

# Seeking Healthcare Datalink for 15 years with Standards



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# Conflict of Interest



- NEC, Fujifilm, Array

# Purpose:

## Direct healthcare datalink



- Correctness
  - Timeliness
  - Large-amount
  - and Burden-free
- 
- In other words, manual handling looked silly.

# 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

Used Slides at CDICS Tokyo Interchange 2009

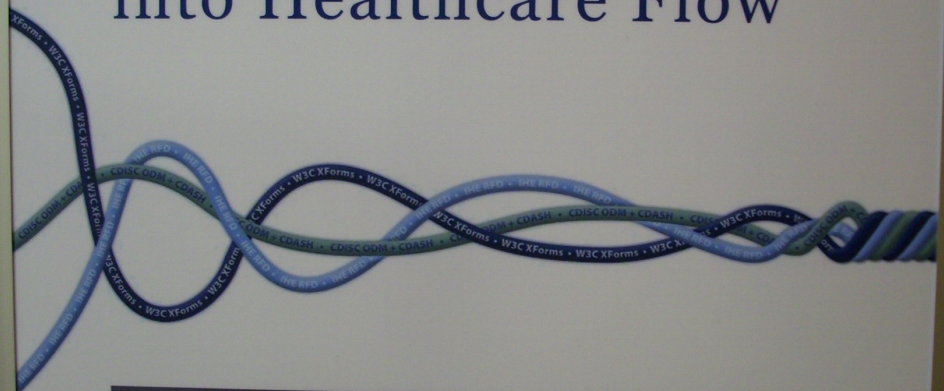


# HL7 Working Group Meeting 10-15 May, 2009, Kyoto Japan



# CDISC Healthcare Link Initiative

## Integrating Research into Healthcare Flow



### RFD Interoperability Test

- CDISC Japan
- HL7 Japan
- IHE Japan

2009.05.14, Kyoto

672

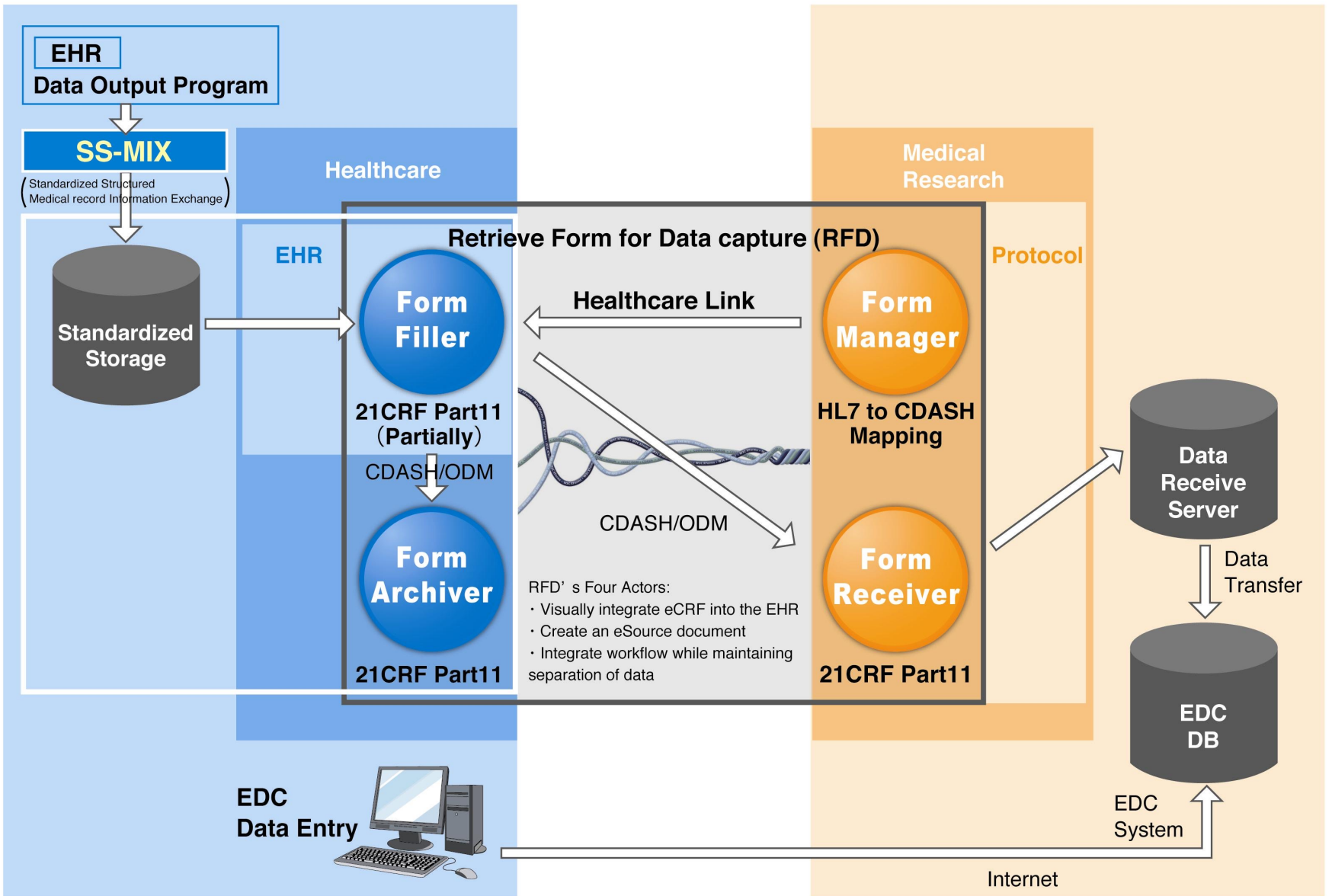
CDISC  
Healthcare Link  
Initiative  
Integrating Research  
into Healthcare Flow

