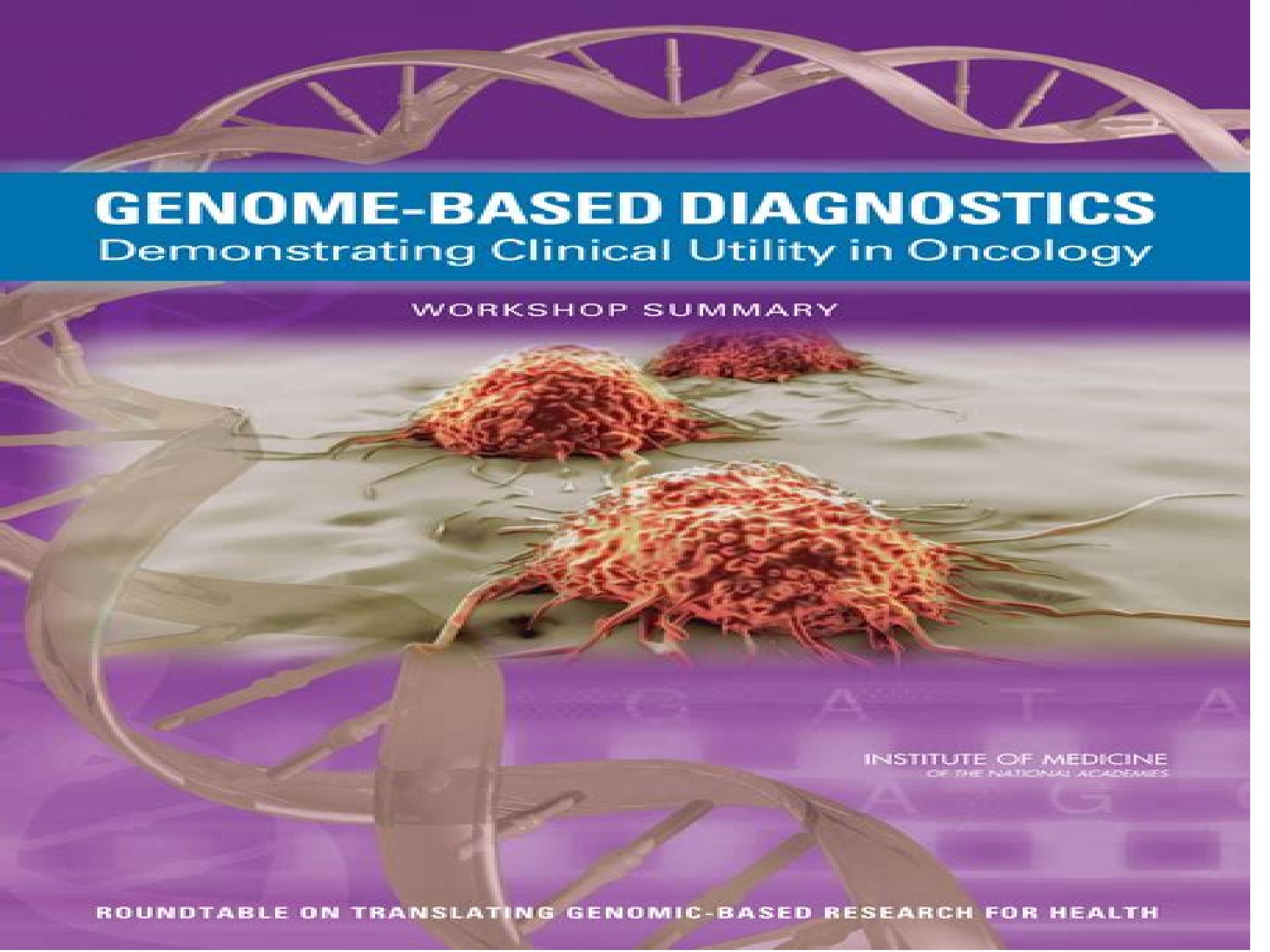
GENOME-BASED DIAGNOSTICS

Demonstrating Clinical Utility in Oncology

WORKSHOP SUMMARY



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

ROUNDTABLE ON TRANSLATING GENOMIC-BASED RESEARCH FOR HEALTH

Genome Based Diagnostics Demonstrating Clinical Utility In Oncology Workshop Summary

