The Study of Standard-Based Electronic Case Report Form Design System

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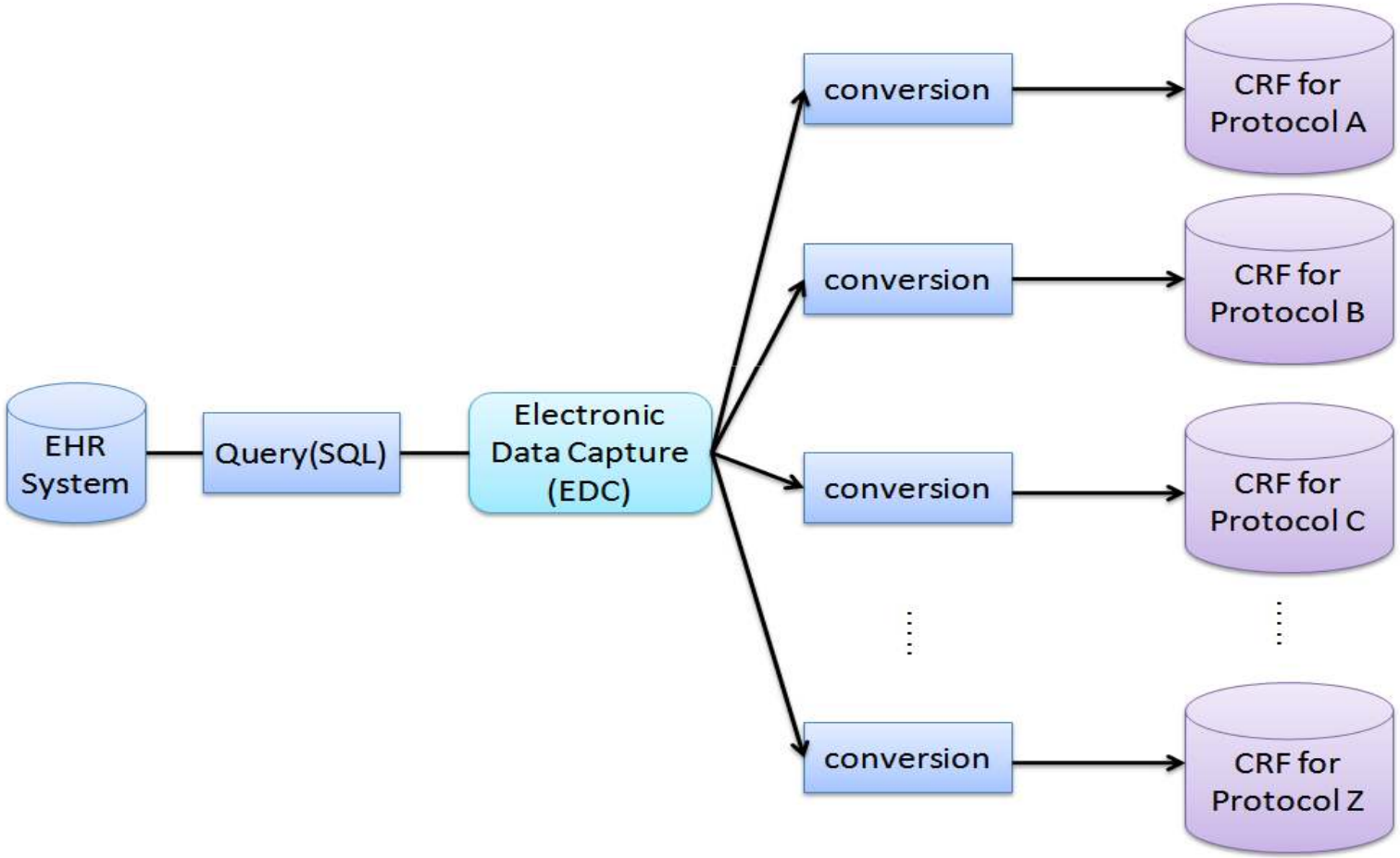
Date :2009/05/08

Challenge for Direct Data Capture



FDA's Critical Path Opportunity List(#45)

- Consensus on Standards for CRFs
  - Improve efficiency and accuracy for data collection

