Trends in Innovation in Middle Income Countries: The Case of Biotechnology

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INNOVATION AND ACCESS TO MEDICAL TECHNOLOGIES
CHALLENGES AND OPPORTUNITIES FOR MIDDLE-INCOME COUNTRIES
A JOINT TECHNICAL SYMPOSIUM BY WHO, WIPO AND WTO
GENEVA, 5 November 2014

Bio Biotechnology Industry Organization

Outline

I. Business Model for Global Bio-pharma Industry

II. The “Global Ecosystem” for Innovation

III. Industry Indicators, Selected Countries

IV. Success Factors & Comparative Assessments

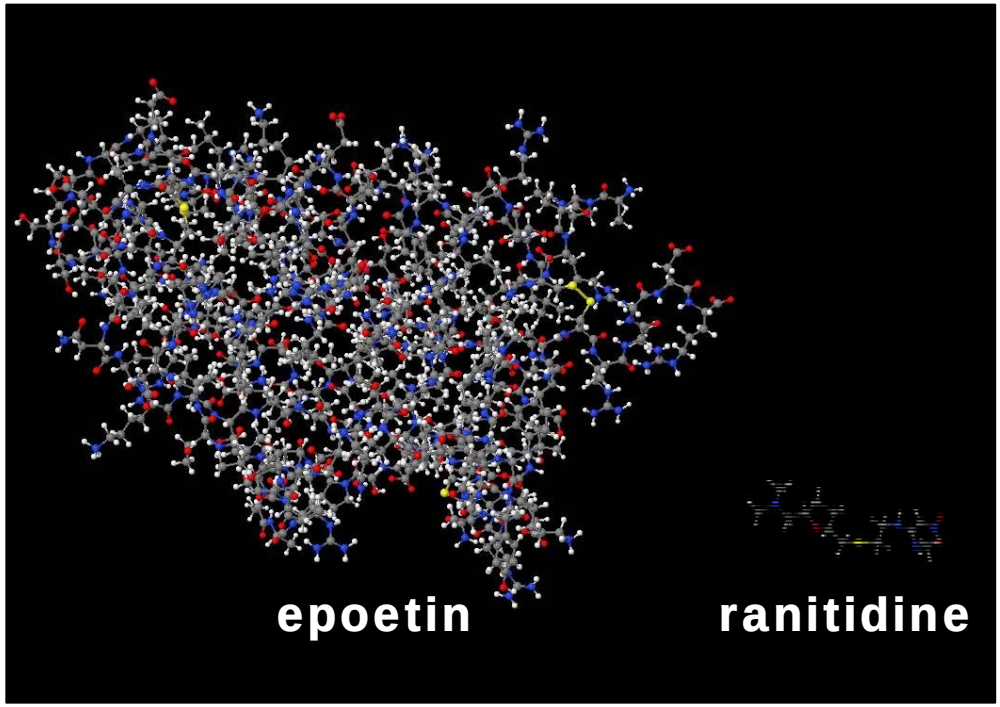
V. Innovation and Access to Medicines: Data on Public Policy Implications

BIO Business Model

- **Lengthy, Expensive and Risky**:
  - Average Development time: 10-15 years
  - Average Cost of Development: $1.2 billion
  - Success Rate: Only 10% of clinical trial projects result in approved drugs

- **Biotech Drugs: Increasingly Important – future of industry**
  - Biologics industry estimated to grow 7% annually between 2011-2016 vs. 3% for the rest of pharma
  - But: development and manufacturing expense high
- **Two-Thirds of Biotech Drugs in Pipeline: Small Companies**

Drugs of Biological Origin Have Multiple Layers of Complexity



Origin	Product	Molecular Weight
Chemical	Aspirin	180
	Ranitidine	351
	Atorvastatin	1209
Biological	Insulin	~5800*
	Epoetin	~30000*
	Factor VIII	~266000*

** brand dependant*

Biotech Development is a Global "Ecosystem"

Basic Research
(Universities, **Public Research Institutions**)

Established Enterprises

Research collaboration, technology transfer

Product development, testing, manufacturing scale-up, sale/distribution

Biotech Companies
(startup/small business)

Funding
(Private Equity, **Public Funding**, Development Partners)

Product Development timeline

Initial Discovery

Development and Validation

Product Identification and Testing

Large Scale Testing, Manufacturing

Regulatory Agencies (FDA/EMA/ PMDA)

