MENA and Latin America: Attractive markets for new opportunities in innovation and generics

Dr Trajko Spasenovski
Life Sciences Consultant – Emerging Markets

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Life Sciences Consultant-Emerging Markets

Clarivate Analytics

Trajko Spasenovski is Life Sciences Consultant helping Emerging Markets management to develop LS strategy to maximize revenues, as well as coordinating the global product and professional services support for the sales teams.

Previously, I have been working for Clarivate Analytics (previously Thomson Reuters) as a Senior Account Manager, working with the SME clients in Scandinavia, East Europe and Israel, growing the sales year after year and keeping the relationships with the existing clients. I have an extensive knowledge in the current pharmaceutical markets, working directly with executives in pharmaceutical and biotech companies and providing them with essential business and scientific intelligence. Prior to TR, I worked in various account management roles in Life Sciences Industry (Labtech International, Promega).

I also worked as a medical researcher in the field of molecular biology and he published scientific papers in high impact journals. I hold a MD degree from Skopje University, and MSc and PhD in molecular microbiology from King's College London

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MENA Pharmaceutical Market

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Middle East and North Africa (MENA)

MENA BY THE NUMBERS

Population: 436 million

GDP: 3.1 Trillion

Source: Cortellis for Competitive Intelligence

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Pharmaceuticals market in the MENA

- The pharmaceuticals market in the Middle East and North Africa offers a lucrative opportunity to pharmaceutical companies

- The biopharma market throughout the region exceeds $20 billion and is growing at about 8% a year.

- Patented drugs make up anywhere from 65 – 80% of the pharmaceuticals market in total sales.

- Algeria, Egypt and the GCC equal one emerging market of about 180 million people, and boasting a compound annual growth rate (CAGR) of 12 – 15%

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MENA Pharmaceutical Market opportunities

As a region, it's got everything a drugmaker could want.

- Expanding and aging population
- Unmet medical need
- Growing middle class.
- The desire and the ability to pay for branded and generic therapies
- Longer life expectancy, lower mortality rates, rising income levels
- Increased prevalence of lifestyle-related diseases such as diabetes.
- Doorway to the largely untapped African market.

Prevalence of Diabetes, Obesity in MENA

PREVALENCE OF DIABETES, OBESITY			
	France	Saudi Arabia	U.S.
Diabetes	7.30%	16%	11%
Obesity	16.90%	35.60%	35%
Source: Boston Oncology LLC			

- Growing market with an increase in age-related diseases

- The incidence of diabetes and obesity is now grater in Saudi Arabia than it is in US or Europe

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Market Highlights - Algeria

- Given Algeria's aspirations to join the World Trade Organization, the country's national legislation is expected to increasingly align with international norms

- The government requires that 45 percent of drug imports be generics

- Algeria has strong local R&D centers, which can help accelerate product launches and address specific market opportunities

- Algeria remained on the U.S. Priority Watch List in 2015 because of its ban on a number of imported drugs and medical devices in favor of local products

Market Highlights - Egypt

- Patented drug sales of approximately $2 billion

- Attractive market with a growing middle class and a well-developed domestic life sciences industry

- The government continues to increase the number of products that qualify as essential medicines

- The recognition of biosimilars approved elsewhere - creating a path for biosimilars being developed specifically for the Egyptian market

- Egypt remains on the U.S. Watch List mainly because of weak IP protection, especially in preventing counterfeits from entering the country

Market Highlights – Morocco, Libya, Tunisia

- Libya: One of the smaller markets in the region, Libya offers the potential for growth, but it is plagued by political disruptions

- Morocco: The country has implemented the final phase of its universal health insurance program.
It boasts a growing middle class, along with an increasing reliance on drug imports.
The government has mandated drug price cuts.

- Tunisia: 39 drug manufacturing companies -joint ventures with international firms for the production of medications for human and veterinary drugs, medical devices and raw materials
Tunisian pharmaceutical sector has experienced steady double-digit growth at between 10% and 15%

Market Highlights – Saudi Arabia

- In Saudi Arabia, patented drugs account for over 80% of pharmaceutical sales, whereas generic drugs account for less than 8%

- strict price controls and mandatory price reductions

- mandatory health insurance coverage required by the government

- the first MENA country to implement a distinct regulatory route for the follow-ons. Under the general guidance, a biosimilar may reference a biologic approved by either the Saudi Food and Drug Authority or the EMA

Market Highlights – UAE, Bahrain, Kuwait

- UAE: Generic drug spending in the UAE is expected to grow from $300 million in 2013 to $470 million in 2018 – a CAGR of about 9 percent
Expected 5.9% growth for patented drugs
The government made health insurance coverage mandatory in 2014

- Bahrain: Patented drug sale of $0.2M
Approximately 80%for patented drugs and less than 6% for generic drugs

- Kuwait – growing population, so health care needs improvemnts
Contain costs, keep the use of fake generics in check
Kuwait was placed on the US Priority Watch list in 2014 due to copyright issues

Market Highlights – Jordan, Lebanon

- Jordan – the only country in the region where total sales of generic drugs (50%) are higher than for patented drugs (33%)

The Jordan Food and Drug Administration reduced prices of 199 domestic and imported drugs, with the discounts ranging from 1 percent to 90 percent of the original price

Biosimilar regulatory path that follows EMA and the International Conference on Harmonisation (ICH) guidelines

- Lebanon - The Health Ministry in 2014 reduced the price of costly drugs by 10 percent to 17 percent.

The country is in the process of reforming its IP laws, but enforcement remains weak, according to the U.S. 2016 Special 301 Report. Lebanon is on the U.S. Watch List.

Market Highlights - Oman

- Oman - the country decreased its planned health care budget from $4.2 billion in 2015 to $3.4 billion in 2016 and only $1.6 billion in 2017

- The Ministry of Health has been reducing the prices of the most commonly used medicines in Oman, in phases over the past years

Patenting in MENA

- Almost every country in the MENA region has updated patent laws

- Patenting of pharmaceutical products or substances

- In some countries patent term extension is possible (ex Morocco)

- Patent laws varies from country to country

RESPONDING TO INSTABILITY IN THE REGION

Foreign companies often partner with a domestic company that has years of experience working in the market

- Have contingency plans in place to transfer manufacturing if key sites are affected by political or social strife

- Develop geographic diversity within the region to reduce the impact of issues arising in one country

- Develop new opportunities in response to political and social changes

- Address drug shortages in areas facing conflict by donating antibiotics, immunosuppressant, cardiovascular products etc to patients

KEYS TO BUILDING A MENA MARKET

- Build the brand, for both generic and patented products
- Use social media and mobile apps to offer patients helpful health tools
- Raise community awareness about health issues and diseases
- Recruit and train a skilled biopharma work force (i.e., offer internships, online courses and scholarships)
- Provide regional training programs and scholarships to global conferences to help MENA doctors keep abreast of medical developments
- Conduct a clinical trial in-country for an approved drug to raise doctors' awareness

The LATAM Pharmaceutical Market As Seen in the Data

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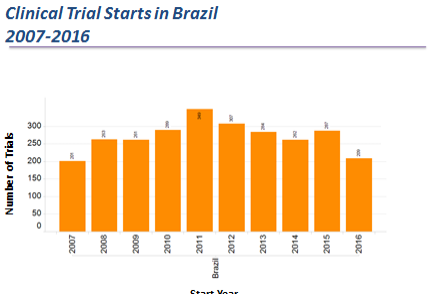
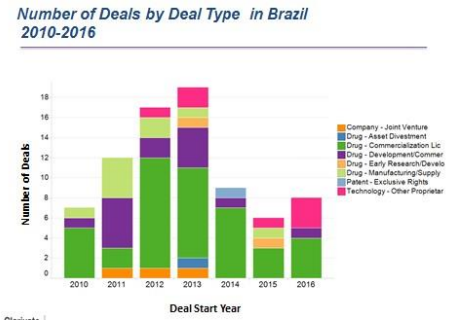
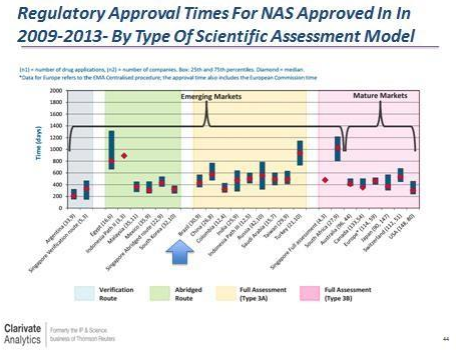
The LATAM Pharmaceutical Market As Seen in the Data (accent on Argentina and Brazil)

- LATAM as a major pharmaceutical market
- Clinical trial starts in Argentina and Brazil
  - Comparison to LATAM
- Research highlights
- Analysis of pharma deals
- Regulatory cycle times in Argentina and Brazil
  - Comparison to other markets
- Biologics and Biosimilars







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The Argentinean Pharmaceutical Market

- Argentina is the fourth-largest pharmaceutical market in Latin America

- Following years of strong expansion, pharmaceutical sales growth has slowed; a result of sharp economic deceleration, erosion of real incomes, and persistent inflation

- Against this backdrop, life sciences companies are facing the dual challenges of providing affordable, effective treatments to consumers and achieving revenue and market goals

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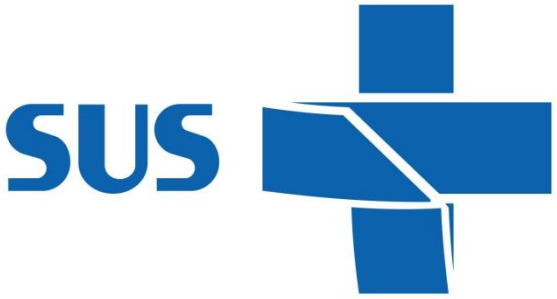
The Brazil Pharmaceutical Market

- Brazil is the 6th largest market worldwide
- Though Brazil boasts a national healthcare program, **Sistema Único de Saúde,** 25 percent of the population opt to purchase private insurance for access to second and third-tier care
- This has resulted in a large patient population with reduced access to beyond-basic level care, leaving potential subjects largely treatment-naïve which promotes not only participation in clinical trials, but retention as well.

Rank	Country	Market ($MM)
Rank	Country	Market ($MM)
1	USA	339,694
2	Japan	94,025
3	China	86,774
4	Germany	45,828
5	France	37,156
6	Brazil	30,670
7	Italy	27,930
8	UK	24,513
9	Canada	21,353
10	Spain	20,741



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Running Clinical Trials in Argentina

- Long timelines and complex regulatory requirements have been one of the primary barriers for growth in the more established Latin American markets, which include Brazil, Argentina and Mexico.
  CenterWatch *Volume 23, Issue 03, 3/1/2016*

- Recently, two of Argentina's government departments - the National Administration of Drugs, Foods and Medical Devices (ANMAT) and the Ministry of Health - announced that they are working together to increase clinical trial activity in the region and country.
  Overcoming Clinical Challenges in BRIC Markets, Thomson Reuters, 2014

NATURE | NEWS

Argentina's researchers occupy science ministry

Young scientists angry at budget cuts say they have been denied permanent jobs.

