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The FDA has given the Ki-67 IHC MIB-1 pharmDx assay a companion diagnostic approval for detecting Ki-67 expression in patients with high-risk early breast cancer who are being considered for treatment ...

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Castle announced data presentations on the Company's dermatologic GEP tests at the 2021 Fall Clinical Dermatology Conference, held Oct. 21-24.

~~Castle Biosciences Presents Data from Suite of Dermatologic Cancer Genomic Tests at Fall Clinical Dermatology Conference 2021~~
Supported by a $2.9 million grant from the National Institutes of Health and led by Robin Queen, the Kevin P. Granata Faculty Fellow and professor of biomedical engineering and mechanics, a team of ...

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Tabletop exercises (TTX) are simulated attacks that help organizations (big and small) prepare for and respond to real-world cyber attacks, like ransomware. They help facilitate important discussions ...

~~Prepare for Ransomware: Three Benefits of Tabletop Exercises~~
Statistics Canada revealed that South Asians have reported lower levels of mental health than any other Canadians during the pandemic: a neuropsychology student explains some of the reasons.

~~How mental health issues get stigmatized in South Asian communities: Culturally diverse therapy needed~~
The frequency of cyberattacks on industrial operations has increased in recent years, with ransomware attacks pa ...

~~KPMG Report: Cyber PHA method braces industrial sector against cybersecurity and safety risks~~
A small-scale study concludes that infrared light therapy may improve memory and motor function of middle-aged people with mild cognitive impairment.

~~Infrared light therapy: A new approach to dementia?~~
US FDA approves Agilent ' s companion diagnostic assay, Ki-67 IHC MIB-1 pharmDx to identify high-risk early breast cancer: Santa Clara, California Saturday, October 16, 2021, 14:3 ...

~~US FDA approves Agilent ' s companion diagnostic assay, Ki-67 IHC MIB-1 pharmDx to identify high-risk early-breast cancer~~
The health and well-being of pregnant women has a major influence on the health of their babies and an adequate intak ...

~~Malnourished mothers a higher risk of delivering babies with poor birth outcomes~~
Despite advances with MRD monitoring, further research and practice advances are needed to continue the trend for improving outcomes in patients with acute lymphoblastic leukemia.

~~Improved Sensitivity, Monitoring Needed for MRD in Adult and Pediatric ALL~~
Quantum computing hits the radar of tech leaders, but will take years to develop for most applications, even as it makes progress.

~~Gartner advises tech leaders to prepare for action as quantum computing spreads~~
A]s temperatures rise and more extreme effects manifest, there is a growing risk of conflict over water and migration, particularly after 2030, and an increasing chance that countries will ...

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Grant Thornton LLP has been awarded a patent by the U.S. Patent and Trademark Office for innovations related to the firm ' s proprietary Whole Ledger Analytics system. Grant Thornton created this system ...

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A team of researchers from Virginia Tech and the University of Virginia will assess second anterior cruciate ligament (ACL) injuries using wearable sensors.

~~Biomedical engineering researchers to study knee re-injury risk~~
Agilent Receives FDA Companion Diagnostic Approval for Ki-67 IHC MIB-1 pharmDx in High-Risk Early Breast Cancer ...

Guides You on the Development and Implementation of B-R Evaluations Benefit-Risk Assessment Methods in Medical Product Development: Bridging Qualitative and Quantitative Assessments provides general guidance and case studies to aid practitioners in selecting specific benefit-risk (B-R) frameworks and quantitative methods. Leading experts from industry, regulatory agencies, and academia present practical examples, lessons learned, and best practices that illustrate how to conduct structured B-R assessment in clinical development and regulatory submission. The first section of the book discusses the role of B-R assessments in medicine development and regulation, the need for both a common B-R framework and patient input into B-R decisions, and future directions. The second section focuses on legislative and regulatory policy initiatives as well as decisions made at the U.S. FDA ' s Center for Devices and Radiological Health. The third section examines key elements of B-R evaluations in a product ' s life cycle, such as uncertainty evaluation and quantification, quantifying patient B-R trade-off preferences, ways to identify subgroups with the best B-R profiles, and data sources used to assist B-R assessment. The fourth section equips practitioners with tools to conduct B-R evaluations, including assessment methodologies, a quantitative joint modeling and joint evaluation framework, and several visualization tools. The final section presents a rich collection of case studies. With top specialists sharing their in-depth knowledge, thought-provoking considerations, and practical advice, this book offers comprehensive coverage of B-R evaluation methods, tools, and case studies. It gives practitioners a much-needed toolkit to develop and conduct their own B-R evaluations.