Gov't & Private Insurers

GLOBAL PATIENTS

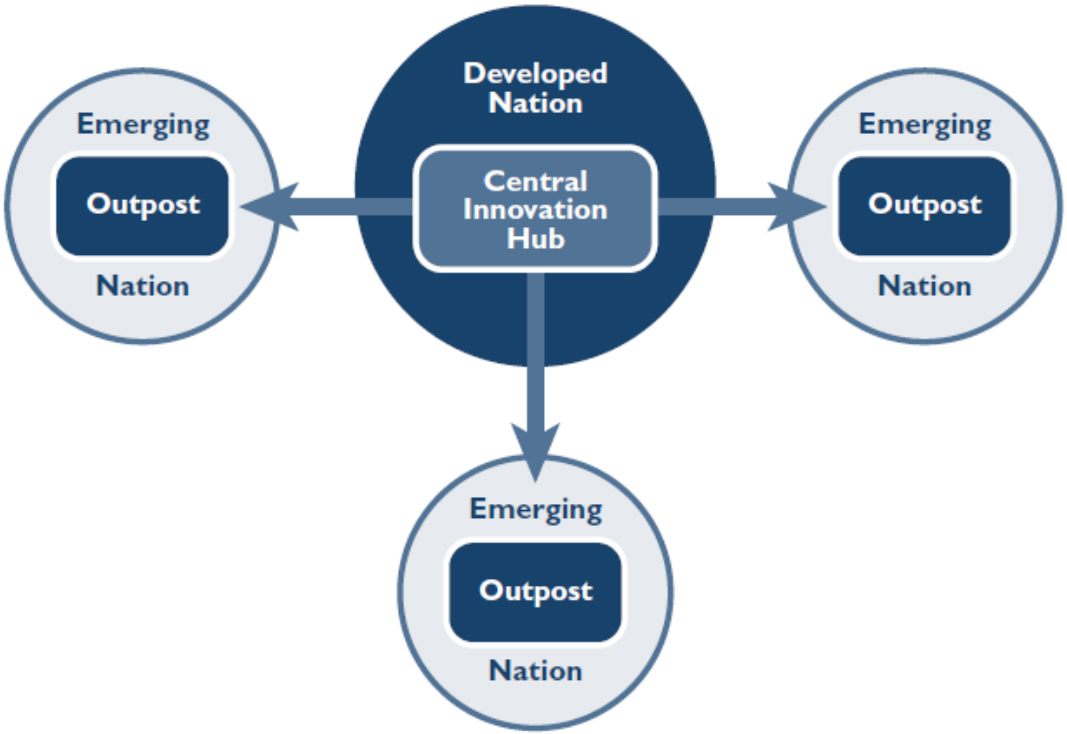
Emerging Countries role in the Ecosystem: Growing

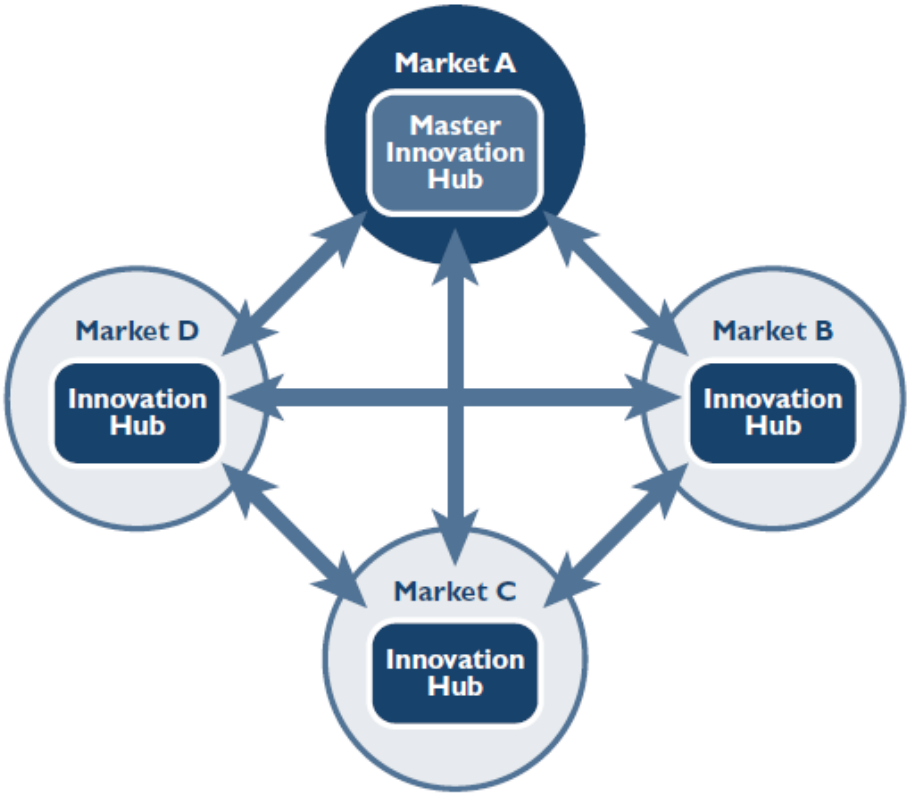
Start of Phase	Relationship
1980	Low-cost manufacturing performed in emerging countries of **products designed for developed** countries.
1995	**Low-cost, routine R&D performed in emerging countries** for products designed for developed countries. Complex R&D remains in developed countries.
2005	**Creative and complex R&D performed in emerging countries** for companies' next-generation products. Low-cost R&D is now a given, and **product design starts to differentiate among the various conditions and needs across markets**.
2015	**All or most stages** of the lifecycle of medical technology **performed collaboratively** with emerging countries. Products are **designed for the specific conditions and needs of unique markets such as emerging countries**.

