CDISC and IHE

PROUDLY PRESENT

New Directions

Life Sciences Bridging to Healthcare

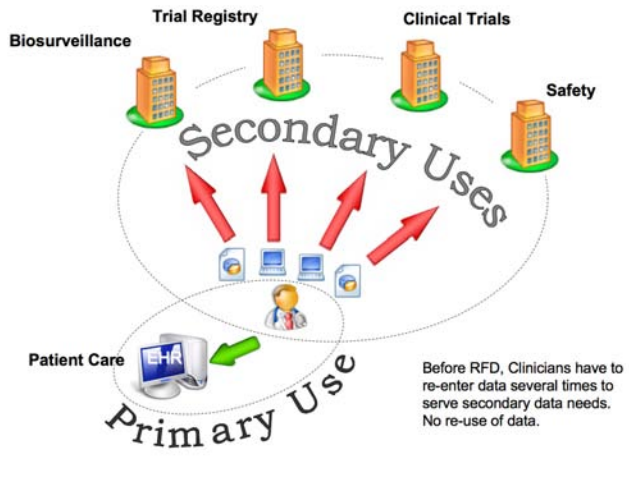
The Clinical Data Interchange Standards Consortium (CDISC) is leading a first-of-its-kind demonstration to prototype the bridging of healthcare data to research and surveillance.

Co-sponsored by Integrating the Healthcare Enterprise (IHE), the New Directions- Life Sciences Interoperability demonstrations employ the IHE profile–Retrieve Form for Data Capture (RFD)–to enable data integration between systems.

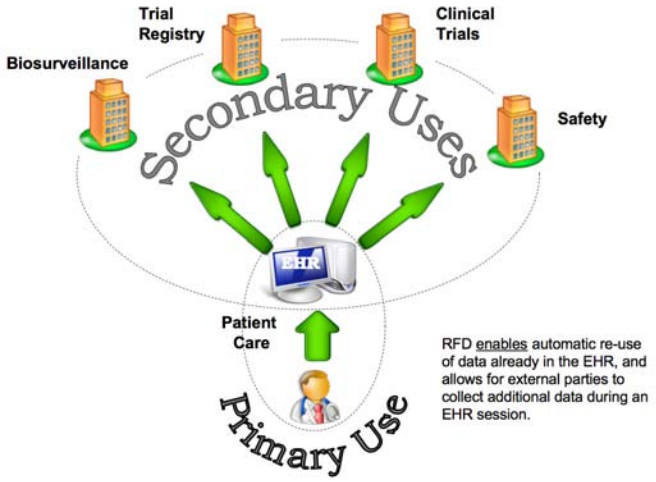
The demonstration depicts five (5) use case scenarios which show how clinical data can be transferred seamlessly between care provider's EHR systems and systems used for clinical research, disease registries, safety surveillance, and disease surveillance.

By collecting these data at a single source– the point of care EHR system–physicians and staff need not re-enter data into specialized research and surveillance applications. Avoiding this redundant data entry reduces data errors and saves the care provider's valuable time while allowing key data to be reported in a timely and accurate manner.

Before Interoperability



With Interoperability



New Directions Industry Scenario Teams

Scenario Sponsor	Scenario Description	Scenario Participants
Pfizer	Drug Safety	Allscripts, Sentrx/Relsys, SAS
Novartis	Clinical Trial: Lab and Image Data	Novartis, Siemens, SAS
Eli Lilly	Clinical Trial: Visit Workflow	Cerner Corporation, Phase Forward, IBM
Genzyme	Disease Registry	Outcome, Allscripts, Digital Infuzion, SAS, Assero/IPL
SAIC/CDC	Biosurveillance	IBM, Allscripts, Cerner, SAS, University of Washington

Regulatory Compliance Oversight

SEC Associates will be providing regulatory oversight to address considerations relevant to 21CFR Part 11 compliance.

