



**The BioBusiness Alliance**  

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**of Minnesota**



## ***Destination 2025***

***Challenges and Opportunities in  
Agriculture, Energy, and Bioscience***

# *Objectives*

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- 1. Background**
- 2. BRIEFLY review the process to develop Destination 2025**
- 3. Review the high level global drivers and resultant recommendations**





# *What is the BioBusiness Alliance?*

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*Industry*



*Academia*

*Government*

**Mission:**

Enhance the well-being of our citizens by mobilizing and connecting the community to support the growth of biobusinesses by providing a roadmap for success, infrastructure, and a welcoming environment.

*Enriching Minnesota's Future through the Biosciences*



**BioBusiness Alliance**  
of Minnesota

# *What is Destination 2025?*

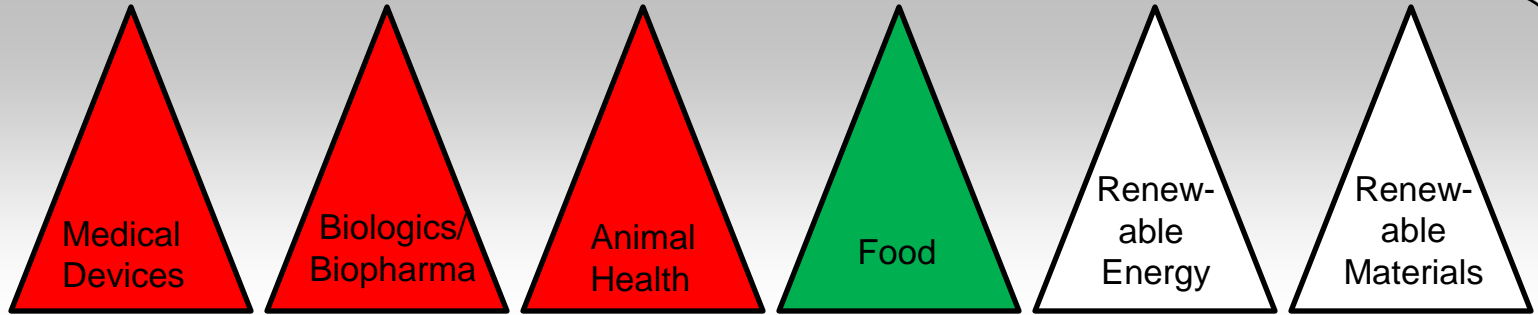
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- **A partnership with Deloitte Consulting, LLC**
- **A twenty year “vision and roadmap” for the lifescience industry in the state of Minnesota that is intended to help ensure our place in the evolving global economy.**

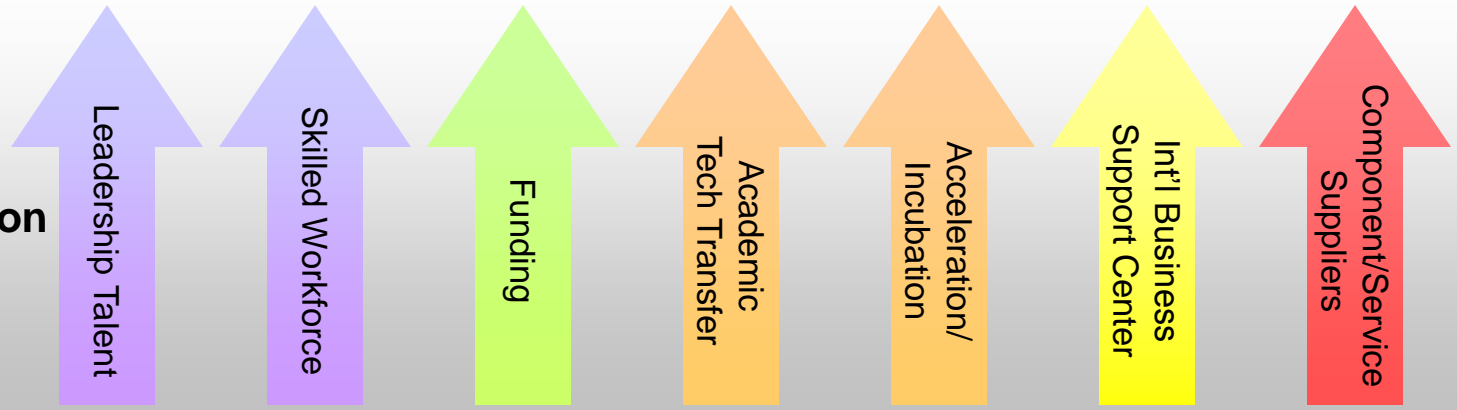


# Minnesota Life Science Community

## Minnesota Industries



## Commercialization Catalysts



## Enabling Knowledge Clusters

Catalysis & Synthesis  
(Biological & Chemical)

