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
AMED

AMED Data Book

First Medium- to Long-Term Plan

(FY 2015 to 2019)

Contents

Overview of the
Japan Agency for Medical Research and Development (AMED)

Objectives

The Japan Agency for Medical Research and Development (AMED) aims to act as a 'control tower' directing integrated research, from basic research to practical application. Furthermore, with Japan poised to become the world's first ultra-aging society, one of the important objectives of AMED is to promote the development of the world's most advanced medical technologies and services, to enable the Japanese people to live the longest and healthiest lives in the world. AMED also aims to become a pillar of Japan's economy by fostering development in the fields of medicine, drugs, and medical devices as strategic industries.

Established: April 1, 2015

Executive Officers (as of April 1, 2021)

President: MISHIMA Yoshinao
Executive Director: JO Katsufumi
Auditor (part-time): INABA Kayo, SHIRAYAMA Shinichi

President Mishima

Number of staff (as of January 1, 2021): 595 (including part-time staff)

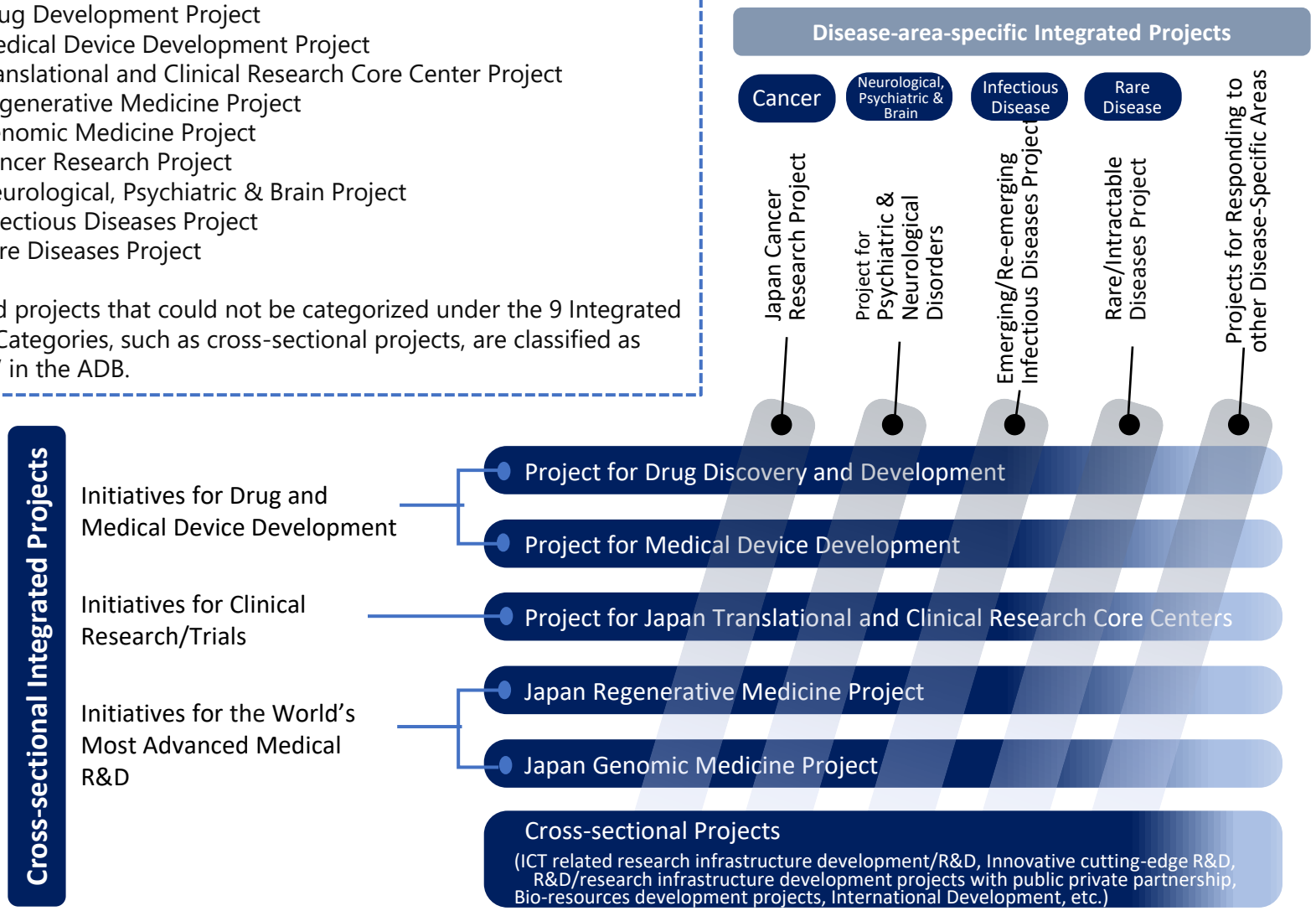
Budget (FY 2020) : 126.8 billion JPY (1.15 billion USD)

Nine Integrated Project Categories during AMED's First 5-Year Term

Nine Integrated Project Categories during AMED's First 5-Year Term:

1. Drug Development Project
2. Medical Device Development Project
3. Translational and Clinical Research Core Center Project
4. Regenerative Medicine Project
5. Genomic Medicine Project
6. Cancer Research Project
7. Neurological, Psychiatric & Brain Project
8. Infectious Diseases Project
9. Rare Diseases Project

Awarded projects that could not be categorized under the 9 Integrated Project Categories, such as cross-sectional projects, are classified as "Others" in the ADB.



Data used in the AMED Data Book (ADB)

The Japan Agency for Medical Research and Development (AMED) operates an in-house database named the “AMED Management System (AMS),” which is developed with the purpose of effective management of AMED’s funding scheme, as well as to promote the overall planning of Japan’s medical R&D funding. Data in this book are derived from the AMS database, with the single exception of 1-1. AMS accumulates information from contracts with supporting institutions.

Section 1. “Basic Statistics” illustrates fundamental figures during the first 5-year period of the Plan after the launch of AMED in April 2015. The tables and diagrams listed in this section show the number of research projects operated by three types of researchers (PIs, co-investigators, or subcontractors), amount of funding, research duration, and institutional classifications.

"Number of awarded projects" represents the number of projects/funds awarded to principal investigators (PIs). “Awards” include other form of research operated by co-investigators or subcontractors, within a framework of R&D projects collaborating/contracting with the PIs. Numbers of awarded projects and awards are counted on an annual basis, therefore, in case an award continues over multiple years, the number of the award is multiplied by the years of research in operation.

The amount funded is the final contracted value in JPY (including indirect expenses, at the end of each fiscal year (FY), including support distributed to co-investigating researchers and institutions, as well as any amount forwarded to subcontracted collaborators by the PIs.

Section 2. “Principal Investigators" refers to the data of researchers registered in the Cross-Ministerial Research and Development Management System (e-Rad) of Japan.

Section 3. “Awarded Projects and Funding" analyzes awarded projects using the keyword tags added to the basic contract information from the AMS database, to understand a broad perspective of medical R&D support by AMED. In addition to the 9 Integrated Project Categories from the first 5 years, the tags examined in the ADB are: Classifications of Disease, AMS Research Categories, product application categories, and developmental stage. These tags are classified into one single category for each awarded project, even if it covers several research areas and diseases.

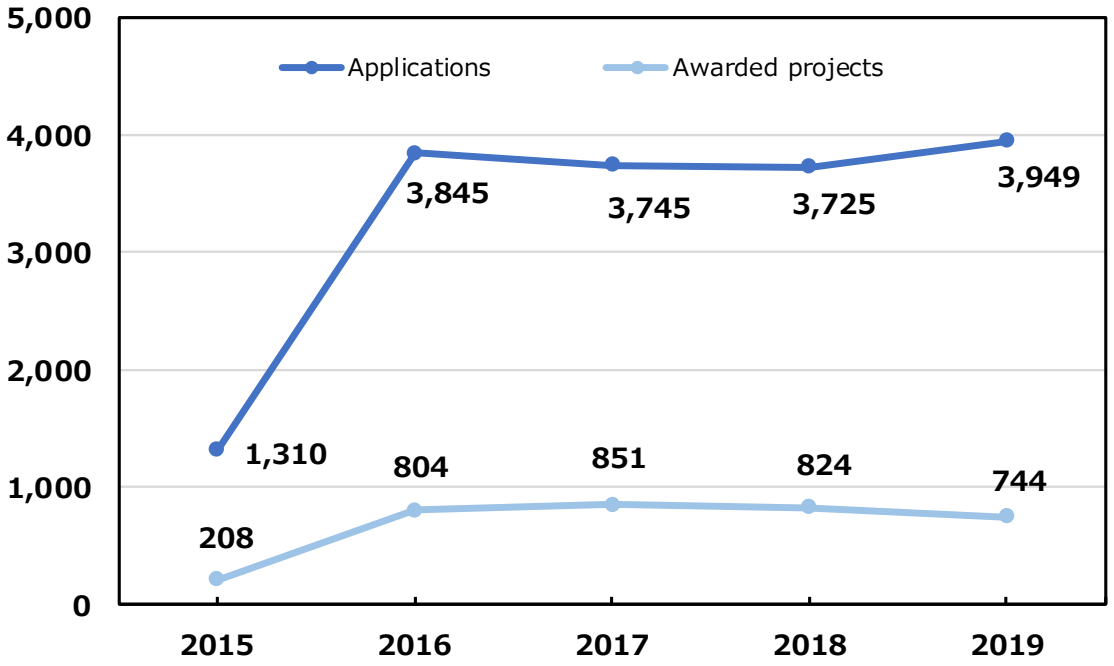
Section 4. "Examples of Analyses using Data from the AMED Management System" introduces cross investigations with AMS keyword tags.

The ADB handles three different datasets for the confirmed statistics for the 5-year term, from 2015 to 2019, by the date the data were extracted from the AMS database. This arrangement is due mainly to AMS update procedures. It is necessary to allow a certain number of months to verify the data accuracy and add adequate tags to analyze the outcomes.

The dates on which each datasets downloaded are: (1) Section 1 and 3: January 27, 2021; (2) Section 2: September 23, 2020; (3) Section 4: February 17, 2021.

1. Basic Statistics

1.1. Number of applications, awarded projects, and success rate



FY	2015	2016	2017	2018	2019
Applications	1,310	3,845	3,745	3,725	3,949
Awarded projects	208	804	851	824	744
Success rate	15.9%	20.9%	22.7%	22.2%	18.8%

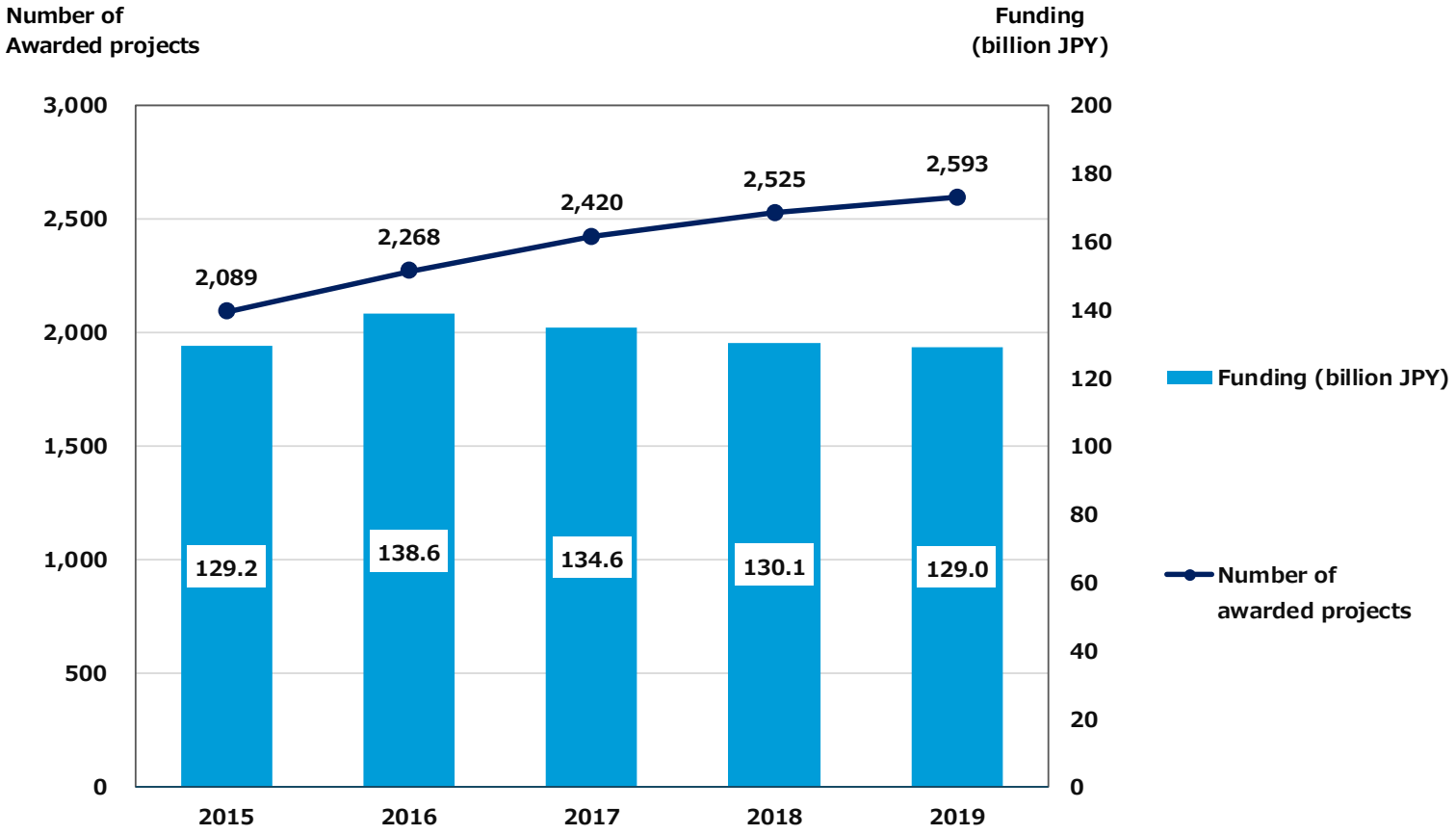
Source: Data provided at AMED HP and other materials

Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

FY 2015 excludes applications and projects awarded prior to the launch of AMED. These research projects are transferred from the ministries which organized the Call for Proposals and decided to adopt for FY 2015.

Success rate (%): Number of awarded projects/Number of applications.

1.2. Number of awarded projects, amount of funding, and funding per awarded project



Fiscal Year	2015	2016	2017	2018	2019	Total
Number of awarded projects	2,089	2,268	2,420	2,525	2,593	11,895
Funding (billion JPY)	129.2	138.6	134.6	130.1	129.0	661.5
Average of funding per awarded project (million JPY)	61.9	61.1	55.6	51.5	49.7	55.6

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of awarded projects and the amount of funding in JPY shown are the total for each fiscal year (FY).

The numbers are the sums of the awarded projects, both newly awarded projects and those continued from the previous year.

1.3. Number of new awarded projects by research duration

Number of new awarded projects by research duration

Research duration	2016	2017	2018	2019	Total	Percentage
less than 12 months	99	104	98	70	371	10.7%
12 to 23 months	169	104	126	127	526	15.1%
24 to 35 months	193	316	239	205	953	27.4%
36 to 47 months	220	264	301	263	1,048	30.1%
48 to 59 months	59	83	18	74	234	6.7%
60 to 71 months	132	127	32	38	329	9.5%
more than 6 years	1	12	2	0	15	0.4%
Total	873	1,010	816	777	3,476	100.0%
Research duration (average)	2years 9months	2years 11months	2years 5months	2years 8months	2years 9months	-

Median research duration: 2 years 11 months

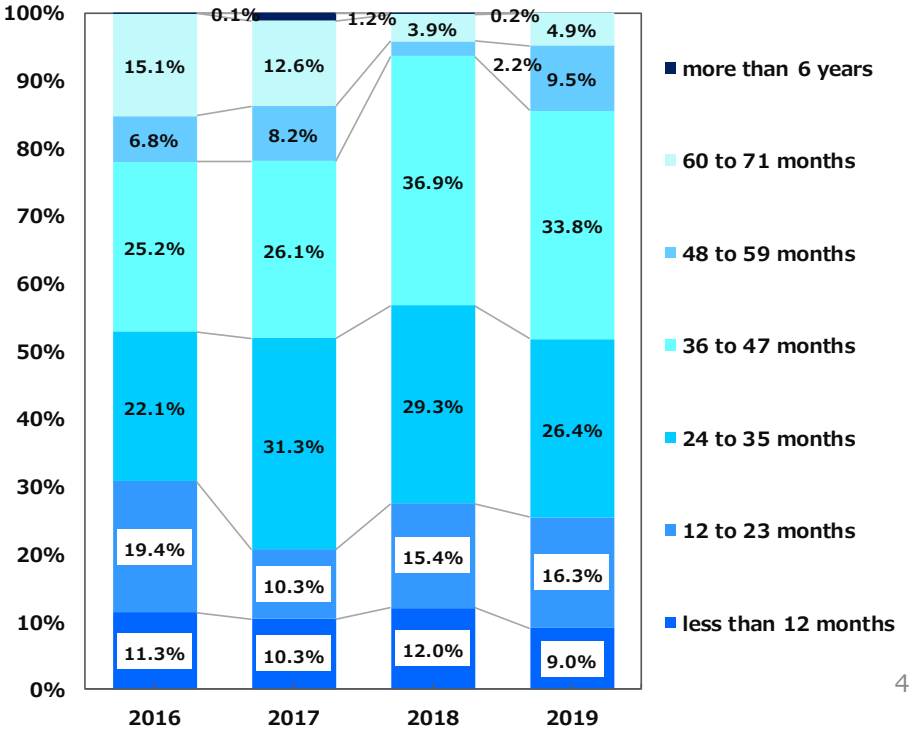
Numbers represents the number of awarded projects starting in each FY.

