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## **Guidelines for Operation and Evaluation of the Moonshot R&D Program in the Health and Medical Fields**

### **1. Program Features**

- The government presents an ambitious goal(s), Moonshot Goal(s) (hereinafter referred to as MS Goal(s)), which attracts people, and R&D concept(s) (hereinafter referred to as the concept(s)), from the perspective of looking toward a future society, and solving domestic and overseas social issues that will arise.
- Challenging R&D concepts by being based more on bold ideas that will not just be extensions of conventional technology, and which are promoted by maximizing knowledge and ideas in the basic research phase.
- To achieve the MS Goal(s), multiple project managers (hereinafter referred to as PMs) are, in principle, selected under respective MS Goal(s), and a program director (hereinafter referred to as the PD) is appointed to direct and supervise, in a unified manner, the program that is comprised of multiple R&D projects (hereinafter referred to as projects) that PMs promote.
- Authority for promoting the project is granted to PMs. Flexible management is promoted under the direction of each PM, while bringing together the wisdom of researchers from all over the world.
- The PD drafts a portfolio (the management plan that summarizes the project components (combination) and resource allocation, etc., (hereinafter referred to as portfolio) to strategically achieve the MS Goal(s), and the research promotion agency (funding agency, hereinafter referred to as FA) make a final decision on the portfolio based on this. The PMs apply diverse knowledge and ideas in the basic research phase, undertake challenging research without fear of failure, and discover and foster innovative research results.
- While utilizing the benefits of the multiple-year funding system and repeatedly restructuring the portfolio, we implement R&D that allows for support for up to 10 years from the start of the research.
- As well as always sharing relevant domestic and overseas R&D trends, we establish the most advanced research support system through which researchers can challenge leading-edge research through cooperation.

- To promote the use of research data<sup>1</sup> generated through research activities and to support advanced research management, we pursue advanced data management, by means such as proactively utilizing the Research Data Infrastructure System (NII Research Data Cloud)<sup>2</sup>.
- Looking ahead to practical use of the R&D results in society in the future, we actively encourage utilization of the R&D results and examine the open and close strategy involving industry from the R&D phase.

## 2. Determination of the MS Goal(s) and Formulation of the Concept(s)

- At the Expert Panel under the Headquarters for Healthcare Policy (hereinafter referred to as Headquarters), the drafted MS Goal(s) is discussed from the perspectives of looking toward a future society and solving domestic and overseas social issues that will arise.
- Headquarters determine the MS Goal(s) in light of discussions from the Expert Panel. When MS Goal(s) are determined, we make sure to establish a research support system to maximize ideas and knowledge from researchers.
- Relevant ministries and offices formulate the concept(s) to achieve the MS Goal(s). Consideration is given to incorporating ideas for achieving the MS Goal(s) and international strategy perspective.
- According to changes in the social environment and advances in science and technology, if deemed necessary, Headquarters add and/or change the MS Goal(s) after evaluating their technical feasibility and listening to domestic and overseas opinions.

## 3. The R&D Promotion System

[Headquarters]

- Headquarters determine the MS Goal(s).
- In principle, the Expert Panel under the Headquarters receives a report on the progress of R&D every year regarding discussions at the Strategy Promotion Council, and advises on the promotion of this entire program from a broad perspective.

[Strategy Promotion Council]

- A Strategy Promotion Council comprised of people from industry, relevant ministries and offices, and researchers, is established to strategically promote R&D, to accelerate the practical use of the R&D results in society, and to achieve effective cooperation and coordination among the relevant ministries/offices and the relevant FAs.
- The duties of the Strategy Promotion Council are listed below:

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<sup>1</sup>Research data means data generated in the R&D process, which is manageable in an electromagnetic form. (Source: the Cabinet Office Report, “Research data infrastructure development and international cooperation working group” October 2019)

<sup>2</sup>The NII Research Data Cloud has started full-fledged operation in 2021 as a research data infrastructure system to promote research data management, disclosure, and retrieval based on the Integrated Innovation Strategy 2019 (the Cabinet approval in June 2019).

