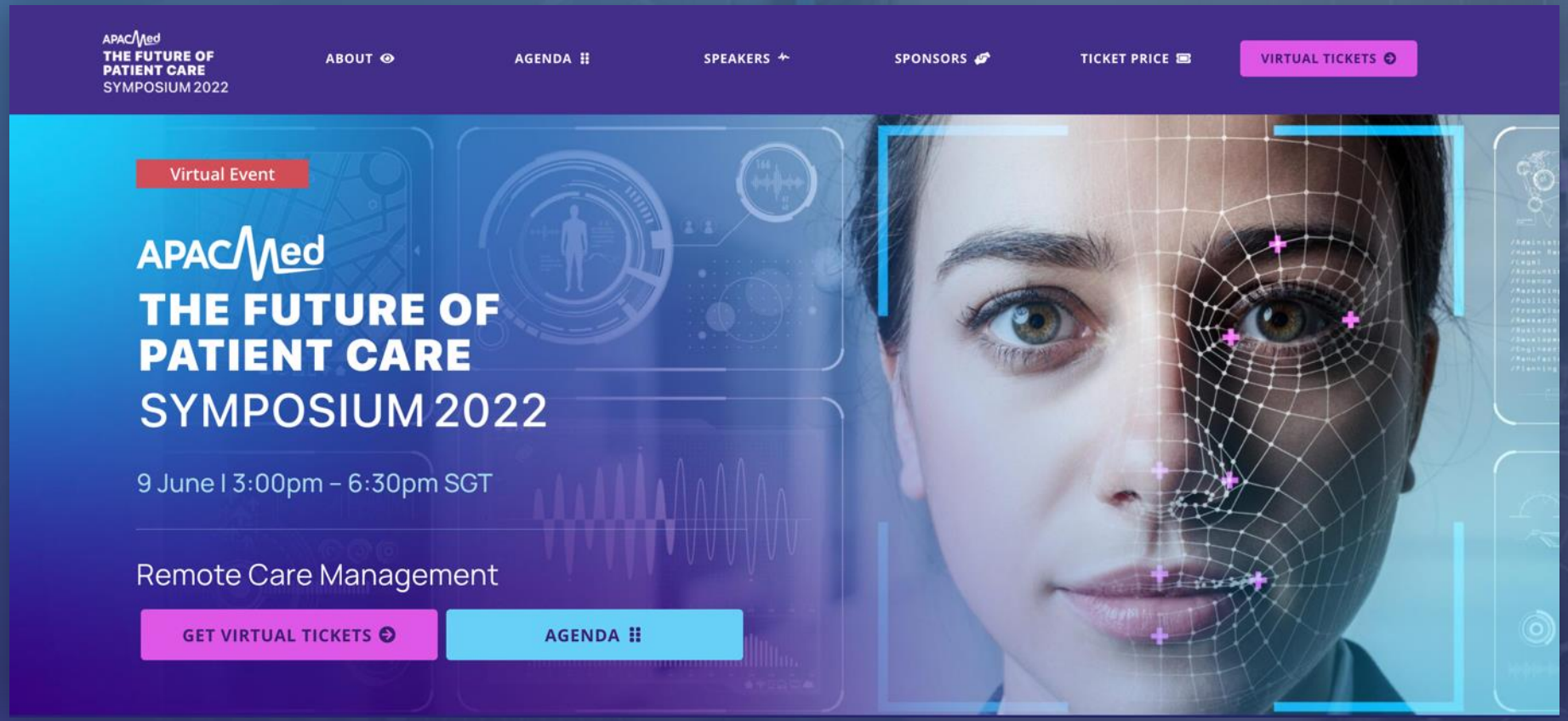

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APACMed
The voice of MedTech

IN PARTNERSHIP WITH

AMDD
Enabling a Healthier Japan

Landscape of digital health reimbursement policies in Japan

Thursday, 2 June 2022
12 -1pm (SGT) / 1-2pm (JPT)

Agenda

Opening Remarks	**Cindy Pelou** (APACMed)
Introduction	**Jun Sekiguchi 関口　淳** (APACMed, AMDD, Baxter)
Presentation and Panel Discussion	- **Dr Kokichi Morimoto 森本耕吉** (Keio University School of Medicine) - **Tomohiro Watanuki 綿貫友洋** (AMDD, Medtronic) - **Jun Sekiguchi 関口　淳** (APACMed, AMDD, Baxter) - **Makoto Tamura 田村　誠** (MTPI / International University of Health and Welfare)
Closing remarks	**Danny Risberg** (Baxter)

About APACMed

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚太 医疗技术协会) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific. APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory convergence. Learn more about the association at **www.apacmed.org**

230 Member companies

20 Of the top 30 MedTech Companies worldwide

130 Startup members

About the APACMed Digital Health Committee

250+ MEMBERS
from **75+ COMPANIES:**
MNCs, SMEs,
Start-ups

OUR MISSION
Support APACMed members across the entire digital health product journey, from regulatory approval to market access and use.

Cindy Pelou
Project Manager
APACMed Digital Health

Board Sponsor:
Elisabeth Staudinger
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OUR VALUE
Share the voice of the industry with the public and private digital health deciders and provide a neutral platform for public-private collaborations on regulatory, cybersecurity, reimbursement, health data, interoperability.

