

Meeting of representatives

Secretariat Report

December 11, 2025

EBC Medical Equipment and IVD Committee

2025 Member Company List (by Legal Entity)

As of 2025 Dec. 01

1	Philips Japan, Ltd.	21	Japan MDC LLC
2	TR3 LLC / Cutera	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	Elekta K.K.	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	Ambu Japan K.K.
11	Mölnlycke Health Care AB.	31	MCRA/ Vorpai Technologies K.K.
12	Medis Medical Imaging Systems B.V.	32	CathWorks Japan LLC
13	GUNZE MEDICAL Ltd.	33	EDAP Technomed Inc.
14	BIOTRONIK Japan Inc.	34	
15	B.BRAUN AESCLAP JAPAN CO., LTD.	35	
16	Thermo Fisher Diagnostics K.K.	36	
17	<i>Life Technologies Japan Ltd.</i>	37	
18	Varian Medical Systems, Inc.	38	
19	Siemens Healthcare K.K.	39	
20	<i>Siemens Healthcare Diagnostics K.K.</i>	40	

As of December 2025, 31 member companies were registered

- Representatives 7
 - Submissions of power attorney 24
 - Delegation to the Chairperson : 18
 - Proxy : 6
 - Unanswered 0
- } 31

Constitution

Election of Meeting Chairperson
- Appointed by Chairperson

- ◆ Quorum(Teisoku) article 17:
Attendance of a majority of members
- ◆ Voting(Hyoketu) article 18:
Majority of members present

Admission

MCRA Japan / Vorpai Technologies K.K.

Withdrawal

AI Medical Service
Medical AI Promotion Institute
PARI Japan GK

15:30 – 15:55 (25min.)

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

3. Opening remark (Chairperson)

- (R) Summary of Activities in 2025
- (D) Activity Policy in 2026

4. Report from Secretariat

- (D) Monthly meeting schedule
- (R) Financial Report 2025
- (D) Budget 2026

15:55 – 16:15 (20min.)

5. Medical Fee SC

16:15 – 16:25 (10min.)

6. Digital Health Task Force

16:25 – 16:40 (15min.)

Break

16:40 – 17:00 (20min.)

7. MD Pharmaceutical affairs SC

17:00 – 17:20 (20min.)

8. IVD SC

9. Closing address (Vice-chairperson)

Chairperson's Opening remark

- ◆ Executive Summary of Activities in 2025
 - ◆ Activity Policy for 2026

Summary of 2025 activities (R)

PMD act

- Market leadership through innovative technologies such as SaMD and AI
- Establishment of a medical information database platform

- Evolving Product Database
- Secondary Use of RWD/RWE
- Collaborative Planning (PMDA&MHLW)
 - Cyber security

- Agile approval review

- Japanese social environment
- Distortions in health care policy

- Healthcare system
- Regional disparities in medical care
 - Stable supply

- Combined non-insurance medical care expenses system
- Preventive medicine/telemedicine
 - Challenge application
- Foreign price adjustments/negative margins

- Attractive and vibrant market with patient benefit

IVD legislation

- International Harmonization
 - Value of IVD

- The usefulness of POCT testing
- Marketability / Economic value

- Welcome to the world of IVD !!

Creation of value aimed at “**patient benefit**” (quality of medical care) and corresponding “**new evaluation**”

- Medical information infrastructure (opening a new era of medical device evaluation through the use of RWD/RWE)
- Patient Journey literacy (integrating prevention, diagnosis, treatment, and prognosis management)

To achieve this,

- Integration of RWD with public data and the creation of an optimized patient journey using AI are necessary.

Specifically,

- Medical devices x Data x AI ⇒ Supporting improved outcomes and medical efficiency
- Remote, home, and personal healthcare through AI and SaMD
- Approval and reimbursement processes using RWD
- Compliance with regulations and international standards

furthermore

- Stable supply : Unprofitable products and Foreign Price Adjustment
- Appropriate regulations tailored to the characteristics of IVD
- MRA: Mutual Recognition Agreement

Secretariat

Major annual events 2025

- Monthly Meeting
- Various review WGs related to the MHLW and the JFMDA
- Coordination meetings within each sub-committee

Feb. : ●Committee Officer Re-election

- Collaborative Planning Practitioner Meeting

Various regulations and operations under PMD act
MD 30 items, IVD 14 items

Jul.: ●Regular Meeting - Reimbursement, Stable supply, Healthcare Material System, etc.

Aug. ●Lecture & Information Exchange Meeting

Medical Device Evaluation – Value Flower

The state of medical care and the policy-making processes

Sep.: ●Regular Opinion Exchange Meeting – PMD act :DB & Utilization, GCP/GPSP, FSC, Device loss, etc.

