Globalization of Drug Development : Stipulation and Perceptibility

Dr Deven V Parmar MD, FCP

# Agenda

- Overview
- Regulatory Perspective
- Global trends in Drug Development/ Clinical trials
- Global Opportunities
- Global Challenges

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#### INTERNATIONAL BESTSELLER

NOBEL PRIZE-WINNING AUTHOR OF GLOBALIZATION AND ITS DISCONTENTS

# MAKING GLOBALIZATION WORK JOSEPH E. STIGLITZ

WITH A NEW AFTERWORD

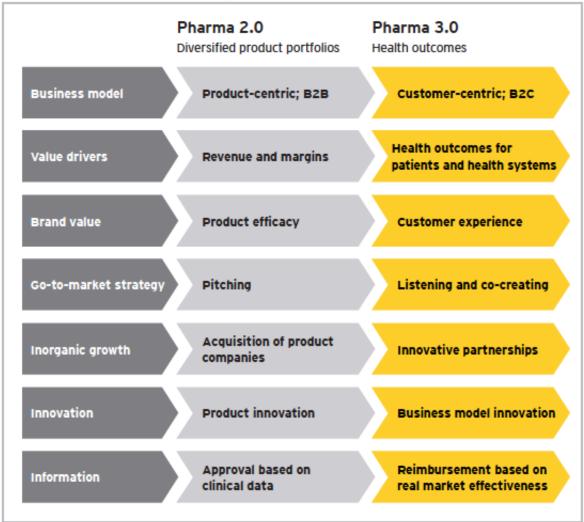
"A brave book. . . . Stiglitz does an excellent job of describing dense topics . . . in language that's understandable and accessible." —Russ Juskalian, USA Today

## **Globalization Works?**

- Many economist & world leaders agree that globalization is supposed to create higher living standards, increased access to foreign markets, investments & open borders.
- However, according to JS, globalization is desperately failing the 80% of the world's population living in developing countries & 40% that lives in poverty.

### The Third Place: HealthCare Everywhere

- Health Care Cost are becoming unsustainable, in large part due to chronic disease epidemic fueled by unhealthy lifestyles, aging populations & increasing standards of living.
- Health Care will become more patient centric & ubiquitous – delivered wherever the patient happens to be.
- Patients who have grown increasing comfortable with empowering technologies are taking more active roles in managing their health & are demanding a different model in the third place.



Pharma 3.0: the shift from products to health outcomes

Move to evidence based, outcomes focused, behavior driven world

Source: Ernst & Young.

#### Progressions : Global Life Sciences, E & Y, 2012

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## **Regulatory Perspective**

#### The United States imports:



80 percent of active pharmaceutical ingredients



80 percent of seafood



40 percent of finished dosage drugs

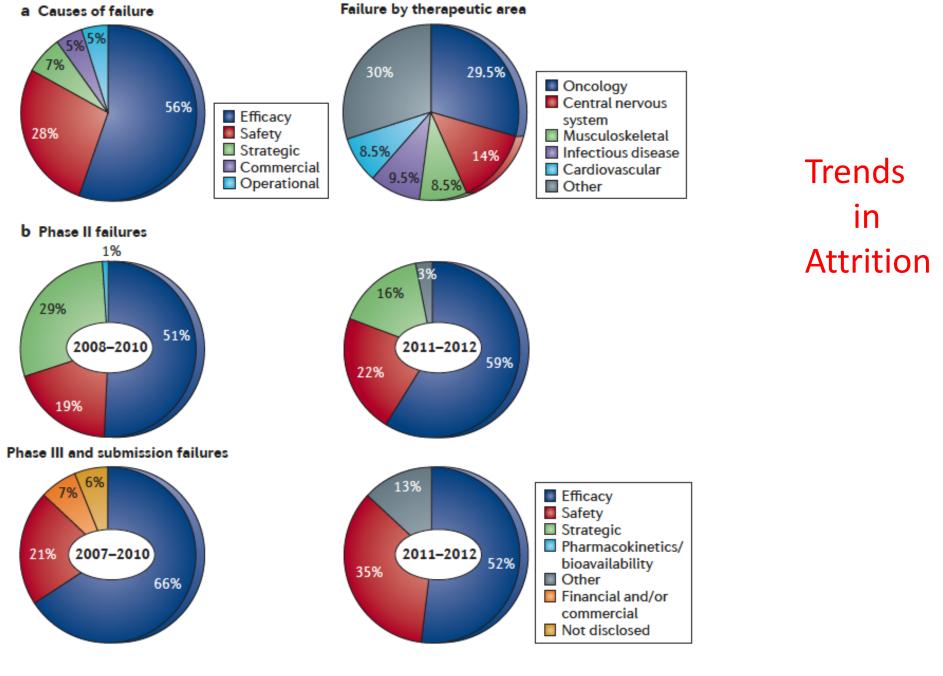


Approximately 50 percent of fresh fruit



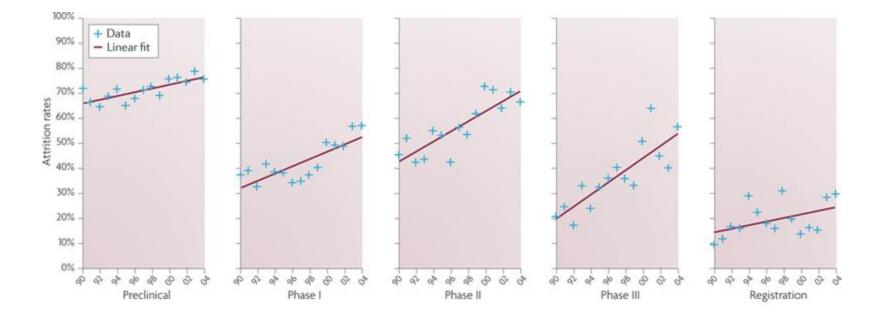
Approximately 20 percent of fresh vegetables

Sources: Hamburg, M. 2011. Food and Drugs: Can Safety Be Ensured In a Time of Increased Globalization? Presented at the Council of Foreign Relations New York Symposium, January 31.



Source: Nature June 2011

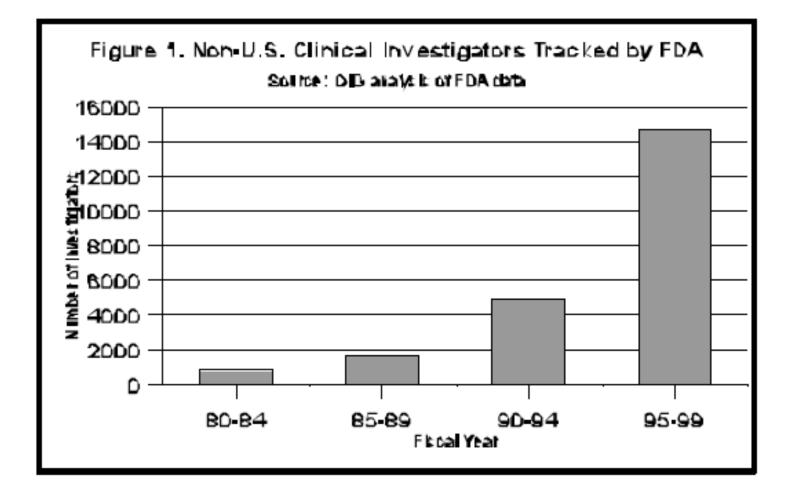
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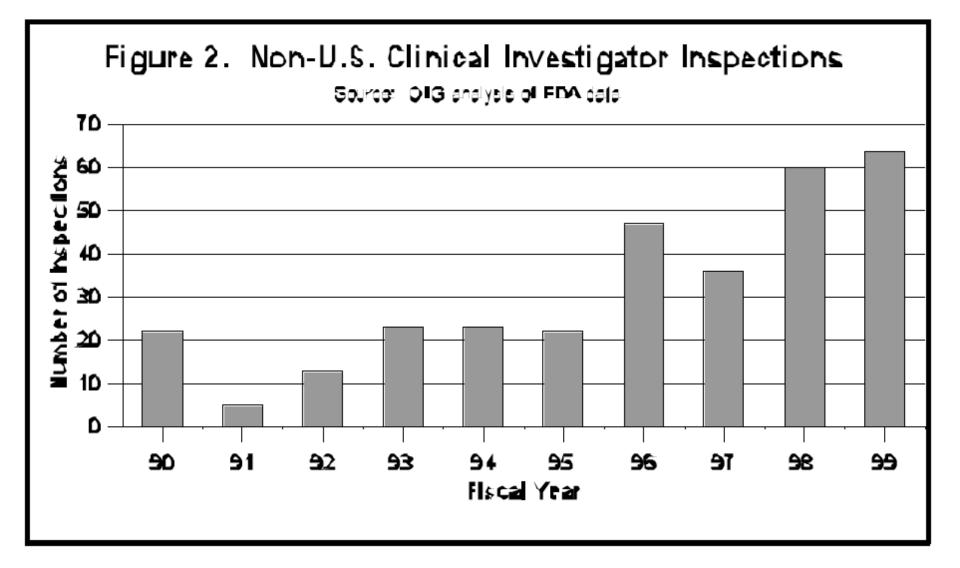
Nature Reviews | Drug Discovery

