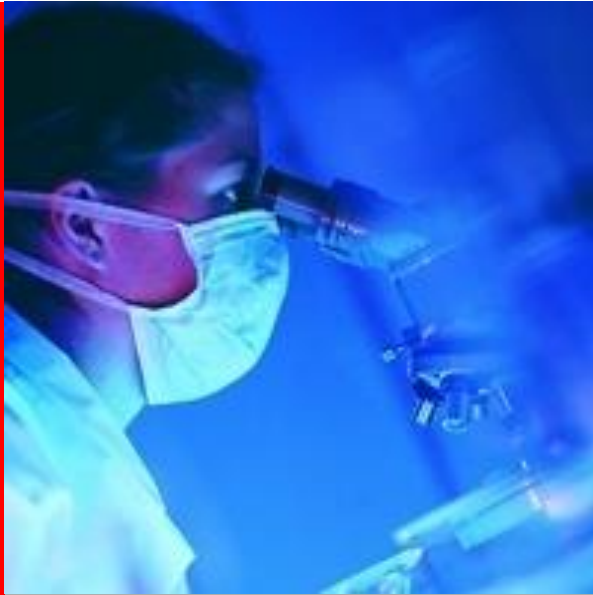


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Virtualization of R&D – How should IT and Service Vendors Respond?

Neil de Crescenzo, SVP and GM, Oracle Health Sciences
Presentation for The PRISME Forum Special Interest Group
October 17, 2011

Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions.

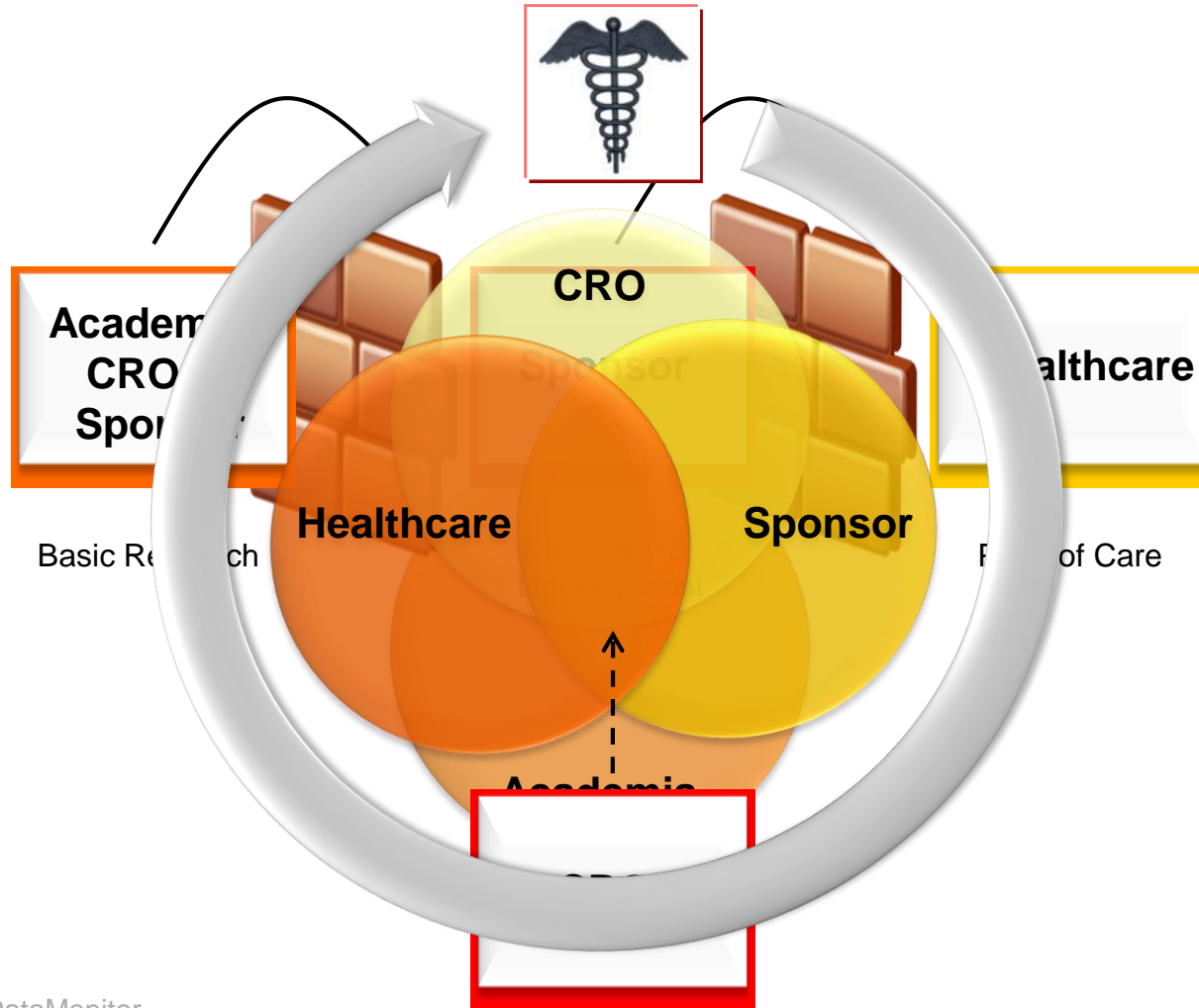
The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

Oracle co-wrote a thought leadership series on life sciences trends in 2009



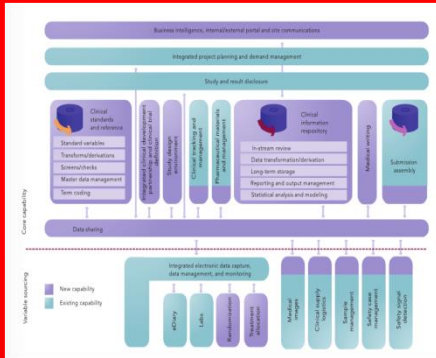
<http://www.touchbriefings.com/ebooks/A1p3ok/oracle-virtual/resources/>

Evolving to a networked model of clinical development and translational research/medicine



Source: adapted from DataMonitor

What should IT and service vendors do to facilitate virtualized R&D?



Build open platforms



Liberate data and insights with open connectivity



Build on today's IT paradigms



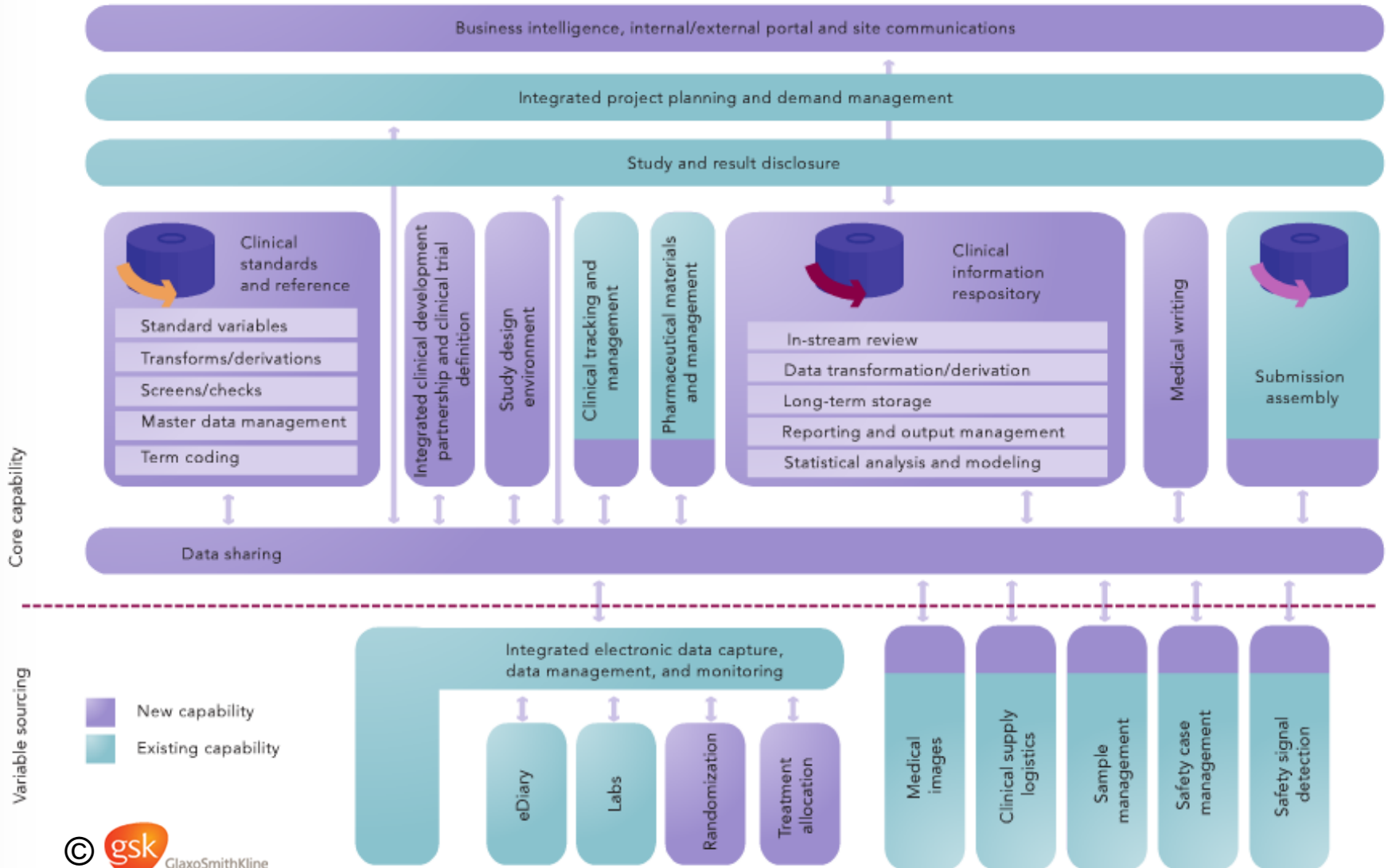
These action support the new health sciences paradigm

