



OVERCOMING VACCINE RESISTANCE WITH LESSONS FROM TOBACCO

BY DOMENICO CRISCUOLO

As the pandemic rages on, skepticism around vaccines rages with it. According to a recently published article in the New England Journal of Medicine, society may have a lesson or two to learn from the tobacco wars when it comes to overcoming vaccination resistance.

“Covid-19 will soon have killed 1 million Americans. When vaccines first became available in late 2020, surveys indicated that about one-third of U.S. adults were keen to be vaccinated, 15% expressed strong resistance to vaccination (a proportion that has stayed constant), and the remainder didn’t harbor strong ideological resistance. About 27% of U.S. adults remain unvaccinated.”

Continue reading [here](#).

TABLE OF CONTENTS

Conversations with the Academy
webinar • P. 2

The Convenience of E-Consent • P. 3

News from the EMA • P. 3

Therapeutic Cancer Vaccines • P.4

The Fight Against
Anti-Microbial Resistance • P. 4

Aspirin for CV Risk Reduction •
P. 5

Leadership in Medical Affairs:
A Testimonial • P. 5

Conversations with the Academy

Presents:

Exploring Horizons with Professional Identity and Sense of Purpose in Medicines Development

July 21, 2022

8:00 AM - 9:00 AM EDT



Pietro Antonio
Tataranni, MD

Chief Medical Officer and
Senior Vice President, Life
Sciences, Pepsico, New York,
USA



Paul Richard Beninger,
MD, MBA

Director, MD/MBA and
MBS/MBA Programs, Associate
Professor, Tufts University,
Boston, USA

The journey to forming professional identity and social purpose as a shared value in the medicines development arena is a critical attribute for greater engagement and for delivering improved patient and health outcomes.

A strong professional identity empowers individuals to act confidently and is associated with career commitment and workplace satisfaction. Professional identity formation entails the development of an individual with internalized values and norms of the profession. As individuals seek career paths, the complex interplay between self-worth and a sense of purpose surfaces along the journey.

Having attained professional qualifications and training, how does one acquire the knowledge and skills to chart a fulfilling career path in medicines development? In this session, we will explore the confluence of education, purpose, and societal backgrounds, in fostering a sense of identity among professionals engaged in medicines development.

Learning Objectives

1. Connect with peer experiences shaping their professional journeys in medicines development and healthcare delivery
2. Understand that despite different backgrounds, passion and common purpose brings awareness of diverse opportunities
3. Share perspectives on future directions in the evolving global biopharmaceutical and related professions
4. Be motivated to explore divergent roles, yet connected with the purpose of promoting universal better health outcomes

[Register Now](#)

THE CONVENIENCE OF E-CONSENT

BY DOMENICO CRISCUOLO

Many Medical Affairs professionals agree that the Informed Consent process is among the weakest part of any clinical trial: consents are too long, wording is difficult to understand, and its terminology frequently uses words not familiar to lay people. The COVID-19 pandemic stimulated the adoption of several digital tools (hence avoiding patients' visits to the hospital) to include the e-consent, a great improvement in the recruitment and retention of patients in clinical trials.



According to Tufts researchers, clinical trials in a variety of therapeutic areas experience patient dropout rates close to 20 %. Although every patient dropout cannot be attributed to failures of the consent process, Advarra's 2021 research titled "Retention in Clinical Trials" highlights a key link between consent and dropouts.

Read the full publication [here](#).

NEWS FROM THE EMA



We are happy to direct you to the newest edition of the EMA monthly newsletter, the June 2022 (159) edition. As usual, it contains the list of new drugs approved in the areas of antivirals, cancer, diabetes, gastrointestinal system, gynecology, hematology, hormone and immune systems, metabolic disorders, musculoskeletal system, nephrology, nervous system, rheumatology, urology, and vaccines. It contains reports of the Scientific Committees and Working Parties meetings, and new guidelines.

It also contains a special section regarding a COVID-19 vaccines safety update for Comirnaty (BioNTech), Jcovden (Janssen-Cilag), Nuvaxovid (Novavax), Spikevax (Moderna Biotech) and Vaxzevria (AstraZeneca). You can read the full newsletter [here](#).

THERAPEUTIC CANCER VACCINES

BY DOMENICO CRISCUOLO

In recent years, immunotherapy has emerged as the fourth weapon against cancer. Thanks to basic research, which clarified the roles of the immune system, many studies are now investigating the continued potential of immunotherapy as the best way to stimulate patients' immune systems. Surgery, radiotherapy and chemotherapy produced important results in all indicators of benefits for the patients, and in the most important one: overall survival. As is well-known⁴, the goal of cancer therapies is an increased survival rate among patients.

Read the full publication from the National Cancer Institute [here](#).



THE ONGOING FIGHT AGAINST ANTIMICROBIAL RESISTANCE (AMR)

The Academy is pleased to continue its exploration of AMR and the need for new antibiotics. The EMA just released the final revised guideline on its evaluation of human medicines for the treatment of bacterial infections.

This document is an additional important step in the harmonization process among Regulatory Authorities, as the indications suggested in the guideline are valid not only for Europe, but also the United States and Japan.

[Click here to read the complete article.](#)

ASK THE ACADEMY: ASPIRIN FOR CV RISK REDUCTION

BY DOMENICO CRISCUOLO & SONEIL GUPTHA

We recently reported changes in guidelines regarding the use of aspirin for the prevention of cardiovascular disease. Any change in well-established guidelines may offer the opportunity for experts to engage in a scientific debate to raise and address key components, as well as improve the understanding of the new guideline.

The Academy asked Professor Soneil Gupta, an experienced cardiologist and a senior member of the Academy, to personally comment on the new guideline. We are pleased to offer his opinion and welcome additional comments from all of you.

Read the full commentary [here](#).



LEADERSHIP IN MEDICAL AFFAIRS: A TESTIMONIAL

The Academy training program for Medical Affairs professionals is based on six modules and covers all aspects of Medicines Development including basic research, marketing and post-authorization trials. In its efforts to provide holistic, comprehensive education, the Academy offers an additional, seventh module. We spoke with Professor Kenneth Kaitin, Chair of the Leadership Module, who offered some further insight into the benefit of participation in the Leadership module.

"IFAPP Academy's Leadership in Medical Affairs Certification Program was created to provide formal training – through lectures, panel discussions, webinars, and real-life case studies – to help you build leadership skills and improve performance within your organization. I encourage you to take advantage of this unique and exciting program."

[Click here to read the complete testimonial.](#)



REFERENCES

1. Bazell, R., Koh, H., & Bloom, B. R. (2022). The Tobacco Wars' Lessons for the Vaccination Wars. *New England Journal of Medicine*, 386(23), 2159–2161. <https://doi.org/10.1056/nejmp2202618>
2. EMA guidance supports development of new antibiotics. (2022, May 24). European Medicines Agency. <https://www.ema.europa.eu/en/news/ema-guidance-supports-development-new-antibiotics#:~:text=As%20part%20of%20its%20efforts,the%20treatment%20of%20bacterial%20infections.>
3. Addendum to the guideline on evaluation of medicinal products indicated for treatment bacterial infections address paediatric-specific clinical data requirements. (2022, May 24). European Medicines Agency. <https://www.ema.europa.eu/en/addendum-guideline-evaluation-medicinal-products-indicated-treatment-bacterial-infections-address>

CONTACT US

420 Lexington Ave. Ste. 300
New York, NY 10170

(332) 333-2438