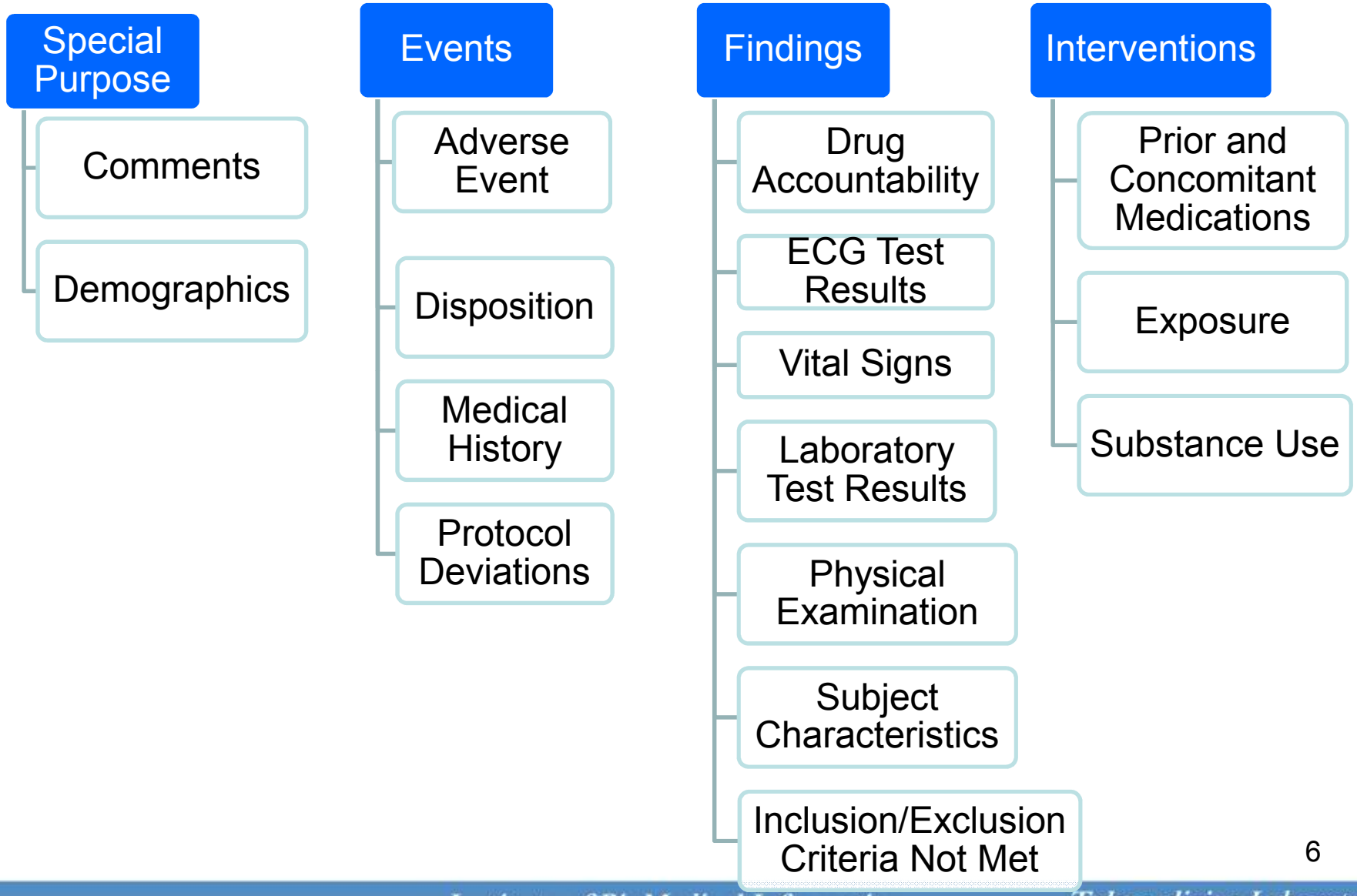
CDISC

- Clinical Data Standards Interchange Consortium (CDISC)
  - Develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

Clinical Data Acquisition Standards Harmonization (CDASH)

- Defines consensus-based CRF content standard
  - Speeding up initiation of new trials
  - Minimizing the need of customization for EDC systems