Source: Nature June 2011

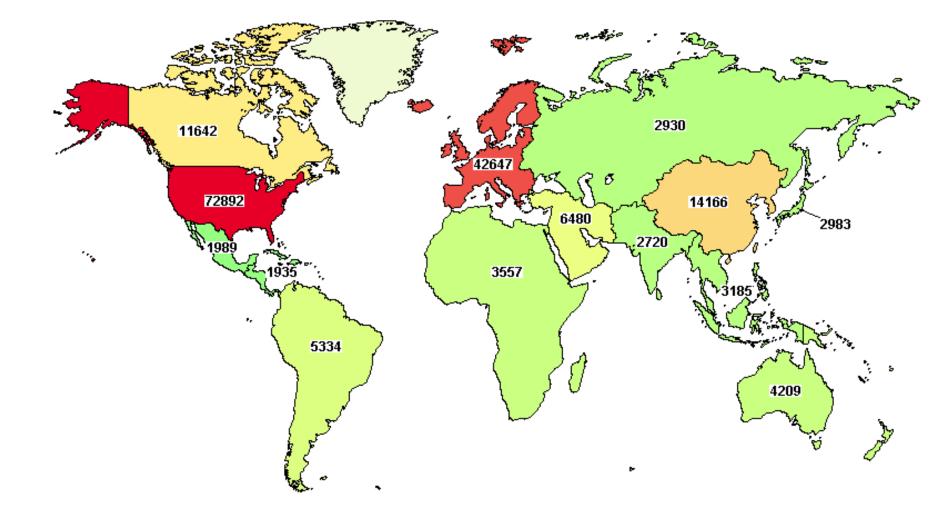
## IND application increased 16 fold...



#### Source: FDA : Globalization of Clinical Trials, 2001

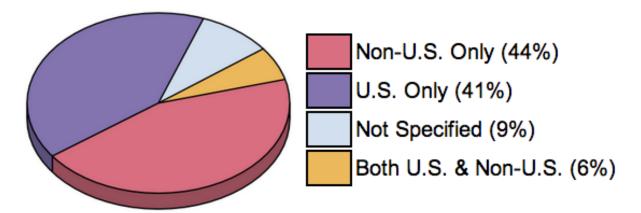


Source: FDA : Globalization of Clinical Trials, 2001



#### Accessed on 22<sup>nd</sup> Nov, 2013 Clinical trial.gov

# Location of Registered Studies



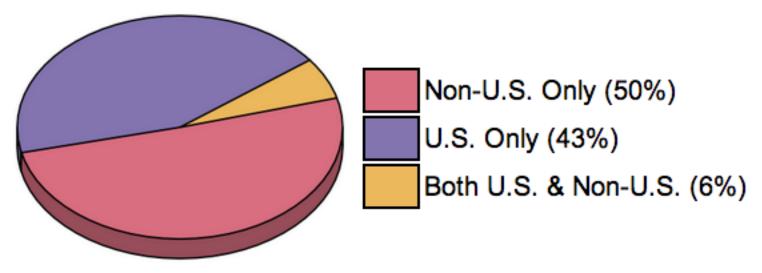
Location	Number of Registered Studies and Percentage of Total
Non-U.S. Only	68,855 (44%)
U.S. Only	63,210 (41%)
Not Specified*	14,043 (9%)
Both U.S. & Non-U.S.	9,682 (6%)
Total	155,790

\* Not Specified: The location of the study was not provided by the Sponsor.

(Data as of November 22, 2013)

Accessed on 22<sup>nd</sup> Nov, 2013 Clinical trial.gov

# Location of Recruiting Studies



Location	Number of Recruiting Studies and Percentage of Total	
Non-U.S. Only	15,937 (50%)	
U.S. Only	13,702 (43%)	
Both U.S. & Non-U.S.	Non-U.S. 1,948 (6%)	
Total	31,587	
(Data as of November 0		

(Data as of November 22, 2013)

Accessed on 22<sup>nd</sup> Nov, 2013 Clinical trial.gov

## Guidance for Industry and FDA Staff

#### FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions

Additional copies are available from: Division of Drug Information, WO51-2201 Office of Communication Center for Drug Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993-002 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm Email: DRUGINFO@fda.hhs.gov (Tel) 301-796-3400; (Fax): 301-847-8714 and/or Office of Communication, Outreach and Development, HFM-40 Center for Biologics Evaluation and Research Food and Drug Administration 1401 Rockville Pike Rockville, MD 20852-1448 http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatorvInformation/default.htm Email: ocod@fda.hhs.gov (Tel) 800-835-4709 or 301-827-1800 and/or Office of Good Clinical Practice Office of the Commissioner http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

> U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research Center for Biologics Evaluation and Research Office of Good Clinical Practice March 2012

В.	SUPPORTING INFORMATION (21 CFR 312.120(b))	5
1.	Investigator Qualifications (Section 312.120(b)(1))	6
	What documentation should the sponsor or applicant provide regarding investigator	
	qualifications?	
2.	Description of the Research Facilities (Section 312.120(b)(2))	7
	Is the name and address of the research facility a sufficient description to address this	
	requirement?	7
3.	Detailed Summary of the Protocol and Study Results and, If Requested, Case Records or	
	Additional Background Data (Section 312.120(b)(3))	7
а.	Would a study report "Synopsis" (as shown in ICH E3, Annex I) provide a sufficiently detailed	
	summary of the protocol and study results?	7
<i>b</i> .	Will FDA need access to case records maintained by the investigator or additional background	
	data such as hospital or other institutional records?	8
4.	Description of the Drug Substance and Drug Product, Including the Components,	
	Formulation, Specifications, and, If Available, the Bioavailability of the Drug Product	
	(Section 312.120(b)(4))	8
	What information should the sponsor or applicant provide to meet the requirement in 21 CFR	
	312.120(b)(4)?	
5.	Information Showing that the Effectiveness Study is Adequate and Well Controlled Under	
	21 CFR 314.126 (Section 312.120(b)(5))	9
	What information should the sponsor or applicant submit to FDA to show that the study is	
	adequate and well controlled under 21 CFR 314.126?	9
6.	The Name and Address of the IEC that Reviewed the Study and a Statement that the IEC	
	Meets the Definition in 21 CFR 312.3 (Section 312.120(b)(6))	
	What does FDA consider an "adequately constituted" IEC?	9
<i>b</i> .	What information must the sponsor or applicant provide to FDA and what information must the	
	sponsor or applicant maintain with respect to the names and qualifications of all IEC members?	
		0
7.	Summary of the IEC's Decision to Approve or Modify and Approve the Study, or to	
	Provide a Favorable Opinion (Section 312.120(b)(7))1	
	How much detail should the sponsor or applicant provide regarding the IEC's decisions? 1	0
<i>b</i> .	After submitting this required documentation in the IND/NDA/BLA, is the sponsor required to	_
	submit IEC actions on continuing review to FDA?	
8.	Description of How Informed Consent Was Obtained (Section 312.120(b)(8))1	
	What level of detail is needed in this description?	1
9.	Description of What Incentives, If Any, Were Provided to Subjects to Participate (Section	
	312.120(b)(9))	
	What information should sponsors or applicants provide to address this requirement?	1
10.	Description of How The Sponsor Monitored the Study and Ensured that the Study Was	
	Carried Out Consistently with the Study Protocol (Section 312.120(b)(10))1	1
	What documentation fulfills the requirement for a description of how the sponsor monitored the	
	study and ensured that the study was consistent with the protocol?	1

