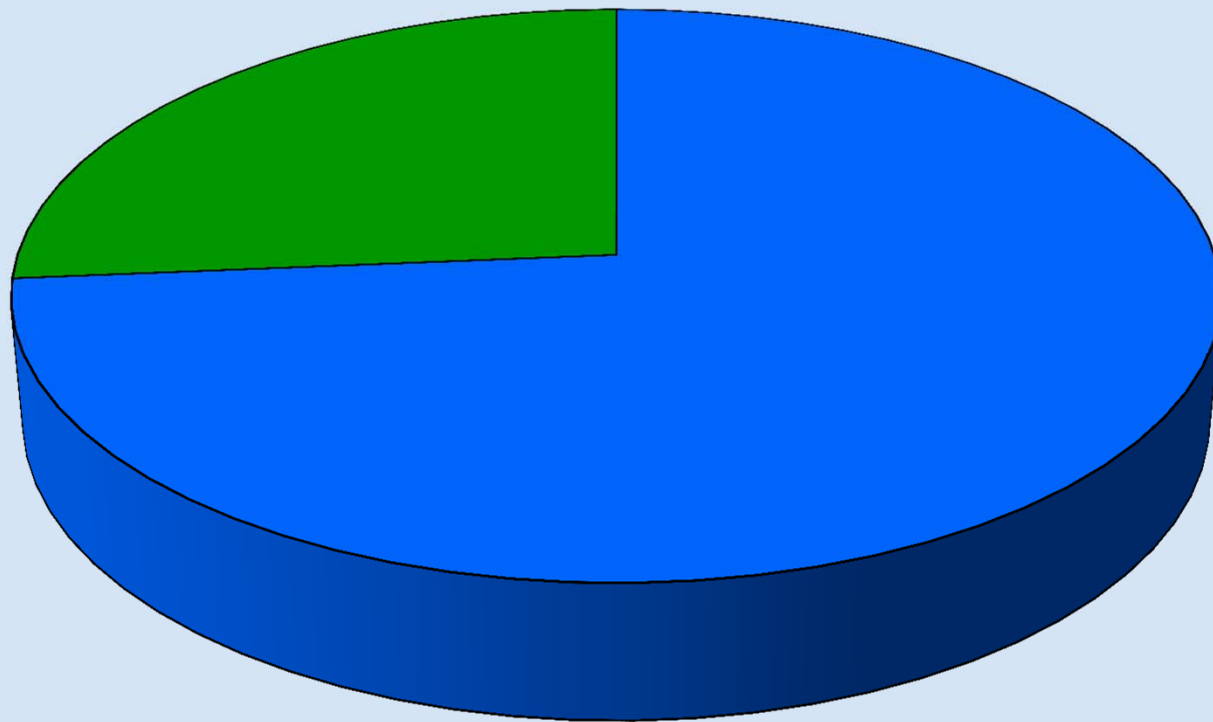


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Distribution of licenses executed in FY 2014

■ New (74%) ■ Amendments (26%)