### RFD Interoperability Test

- CDISC Japan
- HL7 Japan
- IHE Japan

2009.05.14, Kyoto



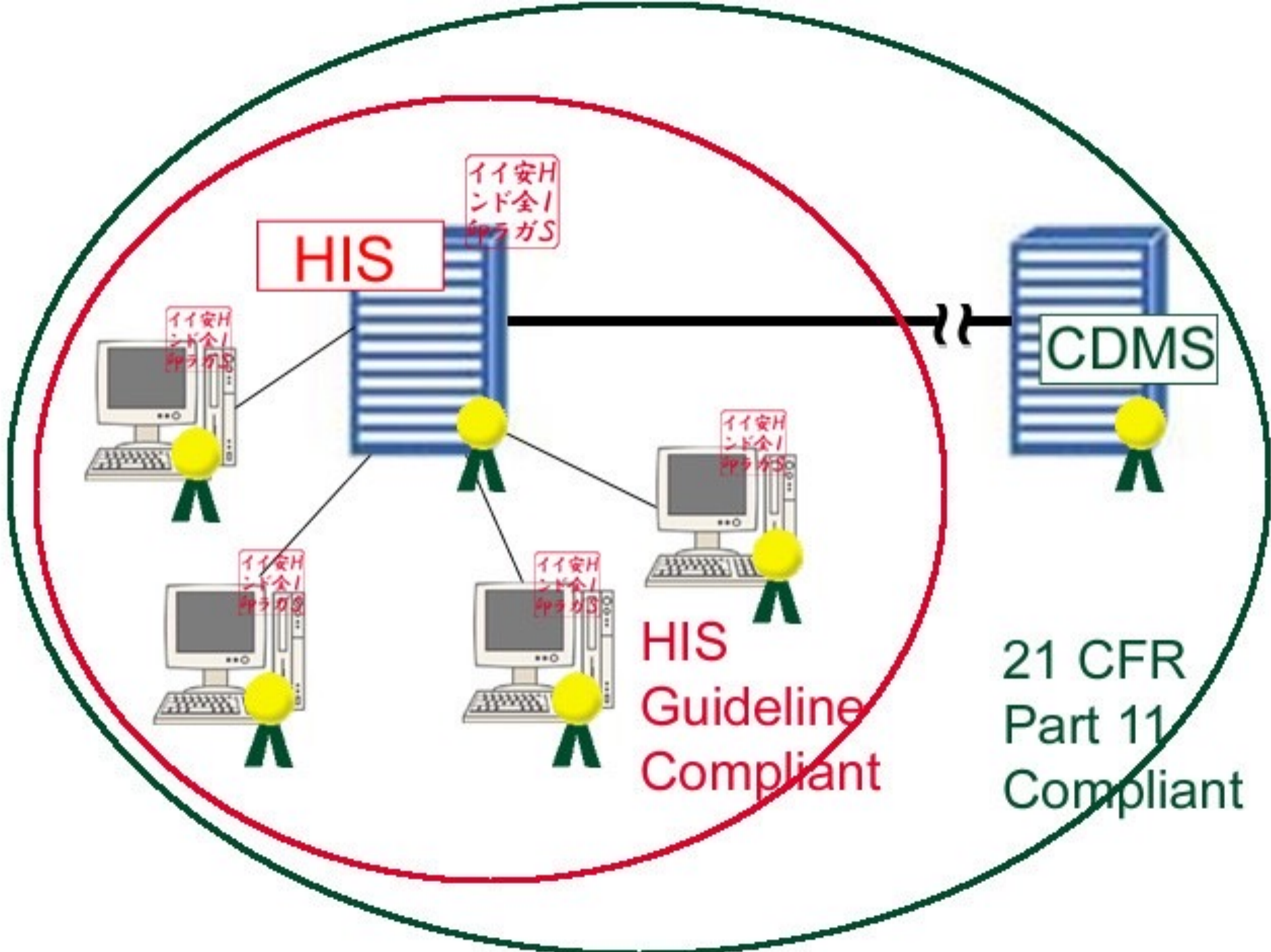


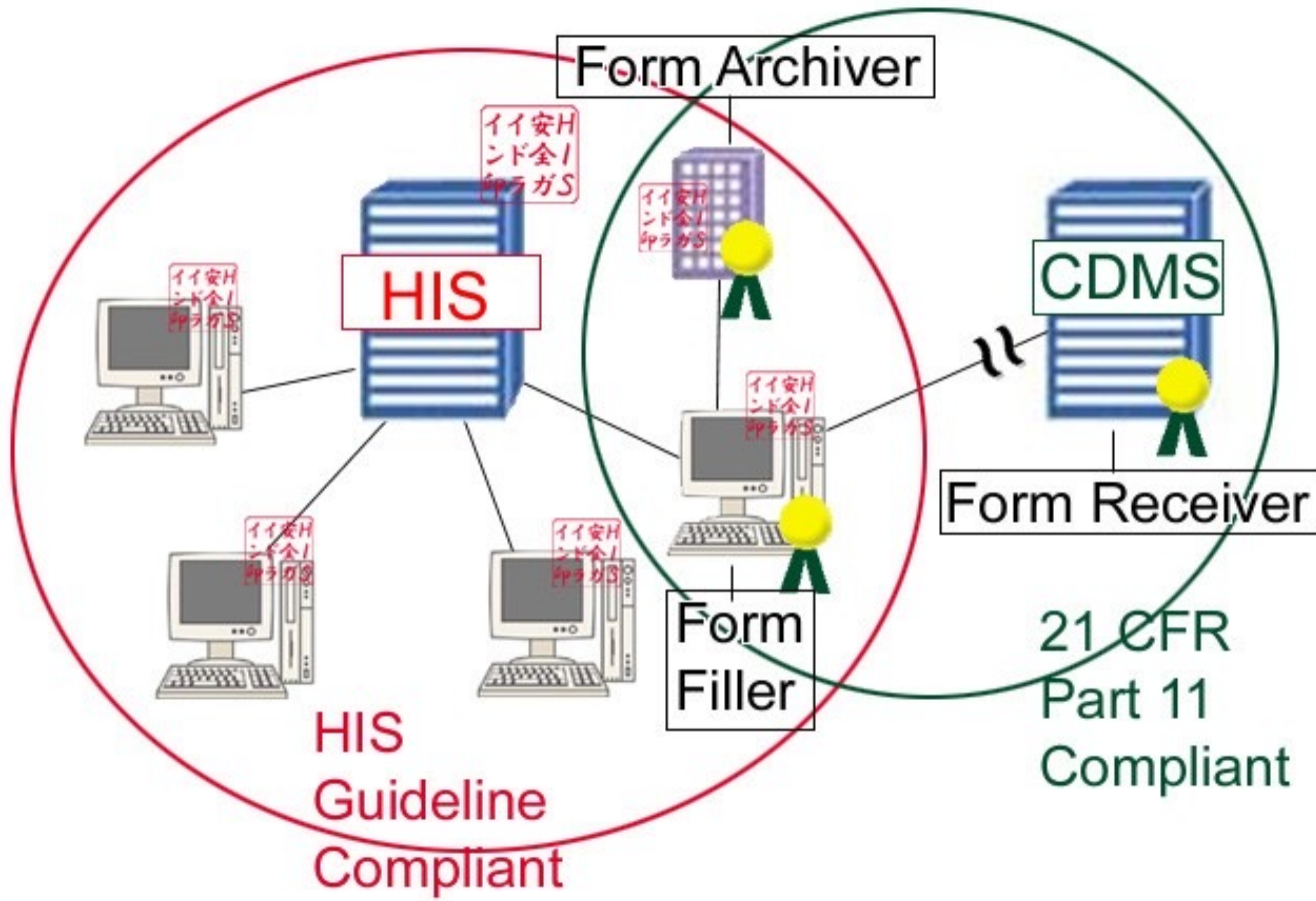
# RFD connection demo



- 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.







Form Archiver

HIS

CDMS

Form Receiver

Form Filler


HIS  
Guideline  
Compliant

21 CFR  
Part 11  
Compliant

# Demo at CDISC Interchange 2008, Arlington



# Adverse event detection and clinical indicator based on nationwide standardized HIS-export infrastructure (SS-MIX storage)



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Hamamatsu University, School of Medicine

