Actionable Clinical Data Insights:
The Key to Improved Collaboration and Workflow



A Case Study for Clinical Analytics

Monday, October 13th, 2014

PhUSE Annual Conference, London

Presenter:



Ben McGraw
Vice President of Marketing
Comprehend Systems

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Agenda

- Gaining Value from Clinical Data Analytics
- Improved Collaboration and Workflow
- Virtual, On-Demand Clinical Data Warehouses
- Q&A

Clinical Development Changing, Changing Info Needs



As the costs of drug development escalate, more value in:

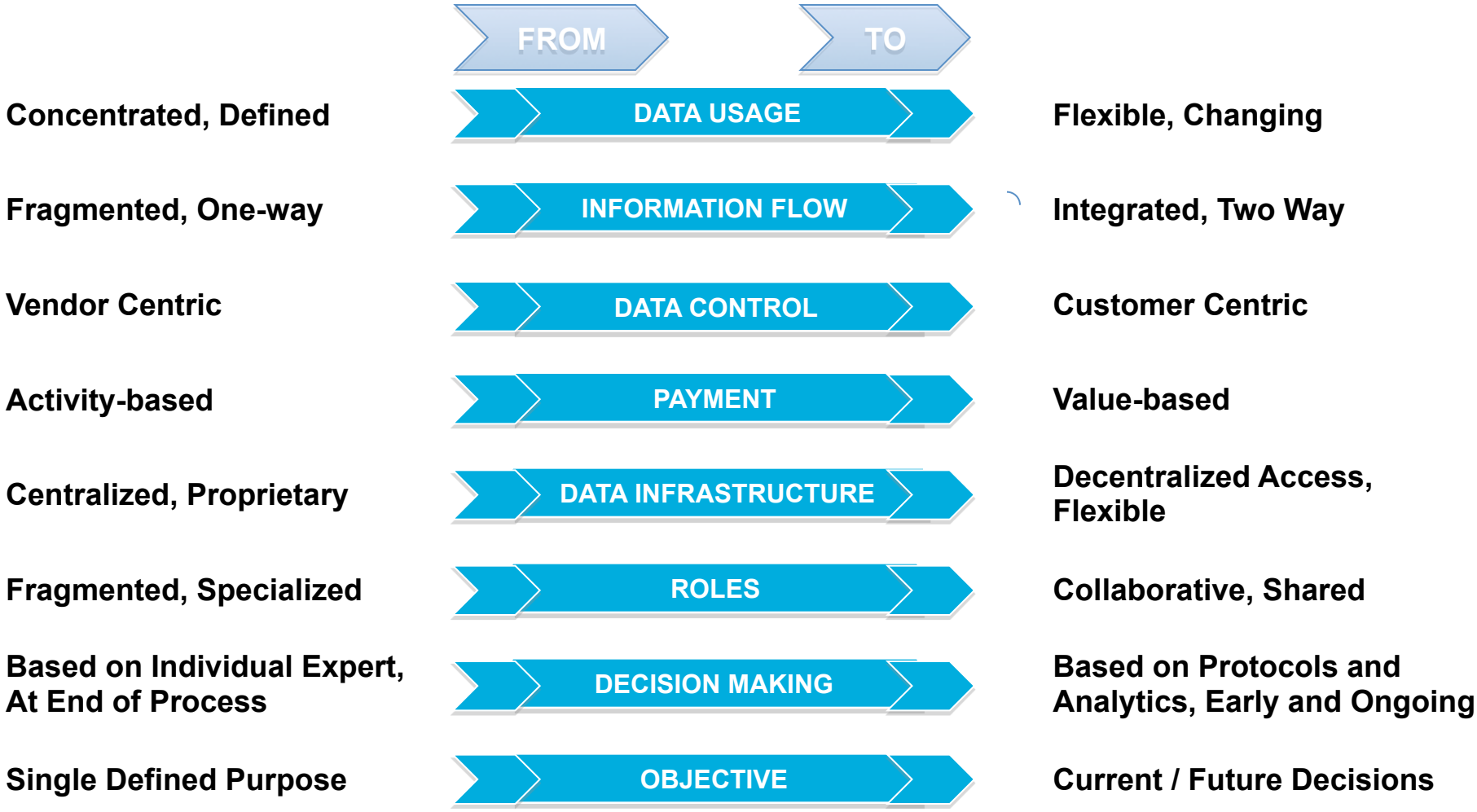
- **Early identification of any issues that can result in savings of time and cost**
- **High quality, inexpensive data to increase confidence**
- **Data transparency**
- **Efficient data transfer**
- **Speedier trial enrollment**
- **Reduced medical review time**
- **Holistic, actionable view of the data at any point in the trial**
- **Access and flexibility in future use of trial data**
- **COLLABORATION & WORKFLOW**

