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Case study

3-Week Database Builds That Withstood FDA Review

Industry: Biotechnology

Product: Fertilo - an ex vivo egg-maturation system - aimed at making IVF and egg freezing shorter, safer, and more effective

Mission: To redefine female reproductive health by developing therapies that improve lives.

Study Scope: 9 concurrent global studies across 4 continents, comprising Randomized Controlled Trials (RCTs) and longitudinal safety registries.

Castor solution: Castor EDC

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The challenge: high-stakes regulatory demands, limited resources

Gameto needed to generate FDA-compliant safety and efficacy data across Peru, Mexico, and Australia to support a US IND submission. The operational reality was severe:

- **Extreme Resource Constraints:** Execute nine concurrent studies with a clinical operations team of just three people and no large CRO.
- **Complex Longitudinal Safety:** Manage longitudinal safety data, including infant development milestones, across diverse local standards.
- **Rapid Deployment Needs:** Deploy regulator-ready databases in weeks, not months, to meet aggressive milestones.

The solution: centralized oversight of decentralized global sites

Gameto used Castor EDC to centralize oversight, allowing the core team to function as their own Data Management unit:

- **Remote Source Data Verification (SDV):** Enabled 100% remote monitoring by capturing high-resolution source documents (blood logs, charts) directly within the EDC for verification.
- **Synthetic Control Arms:** Integrated real-world data (RWD) to build case-matched synthetic controls, comparing Fertilo outcomes against conventional IVF cycles.
- **Global Harmonization:** Deployed fully localized Spanish CRFs for Latin American sites while maintaining a unified, FDA-compliant data structure for the central US regulatory submission.

The results: Data integrity that secured US IND Clearance

By controlling the build and monitoring process internally, Gameto eliminated vendor friction and delivered a pristine regulatory package:

- **US IND Clearance:** The 38-patient dataset—generated entirely ex-US—was accepted by the FDA for immediate Phase 3 entry.
- **Longitudinal Safety:** Successfully tracked 13 ongoing pregnancies and live births with full audit trails.
- **3-Week Build:** Went from protocol-to-live for a randomized controlled trial (RCT) in Peru, including full Spanish localization.

> **We don't have six months to set up a database. We have to learn as we go. [With Castor], we had that flexibility to adjust on the fly without losing quality.**
>
> - Christian Kramme
> Chief Scientific Officer | Gameto

IND clearance
in the United States

Gameto team
of 3

9 studies

4 continents

3 weeks
build time

Multiple languages

Find out how Castor can help you achieve similar results

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