JAMI, president

HL7 Japan, chair

IHE international, board


Used Slides at CDICS Singapore Interchange 2013

# CPOE(Computerized Physician's Order Entry) 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
  - Ministry of Health standard designation ...March 2010
    - HL7 v2.5, HL7 CDA R2, DICOM and IHE PDI, Codes (ICD10, drug code, lab exam code)

# Patients covered by SS-MIX storage (2012/3)

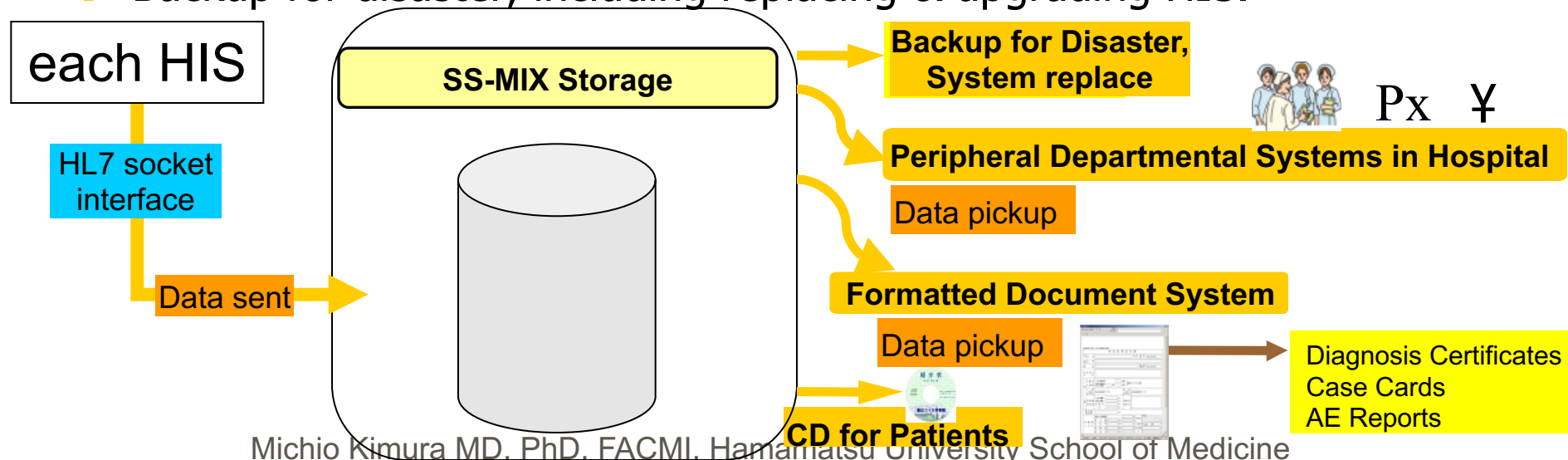


- 70 hospitals are storing both prescriptions and lab results
- Average hospital patients numbers (7000 new patients)
- Average years of storage (2)
- 1,500,000 patients (considering duplication).

