

Ο Ρόλος των Ασθενών στον Σχεδιασμό Κλινικών Μελετών

Νίκος Δέδες
22 Ιουνίου 2019, Αθήνα

Θετική Φωνή
άνδρωσι+HIV

Ευρωπαίος
Πολίτης
της χρονιάς
2016

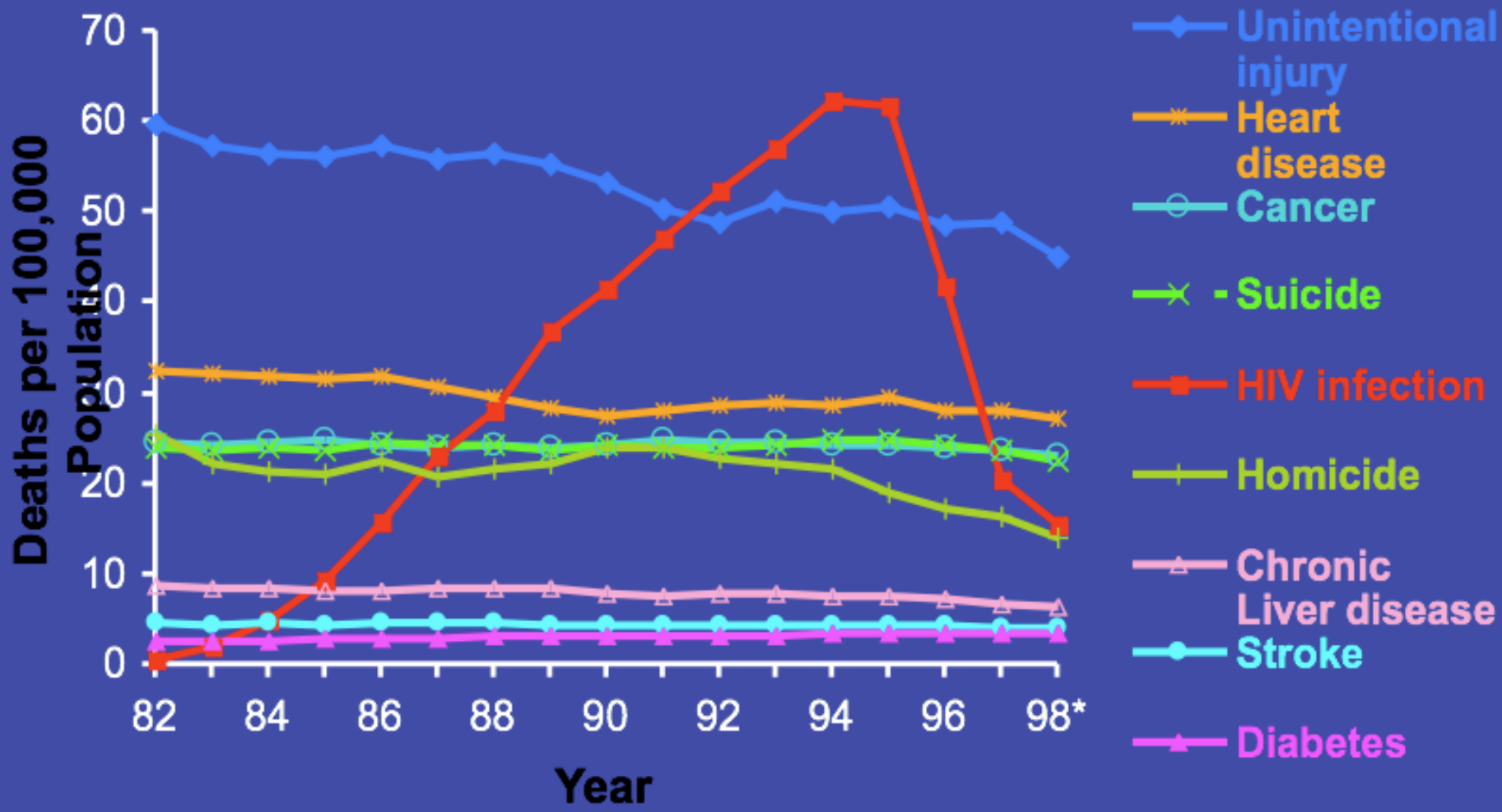


Το παράδειγμα του HIV/AIDS

HIV 38 χρόνια

- 1981: Πρώτο κρούσμα AIDS
- 1982: Το FDA λαμβάνει το πρώτο IND (Investigational New Drug)
- 1983: Βρίσκεται ο ιός HIV
- 1985: Το FDA εγκρίνει το πρώτο HIV τεστ αντισωμάτων
- 1987: Εγκρίνεται το AZT (το πρώτο φάρμακο)
- 1991: Τα DDC και DDI εγκρίνονται
- 1992-2012: 20 χρόνια- 24 καινούργια φάρμακα, 6 fixed dose συνδιασμοί, αμέτρητες νέες παρασκευές φαρμάκων

Causes of Death for men 25-44 in the USA 1982-1998



FDA-Approved Antiretroviral Drugs

NRTI

- Zidovudine
- Didanosine
- Zalcitabine
- Stavudine
- Lamivudine
- Abacavir
- Tenofovir
- Emtricitabine

NNRTI

- Nevirapine
- Delavirdine
- Efavirenz
- Etravirine
- Rilpivirine

PI

- Saquinavir
- Ritonavir
- Indinavir
- Nelfinavir
- Amprenavir
- Lopinavir
- Atazanavir
- Fosamprenavir
- Tipranavir
- Darunavir

Fusion Inhibitor

- Enfuvirtide (T-20)