NanoTech & Materials Science

Bioengineering & Clinical Capabilities

Bioinformatics & Systems Biology

Genomics, Proteomics & High Throughput Biology

Imaging / Navigation

## Foundational Capabilities

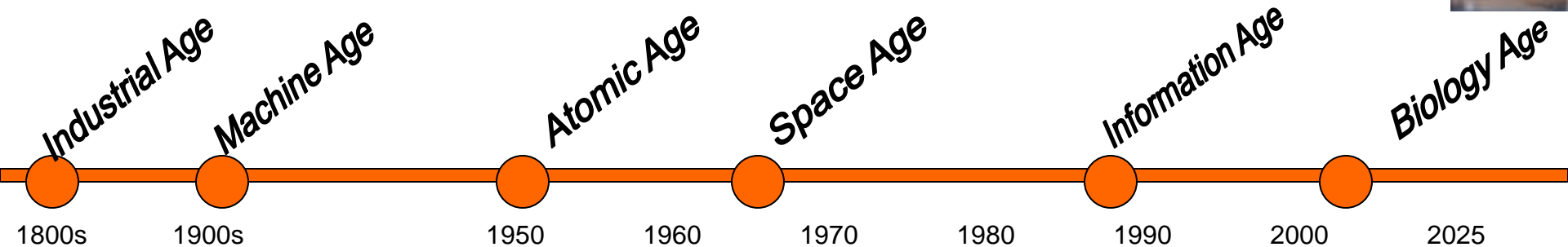
Education

Infrastructure

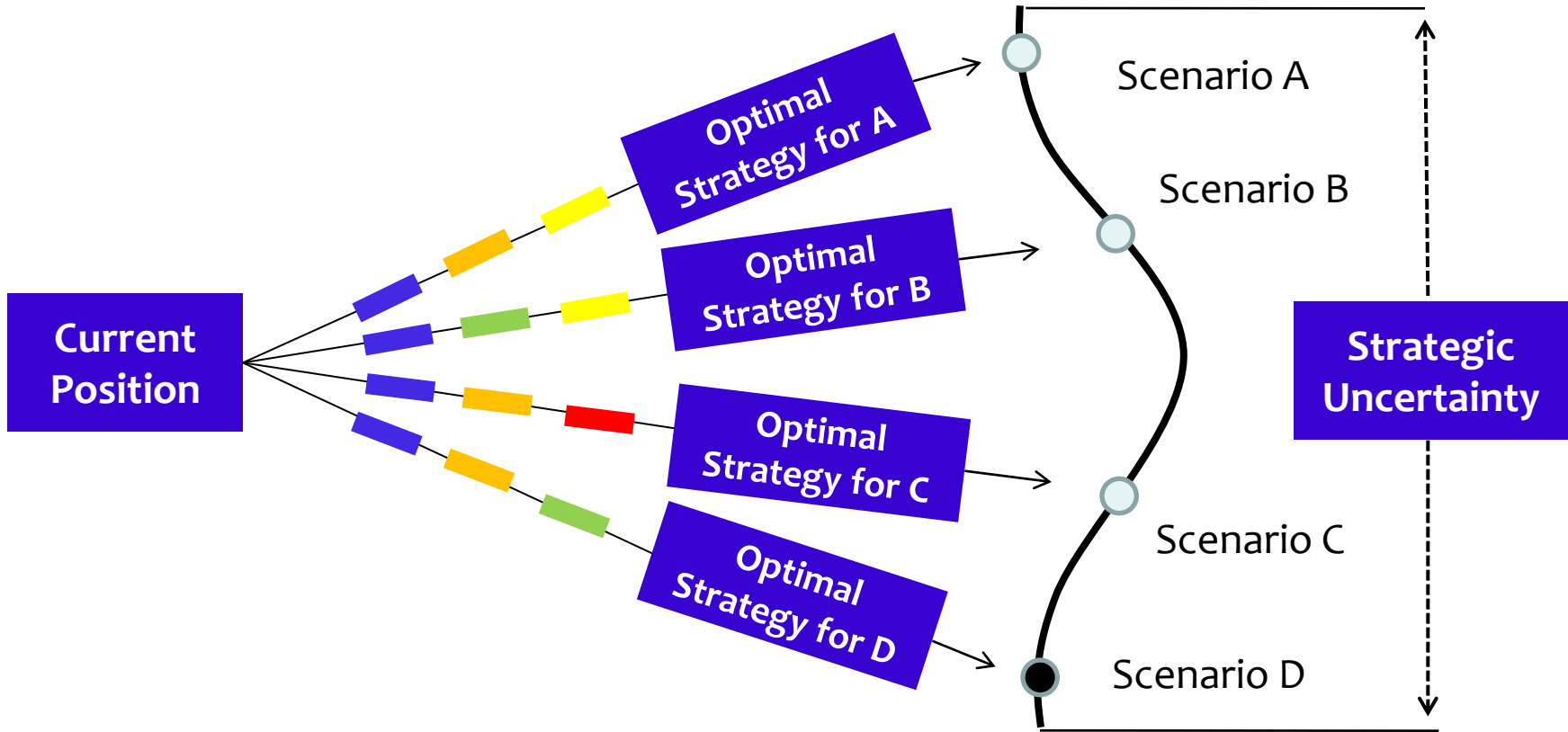
Policy

# *Industry Evolution through the Ages*

Today's advances leverages the accomplishments of previous states, products or technologies

