New Technologies : Scope, Regulations

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Special Webinar:
UNEP- University of Eastern Finland
Course on MEAs, 28 September 2021

Agenda Events Reports Platforms

WORLD ECONOMIC FORUM

Join us

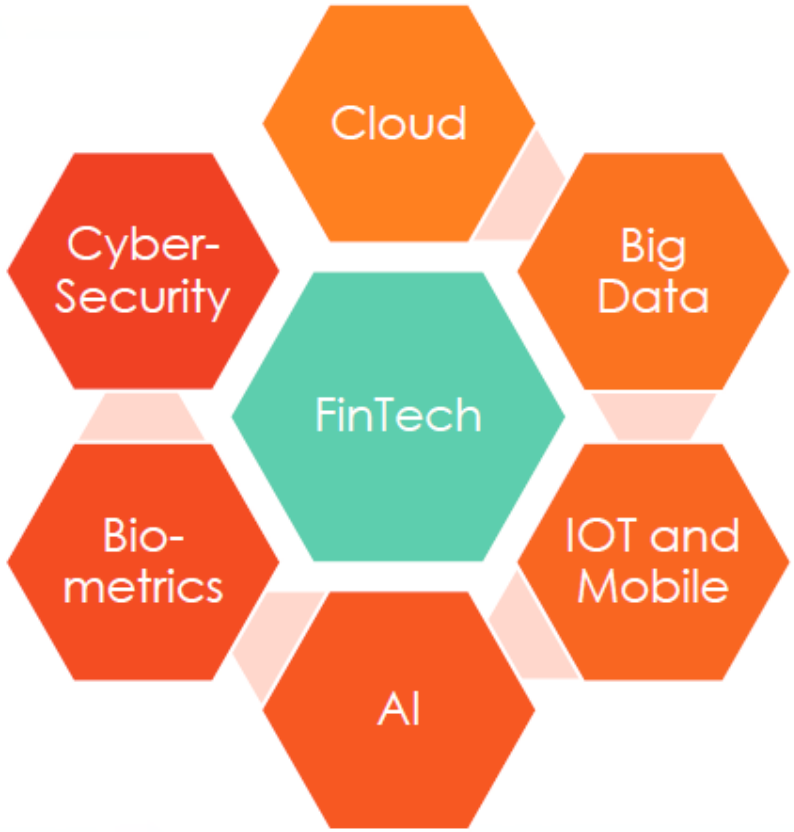
Global Agenda | Pioneers2020 | Emerging Technologies | Future of Health and Healthcare

17 ways technology could change the world by 2025

- Artificial Intelligence
- E-Commerce
- Green Economy
- Intelligent Vehicles
- Internet of Things
- Smart Robots

Technologies & Future

Sector based technology clusters

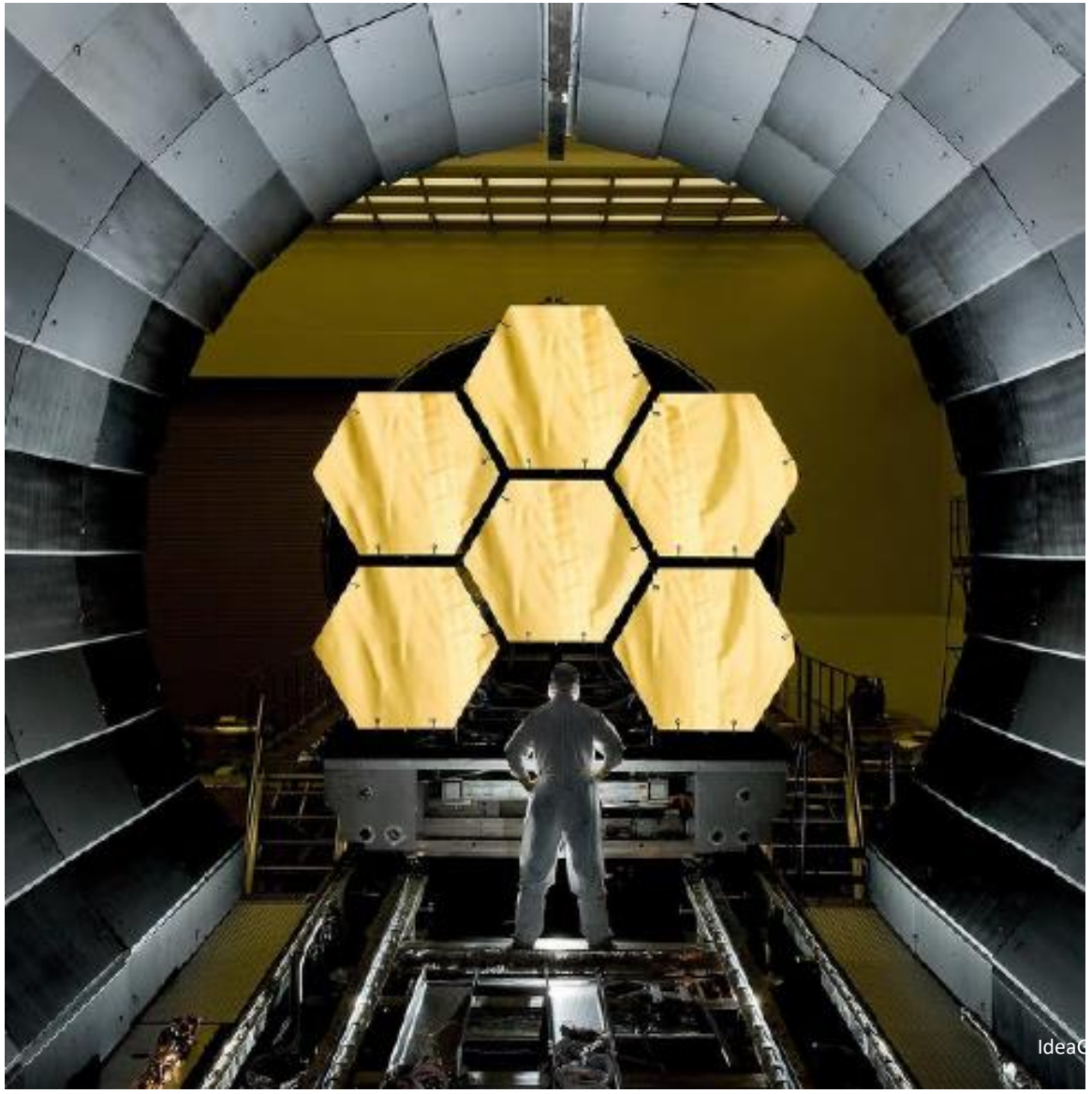


- AgTech
- EdTech
- FinTech
- CleanTech
- GreenTech

UN environment programme

Technologies to Watch !

