IHE RFD (Retrieve Form for Data capture)
Connection Test (Adverse Event Report)

with Ministry Project SS-MIX,
at HL7 Kyoto Working Group Meetings

IHE Japan vice-chair

HL7 Japan chair

Michio Kimura, MD, PhD

Hamamatsu University

HL7 Working Group Meeting
10-15 May, 2009, Kyoto Japan
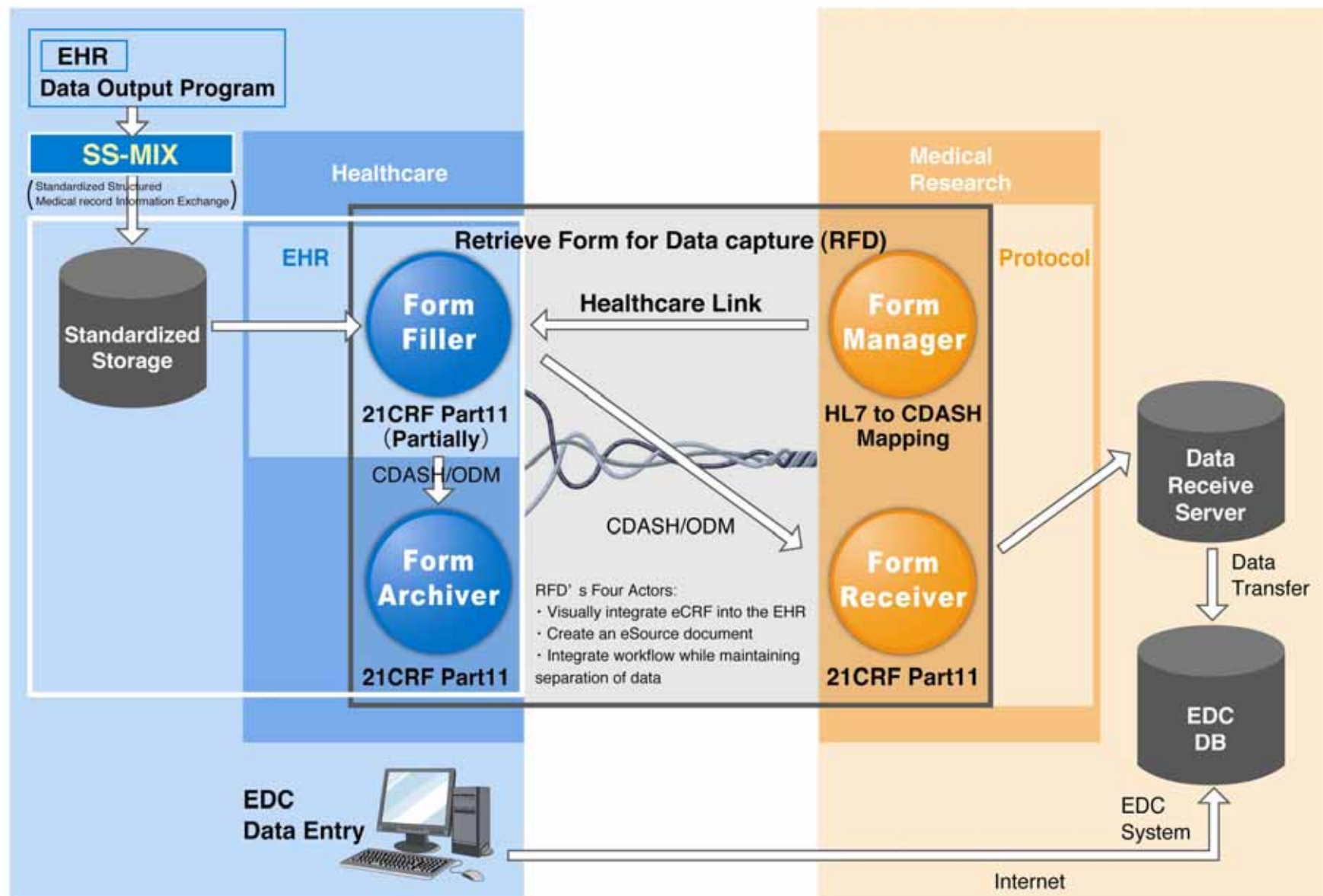
CDISC
Healthcare Link
Initiative
Integrating Research
into Healthcare Flow