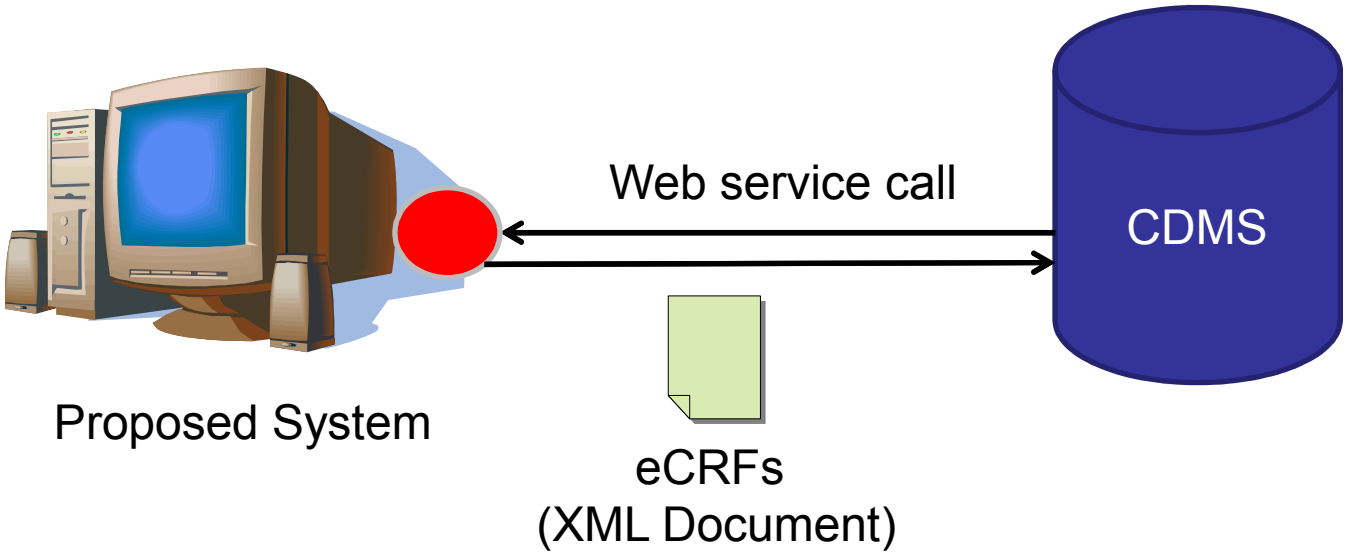
CDASH for Interoperability



Aims

- Building a system to facilitate researchers establishing CDASH-based eCRF

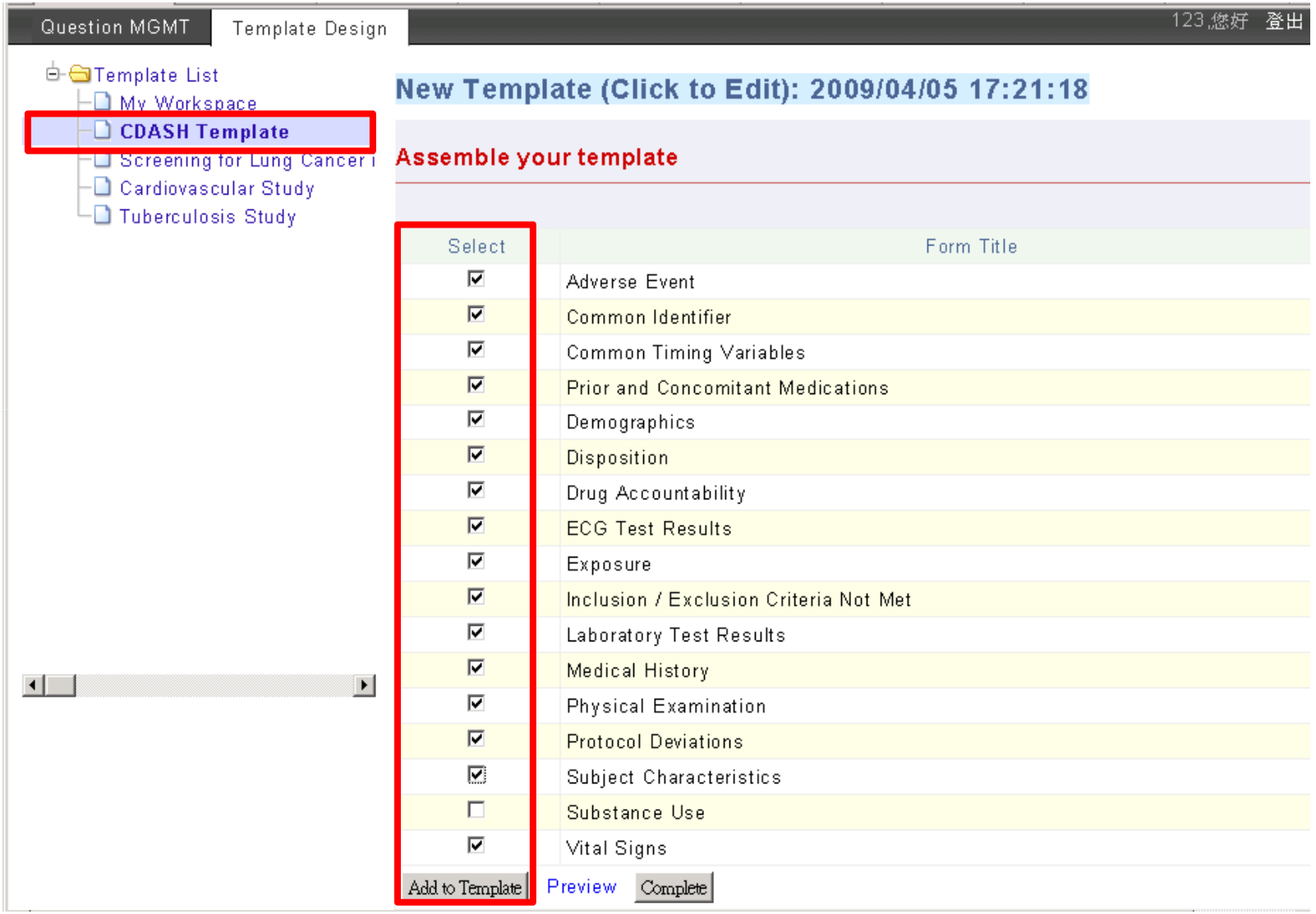
System Scope



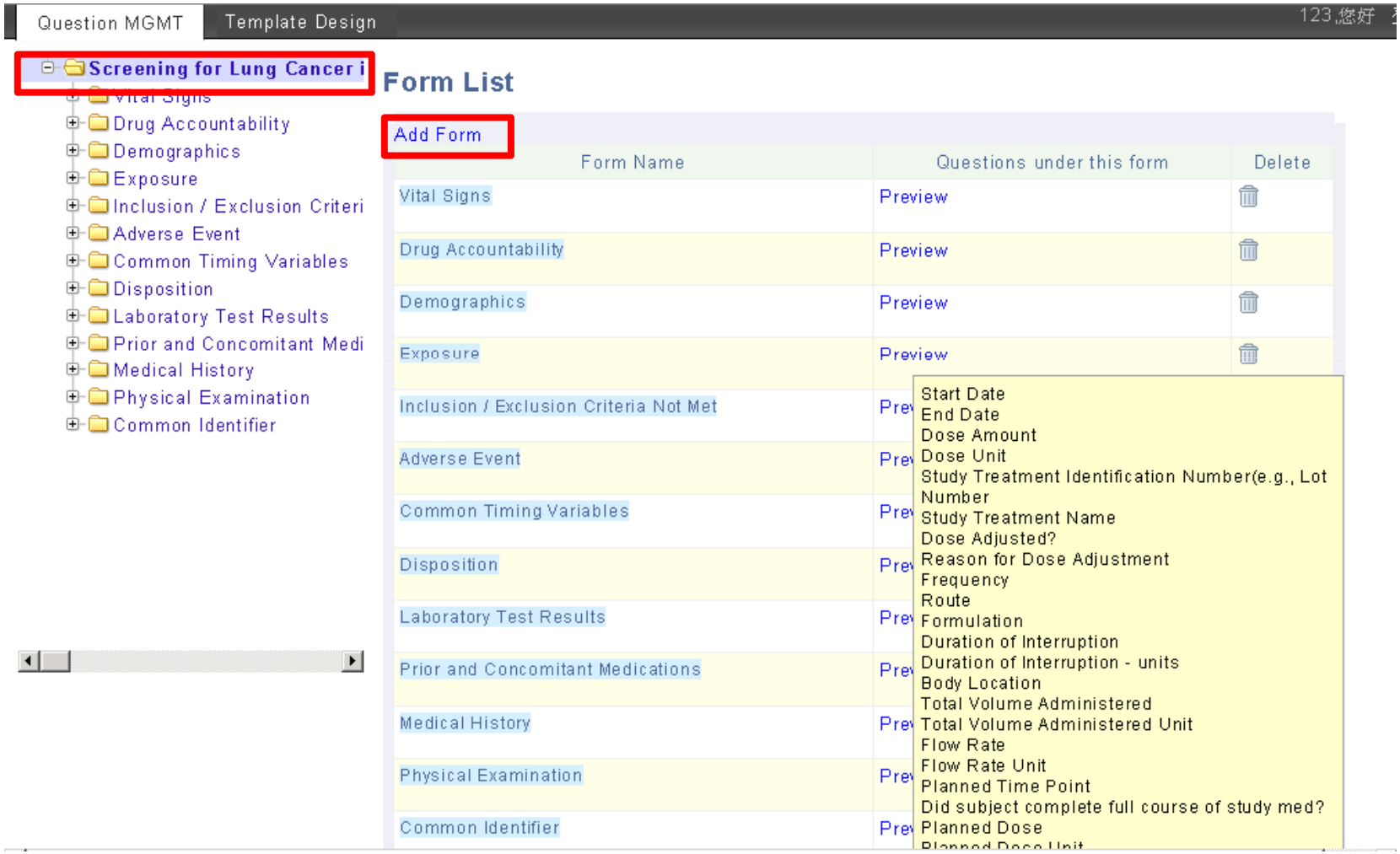
CDMS : Clinical Data Management System

