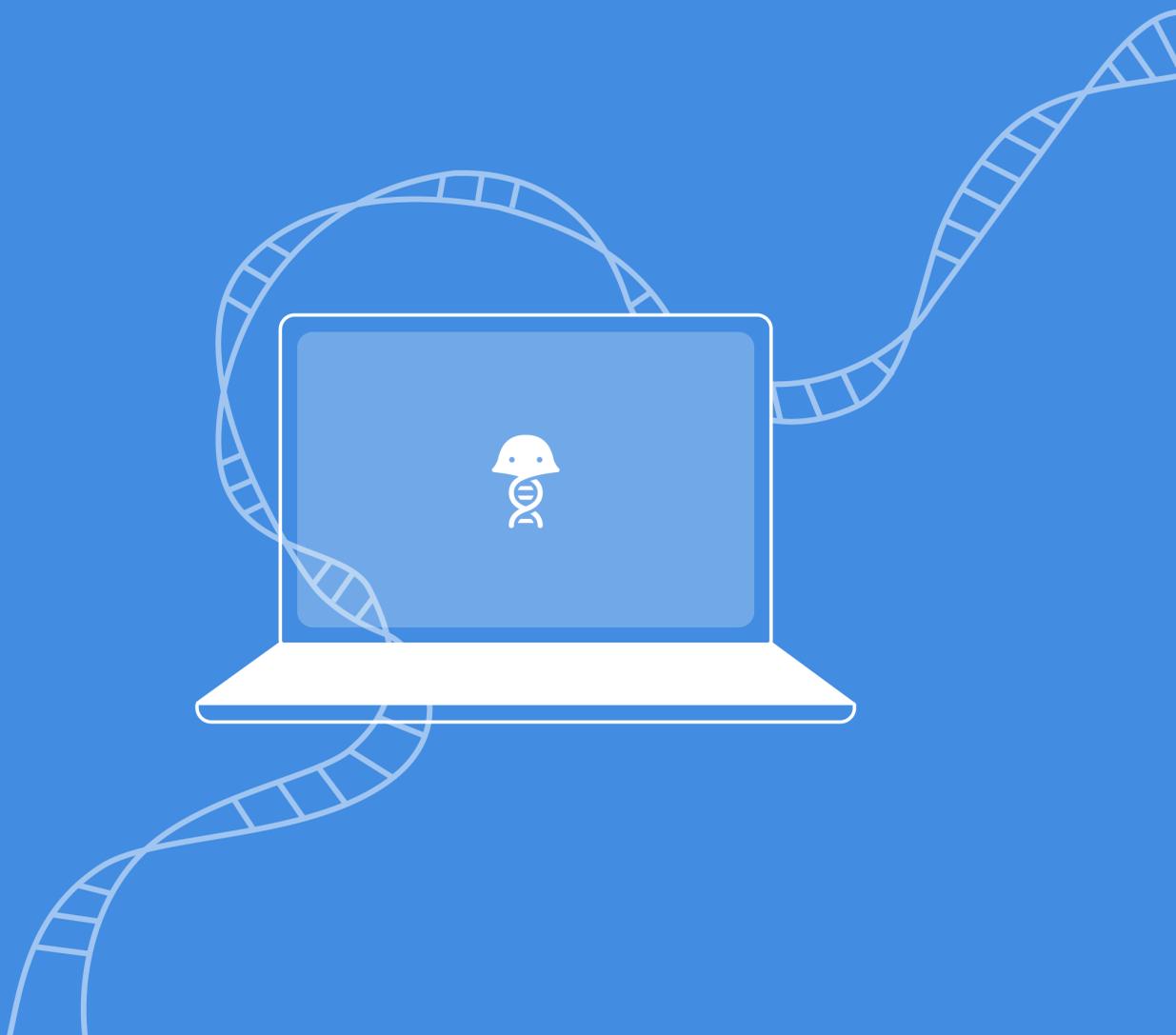




How to Select an ELN for Biology R&D



Overview

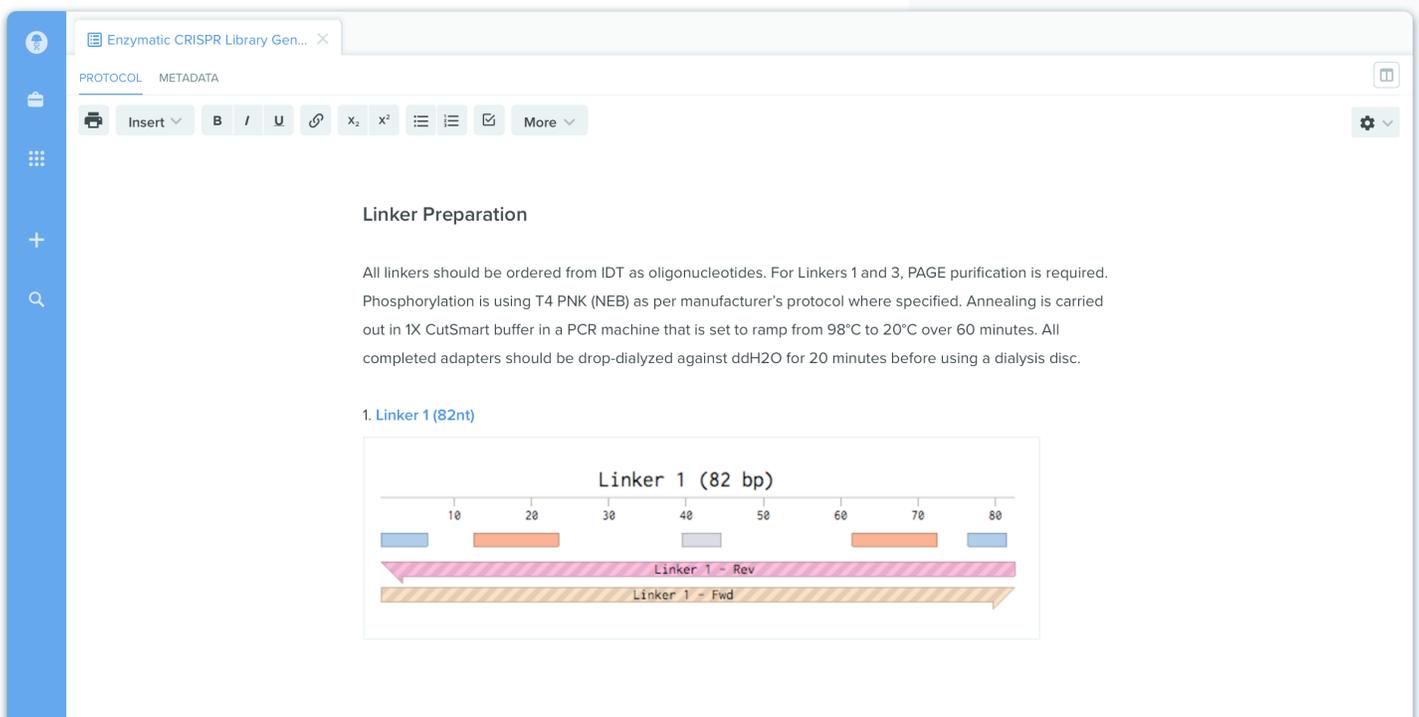
With drug discovery trending towards heightened costs, complexity, and collaboration, ensuring that your R&D organization has the best tools possible for documenting research is more important than ever. But for many scientists and informatics professionals, the electronic lab notebook (ELN) sourcing and evaluation process is complex and murky. It involves a lot of moving parts without a clear market standard to assess against, but the stakes are clear. Implementing an ELN-centric informatics solution is an integral part of ensuring that an R&D organization runs at full efficiency, but if the wrong ELN is implemented, it runs the risk of generating inefficiency, a lack of adoption, and insufficient integration with other systems.

