AMED's Activities to Develop Infrastructure for Promoting Medical Research and Development

APAC DA session : Establishment of Drug Discovery Ecosystem in Asia

April 10, 2020

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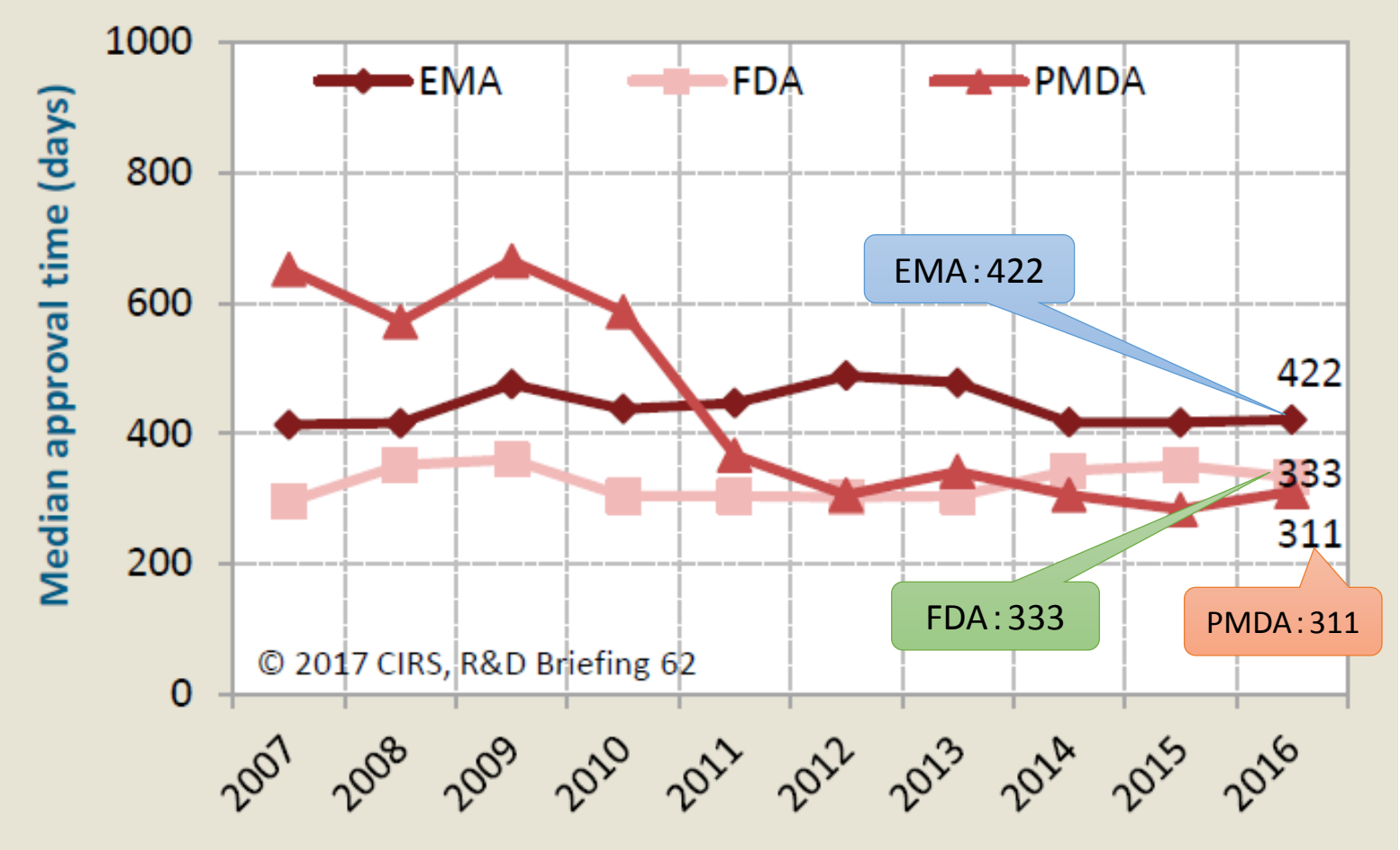
Japan Agency for Medical Research and Development (AMED)

1. About AMED

2. Public – Private Partnership (PPP)

2007-2016年における新有効成分の審査期間（中央値）の比較

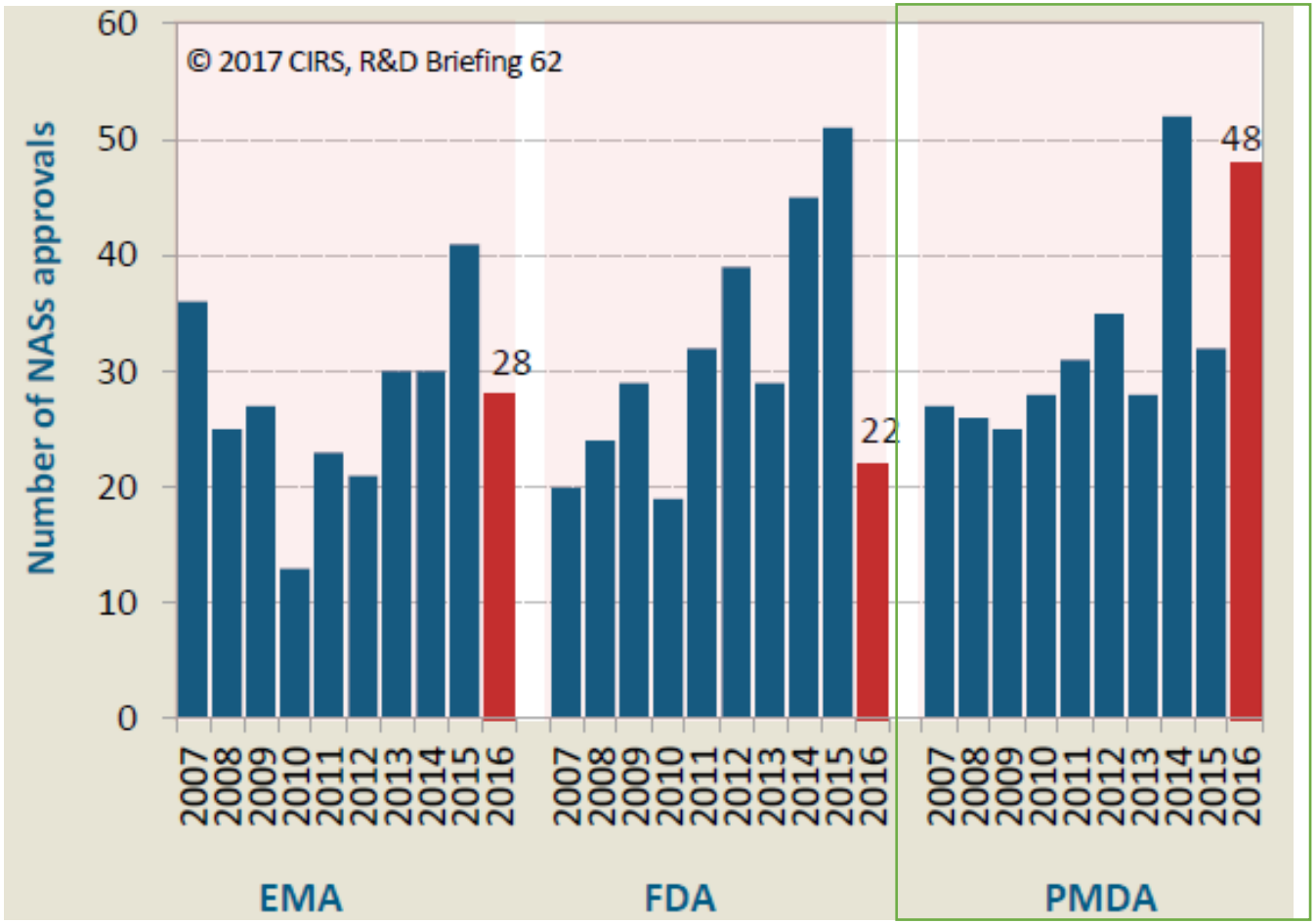
Median approval time for NASs approved by ICH agencies by approval year 2007-2016



