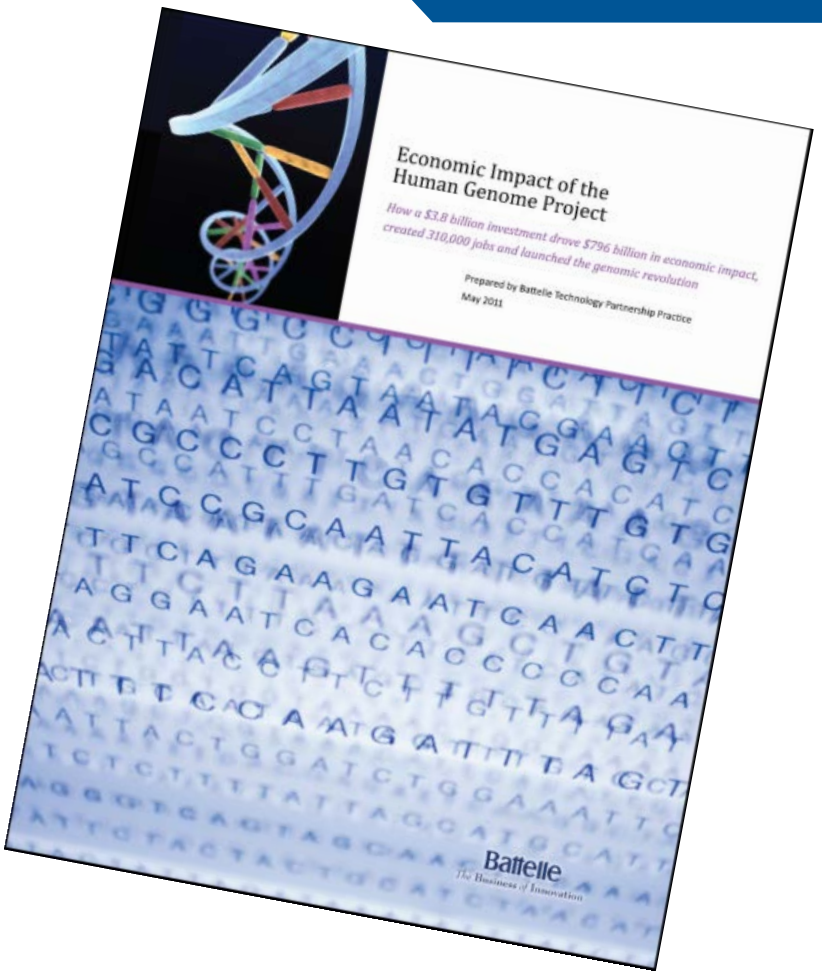
Battelle
The Business of Innovation

Exploring the Health, Scientific and Economic Value of Biomedical Research



Presentation to the NIH Scientific Management Review Board

January 14, 2012

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Technology Partnership Practice