Through our market research with heads of IT and research, as well as various industry consultants, we've assembled this biology ELN-centric guide to:

1. Outline the process for assessing the need for an ELN
2. Provide an overview of the types of ELNs, along with their various benefits
3. Trace the sourcing process through requirements assessment and market research
4. Share industry best practices for vendor evaluation
5. Elaborate on success criteria to ensure ongoing ELN health

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2. Sourcing the Best Solutions
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4. Conclusion

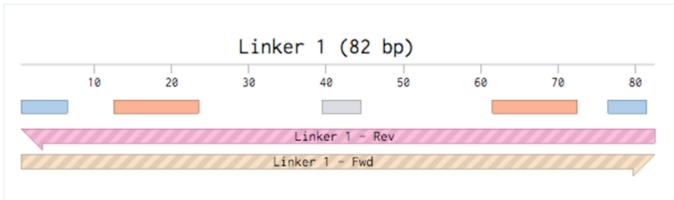


The screenshot shows a web-based interface for an Electronic Lab Notebook (ELN). The browser tab is titled "Enzymatic CRISPR Library Gen...". The interface has a blue sidebar on the left with icons for home, search, and other functions. The main content area is titled "Enzymatic CRISPR Library Gen..." and has tabs for "PROTOCOL" and "METADATA". Below the tabs is a rich text editor toolbar with options like "Insert", "Bold", "Italic", "Underline", "Link", "List", "Text Color", and "Background Color". The main text area contains the following content:

Linker Preparation

All linkers should be ordered from IDT as oligonucleotides. For Linkers 1 and 3, PAGE purification is required. Phosphorylation is using T4 PNK (NEB) as per manufacturer's protocol where specified. Annealing is carried out in 1X CutSmart buffer in a PCR machine that is set to ramp from 98°C to 20°C over 60 minutes. All completed adapters should be drop-dialyzed against ddH₂O for 20 minutes before using a dialysis disc.

1. [Linker 1 \(82nt\)](#)



The diagram illustrates the structure of Linker 1, which is 82 base pairs (bp) long. It shows a sequence of colored blocks representing different components: a blue block at the start, an orange block, a grey block, another orange block, and a final blue block. Below this sequence, two arrows indicate the orientation of the linker: a pink arrow labeled "Linker 1 - Rev" pointing to the left, and a brown arrow labeled "Linker 1 - Fwd" pointing to the right. The x-axis is labeled "Linker 1 (82 bp)" and has numerical markers at 10, 20, 30, 40, 50, 60, 70, and 80.

Assessing the Need for an ELN Solution

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2. Gap Assessment
3. Types of ELNs

Overview

Electronic lab notebooks – from standalone tools to integrated ELN-centric informatics platforms – come in all shapes and sizes. But before deciding what sort of ELN is right for you, you have to identify the need for an ELN in the first place.

Should I Consider an ELN?

For companies without an ELN, there might be some uncertainty over how necessary such a system is. This is understandable, especially if the company is relatively young or if R&D seems to be running fairly smoothly without an ELN. The right ELN, though, can have a profoundly positive impact on a company's productivity and data management practices, as well as make documentation accessible in a scalable manner. Deciding whether ELNs are worth looking into involves deciding whether the long term value of data management, organized record keeping, data access, and ability to manage your company's IP is worth the time spent on the selection, evaluation, and implementation process, as well as the time and money spent on training and maintenance for the ELN.

Especially when a company is just beginning to build out its informatics infrastructure, it's vital to recognize which informatics needs an ELN is meant to address, rather than the needs that, say, a LIMS is meant to address. Of course, an ELN isn't necessarily a holistic informatics solution, and it might be the case that your informatics needs would actually be better addressed by a system other than an ELN. For example, if your company's primary informatics issue is to keep track of numerous aliquots and reagents, then a LIMS or bioregistration system would be better suited than an ELN. As we will discuss, performing a gap assessment, getting a high-level understanding of the different types of ELNs, and soliciting informatics feedback from stakeholders and your broader network will help you identify the informatics problems that you need to address and, then, the type of informatics system best suited to address those problems.

To get a better sense of what companies hope to get out of their ELNs, as well as an outline of the success criteria that any company should be using to assess the health of an existing ELN, skip to the section titled "Measuring an ELN's Success" at the end of this eBook. For companies with an ELN already in place, those success metrics can help you determine whether it's worthwhile to consider an ELN update, but they shouldn't be the sole deciding factor. To supplement them, solicit feedback from everyone whose workflow is touched by the ELN, ask them if they've used any preferable solutions in the past, and reach out to your network beyond your company to compare the success of your existing ELN against theirs.

Gap Assessment

Conducting a preliminary gap assessment involves interviewing representatives of each ELN stakeholder group. An ELN stakeholder is anybody whose workflow is touched by the ELN. Oftentimes there are more stakeholders than you might think; included among them are bench scientists and heads of research, as well as people in informatics or legal.

