REGULATORY CHALLENGES FACING THE INNOVATIVE PHARMACEUTICAL INDUSTRY

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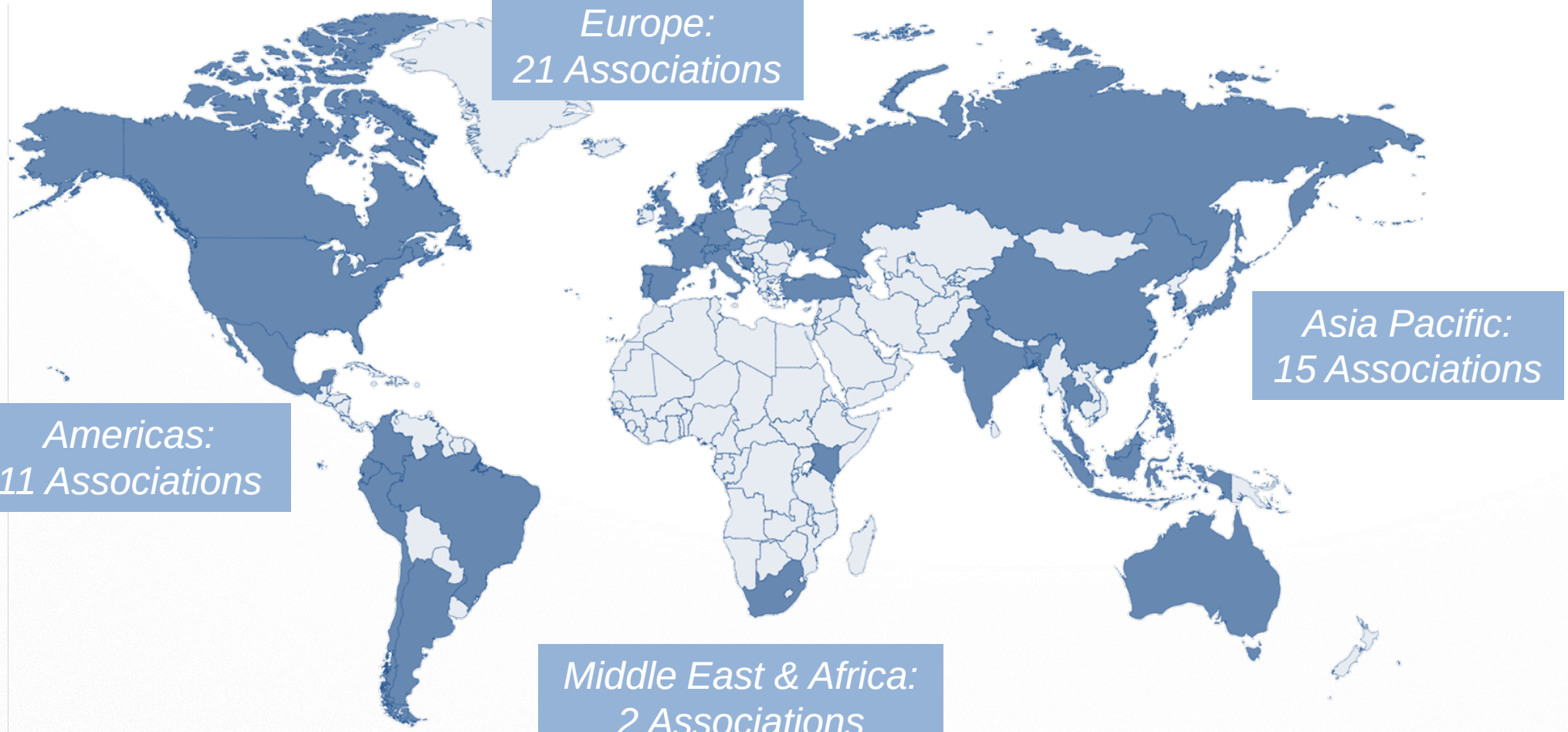
Membership

IFPMA is the **industry interlocutor** globally with ~50 associations and ~40 companies in all 5 continents