Presentation Content

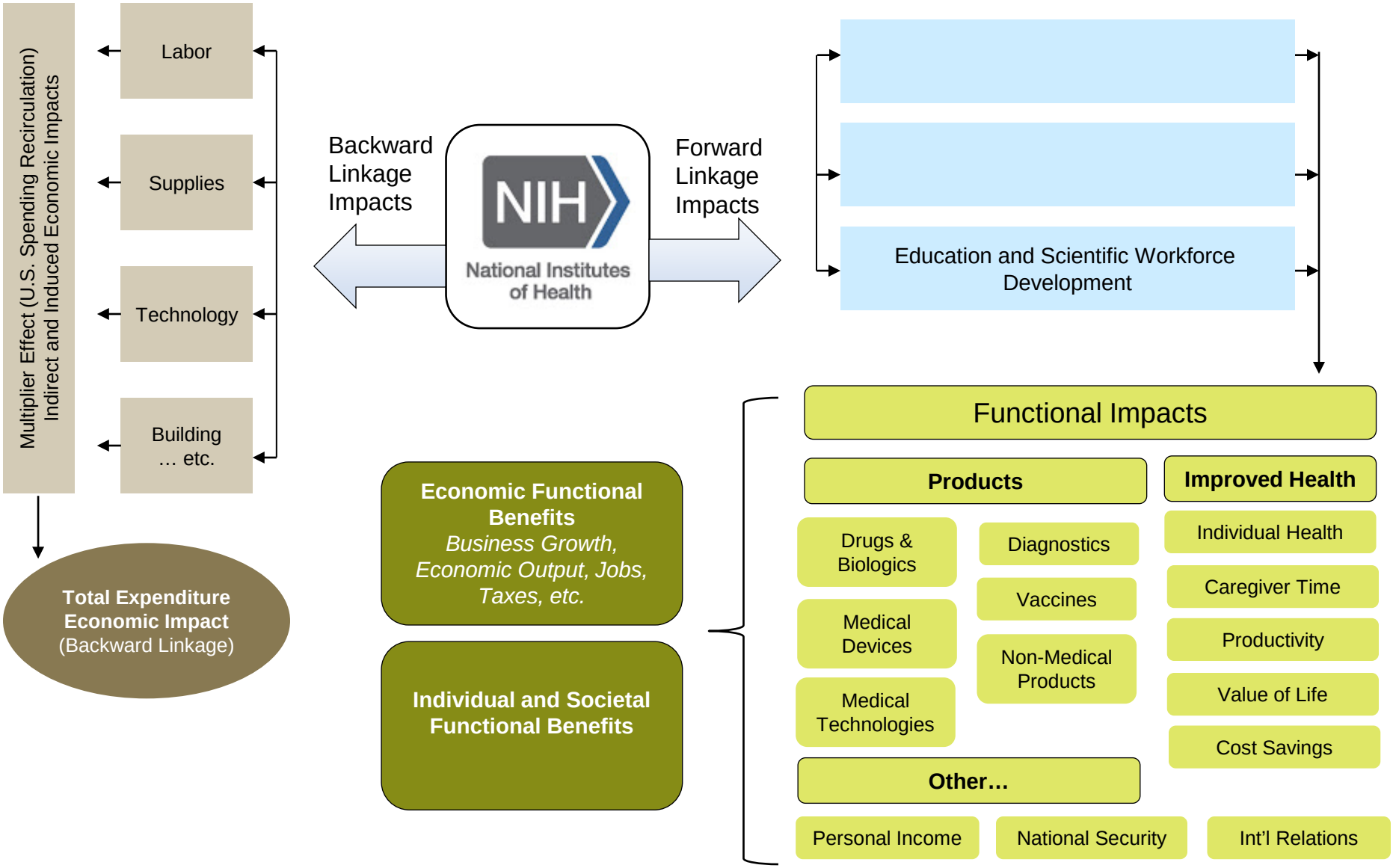
- Battelle TPP credentials
- Background on impacts and impact analysis
- Human Genome Project impact analysis example
- Challenges in evaluating NIH impacts
- Thoughts on potential approaches

