Keep Your Eye on the Prize

Using a commercial lens to optimize clinical development
Agenda

- Introductions
- Integrated Development
- Case Study
- Our Solutions
- Recap and Q&A
Introductions

**Mike Davitian, Director**

*Health Advances*

- Experience in brand strategy, business development (including partnering, licensing and M&A strategy), commercial due diligence, market assessments, forecasting and financial modeling
- Inverness Advisors, LLC, Healthcare Investment Banking Analyst
- Stanford Financial Group, Healthcare Investment Banking Analyst
- Thomas Weisel Partners, Healthcare Investment Banking Analyst
- Williams College, BA, Biology and Economics

**Dan Gober, Senior Director, Business Development**

*PAREXEL*

- BA Economics
- Experience
  - Pharmaceutical Sales, Marketing
  - Market Access
  - Data Management
  - Clinical Research Consulting
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Summary

• Drug development and commercialization is challenging
  – ~$500MM to develop and commercialize a drug
  – Significant risk of clinical and/or commercial failure

• Integration of clinical development and commercial strategy is key. Too often, poor integration contributes to disappointing outcomes

• Integration means managing trade-offs
  – Clinical development affects time to market, R&D cost, and clinical/technical risk
  – Commercial strategy affects the opportunity size, sales and marketing cost, commercial risk, and time to profitability

• Many clinical development considerations have (sometimes unappreciated) commercial implications

• Commercial strategy is ideally integrated at the earliest stages of clinical development and continues throughout the drug’s lifecycle
Development and Commercialization Challenges

Developing and commercializing a drug is enormously expensive and success is far from guaranteed.

Pre-Launch Investments are Large

Clinical Success Rates are Low

Commercial Underperformance is Common

Given the probability and cost of failure, companies must engage early and often with an integrated commercial and clinical strategy and tactical plan.

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1 Mean non-capitalized out-of-pocket costs for investigational compounds in 2013 dollars (DiMasi 2016 J Health Econ).
2 Mean SG&A expenses for pre-commercial biopharmaceutical companies with one lead compound (Davitian 2018 PharmaVOICE).
3 Hay 2014 Nature Biotechnology.
4 Over/underperformance defined as drugs with minimum absolute sales difference of $10MM and minimum relative sales difference of 10% between actual sales and pre-launch sales forecasts. (Davitian 2018 PharmaVOICE).
Integrated Clinical and Commercial Planning

Clinical development pursued in isolation without commercial increases the risk of commercial failure. Clinical and commercial strategies and tactics must be integrated.

- Too often, clinical development proceeds without a robust understanding of the rapidly changing commercial environment
- Products developed without commercial input may fail to adequately differentiate and/or address unmet needs

Your partner should have the capabilities to ensure that your clinical development plans are aligned with your commercial goals and the market realities.
Integrating clinical development and commercial planning means balancing tradeoffs in time, costs, opportunity size, and risk.

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**Clinical Development**

- **Time to Market**
- **Risk**
- **Cost (R&D)**

**Commercial Strategy**

- **Cost (S&M)**
- **Time to Profit**
- **Peak Sales**
- **Risk**
Selected Effects of Clinical Development on Commercial Strategy

The impact of clinical development on the commercial opportunity is complex.

**Development Considerations**

**Indication or Asset Prioritization**
- What is the potential market demand and level of unmet need?
- What is the competitive intensity?
- What are the commercial synergies with other products or across indications for the same product?

**Formulation**
- Where can this drug be administered? By whom?
- How will this product be reimbursed?
- How does this affect our competitive position?
- What patient or provider training/education is needed?

**Target Patient Population**
- How will this product be reimbursed?
- To what extent are diagnostic techniques and tools accessible and well understood?
- What size and type of salesforce is needed to access these patients?
  - Provider specialty
  - Customer concentration
  - Site of care

**Trial Design** *(Size, Length, Endpoints)*
- What is needed to drive provider adoption? Market access?
  - Provider and payer needs are different!
- How does this affect our competitive position?
- What provider or payer education is needed to communicate endpoints, outcomes, or trial design?
Commercial strategy and activities are ideally integrated at the earliest stages of clinical development and continues throughout the product lifecycle.

- Post launch tracking of KPIs
- Course correction based on ROI analysis
- Real World Evidence
- Life-cycle management
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Health Advances and PAREXEL worked with an emerging US biotech to help commercialize a late stage product and outline a path for future growth.

**PAREXEL Regulatory Services (Filings, Including Submission)**

- **Phase 1**: Pre-launch commercialization plan for late stage asset
- **Phase 2**: R&D strategy and indication prioritization for internal R&D engine
- **Phase 3**: Growth strategy into market adjacencies, including organic and inorganic opportunities
Health Advances developed a salesforce strategy that enabled effective coverage of call points while maximizing potential synergies.

- Health Advances was engaged to develop a salesforce strategy that would effectively detail all relevant callpoints at a reasonable cost
- Analyzed revenue and profit returns from different force structures and rep types
  - Analysis leveraged secondary data and feedback from industry experts
- Analysis highlighted synergies between the salesforce models needed for the company's late stage assets
- Resulting salesforce strategy enabled broad coverage at a lower cost than competitor's forces
We developed a roadmap for the company’s R&D engine that prioritized applications and maximized its value.