FY 2015 is not in the table, because FY2015 awards are combination of projects awarded prior to the launch of AMED.

Percentages are relative to the total ~~of~~ number of awarded projects (100%) in each FY.

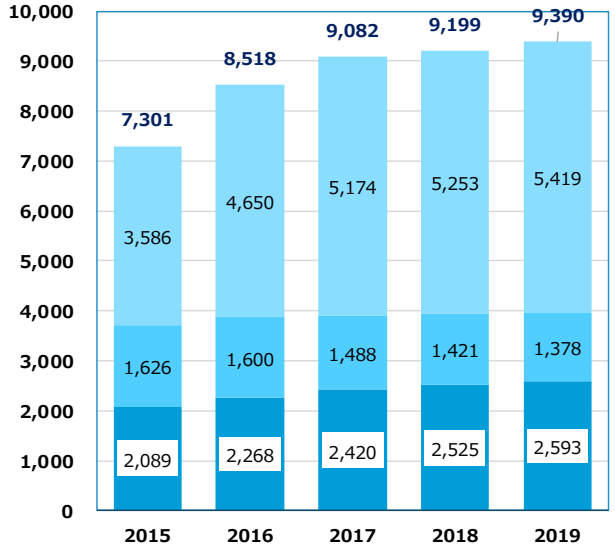
Source: AMS (As of January 27, 2021).
Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

Percentage of newly awarded projects by research duration

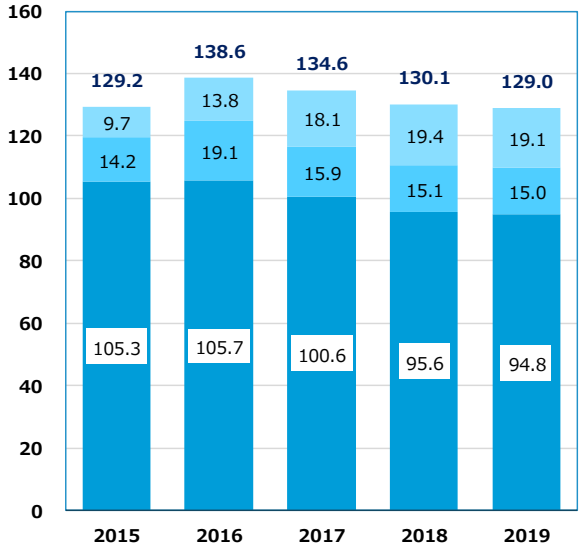


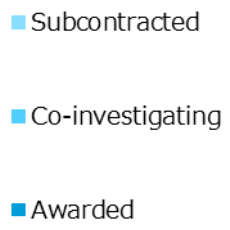
1.4. Research projects by type: 1) Number of research projects and amount of funding

Number of research projects

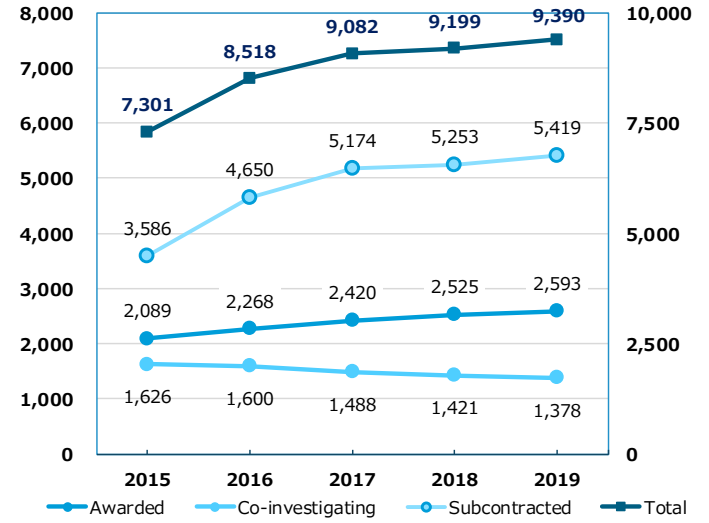


Amount of funding (billion JPY)

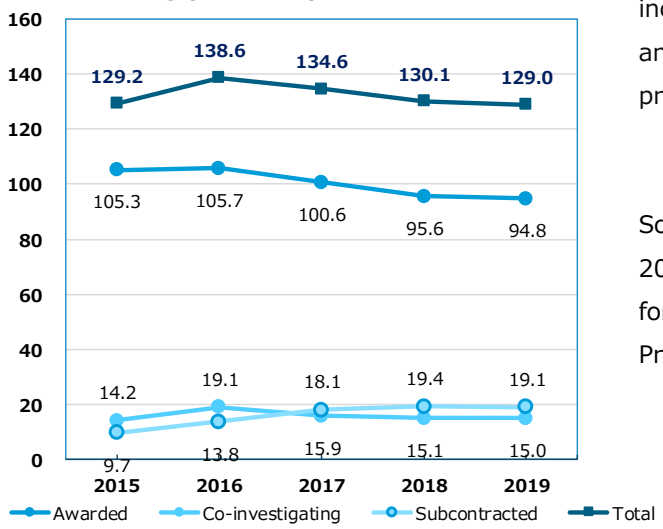




Number of research projects (Total)



Amount of funding (billion JPY)



The numbers and the amounts are for the total number of projects, including newly awarded projects, and projects continued from the previous year.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

Description of the types of research projects

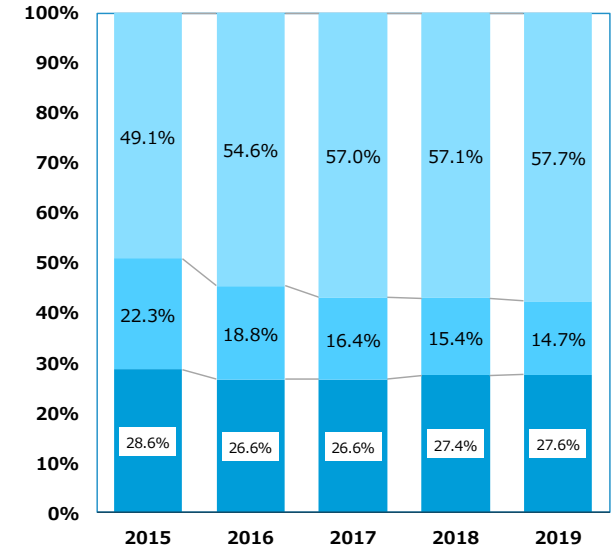
Awarded project: Project awarded by AMED, which is organized by a Principal Investigator (PI).

Co-investigating research project: Project conducted by collaborating institutions. The research contract is made between the institution and AMED.

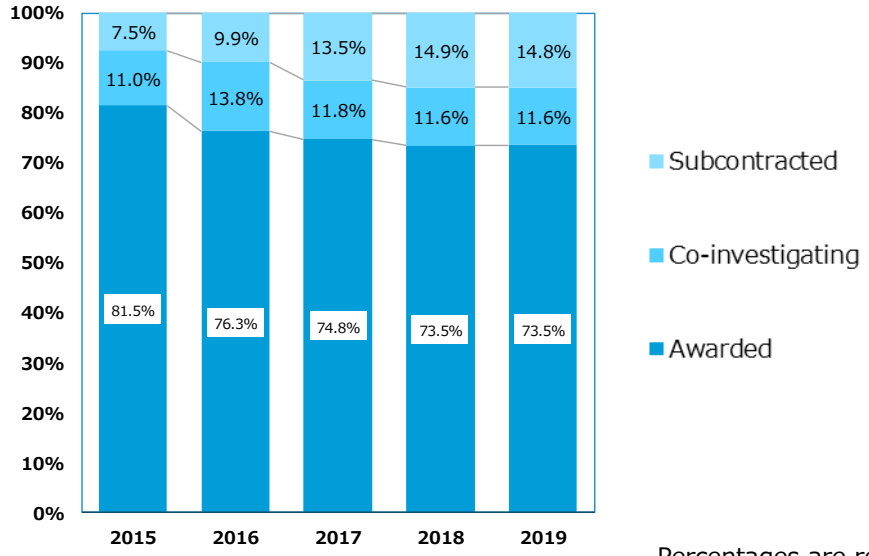
Subcontracted research project: Project conducted by sub-commissioned institutions. The research contract is made between the institution and the PI.

1.4. Research projects by type: 2) As a percentage of all research projects and funding

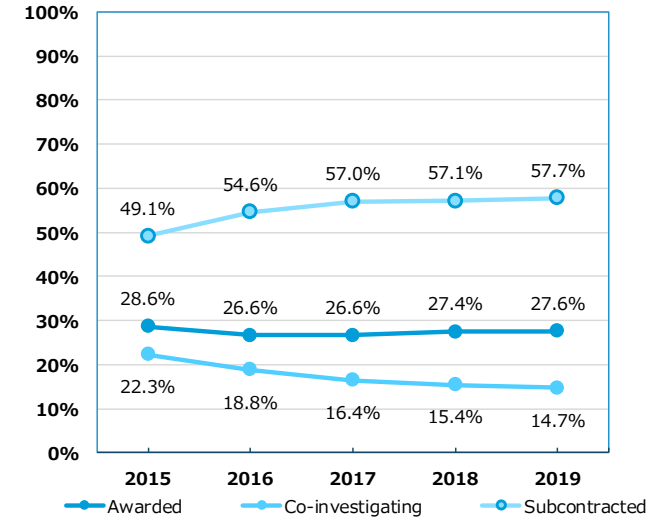
Number of research projects (%)



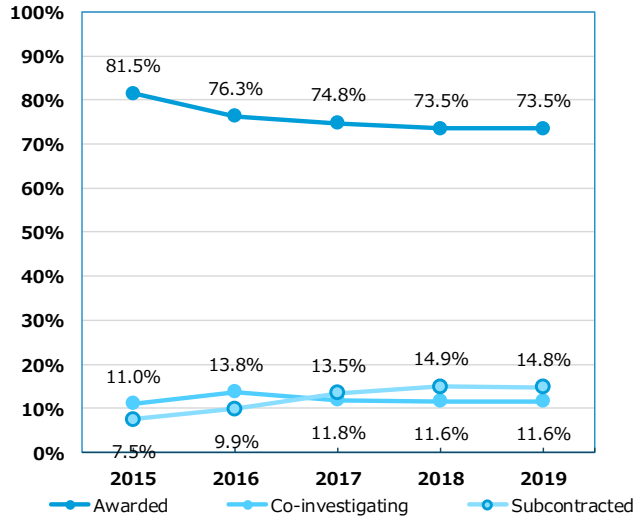
Amount of funding (%)



Number of research projects (%)



Amount of funding (%)



Percentages are relative to the total of number of projects awarded (100%) in each FY.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

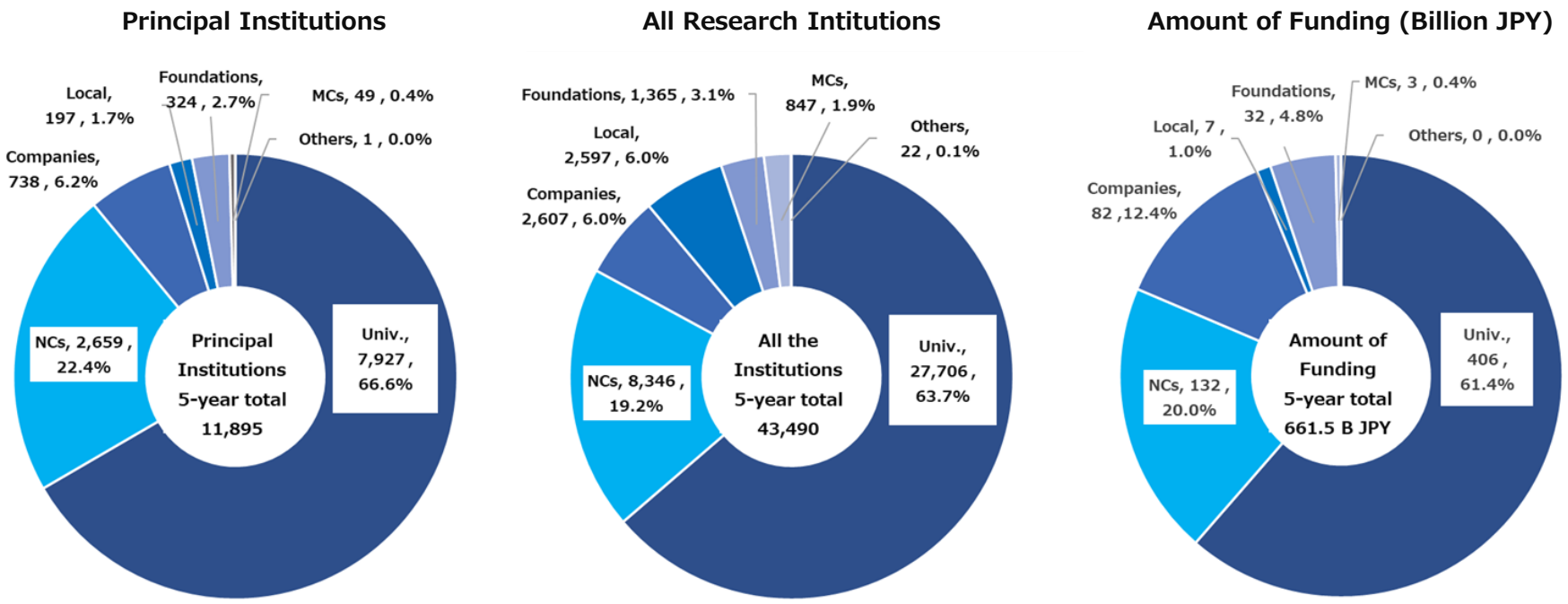
Description of the types of research projects

Awarded project: Project awarded by AMED, which is organized by a Principal Investigator (PI).

Co-investigating research project: Project conducted by collaborating institutions. The research contract is made between the institution and AMED.

Subcontracted research project: Project conducted by sub-commissioned institutions. The research contract is made between the institution and the PI.

1.5. Research projects and funding by the type of institution: 1) 5-year total



Principal institutions (left): Institutions to which the principal investigators are affiliated.

All Research Institutions (middle): Institutions participating in AMED-funded R&Ds, including awarded, co-investigating, and subcontracted projects.

Number of institutions (left and middle): Aggregated total number of institutions in which the research projects in each FY were conducted.

Amount of funding (right): Aggregated fund amount received by each institution to conduct R&D supported by AMED.

Classifications of institutions

Abbreviations used in the charts above are expanded and shown in parentheses below. For more details, see also "Classification of research institutions" page 16.

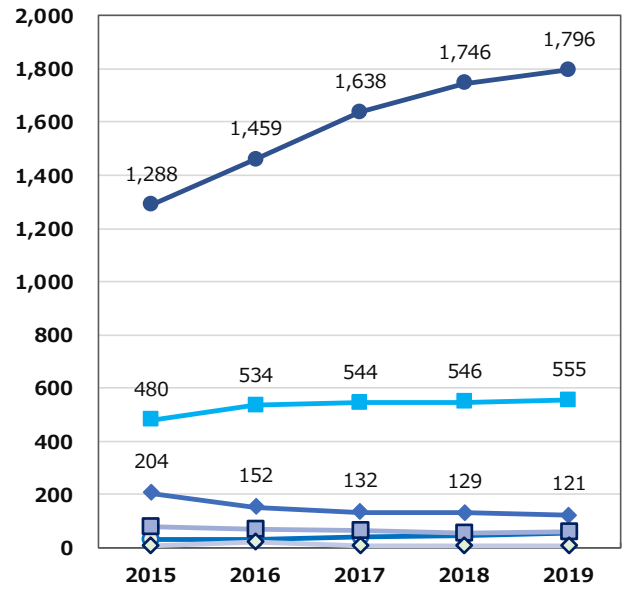
1) Universities (Univ.) ; 2) Incorporated Administrative Agencies and National Research and Development Corporations (NCs); 3) Companies; 4) Local public entities (Local); 5) Foundations and associations (Foundations); 6) Medical Corporations and Social Welfare Corporations (MCs).

