The Art of Synthetic Biology Governance: Scientific Uncertainty and Cross-Borderness

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Washington, DC

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Woodrow Wilson International Center for Scholars

CSynBI

Centre for Synthetic Biology and Innovation

EPSRC Science & Innovation Award: £4.7M, January 2009-October 2014

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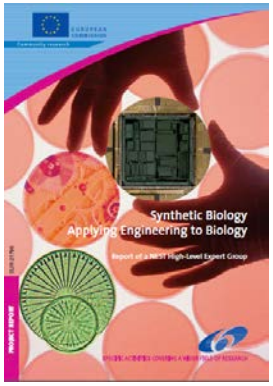
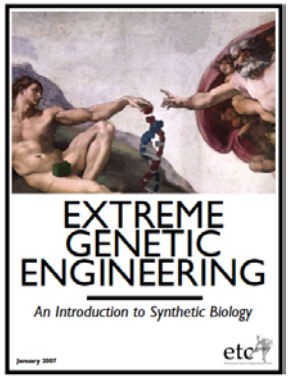
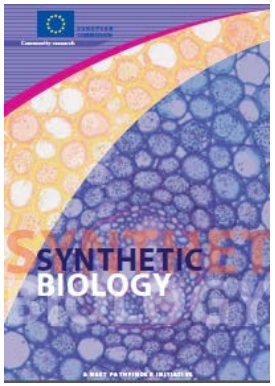
THE ROYAL SOCIETY


Synthetic Biology
Applying Engineering to Biology


Constructing Life
The World of Synthetic Biology

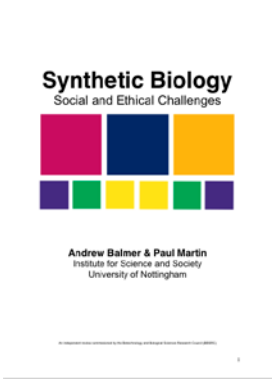

EXTREME
GENETIC
ENGINEERING
An Introduction to Synthetic Biology
etc


SYNTHETIC
BIOLOGY


SYNTHETIC GENOMICS | Options for Governance

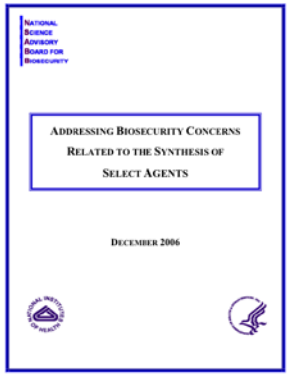

postnote
SYNTHETIC BIOLOGY

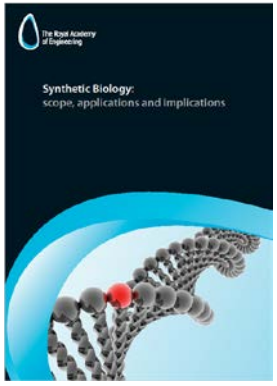

Synthetic
biology
scientific

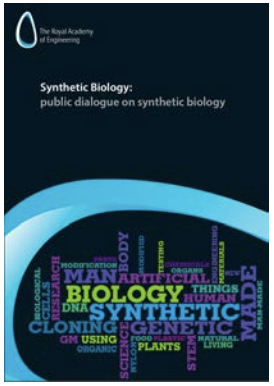

Synthetic Biology
Social and Ethical Challenges
Andrew Balmer & Paul Martin
Institute for Science and Society
University of Nottingham


