Electronic Health Records for Clinical Research

EHR/CR – Functional Profile & HIMSS 2008 Update

Linda King, MT(ASCP)
Eli Lilly and Co.
Representing eClinical Forum and PhRMA EDC/eSource Taskforce

March 18, 2008
Annual CDM DIA, Washington, D.C.

EHR-CR Project:

"Roadmap" to Connecting Healthcare and Research

Project Sponsors & Participants

Sponsors:

eClinical Forum

PhRMA

Gold level partners:

Procter & Gamble

Pfizer

Eli Lilly & Company

In Cooperation With:

HL7 Technical Committee
EuroRec Q-Rec

Global Participants:

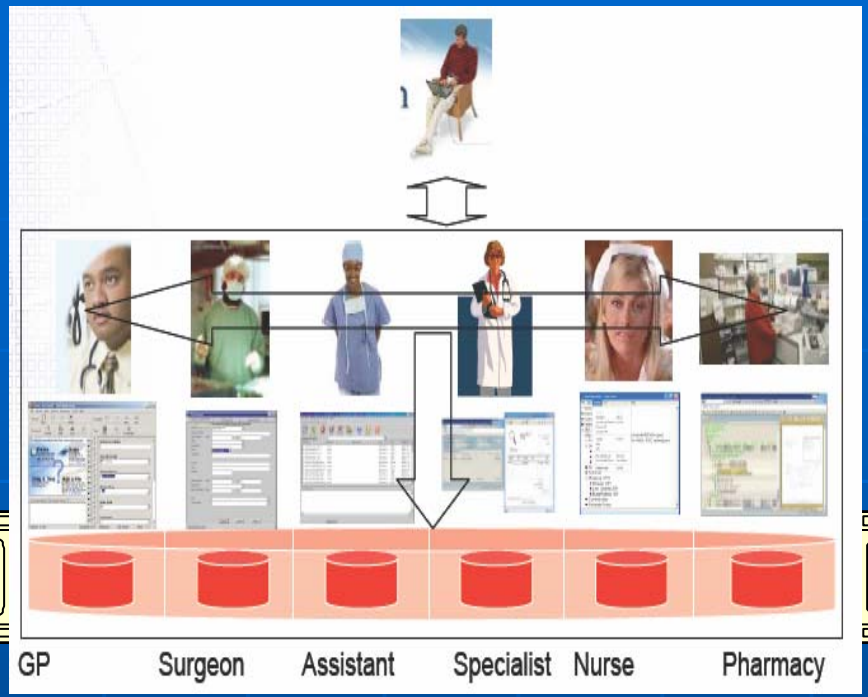
- **Bayer**
- **Boehringer Ingelheim**
- **Bristol Myers Squib**
- **Cerner Corporation**
- **ClinPhone Inc.**
- **Eli Lilly and Company**
- **FDA**
- **Glaxo SmithKline**
- **Hoffman La Roche**
- **Lundbeck**
- **Millennium**
- **NIH: National Cancer Institute**
- **Northrop Grumman**
- **Novartis**
- **Nycomed**
- **Orion**
- **Pfizer**
- **Procter & Gamble**

Agenda

- eHealth
- Problem & Challenge to Clinical Research
- The Vision
- The Opportunity
- EHR/CR Functional Profile Project
- HL7 and EuroRec/Q-Rec EHR Conformance Criteria
- The Profile – aimed at Certification
- EHR/CR “Core” Requirements
- Tier 1 through Tier 3
- HIMSS 2008 Update

eHealth is Driven by the need to…

- Enhance patient safety
- Improve quality of healthcare
- Reduce healthcare costs



eHealth is About…

- Bringing information and knowledge to the point of care
- Realizing this across national & state boundaries
- Moving from specialist-centric to patient-centric information

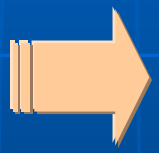
Problem …

- National (EU and US) initiatives for Interoperable Electronic Health Records (eHealth) are causing more and more source data for clinical research to be redundantly collected, first in EHR and then printed and entered into Sponsor's Electronic Data Capture (EDC) systems
- **Potential Pharmaceutical Research benefits of the EHR were NOT initially considered:**
  - Better Patient Safety Monitoring
  - Elimination of Redundant Data Entry
  - Streamlined Healthcare and Clinical Research Workflow Processes
  - Enhanced Recruitment Potential
  - Lower Research Cost
  - Etc.

Business Realities of Drug Development

The Facts

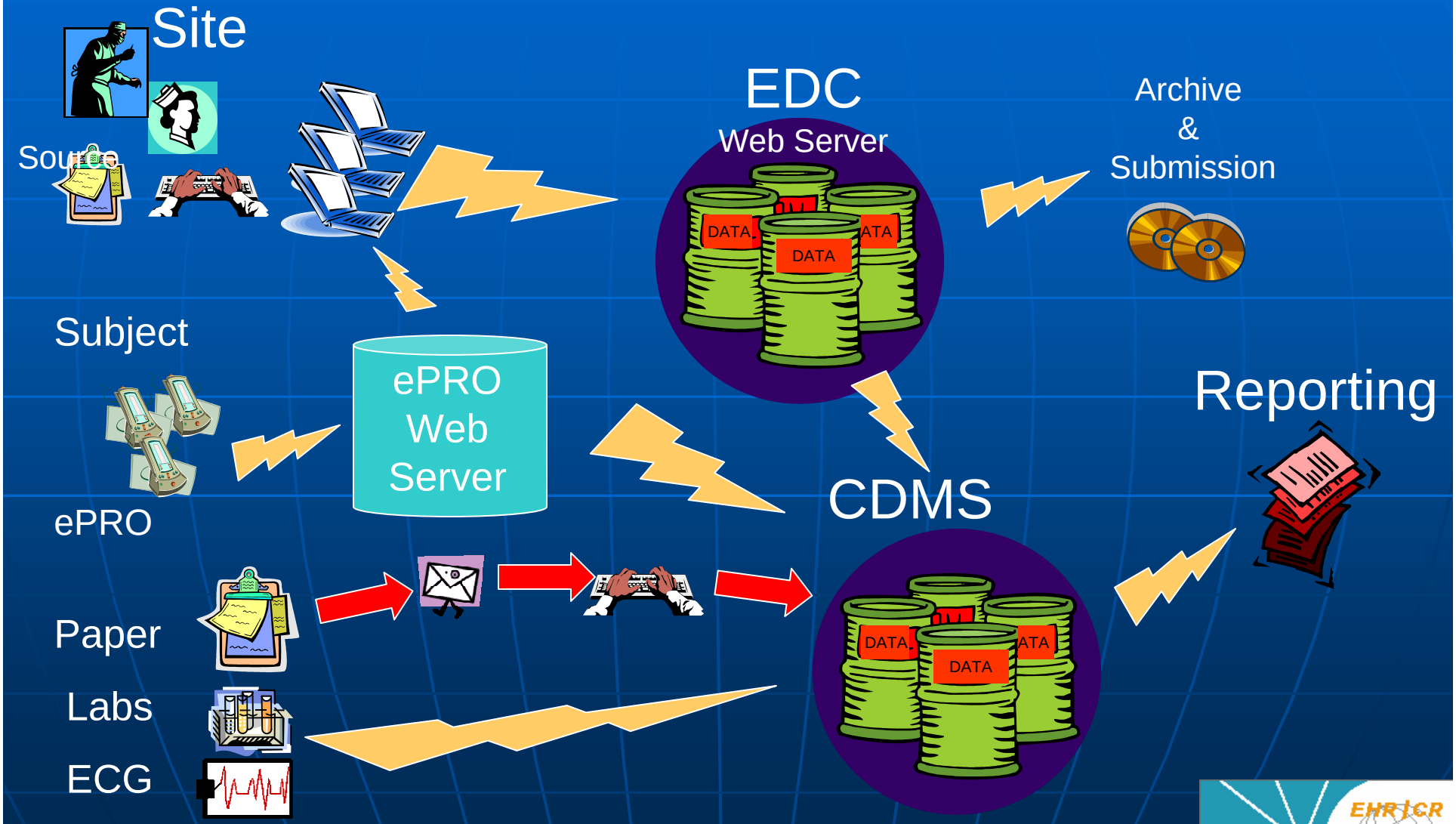
- Innovation of medicines is a high-risk business
  - *Less than 9% of clinical candidates make it to patients*
- The cost and timescale of innovative medicine has escalated
  - *A new molecule can cost $750M -$1.0B and takes 11-15 years to develop*
- Research $ focused where there is a ROI



The Consequences

- Fewer new innovative medicines reaching the patients
- More expensive and late therapies
- Potential medicines not reaching the patient and niche markets of high medical needs not being explored

Electronic Data Capture (EDC)



The Challenge …

Approaches To Clinical Trial Data Capture At Investigator Sites

Patient visit

Historical

Paper Medical Record → Paper CRF → Research Database

Healthcare | Research

Emerging but Duplicative

EDC

Paper or Electronic Medical Record

Hosted Data

Electronic CRF, ePRO, Labs → Research Database

Future Integration

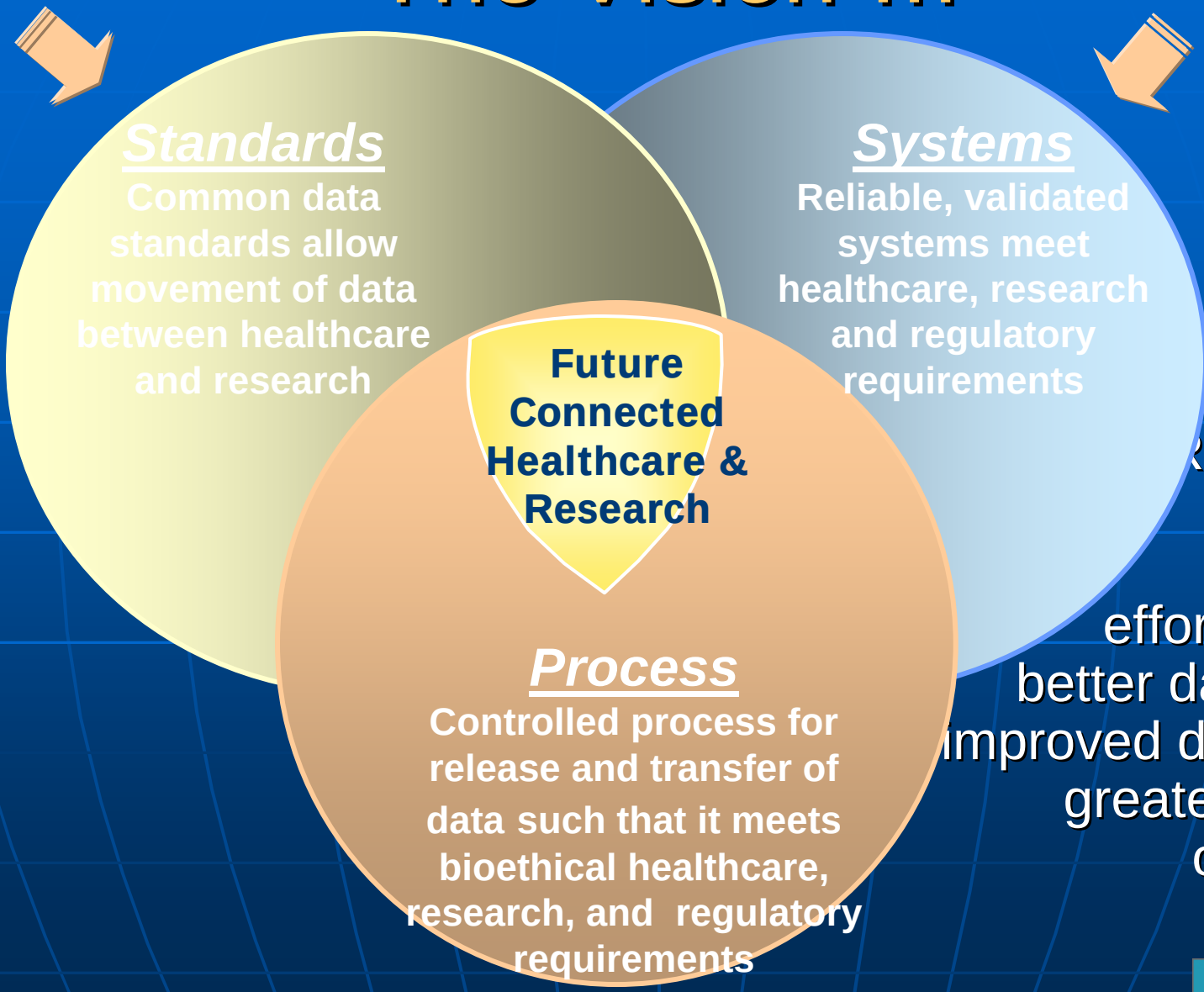
EHR-S

Electronic Health Record

Trial

Trial Specific Data → Research Database

The Vision …



…Results In…

Minimized effort and cost, better data quality, improved drug safety, greater research opportunity

Opportunity to make a Difference

- Invited by HL7 TC (Lenel James) and Q-Rec (Georges DeMoor) to participate in an EHR certification activity to address Clinical Research needs

- Project initiated to develop a Clinical Research Functional Profile (EHR/CR–FP) that can be included in the EHR certification programs in both the US and EU in order to facilitate the inclusion of EHR source data in regulatory submissions

Project Objectives

Develop a Global EHR/Clinical Research Functional Profile (EHR/CR-FP):

- Identify critical capabilities (requirements) for clinical research utilizing EHR systems through:
  - HL7 EHR-S FM
  - Q-Rec (EuroRec) EHR Repository
  - + Clinical Research-specific requirements

- Submit to **HL7** for "standards" acceptance
- Submit to **CCHIT & EuroRec** for consideration in their certification process

Outcomes:

- EHR Vendors: provided with encouragement & requirements for incorporating clinical research functions into their systems

- Sponsors: provide basis for evaluating EHR systems as source data systems

EHR/CR Functional Profile

- Establishes requirements, non-redundant functions, and processes to use patient electronic medical data for clinical research.
- Ensures that data protection (patient privacy), regulatory, and research requirements are met.
- Endorses data standards (such as CDISC CDASH, HL7) for data collection, interpretation and exchange within the medical and research communities.
- Expands and adapts functions of EHR and the associated systems, networks, and processes such that they meet clinical research needs.

Developing an International Profile

- 2 current sources of functions/conformance criteria
  - US HL7 Functional Model
  - EU EuroRec/Q-Rec Certification Criteria Repository (a compilation of EU country criteria)
- Both are…
  - "Work in progress- EuroRec / First Release- HL7"
  - Define several hundred criteria
  - Have their own structure
- Work Plan…
  - Identify clinical research functional requirements: most can be defined from internationally recognized practice, guidelines, regulations
  - Map functional requirements to HL7 and EuroRec/Q-Rec criteria – our requirements provide a map between the two – this is Global!

