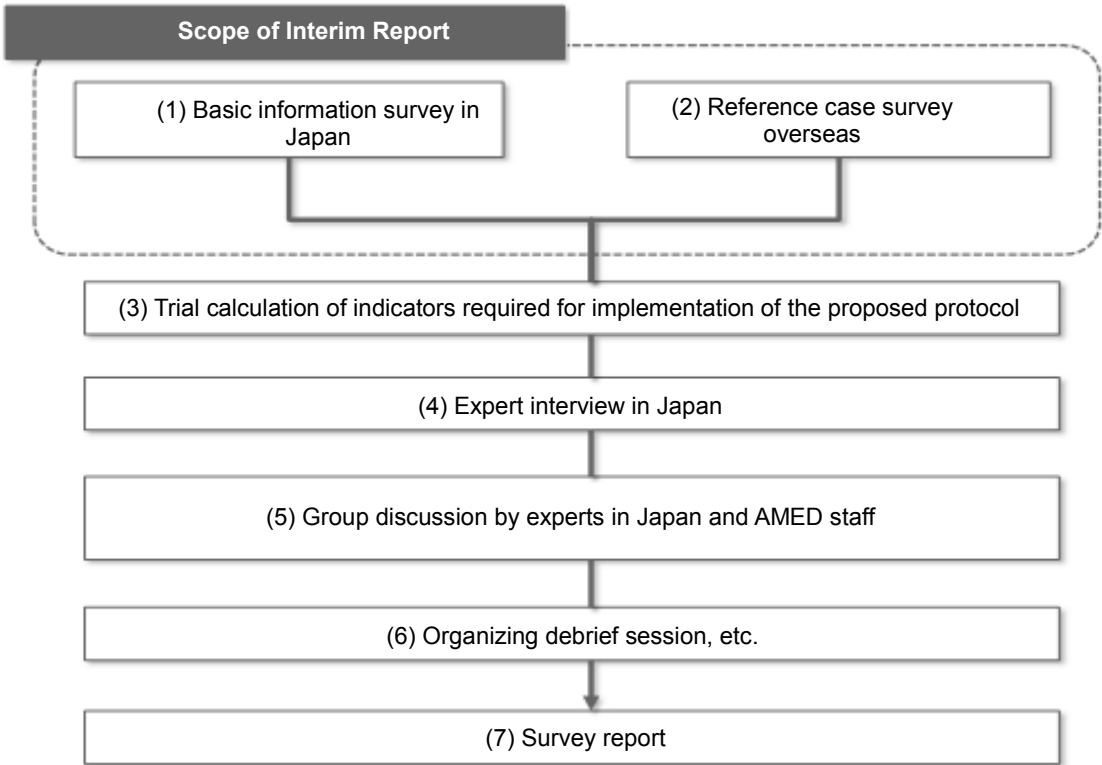


Executive Summary

The Survey shall aim to consider the medical research and development area to be supported by the Japan Agency for Medical Research and Development (hereinafter referred to as “AMED”), and utilize and secure transparency of quantitative information in business management, in other words, it shall aim to collect and organize reference information conducive to the development of a methodology for the acquisition of basic information and the proposal for the development of analysis structure, and collect and summarize expert opinions in evidence-based funding.

As shown in the overview of the survey (Figure/Table 1), the Survey consists of seven items. The scope of this interim report covers (1) basic information survey in Japan, and (2) reference case survey overseas. In the future, based on these survey results conducted both in Japan and overseas, a protocol on the “Method for considering research and development (“R&D”) area to be supported by AMED” will be prepared and proposed to implement the survey contents in (3) and onwards.

Figure/Table 1 Overview of the Survey



Source: Created by EY based on the specifications.

(1) Results of the basic information survey in Japan

In the basic information survey in Japan, desk research and field survey were conducted in order to comprehensively extract public health and socioeconomic quantitative indicators that should be considered when AMED examines the future forecast of socioeconomic issues in Japan, and also to explore and organize quantitative indicators effective for considering R&D areas in health and

medical fields to be promoted to solve future socioeconomic issues that may emerge to seriously affect the people of Japan.