Ethical Issues in
SYNTHETIC BIOLOGY
An overview of the debates

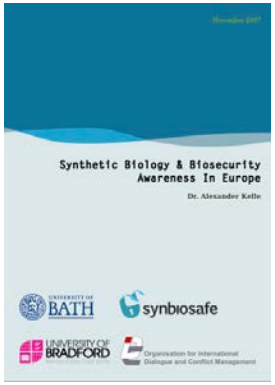

NEW LIFE,
OLD BOTTLES

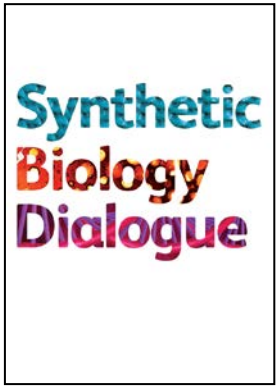

ADDRESSING BIOSECURITY CONCERNS
RELATED TO THE SYNTHESIS OF
SELECT AGENTS
DECEMBER 2006

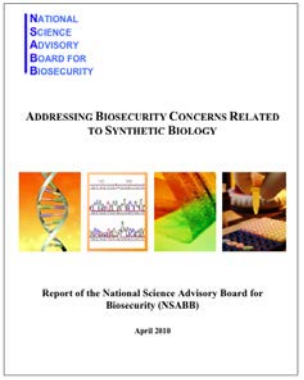

Synthetic Biology:
scope, applications and implications


Synthetic Biology:
public dialogue on synthetic biology


LLOYDS
SYNTHETIC
BIOLOGY
INFLUENCING DEVELOPMENT


Synthetic Biology & Biosecurity
Awareness In Europe
Dr. Alexander Kelle
synbiosafe


Synthetic
Biology
Dialogue


NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY
ADDRESSING BIOSECURITY CONCERNS RELATED
TO SYNTHETIC BIOLOGY
Report of the National Science Advisory Board for
Biosecurity (NSABB)
April 2010

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

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jweymouth@burnesscommunications.com

Embargoed Until:
December 16, 2010
12:01am EST

Presidential Commission on Bioethics Calls for Enhanced Federal Oversight in Emerging Field of Synthetic Biology

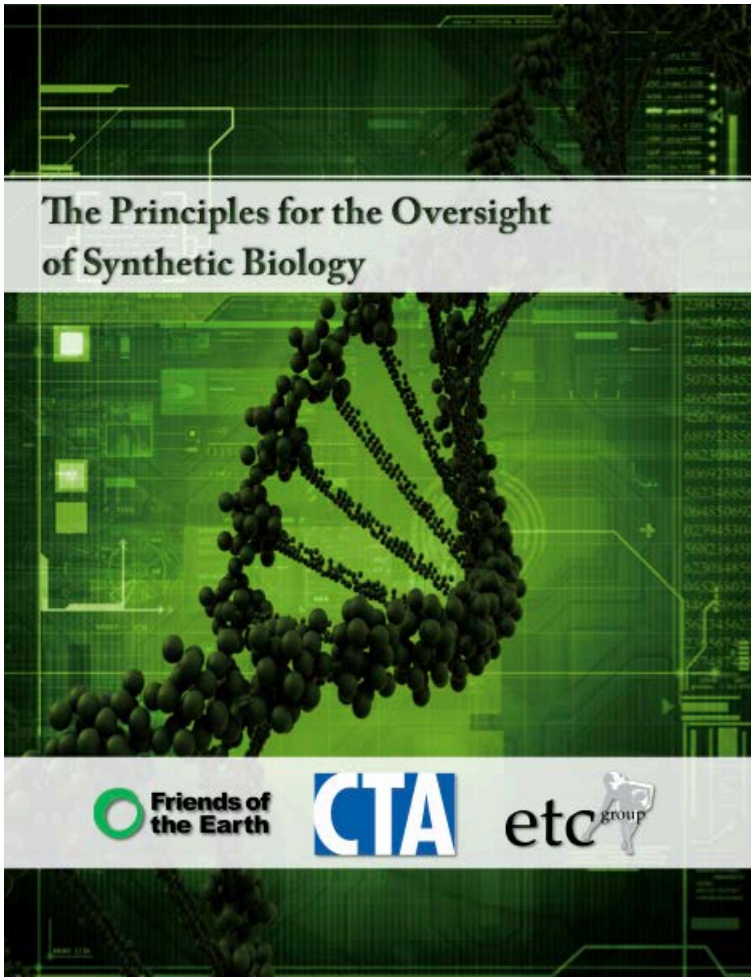
In first report, panel identifies risks and benefits of pioneering research that could lead to new vaccines, drugs and biofuels; develops framework to evaluate emerging technologies

Citing uncertainty about risks, Commission urges enhanced coordination and transparency, ongoing risk analysis, public engagement, and stepped up ethics education for researchers

Washington, DC – The Presidential Commission for the Study of Bioethical Issues today released its first report—a wide-ranging review of the emerging field of synthetic biology—issuing 18 recommendations including a call for coordinated federal oversight of scientists working in both large institutions and smaller settings.

