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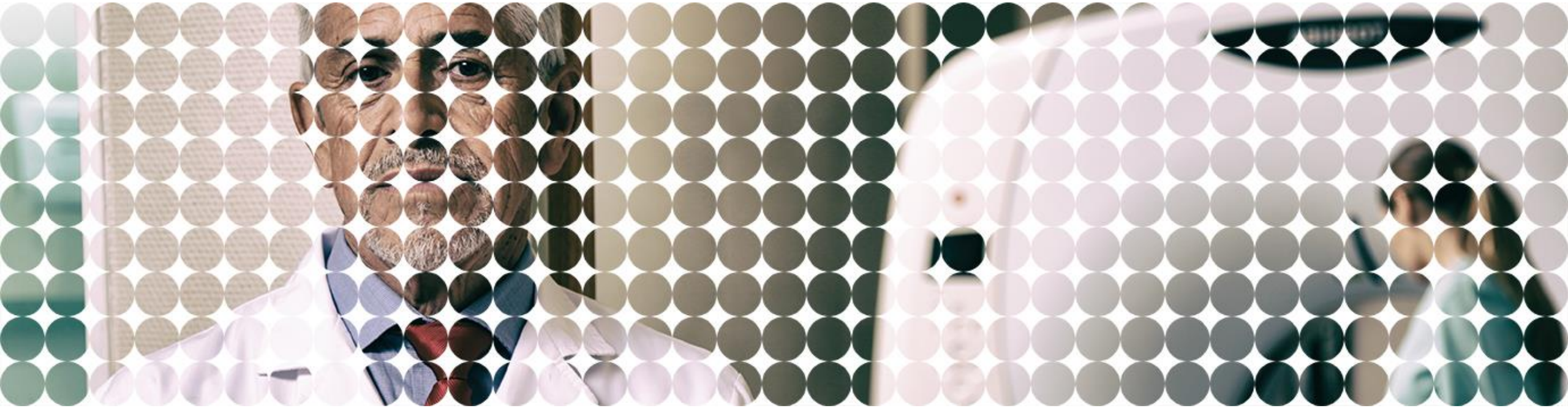


Clinical Research Overview

Lewis Cameron, Executive Vice President Oncology Development

Greetings from London!

The clinical trial pathway

Where from?

- Blockbusters
- e.g. Cardiovascular market
- Traditional clinical trial design
- Paper versus technology

Where are we?

- Shift to personalized medicines
- Oncology key market
- Infectious diseases
- Orphan drugs
- Biosimilars

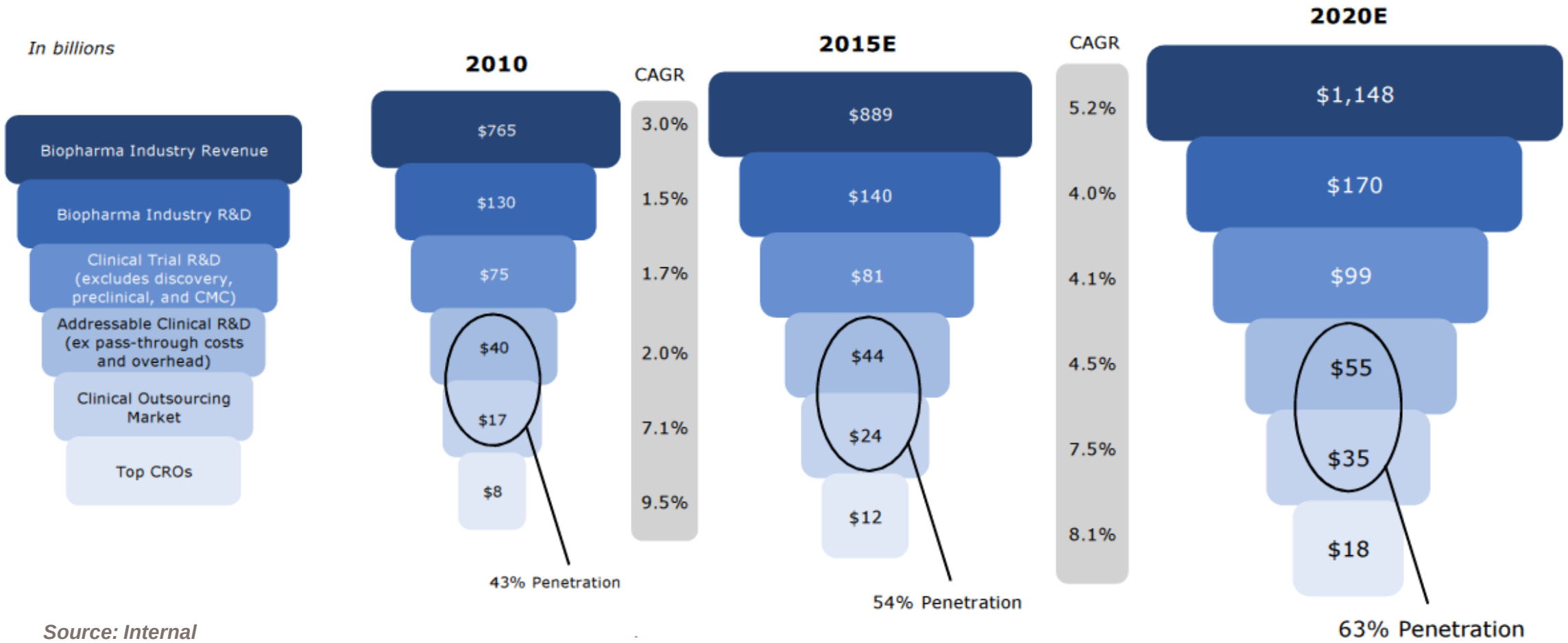
Where to?

