# A construction of support scheme for health technology evidence-generation in Korea

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### Background

The health technology is being developed rapidly, and the investment in the national research and development is being grown continuously. However, the evidence-generation activity is not fulfilling its demand virtually. Because of this, the promising health technology is sometimes not introduced to clinical practice because of the lack of evidence. The gap in the introduction of promising health technology to the clinical site due to such lack of evidence can be sufficiently complemented through the strategic support of evidence-generation on national level. As such, this research aims to suggest the alternative of domestic evidence-generation support system, covering the health technology life cycle.

# The system to support the generation of evidence in health technology

The result of reviewing the research support system of the US, the UK, and Australia showed that these countries already constructed systematic support systems in various fields such as the operation of advisory committee to establish the research plan and methodology as well as the financial support, cultivation of the research personnel, and network construction support to share the result of research process or research result. In the stage of research subject selection, they support the researches by separately operating ITT (investigator-initiated trial). If required by the national level, these countries ensure the balanced research performance by selecting the commissioned research subjects, apart from the investigator-initiated trials. In addition, these countries promote the system improvement to simplify the research procedures.

The ways that were the most frequently used to support the clinical research in Korea are the research fund support and the infra-construction support. The educational support to cultivate the research capability and to improve the quality of researchers, clinical research management system, and the network construction project are also being conducted, but their scale and role are limited. The result of reviewing the evidence-generation support system based on the health technology life cycle showed that most of the support projects were concentrated in clinical research evidence-generation support, and there were comparatively less evidence-generation support activities for promising health technology and research-stage health technology. In particular, the horizon scanning of promising health technology was conducted only by the National Evidence-based healthcare Collaborating Agency (NECA). The support system for scientific generation of evidence shall be improved to prevent it from being concentrated in some specific stages or personal interest area of the researchers.

## The plan to support the generation of evidence in health technology in Korea

I. Horizon scanning of promising health technology

This provides the information to decision makers, researchers, and stakeholder by constantly conducting the activity of horizon scanning of promising health technology in the whole world. This has the advantage to enhance the efficiency of using the national health care R & D resources and expediting the introduction of promising health technology to clinical practice. At present, NECA is the one and only domestic institute that

performs the horizon scanning of promising health technology, where NECA Toolkit (Horizon Scanning Service for Innovative Global Health Technology, H-SIGHT), the Korean-type scanning tool, has been developed and is being operated. For evidence-generation support in the health technology horizon scanning stage, the collaboration with various institutions is inevitable. The support system for the construction of an automatic scanning and development system using IT technology, operation of tailored information service for health technology in development stage, and network formation with relevant domestic and foreign institutions, is necessary. NECA, the institution that currently performs the scanning activity, is considered as the most suitable institution for the operation of relevant process, and for progress, evaluation, and expansion system of the process, we can refer to evidence-generation in Part, "Horizon scanning of promising health technology."

#### II. New health technology in research stage

The new health technology in research stage cannot be introduced to clinical practice because of the lack of evidence in its safety and effectiveness. However, it can guarantee the medical treatment selection health right of the by right and patients encouraging the evidence-generation of promising health technology. NECA and Health Insurance Review & Assessment Service support this new health technology in research stage.

An expert pool RAM (Research Assessment Matrix), which conducts continuous management and consulting of the health technology in a possible research stage, is constructed and operated. The expert pool is operated in matrix type, and it is composed of clinical experts in each department who provide tailored service based on the characteristics of the health technology. The national support system is also constructed for the generation of evidence of grade II-b and grade II-a health technology. The relevant process will be performed by a suitable institution, and the process

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will be strategically carried out based on the introduction, growth, and advancement stages of the process.

#### III. Clinical research for the generation of evidence

At the early stage of investigator-initiated clinical research introduction, most of the support were focused on the promotion of research-oriented hospitals and appointment of clinical research centers. As a part of the infra construction project, a national project team for clinical research for the generation of evidence was established in 2004 to support evidence-focused clinical researches. Among a total of 108 support projects until 2014, however, about 20% of them were concentrated in neoplasm and biased toward the development of diagnosis and treatment methods. The overall research supports system shall be improved because the research support systems in various fields, except the financial support, are insufficiently operated.

To activate the investigator-initiated clinical research, various support systems should be constructed, focused on the part that the researchers cannot carry out independently. In the domestic clinical research support system, the support of the research plan and research methodology is not sufficient enough, and there is no network for the collection of research data. In accordance to this, the support system shall be diversified by establishing a center to solve this obstructive factor, and the research network shall be established. The research network should be in the form of Distributed Research Network (DRN) to prevent the problem of data ownership.

### Expectation effectiveness

The evidence-generation activities concentrated in the personal interests of the researchers can be operated equally by constructing a domestic evidence-generation support system based on the health technology life cycle. For the fields in urgent need of generation of evidence on a national level, the scientific evidence-generation activities shall be promoted through the expansion of the support scale and support opportunity, and if necessary, such research shall be conducted through top-down subject selection.

By systematically managing the new health technology, which is expected to be promising in the future, on a national level, the efficiency of national health care R & D resources can be enhanced, and the international status of Korea in the area of health technology can be improved. By supporting the evidence-generation activities of the health technology in the research stage, the introduction of a promising health technology to the clinical practice can be accelerated. The purpose of this is to merely support the scientific generation of evidence and not for the market entry of the promising health technology or its registration on the health insurance benefit list. This study suggests a research plan that is necessary in performing researches, except the research fund, research method, and the method of research purpose database construction support. Through this, various clinical research support systems can be prepared, escaping from the support system focused on the budget and infra-construction at the early stage of domestic clinical research introduction.

Through the construction of a domestic health technology evidence-generation support system, the right to know about their health, the right to self-decision, and the right for a safe and cost-effective treatment can be guaranteed to Koreans.

#### Keywords

Evidence of health technology, Evidence-generation support system, Horizon scanning for innovative global health technology, New health technology in research stage, Clinical research