Result

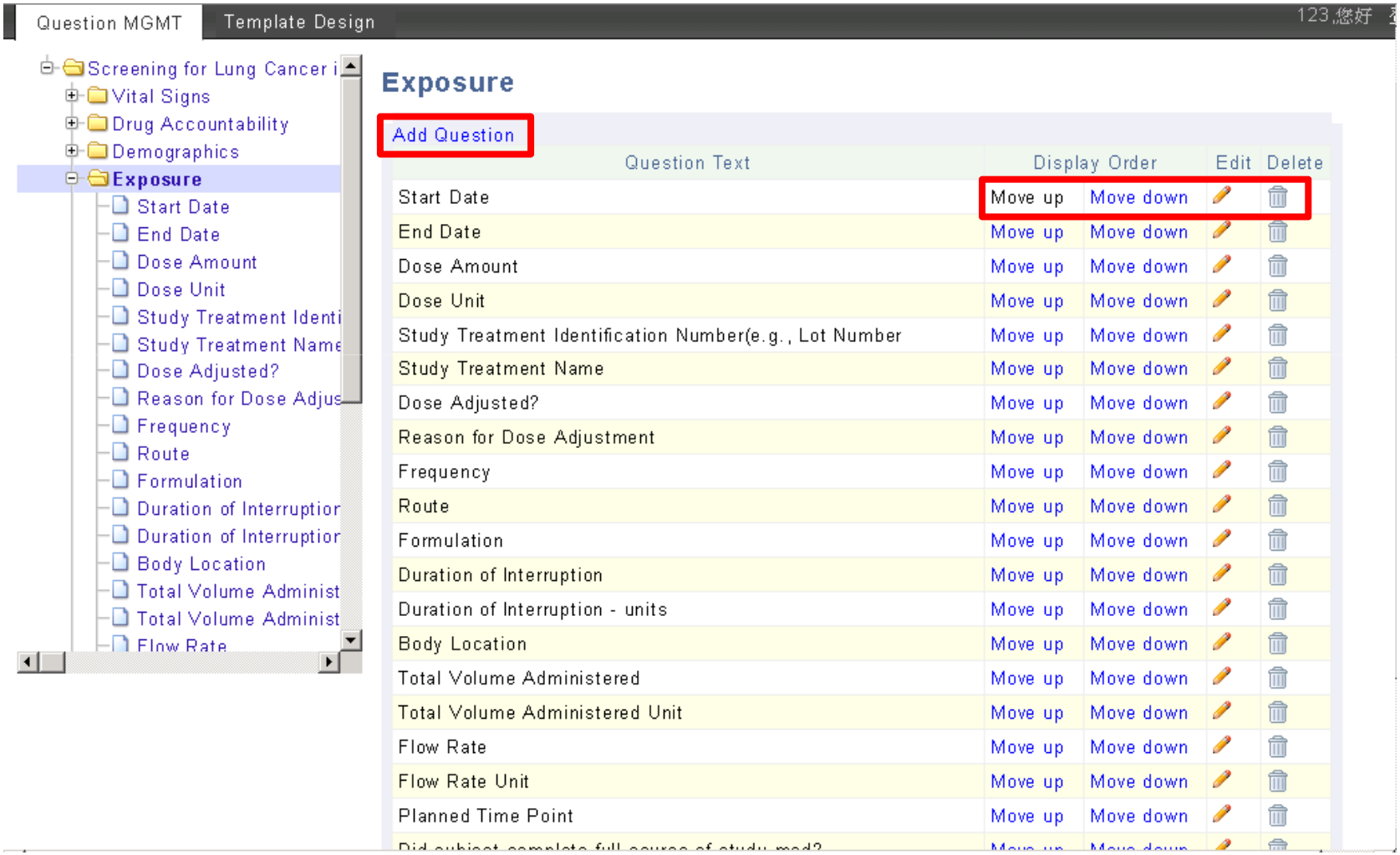
Import Forms from Existing Template



Detail View of Template



Detail View of Form



Discussion and Conclusion

- CDASH-based eCRFs + EDC system →improving efficiency and accuracy
- CDASH focuses on safety data domain

