Digitizing Biology: A tale of two technologies

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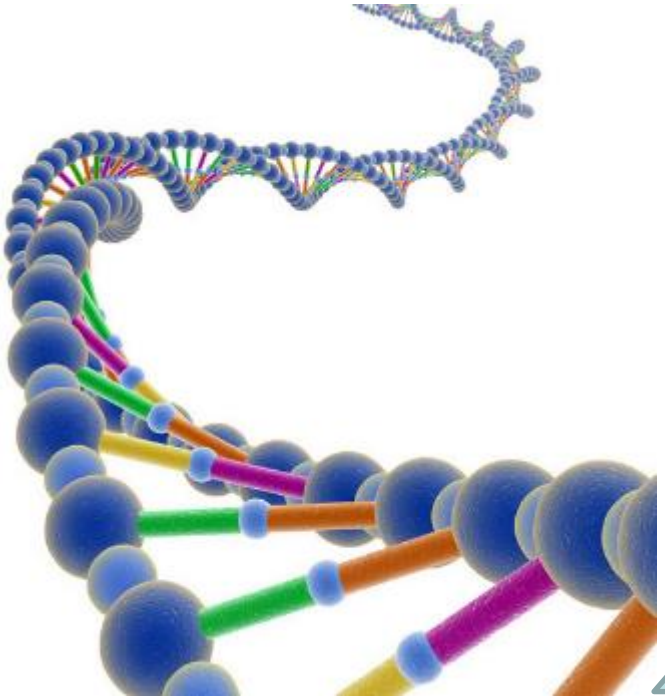
GENOMICS AND SYNTHETIC BIOLOGY:
Reading and writing the genetic code

DNA Sequencing



ACAGATGATACCGACCA
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ACTTAGCTTCTATGAGA
TAGACTACTAGGACTAT
GACCGGATATGCGGATA
CGCGATATCCGAGAGAT
CGTAGAGCTATCTATATT

DNA Synthesis

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DNA Sequencing

- Technological milestones:
  - 1977: Complete genome of a virus (5,000 bases)
  - 1995: Complete genome of a bacterium (1.8 million bases)
  - 2001: Sequence of the human genome (3 billion bases)
- US Governance milestones (focus on humans):
  - 1979: "Belmont Report": Ethical Principles for Human Research
    - Response to public outrage over the Tuskegee Syphilis Study
    - Led to Federal Policy for the Protection of Human Subjects, 1981 (Review of Experiments, Informed Consent, Privacy Protections)
  - 1996: Health Insurance Portability and Accountability Act (HIPAA)
    - Privacy and data security requirements, Right to access your data
  - 2007: Genetic Information Nondiscrimination Act (introduced 1995)
    - Limits on use of genetic information in workplace decisions.

Genetic engineering, DNA synthesis, and synthetic biology

- Technological milestones
  - 1973, Invention of recombinant DNA technology
  - 1982, Human insulin manufactured in bacteria
  - 2002, Synthesis of a virus genome (poliovirus)
  - 2010, Synthesis of a bacterial genome
  - 2012-2013, CRISPR genome engineering
- US Governance milestones
  - 1975, Asilomar Conference on Recombinant DNA
    - Self governance; leads to NIH Guidelines for rDNA research, 1976
  - 1986, Coordinated Framework for the Regulation of Biotechnology
  - 2010, Screening Framework Guidance for Synthetic DNA
  - 2013, NIH Guidelines updated to include synthetic DNA
  - 2017, OSTP attempts to update Coordinated Framework

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Lessons to be learned?

- Importance of the Unanticipated
  - Outrage over Tuskegee Syphilis experiments leads to Human Subjects Protection rules
  - Terrorist attacks of Sept 11, 2001 brings the emerging field of synthetic biology into the spotlight
- Pacing problems
  - Technology advances exponentially
  - Governmental response appears to be slowing
- Importance of self governance and soft governance
  - Has played a significant role in genetic engineering, synthetic biology
  - Less significant role in use of digital sequence information
- Policy evolves, building on earlier decisions
  - Influence of Belmont Report and HIPAA for human sequencing; Asilomar tradition for synthetic biology

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