Challenges in Diagnostic Development and Translation –

An IVD Industry Developer/manufacturer's Perspective

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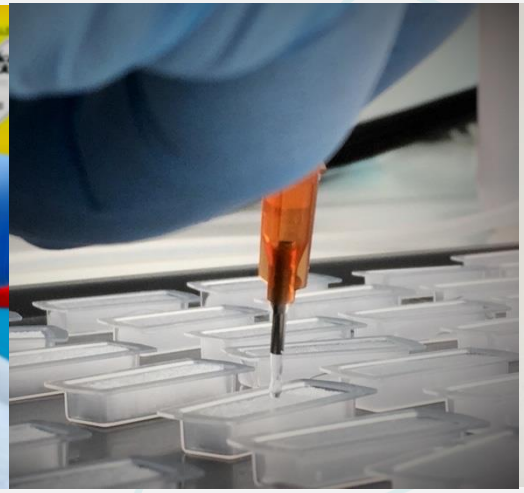
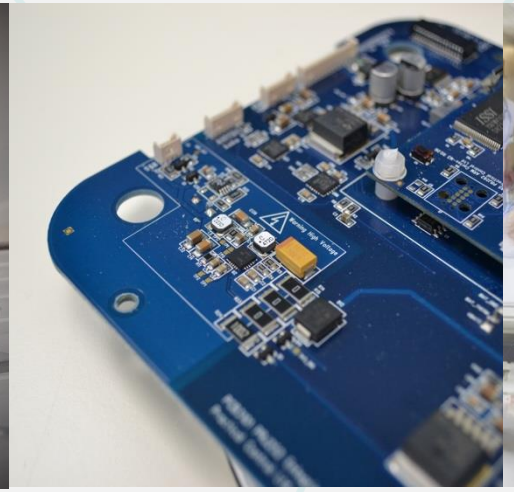
- The team at Medtechtomarket have been responsible for Development, Manufacture, Regulatory, Launch and Distribution of more than 50m Diagnostic Tests + 35,000 instruments across 48 countries
- Most products have been proven in the NHS first
- But we only managed to sell approx. 10,000 diagnostic tests in the UK!!




The Key Challenges for a Business

All successful translation and commercial projects are essentially driven by these factors
…no mention of technology

Management: Understanding the Intended Use

- The most common project issue that we see
- By who, for who, what, where, when, how, why and any limitations of the product.
- Forms the basis of the development plans, labelling claims and underpins the business model

  - Market Research
  - Clinical Engagement
  - Care Pathway Information
  - Financial Planning – Costing, Sales Projections, Business Case strategy, ROI timeframe
  - Route to Market, Breakeven and growth
  - Launch Plan – sometimes Intended Use scope is phased
  - Competitors
  - Keeping the scope manageable/realistic

TIME in Development

Academic research projects and translational funding focus on TRL1-3 and clinical testing to prove the science/technology and publish …

… The Product Development process is to prove the product is safe and effective

Everything needs to be done in sequence

Our average end to end times:

- Full Diagnostic System: 3 years
- Lateral Flow: 21 Months
- Laboratory PCR Reagent System: 20 Months
- Clinical ELISA Test: 22 Months

TRL1-3	***Research Program, Technology and Biomarker Discovery***	Month Number	
		Start	Finish
TRL 1-2	Program Initiation, Regulatory and Handover	1	3
TRL 3-4	Cartridge Design and Feasibility	2	12
TRL 3-4	Analyzer Design and Feasibility	3	12
TRL 3-4	Controls (Calibrators)	5	20
TRL 4-5	Final Prototyping and Design	6	23
TRL 5	Manufacturing Validation	20	24
TRL 5	Verification	18	28
TRL 6	Validation	20	34
TRL 7	**Clinical Validation**	24	35
TRL 7	Labelling	26	35
TRL 8	Regulatory Submission (CE/CA/FDA)	33	35+
TRL 9	Launch Activities	36	

Cost in Development

Full costs and times to launch (includes Regulatory Clinical Trial Costs, tooling etc)

Academic/Translational Projects need to phase the spend in line with grant funding

