

Ventana Companion Diagnostics

***Building the future of pathology
through partnership***





Mission & Vision Overview

Companion Diagnostics & the Value of Personalized Healthcare

Current State & the Future of Companion Diagnostics

Sources and Uses of Information for CDx

Pathologist founded, patient focused

Maintaining a focus on the mission we share with you

Our mission

To improve the lives of all patients afflicted with cancer

Our vision

To empower our customers by providing the highest quality, most innovative cancer diagnostic solutions



Tools to deliver on our mission

A vision to support you in an ever changing environment

The market challenges you face today.....bring opportunities to **differentiate**



Demand for health economic evidence



Medical value assays with published clinical data



Labs doing more with less



Advanced automation to improve quality and reduce labor costs



Increasing competition and price pressure



Integrated AP lab solutions to improve efficiency

Healthcare today is in crisis, as it is expensive, reactive, inefficient & focused largely on one-size-fits-all treatments for events of late stage disease. An answer is personalized, predictive, preventive & participatory medicine.¹





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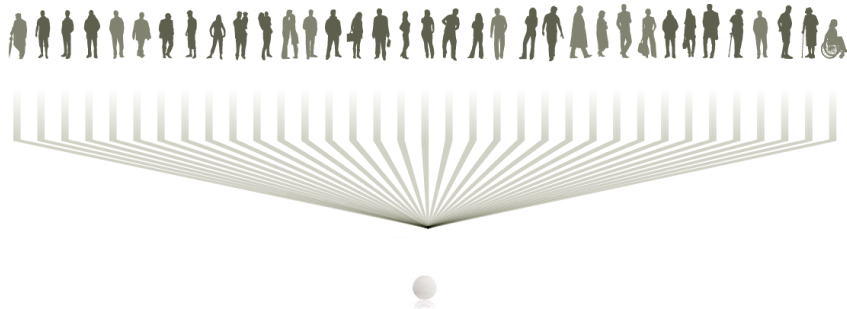
Sources and Uses of Information for CDx

Companion diagnostics & bio-targeted therapy

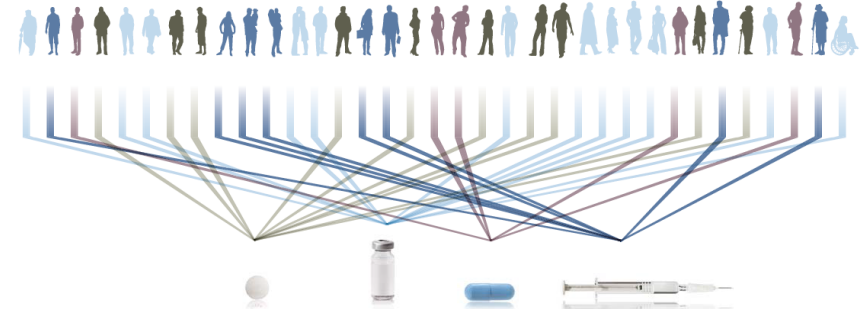
CDx enables patient stratification & is truly customized for all

Standard therapy means
same disease, same therapy

Personalized healthcare means
the right therapy for the right group of patients at the right time



