pugatchconsilium

Strengthening the Life Sciences Sector in Mexico

International Best Practices, Lessons Learned and Evidence from the Field

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Pugatch Consilium Overview

Who are we?

- Boutique research consultancy – specialize in policy impact analysis, economic and statistical modelling
- Focus on innovation, knowledge-intensive industries including health care and life sciences
- Research empirical in nature – based on academic background and work of myself and colleagues

Who have we worked with?

- For last 10+ years worked with governments, international/regional institutions (OECD, WIPO, EU Parliament), academia and industry
- Invited by AMIIF to describe our empirical research and findings

Building a Competitive Biopharma Sector: A Global Race

- Building strong life science sector strategic priority for number of economies
- Not just Mexico, but BRICS, established OECD economies – competition is fierce
- What is the best way to encourage life science innovation and investment?
- Manufacturing decreasing portion of global life science spending – focus should be on **factors and incentives that can attract/build R&D capacity**
- Pugatch Consilium research focuses on four key areas:
  - Understanding best practices from international and academic literature – *Building the Bioeconomy* series of papers
  - Feeling the pulse of local leaders – local executive BCI survey
  - Policy impact analysis: US Chamber Intellectual Property Index and life sciences
  - Biopharma zoom-in: Comparing biomedical FDI through clinical trial activity
- Today's presentation will provide sample research from all four fields

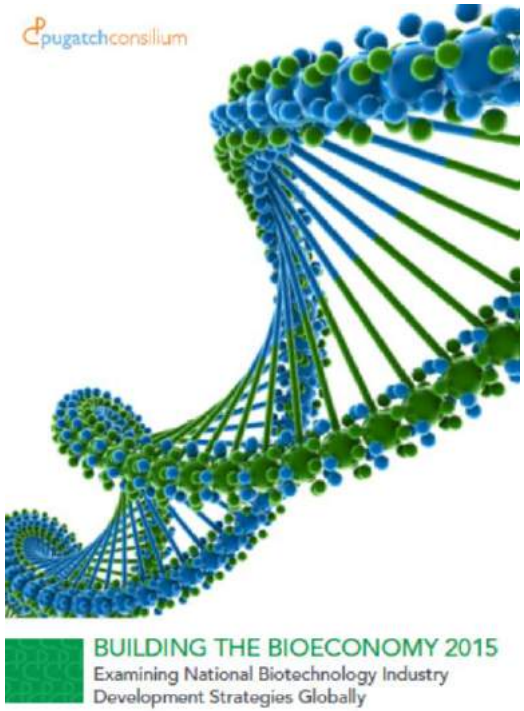
Building the Bioeconomy – Project overview

- Empirical/comparative policy compass of 16 countries' biotech strategies – **Mexico included**

- Identifies and applies 7 enabling factors:
  - Where and how have countries been successful?
  - Which policies have worked?
  - In which areas are there still challenges?

- Can be used as a roadmap and guide by policymakers and countries

- Mexico has many elements in place e.g. National Development Plan and health reform package



