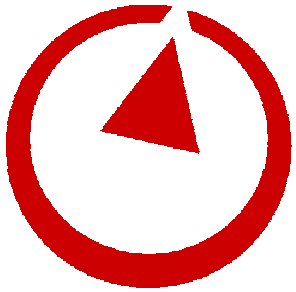

BIO DEUTSCHLAND

Biotechnologie-Industrie-Organisation Deutschland e. V.

BAIN & COMPANY

Promise and Reality of Personalized Medicine 2011

Keynote Speech at the
Bio Deutschland Business Development Conference

Hamburg, July 21, 2011

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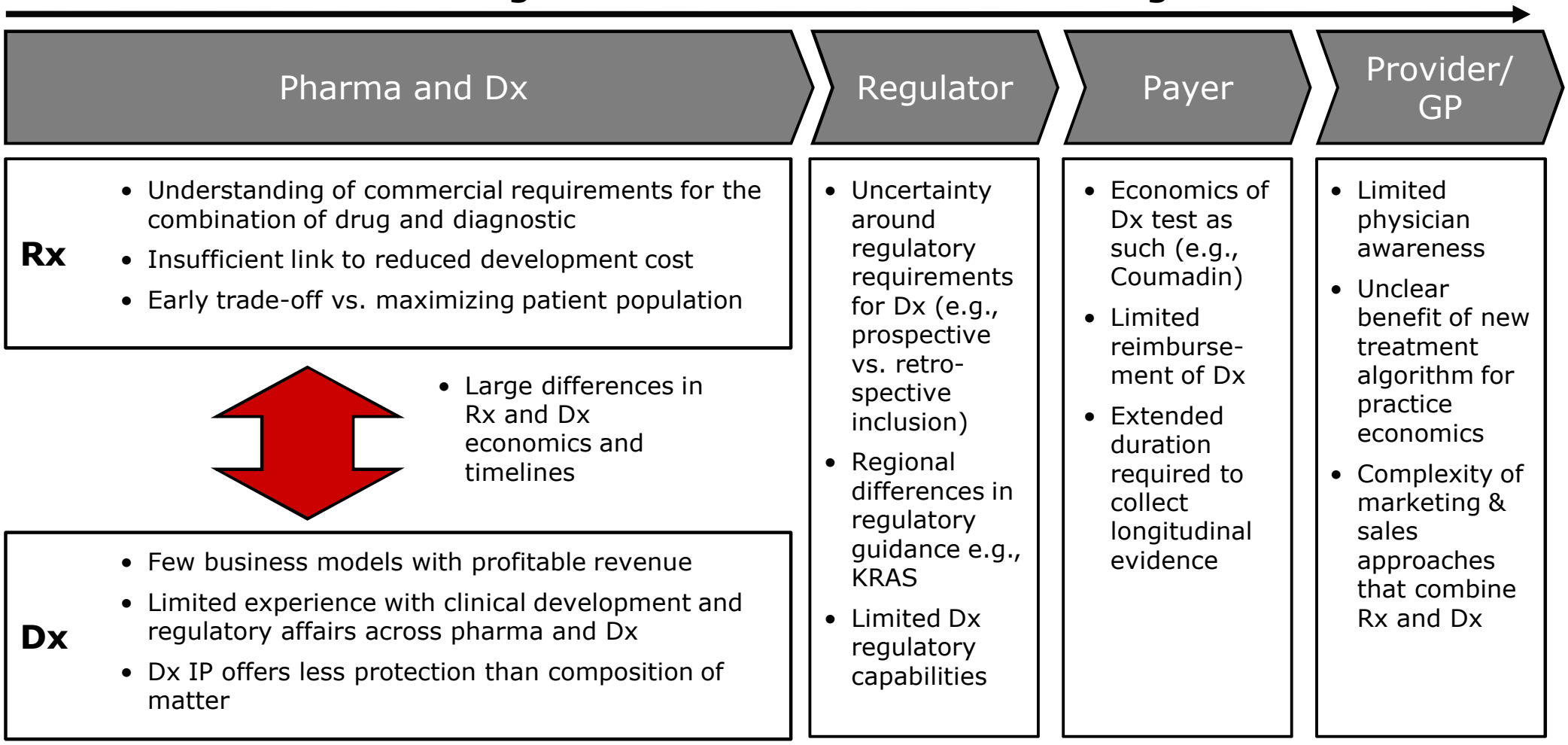
So far, advances in PM have not materialized at the pace originally expected

