

BEYOND VENDOR SCORECARDS:

A PRACTICAL METHODOLOGY FOR ELECTRONIC LABORATORY NOTEBOOK (ELN) SELECTION

Making the right choice demands the right domain knowledge

From small academic centers to large pharmaceutical companies, the use of digital technology in scientific research is on the rise. Electronic laboratory notebooks (ELNs), in particular, are a central component of the digital lab. ELNs are rapidly replacing paper notebooks across the pharmaceutical industry, seeing uptake even in the academic sector (partly due to the advent of viable opensource solutions)1. In its latest report titled, "Electronic Lab Notebook Market: Global Industry Analysis and Opportunity Assessment, 2016-2026", Future Market Insights (FMI) offers a ten-year forecast for global electronic lab notebook market between 2016 and 2026. FMI forecasts the global electronic lab notebook (ELN) market to grow at 10.1% CAGR during the forecast period 2016-2026, and is forecasted to hold a market value of \$615.2 million by 2026². Contrast that with the more mature ERP software market. In a recent report published by Allied Market Research, the global market for ERP software is expected to register a CAGR of just 7.2% during the period 2014-20203. Though ELNs have been around for nearly twenty years, the demand for solutions is growing, as R&D, contract, and commercial labs alike move to stay competitive by leveraging efficiencies associated with a digital lab.

With the stakes so high, how do you ensure that you make the right decision for your organization? Using a traditional vendor scorecard approach often just isn't sufficient for making the decision, because a mix of quantitative and qualitative metrics is needed. For scientists, the ELN is the lifeblood of research and the place where so much time is spent; therefore, sentiments and opinions matter. The trick is to balance opinions with real quantifiable metrics, to ensure buy-in and drive the right decision.

'Guerrero, Santiago et al. "Analysis and Implementation of an Electronic Laboratory Notebook in a Biomedical Research Institute." Published: Aug. 1, 2016. Available at: http://journals.plos.org/plosone/article/id=10.1371/journal.pone.0160428. 2"Electronic Lab Notebook (ELN) Market: Academic End User Segment Projected to Increase at the Highest Growth Rate: Global Industry Analysis and Opportunity Assessment, 2016-2026". 3"ERP Software Market is Expected to Reach \$41.69 Billion, Globally, by 2020." Available at www.alliedmarketresearch.com/press-release/global-ERP-software-market-is-expected-to-reach-41-69-billion-by-2020.html.

WHO CAN TAKE ADVANTAGE OF THIS METHODOLOGY?

- Any organization evaluating or purchasing electronic laboratory notebooks
- Executives seeking to standardize on laboratory informatics vendor selection methodologies
- Project teams faced with specific laboratory informatics vendor selection initiatives

CHALLENGES:

TIME:

- 3-to-6-month cycle time
- 9 months average elapsed time

RESOURCES:

• 5-10 persons on decision team

COST:

 Selection costs 20% to 40% of total vendor costs (software and services)

RISK:

- An inappropriate selection
- Potential project failure
- Negative impact on business processes
- Loss of time and money
- Procurement is challenged with providing a fair, competitive process to support the organization

Like so many other efforts, success comes with preparation and thorough planning. Whether you are transitioning from paper or upgrading to a new system, there are a number of steps you can take to ensure that you make an informed, measured decision that is right for your organization. Let's explore a few of the pre-requisites that you want to check off prior to embarking on a formal selection process.