Battelle Technology Partnership Practice (TPP) Credentials

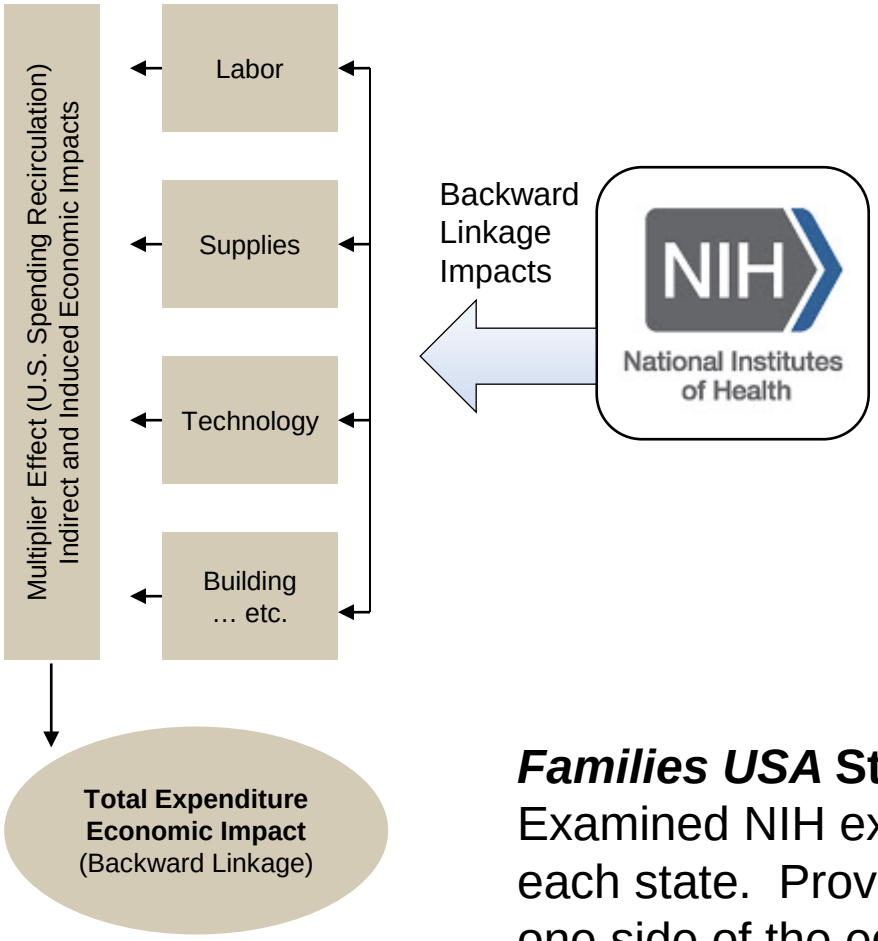
- Battelle is the world's largest independent non-profit scientific research institute
- TPP is Battelle's science and technology-based economic development consultancy
- Experience in a broad range of bioscience impact analyses:

  - Human biomedical (e.g. Mayo Clinic, UPMC, UAMS, Wake Forest)
  - Biosciences (e.g. Ohio State University, Oklahoma State University, University of Nebraska, 15 Southern Land-Grants)
  - Bioscience Industry (e.g. PhRMA, AdvaMed, American Clinical Laboratories Association, NCBC)
  - Major Science Projects (e.g. Human Genome Project)

Types of Impact Analysis:
Difference Between Forward and Backward Linkages



Backward Linkage Example



***Families USA* Study**

Examined NIH expenditures and expenditure impacts in each state. Provides important information, but only on one side of the equation. Use of it alone substantially underestimates the value of NIH funded research.