## To Do List for a Regulator...

- Nature of the challenge
- Improving the efficiency of development through collaboration and communication
- Improving internal FDA processes to support new paradigms
- Staying open to change

Douglas C. Throckmorton, Deputy Director for Regulatory Programs, CDER, FDA DIA April 18, 2012

## **Regulatory Science Activities:** Communication

- Provide clear roadmap to speed development
  - Guidances: Adaptive Trial Designs, Meta-Analysis, Adverse Events Reporting Rule
  - Drug Development Tools:
    - PROs, Biomarkers, Animal Models (CT)
  - PDUFA V proposal for enhanced communications teams to aide drug developers

### Example of Regulatory Innovation: Adaptive Trial Design Guidance

- Adaptive Design Clinical Trials for Drugs and Biologics (2010)
- Goals:
  - Decrease time between discovery & "confirmatory" studies
  - Make studies more likely to succeed by adapting design elements that could not be fully known when the study was planned and powered:
    - effect size
    - event rate in the population
    - most responsive subset
    - the right dose
    - the best study endpoint



Douglas C. Throckmorton, Deputy Director for Regulatory Programs, CDER, FDA DIA April 18, 2012

### Example: International Serious Adverse Event Consortium (iAES)

- Matching phenotyped cases and controls for pharmacogenetic research on important drug-induced SAEs: TdP, Liver toxicity, Allergic Reactions
- Developing effective whole genome genotyping and sequencing methods for SAE research
- Supporting the development of the computational methods necessary for effective GWAS analysis (both genotyping and sequencing)
- Creating a <u>timely</u> and <u>publicly</u> available scientific "databank"(raw data and genetic markers) associated with key drug-induced SAEs
- Managing the intellectual property related to genetic markers associated with SAEs, to ensure broad and open access to all users in all settings
- Initiated in concert with FDA as part of Critical Path Initiative

Douglas C. Throckmorton, Deputy Director for Regulatory Programs, CDER, FDA DIA April 18, 2012

## EMA & FDA Initiative





European Medicines Agency

US Food and Drug Administration

London, 29 July 2009 Doc. Ref. EMEA/INS/GCP/538414/2008 FDA Mod. 20 August 2009

#### **EMEA-FDA GCP Initiative**

#### Terms of engagement and procedures for participating authorities

Pilot Phase (18 months): Start date 01 September 2009

## EMA & FDA Initiative

#### 2. Objectives

- 2.1 To Conduct Periodic Information Exchanges on GCP-Related Activities
  - a. To streamline the sharing of information relevant to GCP inspection planning so that the selection of studies and sites is well informed, and inspection coverage is improved.
  - b. To exchange GCP-related information contained in applications for scientific advice, orphan medicines designation, pediatric investigational plans, marketing authorization or post-authorization activities of significant public health interest.
  - c. To communicate effectively and in a timely manner on inspection outcomes (negative and positive) and their potential impact, where the clinical trials and/or inspected sites/organizations are of common interest.
- 2.2 To Conduct Collaborative GCP Inspections
  - a. To build mutual understanding of, and confidence in, the GCP inspection processes utilized by the EU/EMEA and FDA – through the sharing of information, experience and inspection procedures, and cooperation in the conduct of inspections.
  - b. To improve effectiveness of inspections by sharing best-practice knowledge in order to enhance inspection techniques and processes.
- 2.3 To Share Information on Interpretation of GCP
  - a. To keep each other informed of GCP-related legislation, regulatory guidance documents, position papers, and policy documents that might be in draft or finalized form.
  - b. To identify and act on areas where greater convergence could be achieved to the benefit of the clinical research process.



16 April 2012 EMA/121340/2011 The European Medicines Agency Working Group on Clinical Trials conducted outside of the EU/EEA

Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorisation applications to the EU Regulatory Authorities