Valeria Román

03 January 2017

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"2017– Año de las Energías Renovables"

Ministerio de Salud
Secretaría de Políticas,
Regulación e Institutos
ANMAT

DISPOSICIÓN Nº 4008

BUENOS AIRES, 26 ABR 2017

VISTO la Disposición ANMAT Nº 6677/10 y el expediente nº 1-0047-0000-003833-17-2 del registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica; y

CONSIDERANDO:

Que por la Disposición ANMAT Nº 6677/10 se aprobó el Régimen de Buena Práctica Clínica para Estudios de Farmacología Clínica, teniendo como objetivo sustantivo garantizar y asegurar el máximo cumplimiento de las reglas establecidas, tanto nacionales, como internacionales, en materia de normas y

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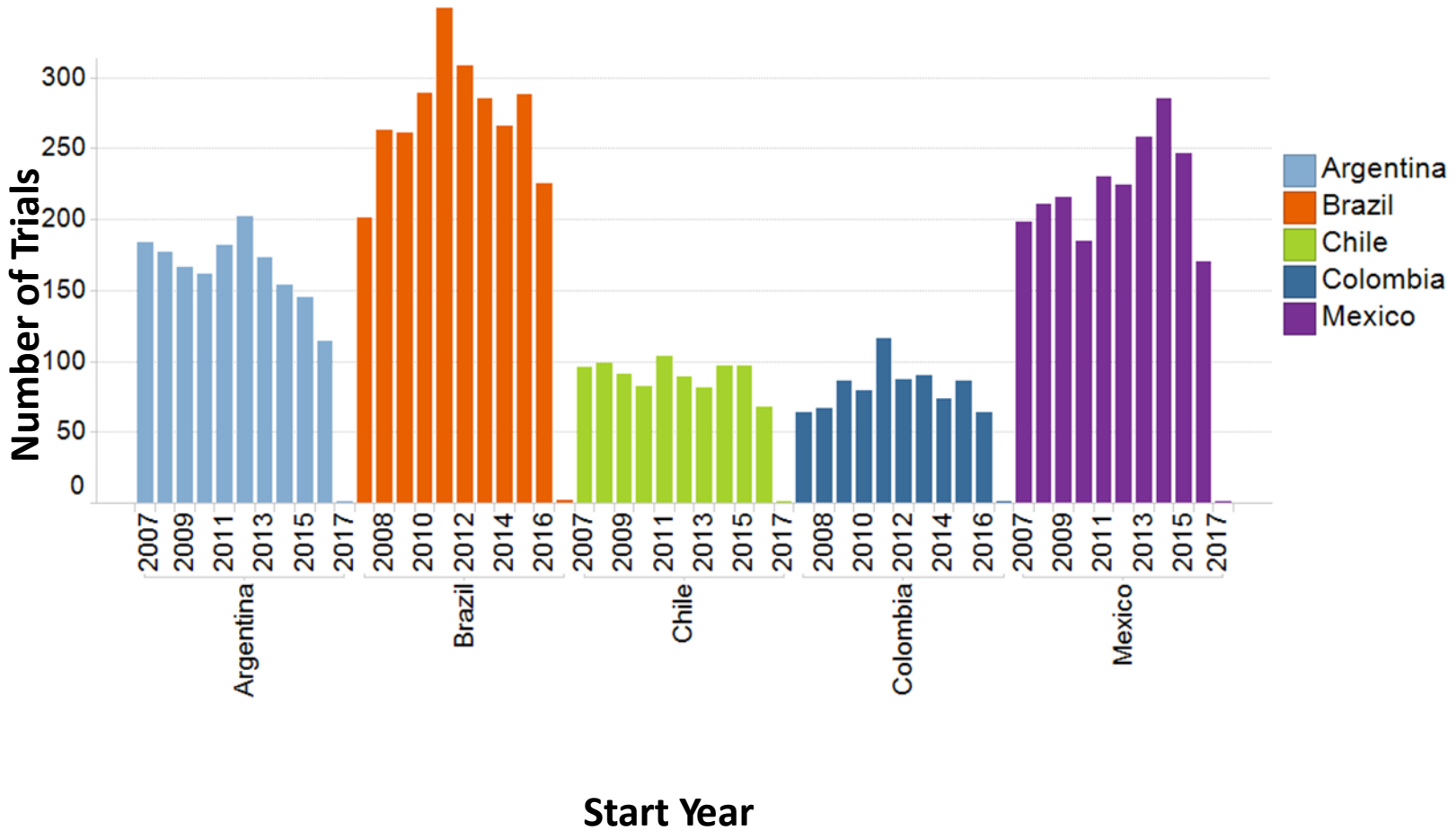
Running Clinical Trials in Brazil

- The rapidly changing clinical landscape, along with the current complexity and lengthiness of approval and import processes, have been cited as the biggest drawbacks in initiating clinical trials in Brazil

- Placebo trials require additional rationale and multiple reviews, increasing timelines and decreasing cost effectiveness.

- The compassionate use program, approved by ANVISA in August of 2013, guarantees free orphan drug supply to those who have participated in a Phase III trial and benefitted from the drug
  - Because the patient population for a rare disease is limited by nature, the sponsor's Brazilian market for the respective orphan drug may be entirely comprised of its successful phase 3 trial patients, negating any profit they may make in the country.

Clinical Trial Starts LATAM Countries 2007-2016



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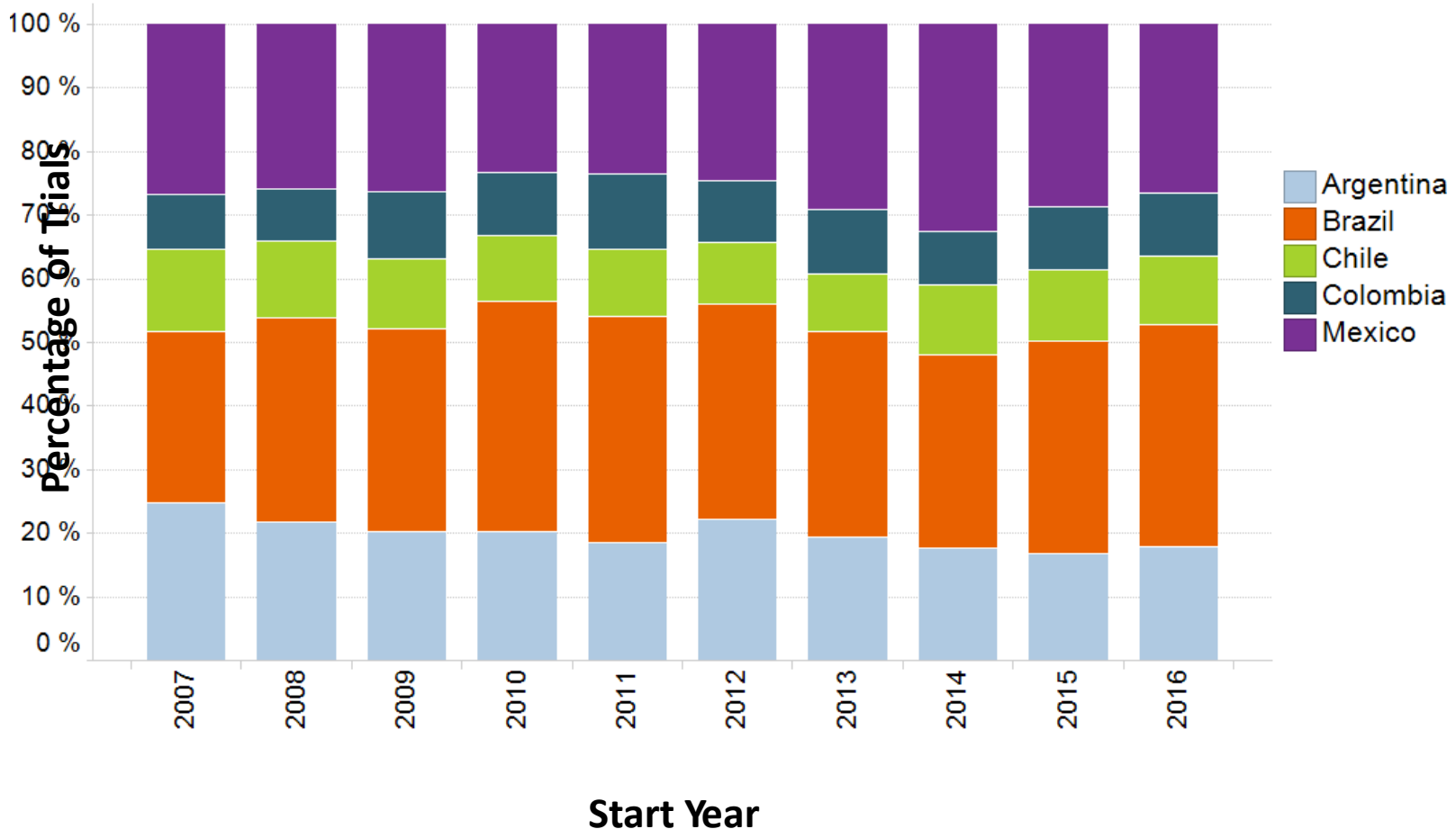
Clinical Trial Starts LATAM Countries 2007-2016



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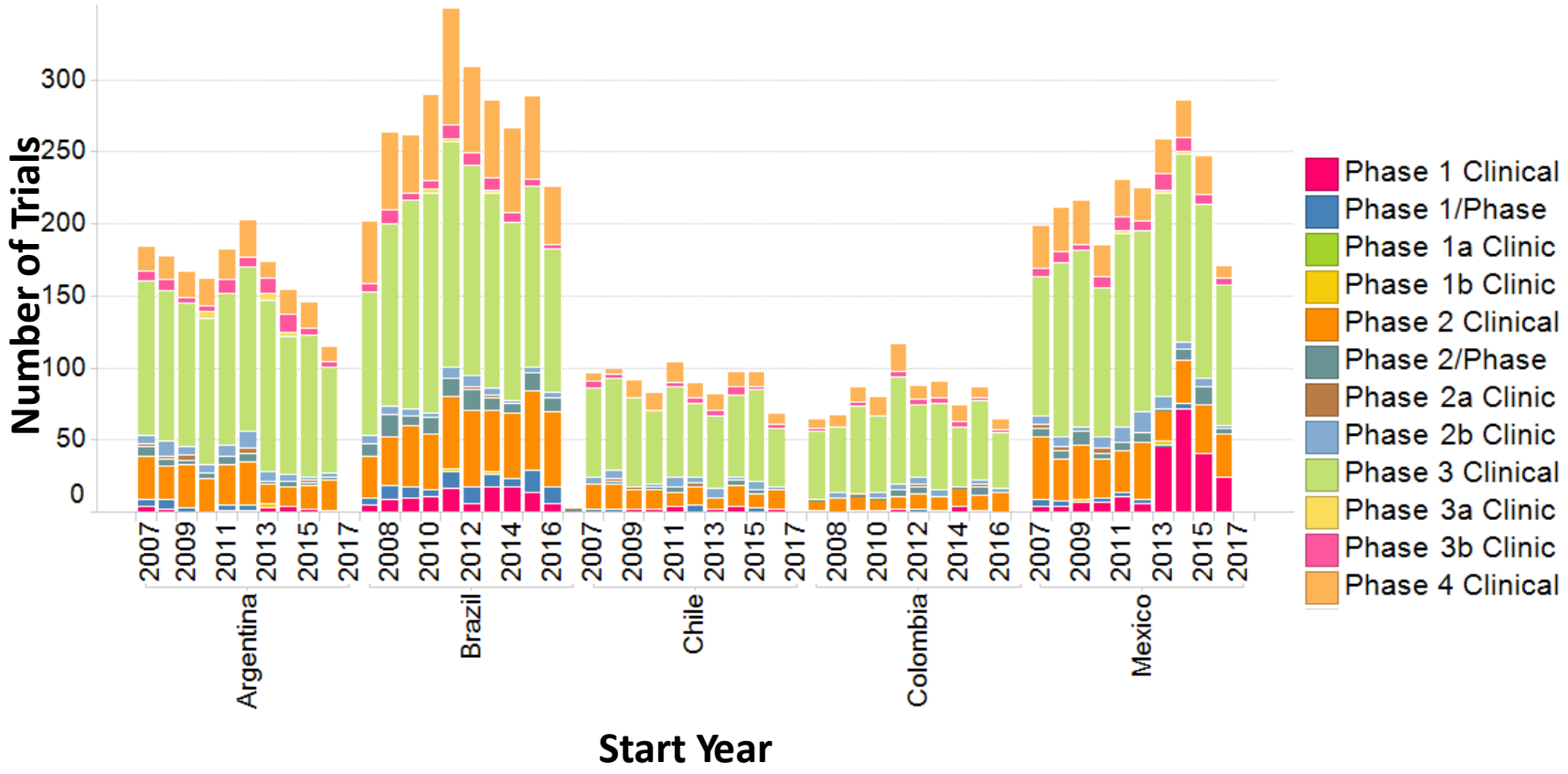
Clinical Trial Starts by Phase LATAM 2007-2016