	1990	1995	2000	2005	2010
Expec-tations for near future	HGP: *"The information generated by the human genome project is expected to be the source book for biomedical science in the 21st century and will be of immense benefit to the field of medicine"*	HGP: *"In two or three decades, we hope to be able to find out what genetic disease a person is at risk for and fix it by putting in a gene that has the appropriate sequence"*	(BMC) Ardeshir Bayat 2002:*"Patients will carry gene cards with their own unique genetic profile for certain drugs aimed at individualized therapy and targeted medicine free from side effects."*	Ohio Health 2007*: "A promising approach to transform the healthcare system is to develop and implement personalized health care."*	Investorplace 2011: *"Double-digit growth predicted during the next several years for MDx, the market is expected to reach $8-billion worldwide by 2015"*
Reality	• Human Genome Project initiated, project planned for 15 years	• ~250 gene-derived products in clinical development, • 100 companies currently have DNA-based therapies in human clinical trials	• HGP announced draft. Overall sequence declared public property • Herceptin admis-sion for metast. breast cancer treatment (US: 1998, EU: 2000) • Antisense hits roadblock	• 9th human geno-me completely sequenced in 2008. However, so far no clear conclusions from genetic risk profile possible • 2003 Glivec approved in EU	• Few PHC products in market: **Herceptin, Glivec, Erbitux, Tarceva and Sprycel** exceed $ 1 B yearly revenue.

Source: genomics.energy.gov ; Seed Magazine, National Geographic, Lit search ; BMC = BioMed Central, Ohio Health Bulletin, Investorplace.com , www.ornl.gov , HGP = Human Genome Project

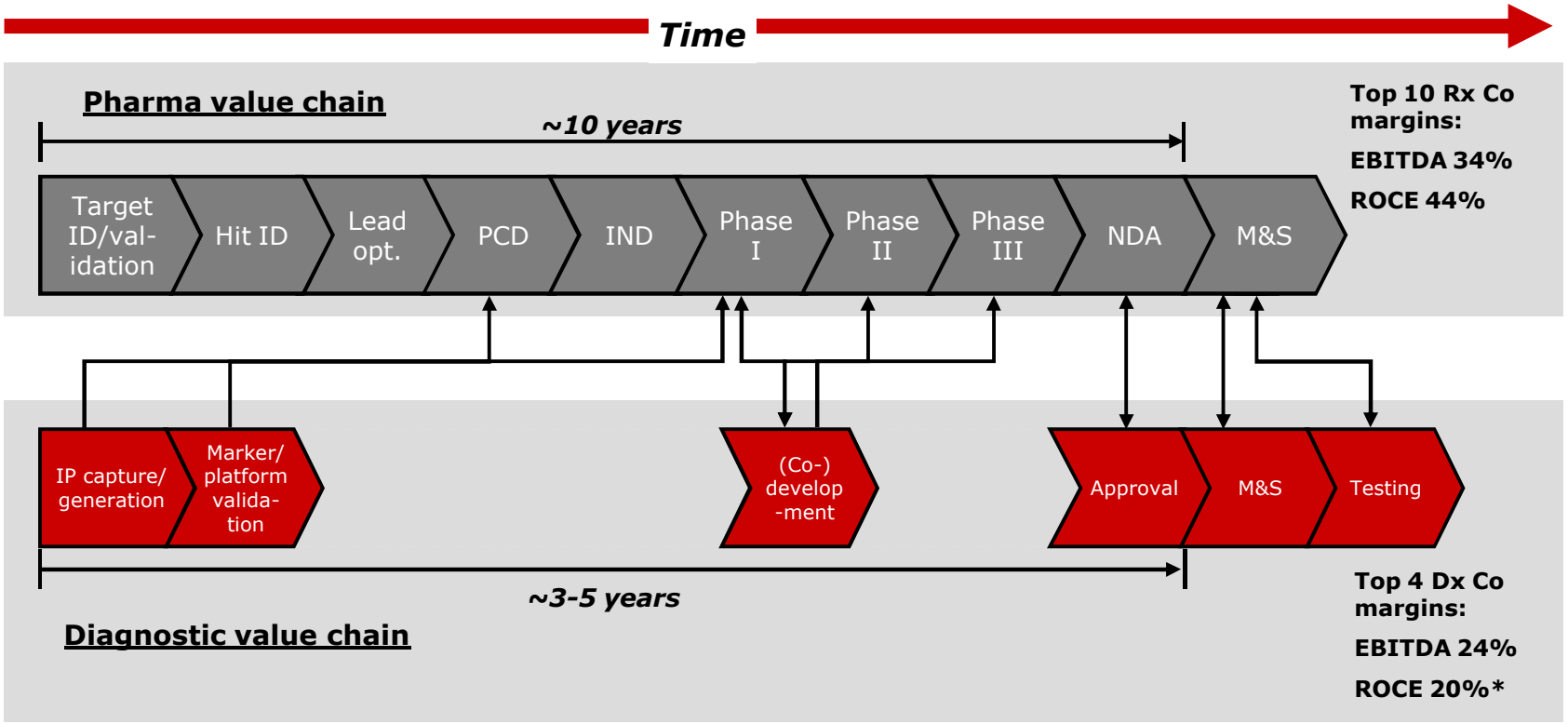
All stakeholders continue to find PM business model challenging

