



ACADEMIA DE CIÊNCIAS FARMACÊUTICAS DO BRASIL
Academia Nacional de Farmácia



**NOVAS FRONTEIRAS
DA PESQUISA CLÍNICA COM
FARMACOS E VACINAS**

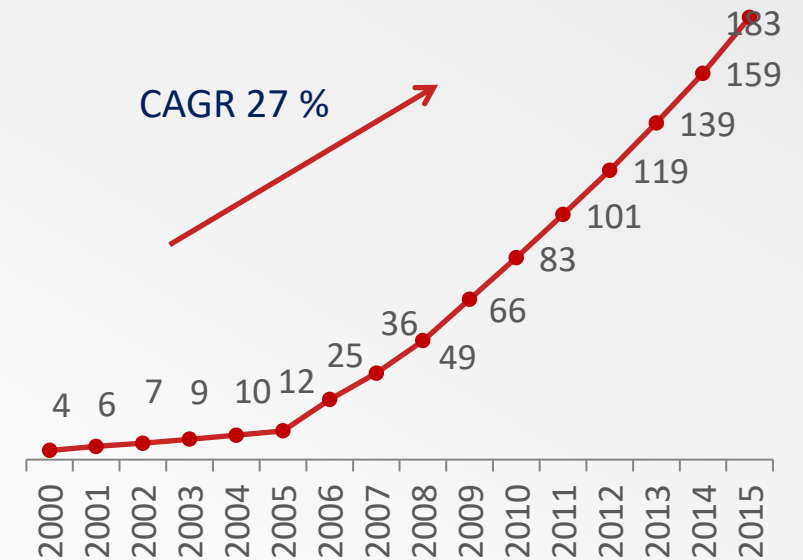
**Rua da Glória, 344 – 2ª andar
luis.russo@ibpclin.com**

Clinical Research Market

IT HAS TO INCREASE, THERE IS NO OTHER WAY

DISEASE	BEFORE TREATMENT	THERAPEUTICS	IMPACT
Coronary	1979 345 deaths/ 100,000 pop. ¹	1980 – 1990 (Inhibithors of ECA, Beta-blockers, Trombolítics / Stents, Defibrilators)	2002 171 deaths/ 100,000 pop. ¹ 50% reduction
Strokes	1960 178 deaths/ 100,000 pop. ¹	Treatment of hyperthension (Diuretics, Inhibitors of ECA, Beta-blocker, Calcium atagonists)	2002 56 deaths /100,000 pop. ¹ 70% reduction
HIV AIDS	1997 6,647 deaths/ 100,000 HIV/AIDS patients	1990 – (Nucleosídeos Reversos – inhibitors of trancriptase, No Nucleosídeos Revers – inhibithors of transcriptase, Proteasis inhibitors)	2003 1,620 deaths/ 100,000 patients 75% reduction
Measles	1963 3-4 millions EUA (~500,000 reports)	1963 (Vaccine)	2000 86 cases in EUA
LeuKemia mielóide	1997 50% of survival in 18 months	2001 (Cirrase Inhibithors)	2004 94% of survival in 3 y.

NUMBER OF REGISTERED STUDIES WORLDWIDE (UNIT: THOUSANDS)



Source: *Clinicaltrials.gov*

Figura 10: Principais indicadores demográficos e econômicos do Brasil.



Fontes: FMI*, IBGE**, IQVIA (MIDAS)***, ONU*

Para o desenvolvimento dos países e seus sistemas de saúde

Figura 4: Benefícios da pesquisa clínica para o país e seu sistema de saúde.

Atrai investimentos e movimentação a economia

- Investimentos diretos em estudos clínicos
- Aumento da atividade econômica no país (impactos indiretos)

Atua como alavanca da produção científica e inovação

- Aumento da produção científica no país
- Redução da perda de recursos humanos para outros países/ aumento da atração de recursos humanos de outros países

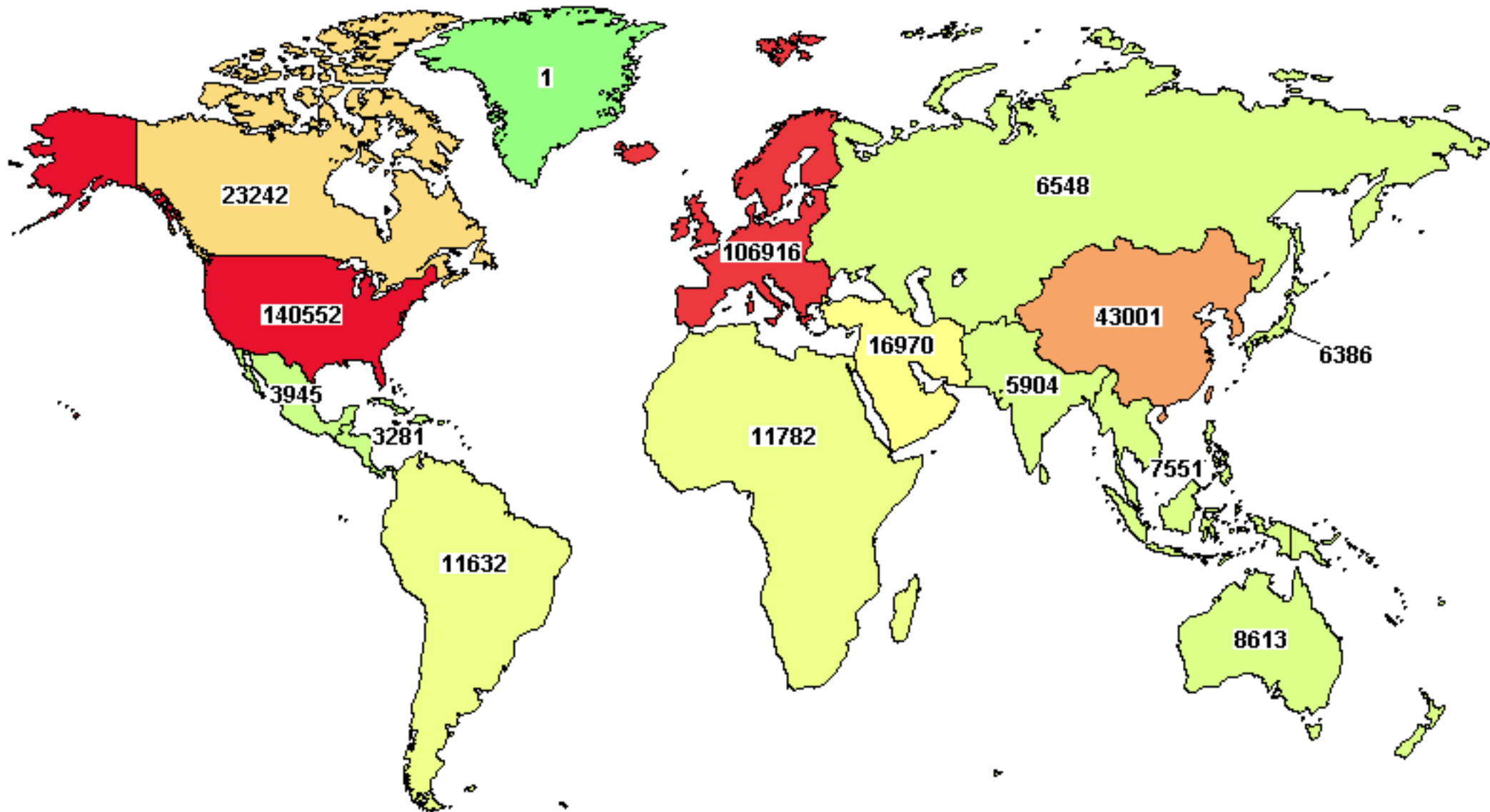
Aumenta o acesso à saúde

- Aumento no padrão de tratamento de pacientes participantes dos estudos clínicos
- Inovações que chegam ao mercado após condução exitosa de estudos, impactam positivamente a qualidade de vida da população