- 1) Receive a report of progress and other matters from the relevant FAs every year in principle, and give advice and approval on the concept of project components and fund allocation, etc., from a global and comprehensive perspective to achieve the MS Goal(s).
  - 2) Advise on the ways and means for the practical use of the R&D results in society. This involves bridging the gap between the R&D and practical use in society, collaborating with the private sector, and attracting well-timed private investment based on role-sharing at the different stages of R&D activities between the public and private sectors. Also provide support for the practical use of the R&D results in society. In addition, give advice to promote international cooperation.
- Progress reports and the minutes of meetings of the Strategy Promotion Council are, in principle, disclosed to give maximum consideration to the transparency of the program's operation and accountability.

[Relevant Ministries and Offices]

- The relevant ministries and offices formulate the concept(s) with the aim of achieving the MS Goal(s), and strategically and collectively promote related R&D, cooperating with other ministries and offices.

[FA]

- FA is responsible for realizing the concept(s) that achieves the MS Goal(s).
- The duties of FA are listed below:
- 1) Appoint a PD who is deemed qualified for each MS Goal, then manage and supervise them. One or more sub-PDs who assist the PD may be appointed, as necessary.
  - 2) After discussions with the PD, openly recruit and select, in principle, more than one PM.
  - 3) Determine a portfolio based on the PD's draft.
  - 4) Instruct the PMs to draw up a project plan under the direction of the PD.
  - 5) Collect and analyze information on domestic and overseas R&D trends and the challenges for the practical use of the R&D results in society, with incorporating the opinions of outside experts, including researchers in humanities and social sciences.
  - 6) Hear from the PD and PMs about the status of the project's progress, the resource allocation and the role-sharing between the public and private sectors, according to the progress of the R&D, and in principle, report the details to the Strategy Promotion Council every year.
  - 7) Provide support for the management of intellectual property, international standardization, public relations, and technical trends surveys, so that the PD and PMs can properly manage these. In addition, identify a promising project (or a part of the project) in an early stage from the perspective of the practical use of its R&D results in society, and ensure that support from specialists can be acquired as necessary so that the capability to identify a project that will be practically used in society in the future can be effectively demonstrated. To gain public understanding and support, help the PD and PMs to smoothly conduct bi-directional communication activities (public dialogue on science and technology) through which they can explain to society their research activities.
  - 8) Since crosscutting support such as ELSI (Ethical, Legal and Social Issues) /mathematical science is also important for R&D acceleration and its practical use in society, provide an opportunity for the PD and crosscutting researchers to exchange their opinions, and establish a system through which a PM can acquire the support of crosscutting researcher(s), if the PD deems it necessary, and if the PM requires it.
  - 9) Promptly appoint a new PD when an accident occurs or a vacancy arises on the PD, or when it is deemed that the PD is not fulfilling their duties. In addition, promptly review the system of the

project in discussion with the PD when an accident occurs or a vacancy arises on a PM, or when the PD deems that the PM is not fulfilling their duties. If it is decided that the project will continue, the details of the PM selection method will be determined by FA including methods other than open recruitment.

- 10) Decide the details of PDs', sub-PDs', and PMs' working conditions.
  - 11) Construct an environment in which young researchers with bold and flexible ideas, who will define future society, can actively participate in a project.
  - 12) The relevant FAs cooperate and share related domestic and overseas R&D trends to build the most advanced research support system.
  - 13) To pursue advanced data management, manage a data catalogue comprised of metadata<sup>3</sup> submitted by PMs and researchers by utilizing system such as the Research Data Infrastructure System.
- When performing these duties, FA strives to create an environment in which researchers can focus on research by improving the efficiency of evaluation work, as well as continue their efforts in cooperation with the relevant ministries and offices, and other research promotion organizations. Also FA utilizes advanced data management to ensure fairness of research, and engages in efforts to prevent a contractor from committing a wrongful act and misapplying research funding.