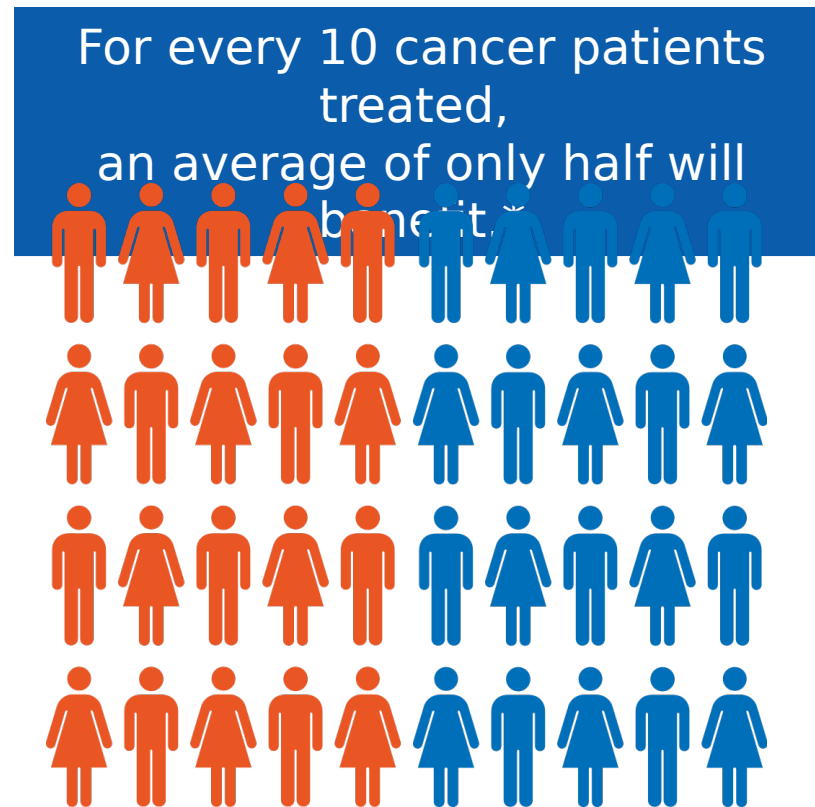
One-size-fits-all approach



Targeted strategy

Why are companions important?

Treatment efficacy historically elusive for oncology



*Source: Roche Personalized Healthcare brochure, 2011

Value of Personalized Healthcare

High value diagnostics benefit physicians, patients & payers

Physicians: easier prescription decisions

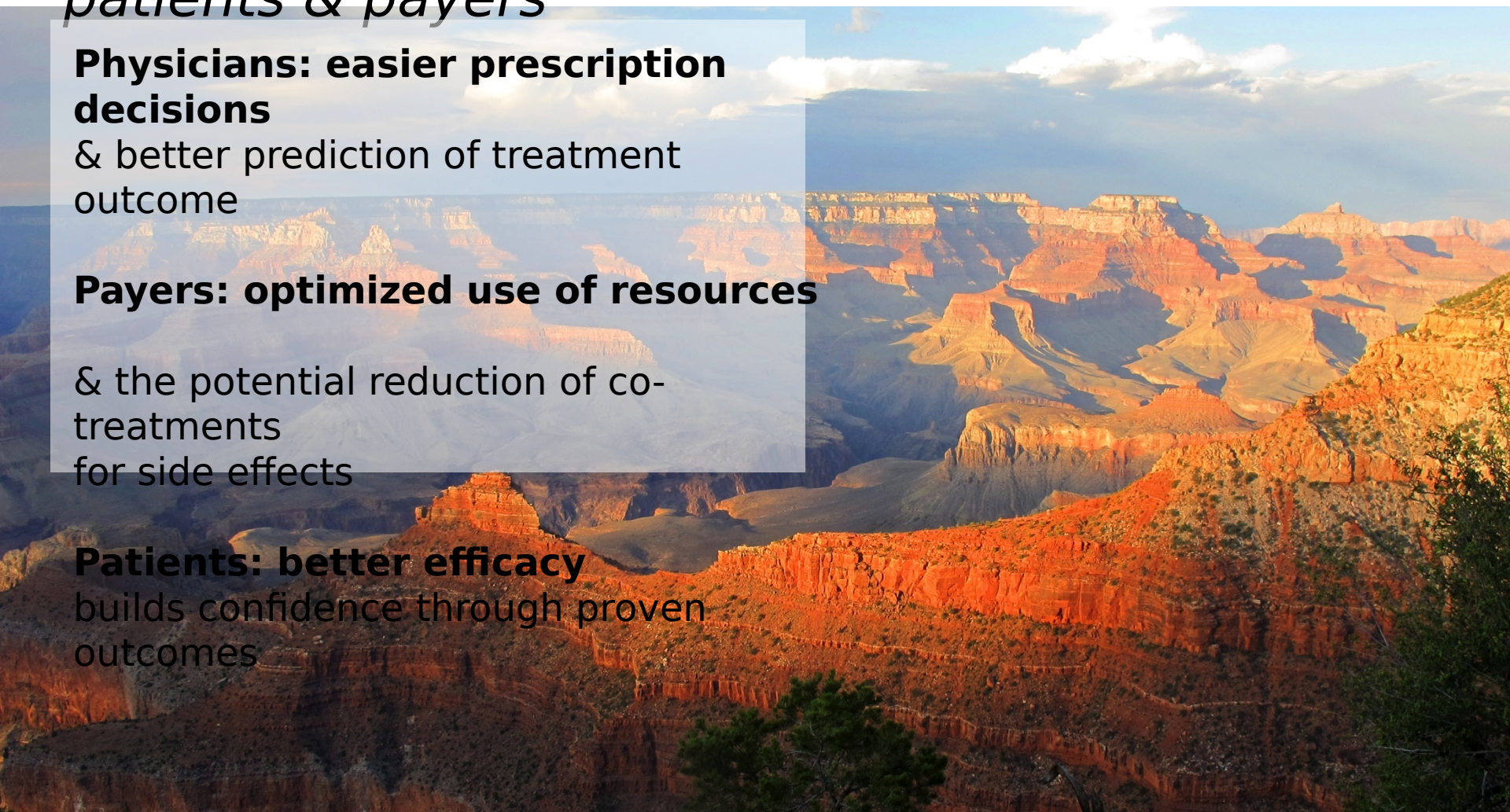
& better prediction of treatment outcome