In order to cover the entire life cycle, from verifying compounds discovered in the environment where researchers conduct R&D, until it has been released and led to solving epidemiological, socioeconomic issues, following six perspectives have been set for the Survey: "1. Epidemiological and economic indicators", "2. Socioeconomic impact", "3. R&D and competitiveness of the market", "4. Research trends in biology, medicine and neighboring fields", "5. R&D environment", and "6. Trends in needs of private sector company and seeds in academia".

In desk research, we conducted a comprehensive extraction of quantitative indicators that have been collected, tabulated and released on a continuous basis through public institutions or research structure using public funds. Scope of the survey, in public and private sectors, also covered epidemiological, economic and social present state and issues in Japan's health and medical fields, present state and issues of R&D environments, and survey and research reports for the future recommendations based on quantitative indicators or independent tabulation and analysis. As a result, a total of 986 indicators were extracted in the six survey perspectives. Among them, 231 cases were obtained excluding indicators not meeting the purpose of the Survey.

Next, matrix analysis was considered as a method of extracting and visualizing fields with serious health and medical issues, where existing solution methodologies and technologies, and private investment are lacking. Matrix analysis is generally used for analyzing and examining fields and areas to be invested in the formulation of business and R&D strategies of companies, etc. Hypotheses on epidemiological, social and economic issues were listed, and quantitative indicators intended to correspond to those issues were organized and used for analysis. We also performed a field survey for items no result could be obtained from desk research regarding indicators for R&D environment and outcomes in particular, and additionally gathered and created indicators based on the results (Figure/Table 2).

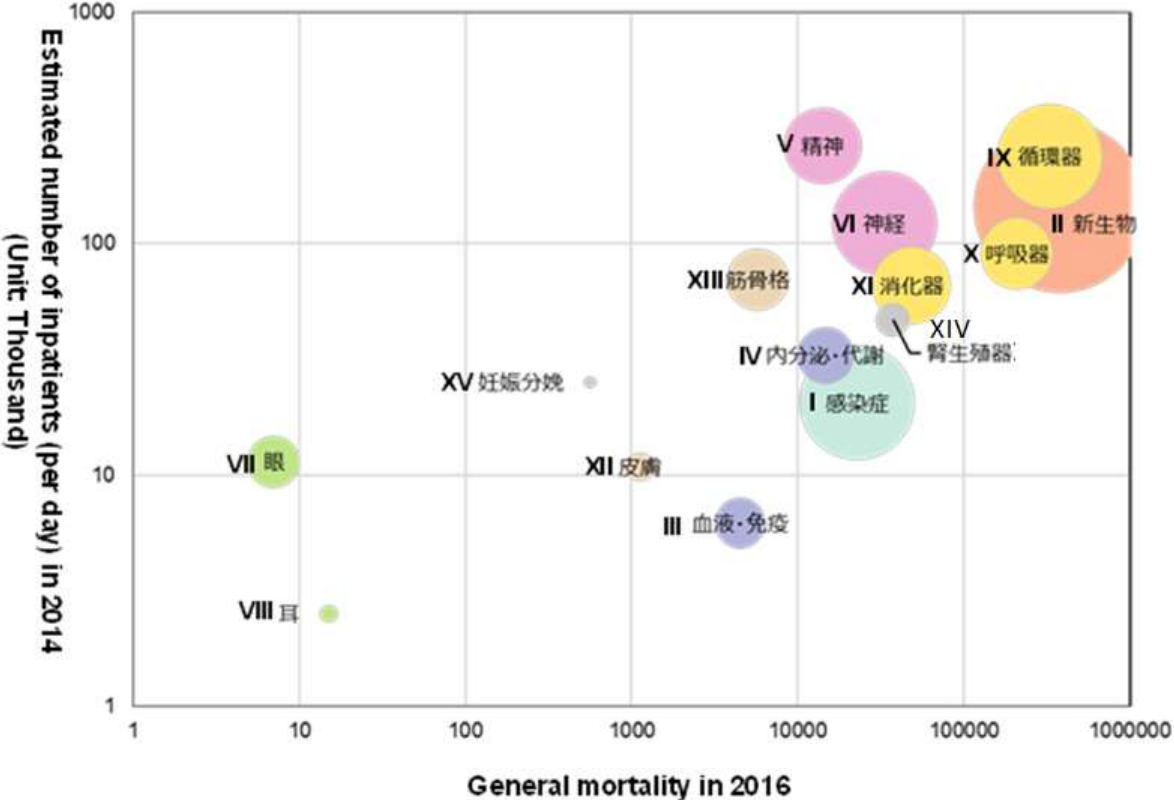
In the matrix analysis, following hypotheses and perspectives were established to consider the extraction of fields.

