The Sponsor-Proxy Model: Bridging Basic Science Discovery

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Introduction

- Investigator-initiated trials (IITs) face major regulatory and operational barriers
- Natural product therapeutics often lack commercial sponsorship
- Basic science investigators often lack sponsor-level regulatory and clinical trial infrastructure
- PSCI developed the Sponsor-Proxy model to bridge translational gaps between laboratory discovery and clinical implementation

Sponsor-Proxy Translational Framework

Preclinical Discovery
• *Angelica gigas* Nakai (AGN) root extracts evaluated in animal models for pharmacokinetics and anti-cancer efficacy
• INM176 identified as an IND candidate containing novel active pharmaceutical ingredients (APIs)

Translational Barriers
• Botanical CMC complexity
• Sponsor regulatory burden
• Rural access to clinical research

Sponsor-Proxy Infrastructure
• Investigator-Initiated Trial Sponsor Support Unit (SSU)
• PhD–MD translational collaboration

Regulatory and Trial Development
• Investigator's Brochure and protocol development
• IND preparation and FDA submission
• Parallel regulatory and operational workflows

Clinical Implementation and Impact
• IND authorization without clinical holds
• Hybrid decentralized laboratory testing
• Expansion of investigator-initiated translational programs

Sponsor-Proxy Model: Role Delineation

Scientific Sponsor (PhD)
- Scientific leadership
- Preclinical discovery and PK/PD biomarker development
- Coordination of investigational product supply

Sponsor Support Unit (SSU)
Sponsor-Proxy Operational Functions
- IND and regulatory coordination
- Protocol and Investigator's Brochure development
- Monitoring plan development and monitor training
- DSMC coordination and safety oversight
- Clinical data management infrastructure
- TMF management and regulatory compliance
- Translational integration of basic science and clinical teams

Clinical PI and Study Team
- Clinical trial conduct
- Participant recruitment and clinical care
- Participant safety oversight
- Clinical coordination and data capture

Participants
- Trial Participation
- Protocol-specified safety assessments

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Translational Outcomes

- ❑ Enabled 2 NIH-funded investigator-initiated IND trials
- ❑ FDA authorization obtained without clinical holds
- ❑ Efficient PRC-to-activation timelines:
  - 112 days
  - 105 days
- ❑ Hybrid decentralized workflows improved feasibility for rural participants
- ❑ Additional natural product IND study recently opened to accrual

Translational Impact

- ➢ Enabled PhD-led discoveries to advance into IND-authorized clinical trials
- ➢ Reduced sponsor-level operational barriers for investigator-initiated studies
- ➢ Facilitated integration of regulatory, operational, and clinical expertise
- ➢ Established a reproducible translational infrastructure framework for academic cancer centers

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***Angelica gigas* Nakai (Korean Angelica)**
INM176: Proprietary ethanol extract of dried roots