Keep thinking Globally!

Certification

HL7 ← EHR/CR → EuroRec mapping

- HL7 – EHR/CR FP will establish conformance to HL7 EHR-S FM and provide an international “standard”
- EuroRec Q-Rec – EHR/CR FP will establish conformance to Q-Rec and provide basis for certification in the EU
- CCHIT – HL7 EHR/CR FP will provide basis for certification in the US

Project Phases

The project is planned in four phases:

- ***Organization*** – Participants, determination of scope, project plan

- Profile Release 1: Core "Essential Now" requirements definition
- Profile Release 2: Expands on Release 1 but further identifies all "Essential Future" requirements into functional tiers

Each profile release will include these phases:

- ***Formalization*** – Analysis of requirements, development of EHR/CR functions and conformance criteria, definition of priority timeframes (Release 1 complete).

- ***Harmonization*** – consolidation and alignment with HL7 and Q-Rec, draft functional profile, solicitation of input from other stakeholders (Release 1 w/ HL7 complete, Q-Rec in progress).

- ***Finalization*** – Conformance and preparation of packages for submission to EHR – TC and EuroRec/Q-Rec, for approval and external publication. (HL7 Ballot submitted Feb 2008, EuroRec/Q-Rec pending) Submission to CCHIT and Q-Rec for certification consideration (pending).

Profile Releases

Release 1: "Core" Requirements

- Ensure that patient data from an EHR system will meet clinical research regulatory requirements for data collection, management, extraction, security, and can be interpreted in a consistent manner (21 CFR Part 11, CSUCI, etc.)

Release 2: Future Requirements

- Functions needed to improve ease-of-use and performance
- Functions necessary to ultimately conduct all clinical research data capture and management through nation-wide health information networks and systems.
- Functions will be divided into levels along the evolution to this ultimate goal. None of the EF functions will be required to be present on "day 1" of using the EHR data for clinical research.

Profile – Essential Now

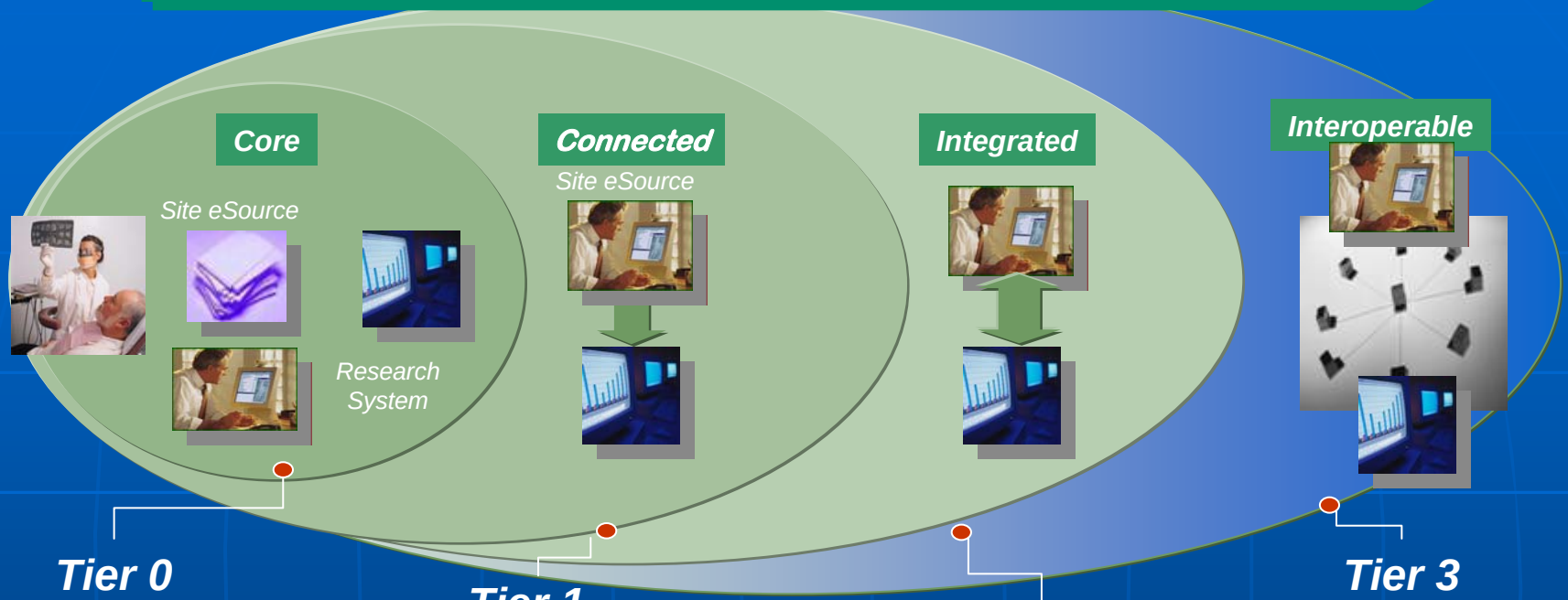
- Ensure that patient data from an EHR system will meet clinical research regulatory requirements for data collection, management, extraction, security, and can be interpreted in a consistent manner (21 CFR Part 11, CSUCI, etc.)
- Functions must be present to use EHR data for clinical research without redundant re-keying and verifying

Profile – Essential Future

- Functions needed to improve efficiency and performance
- Functions necessary to ultimately conduct all clinical research data capture and management through nation-wide health information networks and systems.
- Functions will be divided into levels along the evolution to this ultimate goal. None of the EF functions will be required to be present on "day 1" of using the EHR data for clinical research.

  (Sponsors can provide work-arounds either through processes or sponsor-supplied electronic systems).

Emerging and Future EHR-Research Connectivity and Complexity



Tier 0

Core
(Minimum Requirement)

- EHR systems holding some source data used in Clinical Research meet essential regulatory requirements
- Electronic data can be electronically extracted such that it can be transferred and loaded into a research system
- Research systems must still collect study-specific data

Tier 1

Connected
(Emerging Future)

- Patient study data collected via EHR structured data elements and transferred from EHR via automatic/electronic industry standards
- No further duplication of EHR data
- Study-specific data and queries handled via Research system

Tier 2

Integrated
(Future Vision)

- Relevant data from EHR and Research System components are seamlessly transferred in both directions with no need for data transcription,
- EHR System can capture healthcare and study-specific data
- Study data not collected at site is transferred or available to view via EHR, Research holds no 'source' data.

Tier 3

Interoperable
(Future Ideal)

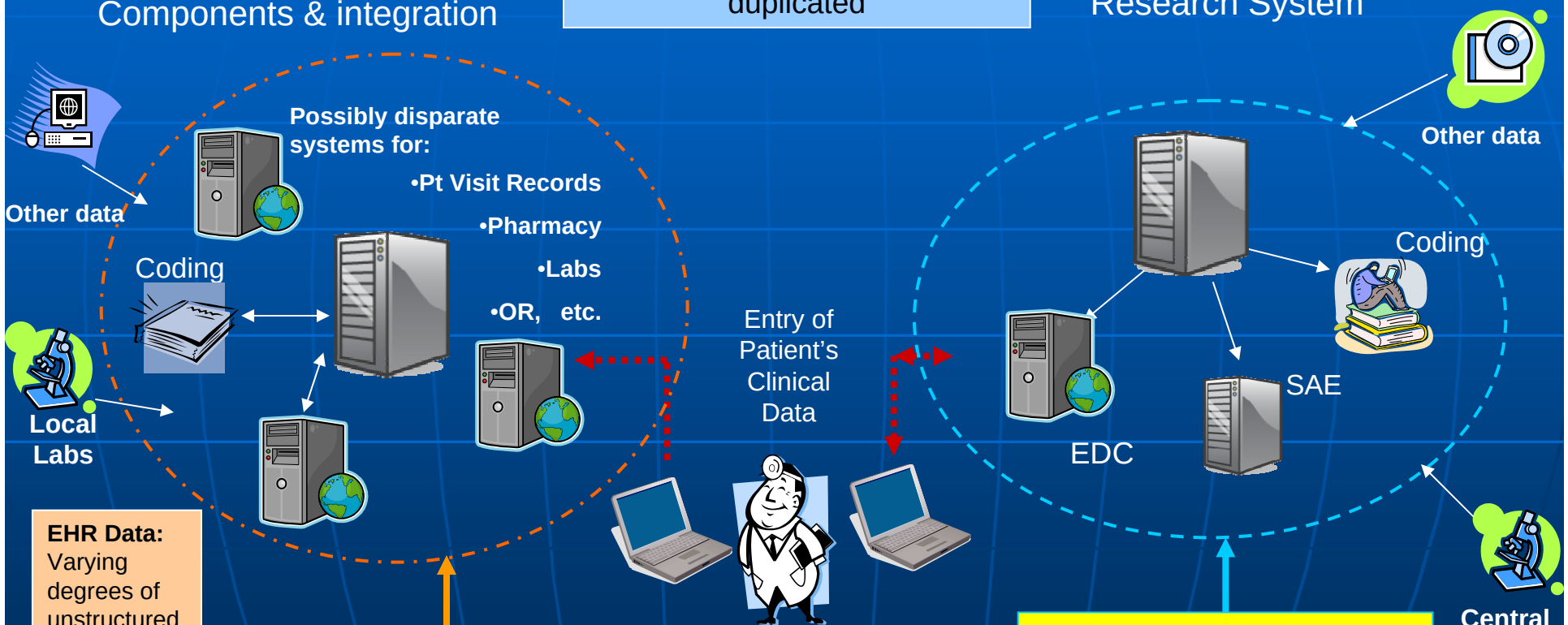
- EHR and Research systems work seamlessly together and sit on same international network.
- Data access & mining capabilities across healthcare & research.
- EHR System holds the complete patient medical record including all clinical study / research data

Current State of Electronic Records

Source data held in EHR may not be appropriate as source for clinical studies; data entry is duplicated

Multiple stages of EHR Components & integration

Sponsor Clinical Research System



EHR Data: Varying degrees of unstructured or non-digital information

Various levels of standards, computer system validation and systems integration depending on country, region, institution.

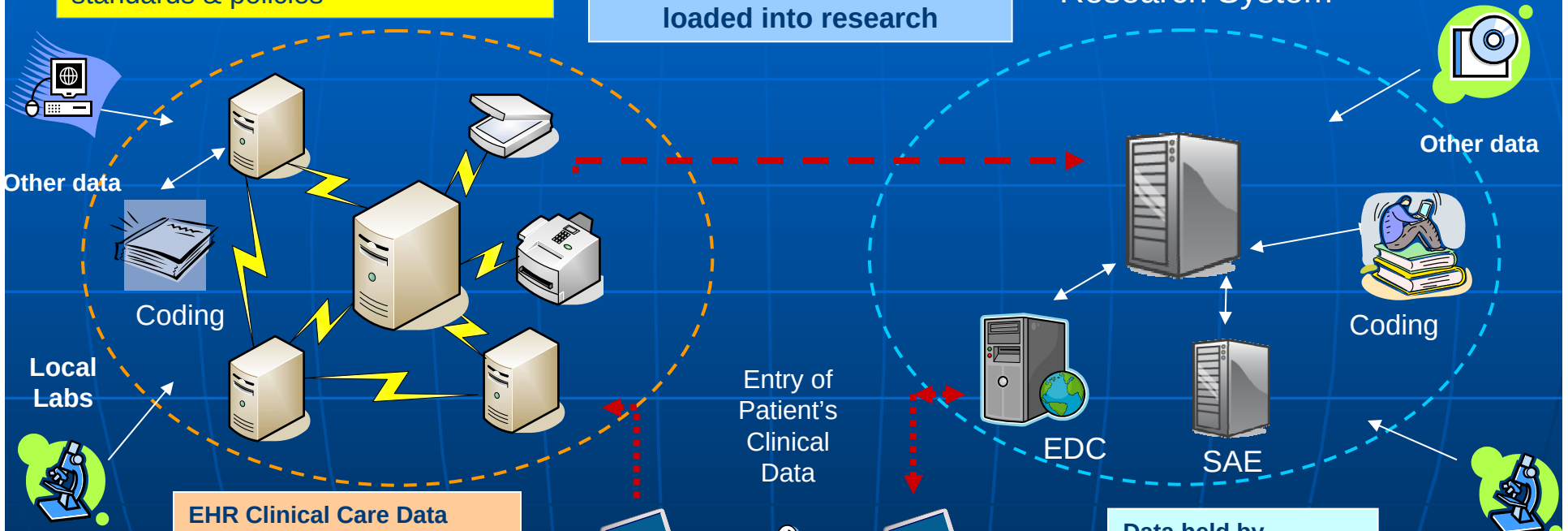
Physician / Investigator

Systems validated & compliant to Industry & Regulatory standards & policies e.g. 21 CFR part 11, CSUCI & ICH GCP

EHR/CR Core Level

Certified **EHR Systems** validated & compliant to Industry & Regulatory standards & policies

