16th DIA Japan Annual Meeting 2019

- Delivering Rational Medicine for All People in the Globe -

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S15 Lessens from Experiences Using MidNet for PV

Overview of Utilization of MID-NET

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DIA

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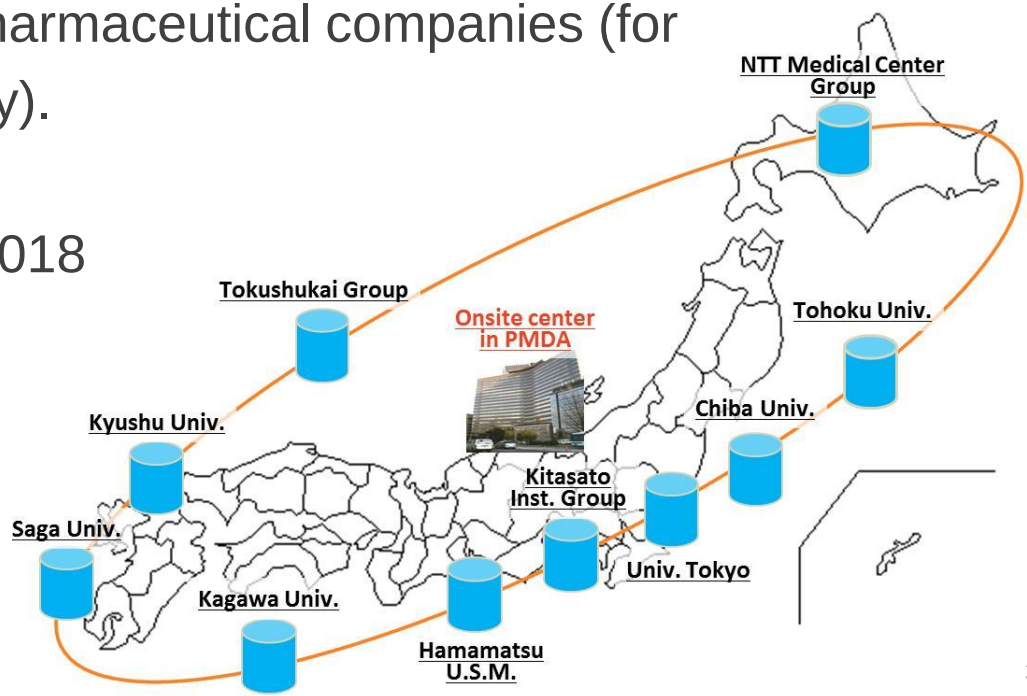
About MID-NET ® (1)

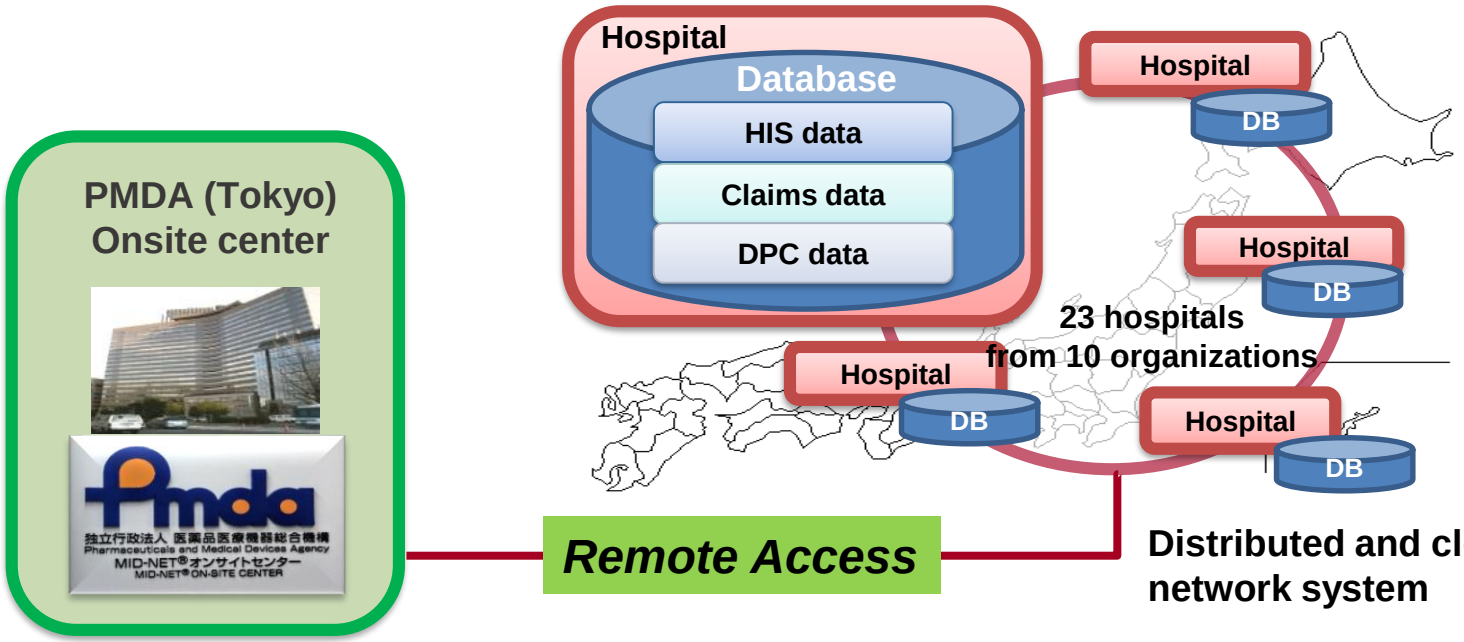
- The Medical Information Database Network (MID-NET) officially launched in April 2018 in Japan.
- PMDA takes responsibility for operation and management of MID-NET in compliance with MID-NET rules and the Ministerial Ordinance on GPSP.
- Aimed for the real-time assessment of drug safety by the government, academia and pharmaceutical companies (for post-marketing database study).
- 10 organizations(23 hospitals)
- 4.7 million patients in 2009 - 2018

