WINCHESTER
business systems

A 2020 Vision for eClinical Systems

Advancing clinical leadership

6 November 2009

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Agenda

- **Overview**
- **Survey Results**
- **Preparing for the future**

Can you avoid knowledge? You cannot! Can you avoid technology? You cannot! Things are going to go ahead in spite of ethics, in spite of your personal beliefs, in spite of everything.

JOSE M.R. DELGADO, *Scientific American,* October 2005

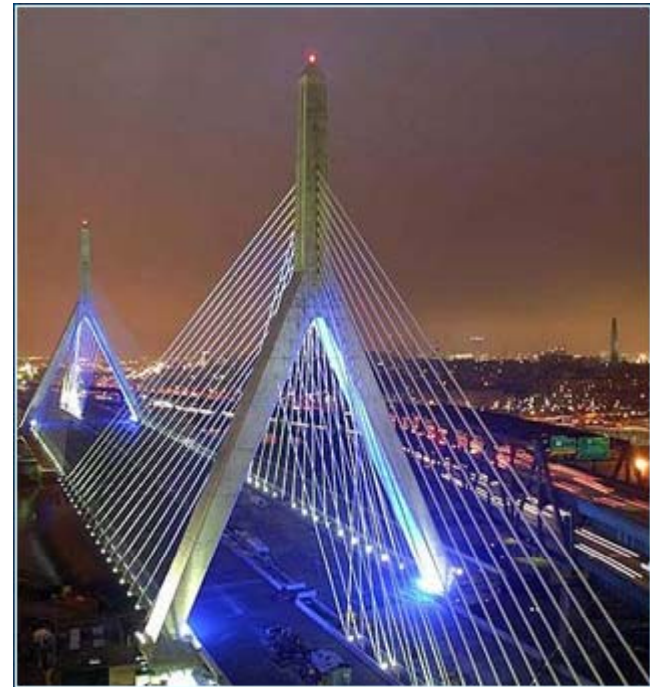*Tomorrow's productivity will not be achieved with yesterday's technology.*

In October 2009, Surveyed over 3,000 Clinical Operations and Data Management practitioners

CLINICAL SYSTEMS SURVEY

Categories

21 Question areas to be rated as:

- *Very Important*
- *Important*
- *May be Important*
- *Not Important*
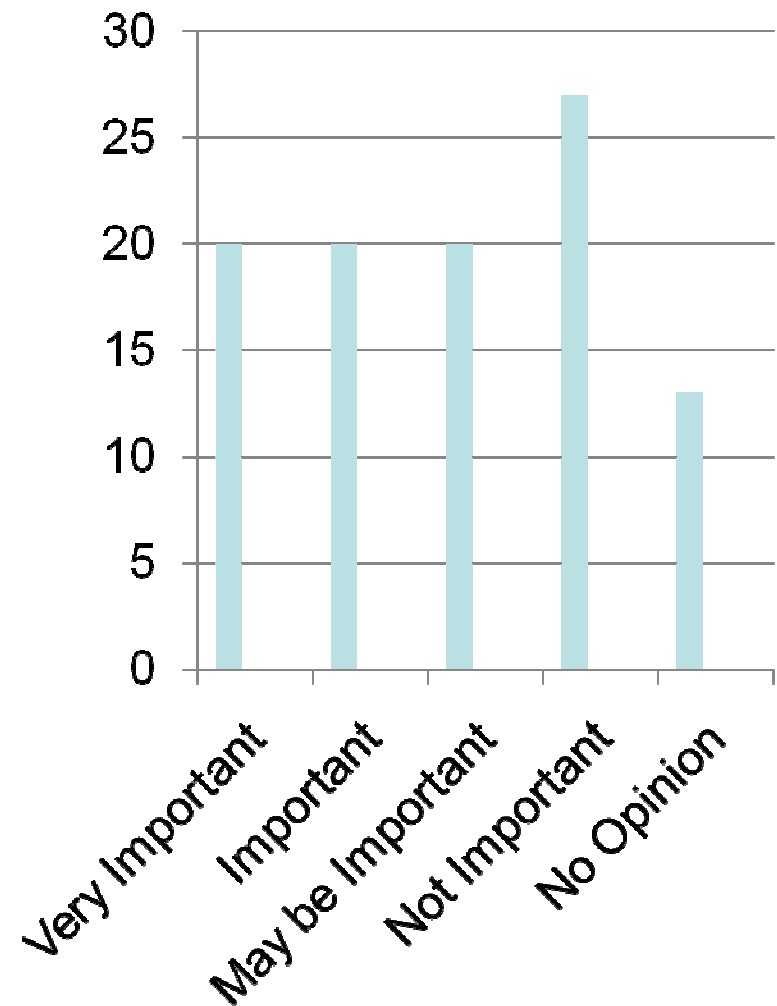- *No Opinion*

Cloud Computing

Defined as: Systems deployed using an off-site model where the computer servers and the software are supplied as a service rather than as enterprise licenses to lower IT costs.

This would include items like cloud computing, systems like VMWare, software as a service (SaaS), etc.

60% of respondents think Cloud Computing is or may be important

You may say I'm a dreamer, but I'm not the only one, I hope some day you'll join us, And the world will be as one.
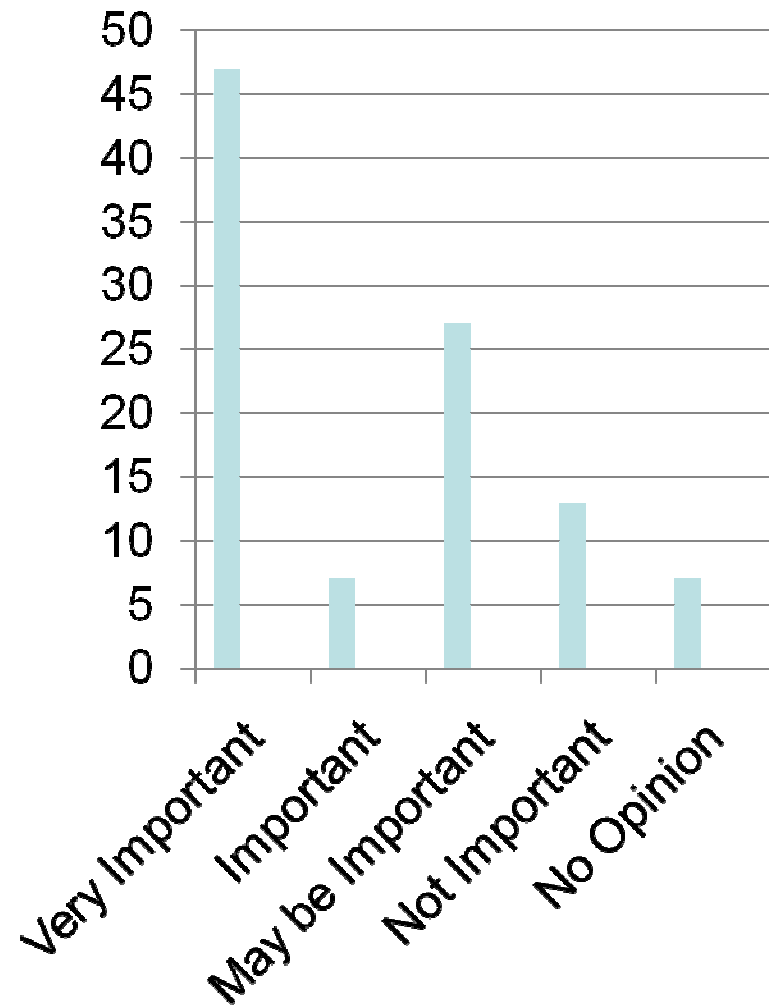
JOHN LENNON, *Imagine*

Category	Value
Very Important	20
Important	20
May be Important	20
Not Important	27
No Opinion	13

Business Intelligence

Business Intelligence -- My company is looking for broader and more-capable business intelligence solutions that can be used to analyze data and provide better scorecards, graphs, tables, and answers.