RFD Interoperability Test

■ CDISC Japan
■ HL7 Japan
■ IHE Japan

2009.05.14, Kyoto

RFD connection demo

- **Form Manager** by Medical Front prepares report form in CDA and sends to Form Filler

- **Form Filler** by SBS Information System receives the form and fills it, most of which are pre-populated by CPOE data, archives it at Form Archiver by SBS, and submits to Form Receiver by Medical Front.

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Post Market Adverse Event Report

- Paper-based
- Manually collected in busy clinics

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Form Filling
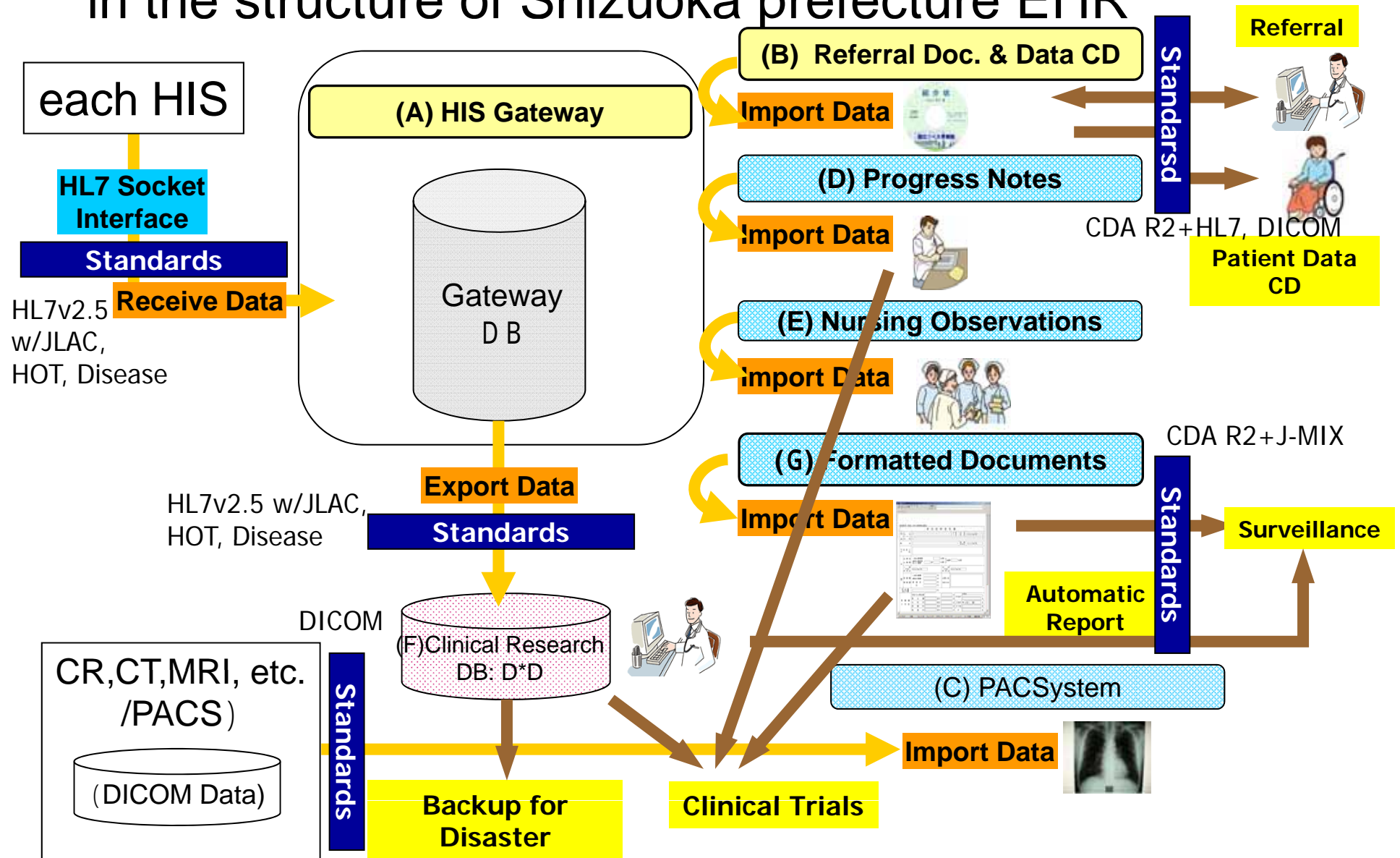
- ⌘ Manually
- ⌘ But, most items are in CPOE and EMR