# Ministry of Health Project: SS-MIX: HL7 standardized clinical information storage Wide variety of applications

■ We have patient demographics, prescriptions & injections, lab results, diagnosis classifications in HL7 v2.5

- PHR
- Making documents, including case cards
- Clinical database
- Interoperability with peripheral departmental systems
- Backup for disaster, including replacing & upgrading HIS.



# Ministry projects on SS-MIX storage



- MoH and PMDA's MIHARI and MID-NET (Japan Sentinel)
- MoH's regional healthcare information sharing (Noto, Urasoe, Miyako)
- METI(Economics, Trade, Industry)'s "My Hospital, Everywhere" project (Noto)
- MoE's 42 national university hospital EMR backup.



# Clinical Information Retrieval System: D\*D

10 years,  
73,709,298  
records of  
prescription,  
lab results,  
diagnosis  
classifications  
at  
Hamamatsu  
Univ. Hosp.  
Searchable in  
time  
sequence in a  
few minutes

臨床研究DBシステム

患者検索 文字列検索 複合検索

患者条件 検査条件 処方条件 注射条件  
病名条件 入院条件 処方条件

■ 検索条件 ■

検査条件 -- [期間:すべて]  
FBS(60以下)

and

処方条件 -- [期間:すべて]  
薬品 = ☆[糖尿]アマリール1mg  
or 薬品 = ★[糖尿]アマリール3mg

and

サラ条件 -- [期間:すべて]  
合併症:昏睡歴 有

検索開始 クリア 検索設定 条件保存  
チェックした条件をクリア 条件読出

■ 検索結果 ■ 1~4/4件中 (16.08秒)

患者番号	氏名	性別	年齢
07	■■■■■	女性	76
22	■■■■■	男性	66
23	■■■■■	女性	60
50	■■■■■	女性	80

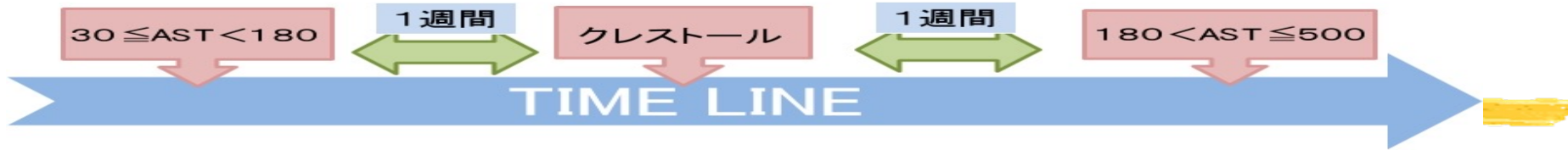
[XML出力](#) [プリント](#)

ページが表示されました

イントラネット

臨床研究DBシステム

# Search example



■ 検査結果一覧      対象期間: 2007年3月から 2010年2月まで      検査結果表示      閉じる

患者ID: [REDACTED]      漢字氏名: [REDACTED]      カナ氏名: [REDACTED]      生年月日: [REDACTED]      性別: 男性

検査名称	基準範囲	単位	05/01		05/05	05/08	05/12	05/15	05/19	
			1回目	2回目				1回目	2回目	
総蛋白	6.7-8.1	g/dl	7.2		6.8	7.0	7.5	7.2	7.4	
アルブミン	4.1-5.1	g/dl	4.1		4.0	4.0	4.4	4.1	4.2	
A/G比	1.00-2.00		1.32		1.43	1.33	1.42	1.32	1.31	
チモール(TTT)	0.7-8.3	KUNDEL単位	1.6							
CK(CPK)	55-204	IU/l	145		73	70	57	47	57	
AST(GOT)	11-30	IU/l	22		17	14	17	15	15	
AST/ALT比			1.4		1.1	1.2	1.2	1.4	1.5	
ALT(GPT)	5-42	IU/l	16		15	12	14	11	10	
LD(LDH)	115-208	IU/l	187		191	201	187	157	147	

単位: IU/l

Done      Local intranet

start      ShizuokaEHR      臨床研究DBシ...      検査結果一覧...      JP      A 般      13:53

Listing up of patients, with AST:30-180 one week before the first prescription of “Crestor” (Rosuvastatin, anti-hyperlipidemia), then AST elevated to 180-500 within one week

"pravastatin (or others, any titer) and AST > 150 subsequently within 2 weeks"

Search result: 83 patients, search time 112.22 seconds

Patient list shows a selected patient has "HIT" prescription twice, 1997/10/22, and 10/29, and graph of AST show peak high value recorded on 1997/11/04, within two weeks of the medication.

