



United States Department of Agriculture  
Research, Education, and Economics

# Public-Private Partnerships in Grains and Health

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## Topics to Be Covered

- White House Public-Private Partnership Initiative
- Ethics of Partnerships
- IP Issues
- Funding and Partnership Models



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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



# 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”





# 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

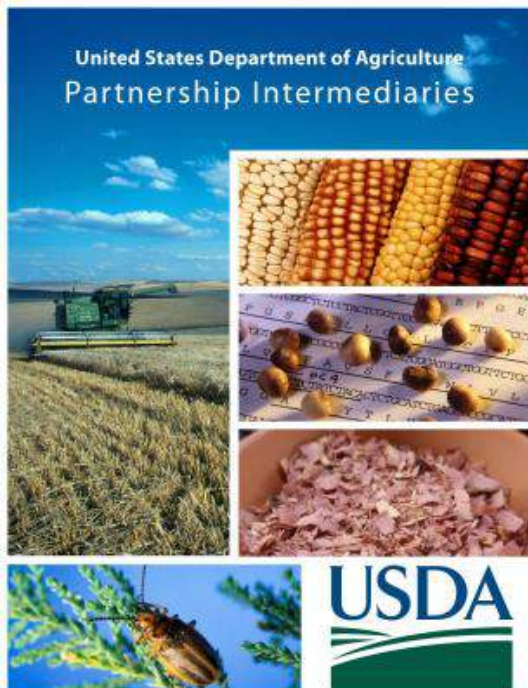


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# Many mechanisms for partnering also address IP issues...

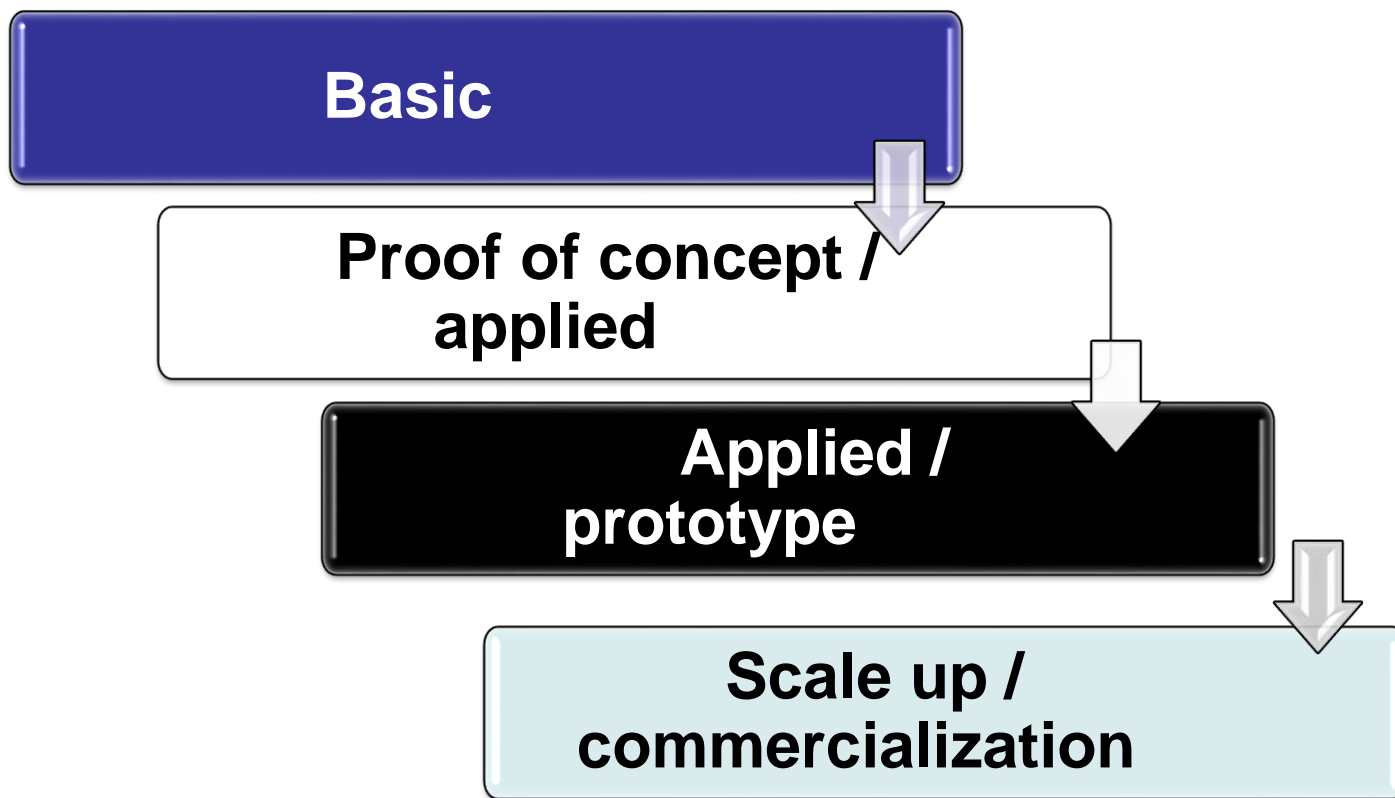
## Technology Transfer Mechanisms



- 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)



## The continuum of research and development ...



Where does “precompetitive” end?





# 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



# 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





# 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
- Dr. Sally Rockey named Executive Director June, 2015



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







# 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.



# 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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# *“This one grand challenge unites us.”*



The American Society of Agronomy, the Crop Science Society of America, and the Soils Science Society of America are dedicated to improving our knowledge of natural resource management to better manage our natural resources to meet the demands of a growing world population.

