

## Commercialization Readiness from Phase 1 to 1<sup>st</sup> Launch: The First Time CEOs Playbook

February 27, 2024, at the BIO CEO & Investor Conference, New York Marriott Marquis

- Course Overview and Introductions
- Why Most Commercial Launches Fail
- Commercial Imperatives That Impact Value: Preclinical – Phase I
  - Target Product Profiles and Differentiation
  - “Defensible” Revenue Forecasting
  - Impacts of the IRA on Development Portfolios
  - Portfolio Prioritization
  - ISAN Naming
  - Early Commercialization Visioning
- Commercial and Medical Affairs Imperatives: Phase II – Phase III (pre-data)
  - Commercialization Roadmap – the Commercial Vision and Costs (to inform corporate strategy)
  - MD, Payer, and HEOR Market Research: Key Inputs for Pivotal Trial Design
  - KOL Development
  - Scientific Narrative
  - MSL
  - Key Hires
  - Commercialization Alternatives
- Commercial and Medical Affairs Imperatives: Positive Data Readout to Launch
  - Updated Commercial Assessment (revenue forecast)
  - Product Strategy and Marketing
  - Market Access, Pricing, and Reimbursement (MAPR)
  - Health Economics and Outcomes Research (HEOR)
  - Sales Force
  - Distribution
  - Commercial Ops and Analytics
  - Training
- Medical Affairs Imperatives
  - Scientific Narrative, KOLs, and Publication Planning
  - Medical Education
  - Medical Affairs Other (Phase IV’s & ISTs, Pharmacovigilance)
    - Launch Critical Success Factors
    - Brand name
    - Branding
    - Value proposition
    - Information technology
    - Hiring plan
- Life Cycle Management
- Course Summary and Wrap