Unleashing the Innovation Lion: How Medical Technology Companies Can Capture True Innovation through Collaboration in Emerging Countries, Frost & Sullivan, **2011**

Models of Innovation for Multinationals Also Changing (leaving out role of small biotechs)

Traditional Model of Global Innovation **vs.** New Model of Global Innovation





Unleashing the Innovation Lion: How Medical Technology Companies Can Capture True Innovation through Collaboration in Emerging Countries, Frost & Sullivan, **2011**

Global Companies Expanding R&D in BRIC Countries: Some recent initiatives

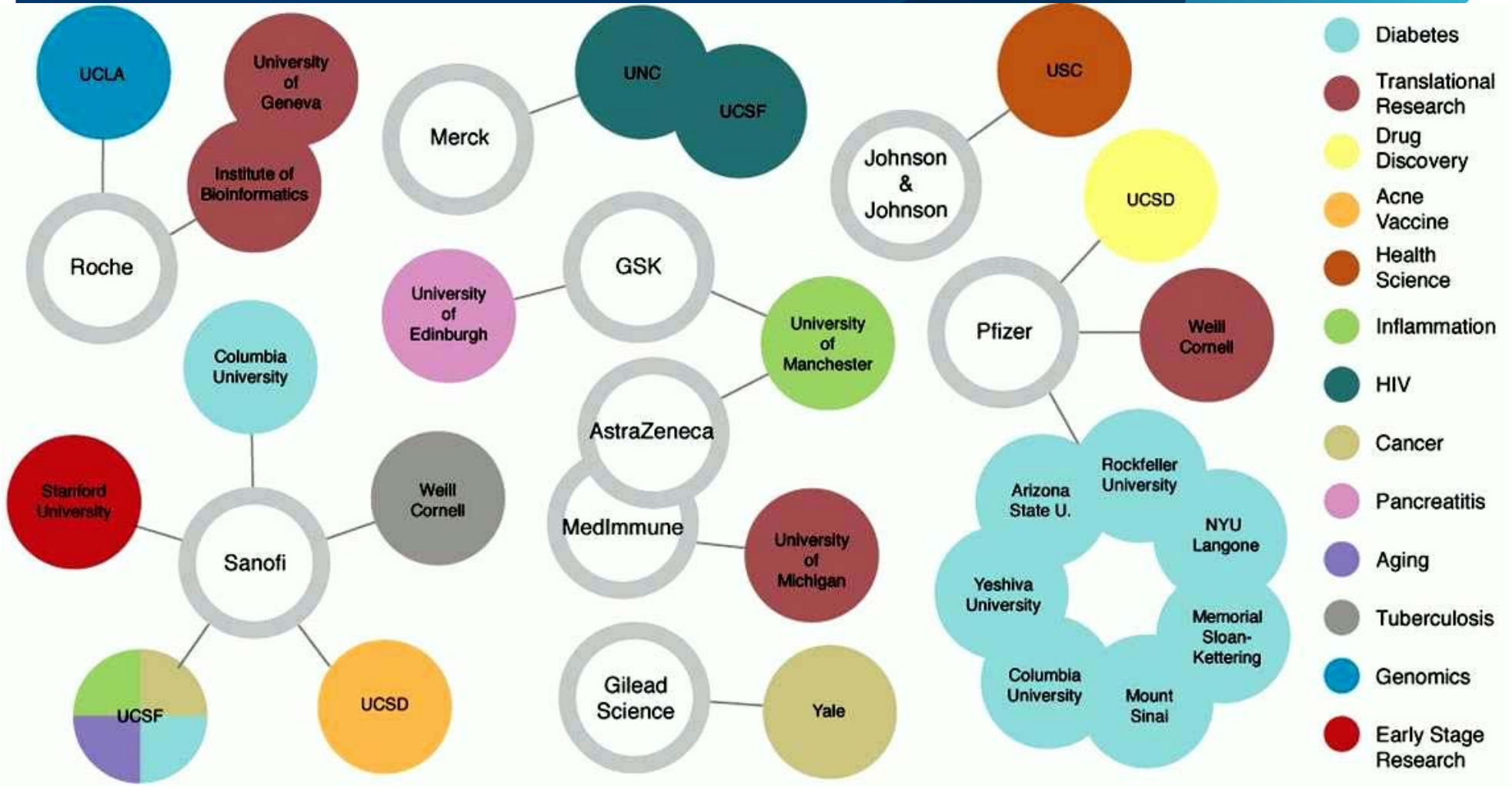
Merck builds new R&D center in China; commits $1.5 billion over 5 years

AstraZeneca establishes predictive science center to develop software to better predict drug safety