Fortalece o sistema de saúde do país

- Incremento da infraestrutura física de atendimento e cuidado ao paciente utilizada em centros de pesquisa
- Acesso e conhecimento mais ágil de novas tecnologias (ex. medicamentos, técnicas cirúrgicas) por equipes de tratamento
- Conhecimento mais íntimo de novas tecnologias contribuem para melhor avaliação de registro e incorporação no país
- Estabelecimento de times multifuncionais em centros de excelência para teste e entrega de inovações
- Aumento da frequência de atualização e treinamento profissional
- Maior aderência à protocolos clínicos e cultura de medicina baseada em evidências
- Redução de custos para o sistema de saúde para pacientes participantes de estudos

Fonte: IQVIA Institute for Human Data Science, 2016 Nota: (*) Novos ingredientes ativos

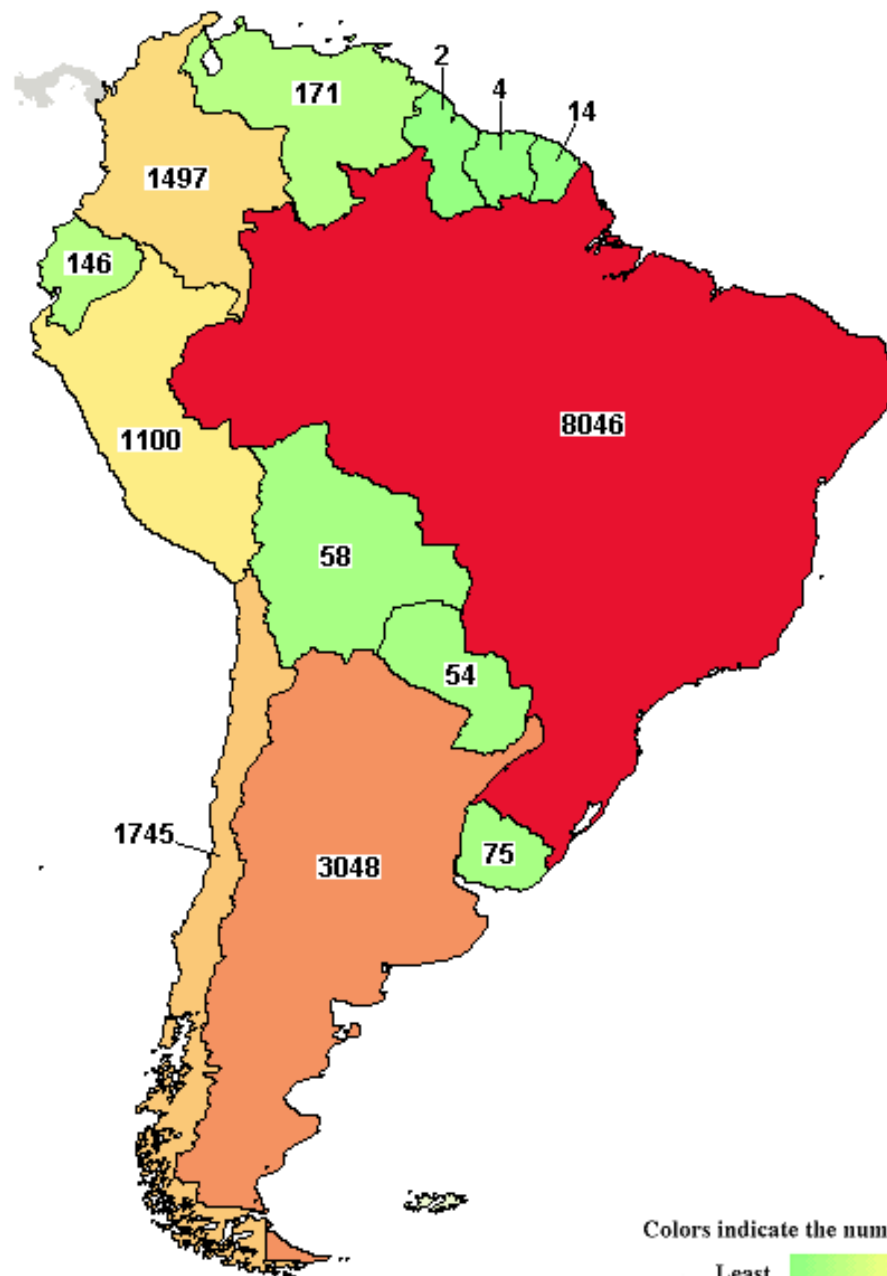


Colors indicate the number of studies with locations in that region.



Labels give the exact number of studies.

Source: <https://ClinicalTrials.gov>



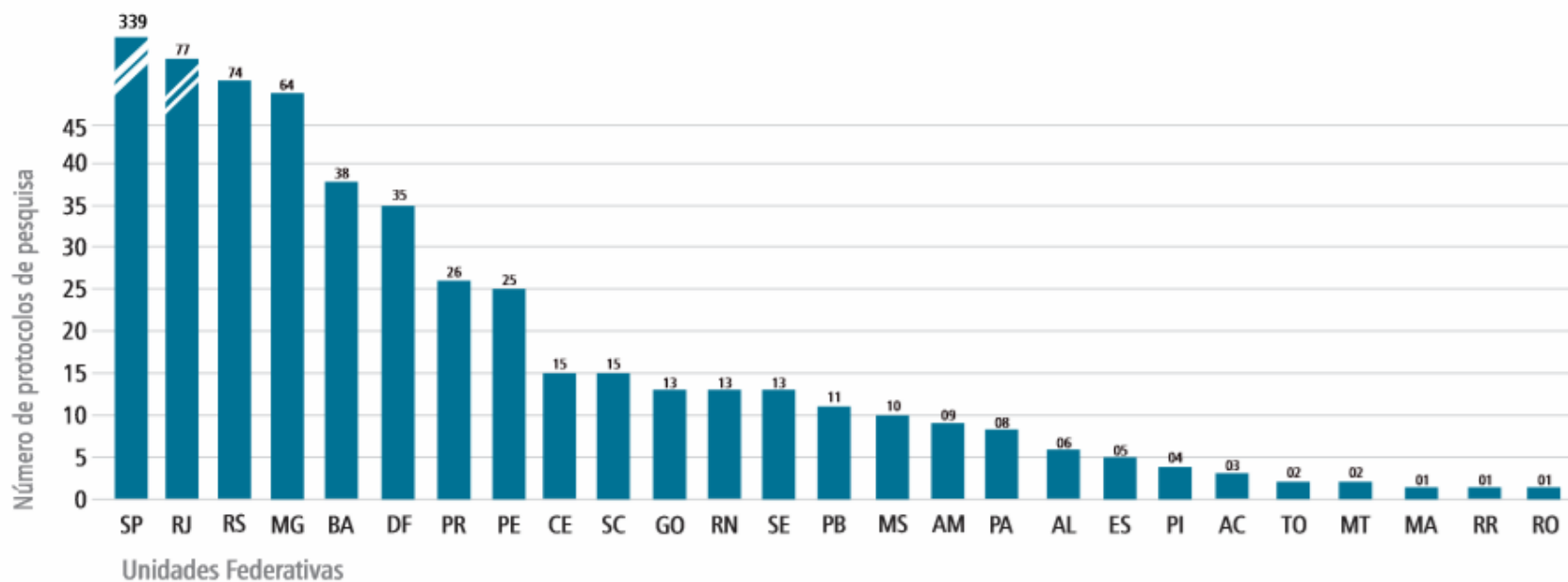
Colors indicate the number of studies with locations in that region.