Integrating the healthcare and life sciences ecosystems



Building an open platform for Clinical Development

Simplified Clinical Development (SCD) at GSK

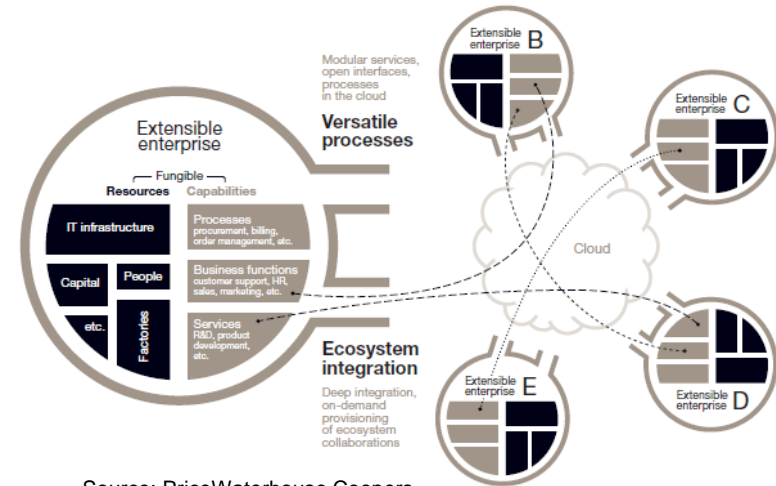
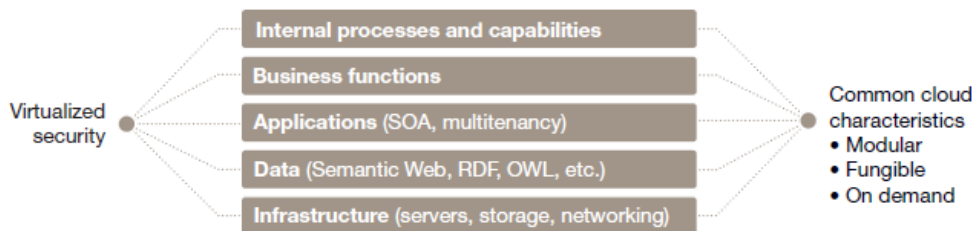
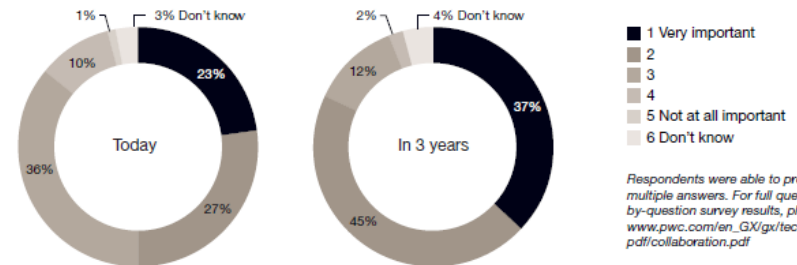


Cloud computing supports flexibility and cross-organizational collaboration



- Cloud computing spending to increase from \$41 billion in 2011 to \$241 billion in 2020 (*Forrester Research*)
- Growth now fueled by outsourcing business services as much as outsourced IT services
- **Moving from data exchange to integrated business processes and workflows**
- **Businesses within an ecosystem collaborate as if organizational boundaries did not exist**

How important is collaboration with nonrelated partners to your company's success today?
How important do you think it will be in three years' time?



“Cloud computing represents the dawn of the extensible enterprise.” *PriceWaterhouseCoopers*

Public clouds enable people, applications, and data to collaborate and develop insights



Provision Your Service. Set up a profile, get an Oracle SSO account, and configure service details.

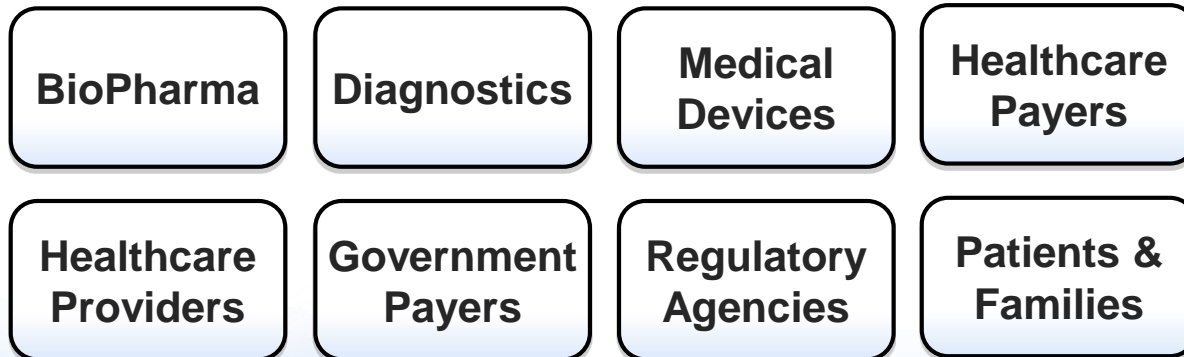
Get a Subscription. Predictable pricing, fixed monthly rates, no term obligation, and no hidden fees.

Add Users. Add administrators, developers, and end users.

Enrich with Content and Packaged Tools. Add third party content and packaged productivity apps.

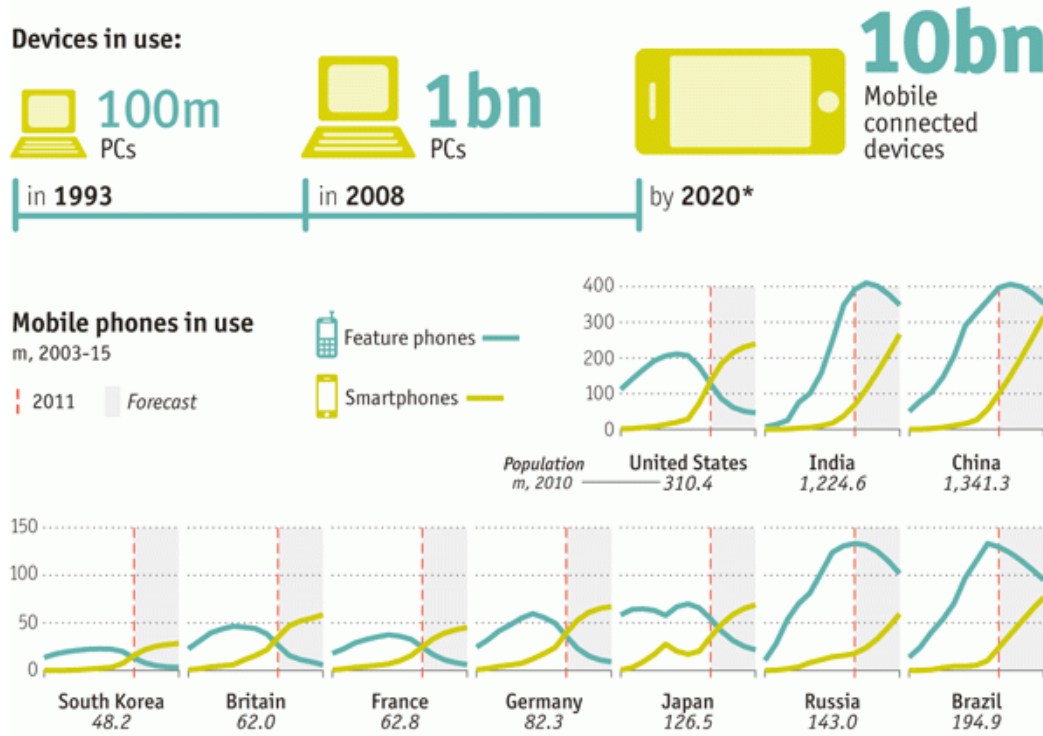
Operate. Scale, monitor, configure, upgrade, or diagnose. Use our tools or your own.

Flex-Deploy. Use a hybrid lifecycle. Your end users and code can deploy on premise or in our cloud.



