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## Update on EU CTR No. 536/2014, Farewell Wishes to Dr. med. Peter Klöpel, and Geographic Trends in Global Pharmaceutical Development

After the lively and inspiring XIII Interdisciplinary Drug Development Expert Workshop on “Successful drug development under cost constraints and complex regulations” (Frankfurt Biotech Innovation Center - FIZ, Frankfurt am Main, 20 April 2018), PPH plus is delighted to offer summaries and links to the complete presentations in two parts.

### EU Regulation No. 536/2014 – Progress since XII PPH plus Expert Workshop

Dr. med. Peter Klöpel, Director Consulting Services and responsible for topic and speaker selection for the Expert Workshops at PPH plus from October 2011, reflected on the domestic and European status quo of measures deriving from the EU Clinical Trial Regulation No. 536/2014.

- The clinical trial authorization procedure ordinance (KPBV, Klinische Prüfung-Bewertungsverfahren-Verordnung) regulating the cooperation between ethics committees (ECs) and the competent federal authorities was released on 12 July 2017.
- The list of ethics committees as currently registered with the BfArM was published on 22 November 2017. A registered ECs’ work assignment plan is available, however, not yet effective; the scale of authority fees is pending. A pilot project involving 35 ECs and one higher federal authority in testing the future clinical trial authorization procedure currently extends to more than 80 completed or pending clinical trial applications.
- In a nutshell, transposition of EU CTR No. 536/2014 to the German national level has been successfully completed to the largest extent. As common knowledge, effective dates of major parts of the updated German Medicines Act depend on the availability of a fully functional EU clinical trial portal and EU database. Latest estimates envisage the pertinent EC commission announcement for the first quarter of 2020.

Full presentation (in German language) available [here](#).

### A Heartfelt Goodbye to a Great Colleague and “See You Again on 17 May 2019”

After an impressive career that had started with family medicine and surgery followed by decades of commitment to highest standards of pharmaceutical medicine as practiced out of US, Japanese, and German BioPharma and CROs, Dr. med. Peter Klöpel will retire in May 2018. On top of his business efforts, Peter Klöpel provided an unbeaten level of volunteer services to the German Society of Pharmaceutical Medicine (DGPharMed), culminating in his DGPharMed chairmanship from 1996 to 2000 that included the presidency of the 11<sup>th</sup> International Conference on Pharmaceutical Medicine (ICPM) in Berlin, Germany, in the year 2000. PPH plus extends sincerest thanks for his support in challenging times and looks forward to welcoming Peter Klöpel back as attendee of the XIV Interdisciplinary Drug Development Expert Workshop as set for 17 May 2019.



### Geographic Trends in Global Pharmaceutical Development - Which Countries Win, Which Countries Lose?

Dr. Vladimir Misik, CEO, SanaClis s.r.o. and Founder & Partner, LongTaal s.r.o, both headquartered in Bratislava, Slovakia, presented the global clinical trial site analytics for the period of 2010 to 2017. The take-home messages of his contribution were as follows:

- More than 70 % of industry-sponsored clinical trials are conducted in developed markets. Europe maintains a clinical trial market share of about 45 % of active clinical trial sites with certain signals of decline.
- The market share outflow to developing markets is halted. Central & Eastern Europe (CEE) is a winner among emerging markets.
- Patient accessibility to clinical trials is highest in North America and CEE, lowest in Middle-East and Africa (MEA) and emerging Asia.
- The gap between clinical trial participation and consumption of marketed pharmaceuticals is highest and widening across several high-growth pharmerring markets.
- Country performance benchmarking between 2010 and 2015 revealed 10 out of top 20 countries globally were from CEE: Bulgaria, Lithuania, Ukraine, Estonia, Poland, Serbia, Czech Republic, Russia, Hungary, and Slovakia.



Full presentation available [here](#).

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