IP Ecosystem, Entrepreneurs, and Sustainable Technology Companies

Harold H. Shlevin, PhD
Advanced Technology Development Center
Enterprise Innovation Institute
Georgia Institute of Technology
shlevin@gatech.edu

Harold H. Shlevin

- 25+ years leadership experience in pharma, medical devices & vaccines companies.
  - –CEO Solvay Pharmaceuticals
  - –Founder CIBA Vision Opthalmics,
  - –Founder Tikvah Therapeutics
- PhD, University of Rochester Medical School, Postdoc. Mayo Clinic
- Assistant Professor – Mayo Medical School
- Multiple advisory boards of for profit and not-for-profit organizations
- Strong regional technology leader

What is Innovation?

Research is the transformation of money into knowledge.

Innovation is the transformation of knowledge into money.

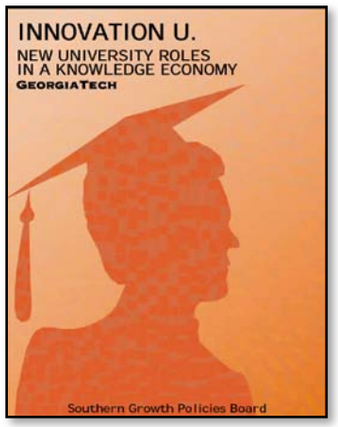
—Dr. Geoffrey Nicholson, 3M

(inventor of the Post-it note)

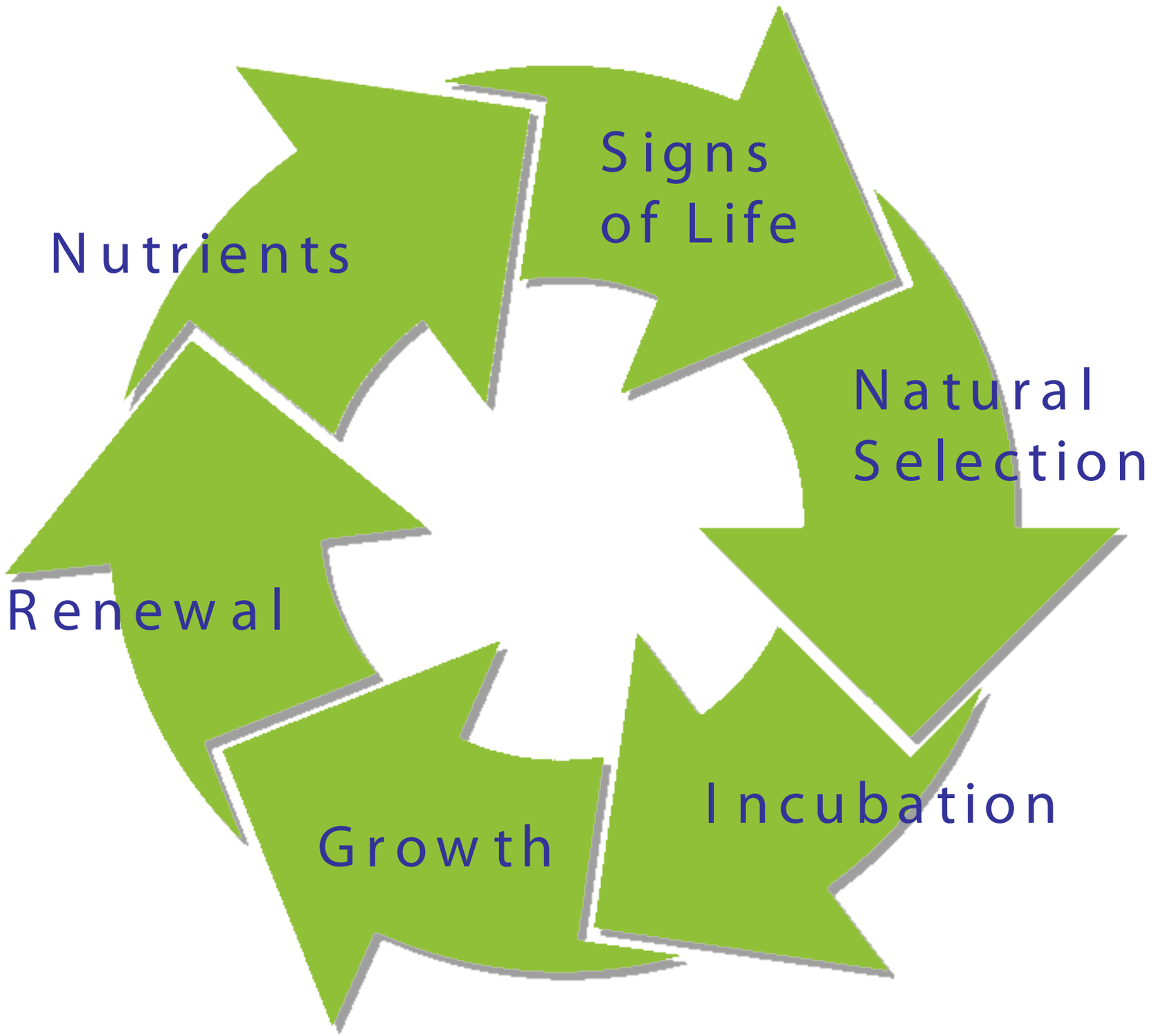
“Innovation U.” Report

- “Virtually every combination of industry relationship or economic development activity can be found at Georgia Tech, and in a very real sense, the university is an operating partner with Georgia state government in the implementation and management of a variety of technology-focused initiatives. Perhaps more than any other research university in North America, economic development is an integral, critical component of the mission of the Georgia Institute of Technology, and this has been true from its very inception.”