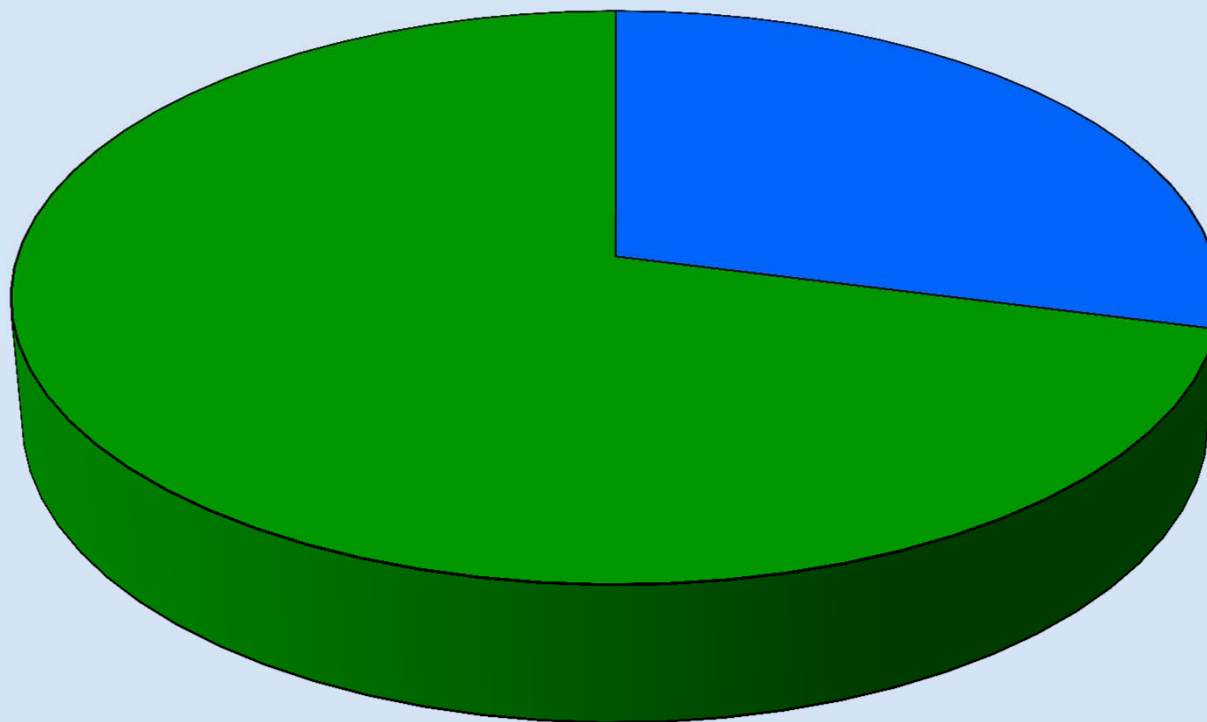


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Distribution of total license portfolio by exclusivity

■ Non-exclusive (29%) ■ Exclusive (71%)



