THE SYNTHETIC BIOLOGY PROJECT AT THE WILSON CENTER: EIGHT YEARS OF ENGAGEMENT AND ANALYSIS

The Synthetic Biology Project was launched in 2008 to ensure that, as synthetic biology moves forward, public confidence in the science and applications remains high, policymakers are informed, and any risks are minimized. To achieve that goal, the project worked with the scientific community in both academia and industry, and with stakeholders in government, NGOs, the business community, and the larger public.

What we accomplished

Our data helped map an emerging field for a wide variety of stakeholders, including policymakers, the press, and industry.

Our project was often the first to anticipate, identify, and address emerging risks.

We identified inadequacies in the existing regulatory system and ways to close gaps.

The project developed a comprehensive understanding of public perceptions of synthetic biology and associated media coverage.

February 2016

Synthetic BIOLOGY PROJECT

Wilson Center

Synthetic Biology Project in 2016 (left to right): *Joyce Koo, Eleonore Pauwels, David Rejeski, Aaron Lovell, and Todd Kuiken*

We would like to thank the Alfred P. Sloan Foundation for their generous support of our project and especially Dr. Paula Olsiewski for initiating this work and believing in its value.

Booklet design: Angelina Fox

We mapped the field with analysis and data

Before the Synthetic Biology Project began, there was no comprehensive mapping of the field -- who was involved, what applications were being developed, or how much money the federal government was spending on research and development. It was a field advancing with no radar or early warning system. Over the past five years, the project generated much of the baseline information that allowed the federal government, regulators, investors, industry, and other stakeholders to better grasp the growth of the field along multiple dimensions, from R&D funding to applications entering the market.

Federal funding analysis: Interestingly, the federal government itself has no overarching picture of synthetic biology funding. The project completed the first analysis of U.S. government investments in synthetic biology in 2011 and updated that analysis in 2015. Both these analyses included breakdowns by agencies, comparisons to foreign investments (with entities such as the European Union and United Kingdom), and breakdowns of funding focused on ethical, social, and legal implications (ELSI), as well as risk research. The most recent analysis highlighted the significant increase in military-funded research, as well as the paucity of research focused on ELSI issues and risk, falling at or below 1 percent of the total government investment and far below similar investments made during the Human Genome Project and under the National Nanotechnology Initiative.

Consumer Products Inventory: First published as a PDF file in 2012, the new interactive, online version of the inventory tracks synthetic biology products and applications that are in the market or approaching the market. One of its more important functions is as an early warning system for regulators who can benefit from a better understanding of likely pressures on the regulatory system. This inventory was modeled on the highly successful nanotechnology Consumer Products Inventory (CPI), started by the Wilson Center in 2007 and maintained to the present (www.nanotechproject.org/cpi/).

The Pentagon Is Putting Big Money Into Synthetic Biology

BUZZFEED, MARCH 30, 2015

Three Recent Developments in Synthetic Biology You Need to Know

***WASHINGTON POST*, MAY 7, 2015**

Like the nanotechnology CPI, the synthetic biology inventory is designed to support the "crowdsourcing" of data, allowing users to contribute information on potential products and applications. The inventory can be accessed on multiple platforms, including laptops, tablets, and mobile phones (www.synbioproject.org/cpi/).

Synthetic biology map: One of the most basic questions spurred by the emergence of synthetic biology is, "Who is doing what and where?" The synthetic biology map puts the field on an interactive global map and allows users to sort by type of actor, such as companies, research institutes, and community labs. Updated twice, it was the first attempt to provide a synoptic and geo-referenced view of the key actors in the synthetic biology space.

Synthetic biology scorecard: In 2012, the project released a scorecard to track the administration's progress on 18 recommendations from the Presidential Commission for the Study of Bioethical Issues' 2010 report, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. The scorecard, which was updated after release and allowed for user input, found relatively few of the recommendations were fully completed within the 18-month timeframe suggested by the bioethics commission. After 6 years, most of the recommendations remain unfulfilled. Project staff also testified before the commission when the report was being compiled.