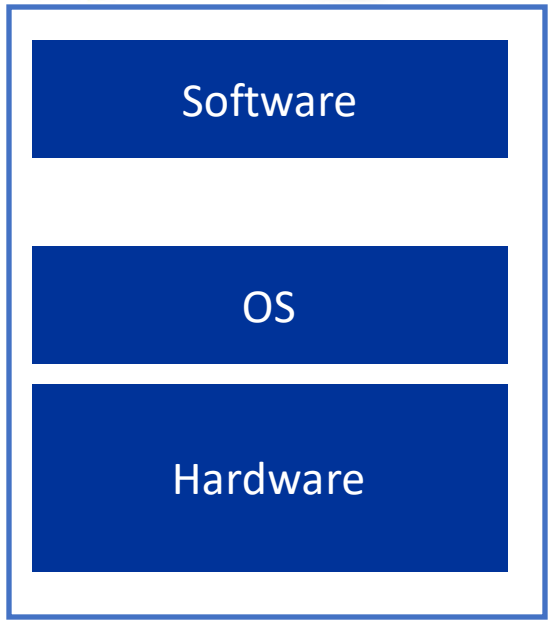
5

Digital Health Reimbursement in Japan

1. Change of regulation for Digital Health

Traditional regulation :

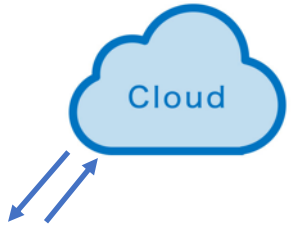
Software is part of device system

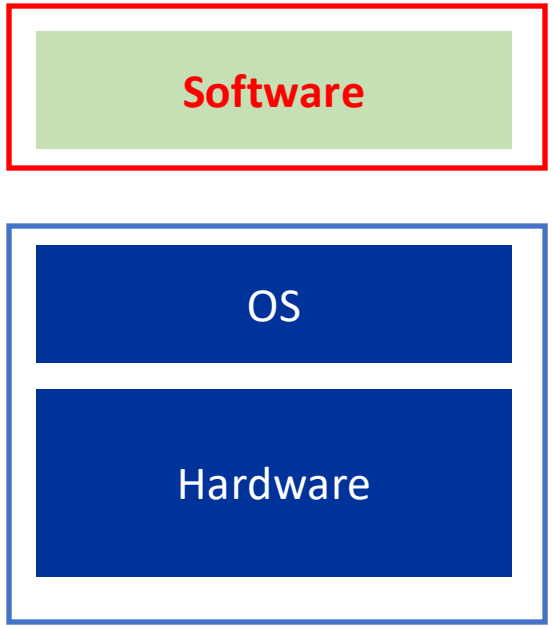


Software is specific to hardware and will be upgraded together

New regulation :

Software is separate as stand-alone medical device





Software can be upgraded separate from hardware and can be changed independently

Sharesource

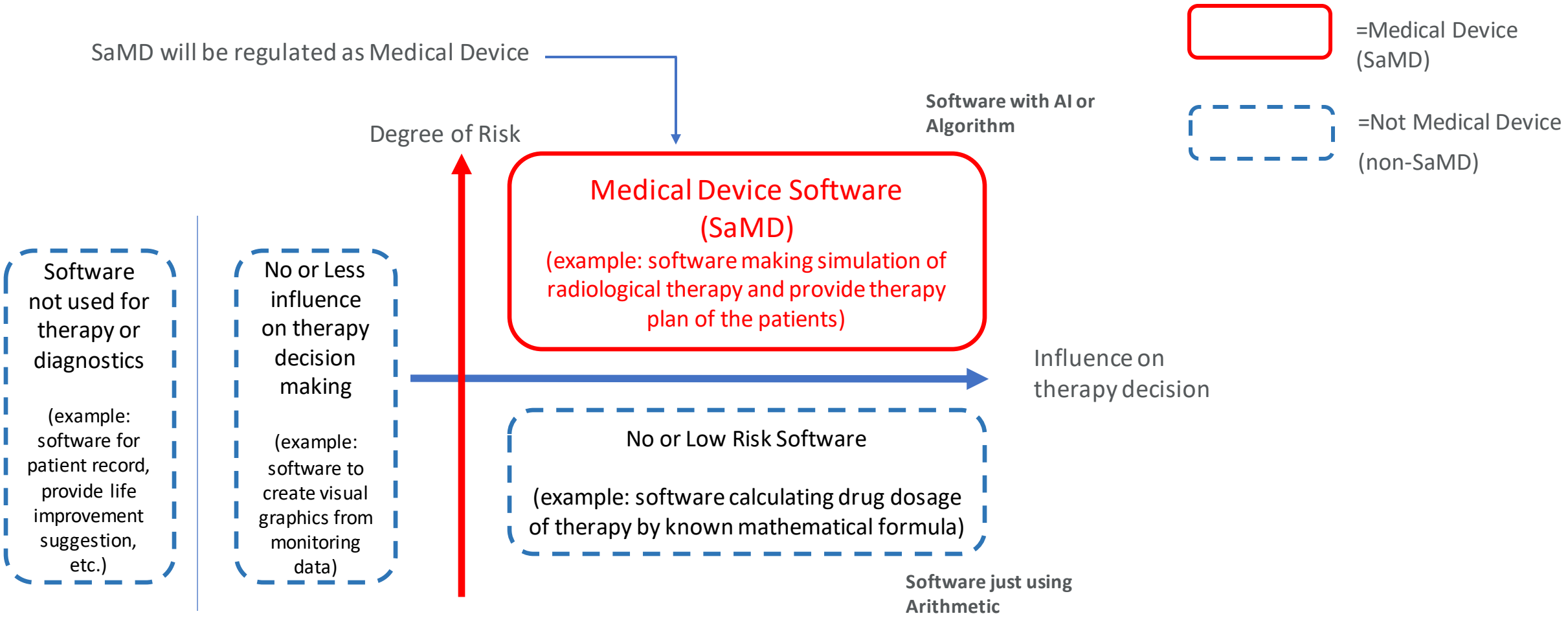
Software as Medical Device = SaMD

Hardware can be medical device

Or

General device

2. Concept of SaMD regulation



Among the healthcare software, relatively high risk and having higher influence over decision on therapy will be defined as Medical Device Software (=SaMD) and thus being reimbursed by national health insurance.

