Research Ethics Review Streamlining Initiatives

CHEER Webinar Agenda and Bios

Monday, November 29th
8:00-10:30 PT / 11:00-13:30 ET / 17:00-19:30 CT

Zoom Meeting Registration Link:
https://queensu.zoom.us/webinar/register/WN_WjSs3iNTRZ-6vxS02dvvng

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1.	Introduction (5 minutes)	*Thierry Lacaze*
2.	The European Clinical Trial Regulation (CTR) with Nordic Implementation Example (25 minutes)	*Pieter Vankeerberghen* *Pirkko Lepola*
3.	Pediatric Clinical Research Ethics Review Specifications in Europe (Enpr-EMA) (15 minutes)	*Pirkko Lepola*
4.	Q&A Period (20 minutes)	
Break (15 minutes)		
5.	Requirements in the US for Single IRB Review of Multi-Site Research: Smart IRB as a Model Solution (20 minutes)	*Barbara E. Bierer*
6.	Working Towards a Single Research Ethics Review Process for Multisite Child Health Studies Across Canada (20 minutes)	*Susan Marlin*
7.	Q&A Period (20 minutes)	
8.	Closing Remarks (5 minutes)	*Thierry Lacaze*

Q&A periods will be moderated by Samantha Drover

About the Presenters

Pieter Vankeerberghen, PhD, Head of Clinical Trials, Data Analytics and Methods Task Force, European Medicines Agency, Netherlands

Pieter Vankeerberghen studied Industrial Pharmacy, obtained a Ph.D. in Pharmaceutical Sciences and holds a master's degree in Informatics. After working for 4 years in R&D, first in Clinical Data Management and later as project manager in human pharmacology, he joined the Belgian authorities AFMPS in 2000. His roles in sequential order are: business process reengineering project leader, transition manager, followed by coordinating the agency's ICT projects and developments and holding a coordinating role in EU Human/Veterinary esubmissions. From 2016 to July 2020 he led the DG pré R&D department for clinical trials and unmet medical need. In this role he was a Member State Product Owner for the CTIS project. From August 2020 he is head of EMA clinical workstream and CTIS programme manager in the Data Analytics and Methods Task Force.

Pirkko Lepola, Executive Secretary of FINPEDMED, General Secretary of NORDICPEDMED at Helsinki University Hospital, Department of Children and Adolescents, Finland. Chair of the Enpr-EMA Coordinating Group

Education: 1995: B.Sc. (Health Care), 2006: M.Sc. (Biotechnology), 2012: Teacher (Pedagogical qualification). 2001-2009: Courses in BioMedical Law and Pharmaceutical Medicine.
Professional Experience: 1995-2006: Various management positions (Clinical Trials) in Pharma Industry and CRO companies, and University Hospital´s Research Organizations. Since 2007 -present: Executive Secretary of FINPEDMED (Finnish Investigators Network for Pediatric Medicines), 2010-2012: Project Manager of FinnTrials–project (Finland), 2013-2017: Researcher in EU GRiP -project (Global Research in Paediatrics), 2014-2019: Project Manager of NORDICPEDMED projects. 2016-present: General Secretary, NordicPedMed (Nordic Investigators Network for Pediatric Medicines), 2017-2021: Consortium Partner in EU PedCRIN (The Paediatric Clinical Research Infrastructure Network)–project; 2018-present: Consortium Partner in the EU/IMI2 c4c (Conect4Children-PanEuropean Pediatric Clinical Research Infrastructure), 2014-2019: Conference creator/co-creator & producer: National Pediatric Drug Therapy Conferences, Nordic Conferences on Pediatric Medicines with Pharma Industry Finland.
Memberships & Expert work: 2010-present: EMA (European Medicines Agency) European Expert, 2010-present: Chair, Enpr-EMA (European Network of Paediatric Research at the European Medicines Agency), 2013-present: Chair, Enpr-EMA Working Group of Ethics. 2013-present: Member of the EFGCP MCWP (European Forum for Good Clinical Practice, Medicines for Children Working Party), 2019-present: Member of the Advisory Board SwissPedNet (The Swiss Research Network of Clinical Pediatric Hubs),
Teaching: 2007-present: Lecturer at Universities, University Hospitals and Universities of Applied Sciences in Finland.
Publications: Articles 11, Book chapters 2, Scientific presentations 50+.

Barbara E. Bierer, MD, Professor of Medicine, Brigham and Women's Hospital, Harvard Medical School

Barbara E. Bierer, M.D., a hematologist-oncologist, is Professor of Medicine at Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH). Dr. Bierer co-founded and now leads the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center), a collaborative effort to improve standards for the planning and conduct of international clinical trials. In this capacity, she works with regulators, pharmaceutical companies, CROs, academia and patients/patient advocates to harmonize policies and approaches for multisite, transnational trials. She is a co-founder of COVID-19 Collaboration Platform and of the non-profit Vivli, a global clinical research data sharing platform. She is also the Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst, and Director of Regulatory Policy for SMART IRB. She serves as Faculty in the Center for Bioethics, HMS, and Affiliate Faculty in the Petrie-Flom Center for Health Law at Harvard Law School. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research, BWH where she founded the Brigham Research Institute and the Brigham Innovation Hub. She is a past chair of SACHRP and has served or serves on the Board of Directors of AAHRPP, PRIMR, MSH, Vivli, North Star IRB, and the Edward P. Evans Foundation. She has authored over 250 publications.

Susan Marlin, President and CEO of Clinical Trials Ontario, Principal Investigator of CHEER

Susan Marlin is the President and CEO of Clinical Trials Ontario (CTO), an organization established by the Province of Ontario in 2012 to make Ontario a preferred location for global clinical trials while maintaining the highest ethical standards. Prior to joining CTO served as the Associate Vice-Principal at Queen's University. Susan worked with the National Cancer Institute of Canada Clinical Trials Group for many years, initially coordinating cancer clinical trials and later leading the development and implementation of the Ethics and Regulatory Office.

Susan has actively engaged in research ethics for many years. She served as President of the Canadian Association of Research Ethics Boards, as a member of the Canadian Institutes of Health Research (CIHR) Research Integrity Committee, the Ontario Cancer Research Ethics Board and the Tri-Agency Panel on the Responsible Conduct of Research. Susan is on the Board of Directors and Executive Committee of Life Sciences Ontario and the Management Team for the Ontario SPOR (Strategy for Patient-Oriented Research) Support Unit. She is an Adjunct Lecturer at Queen's University in Kingston, Ontario and is the nominated principal investigator on a Canadian Institutes of Health Research funded project to streamline research ethics review for child health research across Canada.

Susan was born and raised in Halifax, Nova Scotia. She holds a BSc (Hons) from Dalhousie University and an MSc in Community Health and Epidemiology from Queen's University. She was awarded the Queen's Elizabeth II Diamond Jubilee medal in 2012 in recognition of her work in support of military and veteran health research.