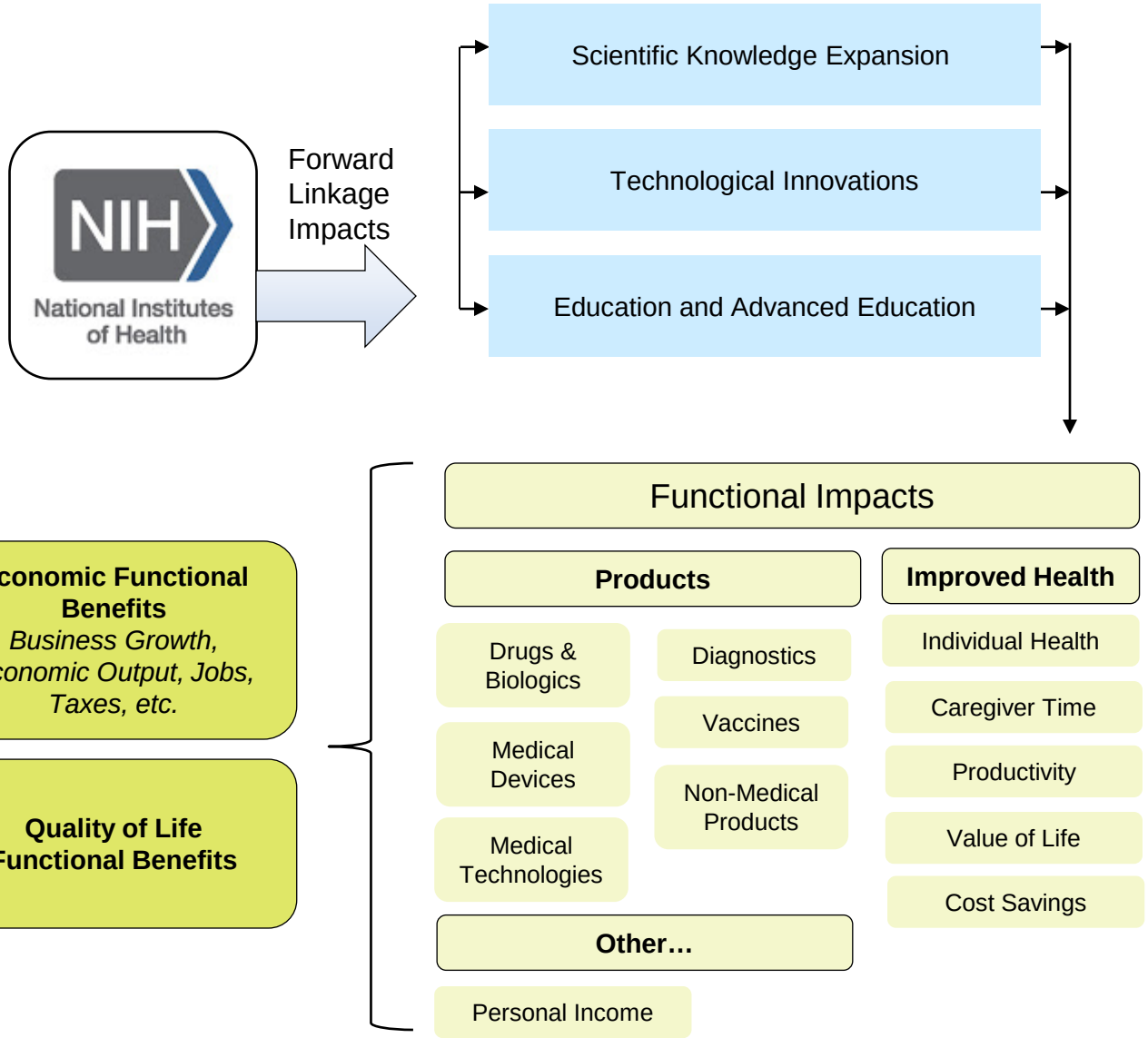
Forward Linkage (Functional Impacts)

Address impacts generated by mission-based activities.