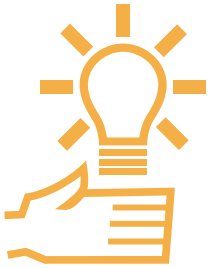


Membership Companies

IFPMA

Strategic focus areas and priorities 2017-2018

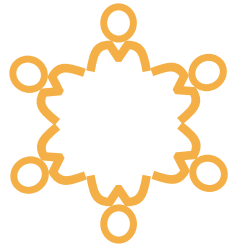
IFPMA



Sound innovation ecosystem

Global health systems challenges

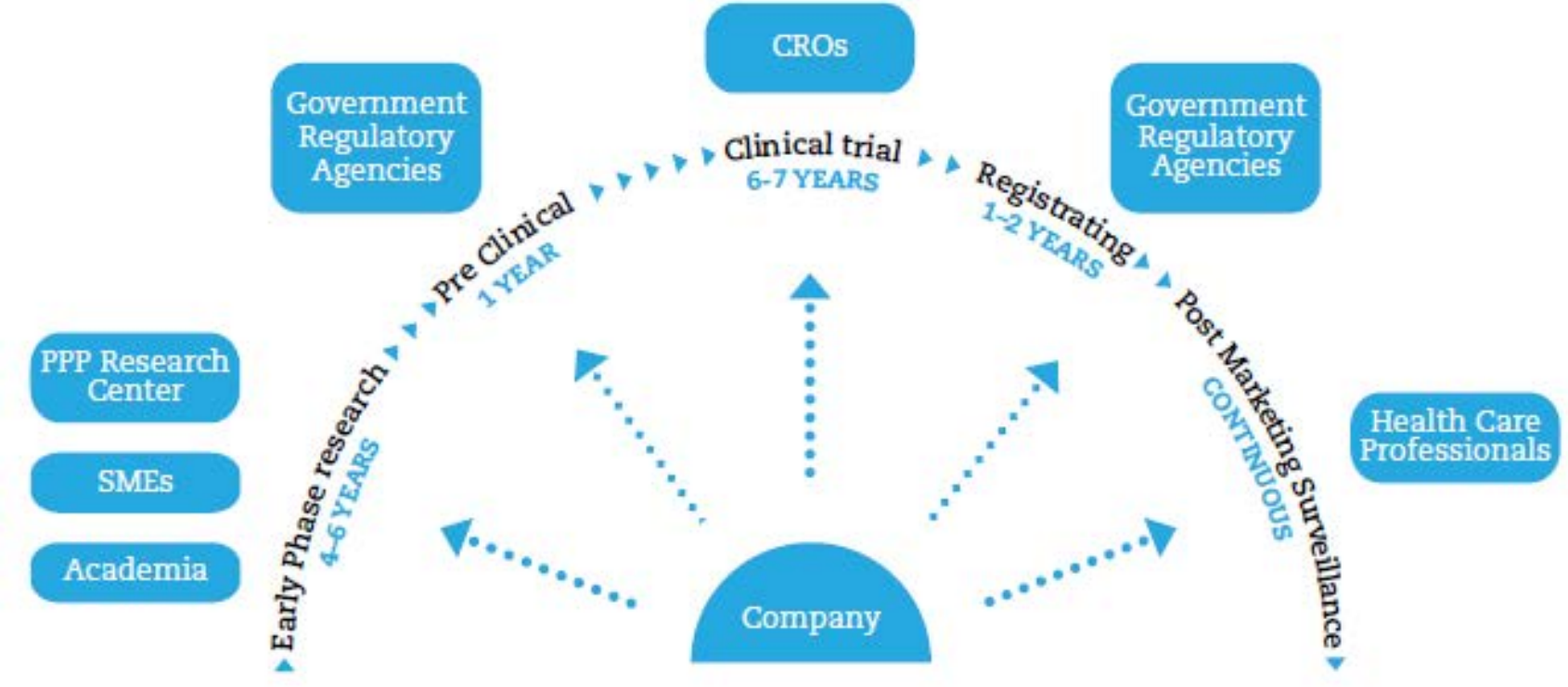
Access quality medicines and vaccines



Integrity and ethics

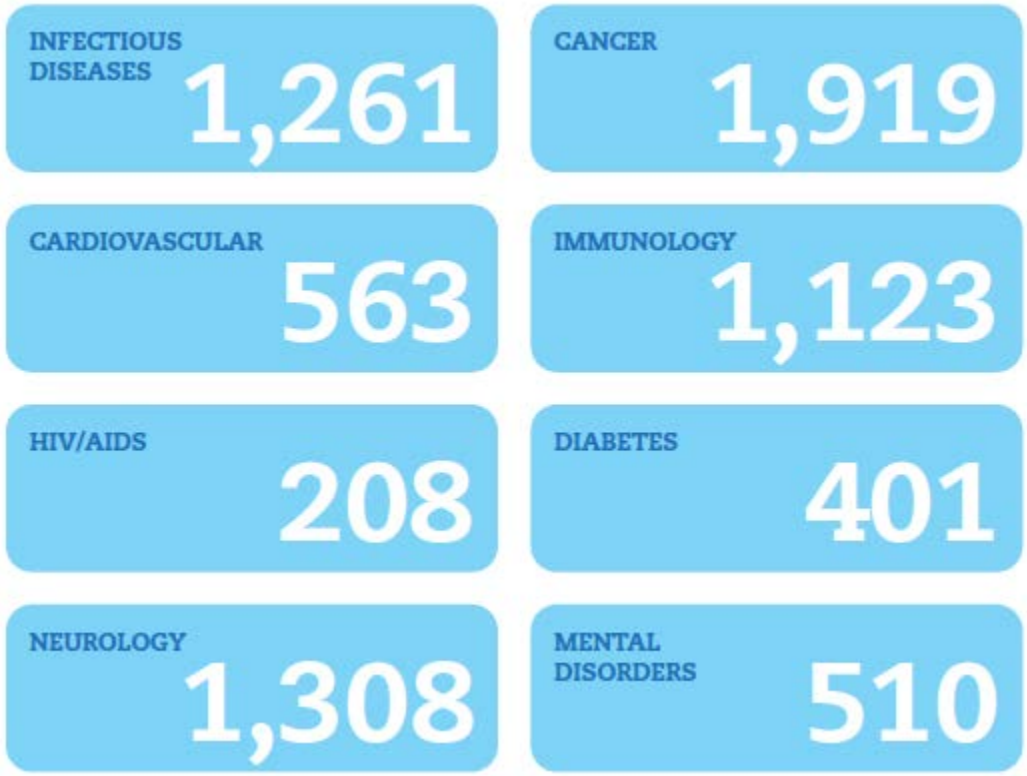
