Terrington DATA MANAGEMENT

Question and Answers: Terrington Data Management Laboratory Software

1) General

Category	General
Question	**Where are your company offices located?**
Answer	Terrington Data Management's offices are based in the IT Centre, York Science Park (York University), York, UK
Question	**How long has your company existed and what services do you supply?**
Answer	Terrington Data Management (TDM) was formed in 2004 TDM operates a full life cycle structure of all its software products. The product design, development, delivery and support are all dealt with by the same personnel. This offers significant benefits to both client and company, principally in terms of efficiency of both development and support issue resolution, product knowledge and requirement capture and conversion.
General	**What is the largest and/or most complex implementation of your system(s)?**
Answer	The largest implementation of the product extends to over 500,000 assets, which in turn equates to approximately 8,000,000 data points, and growing all of the time. The most complex implementation of the product is installed across two continents and three time zones with several hundred users spread across a minimum of three locations. Databases and product installations are held on a number of servers that are located at a third party service providers facilities. This also includes Citrix and interfaces to multiple instances of laboratory equipment.
Question	**What are the advantages of your system has compared to similar products available on the market.**

Category	General
Answer	We believe that our software allows the flexibility that is absent from some of the more rigidly controlled ELNs, but also has the required security controls. This means that our software is suitable for both regulated and non-regulated work, with minimal configuration out of the box.

2) Applications

Category	Applications
Question	**How are samples tracked within your system and how is a chain of custody information maintained?**
Answer	Samples in our software may be tracked in a variety of manners, including automatically moving from one location and status to another following the appropriate approvals, etc. The status of a sample can easily be determined at any time using a variety of reporting/data analysis queries.
Question	**Does your system provide functionality to assign storage location and storage condition to samples, sub-samples, reagents and other controlled samples?**
Answer	Yes
Question	**Does your system allow samples to be associated with a study, or in the case of non-study work, associated with an order?**
Answer	Yes
Question	**Does your system provide functionality to assign tests (i.e., analytical methods) to individual samples or subdivided samples?**
Answer	Yes. This requires a degree of configuration within the system to ensure the smoothest assignation of the appropriate test regime. (This could be performed within the scientific group – i.e. would not require IT expertise)
Question	**Does your system provide functionality to create, modify, approve and lock analytical methods?**

Category	Applications
Answer	Yes, we have a suggested regime for the control of all analytical methods, though it is possible to modify this to accommodate your own systems.
Question	**Does your system provide functionality to create sub-samples and/or aliquots and associate them with the parent sample?**
Answer	Yes.
Question	**Does your system handle the special tracking needs for radioactive materials?**
Answer	Yes, we have configured a comprehensive Radiochemical accounting module, which enabled tracking and accounting of all radioactivity from sample receipt, through various analytical phases to waste accounting and disposal (all monitored against the site license).
Question	**Does your system provide functionality to import data (e.g., samples, tests, reagents) from other systems?**
Answer	Yes, TDM have developed a number of import tools to import client data held in electronic format. A recent project involved over 100,000 items.
Question	**How does your system provide the user with online, step-by-step instructions for the scientific method assigned to the sample and how data can be captured while stepping through the scientific method?**
Answer	Methods may be detailed either using a process-based system, where prompts for each of the processes are made throughout the performance of the method, or via a sample-based system where full details of the method are available at all times, but the analyst only records the data which is considered relevant to that particular sample/sample type. The route that is chosen can be defined by the supervisor, Study Director, etc.
Question	**Does your system provide functionality to prevent deviation from the scientific method being executed and/or allow and track deviations with the appropriate approval?**

