SciNote

SciNote & FDA:

Lab software and compliance

Webinar highlights

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Scope of the webinar

- View on digitalization in scientific organizations
- How to choose the right software and define product requirements?
- Good practice when scoring vendors
- Testing the electronic lab notebook in an organized manner
- How to evaluate pricing and choose among the electronic lab notebook vendors?
- CFR 21 Part 11 and GLP
- Electronic lab notebook validation and defining milestones for implementation
- Cloud software and validation
- Transfer of existing data on paper/ from other systems
- How do you measure success of electronic lab notebook implementation?
- How to encourage the team?
- Speaking of change: Change management, saving time and the pandemic

[See full webinar recording here.]

Take away message

Pandemic shined the spotlight on lab digitalization.

“Pandemic has shone a spotlight on collaborative software, and digitization of processes. For a lot of users, the work was performed via emails, getting comments and approvals etc. COVID-19 has shown people that electronic lab notebooks can save them time, but also what to do with the time that they are saving. It is an opening”

– Bryan Lowry, Center for Drug Evaluation and Research, FDA

How to choose the right software and define product requirements?

“There are 3 separate research focused areas (branches) within our group. It was important at the outset to layout the basic requirements with the management, and with the IT team.”

– Bryan Lowry, Center for Drug Evaluation and Research, FDA

Starting with the management and the IT requirements:

- How does the management want to track progress?
- Does the software enable the management to have a bird’s eye view on the progress, in a simple graphical user interface?
- will the software of your choosing fit into the infrastructure your IT team has set up?

Once you define the management needs, determine what kind of support the IT team can offer from the hardware perspective:

With those things in mind, third stage is to solicitate the users' input:

Example: Select 2 – 3 representatives from each research group. The aim is to define the user requirements:

- How accessible is the software?
- What do you need the software to do?
- Which software solutions are you currently using?
- What have you seen about other software solutions that you like?

"Once all requirements are collected, it can be useful to break them into groups: interface, usability, managing projects that will later on help create evaluation criteria and scoring system"

– Bryan Lowry, Center for Drug Evaluation and Research, FDA

Scoring vendors

Example: Vendors go through 2 cycles of evaluation. First, scoring is based on management and IT criteria, then narrow it down based on user requirements.

At this stage it is important not to overlook certain functionalities of the software and the benefits it can offer or potential pitfalls. It is important to get in touch with the vendors, see how responsive they are in providing the information.

Testing the electronic lab notebook in an organized manner

Once you have the user requirements, test the software to evaluate them.

A software trial is an important step forward as it allows you to explore the software before committing. SciNote offers you free trial of the software. This means you can explore and test the software before committing to anything, the team even guides you through and explains everything on your own use case (this is available upon request).

Good practice example:

- It is good to explore the software freely and think of things that maybe previously haven't been thought of.
- However, to be efficient, define specific things you want the users to do while testing to evaluate the criteria you came up with.
- Make sure you specify the questions: Grading the interface, for example, requires you to also tell the users how to do it, to avoid receiving answers that are too subjective. This will enable you to have numbers at the end of the day and compare relevant data.
- A good approach is to try and use the software in a process scenario

How to evaluate pricing and choose among the electronic lab notebook vendors?

"Once the core 3 – 4 vendors were selected, we reached out, looked at the pricing. There might be a gap in pricing for the same quality of product. Once you start getting the quotes and doing your research, it is a lot more affordable than you'd think"

– Bryan Lowry, Center for Drug Evaluation and Research, FDA

“We looked at it from the price-perspective, and through evaluation requirements, but the last thing we looked at was also not so easily quantifiable: The willingness of vendors to work with us on customization.

The software might not tick every checkbox for requirements. Can the company work with you on smaller customizations? That has been the determining factor of as well”.

CFR 21 Part 11 and GLP: Compliance, GMP, risk assessment

There is no such thing as an out of the box compliant software, it is always used in the context of the processes within the company. Electronic lab notebooks need to be validated in the context of the processes. However, a tool can go a very long way to help you and your QA team to save a lot of effort when you do need to go through the validation process.

