Universität Basel

Juristische Fakultät

EU Clinical Trial Regulation
New Legal Framework for Multicenter Clinical Trials

Friday, December 16, 2016, 1 pm – 5 pm

WWZ Auditorium
University of Basel, Law Faculty, Peter Merian-Weg 8, CH-4002 Basel

Program:

12.30	***Registration***
13.00 – 13.05	***Welcome*** Prof. Dr. Dipl.-Biol. Herbert Zech, University Basel, Faculty of Law
13:05 – 13.15	***Introduction*** Prof. Dr. Claudia Seitz, M.A., University Basel, Faculty of Law Dr. Alexander Meier, Novartis Pharma AG
13.15 – 13.45	***EU Clinical Trial Regulation and the Swiss Human Research Act*** Prof. Dr. Claudia Seitz, M.A., University Basel, Faculty of Law
13.45 – 14.15	***EU Clinical Trial Regulation – A View from Legal and Regulatory*** Dr. Alexander Meier, Novartis Pharma AG
14.15 – 14.45	***Coffee Break***
14.45 – 15.30	***EU Clinical Trial Regulation – A View from the Regulator*** ***"Legal aspects on transparency of clinical data – EMA experience"*** Ioana Ratescu, Legal Advisor, European Medicines Agency (EMA)
15.30 – 16.00	***EU Clinical Trial Regulation – A View from the Industry*** Dr. Judith Creba, Executive Director EU Regulatory Strategy, Novartis Pharma AG
16.00 – 16.30	***EU Clinical Trial Regulation – A View from Data Privacy*** Noemi Alonso Calvo, Data Privacy Officer, Sandoz International GmbH
16.30 – 17.00	***Discussion***
17.00	***Apéro***

Organized by:

Dr. Alexander Meier, Novartis Pharma AG, Basel
Head Legal Global & Pharma Drug Development

Prof. Dr. Claudia Seitz, M.A.
Center of Life Sciences Law / Zentrum für Life Sciences-Recht (ZLSR)
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Apéro provided by Novartis Pharma AG