J.C. van der Stel

Genome Based Diagnostics Demonstrating Clinical Utility In Oncology Workshop Summary:

Genome-Based Diagnostics Roundtable on Translating Genomic-Based Research for Health,Board on Health Sciences Policy,Institute of Medicine,Center for Medical Technology Policy,2014-01-10 Genome Based Diagnostics Demonstrating Clinical Utility in Oncology is the summary of a workshop convened in May 2012 by the Roundtable on Translating Genomic Based Research for Health and the Center for Medical Technology Policy of the Institute of Medicine to foster the identified need for further sustained dialogue between stakeholders regarding the clinical utility of molecular diagnostics The workshop brought together a wide range of stakeholders including patients health care providers policy makers payers diagnostic test developers researchers and guideline developers to identify the challenges and opportunities in advancing the development and use of molecular diagnostic tests designed to guide the treatment and management of patients with cancer The sequencing of the human genome has greatly accelerated the process of linking specific genetic variants with disease These findings have yielded a rapidly increasing number of molecular diagnostic tests designed to guide disease treatment and management Many of these tests are aimed at determining the best treatments for specific forms of cancer making oncology a valuable testing ground for the use of molecular diagnostic tests in medicine in general Nevertheless many questions surround the clinical value of molecular diagnostic tests and their acceptance by clinicians payers and patients has been unpredictable A major limiting factor for the use of these tests has been the lack of clear evidence of clinical utility Genome Based Diagnostics assesses the evidentiary requirements for clinical utility of molecular diagnostics used to guide treatment decisions for patients with cancer discusses methodologies related to demonstrating these evidentiary requirements that meet the needs of all stakeholders and considers innovative sustainable research collaborations for generating evidence of clinical utility involving multiple stakeholders **Genome-Based Diagnostics** Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for Health,2012-07-27 The sequencing of the human genome and the identification of associations between specific genetic variants and diseases have led to an explosion of genomic based diagnostic tests These tests have the potential to direct therapeutic interventions predict risk or onset of disease or detect residual disease As research progresses and an increasing number of associations are found further tests will be developed that can aid in providing personalized treatment options for patients However the adoption of genomic diagnostic tests by health care providers has been limited due to a lack of evidence regarding the clinical utility of many tests Health funders and practitioners lack the data necessary to distinguish which tests can improve practice or the clinical settings in which tests will provide the greatest value The Roundtable on Translating Genomic Based Research for Health held a workshop in November 2010 to determine what evidence is needed and how it is viewed by different stakeholders in order to develop genomic diagnostic tests of clinical value Genome Based Diagnostics summarizes the presentations and discussions that took place throughout the workshop Two presentations in particular sparked extensive

discussion One presentation proposed that all genomic diagnostic tests be reviewed and approved by the Food and Drug Administration The other observed that venture capitalists are no longer investing substantially in the development of genomic diagnostic tests because of a lack of clarity surrounding regulatory and reimbursement pathways Both presentations suggested the need for major changes in the systems used to develop regulate and reimburse genomic diagnostic tests The report also presents the perspectives of different stakeholders in the development of genomic diagnostic tests Each stakeholder group has a different set of needs and issues of importance yet commonalities among them are apparent such as the need to put patients and health outcomes at the center of discussion and action **Biomarker Tests for Molecularly Targeted Therapies** National Academies of Sciences, Engineering, and Medicine,Institute of Medicine,Board on Health Care Services,Committee on Policy Issues in the Clinical Development and Use of Biomarkers for Molecularly Targeted Therapies,2016-07-30 Every patient is unique and the evolving field of precision medicine aims to ensure the delivery of the right treatment to the right patient at the right time In an era of rapid advances in biomedicine and enhanced understanding of the genetic basis of disease health care providers increasingly have access to advanced technologies that may identify molecular variations specific to an individual patient which subsequently can be targeted for treatment Known as biomarker tests for molecularly targeted therapies these complex tests have the potential to enable the selection of the most beneficial treatment and also to identify treatments that may be harmful or ineffective for the molecular underpinnings of an individual patient s disease Such tests are key to unlocking the promise of precision medicine Biomarker tests for molecularly targeted therapies represent a crucial area of focus for developing methods that could later be applicable to other areas of precision medicine The appropriate regulatory oversight of these tests is required to ensure that they are accurate reliable properly validated and appropriately implemented in clinical practice Moreover common evidentiary standards for assessing the beneficial impact of biomarker guided therapy selection on patient outcomes as well as the effective collection and sharing of information related to those outcomes are urgently needed to better inform clinical decision making Biomarker Tests of Molecularly Targeted Therapies examines opportunities for and challenges to the use of biomarker tests to select optimal therapy and offers recommendations to accelerate progress in this field This report explores regulatory issues reimbursement issues and clinical practice issues related to the clinical development and use of biomarker tests for targeting therapies to patients Properly validated appropriately implemented biomarker tests hold the potential to enhance patient care and improve outcomes and therefore addressing the challenges facing such tests is critical **Lung Cancer** Anne-Marie C. Dingemans,Martin Reck,Virginie Westeel,2015-06-01 Lung cancer is the most common cause of death from cancer worldwide it is estimated to cause nearly one in five cancer deaths Most lung cancer patients are diagnosed late and for many of them there are currently no curative therapy options available meaning long term survival is still low Nevertheless enormous progress has been made in the field during the last decade This Monograph provides a

