User Requirement Specifications  
Electronic Lab Notebook

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| --- | --- | --- | --- | --- |
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# Abbreviations and Definitions

## Abbreviations

| **Term** | **Explanation** |
| --- | --- |
| EFPIA  ELN  IMI  ND4BB  Public Partners  SME  TRANSLOCATION | European Federation of Pharmaceutical Industries and Associations  Electronic Lab Notebook  Innovative Medicines Initiative  IMI programme “New Drugs for Bad Bugs”  SMEs and academic institutions  Small or Medium-Sized Enterprise  Research consortium for Topic 2 of IMI ND4BB programme |

## Definitions

| **Term** | **Definition** |
| --- | --- |
| Hierarchy level | Level of aggregation see also project, study and experiment |
| Project | Highest level of aggregation, normally used for a substance (class) |
| Study | Summarizes all results of all experiments belonging to the same experiment type (e.g. a safety study, a carcinogenicity study, a pharmacological study) |
| Experiment | A single experiment within a study. An experiment could be one of a series of same experiments or different experiments belonging to one study (e.g. blood measuring within an animal study |
| Primary data | First recorded data without any modifications |
| Raw data | Defined human readable data, not summarized, but may be processed |
| Original data | Data recorded by an automatic procedure or entered by the operator |
| Changed data | Data changed during the review process. Any change to the data need to be authorized and audited. |
| Curated data | Verified (QC-checked) and accepted data. In case of changes to the original data the change is audited and |
| Annotated data | Data or summaries of data with comments. In contrast to changed data these annotation does not need to be audited |
| Summarized data | Mathematically processed data (descriptive statistics) |
| Results | Scientific interpretation of (summarized) data, normally summarized in a study report |
| Report | Summary document of a study or an experiment containing all study related activities and data together with the scientific interpretation |
| QC-Check | Check that data is correct, e.g. data was uploaded correctly, data is in a predefined range, entered data is compared to a handwritten list |
| Validation of data | Check that data are within a predefined range or if outside, reject data or accept as outliers |
| Validation of method | Proof that the established method is correct and can be used for future measurement in the intended use |
| Validation of software | Test that software can be used in the intended manner for the described process and that the outcome of the software can be trusted |
| Bug fix | Change of program code to reflect a known software deficiency |
| Update | Minor release, mostly bug fixes, no new functionality |
| Upgrade | Major version release, added functionality |
|  |  |

# References

Information on the ND4BB InfoCentre:

<http://screeningport.com/wp-content/uploads/2013/02/ND4BB-Information-Centre-Overview.pdf>

Title 21 CFR Part 11 documentation:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=11>

Title 37 CFR documentation:

<http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title37/37tab_02.tpl>

# Aims of the Project

In 2012 the Innovative Medicines Initiative (IMI) initiated the “New Drugs for Bad Bugs” (ND4BB) programme to join forces against the increasing antimicrobial threat. For all current and future topics launched under this programme, a Central Data Hub (“Information Centre”) containing legacy data from previous research programmes of pharmaceutical industry partners as well as data generated during the lifetime of the whole IMI ND4BB programme needs to be implemented.

This project aims to establish an Electronic Lab Notebook (ELN) solution for the TRANSLOCATION consortium addressing Topic 2 (“Learning from success and failure & Getting Drugs into Bad Bugs”) of the ND4BB programme. The ELN is intended to enable the user group to capture a large diversity of research data (assay data, structures, scripts, documents, presentations, etc.) in a standardized and searchable way, share data between researchers located at geographically distinct sites and to provide an interface to the Central Data Hub to be established.

The intended user group (approximately 50 researchers) comprises all public partners (academic institutions and small or medium-sized enterprises) of the TRANSLOCATION consortium consisting of 14 academic research groups and 5 SMEs located in several countries of the European Union.

# Process Description

Public partners are spread all over the world using the ELN from different locations. The final goal of the project is to have all data stored in one centralized database whether there are satellite databases used or not. The vendor should propose scenarios for accessing the ELN via different techniques and should describe Pros/Cons and limitations for the described solutions.

The ELN will be used by different public partners using a wide variety of laboratory methods and with different level of experiences using ELNs. Especially at Universities the expectations are quite divers as these users are working quite more flexible than users in a more regulated environment like in industry. Thus, the user interface should be intuitive and easy to adapt to individual requirements. On the other hand the ELN should guaranty a high level of standardization. The amount of training required to use the ELN should be limited to the bare necessities.

It is essential for the success of the whole project that access as well as usability of the ELN is acceptable for the users.

