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Standardized Item Sets for NCDs Established by Japanese Clinical Associations and Linking to the CDISC SDTM v3.4

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13:55 - 14:20

STANDARDIZED ITEM SETS FOR NCDS ESTABLISHED BY JAPANESE CLINICAL ASSOCIATIONS AND LINKING TO THE CDISC SDTM V3.4

NAOKI NAKASHIMA, KYUSHU UNIVERSITY

- CDISC is excited to announce the publication of our latest collaborative research project with the Japanese Collaborative Committee for Clinical Informatization in Diabetes Mellitus: "Linking Collaborative Committee Clinical for Informatization in Diabetes Mellitus (CCCIDM) Self-managed Item Sets (SMIS) to the CDISC Study Data Tabulation Model (SDTM) V3.4."
- This project has been instrumental in understanding the needs of Japanese researchers and identifying areas for new standards development. It also marks a significant step forward in our ongoing collaboration with researchers in Japan to advance clinical research standards globally.
- Special thanks to all our partners, including the Japanese Collaborative Committee for Clinical Informatization in Diabetes Mellitus, the Japan Diabetes Society, and the Japan Association for Medical Informatics for their invaluable contributions to this important work. The findings from this project will help to streamline the integration of diabetes and chronic disease management data into global research standards, fostering innovation and improving patient outcomes.

COI Disclosure Information

Naoki Nakashima

I have the following financial relationships to disclose.

Leadership position/advisory role for: No

Stockholder in: Carna Health Support Co.

Patents and royalties from: No

Honoraria（lecture fee) from: No

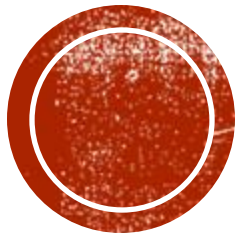
Honoraria(manuscript fee) from: No

Grant/Research funding from: AMED、JSPS、MHLW

Other remuneration from: Joint Researches with Fujitsu、Pfyzer、Janssen

TALKS TODAY

1. **Introduction** of Japanese Standardized Data Item Sets for NCDs
2. Collaboration with **CDISC** to Link the Data Item sets with SDTM(v3.4)
3. Use Cases of Data Item Sets (**What the merits** to establish clinical data item sets)
   - **Clinical Practice**
   - **Clinical Research**
   - **Global Health**



Establishment of Standardized Minimum Data Sets for NCDs

(Diabetes, Hypertension, Dyslipidemia, CKD)

To Standardize Important Items of NCDs for Clinical Practice, Research, and Education in Digital Era **Since 2011**

➢ **9** clinical societies

- ✓ Japan Diabetes Society
- ✓ Japan Arteriosclerosis Society
- ✓ Japanese Society of Nephrology
- ✓ Japanese Society of Hypertension
- ✓ Japanese Society of Laboratory Medicine
- ✓ Japan Association of Medical Informatics
- ✓ Japan Society for the Study of Obesity
- ✓ Japanese Society of Ophthalmic Diabetology
- ✓ Japan Association for Diabetes Education and Care

Formulation & maintenance

➢ **4** diseases

- ✓ Daiabetes
- ✓ Hypertension
- ✓ Dyslipidemia
- ✓ CKD

➢ **2** types of item sets

- ✓ Core item sets
- ✓ Self-management Data item sets(**SMDIS**)

➢ **1** **PHR** recommended settings

- ✓ Based on **SMDIS**

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Background

Self-Management Data Item Sets for Non Communicable Diseases (SMDIS)

Colored Background:
Core Item Sets

Marked by circle (○): **SMDIS**

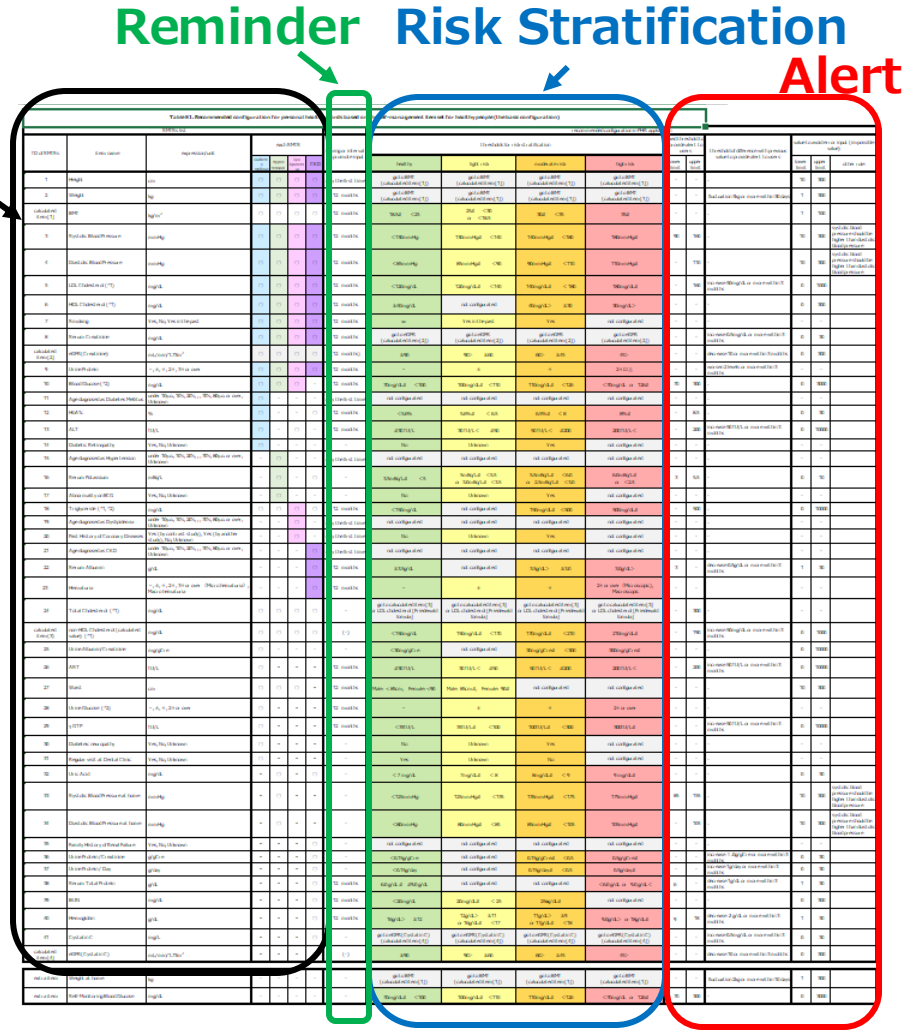
ID of SMIS	Item	Unit, expression	SMIS for Diabetes Mellitus			SMIS for Hypertension			SMIS for Dyslipidemia			SMIS for CKD		
			from Medical	from health chekcup	from home	from Medical	from health check-up	from home	from Medical	from health check-up	from home	from Medical	from health check-up	from home
1	Height	cm	○	○		○	○		○	○		○	○	
2	Weight	kg	○	○		○	○		○	○		○	○	
3	Systolic Blood Pressure	mmHg	○	○		○	○		○	○		○	○	
4	Diastolic Blood Pressure	mmHg	○	○		○	○		○	○		○	○	
5	LDL Cholesterol	mg/dL	○	○		○	○		○	○		○	○	
6	HDL Cholesterol	mg/dL	○	○		○	○		○	○		○	○	
7	Smoking	Yes, No, Yes in the past	○	○		○	○		○	○		○	○	
8	Serum Creatinine	mg/dL	○			○			○			○		
9	Urine Protein	−, ±, +, 2+, 3+or over	○	○		○	○		○	○		○	○	
10	Blood Glucose	mg/dL	○	○		○	○		○	○				
11	Age diagnosed as Diabetes Mellitus	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, Not yet, Unknown	○											
12	HbA1c	%	○	○								○	○	
13	ALT	IU/L	○	○					○	○				
14	Diabetic Retinopathy	Yes, No, Unknown	○											
15	Age diagnosed as Hypertension	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, No, Unknown				○								
16	Serum Potassium	mEq/L				○						○		
17	Abnormality on ECG	Yes, No, Unknown				○								
18	Triglyceride	mg/dL	○	○		○	○		○	○		○	○	
19	Age diagnosed as Dyslipidemia	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, No, Unknown							○					
20	Past History of Coronary Diseases	Yes (by contrast study), Yes (by another study), No, Unknown							○					
21	Age diagnosed as CKD	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, No, Unknown										○		
22	Serum Albumin	g/dL										○	○	
23	Hematuria	−, ±, +, 2+, 3+or over （Micro hematuria）, Macro hematuria										○	○	
24	Total Cholesterol	mg/dL	○			○			○			○		
25	Urine Albumin/Creatinine	mg/gCre	○											
26	AST	IU/L	○	○										
27	Waist	cm		○			○			○				
28	Urine Glucose	−, ±, +, 2+or over	○	○										
29	γ GTP	IU/L	○	○										
30	Diabetic neuropathy	Yes, No, Unknown	○											
31	Regular visit at Dental Clinic (*1)	Yes, No, Unknown	○											
32	Uric Acid	mg/dL				○						○	○	
33	Systolic Blood Pressure at home	mmHg						○						
34	Diastolic Blood Pressure at home	mmHg						○						
35	Family History of Renal Failure(*2)	Yes, No, Unknown										○		
36	Urine Protein /Creatinine	g/gCre										○	○	
37	Urine Protein / Day	g/day										○	○	
38	Serum Total Protein	g/dL										○	○	
39	BUN	mg/dL										○		
40	Hemoglobin	g/dL										○	○	
41	Cystatin C	mg/L										○		

CIS for Diabetes Mellitus　CIS for Hypertension　CIS for Dyslipidemia　CIS for CKD

Naoki Nakashima, et al., Journal of Diabetes Investigation, 10:868, 2019.

