Project Title:

Clinical Evaluations and Applications of an Innovative Optical Coherence Tomography Imaging System in Assisted Reproduction

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Project Abstract/Proposal Summary:

This R&D proposal focuses on advancing the clinical application of Optical Coherence Tomography Imaging System (OCTIS^{TM}) for gynecological and reproductive medicine, specifically targeting the diagnosis, monitoring, and prognosis of endometrial health. OCTIS^{TM}, developed collaboratively by Prof. Ming Wai Kit and Tomophase, is an innovative imaging system that provides minimally invasive, real-time, high-resolution cross-sectional images of epithelial and sub-epithelial tissues. OCTIS^{TM} integrates advanced catheter-based rotational and pullback probes, approved by the FDA, and offers resolution nearing that of microscopy while exceeding ultrasound by 100-250 times.

The project addresses current gaps in gynecological diagnostic tools, such as low sensitivity of imaging methods like ultrasound and the invasiveness of biopsies. The primary aim is to evaluate, optimize, and validate OCTIS^{TM} for clinical applications in reproductive medicine. The study will involve ex vivo and in vivo imaging of the endometrium, hardware and software optimizations to enhance imaging capabilities, and comprehensive clinical validations across multiple centers.

Deliverables include peer-reviewed publications, regulatory approvals (FDA 510K), and patent filings, paving the way for commercialization. If successful, OCTIS^{TM} will revolutionize gynecological diagnostics, offering non-invasive, real-time, high-resolution imaging to millions of women globally, improving outcomes in conditions such as recurrent miscarriage and repeated implantation failure.