MID-NET®
Medical Information Database Network



About MID-NET ® (2)

- Frequent update（every 1 week or 1~3Month）
- Including medical records, claims data and prospective payment data for acute inpatient
- Data codes are standardized across all hospitals (YJ, ICD-10, JLAC10 etc.)
- Laboratory test results are available
- The users can access the database from the onsite center in PMDA.



Available medical information data

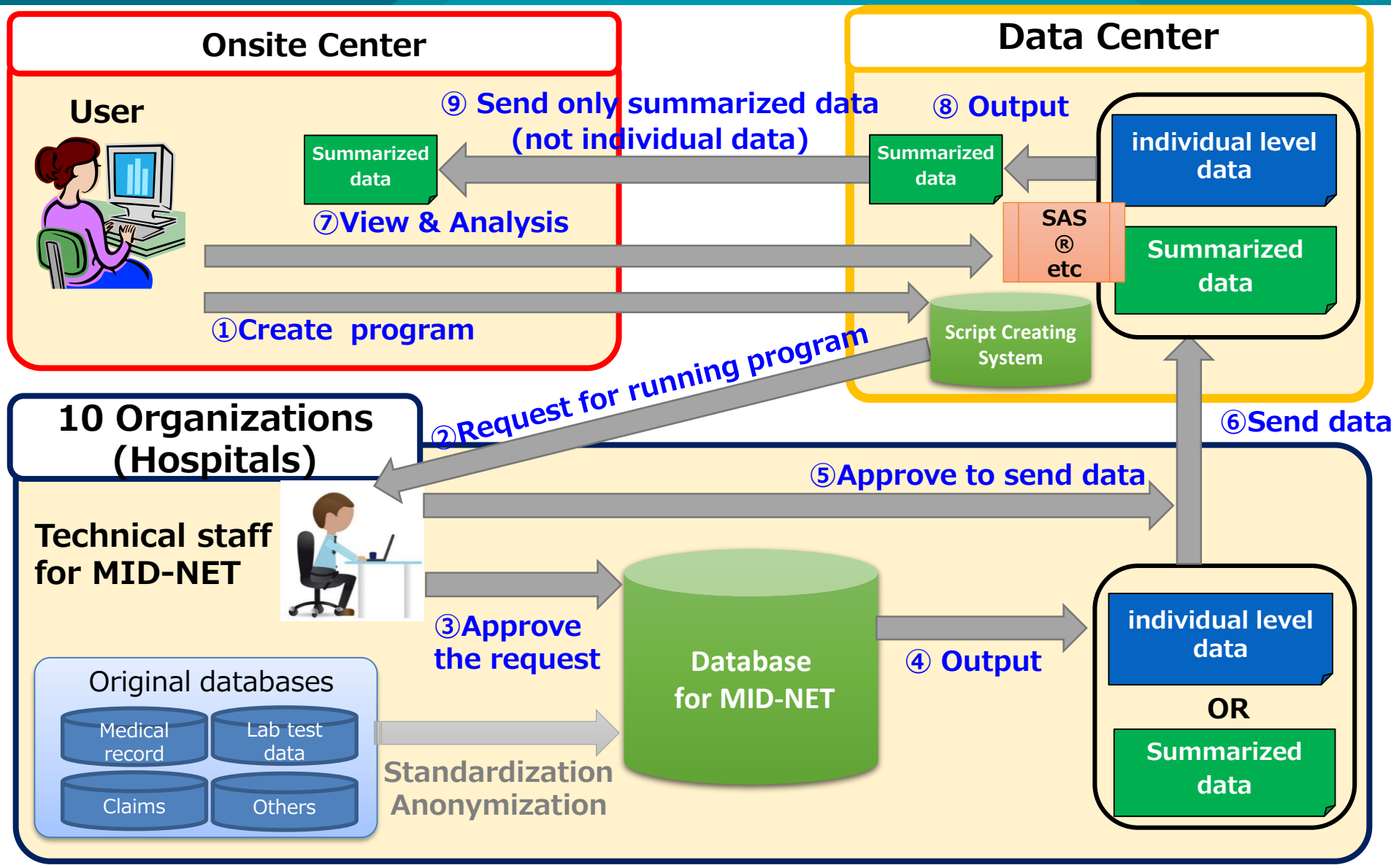
HIS Data

- Patient identifying data
- Medical examination history data (including admission and discharge)
- Disease order data
- Discharge summary data
- Prescription order/compiled data
- Injection order/compiled data
- **Laboratory test result data**
- Radiographic inspection data
- Physiological laboratory data
- Therapeutic drug monitoring data
- Bacteriological test data

Over 260 lab test results are available!

