Stratified Medicines and Companion Diagnostics

An Industry Viewpoint

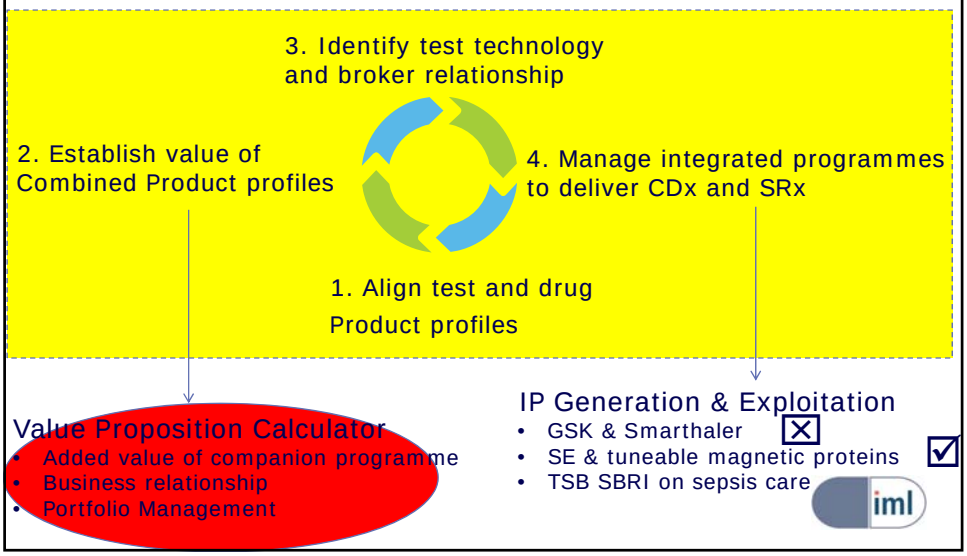
2nd May 2013

Eddie Blair
Managing Director
Integrated Medicines
www.integratedmedicines.co.uk
eddie.blair@integratedmedicines.co.uk

Integrated Medicines Ltd

About IML

- Formed in February 2003, ex-GSK Predictive Medicine Group
- Work within industry, government, other stakeholders



Stratified Medicines

THERAPEUTIC NEED

+

INNOVATIVE MEDICINES

↓

PATIENT-TARGETED THERAPIES

Right Medicine 

Right Patient 

Right Disease 

Right Time 

Right Dose 

Right Response 

Right Price 

3

Stakeholders

Healthcare Providers
(clinicians, primary practitioners, hospital workers)

Patients
(consumer and beneficiary of healthcare)

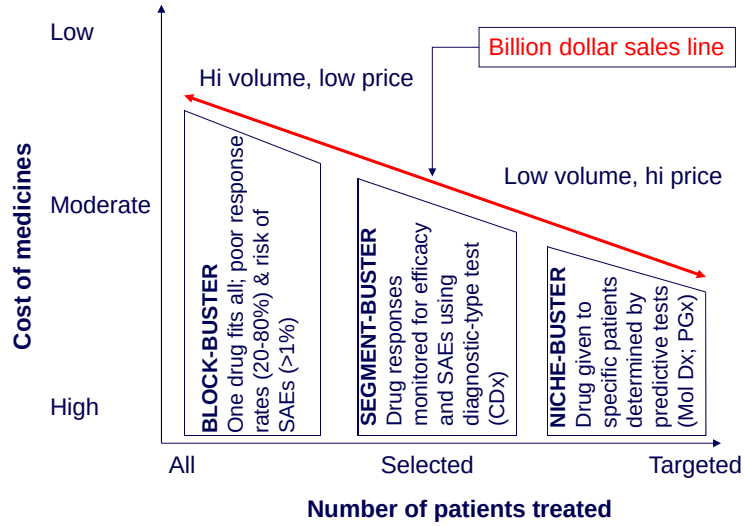
Government/ Regulators/ Payors

Industry
(Pharma co's & associated value-chain, eg, Dx Co, CRO)

Keys issues with medicines today are …..