厚労省「第3回保険医療分野におけるAI活用推進懇談会」(参考)医療機器プログラムの該当性の考え方

3. Regulatory risk classification of medical device and SaMD

Risk Classification		Class I	Class II	Class III	Class IV
Category	Non-Medical Device	General Medical Device (一般医療機器)	Controlled Medical Device (管理医療機器)	Specially Controlled Medical Device (高度管理医療機器)	
Definition		Medical device with extremely low risk in the event of defect/failure	Medical device with relatively low risk in the event of defect/failure	Medical device with relatively high risk in the event of defect/failure	Medical device with very high risk in the event of defect/failure
Certification/Review	(No Regulation)	Self Declaration	Third Party Certification	Third Party Certification or PMDA Review	PMDA Review
Example of Products		IVD Equipment, X-Ray Film, Surgical Instrument, etc.	MRI, CT, Endoscope, Ultrasound, etc.	Artificial Joint, Ventilator, Dialyzer, etc.	Pacemaker, TAVI, Coronary Stent, etc.
Medical Software	Outside PMD-Act* Regulation (Patient Support Application, etc.)		SaMD		

Health Insurance Coverage — **Not Covered** — **Covered**

Risk classification of MD is defined by JMDN**.
Many of the SaMD will be class II or III, whereas mobile patient applications are outside the definition of medical device.

*PMD Act : Pharmaceutical and Medical Device Act
**JMDN: Japan Medical Device Nomenclature

4. Government direction for SaMD reimbursement

Central Social Insurance Medical Council (Chuikyo) announced below criteria for the reimbursement of SaMD for 2022 reimbursement revision.

イ　プログラム医療機器の評価について

○　医療機器該当性のあるプログラム医療機器については、当該製品の特性に応じて、

- 技術料に平均的に包括して評価されるもの
- 特定の技術料に加算して評価されるもの
- 特定の技術料に一体として包括して評価されるもの
- 特定保険医療材料として評価されるもの

があることから、製造販売業者から保険適用希望書が提出された場合には、引き続き他の医療機器と同様に、保険医療材料等専門組織において、それぞれの製品の特性を踏まえ評価する。

Reimbursement evaluation of Medical Device Software (SaMD) will be done in one of the followings;

1. Generally included in overall technical fee
2. Added onto specific technical fee
3. Included in specific technical fee
4. Separately reimbursed as STM*

Assessment will be done at Chuikyo expert panel upon application by the manufacturer of device.