comprehensive overview of the current knowledge of and advances in lung cancer covering areas such as screening tobacco control COPD diagnosis therapy and treatment of early stage lung cancer from both a surgeon s and radiation oncologist s perspective Very recent achievements in innovative fields such as targeted therapies and immunotherapies are also discussed *Gulf War and Health* Institute of Medicine,Board on the Health of Select Populations,Committee on Gulf War and Health: Long-Term Effects of Blast Exposures,2014-04-14 Since the United States began combat operations in Afghanistan in October 2001 and then in Iraq in March 2003 the numbers of US soldiers killed exceed 6 700 and of US soldiers wounded 50 500 Although all wars since World War I have involved the use of explosives by the enemy the wars in Afghanistan and Iraq differ from previous wars in which the United States has been involved because of the enemy s use of improvised explosive devices IEDs The use of IEDs has led to an injury landscape different from that in prior US wars The signature injury of the Afghanistan and Iraq wars is blast injury Numerous US soldiers have returned home with devastating blast injuries and they continue to experience many challenges in readjusting to civilian life Gulf War and Health Volume 9 is an assessment of the relevant scientific information and draws conclusions regarding the strength of the evidence of an association between exposure to blast and health effects The report also includes recommendations for research most likely to provide VA with knowledge that can be used to inform decisions on how to prevent blast injuries how to diagnose them effectively and how to manage treat and rehabilitate victims of battlefield traumas in the immediate aftermath of a blast and in the long term **Refining Processes for the Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests** Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for Health,2014-03-06 Many drug developers have examined new strategies for creating efficiencies in their development processes including the adoption of genomics based approaches Genomic data can identify new drug targets for both common and rare diseases can predict which patients are likely to respond to a specific treatment and has the potential to significantly reduce the cost of clinical trials by reducing the number of patients that must be enrolled in order to demonstrate safety and efficacy A key component of the approval of targeted therapeutics is the ability to identify the population of patients who will benefit from treatment and this has largely hinged on the co development and co submission to the FDA of a companion diagnostic test The co development process or the development of the test and drug for the simultaneous submission to FDA has led to a major alteration in the way that drugs are being developed with traditionally separate entities pharmaceutical and diagnostic companies now working in close collaboration Refining Processes for the Co Development of Genome Based Therapeutics and Companion Diagnostic Tests is the summary of a workshop held by the Roundtable on Translating Genomic Based Research for Health on February 27 2013 to examine and discuss challenges and potential solutions for the codevelopment of targeted therapeutics and companion molecular tests for the prediction of drug response Prior to the workshop key stakeholders including laboratory and medical professional societies were individually

