

# Transformations

RESULTWORKS NEWSLETTER

VOLUME 15 ISSUE 3

*OF SPECIAL INTEREST:*

- **ResultWorks has moved to Plymouth Meeting, PA**
- **Technology, talent and drive to implement eSource solutions**
- **Streamlining Life Sciences Data Curation**
- **Bridging Information between Development & Manufacturing**
- **Increase information management value via RD IM strategy**
- **Tech projects should focus less on technology and more on information**

## R&D INFORMATION MANAGEMENT STRATEGY DESIGN HORIZONTALLY; BUILD VERTICALLY

### Introduction

Life Sciences R&D has historically defined, designed, and implemented vertical solutions to serve specific functional areas and needs. Frequently this was done without regard for an integrated approach. While fine at that time, companies today need to think more broadly about information management as those legacy verticalized solutions are impediments to attaining a more enterprise-wide approach to information management.

If it is going to become a reality, “enterprise” needs to be designed into information solutions. That re-

quires more horizontal designs across business functions of research and development (as well as manufacturing and other dependent functions). At the same time, value needs to be delivered to the business so that they can benefit from technology solutions. The overall approach must balance competencies, capabilities, and value to the business over longer horizons. That approach is defined in the context of a strategic framework with five key components shown in Figure 1.

### 1. Reusable Competencies & Capabilities

Competencies and capabilities are those skills, process-

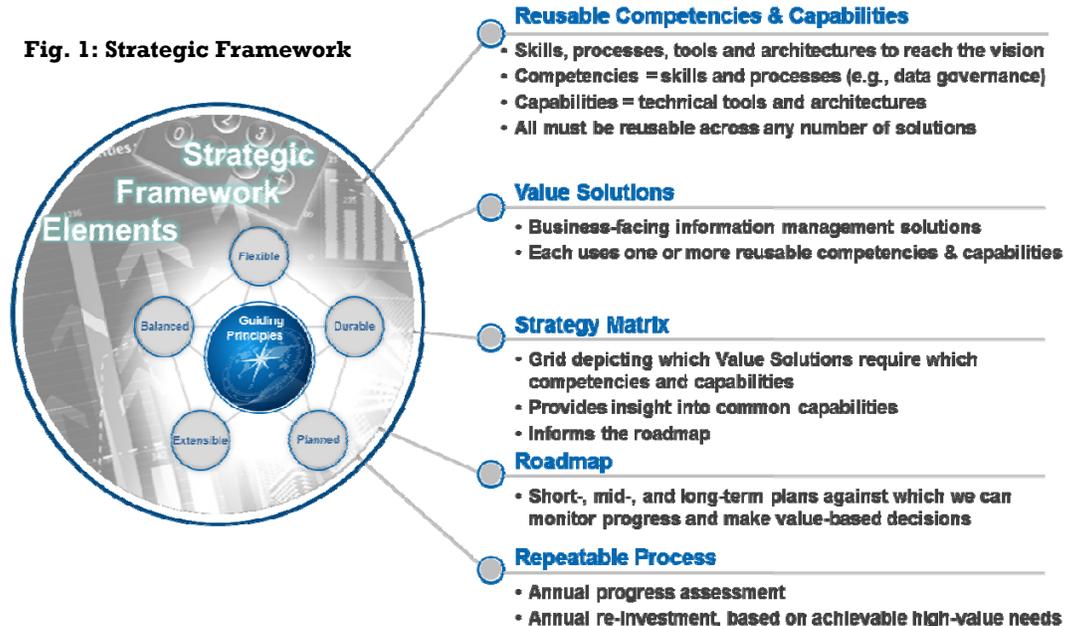
es, and technologies needed to achieve the enterprise information management vision. Examples of these are described in Figure 1. These are supported by a comprehensive technical architecture and defined technical approaches. Competencies and capabilities are built in such a way that they can be reused without significant modification while being incorporated into any number of information management business solutions. The architecture and technical approaches leverage advanced information technologies where

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**Fig. 1: Strategic Framework**







# RESULTWORKS

Transforming Strategy. Delivering Success.

## DELIVERING SUCCESS

New ResultStories (project briefs based on real world successes) are now accessible from our website. One ResultStory describes challenges with streamlining and harmonizing processes and technology to support data curation efforts across the development lifecycle. A strategy was developed accounting for data authored from different sources, common repositories for the data, and organizational alignment to adopt the processes and solutions defined. See [Streamlining Data Curation](#).

Another ResultStory describes an innovative program to tackle the information management challenges in the transfer of a drug product from development to manufacturing. One client decided to prioritize this area, go after the problems, implement solutions, and turn deficiencies into a strategic advantage. See [Bridging Information between Development & Manufacturing](#).

*“ResultWorks has done a really fantastic job of helping us tell a coherent story and develop a strategy around issues that we have been grappling with for years.”*

## RESULTWORKS NEWS

### Recent Events & Appearances:

- Hosted GPSEG Event—Outcome of BIO 2015 Convention in Philadelphia by Chris Molineau, President and CEO of the Pennsylvania Bio organization.

### Current / Recent Client Initiatives:

- Managing Clinical Content
- Laboratory Results Data Management
- Streamlining Data Curation
- Strategy to Bridge Pharmaceutical Development and Manufacturing Information Management
- Early Phase Clinical Trial Data Flow and Management
- Improving Data Quality for the Clinical Trial Registry

### We moved—Now in Plymouth Meeting, PA

Recently we moved from King of Prussia to Plymouth Meeting, PA about 20 miles outside of Philadelphia, PA. See our new address below and on our website.

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## ESOURCE BECOMING A REALITY

For the first time since electronic data capture (eDC) was introduced decades ago, the electronic information age seems to be creeping up on clinical trials, one of the last bastions of paper-based work. In a whitepaper published by the Society for Clinical Data Management entitled “[eSource Implementation in Clinical Research: A Data Management Perspective](#)”, the capture of electronic source data is becoming a reality.

For the longest time, the challenges have added up to insurmountable obstacles. At this time, we have perfect conditions to precipitate the changes necessary to make eSource come alive. These amount to technology, talent, and drive to make it work.

In most aspects, the technology exists to affect what the industry has mostly talked about since the 1980’s—capturing patient data electronically—one time at the source where it is first created. Mobile technologies make the capture possible. Cloud-based solutions make the sharing possible.

The talent pool of technology savvy clinicians today is removing people as the barrier they once were. Clinicians today are asking when, not if they can move to electronic capture of source data. Some are even jumping ahead themselves, taking the initiative to adapt tablets to otherwise paper CRF data capture. How much more effective will they be with well conceived, integrated systems?

The government push toward EHR/EMR systems in the healthcare industry as well as the underlying support for eSource is also calling companies and people to action.

The only ingredient needed now is the drive to make eSource a reality one trial at a time.

## WHY IT FUMBLES ANALYTICS PROJECTS

In a Harvard Business Review article, “[Why IT Fumbles Analytics Projects](#)”, authors Donald Marchand and Joe Peppard argue that technology projects should focus less on technology and more on information. They point out one of our challenges in the pharmaceutical industry with the massive and growing amounts of data we have is to figure out what is useful, and what is just noise.

(To read the full article, click on the link in the title above.)

## ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.