Contribution

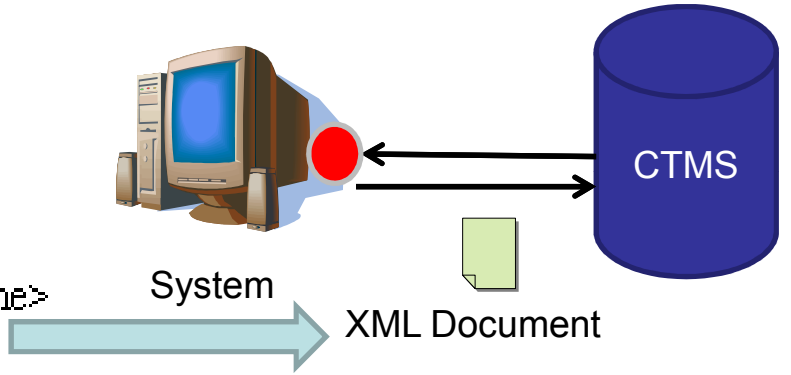
- Direct benefit
  - Speed up creation of CDASH-based eCRFs
  - Enhance the interoperability
- Indirect benefits
  - Minimize customization for EDC system
  - Painless in submission of CRF data to FDA

Thanks for Your Listening!

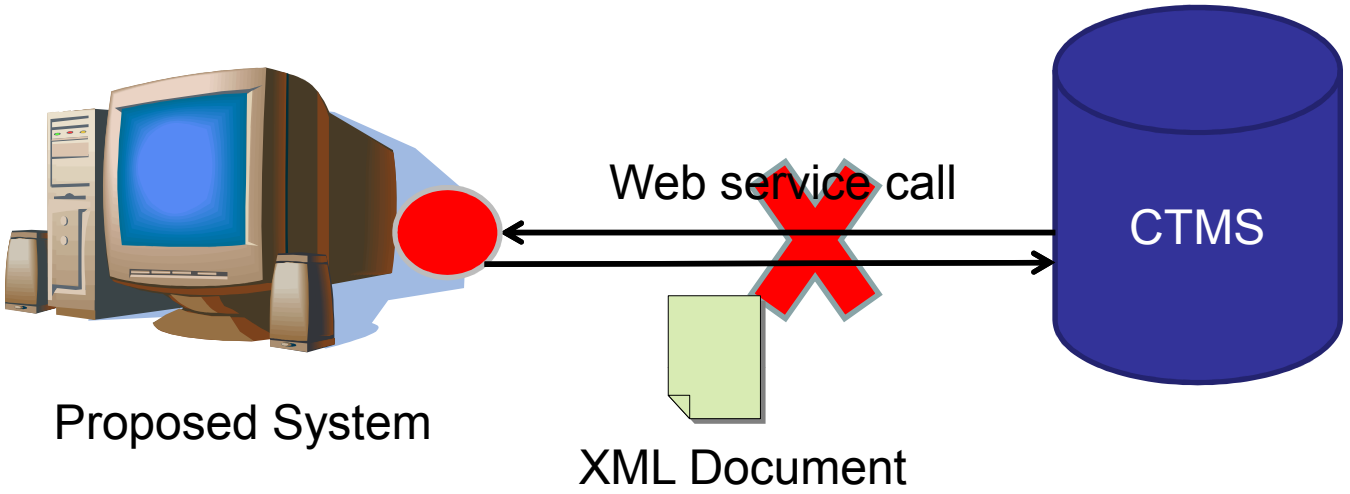
Backup Slides

Structure of eCRF Template

```
<eCRFTemplate>
    <templateName>CDASH Template</templateName>
    <body>
        <form>
            <title> Demographics</title>
            <question>
                <text>Date of Birth</text>
                <type>Date</type>
                <variableName>BRTHDAT</variableName>
                <isRequired> True</isRequired>
            </question>
            …..(other questions under this form)
        </form>
        …..(other forms under this template)
    </body>
</eCRF Template>
```



Limitation



- The overall usefulness of this system is limited to save time from creation of standard-based CRF

Standards Related to This Study

- Study Data Tabulation Model (SDTM)
  - Standard for the submission of CRF data to FDA
- Terminology
  - Distributed as part of NCI's Enterprise Vocabulary Service (EVS)
- Clinical Data Acquisition Standards Harmonization (CDASH)

FDA's Critical Path Opportunity List(#44)

- Development of Data Standards
  - Differences in data archiving convention across sponsors and trials
    - FDA Reviewers

      → Creates opportunities for confusion and error
  - Benefits
    - Enabling the creation of shared data repositories
    - Providing comparing and aggregating information across the NCI's clinical trial
    - Improving the efficiency and accuracy of the routine review

EDC Adoption Rate

- 27-30% of clinical trials

  The Future Vision of Electronic Health Records as eSource for Clinical Research. *The eClinical Forum and PhRMA EDC Task Group,* March 3 2006.