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All pharmaceutical products have inherent risks, and their use involves trade-offs between their therapeutic benefits and their risks. However, the public has a limited understanding of the benefits and risks of drugs, and many individuals believe that drugs approved by the U.S. Food and Drug Administration (FDA) carry no risks. The FDA is responsible for evaluating and balancing the potential risks of drugs with their potential benefits. Assessing, managing, and communicating the benefit-risk profile of a pharmaceutical product is a complex and nuanced scientific, political, and sociological challenge. Once the assessment is made, the FDA is then responsible for managing how to communicate these risks and make healthcare decisions based on them. To explore these issues, the Forum on Drug Discovery, Development, and Translation conducted a public workshop entitled Understanding the Benefits and Risks of Pharmaceuticals, with the broad goals of gaining a better understanding of the current system used to evaluate benefit and risk, and to identify opportunities for improvement. This workshop was held in Washington, D.C., on May 30-31, 2006. The benefit-risk profiles of pharmaceuticals are constantly evolving as new data are collected throughout the life cycle of a drug. Discussions during the workshop focused on the following: (1) premarket assessment, during which clinical trial data are used to assess benefit and risk; (2) communication of that information to prescribing physicians and their patients; (3) healthcare decisions made by prescribing physicians and their patients; and (4) the accumulation of benefit-risk information from postmarketing experience, which feeds back into the other phases. Understanding the Benefits and Risks of Pharmaceuticals: Workshop Summary explains in detail the discussions during this workshop.

Many practitioners in the pharmaceutical industry are still largely unfamiliar with benefit-risk assessment, despite its growing prominence in drug development and commercialization. Helping to alleviate this knowledge gap, Benefit-Risk Assessment in Pharmaceutical Research and Development provides a succinct overview of the key considerations relevant to benefit-risk assessment across the pharmaceutical R&D spectrum, from early clinical development to late-stage development to regulatory review to post-launch assessment. The book first presents interpretations of benefit and risk in the context of a molecule moving from preclinical evaluation into its early testing in humans. It next considers benefit and risk characterization and assessment during a molecule ' s journey from its clinical evaluation in humans through its submission to regulators for marketing approval. Throughout these sections, the book offers insight into the role of benefit-risk assessment in heightening understanding among key stakeholders by shaping questions and guiding discussions among scientists, physicians, developers, and regulatory agencies. The book also focuses on a molecule ' s entry into the marketplace as a drug available for consumption by people. It explores the role of benefit-risk assessment as the relevance of carefully collected clinical efficacy and safety metrics fades in the wake of real-world use and evidence of effectiveness and safety. Bringing together the expertise of 15 contributors from academia and the industry, this book offers an easy-to-read guide to the various facets of benefit-risk assessment in the major stages of pharmaceutical R&D. Suitable for those in both technical and managerial roles, it enables readers to communicate more effectively across their development chain as well as rationally and thoughtfully embed benefit-risk assessment into their R&D processes.