RECOMMENDED CONFIGURATION FOR **PHR** ON SELF-MANAGEMENT DATA ITEM SET FOR NCD

SMDIS



Sheet for Non-Affected Subjects (Healthy～Pre-diseases)

- Risk classification threshold(stratifica
- Alert threshold using fixed values
- Alert threshold by difference with previous values
- Alert threshold to prevent incorrect inputs
- Period for sending reminders

Naoki Nakashima, et al., Journal of Diabetes Investigation, 10:868–875, 2019.

Naoki Nakashima, et al. Diabetology International, 10:85–92, 2019.

Background

Remainder and Threshold for Alert Setting Determined Along with International Guidelines

Table S1. Recommended configuration for personal health records based on the self-management item set for healthy people (the basic configuration)

SMISs list							recommended configuration in PHR application									
ID of SMISs	item name	expression/unit	each SMIS				timing or interval to promote input	thresholds for risk stratification				fixed threshold to provide alert to users		threshold of difference with previous value to provide alert to users	value to avoid error input (impossible value)		
			Diabetes Mellitus	Hyper-tension	Dys-lipidemia	CKD		healthy	light risk	moderate risk	high risk	lower limit	upper limit		lower limit	upper limit	other rule
1	Height	cm	○	○	○	○	only the first time	go to BMI (calculated item[1])	go to BMI (calculated item[1])	go to BMI (calculated item[1])	go to BMI (calculated item[1])	-	-	-	10	300	
2	Weight	kg	○	○	○	○	12 months	go to BMI (calculated item[1])	go to BMI (calculated item[1])	go to BMI (calculated item[1])	go to BMI (calculated item[1])	-	-	fluctuation 3kg or more within 30 days	1	300	
calculated item[1]	BMI	kg/m^2	○	○	○	○	12 months	18.5≦ <25	25≦ <30 or <18.5	30≦ <35	35≦	-	-	-	1	100	
3	Systolic Blood Pressure	mmHg	○	○	○	○	12 months	<130mmHg	130mmHg≦ <140	140mmHg≦ <180	180mmHg≦	90	160	-	10	300	systolic blood pressure should be higher than diastolic blood pressure
4	Diastolic Blood Pressure	mmHg	○	○	○	○	12 months	<85mmHg	85mmHg≦ <90	90mmHg≦ <110	110mmHg≦	-	110	-	10	300	systolic blood pressure should be higher than diastolic blood pressure
5	LDL Cholesterol (*1)	mg/dL	○	○	○	○	12 months	<120mg/dL	120mg/dL≦ <140	140mg/dL≦ < 180	180mg/dL≦	-	160	increase 50mg/dL or more within 3 mohths	0	1000	
6	HDL Cholesterol (*1)	mg/dL	○	○	○	○	12 months	≧40mg/dL	not configurated	40mg/dL> ≧30	30mg/dL>	-	-	-	0	300	
7	Smoking	Yes, No, Yes in the past	○	○	○	○	12 months	No	Yes in the past	Yes	not configurated	-	-	-	-	-	
8	Serum Creatinine	mg/dL	○	○	○	○	12 months	go to eGFR (calculated item[2])	go to eGFR (calculated item[2])	go to eGFR (calculated item[2])	go to eGFR (calculated item[2])	-	-	increase 0.5mg/dL or more within 3 mohths	0	30	
calculated item[2]	eGFR(Creatinine)	$mL/min/1.73m^2$	○	○	○	○	(12 months)	≧90	90> ≧60	60> ≧45	45>	-	-	decrease 10 or more within 3 mohths	0	300	
9	Urine Protein	−, ±, +, 2+, 3+or over	○	○	○	○	12 months	−	±	+	2+以上	-	-	worsen 2 levels or more within 3 mohths	-	-	
10	Blood Glucose (*2)	mg/dL	○	○	○	-	12 months	70mg/dL≦ <100	100mg/dL≦ <110	110mg/dL≦ <126	<70mg/dL or 126≦	70	300	-	0	3000	
11	Age diagnosed as Diabetes Mellitus	under 10y.o., 10's, 20's, , , 70's, 80y.o. or over, Unknown	○	-	-	-	only the first time	not configurated	not configurated	not configurated	not configurated	-	-	-	-	-	
12	HbA1c	%	○	-	-	○	12 months	<5.6%	5.6%≦ < 6.5	6.5%≦ < 8	8%≦	-	8.5	-	0	30	

SMDIS

Reminder period

Threshold for risk stratification

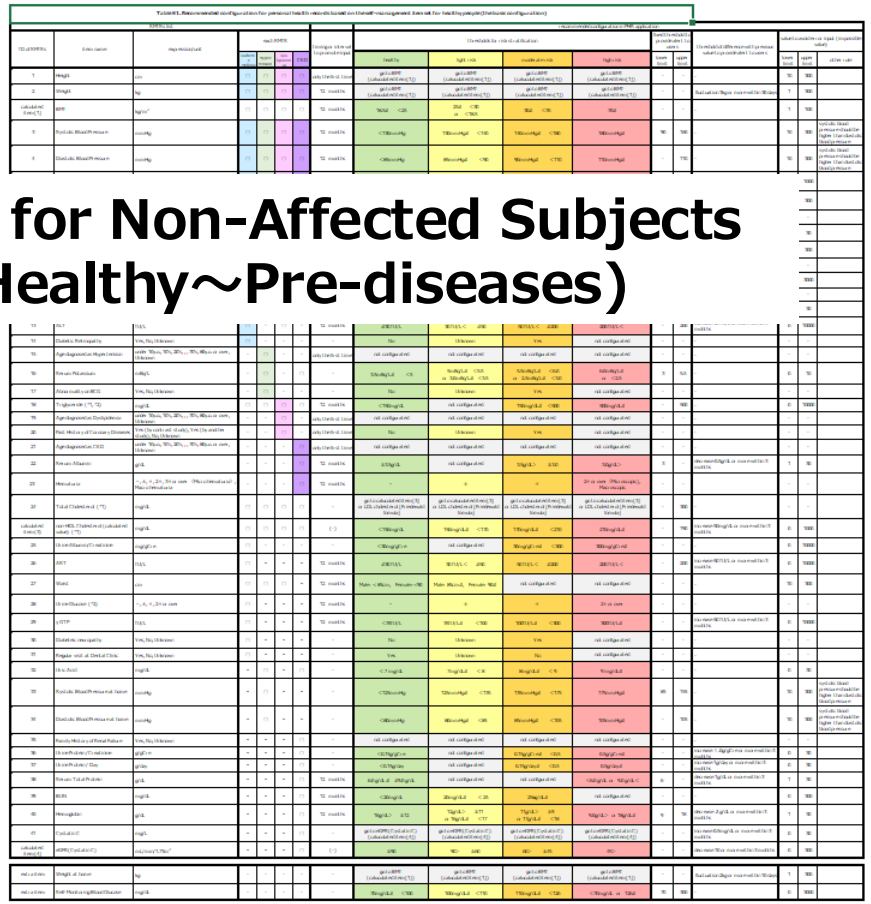
Alert threshold using fixed values

Alert threshold based on difference from the previous value

Threshold to prevent incorrect inputs

Naoki Nakashima, et al., Journal of Diabetes Investigation, 10:868, 2019.

RECOMMENDED CONFIGURATION FOR **PHR** ON SELF-MANAGEMENT DATA ITEM SET FOR NCD



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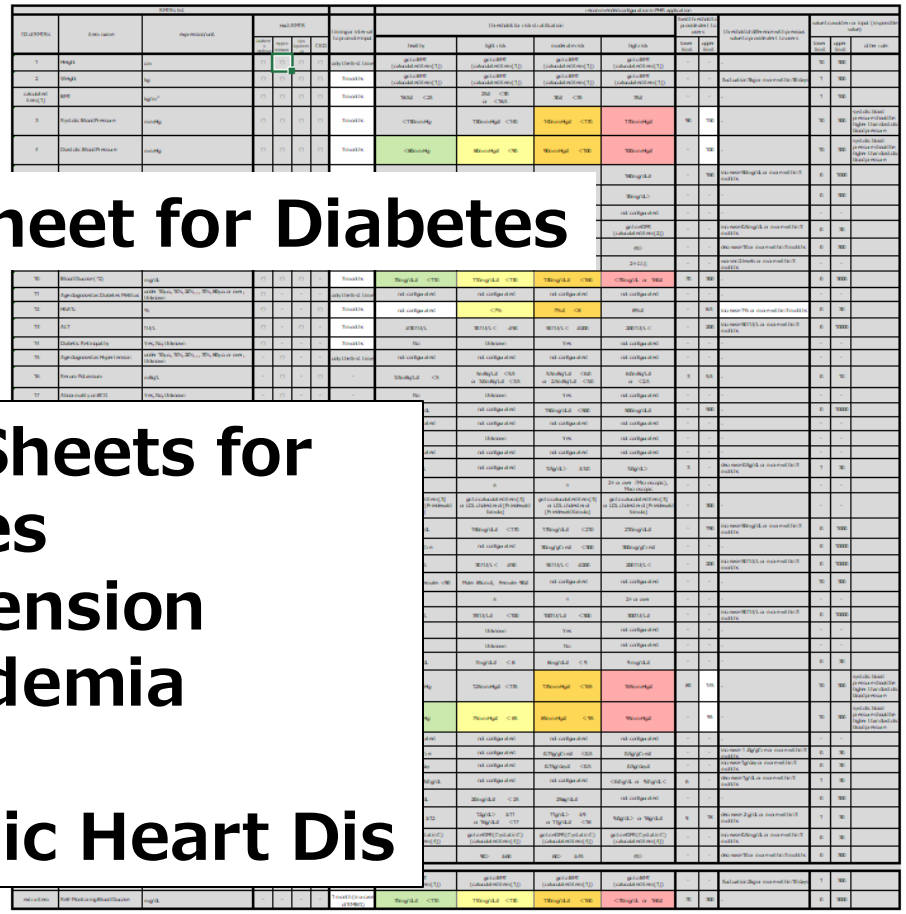
Background

