



CLINICAL TRIALS IN UKRAINE CARRY ON DESPITE WAR

BY DOMENICO CRISCUOLO

Ukraine has a long tradition of performing high-quality clinical trials in a timely manner. The concentration of patients in just a few hospitals, access to innovative therapies, and the quality training received by investigators and other staff members, have made Ukraine an ideal country for clinical trials in the last 20 years. However, the war has created numerous challenges in myriad areas of the country, and Medical Affairs is no exception. [Continue reading here.](#)

TABLE OF CONTENTS

Mysterious Hepatitis
in Kids • P. 2

The Ongoing Pursuit
of Quality First • P. 2

Conversations with the Academy
webinar • P. 3

Continuous Medical
Education • P. 4

MYSTERIOUS HEPATITIS IN KIDS: WHAT WE KNOW AND DON'T KNOW

BY DOMENICO CRISCUOLO

At least 228 probable cases of severe hepatitis in children have been reported across 20 countries worldwide, according to the World Health Organization on May 4. In the United States, the Center for Disease Control and Prevention (CDC) is investigating 109 cases of pediatric hepatitis of an unknown cause. As clinicians, epidemiologists, and other experts search for answers on what is causing serious liver inflammation in affected kids and how to prevent it, it might help to start with what can be ruled out.

Researchers agree that hepatitis A, B, C, D, or E — viruses that more commonly cause acute hepatitis — are not to blame in these cases. Nor are these cases definitively linked to SARS-CoV-2 infection, at least not so far, and there is also no evidence that the COVID-19 vaccination is to blame. ¹ [Click here to keep reading.](#)



THE ONGOING PURSUIT OF QUALITY FIRST IN MEDICINES DEVELOPMENT



In the last 20 years, we have seen a global emphasis on quality as a leading priority in all industrial activities. Cars no longer require checks at short intervals, the goods we purchase in supermarkets clearly indicate their country of origin and expiry date, and so on. The pursuit of quality in Medicines Development is no exception. It is a frequent focus in Academy lectures that professionals in Medicines Development have an ethical obligation to look for top-level quality from laboratory studies (GLP) to clinical studies (GCP) and finally, to the manufacturing of all drugs (GMP). We are often developing drugs to treat patients with severe diseases, and as such, we cannot compromise the quality of our work under any circumstance.

As such, it was with industry-wide frustration that we read the enclosed press release from the EMA...

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— Conversations with the Academy presents:
— **Fraud and Misconduct in Medicines Development**
— June 28, 2022, 8:00 AM - 9:00 AM EDT



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One only needs to watch the news to see examples of fraud and misconduct. But when fraud and misconduct occur in the scientific arena, the consequences may be significant for both patients and healthcare professionals. Research misconduct can seriously undermine the protection and promotion of public health. Therefore, considerable effort is expended in detecting and correcting such events. This webinar will explore past and present scenarios and offer suggestions for preventing fraud in scientific research and medicines development.

Learning Objectives

1. Understand situations where fraud and misconduct occur more frequently
2. Identify the best corrective actions to prevent and to face fraud in scientific research
3. Analyze several real-life examples of fraud and their consequences
4. Appreciate that fraud is still with us, as demonstrated in some examples of COVID-19 studies

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CONTINUOUS MEDICAL EDUCATION IN SWITZERLAND AND BEYOND

BY DOMENICO CRISCUOLO

Switzerland, together with the United Kingdom and Ireland, is one of three European countries which recognized Pharmaceutical Medicine as a medical specialty. This was the result of many efforts of the Swiss Society of Pharmaceutical Medicine (SSPM). Of note, the curriculum of students seeking to access this program is consistent with recommendations provided by a joint working group of professionals from the PharmaTrain Federation, IFAPP, and the Academy. [Continue reading.](#) ²



REFERENCES

1. World Health Organization (23 April 2022). Disease Outbreak News; Multi-Country – Acute, severe hepatitis of unknown origin in children. Available at: <https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON376>
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