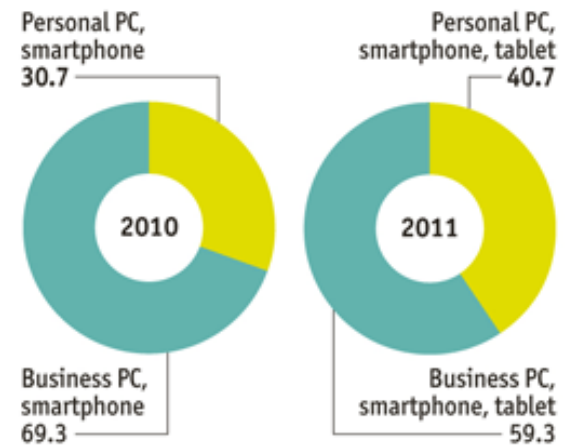
Open, standards based, flexible platforms that connect domain experts, data and applications in a regulatory-compliant framework

Mobile technologies and apps used “at home” are often replacing “company-approved” approaches



Bring your toys to the office

Devices used for access to business applications, %



Source: IDC survey, May 2010 and 2011

Sources: Cisco; Gartner; Informa Telecoms & Media; KPCB; Morgan Stanley; UN; Yankee Group; *The Economist*

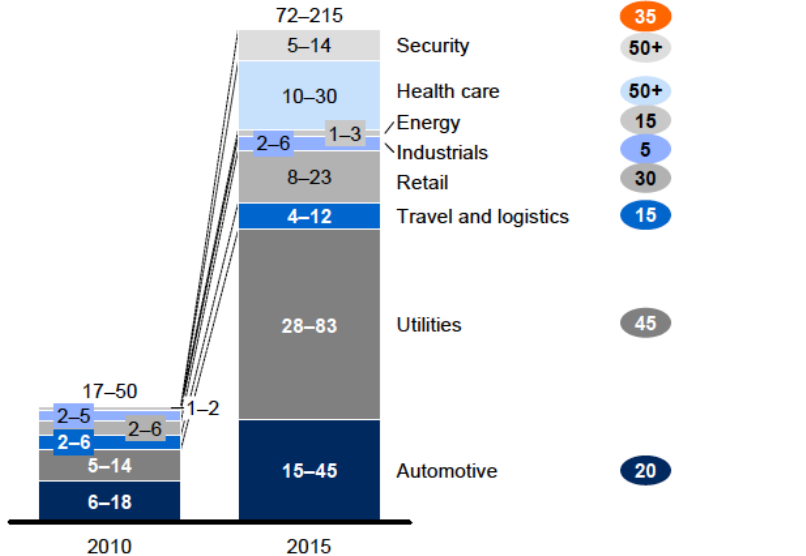
“...IT departments often greatly underestimate how much employees are using their own technology, including social networks and other web services, for work.” – *The Economist*, October 8, 2011

The “Internet of Things” is far more disruptive than just mobile communications (or the iPad)



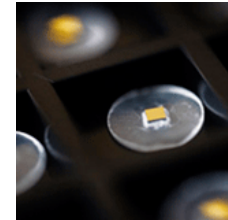
Data generated from the Internet of Things will grow exponentially as the number of connected nodes increases

Estimated number of connected nodes
Million



NOTE: Numbers may not sum due to rounding.

SOURCE: Analyst interviews; McKinsey Global Institute analysis



- GSMA estimates 24 billion connected devices in 2020
- Discovery and insights will increasingly be fuelled by “thing-generated” data

- Proteus ingestible event markers (IEMs) are tiny, digestible sensors made from food ingredients.
- The IEM creates an ultra-low-power, private, digital signal detected by a microelectronic recorder configured as a small bandage style skin-patch.
- The detector date- and time-stamps, decodes, and records information such as type of drug, dose, and place of manufacture, and also measures and reports physiologic parameters such as heart rate, activity, and respiratory rate. Detector data can be combined at the server level with other telemetered parameters such as blood pressure, weight, blood glucose, and patient-generated feedback.

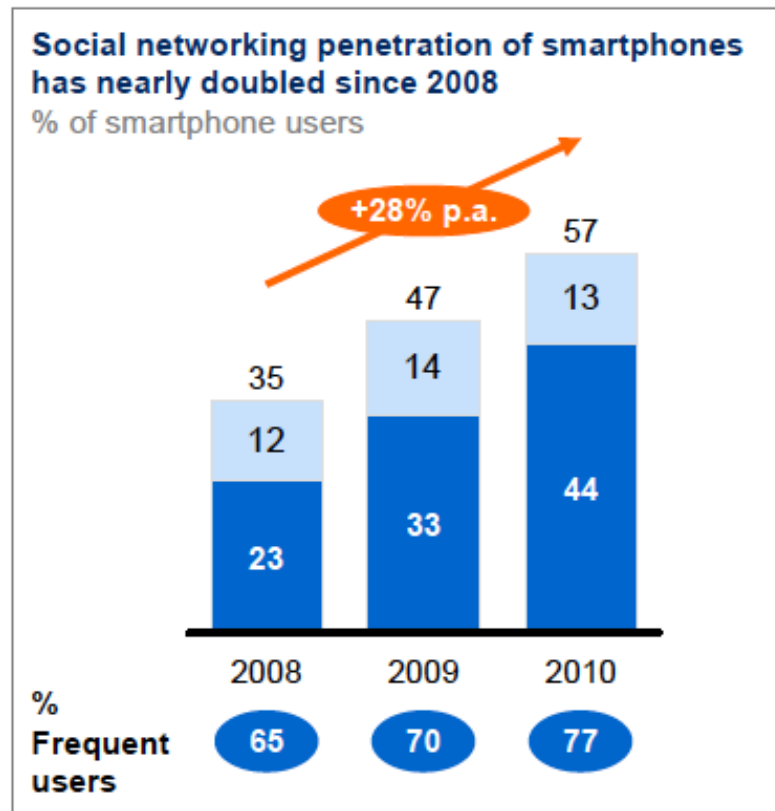
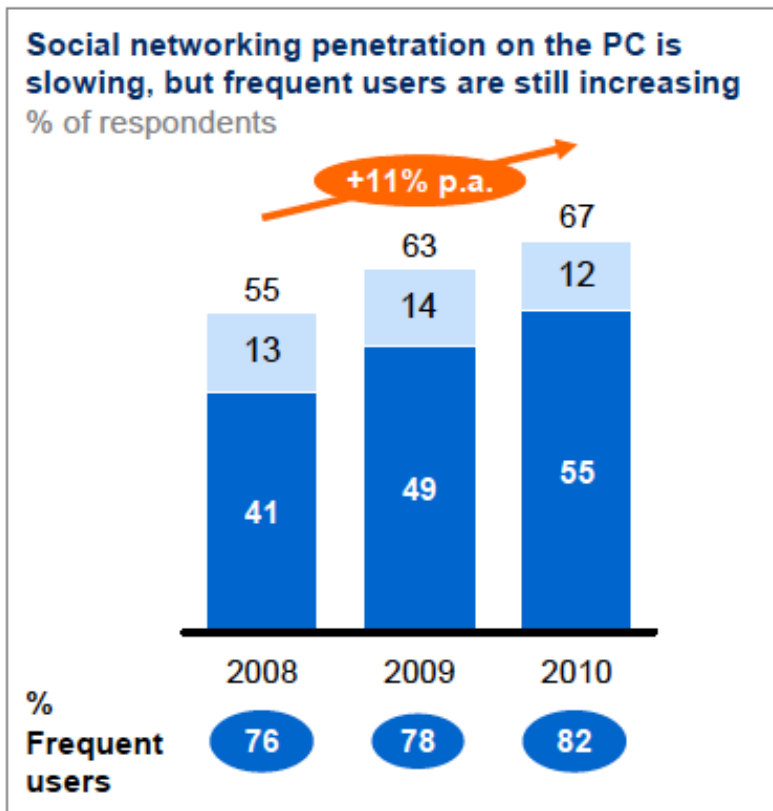
Sources: McKinsey Quarterly, https://www.mckinseyquarterly.com/The_Internet_of_Things_2538;
Proteus Biomedical website: <http://www.proteusbiomed.com/technology/>



Social networks and the ubiquity of mobile communications create a new usage paradigm

The penetration of social networks is increasing online and on smartphones; frequent users are increasing as a share of total users¹

■ Frequent user²



¹ Based on penetration of users who browse social network sites. For consistency, we exclude Twitter-specific questions (added to survey in 2009) and location-based mobile social networks (e.g., Foursquare, added to survey in 2010).

² Frequent users defined as those that use social networking at least once a week.

Social networks will be built for professionals and institutions but connected to outside networks

Oracle Social Network

A secure collaboration tool for everyone you work with.

Overview

Features

Notify Me of Updates

Conversations



Real-Time

Everything within Oracle Social Network happens in real-time.

Multimedia

Text, content, video, and voice all within a stream.

Share

Internal and external groups collaborating securely together.

Business Insights



Application Integration

CTMS, EDC, EHA, Safety, LSH/CDC/LSW, TRC, IRT, OLX, LabPas, CDA

Feeds

Business events posted within Social Network streams.

Gadgets

Update your Applications from within Oracle Social Network.

Content



Annotation

Real-time, shared document markup.

Real-Time Tools

Chat, web and application conference sharing.

Search

Full content, real-time auto complete and context filtering.

Activity Streams



Live Digest

Receive snapshots of your unread activity stream.

Followup

Flag critical information for yourself or others.

Filtering

Focus on what matters to you.



CureTogether

patientslikeme®

medCrowd

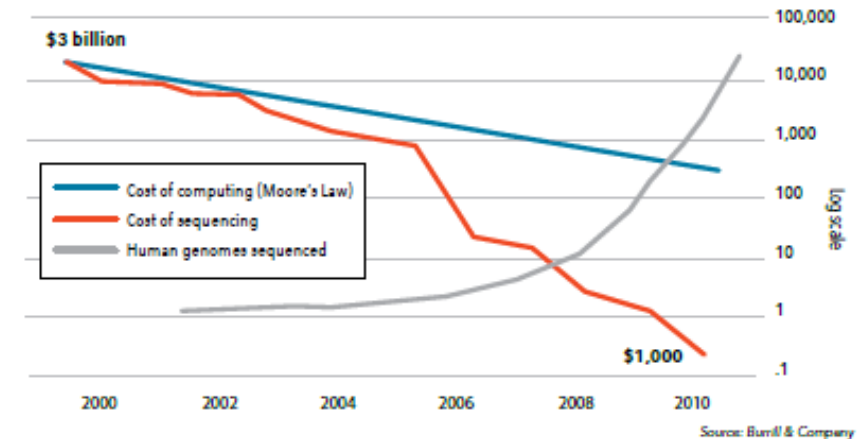
sermo™

ORACLE®

'Omics, clinical/medical data, and imaging will drive data volumes but more importantly insights