Source: Pharmaceutical Research and Manufacturers of America; Frost & Sullivan

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Shifting Expectations in a Data Driven World

Trends Impacting Healthcare From Drug Discovery to Care Delivery

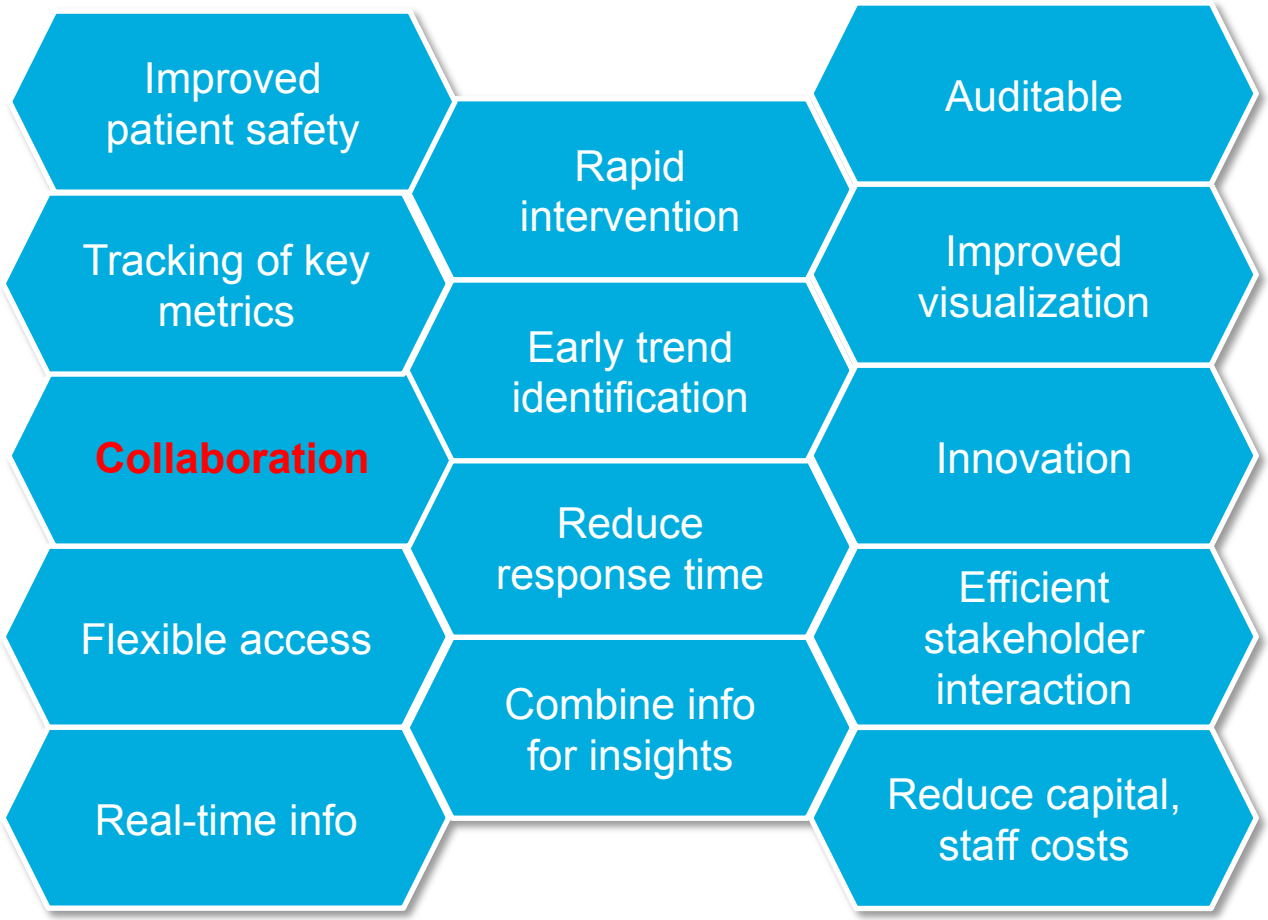


Source: Frost & Sullivan

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Value Creation in Healthcare From Data

Are We Achieving These Benefits in Clinical Trials?



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Source: Frost & Sullivan

Hurdles to Reaching the Promise of the Data Revolution



DATA	INTEGRATION	ANALYTICS	ACTION
We are creating millions of useful data points, from a wide variety of sources…	…But the data is provided in separate point solutions. **FREEING DATA AND INTEGRATING DATA FOR RAPID ANALYSIS ARE KEY**	Timely analytics let us take action based on insights to achieve better outcomes, improve decision making and increase efficiency	Analytics and data need to be made available to a wide range of stakeholders to support rapid short-term decisions and long-term insights

