Four Pillars for New Clinical Information Architectures

Data Management in the Digital Age

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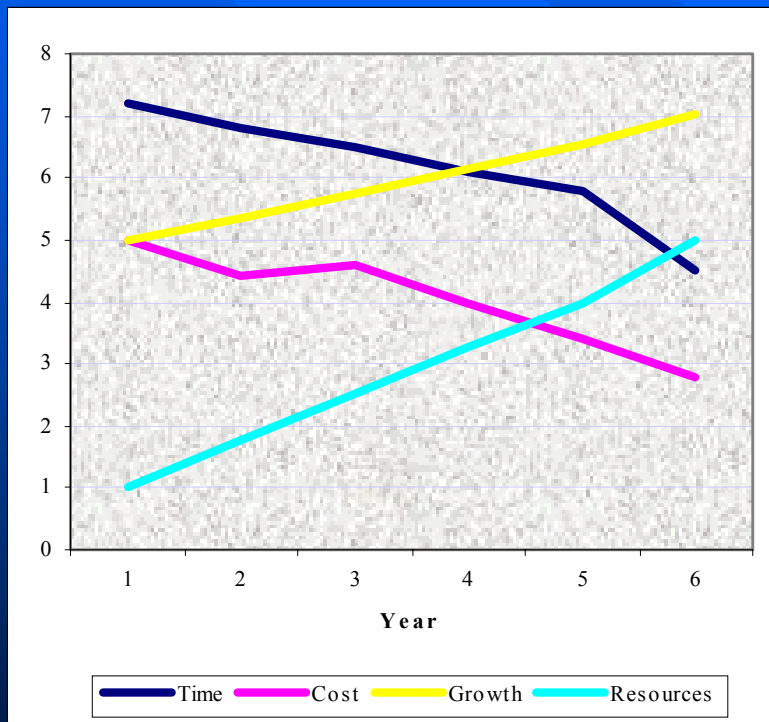DIA CDM Symposium
April 9, 1999

The Uphill Battle

- New Discovery technologies mean more/better candidates
- Bottlenecks in clinical testing
- New Genomic/Pharmaco-genomic opportunities raise the demand even further:
  - Custom drug therapies
  - Profiling target patients
  - Shift from Empirical to Predictive Medicine

The Uphill Battle: By 2005

- Must maintain 7% growth with fewer blockbusters
- Must reduce Development time from 7 to 4.2 years
- Must increase patient and staff Resources by 400%
- Must cut development costs by 20-44%
  - Source: Pharma 2005: An Industrial Revolution in R&D -- Price Waterhouse Coopers

Future Emerging Technologies

Can These Find a Place in CDM?

(Original includes photo images of Aurrichio, a fictitious product that sends and receives email and MIT Media Lab prototypes for displaying computer screens on glasses and providing keyboards that can be sewn into clothing.)

Clinical DM Technologies:
A Plodding History
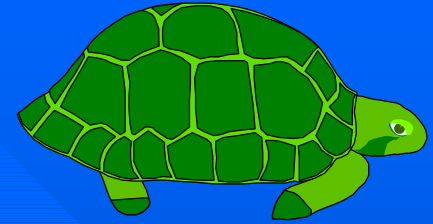
- Trials grow in Volume and Complexity, yet most Processes remain mired in the past
- Industry is slow to adopt new technologies
- Clinical technology products often seem uninspired, uninviting and unexciting
- Vendor breakthroughs are rare and unlikely.
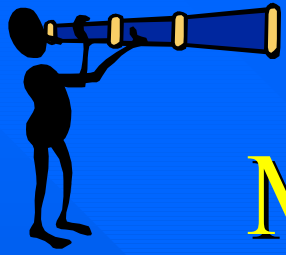
The Future of Clinical Data Management is all around Us

- Don Tapscott, The Digital Economy
- Nicholas Negroponte, Being Digital
- Michael Dertouzos, What Will Be
- Larry Downes and Chunka Mui, Unleashing the Killer App

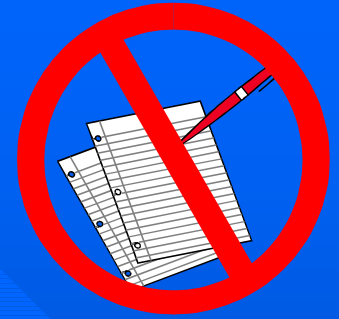(Original includes photo images of book covers)