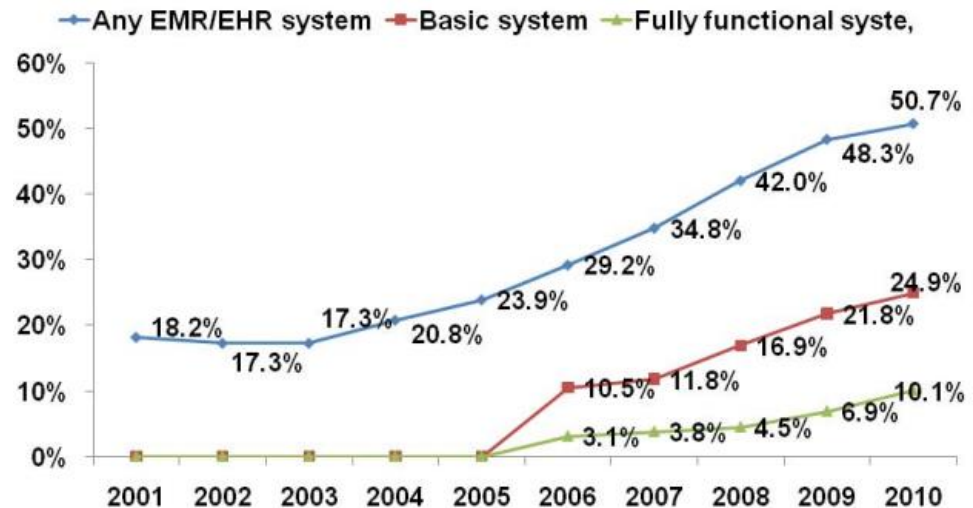


Figure 3.5 The Cost of Sequencing



"In the future of Pharma 3.0, data will not be contained in any single company's central servers – it will be distributed across the ecosystem, often in semantically inconsistent formats. So real-time analytics and integration will be vital. Thoughtful algorithms are a big part of the future, both to make sense of the data and to execute actions derived from these analyses."

Diego Miralles, Johnson & Johnson



Source: CDC/NCHS – National Ambulatory Medical Care Survey. Published in Electronic Medical Record/Electronic Health Record Systems of Office-based Physicians: United States, 2009 and Preliminary 2010 State Estimates. December 2010.

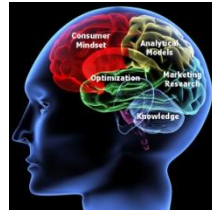
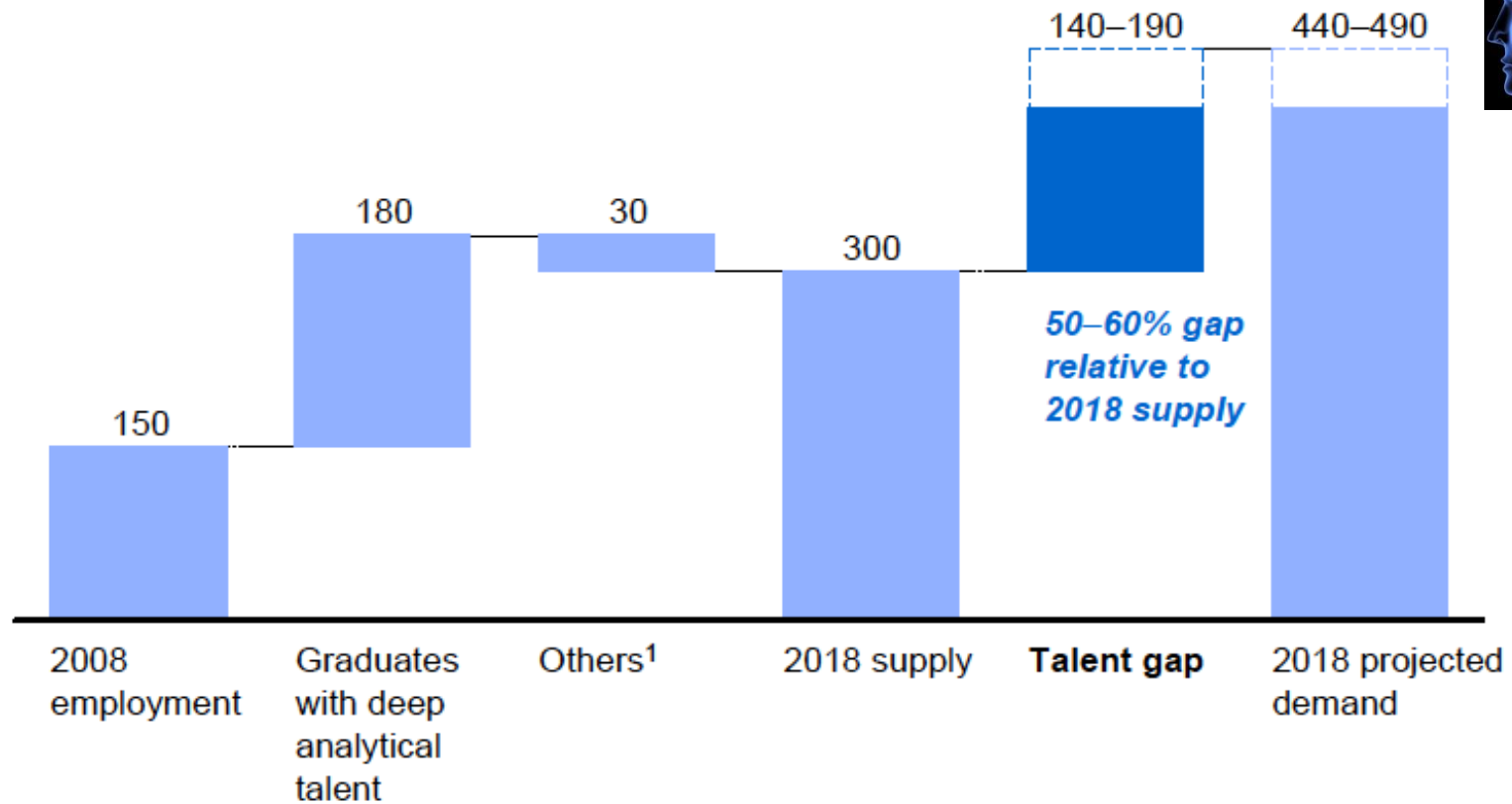
Social networks combined with insights driven by analytics will help address the analytics talent gap

Demand for deep analytical talent in the United States could be 50 to 60 percent greater than its projected supply by 2018

facebook

Supply and demand of deep analytical talent by 2018

Thousand people



¹ Other supply drivers include attrition (-), immigration (+), and reemploying previously unemployed deep analytical talent (+).

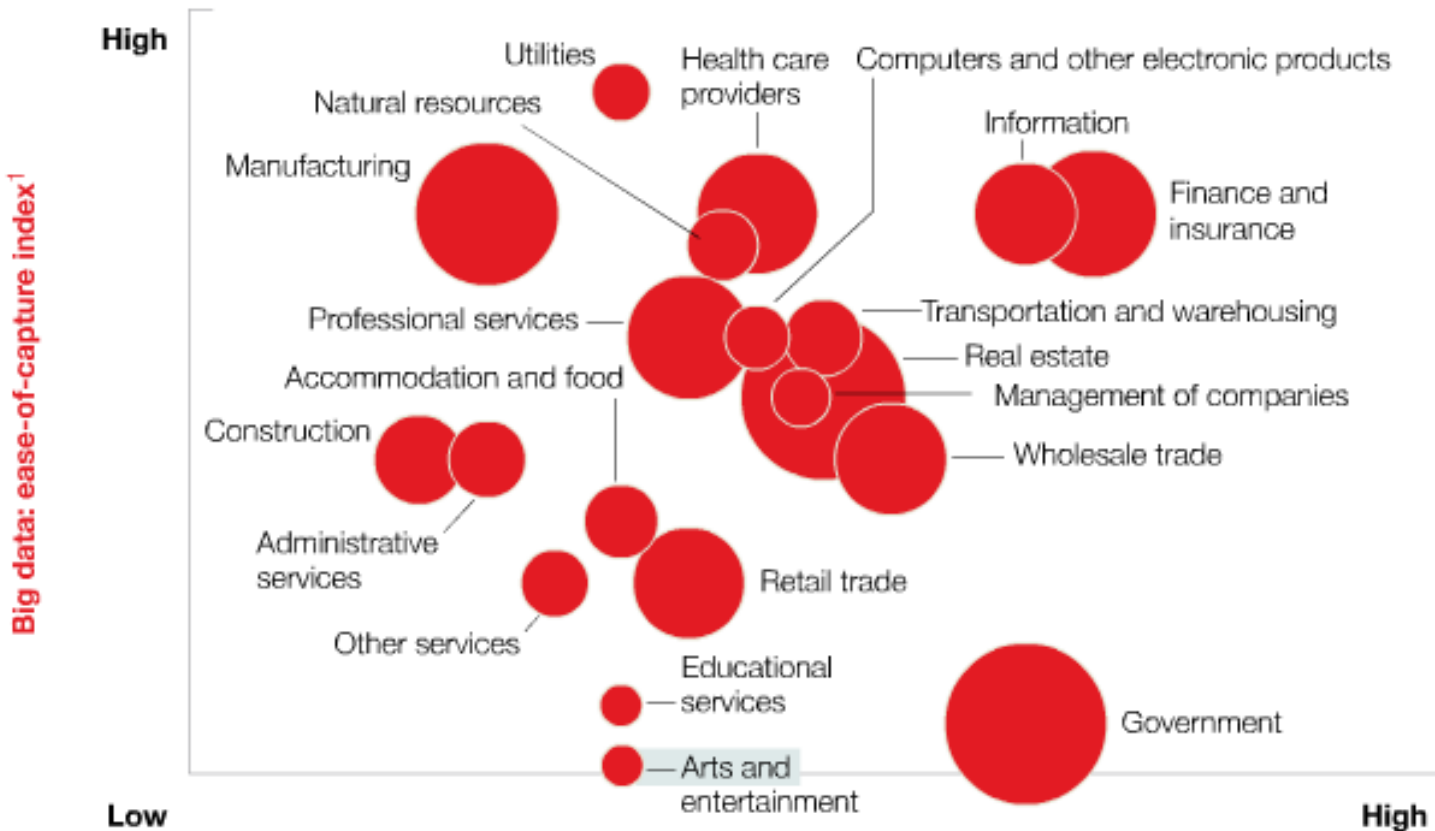
SOURCE: US Bureau of Labor Statistics; US Census; Dun & Bradstreet; company interviews; McKinsey Global Institute analysis