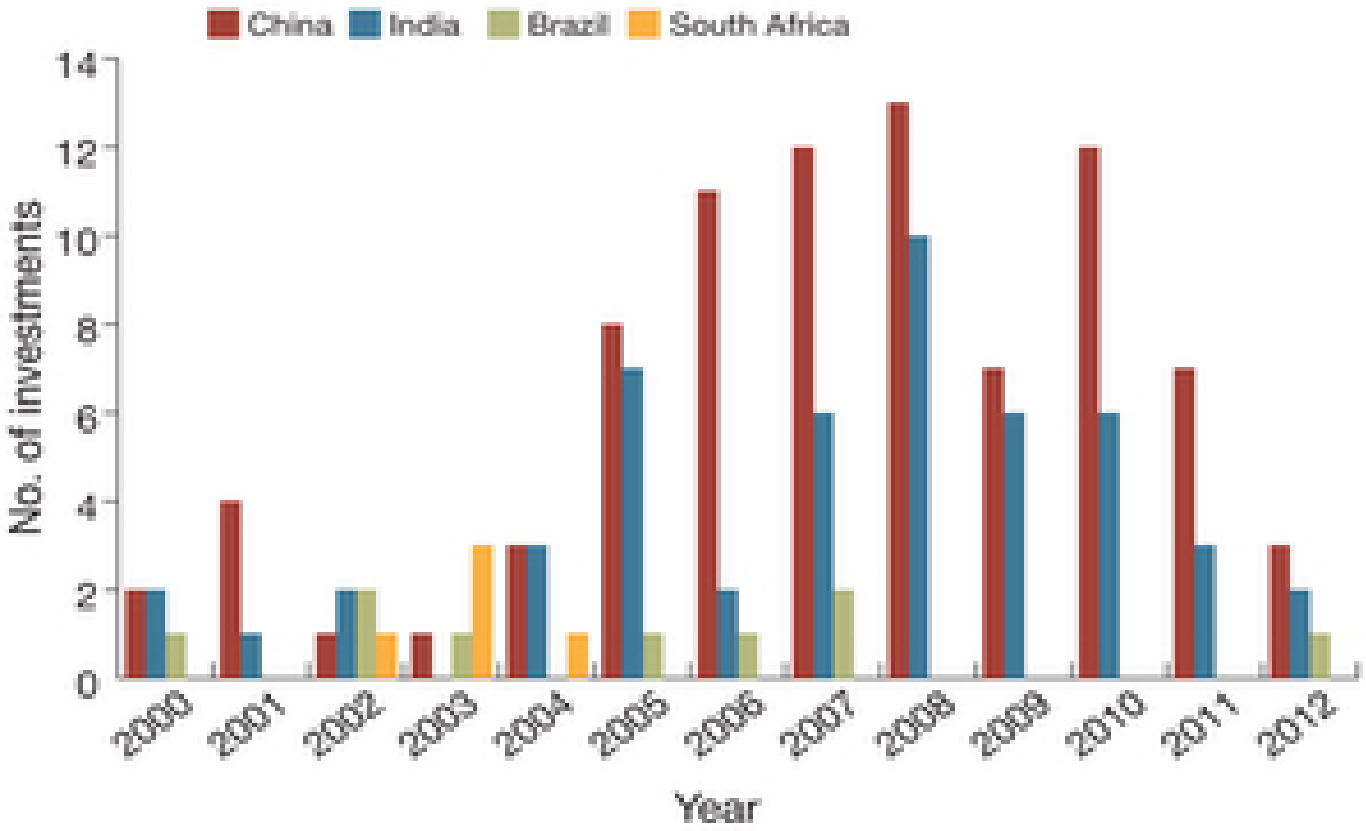
Bayer forms JV with Russian government-owned Yunona Holdings

Industry Collaboration with Academia Increasing

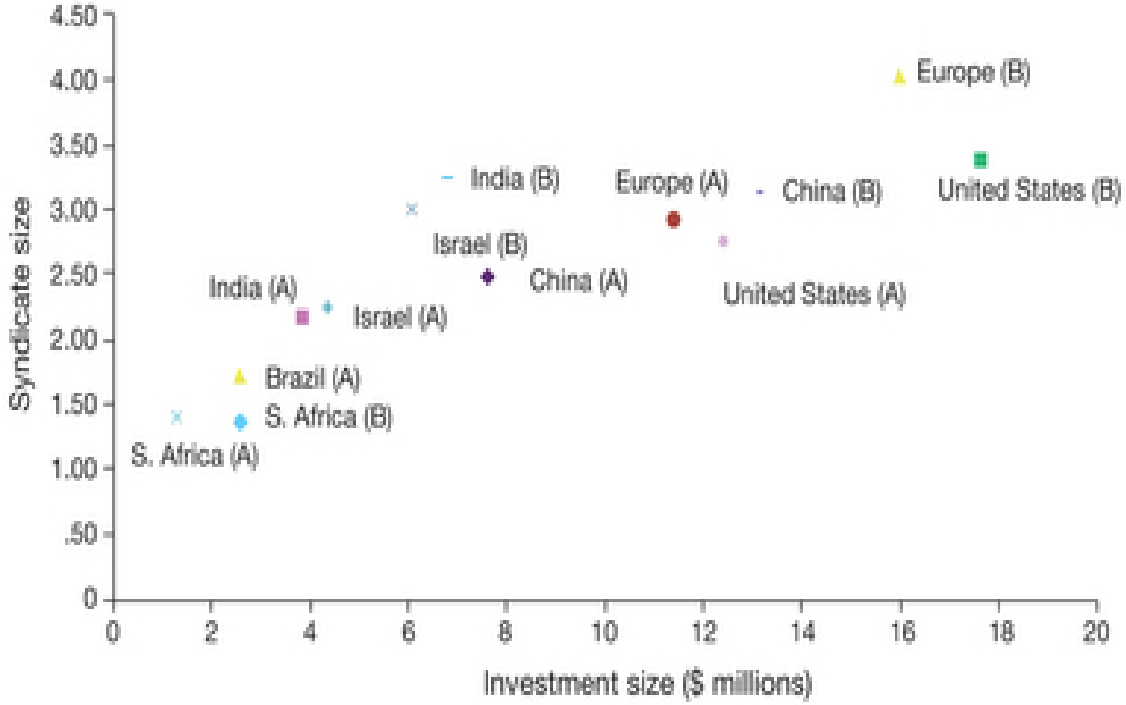
Selection of recent discovery alliances with academic institutions



