



The Action Plan for Taiwan's Biotechnology Taking off

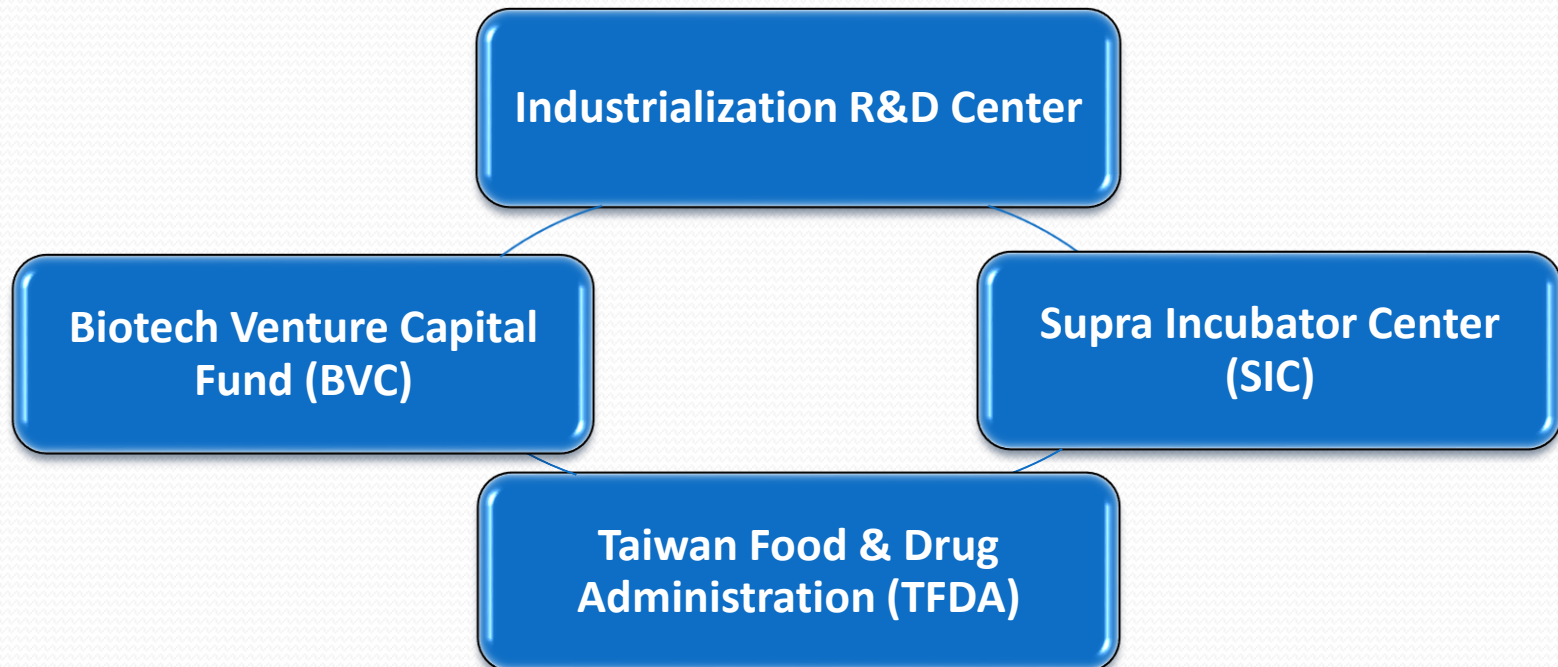
Board of Science & Technology (BOST)

The Executive Yuan

Oct 31, 2012

Overview of the Diamond Action Plan

- In 2009, the Executive Yuan announced the launch of “The Diamond Action Plan for Biotech Takeoff (生技起飛鑽石行動方案)”
- **The four major areas:**



Promotion Framework

Software —

- Providing legal, IP, technical, & business operations-related services

Bridge between industry & academia, and specialized technical evaluation mechanism

Hardware —

Establishing a basic environment conducive for R&D, including:

Protein trial production factory (MOEA or private sector)

- Animal experiment center (NSC)

In principle, privately operated, with investment and construction via the government or private sector

Sites : Hsinchu Biomedical Science Park (medical devices), Southern Taiwan Science Park (medical devices), National Biotechnology Development Park in Nangang (pharmaceuticals)