Entry Inhibitor

- Maraviroc

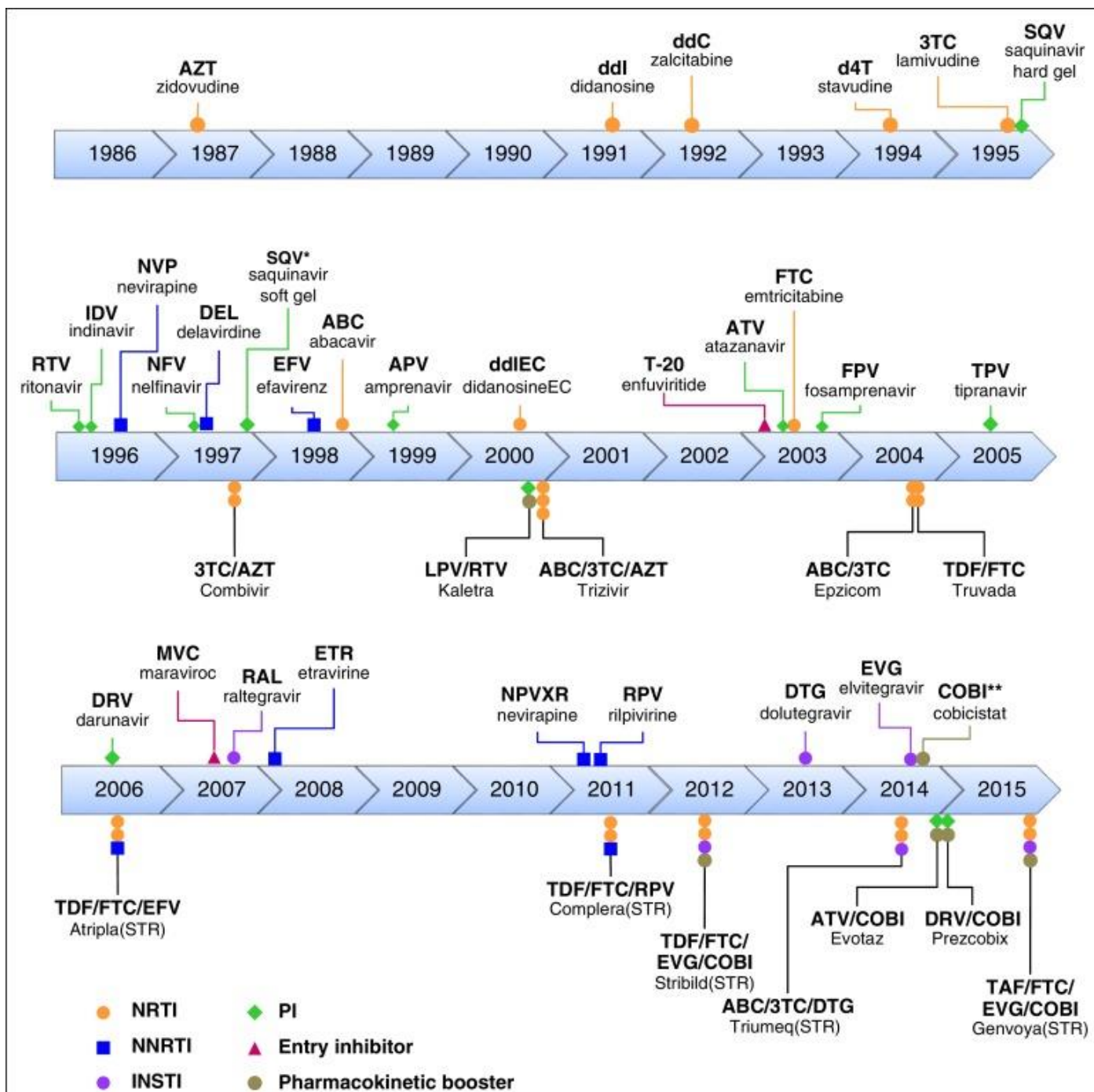
Integrase Inhibitor

- Raltegravir

Combinations

- 6 available, combining 2 or 3 drugs







Haitian Patient, before and after Receiving Free Treatment for HIV Infection and Tuberculosis.

The photograph on the left was taken in March 2003, and that on the right in September 2003. Many impoverished patients in rural Haiti and Rwanda now receive comprehensive medical care through public-private partnerships.