Interactive Inventory Tracks Synthetic Biology Products and Applications

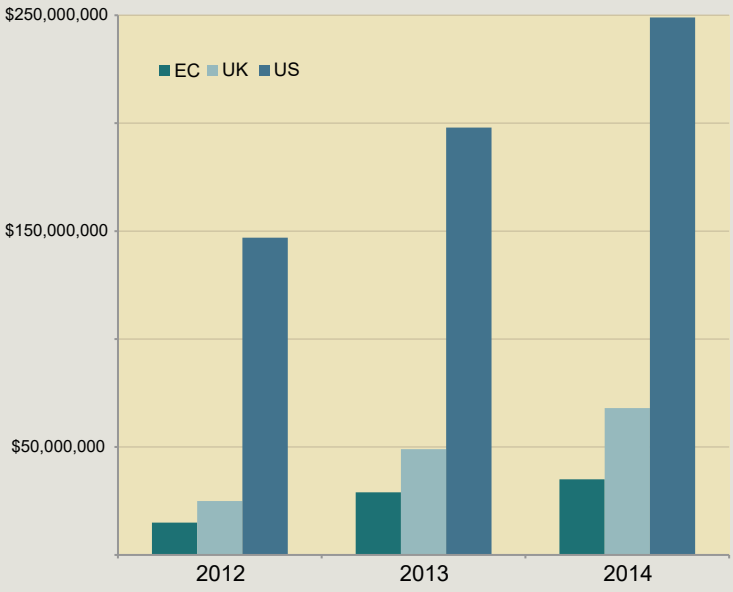
SYNENERGENE.EU, JULY 7, 2015

Mapping **SYNTHETIC BIOLOGY**

The Synthetic Biology Project generated much of the baseline information that allowed the federal government, regulators, investors, industry, and other stakeholders to better grasp the growth of the field.

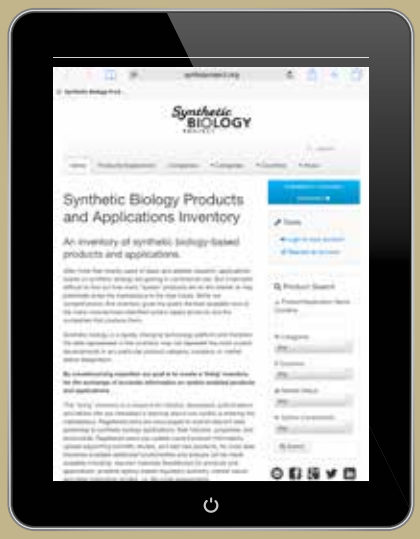
Research Funding

Research Funding for Synthetic Biology in the European Union, United Kingdom, and United States between 2012 and 2014.



