

Coherent IT Strategy for Fast-Moving R&D

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What is your company's IT Strategy for R&D and how effectively is that strategy helping drive your company's success? There are nearly as many answers to those questions as there are companies in the biopharmaceutical industry.

Drug discovery and development relies critically on good information to support creativity and well-balanced progression decisions; yet often the IT organizations and systems used to support R&D have evolved piecemeal over time. This is true for big pharma seeking to support multiple locations, large science staffs, and numerous experimental technologies. It's also true for small biotechs whose IT systems grow erratically, cobbled together in bursts to support each new instrument brought in house.

Compounding these challenges are other much-discussed pressures such as: shrinking IT budgets; the constant churn of new research technologies (HTS, various omics, etc.) whose IT demands are difficult to predict; and big pharma's sudden quest for 'biotech-like' speed by loosening ties between individual research areas. In the latter case, one might ask if an R&D IT strategy spanning multiple research areas is still meaningful.

We believe developing an R&D IT strategy for biopharmaceutical enterprises — whether comprehensive or more limited in scope — is a vital exercise. It's the key tool for identifying important company goals, aligning IT strategy with those goals, and producing an implementation roadmap which, among other things, clarifies how departmental IT systems should interact to support the strategy.

What has changed in recent years — because of the pressures cited above — is the notion that strategy can be sharply separated from deployment activities. For a great many companies, the line between strategy and tactics is necessarily blurred by pressing time and resource constraints. Tessella understands this. Even major projects today generally must start showing outputs from the strategy study in 6 weeks or so; on some projects Tessella's 'agile development' approach may start almost immediately, for example, quickly tackling risk mitigation requirements (e.g. data mirroring) that can't wait while the longer-term strategy is being worked out.

Identifying major goals and winning trust from stakeholders are critical steps in strategy development

It is instructive to consider the R&D IT strategy creation process. Essentially, it's an exercise to determine goals and decide where an organization should put its shared IT resources. The examples below illustrate the scope and kinds of questions Tessella clients tackle:

- One company may decide to maximize its outsourcing activity and therefore build IT systems around widely-used industry standards to facilitate data exchange and external collaboration.
- Another may seek a better technical solution for sharing and mining data across disciplines internally, such as tools to find relationships between proteomic data and targets.
- A big client might have 160 discovery systems – of-

ten the residue of mergers and acquisition — and the challenge is to decide which are important.

Defining these goals and solutions, and prioritizing implementation projects are the keys to successful strategy building. Early identification of risks from hard-to-maintain legacy systems, some of which may rely upon the knowledge of just one or two staff, is another key requirement. Experience has shown the need to upgrade or replace these has a significant impact on sequencing the work in any project.

At this stage, gaining the trust of R&D leaders is critical and best achieved by establishing clarity around strategic goals. This requires sharing of information between projects and sites. Our experience has shown this will only happen if senior R&D leaders demand that projects go beyond their own immediate operational needs when recording and organising their results.

It is also important to hit key, early milestones so stakeholders will stay with you while you deliver the foundational systems which will later extend benefits to their functional areas. Tessella's agile development approach allows rapid delivery of business benefit by allowing information users and creators to collaborate and find the best means to reach a defined and shared business objective.

We have found in many recent drug discovery IT projects that rapid prototyping and iterative development methods such as DSDM and Scrum can clarify key requirements quickly, discovering risks in time to overcome them. Such rapid activities win needed trust, but with a caveat: small, fast-moving teams can find it hard to reach, or even identify, objectives that lie beyond the immediate sight of the responsible users.

As an independent third party with fresh eyes, Tessella is able to catalyze these projects in ways that internal teams alone often cannot. It's not only rivalry among internal groups that can impede progress, but also the distractions arising from doing their 'regular jobs'. We have extensive life science domain expertise as well as broad, cross-industry experience. Our singular focus is on helping the client build the right strategy and employing agile, rapid deployment techniques wherever possible to achieve the strategy goals.

Case history: Changing your business and systems on the fly

A recent engagement illustrates Tessella's strengths at both strategy building and rapidly tackling deployment issues. This client was literally reinventing itself from a chemistry services company to become a pharmaceutical company doing drug discovery. Many of its basic R&D processes needed to change. The client didn't want to simply reprise common practice in the industry but to find areas of competitive advantage.

Within four weeks, Tessella performed a top down review of the company's discovery processes and a bottom up review of its IT systems. The result was a new strategy and three-stage plan. Risk mitigation was tackled first, and while there were no holes in the IT systems, downsizing had left the client without some specific skills as well as vulnerability related to equipment. Interim measures were taken quickly prior to more comprehensive change to be rolled out over time.

The second stage tackled needed process modifications. For example, making greater use of their IDBS ActivityBase systems to hold late stage data; ensuring they were capturing the right information at the right time; and longer term, determining how to integrate the data more effectively to enhance decision-making.

This client already had a flat data structure which greatly facilitates moving data upstream or downstream. We felt this was a competitive advantage and didn't want to break it with any new system deployed. Conversely, we identified processes they could stop doing since they were no longer producing large libraries of chemicals for customers.

A common challenge is determining when to use off-the-shelf software and when to develop custom solutions, discussed more fully below. In this instance, Tessella suggested using an off-the-shelf (OTS) package for a document management solution able to handle regulatory submissions. We led an RFI effort that looked at 16 candidates and quickly settled on one, completing the process in 8 weeks. We now have someone onsite working on IQ/PQ (installation qualification/operational qualification). An OTS solution worked here, but isn't always the best choice.

