



INSIGHTS INTO PAPERLESS
TEST METHOD
EXECUTION IN A
GXP COMPLIANT ENVIRONMENT USING
Logilab ELN

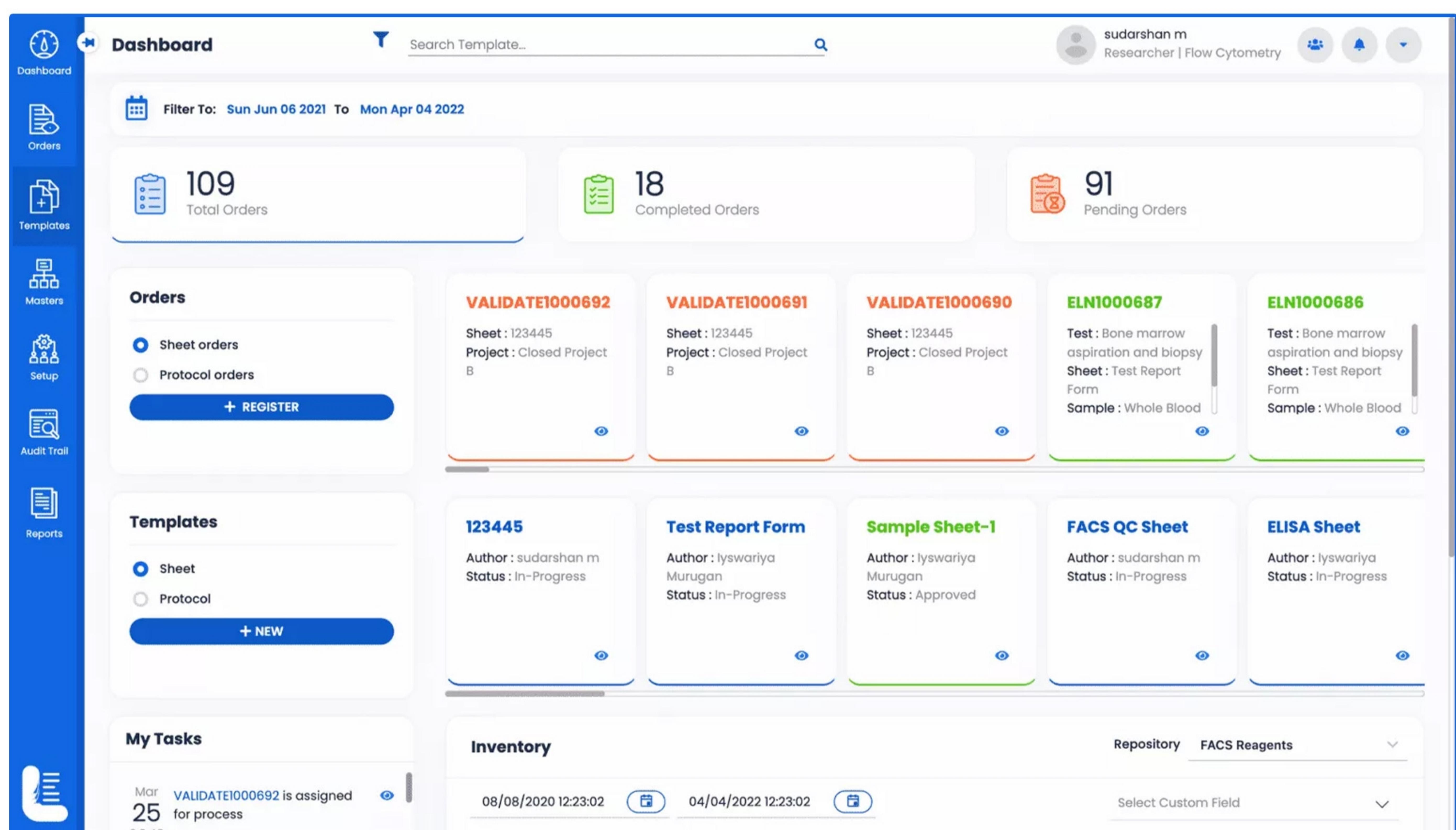
Agaram Technologies' Logilab ELN is an Electronic Lab Notebook meant to shift laboratories from all scientific verticals into a fully paperless environment built for speed, convenience, compliance, and accuracy.

Across pharma, biotech, life sciences, and many other scientific disciplines, Logilab ELN is pivotal for both research data capture and test method execution with its rich array of revolutionary features. It is a powerful catalyst of change and digital transformation, helping laboratories in highly regulated industries to move into a better workflow, safely and without downtime.

Streamlining data capture in revolutionary new ways for QA/QC & research labs

Depending on whether you are a QA/QC or research lab the data capture & compliance requirements might vary drastically. Today's lab informatics market is saturated with ELN solutions that are optimized for one type of lab or the other which makes them unsuitable for environments that require both strict regulatory compliance as well as the freedom for end-users to choose how they want to record & execute their tests and experiments.

In QA/QC labs every activity that needs to be performed in the laboratory has to be fully documented with a proper chain of custody for all samples. Today QC labs rely heavily on paper-based documentation for such activities which eventually leads to poor traceability and human error.



The screenshot shows the Agaram Logilab ELN dashboard with the following key sections:

- Dashboard Summary:** Shows 109 Total Orders, 18 Completed Orders, and 91 Pending Orders.
- Orders:** A section for managing orders with filters for Sheet orders (selected) and Protocol orders. It includes a '+ REGISTER' button.
- Templates:** A section for managing templates with filters for Sheet (selected) and Protocol. It includes a '+ NEW' button.
- My Tasks:** A section showing a task: "VALIDATE1000692 is assigned for process" dated Mar 25, 3:04PM.
- Inventory:** A section showing inventory items: 08/08/2020 12:23:02, 04/04/2022 12:23:02, Repository, FACS Reagents, and Select Custom Field.
- Work Items:** A grid of work items including:
 - VALIDATE1000692: Sheet: 123445, Project: Closed Project B
 - VALIDATE1000691: Sheet: 123445, Project: Closed Project B
 - VALIDATE1000690: Sheet: 123445, Project: Closed Project B
 - ELN1000687: Test: Bone marrow aspiration and biopsy, Sheet: Test Report Form, Sample: Whole Blood
 - ELN1000686: Test: Bone marrow aspiration and biopsy, Sheet: Test Report Form, Sample: Whole Blood
 - 123445: Author: sudarshan m, Status: In-Progress
 - Test Report Form: Author: lyswariya Murugan, Status: In-Progress
 - Sample Sheet-1: Author: lyswariya Murugan, Status: Approved
 - FACS QC Sheet: Author: sudarshan m, Status: In-Progress
 - ELISA Sheet: Author: lyswariya, Status: In-Progress