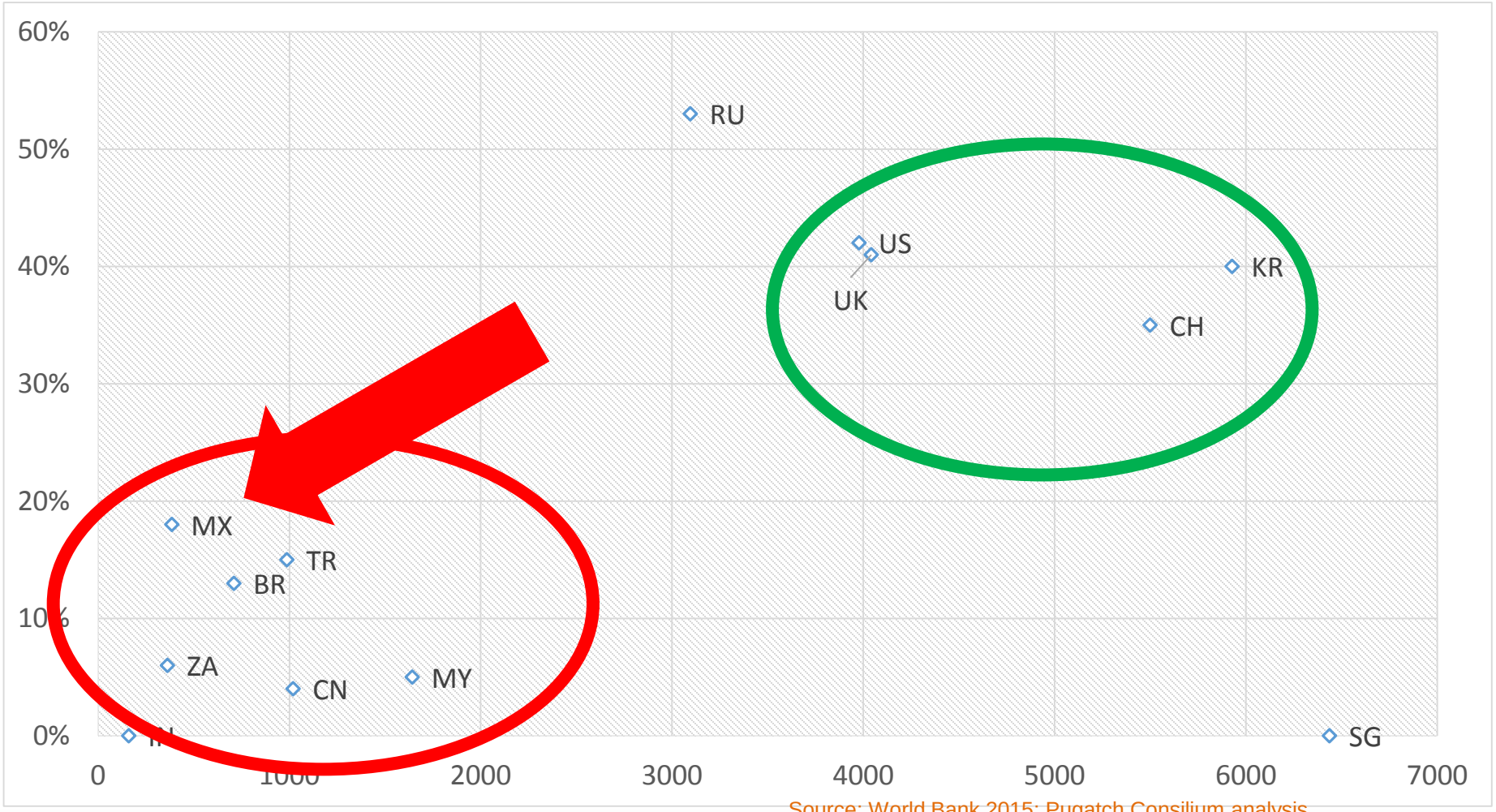
PLAN NACIONAL
DE DESARROLLO
2013 - 2018
GOBIERNO DE LA REPÚBLICA

Seven enabling factors for biotech innovation

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

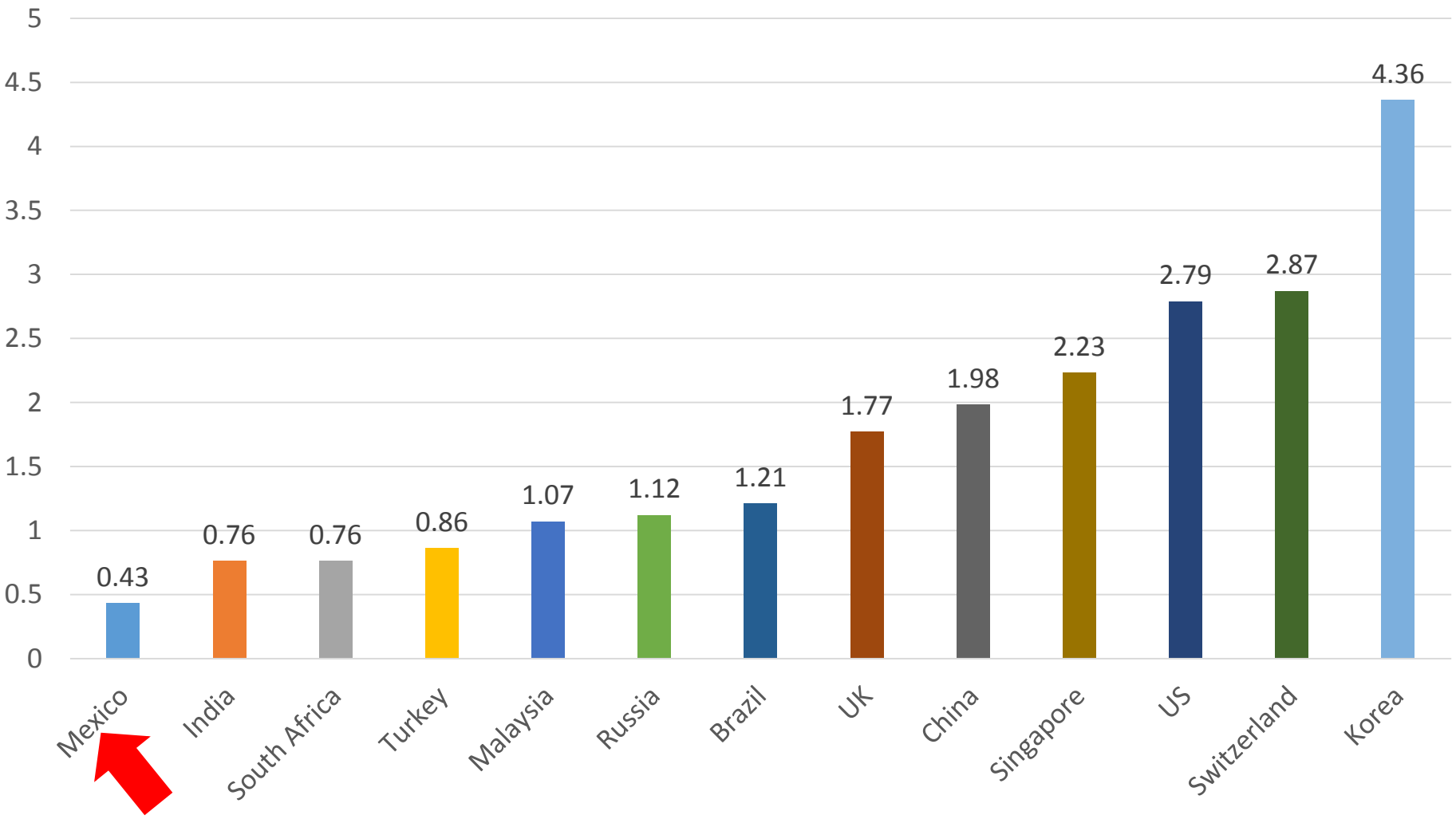
Human Capital Matrix

% of population in tertiary education vs no. of researchers per capita (million population)



Source: World Bank 2015; Pugatch Consilium analysis

R&D Spending, % of GDP, 2012 or latest



Source: World Bank 2015

What do experts on the ground say?

