GMDP academy
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CELEBRATE THE JOURNEY: JOIN THE INAUGURAL GMDP ACADEMY GRADUATION

Join us as we celebrate the outstanding accomplishments of our students who've conquered the Certification in Medicines Development program in the 2023 cohort. This event highlights the rigorous academic journey of our students and marks the launch of a new chapter in their medicines development careers.

Join us via Zoom on January 30, 2024 at 10am EST.

Mark your calendars, and click here to register! Registration is open until the day of the ceremony.

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Conversations with the Academy

Presents:

"The Fantastic World of Immunology"

February 1, 2024
8:00AM to 9:00AM EST

Register to attend

Professor Franco Indiveri
Emeritus Professor
University of Genova, Italy

Dr. Domenico Criscuolo
President & CEO
Genovax, Italy

Join us for an enlightening journey with industry experts, Professor Franco Indiveri and Dr. Domenico Criscuolo, as these esteemed experts guide you through the ever-evolving field of immunology. Over the past few decades, immunology has made remarkable strides, allowing us to delve into the intricate world of lymphocyte sub-populations and comprehend their diverse functions. Furthermore, immunology has emerged as a pivotal player in the management of chronic diseases.

Learning Objectives

- **Gain a comprehensive understanding of the pivotal role played by the immune system in both autoimmune diseases and cancer, delving into the intricate mechanisms underlying these conditions.**
- **Explore significant advancements in the therapeutic landscape of chronic conditions, with a specific emphasis on emerging treatments and breakthroughs that promise transformative outcomes.**
- **Anticipate and examine the novel opportunities that immunotherapy presents in the realm of healthcare, exploring its potential to revolutionize treatment approaches and enhance patient outcomes.**
- **Exclusive Q&A session with our esteemed speakers – your chance to have your questions addressed by the experts.**

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THE LANDSCAPE OF BIOSIMILARS, FDA APPROVAL & SAFETY CONSIDERATIONS IN PATIENT SWITCHING

Biological products, or biologics, are crucial for clinical care, offering safe and effective treatments for various disorders, including vaccines, proteins, and blood products. Biosimilars, which are highly similar to FDA-approved biologics, have an abbreviated regulatory approval pathway, fostering market competition and potentially reducing drug costs.

The U.S. FDA has approved 44 biosimilars for 14 reference products treating conditions like macular degeneration, rheumatoid arthritis, and cancer. Biosimilars can be prescribed for both treatment-experienced and treatment-naïve patients.

Concerns about switching stable patients from a reference product to a biosimilar prompted FDA investigators to conduct a systematic review[1]. Continue reading here.

GOOD GOVERNANCE PRACTICE IN RESEARCH INSTITUTIONS REPORT BY CIOMS NOW AVAILABLE

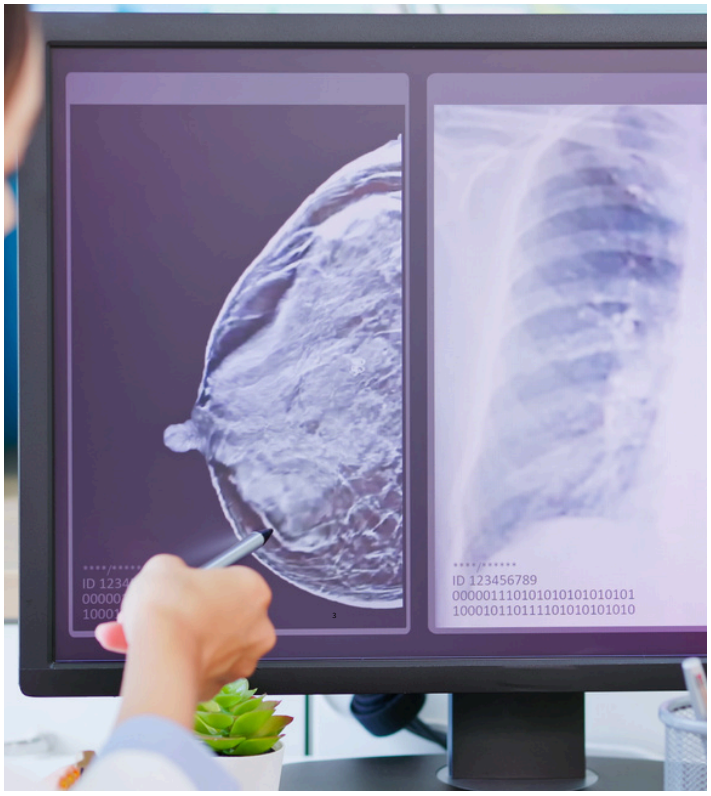
The CIOMS report on Good Governance Practice in Research Institutions is now available. In recent years, the scientific community has born heavy responsibilities to face some unprecedented challenges. Since the 1960s, numerous ethical, professional, and industrial guiding documents were adopted to facilitate and contain the increasingly complex research activities conducted with human participants globally. Many of these guidelines focus on individual researchers' responsibilities to protect research participants while conducting good quality scientific studies.