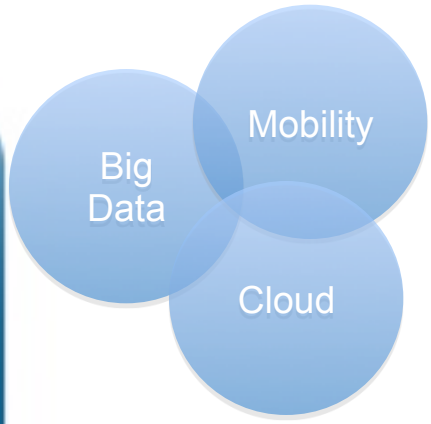
Source: Frost & Sullivan

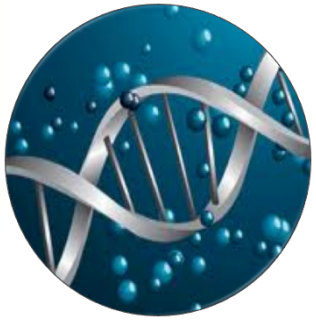
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Cloud Solutions Aligned With Healthcare Shifts

- Cloud allows scale in storing big data
- Collaboration in research means moving partners to the data
- Collaboration requires flexible access and merged data sets
- Cloud is a key enabler of mobilizing data for use by customers and enterprise users







Genomics

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Source: Frost & Sullivan analysis

Why Should We Act Now?

Data free from proprietary CRO systems, available to sponsor for current analysis

