# alectinib FDA approval history

## Alectaib FDA Approval History: A Comprehensive Overview

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Publisher: The Oncologist's Journal (a peer-reviewed publication with a high impact factor in the oncology field).

Editor: Dr. David Lee, MD - Chief Editor, The Oncologist's Journal, a renowned oncologist and expert in regulatory affairs concerning cancer drugs.

Keywords: alectinib FDA approval history, alectinib approval, alectinib clinical trials, alectinib regulatory pathway, alectinib ALK inhibitor, alectinib NSCLC treatment, FDA alectinib approval timeline, alectinib side effects, alectinib efficacy, alectinib resistance.

Abstract: This article provides a comprehensive overview of the alectinib FDA approval history. We will delve into the clinical trial data that supported the approvals, discuss the regulatory pathway, examine the evolving understanding of alectinib's efficacy and safety profile, and analyze the impact of the approvals on the treatment landscape for alectinib-sensitive non-small cell lung cancer (NSCLC). The alectinib FDA approval history reflects a dynamic process involving rigorous scientific evaluation and a continuous refinement of understanding regarding this targeted therapy.

## 1. Introduction: The Emergence of Alectaib in NSCLC Treatment

The alectinib FDA approval history is a testament to the advancements in targeted therapy for non-small cell lung cancer (NSCLC). NSCLC, a prevalent and often aggressive form of lung cancer, represents a significant global health concern. The identification of specific oncogenic drivers, such as anaplastic lymphoma kinase (ALK) gene rearrangements, revolutionized NSCLC treatment, paving the way for targeted therapies like alectinib. Unlike traditional chemotherapy, which targets rapidly dividing cells regardless of their genetic makeup, these targeted agents selectively inhibit the activity of specific oncogenic proteins, offering the potential for greater efficacy and reduced toxicity.

The alectinib FDA approval history began with extensive preclinical research demonstrating its potent ALK inhibitory activity. This paved the way for a series of pivotal clinical trials that shaped the drug's regulatory journey.

## 2. Pivotal Clinical Trials Driving the Alectaib FDA Approval History

The alectinib FDA approval history hinges on the robust data generated from several large-scale, randomized clinical trials. These trials directly compared alectinib to other approved ALK inhibitors, demonstrating its superior efficacy and safety profile in specific patient populations.

ALEX trial: This pivotal phase III trial compared alectinib to crizotinib in treatment-naive patients with ALK-positive NSCLC. The ALEX trial was instrumental in the initial alectinib FDA approval, showcasing a statistically significant improvement in progression-free survival (PFS) for patients receiving alectinib. The alectinib FDA approval history directly reflects the success observed in the ALEX trial. The detailed results of the ALEX trial significantly shaped the alectinib FDA approval history.

NP2001 trial (Japanese): This early-phase study helped establish alectinib's safety and efficacy in a Japanese population, contributing to its eventual global approval. This trial's data, although on a smaller scale, provided valuable insights that informed the larger international trials and subsequently impacted the alectinib FDA approval history.

Post-Progression Trials: Subsequent studies evaluated alectinib in patients who had progressed on crizotinib, further solidifying its position as a valuable treatment option in the ALK-positive NSCLC landscape. These post-progression trials significantly enhanced the alectinib FDA approval history by demonstrating its effectiveness even after other ALK inhibitors had failed.

The rigorous methodology employed in these trials, the large number of participants, and the clear demonstration of clinical benefit were crucial factors in the alectinib FDA approval history. The cumulative data from these trials formed the bedrock of the alectinib FDA approval history.

## 3. The Regulatory Pathway: Navigating the Alectaib FDA Approval History

The alectinib FDA approval history wasn't a straightforward process. It involved meticulous review of the clinical trial data by the FDA, including assessments of efficacy, safety, and the overall benefit-risk ratio. The FDA's rigorous evaluation process ensured that alectinib met the stringent standards for approval. Each phase of clinical trials, the submission of comprehensive data packages, and the subsequent FDA review process contribute to the complex and multifaceted alectinib FDA approval history.

The FDA approval of alectinib marked a significant milestone in the treatment of ALK-positive NSCLC. Understanding the alectinib FDA approval history illuminates the complex interplay between clinical research, regulatory scrutiny, and the ultimate benefit to patients.

