

From Concept to Market

The IND in Drug Development

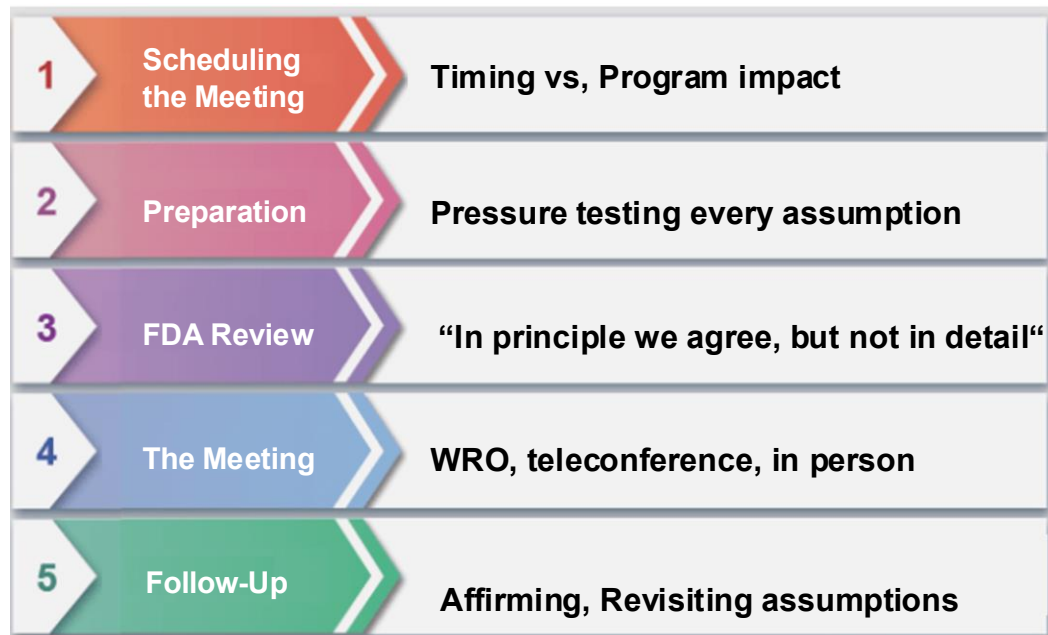
Moving Beyond “May Proceed”

Michael F. Murphy, MD, PhD,
Chief Medical and Scientific Officer
Worldwide Clinical Trials

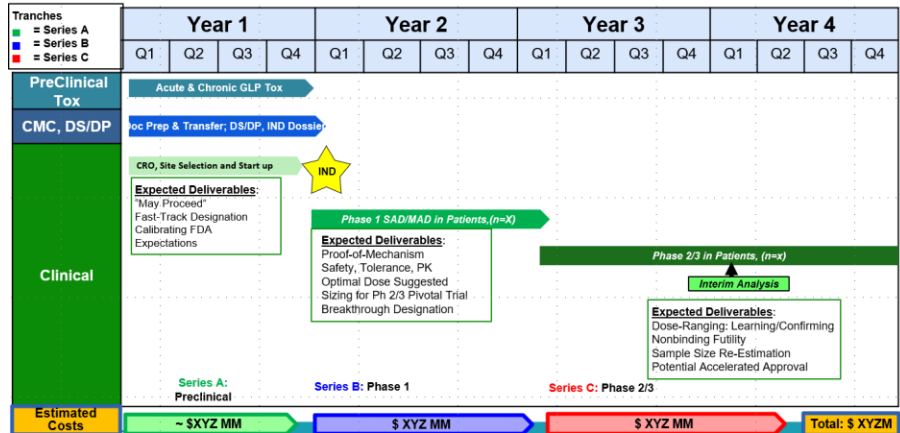
... as the First Step in a Product Narrative

- Approximately 22% efficiency gained
- Peer-reviewed translational validation
- Establishes regulatory cadence
- A vehicle for regulatory “crosstalk”
- Non-clinical & CDP foundation

