

INTERNATIONAL CONFERENCE

**“Medical, ethical and legal aspects of experimental therapy”**

Warsaw, 19 May 2017

**P R O G R A M M E**

09.30 - 10.00      ***Registration***

10.00 – 10.10      ***Opening and welcome remarks:***  
Prof. Andrzej Górski, Polish Academy of Sciences/Medical University of  
Warsaw

**SESSION I**

**Chair: Prof. Andrzej Górski**

10.10 – 10.30      ***Experimental therapy: the EMA perspective***  
Dr. Marisa Papaluca, Senior Scientific Adviser, European Medicines Agency,  
London

10.30 – 10.40      *Discussion*

10.40 – 11.00      ***Compassionate Use in the United States: An Update of Recent  
Industry, Regulatory, Legislative, and Social Factors***  
Dr. Alison Bateman-House, Division of Medical Ethics, NYU School of  
Medicine, Co-Chair, Working Group on Compassionate Use and Pre-Approval  
Access, Deputy Director, Compassionate Use Advisory Committee (CompAC)

11.00 - 11.10      *Discussion*

11.10 - 11.30      ***The ethics of emergency use of unproven interventions outside of  
research” – WHO’s guidance***  
Dr. Abha Saxena, Coordinator, HQ/HIS/IER/REK, World Health Organization,  
Geneva

11.30 – 11.40      *Discussion*

11.40 – 12.00      *COFFEE BREAK*

## **SESSION II**

**Chair: Dr. Jan Borysowski**

- 12.00 – 12.20     ***Access to investigational drugs outside of controlled clinical research - individual and social interests***  
Dr. Joanna Różyńska, University of Warsaw, Center for Bioethics and Biolaw
- 12.20 – 12.30     *Discussion*
- 12.30 – 12.50     ***Access to experimental treatment in the court's interpretation***  
Dr. Agata Wnukiewicz-Kozłowska, University of Wrocław, Faculty of Law, Administration and Economics
- 12.50 – 13.00     *Discussion*
- 13.00 – 13.20     ***Compassionate use and ethics committees***  
Dr. Jan Borysowski, Medical University of Warsaw
- 13.20 – 13.30     *Discussion*
- 13.30 – 14.00     ***Summary and conclusions***
- 14.00 – 15.00     **LUNCH**