Payers: optimized use of resources

& the potential reduction of co-treatments
for side effects

Patients: better efficacy

builds confidence through proven outcomes



Companion diagnostics deliver real value

Help to reduce costs & improve outcomes

\$160B

of drug spend is ineffective¹

\$604M

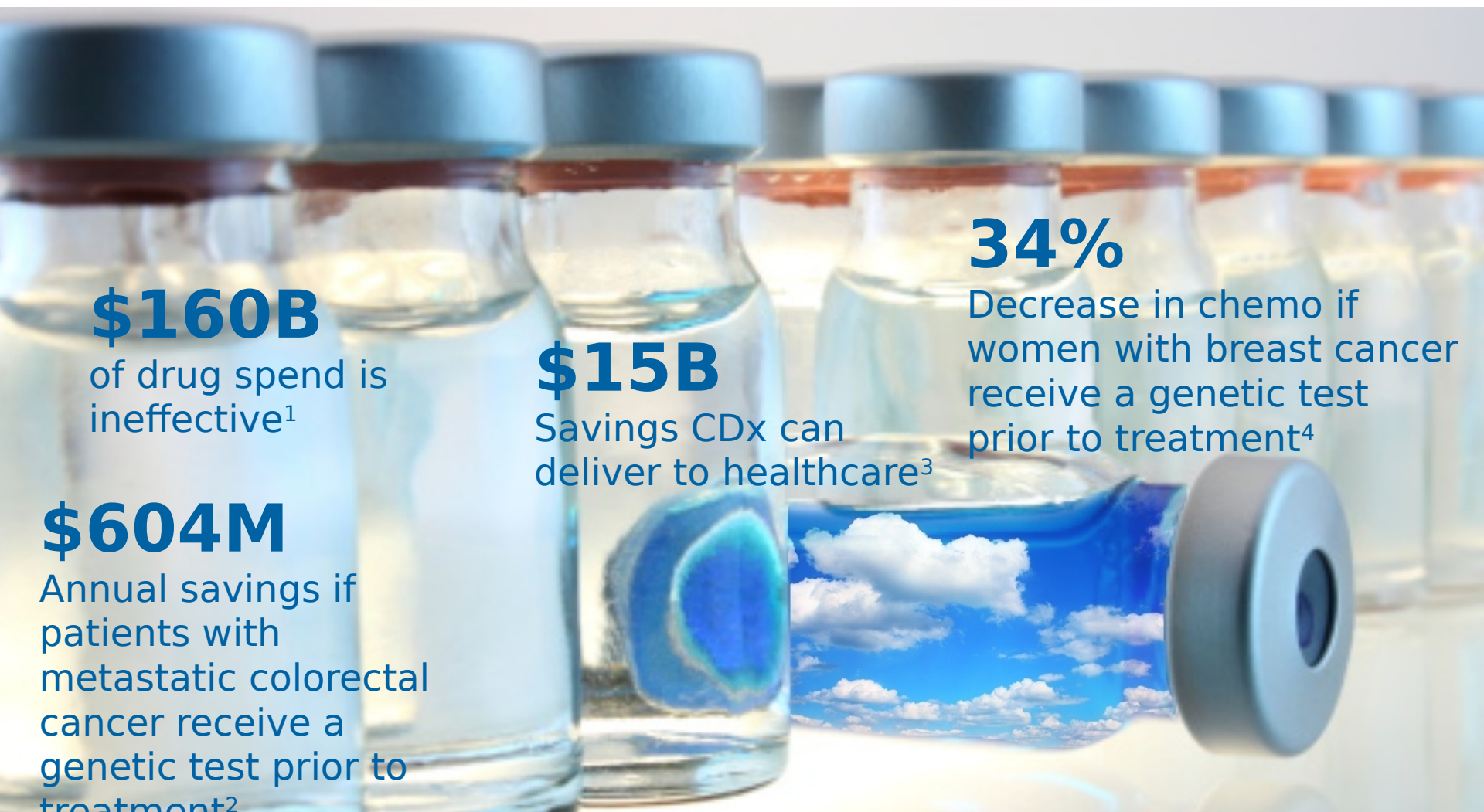
Annual savings if patients with metastatic colorectal cancer receive a genetic test prior to treatment²