  –Southern Growth Policies Board, 2002

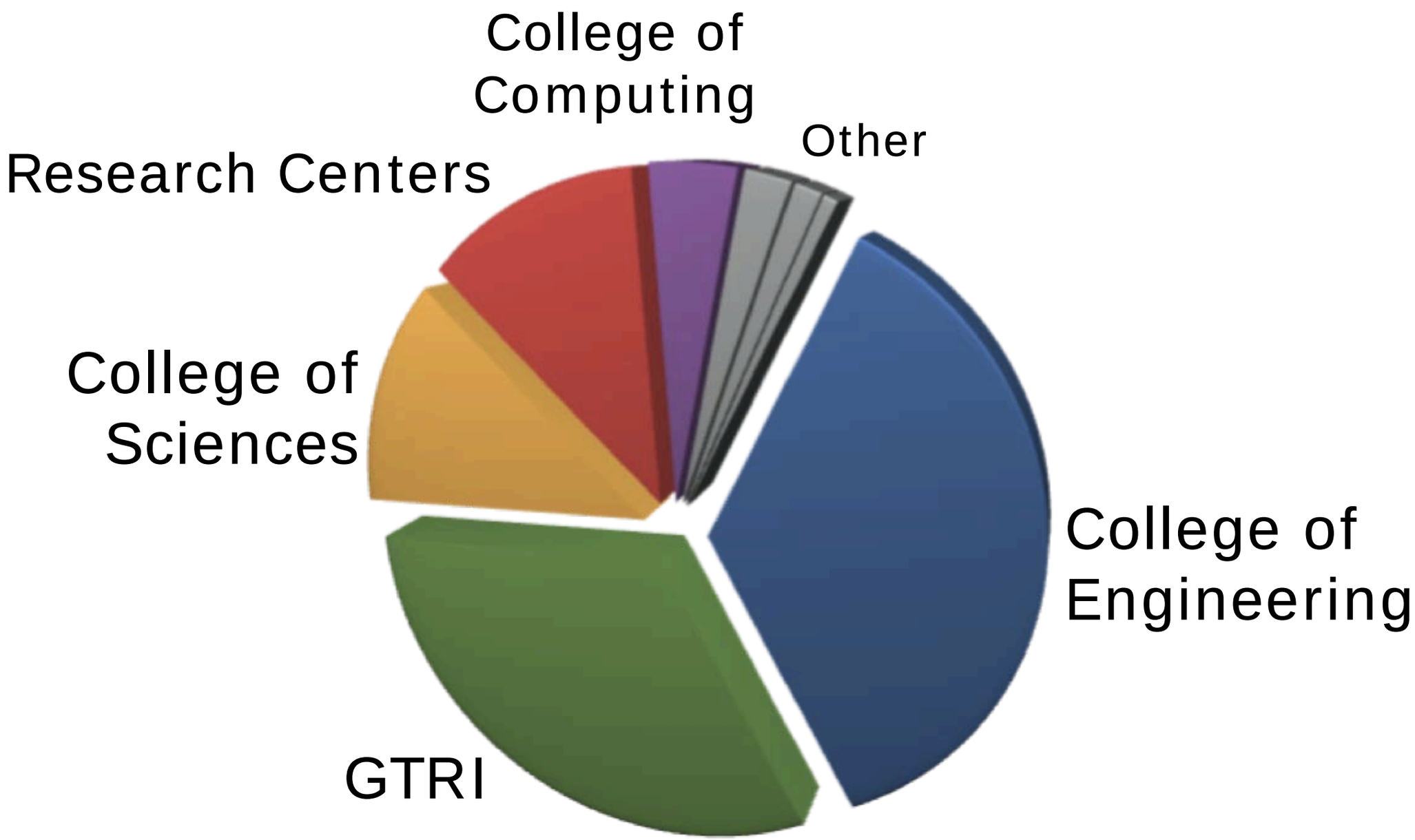


Building an Ecosystem

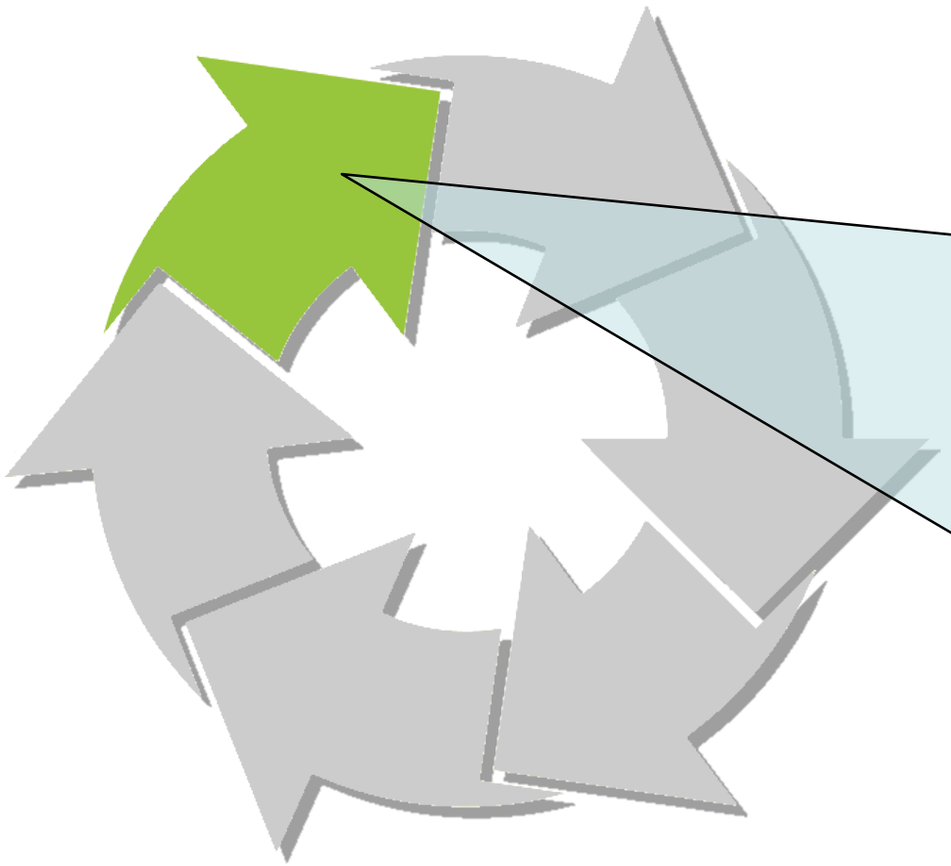


GT Research Distribution

- Over half a billion dollars total R&D on campus for FY2009!

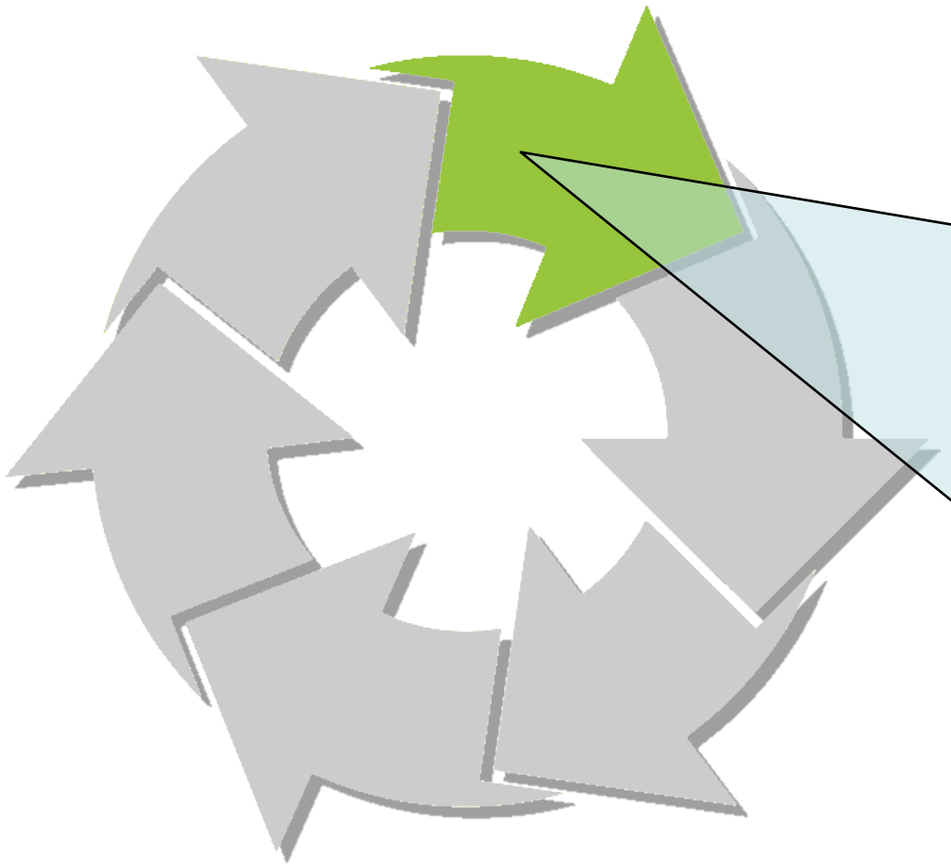


Nutrients



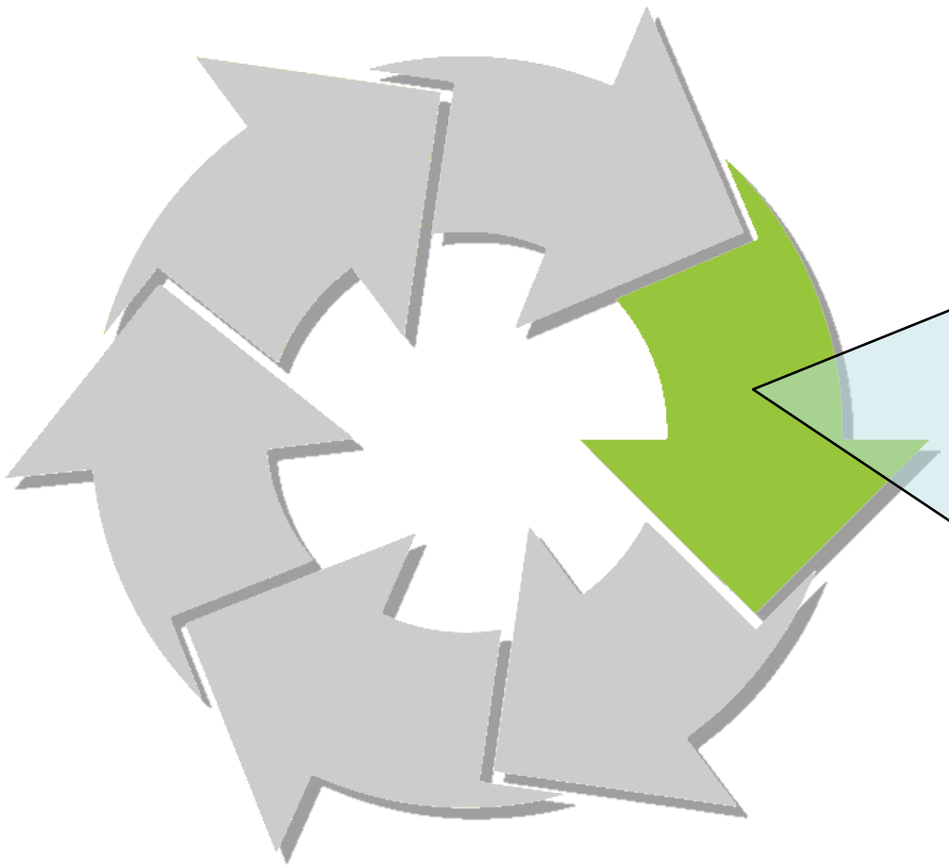
- Recruiting research talent—worldwide
- Georgia Research Alliance (GRA)
  - –Eminent Scholars
  - –Facilities/equipment
- Reinventing academic disciplines
  - –College of Computing
  - –Emory/GT Biomedical Engineering Dept.

