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CASE STUDY

When Academic Excellence Meets Regulatory Reality: Cardiff University's 13-Year Success Story

How Ennov's Platform Stability and Partnership Approach Enabled 100+ Cancer Trials and Seamless MHRA Inspections

Academic Clinical Trials Units face a fundamental challenge: delivering pharmaceutical-grade quality on university budgets. Cardiff University's Centre for Trials Research found the solution in Ennov's future-ready EDC and unified compliance platform—engineered for reliability without compromising innovation.

The result: 13+ years of uninterrupted trial operations across 100+ cancer studies, successful MHRA inspections, and a technology partnership that evolves with academic realities.

MHRA ✓
MHRA-approved platform

100+
trials successfully delivered

13 years
of stable operations

Designation	UKCRC-registered Clinical Trials Unit (CTU)
Team Composition	Multidisciplinary staff across trial management, data, statistics, QA & regulatory
Research Breadth	Oncology, infection/inflammation, brain health, population & social care
Trial Experience	100+ cancer studies delivered over more than a decade

> *"It's just good, stable, reliable software. There's probably not enough of that in the world."*

- Gareth Watson, *Head of Information Systems,* Centre for Trials Research, Cardiff University

The Challenge

UK Clinical Trials Units operate under unique constraints. Cardiff University's Centre for Trials Research—a UKCRC-registered CTU formed from three merged units including the Welsh Cancer Trials Unit—needed an EDC system that could handle the specific demands of cancer research.

Cancer trials present particular challenges:

Long study duration: Many studies run 10+ years	**Complex protocols:** Oncology studies require sophisticated data collection	**Regulatory scrutiny:** MHRA inspections demand comprehensive documentation	**Budget constraints:** Academic funding requires careful resource management

The CTU needed a platform that could support these long-term studies while maintaining regulatory compliance and managing costs effectively.

Why Ennov?

1. **MHRA pre-approval:** Platform already validated for UK regulatory requirements
2. **Proven stability:** Designed for multi-year studies with minimal disruption
3. **Academic focus:** Understanding of CTU operational models and constraints
4. **Complete lifecycle support:** From study startup archiving

The Solution: Ennov Clinical Suite

- **Stable Platform Architecture:** Cardiff deployed Ennov EDC across their cancer trial portfolio. The platform's approach to updates and enhancements allowed Cardiff to commit to decade-long studies while benefiting from ongoing improvements and regulatory updates.
- **Regulatory Integration:** With MHRA pre-approval built in, Cardiff's inspection preparation became more straightforward. Instead of complex validation documentation across multiple systems, they could demonstrate compliance through a single, pre-validated platform.
- **Dedicated Support:** Cardiff worked with an Ennov support team that maintained institutional knowledge and relationship continuity. This partnership approach ensured the platform's evolution remained aligned with Cardiff's research needs.
- **Process Automation:** Cardiff implemented Ennov's integrated archiving capabilities to streamline study close-out processes—a critical workflow as research teams transition between projects while maintaining regulatory compliance.

The Impact

REGULATORY COMPLIANCE

Cardiff successfully completed their most recent MHRA inspection. The integrated platform allowed inspectors to focus on research quality rather than navigating complex system documentation.

OPERATIONAL EFFICIENCY

The platform's template-driven architecture proved effective for cancer research protocols, where studies often share common methodological elements. Cardiff could deploy new trials using proven database structures, reducing setup time while maintaining validation.

STRATEGIC POSITIONING

Cardiff's success with Ennov EDC has positioned them to evaluate the broader Ennov unified compliance platform integration. The proven reliability makes Ennov a candidate for expanded implementation.

Future-Ready By Design

Cardiff's partnership with Ennov extends beyond current capabilities. The unified platform architecture positions Cardiff to expand into eTMF and QMS operations within the same ecosystem, addressing resource optimization needs while maintaining specialized CTU functionality.

Key Takeaways for UK Clinical Trials Units

Platform Reliability Enables Focus
Stable technology allows CTU teams to focus on research rather than system management. For multi-year cancer studies, platform dependability is essential.

Regulatory Preparedness Matters
MHRA inspections are more manageable when your EDC platform comes pre-validated. UKCRC-registered CTUs benefit from vendors with established regulatory relationships.

Partnership Models Drive Results
CTU procurement and research models require vendors who understand academic constraints and timelines. Effective technology partners must value long-term research goals beyond immediate transactions.

"The team has been great. It's quite rare that we've actually had to use support, but when we do, it's first class. They understand us very well and are very responsive when we have problems. It's been really great working with them."

Gareth Watson
Head of Information Systems
Centre for Trials Research, Cardiff University

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Want to Replicate Cardiff's Success?

UK Clinical Trials Units need technology partners who understand that medical research requires dependable systems: built for the long term, validated for compliance, and supported by teams who understand your mission.

Contact Ennov to discuss how our EDC platform can support your clinical operations and research goals.

Start with the platform designed to scale with life sciences growth.

Connect with Ennov's experts today. **ennov.com**

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