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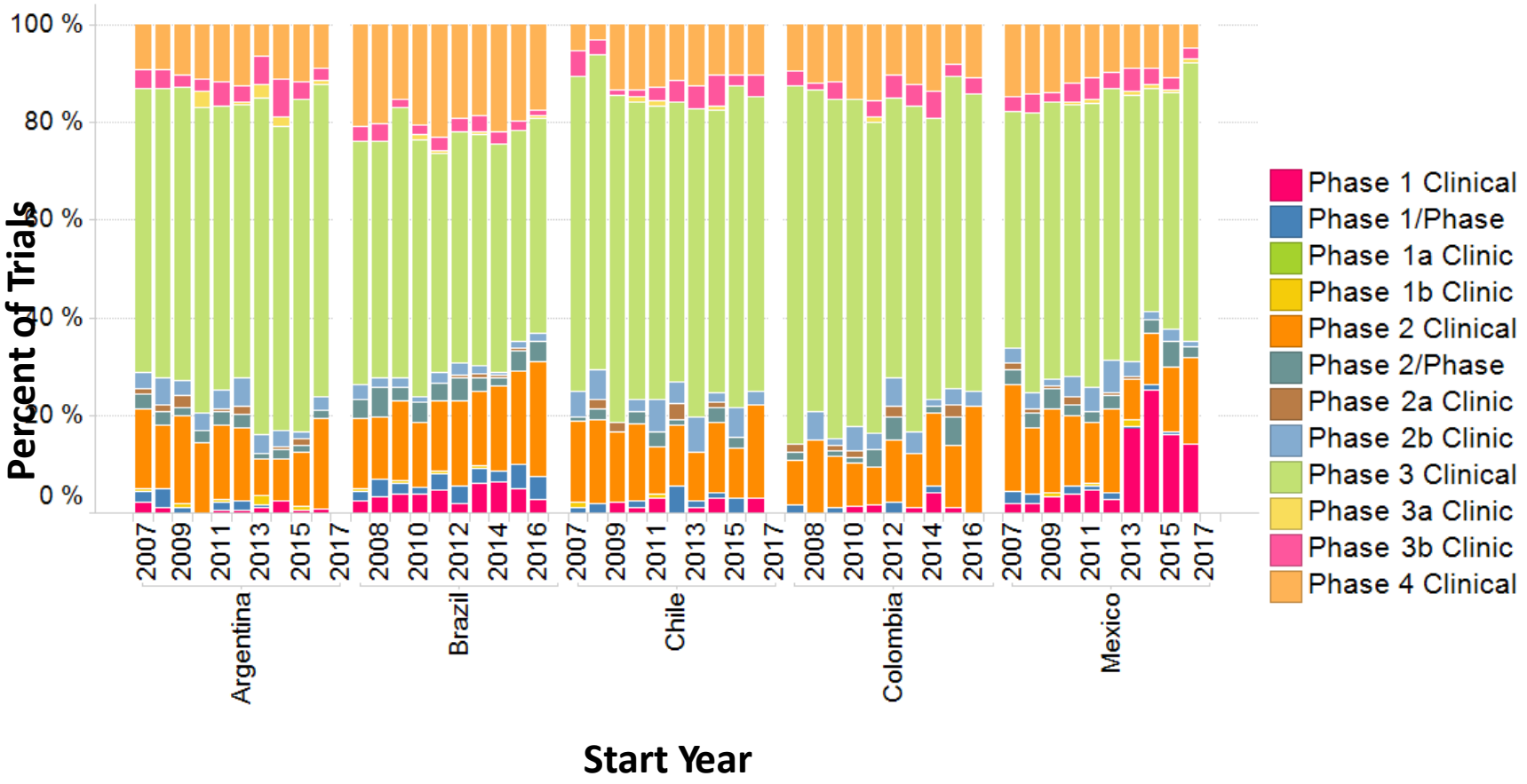
Clinical Trial Starts by Phase LATAM 2007-2016



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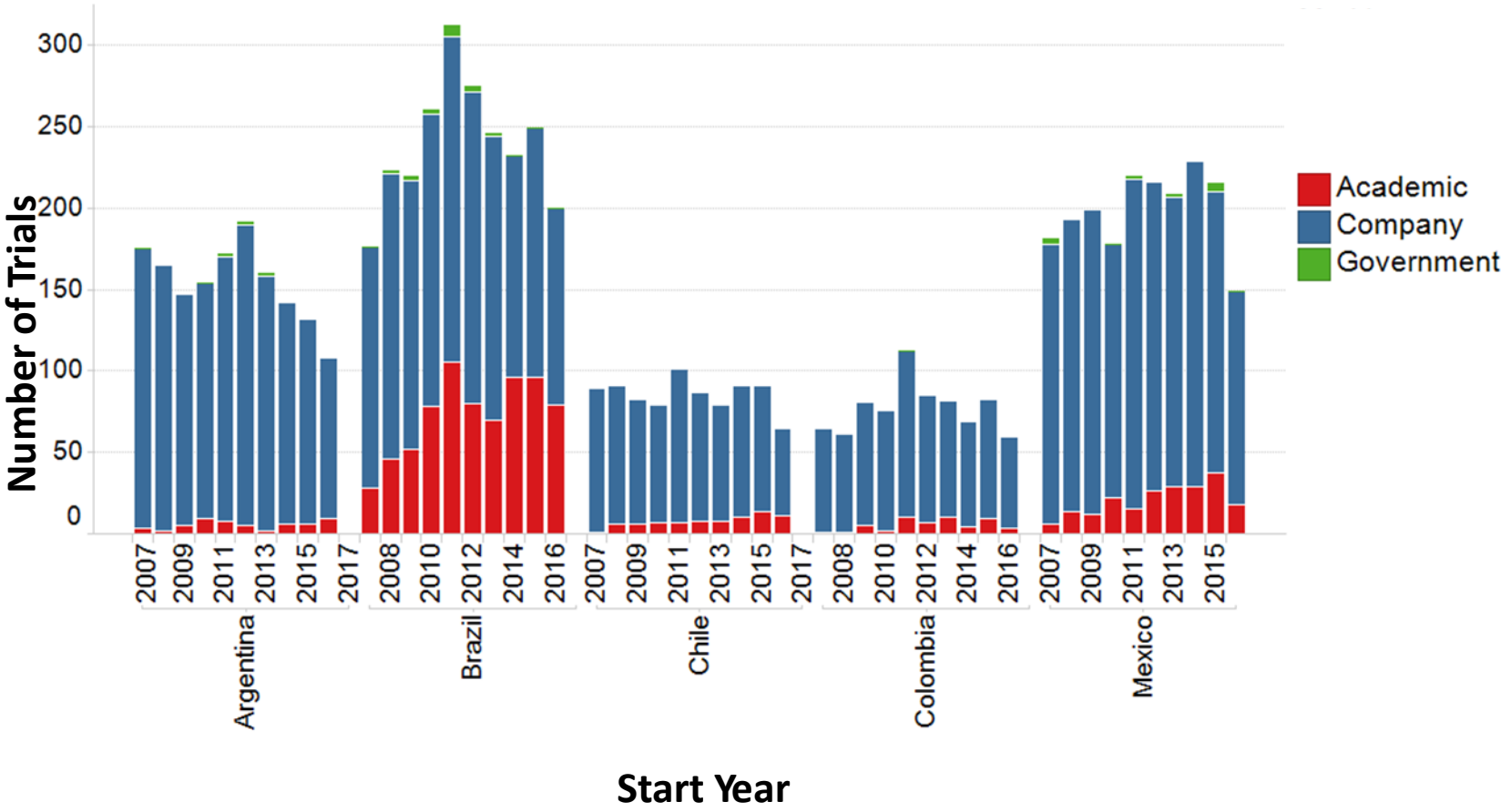
Clinical Trial Starts by Organization LATAM 2007-2016



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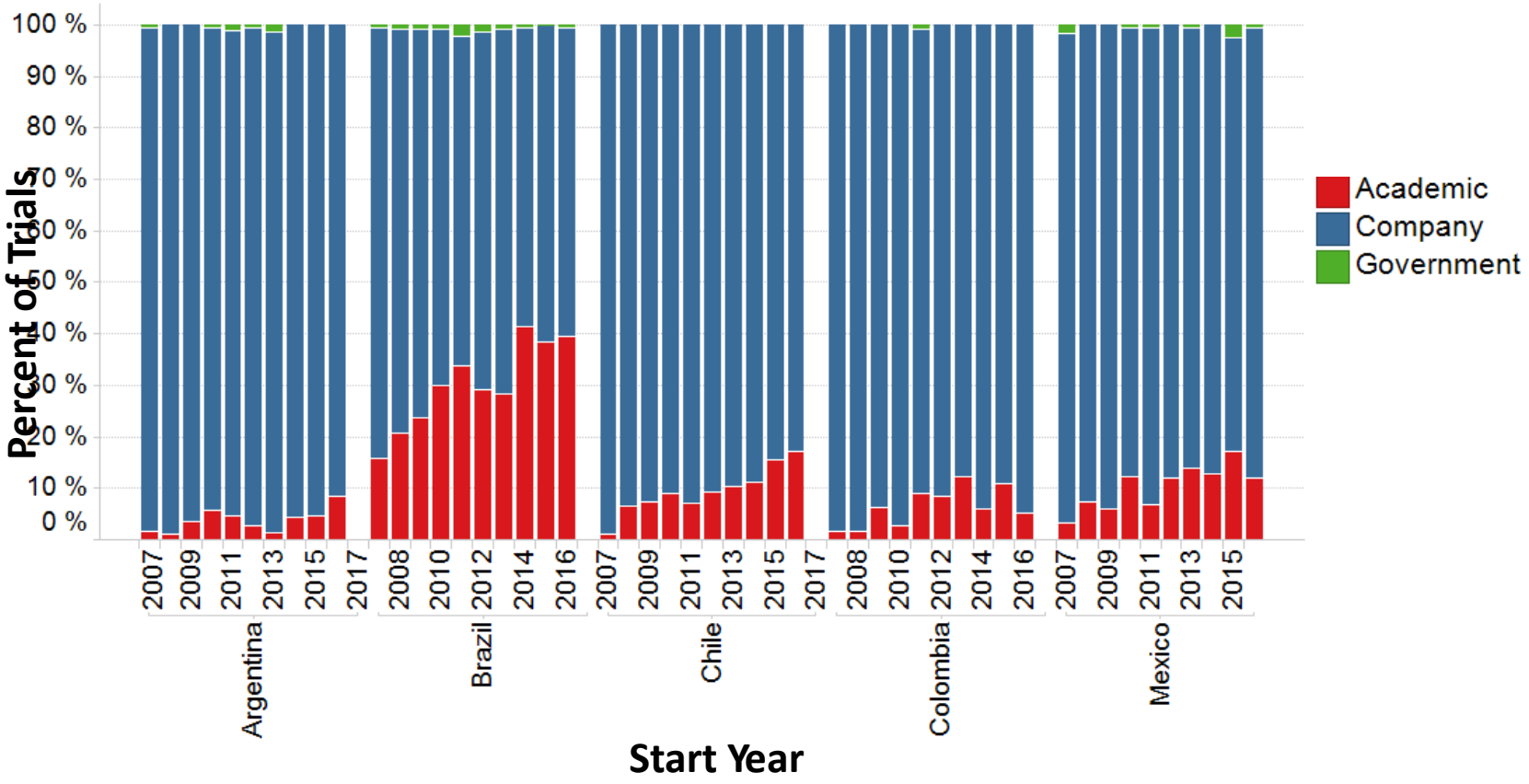