RECOMMENDED CONFIGURATION FOR **PHR** ON SELF-MANAGEMENT DATA ITEM SET FOR NCD



Option Sheet for Diabetes

Option Sheets for
- **Diabetes**
- **Hypertension**
- **Dyslipidemia**
- **CKD**
- **Ischemic Heart Dis**

- Risk classification threshold
- Alert threshold using fixed values
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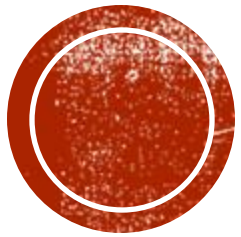


Mapping of the Data Item Sets to CDISC Standards

CDISC: Clinical Data Interchange Standards Consortium

Collaboration with CDISC “Purpose”

- **Since January 2022**
- To understand the needs of Japanese researchers, to inform areas for new standards development to advance clinical research, and to expand collaboration between researchers in Japan and CDISC.
- Focusing on reviewing the diabetes mellitus and associated chronic diseases Self-Management Data Item Sets (SMDIS) identified by Japanese 9 Clinical Societies and to assess **how it can be mapped to existing CDISC standards**.

Collaboration with CDISC ”Methods”

- The project scope was to review the 43 items from the combined SMDISs from diabetes mellitus, hypertension, dyslipidemia, and chronic kidney disease (CKD), assess how they map to existing CDISC Foundational Standards (i.e., Study Data Tabulation Model Implementation Guide (SDTMIG) v 3.42 and controlled terminology, and to identify the gaps. In addition, related Therapeutic Area User Guides (TAUGs) are utilized.

TAUGs

- Diabetes Therapeutic Area User Guide v1.04
- Diabetes Type 1 Therapeutic Area User Guide - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes5
- Diabetic Kidney Disease Therapeutic Area User Guide v1.06
- Dyslipidemia Therapeutic Area User Guide v1.07
- Polycystic Kidney Disease (PKD) Therapeutic Area User Guide v1.08

- To ensure completeness of assessment, keyword searches for the 43 concepts were performed in CDISC’s Examples Collection9 and the CDISC wiki10 as additional resources.

Collaboration with CDISC ”Results”

- Each of the **SMDIS items (total 43)** were searched in the available CDISC Biomedical Concepts.
- **32 were available** (matched) without problems.
- **11 Gaps were defined** as SMDIS items for which no SDTM example was found in the above resources, and/or for which the SDTM modeling strategy would **require further discussion**.

White Paper was published from CDISC in June, 2024

https://www.cdisc.org/news/linking-collaborative-committee-clinical-informatization-diabetes-mellitus-cccidm-self-managed-item-sets-smis-cdisc-study-data-tabulation-model-sdtm-v3-4

LINKING COLLABORATIVE COMMITTEE CLINICAL FOR INFORMATIZATION IN DIABETES MELLITUS (CCCIDM) SELF-MANAGED ITEM SETS (SMIS) TO THE CDISC STUDY DATA TABULATION MODEL (SDTM) V3.4

Linking Collaborative Committee of Clinical Informatization in Diabetes Mellitus (CCCIDM) Self-Managed Item Sets (SMIS) to the CDISC Study Data Tabulation Model v3.4 (SDTM)

Purpose

The purpose of this project was to understand the needs of Japanese researchers, to inform areas for new standards development to advance clinical research, and to expand collaboration between researchers in Japan and CDISC. This project was focused on reviewing the diabetes mellitus and associated chronic diseases Self-Management Item Sets (SMIS) identified by the Japanese Collaborative Committee for Clinical Informatization in Diabetes Mellitus (CCCIDM)[1] and to assess how they map to existing CDISC standards.

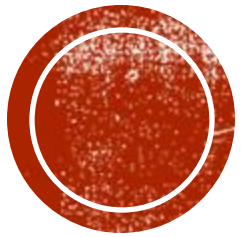
Methodology

The project scope was to review the 43 items from the combined SMISs from diabetes mellitus, hypertension, dyslipidemia, and chronic kidney disease (CKD), assess how they map to existing CDISC Foundational Standards (i.e., Study Data Tabulation Model Implementation Guide (SDTMIG) v 3.4[2] and controlled terminology[3]), and to identify the gaps. In addition to SDTMIG v3.4 and controlled terminology, related Therapeutic Area User Guides (TAUGs) were utilized in the assessment, including:

- Diabetes Therapeutic Area User Guide v1.0[4]
- Diabetes Type 1 Therapeutic Area User Guide - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes[5]
- Diabetic Kidney Disease Therapeutic Area User Guide v1.0[6]
- Dyslipidemia Therapeutic Area User Guide v1.0[7]
- Polycystic Kidney Disease (PKD) Therapeutic Area User Guide v1.0[8]

To ensure completeness of assessment, keyword searches for the 43 concepts were performed in CDISC's Examples Collection[9] and the CDISC wiki[10] as additional resources.
Finally, each of the SMIS items were searched in the available CDISC Biomedical Concepts (BCs).[11] Gaps were defined as SMIS items for which no SDTM example was found in the above resources, and/or for which the SDTM modeling strategy would require further discussion.

1	Height	22	Serum albumin
2	Weight	23	Hematuria
3	Systolic blood pressure	24	Total cholesterol / Non-HDL-cholesterol
4	Diastolic blood pressure	25	Urine albumin/creatinine
5	LDL-cholesterol	26	AST
6	HDL-cholesterol	27	Waist
7	Smoking	28	Urine glucose
8	Serum creatinine	29	γ-GTP



Japanese Government Collaboration and Actual Implementation in PHRs

Japanese History of PHR

From Clinic/Pharmacy

From Daily Life

Digitalization of Paper PHR

- New technology (2010～)
  - IoT
  - Wearable Sensors(including CGM, FGM)

Maternal Child Health Notebook Since 1942

Diabetes Notebook Since 1974

Drug Notebook Since 2000

Fusion!!

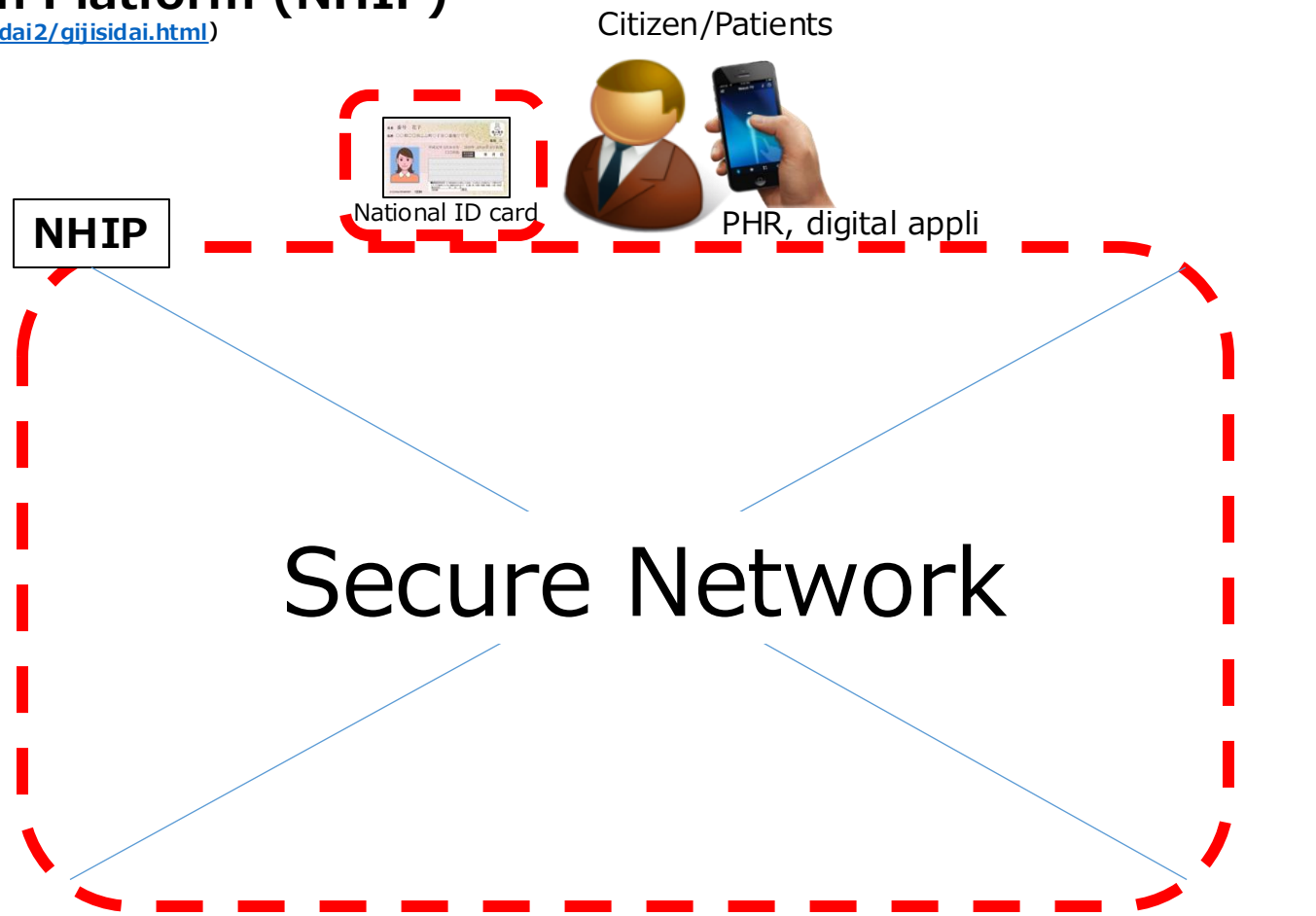
Blood Pressure Record Since 1990's

SMBG Record Since 1980's

Use Case 1: Clinical Practice

Nationwide Healthcare Information Platform (NHIP)