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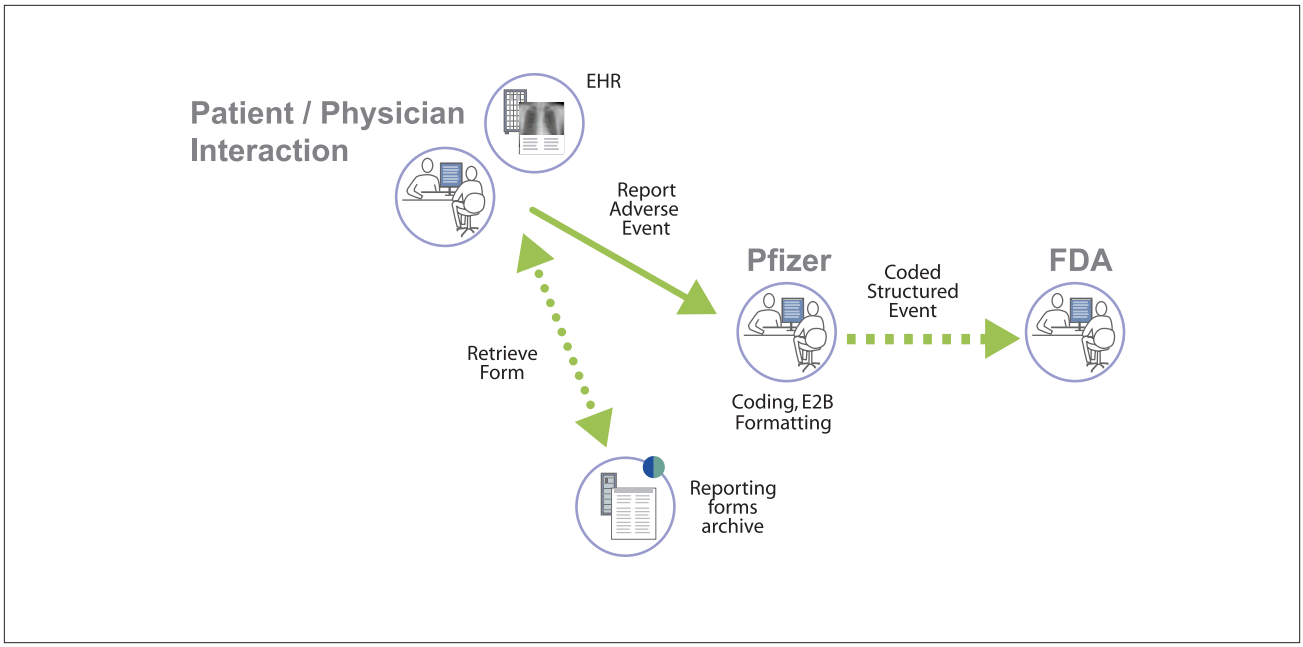
Drug Safety

Streamlining Adverse Event Reporting

Starring: Pfizer · Allscripts · Sentrx · Relsys · SAS



Before Interoperability

- Administrative burden associated with filling out adverse event reports
- Not part of a physician's normal workflow or system
- May require over 30 minutes of time devoted to filling out forms
- Waiting until later to report can lead to errors in accuracy, truncated information, and data duplication errors

With Interoperability

- Administrative burden greatly decreased
- Completing an adverse event report becomes part of normal workflow
- Prepopulation of key data decreases time to complete form, increases quality of data in report
- Near real time completion of primary concern encourages proper clinical judgement
- Providing more widespread and more rapid feedback to regulators and companies can directly improve public health

