



Avoin data ja dataetiikka - Lääkeyrityksen näkökulma



15.3. 2018 / Tarja Jalava





Disclaimer

The views and opinions expressed in the following presentation are my own and do not represent the official policy or position of Bayer.



Clinical Trials -Main international standards of ethical practice

The Declaration of Helsinki

- Since 1964 and now 7th version
- Worldwide standard for ethics in clinical research

ICH-GCP: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

- Since 1996
- Ethical and scientific standards on clinical studies

National laws and regulations





Informed Consent of Trial Subjects

- Informed decision of trial subject
// **Documented** by written, signed, and dated informed consent form
- Trial subject grants access for data to research
- Methods and materials reviewed and approved by IEC & IRBs (and HAs as applicable)





R&D Transparency

Disclosure of clinical trial registry information

www.ClinicalTrials.gov.

<http://www.who.int/trialsearch>

Disclosure of clinical trial results information

[Display of Results on ClinicalTrials.gov](http://ClinicalTrials.gov)

Sharing of clinical trial data with qualified researchers


Anonymized patient-level data

www.clinicalstudydatarequest.com.

Principles for Responsible Clinical Trial Data Sharing

- 1 Enhancing Data Sharing with Researchers
- 2 Enhancing Public Access to Clinical Study Information
- 3 Sharing Results with Patients Who Participate in Clinical Trials
- 4 Certifying Procedures for Sharing Clinical Trial Information
- 5 Reaffirming Commitments to Publish Clinical Trial Results

Principles for Responsible Clinical Trial Data Sharing
Our Commitment to Patients and Researchers



Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**



Summary

Researched-based pharmaceutical companies are committed

- to adhere scientific, ethical and legal principles
- to increase transparency and share of clinical trial information





Thank you!



Bye-Bye

