US HCV EAP CHARACTERISTICS

Lynda Dee, AIDS Action Baltimore
AIDS Treatment Activists Coalition, ATAC

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- **Possible Inclusion Criteria:**
  - Patients who are interferon intolerant?
  - Patients who are ribavirin intolerant?
  - Patients who are not interferon sensitive?
  - Patients with portal or bridging fibrosis?
  - Patients with compensated cirrhosis?
  - Patients with well monitored decompensated cirrhosis?
  - Patients with renal insufficiency?
  - Liver transplant patients?
  - -Patients with HIV-coinfection
  - Patients are eligible if there are no appropriate clinical trials available within a 50 mile radius or if the available clinical trials do not allow concomitant experimental drugs.

- EAP permits patients to use more than one investigational antiviral drug.
- EAP maybe designed to include two antiviral investigational drugs (with or without SOC background regimen?).
- EAP is available once a likely dose has been determined, sufficient drug-drug interaction and safety data are available for patients on a case by case basis and/or for intermediate sized patient groups of as many as 100 patients.
- EAP may be amended to include traditionally larger patient groups once more safety data or other relevant data are available or a separate larger can EAP can be initiated.

- Limited data collected: Demographics, viral load, CD4 counts, current regimens and safety data are the only data collected.
- Minimal forms and labor: Paperwork should be as limited as possible
- Facilitates participation from academia, private physicians, public and private clinics
- Minimizes administrative burden on academic centers, private physicians, public and private clinics: Industry contributions to support necessary EAP staff
- National IRBs are available to provide convenient ethical oversight for private physicians, clinics and academic sites that do not require review from their own IRBs.