Synthetic Biology



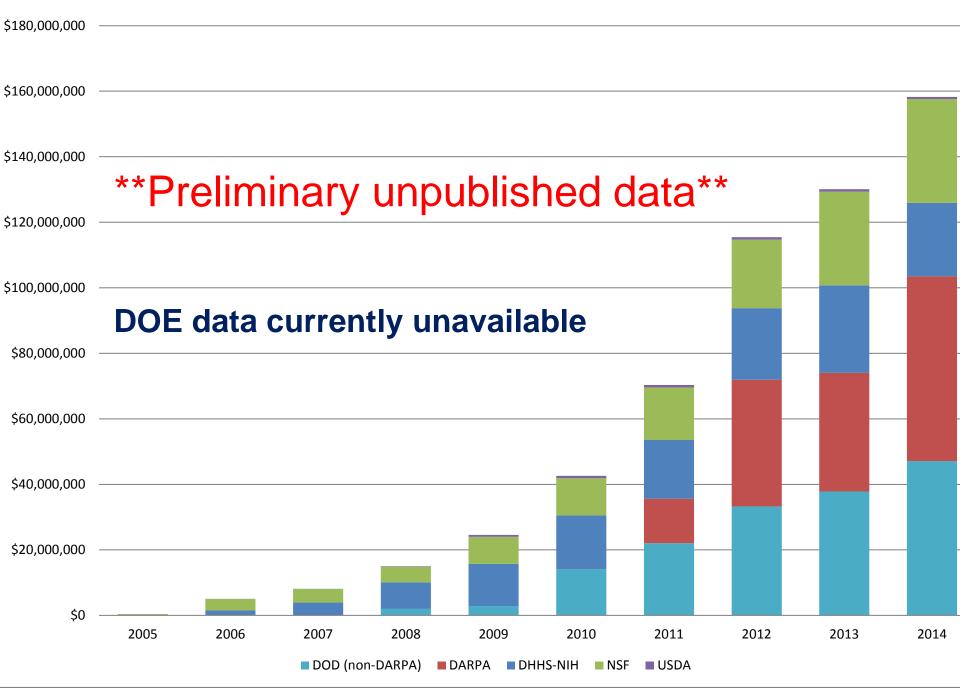


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Outline

- Synbio Landscape in Funding and Applications
- New actors in the space
- Forgotten Biosecurity Issues: Ecology
- Gene Drives
- Governance Issues
- Questions for Discussion

US Funding for Synthetic Biology (with DOD adjustment)



DARPA

Living Foundries

- Living Foundries seeks to transform biology into an engineering practice by developing the tools, technologies, methodologies, and infrastructure to speed the biological design-built-test-learn cycle and expand the complexity of systems that can be engineered.
- ...the infrastructure will generate 1000 new molecules of relevance to the DoD, including chemical building blocks for accessing radical new materials that are impossible to create with traditional petroleum-based feed stocks

Biological Robustness in Complex Settings (BRICS)

- It is expected that technology developed in the BRICS program will enable the safe transition of synthetic biological systems from stringently controlled laboratory environments to more complex settings.
- New Synthetic Ecosystems Program?



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Synbio Project

Synthetic Biology Products and Applications

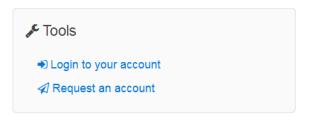
An inventory of synthetic biology-based products and applications.

After more than twenty years of basic and applied research, applications based on synthetic biology are gaining in commercial use. But it has been difficult to find out how many "synbio" products are on the market or may potentially enter the marketplace in the near future. While not comprehensive, this inventory gives the public the best available look at the many manufacturer-identified synbio-based products and the companies that produce them.

This "living" inventory is a resource for consumers, citizens, policymakers, and others who are interested in learning about how synbio is entering the marketplace.

By crowdsourcing expertise our goal is to create a 'living' inventory for the exchange of accurate information on synbio-enabled products.

Registered users are encouraged to submit relevant data pertaining to synthetic biology applications, their function, properties, and producer(s). Registered users can update product information and add new products. You can register for an account here or submit new and updated information to nano@wilsoncenter.org.