- Biopharmaceutical Competitiveness Index (BCI) is a global survey-based index
- Executive opinion survey – seeks to capture opinion of local country managers, decision-makers
- Examines entire biopharmaceutical ecosystem – from clinical environment and R&D to P&R, IP and regulatory environment
- What do local executives think about prevailing market conditions? Is a country worth investing in?
- Results of BCI show that market size is not the deciding factor for investment
- **Policy environment matters!**

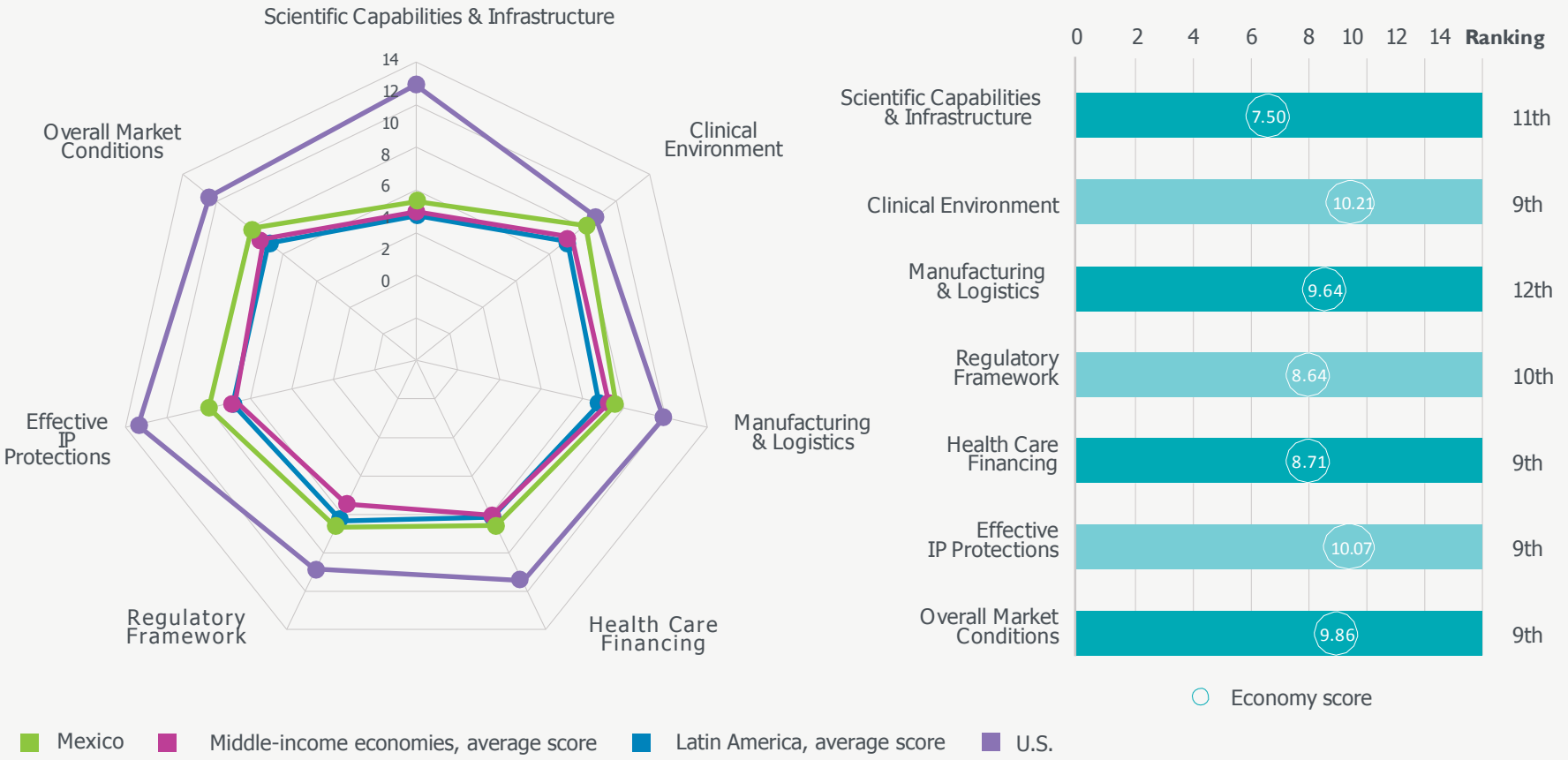
Missing out on multinationals' investment

- Biopharmaceutical Competitiveness & Investment (BCI) Survey – 2015: Mexico's global competitiveness ahead of BRICs but behind OECD markets

FIGURE 4 Overall BCI scores and ranking by economy

Source: Pugatch Consilium, BCI 2015

BCI Mexico results



IP and Market Access – Priority areas

Key areas of strength

- ✔ Relatively low operational costs
- ✔ Basic manufacturing capacity present
- ✔ Implementation of regulatory best practices for basic products
- ✔ Scientific training in the country is good but could benefit from diversification

Key areas of weakness

- ✓ Innovative drugs placed at disadvantage in market access system
- ✓ Substantial challenges in IP enforcement
- ✓ Some deficiencies in quality control and approval of advanced local products (e.g. biosimilars)
- ✓ Need for greater industry incentives and streamlining of administrative processes

Scientific capabilities & infrastructure

- Scientific research standards viewed as being of average quality and lacking diversification in life science research.
- Concerns were raised regarding the ability to successfully translate biomedical research into commercialized products.

Clinical environment

- Clinical research is considered to be relatively low cost and carried out in line with international standards.
- However, remaining red tape in the regulatory system governing clinical trials is viewed as somewhat challenging, though improvements are ongoing.

Manufacturing & logistics

- Capacity to produce high quality APIs is considered to be limited.
- The system for approving products for export is seen as satisfactory (though not excellent).

Regulatory Framework

- The capacity of the health regulator to review new biopharmaceutical products and generics is seen as good, but capacity to review biosimilars limited.
- Local executives cited concerns over pharmacovigilance.

Health care Financing

- Drug coverage narrow in certain areas, with reimbursement mainly provided for cheaper and domestically manufactured products.
- Access to the public market on the basis of medicines' value is limited.