[PD]

- The terms of the PD and sub-PD are, in principle, five years, and they may also be reappointed.
- Any nationality is welcome to be the PD, but the PD is principally based in Japan after being appointed.
- The duties of the PD are listed below:
- 1) To realize the concept(s) and achieve the MS Goal(s), strategically build a draft of portfolio, and promote R&D in a challenging and systematic way.
  - 2) When building a draft of portfolio, in principle, combine multiple projects that take different research approaches by taking into account their R&D innovation and originality, and future economic and social ripple effects, since the chance of success (or failure) and their research results (return) will vary according to their respective research approaches, even among the research projects that aim for the same goal. For example, let's assume there is a project through which significant research results can be achieved, but with a limited chance of success, while there is another project through which a certain level of research results can be achieved with a high chance of success. In such case, funds will be allocated by comprehensively considering the chance of success and research results. In the case of a project that requires technical examination, although research results can be anticipated if successful, the project starts as its feasibility study with a small start. Thereafter the allocation of funding fluctuates according to the progress status.
  - 3) Always understand the progress of R&D based on the portfolio, and manage and supervise in a unified manner the PMs who oversee the relevant projects while constantly reviewing the portfolio, such as allocating resources with a focus on research that is steadily progressing, and discontinuing a project if it is deemed to be unlikely to produce results.
  - 4) Lead the portfolio review based on advice from external evaluators and the Strategy Promotion Council.
  - 5) Objectively evaluate the research content and lead the utilization of private funding, as well as indirectly support PM activity by pursuing the practical uses of the R&D results in the society and

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<sup>3</sup> Metadata provides explanatory information about research data, such as data name, content, administrator, location of storage, contact of administrator, and policy for closure, sharing, and disclosure of research data.

collaboration with the private sector, and promoting international cooperation. In addition, conduct bi-directional communication activities (public dialogue on science and technology) to explain the research activities to society.

- 6) Conduct other actions necessary to promote the research for which the PD is responsible.

[PM]

- All nationalities are welcome to be a PM, but PM is principally based in Japan after being appointed.
- Allow PM to concurrently engage in other work. The time allocated for research (effort rate) is set by FA.
- The duties of a PM are listed below:
  - 1) Under the direction of the PD, refine a proposed project during an open call to improve it, draw up a project plan (target setting of project, preparation of R&D details and implementation schedule, establishment of an R&D system to implement the project, and formulation of a plan to allocate research funding to participating R&D institutions in the project), and strategically implement the project. Moreover, flexibly and nimbly implement project modifications and changes in direction, including practical use of some research results in society.
  - 2) Properly manage intellectual property and information, and actively and strategically promote international cooperation.
  - 3) Objectively evaluate the research content, seek sponsors from private enterprises if R&D is at the phase at which private funding can be used, and also try to draw on private funding. In addition, conduct bi-directional communication activities (public dialogue on science and technology) to explain the research activities to society.
  - 4) Develop a data management plan (DMP) that defines the data to be managed, and also aggregate metadata about the data to be managed from researchers based on DMP, and submit that to FA. In addition, with system such as the Research Data Infrastructure System, store and share the data to be managed, and publish the data to the extent necessary.

#### 4. The R&D Implementation Method

[Open Recruitment and Selection]

- After discussions with the PD, FA openly recruits and selects, in principle, more than one PM inside and outside Japan. On this occasion, establish an evaluation system comprised of outside experts, and ask for the opinions of outside experts to recruit PMs from a comprehensive perspective. Furthermore, when establishing an evaluation system, it should be taken into consideration that the Moonshot R&D Program aims at challenging R&D concepts by being based more on bold ideas that will not just be extensions of conventional technology.
- The following points should be taken into consideration when selecting a PM:
  - They have expert knowledge and a wide human network such as relevant researchers inside and outside Japan, to promote cutting-edge research.
  - They have management and leadership skills such as the ability to establish an optimal R&D system, and nimbly review the system according to the status of progress.
  - Project targets and contents proposed by the PM (hereinafter referred to as proposal details) are challenging and based more on bold ideas than existing proposals, and comprise innovative proposals from which a substantial impact on future industry and society is expected.
  - From the perspective of technical feasibility and practical use of its R&D results in society, appropriate scenarios (hypothesis for success) for achieving the MS Goal(s) by 2040 can be clearly explained.

- The proposals contain top-level R&D capabilities, knowledge, and ideas, regardless of whether they come from inside or outside Japan.

