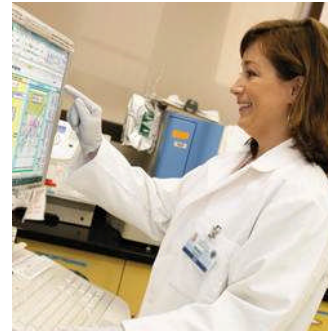


# Evolution of Collaborative R&D

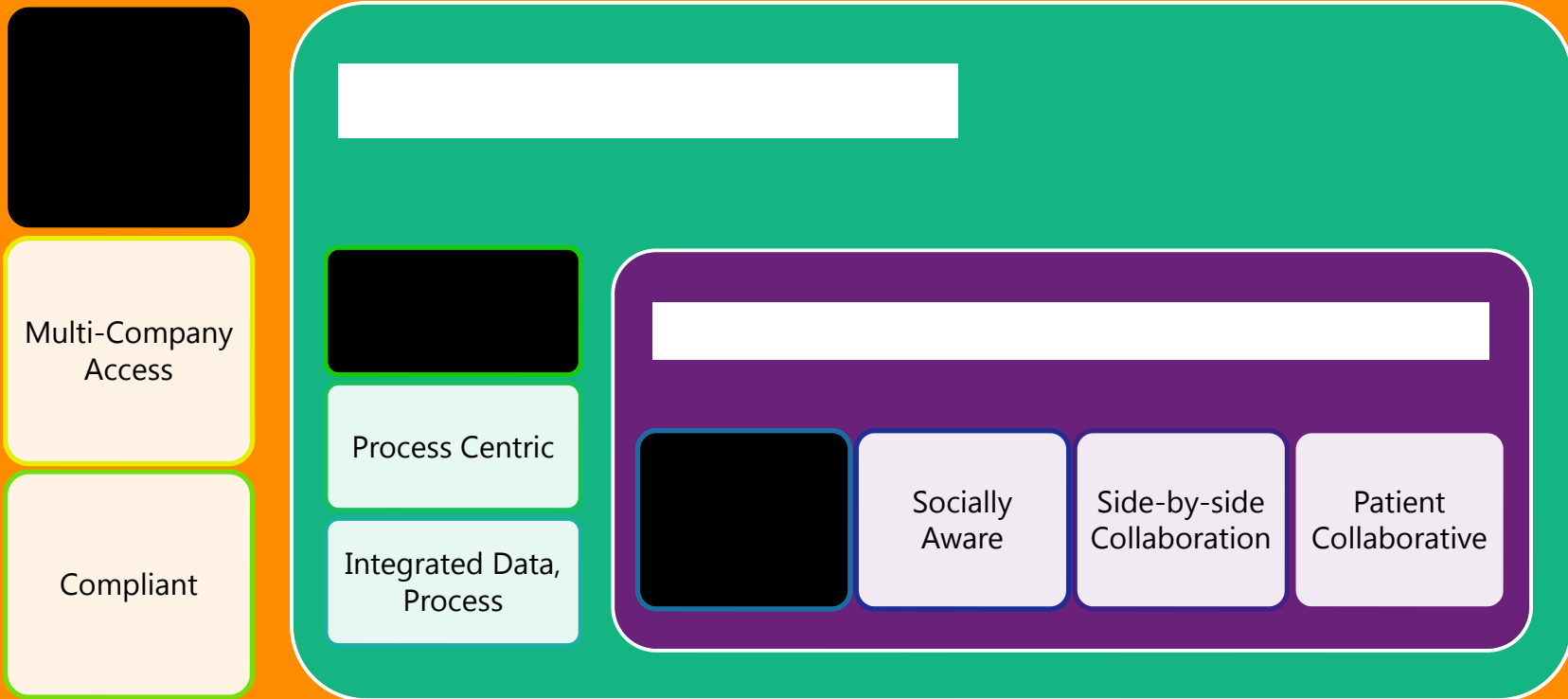
PRISME Forum SIG  
October 25, 2012



Les Jordan  
Chief Technology  
Strategist, Life Sciences  
Microsoft Corporation

# Collaborative R&D Defined

## Document Centric



Collaborative Platform

On-Prem – Cloud Based – Out of the Box – Standards – Open Architecture

# Evolution of Collaborative R&D

2006

Scientist  
Workbench

SharePoint

LIMS Integration

ELN Integration

Presence (Social)

Process Integration

The screenshot shows the 'scientific workbench' web application. The header includes the title 'scientific workbench' and a user greeting 'Welcome Swati Bishnoi'. Below the header, there are navigation tabs for 'Safe Drug Pharmaceuticals', 'Therapeutic Programs', 'Research Projects', 'Chemistry Lab', and 'Biology Lab'. The main content area is divided into several sections:

- Experiment List:** A table showing experiment details. The 'Experiment Stage' is set to 'Target Identification and Validation'. The table has columns for 'Project Code', 'Molecular Biology', and 'Bioassays'.
 

Project Code	Molecular Biology	Bioassays
ONCCTITV01	Amplification of AKT3 gene	IMAC assay for Transcription Factors
ONBCTITV11	PCR primer identification	Sandwich ELISA protocol
ONLCTITV23	Expression in cell lines	HTS cell based assay development
ONSCITIV77	Site directed mutants (chemical mutagenesis)	In-situ hybridization studies
- Experiment Overview:** Provides details for a specific experiment.
 

**Name:** Anthony Kar Role **Role:** Scientist-BioMarker Labs **Date:** 07 June'2007

**Project Code:** ONCCTITV01

**Aim of Experiment:** Identifying Gene Clusters highly expressed in leukemia derived cell lines.

**Design of Experiment:** Histologic features of NCI60 cancer biopsies can be recognized and parsed based on gene expression patterns. The data for one gene corresponds to one row, and each experiment is represented by a column. The ratio of induction/repression is such that the magnitude is indicated by the intensity of the colors displayed.

**Figure-1** Cancer Biopsies submitted by NCI
- Instrument Booking Details:** A table showing instrument booking information.
 

Instrument Code	Instrument Name	Reserved By	Project Code	Booked From	Booked Till
SDPCRABI001	Real Time PCR 7500 (ABI)	Augustine John	ONCCTITV01	05/22/2007	05/23/2007
SDPSEQABI005	454Sequencer	Mark Kilgore	ONBCLILV01	05/31/2007	06/07/2007
SDPHTSCYT017	Cytokinetix-PUMA	Jim Walker	ONCLILV01	06/04/2007	06/11/2007
- SNPs Observed:** A section for viewing observed SNPs.
- Leukemia Experimental Data:** A section for viewing experimental data related to leukemia.
- Scientist Toolkit:** A sidebar containing various tools and resources:
  - Visual Query Builder & Analyser
  - 3-D Molecular Visualization
  - Gene Expression Atlas
  - Cancer Gene Expression Data
  - National Centre for Biotechnology Information
  - iBOX Metadata Search
- Group Members:** A list of group members with their names and roles:
  - Allen Joseph John
  - Augustine John
  - Mark Kilgore
  - Mathew Stephen
  - Jim Walker
  - Steven C. Dennis
  - Ronald Camillo D'Costa
- MicroArray Project Documents:** A table showing microarray project documents.
 

Type	Name	Modified
other cell-line phenotypes		5/9/2007 2:53 PM
Leukemia Cluster		5/9/2007 2:53 PM
clinical		5/9/2007 2:53 PM

The interface also includes a 'Recycle Bin' link in the left sidebar and a 'Site Actions' dropdown in the top right. The bottom status bar shows 'Local intranet' and '100%' zoom.

# Evolution of Collaborative R&D

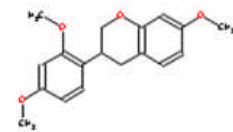
2007  
ChemSpider  
Office App  
Chem 4 Word

Document1 - Microsoft Word

Home Insert Page Layout References Mailings Review View Compound Lookup Design Layout

Search Search InChI OpenBabel MassSpec ChemSpider Services Local Drug Database

**CONSTITUENT COMPOUNDS**  
**3-(2,4-dimethoxyphenyl)-7-methoxy-chroman**

Formula	C18H20O4
SMILES	<chem>Oc1ccc(c(OC)c1)C2Cc3c(OC2)cc(OC)cc3C</chem>
Avg. Mass	300.349 gm mol-1
Structure	

**ISOLATION**

**ChemSpider Services Search**

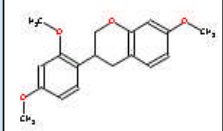
Search for: methoxy-chroman

3-(2,4-dimethoxyphenyl)-6-methoxy-chroman  
3-(2,4-dimethoxyphenyl)-7-methoxy-chroman  
6-bromo-8-methoxy-chroman-3-carboxylic acid  
6-methoxychroman-3-carboxylic acid  
8-[4-[(5-methoxychroman-3-yl)-propyl]-an-8-methoxychroman-3-carboxylic acid

Add to Document

**Preview**

Name 3-(2,4-dimethoxyphenyl)-7-methoxy-chroman  
Formula C18H20O4  
Smiles Oc1ccc(c(OC)c1)C2Cc3c(OC2)cc(OC)cc3C  
Avg. Mass 300.349 gm mol-1



Page: 2 of 2 Words: 47

Start C:\QCRT V2 untitled - Paint V2 Screenshots... OBA Composer Scientist Resear... 2 Microsoft O... 110% 6:47 PM