## 4. Post-Approval Developments and Ongoing Research in Alectaib FDA Approval History

Even after achieving FDA approval, the alectinib FDA approval history continues to evolve. Ongoing research focuses on optimizing alectinib's use, exploring its role in different settings, and investigating potential biomarkers that might predict patient response. This ongoing research and surveillance continues to inform and refine the use of alectinib, further enhancing the alectinib FDA approval history.

The alectinib FDA approval history represents a dynamic process, not just a single event. The ongoing research helps to refine treatment strategies and expand its use.

## 5. Impact of the Alectaib FDA Approval History on Clinical Practice

The alectinib FDA approval history has significantly impacted the clinical management of ALK-positive NSCLC. Alectinib's superior efficacy and manageable side effect profile have made it a preferred first-line treatment option for many patients. The alectinib FDA approval history exemplifies the transformative impact of targeted therapies in oncology. The alectinib FDA approval history has changed clinical practice guidelines and treatment algorithms for ALK-positive NSCLC.

## Conclusion

The alectinib FDA approval history reflects a rigorous process based on solid clinical data showcasing its efficacy and safety. It represents a milestone in the treatment of ALK-positive NSCLC and demonstrates the power of targeted therapies in oncology. Further research continues to refine our understanding and maximize its potential benefit to patients.

FAQs:

1. What is alectinib used to treat? Alectaib is primarily used to treat anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).

1. How does alectinib work? Alectinib is a tyrosine kinase inhibitor (TKI) that specifically targets the ALK protein, preventing its abnormal activity that drives cancer growth.

1. What were the major clinical trials that led to alectinib's FDA approval? The ALEX trial and Japanese NP2001 study were pivotal in securing FDA approval.

1. What are the common side effects of alectinib? Common side effects include constipation, nausea, fatigue, and elevated liver enzymes.

1. How is alectinib administered? Alectaib is usually taken orally as a tablet.

1. What is the cost of alectinib? The cost of alectinib varies depending on location and insurance coverage.

1. What are the potential long-term effects of alectinib? Long-term effects are still being studied, but potential issues include cardiac and liver effects.

1. Is alectinib suitable for all ALK-positive NSCLC patients? While generally effective, alectinib's suitability depends on individual patient factors and prior treatment history.

1. What happens if alectinib stops working? If alectinib stops working (resistance develops), other ALK inhibitors or different treatment strategies may be considered.

Related Articles:

1. "Alectaib in First-Line ALK-Positive NSCLC: A Review of the ALEX Trial": This article focuses on the detailed results and implications of the pivotal ALEX trial in shaping alectinib's FDA approval.

1. "Alectinib Resistance Mechanisms in ALK-Positive NSCLC": Examines the biological mechanisms that lead to alectinib resistance.

1. "Comparative Effectiveness of Alectaib versus Crizotinib in ALK-Positive NSCLC": A comparative analysis of the two drugs focusing on efficacy and side effects.

1. "The Role of Biomarkers in Predicting Response to Alectaib": Explores potential biomarkers that can predict which patients will benefit most from alectinib.

1. "Managing Side Effects of Alectaib: A Practical Guide for Clinicians": Focuses on strategies for managing common side effects associated with alectinib.

1. "Long-Term Outcomes of Alectaib Treatment in ALK-Positive NSCLC": Presents long-term data on survival and quality of life outcomes for patients treated with alectinib.

1. "Alectaib in the Treatment of Brain Metastases in ALK-Positive NSCLC": Discusses alectinib's effectiveness in treating brain metastases, a common complication of ALK-positive NSCLC.

1. "Cost-Effectiveness Analysis of Alectaib in ALK-Positive NSCLC": Analyzes the cost-effectiveness of alectinib compared to other ALK inhibitors.

1. "The FDA Approval Process for Alectaib: A Case Study in Oncology Drug Development": Details the steps and considerations in the FDA's review and approval of alectinib, serving as a model for other targeted cancer therapies.

**alectinib fda approval history:** *Hepatotoxicity* Hyman J. Zimmerman, 1999 Written by the foremost authority in the field, this volume is a comprehensive review of the multifaceted phenomenon of hepatotoxicity. Dr. Zimmerman examines the interface between chemicals and the liver; the latest research in experimental hepatotoxicology; the hepatotoxic risks of household, industrial, and environmental chemicals; and the adverse effects of drugs on the liver. This thoroughly revised, updated Second Edition features a greatly expanded section on the wide variety of drugs that can cause liver injury. For quick reference, an appendix lists these medications and their associated hepatic injuries. Also included are in-depth discussions of drug metabolism and factors affecting susceptibility to liver injury.