- Personalized medicine standard practice
- Cancer / Gene therapy / Immuno-therapy
- Intra patient clinical trials
- Pandemics / epidemics

Key drivers for clinical trials for now and the future

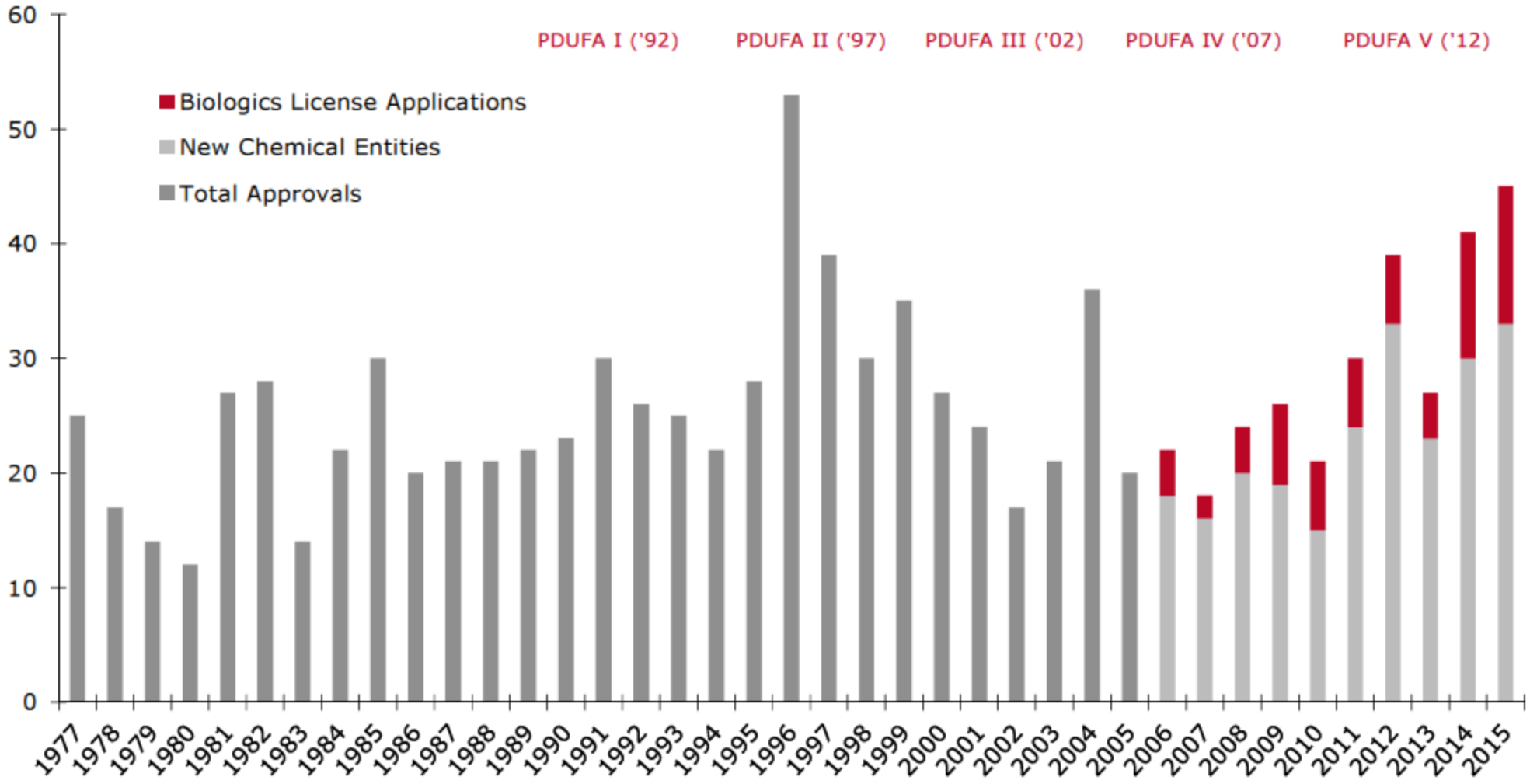
- Financial pressures on pharmaceutical companies and intense competition
- The so called “patent cliff” driven Pharma to re-think their strategies
- Current R&D spend
- Companies externalizing costs to CROs and other service providers
- Reliance on Biotech companies to push early development

