Norms related to Ethical CT: A Patients' Perspective

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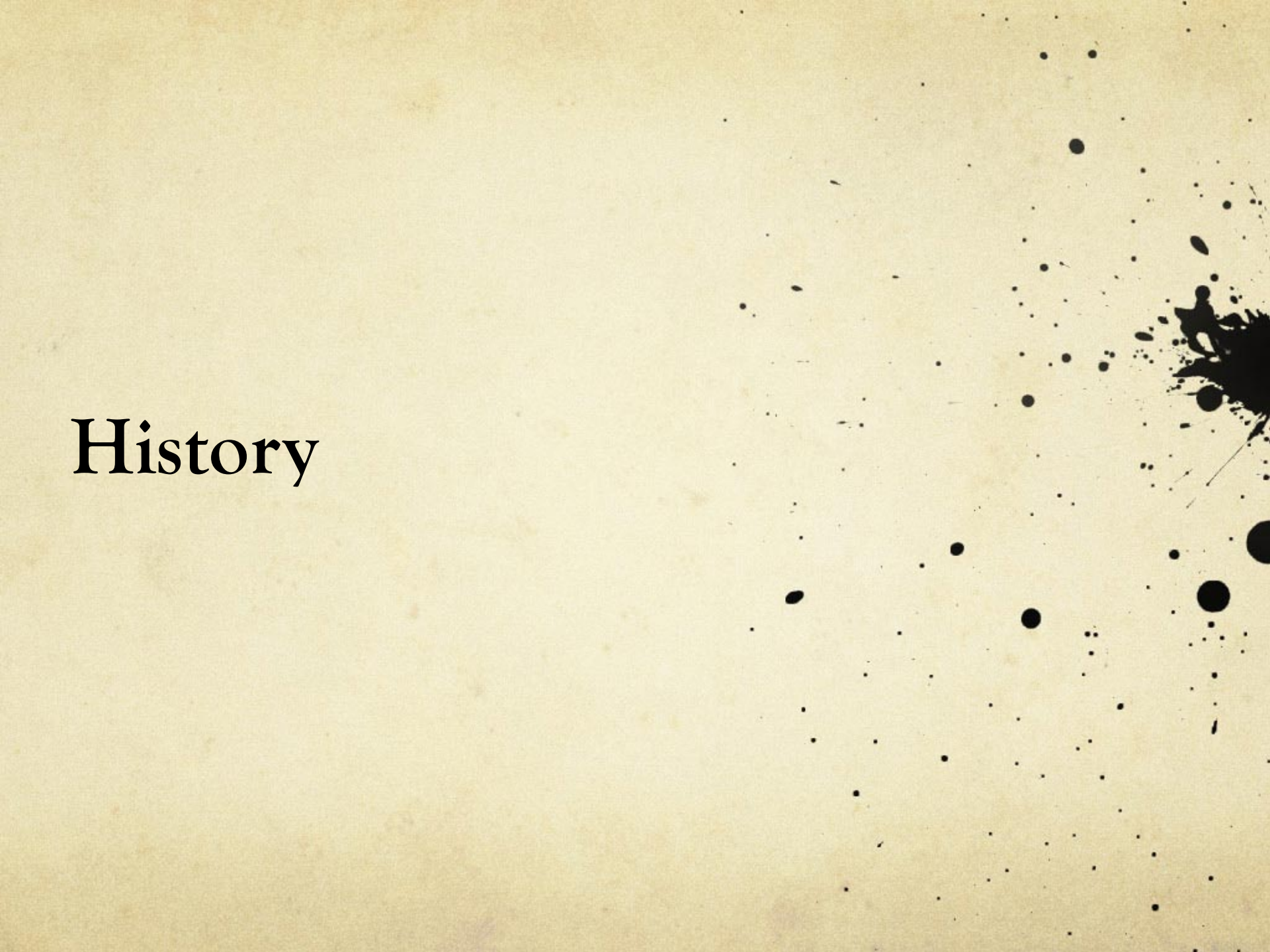
Objectives

- Explain the background of the increasing role of Patients in the cycle of drug development, authorisation and ongoing evaluation
- The benefits and the necessity of patient participation

