Pioneering Partnerships: Business Models for Successful Companion Diagnostic Co-development

Personalized Medicine Partnerships
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Bethesda, MD, USA

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Forward-looking statements

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Regulation G: *The following slides contain certain summary information about QIAGEN N.V.'s sales, gross profit, operating income, net income, and earnings per share over a specific period and the comparable period, which information is presented on a "non-GAAP financial measures" basis rather than in accordance with U.S. generally accepted accounting principles (GAAP). Please review QIAGEN's press releases for information on the company's operating income, net income, and earnings per share for these periods presented on a GAAP basis. Such GAAP-basis information will also be contained in the company's reports on Form 20-F or Form 6-K to be filed with or furnished to the U.S. Securities and Exchange Commission.*

QIAGEN at a glance
Leading provider of sample and assay technologies

	2010	2009	Growth
Net Sales (m $)	1,087	1,010	8%
Net Income* (m $)	222.7	199.6	12%
EPS, adj.* ($)	0.93	0.93	

Intellectual Property (02/11)

- >950 issued patents
- >970 pending patents
- >550 patents under license

Product Range

- >500 consumable products to collect, separate, purify, stabilize, store and amplify target analytes in samples (DNA, RNA, proteins, etc.)
- Instrumentation for above consumables
- Molecular diagnostics and research test kits

> 500,000 Customers

- Molecular Diagnostics (hospitals, labs)
- Pharma (pharmaceutical & biotech companies)
- Academic Research (academia, research institutes)
- Applied Testing (vet., human ID, food testing, etc.)

Employees

- ~3600 employees worldwide

** For more information on the adjusted figures, please refer to the reconciliation tables in QIAGEN's Q4 and fiscal year 2010 earnings release.*

Sample Technology example

Allprep FFPE DNA/RNA for extraction of both DNA and RNA from FFPE

Assay Technology example
CDx assays — EGFR, KRAS, BRAF, PI3K, etc.

QIAGEN products: instruments
Complete platform offering

Sample Processing

Detection

QIAsymphony plus

QIAsymphony

QIAgility

EZ1

Autopure

QIAcube

Multiplexing
LiquiChip

Fragment analysis
QIAxcel

RT-PCR and HRM
RotorGene

Pyrosequencing
PyroMark

Point of Need
ESEQuant Tube Scanner

QIAsymphony RGQ
Extensive assay menu on one system

QIAsymphony RGQ profile

- Potential to transform use of molecular diagnostics
- Menu:
  - EU: >15 CE-marked assays, growing
  - US: developing assay menu
    - 2011: KRAS, Influenza, EBV, CMV
    - Pipeline: 12 assays
- Unprecedented flexibility
  - Fully modular — expand with laboratories
  - Comprehensive — cleared assays and LDTs
  - Cost-efficient — flexible sample handling
- Utility and convenience
  - Wide range of starting materials (incl. FFPE)
  - Fully modular — expands with the lab
  - Parallel processing — up to 300 results/shift
  - Continuous loading — process as available
  - Random access — enables critical care

Market leadership in molecular diagnostics

QIAGEN — Leading in Molecular Diagnostics

- Proven standard in sample and assay technologies
- Unparalleled range of applications in sample technologies
- Largest MDx assay portfolio (~120 tests) & intellectual property estate
- Certified applications and systems

Four “P” Strategy in Molecular Diagnostics

Attain and expand leadership in:

- **Prevention:** screening of non-symptomatic patients to early detect diseases
- **Profiling:** testing of symptomatic patients to create or confirm diagnosis
- **Personalized Healthcare:** testing of pre-diagnosed patients to guide treatments
- **Point-of-Need:** ultra-fast and portable test systems

QIAGEN — Outlook

- High market growth of ~16%, QIAGEN among fastest growing companies in MDx ~20%
- Demand for efficiency: automation and process optimization
- Growing importance of personalized medicine, emerging point-of-need testing

QIAGEN — Benchmark in MDx

Example personalized healthcare
KRAS testing in oncology

Personalized Healthcare (PHC)

- Different reactions to drugs determined by genetic make-up of patients
- Billions of dollars spent each year on ineffective or even harmful therapies
- PHC uses molecular diagnostics to developed tailored treatment strategies for individual patient groups, e.g., in metastatic colon cancer therapies
- Win–Win situation for all parties involved

QIAGEN's Portfolio for Personalized Healthcare

- About 20 assays for PHC applications (e.g., KRAS, EGFR, BRAF)
- More than 15 pharma partnerships to develop companion diagnostics (e.g., Pfizer, Amgen, Merck, AstraZeneca, BMS)
- With KRAS testing, leading first "blockbuster" segment in PHC (~US$100 million market potential) — established as CDx for *Erbitux* and *Vectibix*