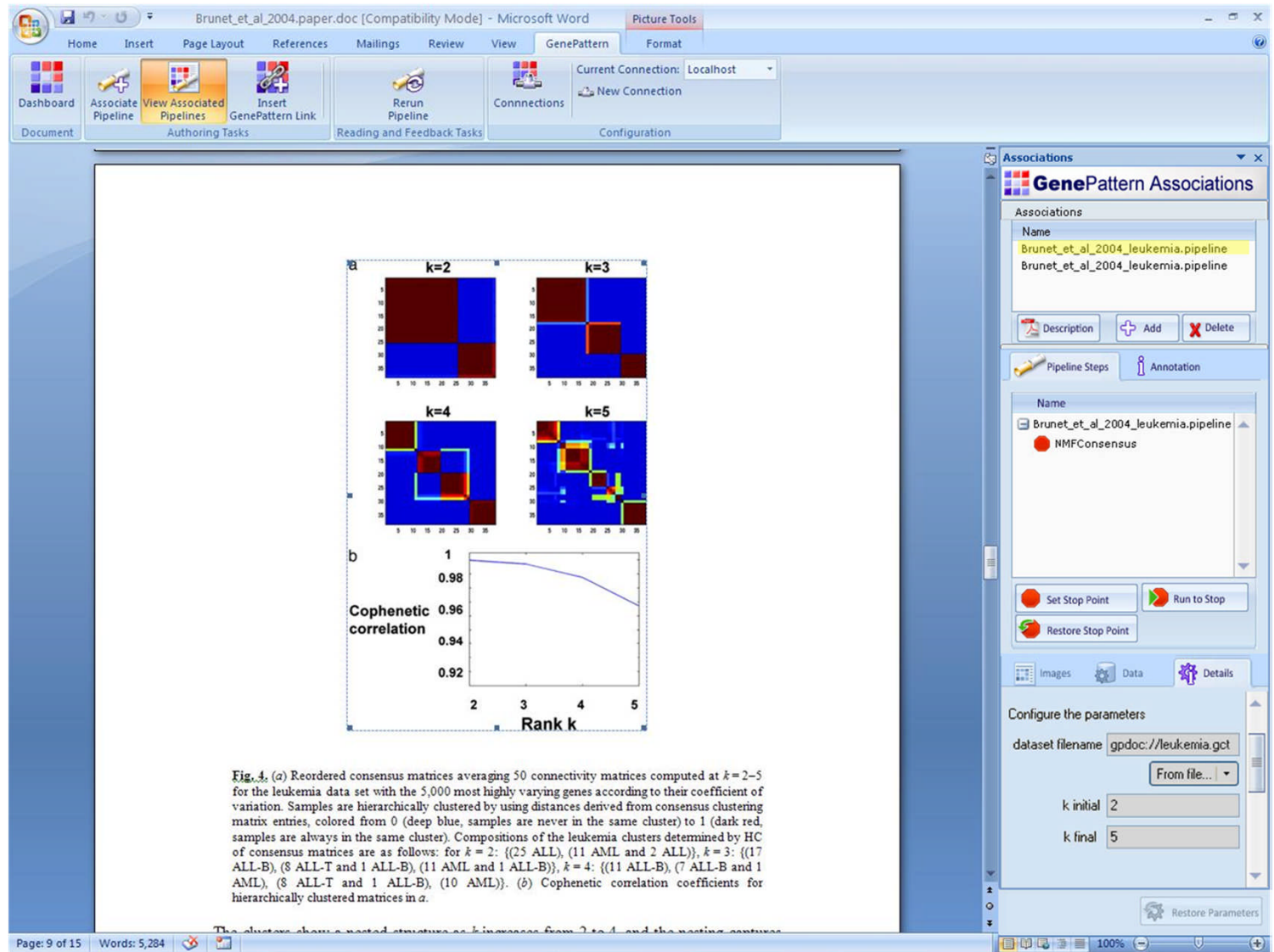
# Evolution of Collaborative R&D

2008

GenePattern  
Associations

OBA

SharePoint  
Word 2007



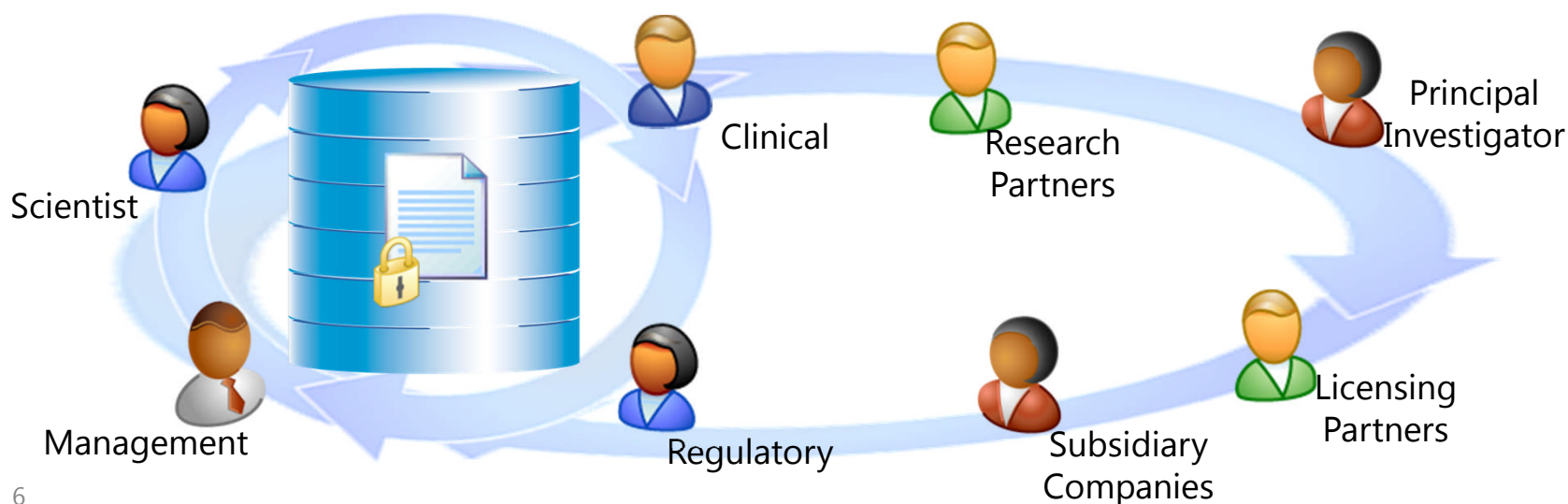
# Compliant Collaboration Across Boundaries

## Compliant Collaboration


- Regulated document mgmt.
  - Enterprise document mgmt.
  - Enterprise metadata mgmt.
  - Real-time collaboration
  - Legacy systems & applications
- 
- GxP, Part 11 Compliance

## Across Boundaries

- Internal and external users
  - Business partners
  - Across geographies
  - Across business entities
  - Single-Sign On
- 
- Collaborative Extranets




# Evolution of Collaborative R&D

Site Actions ▾ 


Browse

Page


Brendan T. Foley ▾




Corporate Compliance  
Project Site for Corporate Compliance Content



I Like It





Tags & Notes



About

Home


Search this site...  


Libraries

- Corporate Compliance
- HR Policies

Lists


- Tasks
- Favorites
- Recently Accessed


 Recycle Bin





 All Site Content


CONTROL, COMPLY, PERFORM





QUMAS is the leader in Enterprise Compliance Solutions with more than 250 global customer deployments and over 15 years experience helping companies in highly regulated industries.




 Corporate Compliance Library


	Type	Name	Modified	Modified By
		Code of Ethics	09/17/2010 14:07	QUMAS\tandrews
		Employee Handbook	08/27/2010 12:50	QUMAS\rbrady
		Staff Notices	09/14/2010 11:31	QUMAS\jsmith

 HR Policies


	Type	Name
		Leave Application Form
		HR Policies Guide
		Health & Safety Manual

 Tasks

Task	Type	Due Date
Revision Required	HR Document Edit	01/01/2011
Training Request	Ethics Training	12/15/2010
Approval Required	Quality Document Approval	12/17/2010

 Favorites

0 Favorite items

 Recently Accessed

0 Recently Accessed items

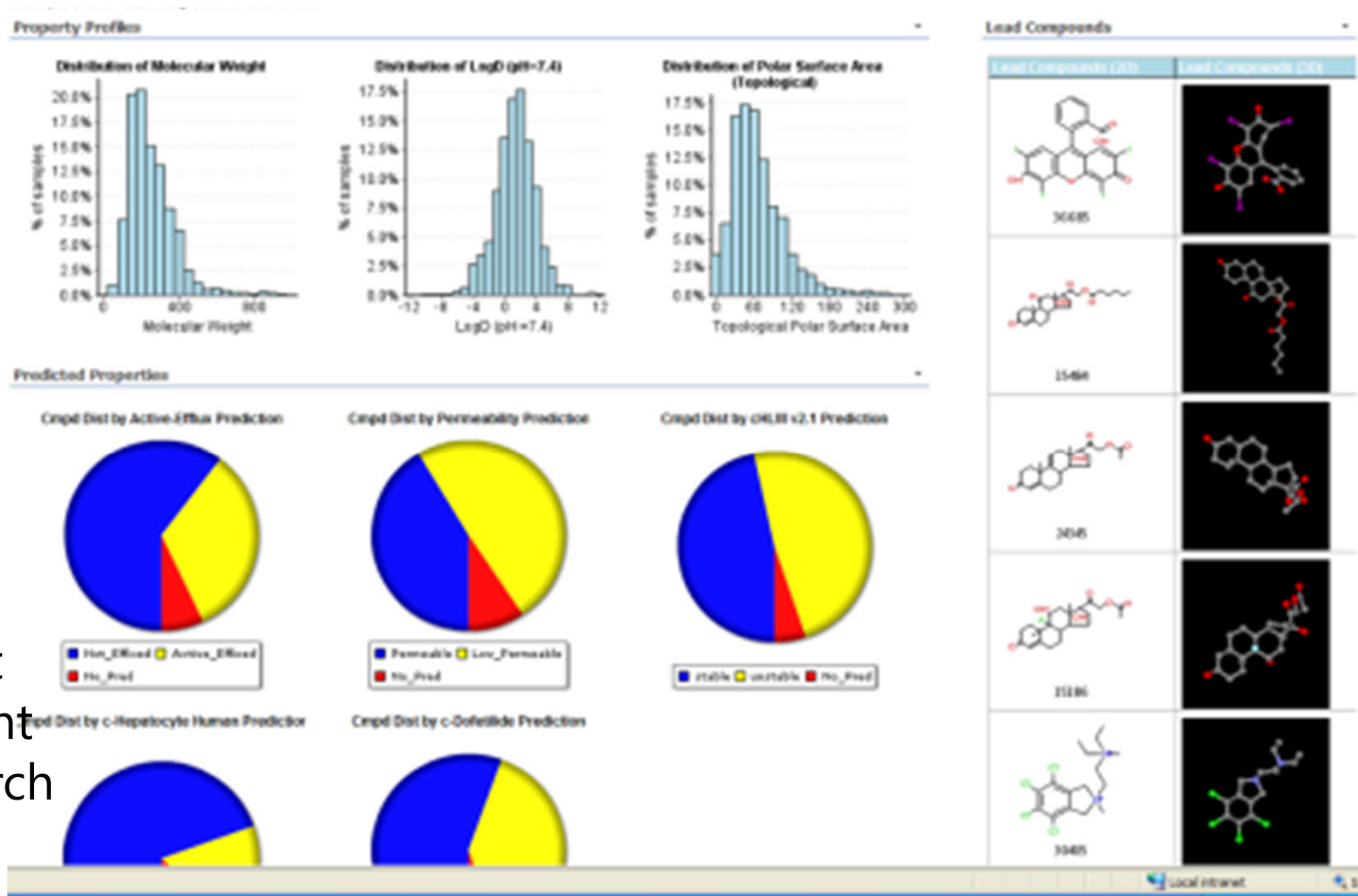
Copyright © 2010 QUMAS

# Evolution of Collaborative R&D

2009  
Accelrys  
Pipeline  
Pilot

SharePoint  
Process  
Intelligence

CambridgeSoft  
FAST/SharePoint  
Chemistry Search



# Evolution of Collaborative R&D

The screenshot displays the Kinematic ELN (Electronic Laboratory Notebook) interface. The top navigation bar includes 'Site Actions', 'Browse', 'eNovator', and 'Page'. The 'Page' tab is active, showing a toolbar with icons for 'Edit Page', 'Edit Properties', 'Delete Page', 'E-mail a Link', 'Approve', 'Reject', 'Workflows', 'Edit Mobile Page', 'Make Homepage', and 'Title Bar Properties'. Below the toolbar, the left sidebar contains a 'Table of Contents' with links to 'Experiment outline and aims.doc', 'Protocols', 'Data', 'Analysis', 'Images and Videos', and 'Site Content'. The main content area is divided into several sections: 'Experiment Properties', 'Experiment Chemical Structures', 'Documents', 'Protocols', 'Analysis', and 'Data'. The 'Experiment Properties' section shows a table with columns for Title, Start Date, End Date, Managed Keywords, and State. The 'Experiment Chemical Structures' section shows a table with columns for Title, Chemical Structure, and Description. The 'Documents' section shows a table with columns for Type, Name, Modified, and Modified By. The 'Protocols' section shows a table with columns for Type, Name, Modified, and Modified By. The 'Analysis' section shows a table with columns for Type, Name, Modified, and Modified By. The 'Data' section shows a table with columns for Type, Name, Modified, and Modified By. The interface is designed for collaborative R&D, allowing users to manage experimental data, protocols, and documents in a structured and accessible manner.