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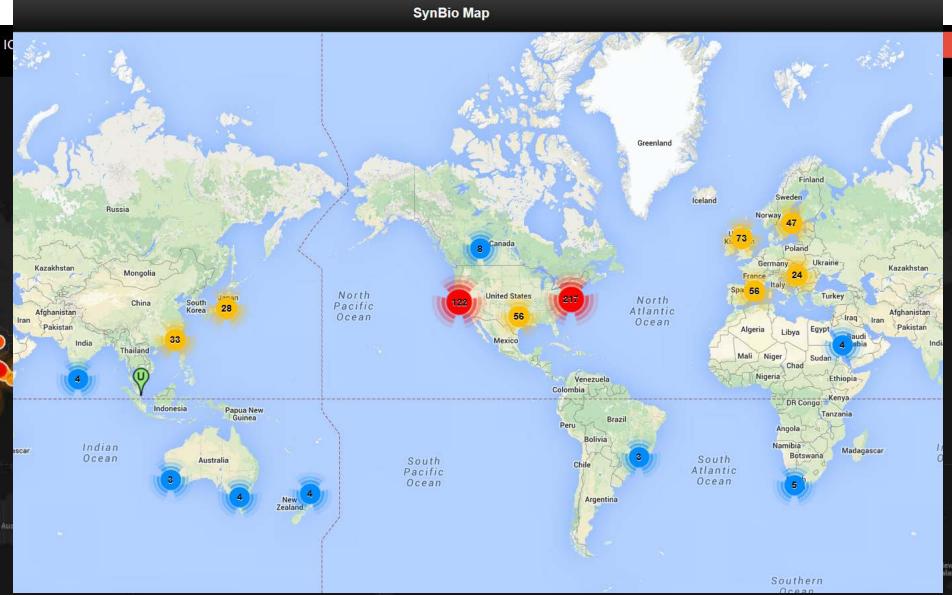


New Actors

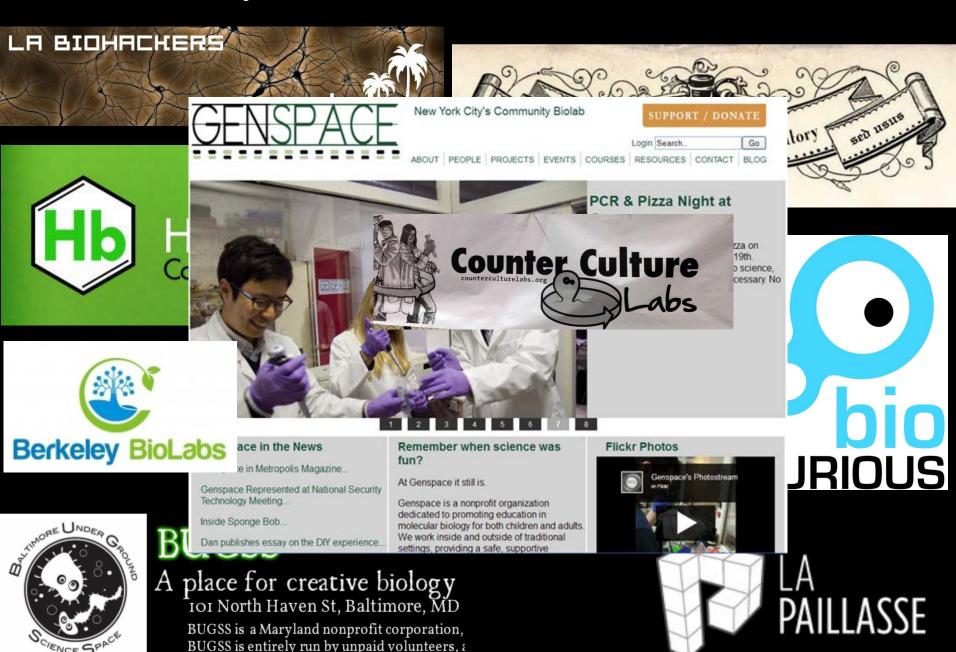
New Funding Models



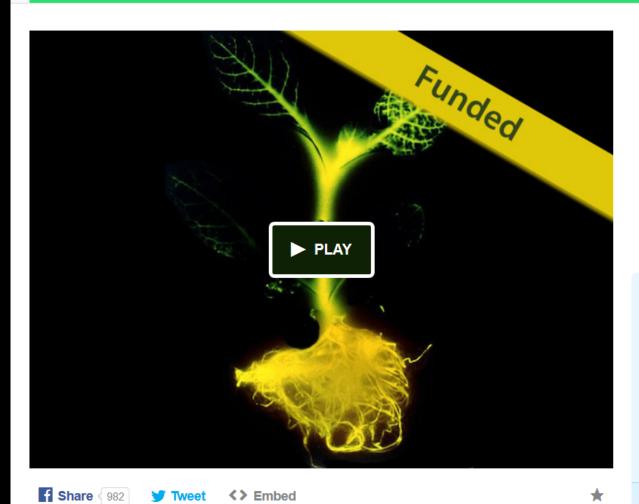
Synthetic Biology



Community Labs – Science is for EVERYONE



Funded! This project was successfully funded on June 7, 2013.