Safety and efficacy

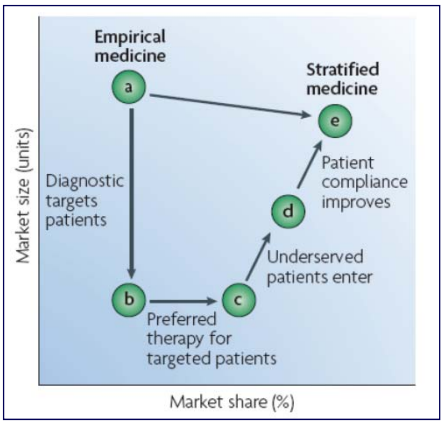
New market models for pharma*

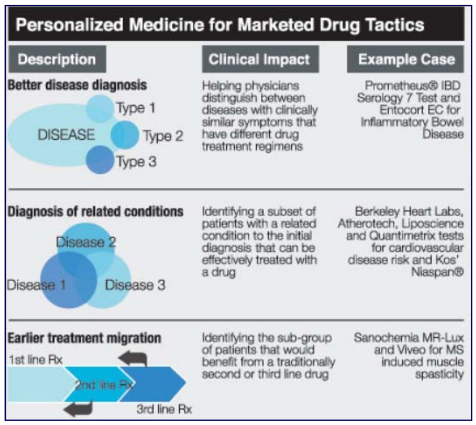


6

*Blair (2009)

CDx offers *increased revenue* through better commercialization*

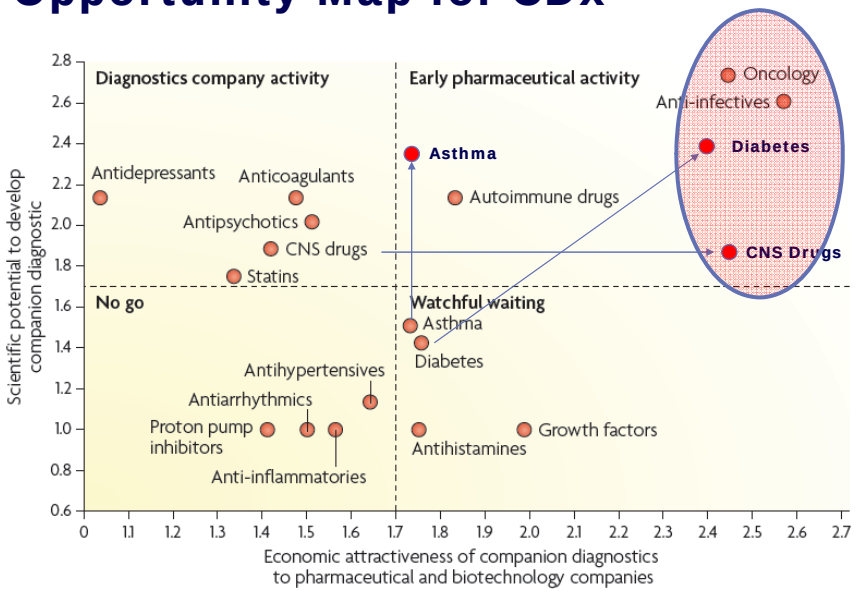




*Trusheim et al NRDD 6: 287 (2007)

*Agarwal PharmExec.com (Jan, 2009)