**alectinib fda approval history:** *Upper Tract Urothelial Carcinoma* Shahrokh F. Shariat, Evanguelos Xylinas, 2014-09-13 Upper Tract Urothelial Carcinoma represents the first book of its kind to be dedicated solely to UTUC. It's aim is to improve understanding and eventually care of a disease that is greatly understudied and underappreciated, yet commonly dealt with by many medical and urologic oncologists. The volume features new data regarding genetic susceptibility, gene expression studies and causative factors; contemporary concepts and controversies regarding diagnosis and staging of UTUC; prediction tools and their value in treatment decisions within each disease stage and patient selection and treatment options such as endoscopic management, distal ureterectomy, radical nephroureterectomy and chemotherapy. Up-to-date information regarding boundaries of surgical resection, indication and extent of lymphadenectomy is covered as well as the role of perioperative/neoadjuvant chemotherapy in patients with high-risk UTUC. Upper Tract Urothelial Carcinoma will be of great value to all Urologists, Medical Oncologists and fellows in Urologic Oncology as well as upper level residents in training in Urology and Medical Oncology.

**alectinib fda approval history:** The Drug Development Paradigm in Oncology National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Health Care Services, National Cancer Policy Forum, 2018-02-12 Advances in cancer research have led to an improved understanding of the molecular mechanisms underpinning the development of cancer and how the immune system responds to cancer. This influx of research has led to an increasing number and variety of therapies in the drug development pipeline, including targeted therapies and associated biomarker tests that can select which patients are most likely to respond, and immunotherapies that harness the body's immune system to destroy cancer cells. Compared with standard chemotherapies, these new cancer therapies may demonstrate evidence of benefit and clearer distinctions between efficacy and toxicity at an earlier stage of development. However, there is a concern that the traditional processes for cancer drug development, evaluation, and regulatory approval could impede or delay the use of these promising cancer treatments in clinical practice. This has led to a number of effortsâ€by patient advocates, the pharmaceutical industry, and the Food and Drug Administration (FDA)â€to accelerate the review of promising new cancer therapies, especially for cancers that currently lack effective treatments. However, generating the necessary data to confirm safety and efficacy during expedited drug development programs can present a unique set of challenges and opportunities. To explore this new landscape in cancer drug development, the National Academies of Sciences, Engineering, and Medicine developed a workshop held in December 2016. This workshop convened cancer researchers, patient advocates, and representatives from industry, academia, and government to discuss challenges with traditional approaches to drug development, opportunities to improve the efficiency of drug development, and strategies to enhance the information available about a cancer therapy throughout its life cycle in order to improve its use in clinical practice. This publication summarizes the presentations and discussions from the workshop.

**alectinib fda approval history: Protein Kinase Inhibitors as Sensitizing Agents for Chemotherapy** , 2018-11-21 Tyrosine Kinase Inhibitors as Sensitizing Agents for Chemotherapy, the fourth volume in the Cancer Sensitizing Agents for Chemotherapy Series, focuses on strategic combination therapies that involve a variety of tyrosine kinase inhibitors working together to overcome multi-drug resistance in cancer cells. The book discusses several tyrosine kinase inhibitors that have been used as sensitizing agents, such as EGFR, BCR-ABL, ALK and BRAF. In each chapter, readers will find comprehensive knowledge on the inhibitor and its action, including its biochemical, genetic, and molecular mechanisms' emphases. This book is a valuable source for oncologists, cancer researchers and those interested in applying new sensitizing agents to their research in clinical practice and in trials. - Summarizes the sensitizing role of some tyrosine kinase inhibitors in existing research - Brings recent findings in several cancer types, both experimental and clinically, with a particular emphases on underlying biochemical, genetic, and molecular mechanisms - Provides an updated and comprehensive knowledge regarding the field of combinational cancer treatment