Fe	FT3	KL-6	CK-MB	Creatinine
K	FT4	LAP	CRP	folate
Ca	GOT(AST)	HbA1c	CYFRA	pH(blood)
Na	GPT(ALT)	PRP	EPO	pCO2
Mg	HBs (+/-)	T3	FSH	pO2
GLU	HBs (IU/ml)	T4	thrombocyte	IgA
ALP	HBs (CIO)	TPHA	monocyte	IgE
AMY	HB virus	TSH	lymphocyte	IgG
ALB	HC virus	TTT	acidocyte	IgM
LDL	hCG	ZTT	basocyte	myoglobin
HDL	hCG-β	γ-GTP	neutrophil	vitaminB12
LDH	PIV-KA-Ⅱ	TG	rheumatoid	hematocrit

Overview of the MID-NET® System

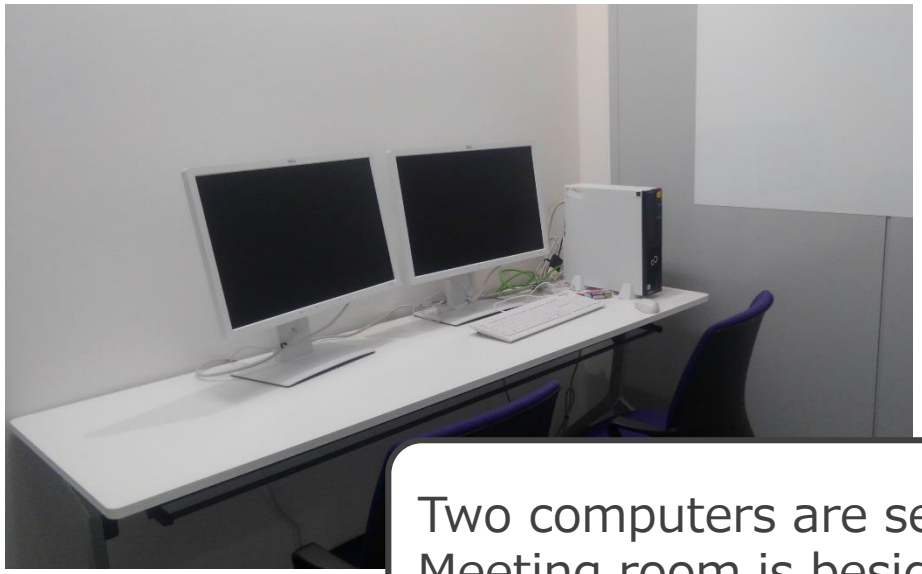


Onsite Center in PMDA

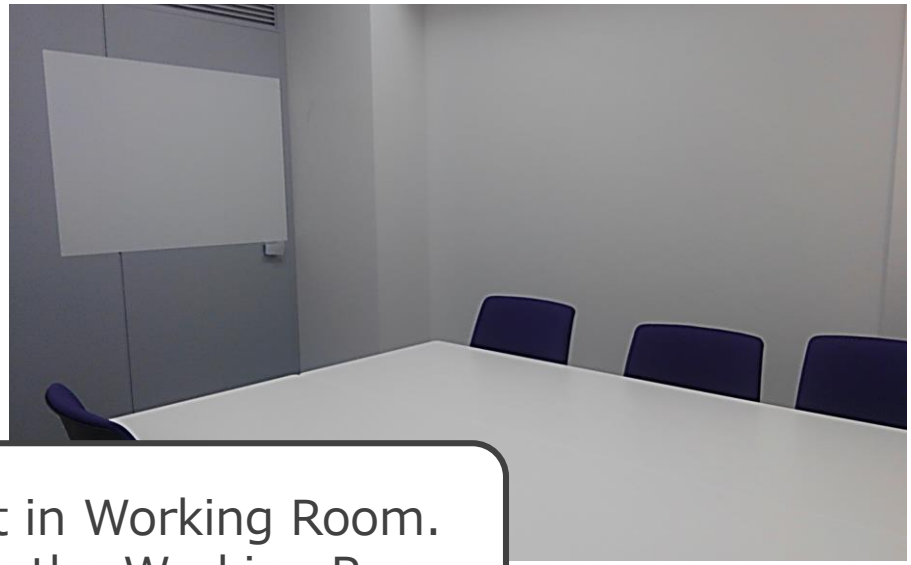
- Reception

IC cards for Working Room and Meeting Room will be rented to users who are properly identified in reception.

- Working Room (with security camera)

