

Technical Summary

StemRNA™ Clinical Seed Clone Used in FertiLO Development (US Phase 3)

1. OVERVIEW

This technical summary describes the use of REPROCELL's StemRNA™ Clinical Seed Clone **VCT-37-F35** which is referenced in a recently published, peer-reviewed paper authored by Gameto, the developers of FertiLO. This iPSC-derived product is currently in Phase 3 clinical development in the United States.

FertiLO is an *in vitro* oocyte maturation technology intended to reduce the reliance on exogenous hormone stimulation and to shorten the duration of standard IVF treatment protocols. This approach is being evaluated for its potential to improve treatment efficiency and patient experience within controlled clinical settings.

USE OF STEMRNA™ CLINICAL SEED CLONE (VCT-37-F35) IN THE FERTILO DEVELOPMENT

- The StemRNA™ Clinical Seed Clone **VCT-37-F35** was derived from a healthy female donor (23-year-old, Caucasian, A+). Manufacturing was performed at REPROCELL's Japan GMP facility, and supplied via REPROCELL USA.
- The clone served as the starting hiPSC source material for the generation of clinical seed and master cell banks. These banks were subsequently used for **transcription factor-mediated differentiation** into ovarian support cells (OSC).

Outcome: The process enabled consistent OSC production and was associated with higher rates of human oocyte to the metaphase II (MII) stage during *in vitro* maturation as reported in comparative evaluations relative to conventional IVM approaches.

WHY THIS MATTERS FOR CELL THERAPY DEVELOPERS

- **Clinically qualified starting material:** Demonstrates real-world use of one of REPROCELL's StemRNA™ Clinical Seed Clones, manufactured under GMP principles.
- **Process consistency:** Supports reproducible iPSC differentiation and reliable cell product performance.
- **Clinical translation:** Illustrates a development pathway from hiPSC starting material to clinical-stage cell therapy application.

2. REPROCELL'S STEMRNA™ CLINICAL SEED CLONES

StemRNA™ Clinical Seed Clones support translational stem cell therapy development. They are generated using REPROCELL's proprietary non-integrative, mRNA-based reprogramming technology and are manufactured at REPROCELL Japan and REPROCELL USA, with manufacturing processes following GMP principles to ensure quality and consistency.

REFERENCE

Paulsen. B. et al. Development of human induced pluripotent stem cell-derived ovarian support cells as a clinical-grade product for *in vitro* fertilization. *Cell Stem Cell*. (2025)