\$15B

Savings CDx can deliver to healthcare³

34%

Decrease in chemo if women with breast cancer receive a genetic test prior to treatment⁴



Companion diagnostics deliver real value

Positive outcomes for patients



Lives are impacted, by knowing biomarker status to qualify patients for potential life saving therapy.

- ALK positive gene mutation status in non-small cell lung cancer qualifies patients for Crizotinib
- Crizotinib increases progression free survival in comparison to standard chemotherapy⁴

The VENTANA ALK (D5F3) Rabbit Monoclonal Primary Antibody is not available for this use in the United States. Check with your local Roche representative for the availability of products in your region and the applicable intended use.



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The need for companions will continue to grow

FDA approvals flat overall but 600% more likely with bio-target

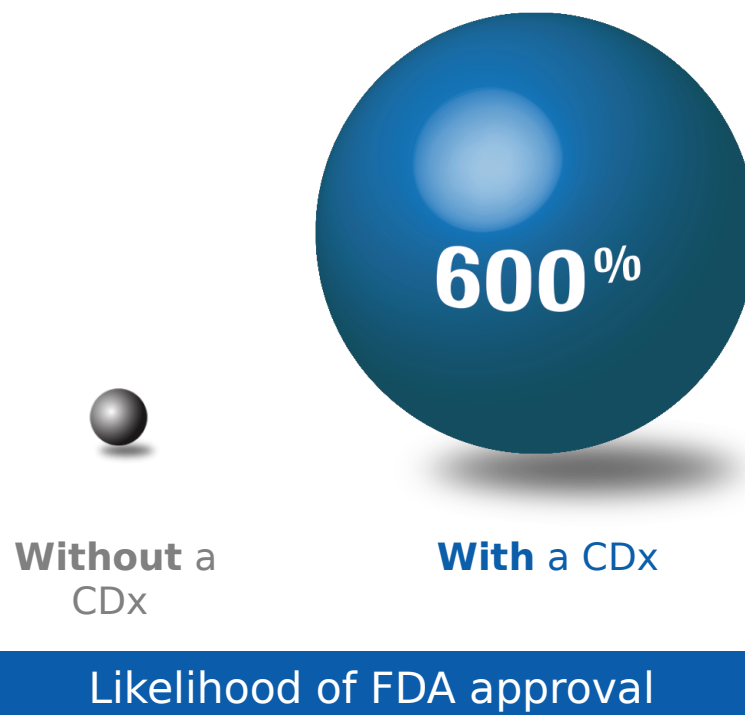
The last ten years in NSCLC

Number of compounds being investigated
+**62%**

R&D funding has **doubled**











FDA approvals – **flat without a companion**

Biomarker targeted therapies **six-fold increase in clinical trial success**



Roche diagnostics market leading CDx portfolio

Our diagnostic offerings cover several therapies &

Biomarker	Technology	Therapy Application	Roche Solution
HER2 *	IHC/ISH	Herceptin, Perjeta, Kadcyla Breast, Gastric	 
EGFR	PCR/IHC	Erbix, Vectibix, Tarceva CRC, NSCLC	 
ALK**	IHC	Xalkori NSCLC	 
BRAF	PCR	Zelboraf, Tafenlar, Mekinist Melanoma	 
C-KIT	IHC	Gleevec GIST	 

*Biomarkers include only those required per FDA approved therapeutic label. **Not all CDx Assays are available in all markets for all indications

What is our strategy?