Least  Most

Labels give the exact number of studies.

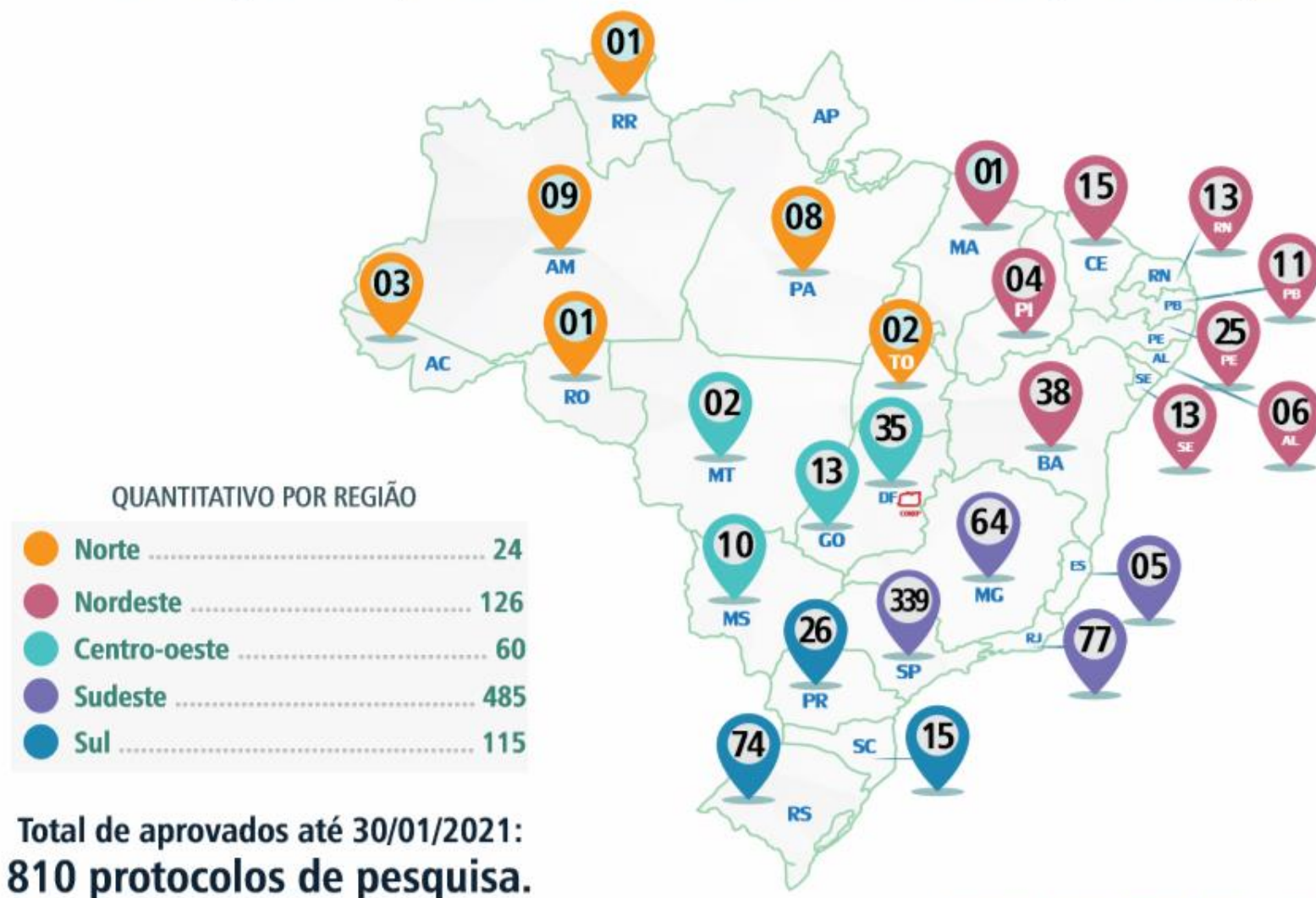
Region Name	Number of Studies
World	371,977
South America	11,632
Argentina	3,048
Bolivia	58
Brazil	8,046
Chile	1,745
Colombia	1,497
Ecuador	146
French Guiana	14
Guyana	2
Paraguay	54
Peru	1,100
Suriname	4
Uruguay	75
Venezuela	171

Número de protocolos de pesquisa relacionados ao coronavírus e/ou à Covid-19 aprovados pela Comissão Nacional de Ética em Pesquisa - Conep em relação às Unidades Federativas.



Fonte: Plataforma Brasil, 2021.

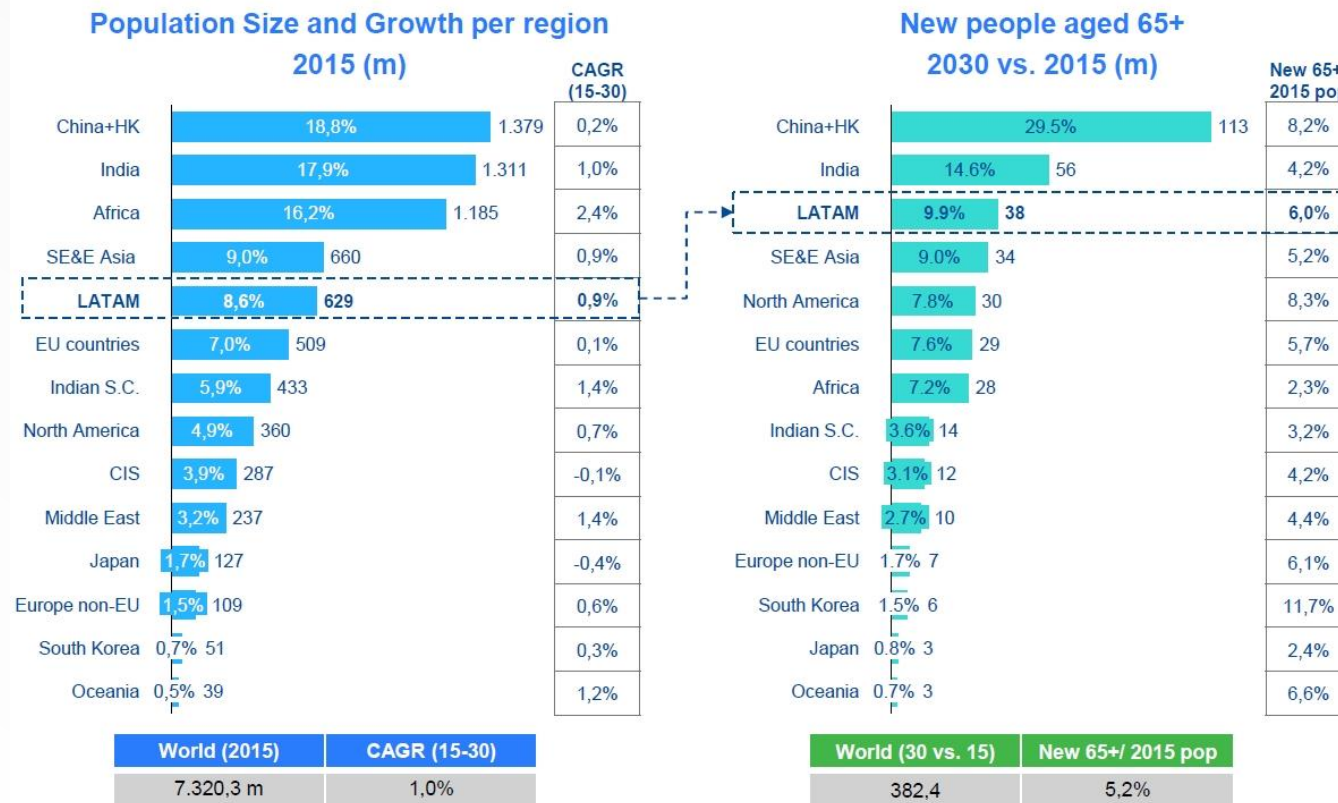
Mapa geral dos protocolos de pesquisa relacionados ao coronavírus e/ou à Covid-19 aprovados pela Comissão Nacional de Ética em Pesquisa - Conep.