Κινητοποίηση Συλλόγων Ασθενών



Credit: Marc Geller



ACTUP protests at AIDS Conference, San Francisco



Protest demonstration, 1988. NATIONAL AIDS CONFERENCE

Photo © Ben Thornberry



Η διακήρυξη του Denver (1983)

"Nothing about Us, Without Us"

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

We are "people with AIDS"

Η διακήρυξη του Denver (1983)

"Nothing about Us, Without Us"

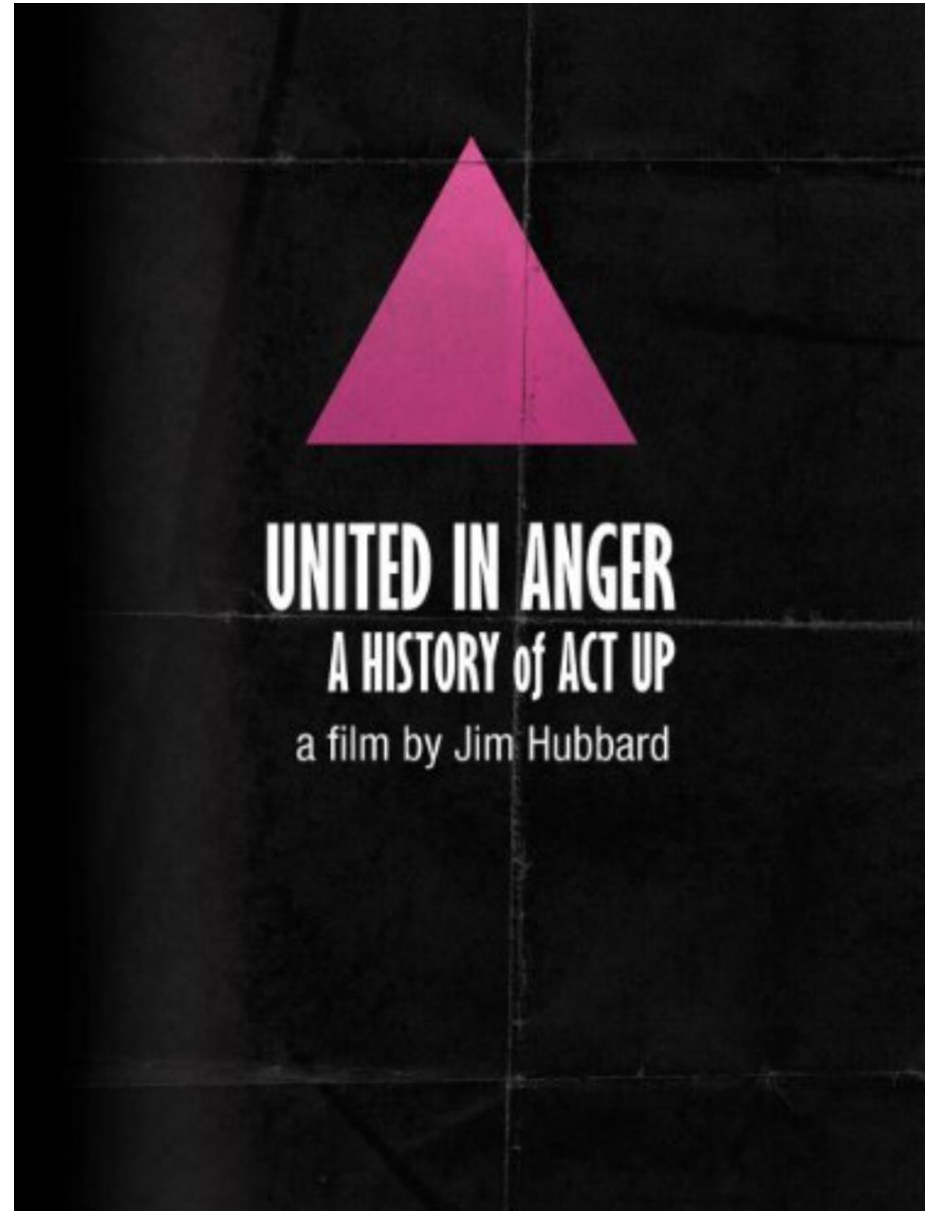
We recommend that people with AIDS...