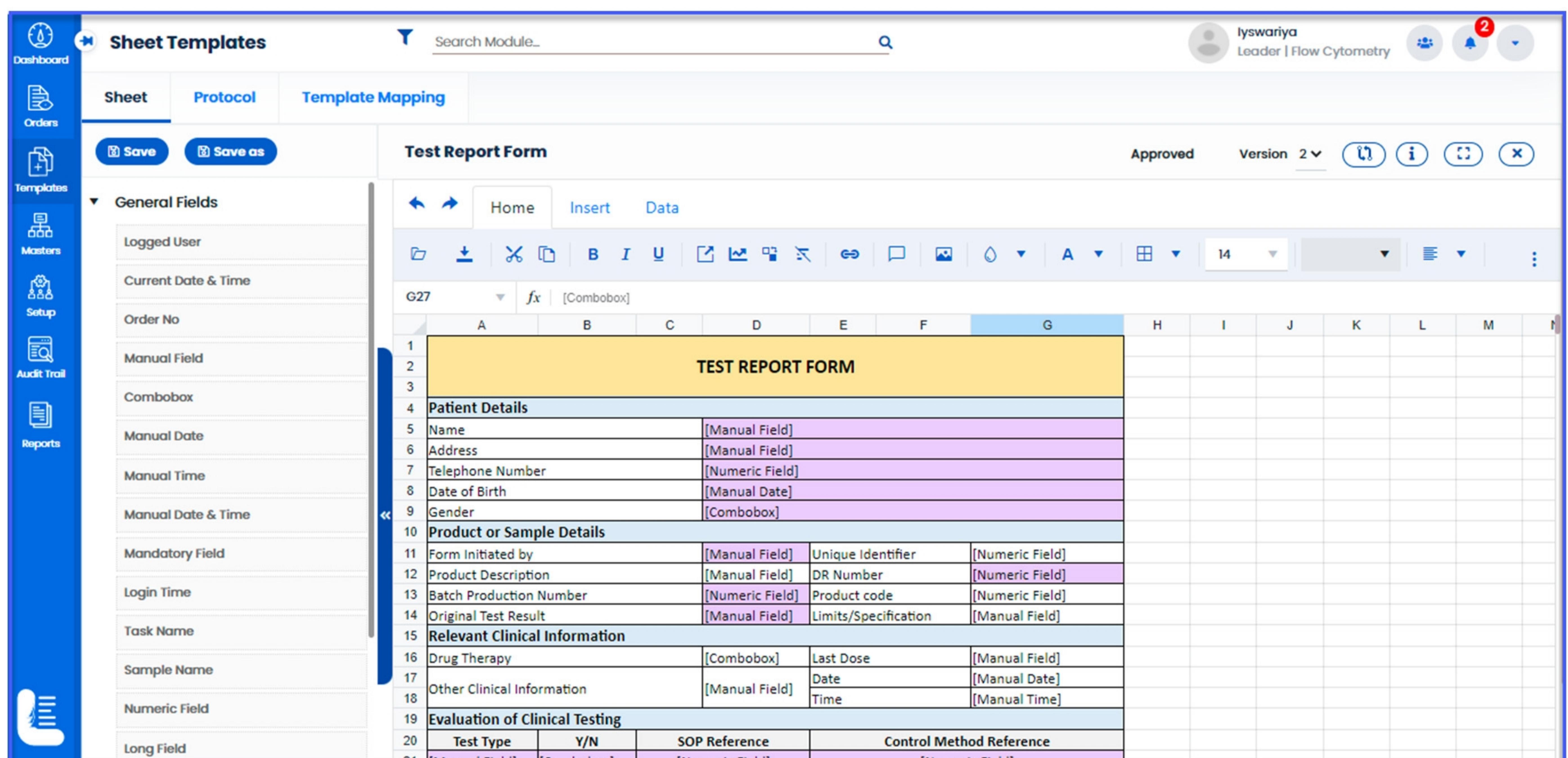
In order to switch to a digital environment, these kinds of labs require a highly compliant and structured data capture solution that cannot be modified or deleted by end-users. The big challenge is to achieve all this using an interface that is familiar to end-users.

Logilab ELN offers powerful data capture tools with a familiar interface that enables QC labs to capture their data in a highly compliant & digital environment

1. Powerful spreadsheet-based UI for structured data capture

Labsheet templates are excel-based templates that are designed to capture structured data into a digital lab notebook or Labsheet that is akin to a regular spreadsheet.

While they might look like your traditional Excel spreadsheets, Labsheets have a leg up on this and other ELN interfaces on multiple fronts.



The screenshot shows the Logilab ELN interface for creating sheet templates. On the left, a sidebar menu includes options like Dashboard, Orders, Templates, Setup, Audit Trail, and Reports. The main area is titled 'Sheet Templates' and shows a 'Test Report Form' template. The template consists of several rows of data, each with a number and a header. The first row is yellow and labeled 'TEST REPORT FORM'. Subsequent rows are divided into sections: 'Patient Details' (rows 4-9), 'Product or Sample Details' (rows 10-14), 'Relevant Clinical Information' (rows 15-18), and 'Evaluation of Clinical Testing' (rows 19-21). Each row contains various input fields such as 'Name', 'Address', 'Telephone Number', 'Date of Birth', 'Gender', 'Form Initiated by', 'Product Description', 'Batch Production Number', 'Original Test Result', 'Drug Therapy', 'Other Clinical Information', 'Test Type', 'Y/N', 'SOP Reference', and 'Control Method Reference'. The interface includes a ribbon bar with tabs like Home, Insert, Data, and a toolbar with icons for file operations and data entry.

Lab sheets can be quickly user-designed through a simple drag & drop interface to create form-like input templates for any type of test, experiment, or day-to-day logbooks, lab checklists, etc.

Tasks, tests, or experiments performed in the laboratory can be associated with these lab sheets and executed. Orders can be placed against samples, projects, tests/tasks and assigned to various users within the lab.

This results in faster, accurate & reliable data capture for the execution of test methods, performing experiments, or calculations.



