



Research in Your Backyard: Japan

Contribution of PhRMA and EFPIA Member Companies to Japan's Society & Economy
Through Clinical Trials of Innovative Medicines

May 2014

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Introduction: Who We Are

We are devoted to advancing public policies that support innovative medical research, yield progress for patients today, and provide hope for the treatments and cures of tomorrow

Introduction

PhRMA Japan represents U.S. based pharmaceutical companies. Our activities vary from promoting healthcare system reform to providing medical information to patients

Mission

PhRMA Japan's mission is to promote the health of patients and contribute to the healthier lives of all people

PhRMA

Introduction

EFPIA Japan represents R&D-based European pharmaceutical companies. We focus on patient needs in Japan, engage in discussions with key stakeholders regarding public health, and work to improve the R&D environment for pharmaceutical companies

Mission

EFPIA Japan's mission is to enhance the health of Japanese patients by introducing innovative drugs and vaccines

EFPIA

PhRMA and EFPIA member companies

PhRMA member companies
AbbVie GK
Amgen Astellas BioPharma K.K.
Biogen Idec Japan Ltd.
Bristol-Myers K.K.
Celgene K.K.
Eli Lilly Japan K.K.
Janssen Pharmaceutical K.K.
MSD K.K.
Mundipharma K.K.
Pfizer Japan Inc.

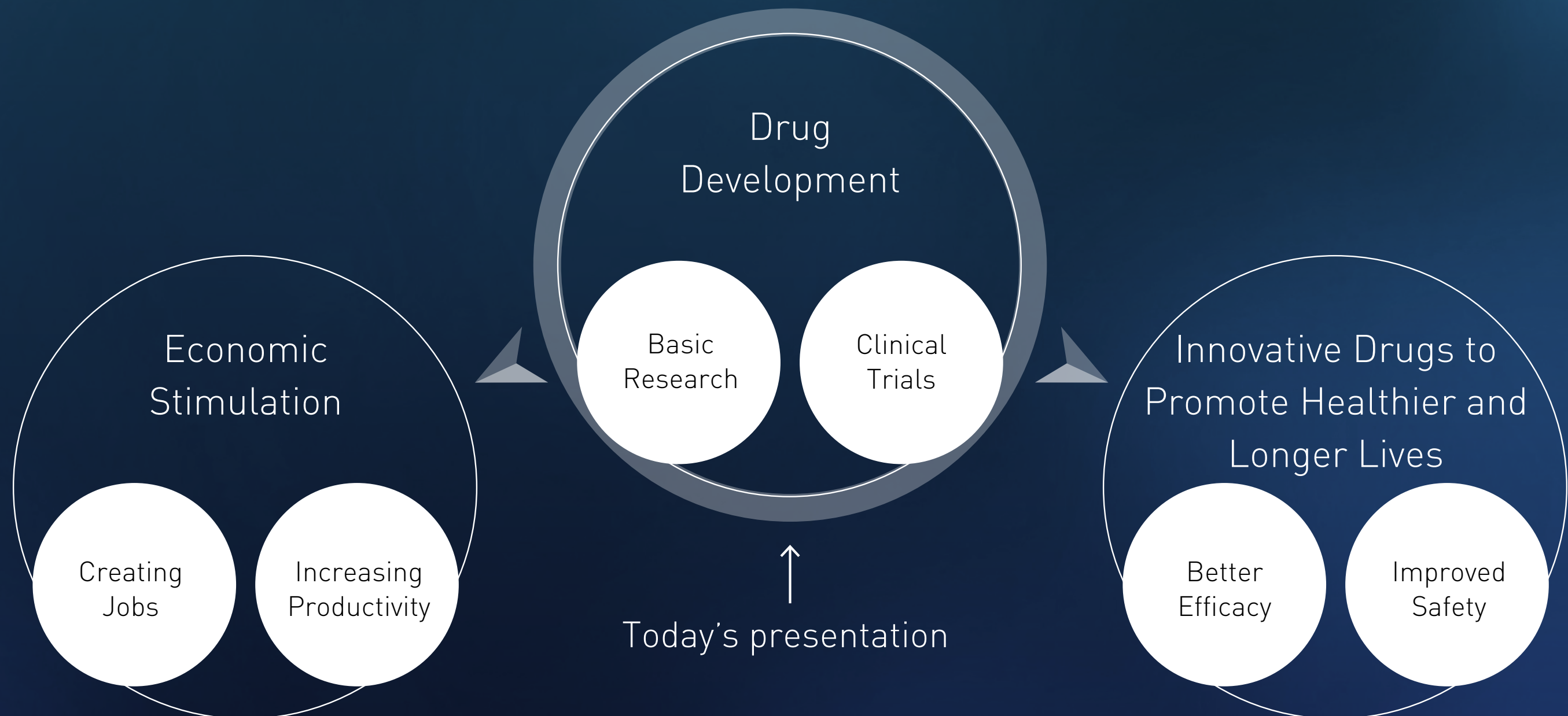
EFPIA member companies	
Abbott Japan Co.,Ltd.	Guerbet Japan K.K.
Actelion Pharmaceuticals Japan Ltd.	Janssen Pharmaceutical K.K.
AstraZeneca K.K.	LEO Pharma K.K.
Baxter Limited	Lundbeck Japan K. K.
Bayer Yakuhin, Ltd	Merck Serono Co.,Ltd.
Bracco-Eisai Co., Ltd.	Nihon Servier Co.,Ltd.
Chugai Pharmaceutical Co., Ltd.	Nippon Boehringer Ingelheim Co ., Ltd.
CSL Behring K.K.	Novartis Pharma K.K.
Ferring Pharmaceuticals Co., Ltd.	Novo Nordisk Pharma Ltd.
Galderma (Japan) K.K.	Sanofi K.K.
GE Healthcare Japan Corporation	Shire Japan K.K.
GlaxoSmithKline K.K.	UCB Japan Co. Ltd.

