Medicines Discovery Catapult

Specification

for

Laboratory Information Management System

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1. Introduction

Alderley Park Lighthouse Laboratory is increasing its ability to support the Department of Health and Social Care Pillar workflows associated with Covid-19 testing, while increasing current integrity, security, flexibility, and performance of current Pillar 2 testing. It is also envisaged that there will be an increase of Pillar 2 capacity and the need for full UKAS ISO15189 accreditation. The LIMS (Laboratory Information Management System) was previously procured to support Pillar 2 and now requires to be refreshed or significantly upgraded to support a compliant and stable business function.

1. Definitions

|  |  |
| --- | --- |
| “**Authorised Users**” | means those employees, agents, and independent contractors of MDC who are authorised by MDC to use the Services. |
| “**Contract**” | means the contract ultimately concluded between MDC and the Supplier pursuant to the Tender. |
| "**DPA 2018**" | Data Protection Act 2018; |
| “**Data Protection and Cybersecurity Legislation**” | (i) the GDPR and any applicable national implementing laws as amended from time to time to the extent that they apply following the exit of the United Kingdom from the European Union.  (ii) the UK GDPR;  (iii) the DPA 2018 to the extent that it relates to processing of personal data and privacy;  (iv) all applicable law about the processing of personal information or privacy;  (v) the Privacy and Electronic Communications Directive 2002/58/EC (as updated by Directive 2009/136/EC) and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426), the Cybersecurity Directive ((EU) 2016/1148), Commission Implementing Regulation ((EU) 2018/151), the Network and Information Systems Regulations 2018 (SI 506/2018),  all as amended or updated from time to time. |
| “**GDPR**” | the UK GDPR as defined in sections 3 and 205 of the DPA 2018. |
| “**Good Industry Practice**” | means the exercise of that degree of skill, care, prudence, efficiency, foresight, and timeliness as would be expected from a leading company within the relevant industry or business sector. |
| “**LIMS**” | means laboratory information management system. |
| “**Maintenance Releases**” | means any update, upgrade, release, or other adaptation or modification of the Software that the Supplier may generally provide to its licensees during the term of the Contract, which may contain, among other things, error corrections, enhancements, improvements, or other changes to the user interface, functionality, compatibility, capabilities, performance, efficiency, or quality of the Software, and includes any New Version. |
| “**MDC**” | means Medicines Discovery Catapult Ltd (Company Number 09928547) and Medicines Discovery Catapult Services Ltd (Company Number 10305216), whose registered office is Block35, Mereside, Alderley Park, Alderley Edge, Cheshire, SK10 4T. |
| “**MDC Data**” | means the data inputted into the information fields of the Software by MDC, by Authorised Users, or by the Supplier on MDC’s behalf, and any data supplied by MDC or otherwise generated by, or derived from MDC’s use of the Services, whether hosted or stored within the Services or elsewhere. |
| “**New Version**” | means any new version of the Software that the Supplier may from time to time release (not deploy) and market generally as a distinct licensed product, as may be indicated by the Supplier’s designation of a new version number. |
| “**Services**” | means the provision of the Software and/or connected maintenance and support services as applicable, given the context in which the term Services is used. |
| “**Software**” | means the Supplier’s proprietary software in machine-readable object code form only, including any error corrections, updates, upgrades, modifications, and enhancements to it provided to MDC. |
| “**Supplier**” | means the person, firm or company who supplies MDC pursuant to the Tender. |
| “**Tender**” | means this document and the accompanying appendices, setting out the requirements and rules for the tender process. |
| “**UK GDPR**” | means Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended or supplemented from time to time by UK law. |

