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PERSONALIZED MEDICINE™

Improving Outcomes, Reducing Costs

Health Care Costs Are Increasing Worldwide

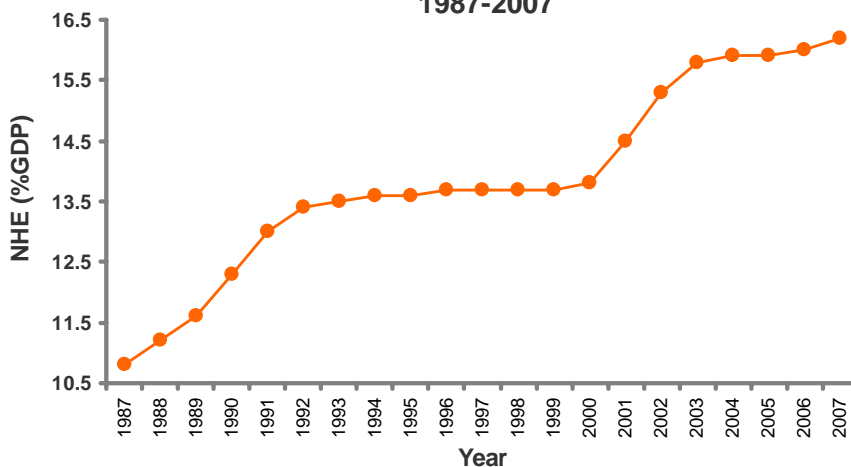


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Over the past 20 years, US national health care expenditures (NHE) have increased over four-fold, rising from 10.8% to 16.2% as a proportion of GDP. In 2007, the US spent over \$2.2 trillion on health care; this is predicted to reach \$4 trillion by 2017.

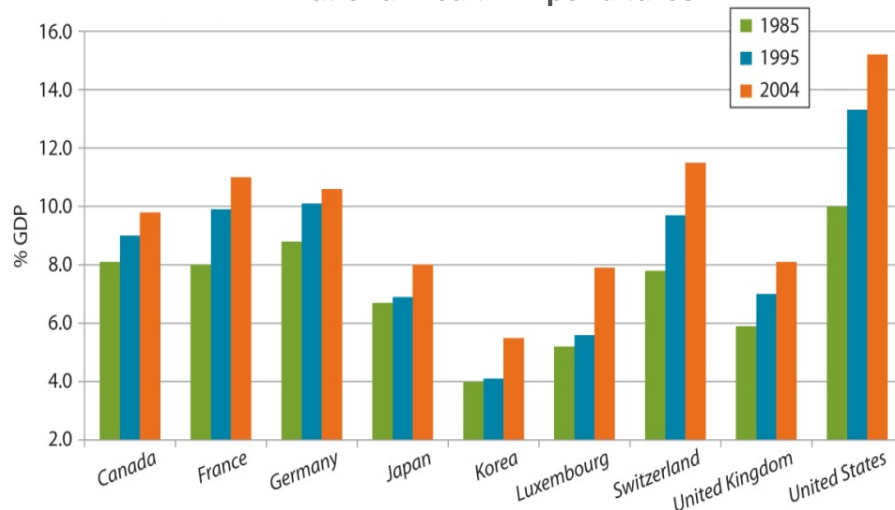
Health care expenditures are a critical issue world-wide. In the past 50 years, health care spending across all OECD countries has grown by 2 percentage points in excess of GDP. At current rates it is predicted that by 2050 most OECD countries will spend more than 20% of GDP on health care.

**U.S. National Health Expenditure as % GDP
1987-2007**



Source: Center for Medicare and Medicaid Services National Health Expenditure Data

