

# AMEDDataBook 2023

### Preface

Japan Agency for Medical Research and Development (AMED) entered its second medium-to long-term plan period, which will take five years, in FY2020. During the second plan period, Research and Development is being promoted in line with the six "integrated projects"<sup>\*</sup> centering on modalities based on the government's second "Healthcare Policy," and Research and Development related to diseases pursued in a format that cuts across the "integrated projects."

This "AMED DataBook 2023" presents the data of the activity achievements in the fourth year (FY2023) of the second plan. The DataBook will help readers appreciate AMED's promotion of medical Research and Development.

> December 2024 Japan Agency for Medical Research and Development (AMED)

<sup>\*</sup> The government's second "Healthcare Policy" states the six "integrated projects": Project for Advanced Drug Discovery and Development, Project for Medical Device and Healthcare, Project for Regenerative Medicine and Cell and Gene Therapies, Project for Genome and Health-Related Data, Project for Basic Medical Research, and Project for Seeds Development and Research Base.

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### **Statistics of DataBook 2023**

AMED collects and stores R&D project information in line with the information at the time of contracting with supporting institutions, and these statistics were produced based on data as of October 2024<sup>\*1</sup>.

The statistical unit is an awarded project. The number of awarded projects and R&D funding are aggregated on an annual basis, and the projects implemented over a period of multiple years are aggregated each implanting year. In these statistics, projects started on or after April 1 of the fiscal year in question are treated as newly awarded projects, and others as ongoing projects.

R&D funding consists of the final contract/payment amount (including indirect costs) at the end of the fiscal year of the commissioned programs, grant programs or special fund programs. Project R&D funding is the total amount of R&D funding for the fiscal year in question including parts of R&D allocated to subsidiary institutions or other subcontracted institutions under the supervision of the PI.

In these statistics where necessary, rounding has been used in the notation of numerical values and therefore the total numerical values in the breakdown do not always equal the total values. The distribution ratio also does not total 100 in some cases. The R&D tags showing the nature of R&D projects include "Target Disease," "Nature of Research," "R&D Phase," "Product Approval Category," "Disease Area," and "R&D Objective," and these statistics have been produced based on these tags.

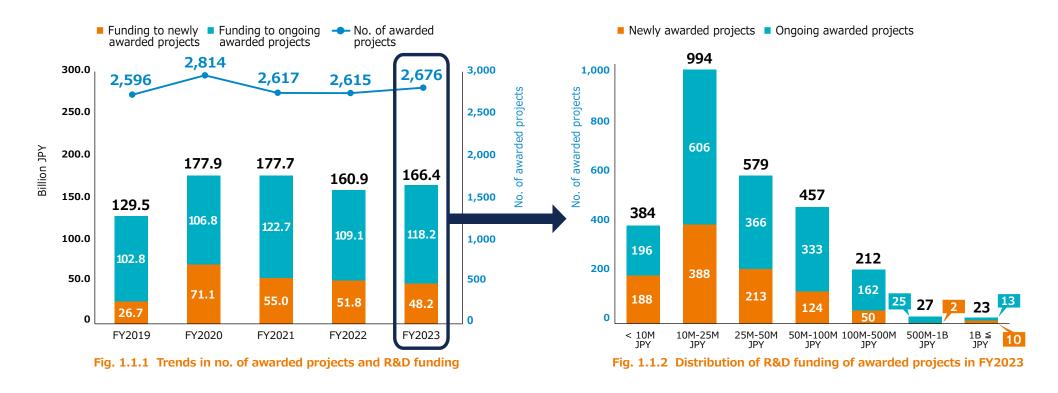
For "Target Disease," "Nature of Research," "R&D Phase" "Product Approval Category," and "Disease Area," one awarded project is attached with one of the categorial tags.<sup>\*2</sup> For "Basic Study" and "Applied Study" in "R&D Phase," they are collectively treated as "Basic/Applied Studies" in these statistics. In the case of "R&D Objective," multiple choices of the categorial tags are possible for a single project.

The classification of R&D tags has changed from FY2023. This DataBook aggregates R&D tags from FY2023 by replacing the R&D tags used until FY2022, in accordance with the data replacement rules established by AMED.

Data accumulated over the past five years are shown as fiveyear changes and data accumulated from the second plan period include the changes from FY2020.

- \*1 The statistics in 4.1 were produced based on calls for proposals information published by AMED (as of October 2024), and the statistics in 4.2 and 4.3 were produced based on the Cross-ministerial R&D Management System (e-Rad) data.
- \*2 For "Disease Area," multiple choices of the categorial tags are possible for a single project in FY2020, and from FY2021 the tags for main "Disease Area" and other "Disease Areas" are attached to a single project. These statistics were produced using the main "Disease Area" data from FY2021 onwards.

### 1.1 No. of Projects, R&D Funding, and R&D Funding per Project



#### Table 1.1.1 Trends in no. of awarded projects, R&D funding, and R&D funding per project

		FY2019			FY2020			FY2021			FY2022			FY2023	
	Total	Newly	COVID -19*	Total	Newly	COVID -19*	Total	Newly	COVID -19*	Total		COVID -19*	Total	Newly	COVID -19*
No. of awarded projects	2,596	778	29	2,814	1,094	305	2,617	945	132	2,615	1,001	79	2,676	975	57
R&D funding (Billion JPY)	129.5	26.7	3.3	177.9	71.1	56.6	177.7	55.0	45.8	160.9	51.8	14.3	166.4	48.2	8.2
R&D funding per project (Billion JPY)	0.05	0.03	0.11	0.06	0.07	0.19	0.07	0.06	0.35	0.06	0.05	0.18	0.06	0.05	0.14
* COVID 10 #0	lated by	ideat n	rojosto												

\* COVID-19-related budget projects

The R&D funding per project is the average figure.

500M - 1B

JPY

Total

10

25

22

36

27

Table 1.1.2 No. of awarded projects by fiscal year and by level of R&D funding

Total

Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because

50M - 100M

JPY

79 224

100M - 500M

JPY

41

77

68

50

Total

25M - 50M

JPY

482 181 991 414 572 230 447 127 276 123

Total

445 183 990 376 487 165 419 126 236

384 188 994 388 579 213 457 124 212

10M - 25M

JPY

552 224 897 273 523 158 379

FY2022 383 213 981 347 535 225 439 131 230

Total

Created based on AMED data (as of October 2024).

necessary information was not available.

< 10M JPY

Total

FY2019

FY2020

FY2021

FY2023

4

1B JPY ≦

1

10

5

5

10

Total

18

2 11

9 21

13

12 11

2 23

1.

### **1.2** By Integrated Project: No. of Projects and R&D Funding **1**) FY2023

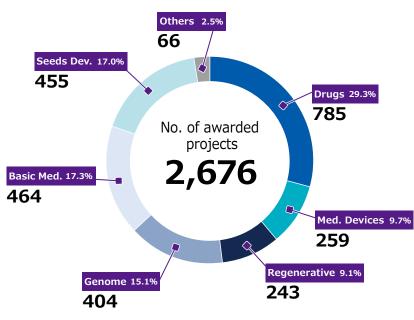


Fig. 1.2.1 No. of awarded projects by Integrated Project in FY2023

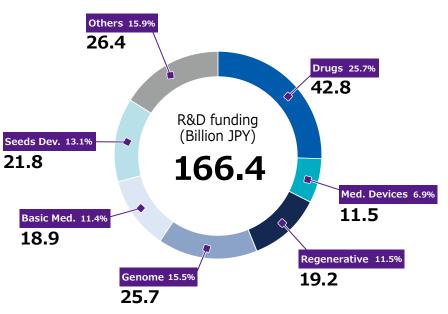


Fig. 1.2.2 R&D funding by Integrated Project in FY2023

#### Table 1.2.1 No. of awarded projects and R&D funding by Integrated Project in FY2023

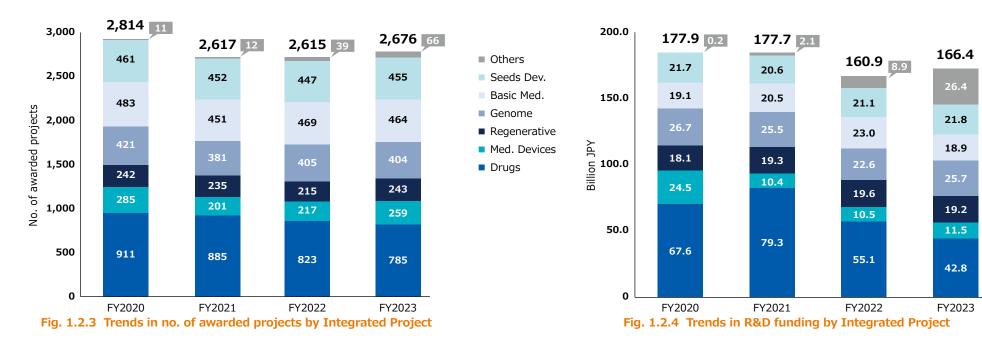
Integrated Project	Abbreviation	No. of awarded projects	R&D funding (Billion JPY)
Project for Advanced Drug Discovery and Development	Drugs	785	42.8
Project for Medical Device and Healthcare	Med. Devices	259	11.5
Project for Regenerative Medicine and Cell and Gene Therapies	Regenerative	243	19.2
Project for Genome and Health-Related Data	Genome	404	25.7
Project for Basic Medical Research	Basic Med.	464	18.9
Project for Seeds Development and Research Base	Seeds Dev.	455	21.8
Others (Special Fund Programs, etc.)*	Others	66	26.4
Total		2,676	166.4