1. Data Management Requirements **(all items are Mandatory unless marked D = Desirable)**
   1. General Requirements
      1. The Supplier shall provide the Services in a timely, skilful, professional, and workmanlike manner by qualified personnel exercising care, skill, and diligence consistent with industry standards, and will devote adequate resources to meet its obligations in accordance with the terms of the Contract.
      2. The Supplier will provide MDC, at no additional charge, all Maintenance Releases each of which will constitute Software and be subject to the terms and conditions of the Contract.
      3. MDC shall have the right, in its sole discretion, to receive any New Versions of the Software that the Supplier may release from time to time, at the best price then charged by Supplier for such New Version. All New Versions provided will constitute Software.
      4. The proposed LIMS must be suitable for use in a Molecular diagnostic (Polymerase chain reaction) workflow.
      5. The LIMS should provide non-LIMS trained personnel the ability to easily access the system data in an intuitive, user-friendly graphical user interface (GUI) with customisable dashboards.
      6. The LIMS should display data from a range of specimens and other user-defined queries, using global and in-process search functions.
      7. The LIMS must allow tabular data to be sorted and filtered.
      8. The LIMS must send on-screen output to a printer or file without contradicting view-only status.
      9. The LIMS must provide single data point entry, (e.g.) sample number, automatically populates other data fields and remembers relevant data so it does not need to be re-entered, selected, or searched for.
      10. The LIMS must eliminate or significantly reduces redundant data entry and paper trails (no reliance on 3rd party software for sample receipt).
      11. The LIMS must provide full database keyword and field search capability including the use of multiple criteria.
      12. The LIMS must allow users to build save and edit queries for future use. The LIMS shall describe the steps required to create reports and output files.
      13. The LIMS must automate the search for, and extraction of, datasets including the export of that data to external applications for additional processing. For example: electronic manifests and transfer of data between instruments and LIMS and other external NHS systems as required (NPEx).
      14. The LIMS should be able to manage both sample and non-sample related data, including images, PDFs and spreadsheets. **(D)**
      15. The LIMS must create and maintain a unique electronic accession record for every sample.
      16. The LIMS should issue sequential numbers for chain of custody tracking and allow for sub-numbering to maintain parent-child relationships.
      17. The LIMS must link objects to other objects (eg. linking a batch of reagents to a series of samples results).
      18. The LIMS must notify users of events such as scheduling, receipt, and completion of tasks.
      19. The LIMS must include the ability to set up alerts via email. **(D)**
      20. The LIMS must track individual users with sample management responsibility and provides user configurable workflows for approval of specimen usage.
      21. The LIMS must have full regulatory clinical compliance (including ISO 27001) within EU/UK law and good clinical laboratory practice.
      22. The LIMS must facilitate specimen tracking from accessioning to disposal, including creating customisable exception reports.
      23. The LIMS must not reject Duplicate Sample ID’s. A record or modification (suffix) of the duplication for further exception decision or comment is acceptable.
      24. The LIMS must have a consent management aspect that ensures all samples are managed in line with ethical requirements.
      25. The LIMS should allow users to create, manage and track viewable sample container schema – including fridge and freezer/storage capacity tracking and management with ability to define exact position and location of every sample within those storage locations.
      26. The LIMS should support 1D and 2D barcoded specimen and plate labelling and tracking.
      27. Authorised Users must have the ability to query the LIMS for audit and tracking purposes.
      28. The LIMS must provide instrument maintenance and calibration management. **(D)**
      29. The LIMS should allow a user to independently add parameter fields on samples at any time during the active state, after implementation while neither voiding the warranty nor requiring supplier to review at a later date.
      30. The LIMS must allow Authorised Users to generate Authorised User defined upload, download and parameter (test) rules via a predefined sample set and a script language format.
      31. The LIMS must include comprehensive scheduling, tracking and flow management of samples (possibly across multiple sites) and has an inter-lab transfer function.
      32. MDC Data is owned by MDC and should be fully portable under the control of MDC for moving MDC Data partially to other systems or wholesale to an alternative LIMS system at the end of the Contract.
      33. The LIMS should not be limited to Molecular diagnostic workflow / sample type; the LIMS should be able to receive/manage multiple sample types typical with a standard diagnostic laboratory.
   2. Reagent, Equipment Control
      1. The LIMS should have stock control capabilities. The systems should allow for the categorisation of stock items using barcoded items and have the ability to track reagent validity (via expiry date and enable regent status’ such as (quarantined, validated or expired). The LIMS system should not allow any un-validated reagent to be used in a live run. The LIMS should have equipment status capabilities to mark instruments “out of service”, “offline”, running QC or “Ready for use (Qc Passed)” Failed instruments should not be able to proceed results to host. (unvalidated). **(D)**
   3. Project Interface Requirements
      1. The GUI must be replicated at each Workstation 1 manual terminal (55) where the scientist dispenses sample into a viral preparation plate; this plate map should allow for positive & negative controls, blanks (for orientation) and have the ability to record deposits into each well which directly inputs into the LIMS database/sample tracking and also be able to record customisable sample conditions.
         * LIMS should be able to interface to the Hamilton Star Liquid Handlers (55) to receive reagent data used and plate ID number directly into LIMS to be used/selected during sample depositing in WS1 Manual/Auto.
         * LIMS should be able to interface to receive automatically generated sample dispensing information from the Hamilton Star which included kingfisher plate number and sample positions and link to the bead Hamilton informationWS2 - Manual Input of RNA Plate information (plate ID and reagents used). The LIMS must have the ability to link this to the 96well plate for auditing.
         * WS3 - The 384-position sample plate is prepared and the reagent used should be recorded against the wells dispensed into. This should be a manual input method and included 3x reagents & PCR plate ID.
         * WS4 - The LIMS systems must be able to receive information on Plate preparation whereby 4x96 well RNA plates (from WS2) are dispensed into the PCR plate (from WS3), the HamiltonMax or Star Liquid handler outputs a file (there formats are available) containing the User, Hamilton ID, Plates and sample dispense (well) information. This information should be ingested and connected to the sample audit trail.
         * WS5 - The LIMS should be able to directly communicate to Ugentec's cloud environment (AWS) to receive Fastfinder middleware output information into LIMS. Information contains SID, Result, Cq values, Fluorescent values, and comments.
         * WS6 - The data in LIMS should be controlled by customizable rules for automatic or manual release and have options to upload via multiple formats/languages.
         * (WS=Workstation – Related to a workflow method in the Molecular diagnostic process)