A preliminary gap assessment should determine just where your existing solution falls short. Ask the stakeholders how they've used the solution over the last 12 months, as well as what the must-have features and main pain points of the existing solution are. Then, ask them what sort of work they envision doing over the next 24-36 months, and how this work would or wouldn't be accommodated by the existing solution. Based on these pain points, determine what an optimized version of the stakeholders' workflow would look like. If there are sufficient gaps between this optimized workflow and what the ELN is capable of delivering, it's a sign that an ELN upgrade may be in order.

Types of ELNs

Before defining search criteria and beginning the ELN sourcing process, it's helpful to understand the ELN landscape in broad terms. Although the following categories aren't by any means strict, ELNs generally tend to fall into one of these buckets. Understanding the pros and cons of each will help you enter the criteria development and sourcing process with a clear framework.

ACADEMIC FREEWARE ELNS

These solutions offer streamlined functionality in a browser-based experience. They vary significantly in terms of their collaboration and review functionality, as well as the extent to which they can be integrated with existing informatics tools and instruments.

PROS

- Most affordable
- Tend to be user-friendly
- Sometimes, more frequent releases of new versions
- Operating system independent

CONS

- Limited functionality not always aligned with scientific needs
- Can't always meaningfully integrate with other tools
- Frequent releases of new versions aren't a sure thing
- Security concerns for low-rent cloud solutions
- Limited functionality for large/complex organizations

LEGACY DESKTOP APPLICATIONS

These are the ELNs that scientists have grown to know. They're "heavyweight" desktop applications that companies historically made large investments in (typically, they cost 50-150% more than cloud-based solutions, along with additional maintenance and upgrade costs) to support extensive informatics infrastructures. Unlike their academic freeware counterparts, they have no shortage of features, which can make them complex and difficult to use, albeit comprehensive.

PROS

- Extensive features
- Support for intricate integrations
- Long track record in pharma

CONS

- Costly to maintain
- Less frequent releases of new versions
- Not always accessible on all operating systems
- Potentially low user compliance
- Costly subscription, implementation, and upgrades

CLOUD-BASED PLATFORMS

The newest of the three categories, these ELNs combine the ease-of-use and accessibility of freeware solutions with the features and integration capabilities of desktop applications. Being part of a platform solution, they come seamlessly unified with other informatics software, such as bioregistration, workflow management, and molecular biology tools, making for new, cross-functional possibilities.

PROS

- Extensive features
- User-friendly
- Enhanced visibility through native and additional integrations
- More frequent releases of new versions
- Potential to only use the necessary elements of the platform
- Operating system independent

CONS

- Costly subscription
- Track record isn't as extensive
- Must ensure the system offers robust APIs for integration capabilities

Beyond particular functional and budgetary concerns, choosing the right category will depend on how much value your company places on the familiarity of a legacy solution relative to the potential to be an early adopter of the next wave of ELNs. Obviously, investing in an ELN that doesn't work today but might work tomorrow isn't always a wise move, but there are alternatives to the ELNs of yesterday.

In answering this question, consider your high-level integration and security requirements. Do you only need to pull data out of the ELN, or do you also need to push data from instruments, or from a sophisticated data analysis system? If you need to push as well as pull data with your ELN solution, you'll have to make sure that your eventual solution is either locally hosted, offers a single-tenant environment (where only your company's work occupies a cloud system's particular database), or offers a robust API for integrations.

Regarding security, how important is storing data locally to your company? In the past, companies have had concerns about the security of cloud solutions, but they're seeing accelerating adoption throughout biotech and pharma. Another security feature to look for is whether the system allows for centralized authentication with other tools. When an ELN-centric informatics system offers this sort of integration, scientists can use a single sign on (SSO) across applications. It's easier to keep track of individual scientists' work and make sure that if a scientist leaves the company, their account is properly deactivated.



Sourcing the Best Solutions

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2. Requirements Analysis
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Overview

After deciding to proceed with an ELN selection process and sussing out the high-level needs of your organization through a gap assessment, it's time to drill down and formalize the particulars of your requirements. Before you begin to source and solicit demos from vendors, however, it's a good idea to decide whether or not you have the bandwidth to manage the entire ELN selection, evaluation, and implementation process.