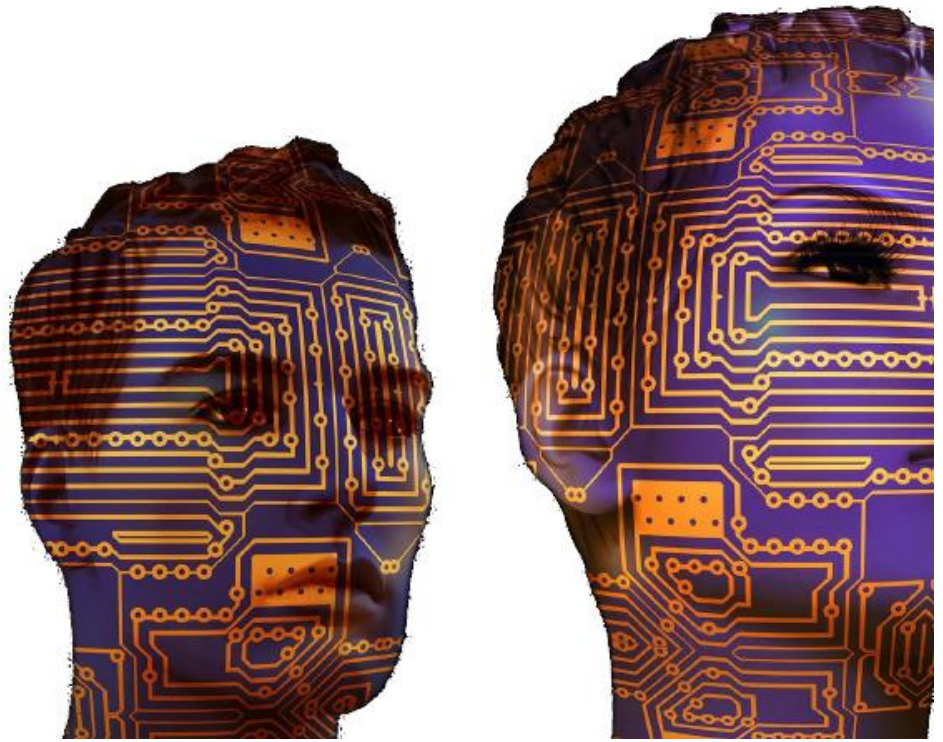
- Quantum Computing
- Gene Editing
- Nano Engineering
- Rapid Organ Growth
- Alternative/Renewable Energy
- E-Healthcare
- Energy Storage
- Hybrid/Electric Cars



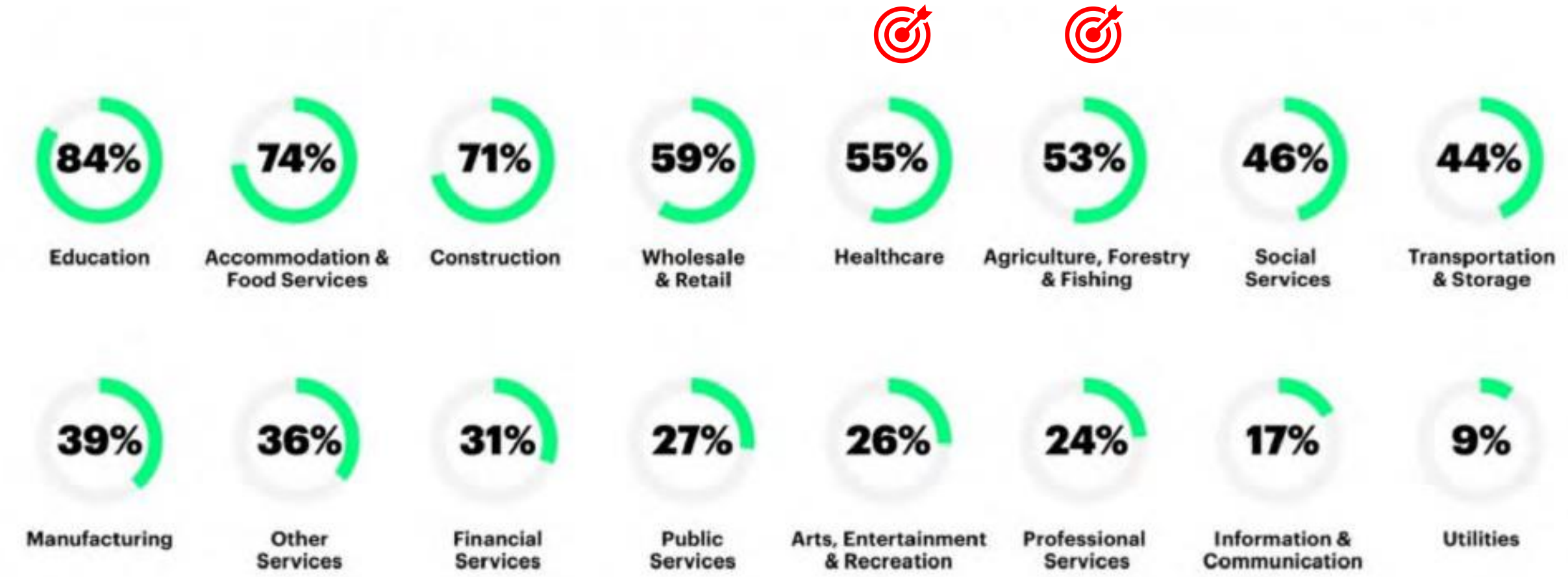
UN environment programme

Artificial Intelligence

- ✓ Market Impact: 17T (PwC)
- ✓ Market Potential: 1.6T (TechCast Global)
- ✓ Take Off: 2022 (TechCast Global)
- ✓ Take Off: 2020 (Gartner)
- ✓ Net Jobs Impact 2020: -1.56% (WEF)