WS0 - It is expected LIMS will be required to interface into Deloittes Validate APP - this to receive information of deliveries to site, the data can be received by a pushed CSV to a local SFTP location on box arrival (containing Box number, contents and sample taken time) or a API query when a box is scanned by LIMS the data is queried directly to Deloittes and the information is returned.

* + - Manual Aliquoting - LIMS must be able to fully replicate manual operations in workstation one where a sample is manually dispensed into a 96 well viral preparation plate manually recording the status of the sample location, the well dispensed into and the sample status (Normal, Leaked, Duplicate). Reagents may also be added at this stage.
    - The LIMS should provide a solution for manually recording leaked samples into the system that can be identified and send to host where required.
    1. The LIMS should be device agnostic and responsive, e.g. the graphical user interface (GUI) resizes according to user device.
    2. Connection types available to interfaces such as Hamilton Star Platforms, Kingfisher Flex (or Middleware), Ugentec and Kainos S3 SFTP bucket.
  1. Records
     1. Data extraction facilities are required, along with a medical dictionary or thesaurus, clinical coding system (or ability to link independent systems) and facilities for Authorise User-defined templates and form letters/email.
     2. Data manipulation facilities are required, along with a medical dictionary or thesaurus, clinical coding system (or ability to link independent systems) and facilities for Authorised User-defined templates and form letters/email.
  2. Management Reports

The LIMS must support timely, accurate and complete management information to enable close monitoring of activity against operational and service plans. Realtime and time range-defined Management and KPI dashboards should be available, e.g. Dwell time, Cycle time broken down by processing step, Controls (positive, negative, internal) results (Ct) tracking over time, any samples exceeding time limit and basic sample counter