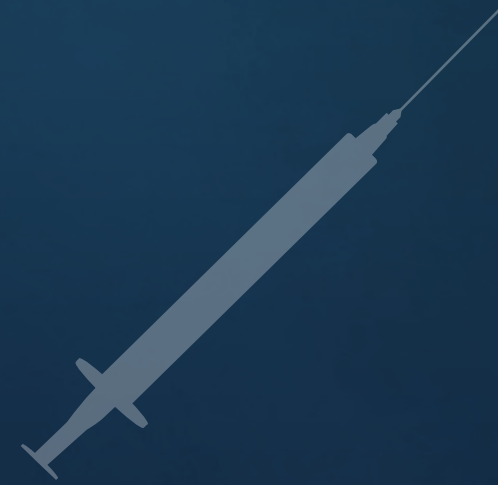


Pharmaceutical Industry and Society

Pharmaceutical companies contribute to the society and economy in multiple ways

Pharmaceutical companies collaborate with local clinics and hospitals to develop new drugs. This in turn provides economic stimulus and leads to innovative new medicines with better efficacy and safety profiles

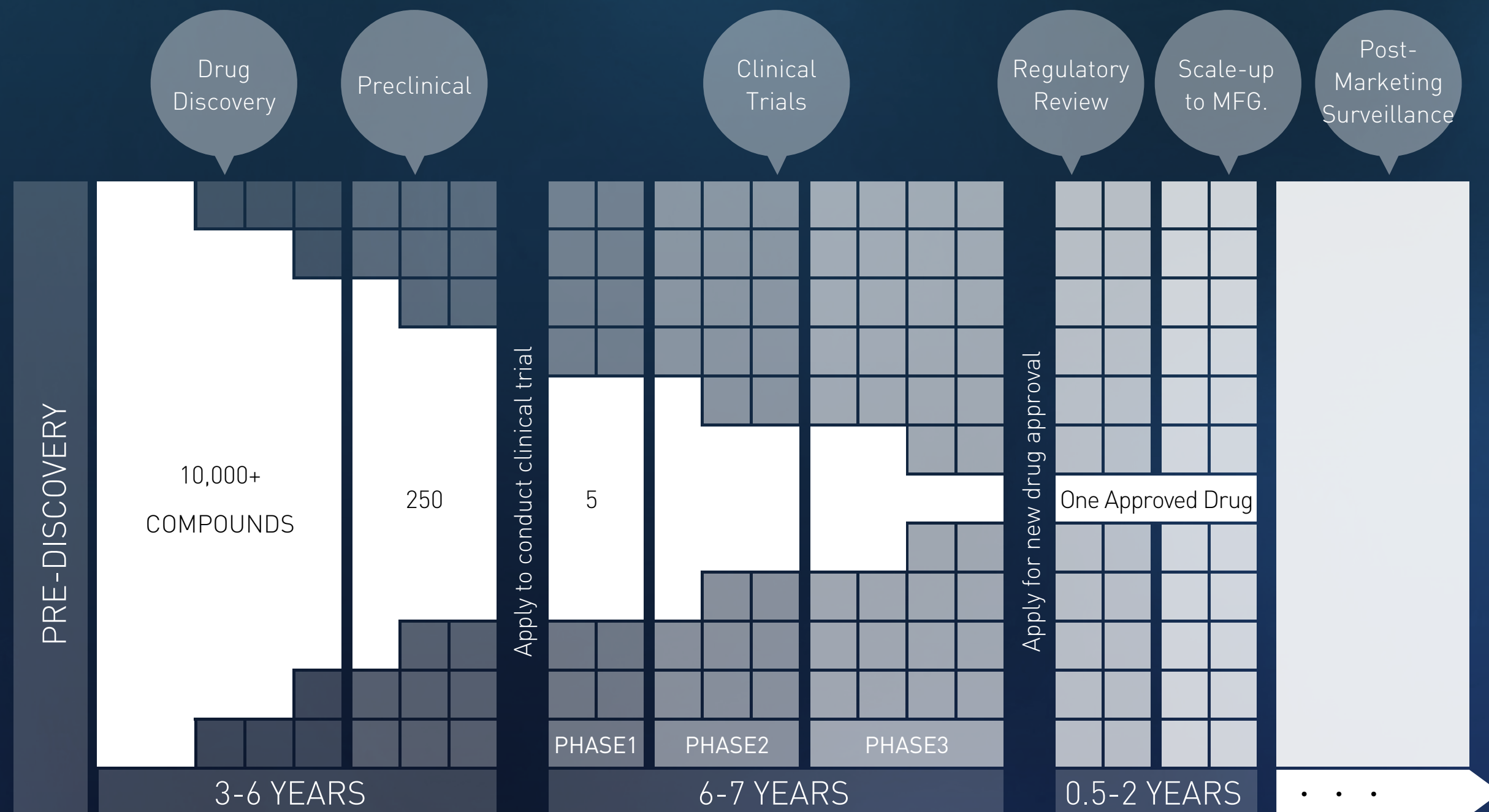




Collaborating on Clinical Trials

Discovering and developing new medicines is a long, complex, and costly process

Developing innovative drugs takes an average of 10-15 years and 1-1.5B USD. On average only one medicine is finally approved and launched for every 10,000 or more compounds initially discovered. Many promising compounds fail after pharmaceutical companies have spent substantial amounts of money on testing and clinical trials



Source: PhRMA

The majority of investment for the development of new drugs is used in conducting clinical trials