FDA and PMDA NAS median approval times converged in 2007-2016, with PMDA the fastest of the three agencies for a third year in a row

新有効成分の承認品目数の比較（2007-2016）

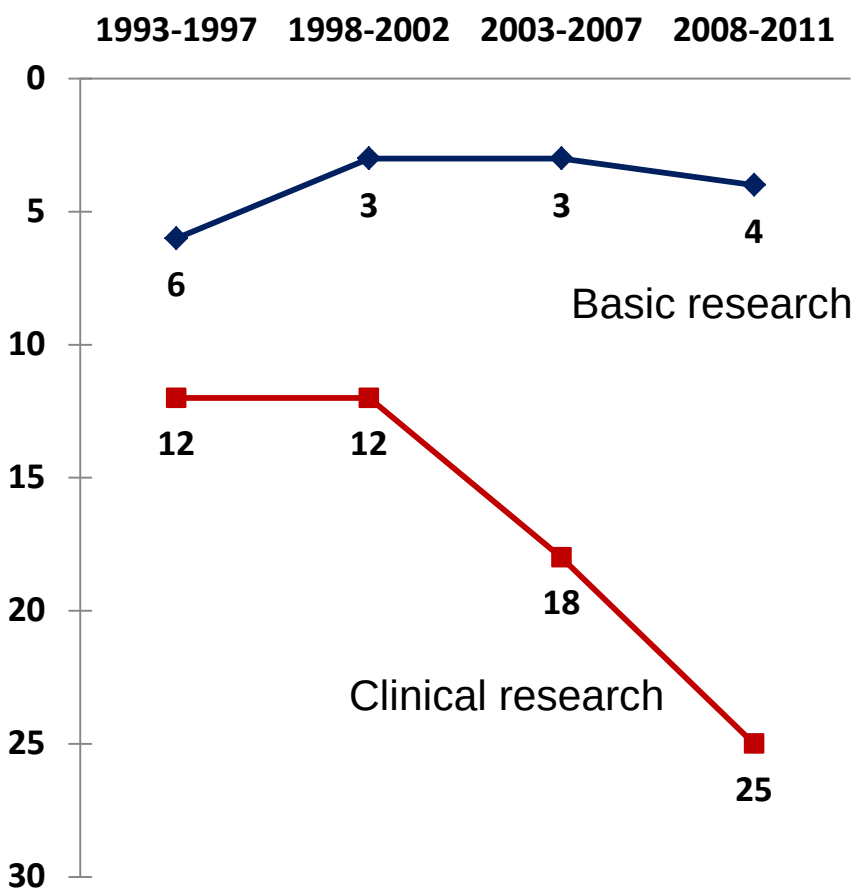
Number of NASs approved by ICH agencies by approval year by approval year 2007-2016



In 2016, PMDA approved the greatest number of NASs (48) of the three ICH agencies , approximately double the NASs compared with EMA (28) and FDA (22).

Centre for Innovation in Regulatory Science (CIRS) , April 2017, R&D Briefing 62

International ranking on major basic and clinical research papers



2003～2007			2008～2011		
rank	country	number	rank	country	number
1	USA	2,674	1	USA	2,011
2	Germany	442	2	Germany	386
3	Japan	369	3	England	284
4	England	314	4	Japan	266
5	France	269	5	France	230

＜No. of major clinical research paper＞

2003～20071			2008～2011		
rank	country	number	rank	country	number
1	USA	2,677	1	USA	2,105
2	England	873	2	England	685
15	China	102	16	China	97
18	Japan	74	18	India	88
25	India	47	25	Japan	55

（Resource）
Ministry of Health and Welfare prepared material

About AMED

国立研究開発法人 日本医療研究開発機構
Japan Agency for Medical Research and Development

President
Makoto Suematsu, MD, PhD

- Founded on April 1st, 2015

<Background>

  - Japan Revitalization Strategy (June, 2013)
  - The Healthcare Policy (May, 2014)
    - Headquarters for Healthcare Policy
    - The Plan for Promotion of Medical Research and Development (July, 2014)

- The core institute to support and conduct Medical R&D and improve Research Environment in Japan

Purpose of Establishment of AMED, Agency Activities

Purpose of establishment

Purpose

Promote medical R&D and improve the environment for such R&D and implement subsidy activities based on "the Plan for Promotion of Medical R&D" for the purpose of integrated promotion of medical R&D from basic research to practical application, smooth application of outcomes, and improvement of the environment for medical R&D in a comprehensive and effective manner.

Date of establishment

April 1, 2015

Agency activities

[1] Promotion of medical R&D and improvement of environment

e.g. Support for and preparation of research equipment necessary to perform researches of regenerative medicine using iPS cells in Kyoto University as a contract project

[2] Dissemination of outcomes of activities described in [1] and promotion of use of the outcomes

e.g. Promote application development by introducing the outcomes of basic researches in drug development to pharmaceutical companies.