* + 1. The system must have the ability to build additional reports and/or have a read only connection to the data source.
    2. Facilities for generation of management reports should be possible. The system must have user customisation facilities, appropriate speed of production of reports (of up to 300,000 samples), effect of reporting on system performance, ability to export data to other applications such as Microsoft Excel and Access. The LIMS must natively interface with the National Pathology Exchange (NPEx) system via sFTP or HL7 v2.3.1.
    3. The LIMS should provide delta-checking facilities for numeric results.
    4. The LIMS should be able to retain a record of the released report in case of the need for rerelease.
    5. The LIMS must be able to reproduce interactive plate maps (Viral plates, RNA plates and PCR plates) where a well can be selected and audit history & result displayed.
    6. The LIMS should be able to select individual tests or groups of tests (user defined profiles) for each individual sample or group of samples.
    7. The LIMS should have a list of stock laboratory tests or investigations to be linked to appropriate disciplines.
    8. The LIMS must have the ability to select individual tests or groups of tests (user defined profiles) for each individual sample or group of samples.
    9. The LIMS must have capacity to process at scale - running up to 150,000 samples per day with approximately 30 concurrent laboratory users - without causing throughput or cycle time bottlenecks at any step or performance issues when running routine management and reporting queries.
    10. Sample load, concomitant reporting, and routine querying (e.g. producing a day or 3 day report) must have no impact on system performance.
    11. The LIMS must provide the following:
        - Ability to export customisable .CSV files for export to SGSS (Sanger) and NPEx via sFTP
        - Exported result should be a consolidated result on “SARS-CoV-2 RNA”
        - Exported result should include CT value(s) for every gene for that assay
        - The Host output content file or string file should be structured in the same way as current formats including headers - Sample, Result, Date Tested, LB ID (AP) CH1Target, CH1-Result,CH1-Cq,CH2Target, CH2-Result,CH2-Cq,CH3Target, CH3-Result,CH3-Cq,CH4Target, CH4-Result,CH4-Cq
        - Exported result field should be be able to report the results as follows: Positive, Negative, PLOD, Void
        - The Host file should be MD5 hashed (fingerprint) prior to upload and prefixed ap-labYYYYMMDDHHMM.(can be completed locally)
    12. The LIMS must have full data export capabilities.
    13. The LIMS must be able to fulfil data migration of data into the LIMS where required.
    14. The LIMS must have the ability to export QC data to NPEx sFTP or any other sFTP via CSV. **(D)**
    15. There must be appropriate Quality Control (QC) functionality for each discipline**.(D)**
    16. The LIMS must process Internal IQC defined by a known sample value used to run as QC – the LIMS should be able to accept an internal sample ID for identification. **(D)**
    17. The LIMS must process External Quality Control (ECQ). **(D)**
    18. The LIMS must be able to process EQA specimens in the same manner as patient results and record and return results to EQA officer within the defined timeframes. **(D)**
    19. The LIMS must be able to capture QC results automatically from analysers and recognise this as non-patient information. **(D)**
    20. The LIMS must be able to capture QC results from data input from worksheets and recognise this as non-patient information. **(D)**
    21. It must be possible for the LIMS to export the captured QC data results into an external data source**.(D)**
    22. It must be possible for the LIMS to archive QC data permanently in such a way that it can be viewed or analysed at a later date. **(D)**
    23. It must be possible for the LIMS to record batch specific information of quality control specimens. **(D)**
    24. There must be the facility within the LIMS to calculate means and standard deviations of QC results within locally defined periods **(D).**
    25. There must be the facility in the LIMS to calculate means and standard deviations of QC results on a rolling basis. **(D)**
    26. QC results must be available graphically as well as numerically within in LIMS**.(D)**
    27. The QC package should allow for the application of Westgard or equivalent rules to QC data.**(D)**
    28. The QC package must be able to track a specimen ID to the most recently related QC results. **(D)**
    29. The QC package must be fully auditable. **(D)**
    30. The LIMS may also be used for biobanking and should therefore have possible options to store a sample directly (manually) into a depicted MTP plate, recording the sample number, and other demographics should it be required.
    31. If the LIMS is used for biobanking, there should be possible options to store a sample directly (manually) into a depicted MTP plate, recording the sample number, other demographics.
    32. BioBank Storage: the ability to track Samples dispensed into storage plates extracted from the testing process. These will not be archived until they are set onto a final customer. Tracking will also show new storage location and extra fields such as availability, final customer**.(D)**
  1. Warnings/Alerts
     1. The LIMS should provide warnings/alerts, e.g. expired reagents, record in use, result not completed by expected turnaround time, etc.
  2. Customisation
     1. Customisation should be available within the LIMS from an Authorised User perspective e.g. test record, report queries, rule creation etc.
     2. The system should allow read only external connectivity (eg ODBC)
     3. If Authorised User customisation is not available as standard at Authorised User level, it should be available as an add-on.
     4. The LIMS must have the ability to create new reports.
  3. Data Search and Export
     1. The LIMS must allow Authorised Users to perform advanced multi-parameter searches on samples and clinical data held within the LIMS. An example search may be:
        + list all assays used with reagent lot number X,
        + all positive samples generated between two dates, etc.
  4. Limitations in the product with regards to search should be minimal.
     1. Advanced searching must be available to all Authorised Users, search parameters Sample ID, Name, Unique identifier maybe used.It must be possible to export searches to saved excel readable file format (.CSV) and include all information pertaining to the search. **(D)**