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

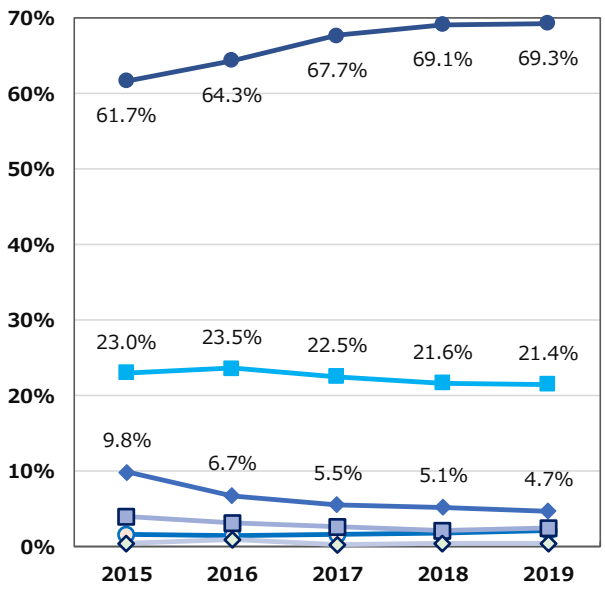
1.5. Research projects and funding by the type of institution:

2) Type of research projects (awarded, co-investigating and subcontracted)

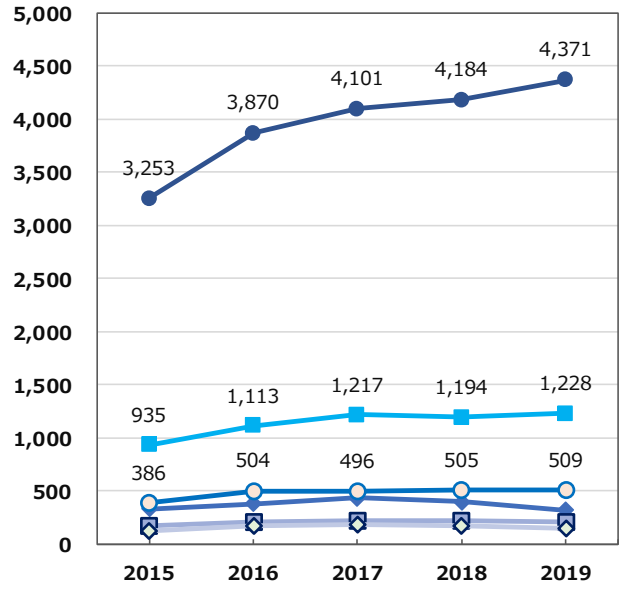
Principa Institutions



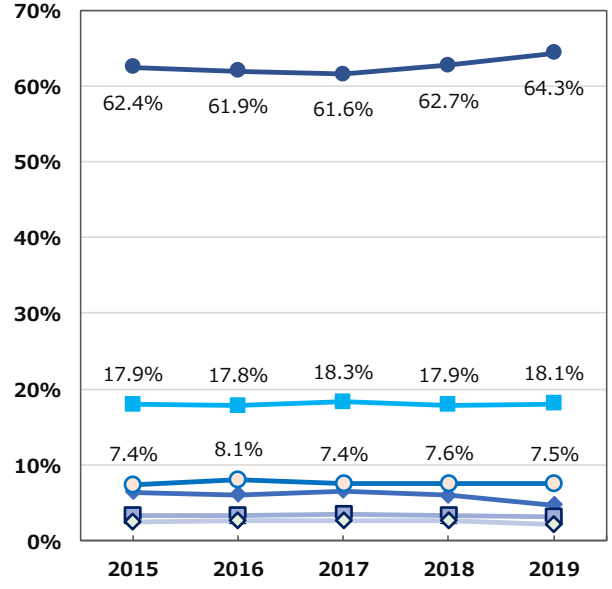
Principal Institusions (%)



Co-investigating/Subcontracted Institusions



Co-investigating/Subcontracted Institusions (%)

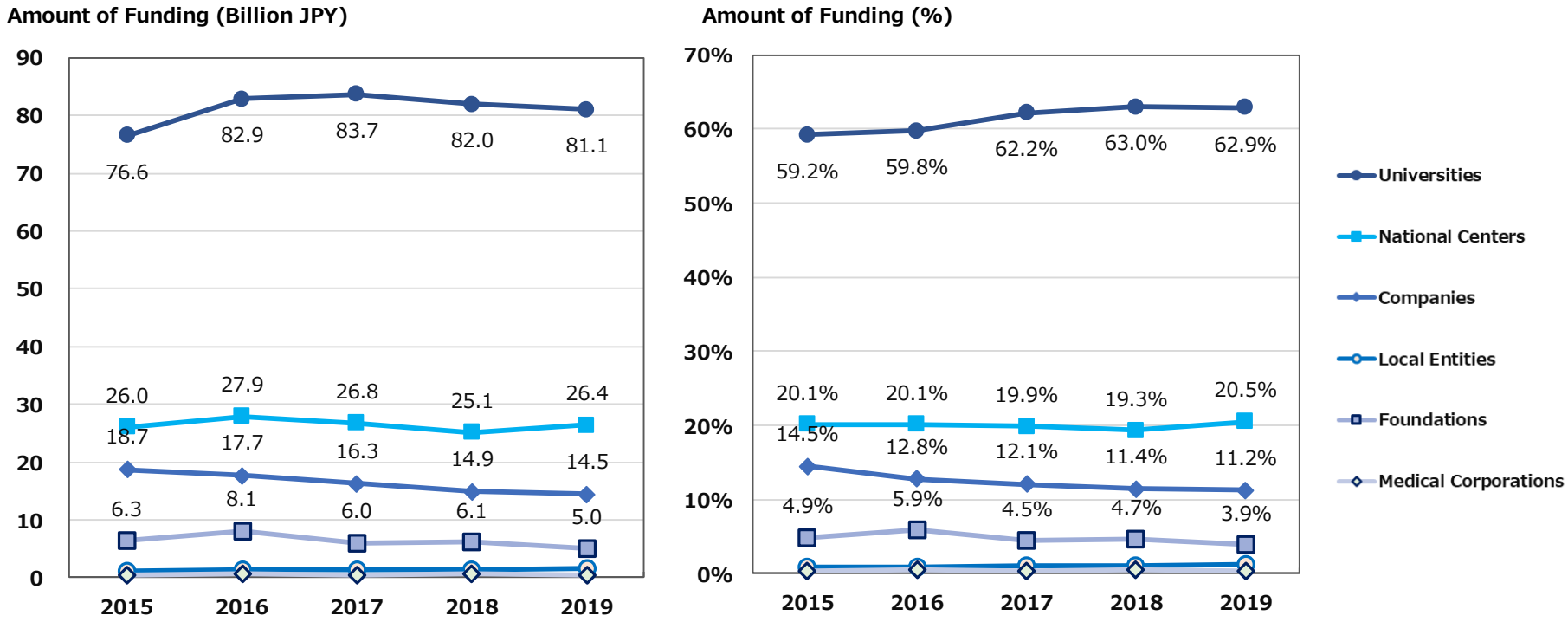


The principal institutions (upper 2 diagrams) are institutions to which the PIs of the R&D projects funded by AMED are affiliated.
Co-investigating/Subcontracted institutions (lower 2 diagrams) undertake the R&D projects funded by AMED in collaboration with or under subcontracts with the PIs.

Percentages are relative to the total number of institutions (100%) that undertook the R&D projects in each FY.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

1.5. Research projects and funding by the type of institution: 3) As a percentage of all research projects



The amount of funding refers to the ~~is~~ sum of the funds received by each institution.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

"Other" is not in the diagram.

Types of research institutions in the ADB

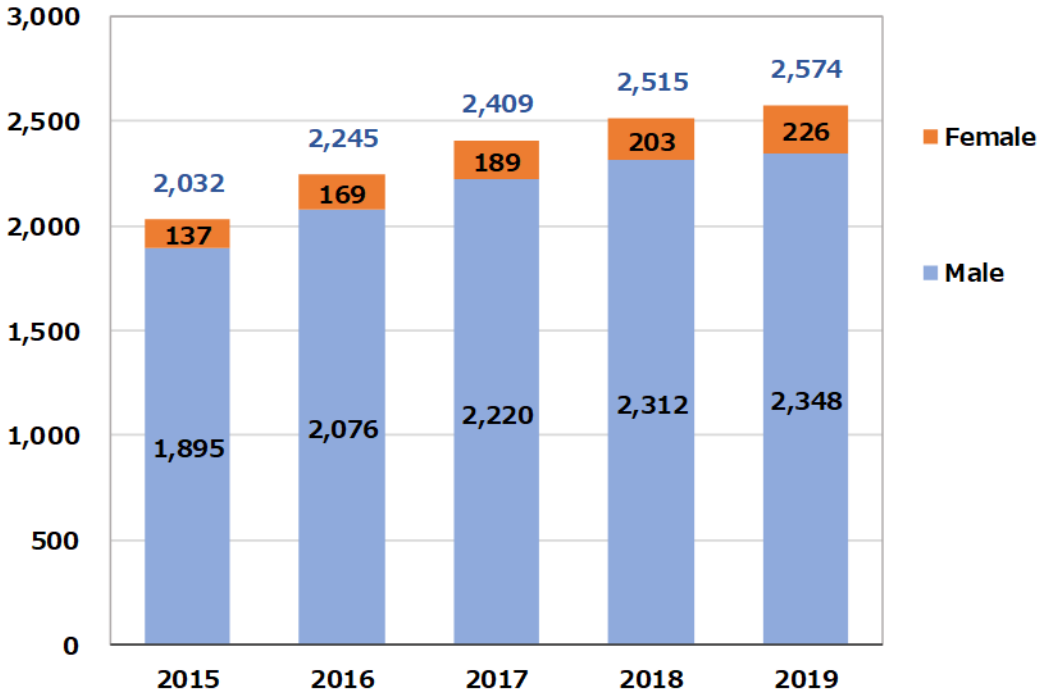
The types of research institutions in the ADB is based on the Cross-Ministerial Research and Development Management System (e-Rad) of Japan, with necessary adjustments made with regard to medical R&D institutions.

Abbreviations in parentheses

- “University (Univ.)" includes university hospitals and National Defense Medical College.
- “Incorporated Administrative Agencies and National Research and Development Institutes (NCs)” includes six National Centers for Advanced and Specialized Medicine in Japan (National Cancer Center, National Cerebral and Cardiovascular Center, National Center for Neurology and Psychiatry, National Center for Global Health, National Center for Child Health and Development, and National Center for Geriatrics and Gerontology), National Research and Development Agency research institutes (RIKEN, etc.), National Research and Development Institute (such as National Institute of Health Sciences, National Institute of Infectious Diseases), Inter-University Research Institute Corporations (such as National Institute of Genetics, National Institutes of Natural Sciences, High Energy Accelerator Research Organization).
- “Companies (Co.)” includes associated group of companies such as the Advanced Biopharmaceutical Manufacturing Technology Research Association of the Japan, and hospitals related to the private company.
- "Local Public Entities (Local)" includes local incorporated administrative agencies, prefectural and municipal hospitals.
- “Foundations and associations (foundations)" includes non-profit making organizations (NPOs).
- “Medical Corporations, and Social Welfare Corporations (MCs)" includes the Japanese Red Cross Society and its related institutions, special corporations, and those institutions related to the National Public Service Mutual Aid Association (such as Toranomon Hospital).

2. Principal Investigators

2.1. Number of principal investigators (PIs): Total, by gender, and percentage of female PIs

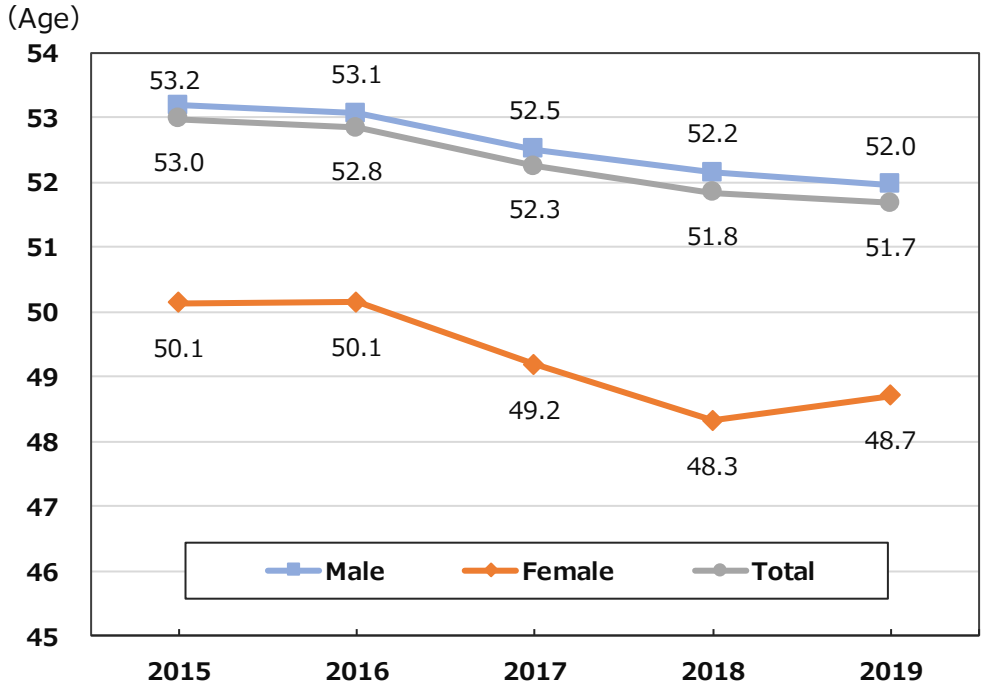


FY		2015	2016	2017	2018	2019
Percent Change (From previous year)	Male	-	9.6%	6.9%	4.1%	1.6%
	Female	-	23.4%	11.8%	7.4%	11.3%
	Total	-	10.5%	7.3%	4.4%	2.3%
Percent of Female PIs		6.7%	7.5%	7.8%	8.1%	8.8%

The gender of the PIs was derived from the e-Rad database (Cross-Ministerial Research and Development Management System).
Number refers to the sum of the PIs for both newly awarded projects and for projects continued from before.

Source: AMS (As of September 23, 2020). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

2.2. Average age of the principal investigators (PIs): Total and by gender

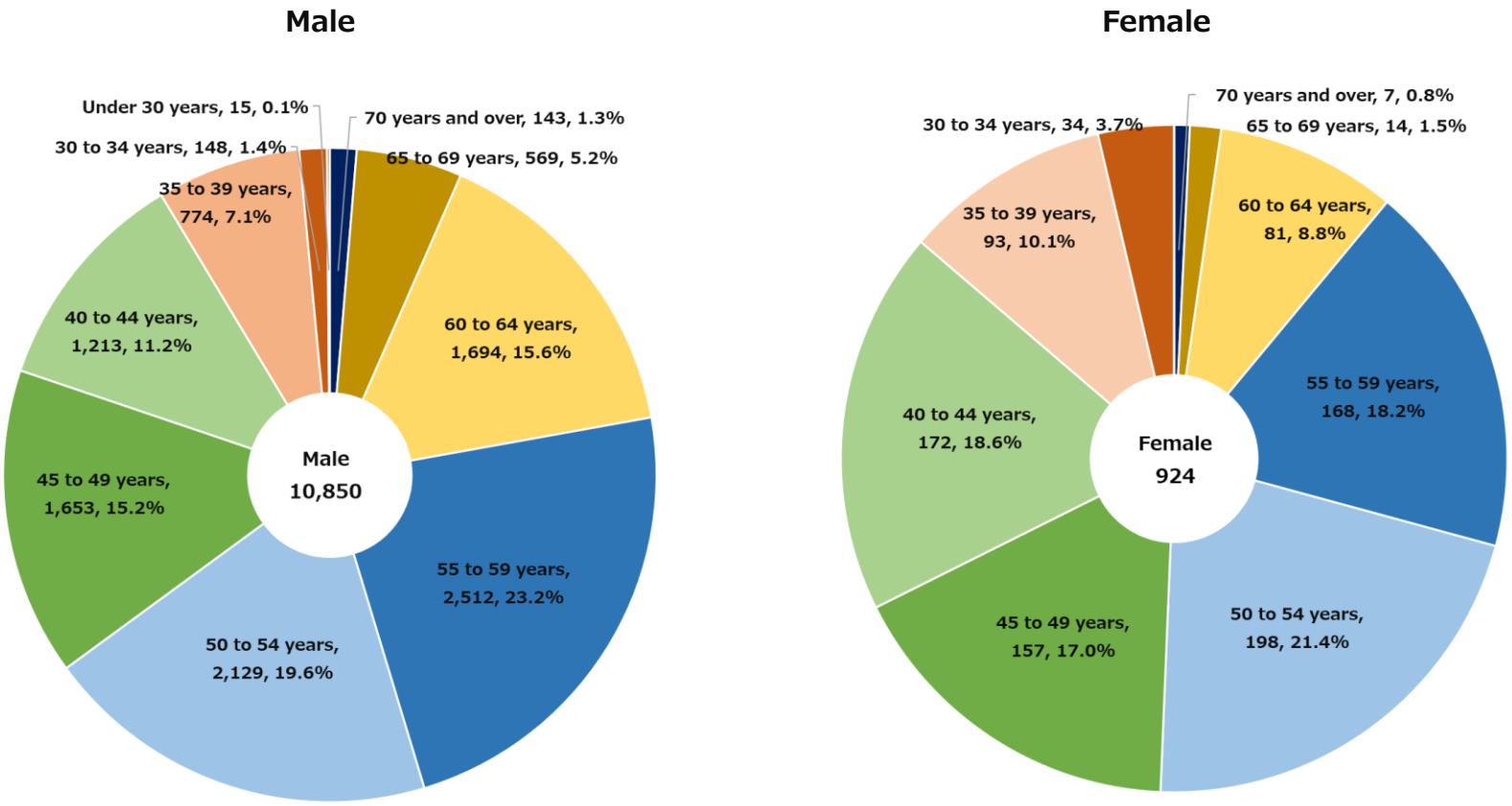


FY	2015	2016	2017	2018	2019	5-year Average
Male	53.2	53.1	52.5	52.2	52.0	52.5
Female	50.1	50.1	49.2	48.3	48.7	49.2
Total	53.0	52.8	52.3	51.8	51.7	52.3

The gender and age of the PIs were derived from the e-Rad database (Cross-Ministerial Research and Development Management System). Age was calculated from the date of birth of the PIs, as of April 1st of the FY in which the awarded project was scheduled to be undertaken. Age average was estimated from the ages of the PIs of the newly awarded projects and that of projects continued from before.

