

Meeting of representatives

Secretariat Report

December 12, 2024

EBC Equipment and IVD Committee

2024 Member Company List (by Legal Entity)

As of 2024 Dec. 01

1	Philips Japan, Ltd.	21	Japan MDC LLC
2	TR3 LLC	22	Roche Diagnostics K.K.
3	Jin Healthcare Consulting	23	Maruho Co., Ltd.
4	RADIOMETER K.K.	24	LivaNova Japan K.K.
5	Beckman Coulter, Inc.	25	Coloplast K.K.
6	BioMérieux Japan Ltd.	26	Draeger Japan K.K.
7	PARI Japan LLC	27	Japan Lifeline Co., Ltd.
8	Integral Co.,Ltd.	28	Corcym Japan K.K.
9	Dornier MedTech Japan K.K.	29	Telix Pharmaceuticals Japan K.K.
10	Nippon BXI Inc.	30	Medical AI Promotion Institute
11	Mölnlycke Health Care AB.	31	AI Medical Service Co., Ltd.
12	Medis Medical Imaging Systems B.V.	32	CathWorks Japan LLC
13	GUNZE MEDICAL Ltd.	33	EDAP Technomed Inc.
14	BIOTRONIK Japan Inc.	34	Elekta K.K.
15	B.BRAUN AESCLAP JAPAN CO., LTD.	35	
16	Thermo Fisher Diagnostics K.K.	36	
17	Life Technologies Japan Ltd.	37	
18	Varian Medical Systems, Inc.	38	
19	Siemens Healthcare K.K.	39	
20	Siemens Healthcare Diagnostics K.K.	40	

As of December 2024, 32 member companies were registered

- Representatives 9
 - Submissions of power attorney 20
 - Delegation to the Chairperson : 14
 - Proxy : 7
 - Unanswered 2
- } 32

Constitution

Election of Meeting Chairperson
- Appointed by Chairperson

- ◆ Quorum(Teisoku) article 17:
Attendance of a majority of members
- ◆ Voting(Hyoketu) article18:
Majority of members present

Admission

- Medical AI Promotion Institute –Feb.
- Elekta K.K. – Jun.
- Ambu K.K. – registration in progress

Withdrawal

- ◆ MC Medical Inc. – Jun.
- ◆ Novocure K.K. – May
- ◆ K.K. TKB – May
- ◆ Guerbet Japan K.K. – Mar.
- ◆ K.K. QIAGEN – Jan.

15:30 – 16:05

1. Confirmation of meeting completion
2. Appointment of meeting chairperson

3. Opening remark (Chairperson)

(R) Summary of Activities in 2024

(D) Activity Policy in 2025

4. Report from Secretariat

(D) Monthly meeting schedule

(R) Financial Report 2024

(D) Budget 2025

16:10 – 16:20 (10min.)

5. Digital Health Task Force

16:20 – 16:50 (30min.)

6. Medical Fee SC

16:50 – 17:00 (10min.)

Break

17:00 – 17:20 (20min.)

7. MD Pharmaceutical affairs SC

17:20 – 17:50 (30min.)

8. IVD SC

9. Closing address (First Vice-chairperson)

Chairman's Opening remark

- ◆ Executive Summary of Activities in 2024
 - ◆ Activity Policy for 2025

■ Strengthening policy advocacy activities

- Continuation :

- ✓ Expanding the scope of challenge applications (securing a period in which trial plans can be drawn up, responding to new efficacy after putting market on) and qualification
- ✓ Recommendations regarding cyber security
- ✓ Regarding the use of RWD for applications and secondary use of medical data including AI
 - Discussion on promoting MDSRP (Medical Device Single Review Program)
 - Regarding the description of the importer's English brand name on the manufacturing and sales approval/certificate
 - Regarding measures to strengthen stable supply ⇒Public-private dialogue/Regular meetings
 - Submission of opinions regarding the revision of the Infectious Diseases Act and the state of infectious disease-related testing

- ✓ Review of the definition of in vitro diagnostic reagents (independence from the “drug” classification under the Pharmaceutical and Medical Devices Act)
 - Review of qualification requirements for MAH General of in vitro diagnostic drugs
 - Review of review categories for pathogen gene items (toward review as approval standard items)

■ Deregulation in Japan and Europe

- ✓ Collaborative plan for optimizing medical device regulations and reviews (5 years) ⇒ Active participation in the new fiscal year
 - Mutual acceptance of GCP compliance survey results based on international joint clinical trials, etc.
 - Introduction to the European Digital Strategy (RWD/RWE, Data Space, requirements for data used in reviews, related laws and regulations, etc.)