CPOE in Japan

- 90%+ in large hospitals (400+ beds)
- Top 2 vendors became able to export patient demographics, prescriptions, lab results, diagnoses, in HL7 v.2 messages
  - by appointment of Ministry of Health Labor Welfare project : SS-MIX
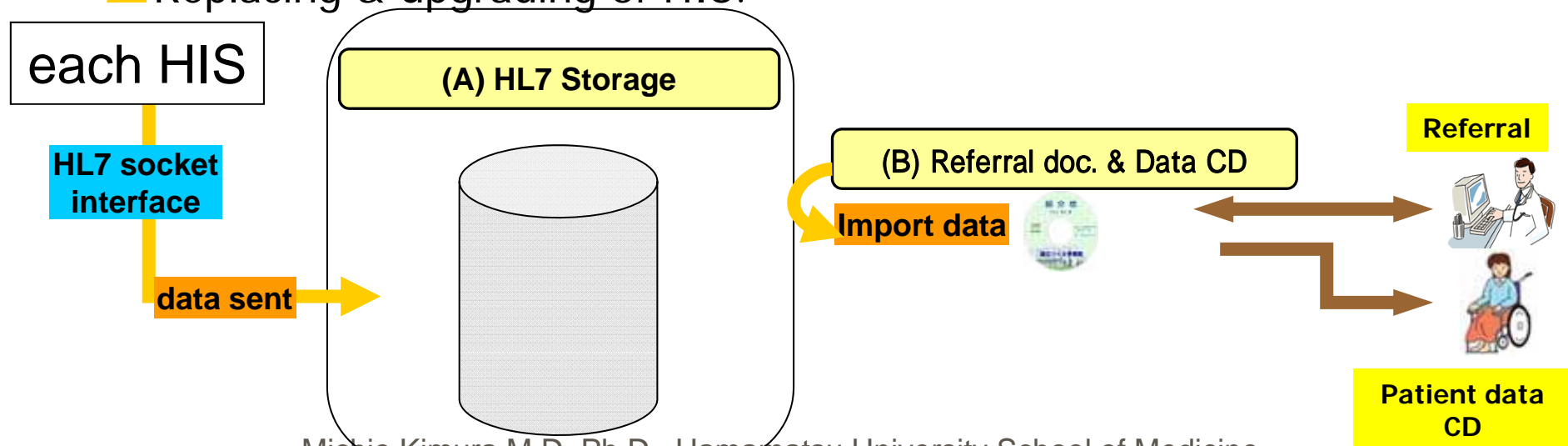   - Standardized Medical Information Exchange Promotion

SS-MIX standardized repository (A):HIS Gateway in the structure of Shizuoka prefecture EHR

each HIS

HL7 Socket Interface

Standards

HL7v2.5 w/JLAC, HOT, Disease

Receive Data

(A) HIS Gateway

Gateway

Export Data

HL7v2.5 w/JLAC, HOT, Disease

Standards

DICOM

(F)Clinical Research DB: D*D

CR,CT,MRI, etc. /PACS

Standards

DICOM Data)

Backup for Disaster

(B) Referral Doc. & Data CD

Import Data

(D) Progress Notes

Import Data

(E) Nursing Observations

Import Data

( ) Formatted Documents

Import Data

Referral

Standarsd

CDA R2+HL7, DICOM

Patient Data CD

CDA R2+J-MIX

Standards

Surveillance

Automatic Report

(C) PACSystem

Clinical Trials

Import Data

Wide variety of applications on HL7 standardized storage by SS-MIX, a Ministry project

