



PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM MICHAL KANTECKI

We continue with our Professional Identity and Medicines Development series. We are pleased to share a well-written essay from Academy alumni Michal Kantecki, MD. We are grateful for Michal's contributions to our community.

Continue reading on page 2 to read more from Michal as he discusses the development and status of his own Professional Identity and what it means in terms of his job, career, and future prospects.

TABLE OF CONTENTS

Professional Identity:
Michal Kantecki • P. 2

Clinical trials in stroke in 2022:
Answers and questions • P. 3

EMA hosts RNA conference • P. 3

CIOMS news and conferences • P. 4

News from the Japanese MHLW
• P. 4

Decentralized trials • P. 5

The EMA and decentralized trials
• P. 6

Flu causing increase in
hospitalizations in Canada • P. 6

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“ I am convinced that a long-term vision of a professional career is crucial to succeeding in building a Professional Identity and one should focus on accumulating knowledge and skills, but even more importantly, acting in a way to build trust, confidence, integrity, and professionalism. Such an attitude allows access to the next level of being recognized not only as an expert, but also as a personification of professionalism. I believe that this is the pinnacle of career development and should be the aim of all of us as Medical Affairs Specialists. ”



Michal Kantecki, MD

Senior Medical Director, Global
Medical Lead: ATM-AVI, Zinfo

CONT'D: PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT

I graduated from medical school more than 25 years ago and worked in a children's hospital for a couple of years thereafter. During this time, I gained substantial knowledge of pediatrics and practical hospital management. I participated in clinical studies as investigator and cooperated with pharma industry. After a few years I realized that my preference is more in organizing healthcare and publishing than actually delivering care to patients, so I moved to the industry. First, to a generic company, then moving to innovating pharma. During all my years in the business, I developed specialized knowledge and several skills. I was exposed to changing parameters as the environment, job requirements, geographic scope, and degree of responsibility, including people management.

Click [here](#) to read the essay in its entirety.

CLINICAL TRIALS IN STROKE IN 2022: ANSWERS & QUESTIONS

In 2022, several clinical trials have answered important research questions about revascularisation, and about the indications for endovascular thrombectomy, but their answers have raised additional questions. For example, two multicentre, open-label, randomized trials (DIRECT-SAFE and SWIFT-DIRECT) compared endovascular thrombectomy alone with combined intravenous thrombolysis and endovascular thrombectomy to find out if intravenous alteplase could be withheld in patients with large vessel occlusion who present directly to a hospital at which endovascular thrombectomy can be done (referred to as mothership patients).

Overall, DIRECT-SAFE and SWIFT-DIRECT show that intravenous alteplase should not be withheld



when endovascular thrombectomy is being done in a mothership setting. However, the findings raise questions about whether there should be guidelines about an acceptable non-inferiority threshold, and who should contribute to these guidelines (doctors, patients, or policymakers)?¹

[Continue reading here.](#)

EMA HOSTED VIRTUAL REGULATORY AND SCIENTIFIC CONFERENCE RE: RNA-BASED MEDICINES



We are pleased to announce that the European Medicines Agency hosted a virtual regulatory and scientific conference on RNA-based medicines on February 2, 2023. The aim of the conference was to promote the development of RNA-based medicines by:

- Identifying scientific and regulatory opportunities and challenges of RNA-based innovative medicines.
- Facilitating dialogue between industry/academia and regulators and raising awareness on scientific and regulatory aspects.
- Identifying gaps in regulatory science.

The conference focused on emerging RNA technologies beyond vaccines. Please see the program posted on the EMA website for more details.²

Continue reading [here](#).

CIOMS: DECEMBER NEWSLETTER, JANUARY CONFERENCES

The CIOMS December 2022 Newsletter is now available. In the fourth quarter of 2022, three recent CIOMS publications were presented at various international events. Two webinars were announced for January. One occurred on 19 January on clinical trials in Africa- the video will be available at this link once it is published. Another was held on January 31: 2023 CoRE webinar series - The CIOMS consensus report on patient involvement.