75% think Business Intelligence is important

History is the witness that testifies to the passing of time . . .
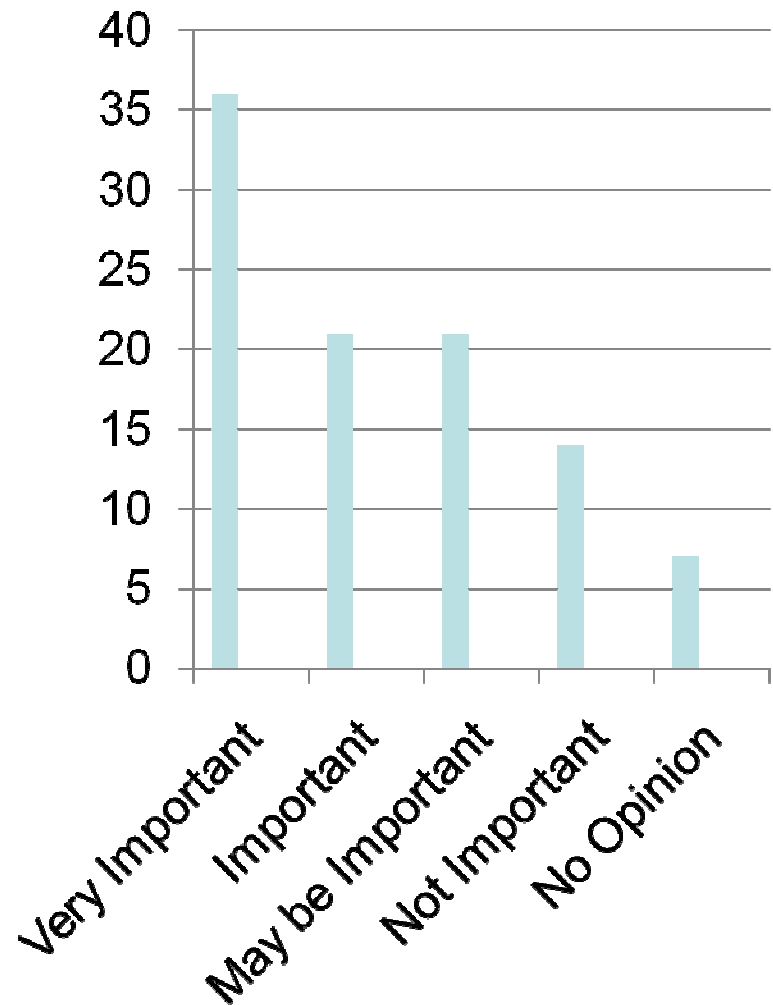
CICERO

Security

Security -- My company is more concerned about and wishes to deploy better system capabilities to keep my company's data secure like using RSA Security's SecurID or similar products that provides additional security and single sign-on capabilities.

75% think Security may be important

R2-D2, you know better than to trust a strange computer.

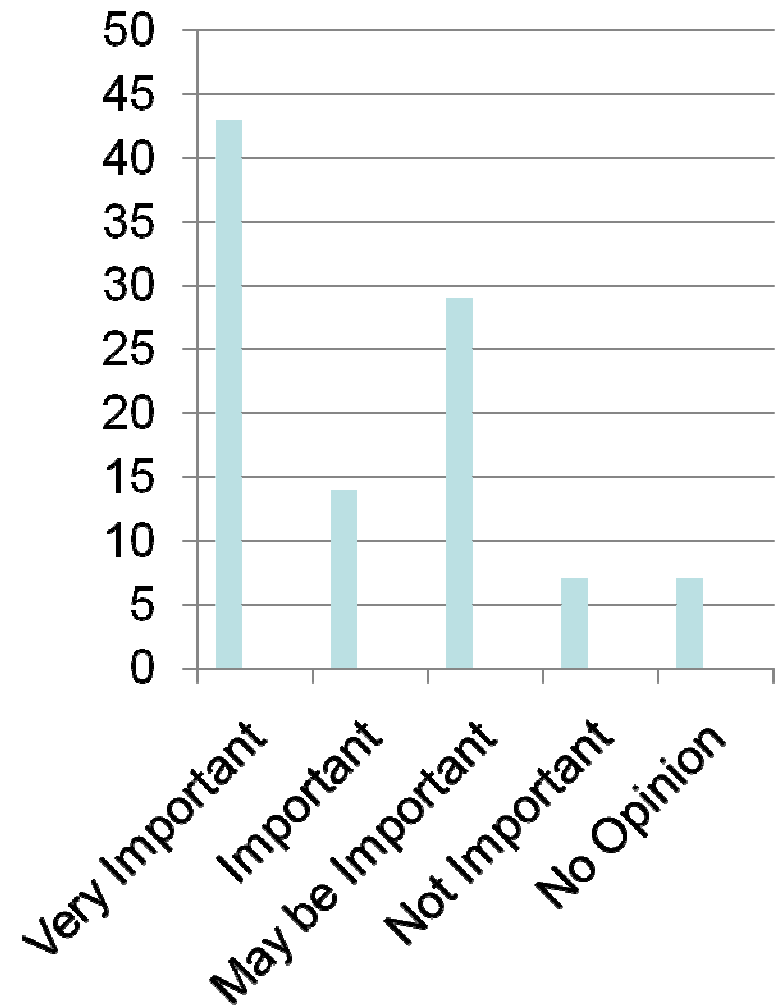*C-3PO, Star Wars Episode V: The Empire Strikes Back*

Unified Communications

Unified Communications -- My company would like to use web-based tools to communicate for meetings, sales presentations, training, etc. – systems like WebEx, Live Meeting, Skype, etc.

85% think Unified Communications may be important

Optimism and pessimism are mere matters of optics . . . .
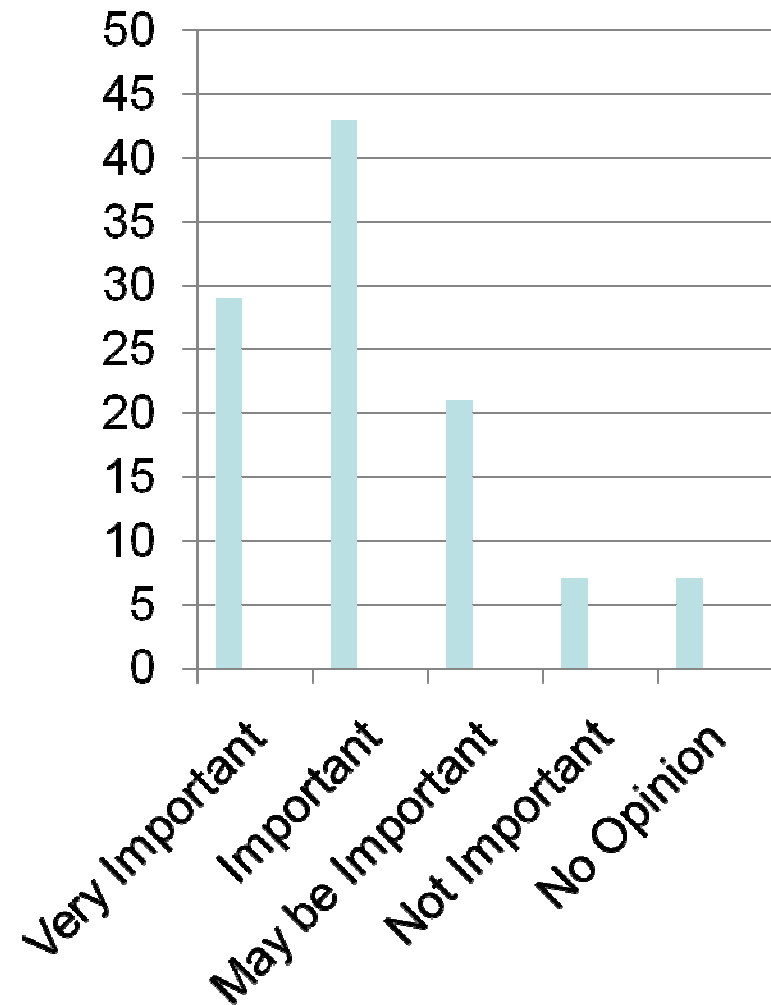
GEORGE WEIGEL

Mobile Workforce

Mobile Workforce -- My company wants to provide continuous improvements to the use of laptops and hand-held mobile devices in remote/home offices and in the field