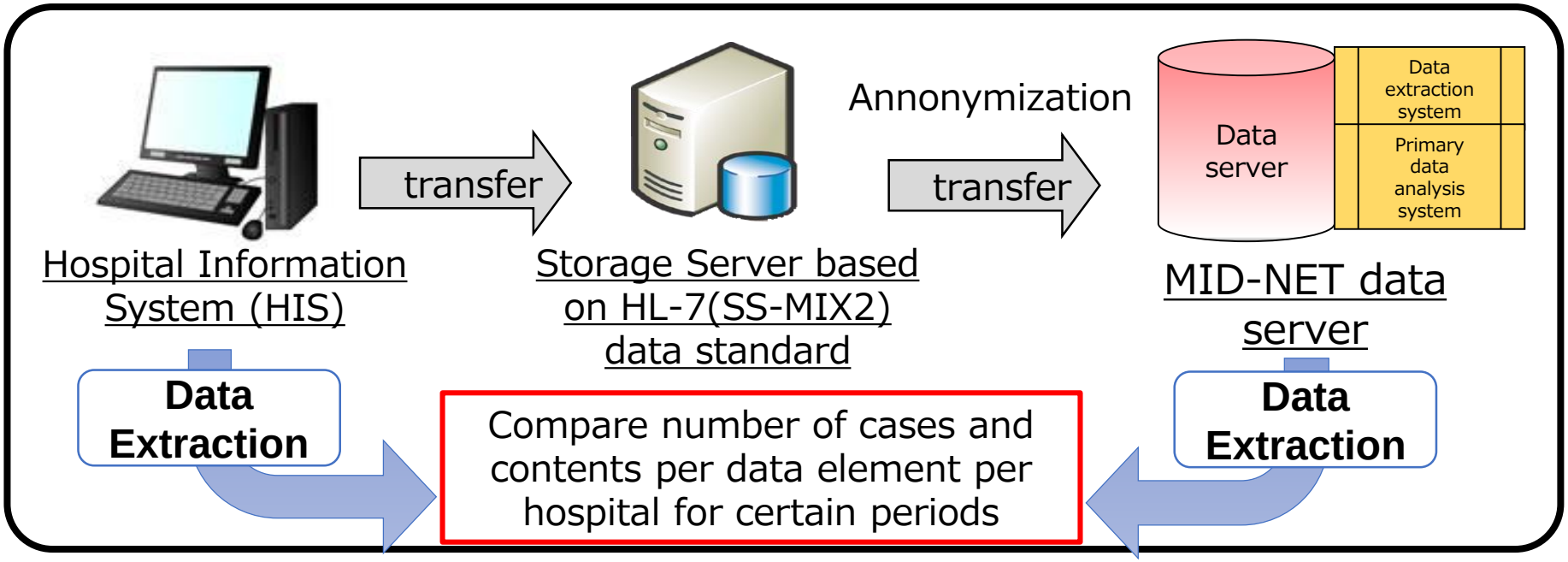


- Meeting Room



Two computers are set in Working Room.
Meeting room is beside the Working Room.