Aug. ~ Nov. ● Chuikyo – Industry Opinion Statements

Nov.: ●Public-Private Dialogue – Patient Journey aimed at Patient Benefits (Quality of Medical Care)

Dec./2026 Jan.: Opinion exchange with EU –EPA (EU-Japan) , TBT*

*TBT: Agreement of Technical Barrier to Trade



(D) 2026 monthly meeting, representative meeting holding plan

Time 2:30 pm to 5:00 pm

Location Siemens Healthcare, 5th floor conference room / WEB

Date		Meeting
1/22	THU	Monthly
2/19	THU	Monthly
3/19	THU	Monthly
4/23	THU	Monthly
5/28	THU	Monthly
6/25	THU	Monthly
7/23	THU	Monthly
8/27	THU	Lecture and Information Exchange Meeting
9/24	THU	Monthly
10/22	THU	Monthly
11/26	THU	Monthly
12/10	THU	Representative Meeting and Information Exchange Meeting

(R) 2025 Financial Report

2025年度 医療機器・IVD委員会 会計報告書

FY 2025 Financial Statement

settlement of acc.

		FY2025 Budget	YTD 2025Nov.	FC 2026/3/31	FY2025 FC2026/3/31 vs Budget
前年度繰越金	Carry-over from previous year	¥14,210,204		¥14,210,204	
会費	Membership fee	¥6,100,000	¥6,100,000	¥6,100,000	100.0%
情報交換会参加費	Participation fee for info. Exchange meeting	¥300,000	¥156,000	¥156,000	52.0%
その他（利子等雑収入）	Other(miscellaneous such an interest)	¥0	¥286,341	¥286,341	#DIV/0!
今年度収入合計	Total revenue for this fiscal year	¥6,400,000	¥6,542,341	¥6,542,341	102.2%
収入合計	Total revenue	¥20,610,204	¥20,752,545	¥20,752,545	
事務局運営費（人件費）	Operating expenses (personnel expenses)	¥3,000,000	¥2,276,875	¥3,415,313	113.8%
代表者会議＋情報交換会	Representative Meeting + Information Exchange Meeting	¥1,800,000	¥1,155,306	¥2,355,306	130.9%
医機連会費	JFMDA membership fee	¥600,000	¥600,000	¥600,000	100.0%
調査・翻訳費	Research and translation cost	¥1,000,000	¥0	¥200,000	20.0%
事務局活動費	Secretariate activity expense	¥150,000	¥60,700	¥100,700	67.1%
部会・TF活動費	Expense for SC and TF activity	¥2,000,000	¥408,894	¥1,408,894	70.4%
HPメンテ費	HP maintenance cost	¥30,000	¥24,195	¥24,195	80.7%
その他（雑費）	Others (miscellaneous expense)	¥20,000	¥13,970	¥23,970	119.9%
支出合計	Total expense	¥8,600,000	¥4,539,940	¥8,128,378	94.5%
本年度収支決算（損益分）	Settlement of accounts for this fiscal year (profit and loss)	¥-2,200,000	¥2,002,401	¥-1,586,037	
本年度繰越金	Carry-over	¥12,010,204	¥16,212,605	¥12,624,168	

(D) 2026 Budget (draft)

予算案 BD (draft)		2025 BD	2026 Mar. FC	vs. BD	2026 BD draft	FY2026 BD vs. FY2025 result FC
		2025年予算	2026年3月FC	vs. 予算	2026年予算案	FY2026予算 vs. FY2025年3月FC
前年度繰越金	Carry-over from previous year	¥14,210,204			¥12,624,167	
会費	Membership fee	¥6,100,000	¥6,100,000	100.0%	¥5,900,000	96.7%
情報交換会参加費	Participation fee for information exchange meeting	¥300,000	¥156,000	52.0%	¥300,000	192.3%
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	¥6,400,000	¥6,542,341	102.2%	¥6,200,000	94.8%
収入合計	Total Revenue	¥20,610,204	¥20,752,545	100.7%	¥18,824,167	90.7%
事務局運営費（人件費）	Operating expenses (personnel expenses)	¥3,000,000	¥3,415,313	113.8%	¥3,200,000	93.7%
代表者会議＋情報交換会	Representative Meeting + Information Exchange Meeting	¥1,800,000	¥2,355,306	130.9%	¥2,400,000	101.9%
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%	¥500,000	250.0%
事務局活動費	Secretariat activity expenses	¥150,000	¥100,700	67.1%	¥100,000	99.3%
部会・TF活動費	Expenses for subcommittee and TF activities	¥2,000,000	¥1,408,894	70.4%	¥1,500,000	106.5%
HPメンテ費	Hpmaintenance cost	¥30,000	¥24,195	80.7%	¥30,000	124.0%
その他（雑費）	Other (miscellaneous expenses)	¥20,000	¥23,970	119.9%	¥20,000	83.4%
支出合計	Total Expenses	¥8,600,000	¥8,128,378	94.5%	¥8,350,000	102.7%
本年度収支決算（損益分）	Settlement of accounts for this fiscal year (profit and loss)	¥-2,200,000	¥-1,586,037		¥-2,150,000	
本年度繰越金	Current year carry-over)	¥12,010,204	¥12,624,167		¥10,474,167	87.2%

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.