#### [Building a Portfolio/Drawing up of a Project Plan]

- FA instructs the PMs to refine a proposed project during an open call to improve it and draw up a project plan under the direction of the PD.
- To realize the concept(s) and achieve the MS Goal(s), the PD strategically builds a draft of portfolio.
- FA determines the portfolio based on a draft of portfolio built by the PD.
- FA establishes a system to check the PD and PMs do not have conflicts of interest during the course of drawing up a project plan and R&D implementation, so as to promote R&D in a fair and appropriate manner.

#### [R&D Implementation]

- Under the direction of the PD, the PMs flexibly and nimbly promote acceleration and deceleration of individual R&D challenges in the projects according to the progress of R&D, and changes in direction, including practical use of some research results in society, with their own authority and responsibilities.
- The PD and PMs always understand domestic and overseas R&D trends, and nimbly review the portfolio and projects according to the progress of R&D. In particular, they strive to understand similar R&D trends overseas, actively attract high-profile overseas researchers, and promote joint research.
- The PD and PMs pursue advanced data management, such as encouraging information exchange among researchers, and data storage, sharing, and disclosure.
- FA actively supports management activities of the PD and PMs, and develops an environment in which outside experts can advise the PD and PMs as required.

#### [Report on the Status of Progress to the Strategy Promotion Council]

- In principle, FA reports on the status of the program's progress and other matters every year to the Strategy Promotion Council, and improves the program (project components and fund allocation, etc.) by receiving the Council's advice and such.

#### [Implementation Period]

- Support is available for up to 10 years from the start of the research (the start of the first project among multiple projects), while the portfolio is repeatedly reviewed.
- FA reports on the results of external evaluations and self-evaluations to the Strategy Promotion Council. After discussing with the PD, they rule on project continuation, acceleration, deceleration, modification, and termination (such as a portfolio review), based on the Council's advice.

- Headquarters evaluate the status of progress of the program's R&D aimed at achieving the MS Goal(s), and the prospects of achieving the MS Goal(s) in the fifth year after the start of research, and decides whether to continue or terminate the program aimed at achieving the MS Goal(s).

## 5. R&D Evaluation

### [Evaluation]

- FA establishes an evaluation system comprised of outside experts, and implement external evaluations.
- External evaluations are, in principle, implemented in the third and fifth years from the start of research. If it is decided that a program will continue for more than five years, it will then be evaluated in its eighth and tenth years. If FA finds it necessary to accelerate the evaluation period according to the project features, an appropriate schedule shall be established in advance.
- In principle, FA implements a self-evaluation based on the evaluation criteria specified in the following section every year (other than those years in which external evaluations are implemented) and reports the results to the Strategy Promotion Council and the relevant ministries and offices that formulate the concept(s). They will also consult with outside experts as necessary. In that case, they will also report the details of their opinions and how they are reflected in the self-evaluation.

### [Evaluation Perspectives]

External evaluation is mainly based on the following perspectives, through which FA specifies detailed evaluation criteria in cooperation with the relevant ministries and offices.

#### <Evaluation of the program>

- The appropriateness of the portfolio aimed at achieving the MS Goal(s)
- The status of progress of the program's R&D aimed at achieving the MS Goal(s)
- The future prospects for the program's R&D aimed at achieving the MS Goal(s)
- PD's management status (including portfolio management, direction to and supervision of PMs, flexibility and nimbleness)
  - Cooperation with industry and the status of bridging the gap between the R&D and practical use in society (including the status of acquiring private funding [matching] and spin-out)
  - Effective and efficient R&D promotion through international cooperation
  - Challenging and innovative efforts based on bold ideas
  - Effective and efficient use of research funding (including role sharing between the public and private sectors, and stage-gates)
  - Bi-directional communication activities (public dialogue on science and technology)
  - FA's support for PD/PM activities

#### <Evaluation of the project>

- The appropriateness of project targets and contents aimed at achieving the MS Goal(s)
- The status of progress toward project targets (particularly comparisons of both domestic and overseas)
  - The future prospects of project targets
  - The status of establishing an R&D system
  - PM's project management status (including flexibility and nimbleness)
  - Status of research data storage, sharing, and disclosure
    - Cooperation with industry and the status of bridging the gap between the R&D and practical use in society (including the status of acquiring private funding [matching] and spin-out)
    - Effective and efficient R&D promotion through international cooperation