Operational regulations (screening transparency & efficiency)

Aiding industrial development

Regional regulatory harmonization

Software —

Reform of organizational culture

Design inducement mechanism

Hardware —

Establishment of foundation for pre-clinical trials (toxicology & PK translational research)

Medical devices rapid trial production center

TFDA
(DOH)

**Industrialization
R&D Center**
MOEA (DCB, ITRI, MIRDC)

SIC
(NSC/Private
Organizations)

BVC
(CEPD)

Investment in stages to diversify risk (ratio: Government 40%, Private Sector 60%)

Top-notch venture capital investment team

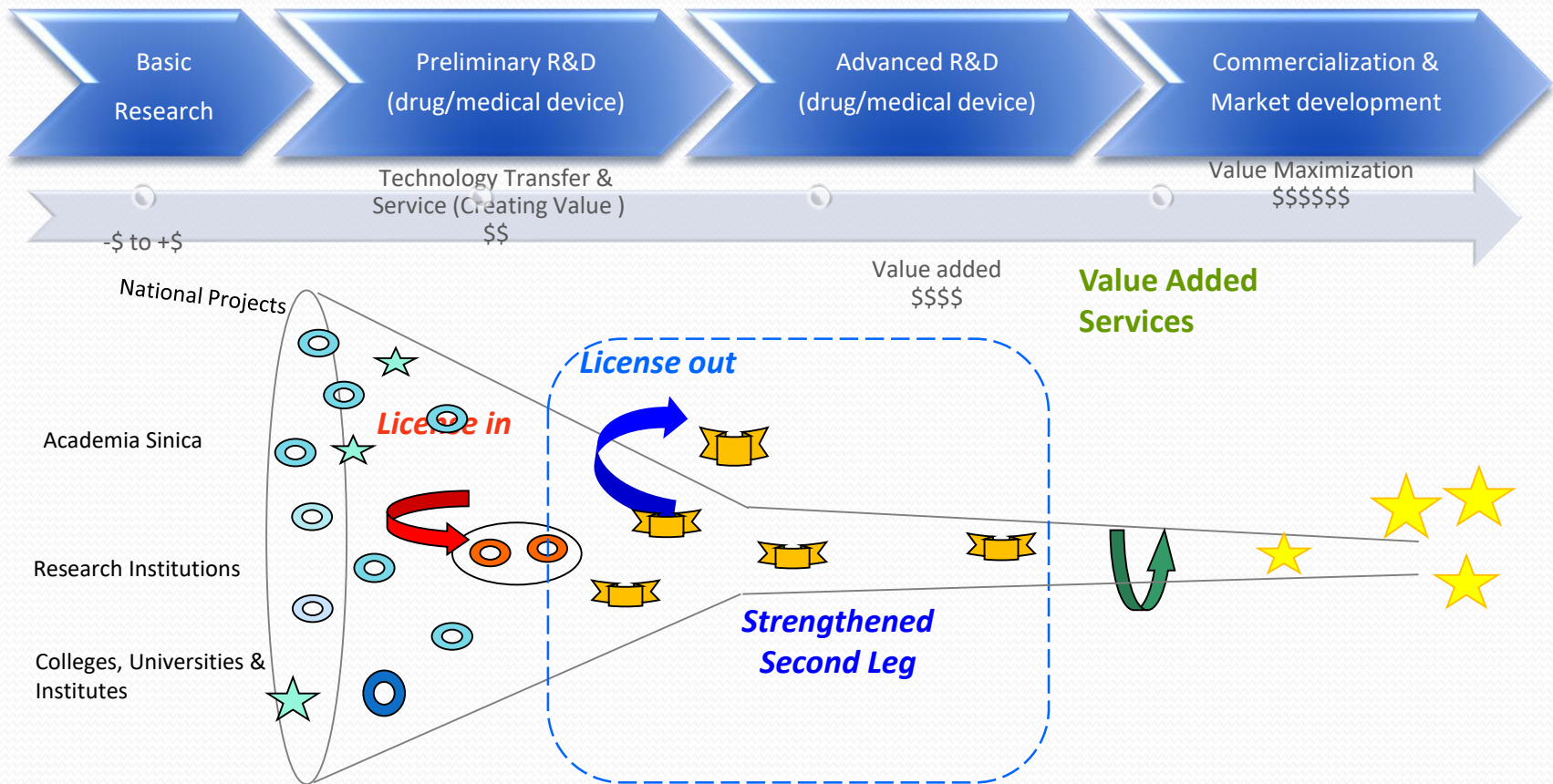
Establishment of management consultant company