Summary of estimated Clinical Trials spending versus industry revenues



Source: Internal

New drug approvals at the FDA have increased dramatically, especially Biologics

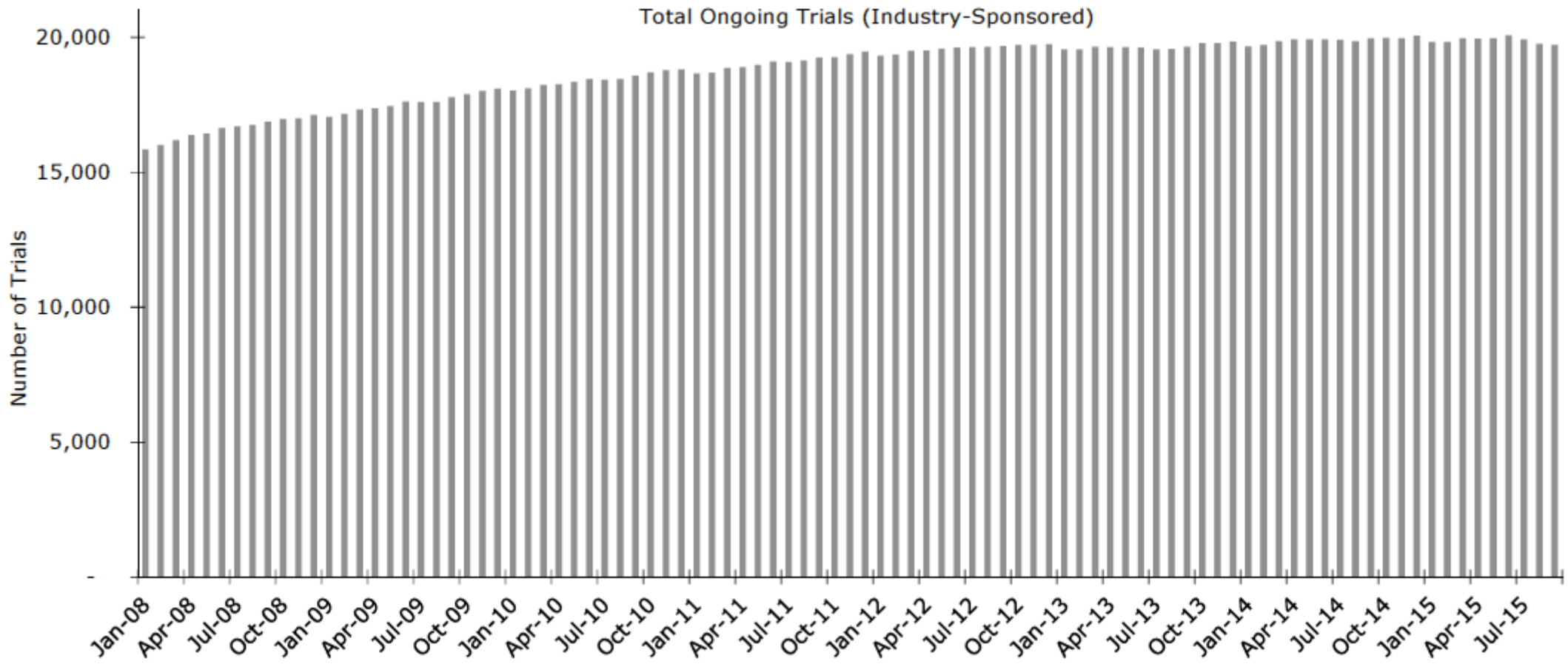


Source: FDA.gov

Factors affecting drug development strategies

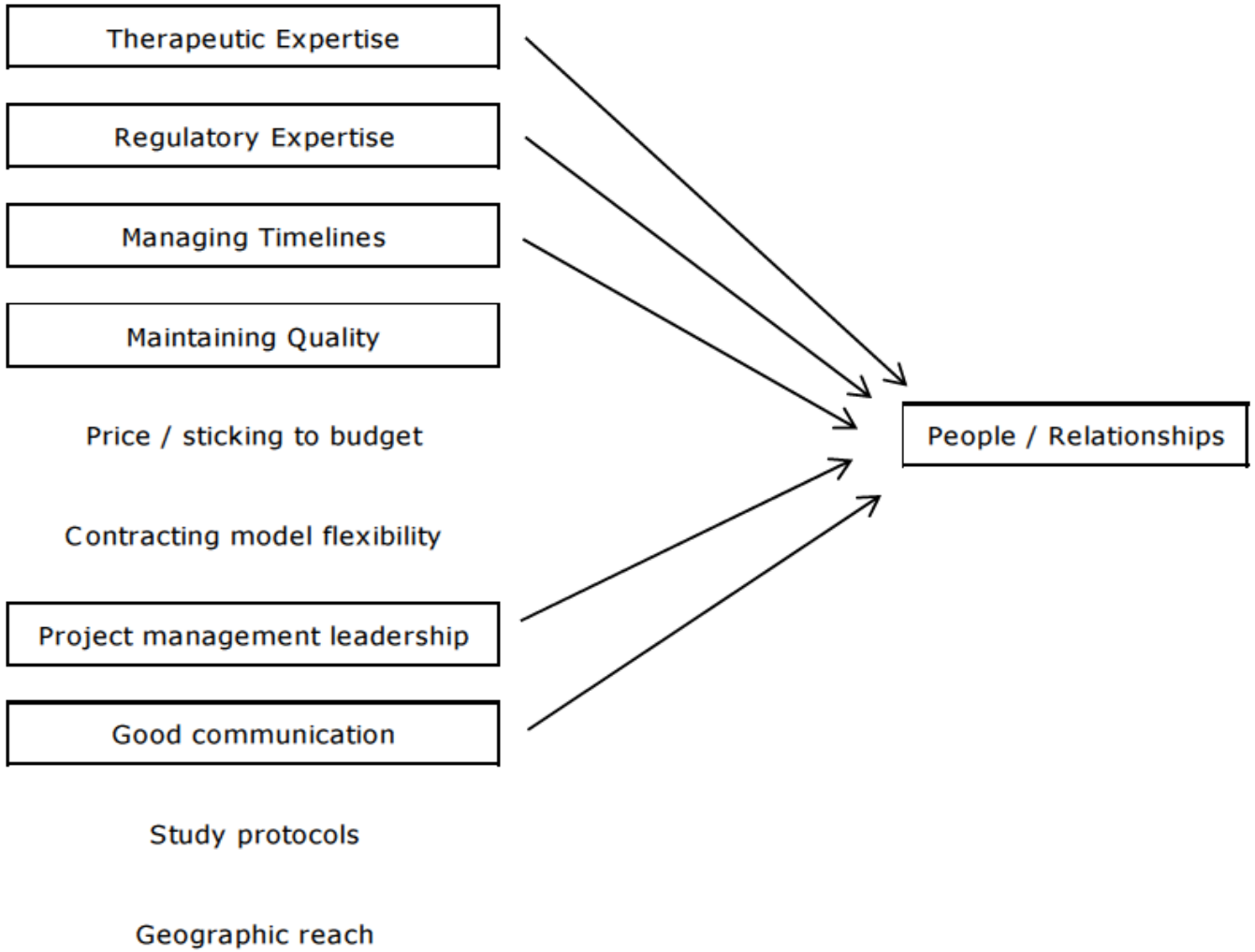
- Ageing population
- The increase in certain diseases and targeted focus
  - CNS – Alzheimer's / Parkinson's
  - Cancer – shift from standard broad spectrum treatments to patient specific approaches
    - Biologics
    - Immuno therapies
  - Orphan Drug
  - Biosimilars
- Number of clinical trials not increasing remarkably but more complex studies

The number of trials has flattened – suggests higher complexity of studies



Source: Clinicaltrials.gov

What DO Sponsors Value?