Create GLOWING PLANTS using synthetic biology and Genome Compiler's software - the first step in creating sustainable natural lighting

8,433 backers

\$484,013

pledged of \$65,000 goal

0 seconds to go



Project by

Antony Evans
San Francisco, CA

- K First created · 22 backed
- Antony Evans 1132 friends
- glowingplant.com

See full bio

Contact me

Pledge \$5 or more

426 backers

Vou'll get a 2"v3" sticker showing the

Color-Changing Flowers

Fort Collins, Colorado, United States & Art

Story Updates 4 Comments 12 Funders 142

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Email

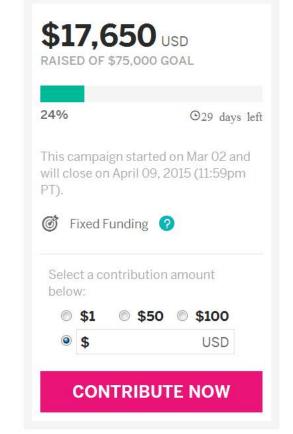
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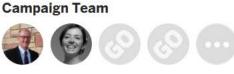
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Beautiful flowers, amazing

https://www.indiegogo.com/projects/color-changing-flowers

Real Vegan Cheese!

Funders 696



Comments 59

Updates 12

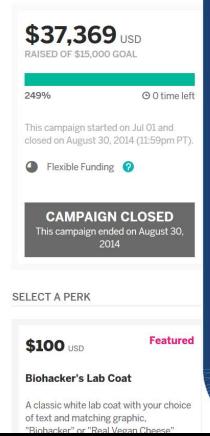
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227

8+1

Story

Biohackers are engineering baker's yeast to produce Real Vegan Cheese. No cows needed!



\$35,000 Broadcasting **Lights! Camer@! Action!** Pro recording equipment for open science Instructional videos! \$30,000 Yeast bioreactor Scaling up from lab scale to kitchen scale \$20,000 Narwhale heese! 0% narwhals thered, 100% chee Because we can \$15,000 Initial **Proof-of-Principle Research** Express cheese croteins in baker's veest

"Real Vegan Cheese is a not a cheese substitute! It all begins with regular old baker's yeast. Through synthetic biology, we engineer our yeast to become milk-protein factories, churning out real milk proteins (known as caseins). These milk proteins are then combined with water, vegan sugar and oil to make a kind of milk which is ultimately converted into Real Vegan Cheese using the age-old cheese-making process." https://www.indiegogo.com/projects/real-vegan-cheese



Discover

Start

O Search Projects

Counter Culture Labs - YOUR biohacking & citizen science lab

by Counter Culture Labs



68

backers

\$17,889

pledged of \$30,000 goal

15

days to go

Back This Project

Remind me

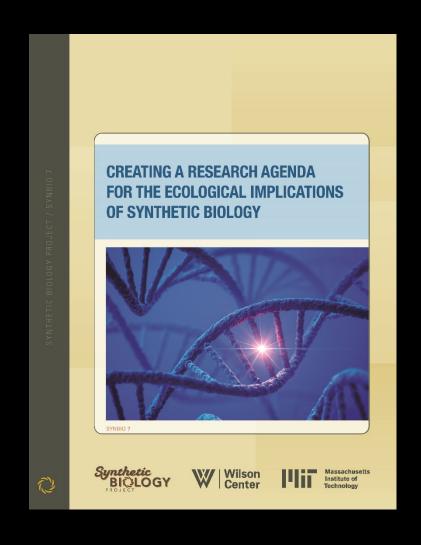
This project will only be funded if at least \$30,000 is pledged by Thu, Jun 11 2015 1:34 PM EDT.

The Forgotten Biosecurity

Ecological Issues

Developing an ecological risk research agenda

- Identification of potential ecological effects of synthetic biology applications
- Identification of critical areas of uncertainty associated with potential ecological effects
- Definition of technical research priorities to develop tools and methods to evaluate ecological effects of synthetic biology applications
- Definition of scientific research priorities to improve understandings of and ways to mitigate ecological effects of synthetic biology applications



What's new and unique?