Capital in initial stage (NT\$7.5 bln – NT\$10 bln)

Target: NT\$60 bln (depending on results and capital raised at various stages)



Overview of the Diamond Action Plan



Increased and enhanced division of work of ministries

		A	B	C
		Pharmaceuticals	Medical devices	Health Care Management
1	National Science Council (integrated training)	• SI²C (Supra Integration and Incubation Center) • Subsidize in Projects. Achieving the effect of seed funds		
2	Ministry of Economic Affairs (Industries promotion)	• Establishing core platform • Undertaking cases and facilitating industrialization		• Branding Taiwan • Providing value-added service and counseling
3	National Development Fund (Venture capital fund)	• Private investment as major. Encouraging 5-10bln small/medium biotech venture capital • Cooperated by National Development Fund		
4	Department of Health (Robust Regulation)	• Regulatory Harmonization • Facilitating pre-clinical trials cross-straits cooperation	• Increasing the efficiency of censorship and counseling services • Developing Medical devices-related regulation	• Early research consigned to associations. Proposing value-added service model

Diamond Action Plan for Biotech Takeoff

Diamond Action Plan for Biotech Takeoff

Strengthen the Translational Research & Preclinical Development

- **NRPB**
- Cross-Ministry Medical Devices Development Project
- DCB, ITRI and PITDC

Establish Bio-technology Venture Capital Fund (BVC)

- Expected Joint Investment: **NT\$60 Billions**
- Initial Stage: **NT\$10 billion**
- 40% from Government, and 60% from Private Sectors

Promote Integrated Incubation Mechanism

- **SI²C** (Supra Integration and Incubation Center)
- Jhubei Biomedical Park
- NanKang Biotech Park

Establish Taiwan FDA (TFDA)

- Inaugurated on **Jan. 1, 2010**
- Set up Regulatory Environment of **International Standard**
- Streamline the Review Process for IND & NDA

Goal: Asian R&D partner for the international biopharmaceutical community

● The Action Plan for Taiwan's Biotechnology Taking off – Enhanced and New Project

Action Plan Phase I (2009-2012) - Established Basic Foundation

Action Plan Phase II (2013-2015) - Creating Successful Cases

Pharmaceuticals/Medical Devices/ Health Care Management

1. Basic Foundation has taken effect increasingly, but needing amendment. Part of cross-ministries coordination still needs improvement .
2. The related measures of action plan should be refined depend on different developing properties of pharmaceuticals and medical devices.
3. Enhancing training of biotech industry workforce, connecting the links between educational attainment and employment outcomes.
4. High quality and efficiency health care management , with properties of knowledge-base economy and potential of value-added exportation.