Source: AMS (As of September 23, 2020). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

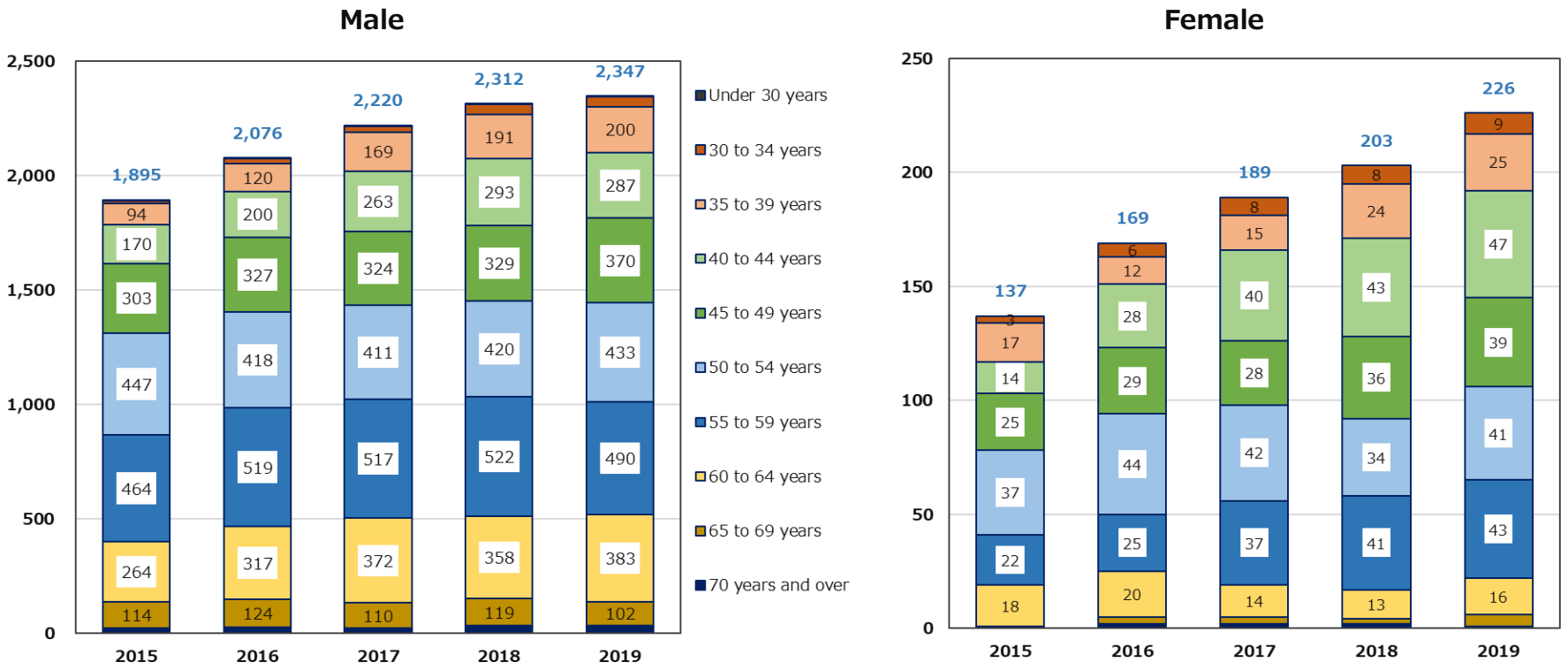
2.3. Number of principal investigators (PIs) by age group and gender: 1) 5-year total



The gender and age of the PIs were derived from the e-Rad database (Cross-Ministerial Research and Development Management System). Age was calculated from the date of birth of the PIs, as of April 1st of the FY in which the awarded project was scheduled to be undertaken. Numbers are the aggregated sums of ~~a~~ newly awarded projects and projects continued from before for each FY.

Source: AMS (As of September 23, 2020). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

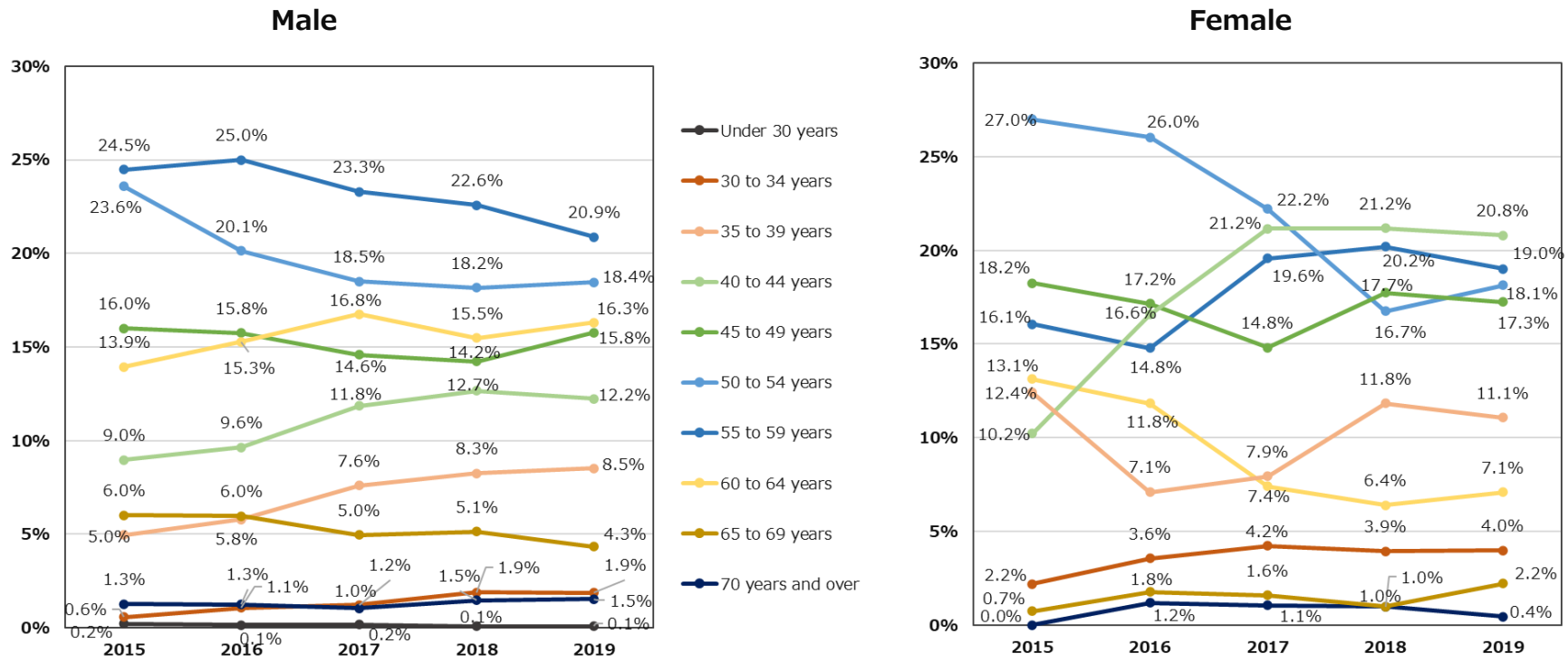
2.3. Number of principal investigators (PIs) by age group and gender: 2) Annual trends



The gender and age of the PIs were derived from the e-Rad database (Cross-Ministerial Research and Development Management System). Age was calculated from the date of birth of the PIs, as of April 1st of the FY in which the awarded project was scheduled to be undertaken. Numbers are the aggregated sums of ~~a~~ newly awarded projects and projects continued from before for each FY.

Source: AMS (As of September 23, 2020). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

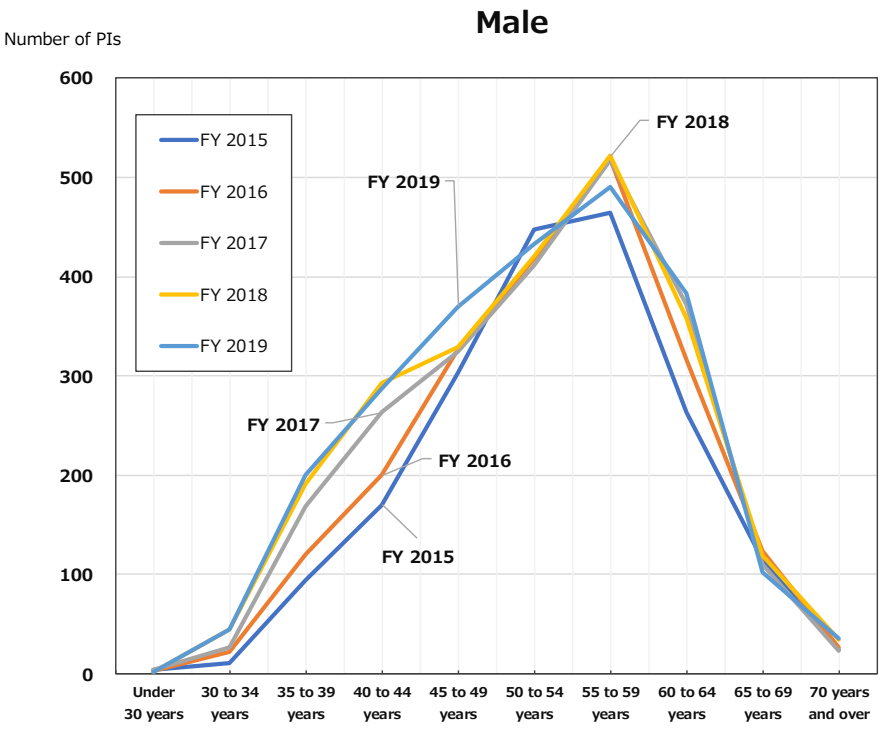
2.3. Number of principal investigators (PIs) by age group and gender: 3) As a percentage of all PIs

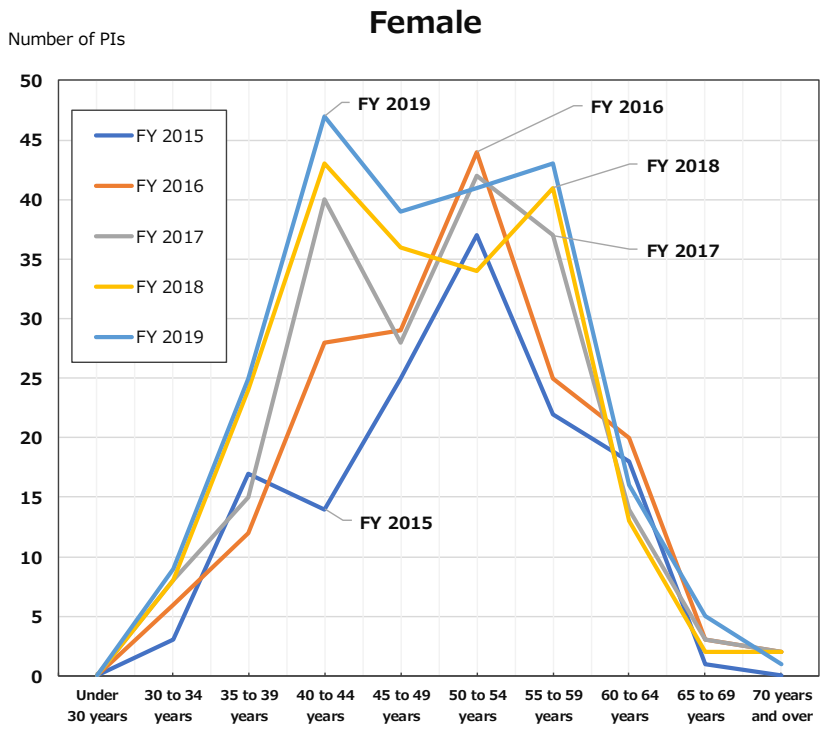


The gender and age of the PIs were derived from the e-Rad database (Cross-Ministerial Research and Development Management System). Age was calculated from the date of birth of the PIs, as of April 1st of the FY in which the awarded project was scheduled to be undertaken. Numbers are the aggregated sums of ~~a~~ newly awarded projects and projects continued from before for each FY.

Source: AMS (As of September 23, 2020). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

2.4. Age groups and annual trends (male and female PIs)





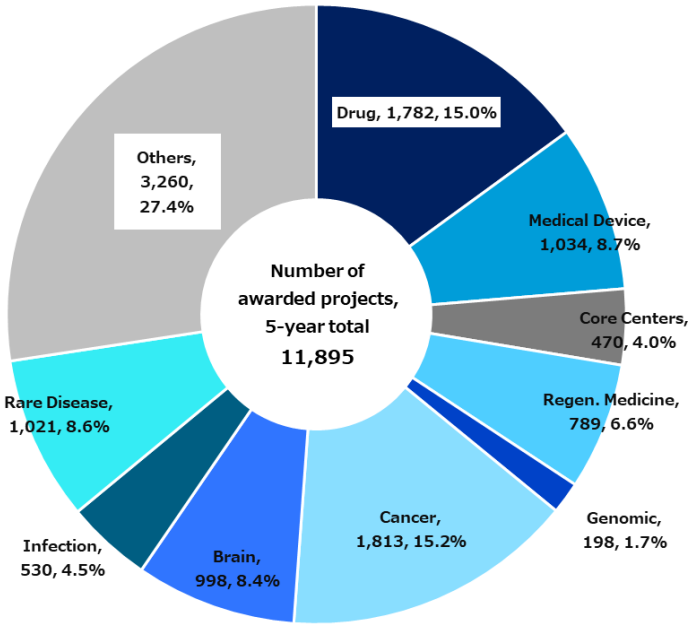
The gender and age of the PIs were derived from the e-Rad database (Cross-Ministerial Research and Development Management System). Age was calculated from the date of birth of the PIs, as of April 1st of the FY in which the awarded project was scheduled to be undertaken . Numbers are the aggregated sums of newly awarded projects and projects continued from before for each FY.

Source: AMS (As of September 23, 2020). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

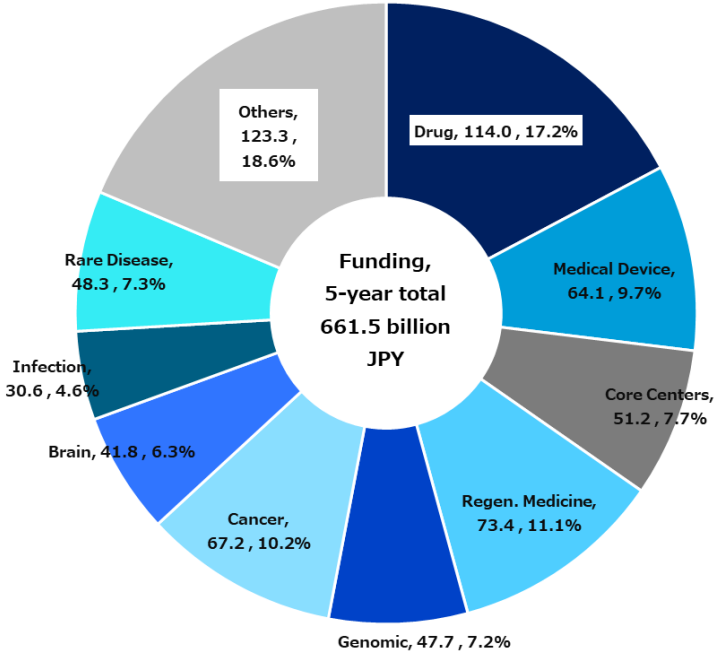
3. Awarded Projects and Funding

3.1. Awarded projects and funding under AMED's 9 Integrated Project Categories (First 5-year Term): 1) 5-year total

Number of awarded projects



Amount of funding (Billion JPY)



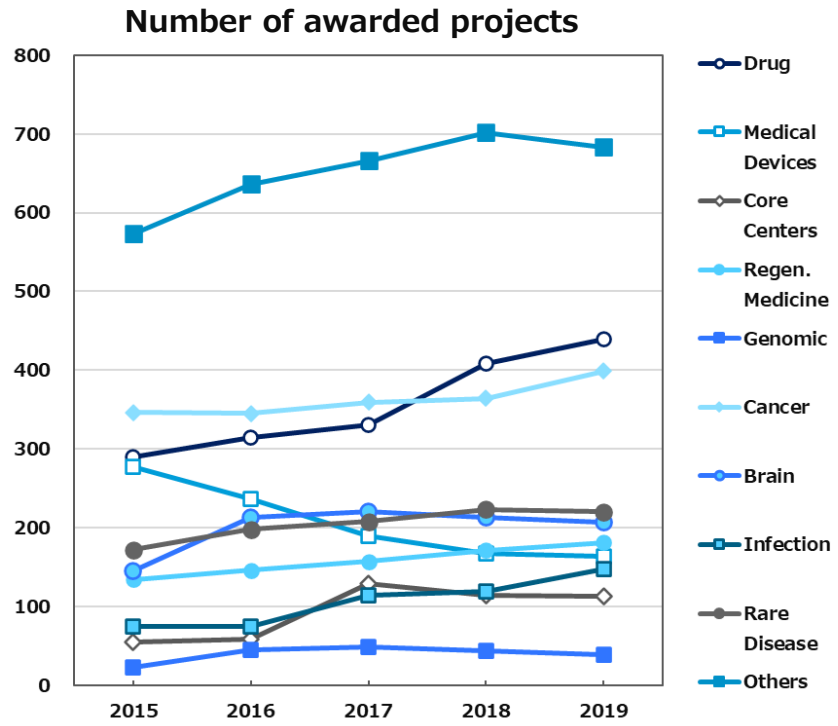
"AMED's 9 Integrated Project Categories (First 5-year Term)" and their abbreviations

