

Dose Optimization In Drug Development Drugs And The Pharmaceutical Sciences

Take Home Messages d5dfacc7b2 Speaker Introduction d5dfacc7b2 Consequences To The Patient d5dfacc7b2 Why are Models Being Encouraged by the Regulatory Agencies? d5dfacc7b2 Two main points to make d5dfacc7b2 Project Significant d5dfacc7b2 Dose Optimization for Anti-Cancer Agents in the Era of Immunotherapy and Targeted Agents - Dose Optimization for Anti-Cancer Agents in the Era of Immunotherapy and Targeted Agents 58 minutes - Elizabeth Garrett-Mayer, PhD joined the American Society of Clinical Oncology (ASCO) in 2017 as Center for **Research**, and ... d5dfacc7b2 Post-market randomized trial designs d5dfacc7b2 Applications Beyond Exposure: Response d5dfacc7b2 Webinar Outline d5dfacc7b2 The FDA's \"Project Optimus\" and Oncology Drugs - The FDA's \"Project Optimus\" and Oncology Drugs 12 minutes, 7 seconds - Julie Bullock, VP, Global Head of Clinical Pharmacology and Translational Medicine at Certara discusses the FDA's Oncology ... d5dfacc7b2 eChalk Talk: How Oncology Drug Developers Can Prepare for FDA's Project Optimus - eChalk Talk: How Oncology Drug Developers Can Prepare for FDA's Project Optimus 31 minutes - Historically, the **dosing**, strategy for oncology **drugs**, has focused on use of the maximum tolerated **dose**,. This has resulted in **drugs**, ' ... d5dfacc7b2 Example: Nivolumab (OPDIVO) d5dfacc7b2 Subtitles and closed captions d5dfacc7b2 Combination Therapy d5dfacc7b2 Risk d5dfacc7b2 Search filters d5dfacc7b2 Project Optimus: Oncology Dose Optimization Based on Clinical Pharmacology Strategy \u0026 MIDD Approach - Project Optimus: Oncology Dose Optimization Based on Clinical Pharmacology Strategy \u0026 MIDD Approach 1 hour, 2 minutes - Since the FDA initiated Project Optimus, considerable effort has been stimulated to better select **doses**, of new oncology products. d5dfacc7b2 Two Proposed Development Pathways d5dfacc7b2 Using the Model to Answer Questions d5dfacc7b2 Take Home Messages d5dfacc7b2 Playback d5dfacc7b2 Introduction d5dfacc7b2 Defining Toxicity Outcomes d5dfacc7b2 Overview d5dfacc7b2 BST Seminar | Continual Reassessment Methods for Dose Optimization | UAB School of Public Health - BST Seminar | Continual Reassessment Methods for Dose Optimization | UAB School of Public Health 42 minutes - Speaker: Dr. Nolan Wages. d5dfacc7b2 Optimizing Drug Development with Model-Informed Decision Making - Optimizing Drug Development with Model-Informed Decision Making 42 minutes - Innovations in statistics, programming and data management are changing the very nature of clinical **development**,. d5dfacc7b2 Common Concerns Regarding the Use of Model- Informed Approaches d5dfacc7b2 Areas for exploration and development Durability of response d5dfacc7b2 Dose optimization in early phase oncology trials, Zheng Liu, IQVIA - Dose optimization in early phase oncology trials, Zheng Liu, IQVIA 37 minutes - Many thanks to Zheng Liu (IQVIA, Australia) for his excellent presentation on '**Dose optimization**, in early phase oncology trials', ... d5dfacc7b2 Predictions of Clinical Endpoint using Biomarker d5dfacc7b2 Typical approach to oncology drug development d5dfacc7b2 Dose Optimization Strategies d5dfacc7b2 Incorporating Findings into the Drug Development Plan d5dfacc7b2 Statistical Challenges d5dfacc7b2 Cost d5dfacc7b2 Intro d5dfacc7b2 Balancing Upfront Costs Against Impact of Failed or Ambiguous POC Findings d5dfacc7b2 Implementation of Trial Optimization by Brenda Gaydos - Transforming Drug Development - Implementation of Trial Optimization by Brenda Gaydos - Transforming Drug Development 43 minutes - Trial **design optimization**, • Improving estimates of risk and use in decision making • Scalable approach to leverage trial simulation. d5dfacc7b2 Demonstration of Increased Confidence During Phase 1b and 2 Study Planning d5dfacc7b2 Common Themes in these examples? d5dfacc7b2 What is Model Informed Drug Development? d5dfacc7b2 Project Optimus \u0026 Pediatric Drug Development - Project Optimus \u0026 Pediatric Drug Development 57 minutes - Certara accelerates medicines to patients using proprietary biosimulation software and technology to transform traditional **drug**, ... d5dfacc7b2 The benefits of using Pharmacokinetic and Pharmacodynamic modeling - The benefits of using Pharmacokinetic and Pharmacodynamic modeling 3 minutes, 18 seconds - Roche's \"Clinical Pharmacology\" team, which is part of the \"**Pharma Research**, and Early **Development**, (pRED)\" unit, uses ... d5dfacc7b2 A Multi-Disciplined Approach d5dfacc7b2 List of approved oncology drugs d5dfacc7b2 CDDF Workshop on Dose Optimization in Early Oncology Drug Development (3-4 April 2023, Amsterdam) - CDDF Workshop on Dose Optimization in Early Oncology Drug Development (3-4 April 2023, Amsterdam) 1 minute, 3 seconds - Key takeaways from Day 1's program of the CDDF Workshop. d5dfacc7b2 Efficacy/Toxicity Designs d5dfacc7b2 Overview of talk d5dfacc7b2 MIDD for Oncological Product Development d5dfacc7b2 Summary of Dose Finding/ Optimization d5dfacc7b2 Welcome Message - Dose Optimization in Oncology Drug Development - Prof. Axel Glasmacher (CDDF, DE) - Welcome Message - Dose Optimization in Oncology Drug Development - Prof. Axel Glasmacher (CDDF, DE) 2 minutes, 47 seconds d5dfacc7b2 Intro d5dfacc7b2 Project Optimus- Reimagining Oncology Drug Development with Dose Optimization - Project Optimus- Reimagining Oncology Drug Development with Dose Optimization 1 hour - Overview By the end of this course, you will be able to understand the following: 1. History and Current status of Project Optimus 2. d5dfacc7b2 Is there a role for cross-over trial designs? d5dfacc7b2 Types of endpoints to consider d5dfacc7b2 Reasons for Failures during Phase 2 and Phase 3 Development d5dfacc7b2 Project Optimus Overview d5dfacc7b2 Is there a role for \"real world\" data? d5dfacc7b2 Trial Simulation for Alt Prime Dosing d5dfacc7b2 The right dose for the right patient: Challenges and opportunities in dose optimization - The right dose for the right patient: Challenges and opportunities in dose optimization 1 hour, 19 minutes - On July 28, the Center for Health Policy at Brookings, in collaboration with the International Consortium for Innovation \u0026 Quality in ... d5dfacc7b2 Using Modeling and Simulation to Support Strategic Decisions d5dfacc7b2 Dose Finding Schematic d5dfacc7b2 Revisiting the Objectives d5dfacc7b2 Immunotherapy Breakthroughs d5dfacc7b2 Spherical Videos d5dfacc7b2 Hybrid designs d5dfacc7b2 Implementation Tools d5dfacc7b2 Failure To Demonstrate Efficacy d5dfacc7b2 Dose optimization in post-market setting d5dfacc7b2 A Brief Introduction d5dfacc7b2 Cost-Savings Associated with the Incorporation of Model-Based Decisions d5dfacc7b2 The Challenge of Drug Development - The Challenge of Drug Development 11 minutes, 54 seconds - MIT Sloan Professor Andrew Lo goes through the **drug development**, cycle, from lab hypothesis, to clinical trial, to licensing and ... d5dfacc7b2 The Critical Milestones in Drug Development d5dfacc7b2 Dose Selection and Optimization in the Adult Population with Dr. Yaning Wang - Dose Selection and Optimization in the Adult Population with Dr. Yaning Wang 1 hour, 7 minutes - This lecture is part of the NIH Principles of Clinical Pharmacology Course which is an online lecture series covering the ... d5dfacc7b2 Title Page d5dfacc7b2 Keyboard shortcuts d5dfacc7b2 Opportunities to Improve Dose Finding and Optimization for Rare Disease Drug Development Recording - Opportunities to Improve Dose Finding and Optimization for Rare Disease Drug Development Recording 4 hours, 58 minutes - The Duke-Margolis Institute for Health Policy, under a cooperative agreement with the U.S. Food and **Drug**, Administration, ... d5dfacc7b2 MIDD Paired Meeting Program d5dfacc7b2 An Example d5dfacc7b2 Clinical Trial d5dfacc7b2