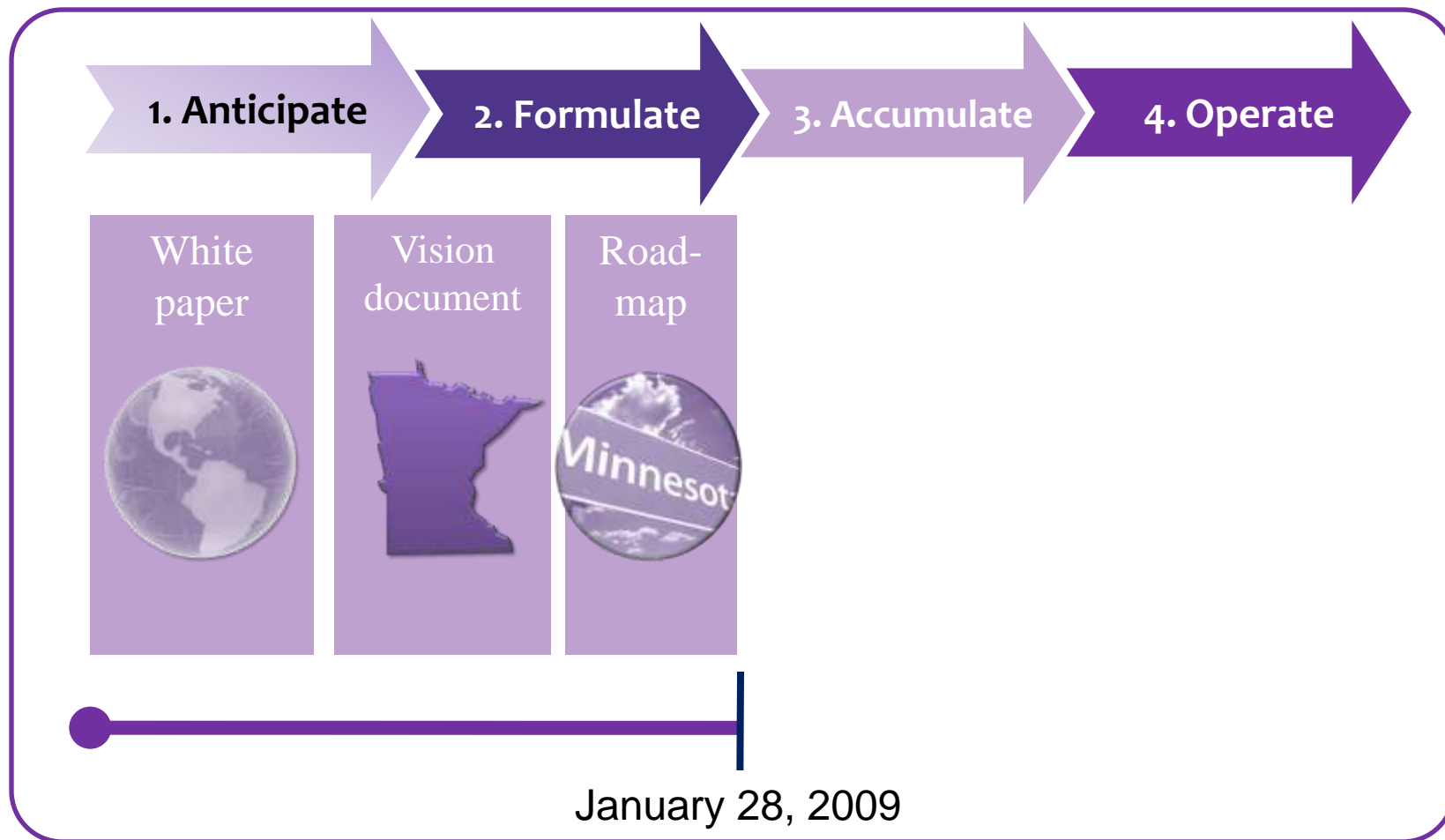


# Strategic Flexibility



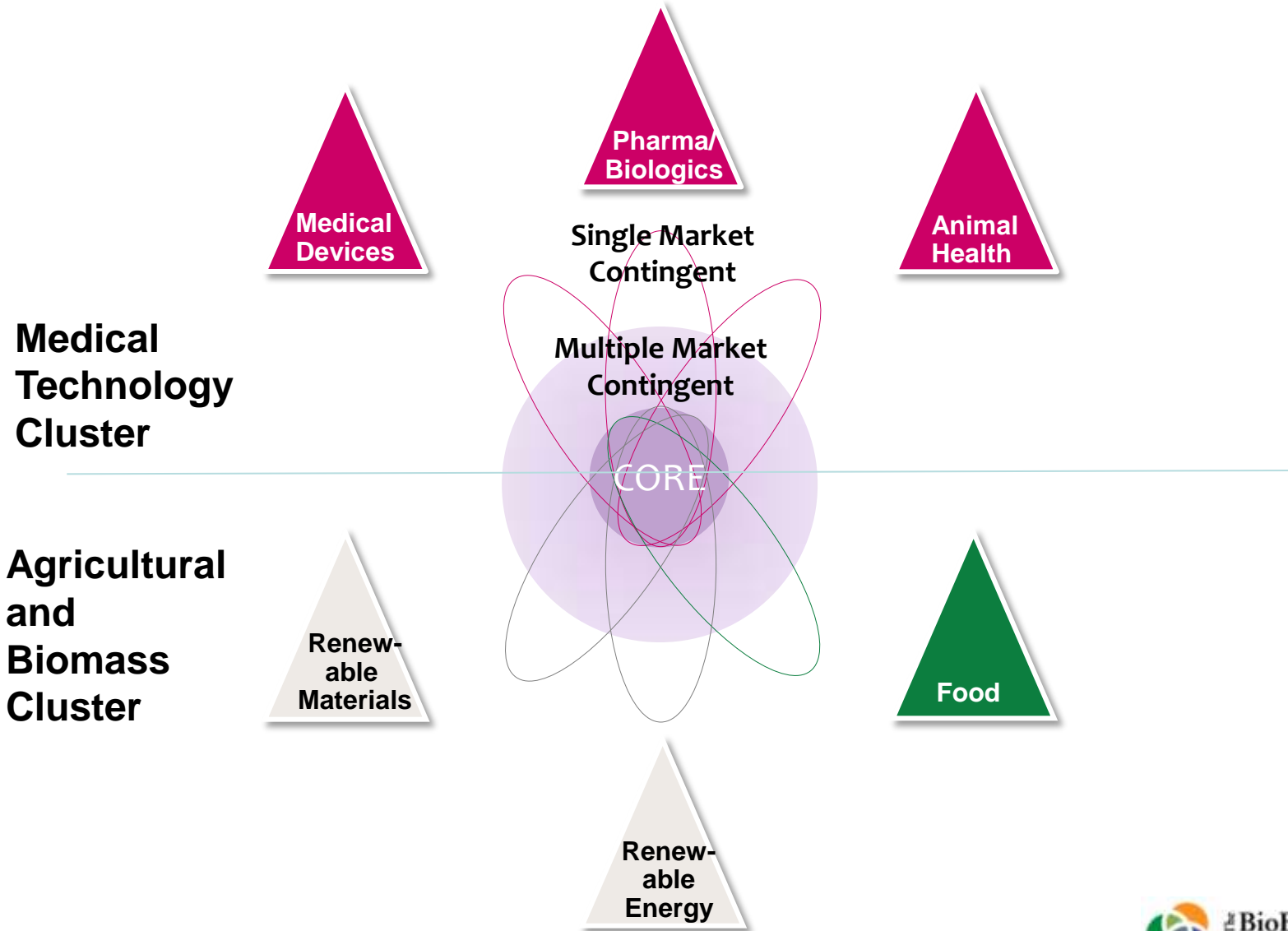


# *Implementation Is Underway*





# Minnesota Bioscience Industries



# *Did You Know?*

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# *What Did We Find?*

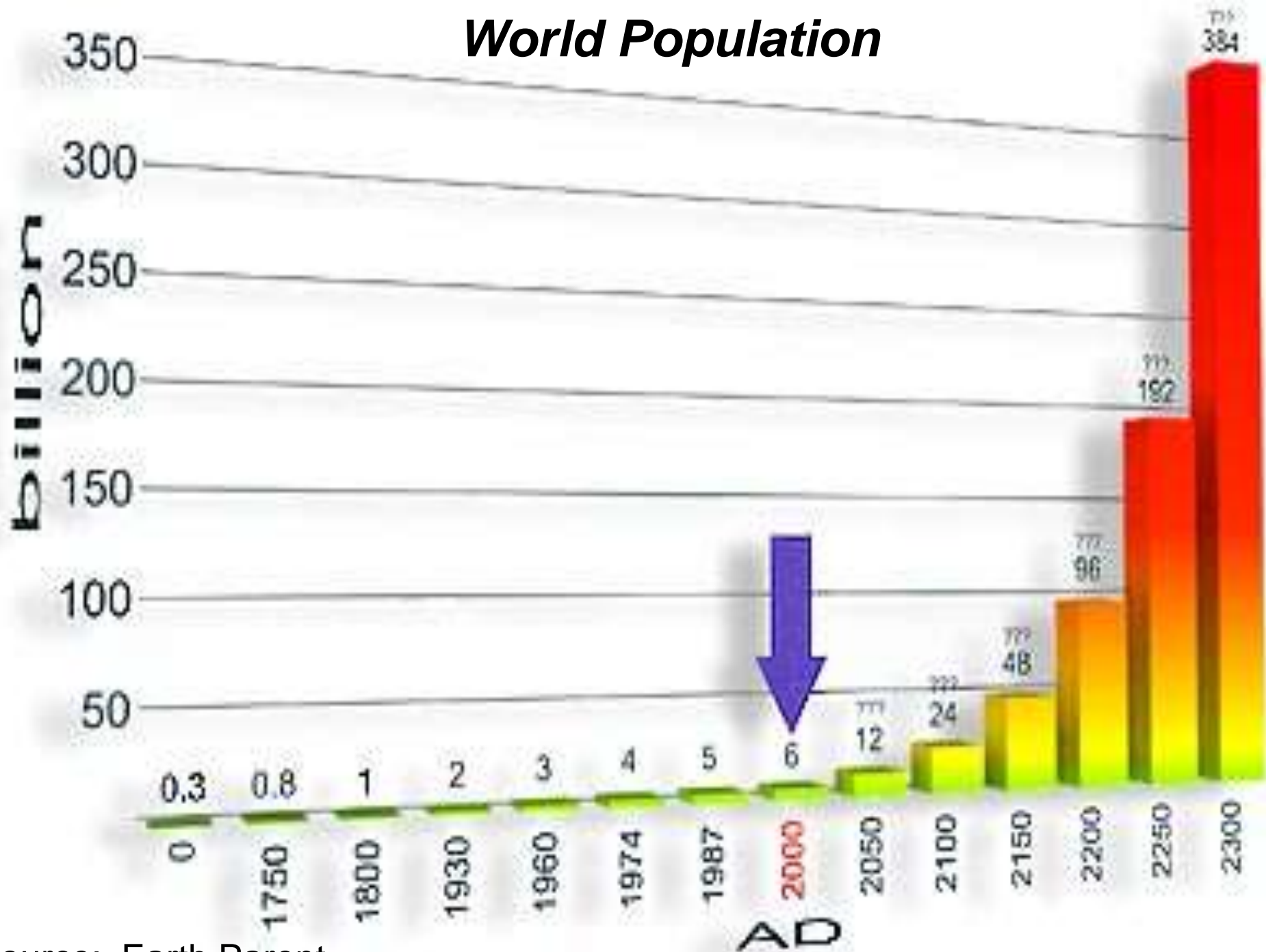
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***“The greatest shortcoming of the human race is the inability to understand the exponential function”***