Early identification of enrollment issues

Risk-based monitoring to reduce site visits

Track, monitor complex protocols

Data available to sponsor for future analysis

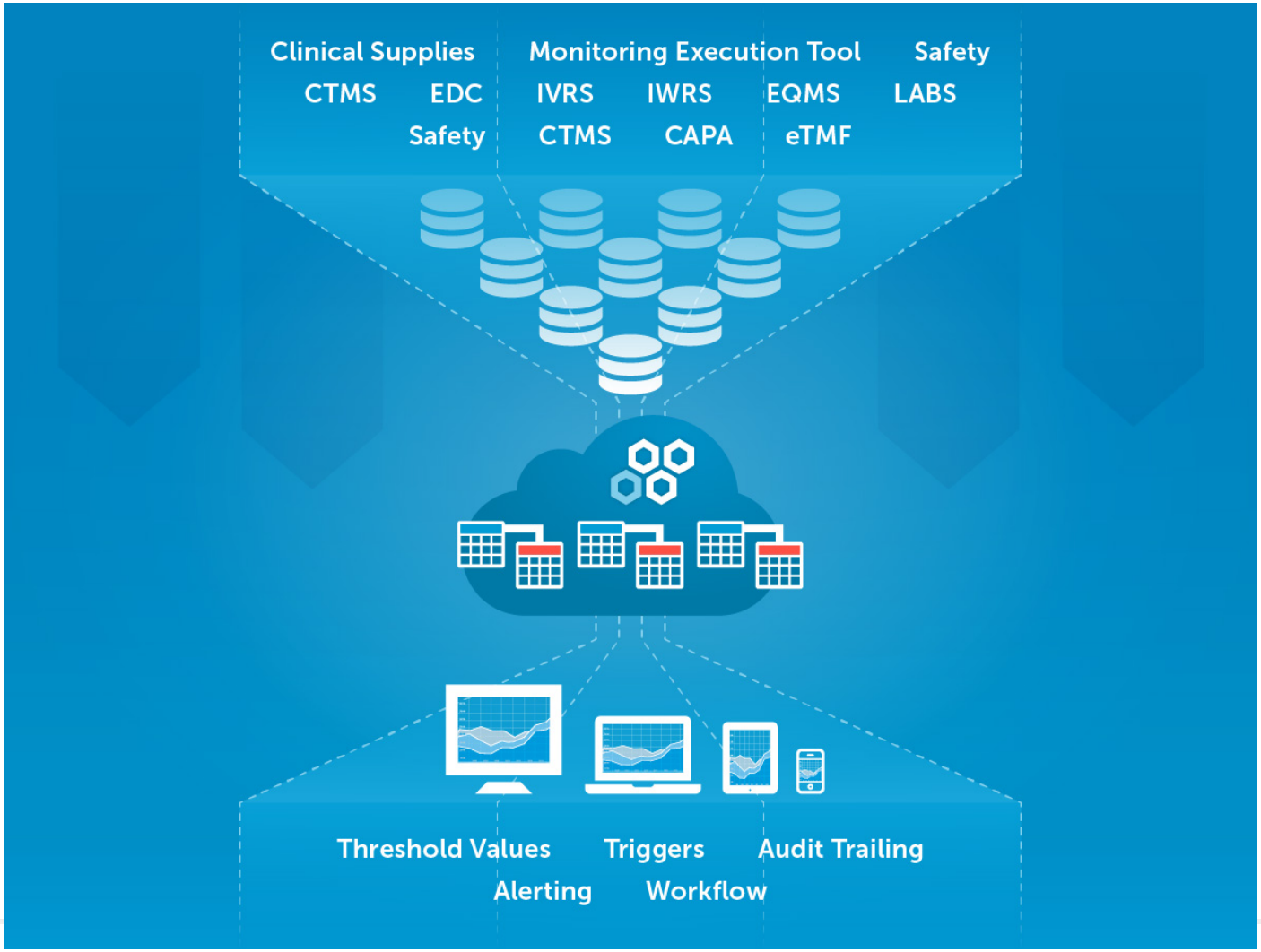
Inherent benefits of cloud solutions

- QUICK ANALYSIS & RAPID RESPONSE
- SAVINGS OF TENS OF THOUSANDS OF $ PER DAY
- 25% - 30% OF TRIAL COSTS
- REDUCE PROTOCOL VIOLATIONS
- INTEGRATION OF DATA FOR CROSS-STUDY ANALYSIS
- ELIMINATE INFRASTRUCTURE COSTS
- FREE IT STAFF FOR STRATEGIC INITIATIVES

Source: Frost & Sullivan

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The Perfect Use Case



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Collaboration



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Deliver Actionable Insights In Real Time Wherever



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Quotes

"CROs should be able to provide sponsors with real-time, multi-source secure access via the cloud to clinical trial data residing in any system."

Ed Campanero
Vice President of Operations, bluebird bio

bluebirdbio™

"The data we collect for our Sponsor customers is readily available to them and can be accessed whenever needed and in the format preferred."

Hunter Walker
Chief Technology Officer, ARG

ARG
ATLANTIC RESEARCH GROUP

Atlantic Research Group

ARG is a world-class clinical research organization dedicated to agile and emerging biopharmaceutical companies. Our **Clinical Process Architecture™** is a highly evolved **framework** within which to build **successful**, **efficient** clinical trials.



Located in Charlottesville, Virginia

Celebrating **10 years** serving our clients in the United States and internationally!

Fundamentally **committed** to the needs of agile and emerging biopharmaceutical companies.

World-class **SaaS clinical systems** development for successful clinical trials.

Emerging biopharma companies are all in – And so are we.

ARG - Strategic Vision

Make information technology a cornerstone of client service

Provides enabling technologies for decision support and adaptive, cost effective clinical trials – as a way to differentiate from other clinical research organizations. Early adopter of cloud technologies – 2006, years before term was commonplace

Clinical development as a source of data

Biopharmaceutical research is a tremendous source of data: patients, drugs, device use, dosages, factors, sites. Support Sponsors by powering their research with analytics.

Sponsors want clinical development success

Adaptive, responsive, and comprehensive client service – from all levels of the organization. A passion for clients' success is critical to ARG's business model.

Clinical Analytics

Optimize clinical trials by looking for outliers

Opportunity for responsive posture towards clinical development: adapting a trial to focus on a specific site, investigator, or protocol characteristic results in more intelligent monitoring and management.

Provide decision support to Sponsors

Analytics and data dashboards allow sponsors to see aggregate reports that summarize real time data: trouble spots and positive developments.

Employees hunger for ways to improve Sponsors' trial experience

Ad hoc analytic queries and data exploration allows ARG trial site managers a way to look for problems (opportunities) before they fully develop.

Operational Efficiency

Power efficiency and accuracy initiatives with our internal data

Improve travel and expense cost effectiveness. Build a history of pass-through expense distributions by location, trial, sponsor so that future estimates can be right-sized.