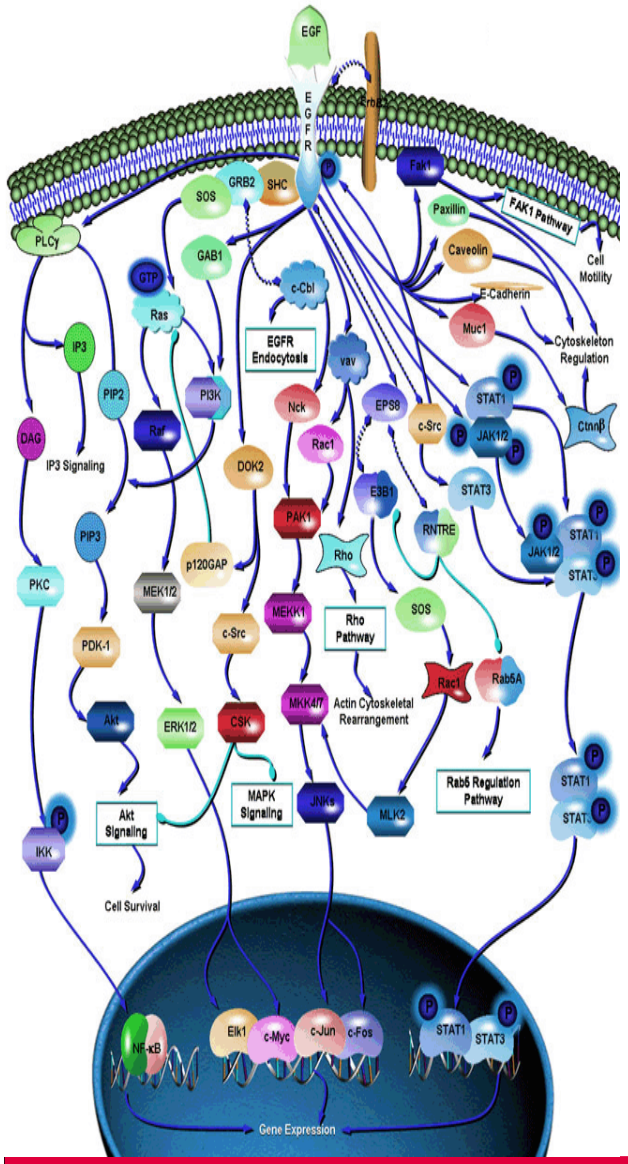
QIAGEN — Outlook

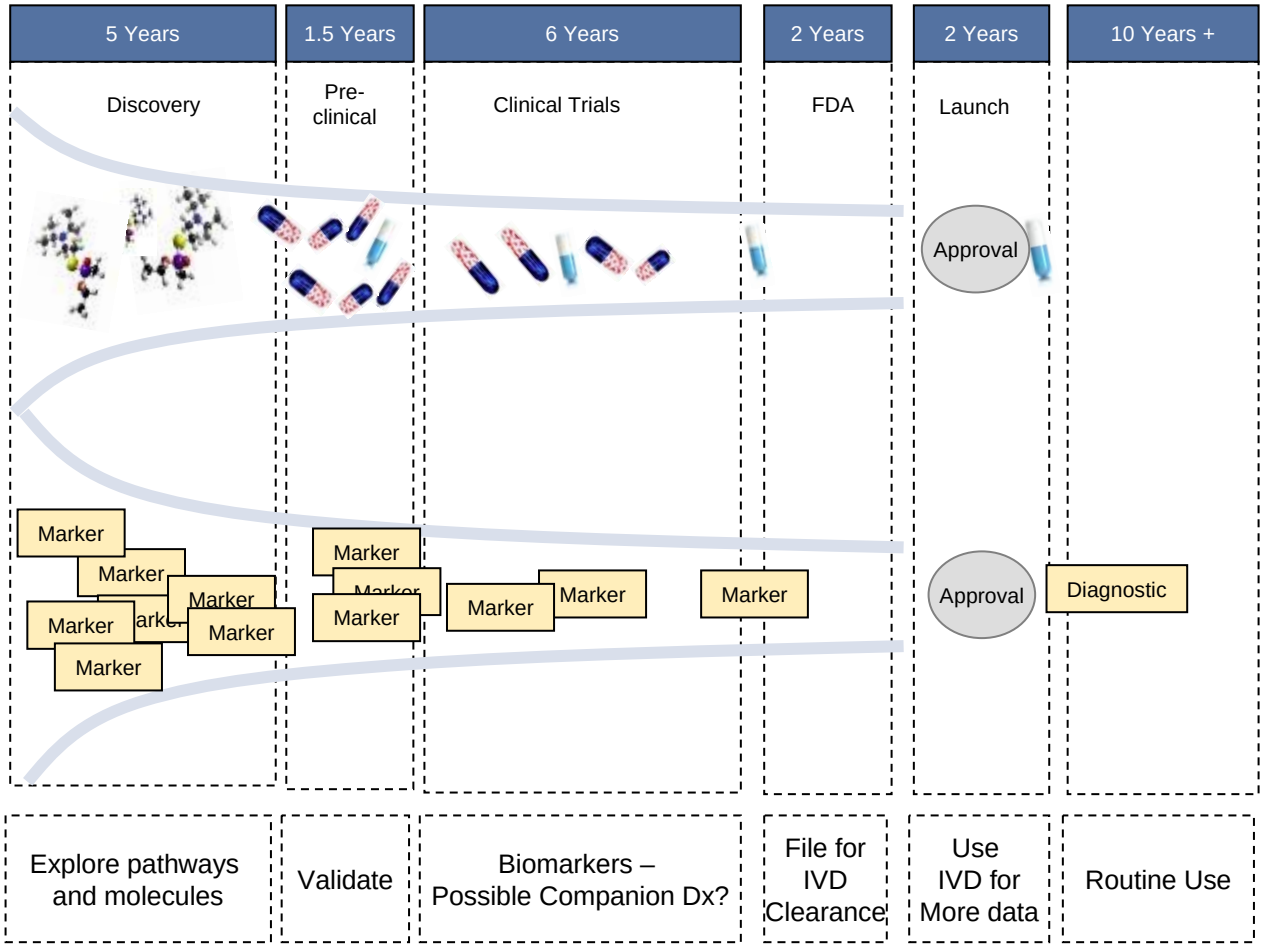
- PHC market volume in 2008 US$ 13 bn. with CAGR of 24% over the last decade
- Strong short- and mid-term pipeline, strong IP portfolio (e.g., PI3K)
- Cost pressures and benefits for all parties involved drive further development and dissemination

A Global Leader in Personalized Healthcare

Translational science to personalized healthcare

Integrating all steps from biomarker discovery to CDx





Aligning synergies to drive efficiency in PHC

QIAGEN's 4 "P" framework in MDx

	Laboratory-based Testing			Point of Need
	Prevention *Asymptomatic patients* *Goal: early detection*	Profiling *Symptomatic patients* *Goal: confirm*	Personalized Healthcare *Pre-diagnosed patients* *Goal: guide therapy*	*No laboratory reachable* *Goal: fast result, on spot*
Market needs	Screening market Ultra-high throughput	Single patient testing Mid–high throughput Highest flexibility	Single patient testing Low–mid throughput Highest flexibility	Rapid turnaround Low throughput Versatile tests
Assay technologies	Examples: • HPV • Chlamydia (CT) / Gonorrhoeae (NG) • Trichomonas • Vaginosis panel • More to come	Examples: • CMV • EBV • HBV • HIV • HCV • Influenza	Examples: • KRAS • EGFR • B-RAF • PI3K • Pathogen Genotyping	Examples: • *care*HPV • HAI • Influenza
Instruments >2010 Fully automated Fully integrated				

Biomarkers & CDx

Known Knowns

“ There are known knowns; there are things we know we know.

