

Case study

From Months to Hours

MMC Medical's EDC Revolution

How a specialized CRO builds first-in-human device studies in 5 hours

Executive Summary

MMC Medical International Consulting Services, a specialized CRO focused on first-in-human device studies, transformed their clinical trial deployment from months to hours using Castor's EDC platform. Since 2019, they've completed over 70 studies with build times as fast as 5 hours, enabling them to support short-duration device trials that traditional EDCs couldn't accommodate.

Key Achievement: Reduced study build time from months to 5 hours while managing 15-18 concurrent studies across multiple therapeutic areas and geographic regions.

5

Hours to Build
Studies

70+

Studies
Completed

7+

Years
Partnership

18

Concurrent
Studies

Read Now →

The Client: MMC Medical's 30-Year Evolution

MMC Medical International Consulting Services was founded in 1992 by Laura Minarsch, who began her career during the early transition from diagnostic cardiology to percutaneous treatment. With over 30 years of experience, MMC has evolved from interventional cardiology specialists to a comprehensive clinical development organization spanning 4 continents.

Strategic Positioning: MMC specializes in early-stage device studies that require rapid execution—from first-in-human feasibility studies through regulatory submissions. Their expertise lies in understanding that device companies need clinical proof quickly to secure funding, partnerships, or acquisition opportunities.

The challenge facing device companies is well-documented: traditional clinical infrastructure designed for pharmaceutical trials often can't accommodate the unique requirements of device validation studies, which typically involve smaller patient populations and accelerated timelines.



We have so many templates that we don't have to go from scratch. Right now we're building a study in five hours. That easeability of importing structures and maintaining characteristics of the fields is really super helpful.

— *Donna Merithew, CTO/Clinical Research, MMC Medical*



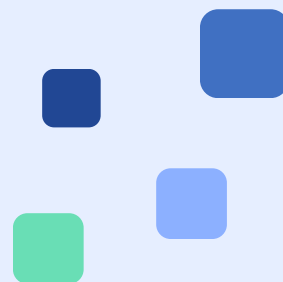
The Challenge

Industry-Wide EDC Challenges

- **Build Time Bottleneck:** Research shows traditional EDC systems require 3-6 months for database creation and validation, fundamentally misaligned with device study timelines
- **Cost Escalation:** Module-based pricing models create unpredictable expenses, particularly challenging for startup device companies with limited budgets
- **Technical Barriers:** Complex EDC implementations often require specialized programming knowledge, creating dependencies on technical resources rather than clinical expertise
- **Regulatory Complexity:** Device studies must balance speed with evolving regulatory requirements, particularly for international submissions

MMC's Strategic Solution

- **Template-Driven Efficiency:** Leveraging validated study structures reduces build time by 95% while maintaining regulatory compliance
- **Predictable Economics:** All-inclusive platform eliminates cost surprises and enables accurate project budgeting
- **Clinical Focus:** Intuitive interface allows clinical teams to maintain control without technical dependencies
- **Adaptive Framework:** Rapid modification capabilities support the iterative nature of device development studies



The Solution

MMC Medical implemented Castor's clinical data management system with Bronze-level professional services, enabling self-service study builds with expert support when needed.

Key Implementation Features:

Template Reusability

Extensive library of validated study templates and form structures for rapid deployment

Form Import Capabilities

Copy and modify existing study structures while maintaining field characteristics

API Integration

Advanced data integration for specialized device studies requiring external data sources

Global Compliance

21 CFR Part 11 compliance for US regulatory requirements and international standards

Study Months Model: Flexible Pricing for Variable Timelines

Challenges for CROs Running FIH Studies

First-in-human device trials often run as short, sprint-style studies with uncertain duration—some wrap in ~3 months while others extend to ~6 months depending on early results. That variability makes traditional vendor-CRO contracting less than ideal because commitments assume fixed timelines.

Likewise, at MMC's scale, multiple studies start and stop asynchronously, so a "multiple concurrent swimlanes" subscription may leave paid capacity idle when sponsors delay or cancel. MMC also can't reliably forecast when sponsors will sign, making it risky to pre-allocate lanes and resources under a fixed subscription model.

