

## **DARE CAB Criteria and Options for Extended ATIs**

### **Main Inclusion Criteria**

- Male or female, age 18+ with no maximum age criteria if people are otherwise healthy and fall within the Inclusion/Exclusion Criteria
- Screening CD4+ T-cell count = >500 cells/mm<sup>3</sup>
- Nadir =  $\geq$ 350 cells/mm<sup>3</sup>

### **Main Exclusion Criteria**

- Any history of an HIV-associated malignancy, including Kaposi's sarcoma and any type of lymphoma, or virus-associated cancers, including cervical and anal cancer
- Active or recent non-HIV-associated malignancy requiring systemic chemotherapy or surgery in the preceding 36 months
- History of or current active hepatitis B (HBV) infection defined as positive HBV surface antigen test
- Active hepatitis C (HCV) infection
  - Severe Liver Disease
  - Severe Renal Disease
- Active and poorly controlled atherosclerotic cardiovascular disease
- Atherosclerotic cardiovascular disease risk by history confirmed by EKGs and stress test
  - History of AIDS defining illnesses occurring less than 10 years ago
- History of neurologic disease, including dementia, PML and strokes
- History of potential immune-mediated medical conditions

### **ART Restart Criteria Options**

- Confirmed CD4 count decline to below 350 cells/mm<sup>3</sup>
- Acute retroviral syndrome
- Sustained or high-level viremia
- 1) viremia > 50,000 copies RNA/mL for four weeks,
- 2) viremia > 10,000 copies RNA/mL 6 weeks,
- 3) viremia > 2000 copies RNA/ml for 12 weeks or
- 4) viremia > 400 copies/RNA for 24 weeks

### **Engagement Options for Partners of Participants**

- HIV testing, PrEP and PEP referral information and counseling provided to participants at the study site
- HIV testing, PrEP and PEP referral information and counseling provided to participants and their partners at the study site
- HIV testing, PrEP and PEP referral information and counseling provided to participants and their partners at the study site and no cost PREP provided to partners by the study site

### **Viral Load Monitoring Options During ATIs**

- Weekly monitoring during weeks 8-12
- Biweekly monitoring thereafter in the absence of viral rebound
- Home testing?