Challenges for successful launch of PM drug



Fundamentally different Rx Co & Dx Co economics & timelines imply tradeoffs

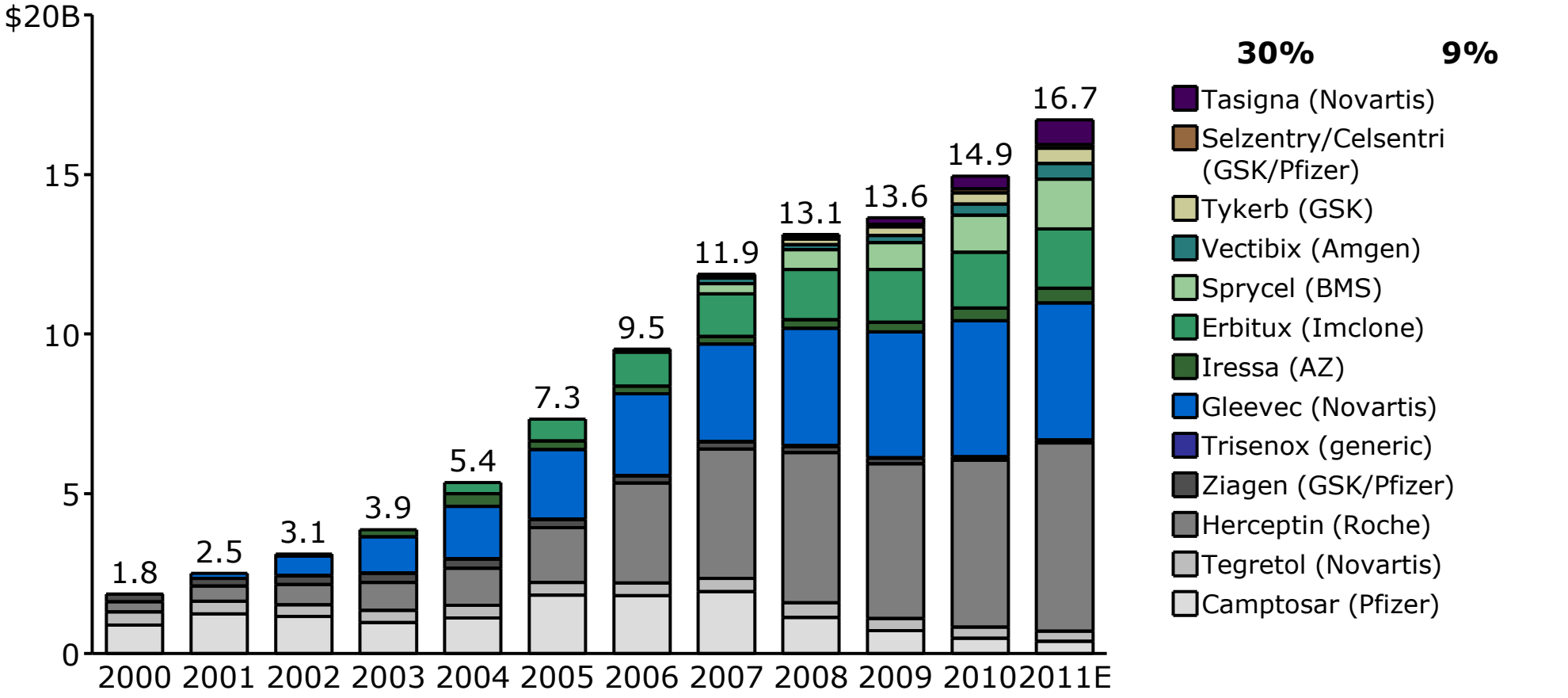
CONCEPTUAL



*ROCE includes Top 3 Dx Cos and excludes Roche Diagnostics
Source: Literature search; Company websites; Company Annual Reports; Company 10-Ks; Bloomberg; Bain Analysis

Even though not as fast as expected, PM-related revenues have grown significantly