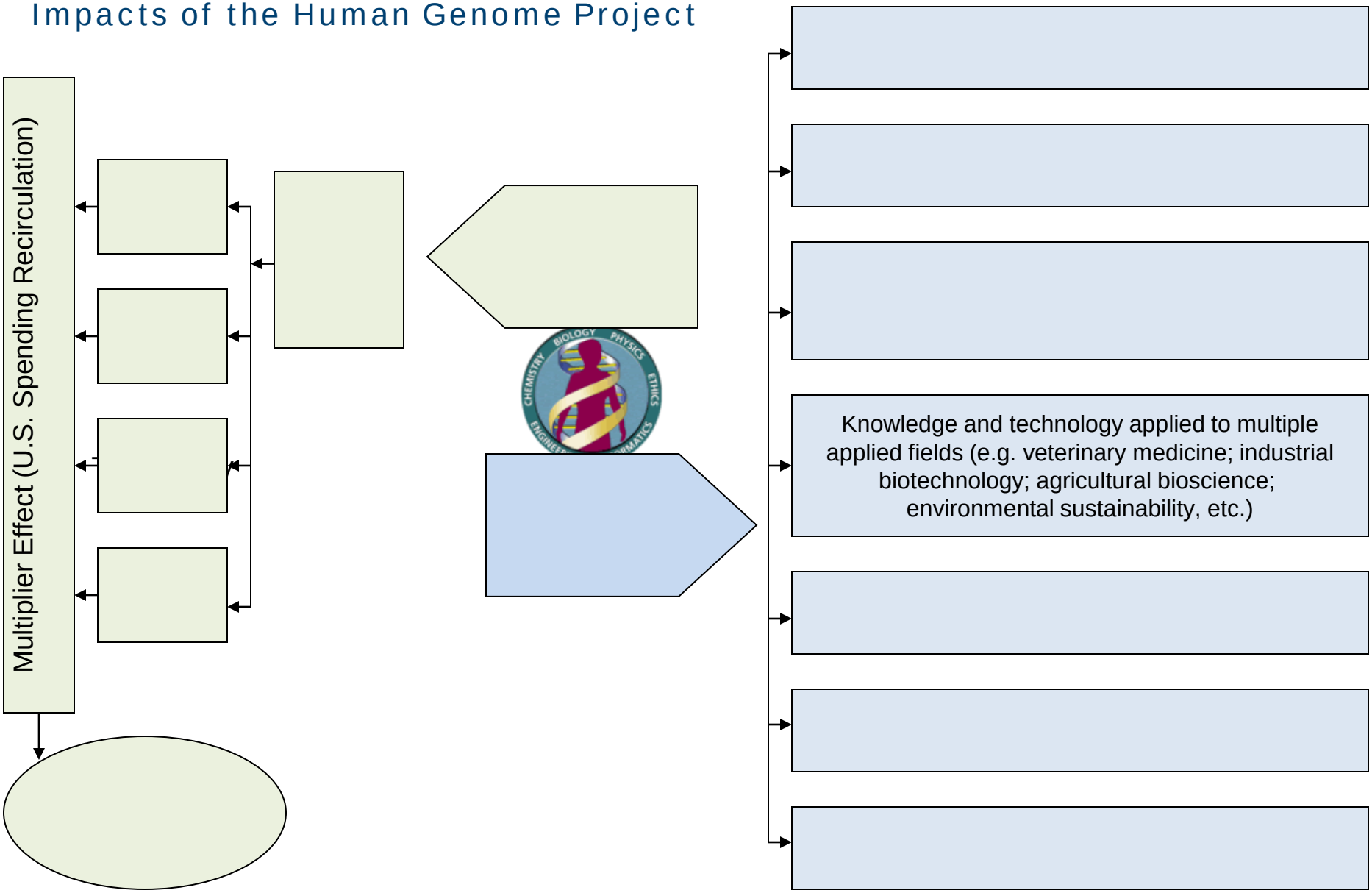
Much more complex to perform.