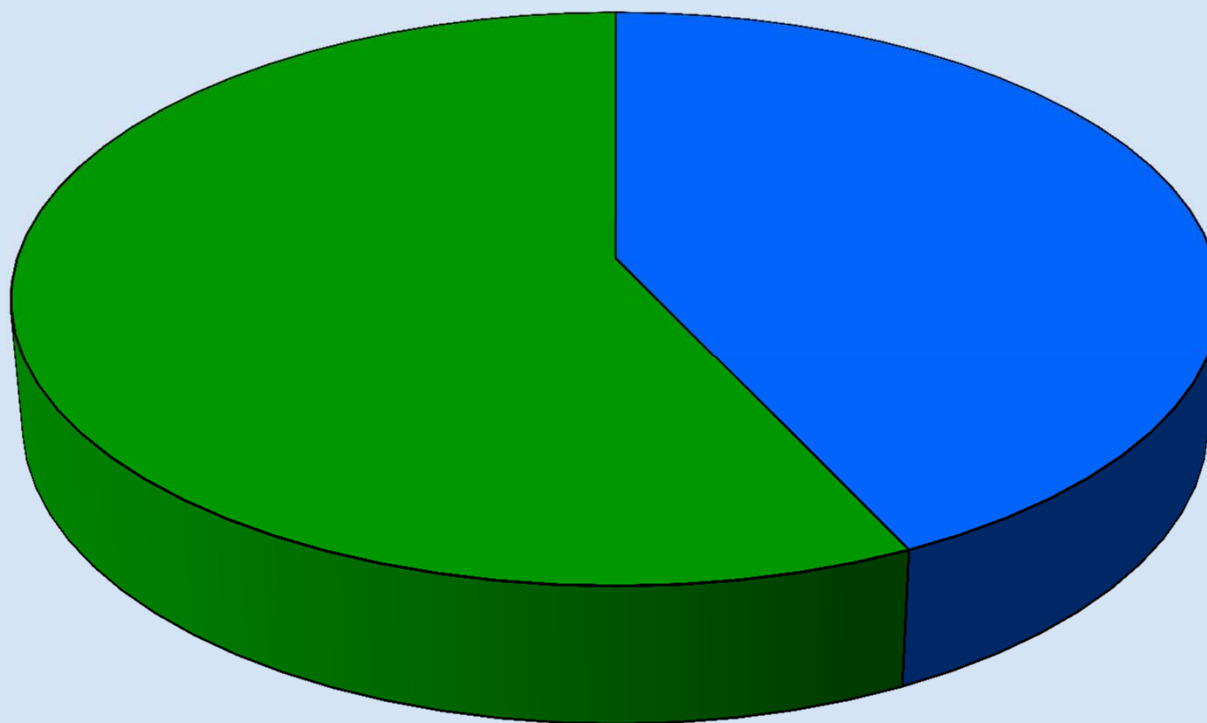


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Distribution of total license portfolio by licensee

■ University (43%) ■ Industry (57%)

