

HBD East 2023

Unique points of medical device development
and advantages of global development

Clinical Research, Innovation and Education Center,
Tohoku University Hospital (CRIETO)

Koji IKEDA

日本の医療機器開発の現状

Current status of medical device development in Japan

- 国内医療機器市場は約4兆円であり、緩やかに成長している

The domestic medical device market is worth \$7 billion and is growing slowly.

- 日本の医療機器領域の市場成長率CAGRは1.8%（米国5.6%）

The market growth rate CAGR in the medical device field in Japan is 1.8% (5.6% in the US)

- 国別売上高では米国（43%）に続く2位（7%）

In terms of sales by country, Japan ranks second (7%) after the United States (43%).

- 診断機器では存在感を発揮しているが、治療機器は伸び悩んでいる

Diagnostic equipment has a strong presence, but therapeutic device does not.

医療機器開発の課題

Issues in medical device development in Japan

- 優れた技術を持つ日本であれば、医療機器開発などわけもないことと高を括って、取り組んでこなかったつけが回ってきている

Because Japan has excellent technology, we thought we could develop medical devices at any time, so we are now paying the price for putting it off.

実際に開発しようとする時 When you actually try to develop...

- 治療機器開発できる企業は少なく、経験がある人材も少ない

There are few companies that can develop therapeutic devices, and there are few experienced personnel.

- 医療機器治験の経験がある人材も少ない

There are few people with experience in medical device clinical trials.

「国民が受ける医療の質の向上のための医療機器の研究開発及び普及の促進に関する基本計画」第2版

“Master plan about research and development of a medical device and promotion of the spread for improvement of the quality of the medical care the people receive”.

医療機器促進法の目的の達成に向けては、

- ①国民にとって有効かつ安全な医療機器が迅速に開発され
- ②遅滞なく国内に上市され
- ③入手可能な状態が維持される必要がある

この3点を基本理念としてビジョンを定めて具体的な方針が定められている。

What is unique points of medical device development?

- 多様性、千差万別な製品が存在

Medical devices are characterized by their diversity, with a wide variety of products available.

- 同じ疾患の治療をする医療機器でもアプローチ、作用機序、使用エネルギー、侵襲性、使い方、使う人、様々である

Even medical devices that treat the same disease have different approaches, mechanisms of action, energy usage, invasiveness, and usage.

- 診断機器、治療機器に特有の課題があるように、製品ごとに課題は異なる

Each product has its own challenges, just as diagnostic and therapeutic devices have their own unique challenges.

What is unique points of medical device development?

- 使用頻度は低いものの、その医療機器がないと医療現場では大変困る類の医療機器も少なからず存在する

Although they are used infrequently, there are quite a few medical devices that would be a problem in the medical field without them.

- 販売量が少なく利益につながりにくいいため、開発に難渋する

Such products are difficult to develop because their sales volume is low and it is difficult to generate profits.

- 民間だけの力では解決しにくい課題である

This is a difficult problem for companies and academia to solve.

Points to keep in mind when developing medical devices in Japan

- 日本では**保険償還制度を熟知**して製品開発を計画しないと承認が取れても**保険償還価格が安くて売れない製品が出来上がる**

In Japan, it is necessary to be familiar with the insurance reimbursement system when planning product development. If you fail to do so, even if you get approval, the insurance reimbursement price will be low and you will end up not making a profit.

- **開発全体を俯瞰して開発戦略を立案する力量と、開発途中で修正を行う柔軟性が求められる**

Human resources involved in medical device development are required to have the ability to oversee the entire development process and formulate development strategies, as well as the flexibility to make modifications during development.

日本の医療機器開発をHBDで活性化できないか？

Is it possible to revitalize Japanese medical device development with HBD?

- 成功している米国のベンチャーエコシステムと日本のベンチャーエコシステムを融合させ、人材、環境、アイデアを共有化して開発を最適化できないか？

Is it possible to combine the successful U.S. venture ecosystem with the Japanese venture ecosystem to share talent, environment, and ideas to optimize development?

- Harmonization by Ecosystem
- 双方の経験、強み、人材を融合させていくことができれば、医療機器開発がグローバル化できるのではないか

If we can combine the experience, strengths, and human resources of both parties, we can globalize medical device development.

Globalize the clinical trial environment

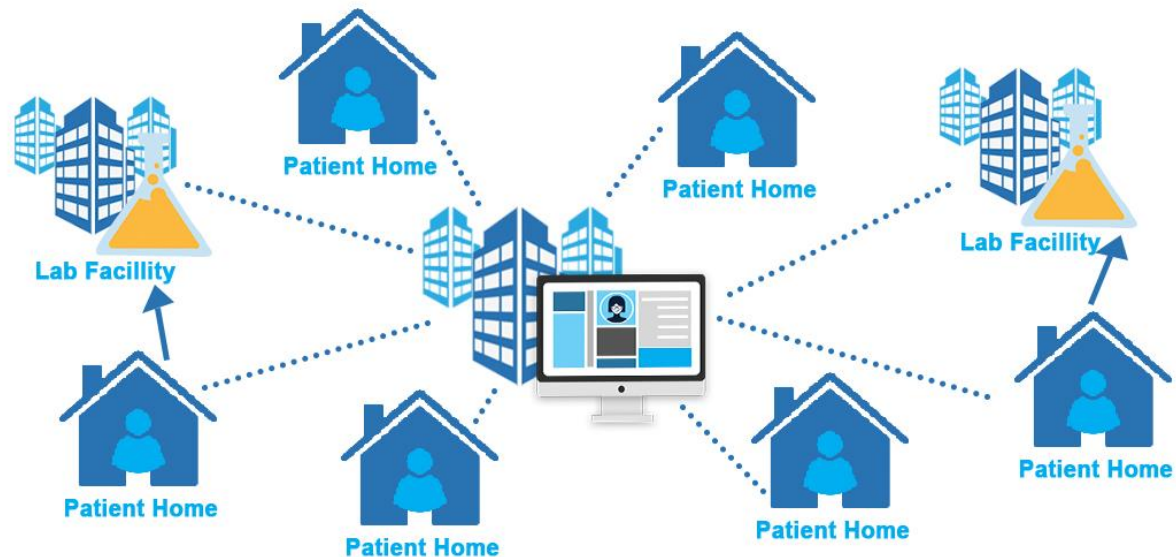
- 分散化臨床試験（DCT）が始まっている

Decentralized clinical trials begin

- DCTの本質は患者中心の臨床試験運営にある

The essence of DCT is patient-centered clinical trial management.

- 将来は国の規制を超えてDCTができるようになるだろうか



Future vision of HBD

- ITの力を活用し、言葉の壁も距離の壁も乗り越えられるなら、開発環境も治験環境も共有できるのではないか。
- HBDによって医療機器の国際共同治験ができるようになり、デバイスラグは改善した。次は国際共同治験をやりやすくなる環境を作って、普及させることが必要と考える。

If we can utilize the power of IT to overcome language and distance barriers, we can share the development environment and clinical trial environment.

HBD has made it possible to conduct international clinical trials for medical devices, and device lag has improved.

Next, I think it is necessary to create an environment that makes it easier to conduct international clinical trials and to popularize them.