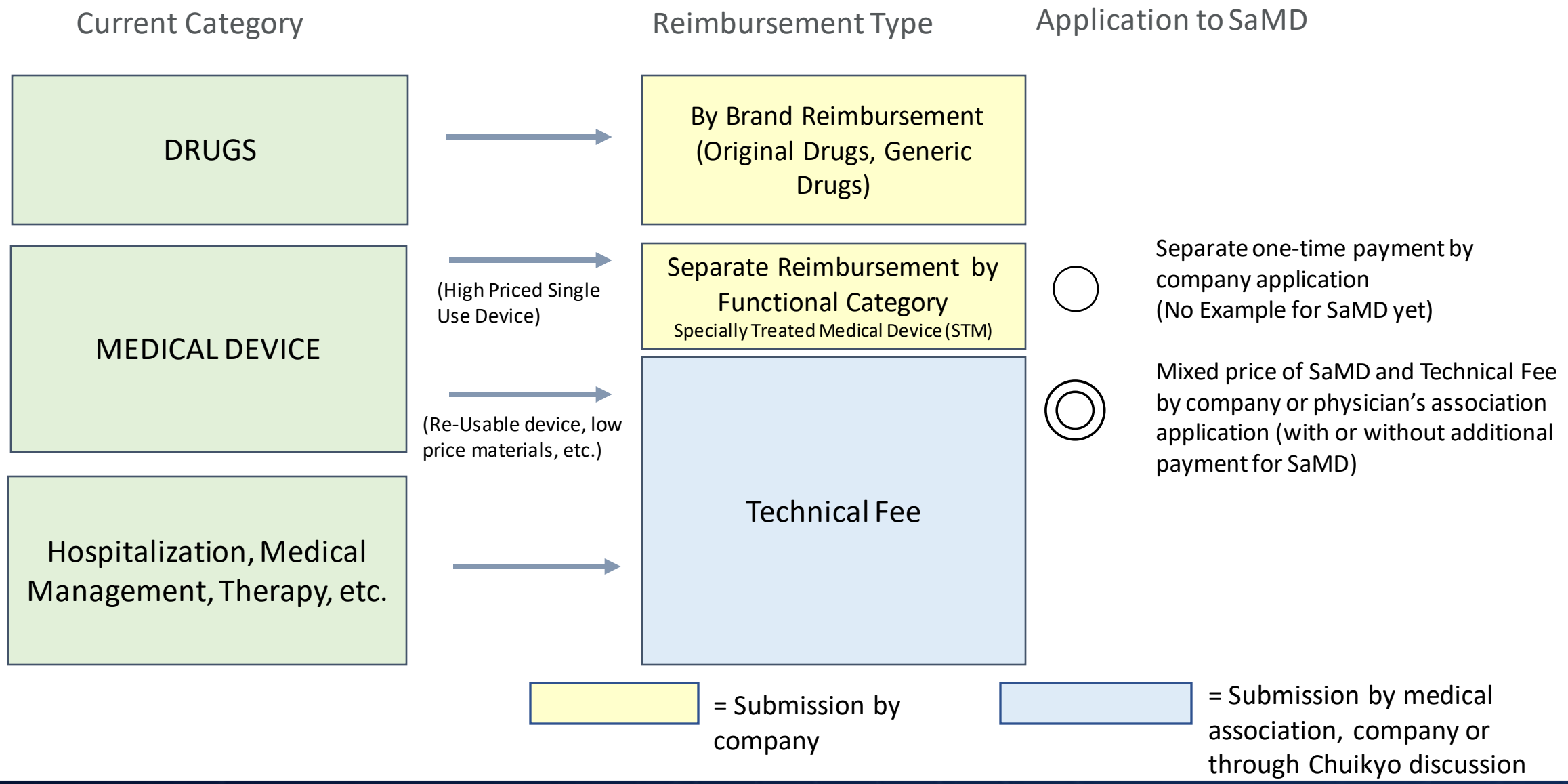
*STM: Specially Treated Medical Device

○　また、プログラム医療機器の特性から、医師の診療をサポートすることで、より少ない医療従事者で同等の質が確保できること等があり得ることから、プログラム医療機器の評価に当たっては、医師の働き方改革の観点を念頭に置きつつ、それぞれの製品の特性を踏まえ、施設基準等への反映も含め評価する。

Therapy supporting software that will reduce HCP workload may be evaluated through medical institution standard (施設基準).

2021年12月22日中医協材料部会「令和4年保険医療材料制度改革の骨子（案）」より引用

5. Reimbursement types and application to SaMD



6. Outline of PD Remote Patient Monitoring Addition

在宅腹膜灌流に係る遠隔モニタリングの評価の新設

➢ 腹膜透析を実施している患者に対する効果的な治療を推進する観点から、在宅自己連続携行式腹膜灌流を行っている患者に対し、継続的な遠隔モニタリングを行い、来院時に当該モニタリングを踏まえた療養方針について必要な指導を行った場合に遠隔モニタリング加算を新設する。

（新）　遠隔モニタリング加算　　115点（月１回に限る）

［算定要件］
遠隔モニタリング加算は、以下の全てを実施する場合に算定する。
ア　自動腹膜灌流用装置に搭載された情報通信機能により、注液量、排液量、除水量、体重、血圧、体温等の状態について継続的なモニタリングを行うこと。
イ　モニタリングの状況に応じて、適宜患者に来院を促す等の対応を行うこと。
ウ　当該加算を算定する月にあっては、モニタリングにより得られた所見等及び行った指導管理の内容を診療録に記載すること。
エ　モニタリングの実施に当たっては、厚生労働省の定める「医療情報システムの安全管理に関するガイドライン」等に対応すること。

Code	C102 Management Fee for Home Peritoneal Dialysis Note 3)PD Remote Patient Monitoring Addition
Price	1,150 yen/$10.5
Period	Monthly, per patient
Contents	PD Remote Patient Monitoring Addition can be reimbursed when continuous remote monitoring and necessary medical management based on its monitoring data was done to APD Patient.
Monitoring	Using regulatory approved communication device, monitor fill volume, drain volume, UF, BP, Weight, temperature, etc.
Condition	Need to record contents of mecical management done by using monitoring data
Guideline	Medical Information System Safety Guideline by MHLW

Peritoneal Dialysis Remote Monitoring was newly reimbursed in 2022 revision.
Evaluation of this class III SaMD was supported by local / global data and realized through discussion at Chuikyo council.

Source: MHLW 2022 Reimbursement revision explanatory material

Landscape of digital health reimbursement policies in Japan

【Basic knowledge】 The most recent remote monitoring service for patients with peritoneal dialysis (PD)

Kohkichi Morimoto, M.D., Ph.D.

a Councilor of the Japanese Society for Dialysis Therapy

Apheresis and Dialysis Center, Keio University Hospital

kohkichi.morimoto@keio.jp

PD, a choice of Renal Replacement Therapy

- Renal replacement therapy (RRT), for end-stage renal disease (ESRD) patients
  - Renal transplant — approx. 1800 cases/year in Japan
  - Dialysis (maintenance or chronic dialysis) — approx. 300,000 patients in Japan
    - Hemodialysis, HD (in-center hemodialysis, home hemodialysis) — 97%
    - Peritoneal dialysis, PD — 3%*

*approx. 15% in the world

- PD is…
  - # home-oriented RRT, much less frequent hospital visit (PD 1/month vs. HD 3/week)
  - # light-burden, compatible with preservation of residual renal function and severe comorbidities (ex. chronic heart failure and valvular dsease, peripheral artery disease, etc.)
  - # lower medical expenses in most countries
  - # much less infrastructure needed

