UNICA STUDENT WEBINAR ON

CLINICAL DRUG DEVELOPMENT IN THE COVID AND (POST) COVID ERA

Thursday, December 10th 2020, 2-4 pm CEST

Zoom Link https://us02web.zoom.us/j/87266148928

WELCOME ADDRESSES (15')

Luciano Saso, President of the Network of the Universities from the Capitals of Europe (UNICA)
Maeva D'Almeida,Vice president of Internal Affairs, European Pharmaceutical Students' Association (EPSA)

PROGRAMME

Novel clinical trial designs by **Josse Thomas**, Guest Lecturer, *KU Leuven* and Senior Consultant, PharmaCS (45')

Drug development in the COVID and post-COVID eras: the perspective of regulators" by **Hans-Georg Eichler**, Senior Medical Officer, European Medicine Agency (EMA) (20')

Discussion (30'), **animated by Maeva D'Almeida**,Vice president of Internal Affairs, European Pharmaceutical Students' Association (EPSA), **Chris van Schravendijk,** Emeritus professor at the Faculty of Medicine and Pharmacy of the Vrije Universiteit Brussel and **Sibel Suzen,** Professor at the Faculty of Pharmacy of University of Ankara

Participation is free
Further information: http://www.unica-network.eu/taxonomy/term/3611
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Prof. Luciano Saso (Faculty of Pharmacy and Medicine, Sapienza University of Rome, Italy) received his PhD in Pharmaceutical Sciences from Sapienza University in 1992. He is author of more than 230 scientific articles published in peer reviewed international journals with impact factor (SASO-L in www.pubmed.com, total impact factor > 500, H-index Google Scholar 47, Scopus 38). He coordinated several research projects and has been referee for many national and international funding agencies and international scientific journals in the last 30 years. Prof. Saso has extensive experience in international relations and he is currently Vice-Rector for European University Networks at Sapienza University of Rome. In the last 15 years, he participated in several projects and has been speaker and chair at many international conferences organised by the UNICA network of the universities from the Capitals of Europe (http://www.unica-network.eu/) and other university associations. Prof. Saso has been Member of the Steering Committee of UNICA for two mandates (2011-2015) and he is currently President of UNICA (2015-2023).

Olga Maeva D'Almeida is a recent graduate Pharmacy student in France, pursuing a double degree in engineering. After 1 year as Events Coordinator for the European Pharmaceutical students association (EPSA), followed by another year as Vice president in charge of International affairs in the National Pharmacy students association of France, She is currently holding the position of Vice President of Internal Affairs in EPSA, taking care of the relation between the members association and the EPSA Team members. Passionate about education and soft skills she attended multiple national or international events, gaining insight about the healthcare system, policy and education in Europe. She became in 2017 an EPSA Soft skills Trainers in 2017. Throughout her studies she gained various experiences through internships in Research, Regulatory affairs, Clinical Trials in Hospital and continuous improvement project management in a Medical device company. EPSA represents over 100 000 pharmaceutical students from 35 countries and 41 members associations. It aims is to bring together pharmacy students and knowledge together promoting professional development and advocate for students best interests

Novel clinical trial designs

Josse R. Thomas
Guest Lecturer Clinical Drug Development KU Leuven, Senior Consultant PharmaCS

Traditional or conventional clinical trials typically study 1 test drug in 1 disease, versus placebo and/or a reference drug. The gold standard is the randomised controlled trial (RCT), with a fixed design (parallel group or crossover), and clinical drug development is usually planned as a series of consecutive or partly overlapping RCTs in different phases. Since a number of years, this approach has been challenged as it is considered to be time consuming, inefficient, expensive, and not adapted to new trends. Therefore, several new clinical trial designs and clinical drug development strategies have been introduced in order to cope with these issues. Some of the most common ones will be presented here in more detail, such as:

- Adaptive designs, i.e. designs that allow pre-planned modifications of the trial and/or its statistical procedures, based on interim-analyses of data from the trial itself.
- Precision medicine trial designs, either evaluating a single therapy in multiple diseases/disease subtypes (basket trial), or multiple therapies in a single disease (umbrella trial).
- Complex innovative designs (CIDs), also known as complex clinical trials (CCTs), master protocols, platform trials, perpetual umbrella trials or multi-arm multi-stage (MAMS) designs/trials, using one overarching (master) trial protocol to answer multiple questions. They feature sub-protocols and extensive adaptations, and allow therapies to enter or leave the platform during the course of the trial.
- Seamless designs, combining the aims of separate phase 1 and 2a trials (early clinical development), or 2b and 3 (late development) trials into one single trial, with the ultimate evolution to a completely seamless clinical drug development.