asked to provide possible solutions to resolve the concerns raised about co development of companion diagnostic tests and therapies Workshop speakers were charged with addressing these solutions in their presentations by providing insight on 1 whether the proposed solutions address the problems described 2 whether there are other solutions to propose and 3 what steps could be taken to effectively implement the proposed solutions **Diffusion and Use of Genomic Innovations in Health and Medicine** Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for Health,2008-06-18 Until fairly recently genetic information was used primarily in the diagnosis of relatively rare genetic diseases such as cystic fibrosis and Huntington s Disease but a transformation in the use of genetic and genomic information is underway While many predictions have been made that genomics will transform medicine to date few of these promising discoveries have resulted in actual applications in medicine and health The Institute of Medicine s Roundtable on Translating Genomic Based Research for Health established in 2007 held its first workshop to address the following questions 1 Are there different pathways by which new scientific findings move from the research setting into health care 2 If so what are the implications of those different pathways for genomics 3 What can we learn from the translation of other new technologies as we seek to understand the translation of genome science into health care Information obtained from the workshop was then used to further discussion and exploration of the answers to these questions This book summarizes speaker presentations and discussions Any conclusions reported should not be construed as reflecting a group consensus rather they are the statements and opinions of presenters and participants **The molecular landscape and promising therapeutic targets in aggressive B-cell non-Hodgkin lymphomas** Niklas Gebauer,Hanno Maximilian Witte,Axel Künstner,Francesco Piazza,Gaël Roué,2023-09-29 Generating Evidence for Genomic Diagnostic Test Development Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for Health,2011-06-27 Ten years after the sequencing of the human genome scientists have developed genetic tests that can predict a person s response to certain drugs estimate the risk of developing Alzheimer s disease and make other predictions based on known links between genes and diseases However genetic tests have yet to become a routine part of medical care in part because there is not enough evidence to show they help improve patients health The Institute of Medicine IOM held a workshop to explore how researchers can gather better evidence more efficiently on the clinical utility of genetic tests Generating Evidence for Genomic Diagnostic Test Development compares the evidence that is required for decisions regarding clearance use and reimbursement to the evidence that is currently generated The report also addresses innovative and efficient ways to generate high quality evidence as well as barriers to generating this evidence Generating Evidence for Genomic Diagnostic Test Development contains information that will be of great value to regulators and policymakers payers health care providers researchers funders and evidence based review groups *Developing Biomarker-Based Tools for Cancer Screening, Diagnosis, and Treatment* Institute of Medicine,National Cancer Policy Forum,2006-11-18 Research has

long sought to identify biomarkers that could detect cancer at an early stage or predict the optimal cancer therapy for specific patients Fueling interest in this research are recent technological advances in genomics proteomics and metabolomics that can enable researchers to capture the molecular fingerprints of specific cancers and fine tune their classification according to the molecular defects they harbor The discovery and development of new markers of cancer could potentially improve cancer screening diagnosis and treatment Given the potential impact cancer biomarkers could have on the cost effectiveness of cancer detection and treatment they could profoundly alter the economic burden of cancer as well Despite the promise of cancer biomarkers few biomarker based cancer tests have entered the market and the translation of research findings on cancer biomarkers into clinically useful tests seems to be lagging This is perhaps not surprising given the technical financial regulatory and social challenges linked to the discovery development validation and incorporation of biomarker tests into clinical practice To explore those challenges and ways to overcome them the National Cancer Policy Forum held the conference Developing Biomarker Based Tools for Cancer Screening Diagnosis and Treatment The State of the Science Evaluation Implementation and Economics in Washington D C from March 20 to 22 2006 At this conference experts gave presentations in one of six sessions In addition seven small group discussions explored the policy implications surrounding biomarker development and adoption into clinical practice Developing Biomarker based Tools for Developing Cancer Screening Diagnosis and Treatment The State of the Science Evaluation Implementation and Economics Workshop Summary presents the conference proceedings and will be used by an Institute of Medicine IOM committee to develop consensus based recommendations for moving the field of cancer biomarkers forward Journal of the National Cancer Institute ,2013 **Policy Issues in the Development and Adoption of Biomarkers for Molecularly Targeted Cancer Therapies** Institute of Medicine,Board on Health Care Services,National Cancer Policy Forum,2015-06-01 A long held goal in oncology has been to develop therapies that target the specific abnormalities in each patient s cancer rather than simply treating cancers based on the tissue of origin In the past decade advances in technology have enabled researchers to relatively quickly and inexpensively determine in minute detail the genetic makeup of tumors Although relatively few targeted cancer therapies are currently available in the clinic and it is not yet clear whether all cancers are driven by genetic changes that can be targeted there is widespread optimism in the cancer community that this new ability to assess the genetic abnormalities in tumors will ultimately lead to better cancer treatments and improved patient outcomes Policy Issues in the Development and Adoption of Biomarkers for Molecularly Targeted Cancer Therapies is the summary of a workshop convened in November 2014 by the Institute of Medicine s National Cancer Policy Forum to discuss recent trends in the development and implementation of molecularly targeted cancer therapies and explore potential policy actions to address specific challenges This report highlights the presentations and discussions at the workshop *Genome-Based Therapeutics* Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for