- 2 Be involved at every level of AIDS decision-making and specifically
- 3 Be included in all AIDS forums with equal credibility as other participants, to share their own experiences and knowledge

ACT UP



- A History of ACT UP
a film by Jim Hubbard



1988 FDA demo



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

Photo © Ben Thornberry

- Dallas Buyers Club
a film by Jean-Marc Valle

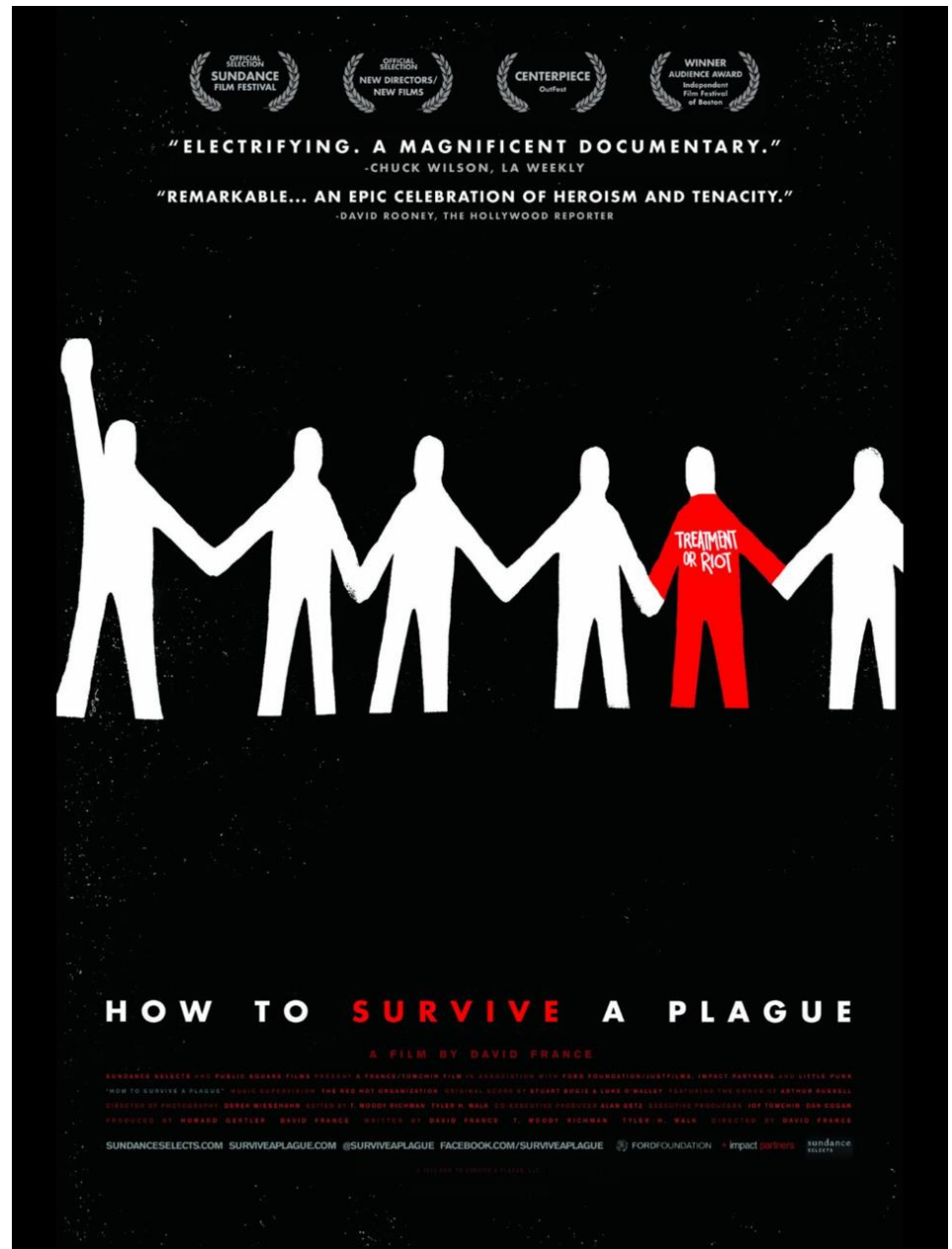


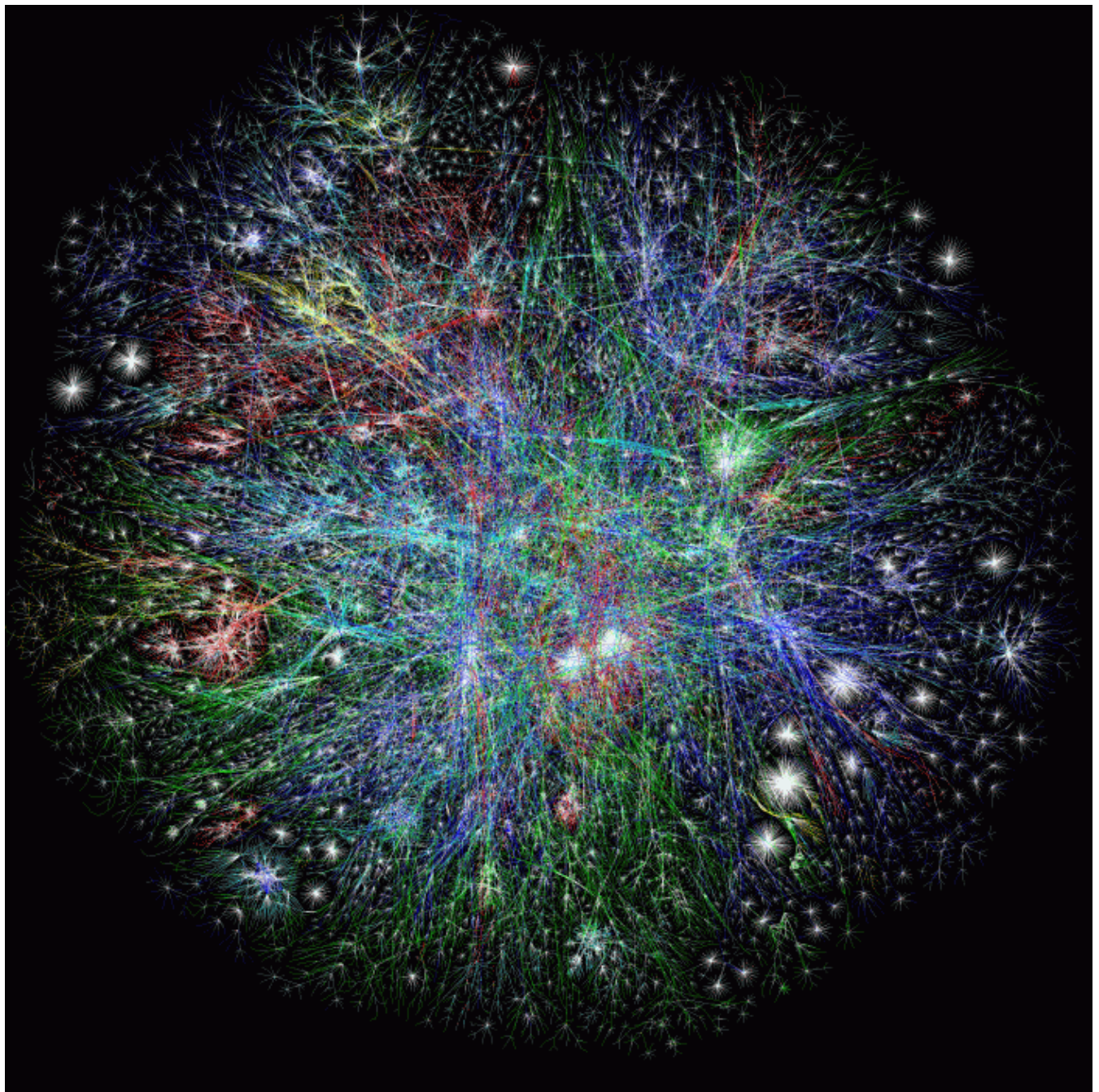
1990 NIH demo



- How to Survive a Plague

a film by David France





Η εποχή της πληροφορίας

Ο όρος αναφέρεται στην ιδέα ότι η σημερινή εποχή χαρακτηρίζεται από την δυνατότητα των ανθρώπων να ανταλλάσσουν και να μεταφέρουν πληροφορίες ελεύθερα και να έχουν άμεση πρόσβαση σε γνώσεις που θα ήταν δύσκολο ή αδύνατο να βρεθούν στο παρελθόν

Wikipedia



TIME

Person of the Year 2006

Citizen involvement

- Informing the public / benchmarking
- Assessing public views / priorities
- Advocacy (patient & consumer) groups
- Formal representation (purchaser & providers)
- Patients rights legislation
- Increasing choice (insurer & provider)
- Participation in clinical decision making

