strategic health innovations

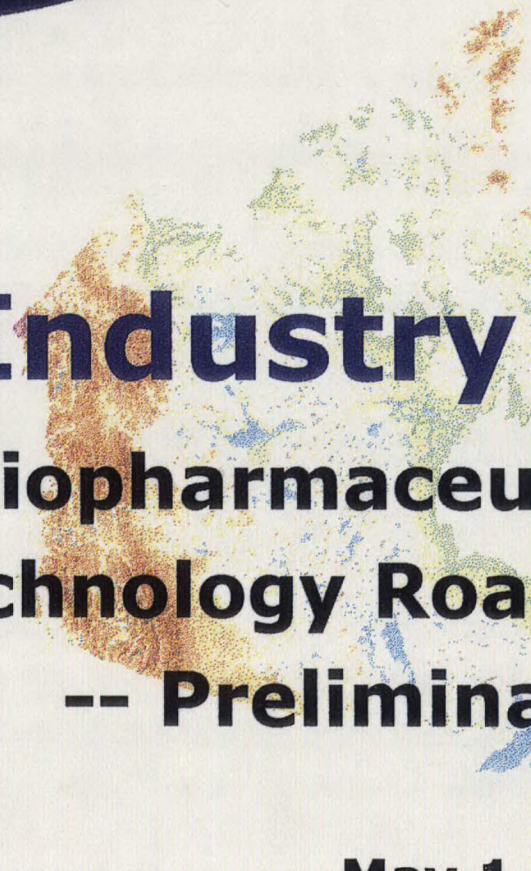
Industry Canada

Biopharmaceutical Industry Technology Roadmap Initiative

-- Preliminary Work --

May 1, 2000

strategic health innovations



Industry Canada

Biopharmaceutical Industry Technology Roadmap Initiative

-- Preliminary Work --

May 1, 2000

Agenda

- Project Scope and Methodology
- Industry Overview
- Overview of Current & Future Technologies
- Consultation Outcomes
- Technology Assessment
- Technology Roadmap Recommendations
- Business Environment Recommendations
- TRM - Next Steps

Scope of Work

- Overview of the Canadian biopharmaceutical industry
- Identify technologies needed to meet future biopharma needs
- Assess Canada's relative strength with regard to these technologies
- Determine Canadian industry's interest in participating in a Technology Roadmap (TRM) Initiative
- Provide recommendations to Industry Canada's Life Sciences Branch

Methodology

Phase 1: Completed primary and secondary research to determine present and future technology needs

Phase 2: Created a value chain representation of the industry

Phase 3: Conducted consultations with sample of key industry and academic stakeholders

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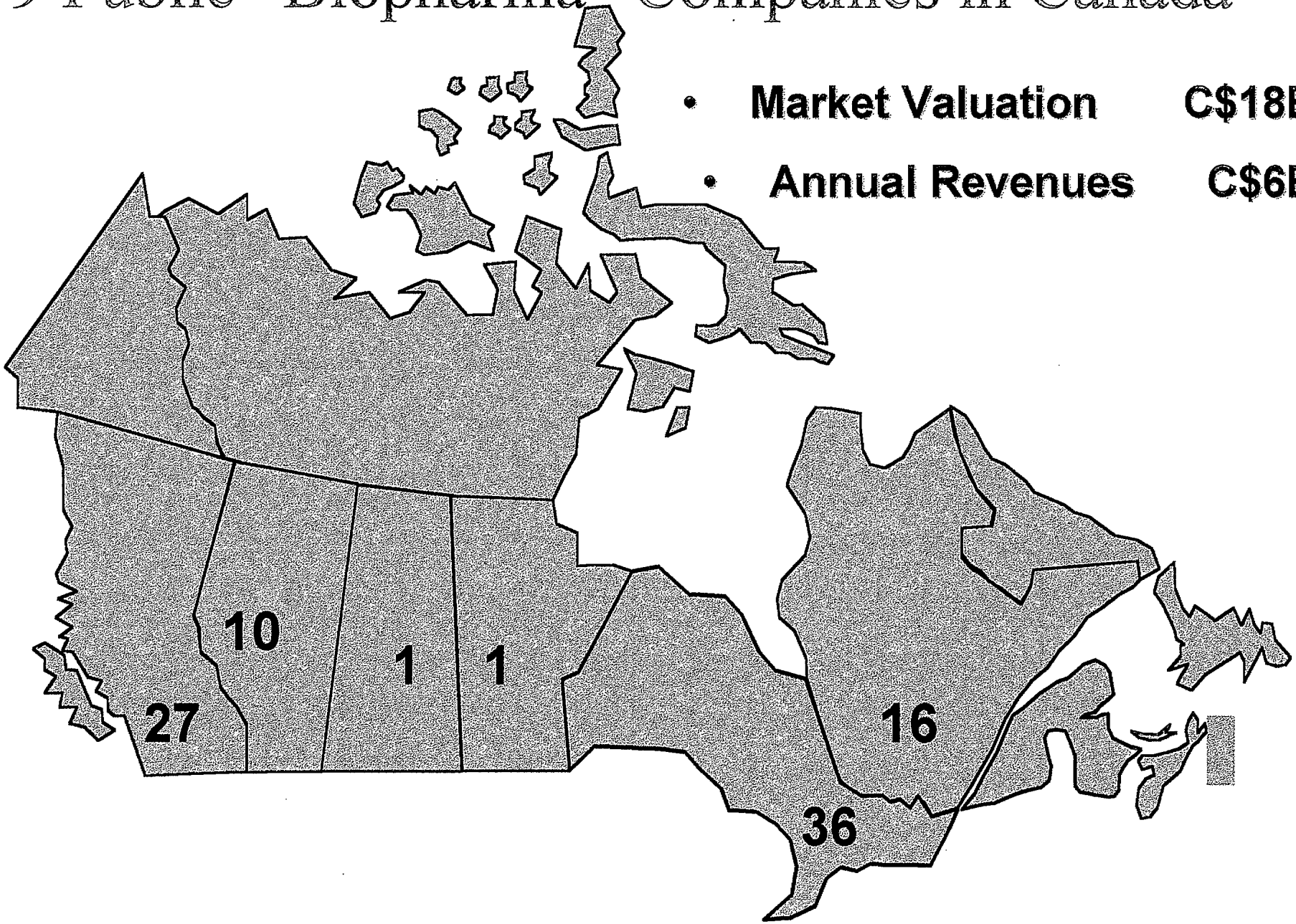
Explosive Growth Worldwide

- **Currently:**
  - 36 biotech drugs on market in Canada generating $207 M in sales in 1997
  - In 1998, 54 biotech drugs approved in U.S.
  - 1998, $15 B (US) international market
  - 800 firms employing 60,000 people worldwide
- **Biologically based drugs:**
  - In 2000, make up 5% of the medicines on the market
  - By 2005, make up 15% of the medicines on the market

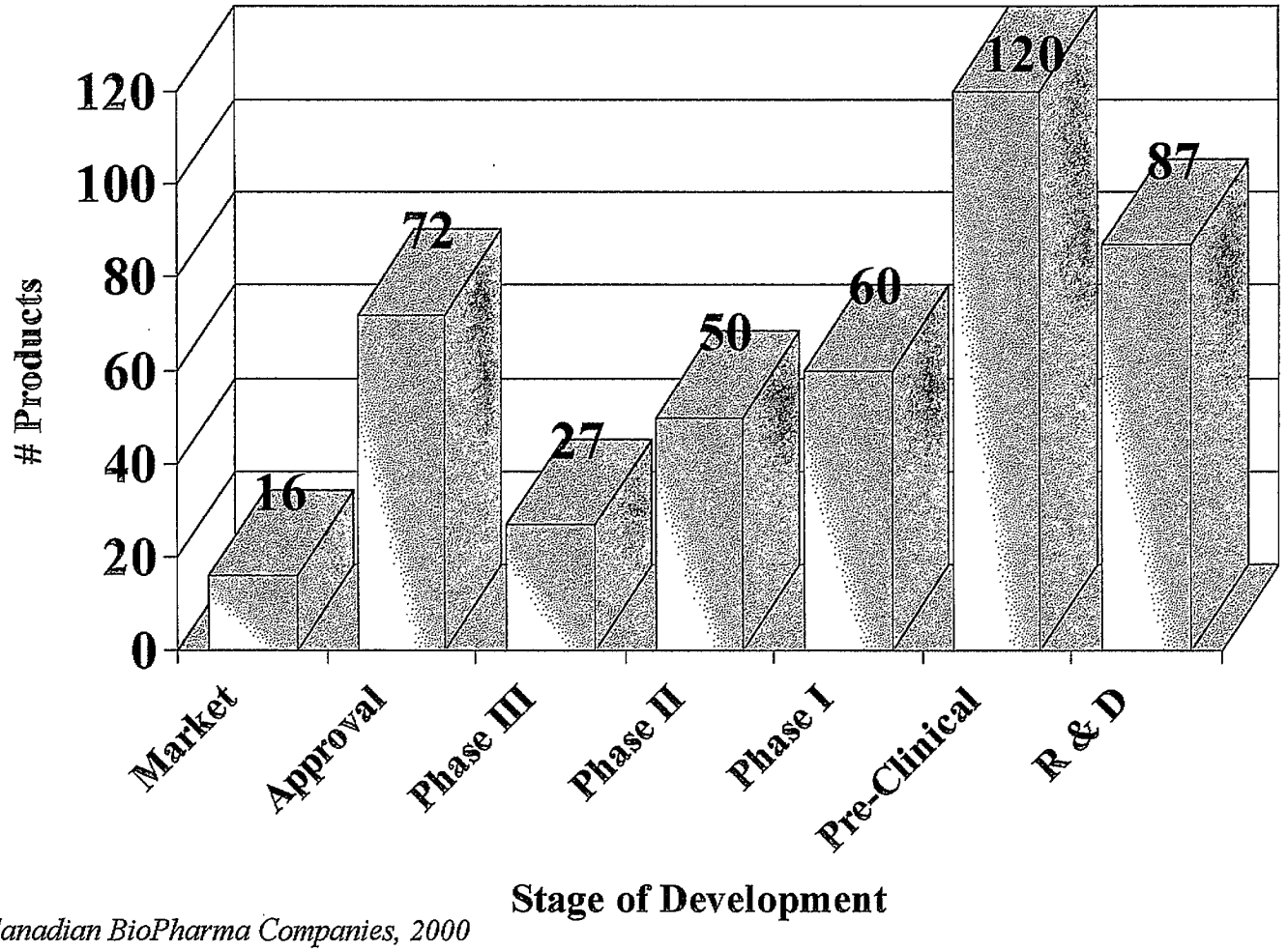
79 Public "Biopharma" Companies in Canada