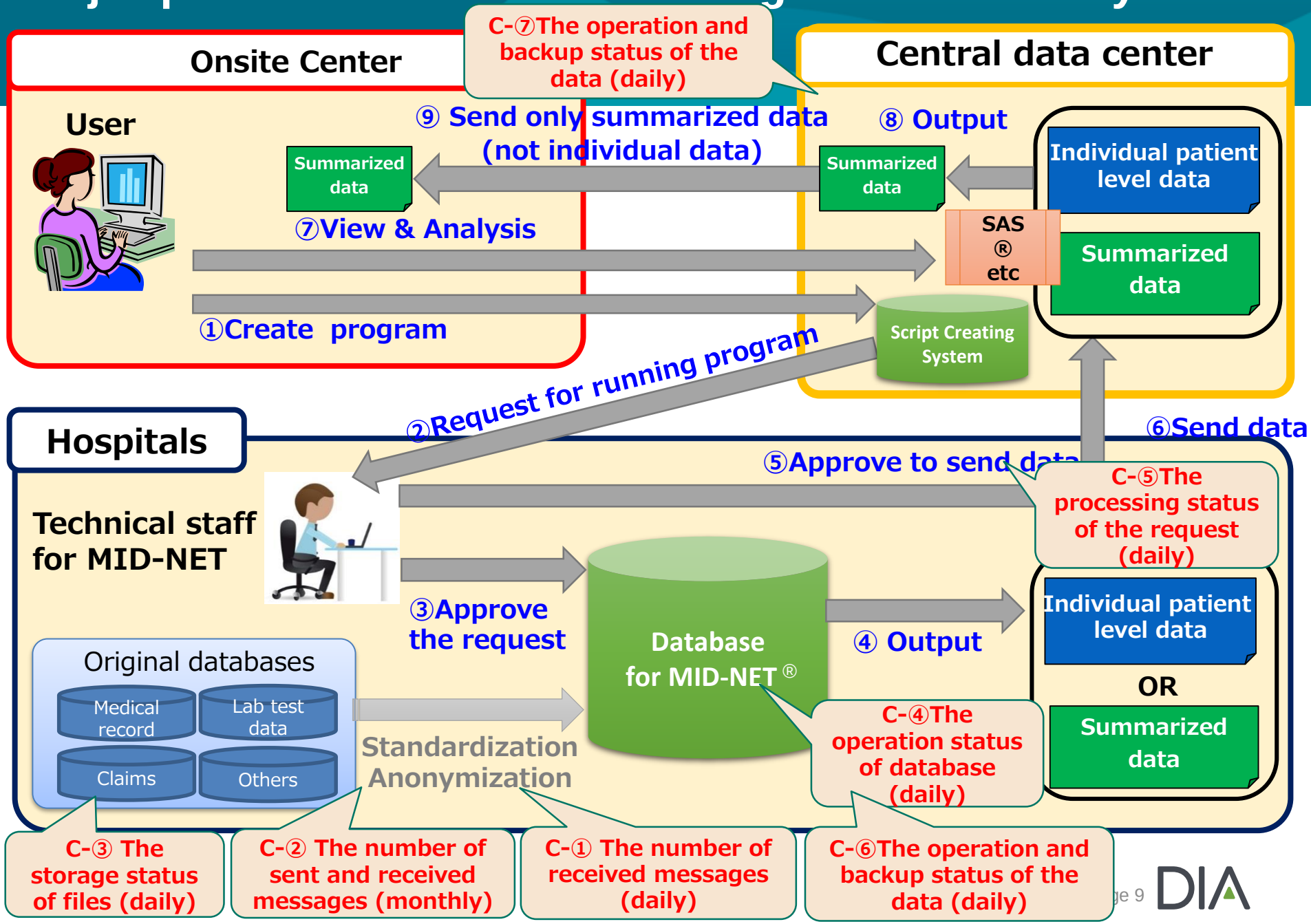
Data consistency verification



Examples of data inconsistency

- Lack of a unit
- Difference in a place of data storage among sites etc.
  e.g.; single dose, daily dose vs total dose

Major points of Routine Monitoring for Data and System



Data consistency in major data

	Diagnostic orders data	Prescription orders data	Injection orders data	Laboratory test data
Chiba University Hospital	100.00% (30,151/30,151)	100.00% (104,359/104,359)	100.00% (141,369/141,369)	100.00% (1,570,704/1,570,704)
Kyushu University Hospital	100.00% (40,314/40,314)	100.00% (128,629/128,629)	100.00% (148,506/148,506)	100.00% (1,135,766/1,135,766)
Tohoku University Hospital	100.00% (42,893/42,893)	100.00% (133,953/133,953)	100.00% (82,859/82,859)	100.00% (1,287,295/1,287,295)
Kishiwada Tokushukai Private Hospital	100.00% (25,801/25,801)	100.00% (61,039/61,039)	100.00% (62,975/62,975)	100.00% (654,823/654,823)
Shonan Fujisawa Tokushukai Private Hospital	100.00% (32,364/32,364)	100.00% (59,411/59,411)	100.00% (43,235/43,235)	100.00% (603,104/603,104)
The University of Tokyo Hospital	100.00% (27,439/27,439)	100.00% (177,077/177,077)	100.00% (21,3939/21,3939)	100.00% (1,729,693/1,729,693)

After the quality management, almost 100% consistency between the original data in the hospital and the data stored in MID-NET® was confirmed

Yamaguchi, M. et al. Pharmacoepidemiol Drug Saf. 2019 Aug 29. doi: 10.1002/pds.4879

Data standardization – Lab test –

Before

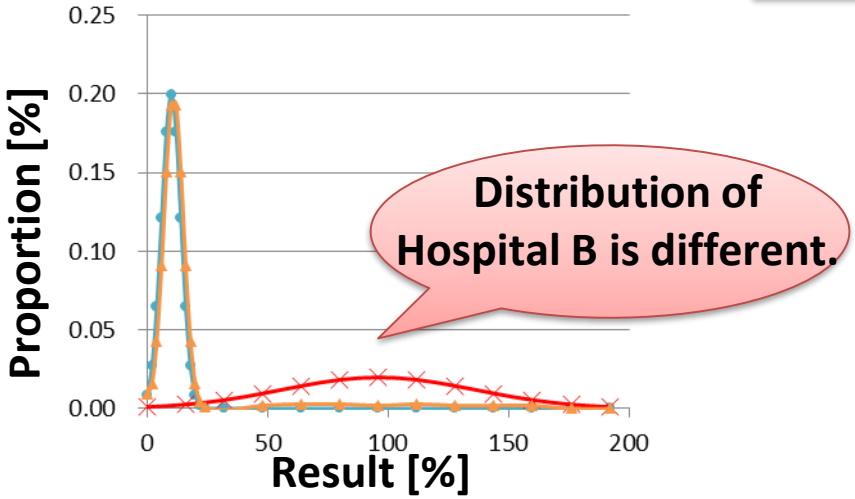
	PtntID	Result	Unit
Hospital A	001	3.3	%
	002	8.5	%
	003	5.4	%
Hospital B	201	54	%
	202	112	%
	203	85	%
Hospital C	301	1.3	%
	302	3.8	%
	303	7.5	%