1. IT Requirements
   1. Regulatory
      1. The LIMS must meet requirements for handling classified information and documents to ISO27001 standards, including logging of changes and access (success or rejection).
      2. The following must be complied with:
         * Human Rights Act (1998)
         * Electronic Communications Act (2000)
         * United Kingdom Accreditation Service (UKAS) Standards For The Laboratory – in particular; Section’s 5.9 and 5.10 ISO 15189 (2012).
         * ISO 1500-1508: Common User Interface - or alignment to.
         * ISO 20000 IT Service Management
         * ISO 9000 Quality and Process Management
         * ISO 22301 Business Continuity
         * ISO 14001 Environmental Management
         * ISO 50001 Energy Management
         * Data Security and Protection Requirement (DSPR) Toolkit - IT Security
         * Cyber Essentials Plus (CE+) - IT Security
         * NHS Interoperability Toolkit (ITK) - Interoperability (National)
         * The vendor should support:
           + HL7 (versions 2.2-2.5 and FHIR) - Interoperability (Transport and Syntactic)
           + ASTM
           + Customisable HL7.
           + sFTP
           + Encrypted VPN,
           + HTTPS, SFTP, TSL/SSL
      3. Patient Identification Standards

<https://www.gs1uk.org/our-industries/healthcare/gs1-standards-for-nhs-acute-trusts/the-three-core-enablers#patient-id>