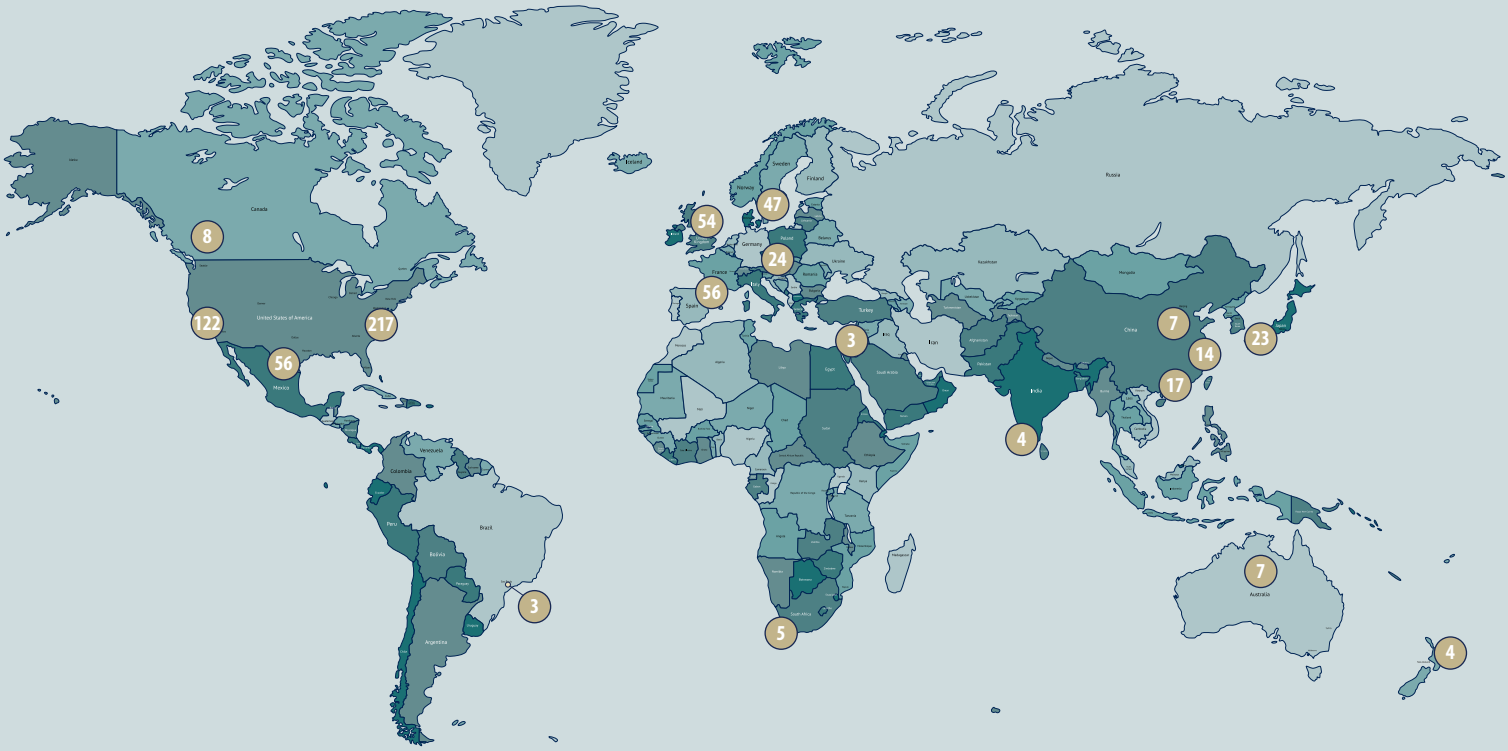
Products and Applications

There was a **58.8 percent increase** in total products on our inventory between 2012 and 2014, jumping from 68 to 108 products. Industry segments seeing the most growth include **industrial enzymes**, **agriculture**, and **materials**.



Who, Where, and What

In 2009, the project began mapping synthetic biology research, finding pockets of activity in **California**, **Massachusetts**, the **United Kingdom** and **Germany**. These areas saw continued growth in 2013, with additional research in China and Japan. The updated map can be used to find companies, universities, research institutions, government and military laboratories, and policy research institutions.



We anticipated, identified, and addressed emerging risks

Over the past six years, the Synthetic Biology Project undertook a number of initiatives to both identify and mitigate potential risks from synthetic biology, focusing on research, development, and commercialization activities taking place in universities and industry. In addition, the project focused on difficult-to-track activities in non-institutional environments like do-it-yourself biology (DIYbio) labs and community groups, which exist outside of the normal reach of biosafety and biosecurity oversight mechanisms.

DIYbio activities: The project worked closely with the DIYbio community to anticipate and manage possible biosafety risks that could be generated by practitioners operating outside of normal institutional environments. This resulted in a number of projects to mitigate possible risks.

- Ethics codes: The project ran workshops in San Francisco and London in 2011 to facilitate the development of voluntary codes of conduct for the communities. Hosting workshops in two countries ensured that the codes developed reflected the hopes and concerns of the different communities.

- Ask-a-Biosafety Expert program: In 2012, the project launched the Ask-a-Biosafety Expert program, a website where DIYbio practitioners can anonymously ask questions about their work and get informed responses from professional biosafety officers. The website collected frequently asked questions (FAQs), providing insights into the experiments and activities being undertaken in various DIYbio settings.

U.S. DIYBIO CODE OF ETHICS

Draft DIYbio Code of Ethics
as agreed by U.S. delegates
July 2011

Open Access
Promote citizen science and decentralized access to biotechnology.

