Implementing a Digital Transformation

By: Chuck Donnelly and Julie Morrison, (RockStep Solutions Inc.)

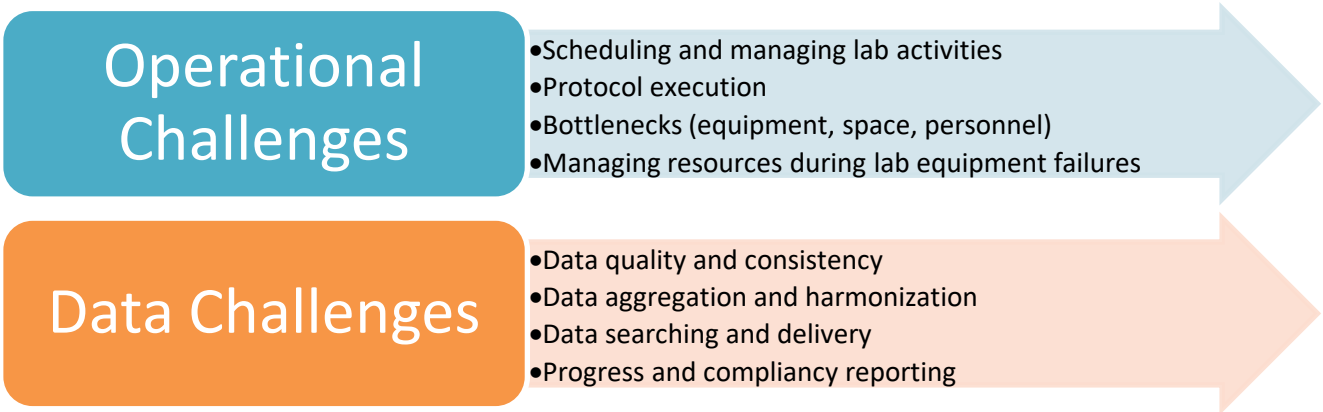
Why Digital Transformation

Is your organization under pressure to improve discovery ROI? According to a 2014 report from the Tufts University Center for the Study of Drug Development, the average cost of going from chemical compound to FDA approved drug is **$2.7B**, and roughly only 1 in 1000 leads makes it to final approval. According to Nature Reviews, the average cost for lead optimization and preclinical in-vivo studies alone is over $0.5B per compound.

Small improvements in efficiency can save millions of dollars annually. In most cases, the need to improve efficiencies and boost quality is imperative for an organization's survival. According to Deloitte 2017, ROI for drug discovery R&D is dropping precipitously, down from 10.1% in 2010 to 3.2% in 2017, for large cap biopharma.

To reverse this downward ROI trend, reducing the number of false starts and improving speed in discovery via digital transformation will be required. Some easy improvements can be implemented immediately to address operational and data inefficiencies. These first steps themselves, if managed correctly, will have quick ROI.

Consider the following challenges encountered in many preclinical R&D departments.



Many pharma, biotech, and CRO companies still manage R&D communications through email and Slack channels. Task-lists and protocols are created in spreadsheets and sent out to the discovery team members by email. Data are collected in spreadsheets, stored in share folders, and delivered via email. This system works okay for small operations but breaks down at scale.

If you are a lab manager or study director, you may be uncertain about study progress and resource usage. When operations go sideways, managing lab crisis or conducting investigations is stressful and difficult.

If these challenges sound familiar, it is probably because your lab informatics system is based on spreadsheets, share folders and emails, or an ad-hoc collection of informatics tools that don't talk to each other. It's time to begin a digital transformation in your organization.

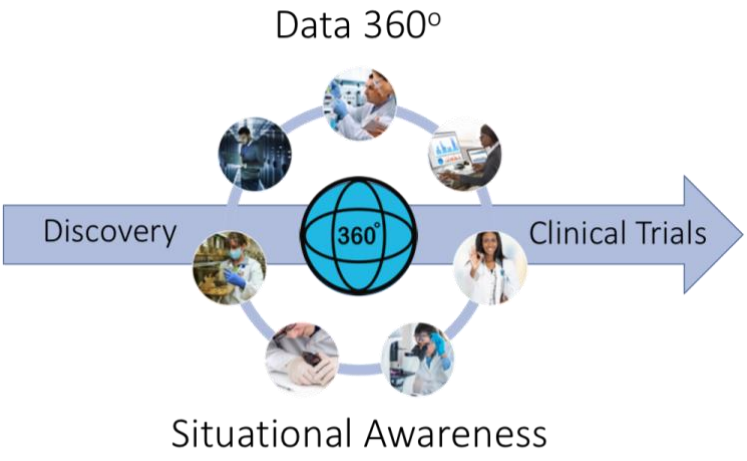
Digitalization: Data 360º and Situational Awareness

What does *digitalize* mean? An everyday example can help. Consider your travel experience. Not long ago, you booked your plane, hotel, car rentals, and entertainment plans separately. Today, one travel application books all of these for you and creates one itinerary. Your smartphone follows your travel and sends location alerts to cloud systems with AI algorithms that help guide you to your destination. When you get off the plane, your rental car or Lyft is waiting for you. The travel industry is *digitalized*.

MIT Sloan Management Review

A blend of technologies, including airline tracking systems, ride share tracking systems with GPS, and digital maps are integrated to your smartphone and serve as your digital travel assistant (DTA). Your DTA has awareness of where you are at all times (*situational awareness*). While on the move, your DTA recommends directions, with alternate routes, and food options based on your personal preferences. Your digital "exhaust" leaves a trail showing where you were, what route you took to get there, what you ate for dinner, etc. It is easy to mine these data to get a *data 360º* view of any point in time in your travels.

