



Strategy Offerings

Tribiosys is a scientific consulting company that designs and develops solutions for analyzing and managing R&D data and processes for pharmaceutical, biotechnology and medical device companies. We employ proven methodologies and best practices around quality and project management, with an experienced staff that has developed and refined these practices over many years via complex projects. Our solutions are designed with multi-tier open, adaptable architectures that leverage existing investments and integrate best-of-breed COTS solutions.

Tribiosys resources work in multi-disciplinary teams that combine scientific and informatics expertise. Tribiosys project teams are experts in the efficient use of IT methodologies to support effective R&D processes. Tribiosys' scientific staff, including Ph.D. level scientists and informaticians has expertise in bio, chemical, process and clinical informatics. Our highly skilled technical staff, including architects and software engineers, has experience in a wide variety of technology platforms, tools and technologies.

Tribiosys has aligned its offerings into four key Practice Areas:

- Scientific Computing
- Laboratory Data and Information Management
- Clinical Data and Information Management
- Regulatory Assessment and Validation

Tribiosys Strategy Offerings

Tribiosys' has a unified strategy offering that spans all the Practice Areas utilized by clients wishing to elaborate, plan, prioritize and budget for downstream projects which could yield quick returns on the investment. We conduct strategy workshops at various levels tailored to meet our clients' needs and budgets.

Some examples of the use of Tribiosys' Strategic offerings include:

1. Business, scientific and technical process identification and optimization.
2. Scientific data integration strategy, application integration and middleware technology selection and planning.
3. Commercial Off The Shelf (COTS) product identification and selection including RFP generation and management.
4. LIMS integration planning.
5. Regulatory compliance (21 CFR Part 11 etc.) and Validation (IQ, OQ, PQ) assessment and remediation planning.
6. Requirements gathering from multiple groups and stakeholders.
7. Generating Use Cases, functional and technical specifications, UI Screen mockups and other design documents.
8. Enterprise project identification and planning.
9. Business case generation and ROI estimation.

Our approach is consistent for every strategy engagement but the workshops will differ depending on the project scope and are tailored to suit client needs. The Strategy Offerings are available at three levels:

- **High-Level Discovery Workshop Strategy Offering**
This discovery workshop usually lasts one week and areas of concern are covered with IT and the stakeholders

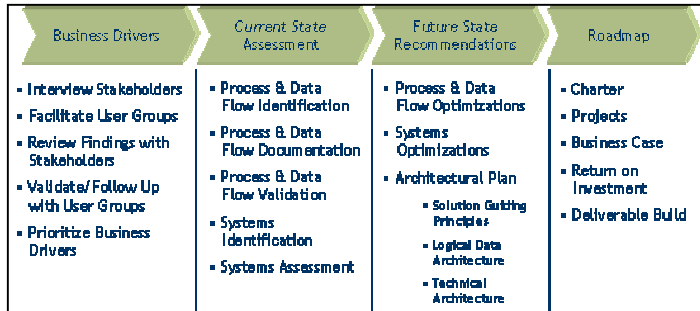
(clinical, regulatory, scientific etc.). Requirements are gathered with the input of the stakeholder experts and assessments are made at an appropriately high level. This type of strategy engagement is appropriate for companies wishing to verify their existing plans or to make a case for further initiatives.

- **Broad-Based Strategy Offering**
In this workshop the requirements, assessments and recommendations are covered in detail with all interested stakeholders over a four week period. Architecture plans are covered in detail and candidate projects with an accompanying roadmap are produced.
- **In-Depth Strategy Offering**
This strategy engagement is used by companies wishing to undertake a top-to-bottom analysis of their processes and data flows. User groups are consulted in detail and extensive planning and business case analysis takes place. The usual timeframe for this engagement is eight to twelve weeks.

	High-Level (Discovery Workshop)	Broad-Based	In-Depth
Business Requirements	High-Level	Detailed (Stakeholder Input)	Detailed (Stakeholder & User Input)
Process & Workflow Assessment	High-Level	Detailed (Stakeholder Input)	Detailed (Stakeholder & User Input)
Technology Assessment	High-Level	Detailed (IT Stakeholder)	Detailed (IT Power Users)
Process Optimizations	High-Level	Detailed	Detailed
Architecture Plan	High-Level	Detailed	Detailed
Roadmap	High-Level	Project	Program & Project
Groups	IT & Science Stakeholders	All Stakeholders	Stakeholders & Groups
Timeline	1 week	4 weeks	8 weeks
ROI		Optional	Included
Business Case		Optional	Included

A Phased Approach

All three of Tribiosys' Strategy Offerings use a phased approach to identifying, validating and designing solutions. Each phase utilizes relevant scientific, clinical, regulatory, business and technical resources to develop the specific deliverables required of that phase.



- **Business Drivers**
In this phase the business requirements are identified by the users and stakeholders in facilitated sessions. Depending on the length of the engagement, multiple rounds of requirements validation may be performed and the project stakeholders are consulted with to prioritize the business drivers.
- **Current State Assessment**
Current processes and data flows are identified, analyzed and mapped. In addition current systems in use are assessed and their interaction with the data flows and processes are determined.
- **Future State Recommendations**
Optimizations to existing processes and data flows are recommended and a system and architectural plan is created. In longer engagements the level of detail includes inter and intra-group process optimizations as well as detailed architectural plans that complement current enterprise technologies.
- **Roadmap**
The roadmap consists of candidate projects mapped to an agreed timeline. Dependencies, risks and budgetary factors are explained. The business case is presented and costs as well as potential returns on investment are calculated.

Example: Discovery Workshop Strategy Offering

High-level discovery workshops usually last one week and participants mostly consist of science, clinical, regulatory and IT stakeholders. Each day has a specific goal and the approach is geared towards the efficient gathering of requirements in the short time allotted. The following explains the day-by-day activities and deliverables of a discovery workshop.

Pre-kickoff Period

Before any workshop can begin a point-of-contact or project manager on the client side must be identified. This person is responsible for coordinating schedules, ensuring the appropriate stakeholders are available and booking meeting rooms at the client site if necessary. An agenda and schedule for the week is then drawn up.

Day One

The Tribiosys team prepares the necessary workshop material including a questionnaire that will be completed by stakeholders. Alternatively a discussion topics list will be drawn up. Both of these documents are used to discover requirements in order to determine the critical success factors. The team will also review any previous pertinent assessments as well as appropriate existing material such as process flows and system architectures. The questionnaire or discussion topics list is distributed before the end of day.

Day Two

Meetings with the appropriate stakeholders take place, usually individually to ensure better scheduling. The questionnaire/discussion topics list is used as a basis to gather pressing requirements and identify key business drivers. Executives are often consulted in a brief but focused visioning and strategy session. A functional requirements JAD session usually takes place in the afternoon.

Day Three

The process flows are mapped by the Tribiosys team and later validated with the appropriate stakeholders. Existing system architectures are also examined and future state enhancements are considered while keeping in mind the corporate enterprise technology vision.

Day Four

The material from the previous three days meetings are assembled and analyzed. Potential solutions and improvements are discussed and any outstanding points of concern or clarification are resolved. The final deliverable is prepared.

Day Five

The implementation roadmap, possible vendor recommendations and overall deliverable are finalized. A formal presentation of the discovery workshop findings and recommendations is held. An open discussion is encouraged and next steps are determined.

Deliverables

- Interview summaries and meeting minutes
- Critical Success Factors
- Key Business Drivers
- Prioritized high level requirements
- System architecture options
- Possible product vendor recommendations
- Overall solution options and presentation
- Phased implementation roadmap