*Dr. Albert Bartlett*

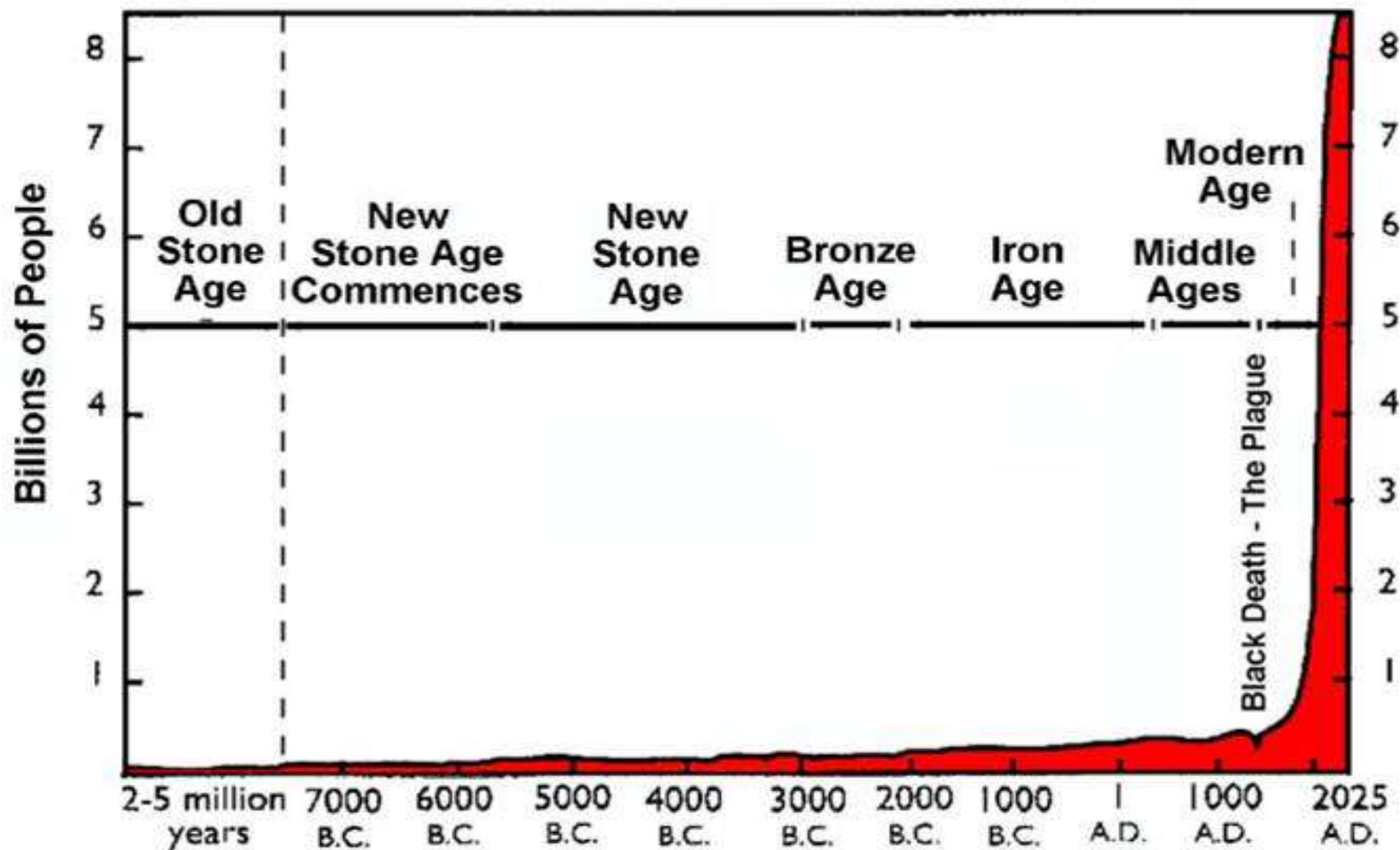


# World Population



Source: Earth Parent

# World Population Growth Through History

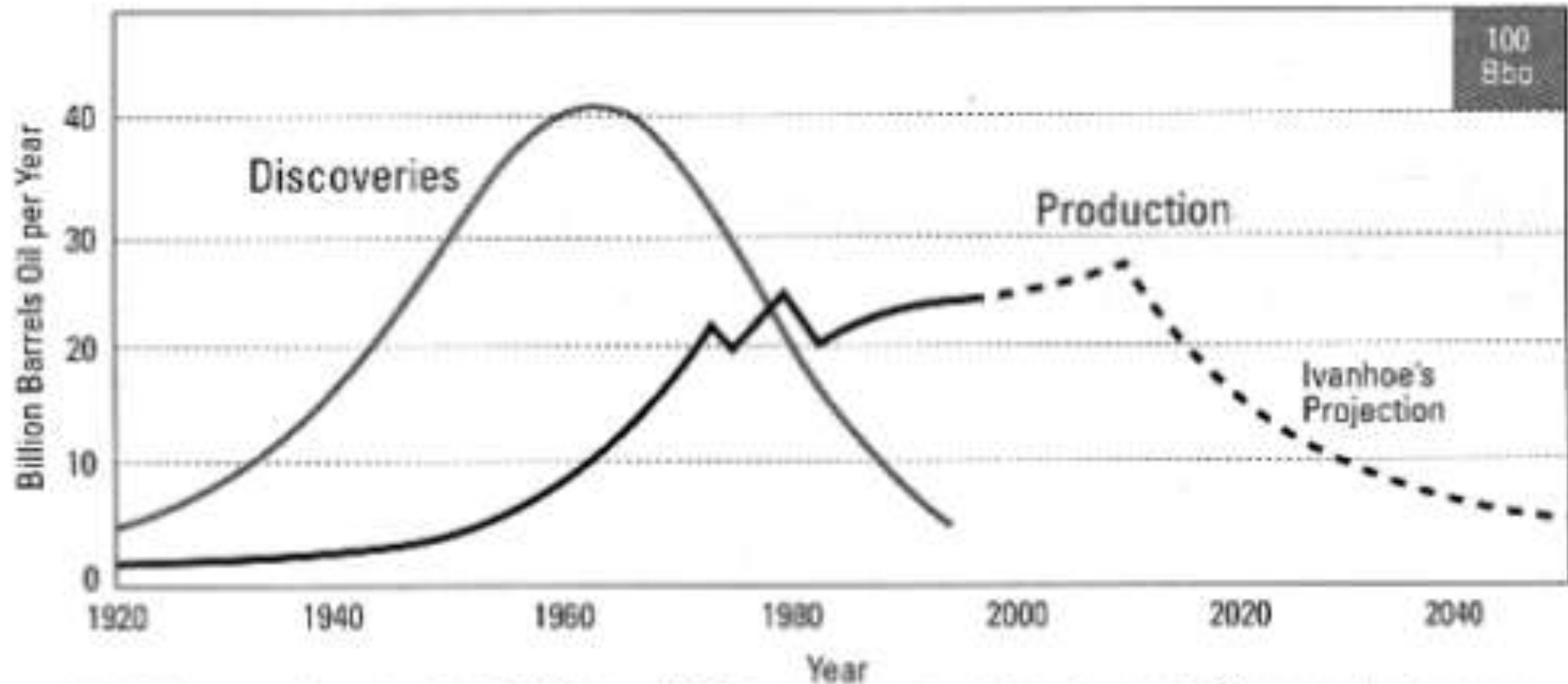


From "World Population: Toward the Next Century," copyright 1994 by the Population Reference Bureau



