



Setting the  
Global Standard  
for Clinical Data

# Business Case for CDISC Standards: Summary

PhRMA-Gartner-CDISC Project  
September 2006

**CLINICAL DATA INTERCHANGE  
STANDARDS CONSORTIUM**

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# Clinical Data Interchange Standards Consortium

CDISC is an open, neutral, non-profit organization that has established worldwide industry standards for the electronic acquisition, exchange, reporting, and archiving of medical research information to improve data quality and patient safety.

Through its Healthcare Link initiative and many collaborations, CDISC is harmonizing research standards with healthcare standards to streamline clinical studies and improve patient care.

CDISC standards facilitate protocol-driven clinical research in the academic, government, biopharmaceutical and other environments; they also facilitate results reporting and regulatory reviews.

[www.cdisc.org](http://www.cdisc.org)

# Summary of Findings





- Per the CDISC Business Case, standards implemented from the beginning can significantly improve processes in a single clinical study, thus saving time and cost
  - *~ 60% of the non-subject participation time*
  - *~ half of the value (~80% savings) in the start-up stage*
- Approximately half of the value is in the study start-up stage.
- Per the CDISC Business Case, standards have additional impact on clinical research
  - *Increase data quality*
  - *Enable data integration, enhancing re-usability in 'knowledge' warehouses to improve science, marketing and safety surveillance*
  - *Facilitate data interchange among partners*
  - *Improve communication among project teams*
  - *Facilitate review of regulatory submissions*
- The calculations in this business case are based upon currently available metrics and benchmark data; more metrics are needed for validation.

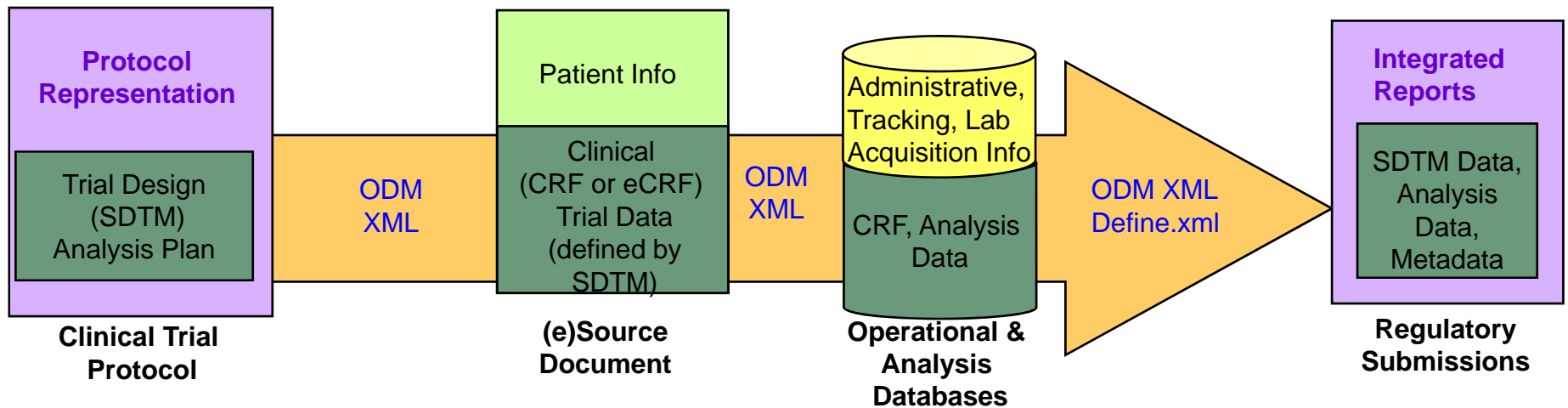
# Variations by Company/Institution

- Savings reaped, cost of implementation and ROI of standards will vary depending on various factors
  - Existing use of proprietary standards
  - Stage of implementation
    - Start-up Stage (70-90% savings)
    - Study Conduct (~ 40% savings)
    - Analysis and Reporting (~ 50% savings)
    - Overall (~ 60% savings)
  - Staff educated in use of CDISC standards
  - Management support
  - Type and size of study
- Note: Mapping to industry standards only ‘at the back end’ to meet submission requirements may facilitate regulatory review and enable integration into a warehouse, but will likely incur a net cost.

[www.cdisc.org](http://www.cdisc.org)

# Data Flow Using CDISC

-  = ODM (transport)
-  = SDTM and Analysis Data (content)
-  = Protocol information (content)
-  = Source data  
(other than SDTM/CRF data)





***The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.***

# *The BRIDG Model\**

*A clinical research domain analysis model (UML)  
initiated by CDISC, BRIDGing*

- *Organizations (CDISC, HL7, FDA, NCI)*
- *Standards*
- *Research and Healthcare*

*Towards semantic interoperability; a Portal to Healthcare*

*Open source ; Collaborative Project*

- *See BRIDG Model on CDISC website  
or [www.bridgmodel.org](http://www.bridgmodel.org)*