- Health Advances was engaged to develop a cogent strategic roadmap for preclinical programs generated by the company’s novel research platform
- Assessed the value and feasibility of each R&D program and potential indications
  - Evaluated the strategic fit with late stage assets, competitive landscape, deal analogs, and development requirements
- Worked closely with senior management to produce a clear strategy to maximize the value of the platform and identify key decision points
  - Decision points included research, clinical, and business development activities
Following our work focused on the company’s core market opportunity, we developed a strategy for the company for growth into an adjacent clinical area.

- Health Advances was engaged to develop a strategy to enable the company to grow into an adjacent market
- Prioritized indications using rigorous commercial, research, and clinical development criteria
  - Screened >170 total indications
  - Conducted a detailed assessment of ~45
  - Profiled 12 in depth
- Synthesized secondary research and feedback from ~10 in-depth interviews to understand unmet needs and identify indications with significant scientific activity
- Outlined a strategy to senior management which included specific clinical-stage business development targets as well as recommendations for longer-term research activities in disease areas that aligned with the company’s unique capabilities
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Together, PAREXEL and Health Advances provide a comprehensive suite of services that enables our clients to develop and pursue fully integrated clinical and commercial strategies.

Development Infrastructure
- Experienced and knowledgeable staff
- Investigator and regulator relationships
- Global footprint
- IT systems and technology
- Supplies and logistics capabilities

Regulatory Pathway

Opportunity Assessment and Prioritization
- Forecasting and valuation
- Epidemiology, diagnosis and treatment paradigms
- Competitive landscape
- Pricing, reimbursement, and market access
- Stakeholder mapping
- Lifecycle management

Clinical Development Planning and Execution

Brand and Launch Strategy and Tactics
Health Advances works with client teams across the product lifecycle, from early development to launch and lifecycle management.

- Which clinical opportunities should be considered?
- What are the clinical/medical unmet needs?
- How would we be positioned?
- What is the optimal clinical trial strategy?
- What is the path to a powerful franchise?

- What level of evidence is required to win?
- Is a companion diagnostic required?
- Are comparators required on the trials?
- Are cooperative groups required?
- What about competitors?

- Is product value proposition supported by the right provider and payer evidence?
- Is optimal market access strategy in place?
- Are target patients localized or dispersed?
- How responsive are target physicians to detailing?
- What type of sales force effort is necessary?

- Are additional indications targetable with launched product?
- What is the level of evidence for these indications?
- Which opportunities have the most unmet need?
- Which opportunities have the simplest clinical development pathway?

- Can we identify attractive assets and opportunities?
- What level of risk/innovation is necessary to move the dial?
- What assets/opportunities are synergistic with existing core franchise?
Our clients value and benefit from our ability to leverage expertise across multiple practice areas as well as diligence and strategy for investors.
WORKING TO SIMPLIFY YOUR JOURNEY

Helped develop 95% of the 200 TOP-SELLING biopharmaceuticals on the market.

We work with all of the TOP 50 BIOPHARMACEUTICAL COMPANIES.

We currently support over 2,600 CLINICAL PROJECTS in 20 THERAPEUTIC AREAS.

Perceptive MyTrials® A SINGLE SHARED TECHNOLOGY PLATFORM.

We can conduct trials in more than 100 COUNTRIES.

Access to our comprehensive global network of:
Expertise | Clinical Resources | Technology

SoCalBio: Keep Your Eye on the Prize
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VALUE PROPOSITION

PAREXEL Biotech helps emerging biopharmaceutical companies reach their goals faster with innovative, tailored solutions that leverage PAREXEL’s global infrastructure powered by unparalleled clinical development, regulatory & strategic consulting and commercialization expertise.

DIFFERENTIATORS

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<th>OPERATIONAL MODEL</th>
<th>BIOTECH DEVELOPMENT ESSENTIALS</th>
<th>BIOTECH ACCELERATOR</th>
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<td>A dedicated team focused on accelerating client objectives through operational execution and efficiency</td>
<td>Fit for purpose integrated solutions &amp; mentorship designed to expedite client goals</td>
<td>Robust thought leadership program that defines biotech trends &amp; best practices by bringing together the best minds across VCs, sponsors, technology, universities &amp; industry leaders</td>
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Summary

Pharma companies face a daunting environment: clinical development and commercialization are expensive and failure is common.

Success requires robust strategies and comprehensive planning to ensure clinical development is aligned with commercial goals and market realities.

- Protocol Optimization
- Regulatory Submissions, Compliance, and Outsourcing
- Phase I–IV studies
- Data Management
- HTA submissions
- Clinical Trial Supplies & Logistics
- Medical Imaging
- Pharmacovigilance & case processing

- Clinical development strategy and prioritization
- Brand and launch strategy
- Lifecycle management
- Market assessment and forecasting
- Valuation and financial analysis
- Partnering and licensing and due diligence
- Pricing, reimbursement and market access
Thank You! Questions?

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