



# Building an Innovation Ecosystem for a Healthier and More Secure Future

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# Fighting COVID-19: Where We Are Today

Since the start of the pandemic, the biopharmaceutical industry has made tremendous progress toward developing safe and effective vaccines and therapeutics to help fight COVID-19

**2,131**

Global Active Clinical Trials for  
Vaccines and Therapeutics

**606**

Unique Therapies in Clinical Trials

**140**

Unique Vaccines in Clinical Trials

*(as of 14 January 2022)*

**335 Vaccine**

Manufacturing and Production  
Deals Around the Globe

**116 Treatment**

Manufacturing and Production  
Deals Around the Globe

*(as of December 2021)*

**9.6 Billion**

Vaccines Administered Globally

**Nearly 5 Billion**

People with at Least 1 Dose



















*(as of 12 January 2022)*

# An Innovation Ecosystem Enabled Scientific Advances in the Fight Against COVID-19

## Vaccines

COMIRNATY®		
VAXZEVRIA®		
Janssen COVID-19 Vaccine		
SPIKEVAX™		
BBIBP-CORV		
CORONAVAC™		
COVAXIN®		
NUVAXOVID™		

## Therapeutics

VEKLURY®		
RONAPREVE™		
OLUMIANT®		
Bamlanivimab and Etesevimab		
XEVUDY®		
ACTEMRA®		
LAGEVRIO®		
REGKIRONA™		
PAXLOVID™		

# Rapid Advancement of COVID-19 Treatments

## Baricitinib: A third therapeutic drug for COVID-19

- To date, **747,000 people** have been treated with baricitinib for COVID-19 worldwide including approximately **20,000 patients in Japan**
- **Approved in Japan** in April 2021
  - **Baricitinib**, a Janus-associated kinase (JAK) inhibitor-is indicated for pneumonia caused by COVID-19 (Limited to patients who require supplemental oxygen)

**February 2020**  
Artificial intelligence identified **baricitinib** as a potential treatment

**May 2020**  
NIH-NIAID:  
Investigator-initiated clinical trial started;  
Japan NCGM joined

**November 2020**  
U.S. FDA issued  
Emergency Use  
Authorization

**December 2020**  
Application for  
approval of additional  
indication in Japan

**April 2021**  
First regulatory  
approval for COVID-19,  
conditioned on PMS to  
track patient safety

# The Economic Impact of the Biopharmaceutical Industry

Driving Economic Impact, Sustaining Productive Workforces and Addressing the Challenges of a Super-Aging Society



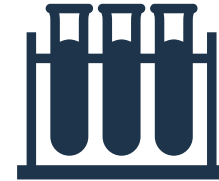
**140,000+**

Direct Biopharmaceutical  
Sector Jobs in Japan



**\$1.7 Trillion**

Global R&D Investment in  
the Last Decade  
(¥14 Trillion in Japan)



**8,000+**

Medicines in Development  
Worldwide

**Hundreds of  
thousands+**

Indirect Jobs

**\$1.2 Trillion**

Global R&D Investment  
Estimated in the Next 5 Years

**74%**

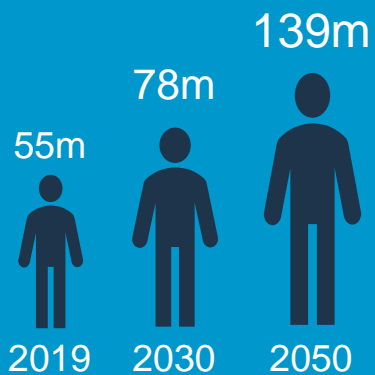
Are Potential First-In-Class  
Treatments

# Tackling Unmet Medical Need

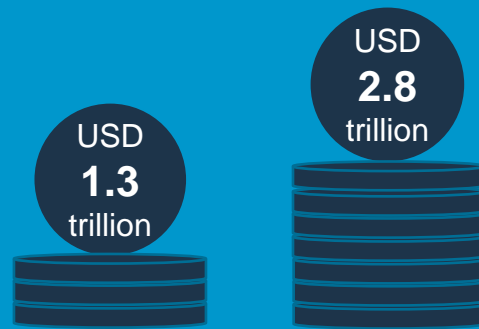
## Progress in Dementia and Alzheimer's Disease

- The number of patients is expected to double every 20 years, reaching 139 million by 2050.
- The costs associated with caring for patients with dementia and Alzheimer's disease makes this a top public health priority.