This report reviews the existing international standards and best practices in the field of health-related research and offers research institutions detailed and specific guidance on how to implement them[2]. Download the report here.

BREAST CANCER SCREENINGS: EFFICACY AND CHALLENGES

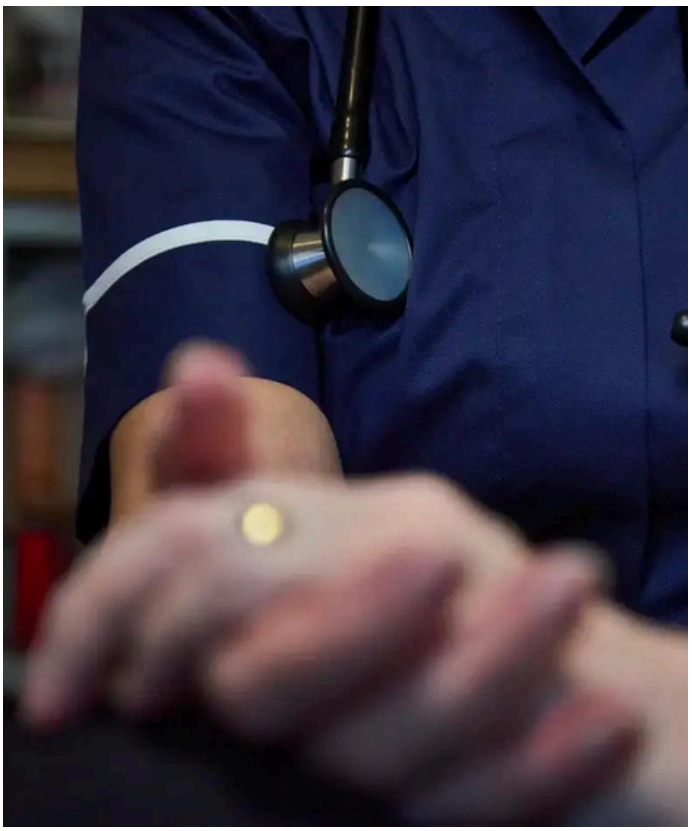
The ongoing debate surrounding mammographic screening for breast cancer has been a persistent and divisive topic for over two decades. The crux of the disagreement lies in the trade-off between potential benefits, such as early detection leading to improved outcomes, and the drawbacks, primarily the high incidence of false-positive results and cases of overdiagnosis.

Despite these controversies, the global landscape of breast cancer has been marked by a concerning increase in both incidence and mortality due to late-stage diagnoses. Technological advancements in screening methods have added complexity to the discourse, contributing to a growing acceptance that screening can indeed extend lives.



However, as the acknowledgment of screening's potential grows, so do the questions surrounding its implementation.[3] Continue reading here.