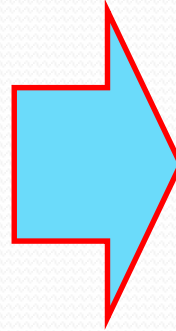
Medical Management Promotion

Health Care Platinum Project

Building medical care and management service and operation model

- Environmental aspect
- Technological aspect
- Regulatory aspect

**Enterprise / House /
Community resident**



Focusing on Industry

Directing the Market demand and R&D of medical management

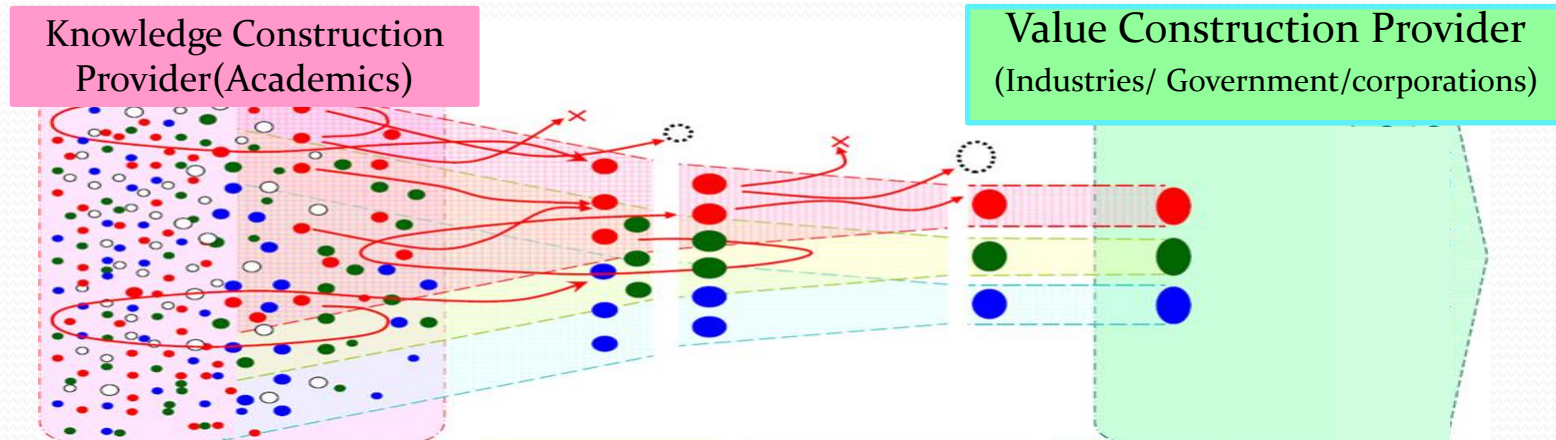
- Developing health value-added application model
- Integrating Medical/Information management, ICT and medical devices
- Building cross-fields health industrial platform

**Health Care Management
Systematization**

Biotech Advanced Workforce Training and Hiring



Perceivable plan: Training 100 Industrial PostDocs every year
Planning to train 300 Industrial PostDocs in 3 years (or start up business)



According to Ministry of Education,
Biotech related Ph.D. Graduates :450-497 per year
Ph.D. students: 3400-3640 per year

According to Industrial Development Bureau,
Ministry of Economic Affairs,
Current Industry needed Postdocs: 140 per year

Benefit :

1. For Youth: Raising youth employment rate
2. For Academia: Directing advanced biotech workforce from academia to industry
3. For Industries: Increasing industrial R&D potential, upgrading industries, and strengthening international market competitive

Anticipated Results

- Target areas: Medical devices and pharmaceuticals

With an annual investment from the “Fund” in 10 candidate drugs at the phase of pre-clinical R&D, future annual profits of NT\$1 billion are projected 3 to 4 years after initiation of the program. The return on the investment from medical devices is projected to be 60% of those generated by pharmaceutical-related investments. Upon completion of raising funds for the BVC Fund (within 7 years), the Fund’s annual profit is expected to grow to about NT\$7 billion.

- The value of output from the biotech industry will **double** over a four-year period, and biotech will rapidly become **a trillion-dollar industry**.
- **Biotech parks** will have matured and industrial clusters will be formed. This will further drive the peripheral industries.



End of Briefing

We look forward to your suggestions and advice.

Goals & Objectives of NRPB

Vision

To develop new therapeutics for disease prevention, diagnosis & treatment

Objectives

1. To develop a fully-integrated biopharmaceutical pipeline
2. To set up comprehensive translational medicine platform and biotech incubation center
3. To strengthen biotech industry value chain and accelerate commercialization

3

Boost commercialization and globalization of research output through international collaborations

2

1

Strengthen IP management and enhance academic/industrial protection

Establish platforms for translational-medical research and foster industrial capacities of biopharmaceutical R&D

Strategy

Strategy:

- Focus on R&D of New Drugs/New Reagents/New Therapeutic Strategies/New Medical Devices in a **Product-Oriented Approach**
- Streamline the Operating Mechanism of **Preclinical Studies & Early Clinical Trials**