National Health Expenditures



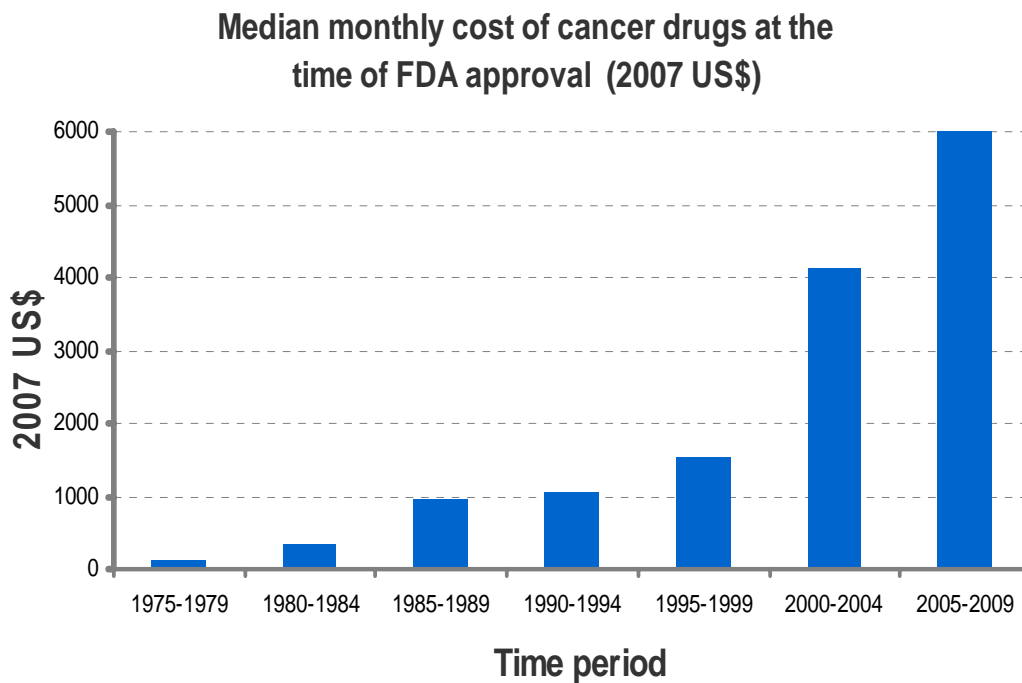
Source: OECD Health Data 2007
http://www.oecd.org/document/16/0,3343,en_2649_37407_2085200_1_1_1_37407,00.html
 Accessed December 4, 2007

“Progress” in Healthcare Usually Increases Costs



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- Increased expenditures usually result from increased treatment-associated costs - most new interventions are more expensive than earlier therapies.
- Current trends in health care favor providing expensive treatments for late-stage disease.
- There has been a disproportional emphasis in research and development on drugs and therapeutics, rather than diagnostics.



Bach PB., N Engl J Med. 2009 Feb 5;360(6):626-33.

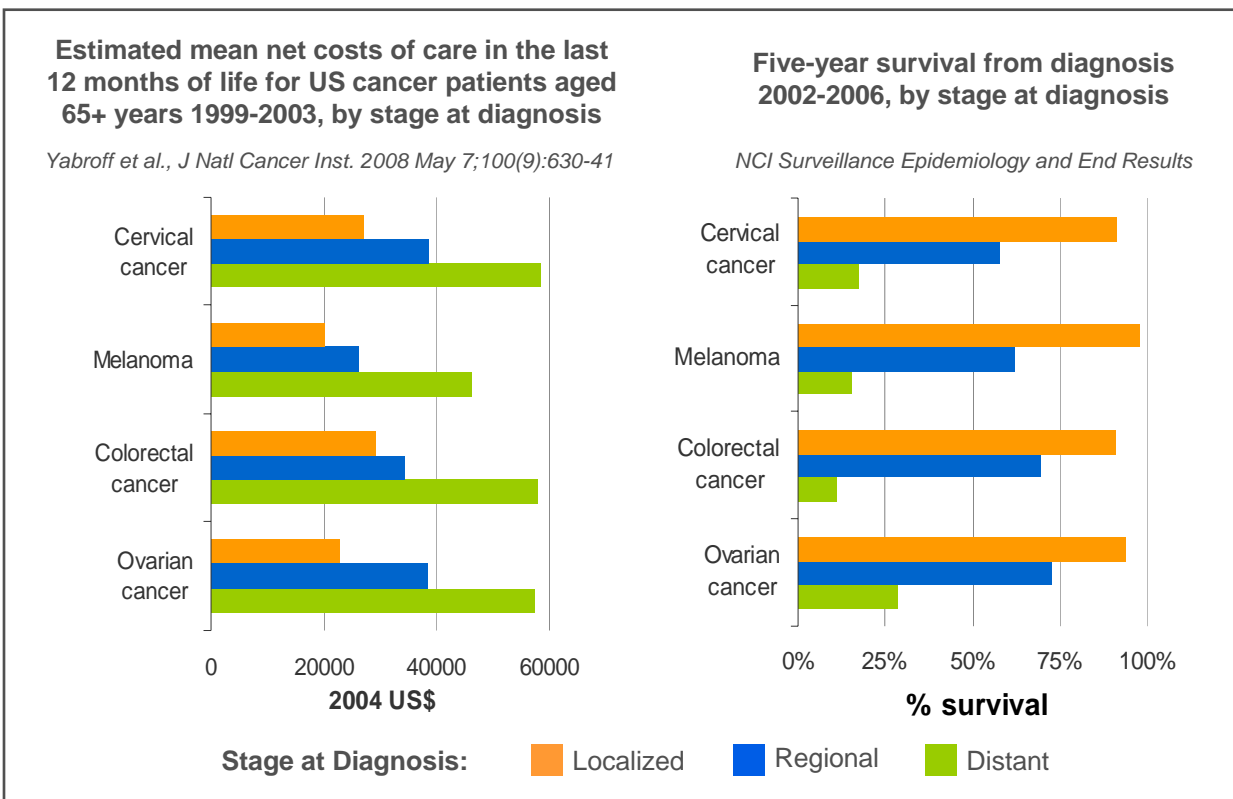
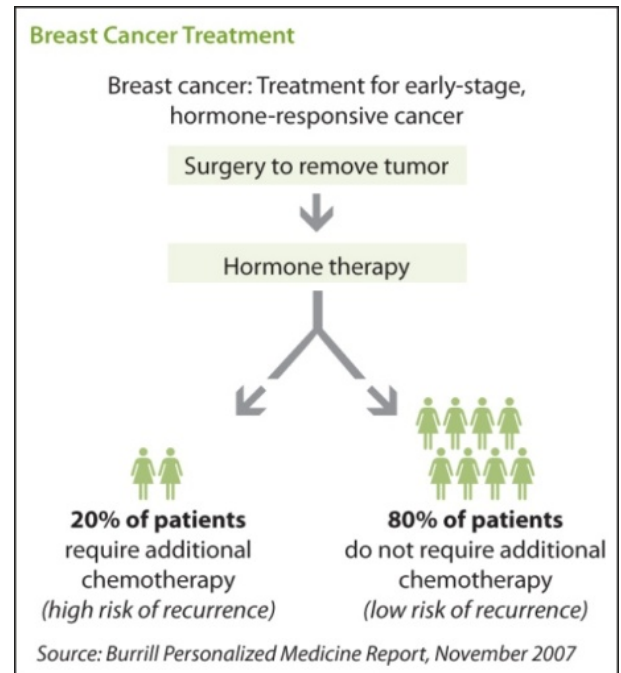
Opportunities for Improved Molecular Diagnostics