Fonte: Plataforma Brasil, 2021.

BRAZIL

AN IMPORTANT MARKET FOR CLINICAL TRIALS



SPONSOR

ONGOING TRIALS

NOVARTIS	75
ROCHE	74
GLAXO SMITHKLINE	44
PFIZER	41
JOHNSON & JOHNSON	40
ASTRAZENECA	39
BRISTOL-MYERS SQUIBB	34
MERCK & CO	28
BAYER	24
BOEHRINGER INGELHEIM	23
AMGEN	18
SANOFI	16
ELI LILLY	14
ABBVIE	14
UCB	13

Source: Clinical Registry Databases (e.g. CT.gov / EU Clinical Trials Register, etc)
Comm1: Only clinical trials sponsored by pharmaceutical companies

BRAZIL

PROGRESS IN REGULATORY LANDSCAPE

3-STEP PROCESS / TIMELINES: 4-6 MONTHS



BRAZILIAN ALLIANCE FOR CLINICAL RESEARCH



Senator **Ana Amélia Lemos**

Figura 29: Benefícios quantificados caso o Brasil amplie seu protagonismo em pesquisa clínica, passando a ocupar a 10ª colocação no *ranking* global.



Fonte: IQVIA (estimativas internas)

HIGHT QUALITY CERTIFIED BY AUDITS AND INSPECTIONS

3-4 Audits & Inspections per year

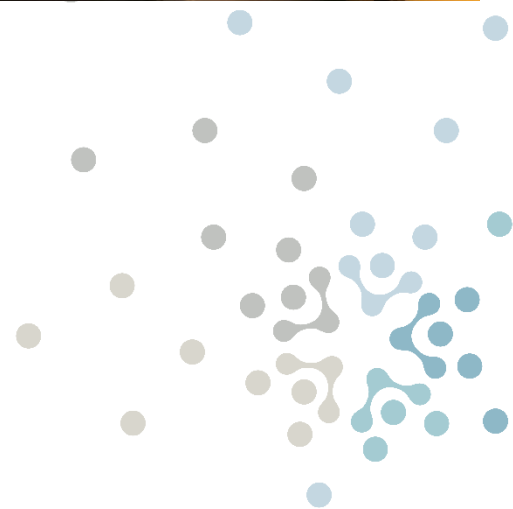
- *Local Regulatory Authorities*
- *Sponsor's*
- *CRO's*
- *BIOCLINICA*
- *EMA*
- *FDA*



No Significant Findings



INFRAESTRUTURA

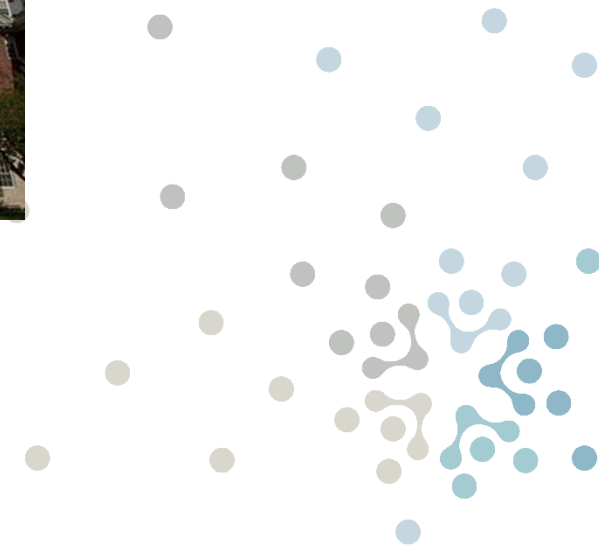


INFRAESTRUTURA



MAIN PRIVATE CLINICAL RESEARCH HUB IN BRAZIL

PPCR HARVARD



Unique and unparalleled expertise:

- In-house physicians, radiologists and scientists
- 100+ M.D. / Ph.D. employees on staff
- Synarc Innovation Technologies team focused on clinical trials imaging research
- Publications
 - Scientific Books: 42
 - Scientific Book Chapters: 277
 - Scientific Articles: >1,400
- Twenty-six patents
- Served on Regulatory (FDA, EMEA) and Standardization Committees and Sponsor Advisory Boards



SCIENTIFIC LEADERSHIP & INNOVATION

Unique and unparalleled expertise:

In-house physicians, radiologists and scientists

12+ M.D. / Ph.D. employees on staff

Publications

Scientific Books

Scientific Book Chapters

Scientific Articles: >100





CTTI Recommendations: Optimizing Mobile Clinical Trials by Engaging Patients and Sites

February 21, 2019

CTTI MISSION:

To develop and drive adoption of practices
that will increase the quality and efficiency of clinical trials



Global Trends in R&D

OVERVIEW THROUGH 2020



MAY
2021



• Luis Augusto Tavares Russo - IBPClin

Total clinical trial starts increased 8% in 2020 as the industry adapted quickly to shifting priorities and logistical challenges