The PIND (Type B) to IND transition



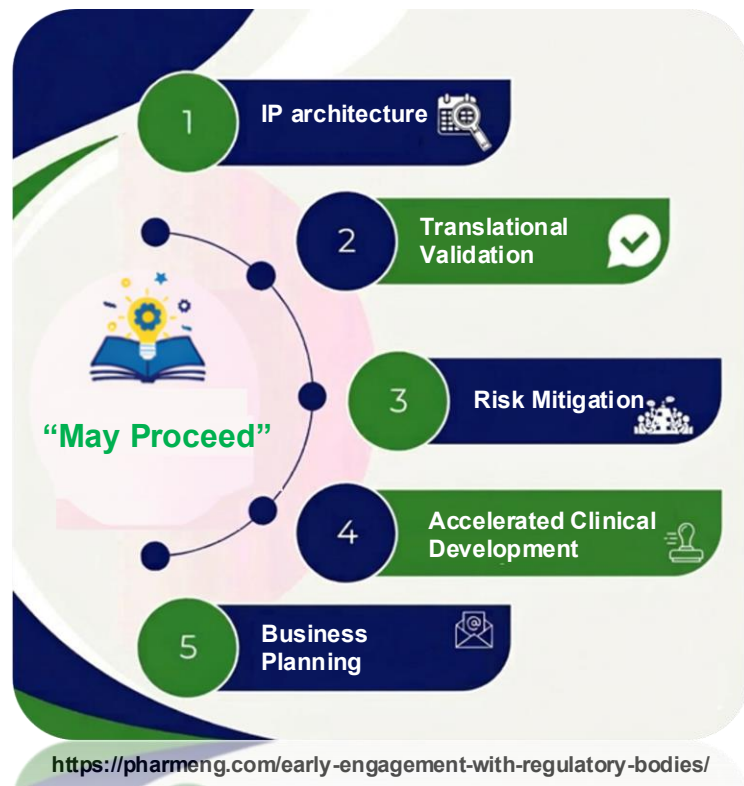
... As a milestone for Development with Inflection Points



- Competitive environment
- Perspectives of subject matter experts, patients
- Target Product Profile (TPP)
- Type, number, schematic, *sequence* of studies
- “Special studies”- waiver, deferral, acceptance
- Framing the program on value, as well as novelty
- Costing estimates and study metrics

...as a strategic business opportunity

- It establishes IP architecture
- “An annuity, not a science project”
- A catalyst for co-development, licensing
- Sequential, contingent, investment decisions
- Creates a “payer signal”



... as a catalyst to define “value”, when novelty is not enough






Nether orderly nor fully rational

- Health Information Technology
- Health Outcomes Research
- CMS
- Self-insured employers
- Commercial plans
- Veterans Administration
- Patient Advocacy
- Pharmacy Benefit Design
- P&T committees
- HTA/pricing bodies ex US

Pre-emptive mitigation

- Comparators & Durability
- Site topology (Integrated Delivery Networks & ACOs)
- Direct and Indirect health care utilization
- “Love your model but send me my data”
- A publication strategy for adoption, access

The Multi-Tiered Utility of an IND--moving beyond “May Proceed”

FDA IND				
 <p>Strategic framework</p>	<p>A First Step in Creating a Product "Narrative"</p>	<p>A framework for a Development Plan</p>	<p>Collaborative Partnerships/ Alliances</p>	<p>A catalyst to define value</p>
 <p>Operational Benefits</p>	<p>Intellectual Property Development in U.S.</p>	<p>Informed “data driven” modification</p>	<p>Risk mitigation strategies through data sharing</p>	<p>Multiple convergent workstreams</p>
 <p>Optimal Outcomes</p>	<p>Access to Innovative Programs through the FDA</p>	<p>Enhanced Visibility & Regulatory “Cross-talk”</p>	<p>Catalyst for Demonstrating Value in Larger Markets</p>	<p>Assuring Adoption, Access as well as Approval</p>