



Medical Device Company, Optos, Amps up ClinOps with Agatha Applications

Optos is a global medical device company founded in 1992 in Scotland by Douglas Anderson. Anderson set out to make a patient-friendly device that captured a digital ultra-widefield image of the retina. The company has built a number of optic devices that image the eye and help with the diagnosis and treatment or supporting treatment for various pathologies. Today, Optos has over 18,000 devices installed across the world.

Giulia Bignami is a Clinical Research Associate and plays several essential roles in the company. After joining Optos two years ago, she now supports the document management of clinical trials, clinical compliance (regulations for medical devices) and supports the team with literature and clinical evidence management. She also led the implementation of two Agatha applications: Agatha Clinical for Trial Master File Management and Agatha Remote ISF for clinical site oversight and remote monitoring.

From her home office in Edinburgh, Scotland, Bignami talked about Optos' path to improving clinical trial documentation management and remote monitoring of clinical trials.

Managing the Trial Master File

Optos managed its trial master file (TMF) through a system integrated with its quality system. It wasn't a dedicated TMF application but a set of clinical sections within the quality system that were partly structured to store their essential trial documents.

Although the ad hoc solution worked, it was felt it did not provide adequate visibility or tracking of documentation for trials. For example, there was no consistency in document structure or names – resulting in things being set up differently. There was also no easy way to perform a gap analysis (e.g., what's missing or what needs to be audited).

Optos realized it needed a solution that would help it with consistent documentation, compliance with regulations, better tracking of clinical documents, sign-off and approval processes, and more.

Some of the critical features Optos looked for in a TMF application included:

- The ability to keep all documentation in a single location, compliant with all storage requirements
- A systematic structure that everyone would recognize and could work with
- Secure cloud storage and backup
- The ability to configure the application to support the specific requirements for medical device documentation

Giulia said that TMF solutions are typically tailored towards pharmaceutical companies and that Optos had a slightly different set of requirements as a medical devices company, which didn't follow the reference standard TMF completely. Optos knew it would need a customizable solution.

After reviewing potential solutions, Agatha Clinical (TMF) was selected. According to Giulia, Agatha provided the customization Optos needed. It also offered a license model that suited the company's needs.

Adopting Remote Monitoring

Like many other medical device, biotech, and pharmaceutical companies managing clinical trials, Optos was affected by COVID-19.

At the time, it had two big trials going on, which needed Optos' clinical research associates to visit sites to carry out monitoring activities. When COVID hit, the company had to develop a different approach to keep its clinical trials going while ensuring that proper (and compliant) monitoring activities were carried out. Changing processes mid-study was a challenge. At the same time, the trials that were started during the COVID wave also needed a new approach to monitoring.

The remote monitoring framework Optos selected had to enable monitors to carry out their activities in a way that felt comfortable compared to what they had been doing.

"Monitors would go out to sites and physically browse the documentation they needed access to and provide feedback to sites. Study coordinators and other site members were often there, and there was this feedback and interaction that you don't get in a remote framework. We wanted to make sure that monitors felt like they could do their job properly even though it was remote and that we were mirroring monitoring procedures."

- Giulia Bignami

One additional concern Optos had when thinking about remote monitoring processes related to compliance with data protection regulations. Other requirements included the ability to perform quality checks and send notes to the site.

Most importantly, it was essential that Optos could configure the Remote Monitoring application to support their needs.

Because they were already using Agatha Clinical for managing the TMF, it was an easy decision to add Agatha's Remote ISF application to their toolset.

Advice for Others Looking to Adopt TMF and Remote Monitoring Applications

There is a lot to think about when you start looking for a TMF or remote monitoring application. Giulia provided two pieces of advice to help with the process.

- **Know Your Processes Well:** The first thing you need is a clear idea of how your processes work because that's what your TMF or remote monitoring system needs to mirror.
- **Plan Ahead:** Think about the structure you want to create. What do you need for each trial? Do you want to create a single structure or multiple structures that fit different types of trials? Thinking ahead is critical.

For remote monitoring, planning is equally important. You have to think about not only what you need but what your sites need.

- How will you implement the processes?
- How can you make things as easy as possible for the site while also making things smooth and functional for the clinical team?
- What potential challenges can you see, and how can you prevent them from happening in your setup?

Access to a free trial to pilot the application is also critical and was crucial to Optos' decision to go with Agatha applications.

"Having the pilot is what made all the difference for us. It's where we learned first hand what it was like to upload documents, to go through all the approval processes and all the different options, including any required configuration. I got to know the application and was able to provide feedback around my concerns, as well as understand what we would need to configure to meet our processes. So it was definitely crucial to our decision."

Giulia Bignami, Clinical Research Associate, Optos

About Optos

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Learn more [about Optos](#).

About Agatha

Agatha, Inc. is a leading strategic software applications provider to the healthcare and life sciences industry. With offices in the US, Europe and Japan, Agatha is dedicated to helping the world's hospitals, biotechnology, pharmaceutical, contract research organizations, and medical device firms optimize the management of their quality, regulatory and clinical documentation and processes.