

# EMA and CDISC

CDISC User group Meeting  
Darmstadt, September 16, 2014

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# Activities Since February

- **April 2, 2014: adoption EU Regulation:  
Strong commitment to transparency**
- **Mid-May 2014: Backpedalling?  
Suspect: intervention by pharma / US...?**
- **May 16, 2014: Press release European Ombudsman**
- **End-May 2014: plan for a phase I: only publish CSR by Oct, 1<sup>st</sup>**
- **June 12, 2014: Management Board agreed to adopt the new  
policy.... → ???**

**→ Next news possibly in Q4/14**