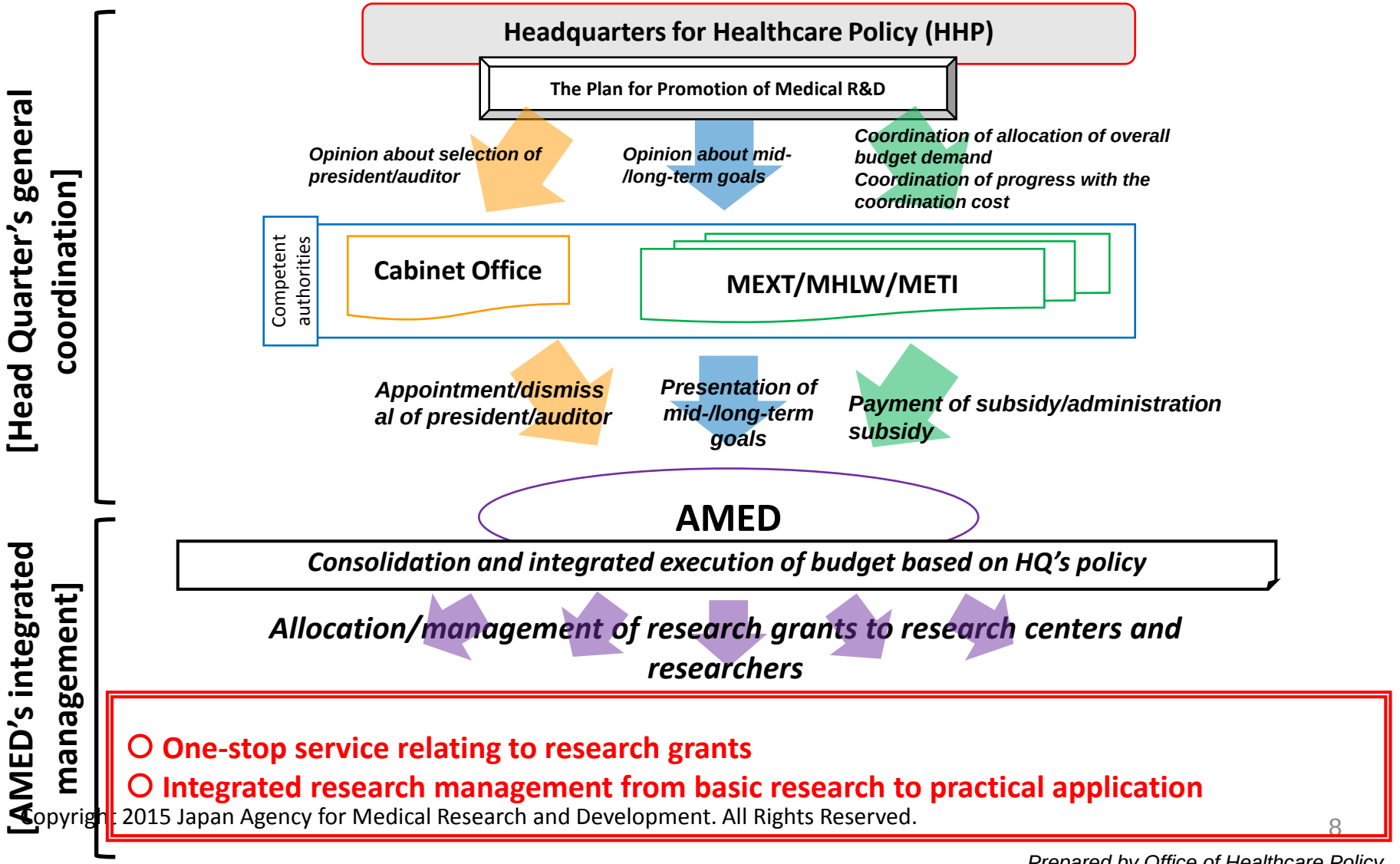
[3] Subsidy for medical R&D and improvement of environment for healthcare R&D

e.g. Subsidy for the development of biopharmaceutical manufacturing technologies, subsidy for the maintenance of the system for performing clinical researches

[4] Services incidental to the activities described in [1] to [3]

e.g. Survey about the trend of R&D/technology development inside and outside Japan, publication of research outcomes, international cooperation through research

New System for Promotion of Medical R&D



Prepared by Office of Healthcare Policy

AMED Budget（FY2018）

	FY2018	FY2017	±
Total amount ［adjusting cost］	126.6 bil. yen ［17.5 bil yen］	126.5 bil. yen ［17.5 bil yen］	+ 0.1 bil. yen ［0］

① Project for Drug Discovery and Development	20.9 bil. yen
② Project for Medical Device Development	12.9 bil. yen
③ Project for Japan TR and CR Core Centers	8.6 bil. yen
④ Japan Regenerative Medicine Project	15.7 bil. yen
⑤ Japan Genomic Medicine Project	10.4 bil. yen
⑥ Japan Cancer Research Project	16.0 bil. yen
⑦ Project for Psychiatric and Neurological Disorders	7.1 bil. yen
⑧ Emerging / Re-emerging Infectious Disease Project of Japan	7.0 bil. yen
⑨ Rare / Intractable Disease Project of Japan	12.4 bil. yen

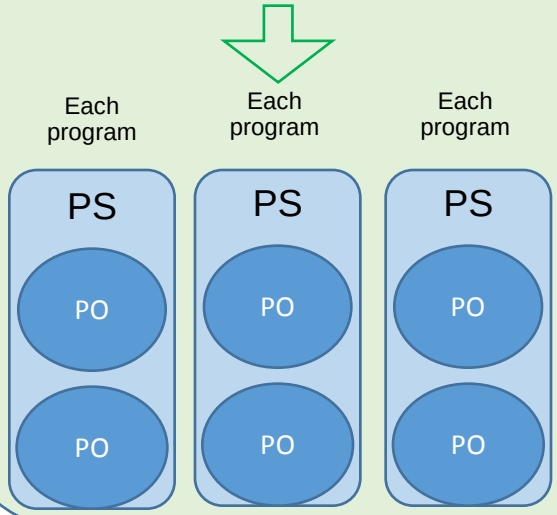
AMED's Program Management System

The program management system is established under the supervision of Program Director (PD) in each of the nine collaboration areas. PD is appointed by the president with input from the competent ministry for the program in the collaboration area.

Program Management System in each collaboration area

PD (Program Director)

- Decides the management policy for the collaboration area (within the range of the subsidy guideline).
- Coordinates the policy and decision for the allocation of funds to each program.
- Inter-PS coordination



Program management system

Program Supervisor (PS) in charge of management of individual programs is assigned under PD and engaged in program management in collaboration with Program Officers (PO).

Roles of PS

PS is engaged in the management of programs based on the understanding of the purpose and themes of the program PS is in charge of.

Roles of PO

PO executes practical operations for the management of programs as an assistant for PS.