### Estimated growth in number of people with dementia, 2019-2050



### Total estimated annual worldwide cost of dementia is \$1.3 trillion and is forecast to be \$2.8 trillion by 2030



- Industry has been investing in research and development in dementia and Alzheimer's disease for more than 30 years.
- Many therapies were not successful, but our understanding of the disease and the science supporting it continues to advance.
- Today there are nearly 100 molecules in late-stage development.
- This progress would not be possible without the world's leading economies investing in health and rewarding innovation.

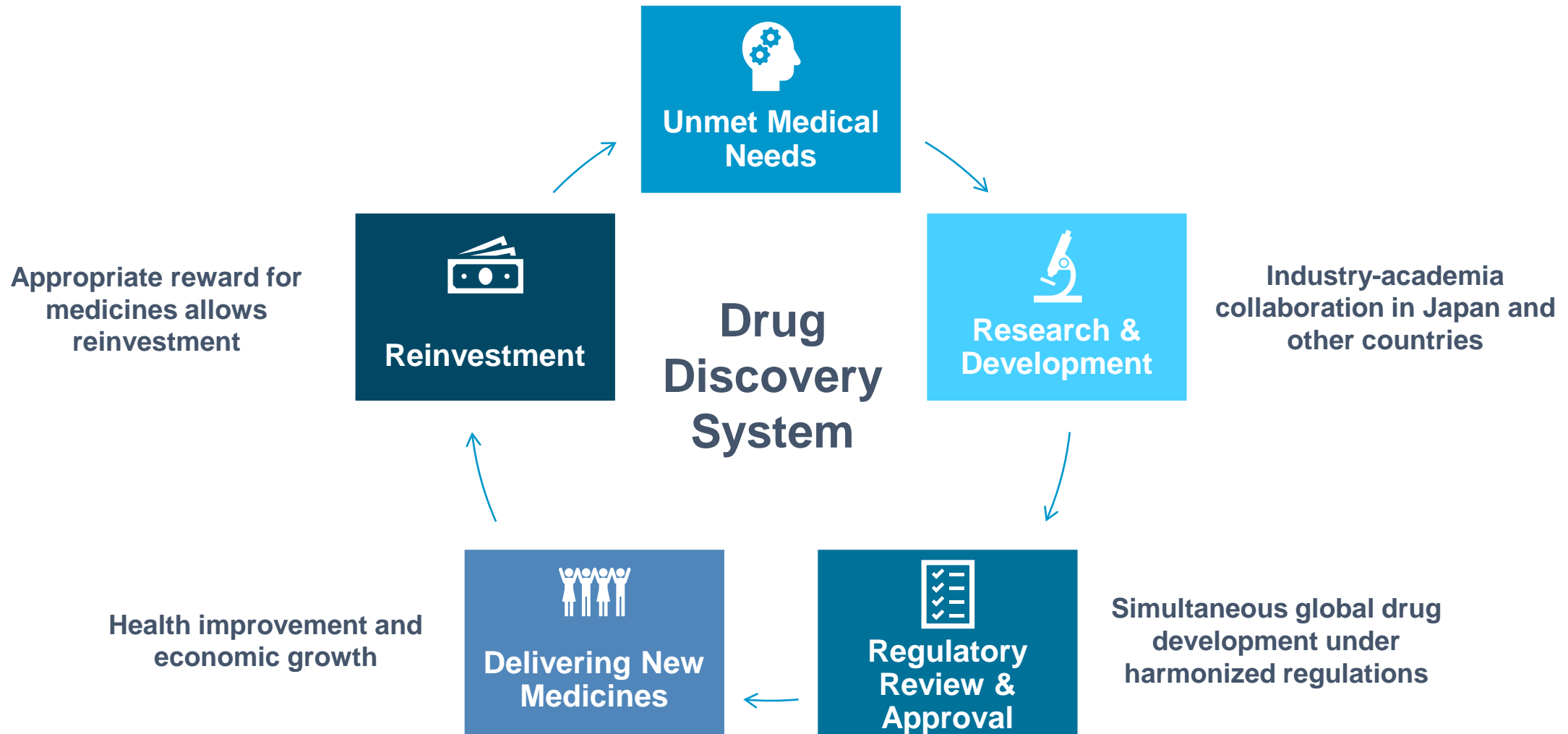