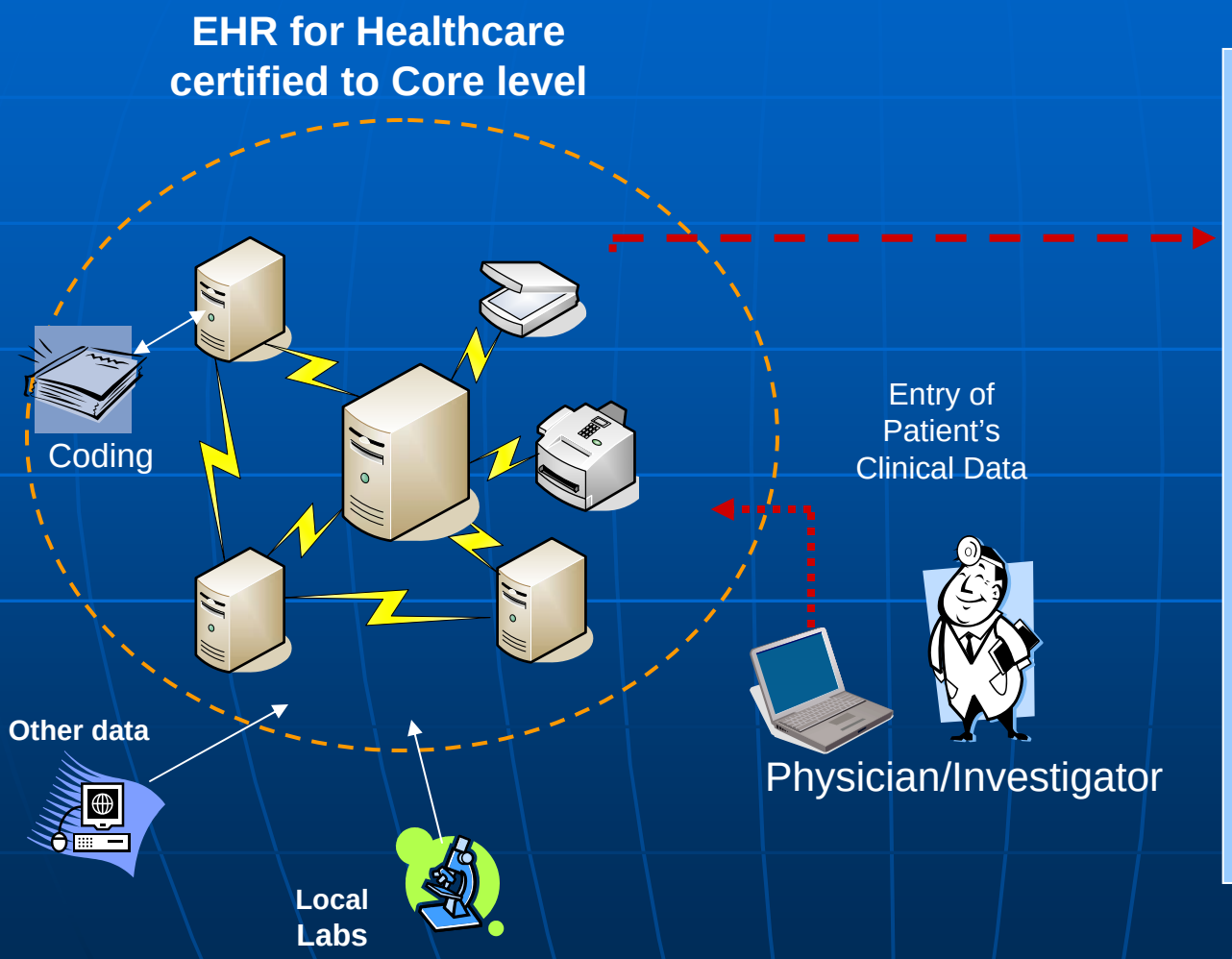
EHR holds" reliable" source for clinical studies; data can be electronically extracted from the EHR system such that it can be transferred / loaded into research



EHR Clinical Care Data includes structured data as modeled by CDASH:
- Problem (Adverse Events)
- Medications
- Demographics
- Medical History
- Vitals / Physical Exam
- Unique IDs for subject, investigator

Data held by Research Systems
- Labs
- EDC (all data not collected via EHR)
- EHR-collected research data
- Other

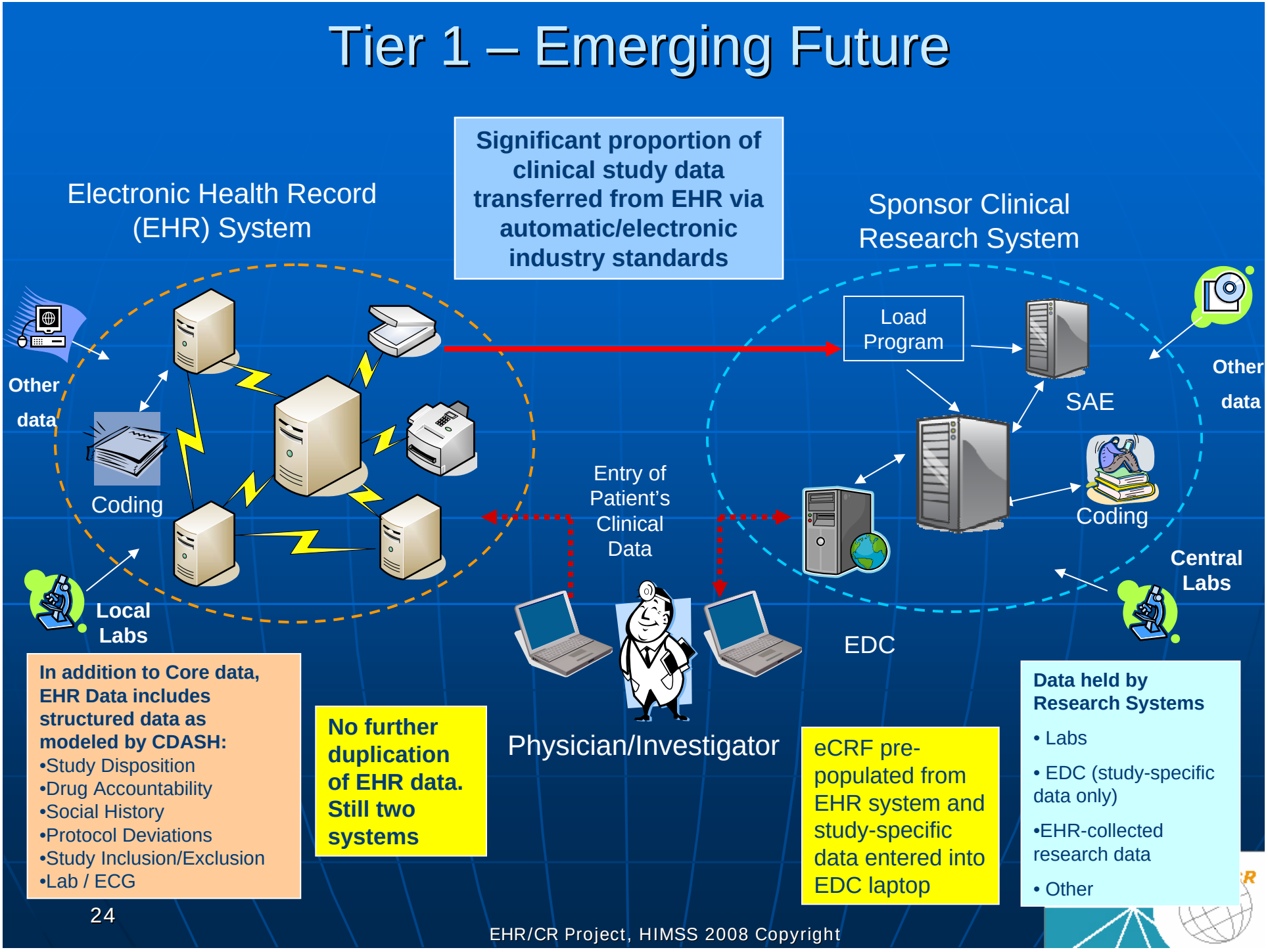
Secondary Uses for Core Level EHR/CR Systems



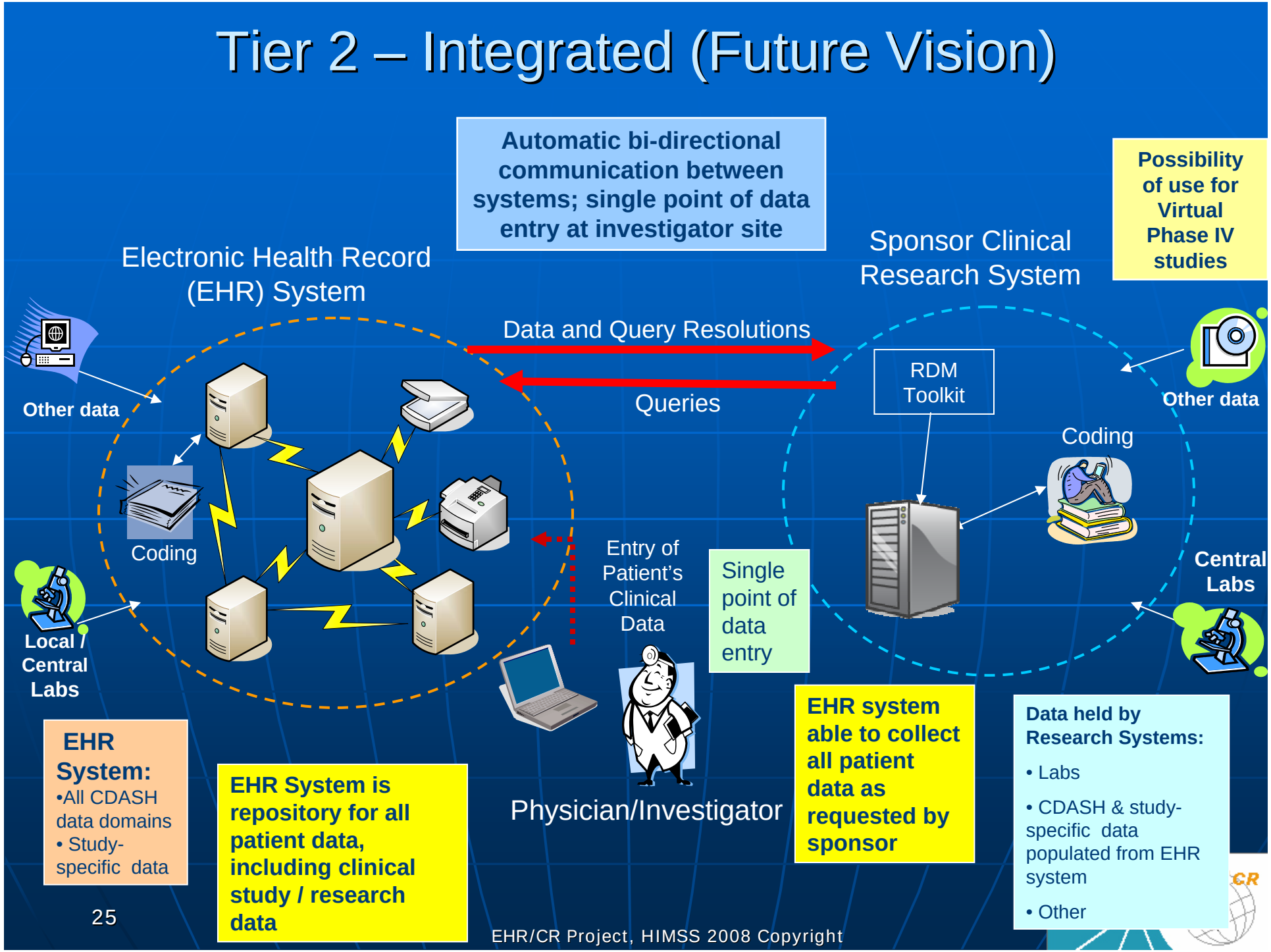
De-identified data from EHR Systems complying to EHR/CR Core level could be used for:

- Some standard Clinical study data capture
- Clinical study Recruitment
- Drug Safety Surveillance
- Document Management for Clinical studies
- Audit Medication Workflow
- Epidemiology
- Outcomes Research (e.g. Pharmaco-economics, Quality of Life)
- Protocol Feasibility
- Data Mining & analytics
- etc.

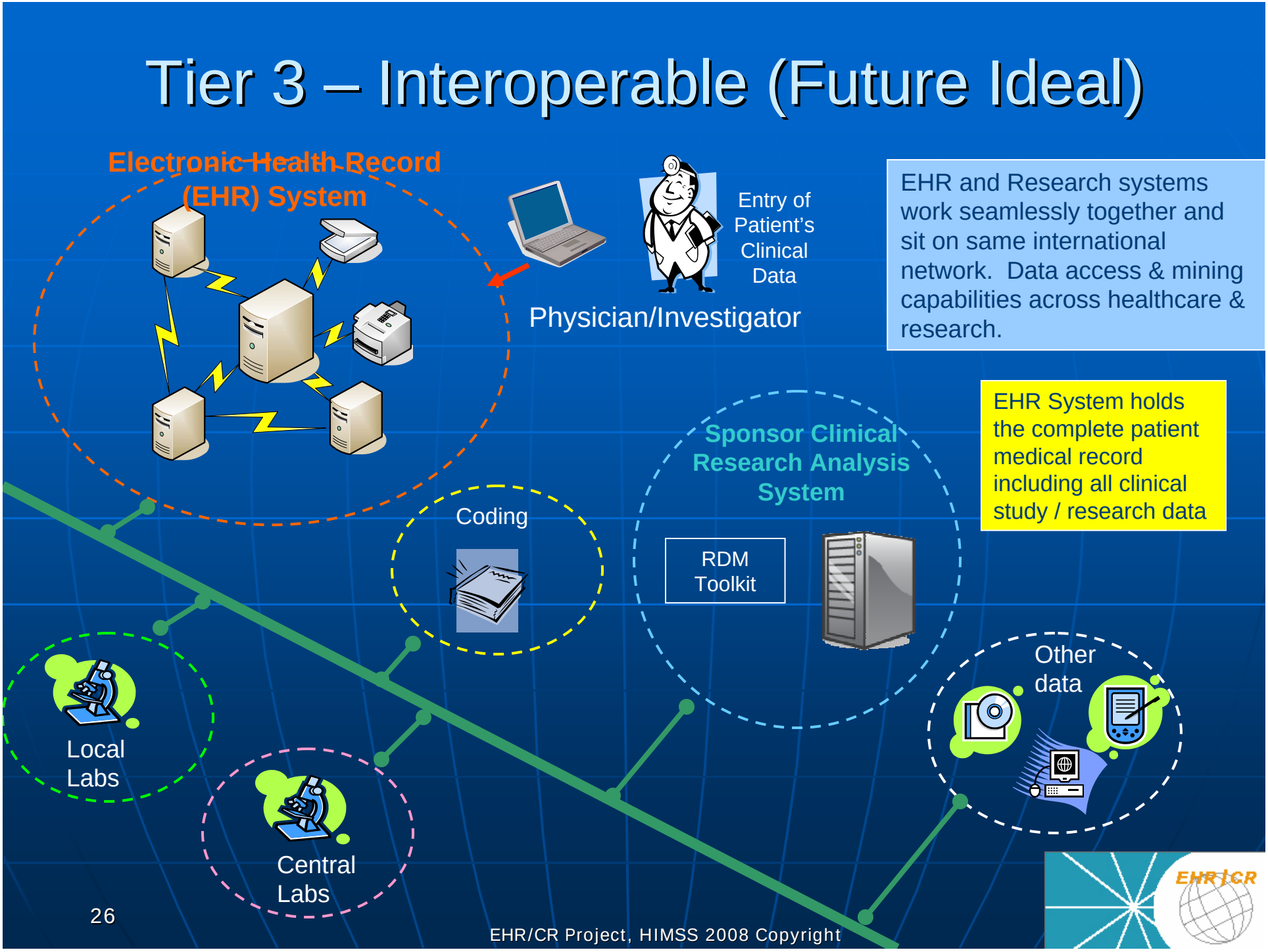
Tier 1 – Emerging Future



Tier 2 – Integrated (Future Vision)



Tier 3 – Interoperable (Future Ideal)



Summary and Next Steps

- Core User Requirements (URs) Document (including Supplement describing “The Vision”) Released Jan ’08 on ehrcr.org website
- Begin HL7 Ballot process (Submitted Feb ‘08, Feedback May ‘08)
- If positive HL7 Ballot, initiate discussions w/ CCHIT (3 Q ’08)
- Map URs to EuroRec/Q-Rec (1 Q ‘08)

Contact us to discuss ways you can participate !