92% think a Mobile Workforce may be important

Nothing, not even a Utopia, can necessarily make the pursuit of happiness a successful one that ends in capture.
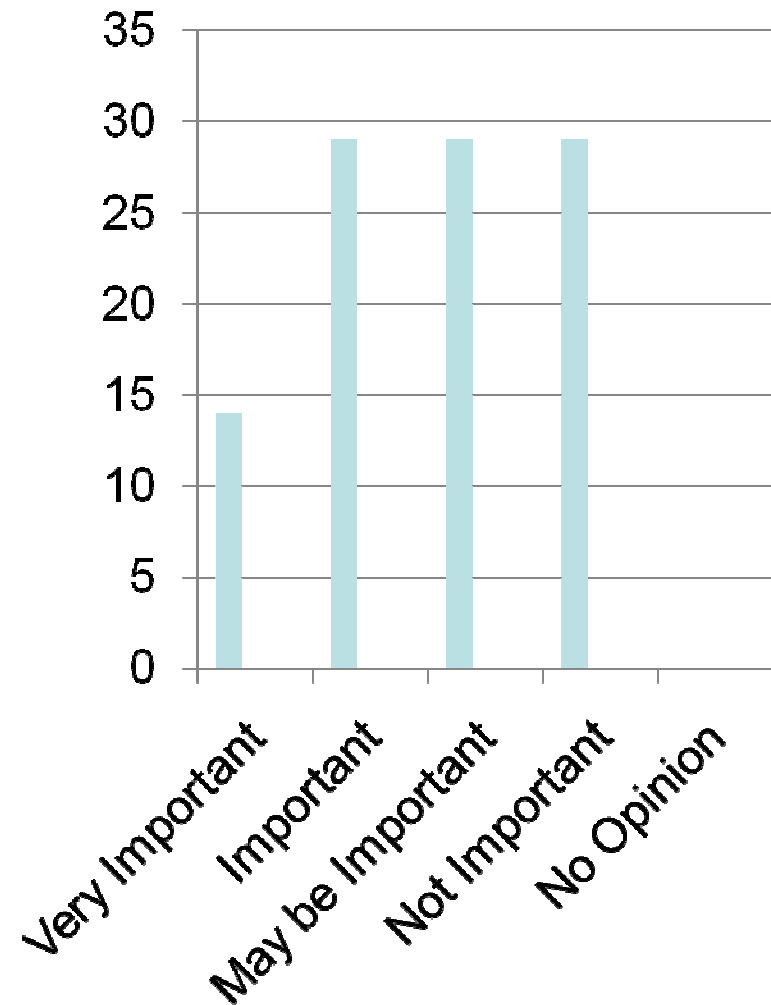
DANIEL NETTLE

Collaboration Techniques

Collaboration Techniques -- My company is beginning to accept the deployment of systems like Lotus Notes, SharePoint, etc. _and_ Social Networking sites including LinkedIn, Facebook, MySpace, for business use.

70% think using Collaboration Techniques may be important

The majority is never right. Never, I tell you! . . . .

HENRIK IBSEN

Social Media is Fast, Cheap, and Easy

Well, Not Quite.

The allure of social media is that it is easy to set up, costs nothing, and grows exponentially. Yet, many companies are discovering exactly the opposite.

Social media that isn't well-tended risks lack of adoption and participation, and becomes anything but social.

Adapted from "Debunking Social Media Myths" by David Armano

For Example

▶ Facebook Pages Sink Job Applicants

According to research conducted by CareerBuilder, social networking poses a serious threat to job seekers who have posted inappropriate information about themselves. With so many IT workers taking advantage of sites such as Facebook, LinkedIn and Twitter these days, tech geeks need to keep future interviewers in mind before bragging about their beer pong champion status or posting crazy pictures.

Reviews of Social Networking Sites

	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
TopTenREVIEWS™ We Do the Research So You Don't Have To.™	Facebook facebook	MySpace myspace.com	Bebo bebo	Friendster @friendster	hi5 hi5	Orkut orkut	PerfSpot PerfSpot	Yahoo! 360 YAHOO! 360°	Zorpia Zorpia.com	Netlog NETLOG

Top 25 Social Networks Re-Rank
(Ranked by Monthly Visits, Jan '09)   compete.com

Rank	Site	UV	Monthly Visits	Previous Rank
1	facebook.com	68,557,534	1,191,373,339	2
2	myspace.com	58,555,800	810,153,536	1
3	twitter.com	5,979,052	54,218,731	22
4	flixster.com	7,645,423	53,389,974	16
5	linkedin.com	11,274,160	42,744,438	9
6	tagged.com	4,448,915	39,630,927	10
7	classmates.com	17,296,524	35,219,210	3
8	myyearbook.com	3,312,898	33,121,821	4
9	livejournal.com	4,720,720	25,221,354	6
10	imeem.com	9,047,491	22,993,608	13
11	reunion.com	13,704,990	20,278,100	11
12	ning.com	5,673,549	19,511,682	23
13	blackplanet.com	1,530,329	10,173,342	7
14	bebo.com	2,997,929	9,849,137	5
15	hi5.com	2,398,323	9,416,265	8
16	yuku.com	1,317,551	9,358,966	21
17	cafemom.com	1,647,336	8,586,261	19
18	friendster.com	1,568,439	7,279,050	14
19	xanga.com	1,831,376	7,009,577	20
20	360.yahoo.com	1,499,057	5,199,702	12
21	orkut.com	494,464	5,081,235	15
22	urbanchat.com	329,041	2,961,250	24
23	fubar.com	452,090	2,170,315	17
24	asiantown.net	81,245	1,118,245	25
25	tickle.com	96,155	109,492	18

Shown here is a listing of Social Media and Networking sites that have become very popular. One listing is one company's view of the top ten sites. The other lists the top 25 sites. It appears that all of the top 10 on the first chart are represented within the second company's listings.

Do you currently use any of these social networking sites?

Strong communities ... embrace change. New discoveries require us to think differently and approach things differently, to think anew.

TOM VILSACK, speech, Jan. 10, 2006

"Change is good! You go First!"

Mike Regentz

MHT Report on October 21, 2009

Which of the following most closely describes your company's policy on visiting social networking sites, such as Facebook, MySpace and Twitter, while at work?

- **Prohibited completely 54%**

- **Permitted for business use only 19%**

- **Permitted for limited personal use 16%**

- **Permitted for any personal use 10%**

- **Don't know/No answer 1%**

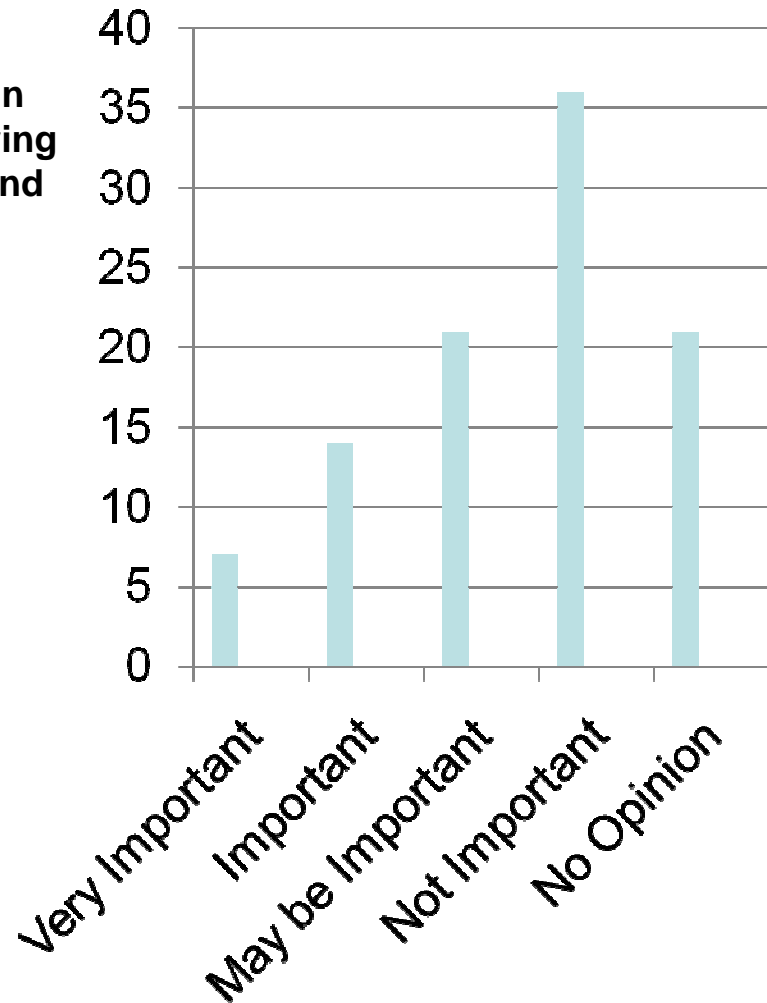**Base: 1,400 CIOs interviewed by phone**

Source: Robert Half Technology

ERP

Enterprise Resource Planning (ERP) -- My company is very interested in improvements in ERP systems to better coordinate manufacturing and supply chain plans with sales forecasts and customer demand.

