Patient Advocacy
Do we need it?

How much do we need to do?

Where does the community fit in?

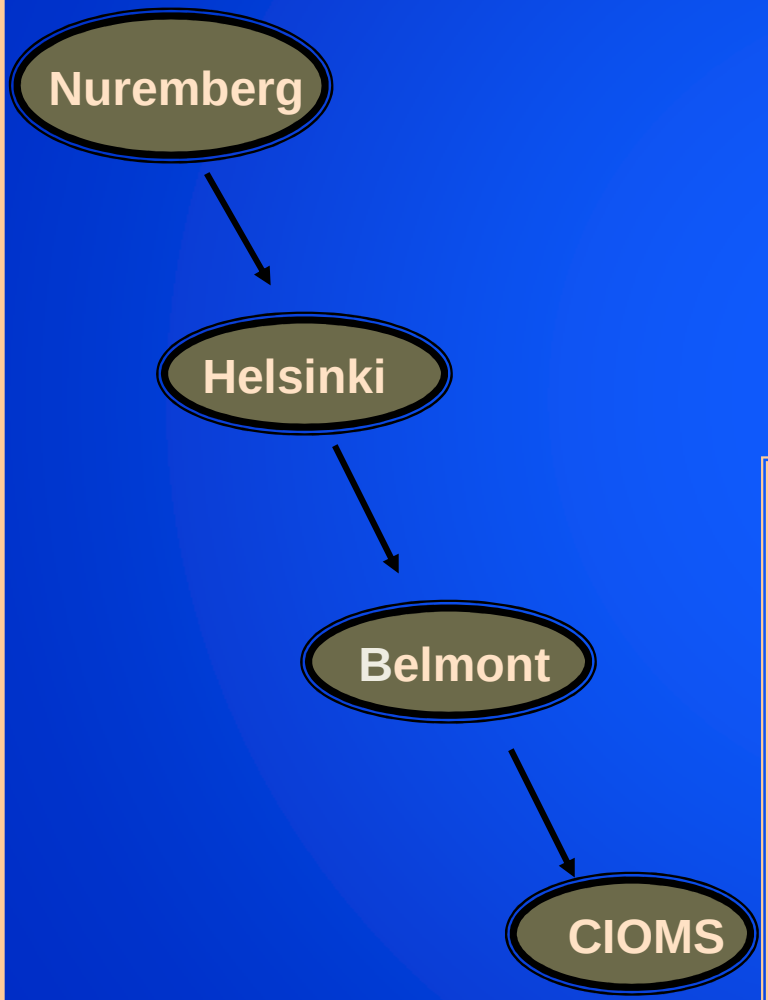
Community Voices in Research

Schloendorff
v.
The Society of the New York Hospital
(1914)

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits as assault for which he is liable in damages."

Justice Benjamin Cardozo
Court of Appeals of New York

Council for International Organizations of Medical Science (CIOMS) Guidelines ‘82



- Informed Consent
- Research in Developing Countries
- Protection of Vulnerable Populations
- Distribution of the Burdens and Benefits
- Role Of Ethics Committees

Ref: Family Health International Research Ethics Training Curriculum / www.fhi.org - (Augmented)