(https://www.cas.go.jp/jp/seisaku/iryou_dx_suishin/dai2/gijisidai.html)



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Use Case 1: Clinical Practice

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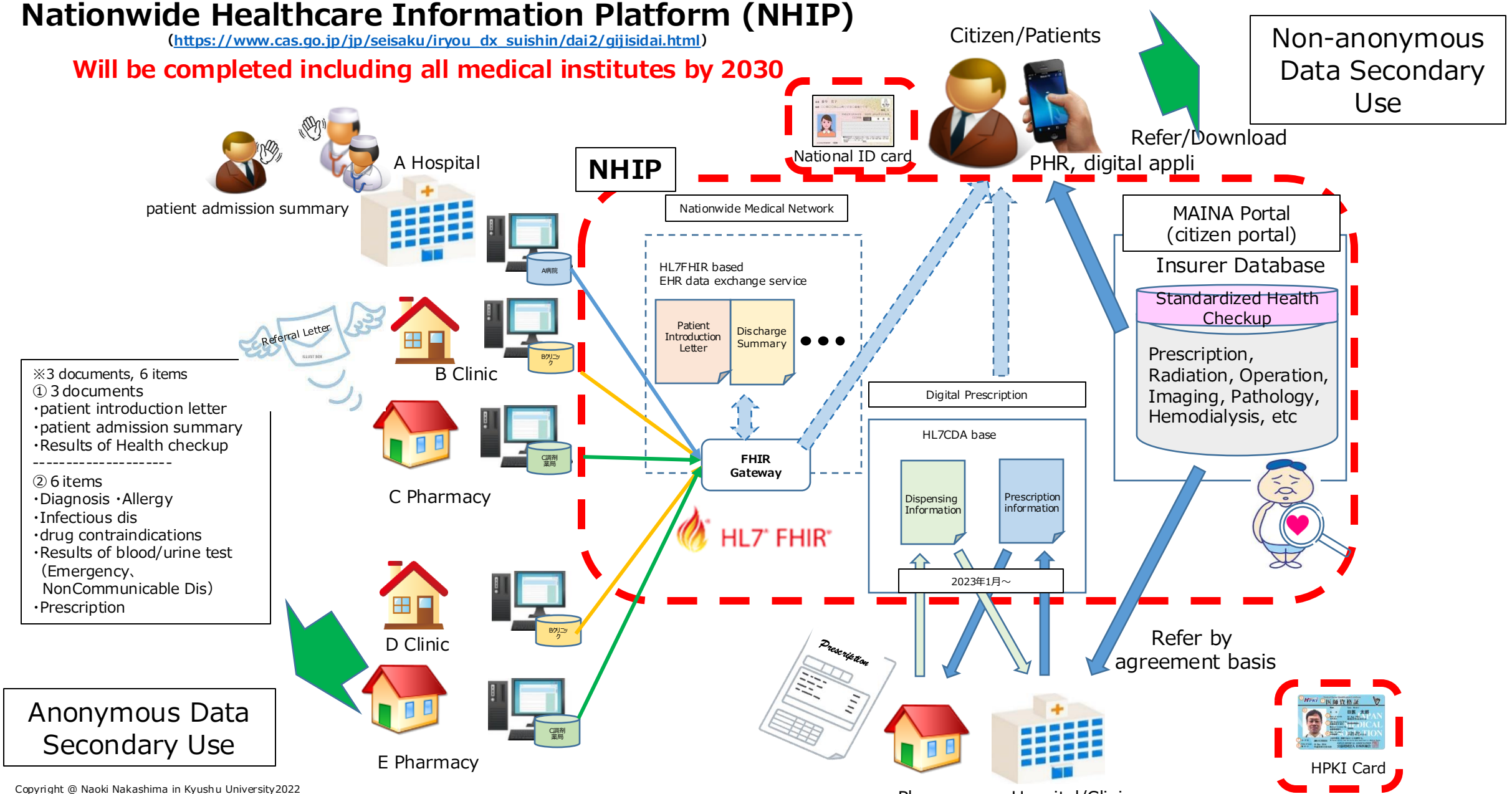
Will be completed including all medical institutes by 2030



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Use Case 1: Clinical Practice

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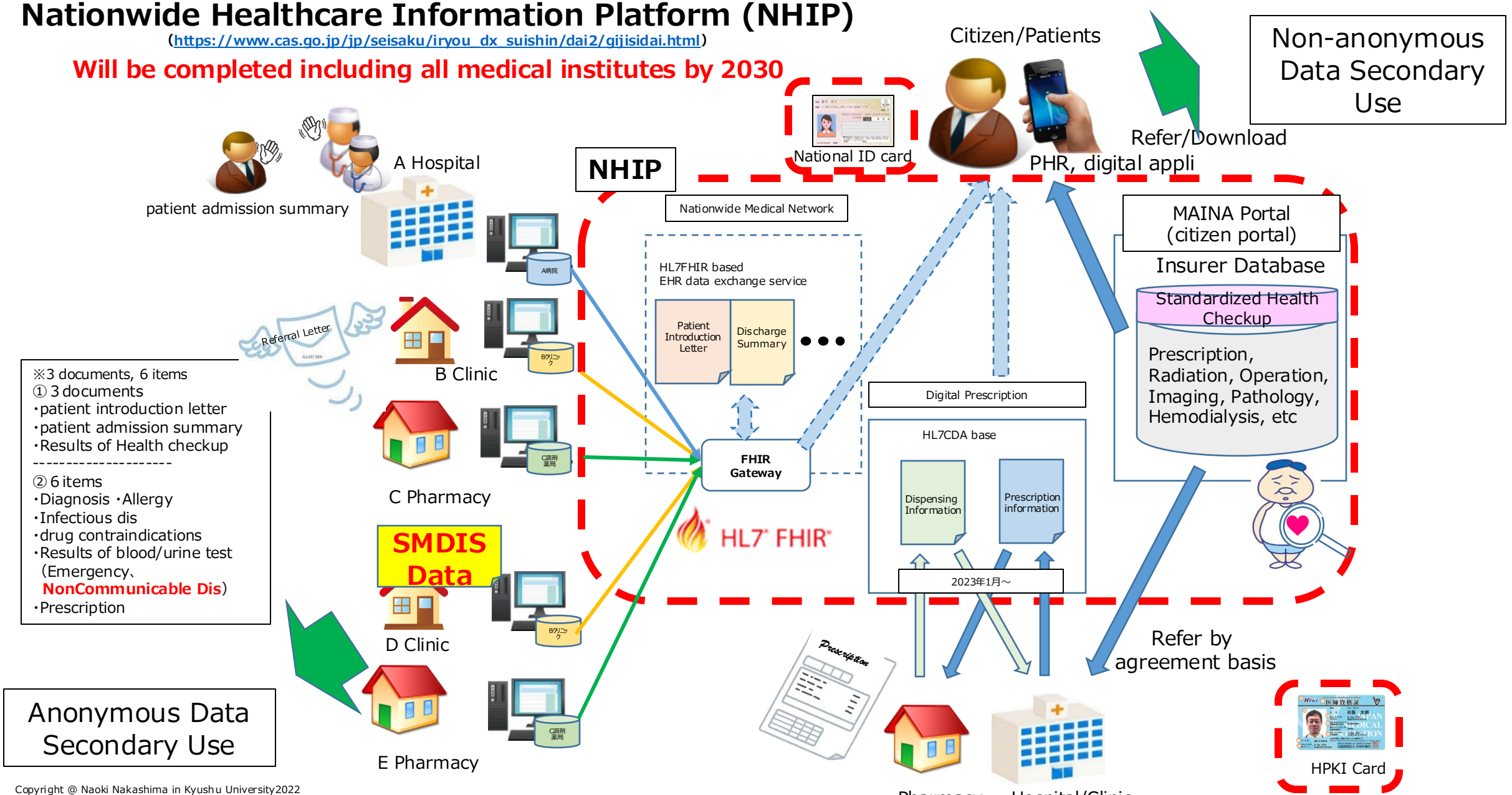

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Use Case 1: Clinical Practice