- Epidemiological, economic and societal issues: Diseases that become serious, diseases that become serious in children, diseases that are dominated by a large number of outpatients, diseases that lead to a decline in healthy life expectancy, and diseases with a concern about the increase in the number of patients in the future.
- R&D environment issues: Diseases with inadequate treatment satisfaction and options, and diseases with low expectation for the increase in treatment options in the immediate future.

The results suggested that there were areas where investment was active although there was existence of issues, and those areas with inadequate treatment options that are unlikely to increase in the immediate future despite the existence of issues, where investment is unlikely to be active.

From April this year, based on the quantitative indicators considered in this study and the contents of the field extraction, the initiative that aims to exhaustively extract fields is anticipated after discussion among experts and others who are representatives of a wide range of stakeholders in health and medical fields.

Figure/Table 2 An example of the matrix analysis
 General mortality (X axis), estimated number of inpatients (Y axis), and investment amount by AMED (bubble size) are plotted by disease classes



I	Certain infectious and parasitic diseases
II	Neoplasms
III	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
IV	Endocrine, nutritional and metabolic diseases
V	Mental and behavioral disorders
VI	Diseases of the nervous system
VII	Diseases of the eye and adnexa
VIII	Diseases of the ear and mastoid process
IX	Diseases of the circulatory system
X	Diseases of the respiratory system
XI	Diseases of the digestive system
XII	Diseases of the skin and subcutaneous tissue
XIII	Diseases of the musculoskeletal system and connective tissue
XIV	Diseases of the genitourinary system
XV	Pregnancy, childbirth and the puerperium

Source: Created by Medilead based on the survey results.

(2) Results of the reference case survey overseas

Regarding the reference case survey overseas, a total of 25 initiatives by three international organizations and eight countries/regions were selected and set as a scope of the survey as reference cases conducive to the development of a methodology for the acquisition of basic information and the proposal for the development of analysis structure in evidence-based funding.

Scope of the initiatives addressed by the Survey was diverse, from formation of a broad concept to promote public policy, gaining a consensus at the global level, and to the setting of concrete R&D area by research funding agency. For this reason, based on the survey results, the scope of this survey was classified into four items: (1) Generic Concept, (2) Policy Making, (3) R&D Management Cycle, and (4) Information Tools, by which the nature of each initiative was organized.

(3) R&D management was further divided into five phases: Strategy for Budget Distribution, R&D area setting, Call and Review, Support and Management for Funded project, and Evaluation and Dissemination of Research Outcome. Of these, the scope of this survey was categorized into three phases: 1) Strategy for Budget Distribution, 2) R&D area setting, and 3) Evaluation and Dissemination of Research Outcome.

Overview of the results of reference case survey overseas was as follows (Figure/Table 3).

Figure/Table 3 Classification of case survey targets

(1) Generic Concept	<ul style="list-style-type: none"> ◆ 2030 Agenda for Sustainable Development (UN) ◆ Health in All Policies (WHO) ◆ Social Determinants of Health (WHO) ◆ Determinants of Health (Canada)
(2) Policy Making	<ul style="list-style-type: none"> ◆ FRESHER (EC) ◆ 2025 – Vision for Science choices for the future (Netherlands) ◆ National Foresight Cooperation (Finland) ◆ Russian S&T Foresight (Russia)
(3) R&D Management Cycle	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>3) Evaluation and Dissemination of Research Outcome</p> <ul style="list-style-type: none"> ◆ European Research Area (EC) <ul style="list-style-type: none"> ◆ RePORT (US NIH) ◆ Researchfish (UK) ◆ The BNCT's work programme (OECD) <ul style="list-style-type: none"> ◆ Open Science Monitor (EC) ◆ GtR (UK RCUK) <p>Support and Management for Funded project</p> </div> <div style="width: 45%; text-align: right;"> <p>1) Strategy for Budget Distribution</p> <ul style="list-style-type: none"> ◆ BOHEMIA (EC) ◆ NIH-Wide Strategic Plan (US NIH) ◆ Catapult Programme (UK Catapult UK) <p>2) R&D area setting</p> <ul style="list-style-type: none"> ◆ Common Fund (US NIH) ◆ Research Recommendation (UK NICE) ◆ NETSCC (UK NIHR) </div> </div> <div style="text-align: center; margin-top: 20px;"> <p>Call and Review for research proposal</p> </div>
(4) Information Tools	<ul style="list-style-type: none"> ◆ Innovation Policy Platform (OECD) ◆ Science, Technology and Innovation Outlook (OECD) ◆ Global Burden of Disease, Injuries and Risk Factors Study (US IHME)