Suzanne.Bishop@ehrcr.org
Richard.Perkins@ehrcr.org
John.Mestler@ehrcr.org
Catherine.Celingant@ehrcr.org

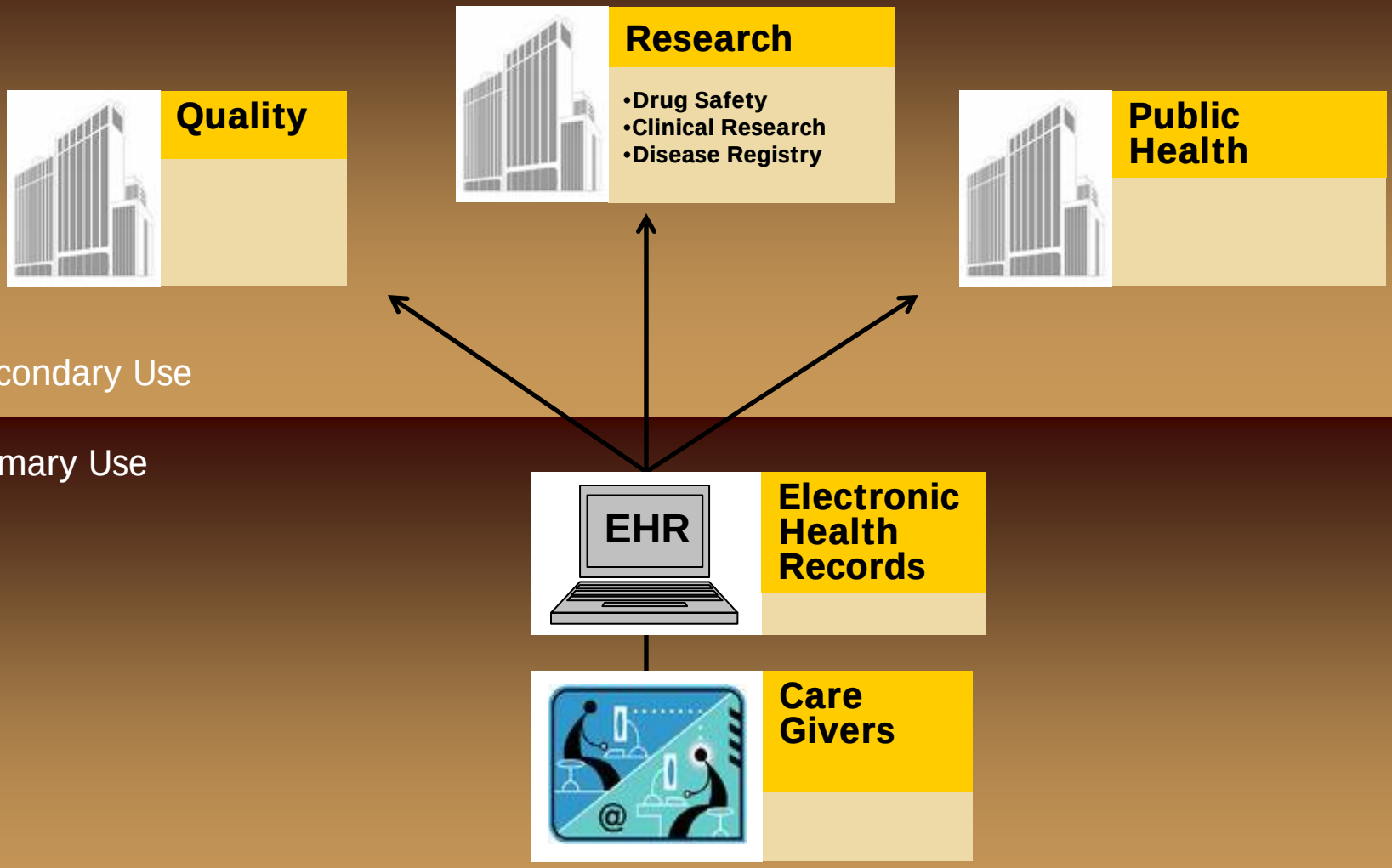
Clinical Research Healthcare Link

Integrating Research into Healthcare Workflow

HIMSS 2008

Slides courtesy of CDISC, Landen Bain

Secondary Use of EHR Data



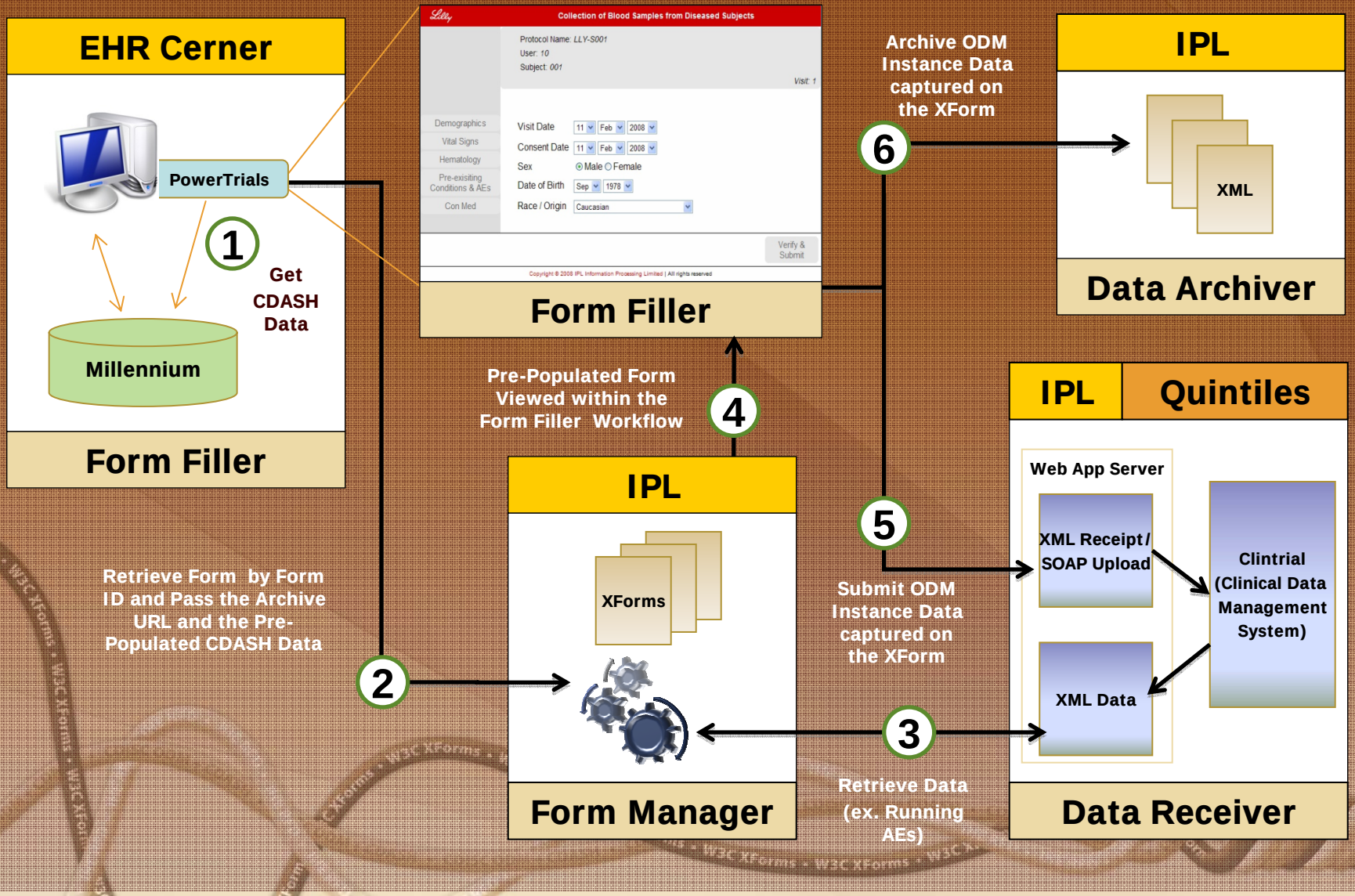
Slides courtesy of CDISC, Landen Bain