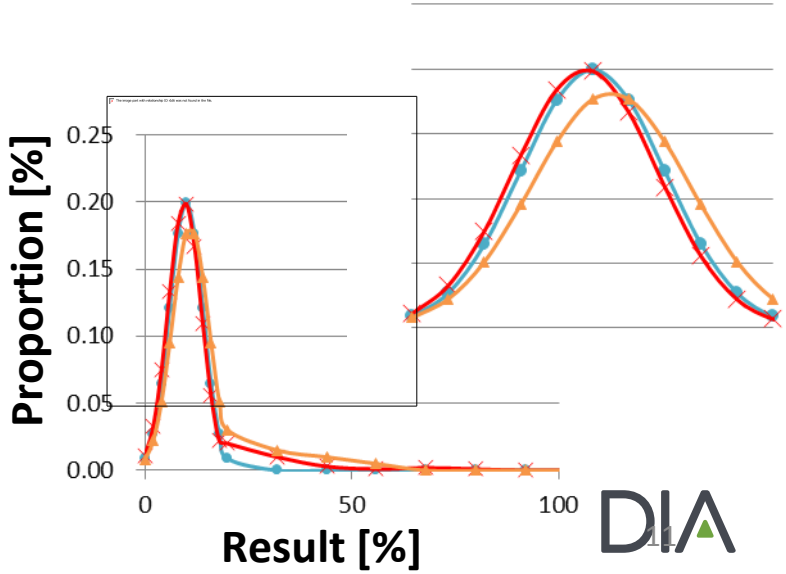
Quality control management

After

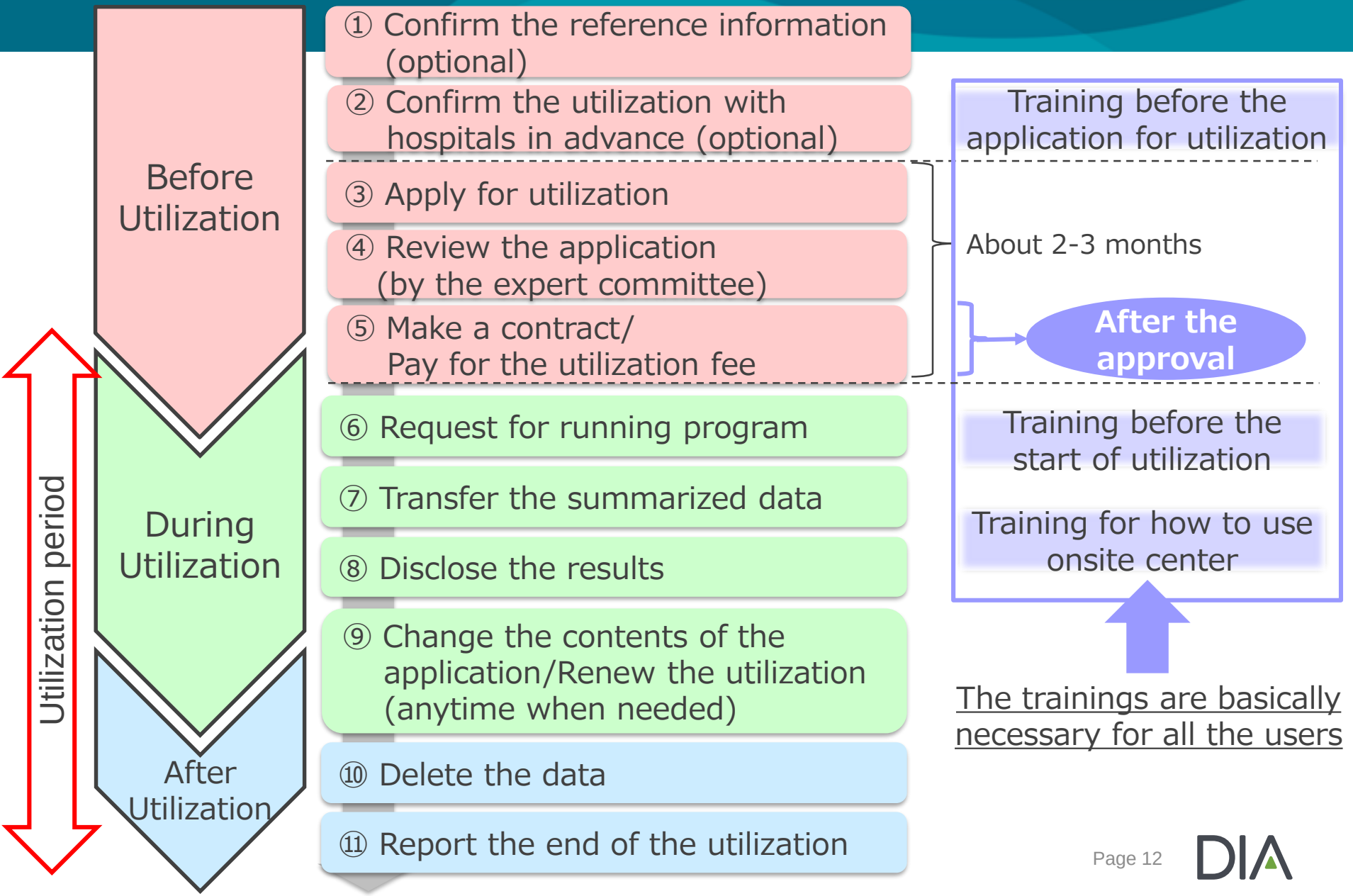
	PtntID	Result	Unit
Hospital A	001	3.3	%
	002	8.5	%
	003	5.4	%
Hospital B	201	54	‰
	202	112	‰
	203	85	‰
Hospital C	301	1.3	%
	302	3.8	%
	303	7.5	%