50% think Deploying a new ERP system may/ may-not be important (to Clinical Operations)

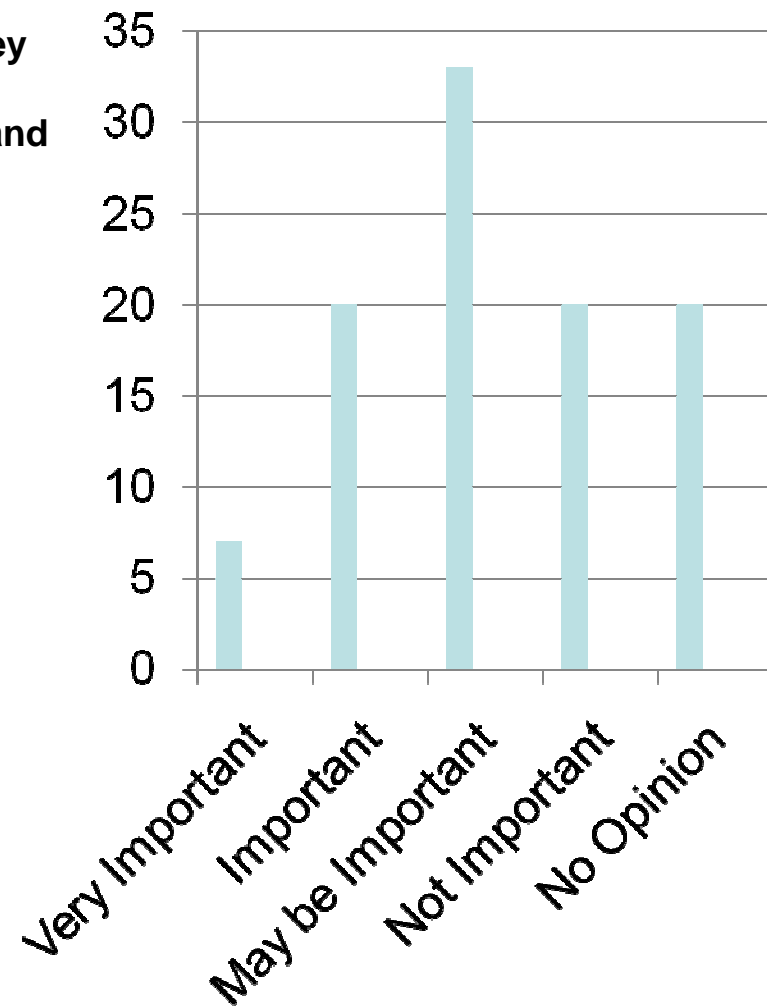*The need of a constantly expanding market for its products chases the bourgeoisie over the whole surface of the globe . . . .*

KARL MARX

IT Management

IT Management -- My company will deploy key software to keep IT costs under control like IBM's Tivoli, CA Unicenter, HP's OpenView, and BMC Performance Manager

60% think IT Management may be important

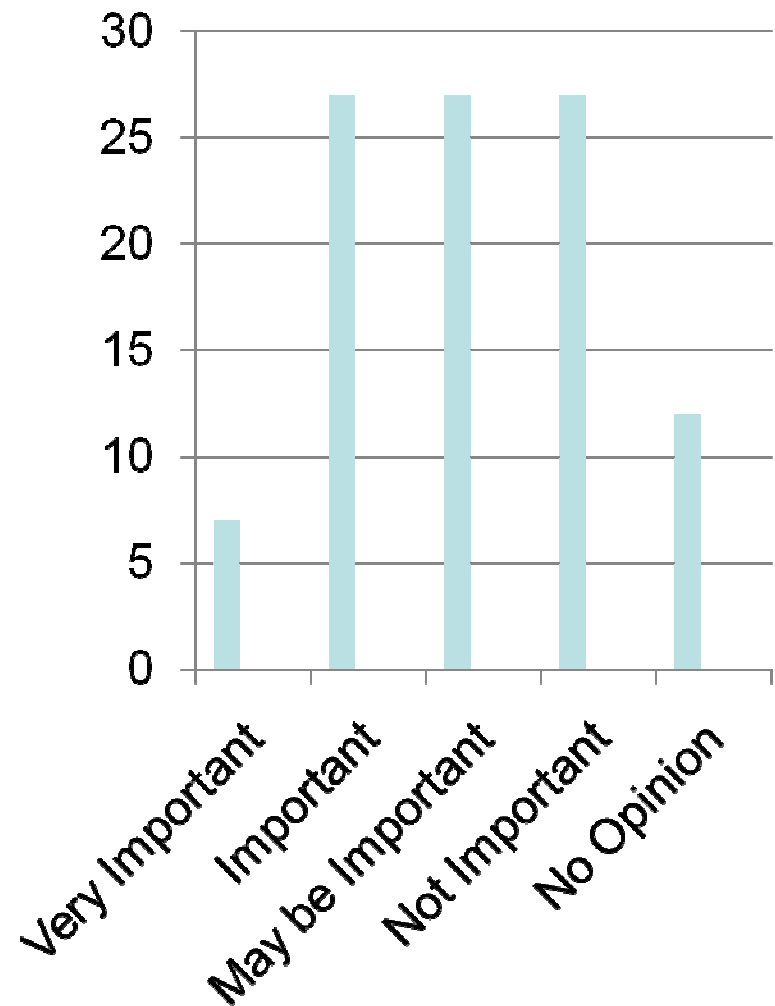*It has become appallingly obvious that our technology has exceeded our humanity.*

ALBERT EINSTEIN

Customer Relationship Management

CRM -- My company will do further deployment of customer relationship management into other areas of my company

30% think CRM may be important

Associate with men of good quality, if you esteem your own reputation; for it is better to be alone than in bad company.

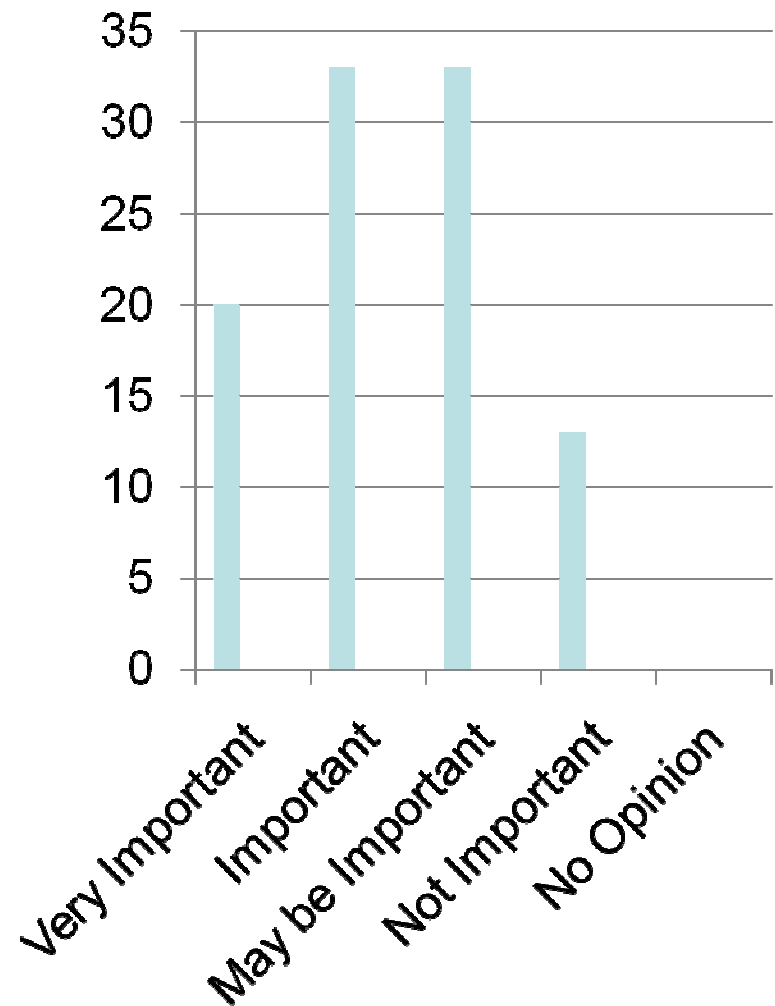GEORGE WASHINGTON

A bar chart with y-axis from 0 to 30. Categories: Very Important (~7), Important (~27), May be Important (~27), Not Important (~27), No Opinion (~12).

