

# Clinical Trials on Trial

## The Patient Perspective

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# History of AIDS activism



# 1988 FDA demo



Act Up members block the entrance to the Food and Drug Administration building, October, 1988.

Photo © Ben Thornberry

# 1990 NIH demo

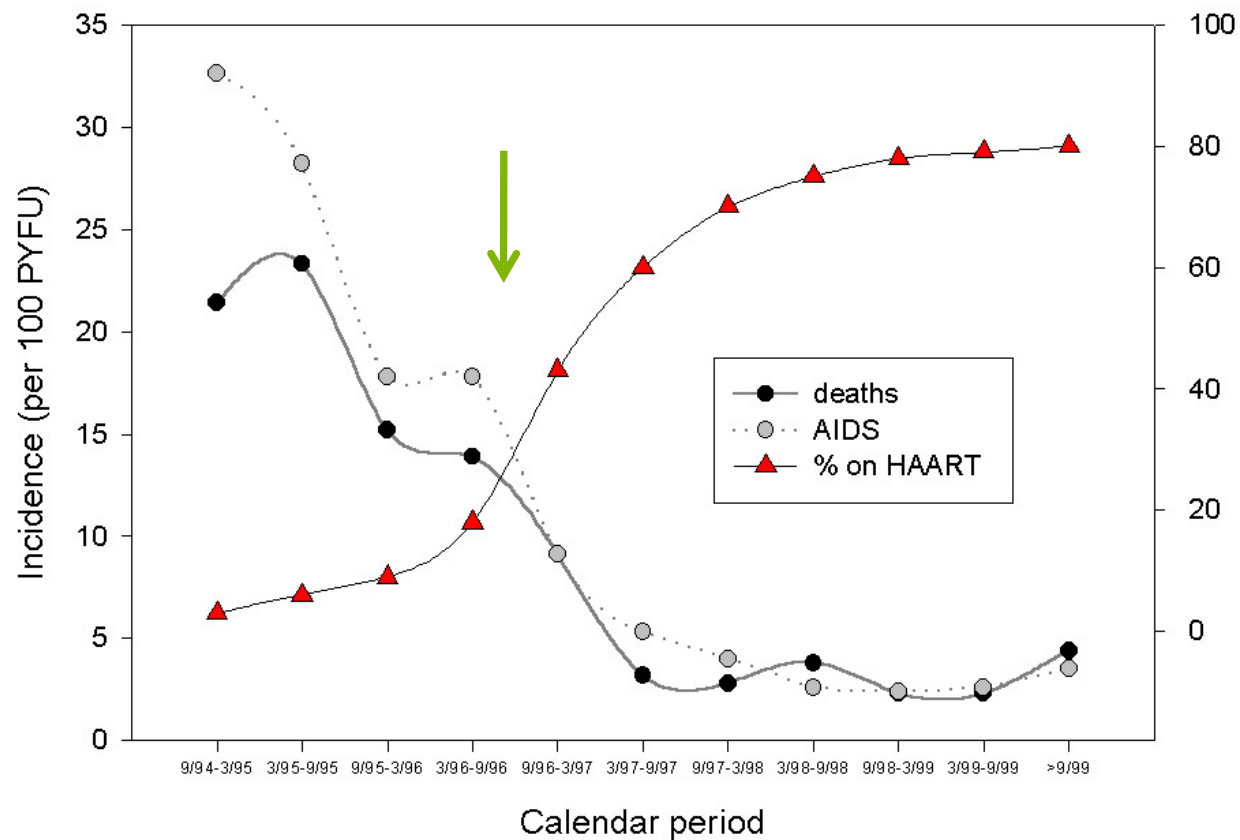


# AIDS treatment activism - USA

- participate in design of clinical trials
- patient reps on committees at NIH, IRBs
- FDA public hearings
- new regulations for accelerated approval
  - surrogate markers: CD4, VL

# 1996 HAART

Figure 13: Benefit of HAART therapy



# GIPA

## 💧 Greater Involvement of People with Aids

Meaningful involvement of PLWHA in all prevention, treatment, care and support decisions – strategy and policy design, funding, implementation and evaluation – will provide effective actions in controlling the epidemic.

# UNGASS Declaration of Commitment on HIV/AIDS

◆ 27 June 2001. Commitment #74:

**... ensure that all research protocols for the investigation of HIV related treatment, including anti-retroviral therapies and vaccines, based on international guidelines and best practices, are evaluated by independent committees of ethics, in which persons living with HIV/AIDS and caregivers for anti-retroviral therapy participate;**



# UNAIDS GIPA Policy brief

- ◆ « Ensure that **people living with HIV are included in the design of ethical research** for new prevention technologies and the development of treatments.» (March 2007)

# Denver PWA statement

- ◆ We condemn attempts to label us as "victims," a term which implies defeat, and we are only occasionally "patients," a term which implies passivity, helplessness, and dependence upon the care of others. We are "People With AIDS."

# Meanwhile in Europe

- 💧 1992: European AIDS Treatment Group (EATG)
- 💧 Deutsche AIDS Hilfe – Actions Traitements – Abraço – Act-Up Paris – AIDES – Nadir – Lila – gTt – NAM – I-Base – TRT-5 – Sensoa – GAT – Synthesis – ...
- 💧 European Community Advisory Board (ECAB)

# European AIDS Treatment Group

## Mission statement

To achieve the fastest possible access to state of the art medical products and devices, and diagnostic tests that prevent or treat HIV infection or improve the quality of life for people living with HIV, or at risk of HIV infection.

# European AIDS Treatment Group

- Policy Working Group
- Capacity-building (advocacy and treatment literacy)
- ECAB: Science & Community involvement

# ECAB – science & community

- ◆ Interactions with **researchers and scientists** (Networks of Excellence, input in scientific conferences, treatment guidelines)
- ◆ with **pharma** (drug development, CT design, community watchdog on AEs, DSMB, Informed Consent)
- ◆ with **regulatory agencies** (EMA, national regulators)

# ECAB – EMEA

- ◆ EMEA Patients' and Consumers' Organisations Working Party
- ◆ Package Leaflets/EPAR summaries: mandatory reviews on legibility, simplification
- ◆ Guidelines on the Clinical Development for the Treatment of HIV, HCV
- ◆ Scientific Advisory Group (SAG)

# Rx activists & CT: Goals

- ◆ 1. Safeguard the health and rights of trial participants
- ◆ 2. Ensure:
  - ◆ the fairness and transparency of the studies
  - ◆ the enrolment of all population groups
  - ◆ the rapid and transparent registration process for HIV medication
  - ◆ the early access to investigational drugs
- ◆ 3. Increase knowledge and information on investigational drugs and new medicines
- ◆ 4. Treatment information and counselling



# Safeguard the health and rights of trial participants

« In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests. »

(Art.6 Declaration of Helsinki, WMA Oct. 2008)

# Nothing about Us, Without Us



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Thank You!

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