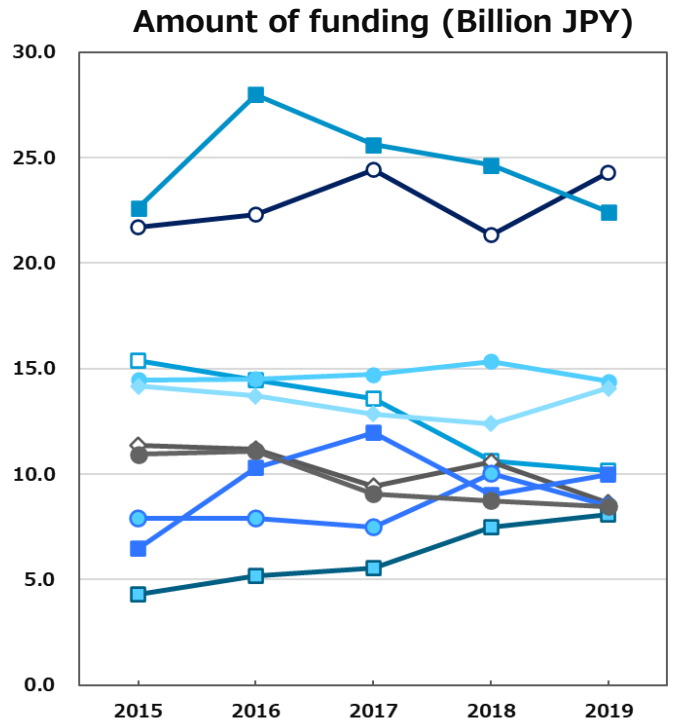
Name of Integrated Projects	Abbreviations
1. Project for Drug Discovery and Development (Drug Project)	Drug
2. Project for Medical Device Development (Medical Device Project)	Medical Device
3. Project for Japan Translational and Clinical Research Core Centers (Core Center Project)	Core Centers
4. Japan Regenerative Medicine Project (Regenerative Project)	Regen. Medicine
5. Japan Genomic Medicine Project (Genome Project)	Genomic
6. Japan Cancer Research Project (Cancer Research Project)	Cancer
7. Project for Psychiatric & Neurological Disorders (Brain Research Project)	Brain
8. Emerging/re-emerging Infectious Disease Project (Infectious Disease Project)	Infection
9. Rare/Intractable Disease Project (Rare Disease Project)	Rare Disease
10. Others	Others

The number of awarded projects and the amount of funding are the sums of/for newly awarded projects and -projects continued from before each FY.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

3.1. Awarded projects and funding under AMED's 9 Integrated Project Categories (First 5-year Term): 2) Annual trends



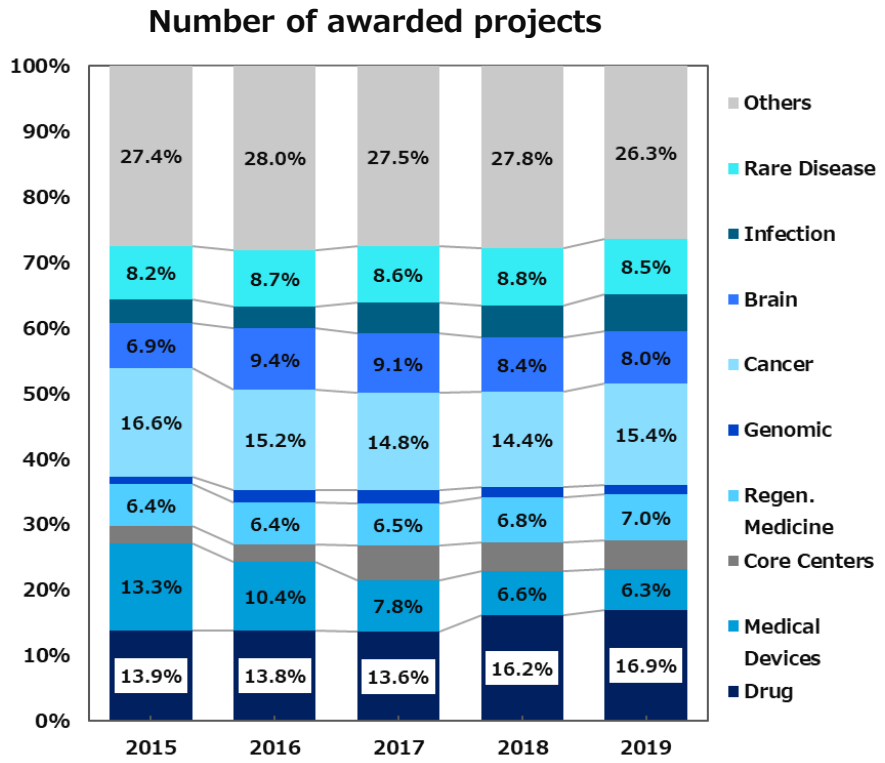


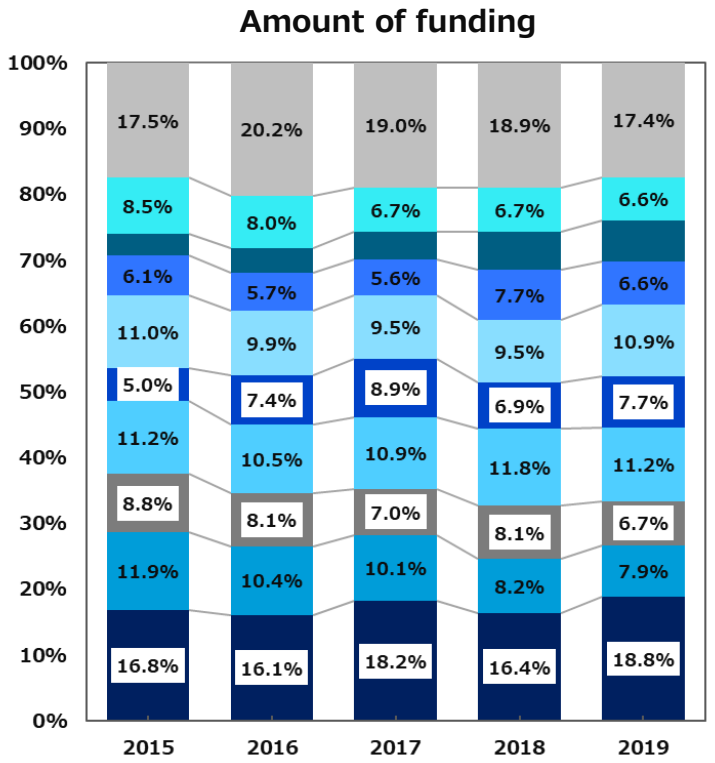
Name of 9 Integrated Project Categories	Number of awarded projects						Funding (billion JPY)					
	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
1. Drug Project	290	314	330	409	439	1,782	21.7	22.3	24.4	21.3	24.3	114.0
2. Medical Device Project	277	237	189	167	164	1,034	15.3	14.4	13.6	10.6	10.2	64.1
3. Core Center Project	55	59	129	114	113	470	11.4	11.2	9.4	10.6	8.6	51.2
4. Regenerative Medecine Project	134	146	157	171	181	789	14.5	14.5	14.7	15.3	14.4	73.4
5. Genomic Medecine Project	23	45	48	43	39	198	6.5	10.3	12.0	9.0	10.0	47.7
6. Cancer Research Project	346	345	359	364	399	1,813	14.2	13.7	12.8	12.4	14.1	67.2
7. Brain Research Project	145	213	220	213	207	998	7.9	7.9	7.5	10.0	8.5	41.8
8. Infectious Diseases Project	74	75	114	119	148	530	4.3	5.2	5.5	7.5	8.1	30.6
9. Rare Diseases Project	172	198	208	223	220	1,021	10.9	11.1	9.1	8.7	8.5	48.3
10. Others	573	636	666	702	683	3,260	22.6	28.0	25.6	24.6	22.4	123.3
Total	2,089	2,268	2,420	2,525	2,593	11,895	129.2	138.6	134.6	130.1	129.0	661.5

The number of awarded projects and the amount of funding are sums for newly awarded projects and continued from before each FY.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

3.1. Awarded projects and funding under AMED's 9 Integrated Project Categories (First 5-year Term): 3) Percentage change





Name of 9 Integrated Project Categories	Number of awarded projects						Funding (%)					
	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
1. Drug Project	13.9%	13.8%	13.6%	16.2%	16.9%	15.0%	16.8%	16.1%	18.2%	16.4%	18.8%	17.2%
2. Medical Device Project	13.3%	10.4%	7.8%	6.6%	6.3%	8.7%	11.9%	10.4%	10.1%	8.2%	7.9%	9.7%
3. Core Center Project	2.6%	2.6%	5.3%	4.5%	4.4%	4.0%	8.8%	8.1%	7.0%	8.1%	6.7%	7.7%
4. Regenerative Medecine Project	6.4%	6.4%	6.5%	6.8%	7.0%	6.6%	11.2%	10.5%	10.9%	11.8%	11.2%	11.1%
5. Genomic Medecine Project	1.1%	2.0%	2.0%	1.7%	1.5%	1.7%	5.0%	7.4%	8.9%	6.9%	7.7%	7.2%
6. Cancer Research Project	16.6%	15.2%	14.8%	14.4%	15.4%	15.2%	11.0%	9.9%	9.5%	9.5%	10.9%	10.2%
7. Brain Research Project	6.9%	9.4%	9.1%	8.4%	8.0%	8.4%	6.1%	5.7%	5.6%	7.7%	6.6%	6.3%
8. Infectious Diseases Project	3.5%	3.3%	4.7%	4.7%	5.7%	4.5%	3.3%	3.7%	4.1%	5.7%	6.3%	4.6%
9. Rare Diseases Project	8.2%	8.7%	8.6%	8.8%	8.5%	8.6%	8.5%	8.0%	6.7%	6.7%	6.6%	7.3%
10. Others	27.4%	28.0%	27.5%	27.8%	26.3%	27.4%	17.5%	20.2%	19.0%	18.9%	17.4%	18.6%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Percentages are relative to the total number of new projects plus projects ~~a~~ continued from before each FY.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

3.2. By International Classification of Diseases: 1) Number of awarded projects and funding

	Number of awarded projects						Funding (billion JPY)					
Classification of Target Diseases	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Infectious/parasitic	193	205	236	247	246	1,127	10.5	11.4	10.6	11.7	10.3	54.5
Neoplasms	478	493	539	549	584	2,643	23.7	28.5	28.3	25.8	25.7	132.0
Blood/blood-forming/immune mechanism	20	23	32	40	39	154	1.1	1.0	1.1	1.4	1.7	6.3
Endocrine/nutritional/metabolic	79	90	94	97	83	443	4.0	4.5	4.5	4.6	3.6	21.3
Mental/behavioral	100	142	146	142	150	680	3.6	4.6	4.2	4.9	5.2	22.4
Nervous system	145	176	172	201	201	895	8.9	9.1	8.9	11.1	9.2	47.1
Eye/adnexa	29	37	43	45	43	197	2.7	2.5	2.8	3.1	2.4	13.5
Ear/Mastoid process	16	15	14	16	11	72	0.4	0.3	0.5	0.4	0.3	1.9
Circulatory system	118	128	141	138	133	658	7.2	7.5	7.5	6.3	8.7	37.2
Respiratory system	34	33	46	51	49	213	1.7	2.8	3.3	3.0	1.4	12.2
Digestive system	54	57	65	75	77	328	3.2	3.4	3.4	3.8	3.5	17.3
Skin/subcutaneous tissue	18	27	30	31	27	133	0.6	1.3	3.0	1.3	1.2	7.4
Musculoskeletal/Connective tissue	63	57	50	54	52	276	2.7	2.5	2.0	2.2	2.0	11.4
Genitourinary system	20	27	36	37	39	159	0.6	0.8	1.1	1.1	1.4	4.9
Pregnancy/childbirth/puerperium	2	4	5	5	5	21	0.0	0.1	0.1	0.1	0.1	0.4
Perinatal period	5	5	7	10	9	36	0.4	0.2	0.2	0.2	0.2	1.2
Malformations or deformations/chromosomal abnormalities	41	42	50	48	52	233	2.3	1.9	1.6	1.7	2.1	9.6
Disease not elsewhere classified	33	33	35	33	39	173	1.1	1.1	2.0	2.1	2.3	8.6
Injury/poisoning/others	54	56	59	62	59	290	2.5	2.4	2.5	2.2	1.9	11.4
External causes	0	1	0	2	2	5	0.0	0.0	0.0	0.0	0.0	0.0
Health status/health services	15	19	12	12	9	67	1.4	2.4	0.9	0.4	0.3	5.4
Codes not specified	76	86	70	42	20	294	10.4	11.2	8.8	4.4	2.8	37.6
Others (Codes not applicable)	496	511	538	585	661	2,791	40.3	39.0	37.6	38.0	42.3	197.2
NA (Codes not available)	0	1	0	3	3	7	0.0	0.2	0.0	0.2	0.3	0.7
Total	2,089	2,268	2,420	2,525	2,593	11,895	129.2	138.6	134.6	130.1	129.0	661.5

The target diseases for the awarded project are classified according to the International Classification of Diseases (ICD-10, 2013), “Codes not specified” and “Others (codes not applicable)” are added to ICD-10. “Codes not specified" represents target diseases that cannot be classified within the ICD-10, and “Others (codes not applicable)" includes no targeted diseases or have multiple codes. AMS "target disease" cites one single classification as the main target for each awarded project.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

3.2. By International Classification of Diseases: 2) Percentage change

	Number of awarded projects (%)						Funding (%)					
Classification of Target Diseases	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Infectious/parasitic	9.2%	9.0%	9.8%	9.8%	9.5%	9.5%	8.1%	8.3%	7.9%	9.0%	8.0%	8.2%
Neoplasms	22.9%	21.7%	22.3%	21.7%	22.5%	22.2%	18.3%	20.6%	21.0%	19.8%	19.9%	20.0%
Blood/blood-forming/immune mechanism	1.0%	1.0%	1.3%	1.6%	1.5%	1.3%	0.8%	0.7%	0.8%	1.1%	1.3%	0.9%
Endocrine/nutritional/metabolic	3.8%	4.0%	3.9%	3.8%	3.2%	3.7%	3.1%	3.3%	3.3%	3.6%	2.8%	3.2%
Mental/behavioral	4.8%	6.3%	6.0%	5.6%	5.8%	5.7%	2.8%	3.3%	3.1%	3.8%	4.0%	3.4%
Nervous system	6.9%	7.8%	7.1%	8.0%	7.8%	7.5%	6.9%	6.6%	6.6%	8.5%	7.1%	7.1%
Eye/adnexa	1.4%	1.6%	1.8%	1.8%	1.7%	1.7%	2.1%	1.8%	2.1%	2.4%	1.9%	2.0%
Ear/Mastoid process	0.8%	0.7%	0.6%	0.6%	0.4%	0.6%	0.3%	0.2%	0.4%	0.3%	0.2%	0.3%
Circulatory system	5.6%	5.6%	5.8%	5.5%	5.1%	5.5%	5.6%	5.4%	5.6%	4.8%	6.8%	5.6%
Respiratory system	1.6%	1.5%	1.9%	2.0%	1.9%	1.8%	1.3%	2.0%	2.4%	2.3%	1.1%	1.8%
Digestive system	2.6%	2.5%	2.7%	3.0%	3.0%	2.8%	2.5%	2.5%	2.5%	2.9%	2.7%	2.6%
Skin/subcutaneous tissue	0.9%	1.2%	1.2%	1.2%	1.0%	1.1%	0.4%	1.0%	2.2%	1.0%	1.0%	1.1%
Musculoskeletal/Connective tissue	3.0%	2.5%	2.1%	2.1%	2.0%	2.3%	2.1%	1.8%	1.5%	1.7%	1.5%	1.7%
Genitourinary system	1.0%	1.2%	1.5%	1.5%	1.5%	1.3%	0.4%	0.6%	0.8%	0.9%	1.1%	0.7%
Pregnancy/childbirth/puerperium	0.1%	0.2%	0.2%	0.2%	0.2%	0.2%	0.0%	0.0%	0.1%	0.1%	0.1%	0.1%
Perinatal period	0.2%	0.2%	0.3%	0.4%	0.3%	0.3%	0.3%	0.1%	0.1%	0.2%	0.2%	0.2%
Malformations or deformations/chromosomal abnormalities	2.0%	1.9%	2.1%	1.9%	2.0%	2.0%	1.8%	1.3%	1.2%	1.3%	1.6%	1.5%
Disease not elsewhere classified	1.6%	1.5%	1.4%	1.3%	1.5%	1.5%	0.9%	0.8%	1.5%	1.6%	1.8%	1.3%
Injury/poisoning/others	2.6%	2.5%	2.4%	2.5%	2.3%	2.4%	1.9%	1.7%	1.8%	1.7%	1.5%	1.7%
External causes	0.0%	0.0%	0.0%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Health status/health services	0.7%	0.8%	0.5%	0.5%	0.3%	0.6%	1.1%	1.7%	0.7%	0.3%	0.2%	0.8%
Codes not specified	3.6%	3.8%	2.9%	1.7%	0.8%	2.5%	8.0%	8.1%	6.5%	3.4%	2.1%	5.7%
Others (Codes not applicable)	23.7%	22.5%	22.2%	23.2%	25.5%	23.5%	31.2%	28.1%	27.9%	29.2%	32.8%	29.8%
NA (Codes not available)	0.0%	0.0%	0.0%	0.1%	0.1%	0.1%	0.0%	0.1%	0.0%	0.2%	0.2%	0.1%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

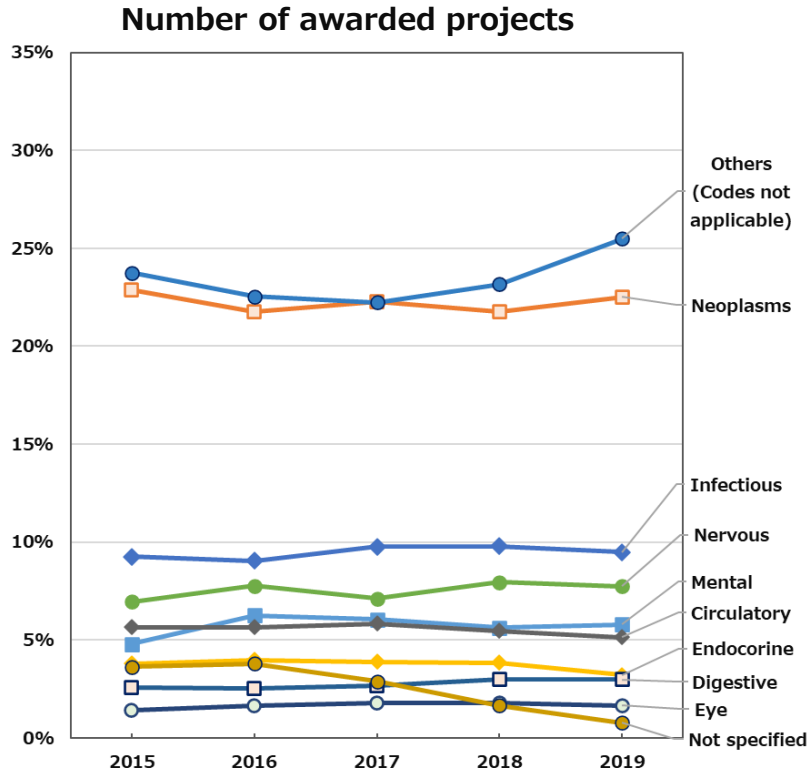
The target diseases for the awarded project are classified according to the International Classification of Diseases (ICD-10, 2013), “Codes not specified” and “Others (codes not applicable)” are added to ICD-10. “Codes not specified" represents target diseases that cannot be classified within the ICD-10, and “Others (codes not applicable)" includes no targeted diseases or have multiple codes.

