



Addressing key bottlenecks in global medical device development: Challenges and strategic solutions

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Col Disclosure and Disclaimer

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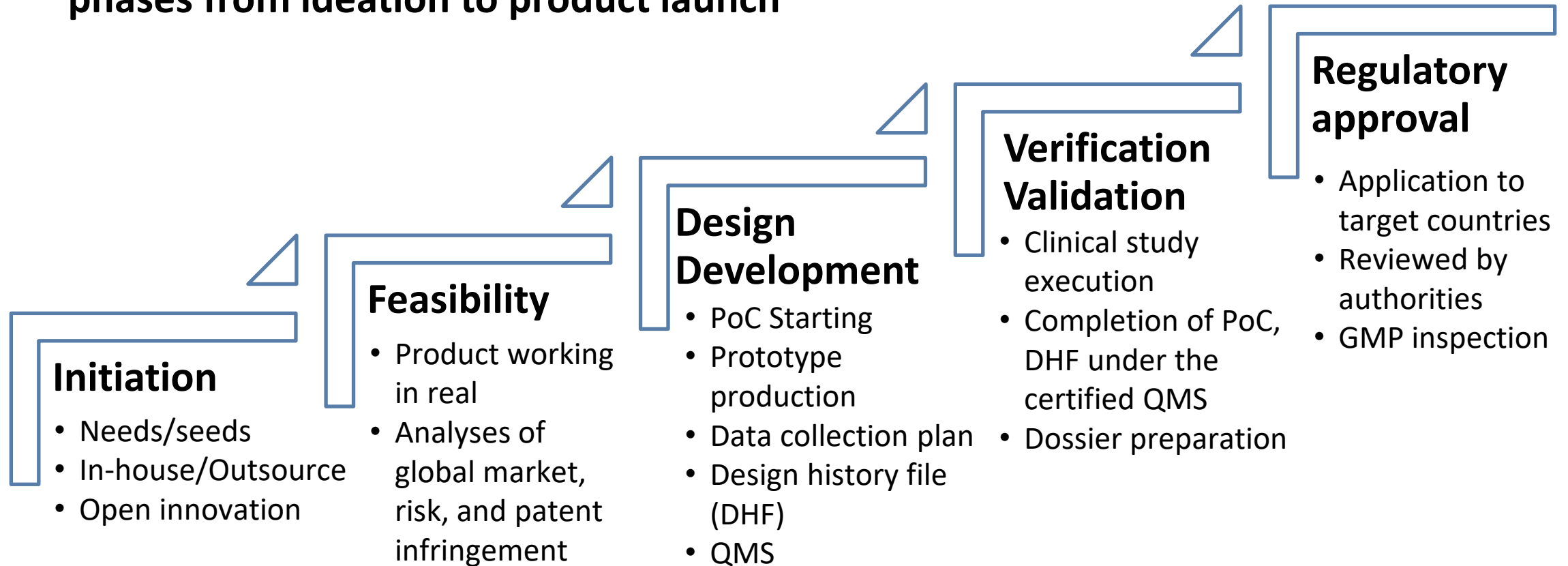
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- Affiliation/Financial Relationship : Employee
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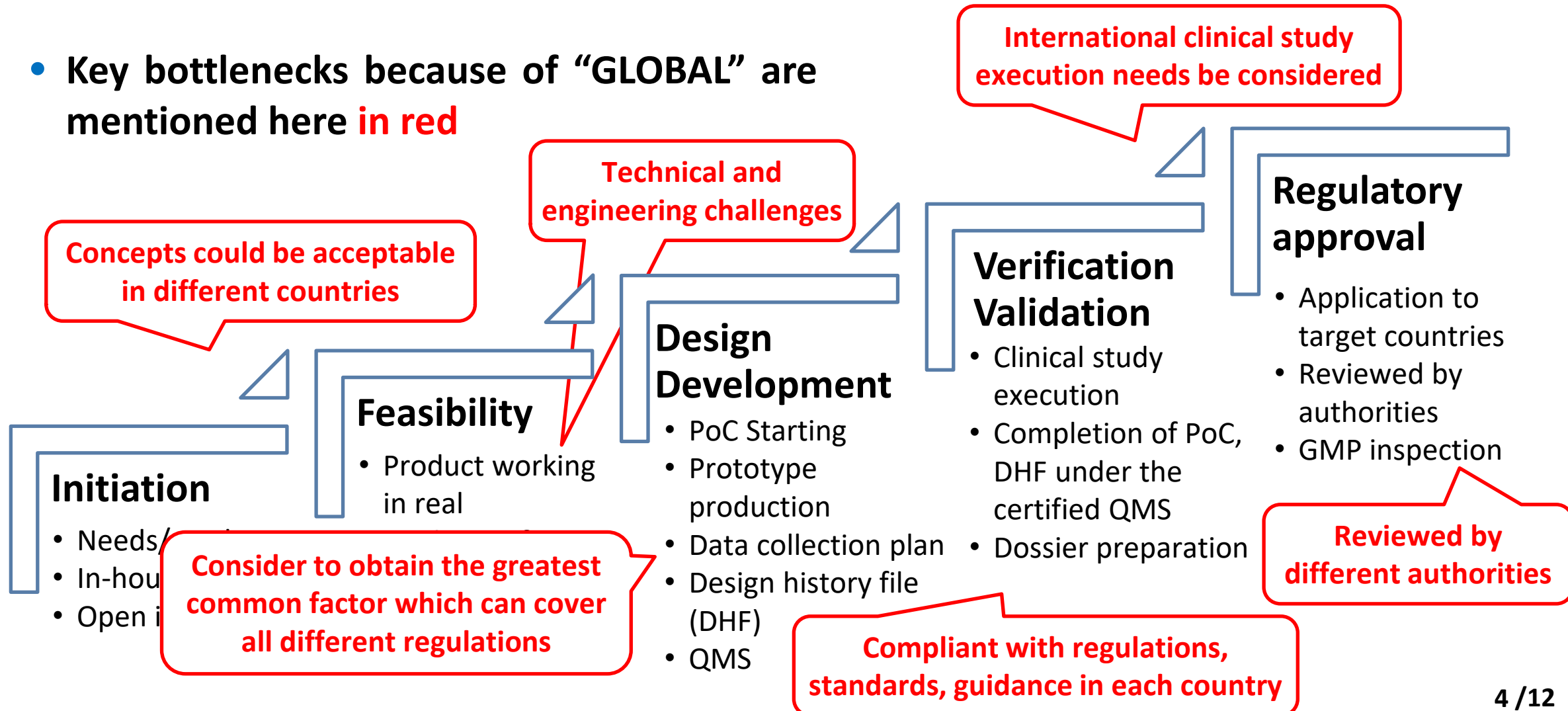
What is Global Medical Device Development?

