Enfuvirtide + Darunavir + RTV + OBR in Treatment Experienced BLQ: Study Design

### Study Design: BLQ

**• Background:** Prospective, open-label, single-arm phase 4 trial evaluating the efficacy and safety of enfuvirtide in combination with darunavir + ritonavir in triple-antiretroviral-class-experienced adults failing their current regimen

**• Inclusion Criteria (n = 142)**
- Triple-antiretroviral-class-experienced
- HIV RNA >2000 copies/mL on current regimen
- No active untreated opportunistic infection, no grade 4 clinical or laboratory abnormality

**• Treatment Arm**
- ENF 90 mg SC BID + DRV 600 mg BID + RTV 100 mg BID + investigator-determined optimized background regimen (OBR)

BLQ = Below the Level of Quantification

Enfuvirtide + Darunavir + RTV + OBR in Treatment Experienced BLQ Study: Results

Week 24: Virologic Response

Enfuvirtide + Darunavir + Ritonavir + OBR

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Week 24: Virologic Response, by Darunavir Susceptibility at Baseline

![Bar chart showing virologic response at Week 24 by Darunavir susceptibility at baseline.](chart)

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Injection Site Reactions and Adherence

**Conclusions**: “Although these findings are limited by the relatively small numbers of participants with darunavir susceptibility changes of ≥ or =10-fold, they suggest that combining enfuvirtide and darunavir-ritonavir with an optimized background regimen in triple-class experienced participants naïve to these agents can result in positive virological and immunological responses regardless of most baseline parameters.”
The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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