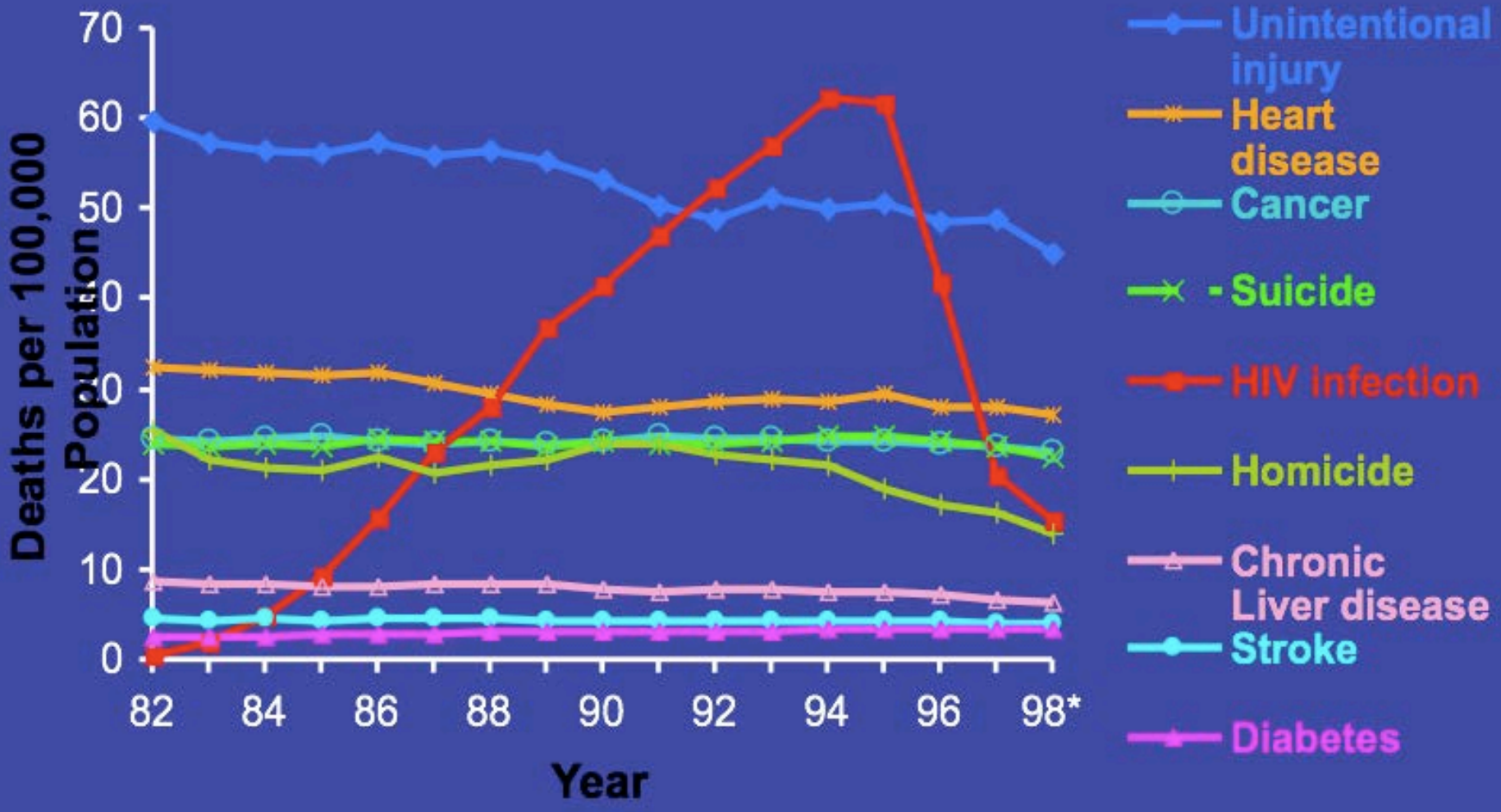
The actors

- Patients
- Doctors
- Industry
- Academics
- Investigators
- Ethics Committees
- Regulatory authorities

History



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



HIV 31 years (AIDS 33)

- 1981: First AIDS reported case
- 1982: FDA receives first IND
- 1983: HIV virus recognised
- 1987-91: AZT, DDC and DDI approved
- 1992-2014: 22 years - 24 new ARVs, 7 fixed dose combinations, numerous new formulations