- Challenging and innovative efforts based on bold ideas
- Effective and efficient use of research funding (including role sharing between the public and private sectors, and stage-gates)
- Bi-directional communication activities (public dialogue on science and technology)

#### [Handling Evaluation Results]

- FA reports on the results of external evaluations and self-evaluations to the Strategy Promotion Council and relevant ministries and offices that formulate the concept(s). The results of external evaluations and self-evaluations are made public in principle.
- FA reports on the results of external evaluations and self-evaluations to the Strategy Promotion Council. After discussing with the PD, they rule on project continuation, acceleration, deceleration, modification, and termination (such as a portfolio review), based on the Council's advice.
- If a project, or some part of a project, is discontinued after a review of the portfolio, FA, the PD and PMs will provide the necessary support so that the secondary research results obtained to that point can be utilized in other businesses and R&D projects, with help from the Strategy Promotion Council.
- FA will announce publicly how the results of external evaluations and self-evaluations were reflected in the project continuation, acceleration, deceleration, modification, and termination (such as a portfolio review).
- FA will make a follow-up evaluation after a certain period of time has elapsed after R&D termination, and conduct a follow-up of the achievements of PMs' projects.

#### 6. Eligible Project Costs

- Costs necessary to promote the projects are taken care of by making withdrawals from the funds established by FA for this program.
- Eligible project costs include the following, with details of costs determined by FA. The indirect cost ratio is 30% for universities and 10% for private enterprises (but 20% for SMEs) among domestic R & D institutions, and the ratio for others is established respectively by FA. In addition, the indirect cost ratio for overseas R&D institutions can be set in consideration of the local economic level. The following R&D may include verification up to POC (Proof of Concept) as necessary.
  - 1) Costs required to implement R&D
  - 2) Costs required for project management
- Costs associated with an application for intellectual property rights (hereinafter referred to as costs for intellectual property rights) may be paid as R&D expenses (direct costs) in a commissioned research contract. If it is difficult to pay the costs for intellectual property rights through direct costs, FA may pay such expenses through a contract executed separately from the commissioned research contract. Costs for intellectual property rights after project termination are borne by the R&D institution.

#### 7. Handling Intellectual Property, etc.

- Intellectual property rights, in principle, belong to the R&D institution that is a contractor, or a researcher belonging to the said institution, by applying Article 17 of the Industrial Technology



Enhancement Act. The PMs place importance on utilizing intellectual property rights to achieve the MS Goal(s), and determine the policy for utilizing intellectual property rights. Procedural details are defined by FA.

- In the case of the participation of a foreign R&D institution, not less than 50% of the foreign R&D institution's ownership interests of the intellectual property rights obtained by carrying out the research, is compelled to belong to FA.
- The transfer of intellectual property rights obtained by carrying out the research, and the establishment and transfer of an exclusive license, shall all require the prior approval of FA.
- Data to be managed shall be managed by the R&D institution that is a contractor, or by researchers belonging to the said institution under their responsibilities in accordance with the data policy of each institution. The categories of storage, sharing, and disclosure of data to be managed shall be clarified based on the open and close strategy, and research data are disclosed to the extent necessary by utilizing system such as the Research Data Infrastructure System.

#### 8. Handling Conflicts of Interest

- Since the PD is responsible for selecting PMs and for building and managing a portfolio, the PD is not allowed to participate as a PM or as a researcher. On the other hand, it is not appropriate to judge conflicts of interest between the PD or PMs and participating R&D institutions by a one-size-fits-all criteria, if that prevents Japan from attaining top-level capabilities in R&D and diverse knowledge as a result. Therefore, FA will render proper judgment on permitting participation or not, in the light of necessity, reasonability, and appropriateness of the respective relationships, with respect to conflicts of interest between the PD and participating R&D institutions in the portfolio that the PD is responsible for building, and between the PMs and participating R&D institutions in projects that the PMs are responsible for drawing up. The results will be published as necessary. The details are defined in documents such as the application guidelines by FA.