Seeking Healthcare Datalink for 15 years with Standards

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HL7 Japan Chair, IHE Int'l Board
ISO TC215 WG2, Science Council of Japan

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)

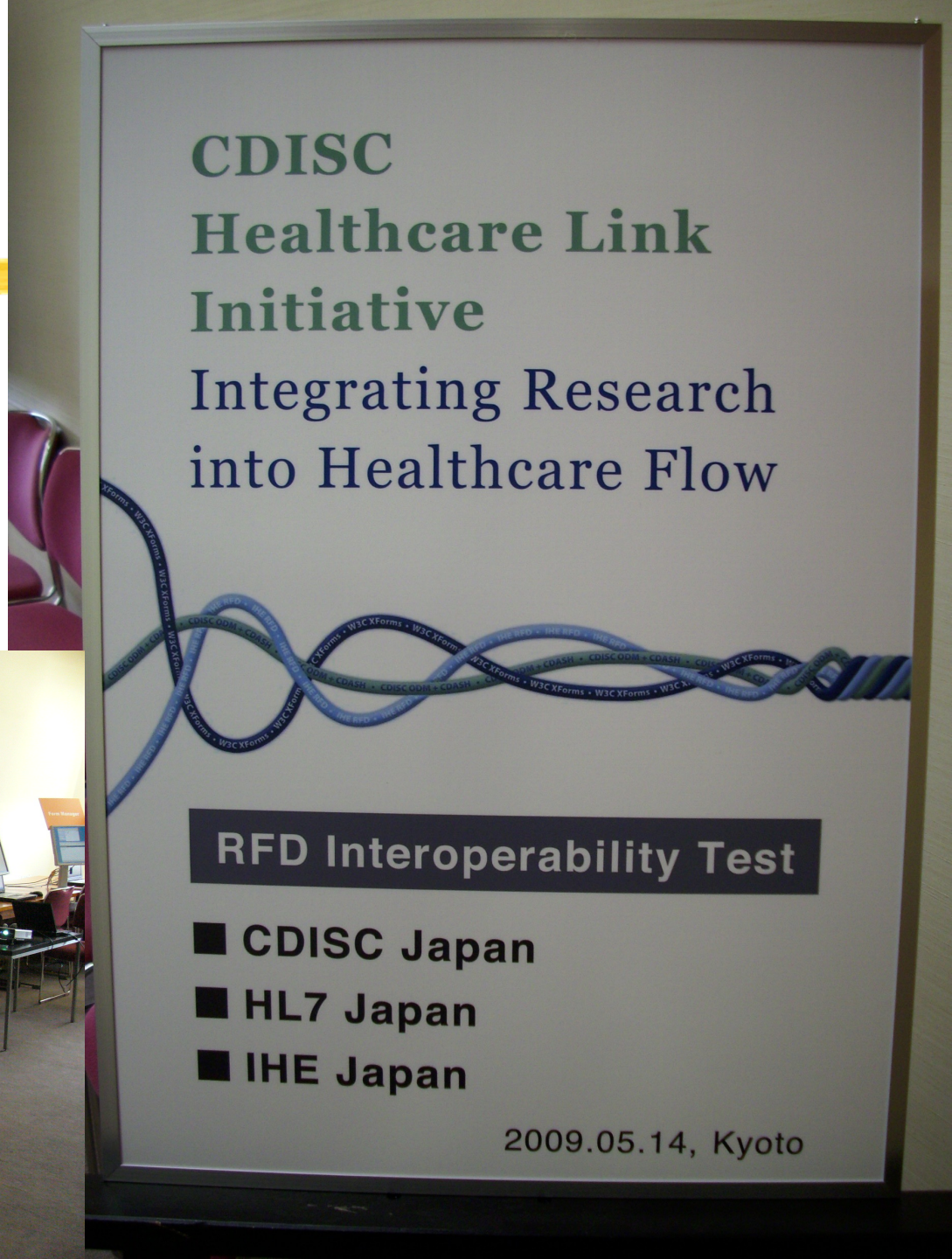
with Ministry Project SS-MIX, at HL7 Kyoto Working Group Meetings

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

672
CDISC
Healthcare Link
Initiative
Integrating Research
into Healthcare Flow
RFD Interoperability Test
CDISC Japan
HL7 Japan
IHE Japan
2009.05.14, Kyoto


