

## APPENDIX 3 – SERVICE LEVEL AGREEMENT 附录 3——服务等级协议

### 1. THE SERVICE 服务

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.

服务包括基于网页的Viedoc软件，该软件允许临床试验申办方及研究中心便利且安全地获取、验证、存储、传输并分析临床研究数据。

### 2. DELIVERY OF THE SERVICE 服务的交付

The service is delivered by utilizing the internet and HTTPS for encrypted and session based asynchronous communication between the 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.

服务通过互联网和HTTPS交付，从而达成客户电脑和软件服务器之间加密的且基于会话的异步通信。为确保真实性、可靠性和保密性，所有通过互联网传输的数据使用传输层安全协议（Transport Layer Security, “TLS”）进行加密。

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 the Customer inactivity has passed, whichever occurs first.

使用软件服务的请求应始终由客户通过网页浏览器发起。之后便建立并持续服务会话，直至客户将会话终止或允许客户保持非活跃状态的时间长度\*用尽，以两者中先发生者为准。

\* 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 heart- beats 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).

\*对于Viedoc 3，不活动的时间跨度是30分钟内没有向服务器发送客户请求。这包括浏览器在没有先行退出的情况下关闭。对于Viedoc 4，不活动的时间跨度为20分钟，在此期间无法检测到客户活动（鼠标移动/点击、键盘输入），或者在过去5分钟内在浏览器中没有检测到活动信息（表明浏览器在未先行退出的情况下关闭，或者互联网连接丢失）。

### 3. CUSTOMER COMPUTER REQUIREMENTS 客户计算机要求

The 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.

客户电脑要求的定义是客户电脑所要求的性能，该性能可实现以预期的图像呈现方式和所承诺的服务响应时间以内的速度使用所有服务功能。

(1) One of the following web browsers:

以下网络浏览器之一：

- a) Chrome, latest 10 major releases (6-week browser release interval)  
Chrome，最新的10个主要版本（6周的浏览器更新发布间隔）
- b) Firefox, latest 15 major releases (4-week browser release interval)  
火狐，最新15个主要版本（4周的浏览器更新发布间隔）
- c) Edge (Chromium ed), latest 10 major releases (6-week browser release interval)  
Edge（Chromium ed），最新10个主要版本（6周的浏览器更新发布间隔）
- d) Safari (MacOS/iOS only), latest 2 major releases (1-year browser release interval)  
Safari（仅限MacOS/iOS），最新2个主要版本（一年的浏览器更新发布间隔）

(2) The web browser must have the default setting to allow:

网页浏览器的默认设置必须允许：

- a) JavaScript  
脚本
- b) Session cookies  
会话缓存
- c) Local web storage (only required by the main portal of Viedoc 4)  
本地网络存储（只有Viedoc 4主门户要求）

(3) Screen resolution

屏幕分辨率

- a) Viedoc 3; at least 800x600  
Viedoc 3；至少800x600
- b) Viedoc 4; at least 1024x768

Viedoc 4; 至少 1024x768

- (4) **Internet connection of at least 384kbit/s**  
互联网连接至少384kbit/s
- (5) **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.**  
出站防火墙政策须许可建立加密HTTP并与使用TLS、443端口（HTTPS）的远程服务器进行通讯。

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.

没有数据永久存储在客户计算机上。当浏览器会话终止时，存储在会话cookies或本地网络存储中的所有数据都会被删除。唯一的例外是Viedoc 4主门户中使用的可选持久cookies，以记住用户是否选择为浏览器颁发2FA信任30天，从而避免在此期间进一步进行第二因素身份验证。

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.