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Molecular diagnostics offer several opportunities for improving health care and reducing costs of treatment, including:

- **Risk assessment:** Identifying individuals at greater risk of developing specific diseases enables the implementation of preventive measures.
- **Early detection:** Treating disease in earlier stages is often less costly and more effective than late-stage disease.
- **Definitive diagnosis and treatment:** The diagnosis of many diseases is challenging due to a lack of distinctive symptoms. Improved diagnostics can help to better identify what therapy a patient requires, while preventing adverse side effects and costs of treatment for those who will not respond.

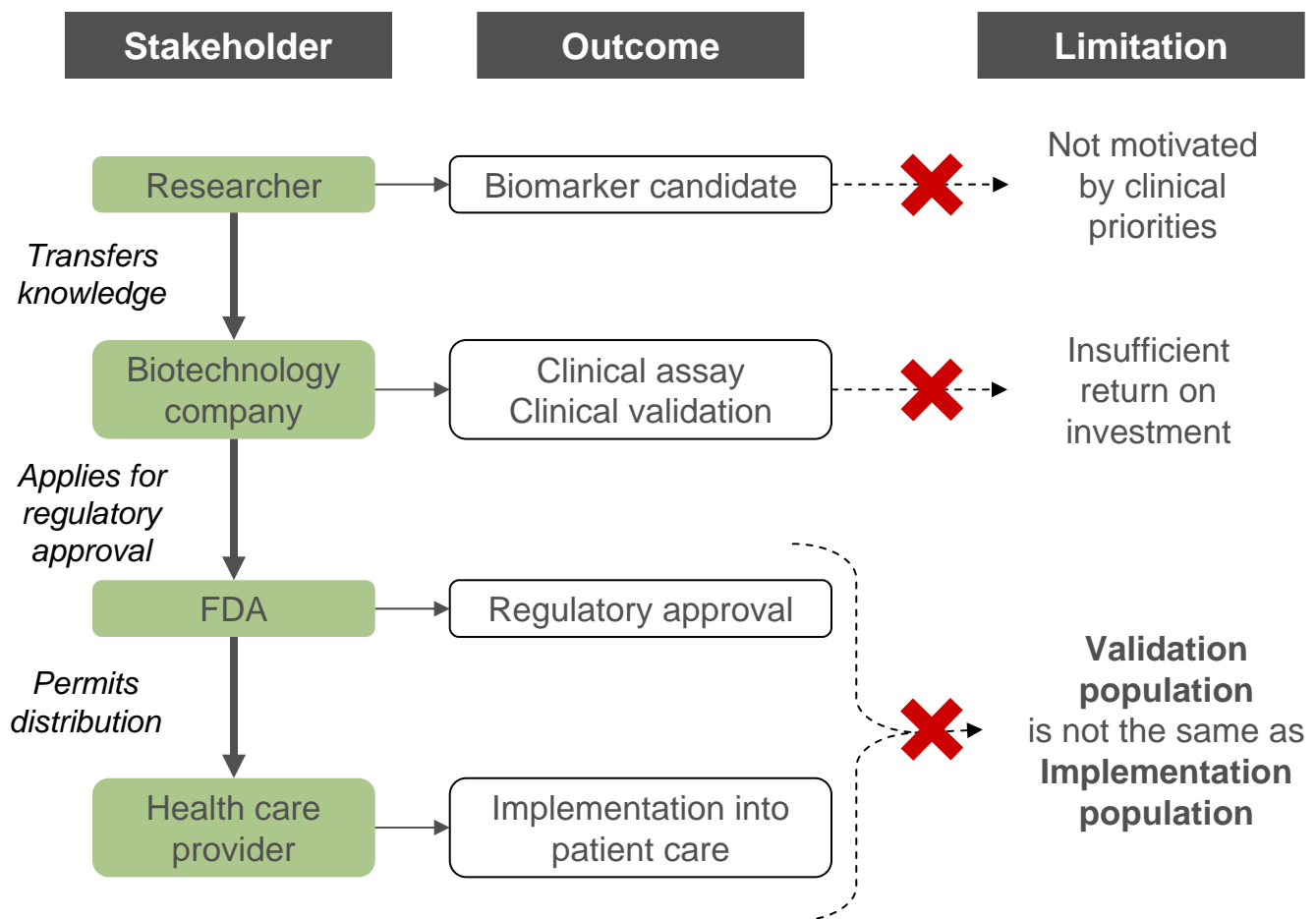


Current Model of Diagnostic Development



There are several limitations to the current model of development for new diagnostics:

- Research priorities for biomarker candidates are not usually motivated by the clinical community and may not meet treatment needs.
- Poor return on investment compared with therapeutics provides inadequate incentives for biotechnology companies to pursue FDA approval.
- In the cases when efficacy data is available for diagnostics, the data is not necessarily directly relevant to the population of interest to the health provider.