March 13th 2012

New declaration calls for precautionary oversight for the emerging field of synthetic biology



WASHINGTON, D.C. — Today a broad coalition of 111 organizations from around the world released *The Principles for the Oversight of Synthetic Biology*, the first global civil society declaration to outline principles that must be adopted to protect public health and the environment from the risks posed by synthetic biology, and to address the field's economic, social and ethical challenges. Until these governance principles are in place, the coalition calls for a moratorium on the release and commercial use of synthetic organisms and products.

ELSI Reports on Synthetic Biology
'ethical, social and legal issues'

More than 40 reports since 2004

28 in 3 year period (2008-2011)

Key features:

- Conflicting narratives co-exist
- Overlook trans-scientific nature of emerging technologies
- Engage in 'speculative ethics'

Conflicting Narratives co-exist

1. **New and risky/Old and familiar**

   Regulatory paradox (fundamental challenge to current regulatory structure… existing framework is adequate)

2. **Economic promise/Economic doldrums**

3. **Call for novel forms of bottom-up participative governance/Continued dominance of traditional top-down government**

Many/most reports on synthetic biology overlook trans-scientific nature of emerging technologies

Common structure of reports:

1. Introduce technical aspects
2. Applications and Economic Promise
3. Regulatory/legal issues (Biosafety, Biosecurity, Intellectual Property)
4. Ethical and philosophical issues (Playing God? What is Life?)
5. Call for public involvement (and social scientists and ethicists)

Assumption:

- Science/technology first
- Ethical/social concerns are **separate** and **downstream** from innovation processes

But we argue that political, cultural, technical and economic dimensions of science and technology are entagled

Many/most reports engage in 'Speculative Ethics'*

Start from the premise that synthetic biology will:

- Produce a registry of standardised, modular, biological parts with well-characterised functions
- Develop modelling methods and computer-aided-design (CAD) tools to design living organisms which will perform human-defined functions
- Provide access to the registry of parts through some kind of 'open source'

Then policy debates focus on: what happens when evil terrorists or naïve DIY-biologists get hold of such a powerful technology?

*The concept of 'speculative ethics' was developed by Alfred Nordmann in the context of public debates on nanotechnology. See Nordmann, A. (2007). "If and Then: A Critique of Speculative NanoEthics." *NanoEthics* 1(1): 31-46.

Speculative Ethics (2)

- ***If*** SB succeeds in producing a registry of standardised, modular, biological parts with well-characterised functions; ***and***
- ***If*** SB succeeds in developing modelling methods and CAD tools to design living organisms (or populations of organisms) which perform desired functions reliably in complex and shifting environments outside the laboratory; ***and***
- ***If*** these standardised biological parts (and the knowledge and methods necessary to assemble them, and the chasses to insert them into, and the CAD tools) are made freely accessible through 'open source';

...*then* maybe we should think about how this technology might be mis-used by evil terrorists or unregulated DIY-biologists

Speculative Ethics (3)

If and ***if*** and ***if*…** ***then*** focus on:

- Power and pervasiveness of SB
- Dual-use and malevolent or naïve users
- Philosophical questions such as: 'Do we have the right to play God?'
- Fantastic promises to solve global challenges

Distracts us from mundane but no less important questions:

1. What are professional scientists working for legitimate public and private sector institutions actually doing, today, in their regulated laboratories?
2. What are the most likely applications to be developed by *benevolent* institutions in the short to medium term? What is their purpose? In what ways do these address global challenges?
3. How this vision of SB obscures questions of uncertainties, complexities, contingencies – at biological, social, political and economic levels

Root causes of 'ELSI' concerns

According to our analysis

- conflicting narratives of synthetic biology
- regulatory paradox
- speculative ethics
- Proliferation of ELSI reports

are all ***social responses*** to two fundamental features of synthetic biology:

SCIENTIFIC UNCERTAINTY

CROSS-BORDERNESS

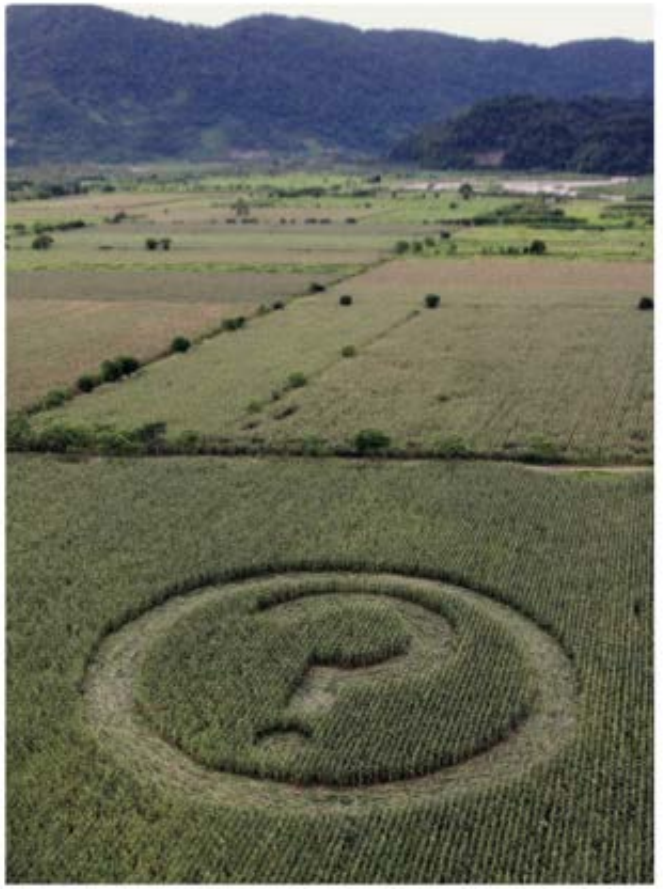
Root causes of 'ELSI' concerns - Scientific Uncertainty

Many future implications of synthetic biology are not only *difficult to predict* but are fundamentally *unknowable*

Not merely calculable risks: provisional unknowns; unknown unknowns; wilful ignorance

= Non-knowing

Cannot be overcome by more knowledge



A UK crop circle, created by activists to signify uncertainty over where genetic contamination can occur.

