Improvement of diagnostic method validation processes in a Finnish hospital laboratory using lean methods and a software solution

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Introduction

Developing new in-house assays or verifying commercial kits in hospital laboratories is increasingly challenging due to strictening regulatory and accreditation requirements. For example, ISO 15189 and the upcoming CE-IVD update set new requirements for validations and verifications. These projects are already complex and burdening, involving a lot of error-prone manual work mainly done in Excel sheets and paper documents.

This study aimed to eliminate manual data management (waste) and improve the quality of validations and verifications using lean methods and a novel, web-based validation software to standardize and automate the validation and verification processes.

This study was done in cooperation between HUSLAB, the largest university hospital laboratory in Finland, and Finbiosoft, a Finnish software company developing Validation Manager™ software. The study focused on validation and verification projects conducted at HUSLAB Department of Virology and Immunology.

Old validation process

Two validation and verification projects were studied, and lean value stream maps were created to identify issues and waste.

1. Project plan
2. Sample collection
3. Test runs
4. Analysis
5. Reporting

Observed issues and waste in old processes

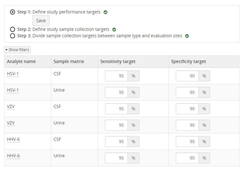
- **Manual data management**: Time and expertise of laboratory personnel is wasted as lot of data management work is done manually in Excel. Potential for errors is increased.
- **Varying practices**: Interpretation of data and results is difficult, analysis decisions are made case-by-case, and results are not comparable.
- **Limited traceability**: Varying data and report formats complicate accreditations. Verifying results is difficult.
- **Waiting**: Validation work competes with routine diagnostics, and work is done outside normal hours.
- **Lacking statistical tools**: Cannot assess the reliability of results. Latest guidelines are not followed.

New validation process

To eliminate waste and increase the quality of validation and verification projects, a new software-guided process model was created to replace earlier process.

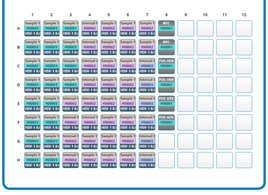
1 Plan

Plan validation study content, parameters and performance goals



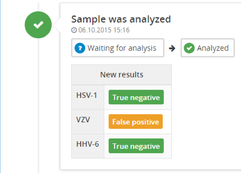
2 Design

Software-guided design of studied samples, test runs and timetable



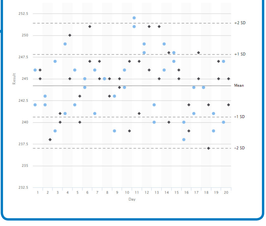
3 Work

Conduct test runs in laboratory, import results electronically



4 Report

Reports created automatically



Results

To evaluate the new process model and the validation software, two simulated validation projects were conducted. The observed benefits of the new model were gathered from interviews after the simulations, and the time savings were calculated by timing the different activities in the simulations and comparing them to observations made during the case projects.

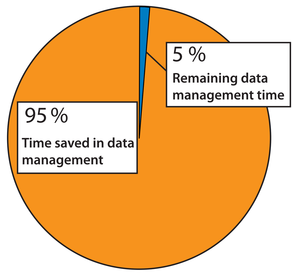
Benefits of the new model

- **Standardized workflow**: All validations and verifications are conducted using a standardized, software-guided workflow based on latest CLSI guidelines
- **Automation of data management**: All data management work previously done in Excel is automatized in the software
- **Automated result analysis and reporting**: Results are analyzed and reports generated immediately after data is imported. Statistical analysis supports latest CLSI guidelines and allows evaluation of result reliability.
- **Error prevention**: As data is transferred electronically and stored in one place in standardized format, manual work is eliminated and potential for human errors is reduced
- **Traceability**: Validation data and analysis decisions are traceable from final reports. All data is available in the software, and there is no need for paper printouts.
- **Transparency**: Progress and accumulated results are visible during validation projects, not just after final reporting

Time saved in validation and verification studies

An estimated 490 working days is spent in verification and validation studies annually in the Department of Virology and Immunology in HUSLAB, with 36% of the work wasted on data management tasks. The study indicates that up to **95% of the wasted time can be saved.**

Time saved in data management



Conclusion

The case study implies that the new lean process together with the validation software enable hospital laboratories to conduct validation studies more efficiently, with increased quality and according to latest regulatory requirements.

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