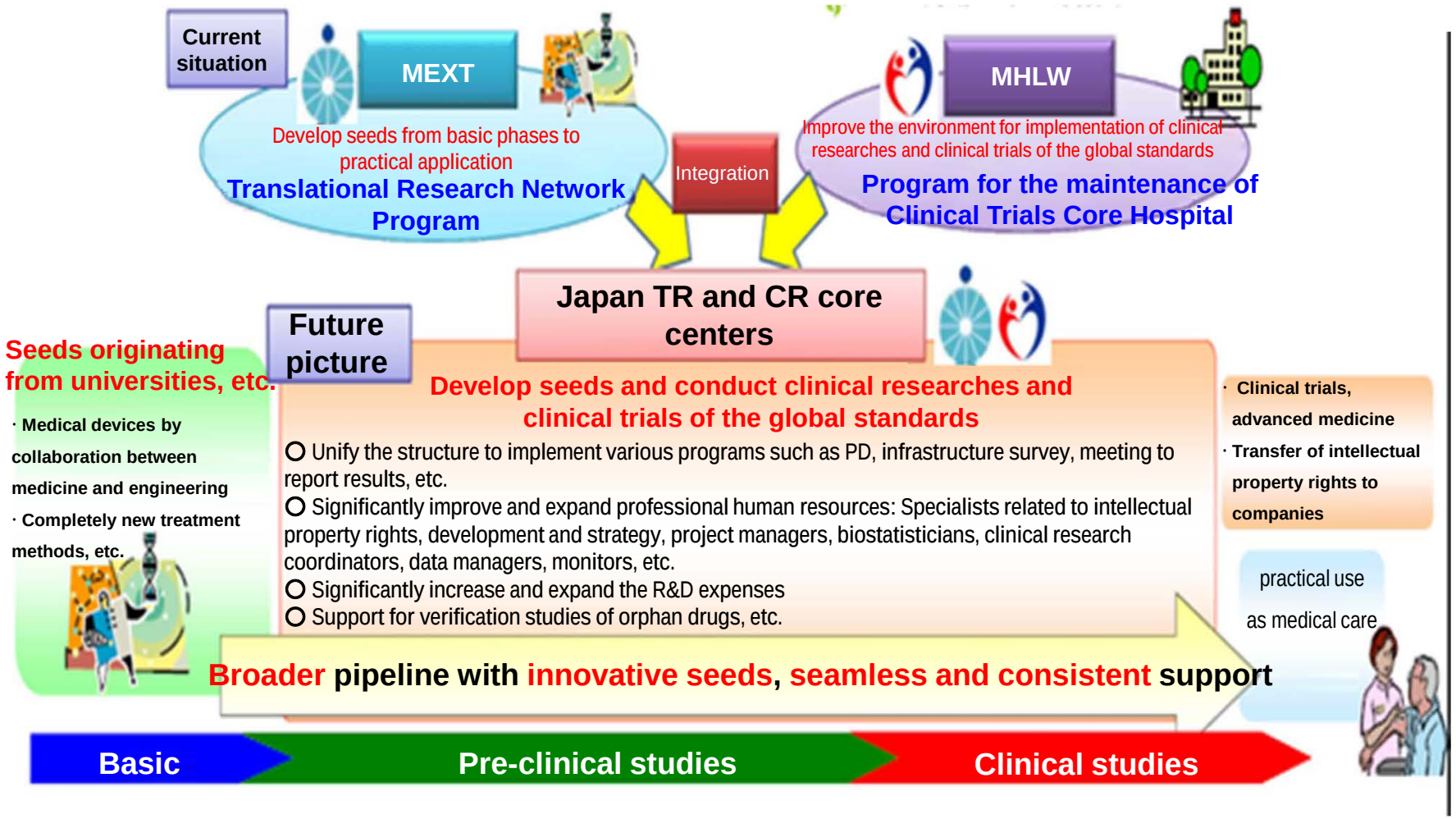
Strengthening the AMED/PMDA Partnership

- To accelerate the creation of innovative medical products
  - ➡ Utilizing AMED/PMDA' s knowledge and experience mutually in operation of each tasks

- ✓ Connecting project adoption by AMED with Pharmaceutical Affairs Consultation on R&D Strategy by PMDA
- ✓ Cooperation of PMDA in project evaluation by AMED
- ✓ Support by PMDA for activities by AMED to improve the clinical research/trial infrastructure (e.g. dispatch of lecturers to training courses)

- ✓ Information sharing (e.g. AMED; medical R&D trends, state of projects, PMDA; trend of the regulation on medical products, state of the Consultation and clinical trials)

Project for Japan TR and CR core centers



Project for Japan TR and CR core centers

Promote to integrate the Support Centers for Translational Researches(TR) and Clinical Trials Core Hospitals(CR) in order to build a system that leads the results of basic researches at universities, etc. to practical application in a consistent manner.

Also, further promote to reinforce the functions of the center including the securing and development of human resources, networking, expansion of seeds, etc.

In addition, conduct high-quality clinical researches and clinical trials according to the ICH-GCP and improve the structure to support multicenter researches by making use of the functions of ARO.

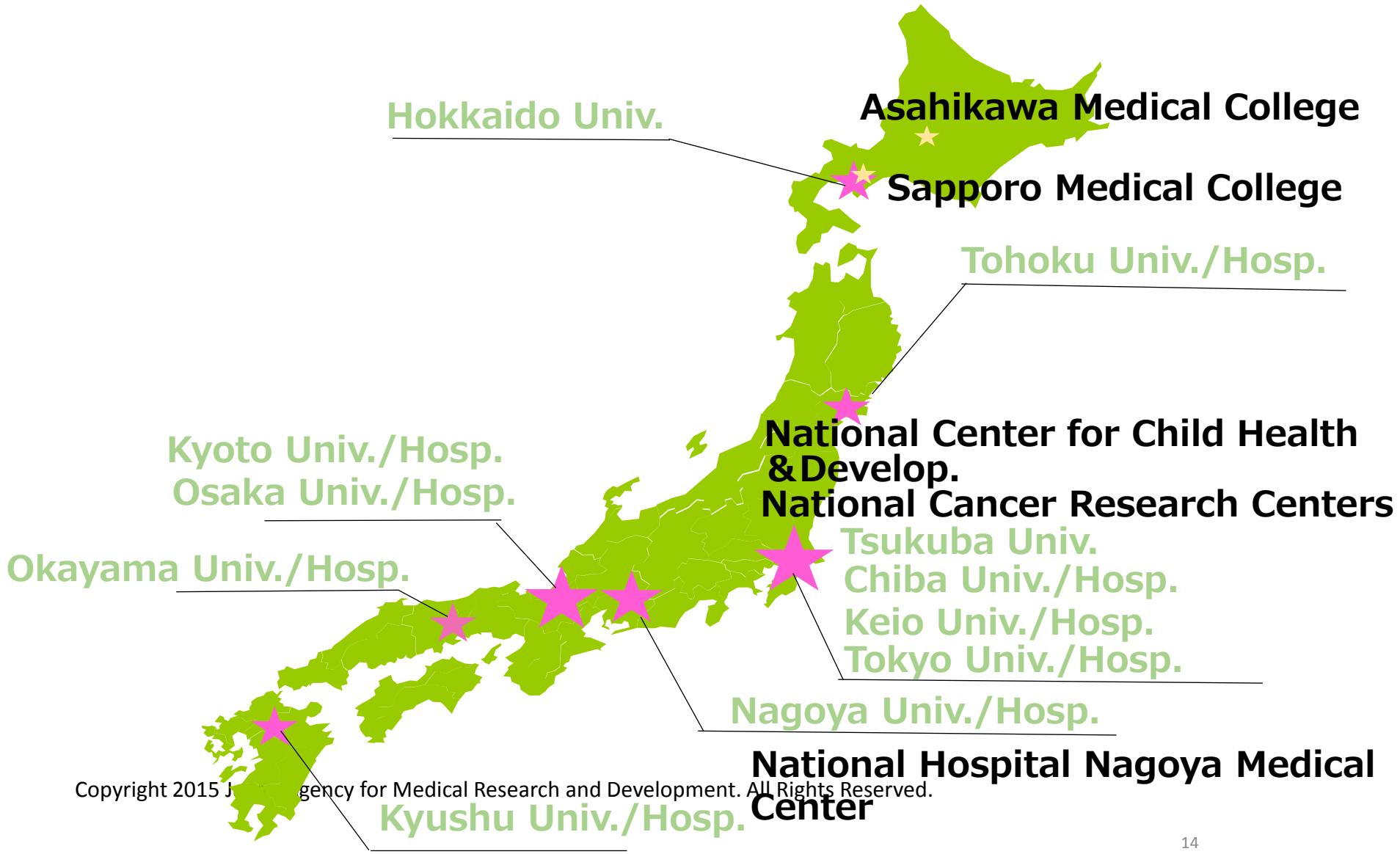
[Targets of achievement by FY2015]

○ No. of notifications of investigator-initiated clinical trials: 21 trials per year
○First in Human (FIH) studies (including sponsor-initiated clinical trials): 26 trials per year

[Targets of achievements by FY2020]

○ No. of notifications of investigator-initiated clinical trials: 40 trials per year
○First in Human (FIH) studies (including sponsor-initiated clinical trials): 40 trials per year

Japan TR and CR core centers



1. About AMED

2. Public – Private Partnership (PPP)

Case 1 (PPP)

From Personalization Medicine to Precision Medicine

- US President HE Obama's initiative (2015/01/20)
- 215Million US$
- Researches especially for Cancer and Orphan diseases related to Genomic Information, environment, and lifestyle etc.

