



Aspirations for good health and life

世界中の人々の健やかな人生のために



Quality and Content Management Cloud

Confidential - 2018

<https://en.agathalife.com>

Agatha Overview

- **Quality and Content Management** for the Life-sciences and Healthcare.
- **Immediately available** on Agatha private compliant cloud.
- **Cloud / Subscription** model.

Agatha Overview

- Around **100 clients world wide** – **From Hospitals to Tier 1 Pharmas.**
- **EU, US** (NJ) and **Japan** (HQ).

Solutions

SOP & EMPLOYEE RECORDS

- Review & Electronic Approval
- Periodic Review
- Employee Records
- Controlled Print



CLINICAL SITE ISF and SPONSOR ETMF

- Management of the **documents** expected during the course of a clinical trial.
- Collaboration between sponsor and clinical site (Hospital).
- **IRB Review, IP Green Light, FDA1572**



REGULATORY

- Management of the drug-related documents required by the Health authorities.



QMS

- Deviations and CAPAs
- Audit
- Complaints
- Change Control





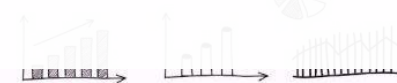
Clients

- **Hospitals and Research.**
 - **Affordable and secured** solution
 - Manage **Investigator Initiated Studies.**
 - **Collaborate** with external partners and other investigational sites.

Clients

- **Pharmaceutical Companies and Medtechs.**
 - Management of **eTMF, SOP, QMS and Regulatory**
 - Management of **expected documents.**
 - Collaboration with **external partners / Sites.**

 INNOVATION





Clients

- **Clinical Research Organizations.**

- Manage clinical and project documentation in one location, consistently, and easily collaborate with your clients.

