Ongoing issues of clinical trials: The patient perspective

ESMO 2008

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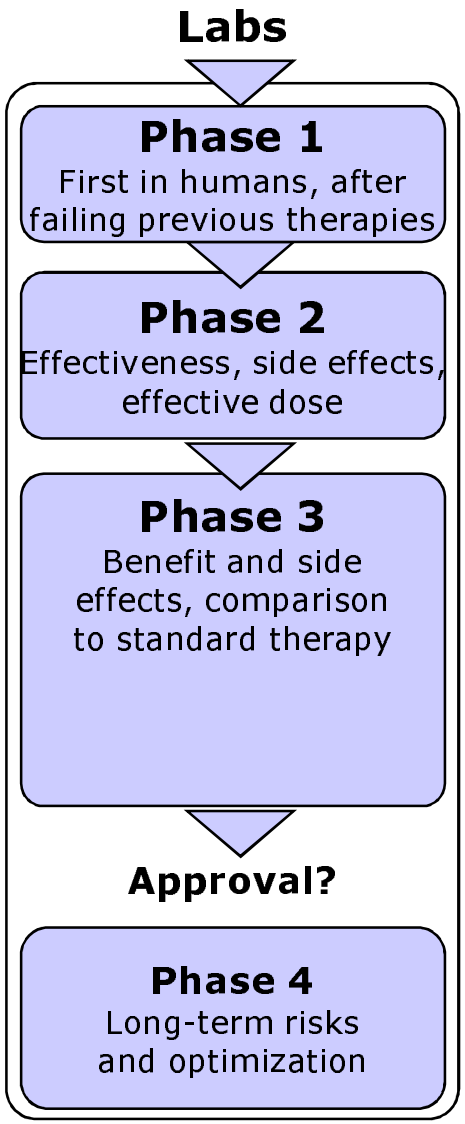
Cancer clinical trials can be life savers...

- Participation in clinical trials can provide significant benefit to patients
- **For those who failed all available therapies**, cancer clinical trials can be life saving.
  Example: Overall response rate to Phase I clinical trials in cancer patients was 10.6%
  (Horstmann: Risks and benefits of phase I oncology trials. NEJM 2005, 352:895-904)
- **In later-stage trials** (Phase IV), patients are usually monitored more closely and with best-in-class diagnostics:
  Resistance/progression might be detected earlier.
- **Altruistic reasons** – supporting research.



...but many patients are reluctant or unable to participate in clinical trials

Doctors uninformed or unwilling

- Doctors are not well informed
- Doctors are unwilling to enroll patients
- Doctors are bound to confidentiality agreements


The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Dangerous Deception — Hiding the Evidence of Adverse Drug Effects

Jerry Avorn, M.D.

September 30 is becoming a day of infamy for drug safety. On that date in 2004, Merck announced that rofecoxib (Vioxx) doubled the risk of

authors advised against further use of the drug, since safer, cheaper alternatives are available.

After the study was published,

Information deficiency

- Patients struggle to find trial information

Loss of public confidence and trust in science

- many myths and misconceptions
- Suspicions about outcome bias, publication restrictions, suppressed data, duplication of research
- Some history of unacceptable practices


BBC NEWS

UK version ● International version About the versions | Low graph

Six taken ill after drug trials

Six men remain in intensive care after being taken ill during a clinical drugs trial in north-west London.

The healthy volunteers were testing an anti-inflammatory drug at a research unit based at Northwick Park Hospital when they suffered a reaction.

The six are being treated at Northwick Park hospital

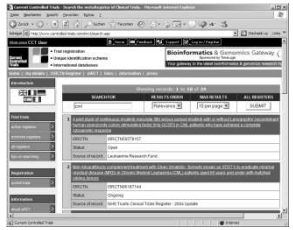
Lack of information access of patients and patient groups is key inhibitor of participation in cancer trials

Today, public trial information…

- is incomplete, inaccurate or outdated
- is not publicly available (EudraCT)
- excludes early trials (Phase I/II), non-commercial trials, therapy optimization trials (e.g. IFPMA portal)
- is in the wrong language (eg. just German)
- shows symptoms of "disappearing data"

WHO trial search engine

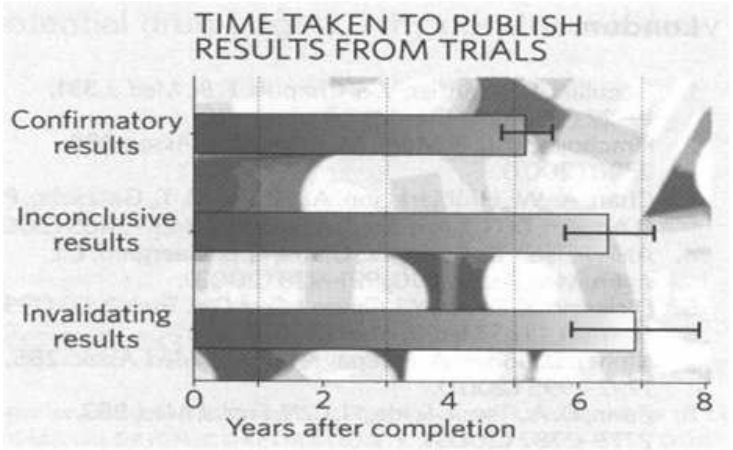
Controlled-trials.com



Clinical studyresults .org

IFPMA Clinical Trials Portal

Trial design & publication: Some facts & figures



- >60% of clinical trials never published (Decullier, BMJ 2005, 331,19).
- Compliance of large registers with WHO's registry platform ICTRP is still poor
- Legal constraints in "patient information", (allegedly to protect patients)
- Clinical Trial Directive has further increased bureaucracy, workload and legal risk

→ **This leads to**

- **delayed recruitment**
- **delayed generation of meaningful clinical data**
- **slow progress or lack of research in Europe**

"Stick and carrot" for science & industry, challenges for legislators

- All stakeholders – including patient groups - must reward good behavior, punish bad practice, and remove barriers for cancer R&D

Actions:

- Patient groups must be able to **join ethics review committees** at trial set-up
- Campaign to **register all cancer trials**, with all relevant information, by the time the trial begins
- **Enforce publication of results**
- Enforce **quality control in registers**
- **Blame non-compliance:** discourage participation in unregistered trials
- **Overcome secrecy** and "competitive worries"
- **Remove legal barriers** (EudraCT, "pull information")

Thank you very much!

Nothing about us – without us!

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CHAMPIONING THE INTERESTS OF EUROPEAN CANCER PATIENTS