Clinical Trial Scenario

Slides courtesy of CDISC, Landen Bain

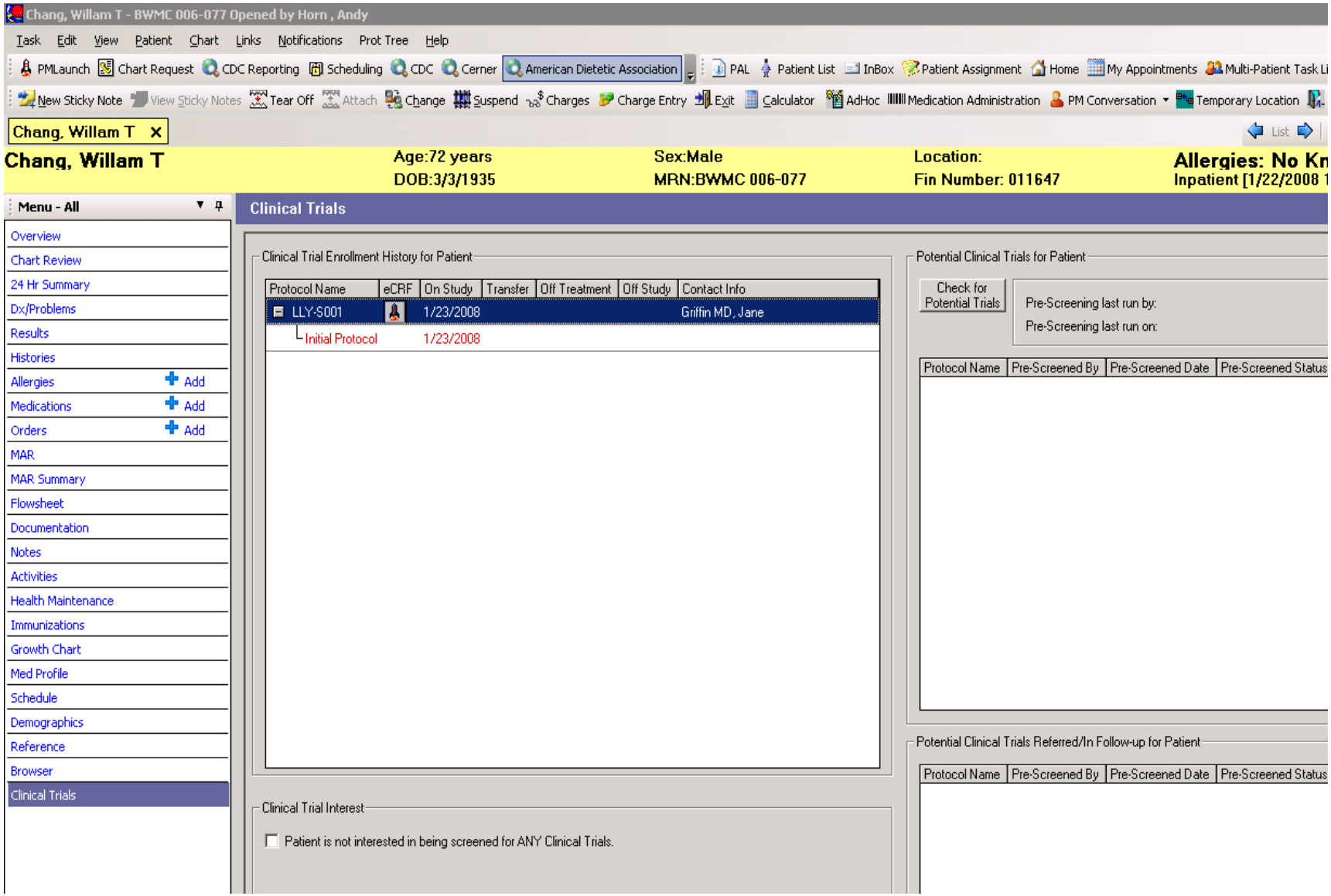
Clinical Trial Workflow

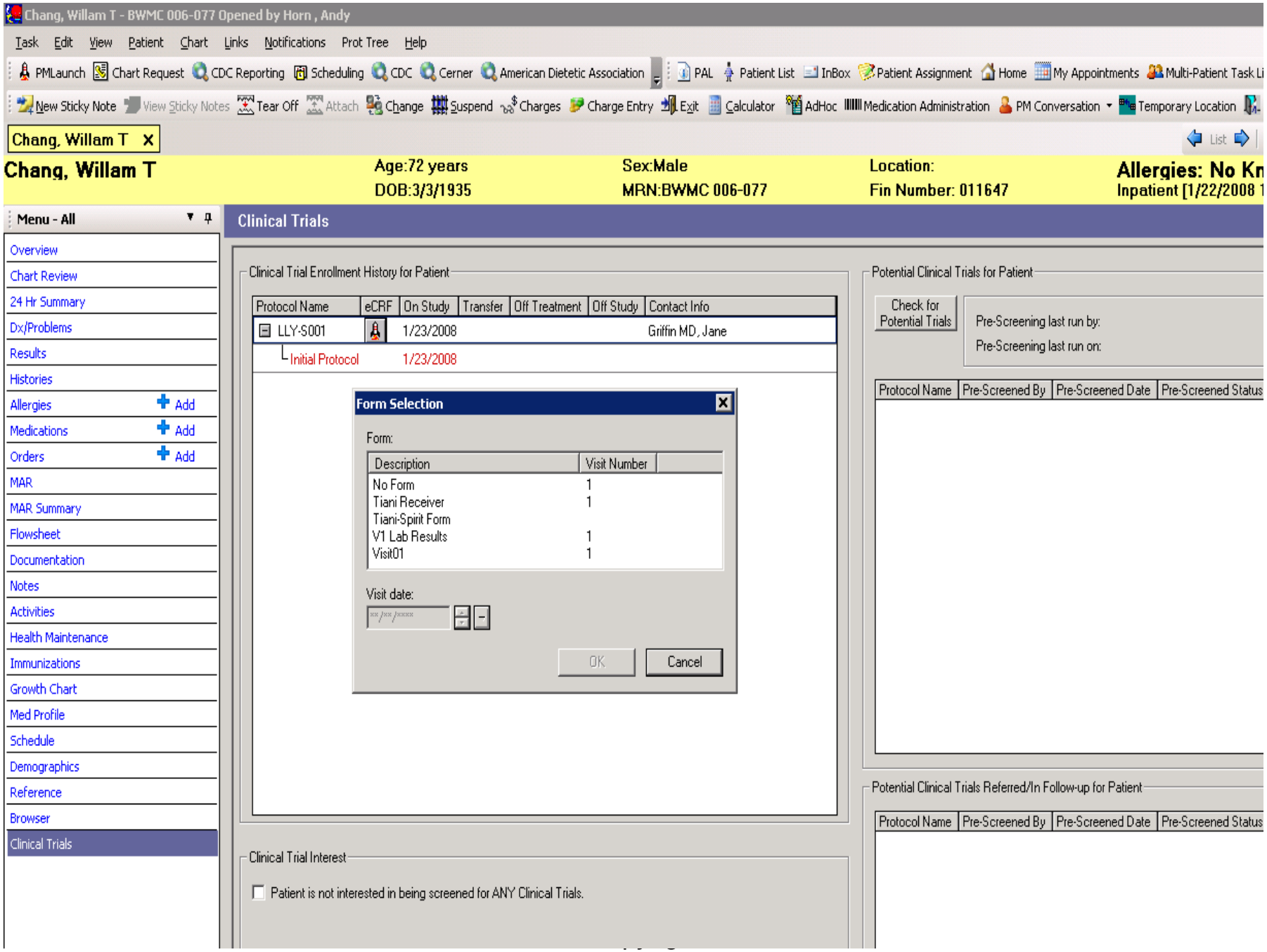
Lilly S001 Protocol

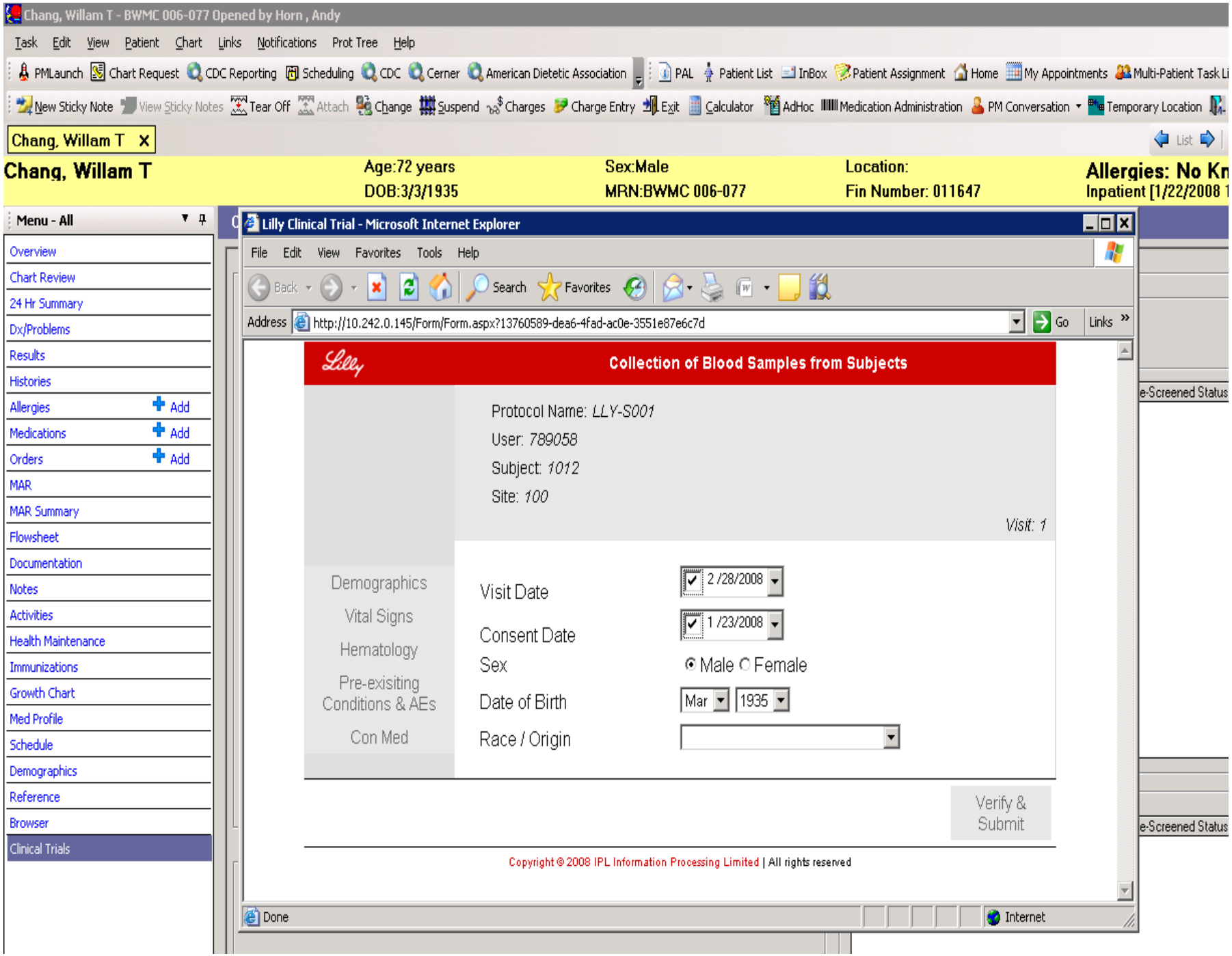


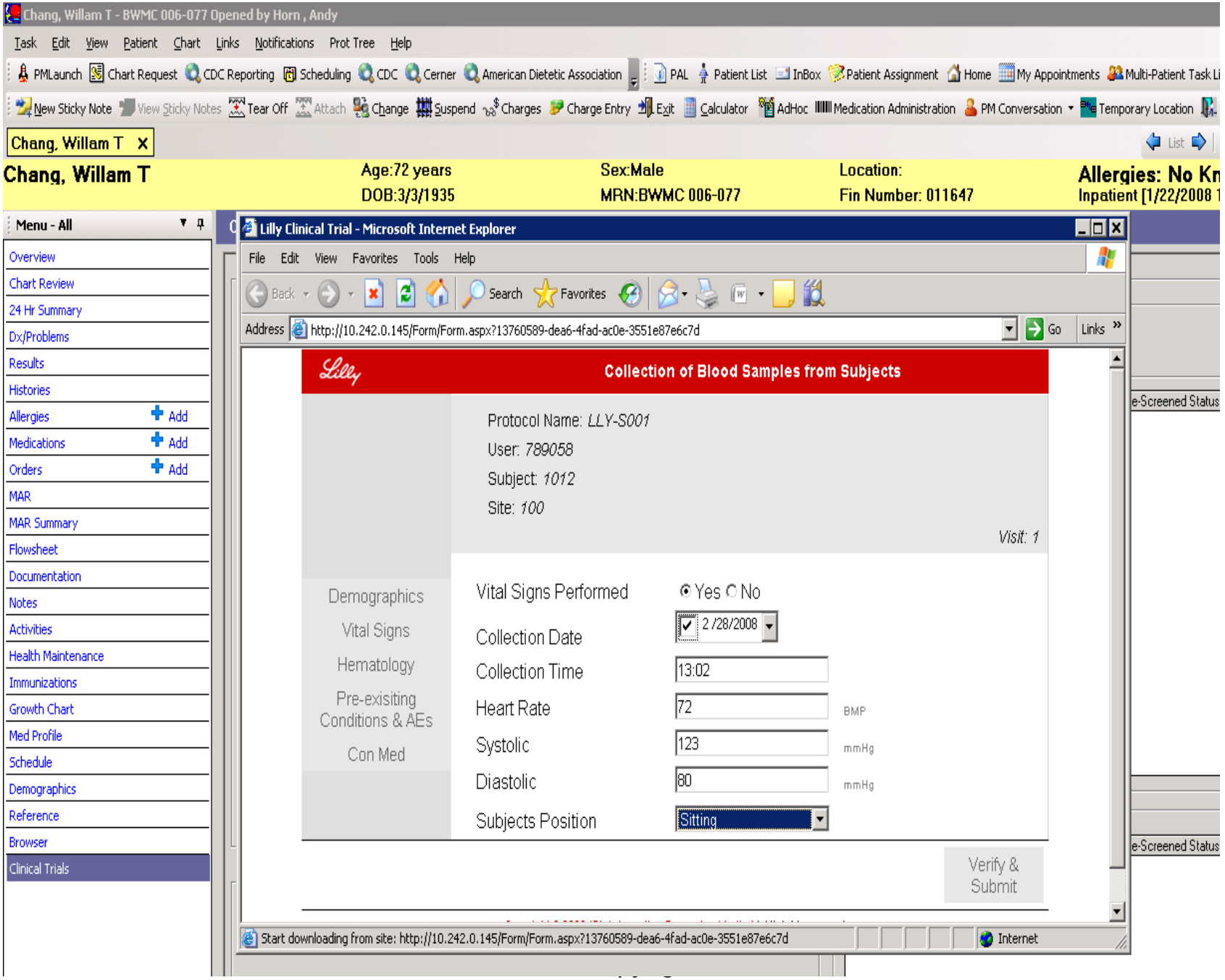
Slides courtesy of CDISC, Landen Bain

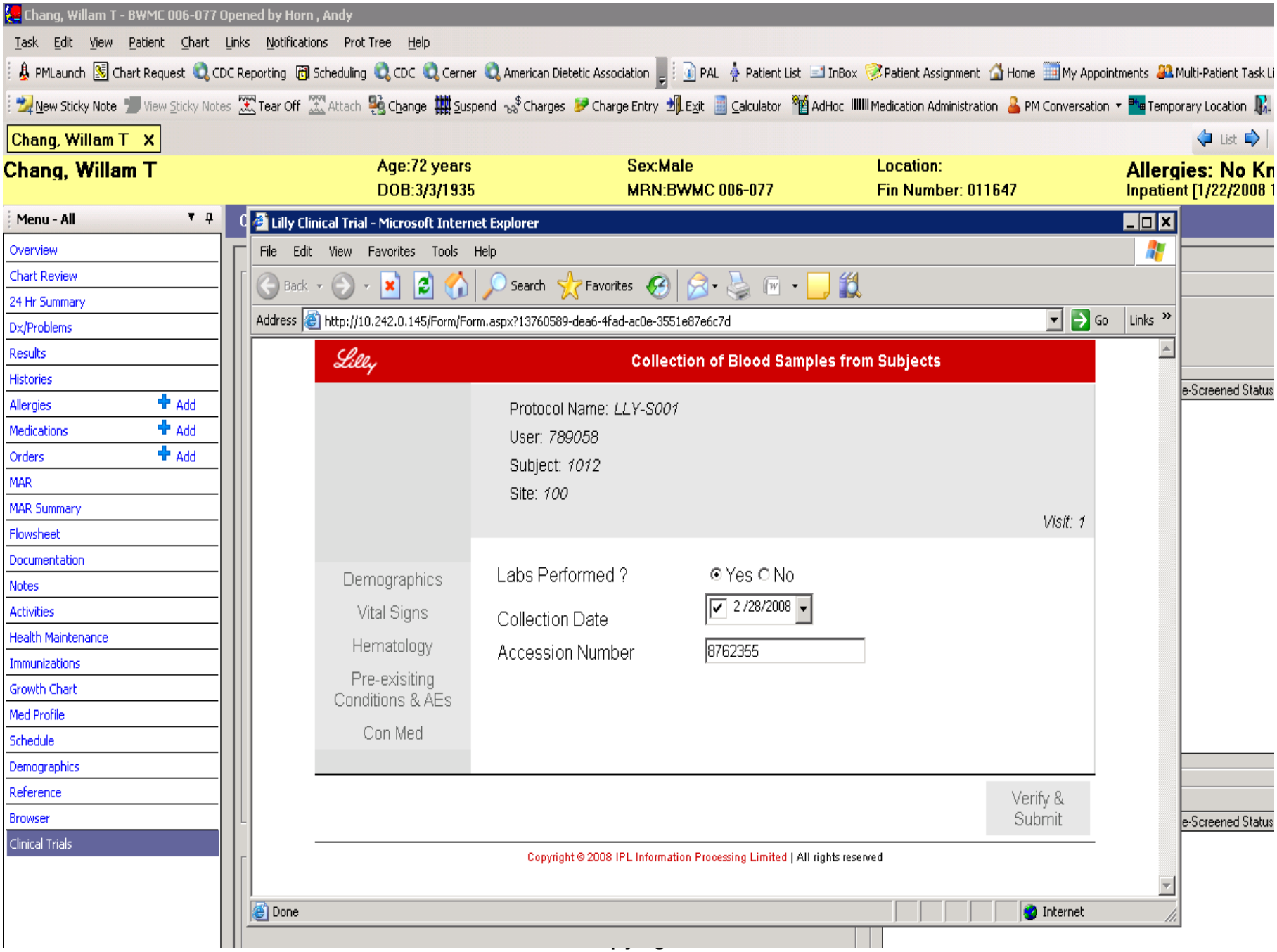
Cerner EHR System- Form Filler
IPL- Form Manager