■ Strengthening relationships with related organizations

- Strengthening relationships with the trade departments of each country's embassies

■ Proposals for reforming medical fees

- ✓ The state of insurance in the two-stage approval system for programmed medical devices (proposal for combination therapy not covered by insurance)
- ✓ Promotion of preventive medicine - Introduction of low-dose lung cancer CT for lung cancer screening (reducing medical costs)
- ✓ Issues with stable supply (unprofitable products, foreign price adjustments, etc.)

■ Strengthening policy advocacy activities

- MD:
- ✓ Expanding the scope of challenge applications (reviewing a period in which trial plans can be drawn up, responding to new efficacy after putting market on) and qualification
 - ✓ Regarding the use of RWD for applications and secondary use of medical data including AI
 - ✓ Promotion of Preventive medicine and Telemedicine

- IVD:
- ✓ Proper evaluation of “Innovation” and POCT
 - ✓ Review of the definition of in vitro diagnostic reagents (independence from the “drug” classification under the Pharmaceutical and Medical Devices Act)
 - Review of qualification requirements for MAH General of in vitro diagnostic drugs
 - Review of review categories for pathogen gene items (toward review as approval standard items)

■ Deregulation in Japan and Europe

- ✓ Collaborative plan for optimizing medical device regulations and reviews (5 years) ⇒ Active participation
- Mutual acceptance of GCP compliance survey results based on international joint clinical trials, etc.

■ Strengthening relationships with related organizations

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- ✓ The state of insurance in the two-stage approval system for programmed medical devices (proposal for combination therapy not covered by insurance)
- ✓ Issues with stable supply (unprofitable products, foreign price adjustments, etc.)

Secretariat

Major annual events 2024

Jan. Information exchange with Deloitte - Stable supply of medical equipment in Europe

Mar. FY2024 Medical Fee Revision Explanation Meeting by MHL

Industry proposals submitted to Minister of MHLW regarding the revision of the PMD Act (MD/IVD)

Lecture: World-leading AI, SaMD and medical innovation

Aug. 40th Anniversary Lecture: Cancer Control in Japan

Oct. Regular Opinion Exchange Meeting

Nov. Public-Private Dialogue

Dec. Regular Meeting (scheduled)

Public-Private dialogue 2024.11.21

Chuikyo Industry Opinion Statement
Medical Association various committee activities
Collaborative plan for expediting medical device reviews
Conference on improving the distribution of medical devices
Study group on ensuring stable supply of medical equipment

monthly meeting



(D) 2025 monthly meeting, representative meeting holding plan

Time: 2:30pm to 5:00pm

Location: Siemens Healthcare, 5th floor conference room/WEB

schedule:

- Thursday, January 23th
- Tuesday, February 20th
- Thursday, March 19st
- Thursday, April 17th
- Thursday, May 22rd
- Thursday, June 19th
- Thursday, July 24th
- **August 28th (Thursday) + Information exchange meeting**
- Thursday, September 18th
- Thursday, October 23th
- Tuseday, November 12th
- **December 11th (Thursday) Representative meeting + Information exchange meeting**