* + 1. NHS Caldicott Principles - Information Governance

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF>

* + 1. Data Protection and Cybersecurity Legislation
    2. Health Insurance Portability and Accountability Act of 1996 (HIPAA) (US only)
    3. The bidder should be transparent on their LIMS SDLC (Release notes & Limited Distribution testing)) and will the supplier agrees to sharing relevant CSV documents (IQ/OQ) relevant to the installed product for AP.
  1. Architecture of Proposed Solution
     1. It is expected that the proposed LIMS may use a serverless technology based in the cloud.
     2. The proposed LIMS must be able to connect to multiple other cloud (Azure & AWS) based solutions. Instances ensuring governance and data integrity
     3. The LIMS should support accessibility via multiple operating systems and support for tablet and mobile devices is required (iPad, windows, android). Management information dashboard containing data such as sample counts, workstation turnaround times, quantity counters (such as number of exceptions) and any reagent, equipment or QC warnings/failures**. (D)**
     4. The LIMS should store detailed records of system user activities which can be viewed by administrative users.
     5. All Authorised User interactions with fields must be stored in audit logs and all audit logs must be time stamped.
     6. The LIMS & Hosted services must provide an audit trail of all activity.
  2. User Management
     1. The LIMS should allow administrators and other Authorised Users to configure multiple levels of Authorised User rights and security by site location, department, group, role and/or specific function.
     2. The LIMS should allow the resetting of user passwords by LIMS & Lab Managers and Authorised Users and have the option of disabling users.
     3. The LIMS solution should support Single Sign on (Azure AD) and Multi Function Authentication **(D)**
     4. The LIMS should lock Authorised Users out after a specified number of consecutive failed log-in attempts.
  3. Reliability, Security and Performance
     1. The Supplier shall ensure that the Services are compliant with applicable laws. All personal data in the LIMS must be processed and/or controlled in accordance with current and future Data Protection and Cybersecurity Legislation.
     2. The LIMS must provide a secure web portal to log issues and issues logged must be transparent to the laboratory to monitor progress on logged issues.
     3. The Software shall be fully audited, and the Contract shall provide for annual audits by MDC and/or its agents to check for compliance.
     4. The Supplier shall ensure that security services are up to date and provided in accordance with accepted Good Industry Practice.
     5. The Supplier and MDC shall take a high degree of technical and organisational measures against unauthorised or unlawful processing of the personal data or its accidental loss, destruction or damage.
     6. The Supplier shall ensure that the Software is free from viruses and vulnerabilities, and the Contract shall require the Supplier to take appropriate precautions to prevent the introduction of any virus or vulnerability into MDC’s systems.
     7. The Supplier shall supply a detailed business continuity and disaster recovery plan in line with Good Industry Practice as part of the Contract.
     8. The Software shall have at-rest and in-transit data protection in accordance with Good Industry Practice, e.g. FDE, https.
     9. MDC Data shall remain secure and only accessible to Authorised Users.
     10. The Supplier shall offer service levels which provide at least a 99.5% annual uptime. LIMS.”must have minimal downtime to cope with 24/7/365 operations. MDC defines availability of the Service as the proportion of time when LIMS is actually available compared with the planned service hours. Scheduled downtime can be excluded from the statement of availability provided that these times have been agreed in advance and with a suitable notice period.
     11. The Supplier shall set out its maintenance procedures in the Contract, which shall be designed to minimise the impact on MDC of any downtime of the Services.
     12. The Supplier shall ensure that the LIMS and any data back-up/business continuity and disaster recovery solution are utilising only UK-based servers.
     13. The Supplier shall procure, install and configure the hosting environment to provide uninterrupted access to the Software throughout the duration of the Contract.
     14. The hosting equipment shall be installed inside a professional UK hosted facility designed for such use.
     15. The Supplier shall perform the hosting, maintenance and support services.
     16. The Software shall be accessible to Authorised Users off-site and away from MDC’s regular premises to allow working-from-home or on partner sites.
  4. MDC Data, Data Backups, and Data Recovery Requirements
     1. MDC shall own all rights, title and interest in and to all of the MDC Data.
     2. The Supplier acknowledges that it will be a processor of MDC for the purposes of Data Protection and Cybersecurity Legislation, and that it will agree to appropriate contractual obligations in accordance with its role and in compliance with the Data Protection and Cybersecurity Legislation.
     3. The Supplier shall develop the back-up schedule, perform scheduled back-ups in conjunction with the customers advice, provide routine and emergency data recovery, and manage the archiving process.
     4. The back-up schedule shall include at least weekly full back-ups and daily incremental back-ups and have no impact on data integrity.
     5. In the event of data loss, the Supplier shall provide rapid recovery services to restore the most recent back-up in accordance with Good Industry Practice.
     6. The Supplier shall ensure the protection of MDC’s confidential information and shall provide a Contract containing appropriate provisions.
     7. The LIMS must have the facility to back up data in accordance with Good Industry Practice.
     8. The Supplier shall supply a detailed business continuity and disaster recovery plan in line with Good Industry Practice as part of the Contract.
  5. Performance
     1. Assuming acceptable network latency/bandwidth we require 95% of page loads/updates must complete in under 1 second.
  6. Application Clients
     1. MDC aims to operate in compliance with the letter and ethos of the Disability Discrimination Act 2005, Human Rights legislation, and the wider access policies of the Funding Councils. The system should comply with W3C accessibility standards WCAG 2.1 level AA, and the Equality Act 2010.
     2. The client terminals will be used directly for manual sample input into MTP's. The System GUI for this purpose should be clear from unrequired menu options and unused buttons.
     3. It is expected that Software and IT resources offered should be accessible to staff with disabilities. Proposals should, where appropriate, take account of accessibility issues.
     4. Authorised Users will wish to re-use data that they have access to in the LIMS. They may wish to choose to print/export all or part of what they see on the screen or they may wish to copy and paste data into other applications for example: word, excel or email. They may elect to view a report on-screen rather than printing/exporting.
     5. The LIMS must accept input through barcode scanners (1D and 2D).
     6. The LIMS must have the ability to connect to network printers and/or provide web page functionality for ensuring a suited print format (e.g Active X, HTML printing standard).