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#### Key 2016 Numbers

Spending ~ \$1.2 Trillion

Spending on Brands \$615-645Bn

Spending on Generics \$400-430Bn

**Developed Country Spending Per Person \$609** 

Pharmerging Country Spending Per Person \$91

Key 2012-2016 Numbers

New Molecular Entity Launches 160-185

Global Spending Growth CAGR 3-6%

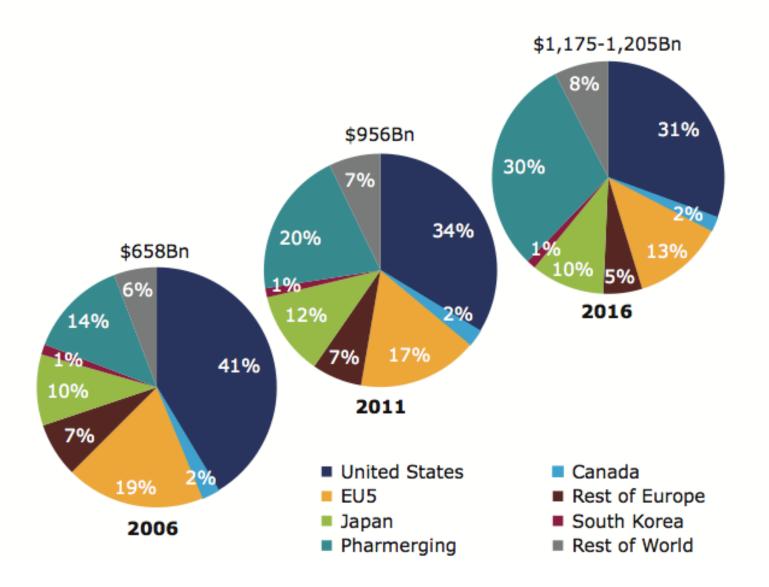
U.S. Spending Growth CAGR 1-4%

Pharmerging Spending Growth CAGR 12-15%

Global use of Medicines: Outlook throu' 2016, IMS health, July 2012

"Patent Dividend" \$106Bn

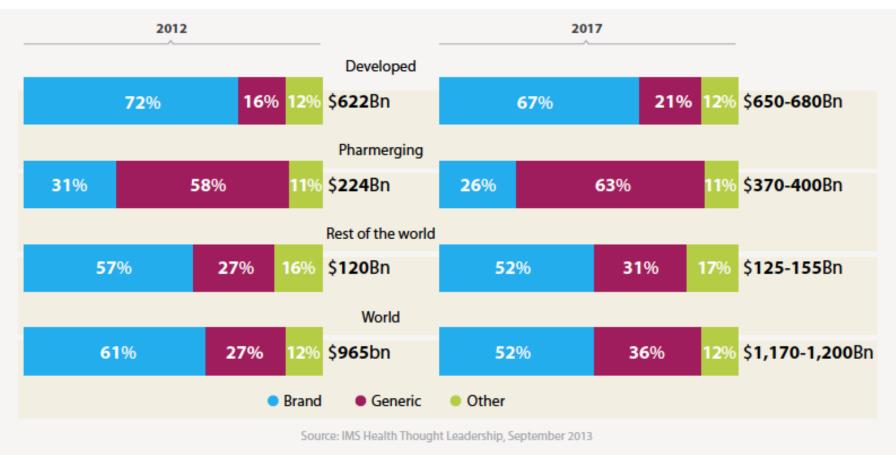
#### Spending by Geography



#### Spending in 2016

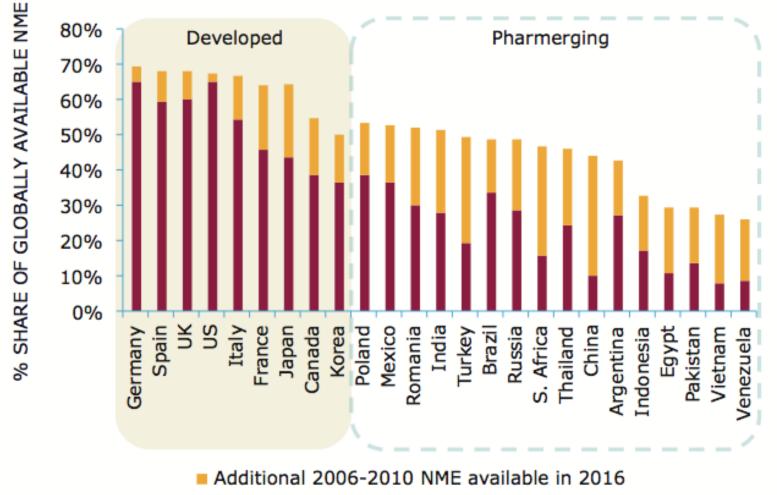
Top 20 Classes, 42%	Others, 58%
Top 20 Classes, 42%	
Immunosuppressants Contraceptives Cephalosporins Antivirals, excl HIV ADHD	\$13-15Bn \$13-15Bn \$13-15Bn \$13-15Bn \$12-14Bn \$12-14Bn

#### Global Spending, 2012 and 2017



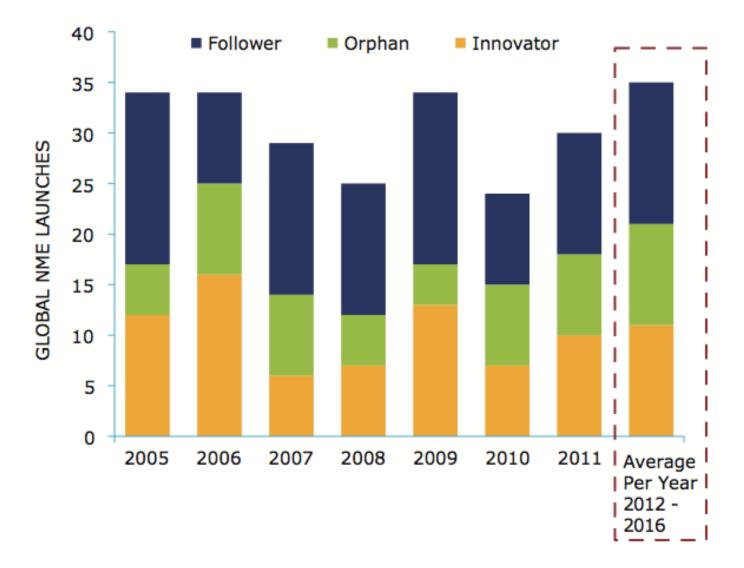
Generics will continue to dominate growth in spending in pharma-emerging markets and will account for 63% of the total market at the end of the forecast period.

#### Global New Molecular Entities Country Availability

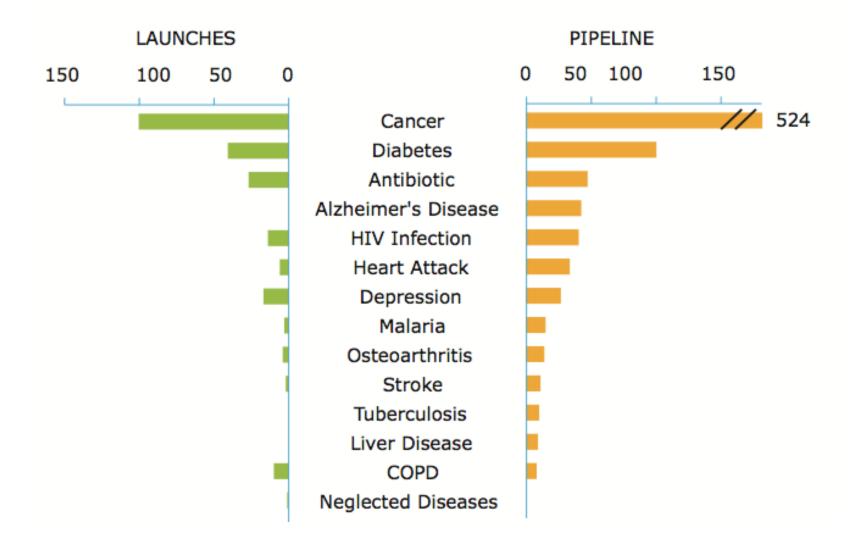


2006-2010 NME available in 2011

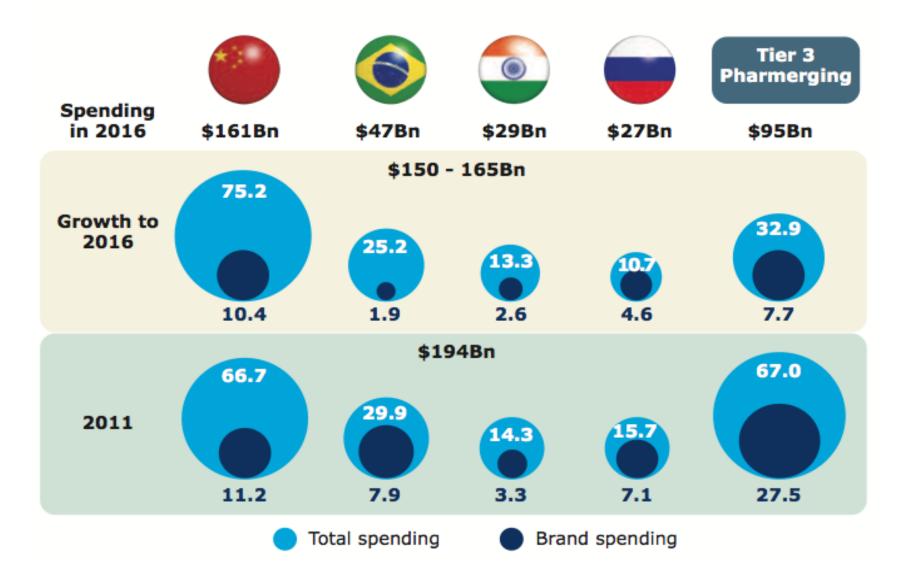
#### **Global Launches of New Molecular Entities**