Considering Consultants

Sourcing the right consultant can be just as daunting as sourcing the right ELN. However, the time saved by hiring the right consultant – particularly for small or emerging biotech companies – , not to mention the value added by their thoroughness and expertise, can make it well worth it.

In particular, hiring an IT consultant to manage sourcing and evaluation for an ELN-based informatics platform can be helpful when a company doesn't have the informatics resources necessary to carry out the process on their own. Beyond not having an established informatics department, a company might be saddled with a particularly complex, poorly documented informatics system that they need a separate, experienced pair of eyes to assess.

Sourcing potential consultants is best handled by leveraging one's network, searching LinkedIn, and reading up on industry reports, which often contain lists of IT consultants and case studies of their past work. When selecting an IT consultant, the two main things to keep in mind are the consultant's track record in vendor selection for companies similar to yours, and the thoroughness of their documentation. You want to be sure that all of their work, as well as the reasoning behind it, is clearly documented so that your own informatics staff can refer back to it. Nothing is more frustrating than when, after a lengthy sourcing and evaluation process, a company is left with a system that's completely unfamiliar to them, and with which they can't familiarize new informatics staff.

Requirements Analysis

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2. Determine must-have functionality for each stakeholder type
3. Project stakeholder requirements out 24-36 months
4. Generate documentation for findings
5. Pass requirements back to stakeholders

IDENTIFY ALL ELN END USERS

If you've decided to undertake an ELN selection and evaluation process without the help of a consultant, the next step is to formalize the conclusions of your gap assessment. If you don't have an ELN already in place, now is the time to identify all potential ELN stakeholders (from scientists to legal) and to determine how they would use an ELN solution in their day-to-day.

DETERMINE MUST-HAVE FUNCTIONALITY FOR EACH STAKEHOLDER TYPE

For this process, it benefits you to be as detailed as possible. What precisely are the features that each stakeholder can't live without on a daily basis? What precisely are the functions that each stakeholder wishes they had access to? Gain a complete understanding of each place the ELN touches or would touch the workflow of each stakeholder, and list out in clear terms exactly what an ideal ELN would have to do.

PROJECT STAKEHOLDER REQUIREMENTS OUT 24-36 MONTHS

An ELN is a long-term investment. It's of little help to get a solution that works for only your present workflows if your workflows are slated to change significantly. Project the requirements of each stakeholder out 24-36 months to identify further must-haves for an ELN.

GENERATE DOCUMENTATION FOR FINDINGS

Based on this assessment, generate documentation clearly listing out the must-haves for each stakeholder. Keep in mind that these requirements aren't entirely informed by the possibilities of existing software and it's unlikely that any solution will perfectly meet every requirement, so they shouldn't be hard-and-fast sticking points later in the process.

PASS REQUIREMENTS BACK TO STAKEHOLDERS

Ranking and refining requirements will come later, but before sourcing vendors, pass the requirements documentation that you produce back to the stakeholders that have been involved in the process so far. Maintaining clarity and obtaining sign-off from everyone involved will ensure that everyone stays on the same page throughout the process.

