



## IFAPP ACADEMY WELCOMES 2022 COHORT

BY DOMENICO CRISCUOLO

In January 2022, the Academy and King's College London welcomed the fifth cohort for the Medical Affairs in Medicines Development certification course. The course is based on 6 modules, each one with 10 lectures and 4 webinars. An additional course, Module 7: Leadership in Medical Affairs, is offered independently of the 6 core modules and still has open slots for enrollment (contact [admissions@ifappacademy.org](mailto:admissions@ifappacademy.org) for more information and applications). [Continue reading here!](#)

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# LANDMARK IMPLEMENTATION OF REGULATION 536/2014

BY DOMENICO CRISCUOLO

January 31, 2022, was a landmark in the history of clinical trials in Europe! Finally, the new Regulation 536/2014 was implemented in the 27 countries of the European Union!

Countries of the European Union already had common legislation for clinical trials, the Directive 2001/20, which failed in the harmonization process as many countries modified it according to National procedures. Regulation 536/2014 cannot be changed at a national level, so the harmonization of processes will be guaranteed...[Continue reading this article here.](#)



## GOOD NEWS IN THE FIGHT AGAINST COVID-19

Good news to all clinicians and patients involved in the fight against Covid-19 infection: in the last months, two new antiviral agents developed by Pfizer and Merck, were almost simultaneously approved by the FDA and the EMA, adding new hopes for a successful fight against the pandemic and for the benefit of all infected patients.

**“THIS EXPRESSION OF CONFIDENCE IN PAXLOVID COMES AT A CRITICAL MOMENT AS EUROPE ADDRESSES THE ONGOING CHALLENGES OF THE PANDEMIC AND AS INFECTION RATES ARE ON THE RISE IN MANY COUNTRIES ACROSS THE GLOBE,”** SAID ALBERT BOURLA, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, PFIZER.

[Continue reading here.](#)

*Conversations with the Academy*

Presents:

## Drug Development in a Post-COVID World

May 12, 2022

8:00 AM - 9:00 AM EDT



Kenneth I Kaitin, PhD  
Professor and Senior Fellow, Tufts  
Center for the Study of Drug  
Development, Tufts University,  
Boston, USA; Advisory Professor,  
Shanghai Medical College, Fudan  
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COVID-19 has fundamentally altered the drug development landscape in ways that are both transformational and far-reaching. From the integration of powerful technologies to assist with the discovery and development of promising new drug candidates, to the adoption of novel, decentralized clinical trial designs, which reduce the burden on patients participating in clinical studies, the drug development enterprise has met the challenge of COVID-19, and is embracing new operational and business models to maximize productivity and ROI going forward.

In this webinar, we will examine the changing global landscape for pharmaceutical R&D, focusing specifically on COVID-19 and its influence on R&D and business strategies, as well as regulatory policies pertaining to the development and approval of important new pharmaceutical therapies.

### Learning Objectives

1. Assess the current economic and regulatory factors that affect pharmaceutical R&D
2. Review the drug development community's response to the COVID-19 pandemic, leading to the development and approval of several highly effective vaccines and therapeutics
3. Examine the longer-term impact of COVID-19 on R&D strategy, business models, and regulatory policy

[Register Now](#)

# NEWS FROM THE LITERATURE

BY DOMENICO CRISCUOLO

We would like to start this series with a short editorial published in The Lancet about the origin of the virus. The publication starts with this sentence “Revealing the origins of SARS-CoV-2 is a prerequisite for cutting off the virus from the root and preventing future spillover of the virus. This work is of great significance in infection disease prevention and control in the face of Disease X.



Although scientists around the world are searching very hard, the origins of SARS-CoV-2 remain elusive. In fact, for many infectious pathogens, although their origins have been traced back decades, the debate around the origins remains alive. HIV is a good first example.....”

[We invite you to read the full text \(just one page\) here.](#)

# BIONTECH FOUNDERS RECOGNIZED AT THE HIGHEST LEVEL



The development of safe and efficacious vaccines against COVID-19 kept all scientists busy in the last two years. We also know that BioNTech scientists, who were already working on the mechanism of action of mRNA, immediately had the idea to use their know-how for the fast development of the first vaccine against COVID-19. This vaccine was developed at high speed and in fact was approved for use in humans in less than one year after the availability of the complete sequence of the viral genome.

BioNTech founders Ugur Sahin and Özlem Türeci received Spain’s highest honor, the Princess of Asturias Award, for their services to science and technology. In the article below, the couple discusses their success and plans for the future.

[Read more here.](#)

## THE FIGHT AGAINST COVID-19: SECOND BOOSTERS AUTHORIZED BY FDA

BY DOMENICO CRISCUOLO

This piece of news is related to the FDA and the important authorization to offer to old and immunocompromised patients a second booster dose of the Pfizer and Moderna COVID-19 vaccines. The scientific reason underlying this decision is, as the FDA informs, that “Current evidence suggests some waning of protection over time against serious outcomes from COVID-19 in older and immunocompromised individuals.

[Continue reading here.](#)



## PROFESSIONAL IDENTITY IN THE LITERATURE

The 2021 End of Program Assessment (EPA) of the Academy course in Medical Affairs was focused on the students’ perception of their Professional Identity. The Academy Board selected this focus as we believe in the importance of consolidating the Professional Identity of all professionals working in Medical Affairs. Professional Identity is frequently defined as “the attitudes, values, knowledge, beliefs and skills shared with others within a professional group”...

In the coming months, look for some of the best essays prepared by the 2021 course students. In preparing these essays, students elaborated on the issue of Professional Identity and shared some interesting personal visions in this important domain.

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