Viedoc 3没有执行上述要求的自动检查。Viedoc 4检查并强制执行浏览器类型和版本，以及对脚本、本地网络存储和会话cookies的支持。

#### 4. AVAILABILITY OF SERVICE

##### 服务的可及性

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

服务目标为系统全年、全天24小时始终可以使用。

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

维护窗口，即出于维护目的允许的服务停机时间，将在以下时间生效：

- (1) **US instance: Saturday between 03:00 – 04:00 Eastern Standard Time (“EST”).**  
美国服务器：东部标准时间（“EST”）周六03:00 – 04:00。
- (2) **Europe instance: Saturday between 07:00 – 08:00 Universal Time Coordinated (“UTC”).**  
欧洲服务器：协调世界时（“UTC”）周六07:00 – 08:00。
- (3) **Japan instance: Saturday between 17:00 – 18:00 Japanese Standard Time (“JST”).**

日本服务器：日本标准时间（“JST”）周六17:00 – 18:00。

- (4) 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.

中国服务器：中国标准时间（“CST”）周六17:00 – 18:00。如果周六是工作日，则使用中国标准时间（“CST”）周日17:00 – 18:00。

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.

该维护时间段不成为默认的服务暂停时间，仅在必要时暂停服务。若需要在该时间段以外开展紧急维护，条件允许时将提前告知该额外时间段。

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.

如果不包括每周一小时的维护窗口，每年根据服务器级别（Viedoc区域）测量，服务的可用性保证为99.8%。

The following causes are excluded from the measurement of availability:

以下原因被排除在可用性测量之外：

- (1) Any unavailability caused by circumstances beyond the **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.

因供应商无法合理控制的情况导致的任何不可用性，包括但不限于不可抗力事件，例如全部或部分由火灾、洪水、风、风暴、闪电或类似情况或禁运造成的任何延迟或未能履行本协议，破坏、恐怖主义、骚乱或内乱、互联网中断或强制遵守任何政府行为、法规或要求的行为。

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

由于客户的计算或网络环境、客户的第三方供应商和/或客户接入互联网原因导致的延误或问题，提供方不承担任何责任。

#### 4.1 VIEDOC CONNECT VIEDOC CONNECT

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

如果Viedoc Connect功能包括在内，Viedoc的总体可用性保证为99.7%。

#### 4.2 VIEDOC AUTO-CODING BY UMC KODA UMC KODA支持的Viedoc自动编码

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.

Viedoc的KODA自动编码是基础供应商UMC提供的。该功能要求客户和UMC之间有许可协议，并被排除在Viedoc的总体可用性保证之外。

### 5. RESPONSE TIME OF SERVICE

#### 服务的响应时间

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.

服务目标是对任何用户，在系统中做任何操作时，系统会在1秒之内响应。有效响应是指，系统正在处理某请求，或有一明确标识表示系统服务正在处理该请求。

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 95<sup>th</sup> percentile, i.e. 95% of all service requests must have completed processing within 2 seconds from the moment the service received the request. 技术层面可测量的服务响应时间保证为2秒（不包括客户服务器的往返时间），定义为收到请求至提供服务花费的时间，按照95%的百分比，即收到服务请求起的2秒内，所有服务请求的95%必须已经完成处理。

This guarantee is not in effect:

该目标不适用于下列情形：

- (1) During maintenance windows  
在系统维护期间
- (2) For the following activities:  
针对以下活动：
  - a) Data export  
数据导出
  - b) Data import

数据导入

- c) Real-time reporting and statistics  
即时报表和统计数据
- d) Administrative activities  
用户管理活动

## 6. DISASTER RECOVERY 灾后复原

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.

灾难在这里被定义为所有常规生产系统出现故障的事件。由于所有生产系统都是冗余系统，因此发生此事件的可能性极小。如果常规生产系统预计无法在24小时内恢复，将启动灾难恢复操作。

### 6.1 RECOVERY TIME OBJECTIVE (RTO) 恢复时间目标 (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.

如果事件发生在协调世界时周一至周五上午6时至下午3时，则RTO或者从灾难中恢复的目标时间为12小时，如果发生在其他时间，则为24小时。

### 6.2 RECOVERY POINT OBJECTIVE (RPO) 恢复点目标 (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.

数据备份会定期自动执行。备份存储并加密在单独的物理位置。此过程保证了灾难性故障发生时的RPO，或者数据可能丢失的最大目标期限。在最坏的情况下，这种损失将限于故障前最后2小时内记录的所有数据。

## 7. INFRASTRUCTURE MONITORING 基础设施监测

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.