- **Market Valuation C$18B**
- **Annual Revenues C$6B**



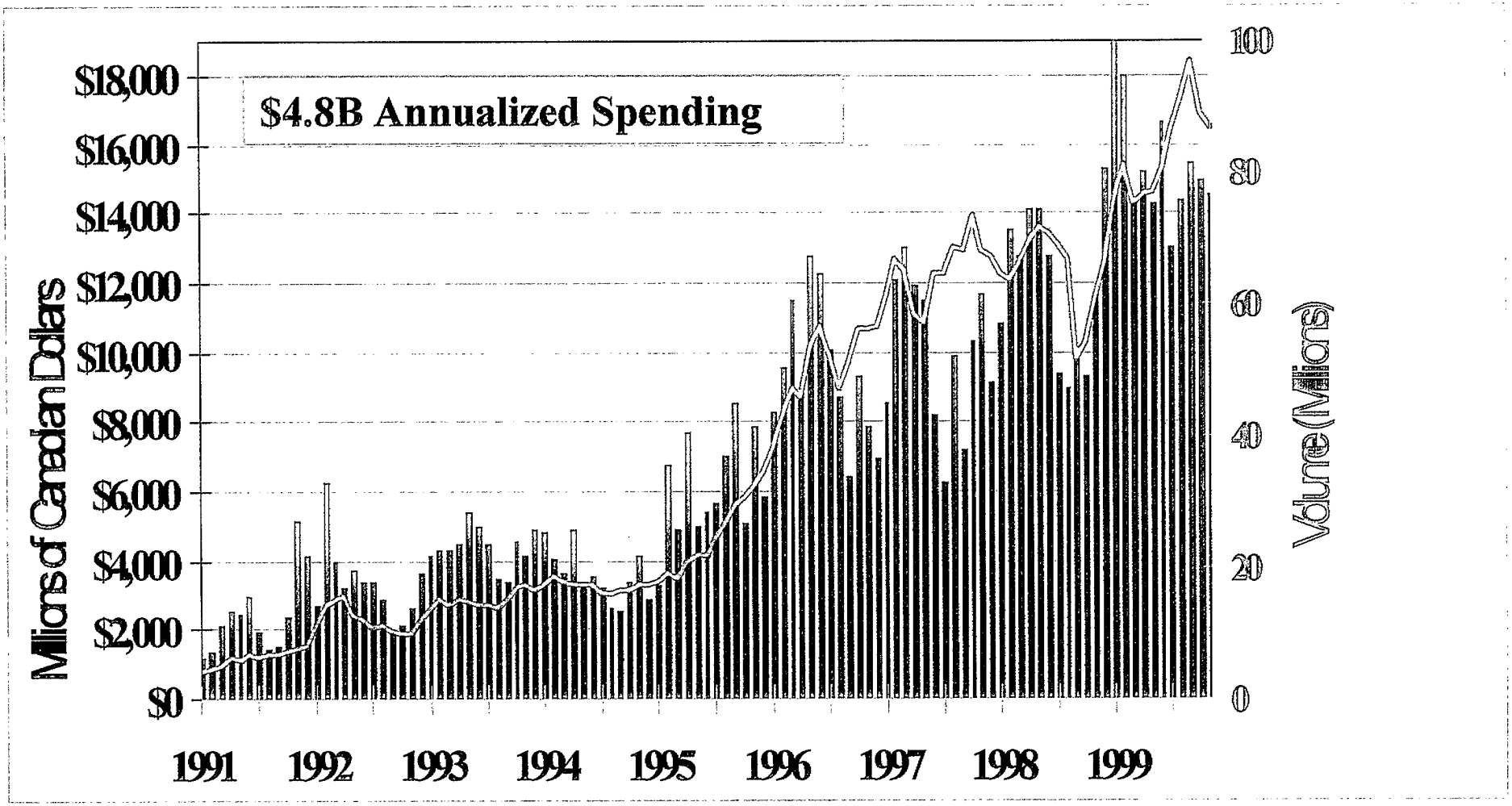
Canadian Biopharma Companies Have 372 Products Under Development

(as of Jan 1, 2000)



Source: Canadian BioPharma Companies, 2000

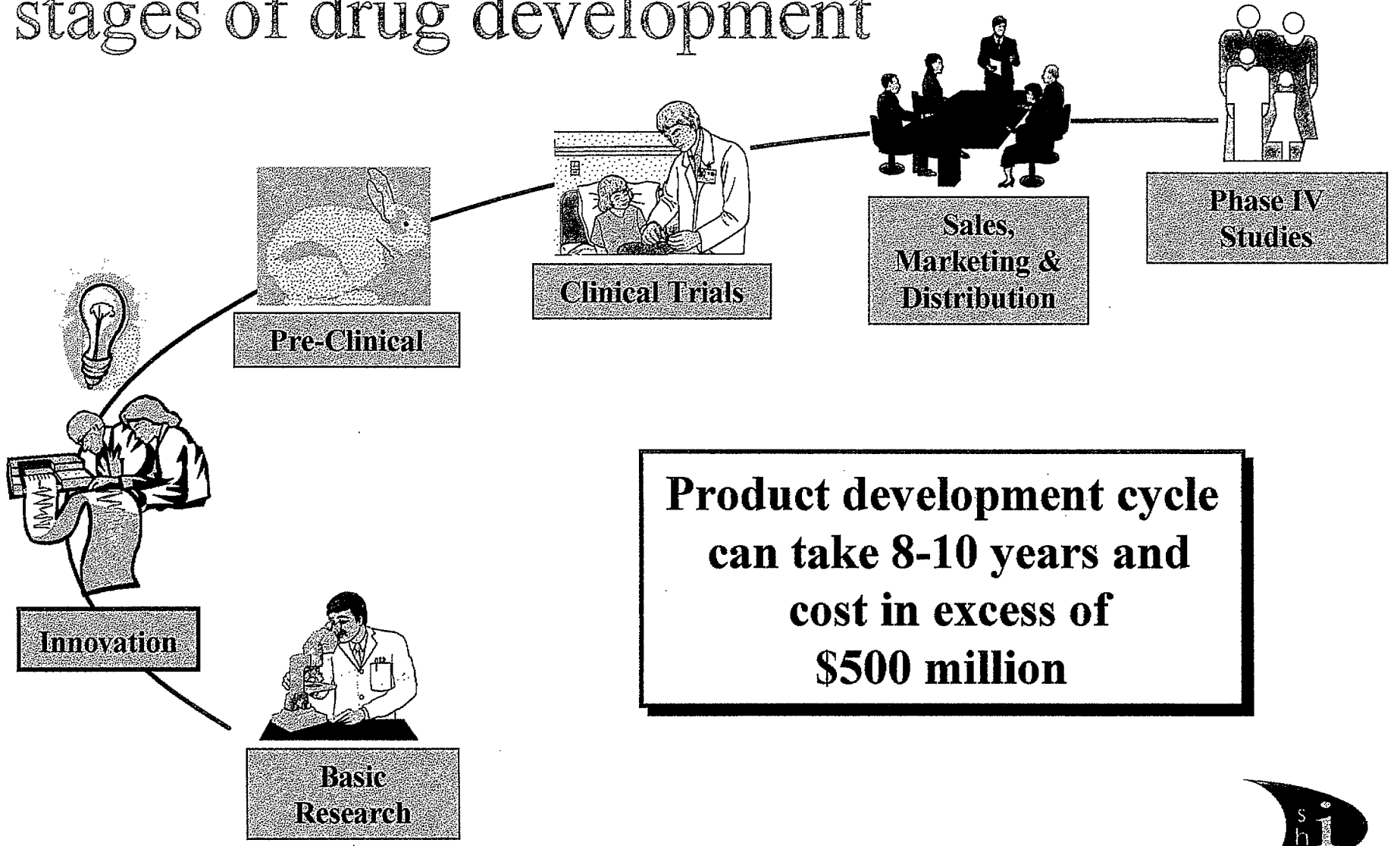
Market valuation of Canadian Biopharma industry has been as high as $18 Billion