Key drivers for clinical trials now and the future

- Complex studies with defined patient characteristics
- Broader reach for patients
- Competitive environment

- Start up
  - Regulatory / Ethics Committees
  - Site contracts
- Recruitment
- Data review

- Medical & scientific expertise
- Experienced clinical trial sites
- Technology advances
  - Electronic Data Capture
  - Risk Based Monitoring

Where can Latin America help?

Need for patients

- Vast population – 600M
- Large urban centres
- Specific disease populations

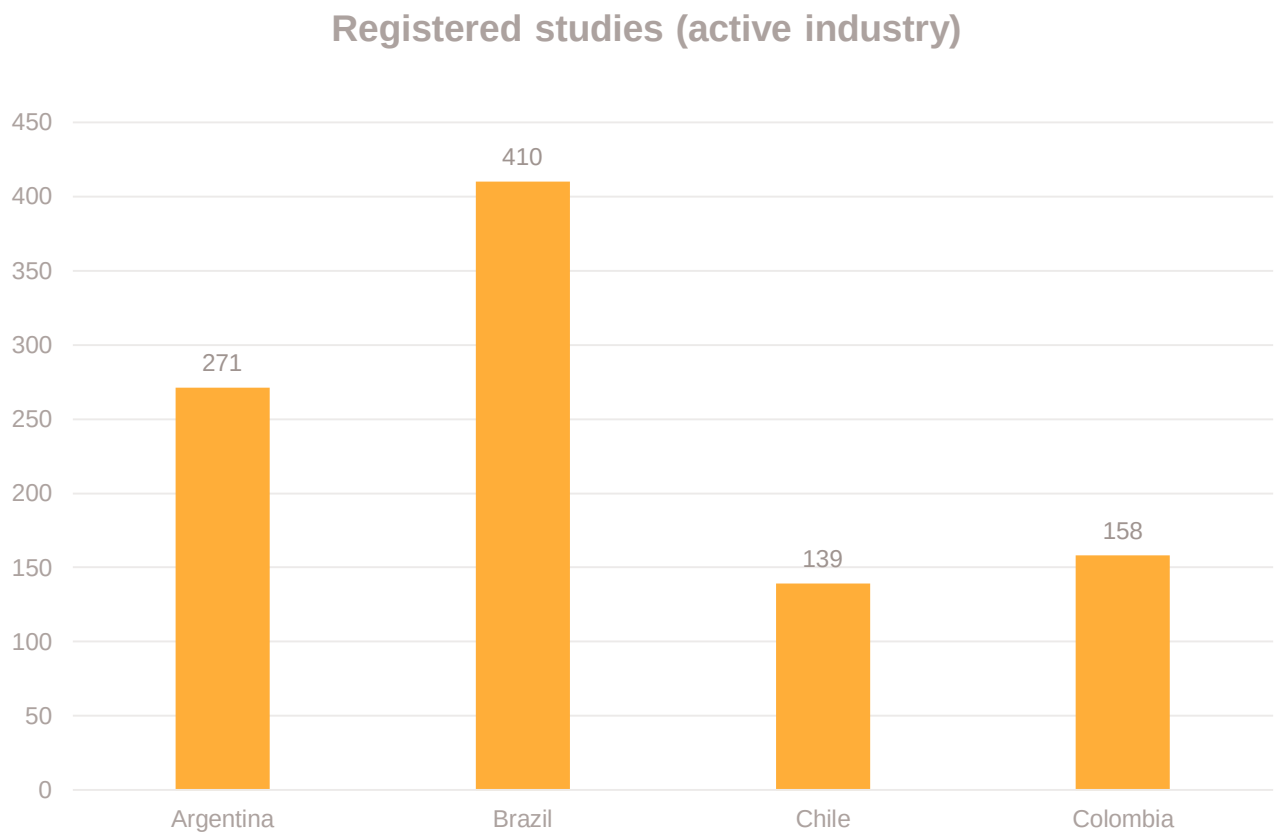
Need for speed

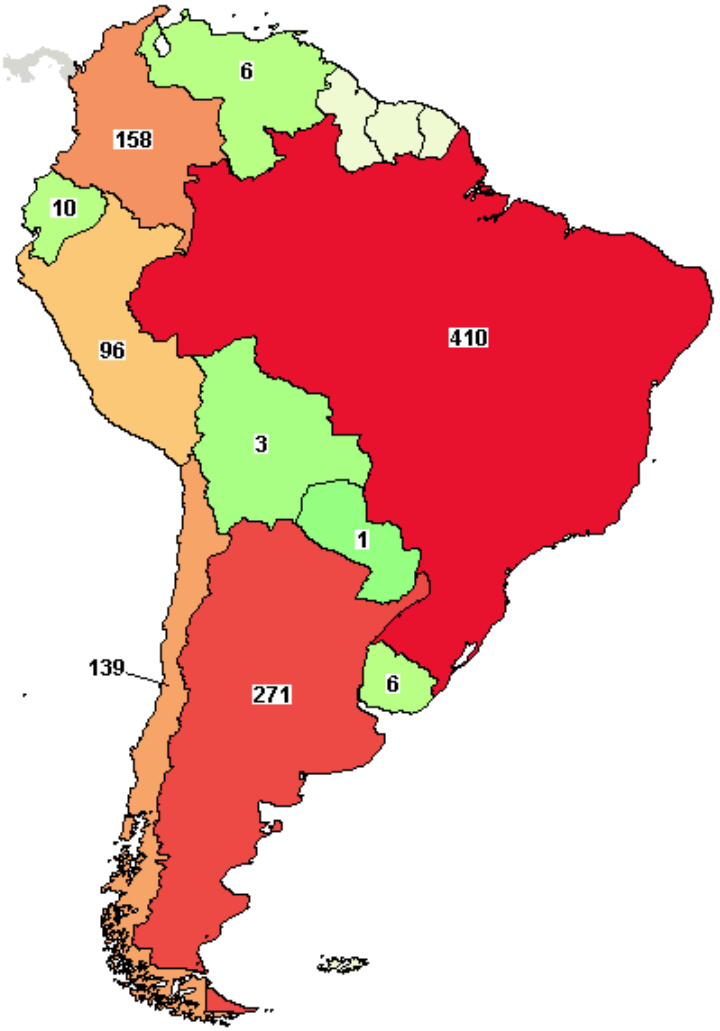
- Regulatory timelines
- Site contract negotiations
- Patient recruitment

Need for expertise & technology

- Highly trained medical personnel
- Experienced clinical trial sites and investigators
- Good infrastructure in urban centres

Registered Studies in Latin America





Source: Clinicaltrials.gov

Quality considerations - FDA Inspections 2005 – March 2014

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Figure 7: FDA Inspections 2005-March 2014

Region	Countries Included (excluding countries with no inspections)	Inspections Since 2005	No Action Required	Voluntary Action Indicated	Official Action Indicated
CIS	Georgia, Russia, Ukraine	102	70.6%	28.4%	1.0%
Latin America	**Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Peru**	**100**	**61.0%**	**38.0%**	**1.0%**
