



Knowing now matters.™



An Industry Perspective on Market Intelligence

Duncan Blair
Director, Public Health Initiatives

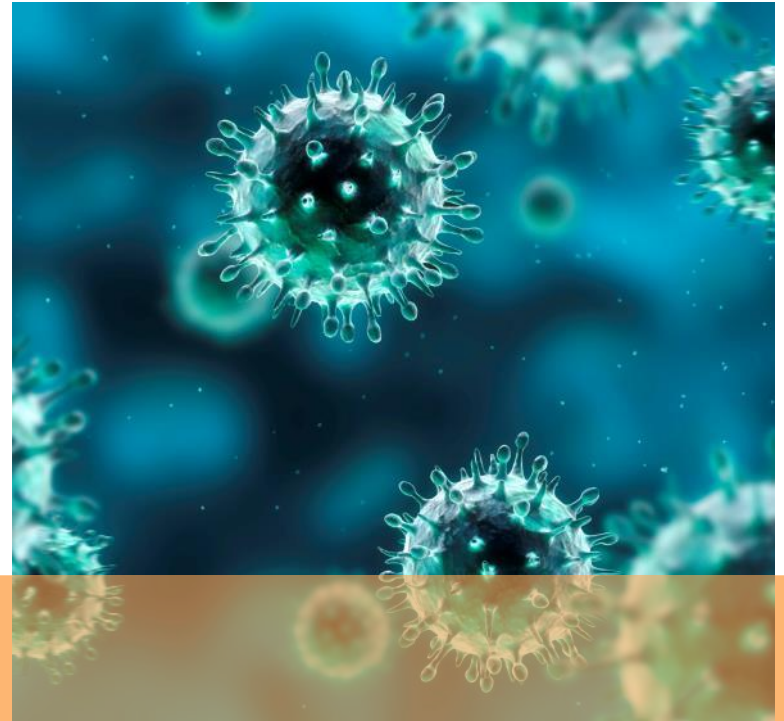
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Outline

- 1 Developing an IVD
- 2 Understanding the market
- 3 Market influences
- 4 Challenges and opportunities
- 5 Moving forward