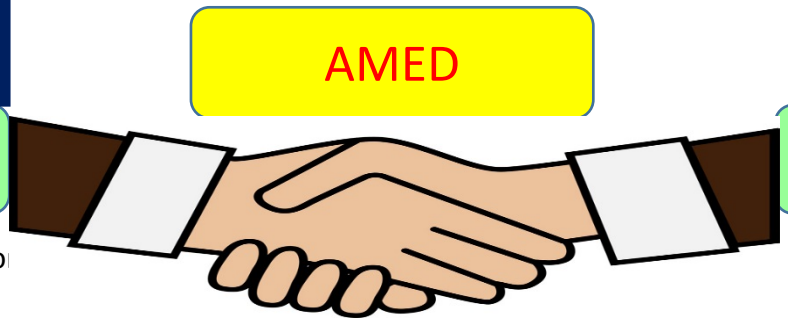
- Diversity of drug R&D
  Various modalities → protein, cell, nucleic acid, regenerative medicine, with companion IVD etc.

- Designation of disease (vs) drug R&D

- Procedure of evaluation for innovative drug

US AMP; Accelerating Medicines Partnership
EU IMI; The Innovative Medicines Initiative

GAPFREE
～ 産学官の垣根をなくす ～



Basic concepts of GAPFREE

To fill the "gap" among G (Government), A (Academia) and P (Private/Pharma companies) and to facilitate drug discovery to meet unmet medical needs

<Solutions>

◎ Adjusting the wish from P and the proposal from A by "matching scheme" supported by G(AMED) before application.

◎ Participation of P in planning of the study design including clinical resource collection.

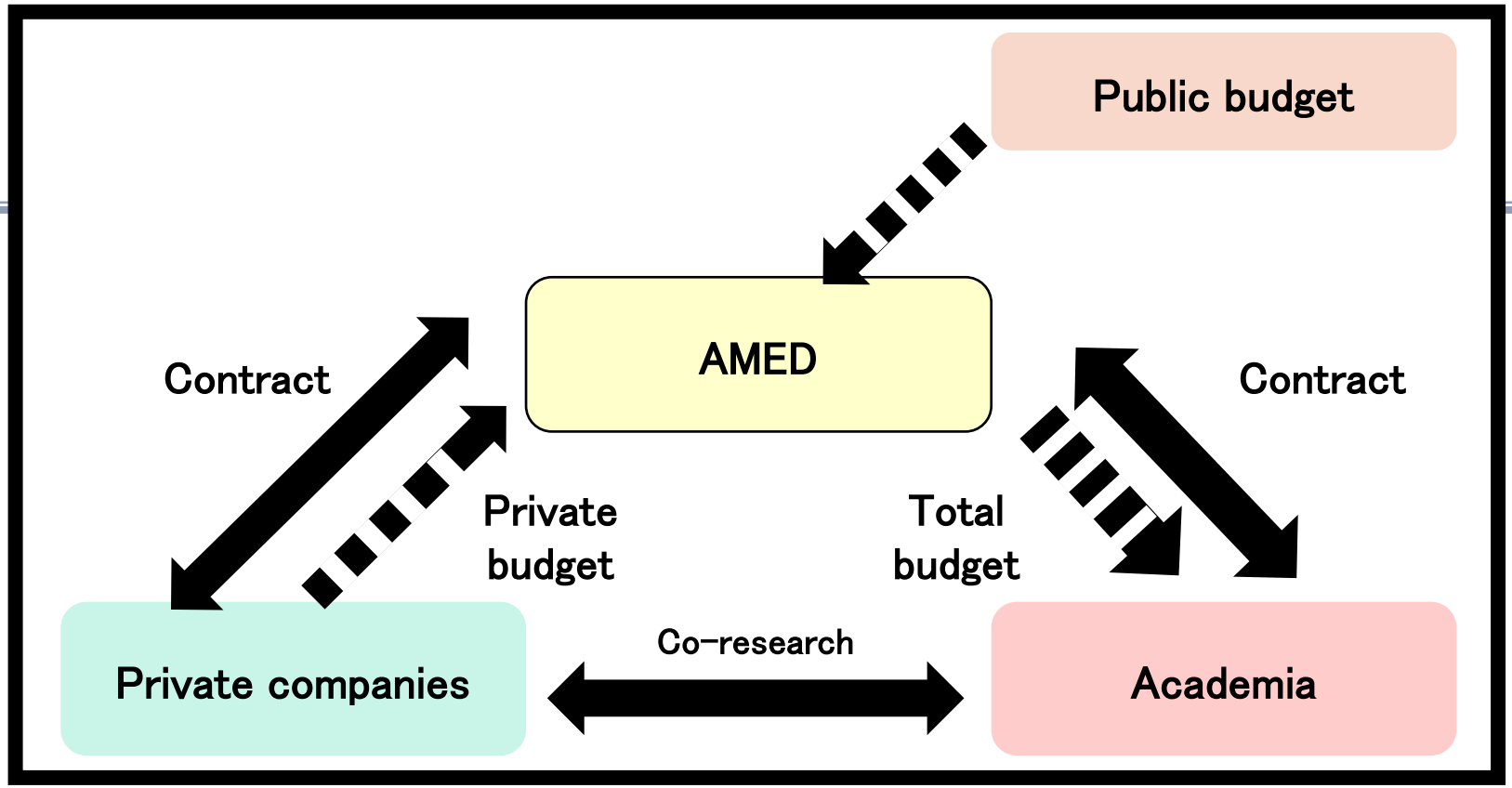
◎ The comprehensive data acquisition from clinical samples using the cutting-edge technology, mainly "multi-omics" analysis.

◎ Big budget available by dual funding from both G(AMED) and P.

GAPFREE

～ 産学官の垣根をなくす ～

Funding for Research to Expedite Effective drug discovery
by Government, Academia and Private partnership



Japanese

GAPFREE

～ 産学官の垣根をなくす ～

AMED

Funding for research to expedite effective drug discovery by Government, Academia and Private partnership

多層的オミックス解析による、がん、精神疾患、腎疾患を対象とした医療技術開発

NCGM【研究開発代表者】 国立国際医療研究センター　プロジェクト長　清水孝雄

アカデミア

オミックス解析拠点

NCC

NCC

NIHS

疾患解析拠点

NCC

NCC

NCC

NCNP

NCGM

参画企業

すべての革新は患者さんのために
CHUGAI 中外製薬
Roche ロシュ グループ

ono 小野薬品

Eisai

Daiichi-Sankyo

astellas
Leading Light for Life

KYOWA KIRIN

GAPFREE 2

Funding for Research to Expedite Effective drug discovery by Government, Academia and Private partnership

Disease research

Research on drug discovery and development for autoimmune bullous diseases with imatinib as a tool

PI: **Kenji KABASHIMA** (Kyoto Univ)

Academia: Kyoto University

Industry: Mitsubishi Tanabe Pharma

Understanding of tumor immune-environment at single cell level in patients with PD-1 immunotherapy treatment

PI: **Toshihiko DOI** (NCC)

Academia: NCC

Industry: astellas, Daiichi-Sankyo, Takeda

Efficacy of inhibitors for microglial activation in the patients with neuroinflammation evidenced by PET

PI: **Yasuyoshi WATANABE** (RIKEN)

Academia: RIKEN

Industry: astellas

Surveillance

Research on drug discovery and development projects by government, academia and private partnership

PI: **Shunsuke ONO** (Univ of Tokyo)

Case 2 (PPP)

Establishment of Clinical Innovation Network (CIN)

