Recommendation

Five Recommendations for Rapid Qualification of New Development Tools for Innovative Medical Products

26 September, 2023

Science Council of Japan

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Abstract

1. Background

When evaluating the efficacy, safety, and quality of newly emerging innovative medical products, it is necessary to update the evaluation methods themselves. However, as sometimes criticized that "evaluating 21st century products with 20th century evaluation methods," the update of evaluation methods tends to lag behind the progress of science and technology. When evaluating a medical product using a new evaluation method, it is necessary to evaluate the evaluation method itself" in the first place. After determining the scope of application of the evaluation technique and verifying its validity with data, guidance on the evaluation method for appropriate use within the scope of application is developed, and the method is made available for use as an evaluation method in non-clinical or clinical trials. This is called Development Tool Qualification. In Japan, even though the guidance for individual evaluation techniques have been developed, there are no explicit rules for qualification procedures of evaluation technique, and measures for this purpose have not been sufficiently discussed in terms of both content and method. Therefore, in this proposal, as a procedure for the qualification of evaluation techniques, we propose development of "the guidance to prepare guidance for evaluation methods" and the relevant policies.

2. Current situation and problems

In the U.S., the policy "the Drug Development Tool Qualification Program (DDTQP) and the Medical Device Development Tool Program (MDDT)" have been established for pharmaceutical products, and in Europe, "the Qualification of novel methodologies for drug development: guidance to applicants". These countries have already developed and implemented a qualification system for evaluation technologies for medical products as a rule-of-rules type policy (a rule to create a rule) which is "a guidance to create guidance for evaluation methods." In the U.S., as this system has been used to submit more than 200 applications, mainly for biomarkers for pharmaceutical products and clinical outcome assessment for medical devices, the qualification of tools has been progressing.

On the other hand, Japan has not developed a rule-of-rules type system that explicitly defines the process, and its policy resources to operate such system are insufficient. As a result, tool qualification has not progressed systematically among technology owners, users, and regulators of evaluation technologies. While evaluation technologies from Europe and the U.S. become de facto, Japan will not only have nothing but to follow the result of qualification for evaluation technologies, but also face the risk of obstacles to promote innovative medical products originating in Japan domestically and overseas.

3. Contents of the proposal

In order to quickly deliver medical products that utilize new technology to patients, it is essential to rapidly qualify evaluation technologies for medical products. To this end, we recommend the following five measures to promote involvement of stakeholders.

⑴ Develop rule-of-rules type guidance

We propose to develop a "rule-of-rules type guidance" that establishes the procedures to qualify individual evaluation methods for evaluating medical products. This will enable to have following benefits:

1) A process for creating guidance that qualifies evaluation methods and specifies how to use such guidance will be defined, and processes and procedures described in the guidance will be disseminated and shared among relevant stakeholders, including owners of evaluation technologies and regulatory authorities;

2) The procedure for voluntarily submission for the start of review work for creating guidance will be clarified;

3) The procedure for transition to the next process will be clarified;

4) Through disclosure of process transition at the time of process transition. transparency and efficiency of such process can be ensured.

In the future, it is required to develop the guidance that establishes the guidance specifying how to develop guidance related to efficacy, safety, and quality of all kinds of medical products (Good Guidance Practice) and to improve the transparency and efficiency of organization and revision of rules.

⑵ Secure the necessary human resources and funds

In order to implement measures to qualify evaluation methods, it is required

to take measures to expand policy resources for regulatory science, including securing human resources to enhance the review system, and developing a subsidy system to subsidize the cost of acquiring data to verify qualification. Additionally, it is also required to establish core research organizations for education, research, and industry-academia collaboration in specific universities, and make such organizations as human resource development organizations for forming governance of advanced medical care by enhancing recurrent education for working adults.

⑶ Build a flexible personnel system

In order to expand the human resources involved in the qualification of medical products evaluation, personnel exchange between industry, government, and academia is essential. However, due to the current rigid personnel system for national civil servants, the more personnel exchanges occur, the worse the treatment for personnel becomes. In order to develop human resources for regulatory design requiring diverse experience, it is necessary to prepare for a personnel system in which personnel exchanges do not bring people disadvantageous treatment, and a structure that supports career path design based on such personnel system.

⑷ Enable evaluation technology holders to understand the benefits of qualification

As it is not sufficient to increase the number of qualification cases merely by establishing a rule-of-rule qualification system, it is necessary to provide motivation and mechanisms to enable university researchers, companies, and other organizations that possess evaluation technology to obtain qualification of their evaluation methods and to move toward the use of the evaluation technology in clinical development. To this end, it is required to develop an ecosystem for the use of evaluation technology, such as disseminating examples of how the system is used, enhancing research grants to support qualification, and supporting commercialization of companies.

⑸ Promote international recognition and use of evaluation technology developed in Japan

It is expected that the number of qualified evaluation methods will increase in the future as Europe and the United States have established qualification

systems for evaluation method. In addition to promote the qualification of evaluation methods in Japan, it is also necessary to develop procedures and support measures for Japanese-originated evaluation methods to be certified in Europe and the United States. In addition to routes such as international technical standards, it is necessary to continue developing the procedures and support measures to enable the evaluation methods developed in Japan to be certified in Europe and the United States as well. It is also required to develop multiple implementation methods, such as procedures for mutually certifying evaluation methods that have been qualified in Europe and the United States in addition to the routes for international technical standards.