We also know there are known unknowns; that is to say, we know there are some things we do not know.

But there are also unknown unknowns — the ones we don't know we don't know. ”

— Former United States Secretary of Defense, Donald Rumsfeld

Black Swan Theory

- The event is a surprise (to the observer)
- The event has a major impact
- After its first recording, the event is rationalized by hindsight, as if it *could* have been expected (e.g., the relevant data were available but not accounted for)

Companion diagnostics
Significantly impacting prescribing

Predictive for Efficacy

Marker	Therapy	Clinical Utilization
HER2	Traztuzumab	High
KRAS	Panitumumab, Cetuximab	High
BRAF	PLX-4032	High
EGFR	Gefitinib, Erlotinib	High
CCR5	Maraviroc	High
MGMT	Temazolomide	Medium

Predictive for Safety

HLA-B5701	Abacavir	High
UGT1A1	Irinotecan	Moderate
CYP450 (2D6)	Tamoxifen	Moderate
TPMT	6-Mercaptopurine	Moderate

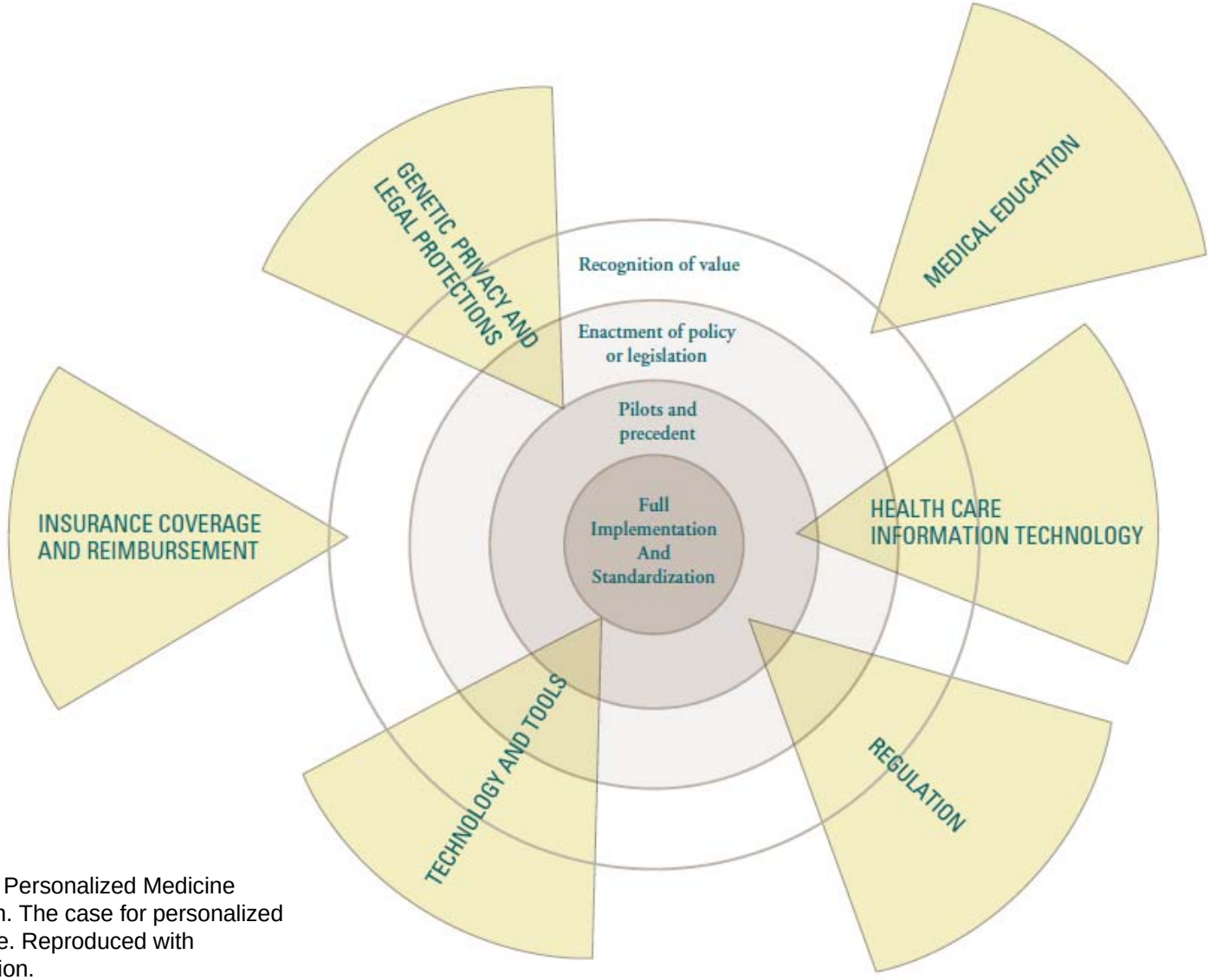
Personalized healthcare
The 5 “P”s — good all round

Stakeholder	Benefit
Pharma companies	Regulatory approval Competitive advantage Increase cost effectiveness of drug
Physicians	Increased safety in treatment decisions Start directly with right treatment and Save valuable time
Payers	Increase efficiency of therapies Save money in healthcare systems
Patients	Best therapy available Avoid unnecessary side effects
Providers (Dx companies, labs)	New market opportunities