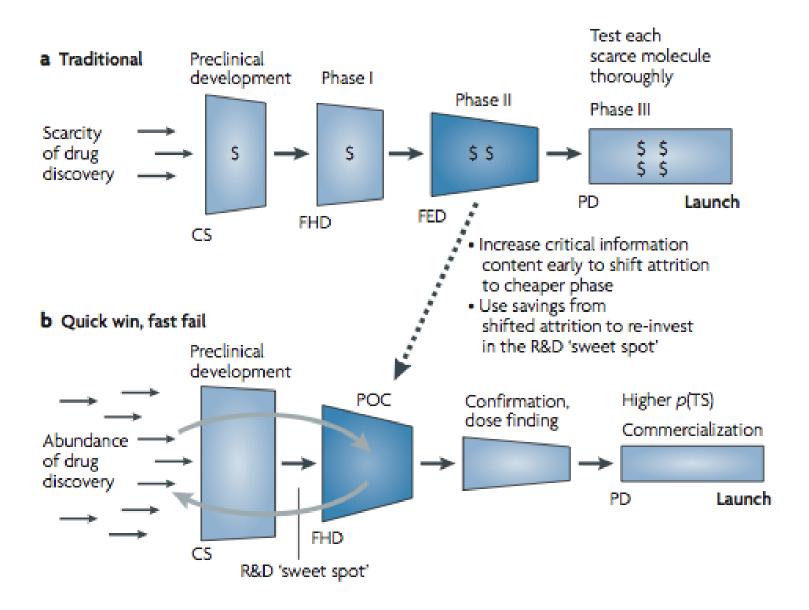
#### Launches & Pipeline in Priority Diseases



## Pharmerging Spending and Growth



Global use of Medicines: Outlook throu' 2016, IMS health, July 2012



Nature Drug Discovery 2010 March; (9): 211 - 213

## A Comparison of the Quality of Data, Assessed Using Query Rates, From Clinical Trials Conducted Across Developed Versus Emerging Global Regions

Drug Information Journal 46(4) 455-463 © The Author(s) 2012 Reprints and permission: sagepub.com/journalsPermissions.nav DOI: 10.1177/0092861512446807 http://dij.sagepub.com

Pankaj B. Desai, PhD<sup>1</sup>, Christopher Anderson<sup>1,2</sup>, and William K. Sietsema<sup>1,2</sup>

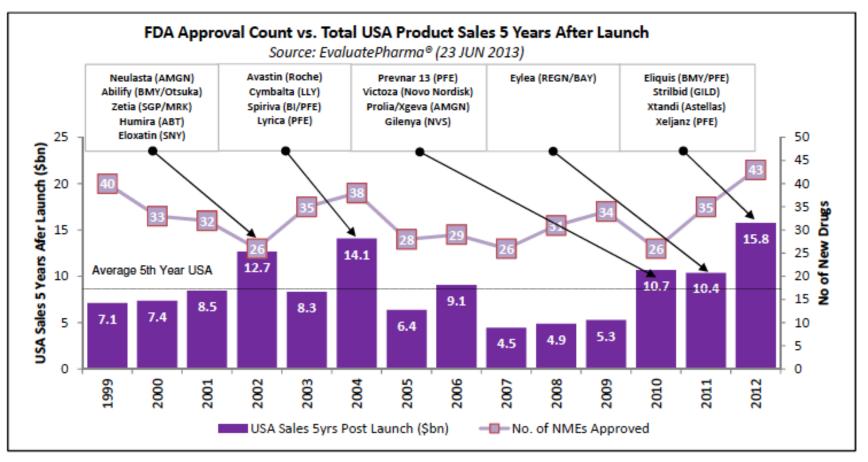
#### Abstract

With increasing globalization of clinical trials, there is a growing concern regarding the quality of data generated from clinical studies conducted in some of the emerging regions. This concern has not been comprehensively addressed thus far because there is limited public access to restricted databases. In this study, we utilized data from 26 large phase II/III trials conducted in multiple regions of the globe by members of the Association of Clinical Research Organization and compared query rates, one of the few measurable parameters of quality of clinical trials data, between different global regions. A query is generated when a discrepancy is noted between protocol or source data and the case report forms (CRFs). A resolution of such an inconsistency is necessitated, which may result in a database change. The studies included in our analyses were conducted at 4721 global sites enrolling 63,871 participants. Overall, the data set included 1.39 million queries, 7.5 million CRF pages, and 95 million data parameters. The number of queries for various regions was added for each trial and normalized to the number of CRF pages or to the number of CRF data parameters. The calculated mean query rates and database change rates were compared using parametric and non-parametric statistical approaches. None of these approaches revealed statistically significant differences in the query rates or the rate of database change when each region was compared to North America or Western Europe. Thus, a comparative assessment of query rates suggests that the quality of clinical trials conducted in emerging countries is consistent with those conducted in developed regions. Despite several limitations of our analyses and the multifaceted complexities of global clinical trials, our findings should alleviate some concerns regarding clinical studies conducted in emerging nations.



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#### FDA Approval Count (NMEs & Biologicals) vs. 5th Year after Launch USA Product Sales

Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
No. of NMEs Approved	35	27	24	17	21	31	18	18	16	21	19	15	24	33
No. of Biologicals Approved	5	6	8	9	14	7	10	11	10	10	15	11	11	10
Total NMEs + Biologicals	40	33	32	26	35	38	28	29	26	31	34	26	35	43
% Chg.		-18%	<b>-3</b> %	-19%	+35%	+9%	<b>-26</b> %	+4%	-10%	+19%	+10%	-24%	+35%	+23%
USA Sales 5yrs Post Launch \$bn	7.1	7.4	8.5	12.7	8.3	14.1	6.4	9.1	4.5	4.9	5.3	10.7	10.4	15.8
% Chg.		+4%	+14%	+50%	-34%	+69%	-55%	+42%	-51%	+10%	+8%	+103%	-3%	+52%
5yr USA Sales per Approval \$m	178	224	264	487	238	371	228	313	172	158	155	411	297	367
% Chg.		+26%	+18%	+84%	-51%	+56%	<b>-39</b> %	+38%	-45%	- <b>8</b> %	-2%	+165%	-28%	+23%

#### Evaluate Pharma: World Preview 2013 Outlook to 2018

### Critical decisions need to be made impacting many parts of the organization

#### Years to Loss of Exclusivity

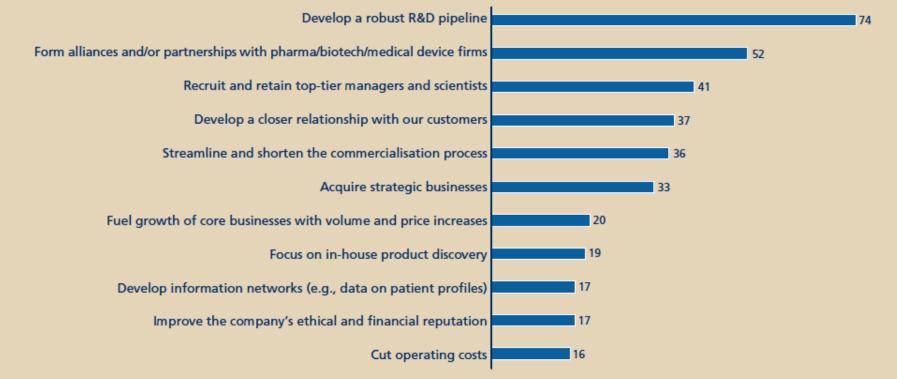
	-5yrs		-3yrs		-1yrs		LoE	+1	yrs	+3yrs	
Product Performance				t generic ero nould I expec		erod	are competito				
Product Strategy Options	/hat LCM options sho pursued? E.g., form combos, purity, pe Should we invest in trials for OTC switc	ns/ eds use	Shoul moneti assets/out What regiona	d we ze our t-license? al/formulatio	import implicat Should 2n	ions? we lice d brand ized ger cts enh:	/ neric?	produ	here additional ct enhancements ould be pursued?	-	Do we require a discontinuation plan?
Pricing & Contracting	_		t's our pricing s LoE e.g., incre		What contracts sl we pursue?	hould		e market access ending LoE?	How should share? How are	we drop price to generic compet	
Field Force/ Promotion		should we o force promo i	ptimize field near LoE?		ld we do with s field force?		uld we change messaging?		promotion should nued post LoE?		where should we readjust promotion strategy?
Manufacturing			nanufacturing v ange post LoE?				ion plans shou optimize profi			outsource g production?	
IP/Legal			continue to clo ent loopholes?	se			orce and moni of patents?	tor			