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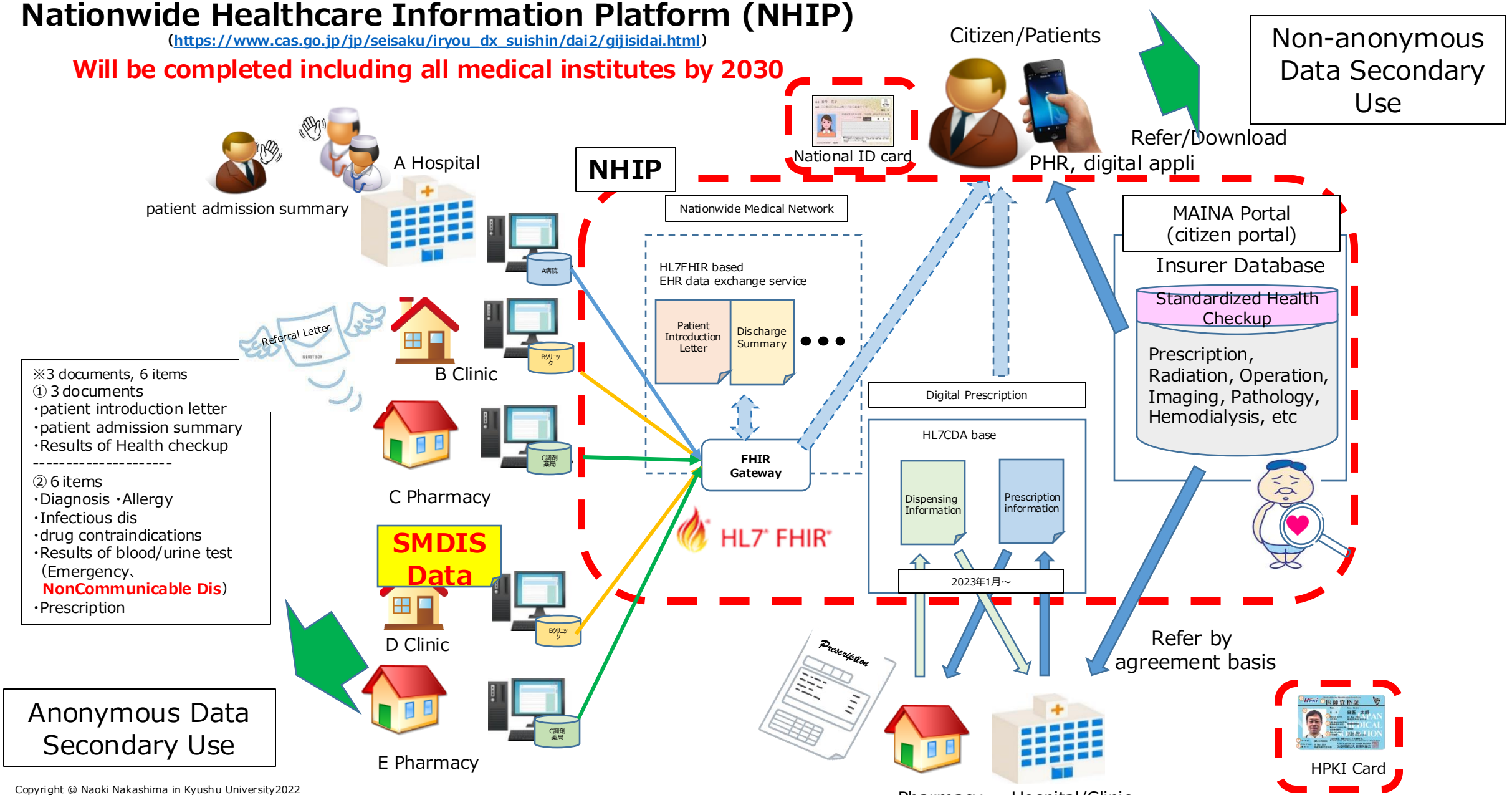

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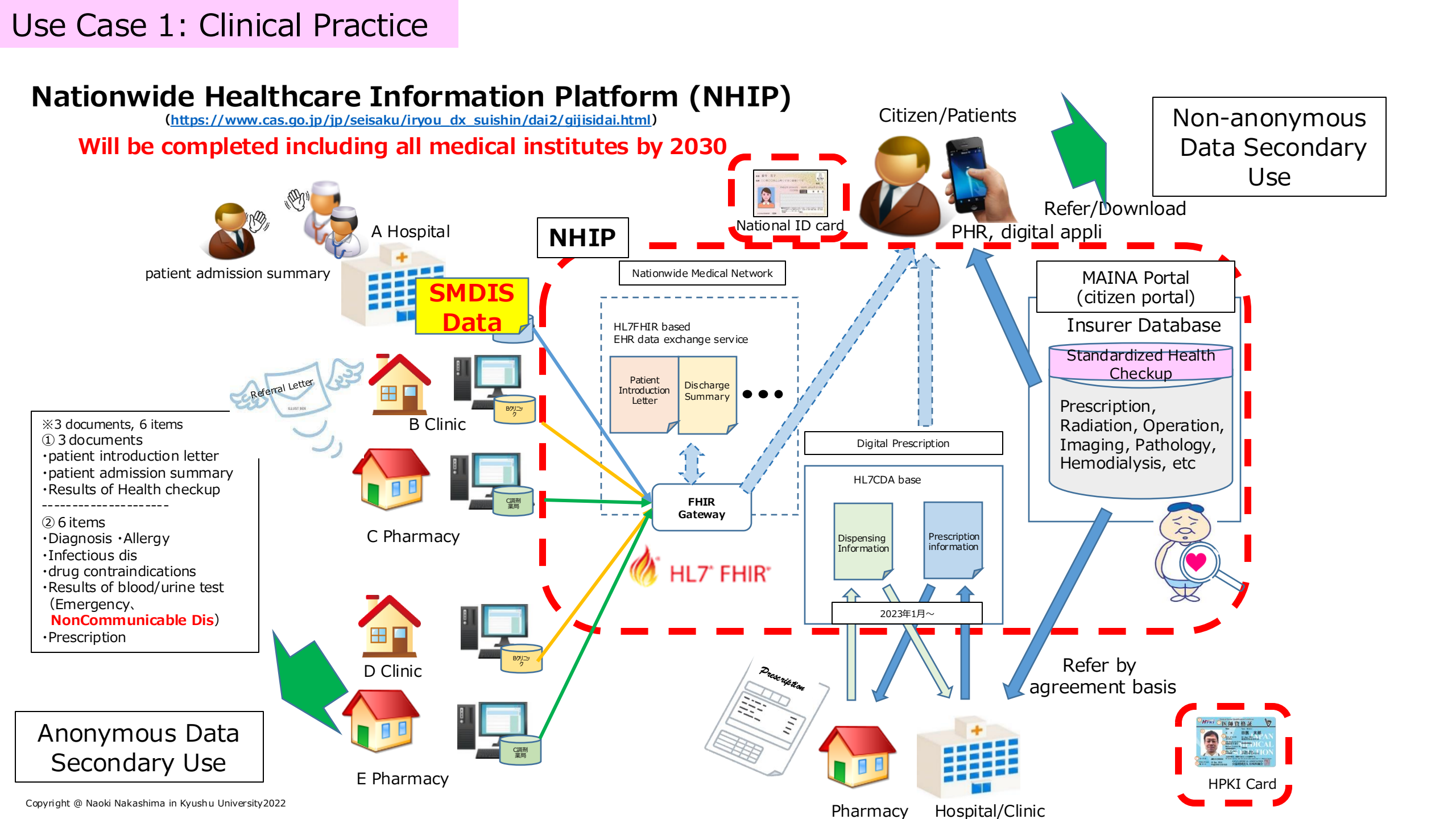

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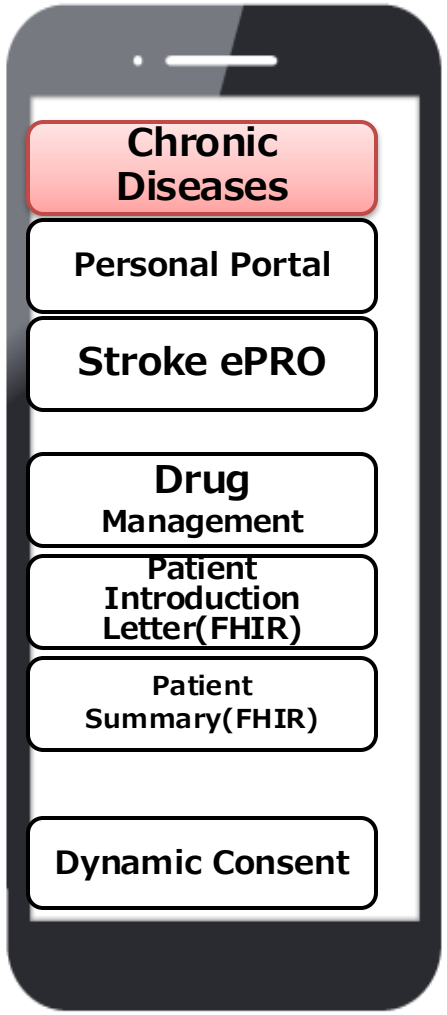
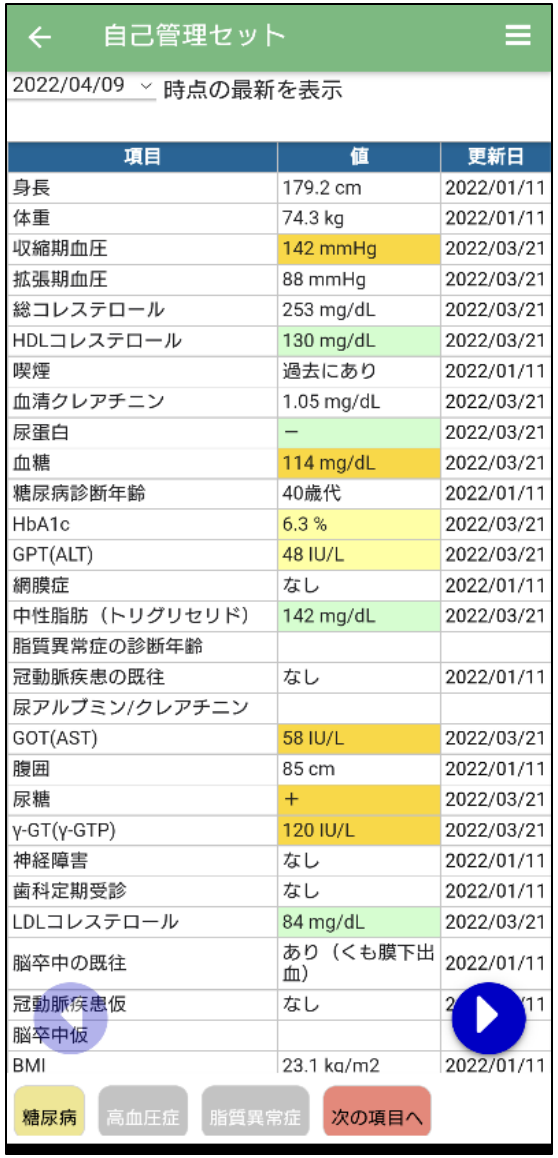
Use Case 1: Clinical Practice