Title	Start Date	End Date	Managed Keywords	State
10 - 087 - Pyrrole Synthesis	10/13/2010 12:00 AM	11/16/2010 12:00 AM	Pyrroles, Synthesis, small molecule, targeted	Active

Type	Name	Modified	Modified By
Document	Experiment outline and aims	10/13/2010 5:32 PM	KIN\Administrator
Document	Experimental Notes	10/13/2010 5:32 PM	KIN\Administrator

Type	Name	Modified	Modified By
Protocol	SOP - 154-09 NMR Request Procedure	10/13/2010 5:23 PM	KIN\Administrator
Protocol	SOP 153-2 Pyrrole Synthesis	10/13/2010 5:24 PM	KIN\Administrator
Protocol	SOP 153-8 - Mass Spec 2310 operation	10/13/2010 5:24 PM	KIN\Administrator

Type	Name	Modified	Modified By
Analysis	Analysis Outline Plan	10/13/2010 5:27 PM	KIN\Administrator
Analysis	Mass Spec Data Fragment Breakdown	10/13/2010 5:27 PM	KIN\Administrator

Type	Name	Modified	Modified By
Data	Mass Spec Data	10/13/2010 5:28 PM	KIN\Administrator
Data	NMR-2310 - 2010-10-13	10/13/2010 5:28 PM	KIN\Administrator

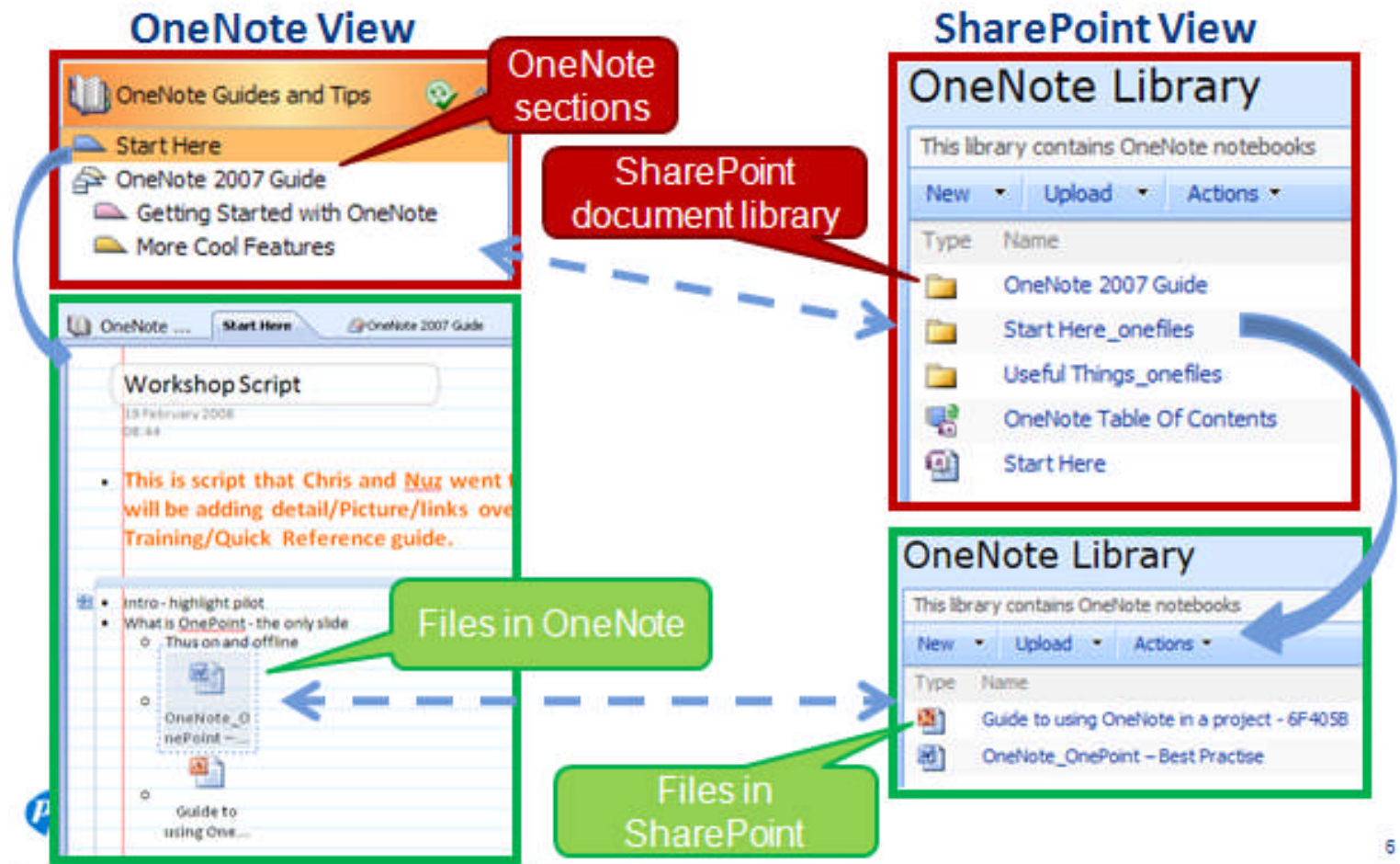
Kinematic ELN



# Evolution of Collaborative R&D

2009  
Pfizer  
"OnePoint"  
Lab  
Notebook

OBA  
SharePoint  
OneNote  
2007





# Evolution of Collaborative R&D

2010

Microsoft  
Biology Tools

SharePoint  
Chem4Word  
ExcelBio

Available  
On  
CodePlex

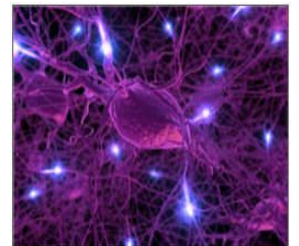
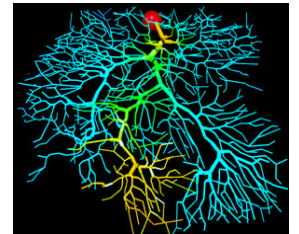
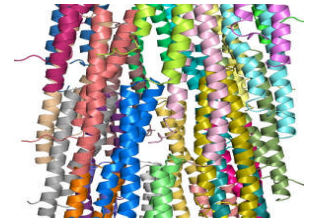
Open  
Source

Tool	Description
Computational Biology Tools	Suite of open source tools produced by MSR.
ExcelBio	Excel Add-in providing the power of the MBF framework inside Excel.
Genome Browser	WPF and Silverlight supported visualization of genomic data.
SilverMap/SilverGene	Silverlight and WPF based visualization of gene associations.
BioHPC	Compute cluster, distributed computation of biological programs offered as web services.
RNA Comparative Analysis Toolkit	Toolkit for the analysis and visualization of biological sequences and structure, interfacing with a novel database system (rCAD).
Trident Workflow Workbench (plus World Add-in)	MBF bioinformatics workflow activities and sample workflows.
GenePattern	Web service for running queries against gene databases. Word add-in supports embedding pipelines in a document and re-running them on the GenePattern server from Word.
Chem4Word	Word add-in to support the authoring and rendering of semantically-rich chemistry information.
Ontology Add-in for Word	Word add-in that enables the annotation of Word documents based on terms that appear in Biological Ontologies (NCBO).
Research Information Centre	Research collaboration framework, initial biomedical public portal offered by British Library.
Article Authoring Add-in For Word	Structured article authoring in accordance with the NLM schema.

# Evolution of Collaborative R&D

## Bioinformatics Research on Windows Azure

- Protein Folding
  - The University of Washington is studying the ways proteins from salmonella virus inject DNA into cells. Used 2000 concurrent cores.
- Joint Genetic and Neuroimaging Analysis
  - France's premier research institute INRIA is using 1000 cores of Azure to study large cohorts of subjects to understand links between genetic patterns and brain anomalies.
- Comparative Genomics
  - Researchers at the University of North Carolina Charlotte are doing large scale operon prediction using Windows HPC Scheduler on Azure using 300 cores to do BLAST analysis. Used 1,000,000 hours.
- Drug Discovery
  - Researchers at Newcastle University in the U.K. are using Azure to model the properties (toxicity, solubility, biological activity) of molecules for potential use as drugs.
- Systems Biology
  - The University of Trento Centre for Computational and Systems Biology have developed an Azure based tool, BetaSIM for modeling and simulating biological systems.



# Evolution of Collaborative R&D

## Data Sources

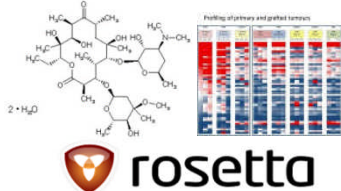
### Instruments

- GCMS
- Sequencers

### LIMS

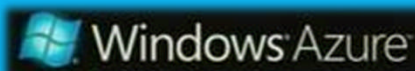
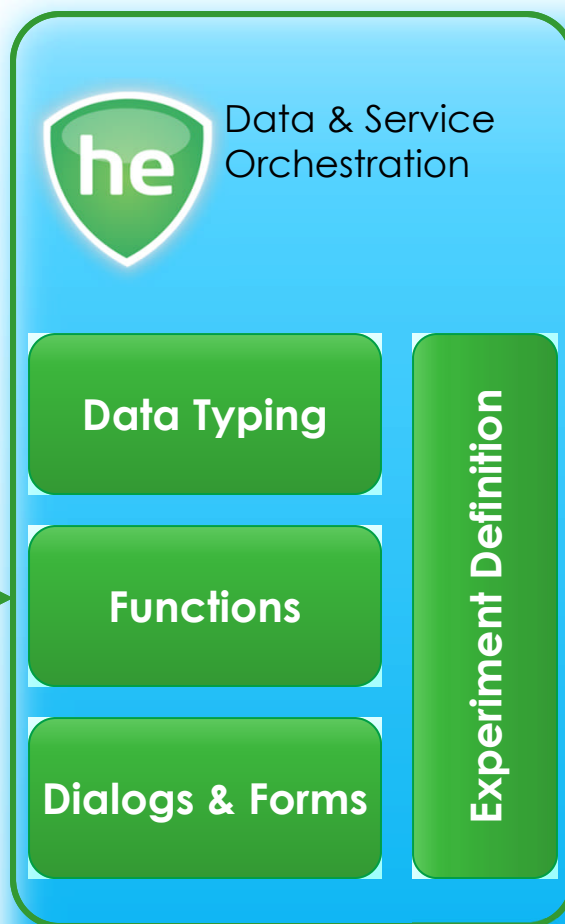
- Nautilus LIMS
- Watson LIMS
- Oracle
-  labtrack

### Analysis



### Public

- NCBI
- BioBank



Ceiba Solutions - Helium

# Evolution of Collaborative R&D

**ChemBlog**

Home Chem2SP Demo **ChemBlog** Document Center News Reports Search Sites

View All Site Content

**Categories**

- Category 1
- Category 2
- Category 3
- Add new category

**Other Blogs**

There are no items in this list.