NanKang Biotech Park



新竹生物醫學園區

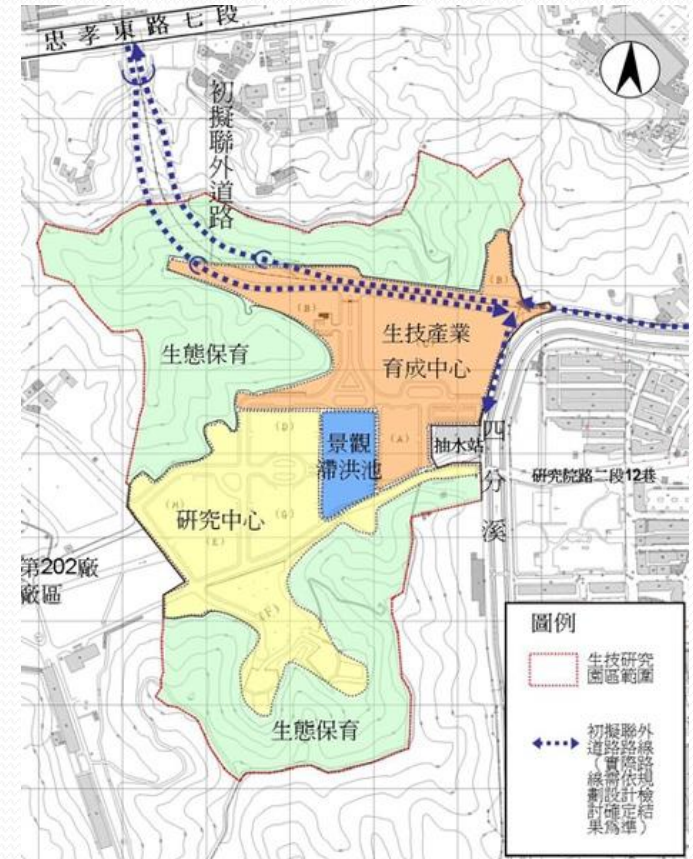
Hsinchu Biomedical Science Park

The **Jhubei Biomedical Park** is focused on pharmaceuticals and medical apparatus. the Park contained more than 30 biotech companies, contributing total revenue of US\$76 million. **NanKang Biotech Park** will be designed and conducted by Academia Sinica.