In 2022-2023, We are conducting PHR PoC using Standardized Minimum Item Sets and Smart on FHIR



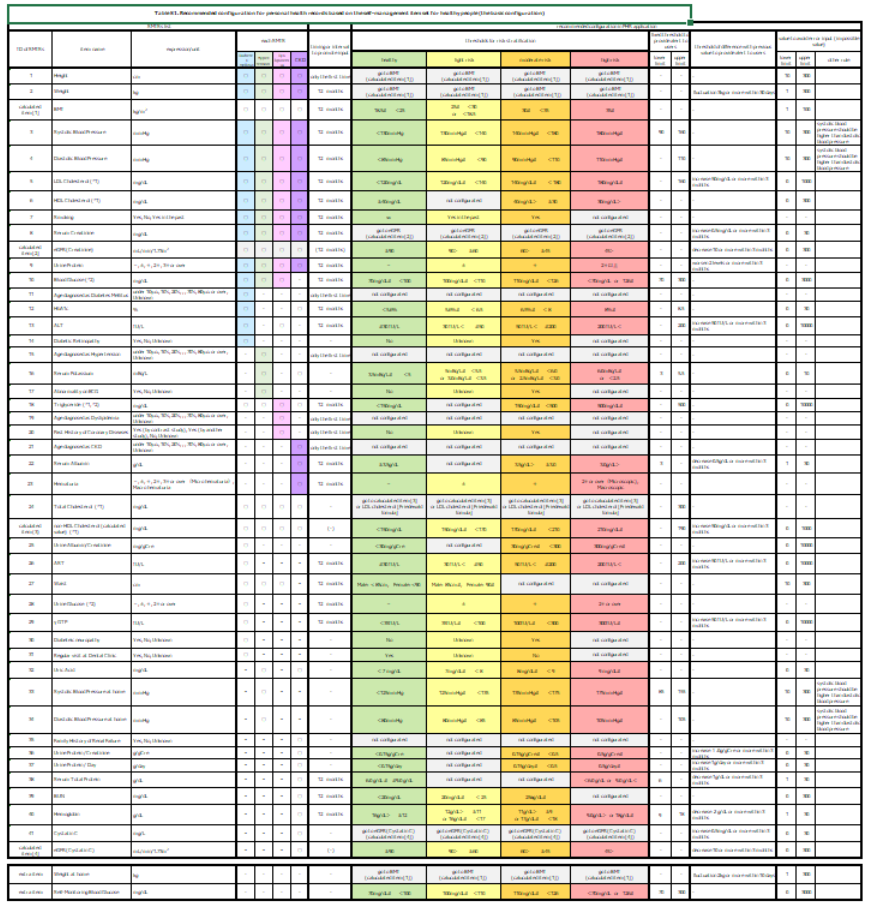
- Healthy
- Mild Risk
- Moderate Risk
- High Risk

検査項目	基準値	値
身長		162.8 cm
体重		
BMI	18.50~24.90	21.0 kg/m2
内臓脂肪面積		80.0 cm2
腹囲		88 cm
腹囲(自己判定)		86 cm
腹囲(自己申告)		80.0 cm
肥満度		
収縮期血圧（その他）	80.00~140.00	137 mmHg
収縮期血圧（2回目）	80.00~130.00	69 mmHg
収縮期血圧（1回目）	80.00~130.00	101 mmHg
拡張期血圧（その他）	~90.00	78 mmHg
拡張期血圧（2回目）	40.00~80.00	85 mmHg
拡張期血圧（1回目）	40.00~80.00	90 mmHg
心拍数		
採血時間(食後)		10時間以上
総コレステロール		
中性脂肪（トリグリセリド）	50.00~149.00	60 mg/dl
HDLコレステロール	40.00~96.00	45 mg/dl
LDLコレステロール	70.00~140.00	88 mg/dl
non-HDLコレステロール	70.00~139.00	135 mg/dl



項目	値	更新日
身長	179.2 cm	2022/01/11
体重	74.3 kg	2022/01/11
収縮期血圧	142 mmHg	2022/03/21
拡張期血圧	88 mmHg	2022/03/21
総コレステロール	253 mg/dL	2022/03/21
HDLコレステロール	130 mg/dL	2022/03/21
喫煙	過去にあり	2022/01/11
血清クレアチニン	1.05 mg/dL	2022/03/21
尿蛋白	−	2022/03/21
血糖	114 mg/dL	2022/03/21
糖尿病診断年齢	40歳代	2022/01/11
HbA1c	6.3 %	2022/03/21
GPT(ALT)	48 IU/L	2022/03/21
網膜症	なし	2022/01/11
中性脂肪（トリグリセリド）	142 mg/dL	2022/03/21
脂質異常症の診断年齢		
冠動脈疾患の既往	なし	2022/01/11
尿アルブミン/クレアチニン		
GOT(AST)	58 IU/L	2022/03/21
腹囲	85 cm	2022/01/11
尿糖	+	2022/03/21
γ-GT(γ-GTP)	120 IU/L	2022/03/21
神経障害	なし	2022/01/11
歯科定期受診	なし	2022/01/11
LDLコレステロール	84 mg/dL	2022/03/21
脳卒中の既往	あり（くも膜下出血）	2022/01/11
冠動脈疾患仮	なし	2022/01/11
脳卒中仮		
BMI	23.1 kg/m2	2022/01/11

RECOMMENDED CONFIGURATION FOR **PHR** ON SELF-MANAGEMENT DATA ITEM SET FOR NCD



Sheet for Non-Affected Subjects (Healthy～Pre-diseases)

- Risk classification threshold
- Alert threshold using fixed values
- Alert threshold by difference with previous values
- Alert threshold to prevent incorrect inputs
- Period for sending reminders

Naoki Nakashima, et al., Journal of Diabetes Investigation, 10:868–875, 2019.

Naoki Nakashima, et al. Diabetology International, 10:85–92, 2019.

Use in Multiple Disease-Registration DBs Based on Real World Data

Use Case 2

The **SMDIS** have been used in multiple diseases-registration DB based on Real World Data for 8years in Japan

Compliant with the diabetes self-management item set

Since 2016

J-DREAMS
Japan Diabetes Societ
(**Diabetes DB**)

SMDIS Data

Easy to utilize data mutually

Compliant with the CKD self-management item set

Since 2016

J-CKD-DB
Japanese Society of Nephrology (CKD DB)

SMDIS Data

SMDIS Data

PHR Server
(open FHIR)

Since 2018

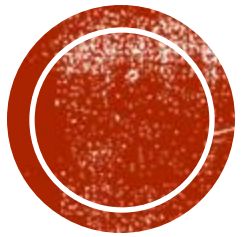
SMDIS Data

J-DOME
Japan Medical Association
Diabetes/hypertension DB

Compliant with 4 types of lifestyle-related disease self-management item sets

Some Japanese PHRs compliant with “PHR recommended settings” based on the lifestyle-related disease minimum item set

Copyright @ Naoki Nakashima in Kyushu University



Establish the healthcare support service in developing countries by Data Item Sets

Use Case 3: Global Health

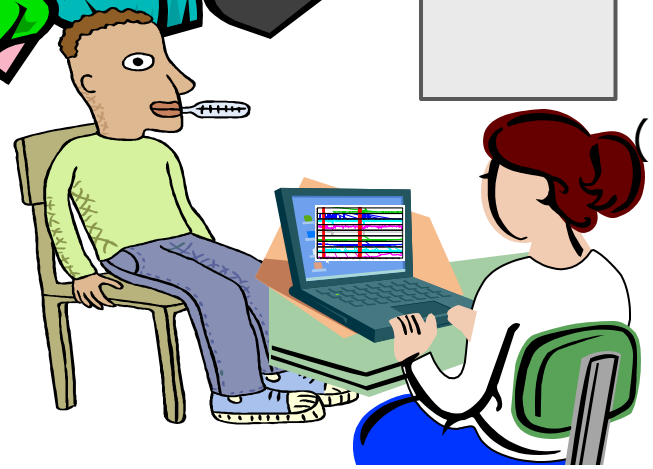
PORTABLE HEALTH CLINIC (PHC) PROJECT SINCE 2009

AN AFFORDABLE, USABLE, SUSTAINABLE AND PREVENTIVE HEALTHCARE SYSTEM FOR UNREACHED PEOPLE

Stratification by results of health check-up by portable clinic

- **Healthy ;**
- **Caution ; Education**
- **Sick ; Telemedicine**
- **Emergent ; Telemedicine and send to hospital**

"Triage"



(Local Healthcare Staff)