Transparency
Enphasize transparency, the sharing of idea, knowledge and data.

Education
Engage the public about biology, biotechnology and their possibilities.

Safety
Adopt safe practices.

Environment
Respect the environment.

Peaceful Purposes
Biotechnology should only be used for peaceful purposes.

Tinkering
Tinkering with biology leads to insight; insight leades to innovation.

Yes, This Exists: A Biohacker Hotline

POPULAR SCIENCE, JULY 27, 2013

- Survey of practices: To counter a growing number of sensationalist articles that overestimated the capabilities and intentions of the DIYbio community, we undertook a survey in 2013 of 350 DIYbio labs, asking practitioners a series of questions about their backgrounds, labs, and work. The survey was published as a report that addressed seven commons myths about DIYbio. The raw results of the survey were also made available for download.

- Postcard project: In 2014, we piloted the "postcard project" for the DIYbio community to improve transparency and information sharing about DIYbio activities across the country. Community members voted (via Twitter) for their favorite DIYbio projects, which were featured on a postcard. To test the program, we designed, printed, and mailed a postcard in January 2012 to about 100 subscribers around the world. After it was sent, around 370 additional people signed up. Work on next iteration of the project is proceeding now with the goal of expanding the competition to other DIY communities, like makers and citizen scientists.

- BUGSS documentary: In 2015, the project produced and released a 7-minute documentary on the growth of DIYbio as seen through a community lab in Baltimore, MD. *The Rise of Do-It-Yourself Biology: A Look at the Baltimore Underground Science Space (BUGSS)* explores a fast-growing community lab that grew out of a group of interested students and professors at a local community college and now offers courses, lectures, and the opportunity to experiment with different aspects of biotechnology. The film also looks at some of the pressing issues around DIYbio generally, from perception to funding.

The DIY Dilemma
Misconceptions about Do-It-Yourself Biology Mean that Opportunities are Being Missed.

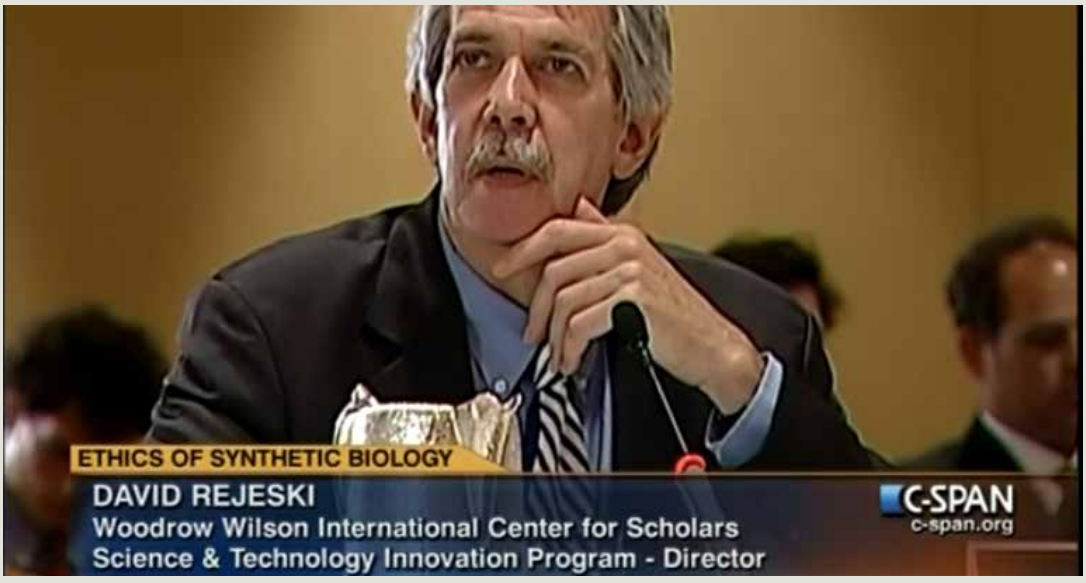
NATURE, NOV. 28, 2013

Upstream analyses: One of the important objectives of the project was to identify and address risks from potential products and applications before they entered the market. To address these issues, the project convened a number of workshops, including developing a transatlantic roundtable in conjunction with the European Union on responsible research and innovation in synthetic biology (2014); a workshop with the Environmental Protection Agency to better understand the regulatory implications of synthetically derived algae (2012); and a second transatlantic workshop on "innovation ecosystems," which brought together Silicon Valley innovators, startups, DIYbio labs, and policymakers (2015).

