

HEALTH ADVANCES

Windhover's Webinar: Is There a Business Model for Companion Diagnostics?

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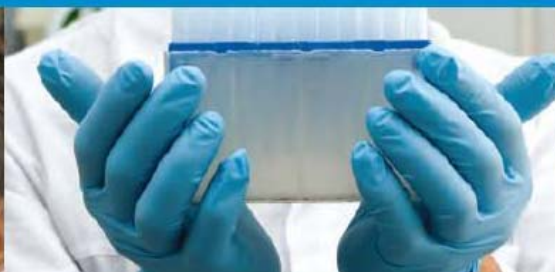
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- *Background*
- *Introductions*
- *Discussion with Panelists*
- *Q & A from the Audience*

Experience. It's What Sets Us Apart.

Health Advances works with diagnostics clients ranging from start-ups focused on one new biomarker to multinationals managing broad product lines around the world. Example projects include:



Laboratory IVD

- ▲ Global diagnostic strategy for major IVD company
- ▲ POC strategy for the developing world
- ▲ Tactics to influence C-suite decision-making
- ▲ Global strategy for molecular diagnostics
- ▲ Application roadmap for novel rapids platform
- ▲ Transaction diligence in anatomical pathology

Biomarkers

- ▲ Global strategy for HIV companion diagnostic
- ▲ Commercialization strategy for latent tuberculosis diagnostic
- ▲ Health economics and pricing for novel prenatal diagnostic
- ▲ Integration of companion diagnostics with biotech company's drug portfolio
- ▲ Marketing strategy for novel colorectal cancer diagnostic
- ▲ Transaction diligence for oncology biomarker company

Imaging

- ▲ Hospital launch strategy for novel cardiac imaging agent
- ▲ Strategic plan for ultrasound-based breast cancer diagnostic
- ▲ Pricing for novel robotic technology for CT image-guided biopsies
- ▲ New market opportunities for retinal imaging technology
- ▲ Clinical trial strategy for Alzheimer's imaging diagnostic
- ▲ Portfolio prioritization for MRI imaging company

Translational Technologies

- ▲ Application roadmap for novel nanoplatform in life sciences
- ▲ Market assessment for stem cell therapy processing tool
- ▲ Consumables strategy for microarray company
- ▲ Market assessment and strategy for a tissue biobank
- ▲ Market assessment for PAT in biomanufacturing
- ▲ Acquisition identification for a diagnostics contract manufacturer

Approach to Diagnostics Commercialization

We employ a holistic approach to strategy development, a necessary approach in this extremely competitive and increasingly regulated space.

Clinical Validity

- Biological pathway clearly elucidated
- Direct link to clinical decision making
- Predictability of specific markers and panels
- Narrowing to valid populations
- Clinical trial design

Competition

- Value proposition over competition
- Current competitors versus pipeline
- Benchmarking opportunities
- M&A opportunities to create or strengthen franchise

Regulatory and Reimbursement

- New FDA guidance
- Health economics and value-based pricing
- Reimbursement guidance
- CLIA role
- Lab involvement and setup
- Allowed marketing materials
- Sample collection, transport, and logistics

Diagnostic Strategy

Commercialization

- Addressable market analysis
- Go-to-market strategy
- Sales force deployment
- Publications, conferences, marketing, training materials
- Long-term versus short-term returns
- Portfolio prioritization and risk management