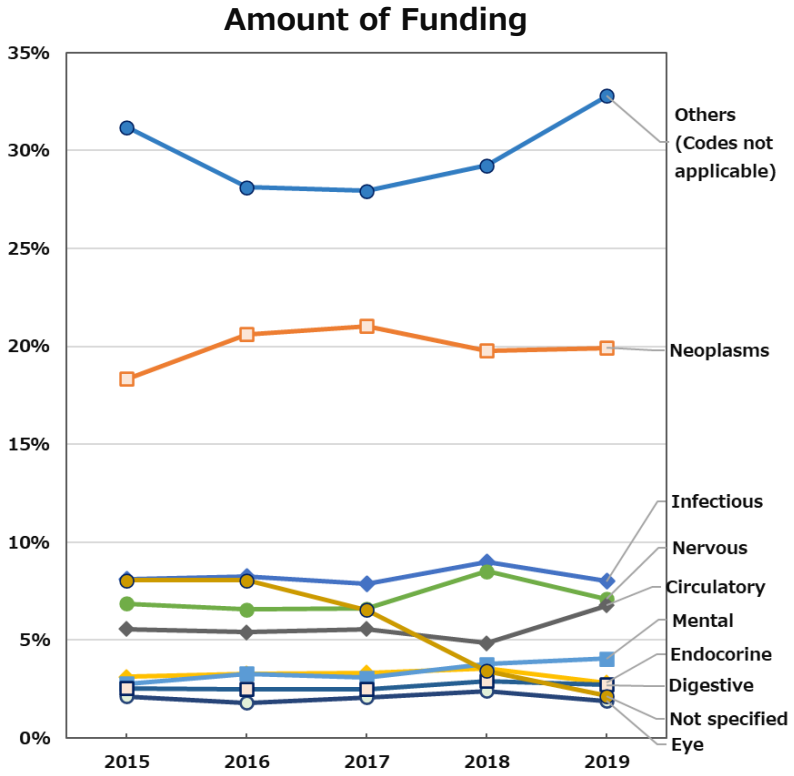
AMS "target disease" cites one single classification as the main target for each awarded project.

Percentage is relative to the total for each FY.

Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

3.2. By International Classification of Diseases: 3) Trends in 10 major disease categories



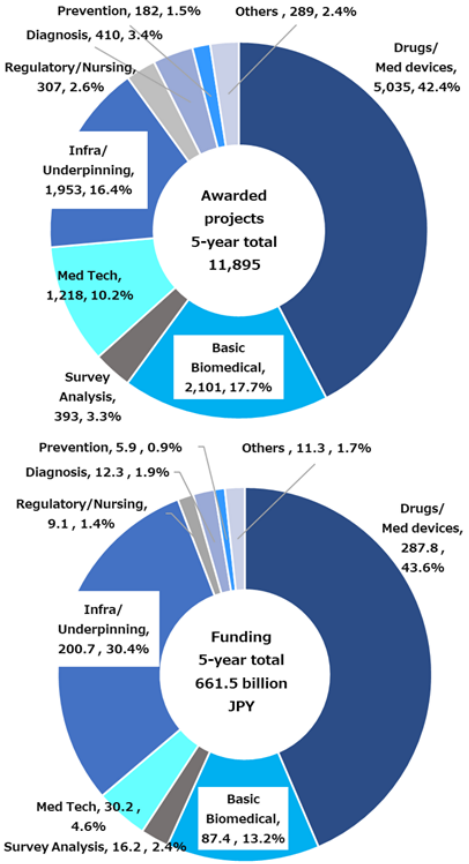


	Number of awarded projects (%)						Funding (%)					
Classification of Target Diseases	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Others (Codes not applicable)	23.7%	22.5%	22.2%	23.2%	25.5%	23.5%	31.2%	28.1%	27.9%	29.2%	32.8%	29.8%
Neoplasms	22.9%	21.7%	22.3%	21.7%	22.5%	22.2%	18.3%	20.6%	21.0%	19.8%	19.9%	20.0%
Infectious/parasitic	9.2%	9.0%	9.8%	9.8%	9.5%	9.5%	8.1%	8.3%	7.9%	9.0%	8.0%	8.2%
Nervous system	6.9%	7.8%	7.1%	8.0%	7.8%	7.5%	6.9%	6.6%	6.6%	8.5%	7.1%	7.1%
Codes not specified	3.6%	3.8%	2.9%	1.7%	0.8%	2.5%	8.0%	8.1%	6.5%	3.4%	2.1%	5.7%
Circulatory system	5.6%	5.6%	5.8%	5.5%	5.1%	5.5%	5.6%	5.4%	5.6%	4.8%	6.8%	5.6%
Mental/behavioral	4.8%	6.3%	6.0%	5.6%	5.8%	5.7%	2.8%	3.3%	3.1%	3.8%	4.0%	3.4%
Endocrine/nutritional/metabolic	3.8%	4.0%	3.9%	3.8%	3.2%	3.7%	3.1%	3.3%	3.3%	3.6%	2.8%	3.2%
Digestive system	2.6%	2.5%	2.7%	3.0%	3.0%	2.8%	2.5%	2.5%	2.5%	2.9%	2.7%	2.6%
Eye/adnexa	1.4%	1.6%	1.8%	1.8%	1.7%	1.7%	2.1%	1.8%	2.1%	2.4%	1.9%	2.0%

Percent changes for 10 major ICD-10 categories.

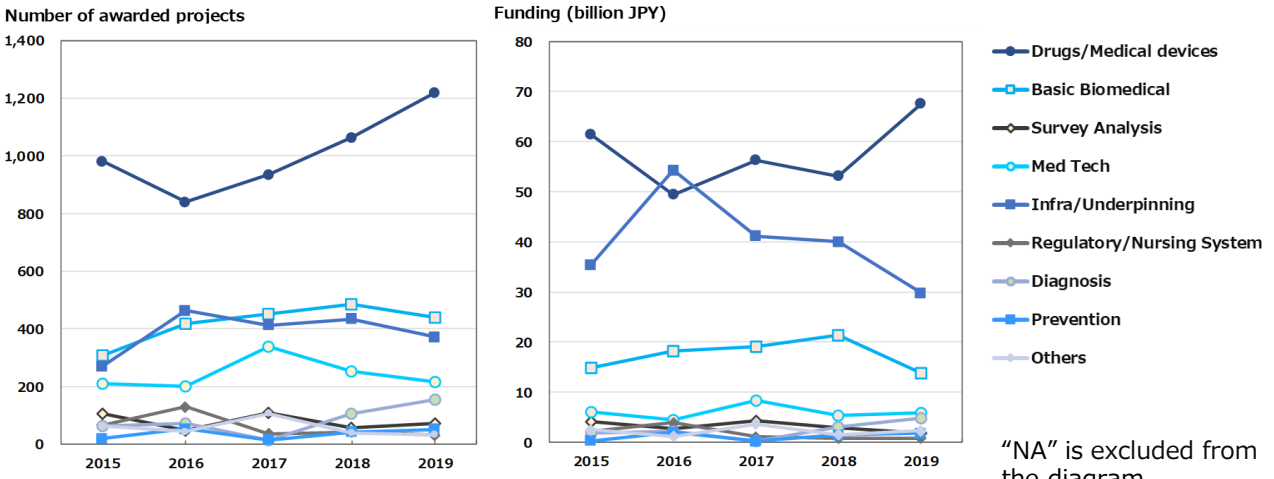
Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

3.3. By AMS Research Categories



○ Definitions of "AMS Research Categories"

1) Pharmaceutical/Medical Device Development <Including development of systems to implement medical devices>
2) Basic Biomedical/Etiologic Studies
3) Survey Analysis <Including fieldwork, surveillances, and monitoring>
4) Medical Technology/Therapeutics Development <Including verification of evidence to improve quality of medical care by compilation of guidelines and other methods>
5) Infrastructure for Drug Discovery/Underpinning <Including discovery of drugs, ICT infrastructure and platforms>
6) Regulatory/Nursing System Improvement and Technical Support <Including advancement of technology supports for the international health system>
7) Diagnosis/Clinical Testing Development and Validation <Excluding development of diagnostic drugs and equipment>
8) Evidence Building for Prevention <Including epidemiology studies>

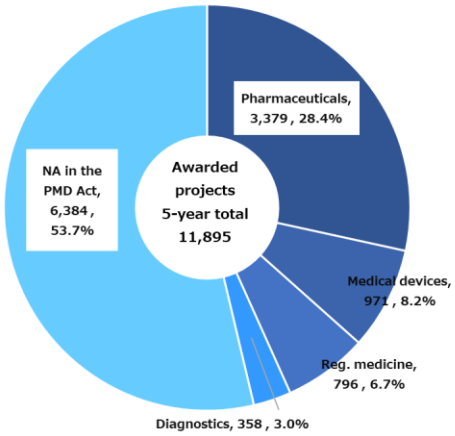


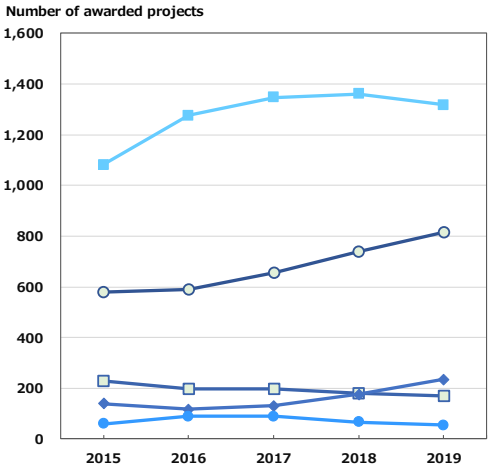
"NA" is excluded from the diagram.

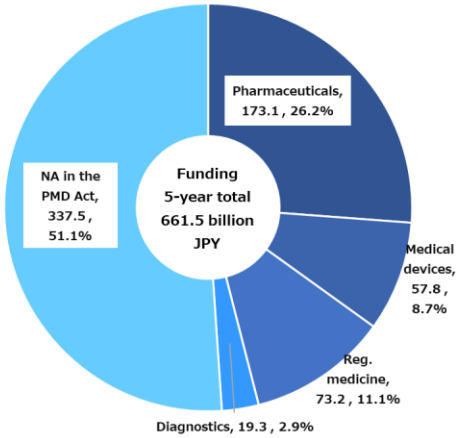
	Number of awarded projects						Funding (billion JPY)					
AMS Research Categories	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Pharmaceutical/Medical Device Development	980	839	934	1,063	1,219	5,035	61.5	49.4	56.3	53.2	67.6	287.8
Basic Biomedical/Etiologic Studies	307	418	451	485	440	2,101	14.9	18.2	19.1	21.4	13.8	87.4
Survey Analyses	105	49	109	57	73	393	4.2	2.8	4.4	3.0	1.9	16.2
Medical Technology/Therapeutics Development	211	200	340	252	215	1,218	6.1	4.4	8.4	5.4	5.9	30.2
Infrastructure for Drug Discovery/Underpinning	271	463	413	435	371	1,953	35.4	54.3	41.2	40.0	29.8	200.7
Regulatory/Nursing System Improvement and Technical Support	67	129	37	42	32	307	2.3	3.9	1.1	0.8	0.9	9.1
Diagnosis/Clinical Testing Development and Validation	64	72	14	105	155	410	1.9	2.2	0.3	3.1	4.8	12.3
Evidence Building for Prevention	20	53	15	43	51	182	0.4	2.0	0.2	1.4	1.8	5.9
Others	64	44	107	40	34	289	2.5	1.2	3.7	1.5	2.3	11.3
NA	-	1	-	3	3	7	0.0	0.2	0.0	0.2	0.3	0.7
Total	2,089	2,268	2,420	2,525	2,593	11,895	129.2	138.6	134.6	130.1	129.0	661.5

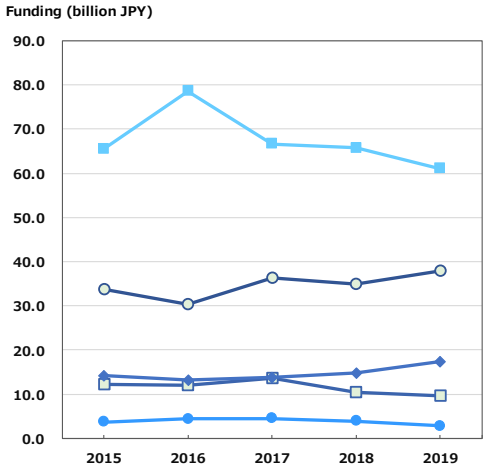
Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

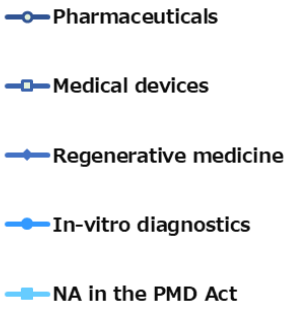
3.4. By product application categories in the PMD Act: 1) All awarded projects











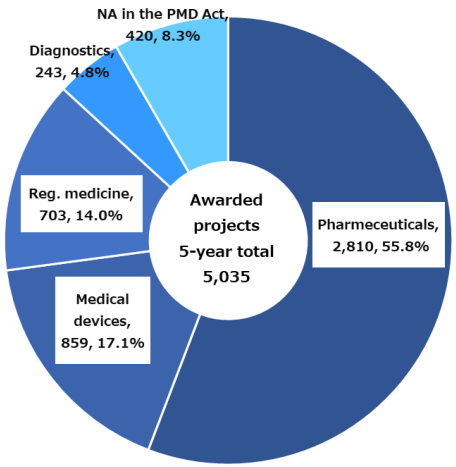
Application categories are based on the Japanese Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Device Act: PMD Act).

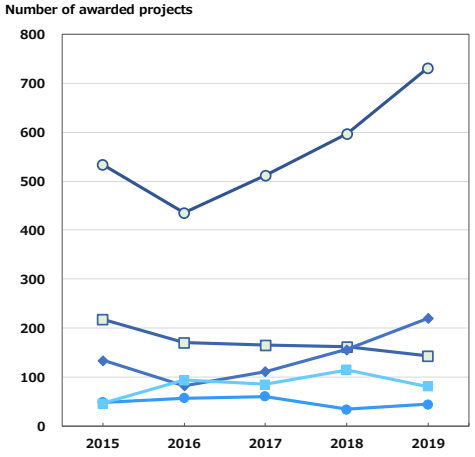
In the AMS database, citing of the application category is mandatory for research under "pharmaceutical and medical device development," but optional for other research.
"NA" is excluded from the diagram.

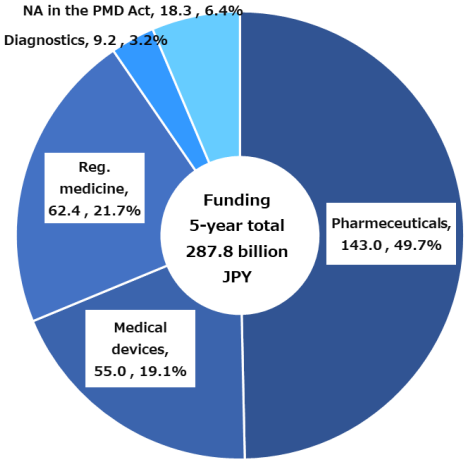
	Number of awarded projects						Funding (billion JPY)					
Application categories	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Pharmaceuticals	579	590	657	739	814	3,379	33.7	30.3	36.3	35.0	37.8	173.1
Medical devices	230	196	196	180	169	971	12.1	12.0	13.5	10.5	9.6	57.8
Regenerative medicine	139	116	131	175	235	796	14.2	13.2	13.7	14.8	17.4	73.2
In-vitro diagnostics	59	89	89	67	54	358	3.6	4.4	4.5	3.9	2.8	19.3
NA in the PMD Act	1,082	1,276	1,347	1,361	1,318	6,384	65.6	78.6	66.6	65.7	61.1	337.5
Data Not Available	-	1	-	3	3	7	-	0.2	-	0.2	0.3	0.7
Total	2,089	2,268	2,420	2,525	2,593	11,895	129.2	138.6	134.6	130.1	129.0	661.5

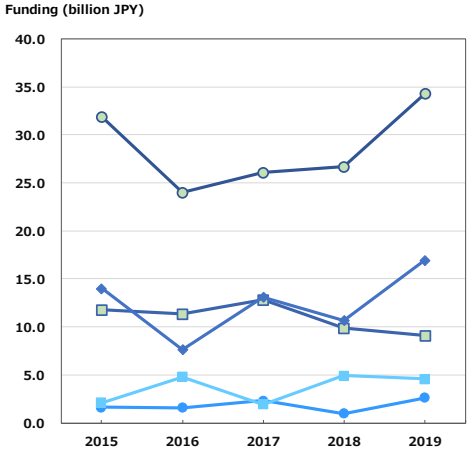
Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

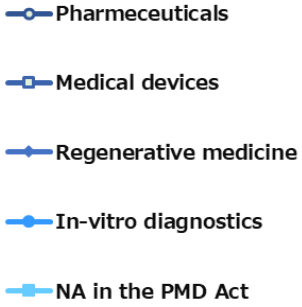
3.4. By product application categories in the PMD Act: 2) Research for “pharmaceutical and medical device development”











Product application categories are based on the Japanese Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Device Act: PMD Act).