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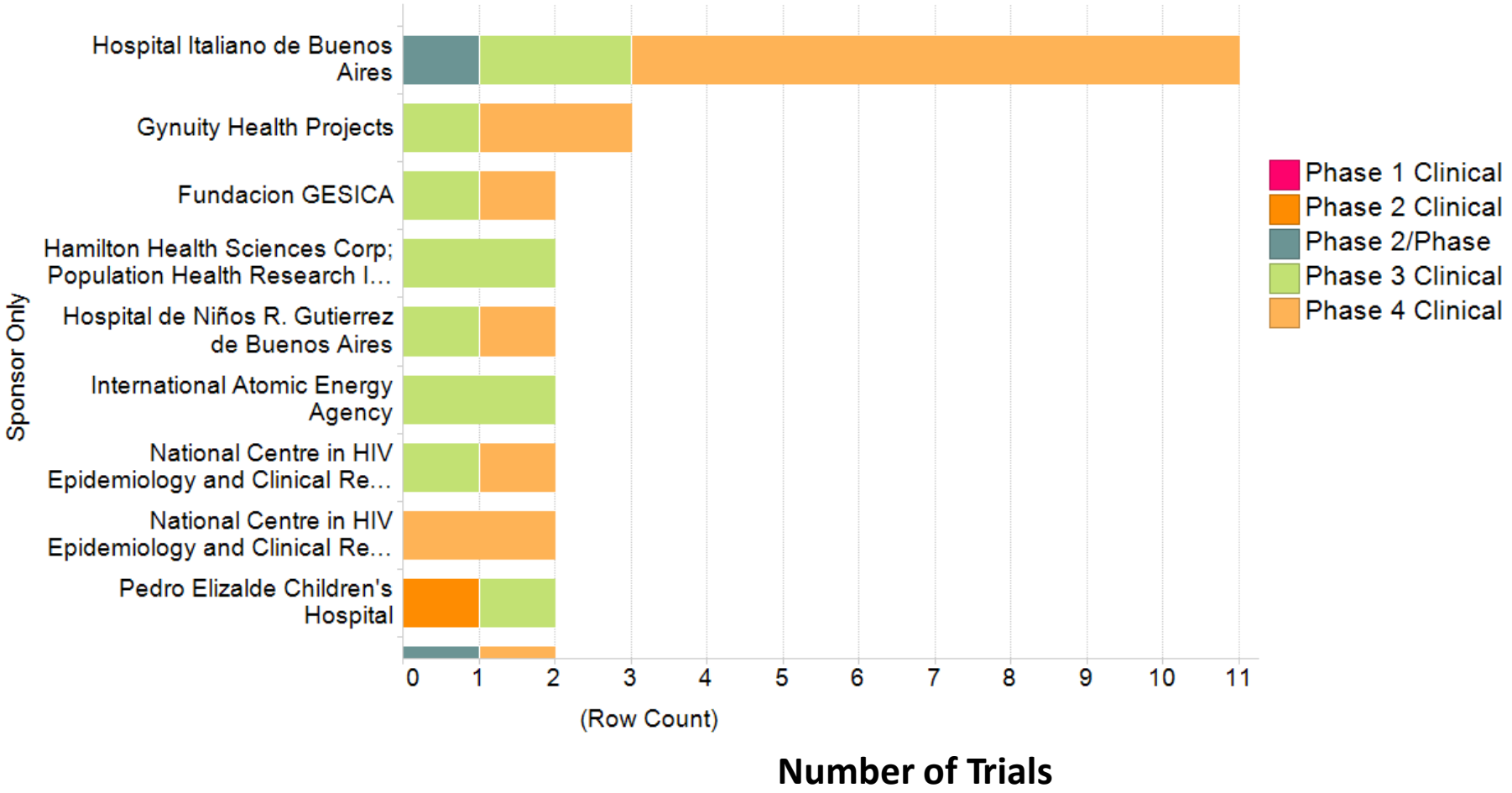
Top Academic Sponsors for Clinical Trial Starts Argentina 2007-2016



Clarivate Analytics

Top Academic Sponsors for Clinical Trial Starts Brazil 2007-2016

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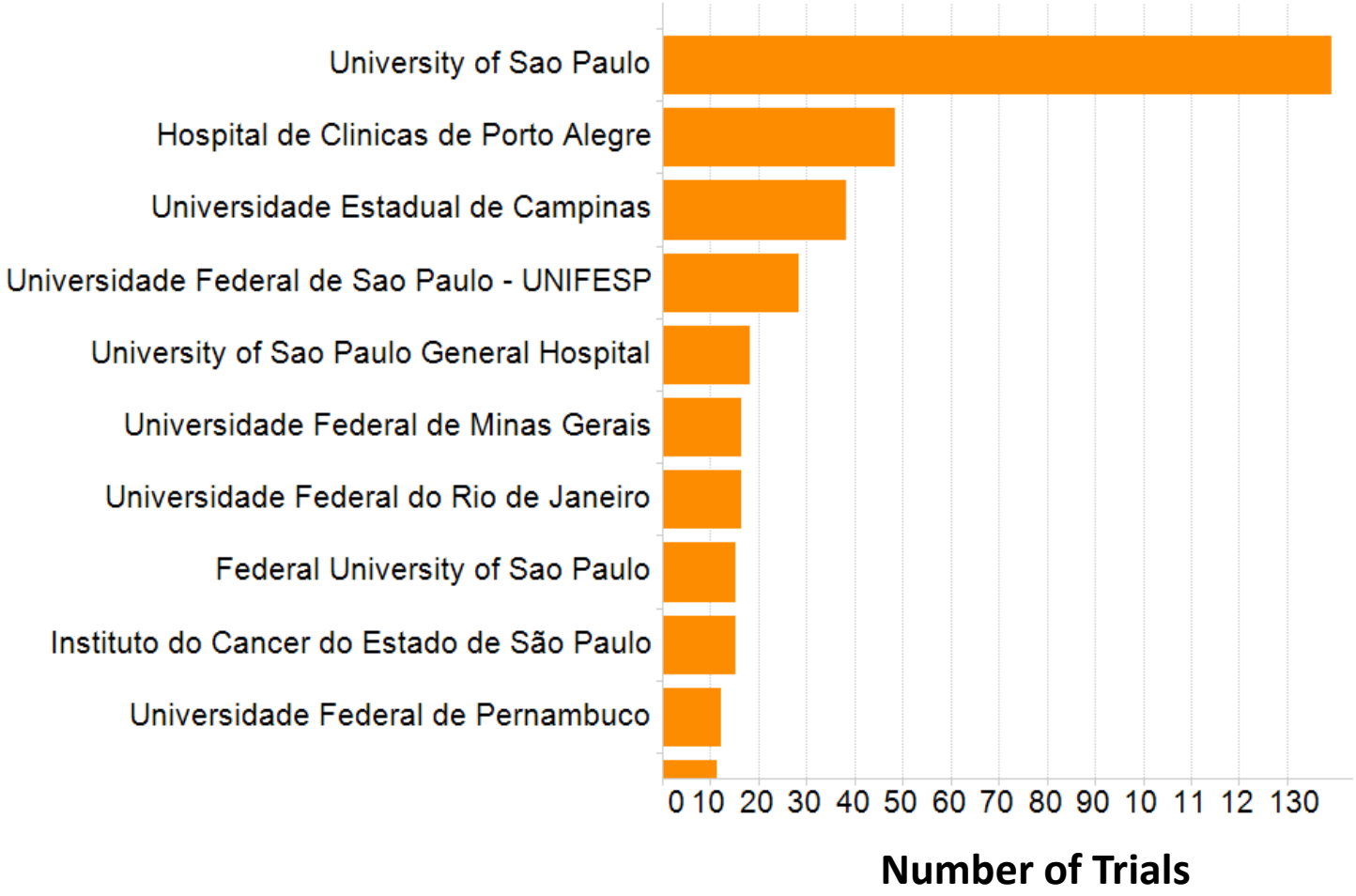

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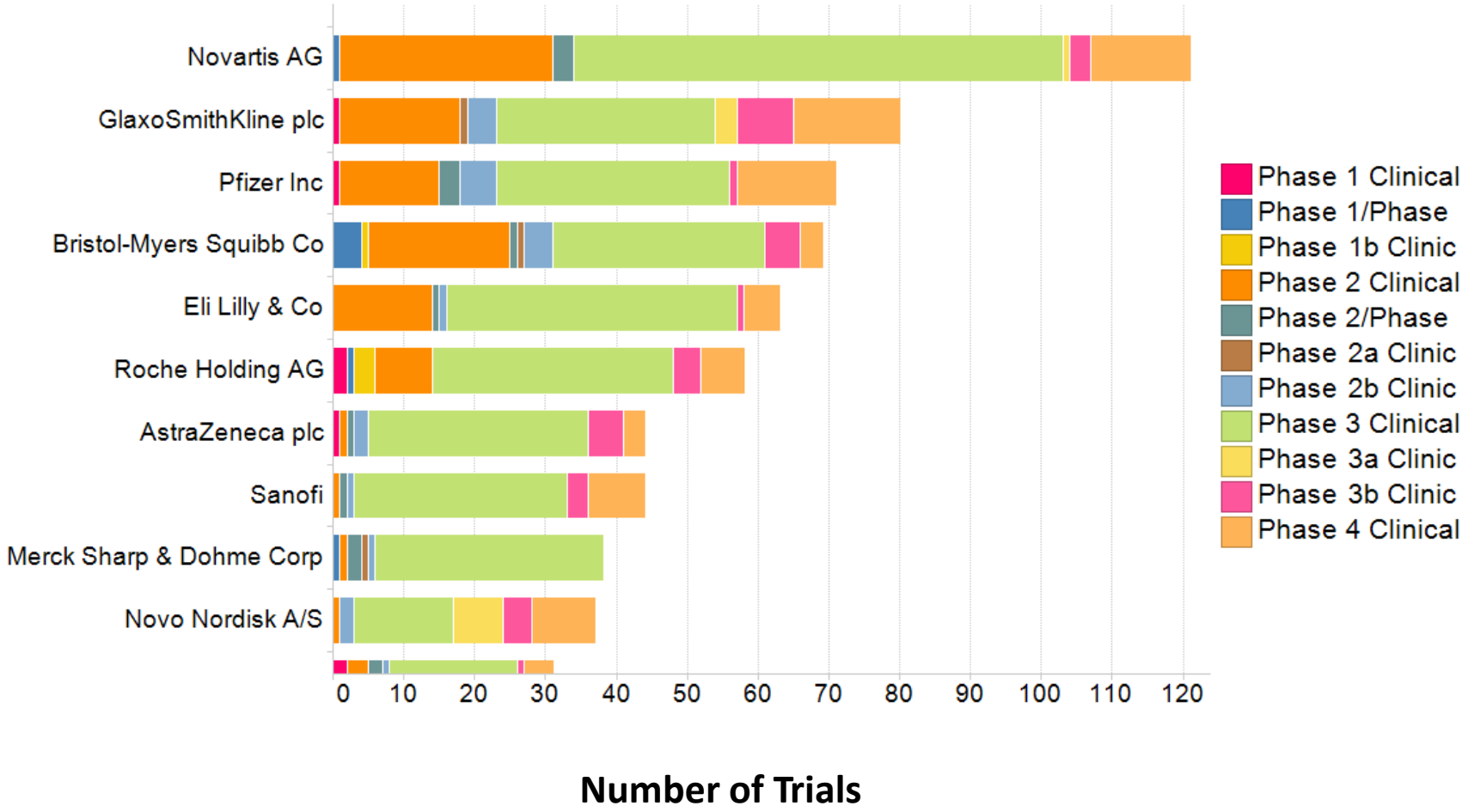
Top Sponsors for Clinical Trial Starts Argentina 2007-2016