LoE Planning & Life Cycle Management

#### Figure 4

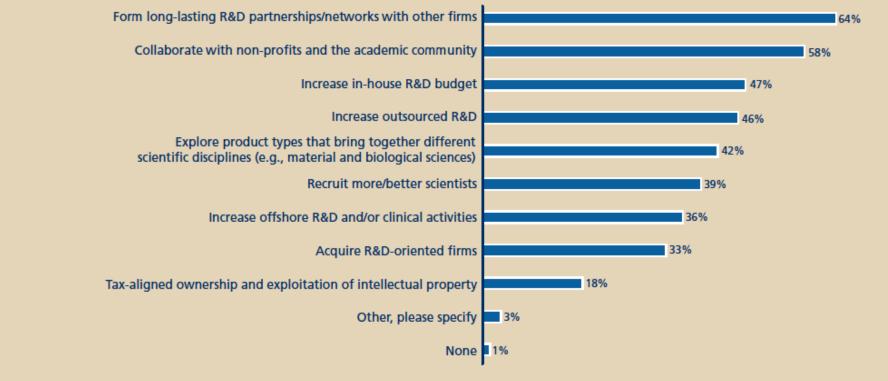
#### IMS Asia Pacific Insight Issue 2, 2012

Which of the following strategies will be the most important in securing your company's continued success through 2015? (% respondents)

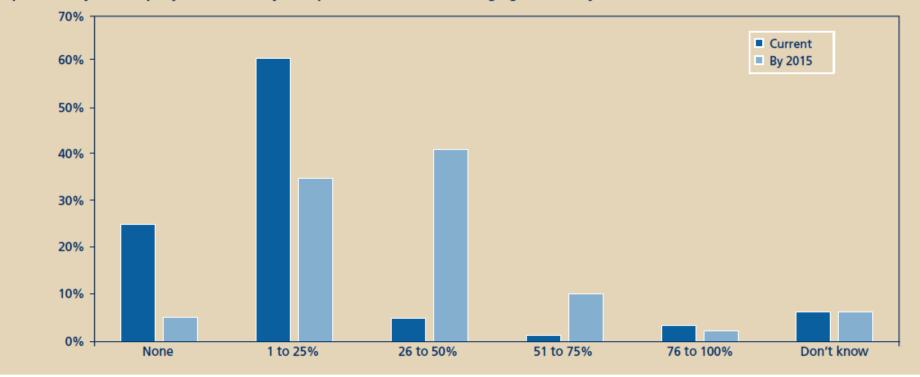


Ref: Deloitte Report : The Future of LifeSciences Industry : Strategies for Success in 2015





Ref: Deloitte Report : The Future of LifeSciences Industry : Strategies for Success in 2015



What portion of your company's revenue currently comes from emerging markets, such as China, India, and Eastern Europe? What portion of your company's revenue do you expect will come from emerging markets by 2015?

*Ref: Deloitte Report : The Future of LifeSciences Industry : Strategies for Success in 2015* 

### Spending by Therapy Area in 2017

op 20 Classes 71	1%	Others 29%	Top 20 Classes	45% Others 55%	
	Developed Markets	Sales in 20	17 (LC\$)	Pharmerging Markets*	(LC\$)
Oncology		\$74-84Bn	Pain		\$22-25Br
Diabetes		\$34-39Bn	Other CNS Drugs		\$20-23Br
Anti-TNFs		\$32-37Bn	Antibiotics		\$18-21Br
Pain		\$31-36Bn	Oncology		\$17-20Br
Asthma/COPD		\$31-36Bn	Hypertension		\$14-17Br
Other CNS Drugs		\$26-31Bn	Diabetes		\$10-12Br
Hypertension		\$23-26Bn	Dermatology		\$10-12B
Immunostimulants		\$22-25Bn	Antiulcerants		\$9-11Bn
HIV Antivirals		\$22-25Bn	Cholesterol		\$6-8Bn
Dermatology		\$22-25Bn	Asthma/COPD		\$3-5Bn
Antibiotics		\$18-21Bn	Anti-Epileptics		\$3-5Bn
Cholesterol		\$16-19Bn	Antivirals excluding HIV		\$3-5Bn
Anti-Epileptics		\$15-18Bn	Immunosuppressants		\$3-5Bn
Immunosuppressants		\$15-18Bn	Allergy		\$3-5Bn
Antipsychotics		\$13-16Bn	Antidepressants		\$3-5Bn
Antiulcerants		\$12-14Bn	Antiplatelet		\$3-5Bn
Antidepressants		\$10-12Bn	Antipsychotics		\$2-3Bn
ntivirals excluding HIV		\$8-10Bn	Heparins		\$1-2Bn
ADHD		\$7-9Bn	Erectile Dysfunction		\$1-2Bn
Interferons		\$6-8Bn	Immunostimulants		\$1-2Bn
		Specialty	Traditional		

Source: IMS Health Thought Leadership, September 2013

#### The biologics market

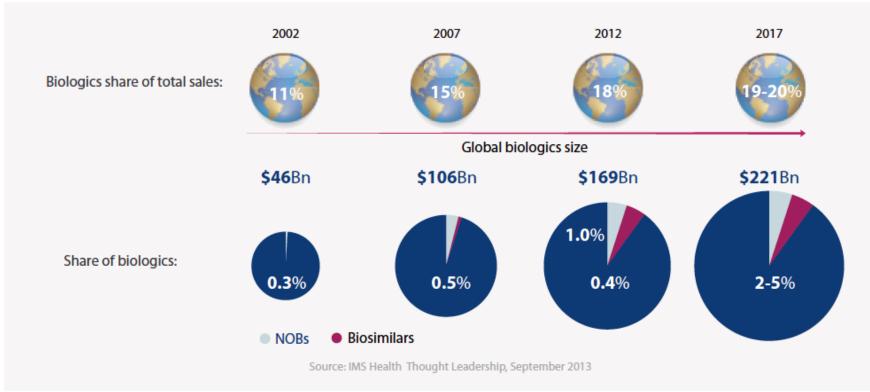


Table 1 Key R&D, publication, patenting, and pharmaceutical market indicators for China, India, Brazil, South Africa and select developed markets

Country	R&D Expenditure as a % of GDP <sup>1</sup>	Gross Expenditure on R&D in Billions USD <sup>1</sup>	Share of Glob Scientific Publica [Annual Grow Rate b/w 2000-2	tions Rate in Patentin th (2000–2006) <sup>2</sup>		ons Pharmaceutical ted Market, 2006-2010
China	1.5 (2008)	102	12%, [23.4%]	26.5%	25.7 (48.8)	17.3% (13.6%)
India	0.80	24.8	2.3%, [4.7%]**	42%*	14.1 (30.4)	16.6% (16.6%)
Brazil	1.10	20.3	1.6%, [12.2%]***	N/A	15.3 (34.4)	13.1% (17.6%)
Canada	1.84 (2008)	24.0	2.7%	3.9%	26.6 (30.2)	5.4% (2.6%)
Germany	2.54	72.2	4%08	5.7%	37.9 (41.5)	3.4% (1.8%)
Japan	3.44	148	4.8%	4.5%	72.4 (102.7)	4.4% (7.2%) ****
United States	2.82 (2008)	398	16%	2.6%	292.8 (344.7)	2.9% (3.3%)

Sources: <sup>1</sup> UNESCO Science Report 2010. Data is for 2007 unless stated otherwise.