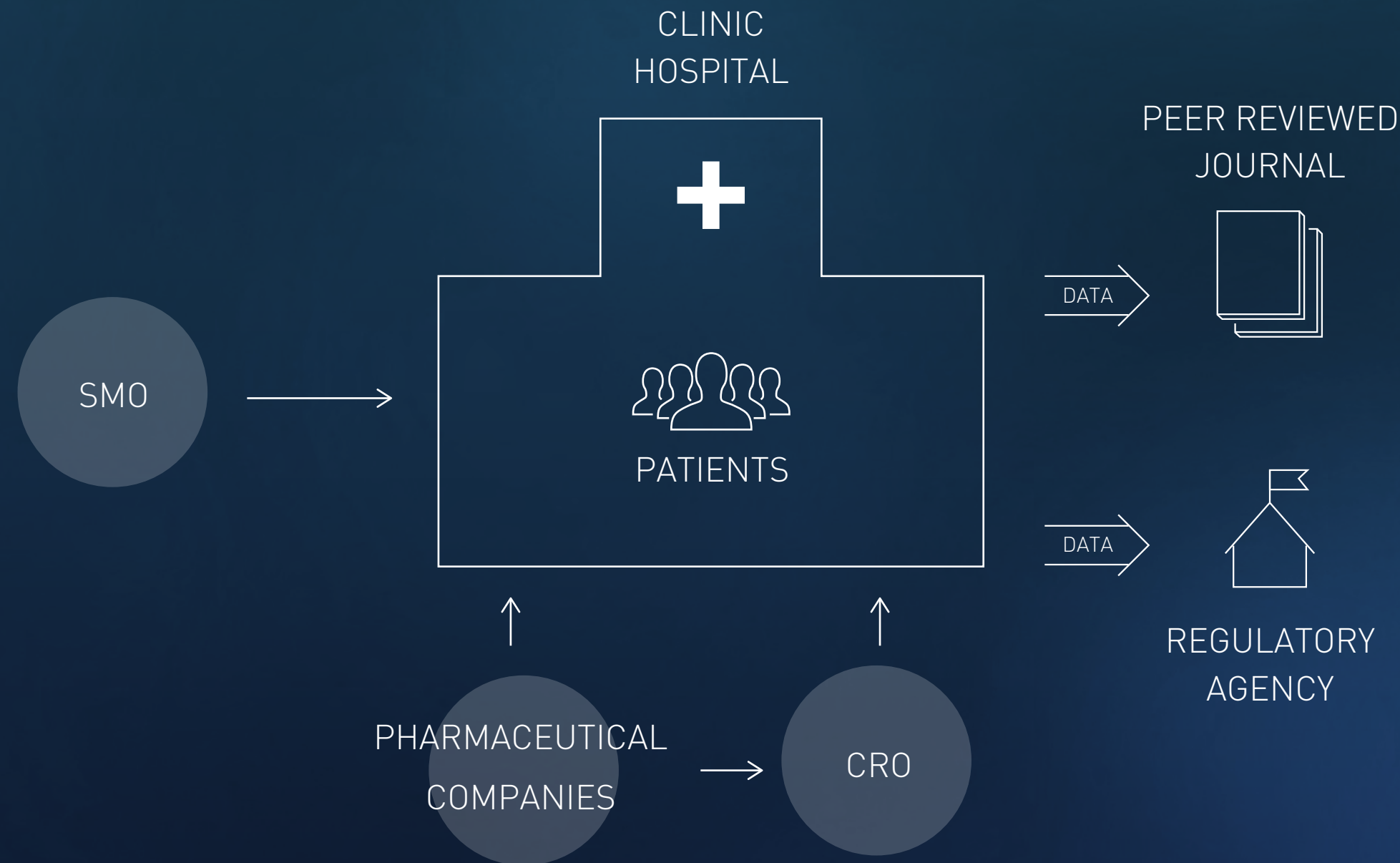
What is a clinical trial?

Computer simulations and animal testing are not enough to determine the efficacy and safety of new drugs for people. Clinical trials are conducted in five phases with the aim of clarifying the impact of experimental drugs on humans



Working with institutions in conducting and supporting clinical trials

Conducting clinical trials involves collaboration between pharmaceutical companies and other institutions, such as hospitals, local clinics, and contract research organizations (CRO)



Pharmaceutical Companies	CRO	Hospitals / Clinics	SMO (Site Management Organizations)
Decide to conduct clinical trials and requests support from CRO	Support pharmaceutical companies with the coordination of clinical trials	Conduct trials performed by physicians and trained research professionals	Provide additional support to hospitals and clinics during trials

Conducting clinical trials with local medical institutions benefits the hosting area