But despite its obvious benefits, this has been a challenging business environment

PMC 2009

The implementation of personalized medicine requires a confluence of several sectors



Personalized medicine in 2011
Three major drivers

Political — Effectiveness to Cost Effectiveness

- WW acceptance: Money spent on healthcare is finite
- Increased emphasis on health technology assessment (HTA)
  Aim: Increase cost effectiveness of treatments
- Pharmaceutical companies are responding
  Trend: Development of companion diagnostics (CDx) to increase cost effectiveness of drugs

Scientific — Therapies to Targeted Therapies

- Advancement in understanding of disease processes lead to target drugs, more closely to specific molecular targets
- Increasing demand for diagnostic tools to identify patients with specific disease sub-types, likely to respond to the therapy
- Omic analysis becoming increasingly feasible

Regulatory — Passive to Active Regulation

- Regulatory Authorities realized benefits CDx can bring to patients
- Both EMEA and the FDA encouraging pharmaceutical companies to explore the use of CDx during drug development

The scale of the US market drives regulatory requirements

FDA are setting the regulatory agenda

Regulatory oversight of therapeutics is similar across the world but the regulation of diagnostics is quite different in different territories

The FDA set the highest standards

- A CDx is considered to be a high-risk device
- New co-development guidance document to be released very soon
- Drug label must make reference to an “FDA approved and validated test”
- The expected approval route is risk based and most likely via PMA vs. 510K

Because the USA is such a significant market for drugs and diagnostics the FDA are setting the global regulatory standards

In Europe, it is significantly easier to bring a diagnostic test to market

- IVD Directive is changing

Asian regulations tend to be fall somewhere between US and EU systems

- Clinical validity must be shown in some local (country specific) populations

The companion diagnostic wish list —

What Pharma look for in a diagnostic partner

Key capabilities & capacities requested from Pharma

	Requirement
Science & Technical	▪ Assays need to be: reliable, robust, and compatible with diagnostic lab operations
Legal, IP&L	▪ Technology, intended use and FTO ▪ Platform and Distribution rights
Regulatory	▪ Approval needed for the drug & the diagnostic (FDA require Dx “system” to be approved)
Availability	▪ Reliable & consistent quality manufacturing to ensure no restriction to access and availability
Commercial	▪ Different models needed depending on level of drug company involvement ▪ Global Sales, Marketing & Distribution
Reimburse-ment	▪ Who will pay for the test and how much?

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Capabilities & capacities requested from Pharma

Science & Technical

Requirement

- Assays need to be: reliable, robust, and compatible with diagnostic lab operations

- The underlying technology of the Medical Device requirement drives selection of prospective partners
  - PCR
  - Sequencing
  - IHC
- FDA define Device as the instrument, apparatus, in vitro reagent, including any component, part, or accessory that is intended for use in the diagnosis
- All components of the workflow must be submitted for the PMA
  - Legal and Commercial Implications

Capabilities & capacities requested from Pharma

Regulatory

Requirement

- Approval needed for the drug & the diagnostic (FDA require Dx “system” to be approved)

- Medical Devices are regulated based upon the relative risk/benefit to the patient and classified in risk (I-III) based upon their intended use
- Most Companion Diagnostics are considered high risk, Class III devices due to clinical decisions and actions that are taken as a result of their use
- Class III devices require Pre-Market Approval (PMA)
- Diagnostic Partner must be competent in the PMA processes as well as those involved in supporting the registrational trial such as Investigational Device Exemption (IDE)
- Diagnostic Partner must also have very rigid and compliant Design Control and Quality Systems
- Diagnostic registrational capacities must match Drug registrational plans

Capabilities & capacities requested from Pharma

Commercial

Requirement

- Different models needed depending on level of drug company involvement
- Global Sales, Marketing & Distribution

Centralized Reference Laboratory or Decentralized Pathology Labs?

- Commercial Model(s) require input:
  - Availability and complexity of Medical Device
  - Footprint of Medical Device
  - Test volume forecast
- Who needs access to the test?
  - Demographic & Geographic reach requirements
    - Sales, Service, Support
- Promotion, Supply chain
- Price, Payors, and Reimbursement

CDx co-development partnership requirements

	Requirement	QIAGEN
Science & Technical	■ Assays need to be: reliable, robust and compatible with diagnostic lab operations	■ Largest Portfolio of Research & Molecular Diagnostic technologies and platforms from sample to result
Legal, IP&L	■ Technology, intended use and FTO ■ Platform and Distribution rights	■ Global Freedom To Operate & Distribute MDx portfolio and supporting workflow products
Regulatory	■ Approval needed for the drug & the diagnostic (FDA require Dx “system” to be approved)	■ Global Regulatory Offices with experienced and successful personnel ■ Portfolio of approved assays (FDA, CE, SFDA)
Availability	■ Reliable & consistent quality manufacturing to ensure no restriction to access and availability	■ FDA cleared Manufacturing sites optimized for global supply of CDx under stringent Quality Systems
Commercial	■ Different models needed depending on level of drug company involvement ■ Global Sales, Marketing & Distribution	■ Direct Global Distribution, OEM / 3rd Party ■ >2000 Global S&M, Manufacturing & Supply
Reimburse-ment	■ Who will pay for the test and how much?	■ National Reimbursement Teams ■ Partner to Boston Healthcare & Bridgehead Int.