Accelerate access to life-saving and life-enhancing medicines and vaccines, for people everywhere.

Pharmaceutical Innovation: A long and complex process



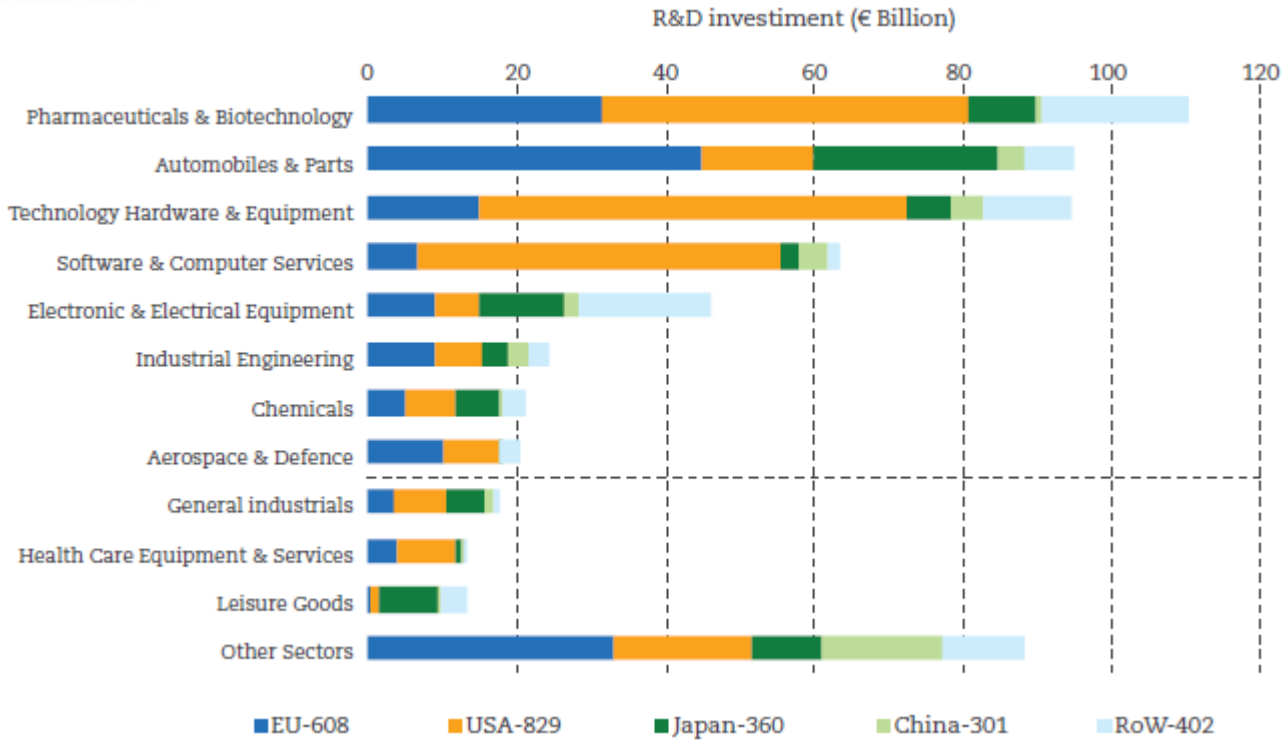
IFPMA (2012) The New Frontiers of Biopharmaceutical Innovation. Geneva: International Federation of Pharmaceutical Manufacturers & Associations, p 9. http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf

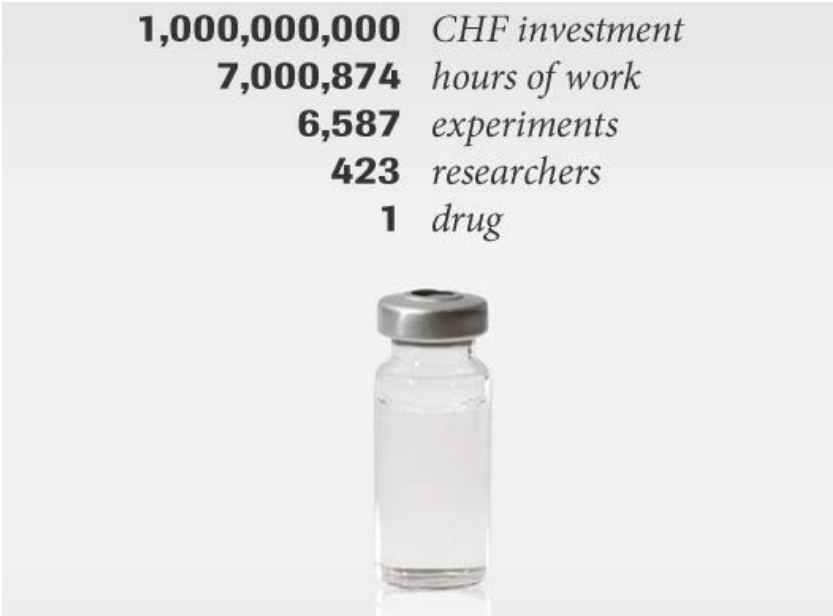
Innovative Medicines: pushing the limits of science with a vibrant pipeline



IFPMA (2017), The Pharmaceutical Industry and Global Health: Facts and Figures 2017. PhRMA (2016) Chart Pack Biopharmaceuticals in Perspective. Washington DC: Pharmaceutical Research and Manufacturers of America, p 22.