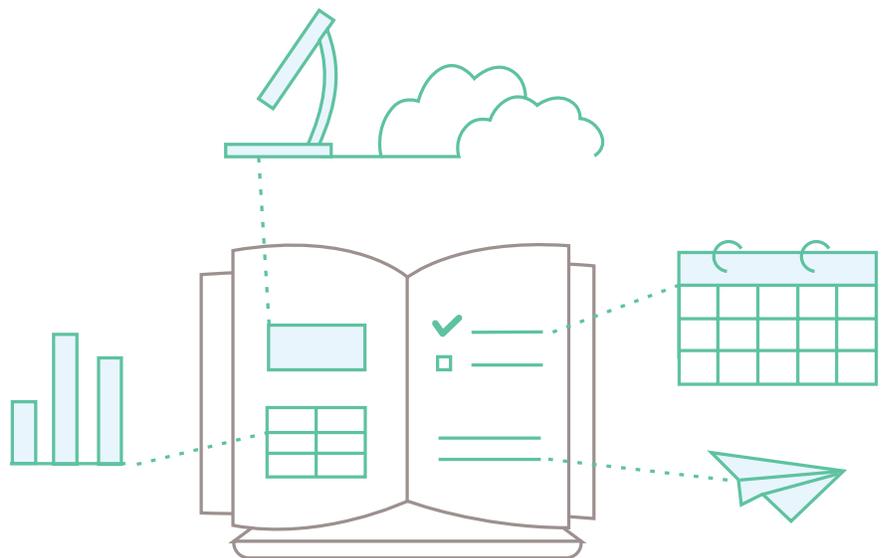
Market Research

With your requirements list and your preliminary bucketing of potential ELN solutions as your guides, it's time to begin identifying potential vendors. The sources for these vendors are pretty much endless: Google, LinkedIn groups, your existing network, your stakeholders, trade shows, the list goes on. This is the least cut-and-dry element of the process, but more than anything, the breadth of your initial search matters.

Especially for newer cutting-edge solutions, there are several up-and-coming vendors that don't have as strong a market presence as some of the legacy solutions. If you're going after these solutions, the more you leverage your network, the better; don't just ask which solutions a contact is using, ask which solutions they considered before they settled on their current solutions. It could be that the solutions they turned down are a better fit for your company, and by doing this, you'll be fully leveraging

others' past market research for your own company.

For each vendor that looks like a potential fit, send them an edited version of your requirements document that doesn't disclose any confidential information, and request details of how their product could meet those requirements. After analyzing the vendor responses, it should be more or less clear which vendors might fit your needs and which definitely do not. Together with representatives of each stakeholder group, identify the four or five most promising vendors and invite them to give a product overview. Limiting your evaluation at this next stage to four or five vendors will ensure that you can give each of them the diligence that the evaluation requires.



Evaluating ELN Vendors

Overview

The high-level requirements document that you generated before commencing market research was informed by stakeholders' needs, but not entirely by the capabilities of software. The evaluation stage is where the two must meet and compromise.

Ensuring that all stakeholders have a say at every stage of this process is integral to making sure that you settle on a solution that works for everybody. Even if it's not perfect for everybody, it's important to make sure everyone has their fair say and understands why and how you ultimately come to your final decision.

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4. Day-Long Workshops and Final Reevaluation
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Product Overviews

KEY TAKEAWAYS

- Based on vendor responses, invite four or five vendors to give an overview
- Invite representatives of all stakeholders to overviews
- Record overviews for easy reference
- Together, evaluate overviews based on their ability to meet your requirements and narrow down to two or three contenders

Having identified the four or five most promising vendors based on their responses to your requirements document, invite them to give an overview of their suite of products, focusing on the tools that are of highest interest to your company. Be sure to invite representatives of all relevant stakeholder groups to these overviews. Evaluate them based on their ability to match the requirements laid out in your document, but again, don't necessarily disqualify a solution just because it lacks or only partially accommodates one of your must-haves at this stage.

However, do keep in mind that vendors structure these product overviews to present themselves in the best light and often tailor them to the use case of their potential customer. If a vendor's overview seems to be absolutely perfect, it might be too good to be true; on the other hand, if a vendor's overview just doesn't seem to be the right fit, that's likely the case.

After a few product overviews, it's easy to lose track of the details setting each product apart, regardless of how differentiated the products might actually be. A good way to help keep track of these differences, as well as reference them in future internal discussions, is to record each overview. This is also helpful if a

stakeholder misses an overview and needs to get caught up to speed, or if any additional stakeholders want visibility into the process.

Furthermore, since the evaluation process can tend to stretch on for a few weeks, having a video to reference makes it much easier later on when the overview might no longer be fresh in stakeholders' minds. It can certainly be frustrating when you have to ask for a second overview because you forgot what was covered in the first one.

Having reviewed the overviews, the team of stakeholders should come together to discuss each vendor and narrow the field of four or five down to two or three main contenders.

Use Case Demos and Technical Assessment

KEY TAKEAWAYS

- Devise and ask remaining vendors to accommodate one or two day-to-day use cases in their product
- Focus on *what* the software has to accomplish rather than *how* you think it should accomplish it
- Assess the solutions' technical capabilities alongside your own security, availability, and integration needs

Having narrowed the field, the stakeholders' next task is to write out one or two key use cases that they'd like to see the vendors implement in their systems. These use cases should reflect, in as specific terms as possible, the day-to-day tasks that stakeholders need to be able to accomplish using a potential ELN system. They should be designed to make sure that the solution can accommodate particular tasks that your company needs to accomplish.