**74** drugs in phase 2



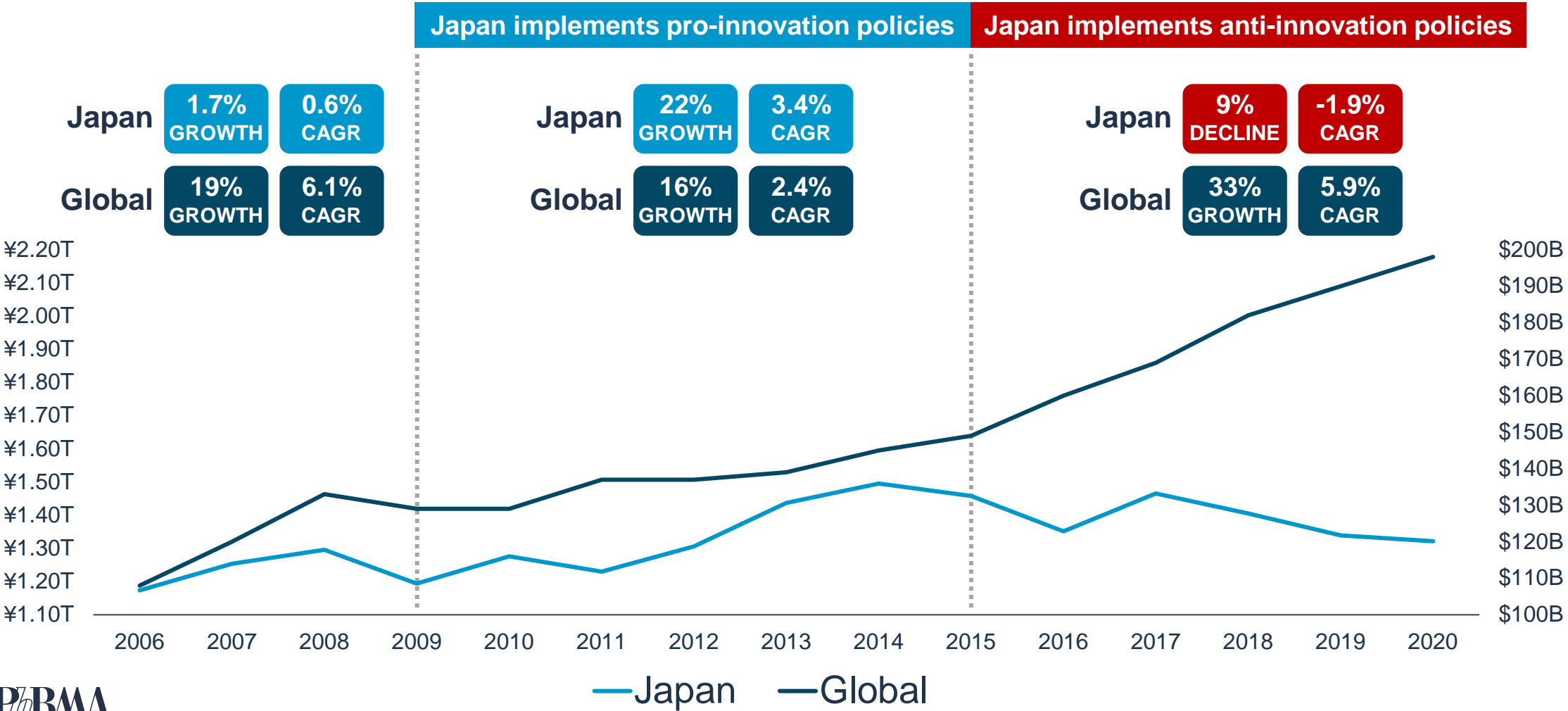
**28** drugs in phase 3

# Japan Needs to Enhance its Biopharmaceutical Innovation Ecosystem





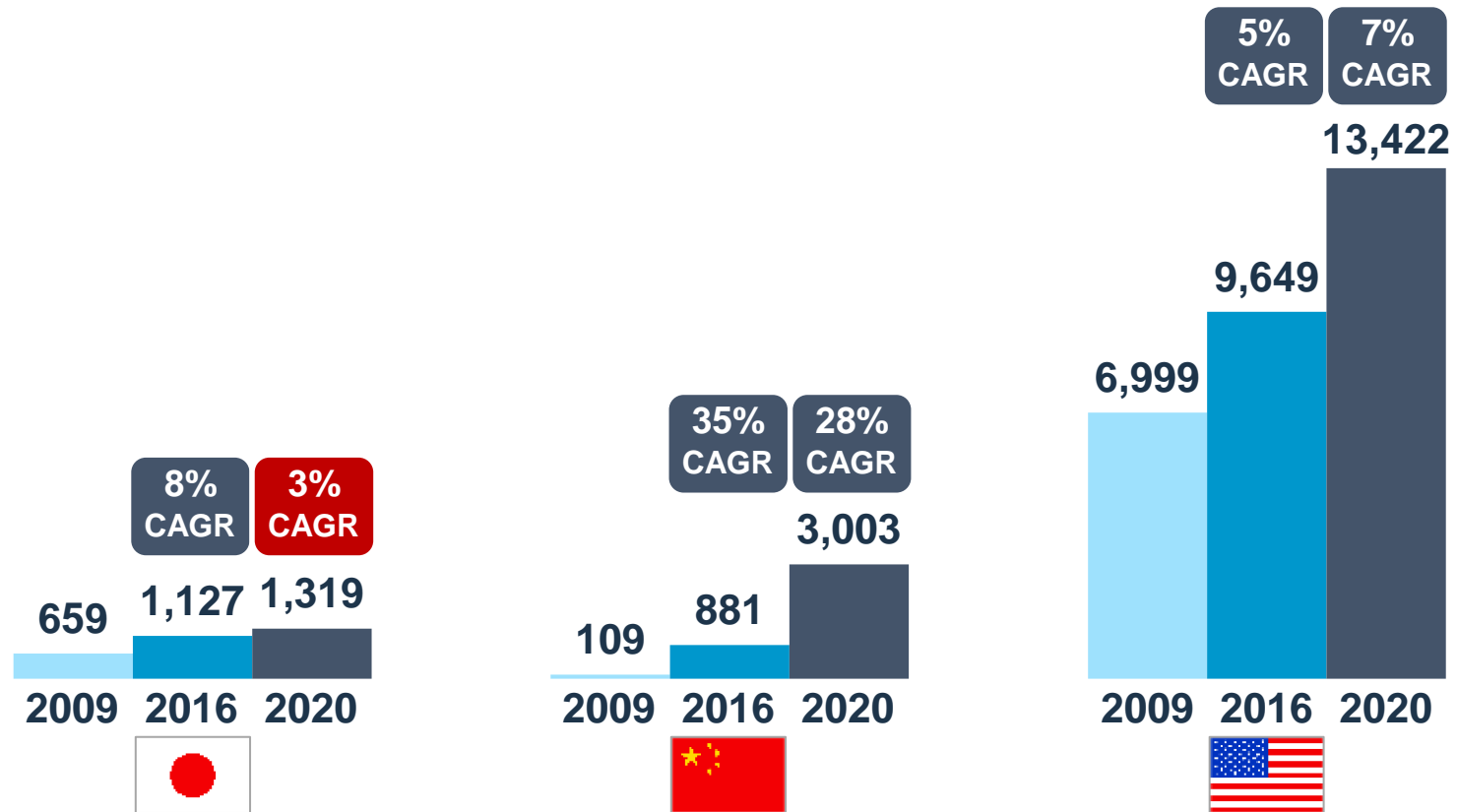
# Recent Policy Changes Have Negatively Impacted Biopharmaceutical Industry R&D Investment in Japan