PPM Model of Diagnostic Development

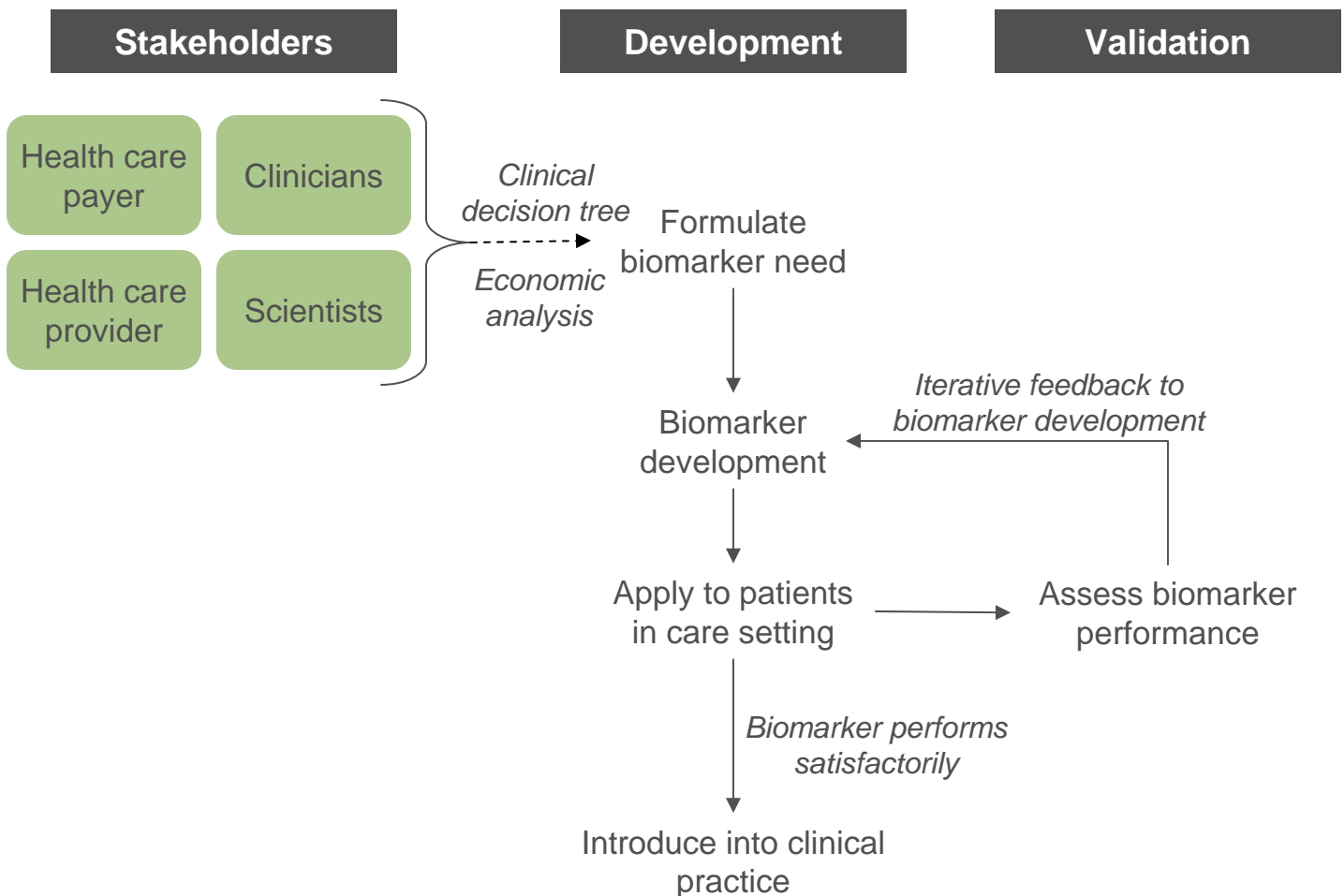


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PPM introduces a new model, which features the following characteristics:

- Cohesive and interactive partnerships between health insurers, providers, clinicians, and scientists throughout the development and validation processes.
- Validation of diagnostics that is guided by clinical and economic drivers and analysis, and takes place in the health care systems in which they will be implemented.
- Collaborative, prospective and evidence-based evaluation of diagnostic tests within health systems to validate and introduce the new test to patient management.