An estimated 48 percent of the population takes at least one prescription drug in a given month. Drugs provide great benefits to society by saving or improving lives. Many drugs are also associated with side effects or adverse events, some serious and some discovered only after the drug is on the market. The discovery of new adverse events in the postmarketing setting is part of the normal natural history of approved drugs, and timely identification and warning about drug risks are central to the mission of the Food and Drug Administration (FDA). Not all risks associated with a drug are known at the time of approval, because safety data are collected from studies that involve a relatively small number of human subjects during a relatively short period. Written in response to a request by the FDA, Ethical and Scientific Issues in Studying the Safety of Approved Drugs discusses ethical and informed consent issues in conducting studies in the postmarketing setting. It evaluates the strengths and weaknesses of various approaches to generate evidence about safety questions, and makes recommendations for appropriate followup studies and randomized clinical trials. The book provides guidance to the FDA on how it should factor in different kinds of evidence in its regulatory decisions. Ethical and Scientific Issues in Studying the Safety of Approved Drugs will be of interest to the pharmaceutical industry, patient advocates, researchers, and consumer groups.

On October 17, 2014, spurred by incidents at U.S. government laboratories that raised serious biosafety concerns, the United States government launched a one-year deliberative process to address the continuing controversy surrounding so-called "gain-of-function" (GOF) research on respiratory pathogens with pandemic potential. The gain of function controversy began in late 2011 with the question of whether to publish the results of two experiments involving H5N1 avian influenza and continued to focus on certain research with highly pathogenic avian influenza over the next three years. The heart of the U.S. process is an evaluation of the potential risks and benefits of certain types of GOF experiments with influenza, SARS, and MERS viruses that would inform the development and adoption of a new U.S. Government policy governing the funding and conduct of GOF research. Potential Risks and Benefits of Gain-of-Function Research is the summary of a two-day public symposia on GOF research. Convened in December 2014 by the Institute of Medicine and the National Research Council, the main focus of this event was to discuss principles important for, and key considerations in, the design of risk and benefit assessments of GOF research. Participants examined the underlying scientific and technical questions that are the source of current discussion and debate over GOF research involving pathogens with pandemic potential. This report is a record of the presentations and discussion of the meeting.

The Textbook of Pharmacoepidemiology provides a streamlined text for evaluating the safety and effectiveness of medicines. It includes a brief introduction to pharmacoepidemiology as well as sections on data sources, methodology and applications. Each chapter includes key points, case studies and essential references. One-step resource to gain understanding of the subject of pharmacoepidemiology at an affordable price Gives a perspective on the subject from academia, pharmaceutical industry and regulatory agencies Designed for students with basic knowledge of epidemiology and public health Includes many case studies to illustrate pharmacoepidemiology in real clinical setting

The regulation of potentially hazardous substances has become a controversial issue. This volume evaluates past efforts to develop and use risk assessment guidelines, reviews the experience of regulatory agencies with different administrative arrangements for risk assessment, and evaluates various proposals to modify procedures. The book's conclusions and recommendations can be applied across the entire field of environmental health.

Benefit-risk assessment is at the centre of the approval process for every new medicine. The ability to assess the risks of a new medicine accurately and to balance these against the benefits the medicine could bring is critical for every regulatory authority and pharmaceutical company. Despite this there are very few tried and tested evaluative models currently available. The authors of this book have developed a new, pioneering tool for the assessment of benefits and risks for new medicines in development. This model utilises a multi-criteria decision analysis which involves selecting, scoring and weighting key benefit and risk attributes and leads to an overall appraisal of benefits and risks of medicines. Benefit-Risk Appraisal of Medicines establishes the background and criteria required to assess benefit and risk in general and reviews the current practices by regulatory authorities and the pharmaceutical industry, including those models currently available. It outlines the development and evaluation of the authors ' new model and analyses the implications of its implementation. Describes an innovative, systematic model which leads to transparent and responsible benefit-risk decision making Contributes important ideas to the debate on benefit-risk appraisal Provides a future framework for benefit-risk appraisal of medicines Benefit-Risk Appraisal of Medicines covers the entire process from the discovery of new medicines to their marketing and is ideal for all those who work in the pharmaceutical industry and regulatory authorities, as well as post-graduate students of pharmaceutical medicine and clinical pharmacology.