5 Relevant Themes of the Digital Economy

1) Digitization
2) Knowledge
3) Convergence
4) Immediacy
5) Discordance

Theme 1 - Digitization

- ***Digital Economy:***
  - Bits, not Atoms
- ***Clinical Research:***
  - Voice data, voice recognition, digital images, gene maps -- not paper CRFs
  - All relevant information on the network
  - Digital Transactions (e.g., registrations, payments), Digital Information, THUS ...
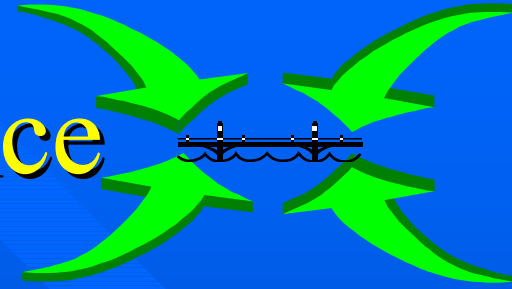
Theme 2 - Knowledge

- ***Digital Economy:***
  - The new economy is a knowledge economy
- ***Clinical Research:***
  - Information will have intrinsic value
  - Data management will be knowledge work
  - Data will be mined, projected and reused
  - Physicians and patients provide information
  - Drug developers will pay for it -- THUS ...

Theme 3 - Convergence

- **Digital Economy:**
  - Computers/content/communications come together.
- **Clinical Research:**
  - Technology/Information/Data Exchange becomes constant and real-time on a global scale
  - Systems are indistinguishable from the process
  - CRAs, Data Managers and Sites conference over clinical information
  - Clinical Research occurs on internet time, THUS ...

Theme 4 - Immediacy
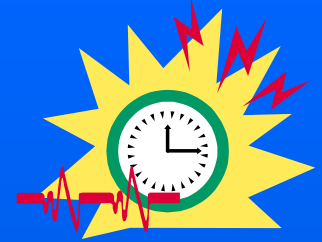
- ■ *Digital Economy:*
  - – Real-time business
- ■ *Clinical Research:*
  - – Real-time trials
  - – Real-time analysis
  - – Real-time program design
  - – Rapid, Real time simulations
  - – Real time go/no-go decisions, THUS ...

Theme 5 - Discordance

- ***Digital Economy:***
  - Traumatic new social dialectics
  - Technology as disruptor/enabler
- ***Clinical Research:***
  - CRAs ➡ "Telemonitors"
  - Data Managers ➡ "Data Shepherds" / Information Stewards
  - Investigators ➡ Information Providers
  - CRCs ➡ Operations Managers
  - Technology ➡ Everywhere!

Why Aren't Clinical Applications Like Digital Economy Technologies?

- Too expensive
- Too regulated
- Too different
- Too scientific
- Too difficult to support reliably
- Too many -- Excuses!

Digital themes -- with Discordance -- are with us anyway!

The Solution

- Follow the Digital Economy as a guide for creating new Clinical Technologies:
  - Seamless, accessible Digital information
  - Retained, reusable knowledge
  - Rapid, flexible, personalized Applications
  - Real-time reinvention
  - Fun.