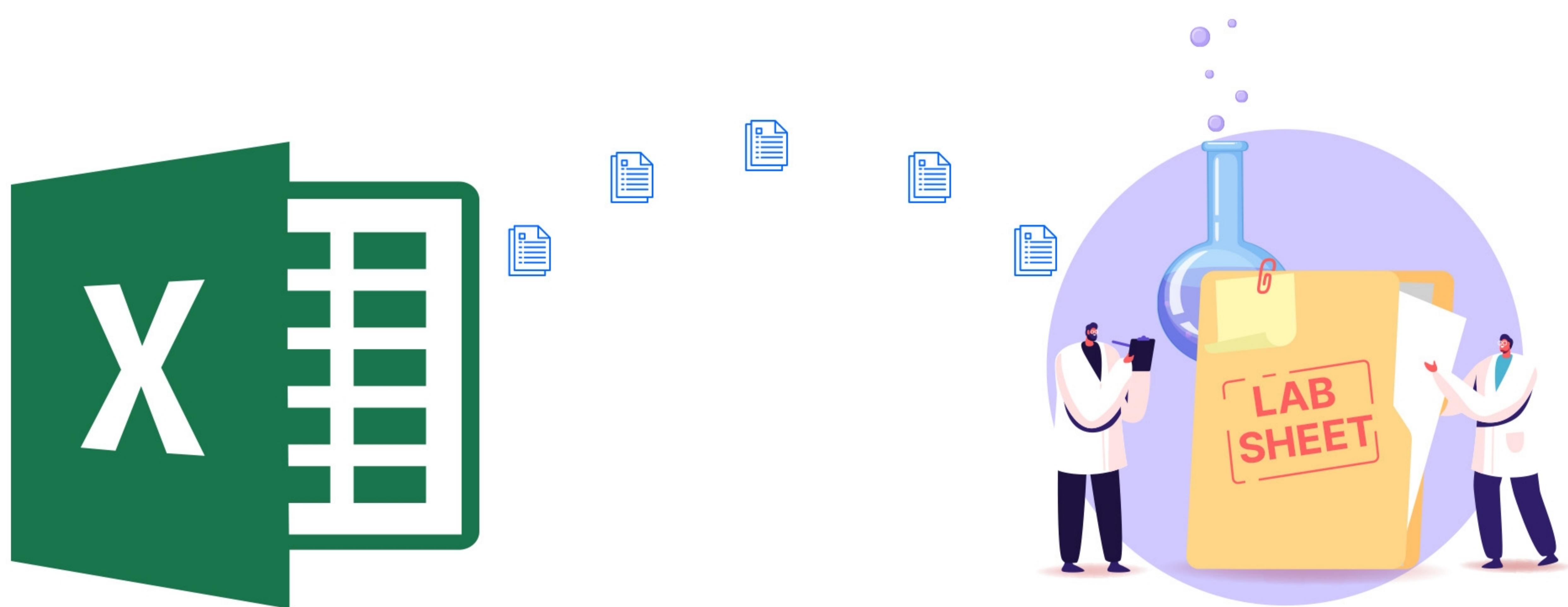
2) Ensuring a smooth transition from existing workflows

Most QA/QC laboratories today already rely on contemporary Excel sheets for data capture and processing. For many ELN alternatives, this can hamper a smooth transition due to the complexity of data migration from excel sheets & reliance on complex formulas to perform calculations for tests. But that's not the case with Logilab ELN,

Logilab ELN offers full Excel compatibility, enabling the import & export of Excel documents directly into your Lab sheets. So, users can import and start working on their existing spreadsheets directly without any special integration.

Logilab ELN also has full support for formulas that can be used to perform calculations similar to excel but in a much more controlled environment.

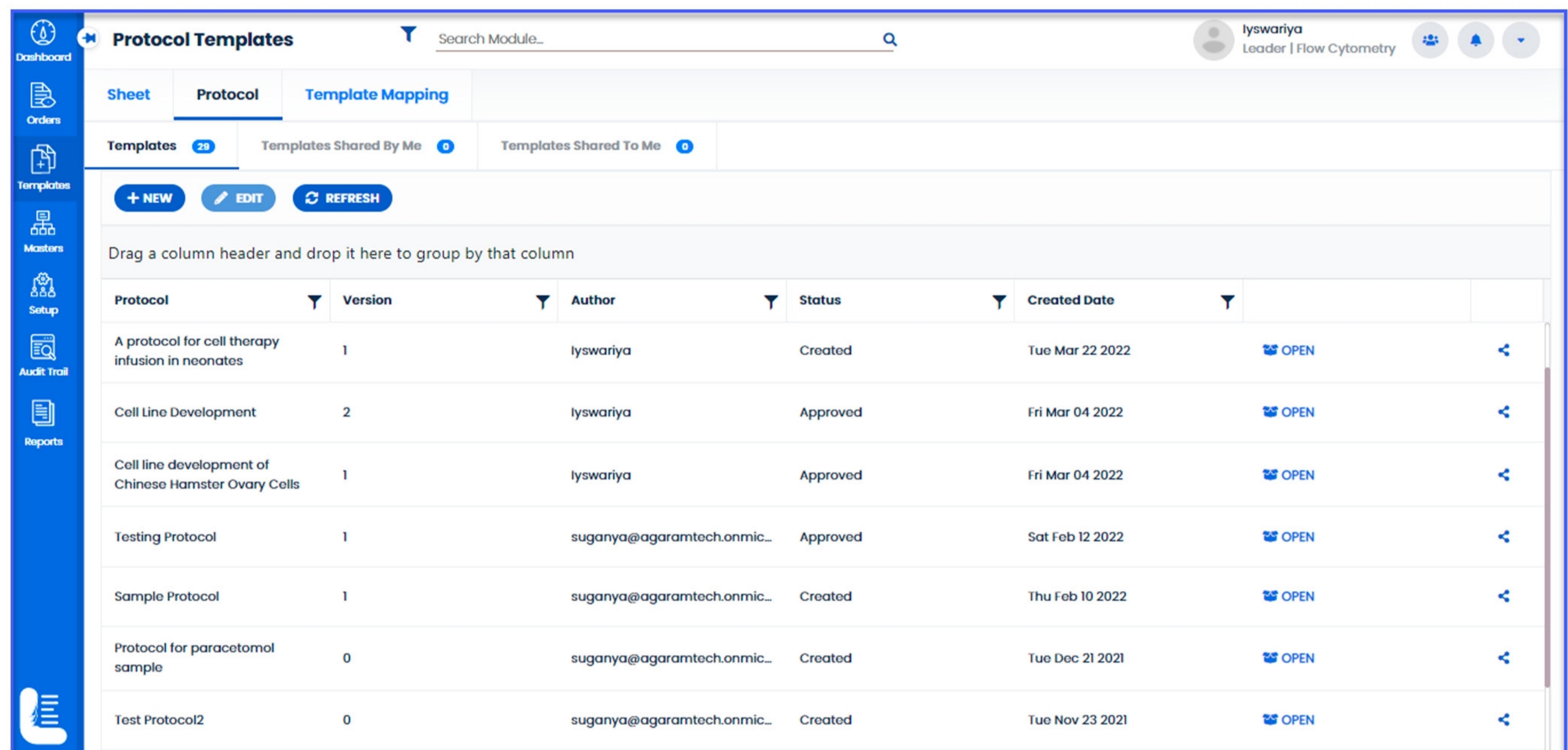
Labsheets' can be cross-linked to ensure easy access to data segregated across different lab sheets. This data linking concept works similar to the Excel sheet linking principle and can become useful for data summarization and associating results from multiple tests or tasks with each other.