The Jhubei Biomedical Park



NanKang Biotech Park

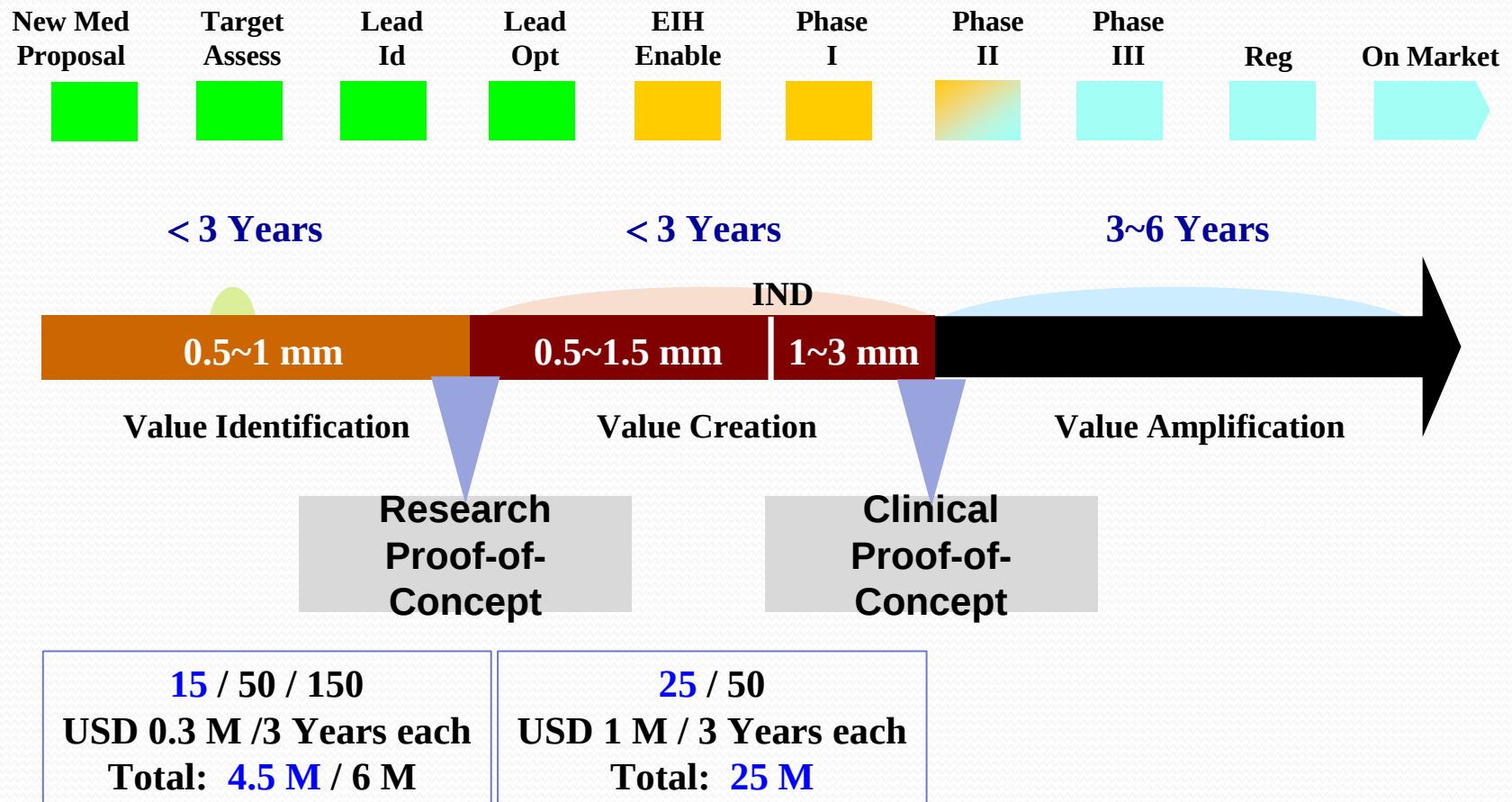


Goals of NRPPB (1)

1. **Integrate national R&D resources** and establish a strong R&D environment.
2. Establish and streamline the operation of **pre-clinical and early clinical trials**, realizing the **commercialization** of biomedical research.
3. Improve the **management of intellectual properties** and promote the **academy/industry collaboration**.
4. Develop **globalized R&D strategies** to cultivate Taiwan as a center of international biomedical industries.
5. Develop more effective and economical technologies and applications on **disease prevention, diagnosis, and treatment**, to improve the well-being of people and minimize waste of medical resources.

Goals of NRPB (2)

- 10 cases reach Research Proof-of-Concept in 5 Years
- 5 cases reach Clinical Proof-of-Concept in 5 Years (each can be valued at up to USD 200M)



U.S. pushes for more scientists, but the jobs aren't there

By [Brian Vastag](#), Published: July 8, 2012

Research jobs slashed

Since 2000, U.S. drug firms have slashed 300,000 jobs, according to an analysis by consulting firm Challenger, Gray & Christmas. In the latest closure, Roche last month announced it is shuttering its storied Nutley, N.J., campus — where Valium was invented — and shedding another 1,000 research jobs.

One reason: A glut of new biomedical scientists that entered the field when the economy was healthier. From 1998 to 2003, the budget of the National Institutes of Health doubled to \$30 billion per year. That boost — much of which flows to universities — drew in new, young scientists. The number of new PhDs in the medical and life sciences boomed, nearly doubling from 2003 to 2007, according to the NSF.

Although the injection of \$10 billion in federal stimulus funds to the NIH from the American Recovery and Reinvestment Act of 2009 “created or retained” 50,000 science jobs, according to the NIH, that money is running dry, putting those positions at risk.

The lack of permanent jobs leaves many PhD scientists doing routine laboratory work in low-wage positions known as “post-docs,” or postdoctoral fellowships. Post-docs used to last a year or two, but now it’s not unusual to find scientists toiling away for six, seven, even 10 years.



NATIONAL BIOECONOMY BLUEPRINT

this 2012 National Bioeconomy Blueprint has two purposes: to lay out strategic objectives that will help realize the full potential of the U.S. bioeconomy and to highlight early achievements toward those objectives.

- 1. Support R&D investments that will provide the foundation for the future U.S. bioeconomy.**
- 2. Facilitate the transition of bioinventions from research lab to market, including an increased focus on translational and regulatory sciences.**
- 3. Develop and reform regulations to reduce barriers, increase the speed and predictability of regulatory processes, and reduce costs while protecting human and environmental health.**
- 4. Update training programs and align academic institution incentives with student training for national workforce needs.**
- 5. Identify and support opportunities for the development of public-private partnerships and precompetitive collaborations—where competitors pool resources, knowledge, and expertise to learn from successes and failures.**