Implementers

Allscripts

Sentrx

Relsys

SAS

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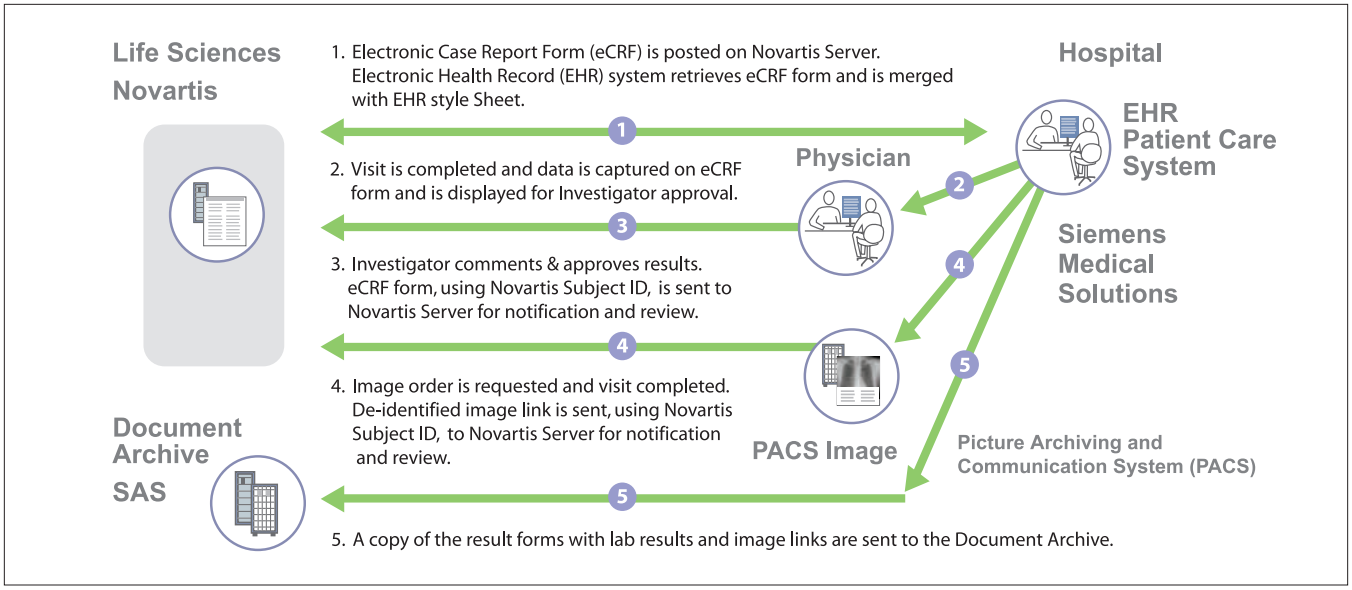
Clinical Trial: Lab and Image Data

Innovating Local Labs and Imaging Electronic Data Capture (EDC)

Starring: Novartis · Siemens Medical Solutions · SAS



Before Interoperability

- For Labs & Images – Clinical investigator or study nurse must manually copy results onto a Case Report Form (CRF) using captured data from an EHR system print-out, lab report or image assessment causing errors and work disruption.
- The data entry may occur days or weeks after the information is collected on the CRF.
- In addition, without the automated transfer of the image, a user must manually access the Siemens Radiology Information System (RIS)/ Picture Archiving and Communication System (PACS) and request that the image be placed on a CD/DVD which will then be mailed to Novartis or a trusted third party.
- Additional effort is needed by sponsor to archive source documents.

With Interoperability

- Information is collected electronically during the normal patient care process. Data available from the EHR is pre-populated in the electronic clinical trial form, reducing manual effort, errors and workflow disruption.
- The information is then immediately available to the Novartis system once the form has been submitted.
- Similarly, the image referenced in the submitted form is electronically transferred from the Siemens PACS system. The reference image can be stored in the Novartis system and sent to a trusted third party. All of the information is available within the Novartis Clinical Research System within minutes of the submission of the form by the physician.
- All transmitted source documents are electronically archived.