Computing Infrastructure

Computing Infrastructure -- My company is interested in providing higher computing and network speeds for both the Internet and Intranet (network).

85% think "*speeds and feeds*" may be important

Patience, n. A minor form of despair, disguised as a virtue.
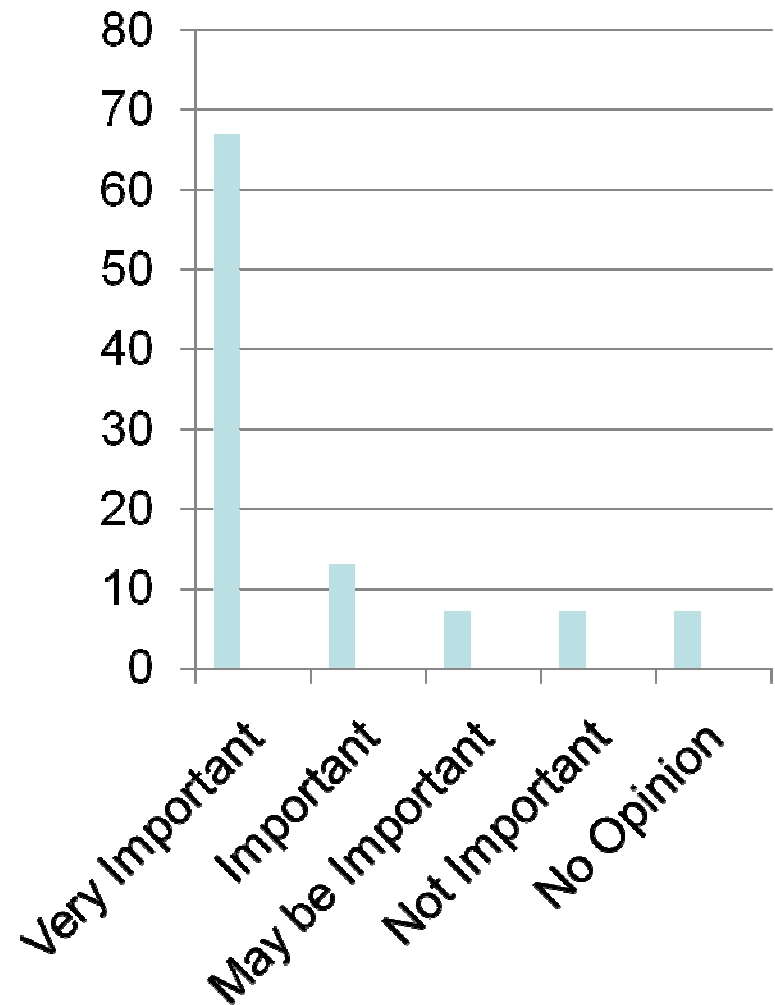
AMBROSE BIERCE, The Devil's Dictionary

System Integration

Integration -- My company is looking for better integration between EDC, CTMS, IVRS, ePRO, and other systems.

85% think integrating all eClinical systems may be important

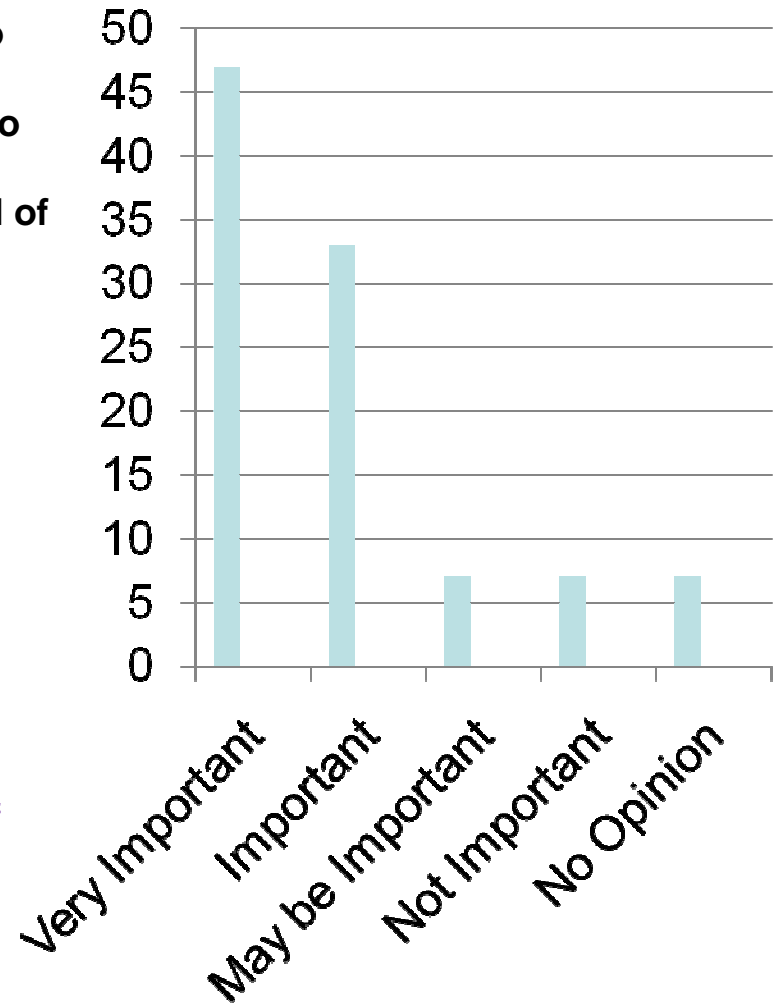*You can never plan the future by the past.*

EDMUND BURKE

Investigator Portal

Investigator Portal -- My company wishes to deploy a single website where investigator sites may log in using a "single sign on" into the site and gain immediate access to the clinical trials they are active on including all of the eClinical systems in use -- IVRS, EDC, CTMS, ePRO, etc.

85% think deploying an Investigator Portal may be important

We did not come to fear the future. We came here to shape it.

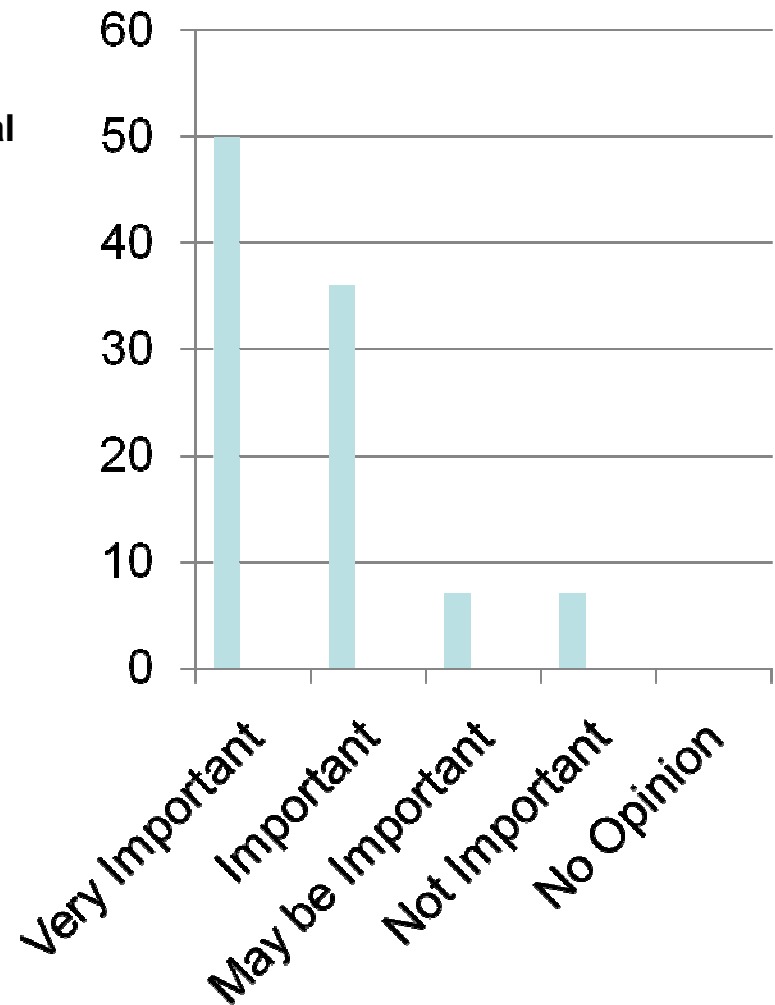BARACK OBAMA, speech to joint session of Congress, Sep. 9, 2009

EDC – Electronic Data Capture

EDC -- My company will deploy electronic data capture system(s) for most or all clinical trials at my company.