Category	Applications
Answer	Yes, there are a number of ways this can be achieved within the system – in particular the use of "Exceptions" which raise an alert whenever certain conditions are met, e.g. value out of range, use of expired equipment, standard, reagent, etc. (with authorization).
Question	**What scientific instruments/instrumentation software (e.g. Balances, Mass Specs, Empower, etc.) your software can interface with and whether this interface is file transfer based or achieved via some other data transfer mechanism.**
Answer	A number of instruments can be interfaced directly to our software via simple USB-USB connections or RS232 serial communication (e.g., Balances, pH meters). Other instruments can be interfaced via file transfers where required.
Question	**How does your software lock down the data to prevent a user from modifying the results between the time the file is saved from the instrument and the time it is imported into your system?**
Answer	This depends on the data being transferred and may need to be discussed on an individual basis. In general, it is possible to produce simple files to transfer between other software and our software.
Question	**Does your system provide the functionality to automatically identify invalid assays (e.g., QC sample results are not in spec) or invalid results (e.g., variance of results is too great)?**
Answer	Acceptance limits may be automatically applied to any numeric values.
Question	**Does your system provide functionality to perform calculations on raw data provided by instrumentation and/or manual entry to produce a final result?**
Answer	Yes, there are a wide range of calculations possible within the software.
Question	**What standard reports come "out of the box" with your system?**

Category	Applications
Answer	There are a range of preconfigured reports which are supplied “out of the box”, including: • Expired Asset Report, which looks at any equipment, standards, reagents, etc. that have expired/are due to expire over a defined period • QA Report – enables the viewer to view all activities within the selected project in the order in which they occurred (together with listing things such as all Users on that project, any Exceptions, etc) • Exception Report, which shows any values outside normal limits across a project/series of projects. • Appointment Report, which shows the status of all scheduled procedures.
Question	**Does your system provide the functionality to generate result tables?**
Answer	Yes, it is possible to generate various tables using our software which can then be exported as required to MS Excel files).
Question	**How are custom reports typically created with your system?**
Answer	There are two main ways to produce custom reports using our software: • OPAL - is a custom application for the generation of study reports (please contact us for further details) • Grid Views - this tool is extremely simple to use and reports can be created quickly and simply by any user (with the appropriate permissions).
Question	**Does your software provide a tool whereby an end user (i.e., non-IT professional) can query the database easily?**
Answer	Yes. There are a number of ways to query the database. In-built search tools allow simple or more complex queries to the database. The search tools are extremely intuitive and require minimal training to implement successfully.
Question	**Does your system provide the functionality to track whether samples were returned to the client or disposed of?**
Answer	Yes.

Category	Applications
Question	**In what data formats can data be exported out of your system? (e.g., SAS, CSV, XML)**
Answer	This depends on the data being exported. Reports, etc. can be exported using CSV and various other simple exporting mechanisms. All data can be exported using XML.
Question	**How does your software track exceptions/out-of-specification?**
Answer	Exceptions are 'out of specification' values. To resolve these, action must be taken to approve the exceptions with appropriate comment. The exception then moves to the Accepted status, but is still present and can clearly be seen. An additional way of performing this functionality is through the use of the Approved function. If any data has not reached the approved status, then it cannot be used without further comment/authorization.
Question	**How does your system provide functionality to notify users, internal and external to the system, for any discrepancies/exceptions that may be encountered?**
Answer	This can be achieved in several ways, for example: • There is workflow e-mailing within the software, so that users/approvers can be informed of the progress of issues. • Exceptions as previously mentioned. • The system administrator is automatically informed of any attempts to log in without an approved user name/password combination.
Question	**Does your system provide functionality for logging and tracking Reagents (from consumables to test materials to prepared reagents)?**
Answer	Yes. There are ideal systems provided for this functionality. These can be easily modified if the user's requirements differ from those provided out of the box.
Question	**Does your software have the ability to track the quantities available and usage of non-sample solutions and reagents and which test runs they were used on?**