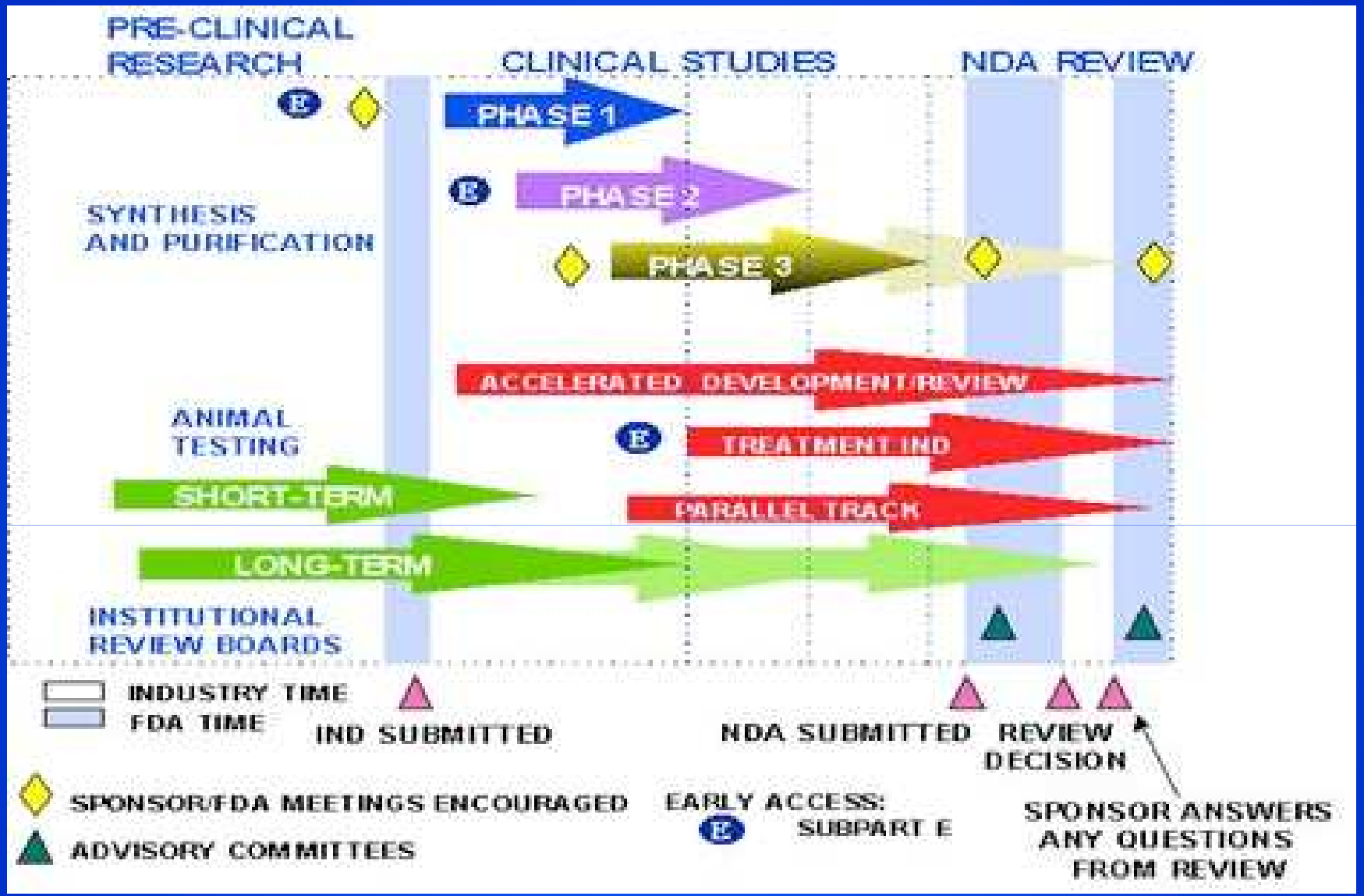
Community Voices in HIV Research

We interrupt these proceedings to bring you the following infamies!!

Five Examples

- Jewish Chronic Disease Hospital - Brooklyn (1963)
- Milgram Experiment (1961-1985)
- Willowbrook Hepatitis Study (1955)
- Oregon State Prison Project (1963)
- Tuskegee Study (1932-1972)

(Legal Precedent for Informed Consent in the United States, established in 1914)


PRE-CLINICAL RESEARCH
CLINICAL STUDIES
NDA REVIEW
PHASE 1
PHASE 2
PHASE 3
SYNTHESIS AND PURIFICATION
ACCELERATED DEVELOPMENT/REVIEW
ANIMAL TESTING
TREATMENT IND
SHORT-TERM
PARALLEL TRACK
LONG-TERM
INSTITUTIONAL REVIEW BOARDS
INDUSTRY TIME
FDA TIME
IND SUBMITTED
NDA SUBMITTED
REVIEW DECISION
SPONSOR/FDA MEETINGS ENCOURAGED
ADVISORY COMMITTEES
EARLY ACCESS: SUBPART E
SPONSOR ANSWERS ANY QUESTIONS FROM REVIEW