Delivering business value and establishing appropriate metrics keeps projects on track

Clients frequently ask about ROI and how to measure it. That can be challenging because a fair amount of time must usually pass before it's possible to demonstrate ROI. But there are certainly metrics for business value delivered. Time is one, and it can be measured several ways including time to deployment and also process time saved. Cost is another. Quality is a third metric, and here, for example, you might be looking at compound collection quality as measured against Lipinski's Rule of Five.

A more subtle quality measure is the quality of decision making, so for example, the ability to pull together all of the relevant information at the point where you choose a lead or candidate or something like that and make a better decision. Defining these measures of business value and their associated milestones is typically part of the strategy building process.

Perhaps the core issue in pharmaceutical R&D IT today is the challenge of developing tools and governance practices to ensure the right data is aggregated and shared more widely to improve and speed decision making. Broadly labelled 'translational medicine', this imperative touches all R&D IT strategy, and of course, reaches into the clinic as well.

R&D pipeline quality benefits from knowledge integration through proactive management and a 'federated' infrastructure

It's clear that sustained improvement in R&D performance requires use of one project's results, positive or negative, as learning toward a future project's success. This increasingly means pulling information upstream against the flow of the R&D process. Upstream information flow can help pipeline quality in several ways:

- Clinical chemistry results may carry clues to mechanism or future side-effects, useful to the next discovery project.
- Patterns of activity across multiple targets, studied in different research projects or areas, can in-

dicating safety margins.

- Linking targets, pathways and disease interventions may allow re-purposing of drugs already approved for other indications that have an established safety record.
- Feedback on the prevalence of different failure modes can be used to determine what effort to apply in 'de-risking' projects; while all tests are eventually performed, the most effective plans examine the high-risk areas first¹.

We have found that stimulating this upstream flow usually takes active intervention by management. A knowledge sharing 'contract' is often a useful device to encourage project teams to release and organise information needed by others.

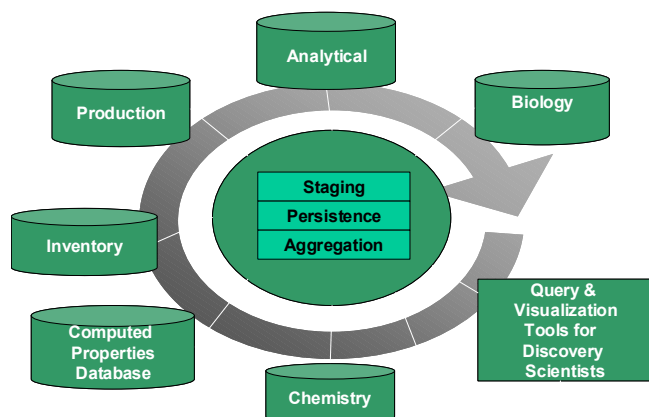
Still, such cross-project knowledge management can meet resistance for a variety of reasons such as: no two projects are quite the same; changes in assay protocols cause differences in the data; summarising and contrasting similar but not entirely equivalent results is difficult.

Generally, the resistance to sharing data can be overcome if its mutual benefits are made clear, but the practical key to open information doors between projects is investment in meta-data:

- Identify commonalities in pathways and mechanisms, to compare projects.
- Pool reliability and calibration information to compare assay effectiveness.
- Agree on data definitions to allow the pooling of results, at the summary level, that may have been obtained at many different places at times and even different experimental systems.
- Perform success, failure and root cause analysis.

Accomplishing this takes effort and the benefits must be sold to busy project and line managers. What's more, worldwide standardisation of data and IT including use of strict data standards is feasible, indeed essential, in Phase 3 clinical trials, but not realistic in a 'discovery' culture. In our experience, a federated approach is more practicable.

¹ Test cost and time, as well as contribution to risk reduction, come into the planning equation. The prior view on risk will differ between research areas, within a company, but the underlying hazards at the compound or target level are independent of the research organisation, so there are opportunities for cross-site sharing.



A 'federated' database architecture is a set of heterogeneous databases that, through common meta-data, can provide a unified search. It allows much wider use of commercial packages to meet local and tactical needs.

Use of commercial packages requires compromises but releases effort from the IT organisation, to support true innovation

Our R&D clients increasingly ask us to specify and source commercial packages, e.g. instrument data capture, sample management (requesting and inventory). These days, who builds a chemical search application in-house? Use of such packages avoids much effort on requirements capture, as they satisfy the basic, common needs of the whole industry. This saves time, reduces risks and builds the essential user trust in delivery by the IT organisation.

However, choice of a commercial package can frustrate efforts towards a single technical architecture or standard (e.g. open source, or service oriented architecture). Unlike manufacturing and financial there is no dominant 'enterprise research system', and perhaps never could be. R&D work is varied, and so uses diverse packages. Overlaps, such as between the scope of electronic lab notebooks and LIMS packages, can complicate planning and require clarity on the information model and standards for interfacing (e.g. SoA).

A further perspective is that while it's often possible to find commercial software that works quite nicely, you can only be as good as the competitors who also have the same packages. We recommend that you focus the available manpower for IT custom build within Discovery groups into two areas:

- New science that is a source of R&D process innovation and differentiation, such as reproducible processing and objective interpretation of complex biomarker data.
- New knowledge that comes from search over multiple results.

Conclusion

Putting value on an IT strategy is easier if there is an end-to-end view, from target to market, of the causes and effects of good and bad information and good and bad decisions. This forges the essential link between science, information, IT and the business that must fund the IT investment. Tessella understands these issues. We have worked with hundreds of biopharmaceutical companies, helping them build R&D IT strategies and deploy systems around their particular set of goals.

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