Effective iP Protections

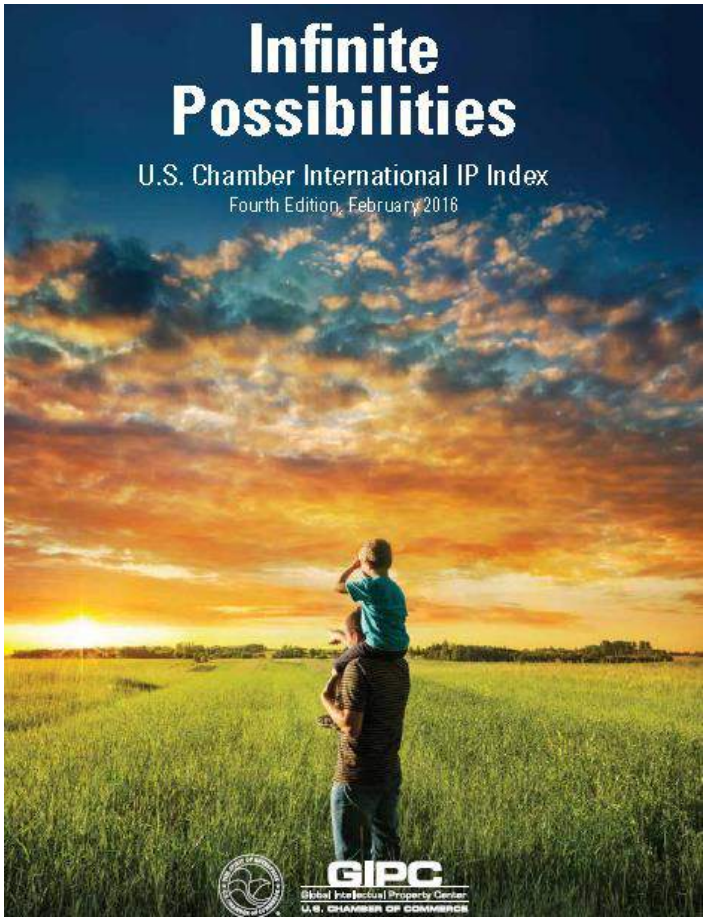
- Biopharmaceutical IP protections are generally perceived to be acceptable, with specific concerns raised over scope of regulatory data protection.
- Enforcement of IP rights is seen as a major challenge, with anti-counterfeiting actions perceived as fairly ineffective.

Overall Market conditions

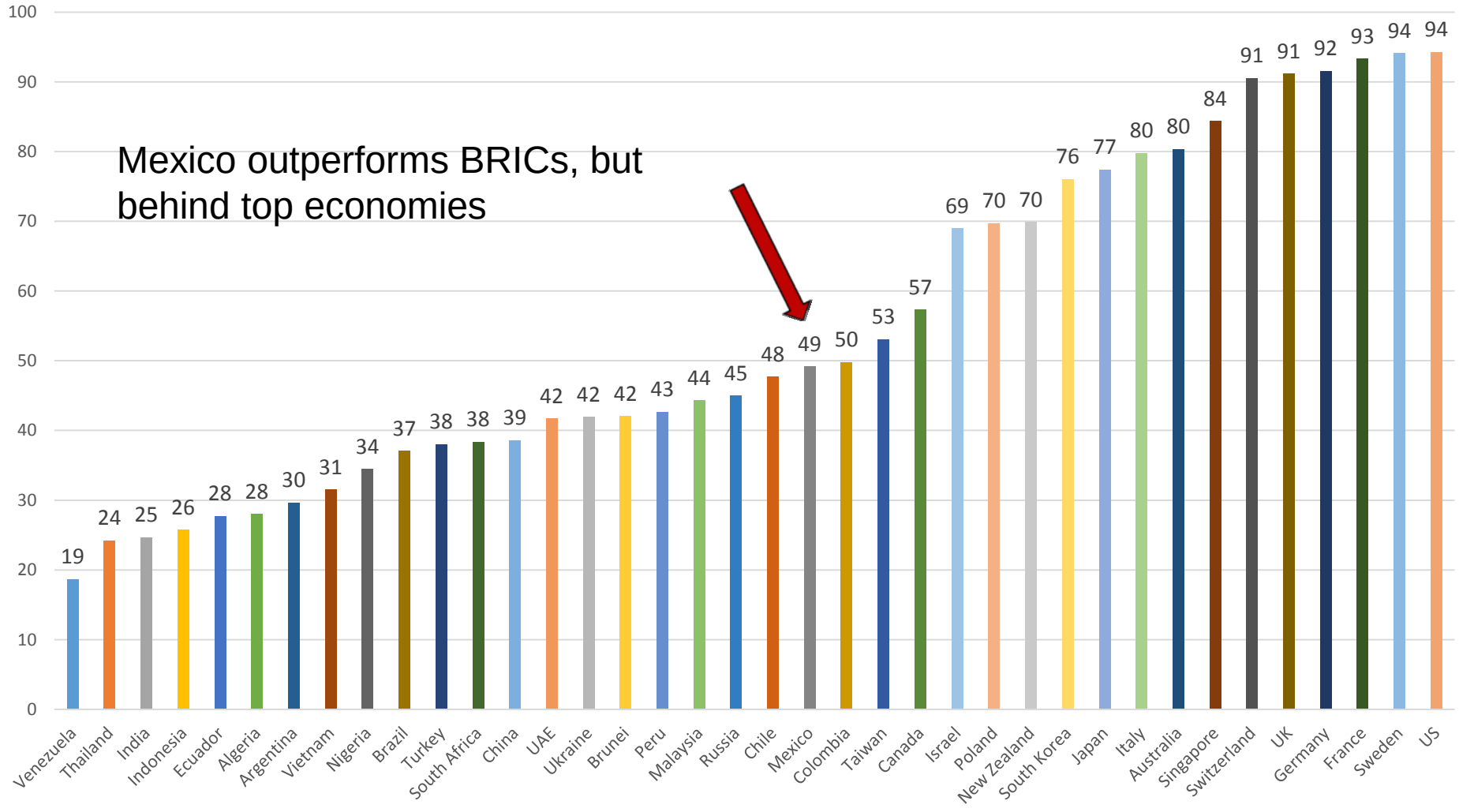
- The tax environment is viewed as somewhat unattractive.
- However, local executives cite a good level of cooperation with government.