- 45% of clinical trials

  EDC Adoption in Clinical Trials: A 2008 Analysis
  CenterWatch survey in *Bio-IT World*, 2008

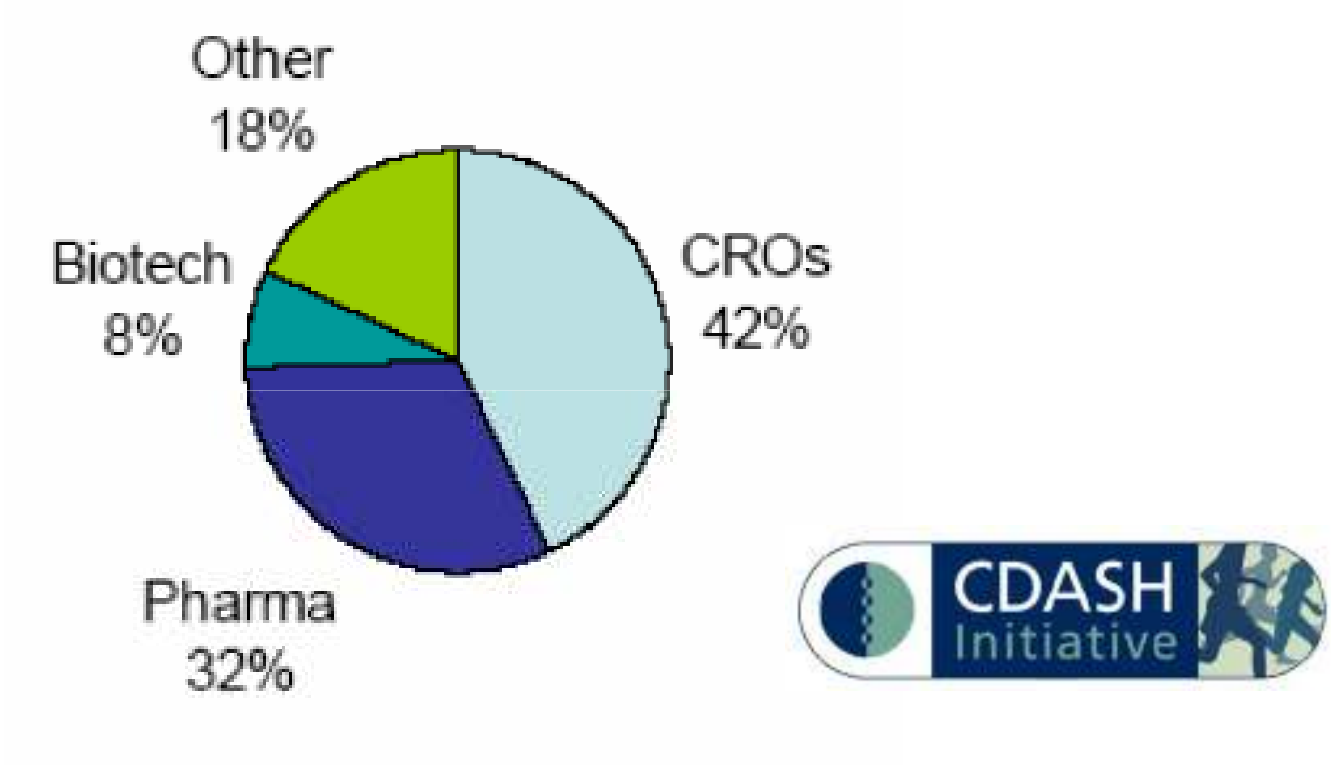
Openclinica

	Proposed System	Openclinica
CDASH-based eCRF Template	✓	✓
Free	✓	✗
Uncoupled with CTMS	✓	✗

Standard CRF of CaBIG

- **Round 1:**
  - Demography Documents
- **Round 2:**
  - Adverse Events Documents
  - Baseline Assessment Documents
  - Participant Enrollment/Registration Documents
  - Participant Identification Documents
  - Protocol Deviations Documents

Participants in the CDASH Initiative



Others = Academic Research Organizations, Government (NIH, NCI), Hospitals, Universities, and Military

Participating Companies, Agencies and Institutions (1)

1. Abbott
2. Accenture
3. Accovion GmbH
4. AdvaMed
5. American Medical Informatics Association (AMIA)
6. Amgen
7. ArisGlobal, LLC
8. Association of Clinical Research Organizations (ACRO)
9. Association of Clinical Research Professionals (ACRP)
10. Astellas
11. AstraZeneca
12. Bausch & Lomb
13. Baxter
14. Baylor College of Medicine
15. Biogen Idec
16. Biopharma Data Services
17. Biotechnology Industry Organization (BIO)
18. Boehringer Ingelheim
19. Boston Scientific Corporation
20. Bristol-Myers Squibb
21. Brown University
42. Enzon Pharmaceuticals, Inc.
43. Ethicon (Johnson & Johnson)
44. Exelixis
45. Fast Track Systems
46. Food and Drug Administration (FDA)
47. Formedix Inc.
48. Forest Laboratories, Inc.
49. Genentech, Inc.
50. Genzyme Corp.
51. Gilead Colorado, Inc.
52. GlaxoSmithKline
53. Global Research Services, LLC
54. Harvard Clinical Research Institute
55. Health Decisions
56. HealthRoad Co. Ltd,
57. ICON Clinical Research
58. ImClone Systems Incorporated
59. Insmed Incorporated
60. InterMune, Inc.
61. Johnson & Johnson
62. Kai Research

Participating Companies, Agencies and Institutions (2)