CDx collaboration structures

Service and Commercial Partner
- Bespoke assay development
- Fee for service
- Fixed-price milestone based

Master Collaboration
- Framework for rapid & (contractually) easy project initiation

Risk & Return Share
- Shared product development
- Royalty return on Rx Sales
- Sales performance milestones

Needs Assessment	Capability Fulfilment	Clinical Protocol Assessment	Regulatory Alignment	Clinical Program Review	CDx Program Plan Creation
Client Team interviews & consultation	Legal	Trial design	Regional requirements	Timelines	Resource allocation
Request For Information	IP&L	Enrolment criteria	RX and Dx gates	Design	Milestoning
Match to QIAGEN portfolio	FTO	Geography	Statistical	Statistical	Costing and program estimation
Strategic expansion	Technology	CRO partners	Registration	Sample acquisition	Financing
	Platform		Manufacture		
	Distribution				
	Commercial				
	Lifecycle				

RxDx partnership considerations
Ensuring the Win–Win

	Rx	Dx
Commercializing Companion Diagnostics		
Biomarker identification	✓	
Analytical validation		✓
Clinical validation	✓	✓
Commercialization	✓	✓
Driving test adoption and clinical use	✓	✓
Biomarkers are only useful to the patients if they are ordered and used by physicians		
Factors Affecting Companion Test Adoption		
Actionable result	✓	✓
Access to the test		✓
Reimbursement	✓	✓
Physician education	✓	✓
Market awareness	✓	✓
Acceptance of test by physicians	✓	✓
Acceptance of test by patients	✓	✓

Plotting a course to commercialization —

QIAGEN's experiences in the development and launch of the *therascreen*® KRAS PCR Kit and the *therascreen*® EGFR PCR Kit companion diagnostics

How does the PHC market work?

Market is influenced by other stakeholders

- Patients — better outcomes
- Pharma — sell more drugs
- Providers — spend less money

Diagnostic tests ordered by doctors

- Clinical utility
- Benefit to patients

Diagnostic tests are provided by diagnostic labs

- Major reference labs
- Smaller hospital labs
- Specialised labs

Labs can also develop their own tests (LDTs) **(FOR NOW — FDA?)**

Diagnostic products are supplied by diagnostic companies

- Small number of global players with complete systems
- Larger number of companies offering partial solutions

Current regulatory environment further creates a unique opportunity

Background

- Original situation with LDTs
  - Simple, well-understood pathology tests
  - Low-risk tests or those that diagnosed rare diseases and conditions
  - Usually used by physicians and pathologists within a single institution
  - No FDA approved test available

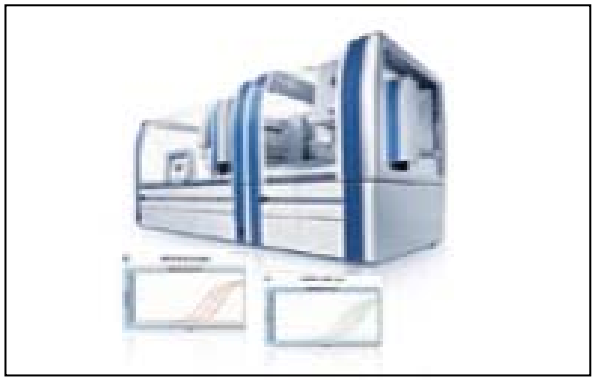
- Today
  - More complex LDTs
  - Often used to assess medium- to high-risk but relatively common diseases and conditions
  - Used to inform critical treatment, often in geographically distant commercial labs

Creation of new regulations for LDTs — FDA Guidance document expected this year

- Control of RUO product use
- Enforcement should be risk based
- Requirement for post market surveillance/reporting

Illustration of the diagnostic business model

System Placement



- Dx company places systems
- Dx company finances systems
- High sales effort
- High up-front investment

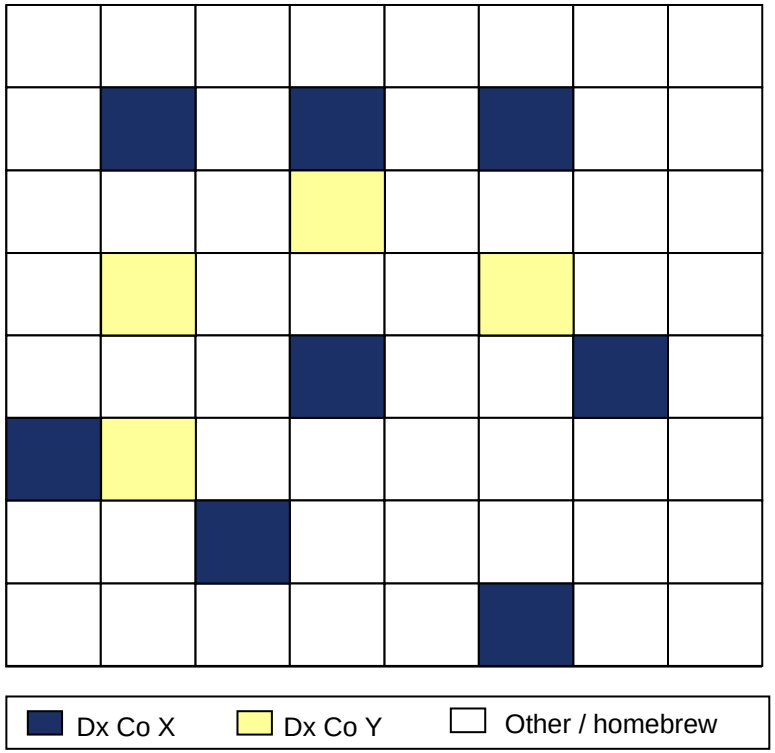
Harvesting Reagent Stream: Sample Prep and Assay Reagents

- Harvest reagent streams over long time — 5 year contracts
- Reagent stream refinances instrument investment
- Low sales effort and high service effort
- Guaranteed business for years: stable cash-flow

System business is very sustainable

First to market is very rewarding
Diagnostic industry runs an attractive business model

Individual labs in the Dx lab market



Success in new developing market

Very high entry barriers exist
- Contracts on closed platforms
- Not enough volume to have more suppliers

First mover creates enormous value
- Saturates the market as it develops

Contracts establish long term customer business for >5 years

In saturated segments: Difficult to increase market share

Diagnostic system business: first mover advantage can establish very attractive position

