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Appendix 3 – Service Level Agreement

1. THE SERVICE

The service consists of the Viedoc Software; a web-based software application that allows clinical trial sponsors and investigative sites to easily and securely collect, validate, store, transmit and analyze clinical study data.

2. DELIVERY OF THE SERVICE

The service is delivered by utilizing the internet and HTTPS for encrypted and session based asynchronous communication between Customer computer and software server. To ensure authenticity, integrity, and confidentiality all data transported over internet is encrypted using the Transport Layer Security (TLS) protocol.

A request for software service is always initiated by the Customer, using a web browser. A service session is then established and maintained until the Customer terminates it by logging out or a timespan* of Customer inactivity has passed, whichever occurs first.

* For Viedoc 3, the timespan of inactivity is 30 minutes of no Customer requests to the server. This includes if the browser was closed without first logging out. For Viedoc 4, the timespan of inactivity is 20 minutes where no Customer activity could be detected (mouse-movements/clicks, keyboard input) or if no heartbeats have been detected from the browser during the last 5 minutes (indicating that the browser was closed without first logging out, or that internet connectivity was lost).

3. CUSTOMER COMPUTER REQUIREMENTS

Customer computer requirements are defined as capabilities required by the Customer computer to use all features of the service with the intended graphical presentation and within guaranteed response times of the service.

- One of the following web browsers:

    - Chrome, latest 10 major releases (6-week browser release interval)

    - Firefox, latest 15 major releases (4-week browser release interval)

    - Edge (Chromium ed), latest 10 major releases (6-week browser release interval)

    - Safari (MacOS/iOS only), latest 2 major releases (1-year browser release interval)

- The web browser must have the default setting to allow:

    - JavaScript

    - Session cookies

- Local web storage (only required by the main portal of Viedoc 4)

- Screen resolution

  - Viedoc 3; at least 800x600

  - Viedoc 4; at least 1024x768

- Internet connection of at least 384kbit/s

- Outbound firewall policy allowing encrypted HTTP to be established and communicated to a remote server on port 443 (HTTPS) using TLS version 1.2 or higher.

No data is permanently stored on the Customer computer. All data stored in session cookies or local web storage is deleted when the browser session is terminated. The only exception to this is the optional persistent cookie used in the main portal of Viedoc 4 to remember if a user chooses to issue a 2FA-trust for the browser for 30 days, and thus avoid further second-factor authentication during this period.

Viedoc 3 has no automatic checks enforcing the above requirements. Viedoc 4 checks for, and enforces, browser type and version, and support for JavaScript, local web storage and session cookies.

4. AVAILABILITY OF SERVICE

The service is targeted to be always available; 24 hours a day, every day of the year.

A maintenance window, i.e. allowed service downtime for maintenance purposes, is to be in effect on every:

- US instance: Saturday between 03:00 – 04:00 Eastern Standard Time ("EST").

- Europe instance: Saturday between 07:00 – 08:00 Universal Time **Coordinated ("UTC").**

- Japan instance: Saturday between 17:00 – **18:00 Japanese Standard Time ("JST").**

- China instance: Saturday between 17:00 – **18:00 Chinese Standard Time ("CST"). If** Saturday is a working day, Sunday between 17:00 – 18:00 Chinese Standard Time ("CST") **will be used.**

This maintenance window is not service downtime by default, but only when necessary. If emergency maintenance is needed outside of this window it will be communicated through the Viedoc status page https://status.viedoc.com as soon as possible. Customers can subscribe to email or SMS notifications from this page.

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With the weekly one-hour maintenance window excluded, the availability of the service is guaranteed to 99.8% measured on an instance level (Viedoc region) on an annual basis.

The following causes are excluded from the measurement of availability:

- **Any unavailability caused by circumstances beyond Provider's reasonable control** including without limitation a force majeure event such as any delay or failure in performance hereunder caused in whole or in part by fire, flood, wind, storm, lightening, or similar, or by embargo, acts of sabotage, terrorism, riot or civil unrest, internet outages, or mandatory compliance with any governmental act, regulation or request.

- **Provider assumes no responsibility for delays or problems that result from Customer's computing or networking environment, Customer's third**-party vendors and/or **Customer's access to** internet.