Source: National Bank Financial

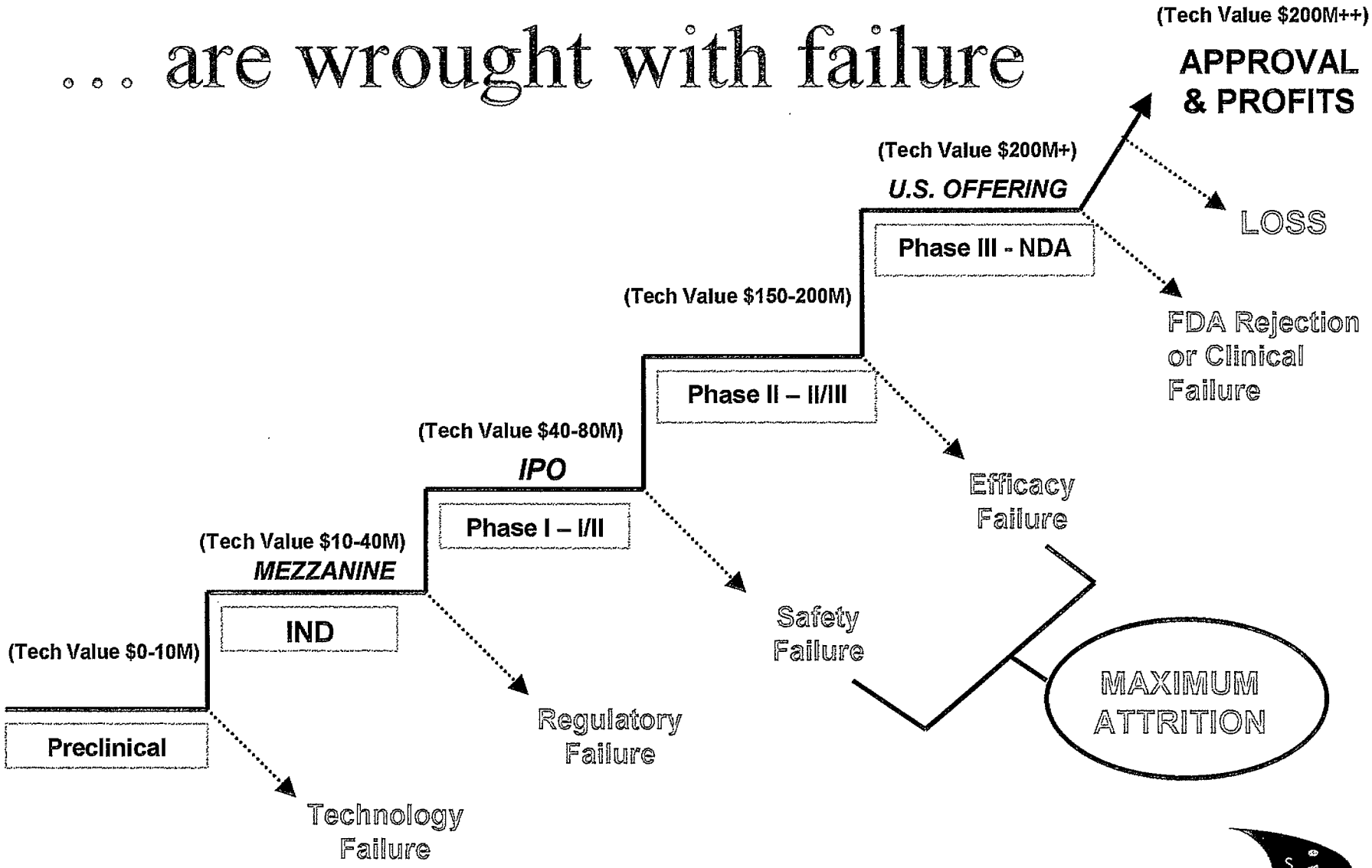
**As of November 1, 1999*

Canadian companies are involved in all stages of drug development

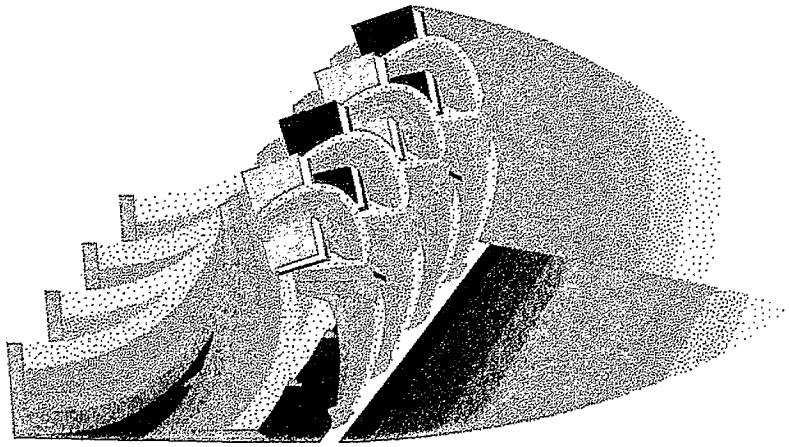


Product development cycle can take 8-10 years and cost in excess of $500 million

Steps to Success . . .
. . . are wrought with failure



Challenges Facing The Biopharma Industry Worldwide



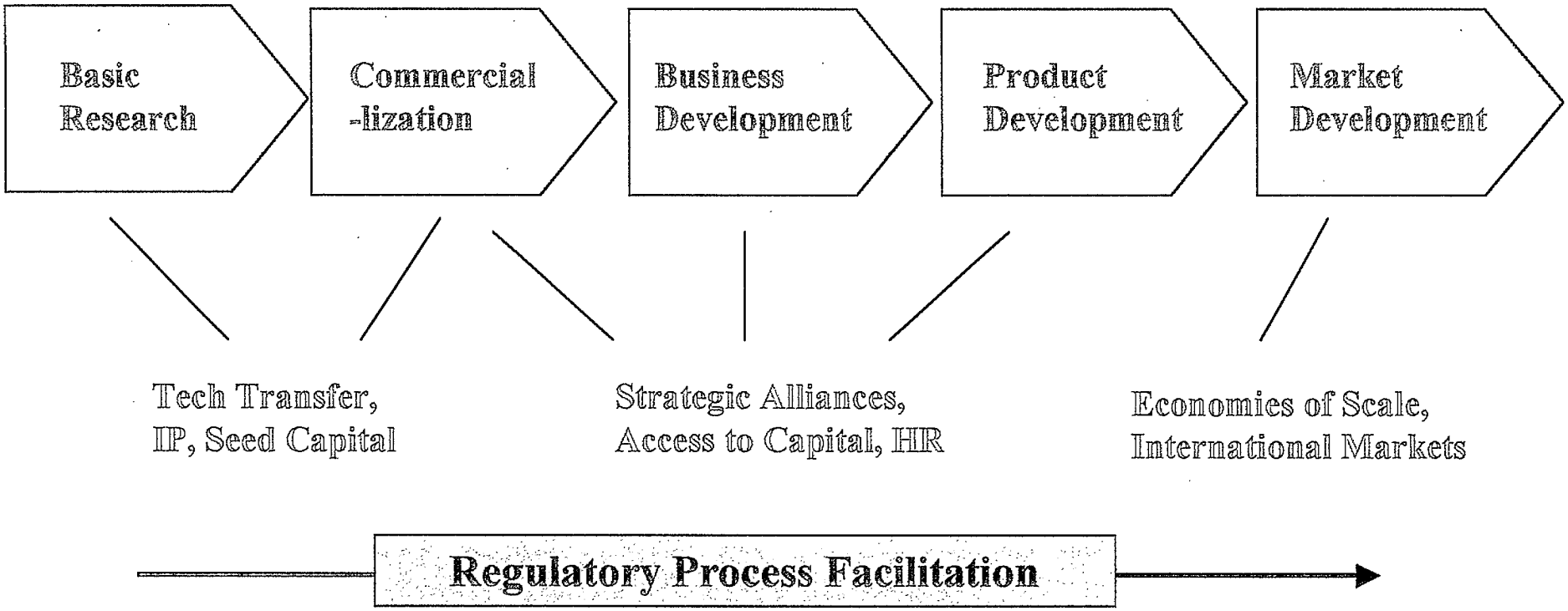
- Cost containment, (higher health care costs, lower drug sales)
- Patent expiration
- Shorter periods of exclusivity
- Fewer blockbuster drugs
- Changing consumer landscape
- New technology platforms are increasing competition

Product Development

ROI greater downstream in product development

Basic Research	25
Phase I Clinical Trial	5-10
Phase II Clinical Trial	10-15
Phase III Clinical Trial	15-25
Manufacturing and Marketing	35+

Value Chain Analysis



Source: Strategic Health Innovations, 2000

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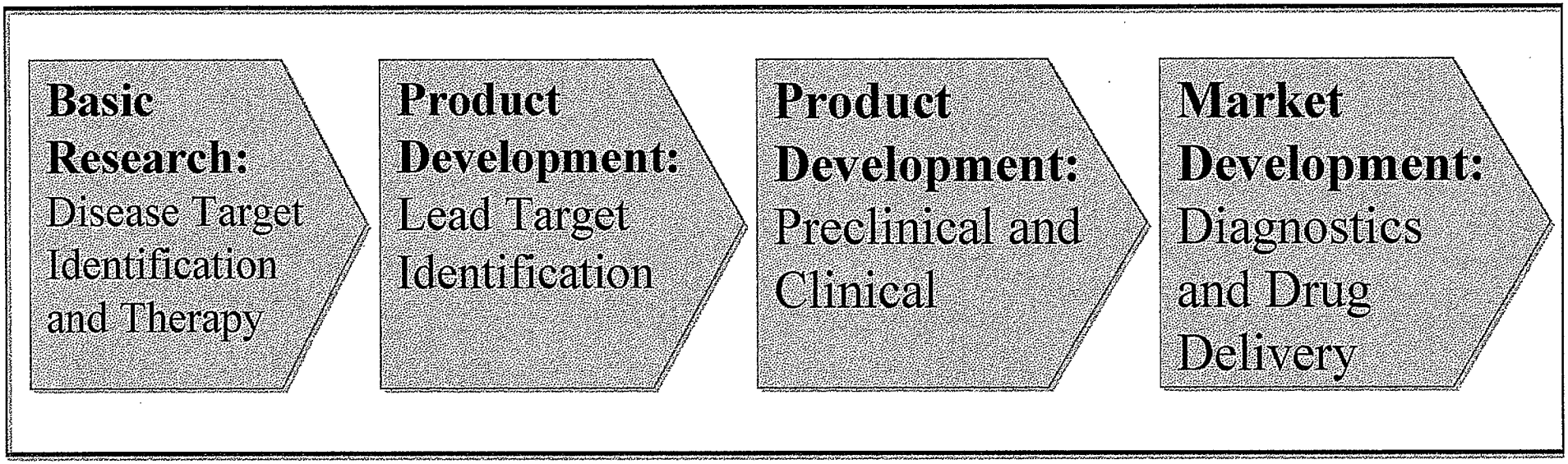
Drug Discovery Stages



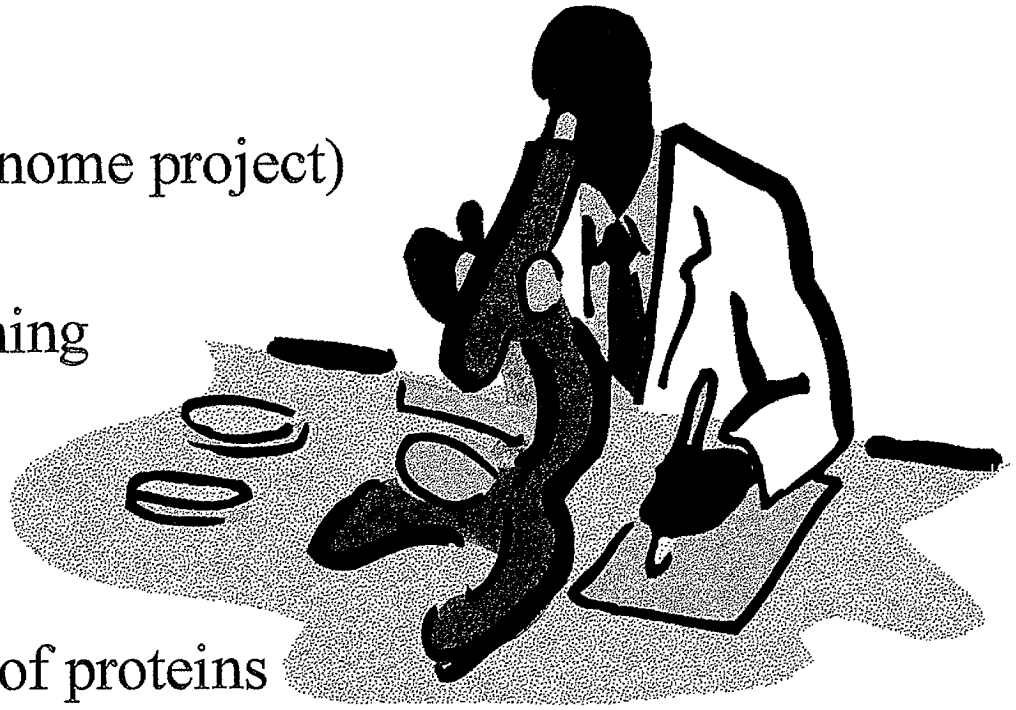
Source: Strategic Health Innovations, 2000