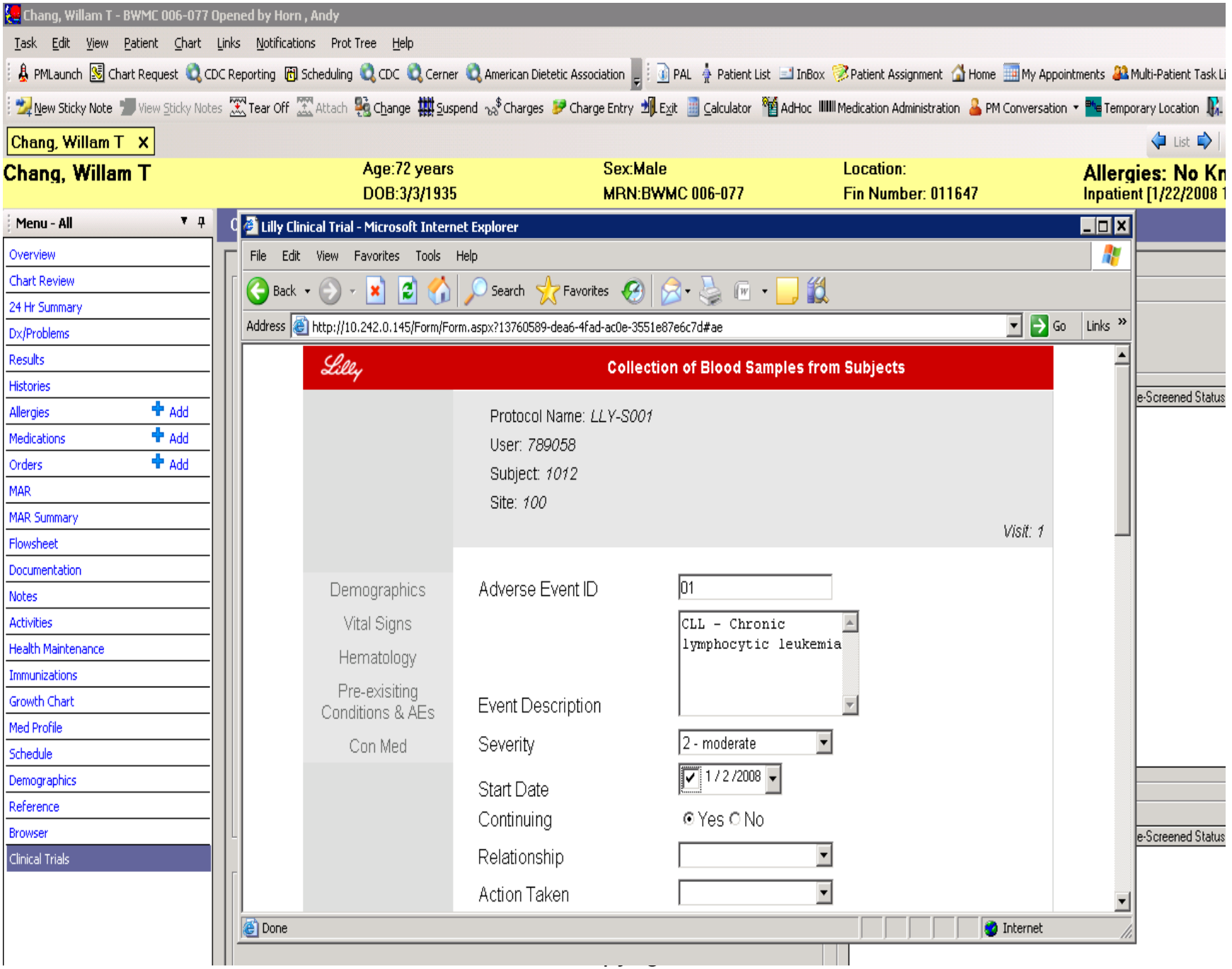


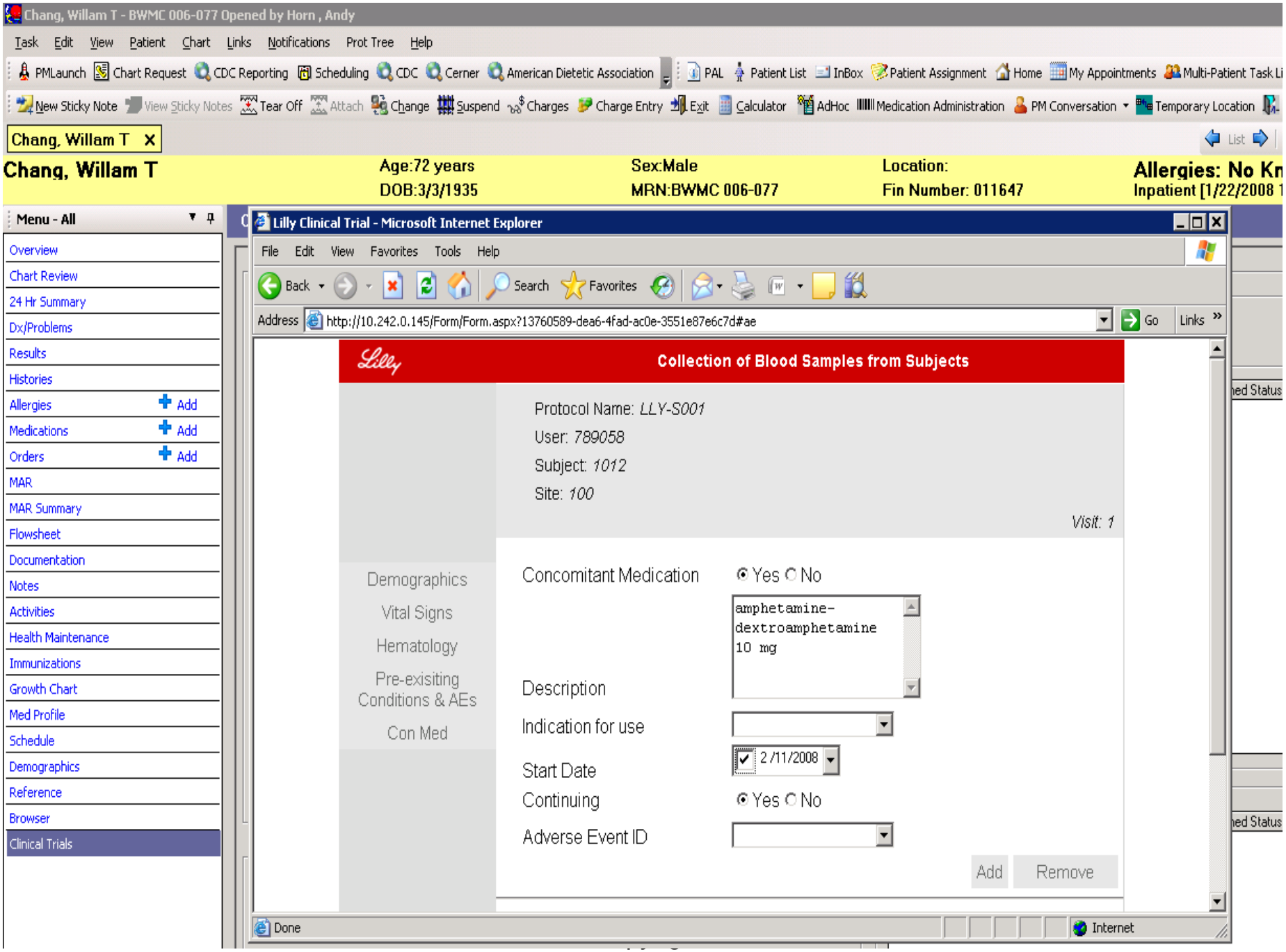

Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
List
Chang, Willam T
Age:72 years
DOB:3/3/1935
Sex:Male
MRN:BWMC 006-077
Location:
Fin Number: 011647
Allergies: No Kn
Inpatient [1/22/2008 1
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Clinical Trials
Clinical Trial Enrollment History for Patient
Protocol Name
eCRF
On Study
Transfer
Off Treatment
Off Study
Contact Info
LLY-S001
1/23/2008
Griffin MD, Jane
Initial Protocol
1/23/2008
Form Selection
Form:
Description
Visit Number
No Form
1
Tiani Receiver
1
Tiani-Spirit Form
V1 Lab Results
1
Visit01
1
Visit date:
//****
OK
Cancel
Potential Clinical Trials for Patient
Check for Potential Trials
Pre-Screening last run by:
Pre-Screening last run on:
Protocol Name
Pre-Screened By
Pre-Screened Date
Pre-Screened Status
Potential Clinical Trials Referred/In Follow-up for Patient
Protocol Name
Pre-Screened By
Pre-Screened Date
Pre-Screened Status
Clinical Trial Interest
Patient is not interested in being screened for ANY Clinical Trials.

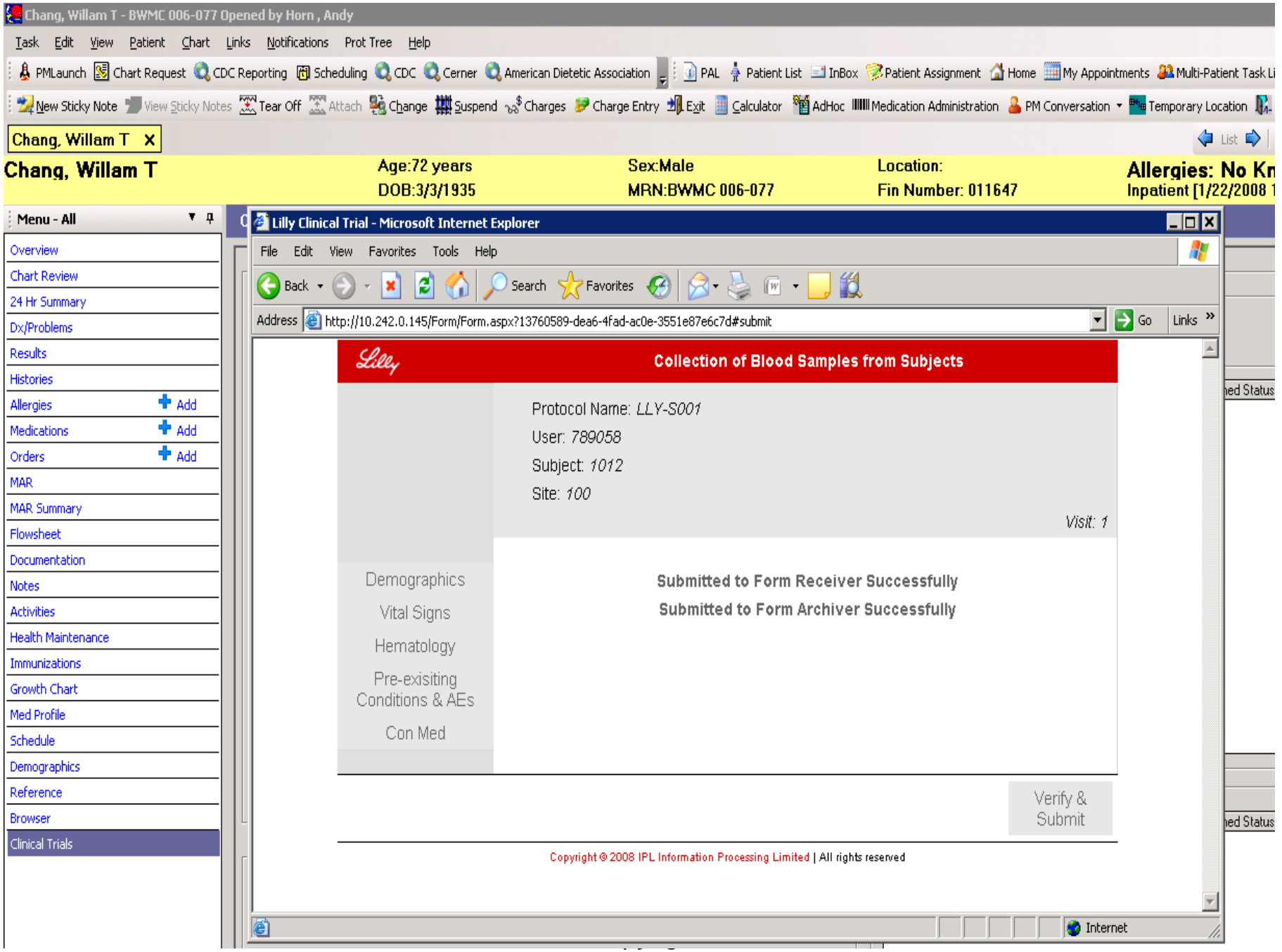

Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
List
Chang, Willam T
Age:72 years
DOB:3/3/1935
Sex:Male
MRN:BWMC 006-077
Location:
Fin Number: 011647
Allergies: No Kn
Inpatient [1/22/2008 1
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Lilly Clinical Trial - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d
Go Links
Lilly
Collection of Blood Samples from Subjects
Protocol Name: LLY-S001
User: 789058
Subject: 1012
Site: 100
Visit: 1
Demographics
Vital Signs
Hematology
Pre-exisiting Conditions & AEs
Con Med
Visit Date 2/28/2008
Consent Date 1/23/2008
Sex Male Female
Date of Birth Mar 1935
Race / Origin
Verify & Submit
Copyright © 2008 IPL Information Processing Limited | All rights reserved
Done
Internet
e-Screened Status
e-Screened Status


Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
Chang, Willam T Age:72 years DOB:3/3/1935 Sex:Male MRN:BWMC 006-077 Location: Fin Number: 011647 Allergies: No Kn Inpatient [1/22/2008
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Lilly Clinical Trial - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d
Go Links
Lilly
Collection of Blood Samples from Subjects
Protocol Name: LLY-S001
User: 789058
Subject: 1012
Site: 100
Visit: 1
Demographics
Vital Signs
Hematology
Pre-exisiting Conditions & AEs
Con Med
Vital Signs Performed Yes No
Collection Date 2/28/2008
Collection Time 13:02
Heart Rate 72 BMP
Systolic 123 mmHg
Diastolic 80 mmHg
Subjects Position Sitting
Verify & Submit
Start downloading from site: http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d
Internet
e-Screened Status
e-Screened Status

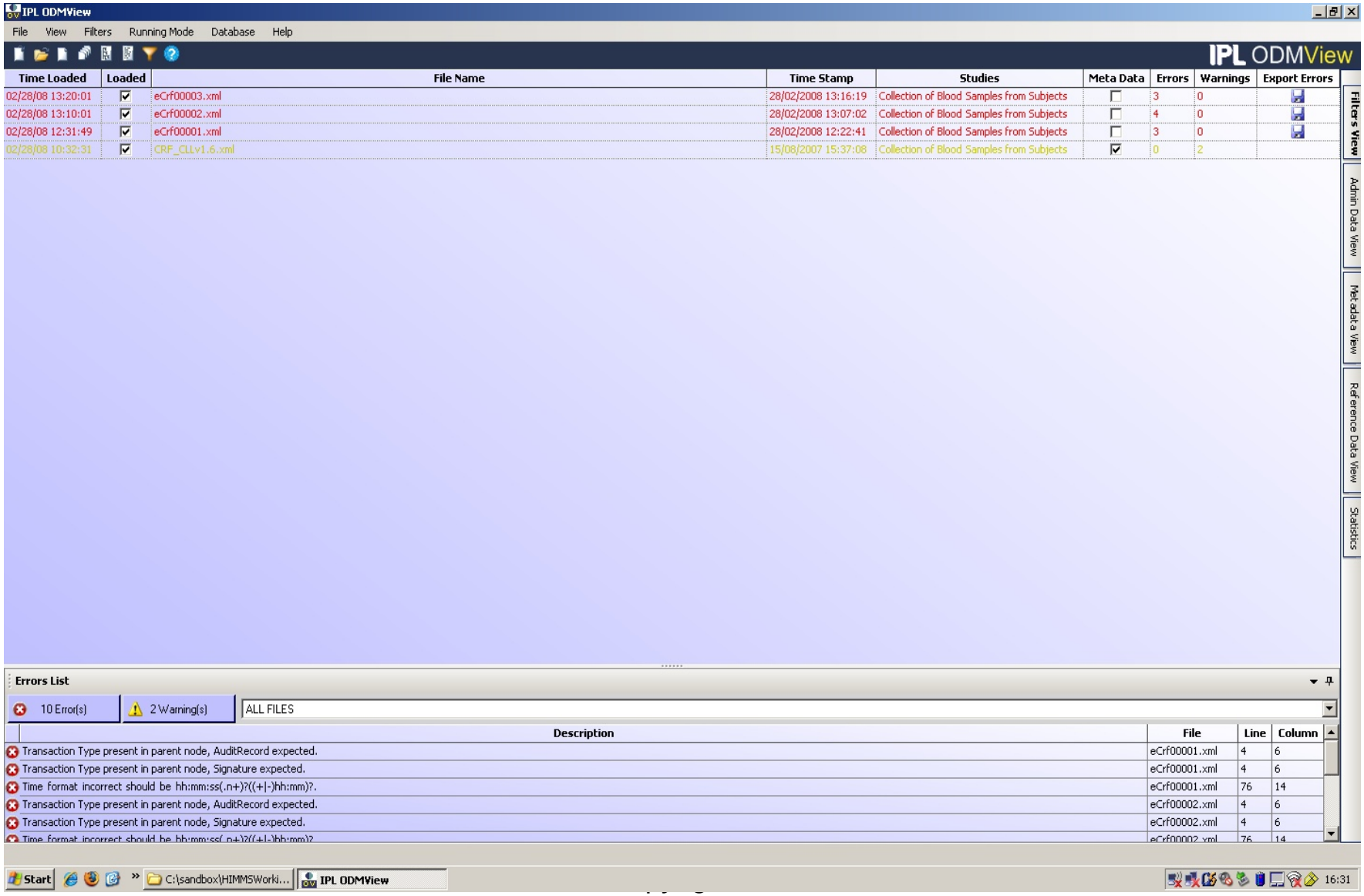

Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
Chang, Willam T
Age:72 years
DOB:3/3/1935
Sex:Male
MRN:BWMC 006-077
Location:
Fin Number: 011647
Allergies: No Kn
Inpatient [1/22/2008
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Lilly Clinical Trial - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d
Go Links
Lilly
Collection of Blood Samples from Subjects
Protocol Name: LLY-S001
User: 789058
Subject: 1012
Site: 100
Visit: 1
Demographics
Vital Signs
Hematology
Pre-exisiting Conditions & AEs
Con Med
Labs Performed ? Yes No
Collection Date 2 /28/2008
Accession Number 8762355
Verify & Submit
Copyright © 2008 IPL Information Processing Limited | All rights reserved
Done
Internet
e-Screened Status
e-Screened Status