***\*Biomedical Research Integrated Domain Group (BRIDG) Model***

# CDISC Business Case Project: Opening Remarks

- This project took place in four stages:
  - Stage I Interviews
    - Interviews were conducted with big Pharma, CROs and FDA to understand their perspectives on current issues and challenges
  - Stage II Top-down estimate of potential savings to biopharma industry
    - Estimate conducted by Gartner based upon their experiences with standards implementations in other industries
  - Stage III CDISC bottom-up estimate of potential savings for a trial and a submission
    - Based upon benchmark data (Tufts, CMR, Parexel Source Book) and Gartner estimates for standards implementations from other industries.
  - Stage IV More rigorous set of interviews with a larger sampling of stakeholders in the biopharmaceutical industry
    - Gathered actual subjective and objective information on experiences implementing CDISC standards
    - Estimates were made based upon metrics gathered, along with industry benchmark data from CMR, Tufts, and the Parexel Source book.
- ***This summary is primarily from Stage IV, having learned from the first three stages***
- There is still a need to gather additional metrics in this area.
- Company-specific and study-specific calculations will be the most relevant to any individual company.



- ***Implementation Recommendations and additional information can be found in the full Business Case report on the CDISC website, Members' Area.***
  - *[www.cdisc.org](http://www.cdisc.org) – See your CDISC member representative for your corporate passcode to the members area.*
- ***CDISC also offers a book that covers these Implementation Recommendations.***
  - *Available for purchase on the CDISC website.*

# Where the CDISC Standards are Applied

Study Start-up	Study Conduct	Analysis/Reporting	Submission
<i><b>PRM</b></i> <i><b>ODM</b></i> <i><b>CDASH</b></i>	<i><b>ODM</b></i> <i><b>LAB</b></i> <i><b>CDASH</b></i>	<i><b>SDTM</b></i> <i><b>ADaM</b></i>	<i><b>PRM</b></i> <i><b>SDTM</b></i> <i><b>SEND</b></i> <i><b>ADaM</b></i>

PRM = Protocol Representation Model

ODM = Operational Data Model

SDTM = Study Data Tabulation Model (Note: includes SEND, as applicable)

SEND = Standard for the Exchange of Non-clinical Data

ADaM = Analysis Dataset Model

# Standards Impact On Clinical Study Activities

Study Start-up	Study Conduct	Analysis/Reporting	Submission
<ul style="list-style-type: none"> <li>•Study design</li> <li>•Protocol development</li> <li>•CRF development</li> <li>•DB Structure/validation</li> <li>•Edit Checks/validation</li> <li>•LAB/ECG specs</li> <li>•Site/PI Identification</li> </ul>	<ul style="list-style-type: none"> <li>•Patient recruitment</li> <li>•Data acquisition</li> <li>•Data exchange</li> <li>•SD verification</li> <li>•Site monitoring/audits</li> <li>•Transfer lab/ECG data</li> <li>•Site audits</li> </ul>	<ul style="list-style-type: none"> <li>•Data analysis</li> <li>•Safety assessment</li> <li>•Analysis table prep</li> <li>•Clinical assessments</li> <li>•Report generation</li> </ul>	<ul style="list-style-type: none"> <li>•Clinical Study Report</li> <li>•ISS/ISE preparation</li> <li>•Clinical-statistical integrated report</li> <li>•Listings, tabulations and datasets</li> <li>•eCTD file structure</li> </ul>
<ul style="list-style-type: none"> <li>•Site evaluation</li> <li>•Site initiation</li> <li>•Patient recruitment plan</li> <li>•Critical documents</li> <li>•IRB approvals</li> <li>•Training of team/sites</li> <li>•Randomization plan</li> <li>•Test article prep</li> <li>•Statistical analysis plan</li> <li>•Analysis table shells</li> </ul>	<ul style="list-style-type: none"> <li>•Database QA and lock</li> <li>•Analysis programming</li> <li>•Initial stat tables</li> <li>•Study closeout/archive</li> </ul>		
5 months	Patient participation + 4 months	5 months	12 months

80%

40%

50%

*Savings with standards*

 = Activities that can be streamlined with standards

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5 months	Patient participation + 4 months	5 months	12 months