- In this case, the process is divided into five phases from ideation to product launch



Key Bottlenecks in Global Medical Device Development

- Key bottlenecks because of “GLOBAL” are mentioned here **in red**





Key Bottleneck Solutions

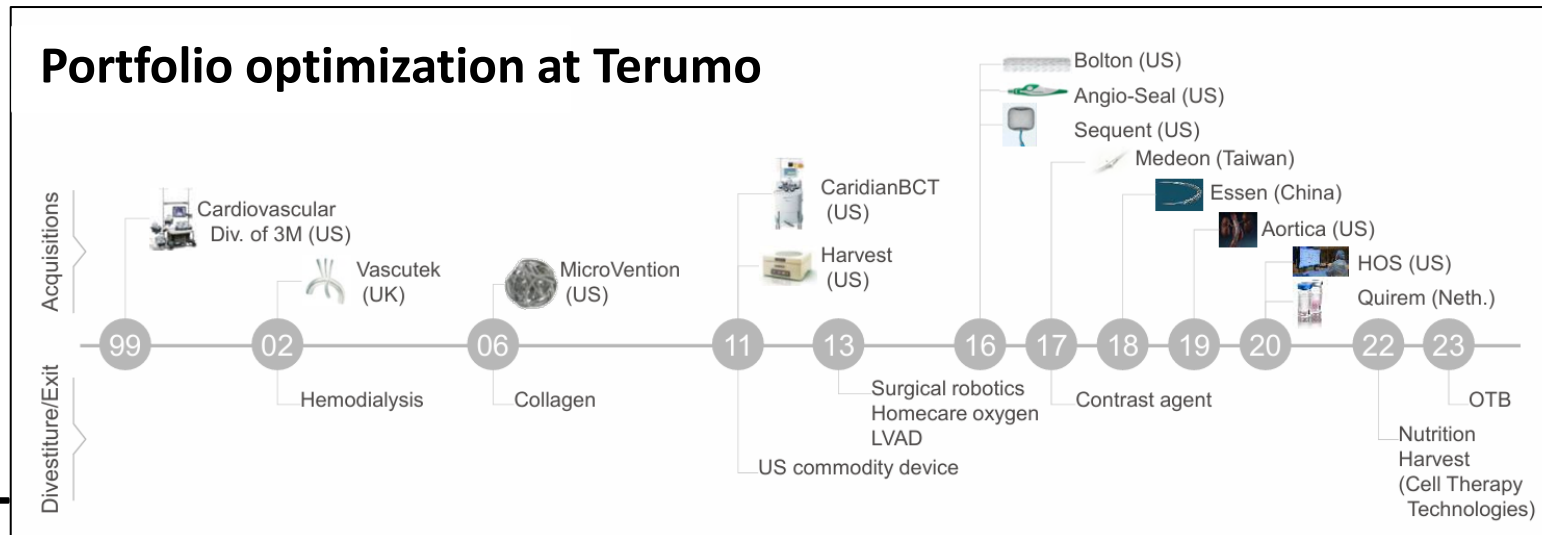
- Any key bottlenecks regarding technical and engineering challenges could be solved by collaboration among physicians, engineers, and scientists with their individual specialties in medical expertise, engineering design, and scientific research along with state-of-the-art technologies such as generative AI
- In the case of global medical device development, it is vital to have a deep understanding of regulatory frameworks of individual countries as global harmonization is still underway