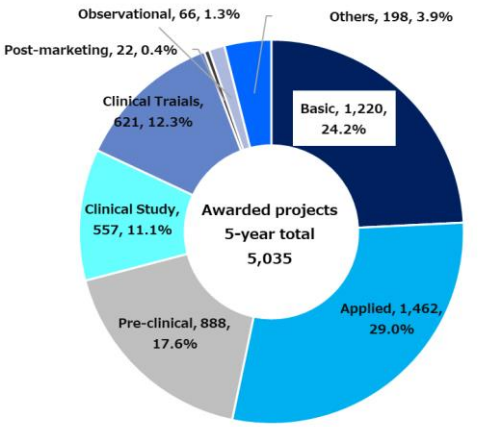
In the AMS database, citing of the application category is mandatory for research under “pharmaceutical and medical device development.”

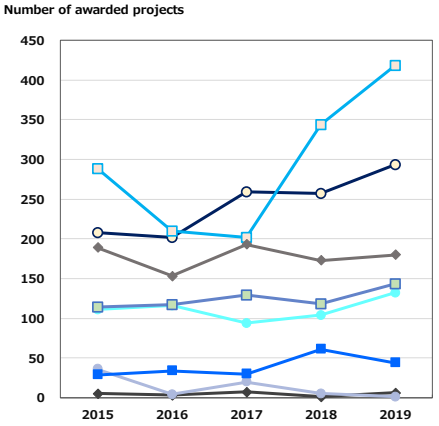
Application categories of "Research for pharmaceutical/medical device development"

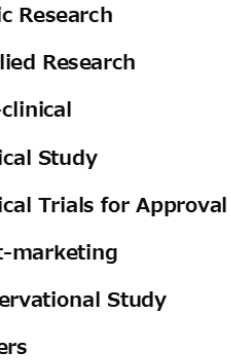
	Number of awarded projects						Funding (billion JPY)					
Application categories	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Pharmeceuticals	534	436	512	597	731	2,810	31.9	24.0	26.1	26.7	34.3	143.0
Medical devices	218	171	166	161	143	859	11.8	11.4	12.8	9.9	9.1	55.0
Regenerative medicine	134	82	111	156	220	703	14.0	7.6	13.1	10.7	17.0	62.4
In-vitro diagnostics	48	57	60	34	44	243	1.6	1.6	2.3	1.0	2.6	9.2
NA in the PMD Act	46	93	85	115	81	420	2.1	4.8	1.9	4.9	4.6	18.3
Total	980	839	934	1,063	1,219	5,035	61.5	49.4	56.3	53.2	67.6	287.8

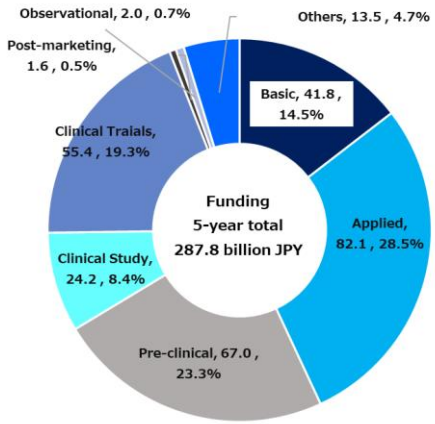
Source: AMS (As of January 27, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

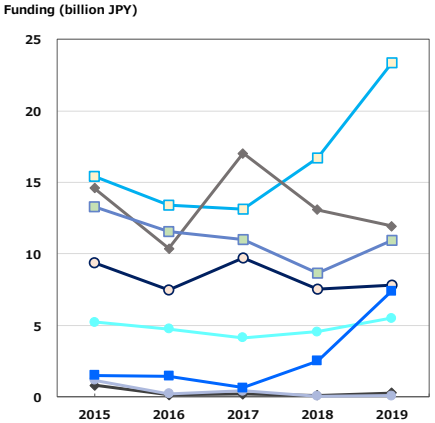
3.5. Development stages of “Research for pharmaceutical and medical device development”











In the AMS database, citing of the application category is mandatory for research under “pharmaceutical and medical device development.”

Source: AMS (As of January 27, 2021).
Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

Development stages of "Research for pharmaceutical/medical device development"

	Number of awarded projects						Funding (billion JPY)					
Development stage	2015	2016	2017	2018	2019	Total	2015	2016	2017	2018	2019	Total
Basic Research	208	202	259	257	294	1,220	9.4	7.5	9.7	7.5	7.8	41.8
Applied Research	288	210	202	344	418	1,462	15.4	13.4	13.1	16.7	23.4	82.1
Pre-clinical	189	153	193	173	180	888	14.6	10.4	17.0	13.1	11.9	67.0
Clinical Study	111	116	94	104	132	557	5.2	4.8	4.2	4.6	5.5	24.2
Clinical Trials for Approval	114	117	129	118	143	621	13.3	11.6	11.0	8.6	11.0	55.4
Post-marketing	5	3	7	1	6	22	0.8	0.1	0.2	0.1	0.3	1.6
Observational Study	36	4	20	5	1	66	1.2	0.2	0.4	0.1	0.1	2.0
Others	29	34	30	61	44	198	1.5	1.4	0.6	2.5	7.4	13.5
NA	-	-	-	-	1	1	0.0	0.0	0.0	0.0	0.1	0.1
Total	980	839	934	1,063	1,219	5,035	61.5	49.4	56.3	53.2	67.6	287.8

4. Examples of Analyses using Data from the AMED Management System

AMS data used in section 4

Updated data on February 17, 2021

Excluding whole-data items related to the Medical Research and Development Innovation Infrastructure Creation Project (CiCLE), a total of 11,895 awarded projects were tabulated using a special web tool for analyses and visualization of the AMS data items, developed for overviewing research trends and providing reference information to explore inter-project collaboration and cross-projects research directions on an “All-AMED” scale.

4.1. Overview of R&D funding

4.1.1. Cross analysis of AMS Research Categories x ICD-10 Classifications of Disease: 1) Number of awarded projects

Cases

	Pharmaceutical/ Medical Device Development	Basic Biomedical/Aetiolgy Studies	Survey Analyses	Medical Technology/ Therapeutics Development	Infrastructure for Drug Discovery/ Underpinning	Regulatory/Nursing System Improvement and Technical Support	Diagnosis/Clinical Testing Development and Validation	Evidence Building for Prevention	Others	Total
Infectious/parasitic	453	279	146	66	71	7	72	26	7	1,127
Neoplasms	1,598	212	28	462	174	11	93	42	23	2,643
Endocrine/nutritional/metabolic	71	47	5	12	11	2	6	0	0	154
Blood/blood-forming/immune mechanism	188	88	12	43	52	24	12	22	2	443
Mental/behavioural	145	165	25	145	96	19	54	22	9	680
Nervous system	439	211	15	105	77	2	38	1	7	895
Eye/adnexa	118	10	8	5	43	5	4	0	4	197
Ear/Mastoid process	32	8	6	16	1		7	2	0	72
Circulatory system	348	87	27	109	45	5	26	9	2	658
Respiratory system	97	35	26	23	20	0	7	5	0	213
Digestive system	210	61	8	16	22	6	5	0	0	328
Skin/subcutaneous tissue	44	58	1	14	9	2	2	3	0	133
Musculoskeletal/Connective tissue	155	53	6	30	12	6	9	3	2	276
Genitourinary system	68	40	4	19	6	2	15	5	0	159
Pregnancy/childbirth/puerperium	5	12		1			1	2	0	21
Perinatal period	13	3	4	4	2	3	7	0	0	36
Mal- or de-formations/chromosomal abnormalities	118	45	7	32	15	14	0	2	0	233
Disease not elsewhere classified	48	49	6	18	11	20	5	9	7	173
Injury/poisoning/other consequences	136	45	4	30	41	25	3	4	2	290
External causes	0	0	1	1	2	1	0	0	0	5
Health status/health services	27	0	5	7	13	7	3	4	1	67
Special purposes	0	0	0	0	0	0	0	0	0	0
Others (disease code not applicable)	662	502	42	34	1,146	131	39	14	221	2,791
Codes not specified	60	91	7	26	84	15	2	7	2	294
Total	4,582	1,822	247	1,152	1,882	300	338	156	282	10,761

Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of target diseases was aggregated by adding "N/A (No target diseases)" and "Other" to the ICD-10 International Classification of Diseases, 10, 2013.

Only awarded projects tagged with both AMS Research Categories and target diseases were used.

4.1.1. Cross analysis of AMS Research Categories x ICD-10 Classifications of Disease: 2) Funding

Billion yen

	Pharmaceutical/ Medical Device Development	Basic Biomedical/Aetiolgy Studies	Survey Analyses	Medical Technology/ Therapeutics Development	Infrastructure for Drug Discovery/ Underpinning	Regulatory/Nursing System Improvement and Technical Support	Diagnosis/Clinical Testing Development and Validation	Evidence Building for Prevention	Others	Total
Infectious/parasitic	25,227,470,256	8,047,272,318	8,446,178,571	1,382,191,733	5,819,284,499	98,534,721	2,824,462,127	1,331,582,600	1,331,747,519	54,508,724,344
Neoplasms	79,654,032,533	10,294,211,786	1,030,877,153	13,541,443,071	21,538,025,811	535,691,381	2,635,523,802	1,501,953,794	1,291,352,945	132,023,112,276
Endocrine/nutritional/metabolic	9,668,577,489	4,161,034,388	116,306,040	863,248,580	5,056,802,965	294,267,516	579,440,598	670,112,696	9,680,000	21,419,470,272
Blood/blood-forming/immune mechanism	3,748,058,604	1,476,975,296	41,638,997	112,341,921	676,423,242	50,620,000	178,120,000	0	0	6,284,178,060
Mental/behavioural	5,532,689,067	6,439,240,888	1,295,359,010	2,686,628,699	3,127,458,743	316,453,817	1,486,750,271	1,459,215,774	89,047,500	22,432,843,769
Nervous system	23,658,170,096	15,107,841,814	187,050,000	2,742,450,581	4,382,528,047	23,324,000	967,765,977	6,487,000	36,429,400	47,112,046,915
Eye/adnexa	9,735,751,496	396,389,891	51,100,000	57,305,000	3,196,610,935	50,004,615	48,165,400	0	15,860,000	13,551,187,337
Ear/Mastoid process	1,101,222,231	482,405,955	32,335,764	157,487,714	4,270,000	0	54,663,401	25,220,000	0	1,857,605,065
Circulatory system	24,615,694,345	2,958,218,070	283,717,001	2,270,490,445	6,205,414,462	21,180,000	712,145,306	130,928,000	9,750,000	37,207,537,629
Respiratory system	4,262,294,603	805,953,180	2,645,050,923	414,410,525	3,706,243,083	0	216,898,900	185,270,000	0	12,236,121,214
Digestive system	12,217,686,512	2,378,308,686	311,590,000	205,217,000	2,016,685,838	53,802,000	132,970,900	0	0	17,316,260,936
Skin/subcutaneous tissue	1,793,846,979	1,595,157,378	8,619,000	210,359,000	3,661,079,996	42,490,000	83,994,990	34,060,000	0	7,429,607,343
Musculoskeletal/Connective tissue	7,733,714,290	1,625,460,492	86,688,000	361,018,906	1,230,743,112	156,340,000	113,768,540	49,182,000	11,499,800	11,368,415,140
Genitourinary system	2,765,162,889	969,861,988	71,017,998	453,601,122	175,390,000	13,000,000	385,813,680	57,200,402	0	4,891,048,079
Pregnancy/childbirth/puerperium	70,417,909	235,175,800	0	12,000,000	0	0	17,000,000	29,500,000	0	364,093,709
Perinatal period	556,031,598	44,200,000	126,250,000	63,458,000	76,159,000	27,200,000	295,709,000	0	0	1,189,007,598
Mal- or de-formations/chromosomal abnormalities	5,960,651,595	1,208,321,186	49,042,000	493,909,497	834,462,903	1,171,429,528	0	21,000,000	0	9,738,816,709
Disease not elsewhere classified	2,728,013,340	4,275,117,418	43,983,260	305,829,633	690,240,781	306,347,790	103,229,300	97,895,100	96,841,000	8,647,497,622
Injury/poisoning/other consequences	5,825,849,978	1,306,777,037	102,600,000	441,004,896	2,870,590,159	839,128,425	45,750,000	42,716,700	16,055,000	11,490,472,195
External causes	0	0	10,000,000	8,500,000	24,050,000	7,225,000		0	0	49,775,000
Health status/health services	1,739,233,338	0	88,971,999	46,172,000	3,119,131,856	33,644,258	252,199,999	30,820,000	45,449,000	5,355,622,450
Special purposes	0		0	0	0	0	0	0	0	0
Others (disease code not applicable)	45,280,002,427	17,679,019,170	972,597,468	1,693,265,354	117,631,884,416	4,492,842,344	1,109,866,817	127,428,076	8,339,966,579	197,326,872,651
Codes not specified	14,482,360,451	5,924,272,382	164,700,000	1,667,987,911	14,740,531,380	528,839,600	37,000,000	69,750,000	5,343,520	37,620,785,244
Total	288,356,932,026	87,411,215,123	16,165,673,184	30,190,321,588	200,784,011,228	9,062,364,995	12,281,239,008	5,870,322,142	11,299,022,263	661,421,101,557

Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of target diseases was aggregated by adding "N/A (No target diseases)" and "Other" to the ICD-10 International Classification of Diseases, 10, 2013.

Only awarded projects tagged with both AMS Research Categories and target diseases were used.

4.1.2. Cross analysis of AMS Research Categories × 9 Integrated Project Categories (First 5-year Term):

1) Number of awarded projects

Cases

	Pharmaceutical/ Medical Device Development	Basic Biomedical/Aetiolgy Studies	Survey Analyses	Medical Technology/ Therapeutics Development	Infrastructure for Drug Discovery/ Underpinning	Regulatory/Nursing System Improvement and Technical Support	Diagnosis/Clinical Testing Development and Validation	Evidence Building for Prevention	Others	Total
Project for Drug Discovery and Development	883	11	32	28	724	72	6		26	1,782
Project for Medical Device Development	772	20	1	22	95	77	27		14	1,028
Project for Japan Translational and Clinical Research Core Centers	225			8	227		4		6	470
Japan Regenerative Medicine Project	448	111	2	6	207	5	1		9	789
Japan Genomic Medicine Project	13	74	2	8	89		8		4	198
Japan Cancer Research Project	1,079	79	23	441	60	6	82	34	9	1,813
Project for Psychiatric & Neurological Disorders	183	388	23	161	125	7	80	23	8	998
Emerging/re-emerging Infectious Disease Project	176	112	88	25	54	1	44	28	2	530
Rare/Intractable Disease Project	530	169	40	172	58	43	7		2	1,021
Others	726	1,137	182	347	314	96	151	97	209	3,259
Total	5,035	2,101	393	1,218	1,953	307	410	182	289	11,888

Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

Only awarded projects tagged with both AMS Research Categories and 9 Integrated Project Categories were used.