What We Need

- Dependable technology *Infrastructure* that works all the time for everyone

- Trusted *Privacy* and security solutions

- Common *Standards* for information structure and content

- *Applications* that can be rapidly assembled as components
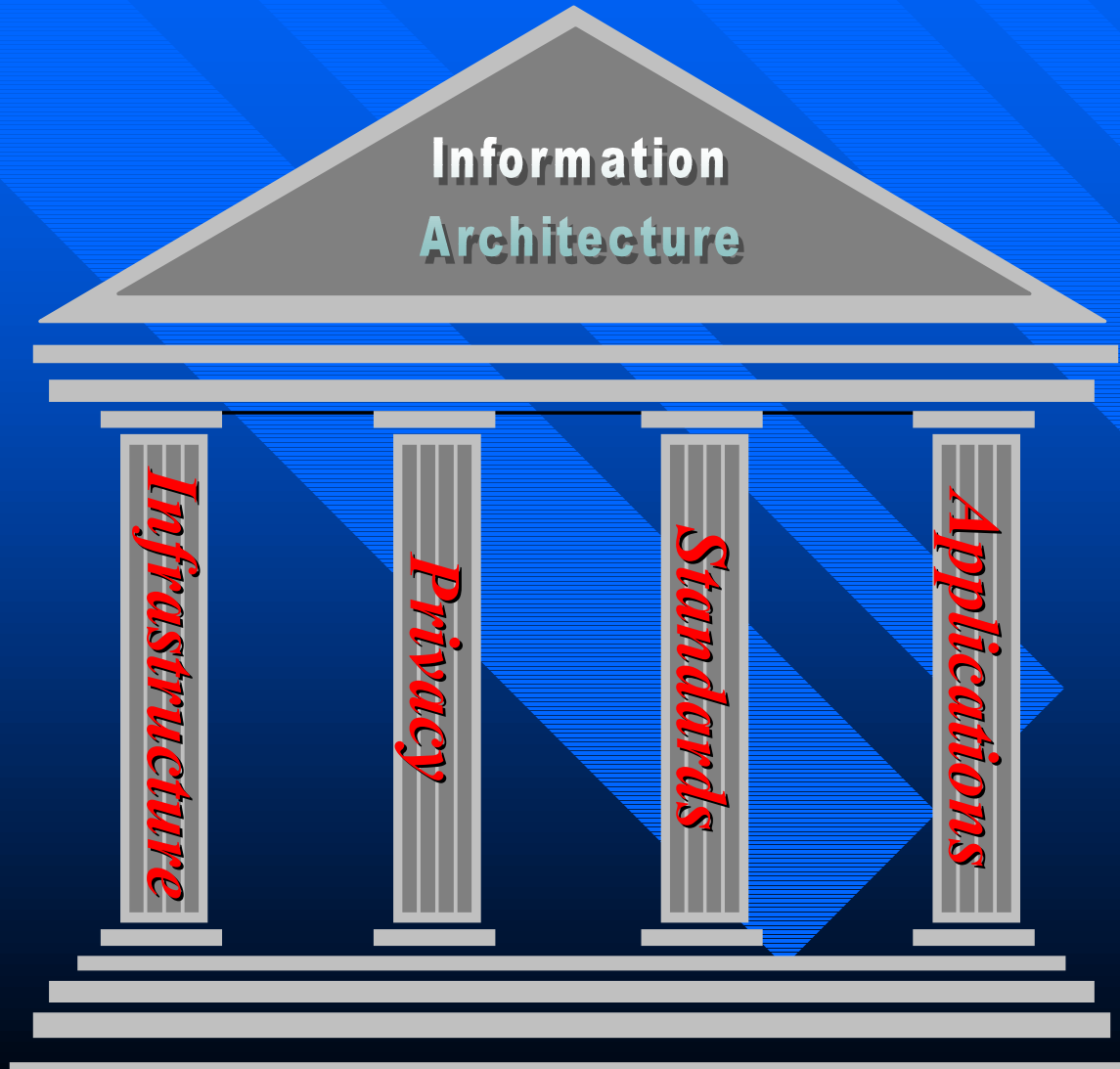
Pillar 1 - Systems Infrastructure

Infrastructure

- Fast, secure, open internet connectivity -- for all
- Prevalent, open-standards technology that works -- even for non-technologists
- Improved information and knowledge bases
- Ability to accommodate a variety of "best fit" appliances for capturing and accessing data.
- Flexibility to adjust to preferences of the individual "community of one."

Infrastructure: The price of entry if you want to play.

Pillar 2 - Privacy & Security

Privacy

- Industry and Physicians must be Proactive in ensuring patient privacy.
- Need a standardized industry solution for security and privacy with strong vendor tools
- HIPAA (HIPPA) will mandate privacy controls for health care, enabling integration of clinical research with health care delivery
- Increases opportunity: e.g., expanded repository for ongoing meta-analysis and outcomes research.

Privacy: The key barrier to convergence and knowledge.

Pillar 3 - Information Standards

- Embrace standards -- Learn from finance, utilities and telecommunications

- Plan studies with the end in mind -- collect only essential data elements

- Approach content standards from the output side – consider what FDA, investigators, marketing, et al need

- Seek compatibility with tech and health industry standards (HL-7, IEEE, etc.) without increasing complexity

- Future trends point to secure XML E-Forms, not proprietary systems

Standards: The common language for conducting digital business.

Pillar 4 - Plug & Play Applications

■ Advanced, flexible, modular object components that can be rapidly combined and integrated within a broad information architecture without complex coding:

- Capture data directly at the source

- Operate on warehoused data, not discrete bespoke databases

- Comprise all relevant processes including CRF data capture, Trial Management, Safety Monitoring, etc.

- Serve a community comprising patients, sites, CROs, regulators and sponsors.

Applications: The pay-off.

A Clinical Information Architecture Based on 4 Pillars

Technology Infrastructure

Clinical Data Warehouse & Document Repository

Clinical　Trials Management　Safety
Genomic　Screening　Pre-Clinical
Regulatory　Sales/Marketing　Outcomes
Learnings　Analysis History　Knowledge
Audit/Change Data

Sponsors

Public Information

MetaData Standards (and XML DTDs)

Security and Privacy Controls

Applications

XML Filter

Vendors

Investigator Data

FDA Public Data Warehouse

XML Filter

Investigators

Patients

Regulators

Looking Forward: Clinical Data Management in the Digital Age

"The fundamental difference between a dog and a human being is simple: When you point with your finger, the dog looks at the tip."

--Nicholas Negroponte

In Conclusion . . . .

The Only Limit to our Realization of tomorrow will be out doubts of today. Let us move forward with a strong and active faith.

-- F. D. R.

Information Architecture

Systems

Privacy

Standards

Applications

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