Signs of Life



- Emphasis on interdisciplinary research
- Research centers
  - Over 100 on campus, from textiles to nanoscience
  - BME, Nanotech, MARC, MiRC, GEDC, Broadband Institute, GTEC Tissues, etc.
- GRA Phase Zero awards

Natural Selection



- Intellectual property protection (OTL)
- VentureLab
  - –Business plan
  - –Management
  - –Money
- GRA Phase I and II awards
- GT Edison Fund
- SBIR Assistance

Commercialization Services

Intellectual Property Goals

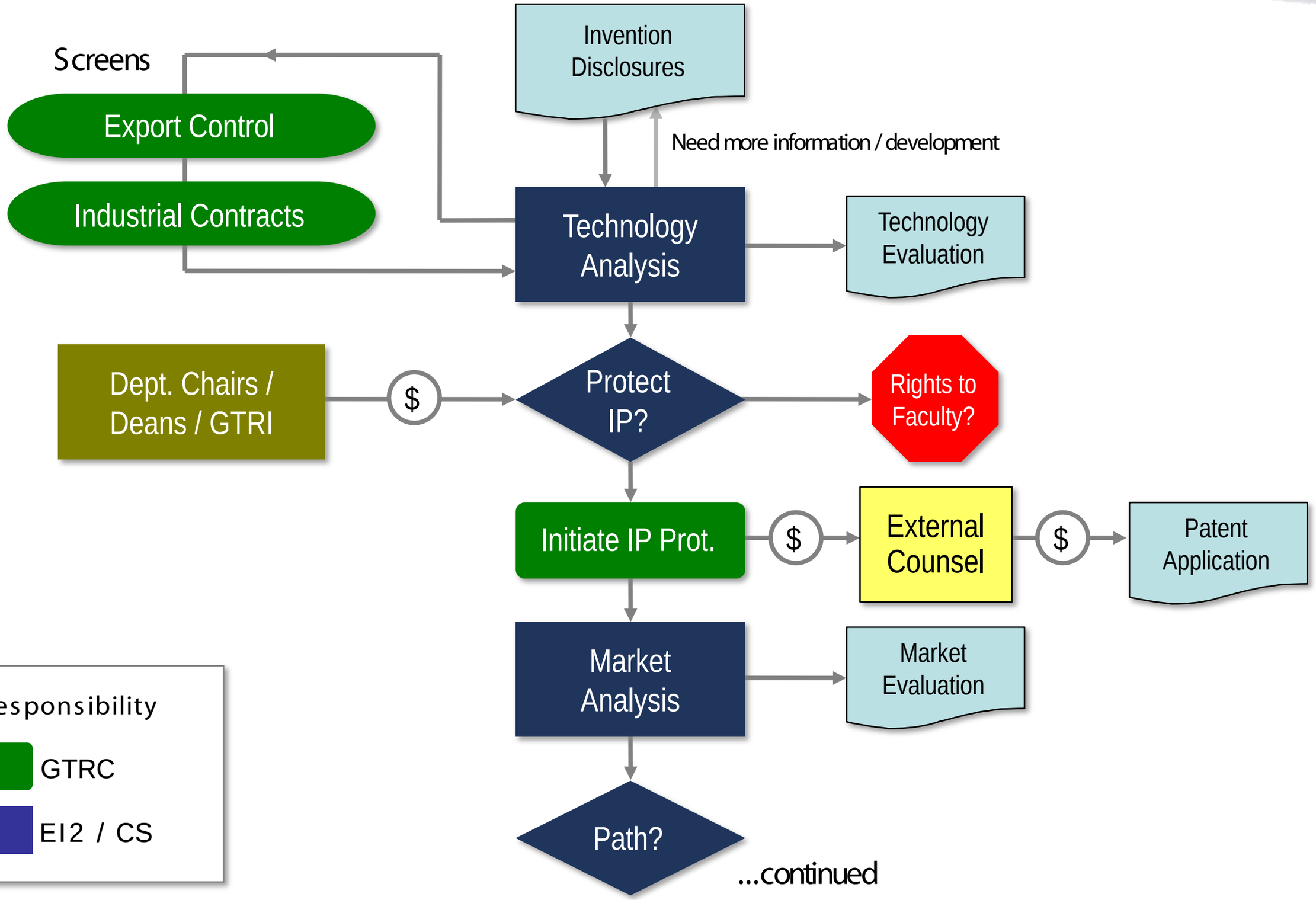
- Reward the faculty for creation of valuable IP
- Support innovation & strengthen research programs
- Strengthen global reputation
- Attract top-quality faculty & students
- Add value to intellectual property
- Strengthen industry relationships
- Create successful entrepreneurs
- Strengthen local technology community
- Help human-kind

Converging Challenges

- Increasing number of disclosures drives overall demand
- "The World is Flat"
  - Increasing GT demand for overseas filings
    - Drives patent cost from ~$15K to ~$100K
  - Increasing competition for research partnerships from overseas universities
- Increasing ratio of biotech at GT (requires overseas protection)
- USPTO proposed limitations on claims, etc.