Expanded Access

- Initiated by activists
- Known initially as “parallel track”—
  runs in parallel with Phase III
- Provides access to drug with less clinical trial restrictions as soon as safety can be established, ie, before Ph III
- Provides more safety data
- *Often* companies wait until last minute

Post Marketing - Phase IV

- Studies performed after approval - *required* (no longer simply *recommended)* by the FDA
- Can answer many important questions
  - Long-term effectiveness
  - Longer-term toxicities
  - Which regimen is best (head-to-heads)
- A big issue with sponsors

"I STOPPED TAKING THE MEDICINE BECAUSE I PREFER THE ORIGINAL DISEASE TO THE SIDE EFFECTS."

Accelerated vs. Traditional Approval

- *Accelerated approval*: changes at week 24 (*developed due to activism who used the "life-threatening" aspect*)
- *Traditional approval*: changes at week 48 (wk 96)

Approval Time for Drugs

- Retrovir - first drug approved 1987
- Time between ANDA and approval - 6 months
- It takes on average < 5 years to approve an AIDS drug after an IND
  - Raltegravir took 2.1 years from first HIV+ person to ANDA

What is an activist?

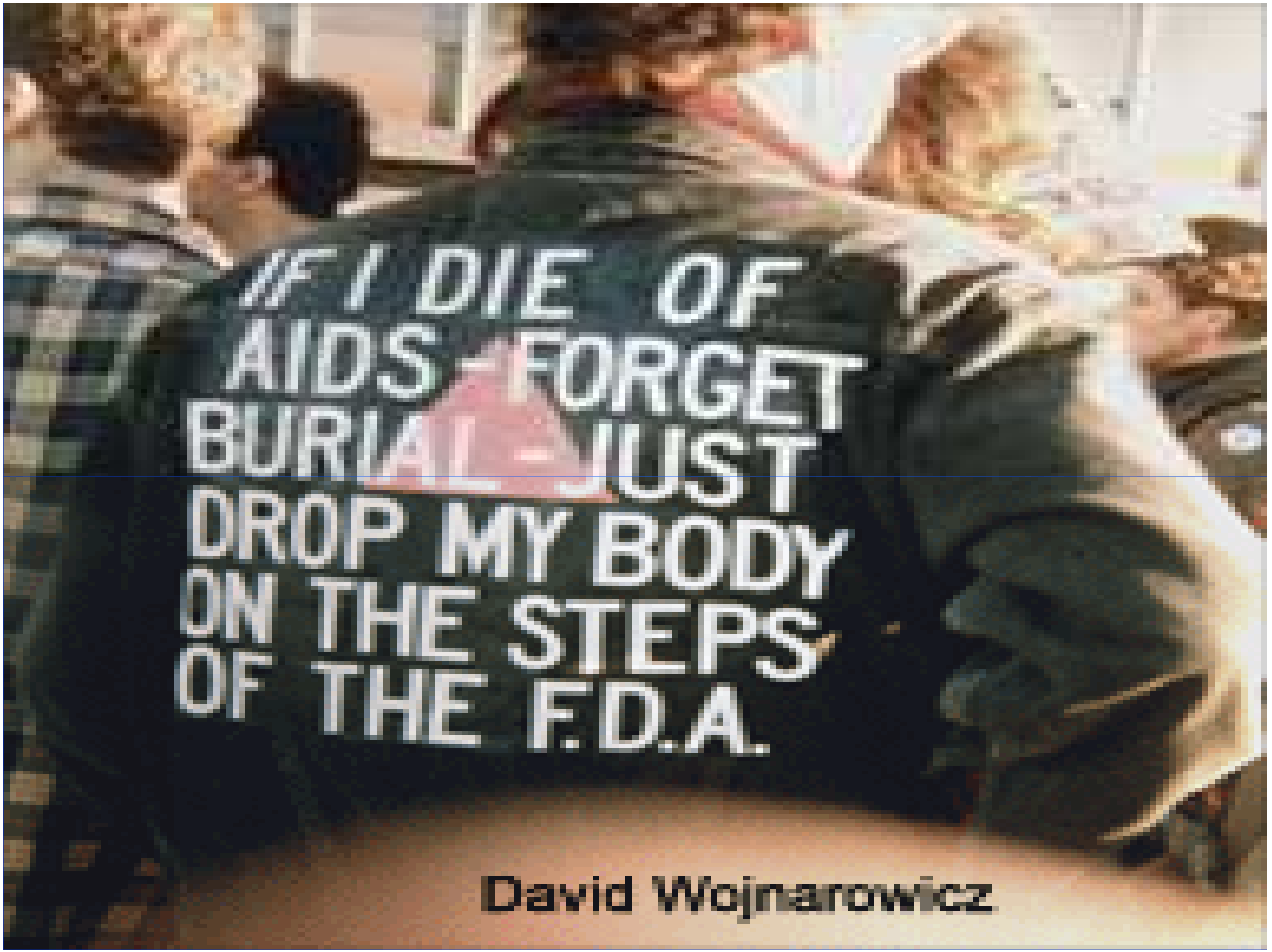
- 1. an especially active, vigorous advocate of a cause, esp. a political cause.–adjective
- 2. of or pertaining to activism or activists: an activist organization for environmental concern(s).
- 3. advocating or opposing a cause or issue vigorously, esp. a political cause: Activist opponents of the President picketed the White House.
- www.dictionary.com, retrieved 7 Mar 2007