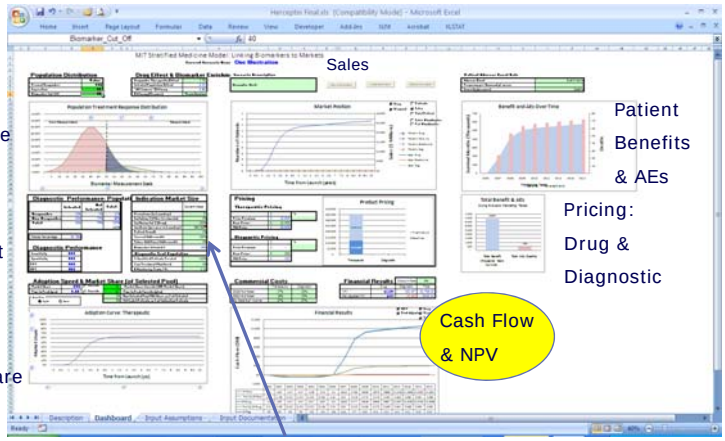
Opportunity Map for CDx*



*Davis et al (2009) Nature Rev Drug Disc 8: 279

MIT Stratified Medicine Model*

Linking Development & Biomarker Performance to Patients & Markets



*Trusheim et al Nature 2011

PharmaCo-DxCo Relationships*

4. AZ/ Prom budesonide and Prometheus Serology 7 test	1. Pfizer maraviroc and Monogram trofile test
2. Amgen panitumumab and KRAS test	3. GSK abacavir and HLA SNP test

Relationship structure

Lo Hi

Diagnostics Partner Influence
(∝ Pharmaceutical Partner Urgency)

*Blair (2008), Blair (2010); Blair & Blakemore (2011)

10

NPV* Matrix v2

Revenue Scenarios	New Test Co-Developed with New Drug	Existing Test Made/ Used to Order for New-to-Market Drug	Existing Test Rescues Drug Sales (Repositioning?)
Full Risk-Sharing (5% drug royalty)	**NPV A** Costs to Dx Co = $FULL Rx revenues to Dx Co = $5% Dx Co Rx risk = Exposed	**NPV B** Costs to Dx Co = $FULL Rx revenues to Dx Co = $5% Dx Co Rx risk = Exposed	**NPV C**** Costs to Dx Co = $FULL Rx revenues to Dx Co = $5% Dx Co Rx risk = Exposed
Hybrid Risk & Fee (2% drug royalty)	***NPV D*** *Costs to Dx Co = $PART* *Rx revenues to Dx Co = $X+2%* *Dx Co Rx risk = Exposed*	***NPV E***** *Costs to Dx Co = $PART* *Rx revenues to Dx Co = $X+2%* *Dx Co Rx risk = Part Exposed*	***NPV F*** *Costs to Dx Co = $PART* *Rx revenues to Dx Co = $X+2%* *Dx Co Rx risk = Part Exposed*
Fee-for-Service (No royalty)	**NPV G**** Costs to Dx Co = $0 Rx revenues to Dx Co = $0 Dx Co Rx risk = Part Exposed	**NPV H** Costs to Dx Co = $0 Rx revenues to Dx Co = $0 Dx Co Rx risk = Not Exposed	**NPV I** Costs to Dx Co = $0 Rx revenues to Dx Co = $0 Dx Co Rx risk = Not Exposed

Relationship Scenarios

**NPV discount factor varied (10%, 12.5%, 15%) as surrogate for relative risk*
***Red text is most-likely revenue-relationship scenario intersection*