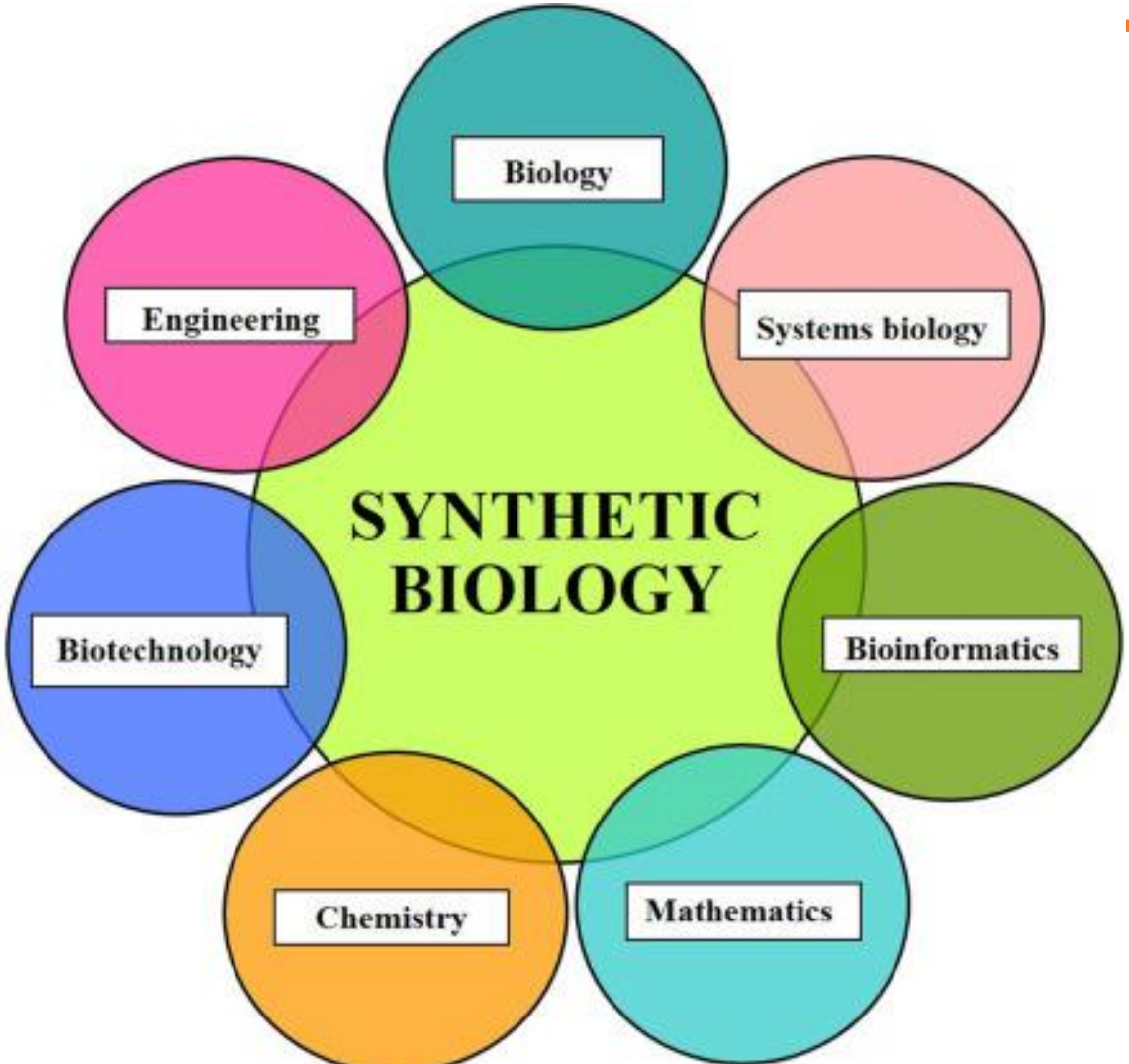


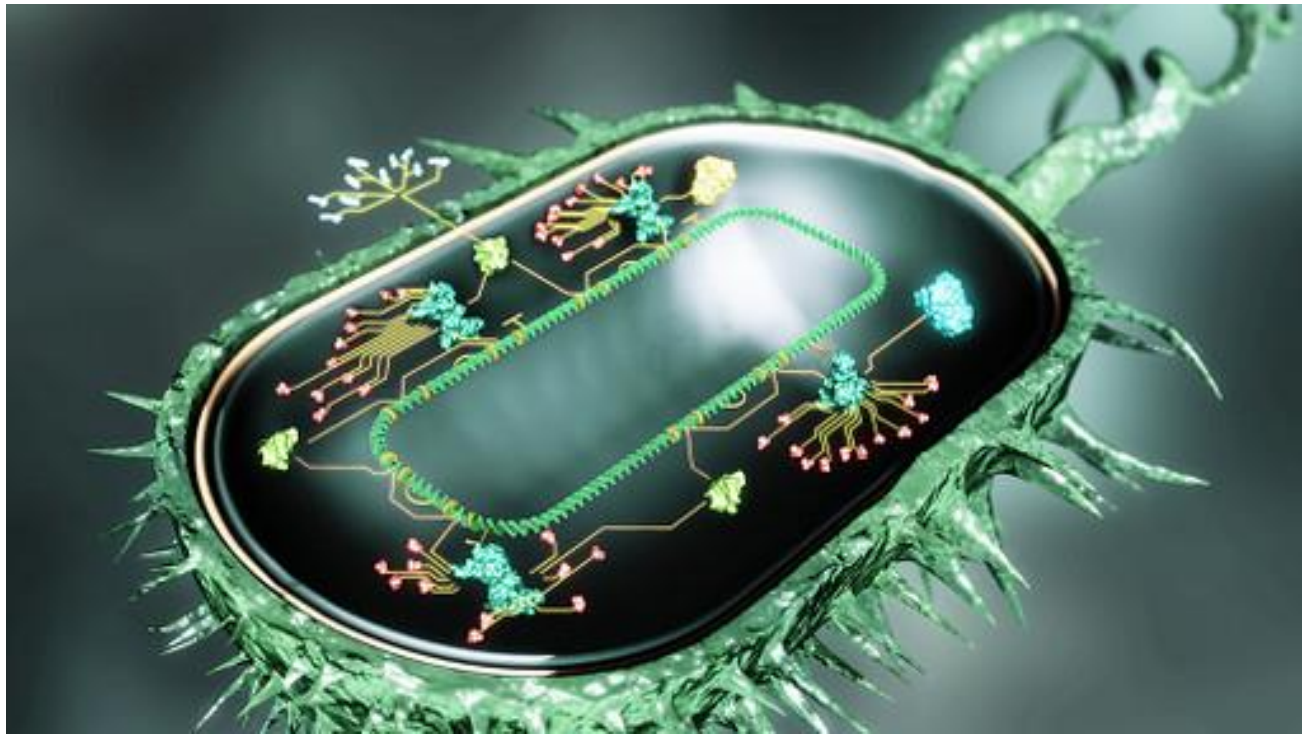
AI and Sectors



Share-of-profit increase per industry between baseline in 2035 and AI steady state in 2035 in %, **Source:** Accenture and Frontier Economics.

Synthetic Biology





SYNTHETIC BIOLOGY MARKET ANALYSIS

MARKET SIZE (2018)

US$ 6.09 BN

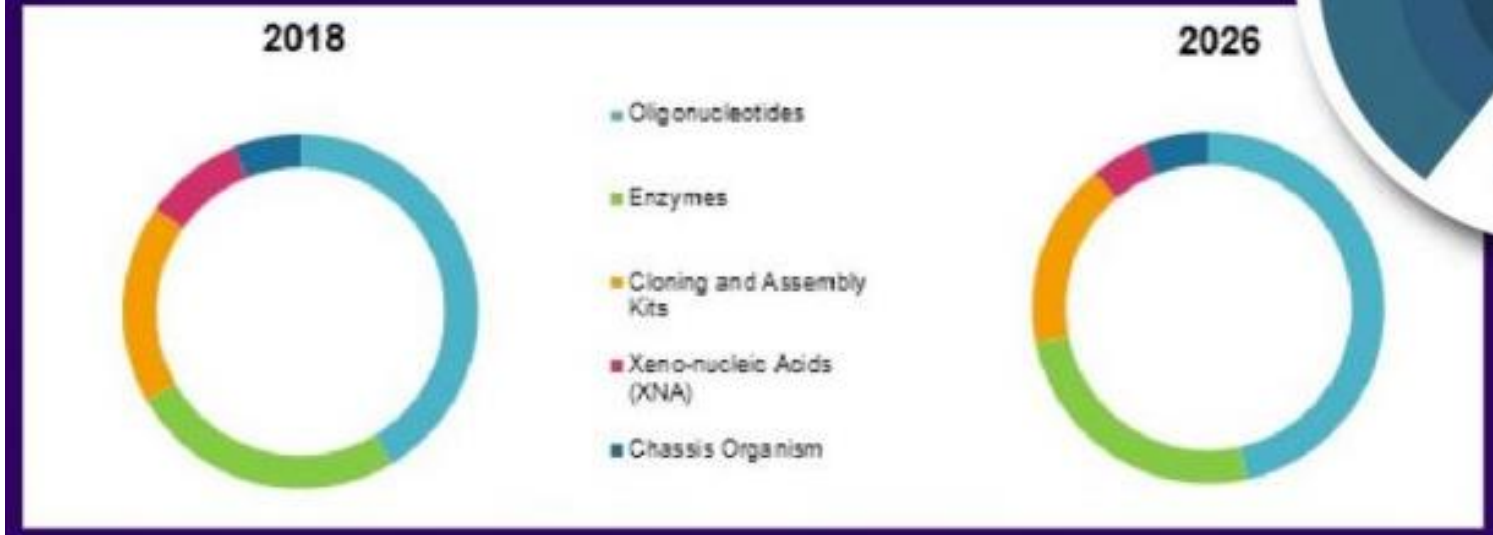
MARKET SIZE (2026)

US$ 62.8 BN

CAGR

33.9%

Global Synthetic Biology Market Share (%), By Product Type: 2018 & 2026



Top 10 BioTech Trends & Innovations in 2021

4351

Startups & emerging companies analyzed

Data provided by StartUs insights — March 2021

Synthetic Biology

- 1990s – recombinant DNA technologies graduated to include gene sequencing, omics technologies, bioinformatics
- 2000s – Systems biology focused on integrating big data with modelling, promoting prediction and understanding of cell functions at one time.
- Synthetic biology took shape to take Systems biology further taking design and engineering of molecular biology to new levels – focus still largely on microorganisms

  2003 synthetic virus was created

  2008 first synthetic complete chromosome

  2009 ‘microinjection’ of complete chromosome into a bacterial cell

  20th May, 2010 the Craig J Venter Institute combined all these into ‘Synthia’ (the parent of ‘Synthia’ is a computer ?)