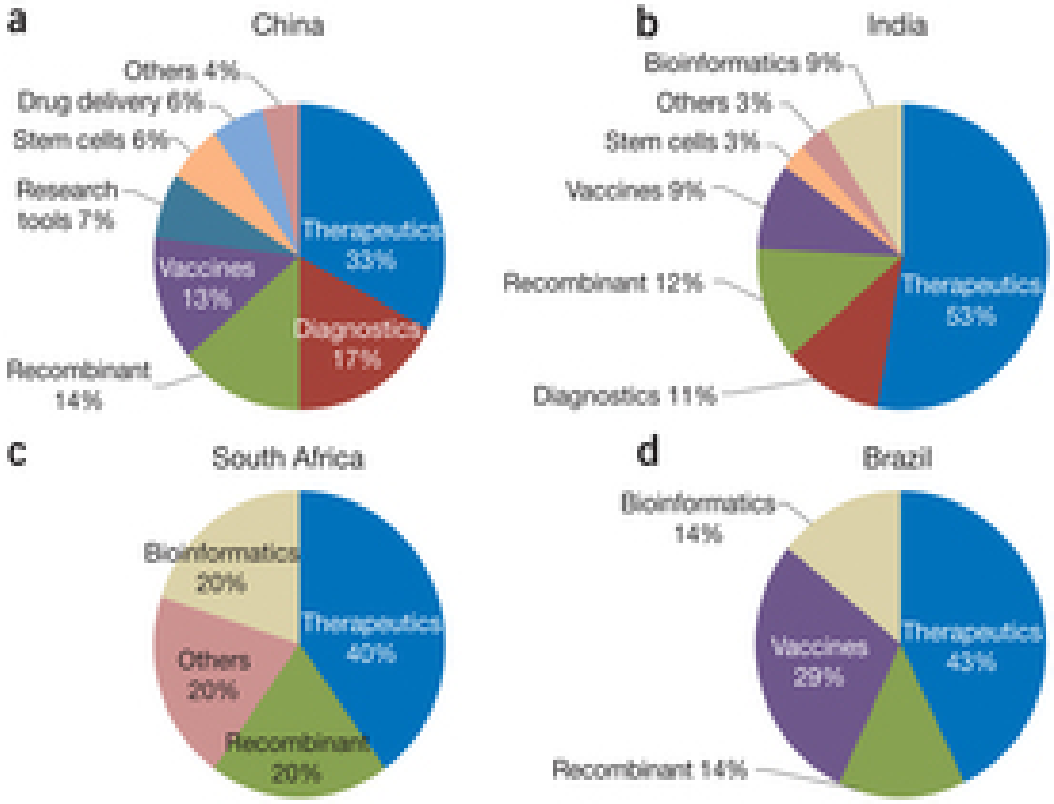
Venture Capital Deals in Some MICs



Size of VC Deals



Types of VC INvestments



Exploiting Economic Needs: Governments Become Investors

RUSNANO
Russian Corporation of Nanotechnologies

Rusnano enters $760M partnership with Domain Associates and $200M with Burrill IV

MTDC

Malaysian Technology Development Corporation co-manages the $150 million Malaysian Fund with Burrill & Company

BNDES

BNDES teams up with six other institutions to invest in Burrill Brazil I

Executive Yuan
Republic of China (Taiwan)

Taipei Authorities launch $1.8 billion fund as part of “biotechnology takeoff package”

Industry Indicators, Selected Countries

- Overall Market Trends in MICs
- China
- Malaysia
- Chile
- Brazil
- India

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Healthcare Demand Trends in MICs

- **Market**:
  - Developed world dominates current bio-pharma sales
  - Emerging markets' growth rates are 2-5x developed market rates
- **Demographics**:
  - Growing and aging population in emerging markets is driving demand for new therapies
- **Affordability**:
  - Rising income
    - E.g. middle class will account for 75% of urban households in China by 2020
  - Availability of health insurance is rising in emerging markets
    - E.g. 45% of India's population is expected to have insurance by 2020
    - But: Markets are "tiered"
- **Improving Medical Infrastructure**
- **Increasing Consumer Demand**