Pharmaceutical industry invests more in R&D than any other sector

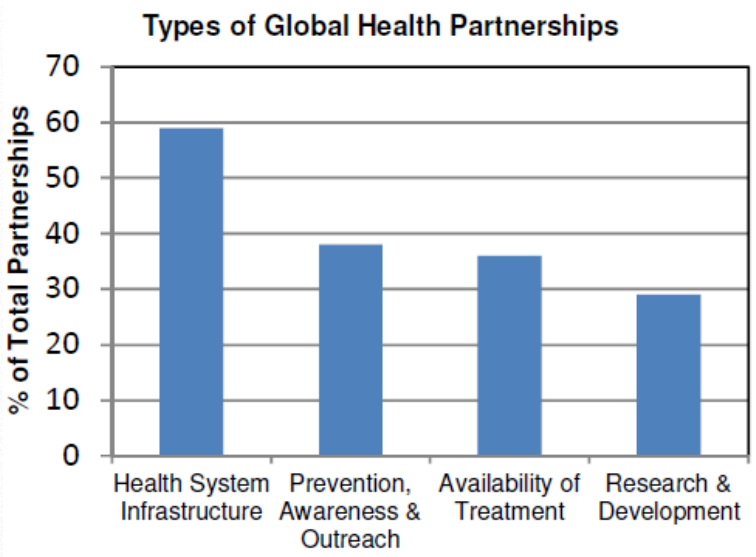


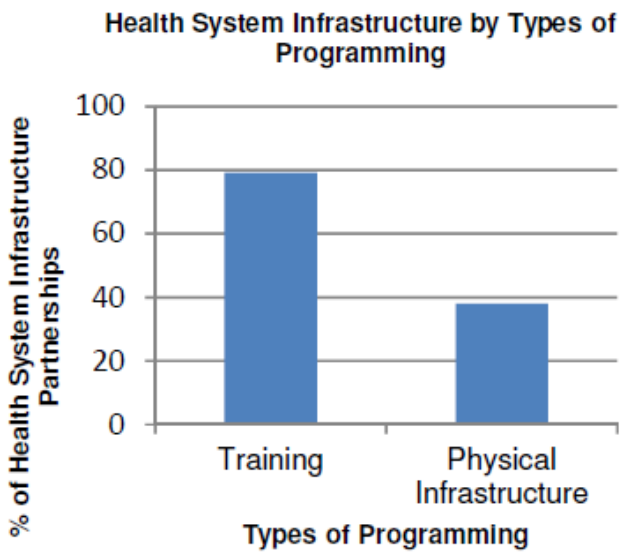


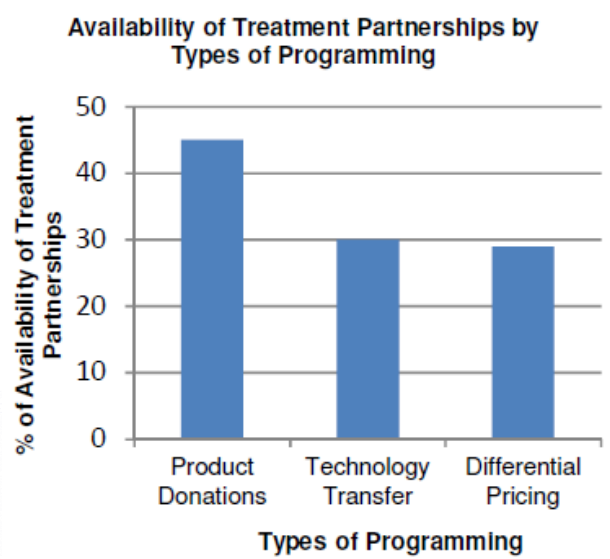
European Commission (2015) The 2015 EU Industrial R&D Investment Scoreboard; p50.
http://iri.jrc.ec.europa.eu/scoreboard15.html

Industry's efforts to reduce regulatory hurdles and improve access to medicines

- Industry is committed to deliver medicines to all those who need it and to improve public health.
- The pharmaceutical industry has over 300 partnerships in many countries designed to improve access to medicines and strengthen healthcare systems.
- Most initiatives are cross-cutting and multi-faceted in nature, reflecting the need for an integrated, comprehensive approach in moving forwards.







Source: BSR (2012) 'Working toward Transformational Health Partnerships in Low- and Middle-Income Countries'; IFPMA (2015) 'Translating Principles into Practice'

Key Regulatory Hurdles

1. Multiple country requirements/processes for **initial registration** medicines and vaccines

2. Lack of **good manufacturing practices (GMPs)** convergence leading to duplicative inspections

3. Unpredictable processes and timelines for review and approval of **post approval changes (PACs)**

Key Regulatory Hurdles

1. Registration Procedures

Multiple country processes for initial registration leads to delay in market entry.