Bringing science and the clinic closer together will ultimately lead to care pathways that are both clinically and economically more effective.

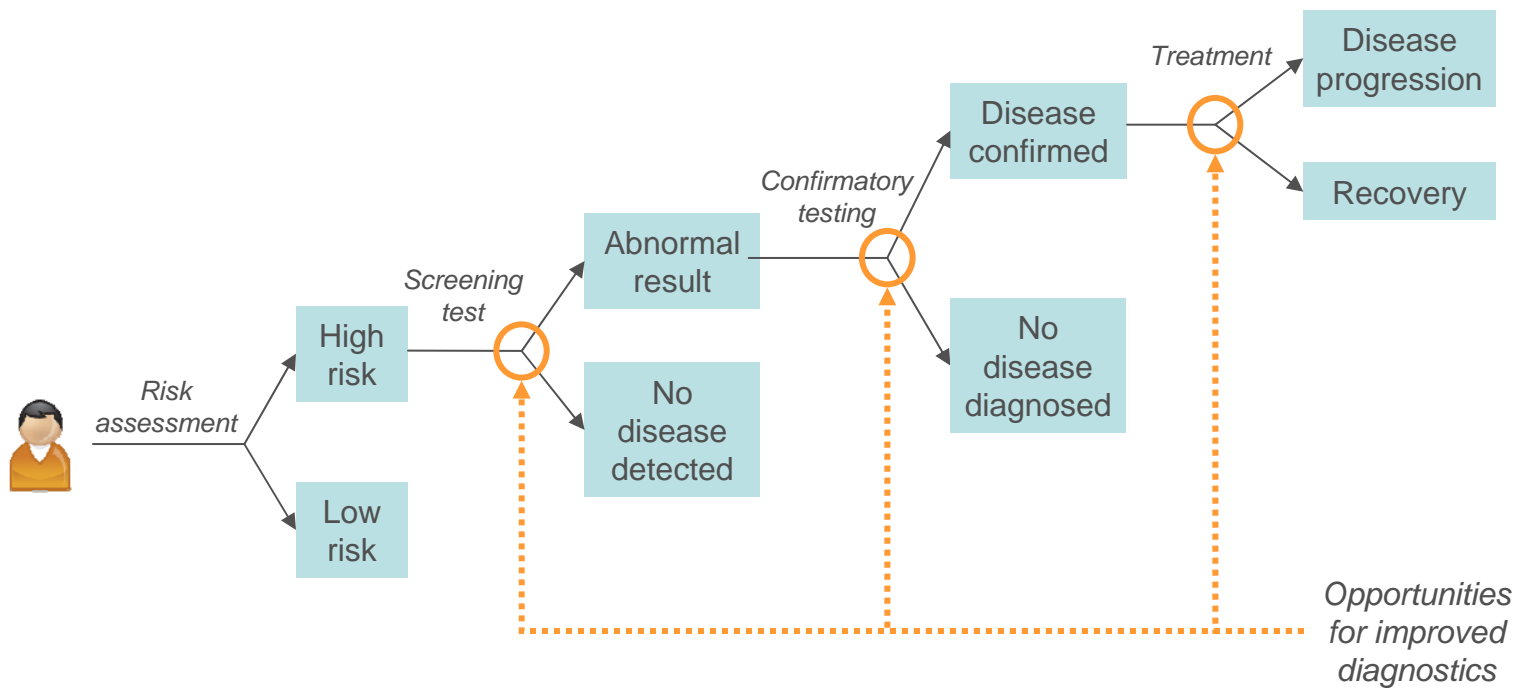


Health Economics Analysis: Decision Tree for Disease Management



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PPM helps health care providers and payers identify patterns of current clinical care and expenditure within the health care system (as opposed to guidelines or clinical trials). This analysis identifies key decision points in clinical pathways where better diagnostics can improve care and reduce costs.



