Paper FC11

Critical Success Factors in Pharmaceutical Innovation

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ABSTRACT

Technology is one of the most important factors that will influence which pharmaceutical companies prevail in the information age. Effective, efficient and timely implementation of tools that speed information delivery is a primary driver of competitive advantage. However, difficulty often arises in determining how to adopt tools and integrate them into the business. Interruptions to the business and failures in software acquisition are frequently costly, in terms of money, resources, and lost opportunities necessitating an innovation-based approach. We discuss strategy and considerations essential to matching SAS technologies with key business drivers at the corporate scale. In addition, we will discuss our vision for future software opportunities that would significantly enhance pharmaceutical research.

Below is an outline summary of this paper. The final paper will be distributed at the presentation.

INTRODUCTION

Pharmaceutical companies are in an ever-increasing contention for innovation, revenue and market share. Competitive advantage in this environment requires the ability to exploit information vertically *and* horizontally throughout the organization so that sound, timely decisions can be made. While current SAS software tools are integrated into various points in the discovery, development and sales of new therapeutic agents, there is currently no integrated platform to service informatics needs across the whole corporation.

We present a brief review of some of the SAS tools that exist today and the impact they have in pharmaceutical use. In addition, a vision will be discussed for what kinds of integrated solutions could be provided to optimize the drug discovery and development process so that pharmaceutical companies can provide better, more cost effective solutions to unmet medical needs.

UNDERSTAND THE BUSINESS

This section will discuss the importance of a holistic view of the business and the considerations necessary to innovate.

Key issues in pharmaceutical research:
- Strategy
- Technological efficiencies
- R&D
  - Pharmacogenomics
  - Predictive Modelling (In silico)

Critical Success Factors:
- Identify drivers
- Recognize needs
  - Assess context
  - Prioritize importance
  - Determine magnitude
- Understand Infrastructure
- Evaluate constraints
- Project needs
- Envision solution
- Research candidates
- Build the case
  - Decision Makers
  - Practitioners

Involve stakeholders
Secure advocates
Broadcast concept

INTEGRATE ENABLING TECHNOLOGIES

This section will describe the pharma process with a schematic of various current solutions/tools at appropriate points in the pharmaceutical development lifecycle and the impacts they have. See figure 1. We will discuss:

SAS Scientific Discovery:
- SAS Research Data Management
  - Data accessibility/management
  - Legacy system Integration
  - Regulatory Compliance
- SAS MicroArray Solution
  - Target Identification/Lead Optimization
  - Standardizing Microarray Processes
  - Data Sharing
  - Analysis
  - Visualization
  - Integration with JMP-nice feature
- SAS/Genetics
  - Relationship identification

SAS Drug Development:
- Data Integration
- Warehousing, Analysis, Reporting
- 21 CFR 11 compliance

SAS CRM for Pharma
- Campaign Design
- Targeting Channels
- Customer Identification

SAS Intellivisor for Pharma
- Optimize DTC marketing
- Marketing effectiveness

SAS Patent Portfolio Management for Pharma
- Regulatory Compliance
- Validate Financial Reports
- Manage Acquisition Risk
- Manage Litigation Risk
- Identify R&D Opportunities

INNOVATION

This section will begin with a discussion of what defines innovation, how it is incorporated into the business and describes some critical success factors for tool adoption.

Companies often strive to acquire the latest tools and technologies but if these are not effectively integrated into business processes then the investment is essentially wasted.

Success does not depend on how many tools and technologies a company has but rather how those tools and technologies are leveraged to meet informatics needs.

Competitive advantage can be gained by rapidly integrating new technologies in the workplace. A common practice is for companies to delay the implementation of new releases due to concerns over bugs and resources required to manage the conversion. A strategic decision to rapidly integrate new releases and products as quickly as possible provides innovative companies a leg up on their more conservative competition. For example, few pharmaceutical companies initially invested in Enterprise Miner to enhance drug discovery research. Those companies that chose to risk investing in the new technology gained advantage by being able to use this award winning product for years before their competitors.

Critical Success Factors for Innovation:
- Develop Strategy
- Investigate trends
- Assess options
- Advance corporate direction
- Accommodate architecture
- Further capabilities
- Require extensibility
- Incorporate business process
- Consider culture
- Recognize solutions
- Choose a tool
- Propose solution

Identify Application
Assess fit
Evaluate thoroughly
Ensure integration
Market idea
Secure buy-in
Involve vendor

IMPLEMENTATION

This section will discuss critical success factors for executing a successful implementation of tools/solutions.
Critical Success Factors for Implementation:

Think realistically
Prepare carefully
Be thorough
Be Flexible
Be Adaptive
Plan use
Deliver persuasively
Secure Funding
Provide exposure
Employ pilot
React quickly
Plan Contingencies
Supply training
Use appropriately
Demonstrate ROI