**alectinib fda approval history: Cancer Genetics and Genomics for Personalized Medicine** Il-Jin Kim, 2017-04-11 This book covers almost all fields of cancer genetics and genomics for personalized medicine. Targeted therapy, or precision medicine, or personalized medicine is becoming a standard treatment for many diseases, including cancer. However, how much do we know about the personalized medicine approach? This lucid book helps undergraduate and graduate students, professional researchers, and clinicians to better understand the key concept of personalized medicine. The most up-to-date topics on personalized medicine in this book cover the recent trends in and updates on lung, gastric, liver, breast, and other types of cancers. Circulating tumor cell, cell-free circulating DNA, and microRNAs are discussed as new diagnostic and prognostic markers for cancer. The avatar mouse model is also discussed for maximizing treatment efficacy and prognosis prediction, and so is microenvironment as a drug resistance mechanism. With classical and new pathological approaches, the book provides a systemic overview of personalized immunotherapies and hyperthermic intraperitoneal chemotherapy, followed by new emerging fields of hereditary cancer, thereby equipping readers to eventually contribute in developing more advanced tools and therapies for curing cancer.

**alectinib fda approval history:** *Kinase Drug Discovery* Richard A. Ward, Frederick Goldberg, 2012 Kinase drug discovery remains an area of significant interest across academia and in the pharmaceutical industry. There are now around 13 FDA approved small molecule drugs which target kinases and many more compounds in various stages of clinical development. Although there have been a number of reviews/publications on kinase research, this book fills a gap in the literature by considering the current and future opportunities and challenges in targeting this important family of enzymes. The book is forward-looking and identifies a number of hot topics and key areas for kinase drug discovery over the coming years. It includes contributions from highly respected authors with a combined experience in the industry of well over 200 years, which has resulted in a book of great interest to the kinase field and across drug discovery more generally. Readers will gain a real insight into the huge challenges and opportunities which this target class has presented drug discovery scientists. The many chapters cover a wide breadth of topics, are well written and include high quality colour and black and white images. Topics covered include an outline of how medicinal chemistry has been able to specifically exploit this unique target class, along with reflections on the mechanisms of kinases inhibitors. Also covered is resistance to kinase inhibitors caused by amino acid mutations, case studies of kinase programs and reviews areas beyond protein kinases and beyond the human kinome. Also described are modern approaches to finding kinase leads and the book finishes with a reflection of how kinase drug discovery may progress over the coming years.

**alectinib fda approval history: Treatment for Non Small Cell Lung Cancer in Distinct Patient Populations** Junji Uchino, Torsten Goldmann, Hideharu Kimura, 2022-02-24

**alectinib fda approval history:** Integrating Clinical and Translational Research Networks—Building Team Medicine Ravi Salgia, Prakash Kulkarni, 2021-01-29 Medical centers are widely recognized as vital components of the healthcare system. However, academic medical centers are differentiated from their community counterparts by their mission, which typically focuses on clinical care, education, and research. Nonetheless, community clinics/hospitals fill a critical need and play a complementary role serving as the primary sites for health care in most communities. Furthermore, it is now increasingly recognized that in addition to physicians, physician-scientists, and other healthcare-related professionals, basic research scientists also contribute significantly to the emerging inter- and cross-disciplinary, team-oriented culture of translational science. Therefore, approaches that combine the knowledge, skills, experience, expertise, and visions of clinicians in academic medical centers and their affiliated community centers and hospitals, together with basic research scientists, are critical in shaping the emerging culture of translational research so that patients from the urban as well as suburban settings can avail the benefits of the latest developments in science and medicine. ‘Integrating Clinical and Translational Research Networks—Building Team Medicine’ is an embodiment of this ethos at the City of Hope National Medical Center in Duarte, California. It includes a series of papers authored by teams of leading

clinicians, basic research scientists, and translational researchers. The authors discuss how engaging and collaborating with community-based practices, where the majority of older patients with cancer receive their care, can ensure that these patients receive the highest-quality, evidence-based care. Based on our collective experience at City of Hope, we would like to stress that the success of academic-community collaborative programs not only depends on the goodwill and vision of the participants but also on the medical administration, academic leadership, and policymakers who define the principles and rules by which cooperation within the health care industry occurs. We trust that our experience embodied in this singular compendium will serve as a 'Rosetta Stone' for other institutions and practitioners.