CDISC
Healthcare Link
Initiative
Integrating Research
into Healthcare Flow
RFD Interoperability Test
CDISC Japan
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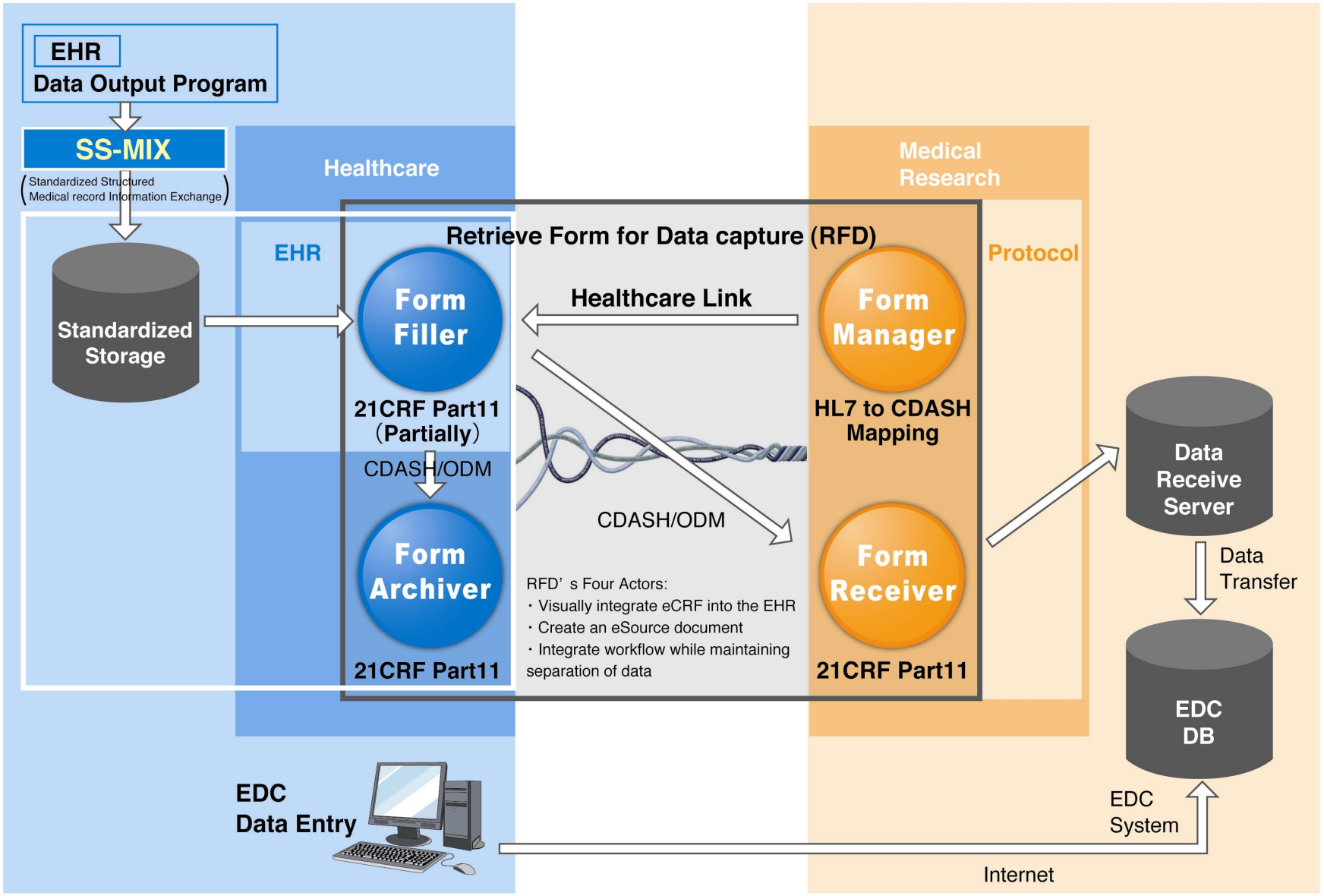
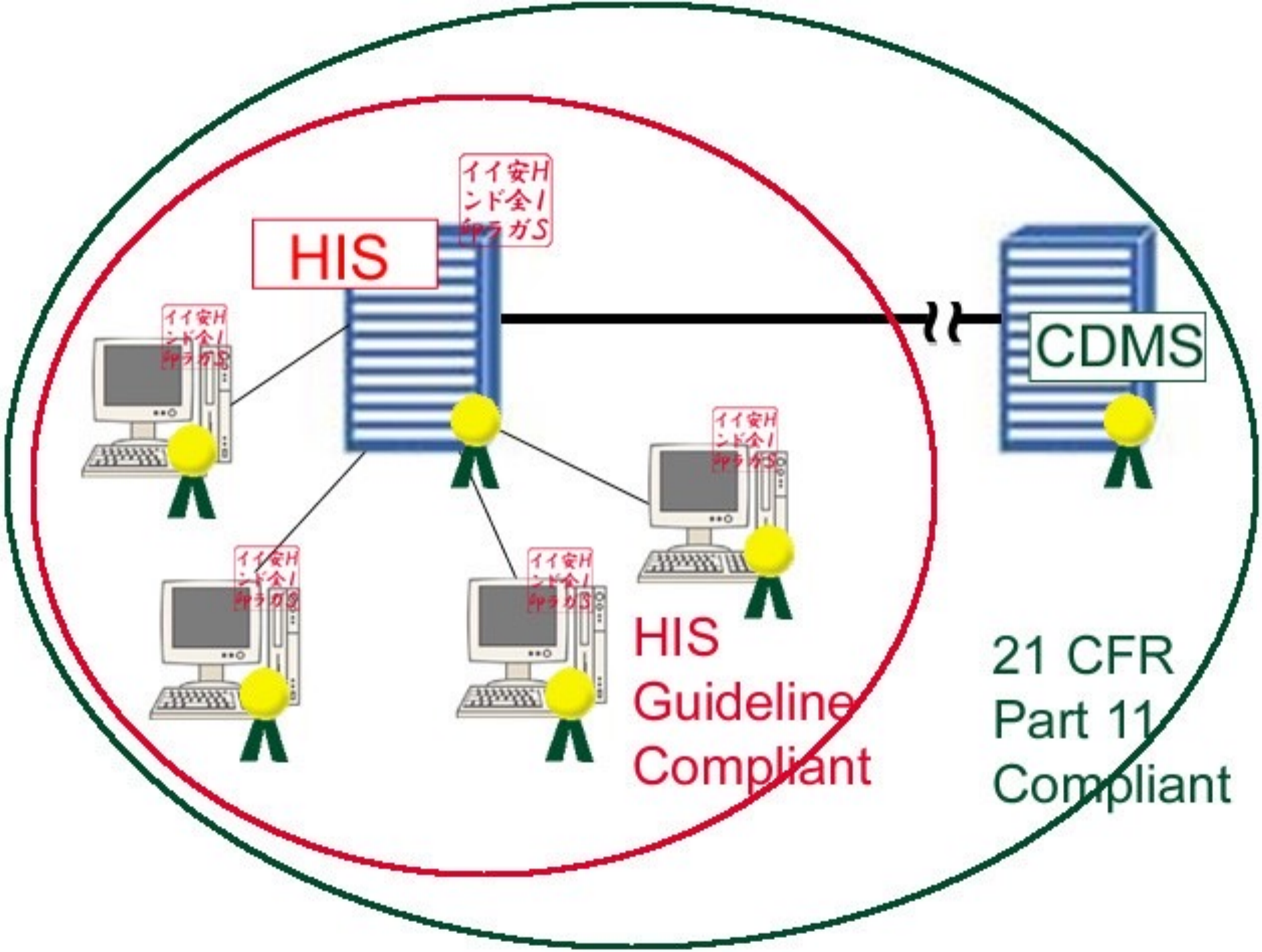
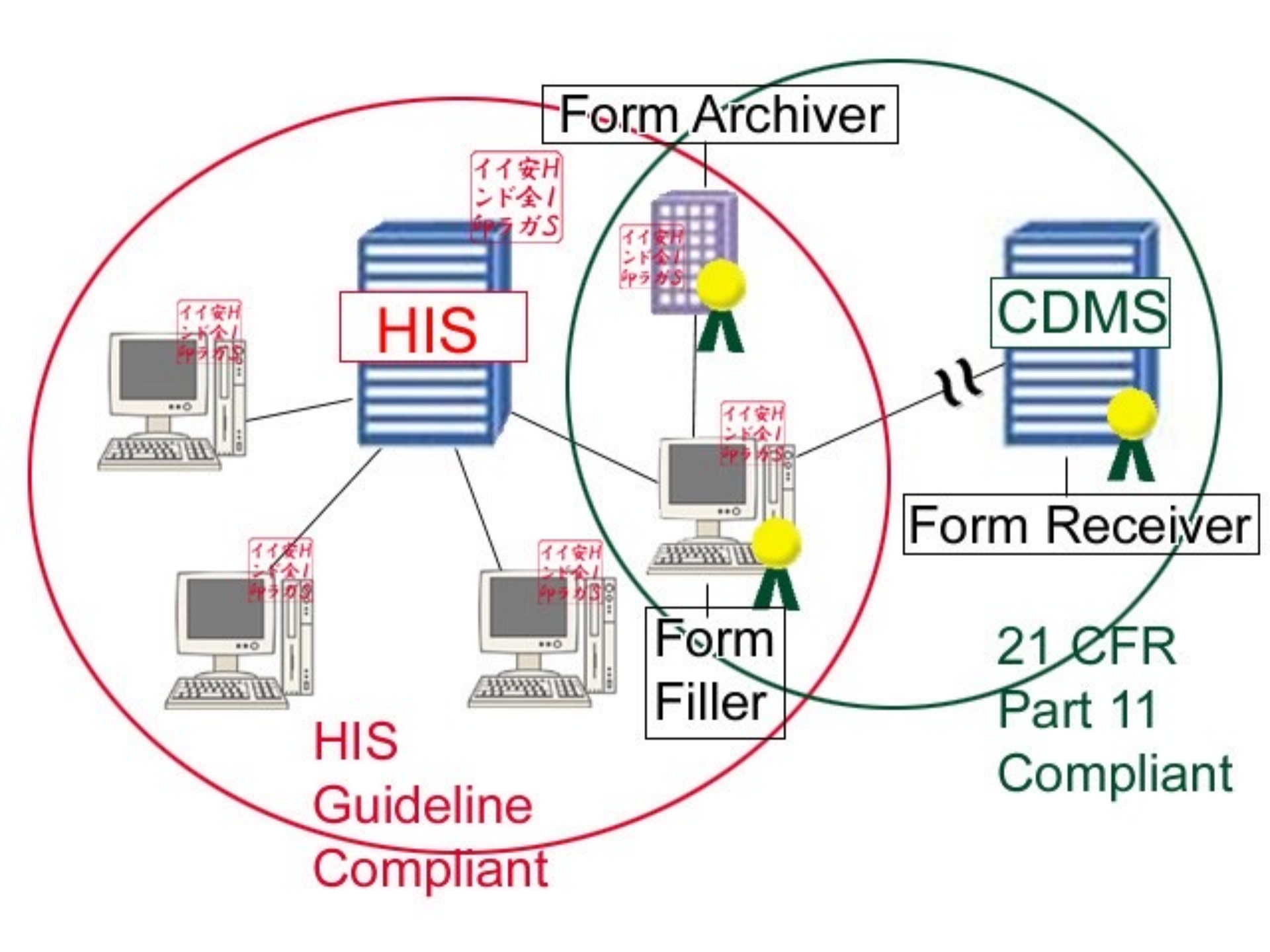
2009.05.14, Kyoto