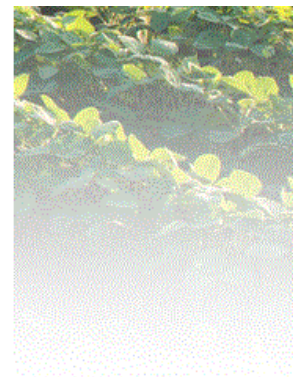
## The Grand Challenge

*Sustainably improve the human condition for a growing global population in a changing environment.*

This one grand challenge unites us. Each scientific discipline and sector of the economy will offer their own unique solutions to this grand challenge. Here we layout our vision and recommendations that will enable innovative, science-based solutions.

## Science Frontiers

The following science frontiers identify the most promising opportunities in the next decade whose investigation will establish a foundation of information that will propel the scientific discipline beyond the current state of knowledge while addressing the grand challenge.



AMERICAN SOCIETY OF AGRONOMY	CROP SCIENCE SOCIETY OF AMERICA	SOIL SCIENCE SOCIETY OF AMERICA
Sustainable Intensification	Crop Frontier: Crop Improvement and Adapting to Climate Change	Food, Energy, And National Security Through Soil Education
Enhancement of Ecosystem Services Provided by Agriculture	Human Frontier: Connections between Food and Health	Climate Change and Soil Processes
Socially and Economically Viable Agriculture Systems	Global Frontier: Sustainable Environmental Management	Healthy Soils, Healthy People
		Soil and Water Quality





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# The American Journal of CLINICAL NUTRITION

## Achieving a transparent, actionable framework for public-private partnerships for food and nutrition research<sup>1-4</sup>

Nick Alexander,<sup>5</sup> Sylvia Rowe,<sup>6</sup> Robert E Brackett,<sup>7</sup> Britt Burton-Freeman,<sup>7</sup> Eric J Hentges,<sup>8</sup> Alison Kretzer,<sup>8</sup> David M Klurfeld,<sup>9</sup> Linda D Meyers,<sup>10</sup> Ratna Mukherjee,<sup>11</sup> and Sarah Ohlhorst<sup>10\*</sup>

<sup>5</sup>Media Concerns, Lewes, DE; <sup>6</sup>SR Strategy LLC, Washington, DC; <sup>7</sup>the Institute for Food Safety and Health, Illinois Institute of Technology, Chicago, IL; <sup>8</sup>the International Life Sciences Institute North America, Washington, DC; <sup>9</sup>the USDA Agricultural Research Service, Beltsville, MD; <sup>10</sup>the American Society for Nutrition, Bethesda, MD; and <sup>11</sup>DuPont Nutrition and Health, St. Louis, MO.

### ABSTRACT

Officers and other representatives of more than a dozen food-, nutrition-, and health-related scientific societies and organizations, food industry scientists, and staff of the USDA, the CDC, the Food and Drug Administration, and the NIH convened on 8 December 2014 in Washington, DC, to reach a consensus among individuals participating on guiding principles for the development of research-oriented, food- and nutrition-related public-private partnerships. During the daylong working meeting, participants discussed and revised 12 previously published guidelines to ensure integrity in the conduct of food and nutrition research collaborations among public, nonprofit, and private sectors.

ducted, internationally and domestically, both by government agencies and by private-sector organizations. However, until the

<sup>1</sup> This publication is a summary of a working meeting held on 8 December 2014 to discuss and reach a consensus on guiding principles for public-private partnerships related to food and nutrition research. The activity was undertaken by the American Society for Nutrition (ASN) through a cooperative agreement with the USDA. As a meeting summary, the article was reviewed for accuracy by participants at the meeting (see **Supplemental Information** for the attendee list). The article did not undergo a separate editorial peer review by the editors of *The American Journal of Clinical Nutrition*. ASN's journals feature a section







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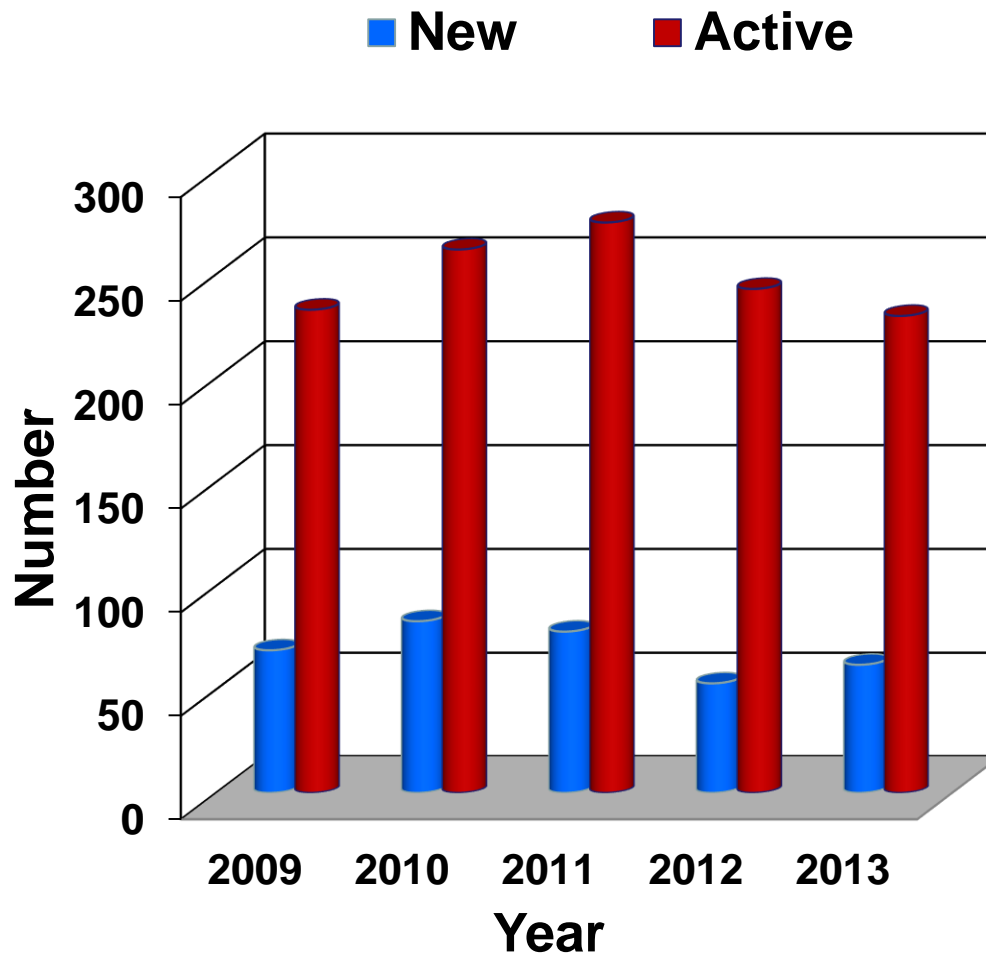
**Thank you!**