Coordinating co-marketing of a drug–diagnostic with Pharma

Physician

Makes decision for biopsy and analysis of tumor profile

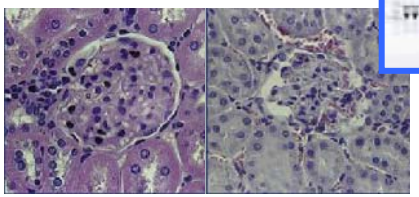
Physician
Specialist

Collect sample from patient and sends to pathologist for testing

Physician

Treatment decision based on results

QIAGEN's MDx Lab Sales & Marketing Focus



Pathologist

Diagnose condition dissect cells and send to molecular lab for molecular analysis

Molecular Pathologist

Extracts nucleic acid from sample and runs QIAGEN's *therascreen* test

Market adoption is influenced by many factors
A true partnership approach is required

Clinical Utility
- Is the test Standard of Care?
- Existence/severity/utility of therapeutic options available
- How close is the connection between the result and patient care?
- How often is an actionable result delivered?
- Turnaround time
- Our reporting capabilities back to the client
- Availability of specialists for consult
- Ease of ordering the test

Clinical Validity & Scientific Evidence
- Supporting publications/seminal article in major journal
- Sensitivity and specificity; reproducibility, precision
- Clinically reportable range; reference intervals
- Specimen matrix, stability

Paradigm Shift?
- Economic: impact on current economics of care
- Political: physician ordering habits. Is financial reward moved from one group to another?

Regulatory Acceptance
- CPT coding
- FDA approval
- Guidance from CMS

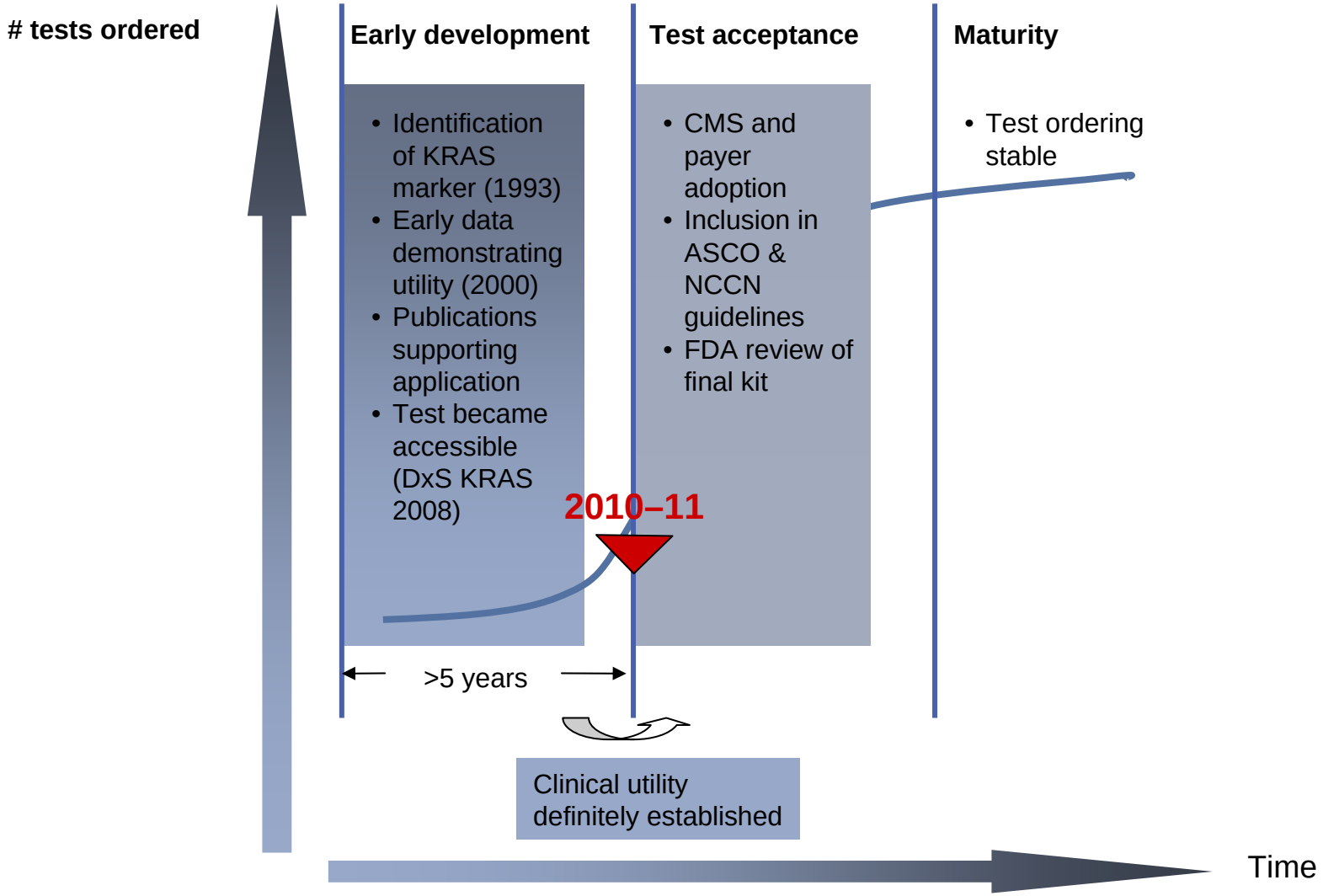
Advocacy
- Thought leader involvement/acceptance
- Endorsement from advocacy/patient groups
- Endorsement from professional organizations

Payor Adoption
- Managed care contracts
- Edit checks on claims
- Federal government adoption
- State government adoption

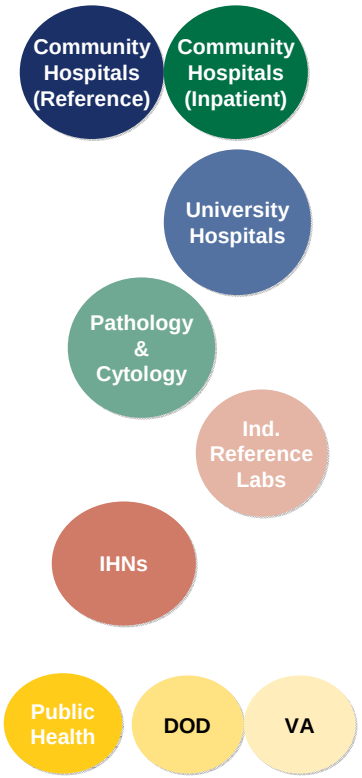
Promotional Efforts
- Price
- Size and structure of the target physician specialty
- Marketing focus and effort
- Sales comprehension, focus and effort
- Partnership efforts