Technology Drivers

BR | PD 1 | PD 2 | MD

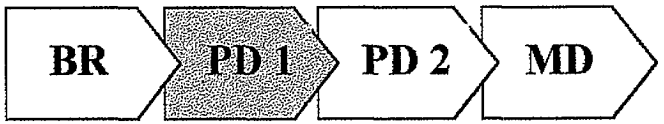
Basic Research:
Disease Target Identification & Therapy

- **Genomics**
  - Gene discovery (eg. genome project)
  - Gene chip technology
  - High throughput screening
  - Functional genomics
  - Bioinformatics
- **Proteomics**
  - Functional elucidation of proteins
  - 3D structures (mass spectrometers)



Technology Drivers

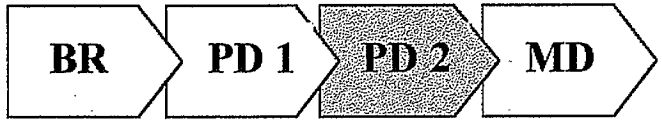
Product Development I: Lead Target Identification



- **Combinatorial Chemistry**
  - Synthesis of a large variety of compounds that can be screened for the presence of a drug target
  - Chemical "libraries" for screening
- **High Throughput Screening**
  - Analytic technologies to screen large numbers of elements for a particular biological characteristic
  - Affinity processes to separate elements of interest
- **Rational Drug Design**
  - Structural design based on 3D shape of the target receptor
  - 3D elucidation through of target by X-ray crystallography

Technology Drivers

Product Development II: Preclinical & Clinical

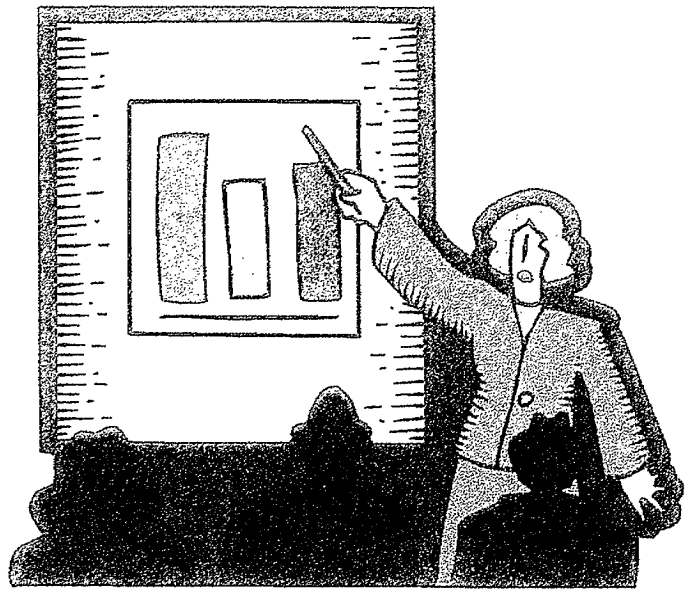


- **Pharmacogenetics**
  - Targeting drug response and development based on genotype (eg, Wellcome Trust SNP Consortium)
- **New Therapeutics**
  - Gene therapy
  - Cellular therapy
  - Photodynamic therapy
  - Carbohydrate Based therapy
  - Monoclonal antibodies
  - Angiogenesis
  - Transgenic models

Technology Drivers

Market Development: Diagnostics & Drug Delivery

- **Drug Delivery**
  - Needleless technology
  - Silicon chip delivery
  - Aerosols
- **Diagnostics**
  - Gene chip (nanotechnology)
- **Information Technology**
  - WWW consumer based interactions
  - Trial recruitment
  - Home DX with WWW based support and advice



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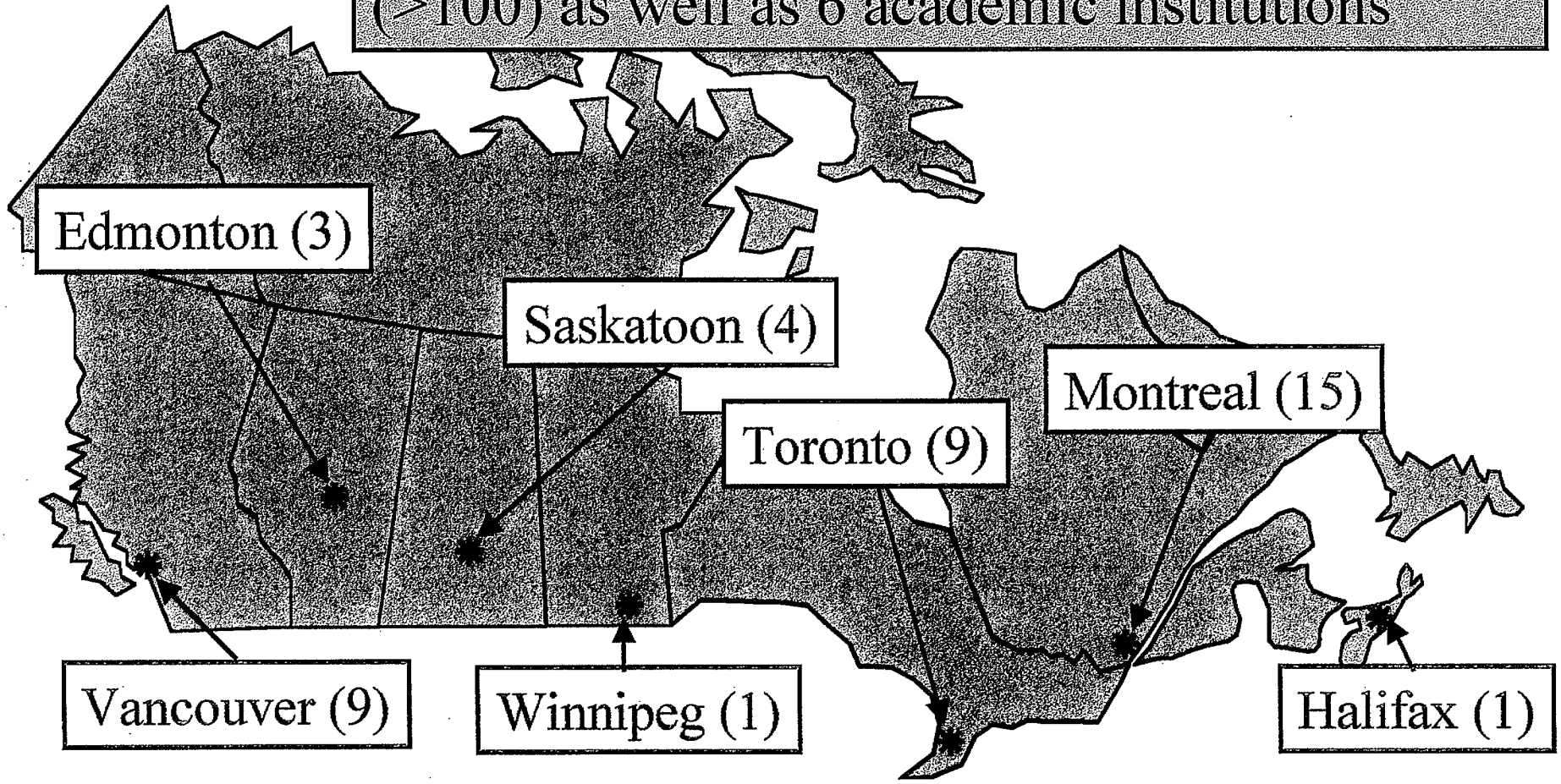
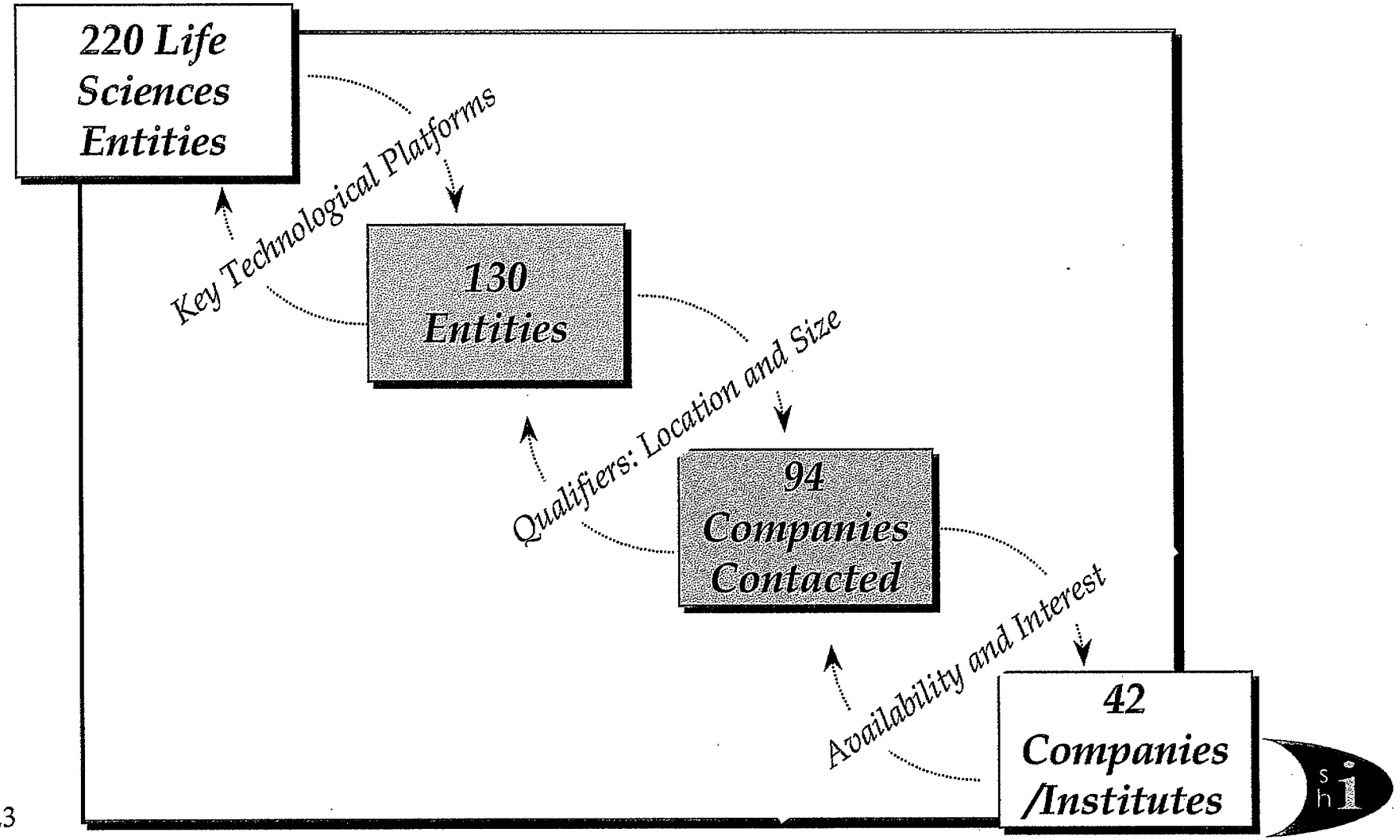
Consultation Methodology