Measure employee performance and satisfaction

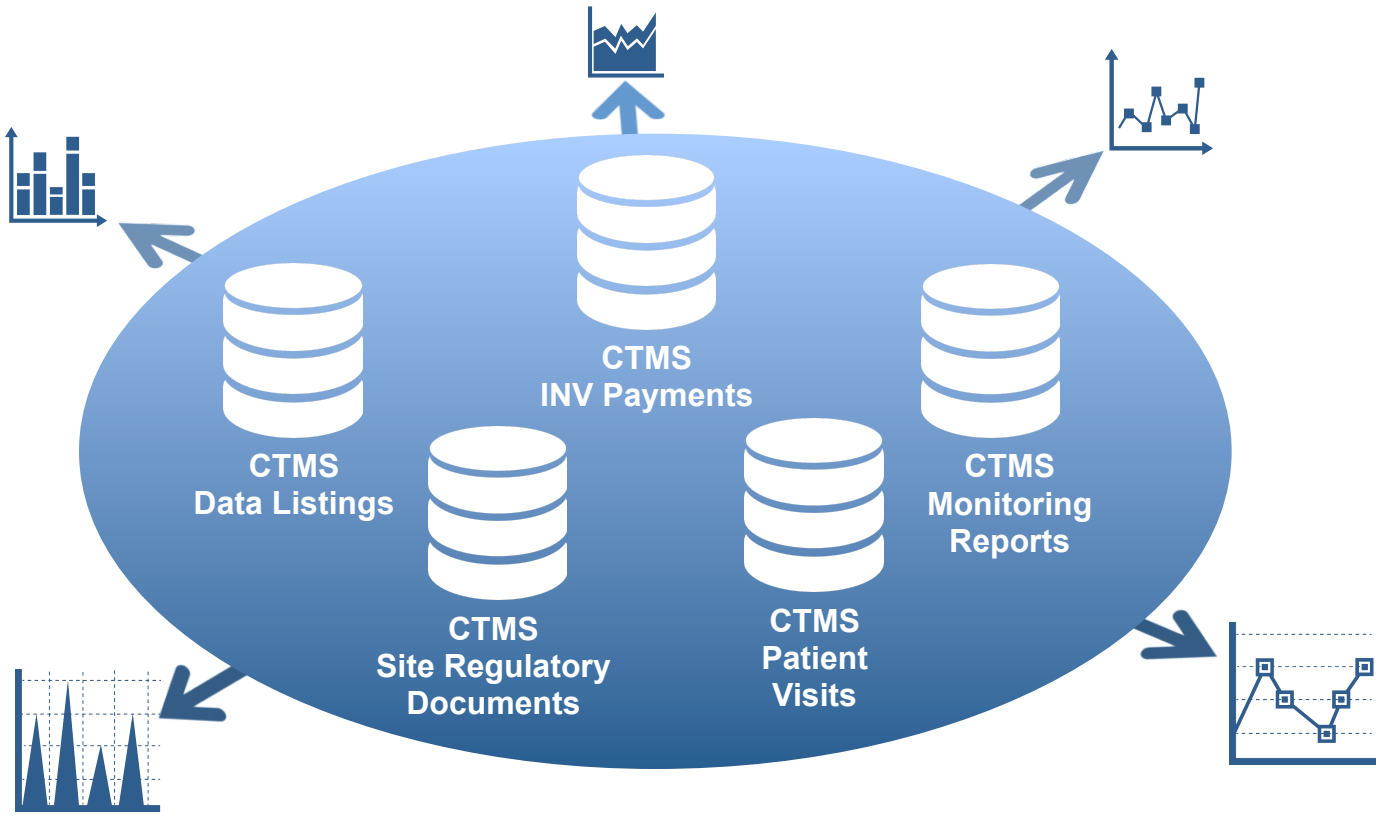
Implement performance improvement and compensation-based incentives, using operational data to augment qualitative performance metrics.

Data Silos



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Life Before SaaS-based Virtual On-Demand Data Warehouse