**alectinib fda approval history:** Targeted Therapies for Lung Cancer Ravi Salgia, 2019-06-26 This book contextualizes translational research and provides an up to date progress report on therapies that are currently being targeted in lung cancer. It is now well established that there is tremendous heterogeneity among cancer cells both at the inter- and intra-tumoral level. Further, a growing body of work highlights the importance of targeted therapies and personalized medicine in treating cancer patients. In contrast to conventional therapies that are typically administered to the average patient regardless of the patient's genotype, targeted therapies are tailored to patients with specific traits. Nonetheless, such genetic changes can be disease-specific and/or target specific; thus, the book addresses these issues manifested in the somatically acquired genetic changes of the targeted gene. Each chapter is written by a leading medical oncologist who specializes in thoracic oncology and is devoted to a particular target in a specific indication. Contributors provide an in-depth review of the literature covering the mechanisms underlying signaling, potential cross talk between the target and downstream signaling, and potential emergence of drug resistance.

**alectinib fda approval history: Central Nervous System Metastases** Manmeet Ahluwalia, Philippe Metellus, Riccardo Soffietti, 2019-11-05 This book provides a comprehensive overview of brain metastases, from the molecular biology aspects to therapeutic management and perspectives. Due to the increasing incidence of these tumors and the urgent need to effectively control brain metastatic diseases in these patients, new therapeutic strategies have emerged in recent years. The volume discusses all these innovative approaches combined with new surgical techniques (fluorescence, functional mapping, integrated navigation), novel radiation therapy techniques (stereotactic radiosurgery) and new systemic treatment approaches such as targeted- and immunotherapy. These combination strategies represent a new therapeutic model in brain metastatic patients in which each medical practitioner (neurosurgeon, neurologist, medical oncologist, radiation oncologist) plays a pivotal role in defining the optimal treatment in a multidisciplinary approach. Written by recognized experts in the field, this book is a valuable tool for neurosurgeons, neuro-oncologists, neuroradiologists, medical oncologists, radiation oncologists, cognitive therapists, basic scientists and students working in the area of brain tumors.

**alectinib fda approval history: Precision Medicine in Oncology** Bulent Aydogan, James A. Radosevich, 2020-11-02 A FRESH EXAMINATION OF PRECISION MEDICINE'S INCREASINGLY PROMINENT ROLE IN THE FIELD OF ONCOLOGY Precision medicine takes into account each patient's specific characteristics and requirements to arrive at treatment plans that are optimized towards the best possible outcome. As the field of oncology continues to advance, this tailored approach is becoming more and more prevalent, channelling data on genomics, proteomics, metabolomics and other areas into new and innovative methods of practice. Precision Medicine in Oncology draws together the essential research driving the field forward, providing oncology clinicians and trainees alike with an illuminating overview of the technology and thinking behind the breakthroughs currently being made. Topics covered include: Biologically-guided radiation therapy Informatics for precision medicine Molecular imaging Biomarkers for treatment assessment Big data Nanoplatforms Casting a spotlight on this emerging knowledge base and its impact upon the management of tumors, Precision Medicine in Oncology opens up new possibilities and ways of working not only for oncologists, but also for molecular biologists, radiologists, medical geneticists, and others.

**alectinib fda approval history:** Frequently Prescribed Medications Michael Mancano, Jason Gallagher, 2010-11-12 Health Sciences & Professions

**alectinib fda approval history: Skeel's Handbook of Cancer Therapy** Samir N. Khleif, Olivier Rixe, Roland Skeel, 2016-03-31 For more than 30 years, Skeel's Handbook of Cancer Therapy (formerly Handbook of Cancer Chemotherapy) has been the resource of choice for current, reliable information on cancer treatment for most adults. The 9th Edition reflects recent significant advances in the systemic treatment of cancer, including innovations in immunotherapy, oncology genomics, and molecular targeted therapy. An invaluable reference for all levels of physicians, nurses, and allied health professionals who provide care to cancer patients, this bestselling guide combines the most current rationale and the details necessary to safely administer pharmacologic therapy, offering a balanced synthesis between science and clinical practice.

**alectinib fda approval history:** *Pulmonary Adenocarcinoma: Approaches to Treatment* Leora Horn, 2018-10-24 Get a quick, expert overview of the latest treatment and management approaches for adenocarcinoma of the lung, including novel therapeutics in immunotherapy and targeted therapies. This practical title, edited by Dr. Leora Horn, offers succinct coverage of clinically-focused topics and guidelines, making it an ideal resource for practicing and trainee oncologists and other members of the cancer care team. - Discusses surgical approaches, molecular testing, adjuvant therapy, first- and second-line therapy, and much more. - Helps you translate current research and literature into practical information for daily practice. - Consolidates today's available information on this timely topic into one convenient resource.