Engagement around risk issues: Our staff has worked with federal agencies, as well as key international, state, and local agencies, to increase staff or expertise dedicated to synthetic biology risk. This work includes:

- Serving on the advisory board for the Defense Advanced Research Projects Agency's Living Foundries program
- Advising the International Genetically Engineered Machines (iGEM) competition on risk issues and serving on iGEM's biosafety panel
- Providing input to the Federal Bureau of Investigation, the National Research Council and National Academy of Sciences, and the National Intelligence Council
- Serving on the United Nations Convention on Biological Diversity Ad Hoc Technical Expert Group on Synthetic Biology

Our staff also testified before the Presidential Commission for the Study of Bioethical Issues, the National Security Agency Advisory Board, National Academies of Science, and the National Science Foundation Advisory Committee for Environmental Research and Education. Staff also engaged with Republicans and Democrats on the House Science Committee, as well as other key lawmakers working on science and technology issues.



Governing **SYNTHETIC BIOLOGY**

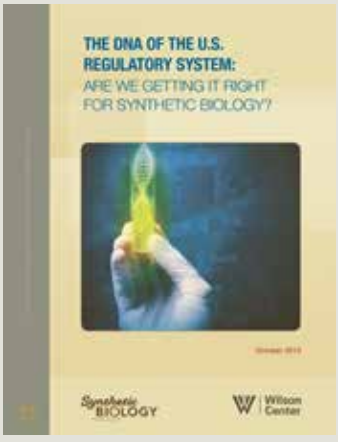
The Synthetic Biology Project helped to identify and mitigate potential risks from synthetic biology, focusing on research, development, and commercialization activities taking place in universities, industry, and non-institutional environments such as DIYbio spaces

The First Codes of Conduct for DIYBio

The project developed the first codes of conduct for DIYbio, hosting workshops in Europe and the United States to develop codes unique to regional participants. Both codes focused on open access, transparency, education, and other issues – though the participants prioritized the concepts differently.

Ask-A-BioSafety Expert

Launched in January 2013, the Ask-A-Biosefety Expert website has fielded more than 100 questions online from DIYbio practitioners, which has resulted in informative articles on 22 DIYbio topics. The site can be visited at: http://ask.diybio.org/

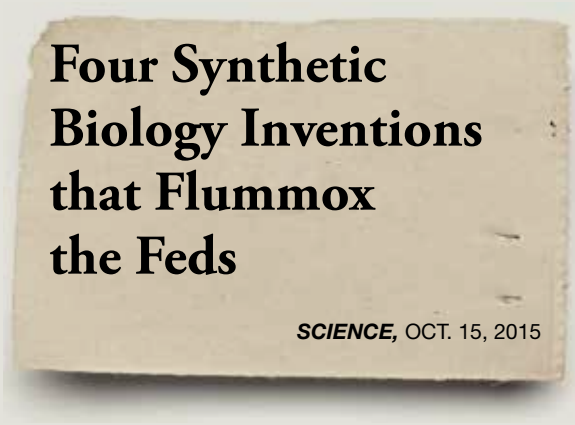


First Comprehensive Regulatory Analysis

To clarify the path to market for synthetic biology applications, the project developed the first-ever legal analysis of how products move through the U.S. regulatory framework. The guide included case studies of actual applications in five areas: biopesticides, biomining products, synthetic mosquitoes, synthetic squalene, and the glowing plants project.

We identified inadequacies in the existing regulatory system and ways to close gaps

The Synthetic Biology Project pursued a number of initiatives to help stakeholders better understand the regulatory process surrounding synthetic biology in an effort to ensure applications get to market in a safe and efficient fashion.