Understanding Synthetic Biology Organisms

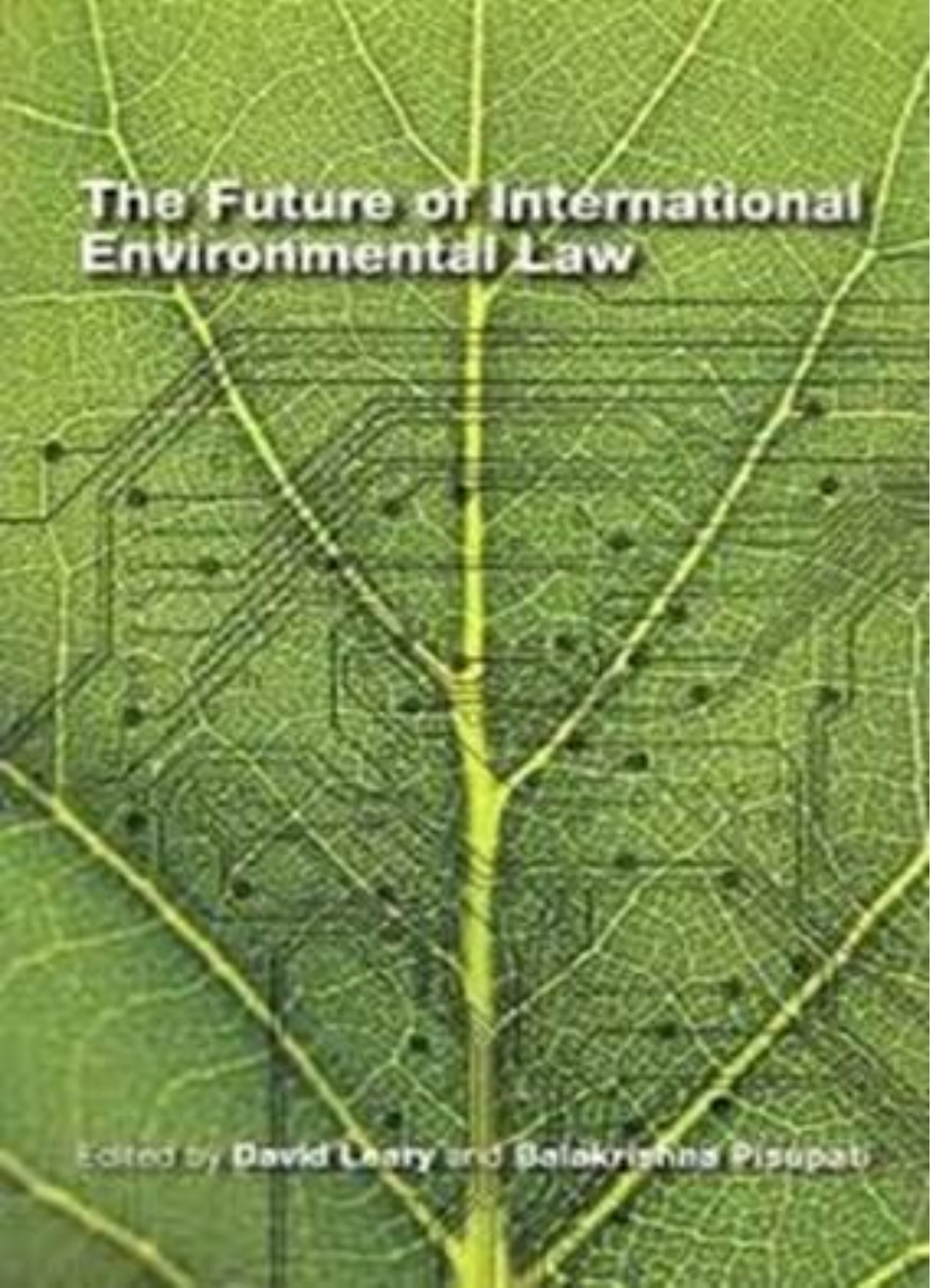
Synthetic biology refers to both:

- the design and fabrication of biological components and systems that do not already exist in the natural world
- the re-design and fabrication of existing biological systems.

Synthetic Biology and Biotechnology

Improving the production of a certain metabolite by tinkering with some of the components of a metabolic network will fall within the realm of Biotechnology.

On the other hand, the introduction of several exogenous enzymes in an organism to produce a new compound will fall within the scope of Synthetic Biology.



2010 book edited by David Leary and Balakrishna Pisupati on **“The Future of International Environmental Law”**