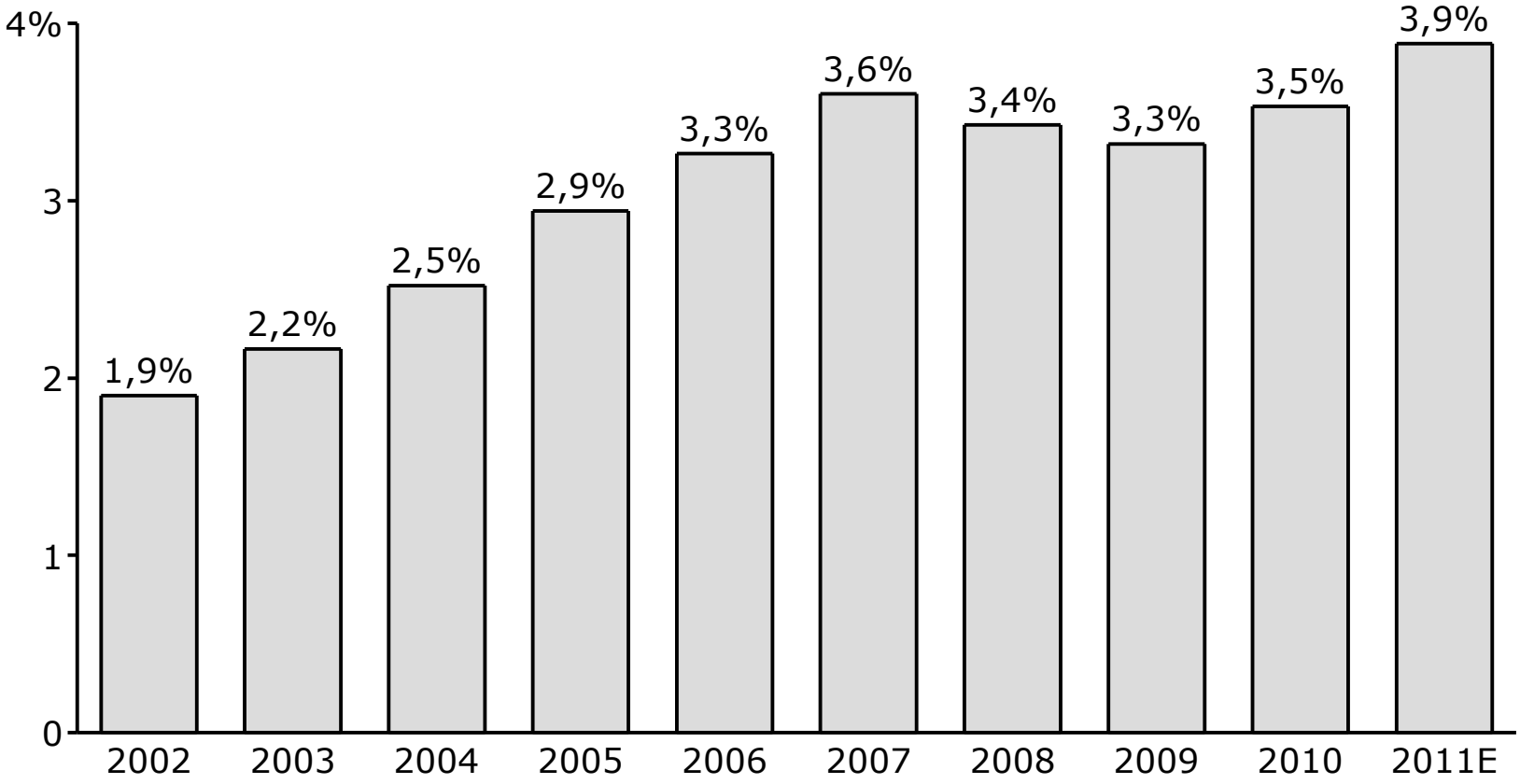
Revenue of drugs requiring biomarker/companion diagnostic as part of labelled indication (in $B)



Note: Tarceva not included given EGFR test not required by label (despite being listed in genomics@FDA table)
Source: EvaluatePharma, Team analysis

PM drugs with companion diagnostics represent increasing share of drug spend in top 7 markets