Adapted from den Exter in Figueras et al (2005)

EATG (European AIDS Treatment Group)

- Founded in 1992
 - 180+ members from 45 countries involved in local NGOs and related to 30+ networks
- Mission
 - Ensure fastest possible access to state of the art medical products or devices and diagnostic tests that can contribute to the prevention or treatment of HIV and related diseases
- Fields of activities
 - Treatment information
 - Training and capacity building
 - Drug development and clinical research
 - Policy / Advocacy

ECAB – November 1997 (European Community Advisory Board)

- to advise the research community on the needs of the patient community and the appropriateness of proposed research
- to advise the community on the aims and expectations of a research proposal and the appropriateness of the research

ECAB objectives

- Review clinical trial design at the planning stage
- Impact inclusion criteria to reflect real life
- Review and simplify informed consent sheets
- Suggest trials that reflect patient and community needs
- Negotiate expanded access programs

Εκπαίδευση & Διαλέξεις

- Good Clinical Practice
- Statistics
- Immunology
- Pharmacology
- Virology
- Hepatitis co-infection
- Pharmacovigilance
- Reproductive health
- Clinical Trial's design
- Evidence based medicine
- Clinical Trials Networks
- Cohorts
- EMA – Regulatory authorities
- Pharmacoeconomics - Health Economics
- Prevention Research
- Media Relations

2007 (updated 2011)

Good participatory practice guidelines for biomedical HIV prevention trials



UNAIDS
Joint UN Programme on HIV/AIDS

AVAC
Alliance for Vaccine Access and Coverage

Good participatory practice guidelines for biomedical HIV prevention trials 2011



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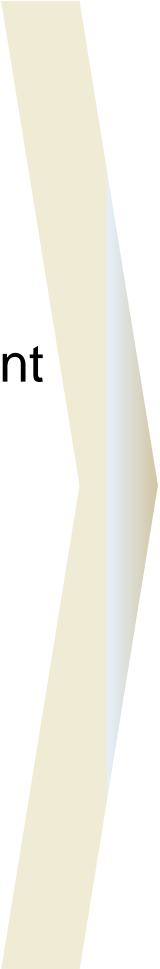
EUPATI

Patient Expert Training Courses

EUPATI empowers patients with education in key areas of medicines R&D

Provides objective, credible, correct and up-to-date information to patients and patient advocates about:

1. Discovery of Medicines & Planning of Medicine Development
2. Non-Clinical Testing and Pharmaceutical Development
3. Exploratory and Confirmatory Clinical Development
4. Clinical Trials
5. Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmaco-epidemiology
6. HTA principles and practices