Economic Modeling of a New Molecular Diagnostic



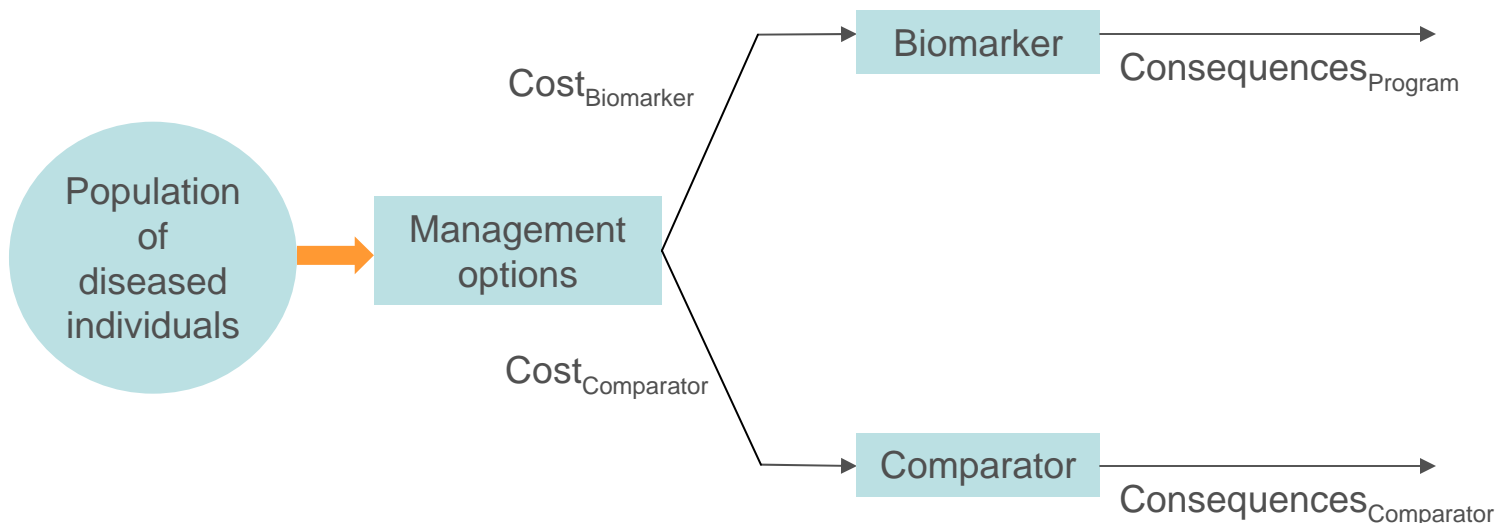
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Economic analysis calculates the value of new diagnostics and associated care pathways compared to current treatment. Cost-effectiveness analysis enables PPM and its partners to:

- compare the potential value of new diagnostics with existing care pathways;
- calculate performance benchmarks that new diagnostics would have to meet to improve clinical and cost effectiveness;
- conduct ongoing outcomes evaluations to determine the actual value of a test during validation studies and once it has been implemented into clinical practice.