23. Cambridge Cognition
24. CEDRA
25. Cephalon
26. Cleveland Clinic (CCF)
27. Clinical Data Interchange Standards Consortium (CDISC)
28. Clinical Research Forum
29. CliniPharma Consulting
30. Cognizant Technology Solutions
31. Commitum AB
32. Covidien (formerly Tyco Healthcare/Mallinckrodt)
33. Critical Path Institute
34. CSS Informatics
35. CV Therapeutics
36. Daedalus Software, Inc
37. DataLabs
38. DataScene
39. Duke Clinical Research Institute (DCRI)
40. Eisai Global Clinical Development
41. Eli Lilly and Company
64. Kestrel Consultants
65. Kos Pharmaceuticals, Inc.
66. Lab Connect LLC
67. Medidata
68. Medifacts
69. Merck & Company
70. Millennium Pharmaceuticals, Inc.
71. National Institutes of Health (NIH)
    - Clinical Research Policy Analysis and Coordination Program
    - National Cancer Institute (NCI); caBIG
    - National Cancer Institute - Center for Bioinformatics
    - National Center for Research Resources (NCRR)
    - National Institute of Child Health and Human Development (NICHD)
    - National Library of Medicine (NLM)
    - NCI Cancer Therapy Evaluation Program
    - NCI Enterprise Vocabulary Service
    - NIH Office of Biotechnology Activities (OBA)
72. Nextrials, Inc.
73. Nounsware Company
74. Novartis Pharmaceuticals Corporation

Participating Companies, Agencies and Institutions (3)

75. Octagon Research Solutions
76. Ofni Systems Inc.
77. Omnicare
78. Oracle Health Sciences
79. Organon
80. Othera Pharmaceuticals, Inc
81. PAREXEL International
82. Percipenz
83. Pfizer, Inc.
84. Pharmaceutical Research and Manufacturers Association (PhRMA)
85. PharmaNet, Inc
86. Phoenix Data Systems
87. PHT Corp
88. PPD, Inc.
89. PRA International
90. Procter & Gamble
91. PTC Therapeutics
92. QIMR
93. Quintiles Transnational
94. Regeneron
95. Rho Inc.
96. RTI International
97. Schering-Plough Corporation
98. Schwarz BioSciences
99. Society for Clinical Data Management (SCDM)
100. SpaceLabs Healthcare
101. Statistics & Data Corporation
102. Stellar Systems
103. Synteract, Inc
104. TAKE Solutions Inc.
105. Takeda Global Research & Development Centre (Europe) Ltd.
106. Teva Neuroscience
107. The University of Texas Health Science Center at Houston
108. Tyco Healthcare Mallinckrodt
109. UCB Pharma SA
110. University of California, Irvine
111. University of Pennsylvania School of Medicine
112. University of Utah Health Science Center
113. Wake Forest University Baptist Medical Center
114. Westat Inc.
115. Wyeth Inc.
116. ZymoGenetics

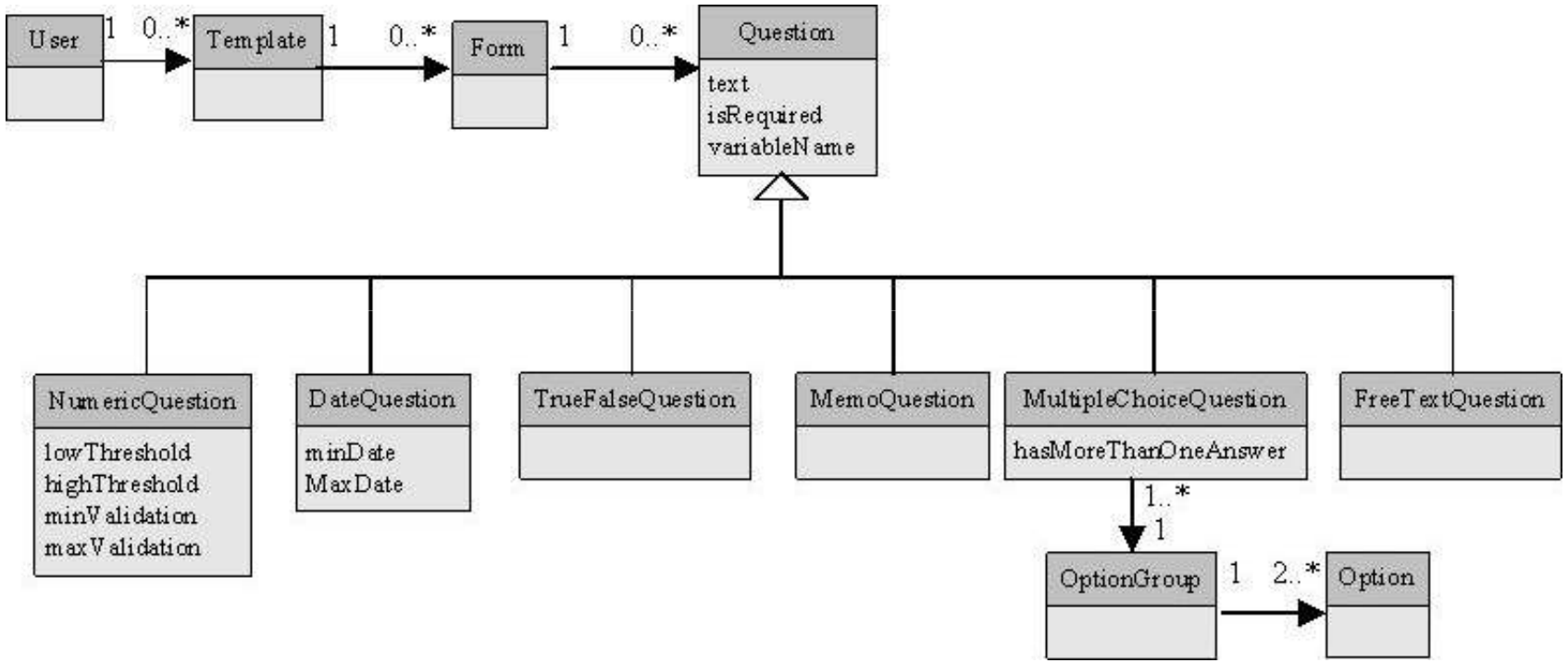
Benefits

- will provide a standardized mechanism for comparing and aggregating information across the NCI's clinical trial portfolio
- a harmonized CRF library will improve the efficiency and accuracy of the routine review of safety, efficacy, and administrative data from ongoing NCI-funded clinical trials. Finally, by reducing the time spent in developing a data collection strategy per trial, this core library will allow for faster initiation of new trials; thus, speeding the process of delivering new and improved treatments to patients.