Offer pharma a premiere end to end solution

Biomarker Research

Pharma Services

IVD Development

Product Marketing & Commercialization

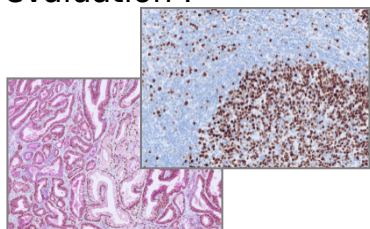
Antibody Development

Rabbit Monoclonal Antibody manufacturer of first-in-class clones for RUO/IVD.



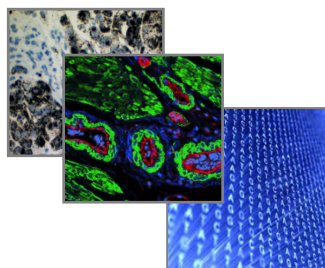
DISCOVERY Portfolio

Instruments & Reagents that empower Pharma to conduct Biomarker evaluation .



Assay Prototyping

Biomarker evaluation, efficient & robust LDT development



CAP/CLIA Lab

In-house lab for first in-human clinical trials and rapid "go/no-go" project determination



(CLIA Certified)

Pathology Expertise

Dedicated to Pharma clinical trials, assay algorithm development, CDx Assay training