EHR
Data Output Program
SS-MIX
Standardized Structured
Medical record Information Exchange
Healthcare
Medical
Research
EHR
Retrieve Form for Data capture (RFD)
Protocol
Standardized
Storage
Form
Filler
Healthcare Link
Form
Manager
21CRF Part11
(Partially)
HL7 to CDASH
Mapping
CDASH/ODM
CDASH/ODM
Data
Receive
Server
Form
Archiver
Form
Receiver
RFD's Four Actors:
・Visually integrate eCRF into the EHR
・Create an eSource document
・Integrate workflow while maintaining
separation of data
Data
Transfer
21CRF Part11
21CRF Part11
EDC
DB
EDC
Data Entry
EDC
System
Internet

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.


HIS
CDMS
HIS
Guideline
Compliant
21 CFR
Part 11
Compliant


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)

Michio Kimura, MD, PhD
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

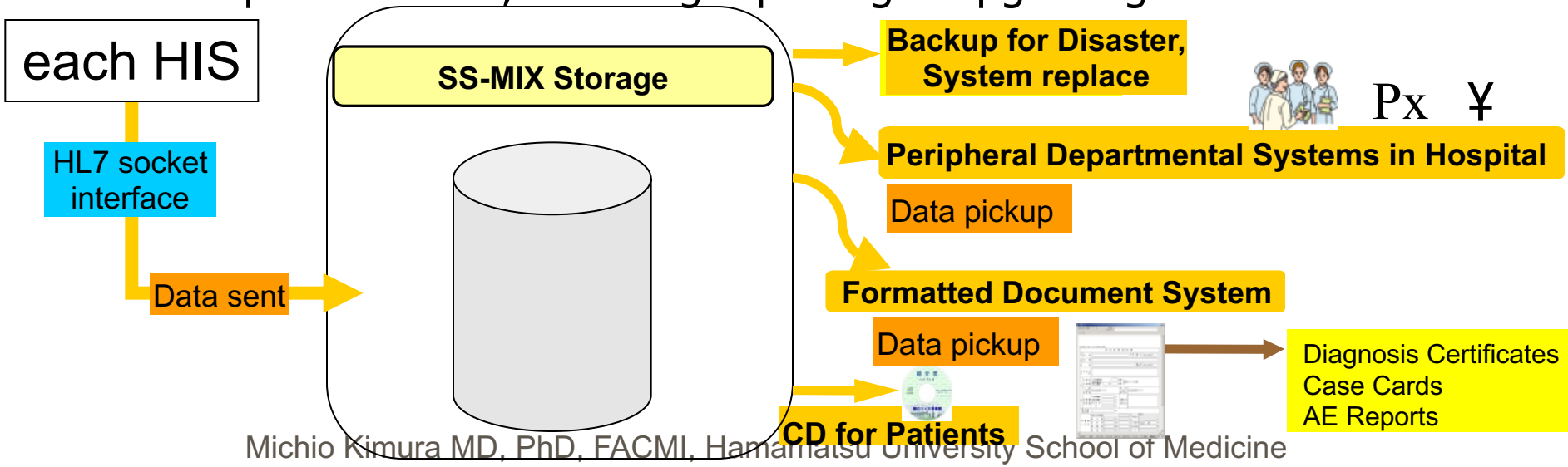
- 90%+ in large hospitals (400+ beds)
- Top 2 vendors became able to export patient demographics, prescriptions, lab results, diagnoses, in HL7 v.2 messages
  - Ministry of Health standard designation ...March 2010
    - HL7 v2.5, HL7 CDA R2, DICOM and IHE PDI, Codes (ICD10, drug code, lab exam code)

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

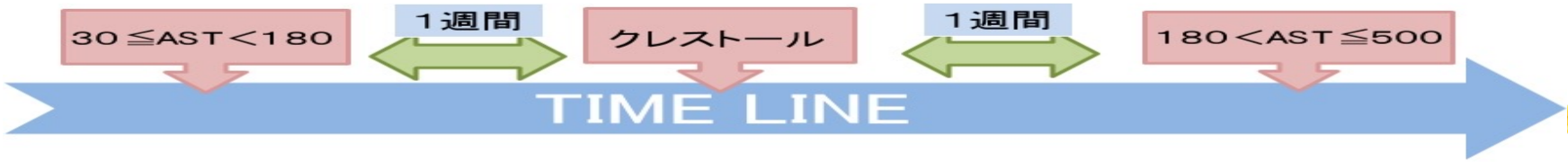
- MoH and PMDA's MIHARI and MID-NET (Japan Sentinel)
- MoH's regional healthcare information sharing (Noto, Urasoe, Miyako)
- METI(Economics, Trade, Industry)'s "My Hospital, Everywhere" project (Noto)
- MoE's 42 national university hospital EMR backup.