Source: Created by EY based on the survey results.

Among them, the characteristics of initiatives classified in 2) R&D area setting under (3) R&D Management Cycle are organized (Figure/Table 4). In order to promote R&D in the medical field, those initiatives in the R&D area for which research funding agencies were encouraged to subsidize were classified under R&D area setting. These initiatives are directly informative when preparing a protocol proposal on the "Method for considering R&D area to be supported by AMED". In particular, the National Institutes of Health (NIH) and the National Institute for Health Research (NIHR), which are research funding agencies, conduct portfolio analysis utilizing institutional basic information to determine the novelty and redundancy of R&D topics. Accordingly, AMED also expects to develop and utilize basic information for R&D area setting.

Figure/Table 4 Results of reference case survey overseas related to R&D area setting

Name of Initiative	Common Fund	Research recommendation	Selection of Research Topics in NETS Program
Country/Region and Organization	US NIH	UK NICE	UK NIHR
Characteristics	Setting and subsidizing cross-sectoral R&D areas beyond NIH institutions. Define five criteria for R&D area to determine the area to be subsidized by Common Fund according to the following protocols: (i) prioritize by discussion based on expert advice on the scientific needs and the impact of research, and (ii) organize workshops and set R&D areas by portfolio analysis.	In the course of preparing clinical practice guidelines, identify the R&D area to be subsidized as research recommendations according to the following protocol: (i) identify important gaps lacking evidence as Uncertainty, (ii) convert Uncertainty into Research Question to create research recommendation, and (iii) prioritize research recommendations. Research recommendations specified by NICE is proposed to NIHR and the R&D area to be subsidized is selected after the internal review of NIHR.	Based on the framework that enhances the value of research, select research topics to be subsidized by the NETS program to address the needs of various stakeholders through three methods: (i) researcher-led workstream, (ii) committee-led workstream, and (iii) collaboration with key stakeholders. In (ii), criteria for assessing the importance of research topics are defined and portfolio analysis is carried out for determination of novelty.
Reference for the Survey	Setting criteria for R&D area, questions used in discussion for prioritizing R&D areas, and implementation method of portfolio analysis using basic information.	Methods of setting R&D area according to (i)-(iii), and criteria for prioritizing research recommendations.	Selection process of research topics by committee-led workstream utilizing external experts, and implementation method of portfolio analysis using basic information.

Source: Created by EY based on the survey results.