KRAS test adoption phases

At start of the growth phase



Targeting the right customer by institution
Key takeaways by institution type



Community Hospitals are profitability-minded, particularly if they serve as a local/regional reference lab

University Hospitals want multiple services and support but also desire efficiency as it supports their business plans

Pathology/Cytology Labs want test standardization and greater efficiency

While profit is important to **Independent Reference Labs**, increased efficiency and customer support are the key drivers

IHNs also want a breadth of services as well as automation solutions to help improve workflow and efficiency

Public Health, **VA** (Veterans Affairs Hospital Labs) and **DOD** (Department of Defense Hospital Labs) seek reliability and ease of use

Segmentation
What does it mean for personalized healthcare?

Based on segmentation, important criteria for labs are:

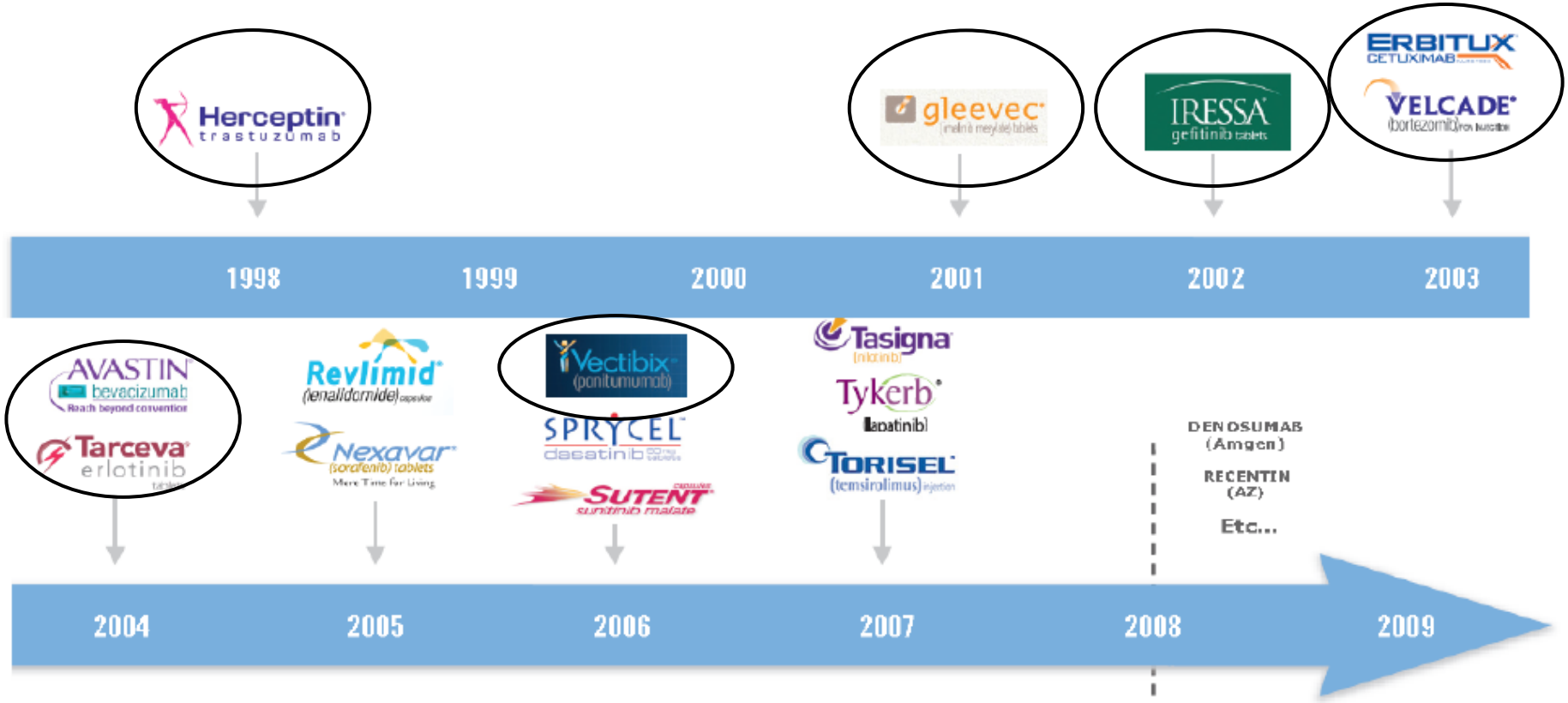
- PMA label and approved test
- Reimbursement
- Workflow and menu
- Adoption of the new test
- Training
- Positioning
- Data to support the new test