- ⌘ We have patient demographics, prescriptions & injections, lab results, diagnosis classifications in HL7 v2.5
  - ⌃ PHR
  - ⌃ Making documents
  - ⌃ Data retrieval
  - ⌃ Interoperability with peripheral systems
  - ⌃ Replacing & upgrading of HIS.

each HIS

(A) HL7 Storage

HL7 socket interface

data sent

(B) Referral doc. & Data CD

Import data

Referral

Patient data CD

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患者情報 1014360   Suruga Aoi   患者指定   編集文書指定 新規文書作成

1952/07/17生まれ 女性 患者情報   文書修正・削除 ×××××TabletsEventReport (00000035) [修正]

処方歴   2008/06/08〜2008/09/08   文書登録 文書印刷   処方歴の添付 臨床検査歴の添付

2008/04/21
  OHP (surgery
    Rp1
      Amloc
      Lipitor
      ACTO
      1 time
2008/05/26
  OHP (surgery
    Rp1
      Amloc
      Lipitor
      ACTO
      1 time
2008/06/09
  OHP (surgery
2008/06/23
  OHP (surgery

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【Chemical laboratory results】

Item	Unit	Reference value		Before medication 2008 / 06 / 09	Through medication 2008 / 06 / 23	2008 / 07 / 07	2008 / 07 / 22	After medication 2008 / 08 / 18	Follow ups 2008 / 09 / 01
GOT(AST)	IU/L	8	38	14	21	12	15	14	15
GPT(ALT)	IU/L	4	43	9	31	10	10	9	10
A L P	IU/L	110	354	147	169	167	167	147	167
L D H	IU/L	121	245	139	122	148	185	139	185
T－Bil	mg/dl	0.2	1.2	0.7	0.4	0.5	0.3	0.7	0.3
U r e a－N	mg/dl	8	22	12	16	13	8	12	8
C r e	mg/dl	0.47	0.79	0.53	0.55	0.57	0.59	0.53	0.59
R B C	*10^4/ul	376	500	397	401	417	417	397	417
H G B	g/dl	11.3	15.2	12.8	13.0	13.6	13.6	12.8	13.6

Abnormal data should be reported in the AE report

検査結果歴

	2008 09/01	08/
GOT(AST)	15	
GPT(ALT)	10	
ALP	167	1
LDH	185	1
T－Bil	0.3	(
Urea－N	8	
Cre	0.59	0.
T－CHO	212	1
Ca	8.5	!
CRP		!
TP	6.4	!
Na	144	1
K	4.3	!
Cl	110	1
RBC	417	3
HGB	13.6	1:
WBC	6.9	
HT	39.5	3

患者情報　1014360　　　　Suruga Aoi　　　　患者指定　　編集文書指定　新規文書作成

1952/07/17生まれ　　女性　患者情報　　　　　　　　文書修正・削除　xxxxxTabletsEventReport (00000035) [修正]

処方歴

- 2008/04/21
  - OHP（surgery）
    - Rp1
      - Amlodipine Tablets 2.5mg 1 TAB
      - Lipitor Tablets 10mg 1 TAB
      - ACTOS Tablets 15mg 1 TAB
        1 time per day, after breakfast 28 Days
- 2008/05/26
  - OHP（surgery）
    - Rp1
      - Amlodipine Tablets 2.5mg 1 TAB
      - Lipitor Tablets 10mg 1 TAB
      - ACTOS Tablets 15mg 1 TAB
        1 time per day, after breakfast 28 Days
- 2008/06/09
  - OHP（surgery）
- 2008/06/23
  - OHP（surgery）
- 2008/07/07

2008/06/08～2008/09/08　　　文書登録　文書印刷　　　処方歴の添付　臨床検査歴の添付

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【Adverse Events】

○ N　　　◉ Y　────▶ Report in the followings

Severe event number :
1. Death
2. Thread to death
3. Permanent disorder
4. Extension of hospitalization
5. Other severe events to avoid above situations
6. May cause disorder in descendants