11

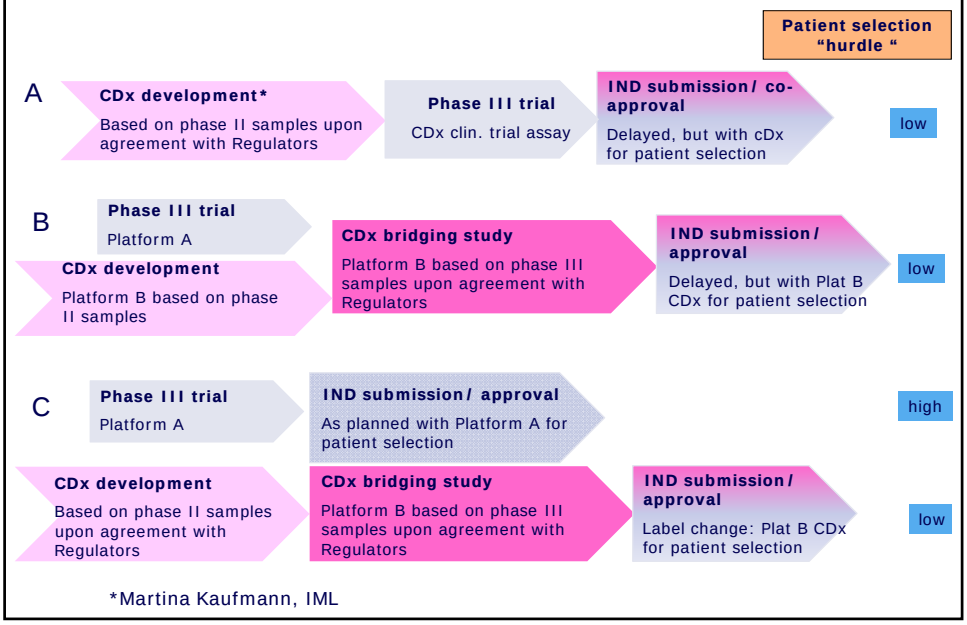
The Price vs Value Imbalance*

Targeted Therapy	Annual Price	Companion Diagnostic	Test Price	Model	Value
Xalkori (critozinib, Pfizer)	$115,200	Vysis ALK Break Apart In Situ Hybridisation FISH Probe Kit (Abbott Molecular)	$1,500	**Turnaround** (ALK positivity ~7%)	TBD
Zelboraf (vemurafenib, Plexxikon/ Diiachi-Sankyo/ Roche)	$56,400	Cobas 4800 BRAF V600 Mutation Test (Roche Molecular)	$120 - $150	**Integrated** (BRAF V600E mutation ~40%)	$144M ($213M**)
Herceptin (trastuzumab, Genentech/ Roche)	$70,000	HercepTest (Dako)	$500	**Turnaround** (HER-2 expression score 3+ ~ 10%)	$620M**

* Blair, E.D., Stratton, E.K. and Kaufmann, M. 2012b.
** Projected Annual Sales 2012 based on HY12 – roche.com