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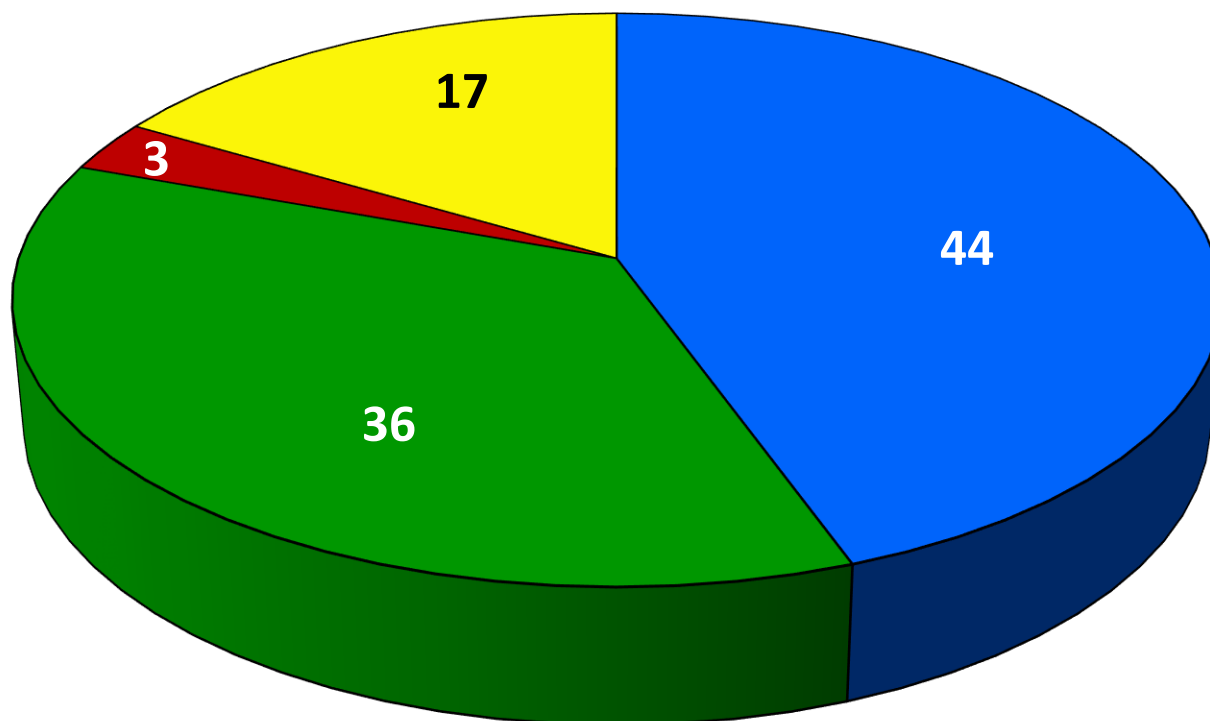
# Number of New and Active CRADAs FY 2009-2014