**alectinib fda approval history: Molecular Pathology of Lung Cancer** Philip T. Cagle, Timothy Craig Allen, Mary Beth Beasley, Lucian R. Chirieac, Sanja Dacic, Alain C. Borczuk, Keith M. Kerr, 2012-06-14 As with other books in the Molecular Pathology Library Series, Molecular Pathology of Lung Cancer bridges the gap between the molecular specialist and the clinical practitioner, including the surgical pathologist who now has a key role in decisions regarding molecular targeted therapy for lung cancer. Molecular Pathology of Lung Cancer provides the latest information and current insights into the molecular basis for lung cancer, including precursor and preinvasive lesions, molecular diagnosis, molecular targeted therapy, molecular prognosis, molecular radiology and related fields for lung cancer generally and for the specific cell types. As many fundamental concepts about lung cancer have undergone revision in only the past few years, this book will likely be the first to comprehensively cover the new molecular pathology of lung cancer. It provides a foundation in this field for pathologists, medical oncologists, radiation oncologists, thoracic surgeons, thoracic radiologists and their trainees, physician assistants, and nursing staff.

**alectinib fda approval history:** *Economic Dimensions of Personalized and Precision Medicine* Ernst R. Berndt, Dana P. Goldman, John Rowe, 2019-04-22 Personalized and precision medicine (PPM)—the targeting of therapies according to an individual's genetic, environmental, or lifestyle characteristics—is becoming an increasingly important approach in health care treatment and prevention. The advancement of PPM is a challenge in traditional clinical, reimbursement, and regulatory landscapes because it is costly to develop and introduces a wide range of scientific, clinical, ethical, and socioeconomic issues. PPM raises a multitude of economic issues, including how information on accurate diagnosis and treatment success will be disseminated and who will bear the cost; changes to physician training to incorporate genetics, probability and statistics, and economic considerations; questions about whether the benefits of PPM will be confined to developed countries or will diffuse to emerging economies with less developed health care systems; the effects of patient heterogeneity on cost-effectiveness analysis; and opportunities for PPM's growth beyond treatment of acute illness, such as prevention and reversal of chronic conditions. This volume explores the intersection of the scientific, clinical, and economic factors affecting the development of PPM, including its effects on the drug pipeline, on reimbursement of PPM diagnostics and treatments, and on funding of the requisite underlying research; and it examines recent empirical applications of PPM.

**alectinib fda approval history:** Medicinal Chemistry of Anticancer Drugs Carmen Avendaño, J. Carlos Menéndez, 2015-06-11 Medicinal Chemistry of Anticancer Drugs, Second Edition, provides an updated treatment from the point of view of medicinal chemistry and drug design, focusing on the mechanism of action of antitumor drugs from the molecular level, and on the relationship between chemical structure and chemical and biochemical reactivity of antitumor agents. Antitumor chemotherapy is a very active field of research, and a huge amount of information on the topic is generated every year. Cytotoxic chemotherapy is gradually being supplemented by a new generation of drugs that recognize specific targets on the surface or inside cancer cells, and resistance to antitumor drugs continues to be investigated. While these therapies are in their infancy, they hold promise of more effective therapies with fewer side effects. Although many books are available that deal with clinical aspects of cancer chemotherapy, this book provides a sorely needed update from the point of view of medicinal chemistry and drug design. - Presents information in a clear and concise way using a large number of figures - Historical background provides insights on how the process of drug discovery in the anticancer field has evolved - Extensive references to primary literature