干扰提供服务的任何情况都会在服务状态页面 <https://status.viedoc.com> 进行交流，可以订阅自动通知。

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.

基础设施的完整性和可用性由供应商的运营团队一年365天、每天24小时进行监测。操作验证和连接测试自动进行，每5分钟进行一次。加密算法测试和漏洞扫描定期进行。与基础系统有关的安全热补丁采用基于风险的方法进行分析，并相应地进行应用。

## 8. CUSTOMER SUPPORT

### 客户支持

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

经Viedoc认证的研究设计人员和eTMF经理可通过电子邮件热线与Viedoc客户支持部门联系。

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.

Viedoc客户支持部门就如何最好地使用软件、改进和检测研究配置中的错误以及回答其他与产品相关的问题提供建议。客户组织内部的问题也可通过经认证的研究设计人员和eTMF经理上报至Viedoc客户支持部门。

The system configuration and troubleshooting support chain is as follows:

系统配置和故障排除支持链如下：

### Support for the Software (excluding the TMF)

#### 软件支持（不包括TMF）

Study Manager (and other personnel within the customer and study	[seek support from] → [寻求支持] →	Certified Study Designers within the Customer organization 客户组织内的经认证研究设计人员	[seek support from] → [寻求支持] →	Viedoc Customer Support Viedoc客户支持部门
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organization) 研究经理（以 及客户和研究 机构的其他人 员）				
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**TMF Support**

**TMF支持**

Study Manager (and other personnel within the Customer and study organization) 研究经理（以 及客户和研究 机构的其他人 员）	[seek support from] → [寻求支持] →	Certified eTMF Managers within Customer organization 客户组织内的经认 证eTMF经理	[seek support from] → [寻求支持] →	Viedoc Customer Support Viedoc客户支 持部门
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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):

您可以通过以下电子邮件地址联系到Viedoc客户支持部门，该部门将在相关地区的工作时间内提供服务（对于世界其他地区，提供服务的时间可能因国家而异）：

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

美国：[support@viedoc.com](mailto:support@viedoc.com) 和 [tmfsupport@viedoc.com](mailto:tmfsupport@viedoc.com) （支持语言为英语）

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

欧洲：[support@viedoc.com](mailto:support@viedoc.com) 和 [tmfsupport@viedoc.com](mailto:tmfsupport@viedoc.com) （支持语言为英语）

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

中国：[support@viedoc.cn](mailto:support@viedoc.cn) 和 [tmfsupport@viedoc.cn](mailto:tmfsupport@viedoc.cn) （支持语言为中文）

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

日本：[support@viedoc.jp](mailto:support@viedoc.jp) 和 [tmfsupport@viedoc.jp](mailto:tmfsupport@viedoc.jp) （支持语言为日语）

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

世界其他地区：[support@viedoc.com](mailto:support@viedoc.com) 和 [tmfsupport@viedoc.com](mailto:tmfsupport@viedoc.com) （支持语言为英语）



9. END USER SUPPORT

终端用户支持

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.

要为系统访问和研究相关问题提供充分支持，就必须了解支持链中的下一级用户和研究协议。这一点从隐私法规和信息安全的角度也很重要。本软件的设计消除了对集中服务台的需求，因为集中服务台通常会在该等重要方面遇到困难。因此，终端用户支持由客户和研究机构通过自助服务功能和内置用户支持功能进行处理。

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

最佳实践支持链应通过以下授权来实施：

Study Subjects 研究主体	[seek support from] → [寻求支持] →	Site Personnel 现场人员	[seek support from] → [寻求支持] →	Site Manager 现场经理	[seek support from] → [寻求支持] →	Study Manager 研究经理	[seek support from] → [寻求支持] →	Customer Organization Administrator 客户组织管理员
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