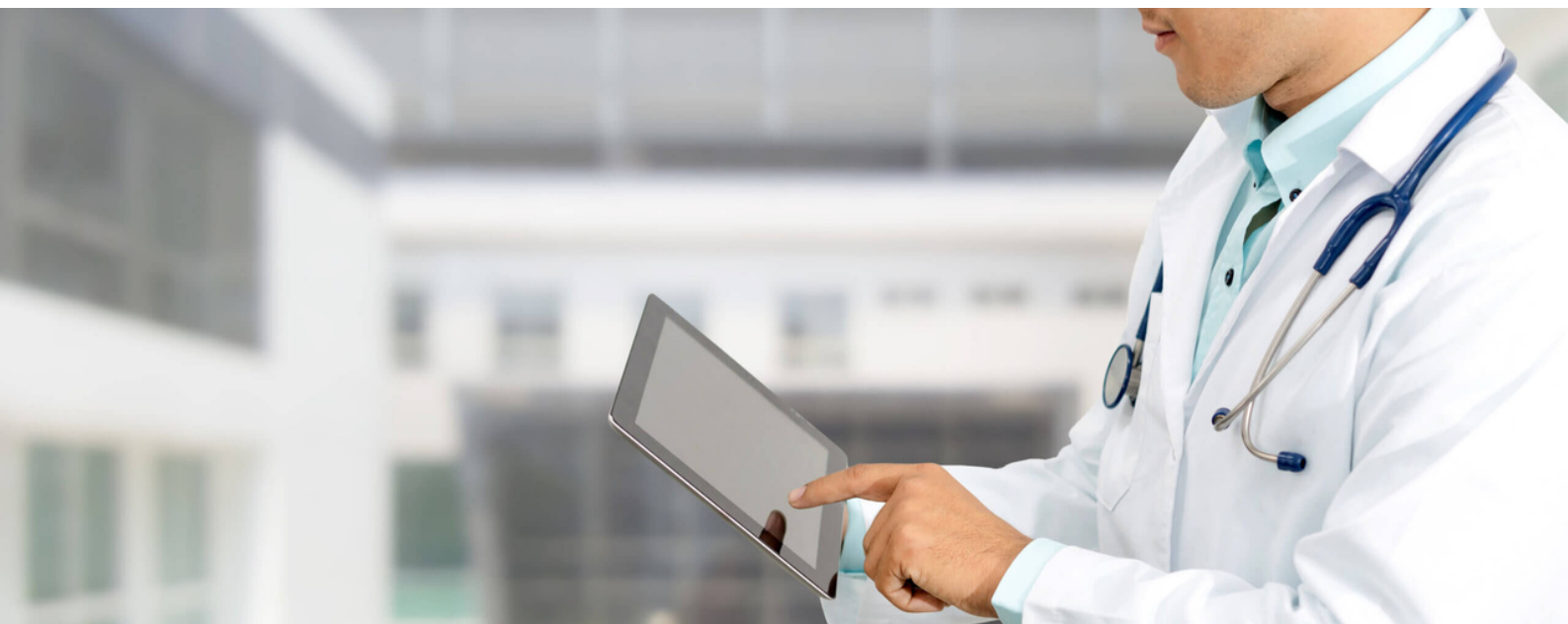
The newsletter further includes information on global health issues and developments related to the CIOMS areas of work. The 2021 consensus report on Clinical research in resource-limited settings will be considered in future WHO guidance.



The Chinese translation of another CIOMS pharmacovigilance report has been distributed, as well. This has immediately become one of the top ten downloads of CIOMS publications.³

Continue reading [here](#).

NEWS FROM THE JAPANESE MINISTRY OF HEALTH, LABOUR AND WELFARE



The Japanese Ministry of Health, Labour and Welfare has the responsibility of the National Agency for drugs. The messages offered to Japanese citizens are very clear and contain illustrations to better explain the key recommendations.

You can visit their website [here](#).

NEWS REGARDING DECENTRALIZED TRIALS

In collaboration with the EMA and the European Union, the Heads of Medicines Agencies (HMA) issued a guideline called 'Recommendation Paper on Decentralized Elements in Clinical Trials'.

More and more, clinical trials on Investigational Medicinal Products (IMPs) are using procedures conducted outside the traditional 'clinical trial site', a concept usually referred to as decentralization. In addition, there is increasing use of digital tools within clinical trials. The COVID-19 pandemic highlighted the importance and usefulness of digital tools and decentralized procedures in a healthcare setting and in clinical trials.



The guidance on the management of clinical trials during COVID-19 pandemic provided a set of recommendations that included adjustments to the informed consent process.⁴

Continue reading [here](#).

ARE YOU A PART OF OUR GLOBAL COMMUNITY?

Want to be featured in a future edition of the Academy newsletter? Do you have an update you'd like to share with the IFAPP Academy network? We invite you to share a professional achievement, job transition, or personal milestone and welcome your submissions.

Email your news and updates to community@ifappacademy.org.



THE EMA AND DECENTRALIZED TRIALS

The European Commission (EC), the Heads of Medicines Agencies (HMA), and the European Medicines Agency (EMA) have published recommendations that aim to facilitate the conduct of decentralized clinical trials (DCTs) while safeguarding the rights and well-being of participants as well as the robustness and reliability of the data collected. This is an outcome of their joint initiative to Accelerate Clinical Trials in the European Union (ACT EU).

Traditionally, clinical trials have been conducted at specific clinical trial sites where patients had to travel. The aim of DCTs is to make it easier for patients to participate in clinical trials by reducing the need to travel to central trial sites. This approach has the potential to make clinical trials...



available to a broader demographic of participants and reduce drop-out rates.

Decentralization is enabled by the advancement of digital tools, telemedicine and more mobile and local healthcare. It includes aspects such as home health visits, remote monitoring and diagnostics, direct-to-patient shipment of study drugs, and electronic informed consent.⁵ Read more [here](#).

FLU CAUSES HUGE SPIKE IN CHILD HOSPITALIZATIONS IN CANADA



Clinicians and parents in Canada are watching with concern as pediatric hospitalizations for seasonal influenza climb — at present, they are at more than ten times the normal rate for this time of year. In late November, weekly admissions were 50% higher than at the record peak for at least the past seven flu seasons. “The younger age group is being hit unusually hard for this time of year,” says Alyson Kelvin, a virologist at the Vaccine and Infectious Disease Organization at the University of Saskatchewan in Saskatoon, Canada.

Unusually, flu-based hospitalizations are currently higher for children aged 0–4 years than for people aged over 65. Continue reading [here](#).⁶

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