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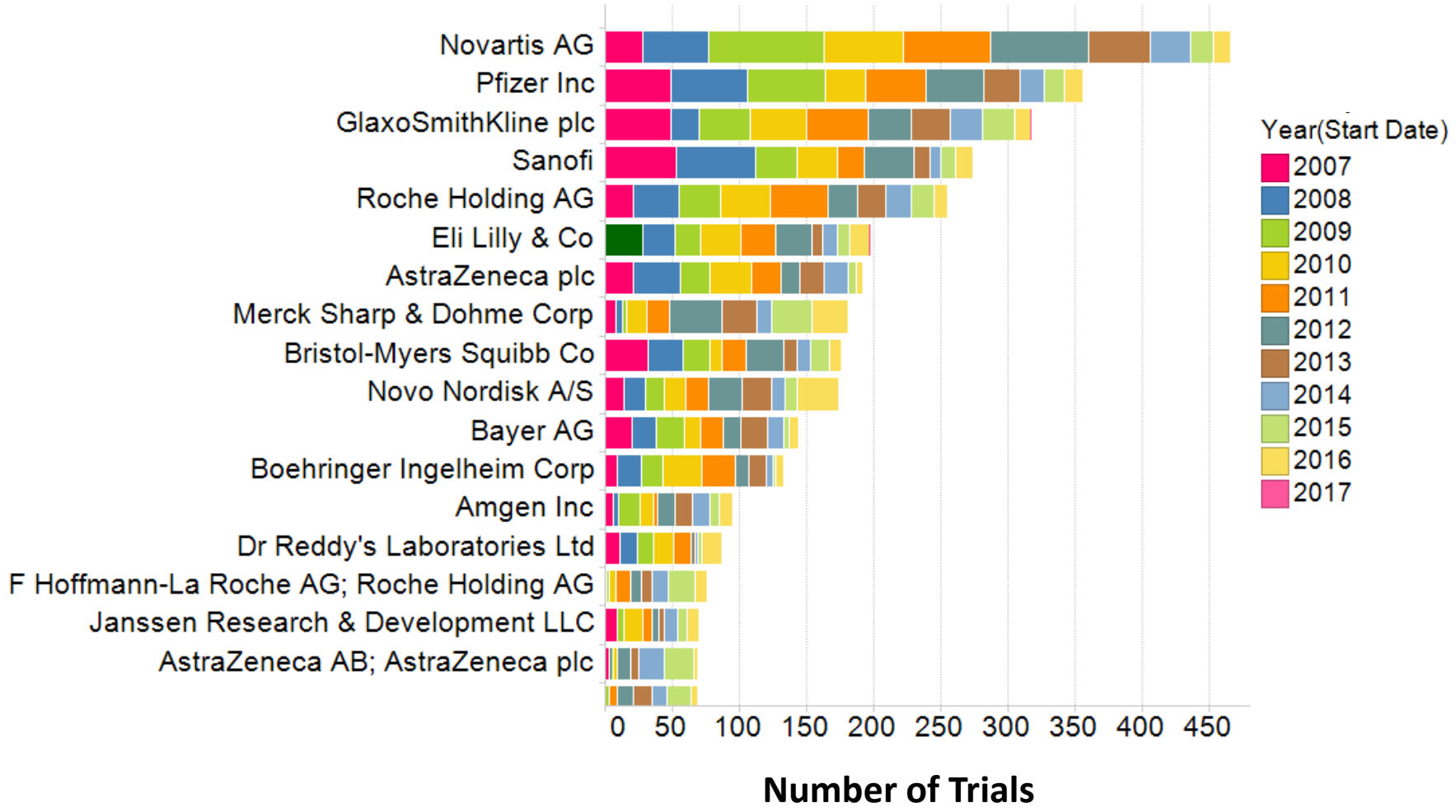
Top Industry Sponsors for Clinical Trial Starts Brazil 2007-2016



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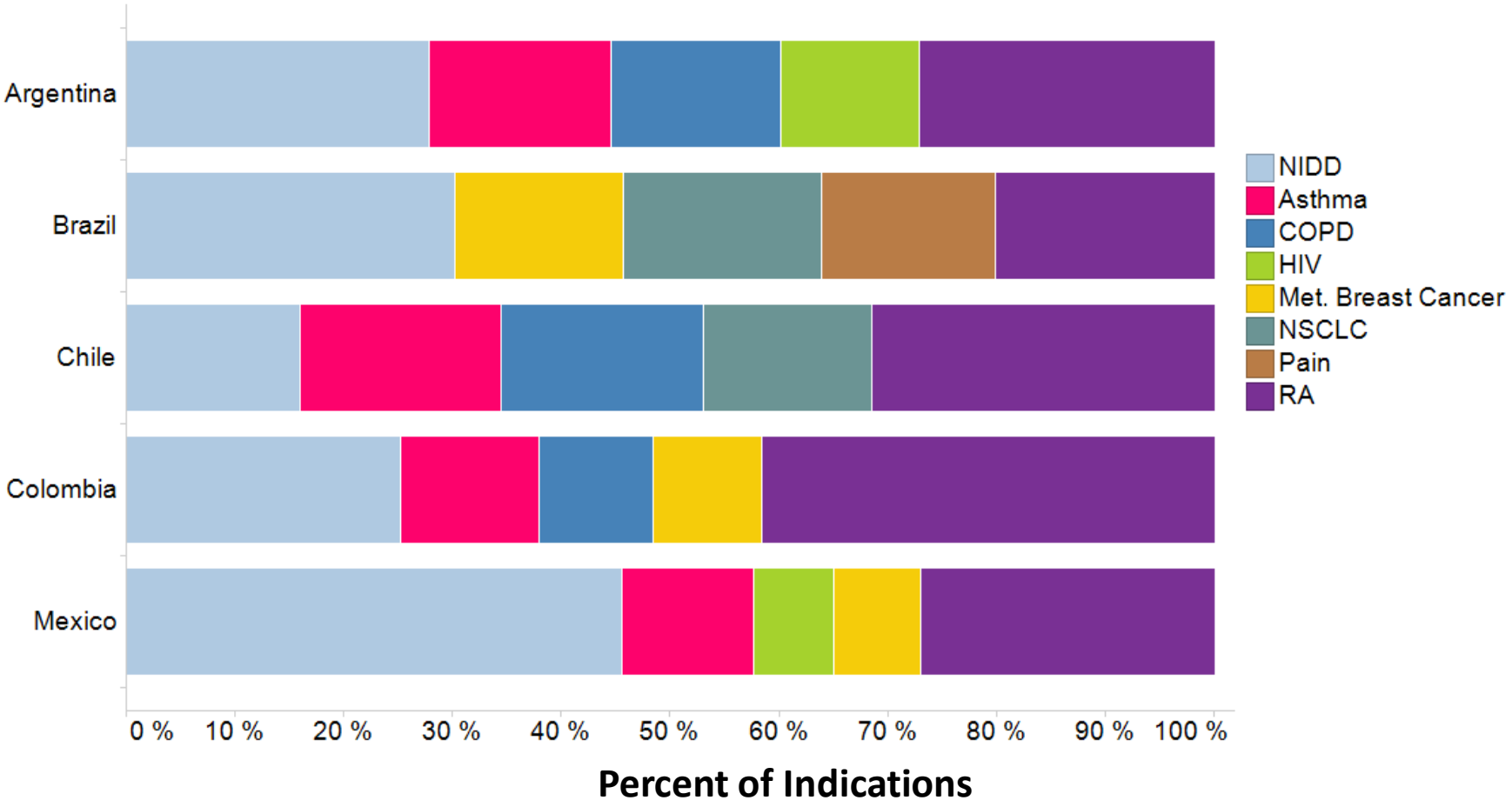
Top 5 Indications for Clinical Trial Starts for LATAM 2007-2016



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Deals

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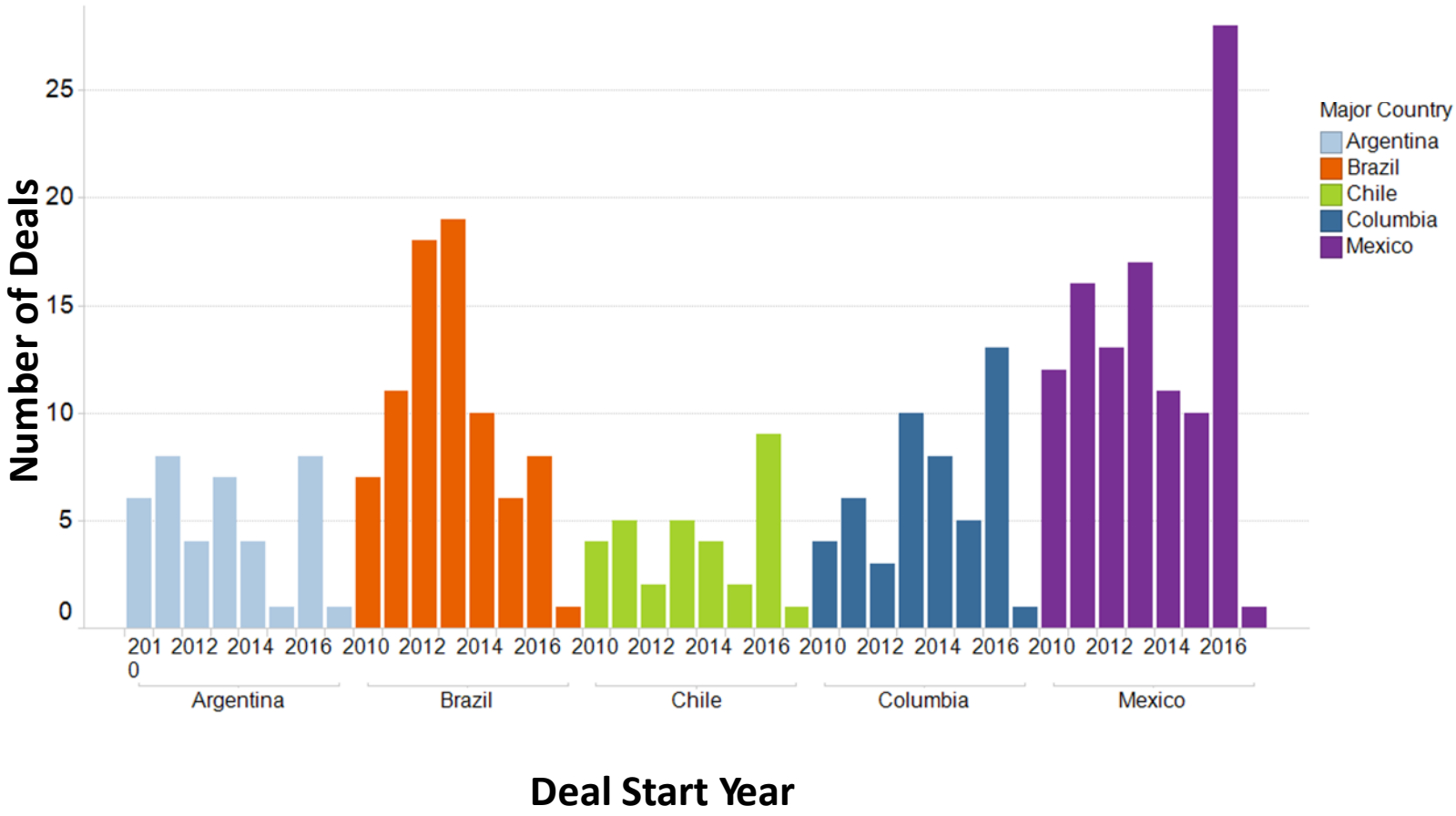
Number of Deals by Year In LATAM Countries 2010-2016