Positive Relationship: Protecting IP and investment

- US Chamber International IP Index – measures strength of national IP environment in 38 economies including Mexico
- Index tracks availability and strength of all forms of IPRs including sector specific indicators for life sciences e.g. RDP, PTE, patentability etc
- Key part of Index statistical analysis of relationship between Index scores and economic variables
- Key finding: overall positive relationship – **especially for life sciences related fields of economic activity!**



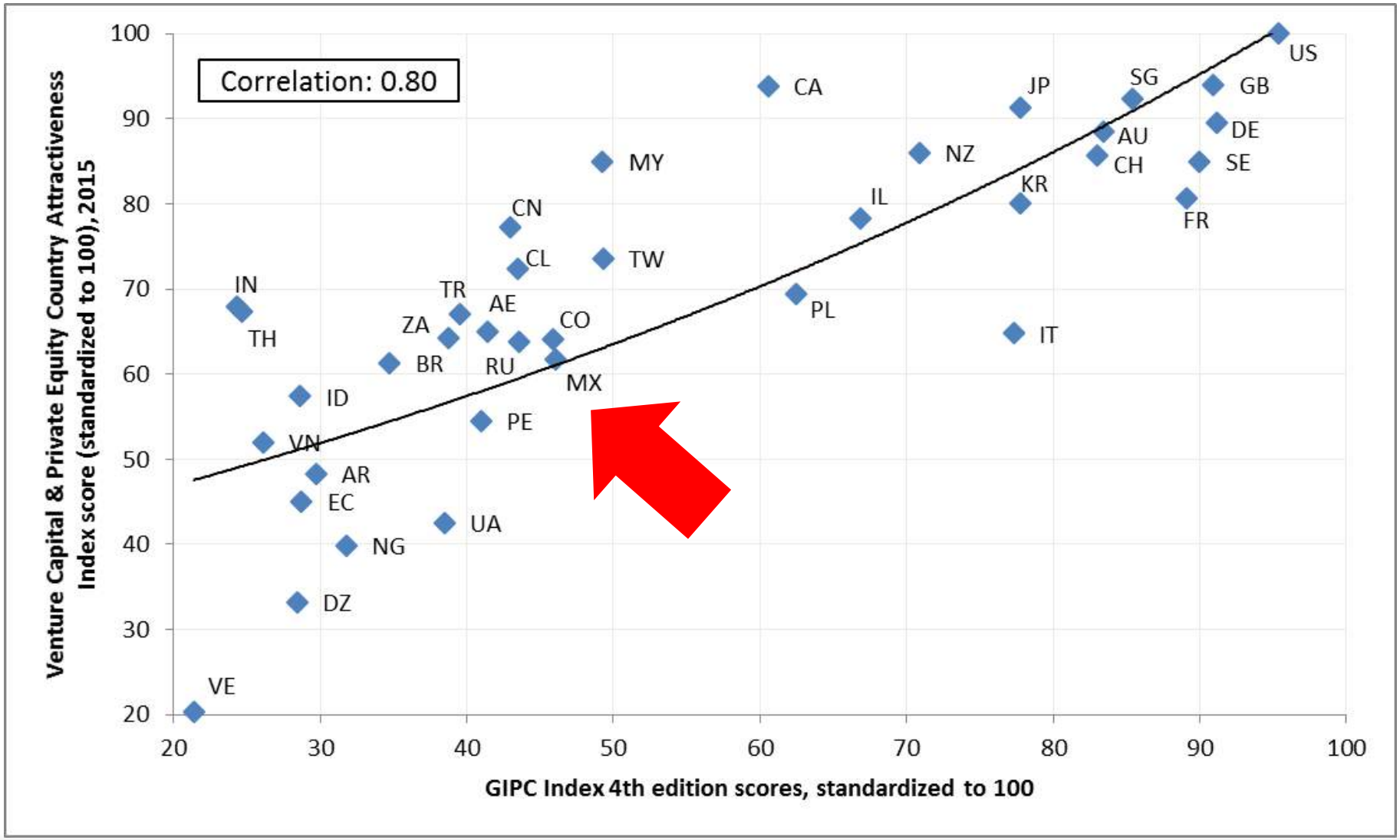
IP Index 2016, life sciences score, % available score



Mexico and the International IP Index

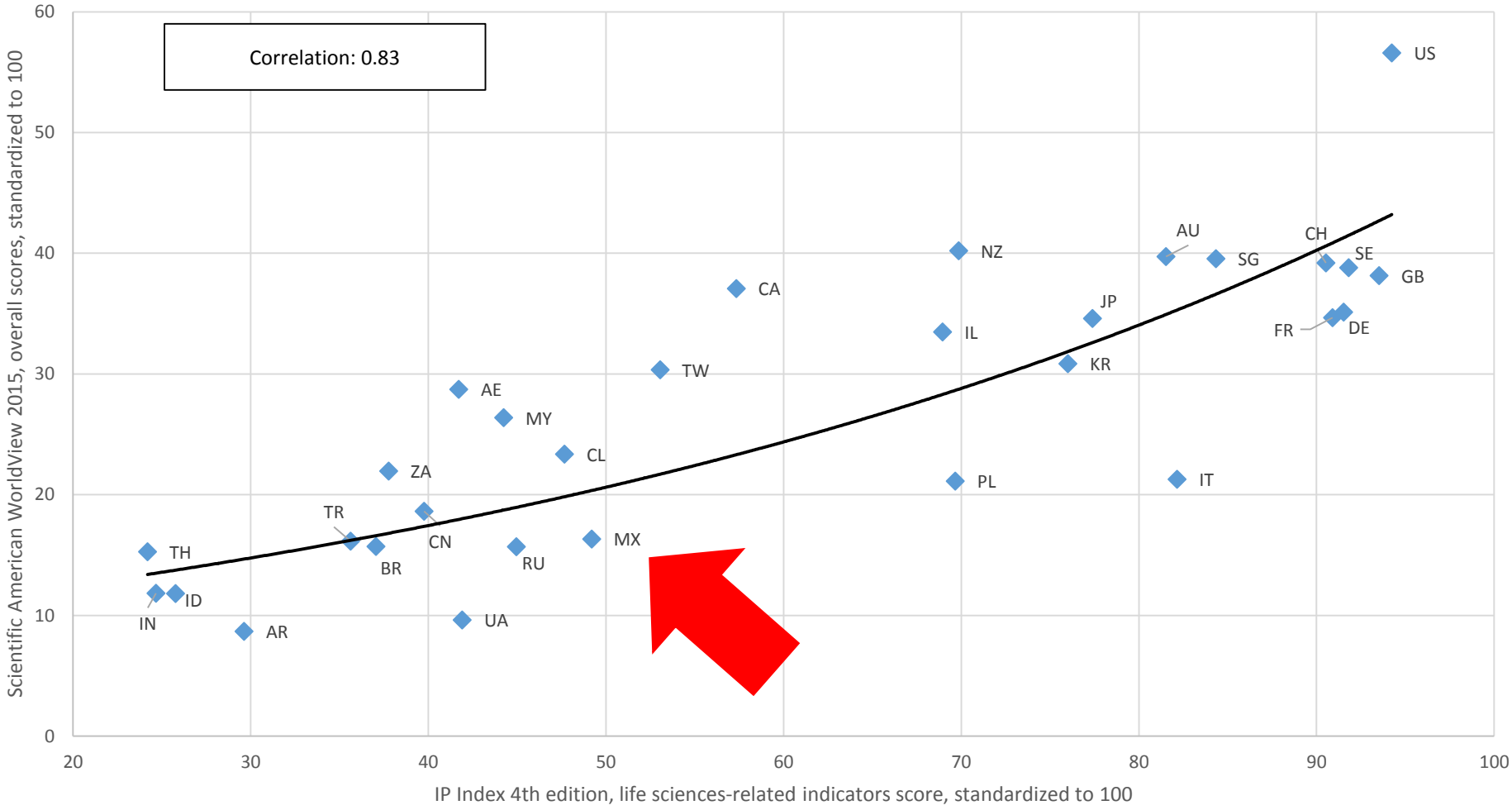
- Mexico has one of the highest middle-income overall scores
- For life sciences Mexico receives 49% of total possible score – ahead of BRICs but behind Korea, Singapore, OECD economies
- Current challenges:
  - Regulatory data protection – no primary or secondary legislation in place; and lack of clarity for coverage of biologics
  - Enforcement and linkage mechanisms for patent infringing follow-on products
- These challenges are holding back Mexico's life sciences environment – making Mexico less competitive
- Looking at economic outputs (access to venture capital, biotech innovation and rate of clinical trials) **Mexico could be performing at a higher level**