IN ADDITION THESE,

- **A global business strategy** can also be one of the essential solutions for achieving key goals, obtaining worldwide regulatory approvals, distributing products globally, and finally expanding our business which is our biggest target as a global medical device company

Strategic Solutions to Achieving Global Business Success

- **Optimization** of the business portfolio through not only acquisitions but also divestitures or exits
- **Strengthening** in-house development capabilities in core technological fields, such as surface modification, coating, in-vivo/in-vitro evaluation, precision, uniform molding, etc.
- **Investment** in startup companies, which could be considered one of the R&D activities
- **Creating synergies** through venture investments and in-house development



Recent Efforts to Strengthen Terumo's Business

- Acquired OrganOx Limited, a leading innovator in organ preservation devices, marking strategic entry into the organ transplantation-related sector (Aug 25th, 2025)
- Signed a distribution agreement with MedHub-AI to market the "Autocath FFRTM", MedHub-AI's SaMD, in Japan (Jun 17th, 2025)
- Entered into agreement between Terumo and WuXi Biologics on a Drug Product Plant in Leverkusen, Germany, to accelerate CDMO business globally (May 14th, 2025)



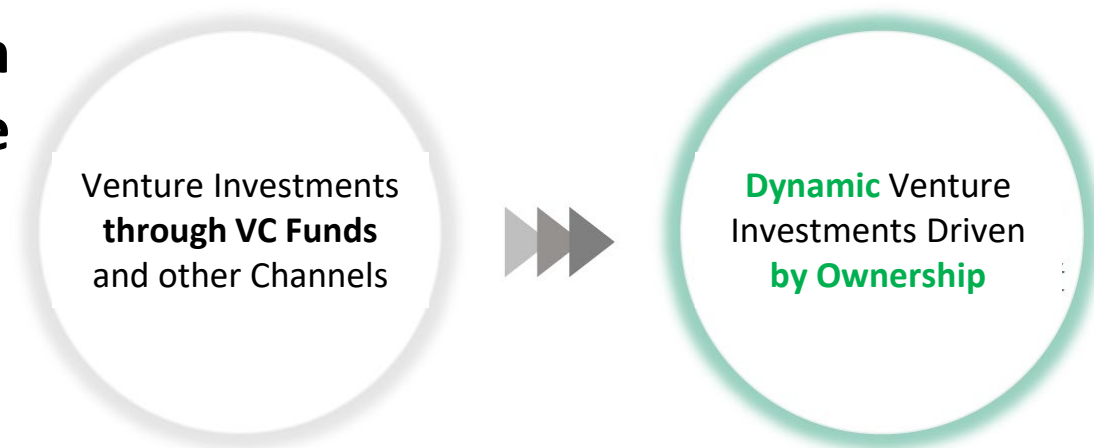
Opened new R&D center in the U.S.