Ultimately, they needed a solution that accommodates variable study durations, minimizes the overhead of contracting each study individually, and still allows them to benefit from economies of scale.

Castor's Flexible Pricing Solution

Castor and MMC use a Study Months model that lets CROs purchase a bank of study months across their desired modules (i.e. EDC, ePRO, and eConsent) for an agreed upon period. MMC draws down this balance only when a study is active, matching spend to real utilization and avoiding the cost of idle lanes.

The model preserves economies of scale by pricing at volume while keeping scope flexible across study starts, stops, and pivots. Practically, this:

Reduces Financial Risk

Pay only for active study time, not reserved capacity

Simplifies Planning

Predictable cost structure with flexible utilization

Aligns Platform Access

Matches MMC's sprint-like FIH operating cadence

Enables Growth

Add modules and capacity as business expands



It's about flexibility and ease of use. There's nothing easier to train sites on. They really like the navigational tool of Castor and the quick online updates.

— Donna Merithew, CTO/Clinical Research, MMC Medical

Results & Impact

95% Time Reduction

Study builds reduced from months to 5 hours using template library

Concurrent Study Management

Successfully managing 15-18 active studies simultaneously

Cost Efficiency

Single coordinator can manage entire study lifecycle vs. multiple staff

Client Retention

Long-term partnerships with device companies due to rapid deployment capabilities

Industry Context: Research on clinical trial efficiency shows that rapid deployment capabilities are increasingly critical for device companies competing in fast-moving markets. MMC's transformation exemplifies how operational excellence in clinical data management directly enables medical device innovation.

Specialized Use Cases

Real-World Application: Optical Device Integration

A compelling example involves advanced optical coherence tomography devices used in complex cardiovascular procedures. Traditional data capture requires manual transcription of instrument readings, introducing both delays and potential errors that can compromise study data integrity.

MMC's solution leverages Castor's API integration capabilities to automatically capture instrument data, creating a seamless workflow that reduces coordinator burden while improving data quality—a critical factor for device studies where precision measurements drive regulatory approval.



They were able to take the data from a particular instrument and pull it daily so it matches and coincides into a form in Castor. It's very seamless and really powerful.

— Donna Merithew on API Integration Success

Explore How Castor Enables Rapid EDC Implementation

See the platform capabilities that power MMC Medical's 5-hour study builds

Study Build Demo

Experience the template-driven study building process that enables MMC Medical's 5-hour deployments

[View Interactive Demo](#)

Site Data Entry View

See the intuitive interface that makes site training effortless for MMC Medical's international studies

[Explore Site Experience](#)

Data Import Capabilities

Discover the API integration features that power MMC Medical's optical device data automation

[See Integration Demo](#)

Data Export & Reporting

Learn how MMC Medical efficiently manages data export for 15-18 concurrent device studies

[Try Export Demo](#)

Key Insights for Clinical Operations Leaders

MMC Medical's transformation offers valuable lessons for organizations evaluating EDC solutions for specialized study types:

Template Strategy

Investing in reusable template development pays dividends across multiple studies—the time spent building comprehensive templates is recovered within the first few implementations

Service Level Alignment

Experienced teams benefit from self-service models with expert backup rather than full-service approaches that can slow deployment