Category	Applications
Answer	Yes. There are ideal systems provided for this functionality as described. In addition these can be easily modified if the user's requirements differ from those provided out of the box. Tracking of the use of these solutions/reagents can easily be performed using the various database queries available to the user.
Question	**Does your system provide functionality to confirm method materials availability and validity, such as expiry date?**
Answer	Yes. There are ideal systems provided for this functionality as described. In addition these can be easily modified if the user's requirements differ from those provided out of the box.
Question	**Does your system provide functionality to track instrumentation availability (e.g. in service, out of service pending calibration, etc.) and prevent the use of instrumentation that is not in service?**
Answer	Yes. There are ideal systems provided for this functionality as described. In addition these can be easily modified if the user's requirements differ from those provided out of the box.
Question	**Does your system provide functionality to track whether a user is qualified to execute an analytical method or not and prevent the user from performing the method if they are not qualified?**
Answer	This would be possible using existing functionality.
Question	**Is your software GLP, GMP, GCP and CFR 21 Part 11 compliant?**
Answer	Yes. Our software is compliant with these standards as long supporting systems are in place (SOPs, training, etc.)
Question	**Does your system provide functionality to reserve/schedule resources (such as instruments) for a test run?**
Answer	There is a detailed scheduling function within the software. This can include scheduling of individual procedures or equipment and other resources.
Question	**Has your proposed system been successfully audited by FDA and/or AFFSAPS and/or EMEA at any customers sites?**
Answer	Regulatory inspections have successfully been performed at several sites with no significant issues.

3) Set-up

Category	Set-up
Question	**Is the set-up of the system and database always carried out by your company or do you have a technology transfer program in place in order for your clients to carry out their own set-up?**
Answer	Typically, TDM perform the initial installation of the software. Installations have taken place on the clients premises and also remotely via a secure login. We also provide support for the installation of the database (Oracle, SQL Server). When requested we can perform the database installation. We provide a comprehensive installation and system manuals. Typically patches and upgrades are installed by the client's IT staff, however, this is a service offered by TDM if required. We offer 'System' level training for IT support staff.

4) Technical

Category	Technical
Question	**What mechanism do you use to determine the content of a functional release?**
Answer	TDM takes feedback from their clients. All requests are tracked via internal Change Request Forms. These are reviewed and prioritized to determine what will go into the next release. There are also internally generated improvements that follow the same path.
Question	**What is the frequency of functional releases?**
Answer	Typically, we would release a new version every 6-12 months.
Question	**Are upgrades and bug fixes included in your maintenance costs? Please give details.**

Category	Technical
Answer	Yes, bug fixes and upgrades are covered by maintenance costs. Maintenance/support costs are typically 20% of purchase price for an ON-PREMISE solution and included in a HOSTED solution.
Question	**Do you offer a migration plan or tools to assist in upgrading to a new release?**
Answer	Typically, upgrading to a new release will be handled by installer software, making it a very simple process. Full documentation for upgrading will be provided. If any database changes are required, this again will be automated via a database upgrade tool.
Question	**Is full software lifecycle documentation available for the Software including IQ/OQ documentation and Validation Testing documentation?**
Answer	Yes
Question	**If a technology transfer is carried out, what elements will your company still be responsible for (e.g., software development, etc.)?**
Answer	Following technology transfer the clients will be able to provide: - IT support - Generate form templates, setting up workflow etc. - Configure device interfaces - Manage Security - Configure LDAP for Active Directory TDM will maintain responsibility for software development
Question	**Does your software offer integration with any other LIMS, ELN systems and/or instrument platforms?**
Answer	Although there are no formal integrations with LIMs systems we have provided custom integration on request. There are no technical issues with extending this to more complex data transfer and integration routines. As a general point we have found that many users ask about integration, but then in practice find that this involves two distinct data sets, so the requirement for more complicated integration has not been requested.