4.1.2. Cross analysis of AMS Research Categories × 9 Integrated Project Categories (First 5-year Term):

2) Funding

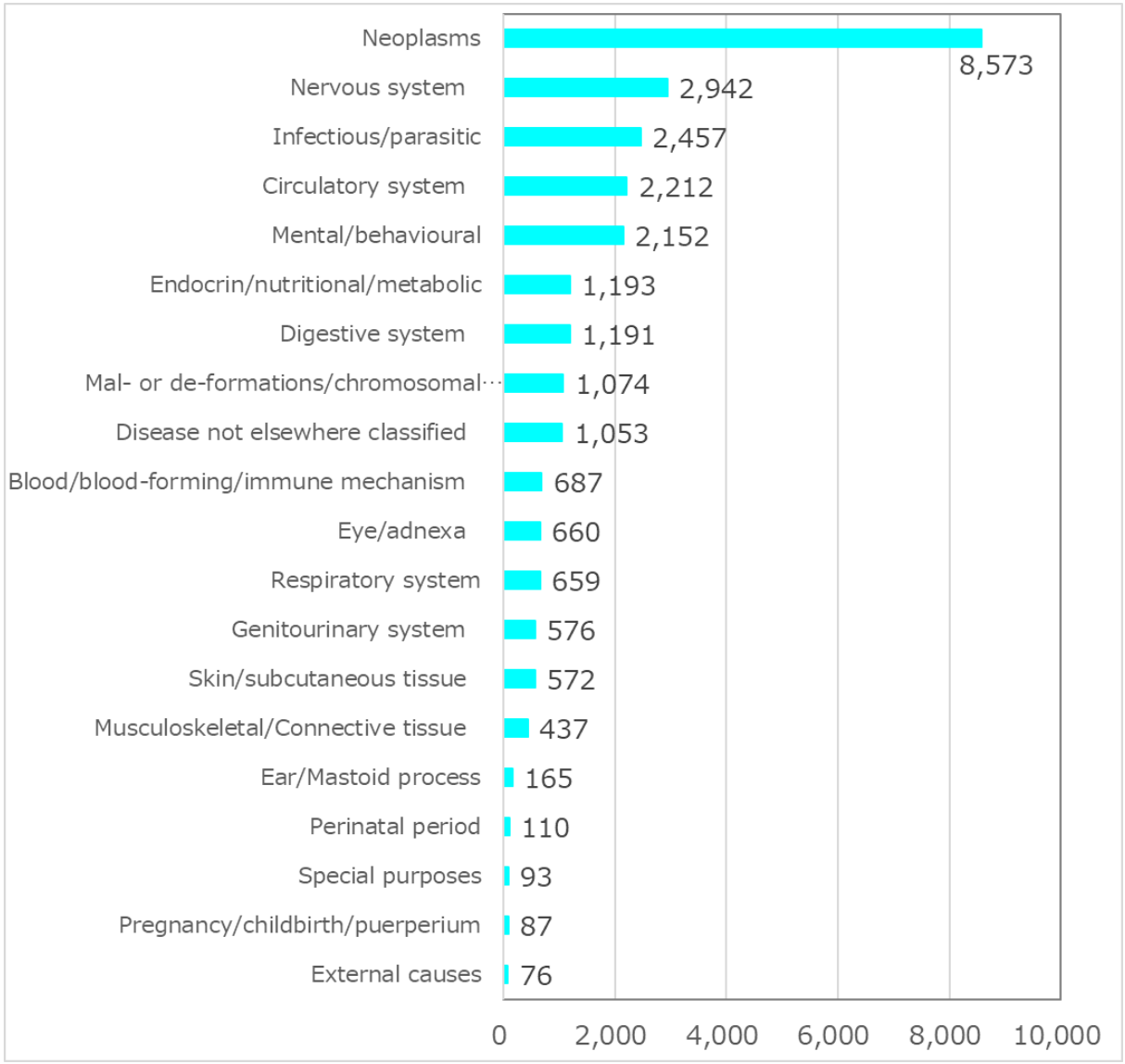
Billion yen

	Pharmaceutical/ Medical Device Development	Basic Biomedical/Aetiolgy Studies	Survey Analyses	Medical Technology/ Therapeutics Development	Infrastructure for Drug Discovery/ Underpinning	Regulatory/Nursing System Improvement and Technical Support	Diagnosis/Clinical Testing Development and Validation	Evidence Building for Prevention	Others	Total
Project for Drug Discovery and Development	50.0	0.2	0.5	0.4	60.5	0.7	0.1	0.0	1.5	113.9
Project for Medical Device Development	53.6	0.7	0.0	1.0	3.1	3.9	0.9	0.0	0.8	64.0
Project for Japan Translational and Clinical Research Core Centers	14.5	0.0	0.0	0.4	36.1	0.0	0.1	0.0	0.2	51.3
Japan Regenerative Medicine Project	45.1	4.0	0.0	0.2	22.1	0.5	0.1	0.0	1.6	73.6
Japan Genomic Medicine Project	0.8	10.4	0.5	1.5	33.8	0.0	0.6	0.0	0.1	47.7
Japan Cancer Research Project	41.9	2.0	1.0	12.2	4.4	0.4	2.6	1.4	1.2	67.1
Project for Psychiatric & Neurological Disorders	6.2	21.7	1.3	3.9	4.5	0.1	2.4	1.4	0.0	41.5
Emerging/re-emerging Infectious Disease Project	6.4	2.9	9.3	0.8	6.5	0.0	2.1	1.4	1.2	30.6
Rare/Intractable Disease Project	30.8	4.7	0.4	2.8	7.3	1.9	0.1	0.0	0.1	48.1
Others	39.0	40.7	3.1	6.9	22.4	1.6	3.2	1.6	4.5	123.0
Total	288.4	87.4	16.2	30.2	200.8	9.1	12.3	5.9	11.3	661.6

Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.
Only awarded projects tagged with both AMS Research Categories and 9 Integrated Project Categories were used.

4.2. Total Numbers, Including All Related Diseases

4.2.1. 5-year total of ICD 10 Classification of Diseases (aggregated); 1) Number of awarded projects

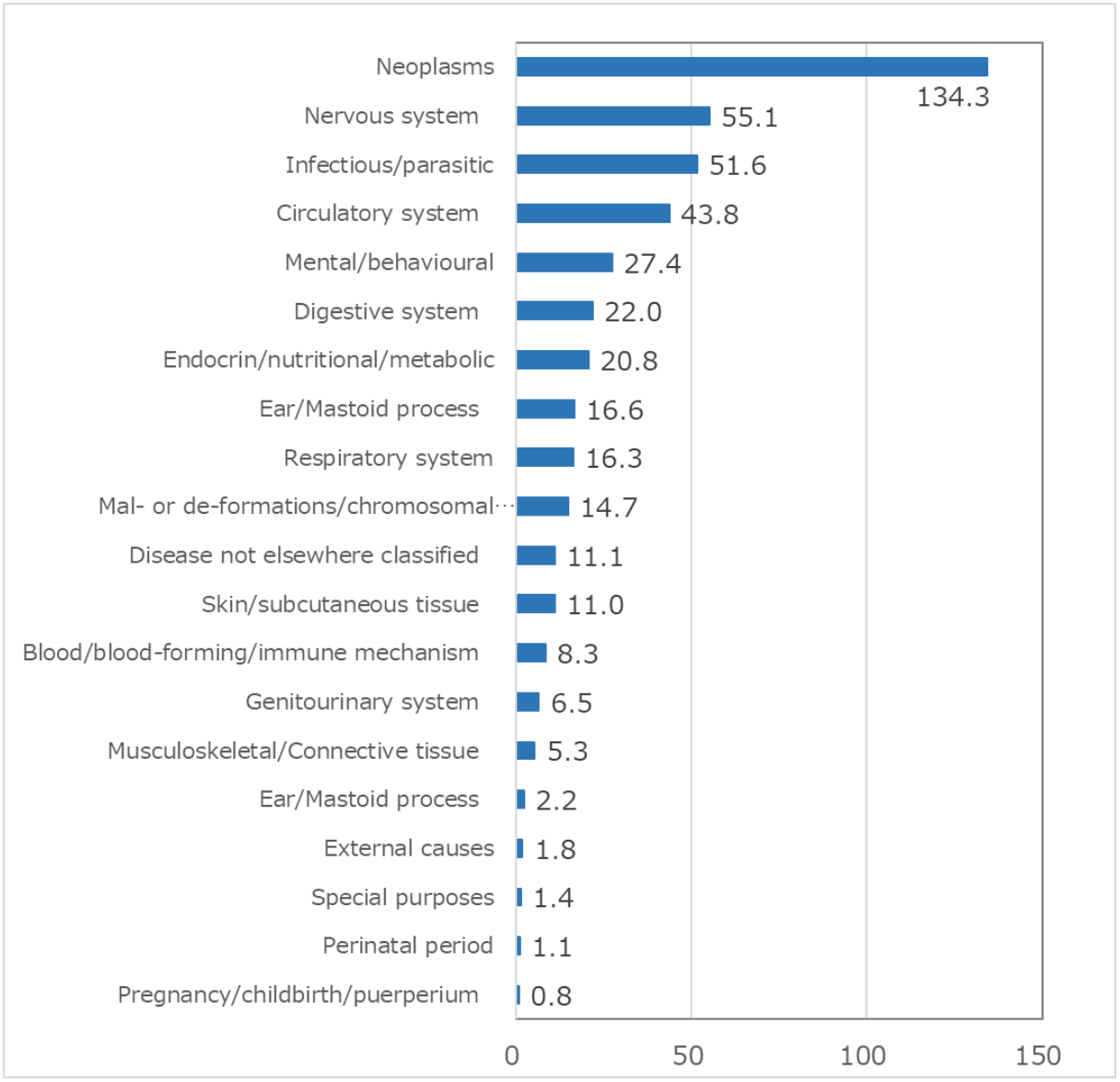


Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of target diseases was aggregated based on the ICD 10 International Classification of Diseases, 10, 2013, after excluding "Injury, poisoning and other exogenous effects" and "Factors affecting health status and use of insurance services".

Awarded projects tagged “N/A (No target diseases)” or “Other” were excluded.

4.2.1. 5-year total of ICD 10 Classification of Diseases (aggregated): 2) Funding (total amount)



Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of target diseases was aggregated based on the ICD 10 International Classification of Diseases, 10, 2013, after excluding "Injury, poisoning and other exogenous effects" and "Factors affecting health status and use of insurance services".

Awarded projects tagged “N/A (No target diseases)” or “Other” were excluded.

In case of two or more related diseases, the funded amount was aggregated by proportional division.

4.2.2. Changes of ICD 10 Classification of Diseases (aggregated): 1) Number of awarded projects

Cases

	Number of awarded projects (Total number)					
Classification of Related Disease	2015	2016	2017	2018	2019	Total
Infectious/parasitic	439	474	508	470	454	2,345
Neoplasms	1,330	1,376	1,520	1,627	1,619	7,472
Blood/blood-forming/immune mechanism	126	145	159	128	100	658
Endocrin/nutritional/metabolic	253	274	257	199	174	1,157
Mental/behavioural	327	489	446	414	383	2,059
Nervous system	539	630	612	533	472	2,786
Eye/adnexa	119	141	143	125	98	626
Ear/Mastoid process	41	43	32	27	18	161
Circulatory system	454	504	466	360	323	2,107
Respiratory system	124	126	139	119	112	620
Digestive system	190	213	266	245	247	1,161
Skin/subcutaneous tissue	100	122	134	109	90	555
Musculoskeletal/Connective tissue	90	84	97	82	69	422
Genitourinary system	97	117	124	102	101	541
Pregnancy/childbirth/puerperium	14	17	16	17	20	84
Perinatal period	15	18	24	22	25	104
Mal- or de-formations/chromosomal abnorma	230	243	238	160	159	1,030
Disease not elsewhere classified	218	254	240	164	147	1,023
Injury/poisoning/other consequences	12	14	17	18	15	76
External causes	7	12	18	17	32	86
Total	4,725	5,296	5,456	4,938	4,658	25,073

Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of target diseases was aggregated based on the ICD-10 International Classification of Diseases, 10, 2013, after excluding "Injury, poisoning and other exogenous effects" and "Factors affecting health status and use of insurance services".

Awarded projects tagged “N/A (No target diseases)” or “Other” were excluded.

4.2.2. Changes of ICD 10 Classification of Diseases (aggregated): 2) Funding (total amount)

Billion yen

Classification of Related Disease	Funding (Total amount, Billion yen)					
	2015	2016	2017	2018	2019	Total
Infectious/parasitic	9.5	9.9	9.6	11.4	9.8	50
Neoplasms	24.2	30.1	30.1	26.3	27.7	138
Blood/blood-forming/immune mechanism	1.7	1.5	1.4	1.7	1.8	8
Endocrin/nutritional/metabolic	3.8	4.4	4.2	4.2	3.8	20
Mental/behavioural	4.8	5.5	5.3	5.8	5.5	27
Nervous system	10.7	10.9	10.8	12.6	10.2	55
Eye/adnexa	3.6	3.4	3.6	3.6	2.6	17
Ear/Mastoid process	0.4	0.4	0.6	0.6	0.5	3
Circulatory system	9.0	9.5	9.2	7.9	9.7	45
Respiratory system	3.0	4.1	3.9	2.8	1.8	16
Digestive system	4.0	4.2	4.4	4.6	4.6	22
Skin/subcutaneous tissue	1.5	2.2	3.6	1.9	1.6	11
Musculoskeletal/Connective tissue	1.1	1.0	1.1	1.4	1.1	6
Genitourinary system	0.9	1.2	1.5	1.5	1.5	7
Pregnancy/childbirth/puerperium	0.1	0.3	0.1	0.2	0.2	1
Perinatal period	0.4	0.1	0.1	0.2	0.3	1
Mal- or de-formations/chromosomal abnormalities	2.9	2.7	2.5	2.4	3.1	14
Disease not elsewhere classified	2.4	2.3	2.4	2.2	2.1	11
Injury/poisoning/other consequences	0.4	0.4	0.4	0.3	0.3	2
External causes	0.1	0.1	0.1	0.1	2.7	3
Total	84	94	95	92	91	456

Source: AMS (As of February 17, 2021). Excludes Cyclic Innovation for Clinical Empowerment (CiCLE) Projects.

The number of target diseases was aggregated based on the ICD-10 International Classification of Diseases, 10, 2013, after excluding "Injury, poisoning and other exogenous effects" and "Factors affecting health status and use of insurance services".

Awarded projects tagged “N/A (No target diseases)” or “Other” were excluded.

In the case of two or more related diseases, the funded amount ~~of given award~~ was aggregated by proportional division.

5. Glossary

Term	Description
AMS	Abbreviation for AMED Management System. AMS is an in-house database which comprehensively incorporates research projects funded by AMED.
AMS Research Categories	The AMS categorial tag to classify the character of individual awarded projects, uniquely defined by AMED. Eight categories are listed as below. 1) Pharmaceutical/Medical Device Development <Including development of systems to implement medical devices> 2) Basic Biomedical/Aetiologic Studies 3) Survey Analysis <Including fieldwork, surveillances, and monitoring> 4) Medical Technology/Therapeutics Development <Including verification of evidence to improve the quality of medical care by compilation of guidelines and other methods> 5) Infrastructure for Drug Discovery/Underpinning <Including discovery of drugs, ICT infrastructure and platforms> 6) Regulatory/Nursing System Improvement and Technical Support <Including advancement of technology supports for the international health system> 7) Diagnosis/Clinical Testing Development and Validation <Excluding development of diagnostic drugs and equipment> 8) Evidence Building for Prevention <Including epidemiology studies>
Awarded project	Research project awarded and funded to individual principal investigators by AMED.
Co-investigator research project	R&D conducted by collaborating institutions under the leadership of the PI, who is adopted by AMED. AMED directly allocates funds to the contributory co-investigating institutions.
Cyclic Innovation for Clinical Empowerment (CiCLE)	CiCLE is AMED's program, launched in 2017, which aims at creating a foundation (including human resources) for ~~a~~ radical transformation of the way R&D is conducted in response to the needs arising in clinical settings and for accelerating the practical application of pharmaceutical products. It also seeks to drive the creation of an environment that strongly fosters open innovation in the field of medical research and development through the combined efforts of the government, academia, and the private sector.
Development stage	The AMS categorial tag to categorize the developmental stage of the products developed/tested in the given awarded project. The 7 developmental stages are; basic research, applied research, nonclinical and preclinical research, clinical trials, MD-lead clinical trials, post-marketing surveillance, and observational research. One stage is cited per year of the active project. It is mandatory to quote the developmental stage tag in "Research aimed at the development of pharmaceuticals and medical devices," but for the other types of research, it is optional.
First Medium- to Long-Term Plan	AMED, as a Japanese National Research and Development Agency, is set to launch a Medium- to Long-Term Plan to achieve its objectives, and this is stated in Article 35, Paragraph 5 of the Act on General Rules for Incorporated Administrative Agency (No. 103 Act in FY 1999). The five-year period of FY 2015 to 2019 is the first term of the Plan. The ADB provides a statistical overview of the awarded projects supported and funded during the five-year period. An outline of the first Plan is attached in this Book and the plan itself is listed in https://www.amed.go.jp/content/000061094.pdf (in Japanese).

Term	Description
ICD-10 disease classification	ICD is an abbreviation of "International Statistical Classification of Diseases and Related Health Problems" created and endorsed by the World Health Organization (WHO), and ICD-10 is its 10th revised version. The Ministry of Health, Labour and Welfare of Japan currently compiles the "Statistical classification of diseases, injuries and causes of death (FY2013 version)", derived from ICD-10, to register the statistical data and medical records in Japan. The AMS database uses the Chapter, the primary category, of ICD-10 as its disease tag.
Nine Integrated Project Categories (First 5-year Term)	AMED's 9 Integrated Project Categories (First 5-year Term) are listed below. They are aimed at promoting seamless medical R&D, from basic research to practical application, and at applying the outcomes of such research in practice. 1) Project for Drug Discovery and Development (Drug Project) 2) Project for Medical Device Development (Medical Device Project) 3) Project for Japan Translational and Clinical Research Core Centers (Core Center Project) 4) Japan Regenerative Medicine Project (Regenerative Project) 5) Japan Genomic Medicine Project (Genome Project) 6) Japan Cancer Research Project (Cancer Research Project) 7) Project for Psychiatric & Neurological Disorders (Brain Research Project) 8) Emerging/re-emerging Infectious Diseases Project (Infectious Diseases Project) 9) Rare/Intractable Diseases Project (Rare Diseases Project) In the AMS, the Project classification is allocated into 10 categories, with the addition of "others" to the above. For your reference, these projects were originally started as "Projects to promote cooperation among the ministries" in the early days of the first 5-year term, and subsequently revised as "Integrated Projects" of disease-area-specific and cross-sectional R&Ds. Details are provided in https://www.amed.go.jp/content/000033777.pdf (in Japanese).
Principal investigators (PIs)	Leading researcher, who has the appropriate level of authority and responsibility to direct the awarded research project.
Product application categories	The AMS categorial tags of four products (pharmaceuticals, medical devices, regenerative medical products, and *in-vitro* diagnostics) of AMED's focuses, are defined in Article 2 of the "Act on Quality, Efficacy and Safety of Drugs and Medical Devices (commonly known as the Pharmaceutical and Medical Devices Act)" to receive regulatory approval. In the AMS, it is mandatory to quote the categorial tag applications for research awards aimed at the "development of pharmaceuticals and medical devices," while it is optional for the other R&D types.
R&D funding	Research and development funds that AMED grants and allocates to the research institutions, including universities and National Research and Development Institutes. In the present data book, no categories are defined or classified depending on the financial sources of the awards, neither commissioned nor supplementary expenses.
Research project	Individual research and development conducted with AMED's funding by principal investigator(s), co-investigator(s) or sub-contractor(s).
Subcontracted research project	Subcontracted research project appointed by the PI, is to take a part of the awarded project The PI forwards R&D funding to the subcontractors.

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AMED Data Book: First Medium to Long-term Plan Period (FY 2015 to FY 2019)

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Published June 2021