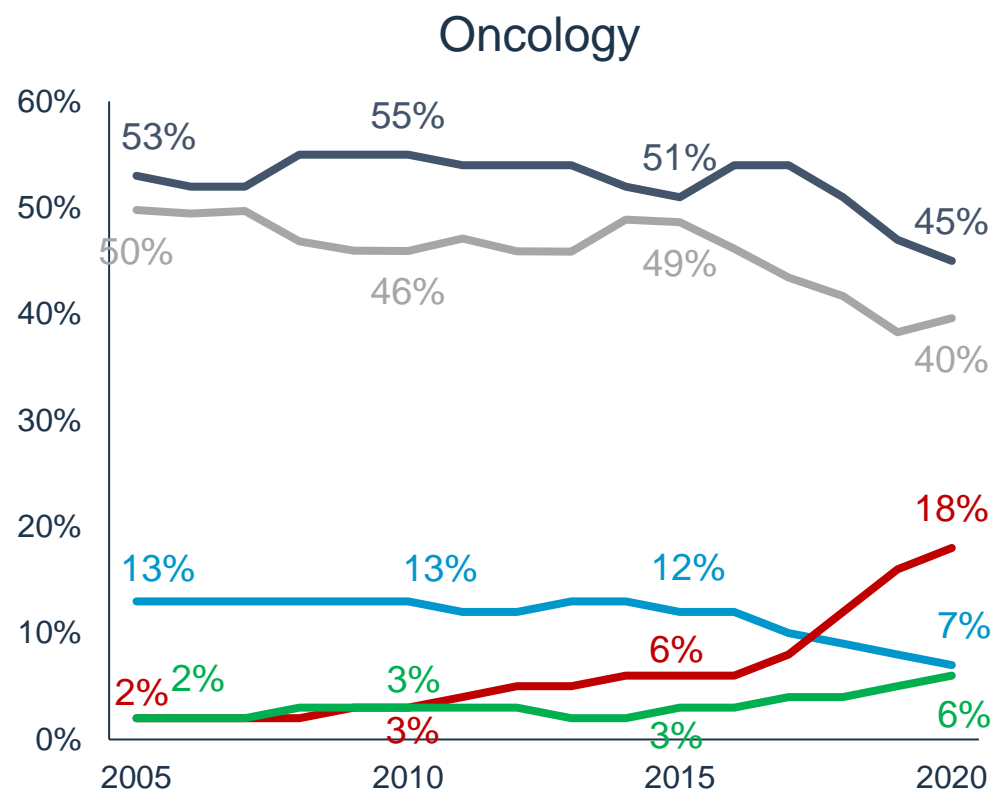
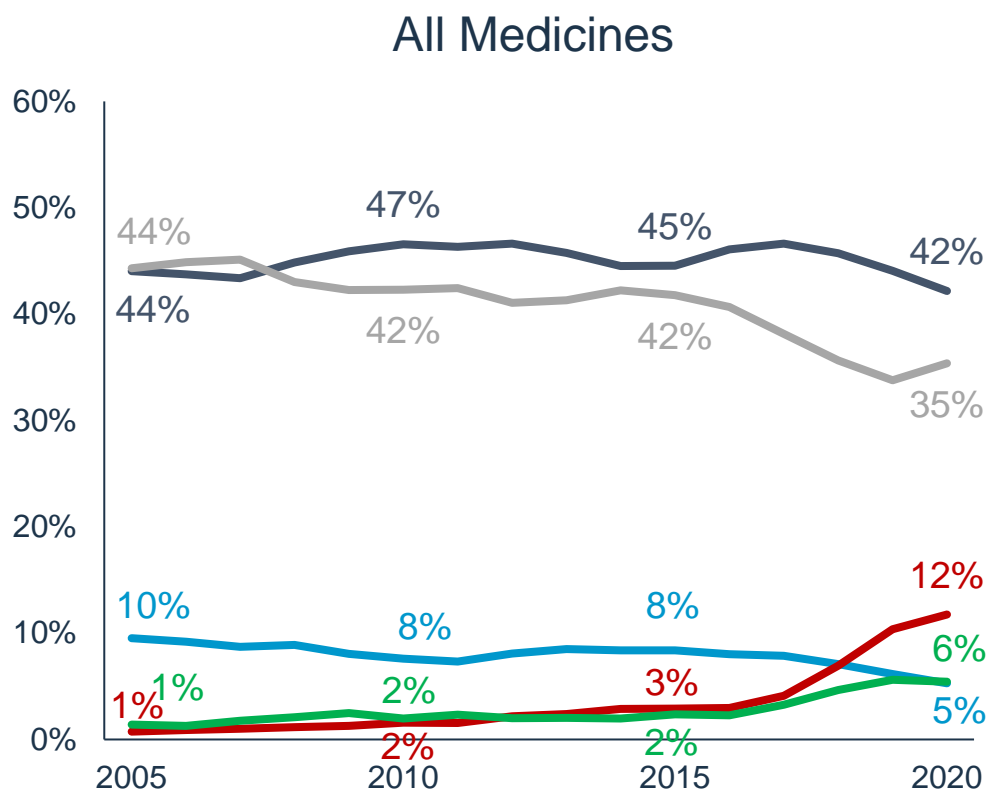
# Biopharmaceutical Clinical Trial Activity Has Slowed in Japan While Growing in the United States and China