Mevalotin (Pravastatin) and other generic drugs prescribed, and within 2 weeks, recorded AST > 150

Result: 83 patients, search time 112.22 seconds

List of patients, with "sequence" timing dates. First patient has "HIT" sequence timing twice, 1997/10/22, 1997/10/29

AST=176 on 1997/11/04

The screenshot shows a Microsoft Internet Explorer browser window displaying a clinical database search interface. The main window is titled "臨床研究DBシステム(時系列検索) - Microsoft Internet Explorer". The search criteria are defined as follows:

- 患者条件 (Patient Conditions): 期間: すべて (Period: All)
- 副条件範囲 (Sub-condition Range): 当日から2週間後 (From the day to 2 weeks later)
- 検査条件 (Test Conditions): 期間: すべて (Period: All)
- 副条件 (Sub-condition): AST(GOT) (150以上) (AST(GOT) (150 or more))
- 処方条件 (Prescription Conditions): 期間: すべて (Period: All)
- 主条件 (Main Condition): 薬品 = ☆メバロチン/錠5mg (Drug = ☆Mevalotin/5mg tablets)

The search results show 83 patients. The first patient (ID 00000004) is highlighted. The list shows the following sequence of dates and genders:

- 1997/10/22 (Male)
- 1997/10/29 (Female)
- 1997/10/29 (Female)
- 1997/10/29 (Male)
- 1997/10/29 (Female)
- 1997/10/29 (Male)
- 1997/10/29 (Male)
- 1997/10/29 (Male)
- 1997/10/29 (Male)
- 1997/10/29 (Male)
- 1997/10/29 (Male)

The "指定条件処方履歴" (Prescription History for Specified Conditions) table shows the following data:

処方日付	診療科	用量	服用方法	回診/日数
1997.09.23	一内	1錠	1日1回朝食後	2日
1997.09.25	一内	1錠	1日1回朝食後	7日
1997.10.01	一内	1錠	1日1回朝食後	7日
1997.10.08	一内	1錠	1日1回朝食後	7日
1997.10.15	一内	1錠	1日1回朝食後	7日
1997.10.22	一内	1錠	1日1回朝食後	7日
1997.10.29	一内	1錠	1日1回朝食後	7日
1997.11.05	一内	1錠	1日1回朝食後	7日

The "検査結果" (Test Results) table shows the following data for AST (GOT):

検査名称	基準範囲	単位	08/13	08/21	08/27	08/29	09/01	09/11	09/16	09/22	09/29	U/L
AST(GOT)	11-30	IU/L	28	26	35	30	27	30	27	26	41	

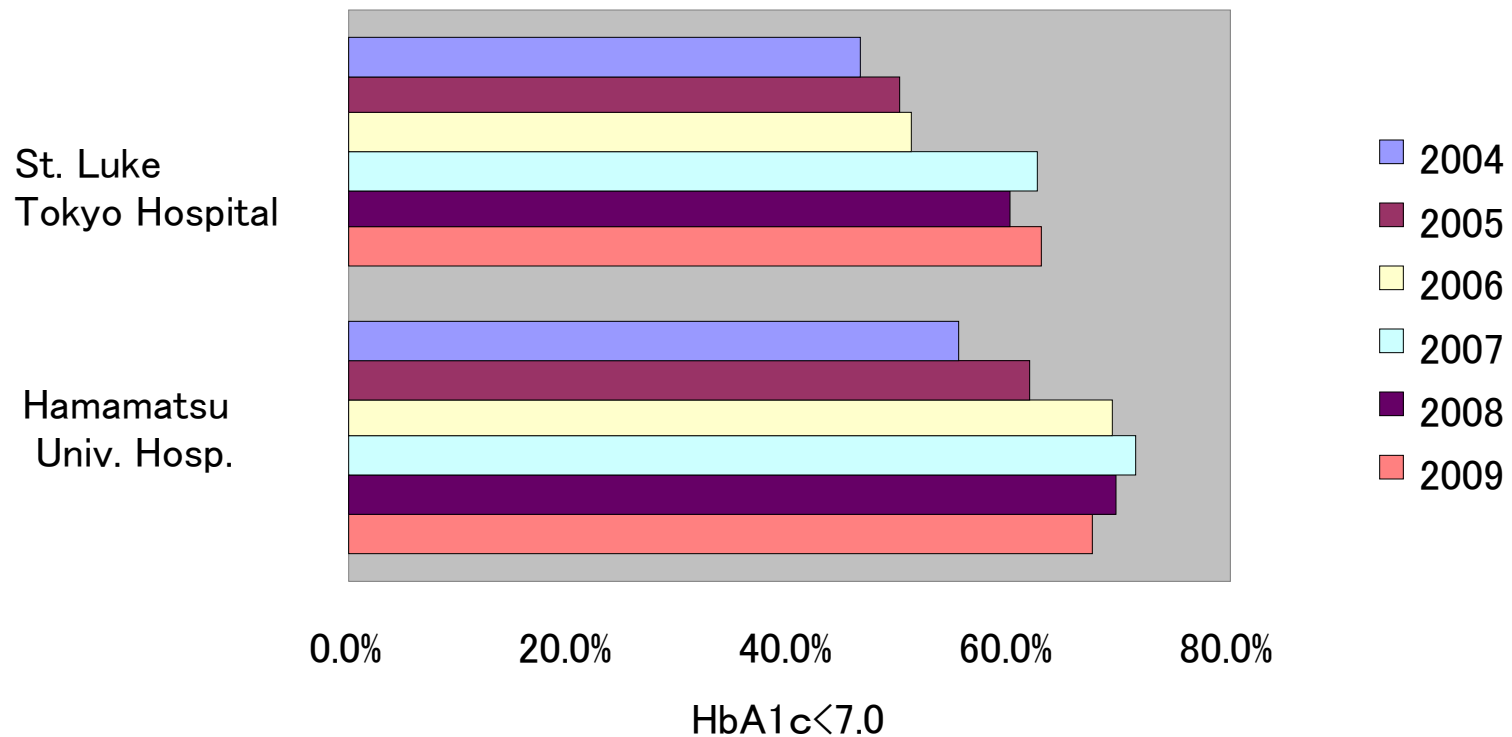
The graph shows the AST (GOT) trend for the patient. The Y-axis represents AST (GOT) in IU/L, ranging from 0 to 180. The X-axis represents dates from 1997/08/13 to 1997/12/15. A significant peak is observed on 1997/11/04, with a result value of 176 IU/L.