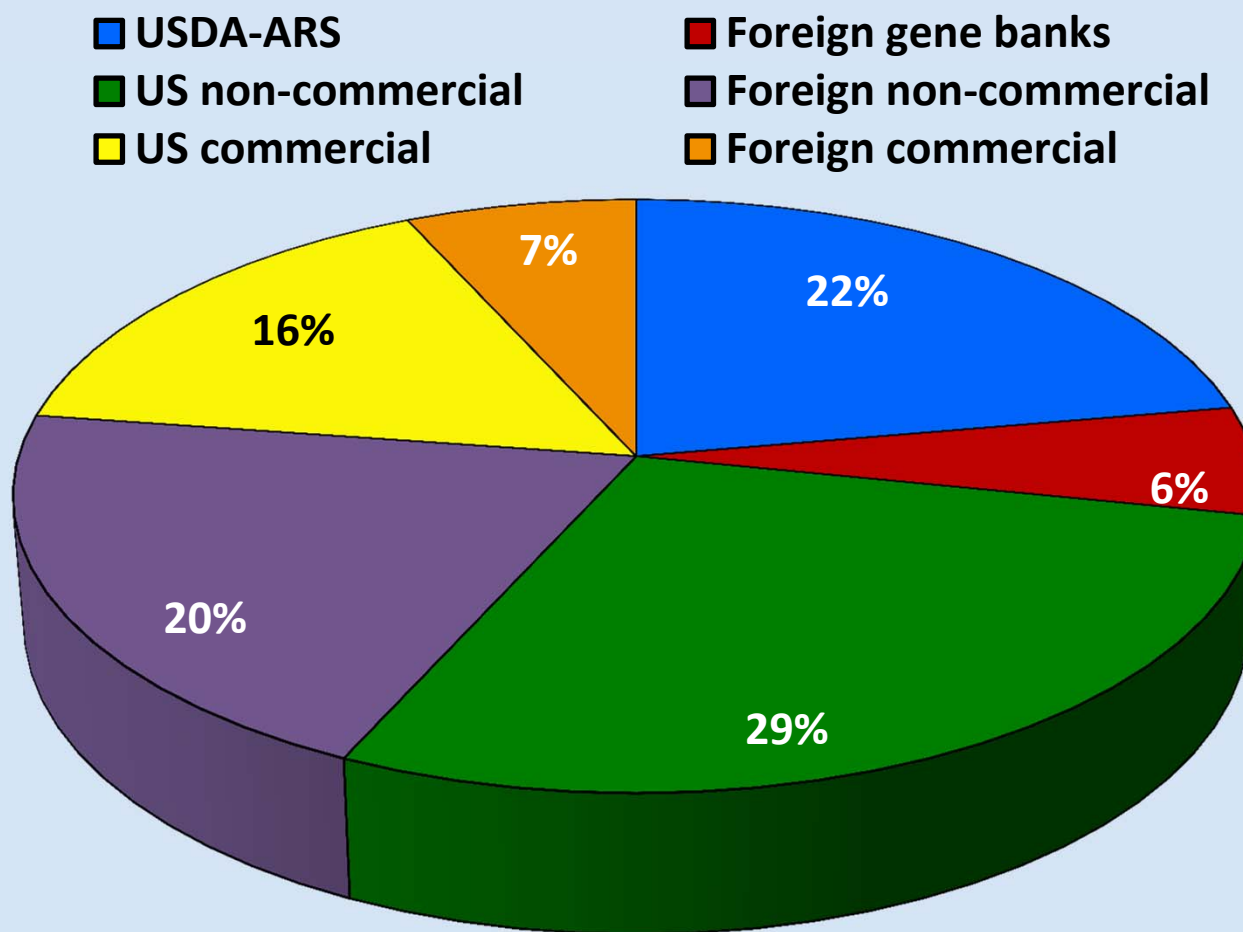




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Germplasm distribution in FY 2013