Scott Ramsey

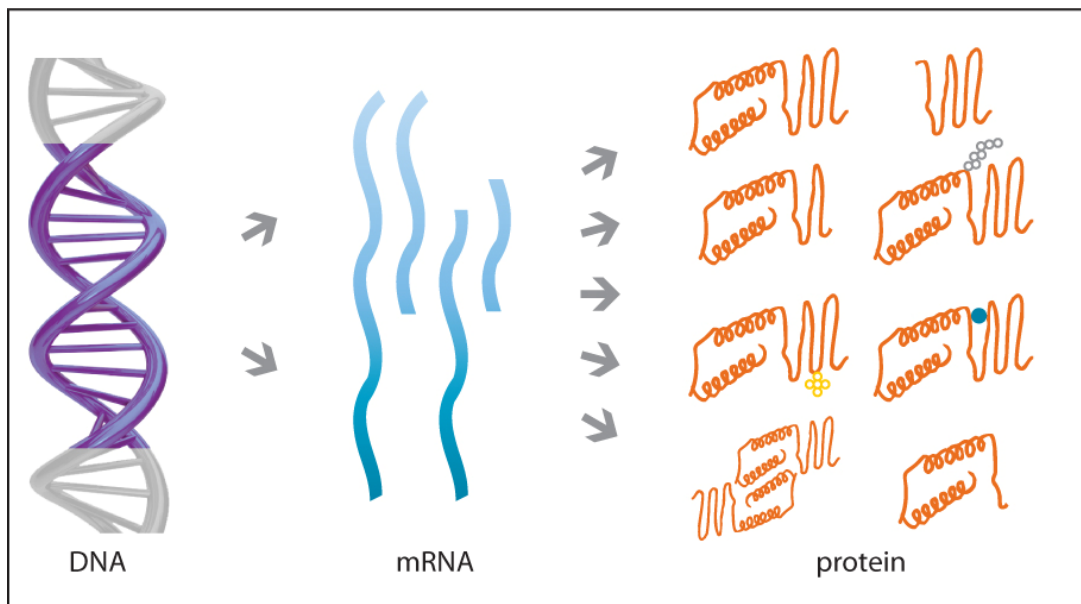


From: Drummond MF et al. *Methods for the Economic Evaluation of Health Care Programmes*, Oxford, 1997

Proteins Will Be Better Molecular Diagnostics



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While technological advances in genomics and transcriptomics continue to provide valuable insights into human disease, recent advances in detecting proteins provide new opportunities for better molecular diagnostics:

- Proteins are closer to physiological conditions than DNA.
- There is much greater variation amongst proteins compared to DNA.
- Proteins are more easily obtained through non-invasive blood samples.

PPM draws on the expertise of its three partner institutions to identify promising diagnostics and biomarkers in development that are ready for clinical validation. In addition, a dedicated industrial-scale high-throughput proteomics facility, along with cutting-edge resources and expertise in genomics, transcriptomics and bioinformatics, enables PPM to conduct its own biomarker discovery and validation activities as necessary.



PPM is uniquely positioned to bring together health care systems and diagnostics developers in partnership. In each project, PPM and Partners combine resources and knowledge to develop biomarkers that address the specific needs of partnering health care systems. The Partners will each contribute according to their capabilities and expertise.

PPM

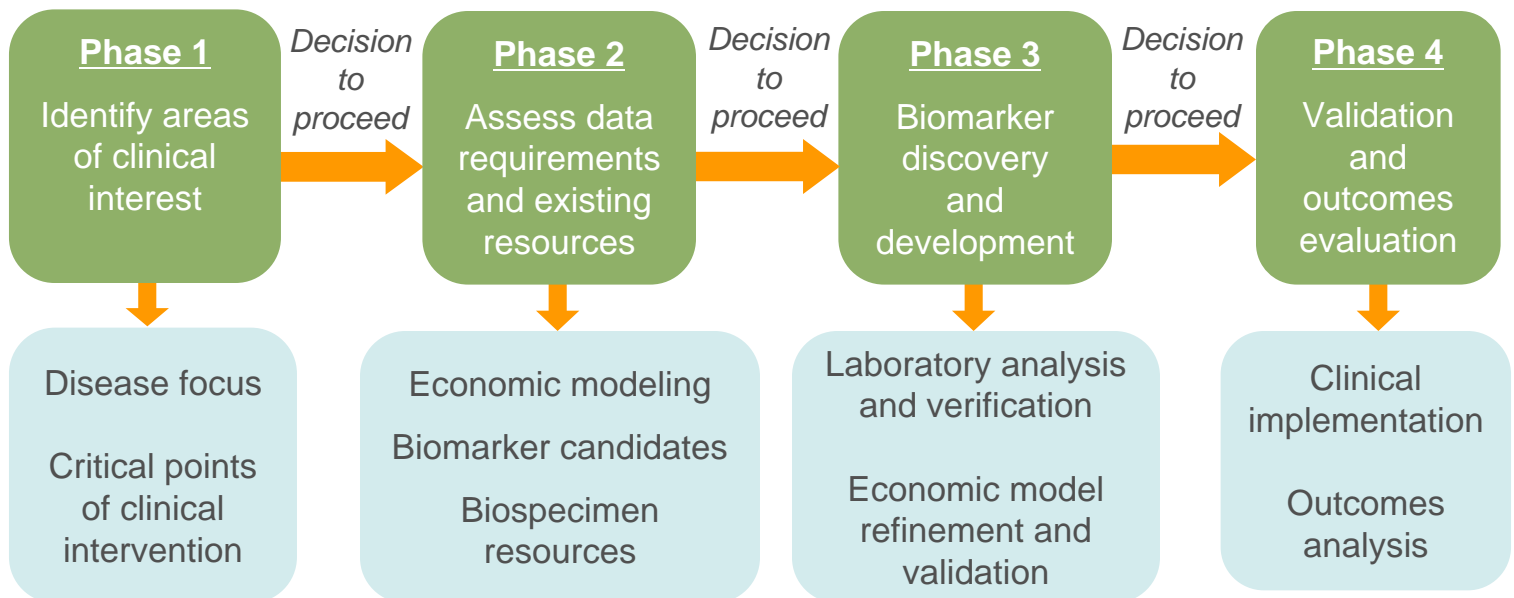
- Design and manage project
- Map clinical decision tree
- Identify decision nodes of opportunity
- Research existing biomarker knowledge
- Acquire academic and biotech partners
- Oversee biomarker discovery, verification and validation
- Evaluate data