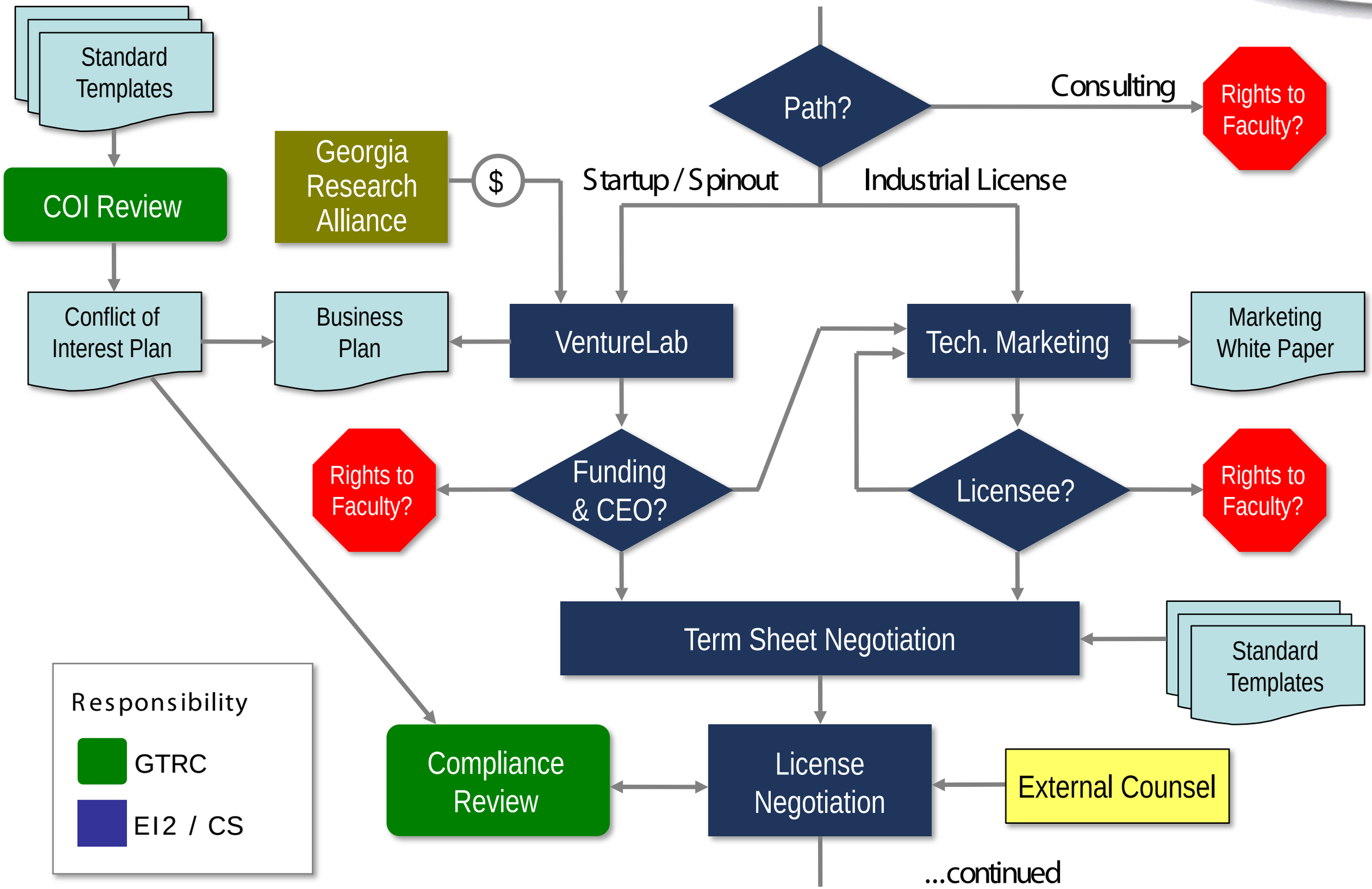
IP Mgmt./Evaluation

Georgia Tech Enterprise Innovation Institute

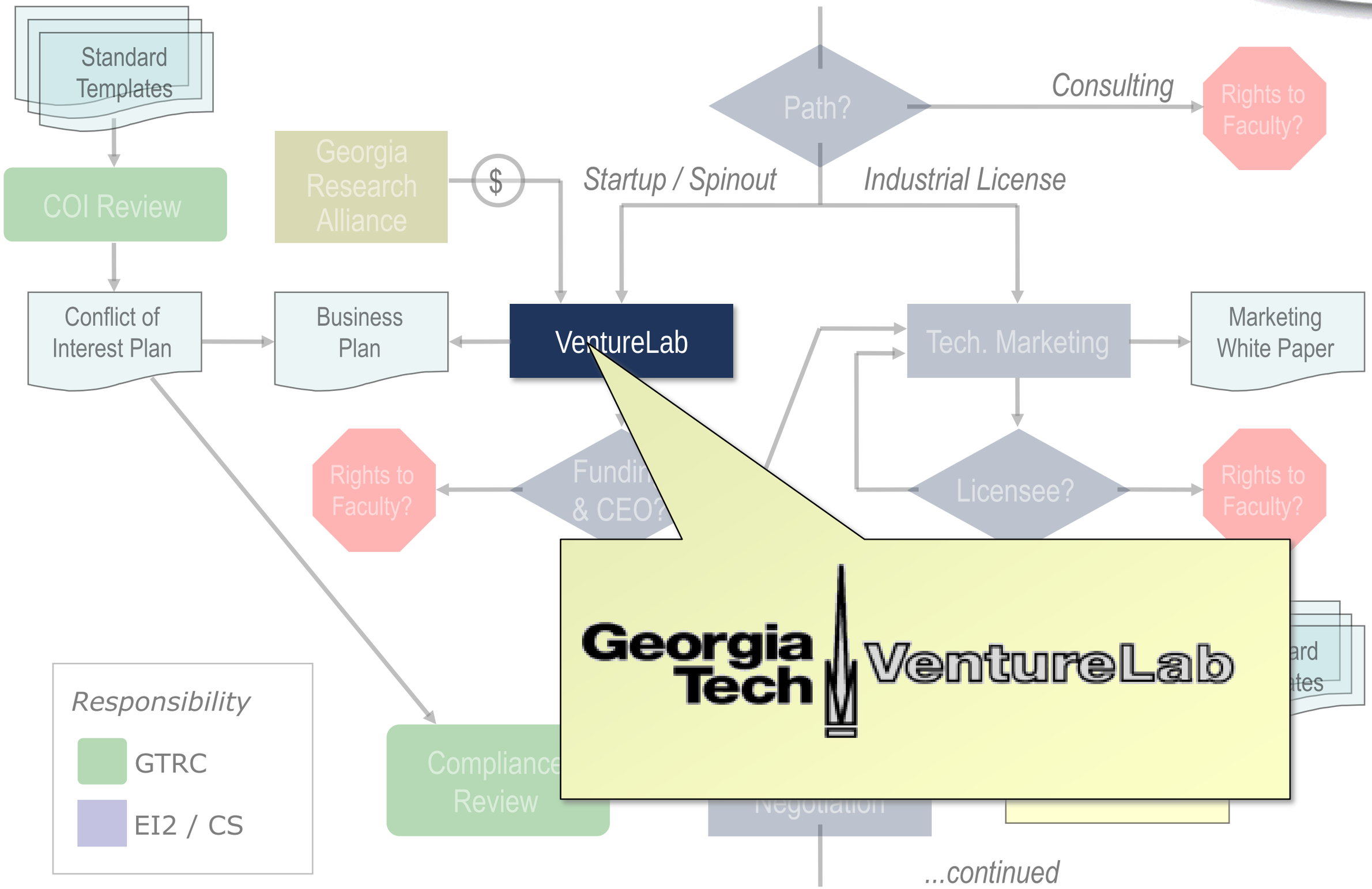


IP Business Development

Georgia Tech Enterprise Innovation Institute



IP Business Development



VentureLab

- Founded September 2001
  - –Now a model for other universities
  - –Part of Enterprise Innovation Institute
- Staff has substantial private-sector experience
- Faculty-focused process
  - –Risk identification and mitigation
  - –Venture-backable innovations
- Goal: Successful startup companies based on Georgia Tech research

VentureLab

- Market
- Milestones
- Meetings
- Management
- Money

Money

SBIR Assistance Program for the State of Georgia

•Assistance with small-business grants from eleven Federal agencies.

GEORGIA RESEARCH ALLIANCE

•Grants and loans to startups based on Georgia university research.

GEORGIA TECH EDISON FUND

•Equity investments in startups with a connection to Georgia Tech.

Georgia SBIR Assistance

- Small business R&D funding available from eleven Federal agencies
  - –NASA, DOD, DOE, NIH, EPA, etc.
- Grants, not loans or equity!
- For help with SBIR and STTR process, visit <http://www.innovate.gatech.edu/sbir>.
- Up to $850K available across two phases of development

SBIR Assistance Program for the State of Georgia

Georgia Research Alliance

- Recruiting Eminent Scholars from all over the world to Georgia
- Investing in university capital equipment
  - –Over $600 million in last 15 years
- Innovation grant program
  - –Phase 1: up to $50K to university R&D
  - –Phase 2: up to $100K to university (must be matched—equity, SBIR, sale of services, etc.)
  - –Phase 3: up to $250K loan to company (must be repaid upon success or leaving Georgia)

GEORGIA RESEARCH ALLIANCE

GRA Matching Funds

- Provides up to 4:1 non-dilutive leverage for initial outside investment:

	Equity, Other Grants, etc.	GEORGIA RESEARCH ALLIANCE
Phase I		$50K grant to university
Phase II	$100K validation investment	$100K matching grant to univ.
Phase III		$250K loan
Total	$100K	$400K

VentureLab

- Market
- Milestones
- Meetings
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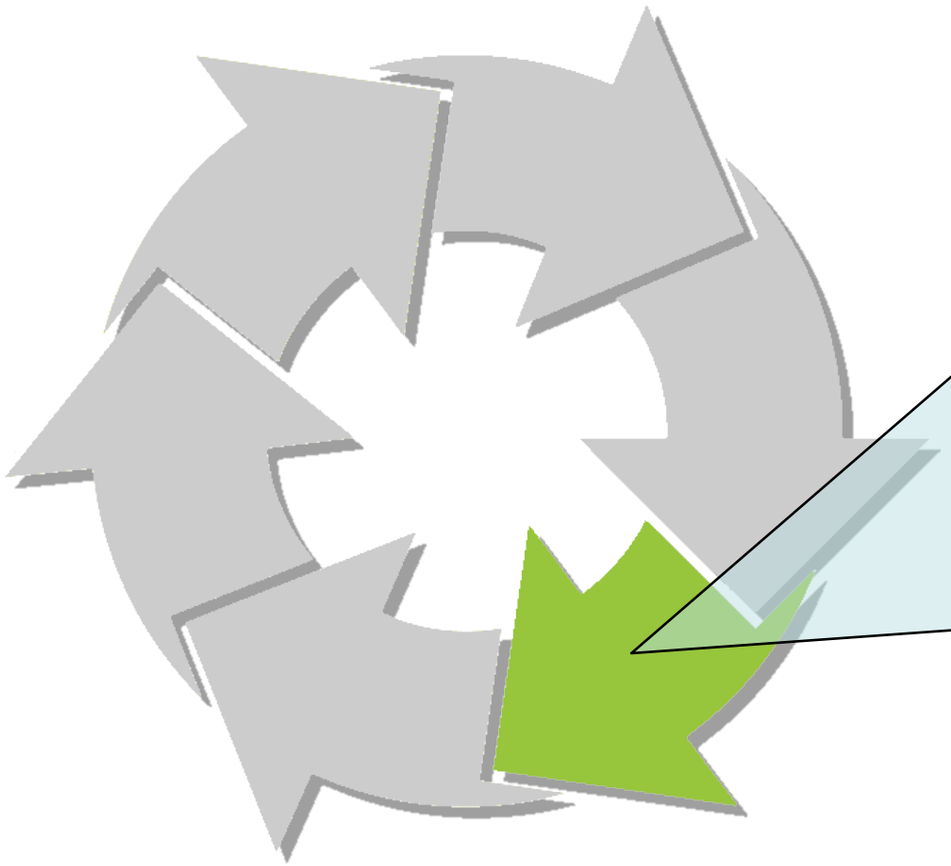
- Money

Incubation



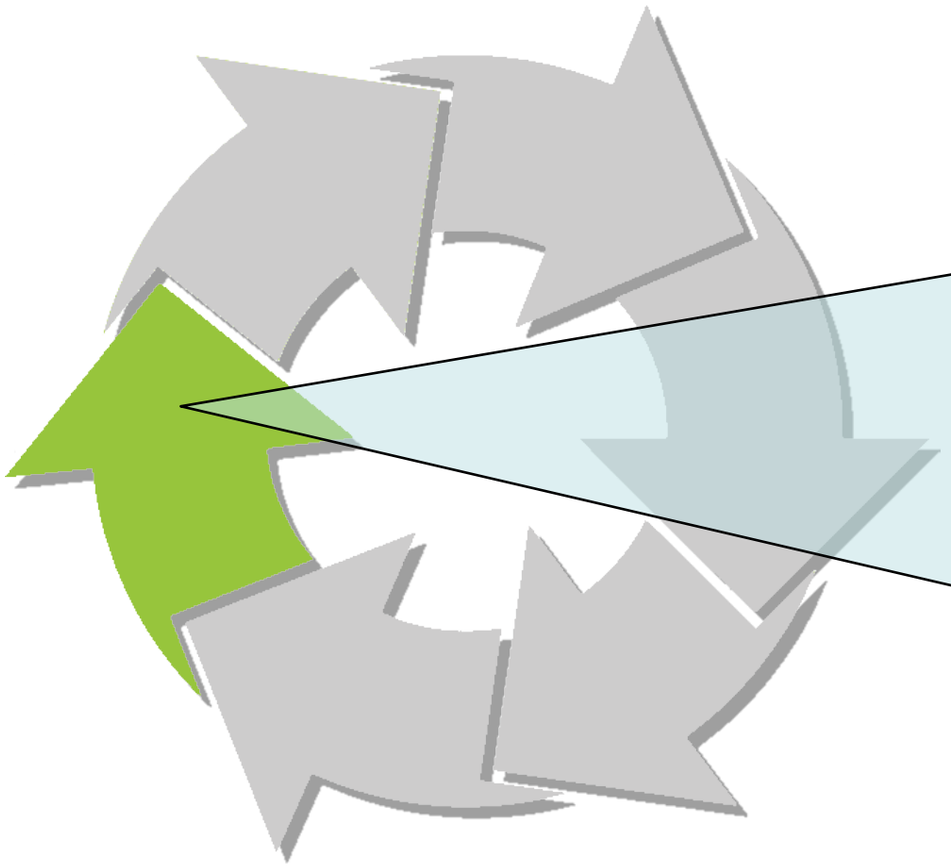
- Advanced Technology Development Center (ATDC)
- GRA Phase III loans
- Ga. Seed Capital Fund
- Minority Business Enterprise Center
- National VC attention
- Centers of Innovation
  - –Statewide tech areas