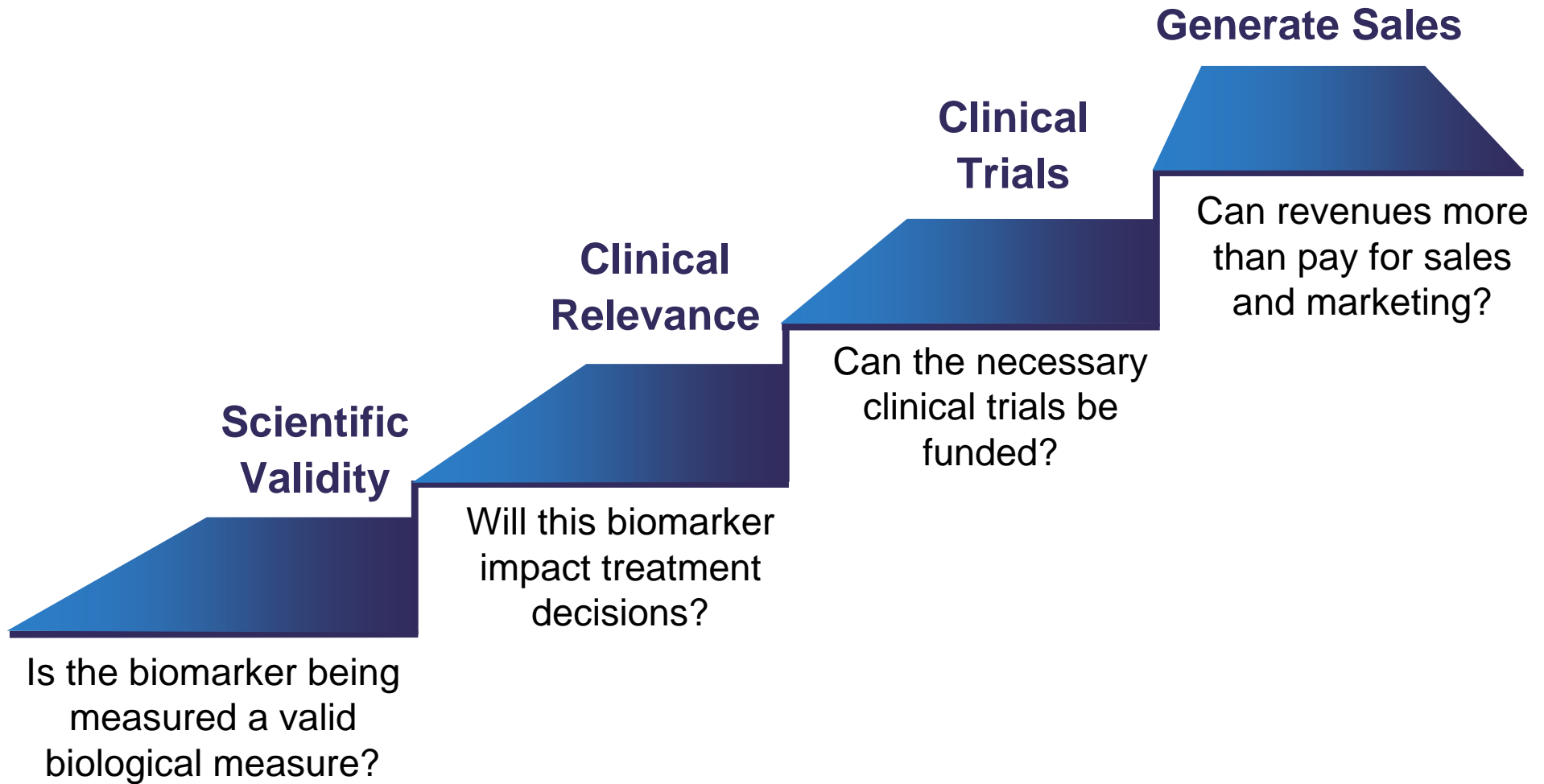
Health Advances works with companies on all facets of biomarker strategy development.

Recent Projects Include:

- Global strategy for HIV companion diagnostic
- Commercialization strategy for latent tuberculosis diagnostic
- Health economics and pricing for novel prenatal diagnostic
- Integration of companion diagnostics with biotech company's drug portfolio
- Marketing strategy for novel colorectal cancer diagnostic
- Transaction diligence and partner support for international oncology biomarker company

Diagnostic developers must clear multiple hurdles to success.