- Established “D-TECT” (Discovery and TEchnology Center of Terumo), a new R&D center in the United States on April 1st, 2025. Strategically located in Aliso Viejo, CA
- D-TECT will facilitate collaboration with local medical institutions, academia and startups to reinforce Terumo’s global Corporate R&D capabilities
- Supports R&D functions of the Terumo Group companies across the country by utilizing its own core technology

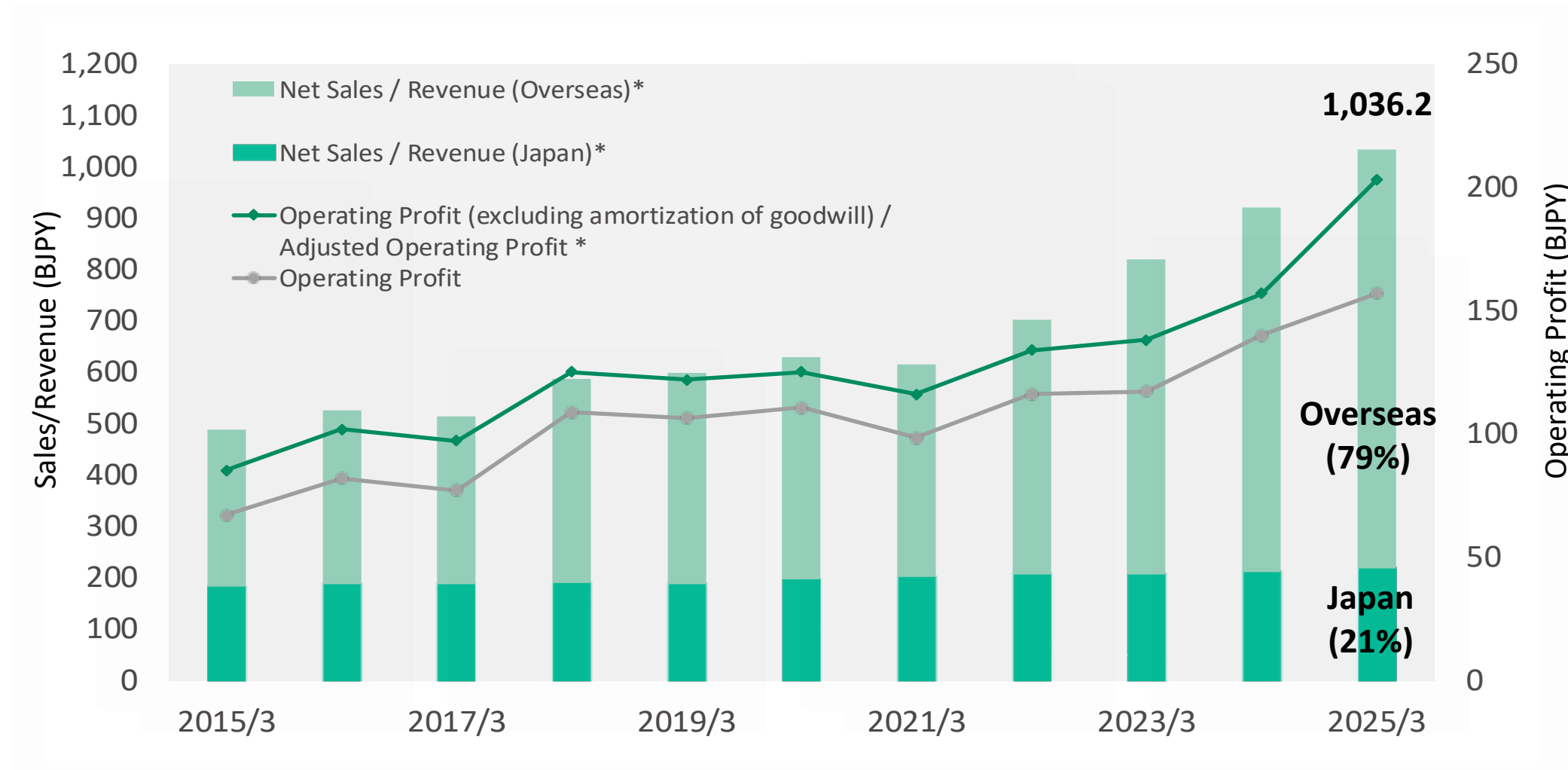


Established Corporate Venture Capital “Terumo Ventures”