Another major success factor of the project is the possibility to transfer the data from the ELN to the Central Data Hub (“Information Centre”). Until now neither the target database nor the type of data stored in this Information Centre is defined. It can be expected that the data from the ELN cannot not be transferred into the Information Centre in one batch run but will be transferred in small portions. Therefore either a detailed database description is essential for this transfer procedures or a sophisticated export functionality of data and meta data from the ELN to a generic format (CSV, XML) is required.

## Functionality Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 4.1-1 | The software enables storage of all data types as specified in Appendix A | 1 |
| 4.1-2 | The software must ensure for all users to create and use templates for projects, studies and experiments and the templates can be shared among users | 1 |
| 4.1-3 | It shall be possible to create a new experiment by cloning an existing experiment. Information such as Date of Creation, Author and Author Site will be updated automatically. It shall be possible to determine from a cloned experiment which write-up it was cloned from | 1 |
| 4.1-4 | It shall not be possible to close an experiment unless all mandatory data has been entered | 1 |
| 4.1-5 | It shall be possible for an author to recall a write-up from review and for a reviewer possible to forward or transfer assigned tasks to other reviewers | 1 |
| 4.1-6 | If an experiment remains open (with no activity) for a prolonged period of time, the author shall be notified (optionally by E-mail) | 1 |
| 4.1-7 | The software enables highly granular configuration of the data hierarchy (e.g. user, group, project, experiment) with configurable access rights for users on each level | 1 |
| 4.1-8 | The system shall manage the editing of ‘multi-author’ experiments such that no conflicts are experienced between the author and contributor(s) |  |
| 4.1-9 | The ELN solution allows the implementation of dictionaries with extensive maintenance capabilities for assigned users | 1 |
| 4.1-10 | The system shall warn the user if the file they are embedding is greater than a size specified by the system | 2 |
| 4.1-11 | It shall not be possible to close an experiment unless all mandatory data has been entered. |  |
| 4.1-12 | It must be possible to create and edit scientific and mathematical equations in whatever text editing solution the system offers |  |
| 4.1-13 | It shall be possible to insert links to raw data files stored outside of the ELN in approved data stores within the TRANSLOCATION consortium. Clicking on these links shall open the file using the associated application if it is available on the PC that the user is working at. |  |
| 4.1-14 | The system shall provide each user with information on pending tasks and requests from other users | 1 |
| 4.1-15 | If a write-up remains open (with no activity) for a prolonged period of time, the author shall be notified (optionally by email). | 2 |
| 4.1-16 | The software allows to create experiment reports that are exportable as pdf | 1 |
| 4.1-17 | Experiments must allow to request countersigning tasks from specified reviewers | 1 |
| 4.1-18 | The software provides comprehensive version-tracking of content and uploaded files | 1 |
| 4.1-19 | The whole ELN content (including attached files) must be fully searchable | 1 |

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 4.1-20 | The software must provide the option to store large supplementary data separately | 1 |
| 4.1-21 | It shall be possible to deactivate a user account if that user leaves the company, goes on long-term leave or moves to a department where BioELN use is not required, without loss of information within the system. |  |
| 4.1-22 | The ELN software must provide basic analysis tools and integration possibilities for third party software | 2 |
| 4.1-23 | Uploaded images must be annotatable and annotations must be searchable | 2 |
| 4.1-24 | Business rules and Standard Operating Procedures (SOPs) can be implemented | 2 |
| 4.1-25 | Projects, studies or experiments based on a template can be individually restructured | 2 |

## 4.2 Data Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 4.2-1 | Data must be assigned explicitly | 1 |
| 4.2-2 | Configurable mandatory data entry fields for metadata must be possible | 1 |
| 4.2-3 | Configurable optional data entry fields for metadata must be possible | 1 |
| 4.2-4 | Quality checks on each entry level must be configurable | 1 |
| 4.2-5 | Rejected data must be excluded from reporting or marked as invalid | 2 |

## 4.3 Output Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 4.3-1 | Export of single ELN experiments and experiment reports as Word document and pdf must be supported | 1 |
| 4.3-2 | Export of single database entries | 1 |
| 4.3-3 | A whole database export must be possible | 1 |

# Superior Functionalities

## Authorisation concept

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.1-1 | Definition of administrators, superusers and users and a highly granular definition of access rights is required | 1 |
| 5.1-2 | The software must allow to define roles and groups and assign users to groups and roles | 1 |
| 5.1-3 | It shall be possible to deactivate a user account if that user leaves the consortium or goes on long-term, without loss of information within the system | 1 |
| 5.1-4 | User access rights must be changeable on a per study basis | 2 |

## System Technology Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.2-1 | The software server must run on common work group server hardware | 1 |