Looking ahead —

Where now for companion diagnostics?
New potential therapeutic areas to explore

Targeted therapies in oncology over the past 10 years

What does the next 10 hold? PHC will surely drive CER



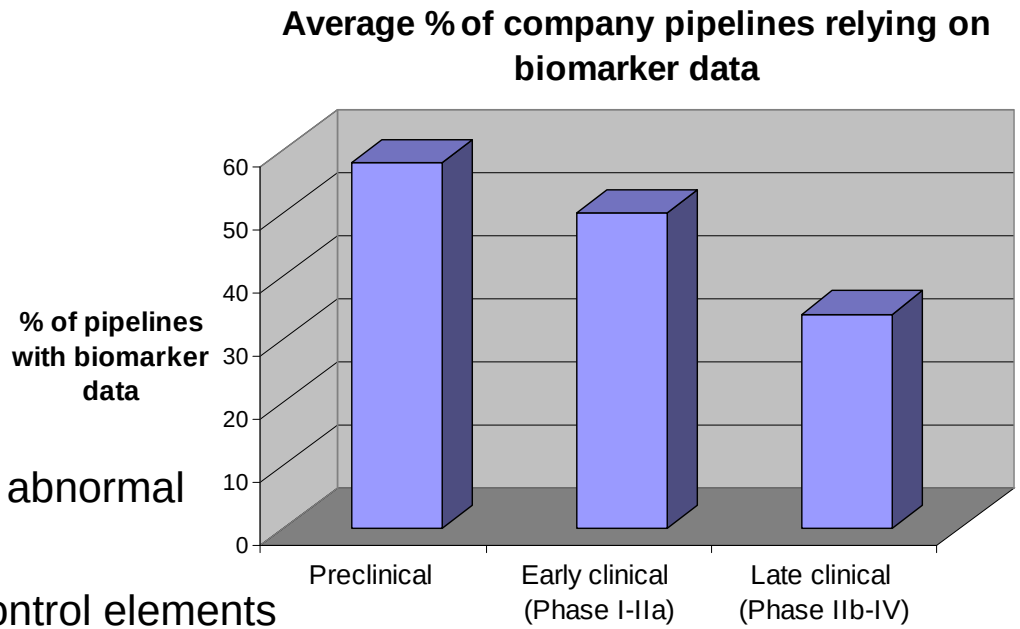
Source: IMS Business Review 2008

Where will personalized medicine expand next…

- Disease complexity and unmet need will drive the application uptake and use of biomarkers to deliver personalised medicine where efficacy can be shown

- Multi-parameter biomarker strategies facilitate go/no-go decisions especially in complex disease scenarios:
  - Imaging
  - Molecular
  - Protein
  - Metabolite
  - Cognitive

- Host vs. Disease
  - What is normal vs. what is now abnormal
    - Aberrant pathways
    - Aberrant transcription & control elements
      - Non-coding
      - MicroRNA
      - Epigenetic



Source: Tufts Center for the Study of Drug Development (CSDD) 2010

Moving away from oncology

- CDx started with Infectious Disease
  - Antibiotic resistance
  - AIDS
  - MDR genes (HIV & HCV)

- Oncology CDx will get increasingly complex
  - MGH — Genotyping 101 mutations
  - Microarrays, deep sequencing, robustness, data, regulatory authorities, proving clinical relevance
    - Lack of standards and processes for biomarker validation
    - Challenge of co-developed drug/device technologies
    - Clinical trial design
    - Re-labelling of existing drugs with well-established pharmacogenomic variants
    - Role of post-marketing surveillance and Phase IV studies
    - Different regulatory regimes for manufactured devices and tests developed in-house

- AutoImmune (Host/Local Response)
- CNS
  - Cognition
  - Neuro
  - Pain

- Latent disease/disease prevention

Takeda and Zinfandel Pharmaceuticals sign licensing agreement for Alzheimer's disease biomarker in combination with pioglitazone

Takeda Pharmaceutical Company Limited

Osaka, Japan - Janurary 11, 2011 and Durham, NC -January 10, 2011 – Takeda Pharmaceutical Company Limited and Zinfandel Pharmaceuticals, Inc. today announced that they have entered into an exclusive, worldwide licensing agreement regarding Zinfandel's TOMM40 assay as a biomarker for the risk of Alzheimer's disease, including potential use of the assay in combination with pioglitazone in high-risk older adults with normal cognition. Pioglitazone is the active ingredient currently marketed in Takeda's ACTOS® (pioglitazone HCl).

The TOMM40 biomarker, recently discovered by a team led by Allen Roses, M.D., Chief Executive Officer of Zinfandel, is being developed to identify individuals at high risk of developing Alzheimer's disease within the subsequent five years. Under this license agreement, Takeda and Zinfandel will attempt to prospectively validate the TOMM40 biomarker as a test of individual risk.

"There is intense interest within the medical community in identifying treatments to help delay progression or potentially prevent the onset of Alzheimer's disease, in an effort to reduce the burden of this disease," said Shigenori Ohkawa, Ph.D., Chief Scientific Officer, Takeda Pharmaceutical Company Limited. "We are energized by this partnership and the opportunity to develop an effective treatment for healthy at-risk older adults."

Under the terms of agreement, Zinfandel will receive an upfront payment of $9 million and subsequent payments of up to $78 million for development milestones from Takeda. Additional commercial milestones and royalties were also outlined in the agreement. Takeda will obtain an exclusive license, with the right to sublicense, develop, make, use and commercialize the TOMM40 biomarker assay, and to use the assay to identify high-risk older adults who would be candidates for clinical trials with pioglitazone to evaluate its utility.

"At Zinfandel, we have been exploring pharmacogenetics in general, and the TOMM40 biomarker specifically, to identify at-risk individuals who may be candidates for treatment in a pharmacogenetics-assisted clinical trial," said Dr. Roses. "We look forward to working with a partner like Takeda, who shares our commitment to reducing the prevalence of Alzheimer's disease over the next 20-30 years."

Alzheimer's disease is a degenerative brain disease characterized by a progressive decline in memory, thinking, comprehension, calculation, language, learning capacity and judgment sufficient to impair personal activities of daily living. Approximately 18 million people worldwide are currently suffering from Alzheimer's disease, and the rate of occurrence doubles every five years for those between 65 and 85 years of age.

Summary

- Robust science is driving partnerships in CDx
  - Regulatory policy ensures only the best is delivered
  - Dx partners must show experience & be able to deliver the broader picture
- Start early and start with the end in mind (Platform)
  - What will the Dx/Rx landscape look like at launch?
    - Who, how, where, when, and why will the test be used?
- Commercial strategies must foster the businesses goals of all stakeholders
  - There are many differences
- Personalised Healthcare is now a reality
  - Essential for the success of next generation therapies
  - Our investment in science is delivering value through innovation most importantly; benefits for patients
- Let's work together and make a difference

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