Developing an IVD



Developing a new IVD product





Developing a new IVD product



Diagnostic need

Market assessment

Regulation



Idea

IVD concept

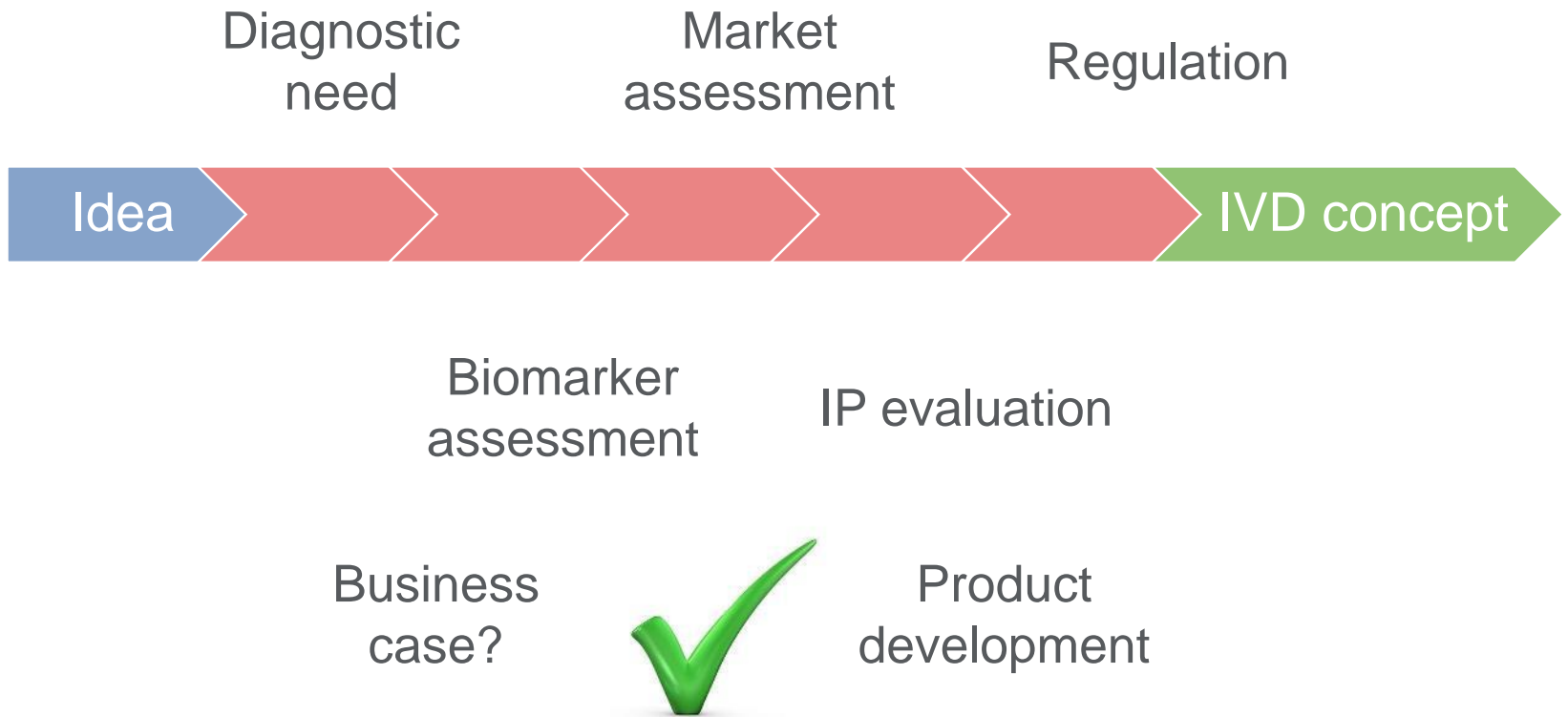
Biomarker assessment

IP evaluation





Developing a new IVD product





Understanding the market



Understanding the market

The IVD market is highly regulated yet incredibly complex

- Despite regulation great market uncertainties remain, especially in LMICs.
- Implementation of regulation can be variable and unpredictable.

Market sizing

- Total potential market.
 - Relatively simple to calculate and understand.
 - Important information for planning and market development.
 - Insufficient and misleading for forecasting/budgeting purposes.
- Actual or realizable market.
 - Not driven purely by epidemiology.
 - Far more complex than total potential market, many influencing factors.

Naturally occurring

- Seasonality
- Emerging diseases
- Epidemics



Human factors

- Changes in socioeconomic circumstances
- Policy and guideline changes and evolutions
 - Local (national), regional, international
- Major donor and funding decisions
- Introduction of new technologies





Challenges and opportunities



Challenges and opportunities

Setting dependent

- E.g. low versus high income markets.

LMIC markets can be particularly challenging

- Complex interplay between local and international policies and priorities.
- Policy and decision making processes not always clear or transparent.
- Significant historical forecasting missteps.
 - Poorly understood background and assumptions.

There have been significant discrepancies between diagnostic demand forecasts and realization



Challenges and opportunities

There is room to improve the quality of the dialogue about diagnostics

- Much of the conversation about diagnostic markets is based on assumptions and experience with drugs but this does not make sense
- Competition
 - What does it mean?
 - How does market shaping fit in?
- Ethical, equitable and accessible pricing versus “cheap”
- Headlines do not tell the whole story

What is said on the soapbox can really matter

- Statements and predictions about markets and market changes have the potential to significantly impact investment



Summary: What would be valuable for industry?

Stability, Predictability, Reliability

- Forecasts
- Estimates

Consistent application of policy

- Equal application, e.g. quality policies
- Access to business

Transparency

- Policy decision making process, policy implementation
- Market intelligence and market
 - Publication of methodologies, assumptions, peer review, open access

Sophisticated dialogue

- Eliminate use of inappropriate assumptions
- Greater attention to detail and accounting for nuance and complexity



Thank you