Number of Medicines in Development Across All Clinical Trial Phases in Japan, China and the United States



# China Recently Surpassed Japan in Developing the Next Generation of New Medicines

Country Share of Early-Stage Pipeline Based on Company Headquarter Location, 2005-2020

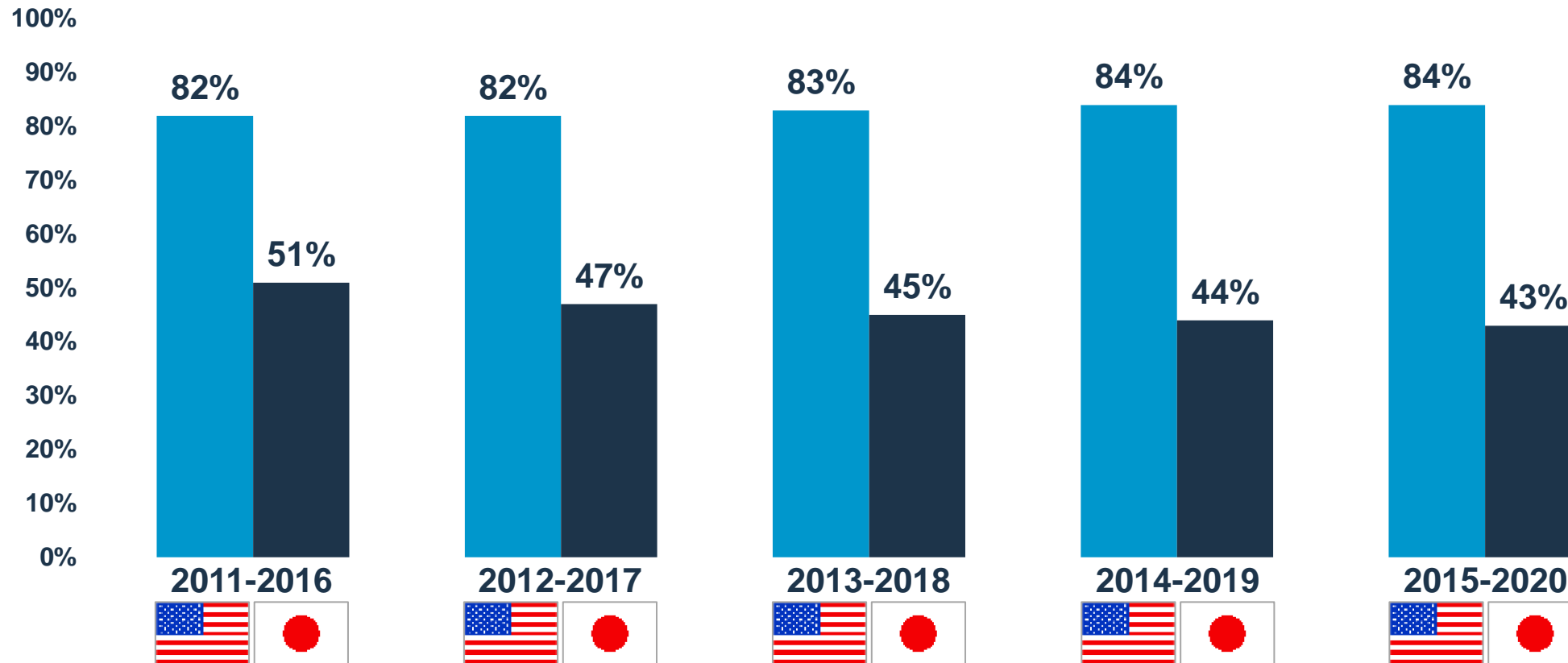


■ United States   
 ■ Japan   
 ■ China   
 ■ Korea   
 ■ All Other

# A Return of the Drug Lag?

The Speed With Which Global New Medicines Are Launched in Japan Has Steadily Declined Following Harmful Policy Changes

Percentage of Prior Five Years of Global New Medicines Available in Japan vs. the United States from 2016 to 2020