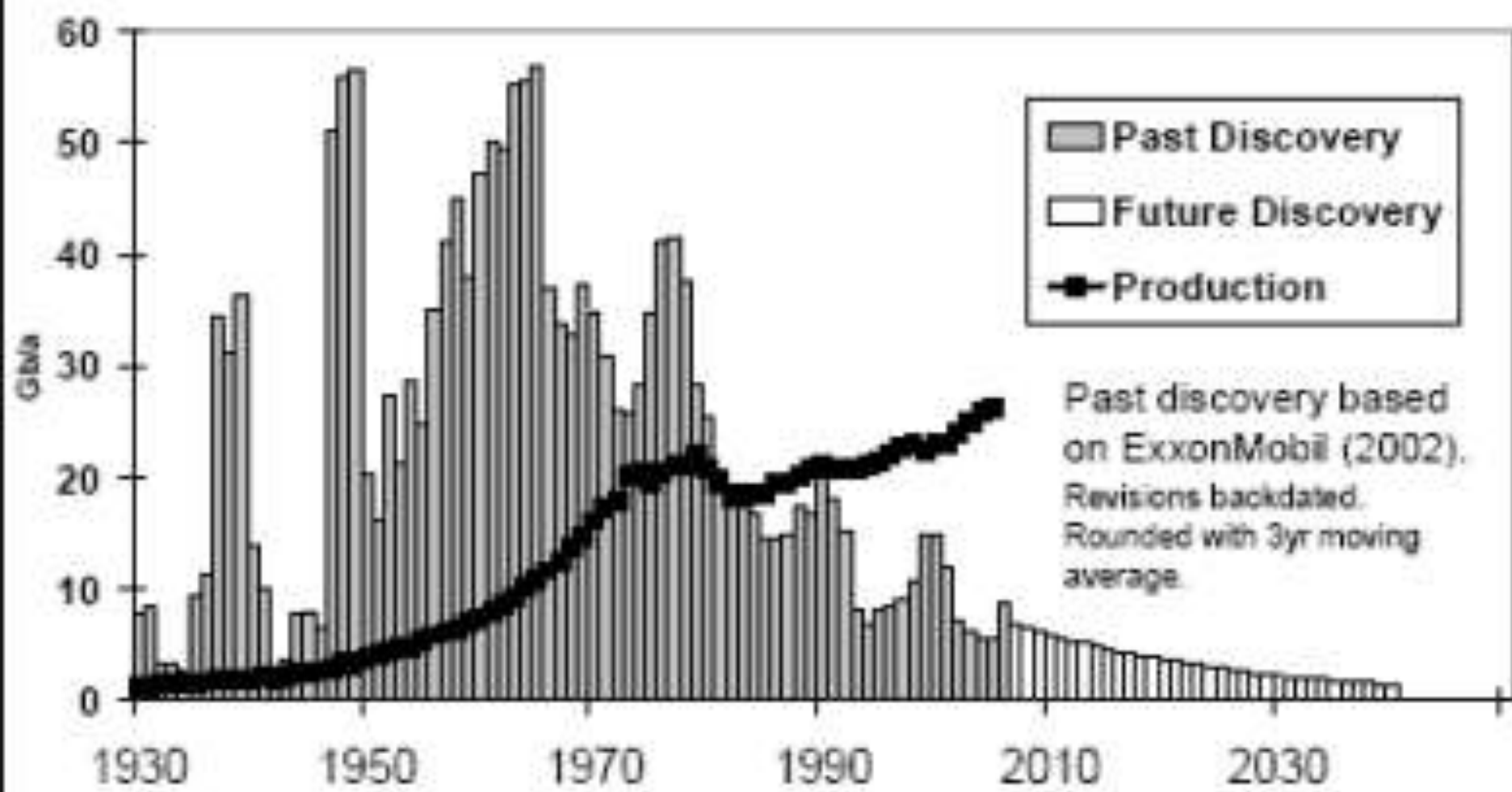
# World Oil Supply

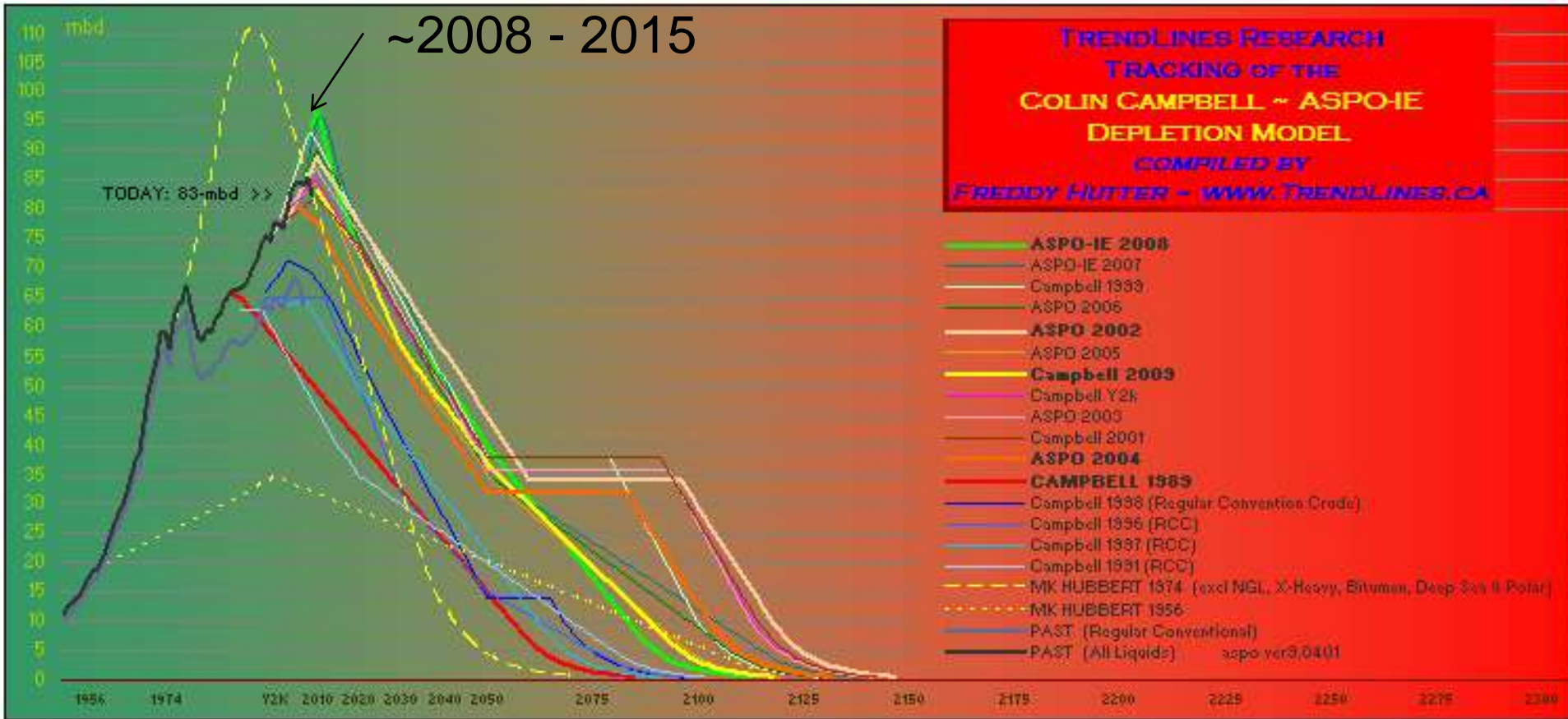
The two areas (Discoveries and Production) must ultimately be equal, since one cannot produce more oil than has been discovered.