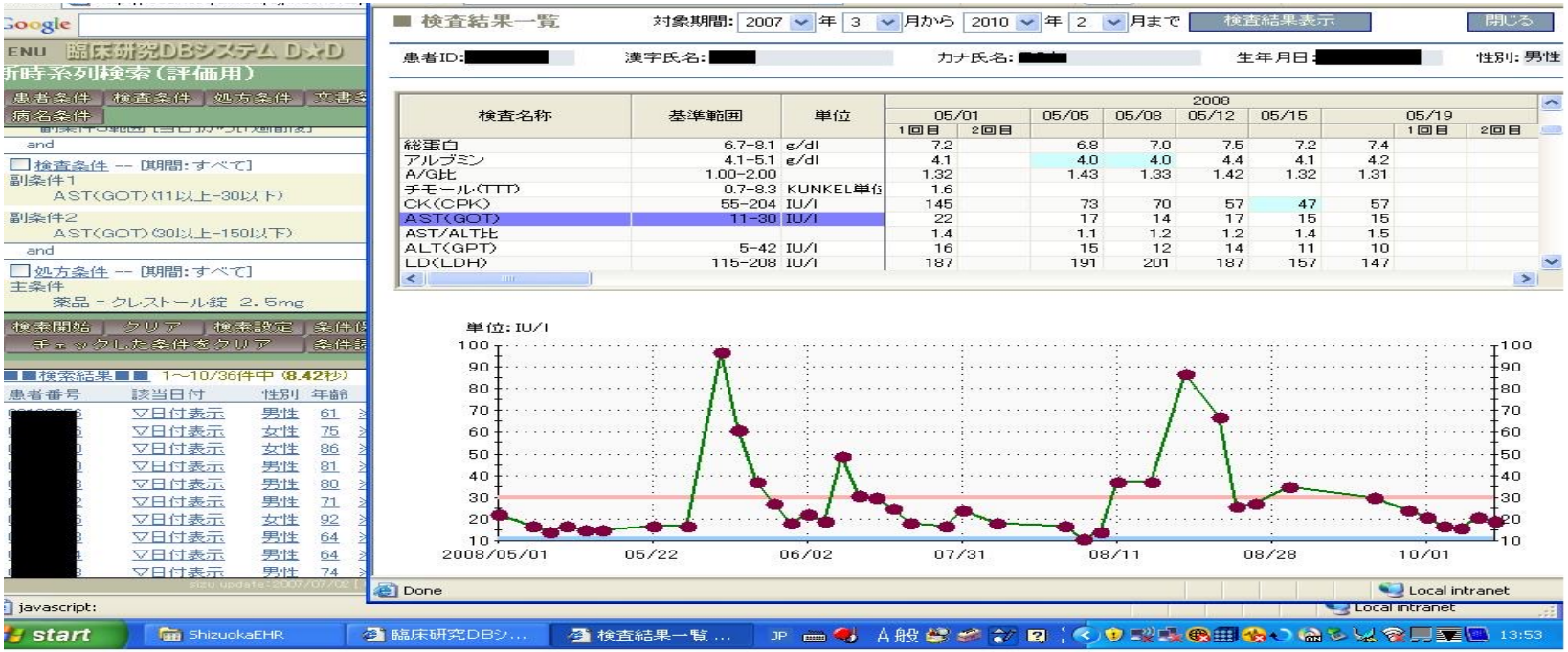
Clinical Information Retrieval System: D*D

10 years, 73,709,298 records of prescription, lab results, diagnosis classifications at Hamamatsu Univ. Hosp.

Searchable in time sequence in a few minutes

Search example





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

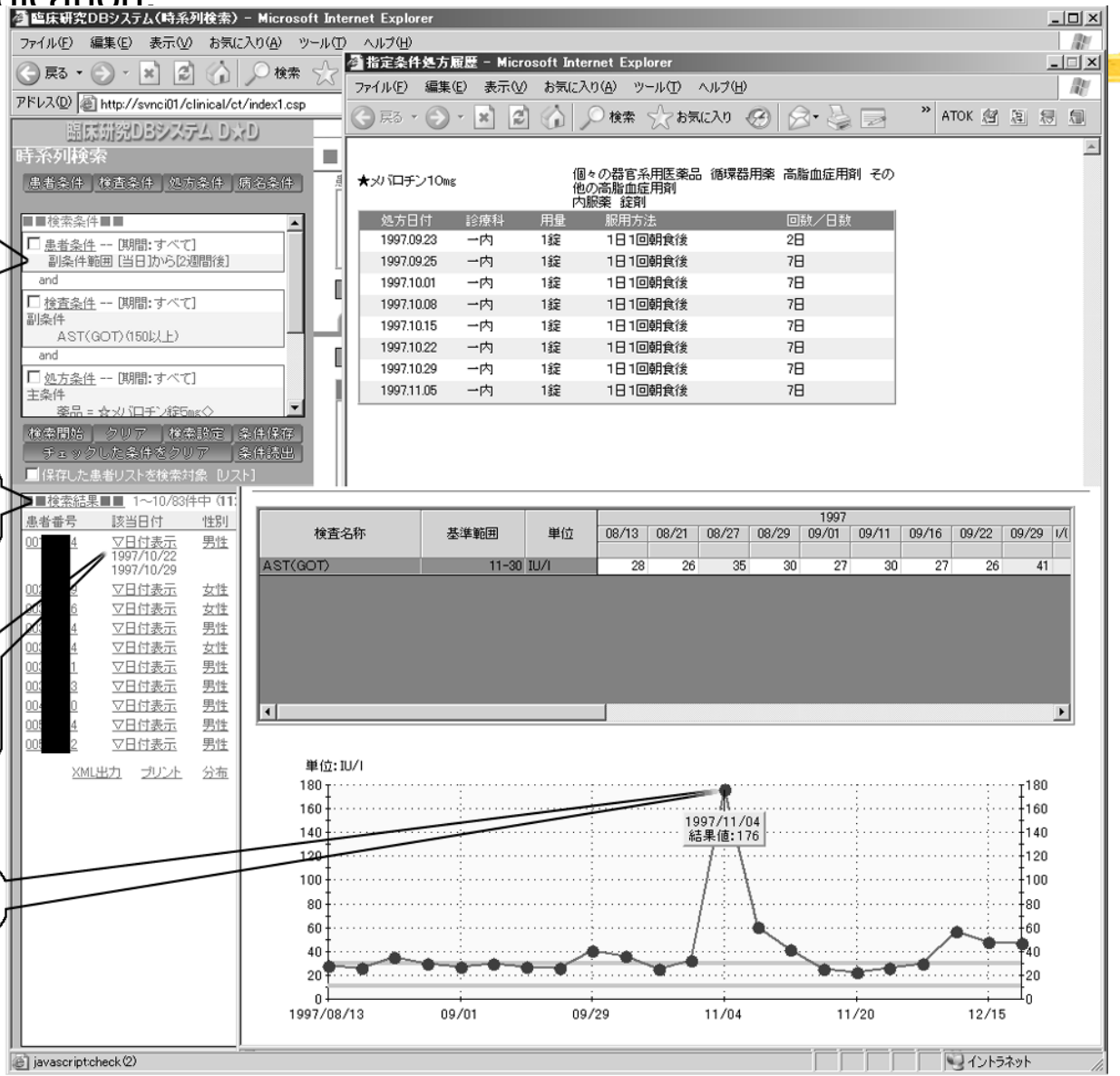
"pravastatin (or others, any titer) and AST > 150 subsequently within 2 weeks"
Search result: 83 patients, search time 112.22 seconds
Patient list shows a selected patient has "HIT" prescription twice, 1997/10/22, and 10/29
and graph of AST show peak high value recorded on 1997/11/04,
within two weeks 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