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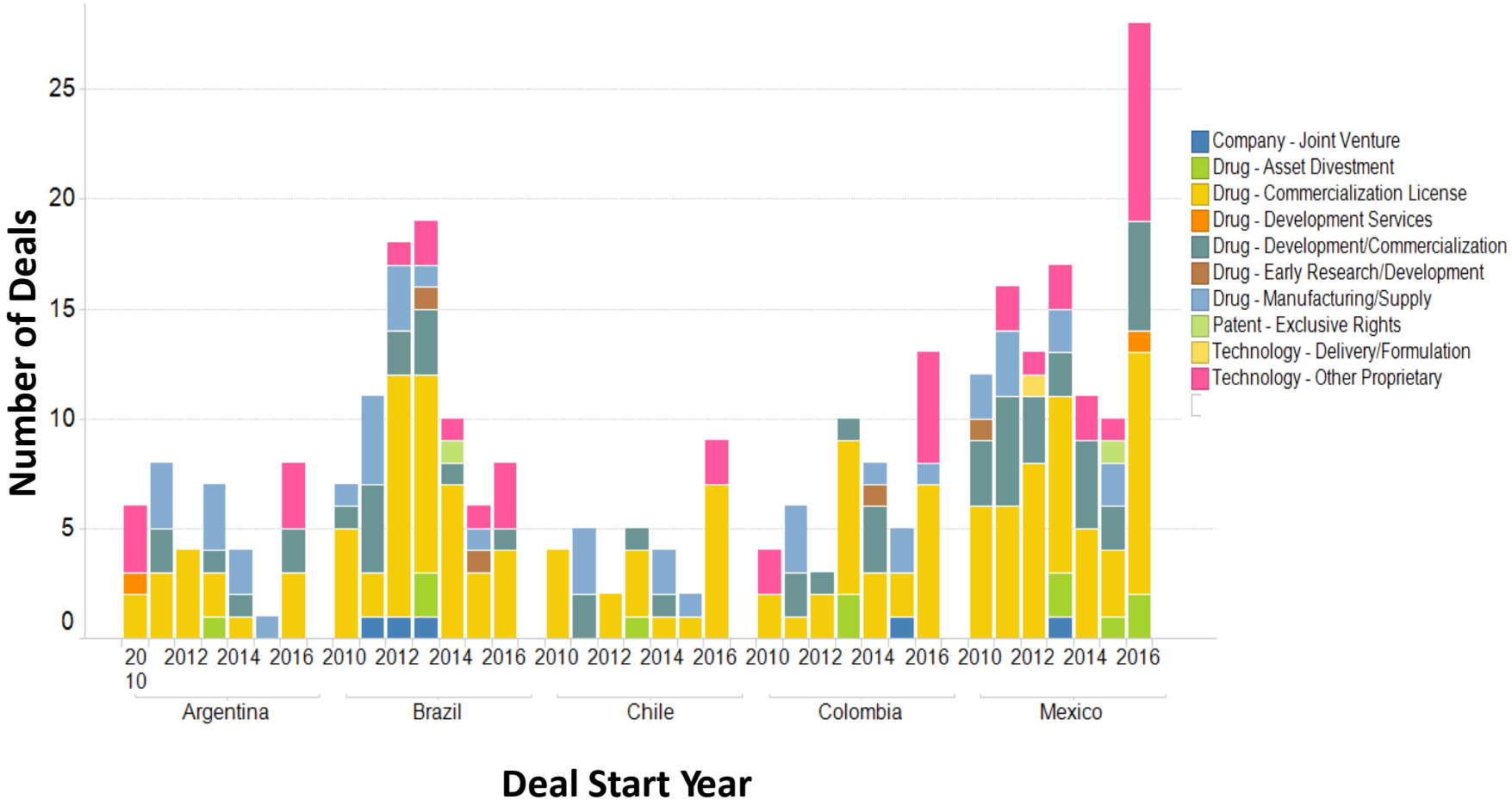
Number of Deals by Year In LATAM Countries 2010-2016



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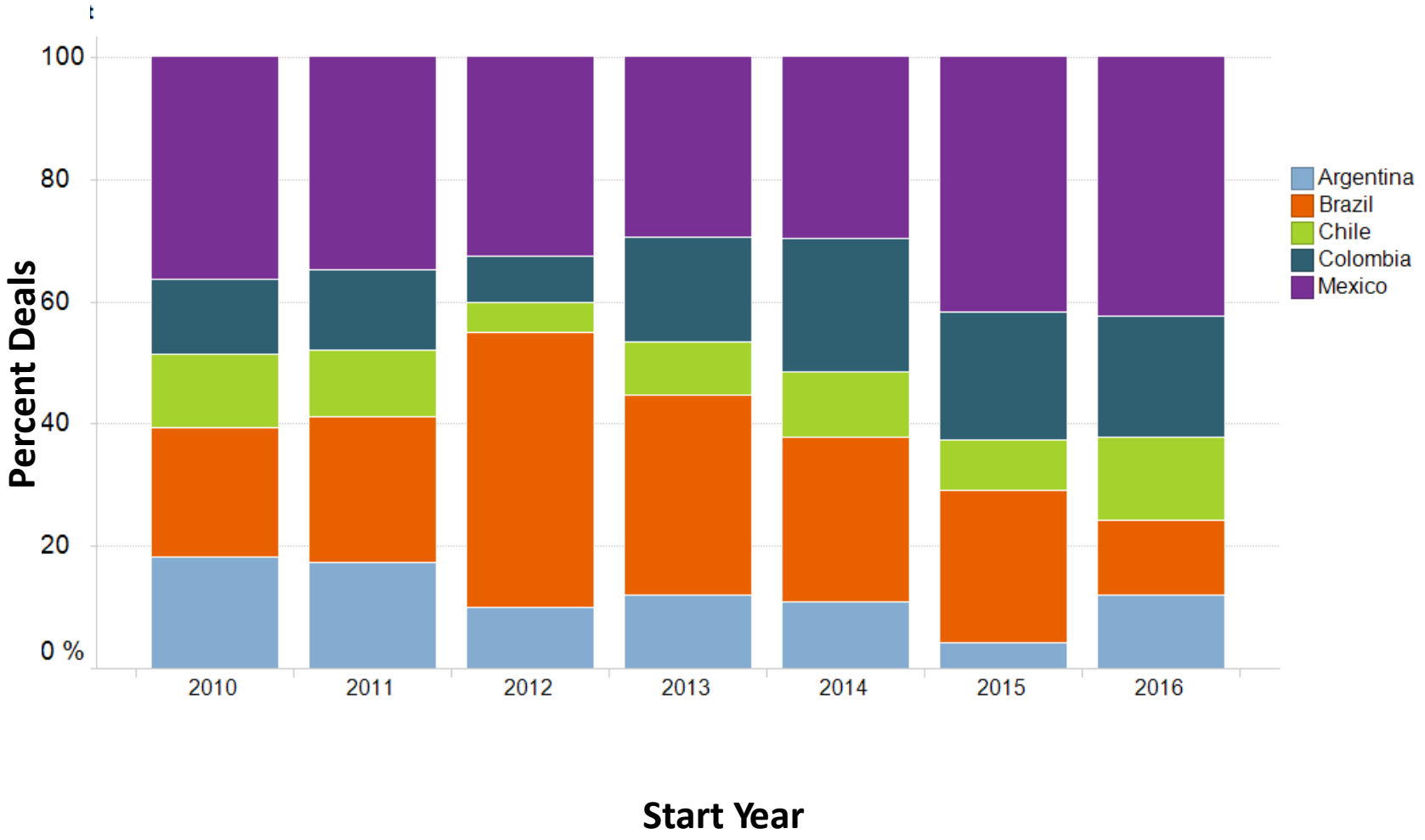
Percent of Deals by Country In LATAM Countries 2010-2016



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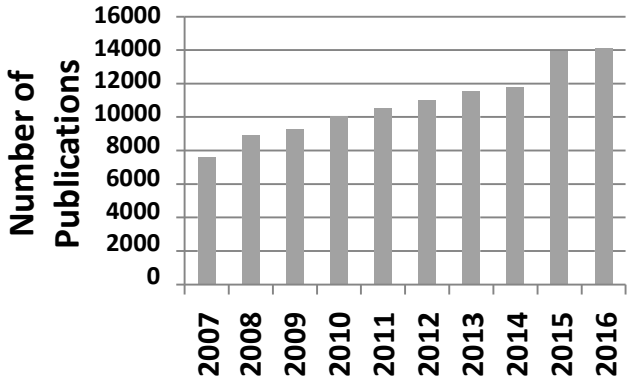
Research Highlights In Argentina

- Latin America is a fast-growing region utilizing stem cell research for the development of Regenerative Medicine. In Argentina the18 stem cell research projects funded in 2008 increased to 47 projects in 2012.

- Argentina has a long tradition in high-quality scientific research, based on the free access to public education, including university, and the excellent training of its human resources. However, the scientific productive matrix was traditionally affected by political turmoil. The budget dedicated to scientific research was one of the first to be trimmed upon an economical and/or political crisis



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Research Highlights In Argentina

LATIN AMERICA

Improving traceability: Argentina takes global lead fighting fakes

By Sergio Held
Contributing Writer

Friday, July 11, 2014

Printer-friendly version

BOGOTA, Colombia – A relatively young system to trace pharmaceutical products fr
patient has put Argentina at the forefront of the global fight against fake drugs.

The system, which Argentina has been implementing since 2011, won special recogr
67th session of the World Health Assembly in Geneva. "Argentina took the road of in
took some time and it impacted the whole sector," said Fabien Nodet, founder and C
Buer
sect

CUBA: CAUTIOUS OPTIMISM PREVAILS

Argentina and Cuba join forces to rev up biotech development

By Sergio Held
Staff Writer

SHARE

Wednesday, December 24, 2014

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BOGOTA, Colombia – The National Council of Genetic Engineering of Cuba (CIGB) and the National Council of Technical and Scientific Researches of Argentina (Conicet) have agreed to team up for the

esearch capabilities and modern equipment available to
he laboratory stage, Conicet´s president Roberto Salvarezza
Conicet with consulting and assisting in introducing products

Argentina: Opportunities ahead as optimism returns in biotech sector

By Sergio Held
Staff Writer

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Monday, June 6, 2016

Printer-friendly version

BOGOTA, Colombia – A political U-turn in Argentina last year has led to a sudden b
future of the country's biotech sector and could set the stage for rapid growth in the

The election of President Mauricio Macri last year marked the beginning of a series
country's policy landscape, including the opening of trade and settlements after a m
country's bonds that has allowed Argentina to return to international bond markets.
among the many that are looking forward to better days.

Argentina's Sinergium joins efforts to develop Zika virus vaccine

By Sergio Held
Staff Writer

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Tuesday, April 26, 2016

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HONG KONG – Efforts are under way in Latin America to speed up the development of a vaccine for the Zika virus that has ran rampant in parts of the continent, most notably Brazil. The latest such effort comes from Sinergium Biotech SA, of Buenos Aires, Argentina, which said that it has joined a consortium to develop a Zika virus vaccine with Protein Sciences Corp., of Meriden, Conn., and corporate-funded NGO Fundación Mundo Sano. This is a significant move to combat the most recent outbreak of the disease that is seriously affecting the Latin American region

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Brazilian Pharma Registers First API Based On Biodiversity

- Cristália based in Itapira, Sao Paulo, has obtained the very first biodiversity-based registration from Anvisa of a biological active pharmaceutical ingredient (API).

- Cristália's API is an enzyme called collagenase Cristalia, used in ointments to treat wounds, burns and necrotic tissue. To date, Brazil has had
to rely on imports of collagenase

CRISTÁLIA
PRODUTOS QUÍMICOS FARMACÊUTICOS LTDA.

- "Cristália's collagenase represented the first biological API and finished product registration granted by Anvisa, 100 percent manufactured
in Brazil and obtained from a Clostridial strain isolated from Brazilian biodiversity,"

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Regulatory

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Regulatory Process in Argentina - highlights

- Argentina is a country that relies heavily on decisions made by countries that it considers of 'high sanitary surveillance'. Thus, the registration process will depend on in what countries a drug product is already being **marketed** in, regardless of the country of origin or countries where the pharmaceutical is registered but not marketed

anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

- On April 26th, 2017 The Ministry of Health in Argentina (ANMAT) has issued a new regulation that shortens the timelines for the approval of clinical trials from 160 business days to 70 days (60 days for review and 10 days for administrative paperwork). If ANMAT does not process the cases within that period, the approval would be automatic.