Health,2012-11-21 The number of new drug approvals has remained reasonably steady for the past 50 years at around 20 to 30 per year while at the same time the total spending on health related research and development has tripled since 1990 There are many suspected causes for this trend including increases in regulatory barriers the rising costs of scientific inquiry a decrease in research and development efficiency the downstream effects of patient expirations on investment and the lack of production models that have successfully incorporated new technology Regardless this trajectory is not economically sustainable for the businesses involved and in response many companies are turning toward collaborative models of drug development whether with other industrial firms academia or government Introducing greater efficiency and knowledge into these new models and aligning incentives among participants may help to reverse the trends highlighted above while producing more effective drugs in the process Genome Based Therapeutics explains that new technologies have the potential to open up avenues of development and to identify new drug targets to pursue Specifically improved validation of gene disease associations through genomics research has the potential to revolutionize drug production and lower development costs Genetic information has helped developers by increasing their understanding of the mechanisms of disease as well as individual patients reactions to their medications There is a need to identify the success factors for the various models that are being developed whether they are industry led academia led or collaborations between the two Genome Based Therapeutics summarizes a workshop that was held on March 21 2012 titled New Paradigms in Drug Discovery How Genomic Data Are Being Used to Revolutionize the Drug Discovery and Development Process At this workshop the goal was to examine the general approaches being used to apply successes achieved so far and the challenges ahead

Genome-Based Diagnostics Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for Health,2012-06-27 The sequencing of the human genome and the identification of associations between specific genetic variants and diseases have led to an explosion of genomic based diagnostic tests These tests have the potential to direct therapeutic interventions predict risk or onset of disease or detect residual disease As research progresses and an increasing number of associations are found further tests will be developed that can aid in providing personalized treatment options for patients However the adoption of genomic diagnostic tests by health care providers has been limited due to a lack of evidence regarding the clinical utility of many tests Health funders and practitioners lack the data necessary to distinguish which tests can improve practice or the clinical settings in which tests will provide the greatest value The Roundtable on Translating Genomic Based Research for Health held a workshop in November 2010 to determine what evidence is needed and how it is viewed by different stakeholders in order to develop genomic diagnostic tests of clinical value Genome Based Diagnostics summarizes the presentations and discussions that took place throughout the workshop Two presentations in particular sparked extensive discussion One presentation proposed that all genomic diagnostic tests be reviewed and approved by the Food and Drug Administration The other observed that venture capitalists

are no longer investing substantially in the development of genomic diagnostic tests because of a lack of clarity surrounding regulatory and reimbursement pathways Both presentations suggested the need for major changes in the systems used to develop regulate and reimburse genomic diagnostic tests The report also presents the perspectives of different stakeholders in the development of genomic diagnostic tests Each stakeholder group has a different set of needs and issues of importance yet commonalities among them are apparent such as the need to put patients and health outcomes at the center of discussion and action **Biopsy Interpretation of the Breast** Stuart J. Schnitt,Laura C. Collins,2009 A practical guide for the diagnostic surgical pathologist this book presents the diverse spectrum of pathologic alterations that occur in the breast in a manner analogous to the way they are encountered in daily practice Lesions are grouped according to their histologic patterns to simulate the way pathologists face these lesions as they examine microscopic slides The approach is based on pattern recognition and emphasizes differential diagnosis The book contains over 500 full color photomicrographs and 50 tables summarizing key clinical and pathologic features and differential diagnostic issues A companion Website will offer 900 full color images plus the fully searchable text and a test bank that is ideal for board preparation **Psychische gezondheidszorg op maat** J.C. van der Stel,2015-02-26 Het lukt vooralsnog niet om de incidentie en prevalentie van ernstige psychische problematiek terug te dringen Aangezien de bevolking steeds ouder wordt en de schaarste aan financi le middelen toeneemt is het essentieel dat we in deze sector eerder beter goedkoper en bij meer mensen resultaten boeken Dit veronderstelt veel meer kennis en kunde dan nu ter beschikking staat n het veronderstelt de actieve betrokkenheid van degenen waar het uiteindelijk om gaat In Psychische gezondheidszorg op maat wordt een lans gebroken voor een psychische gezondheidszorg die echt werk maakt van het ontwikkelen en toepassen van behandelstrategie n die zijn toegesneden op individuele pati nten of cli nten Om deze strategie n te kunnen ontwikkelen is er behoefte aan meer kennis van de mechanismen determinanten en omstandigheden waaronder aandoeningen ontstaan en zich ontwikkelen Een centrale doelstelling van dit boek is dat de psychiatrie respectievelijk de psychische gezondheidszorg kan n moet innoveren In het denken handelen en organiseren kan een substanti le verbetering optreden Deels kan dit al met bestaande middelen Voor een ander deel gaat het erom de onderzoeksprogramma s aan te passen evenals de werkwijzen van instellingen en die van beroepsbeoefenaren Daarbij is het belangrijk ook na te gaan hoe elders in de gezondheidszorg voortgang is geboekt zoals bijv in de oncologie Het accent ligt in dit boek op klinisch herstel maar verbeteringen op dat vlak staan in nauwe samenhang met resultaten op het vlak van functioneel maatschappelijk en persoonlijk herstel *Pathobiology of Human Disease* ,2014-08-01 Pathobiology of Human Disease bridges traditional morphologic and clinical pathology molecular pathology and the underlying basic science fields of cell biology genetics and molecular biology which have opened up a new era of research in pathology and underlie the molecular basis of human disease The work spans more than 48 different biological and medical fields in five basic sections Human Organ Systems Molecular Pathology Basic Mechanisms of Diseases Animal