Implementers

Novartis

Siemens Medical Solutions

SAS

Contacts

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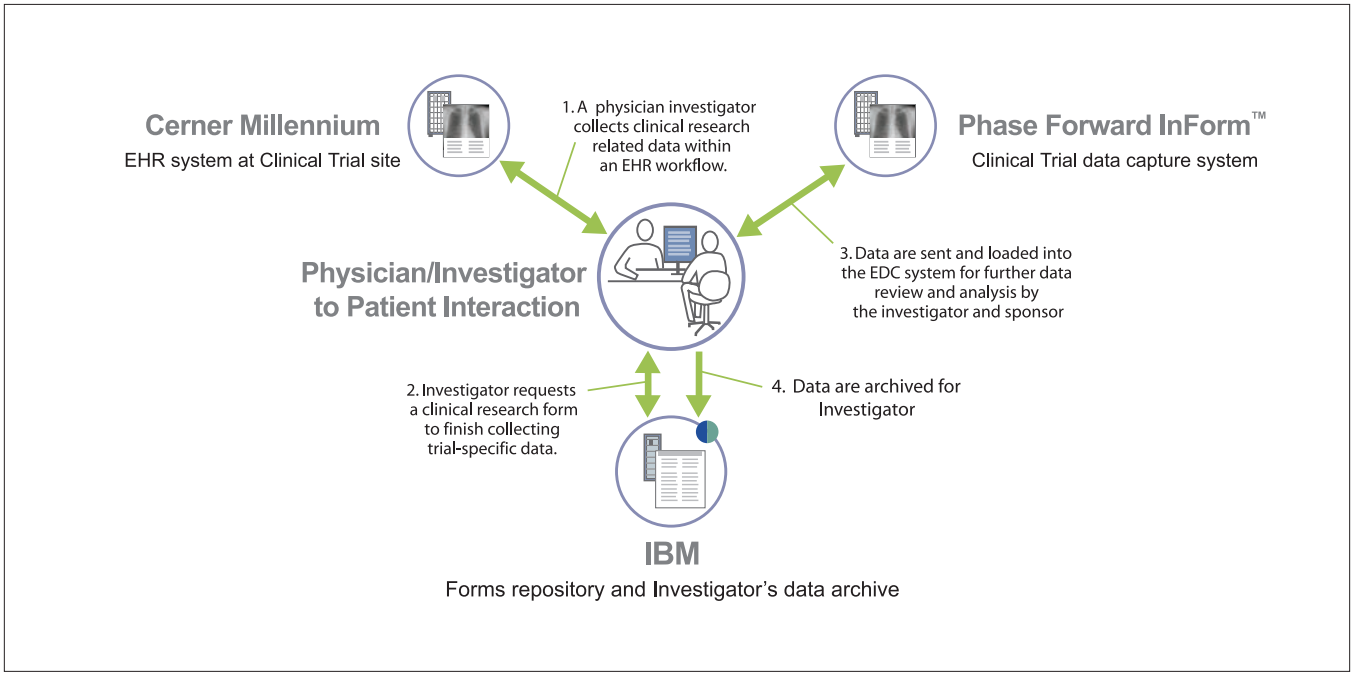
Clinical Trial: Visit Workflow

Streamlining the Clinical Trial Workflow

Starring: Lilly · Cerner Corportion · Phase Forward · IBM



Before Interoperability

- Manual data entry utilizing paper or electronic case report forms
- Different computers or web portals (outside the EHR system workflow) for each sponsor
- Unique logins
- Various case report form layouts
- Different data elements and data formats required depending on the sponsor or the trial
- Perception of 25% sites surveyed: EDC is increasing their workload (upfront)

With Interoperability

- Minimize redundant data entry
  - Increase efficiency
  - Improve data quality
- Integrate research into clinical care EHR system workflow
  - Facilitate and promote research reaching more clinicians and more patients
  - Enhance patient safety and protocol compliance while maintaining patient privacy
- Standardize clinical trial data collection
  - Assure data security and confidentiality
  - Enable data integration/analysis across trials
  - Reduce data monitoring and auditing needs
  - Support regulatory requirements

