



Lessons from success: Rethinking collaboration among stakeholders in medical device innovation

Clinical Research, Innovation and Education Center,
Tohoku University Hospital (CREITO)
Koji IKEDA



What is device lag?

デバイスラグとは何だったのか

開発された新製品の市場導入の時期に差が生まれること

その原因は、規制の違いなどと言われていたが、

結局は、科学的かつ合理性がある規制に生まれ変わる時期に発生した、科学的かつ合理性がある審査とは何か、産官学が理解するために生じた時間的ロスが原因ではないか

The cause of the device lag has been said to be differences in regulations between Japan and the US, but ultimately, it may be due to the time lost as industry, government, and academia struggled to **understand what constitutes a scientific and rational review**, which occurred at a time when the review system was being reborn as one based on scientific and rational regulations.



What is device lag?

デバイスラグとは何だったのか

当時の日本は科学的で合理性のある規制に向き合う企業やアカデミアはほとんどいない状況だったため、科学的かつ合理性がある規制とは何か、皆で考え、議論するための場が必要であった。

At the time, there were very few companies or academics in Japan that were concerned with scientific and rational regulations, so there was a need for a forum where everyone could think and discuss what scientific and rational regulations were.

That was **the town hall meeting**.



What did the HBD activities bring? HBD活動がもたらしたものは何だったか？

HBDの特長は**日米の産官学**が集い継続的に議論される環境にある
HBDは、デバイスラグの原因に挙げた**科学的で合理的な規制**への理解を共有する場として機能し、デバイスラグの改善に大きく寄与した

HBD's unique feature is its environment, where **Japanese and U.S. industry, government, and academia** come together for ongoing discussions.

HBD serves as a forum for sharing an understanding of **scientific and rational regulations**, which are cited as a cause of the device lag, and has made a significant contribution to improving the device lag.



What did the HBD activities bring? HBD活動がもたらしたものは何だったか？

科学的で合理的な規制とは何か学ぶためには、**具体的な案件で実際に経験すること**が最も理解が得やすい

具体的にどのようなギャップがあるか可視化し、解決することが**最も合理的な解決手段**であることをHBDは示した

The easiest way to learn about scientific and rational regulations is to gain **practical experience in specific cases**.

HBD showed that **the most rational solution** is to visualize specific gaps and resolve them.



What's the problem in Japan? 日本では何が問題になっているのか？

世界最先端の医療機器が**日本の患者に使えない**状況が発生している
その原因は**デバイスラグと異なり**、規制調和だけで解決することは難しい
様々な要因で日本の保険償還価格は**海外企業にとって採算性が悪くなっている**

We are now facing a situation where the world's most advanced medical device is **unavailable to Japanese patients**.

Unlike device lag, the cause of this is difficult to resolve through regulatory harmonization alone.

Due to various factors, Japanese insurance reimbursement prices have become **unprofitable for foreign companies**.



What can be done to bring better medical devices to Japanese patients? より良い医療機器を日本の患者に届けるには？

日本での医療機器開発を活性化する

海外企業が日本に医療機器を導入しやすくする

Stimulate medical device development in Japan.

Make it easier for foreign companies to import medical devices into Japan.

HBDは両方の課題に貢献できると確信している

I believe HBD can contribute to both challenges.



What problems need to be solved? 解決すべきどのような課題があるのか

日米ともに革新的な医療機器をスタートアップが取り扱う事例が増えている
In both Japan and the United States, startup companies often handle innovative medical devices.

日本参入のハードルはスタートアップの方が高いと感じている
The hurdles to entering Japan are higher for startup companies.

米国の医療機器スタートアップが日本で薬事承認を取得するための課題は多い
US medical device startups face many challenges in obtaining regulatory approval in Japan.

What problems need to be solved? 解決すべきどのような課題があるのか

日本製品を米国に導入する際に、米国申請時で新たに必要となる試験がある
例えば、使用模擬試験をGLPに準拠する必要がある

日本人だけの臨床試験成績では承認が取れない

日本で臨床試験をしても、動物実験が求められるケースがある

When introducing Japanese products to the US, certain new tests will be required at the time of US application.

For example, animal testing other than safety testing will need to comply with GLP. Approval cannot be obtained based on the results of clinical trials involving only Japanese people.

Even if clinical trial results are available in Japan, there are cases where animal testing is required.



What can we do to solve it? 解決するために何ができるのか？

具体的な案件を一緒に行って解決方法を考えればいい

We can think of solutions **by doing together** on **specific projects**.

規制だけでなく、開発段階のハーモナイゼーションも必要ではないか

Isn't harmonization of the development stage also necessary?

スタートアップの海外展開を活性化することはできないか？

Is it possible to stimulate the international expansion of medical device startups?

There is work to be done to provide better medical care to patients.

HBDの特長は日米の産官学が集い継続的に議論される環境にある

HBD's unique feature is its environment, where Japanese and U.S. industry, government, and academia come together for ongoing discussions.

個別案件で具体的に議論を行うことが、相互の理解を得る方法として優れている

Specific discussions on individual cases are an excellent way to gain mutual understanding.

患者により良い医療を提供するために、HBDに出来ることがある

There are things HBD activity can do to provide better medical care to patients.



Thank you/Questions

Disclaimer

This document was produced by the HBD steering committee. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the HBD steering committee.

Copyright 2025 by the HBD steering committee.