90% think deploying EDC may be important

It is the tension between creativity and skepticism that has produced the stunning and unexpected findings of science.
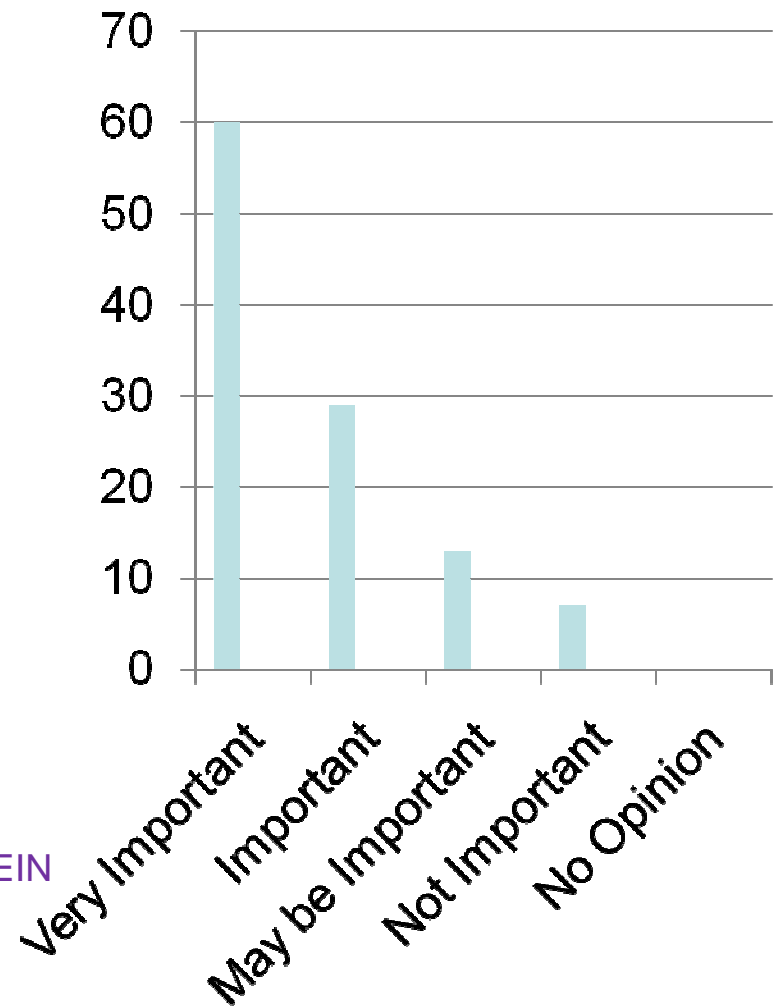
CARL SAGAN

CTMS – Clinical Trial Management System

CTMS -- My company will deploy a single clinical trial management system to help manage our company's clinical operations, documents, etc.

90% think deploying a CTMS may be important

As our circle of knowledge expands, so does the circumference of darkness surrounding it.
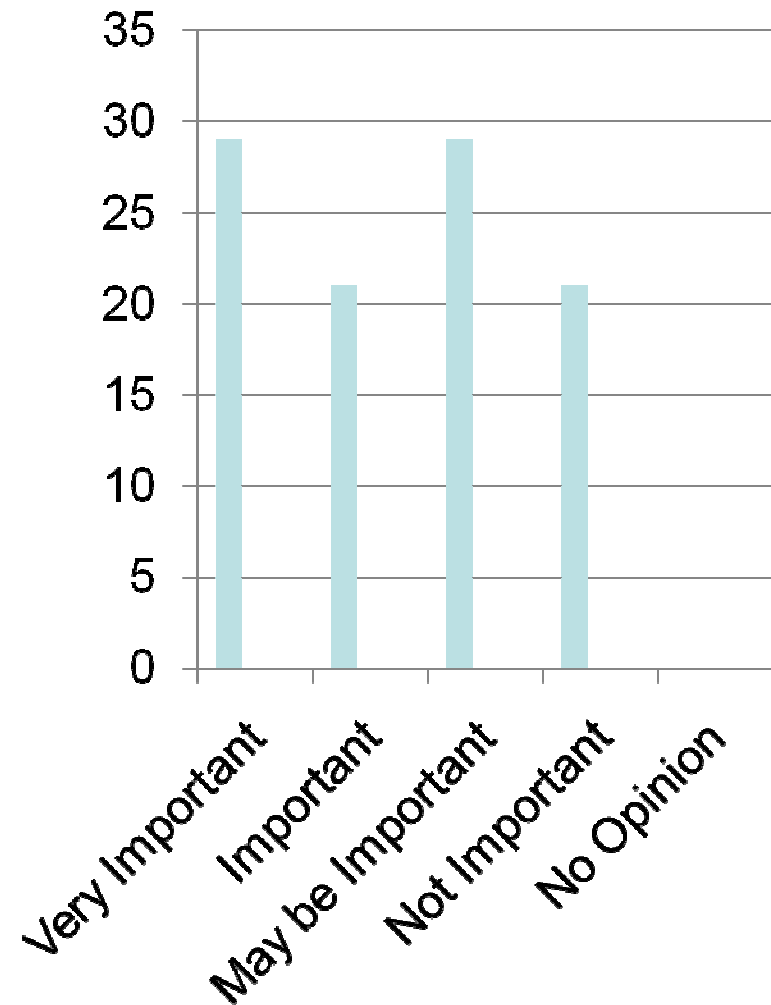
ALBERT EINSTEIN

IVRS – Interactive Voice Response System

IVRS -- My company will implement the use of an automated interactive voice response system for use on most trials.

80% think deploying an IVRS may be important

An expert is someone who knows some of the worst mistakes that can be made in his subject and how to avoid them.

WERNER HEISENBERG, *Physics and Beyond*

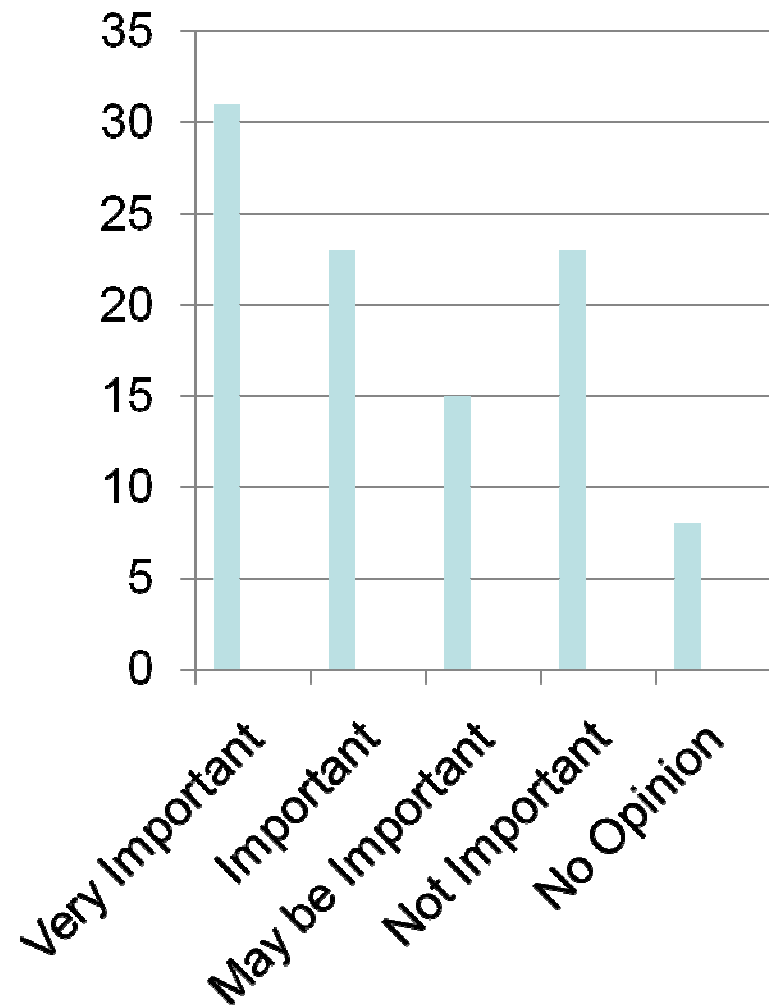# LIMS – Laboratory Information Management System

LIMS -- My company will deploy a laboratory information management system.

