



## PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT

BY OLGA LUCÍA ANGARITA

The Academy is grateful for the student contributions which allow us to continue our series on Professional Identity in Medicines Development. The essays we feature here were among the top-scoring essays prepared by students of our Academy Medical Affairs course. Below is an excerpt from an essay by Olga Lucía Angarita in which she was asked to “Discuss the development and status of your own Professional Identity, and what it means in terms of your job, your career, and future prospects.” (See page 2).

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"As I conducted an attributes analysis to define myself as a professional, I concluded that I have a defined identity; I can identify, analyse, and negotiate conflicts between my professional values and the challenges of my profession in Medical Affairs. Hence, I consider being in stage four based on the R Kegan scale<sup>1</sup>. I know who I am and what motivates me.

Since I was a kid, I desired to dedicate my life to the service of humanity, and I found in medicine the means to fulfill this dream. I have built my professional identity on a fundamental principle promised through the Hippocratic Oath at the end of my career as a physician... to ensure the patient's benefit by performing with honour and righteousness. My parents always expected me to be fair and responsible, and as I have grown in this profession, I have abided by what I was taught as a child and what I committed to as a physician. I have integrated these values into my personal life, and they are a foundational part of my professional identity as well.

From the different roles I have performed (e.g., Medical Manager, Compliance Officer, and currently Medical Operations Lead), I have and continue to forge my professional identity. It has been a collaborative process between positive and negative experiences coming from stakeholders such as patients and caregivers. They have helped me comprehend the impact that diseases and treatments have on them, and to better understand their fight to ensure adequate access to healthcare and medications to control their illness and symptoms. In my life, I have worked for two large pharmaceutical companies with corporate values like quality, integrity, and collaboration that I have incorporated in my professional identity.

- Olga Lucía Angarita, MD, MSc



Olga Lucía Angarita A. MD, MSc, Master in Bioethics, Universidad de la Sabana . She is experienced in Medical Affairs, R&D, and Integrity functions as Medical Operations Lead, Medical Manager, Development Quality Assurance, and Compliance Officer in Pharmaceutical companies such as Novartis and Takeda.

Thank you for sharing your unique perspective with the Academy and its readers. To read the essay in its entirety, [please click here](#).



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## RESEARCH ETHICS IN LATIN AMERICA: WHERE DO THEY STAND?

Latin America is a highly populated region, and most people, especially in Brazil and Argentina, live in large cities. This is an ideal situation for the implementation of clinical trials, as the dense populations guarantee the availability of patients. In addition, the globalization of the pharma industry and the entrepreneurial spirit of several CROs made Latin America and the Caribbean an important geographical area for the implementation of clinical trials.

But, what about research ethics? The Pan American Health Organization (PAHO) devised a strategy that includes objectives and indicators to address core components of research ethics systems.

## EXAMINING THE PHENOMENON OF BIOCREEP



The authors of this manuscript assessed 22 countries in Latin America and the Caribbean using these indicators. Most countries have adopted legal instruments to govern research with human participants and have implemented national bodies tasked with the oversight of research ethics committees.<sup>2</sup>

Continue reading [here](#).

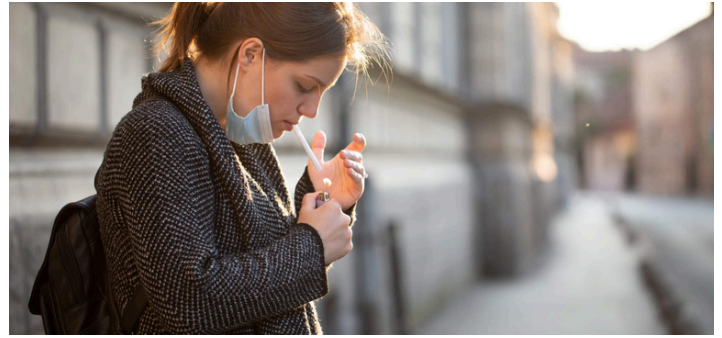
Biocreep refers to the cyclical phenomenon where a slightly inferior treatment becomes the active control for the next generation of NI trials which over time leads to degradation of the efficacy of the investigational treatment.

"A product can be considered bioequivalent to the brand-name drug if after administration of the same dose, it exhibits a similar degree and rate of absorption. These features guarantee the comparability of two drug preparations in terms of in vivo efficacy and safety and make them interchangeable and replaceable. Since efficacy studies are not necessary, some clinicians and patients have expressed concerns about the therapeutic equivalence of generic drugs."<sup>3</sup>

Continue reading [here](#).