# Now Is the Time for Japanese Policymakers To Return To Prioritizing Innovation

**Our requests to help ensure that Japan remains at the forefront of global biopharmaceutical innovation**

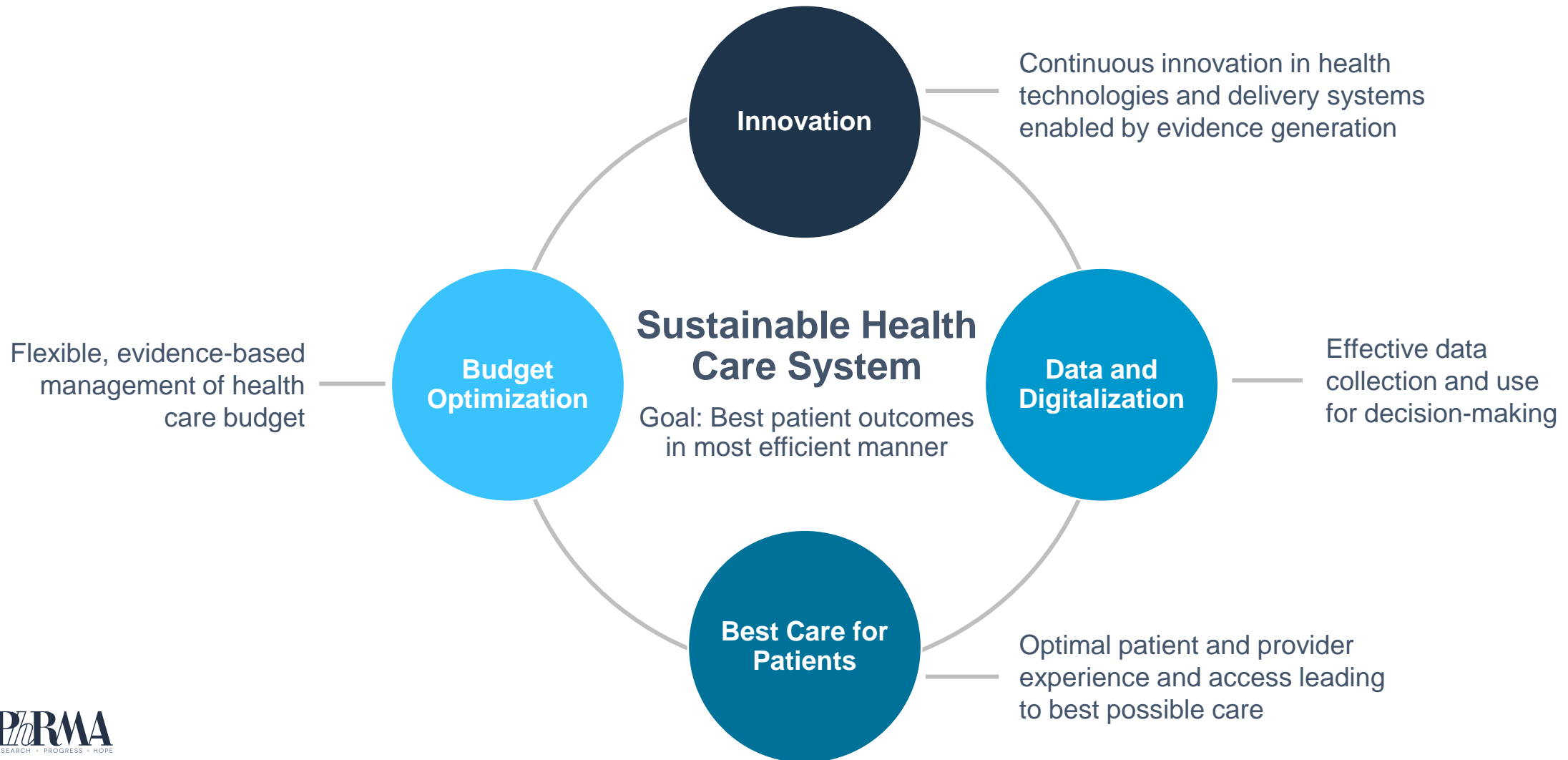
Ensure a transparent and predictable drug pricing system that rewards innovation

Improve expedited regulatory review systems and adopt new accelerated regulatory pathways

Incorporate digital technology and real-world data to enhance the speed, predictability and safety of drug development

Foster public-private collaboration through increased opportunities for dialogue on shared goals