The DNA of the U.S. Regulatory System: This 2015 report examined the current regulatory pathway for different synthetic biology applications, such as glowing plants, genetically engineered mosquitoes, biopesticides, and biomining chemicals. The first report of its kind, it was authored by attorneys at the law firm Bergeson and Campbell LC.

Advice on the Coordinated Framework: In July 2015, the White House requested comments on an interagency effort to update the Coordinated Framework for Regulation of Biotechnology. The project submitted notes to the White House Office of Science and Technology Policy before the memo was issued, some of which were reflected in the final memorandum, and also prepared a set of official comments based on our work in the field.

U.S. and international workshops: EPA began its ongoing process to address the regulation of genetically modified algae in summer 2015. In 2012, the agency asked the project to host a stakeholder meeting to understand the data needs and testing methods for regulating synthetically derived algae. The results of that meeting directly informed the agency's 2015 effort to revamp its regulation of synthetic algae applications. In summer 2014, the project also hosted meetings with colleagues from Europe to discuss synergies for better international coordination on responsible development and innovation of synthetic biology.

The project developed a comprehensive understanding of public perceptions of synthetic biology and associated media coverage

Like many emerging technologies, the public is largely unaware of synthetic biology. The Synthetic Biology Project looked at the evolving public perception towards synthetic biology, as well as examining how the media covered the technology.

Media analyses: The project generated more than eight years of data to explore how synthetic biology was covered by the media in both the United States and Europe. This included tracking absolute coverage, how synthetic biology was portrayed by the press, and highlighting differences in U.S. and E.U. coverage. The two resulting reports represent the first longitudinal, cross-cultural analysis of media coverage. A new update is presently being prepared for the last four years, which will expand the data set to more than a decade.

Focus groups: The project conducted two sets of focus groups and a national telephone survey help provide qualitative and quantitative data about public attitudes towards synthetic biology. The poll and focus groups provided the first understanding of specific attitudes towards synthetic biology, as well as extending a line of perceptions surveying that began with our earlier work focused on nanotechnology.

Americans Split on Risks and Benefits of Synthetic Biology

***NATURE*, SEPT. 9, 2010**

The Promises and Perils of Synthetic Biology

***NEWSWEEK*, MARCH 11, 2015**

The project conducted two focus groups in September 2011 and two additional two focus groups in April 2014. Compared to the 2011 focus groups, there was no discernible change in awareness – none of the participants in the sessions were familiar with synthetic biology – but they make associations and inferences about it based on their understanding of the terms "synthetic" and "biology."

National surveys: In March 2013, the project released the first national, statistically valid survey of public perceptions of synthetic biology among adult Americans. The report found there has been little change in public awareness of synthetic biology since previous surveys. In the poll, 23 percent of adults surveyed said they had heard a lot or some about synthetic biology.

In May 2015, as the House Science Committee geared up to hold its first hearing on germline-editing technology, the project completed the first-ever national survey of public attitudes about manipulating the human germline. The survey largely found Americans to be ambivalent about gene editing, but many support a moratorium on human-based research until safeguards can be put into place. The results of the poll were included in the hearing material supplied to committee members by their staff and circulated to the press.

Communications guidelines: The project also released A Guide for Communicating Synthetic Biology in 2014. One of the project's most-downloaded reports, it is the first how-to guide for communicating synthetic biology designed specifically for scientists, businesses, and public information officers at universities and government agencies. Drawing on our survey and focus groups, as well as research on risk communication, the guide provides recommendations on how to build trust, reduce confusion, and improve media outreach when discussing synthetic biology.

Metaphors: From January to May 2012, project staff member Eleonore Pauwels studied the role of engineering metaphors within the discipline of synthetic biology. Using data-mining software, she explored the peer-reviewed literature on synthetic biology and identified the most-common metaphors and their related conceptual categories. Through laboratory observation, interviews, and qualitative analyses, she further conducted an in-depth investigation to better understand the origin of the metaphors and how they are used in scientific and public communication.