Regulatory Experience

Clinical Trial Support

Commercial Support

Education, pre-launch, training product marketing & commercialization

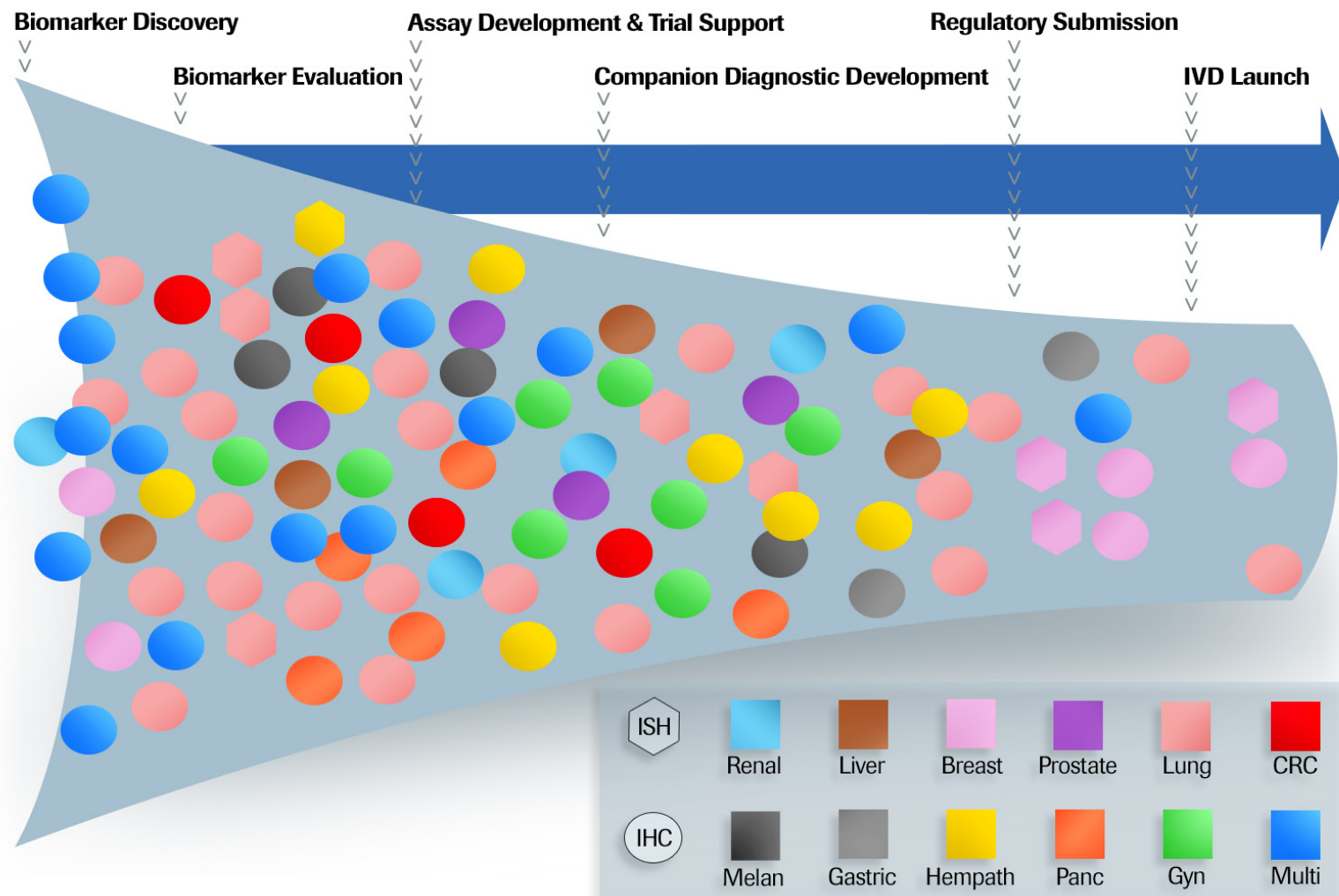


- Industry's #1 Commercial and Technical Support Network