An issue of scale and other challenges…

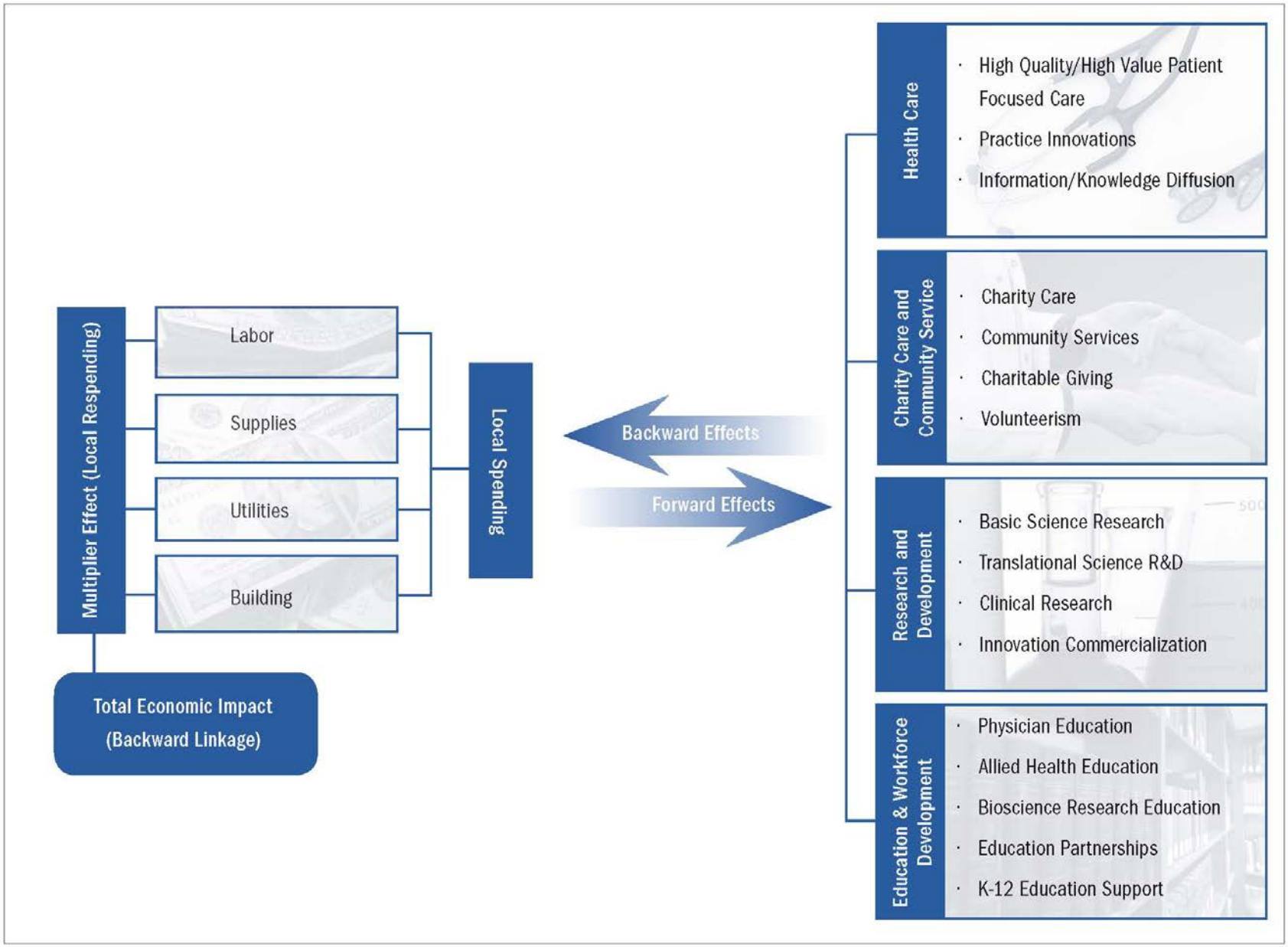
- **233 NIH research/disease areas**
- **44,500 NIH research awards in 2012 alone**



Comprehensive Backwards and Forwards Linkage Impact Example: Battelle's Study of the Economic and Functional Impacts of the Human Genome Project



A Similar Approach in Battelle's Analysis of Mayo Clinic Impacts



HGP impact study worked because...

- A single definable project of large-scale
- Industry agreed “HGP was foundational in the emergence and growth of the genomics industry”
- Able to identify components of industry output allocable to genomics and then use input/output analysis to model impact
- Significant impact analysis project budget enabled an in-depth analysis
- Ten-year time horizon from draft genome publication
- Many publications, reports, books etc. on the project, its history, and various functional applications of genomics.

Impact of Genomics and Genomics-Enabled Industry Activity 2010

(in Millions, 2010 $)

Impact	Employment (Jobs)	Personal Income	Output	State/Local Tax Revenue	Federal Tax Revenue
Direct Effect	51,655	5,577.2	22,627.5	212.3	952.2
Indirect Impacts	109,520	7,593.1	22,725.9	922.5	1,522.8
Induced Impacts	149,185	6,835.7	21,792.6	1,244.0	1,468.4
Total Impact	**310,360**	**20,006.1**	**67,146.0**	**2,378.8**	**3,943.4**
Impact Multiplier	6.01	3.59	2.97	11.21	4.14

In 2010 alone, genomics and associated research and industry activity directly and indirectly generated:

- **$67 billion in U.S. economic output**
- **$20 billion in personal income for Americans**
- **310 thousand jobs.**