Donoghoe, N. *et al.* "Medical Device Growth in Emerging Markets: Lessons from Other Industries", *In Vivo: The Business and Medicine Report*, **2012**

Status of Medical Biotech Industry in China

Industry Growth

Biotechnology identified as Strategic Economic Industry in 12th 5 Year Plan

Global therapeutic biologics industry is an important component in pharma industry

- 17% of total global Pharma market
- 10 out of top 30 Pharma products by revenue are biologics

Biotech R&D spending in China: $6 billion annually

Economic Contribution

An important component of bio-industry, help transform to knowledge-based economy

- Bio-industry expected to grow at 20% CAGR and reach $640 Bn by 2015

Still underdeveloped and emerging

- Only 2% share in World's therapeutic biologics market vs 7% for China Pharma market

Source: IMS, EveulatePharma, literature search, BCG analysis

Malaysia's Bioeconomy

Indicators	Phase I (2005-2010)	Phase II (2011-2015)	Phase III (2016-2020)	Total (2005-2020)	Achievements in 2005-2011 period
Investment by private Sector and Government	RM6 bil	RM9 bil	RM15 bil	RM30 bil	RM10.7 bil
Number of BioNexus companies	25	25	50	100	210
Employment (at end period)	40,000	80,000	160,000	280,000	55,904
Annual Revenue (at end period)	RM20 bil	RM80 bil	RM170 bil	RM270 bil	RM14.2 bil
Contribution to GDP	2.5%	4.0%	5.0%	5.0%	2.2%

Table source: ITALIA; Data sources: Malaysian Biotechnology Corporation (BiotechCorp) – BiotechCorp Annual Report 2011; Malaysian Biotechnology Corporation Score Card Report (October 2011)

URL:
http://www.ice.gov.it/paesi/asia/malaysia/upload/173/Overview%20of%20Malaysian%20Biotechnology%20Industry%20(December%202012).pdf

Chile's Bioeconomy

- Clinical Trials Destination:
  - Chile is in the top 25 countries for clinical trials for infectious diseases and central nervous system disorders (25th Annual Report on Life Sciences, Burrill & Co. 2011)
  - In 2009 there were 425 studies under development, more than 30 clinical research institutions, 300 testing sites, and more than 200 researchers

URL: http://www.chilebiotech.cl/

URL: http://www.chilebiotech.cl/

Brazil's Bioeconomy

- Brazil has globally competitive biotech companies engaged in agricultural biotech and biofuels. Med sector much smaller.
  - Much in interest in expanding into medical biotech

- Status of med-biotech industry:
  - 40% of biotech *companies* are in medical field (though small);
  - Not currently global – most produce only for domestic market;
  - 95% of companies have a relationship with academic or government research institution;
  - 78% receive government funding for R&D
  - Only 14% get venture capital financing
  - 40% have patent applications

India's Bioeconomy

- Government Goal: $100 billion industry by 2025

- Current Status of Industry:
  - 350 companies, $4.3 billion in revenue (2013)
  - 20 largest companies account for half of total revenue
  - 60% of world vaccine supply
  - Growth fast, but slowed in recent years (from 20% CAGR to 15%)
  - First innovative biotech products now being launched
- R&D spending in biotech: $2 billion in 2012 – 80% private sector
- Several Indian companies now manufacturing abroad:
  - Ranbaxy, Dr. Reddy's and CIPLA all have plants in Malaysia

Success Factors and Comparative Assessments

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7 Enabling Factors For Biotech

Key enabling factors	Explanation
Human capital	A basic and fundamental building block for the biotech sector is the availability of high skilled and technically trained human capital
Infrastructure for R&D	R&D infrastructure and capacity is critical: total R&D expenditure; patenting intensity; biotech R&D expenditure; life science investment levels; public-private partnerships; and academic and scientific citations
Intellectual property protection	Patents and regulatory data protection are of real importance to biotech and biopharmaceutical innovation – incentivize and support R&D of new technologies and products.
Regulatory environment	The regulatory and clinical environment shapes incentives for innovation and establishing adequate levels of quality and safety for biotech products, particularly biopharmaceuticals
Technology transfer	Technology transfer is an important mechanism for commercialising and transferring research from public and governmental bodies to private entities and private to private entities
Market and commercial incentives	Market and commercial incentives include tax incentives, general support for basic research and R&D credits for investments in plant, equipment and other R&D infrastructure For biopharmaceutical sector incentives determined by pricing and reimbursement systems for medicines and health technologies – can have a profound impact on commercial and market incentives for innovation in health and biotech R&D
Legal certainty (incl. RoL)	The general legal environment including as it relates to the rule of law and the rule of law within a business context is crucial to commercialization and business activities