Reporting is done in separate modules

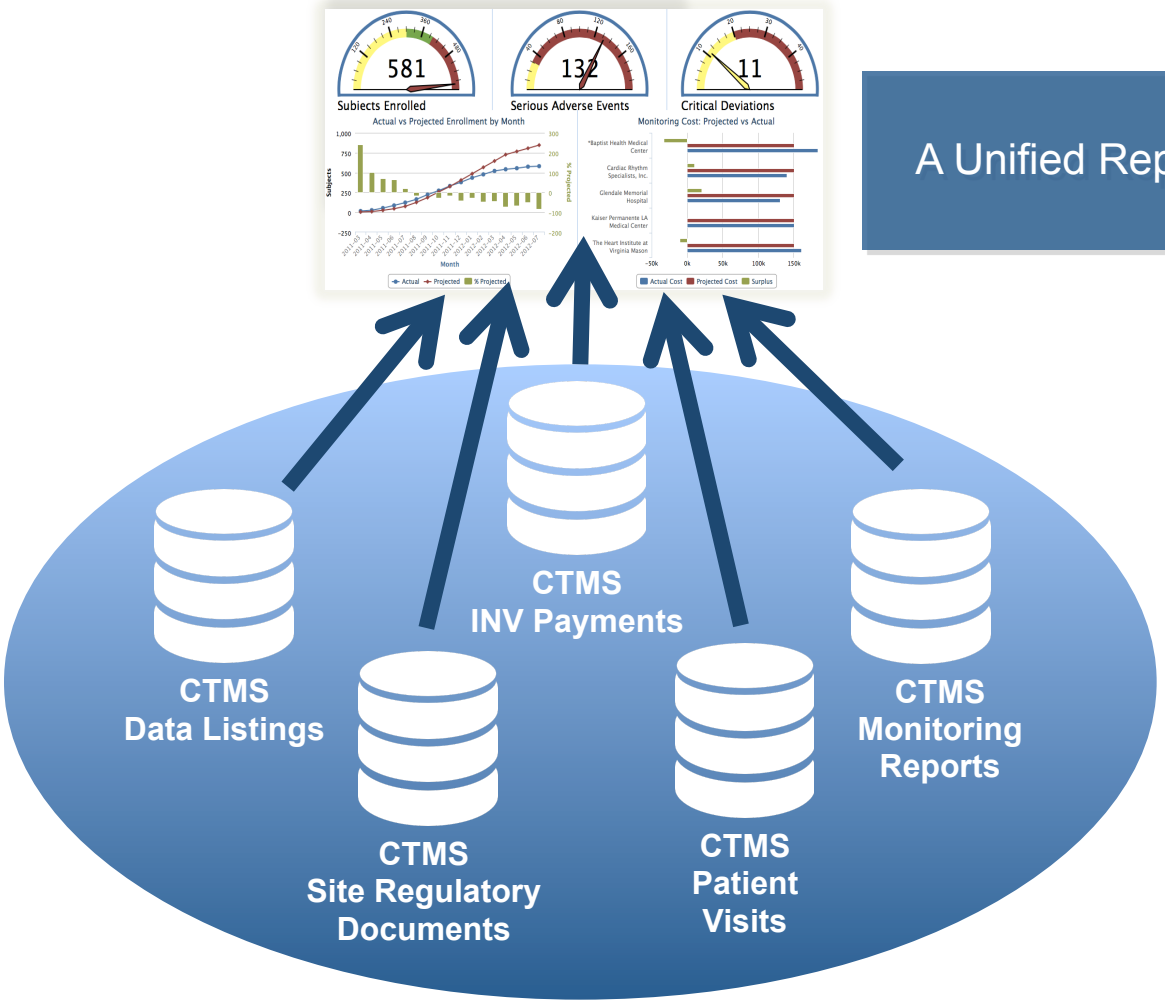
Data remain in silos

Supporting the needs of sponsors and operations was difficult

Sponsor self-support was not possible

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SaaS-based Virtual On-Demand Data Warehouse



A Unified Reporting Interface

One place for browsing and analyzing your data

Dashboards and reports are customized for each user or group's needs

Collaboration Around Analytics

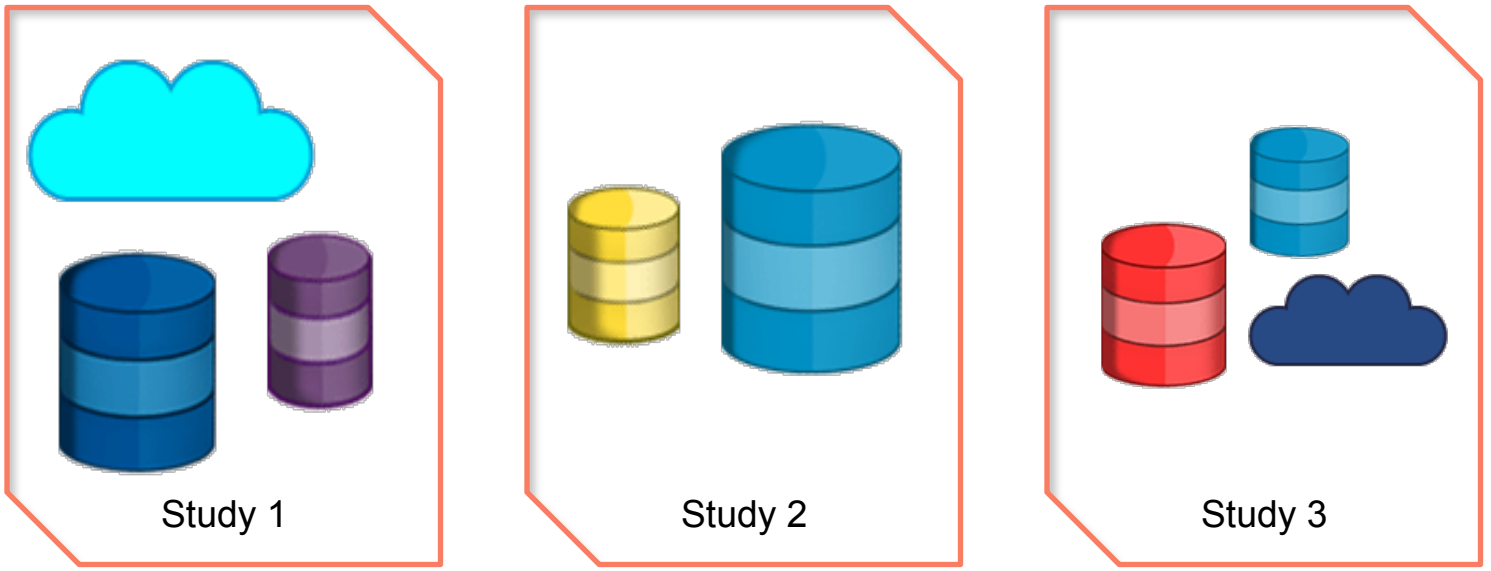
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Must Haves

- **SaaS-based** – no capital expense, no on-site installation, easy setup
- **Multi-data source access** – EDC, CTMS (TrialVista), Safety, ePro, Lab, SDTM, Excel, etc.
- **Real-time** – Cloud automatically updates information from source systems
- **Collaboration Enabled** – in application chat and task assignment
- **Technology-based offering vs. professional services-based**
- **Single Source of Truth** - data pulled directly from source systems

Typical Problem

Multitude of data collection systems, even within a single study. EDC, CTMS, ePRO, Lab, Safety, and more!