Category	Technical
Question	**Are there any limitations on internet browser version/type?**
Answer	No, the web application is cross-browser compliant
Question	**Describe your software's reporting capabilities and any integration with third party reporting vendors**
Answer	The software has in-built standard reports and users can configure their own reports using Grid Views. We also have APIs with other software systems e.g., Power BI
Question	**Does your system support open system architecture i.e., flexible interface and integration of various devices to the system?**
Answer	Yes, the user can define the structure in which you hold data and configure interfaces to laboratory devices, build forms and asset templates. AS LONG AS THEY HAVE PERMISSION TO DO SO (defined by roles)
Question	**If a software bug is found by a customer that is significant, do you have a service level agreement on how quickly you will get a patch for the bug tested and available to your customers?**
Answer	Yes, there will be a service level agreement in place. All efforts will be made to get the patch as quick as possible. On most occasions we have provided a next day service for significant bugs that can be replicated, with patches software available for download via a secure area on our website.
Question	**What is your vision on how your product will evolve in next 2 to 5 years?**
Answer	Our software development is customer-led. As new software development tools have appeared we have updated much of the web based system. We would expect to continue to focus on the core functionality (particularly with the web version), whilst adding a range of modules specifically focused on different analytical areas.

5) Security

Category	Security
Question	**Does the system allow role definitions?**

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<tr><th>Category</th><th>Security</th></tr>
<tr><td>Answer</td><td>Yes, each role has a set of predefined permissions. Each user may be assigned multiple Roles, one or more of which can be assigned to each study/project/area of work.

User Groups can also be created, so that each user only needs to be assigned to the User Group rather than each individual study (for example).</td></tr>
<tr><td>Question</td><td>Does the system allow user profiles?</td></tr>
<tr><td>Answer</td><td>Yes, as detailed above.</td></tr>
<tr><td>Question</td><td>What facilities are provided to prevent unauthorized access to data?</td></tr>
<tr><td>Answer</td><td>
User Name and Password are required to login to our software.
Users are only granted access to studies/projects that have been allocated to them.
Within a study a user can only perform actions as defined by their role within the system.
Users can be granted different roles on different studies.
All actions performed within the system are fully audit trailed.
Failed login attempts are notified to the system administrator.
The user is automatically logged off after a period of inactivity.
Users are forced to create passwords that fit within the companies IT policy.
Optionally our software can operate using Active Directory so users can use their existing network login credentials.
The database is password protected.
No passwords are held in source code.
The design of the database make it very difficult to put meaning to data – data is stored separately to the data prompt.
If no access is granted to a study/project the user will not be aware that it exists.
User Name and password are required to save data.
Our software is split into various modules – again user rights are defined per module.
</td></tr>
<tr><td>Question</td><td>Is there any encryption of the data held on the database?</td></tr>
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Category	Security
Answer	All our software data is held in a database (Oracle or SQL server). Although the data in not encrypted such is the design of the database that the data entered by a user is split across many tables. The background layout, the data, the audit records etc. are all separated making it extremely difficult to put any meaning to the data when viewing the tables. All the data points are stored against an index (this is separate from the prompt or label used to visually identify the data point when entered by the user).
Security	**Does your system allow data separation between different functional units and/or locations using a centralized system?**
Answer	Yes, it is possible to subdivide data into whichever functional units you require. The use of User Groups enables the user to easily assign shared information for which access is wanted by many operational areas. Similarly individual studies, processes, areas can have distinct areas within the software to which only a specialized group of users are given access. N.B. A user will only be able to view data to which they have been assigned – they need not necessarily be aware of other data if desired.

6) Auditing

Category	**Auditing**
Question	**Does the system provide auditing of all transactions?**
Answer	Yes, every single data entry is date and time stamped, with details of the user, etc.
Question	**Does the system provide auditing of configuration changes to the application?**
Answer	Yes, the System Audit Log details any high level configuration changes.
Question	**Can the system be configured to audit trail transactions differently based on transaction type (e.g. GLP vs GMP vs a transaction not governed by GxP)?**

Category	**Auditing**
Answer	In general it is easier to apply a single set of auditing requirements to all data within the same database, though there is obviously no need to view much of this audit trail data. For specific process it is possible to differentiate the amount of data recording and therefore audit trailing. The use of different templates makes it easier to differentiate GLP versus non-reg. studies, etc.
Question	**Does the system provide on-line access to view and print audit trail data?**
Answer	Yes. It is possible to view and print (online) Form Audit Logs (audit trails for individual procedures/processes).
Question	**Are there standard reports available to provide audit information on configuration changes, project/study/sample and other data?**
Answer	Yes, there are a number of standard reports available to provide the data indicated.