Comparative Global Assessments

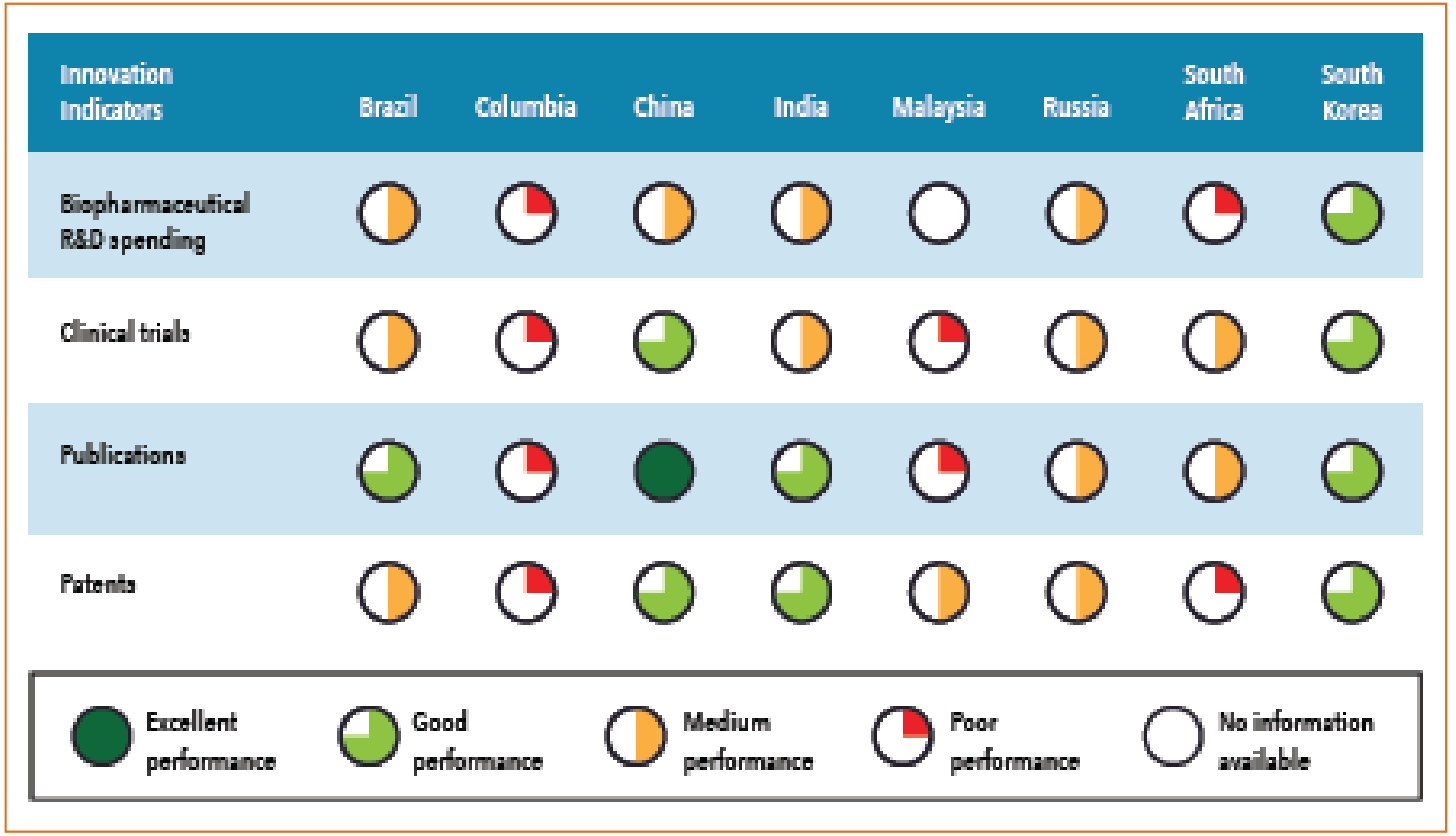
- Pricewaterhouse Coopers Scorecard, 2011
- Charles River Associates, 2012
- Scientific American Biotech Worldview, 2014

Pricewaterhouse Coopers Innovation Scorecard 2011

	USA	Brazil	China	India
Market incentives	5.5	2.8	6.8	5
Healthcare incentives	9	1.4	1.6	1
Innovative resources	6.8	3.2	2	1.8
Innovative output	7.7	1.7	3.5	2.5
Regulatory approval process	5.3	5.3	5.7	5.8
Legal environ. & impact on business	8.3	1.8	4	3.2
Needs & infrastructure	5.9	3.1	3.2	2.2
Demand for healthcare	8.3	3.2	1.6	1.4
Investment environment	5.8	2.9	3.2	2.9
Medical technology commercialization	8.5	1.9	2.7	1.4