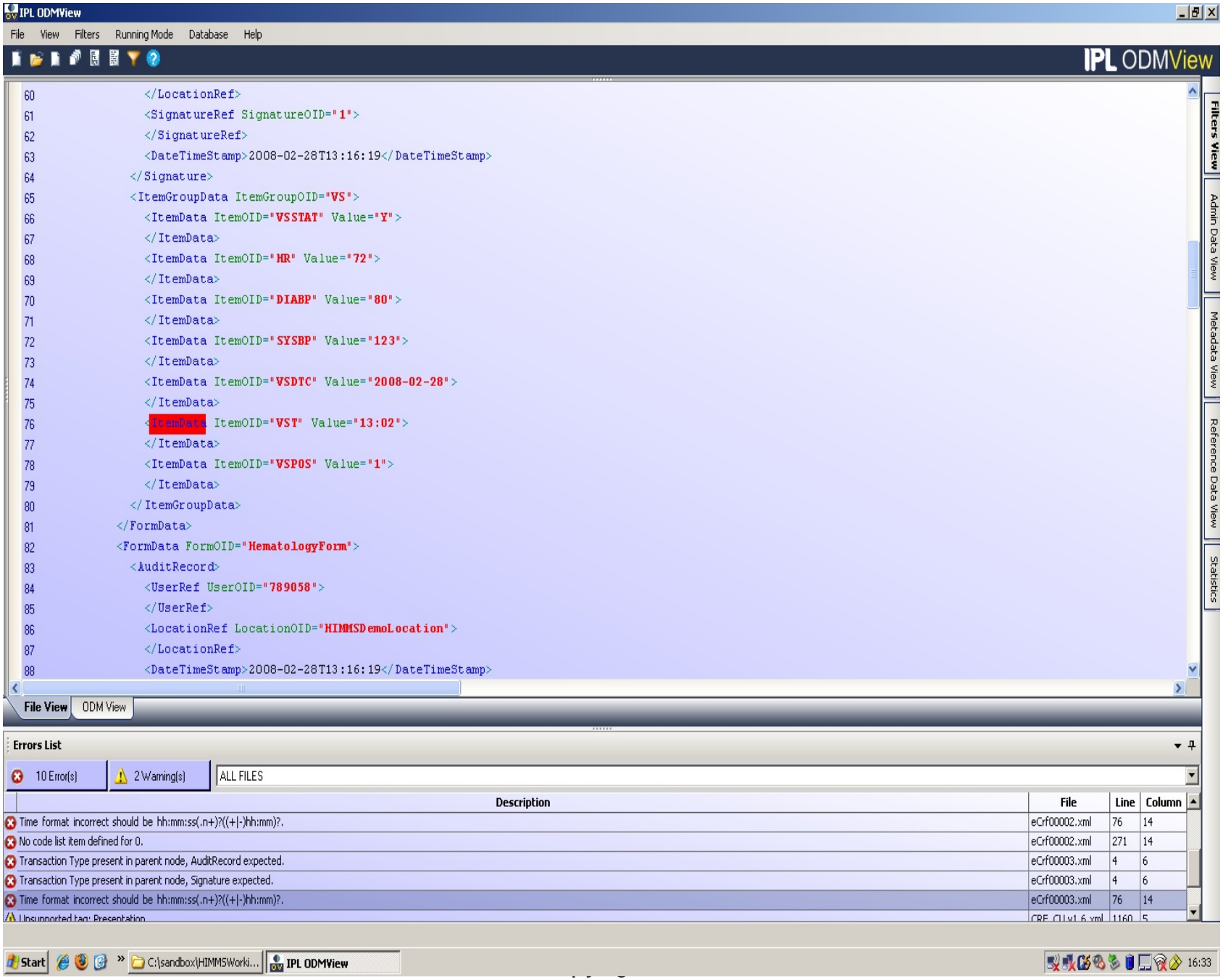

Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
List
Chang, Willam T
Age:72 years
DOB:3/3/1935
Sex:Male
MRN:BWMC 006-077
Location:
Fin Number: 011647
Allergies: No Kn
Inpatient [1/22/2008
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Lilly Clinical Trial - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d#ae
Go Links
Lilly
Collection of Blood Samples from Subjects
Protocol Name: LLY-S001
User: 789058
Subject: 1012
Site: 100
Visit: 1
Demographics
Vital Signs
Hematology
Pre-exisiting Conditions & AEs
Con Med
Adverse Event ID
01
Event Description
CLL - Chronic lymphocytic leukemia
Severity
2 - moderate
Start Date
1 / 2 /2008
Continuing
Yes No
Relationship
Action Taken
Done
Internet
e-Screened Status
e-Screened Status

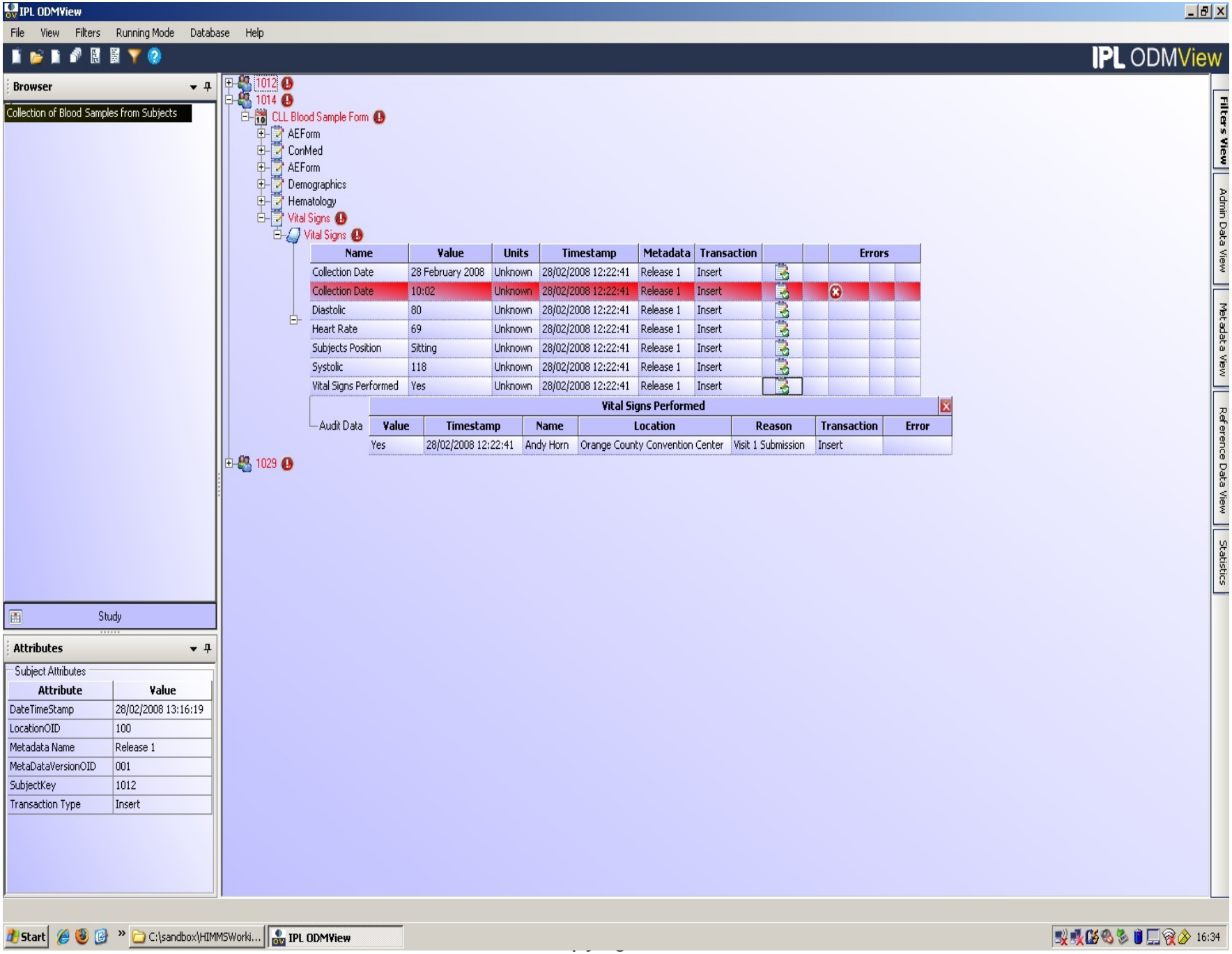

Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
List
Chang, Willam T
Age:72 years
DOB:3/3/1935
Sex:Male
MRN:BWMC 006-077
Location:
Fin Number: 011647
Allergies: No Kn
Inpatient [1/22/2008
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Lilly Clinical Trial - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d#ae
Go Links
Lilly
Collection of Blood Samples from Subjects
Protocol Name: LLY-S001
User: 789058
Subject: 1012
Site: 100
Visit: 1
Demographics
Vital Signs
Hematology
Pre-exisiting Conditions & AEs
Con Med
Concomitant Medication
Yes No
amphetamine-dextroamphetamine 10 mg
Description
Indication for use
Start Date
2/11/2008
Continuing
Yes No
Adverse Event ID
Add
Remove
Done
Internet


Chang, Willam T - BWMC 006-077 Opened by Horn , Andy
Task Edit View Patient Chart Links Notifications Prot Tree Help
PMLaunch Chart Request CDC Reporting Scheduling CDC Cerner American Dietetic Association PAL Patient List InBox Patient Assignment Home My Appointments Multi-Patient Task Li
New Sticky Note View Sticky Notes Tear Off Attach Change Suspend Charges Charge Entry Exit Calculator AdHoc Medication Administration PM Conversation Temporary Location
Chang, Willam T
Chang, Willam T
Age:72 years
DOB:3/3/1935
Sex:Male
MRN:BWMC 006-077
Location:
Fin Number: 011647
Allergies: No Kn
Inpatient [1/22/2008 1
Menu - All
Overview
Chart Review
24 Hr Summary
Dx/Problems
Results
Histories
Allergies Add
Medications Add
Orders Add
MAR
MAR Summary
Flowsheet
Documentation
Notes
Activities
Health Maintenance
Immunizations
Growth Chart
Med Profile
Schedule
Demographics
Reference
Browser
Clinical Trials
Lilly Clinical Trial - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://10.242.0.145/Form/Form.aspx?13760589-dea6-4fad-ac0e-3551e87e6c7d#submit
Go Links
Lilly
Collection of Blood Samples from Subjects
Protocol Name: LLY-S001
User: 789058
Subject: 1012
Site: 100
Visit: 1
Demographics
Vital Signs
Hematology
Pre-exisiting Conditions & AEs
Con Med
Submitted to Form Receiver Successfully
Submitted to Form Archiver Successfully
Verify & Submit
Copyright © 2008 IPL Information Processing Limited | All rights reserved
Internet

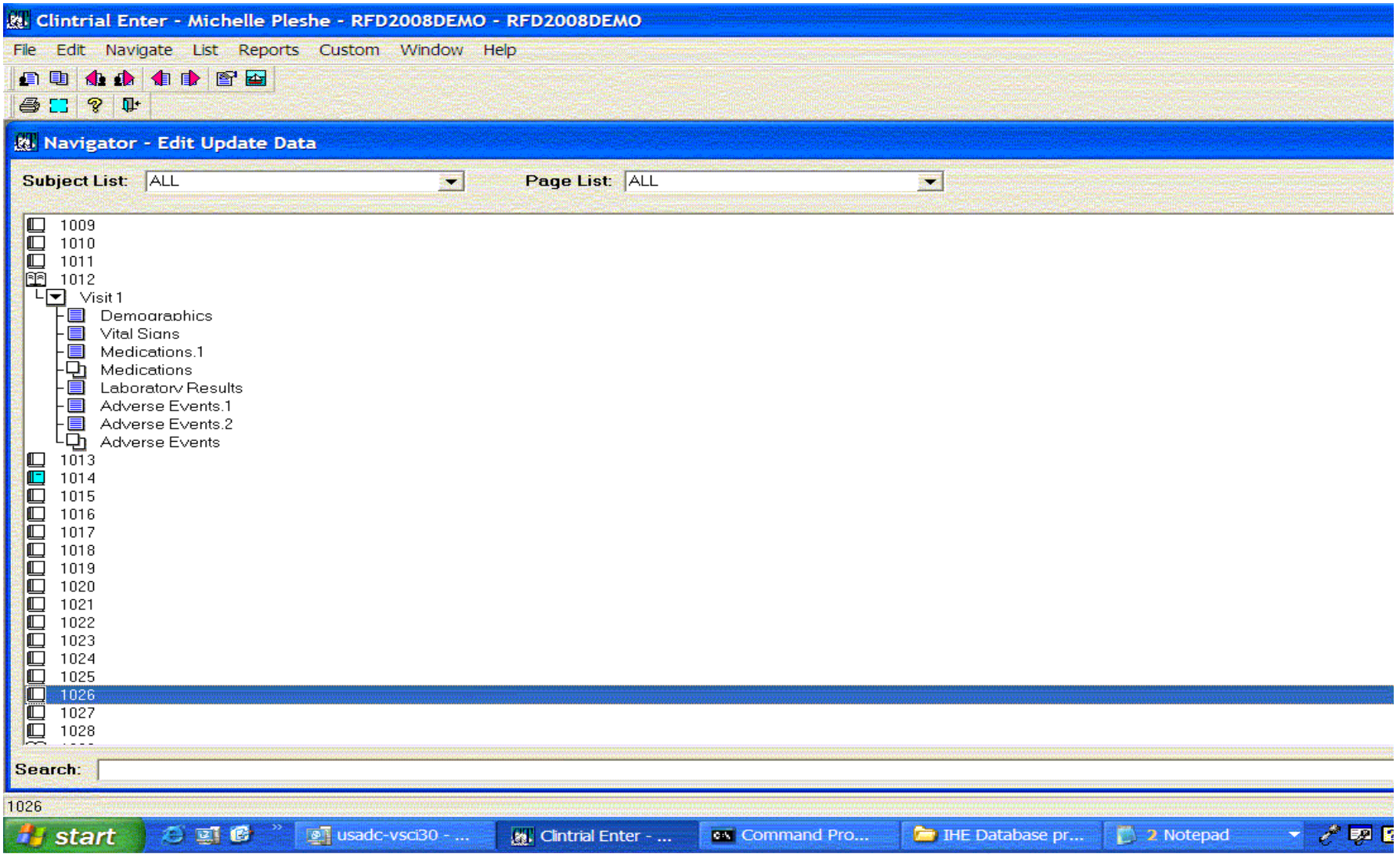
IPL Data Archiver (ODM)