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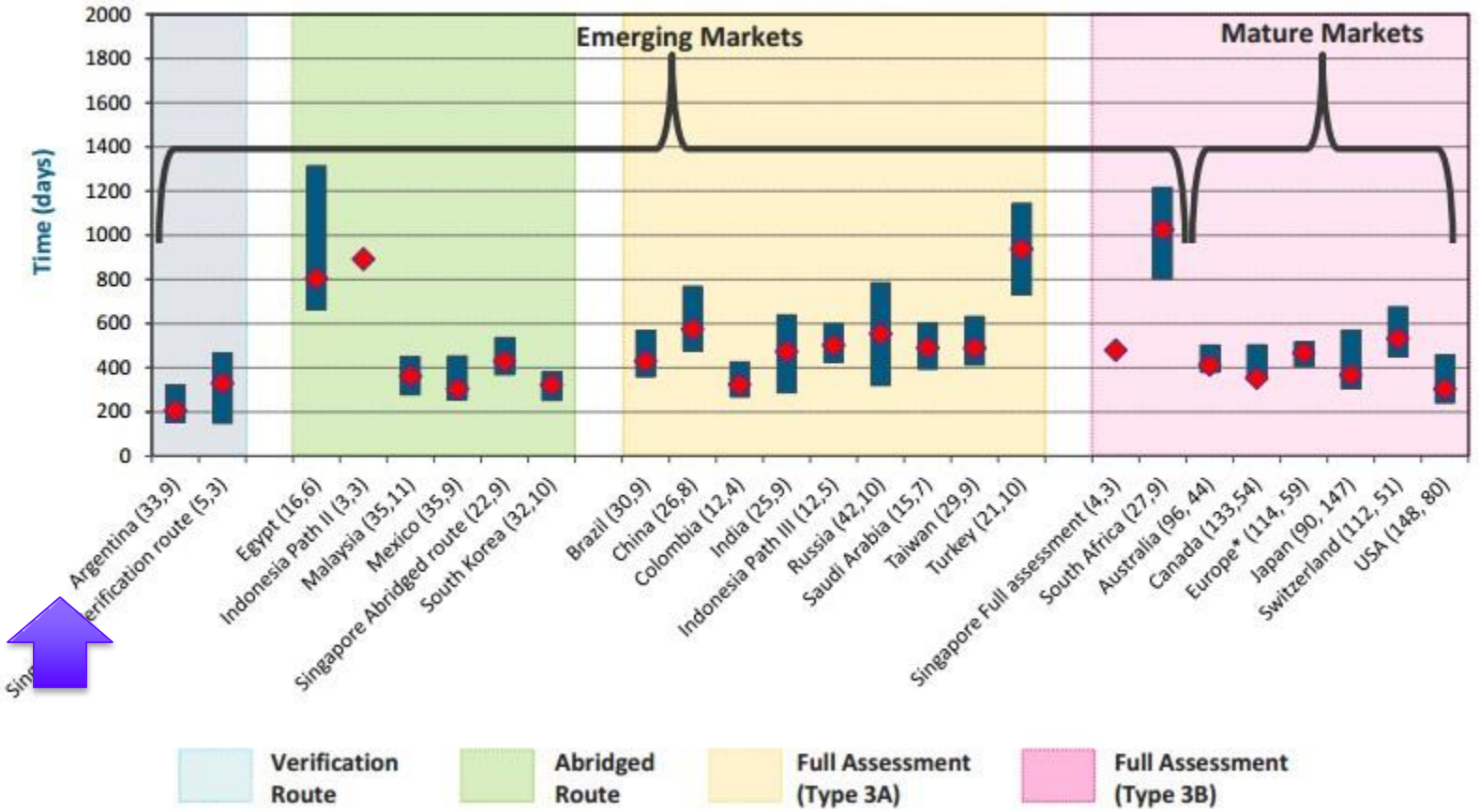
Regulatory Approval Times For NAS Approved In In 2009-2013- By Type Of Scientific Assessment Model

(n1) = number of drug applications, (n2) = number of companies. Box: 25th and 75th percentiles. Diamond = median.
*Data for Europe refers to the EMA Centralised procedure; the approval time also includes the European Commission time



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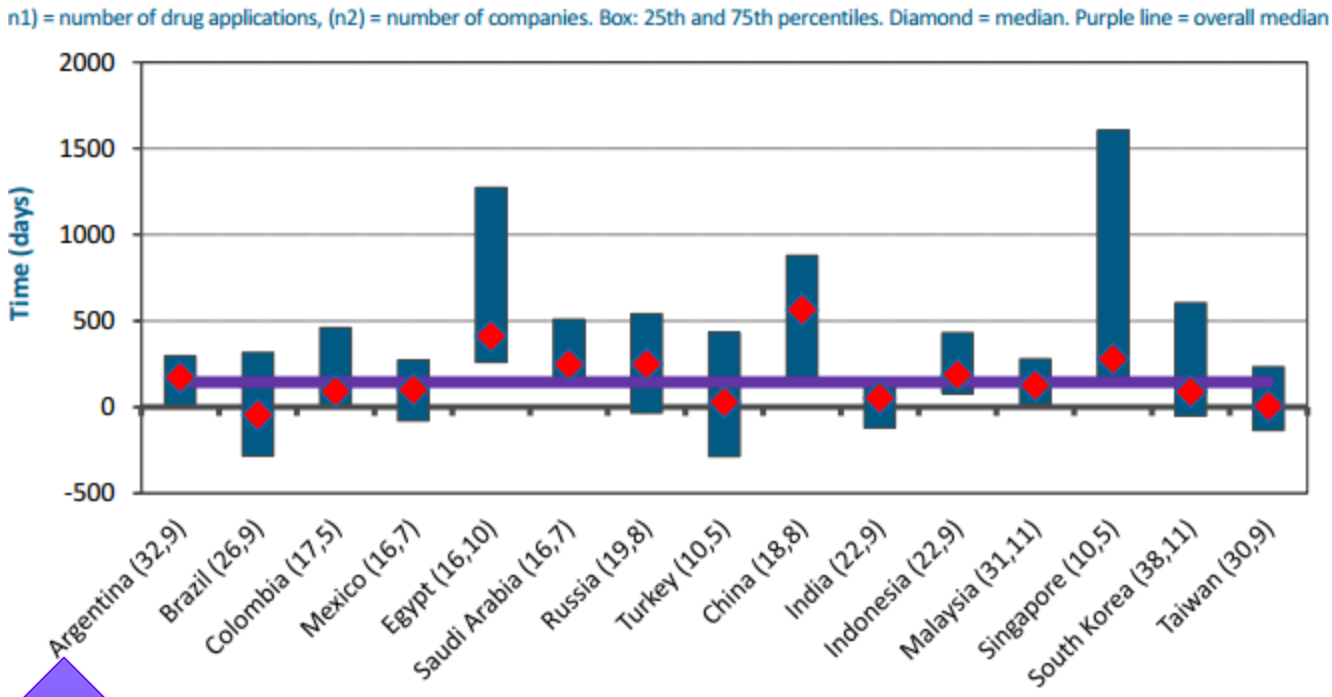
Magda Bujar Prisha Patel Neil McAuslane
Centre for Innovation in Regulatory Science – CIRS, London UK

Time Between The Authorization In The CPP Issuing Country And Submission In The Importing Country

The NAS application submission is dependent on CPP submission timing.

Overall median time between approval in CPP issuing country and submission to the country was 144 days; Argentina is at the median of the cohort



The Certificate of a Pharmaceutical Product is needed by the importing country when the product in question is intended for registration with the goal of commercialization or distribution in that country

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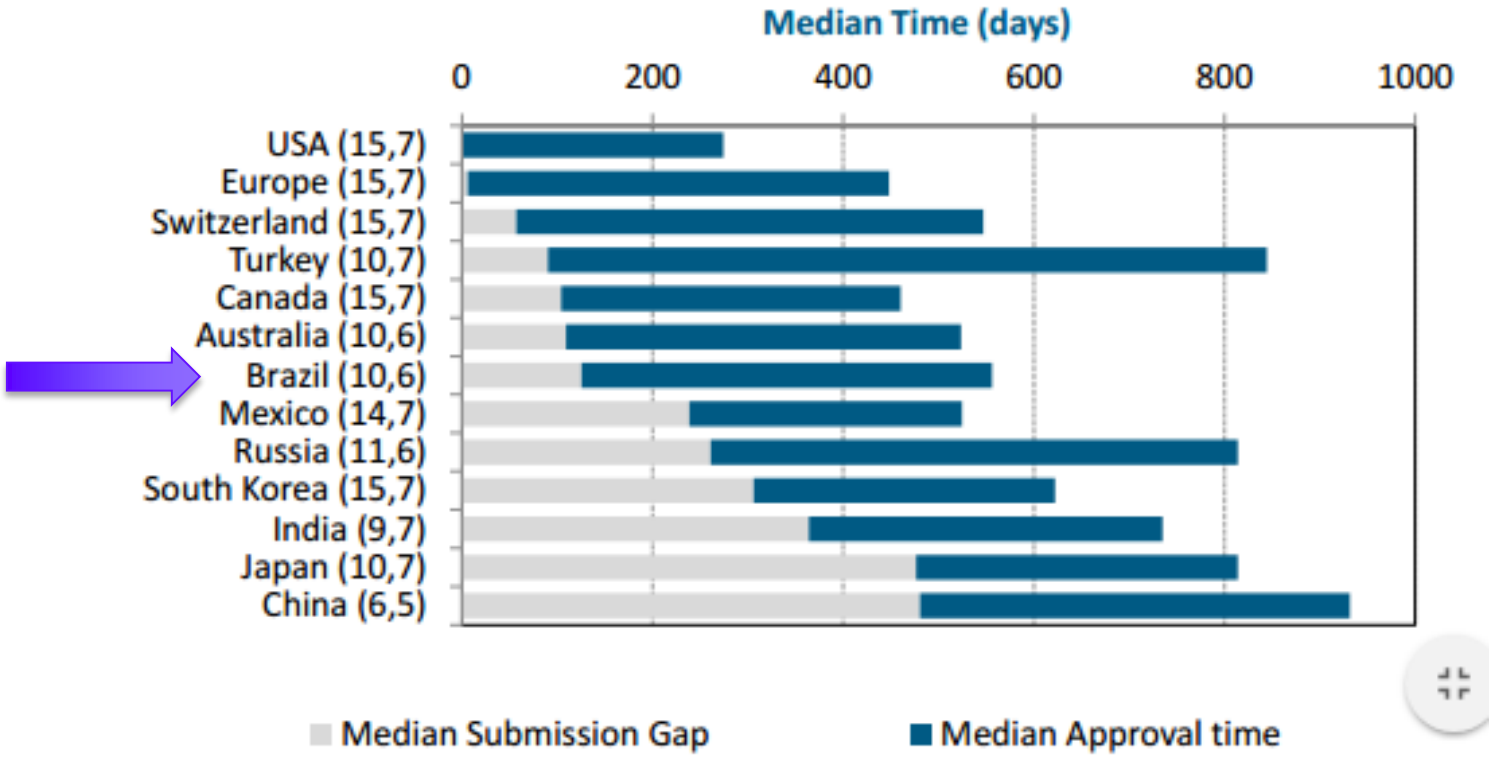
Drug Lag And Approval Time For 15 NASs Approved In MM And BRIC-TM Jurisdictions In 2009-2013



In terms of company strategy, although companies submit first in EU and US which carry out a full review, they also submit to some EM countries before first world approval (Turkey and Brazil). This is partly due to the fact that these EM jurisdictions do not require a CPP at time of submission.

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Generics

- Prescription drugs account for nearly half of the market, while OTC drugs make up for 27% of the sector. Generics account for 23% as of present.

