European Ombudsman

Public Conference on Clinical Drug Trials

Session 2 – Transparency & access to clinical trial data

Jan Stadler, Inquiry Coordination Unit

European Ombudsman Emily O’Reilly

European Ombudsman

- Investigates maladministration within EU administration
- Complaints by citizens, civil society and companies
- Strategic inquiries on public interest issues

Clinical Trial Data Transparency

- Transparency serves key public interests: accountability, public health

- 2015: New EMA policy on proactive publication of clinical trial data

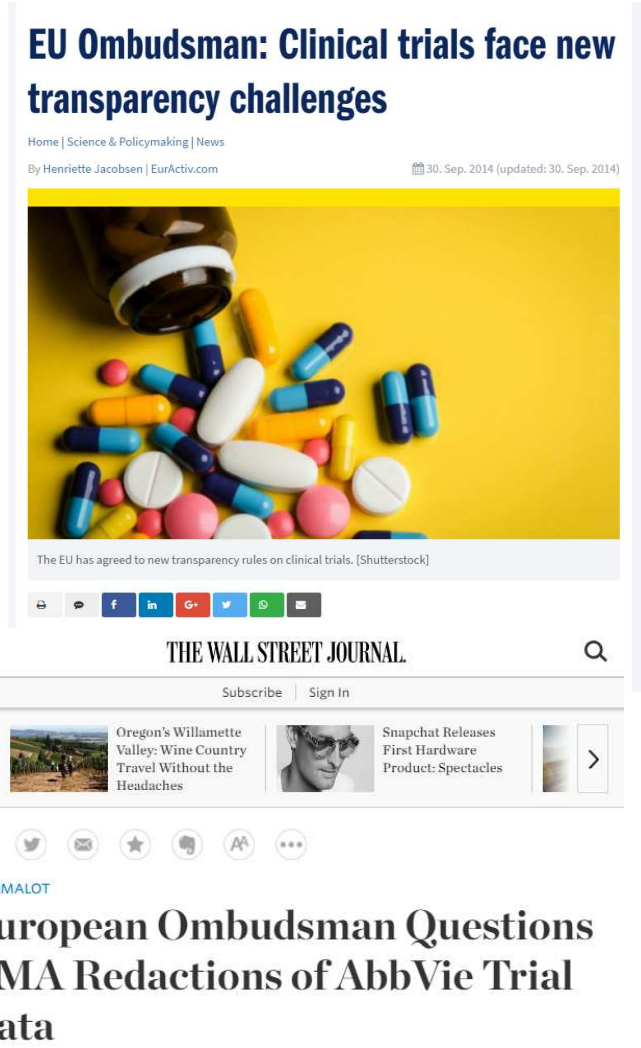
Citizen’s right to request access to EU documents

- EU rules on access to documents: Regulation 1049/2001
- Possible exceptions to access:
  - Data protection
  - Commercial interests, etc.
- Overriding public interest (e.g. public health)?

Ombudsman cases

- OI/3/2014/FOR *Humira*:
  - Public health generally more important than commercial interests

- All decisions available on our website: ombudsman.europa.eu



EU Ombudsman: Clinical trials face new transparency challenges

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By Henriette Jacobsen | EurActiv.com

30. Sep. 2014 (updated: 30. Sep. 2014)

The EU has agreed to new transparency rules on clinical trials. [Shutterstock]

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