Benefits



GxP Features



eTraining



Local Business
Support



Validation and
Compliance

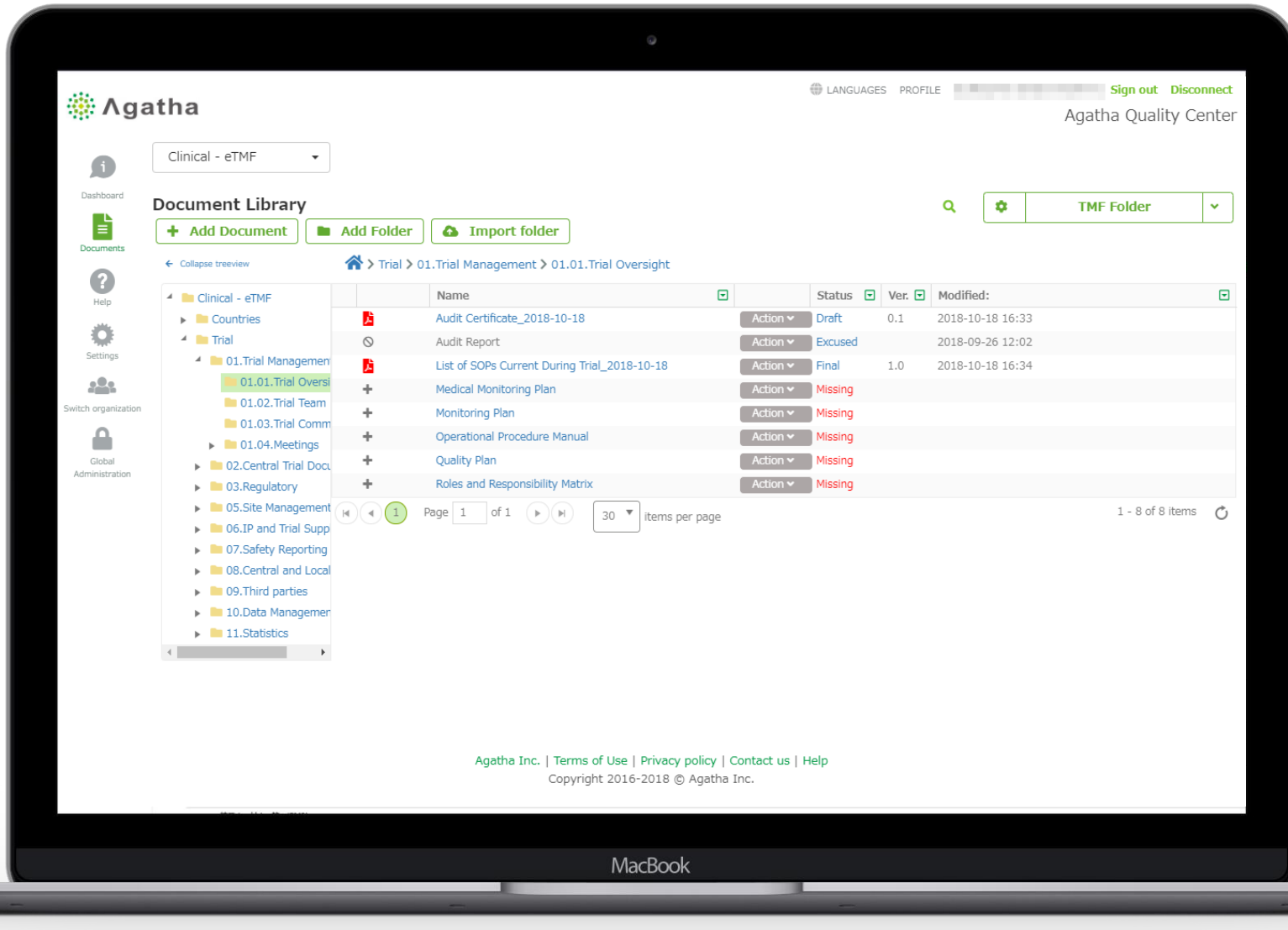


Secured Cloud
Service



Affordable

Questions?





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今 私たちができること



Benefits



GxP Features

“Agatha is fully equipped with all the functions necessary to manage GxP documents.”

- Audit Log
- Electronic signature
- Compliant PDF Rendition
- Periodic Review
- User Policy Management
- Document Acknowledgement
- Document Quality Control
- Artifact and template management
- Auditor's view
- ***Compliant data export***

Benefits



eTraining

“Users receive training using video clips, and acknowledge their training when they start using Agatha.”


Agatha Policy

Published date 8/7/2016

Agatha Policy Acknowledgement.

Please watch the Agatha eTraining video and acknowledge your training.

The Document Management Cloud Service
for Life-Sciences and Healthcare!

 **Agatha**

0:03 / 10:10

Enter your email and password to
approve the policy.
System policies must be approved
to use the system.

Email

operation.eutjdoe@agathalife.com

Password

Password

Read and understood

Log out

Policy 1 of 1 unapproved policies.

Benefits

Local Business Support



“Agatha's Support Team fully understands business operations in medical and pharmaceutical industries, and answers your questions clearly.”

- Expert in GxP compliance.
- Understands SOP management.
- Local support in US, Europe and Japan.

Benefits

Validation and Compliance

“We provide you with a validated system that is compliant with GxP regulations and FDA 21 CFR Part 11. You will be up and running in PROD in a few days.”

- Platform is validated (multi-tenant Cloud Environment).
- Standard processes are validated (OQ/PQ) for each release.
- Changes of parameters are validated.
- Compliance check list against FDA 21 CFR Part 11 (electronic records and signature). Compliance letter can be provided to clients.
- This means that clients do not need to perform any validation to start using Agatha.

Benefits

Secured Cloud Service

“ Agatha offers a highly secure, highly reliant, high performance, compliant, cloud service.”

- Agatha is partner of AWS, largest hosting provider in the world.
- Agatha Cloud satisfies the requirements of our most security-sensitive customers. <https://aws.amazon.com/compliance/>.
- End-to-end data encryption during transit and at rest.
- Strong segregation of non-productive and productive environments through Virtual Private networks.
- Each environment only exposes a reverse proxy server making the internal topology of the Agatha environment completely private.
- Agatha validation and production environments are only accessible to a handful of authorized personnel.



Benefits

Secured Cloud Service

“Agatha offers a highly secure, highly reliant, high performance, compliant, cloud service.”

Figure 1. Magic Quadrant for Cloud Infrastructure as a Service, Worldwide



Source: Gartner (August 2016)

☼ Benefits

Affordable

“Agatha team delivers high-quality, low-cost service, leveraging cutting-edge technology, know-how and expertise.”

- True multi-tenant cloud, hosted on AWS, the largest hosting provider in the world.
- Plenty parameters to adjust our solutions to your business needs, but we don't allow customizations. We don't have to maintain several versions of our solution. We focus on R&D.
- Automated provisioning process: go and register online, and get an environment ready-to-use in a minute.
- Up and running in production a few days (including training, adjustment of parameters etc.) We don't charge hundreds of thousands of dollars for setting up your environment.
- We validate and test for you! We run OQ/PQ for each release for you (through automated and manual testing) so that you don't have to worry about it.





<https://corporate.m3.com/en/>

- Established in 2000
- Revenue: 650 M USD.
Earnings: 200 M USD
- 3,600 employees



<https://www.mickk.com/.en/>

- Established in 1999
- Leading Technology VC in Japan