Often, companies make the mistake of composing these uses cases based on specifically *how* they want the software to function rather than *what* they want the software to accomplish. Instead of saying, "The ELN has to let us insert text boxes on images," it's more effective to say, "The ELN has to let us annotate images in some way." The solution might not be structured exactly as you imagine, but as long as there is a workable solution, its structure might not make much of a difference.

After putting together one or two of these use cases, relay them back to the vendors and give them a week or two to prepare for an in-depth walkthrough of how each use case would appear in their system.

Use case demos are helpful for evaluating functionality from a scientist's perspective, but simultaneous to these, task a relevant informatics employee with conducting a technical assessment of the potential solutions. This evaluation should comprise security, availability, and integration capabilities. Depending on your needs, the questions to be asking at this stage might revolve around if the solution's SSO can integrate with your authentication system, if its backups are encrypted and geographically isolated from main systems, if downtime is required for routine updates, and if its APIs are sufficient for the sorts of integrations that will be necessary for your scientists. Obviously, if a solution doesn't line up with your technical needs, the features that it offers to scientists might not matter.

Weighted Decision Matrix

KEY TAKEAWAYS

- Develop weighted decision matrix to identify relative importance of various ELN functions
- Underscore primary needs rather than search for a solution that's perfect
- Use weighted decision matrix to focus conversation rather than be the be-all, end-all for a decision

Before the final use case demos, you need a more refined way of measuring the vendors' success. Now that you have a good idea of the functionality that's out there and that might be important to your use cases, put together a weighted decision matrix that lists out all the values that an ELN should have, as well as how important each of those values is.

Example categories might include core functionality, security, and ease of deployment, with each category weighted based on its overall importance and broken down into specific features that you think will be necessary to support your workflows. A weighted decision matrix can also include a "nice-to-haves" section. Each feature should be assigned a numerical value based on if a particular solution supports it, with these numerical values being weighted and added up to generate a value reflecting the solution's

overall fit. The final value generated should serve as a guide for evaluating the use case demos, but a difference of a point or two between solutions shouldn't make or break a buying decision.

Rather than serve as a list of inflexible needs, a weighted decision matrix should help you identify your primary needs so that your ELN evaluation doesn't get derailed searching for a perfect solution that doesn't exist. It's highly unlikely that any ELN will have every single feature you're looking for (and even less likely that it would structure all that functionality in exactly the way you imagine), but an ELN evaluation shouldn't be about finding some mythical solution; it should be about identifying your needs and finding the solution that best meets them.

An additional value of the weighted decision matrix is to align the decision-

making criteria of all stakeholders involved. Stakeholders should sign off on a decision matrix before the use case demos so that everyone's on the same page going in. In all situations, the matrix should be the facilitator, rather than the decider, of discussions.

An example of a weighted decision matrix. Note how there are columns for multiple vendors, which makes it easy to compare across vendors in the same sheet.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1														
2			Weighted Decision Matrix											
3														
4														
5														
6			Core Functionality	Category Weight	Topic Weight									
7		1.1	Strong biology support including molecular biology functionality to support sequence design	30	30									
8		1.2	Support for free form input to design experiments		10									
9		1.2	Ability to integrate with Reg and Inventory systems		10									
10		1.3	Ability to store and manage assay dev data		10									
11		1.4	Robust, secure collaboration tools incl. notebook sharing (incl. audit trails).		10									
12		1.5	Configurable witnessing workflows including reminders and alerts.		10									
13		1.6	Support for experiment templates and protocols		10									
14		1.7	Web-based to allow secure collaboration across sites (incl. CROs)		10									
15														
16					0	0	0	0					Score in Category	
17														
18			Vendor Assessment	15										
19		2.1	Proven record of successful ELN deployments		20									
20		2.2	Reference checks - vendor provided and TRV		20									
21		2.3	Technology stack assessment		10									
22		2.4	Implementation and long term support strategy (same team?)		15									
23		2.5	Domain expertise required for successful implementation.		15									
24		2.6	"gut-feeling" score		20									
25						0	0	0					Score in Category	

Day-Long Workshops and Final Selection

KEY TAKEAWAYS

- Pick one or two vendors for a day-long, scripted workshop
- Solicit feedback based on how close the product comes to achieving an optimized workflow
- Collate evaluators' feedback and adjust weighted decision matrix
- Reconvene to decide on a final vendor

After evaluating the use case demos with the weighted decision matrix focusing the discussion, it's time to pick at most two vendors for a day-long, scripted workshop. At this stage, certain companies and consultants prefer to organize a 1-2 week hands-on evaluation for various stakeholder groups, but because stakeholders are typically still occupied by their day-to-day work, this approach can run into low compliance and uneven feedback.