3) Addressing free-form data capture for research labs using protocols

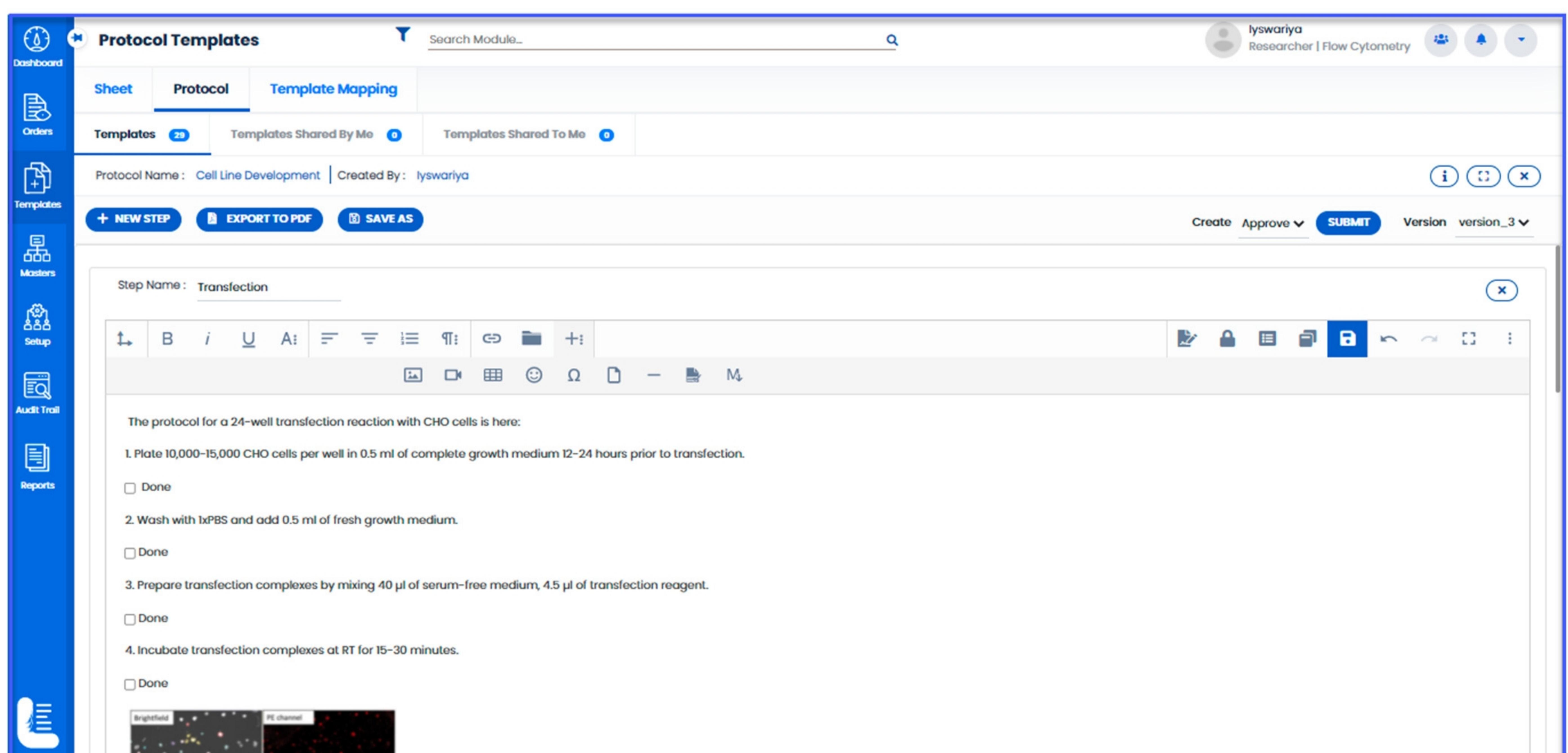
Data isn't always available in a structured and easy-to-process format. An enormous amount of free-form data typically churns up while performing experiments & recording research data during R&D.

Researchers may not have a predefined test method or template to capture such data. In this case, data recorded is more free-form and requires the ELN to allow for unrestricted data capture with support for different formats.



This screenshot shows the 'Protocol Templates' list view in the Logilab ELN. The left sidebar includes links for Dashboard, Orders, Templates, Masters, Setup, Audit Trail, and Reports. The main header has tabs for 'Sheet', 'Protocol' (which is selected), and 'Template Mapping'. A search bar and user profile are at the top right. Below the tabs is a row of buttons: '+ NEW', 'EDIT', and 'REFRESH'. A note says 'Drag a column header and drop it here to group by that column'. The table lists seven protocols:

Protocol	Version	Author	Status	Created Date	Action
A protocol for cell therapy infusion in neonates	1	lyswariya	Created	Tue Mar 22 2022	
Cell Line Development	2	lyswariya	Approved	Fri Mar 04 2022	
Cell line development of Chinese Hamster Ovary Cells	1	lyswariya	Approved	Fri Mar 04 2022	
Testing Protocol	1	suganya@agaramtech.onmic...	Approved	Sat Feb 12 2022	
Sample Protocol	1	suganya@agaramtech.onmic...	Created	Thu Feb 10 2022	
Protocol for paracetomol sample	0	suganya@agaramtech.onmic...	Created	Tue Dec 21 2021	
Test Protocol2	0	suganya@agaramtech.onmic...	Created	Tue Nov 23 2021	