The “Internet of Things” plus extreme data volumes and heterogeneity create a “Big Data” challenge...and opportunity



Example: US economy

○ Size of bubble indicates relative contribution to GDP



Source: McKinsey Quarterly, https://www.mckinseyquarterly.com/Strategy/Innovation/Are_you_ready_for_the_era_of_big_data_2864#sidebar

Big data: value potential index¹



Four data pools exist in health sciences that can be leveraged within a common data mgt infrastructure

Data pools

Pharmaceutical R&D data

- Owner: Pharmaceutical companies, academia
- Example datasets: clinical trials, high throughput screening (HTS) libraries

Clinical data

- Owners: providers
- Example datasets: electronic medical records, medical images

Activity (claims) and cost data

- Owners: payors, providers
- Example datasets: utilization of care, cost estimates

Patient behavior and sentiment data

- Owners: various including consumer and stakeholders outside health care (e.g., retail, apparel)
- Example data sets: patient behaviors and preferences, retail purchase history, exercise data captured in running shoes

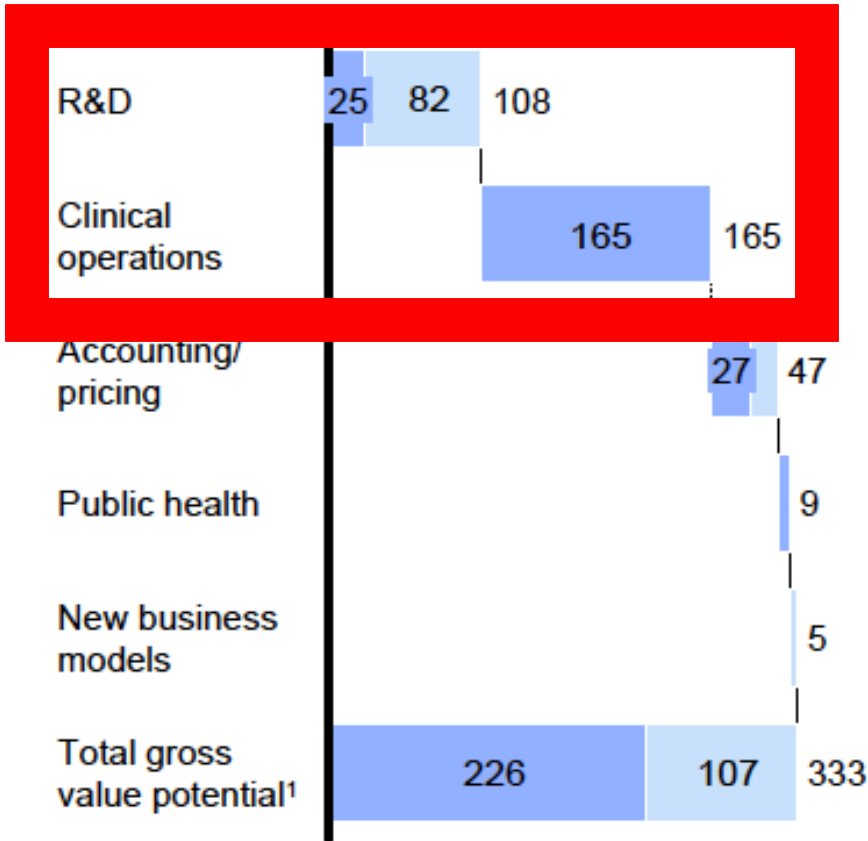
Integration of data pools required for major opportunities



A data mgt infrastructure across the health sciences ecosystem captures the majority of the ROI



Value potential from use of big data
\$ billion per year



Lever examples

Predictive modeling to determine allocation of R&D resources, clinical trial design, and personalized medicine

Comparative effectiveness research (CER), clinical decision support system, and dashboards for transparency into clinical data

Advanced algorithms for fraud detection, performance-based drug pricing

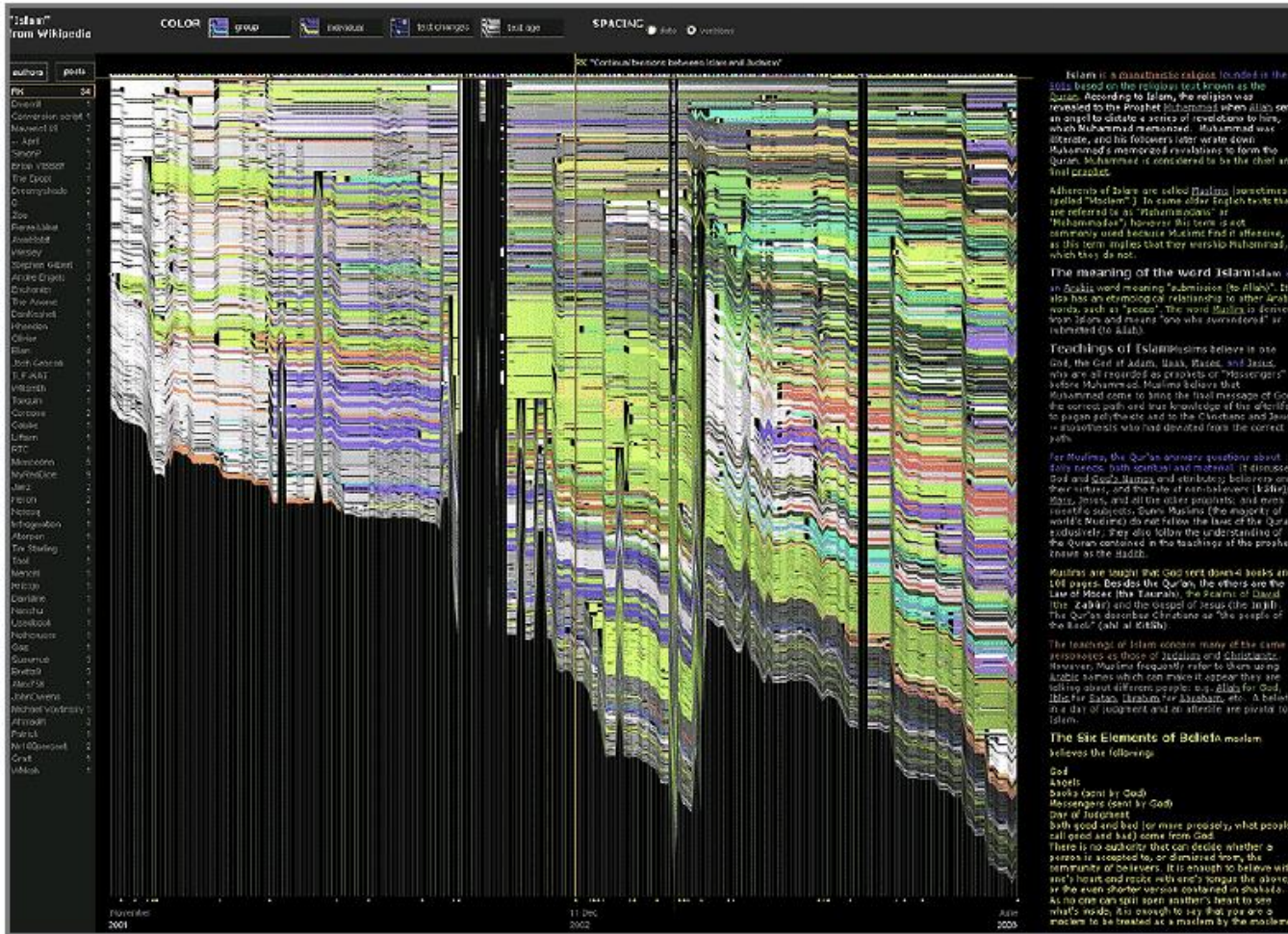
Public health surveillance and response systems

Aggregation of patient records to provide datasets and insights; online platforms and communities

¹ Excluding initial IT investments (~\$120 billion–\$200 billion) and annual operating costs (~\$20 billion per annum).

SOURCE: Expert interviews; press and literature search; McKinsey Global Institute analysis

Analytics will move from “reporting” to auto-generating insights – even for protocols...



- “History flow” visualizes the evolution of a document through time and the contribution of multiple authors.
- Time appears on the horizontal axis, while contributions are on the vertical axis; each author has a different color code and the vertical length off a bar indicates the amount of text written by each author.

Communities can add value for professionals in health sciences and increasingly patients and families



- Brings together experts in oncology, information technology, computational biology, pharmaceutical drug development, and personalized medicine
- Captures, organizes, analyzes, integrates and presents most up-to-date medical facts from a vast array of sources
- Currently has a 10,000 oncologist, collaborative network
- Helps enables community physicians to practice more precise medicine for complex conditions
- Provides members with knowledge needed to treat patients with the more accurate, individualized medicine
- Goal is to provide “Knowledge Medicine” for cancer care



sermo™



medCrowd

patientslikeme



PharmaWall is a fully moderated application that allows companies to engage with Facebook® users in a regulatory-friendly social setting.