Ordinary , emergency

- Phone call
- email
- SNS

DB

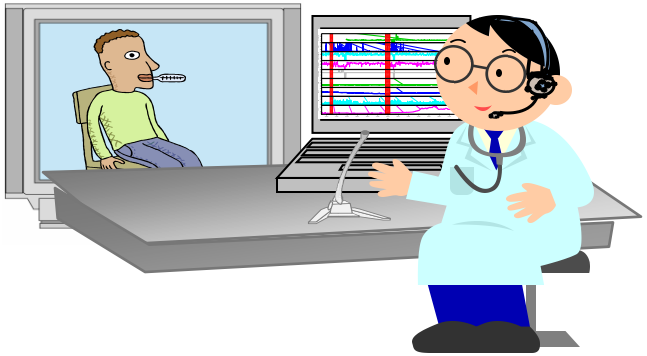
Cloud

Disease Management Office

Call Center (by doctors)

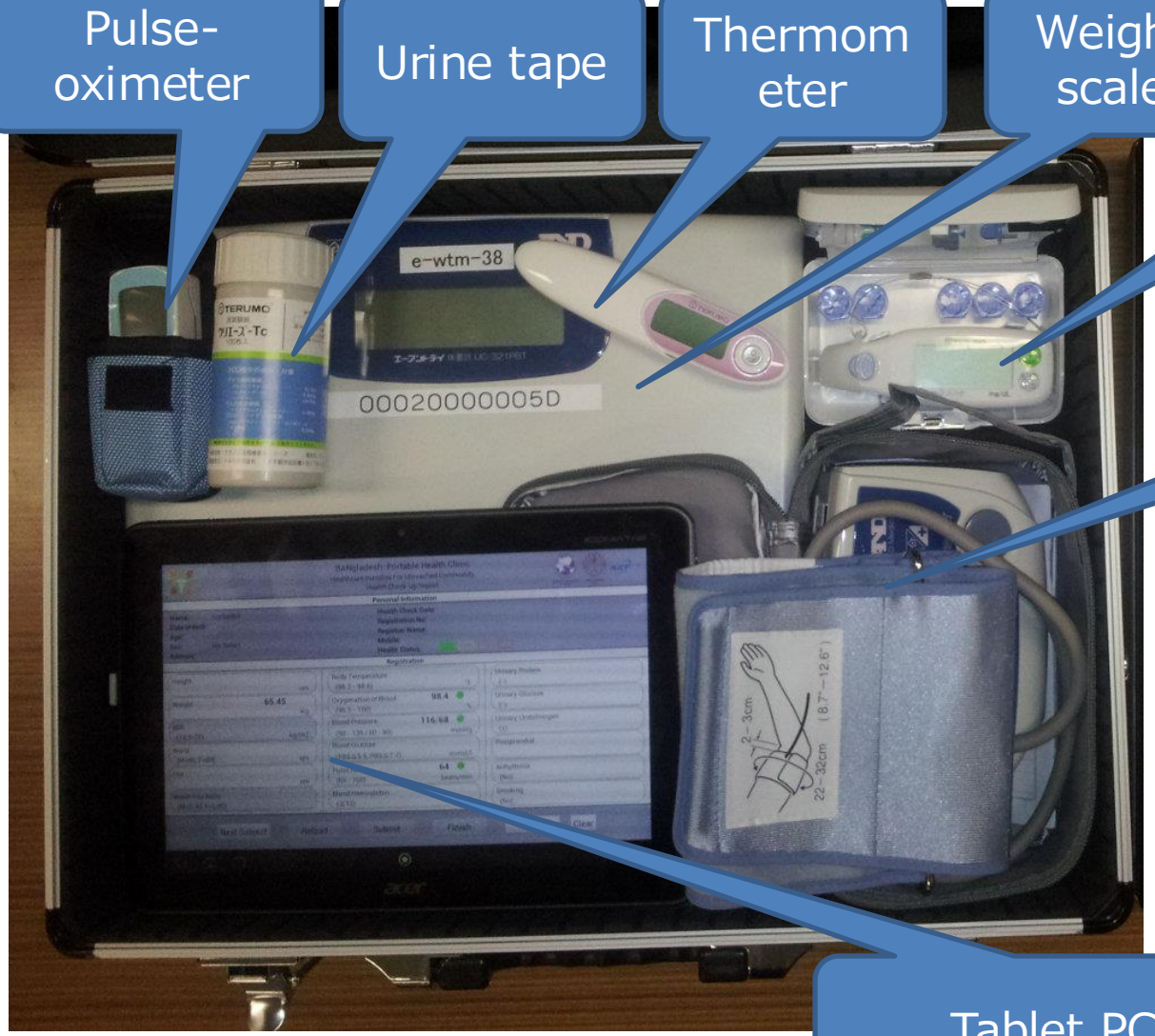
Sick **Emergent**

Remote-medicine/prescription



Use Case 3: Global Health

Sensors in PHC package : Data transmission with Body Area Network



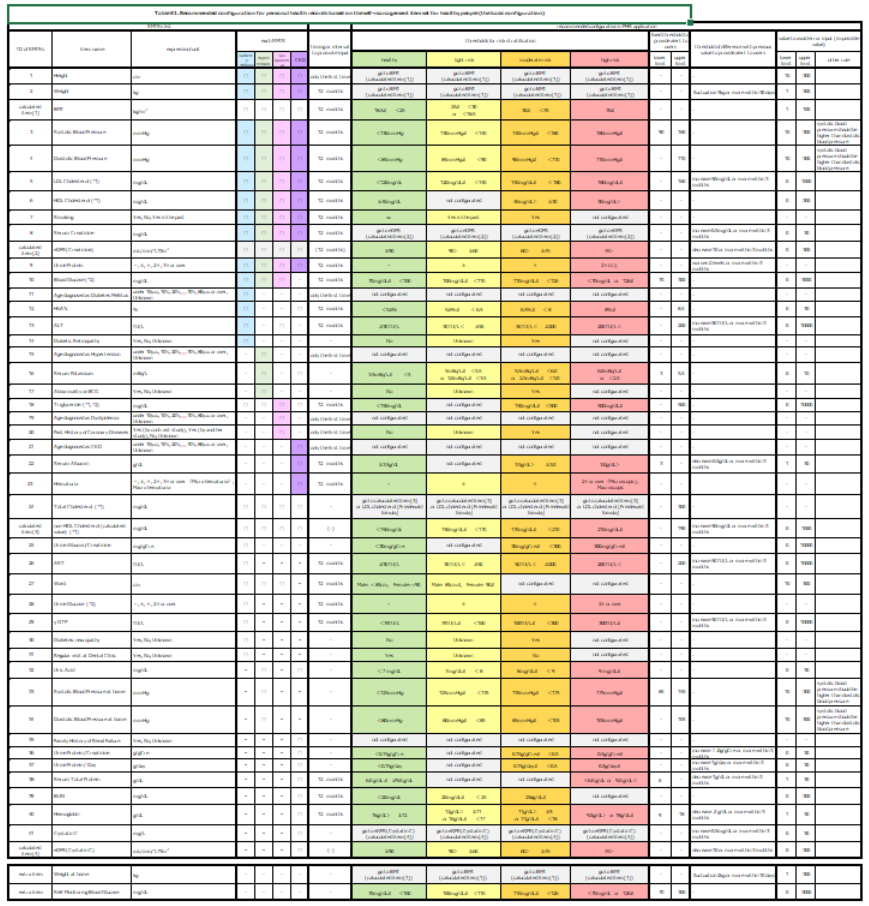
Healthcare Staff

Use Case 3: Global Health

Basic Triage Protocol for non-communicable diseases (B-Logic)

	Healthy	Caution	Sick	Emergent
Waist	Male <90cm	≧90cm		
	Female <80cm	≧80cm		
Waist/Hip Ratio	Male <0.9	≧0.90		
	Female <0.85	≧0.85		
Body Mass Index(BMI)	<25	25≦ <30	30≦ <35	35≦
Blood Pressure (mmHg)	<130	130≦ <140	140≦ <180 (need double check)	180≦
	<85	85≦ <190	90≦ <110 (need double check)	110≦
Fasting Blood Sugar (FBS)	<100mg/dl	100≦ <126	≧126mg/dl (Double check)	≧126mg/dl X 2times
Postprandial Blood Sugar (PBS)	<140mg/dl	140≦ <200	≧200mg/dl (Double check)	≧200mg/dl X 2times
Urine Protein	— ・±		≧＋ (Double check)	
Urine Sugar	— ・±	≧＋		
Urobilinogen	Normal or ±		Positive or ＋ (Double check)	
Pulse Ratio	60≦ <100	50≦ <60 100≦ <120	<50 (Double check) 120≦ (Double check)	
Arrythmia	None		＋ (Double check)	
Smoking	None	＋		
Skin lesion	None		＋	
Body Temperature	<37℃	98.6 F≦ <99.5 F 37℃≦ <37.5℃	99.5F ≦ (37.5℃≦) (Double check)	
SpO2	≧96%	93≦ <96	90≦ <93 (Double check)	<90%
Hemoglobin	≧12g/dl	10≦ <12g/dl	8≦ <10g/dl	<8g/dl