# Other examples at Hamamatsu Univ. Hosp.

- In 2007, patients recorded HbA1c=6.6-8.0, and re-examined within 3 weeks
  - -5.8: 55 cases, 5.9-6.5: 289 cases, 6.6-8.0: 657 cases, 8.1+: 192 cases
- Gemzar (Gemcitavin for cancer) first prescription: 181 cases in 2007
  - Then, diagnosed as interstitial pneumonia (ICD-10 J84.x) : 7 cases
- Stroke onset, and recurrence within 3 years?
  - “Stroke” is a disease used for the reason to examine CT or MRI, which includes full of noises.

# Hospital performance indicators

## HbA1c control of diabetes patients by the year



# Japan's Cabinet's New IT Project “Pharmacovigilance by HIS data”

- PMDA(FDA of Japan) already launched 5 year project in 2009
- Court order of slow disqualification of hepatitis C virus contaminated drug case, and Drug rag problem
- “Not only pre market clinical trials, post market surveillance, spontaneous report, also HIS data should be utilized”
  - HL7 standardized SS-MIX infrastructure makes reporting easier

# Protocol example

## ■ Neuroleptic Malignant Syndrome by Olanzapine (Zyprexa<sup>R</sup>)

■ ICD10: G210

■ CPK > 1000

■ 3 cases out of 323 (0.97%)

Michio Kimura MD, PhD

候補テーマ①：オランザピンによる悪性症候群

対象者検索条件(新規処方症例)

主条件

A) 対象期間:2007年7月1日～2010年1月31日

B) 対象薬:オランザピン<sup>※1</sup>の処方あり

C) 投与時年齢:20歳以上

除外条件

D) 対象期間:2007年4月1日～2007年6月30日

E) 対象薬:オランザピンの処方あり

投与時年齢設定なし□

対象者 条件式: {A) and B) and C)} not { D) and E) }

ケース検索条件(副作用発現症例)

a) 病名:オランザピンの全処方から□2か月以内に悪性症候群(ICD10:G210)確定診断あり

主条件

b) 臨床検査値:□オランザピンの全処方から2か月以内にCPK1000 IU/L以上

除外条件

c) 臨床検査値:オランザピンの初回投与3週間前にCPK1000 IU/L以上

d) 処方:オランザピンの全処方から2か月以内にダントロレンナトリウム(注射薬)<sup>※2</sup>の処方あり

ケース 条件式: [ a) or { b) not c) } or d) ] and 対象者

# Measured and confirmed adverse events in step 2

- “Low Na after Thiazide diuretics” (59 cases out of 2303 first prescriptions, 2.6%)
- “Low K after Thiazide diuretics” (17 cases out of 2303 first prescriptions, 0.7%)
- “Low white cell after H2 receptor antagonists” (545 cases out of 35846 first prescriptions, 1.5%)
- “Low platelet after H2 receptor antagonists” (103 cases out of 35846 first prescriptions, 0.3%)
- “Peripheral nerve disturbance after Statins (HMG-CoA inhibitors)” (206 cases out of 8735 first prescriptions, 2.4%)



# Evaluations of this trial



- \*Time and effort for this trial are very low. It took one day in each hospital to search all five hypotheses.
- \*Detection by lab results is easily done, while detection by diagnostic disease involves noises.
- \*This method gives us population, total number of prescribed patient, which gives us real percentage.
- \*Percentage of patients with bad general condition is high in the five hospitals, as they are all large acute care hospitals. The cause of cytopenia may be because of this, not by the prescriptions.

# A New HIS Network Project by MHLW/PMDA (MID-NET project)(former, Sentinel Japan)

- Drug safety assessment and validation from 10,000,000 patients (hopefully)
- Budget 1.1 B yen(\$15M) for 2012
  - 3 year total 2.6 B yen
  - Planned to be applied to 10 core hospitals including Hamamatsu University hospital
    - These hospitals cover 2,000,000 patients
  - Based on the clinical search database D\*D, which was used at MIHARI in Shizuoka
- "CPOE based" means AE can be detected real time without delay (weekly protocol dispatch, planned)



### ロンドンの先に

日本サッカーの夏

【総合政治】 2



### 就活 夏に総点検

反省点を次に生かす

【大 学】 10

# 日本経済新聞

8月13日

月曜日

発行所・日本経済新聞社  
東京本社 電話(03)3270-0251  
〒100-8161 東京都千代田区千代田1-3-7  
大阪本社 電話(06)6943-7111  
名古屋支社 電話(052)243-3311  
西部支社 電話(092)473-3300  
札幌支社 電話(011)281-3211



Daiwa Lease  
大和ハウスグループ

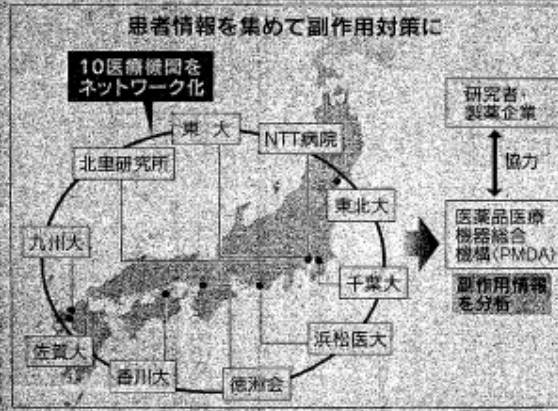
リースを通じて、  
未来をつなぐ。

# 薬、安全性向上へ10機関

## 国の副作用データベースに参加 1000万人分蓄積

厚生労働省は医薬品の安全性を高める目的で患者情報を集める。今年度から東大病院など10の医療機関と連携し、2015年度までに患者名で1000万人規模のデータベースを作成。副作用の発症率や被害状況を分析する。日本では薬を服用した人数を調べる手段がなく、副作用への対応が遅れが懸念されている。患者情報の収集を薬害の全容把握や、副作用の少ない薬の開発に生かす。