Challenges to Biomarker Diagnostic Success



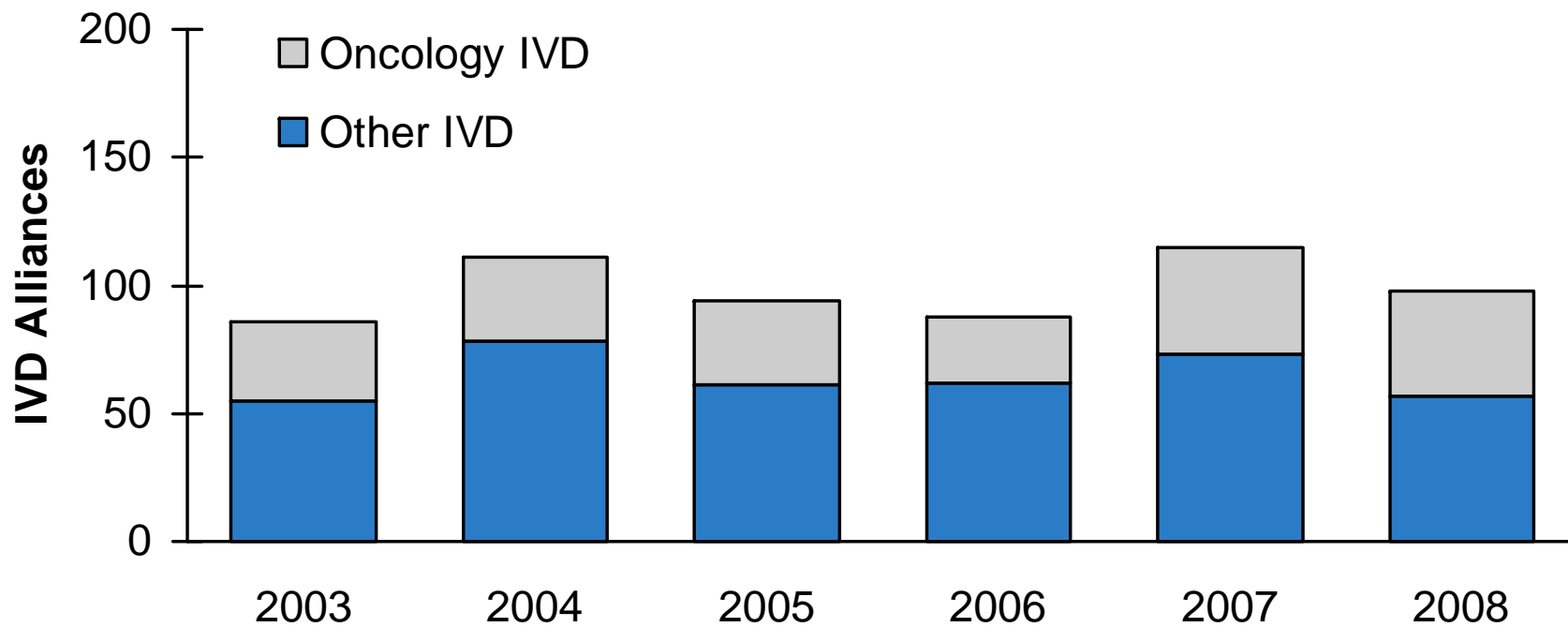
Source: Pothier, Hochberg. "Biomarker Diagnostics: Place Your Bets Wisely" *IN VIVO*, Jan 2008

In Vitro Diagnostic Alliances

Companies have tentatively been collaborating in this space.