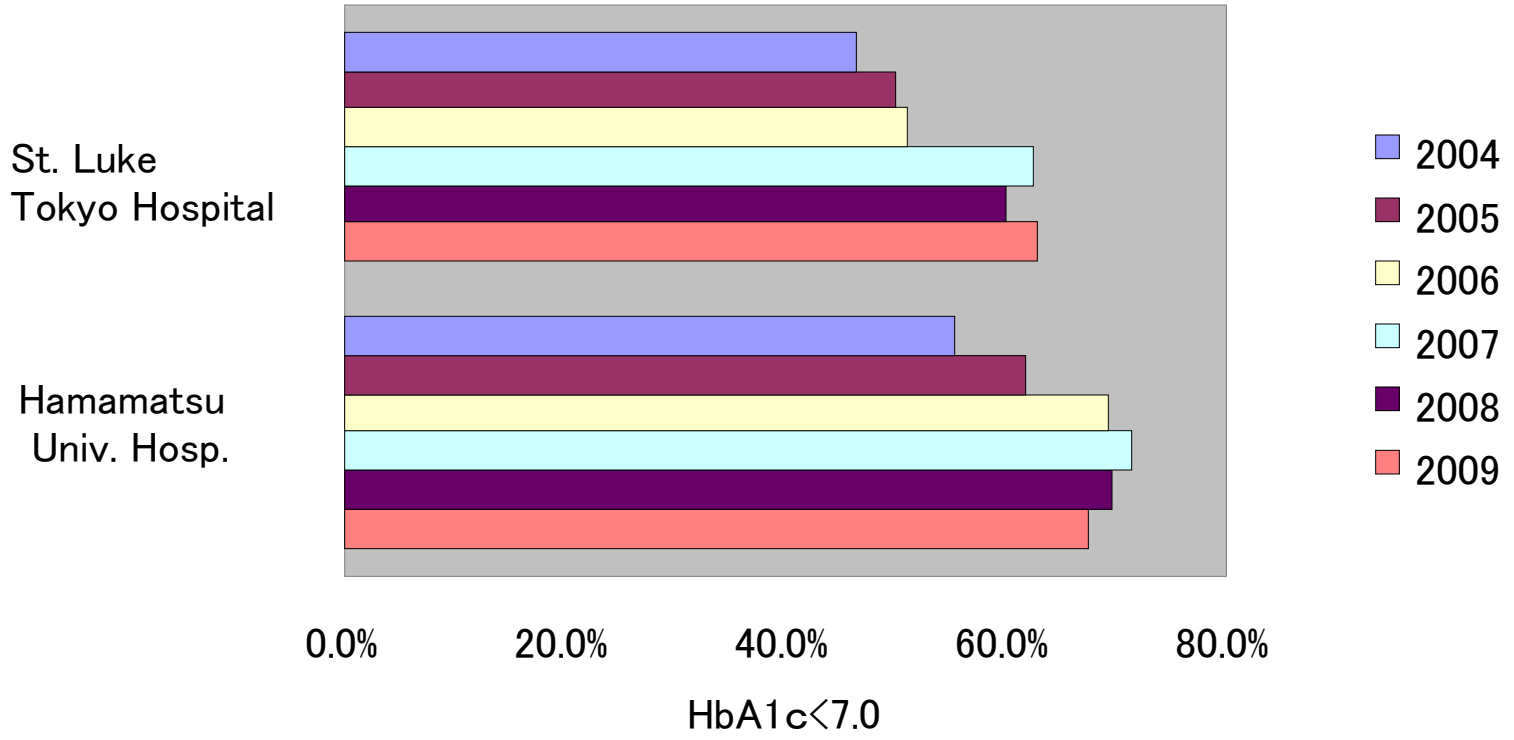


Other examples at Hamamatsu Univ. Hosp.

- 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 strandardized SS-MIX infrastructure makes reporting easier

Protocol example

- Neuroleptic Malignant Syndrome by Olanzapine (Zyprexa^{R})
  - ICD10: G210
  - CPK>1000
- 3 cases out of 323 (0.97%)

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※1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カ月以内に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カ月以内にダントロレンナトリウム（注射薬）※2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 Stacins (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)

nikkei NP 081312-1.pdf - Adobe Reader
ファイル(F) 編集(E) 表示(V) 文書(D) ツール(T) ウィンドウ(W) ヘルプ(H)
1 / 1 105% 検索

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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】 19

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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

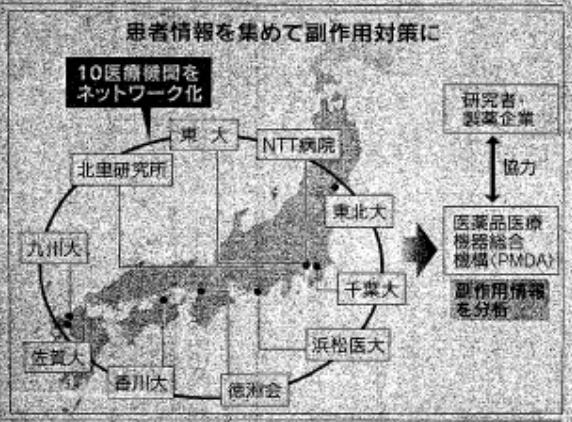
厚生労働省は医薬品の安全性を高める目的で患者情報を集める。今年度から東大病院など10の医療機関と連携し、2015年度までに匿名で1000万人規模のデータベースを作成。副作用の発生確率や被害状況を分析する。日本では薬を服用した人数を調べる手段がなく、副作用への対応の遅れが懸念されている。患者情報の収集を薬害の全容把握や、副作用の少ない薬の開発に生かす。