RECOMMENDED CONFIGURATION FOR **PHR** ON SELF-MANAGEMENT DATA ITEM SET FOR NCD



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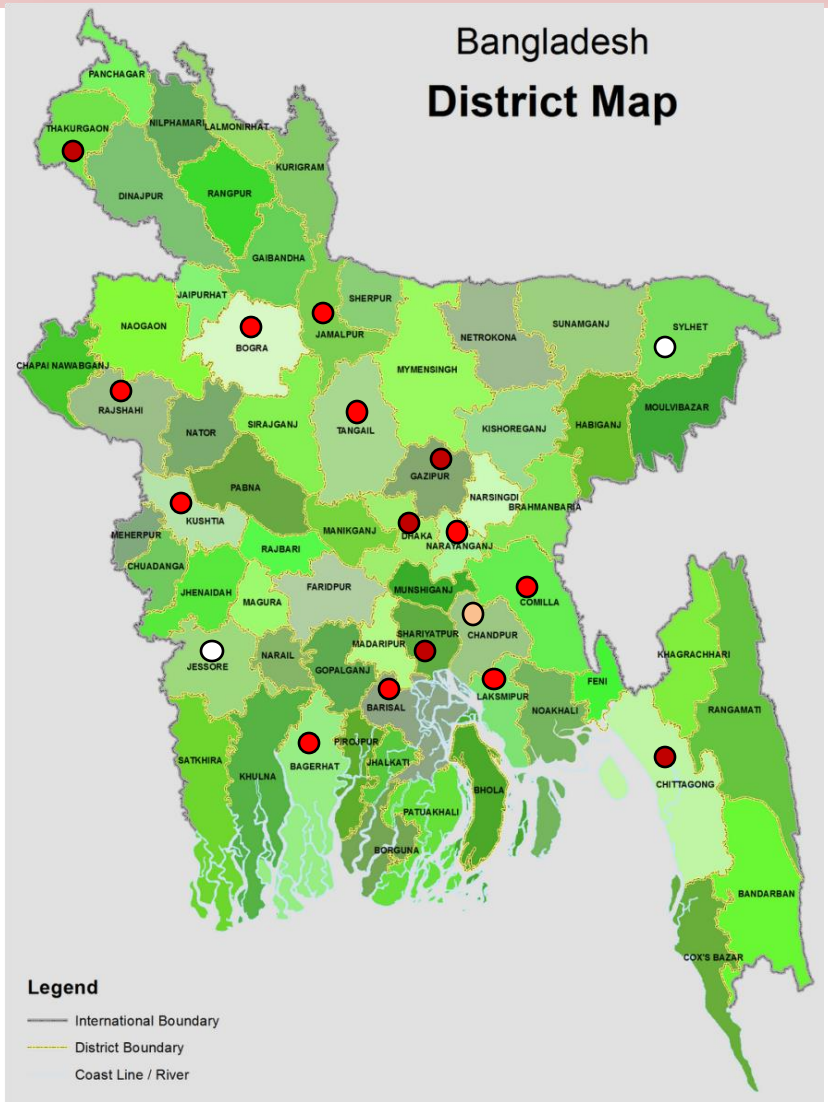
Use Case 3: Global Health

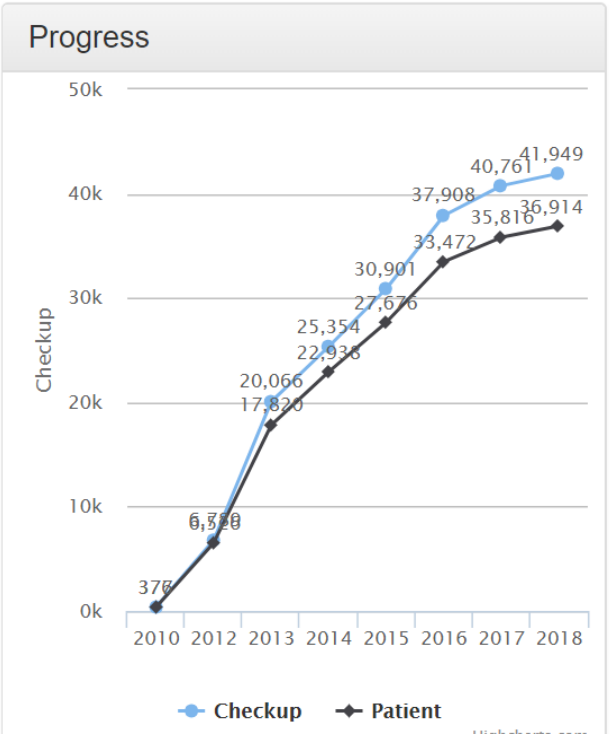
Matching by sex because of Islam

Services State in Bangladesh



As on December 31, 2018

Year	Total Checkup	Health Status			
		🟢	🟡	🟠	🔴
2010	377	103	15	248	10
2012	6,412	1,056	4,035	1,084	237
2013	13,277	1,595	6,781	4,301	546
2014	5,288	1,004	2,278	1,659	326
2015	5,547	1,330	1,429	2,016	772
2016	7,007	1,875	1,614	2,255	1,069
2017	2,853	366	800	868	361
2018	1,188	95	410	325	121
Total	**41,949**	**7,424**	**17,362**	**12,756**	**3,442**

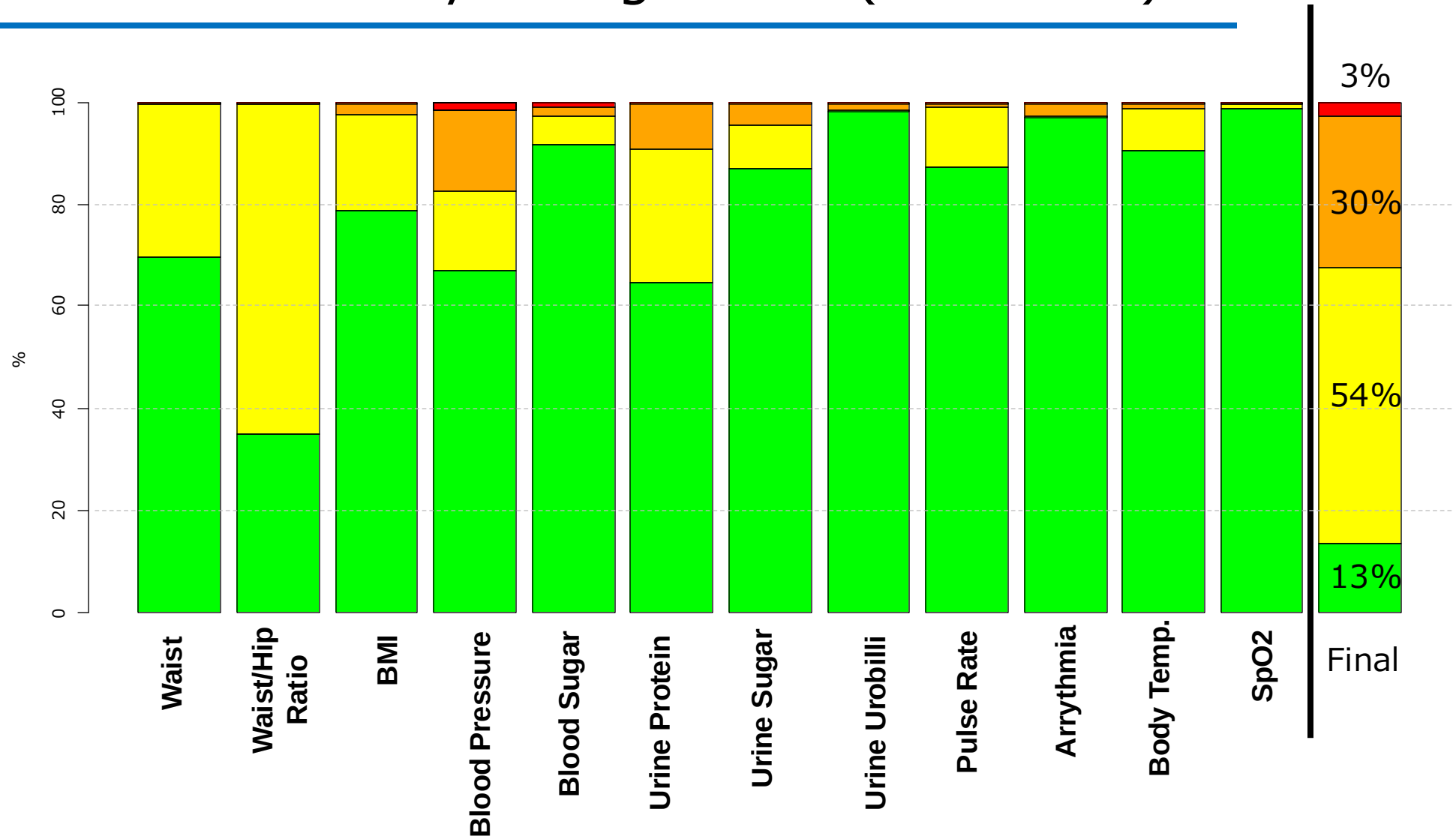


24,786 (61%)

16,198 (39%)

Yasunobu Nohara, Naoki Nakashima, et al.,
Journal of Medical Internet Research, 17:1-14, 2015.

Results of each checkup and final stratification by B-Logic v2.0 (N=16741)



Use Case 3: Global Health

PHC partners （2024）

https://portablehealth.clinic/

Medical/Healthcare/Epidemiology/Statistics/Bioscience/ICT/specialists

SMDIS

B-Logic

2023～

ROCINANTES

2016～

BIYANI
Where you can trust

KYUSHU UNIVERSITY

2010～

2018～

2010～

GRAMEEN COMMUNICATIONS

2019～

UNIVERSITAS GADJAH MADA

2019～

UMS
UNIVERSITI MALAYSIA SABAH

Conclusion

- We are living in the early phase of medical DX
- To glow digital health and DX appropriately, Standard Data Item Sets in each clinical area should be important
- We showed the Japanese cases of Data Item Sets for NCDs
- Standard Data Item Sets are useful in;
  - Clinical practice, preventive healthcare, including patient engagement
  - Clinical Research
  - Global Health