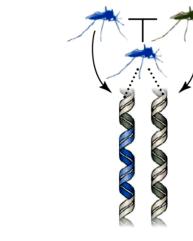
- Novelty and Speed
 - Synthetic biology techniques push beyond incremental changes to organisms and the leap from old to "new" could transcend common evolutionary pathways.
 - The pace at which these leaps could occur is unprecedented
- Eco-evolutionary dynamics
 - Research should incorporate the simultaneous drivers of ecology and evolution, as opposed to progress in one area while holding the other constant.
 - All new theory and data should take into account this dynamic

Priority Research Areas

- 1. Comparators
- 2. Phenotypic characterization
- 3. Fitness, genetic stability, and lateral gene transfer
- 4. Control of organismal traits
- 5. Monitoring and surveillance
- 6. Modeling
- 7. Standardization of methods and data

Gene Drives

Using nature as a bioweapon?



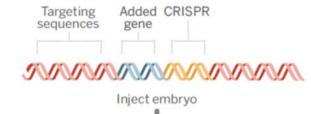
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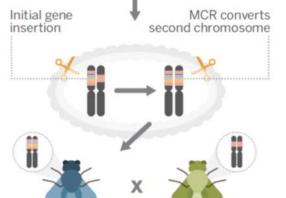
C

Standard altered ge 1 copy inherited fror 50% chance of pass

Driven to excess

A method dubbed mutagenic chain reaction (MCR) may be able to drive an added gene, such as one for disease resistance, through an insect population.



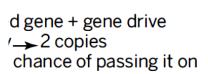


Normal

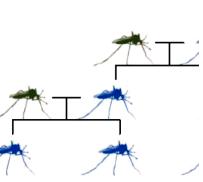
Embryo



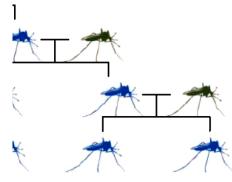
Mutant



Repair



How endonuclease gene drives s have a 50% chance of being inherit can increase this chance to nearly 1 cause the cell to copy the altered ge always inherited, the gene drive can associated trait reduces the reprod now widely used for genome engine Cas9 through sexually reproducing



) Altered genes (blue) normally ganism (gray). (B) Gene drives ing the alteration, which can y ensuring that the gene is almost ver many generations, even if the eloped CRISPR nuclease Cas9, anges that can be generated with

BIOTECHNOLOGY

Biologists devise invasion plan for mutations

"Gene drive" technique could fight insect-borne disease, but some call for safeguards

By John Bohannon

with multiple mutations. That's typically painstaking work, requiring large numbers

discussions with UC San Diego, the university gave the experiment the green light if

Science – March 19, 2015

"What will spread is not literally their mutant flies, but their protocol." (Church)

"And how could we not publish this work? Nothing is served by hiding things. The whole point is to show that it is possible and have a public discussion" (Bier)

Science – August 2014
"For emerging technologies that affect the global commons, concepts and applications should be published in advance of construction, testing, and release" (Oye et al.)

BIOTECHNOLOGY

Regulating gene drives

Regulatory gaps must be filled before gene drives could be used in the wild

By Kenneth A. Oye,^{1,2*†} Kevin Esvelt,^{3*} Evan Appleton,⁴ Flaminia Catteruccia,^{5,6} George Church,³ Todd Kuiken,⁷ Shlomiya Bar-Yam Lightfoot,² Julie McNamara,² Andrea Smidler,^{5,8} and James P. Collins⁹

cannot be used to engineer populations of viruses or bacteria. Second, a newly released drive will typically take dozens of generations to affect a substantial proportion of a target population, unless drive-containing

Scientists Seek Ban on Method of Editing the Human Genome

By NICHOLAS WADE MARCH 19, 2015

New York Times – March 19

"We worry about people making changes without the knowledge of what those changes mean in terms of the overall genome. I personally think we are just not smart enough and won't be for a very long time to feel comfortable about the consequences of changing heredity, even in a single individual" (Baltimore)