Companies Try to Solve By:



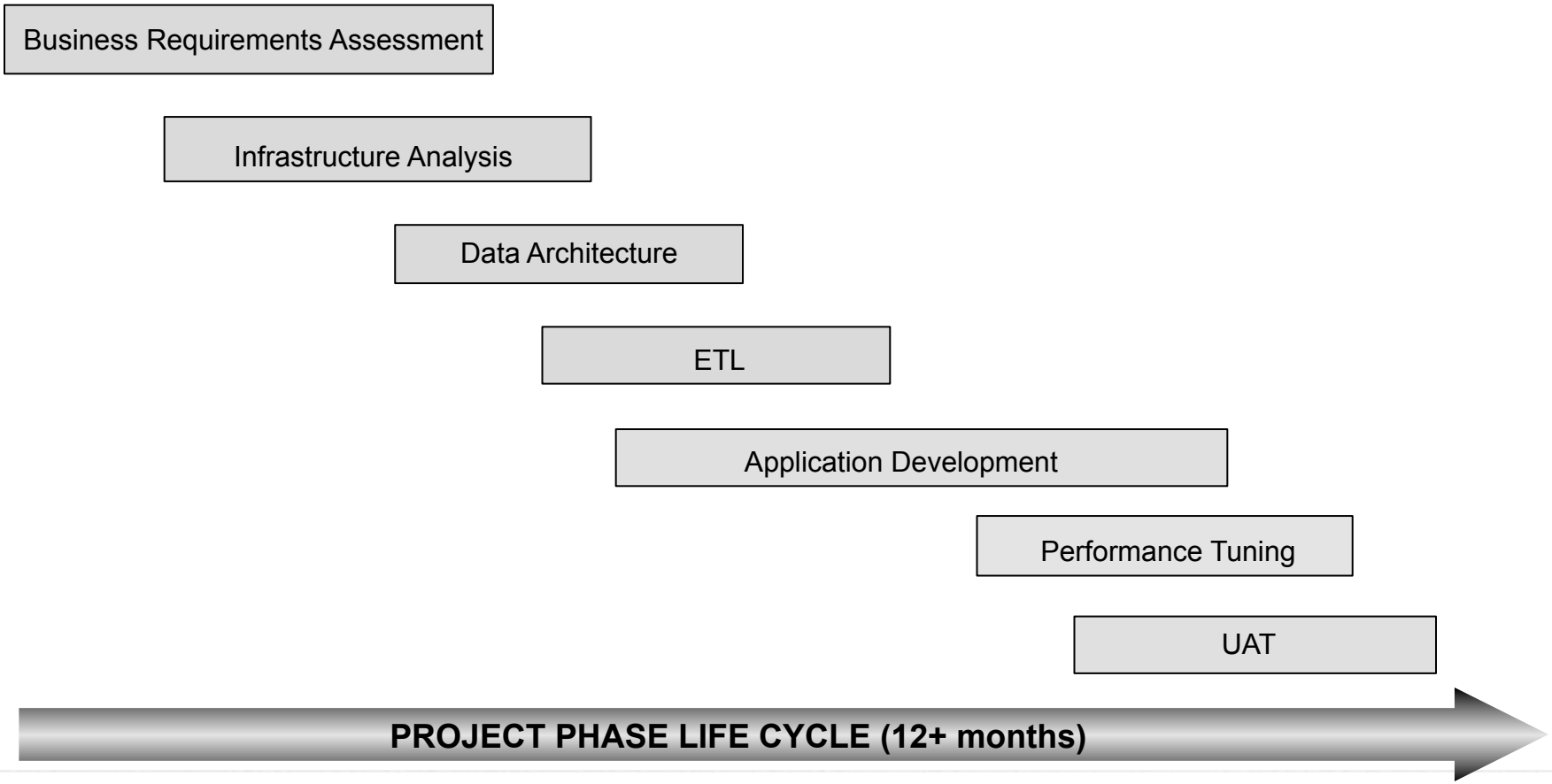
Manual processes and Excel



Data warehousing + ETL + BI tools

Traditional Data Warehouse Project

- Implementing on-site data warehouse is long, arduous, and costly



Ideal Project Implementation Milestones



- Data sources
- Data access
- Sample reports
- Business reqs
- Project scope

- Duration: 5 days

- Configure adapter
- Data source and column mapping
- Refines reqs
- (iterative)

