



EUROPEAN BUSINESS COUNCIL IN JAPAN
THE EUROPEAN (EU) CHAMBER OF COMMERCE IN JAPAN

Digital Health Task Force

- Representative Meeting 2022 -

December 8, 2022

Shinichi Eda, Ph.D

EBC, MEDICAL EQUIPMENT & DIAGNOSTICS COMMITTEE

Executive Summary

- 1) Digital Health (DH) Task Force (TF) established in July 2021 continued and expanded its efforts in 2022, aiming to
 - share and align DH related information/actions in Subcommittees
 - introduce overseas DH regulations and reimbursement systems to Japanese authorities and industry groups

- 2) In 2022, the TF made following activities;
 - held TF Team meeting 10 times & exchanged the information and thoughts
 - held Webinar on DiGA, innovative reimbursement system for SaMD in Germany; 145 participants with positive feedback
 - made proposals to government bodies e.g., MHLW & METI

Executive Summary

- 4) In 2023, the TF will continue to work on
- internal information sharing and alignment of opinions & actions
 - holding lectures internally as well as to external stakeholders
 - being involved in policy discussion with authorities

<Planned Actions>

To external stakeholders

- make proposals in official meetings with e.g., MHLW and METI
- follow-up webinar of DiGA; 2nd half of 2023

To EBC internal members

- hold educational lecture for EBC members

Agenda

- 1) Scope
- 2) Activities in 2022
 - Taskforce Meetings
 - Introduction of overseas regulations : DiGA Webinar
 - Involvement in the activities for making proposals to government authorities
- 3) Action plans for 2023

Scope

- 1) Scope of EBC Digital Health Task Force (DHTF)
 - Collect, analyze, and introduce overseas DH regulations and reimbursement systems to Japanese authorities and industry groups
 - Share and align DH related information/actions between Subcommittees
 - Collaborate with local industry groups such as JFMDA and AMDD

Activities in 2022

1) Taskforce Meeting

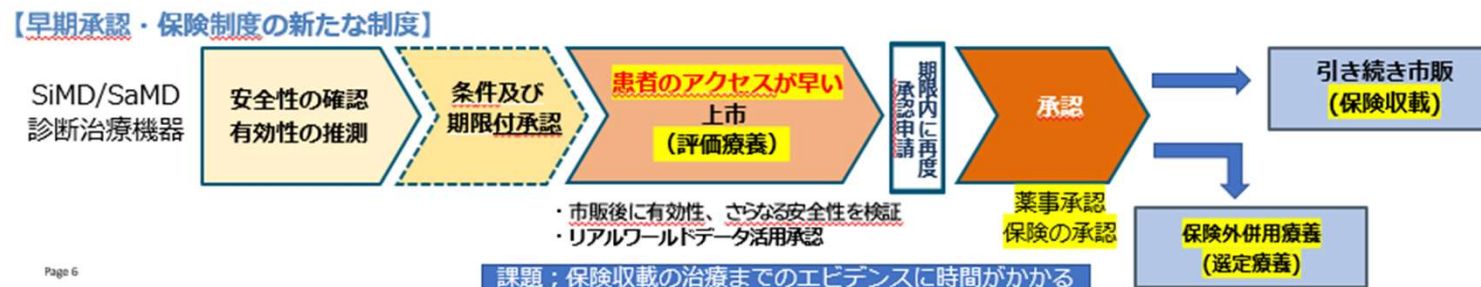
- Held 10 times on monthly basis, where Information of sub-committees and JFMDA Working Groups shared and discussed Policy proposals for authorities discussed

2) Introduction of overseas situation

- DiGA webinar held on November 7th (2nd webinar following 2021) Details shown in the following slides

3) Involved in policy discussion

- 2 step approval process based on DiGA was proposed at Public-Private Discussion held by MHLW on November 28 (see below)



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🌐 2022年11月 7日 (月) 17:00 ~ 18:30



German DiGA Process – Update 2022-

ー ドイツにおけるプログラム医療機器に関する保険償還 Update 2022 ー

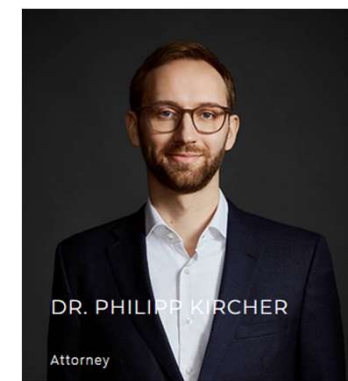
本日の内容：

1. EBCからご挨拶
2. DiGAに関する講演 (日本語通訳付き)
3. Q&A (日本語通訳付き)

講師：

Dr. Philipp Kircher

DiGA創設において、連邦保健省に助言を行った ThinkTank HIH (Health Innovation Hub ; 現在は解体) のメンバー。弁護士としてDiGAのケースに関わっている。



DiGA Webinar held on November 7, 2022


Summary of DiGA Webinar -1-

1) Contents

- Greetings by Mr. Mori/Chair of EBC MD&IVD Committee
- Lecture by Philipp Kircher
- Q&A: 8 inquiries were discussed in webinar, 2 questions answered later

Webinar is video recorded, Slides shared

2) Participants

- 145 (ca. 140 till the end)  Up from 110 in 2021
- 59 responded post webinar questionnaire
- 72% of respondents rated the webinar useful ~ quite useful

Summary of DiGA Webinar - 2 -

3) Overview & Remarks

- Positive & negative aspects of DiGA were presented, based on the actual cases after law enforcement in 2020
 - + : many cases (153 up to end Oct. 2022) applied due to the benefits of the process
 - speedy introduction of SaMD with temporary reimbursement defined by manufacturers
 - clinical usefulness verified with RWD during temporary approval period
 - : many cases (84 cases) withdrawn due to insufficient preparation
 - significant reduction of reimbursement after final approval
- Feedback of participants
 - 2 step approval process would be applicable to Japanese system
 - temporary reimbursement point by manufacturers might not fit to Japan

Action plan for 2023

1) Involvement in the policy discussion with authorities

- Contribution to regular meeting/discussion with MHLW
- Involvement in the working group organized by METI

2) Hold seminars

<to external stake holders>

- Follow-up webinar on DiGA : latter half of 2023
- Seminar by local experts
 - Development of SaMD
 - Personal information protection law and PHR

<internal seminar within EBC>

- to be planned

**Thank you for your kind support to
the activities of EBC in 2022**