BIOETHICS

Embryo engineering alarm

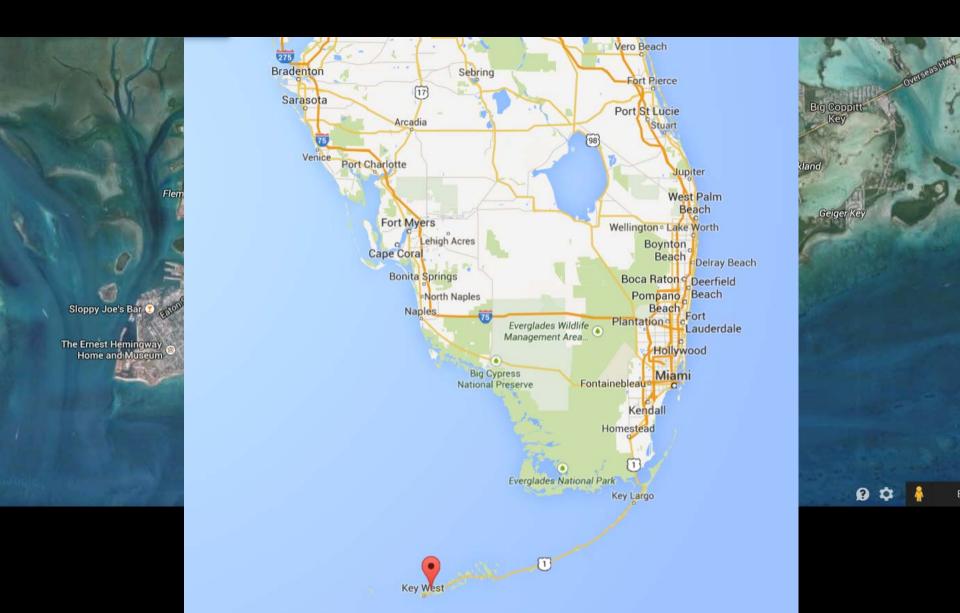
Researchers call for restraint in genome editing

By Gretchen Vogel

trigger a public backlash that would block

Science - March 19
"What is the scenario that
we're worried about? That
it won't work well
enough? Or that it will
work too well? (Church)

Dengue Disease Control



Oxitec Solution

- Until 2009, no reports of Dengue since 1934
 - 2009 22 people; 2010 66 cases
- Aedes aegypti
 - Feed mostly on humans
 - Only females bite
- Key Haven Florida 444 houses
- Petition 149,000 signatures
- 1600 emails to mosquito control district



New poll on gene drives

- Which of the following statements best describes your feelings about this new technique for changing an organism's DNA?
 - Total Positive Development 20%
 - Total Mixed both a positive and a negative development 62%
 - Total Negative Development 18%

Net Positive 66%

- Curing diseases, stopping diseases, illnesses, preventing diseases (15)
- Cure, eliminate genetic diseases/ abnormalities/ mutations/disorders/lessen impact (11)
- Curing, eliminating diseases like cancer(9)
- DNA, changing, altering, improving DNA (4)
- Will benefit people, will be good for the people, will help people, keep people healthier (3)

Net Negative 68%

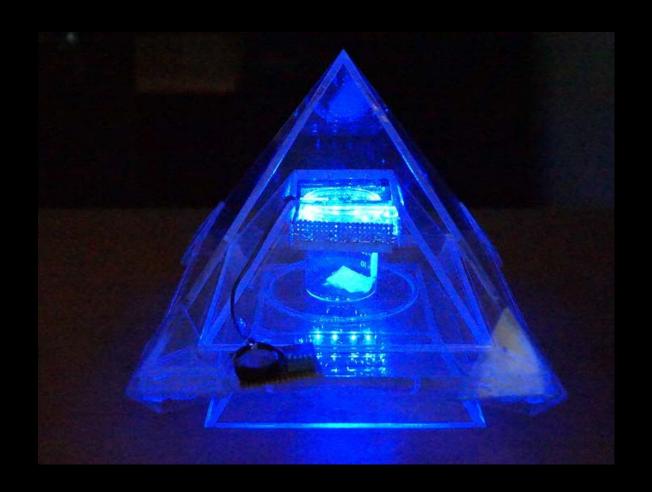
- Unnatural, messing around with nature, playing God (15)
- Potential for damage/harm, dangerous, bad side effects (15)
- Oppose DNA manipulation, altering humans/their traits (10)
- Potential for misuse/abuse (8)
- Too many unknowns, opening Pandora's box (3)

Moratorium?

- Please indicate below to what degree you favor or oppose temporarily stopping research using these techniques on humans until ethical guidelines and safety controls are in place.
 - Total Favor 45%
 - Total Oppose 12%
 - Total Favor with Leaners 72%
 - Total Oppose with Leaners 28%

Governance Void....

- Government seemed caught off guard with Glowing Plants
- No FDA decision in sight for Oxitec
 - FDA not equipped to conduct environmental assessments nor do they possess mosquito expertise
- No coordinated funding plan
- Little to no funding for eco-risk research
- White house directive on coordinated framework?
- New NIST initiative
- New EPA plan?
- NAS study on gene drives (will take at least a year)
- Impact of DARPA funding?
- Presidential election starting next year opportunity to re-boot?
- Synbio @ United Natios CBD



How would the U.S. Regulate this?

So now what.....