4.1. VIEDOC CONNECT

If the Viedoc Connect feature is included the overall availability guarantee of Viedoc is 99.7%.

4.2. VIEDOC AUTO-CODING BY UMC KODA

Viedoc auto-coding by KODA is provided by the underlying vendor UMC. This feature requires a license agreement between the Customer and UMC and is excluded from the overall Viedoc availability guarantee.

5. RESPONSE TIME OF SERVICE

The service is targeted to respond to any user action within 1 second. A valid response is either the request being served or a clear sign indicating that the service is processing the request.

The technically measurable response time of the service, defined as time taken from the request has been received until the request has been served, is guaranteed to 2 seconds (excluding time for Customer-server round-trip) according to the 95th percentile, i.e. 95% of all service requests must have completed processing within 2 seconds from the moment the service received the request.

This guarantee is not in effect:

- During maintenance windows

- For the following activities:

    - Data export

- Data import

- Real-time reporting and statistics

- Administrative activities

6. DISASTER RECOVERY

Disaster is here defined as the event of all regular production systems being out of order. Since all production systems are redundant, the occurrence of this event is considered highly unlikely. Actions to recover from disaster will be initiated if regular production systems are not estimated to be restored within 24 hours.

6.1. RECOVERY TIME OBJECTIVE (RTO)

RTO, or target time to recover from disaster, is 12 hours if the event occurred between 06 am - 03 pm UTC, Monday through Friday, and 24 hours at all other times.

6.2. RECOVERY POINT OBJECTIVE (RPO)

Backups of data are automatically performed on a regular basis. Backups are stored and encrypted in a separate physical location. This process guarantees the RPO, or maximum targeted period in which data might be lost, in the event of a disastrous failure. This loss will be limited to all data recorded during the last 2 hours prior to the failure in the worst case.

7. INFRASTRUCTURE MONITORING

Any disturbances to the service delivery are communicated on the service status page https://status.viedoc.com, which can be subscribed to for automated notices.

The integrity and availability of the infrastructure is monitored 24 hours a day, 365 days a year, by the Provider´s operations team. Operational Qualification and connectivity tests are automated and performed every 5 minutes. Encryption algorithm tests and vulnerability scans are performed on a regular basis. Security hotfixes relating to underlying systems are analyzed using a risk-based approach and applied accordingly.

8. CUSTOMER SUPPORT

Study Designers and eTMF Managers that have been certified by Viedoc have an email hotline to the Viedoc Customer Support.

The Viedoc Customer Support provides advise on how to best use the Software, improve and detect errors in the study configuration and answer other product related questions. Questions from within the Customer's organization can also be escalated to the Viedoc Customer Support through the certified Study Designers and eTMF Managers.

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The system configuration and troubleshooting support chain is as follows:

Support for the Software (excluding the TMF)

Study Manager (and other personnel within the customer and study organization)	[seek support from]→	Certified Study Designers within Customer organization	[seek support from] →	Viedoc Customer Support

TMF support

Study Manager (and other personnel within the Customer and study organization)	[seek support from]→	Certified eTMF Managers within Customer organization	[seek support from] →	Viedoc Customer Support

The Viedoc Customer Support can be reached through the email addresses below and will be available during business hours in the relevant region (for region Rest of the world, availability can vary depending on country):

US: support@viedoc.com and tmfsupport@viedoc.com (support available in English)

Europe: support@viedoc.com and tmfsupport@viedoc.com (support available in English)

China: support@viedoc.cn and tmfsupport@viedoc.cn (support available in Chinese)

Japan: support@viedoc.jp and tmfsupport@viedoc.jp (support available in Japanese)

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Rest of the world: support@viedoc.com and tmfsupport@viedoc.com (support available in English)

9. END USER SUPPORT

Adequate support regarding system access and study related questions requires knowledge of the next user level in the support chain and the study protocol. This is also important from a privacy regulation and information security perspective. The Software is designed to eliminate the need for a centralized helpdesk that typically struggles with these important perspectives. End-user support is thus handled by the Customer and the study organization through self-service functionality and built-in user support functions.

A best-practice support chain should be implemented with the following delegations:

Study Subjects	[seek support from] →	Site Personnel	[seek support from] →	Site Manager	[seek support from] →	Study Manager	[seek support from] →	Customer Organization Administrator