Beyond solving the problems of compliance and uneven feedback, a day-long, scripted workshop can also give you an idea of how effective a vendor's training procedures are, and of how intuitive the product is in use. To do this, work together with a vendor to develop multiple roughly 2-hour workshops that cover primary use cases for various stakeholder groups. Be sure to align this script with your weighted decision matrix. Ask the vendor to come on-site and run your stakeholder groups through each session, soliciting feedback from your stakeholders after the workshops have completed.

Next, analyze your evaluators' feedback and adjust the weighted decision matrix accordingly. It might be the case that your original matrix criteria were off because particular features ended up being more or less important than you expected. Be sure to get stakeholder approval for these adjustments to the matrix, and again, using the matrix as a guide to facilitate the discussion (in tandem with evaluators' feedback), reconvene with the other stakeholder representatives to decide on a final vendor.

Measuring an ELN's Success

Now that you've adopted a new ELN, it's important that you continuously measure its success. Of course, the needs of companies differ, and so the places where ELNs succeed or come up short do as well. There are, however, a few common ways to measure the success of an ELN so that you make sure you're using your new tool to its fullest.

SCIENTIST USAGE

It may seem obvious, but one rule of thumb that holds true across organizations for assessing the success of an ELN is the number of scientists using it and the number of experiments being created. No solution will ever see universal adoption, and although scientists might get their data into a mandatory solution eventually, a high rate of scientists actively using an ELN on a daily basis is a strong indicator of scientists' happiness with the solution. Make sure to track not only the number of users but the frequency of their use.

COMPENSATORY TOOLS

When an ELN isn't sufficiently functional or user-friendly, scientists look elsewhere for tools that can compensate. They might record their experiments in a paper notebook and then scan the pages into their ELN, or they might even record their experiments in another ELN before exporting those entries into the "official" ELN.

In both of these cases, the scientist might appear to be a dedicated ELN user based on their activity, but recording notes in multiple systems raises a security and transparency risk. An effective ELN will give managers a way to assess this tendency, such as visibility into scientists' entries, and ensure that documentation is in line with best practices.

IMPACT ON PRODUCTIVITY AND COST SAVINGS

Different companies track productivity differently; an established biopharma company might track the total investment of time and capital necessary to bring a new drug to market, while an emerging company might track the average time between experimental results and data entry, or the rate at which decision-quality data is generated. It might seem doubtful that an ELN could really have a measurable impact on drug development costs, but several studies have reported that scientists spend roughly 30% of their time in the lab on busy work such as note-taking. Similarly, research heads who are satisfied with their ELNs have reported productivity increases upwards of 30%. Whatever productivity means to you, you should be able to at least estimate your ELN's organization-wide effects on productivity.

Conclusion

Sourcing and evaluating an ELN solution is never a cut-and-dry process, but by being methodical and following these best practices, you can maximize your chances of finding the solution that's right for you. In this guide, we traced a complete ELN selection process, from identifying the need for an ELN, to sourcing and, lastly, evaluation. We stressed the importance of simultaneously refining your requirements and your list of potential vendors so that you avoid disqualifying a solution too early while still being thorough in your vetting. We also emphasized getting stakeholder buy-in at every stage of the process to make sure that

everyone affected by the ELN supports and understands the decision you reach. But lastly, keep in mind that this guide shouldn't serve as the ultimate decider of how to go about your ELN evaluation. Evaluations can take on a lot of different forms and still be successful. The suggestions gathered here are the results of market research conducted with heads of IT and leading industry consultants, but don't be afraid to go off-script if you think that would work better for you. Hopefully, this guide can serve as a starting point for your own evaluation, whatever structure it ends up taking.