**Value**

**Implementation Tradeoffs: Greatest Value when Standards Implemented in Study Start-up**

80%

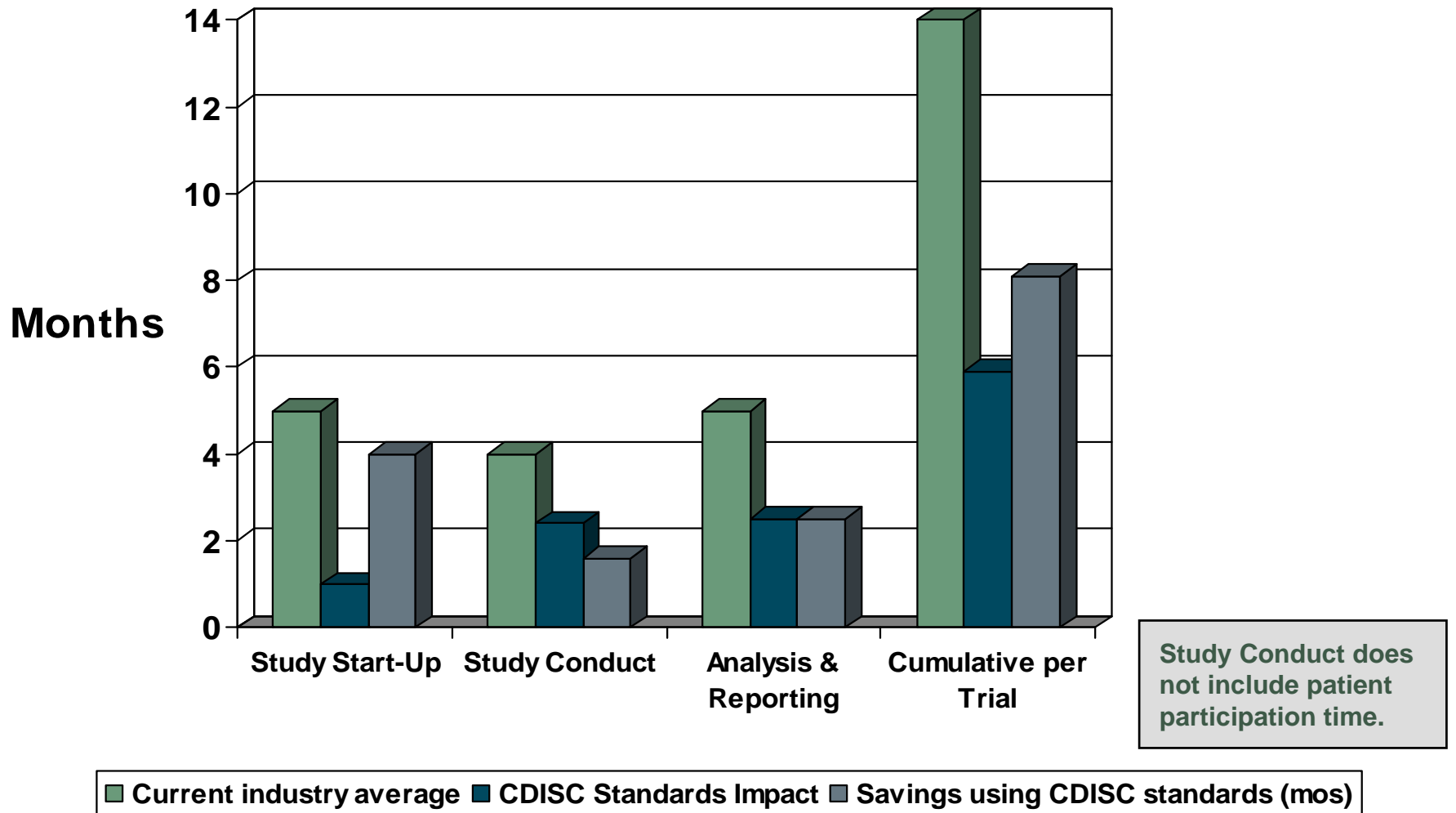
40%

50%

*Savings with Standards*

 = Activities that can be streamlined with standards

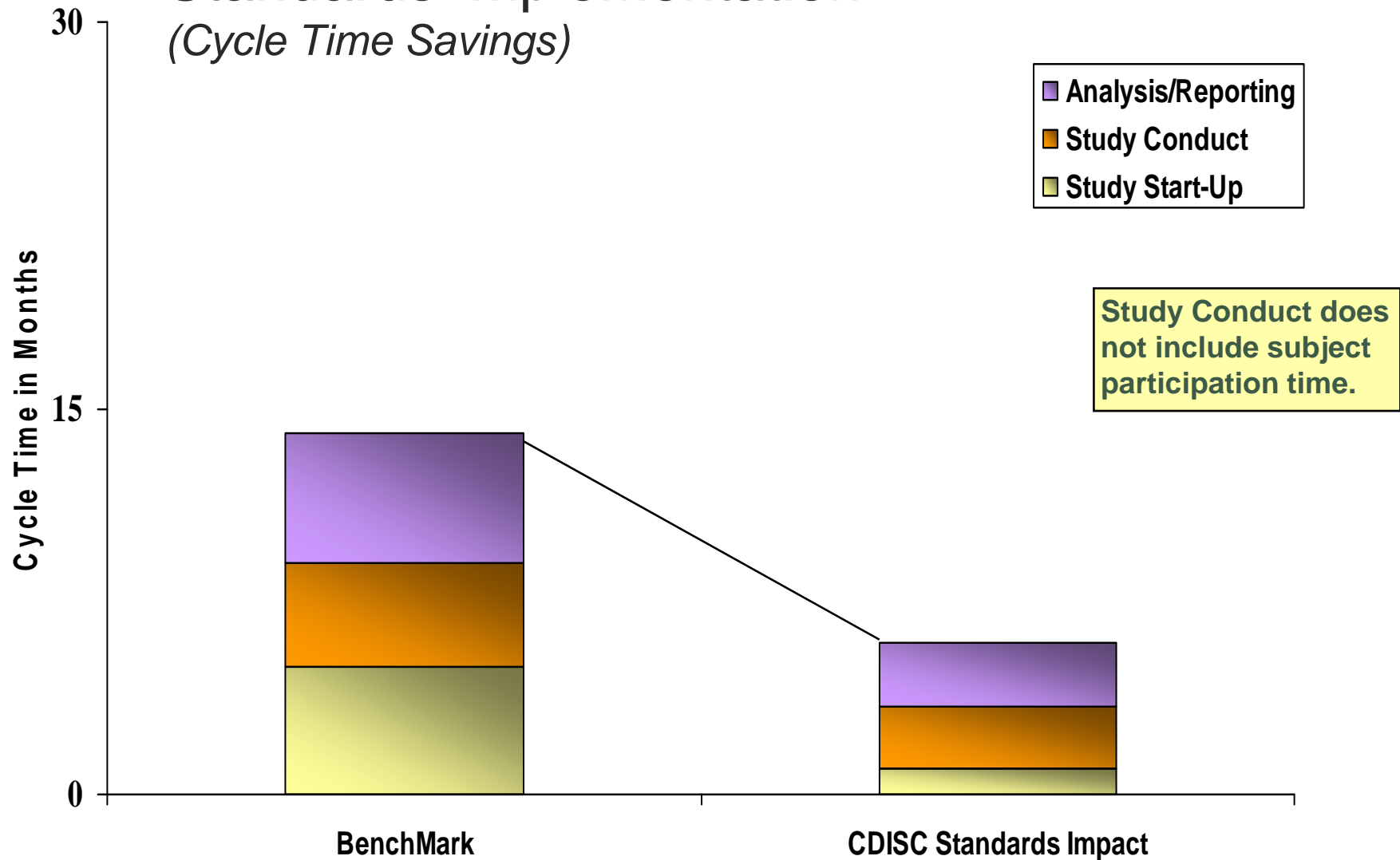
# Impact of CDISC Standards on Clinical Study Cycle Time



*Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.*

# Quantifying the Value of CDISC Standards Implementation

(Cycle Time Savings)



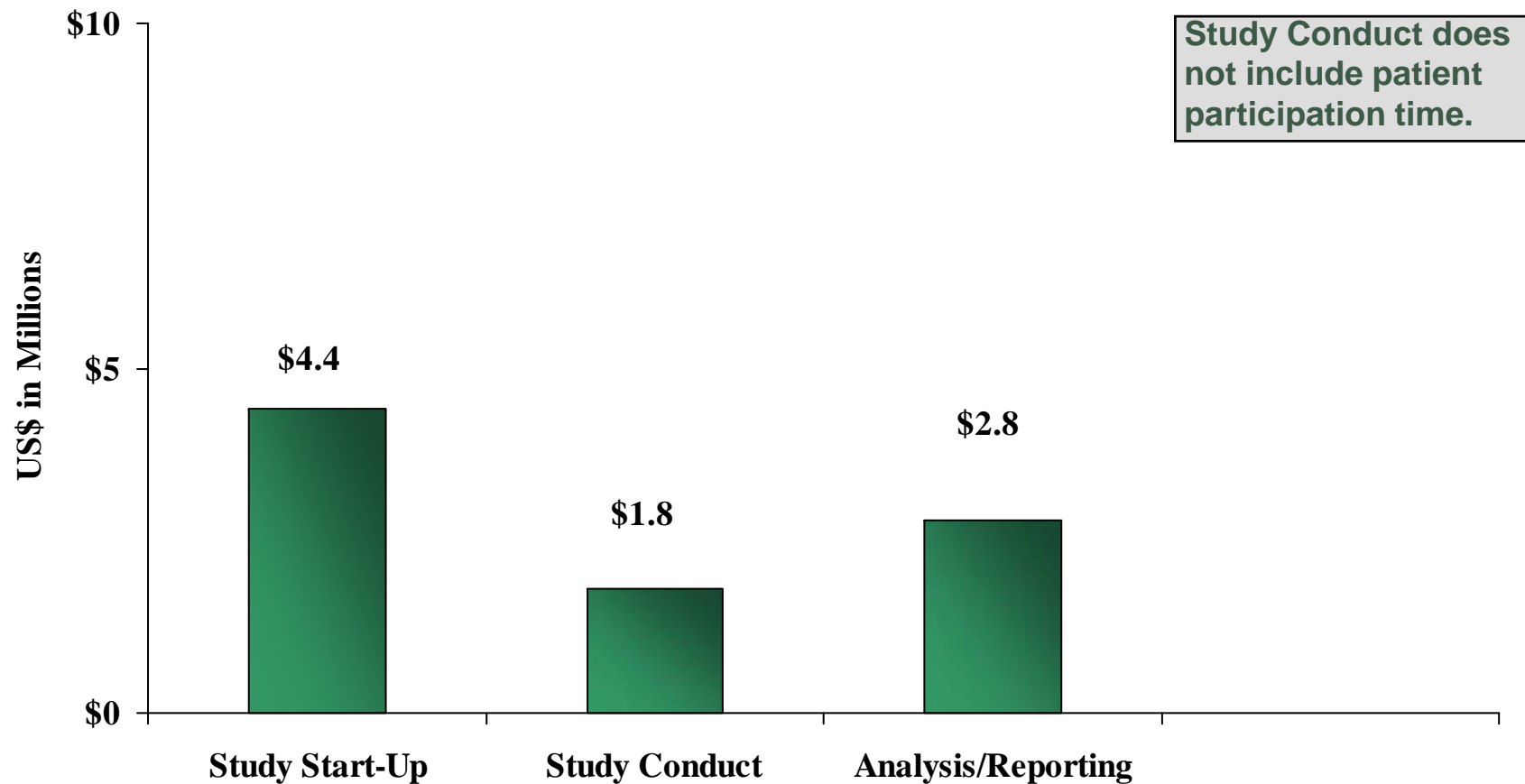
*Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.*