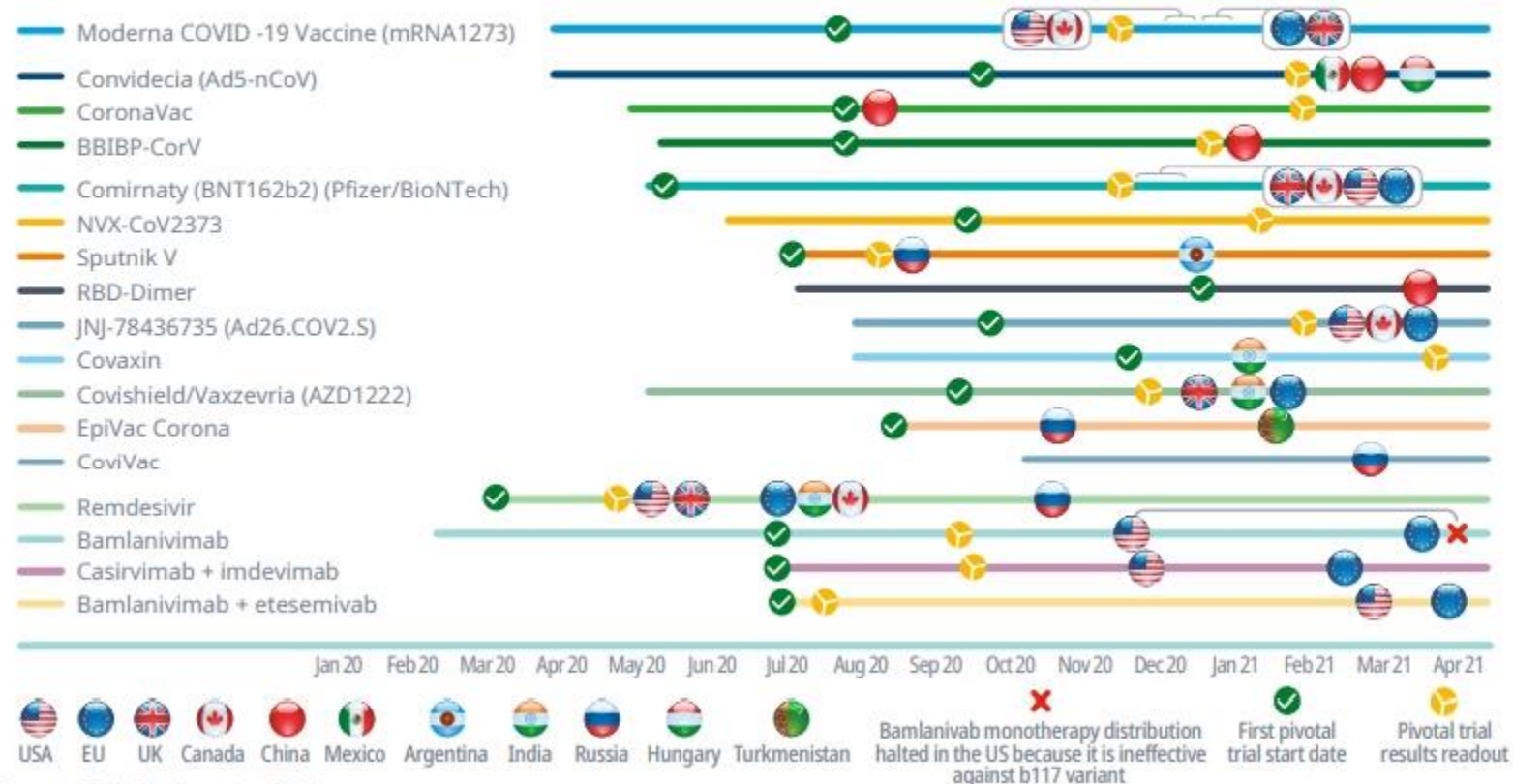
Exhibit 1: Total Number of Clinical Trials by Phase 2010-2020



Source: Citeline Trialtrove, Apr 2021; IQVIA Institute, Apr 2021

The global efforts focused on COVID-19 yielded rapid development and approval of 12 vaccines and 4 new therapeutics

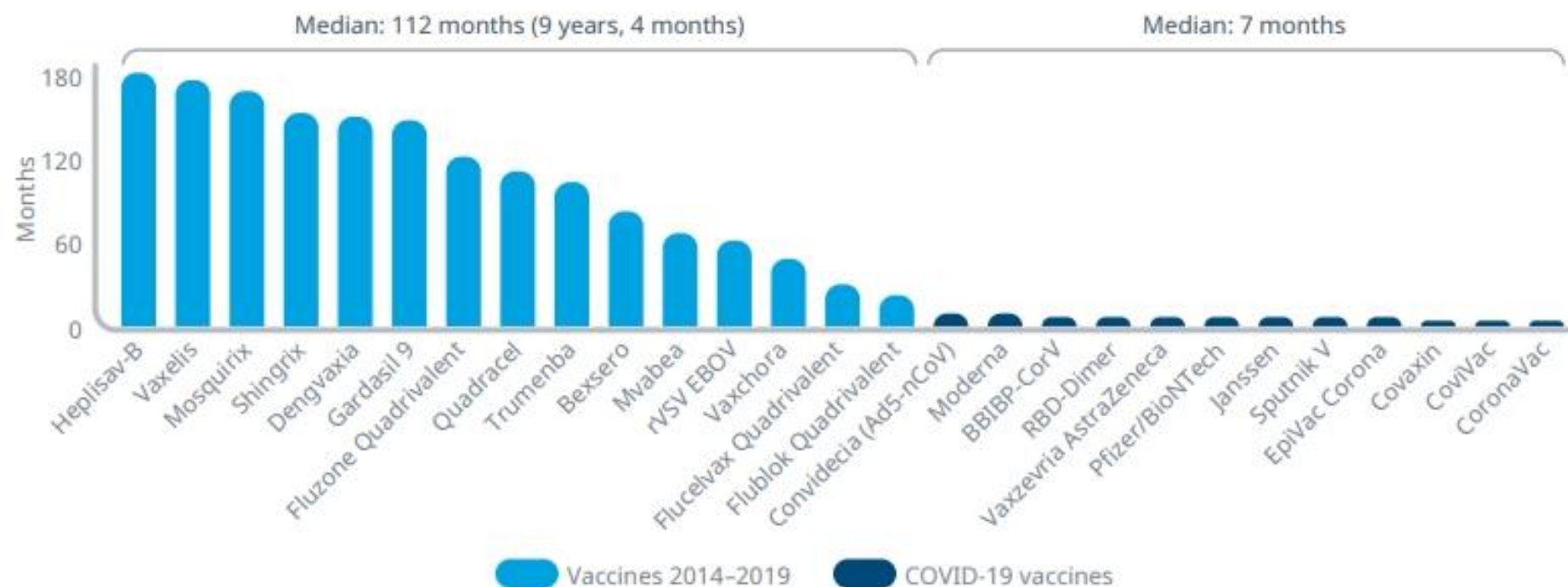
Exhibit 7: Timelines of Global COVID Vaccines and Therapeutics Trials and Their Authorization for Emergency Use/Approval by Country



Source: IQVIA institute, Apr 2021

COVID-19 vaccines were developed and approved in an average of 7 months compared to 9 years and 4 months for other vaccines

