**APPENDIX NO. 3 TO THE ToR**

**Description of the Object of Contract**

**Technical specifications of the electronic laboratory notebook**

Acquisition of software to manage results, laboratory equipment and laboratory facilities was planned.

Quantity: -One set for at least 30 users

The electronic laboratory notebook must meet the following requirements:

* Software (installed on user servers) to manage experimental results and laboratory equipment and meeting the following requirements
* The electronic laboratory notebook must be able to be applied to research and discovery in university life sciences;
* The language of the electronic laboratory notebook must be English.
* The electronic laboratory notebook must provide the ability to document and record test data in notebook forms and as attachments. The data recorded in the notebook forms and as attachments must be accessible from a single working page;
* Data must be recorded, organised and stored in accordance with the project structure with the different roles and access levels of the staff involved. It must be possible to define and change each employee's access level: access to specific data (notepad forms) and permitted functions;
* The team leader/administrator must have full access to all studies and results, and must be able to define the level of access of the staff involved;
* The electronic laboratory notebook must include integrated Microsoft Excel, Word and Power Point applications or an equivalent application that allows Excel worksheets to be opened, edited and saved without the need to install Microsoft Excel, Word and Power Point software on the computer;
* There must be a free add-on to edit attached files without the process of manually downloading, editing and uploading them. The add-on must recognise file formats for which the corresponding software is installed on the computer;
* The electronic laboratory notebook must provide the ability to create databases of samples taken, reagents, equipment workload, equipment validation. It must be possible to track samples from creation, including information on their inclusion in experiments, parents and ancestors, physiological data
* The electronic laboratory notebook must provide full tracking of sample collections and individual samples
* The electronic laboratory notebook must be equipped with a search engine for searching all electronic laboratory notebook databases. It must be possible to search for words, phrases or numbers in all text fields to be registered
* The electronic laboratory notebook must provide the ability to create, update and save protocol templates or standard operating procedures that can then be added to research projects, including not only text fields but also dynamic
* The electronic laboratory notebook must keep a complete audit log of all recorded experimental data, samples and protocols, and record all old versions of protocols and standard operating procedures
* The electronic laboratory notebook must provide the ability to work in accordance with Good Laboratory Practice (GLP)
* The electronic laboratory notebook must provide the ability to sign and counter-sign experiments with electronic signatures to be locked for further modification in accordance with 21 CFR Part 11 of the US Food and Drug Administration guidelines.
* The electronic laboratory notebook must be able to generate barcodes/QR codes for all registered samples, instruments and equipment. It must be possible to link existing barcodes to newly registered samples.
* It must be possible for the electronic laboratory notebook to handle all protocols and standard operating procedures. It must be possible to upload images and files for experiments as well as for samples.
* Within the electronic laboratory notebook, it should be possible to annotate images.
* Audit logs and records should form part of all sections of the electronic laboratory notebook
* The electronic laboratory notebook must support scientific formulas and equations.
* It must be possible, either directly or via specialised, off-the-shelf add-ons, to connect the electronic laboratory notebook to various raw data acquisition and barcode printing devices:
* The manufacturer of the electronic laboratory notebook must be certified to NEN-EN-ISO/IEC 27001:2017+A11:2020
* The electronic lab notebook must be compatible with Microsoft Windows or macOS operating systems
* There must be a freely available mobile application of the corresponding electronic laboratory notebook suitable for Android and iOS operating systems
* The following add-ons must be available free of charge to extend the functionality of the electronic laboratory notebook:
	+ 2D barcode creator;
	+ 2D barcode import;
	+ Add-on supporting barcode printer connectivity and barcode printing;
	+ An add-on that allows the connection of a reference library (e.g. Mendeley) to an electronic laboratory logbook;
	+ An add-on that visualises the family tree of the sample;
	+ Add-on for printing labels
* The manufacturer of the electronic laboratory notebook must provide the software in the form of perpetual licences and SaaS.
* The manufacturer of the electronic laboratory notebook must provide software updates and maintenance for SaaS and separate software update and maintenance packages for perpetual licences.

Technical solutions

The software must be installed on local servers and meet the following requirements;

* + Strict adherence to IT compliance and validation policies
	+ Single user login option via AD, ADFS, SAML LDAP
	+ Acceptance Server implementation option
	+ The application must run on Microsoft Windows Server 2016
	+ Ability to enforce two-step verification at login.
	+ Have full system administrator functions for overall system control
	+ The system should have a full REST API and Software Development Kit available for other system integrations
	+ It must be possible to create custom additions
	+ Password settings should be adjusted in terms of length, characters, etc. in accordance with the institute's preferences.
	+ It should be possible to export all data from the system in multiple formats such as HTML, PDF, XML and JSON.
	+ Updates should be implemented in accordance with a quarterly schedule and the dates of such updates provided well in advance.
	+ Technical training and support is to be provided to both key users and end users.

Additional requirements:

* + Supplier must comply with GDPR requirements
	+ It must always be possible to upgrade to more users.
	+ Guarantee: 3 years of support and manufacturer's warranty for the product offered. Product update a minimum of once every 12 months from the date of purchase.