System Design Requirements

- Web-based architecture
- In-house reusable and domain-specific eCRF library
- Public eCRF library
- Intuitive and user-friendly interfaces

Class Diagram

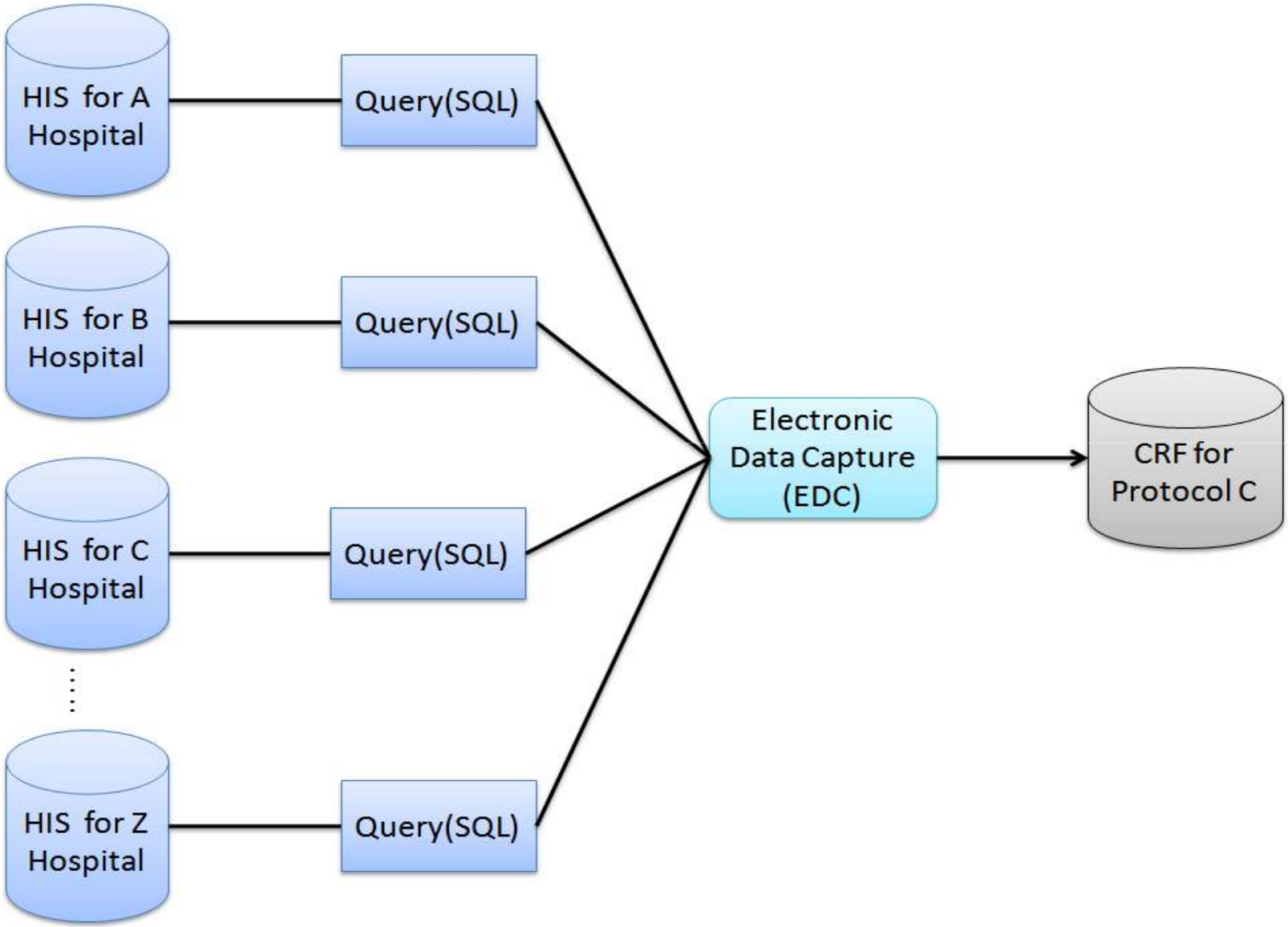


BRIDG Model

- Semantic foundation for all data interchange specifications in HL7, CDISC, the NCI, and caBIG

The BRIDG Project: A Technical Report.
J Am Med Inform Assoc, 2008; 15: 130-137

- Difference between BRIDG model and CDASH model
  - The BRIDG model copes with the interoperability issues between clinical trial management systems
  - The CDASH model deals with the interoperability issues between clinical trial management systems and EHR systems


HIS for A Hospital
HIS for B Hospital
HIS for C Hospital
HIS for Z Hospital
Query(SQL)
Query(SQL)
Query(SQL)
Query(SQL)
Electronic Data Capture (EDC)
CRF for Protocol C