<sup>2</sup> OECD Science, Technology and Industry Outlook 2010. Share of publications is for 2008, except for India where this share represents 2006 Data

<sup>3</sup> DataMonitor 2010, Country-specific Pharmaceutical Industry Profile Reports.

\* Estimate for India is for period 1997–2004.

\*\* Estimate for India is for 1995–2005.

\*\*\* Estimate for Brazil is for 1998-2008.

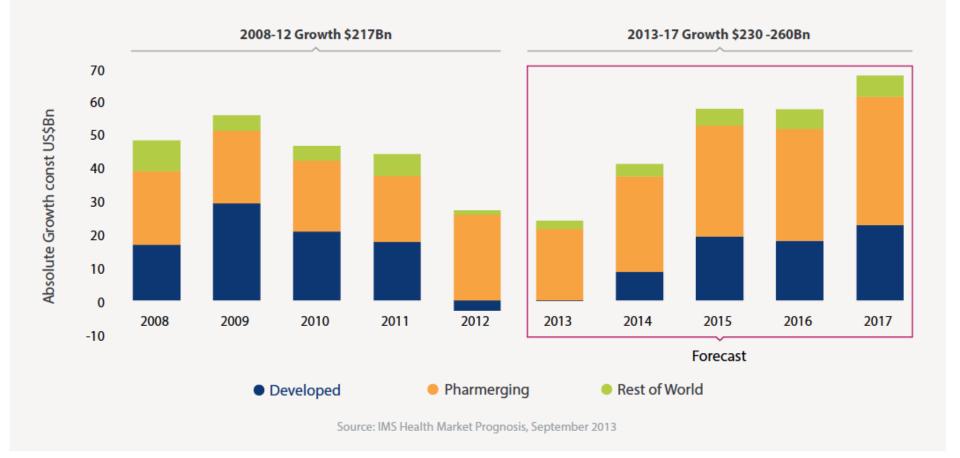
\*\*\*\* Data for 2005-2009 and 2009-1014.

CAGR stands for Cumulative Annual Growth Rate.

# Growth in the emerging countries continues to outpace the developed countries.

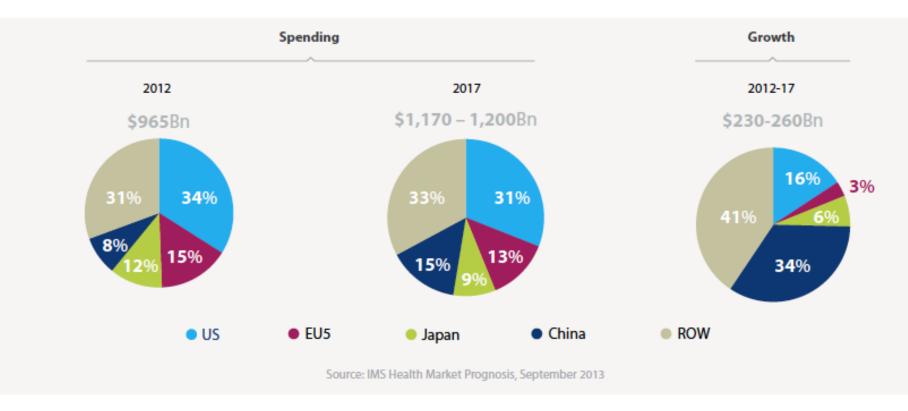
Rezaie et al. Health Research Policy and Systems 2012, 10:18

#### Global Growth, 2008-2017

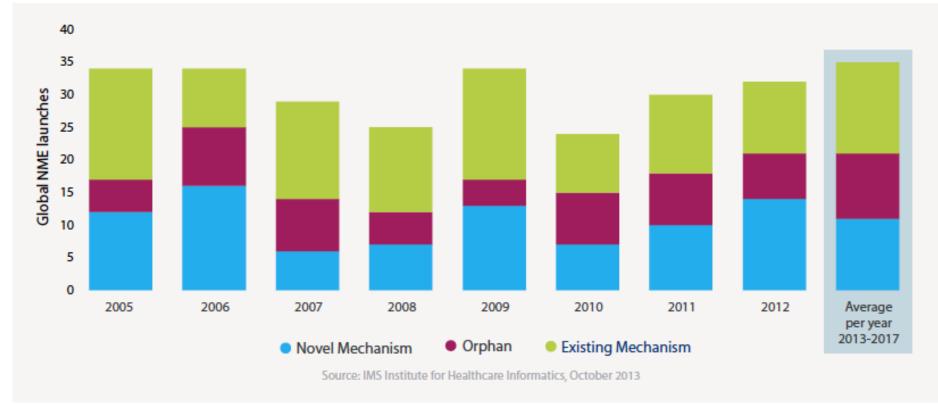


Growth in pharma - emerging markets will increase from \$26Bn in 2012, to \$30-50Bn in 2017, primarily due to increased access to medicines as infrastructure and health systems evolve.

#### Geographic distribution of medicine spending



The U.S., EU5, Japan and China account for just under 70% of total global medicine spending



#### **Global Launches of New Molecular Entities**

Increasing numbers of innovative new medicines and orphan drugs are expected to be launched.

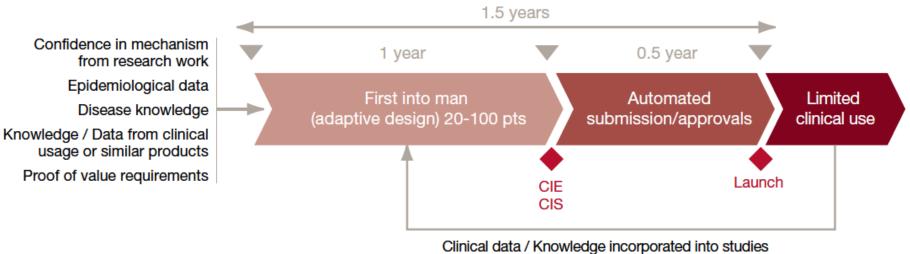
# Agenda

- Overview
- Regulatory Perspective
- Global trends in Drug Development/ Clinical trials
- Global Opportunities
- Global Challenges

# **Global Challenges**

- Regulatory approval
- Medical Infrastructure
  - Addressing adverse events
  - Access to healthcare system
  - Access to specialists
  - Training Investigators
- Culture & Language
- Geography

# **Global Challenges**



on future indications/populations

Source: PwC

## **Development process in 2020**

## Strategic area 1: addressing public-health needs

Objectives <sup>22</sup>	Impact/result indicators	
Stimulate medicines development in areas of unmet medical needs, neglected diseases and rare diseases, and for all types of medicines for veterinary use.	<ul> <li>Increase in the number of scientific-advice requests for medicines for unmet medical needs, neglected diseases and rare diseases, and for all types of medicines for veterinary use.</li> </ul>	EMA Roadmap 2015
	<ul> <li>Increase in the use of specific procedures such as Article 58 procedures (under Regulation (EC) No 726/2004).</li> </ul>	
Facilitate new approaches to medicines development.	<ul> <li>Existing model for medicines regulation is adapted to enable integration of new and emerging science.</li> </ul>	
Apply a more proactive approach to public-health threats where medicines are implicated.	<ul> <li>Effective preparedness mechanisms that take due account of learnings from previous public-health threats/crisis situations are available.</li> </ul>	
	<ul> <li>The 'One World, One Health' concept is applied to link the protection and improvement of animal health with the protection and improvement of human health.</li> </ul>	
	<ul> <li>The Committee for Medicinal Products for Veterinary Use (CVMP) Strategy on Antimicrobials 2011- 2015<sup>23</sup> is successfully completed.</li> </ul>	