Data distribution

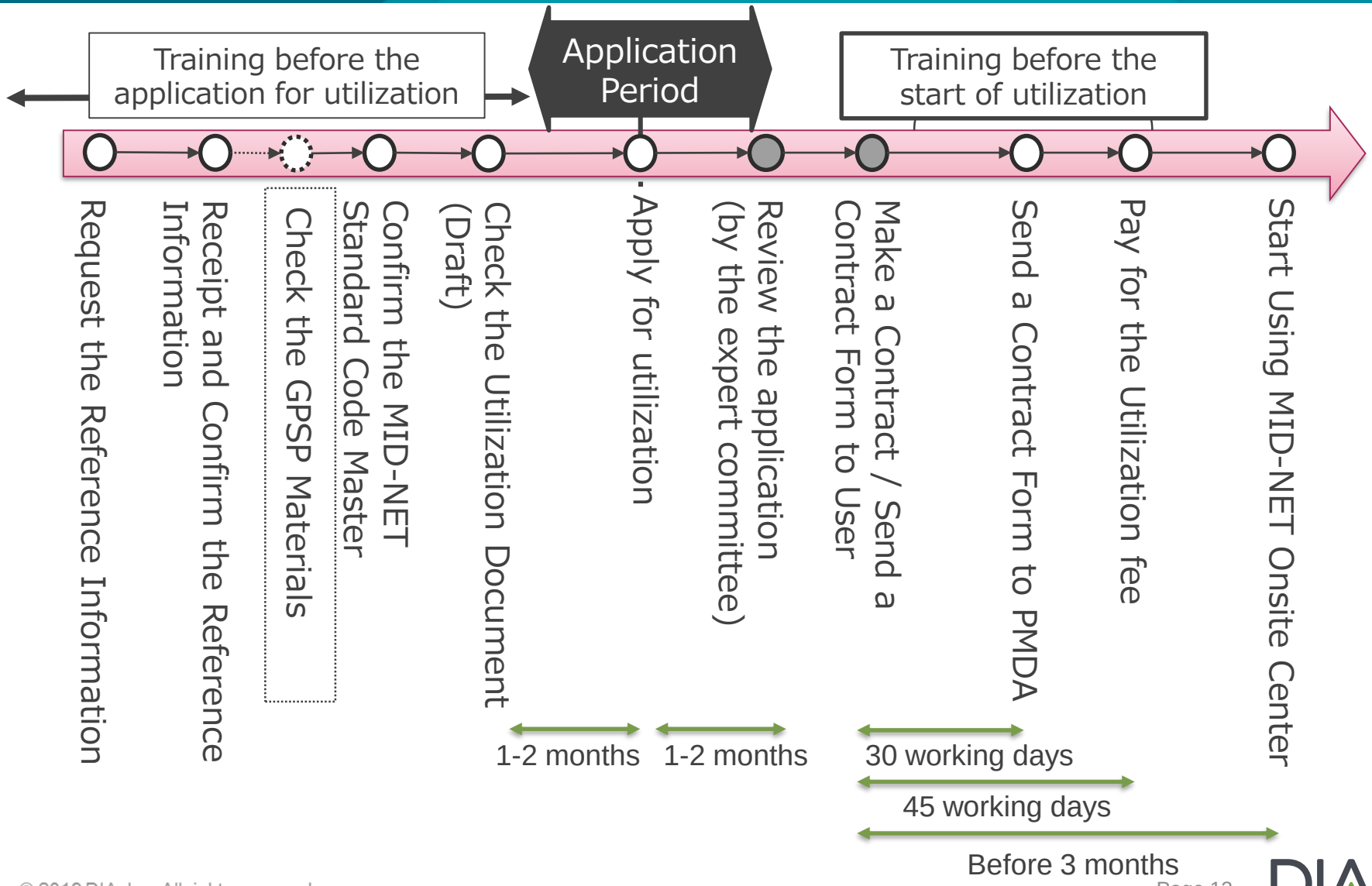




The flow chart of utilization



Time Schedule for MID-NET Utilization



Making a Code List

◆【Ex】Standard MID-NET Code Master（Disease（Basic））

病名管理番号	変更区分	病名表記	病名表記カナ	採択区分	病名交換用コード	ICD10-2013コード	ICD10-2013複数分類コード	予備項目1	予備項目2	レセ電算コード	傷病名省略名称	使用分野	変更履歴番号	更新日	移行先病名管理番号	単独使用禁止区分	保険請求外区分
01234567	0	△△出血	△△シュッケツ	0	AAAA	A123	D987			1234567	△△出血	1	999			00	0
12345678	1	□アレルギー	□アレルギー	1	BBBB	B456	E876			2345678	□アレルギー	2	888	20201110	88888888	01	0
23456789	2	○×低下症	○×テイカショウ	2	CCCC	C789				3456789	○×低下症	3	777	19990513		00	1

◆【Ex】MID-NET Master for Making Code List（Disease（Basic））

病名管理番号	病名表記	病名交換用コード	ICD10-2013コード	ICD10-2013複数分類コード	レセ電算コード
01234567	△△出血	AAAA	A123	D987	1234567
12345678	□アレルギー	BBBB	B456	E876	2345678
23456789	○×低下症	CCCC	C789		3456789

調査・研究計画書案の標題		
利活用番号		
抽出対象となるデータの期間	自（年月日）	
	至（年月日）	

利用するテーブル名	抽出・出力別	分類等（自由入力）	利用するコード体系	条件設定するコード	コード名が指すもの
（例）検体検査情報	（例）抽出条件	（例）肝機能検査	（例）JLAC10コード	（例）3A015000002327101	（例）アルブミン

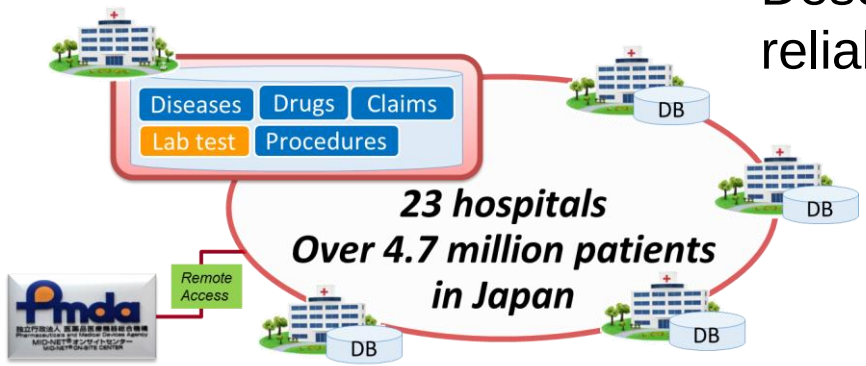
Scientific publication of MID-NET®

ORIGINAL REPORT

Establishment of the MID-NET® medical information database network as a reliable and valuable database for drug safety assessments in Japan