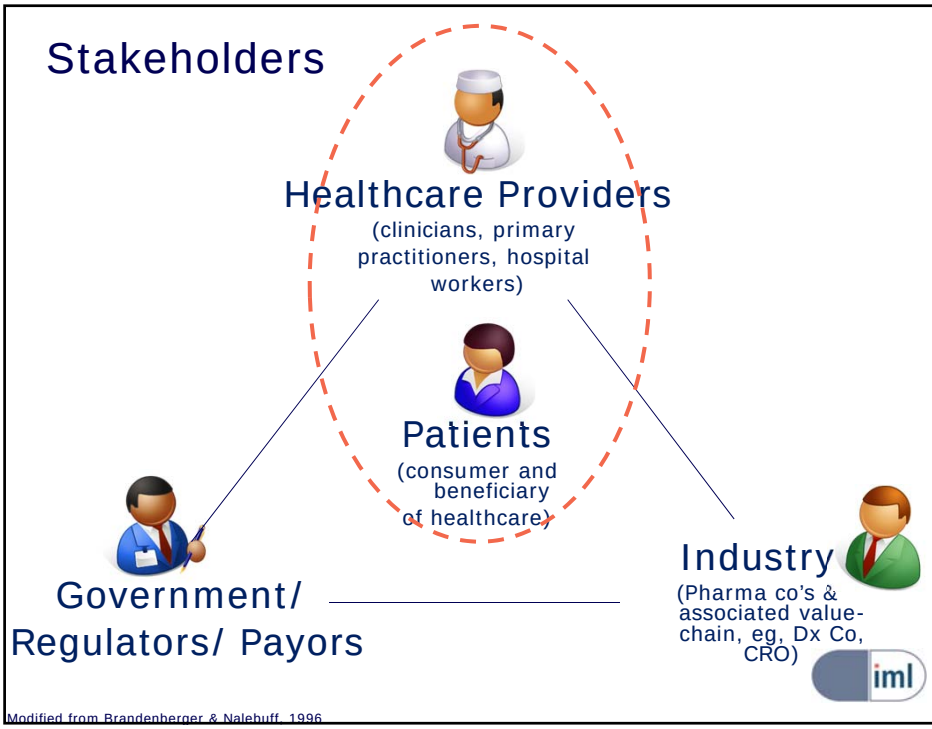
12

Mitigating Delays – Platform Bridging*



*Martina Kaufmann, IML

Stakeholders



Modified from Brandenberger & Nalebuff, 1996

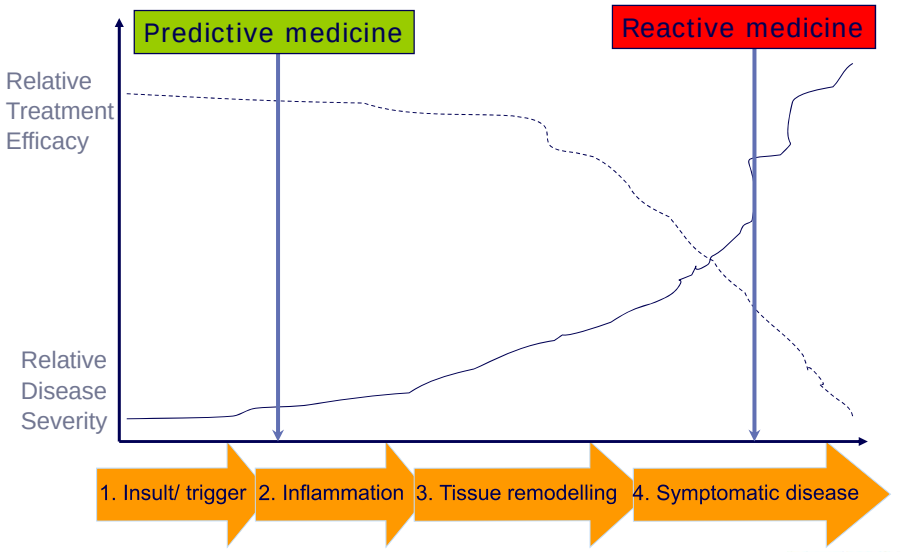
Relationships

British Medical Journal 1999;319 (18 September):762.

15

Predictive Medicine

Earlier diagnosis + effective treatment = better long term outcome



16

Observations

- If patient is not obviously ill, how will benefit be measured and compensated?
- How will clinical studies demonstrate *preventative* benefit in timescale of drug development?
- Will prevention of one disease merely postpone eventual burden on healthcare system?
- How will insurers and other parties view risk based on prediction and prevention?

Bibliography

Little S, Blair ED: Phar
market models. Insigh
www.insightpharmare

Blair, E.D. Assessing t
drug development and

Blair, E.D. Predictive te
World (Autumn) **2009**

Blair, E.D. Molecular di
assessed opportunities
143–161.

Blair, E.D. Blakemore,
harness the value. *Dru*

Blair, E.D., Stratton, E.
Companion Diagnostics and Stratified Medicines. *Expert Rev Mol Diagn* **2012**, 12 (8): 782-785.

Blair, E.D., Stratton, E.K. and Kaufmann, M. Aligning the Economic Value of Companion Diagnostics and Stratified Medicines. *J. Pers. Med.* **2012**, *2*, 257-266.

Blair ED, Clarke BR & O'Neill T (2011)

Sustaining development of stratified medicines in the UK healthcare system: a commentary

***Personalized Medicine* 8:** 517–521

Thomas J, Stratton E & Keppens M (2012)

Companion diagnostics: emerging strategies and issues in pharmaceutical development

***Expert Rev. Mol. Diagn.* 12:** 561–563