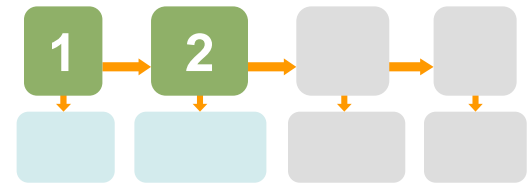
Health Care System

- Recruit patient population
- Provide clinical expertise
- Acquire tissue/blood specimens
- Collect outcome data



- A four-phase process will develop, outline and implement the critical steps for each project.
- In each phase, evaluation of clinical, economic and biomarker performance factors will motivate the decision to proceed to the next phase.





Phase 1: Identify areas of clinical interest

General goals

Assess:

- Areas of medical need
- Current clinical practice
- Performance of current diagnostics and therapeutics
- Opportunities for biomarkers

Time required

1 – 3 months

Activities

- Examine standard of care
- Consult with clinician experts

Phase 2: Assess data requirements and existing resources

General goals

Identify and evaluate data and existing resources required for a successful project

Time required

12 – 18 months

Activities

Economics

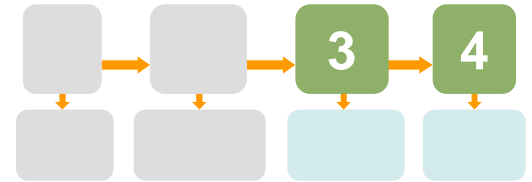
Develop a preliminary economic model to describe opportunities to improve outcomes and reduce costs

Biomarkers

Identify biomarkers in clinical use and those under development

Biospecimens

Identify and assess resources for biospecimen collection



Phase 3: Biomarker Discovery and Development

General goals

- Expand and consolidate economic models
- Develop and verify biomarker panels and assays in the laboratory

Time required

2 – 4 years

Activities

Economics

- Expand, refine and validate economic models
- Collect primary data (if necessary)

Biomarkers

- Prioritize biomarker candidates
- Biomarker discovery
- Biomarker verification
- Develop assay

Biospecimens

- Collect samples for discovery and verification
- Plan sample acquisition for Phase 4

Phase 4: Validation and Outcomes Evaluation

General goals

- Implement biomarker test in the clinical setting
- Correlate with patient outcomes
- Economic analysis of biomarker impact

Time required

1 – 3 years

Activities

Economics

- Cost-effectiveness analysis alongside clinical validation effort
- Iterative feedback with clinical data

Biomarkers/Biospecimens

- Validation in the clinical system
- Iterative process between laboratory assays and clinical outcomes



PPM is a founding partner of the Forum for Personal Health. Members of the Forum can share ideas and solutions to cultivate efficient, needs-driven and evidence-based approaches to developing diagnostics that emphasize prevention, early intervention and cost-effectiveness.

Forum for Personal Health

Goal: To connect science, industry and policy for a healthier world

Format: National and international leaders meet in Seattle, Phoenix and Washington DC to develop robust policy initiatives for health care reform

Members: Major employers
Healthcare providers
Healthcare payers
Diagnostics companies
Government policy makers



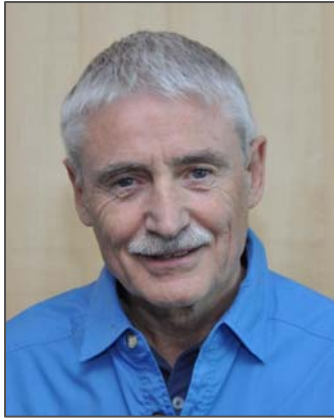
Michael Birt

Leadership and Supporting Foundations



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Lee Hartwell, Alan Nelson and Jeffrey Trent are the three members of the executive committee that provides leadership for PPM.



Lee Hartwell
*President and Director, Fred Hutchinson
Cancer Research Center*

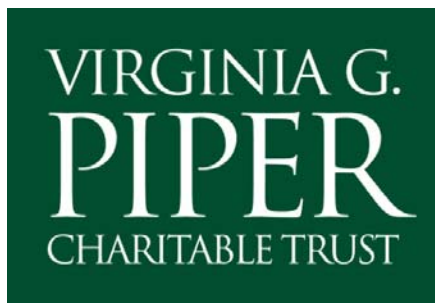


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Jeffrey Trent
*President and Scientific
Director, TGen*

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