Market share of PM drugs with companion diagnostic*

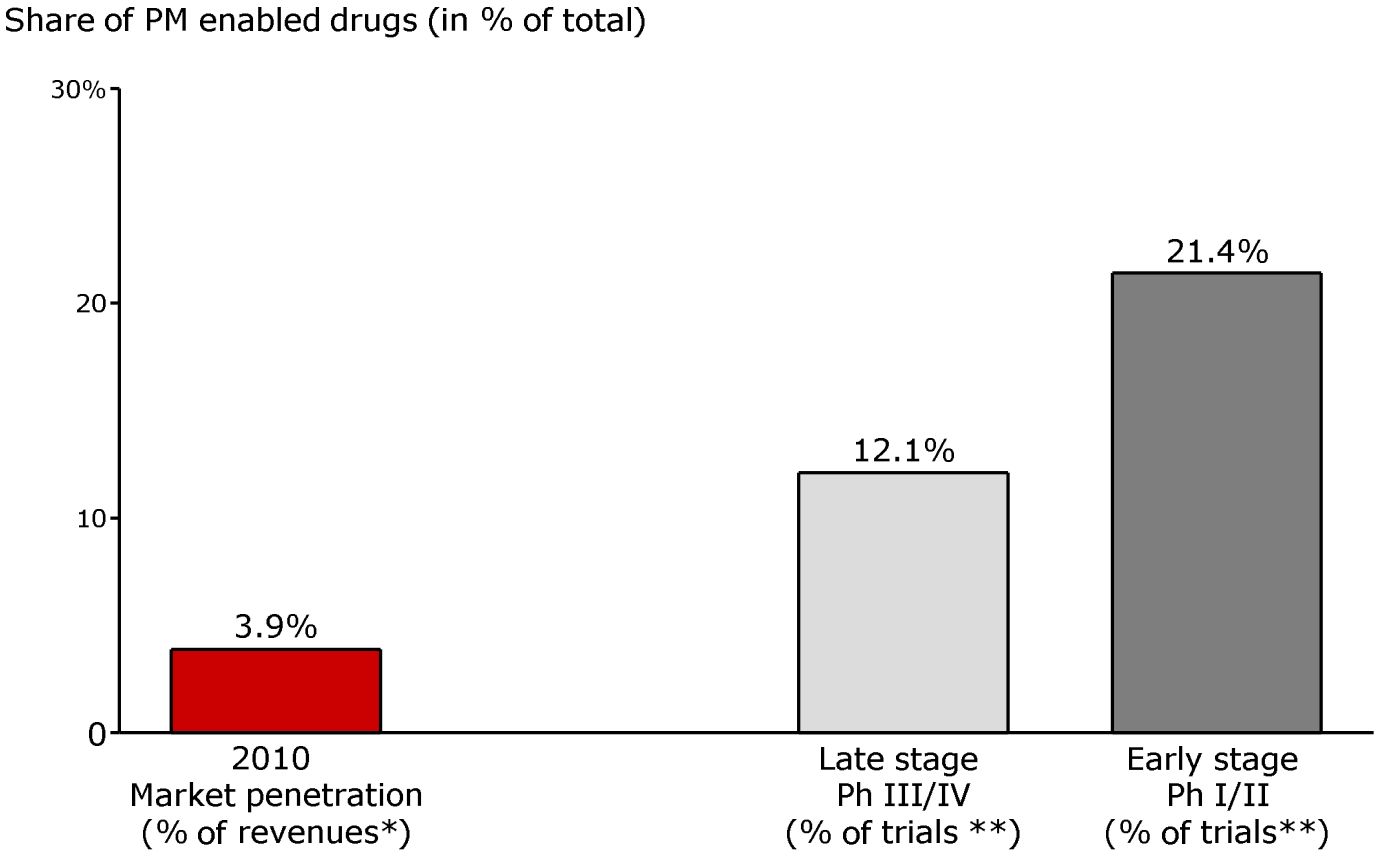


	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011E
Branded pharma market* ($B)	282	303	324	345	375	402	415	431	436	441