Need to consider cost of Launch, Adoption and Roll Out too…

Project Type	Total Cost	Years			
		1	2	3	4
Full IVD system	£5.2m	£1.1	£1.7	£2m	£0.4m
Lateral Flow	£0.6m	£0.3	£0.2		
ELISA	£0.6m	£0.3	£0.3		
PCR (Lab/Multiplex)	£0.7m	£0.4	£0.3		
Manufacturing set up	£0.2m	£0.2			

Translational funding gaps

Project Scoping

- Technology Applications
- Market and Clinical Need Analysis
- Business Planning
- Regulatory and IP review

£10-30K TRL 1-2

Proof of Concept & Prototyping

- Full Technical Handover and mirror the academic testing
- Product Concept Design and Feasibility
- Early Functional prototypes
- Prototypes for Clinical Piloting

£100-250K TRL 3-4

- Clinical Demonstration of Technology

£200-800+K

Full Product Development & Launch

- *Manufacturing Verification and Validation*
- *Product Verification*
- *Product Validation*

TRL 5-6

- *Regulatory Clinical Studies*

TRL 7

- *Labelling and Packaging Validation*
- *Regulatory Submissions*
- *Launch Activities*
- *Ongoing Manufacture*

TRL 8-9

Finance Challenges

- **Grant Funding**
  - Increasingly competitive
  - Resource Intensive
  - Low probability of success
  - Focus on Technology not Product
  - Funding Cycles intermittent – delays/breaks in the development

- **Equity Investment**
  - Very resource intensive
  - Increased risk aversion and need to syndicate
  - Perceptions of higher risk and lower returns in IVD
  - 12-18 month process
  - Management key
  - Poor Regional Coverage for investment deployment
  - International Launch Essential (UK-only strategy unlikely to be backed)
  - 3 year investment cycles and ROI expectations of around 5-6 years

Territory Adoption Considerations (UK)

- UK: Self-Declaring for general IVDs (majority of IVDs)
  - **But UK NHS historically very slow and difficult to get adoption and roll out – so commercially very risky**
  - Still need ISO13485 and assumed compliance of technical file – so no shortcut to the costs
  - Dominated by Hospital Lab market (limited Point of Care)
  - Excellent for evidence building and Research Studies
  - Adoption: Multiple channels, decision layers and procurement gates
  - Roll Out: Trust by Trust sales process is expensive and takes time x 210 times!
  - Community Diagnostic Centres – may provide new opportunity

10 Year Plan

- *NICE Technology Appraisals will focus on certain themes (eg. Adolescent Mental Health) from April 2026 – no legal mandate for everyone else.*
- *Innovator Passport System from April 2026, following 'robust evaluation' by a single NHS organisation designed to speed roll-out. Adoption and times of 'robust evaluation' need clarity.*
- *includes Industry IVD Service Outsourcing – and this could restrict SME/new entrants*

Territory Consideration - EU and USA

- FDA Approval process depends on Product
  - USA is 50% of the World's Healthcare Budget
  - Highly mature IVD infrastructure: Distributors, walk-in diagnostics, Physicians Office Labs, Clear Reimbursement, early adopters, reagent rental revenue option.
  - Distribution can drive quick sales, break-even and growth
  - Allow for 18 months to gain accreditation from submission
  - Approx. 3-4 years after launch to breakeven
- CE: Technical file review through Notified Bodies
  - 12 Month lead time to get a Technical Review
  - Germany (Reimbursement Driven), Italy and France are good adopters – and good EU distribution.
  - Approx. 3-4 years after launch to breakeven

A need to accelerate both adoption and roll out

T = -3	T = -2	T = -1		T = 1	T = 2	T = 3	T = 4	T = 5	T = 6	T = 7	T = 8	T = 9	T = 10	T = 11	T = 12
Development			UK												
			Self Certify	Launch			Adoption	Roll Out	Roll Out	Roll Out	Roll Out	Roll Out	Roll Out	Roll Out	Full Adoption
				Real World Studies											
				NICE Technology Appraisals											
				Innovator Passport											
			USA / EU												
			Submission	Launch	Adoption	Breakeven	Breakeven	Growth	Growth	Growth	Growth	Growth	Growth	Growth	Growth
				Ongoing KOL Studies											

What would you bet your mortgage on?

Thank You!

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