www.ennov.com
contact@ennov.com
+1 (833) 366-6887

CASE STUDY

How ARCAGY-GINECO Built a Complete Research Operations Platform with Ennov

How a 50-person academic research group replaced fragmented, outdated tools with a self-configured, unified platform covering study management, quality, eTMF, and analytics across internal and CRO-managed studies.

Every year, ARCAGY-GINECO must produce operational KPIs for studies, quality assurance, and management reporting across a busy oncology research portfolio. Gathering and consolidating those KPIs used to take almost a full week.

Today, it takes two hours.

That change did not happen by accident. It happened because ARCAGY-GINECO made a deliberate decision to implement a custom platform that fits the way its team works. Over seven years, the organization built a complete ecosystem on Ennov, covering study management, quality documentation, eTMF, and analytics. It now supports both internally managed activities and studies supported by external CRO partners.

95%
Faster Operational KPI Reporting

4-in-1
CTMS, QMS, eTMF, Analytics

7+
Years of Ennov Partnership

Industry	Nonprofit / Academic Clinical Research
Headquarters	France
Employees	<100
Research Area	Oncology, gynecology
Regulatory Scope	ICH GCP, EU Clinical Trials Regulation, GxP
Modules in use:	Process (CTMS), Document Management (QMS and eTMF), Analytics, and CRO/EDC integration

The Challenge: Too Many Systems, Too Little Visibility

ARCAGY-GINECO is a non-profit academic clinical research group conducting oncology and gynecology trials across sites worldwide. With around 50 people managing multiple studies simultaneously, it needed systems that could support both scale and consistency.

Why ARCAGY-GINECO Needed a Unified Research Operations Platform:

- **An outdated, fragile home-built system that required expensive specialist developers to maintain.**
- **No shared working framework across project teams, leading to inconsistent processes.**
- **No central visibility across studies, making it difficult to track enrollment, site activity, and clinical milestones in one place.**
- **Annual reporting required days of manual work to compile data from across the portfolio.**
- **Some studies relied on operational support from external CRO partners, creating a gap in operational visibility.**
- **A lean team of 50 that needed enterprise-grade oversight without enterprise-level resources.**

Why Ennov? Three Factors That Made the Difference

ARCAGY-GINECO evaluated several options, but with Ennov, three factors stood out.

1. **Interconnection:** Key eCRF and CTMS data could be brought into a central platform across both internally managed studies and studies supported by external CRO partners.
2. **Flexibility:** The system could be configured around ARCAGY-GINECO's processes and evolve over time as its workflows, data needs, and priorities changed.
3. **Analytics:** Custom dashboards gave the organization visibility into enrollment, site activity, workload, and portfolio performance.

> *"Ennov gives us a complete and interconnected platform. Today, it saves us time. Not just for managers, but for all team members."*

- Sebastien Armanet, ***Managing Director,*** Arcagy-Gineco

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The Solution: A Platform Built Piece by Piece

ARCAGY-GINECO did not adopt a rigid, pre-built system. It used Ennov's core platform as a foundation and built its environment progressively around its own processes, workflows, and data needs.

The phased approach was deliberate. Rather than imposing a full system all at once, ARCAGY-GINECO expanded capabilities step by step, making change easier for teams to adopt, and ensuring each addition delivered practical value.

From CTMS to eTMF: A Unified Research Operations Platform

- **One shared CTMS for all studies:** Sites, patients, visits, reports, study teams and milestones are now tracked in one environment, giving all project teams a common structure and a shared way of working.
- **Visibility across internal and CRO-supported studies:** Integrated eCRF and CTMS data flows into the platform, providing one view across internally managed studies and studies supported by external CRO partners.
- **Dashboards that teams actually use:** Teams can plan visits, managers can monitor workload, and project teams can track enrollment, operational follow-up, milestones, and study indicators without manual consolidation.
- **Connected Quality and eTMF workflows:** Quality documents can be generated from study activity and filed automatically in the right place, turning eTMF work into a time-saver rather than an added burden.

The Results: Faster Execution, Better Visibility

The clearest proof of value is how quickly operational KPIs can now be pulled and consolidated. Work that once required a full week of manual compilation can now be completed in just a few hours.

UNIFIED OVERSIGHT

One platform now supports study management, quality documentation, eTMF, and analytics, with shared data and processes across teams.

CONNECTED VISIBILITY

Integrated eCRF and CTMS data gives Arcagy-Gineco one view across internally managed studies and studies supported by external CRO partners.

TIME SAVED

Operational KPI reporting dropped from almost a week to just a few hours. Project teams now save time daily, with faster eTMF workflows and less manual work thanks to dashboards.

Day-to-day, the impact is equally practical. Clinical Research Associates use the system to plan visits and track workload. Managers can see team activity and set priorities more clearly. Project teams can monitor study indicators directly, without waiting for manual consolidation.

Just as importantly, intuitive dashboards made reporting accessible to everyone, not just advanced Excel users.

Future-Ready By Design

ARCAGY-GINECO continues to evolve with the platform. The next step is using the same configuration approach to implement a document placeholder system, allowing teams to define required documents in advance and track their completion. Additionally, the organization plans to automatically generate follow-up letters for sites directly from visit reports, further streamlining communication and reducing manual effort.

The organization is also exploring the use of electronic signature and certificate features, which would add another layer of traceability and compliance to existing workflows.

Because everything is built on the same Ennov platform, new capabilities can be added progressively, extending functionality without disrupting what already works. The foundation remains stable, while the system becomes more unified and easier for teams to use.

ARCAGY-GINECO demonstrated that a lean team can achieve enterprise-level visibility. The right platform, intentional configurations and technical expertise together remove the need for large infrastructure or large budgets.

"In clinical research, eTMFs are often seen as adding to the work load. For us, it's the opposite. Our team now spends less time per document while delivering higher-quality documentation."

Sebastien Armanet
Managing Director
Arcagy-Gineco

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