Add new link

**Links**

- Photos
- Archive
- Archive (Calendar)
- Add new link

**RSS Feed**

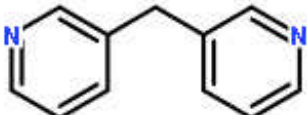
Home > ChemBlog

3/3/2011

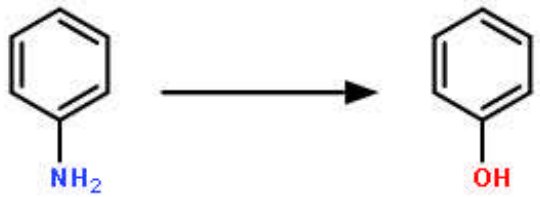
## Blog for Chemists

With the OLN.Chem4SharePoint add-on, your SharePoint Blog is much more fun. I'm working compound SG-999322-02

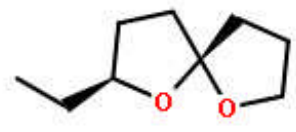
Here is a molecule:



And a reaction:



**SG-999322-02**



Scilligence – Blog for Chemists

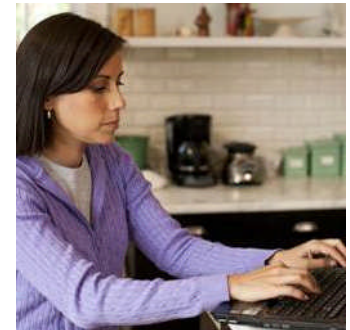
# Can a pharma engage directly with patients?

Ethical Barriers

Legal Barriers

Regulatory Barriers

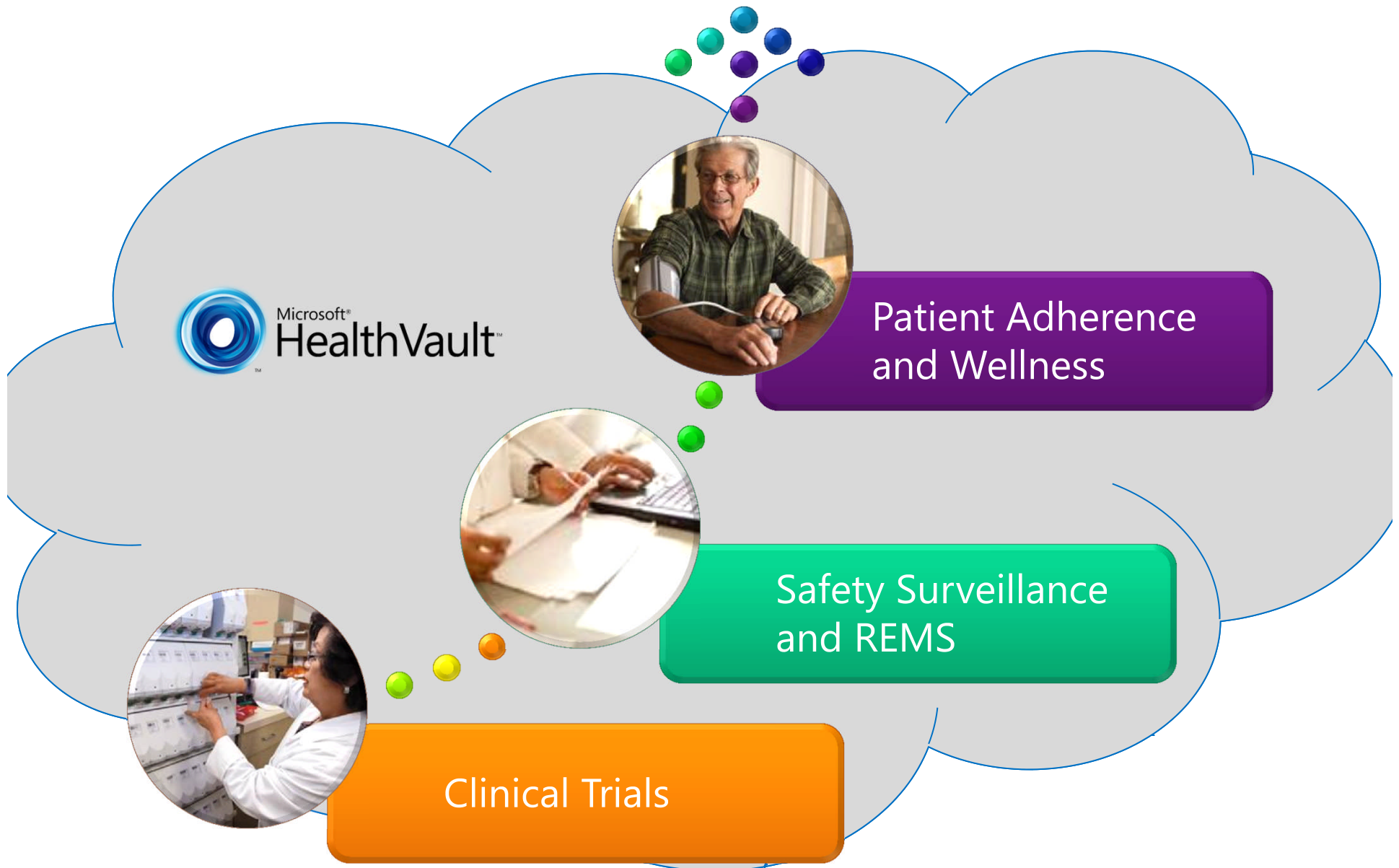
Trust Barriers



Not only can pharma engage with patients,  
Pharma companies should engage with patients

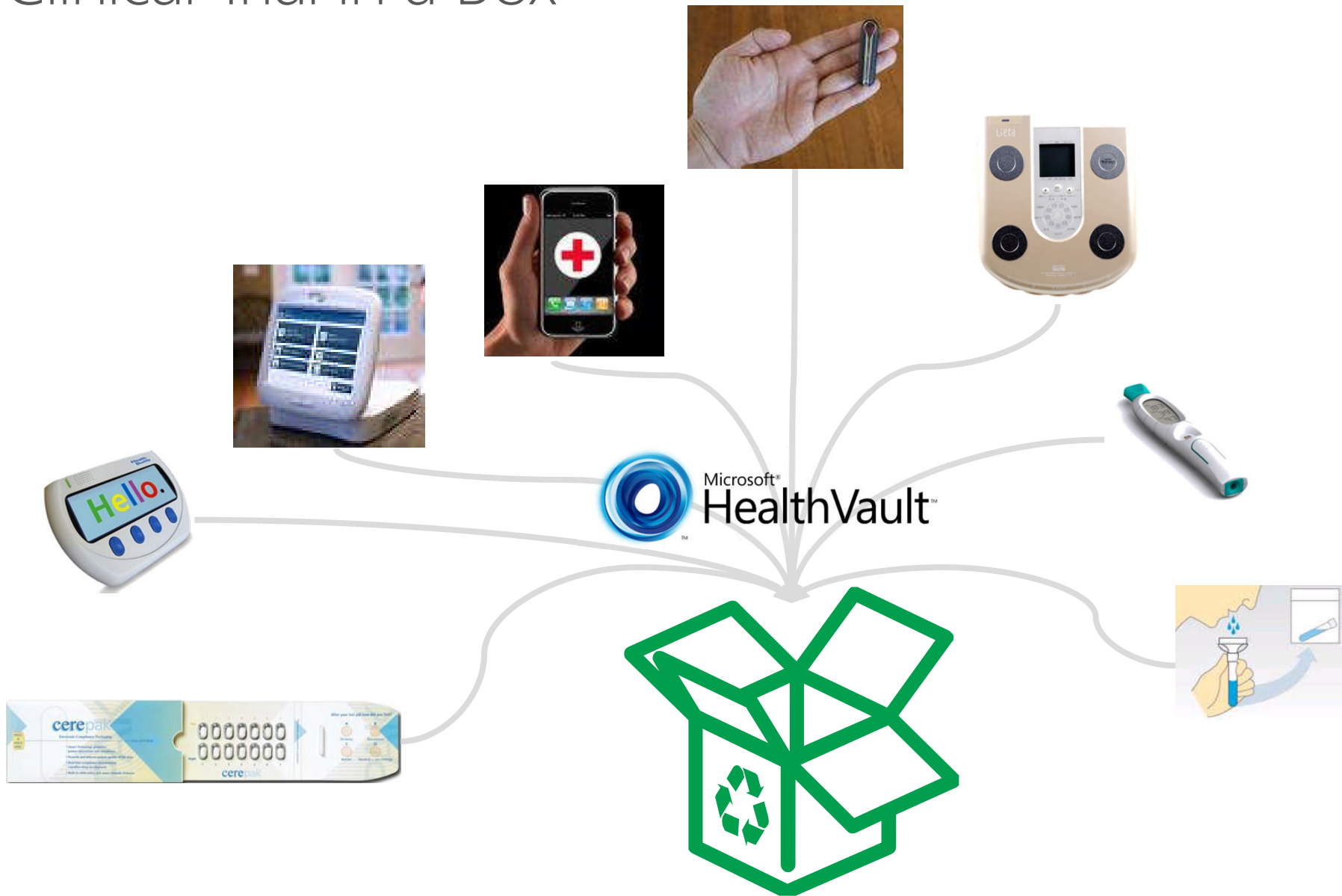


# Levels of Patient Engagement



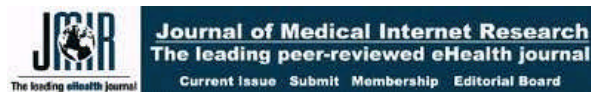


# Evolution of Collaborative R&D Clinical Trial in a Box



# Evolution of Collaborative R&D

## Patients sharing Data for Research



J Med Internet Res. 2010 Apr-Jun; 12(2): e14.  
Published online 2010 May 25. doi: [10.2196/jmir.1356](https://doi.org/10.2196/jmir.1356).