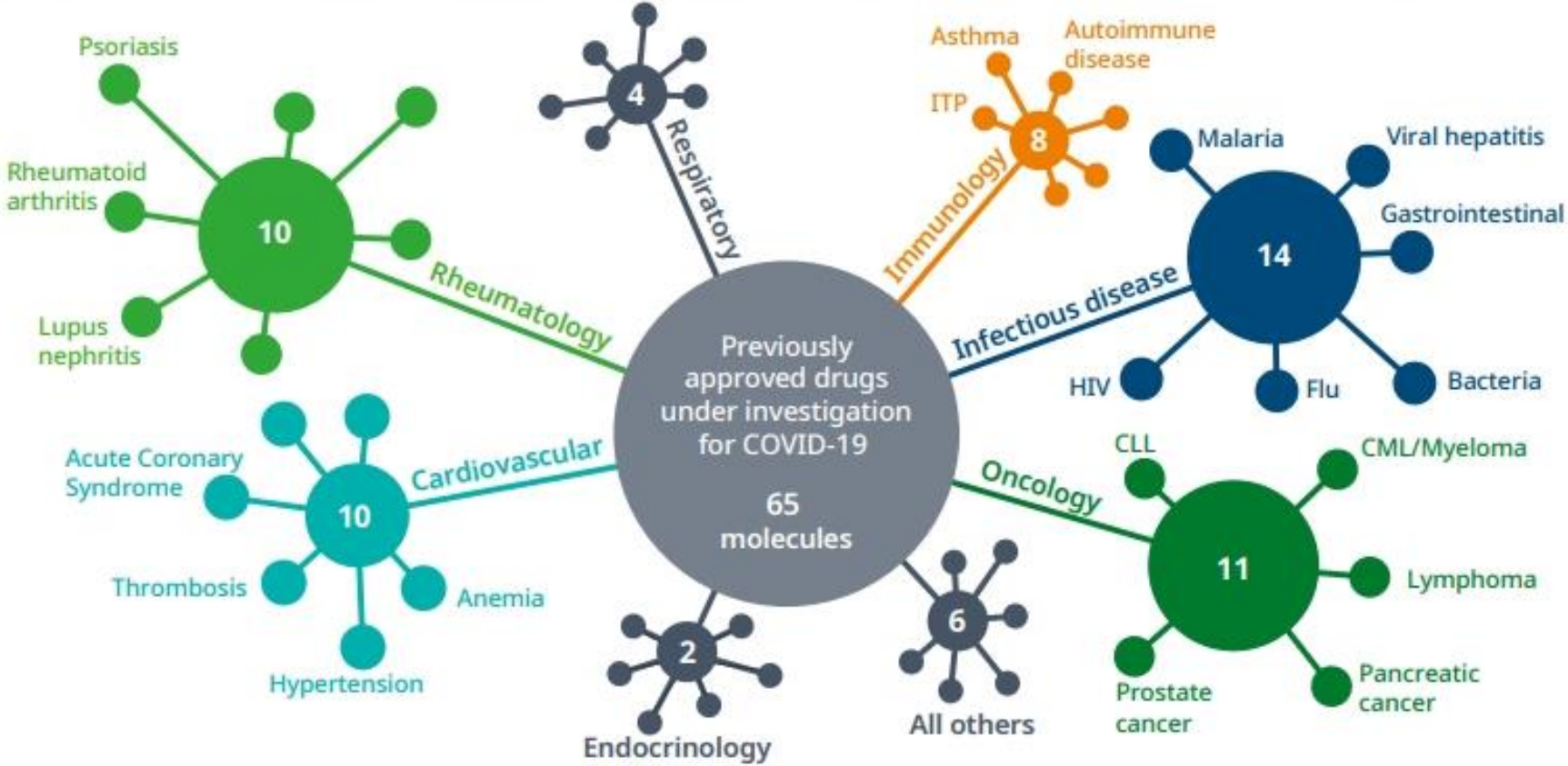
Exhibit 8: Time (in months) from a Vaccine's First Clinical Trial Start to First Authorization



Source: IQVIA Institute, Apr 2021

COVID-19 trials continue for 65 previously approved molecules, reflecting the breadth of effort underway to find effective therapies

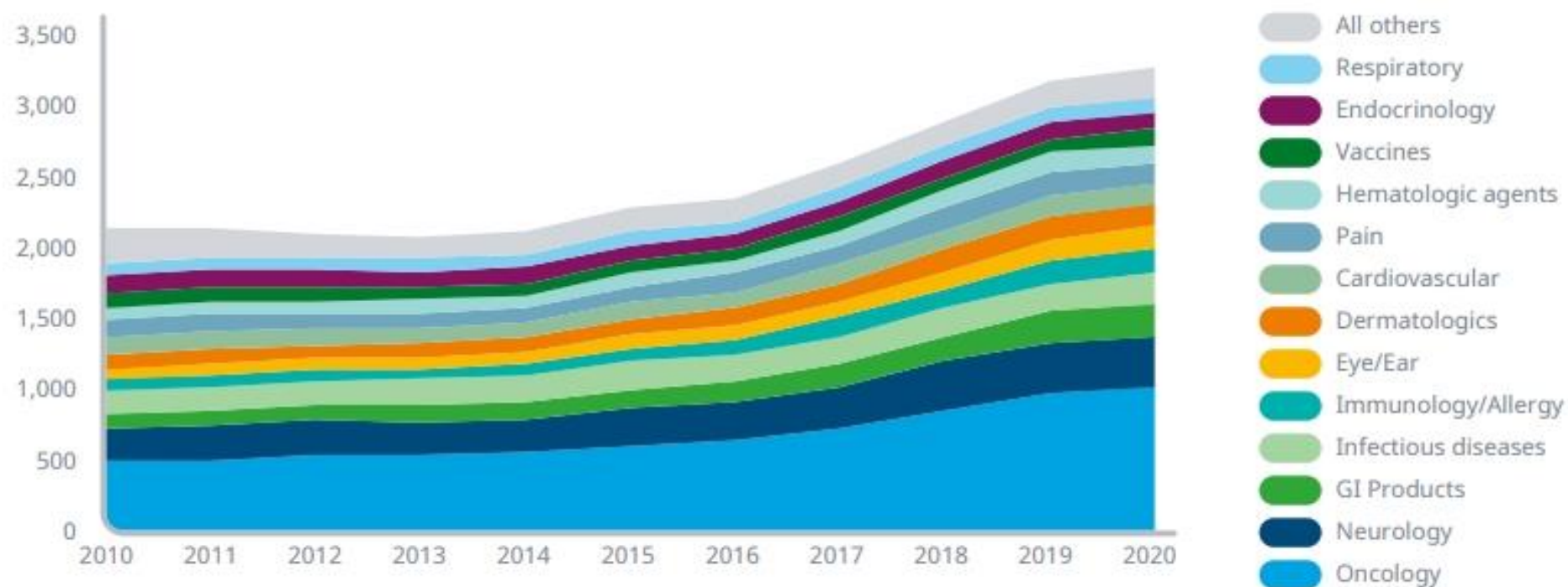
Exhibit 9: Currently Marketed Medicines by Disease and Indication Undergoing Research for COVID-19



Source: IQVIA Pipeline Intelligence; IQVIA Institute, Feb 2021

Growth in the late-stage pipeline continued in 2020, bringing total expansion to 43% since 2015

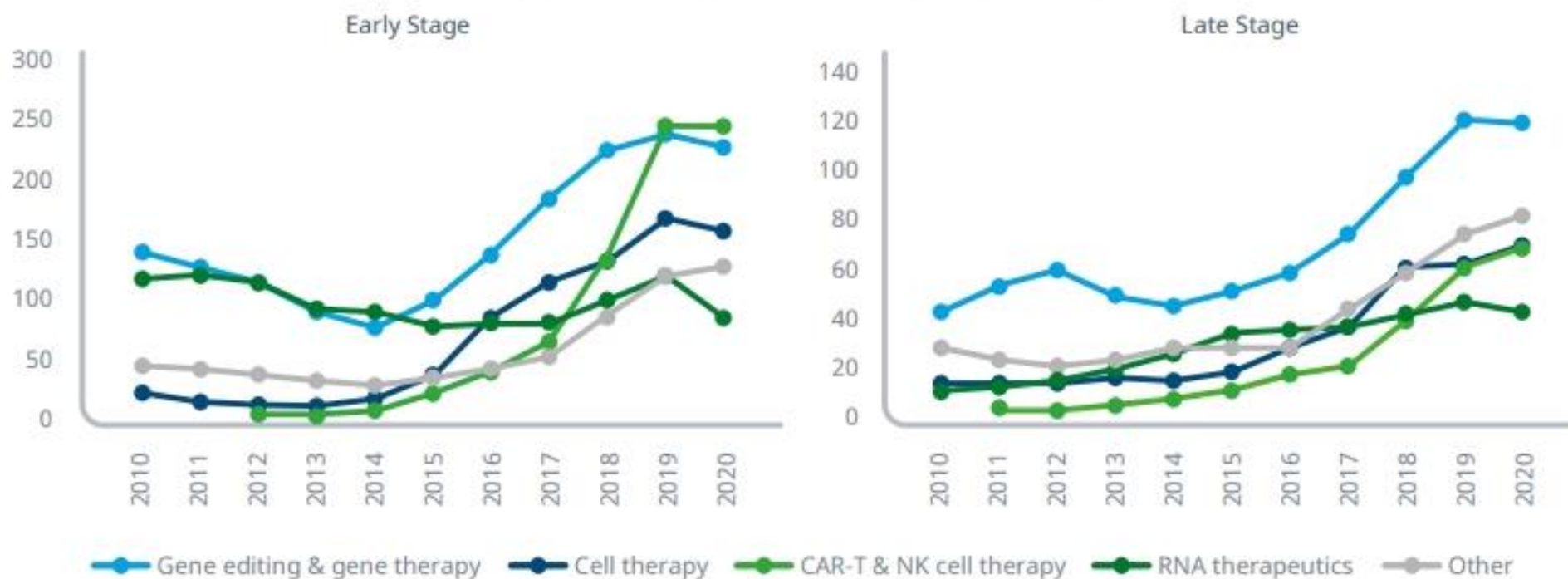
Exhibit 23: Number of Late-Stage Pipeline Products by Therapeutic Drug Class, 2010–2020