- Largest Global Installed Base
- #1 in IHC Market Share in all Regions

Delivering on our vision

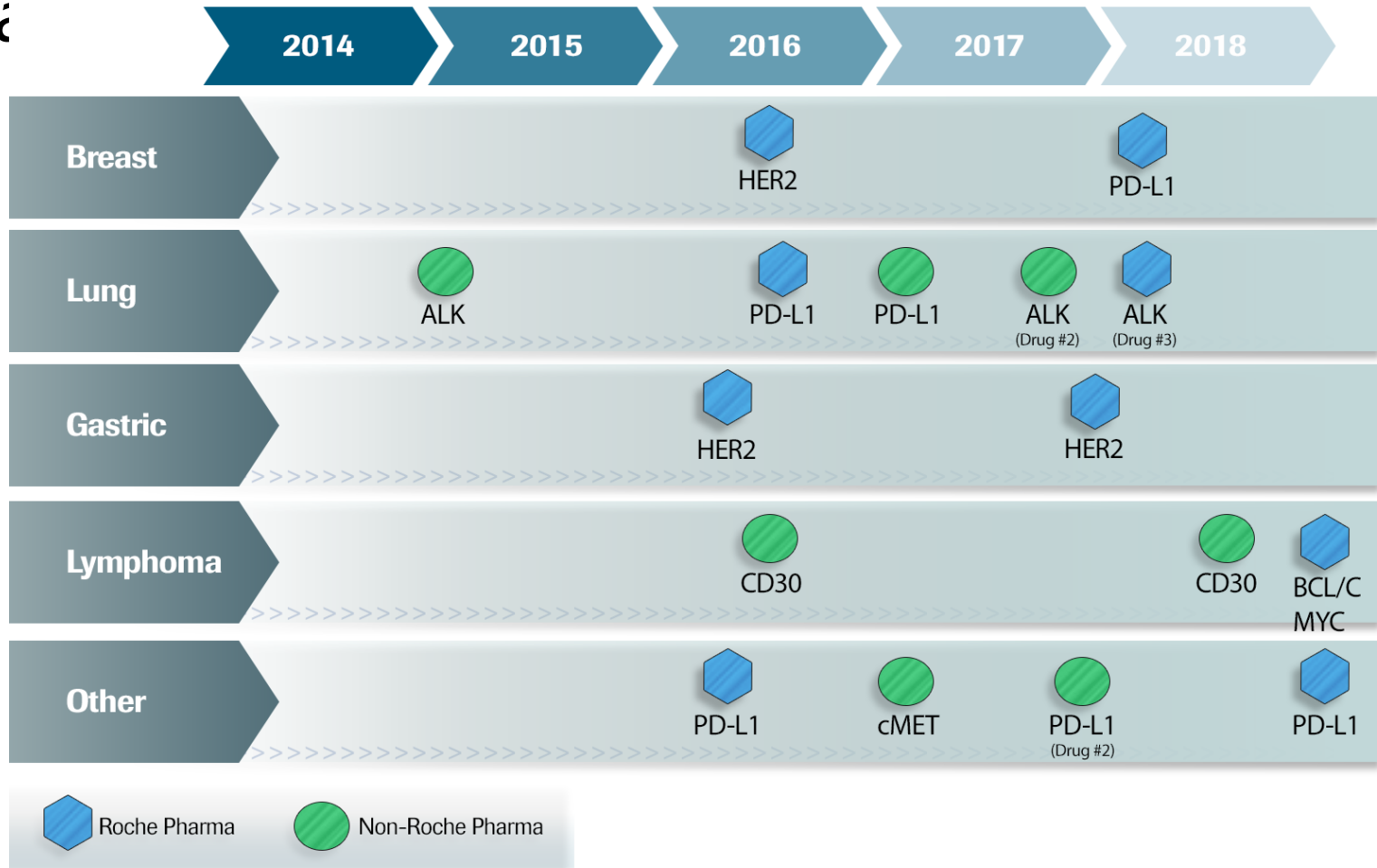
Building a robust pipeline of innovative