PMCID: PMC2956225

Copyright ©Elissa R Weitzman, Liljana Kaci, Kenneth D Mandl. Originally published in the Journal of Medical Internet Research (<http://www.jmir.org>), 25.05.2010

### Sharing Medical Data for Health Research: The Early Personal Health Record Experience

Reviewed by Jason Bonander

Elissa R Weitzman, ScD MSc,<sup>1,2,3</sup> Liljana Kaci, MSW,<sup>1,4</sup> and Kenneth D Mandl, MD MPH<sup>1,3,4,5</sup>

<sup>1</sup>Manton Center for Orphan Disease, Children's Hospital Boston, Boston, United States

<sup>2</sup>Division of Emergency Medicine, Children's Hospital Boston, Boston, United States

<sup>3</sup>Children's Hospital Informatics Program at the Harvard-MIT Division of Health Sciences and Technology, Children's

### Results

Of PHCR users, 138 out of 151 (91%) were willing to share medical information for health research with 89 (59%) favoring an opt-in sharing model. Willingness to share was conditioned by anonymity, research use, engagement with a trusted intermediary, transparency around PCHR access and use, and payment. Consumer-



# Evolution of Collaborative R&D

## Enable Clinical Trial Participants to “Go Social”

**Left Page: Fingolimod Blog Post**

**Fingolimo**  
A hypochondriac joins a...  
Starting a weight loss plan and feeling better  
May 24

**Middle Page: ThisIsMS**  
an unbiased multiple sclerosis community  
Home | Your Account | Modules  
• Home  
• Content  
• Downloads  
• Encyclopedia  
• FAQ  
• Feedback  
• Forums  
• Journal  
• Private Messages  
• Recommend Us  
• Search  
• Site Map  
• Stories Archive  
• Submit News  
• Surveys  
• Top 10  
• Topics  
• Web Links  
• Your Account

**Right Page: patientslikeme**  
Join Now! (It's free)  
Existing users, please Login  
Patients | Treatments | Symptoms | Research  
Search this site Search FAQ  
Filter by: All Please type at least 3 letters to choose a condition patients  
Home > Evaluations from Patients who take Fingolimod clinical trial  
**Evaluations from Patients who take Fingolimod clinical trial**  
Category: Others  
Most Popular Types: FTY720, TRANSFORMS CFTY720D2302, CFTY720D2309 (Show all)  
See also: Fingolimod  
Overview Individual Patient Evaluations  
6 patient evaluations for Fingolimod clinical trial  
Sort by: Helpfulness | Most Recent

Date	Dosage	Efficacy	Side Effects	Adherence	Burden
Aug 03, 2010	0.5 mg Daily	Moderate	None	Always	Not at all

**Forum Post:**  
Purpose: Participate in clinical trial (Started Oct 29, 2007)  
I LOVE not having to do injections anymore. I am in my 2nd year and was told at my last visit that my visits will continue until drug approval or if I should have a major reaction that has been reported, such as macular degeneration. So far, this has been wonderful!  
Cost: monthly  
1 helpful mark

**Another Post:**  
Purpose: MS (Multiple Sclerosis) (Started Nov 18, 2008)  
Date: Sep 01, 2009 Dosage: Daily Efficacy: ? Can't tell Side Effects: 0 helpful marks

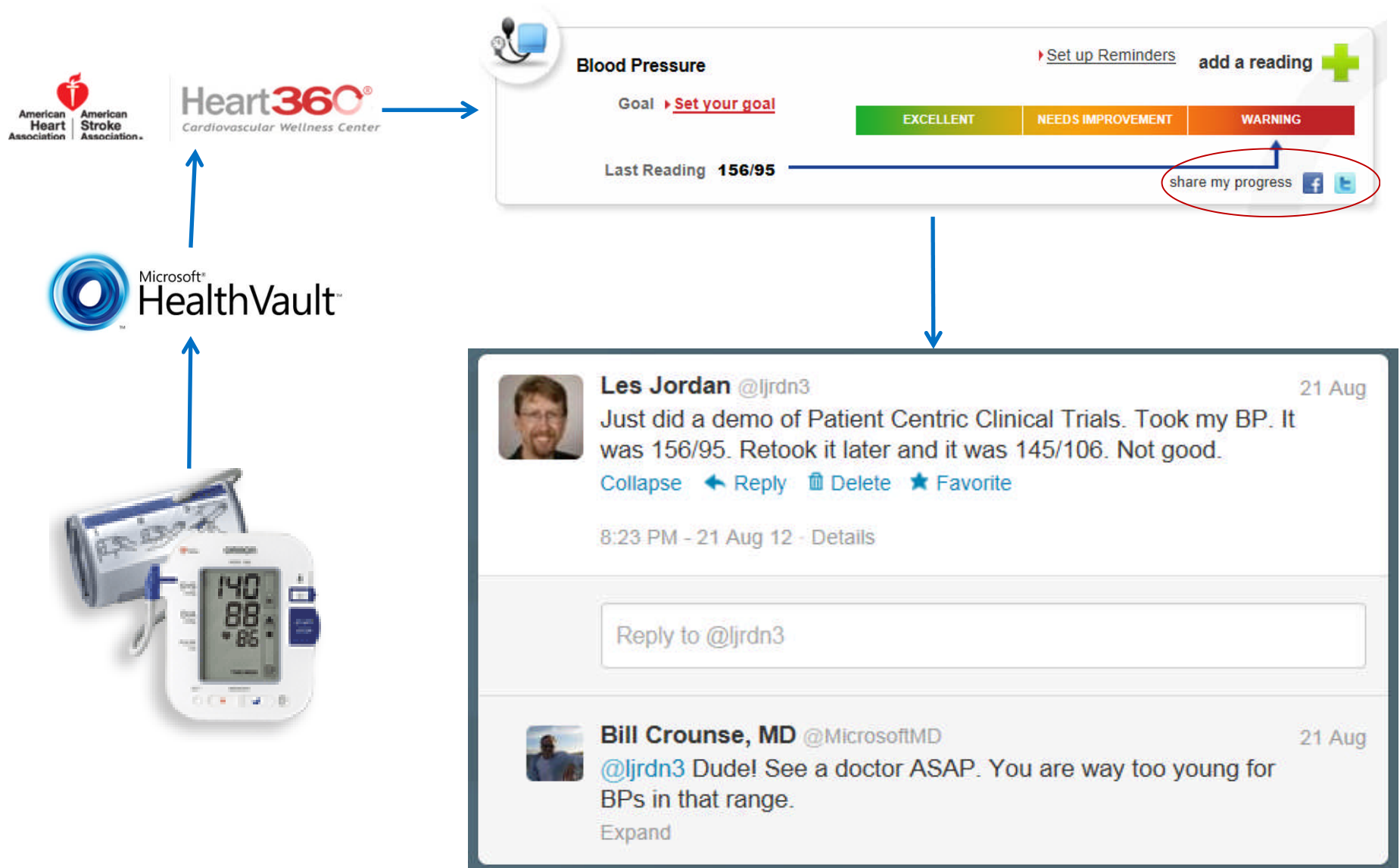
**Another Post:**  
Purpose: Other (Started Apr 08, 2003)  
Date: Jun 01, 2009 Dosage: 1 mg Daily Efficacy: None Side Effects: 0 helpful marks

**Another Post:**  
Purpose: MS (Multiple Sclerosis) (Started Jan 11, 2008)  
Date: Jan 10, 2009 Dosage: 1 Daily Efficacy: Slight Side Effects: 0 helpful marks

**Forum Post:**  
Author: flipflop Family Elder  
Joined: Nov 10, 2005 Posts: 176  
I'm trying to decide if I will participate in the phase III clinical trial of FTY720. I need to decide now, even if the clinical trial should only begin in March. That's because there must be a 3 month wash-out period (no interferon or glatiramer acetate) before the screening visit for the Phase 3 FTY720 study. I've been on Copaxone for 4.5 years but I had 2 relapses this year. Like most people here, I would love to be on a more

**Thought Bubble:**  
How do we interpret CT signals?  
Eligibility Criteria  
Blinding  
Safety Reporting

# Do Patients Really Socially Share?

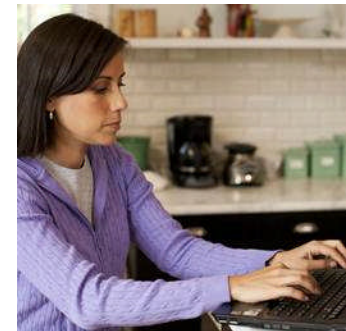


# PPD Launches Innovative Technology Portal to Improve Patient Retention in Clinical Trials

The PPD PatientView portal leverages Microsoft HealthVault. The innovative online portal links clinical trial participants with biopharmaceutical companies, physicians, and healthcare resources to enhance patient connectivity and improve retention in clinical trials.



Patient access  
to data



**PPD**<sup>®</sup>



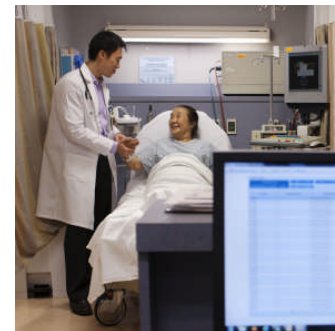
Patient loss  
during study

“Regulatory agencies are requiring longer, more complex clinical studies, increasing the likelihood of patients leaving a clinical study before it's completed. The loss of patients during a trial can lead to increased costs and delay the trial's completion.”

— Mike Wilkinson, Executive Vice President and CIO, [PPD](#)



# Microsoft Cloud Services & GxP Compliance





# Cloud Compliance



- **SAS70 Type II**
- **ISO 27001**
- **Safe Harbor**
- **HIPAA w/ BAA available**
- **FISMA**



- **ISO 27001**
- **Safe Harbor**
- **SAS70 Type II**
- **HIPAA w/ BAA expected in April 2011**
- **FISMA**



- **ISO 27001 (done for Windows Azure)**
  - **Safe Harbor Q3 FY12 (for Windows Azure)**
  - **HIPAA w/ BAA Q4 FY12 (for Windows Azure)**
  - **FedRAMP (Successor to FISMA) – planning in progress**
- SQL Azure, CDN, Active Directory ACS, Caching and Service Bus on roadmap for FY13**

**Global Foundation  
Services  
(Microsoft Data  
Centers)**

**SAS70 Type II  
ISO 27001  
Safe Harbor  
FISMA (by product)  
HIPAA (by product)**

# Qualified Environments

How Microsoft may enable FDA/GxP environments

- Compliance across multiple standards
- Microsoft provides proof of qualification
- As per regulations, the implementing company (customer) is responsible for validation of the app
- Given each customer's QA department has a different view of regulations, Microsoft will consider change requests for individual pieces of documentation to satisfy QA department needs
- This approach has been taken by a Windows Azure customer, who successfully completed a validation & qualification review with a former FDA auditor.

SAS 70 Type II  
SAFE Harbor  
ISO 27001  
HIPAA BAA  
FISMA

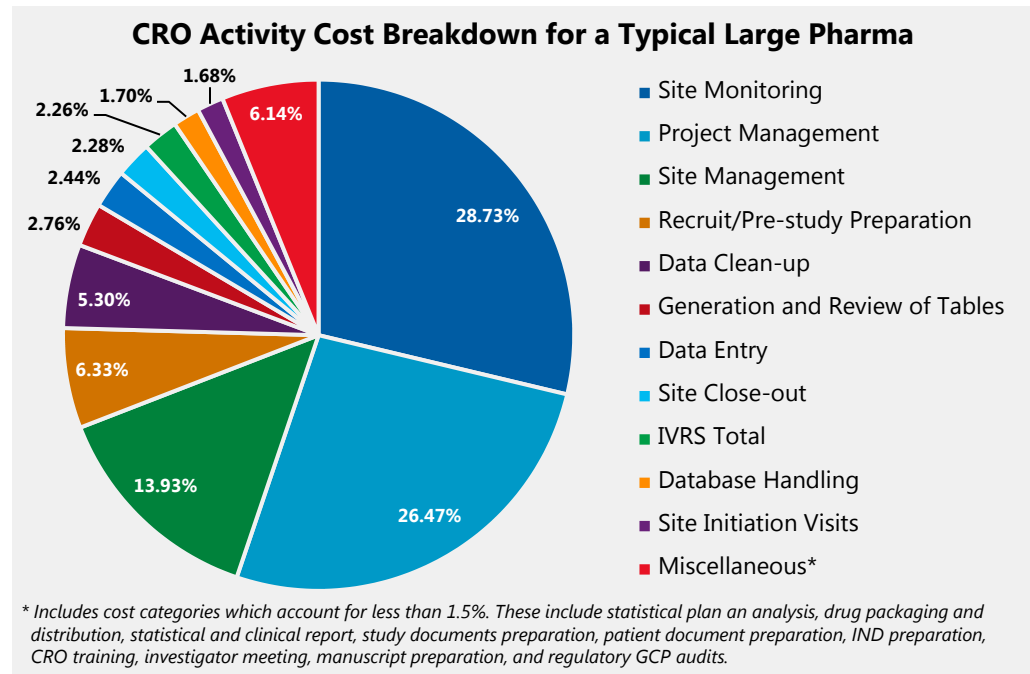
A portrait of a man with a shaved head and a light beard, wearing a white lab coat over a light blue collared shirt. He is looking slightly to the left of the camera with a neutral expression. The background is a plain, light green wall. In the lower-left corner, there is a solid blue square containing the text 'Q&A' in white.