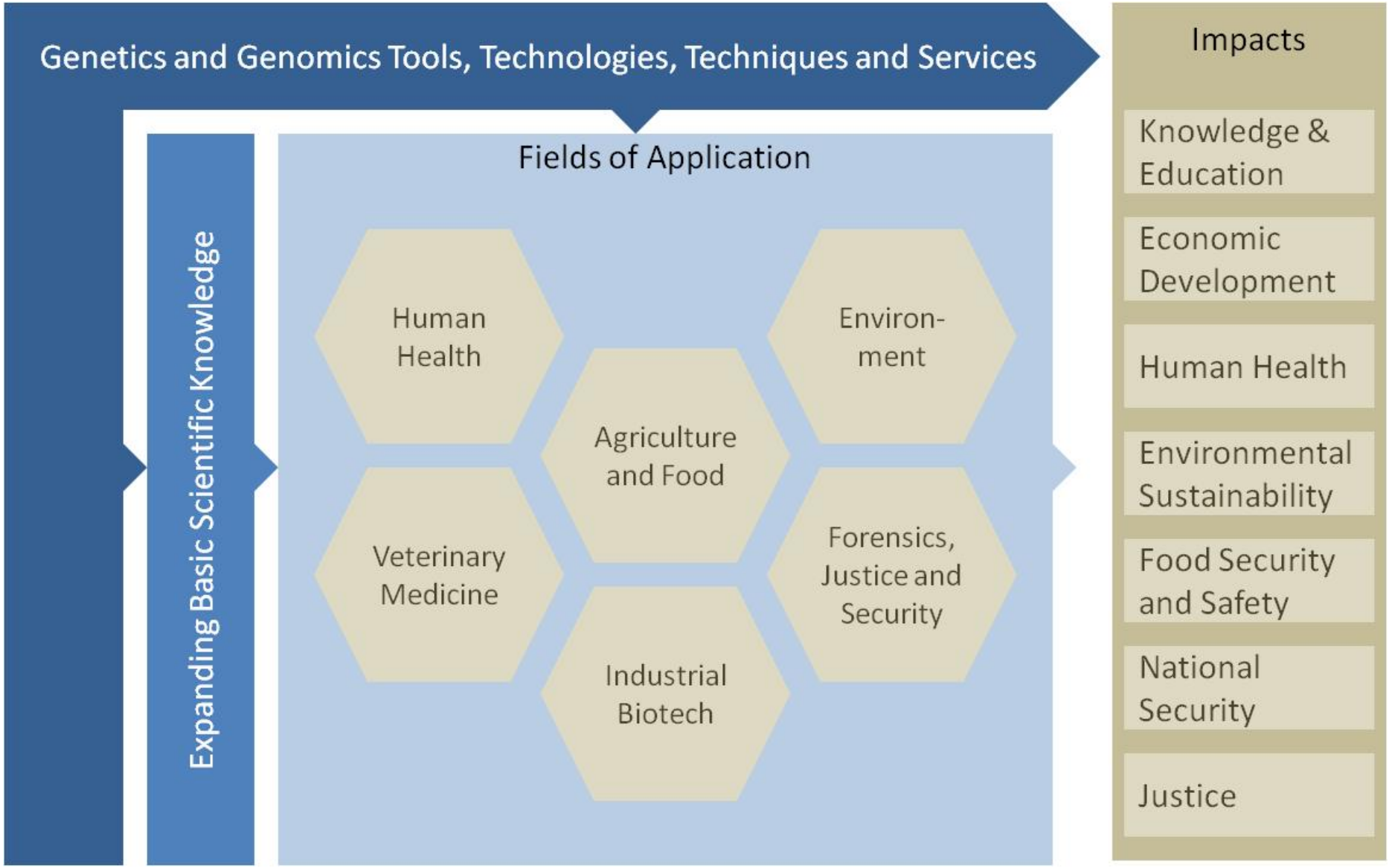
Cumulative Economic Impact of Human Genome Sequencing, 1988–2010 (in Billions, 2010 $)

Impact	Personal Income	Output	State/Local Tax Revenue	Federal Tax Revenue
Direct Effect	71.4	264.8	3.5	13.0
Indirect Impacts	89.2	265.8	10.8	18.0
Induced Impacts	83.3	265.7	15.2	17.9
Total Impact	**243.9**	**796.3**	**29.5**	**48.9**
Impact Multiplier	3.42	3.01	8.37	3.75

Between 1988 and 2010 the human genome sequencing projects and associated research and industry activity directly and indirectly generated:

- **$796 billion in U.S. economic output**
- **$244 billion in personal income for Americans**
- **$49 billion in federal taxes**