PD, a choice of Renal Replacement Therapy

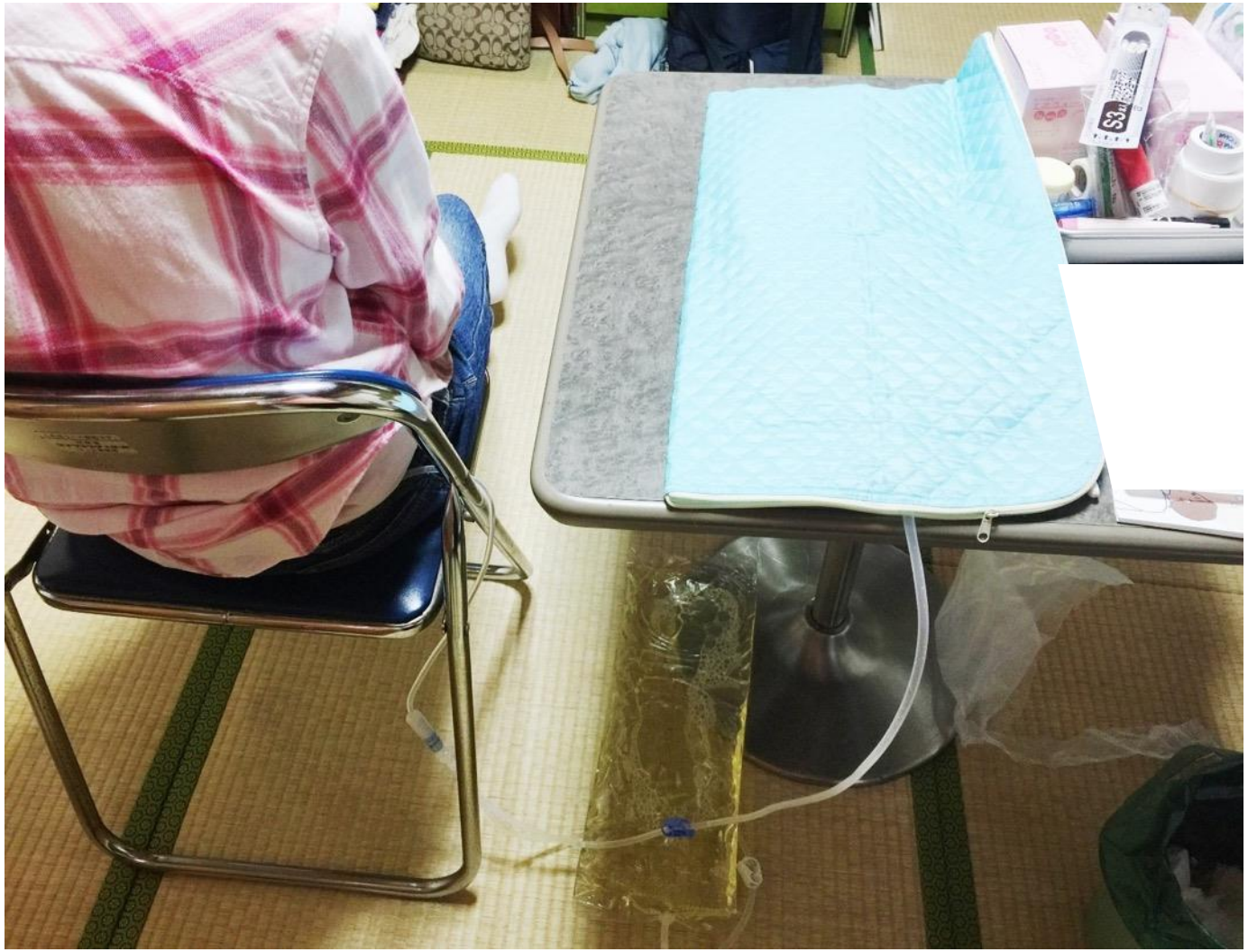
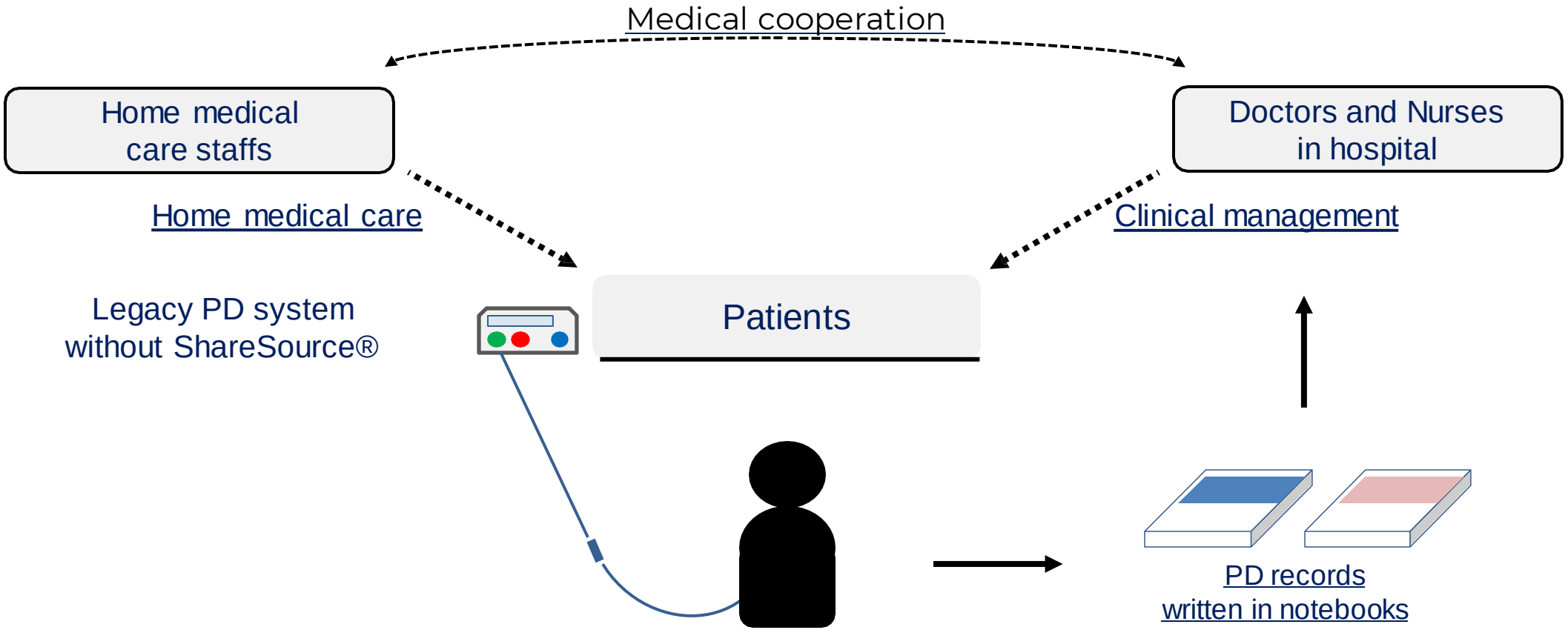