Implementers

Cerner Corporation

Phase Forward

IBM

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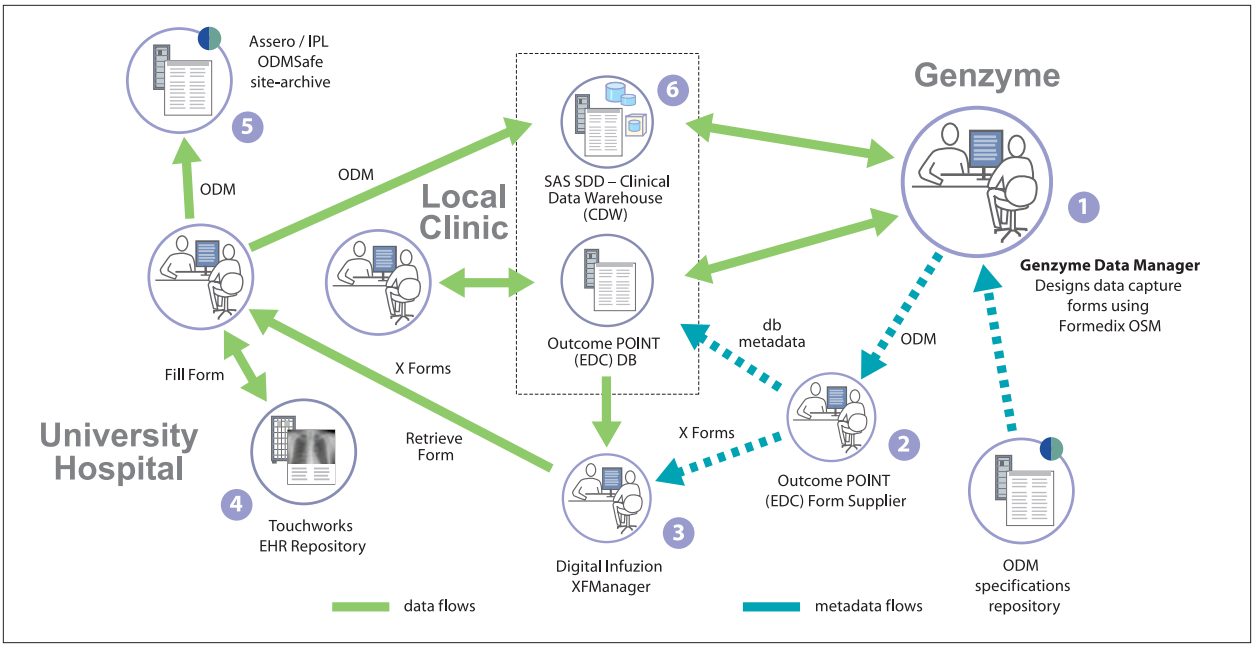
Disease Registry

An Ordinary Patient with a Rare Disease

Starring: Genzyme · Allscripts · Asserro / IPL · Digital Infusion · Formedix · Outcome · SAS



Before Interoperability

- Considerable time and expense associated with building specialized technical solutions for rare disease registries.
- Separate logon for EMR and LSD disease registry.
- Duplicate data entry in EMR and LSD disease registry.
- Different user interface in EMR and LSD disease registry
- Lack of notification when new data is available for inclusion in the LSD disease registry
- Lack of feedback when data in the LSD disease registry requires further clarification.
- Difficult to gather broad based longitudinal information about the rare disease.

With Interoperability

- Time and expense invested in reusable standards based study definitions; Easier to deploy to multiple platforms.
- Single sign-on enabled.
- Reduction in duplicate data entry
- EMR users know when new info is available for the LSD disease registry.
- More feedback when data in LSD disease registry requires further clarification.
- Easier to collect broad based longitudinal data, improving understanding of the rare disease, ultimately improving patient care.