Sample Calculations When Standards are Implemented in the Study Start-up Stage  
 NOTE: Each company should use their own time and cost baselines.

Start-up Time (mos)	% Savings w/ Stds	Net mos saved	Conduct mos w/o Subject participation time***	% Svngs w/ Stds	Net mos saved	Analysis & report (mos)	% Svngs w/ stds	Net mos saved	Total mos saved	Cost Savings	“Value” (Cost of Clinical Res per day)
5	(80%) x 0.8	4	4	(40%) x 0.4	1.6	5	(50%) X 0.5	2.5	8.1	Multiply time saved x actual cost of study/month	X \$37,000 (Tufts loaded cost per day) ~ \$9M
4	x 0.8	3.2	3	x 0.4	1.2	3	X 0.5	1.5	5.9		
2	x 0.8	1.6	2	x 0.4	0.8	2	X 0.5	1.0	3.4		
12	x 0.8	9.6	7	x 0.4	2.8	7	X 0.5	3.5	15.9		
Your time	x 0.8	= A	Your non-subject participation time (LPO->DBL)	x 0.4	= B	Your time	X 0.5	= C	A + B + C = Y	Y x cost per month	Y x \$37K per day

# Quantifying the Value of CDISC Standards Implementation

*(Direct Development Cost Savings for a Single Study)*

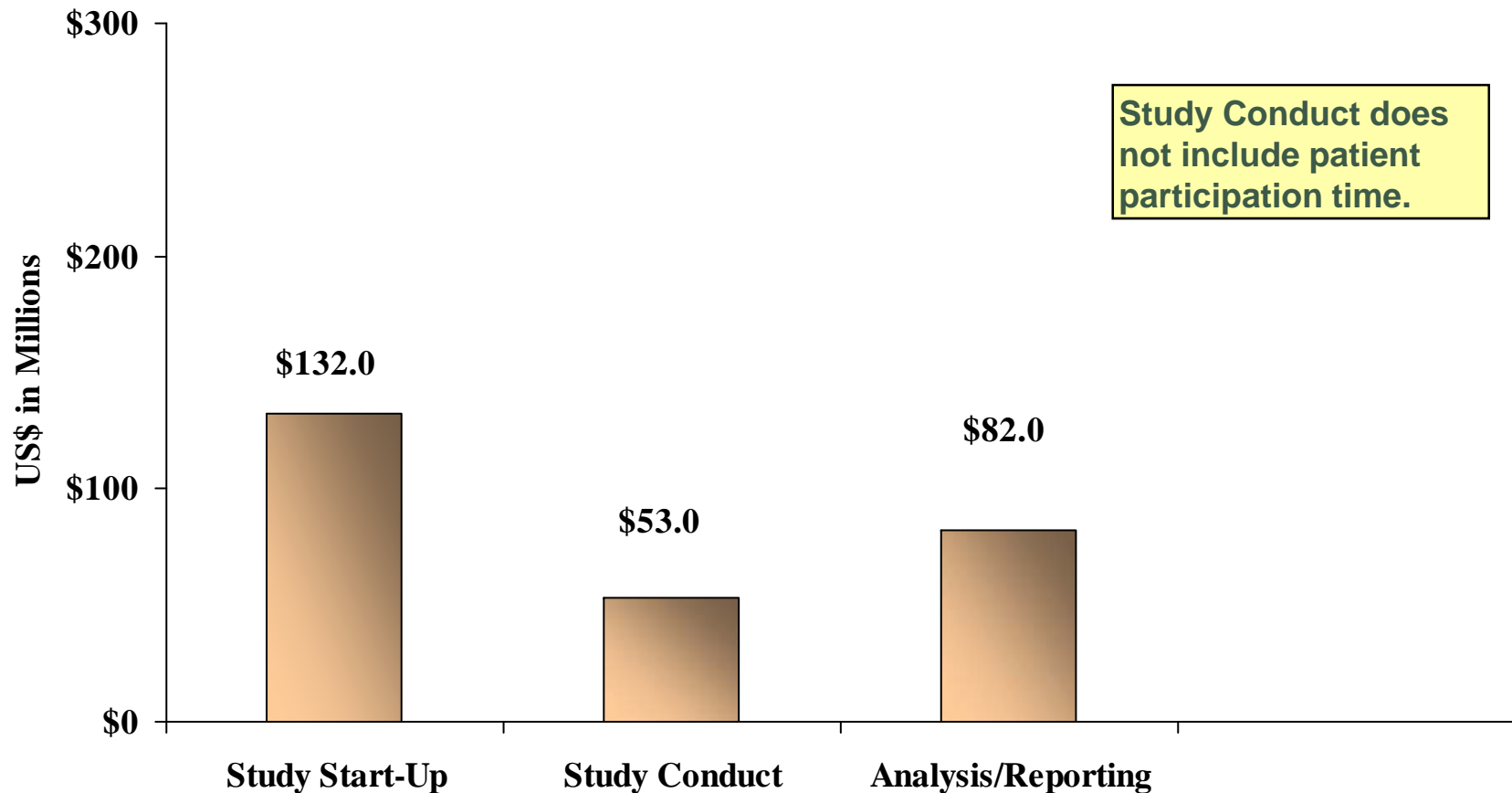


Assumes \$37,000 average daily out-of-pocket development cost (Tufts CSDD 2005 estimate). Figures are benchmarks based on aggregated data; study-specific costs and time metrics will vary.



# Quantifying the Value of CDISC Standards on Implementation Revenue Opportunity

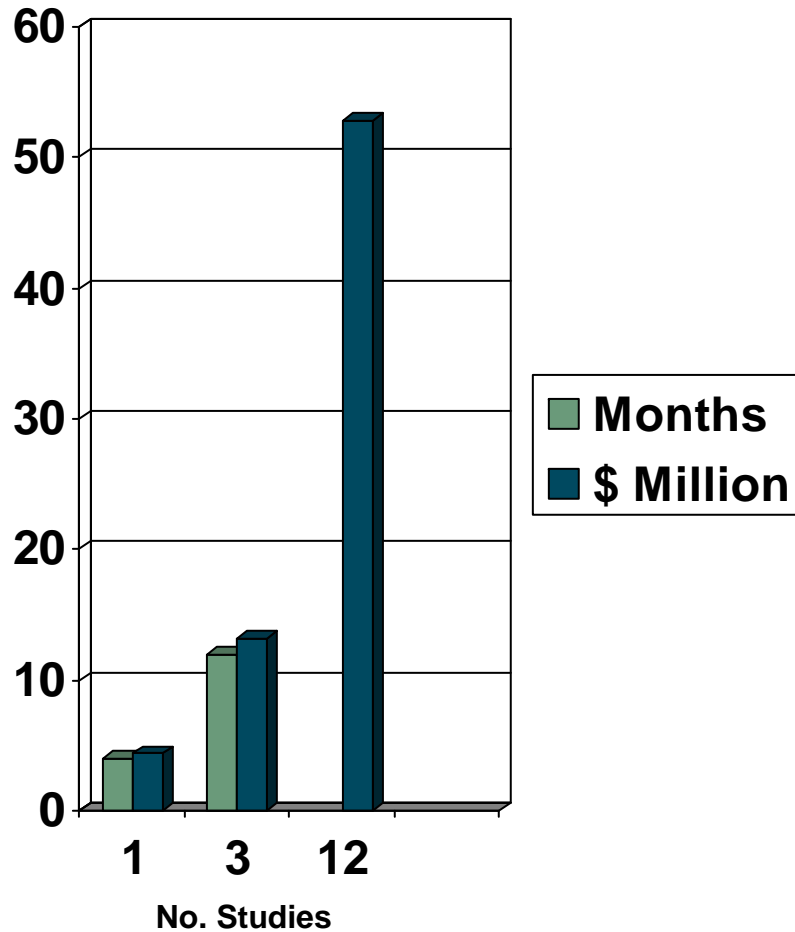
*(Average New Prescription Revenue Gained per Day for a Single Product)*



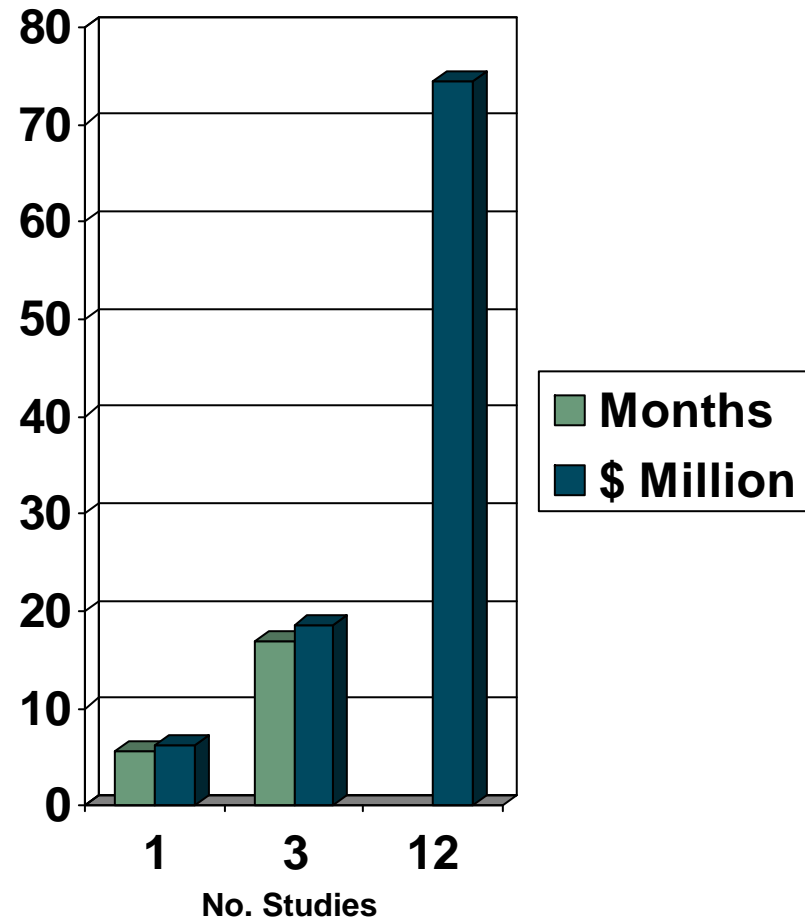
Assumes \$1.1 million average daily prescription sales for a typical drug (Tufts CSDD 2005 estimate). Figures are benchmarks based on aggregated data; study-specific costs and time metrics will vary.