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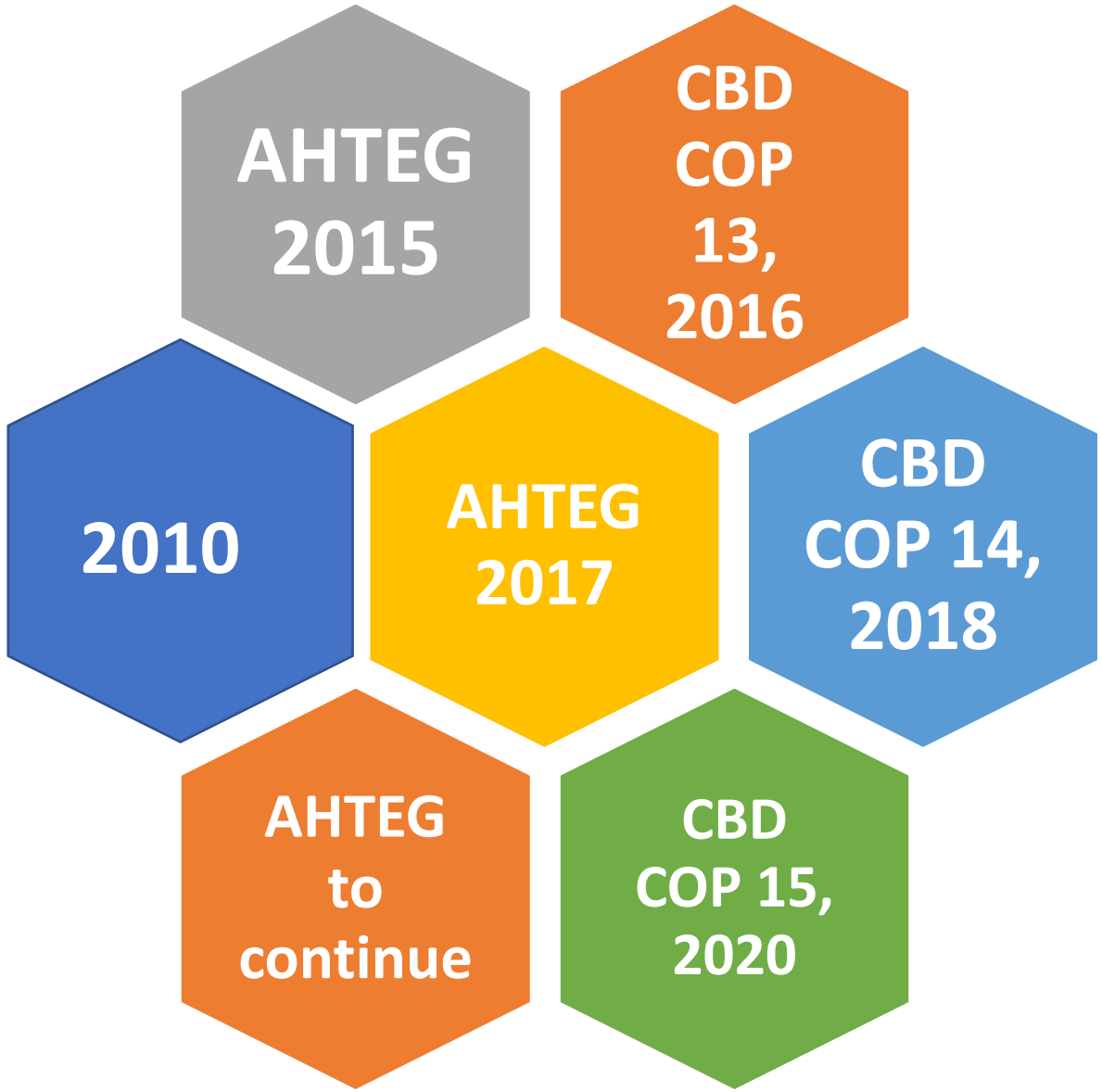
Chapter by Michele Garfinkel and Robert Friedman (CJVI)

Discussions under the CBD



Perspectives on Biosafety

USA – Any product is safe unless it is proven risky

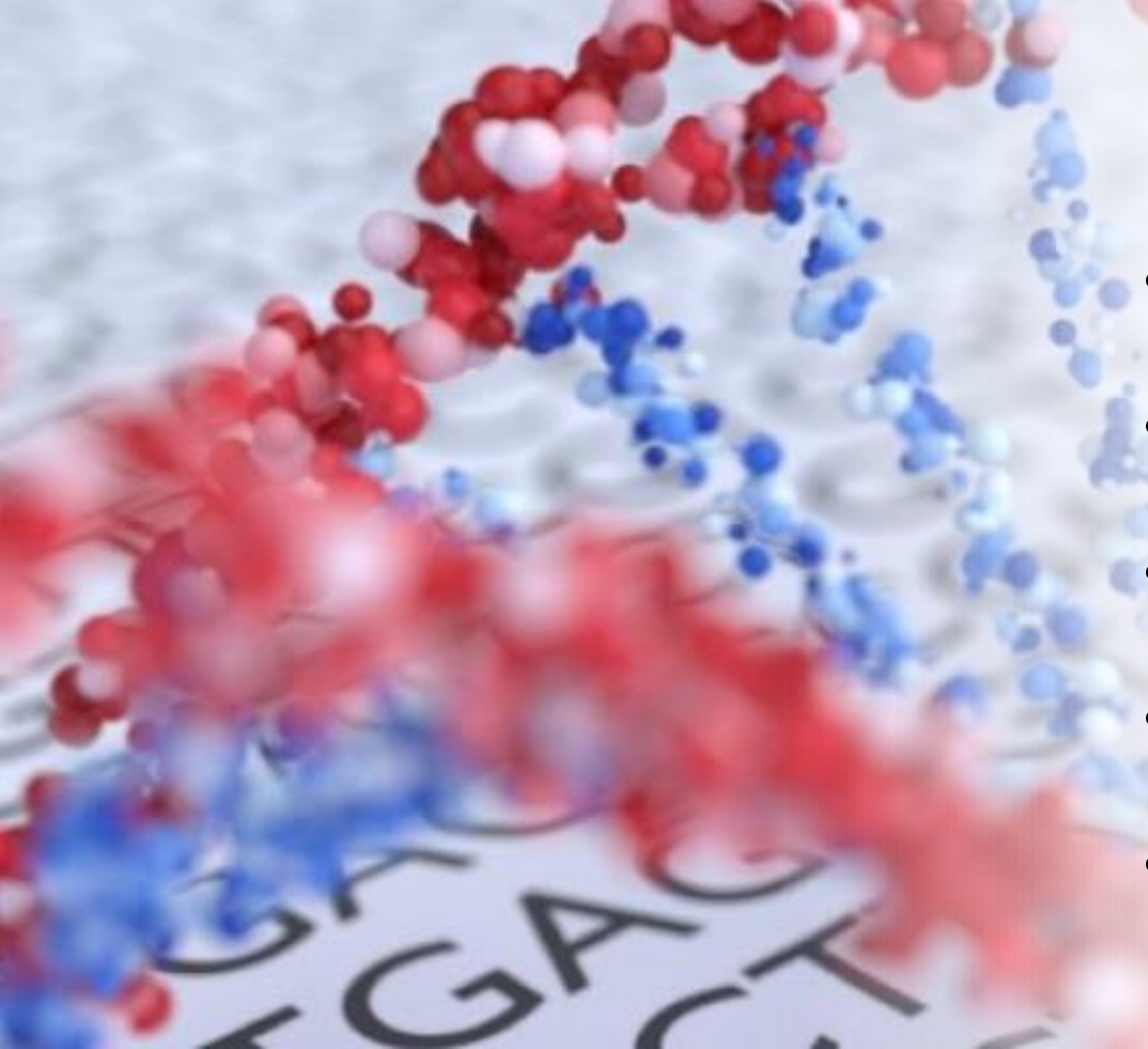
France – Any product is risky until proven safe