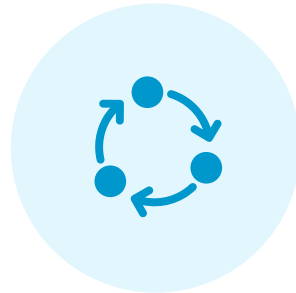
# An Innovation Ecosystem Should Serve as the Foundation for a Sustainable & Resilient Health Care System



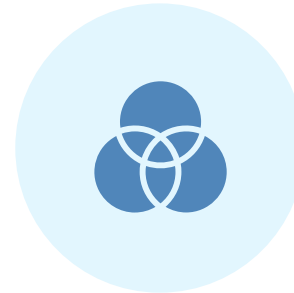
# The Biopharmaceutical Industry Is Ready To Do Our Part

## Coming Together To Tackle Common Goals

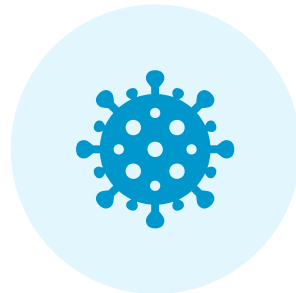
Supporting a thriving  
biopharmaceutical  
innovation ecosystem



Ensuring the sustainability  
and resiliency of the health  
care system



Enhancing pandemic  
preparedness



Promoting early access to  
needed medicines for  
Japanese patients