1. Implementation Stage
   1. It is business critical to MDC that any transition of the LIMS service will need to be seamless. MDC therefore expects the Contract to contain robust implementation and transition provisions and clear remedies for delay which protect MDC.
   2. The LIMS shall be implemented up to 12 weeks of signing the Contract. There will be up to an 8 week period for phase 1 of implementation. Phase 2 of the implementation will take place thereafter. The Contract should reflect this.
      1. Phase 1 is defined as – Like For Like workflow & Functionality.
      2. Phase 2 to include advanced reporting, additional connections and workflow modifications.
   3. The Supplier shall provide a finalised implementation plan as part of the Contract.
   4. Deliverables of the implementation plan shall be formally accepted between the Supplier and MDC at the start of the implementation period.
   5. Pre-existing data available as pdf shall be uploaded to the LIMS during the implementation period.
2. Fees
   1. In consideration of, and as payment in full for, the rights and license to use the Software, MDC shall pay to the Supplier the fees as set forth in the Contract.
   2. In consideration of the Supplier providing the Services, MDC shall pay the Supplier the fees set forth in the Contract subject to and in accordance with the terms and conditions of the Contract.
   3. The Contract shall include separately identified costs for implementation, if applicable.
   4. The Contract shall include separately identified hosting set-up fees and annual hosting fees if applicable.
   5. The Contract shall include separately identified costs for maintenance and support services.
   6. The Contract shall include a separately identified annual software licence fee for 50 Authorised Users, and a mechanism for adding or removing Authorised Users where required by MDC.
   7. The Contract shall include an appropriate service credit regime in the event the Supplier fails to meet the service levels stated.
3. Licences
   1. The Supplier shall grant MCD a non- exclusive, royalty-free, irrevocable license, non-sublicensable right to use the Software.
   2. MDC will purchase licences granting access to individual Authorised Users, and the Contract shall provide a mechanism to allow for the addition, removal, and replacement of Authorised Users within the number of licences granted.
   3. MDC shall have the ability to create and grant access to additional individual Authorised Users in excess of the original purchased licences on a pro-rata basis. MDC will be charged for these additional licences according to a fee schedule mutually agreed by MDC and the Supplier.
   4. The Supplier shall be responsible for obtaining and maintaining all necessary licences, consents and permissions needed to provide the Services, and shall ensure that MDC is able to use the Services without infringing any third party’s intellectual property rights.
4. Training & Support Service
   1. The Contract shall include the provision for training of five Authorised Users as administrator level users and up to 20 key users during the implementation period, additional training may be required at a cost agreed with MDC.
   2. The Supplier shall provide MDC with technical support as part of the Contract, with support requests limited to administrators.
   3. The Supplier shall provide first-line support on a 24x7 basis. Second line support should be available during normal working hours.
   4. The Supplier shall provide response times and fix times to correct any Service issues.
   5. The Supplier shall provide additional appropriate service levels in respect of the maintenance and support services.
   6. The Supplier shall maintain the Software as part of the Contract.
   7. The Contract shall contain at least a yearly update of the Software to its most current release, if available.
   8. Before the Supplier makes changes to integration interfaces between the Software and MDC’s internal data stores or systems, the Supplier shall provide sufficient notice and support to MDC in order to ensure the continued operation of any integration interfaces affected by such changes.
5. Software Specifications
   1. Collaboration
      1. Different levels of access shall be refined on an administrator level, allowing MDC’s administrator-level Authorised Users to alter this without the need to engage the Supplier’s support service.
6. Implementation of additional features
   1. Future implementation of additional features
      1. The Supplier shall, if required by MDC, provide connections & setup for additional diagnostic services as part of the Services. Services such as Biochemistry, Serology, Microbiology or Haematology may be required to be performed alongside the Services and form part of the LIMS. Any additional software used in the provision of the serology services will need to integrate with the Software and shall comply with all Data Protection and Cybersecurity Legislation and within agreed timescales.
      2. It shall be possible to implement additional features into the LIMS during the Contract period as fee-for-service.
      3. The Supplier shall provide a Contract which provides for a suitable call-off structure for statements of work that can detail the terms of such additional features under the Contract, and an appropriate change control procedure to allow for the negotiation of the terms related to such additional features.
7. NewCO