Keep it complex

Stirling, Andy (2010). "Keep it complex." Nature **468**(7327): 1029-1031

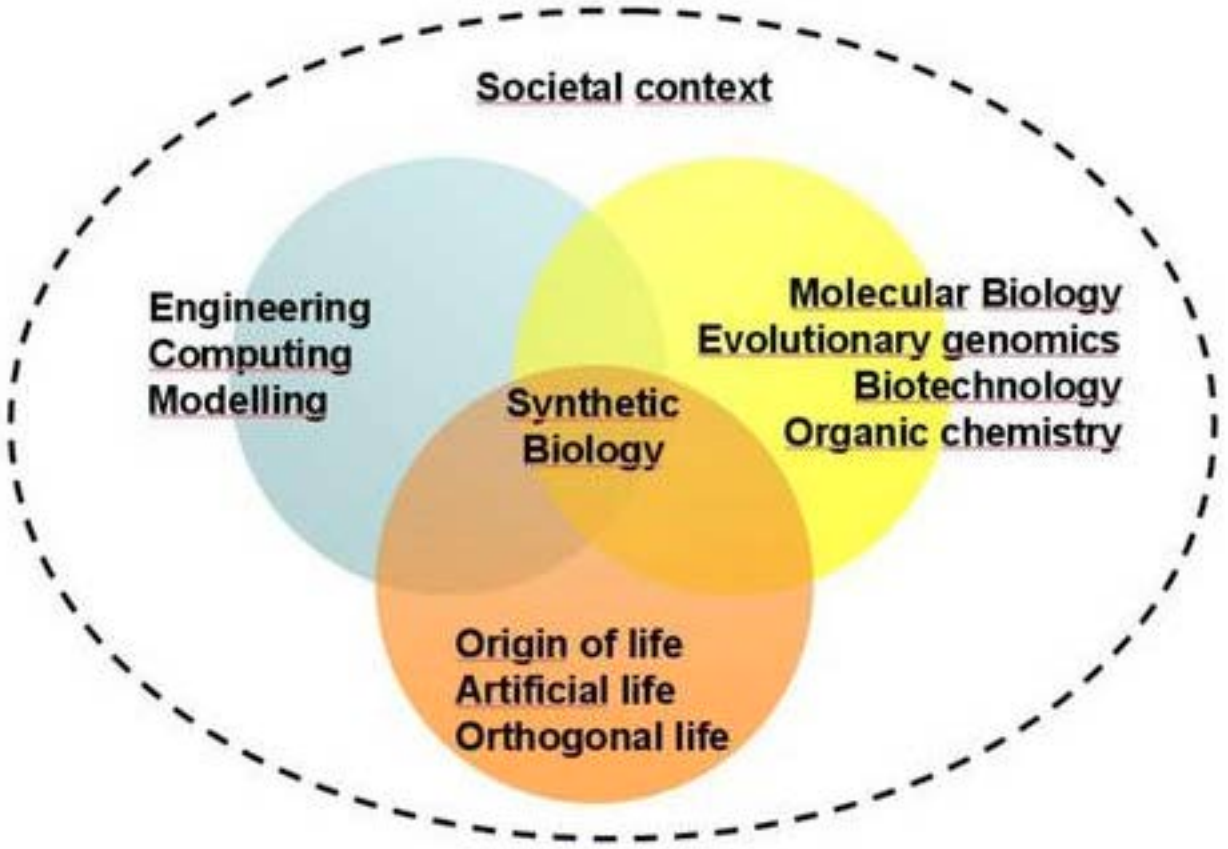
Root causes of 'ELSI' concerns – Cross-Borderness

Inter-relations across:

- Geopolitical regions
- Academic disciplines