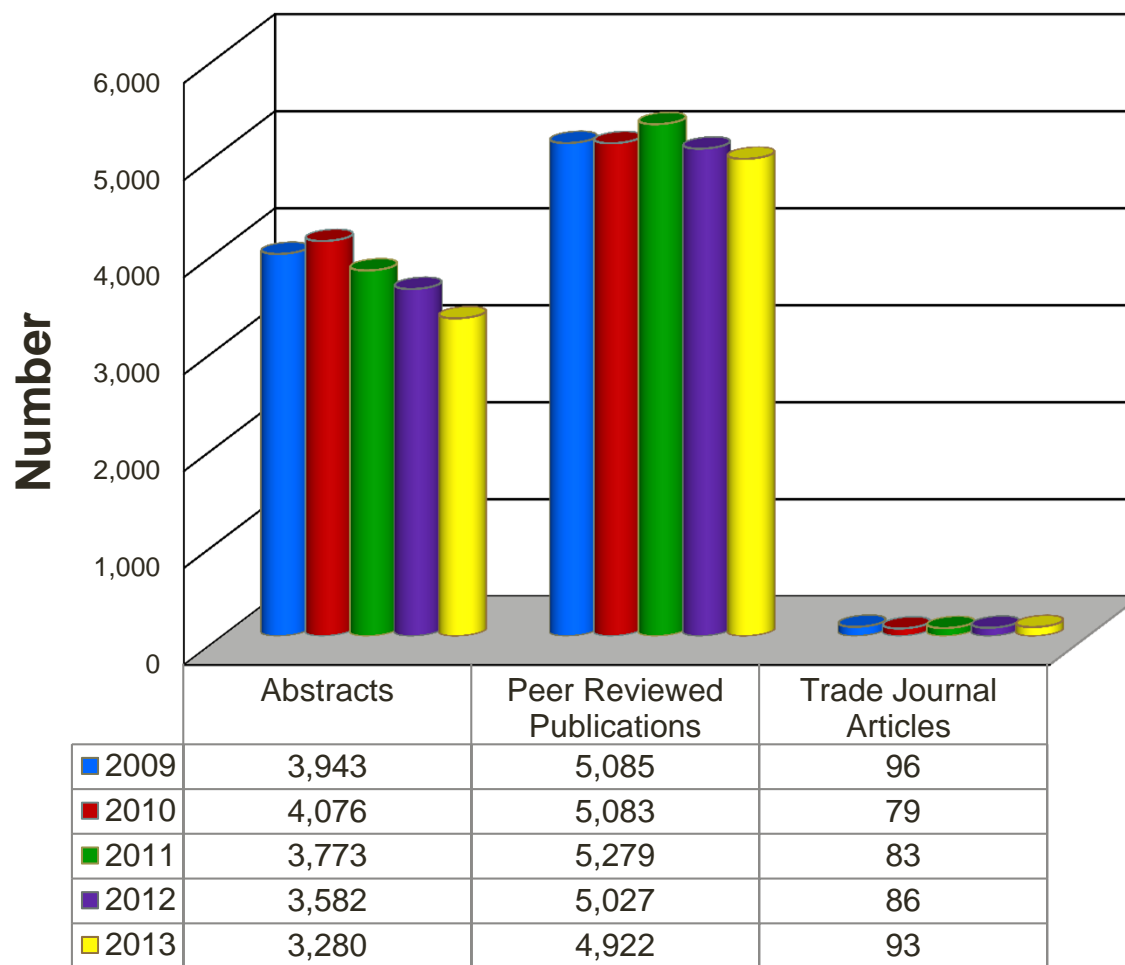




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Number of ARS-approved publications FY2008-2012

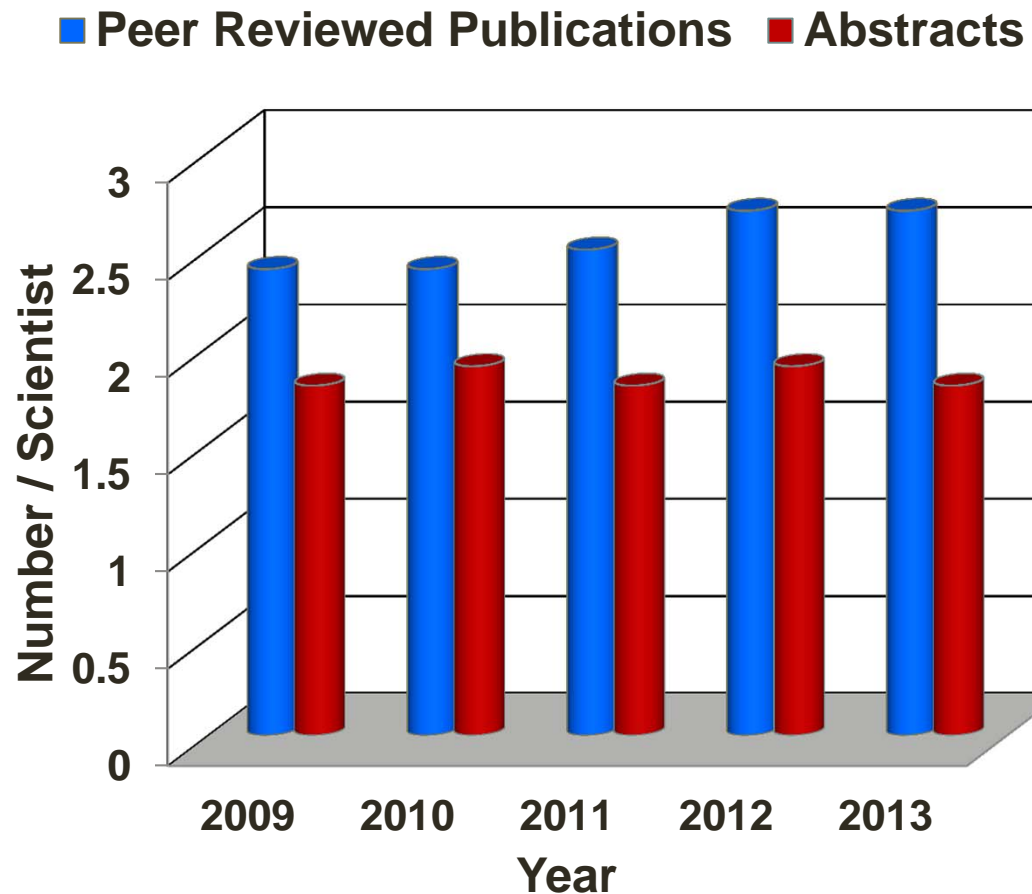




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Number of peer reviewed publications and abstracts per scientist





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- **Abbott-Illinois Grand Challenge**

- To conduct pioneering research on impact of nutrition on human brain and cognition
- To identify and capitalize on potential beneficial effects of nutritional compounds for enhancing, maintaining, and/or restoring fundamental aspects of learning, memory, and cognition

- **MARS – UC Davis World Food Center**