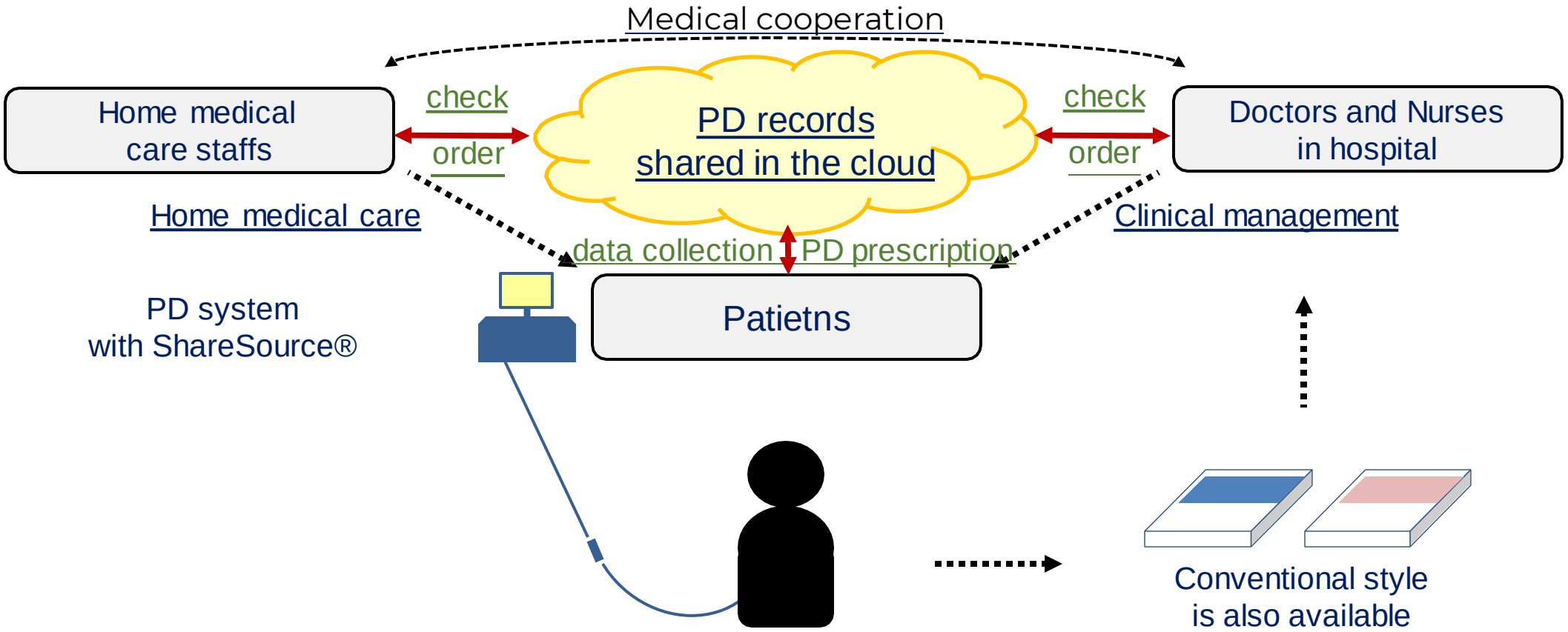
Photo presentation for education is allowed by the patient and his/her family.

Legacy clinical data management in PD



- PD is home-oriented, and medical staffs *must* collect the results of the therapy.
- Patients write their PD records in notebooks, bring them to the hospital. Medical staffs assess the data for clinical management. The data are shared with home medical care staffs in some cases.

Clinical data management in PD, with ShareSource®



- ShareSource®, a connectivity platform for automated PD, enables cloud data sharing.
- With ShareSource®, the data are shared interactively (data collection /prescription). Medical staffs (*both* in-hospital care *and* home care) can share the data very easily.