All these novel designs and development strategies will be illustrated with examples, especially from the field of oncology (where they are particularly well introduced), but also with CCTs initiated during the current Covid-19 pandemic. Finally, their advantages will be discussed, together with the operational challenges they pose.

Josse R Thomas graduated as a Pharmacist and holds a PhD degree in Medical Sciences (pharmacology) from the University of Leuven. He is also certified as Clinical Pharmacologist and has more than 30 years of experience in clinical drug development in the pharmaceutical industry. In addition, he holds various academic and consulting positions, including Guest Lecturer at KU Leuven (clinical drug development), member of the Research Ethics Committee of UZ/KU Leuven, member of the Clinical Trials Board of KCE, member of the working group at the FAMHP for the implementation of the EU Clinical Trials Regulation & Medical Devices Regulation in Belgium, and Senior Consultant at PharmaCS. He is also co-author of the book ‘Global New Drug Development: An Introduction’, published by Wiley-Blackwell, and a reference in its field.

Drug development in the COVID and post-COVID eras: the perspective of regulators"

Hans-Georg Eichler
Senior Medical Officer, European Medicine Agency (EMA)

This talk will give a brief overview of the processes and initiatives in place at the European Medicines Agency (EMA) to support drug development and to facilitate interactions between academic developers/investigators and regulators. In the second part, experiences from the ongoing Covid drug and vaccine development as well as potential learnings for the post-Covid era will be discussed.

Hans-Georg Eichler, M.D., M.Sc., is the Senior Medical Officer of the European Medicines Agency, where he is responsible for coordinating activities between the Agency's scientific committees and giving advice on scientific and public health issues. From 2015 to 2018 he was the scientific lead for the IMI ADAPT SMART consortium on Adaptive Licensing.
Prior to joining the European Medicines Agency, Dr. Eichler was at the Medical University of Vienna in Austria for 15 years. He was vice-rector for Research and International Relations since 2003, and professor and chair of the Department of Clinical Pharmacology since 1992. His other previous positions include president of the Vienna School of Clinical Research and co-chair of the Committee on Reimbursement of Drugs of the Austrian Social Security Association. His industry experience includes time spent at Ciba-Geigy Research Labs, U.K., and Outcomes Research at Merck & Co., in New Jersey. Dr. Eichler graduated with an M.D. from Vienna University Medical School and a Master of Science degree in Toxicology from the University of Surrey in Guildford, U.K. He trained in internal medicine and clinical pharmacology at the Vienna University Hospital as well as at Stanford University.

Chris van Schravendijk is Emeritus professor at the Faculty of Medicine and Pharmacy of the Vrije Universiteit Brussel. His research was focused on cellular biology, prediction and prevention of type-1 diabetes. As faculty professor he was responsible for the Introductory course on Scientific Thought and Evidence Based Medicine in the first Medical Bachelor year and for the Bachelor course on Formulation and Development of a Scientific Hypothesis in the third Bachelor year of Medicine and Biomedical Sciences. Between 2008 and 2016, he was the Director of the Doctoral School of Life Sciences and Medicine, with more than 200 PhD students. He has a long standing interest in international benchmarking and harmonization in the area of Higher Education (MEDINE, MEDINE-2, ORPHEUS) with focus on the place of the research component in the undergraduate medical curriculum as well as on career perspectives of academic graduates in the life sciences. As emeritus he is particularly interested in PhD workshops promoting better awareness of research integrity as well as job opportunities in the area of the Life Sciences.

Professor Sibel Suzen, Ankara University, Faculty of Pharmacy, UNICA steering Committee member. Sibel Süzen is professor at the Faculty of Pharmacy of Ankara University. Her research is focused on the synthesis and development of antioxidant-based anticancer compounds, their biological evaluation, melatonin-based compounds in drug research. She graduated from Ankara University Faculty of Pharmacy in 1985. After completing her Master's Degree in Pharmaceutical Chemistry at the same university in 1989, she received her doctorate in 1997 from the University of Swansea, UK, Department of Chemistry. She continued her research at Swansea University in various years. She has been a member of European Farmacopea expert in Group (Semi synthetic and synthetic compounds) since 2011. In the last 10 years, she has been working as Institutional Erasmus Coordinator, Internationalization and Foreign Relations Coordinator of Ankara University. She has been coordinating the opening of English taught programs as well as international projects, internship agreements and educational programs of the EU. She was vice-rector for International Relations and Projects at Ankara University since 2019-20. She carried out numerous projects supported by Tübitak and University resources. She is the author of more than 100 scientific articles and many chapters in various books both in Turkey and abroad. She worked as project manager and organized several scientific meetings. She has been a member of the Editorial Board of various scientific journals.