Consulted 36 biopharma and service companies ranging from small (<30) to large (>100) as well as 6 academic institutions



Methodology for Participants' Selection

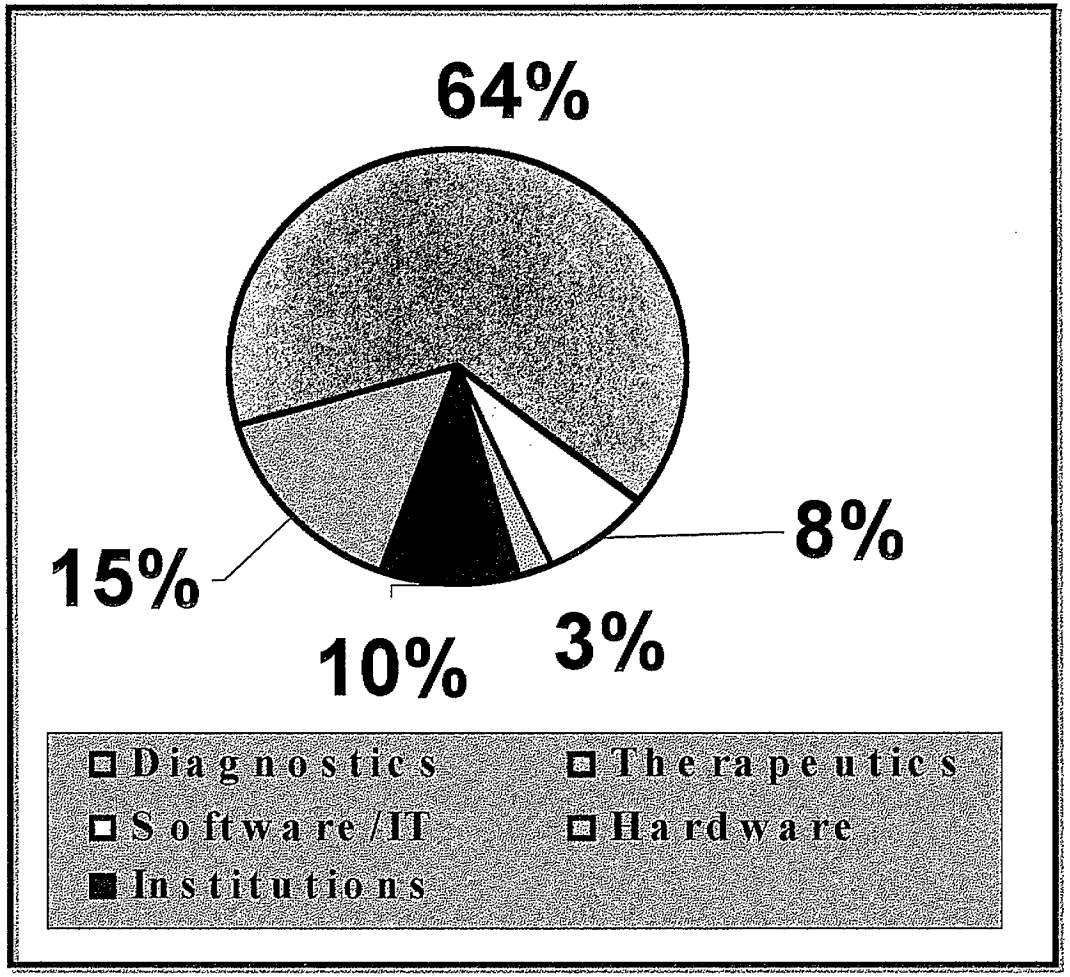


Issues Discussed During Each Stakeholder Consultation Include:

- ✓ Stakeholder's stage of involvement according to the value chain
- ✓ Industry themes and trends
- ✓ Current and future technology needs
- ✓ Canadian strengths, weaknesses, opportunities and threats
- ✓ Canada's global competitiveness in biopharma
- ✓ Interest in participating in an industry-led and government-facilitated Technology RoadMap Initiative

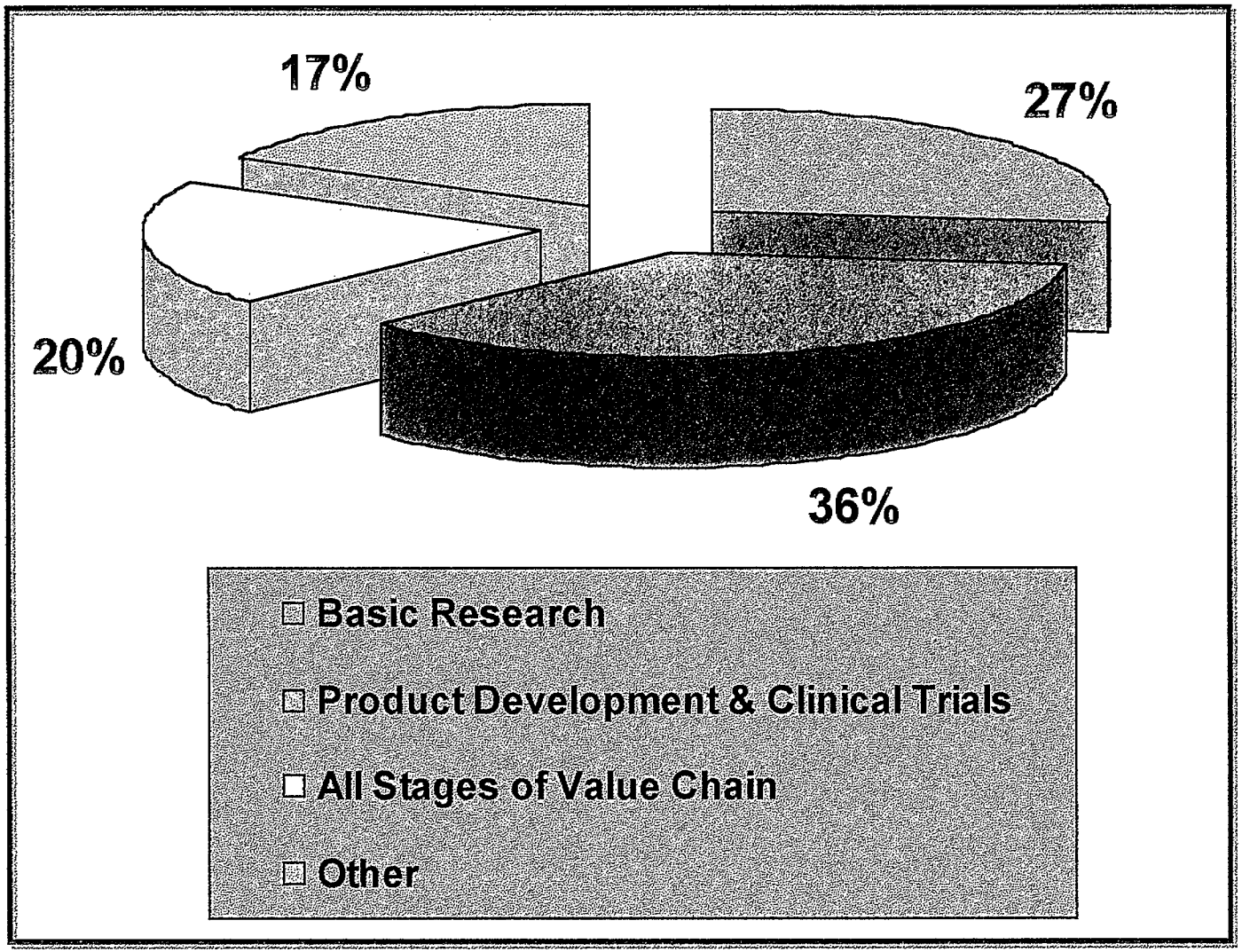
Consultation Participants by Industry Subsector

- 2/3 of the companies consulted focus on therapeutics
- Less than 1/3 of the companies are conducting R&D in non-therapeutic subsectors

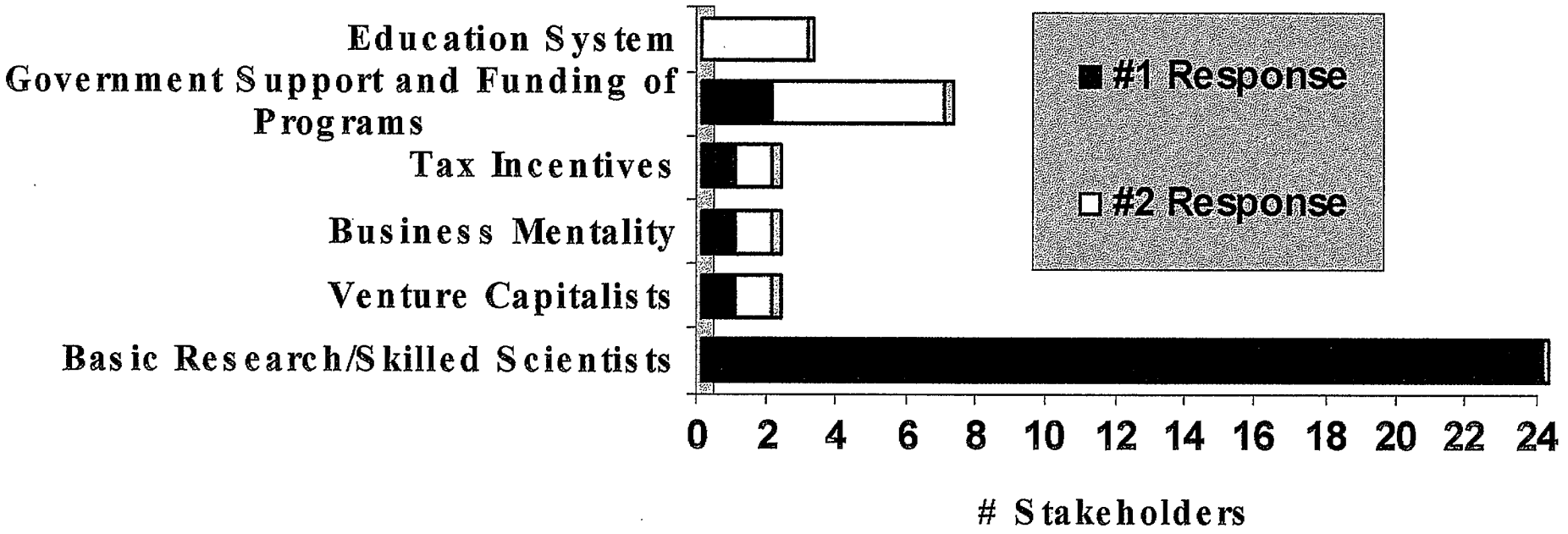


Drug Discovery Stages:

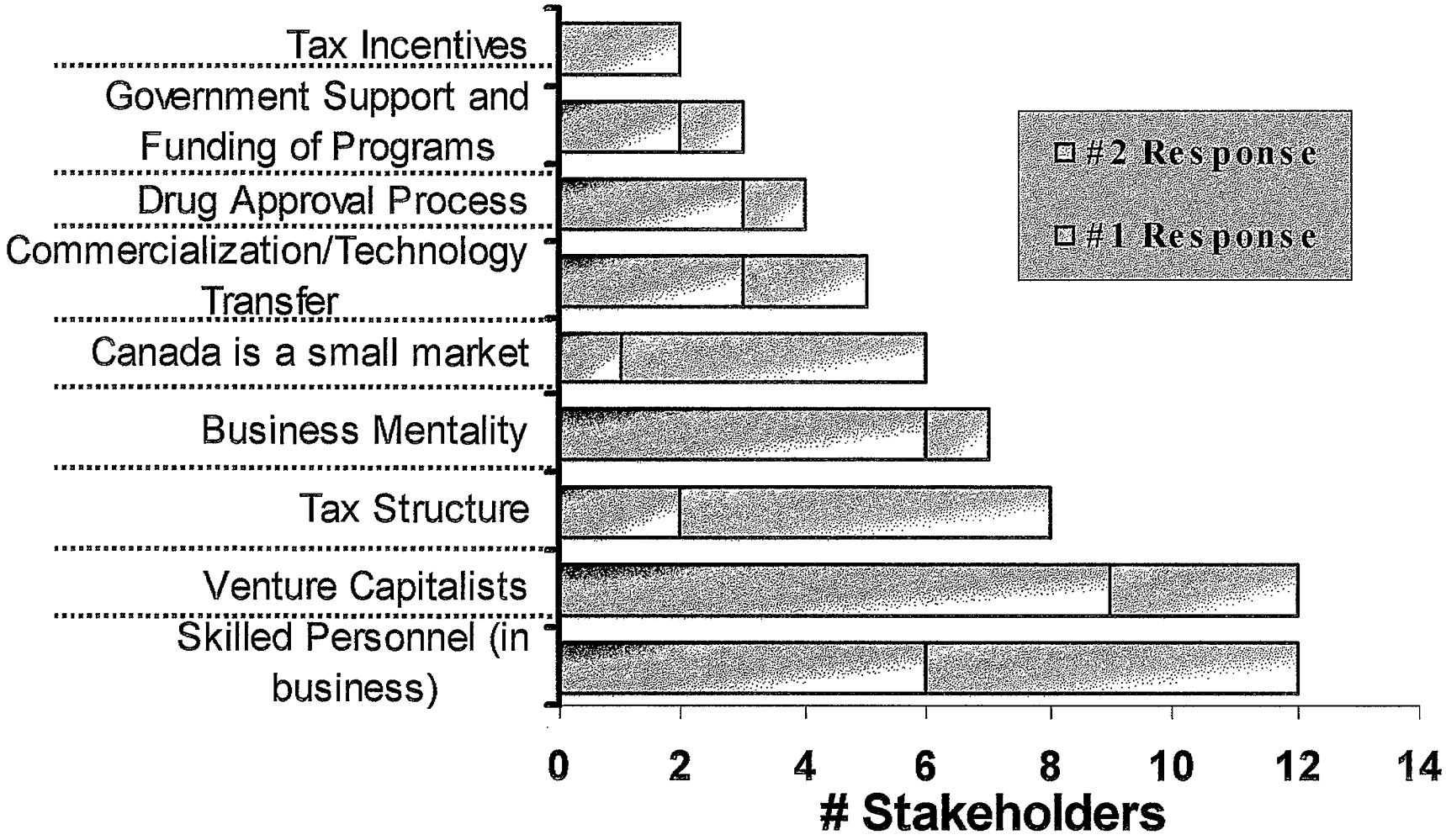
Stakeholder Stage of Involvement



Canada's Business Environment Strengths

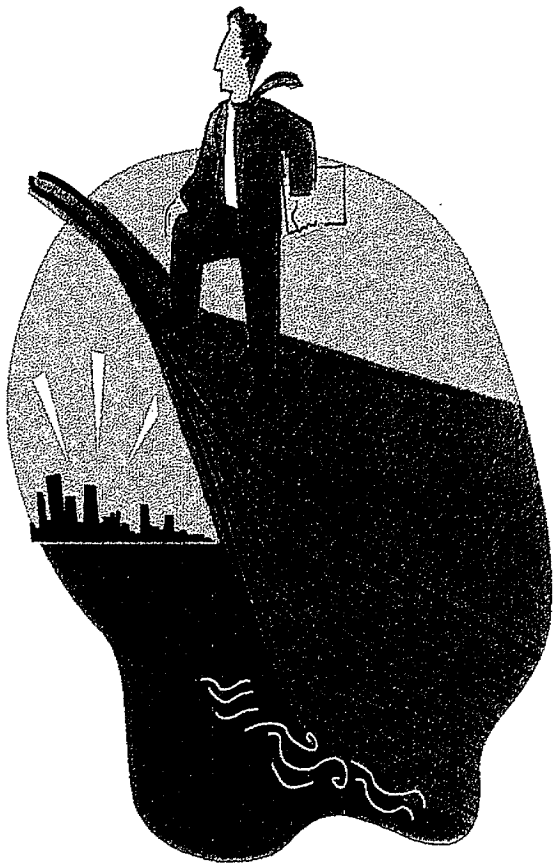


Canadian Business Environment Weaknesses



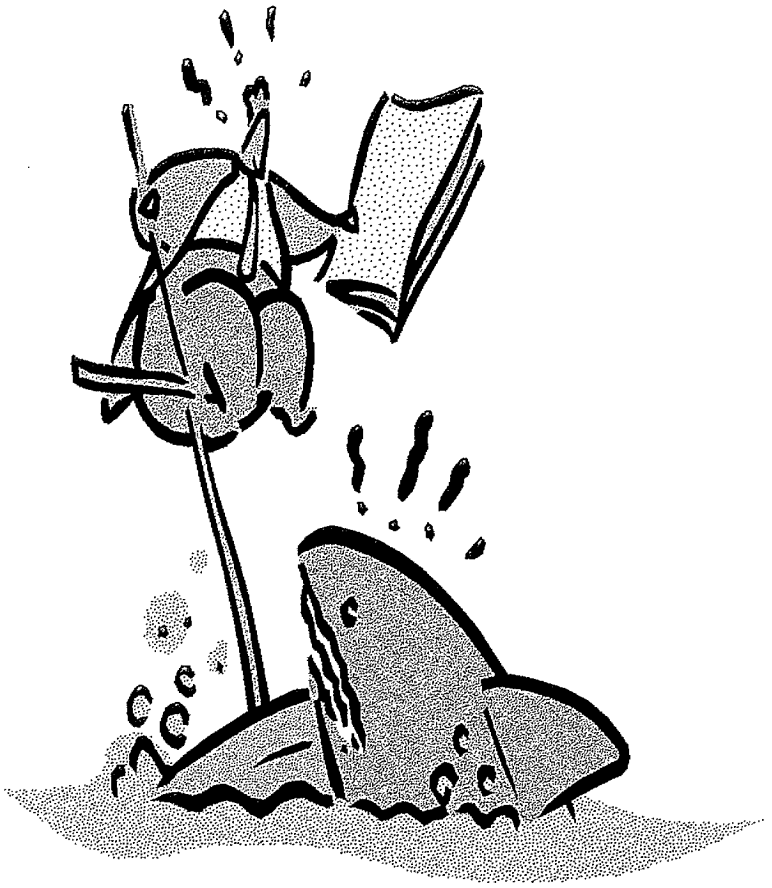
Canadian Biopharma Industry Opportunities

- Potential to be the **top-ranked country worldwide for clinical trials**
- Potential to develop **innovative technological niches,** e.g. drug delivery, contraception, gene therapy, nanodesign
- Formalize cross-sector networking and **develop leadership in cross-sector research in convergent technologies**
  - **Information technology** (a Canadian strength) is cheaper to develop than biotechnology
- Ethnic composition lends itself to **founding population research**
- Lead in areas where knowledge and expertise are important, e.g. **genetic epidemiology or disease pathophysiology**



