As a result of shrinking resources for the initiation and conduct of clinical trials, establishing strategies to maximize reuse of data collection tools becomes vital. Creating a data collection tool (i.e., case report forms [CRFs]) that can be quickly and systematically created and cloned is paramount. The eCRF ideally captures protocol-specific data in a manner to support the needs of the Principal Investigator (PI), institution, sponsor, and other regulatory/reporting groups. Controlled vocabularies to create metadata that defines the data collected needs to be available.

**Research Costs Related to the Conduct of Clinical Trials:**
- Data collection and management
- Research physician and nurse time
- Analysis of results
- Tests performed purely for research purposes

**General Drug Development Statistics**
- Average cost of developing a new drug is approaching $1 billion which is up from approximately $800,000 and $231,000 in 2000 and 1990, respectively
- Clinical costs grew more than five times as fast as pre-clinical research and development
- 20% – 40% of clinical trials were using electronic data entry (EDC)

<table>
<thead>
<tr>
<th>Clinical trial</th>
<th>Actual EDC budget $47,952</th>
<th>Eligibility $47,952</th>
<th>Actual EDC $47,952</th>
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<tr>
<td>Phase I</td>
<td>$59,940</td>
<td>$69,440</td>
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<td>Phase II</td>
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<td>Phase IV</td>
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In 2002, the National Cancer Institute (NCI) Center for Cancer Research (CCR) initiated a partnership with NCI Center for Biomedical Informatics and Information Technology (CBIIT) to develop a single research database built according to best practices that could also maintain data from multiple disparate legacy databases. The database is called C3D - Cancer Clinical Centralized Database. Core to the successful development of the new database is the development of standard template electronic case report forms (e-CRF). Each field within the eCRF is identified against common data elements (CDEs). If no CDE exists, curation of new CDEs within Cancer Data Standards Repository (caDSR) is completed. Finally, eCRFs, related instructions, and validation/derivation rules are developed. There are various stakeholders involved in the process and oversight is done by the CCR Configuration Control Management Group (CCMG).

**Components of Good CRFs:**
- Gather complete and accurate data that answers study questions
- Promote accurate data entry
- Organize data in a format that facilitates data analysis
- Data collection and management

**Advantages of Standard eCRF Templates:**
- Enforce data integrity and efficiency of form completion
- Improve quality of data collected and increase efficiency of data analysis

**DISCUSSION**
There have been a number of lessons learned including the need to educate all stakeholders about clinical trials and informatics:
- Early involvement of Domain Experts is essential for Standard eCRF development
- Change and Configuration Management Group with appropriate stakeholder representation is key to Standardization Efforts
- Development of Standards and Procedures take time
- eCRF Instruction Manual essential for Quality Data Management
- Comprehensive Curation Requests ensure quick turnaround time

The implications for the future include applying these processes, standards and infrastructure to the caBIG™ community and other groups. Extension of CCR CCMG model to the caBIG™ community, with membership of CCR CCMG in the caBIG™ structure to harmonize business rules, workflow, strategies.