SOURCES: Discoveries Curve adapted from USGS/Masters, 1994. Production Curve extrapolated by author to match Discoveries volume (area under Discoveries Curve).









# *Emerging Global Drivers*

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## **Clean, Green & Renewable Energy & Technology**

- Will increase driven by increasing energy prices, environmental concerns, and public policy to support economic growth

## **Agricultural products for food**

- Social change will drive niche and organic markets, and demographics will drive access, globalization, cost control and volume.

## **Forest and agricultural biomass for energy and materials**

- Climate change and land degradation will increase demand for efficiency and sustainability



# *Emerging Global Drivers*

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## **Food, Energy & Health Care**

- Global changes in demographics, cost, political environments and evolving economies will increase demand

## **Employment**

- Shaped by workforce availability and globalization

## **Healthcare and Patient Therapy**

- Reshaped by: personalized medicine, convergence between different technologies and lifestyle



# *What Does It Mean?*

Demographics will drive access, globalization, cost control and volume.

Reshaped by: personalized medicine, convergence between different technologies and lifestyle

Increasing energy prices, environmental concerns, will drive public policy: "polluters pay"

The future economy will be shaped by workforce availability, globalization and developing economies

Climate change and land degradation will increase demand for efficiency and sustainability

Changes in demographics and political environments will increase demands in some economies, and instability in others.



# *Medical Devices*

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**1. Expand the application of active implantable device technology**

**2. Establish leadership in next generation technology**



# *Biologics & Biopharmaceuticals*

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**1. Diagnostics and  
Monitoring**

**2. Metabolic Disease  
Management**



# *Animal Health*

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1. Convergence with  
Human Health

2. Growth (vaccines)



# *Food*

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1. To be determined...



# *Renewable Energy*

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1. Establish decision making capability for Biomass Management

2. Heat generation as part of “25 X 25”





# *Renewable Materials*

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**1. Engineering and  
product manufacturing**

**2. Support expansion of  
new chemistry**



# *Community Capabilities*

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Center for Nanotechnology

Seed Funds

Center for Device Engineering

Center For Bioinformatics

R & D Tax Credits

Biosciences Education-  
Industry Partnership  
Council

Center for Biomass  
Management

# *Enabling Knowledge Clusters*

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Enabling  
Knowledge  
Clusters

Catalysis &  
Synthesis  
(Biological &  
Chemical)

NanoTech &  
Materials  
Science

Bio-  
engineering  
& Clinical  
Capabilities

Bio-  
informatics  
&  
Systems  
Biology

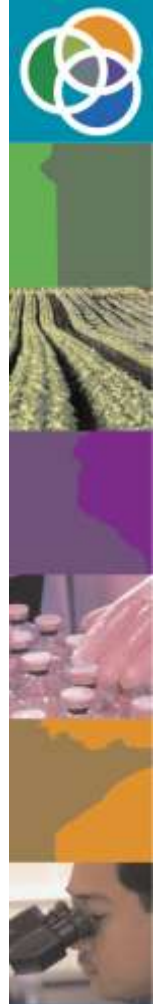
Genomics,  
Proteomics  
& High  
Throughput  
Biology