Conducting clinical trials for new drug development contributes to local economies
and improves the quality of life for local citizens

Providing advanced
treatment

Medical facilities conducting clinical trials are able to provide advanced medical treatments to their patients in these locales

Contributing to
local economy

The spending on clinical trials in Japan goes to hospitals and clinics nationwide and supports local economies

Creating jobs

Related stakeholders (local medical facilities and pharmaceutical companies) employ local staff to support clinical trials

PhRMA and EFPIA member companies conduct many clinical trials yearly across all prefectures of Japan

682

CLINICAL TRIALS*

11,653

SITES**

of clinical trial conducted



16+

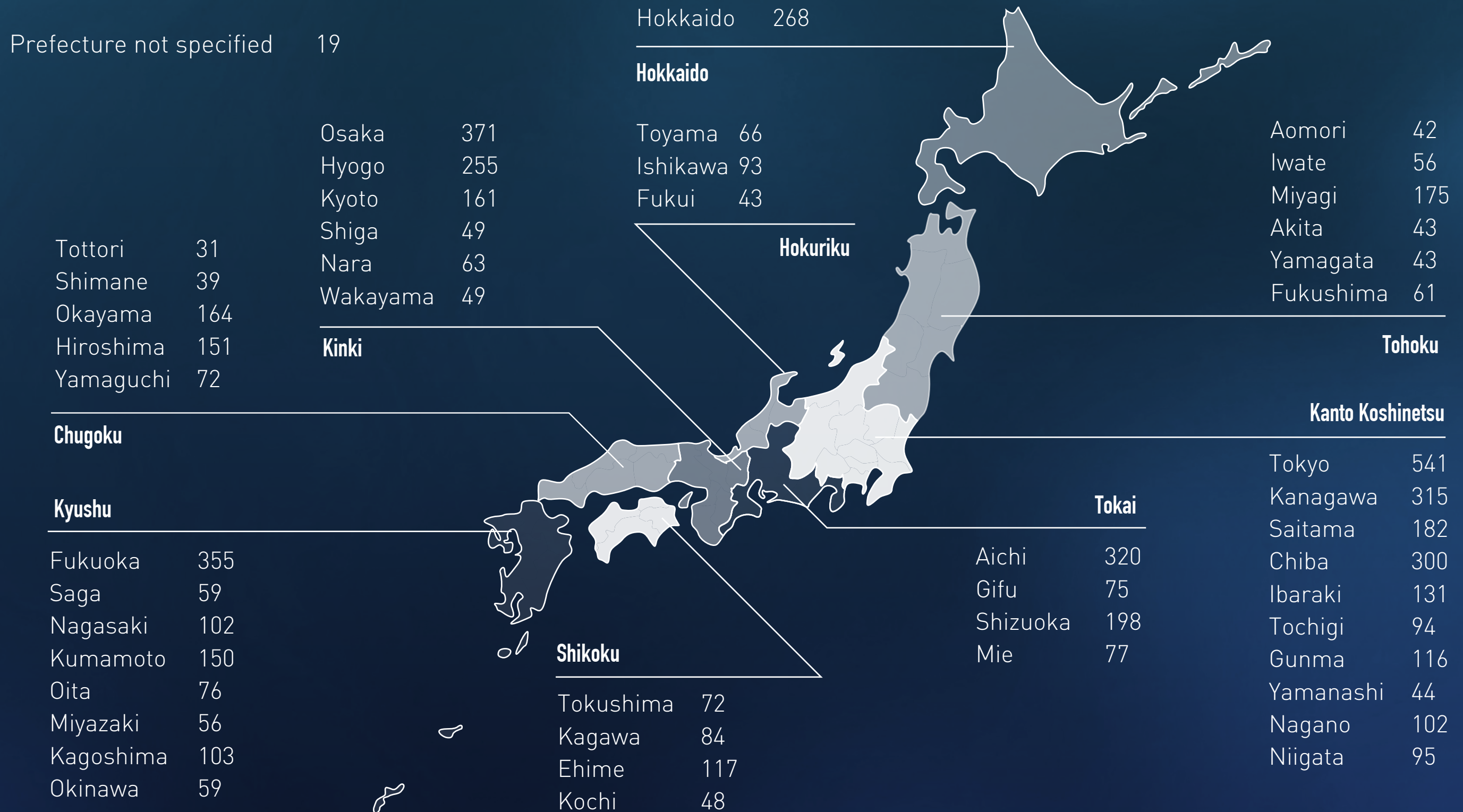
THERAPEUTIC AREAS

- Allergy
- Cardiology
- CNS
- Dermatology
- Endocrine Metabolic Disease
- Gastroenterology
- Hematology
- Immunology
- Infectious Disease
- Musculoskeletal Disease
- Oncology
- Ophthalmology
- Respiratory Disease
- Urology
- Rare Diseases
- Others

Source: www.clinicaltrial.gov (2013 data)

*Figures do not include post marketing surveillance **Individual sites participating in multiple trials are counted multiple times

How many of the 682 clinical trials conducted by PhRMA and EFPIA member companies in Japan are conducted in each prefecture?