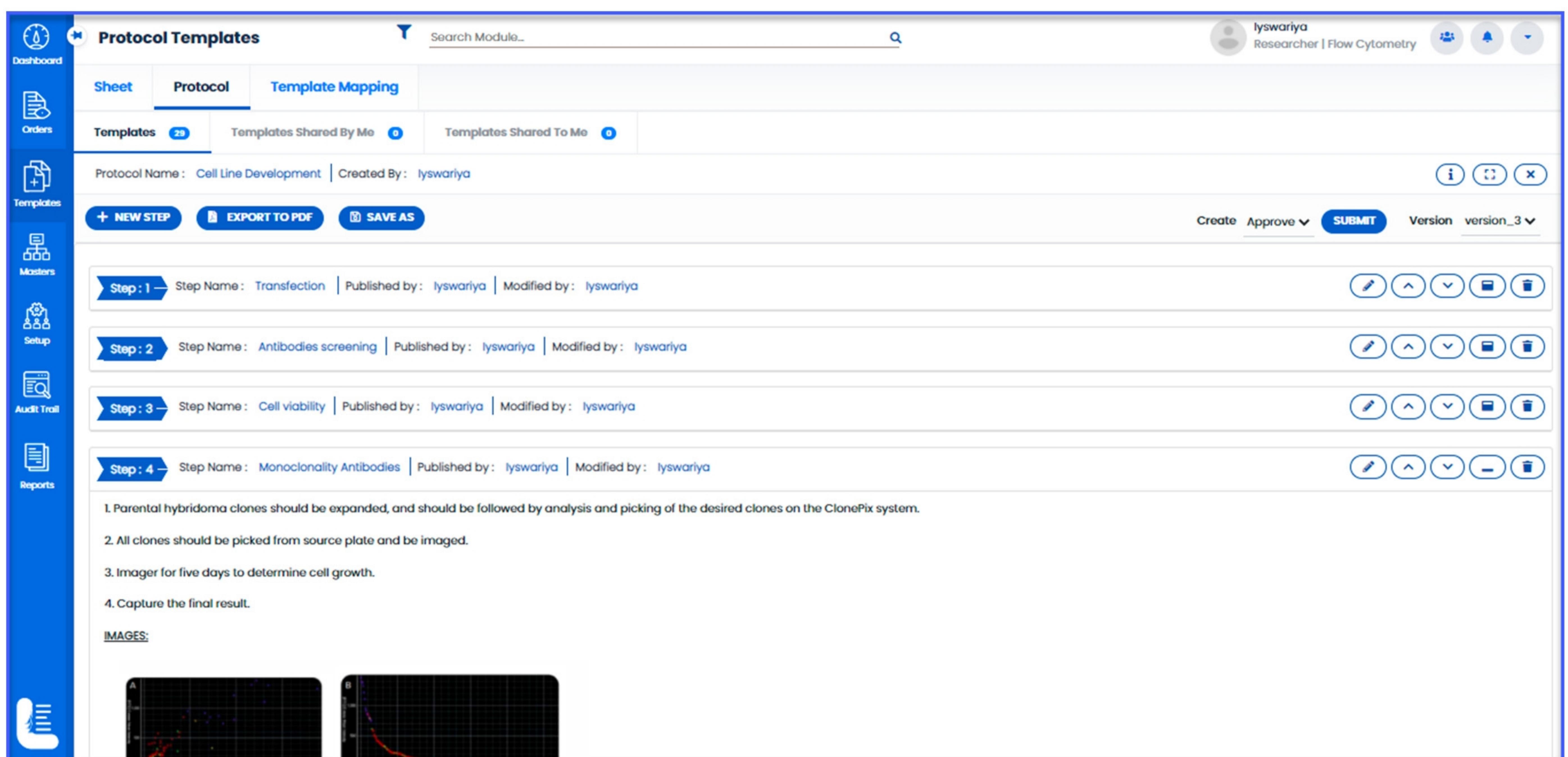


This screenshot shows the 'Protocol Templates' detail view for the 'Cell Line Development' protocol. The left sidebar and top navigation are identical to the previous view. The main area shows the protocol details: 'Protocol Name: Cell Line Development' and 'Created By: lysiariya'. Below this are buttons for '+ NEW STEP', 'EXPORT TO PDF', and 'SAVE AS'. On the right are 'Create', 'Approve', 'SUBMIT', 'Version', and 'version_3' buttons. The main content area shows a step named 'Transfection' with a rich text editor toolbar. Below the toolbar is a list of steps:

- Plate 10,000–15,000 CHO cells per well in 0.5 ml of complete growth medium 12–24 hours prior to transfection.
- Wash with 1xPBS and add 0.5 ml of fresh growth medium.
- Prepare transfection complexes by mixing 40 µl of serum-free medium, 4.5 µl of transfection reagent.
- Incubate transfection complexes at RT for 15–30 minutes.

Each step has a 'Done' checkbox. At the bottom is a small image showing a brightfield and fluorescence microscopy image of cells.





The screenshot shows the Logilab ELN Protocol Templates module. On the left, a sidebar lists various modules: Dashboard, Orders, Templates, Masters, Setup, Audit Trail, and Reports. The main area is titled "Protocol Templates" and has tabs for "Sheet", "Protocol" (which is selected), and "Template Mapping". It displays a protocol named "Cell Line Development" created by "lswariya". The protocol consists of four steps:

- Step : 1**: Step Name: Transfection | Published by: lswariya | Modified by: lswariya
- Step : 2**: Step Name: Antibodies screening | Published by: lswariya | Modified by: lswariya
- Step : 3**: Step Name: Cell viability | Published by: lswariya | Modified by: lswariya
- Step : 4**: Step Name: Monoclonality Antibodies | Published by: lswariya | Modified by: lswariya

Below the steps, there is a list of instructions:

1. Parental hybridoma clones should be expanded, and should be followed by analysis and picking of the desired clones on the ClonePix system.
2. All clones should be picked from source plate and be imaged.
3. Imager for five days to determine cell growth.
4. Capture the final result.