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

\* Among "Others," AMED provided 22.1 billion JPY in funding for 40 projects through the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA).

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### **1.2** By Integrated Project: No. of Projects and R&D Funding **2**) Trends



#### Table 1.2.2 Trends in no. of awarded projects and R&D funding by Integrated Project

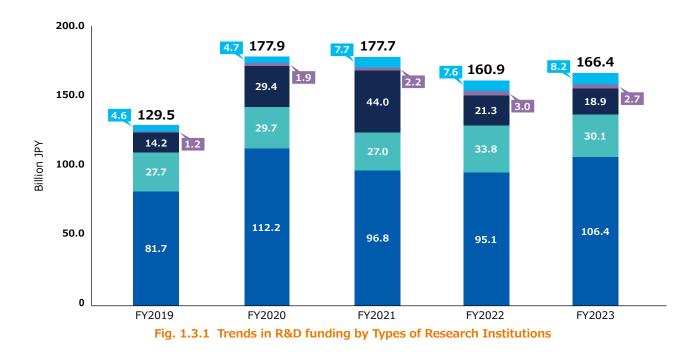
Tabaguakad Duraiash	Abbreviation	No. of awarded projects				R&D funding (Billion JPY)			
Integrated Project	Addreviation	FY2020	FY2021	FY2022	FY2023	FY2020	FY2021	FY2022	FY2023
Project for Advanced Drug Discovery and Development	Drugs	911	885	823	785	67.6	79.3	55.1	42.8
Project for Medical Device and Healthcare	Med. Devices	285	201	217	259	24.5	10.4	10.5	11.5
Project for Regenerative Medicine and Cell and Gene Therapies	Regenerative	242	235	215	243	18.1	19.3	19.6	19.2
Project for Genome and Health-Related Data	Genome	421	381	405	404	26.7	25.5	22.6	25.7
Project for Basic Medical Research	Basic Med.	483	451	469	464	19.1	20.5	23.0	18.9
Project for Seeds Development and Research Base	Seeds Dev.	461	452	447	455	21.7	20.6	21.1	21.8
Others (Special Fund Programs, etc.)*	Others	11	12	39	66	0.2	2.1	8.9	26.4
Total		2,814	2,617	2,615	2,676	177.9	177.7	160.9	166.4

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

\* Among "Others," AMED provided 6.4 billion JPY in funding for 22 projects in FY2022, and 22.1 billion JPY for 40 projects in FY2023 through the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA).

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#### 1.3 By Type of Research Institution: Allocation of R&D Funding



Others
<ul> <li>Incorporated Foundations/ Associations, etc.</li> </ul>

- Local public entities, etc.
- Companies, etc.
- Incorporated Admin. Agencies / Nat'l Research Institutes
- Universities, etc.

#### Table 1.3.1 Trends in R&D funding by Types of Research Institutions

Types of Research Institutions	R&D funding (Billion JPY)							
Types of Research institutions	FY2019	FY2020	FY2021	FY2022	FY2023			
Universities, etc.	81.7	112.2	96.8	95.1	106.4			
Incorporated Admin. Agencies / Nat'l Research Institutes	27.7	29.7	27.0	33.8	30.1			
Companies, etc.	14.2	29.4	44.0	21.3	18.9			
Local public entities, etc.	1.2	1.9	2.2	3.0	2.7			
Incorporated Foundations/Associations, etc.	4.6	4.7	7.7	7.6	8.2			
Others	0.03	0.03	0.03	0.03	0.02			
Total	129.5	177.9	177.7	160.9	166.4			

Refer to 5.1 "Types of Research Institutions" with regard to Types of Research Institutions. > P25

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Others" in the Types of Research Institutions have been omitted in the graph.

### **1.4** By Target Disease 1) No. of Projects

#### Table 1.4.1 Trends in no. of awarded projects by Target Disease

	No. of awarded projects								
Target Disease	FY2019	FY2020	FY2021	FY2022	FY2023				
Certain infectious and parasitic diseases	249	273	288	311	345				
COVID-19	28	246	109	88	11				
Cancer (neoplasms)	596	592	632	589	601				
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	42	35	26	34	123				
Endocrine, nutritional and metabolic diseases	86	96	109	103	99				
Mental and behavioural disorders	152	164	126	152	140				
Diseases of the nervous system	211	192	190	203	316				
Diseases of the circulatory system	136	130	149	145	168				
Diseases of the respiratory system	50	60	59	51	61				
Diseases of the digestive system	81	78	77	82	121				
Diseases of the eye and adnexa	43	34	31	33	40				
Diseases of the ear and mastoid process	11	15	14	15	16				
Diseases of the skin and subcutaneous tissue	28	28	27	30	40				
Diseases of the musculoskeletal system and connective tissue	53	71	67	82	70				
Diseases of the genitourinary system	42	45	43	42	40				
Pregnancy, childbirth and the puerperium	6	7	10	14	14				
Certain conditions originating in the perinatal period	9	11	12	11	15				
Congenital malformations, deformations and chromosomal abnormalities	54	39	46	46	15				
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	42	50	32	35	4				
Injury, poisoning and certain other consequences of external causes	66	59	42	41	6				
External causes of morbidity and mortality	2	2	-	1	4				
Factors influencing health status and contact with health services	9	10	10	4	8				
Others	20	29	45	70	65				
Diseases unspecified	572	518	468	432	354				
Unknown	8	30	5	1					
Total	2,596	2,814	2,617	2,615	2,676				

"Target Diseases" have been aggregated by adding "Others" and "Diseases unspecified" to the large classification (chapter) of WHO's International Statistical Classification of Diseases and Related Health Problems (ICD-10, 2013).

AMED confers one of the ICD-10 classification of diseases as a main "Target Diseases" for each project. "Others" means awarded projects targeting diseases that are not possible to classify in ICD-10.

The category of "Diseases unspecified" includes research projects supporting the cross-disease research infrastructure, as well as basic research projects that have not yet specified "Target Diseases" but may target a wide variety of diseases in the future. ICD-10 uses "Codes for special purposes" for a provisional assignment of new diseases of uncertain etiology or emergency use, and COVID-19 has been given a code for special purposes. In this table, it is displayed as COVID-19.

Among the AMED R&D projects, the projects to which codes for special purposes apply consisted almost entirely of COVID-19 except two projects in FY2021 and one project in FY2022.

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from this figure because necessary information was not available.

The data bars in this table assume, for each fiscal year, the value of 100 for the "Target Diseases" of the largest number of projects in the year, and illustrate the size of the respective "Target Diseases" by relative ratio. However, the "Unknown" category is excluded.