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

■ Universities      ■ Small Businesses  
■ Start-ups      ■ Other



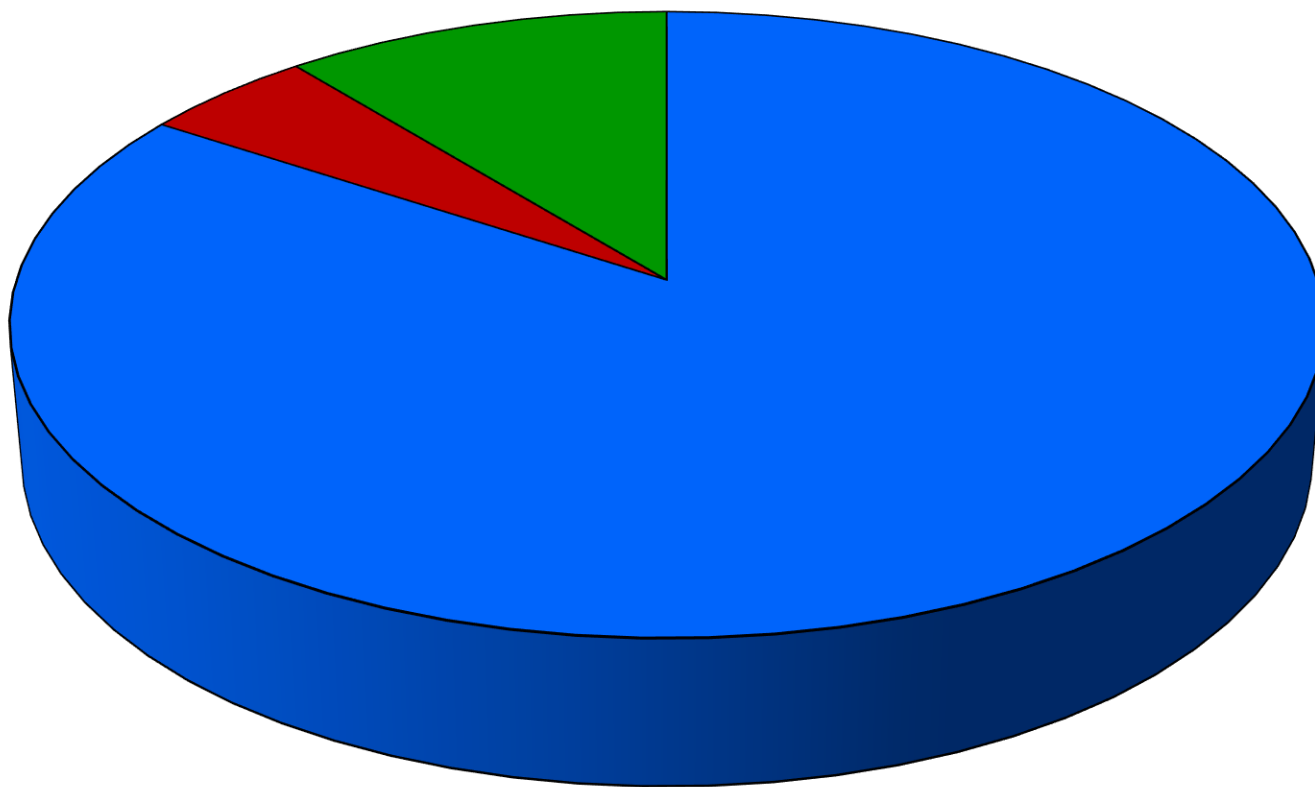


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# Number of Tech Transfer Agreements by Type in FY 2014

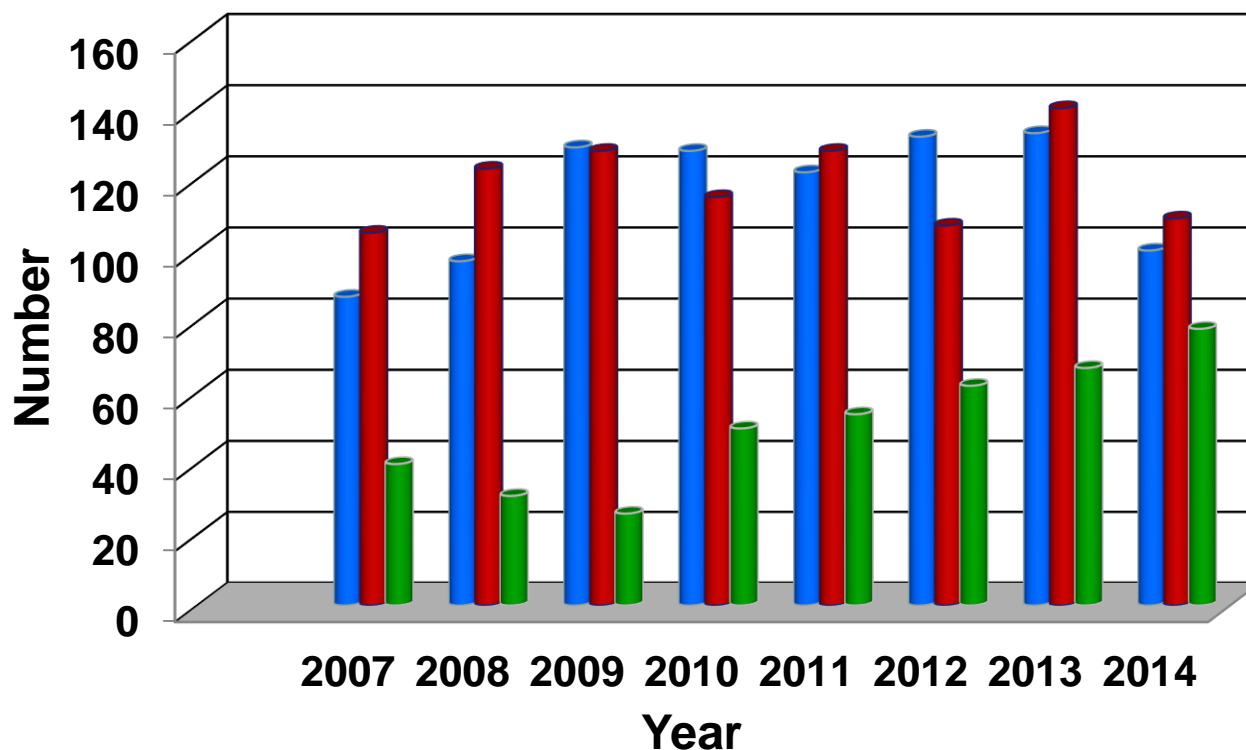
■ MTAs (84%)   ■ CRADAs (5%)   ■ MTRAs (11%)