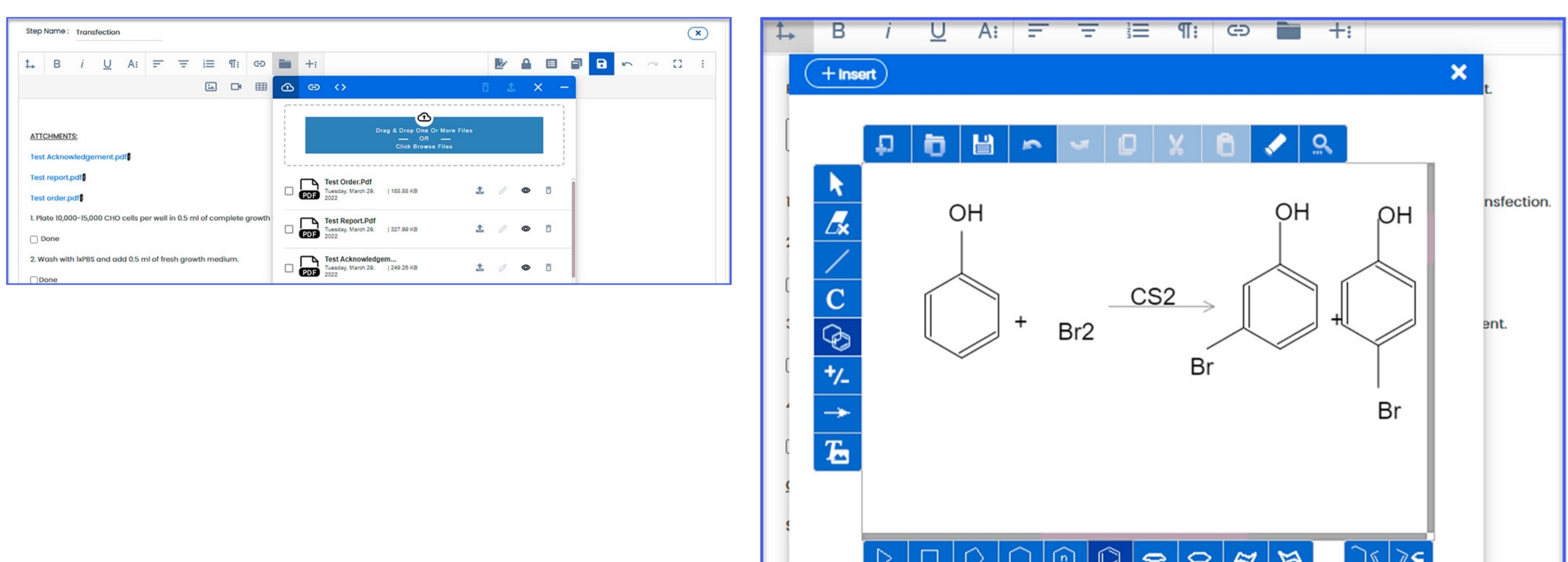
Under the "IMAGES:" section, two small thumbnail images labeled A and B are shown, representing experimental results.

Data isn't always available in a structured and easy-to-process format. An enormous amount of free-form data typically churns up while performing experiments & recording research data during R&D.

Researchers may not have a predefined test method or template to capture such data. In this case, data recorded is more free-form and requires the ELN to allow for unrestricted data capture with support for different formats.

Logilab ELN enables users to capture free-form data for experiments through protocol-based templates that are used to record step-by-step experimental/test procedures where users can create & execute multi-steps procedures.

The data inside the protocols can be recorded in multiple formats such as text, tables, images, attachments, chemical drawings, mathematical formulas, etc, making them more suitable for free-form data capture.



The image contains two side-by-side screenshots of the Logilab ELN interface demonstrating free-form data entry:

Left Screenshot: This shows a protocol step titled "Transfection". It includes a toolbar at the top with various icons. Below the toolbar, there's a section for "ATTACHMENTS" containing several PDF files (Test Acknowledgement.pdf, Test report.pdf, Test order.pdf). There are also some text notes and checkboxes related to cell culture conditions.

Right Screenshot: This shows a "Insert" dialog box. It features a toolbar at the top and a large central area for drawing chemical structures. A chemical reaction is drawn: Oc1ccccc1 + Br2 -> CS2 -> Oc1cc(Br)ccc1 + Oc2ccccc2Br. The reaction arrow is labeled "CS2". The dialog also includes a toolbar with various chemical drawing and selection tools along the bottom.



This gives researchers the choice to either follow pre-defined SOPs during method execution or just create one on the fly depending on the task at hand.

4) Instrument-based data capture using an advanced parsing engine

Most labs usually work with data generated from hundreds of instruments for their day-to-day experiments and tests. In such cases, Manual transcription is impossible due to the sheer volume of data that is being generated by these instruments each day.

Manual data entry increases the risk of human error while also being extremely time-consuming. To combat these issues, we developed an advanced parsing engine that can automatically parse data of interest from instrument output files.

Instrument data fields can be inserted into lab sheets, where data from instrument output files can be parsed and automatically populated. These results can further be used for calculations, reports, etc.

Integration with Logilab SDMS takes things even further where data can automatically flow based on the instrument type, test, etc

5) Browser-based reporting tool for auto-summarization of captured data

For every QA/QC & research laboratory, lab reports are very dynamic in nature. The reporting requirements might vary drastically depending on the project at hand.

Typical reporting tools only offer static templates for reporting and need the support of developers to make any significant change to the structure of the report. End-users have not had the opportunity to design or summarize their data the way they want.

To combat this, we introduced a highly flexible word-based document editor which also doubles up as a robust reporting tool, enabling laboratories to:





Create or import existing Word documents as report templates



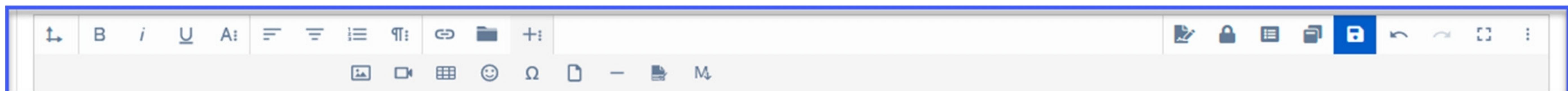
Collaborate with project teams to edit documents



Auto-generate custom reports based on ELN tag fields



Store all your reports in a controlled environment



The screenshot shows the Logilab ELN software integrated with Microsoft Word. On the left, a vertical sidebar lists modules: Dashboard, Orders, Templates, Masters, Setup, Audit Trail, and Reports. The main area is a Microsoft Word window titled "Report Template- New.docx". The document content includes company details ("DiscGenics" logo, address, phone number) and a table titled "Evaluation of Clinical Testing" with four columns: Test Type, Yes/No, SOP Reference, and Control Method Reference. The Word ribbon at the top has tabs for Home, Insert, Layout, References, Collaboration, and Plugins. The status bar at the bottom shows "Page 1 of 1", "All changes saved", "English (United States)", and zoom levels.

User-defined tag fields can be inserted into ELN Labsheets for data of interest which can then be inserted into report template documents for automatic generation of reports.

Using these tags, data from multiple tests and experiments can be auto-summarized into a single comprehensive report without any data manual entry.

Labs can therefore quickly summarize data, draw conclusions, and offer recommendations based on project outcomes. What's more, the automated processes alleviate human error, ensuring the integrity of your datasets and information at large.