## MORE ACTIONS TO BAN TOBACCO AND E-CIGARETTES!

As part of the EU's plan for a tobacco-free generation by 2040, the European Commission has proposed a plan to ban the sale of flavored, heated tobacco products. A study from the European Commission, published in June 2022, showed a 10% increase in sales of heated tobacco products, such as vapes, between 2018 and 2020 in more than five member states. Furthermore, heated tobacco products accounted for more than 2.5% of total sales of tobacco products across the EU. With the majority of lung cancers caused by tobacco, it is hoped that this proposed ban will help reduce tobacco smoking and thus reduce related cancer mortality and morbidity.



The proposal is currently under review with EU member states and the European Parliament. Once published, member states will have 8 months to transpose the directive into law, and 3 months before the provisions will start to apply.

Also in June 2022, an independent review set out an ambitious plan to make England smoke-free by 2030.<sup>4</sup>

Continue reading [here](#).

## NEWS FROM THE FDA: GUIDANCE FOR NEONATES AND CLINICAL PHARMACOLOGY ANNOUNCED



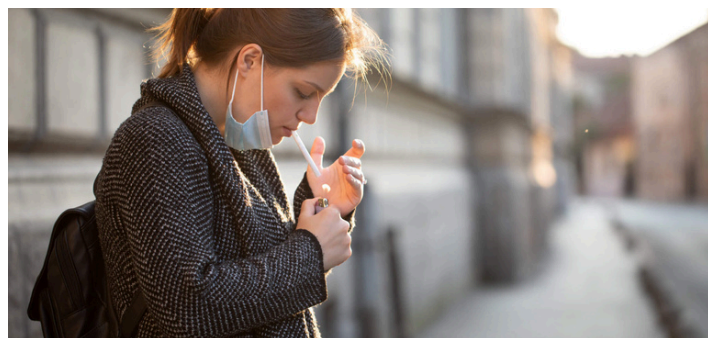
In the last two decades of the 21st century, many pediatricians and all scientific associations related to pediatrics, started a campaign to make regulatory authorities aware that most drugs that had marketing authorization had no clinical trials in children. Because of this lack of scientific evidence, all pediatricians were obliged to prescribe drugs to pediatric patients based only on their personal experience. This pressure was successful and all regulatory authorities, first of all, the FDA and the EMA, made it mandatory to submit, at the time of the NDA application, the results of clinical trials performed both in adults and in children.

The first 3 categories of children represent the most fragile population: hence the FDA's issuance of a new guideline for the planning and implementation of clinical trials.

Continue reading [here](#).

## ANTIBIOTIC-RESISTANT BACTERIA EMERGING IN COMMUNITY SETTINGS

A new study from the Centers for Disease Control and Prevention (CDC) found that a surprising proportion of cases of carbapenem-resistant Enterobacterales (CRE) are found in isolates from patients in the community (CA-CRE). They had previously been thought to be healthcare-associated infections (HCA-CRE). Traditionally, CRE has been thought of as a nosocomial infection, acquired in a hospital or other healthcare facility (nursing home, long-term acute care hospital, dialysis center). This is the first population-level study to show otherwise, with fully 10% of the CRE isolates found to be community-acquired.



CREs are a group of multidrug-resistant bacteria considered an urgent health threat by the CDC because they can rapidly spread between patients, especially those who are most seriously ill and vulnerable, and because they are so difficult to treat. These patients often require treatment with new antibiotics, such as colistin, and carry a high mortality rate — up to 50% in some studies.<sup>5</sup>

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## NEWS FROM THE EMA: EMA REVIEWING DATA ON SABIZABULIN FOR COVID-19



EMA's Emergency Task Force (ETF) has started a review of data on the use of sabizabulin for treating COVID-19. The review will look at all available data, including data from a study involving hospitalized patients with moderate-to-severe COVID-19 who are at high risk of acute respiratory distress syndrome and death. The results of this study indicate that sabizabulin treatment could reduce the number of deaths in these patients compared with placebo.

Although the developer, Veru, has not yet applied to EMA for marketing authorization or a rolling review, the review (based on data from the company) will assist EU Member States who may consider allowing use of the medicine before a possible authorization.<sup>6</sup>

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# 2022 HEATWAVES: FAILURE TO PROACTIVELY MANAGE RISKS

We are all experiencing important climate changes, regardless of where we live on the planet. The consequences of these profound climate changes can be very severe for global health. According to this editorial in the Lancet, “Human-induced climate change has made extreme heatwaves, wildfires, and flash floods substantially more likely and more severe. Yet, health impacts are widely underestimated. Most countries have failed to adequately plan, adapt, and use evidence-based information to protect their populations. For some countries, this is a dangerous failure of action, but others lack the adequate human and financial resources to respond.

So far this year, India, Pakistan, the USA, China, and Europe have experienced extreme and dangerous heatwaves that damaged vital infrastructure and threatened to overwhelm emergency service capacity. The mortality toll is staggering.<sup>7</sup>



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

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