FUTURE OPPORTUNITIES

This section discusses what tools/solutions are needed to better address pharma needs in a holistic, integrated way. Problem statement: many disjoint products can be implemented across early R&D, but a comprehensive workbench is what is needed. We provide a vision for the future of an Integrated Platform for Pharmaceutical informatics. A platform for Pharma, chemical, and material sciences with the ability to define and use an abstract data type within SAS software to facilitate handling of:

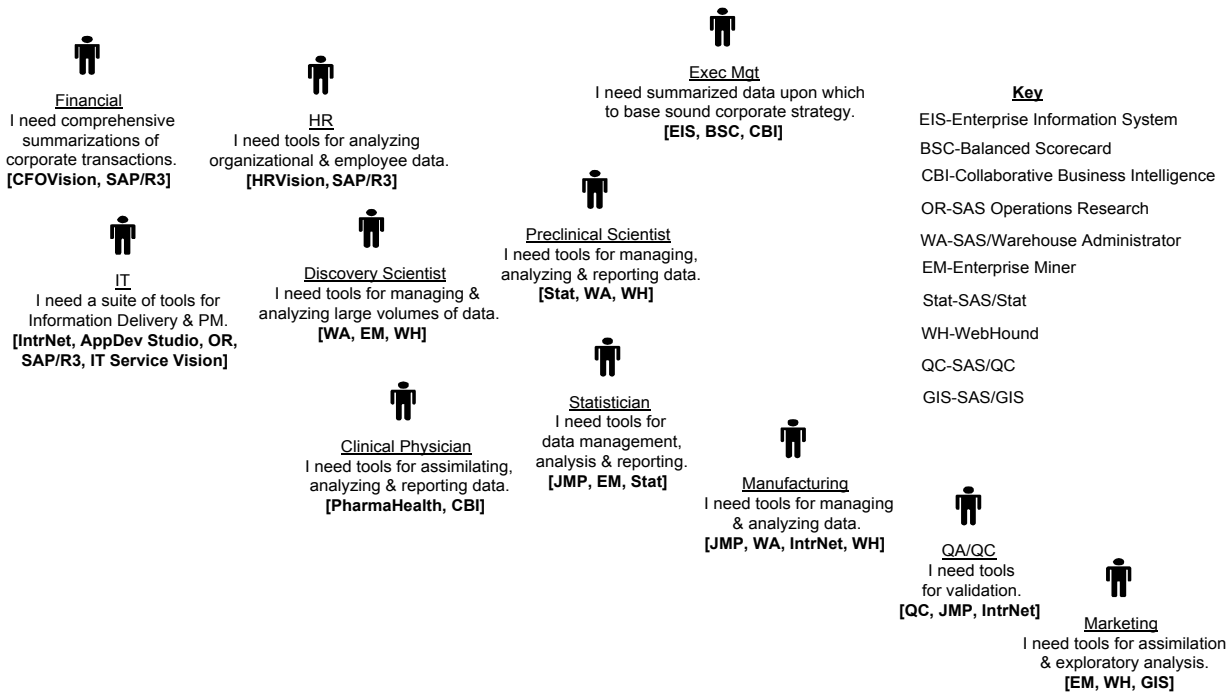
-Chemical structure
-Analytic Spectra
-Molecular formula

While SAS software has been well integrated into various components of pharmaceutical companies there are a number of areas remaining where a new SAS solution could make a significant impact. By providing solutions suitable for all facets of a pharmaceutical company one can attain a level of vertical integration once only dreamed about. A number of examples will be given where new SAS Solutions/tools could help move us to that goal. Existing non-SAS products will be mentioned to illustrate the type of technology required.

MDL (ISIS) & Pipeline Pilot-Data Search Engine
Tripos: Chemical Informatics and modeling
ID-BS (Activity Base)-Data warehousing and input engine
Accelrys-Computational Screening Support
DVS-Visualization and experimental design
Spotfire-Visualization

One of the biggest issues SAS software needs to address to become even more valuable to pharma is the ability to read and recognize chemical structure information. ISIS Software [ref] is a common platform that pharmaceutical companies rely on to access chemical structure and biological assay information. However, this software is very difficult to use, requires pre-designed forms to display data. The critical features needed for SAS software to address these needs are the ability to search, display, and print chemical structure information along with desired biological or other data coming from the warehouse.

Another area in need of enhanced solutions is in the acquisition of data. While SAS software currently provides a variety of tools to input and retrieve data from various sources there are no built in facilities to interface with common robotics systems to facilitate pharmaceutical data acquisition. ActivityBase [ref] is an example of software designed to fill this niche. However, this software contains very few statistical tools and its data mining capabilities are limited.



SUMMARY

This section contains a summary of critical success factors for pharmaceutical innovation and our vision for an integrated platform for early R&D.

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TRADEMARK NOTICE

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