Media outreach: The project sought to provide key context around advancements, discoveries, and currents events in the field. Staff from the project were asked to present at conferences, workshops, and events and called upon by lawmakers, companies, and stakeholders to provide context on new genetic engineering applications. Staffers also spoke with members of the media to help reporters and their audiences better understand synthetic biology, from journals like *Science* and *Nature* to global newspapers like the *New York Times*, *Washington Post*, and *Le Monde* to broadcast outlets like the *BBC*, *CBC*, and *NPR*.

Communicating **SYNTHETIC BIOLOGY**

The Synthetic Biology Project pushed the conversation about this emerging technology through engaging reports and media outreach.

318,086

SynBioProject.org pageviews between April 1, 2011 and Aug. 31, 2015

2,139

Twitter followers (@SynBioProject)

67,993

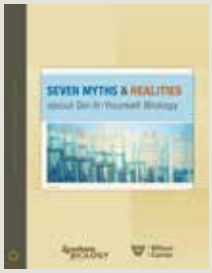
PDF downloads of Synthetic Biology Project reports

Popular Synthetic Biology Project Publications

Trends in American and European Press Coverage of Synthetic Biology (2008)

New Life, Old Bottles (2009)

Ethical Issues in Synthetic Biology (2009)



Seven Myths About Do-It-Yourself Biology (2013)

A Guide for Communicating Synthetic Biology (2014)

Downloads of Synthetic Biology Project Reports Have Grown Since 2008

Synthetic Biology Project research and experts appeared in key media outlets.

nature

Science

The New York Times

The Washington Post

CBC Radio-Canada

npr

BBC

San Jose Mercury News

For the Next Generation

The Synthetic Biology Project was dedicated to engaging the next generation of students in synthetic biology. We hosted more than a dozen interns from seven different universities who helped with our research, events, and outreach efforts.

Kunj Bhatt
University of Virginia
Mechanical Engineering

Bunmi Emenanjo
Johns Hopkins University
Bioscience & Regulatory Affairs

Josh Fass
University of Virginia
Biomedical Engineering

Sumer Ghazala
University of Michigan
Finance, Economics, & Political Science

Joyce Koo
University of Maryland
Biological Sciences

Chamille Lescott
Massachusetts Institute of Technology
Biological Engineering

Amelia Mockett
Massachusetts Institute of Technology
Biological Engineering

Eric Rouge
George Washington University
International Science & Technology Policy

Justin Rousso
George Washington University
History & International Politics

Wilson Ruotolo
University of Virginia
Mechanical Engineering

Ralph D. Turlington III
Massachusetts Institute of Technology
Technology & Policy

Apratim Vidyarthi
University of California-Berkeley
Nuclear Engineering & Applied Mathematics

Leveraging

During the course of the project, the Synthetic Biology project raised additional funding of more than $600,000 from the following sources: European Union, National Science Foundation, Great Lakes Protection Fund, Environmental Protection Agency, Federal Bureau of Investigation, Finnish Academy, and internal federal conference funds from the Wilson Center.

Our digital legacy

The Synthetic Biology Project is committed to maintain its digital projects online throughout the coming years. Project publications, inventories and other information can be found here: www.synbioproject.org.

Advice

The Synthetic Biology Project provided advice and support to key organizations working in synthetic biology development and regulation. The project was part of the advisory boards of National Science Foundation's Synthetic Biology Engineering Research Center (SynBERC), the Open Plant project in the United Kingdom, DARPA's Living Foundries project, and the synthetic biology Leadership Excellence Accelerator Program (LEAP).

synberc

OpenPlant
OPEN TECHNOLOGIES FOR PLANT SYNTHETIC BIOLOGY

DARPA

LEAP
Synthetic Biology
Leadership Excellence Accelerator Program

Publications of the Synthetic Biology Project

Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology (2015)

The DNA of the U.S. Regulatory System: Are We Getting It Right for Synthetic Biology? (2015)

U.S. Trends in Synthetic Biology Research Funding (2015)

Public Attitudes Regarding New Technology for Editing DNA (2015)

A Guide for Communicating Synthetic Biology (2014)

Creating a Research Agenda for the Ecological Implications of Synthetic Biology (2014)