Imaging /  
Navigation

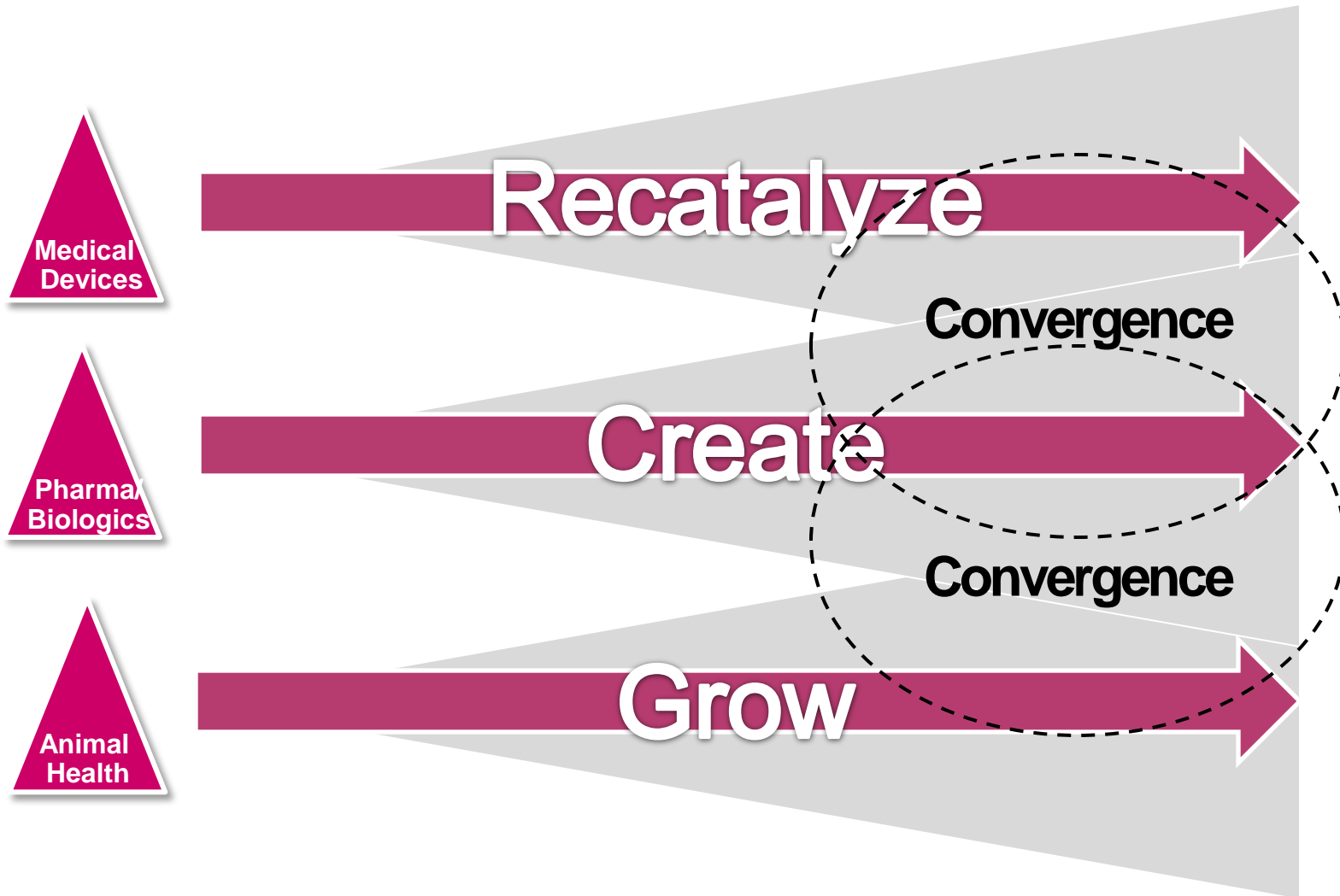
## **Core Enabling Knowledge Clusters**

- NanoTech
- Bioinformatics
- Systems Biology

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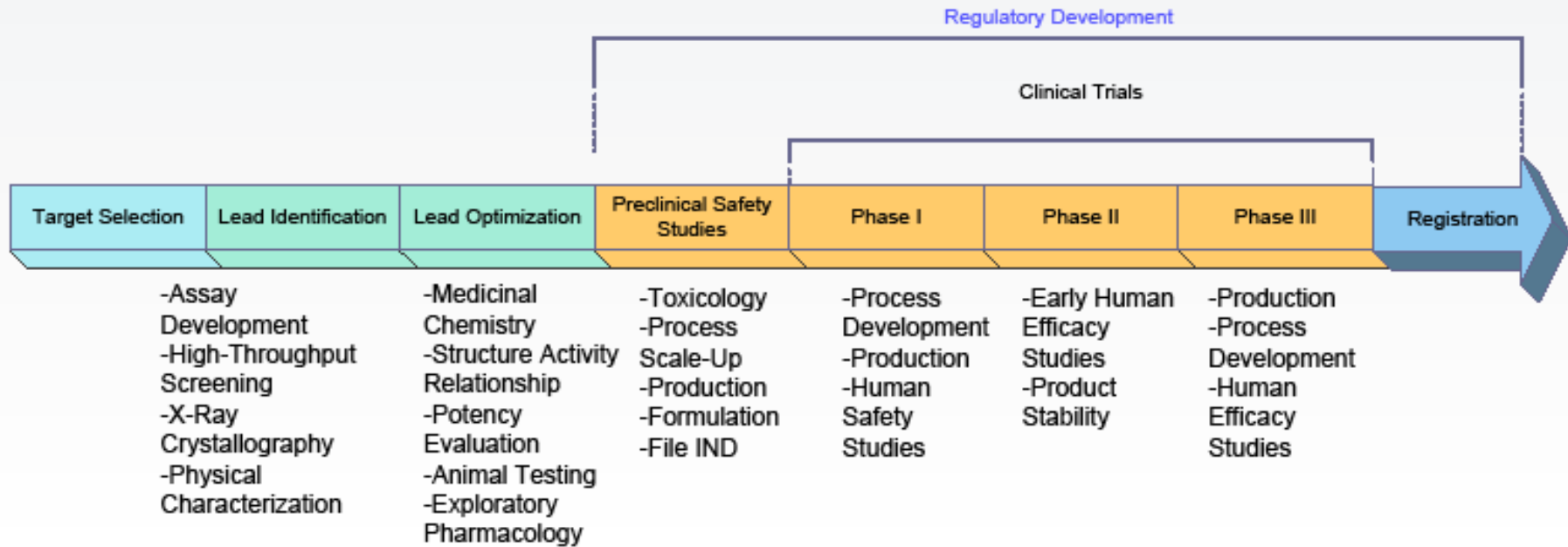
# Medical Technology Cluster



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# Drug Development



# Drug Development Life Cycle

**Basic  
Science**

**Drug  
Discovery**

**Drug  
Development**

**Primary Job  
Creation**

Target Selection    Lead Identification    Lead Optimization    Preclinical Safety Studies    Phase 1    Phase 2    Phase 3    Registration

**Private Sector**  
U of M  
Mayo  
Other

**Production is being sent out of state:**  
MFG Scale Up  
Regulatory  
Animal Testing

**Today: East & West Coast**

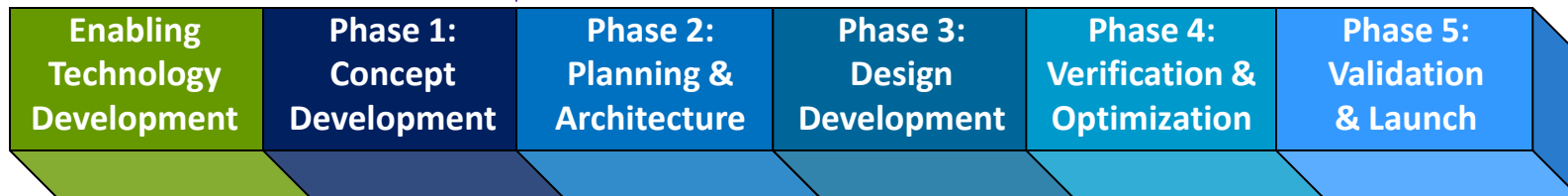
**Minnesota is a leader  
in basic science and  
drug discovery.**



# Medical Device Development

## Product Development

## Regulatory Development



- |  |  |   |   |   |  |
|--|--|---|---|---|--|
| <ul style="list-style-type: none"> <li>- Materials</li> <li>- Manufacturing</li> <li>- Electronics</li> <li>- Controls</li> <li>- Software</li> <li>- Thermal</li> <li>- Packaging</li> <li>- Wired/Wireless Communications</li> </ul> | <ul style="list-style-type: none"> <li>- Define Inputs</li> <li>- Preliminary Requirements Document</li> <li>- Develop Concepts</li> <li>- Evaluate Concepts: Mockups, Prototypes, Simulations</li> <li>- Early Biocompatibility Studies</li> <li>- Review Intellectual Property</li> <li>- Preliminary Market and Financial Assessment</li> </ul> | <ul style="list-style-type: none"> <li>- Requirements (incl. regulatory &amp; standards)</li> <li>- Product Architecture: Electrical, Software, Mechanical</li> <li>- Regulatory Strategy (510k, PMA)</li> <li>- Reimbursement Strategy</li> <li>- Clinical Plan</li> <li>- Risk Management Plan</li> <li>- Manufacturing Strategy</li> <li>- Detailed Project Plan</li> <li>- Business Plan</li> </ul> | <ul style="list-style-type: none"> <li>- Specifications</li> <li>- Detail Design: Mechanical Models &amp; Drawings, Electrical Schematics, Software Code</li> <li>- Packaging Design</li> <li>- Bill of Materials (BOM) &amp; Cost of Goods (COG)</li> <li>- Risk Assessments (FTA, FMEA, HAZOP)</li> <li>- Test Plans</li> </ul> | <ul style="list-style-type: none"> <li>- Verification Testing</li> <li>- Biocompatibility Testing</li> <li>- Sterilization Testing</li> <li>- Software Validation</li> <li>- Supply Chain</li> <li>- Device Master Record</li> <li>- Manufacturing Pilot Line</li> <li>- Process FMEA</li> <li>- Shelf Life Testing</li> <li>- Packaging &amp; Ship Testing</li> <li>- User, Training &amp; Sales Documentation</li> <li>- Regulatory Submission</li> </ul> | <ul style="list-style-type: none"> <li>- Product Training</li> <li>- Final Instructions For Use (IFU)</li> <li>- Service Plan</li> <li>- Trace DI's to DO's</li> <li>- Risk Management Report</li> <li>- Close Design History File</li> <li>- Verify &amp; Validate Manufacturing Equipment &amp; Processes</li> <li>- Clinical Studies</li> <li>- Manufacturing Ramp</li> </ul> |
|--|--|---|---|---|--|