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

■ Invention Disclosures ■ Patents Filed ■ Patents Issued



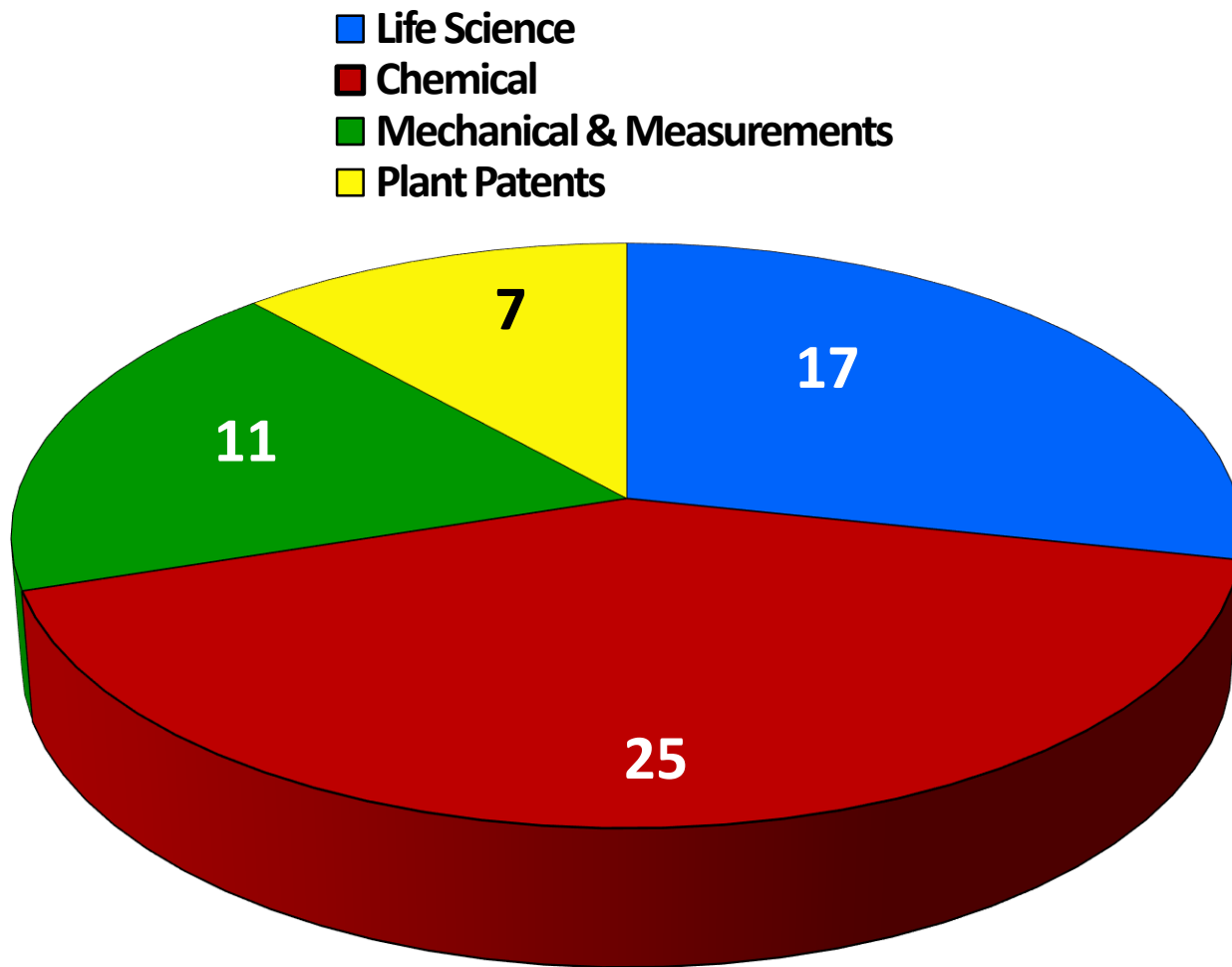




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# Number of patents issued in FY 2013 by scientific discipline



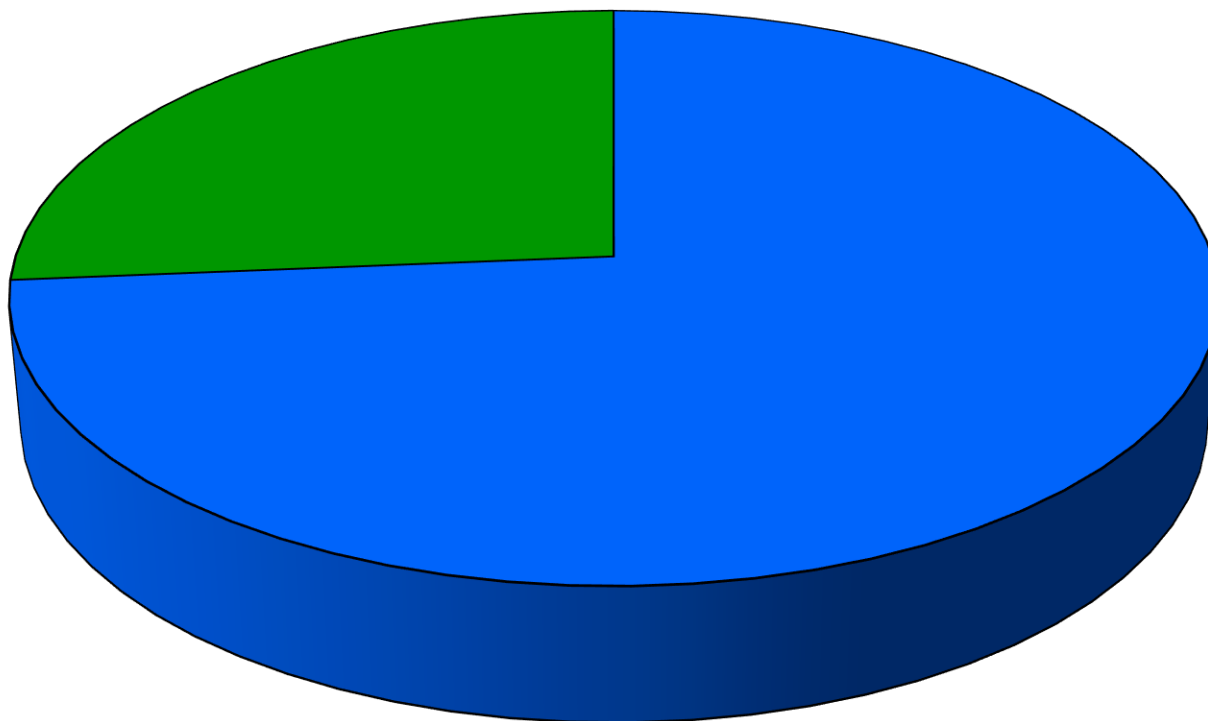


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# Distribution of licenses executed in FY 2014