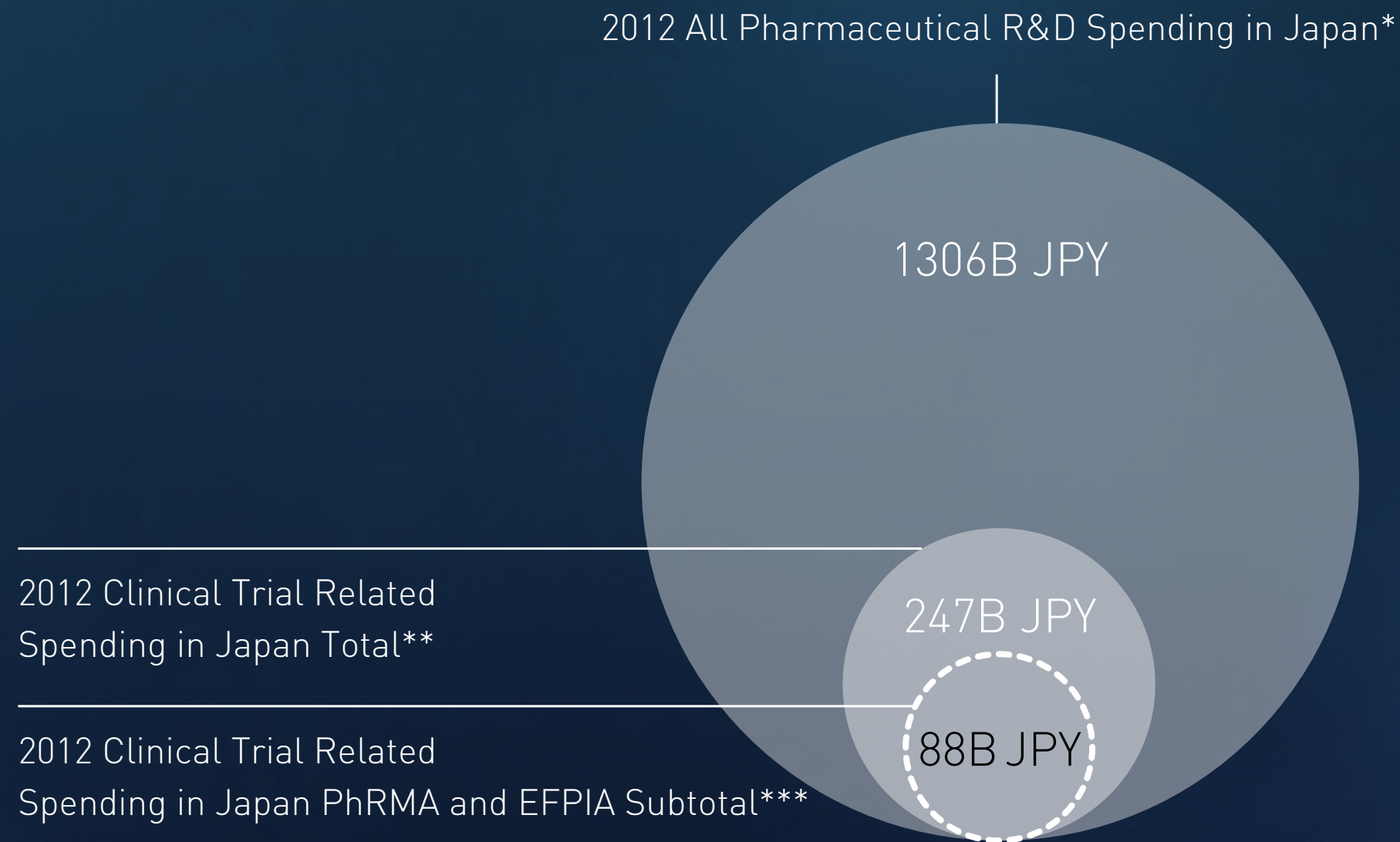


Source: www.clinicaltrial.gov (2013 data)



R&D Spending, Trends, and Results

PhRMA and EFPIA companies represent a significant share of the research and development spending in Japan



Source: JPMA data based on company disclosures for fiscal year 2012

*Report on the Survey of Research and Development 2013, Ministry of Internal Affairs and Communications ** 72 JPMA companies *** 19 PhRMA and EFPIA companies participating in JPMA
Note: The 1,306 billion yen figure includes all pharmaceutical R&D expenditures made during fiscal year 2012 by all companies in Japan. The 247 billion yen and 88 billion yen figures refer only to clinical research related spending during fiscal year 2012 disclosed by JPMA member companies

To deliver innovative drugs in a timely manner, PhRMA and EFPIA members are increasing simultaneous global development including Japan to reduce “drug lag” *

The trend to perform global development simultaneously has been increasing
in countries around the world including Japan

Trends in Global Simultaneous Development
for PhRMA / EFPIA Companies



● Number of Global Simultaneous Development Clinical Trials Including Japan

Source: PhRMA research

Number of phase 3 clinical trials under development conducted by PhRMA / EFPIA companies (The study had a total of 19 companies – 10 of which are PhRMA / EFPIA related)

* “Drug lag” refers to the delay to approve a new drug such as cases in Japan where approval is delayed compared to other countries, such as the U.S. and Europe.