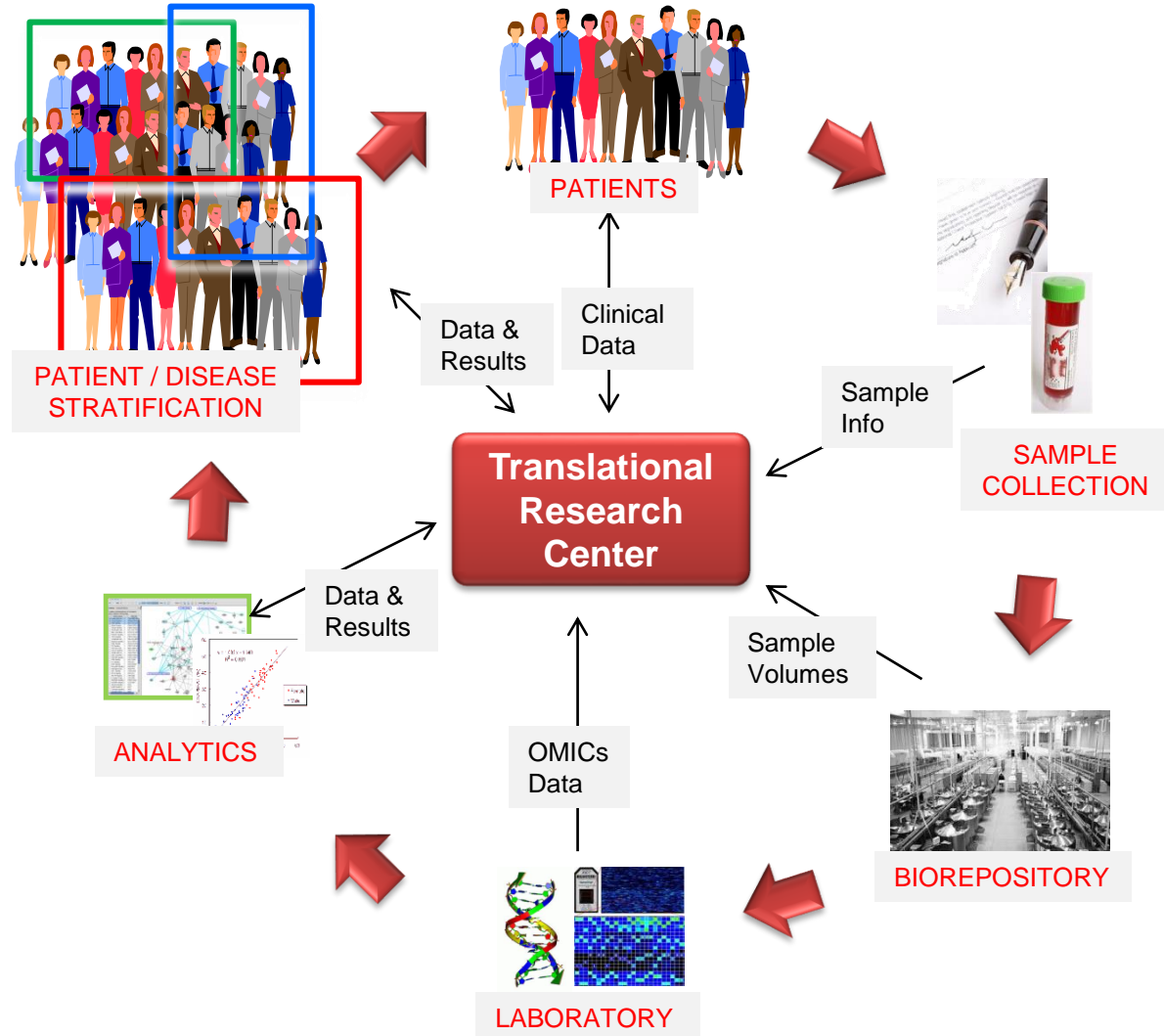
Example: Scaling Clinical Research with Oracle's Translational Research Center (TRC)

- Proactive consenting
- Sample data access
- Testing
- Data management
- Analytics/insights



NEW ADMITS

Best-Fit Treatment Options Report



Cohort Selection

Gene expression profiling of Grade-IV Glioblastoma patients

- Select patients who
 - have consented to Complete Cancer Care (CCC)
 - have diagnosed with Grade-IV Glioblastoma
 - have specimen necrosis < 50%
 - have specimen nuclei > 80%

Patient Information

Patient Information (page 1 of 2)

Patient ID

Gender

Marital Status

Age (in Years) Between -

Date of Birth Between  - 

Deceased Date Between  - 

Ethnicity

Race

Consent Type Code

Consent Type Name

Consent Status

Consent Start Date Between  - 

Consent End Date Between  - 

Patient Count: 3451

Cohort Selection

Gene expression profiling of Grade-IV Glioblastoma patients

- Select patients who
 - have consented to Complete Cancer Care (CCC)
 - have diagnosed with Grade-IV Glioblastoma
 - have specimen necrosis < 50%
 - have specimen nuclei > 80%

Diagnosis (page 1 of 3)

Diagnosis Top Level Name	<input type="text"/>	Diagnosis Top Level Code	<input type="text"/>
Level 6 Name	<input type="text"/>	Level 6 Code	<input type="text"/>
Level 5 Name	<input type="text"/>	Level 5 Code	<input type="text"/>
Level 4 Name	<input type="text"/>	Level 4 Code	<input type="text"/>
Level 3 Name	<input type="text"/>	Level 3 Code	<input type="text"/>
Level 2 Name	<input type="text"/>	Level 2 Code	<input type="text"/>
Level 1 Name	<input type="text"/>	Level 1 Code	<input type="text"/>
Diagnosis Name	<input type="text" value="Glioblastoma NOS"/>	Diagnosis Code	<input type="text"/>
Anatomical Site Top Level Name	<input type="text"/>	Anatomical Site Top Level Code	<input type="text"/>
Anatomical Site Level 4 Name	<input type="text"/>	Anatomical Site Level 4 Code	<input type="text"/>
Anatomical Site Level 3 Name	<input type="text"/>	Anatomical Site Level 3 Code	<input type="text"/>
Anatomical Site Level 2 Name	<input type="text"/>	Anatomical Site Level 2 Code	<input type="text"/>
Anatomical Site Level 1 Name	<input type="text"/>	Anatomical Site Level 1 Code	<input type="text"/>
Anatomical Site Name	<input type="text"/>	Anatomical Site Code	<input type="text"/>
Status	<input type="text" value="Grade IV - Primary;Gr"/>		
Age at First Onset (In Years) Between	<input type="text"/>		
Onset Date Between	<input type="text"/>	<input type="text"/>	
Date Reported Between	<input type="text"/>	<input type="text"/>	
End Date Between	<input type="text"/>	<input type="text"/>	

Patient Count: 501

Cohort Selection

Gene expression profiling of Grade-IV Glioblastoma patients

- Select patients who
 - have consented to Complete Cancer Care (CCC)
 - have diagnosed with Grade-IV Glioblastoma
 - have specimen necrosis < 50%
 - have specimen nuclei > 80%

Diagnostic Test

Diagnostic Test (page 1 of 3)

Test Name: Specimen Necrosis

Test Code:

Test Date: Between -

Result (numeric): Between - 50

Result (numeric) Units:

Result (text):

Patient Count: 394

Cancel Next Apply Reset

Diagnostic Test

Diagnostic Test (page 2 of 3)

Test Name: Specimen Nuclei

Test Code:

Test Date: Between -

Result (numeric): Between 80 -

Result (numeric) Units:

Result (text):

Patient Count: 394

Previous Next Apply Reset

Cohort Selection and Exporting the Results

Gene expression profiling of Grade-IV Glioblastoma patients

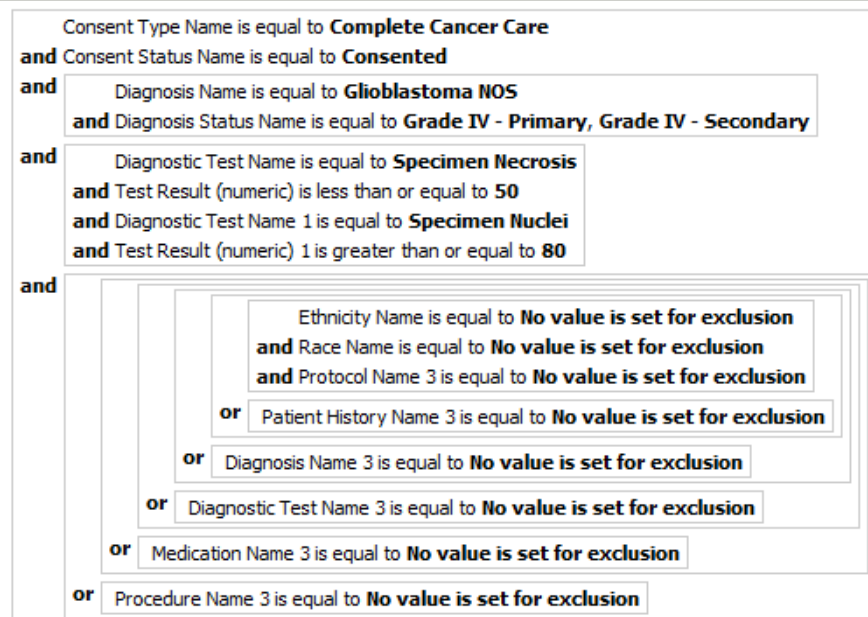
- Select patients who
 - have consented to Complete Cancer Care (CCC)
 - have diagnosed with Grade-IV Glioblastoma
 - have specimen necrosis < 50%
 - have specimen nuclei > 80%