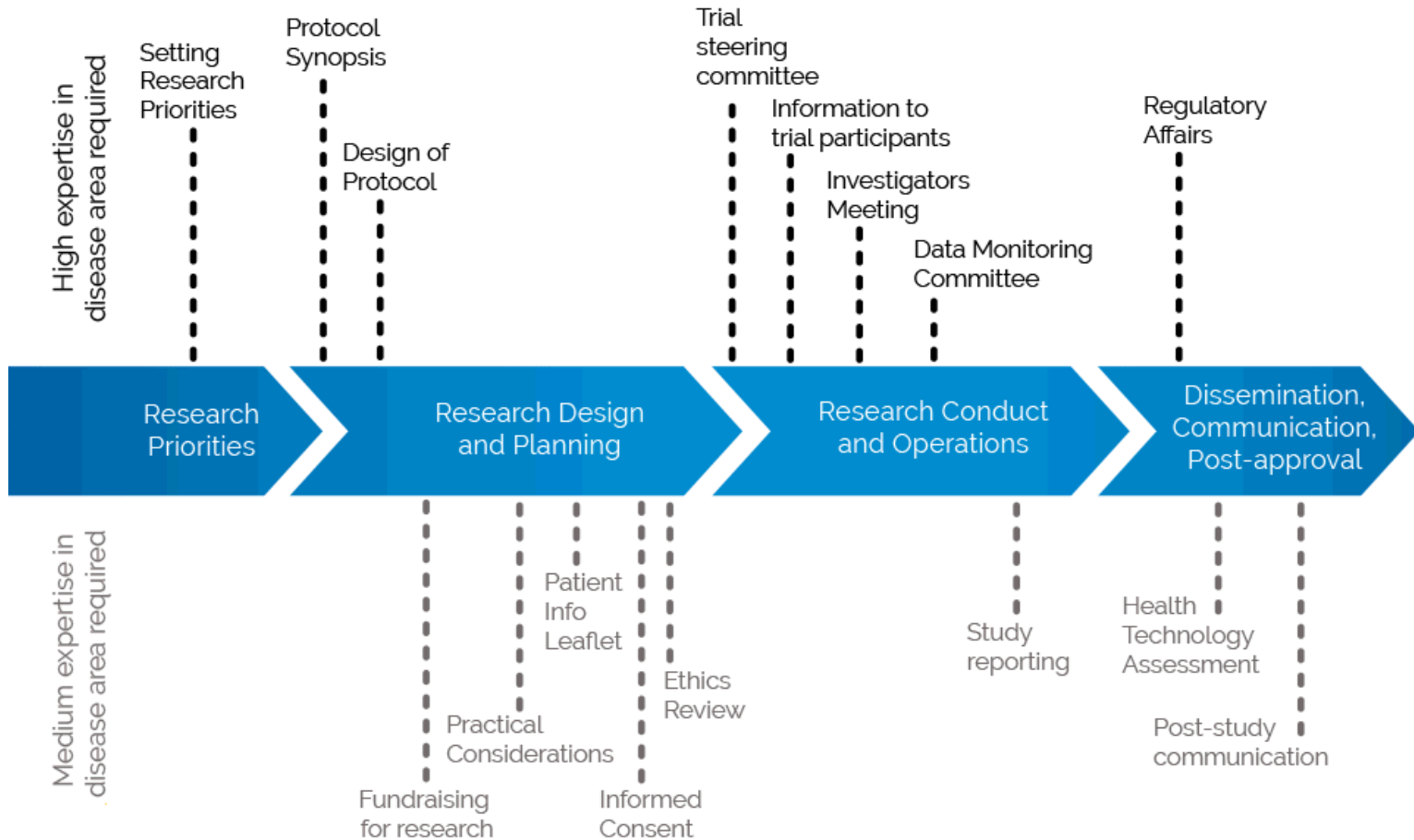


EUPATI
Course
&
Toolbox

Involvement across the board



Source: Geissler, Ryll, Leto, Uhlenhopp – www.eupati.eu



Source: Geissler, Ryll, Uhlenhopp, Leto (2017): www.eupati.eu

Women's Vote

- Germany 1918
- France 1944
- United Arab Emirates 2006
- Lichtenstein 1984
- Iraq 1980
- Switzerland 1971
- Vatican -----

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