■ New (74%)    ■ Amendments (26%)



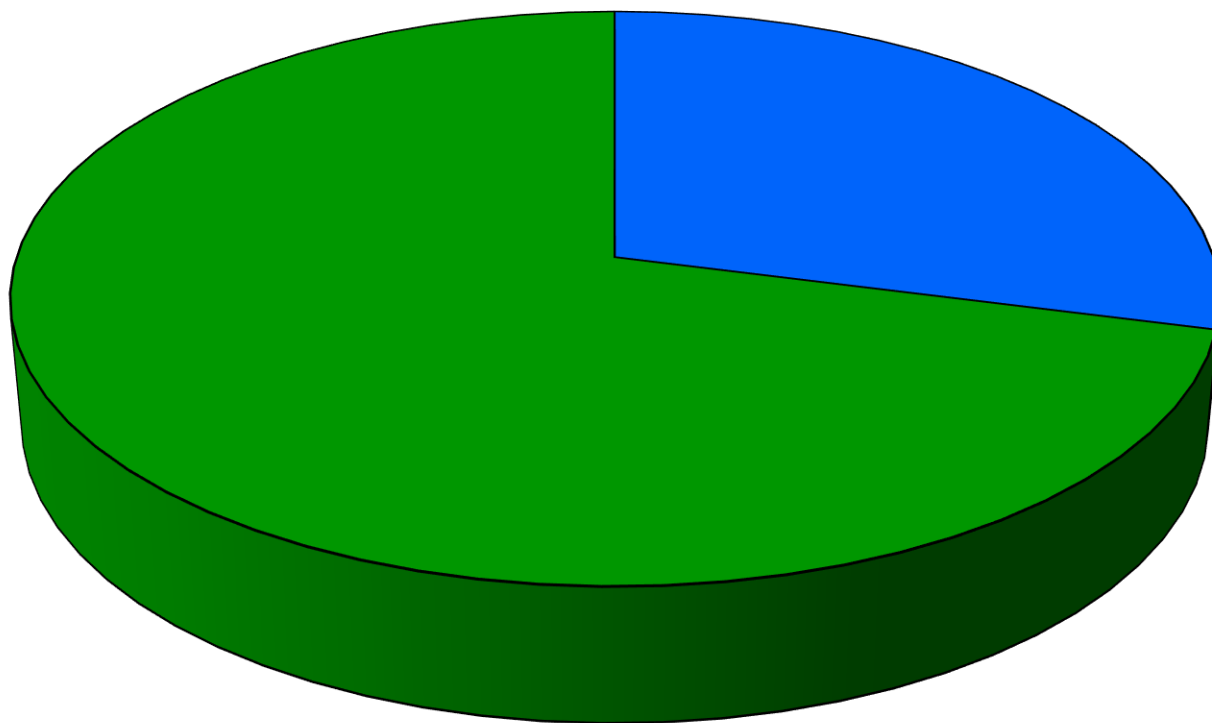


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# Distribution of total license portfolio by exclusivity

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



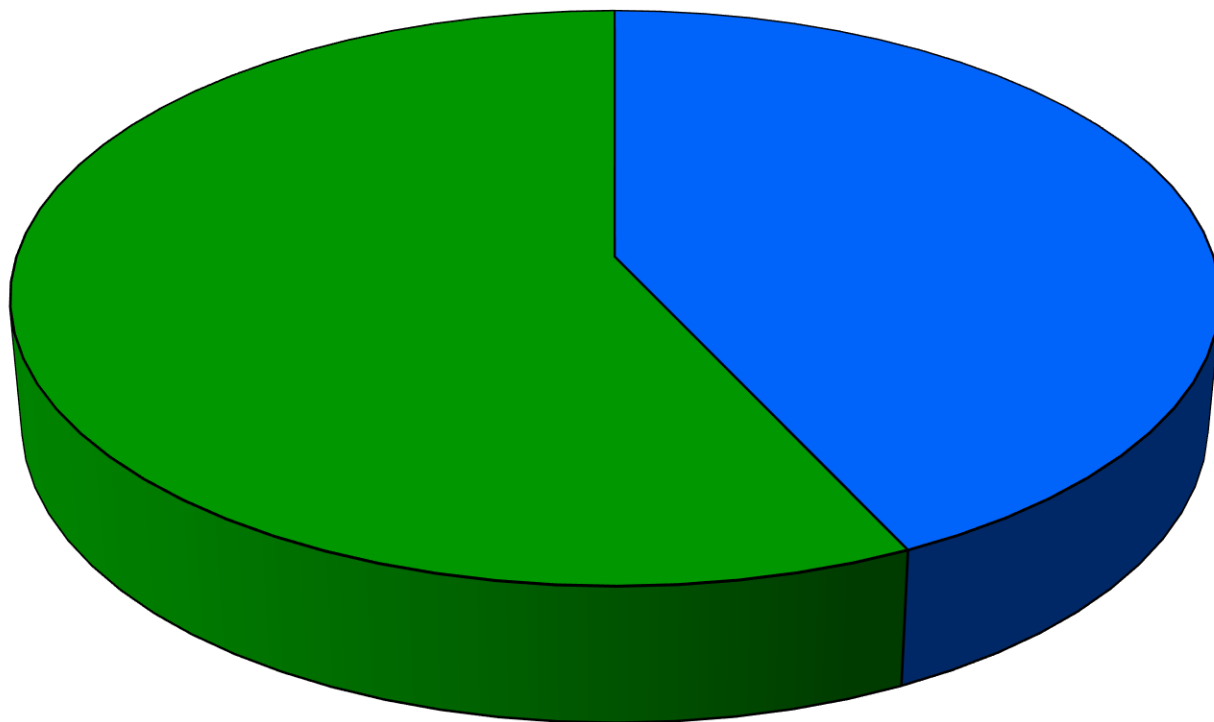


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# Distribution of total license portfolio by licensee

