

Service and Support Document

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Medical Database Systems

Medical Database Systems (MED.systems) offers web-based solutions for the electronic data capturing and management of Clinical Trials. The services and systems have been designed with a number of objectives in mind:

- Multi-Trial. The system can be used to manage multiple trials. Key users (e.g. project managers and coordinators) thus can manage multiple trials from a single environment.
- Easy to Use. System are designed for ease of use resulting in fewer usability issues raised by the sites, higher quality of captured data and fewer data queries.
- Easy to Deploy. The system is 100% web-based and thus requires no local installation or software configuration making it easy to deploy; even for multiple, international sites.
- User Empowerment. The system is designed to allow power-users to further tune and amend the questionnaires; this includes, among other things, adding / amending data validations, changing the 'flow' of questionnaires, adding / maintaining users and sites, etc.
- Cost Effective. The systems has been designed to deliver a very cost effective, qualitative and flexible database facility.

MED.systems is specialized in niche case management solutions based on the innovative CaseMaster® application platform. MED.systems is an active member of the CaseMaster® Developers Community.

MED.systems believes that software solutions are not a one-off product but an ongoing service.

1. Quality and Compliance

- a. The service will have been developed in accordance to the current best practices of software engineering.
- b. The service is compliant with relevant industry guidelines; the supplier will update the platform in the light of changes to the guidelines and will do so free of charge where these guidelines can reasonably be seen as directly applicable to the platform.

2. Hosting

- a. MED.systems manages a state-of-the-art, ISO28k certified data centre facility for secure and scalable hosting. The data centre is implemented in accordance to the current best practices in cloud computing and associated security standards.

- b. The application has a guaranteed availability of 99% per calendar month and downtime over and above, providing it can unambiguously be attributed to the hosting facility, is refunded in pro-rata of the downtime
- c. The data is stored secured and redundant in accordance with best practices and a daily copy of the data is made to off-site premises. The maximum data loss is thus guaranteed to be 24 hours maximum.

3. Support Entitlement

- a. The Client is entitled to support on the Service and / or System providing that this Agreement is still active and has not been voided.
- b. The Supplier will ensure to provide sufficient capacity of knowledgeable resources to meet its' obligations resulting from right-to-Support as outlined in this Software Service Agreement.
- c. Support is the collective set of procedures, rights and obligations designed to ensure the ongoing correct workings of the Service and / or System and / or the ongoing successful deployment of the Service and / or System by the Client ("the Support Service").

4. Support Organization

- a. The Supplier will operate a service desk system and make available a dedicated telephone number and email address for support purposes.
- b. The service desk is available during office hours (9:00 – 17:00 Central European Time) by phone / email. The support desk is closed during Christmas (25th, 26th December) and New Years Day (January 1st).

5. Support Requests

- a. A Support Request is a request for service issued by the Client to the Supplier and is covered by the Software Service Agreement.
- b. Each Support Request will fall into one of the following categories
 - i. Request for Consultancy – The Client requests the Supplier for information where this information can reasonably be seen as related to the Service and / or System.
 - ii. Request for Investigation – The Client requests the Supplier to investigate and event or behaviour otherwise of the Service and / or System.
 - iii. Notice of Incident – The Client notifies the Supplier of an incident, which can reasonably be seen as related to the Service and / or System. An incident (or Bug) is where the behaviour of the Service and / or System can reasonably be seen as deviating form its' intended behaviour.
 - iv. Request for Service / System Change – The Client requests the Supplier to consider an amendment, enhancement or change otherwise to the Service and / or System. A need for Change (or Enhancement) is where the Client can reasonably see the behaviour of the Service and / or System as deviating form the behaviour as desired.

- c. Each Service Request will be assigned one of the following severities based on the impact to the business and / or user base:
- i. Critical – The Service and / or System (or large sections thereof) is / are unavailable to all or a large number of users or can reasonably be seen as unfit for purpose.
 - ii. High – The Service and / or System (or large sections thereof) are available only at greatly reduced service levels and / or at greatly increased cost and / or risk where no workaround is available to remedy the situation.
 - iii. Medium - The Service and / or System (or large sections thereof) are available only at greatly reduced service levels and / or at greatly increased cost and / or risk and a workaround is available to remedy the situation.
 - iv. Low – The Service and / or System is available and fit for purpose but the service levels or quality otherwise can be further improved.

6. Support Process

- a. The Supplier has implemented processes and systems to deliver the Support in line with best industry practices.
- b. The Client must designate a limited number of trained and named resources that are authorised and mandated by Client and Supplier to contact the Supplier under the terms and conditions of Support. The Client must inform the Supplier in case the details of the authorised resources change.
- c. All communication related to the execution of the Support Service is in English unless mutually agreed otherwise.
- d. Both parties have the responsibility to inform the other party of any inaccuracy, misinterpretation, misunderstanding and / or miscommunication otherwise resulting from the use of language (English or otherwise) and no claim or rejection of obligation can result from what can reasonably be seen as a genuine miscommunication of any sort.
- e. Service Levels
 - i. The Supplier must confirm receipt each Support Request using the appropriate Support Channel to the Client within 1 working hour.
 - ii. The Supplier must provide the Client with a resolution in accordance with the following Service Level Agreement table:

Severity	Service Levels
Critical	<p>The Supplier will start to work on a permanent resolution or acceptable workaround as soon as he is made aware of the critical incident.</p> <p>The Supplier is obliged to continue to work (regardless of Service Hours and / or applicable working directives) on the request until a permanent resolution or workaround has been devised and implemented which the Client deems as acceptable.</p> <p>The Supplier is obliged to keep the Client informed about progress (or lack thereof).</p>

High	<p>The Supplier will start to work on a permanent resolution or acceptable workaround within 4 working hours of being made aware of the incident with severity high.</p> <p>The Supplier is obliged to continue to work during Service Hours on the request until a permanent resolution or workaround has been devised and implemented which the Client deems as acceptable.</p> <p>The Supplier is obliged to keep the Client informed about progress (or lack thereof).</p>
Medium	<p>The Supplier will inform the Client of an estimated resolution date within 7 working days of receipt of the Support Request. The resolution day will be within 30 working days of receipt of the Support Request</p>
Low	<p>The Supplier will inform the Client of an estimated resolution date within 7 working days of receipt of the Support Request. The resolution day will be agreed with the Client</p>

7. Escalation

- a. Both the Client and the Supplier can start an escalation process in the event of a perceived fail-to-deliver under the terms and conditions of the Software Service Agreement.
- b. The other party will be notified by any means of communication, which is deemed appropriate, and the escalation will have to be confirmed in writing. The details of the perceived fail-to-deliver have to be presented to the other party.
- c. The other party will have to confirm and acknowledge the escalation.
- d. Both parties will have to allocate sufficient management attention to an escalation in progress.
- e. During an escalation progress ad-hoc service levels will be mutually agreed and adhered to.
- f. In case of a failure to resolve the issue either party can request mediation by an authorised and mutually recognized third party whose decisions will be binding to both parties.
- g. Both parties will have to acknowledge to one-another where they feel that the escalation can be closed.
- h. Once an escalation is closed it can no longer be seen as influencing the Support Service in any way.

8. Support includes:

- a. Any bug fixes.
- b. Any consultancy directly related to use of the application.
- c. Any quotes for enhancements to the system:
 - i. Enhancements which are seen as adding to the value proposition of the MED.systems may, at the discretion of the Supplier, be added to the main development program and made available free of charge for existing customers.
 - ii. Case specific enhancements will be delivered on a fixed price basis.

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