This delay is mainly due to

- repeat assessments/inspections
- limited technical/HR capacity

There is **no harmonization** of requirements

Typical duration in months, median

Registration pathway		Spread from 1st NRA submission to last NRA submission	Sub-Saharan Africa NRA approval time
Drug (small molecule)	Novel, SRA first	52	11
	Generic, NRA first	~24	~18
Vaccine	SRA first	78	16
	NRA first	UN-delivered Vx historically not typically registered	UN-delivered Vx historically not typically registered

Data from CEO Roundtable member registration data received as of 1/7/2013; PQ approval times from WHO PQ data, NRA/SRA data from FDA/EMA databases, CIRS, WHO PARs, and online research; **BCG analysis**

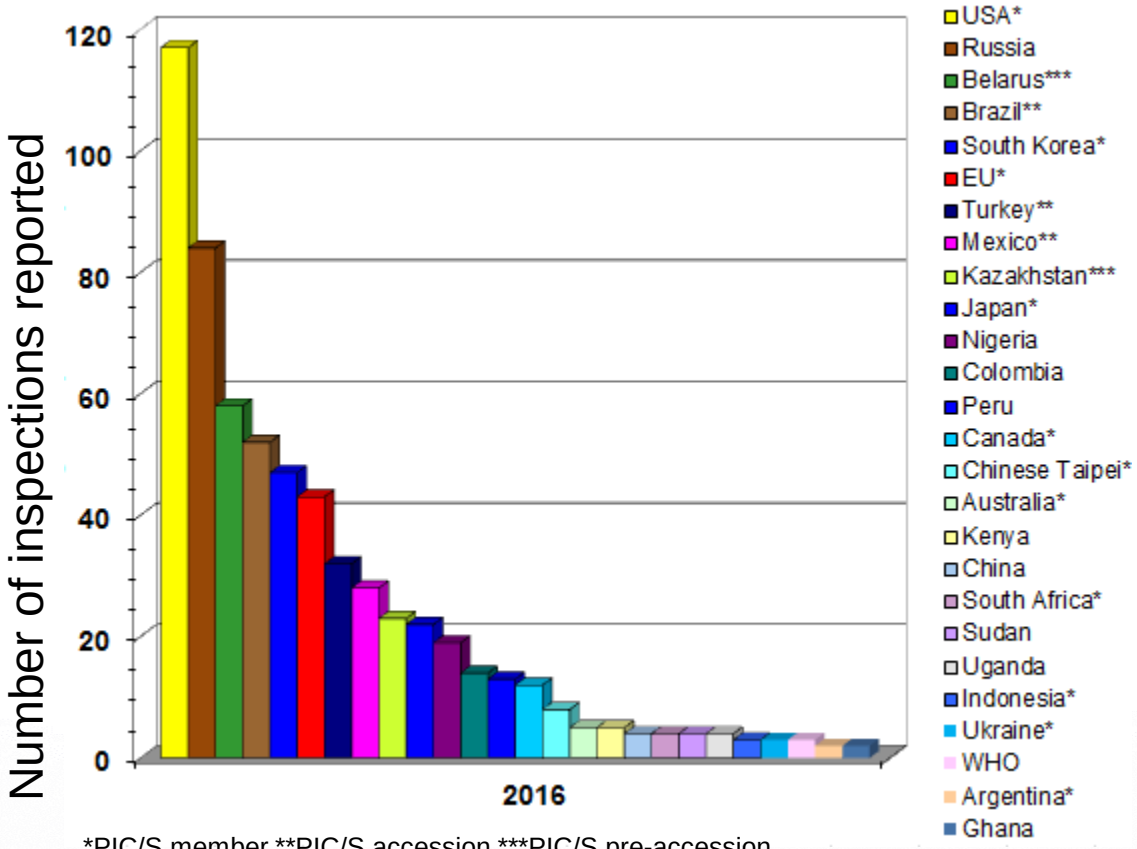
Key Regulatory Hurdles

2. Good Manufacturing Practices (GMPs)

Estimated resources used in 2016

- >100,000 h invested by regulators
- >800,000 h invested by 23 companies

Convergence on good manufacturing practice standards is important to achieve a reliable global supply of quality medicines.