# Savings with CDISC Standards

*Study Start-up Only*



*Study Start-up and Conduct*



*Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.*

# Regulatory Submissions and Standards

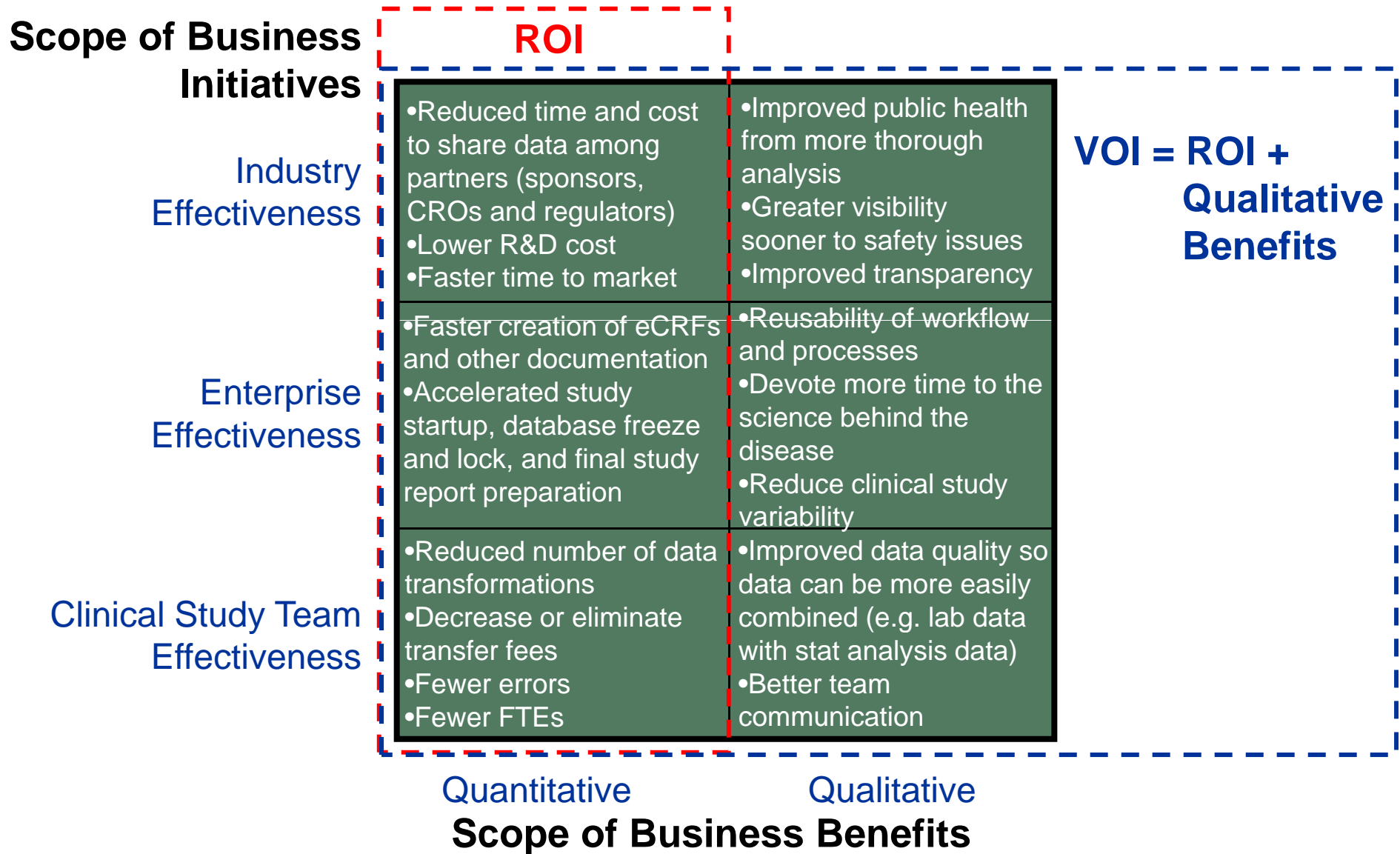
- **Benchmark data** (from Parexel Source Book, CMR, Tufts):
  - 12 months time to prepare submission
  - Mean of 11.8 studies per submission
- Standards would impact submission time by:
  - Reducing the time needed for clinical studies on the critical path, thus reducing overall program development cycle time
  - Improving the ISS/ISE process
  - Streamlining the clinical study report process (re-use of protocol elements, study files - tag, element and leaf structure and report format and data presentation)
  - Facilitating the regulatory review
  - Reducing FDA queries and/or time to respond to these
- The impact of standards on time to submission and cost will be dependent upon the company's internal submission preparation processes and where standards are implemented.