大学病院のほかNTT病院、徳洲会病院も参加する。12年度はまず東大で着手。13年度までに、10機関が持つ情報システムを厚労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が中心で、病名や各種の検査結果、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発行する診療報酬明細書（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い。PMDAは薬事法に基づいて副作用の情報を集めているが、患者の副作用に気付いた製薬会社や医師から報告を受ける仕組みで報告数

薬を
わから
確率は
副作用
症状な
い。被
予測す
困難な
薬害が



主な内需企業のアジアでの金融拠点設立の動き

消費増税 再生への一里塚 下

常識では理解しにくい思考回路をもつ国会議員が民主党にいる。6月26日、衆院本会議で社会保障・税一体改革法案を採決したとき、子育て支援

源をつくらなければならない。企業経営を直撃する社会保険料の引き上げが限界に近づいているからこそ、民自公3党は消費税増税を選択した。

筋を通したともいえる。

民主党内だけでなく、野党の自公両党にもばらまき願望が漂う。3党の合意文書に低所得の年金受給者への給付金制度を入れさせたのが典型だ。

ない。2012年度予算をおさらいしてみよう。一般会計90兆3千億円のうち社会保障費は26兆4千億円と、地方交付税を除くその他歳出の合計を上回る。それらをまか

%弱の
赤字国
工面し
にまわ
度の国
が、新
に回す

年金・医療 ばら

Daiwa Lease
大和ハウスグループ
リースを通じて、未来をつなぐ。

A般 CAPS KANA 9:45 2012/09/18

“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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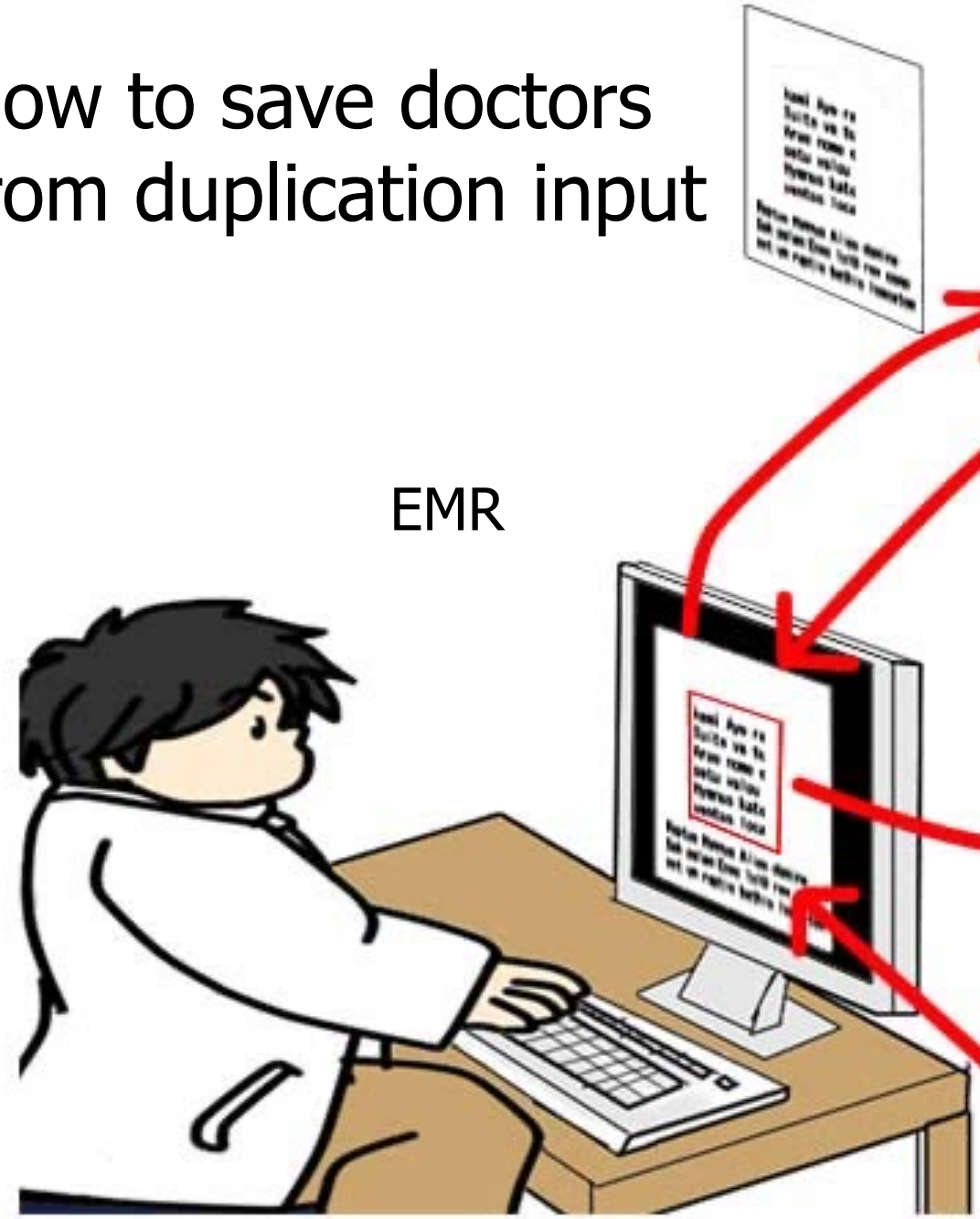
IHE Int'l board
JAMI past President