Yamaguchi M. et al. Pharmacoepidemiol Drug Saf. 2019 10.1002/pds.4879

Describing how to ensure the reliability of the database



The utilization and challenges of Japan's MID-NET® medical information database network in postmarketing drug safety assessments: A summary of pilot pharmacoepidemiological studies

Describing pilot studies and applicability of the database for drug safety assessment

Yamada, K. et al. Pharmacoepidemiol Drug Saf 28, 601-8 (2019). 10.1002/pds.4777

The Current Status of the utilization

■ Approved studies for MID-NET use (by Sep 2019)

➢ Utilization for safety assessment by PMDA : 35 studies

- ✓ Influence of hepatitis C therapeutics on blood coagulation in patients taking warfarin (12 studies)
- ✓ Risk of thrombocytopenia in patients with prescription of G-CSF(granulocyte colony-stimulating factor) formulations (4 studies)
- ✓ Detection for the abnormal value on renal functional test in patients taking direct-acting antivirals for hepatitis C (11 studies)
- ✓ Methodological consideration for the risk assessment of drug-induced hepatic impairment (6 studies).
- ✓ Implementation status of laboratory tests relate to the granulocytepenia associated with thiamazole (1study)
- ✓ Risk factors for the granulocytepenia associated with thiamazole (1study)

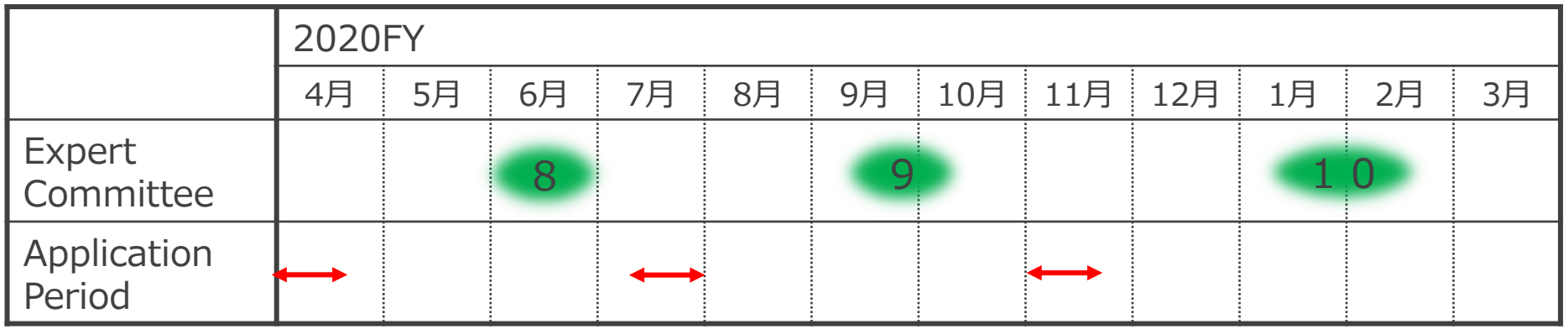
➢ Post-marketing DB study by MAH : 3 products

- ✓ IBRANCE Capsules
- ✓ PRALIA Subcutaneous Injection 60 mg Syringe
- ✓ ATOZET Combination Tablet

➢ Other : 2 studies

- ✓ Characterization of MID-NET data focusing on patients using oral anticoagulant.
- ✓ Implementation status of the test on hepatitis B virus infection prior to prescribing drugs for chronic hepatitis C, including ERELSA Tablets 50mg and GRAZYNA Tablets 50mg(EBR + GZR)

Application Period for Using MID-NET



Expert Committee	Application Period	Training before the Application
No. 8	2020/4/1 (Wed) ～ 2020/4/17 (Fri)	Feb 2020
No. 9	2020/7/13 (Mon) ～ 2020/7/31 (Fri)	May 2020
No. 10	2020/11/2 (Mon) ～2020/11/20 (Fri)	Sep 2020

MID-NET Symposium 2020

MID-NETシンポジウム～現状と今後の展開～

- 日時：2020年1月22日（水）
- 場所：日本消防会館（ニッショーホール）
- プログラム（案）：
  - 基調講演
  - 第1部：MID-NET®本格運用後の状況
  - 第2部：MID-NET®関連の研究班の取り組み
  - 第3部：MID-NET®の将来構想と関連事業
    - 詳細が決まり次第、下記HPで更新していきます。
      https://www.pmda.go.jp/safety/symposia/0013.html
- 参加申し込みは、11月以降に案内予定

MID-NET®
Medical Information Database Network

PMDA web site

https://www.pmda.go.jp/
https://www.pmda.go.jp/safety/mid-net/0001.html

Contact Address

wakaru-midnet@pmda.go.jp

Thank you very much for your kind attention!

DIA