- Industrial sectors (pharmaceutical, oil & gas, chemical, industrial biotech, food & agriculture…)

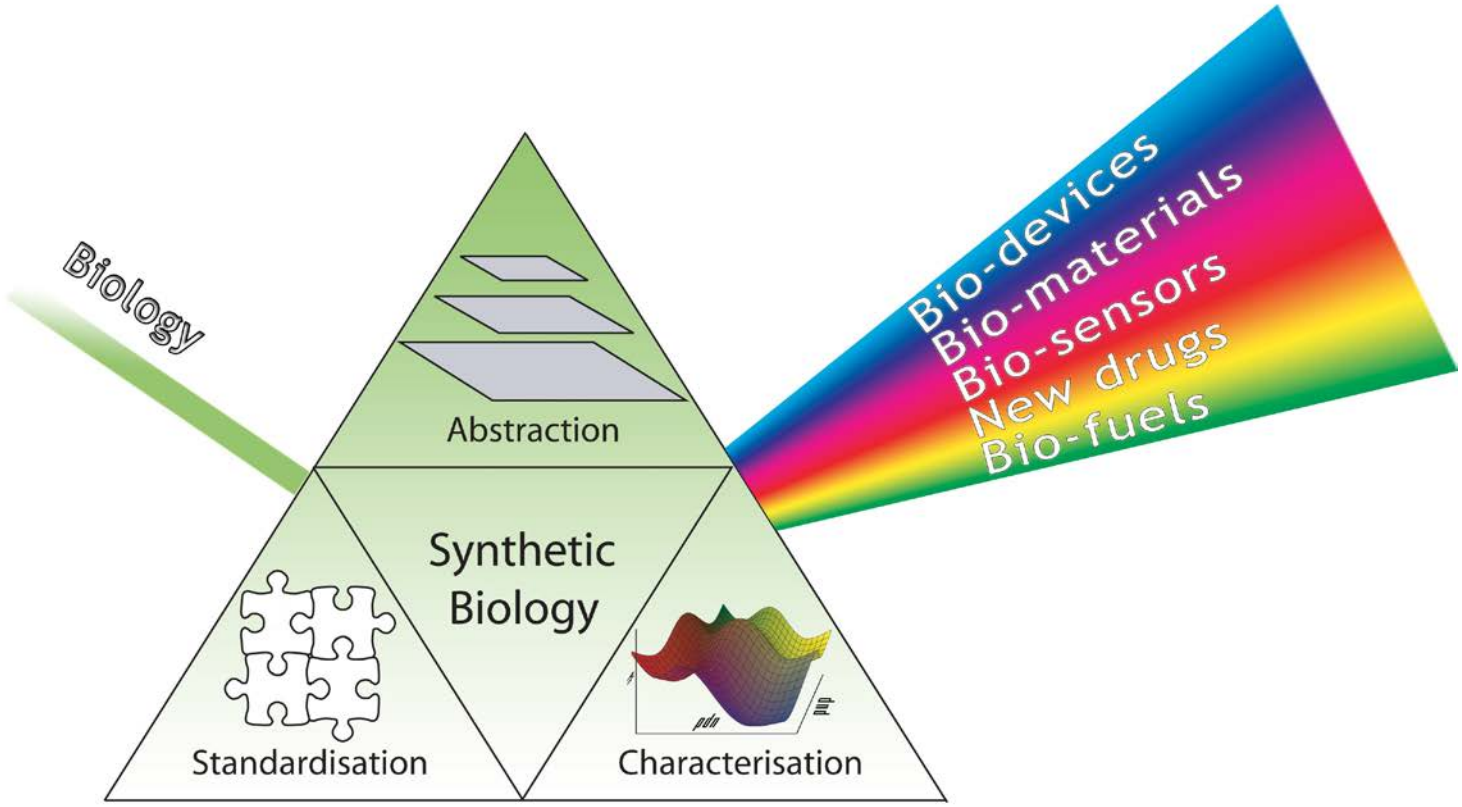
Synthetic biology ***explicitly aims to create synergies*** within and across each of these levels