Robust IP environment = more venture capital

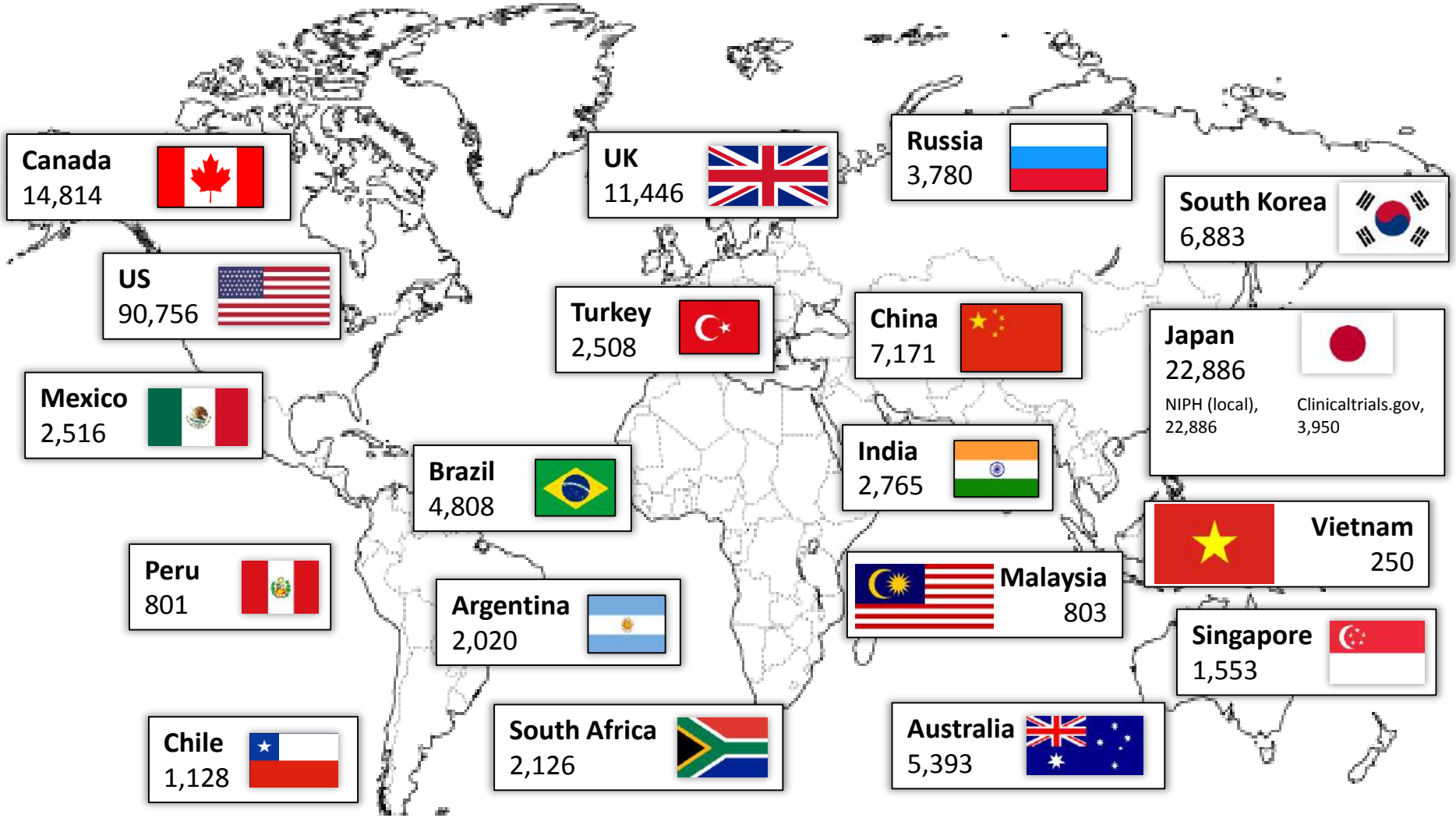


Biotechnological innovation depends on protecting IP

Association between IP Index life sciences scores and Scientific American WorldView scores, 2015/6