Entrepreneur Services

ATDC Offerings

- Consulting
  - Strategic business advice
- Community
  - Interaction with other entrepreneurs
- Connections
  - Connections to people and resources
- Centre
  - Facilities designed for startups
- Credibility
  - Instant recognition

Cycle of Renewal



Strategic Partners Office

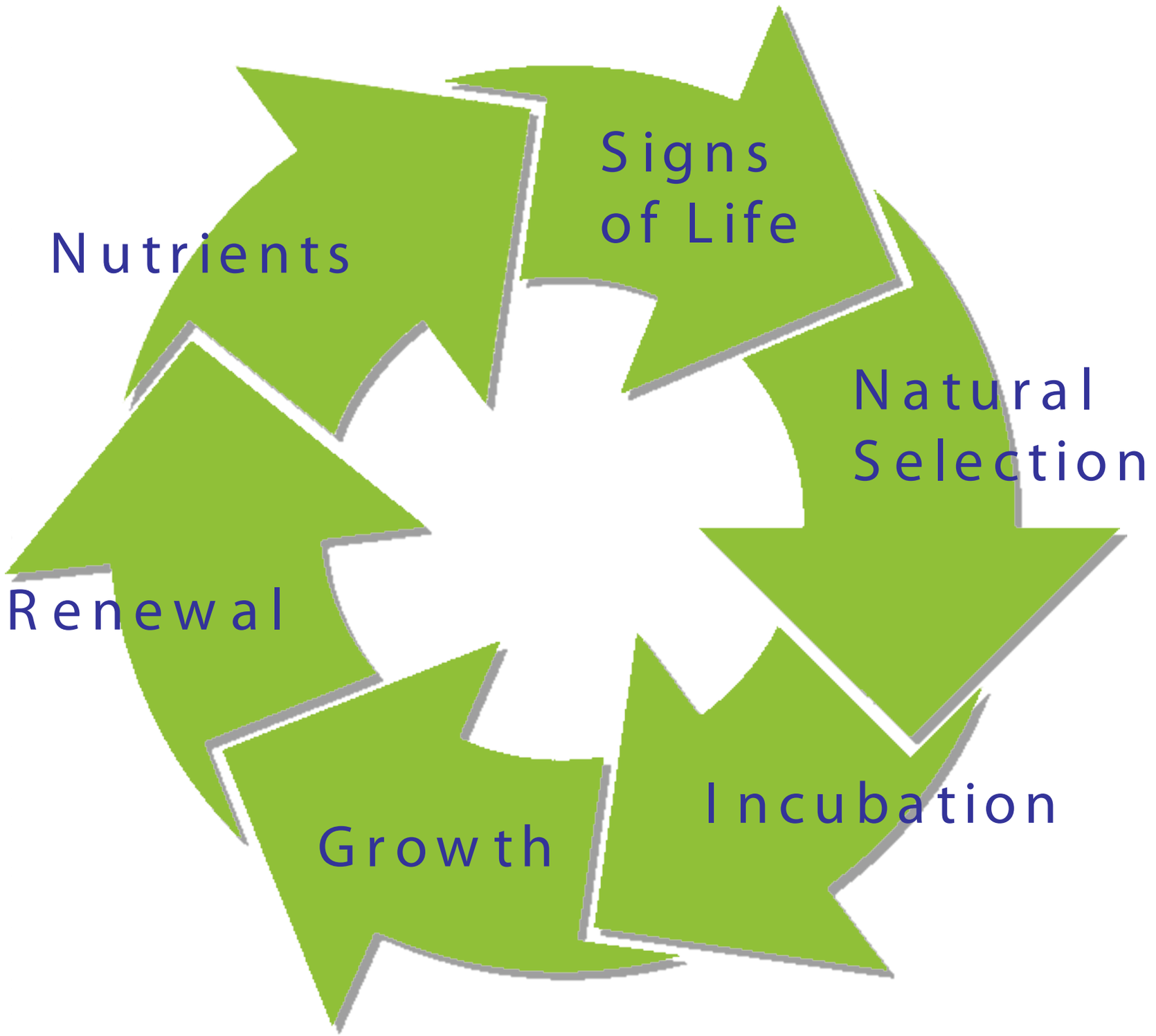
- Serves as a bridge to Georgia Tech services and resources
  - Expand interaction with key local, state, national and international corporations
  - Seminars, workshops & technology briefings
  - Access to test beds, research labs, unique equipment & expertise

Cycle of Renewal

Klaus Advanced Computing Bldg.

- Successful companies
  - Sponsoring research
  - Hiring GT graduates
  - Spinning off new companies
- Successful graduates
  - Charitable giving
  - Angel investment
  - Mentoring
- More nutrients for the ecosystem!

Building an Ecosystem



Importance of Patents to Pharmaceutical Innovation

INDUSTRY	Would NOT have been Introduced	Would NOT have been Developed
Pharmaceuticals	65	65
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Electrical Equipment	1	11

Mansfield, Mgmt Sci., Feb., 1986

Selected Advances in the 20th Century

Georgia Tech Enterprise Innovation Institute

1900s – 1940s

1900–1929

1900 – U.S. life expectancy is 45
1908 – Tuberculosis vaccine
1922 – Insulin for diabetes
1924 – Tetanus vaccine
1928 – Discovery of penicillin

1930s & 1940s

1932 – First antibiotic (sulfa drugs)
1935 – Discovery of cortisone
1938 – First epilepsy Rx
1948 – First chemotherapy Rxs

1950s – 1970s

1950s

1950 – Discovery of prednisone
1951 – First Rx for depression
1953 – First leukemia Rx
1954 – Polio vaccine
1958 – First diuretic to treat high blood pressure

1960s & 1970s

1963 – Measles vaccine
1967 – First beta blocker
1968 – First anti-rejection medicines for organ transplants
1972 – Advances in anesthesia
1977 – First non-surgical treatment for ulcers
1978 – First biotech product (synthetic human insulin)

1980s – 2000

1980s

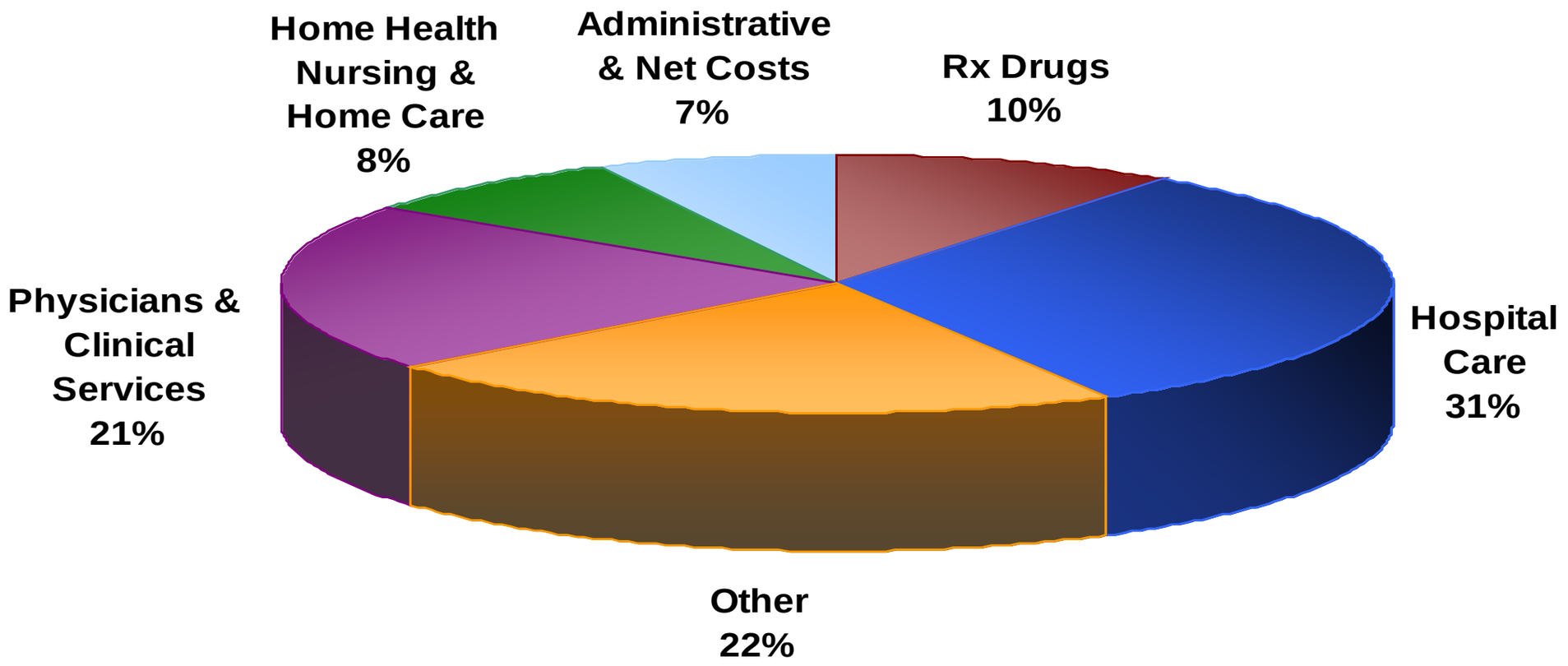
1981 – First ACE inhibitor to treat high blood pressure
1986 – First monoclonal antibody treatment
1987 – New class of depression medicines (SSRIs)
– First AIDS Rx
– First statins to lower cholesterol

1990s

1993 – First Alzheimer's Rx
1994 – New breast cancer Rx
- Polio eradicated in the Americas
1995 – AIDS Rx advance (HAART)
1995–97 – Four new classes of oral diabetes Rxs
1997–98 – Advance in Parkinson's Therapies

Sources: Innovation.org, Great Moments in Innovation, http://www.innovation.org/index.cfm/nonav/Great_Moments_in_Innovation; NIH, National Institute of Allergy and Infectious Disease, Tuberculosis (TB), Age of Optimism, http://www3.niaid.nih.gov/topics/tuberculosis/Research/researchFeatures/history/historical_optimism.htm.