（Preparation of Clinical Development Infrastructure by Use of Patient Registry）

[Background and Issues]

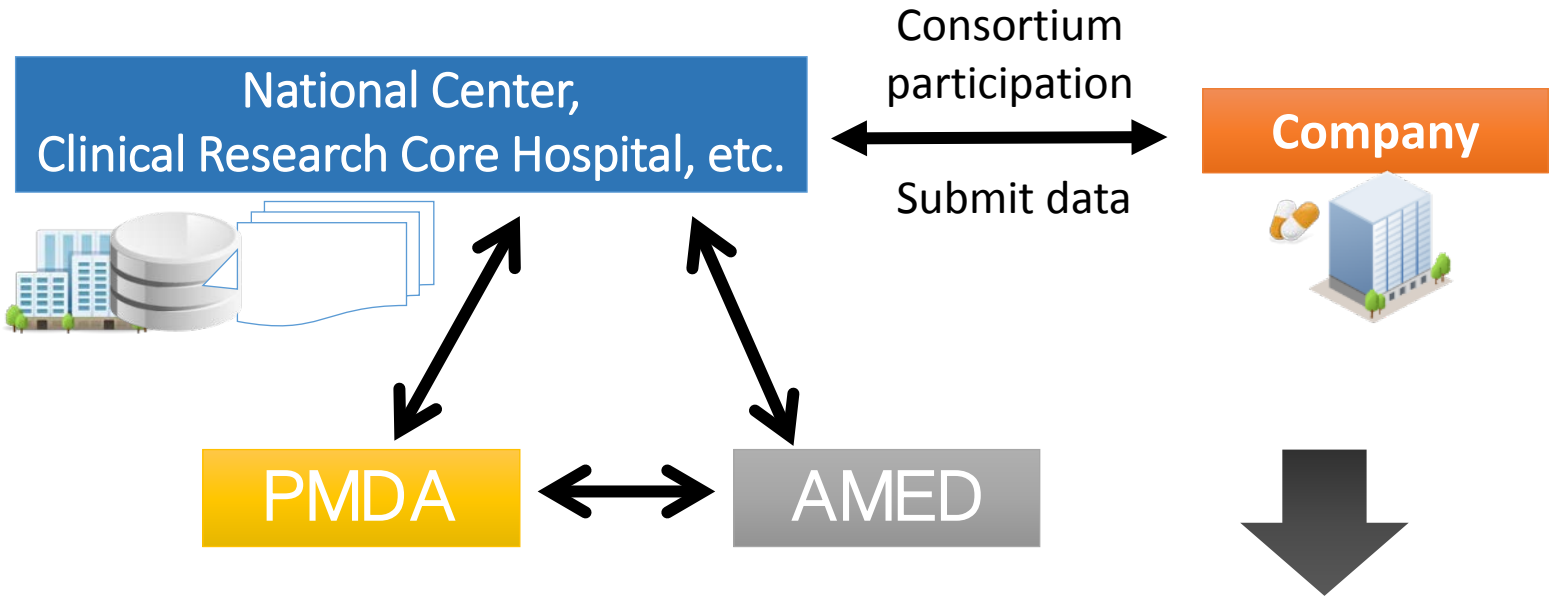
・R&D cost is increasing worldwide.

・These days, use of patient registries are attractive as a new clinical development method.

[Abstract of the measures]

・Establishing the network to use patient registries

・Usage for clinical trials based on regulatory science (RS)



Stimulation of R&D
Attract foreign manufacturers

Project related CIN supported by AMED

New Development and Improvement of Patient Registry System*		
Industry-Academia Collaborated Registry System Establishment using National Cancer Genome Screening Establishment to contribute to the development of new cancer drugs (SCRUM-Japan)	Atsushi Otsu	National Cancer Center Hospital East
Patient Registry System Research and Development of Amyotrophic Lateral Sclerosis	Gen Sobue	Nagoya University
Construction of Patient Registry System to Promoting the Clinical Innovation Network in Drug Development for Intractable Diseases and Rare Diseases	Harumasa Nakamura	National Center of Neurology and Psychiatry

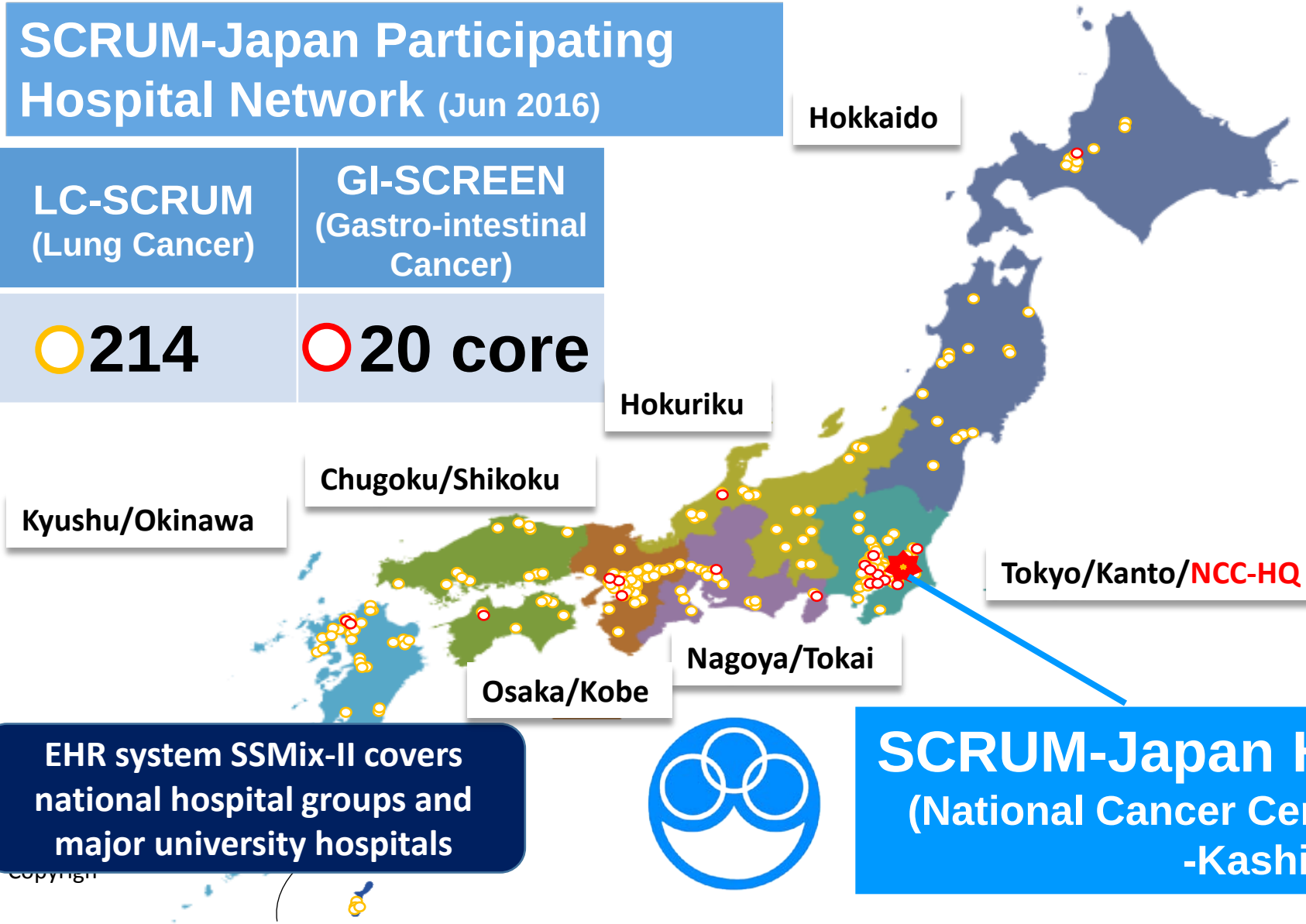
*Patient Registry System for Medical Devices Research is also being conducted.