Used Slides at CDICS Chicago Interchange 2015

How to save doctors from duplication input



EMR

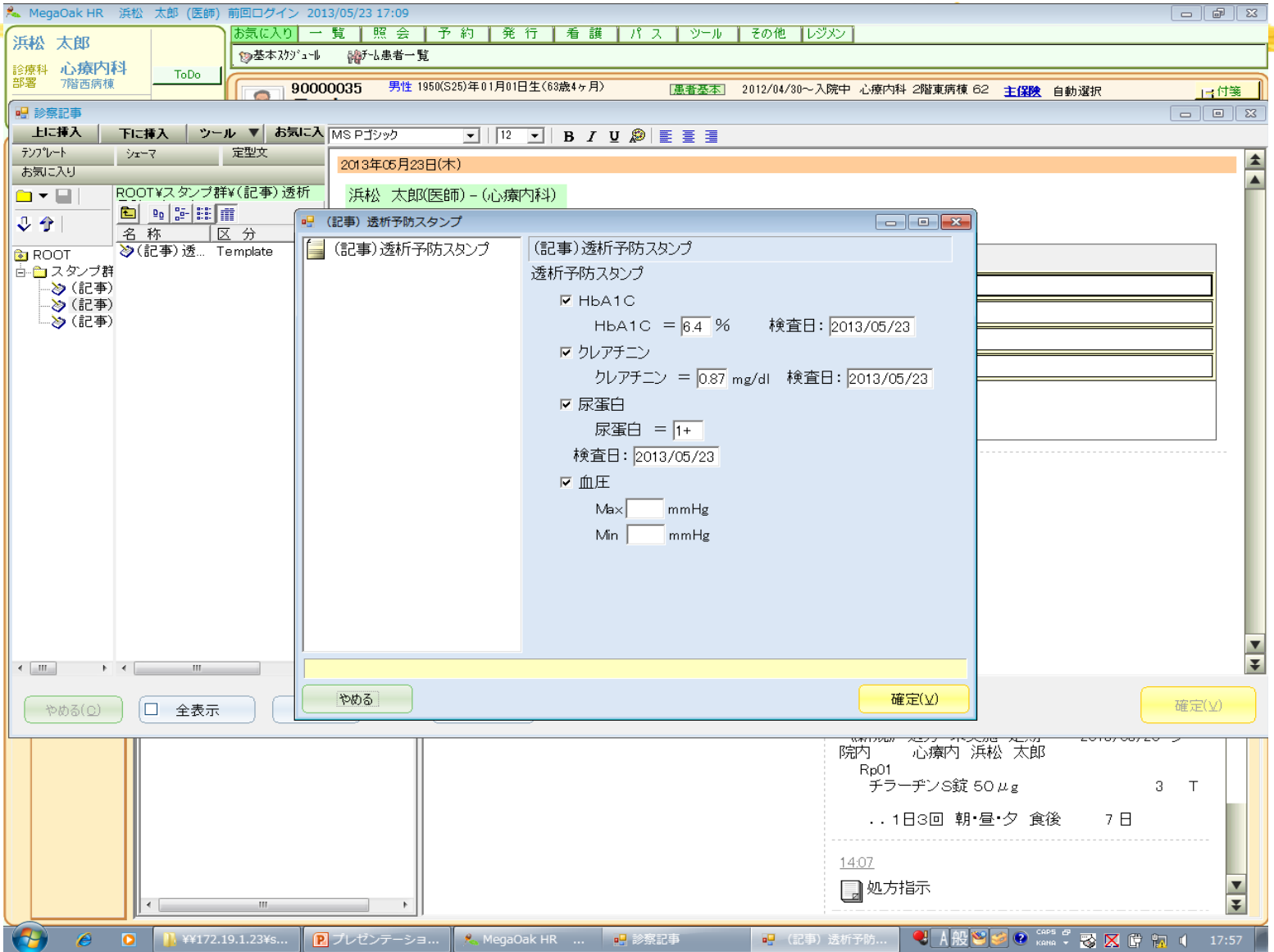
3. Archived with notes as medical record for audit