Source: IQVIA Pipeline Intelligence, Dec 2020; IQVIA Institute, Mar 2021

The next-generation biotherapeutic pipeline is focused on gene editing, CAR-T and RNA therapeutics in both early and late phases

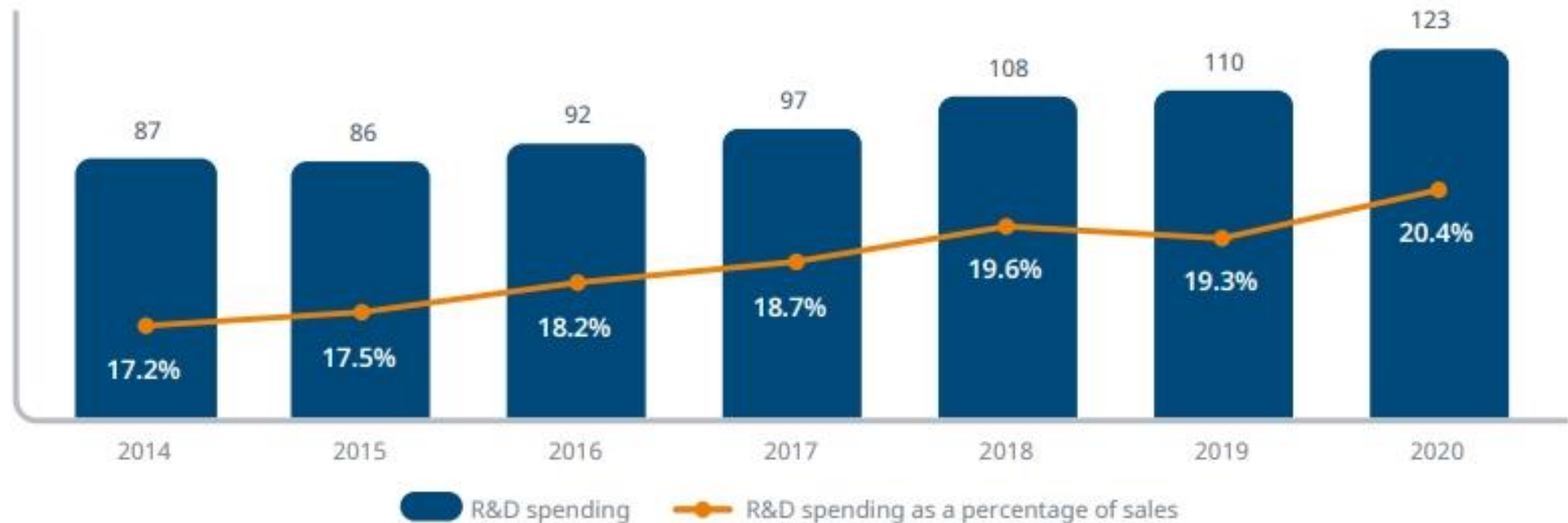
Exhibit 27: Next-Generation Biotherapeutics Early- and Late-Stage Pipeline by Mechanism



Source: IQVIA Pipeline Intelligence, Dec 2020; IQVIA Institute, Mar 2021

R&D expenditure by large pharma corporations totaled a record \$123 billion in 2020, and exceeded 20% of revenue for the first time

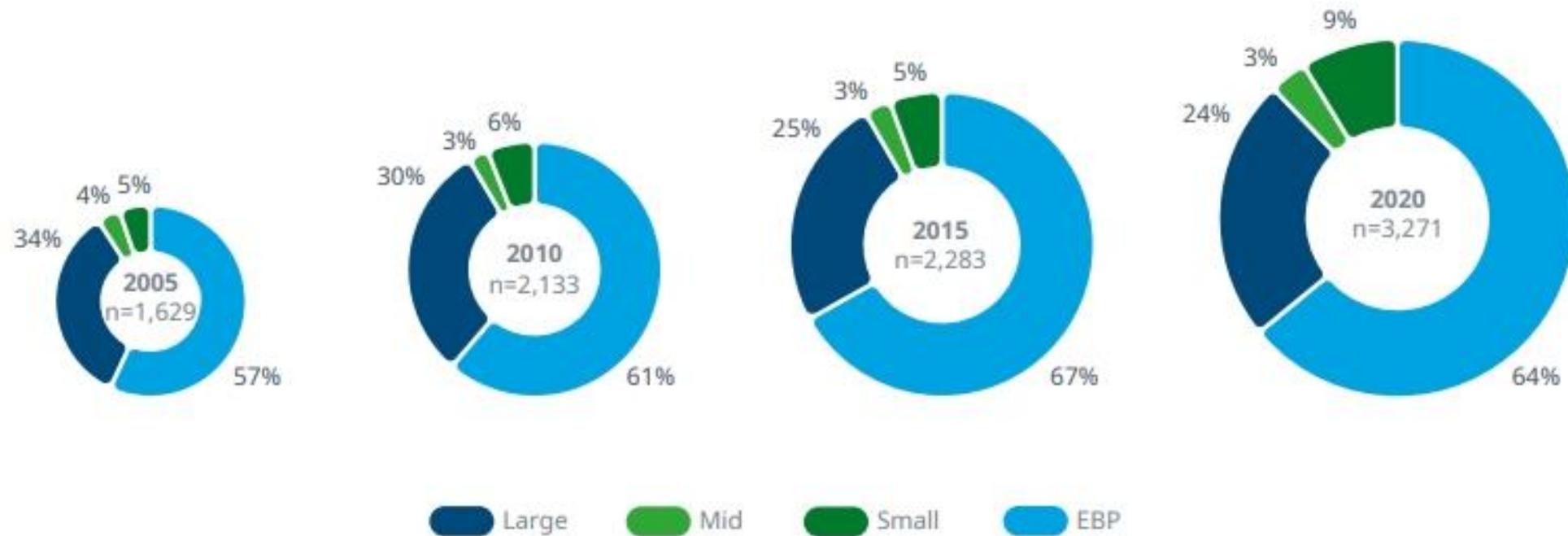
Exhibit 30: Large Pharma R&D Spending and Spending as a Percentage of Sales 2016–2020, US\$Bn