65% think deploying a LIMS may be important

No organic law can ever be framed with a provision specifically applicable to every question which may occur in practical administration.

No foresight can anticipate nor any document of reasonable length contain express provisions for all possible questions.
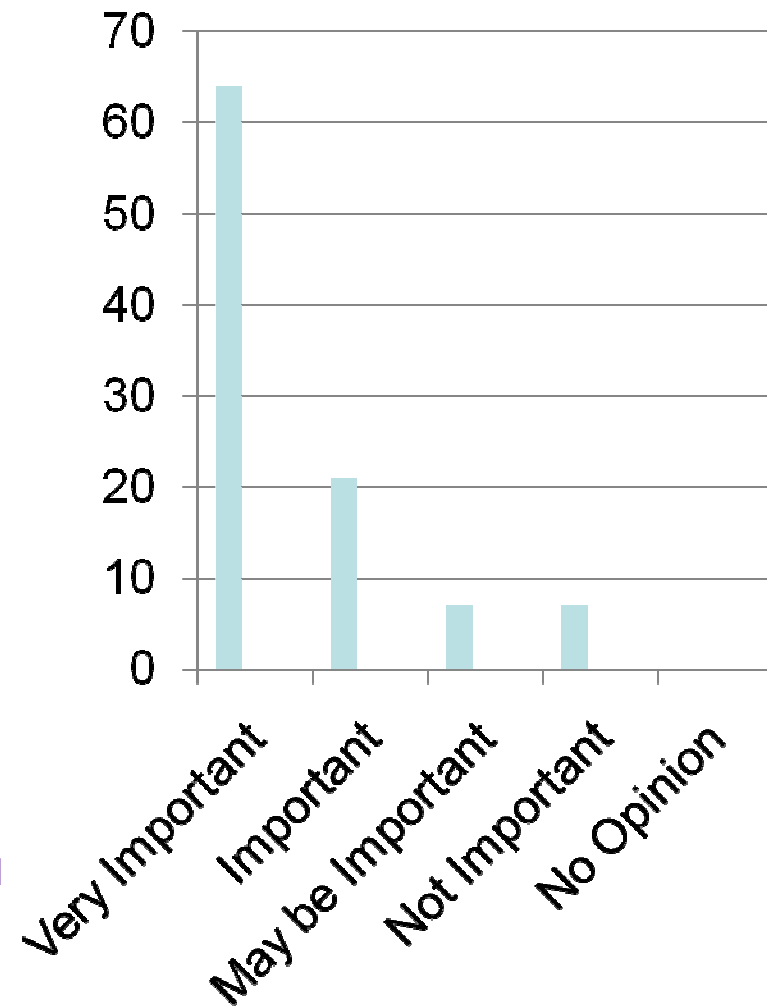
DMS – Document Management System

DMS -- My company will deploy a document management system.

90% think deploying a DMS may be important

Laws or ordinances unobserved, or partially attended to, had better never have been made.
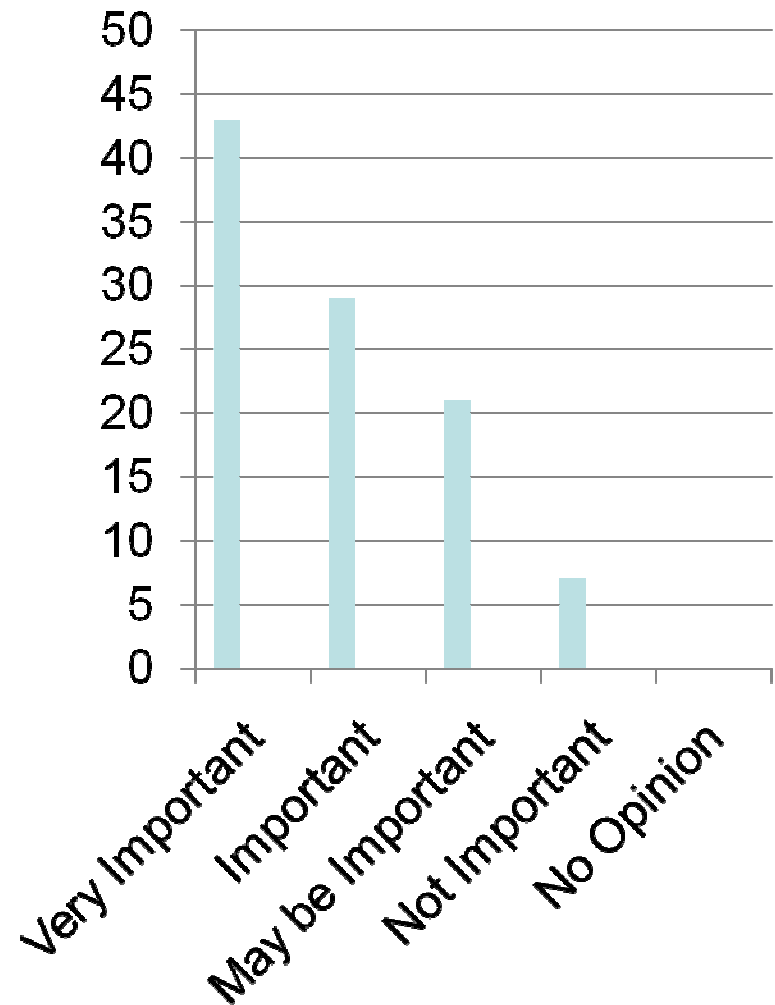
GEORGE WASHINGTON

AERS – Adverse Event Reporting System

AERS -- My company will deploy an adverse event reporting system.

90% think deploying an AERS may be important

There is in the worst of fortune the best of chances for a happy change.

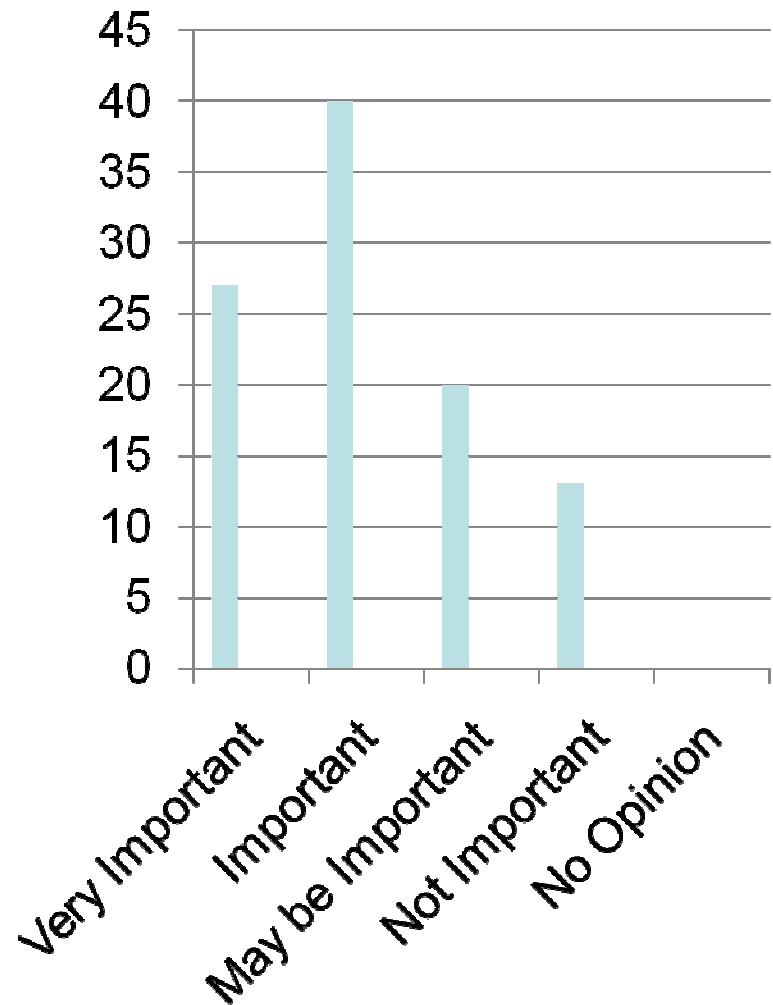EURIPIDES

EDMS – Data Management System

EDMS -- My company will deploy a data management system to manage clinical trial data.

85% think deploying an EDMS may be important

Confidence doesn't come out of nowhere.

It's a result of something... hours and days and weeks and years of constant work and dedication.