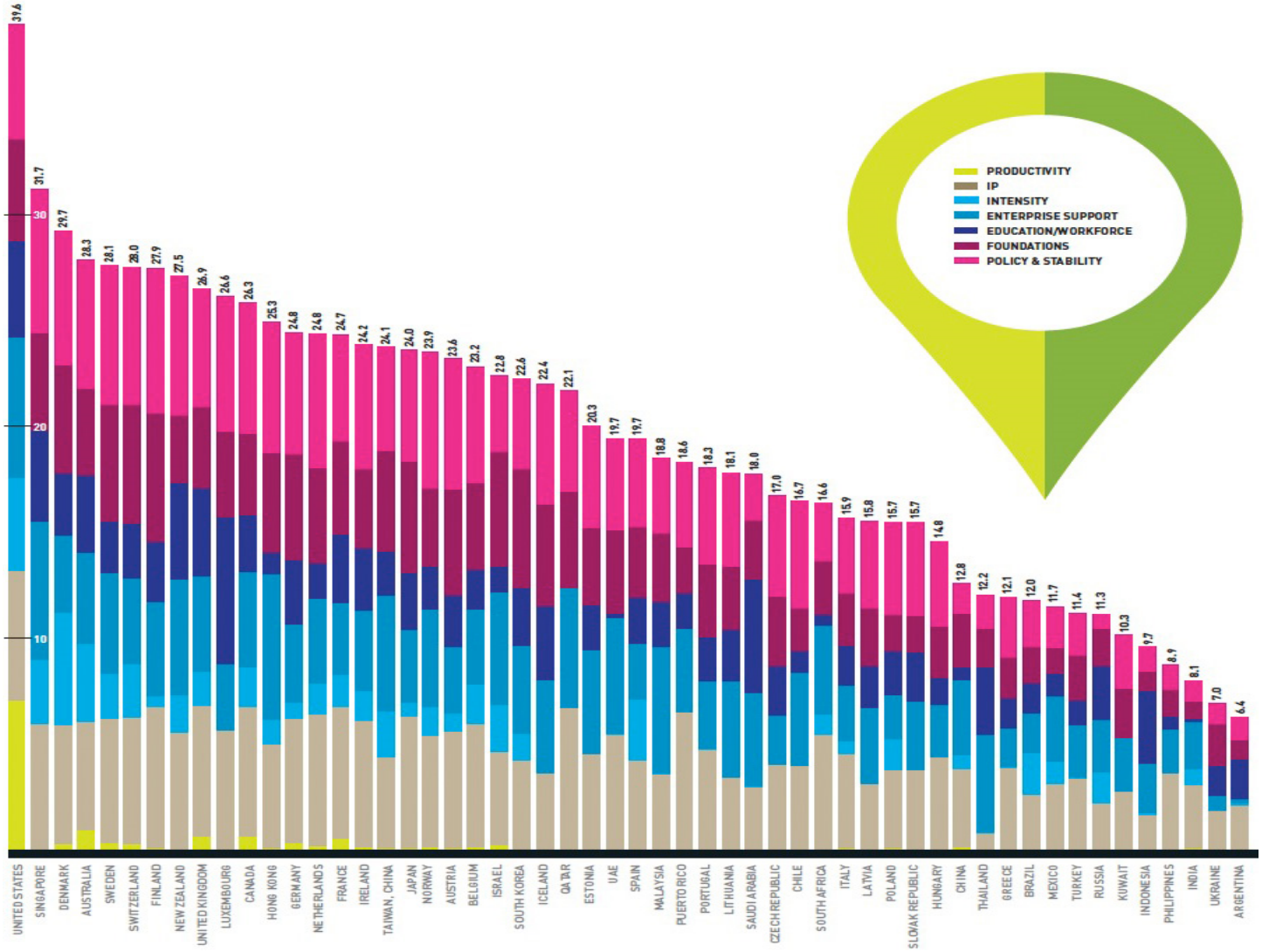
http://www.pwc.com/us/en/health-industries/health-research-institute/innovation-scorecard/background.jhtml

BIO Innovation Performance in MICs



Sources: Burrill & Company; Charles River Associates, Policies that Encourage Innovation in Middle Income Countries, 2012

Scientific American Rankings of Biotech Innovation Capabilities, 2014



Innovation and Access: Recent Independent Data

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Innovation and Access: What does the data show

Two recent comprehensive empirical studies shed light on the factors that determine success in innovation and in promoting access to medicines:

- Pugatch Consilium Study on Clinical Trial Activity (October 2014)
- National Bureau of Economic Research study, "Patents and Global Diffusion of New Drugs" (September 2014)
- ***N.B: Neither study financed by industry***

Innovation: Clinical Trial Intensity

- One key indicator of innovation in biopharma area: intensity of clinical trials. Accounts for 55%-75% of new drug R&D.
- *Pugatch Consilium Study*: Studied Clinical Trial (CT) Activity in 23 countries, using US NIH data. Ran it against "IP Index" scores and other factors (health system , population)
- **Key Findings:**
  - Regression analysis shows that **dedicated pro-innovation environment (measured as spending on R&D and IP protection) actually more important to clinical trial activity** than the intensity of physicians and hospitals.
  - Positive correlation between strength of IP protection and clinical trial activity
  - BRICs underperform in terms of CT intensity

IP and Diffusion of New Drugs: NBER Study

- Most comprehensive study of the relationship between IP and access to new medicines ever done:
  - Studied 642 new drugs launches in 76 countries over a 21 year period (1983-2002)
- **4 Key findings**:
  - New drugs become available in some countries only long after initial launch globally;
  - ***Patent policies strongly affect how quickly new drugs launched; Longer and Stronger patents "substantially speed up" launch. Findings robust: study controlled for economic and demographic factors***
  - ***Strong pharma price regulations significantly delay launch***
  - Local market size (in economic terms) has big impact on launch

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