*Revenues for USA, EU5 and Japan; Source: EvaluatePharma, PharmaVitaeMonitor

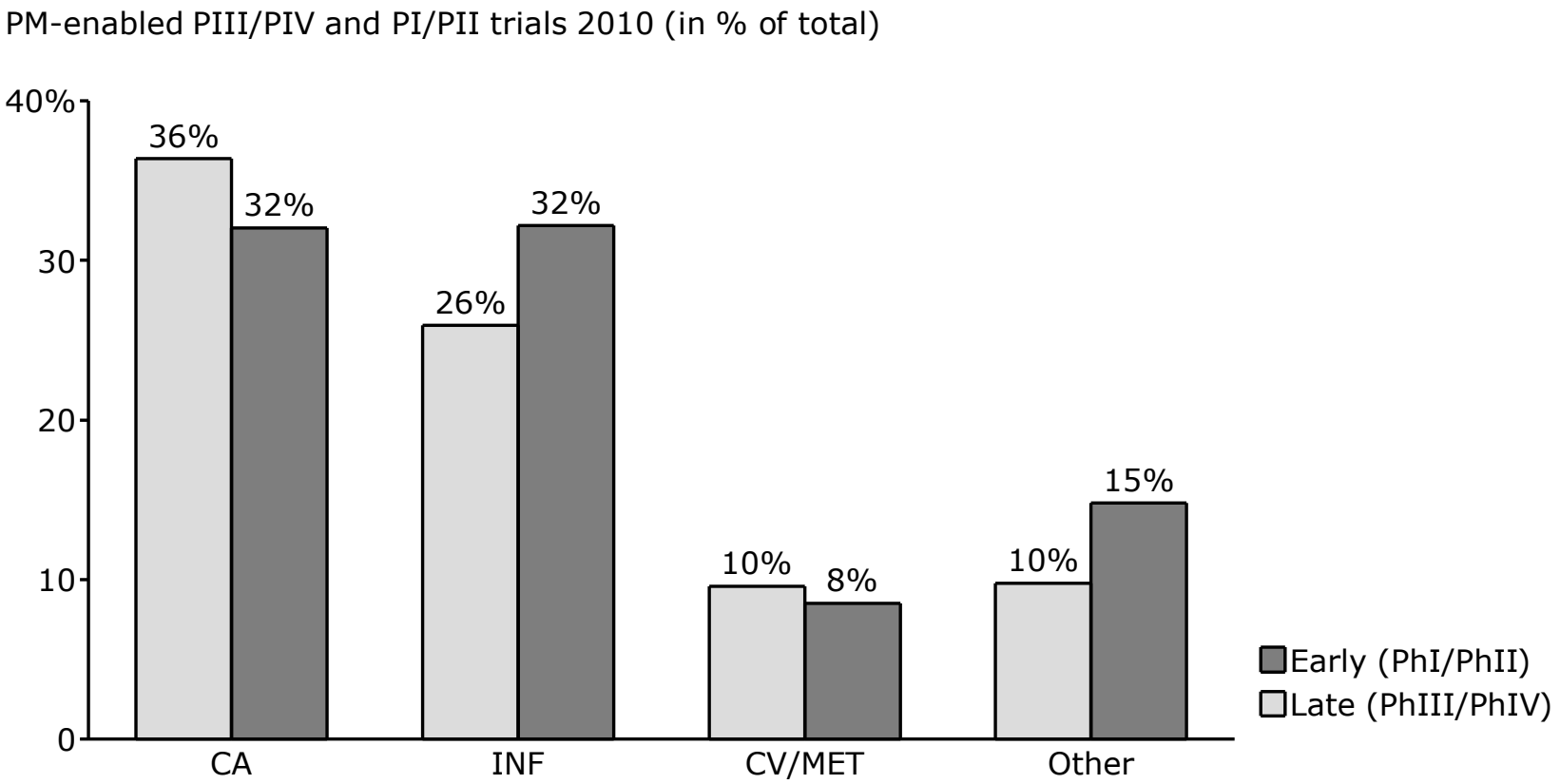
Over time, penetration of PM is set to increase by volume and value

INDICATIVE



Note: * per previous definitions -Top 7 (former top 10 after mergers) Pharma companies applying PM and against top 7 revenues; ** Share of trials of top 7 (former top 10) PM players

Early phase PM enabled research covering few large therapeutic areas, further TAs to follow