ShareSource® RCT

- We conducted a clinical study to evaluate clinical effectiveness of Share Source®.
- A crossover RCT, with 15 patients, for 24 weeks. The primary outcome was TSQM-9, the secondary outcomes were KDQOL-SF, healthcare resource consumption, PD prescription change（reflecting prescription optimization）and other clinical events.

Variables	**ShareSource® +**	**ShareSource® -**	***P*-value***
average medical consultation time	14 min 02 sec	16 min 38 sec	0.005
% of PD prescription change	64%	9%	0.04†
Healthcare resource consumption	0.92 ± 1.44	1.92 ± 2.64	0.08
hospital visit without reservation	0.33 ± 0.65	0.50 ± 1.24	0.56
telephone contact from patient	0.41 ± 0.79	0.67 ± 0.98	0.28
telephone contact from hospital	0.17 ± 0.39	0.42 ± 0.67	0.28
emergency hospital admission	0 ± 0	0.17 ± 0.39	0.17
emergency dialysis	0 ± 0	0.17 ± 0.39	0.17

Uchiyama K, Morimoto K, et al. Int Urol Nephrol. 2022 Apr 1;1–9. doi: 10.1007/s11255-022-03178-5.

ShareSource® RCT

Variables	ShareSource® +	ShareSource® -	*P*-value*
TSQM-9（Satisfaction）			
Effectiveness	63.0 ± 20.7	57.3 ± 20.1	0.02
Convenience	77.8 ± 16.6	64.1 ± 16.8	<0.001
Overall satisfaction	64.8 ± 18.2	57.8 ± 25.6	0.25
SF-36（HRQoL）			
Physical functioning	66.7 ± 22.4	62.7 ± 27.8	0.08
Physical role functioning	60.9 ± 31.0	62.0 ± 30.8	0.65
Body pain	55.5 ± 24.1	54.7 ± 23.6	0.25
General health	47.8 ± 24.0	38.0 ± 25.0	0.007
Vitality	46.4 ± 21.2	44.2 ± 26.3	0.13
Social functioning	62.5 ± 35.4	50.0 ± 38.5	0.22
Emotional role functioning	73.6 ± 34.2	73.1 ± 34.4	0.67
Mental health	72.9 ± 20.1	70.8 ± 19.3	0.60
PCS	34.4 ± 15.9	34.1 ± 15.8	0.25
MCS	49.7 ± 10.8	47.9 ± 8.6	0.25
RCS	42.5 ± 17.4	40.8 ± 17.5	0.64

Uchiyama K, Morimoto K, et al. Int Urol Nephrol. 2022 Apr 1;1–9. doi: 10.1007/s11255-022-03178-5.

Impact of digital health reimbursement policies in PD

- ShareSource® is the FIRST insurance-covered digital health service for dialysis patients in Japan. Compared with artificial cardiac pacemakers（400,000 patients）, CPAP（500,000 patients）and HOT（170,000 patients）, the new coverage is for much less patients（10,000 patients）.

【PROS】# It would accelerate development and clinical application of digital health / remote monitoring devices and services.

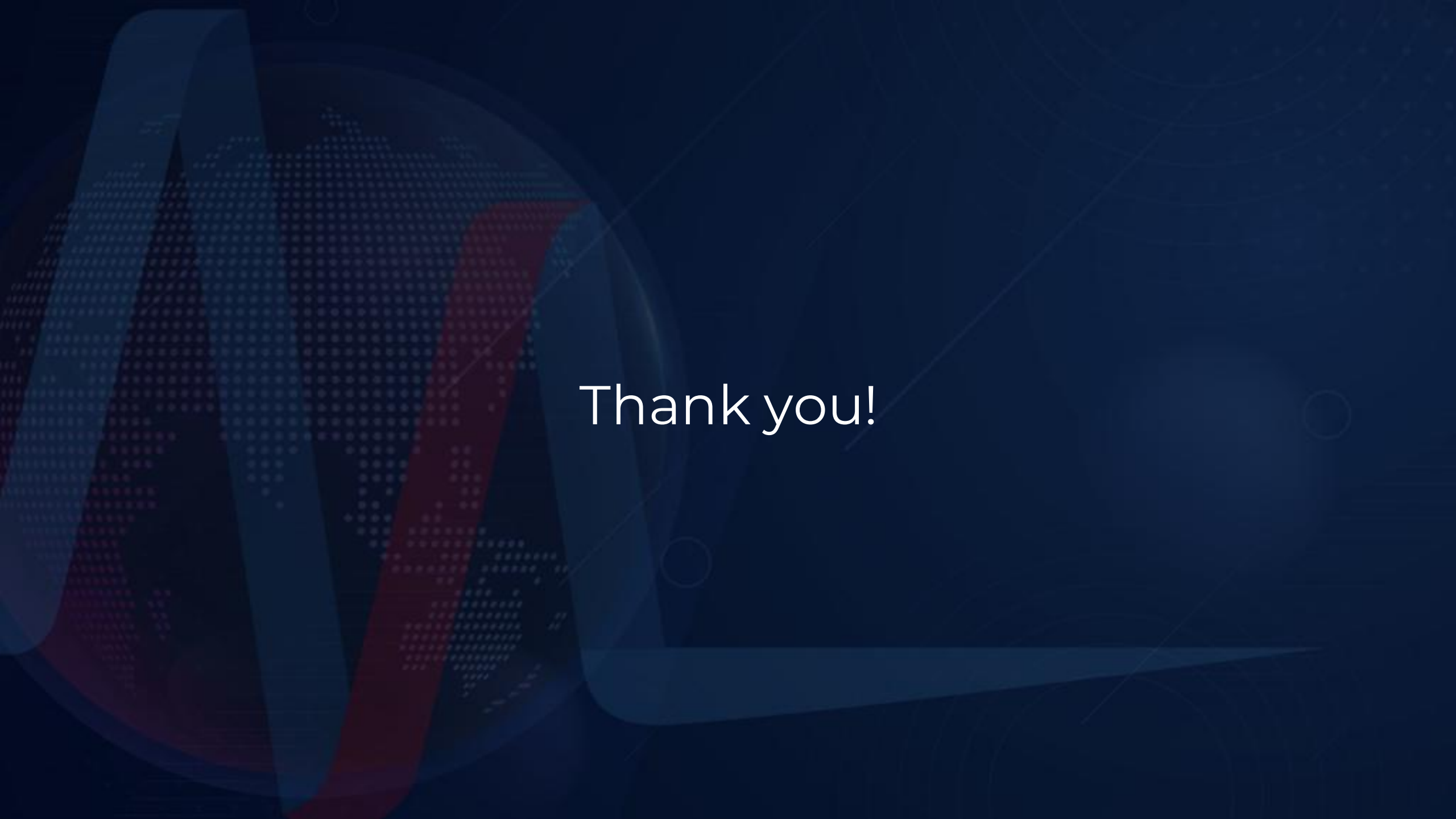
It would be a turning point of the insurance-coverage policies in Japan.