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

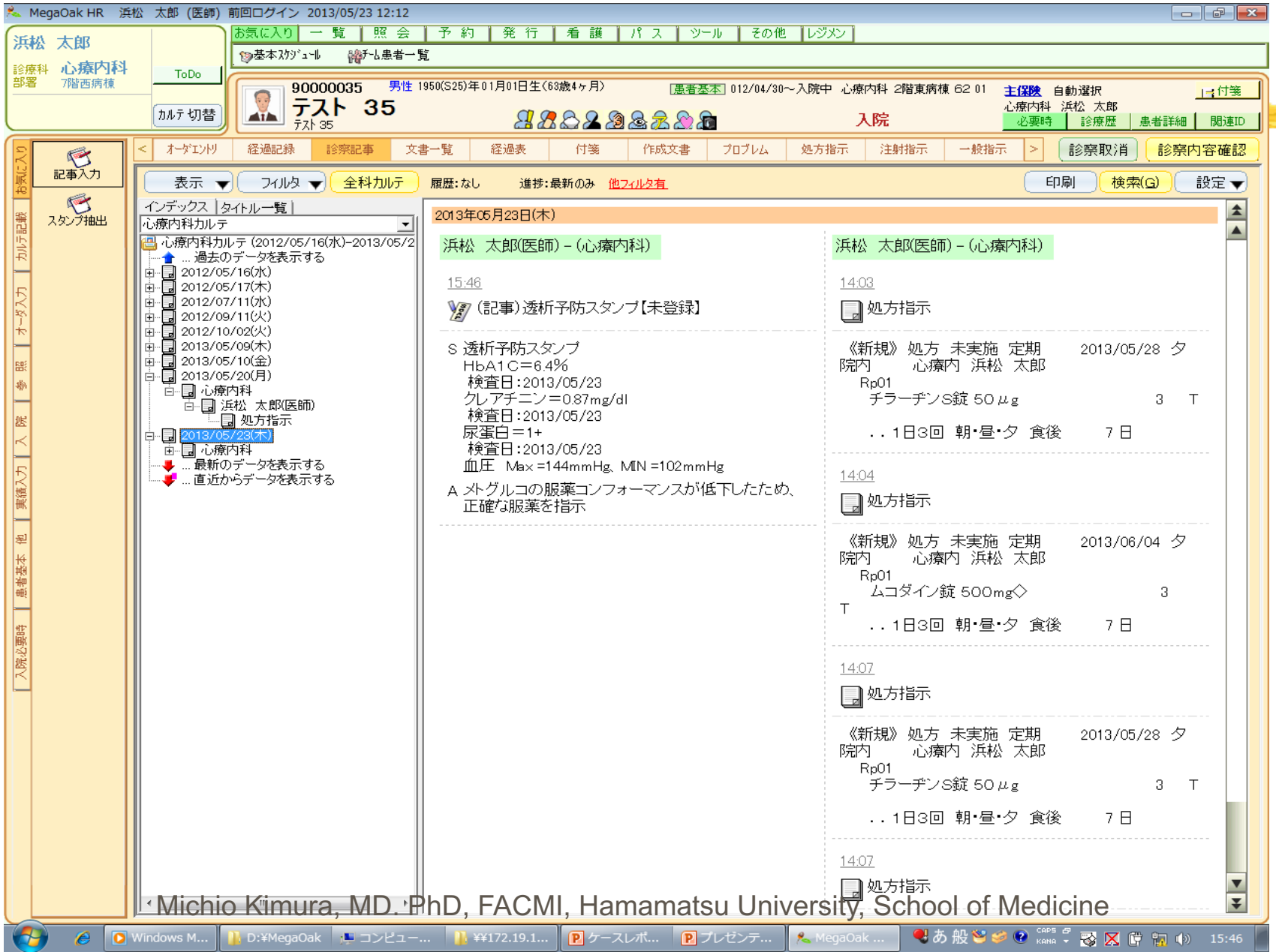
4. eCRF

2. Additional notes of medical record

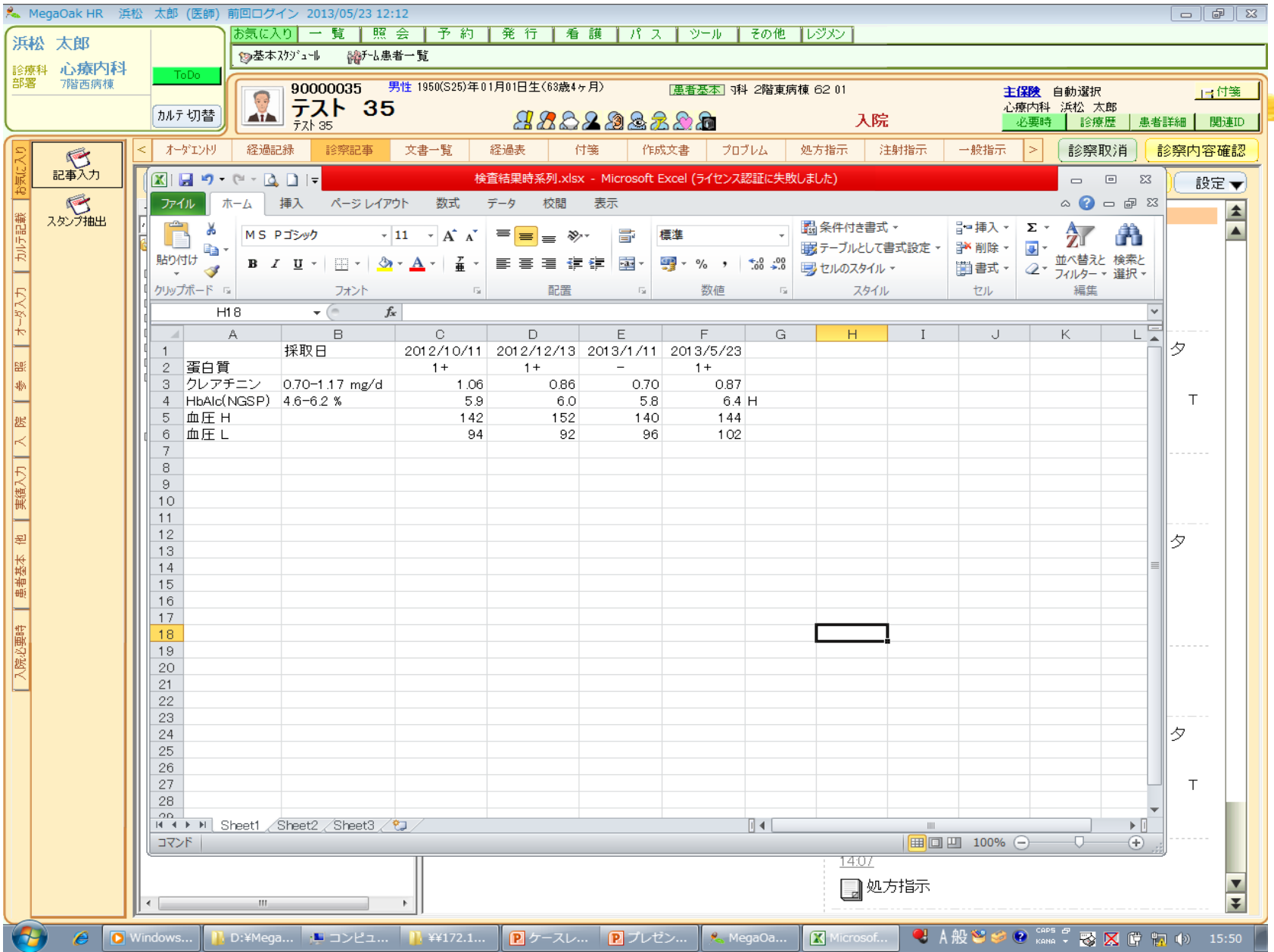
Diabetes case card schema on EMR (data type is controlled)



Schema contents are archived as EMR



And schema contents go to DB (xls)



Slides now!

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.

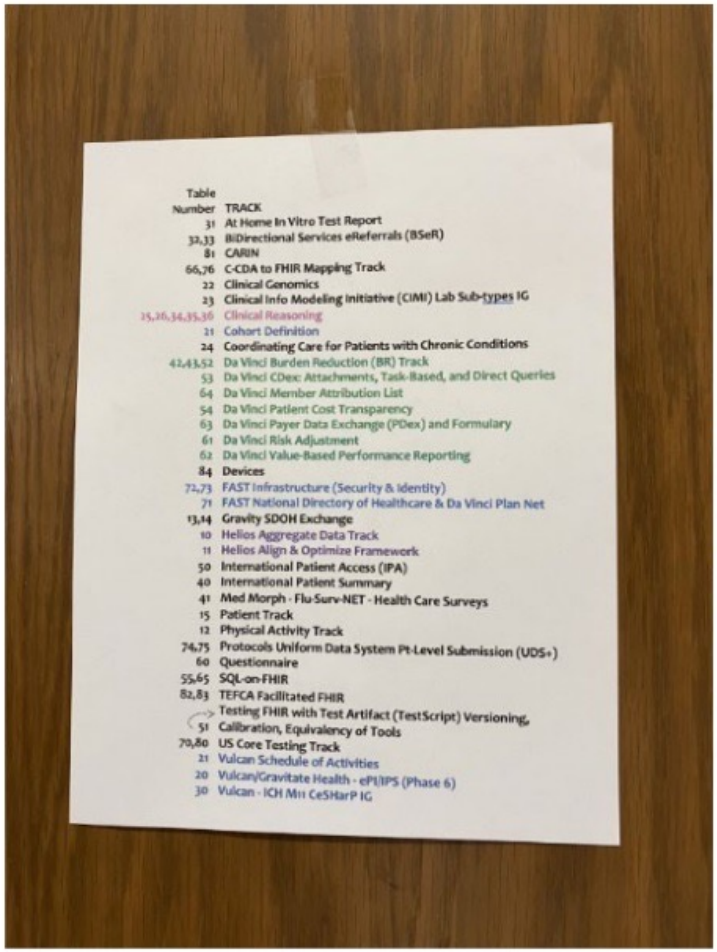
- For doctors' note contents, template use may help without increasing doctors burdens.
- For additional feature investment justification, Ministry designation of standards to be used for exporting patient data was helpful, for the case of SS-MIX standard storage by HL7 v2.5 prescription and laboratory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



Michio Kimura, MD. PhD, FACMI, MSCJ, Kawasaki Medical and Health University

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.