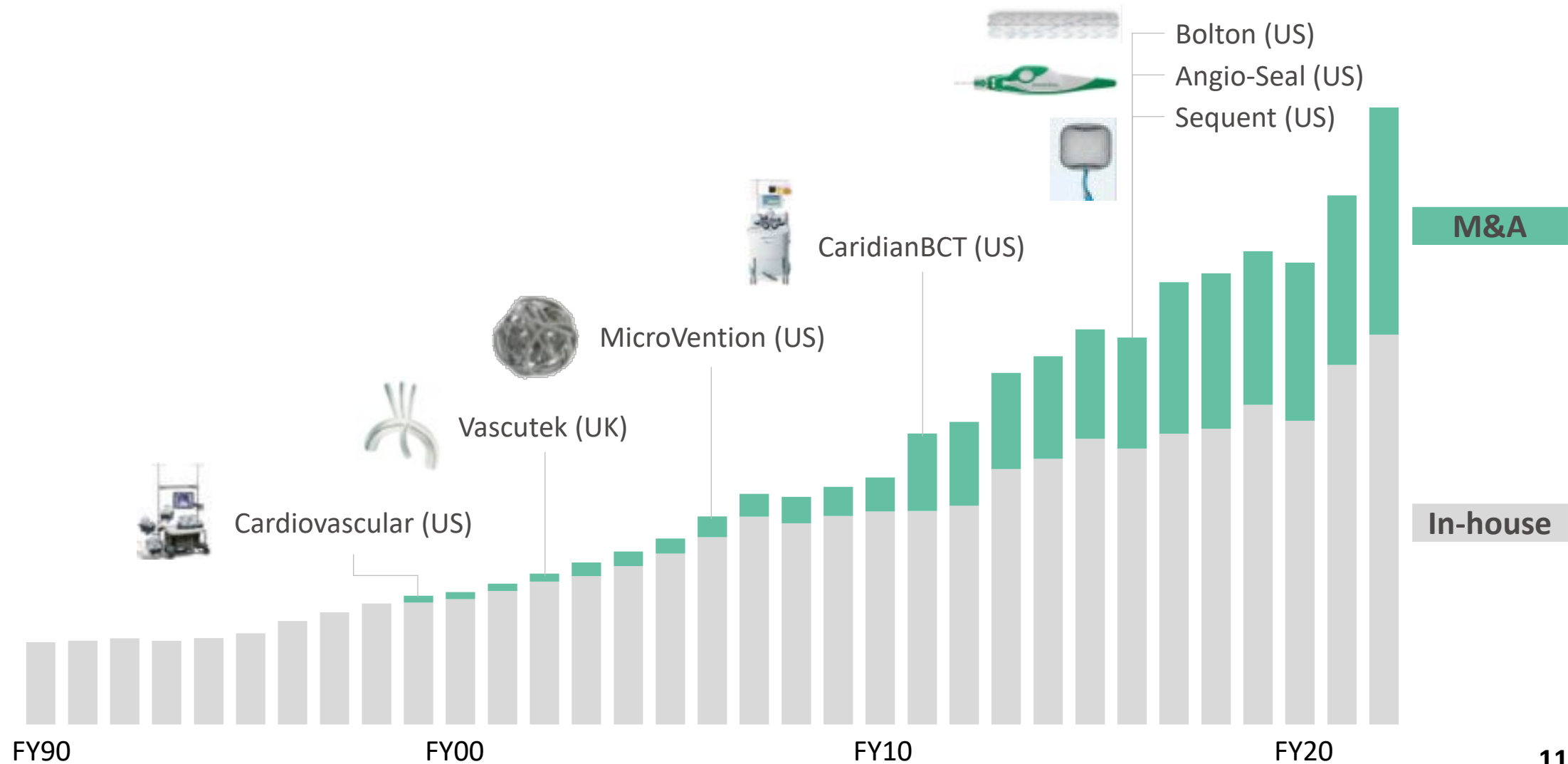
- Responsible for leading the Group’s venture investments, as a department within Terumo Americas Holding, Inc. on Aug. 1st, 2024
- Plan to invests US\$ 75 million over the next five years in early-stage companies
- Continue to enhance its ability to create innovation through a combination of internal development and partnerships with external parties to further expand the value it provides to society



Continuing to Achieve Sustainable and Profitable Growth



Business Contribution through In-house Development and M&A



Take Home Message

- During the development process, any key bottlenecks, such as technical and engineering challenges, could be solved by **collaboration among physicians, engineers, and scientists** with their individual specialties and state-of-the-art technologies in medical expertise, engineering design, and scientific research, respectively
- **Global business strategy** is also one of the key solutions to achieve the goals not only getting regulatory approval and distributing our products worldwide, but also expanding our business, which is our biggest target as a global medical device company
- To achieve business success as a company, adopting **well-designed strategic solutions** is significant. Key strategies are **optimizing** the business portfolio, **enhancing** in-house development capabilities, **investing** in startup companies, and **encouraging synergies** between the company's core technologies and innovations from startups
- To deepen understanding of regulations and harmonization globally. It is the responsibility of industries to fully understand the content of these new regulations and utilize new frameworks, and then **develop effective application strategies**, which is an essential process to realizing our growth strategy



Thank you/Questions

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