Conducting more global simultaneous clinical trials shortens the drug lag

PhRMA and EFPIA member companies obtained approval for 132 new drugs* in Japan over the last 7 years

Number of Drugs Approved in Japan



● Japan Total

● PhRMA and EFPIA Companies

Source: PMDA web site

*New drugs refer to New Molecular Entities only approved between April 2007 and February 2014 (Other approvals, such as new indications, are excluded).

Besides the approvals obtained by PhRMA and EFPIA companies, other approvals include products licensed from global companies

What are Therapeutic Areas?

Therapeutic areas are general categories of illnesses, such as the examples below

Therapeutic Area	Example
Allergy	Allergic rhinitis, Asthma, Atopic dermatitis, etc.
Infectious disease	Influenza, Hepatitis C/B, Herpes, etc.
Hematology	Anemia, Hemophilia, etc.
Respiratory disease	COPD, Bronchiectasis, etc.
Oncology	Gastric cancer, Lung cancer, Breast cancer, etc.
Cardiology	Heart failure, Brain ischemia, Hypertension, etc.
Gastroenterology	Gastric ulcer, Reflux esophagitis, etc.
CNS	Alzheimer's disease, Depression, Epilepsy, etc.
Urology	Nocturia, Lupus nephritis, etc.
Dermatology	Acne, etc.
Ophthalmology	Age-related macular degeneration, Uveitis, etc.
Immunology	Rheumatoid arthritis, Crohn's disease, Psoriasis, etc.
Musculoskeletal disease	Osteoporosis, Lower back pain, etc.
Endocrine metabolic disease	Diabetes mellitus, Hypercholesterolemia, Hyperphosphatemia, etc.
Rare disease	Gaucher disease, Myelofibrosis, Behcet's disease, etc.



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