### **1.4** By Target Disease 2) R&D Funding

#### Table 1.4.2 Trends in R&D funding by Target Disease

	R&D funding (Billion JPY)								
Target Disease	FY2019	FY2020	FY2021	FY2022	FY2023				
Certain infectious and parasitic diseases	10.4	9.6	23.1	13.8	31.8				
COVID-19	3.0	39.8	30.3	16.5	3.8				
Cancer (neoplasms)	26.5	23.4	32.2	31.3	30.2				
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	1.7	1.3	1.0	1.2	4.9				
Endocrine, nutritional and metabolic diseases	3.8	3.2	5.4	4.5	5.6				
Mental and behavioural disorders	5.3	7.8	6.5	9.0	6.2				
Diseases of the nervous system	9.5	9.1	10.6	14.8	20.4				
Diseases of the circulatory system	8.9	5.8	6.9	6.5	6.2				
Diseases of the respiratory system	1.4	3.8	3.2	2.4	4.9				
Diseases of the digestive system	3.7	3.1	3.0	3.0	5.5				
Diseases of the eye and adnexa	2.4	1.7	1.6	1.5	2.9				
Diseases of the ear and mastoid process	0.3	0.4	0.3	0.4	0.5				
Diseases of the skin and subcutaneous tissue	1.5	1.0	1.3	1.7	1.8				
Diseases of the musculoskeletal system and connective tissue	2.0	2.6	2.7	3.4	3.5				
Diseases of the genitourinary system	1.4	1.8	1.3	1.4	1.5				
Pregnancy, childbirth and the puerperium	0.2	0.2	0.2	0.6	0.3				
Certain conditions originating in the perinatal period	0.2	0.4	0.5	0.5	0.5				
Congenital malformations, deformations and chromosomal abnormalities	2.2	1.8	2.1	2.1	0.5				
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	2.4	3.0	1.2	1.8	0.2				
Injury, poisoning and certain other consequences of external causes	2.2	2.5	2.6	2.1	0.1				
External causes of morbidity and mortality	0.02	0.02	-	0.01	0.2				
Factors influencing health status and contact with health services	0.3	0.5	0.3	0.2	0.2				
Others	2.6	1.3	1.5	4.7	4.9				
Diseases unspecified	37.0	53.1	39.8	37.7	29.9				
Unknown	0.5	0.8	0.1	0.01	_				
Total	129.5	177.9	177.7	160.9	166.4				

"Target Diseases" have been aggregated by adding "Others" and "Diseases unspecified" to the large classification (chapter) of WHO's International Statistical Classification of Diseases and Related Health Problems (ICD-10, 2013).

AMED confers one of the ICD-10 classification of diseases as a main "Target Diseases" for each project. "Others" means awarded projects targeting diseases that are not possible to classify in ICD-10.

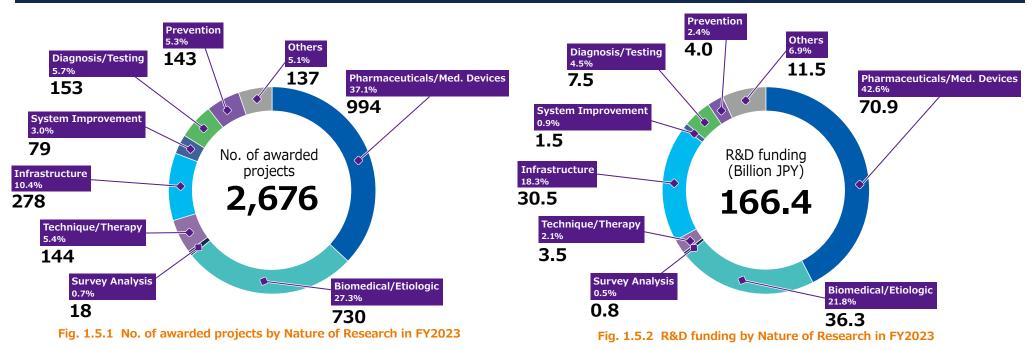
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Among the AMED R&D projects, the projects to which codes for special purposes apply consisted almost entirely of COVID-19 except two projects in FY2021 and one project in FY2022.

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from this figure because necessary information was not available.

The data bars in this table assume, for each fiscal year, the value of 100 for the "Target Diseases" of the largest number of projects in the year, and illustrate the size of the respective "Target Diseases" by relative ratio. However, the "Unknown" category is excluded.

### **1.5** By Nature of Research 1) No. of Projects and R&D Funding in FY2023

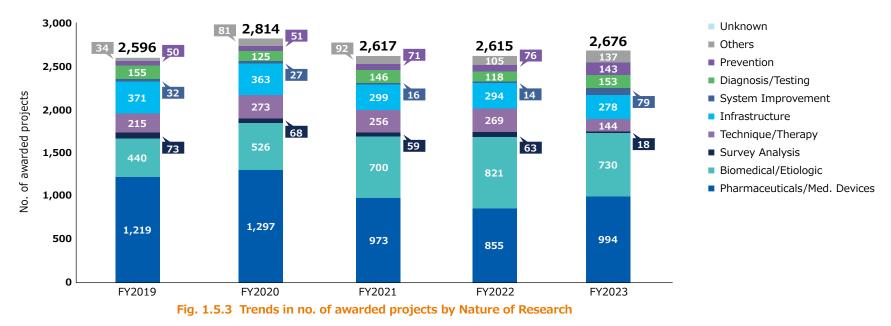


#### Table 1.5.1 No. of awarded projects and R&D funding by Nature of Research in FY2023

Nature of Research	Abbreviation	No. of awarded projects	R&D funding (Billion JPY)
Pharmaceutical/Medical Device Development	Pharmaceuticals/Med. Devices	994	70.9
Basic Biomedical/Etiologic Studies	Biomedical/Etiologic	730	36.3
Fact-finding Survey Analysis	Survey Analysis	18	0.8
Medical Technique/Standard Therapy Dev.	Technique/Therapy	144	3.5
Research/Drug Discovery Infrastructure Development	Infrastructure	278	30.5
Regulatory/Nursing System Improvement and Technical Support	System Improvement	79	1.5
Development, Establishment, and Validation of New Diagnostic/Testing Methods and Systems	Diagnosis/Testing	153	7.5
Evidence Building for Prevention	Prevention	143	4.0
Others	Others	137	11.5
Total		2,676	166.4

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

### **1.5** By Nature of Research 2) No. of Projects

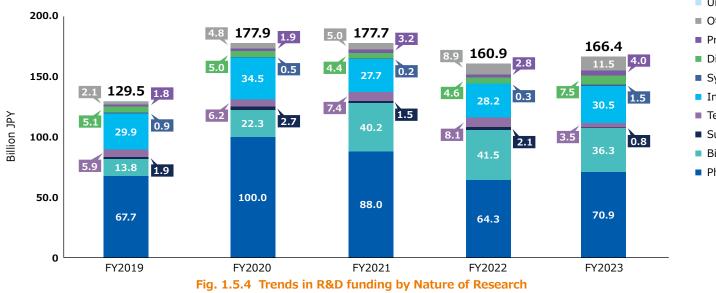


#### Table 1.5.2 Trends in no. of awarded projects by Nature of Research

Nature of Research	Abbroviation	No. of awarded projects						
Nature of Research	Abbreviation		FY2020	FY2021	FY2022	FY2023		
Pharmaceutical/Medical Device Development	Pharmaceuticals/Med. Devices	1,219	1,297	973	855	994		
Basic Biomedical/Etiologic Studies	Biomedical/Etiologic	440	526	700	821	730		
Fact-finding Survey Analysis	Survey Analysis	73	68	59	63	18		
Medical Technique/Standard Therapy Dev.	Technique/Therapy	215	273	256	269	144		
Research/Drug Discovery Infrastructure Development	Infrastructure	371	363	299	294	278		
Regulatory/Nursing System Improvement and Technical Support	System Improvement	32	27	16	14	79		
Development, Establishment, and Validation of New Diagnostic/Testing Methods and Systems	Diagnosis/Testing	155	125	146	118	153		
Evidence Building for Prevention	Prevention	50	51	71	76	143		
Others	Others	34	81	92	105	137		
Unknown	Unknown	7	3	5	_	-		
Total		2,596	2,814	2,617	2,615	2,676		

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Unknown" in the Natures of Research have been omitted in the graph.