# Efficiencies and Effectiveness Not Considered in the Calculations

- Site personnel and monitoring efficiency during patient participation period
- Recruitment
- Source document validation and randomization
- Safety surveillance
- Reuse (e.g. protocol, disease population data, CRF/eCRF designs)
- Training
- Improved team communication

***Opportunity value is doing more trials with the same number of people***

# Expanded ROI Includes Value of Investment



# Benefits from Standards - Cost, Time and Beyond

## Summary

- Standards make communication easier
  - Enforce a common language with others
  - Simplify decisions, e.g. on case report forms
- Allows people to understand and perform their jobs better
  - Learn the job once and perform it consistently
- Standards improve quality and are responsible for gains in efficiency.
  - essential to streamline workflow and automate processes
  - can do more with the available resources
- Data is more valuable to a merger or acquisition partner if provided in a standard format
- Auditors can review processes more easily and confirm they have been validated; standards are self-documenting and have standard audit trails incorporated

# Benefits from Standards - Cost, Time and Beyond

## Summary (2)

- Standards provide new opportunities to use data better because it can be readily integrated; easy joins and merges; can integrate on an ongoing basis
  - ‘Re-use without re-work’
  - Ability to respond to regulatory queries more easily (Value up to \$8 M in resources)
  - Eliminate some proposed post marketing studies because information and knowledge can be extracted from a standards-based repository
  - Information available for trial simulation, knowledge-based trial design, improved safety surveillance and efficacy analyses and other new insights
- Enables ‘plug and play’ tool/application selection and facilitates retirement of old systems
- Can use common viewing tools if data are in standard format
- CDISC and HL7 will help make EHR real – standards will enable the healthcare and research link

# Key Messages for Management from the PhRMA-Gartner-CDISC Project

- The value of standards extends far beyond process efficiency.
  - Higher quality data/information
  - Realtime integrated data e.g. safety surveillance, marketing, submission, study design
  - Reusability of information to enhance science
  - Improved communication among project teams and business partners
  - Facilitated regulatory review process
- Standards save significant time and money, especially when implemented in the study startup stage.
- Organizations are becoming proactively compliant with CDISC standards.
  - FDA's endorsement important; mandate still needed
- Harmonization of standards across clinical research and with healthcare is a core strategic goal.
  - Enter the data only once - at the site
  - Streamline investigator participation in research



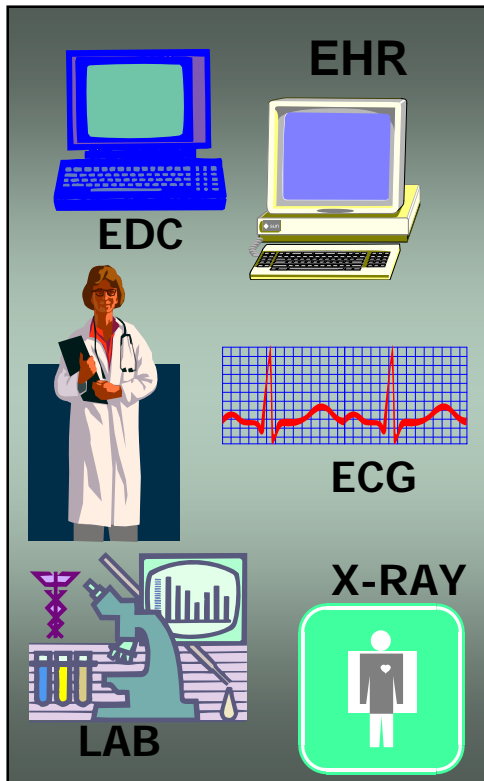
# Gartner's Summary Conclusions

- Most biopharmaceutical companies are:
  - spending more money and taking more time to complete clinical research than is necessary
  - not gathering metrics on the industry's \$60B investment
  - have duplicate IT infrastructure, applications and personnel
  - getting charged more by vendors (CROs and tech providers) because of extra work for data conversions
  - exposing their companies to potential litigation because they cannot routinely mine the data for safety signals
  - leaving money on the table because they cannot get realtime information on the 'customer experience' (e.g. for new indications)

# Vision – Medical Innovation

Collect Data Once,  
(Various Sources)

“Rolling Warehouse”  
Multiple Downstream Uses



CDISC Standards  
Real-time Integration

Regulatory Authority



Sponsor

Public Registries  
and IRBs



CRO or Partner

**CDISC** operates to advance the continued improvement of public health by enabling efficiencies in medical research and related areas of healthcare.



**Strength *through* collaboration.**

***As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.***