companion diagnostics



New CDx products on the horizon

The future is clear for key diseases and targets





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Information Tsunami

1,000,000,000 CHF
Investment*
7,000,874 Working hours
6,587 Experiments
423 Scientists
1 Drug



19,155,303 PubMed
Articles+
94,941 Research institutes
43,048 Gene sequences
4,946 Journals
1 Fact



Driving question:
**How can we efficiently process the huge amount of information
for our scientists
such that they can focus on innovation ?**

Scientific & Business Information

Services

Scientific Information

- Individual Searches
- Continuous Searches (Alerts)
- Structure & Substructure Search
- Gene & Protein Sequence Search



**Get
information to
innovate!**

Scientific Information Services

Business Information

- Business News
- Market & Company Reports
- Cooperations & Licences, M&A



Enduser Services

- Training
- Support
- Helpdesk



Analytics Services

- Data - & Text Mining
- Patent Landscaping
- Application Development

Patent Information

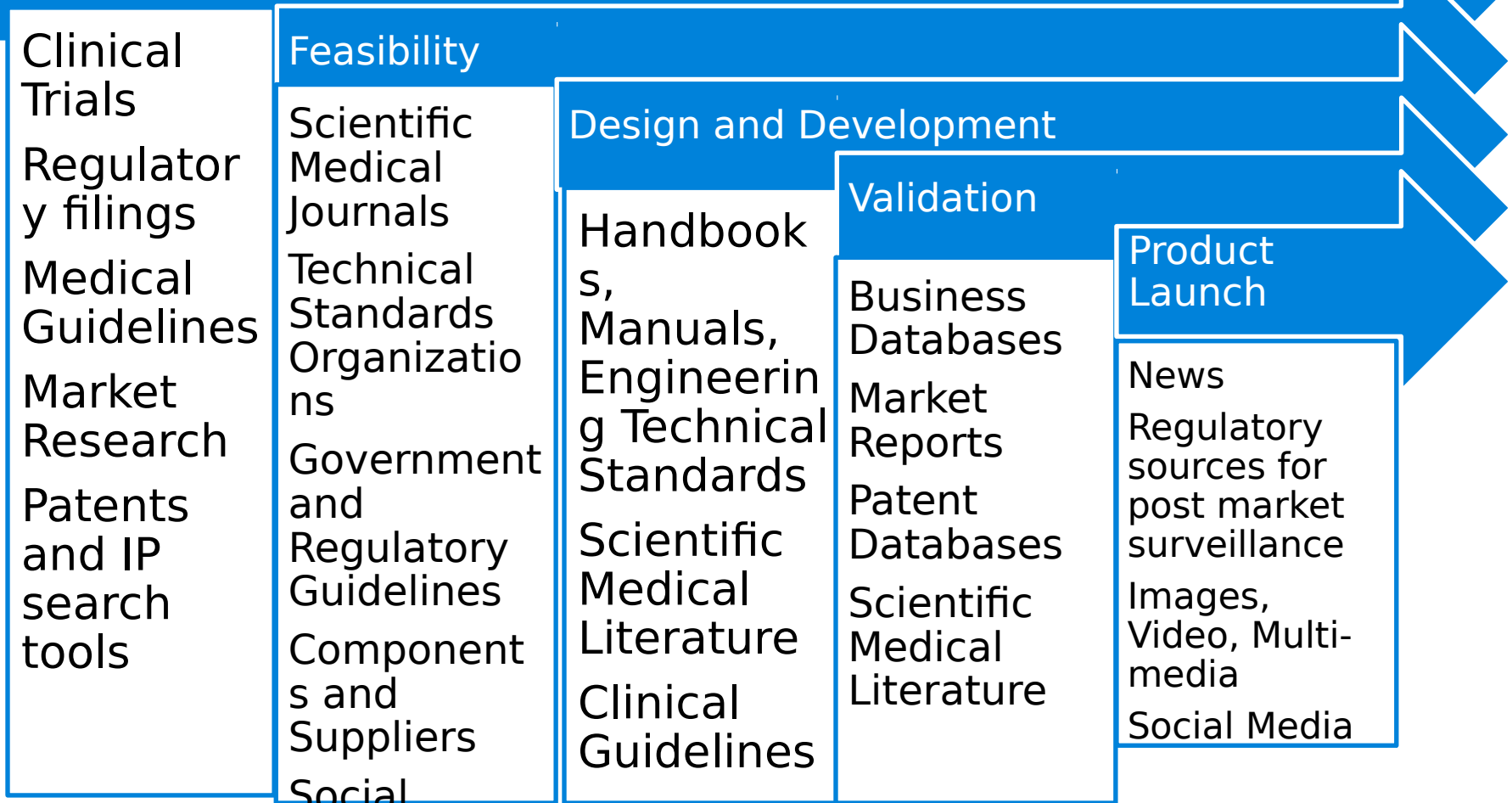


- Freedom to operate (FTO)
- State of the Art
- Infringement/Validity Search
- Patent Landscaping/Mining



Information Sources Companion Dx Development

Initiation/ opportunity/ risk analysis - Ongoing Research and Monitoring



Pietzsch, J. B., Shulzas, L. A., Paté-Cornell, M. E., Yock, P. G., & Linehan, J. H. (2009). Stage-gate process for the development of medical devices. *Journal of medical devices*, 3(2), 021004.

Companion Dx Information Resources

Databases

- Citeline Trial Trove/ Pharma projects - Clinical Trials, drug profiles
- Cortellis (Thomson Reuters)
- Adis R&D Insight (Springer)

Associations

- American Society of Clinical Oncology Meeting Library (ASCO)
- American Association for Cancer Research Meeting Abstracts (AACR)
- College of American Pathologists (CAP)
- National Comprehensive Cancer Network (NCCN)
- European Society for Medical Oncology (ESMO)

Regulatory and News

- [FDA Companion Diagnostics](#)
- [List of Cleared or Approved CDx Diagnostic Devices](#)
- Pharma & MedTech Business Intelligence
- Genome Web
- BioCentury
- Bio Pharma Dive

References

- 1) **The Case for Personalized Medicine**, 3rd Edition The Personalized Medicine Coalition (Oct 2011)
- 2) Shankaran V. Conference presentation at the **Gastrointestinal Cancers Symposium**. January 2009. Medscape web site. (Available at: <http://www.medscape.com/viewarticle/586946>)
- 3) **Genomic Health. Economic Validity**. Genomic Health web site. (Available at: <http://www.genomichealth.com/en-US/sitecore/content/Home/Breast/ManagedCareOrgs/EconomicValidity.aspx>)
- 4) **Crizotinib versus Chemotherapy in Advanced ALK-Positive Lung Cancer**
Alice T. Shaw, M.D., Ph.D., Dong-Wan Kim, M.D., Ph.D., Kazuhiko Nakagawa, M.D., Ph.D., Takashi Seto, M.D., Lucio Crinó, M.D., Myung-Ju Ahn, M.D., Tommaso De Pas, M.D., Benjamin Besse, M.D., Ph.D., Benjamin J. Solomon, M.B., B.S., Ph.D., Fiona Blackhall, M.D., Ph.D., Yi-Long Wu, M.D., Michael Thomas, M.D., Kenneth J. O'Byrne, M.D., Denis Moro-Sibilot, M.D., D. Ross Camidge, M.D., Ph.D., Tony Mok, M.D., Vera Hirsh, M.D., Gregory J. Riely, M.D., Ph.D., Shrividya Iyer, Ph.D., Vanessa Tassell, B.S., Anna Polli, B.S., Keith D. Wilner, Ph.D., and Pasi A. Jänne, M.D., Ph.D.
N Engl J Med 2013; 368:2385-2394 [June 20, 2013](#) DOI: 10.1056/NEJMoa1214886



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Empowering | [Personalized Healthcare](#)

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***Doing now what patients need
next***