Q&A

# Patient engagement in clinical trials

The increasing need for Life Science companies to engage with patients

- Patient and investigator recruitment failures
- Majority of work at sites is non-value-add
- EMR/EHR has not been heavily leveraged in trials
- Inefficient processes based on antiquated technology
- Lack of a true clinical information repository including operational and clinical data



Source: Medidata CRO Contractor Fact Sheet, Aug. 2010

# Patient Engagement:

## The cost of non-adherence

### Non-adherence results

- 5.4 times increased hospitalization and death for patients with high blood pressure
- 2.5 times increased risk of hospitalization for diabetes patients
- As many as 40% of nursing home admissions
- US\$2,000/year in physician visit costs
- US\$100 to US\$300 billion per year (overall)

2.5x

Increased risk of  
hospitalization with  
diabetes

40%

Of nursing home  
admissions

US\$2K

Annually in physician  
visit costs



# Patient Engagement: The cost of non-compliance

The cost of non-compliance for the average pharmaceutical brand is 38% of its sales, and US\$65 billion in lost revenue for the industry, with an additional US\$8 billion annual revenue loss for pharmacies in unfilled prescriptions.

Average cost of  
non-compliance:

**38%**

of sales

Lost revenue  
for the industry:

**US\$65B**

Prescriptions  
never filled:

**US\$8B**

annually

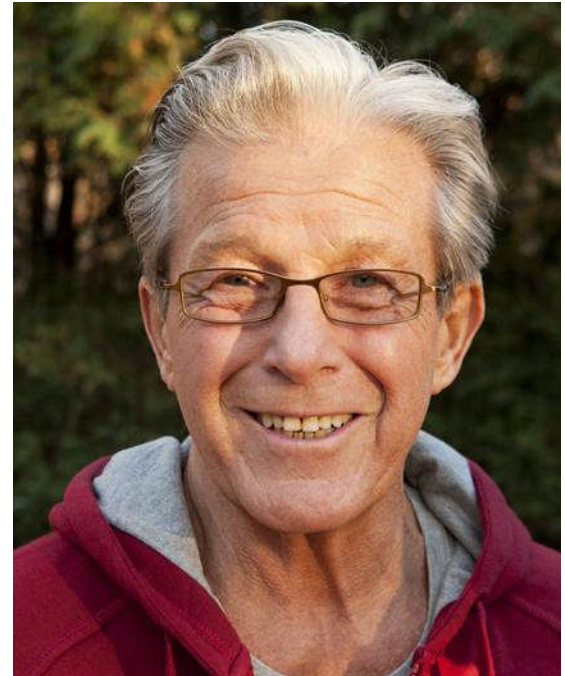




# Patient Engagement: Post-Marketing

The increasing need for Life Science companies to engage with patients

- Evolving Life Science companies from FIPNET to FIPCO
- Pharma partnerships with Providers and Payors
- Apps and sites based on adherence and information
- “Own” a Therapeutic area
- Address Provider concerns
  - Reduce readmissions
  - Uncompensated care
  - Leverage primary care physicians

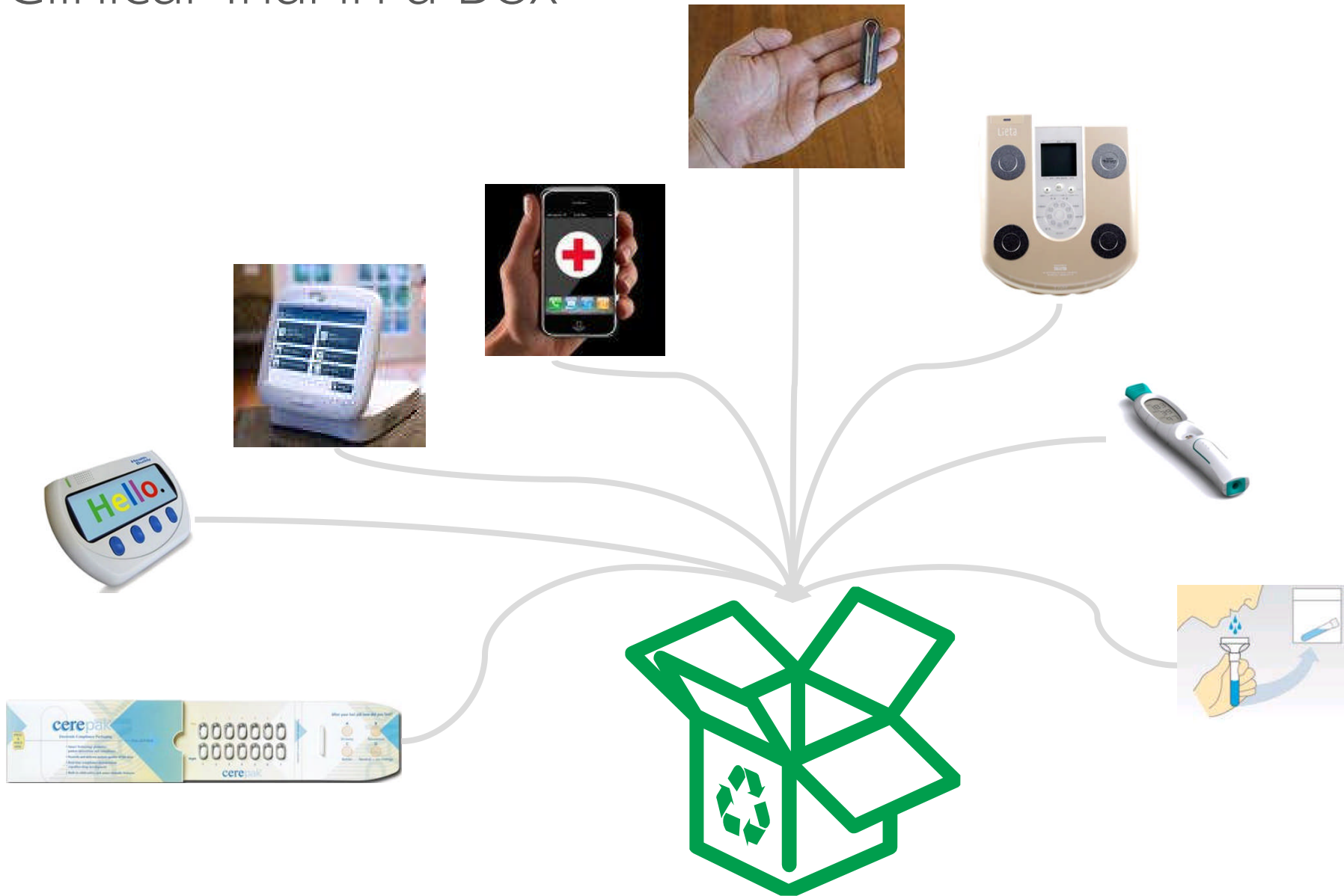


# What if: Clinical trials used common medical devices



- Glucometers
- Pulse Oximeters
- Blood Pressure
- Peak Flow Meters
- Weight Scales
- Home Hemodialysis
- Pacemakers
- Etc.

# Enhanced ePRO – Common devices create Clinical Trial in a Box



# Clinical Trial in a Box Extended: Outsource lab work

The screenshot shows the Quest Diagnostics website. At the top, there are navigation links: "Make appointment", "Confirm/change/cancel appt", "Find location", and "Get my results". Below these are links for "Home", "About Us", "Site Directory", "Privacy Policy", and a "Search" button. A secondary navigation bar includes "destination:HEALTH", "Patient Health Library", "Locations", "Email Reminders", "Contact Us", and "Pay Your Invoice".

The main content area is titled "Become a VIP (Very Informed Patient)" and "Get Your Lab Results Online From Your Participating Physician". It features a diagram showing a doctor icon at the top, with arrows pointing down to three boxes labeled "Google health", "keas", and "HealthVault".

By following these steps:

1. Create a Quest Diagnostics account
2. Connect to your participating physician
3. Connect to the Personal Health Record (PHR) of your choice

A "Get Started Now" button is located below the steps.

Being a Very Informed Patient (VIP) means anytime access to your **online medical records**, so you can be more informed when speaking to your doctor about your health.

On the left side of the page, there is a sidebar with links under "Patients & Consumers": "Having a lab test?", "FAQ - Lab", "Make an Appointment", "Confirm / Change / Cancel Appointment", and "Find a Location". Below this are links for "Get Your Results" and "Patient Results". Under "Health Information", there are links for "destination:HEALTH", "Patient Health Library", "Health Reminder", "Emails", and "Health & Wellness".

Users (with physician participation) can **easily import** test results into their HealthVault account.

They can order commonly used diagnostic tests online, and **share test results** with additional providers.

Those with chronic conditions can more **closely track** their health status.

"Diagnostic testing is the foundation of a patient's health and informs approximately 70 percent of health care decisions physicians make on behalf of their patients."

-Jon R. Cohen, senior vice president and chief medical officer, Quest Diagnostics

# Enable Clinical Trial Participants to "Go Social"



**Fingolimod**  
A hypochondriac joins a  
Starting a weight loss plan and feeling better  
May 24

**ThisIsMS**  
an unbiased multiple sclerosis community

**patientslikeme**  
Join Now! (It's free)  
Existing users, please Login

**Evaluations from Patients who take Fingolimod clinical trial**  
Category: Others  
Most Popular Types: FTY720, TRANSFORMS CFTY720D2302, CFTY720D2309 (Show all)  
See also: Fingolimod

Date	Dosage	Efficacy	Side Effects	Adherence	Burden
Aug 03, 2010	0.5 mg Daily	Moderate	None	Always	Not at all

**Purpose:** Participate in clinical trial (Started Oct 29, 2007)

**Purpose:** MS (Multiple Sclerosis) (Started Nov 18, 2008)

Date	Dosage	Efficacy	Side Effects
Sep 01, 2009	Daily	Can't tell	

**Purpose:** Other (Started Apr 08, 2003)

Date	Dosage	Efficacy	Side Effects
Jun 01, 2009	1 mg Daily	None	

**Purpose:** MS (Multiple Sclerosis) (Started Jan 11, 2008)

Date	Dosage	Efficacy	Side Effects
Jan 10, 2009	1 Daily	Slight	

**How do we interpret CT signals?**  
**Eligibility Criteria**  
**Blinding**  
**Safety Reporting**

**flippopper**  
Family Elder  
Joined: Nov 10, 2005  
Posts: 176

I'm trying to decide if I will participate in the phase III clinical trial of FTY720. I need to decide now, even if the clinical trial should only begin in March. That's because there must be a 3 month wash-out period (no interferon or glatiramer acetate) before the screening visit for the Phase 3 FTY720 study. I've been on Copaxone for 4.5 years but I had 2 relapses this year. Like most people here, I would love to be on a more