In Vitro Diagnostic Deals

Alliances: 2003-2008



Percentage Oncology Deals of All IVD

36% 30% 35% 30% 37% 42%

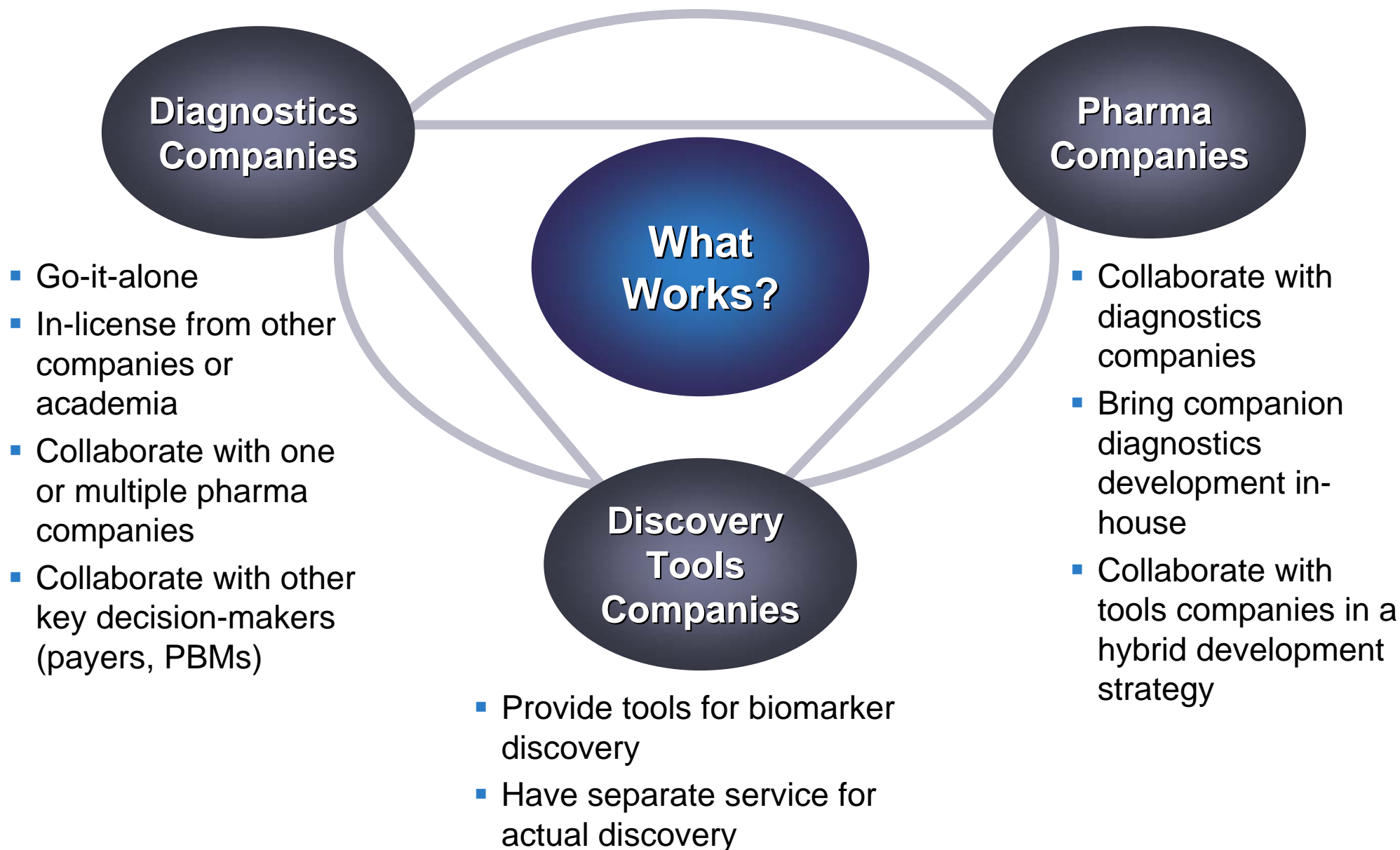
“Companion Diagnostic” Oncology Deals

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Source: Health Advances analysis, Windhover SIS 2009.

Current Models

Several options exist in companion diagnostics development, all with their own risks and benefits.



- *What are the current approaches to companion diagnostics from a business perspective?*
- *What are the drivers and barriers to each approach?*
- *Which high-value opportunities can sustain a business?*
- *Is collaboration the answer, and if so, in what form?*
- *What is the future of companion diagnostics development?*

Webinar Panelists



Rosanne Welcher

*General Manager & VP,
R&D*



Mickey Urdea

CEO



Iain Miller

*Senior Director,
Theranostics*



Peter Collins

*Senior Vice President of
Business Development*



**Kristin Ciriello
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