■ University (43%) ■ Industry (57%)

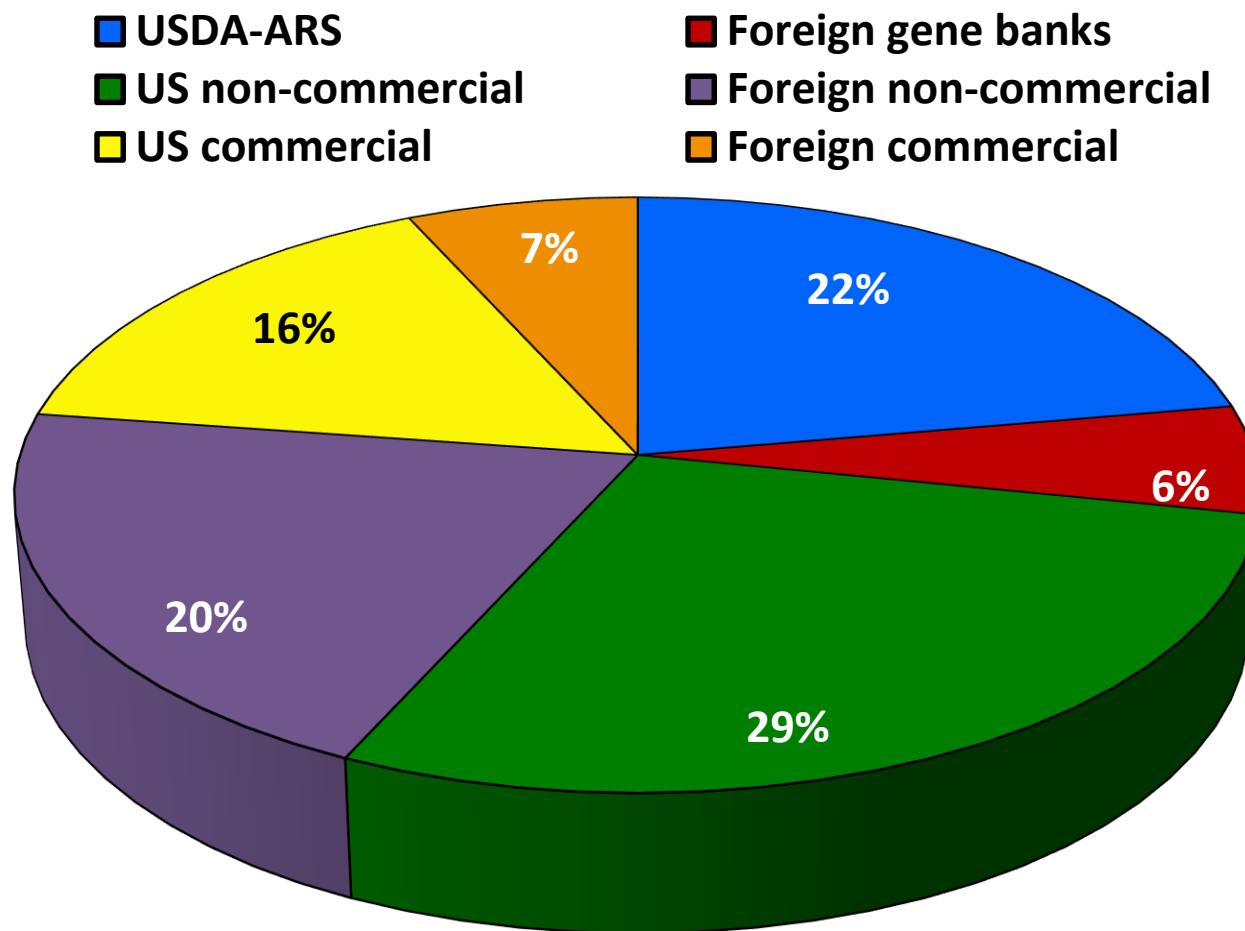




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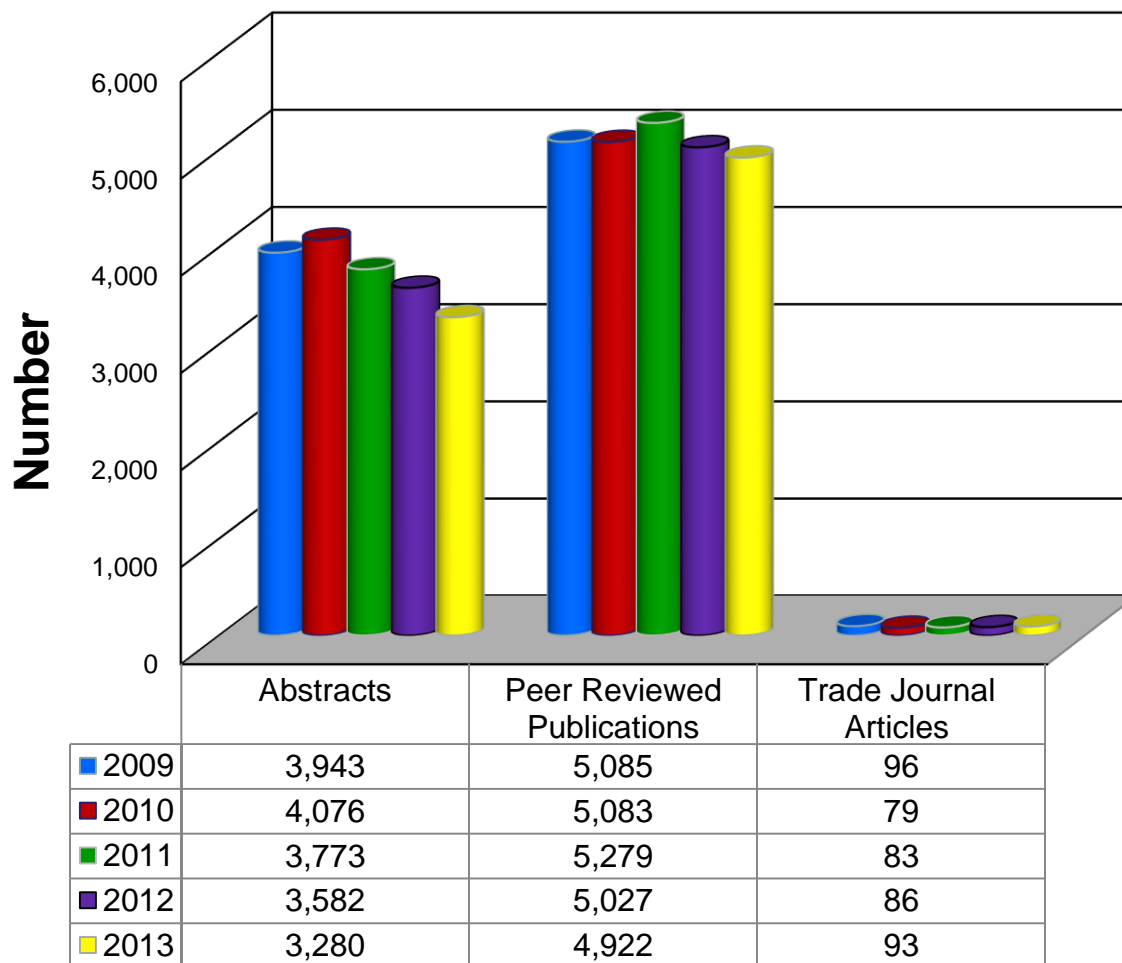