Cross-Borderness - Disciplines



Source: European Science Foundation EuroSYNBIO programme
http://www.esf.org/activities/eurocores/running-programmes/eurosynbio.html

Cross-Borderness – Industrial Sectors



Cross-Borderness – Geopolitical

Mapping the Emerging Synthetic Biology Landscape: Locations of companies, government laboratories, research institutions, and universities conducting synthetic biology research and policy centers examining issues surrounding synthetic biology.

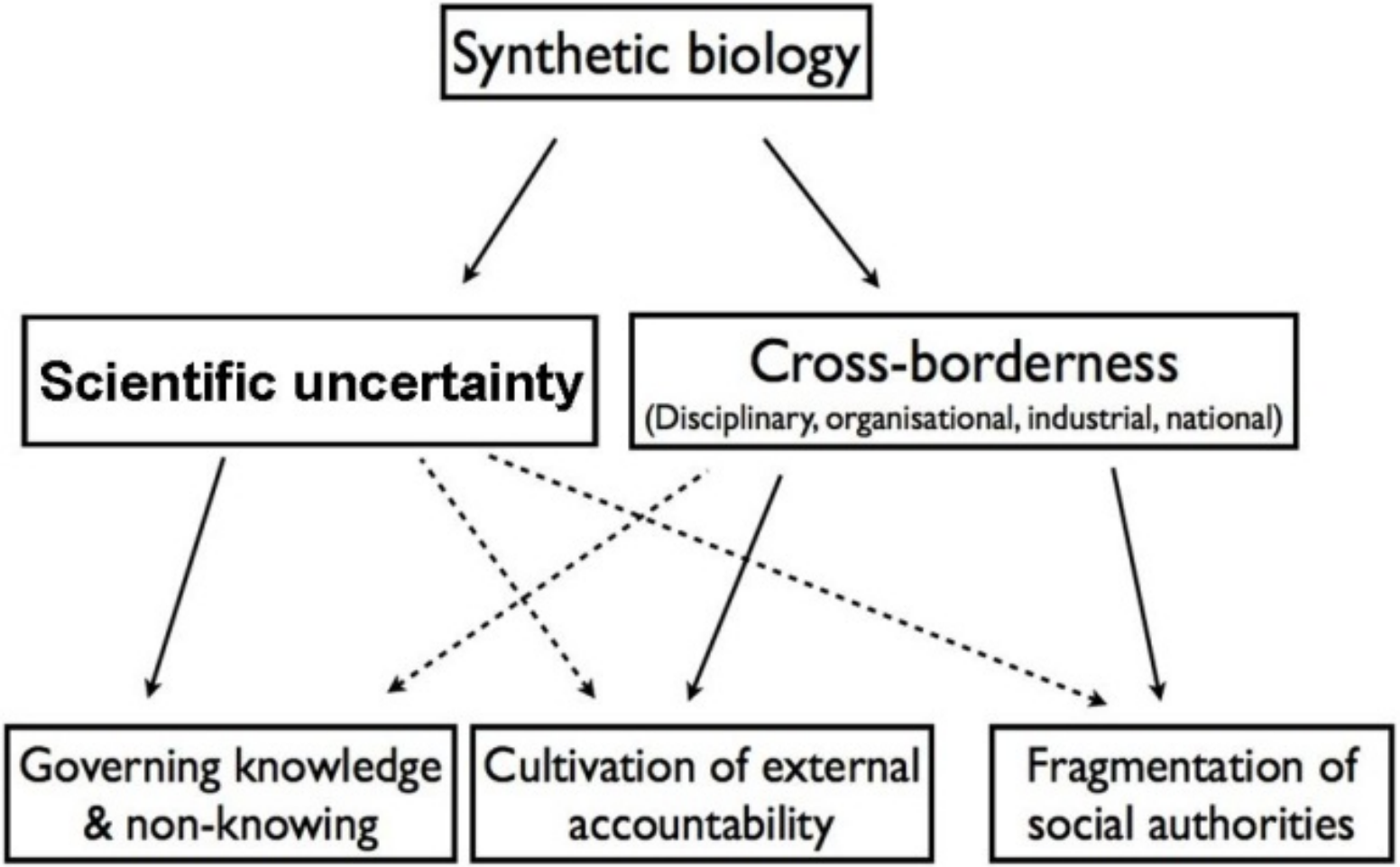
Source; http://www.synbioproject.org/library/inventories/map/

Importance of transnational initiatives

- Cross-border research funding
- Transnational administration of infrastructure and data (Registry of biological parts and BioFABs)
- Governance propositions produced by international organisations and multinational groups
  - OECD, CBD, United Nations, European orgs
  - OECD/NSF/Royal Society
  - 6 Academies (US/China/UK)

Significance:

- Emerging governmentalization (capacity to govern) of non-state actors
- Nation-states need to find ways to transform their authority into transnational agents


Synthetic biology
Scientific uncertainty
Cross-borderness
(Disciplinary, organisational, industrial, national)
Governing knowledge & non-knowing
Cultivation of external accountability
Fragmentation of social authorities

The ‘Art’ of Governance (1)

- Change governance *ethos* rather than organisational *design*
- Subject of governance is not an *object* but *interactions*
- Monitoring of and responding to the evolving regulatory roles of various interest-related bodies – rather than establishing pre-configured a international governance institution
- Consider current and emerging actors and new unforeseeable governance bodies (iGEM)

The 'Art' of Governance (2)

- Ensure that diversity of social actors involved or affected can interact and express their perspectives and interests; that these are considered in decision-making and that their power-leverage is made visible (don't expect to achieve consensus as no decisions will suit all actors)
- Explicitly acknowledge and account for non-knowing: aim is not to predict the unpredictable but to enhance social resilience to scientific unpredictability
- Purpose is not to prescribe how things should be but to elicit how things could be

‘Vision assessment’ proposed by Alfred Nordmann

“Envisioned technologies are viewed as incursions on the present and will be judged as to their likelihood and merit: How credible are these claims, and do these technologies solve acknowledged problems? More generally: What do these visions tell us about the present, what is their implicit criticism of it, how and why do they require us to change?”

Source: Nordmann, A. (2007). "If and Then: A Critique of Speculative NanoEthics." *NanoEthics* 1(1): 31-46.