大学病院のほかNIT病院、徳洲会病院も参加する。12年度はまず大抵の手。13年度までに、10機関が持つ情報システムを厚生労働省が導入するデータベースに接続し、収集を本格化する。蓄積するのは、カルテに記載した情報を中心に、何名か各種の検査結果、処方した薬とその副作用など。病院が医療費の支払いを請求するために行う診療報酬明細書(レセプト)の情報も集める。患者の同意を得たうえで、個人が特定できないようにする。情報は独立行政法人、医薬品医療機器総合機構(PMDA)や研究者が自由に引き出して分析できるようにする。



現状では、特定の薬の利用状況を知るには、メーカーが出荷数量などで推測するしかなく、PMDAは薬事法に基づいて副作用の情報を集めているが、薬害の副作用に気が付いた製薬会社や医師から報告を受ける仕組みがない。2012年度予算案の筋を通じたともいえる。民主党内だけでなく、野党の自公両党にもばらつき懸念が浮く。3党のうち社会保険費は20兆円、厚生労働省が負担する。4千億円と、地方交付税制度の国費を除くその他繰出の合計が、新入国費をまかす。それをまかす。

### 消費増税

#### 再生への一里塚

常識では理解しにくい。増税をつらななければならぬ。思惑も踏まえて国会議員。企業経営を直撃する。民主党に。6月26日の衆院本会議で社会保障増税を採らざる。民主党は消費税増税を採らざる。民主党は消費税増税を採らざる。

### 年金・医療ばら

筋を通じたともいえる。民主党内だけでなく、野党の自公両党にもばらつき懸念が浮く。3党のうち社会保険費は20兆円、厚生労働省が負担する。4千億円と、地方交付税制度の国費を除くその他繰出の合計が、新入国費をまかす。それをまかす。


# “Pharmacovigilance by HIS data” pros & cons



- “Early detection of side effects” will be welcomed by citizens
- Japan’s high percentage of CPOE makes advantage
- Based on “all case data”
  - less selection bias
  - we have population counts
- Easy importable information is Px history, lab results. Disease classifications are doubtful, and symptom and sign descriptions are difficult.

# Getting data out of HIS in a standardized way

- Healthcare Link in Japan



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HL7 Japan chair  
IHE Int'l board  
JAMI past President

Used Slides at CDICS Chicago Interchange 2015

# How to save doctors from duplication input

EMR



3. Archived with notes as medical record for audit

1. Case card XML schema, stamped, some items filled from HL7 storages, 518 hosps. in Japan

4. eCRF

2. Additional notes of medical record

# Diabetes case card schema on EMR (data type is controlled)

MegaOak HR 浜松 太郎 (医師) 前回ログイン 2013/05/23 17:09

お気に入り 一覧 照会 予約 発行 看護 パス ツール その他 レジメン

基本スタンプ 好患者一覧

90000035 男性 1950(S25)年01月01日生(63歳4ヶ月) 患者基本 2012/04/30~入院中 心療内科 2階東病棟 62 主保険 自動選択 付箋

診察記事

上に挿入 下に挿入 ツール お気に入り MS Pゴシック 12 B I U

2013年05月23日(木)

ROOT¥スタンプ群¥(記事)透析

ROOT

スタンプ群

(記事)

(記事)

(記事)

(記事)

(記事) 透析予防スタンプ

(記事) 透析予防スタンプ

(記事) 透析予防スタンプ

HbA1C  
HbA1C = 6.4 % 検査日: 2013/05/23

クレアチニン  
クレアチニン = 0.87 mg/dl 検査日: 2013/05/23

尿蛋白  
尿蛋白 = 1+  
検査日: 2013/05/23

血圧  
Max: mmHg  
Min: mmHg

やめる(○) 全表示 やめる 確定(✓) 確定(✓)

院内 心療内科 浜松 太郎

Rp01  
チラーヂンS錠 50μg 3 T  
..1日3回 朝・昼・夕 食後 7日

14:07  
処方指示

¥¥172.19.1.23¥s... プレゼンテーション... MegaOak HR ... 診察記事 (記事) 透析予防... 17:57

# Schema contents are archived as EMR

The screenshot displays a medical EMR system interface. At the top, the user is identified as '浜松 太郎 (医師)' (Hiratsuka Taro, MD) with a login time of 2013/05/23 12:12. The patient's information includes ID 90000035, name テスト 35 (Test 35), age 63, and sex male. The patient is currently hospitalized in the Cardiology department (心療内科) on the 2nd floor of the East Building (2階東病棟). The interface shows a navigation menu on the left with options like '記事入力' (Article Input) and 'スタンプ抽出' (Stamp Extraction). The main area displays a list of medical history entries (診療記事) for the patient, with the selected entry dated 2013年05月23日 (Thursday). The entry details include a consultation with Dr. Hiratsuka Taro (心療内科) at 15:46, a note about dialysis prevention stamps, and laboratory results for HbA1c (6.4%), creatinine (0.87 mg/dl), and urine protein (1+). Below the text, there are sections for '処方指示' (Prescription Instructions) for three dates: 2013/05/28, 2013/06/04, and 2013/05/28. Each section lists the medication 'チラーヂンS錠 50μg' (Chlorthalidone tablets) with a dosage of 3 tablets per day, to be taken after meals. The interface also includes a sidebar with various icons and a bottom taskbar with system icons and the time 15:46.