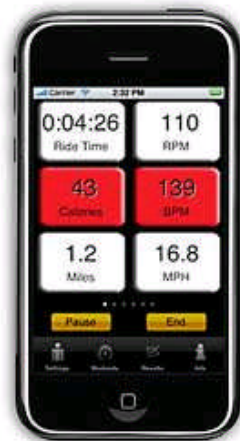


# Utilize common consumer devices

*"Enhanced ePRO"*



*Nike+ users have logged enough miles for 17,680 laps around the world*



*11,775 health & fitness apps for iPhone / iPad*

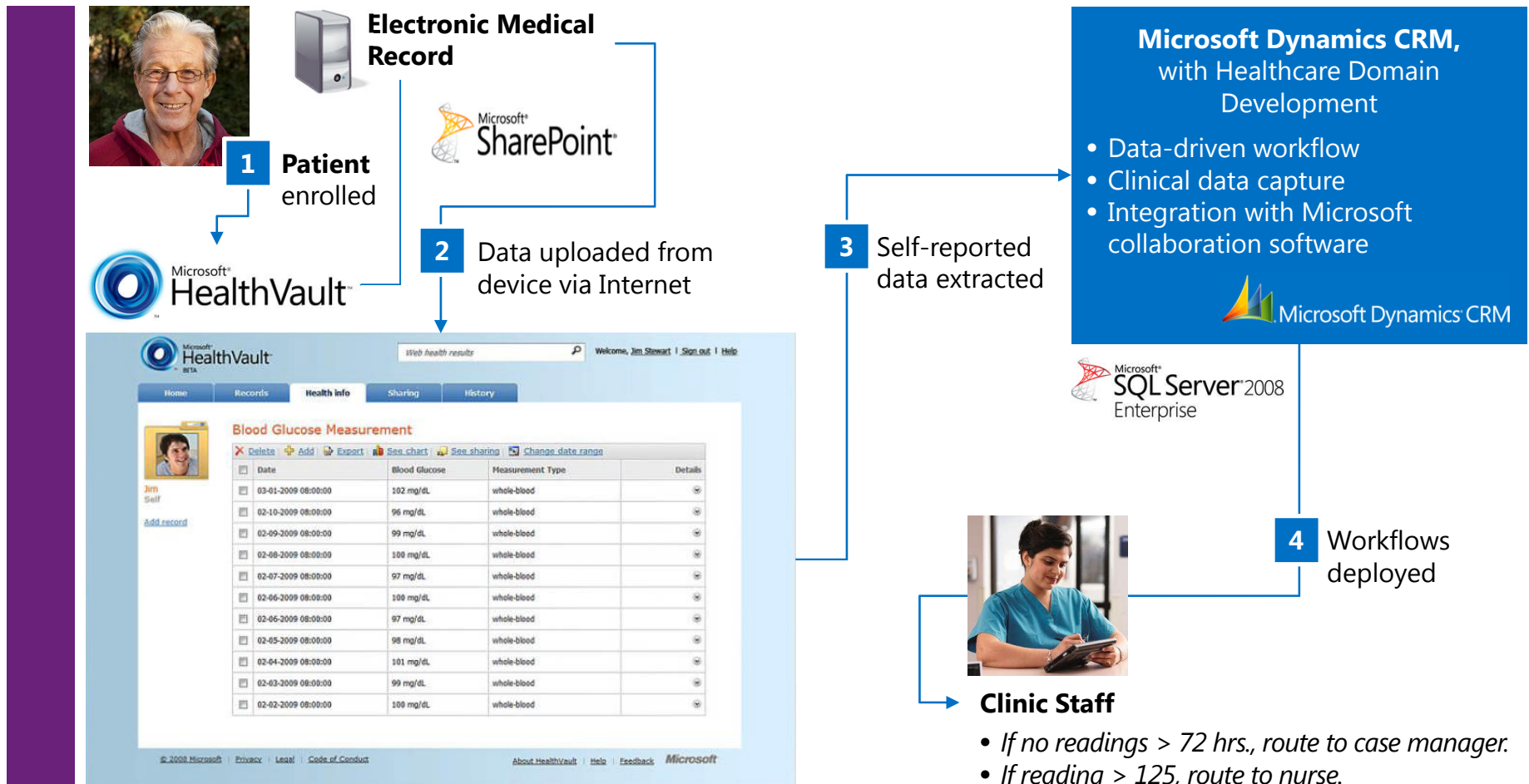


*Fitbit: Steps walked, altimeter, quality of sleep...  
...and tamagotchi*



# Patient engagement example

*Cloud based, device independent monitoring for adherence and clinical trials*

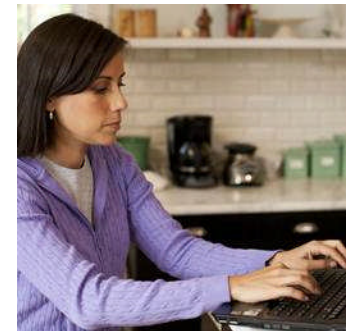


# PPD Launches Innovative Technology Portal to Improve Patient Retention in Clinical Trials

The PPD PatientView portal leverages Microsoft HealthVault. The innovative online portal links clinical trial participants with biopharmaceutical companies, physicians, and healthcare resources to enhance patient connectivity and improve retention in clinical trials.



Patient access  
to data



**PPD**<sup>®</sup>

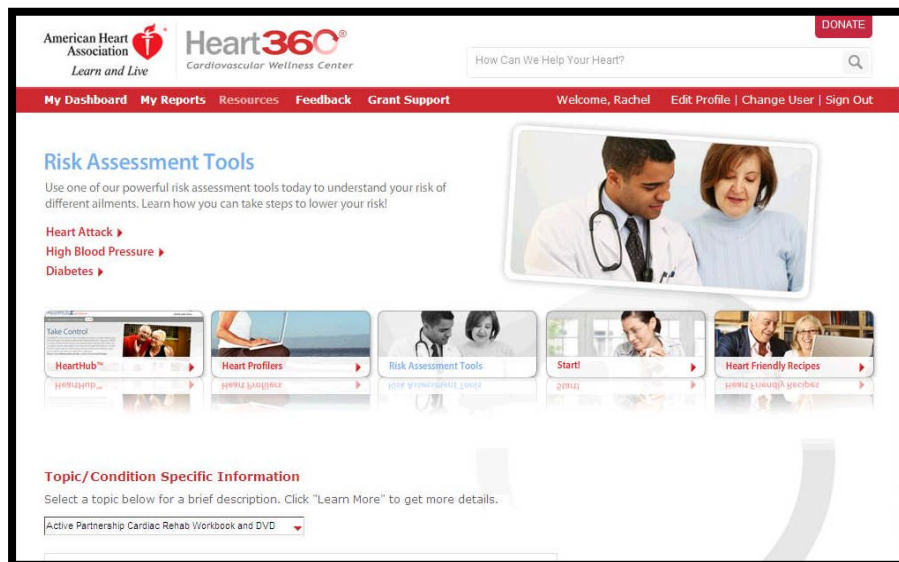


Patient loss  
during study

“Regulatory agencies are requiring longer, more complex clinical studies, increasing the likelihood of patients leaving a clinical study before it's completed. The loss of patients during a trial can lead to increased costs and delay the trial's completion.”

— Mike Wilkinson, Executive Vice President and CIO, [PPD](#)

# Chronic Condition Management Patient Engagement by American Heart Association



This online wellness center helps people **track and manage** risk factors for heart attack, heart disease and stroke.

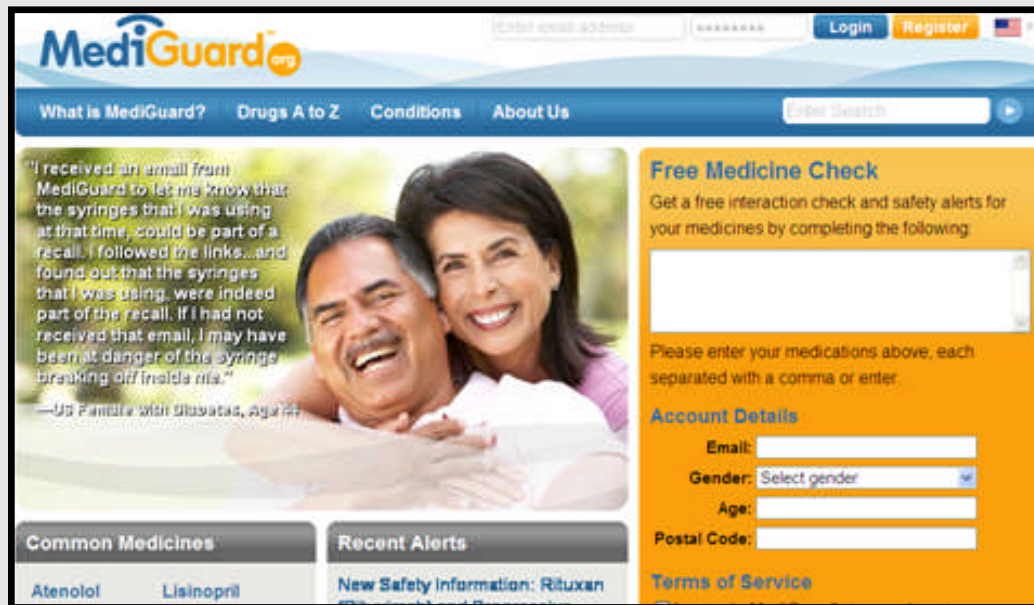
Tracks blood pressure, cholesterol, blood glucose, weight, physical activity and medications.

Can receive information **from HealthVault-enabled devices** and applications, and share that data with the caregiver.

"The ability to monitor weight, blood pressure and activity levels of heart failure patients on a regular basis ensures more timely doctor visits and avoidance of more expensive interventions."

- Randall C. Starling, MD, Cleveland Clinic

# Medication Management Patient Engagement by MediGuard



The screenshot shows the MediGuard.org website. At the top is the MediGuard.org logo and a search bar. Below the logo is a navigation menu with links: "What is MediGuard?", "Drugs A to Z", "Conditions", and "About Us". A search bar is also present in the navigation area. The main content area features a large image of a smiling couple. To the left of the image is a testimonial from a 44-year-old female with diabetes. To the right is a "Free Medicine Check" section with a text input field for medications and a "Check" button. Below this is an "Account Details" section with fields for Email, Gender (a dropdown menu), Age, and Postal Code. At the bottom, there are sections for "Common Medicines" (listing Atenolol and Lisinopril) and "Recent Alerts" (listing New Safety Information: Rituxan). A "Terms of Service" link is also visible.

MediGuard.org

What is MediGuard? Drugs A to Z Conditions About Us

"I received an email from MediGuard to let me know that the syringes that I was using at that time, could be part of a recall. I followed the links...and found out that the syringes that I was using, were indeed part of the recall. If I had not received that email, I may have been at danger of the syringe breaking off inside me."  
—Us Female with Diabetes, Age 44

**Free Medicine Check**  
Get a free interaction check and safety alerts for your medicines by completing the following:

Please enter your medications above, each separated with a comma or enter

**Account Details**  
Email:   
Gender:   
Age:   
Postal Code:

**Common Medicines**  
Atenolol Lisinopril

**Recent Alerts**  
New Safety Information: Rituxan

[Terms of Service](#)

Helps consumers **monitor the safety of their medications**, including side effects, duplicative treatment and drug interactions.