*PIC/S member **PIC/S accession ***PIC/S pre-accession

EFPIA (2016): Annual Regulatory GMP/GDP Inspection Survey 2016 Data

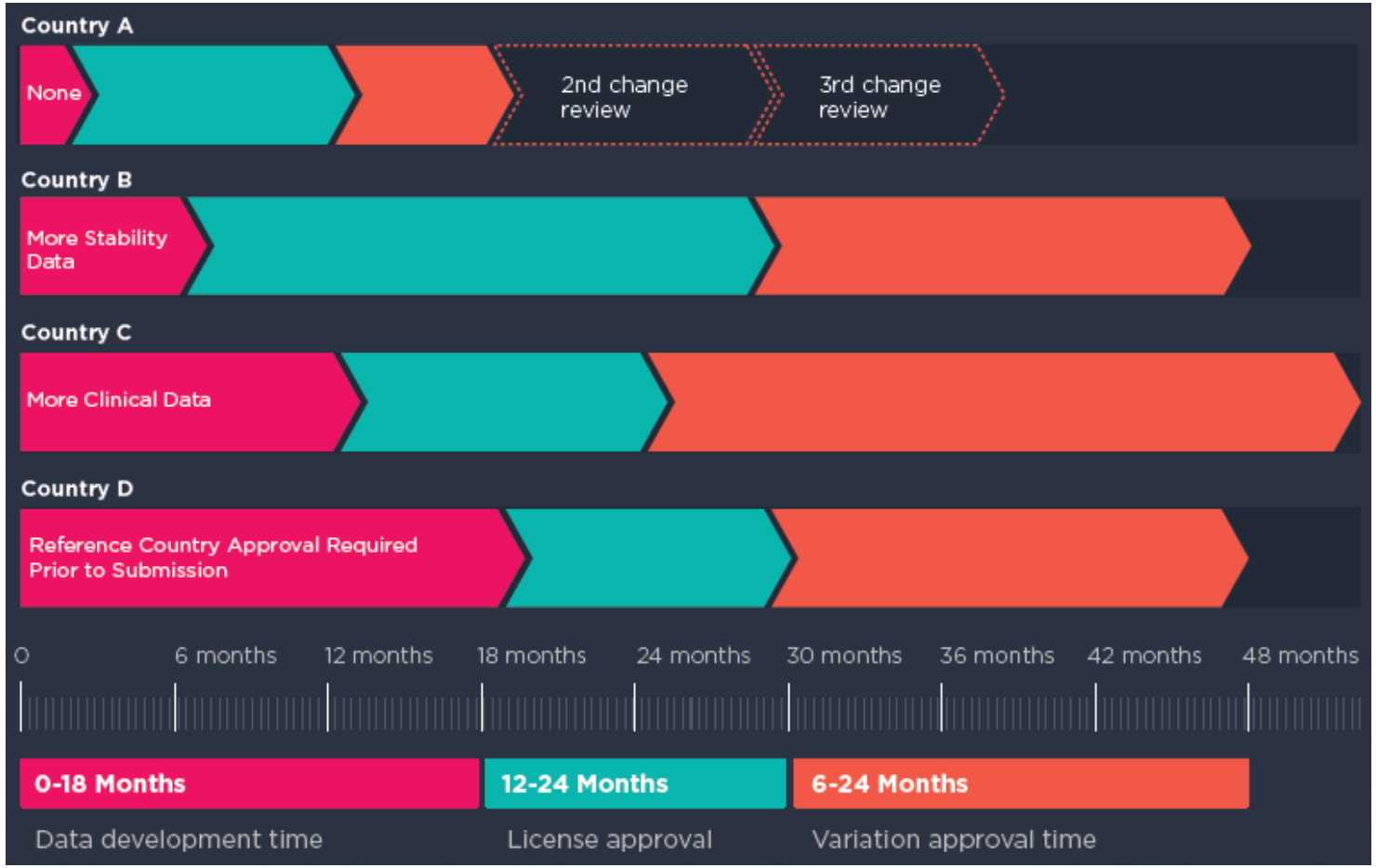
Key Regulatory Hurdles

3. Post Approval Changes (PACs)

Regulatory processes for PACs differ between countries delaying patient access

- Approval timelines
- Reporting and data requirements
- Reporting categories

Convergence on PAC processes is crucial for continuous supply of medicines.



IFPMA (2015): Supply chain post-approval change infographic.

IFPMA 2018 Regulatory Priorities

- Regulatory System Strengthening
- Pharmacovigilance
- WHO Prequalification Program
- Post Approval Changes

Industry is committed to improve access to medicines