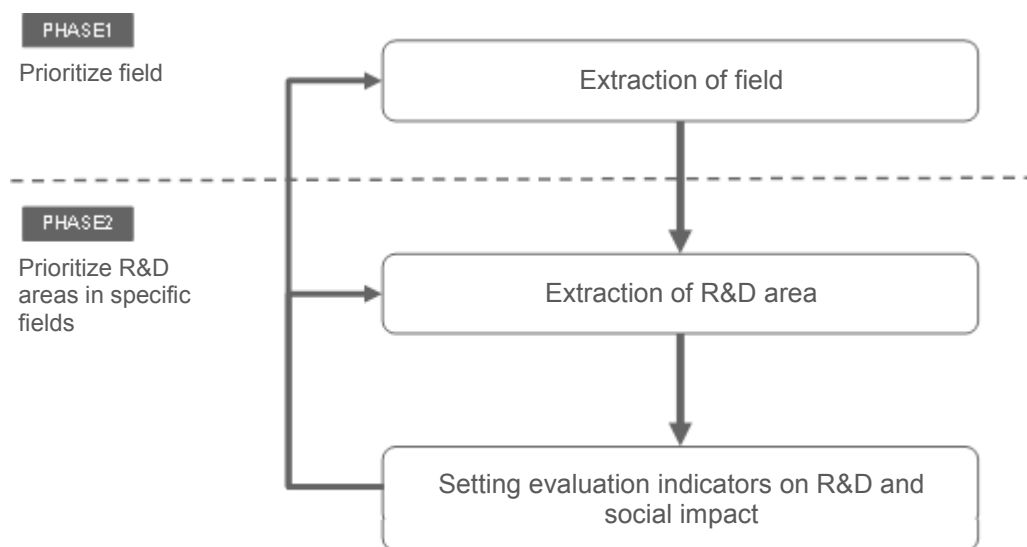
(3) Future prospects

Based on the results of basic information survey in Japan and reference case survey overseas, a protocol proposal on the "Method for considering R&D area to be supported by AMED" is considered in designing the survey for the next fiscal year.

In the process of basic information survey in Japan, it was suggested that a field could be selected based on social and economic needs. Also based on the result of reference case survey overseas, key fields were set by prioritization in extracting R&D area.

Based the above results, for AMED to draft a protocol proposal that experimentally sets R&D area that AMED should support in the next fiscal year, we propose to implement two trial phases: Prioritize field (PHASE 1), and prioritize R&D area in specific field (PHASE 2). (Figure/Table 5).

Figure/Table 5 Scope of drafting protocols



Source: Created by EY based on the survey results.

In the future, following points will be considered in defining a protocol proposal for prioritizing the field and R&D area that AMED should support.

<Creating a framework for prioritizing field and R&D area (tentative name)>

In the Survey, we will consider and prepare a "Framework for Prioritizing Field and R&D Area (tentative name)" which is the premise of the proposed protocol.

By placing the Mission at a higher level, Framework will form an essential part of navigation so as to conform to the Vision of the health/medical strategy and the purpose (Mission) of AMED, and of prioritizing field and R&D area.

After considering the research impact sought by AMED, we will define the criteria required for the field and R&D area to be extracted in this survey and extract the R&D area expected to trigger such research impacts.

<Prioritizing field and R&D area by collecting information on quantitative indicators>

In the basic information survey in Japan, from the viewpoint of identifying the field with large social and economic needs in Japan, that is, from the viewpoint of identifying the field with significant issues but sufficient measures are not shared, quantitative indicators were gathered and combined, especially in terms of diseases, and matrix analysis was carried out. By presenting the results of matrix analysis to experts with different perspectives in various fields and encouraging discussion, we will exhaustively extract new fields in aiming to satisfy social and economic needs in Japan. When aiming at setting R&D area after extracting the field, it is essential to collect and analyze the indicators in a field-specific viewpoint. We will need to organize indicators used in analysis by setting field-specific issues, and collect and create new indicators if needed.

By creating matrix analysis and graphs based on integrated indicators on social and economic needs and R&D seeds and comparing and contrasting with graphs using individual quantitative indicators, we expect to acquire insights that cannot be obtained only by comparing individual graphs.

<Suggestions from reference case survey overseas in prioritizing field and R&D area>

- In the process of extracting the field and R&D areas utilizing basic information in Japan, it is effective to calculate future indicators and use them as a material to prioritize in light of backcasting based on social, economic and technology trends of the future as well as past and present indicators.
- In addition to extracting the field and R&D area by a quantitative methodology, gap information on unsatisfactory R&D areas is gathered based on literatures, experts, etc. It can be used as a potential new R&D area with reference to the existing research results and AMED's portfolios.
- When extracting the field and R&D area in collaboration with experts, it is important to set "questions" that draw effective knowledge from experts based on the criteria required of field and R&D area, after shared recognition of participants on the output is established by creating and presenting the said Framework.

Based on the above survey results, we plan to design and implement the survey for the next fiscal year in order to acquire suggestions on basic information toward utilization of evidence from both qualitative and quantitative data through review on the method of extracting field and R&D area that AMED should support.