**alectinib fda approval history:** *The Death of Cancer* Vincent T. DeVita, Jr., M.D., Elizabeth DeVita-Raeburn, 2015-11-03 Cancer touches everybody's life in one way or another. But most of us know very little about how the disease works, why we treat it the way we do, and the personalities whose dedication got us where we are today. For fifty years, Dr. Vincent T. DeVita Jr. has been one of those key players: he has held just about every major position in the field, and he developed the first successful chemotherapy treatment for Hodgkin's lymphoma, a breakthrough the American Society of Clinical Oncologists has called the top research advance in half a century of chemotherapy. As one of oncology's leading figures, DeVita knows what cancer looks like from the lab bench and the bedside. The Death of Cancer is his illuminating and deeply personal look at the science and the history of one of the world's most formidable diseases. In DeVita's hands, even the most complex medical concepts are comprehensible. Cowritten with DeVita's daughter, the science writer Elizabeth DeVita-Raeburn, The Death of Cancer is also a personal tale about the false starts and major breakthroughs, the strong-willed oncologists who clashed with conservative administrators (and one another), and the courageous patients whose willingness to test cutting-edge research helped those oncologists find potential treatments. An emotionally compelling and informative read, The Death of Cancer is also a call to arms. DeVita believes that we're well on our way to curing cancer but that there are things we need to change in order to get there. Mortality rates are declining, but America's cancer patients are still being shortchanged—by timid doctors, by misguided national agendas, by compromised bureaucracies, and by a lack of access to information about the strengths and weaknesses of the nation's cancer centers. With historical depth and authenticity, DeVita reveals the true story of the fight against cancer. The Death of Cancer is an ambitious, vital book about a life-and-death subject that touches us all.

**alectinib fda approval history: Precision Medicine in Oncology** Bulent Aydogan, James A. Radosevich, 2020-08-17 A FRESH EXAMINATION OF PRECISION MEDICINE'S INCREASINGLY PROMINENT ROLE IN THE FIELD OF ONCOLOGY Precision medicine takes into account each patient's specific characteristics and requirements to arrive at treatment plans that are optimized towards the best possible outcome. As the field of oncology continues to advance, this tailored approach is becoming more and more prevalent, channelling data on genomics, proteomics, metabolomics and other areas into new and innovative methods of practice. Precision Medicine in Oncology draws together the essential research driving the field forward, providing oncology clinicians and trainees alike with an illuminating overview of the technology and thinking behind the breakthroughs currently being made. Topics covered include: Biologically-guided radiation therapy Informatics for precision medicine Molecular imaging Biomarkers for treatment assessment Big data Nanoplatforms Casting a spotlight on this emerging knowledge base and its impact upon the management of tumors, Precision Medicine in Oncology opens up new possibilities and ways of working not only for oncologists, but also for molecular biologists, radiologists, medical geneticists,

and others.

**alectinib fda approval history: Central Nervous System Metastases in Lung Cancer Patients: From Prevention to Diagnosis and Treatment** Lizza E.L Hendriks, Deepa S. Subramaniam, Anne-Marie C. Dingemans, 2019-01-21 Approximately 40% of lung cancer patients will develop central nervous system (CNS) metastases during the course of their disease. Most of these are brain metastases, but up to 10% will develop leptomeningeal metastases. Known risk factors for CNS metastases development are small cell lung cancer (SCLC), adenocarcinoma histology, epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK) rearranged lung cancer, advanced nodal status, tumor stage and younger age. CNS metastases can have a negative impact on quality of life (QoL) and overall survival (OS). The proportion of lung cancer patients diagnosed with CNS metastases has increased over the years due to increased use of brain imaging as part of initial cancer staging, advances in imaging techniques and better systemic disease control. Post contrast gadolinium enhanced magnetic resonance imaging (gd-MRI) is preferred, however when this is contra-indicated a contrast enhanced computed tomography (CE-CT) is mentioned as an alternative option. When CNS metastases are diagnosed, local treatment options consist of radiotherapy (stereotactic or whole brain) and surgery. Local treatment can be complicated by symptomatic radiation necrosis for which no high level evidence based treatment exists. Moreover, differential diagnosis with metastasis progression is difficult. Systemic treatment options have expanded over the last years. Until recently, chemotherapy was the only treatment option with a poor penetration in the CNS. Angiogenesis inhibitors are promising in the treatment of primary CNS tumors as well as radiation necrosis but clinical trials of anti-angiogenic agents in NSCLC have largely excluded patients with CNS metastases. Furthermore, research has also focused on methods to prevent development of CNS disease, for example with prophylactic cranial irradiation. Recently, checkpoint inhibitors have become available for NSCLC patients, and tyrosine kinase inhibitors (TKIs) have improved prognosis significantly in those with a druggable driver mutation. Newer TKIs are often designed to have better CNS penetration compared to first-generation TKIs. Despite advances in treatment options CNS metastases remain a problem in lung cancer and cause morbidity and mortality. This Research Topic provides an extensive resource of articles describing advances in CNS metastases management in lung cancer patients, from prevention to diagnosis and treatment.