Bench to Bedside Chat Pharmacology and Dose Optimization for First-in-Human Oncology Trials - Bench to Bedside Chat Pharmacology and Dose Optimization for First-in-Human Oncology Trials 1 hour, 27 minutes - This video discusses important concepts to consider for pharmacology and **dose optimization**, in oncology first-in human trials. d5dfacc7b2 Project Optimus - FDA's New Dose Optimization \u0026 Selection Paradigm in Oncology Drug Development - Project Optimus - FDA's New Dose Optimization \u0026 Selection Paradigm in Oncology Drug Development 1 hour, 5 minutes - 0:00 Title Page 2:15 Speaker Introduction 5:15 Webinar Outline 6:05 Project Optimus Overview 8:05 List of approved oncology ... d5dfacc7b2 Why are we still using the current standard d5dfacc7b2 General d5dfacc7b2 Challenges with \"de-escalation\" studies d5dfacc7b2 The Optimal Cancer Care Alliance (OCCA) d5dfacc7b2 Oncology Drug Development and Dose Optimization: What Are the Implications of Project Optimus? - Oncology Drug Development and Dose Optimization: What Are the Implications of Project Optimus? 14 minutes, 30 seconds - More on this story: ... d5dfacc7b2 How did these trials evolve after breakthrough designation? d5dfacc7b2 Key publications d5dfacc7b2

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