Perceptions of Synthetic Biology and Neural Engineering (2014)

Tracking the Growth of Synthetic Biology: Trends for 2013 (2013)

Seven Myths and Realities about Do-It-Yourself Biology (2013)

The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts (2013)

Awareness & Impressions of Synthetic Biology (2013)

Trends in American and European Press Coverage of Synthetic Biology: 2008 – 2011 (2012)

Draft Synthetic Biology Applications Inventory (2012)

Synthetic Biology Newsletter #2 (2011)

Synthetic Biology Newsletter #1 (2010)

Awareness and Impressions of Synthetic Biology (2010)

Trends in Synthetic Biology Research Funding (2010)

Nanotechnology, Synthetic Biology and Public Opinion (2009)

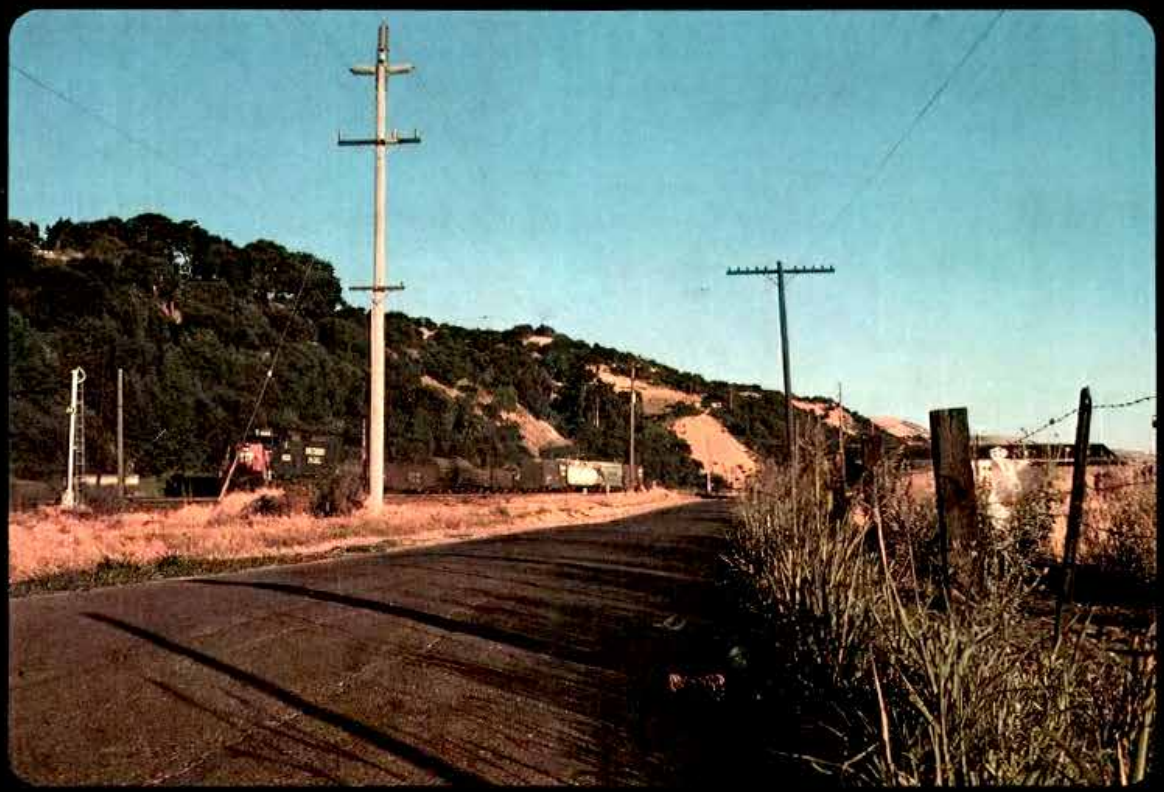
Ethical Issues in Synthetic Biology (2009)

New Life, Old Bottles (2009)

Trends in American and European Press Coverage of Synthetic Biology (2008)

Poll: Risk and Benefits of Synthetic Biology and Nanotechnology (2008)

Thanks to all who helped us along the way.



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