### 1.5 By Nature of Research 3) R&D Funding





- Survey Analysis
- Biomedical/Etiologic
- Pharmaceuticals/Med. Devices

#### Table 1.5.3 Trends in R&D funding by Nature of Research

Nature of Research	Abbroviation	R&D funding(Billion JPY)					
	Abbreviation		FY2020	FY2021	FY2022	FY2023	
Pharmaceutical/Medical Device Development	Pharmaceuticals/Med. Devices	67.7	100.0	88.0	64.3	70.9	
Basic Biomedical/Etiologic Studies	Biomedical/Etiologic	13.8	22.3	40.2	41.5	36.3	
Fact-finding Survey Analysis	Survey Analysis	1.9	2.7	1.5	2.1	0.8	
Medical Technique/Standard Therapy Dev.	Technique/Therapy	5.9	6.2	7.4	8.1	3.5	
Research/Drug Discovery Infrastructure Development	Infrastructure	29.9	34.5	27.7	28.2	30.5	
Regulatory/Nursing System Improvement and Technical Support	System Improvement	0.9	0.5	0.2	0.3	1.5	
Development, Establishment, and Validation of New Diagnostic/Testing Methods and Systems	Diagnosis/Testing	5.1	5.0	4.4	4.6	7.5	
Evidence Building for Prevention	Prevention	1.8	1.9	3.2	2.8	4.0	
Others	Others	2.1	4.8	5.0	8.9	11.5	
Unknown	Unknown	0.5	0.03	0.1	-	-	
Total		129.5	177.9	177.7	160.9	166.4	

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Unknown" in the Natures of Research have been omitted in the graph.

### 1.6 By Disease Area : No. of Projects and R&D Funding

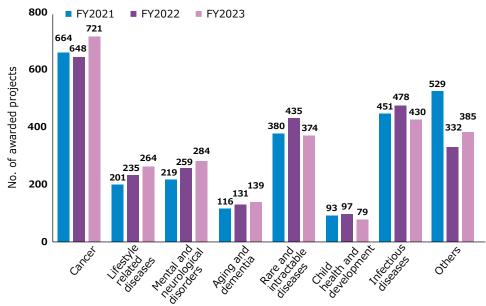


Fig. 1.6.1 No. of awarded projects by Disease Area

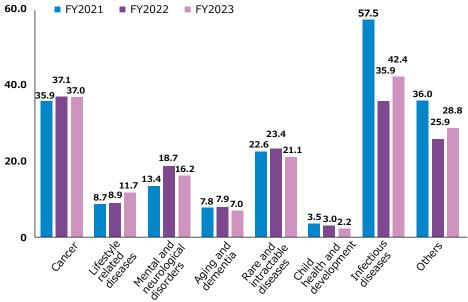


Fig. 1.6.2 R&D funding by Disease Area

Table 1.6.1	No. of awarded projects and R&D funding by Disease Area
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Disease Area		No. of award	led projects		R&D funding(Billion JPY)			
Disease Area	FY2020*	FY2021	FY2022	FY2023	FY2020*	FY2021	FY2022	FY2023
Cancer	617	664	648	721	26.0	35.9	37.1	37.0
Lifestyle related diseases	246	201	235	264	8.0	8.7	8.9	11.7
Mental and neurological disorders	275	219	259	284	10.5	13.4	18.7	16.2
Aging and dementia	179	116	131	139	10.8	7.8	7.9	7.0
Rare and intractable diseases	433	380	435	374	22.5	22.6	23.4	21.1
Child health and development	64	93	97	79	1.6	3.5	3.0	2.2
Infectious diseases	631	451	478	430	56.6	57.5	35.9	42.4
Others	735	529	332	385	58.8	36.0	25.9	28.8

In FY2021 there were multiple choices for disease areas among 22 projects, and all choices were aggregated. "Others" includes basic R&D projects on non-specifiable diseases and R&D projects on research/drug discovery infrastructure development. Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

Billion JPY

\* Since multiple choices for a single awarded project were possible in FY2020, the reference values are presented in Tab 1.6.1. They are not shown on the graphs.

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### 1.7 By R&D Objective : No. of Projects and R&D Funding

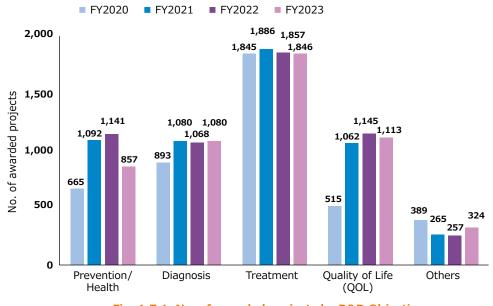


Fig. 1.7.1 No. of awarded projects by R&D Objective

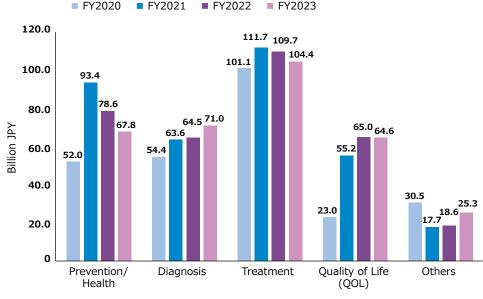


Fig. 1.7.2 R&D funding by R&D Objective

#### Table 1.7.1 No. of awarded projects and R&D funding by R&D Objective

D& D. Ohiostiva		No. of award	led projects		R&D funding (Billion JPY)			
R&D Objective	FY2020	FY2021	FY2022	FY2023	FY2020	FY2021	FY2022	FY2023
Prevention/Health	665	1,092	1,141	857	52.0	93.4	78.6	67.8
Diagnosis	893	1,080	1,068	1,080	54.4	63.6	64.5	71.0
Treatment	1,845	1,886	1,857	1,846	101.1	111.7	109.7	104.4
Quality of Life (QOL)	515	1,062	1,145	1,113	23.0	55.2	65.0	64.6
Others	389	265	257	324	30.5	17.7	18.6	25.3

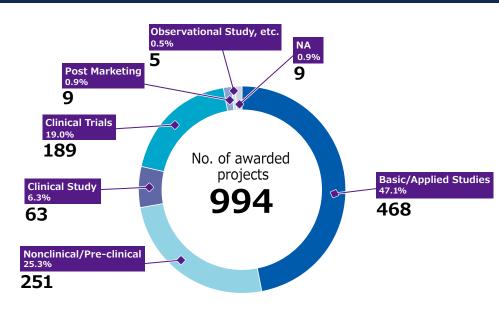
For a single awarded project, there were possible in multiple choices for develop objectives.

"Others" includes both of R&D projects on "Research/Drug Discovery Infrastructure Development" and "Basic Biomedical/Etiologic Studies."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

### 2. R&D Projects for Pharmaceutical/Medical Device Development

### 2.1 By R&D Phase 1) No. of Projects and R&D Funding in FY2023





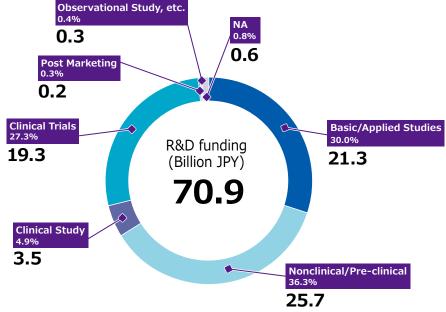


Fig. 2.1.2 R&D funding by R&D Phase of research for "Pharmaceutical/Medical Device Development" in FY2023

#### Table 2.1.1 No. of awarded projects and R&D funding by R&D Phase of research for "Pharmaceutical/Medical Device Development" in FY2023

	•					
R&D Phase	No. of awarded projects	R&D funding (Billion JPY)				
Basic/Applied Studies	468	21.3				
Nonclinical/Pre-clinical	251	25.7				
Clinical Study	63	3.5				
Clinical Trials	189	19.3				
Post Marketing	9	0.2				
Observational Study, etc.	5	0.3				
NA	9	0.6				
Total	994	70.9				

These data show the "R&D Phase" that are required to be attached to awarded projects for "Pharmaceutical/Medical Device Development."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

### **R&D Projects for Pharmaceutical/Medical Device Development**

### 2.1 By R&D Phase 2) No. of Projects

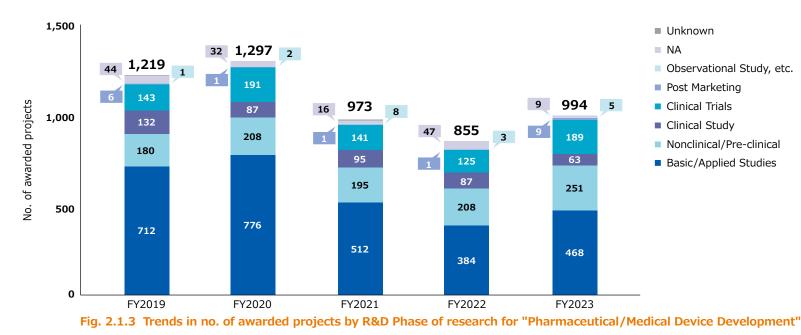


Table 2.1.2	Trends in no of a	warded projects b	y R&D Phase of resea	arch for "Pharmaceut	ical/Medical Devic	e Develonment"
	in enus in no. Or a	iwalueu projects b	y rad flase of lesea	inclution Filannaceut	ical/medical Devic	