PRE-REQUISITE #1: Understand the critical requirements

The first step is understanding your key requirements, from the business user community as well as from an IT infrastructure/strategic fit standpoint. Knowing what you want from an ELN up front can keep you on track (and on budget) when it comes time to do a vendor evaluation and make a final selection. Similarly, knowing what you're measuring a current vendor against can help you provide feedback while promoting an environment of transparency and continuous improvement. The must-have requirements will form the basis for much of the evaluation. You may wonder, is it necessary to conduct a full requirements gathering exercise prior to the vendor selection process? The answer is no, not likely. What you will need to do is to understand the major software features/categories that will drive the selection process. Often, this comes down to understanding the functional areas that the ELN must support and how they are working today. Synthetic chemists who currently have an ELN, for example, are not likely to give up critical functionality around structure handling. Therefore, the new system must have a baseline of features that support the workflows already in place. Paper-based workflows are easier to replace, generally speaking, but a prioritization is still critical for formulating the right selection criteria. It is likely you will not be able to replace all paper workflows (especially in an initial implementation), so it is important to take a pragmatic approach and perform due diligence around which workflows provide the greatest ROI for the organization. Beyond satisfying the business requirements, the system architecture and integration needs will also drive the decision-making progress. Do you want to work in the cloud? But do you also have heavy equipment integration requirements? What about security and being able to open up the platform to collaborators in Asia? These are all essential questions that a system architect can and must help you navigate.

PRE-REQUISITE #2: Build a cross-functional team to make the decision

A common mistake is to limit the process to a narrow group of stakeholders, such as the immediate user community. While this may make the selection process simpler today, it may result in a short-sited decision with lasting consequences for the organization. For example, as the organization scales, will you need to open up the ELN for use to CROs and other global partner organizations? Without including key stakeholders in IT, including enterprise architects, you may be wooed by functionality that suits your needs today, but inadvertently select a platform that does not enable robust, secure collaboration in the future. It is advisable to build a decision team or task force with stakeholders who will be impacted by the ELN, both in the short-term and long-term. For example, let's say you do not need to validate the system for GxP use today, but that is something you anticipate in the future. It is critical to include quality assurance representatives in the conversation early, so they can help you assess the "GxP readiness" of a platform. In most organizations, you will want to include representatives from the business community, IT, procurement, quality, and perhaps other organizations who may need read-only access to the information (such as legal). In addition to the right qualifications, it is critically important to ensure that you have organizational and management buy-in for the effort prior to assembling a selection team. Too often, task force members simply do not have the time to contribute adequately to the effort. The selection process should be managed like other any project, with dedicated resources fully committed with backing from the organization.

PRE-REQUISITE #3: Perform a stakeholder and criticality analysis

Now that you have a team in place, performing a stakeholder and criticality analysis can be very helpful to perform **prior** to formalizing the ELN selection methodology. Why? To be successful, you have to ensure you have stakeholder agreement (to minimize any adverse impact) and resources to implement changes and achieve desired business outcomes. You want to avoid having unnecessary delays in implementing the system, while making the appropriate linkages early to mitigate the impact on other critical business activities. It comes down to the following: do you understand who the ELN will impact (and how) and have you considered the level of criticality of that impact? Answering those two questions for the critical stakeholders will help drive consensus on the selection methodology.

In practical terms, business areas with the greatest impact should drive the selection process. But it is also critical not to forget anyone and to remember that frequency of use does not necessarily map to business criticality. Your legal team, for example, may not be actively involved in the day-to-day use of the ELN. In fact, they may have only read-only access or access through reported information. However, the impact of the ELN on the legal team is likely to be business critical, particularly for early-stage discoveries that the company needs to protect.

For illustrative purposes, here is an example of criterion for business criticality. This should be tailored to meet the needs and specific requirements of your organization. By linking the criticality of the system to the stakeholders, you have a way to rank the impact, in turn providing a basis for weighting quantitative criteria in the selection model.

Table 1. Assessing the criticality of the system to the stakeholder community (for illustrative purposes).

LEVEL	CRITERIA 1	CRITERIA 2
Business Critical	Estimated that it has critical effects on data quality, safety, or business outcomes	Is related to GxP or impacts regulatory compliance (related to audit/inspection findings)
Business Impacting	Process alignment (new role, task re-allocation or organizational change)	Process improvement including fixes of IT system validation gaps
Business Routine	Changes in role or title	Other administrative changes

THE SELECTION METHODOLOGY

Astrix has developed a robust, customizable methodology that can be used for ELN selection or most any laboratory informatics platforms. The methodology includes both a quantitative and qualitative component and covers a comprehensive set of criteria that have proved to be the most important across many ELN selection projects.

