

# Meeting of representatives

## Secretariat Report

December 07, 2023

**EBC Equipment and IVD Committee**

## As of December 2023, 34 member companies were registered

- Representatives 10
  - Submissions of power attorney 23
    - Delegation : 14
    - Substitute : 9
  - Not answered 1
- } 33

### Constitution

**Election of Meeting Chairperson :  
Appointed by the Chairperson**

**Teisoku (Article 17) : Attendance of a  
majority of members  
Voting (Article 18) : Majority of  
members present**

### Admission

- TR3 LLC 2023Mar.
- AI Medical Service Co., Ltd. 2023Mar.
- Jin Healthcare Consulting 2023May
- CathWorks Japan LLC 2023Jun.
- Beckman Coulter, Inc. 2023 Nov.
- (PARI Japan LLC 2024Jan.)

### Withdrawal

- ◆ ZAP Surgical Japan LLC 2023 Mar.

As of 2023 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	Guerbet Japan KK	27	Japan Lifeline Co., Ltd.
8	Integral Co.,Ltd.	28	Corcym Japan K.K.
9	QIAGEN K.K. -Japan	29	Telix Pharmaceuticals Japan K.K.
10	Nippon BXI Inc.	30	Novocure K.K.
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	Japan Medical Next K.K.
15	B.BRAUN AESCLAP JAPAN CO., LTD.	35	K.K. TKB
16	Thermo Fisher Diagnostics K.K.	36	Dornier MedTech Japan K.K.
17	Life Technologies Japan Ltd.	37	PARI Japan LLC
18	Varian Medical Systems, Inc.	38	
19	Siemens Healthcare K.K.	39	
20	Siemens Healthcare Diagnostics K.K.	40	

## **15:30 – 16:00 (20 minutes)**

1. Confirmation of meeting completion
2. Appointment of meeting chairman
3. Opening remark - Chairman
  - (R) Summary of Activities in 2023
  - (D) 2024 Activity Policy
4. Report of the Secretariat
  - (D) monthly meeting Schedule
  - (R) Financial Report 2023
  - (D) The 2024 Budget

## **16:00 - 16:15 (15 minutes)**

5. Digital Health Task Force
  - 2023 Activity Report
  - 2024 Activity Policy

## **16:15 – 16:45 (30 minutes)**

6. MD / Medical Fee Subcommittee
  - 2023 Activity Report
  - 2024 Activity Policy

## **16:45 - 16:55**

Break

## **16:55 – 17:15 (20 minutes)**

7. MD / Pharmaceutical Affairs Subcommittee
  - 2023 Activity Report
  - 2024 Activity Policy

## **17:15 – 17:45 (30 minutes)**

8. IVD Subcommittee
  - 2023 Activity Report
  - 2024 Activity Policy

## **17:45 -**

9. Closing remark – Vice chairperson (IVD)

# Chairman's Opening remark

- ◆ Executive Summary of Activities in 2023
  - ◆ Activity Policy for 2024

## ■ Strengthening policy advocacy activities

- 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
- Qualification and Clarification of the evaluation of program medical devices and strengthening of examination system (PMDA/MHLW Consultation Desk)
- 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) ⇒ Regular opinion exchange meeting
- Regarding the description of the importer's English brand name on the manufacturing and sales approval/certificate
- Communicate abroad about Japanese regulations ⇒ Collaborative plan/English translation
- Regarding measures to strengthen stable supply ⇒ Public-private dialogue/Regular meetings
- Development of implanted medical device information into medical data ⇒ Regular opinion exchange meeting
- 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 drugs ⇒ Public-private dialogue and regular opinion exchange meetings
- 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 regulation and review (5 years)
  - ⇒ Active participation in the final year
- Mutual acceptance of GCP compliance survey results based on international joint clinical trials, etc. (regular opinion exchange meetings)
- Webinar held on German medical insurance and reimbursement system (including DiGA)
- Introducing the European Digital Strategy

## ■ Strengthening relationships with related organizations

- Cooperation with the Delegation of the European Union to Japan
- EBC White Paper
- Liberal Democratic Party Health, Labor and Welfare Committee ⇒ Lecture: Chairman Tabata “Trends in Digital Health”

## ■ 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

### - 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 drugs (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.)

# Secretariat



## Major annual events 2023

Jan : **Regular meeting (FY2022)**

Jun : Japan Small and Medium Enterprise Agency 8Business matching measures between overseas and Japanese companies) briefing session

**MDR/IVDR study session (MHLW, PMDA etc.)**

Jul : **Regular meeting (FY2023)**

**Aug : Medical DX lecture/ German insurance system lecture sessions**

- Overview of the German insurance system and insurance reimbursement system –Ms. Keiko Yoshida
- Looking ahead to the 2024 medical fee revision :Trends in digital health – Mr. Hiroaki Tabata

Sep : **Regular opinion exchange meeting** regarding approval reviews and safety measures for medical devices and in vitro diagnostic reagents

Nov : **Public-private dialogue** to create innovative medicines, medical devices, regenerative medicine products, etc.

Dec : EBC White paper



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) 2024 monthly meeting, representative meeting holding plan

Time: 2:30pm to 5:00pm

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

schedule:

- Thursday, January 25th
- Tuesday, February 20th
- Thursday, March 21st
- Thursday, April 18th
- Thursday, May 23rd
- Thursday, June 20th
- Thursday, July 18th
- **August 22nd (Thursday) + Information exchange meeting**
- Thursday, September 19th
- Thursday, October 17th
- Thursday, November 14th
- **December 12th (Thursday) Representative meeting + Information exchange meeting**



# (D) 2024 Budget (draft)

予算案 BD (draft)		2023 BD	2024Mar. FC	vs. BD	2024 BD draft	2024Mar.FC vs. 2023Mar. FC
		<b>2023年予算</b>	2024年3月FC	vs. 予算	<b>2024年予算案</b>	予算 vs. 2024年3月FC
前年度繰越金	Carry-over from previous year	¥13,512,275			¥13,529,764	
会費	Membership fee	¥6,200,000	¥6,300,000	101.6%	¥6,700,000	106.3%
情報交換会参加費	Participation fee for information exchange meeting	¥300,000	¥276,000	92.0%	¥300,000	108.7%
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	¥6,500,000	¥6,596,061	101.5%	<b>¥7,000,000</b>	106.1%
収入合計	Total Revenue	¥20,012,275	¥20,108,336	100.5%	¥20,529,764	102.1%
事務局運営費 (人件費)	Operating expenses (personnel expenses)	¥3,400,000	¥2,985,609	87.8%	¥3,400,000	113.9%
代表者会議 + 情報交換会	Representative Meeting + Information Exchange Meeting	¥1,800,000	¥1,712,100	95.1%	¥1,800,000	105.1%
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	¥600,000	¥831,400	138.6%	¥1,000,000	120.3%
事務局活動費	Secretariat activity expenses	¥200,000	¥88,444	44.2%	¥150,000	169.6%
部会・TF活動費	Expenses for subcommittee and TF activities	¥3,000,000	¥325,000	10.8%	¥2,000,000	615.4%
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	¥11,824	59.1%	¥20,000	169.1%
支出合計	Total Expenses	¥9,650,000	¥6,578,572	68.2%	<b>¥9,000,000</b>	136.8%
本年度収支決算 (損益分)	Settlement of accounts for this fiscal year (profit and loss)	¥-3,150,000	¥17,489		<b>¥-2,000,000</b>	
本年度繰越金	Current year carry-over)	¥10,362,275	¥13,529,764		¥11,529,764	111.3%

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.