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ANNOUNCING THE 2023 GLOBAL FELLOWS AWARD CEREMONY & THE DIGITAL CAPABILITIES IN MEDICINES DEVELOPMENT SYMPOSIUM IN LONDON

Mark your calendars! We are excited to announce a long-awaited event for all our Global Fellows in Medicines Development. On May 22, 2023, we will gather in London to celebrate our first and second groups of fellows, now almost 200 strong, and to explore Digitial Capabilities in Medicines Development. Join us at King's College facilities for this amazing opportunity to recognize our esteemed fellows and to network, learn, and exchange ideas with some of the brightest minds in the field.

Can't make it to London? No problem! We have virtual attendance options available.

- Check out the formal agenda for more details.
- Register here for virtual attendance.
- For information from King's College London, click here.

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PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNA

We are pleased to share the second of two well-written essays by Academy alumna María Beatriz Greaves. We extend our gratitude to María for her contributions to our learning community. This essay asked her to "**Discuss Professional Identity and the Sense of Purpose in Medicines Development and their relevance for professionals involved in the field**."

Despite many differences between industry and clinical practice, the similarities can find resonance with the sense of purpose of the Medicines Development professional: the dedication to improve the lives of patients; the commitment to scientific rigor; though no longer involved in the daily care of patients, the knowledge that they contribute to therapeutics that impact thousands of patients [1]. Medicines Development professionals feel proud of and engaged in their work when they sense connection with their purpose or identify with the core purpose of their organization. Purpose then serves as a compass, guiding decision-making and aiding the resolution of ethical dilemmas [2].

Self-reflection, the reevaluation and discussion of past tactics, strategy and experiences and our roles in them, allows us to build our own stories, internalize what makes sense and build and strengthen our Professional Identity [1]. It allows us to recognize our value, identify the skills needed to meet short and long term demands of an environment in continuous change, plan accordingly and allow our career to advance [3]. Professional Identity is strengthened by positive work experiences, opportunities to develop skills and gain expertise, having good role models, earning trust and responsibility, having satisfaction with goals attained, and by feeling part of something bigger [4].

Medicines Development professionals with a strong Professional Identity and sense of purpose commit to providing best practices and act with integrity. In a changing landscape, they find the motivation to adapt, learn and innovate. They share and grow knowledge and influence through interaction with team members, cross-functional teams and other Medicines Development professionals; and at the end of the day, look back, and make honest critical reflections and grow [5].

María Beatriz Greaves is an Opthalmologist and Medical Advisor at Laboratorios Théa, Barcelona, Spain.

Click here to read her complete essay.

LONG COVID: 3 YEARS IN

March 11 marked 3 years since WHO declared COVID-19 to be a pandemic. While the world is determined to move on from the acute phase, at least 65 million people are estimated to struggle with long COVID, a debilitating post-infection multisystem condition with common symptoms of fatigue, shortness of breath, and cognitive dysfunction, impairing their ability to perform daily activities for several months or years. Although the majority of patients infected with SARS-CoV-2 recover within a few weeks, long COVID is estimated to occur in 10–20% of cases and affects people of all ages, including children, with most cases occurring in patients with mild acute illness. The consequence is widespread global harm to people's health, wellbeing, and livelihoods—an estimated one in ten people who develop long COVID stop working, resulting in extensive economic losses.

In 2021, a coordinated research and health-care agenda was suggested to tackle this new medical challenge. However, progress has been excruciatingly slow due to lack of attention and resources.[6]

Continue reading here.

ONE HEALTH ACTION FOR HEALTH SECURITY AND EQUITY

Implementing One Health requires transdisciplinary approaches that focus on the health of animals, humans, and ecosystems worldwide. A new One Health High-Level Expert Panel (OHHLEP) advises the Quadripartite of the Food and Agriculture Organization of the United Nations, the UN Environment Programme, WHO, and the World Organisation for Animal Health on more effectively and collaboratively addressing member states' needs in preventing and preparing for future health emergencies. The OHHLEP's guiding principles have gained rapid global acceptance and paved the way for enhanced collaboration on communicable and non-communicable disease threats.[7]

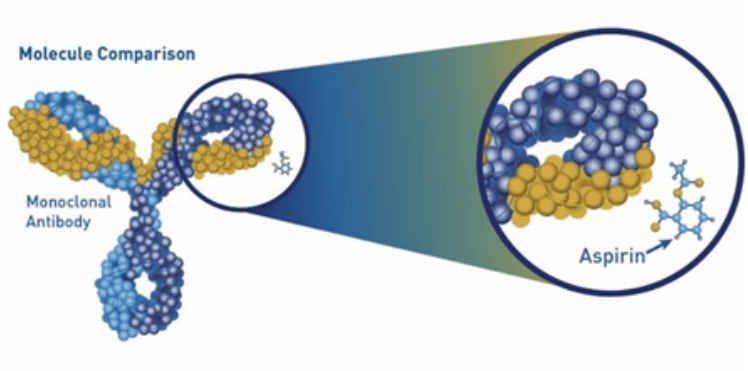
Check out this article to learn more about the Quadripartite's One Health Joint Plan of Action and how it aims to sustainably optimize and balance the health of humans, animals, and ecosystems.