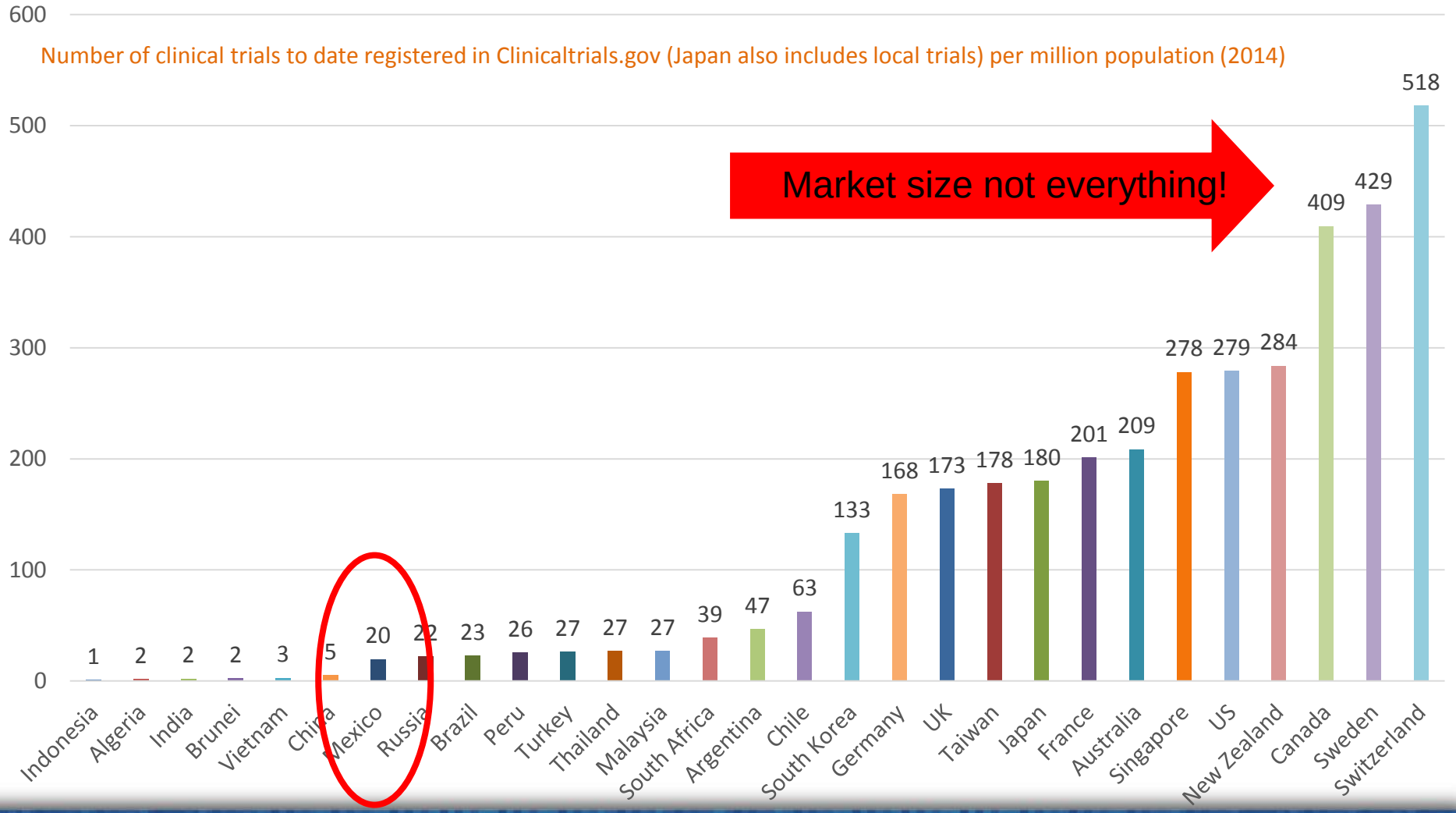


Number of CTs to date – Global Overview*



* As registered in *Clinicaltrials.gov* database in January 2016

Clinical research per capita – Size doesn't matter



Cutting edge research: Top performers Phase I and II

Top performers

TABLE 1 Clinical trial activity by phases in selected countries, 2013[25] (based on number of clinical trials with a registered start date in 2013)

Country	No. of CTs (2013)	No. of phase I trials	No. of phase II trials	No. of phase III trials	No. of phase IV trials
US	3872	1223	1535	708	406
EU-5 (total)	3187	564	992	1280	346
Canada	740	105	232	312	85
Germany	733	154	235	279	63
UK	694	187	202	238	67
France	676	96	225	278	77
South Korea	551	114	126	208	101
China	529	66	179	148	136
Italy	527	55	164	229	79
OECD (average)	441	90	140	161	49
Belgium	428	83	114	178	52
Netherlands	371	86	88	148	46
Australia	350	69	93	172	16
Japan	305	53	81	146	24
Poland	293	10	77	184	20
Israel	289	43	84	122	34
Russia	266	25	60	161	20
Czech Republic	238	12	65	143	18
Brazil	233	27	47	120	38
Hungary	230	14	71	128	17
Turkey	151	3	23	87	36
South Africa	144	14	35	85	10
Mexico	140	7	22	93	16
Argentina	128	6	18	92	12
India	117	13	29	60	15
Thailand	117	8	35	48	26
Greece	108	4	25	65	14
Romania	107	5	15	83	4
Ukraine	92	0	17	72	3
Egypt	75	10	21	22	18
Colombia	61	2	17	36	6
Malaysia	57	3	10	36	8
Lithuania	47	1	11	33	2
Croatia	43	2	5	30	6
Vietnam	27	3	6	12	6
UAE	19	0	0	8	11
Indonesia	18	1	7	5	5
Saudi Arabia	18	1	6	4	7
Chile	16	1	3	9	3
Nigeria	6	2	4	0	0