The UK – Any product is risky even if proven safe

European Union – European Academies paper – regulatory oversight, prioritization of technologies, participation of stakeholders

US – National Research Council, National Science Advisory Board for Biosecurity, DOE policy guidance

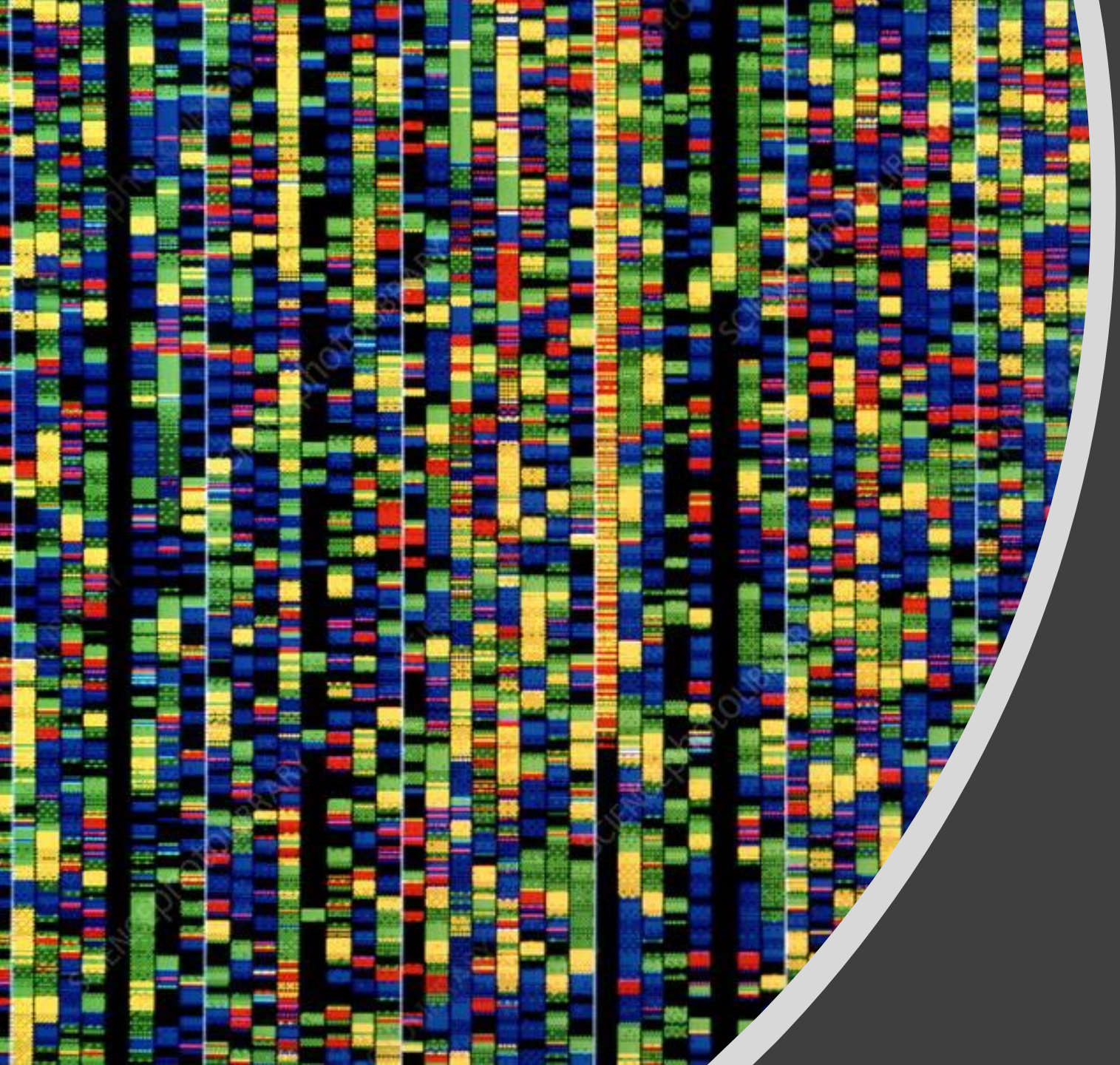
The International Consortium for Polynucleotide Synthesis (ICPS) and International Association for Synthetic Biology (IASB) guidelines



Status and Trends

- Scope of modification expanded
- New gene editing tools helping
- Engineered gene drives increasingly used
- ‘Do-It-Yourself’ (DIY) community increasing
- Machine learning, AI, genetic circuits use increasing.


