Navigating the Road to Commercialization:
Key Steps and Strategy Models to Consider

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Overview of Today’s Discussion

• Key Activities from Early Days to Approval
• Building an Initial Forecast
• Strategy Models:
  • Follow the patient
  • Follow the process
• Moving from Strategy to Tactics
Commercial planning starts as early as pre-IND

**Pre-IND**

- **Is There a Market?**
  - Define unmet need
  - Develop and Test TPP
  - Engage 3-5 KOLs
  - First in class or best in class?

- **Market Sizing & Dynamics**
  - Draft forecast
  - Market research ‘light’
  - Broaden KOL advisors

**Phase I**

- Early Commercial Plans
  - Product positioning
  - Commercial organization design
  - Cross-functional resource requirements
  - Communication Plan
  - KOL strategy

**Phase II**

- **Phase III**
  - **Launch Strategy**
    - Three C’s
    - Access
    - Messaging and branding
    - Quantitative research
    - Initiate cross-functional launch team
    - KOL engagement
    - Disease or MOA education

- **Tactical Launch Readiness**
  - Label language / risk mitigation
  - Marketing and sales buildout
  - Pricing
  - Payers & reimbursement
  - Distribution Contracting
  - IT systems
  - Financial reporting
  - Societies and advocates
  - KOL Speaker programs

**Filing**

- **PDUFA**
Setting up your forecast model – Starting with the patient funnel

1. Patients Eligible for Your Drug
2. Intent to Treat Population
3. Patients Treated
4. Multipliers to get to Annual Treatments
Early Strategy Development – Follow the patient

Referral patterns

New opportunities

Target customers

Forecast model inputs

Competitive environment

Product Positioning
Developing Your Non-Promotional Strategy – Follow the process

* These analyses inform non-promotional tactics and decision-making only
Transitioning from Strategy to Tactics – Using the consumer buying process as a tactical guide

Awareness → Belief → Trial → Advocacy
Commercial activities (and budget) then begin the race to the finish line

<table>
<thead>
<tr>
<th>Pre-Data</th>
<th>Post data to 3 months before PDUFA</th>
<th>Peri-launch to Year 1</th>
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</thead>
<tbody>
<tr>
<td>$0.5-$3.5M</td>
<td>$4-8M</td>
<td>$20-50M</td>
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