The idea here is to develop a selection tool that includes the most important features of the ELN system (and their business criticality) and use that, together with several other selection criteria, to score the vendors on a quantitative basis. The scoring involves using weighted values (specific to each organization), which in turn reflects the importance to the organization. Assuming you have built a cross-functional selection team, you may delegate certain aspects of the evaluation to different groups. The business community, for



example, is in the best position to assess the software features, while the IT organization may be better equipped to assess the technical capabilities. If you have multiple departments involved in the decision, it is critical to have at least one delegate from each area who is empowered (and responsible) for representing its opinions.

Note that there are many ways to assess the software features/usability. You may start with a vendor demonstration, followed by a pilot period. It is important to take the time you need to understand the features and functions prior to completing the assessment.

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SCORE THE VENDORS

Once the selection tool is complete, it is time to score the vendors. As mentioned, it is important to do the due diligence on the vendor, platform and its functionality prior to scoring. This will involve discussions with the vendor, demonstrations, and likely testing of the software.

POST-SCORING: Have we got it right?

Now that you have the scores, it is best practice to challenge the results, particularly if the data are not pointing strongly to one choice over another. The qualitative assessment process is designed to support and reinforce the findings from the quantitative assessment. Through a series of interviews which involve review of the quantitative findings, the qualitative analysis seeks to uncover any inconsistencies between the data collected and the user sentiment. Did users generally prefer one vendor, even though certain functions from their system were scored appreciably lower? It is important to understand if the quantitative analysis is sufficient to stand on its own. Were there other areas of importance that were not covered, or perhaps some of the weightings in the model need to be corrected to reflect reality? All of these considerations are important for ensuring alignment on the decision and buy-in from the immediate team as well as the extended user community.

CONCLUSION:

If all of this seems like a big endeavor, it is. There is a lot involved in making the right decision, but the efforts here are not wasted and should assist in moving the implementation phase forward once the selection process is complete. The stakeholder assessment and criticality analysis can help you stage the project to ensure that the roll-out is successful and the most critical needs are covered, for example. It can also separate the "must-haves" from the "nice-to-haves" and eliminate the need for drawn out discussions when timelines are looming. In addition, having a fair, balanced and transparent process for selection of a critical platform such as the ELN will help support the change that is to come. In the end, the project team is left with a defensible, cross-functional story to support vendor selection and justify key decisions.

ASTRIX CAN HELP

Our clients save time and expense while reducing the risks associated with ELN technology selection. We can help you tailor the approach to the specific needs of your organization. With an out-of-thebox methodology and flexible selection tool, we can help you save as much as two-thirds of the time required to do ELN vendor selection. Benefits of this approach include:



- Up to two-thirds less time spent based on our leverageable methodology.
- Decision tools for vendor selection enables project teams to make better, faster and more cost-effective decisions through definition of a comprehensive set of criteria and provide best practices structure and weighting of decision criteria.
- Promotes collaboration Gain critically important internal collaboration necessary to reach the right decision in a timely manner.
- Vendor neutrality Working with a neutral third party such as Astrix means that project team
 members don't have to bet their careers on a vendor selection process that may be influenced by
 vendor hype, politics and the disparate backgrounds of members of the decision team.

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Astrix Technology Group is an informatics consulting, professional services and staffing company dedicated to servicing the scientific community for over 20 years. We shape our clients' future, combining deep scientific insight with the understanding of how technology and people will impact the scientific industries. Our focus on issues related to value engineered solutions, on demand resource and domain requirements, flexible and scalable operating and business models helps our clients find future value and growth in scientific domains. Whether focused on strategies for Laboratories, IT or Staffing, Astrix has the people, skills and experience to effectively shape client value. We offer highly objective points of view on Enterprise Informatics, Laboratory Operations, Healthcare IT and Scientific Staffing with an emphasis on business and technology, leveraging our deep industry experience.