Adverse event	Severity	Disposition		Outcome	Relation
		Medication	Others		to this drug
Coma date 2008 / 08 / 15	○ Severe ↳ Severe event # (　) ◉ Not.Severe ↳ ○ Slight ◉ Not.slight	◉ Continue ○ Dose.decrease ○ Interruption	○ N　○ Y	Outcome date 2008 / 08 / 15 ◉ Recovery ○ Better ○ Not.recovered Recovery.with.Sequel ○ Death ○ Unknown	○ Apparently.related ○ Probably.related ◉ Possibly.related ○ No.relation ○ No.enough.evidence
 date ___ / ___ / ___	○ Severe ↳ Severe event # (　) ○ Not.Severe ↳ ○ Slight ○ Not.slight	○ Continue ○ Dose.decrease ○ Interruption	○ N　○ Y	Outcome date ___ / ___ / ___ ○ Recovery ○ Better ○ Not.recovered Recovery.with.Sequel ○ Death ○ Unknown	○ Apparently.related ○ Probably.related ○ Possibly.related ○ No.relation ○ No.enough.evidence
 date ___ / ___ / ___	○ Severe ↳ Severe event # (　) ○ Not.Severe ↳ ○ Slight ○ Not.slight	○ Continue ○ Dose.decrease ○ Interruption	○ N　○ Y	Outcome date ___ / ___ / ___ ○ Recovery ○ Better ○ Not.recovered Recovery.with.Sequel ○ Death ○ Unknown	○ Apparently.related ○ Probably.related ○ Possibly.related ○ No.relation ○ No.enough.evidence
	○ Severe	○ Continue	○ N　○ Y	Outcome date ___ / ___ / ___	○ Apparently.related

検査結果歴

	2008						
	09/01	08/18	08/04	07/22	07/07	06/23	06/09 0!
GOT(AST)	15	14	12	15	12	21	14
GPT(ALT)	10	9	9	10	10	31	9
ALP	167	147	146	167	167	169	147
LDH	185	139	149	185	148	122	139
T-Bil	0.3	0.7	0.4	0.3	0.5	0.4	0.7
Urea-N	8	12	12	8	13	16	12
Cre	0.59	0.53	0.54	0.59	0.57	0.55	0.53
T-CHO	212	175	201	212	212	176	175
Ca	8.5	8.5	8.7	8.5	8.9	8.2	8.5
CRP		2.0				0.3	2.0
TP	6.4	5.8	5.8	6.4	6.4	5.8	5.8
Na	144	140	138	144	146	140	140
K	4.3	4.0	4.3	4.3	4.7	4.2	4.0
Cl	110	104	105	110	99	104	104
RBC	417	397	390	417	417	401	397
HGB	13.6	12.8	12.9	13.6	13.6	13.0	12.8
WBC	6.9	7.1	4.5	6.9	6.9	7.7	7.1
HT	39.5	37.9	37.6	39.5	39.5	38.3	37.9