R&D Phase	No. of awarded projects							
Rad Flidse	FY2019	FY2020	FY2021	FY2022	FY2023			
Basic/Applied Studies	712	776	512	384	468			
Nonclinical/Pre-clinical	180	208	195	208	251			
Clinical Study	132	87	95	87	63			
Clinical Trials	143	191	141	125	189			
Post Marketing	6	1	1	1	9			
Observational Study, etc.	1	2	8	3	5			
NA	44	32	16	47	9			
Unknown	1	_	5	-	-			
Total	1,219	1,297	973	855	994			

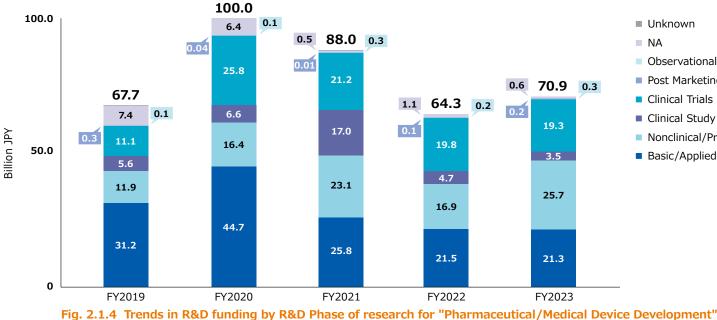
These data show the "R&D Phase" that are required to be attached to awarded projects for "Pharmaceutical/Medical Device Development."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Unknown" in the "R&D Phase" categories have been omitted in the graph.

2.

#### **R&D Projects for Pharmaceutical/Medical Device Development** 2.

### 2.1 By R&D Phase 3) R&D Funding



Observational Study, etc. Post Marketing Clinical Trials Clinical Study Nonclinical/Pre-clinical Basic/Applied Studies

Table 2.1.3 Trends in R&D funding by R&D Phase of research for "	'Pharmaceutical/Medical Device Development"
------------------------------------------------------------------	---------------------------------------------

R&D Phase	R&D funding (Billion JPY)							
Rad Flidse	FY2019	FY2020	FY2021	FY2022	FY2023			
Basic/Applied Studies	31.2	44.7	25.8	21.5	21.3			
Nonclinical/Pre-clinical	11.9	16.4	23.1	16.9	25.7			
Clinical Study	5.6	6.6	17.0	4.7	3.5			
Clinical Trials	11.1	25.8	21.2	19.8	19.3			
Post Marketing	0.3	0.04	0.01	0.1	0.2			
Observational Study, etc.	0.1	0.1	0.3	0.2	0.3			
NA	7.4	6.4	0.5	1.1	0.6			
Unknown	0.1	-	0.2	-	-			
Total	67.7	100.0	88.0	64.3	70.9			

These data show the "R&D Phase" that are required to be attached to awarded projects for "Pharmaceutical/Medical Device Development."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Unknown" in the "R&D Phase" categories have been omitted in the graph.

**R&D Projects for Pharmaceutical/Medical Device Development** 

2.2 By Product Approval Category 1) No. of Projects and R&D Funding in FY2023

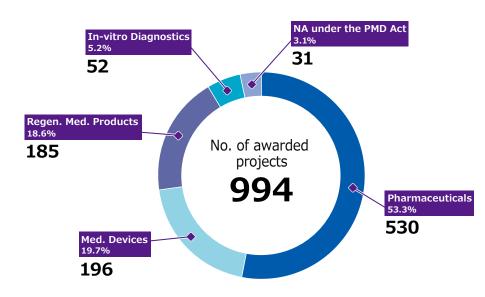


Fig. 2.2.1 No. of awarded projects by Product Approval Category of research for "Pharmaceutical/Medical Device Development" in FY2023

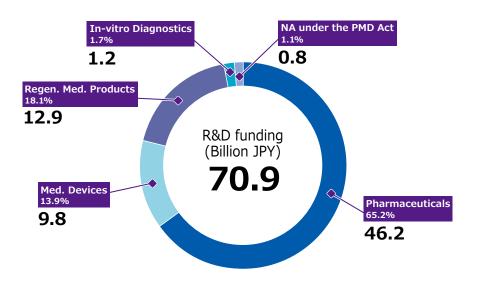


Fig. 2.2.2 R&D funding by Product Approval Category of research for "Pharmaceutical/Medical Device Development" in FY2023

#### Table 2.2.1 No. of awarded projects and R&D funding by Product Approval Category of research for "Pharmaceutical/Medical Device Development" in FY2023

Product Approval Category	No. of awarded projects	R&D funding (Billion JPY)
Pharmaceuticals	530	46.2
Medical Devices	196	9.8
Regenerative Medicine Products	185	12.9
In-vitro Diagnostics	52	1.2
NA under the PMD Act	31	0.8
Total	994	70.9

These data show the "Product Approval Categories" that are required to be attached to awarded projects for "Pharmaceutical/Medical Device Development."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available.

2.

### 2. R&D Projects for Pharmaceutical/Medical Device Development

### 2.2 By Product Approval Category 2) No. of Projects

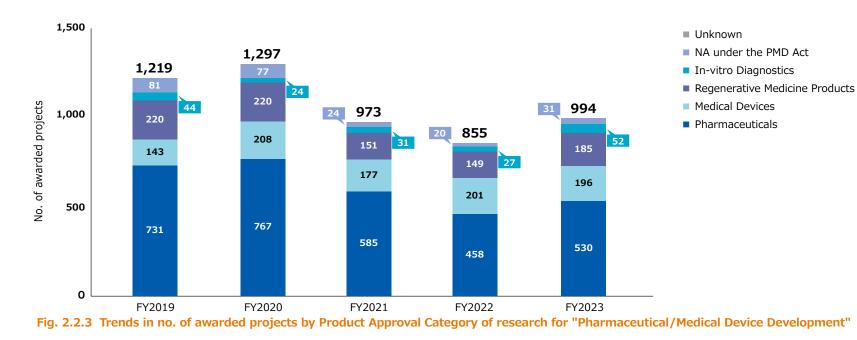


Table 2.2.2 Trends in no. of awarded projects by Product Approval Category of research for "Pharmaceutical/Medical Device Development"

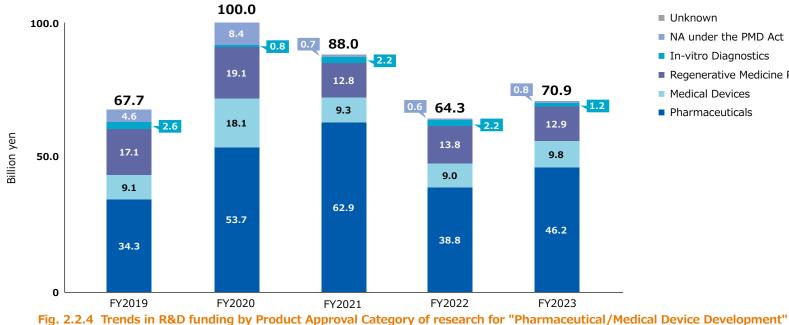
Product Approval Category	No. of awarded projects							
	FY2019	FY2020	FY2021	FY2022	FY2023			
Pharmaceuticals	731	767	585	458	530			
Medical Devices	143	208	177	201	196			
Regenerative Medicine Products	220	220	151	149	185			
In-vitro Diagnostics	44	24	31	27	52			
NA under the PMD Act	81	77	24	20	31			
Unknown	-	1	5	-	-			
Total	1,219	1,297	973	855	994			

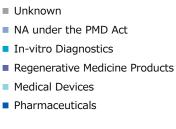
These data show the " Product Approval Categories" that are required to be attached to awarded projects for "Pharmaceutical/Medical Device Development."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Unknown" in the "Product Approval Category" have been omitted in the graph.