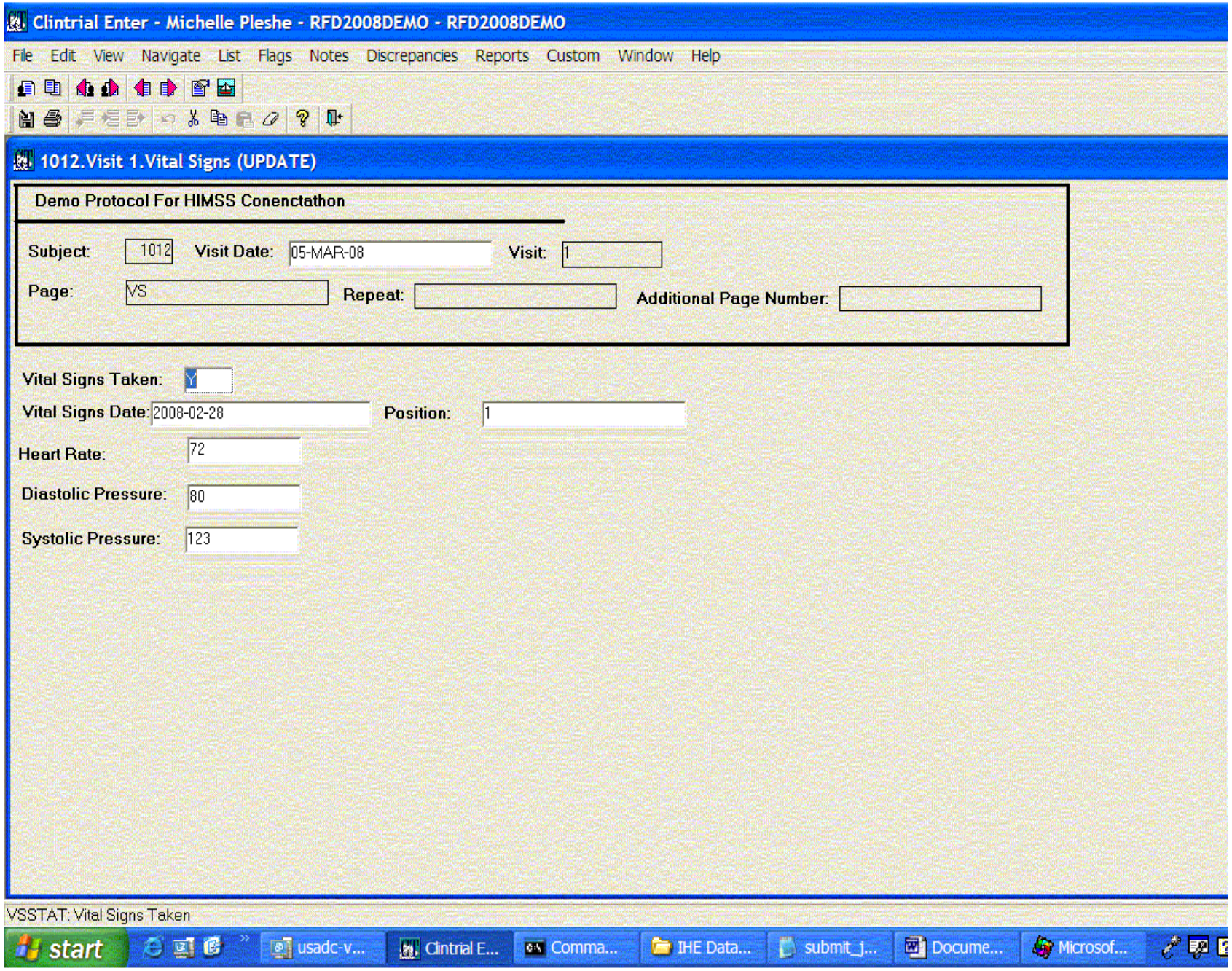


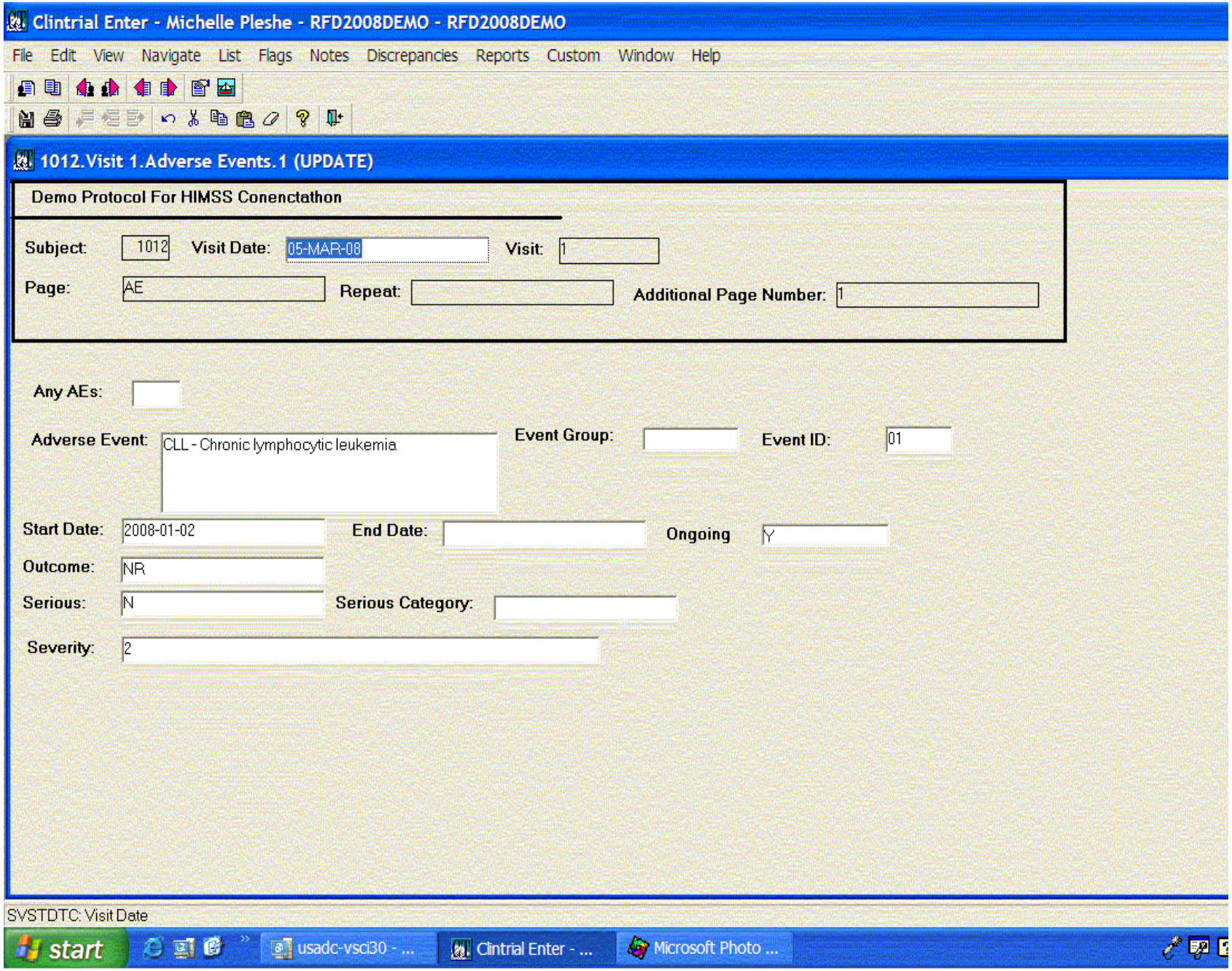

IPL ODMView
File View Filters Running Mode Database Help
IPL ODMView
</LocationRef>
<SignatureRef SignatureOID="1">
</SignatureRef>
<DateTimeStamp>2008-02-28T13:16:19</DateTimeStamp>
</Signature>
<ItemGroupData ItemGroupOID="VS">
<ItemData ItemOID="VSSTAT" Value="Y">
</ItemData>
<ItemData ItemOID="HR" Value="72">
</ItemData>
<ItemData ItemOID="DIABP" Value="80">
</ItemData>
<ItemData ItemOID="SYSBP" Value="123">
</ItemData>
<ItemData ItemOID="VSDTC" Value="2008-02-28">
</ItemData>
<ItemData ItemOID="VST" Value="13:02">
</ItemData>
<ItemData ItemOID="VSPOS" Value="1">
</ItemData>
</ItemGroupData>
</FormData>
<FormData FormOID="HematologyForm">
<AuditRecord>
<UserRef UserOID="789058">
</UserRef>
<LocationRef LocationOID="HIMMSDemoLocation">
</LocationRef>
<DateTimeStamp>2008-02-28T13:16:19</DateTimeStamp>
Filters View
Admin Data View
Metadata View
Reference Data View
Statistics
File View
ODM View
Errors List
10 Error(s)
2 Warning(s)
ALL FILES
Description
File
Line
Column
Time format incorrect should be hh:mm:ss(.n+)?((+|-)hh:mm)?.
eCrf00002.xml
76
14
No code list item defined for 0.
eCrf00002.xml
271
14
Transaction Type present in parent node, AuditRecord expected.
eCrf00003.xml
4
6
Transaction Type present in parent node, Signature expected.
eCrf00003.xml
4
6
Time format incorrect should be hh:mm:ss(.n+)?((+|-)hh:mm)?.
eCrf00003.xml
76
14
Start
C:\sandbox\HIMMSWorki...
IPL ODMView
16:33


IPL ODMView
File View Filters Running Mode Database Help
IPL ODMView
Browser
Collection of Blood Samples from Subjects
Study
Attributes
Subject Attributes
Attribute Value
DateTimeStamp 28/02/2008 13:16:19
LocationOID 100
Metadata Name Release 1
MetaDataVersionOID 001
SubjectKey 1012
Transaction Type Insert
1012
1014
CLL Blood Sample Form
AEForm
ConMed
AEForm
Demographics
Hematology
Vital Signs
Vital Signs
Name Value Units Timestamp Metadata Transaction Errors
Collection Date 28 February 2008 Unknown 28/02/2008 12:22:41 Release 1 Insert
Collection Date 10:02 Unknown 28/02/2008 12:22:41 Release 1 Insert
Diastolic 80 Unknown 28/02/2008 12:22:41 Release 1 Insert
Heart Rate 69 Unknown 28/02/2008 12:22:41 Release 1 Insert
Subjects Position Sitting Unknown 28/02/2008 12:22:41 Release 1 Insert
Systolic 118 Unknown 28/02/2008 12:22:41 Release 1 Insert
Vital Signs Performed Yes Unknown 28/02/2008 12:22:41 Release 1 Insert
Audit Data
Vital Signs Performed
Value Timestamp Name Location Reason Transaction Error
Yes 28/02/2008 12:22:41 Andy Horn Orange County Convention Center Visit 1 Submission Insert
1029
Filters View
Admin Data View
Metadata View
Reference Data View
Statistics
Start
C:\sandbox\HIMMSWorki...
IPL ODMView
16:34

Lilly/Quintiles- Data Receiver




Clintrial Enter - Michelle Pleshe - RFD2008DEMO - RFD2008DEMO
File Edit View Navigate List Flags Notes Discrepancies Reports Custom Window Help
1012.Visit 1.Vital Signs (UPDATE)
Demo Protocol For HIMSS Conenctathon
Subject: 1012 Visit Date: 05-MAR-08 Visit: 1
Page: VS Repeat: Additional Page Number:
Vital Signs Taken: Y
Vital Signs Date: 2008-02-28 Position: 1
Heart Rate: 72
Diastolic Pressure: 80
Systolic Pressure: 123
VSSTAT: Vital Signs Taken
start
usadc-v...
Clintrial E...
Comma...
IHE Data...
submit_j...
Docume...
Microsof...


Clintrial Enter - Michelle Pleshe - RFD2008DEMO - RFD2008DEMO
File Edit View Navigate List Flags Notes Discrepancies Reports Custom Window Help
1012.Visit 1.Adverse Events.1 (UPDATE)
Demo Protocol For HIMSS Conenctathon
Subject: 1012 Visit Date: 05-MAR-08 Visit: 1
Page: AE Repeat: Additional Page Number: 1
Any AEs:
Adverse Event: CLL - Chronic lymphocytic leukemia
Event Group: Event ID: 01
Start Date: 2008-01-02 End Date: Ongoing Y
Outcome: NR
Serious: N Serious Category:
Severity: 2
SVSTDTC: Visit Date
start
usadc-vsci30 - ...
Clintrial Enter - ...
Microsoft Photo ...

Next Steps

- Define roles and responsibilities for set-up and execution of RFD
- Document set-up requirements for site, sponsor, archiver
- Establish workflow processes at site
- Define operational definition of datalock
- Implement in ‘real-world’ setting


Questions?
For more information on EHR/CR project…
www.EHRCR.org
On HIMSS 2008…
king_linda_s@lilly.com
EHR|CR