Digital
Sequence
Information



DSI

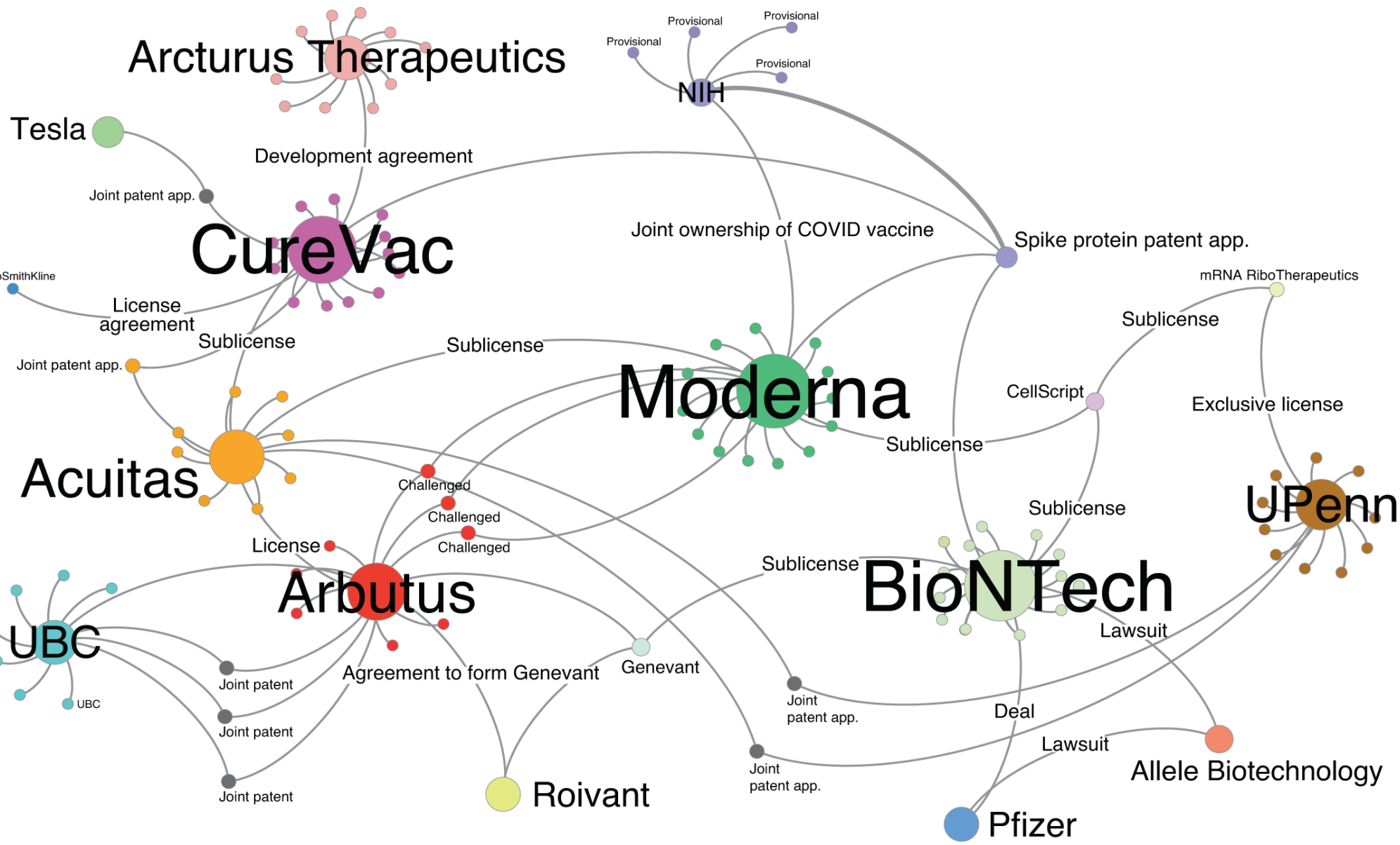
- In use for decades
- Repositories exist
- Mandatory deposit of sequence information for scientific publications
- Freely used and exchanged – subject to some oversight by different agencies eg. EMBL, GISAID….

SCIENCE / APRIL 2, 2020

Sachin Sathyarajan Balakrishna Pisupati

Science, Open Data and the COVID-19 Pandemic

COVID taught us some key lessons on science, policy, politics



The patent maze!!

1.2 million COVID GS available through GISAID

DSI, Synthetic Biology and ABS

Synthetic biology researchers are increasingly having access to a variety of cost-effective and highly efficient tools to put this DSI to use. There is an interest among the companies in the US for having an open source model for the DSI similar to computer software. The open source approach attaches some conditions to the use of data involving user agreements or Material Transfer Agreements (MTAs).

The DSI is uploaded to publicly accessible internet databases. There has been several industry professionals actively advocating for a "Synthetic Biology Commons". The scientists involved with the Registry of Standard Biological created the BioBricks Foundation to coordinate a Synthetic Biology Commons.

In 2017, Twist Bioscience and the BioBricks Foundation announced a partnership to make 10,000 genes freely available to synthetic biology researchers.

BioBricks then will manage this open source library that will be made available to researchers based on an Open Material Transfer Agreement (OpenMTA).

There will be a standard access fee in which users will pay a small charge for accessing the open source library. The bottom-line is that the DSI can be made available widely to researchers and hobbyists alike using the open source model.

Synthetic Biology and Nagoya Protocol

- ✓ Synthetic biology and NGS has the potential to bypass the CBD/NP framework entirely.

- ✓ Researchers can take genetic code that has been uploaded online, and using a DNA synthesizer produce new substances and perhaps even new organisms. The final synthetic biology products are eligible for utility patent protection in many jurisdictions.

Some Key Issues !

- Concerns regarding the potential for digital misappropriation in projects like that of EBP threaten the provider countries to enter into any agreement altogether.
- Brazil has initiated Nagoya plus clauses exerting their rights over DSI even if held outside their borders. The new Brazilian law expands the meaning of “access to genetic resources”
- Synthetic biology researchers may not even realize that the use of DSI is objectionable according to provider country laws. A provider country like Brazil considers DSI to be the same as accessing physical samples.
- A researcher in the US obtaining DSI from a commons library may not recognize this layer of ABS issues.

- The technology driven user countries are preparing for an open source model of innovation in the synthetic biology sector.

- However it will be not as easy as the open source model in the software sector. The significant difference from the software model is an additional layer of ABS issues.

- With the proliferation of proprietary rights on synthetic biology products that are built using the open source platform, it is important to ensure a fair and sustainable share for the Global South.

Tools like the Basic Local Alignment Search Tool (BLAST) available with the U.S National Institutes of Health (NIH) and the National Center for Biotechnology Information (NCBI) facilitates finding the same DNA sequence in other possible organisms found within other jurisdictions. Through BLAST, a credible ABS bypass tool is available in the US and can potentially defeat the efforts of the CBD/NP.

What we need is a **"Nagoya Protocol Plus"** approach to dealing with DSI and Synthetic Biology now.

Can we come up with this soon?

Where from here ?

- ✓ Emerging technologies are complex
- ✓ Capacities to understand, regulate, use and apply are needed
- ✓ Innovation law is being redefined
- ✓ Transdisciplinary approaches are key.