Applied Ethics & Societal Aspects in Applied Human Pharmacology

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European AIDS Treatment Group - EATG

- Founded 1992, Berlin
- <100 members, 35 WHO Euro countries, majority patients
- Mission: achieve fastest possible access to state of the art medical products & devices, and diagnostic tests that prevent or treat HIV infection or improve QoL for PLWHA
- To enable people with HIV to have maximum control over the treatment and research agenda
- WGs: ECAB, Policy, DWMG

1980s - Days of Desperation

- No medications
- Smuggling drugs
- Guerilla trials
- Manufacturing drugs
- "Buyer's Clubs"

FDA Demo
October 1988

"Storm the NIH"
May 1990

US activists & FDA

- FDA Personal Use Importation Policy 1986
- New FDA "Treatment IND Regulations"
  "Parallel Track" 1988
- Significantly enhanced large scale access to experimental drugs to >1000 patient EAPs
- Accelerated Approval Regulations 1991

European activists & EMA

- May 1996: Delegation discussing utility of viral load to accelerate new product evaluation
- Sep 1997: EATG informs on surrogate markers (NFV approval)
- Nov 1997: Points to consider ARV assessment
- 1998: Delegation meeting CHMP. Regular interaction since
- 2001: New criteria for conditional approval
- Gilead first to apply, patients benefit, access almost 12 months accelerated
- 2007: NFV EMS toxicity & withdrawal
- 2008: Patients part of PedCo
- 2010: Patients joining PhVWP

Drug development: 10 challenges

- ✓ Compassionate use
- ✓ Access to new & innovative medicinal products
- ✓ PO involvement in scientific advice for all drug applications
- ✓ Transparency CHMP WP / SAG meetings
- ✓ Future phase III trial design in ARV development
- ✓ More strategy trials, more non-commercial trials
- ✓ More & better phase IV studies (RMS, PASS, ENCePP)
- ✓ Harmonise pharmacovigilance – implement new legislation
- ✓ Revision European CT legislation
- ✓ Improve & harmonise work of ethics committees

Future issues

- ✓ Drug reimbursement in EU member States
- ✓ HTA - parallel process to EMA approval?
- ✓ Promote greater use of high-quality observational studies & retrospective analysis where appropriate
- ✓ Develop clear guidance on enrichment, adaptive design, & drug/test co-development
- ✓ DNA collection in registration trials - ethical issues
- ✓ Promote consortia to focus on biomarkers qualification especially for drug safety (ENCePP, PROTECT)
- ✓ Explore potential incentives for innovative development of drug/test combinations
- ✓ Move from one drug/one test paradigm to one chip/many drugs to facilitate a priori use of genetics
- ✓ More, better & earlier data from women at drug approval (PROTECT)

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