### **R&D Projects for Pharmaceutical/Medical Device Development**

### 2.2 By Product Approval Category 3) R&D Funding





#### Table 2.2.3 Trends in R&D funding by Product Approval Category of research for "Pharmaceutical/Medical Device Development"

Product Approval Category	R&D funding (Billion JPY)							
	FY2019	FY2020	FY2021	FY2022	FY2023			
Pharmaceuticals	34.3	53.7	62.9	38.8	46.2			
Medical Devices	9.1	18.1	9.3	9.0	9.8			
Regenerative Medicine Products	17.1	19.1	12.8	13.8	12.9			
In-vitro Diagnostics	2.6	0.8	2.2	2.2	1.2			
NA under the PMD Act	4.6	8.4	0.7	0.6	0.8			
Unknown	-	0.01	0.2	-	-			
Total	67.7	100.0	88.0	64.3	70.9			

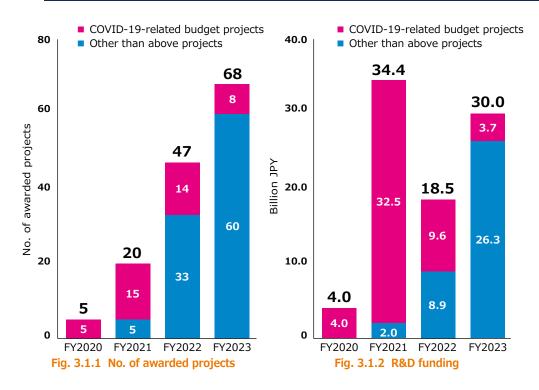
These data show the "Product Approval Categories" that are required to be attached to awarded projects for "Pharmaceutical/Medical Device Development."

Created based on AMED data (as of October 2024). Cyclic Innovation for Clinical Empowerment (CiCLE) is excluded from these figures because necessary information was not available. The numerical values for "Unknown" in the "Product Approval Category" have been omitted in the graph.

2.

3. Special Fund Programs

### 3.1 No. of Projects and R&D Funding (COVID-19, Research Institution)



#### Table 3.1.1 No. of awarded projects and R&D funding

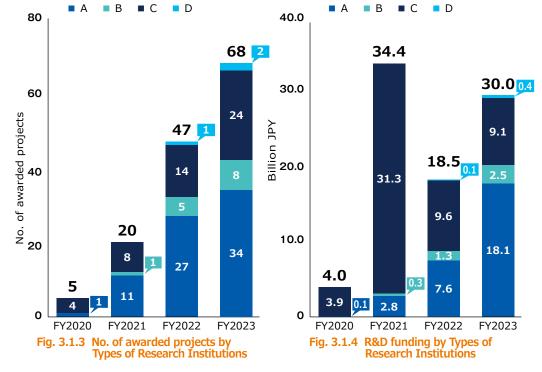
		FY2020			FY2021		FY2022			FY2023			
	AMED total			AMED total			AMED total			AMED total			
		Special prograr				Special fund programs		Special fund *1 programs				Special fund *1 programs	
			COVID -19 *2			COVID -19 *2			COVID -19 *2			COVID -19 *2	
No. of awarded projects	2,814	5	5	2,617	20	15	2,615	47	14	2,676	68	8	
R&D funding (Billion JPY)	177.9	4.0	4.0	177.7	34.4	32.5	160.9	18.5	9.6	166.4	30.0	3.7	

\*1 Among the "Special fund programs," AMED provided 6.4 billion JPY in funding for 22 projects in FY2022, and 22.1 billion JPY for 40 projects in FY2023 through the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA).

\*2 COVID-19-related budget projects

4

Created based on AMED data (as of October 2024).

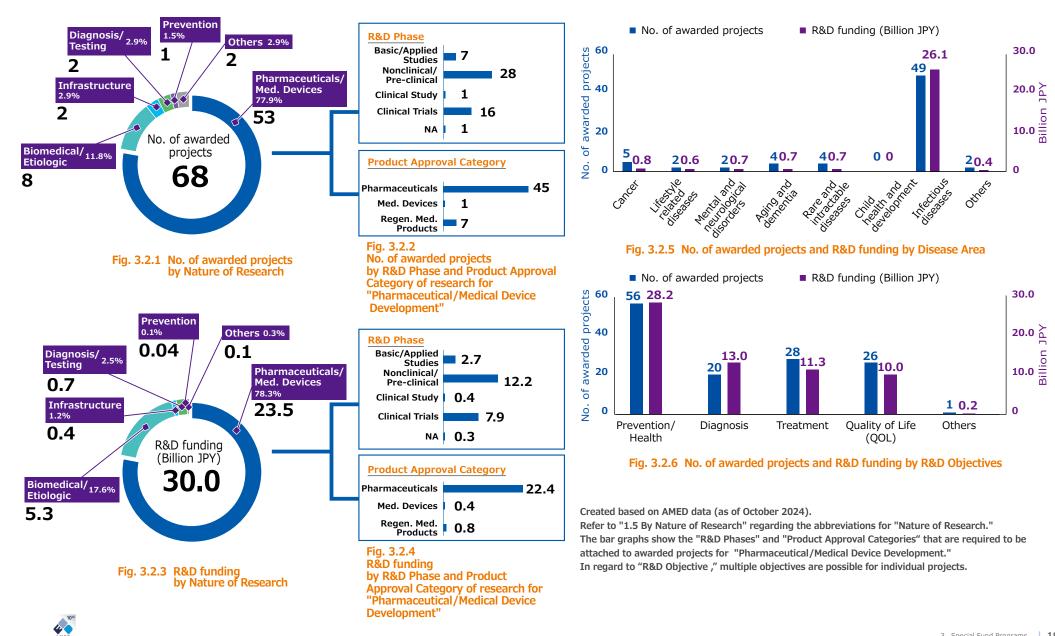


#### Table 3.1.2 No. of awarded projects and R&D funding by Types of Research Institutions

	FY2020		FY2021		FY2022		FY2023	
Type of Research Institution	No. of awarded projects	R&D funding (Billion JPY)	No. of awarded projects	R&D funding (Billion JPY)	No. of awarded projects	R&D funding (Billion JPY)	No. of awarded projects	R&D funding (Billion JPY)
Universities, etc. (A)	1	0.1	11	2.8	27	7.6	34	18.1
Incorporated Admin. Agencies/ Nat'l Research Institutes (B)	-	-	1	0.3	5	1.3	8	2.5
Companies, etc. (C)	4	3.9	8	31.3	14	9.6	24	9.1
Incorporated Foundations/ Associations, etc. (D)	-	-	-	-	1	0.1	2	0.4
Total	5	4.0	20	34.4	47	18.5	68	30.0

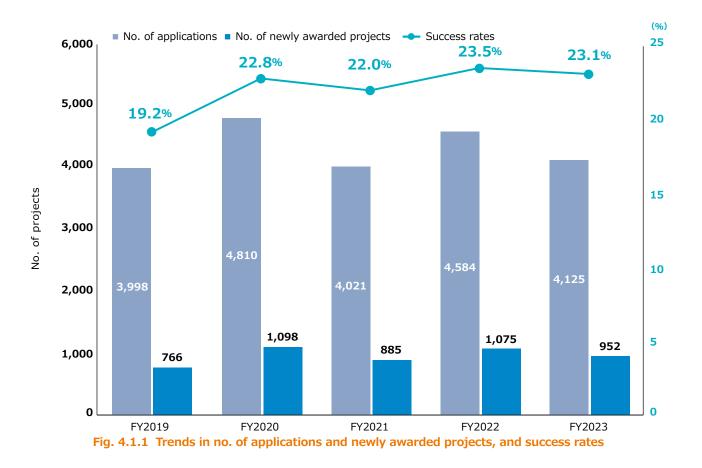
**Special Fund Programs** 3.