## User Interface Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.3-1 | A web client must be available | 1 |
| 5.3-2 | It must be possible to carry out customisation (code changes), to meet specific Discovery needs, via a comprehensive SDK. This shall allow the implementation of Business Rules, workflows and the design of interfaces to in-house systems, without necessarily requiring the vendor to carry out the work. | 2 |
| 5.3-2 | It must be possible to prevent the loading of encrypted files or password-protected files to a write-up. | 2 |

## Error Processing Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.4-1 | Uploading data should not influence the accessibility of the system by other users | 1 |
| 5.4-2 | Errors must be collected in a log file and human readable | 2 |

## Interface Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.5-1 | The software shall support direct instrument import | 2 |
| 5.5-2 | A list of supported instruments must be provided by the vendor | 2 |

## Data Migration Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.6-1 | The vendor ensures that the ELN database is exportable and accessible by standard database applications | 1 |
| 5.6-2 | The ELN database must be freely and fully accessible via standard interfaces not only during the licensing period but also after the license of the software has expired | 1 |
| 5.6-3 | Preexisting data of the TRANSLOCATION consortium stored in commercial ELN solutions must be easily importable | 2 |

## Archiving Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.7-1 | Archived data must be protected from any changes | 1 |
|  |  |  |

## Data Protection Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.8-1 | Data backup and recovery must be possible via a centralised ELN software management tool | 1 |
| 5.8-2 | The system must be able to detect and report attempts at unauthorised access and have safeguards built in to prevent such attempts. | 1 |
|  |  |  |

## Documentation Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 5.9-1 | The vendor must deliver an extensive technical specification of the system | 1 |
| 5.9-2 | The ELN must have comprehensive online help capability | 1 |
| 5.9-3 | The database structure with all relations must be documented and accessible for administrators | 1 |
| 5.9-4 | The vendor must deliver an English operating manual for administration | 2 |
| 5.9-5 | The vendor shall provide a list of the common maintenance tasks required to keep the ELN system running optimally, along with the regularity with which such tasks should be performed. Such routine maintenance should be possible without the need to go back to the vendor for consultancy. | 2 |
| 5.9-6 | The vendor will also provide information on additional system maintenance routines that need to be performed periodically, based on configuration changes, feature requests, and fixes.  If some changes are needed for a specific defect, vendor representatives are expected to be available and onsite (if required) to resolve. | 2 |

# Infrastructure Requirements

## System Operation Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 6.1-1 | The system allows access by multiple users and from multiple sites in parallel | 1 |
| 6.1-2 | The solution must be available during 8am until 6pm Monday to Friday, locally at each site. The system shall be available on-line for 99% of the core hours.  A lower level of availability will be acceptable outside these hours |  |
| 6.1-3 | Full operation of the system must be recovered after a major failure within one working day | 1 |
| 6.1-4 | In the event of system recovery, no more than 25 minutes of data should be lost | 2 |
| 6.1-5 | The back-end system should support a replicated/redundant configuration on two different sites or operating in a master-slave fashion with automatic fail-over | 2 |

## Operating System Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 6.2-1 | The server application must be able to run on a standard server OS | 1 |
| 6.2-2 | Clients must be able to be accessed under Windows, Linux and Mac OS | 1 |

## Network Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 6.3-1 | An Internet bandwidth of 5 Mbit/s is sufficient for the “smooth operation” of the software for the users of the consortium | 1 |

## Server Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 6.4-1 | The ELN must use a standard database (ORACLE, MySQL, PostgreSQL) for data storage | 1 |

## Workplace Computer Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 6.5-1 | The system must run on desktop PCs and Laptops equipped with standard computer hardware | 1 |
|  |  |  |

# Manufacturer Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 7-1 | The vendor must install a fully functional ELN software on the provided hardware and document the whole installation process | 1 |
| 7-2 | The vendor must provide support to users and administrators during normal working hours in Europe | 1 |
| 7-3 | The system must be operational within 2 months after contract signature | 1 |
| 7-4 | On-site support must be available within defined reaction times | 2 |
| 7-5 | System updates must be supported by the vendor | 2 |
| 7-6 | It must be possible to deploy the ELN in a phased approach, deploying first to an initial set of users and then bringing additional groups of users online at a later time. In other words, there must not be any constraints related to the design and construction of the system that prevent this being possible. | 2 |

# 

# Part 11 Requirements

| **URS** | **Requirement** | **Prio.** |
| --- | --- | --- |
| 8-1 | The E-signatures within the software must support 37CFR compliance in order to protect intellectual property and inventions. | 1 |
| 8-2 | The ELN full audit trail must support CFR 21 part 11 for regulatory compliance with GxP guidelines | 1 |
| 8-3 | The audit trail functionality must be configurable, i.e. changes only, data entry and changes, etc. | 2 |
| 8-4 | The visibility of the audit trail must be configurable, i.e. for operator only, for admin only etc. | 2 |