# Germplasm distribution in FY 2013





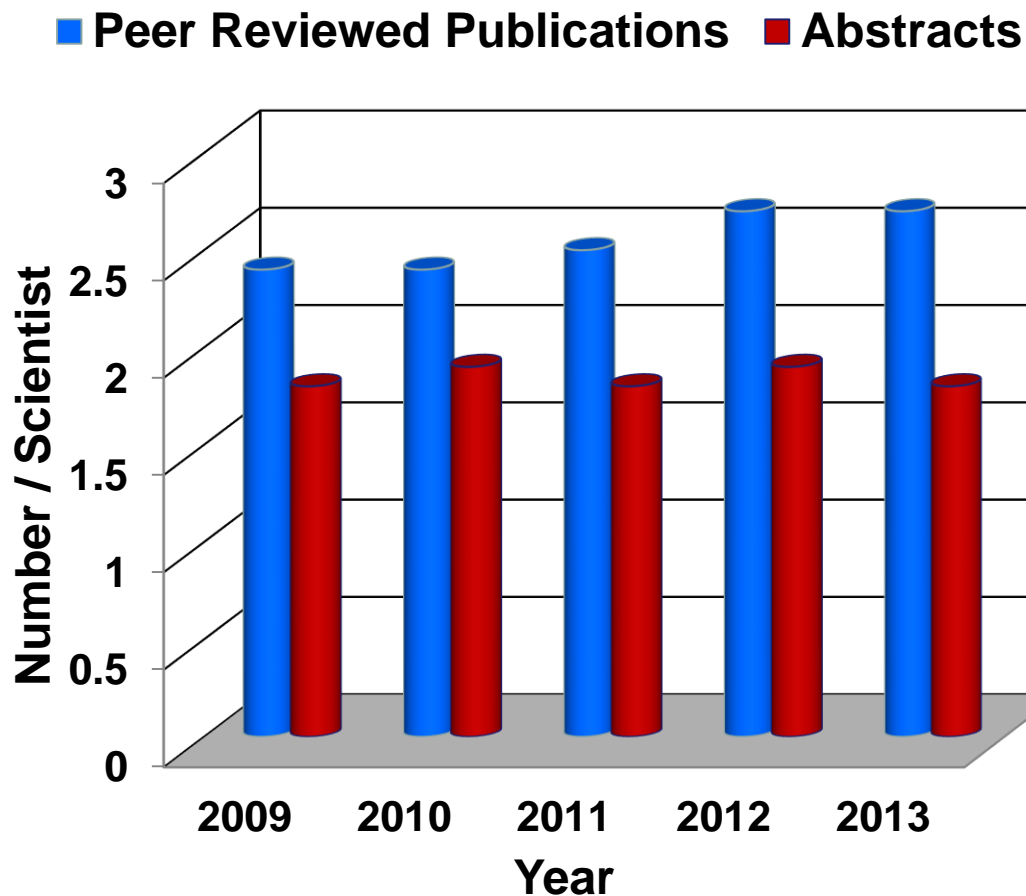


# Number of ARS-approved publications FY2008-2012





# 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**