7) Operations Environment

Category	Operations
Question	**What are the back-up and/or recovery capabilities of your application?**
Answer	There are a wide range of different backup/disaster recovery scenarios available to ensure maximum up-time. The choice would depend on your specific requirements and company policy. The back-up and recovery process would typically be consistent with other IT systems. There are no specific limitations associated with the backing up of the database. None of our existing clients have experienced any issues with data backup or loss.

8) Archival capability

Category	Archiving
Question	**How is data archived by your system (e.g., by study, by order, data archived to a separate environment, etc.)**

Category	Archiving
Answer	There are several ways to archive data - in particular by whole study, or over a period of time (e.g., Study xyz from Jan 2022to Dec 2022). Individual data processes can also be archived if this was required. The archiving wizard allows three main options at the end of the archive process: • Remove the data from the database at the end of the process • Leave the data on the current database, but make read only (access can also be removed for all users except the archivists) • Leave the data unchanged – this is effectively a "snapshot" of the project at that moment in time. N.B. Archiving is controlled by User Role.

9) Administration

Category	Administration
Question	**Does your system provide tools to maintain user roles and profiles?**
Answer	Yes
Question	**How are system configuration settings are managed by user role (e.g., can every task appearing on a dropdown menu be configured by role?)**
Answer	The vast majority of tasks can be configured by Role, which are effectively a set of permissions. Each user may have several available roles which would enable them to perform more or fewer tasks. For example the same user might have a "Study Director" (or similar) role for a particular study, but merely the "Analyst" role for another study.
Question	**Is the system able to automatically reset and produce new passwords for users?**

Category	Administration
Answer	Yes. There is a choice of using Windows Active Directory passwords (which take the password from your normal Windows accounts), or to have software-specific password regime, where the frequency of changing and password complexity can be controlled as required.

10) Training

Category	Training
Training	**What is a typical user training approach for your system?**

Category	Training
Answer	There is a wide range of training available, which will depend on individual requirements. In general, we would recommend system administrator/super user training for a small number of people (which will take approximately 2-3 days). This would include enough information for these users to then train other users for the specific procedures to be followed. Additional training for "normal" users takes approximately 1 day, though if the implementation was phased individual processes could be taught in as little as half a day. We have generally performed all of our training face-to-face, and provide detailed training documentation so that it is easier for the initially trained users to pass this training on to other staff. If a specific requirement for training meant that web-based training was suitable we would be happy to provide this.

11) Support Services

Category	Support services
Question	**How are helpdesk services provided by your company to support?**
Answer	We operate a full support service during normal office hours with an out of hour's service being negotiated on a client-by-client basis.
Question	**Are these services provided by your company or via a third-party vendor?**
Answer	All services are operated through TDM
Question	**What hours of availability are covered via your helpdesk?**
Answer	Standard hours are 08.00hrs to 17.00hrs GMT (adjusted for BST) Monday to Friday, excluding UK public holidays. Extended hours are by negotiation.
Question	**What service levels do your support services operate to?**

Category	Support services
Answer	We aim to achieve the following terms: • Acknowledgement of support issue within two working hours • An initial assessment of support issue to client within eight working hours • A formal answer with proposed plan of action within 48 working hours
Question	**What performance levels have your helpdesk operations achieved over the last two years?**
Answer	100% of reported faults were acknowledged within two working hours 85% of reported faults were resolved within eight working hours of initial notification
Question	**Does your system have the capability for users to report errors to the system administrator directly within the application?**
Answer	This can be accommodated within the application using the workflow functionality.