The Functional Impacts of Genomics



Functional Applications

Molecular Diagnostics

Pharmacogenomics and Drug Discovery

Regenerative Medicine/ Stem Cells

Tissue/Organ Donor Matching

Gene Therapy

Human Remains Identification

Biosecurity (Pathogen ID/Detection)

Vaccines

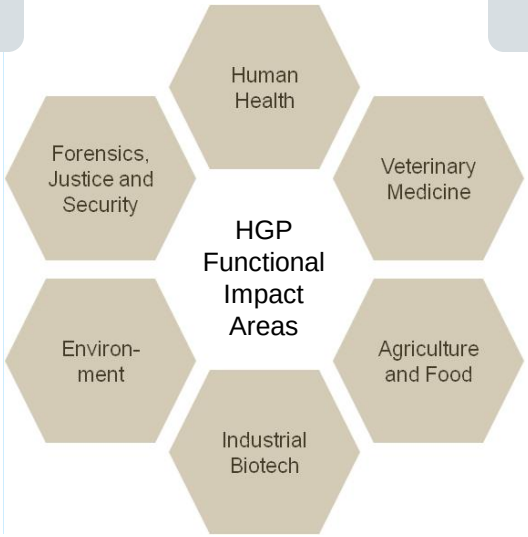
Animal Models/ Comparative Genomics

Paternity Testing

Zoonotic Disease ID and Characterization

DNA Fingerprinting

Pedigree Establishment and Animal Improvement



Illegal/Endangered Animal Parts ID

Livestock Improvement and Health

Biodiversity Studies/ Metagenomics

Improved Crops (Input and Output Traits)

Pollution Control and Mitigation

Functional Foods and Nutraceuticals

Carbon Dioxide Capture

Plant Disease Diagnostics

Biofuels and Bioenergy

National DNA Databank (CODIS)

Food Processing Technologies

Biobased Chemicals and Biomaterials

BioPharming

Industrial Enzymes/ Biocatalysis

Drugs and Biologics Production

Challenges for a Forward-Linkage NIH Impact Analysis

- Volume and broad-scope of NIH activity (hundreds of thousands of projects).
- Time horizon from bench to bedside.
- Complex pathways from discovery to commercialization.
- “Sharing-out” of multiple technology contributions in an end product.
- Data availability on research outcomes in relation to publications, citations, intellectual property and commercialization.
- Geographic variation in innovation ecosystems.
- Variability in measures for various functional impact types.
- Potential cost and time required to do the subject justice.

Options

- **Case studies**
  - HGP study made a compelling case. Other major NIH programs may also.
  - A definitely “do-able” approach.
  - However, cannot generalize impact of all NIH projects from a few cases.
- **Industry surveys**
  - Top “x” number of biomedical products by sales (study their derivation).
  - Top “x” number of recent FDA approvals (study derivation).
  - Work with industry/PhRMA to study product genealogy.
  - Again, “do-able”.
- **Longitudinal data analysis**
  - Matching patents to researchers.
  - Citations analysis can show impact on science knowledge.
  - What data does NIH already collect?

Conclusions

- Performing an appropriately in-depth assessment of NIH impacts can be done, but it's a complex and challenging assignment.
- Functional impacts must be evaluated – they are the *raison d'etre* for the NIH – but, therein lies the complexity.
- Will likely require industry cooperation in case studies.
- Study may be of fundamental importance to U.S. funding of science moving forward. Therefore, it must be rigorous and defensible.
- Battelle has the capability to design and execute such analysis, and a track record in doing so.

Battelle's full report on the Human Genome Project is available online at:

http://www.battelle.org/docs/default-document-library/economic_impact_of_the_human_genome_project.pdf?sfvrsn=2

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TPP Areas of Expertise

- Impact Assessment
- Technology-Based Economic Development – Strategies and Action Plans
- Core Competency Identification
- Cluster Analysis and Cluster Development
- Technology Talent & Workforce Development
- Entrepreneurial Development and Capital Planning
- Technical Assistance and Problem Solving
- Program Design and Implementation Services
- Benchmarking