### 3.2 By R&D Categorial Tag : No. of Projects and R&D Funding in FY2023



4. Awarding of Projects by AMED and New Principal Investigators (PIs)

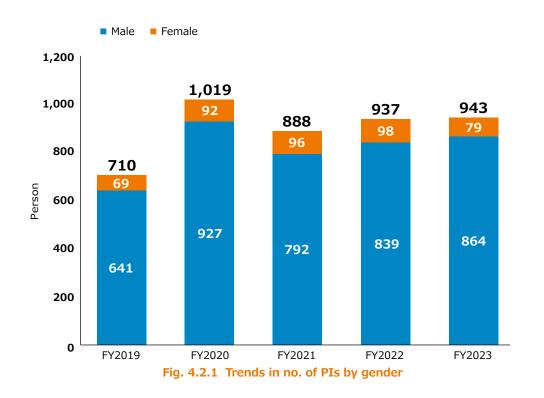
4.1 No. of Applications and Newly Awarded Projects, and Success Rates

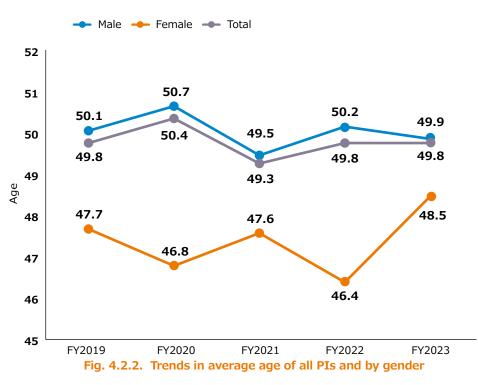


#### Table 4.1.1 Trends in no. of applications and newly awarded projects, and success rates

	FY2019	FY2020	FY2021	FY2022	FY2023
No. of applications	3,998	4,810	4,021	4,584	4,125
No. of newly awarded projects	766	1,098	885	1,075	952
Success rates	19.2%	22.8%	22.0%	23.5%	23.1%

Success rates are the percentage of all newly awarded projects to the number of applications. They were calculated based on calls for proposals information by AMED (as of October 2024). 4. Awarding of Projects by AMED and New Principal Investigators (PIs)
4.2 New Principal Investigators (PIs): No. by Gender and Average Age





#### Table 4.2.1 Trends in percentage of female PIs

	FY2019	FY2020	FY2021	FY2022	FY2023
Percentage of female PIs	9.7%	9.0%	10.8%	10.5%	8.4%

#### Table 4.2.2 Trends in average age of PIs

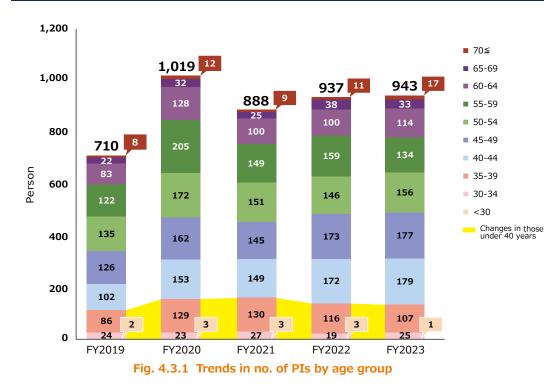
	FY2019	FY2020	FY2021	FY2022	FY2023
Male	50.1	50.7	49.5	50.2	49.9
Female	47.7	46.8	47.6	46.4	48.5
Total	49.8	50.4	49.3	49.8	49.8

The newly awarded projects for a certain fiscal year are the projects launched in that fiscal year.

The number of PIs is the aggregate number for the newly awarded projects in each fiscal year, and their ages are as of the start of each fiscal year of research launch based on their birth dates. The figures and tables were produced using data for awarded projects from the Cross-ministerial R&D Management System (e-Rad) (all as of October 2024). Note that data for which gender and birth date are unknown have been omitted.

Awarding of Projects by AMED and New Principal Investigators (PIs) 4.

4.3 New Principal Investigators (PIs): No. by Age Group 1) Total



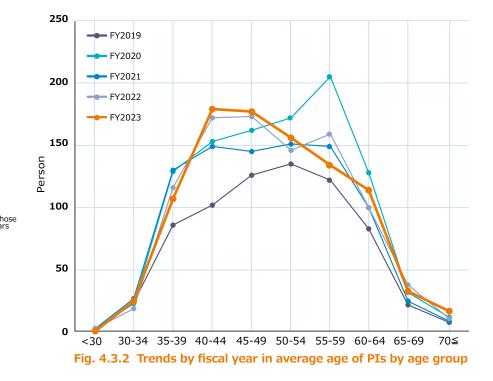


Table 4.3.	Table 4.3.1 Trends in no. of PIS by age group				
Age group	FY2019	FY2020	FY2021	FY2022	FY2023
<30	2	3	3	3	1
30-34	24	23	27	19	25
35-39	86	129	130	116	107
40-44	102	153	149	172	179
45-49	126	162	145	173	177
50-54	135	172	151	146	156
55-59	122	205	149	159	134
60-64	83	128	100	100	114
65-69	22	32	25	38	33
70≦	8	12	9	11	17
Total	710	1,019	888	937	943

### Table 4.3.1 Trends in no. of PTs by age group

The newly awarded projects for a certain fiscal year are the projects launched in that fiscal year.

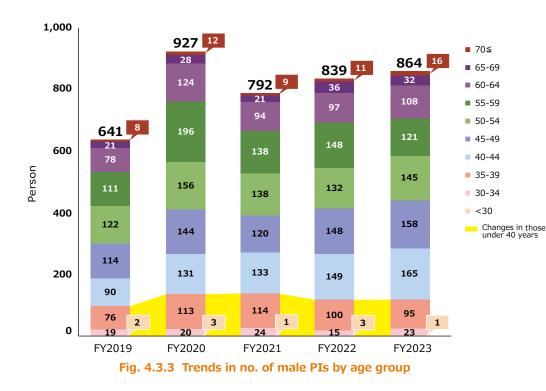
They were calculated by age group based on the number of PIs is the aggregate number for the newly awarded projects in each fiscal year, and their ages are as of the start of each fiscal year of research launch based on their birth dates.

The figures and tables were produced using data from the Cross-ministerial R&D Management System (e-Rad) awarded projects (all status, as of October 2024).

Note that data for which gender and birth date are unknown have been omitted.

4. Awarding of Projects by AMED and New Principal Investigators (PIs)

4.3 New Principal Investigators (PIs): No. by Age Group 2) Male PIs



	250	
		FY2019
		FY2020
	200	FY2021
		•• FY2022
		•• FY2023
	150	
	Person	
	Per	
	100	
2		
	50	
	0	<30 30-34 35-39 40-44 45-49 50-54 55-59 60-64 65-69 70≦
	Fig	. 4.3.4 Trends by fiscal year in average age of male PIs by age group

Table 4.3.2	Trends	in no. of	male PIs	by a	ige group	

Age group	FY2019	FY2020	FY2021	FY2022	FY2023
<30	2	3	1	3	1
30-34	19	20	24	15	23
35-39	76	113	114	100	95
40-44	90	131	133	149	165
45-49	114	144	120	148	158
50-54	122	156	138	132	145
55-59	111	196	138	148	121
60-64	78	124	94	97	108
65-69	21	28	21	36	32
70≦	8	12	9	11	16
Total	641	927	792	839	864

The newly awarded projects for a certain fiscal year are the projects launched in that fiscal year.

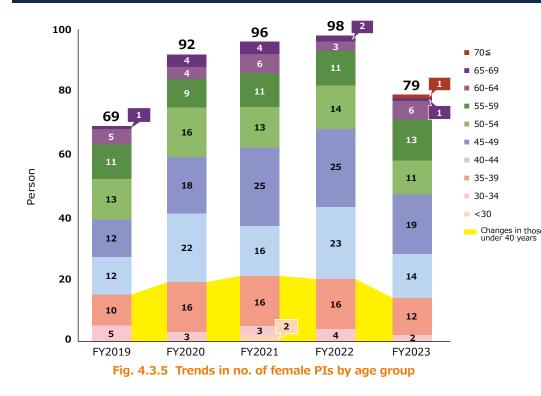
They were calculated by age group based on the number of PIs is the aggregate number for the newly awarded projects in each fiscal year, and their ages are as of the start of each fiscal year of research launch based on their birth dates.

The figures and tables were produced using data from the Cross-ministerial R&D Management System (e-Rad) awarded projects (all status, as of October 2024).

Note that data for which gender and birth date are unknown have been omitted.

#### Awarding of Projects by AMED and New Principal Investigators (PIs) 4.

4.3 New Principal Investigators (PIs): No. by Age Group 3) Female PIs



		30	
		50	FY2019
			FY2020
		25	- FY2021
			- FY2022
		20	FY2023
	u		
	Person	15	
	Δ.		
se		10	
		10	
		5	
		0	
		U	<30 30-34 35-39 40-44 45-49 50-54 55-59 60-64 65-69 70≦
		Fig.	<b>4.3.6</b> Trends by fiscal year in average age of female PIs by age group

Table 4.3.	Table 4.3.5 Trends in no. of female PIs by age group				
Age group	FY2019	FY2020	FY2021	FY2022	FY2023
<30	0	0	2	0	0
30-34	5	3	3	4	2
35-39	10	16	16	16	12
40-44	12	22	16	23	14
45-49	12	18	25	25	19
50-54	13	16	13	14	11
55-59	11	9	11	11	13
60-64	5	4	6	3	6
65-69	1	4	4	2	1
70≦	0	0	0	0	1
Total	69	92	96	98	79

The newly awarded projects for a certain fiscal year are the projects launched in that fiscal year.