Health Care Dollar Spending



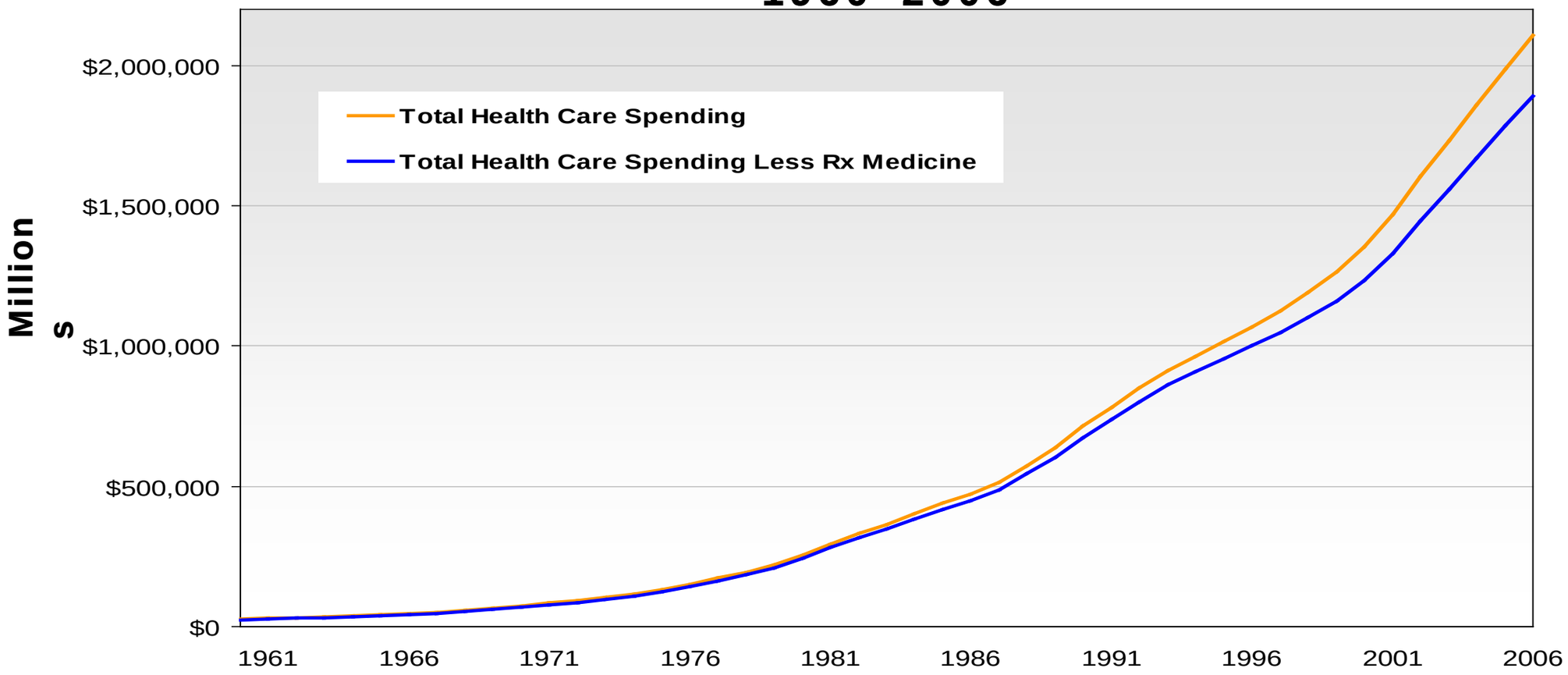
*Note: “Other” includes medical care provided by private employers for employees at their work site, government spending for non-specified medical care by service usually delivered in schools, military field stations, and community centers.

Source: CMS, “National Health Expenditures,” at http://www.cms.hhs.gov/NationalHealthExpendData, accessed January 6, 2009.

Medicines Account for a Small Share of Health Spending Growth

In 2006, U.S. National Health Expenditures were $2.1 trillion; without prescription medicines, the total would have been $1.9 trillion

Total Health Care Expenditures With and Without Prescription Medicines 1960–2006



Source: CMS, Historical National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960–2006, at http://www.cms.gov, accessed Jan. 9, 2007.

Federal & Industry Roles in Research and Development

Government and biopharmaceutical industry research are complementary

Private Sector –

NIH – $31.2B[3]

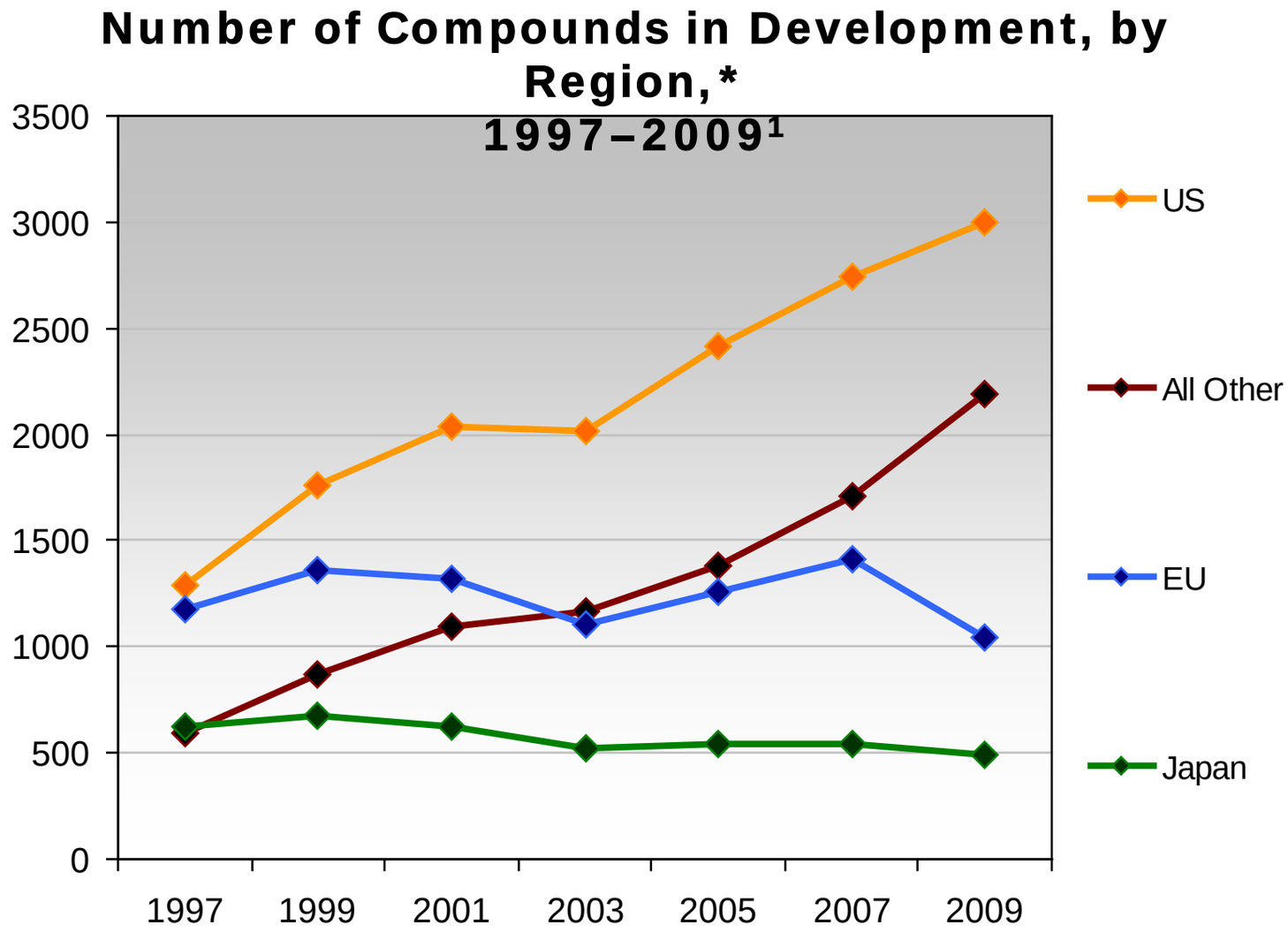
> *There is an ecosystem of science and biotechnology. Public organizations, patient organizations, universities, Congress, FDA, all of this is an ecosystem that is envied in the rest of the world.*
>
> *– E. Zerhouni, Director of NIH*

Sources: [1]Burrill & Company, analysis for PhRMA, 2010 (Includes PhRMA research associates and nonmembers) in PhRMA, "Profile 2010, Pharmaceutical Industry;" PhRMA, "PhRMA Annual Membership Survey," 2010; [2]Adapted from E. Zerhouni, Presentation at Transforming Health: Fulfilling the Promise of Research, 2007; [3]NIH Office of the Budget, "Natiional Institutes of Health: Enacted Appropriations for FY 2008-FY 2010," http://officeofbudget.od.nih.gov/pdfs/FY11/FY%202010%20Enacted%20Appropriations.pdf.