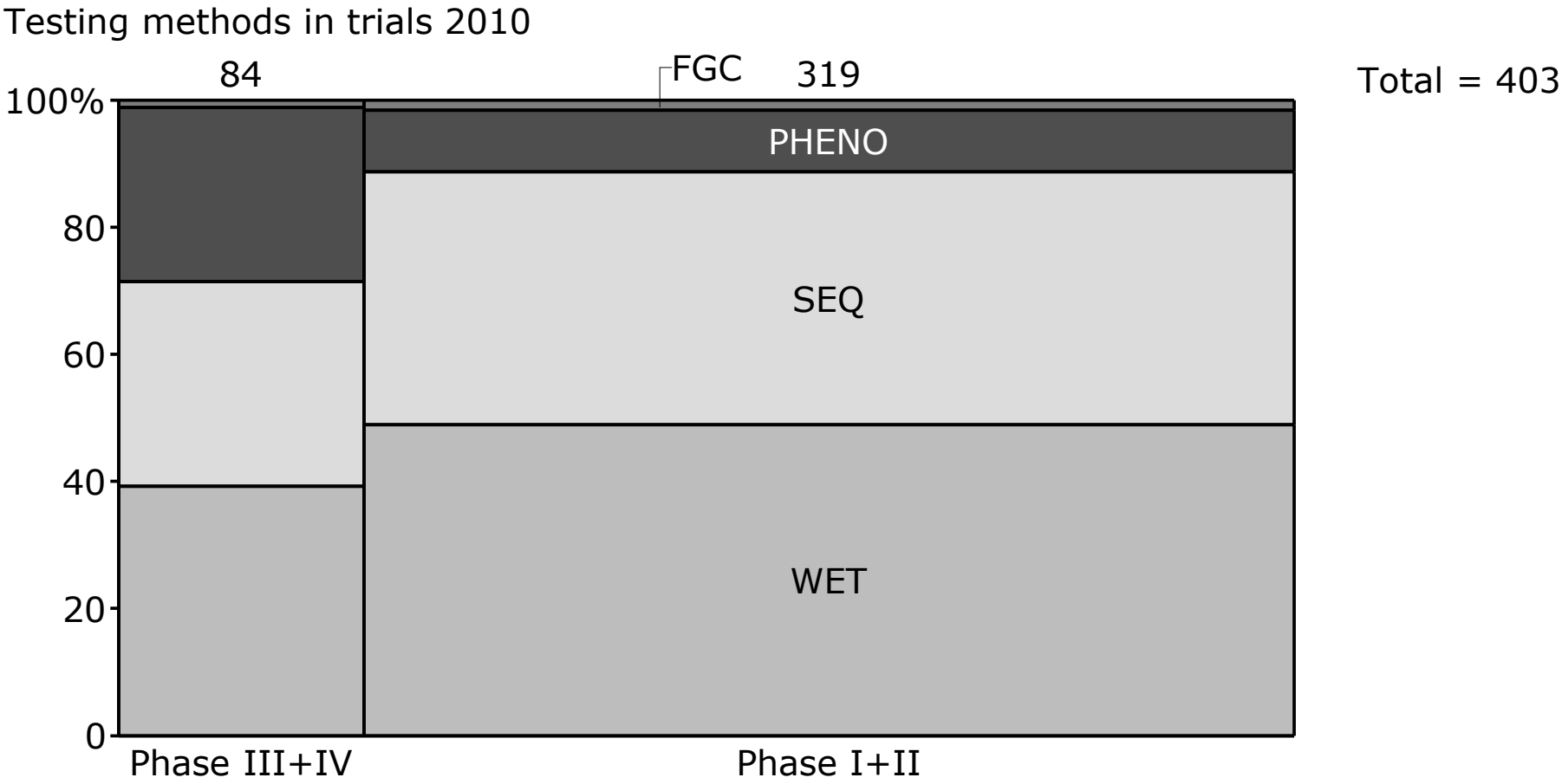


Note: Infectious disease excludes HIV trials

PM-enabled indicates the active use of biomarkers as part of the clinical trial, and includes use in patient selection, and disease selection

Source: ClinicalTrials.gov, Bain analysis

Over time more MDx expected in labels, modern methods growing slowly

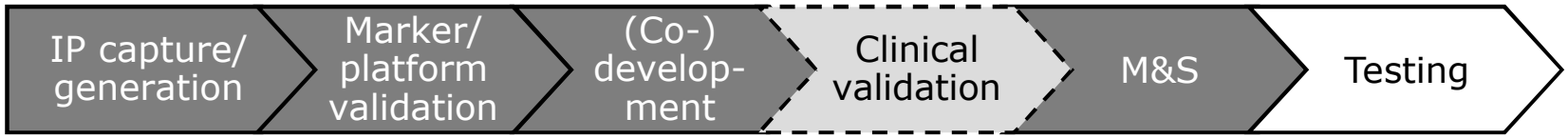


WET	= Wet lab e.g. IHC, ELISA	PHENO	= Phenotyping (Anamnesis, family history)
SEQ	= Gene Sequencing, PCR	FGC	= FISH and Gene chips