# And schema contents go to DB (xls)

The screenshot displays a medical information system interface. At the top, the user is identified as 浜松 太郎 (Hiratsuka Taro), a doctor, with a login time of 2013/05/23 12:12. The patient record for 90000035 (Test 35) is shown, including a photo and personal details. A navigation bar contains various menu items like 'お気に入り' (Favorites), '一覧' (List), '照会' (Inquiry), '予約' (Reservation), '発行' (Issuance), '看護' (Nursing), 'パス' (Pass), 'ツール' (Tools), and 'その他' (Others). A sidebar on the left offers options like '記事入力' (Article Input) and 'カルテ切替' (Chart Switch). The main window shows a Microsoft Excel spreadsheet titled '検査結果時系列.xlsx' (Lab Results Time Series). The spreadsheet contains the following data:

	A	B	C	D	E	F	G	H	I	J	K	L
1		採取日	2012/10/11	2012/12/13	2013/1/11	2013/5/23						
2	蛋白質		1+	1+	-	1+						
3	クレアチニン	0.70-1.17 mg/d	1.06	0.86	0.70	0.87						
4	HbA1c(NGSP)	4.6-6.2 %	5.9	6.0	5.8	6.4 H						
5	血圧 H		142	152	140	144						
6	血圧 L		94	92	96	102						

The Excel window also shows the ribbon with tabs for 'ファイル' (File), 'ホーム' (Home), '挿入' (Insert), 'ページレイアウト' (Page Layout), '数式' (Formulas), 'データ' (Data), '校閲' (Review), and '表示' (View). The status bar at the bottom indicates the time is 14:07 and the active window is '処方指示' (Prescription Instruction).


# Where are we now?

- MID-NET is marketed by PMDA
  - Only good for drugs which can be evaluated by prescriptions and lab results
    - which are about 1/4 of all
  - COI of PMDA, approve and examine
- We have prescription, lab results
  - forward to injection record, reports of examinations (must be structured and vocabulary controlled) , then to signs and symptoms.

# Through 15 years



- For safety guideline problem, IHE RFD profile may sort out the barriers of participating systems.
- For context difference, prescription and laboratory result data look like context free object both for clinical use and secondary use. MID-NET project of PMDA depends on this, but adverse event detected only by them are limited.

- 
- For doctors' note contents, template use may help without increasing doctors burdens.
  - For additional feature investment justification, Ministry designation of standards to be used for exporting patient data was helpful, for the case of SS-MIX standard storage by HL7 v2.5 prescription and laboratory data.

# Needs validations



- MID-NET is good for early detection, but to confirm, validated records are needed
  - MID-NET does SDV to SS-MIX storage of prescription and lab results
    - which limits the number of participating hospitals
    - Kyushu University is now submitting experienced validation methods to ISO as TR
- We need validation guidelines.

# Then, HL7 FHIR breaks!



# FHIR Connect-a-thon

Table Number	TRACK
31	At Home In Vitro Test Report
32,33	BIDirectional Services eReferrals (BSeR)
81	CARIN
66,76	C-CDA to FHIR Mapping Track
22	Clinical Genomics
23	Clinical Info Modeling Initiative (CIMI) Lab Sub-types IG
15,16,34,35,36	Clinical Reasoning
21	Cohort Definition
24	Coordinating Care for Patients with Chronic Conditions
42,43,52	Da Vinci Burden Reduction (BR) Track
53	Da Vinci CDex: Attachments, Task-Based, and Direct Queries
64	Da Vinci Member Attribution List
54	Da Vinci Patient Cost Transparency
63	Da Vinci Payer Data Exchange (PDex) and Formulary
61	Da Vinci Risk Adjustment
62	Da Vinci Value-Based Performance Reporting
84	Devices
72,73	FAST Infrastructure (Security & Identity)
71	FAST National Directory of Healthcare & Da Vinci Plan Net
13,14	Gravity SDOH Exchange
10	Helios Aggregate Data Track
11	Helios Align & Optimize Framework
50	International Patient Access (IPA)
40	International Patient Summary
41	Med Morph - Flu Surv-NET - Health Care Surveys
15	Patient Track
12	Physical Activity Track
74,75	Protocols Uniform Data System Pt-Level Submission (UDS+)
60	Questionnaire
55,65	SQL-on-FHIR
82,83	TEFCA Facilitated FHIR
	Testing FHIR with Test Artifact (TestScript) Versioning,
51	Calibration, Equivalency of Tools
70,80	US Core Testing Track
21	Vulcan Schedule of Activities
20	Vulcan/Gravitare Health - ePI/IPS (Phase 6)
30	Vulcan - ICH M1 CESHIP IG



# Good things on FHIR



- You can find programmers on RESTful and JSON, compared to HL7 v2 `|`
- Each resource are structured, need only tab and value vocabulary control
- US government funds.



# Bad things on FHIR



- 80% rule, less rigid standard
- Hundreds of implementation guidelines for each project
  - Software for FHIR implementation at project A would not fully usable at project B
- https: protocol can send 1GB studies of MRI?.

# Final remarks



- Slowly advancing,
  - first, prescriptions and lab results
  - second, examination reports, if structured
  - then, we can get narrative things
    - Can AI(Natural Language Recognition) help?
- Validation standards/guidelines needed
- Looking for early detection? or evidence for approval/clinical practice?
  - Certainty, validity depend on the purpose.