Models Other Model Systems Experimental Pathology Clinical Pathology Each article provides a comprehensive overview of the selected topic to inform a broad spectrum of readers from research professionals to advanced undergraduate students Reviews quantitative advances in the imaging and molecular analysis of human tissue new microarray technologies for analysis of genetic and chromosomal alterations in normal and diseased cells and tissues and new transgenic models of human disease using conditional tissue specific gene targeting Articles link through to relevant virtual microscopy slides illustrating side by side presentation of Normal and Disease anatomy and histology images Fully annotated with many supplementary full color images graphs tables and video files linked to data sets and to live references enabling researchers to delve deeper and visualize solutions **The National Cancer Institute Early Detection Research Network** S. Srivastava,2008 A field in cancer research and diagnosis is based on the concept of stem progenitor cells as being the primary targets of neoplastic transformation tumor stem cells TSC It is believed that similar to normal tissue organization tumor progression is driven by the TSC component *Cumulated Index Medicus* ,1985 *The Economics of Genomic Medicine* Institute of Medicine,Board on Health Sciences Policy,Roundtable on Translating Genomic-Based Research for Health,2013-07-20 The sequencing of the human genome and the identification of links between specific genetic variants and diseases have led to tremendous excitement over the potential of genomics to direct patient treatment toward more effective or less harmful interventions Still the use of whole genome sequencing challenges the traditional model of medical care where a test is ordered only when there is a clear indication for its use and a path for downstream clinical action is known This has created a tension between experts who contend that using this information is premature and those who believe that having such information will empower health care providers and patients to make proactive decisions regarding lifestyle and treatment options In addition some stakeholders are concerned that genomic technologies will add costs to the health care system without providing commensurate benefits and others think that health care costs could be reduced by identifying unnecessary or ineffective treatments Economic models are frequently used to anticipate the costs and benefits of new health care technologies policies and regulations Economic studies also have been used to examine much more specific issues such as comparing the outcomes and cost effectiveness of two different drug treatments for the same condition These kinds of analyses offer more than just predictions of future health care costs They provide information that is valuable when implementing and using new technologies Unfortunately however these economic assessments are often limited by a lack of data on which to base the examination This particularly affects health economics which includes many factors for which current methods are inadequate for assessing such as personal utility social utility and patient preference To understand better the health economic issues that may arise in the course of integrating genomic data into health care the Roundtable on Translating Genomic Based Research for Health hosted a workshop in Washington DC on July 17 18 2012 that brought together economists regulators payers biomedical researchers patients providers and other stakeholders to discuss the many

factors that may influence this implementation The workshop was one of a series that the roundtable has held on this topic but it was the first focused specifically on economic issues The Economics of Genomic Medicine summarizes this workshop

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