(R) 2024 Financial Report

Forecast March 2025

決算予想報告		2024 BD	2024Nov. Actual	vs. BD	Expected costs to be incurred by March 2025	2025Mar. FC	FC vs. BD
		2024年予算	2024年11月実績	vs. 予算	2025年3月までに発生する予定費用	2025年3月末FC	FC vs. 予算
前年度繰越金	Carry-over from previous year	¥14,643,758				¥14,643,758	
会費	Membership fee	¥6,700,000	¥5,900,000	88.1%	¥0	¥5,900,000	88.1%
情報交換会参加費	Participation fee for information exchange meeting	¥300,000	¥167,000	55.7%	¥180,000	¥347,000	115.7%
その他 (利子等雑収入)	Other (miscellaneous income such as interest)		¥1,106				#DIV/0!
今年度収入合計	Total revenue for this fiscal year	¥7,000,000	¥6,068,106	86.7%	¥180,000	¥6,248,106	89.3%
収入合計	Total Revenue	¥21,643,758		0.0%		¥20,891,864	96.5%
事務局運営費 (人件費)	Operating expenses (personnel expenses)	¥3,400,000	¥1,804,417	53.1%	¥902,209	¥2,706,626	79.6%
代表者会議 + 情報交換会 (夏・冬)	Representative Meeting + Information Exchange Meeting	¥1,800,000	¥1,768,712	98.3%	¥1,260,000	¥3,028,712	168.3%
医機連会費	JFMDA membership	¥600,000	¥600,000	100.0%	¥0	¥600,000	100.0%
調査・翻訳費	Research and translation costs	¥1,000,000	¥0	0.0%	¥200,000	¥200,000	20.0%
事務局活動費	Secretariat activity expenses	¥150,000	¥123,477	82.3%	¥40,000	¥163,477	109.0%
部会・TF活動費	Expenses for subcommittee and TF activities	¥2,000,000	¥181,737	9.1%	¥150,000	¥331,737	16.6%
HPメンテナンス費	Hp maintenance cost	¥30,000	¥24,195	80.7%	¥0	¥24,195	80.7%
その他 (雑費)	Other (miscellaneous expenses)	¥20,000	¥13,090	65.5%	¥5,000	¥18,090	90.5%
支出合計	Total Expenses	¥9,000,000	¥4,515,628	50.2%	¥2,557,209	¥7,072,837	78.6%
本年度収支決算 (損益分)	Settlement of accounts for this fiscal year (profit and loss)	¥-2,000,000				¥-824,731	
本年度繰越金	Current year carry-over)	¥12,643,758	¥16,192,553			¥13,819,027	109.3%

(D) 2025 Budget (draft)

予算案 BD (draft)		2024 BD	2025Mar. FC	vs. BD	2025 BD draft	FY2025 BD vs. FY2024 result FC
		2024年予算	2025年3月FC	vs. 予算	2025年予算案	FY2025予算 vs. FY2024年3月FC
前年度繰越金	Carry-over from previous year	¥14,643,758			¥13,819,027	
会費	Membership fee	¥6,700,000	¥5,900,000	88.1%	¥6,100,000	103.4%
情報交換会参加費	Participation fee for information exchange meeting	¥300,000	¥347,000	115.7%	¥300,000	86.5%
その他 (利子等雑収入)	Other (miscellaneous income such as interest)	¥0	¥0		¥0	#DIV/0!
今年度収入合計	Total revenue for this fiscal year	¥7,000,000	¥6,248,106	89.3%	¥6,400,000	102.4%
収入合計	Total Revenue	¥21,643,758	¥20,891,864	96.5%	¥20,219,027	96.8%
事務局運営費 (人件費)	Operating expenses (personnel expenses)	¥3,400,000	¥2,706,626	79.6%	¥3,000,000	110.8%
代表者会議 + 情報交換会	Representative Meeting + Information Exchange Meeting	¥1,800,000	¥3,028,712	168.3%	¥1,800,000	59.4%
医機連会費	JFMDA membership	¥600,000	¥600,000	100.0%	¥600,000	100.0%
調査・翻訳費	Research and translation costs	¥1,000,000	¥200,000	20.0%	¥1,000,000	500.0%
事務局活動費	Secretariat activity expenses	¥150,000	¥163,477	109.0%	¥150,000	91.8%
部会・TF活動費	Expenses for subcommittee and TF activities	¥2,000,000	¥331,737	16.6%	¥2,000,000	602.9%
HPメンテナンス費	Hp maintenance cost	¥30,000	¥24,195	80.7%	¥30,000	124.0%
その他 (雑費)	Other (miscellaneous expenses)	¥20,000	¥18,090	90.5%	¥20,000	110.6%
支出合計	Total Expenses	¥9,000,000	¥7,072,837	78.6%	¥8,600,000	121.6%
本年度収支決算 (損益分)	Settlement of accounts for this fiscal year (profit and loss)	¥-2,000,000	¥-824,731		¥-2,200,000	
本年度繰越金	Current year carry-over)	¥12,643,758	¥13,819,027		¥11,619,027	91.9%

ご清聴ありがとうございます
今後とも委員活動へのご理解ご協力を賜りますようお願いいたします

Thank you for your attention
We ask for your continued understanding and cooperation in the
activities of the committee members.