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

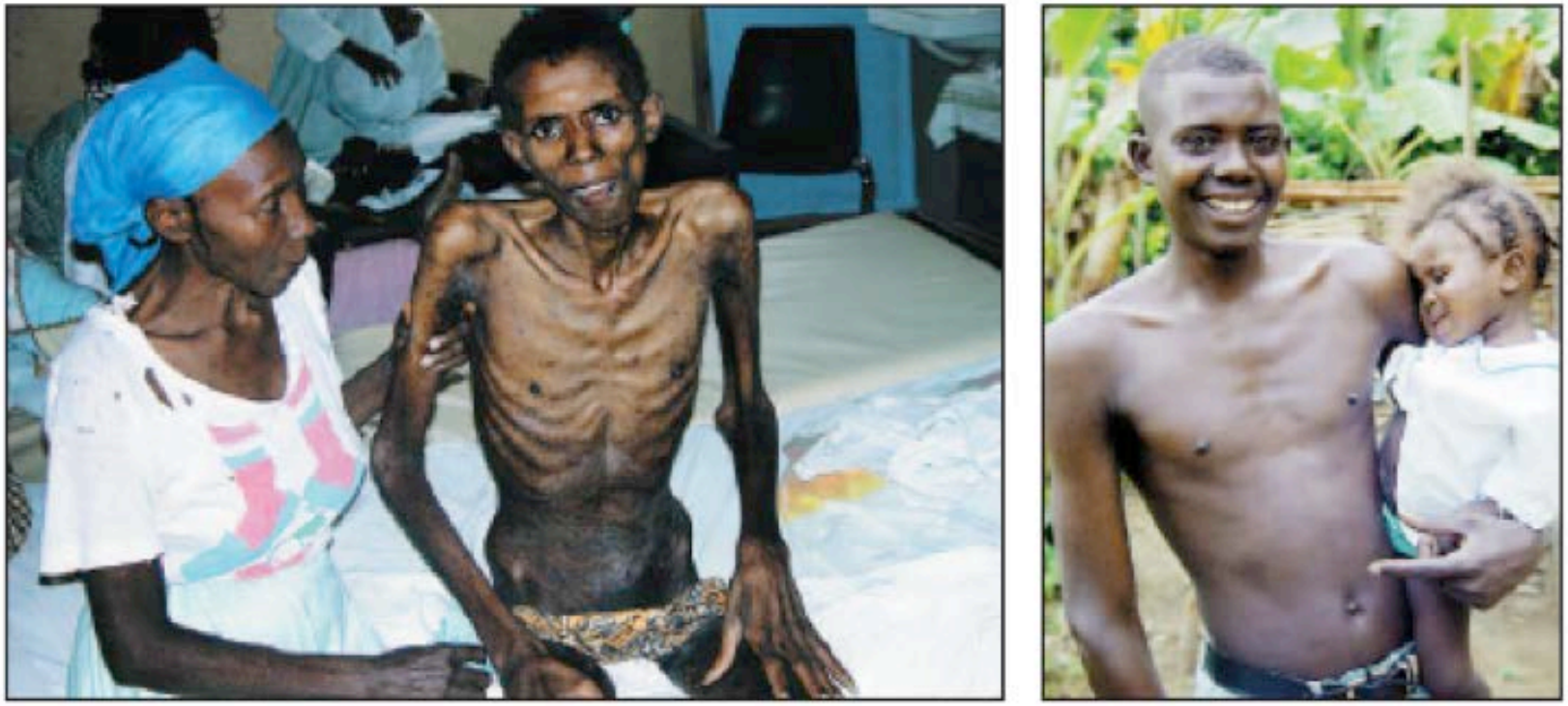
- Maraviroc

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.