100+ CTs 50-99 CTs 0-49 CTs

Source: Pugatch Consilium, Clinicaltrials.gov

Clinical trials on biologic drugs

- Biologic medicines and technologies are increasingly being used in treatment of most difficult conditions as well as in cutting-edge medical research

- Given size, complexity and inherent instability of a biologic, the R&D process requires a considerable level of stability and technical capacity

- Testing biologic drug in a CT necessitate a highly-controlled environment:
  - The transportation and storage of the drug are controlled
  - The trial protocols are strictly adhered to
  - Patients are monitored carefully

- Although in absolute terms Mexico's rate is one of the highest in the region the % share of biologic trials is quite low

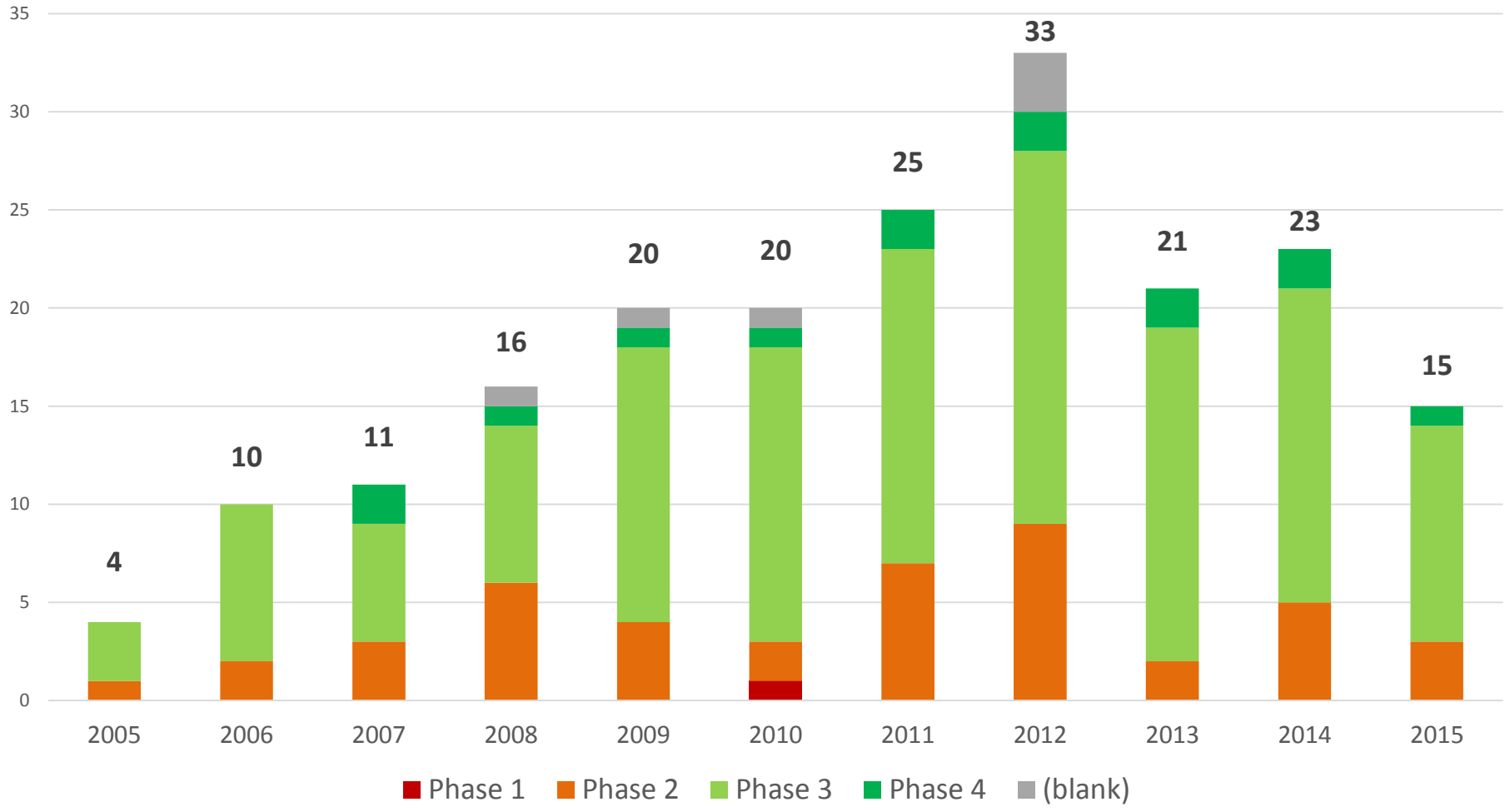
- **More importantly phase I and II trials are very low**

Clinical trials of biologic drugs: a regional comparison

Country	Total number of CTs to date	Number of CTs on biologic drugs	% share of total
Colombia	903	102	11.30%
Peru	801	87	10.86%
Argentina	2018	163	8.08%
Chile	1129	91	8.06%
Mexico	2513	198	7.88%
Brazil	4803	251	5.23%
Venezuela	154	3	1.95%
Ecuador	107	0	0.00%

Source: *Clinicaltrials.gov*, 2016; analysis: Pugatch Consilium

Clinical trials of biologic drugs, Mexico, by year and phase



Source: Clinicaltrials.gov, 2016

Summing up: What does all this mean for Mexico?

- Building a competitive life science sector is not easy – requires getting "hardware" and "software" policies right

- R&D infrastructure, human capital, regulatory, commercial incentives, P&R, IP – all essential and work together to create enabling environment

- Mexico has clear strengths – regulatory reforms, increased speed in market authorization, efforts to improve and streamline are recognized

- But challenges remain:
  - **R&D infrastructure and human capital:** R&D spending and capacity still limited compared to top OECD countries – long term challenge!
  - **P&R:** Existing policies still limit value of innovative drugs – reimbursement and inclusion on public formularies difficult
  - **IP:** Mexico has many life science IPRs in place but lack of clarity on RDP and biologics identified by executives on the ground as key areas of concern

Thank you!