Canadian Biopharma Industry Threats

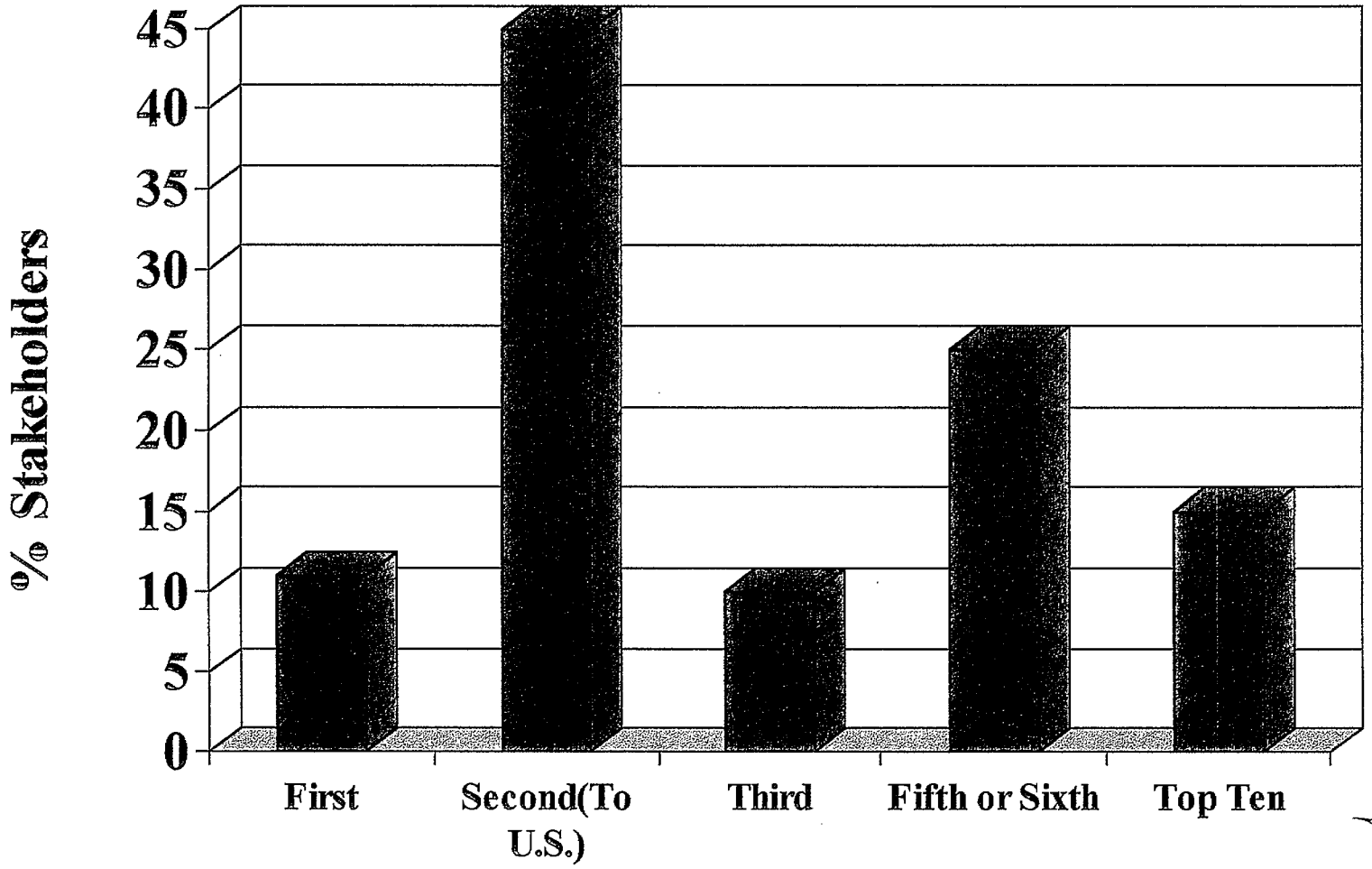
- International threats
  - Perception that countries such as Germany and Ireland have displaced Canada from its rank of 2nd or 3rd several years ago
- Canada will export basic research and buy it back at a more developed stage
- Being relegated to "toolkit" companies that develop and then sell technologies, rather than developing health care drug products



Provincial Themes

- **Quebec**
  - Satisfied with business structure, tax credits, and tax holidays
  - McGill perceived to be excellent at technology transfer
- **British Columbia**
  - BC NDP government poorly perceived by biotech sector (lack of funding and tax incentives)
  - UBC located incubator and biotechnology co-op programs well regarded
- **Ontario**
  - Lack of tax incentives was key concern
  - Newly created Biotech incubator fund was viewed positively

Canada's Global Competitiveness: International Ranking of Canadian Biopharma



Industry Themes & Trends

Themes

- Canada is globally recognized for innovation in **basic research**
- Geographical dispersion and provincial barriers have created a **need for infrastructure and community** for industry to interact, learn from each other, collaborate, and obtain critical mass
- Result of technological convergence is that **no one individual or company will have the expertise** to develop basic research and commercial products
- A **mechanism for creating linkages** between the key stakeholders—government, academia, pharma, biotech, hospitals and NCEs—would enhance the business infrastructure for developing drug products in Canada
- Need to **identify specific niches** in which Canadians can compete, e.g. clinical trials and innovative technologies
- Some firms feel they may have to become American to grow unless Canada **improves the business infrastructure and enhances recognition and valuation**

Industry Themes & Trends

Trends

- Due to the **high burn rate** many firms need to partner earlier than expected
- Most Canadian biopharma companies have strategies for **retaining their technological products in-house** for as long as possible since a higher return on investment is gained as we move along the value chain
- Convergence of technology is creating the **need for cross-sector academic research** and increasing the time spent on sourcing strategic partners
  - The most desirable alliances are with Cdn biopharma, Cdn academia, and non-Cdn pharma and biopharma

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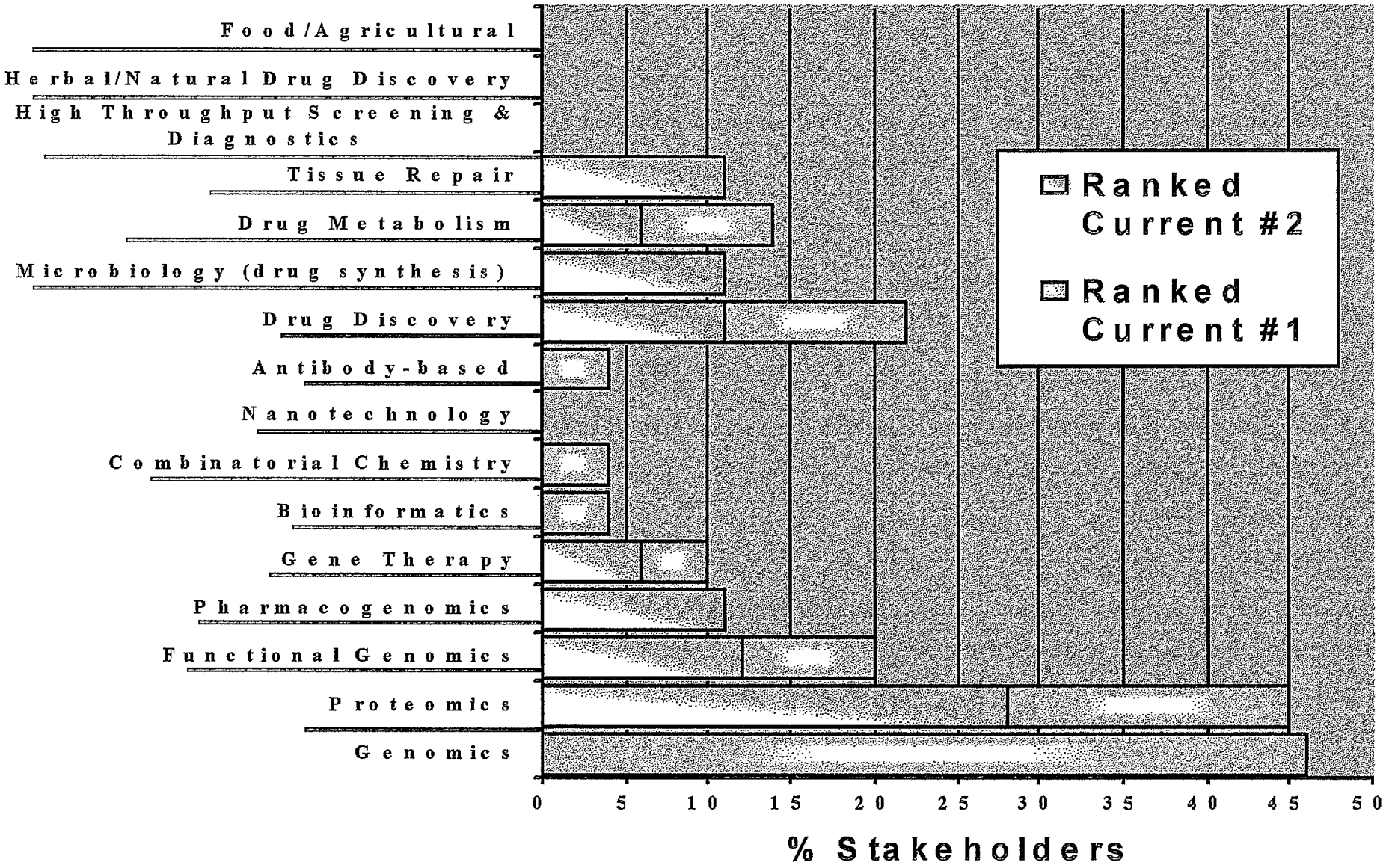
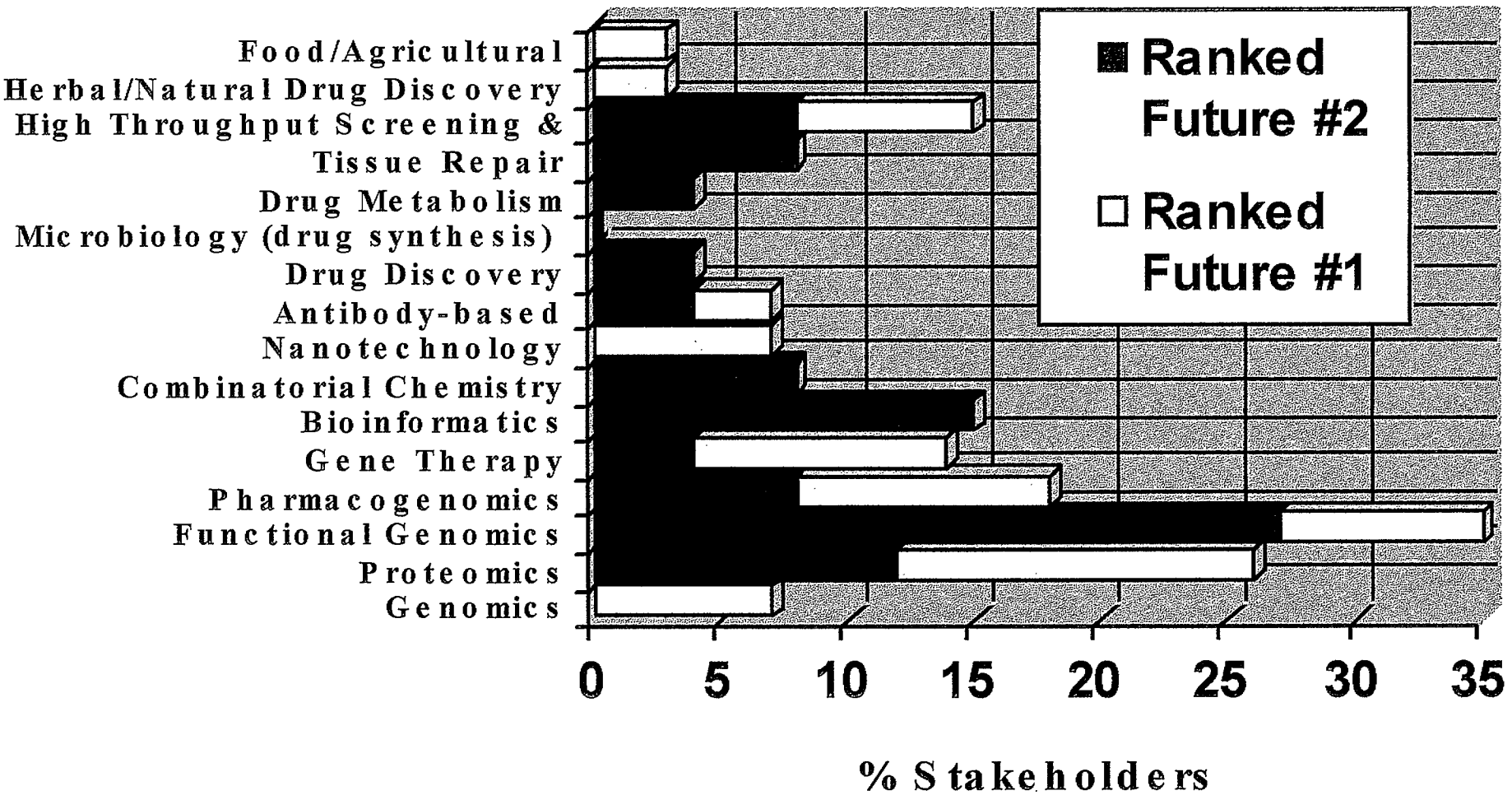
Most Important Technologies Needed for the Biopharma Industry Today