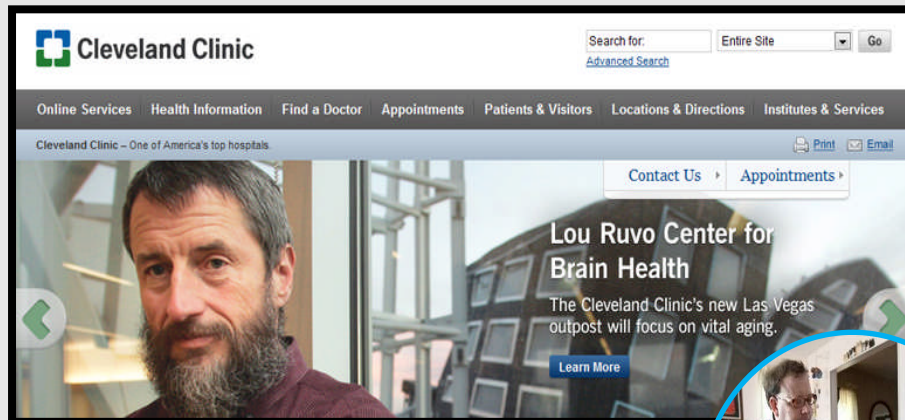
Provides patient and physician with updated safety alerts.

MediGuard.org's user community can share medication experiences.



# Clinical Case Study – Cleveland Clinic

Patients used digital blood-pressure readers to upload readings to their personal electronic medical record. The system notifies a Cleveland Clinic doctor if the readings hint of a medical issue.



After patient David Jesse started to record his blood pressure readings daily, his doctor noticed patterns and adjusted his medication. As a result, Jesse's blood pressure has stabilized.



## Results:

Cleveland Clinic has **180,000 patients using an electronic personal medical record** called MyChart, linked to HealthVault at the patient's direction.

Studies indicate that the continuous management of chronic disorders can **result in better outcomes for patients.**

"I'm thinking about how we will deliver care to patients in the 21st century. That will mean delivering that care in different venues—beyond the doctor's office and beyond the hospital bed."

- C. Martin Harris, M.D., Chief Information Officer, Cleveland Clinic

# Patient Engagement can benefit Life Sciences

## Reduce patient loss in clinical trials

- PPD, Cleveland Clinic, and others are using Patient Engagement technologies to reduce patient loss during clinical trials.

## Manage chronic conditions

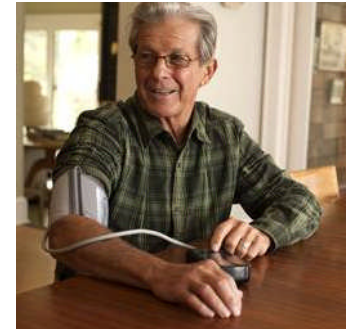
- Cleveland Clinic, New York Presbyterian Hospital, Kaiser Permanente, and others have run trials that show patient engagement portals improve patient outcomes.

## Manage Adherence

- Changing the fact that 50% of all prescriptions are not taken correctly, and US\$8 billion in prescriptions are never filled, indicates how much patient engagement could be worth to pharma.

50%

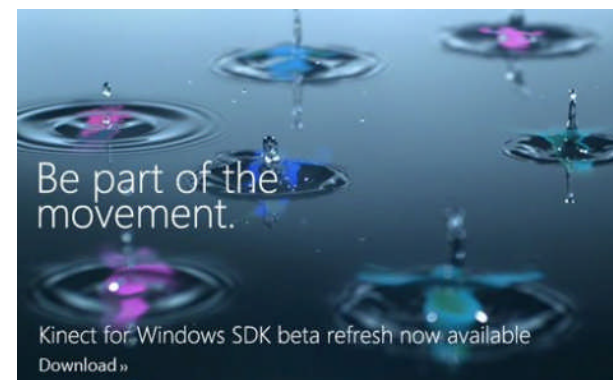
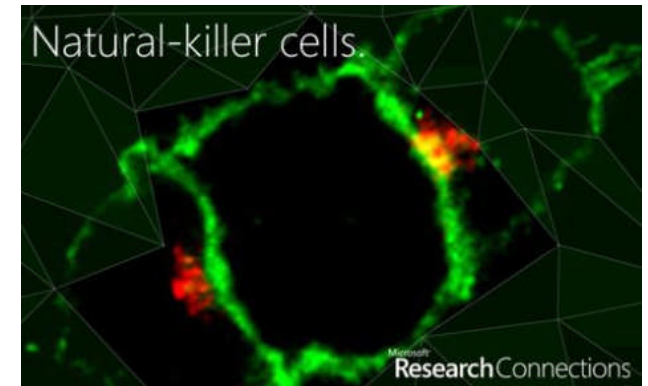
of all prescriptions are  
not taken correctly



US\$8B

annual revenue lost in  
unfilled prescriptions

# Microsoft Research Efforts



# Microsoft Life Sciences Resources

Customer and Partner Ready Collateral and Guidance

- Life Sciences Solutions & Partner Listings

[www.microsoft.com/lifesciences](http://www.microsoft.com/lifesciences)

- Whitepapers & Architectural Guidance

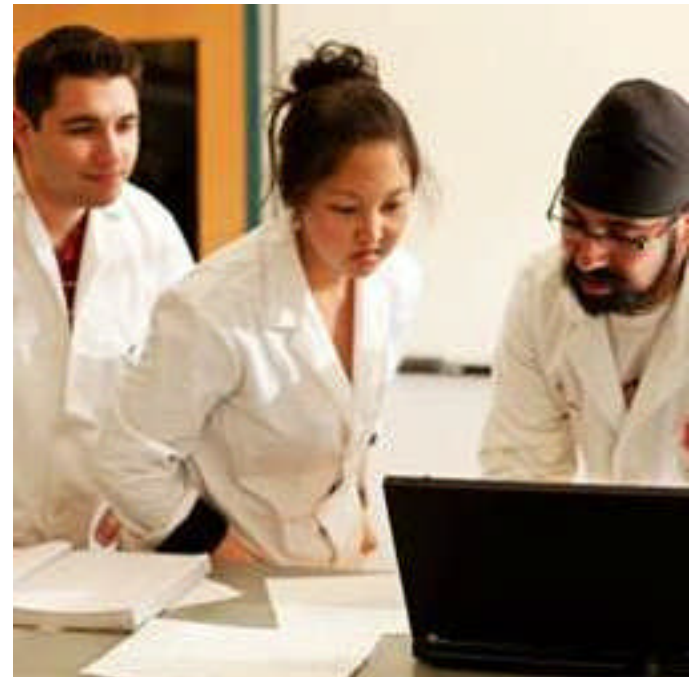
[msdn.microsoft.com/architecture/lifesciences](http://msdn.microsoft.com/architecture/lifesciences)

- Case Studies

[www.microsoft.com/casestudies](http://www.microsoft.com/casestudies)

- Examples

- SharePoint 2010 Configuration Guidance for Part 11 Compliance
- Using Visual Studio for 21 CFR Part 11 & Traceability Matrices
- Mapping Microsoft Development Practices to V-Model
- Compliance in the Cloud





A portrait of a man with a shaved head and a light beard, wearing a white lab coat over a light blue shirt. He is looking slightly to the left of the camera with a neutral expression. The background is a plain, light-colored wall. A blue square is overlaid on the left side of the image, containing the text 'Q&A' in white.

Q&A





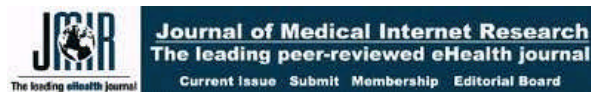
[www.microsoft.com/health](http://www.microsoft.com/health)

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# Patients sharing Data for Research



J Med Internet Res. 2010 Apr-Jun; 12(2): e14.  
Published online 2010 May 25. doi: [10.2196/jmir.1356](https://doi.org/10.2196/jmir.1356).

PMCID: PMC2956225

Copyright ©Elissa R Weitzman, Liljana Kaci, Kenneth D Mandl. Originally published in the Journal of Medical Internet Research (<http://www.jmir.org>), 25.05.2010

## Sharing Medical Data for Health Research: The Early Personal Health Record Experience

Reviewed by Jason Bonander

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### Results

Of PHCR users, 138 out of 151 (91%) were willing to share medical information for health research with 89 (59%) favoring an opt-in sharing model. Willingness to share was conditioned by anonymity, research use, engagement with a trusted intermediary, transparency around PCHR access and use, and payment. Consumer-



# Patients as *Participants*

## Subject

someone who is an object of investigation

## Participant

someone who takes part in an activity



## Share study learnings & results



## Share clinical data



Tuesday, June 7, 2011 As of 12:00 AM New York 86° | 73°

## THE WALL STREET JOURNAL. HEALTH

HEALTH INDUSTRY | JUNE 7, 2011

## A Clinical Drug Trial Via Phone, Computer

By JENNIFER CORBETT DOOREN

Pfizer Inc. is conducting a drug trial in which patients participate from their homes using computers and smartphones rather than visiting a clinic.

The company plans to compare the results to those obtained from a previous, traditional trial of the same drug. The study involves the company's overactive-bladder drug Detrol.

If successful, the methods used in the study might eventually be used to help drive down the high cost of bringing new medicines to market.

The Food and Drug Administration recently signed off on Pfizer's study, which is believed to be the first all-electronic, home-based study of a drug to receive agency approval.

### Take-Home Drug Test

Pfizer's Detrol study, dubbed Remote, uses Internet ads to recruit participants.

- The 16-week study compares Detrol to a placebo.
- Potential participants are directed to the study's website to enroll.

It is designed to replicate the results of a 600-patient study conducted in 2007 through traditional methods comparing Detrol to a placebo over a four-month period. Pfizer will announce the launch of the study at a National Library of Medicine clinical trials conference on Tuesday.

# The drive to Personalized Medicine



Massachusetts General Hospital Cancer Center Opens  
Molecular Pathology Lab To *Genetically Profile* All Patient  
Tumors



**Scripps Translational  
Science Institute**

Landmark Research Study Is Launched To Assess  
Impact Of Personal Genetic Testing

Dana-Farber Teams With Merck On Cancer Genomics



UCSF, Pfizer Sign Collaborative Research Deal



Moffitt Cancer Center Research Team Wins \$10 Million Grant



BCM Awarded Cancer Genome Atlas Grant

# Trials are increasingly complex

More complex clinical trial designs place demands on staff, discourage patient enrollment/retention

Measurement	1999	2005	% change	<div> <div></div> 1999           <div></div> 2005         </div>
Procedures per Trial Protocol (median) (e.g., bloodwork, routine exams, x-rays)	96	158	65%	<div> <div> </div> <div> </div> </div>
Clinical Trial Staff Work Burden (measured in work-effort units)	21	35	67%	<div> <div> </div> <div> </div> </div>
Length of Clinical Trial (days)	460	780	70%	<div> <div> </div> <div> </div> </div>
Clinical Trial-Participant Enrollment Rate (% of volunteers meeting trial criteria)	75%	59%	-21%	<div> <div> </div> <div> </div> </div>
Clinical Trial Participant Retention Rate (% of participants completing trial)	69%	48%	-30%	<div> <div> </div> <div> </div> </div>

Source: Tufts Center for the Study of Drug Development