Demo at CDISC Interchange 2008, Arlington

Demo at HIMSS 2009 Chicago

⌘ IHE Interoperability Showcase

University School of Medicine

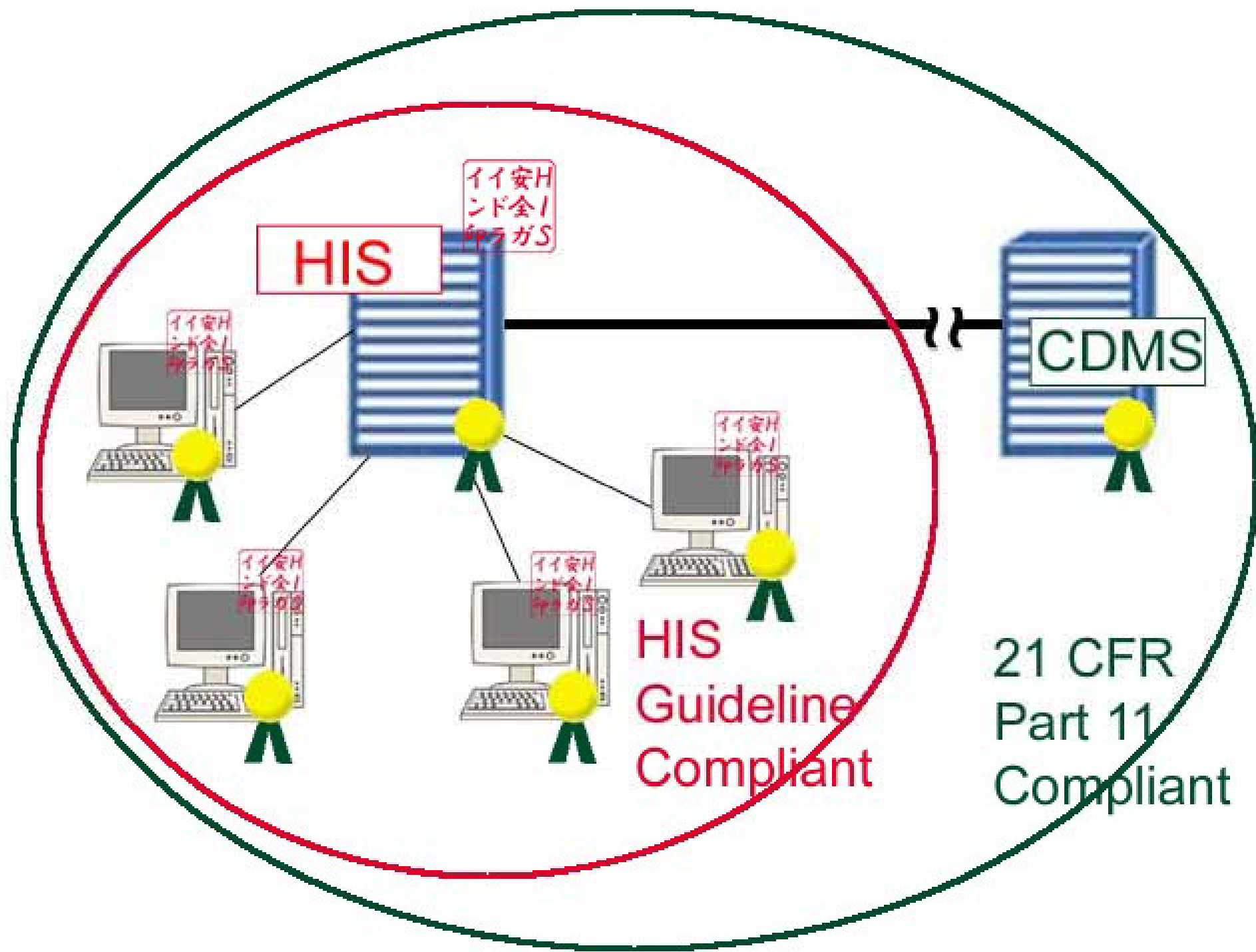# IHE Japan Connect-a-thon

- Oct 26-30, 2009, Tokyo
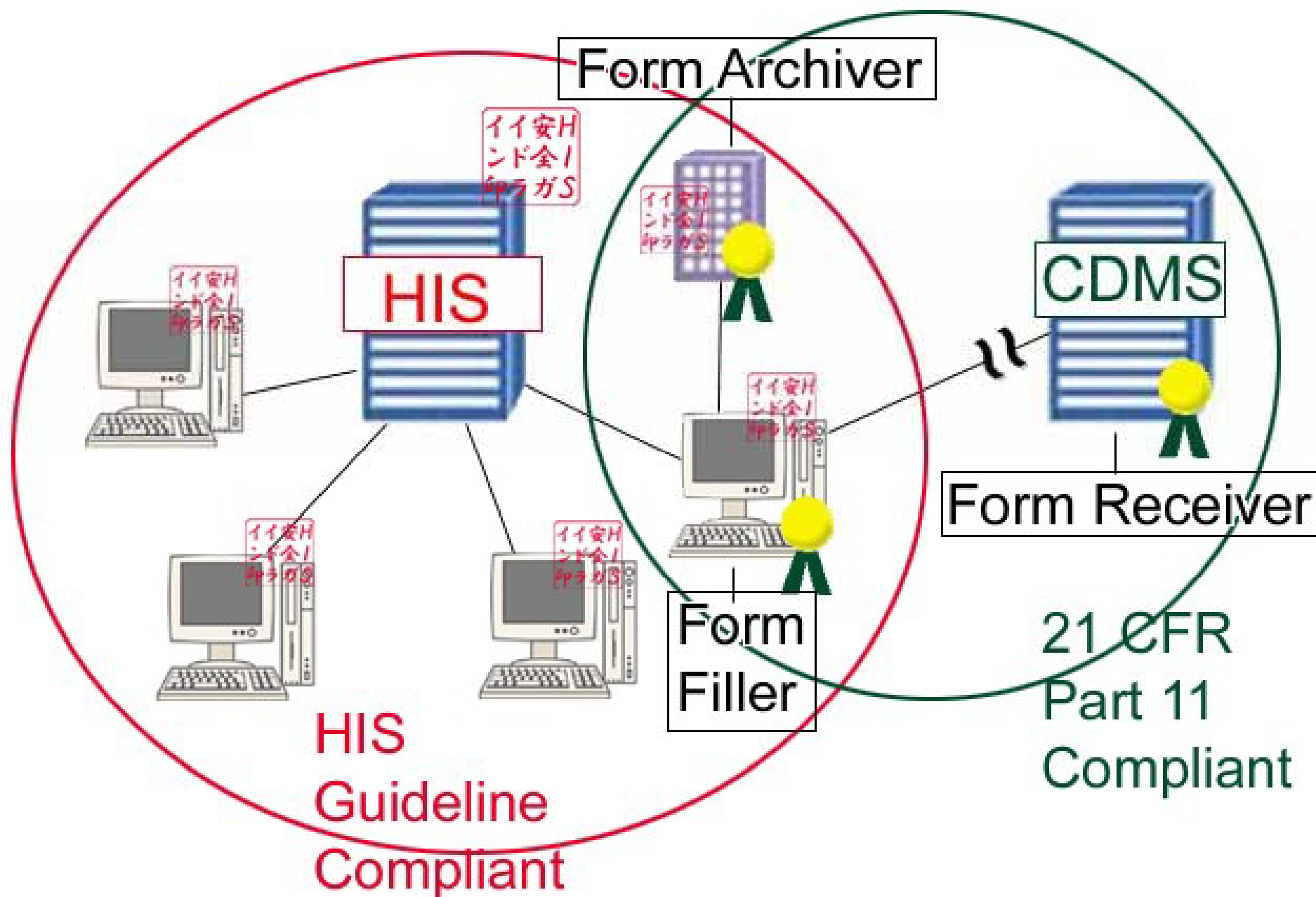- Radiology, Laboratory, Cardiology, IT Infrastructure which will include RFD
- http://www.ihe-j.org/en/

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Current Status

- ⌘ 20 Hospitals mainly in Shizuoka prefecture are ready with SS-MIX standardized repository
- ⌘ About 50% of all large hospitals in Japan has HL7 v2.5 export feature (EMR: Fujitsu GX series, FX series, NEC HR series, SBS Prime-Karte series, Software Service e-Karte series)
  - ⌂ They only need to add hardware for the repository, as repository software is provided from Ministry project SS-MIX
- ⌘ This form filler can be 21 CFR Part 11 compliant

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Current Status(2)

- ⌘ PMDA (FDA in Japan) launched a 5 year project for "Safety Data Extraction from HIS through IT" with 4 subgroups
  - ⌃ e-Claim data, HIS data through SS-MIX, Post market form, Voluntary report submission
  - ⌃ SS-MIX team uses high-speed clinical information retrieval system D*D, which is working at 5 Shizuoka hospitals.

End of presentation

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