Source: clinicaltrials.gov , Bain analysis

Players in MDx segment execute different underlying business models

PRELIMINARY



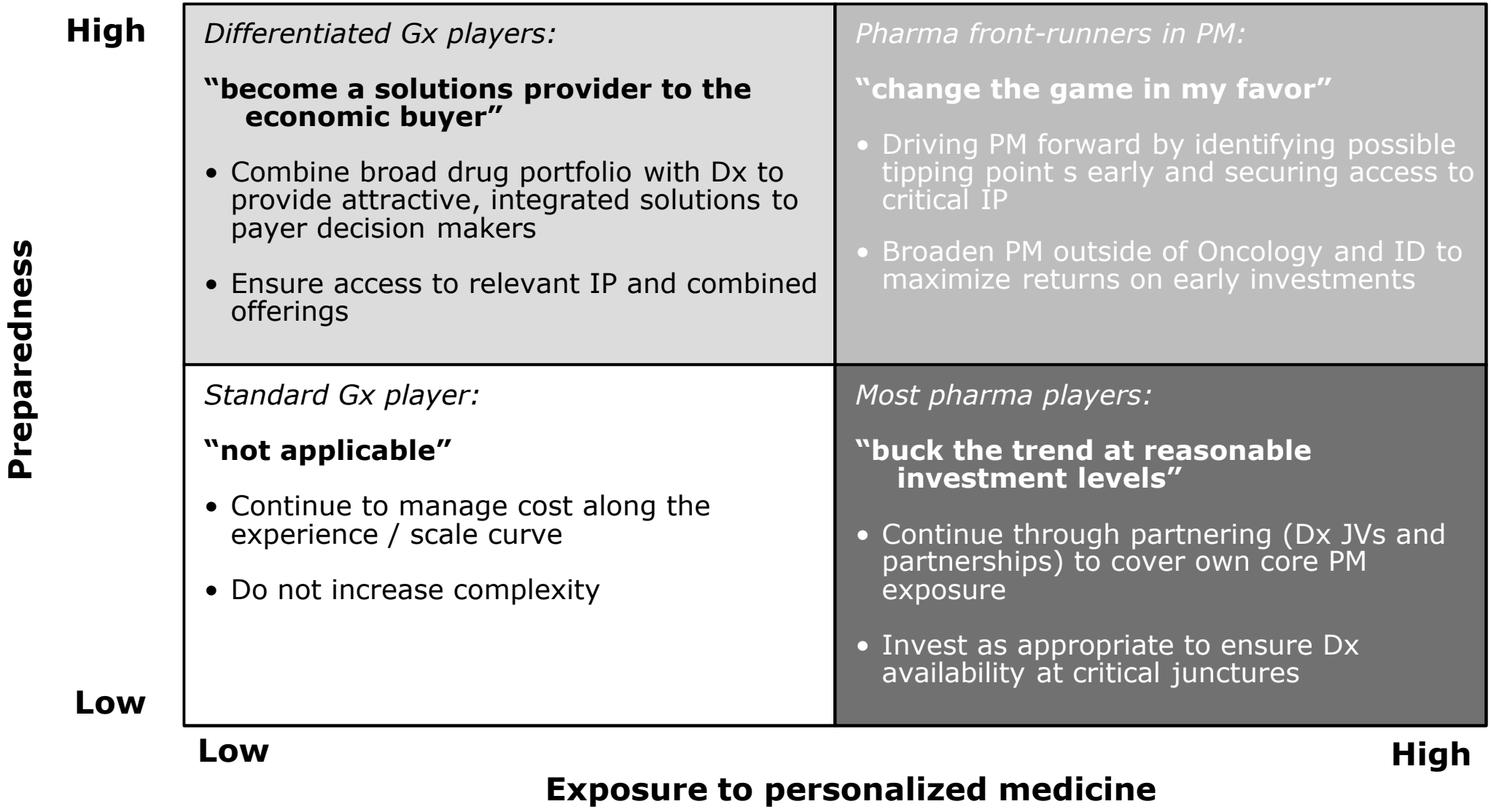
	Examples
Innovator/ Licensor	Epigenomics
Development service	Caprion Proteomics
Product-based sales (e.g. IVD producers)	Roche Diagnostics, Gen-Probe, Myriad Genetics, Qiagen
Service-based sales	LabCorp, Quest Diagnostics
Smaller, focused providers (Other)	Genomic Health, Celera

Note: Smaller, focused providers often develop disease-linked diagnostics for use in clinical trials, with limited regulatory submission
Source: Literature search; Company websites; Company Annual Reports; Company 10-Ks

Successful MDx businesses shaping around specialized players with distinct characteristics

	Niche player genomic health	Focused player Dako	Platform player GEN-PROBE
Product / technology	• **2 Oncotype Dx** prognostics test to guide breast and colon cancer risk assessment and treatment selection	• **Cancer diagnostics portfolio** incl. reagents and instruments with primary focus on **Immunohistochemistry**	• **Proprietary diagnostics technologies and services** with focus on ID across broad range of TAs
Regulatory approval / reimbursement	• **Clinical-economical studies** to accelerate adoption, but **lacks FDA approval** • **Reimbursed** by Medicare and major managed care organizations in the US • **Included in ASCO/NCCN guidelines**	• **Multiple test kits with FDA approval** including HER2, TOP2A and EGFR as target • Various products with **reimbursement** from public authorities	• Only **FDA-approved** blood-screening assay for simultaneous detection of HIV-1 and Hepatitis C Virus
Key collaborations and acquisitions	• **Exclusive agreements** with Medical Solutions (UK) and Palex Medical S.A. (Spain, Portugal) • **Collaboration** with Pfizer for renal cell carcinoma prognostic test	• **Framework agreement** with **AZ** on the development of companion Dx • Various other **pharma partnerships** e.g., with **Genentech** and **BMS**	• **Acquired** Tepnel Life Sciences plc (April 2009) and Prodesse, Inc (December 2009)

For Rx (Pharma) possible strategic options vary depending on skills & assets already owned



Personalized Medicine - Promise and Realities 2011

- "The Promise" continues to be there and remains significant

- Reality looks different than we thought it would, but gradually sets in
  - -4% penetration today
  - -20%+ on horizon

- Continued success in this field requires
  - -Better understanding of business models and opportunities between Rx and Dx
  - -Clear strategic choices supported by early and sometimes audacious investments in capabilities and new technologies