Future Technology Needs



Technology Drivers

Themes

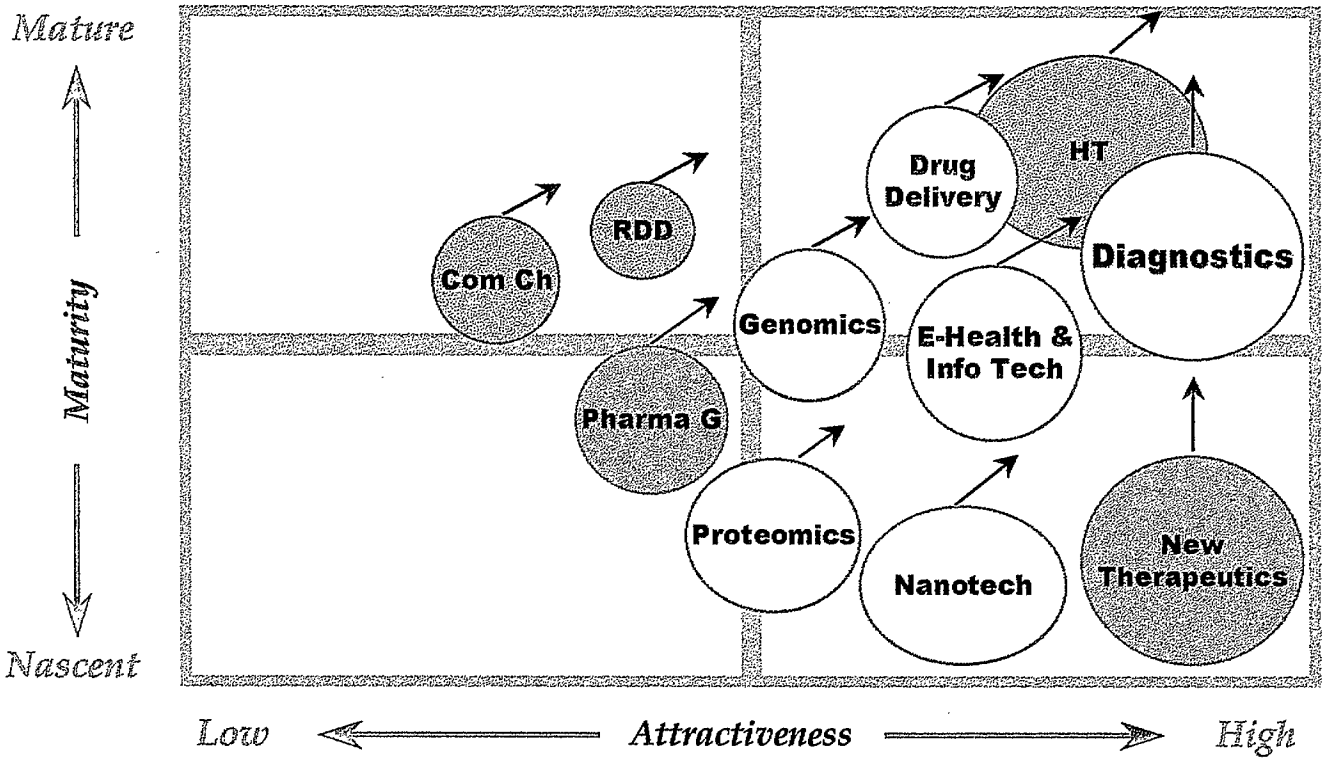
- Canada has a **wealth of scientific and technological expertise** that is waiting to be recognized and accessed
- There is a **lack of critical mass**, especially compared with the United States, in the promising technologies of the future
- Canadian companies are now looking forward to the **"post-genomics" era** in which the information gathered from the Human Genome Project will be interpreted and applied to drug targets

Technology Drivers

Themes

- Critical future technologies will be **functional genomics, proteomics, gene therapy** and **pharmacogenetics**
- **Canadians *have* the technological expertise to develop products that will drive the biopharma industry over the next 5 to 10 years**

Several technologies will lead the next biopharmaceutical revolution



Notes:

1. *Size of circles represents the size of the market*
2. *The arrows denote the direction of growth*
3. *Colours denote drug discovery stage*

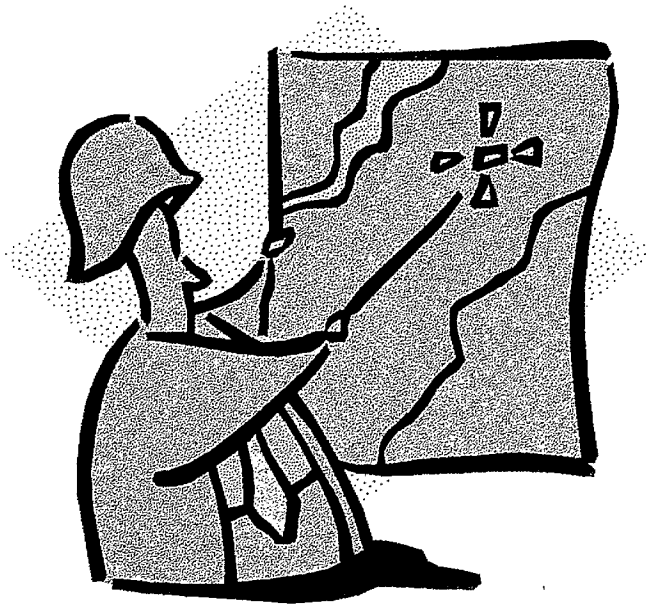
Com Ch = Combinatorial Chemistry
HT = High Throughput Screening
RDD = Rational Drug Design
Pharma G = Pharmacogenomics
DD = Drug Delivery

Yellow = Basic Research
Blue = Product Development 1
Green = Product Development 2
White = Market Development

All of those consulted were interested in participating in a full scale "Technology Roadmap"

However, concerns included:

- Level of **time commitment**
- Level of **interaction** (e.g. number of people involved in discussions)
- Assurance that there would be **wide representation across stakeholders**, including government funding agencies, pharma, venture capital and government industry reps



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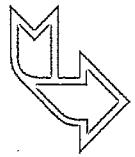
TRM Recommendations

1. Implement the Technology Roadmap Initiative for the Biopharmaceutical industry.

Action Step

Ensure that stakeholders' concerns are addressed before and during implementation of the TRM

2. Examine models for different formats for implementing the TRM



Action Step

Examine models such as the Ontario Jobs and Investment Board format of small round-tables in separate pools with final presentations to the entire group.

TRM Recommendations

3. Expand the Technology Roadmap to include other industry sectors and technologies.

Action Step

Include representation from related technologies

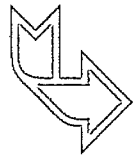
4. Ensure Roadmap process is well designed.

Action Step

Design Roadmap efficiently and effectively to ensure that individuals have a defined role as catalysts and that interactions between Biopharma firms and companies from other industries are achieved.

TRM Recommendations

5. Ensure that there is sufficient representation from larger biotech/pharma companies.



Action Step

Invite larger biotech/pharma stakeholders to the Technology Roadmap Initiative

6. Create an opportunity for follow-through.

Action Step

Ensure involvement of Deputy Minister and Minister so that industry retains confidence and is not disillusioned by the process

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Recommendations

- **Educate consumers, analysts and investors** about Canadian biopharmaceutical opportunities in order to recognize the value in the market
- Concentrate **more funding on fewer companies with niche and competitive concepts**, e.g. Ventures West's new $200 million fund
- **Establish a more favourable regulatory environment** to approve future technological products, e.g. pharmacogenomic products

Recommendations

- **Celebrate successes** in biopharmaceuticals
- **Benchmark other countries with regards to business infrastructure for biopharmaceuticals**,
  - U.S. Small Business Granting Program and stock option taxation
  - Germany/Europe's potential to leapfrog Canada
  - Ireland's government focus on decreasing taxes and improving investment opportunities
- Create a community or **system for linking geographically disparate companies** in order to obtain critical mass in technological expertise

Recommendations

- **Ensure accurate and speedy dissemination of information** regarding the availability of new funding programs and incentives
- Interact with agencies such as Genome Canada as well as national and provincial funding programs (such as Technology Partnerships Canada) to **highlight funding and infrastructure programs for novel technologies**
- **Implement training programs in new critical fields** of biopharma
  - Link with BIOTECanada and BHRC

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TRM - Next Steps

- Organize a preliminary national **roundtable conference** with approx. 40-50 stakeholders
- Conduct an international **benchmarking study** to identify innovative processes and programs
- Formation of **subcommittees** to facilitate the TRM process
- **Continue to conduct industry consultations** (carried out by IC or other group) to maintain focus, obtain continuous input, and build enthusiasm and consensus
- Form a TRM **Project Steering Committee**...

Project Steering Committee
-- Suggested Members --

- Gordon Stranks
  - BioTools Inc, Alberta
- Alan Bernstein
  - Director, Samuel Lunenfeld Institute, Ontario
- Jeremy Carver
  - President and CEO, GlycoDesign Inc, Ontario
- Graham Strachan
  - Senior Advisor Business Development, University of Toronto, Ontario
- Andre de Villers
  - President and CEO, Theratechnologies Inc., Quebec
- Michael Winther
  - Quantanova Inc.. Quebec

Borys Chabursky, President

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