【CONS】# Effect of digital health on clinically important outcomes is still unclear. Larger clinical studies should be conducted.

The increasing amount of data would be burden on medical staffs. Data-analyzing services and/or the additional coverage of the additional burden will be welcomed.

Thank you for listening！

Closing remarks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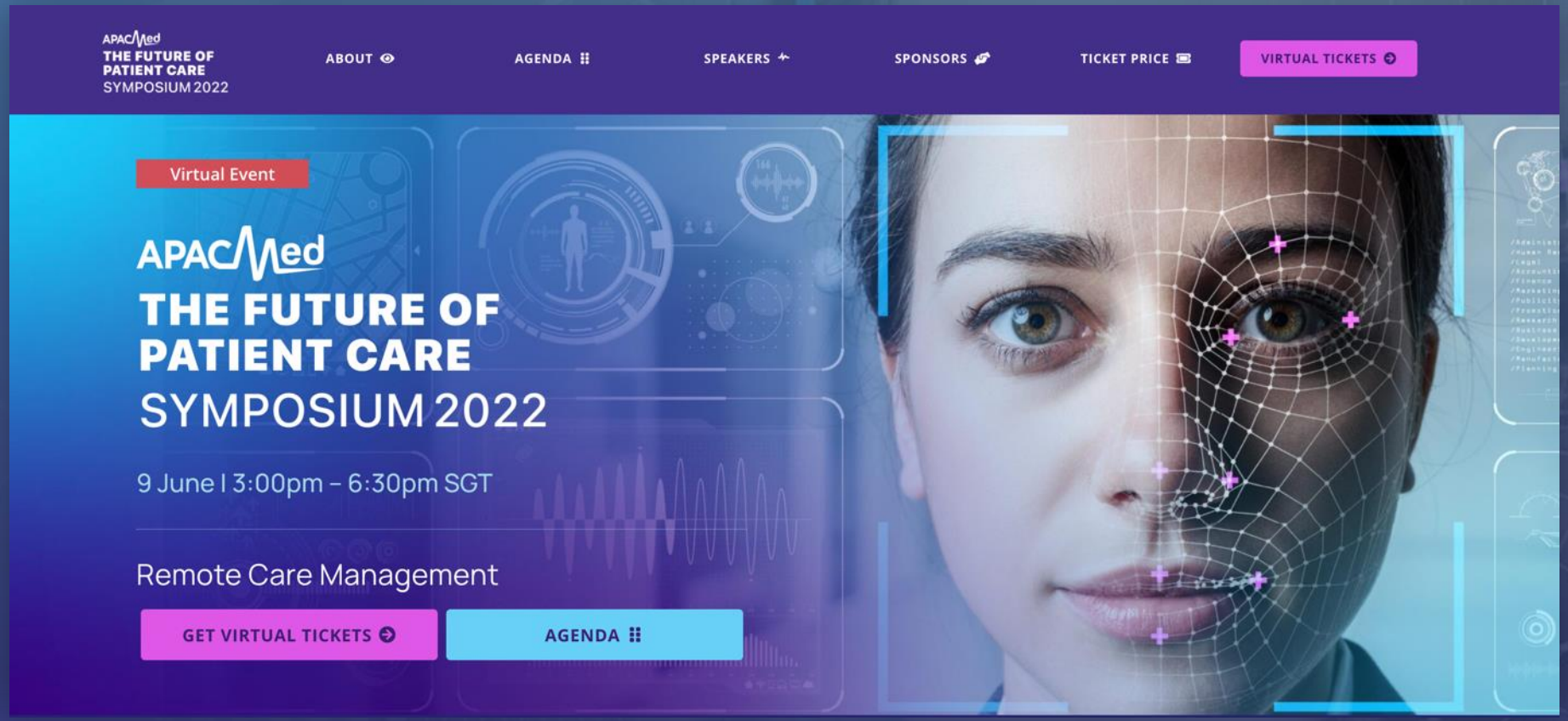

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