Total Patient Count

Patient count: 394

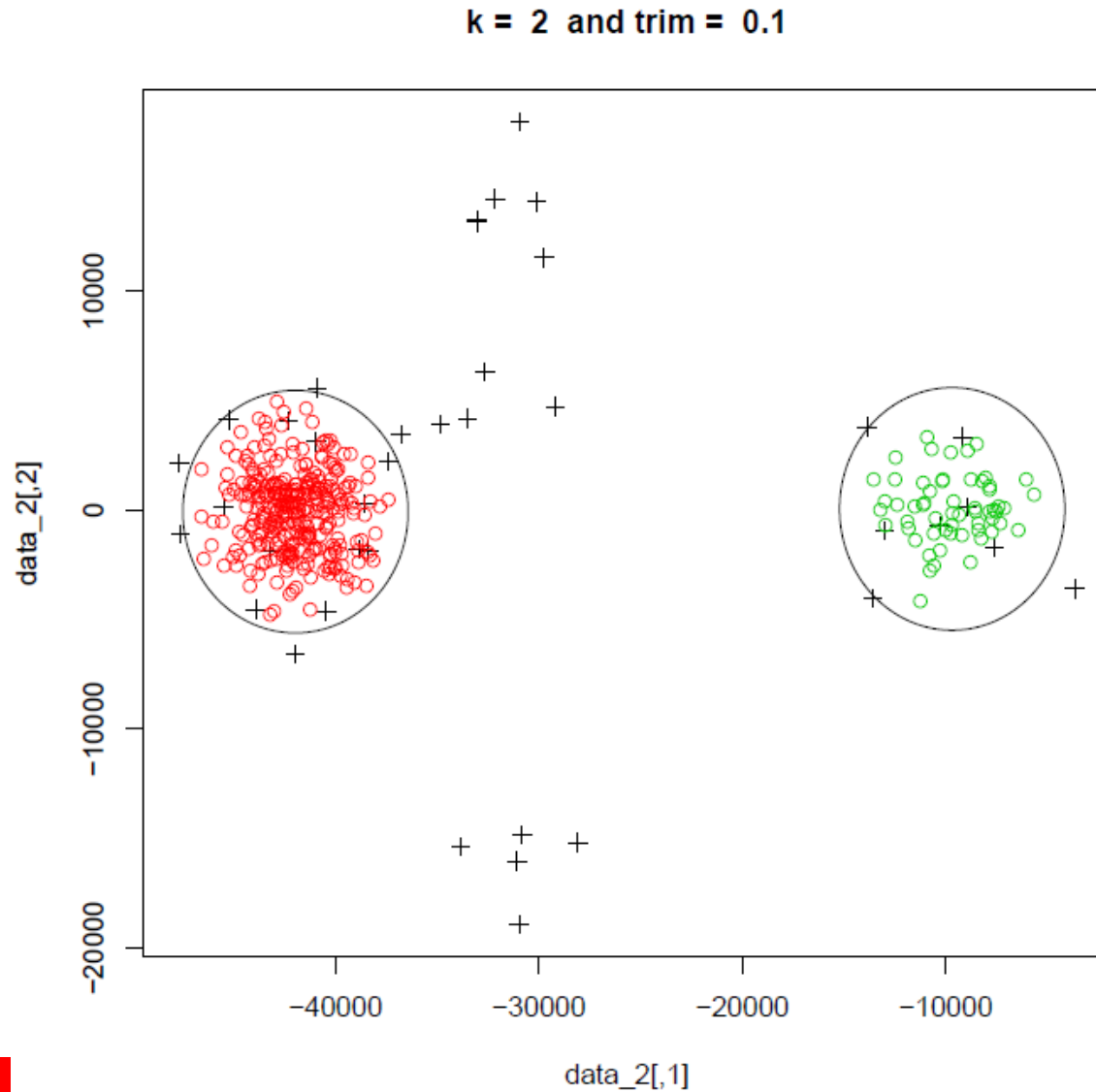
Oracle recommends to limit cohort size before listing patients or showing timelines.

Summary of Filtering Criteria Applied



[Refresh](#) - [Print](#) - [Export](#) - [Copy](#)

Clustering results based on a subset of genes



Kaplan-Meier survival analysis of these two groups

The screenshot displays the Oracle Phase Forward CDC interface. On the left is a file tree showing the project structure under 'Oracle_TRC' > 'Cancer_Research' > 'Brain' > 'Glioblastoma' > 'Programs' > 'SurvivalAnalysis.R, 8'. The main window shows a 'Running Jobs' table with the following data:

Name	Status	Queued	Started	Completed	Run/Record	Message
SurvivalAnalysis	COMPLETED	16Sep11 15:01:39	16Sep11 15:01:43	16Sep11 15:01:46	RUN RECORD	The job executed successfully.
SurvivalAnalysis	COMPLETED	16Sep11 14:55:34	16Sep11 14:55:38	16Sep11 14:55:39	RUN RECORD	The job executed successfully.
SurvivalAnalysis	FAILED	16Sep11 14:53:54	16Sep11 14:53:58	16Sep11 14:53:59	RUN RECORD	The job failed.
SurvivalAnalysis	FAILED	16Sep11 14:52:39	16Sep11 14:52:43	16Sep11 14:52:46	RUN RECORD	The job failed.

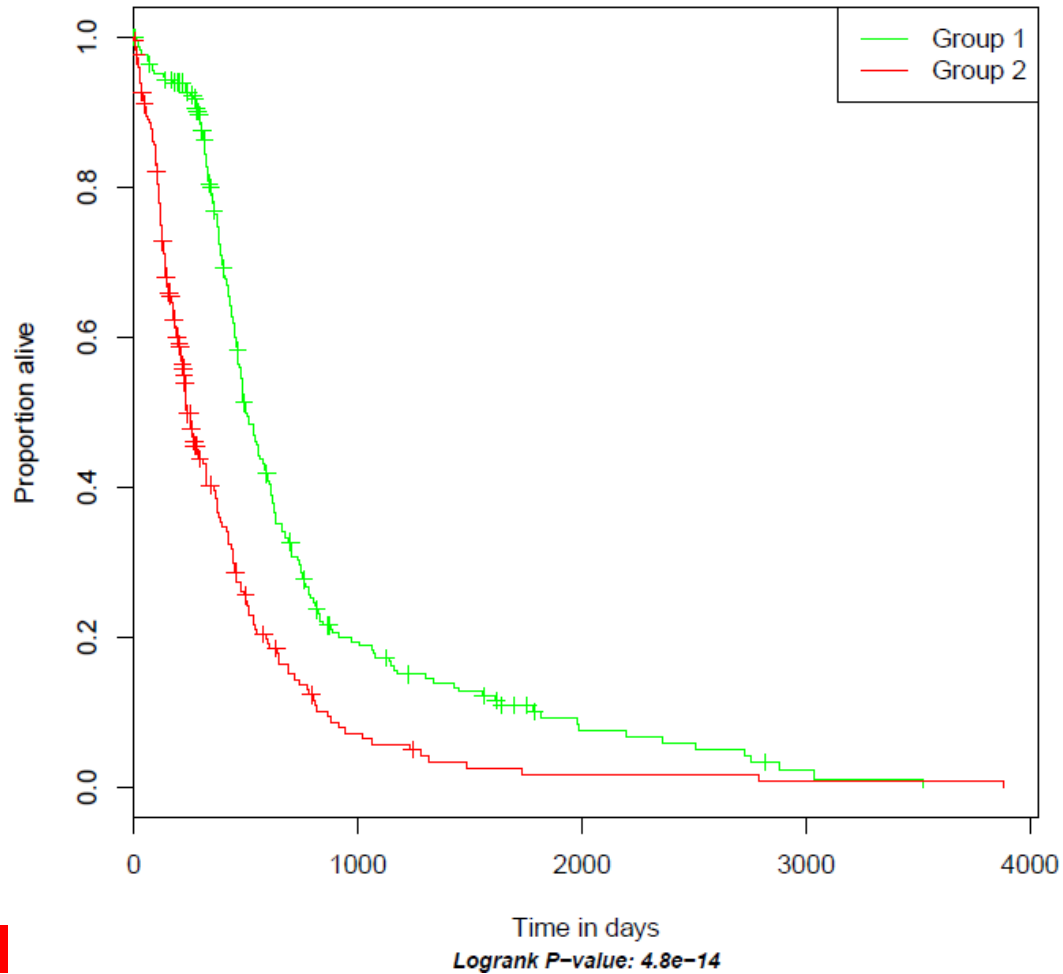
Below the table, a progress window shows the following steps:

- Recording run SurvivalAnalysis
 - Running on server localhost1
- Preparing documents
 - Getting TRC Test TCGA GBM Survival data no null.txt_1 from database.
 - Getting PATIENT Expression groups.txt_1 from database.
 - Getting SurvivalAnalysis.R_8 from database.
 - Checked in SurvivalAnalysis_job_params.xml_5
- run SurvivalAnalysis
 - Checking out SurvivalPlot.pdf_1
 - Checking out SurvivalAnalysis.out_4
 - Checked in SurvivalPlot.pdf_2
 - Checked in SurvivalAnalysis.out_5

On the right, an Adobe Reader window displays a Kaplan-Meier survival plot titled 'Segregation by Group'. The y-axis is 'Proportion alive' (0.0 to 1.0) and the x-axis is 'Time in days' (0 to 4000). Two curves are shown: Group 1 (green) and Group 2 (red). Group 1 shows a higher survival rate over time. The plot includes a legend and a Logrank P-value of 3.7e-08.