# *Agricultural and Biomass Cluster*



**Forests**

**Existing Markets: Lumber, Paper, Energy**

**Growing Markets: Bioactives & Renewable Materials and Energy**

**Agricultural Plants**

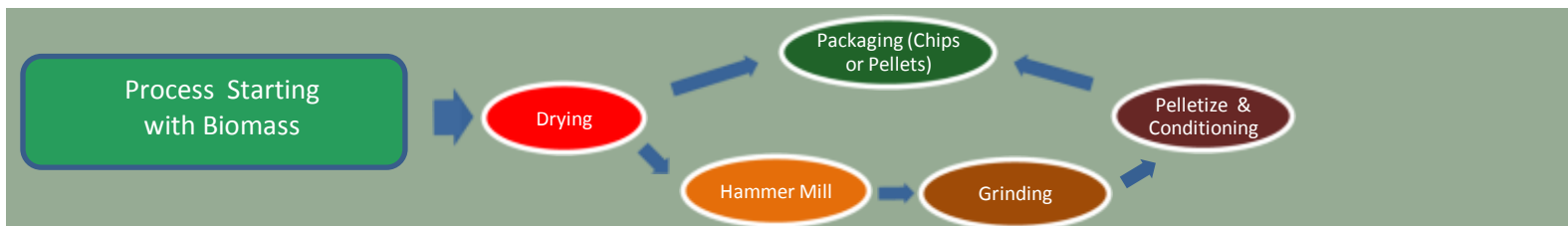
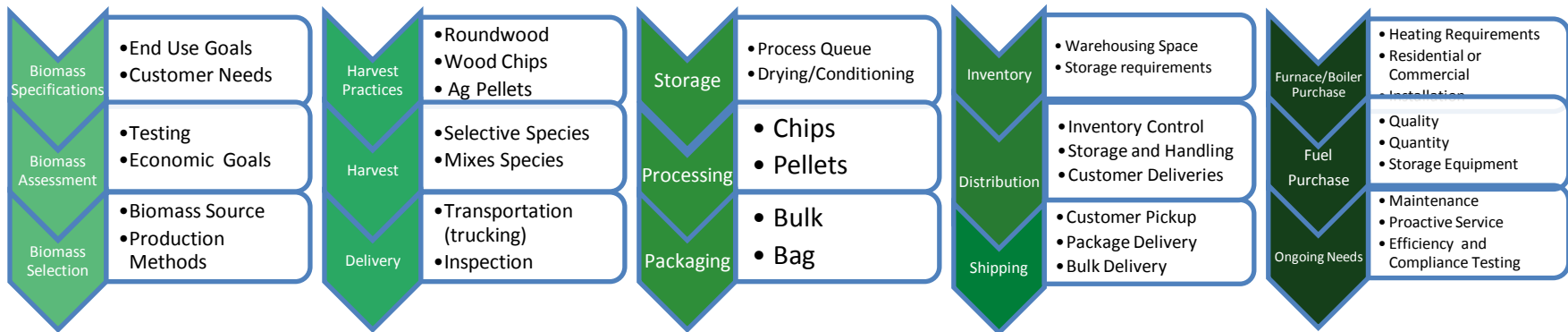
**Existing Markets: Human & Animal Food, Energy**

**Growing Markets: Functional Foods & Renewable Materials and Energy**

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# SOLID FUEL BIOMASS SUPPLY CHAIN



**Key Performance Indicators (KPI's):** Efficiency (\$/unit produced); Quality of Biomass (\$/ton or pound); Equipment Capacity (tons/hour)

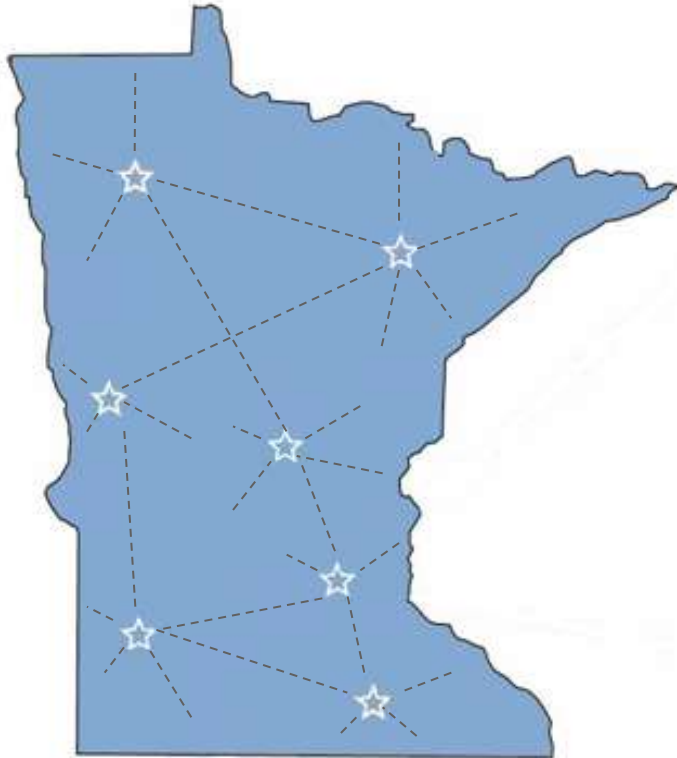
At Step 3, biomass feedstock may be delivered to a **biorefinery** where it may be converted through biochemical or thermochemical processes for combined heat and power (CHP) or fuels, chemicals, and renewable materials.

Step 3 may include the processing of biomass feedstock that results in **densification**, whereby, further steps may be required to get a product to end market for use in biomass heating appliances (reflected in Steps 4 & 5).

# Minnesota Life Science Community

Mission: Drive growth of a knowledge based economy

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## Critical Components:

- **CHAMPIONS** with significant technical and industry knowledge
- Inventoried **strengths and capabilities**
- **Academic support** for work force, research, technology
- Acceleration capability (**money, management, technical know-how**)
- Appropriate **policies**
- A **strategy** and **community** that supports it

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***Thank You!***

[www.biobusinessalliance.org](http://www.biobusinessalliance.org)