“It is important to challenge the vendors, which supporting services do they have to help you implement the software? For example: IQ, OQ protocols and user onboarding can really help you implement the electronic lab notebook in your lab”

- Matjaz Hren, PhD, VP of Product management, SciNote

What ELN validation looks like and what are the milestones

“It is recommended to set up the ELN A-team of people who will be dedicated to implement the software in your team. It doesn’t have to be a large team; it doesn’t have to be the full-time obligation. You need the team of dedicated individuals who will make sure deadlines are met, help others who are involved etc. This can make a real difference between the success or failure in the adoption of the tool”

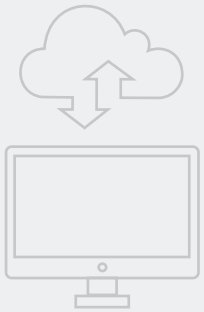
- Matjaz Hren, PhD, VP of Product management, SciNote

First task for your A-team should be to create the realistic set of implementation milestones

- Every new tool brings a disruption; it is a change in the
- processes.
- So, start with mapping your processes and your data flows, and determining how to transfer them into the new tool.
- This will bring out the gaps and help you define the next milestones.

Cloud software and validation

Updates in the software are a thing to consider. If you are buying a service that runs in the cloud, these types of software solutions have more frequent updates, which is a good thing because the software is up to date with the latest requirements and is keeping up with technology.



Every time there is an update you will have to re-validate it. It is important to know how frequent are the updates and if the vendor can support you. Vendors can have IQ and OQ processes written up and made available to you to help with the validation process. SciNote has you covered on that as well.

What about existing data on paper and other systems?

To decide what to do with the legacy data, there are a few options labs usually consider:

- Do you have data on paper and/or another software?
- Do you need to do a clean cut, or is a gradual approach better?

- This article explains everything more in detail. Transfer to the unified, digital system is also an opportunity to make your existing system more simple, more lean and accept the changes that come with that.

In addition, there is a possibility to identify a separate vendor to digitize legacy data: they can come in, evaluate the files, scan them - and in the process, assign metadata to each file. These kinds of external services can be used for legacy data in large organizations.

How to make sure you strike the right balance between lean processes and compliance requirements?

Regulated doesn't always equal complex.

Transition can be a good opportunity to simplify things and try to figure out how to optimize your processes and simplify the overall quality management system once everything is digitized and traceable.

How do you measure success of electronic lab notebook implementation?

1. Short term metrics and KPIs:

Examples: time required to get sample result, time to generate report, time to retrieve data, time to find audit trail for specific record, time to collect all signatures or electronic signatures

2. Long term metrics related to accessibility and usability:

Ability for the employees to perform work in a compliant manner even remotely when required, FAIRness of data etc.
In a research environment, it would be: user feedback – is there frustration? Is the software meeting the needs of the lab? Time spent trying to fix the potential problems? Effectiveness of collaboration with the vendors support team?

How to get the buy in from the users and make them a part of the process?

Implementation is not always necessarily focused on each individual user. It is important to provide the necessary training and include the members of the team. That will hopefully take care of the majority of users. But there is major importance in 10% of the strugglers as well, people resistant to change.

Encouraging the team to adapt to the new system:

- Taking personal time with the struggling users, 1:1 discussion, talking them through
- Clear documents, clear SOP, clear instructions for the software
- Help from the vendor's side: user onboarding, responsiveness, materials and tutorials

Clear quality documents, personal time with the ones who are struggling, and doing the best with the majority of users is very important.

How to get started with SciNote?

“I also want to thank you very much for your superior support. With your help we implemented SciNote really fast and also improved many things. Only to mention a few of them: have everything digitalized, save time by using templates and protocols, finding experiments or material in record time, having all laboratory notes organized in one place. “

– Sabrina Rottal, VelaLabs

Schedule a demo with SciNote specialists:

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