Source: Data taken from company financial statements; IQVIA Institute, Feb 2021

Emerging biopharma companies are responsible for most of the late-stage pipeline, though their share fell in 2020

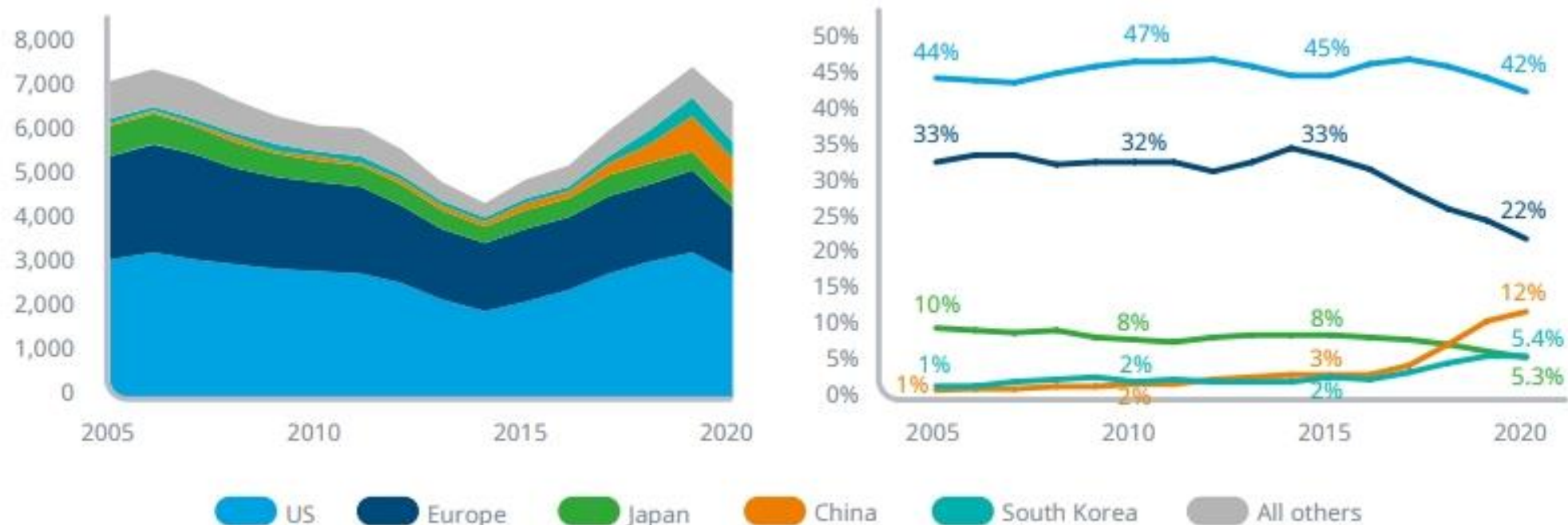
Exhibit 35: Percent of Late-Stage Pipeline by Company Segment, 2005, 2010, 2015, 2020



Source: IQVIA Pipeline Intelligence, Dec 2020; IQVIA Institute, Mar 2021

Drugs from China-headquartered companies have risen to 12% of the early-stage pipeline from 2% a decade ago

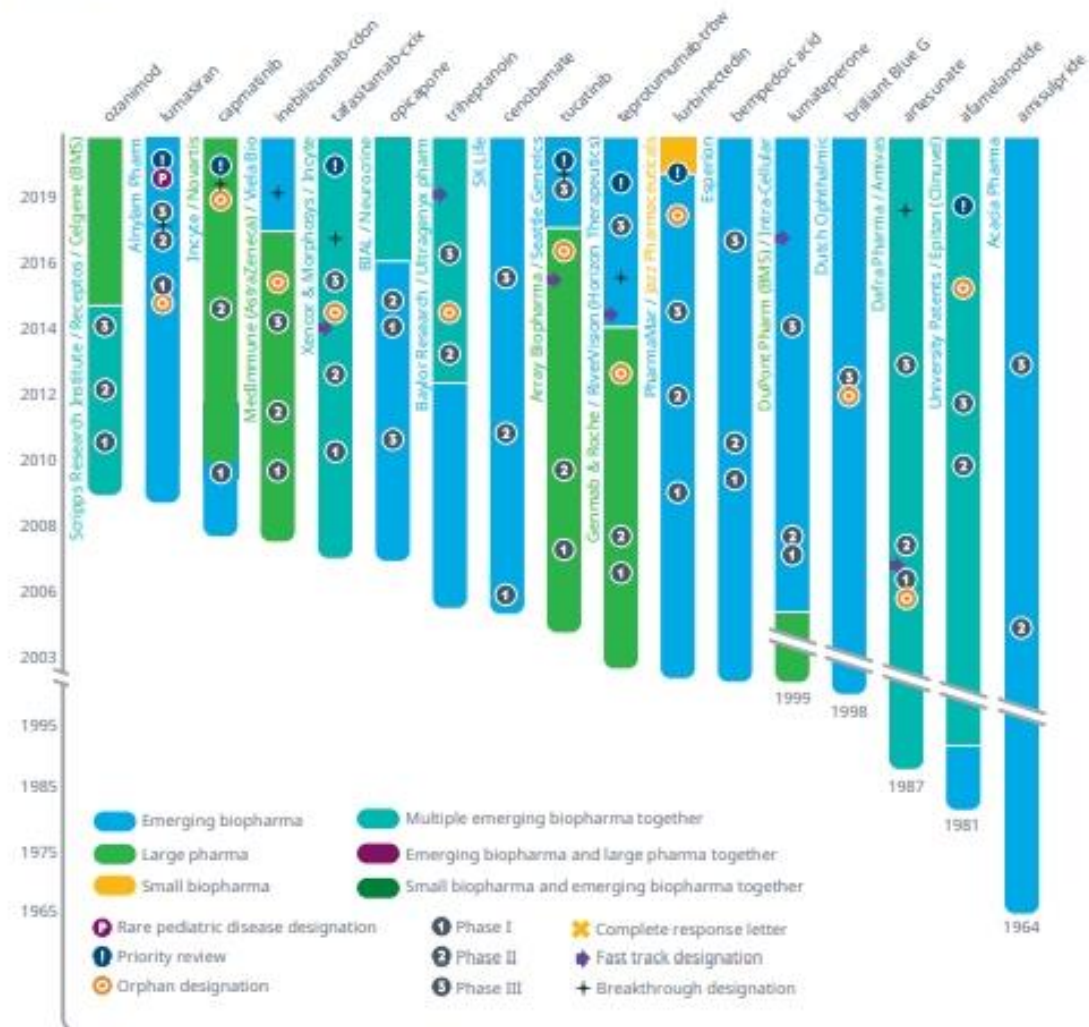
Exhibit 36: Number of Drugs Over Time and Country Share of Early-Stage Pipeline Based on Company Headquarter Location 2005-2020



Source: IQVIA Pipeline Intelligence, Dec 2020; IQVIA Institute, Apr 2021

Some products launched by emerging biopharma companies were older medicines never previously launched in the U.S. and given new uses

Exhibit 46b



Source: IQVIA Patent Intelligence; IQVIA Pipeline Intelligence; IQVIA Institute, Mar 2021



IBPClin
Glória Trade Center



“Our mission is to conduct clinical trials with integrity, ethics, confidentiality and safety for Brazilian population”

“Our Vision is a leadership of the first network of private research units in Brazil and Latin America”

Luis.russo@ibpclin.com