## Strategic area 2: facilitating access to medicines

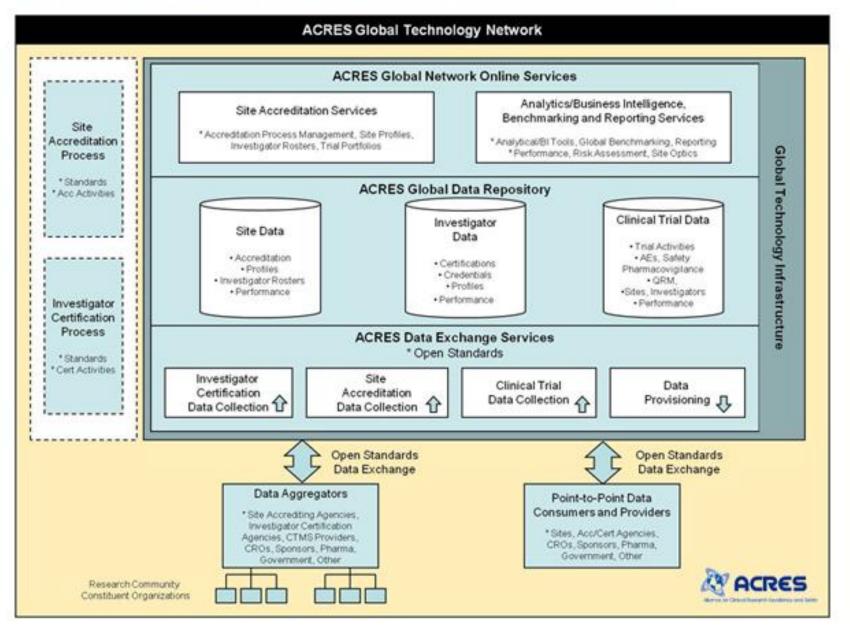
Objectives	Impact/result indicators
Address the high attrition rate during the medicines-development process.	<ul> <li>Increase in the percentage of successful marketing-authorisation applications for new medicinal products by encouraging that scientific advice is sought and adhered to.</li> </ul>
	<ul> <li>Scientific information on failed medicines-development processes is made available to the scientific community.</li> </ul>
Reinforce the benefit/risk-balance assessment model.	<ul> <li>Increased inclusion of quantitative elements, alongside an improved elaboration of the rationale for the decision/opinion in the benefit/risk considerations, for subsequent publication in the European public assessment reports (EPARs) (medicines for human use).</li> </ul>
	<ul> <li>The concept and practice of benefit/risk assessment are embedded as part of the scientific- review process and subsequently communicated in EPARs as part of the methodology used for assessment (medicines for veterinary use).</li> </ul>
Continue to improve the quality and the regulatory and scientific consistency of the outcome of the scientific review.	<ul> <li>Structured external surveys performed by the Agency's stakeholders on the outcome of the scientific reviews demonstrate an increase in the quality and the consistency.</li> </ul>

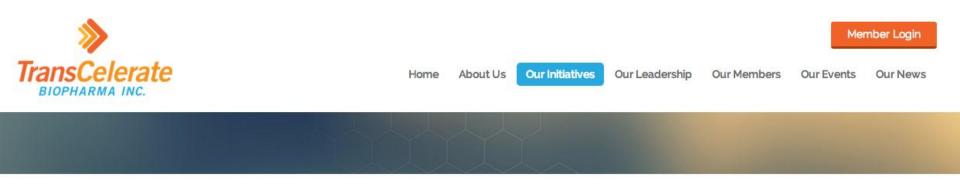
### EMA Roadmap 2015

# Strategic area 3: optimising the safe and rational use of medicines

Objectives	Impact/result indicators
Strengthen the evidence base in the post-authorisation phase to enable better regulatory decision-making.	<ul> <li>A regulatory model that facilitates the post-authorisation collection of data on benefits and risks of medicinal products is put at the disposal of the regulatory system.</li> </ul>
	<ul> <li>A pharmacovigilance framework appropriate to the needs and priorities of the veterinary sector is developed as an outcome of the European Commission's impact assessment of the legislation for veterinary medicines.</li> </ul>
Enhance patient safety by avoiding unnecessary risks to patients as a result of the use of medicines.	<ul> <li>A revised risk-management concept f that targets both novel pharmacovigilance methodologies and a risk-minimisation toolbox better adapted to reduce harm is available.</li> </ul>
Become a reference point for information on medicines evaluated by the Agency.	<ul> <li>A high-quality, informative and targeted set of information on medicines falling within the sphere of the Agency's responsibilities is proactively put at the disposal of the EU regulatory network at the moment of licensing/updating of the marketing authorisation.</li> </ul>
Improve the decision-making process by taking due account of patient experience, thus contributing to the rational use of medicines.	<ul> <li>Conclusions from outcomes-research projects analysing the impact of regulatory decisions on public health are used to provide input into future regulatory policy decision-making.</li> </ul>

## **GLOBAL TECHNOLOGY NETWORK**

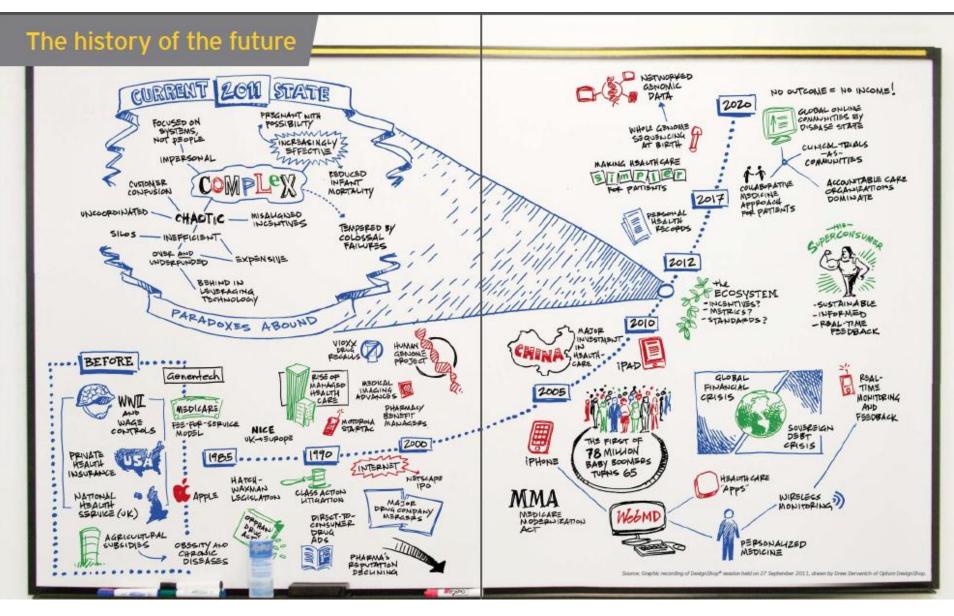




### **Our Initiatives**

At launch, TransCelerate chose the following projects as initial areas of focus: development of risk-based site monitoring approach and standards, development of a shared user interface for investigator site portals, mutual recognition of study site qualification and training, development of clinical data standards, and establishment of a comparator drug supply model.

Risk-Based Monitoring | Site Qualification and Training | Clinical Data Standards | Comparator Drugs | Shared Investigator Portal



Progressions : Global Life Sciences, E & Y, 2012

# Moving Ahead.

- Innovation, the ultimate engine of growth for the global provision of medicines, will see a revival of activity through 2017, with increases in the number of global innovative launches since 2010.
- Growth in pharma-emerging markets will increase from \$26Bn in 2012, to \$30-50Bn in 2017, primarily due to increased access to medicines as infrastructure and health systems evolve.
- Patient-centric approach will transform clinical development, as deep insights allow for more efficient product development and a better understanding of patients' needs.

## Thank you