How Logilab ELN facilitates effective GLP and 21 CFR Part 11 Compliance

1) Data traceability and review

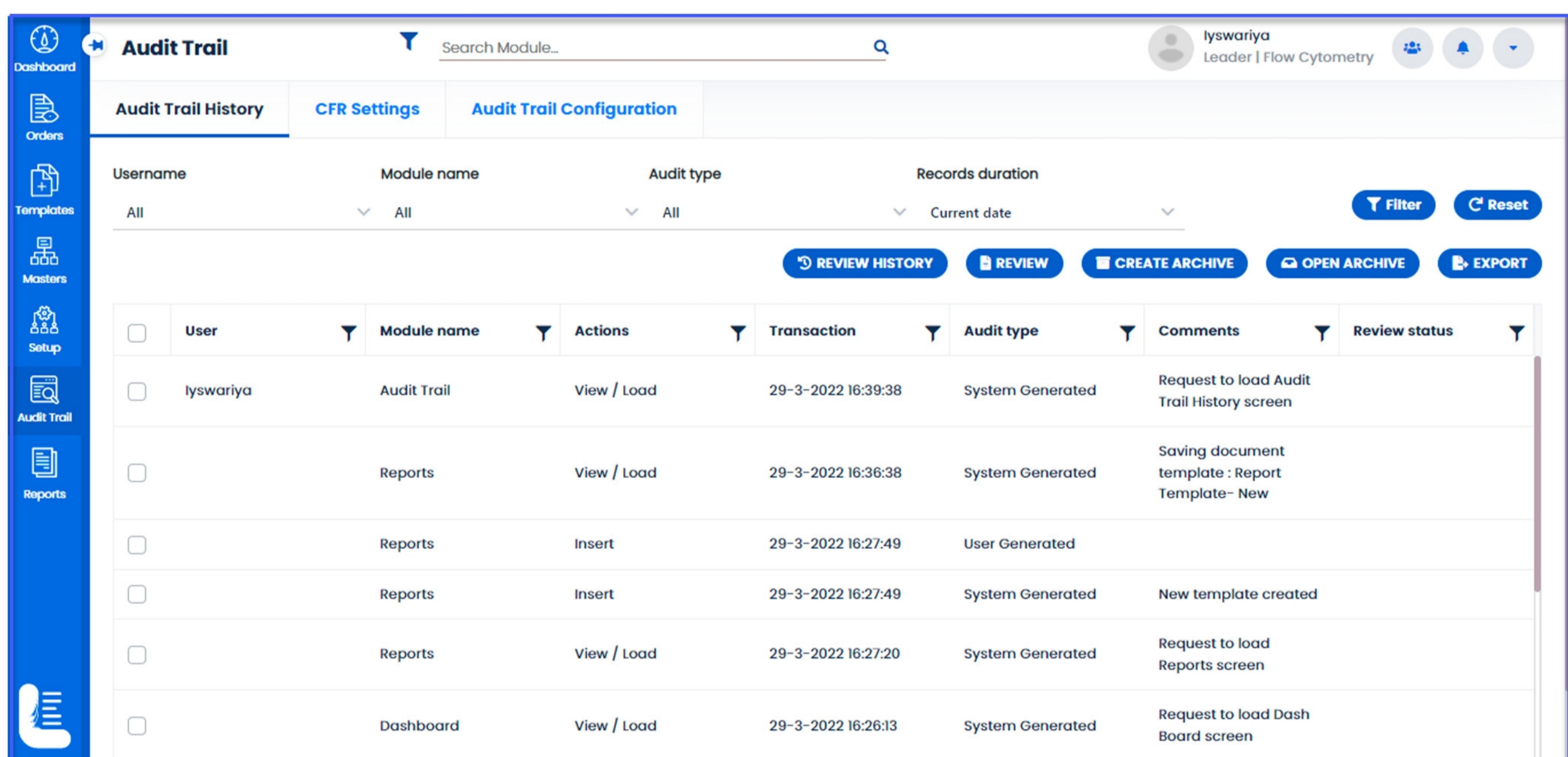
For laboratory staff and QA/compliance managers, the Logilab ELN simplifies efficient test method review and approval down to a tee. Thanks to efficient test method approval and review, including fully configurable workflows, oversight becomes easy and fault-proof.

Configurable workflows also offer many other advantages beyond the management's point of view. For instance, Logilab ELN's version and release control capabilities make it possible to track the changes made to data & test results over time, by automatically versioning all changes made to the captured data.

This traceability, in the long run, enables labs to track variables in test methods, results in entry, changes, etc all while keeping the original data intact.

2) GxP controls for regulatory compliance

Depending on your laboratory's specific niche, there may be a variety of GxP regulations and policies to watch out for. GxP is a set of guidelines formulated to ensure the safety and quality of life sciences products while maintaining process control throughout every stage of manufacturing, control, storage, and distribution.



The screenshot shows the Audit Trail module interface. The left sidebar has icons for Dashboard, Orders, Templates, Masters, Setup, Audit Trail (selected), and Reports. The main header says "Audit Trail" with a search bar and user info for "lyswariya". Below the header are tabs: "Audit Trail History" (selected), "CFR Settings", and "Audit Trail Configuration". The main area has filters for "Username" (All), "Module name" (All), "Audit type" (All), and "Records duration" (Current date). Buttons include "Filter", "Reset", "REVIEW HISTORY", "REVIEW", "CREATE ARCHIVE", "OPEN ARCHIVE", and "EXPORT". A table lists audit logs:

User	Module name	Actions	Transaction	Audit type	Comments	Review status
lyswariya	Audit Trail	View / Load	29-3-2022 16:39:38	System Generated	Request to load Audit Trail History screen	
	Reports	View / Load	29-3-2022 16:36:38	System Generated	Saving document template : Report Template- New	
	Reports	Insert	29-3-2022 16:27:49	User Generated		
	Reports	Insert	29-3-2022 16:27:49	System Generated	New template created	
	Reports	View / Load	29-3-2022 16:27:20	System Generated	Request to load Reports screen	
	Dashboard	View / Load	29-3-2022 16:26:13	System Generated	Request to load Dash Board screen	



Without GxP or version control on documents, it's easy for your laboratory, or one of your personnel, to infringe on FDA policies without knowing it. The result can be misdemeanor fines of up to \$250,000 among other stern consequences.

Laboratories can breathe easier thanks to Logilab ELN's GxP controls.

- Role-based user access – User groups and project management
- Review and approval of data by assigned reviewers or approvers which ensures accountability.
- Version control of records and maintaining of version history
- Time-stamped audit trails – to track what actions are done by who at what time
- Time-stamped electronic signatures – to enforce accountability. The electronic signature is unique to one individual and indisputably linked to the respective electronic record in a way to prevent fraudulent use.
- View and Export all electronic data in a human-readable format,
- Data indexing by metadata
- Archiving of the data to a secured central database which ensures data security
- Product developed by Software validation, including testing and overall performance assessment to ensure fully functional performance and reliability

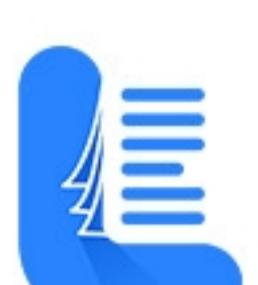
Logilab ELN's role in 21 CFR Part 11 Compliance

21 CFR Part 11 is part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). Part 11 sets out how a company operating in the US can use electronic quality records and digital signatures in place of paper-based documentation and 'wet signatures' in such a way that complies with FDA regulations.