Medical Research in U.S. Outpaces the Rest Of the World

Georgia Tech Enterprise Innovation Institute

> *...in the late 1980s only 41% of the top 50 innovative drugs were of American origin, in the late 1990s...[it had] climbed to 62%....*
>
> *In 1990, the pharmaceutical industry spent 50% more on research in Europe than in the U.S. In 2001, the situation was reversed with 40% more spent in the U.S.[2]*
>
> *–Gunter Verheugen, Vice-President of the European Commission for Enterprise and Industry*

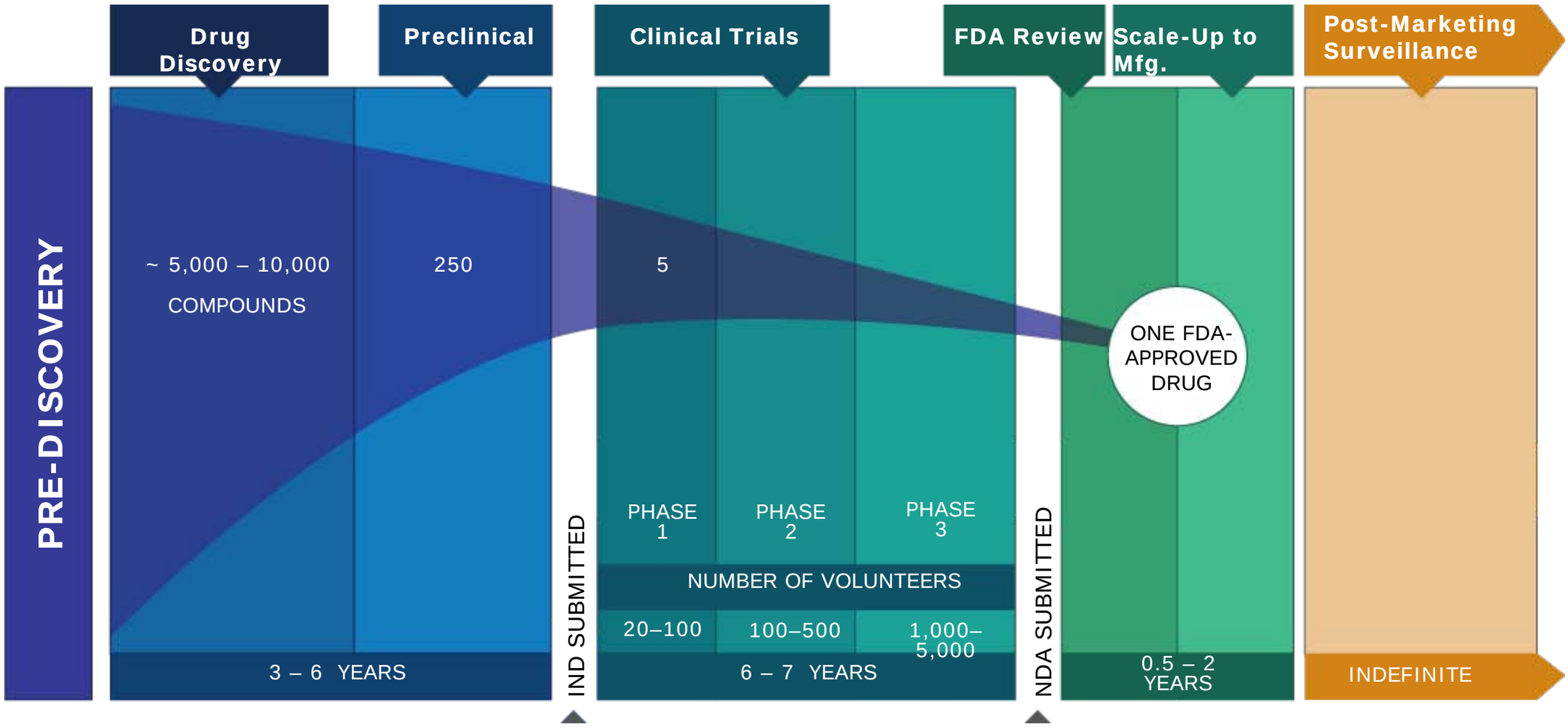


*Note: Reflects the number of compounds in clinical trials or awaiting approval as of June of each year. Compounds in development for multiple regions are counted in each region for which regulatory approval is sought, and multiple indications are counted only once.

Sources: 1Adis R&D Insight, Custom data run, February 2009, January 2010; [2]G. Verheugen, "Address to the Concluding Session of the European Track" (Lyon) 2005.

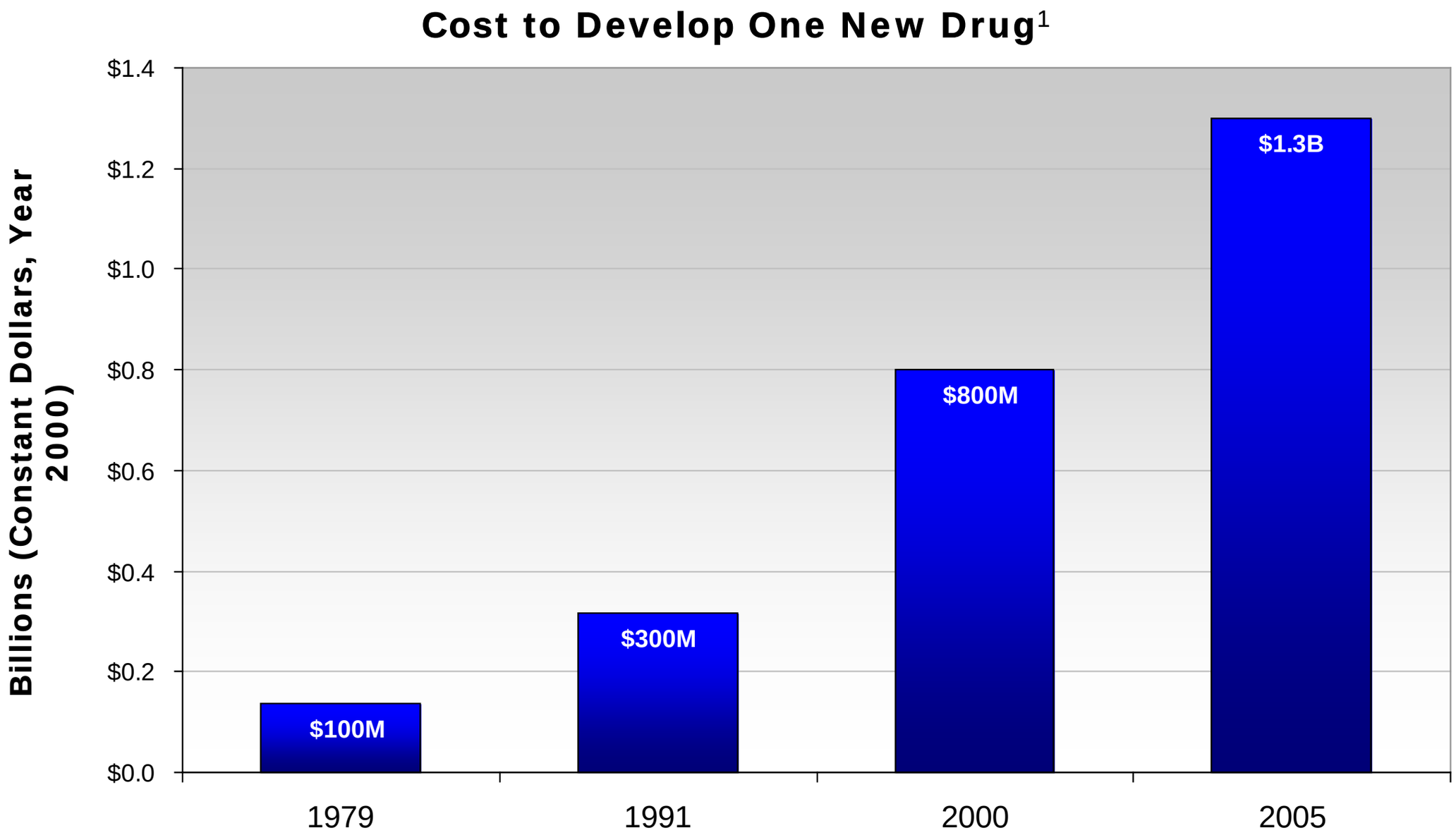
Drug Development Takes Longer

Developing a new medicine takes an average of 10–15 years; the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process”



Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, *Research and Development in the Pharmaceutical Industry*, 2006.