Implementers

Allscripts

Assero / IPL

Digital Infuzion

Formedix

Outcome

SAS

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Biosurveillance

Standardizing and Facilitating Data Collection for Enhanced Biosurveillance

Starring: SAIC · CDC · Allscripts · Cerner · IBM · SAS · University of Washington

SAIC in cooperation with the Centers for Disease Control and Prevention (CDC) will demonstrate how the World Wide Web Consortium (W3C) XForms standard, along with integration software components defined by the Integrating the Healthcare Enterprise (IHE) Retrieve Form for Data Capture (RFD) profile, can be used to standardize and facilitate the reporting of public health threats. RFD enables powerful XForms-based surveillance instruments to be integrated into the routine healthcare workflow, reducing the reporting burden while assuring that collected data are consistent and instantly analyzable – thus improving our nation's ability to continuously monitor health and to rapidly respond to health emergencies.

Before Interoperability

- Providers report public health threats via paper forms and fax, or disease-specific applications.
- Reporting variability adversely affects data quality, utility, and timeliness.
- Rapid detection of pubic health threats challenging.
- Collaboration among public health organizations onerous.

With Interoperability

- Providers report public health threats as part of their routine workflow.
- Standard questions, response sets, and terminologies produce high-quality data that are instantly analyzable, enabling more rapid detection of public health threats and facilitating collaboration among public health partners

Implementers

Allscripts

Cerner

IBM

SAS

University of Washington

Contacts

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From Science to Solutions

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Regulatory Compliance Oversight

SEC Associates, Inc. is providing regulatory compliance oversight to the New Directions – Life Sciences Interoperability demonstration teams. In this capacity, SEC is addressing 21 CFR Part 11 and GCP records compliance issues that are likely to affect various scenarios. Several key considerations are noted below. Not all of the questions raised apply to every scenario; and the Biosurveillance scenario may be exempt from most or all of them. The issues listed below are focused primarily on the limited scope of this demonstration. For example, all data flows unidirectionally from EHRs to other systems (EDC, disease registry, SAE processing center, etc.); queries and data reconciliation upstream to the EHR are beyond the scope of this demonstration.

GCP Record Requirements

- Who controls the source data? How?
- How can monitors and regulators inspect, copy, and verify records and reports against source data archives?
- When a physician submits an AE form to FDA/Pharma via EHR/NHIN, does Pharma know with certainty that FDA received it?
- How is record retrievability and usability assured over the entire retention period?

Date/Time Stamps

- How will date/time stamps be applied across systems to ensure consistency?
- Will systems synchronize with a trusted third party source for date and time?

Audit Trails

- Are audit trails enabled as a means of ensuring that only authorized additions, deletions, or alterations have occurred within the EHR, EDC, registry, & archives?

System Dependability

- What assurance is there that EHR data received by EDC or other system is accurate and trustworthy?
- How are accurate and complete data translations and transformations assured?
- How are accuracy, completeness, data edits, etc., assured as various components (EHR, EDC, SAE processing center, etc.) undergo software and hardware revisions?

Contingency Plans

- If the source archive stays at the CI site, is it properly backed up? Do plans exist for data recovery if necessary?
- Have alternative recording methods been developed in case the electronic systems are unavailable?

System & Transmission Security

- As records are transmitted from EHR to other systems over the internet, how are data integrity, authenticity and confidentiality assured?
- How does the EHR system authenticate itself as a trusted source to the EDC system, disease registry, archive, etc?
- Are user authentication and access controls adequate?
- Are audit trails adequately protected?
- What assurance is there that the X-Form cannot be used for unauthorized access or to introduce a virus or worm to the receiver?
- Will sites track who had access (and at what level or role) to the EHR, EDC and archive over the course of the trial?

Risk Assessment

Has a risk assessment been performed for each of the above categories?

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