- The generic industries in Argentina and Brazil has been experiencing some decline in recent years, though it has managed to increase its market share. The market has seen fierce competition within domestic players and this has affected the overall value growth of the industry.
- In Argentina move to Biosimilars is evident

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Biologics and Biosimilars – Argentina outlook

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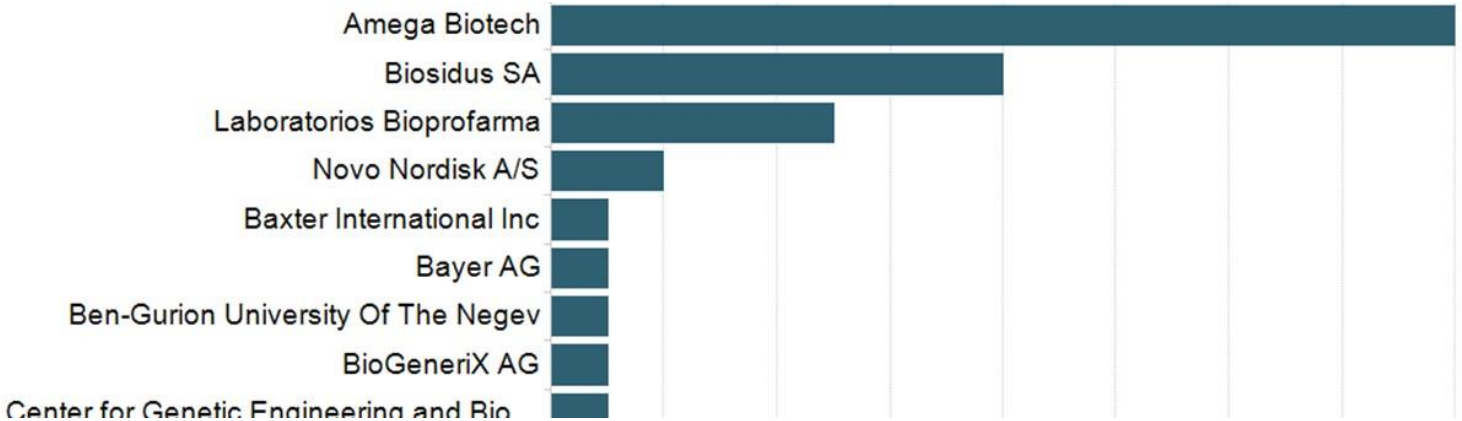
Biologic Drugs in Argentina

- The biopharmaceutical industry started in Argentina in the early 1980s with the foundation of BioSidus, an R&D firm that in 1990 produced and commercialized an erythropoietin biosimilar, becoming the first in South America.

- Biologics are commercialized in Argentina, but between 75 and 85% is for exports to more than 30 countries in Latin America, Africa, Asia and Europe.



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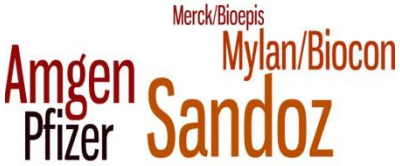
DOI: 10.4172/0975-0851.S1.002

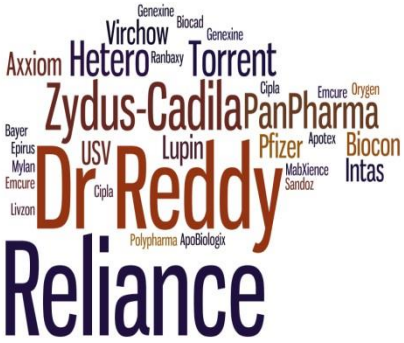
Global Biosimilar Players by Region

US



Europe

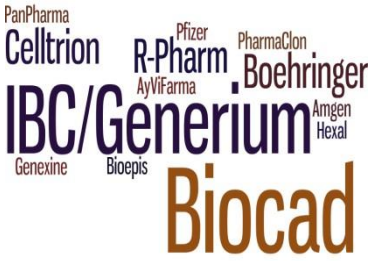
India



ASEAN

LATAM

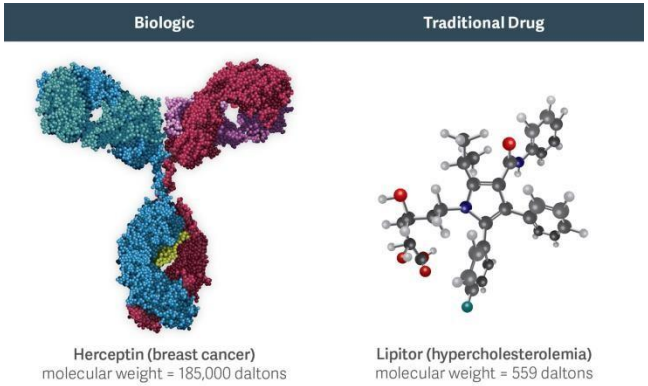
Russia



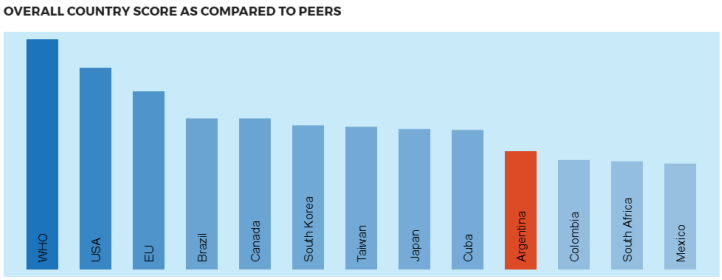
** Active drugs; Phase III and above Source: Cortellis*

Biosimilars Regulations in Argentina

- ANMAT in Argentina has developed their own biosimilar regulatory abbreviated pathways, by merging WHO and EMA guidelines for biosimilars with their own political, economic and historic context



- The Center for Biologic Policy Evaluation lists Argentina as **Partially Compliant.**
  - The WHO guidance was compared to the relevant sections across the ANMAT guidelines resulting in an overall score for Argentina of **2.57/5.** This means the ANMAT guidelines are partially or fully compliant with WHO in some areas, but in more than half of the policy components, they are minimally or non-compliant with WHO standards



https://biologicspolicy.com/country/argentina

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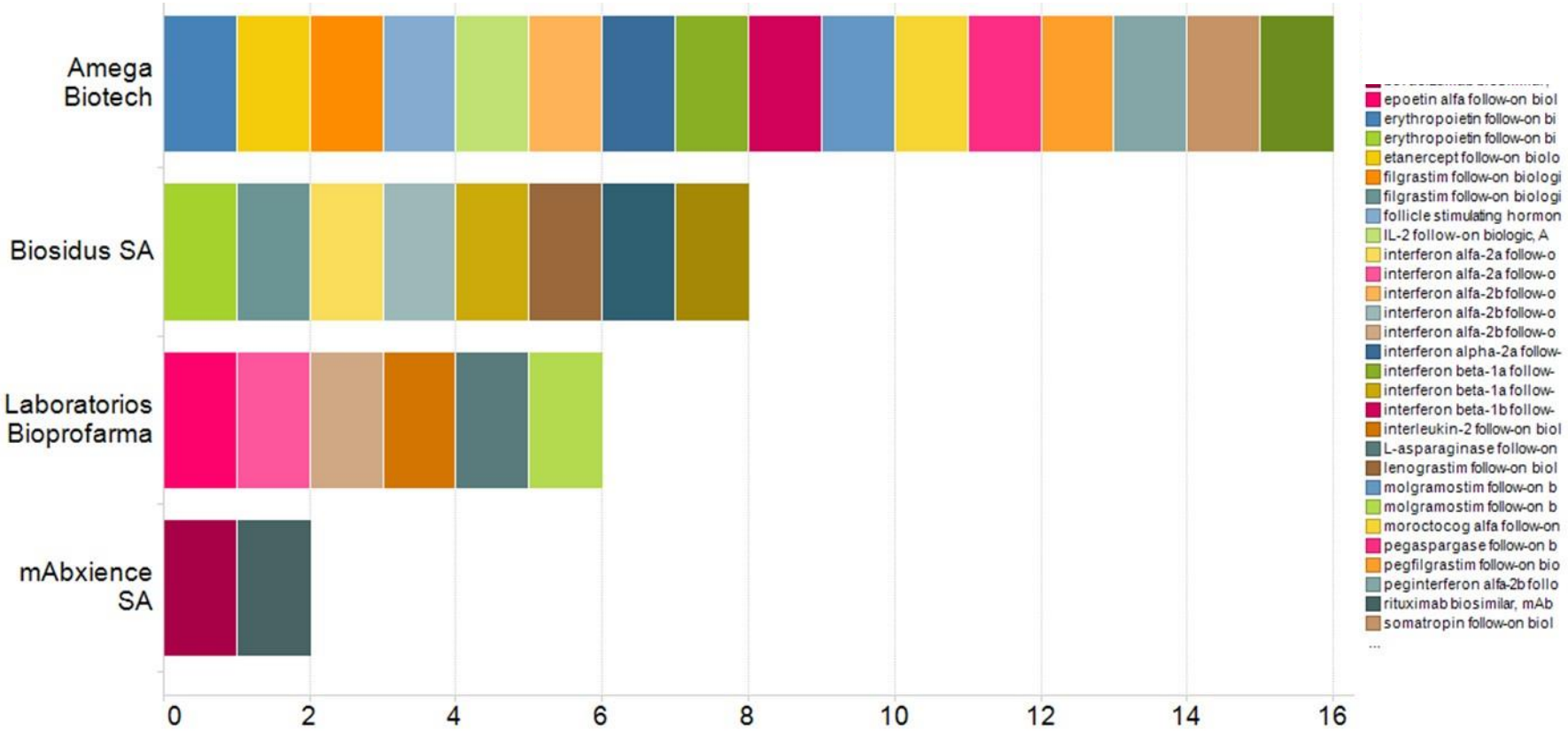
Biosimilars In Argentina by Drug Name



Number of Biosimilars

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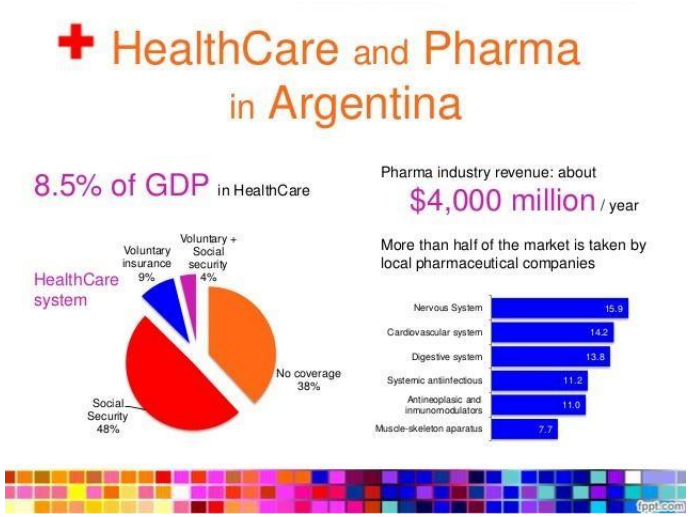
Summary - Argentina

- Following years of strong expansion, pharmaceutical sales growth has slowed; a result of sharp economic deceleration, erosion of real incomes, and persistent inflation
- Clinical trial starts have decreased in recent years similar to other LATAM countries but reforms are in place to increase trial starts
- Academic involvement is lower than other LATAM countries but is on the rise
- Biologics and biosimilars will be more important in the future of the Argentinean Pharmaceutical Industry

ARGENTINA IN FACTS & FIGURES	
Population (2013)	41.45 million
GDP (2013)	USD 609.9 billion
Total Healthcare spending (2012)	8.5% of GDP
Annual Retail pharmaceutical spending (October 2014)	USD 6.1 billion
Pharmaceutical plants	110
Foreign owned Pharmaceutical plants	17
National Labs share of total market (2014)	57%
OTC share of total market (2014)	10%



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Summary - Brazil

- Brazil is the 6th largest market worldwide
- Brazil ranks highest in clinical study starts among LATAM countries
- An increasing focus on earlier phase clinical trials is good news for the innovative research efforts
- Brazil ranks among the leaders in approval times after submission
- Brazil continues to have a strong generics market

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