- Duration: 2-3 weeks

- Develop reports & dashboards
- Unit testing
- Refine reqs
- (iterative)

- Duration: 1-2 weeks

- Training
- Refine system, reports, and processes

- Duration: 1-3 weeks

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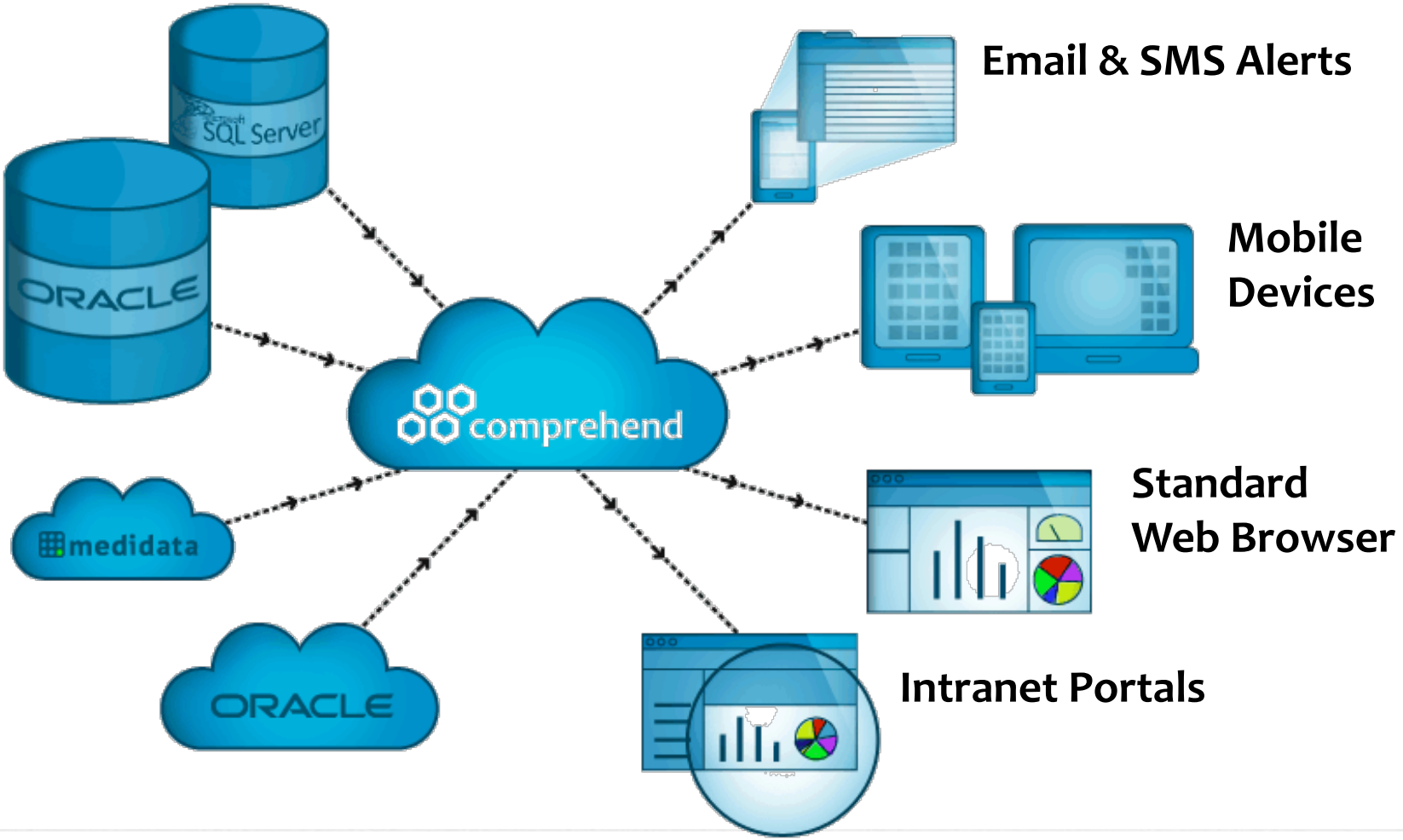
Typical Project Plan

	WK1	WK2	WK3	WK4	WK5	WK6
Define						
Configure						
Develop						
Training						
UAT						
Customer Staffing						
IT point of contact						
Business / end users						

- IT resource time: less than 20 hours total
  - Network / Infrastructure engineer and DBA
- Business user time: less than 5 hours / week
  - Subject Matter Expert

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Connect Clinical Data & Make It Accessible



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Not Business Intelligence



Happy Sponsors

"Comprehend is filling a critical unmet need and driving change in an industry that's desperate for innovation."

Sharon Shacham
President &
Chief Scientific Officer

Karyopharm Therapeutics

Eric Humphriss
Vice President of Operations

VERSARTIS

"I'm thrilled we made the decision to deploy Comprehend as part of our operations."

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Q&A

