

# The Sponsor-Proxy Model: Bridging Basic Science Discovery

Xin Liu, MD, Ph.D<sup>1</sup>, Doris Shank, MSN, RN<sup>1</sup>, Junxuan Lü, Ph.D<sup>1,2</sup>, Monika Joshi, MD, MRCP<sup>1</sup>

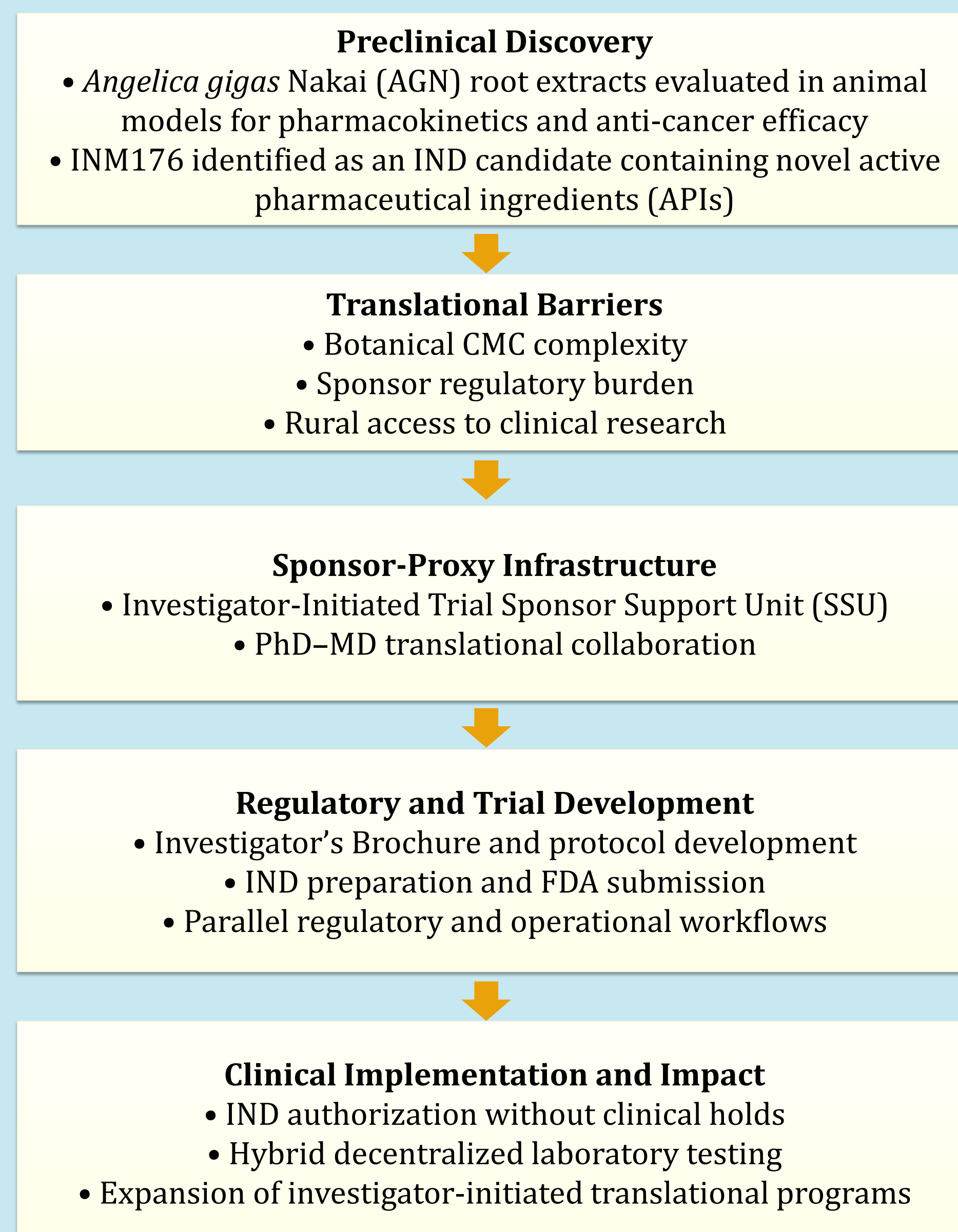
<sup>1</sup> Penn State Cancer Institute, <sup>2</sup> Penn State College of Medicine, Department of Neuroscience and Experimental Therapeutics