Cross-sectional study on Patient Registry System		
Research on Measures to Promote Clinical Innovation Network by using Patient Registry System Effectively	Shinichi Takeda	National Center of Neurology and Psychiatry
Study of Clinical Research Design to Improve Clinical Development Efficiency by Using Patient Registry Data	Kunihiko Hayashi	Graduate School of Gunma University
Establishment of Registry Information Hub for the acceleration and promotion of CIN concept	Norihiro Kokudo	National Center for Global Health and Medicine

SCRUM-Japan: a nation-wide, multi-centric cancer genome screening program

SCRUM-Japan Participating Hospital Network (Jun 2016)

LC-SCRUM (Lung Cancer)	GI-SCREEN (Gastro-intestinal Cancer)
○214	○20 core



EHR system SSMix-II covers national hospital groups and major university hospitals

SCRUM-Japan HQ
(National Cancer Center -Kashiwa)

SCRUM-Japan: A successful academia-industrial collaboration program incentivising data sharing among pharmaceutical sectors

Central Testing at CLIA Labs: Oncomine Cancer Research Panel

Genome data

Commission

Advisory board

Genome data

Annotated report

Clinical Samples

Annotated report

Clinical Samples

LC-SCRUM-Japan

LC SCRUM

SCRUM-Japan

NCC Management Office

Contract, COI Accounting

EPOC-TR Data Center

NCC EPOC Exploratory Oncology Research & Clinical Trial Center 早期・探索臨床研究センター

Clinico-genome database

GI-SCREEN-Japan

GI-SCREEN GI-SCREEN GI-SCREEN GI-SCREEN

CURE a patient of Gastrointestinal Cancer

Registration

Contract

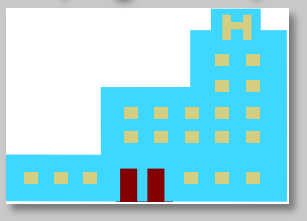
Funding

Contract

Data sharing

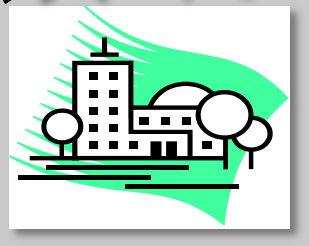
Registration

Contract



LC-SCRUM Participating Centers

Astellas	Astra Zeneca	Amgen	Eisai	Ono	Kyowa Kirin	MSD	Merck Serono
Daiichi-Sankyo	Taiho	Takeda	Chugai	Pfizer	Novartis	Eli Lilly	



GI-SCREEN Participating Centers

Case 3/4 (PPP)