When it comes to digitalization, research labs have not kept pace with travel and other consumer industries. However, lab digitalization is an emerging IT discipline. **The goal of lab digitalization is to assist lab managers with situational awareness to support real-time decision making, manage operations, and to give scientists a *data 360º* view into their studies.** Machine Learning and AI algorithms can provide operational guidance and suggest alternate strategies. For example, suppose a piece of lab equipment fails in the middle of a busy day, and you need to re-task your team to complete priority work through this unplanned equipment bottleneck. You need to consider where others are in their work, what their priorities are for completing tasks, what the risks are for everyone, and what is now possible to complete today. Situational awareness with AI tools operating on data 360º can recommend options and help you make key decisions quickly with the best possible outcomes.



Data 360º is a byproduct of digitalization and goes hand-in-glove with situational awareness. Data 360º implies that for any important object in your research study, you should be able drill into the study database for all pertinent information related to that object. Consider, for example, an aging study using laboratory mice. If one cohort of mice has an unusually long health span, scientists will want to learn everything about that cohort going back to when the study began. They will want to know about their genetics, animal housing, environmental conditions inside the cages, light/dark cycles in the animal rooms, exercise, noise, diet, water intake, handlers, bedding, etc. over the course of years. With these data, they can then set up follow-on experiments to validate the results and/or modify parameters to learn more. In the lab, data 360º applies to individual animals, cohorts, whole studies, specific tests within a protocol, or any other important research object.

Where to Start

The challenges of successful digital transformation are social, business-related, and technical. Digital transformation is a chasm crossing of sorts. If executed poorly, you will fail and fall into the chasm, wasting resources and potentially damaging your business. If you choose not to undertake a digital transformation, you will remain stuck on the wrong side of the chasm watching your competitors, who have successfully crossed and advanced their businesses at your organization's expense. Depending on an organization's current state of technical maturity and culture for change, the path may be easier for one organization than another.

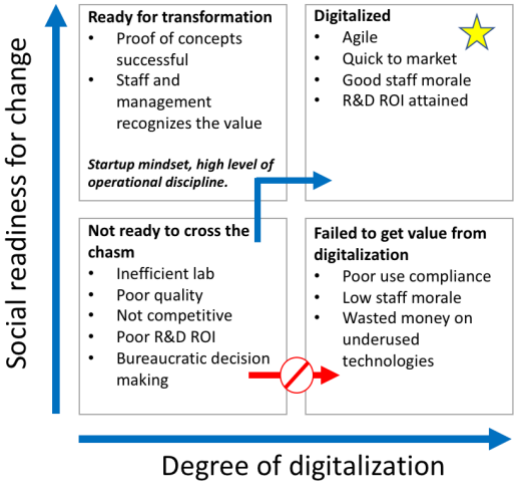


Figure 1: The path to digitalization requires social readiness in your company. Companies with startup mind sets and disciplined processes will have a higher chance of successful digital transformation.

The first step is to assess your company's cultural readiness for change. If your company has a startup culture for innovation coupled with a high level of operational discipline, you are most prepared to make the crossing. If your company has a lot of bureaucracy with sluggish decision-making processes, your work will be more difficult (Figure 1). Dealing with organizational culture change is beyond the scope of this blog article, but you need to be aware that social readiness is key to success.

Where you start depends on your most pressing needs. The authors of this article recommend engaging technology consultants, such as Gartner, Accenture, EPAM, or Ernst and Young, to help guide your technical architecture. If there are pressing needs for technology that can't wait, identify systems that are built with the lab of the future in mind (e.g. select pure cloud applications over on-premises or cloud hosted applications).

Organizations taking on digital transformation will often create a new full-time position for a technology visionary with a title like *Head of Emerging Technologies* or *Head of Digital Transformation.* This position will lead a cross-department process engaging scientific stakeholders and IT staff alike. They will initially need to create process and architecture maps documenting current operations and desired future-state operations.

With process maps completed and future states under consideration, the hard part begins. You need to develop business cases and analyze the costs of the technologies and the costs of change. Look for areas where you can get quick wins and launch a proof of concept (POC) with well-defined success metrics. You will need to get quick momentum to convince the skeptics. Tech startup companies are good partners in this transformation process since they are agile, move quickly, and are innovation leaders.

Once you have some small wins, use the captured data to develop KPIs for measuring progress and success in preparation for presentation to high-level business stakeholders.

Keep in mind that deployments, even POCs, must be well managed by experienced project managers so they do not run over budget and/or miss their targets killing your organization's appetite for technology and process change. If the POC fails, the company may fall into the transformation chasm or run back to the other side.

Where to Look for Business Value

It is key to define clear business value with KPIs to measure your progress. Business value will come from improved security, quality, efficiencies, and/or enabling research that was not possible before the transformation. Here are a few tips:

Operations: Ask your lab teams to quantify how much time is wasted by resource conflicts, resource waste, or unclear directions.

The data tsunami: Learn about the challenges of searching data. Most labs have tons of data but can't find it. Is it sometimes easier to redo a study than try to find data that has already been captured?

Chain of custody: Does your organization know who did what, when, what animals were used, what reagent lots were used, and how long each task took? If you can't easily answer those questions for any study going back to any point in time, you will have difficulty reporting for compliance and conducting research investigations.

Data security and data sharing: How easy is it for your organization to securely share data within your organization, across your global sites, and with collaborators? Can you audit who viewed what data and when?

Conclusions

Industry winners will digitalize before their competitors. The goal is to maximize the value of your data to drive discovery forward, improve efficiency and quality, and get to market faster. Waiting to digitalize will put your organization at a competitive disadvantage, and failure during digital transformation can drain resources and reduce an organization's appetite for change. The path to success of transformation will depend on your organization's ability to manage change, define business cases, and execute on new technology. Technology startups are leading innovators and should be seriously considered as major players in your transformation.