FDA RESOURCE: OVERVIEW OF BIOSIMILARS

Check out the FDA's biosimilars resource! Designed for both healthcare professionals and patients, these pages provide valuable information on the safety and efficacy of biosimilars. With more treatment options and increased access to life-saving medications, biosimilars have the potential to lower healthcare costs through competition. Learn more about biosimilars' use in treating a range of illnesses, including psoriasis, Crohn's disease, arthritis, diabetes, and cancer.[8]

Read a general introduction to biosimilars on the Academy website here.

Access the biosimilars resource on the FDA's website here.



This image from the FDA's biosimilars overview website illustrates the significant difference between aspirin and a monoclonal antibody.

NEWS FROM THE EMA: PEDIATRIC REGULATION

EU regulators have made significant progress in boosting the development of medicines for children by improving pediatric regulatory processes. The European Medicines Agency (EMA) and the European Commission (EC) action plan on pediatrics has strengthened the focus on unmet medical needs, adapted regulatory processes to support innovation, and increased the alignment of data requirements between decision-makers. One major outcome is the launch of a pilot phase for a 'stepwise PIP' agreement, allowing partial development programs conditional on the development of a full PIP once evidence becomes available. These achievements are highlighted in the closing report of the EMA and EC action plan on pediatrics.[9]

Click here to read more about the key improvements brought by the pediatric action plan.

QUALITY CONTROL AND CHILDHOOD CANCER MEDICINES

An article from the Lancet brings devastating news from the Bureau of Investigative Journalism. On January 25, 2023, the Bureau published evidence that at least 70,000 children with cancer in 90 countries are at risk of being treated with contaminated and low-quality asparaginase.

Shockingly, at least seven manufacturers are continuing to sell their products despite being warned that they don't meet minimum quality assurance. The investigation shows that poor regulation and oversight continues to cultivate a market for dangerous generic products to flourish, putting children's lives at risk. As countries struggle to maintain treatments for patients during the global cost of living crisis it's more important than ever to ensure that rigorously enforced standards are in place to prevent harm being done to children with cancer. Click here to read more. [10]

CLINICAL TRIAL DIVERSITY CONTINUES TO FACE CHALLENGES

Are clinical trials truly representative of diverse populations? Policymakers and biopharma companies have recognized the importance of assessing drugs and medical products on a wide range of ethnic and racial populations, but achieving equitable patient representation in clinical trials has been a challenge.

After years of FDA issuing guidance documents and launching programs to encourage sponsors to seek broader representation in clinical trials, policymakers have added a “stick” to the process: research sponsors now will be required to tackle this issue by submitting Diversity Action Plans (DAPs) to the agency when proposing and seeking approval of Phase III and pivotal studies. This provision was included in the Food & Drug Omnibus Reform Act (FDORA), approved by Congress in December 2022 as part of the massive Consolidated Appropriations Act that authorized federal spending for 2023.

FDA has a year to issue guidance on the program, and there may be some waivers and exceptions, as for bioequivalence studies. But diversity plans will be required for most clinical development programs. FDA will hold a public workshop on the program, issue additional guidelines on specific topics, and submit annual reports to Congress once the program gets going.[11] Learn more about this groundbreaking legislation and its potential impact on healthcare in the future.

BEMPEDOIC ACID AND CARDIOVASCULAR OUTCOMES IN STATIN-INTOLERANT PATIENTS

A recent study published in NEJM suggests that bempedoic acid, an ATP citrate lyase inhibitor, may be a promising alternative for patients who cannot tolerate statins due to side effects. The study found that bempedoic acid was associated with a lower risk of major adverse cardiovascular events in statin-intolerant patients. The drug reduces LDL cholesterol levels and has a low incidence of muscle-related adverse events. These findings offer hope for patients who are unable or unwilling to take statins, highlighting the need for alternative treatment strategies.[12]

Read more here.

GLOBAL TRENDS IN R&D 2023

Check out the latest IQVIA Institute report on global R&D trends and activities. As our readers will likely find this to be an interesting and substantial source of information, we will highlight different areas in this and upcoming newsletters. This edition emphasizes key findings in R&D investment activities.

Key highlights include the restoration of biopharma investment flows and deal activity in the US to pre-pandemic levels, a decline in venture capital investments into European companies, and the shift in deal activity towards China and South Korea-based companies. Additionally, the report reveals that the largest pharmaceutical companies invested a record $138Bn in R&D expenditure in 2022, with an increase in deals involving emerging biopharma with larger companies.[13]

Click here to read more.

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Thanks for reading!

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