Logilab ELN has the following features developed to enable organizations to comply with 21 CFR Part 11 regulations.

1) Validation:

Logilab ELN is tested and released for customers. It is also validated against operational qualification (OQ) tests which are performed during implementation with relevant documentation to justify the same. Invalid and altered records can be discerned by the [S1] automatic versioning feature in Logilab ELN.



2) Record Generation

Data can be downloaded for copying, reviewing, and printing by users with appropriate privileges. The original data will reside within the system in electronic format for any verification. Logilab ELN has a user-friendly wide-range search function with search results showing all document changes and iterations, indicating what is a ‘final version’, as well as displaying the digital signatures of any approval they were subject to. Since no data can be deleted within the system and the system has a built-in versioning capability, old or previous versions of data do not get obscured.

3) Audit Trails

Logilab ELN generates an audit trail of user(s) login, log-off, and user actions that create and edit, (records cannot be deleted in Logilab ELN). System audit trails are automatic and cannot be intervened or modified by users. Audit trails are available in relevant areas of application that authenticates the action by way of requesting a username, password, pre-defined reason, and a comment. It also records every change in data if any along with the server date and time-stamp. The audit trail is non-editable, searchable, printable, and exportable for review.

4) Operational Controls

Logilab ELN has validations in place that allow only valid sequences of operations to be performed, which cannot be modified. The system works in an automated fashion to fetch data generated by instruments and it checks for the source of data and its validity before being uploaded to the server. Any change in source data like creation, editing, or deleting is detected by the system and audit trailed.

5) Security Controls

Data within Logilab ELN is protected from unauthorized access or modification by applying security and access control measures. Data or records within the system can be accurately retrieved throughout the records retention period. Logilab ELN is only accessible through a valid “username” and “password” which gives access to only authorized users. Logilab ELN allows only unique combinations of username and password which means no two users can have the same username-password combination value as the same.

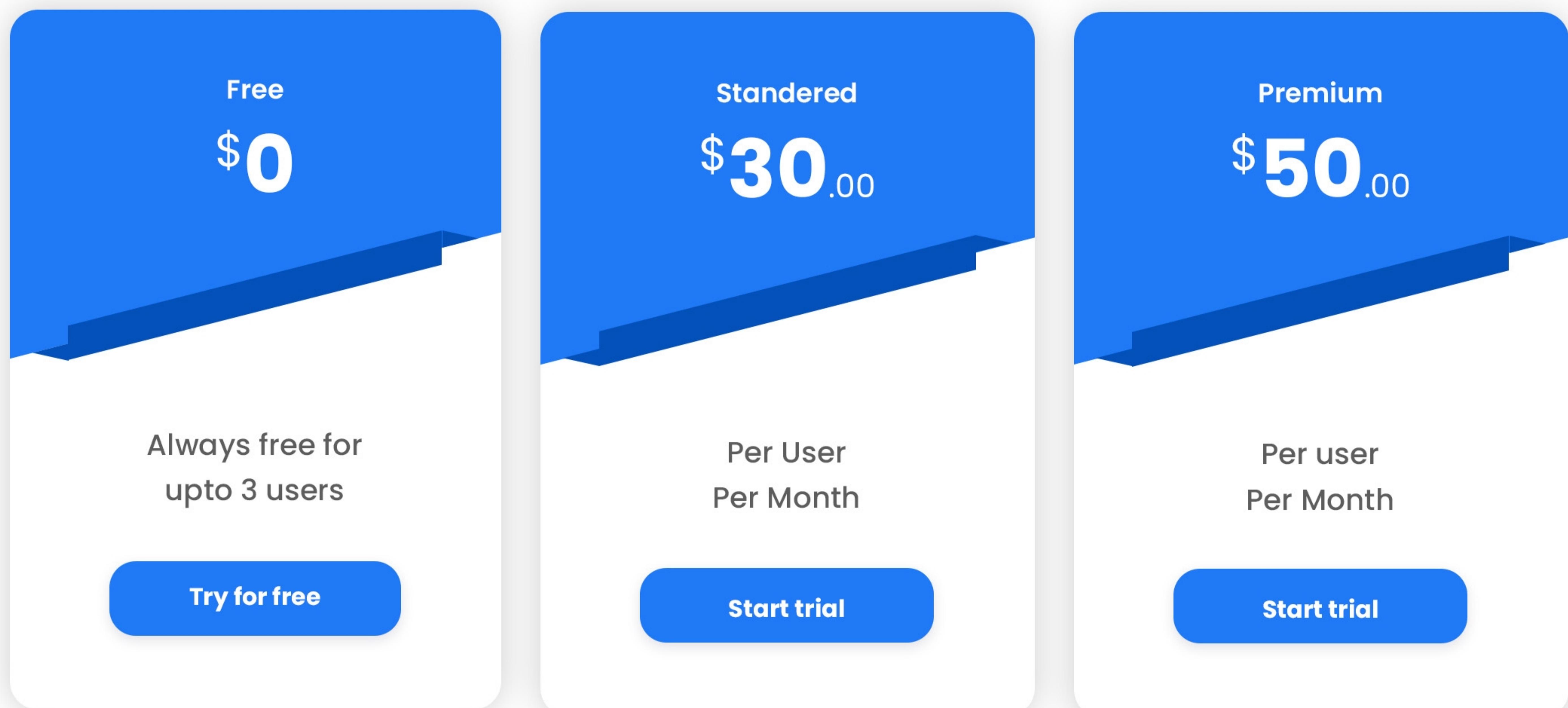


6) Electronic Signatures

Whenever electronic signatures are to be executed, the system prompts for username, password, pre-defined reason, and comments. This mandatory process conveys the literal meaning. The implications of the action about to be taken are also displayed such that it takes cognizance of the person performing such action.

Logilab ELN has it all for elevated data capture

Enabling structured & structured data capture, facilitating multi-instrument data parsing capabilities, managing laboratory inventories, enabling complex calculations, and not forgetting the robust data versioning capabilities, the Logilab ELN is the most versatile and powerful electronic lab notebook on the market.





Logilab

ELN

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