Patients Mobilisation

Denver Declaration (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

1988 FDA demo

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

Photo © Ben Thornberry

1990 NIH demo

EATG European AIDS Treatment Group

twenty years of treatment activism

ECAB: European Community Advisory Board - November 1997

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

ECAB objectives

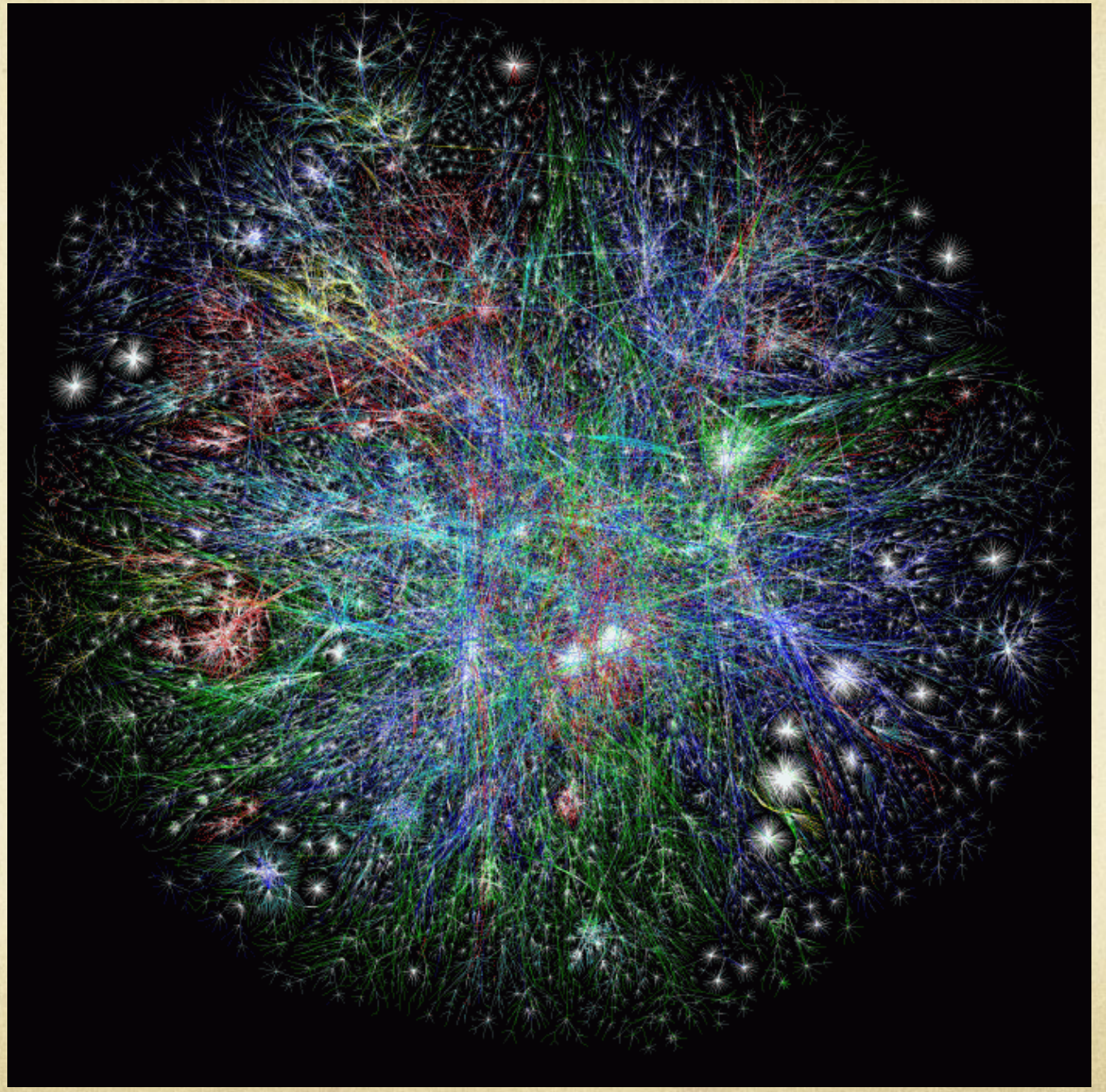
- Review clinical trial design at the planning stage
- Impact inclusion criteria to reflect real life
- Review and simplify informed consent sheets
- Suggest trials that reflect patient and community needs
- Negotiate expanded access programs

How was that made possible?

Information Age

is an idea that the current age will be characterized by the ability of individuals to transfer information freely, and to have instant access to knowledge that would have been difficult of impossible to find previously

Definition: WikiPedia



Patient - Citizen

- Informed
- Engaged
- Consulted
- Involved
- Control

TIME Person of the Year 2006

Staying Informed

- Drug Interactions
- HIV Drug Trials
- Glossaries
- HIV News
- Personal Data

Patients and Clinical Trials

Taken for granted

- I want simple explanation of the research question
- I need adequate time and space to review the trial and consider participation
- What are all my options with existing interventions
- What are the risks
- Protections and insurance is in place
- Confidentiality of my data

What do I want?