ROGER STAUBACH

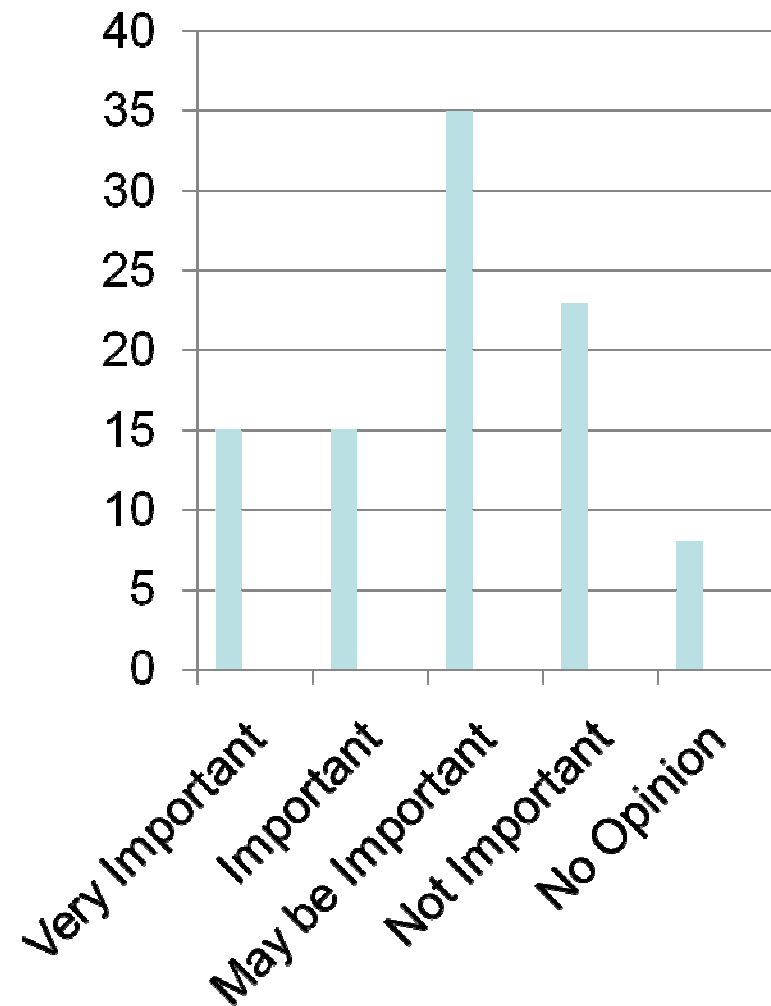# ePRO – Patient Reported Outcomes System

ePRO -- My company will deploy an electronic patient reported outcomes system

75% think deploying an ePRO system may be important

When you have eliminated the impossible, whatever remains,

however improbable, must be the truth.

SIR ARTHUR CONAN DOYLE

Clinical Repository

Repository -- My company will deploy a corporate clinical repository to store all clinical trial data in a single repository.
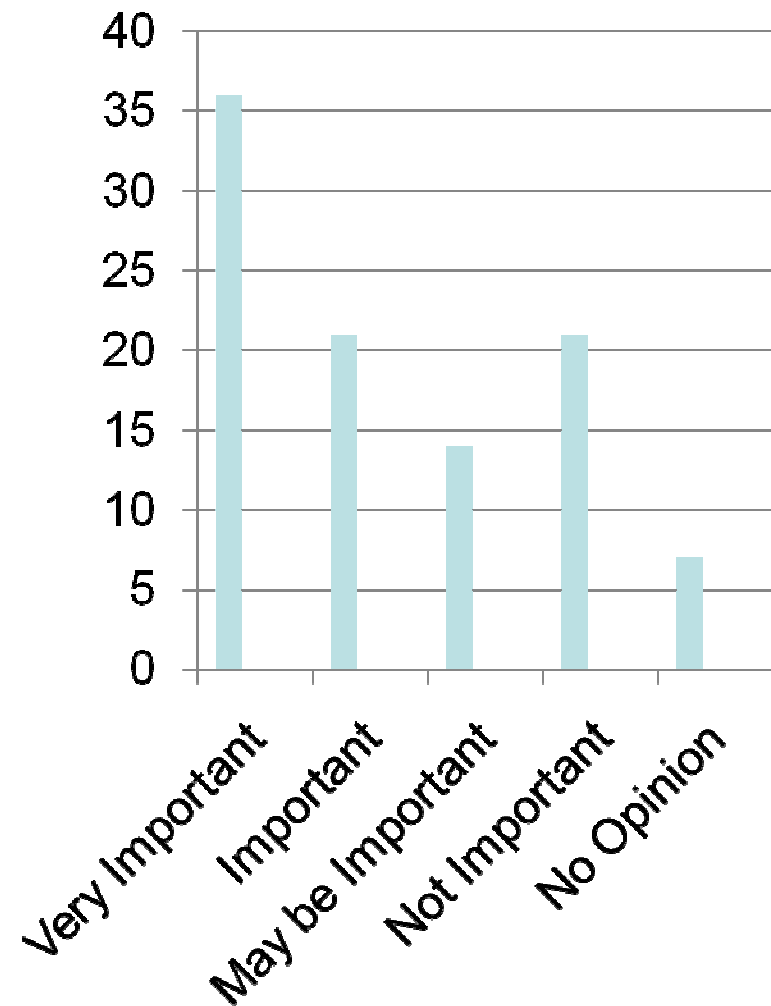
70% think deploying a clinical data repository system may be important

In a free society, there comes a time when the truth –

however hard it may be to hear, however impolitic it may seem to say –

must be told.

AL GORE

Some tips to help you get ready

PREPARE FOR THE FUTURE

3 Tips for the Remote Worker

More and more companies are opting to keep employees at home to save money and conserve energy:

- **Keep on top of your email.**

- **Be present via instant messenger.**

- **Set up regular check-ins.**

Adapted from "Master the Art of Working Remotely" by Gina Trapani.

3 Questions to Assess Your Change Readiness

Leaders need to be on the lookout for what today's quickly changing business landscape means to them and their organizations.

- **Do you see opportunities others don't?**

- **Can your customers live without you?**

- **Are you learning as fast as the world is changing?**

Adapted from "The 10 Questions Every Change Agent Must Answer" by Bill Taylor.

4 Tips to Optimize Your Workspace for Productivity

Here are four tips to design a space that helps, not hinders, your ability to get work done.

- **Cut the clutter.**

- **Keep frequent-use items close.**

- **Put related items together. Group items by task.**

- **Adjust as needed.**

Adapted from "Organize Your Workspace for Maximum Productivity" by Gina Trapani.

Make a Parking Lot

- **To Dos that seem to come up**
- **Things I'll do later**
- **Calls to make**
- **Follow ups**

4 Ways to Exceed Client Expectations

Use these four tips to go above and beyond and win a client for life:

1. **Beat the deadline.**
2. **Ask proactive questions.**
3. **Know when to defer.**
4. **Give feedback.**

Decide What to Ignore

- **Create a list of Diversions.**
  - **Don't make you happy,**
  - **Getting in the way of your productivity**
  - **Detract from your ability to focus on your goals.**
- **Get rid of irrelevant newsfeeds**
- **Be selective about which emails you read and respond to**
- **Ask yourself whether it's truly worth your limited time.**

Adapted from "Two Lists You Should Look at Every Morning" by Peter Bregman.

Think Positively, Yes, Even in this Economy

- **Treat employees as contributors, not costs.**
- **Trust your employees. Don't hold back information.**
- **Challenge your people.**

Do Something Remarkable for Customers

- **Only exceptional service distinguishes your company from rivals.**

- **How to provide such service?**

- **Use ritual, tradition, and cultural indoctrination to foster a hunger among employees to do something remarkable--and memorable--for customers.**

- **Take Best Buy's Geek Squad**

- **The Geeks generate $1 billion in annual revenues**

Adapted from "A Geek's Guide to Great Service," by Bill Taylor on "Practically Radical."

Don't Put out the Fire, Let it Burn

- **Forest fires are an essential part of a healthy ecosystem.**
- **Recessions are the economy's forest fires**
- **Prepare for them as opportunities**
- **When the fire is out, discover the room you now have for new things to grow**
- **New ideas, new strategies, and new opportunities.**

Adapted from "Surviving a Recession — And a Wildfire" by Adam Werbach.

Presenter

Man is not limited as much by his tools as by his vision.

Michael O. Regentz, CSI, CeBSA

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