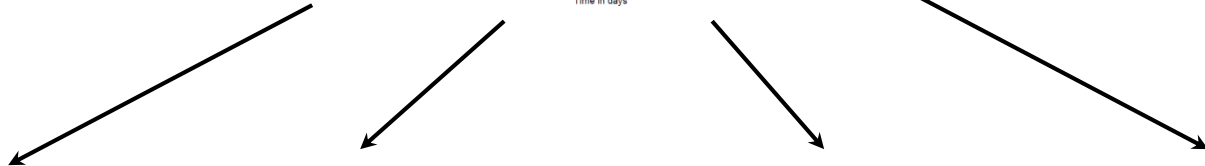
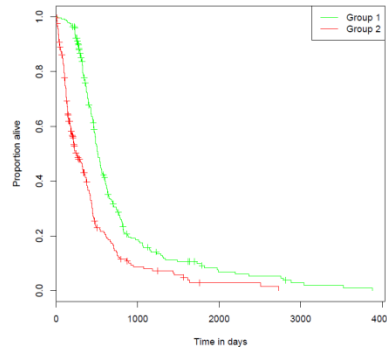
Analysis yields insights on patients survival differences based on molecular signature

Segregation by Group

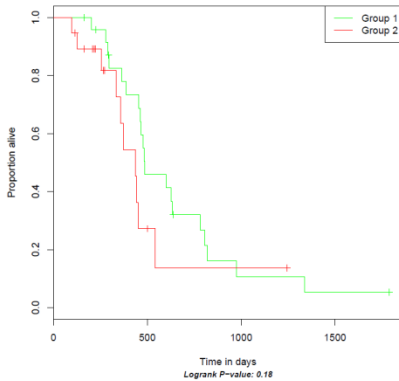


The two groups are further stratified based on medication

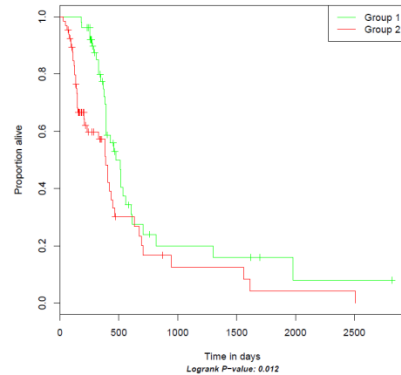
Segregation by Group, All patients



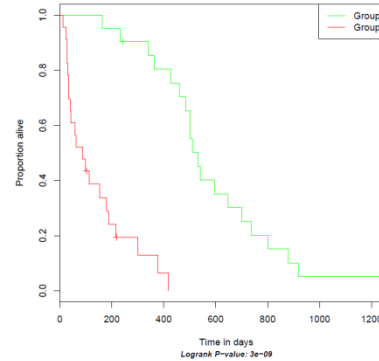
Segregation by Group, Avastin patients



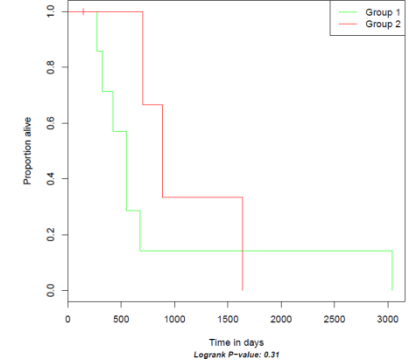
Segregation by Group, Temozolomide patients



Segregation by Group, Dexamethasone patients



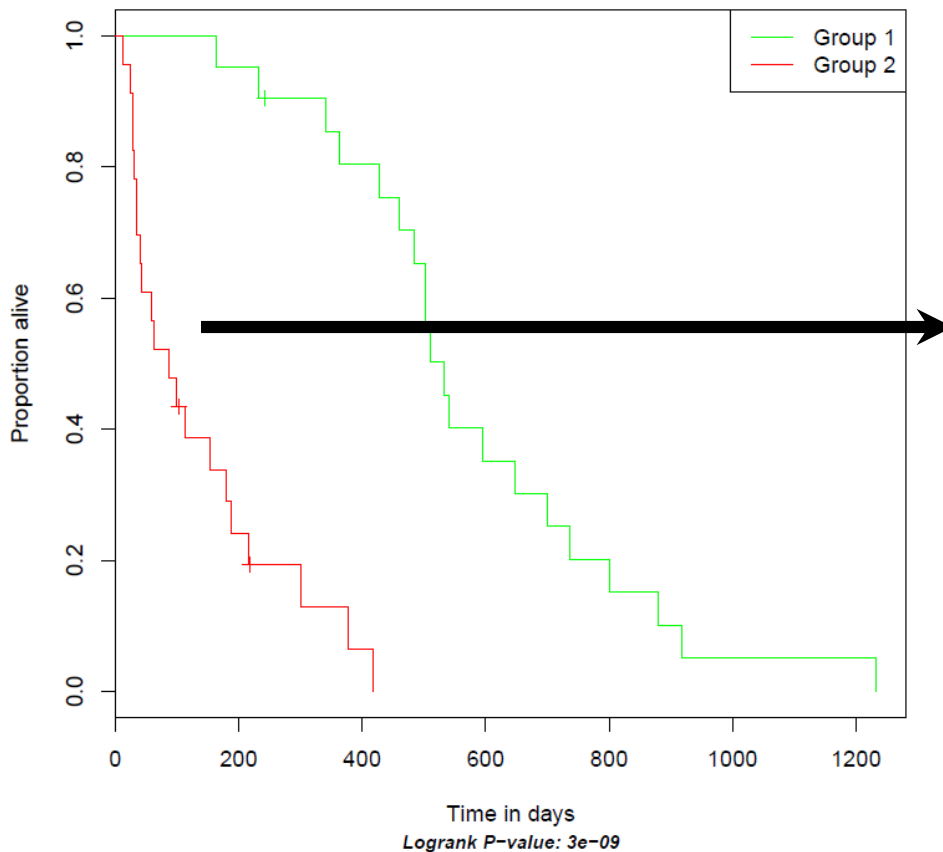
Segregation by Group, Tarceva patients



Insight

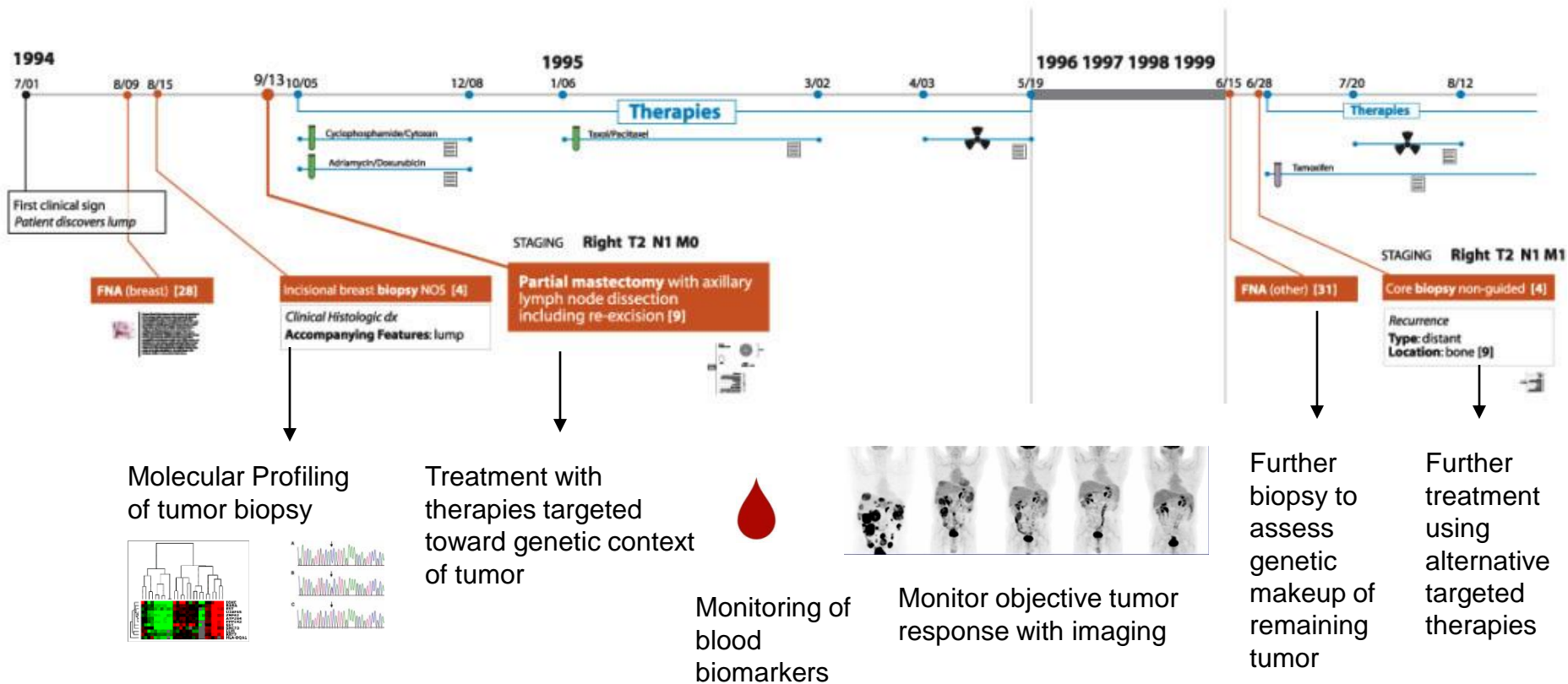
Actionable insight: patients in group 2 do not respond well to Dexomethasone

Segregation by Group, Dexamethasone patients



- Save unnecessary expense by not treating these patients with therapy that is likely to not benefit them
- Increase quality of life by sparing them unwanted side effects of likely ineffective therapies
- Enroll these patients in any available new investigational drug trials based on their tumor genetic profile

Transforming care through personalized medicine



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