MDC may form a new subsidiary company (“**NewCo**”). In the event that NewCo is incorporated, it is anticipated that all contracts associated with the Lighthouse Laboratories will novate to NewCo. The Supplier should be willing to novate the Contract to NewCo at the option of MDC (insofar as possible). In the event that either party is incapable or unwilling to novate the Contract to NewCo, NewCo shall make a direct award for the Services as opposed to MDC.

1. Contract commencement and termination
   1. The Supplier should note that the commencement date for the Services is to be agreed (and MDC shall have no obligation to proceed with the Services following Contract award).
   2. The Contract shall contain a provision which allows MDC to terminate the Contract on notice without cause. MDC will be prepared to enter into a Contract with the Supplier for, for example, until 31st December 2021, however all costs associated with the Services must be clearly set out in the Contract.
   3. The Contract shall also provide MDC with all standard termination rights, including for Supplier breach, insolvency, and an event of force majeure.
   4. MDC shall have specific rights of termination in relation to any Supplier breaches of confidentiality, Data Protection and Cybersecurity Legislation, or third-party intellectual property rights.
   5. The Supplier shall make all MDC Data accessible in a readable format (\*rtf or \*pdf) within one month of Contract termination.
   6. The Supplier shall provide an exit plan as part of the Contract on how MDC Data is delivered to MDC at the end of the Contract. The Contract shall provide that such exit plan is put in place within 3 months and regularly updated by the Supplier.
2. Risk and liability
   1. The Contract shall provide appropriate warranties from the Supplier in accordance with Good Industry Practice, including in respect of the performance of the Services, its ownership of all necessary proprietary rights needed to provide the Services, and its compliance with applicable laws.
   2. The Supplier shall obtain and maintain appropriate insurance cover commensurate with the risk of loss to MDC for the duration of the Contract.
   3. The Contract shall provide for limitations on liability commensurate with the value of the Contract and the Services and in accordance with the insurance cover available to the Supplier.
   4. The Supplier shall, on an unlimited basis, indemnify MDC against losses arising out of any Supplier breach of third-party intellectual property rights, confidentiality, and the Data Protection and Cybersecurity Legislation.

Other contractual requirements

* 1. The Contract shall contain appropriate standard commercial clauses, including that:
     1. MDC’s agreement must be provided before any variations can be made.
     2. the Supplier shall only be permitted to subcontract its obligations with MDC’s consent.
     3. an appropriate governance process is put in place for managing the day-to-day running of the Services and for reporting and reviewing the performance of the Services and service levels (on at least a monthly basis).
     4. the parties shall provide reasonable cooperation to each other to enable the enjoyment of rights and performance of obligations under the Contract.
     5. an appropriate dispute resolution process is implemented to try and resolve any issues; and
     6. detailing methods of communication for the certainty of both parties.
     7. all issues, questions and disputes concerning the validity, interpretation, enforcement, performance, and termination of the Contract shall be governed by and construed in accordance with the laws of England and Wales.