They were calculated by age group based on the number of PIs is the aggregate number for the newly awarded projects in each fiscal year, and their ages are as of the start of each fiscal year of research launch based on their birth dates.

The figures and tables were produced using data from the Cross-ministerial R&D Management System (e-Rad) awarded projects (all status, as of October 2024).

Note that data for which gender and birth date are unknown have been omitted.

## 5. Supplementary Notes5.1 Types of Research Institutions

#### Table 5.1 Types of Research Institutions

Category in the DataBook	Type of entity					
	National universities					
Universities, etc.	Public universities					
onversities, etc.	Private universities					
	Inter-University Research Institute Corporations, etc.					
Incorporated Admin. Agencies/	Incorporated Administrative Agencies					
Nat'l Research Institutes	National Research Institutes					
	Companies					
Companies, etc.	Medical Corporations, Social Welfare Corporations, etc.					
	Local public entities					
Local public entities, etc.	Local Incorporated Administrative Agencies					
	Incorporated Foundations					
Incorporated Foundations/Associations, etc.	Incorporated Associations					
incorporated Foundations/Associations, etc.	Public Interest Corporations					
	Special Corporations and Specially-authorized Corporations					
	Religious Corporations					
Others	Overseas institutions					
	Others					

From FY2022 junior colleges and colleges of technology have been moved from the "Others" to "Universities."

### 5.2 Glossary

Term	Description	Term	Description
Awarded project	A general term for R&D projects and their equivalents that are funded by AMED including projects conducted at subsidiary institutions or other subcontracted institutions under projects selected by AMED.	Disease Area	The seven disease areas stipulated in the sec Healthcare Policy as being social issues in contempo and future Japanese society with a view to demogra movement in the year 2040. In the DataBook, in event that an awarded project does not fit into an
OVID-19-related	Refers to the COVID-19-related R&D projects that AMED		the seven categories or if it is not research regarding
oudget projects	supported with supplementary budgets for COVID-19		specific disease area, it is treated as "Others."
	countermeasures.		· Cancer
	The COVID-19-related budget projects in the DataBook are based on "AMED R&D Regarding COVID-19		Lifestyle related diseases
	Countermeasures"		(including circulatory system and diabetes) <ul> <li>Mental and neurological disorders</li> </ul>
	https://www.amed.go.jp/content/000112086.pdf		Aging and dementia
	(Japanese language only.)		· Rare and intractable diseases
			<ul> <li>Child health and development</li> </ul>
Cyclic Innovation for Clinical Empowerment	Through the provision of large-scale and long-term loans (in principle up to 10 years with a ceiling of 10 billion		• Infectious diseases (including AMR)
CiCLE)	JPY) to bear the burden of technology risks by AMED,	ICD-10 Disease	ICD is an abbreviation of "International Statis
	AMED is promoting the creation of an infrastructure for innovation to accelerate the R&D and practical	Classification	Classification of Diseases and Related Health Proble created and endorsed by the World Health Organiz
	application of pharmaceuticals, medical devices and		(WHO), and ICD-10 is its 10th revised version.
	other medical products.		Ministry of Health, Labour and Welfare of Japan curr
			compiles the "detailed list of statistical classifica

of diseases, injuries and causes of death (FY2013 version)," derived from ICD-10 (2023 version), to register the statistical data and medical records in Japan. AMED uses the ICD-10 large categories (chapters) as "Target Disease" categorial tags for the AMED R&D projects. In the DataBook, the ICD-10 category (chapter) of "Neoplasms" is shown as "Cancer (Neoplasms)." Note that in ICD-10 codes for special purposes are used for the provisional assignment of new diseases of uncertain etiology or emergency use, and these include COVID-19. In the DataBook, they are shown as

"COVID-19."



Term	Description	Term	Description
Integrated Projects (second term)	The six integrated projects centering on modalities, stipulated in the second Healthcare Policy.	Nature of Research	A categorial tag to classify the "Nature of Research" of individual awarded projects, uniquely defined by AMED. Eight categories are listed as below.
	<ol> <li>Project for Advanced Drug Discovery and Development</li> <li>Project for Medical Device and Healthcare</li> <li>Project for Regenerative Medicine and Cell and Gene</li> </ol>		<ul> <li>Pharmaceutical/Medical Device Development (including development of systems linking to medical device development)</li> </ul>
	Therapies		Basic Biomedical/Etiologic Studies
	<ul><li>4) Project for Genome and Health-Related Data</li><li>5) Project for Basic Medical Research</li></ul>		<ul> <li>Fact-finding Survey Analysis (including fieldwork, surveillances, and monitoring)</li> </ul>
Medium- to long- erm plan	6) Project for Seeds Development and Research Base AMED, as a Japanese National Research and Development Agency, is set to launch a medium- to		<ul> <li>Medical Technique/Standard Therapy Development (including evidence building to improve the quality of medical care by compilation of guidelines and other methods)</li> </ul>
term plan	long-term plan to achieve its objectives, and this is stated in Article 35-5 of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999). The period of AMED's first medium- to long-term plan was from FY2015 to FY2019, and the period of the second medium- to long-term plan was from FY2020 to FY2024. First and Second medium- to long-term plan: https://www.amed.go.jp/koukai/kouhyou.html#anc-3 (Japanese language only.)		<ul> <li>Research/Drug Discovery Infrastructure Development (including drug discovery technologies, ICT infrastructure and platforms)</li> </ul>
			<ul> <li>Regulatory/Nursing System Improvement and Technical Support (including advancement of technology supports for the international health system)</li> </ul>
			<ul> <li>Development, Establishment, and Validation of New Diagnostic/Testing Methods and Systems (excluding development of diagnostic drugs and equipment)</li> </ul>
			<ul> <li>Evidence Building for Prevention (including epidemiology studies)</li> </ul>
		Principal Institution/ Principal Investigator (PI)	Principal institution/Principal Investigator (PI) of R&D projects awarded by AMED



Term	Description	Term	Description
Product Approval Category	One of the categorial tags for AMED R&D projects. It is attached to one of the four items eligible for AMED R&D support (Pharmaceuticals, Medical devices, Regenerative medicine products, and In-vitro diagnostics) from among the items defined in Article 2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Devices Act: PMD Act). The attachment of categorial tags is necessary when the "Nature of Research" is "Pharmaceutical/Medical Device Development," but the attachment of categorial tags is optional for projects of different "Nature of Research."	Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response(SCARDA)	Based on the na the Vaccine Deve the Strategic Cent Research and De Response (SCARD/ 2022, with the mis funding and to pror centers. In anticipation of fi support is provid allocation of budge with rapid and agi the event of an infe
R&D Objective	One of the categorial tags for AMED R&D projects. The "R&D objectives" for the main research themes are categorized into the following four. • Prevention/Health • Diagnosis • Treatment • Quality of Life (QOL) If R&D projects do not fit into any of the above four or do not have any specific "R&D objective", they are treated as "Others."	Second Healthcare Policy	Pursuant to Article Advancement Act Policy was stipulate a comprehensive a the government s and the creation of society in which p in order for the es public can live hea (a society in which
d Phase	One of the categorial tags for AMED R&D projects. The "R&D phase" of R&D support is categorized into Basic Study, Applied Study, Nonclinical Study/Pre-clinical Study, Clinical Study, Clinical Trials, Post Marketing, and Observational Study, etc. The attachment of categorial tags is necessary when the "Nature of Research" is "Pharmaceutical/Medical Device Development," but the attachment of categorial tags is optional for projects of different "Nature of Research."		The Second Policy FY2024 as the pe the Cabinet on Mar April 9, 2021).



Term	Description
Special Fund Programs	Programs that are established pursuant to the Act on Improving the Capacity, and the Efficient Promotion of Research and Development through Promotion of Research and Development System Reform. The programs secure in advance the financial resources for several years, thus enabling flexible support for their stable and efficient implementation.
The Cross-ministerial R&D Management System(e-Rad)	The Cross-ministerial R&D Management System. This is a cross-ministerial system to put online the series of processes regarding R&D management (receipt of application => review => selection => awarded project management=> accomplishment report) centering on the competitive research funding system, which went into operation from January 2009. https://www.e-rad.go.jp/en/



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