A Simplified Formula for Treatment Activism

What is Broken? +	Select a Strategy =	Intended Solution
Motivation?	*Targets & action plan?*	*Outcome over time*

A Few Examples:

Drug Price Increase	Meet with the Drug Company Sign-on community letters	Price Reduction or Freeze
↓ Clinical Trial Recruits	Investigation of Sites	Better Numbers
↓ Studies in valid pop's	Meetings With Company and Implementation	New Study Design


IF I DIE OF
AIDS - FORGET
BURIAL - JUST
DROP MY BODY
ON THE STEPS
OF THE F.D.A.
David Wojnarowicz

What takes up our day?

- New classes
- Managing Adverse Events
- Expanded access programs
- PK data, data in real people
- Cross-resistance
- Multi-experimental drugs
- When to start / what to start with
- Formulation / administration
- Non-traditional medical therapies
- Ageing
- Inflammation
- Microbial translation
- Enhancing immunity
- Immunomodulators
- Cellular reservoirs
- Prevention
- Coinfections
- Government support of research
- Affordable

Drug Development Committment

- Women, people of color, *study populations*
- Coinfections
- *Informed consent*
- *Inclusion/exclusion*
- Salvage (late stage) treatments
- *Post-marketing commitments & long-term follow-up*
- Protocol development

Specific issues for Trials

- Limitations of surrogate markers: disease
- Forging relationships with sponsors
- Need treatment strategies—trials must do more!
- Understanding pathogenesis
- Multi-experimental agent trials

Community Advisory Board

•CABs communicate information from the broader Community to the study - design, accrual, participants' rights and responsibilities, etc.
•The research question addresses a health issue that is important to the community.
•There is sense of partnership in study team.
•The Sponsor answers all questions and/or doubts of the PO / CAB, including potential *risk/benefit* to participants.

•For a trial to be + successful, it is important to obtain general support from the communities that will be involved in the research
•The CAB can act as a liaison between the researchers and the community; researchers can consult with CABs or other community groups about upcoming trials
•CABs are not responsible for recruitment, they may facilitate it, ie help design a flyer and suggest how and where to reach potential participants, w/o distributing it
•CABs give feedback to researchers

In real life…

- We need to be flexible (unforeseen challenges)
- We need to always revisit the critical steps, tools, approaches used to achieve past specific successes
- We need to be seen as providers and experts
- We need to find new partnerships
- We need to support and offer possible ways forward
- We need to expand

Eurordis can…

- Help in e-learning
- Help in negotiation with sponsors (ie, Clinical Trials Charter)
- Help federations solidify and expand
- Get you more involved with European Regulatory Authorities (EMA)

Thank you

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