The Cost of Developing a New Drug Has Increased

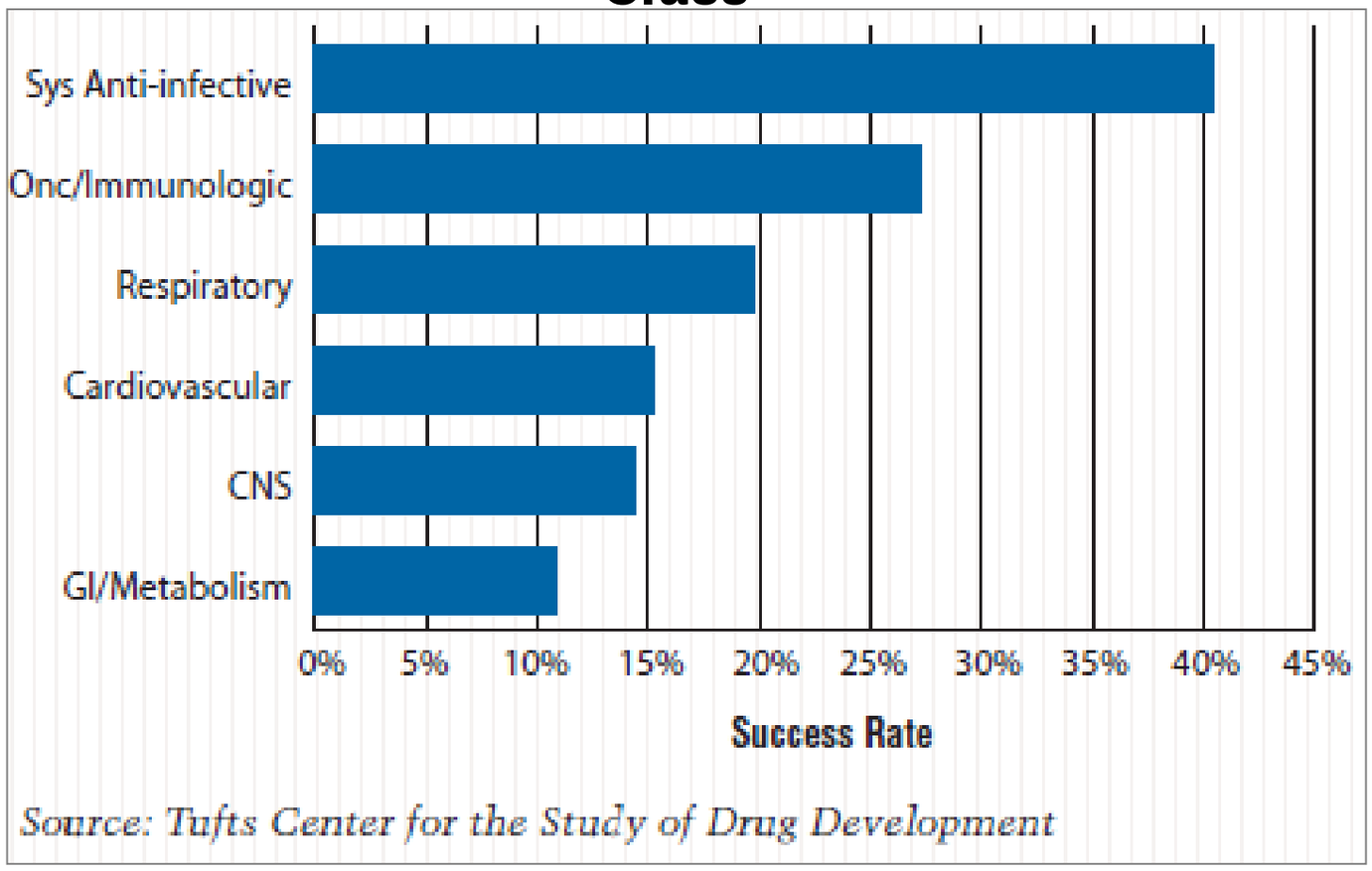


Sources: [1]J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007; J. DiMasi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003.

Probability of Success for New Drugs Is Small

Approximately 20% of self-originated new drugs that enter clinical testing will receive U.S. marketing approval.[1]

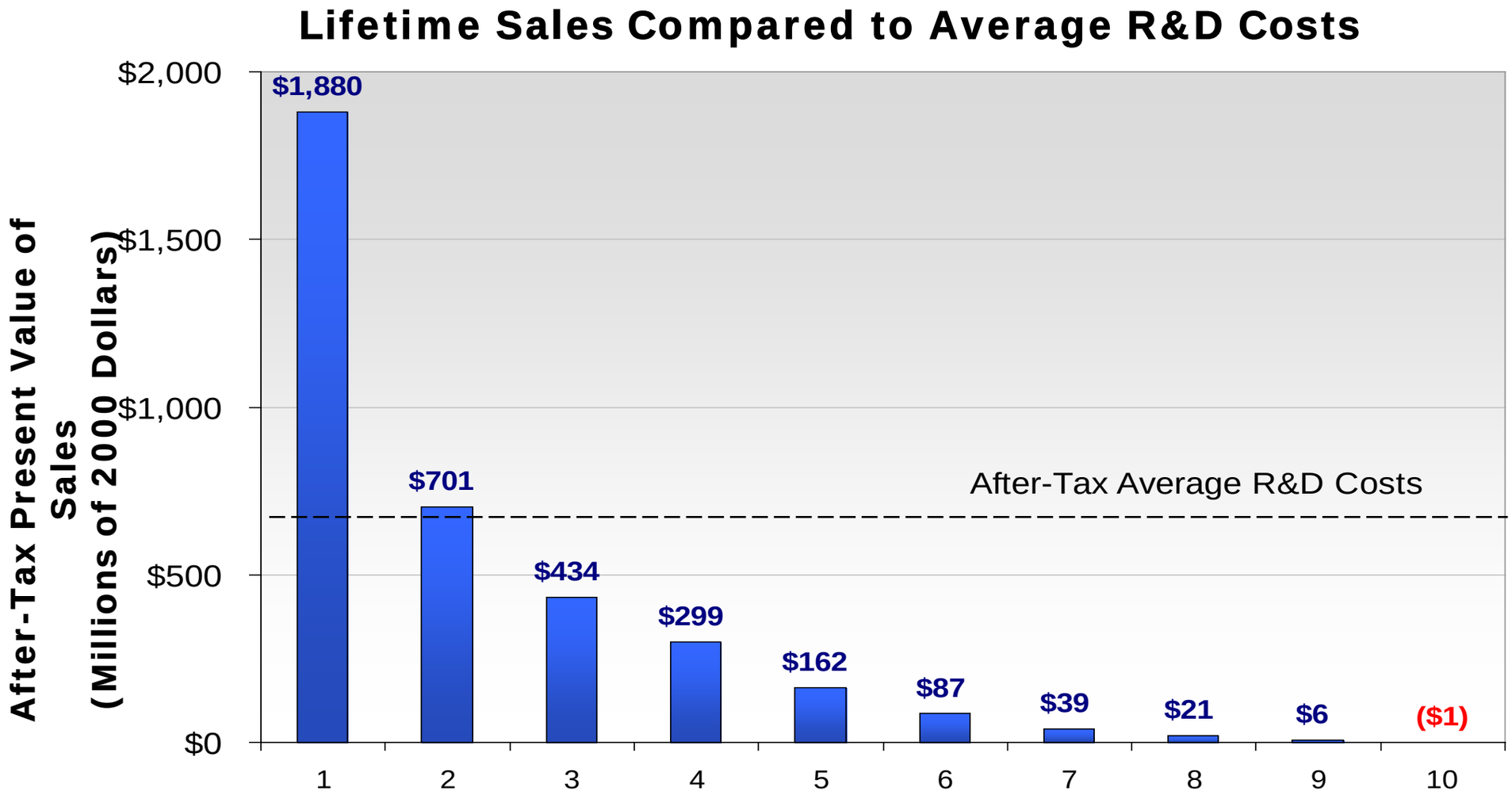
Clinical Approval Success Rates by Therapeutic Class[1]



Source: Tufts Center for the Study of Drug Development

Source: [1]Tufts Center for the Study of Drug Development, "New drugs entering clinical testing in top 10 firms jumped 52% in 2003-05," Impact Report, 2006.

Few Medicines Are a Commercial Success



Note: Drug development costs represent after-tax out-of-pocket costs in 2000 dollars for drugs introduced from 1990–94. The same analysis found that the total cost of developing a new drug was $1.3 billion in 2006. Average R&D Costs include the cost of the approved medicines as well as those that fail to reach approval.

Sources: J. A. Vernon, J. H. Golec, and J.A. DiMasi, "Drug development costs when financial risk is measured using the Fama-French three-factor model." Health Economics, (2009). ; J. DiMasi and H. Grabowski, “The Cost of Biopharmaceutical R&D: Is Biotech Different?,” Managerial and Decision Economics, 2007.

Why Make the Investment?

"Without the sense of security which property gives,
The land would still be uncultivated"

F. Quesnay, 1773

For Further Information

Harold H. Shlevin

Manager, Advanced Technology Development Center

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<shlevin@gatech.edu>

(404) 385-7372