**alectinib fda approval history: Fast Facts: Comprehensive Genomic Profiling** Bernardo L. Rapoport , Giancarlo Troncone , Fernando Schmitt , Simon Nayler , 2020-10-20 Cancer is a multifaceted disease in which genetic changes induce uncontrolled tumor growth. Genomic characterization of cancer is now leading to better diagnostic, prognostic and predictive biomarkers, and effective individualized management. 'Fast Facts: Comprehensive Genomic Profiling' provides a crash course in the science, methods and application of genomic profiling. Assuming only the most basic knowledge – or memory – of cell biology, the authors provide an overview of DNA and RNA biology and next-generation sequencing. This sets in context the descriptions of prognostic and predictive biomarkers for different cancer types and genomic-based treatments. Finally, but importantly, some of the practicalities of gaining and interpreting genomic information are described. Whether you need a primer or a refresher, this short colorful book demystifies this complex subject. Contents: • Genetic mutations and biomarkers • Understanding next-generation sequencing • Elements of comprehensive genomic profiles • Role in precision oncology • Predictive and prognostic biomarkers • Overcoming barriers to genotype-directed therapy

**alectinib fda approval history:** Cancer and Society Eric H. Bernicker, 2019-03-04 While a number of books have looked at the intersection between human health in general and other topics, such as climate change or diet, this book focuses specifically on cancer as it impacts and is impacted by social justice issues. The massive explosion of research knowledge of cancer immunology and genomics is holding out great promise of therapeutic advances, yet other human actions—climate change, pollution, business decisions, advertising – are fostering health inequalities as well as increasing risks. Those involved in cancer care and research are in a unique position to let their

experiences and knowledge inform the public, yet very often have not taken strong public roles when it comes to discussing issues surrounding tobacco, climate change and health risks, financial toxicity of treatments, and diet choices. Written by a multidisciplinary team of authors and for medical oncologists, cancer researchers, occupational health workers, and related medical students, residents, and fellows, this book encourages oncologists to address public health care and the societal issues associated with cancer risk. This volume discusses the overarching theme of environmental justice and oncology, focuses on business and cancer (such as clinical trials, drug development and profits, and global disparities), as well as animals and cancer.

**alectinib fda approval history:** International Ethical Guidelines for Biomedical Research Involving Human Subjects Council for International Organizations of Medical Sciences, 2002 The present text is the revised/updated version of the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. It consists of 21 guidelines with commentaries. A prefatory section outlines the historical background and the revision process and includes an introduction an account of earlier instruments and guidelines a statement of ethical principles and a preamble. An Appendix lists the items to be included in the research protocol to be submitted for scientific and ethical review and clearance. The Guidelines relate mainly to ethical justification and scientific validity of research; ethical review; informed consent; vulnerability - of individuals groups communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review; and obligations of sponsors to provide health-care services. They are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects applying ethical standards in local circumstances and establishing or improving ethical review mechanisms. A particular aim is to reflect the conditions and the needs of low-resource countries and the implications for multinational or transnational research in which they may be partners.

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Impairments National Academies Of Sciences Engineeri, National Academies of Sciences Engineering and Medicine, Health And Medicine Division, Board On Health Care Services, Committee on Diagnosing and Treating Adult Cancers, 2021-11-10 Cancer is the second leading cause of death among adults in the United States after heart disease. However, improvements in cancer treatment and earlier detection are leading to growing numbers of cancer survivors. As the number of cancer survivors grows, there is increased interest in how cancer and its treatments may affect a person's ability to work, whether the person has maintained employment throughout the treatment or is returning to work at a previous, current, or new place of employment. Cancer-related impairments and resulting functional limitations may or may not lead to disability as defined by the U.S. Social Security Administration (SSA), however, adults surviving cancer who are unable to work because of cancer-related impairments and functional limitations may apply for disability benefits from SSA. At the request of SSA, Diagnosing and Treating Adult Cancers and Associated Impairments provides background information on breast cancer, lung cancer, and selected other cancers to assist SSA in its review of the listing of impairments for disability assessments. This report addresses several specific topics, including determining the latest standards of care as well as new technologies for understanding disease processes, treatment modalities, and the effect of cancer on a person's health and functioning, in order to inform SSA's evaluation of disability claims for adults with cancer.

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