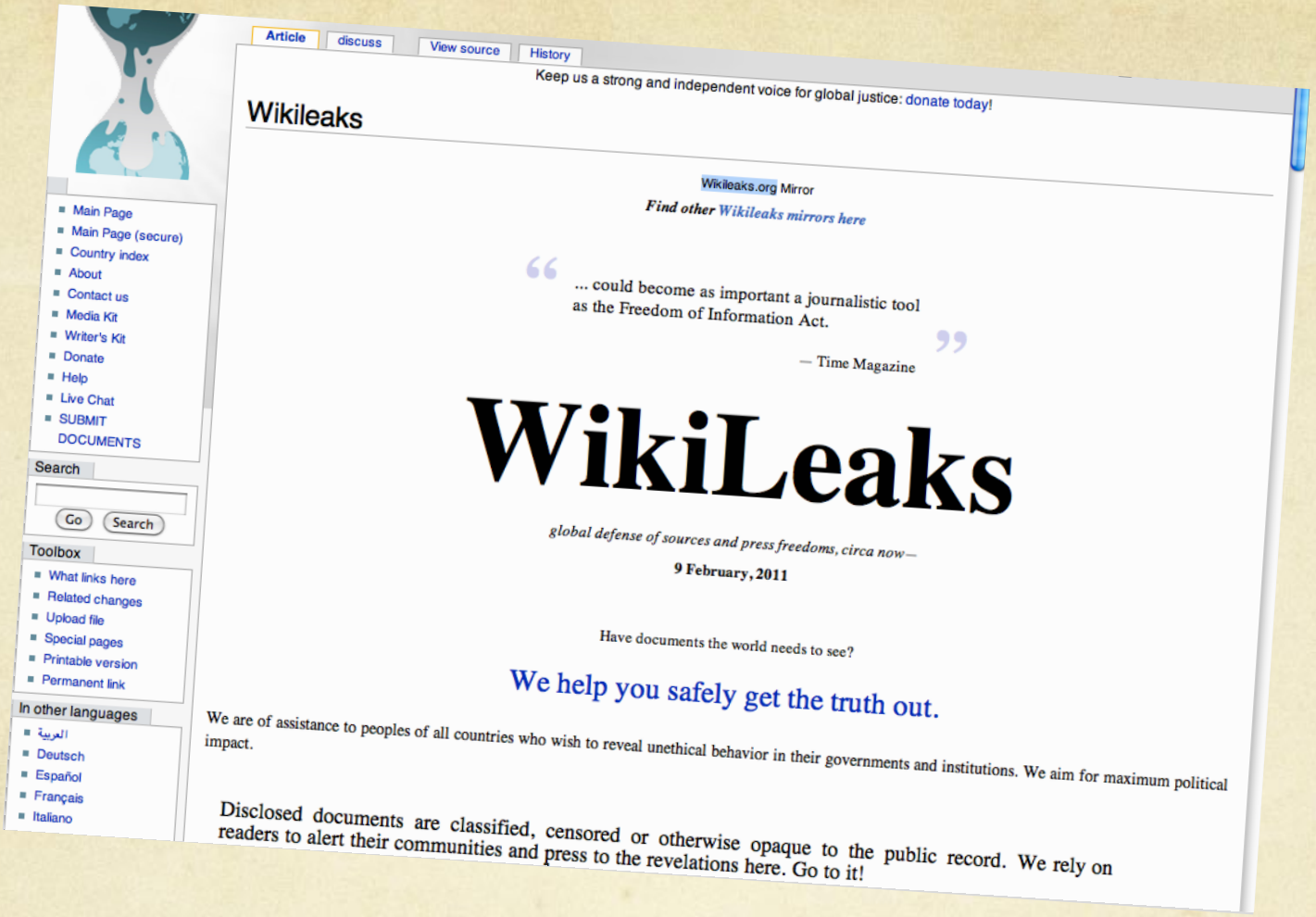
- Find out about trials
- Review by patient group
- Be informed of due process
- Who can I ask about what is presented to me?
- What other research on the same condition?
- How many people and for how long have be tested with this new interventions/drug

What do I want?

- When and how will I get the results of the trial?
- Is this trial addressing everybody?
- Will there be a follow up?
- Is my time respected?

Transparency Imperative


APRIL 22, 2002
Powell's Mission Impossible
TIME
HOW MEDICAL TESTING HAS TURNED MILLIONS OF US INTO ...
HUMAN GUINEA PIGS
www.time.com AOL Keyword: TIME



Demand for access to information

Why Transparency?

- Access to information leads to the empowerment of the patient and the citizen
- Transparency is the first step towards stakeholder involvement and participation

Reasons for full Access

- Reputation of Industry and Regulators
- Quality & Innovation of Clinical Research
- Medicines are a Public Good
- Data of Interventional Studies on Human Subjects

Clinical Trials

- Trial concepts
- Design
- Protocols & Informed Consent
- Results
- Raw Data

Is this possible?

Women's Vote

Germany	1918
France	1944
United Arab Emirates	2006
Lichtenstein	1984
Serbia & Montenegro	1946
Switzerland	1971
Vatican	------

Thank you!