PREVENTING HEALERS FROM BECOMING KILLERS



In a groundbreaking initiative, The Lancet Commission unveils a significant historical investigation, delving into the darkest chapters of medicine: Nazi medicine. The recently launched report, titled "The Lancet Commission on medicine, Nazism, and the Holocaust: historical evidence, implications for today, teaching for tomorrow," marks the first-ever comprehensive exploration dedicated to the role of medicine during the Nazi era. Released on November 9, this scholarly endeavor provides the most up-to-date evidence on the history of Nazi medicine and its chilling connection to the infamous "Final Solution". The report is a response to the prolonged reluctance of the medical community, both in Germany and globally, to confront and engage with this dark chapter of history.[4] Continue reading here.

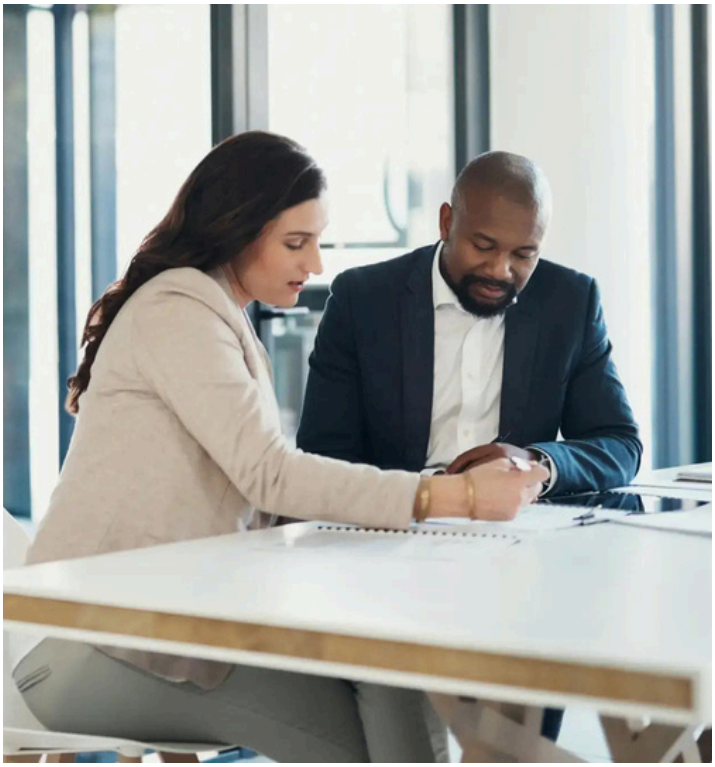
RECOGNIZING HISTORICAL INJUSTICES IN MEDICINE AND THE JOURNAL

The Journal and various medical institutions have historically advocated and justified the mistreatment of groups based on their race, ethnicity, religion, gender, and physical or mental conditions. In an effort to confront this history, the Journal has commissioned an independent group of historians has been commissioned to examine different facets of these biases and injustices. The series aims to initiate a conversation, facilitating a learning process from past mistakes and providing insights to prevent the occurrence of new ones.

From the Journal: “Our goal is not to cause further pain. In fact, after some deliberation, we and the historians decided that we should not republish some of the most egregious language to be found in our archives.

Nevertheless, the series will reveal problems that we must reckon with now, while offering us an opportunity to consider our contemporary beliefs as well.”[5]Read more here.

EMA SEEKS INPUT ON REVISED GUIDELINES FOR 3RS APPROACHES IN MEDICINAL PRODUCT EVALUATION



The European Medicines Agency (EMA) has released a Concept paper for public consultation, focusing on revising guidelines related to the regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches. The initial guideline, adopted nearly seven years ago, aimed to encourage stakeholders and authorities to adopt and support the development of 3Rs testing approaches, intending to replace, reduce, and refine in vivo animal studies for both human and veterinary medicinal products.

Stakeholders are invited to provide comments on these proposed revisions by February 28, 2024, utilizing the EU survey provided for this purpose. Click here to access the survey and provide comments.

GMDP ACADEMY'S COMPLETE COURSE CATALOG FOR THE 2024 ACADEMIC YEAR NOW AVAILABLE

We have some incredible offerings to take your career in Medicines Development to the next level. Checkout our complete course catalog for the 2024 Academic year.

Click **here** to view or download!

Email **community@gmdpacademy.com** for more information.

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Thanks for reading!

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