India	India	44	59.1%	40.9%	0.0%
CEE	Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Serbia, Slovakia	166	54.2%	45.2%	0.6%
Western Europe	Austria, Belgium, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom	242	50.8%	48.3%	0.8%
United States	United States	2099	49.5%	43.7%	6.7%
Asia Pacific	Hong Kong, Malaysia, Philippines, South Korea, Taiwan, Thailand	48	47.9%	52.1%	0.0%
China	China	19	42.1%	57.9%	0.0%

Source: http://www.fda.gov/downloads/Drugs/InformationOnDrugs/UCM111343.zip

Advantages and challenges in Latin America

Pros

- Access to clinical trial patient population
- Large urban centres
- Highly qualified and trained personnel
- Recognition of industry standards ICH / GCP
- Only 2 languages – Spanish & Portuguese

Cons

- Regulatory and EC timelines still a challenge for study start up
- Site contracts complex and not standard
- Cultural misunderstandings

Key points for discussion

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CHANGING POPULATION AND DISEASES

Ageing. Infectious diseases

Clinical trial complexity

Large pool of people. Personalised medicine.

4

KEY ASPECTS

In the Globalization of Clinical Research

NEED FOR SPEED

Industry shift and competitive landscape. Competition with other regions.

BRAZIL IS A GREAT OPTION

Patients /Expertise /Increasing market share

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Thank You