Biostatisticians incubation program

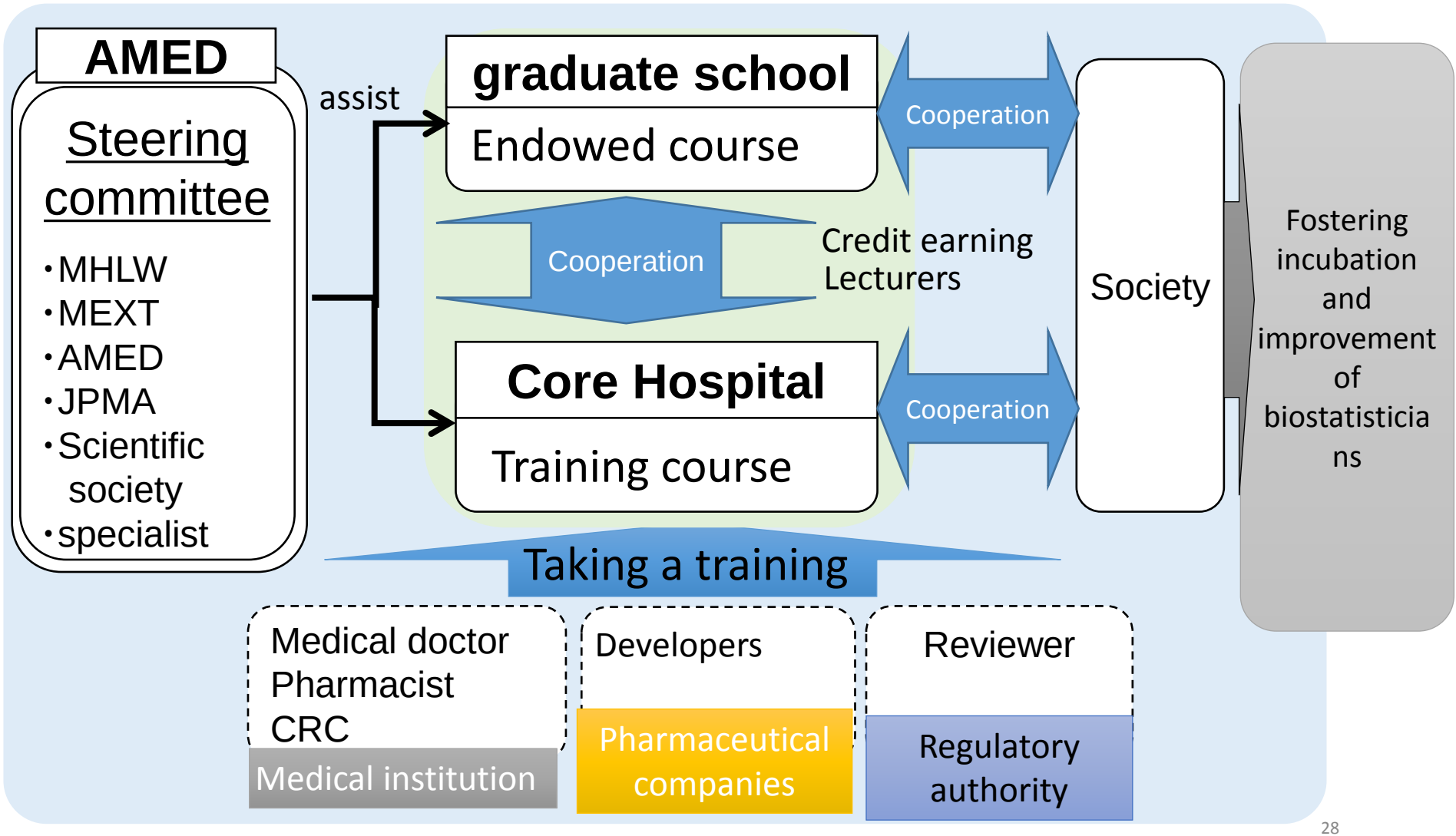
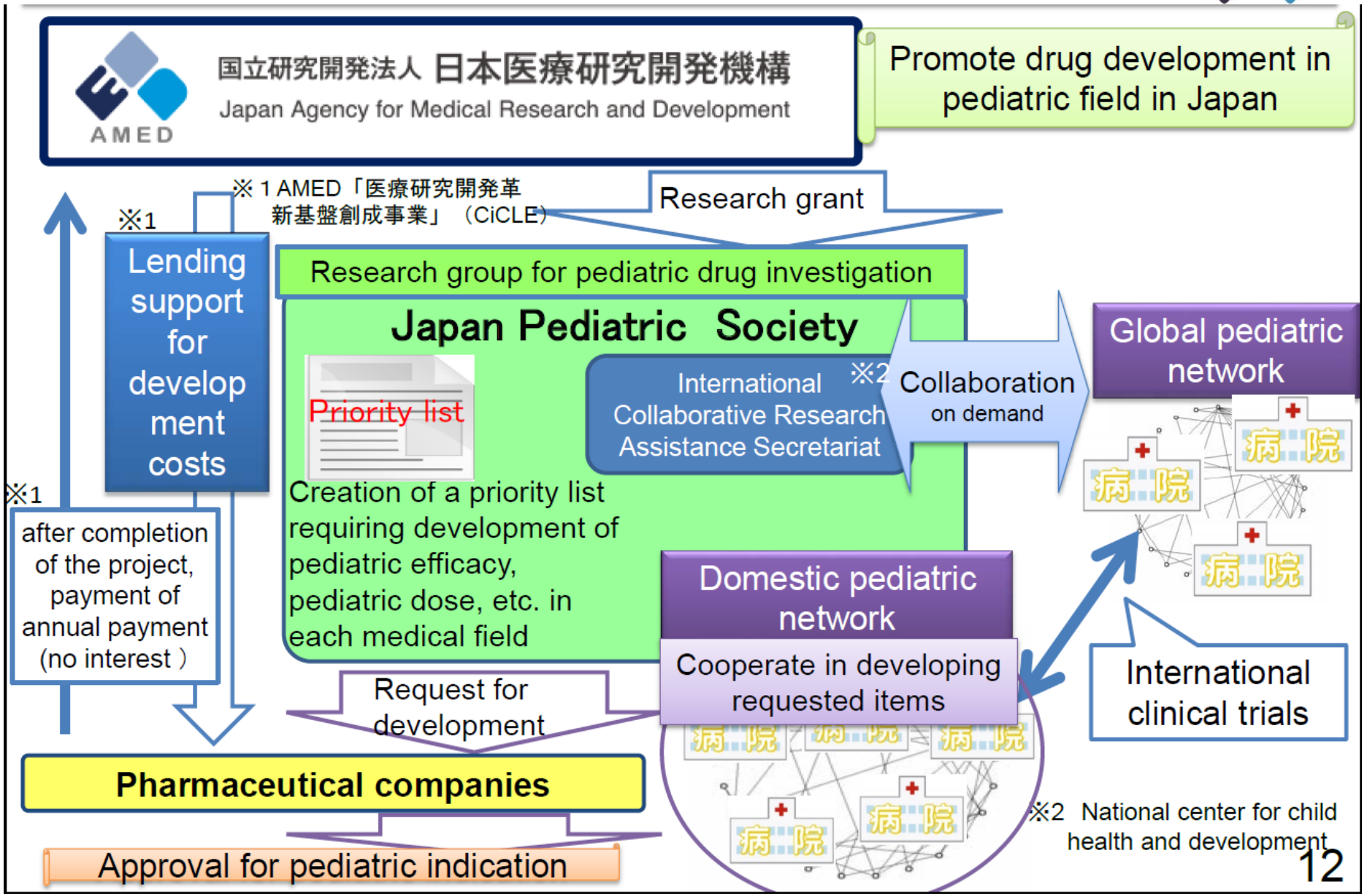
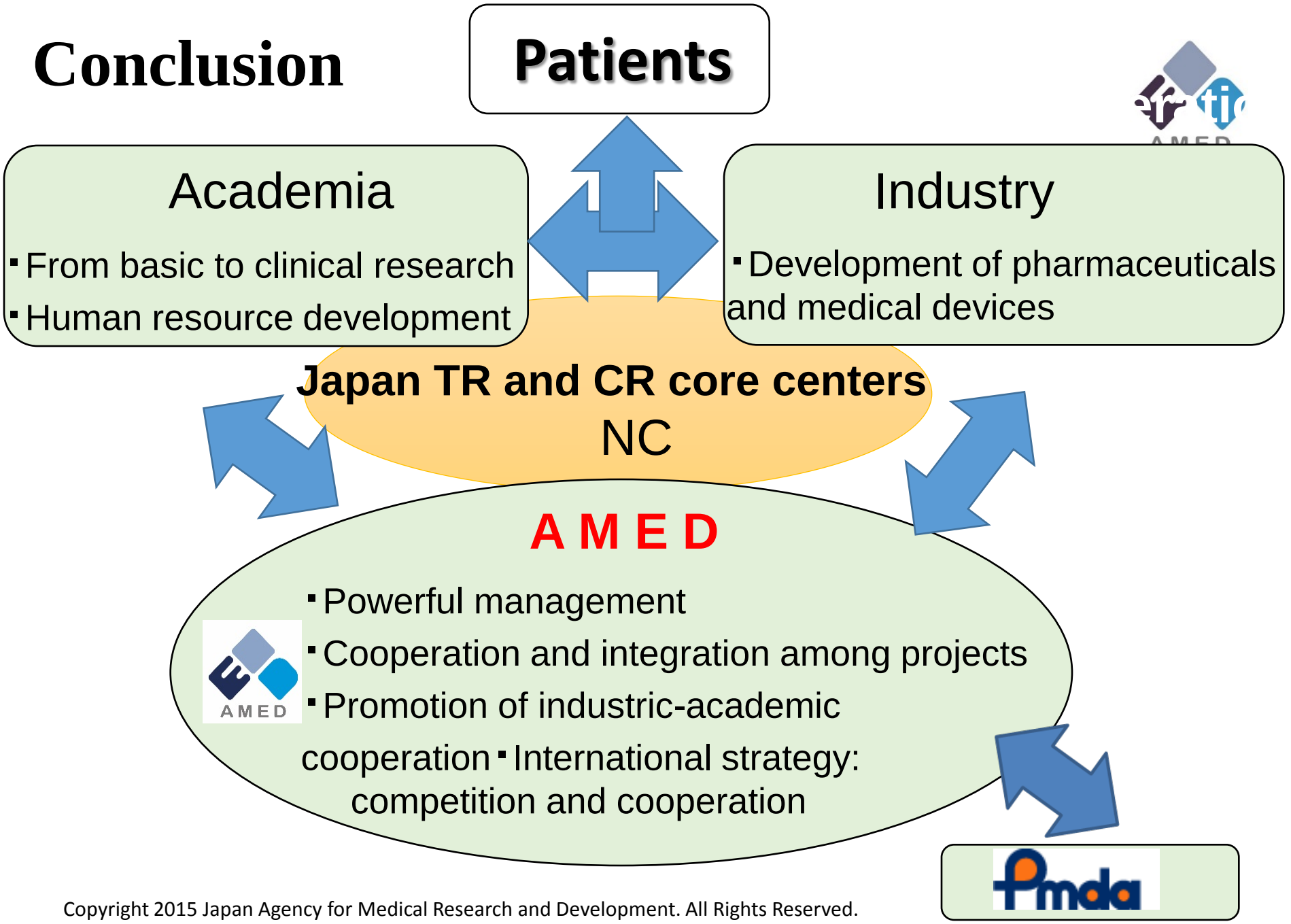


Image of “Medical Pediatric Breakthrough Program”

(tentative name)



Conclusion



Thank you for your attention