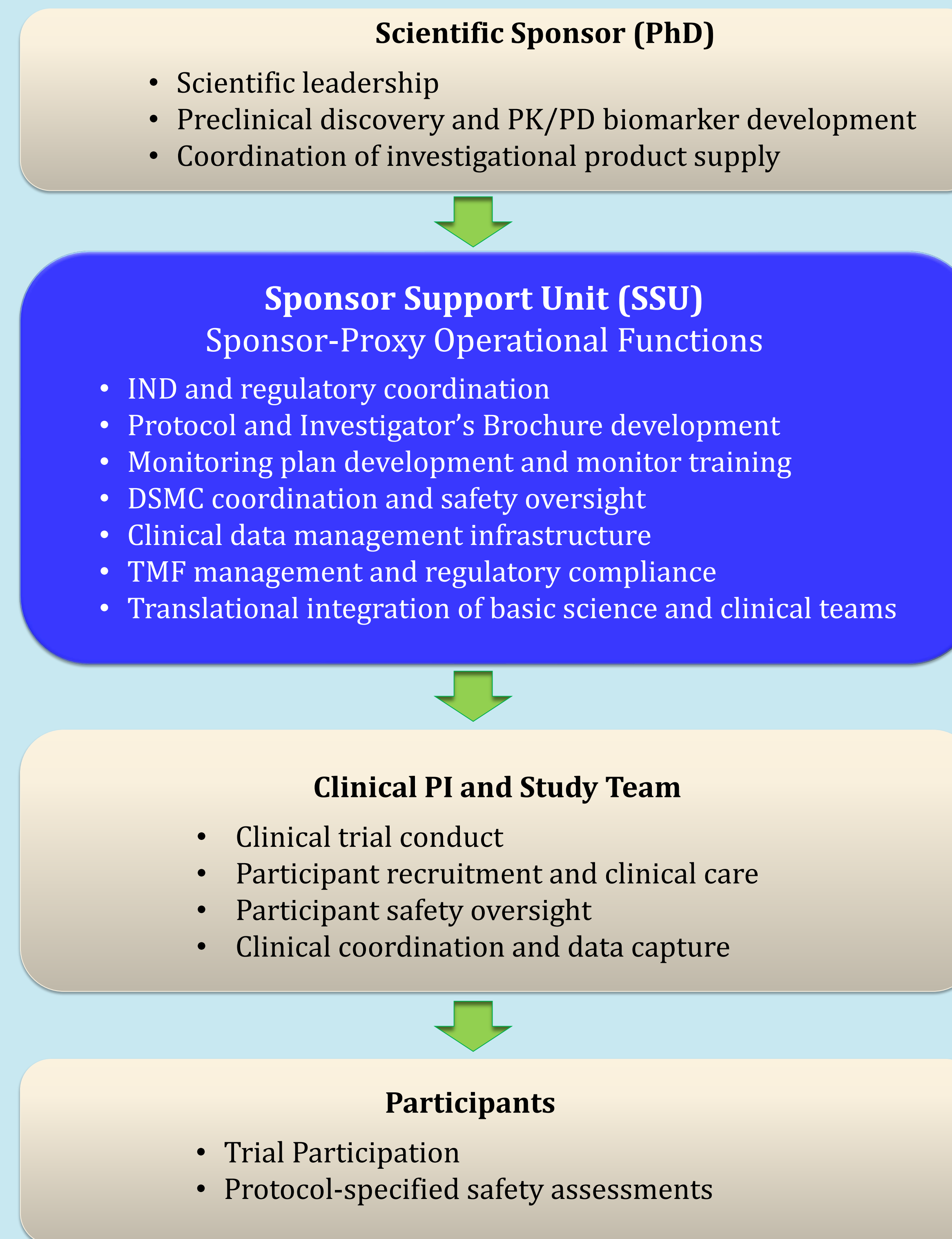
## Introduction

- 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



## Sponsor-Proxy Model: Role Delineation



Corresponding Author Contact Email: [mjoshi@pennstatehealth.psu.edu](mailto:mjoshi@pennstatehealth.psu.edu)

## Translational Outcomes

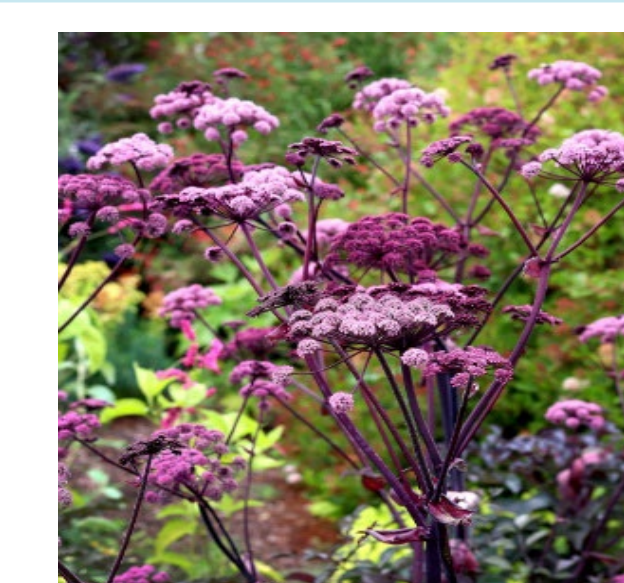
- Enabled 2 NIH-funded investigator-initiated IND trials
- FDA authorization obtained without clinical holds
- Efficient PRC-to-activation timelines:
  - 112 days
  - 105 days
- Hybrid decentralized workflows improved feasibility for rural participants
- Additional natural product IND study recently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

## Acknowledgments

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- Penn State CTSI Clinical Research Center
- PSCI Clinical Trials Office
- Study participants and collaborators



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