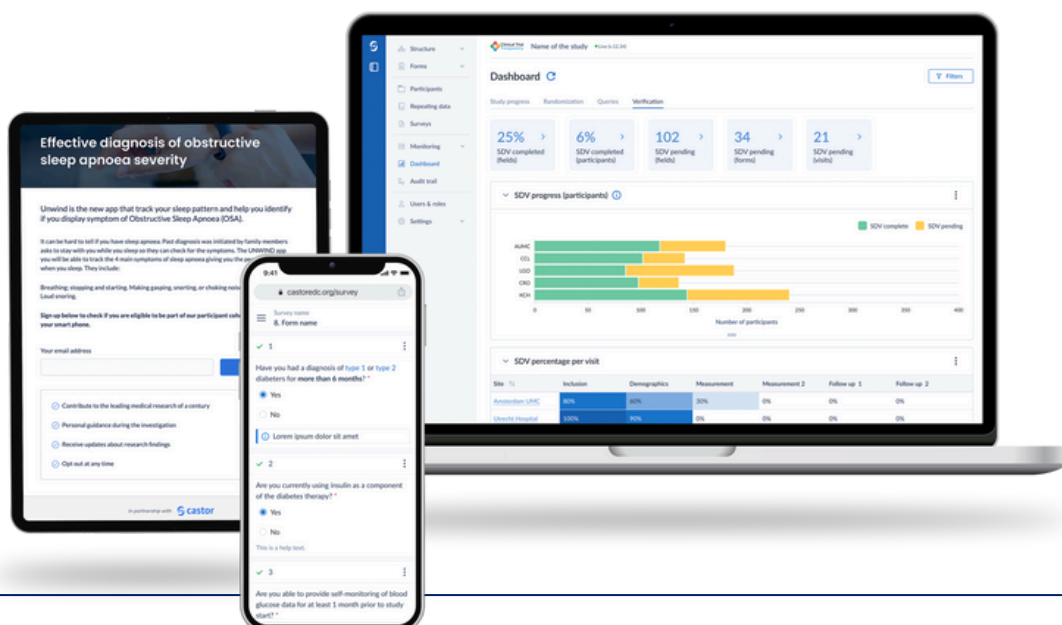
Integration Planning

Early consideration of data source integration prevents downstream complications and enables advanced automation capabilities

Scalability Framework

Platform choice should support growth from single studies to concurrent multi-study management without operational restructuring

Strategic Takeaway: Success in device study EDC implementation depends more on operational alignment and template strategy than on platform complexity. MMC Medical's approach demonstrates that the right combination of platform capabilities and service model can transform operational efficiency while maintaining regulatory compliance.



Ready to Transform Your Study Build Process?

See how Castor's template-driven approach can accelerate your clinical operations, just like MMC Medical's revolutionary 5-hour builds.



Rapid Deployment

Template libraries and form import capabilities for accelerated study builds



Advanced Integration

API capabilities for specialized device data automation



Scalable Operations

Manage multiple concurrent studies with streamlined workflows

[Schedule Your Platform Demo](#)

See firsthand how Castor enables rapid, compliant EDC implementation

Frequently Asked Questions

How does MMC Medical achieve 5-hour study builds consistently?

MMC leverages Castor's extensive template library and systematic reuse strategies. They identify similar previous studies, copy the entire structure including forms and logic, then customize specific elements for the new protocol. This approach maintains field characteristics and validations while adapting to new requirements—transforming what traditionally takes months into a 5-hour process.

What makes device studies different from pharmaceutical trials?

Device studies typically involve smaller patient populations (5-20 subjects vs. hundreds), shorter durations (30 days to 1 year vs. multi-year trials), and need to prove safety/efficacy concepts quickly for regulatory approval or acquisition scenarios. Traditional EDC systems designed for large pharmaceutical trials often can't accommodate these rapid timelines and budget constraints.

Why choose international locations for first-in-human studies?

FDA regulations require proof of safety and efficacy in human subjects before US trials. International locations like Paraguay, Lithuania, and New Zealand offer faster ethics approval (often within one month vs. 3-6 months in the US) and established relationships with key opinion leaders. This regulatory pathway is essential for device companies needing to generate safety data efficiently.

How does Bronze service level support specialized CROs?

Bronze service provides self-build capabilities with expert support when needed. Experienced teams like MMC Medical can handle routine builds independently while accessing specialized support for complex issues, API integrations, and technical guidance—delivering cost efficiency without compromising capability.

What's the typical timeline for device study deployment?

With MMC Medical's optimized approach, device studies can move from protocol finalization to first patient enrollment in 4-6 weeks: 5 hours for EDC build, 2-4 weeks for ethics committee approval in target markets, and 1-2 weeks for site activation and training. This timeline enables device companies to generate critical safety data within funding and development windows.

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