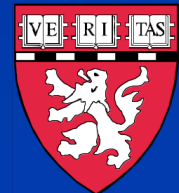


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# **ACTG A5175: The PEARLS Trial**

**Daniel R. Kuritzkes, MD  
Brigham & Women's Hospital  
Harvard Medical School**



# ACTG A5175

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- A phase IV, prospective, randomized, open-label evaluation of the efficacy of once-daily protease inhibitor and once-daily non-nucleoside reverse transcriptase inhibitor-containing therapy combinations for initial treatment of HIV-1 infected individuals from resource-limited settings

# Study design

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- Regimens: AZT/3TC/EFV  
VS  
TDF/FTC/EFV  
VS  
ddI/FTC/ATV
- N=1520
- Primary endpoint: time to treatment failure  
(death, AIDS, VL >1,000 c/mL)

# Participating sites

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Rio de Janeiro, Brazil

Porto Alegre, Brazil

Port-au-Prince, Haiti

Chennai, India

Pune, India

Blantyre, Malawi

Lilongwe, Malawi

Lima, Peru

Johannesburg, South Africa

Durban, South Africa

Chiang Mai, Thailand

Harare, Zimbabwe

University of Washington, U.S.

Johns Hopkins University, U.S.

Vanderbilt University, U.S.

Cornell Clinical Trials Unit, U.S.

Columbia University, U.S.

University of Colorado, U.S.

The Miriam Hospital, Brown  
University, U.S.

University of North Carolina, U.S.

University of California, San  
Francisco, U.S.

University of California, Los  
Angeles, U.S.

# Challenges in drug procurement

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- **Willing pharmaceutical collaborators**
- **International distribution networks**
- **Local registration/importation requirements**
- **Cost**
- **Brazil and India: a special case**

# Ties that bind:

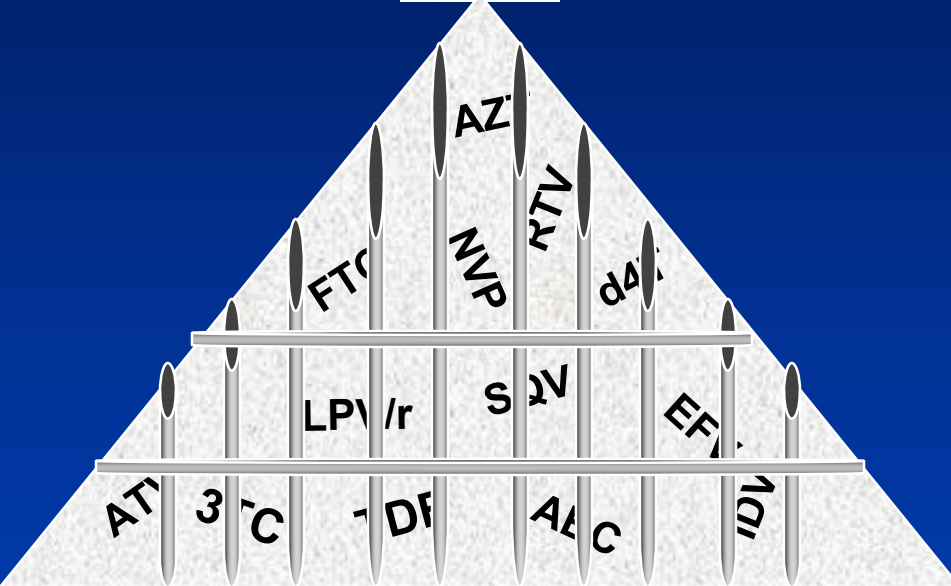
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- **Barriers to purchase of licensed drug**
  - Reluctance to permit use of grant funds to buy drug
- **Barriers to use of locally manufactured drug**
  - No defined policy
  - No standing review committee
  - No published procedure
- **Barriers to use of PEPFAR drug**
  - Reluctance to graft research onto care

# Ties that bind

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Can't buy drug



Can't use local drug

Can't use PEPFAR drug