EuroSIDA hepatotoxicity event form

The form should be completed for all EuroSIDA participants who have discontinued cabotegravir +/- rilpivirine (either long-acting injectable or lead-in therapy to long-acting injections) or an oral 2-drug regimen with dolutegravir + rilpivirine or dolutegravir + lamivudine (3TC) due to liver-related clinical events, any possible liver toxicity, other causes (not specified) or unknown causes.

Hepatic laboratory values

For all laboratory values, please enter all results within **three months prior to and one month after** latest date of cabotegravir injection (with or without rilpivirine) or date of stopping oral dolutegravir/lamivudine or dolutegravir/rilpivirine.

Clinical symptoms and findings in relation to treatment with long-acting cabotegravir (with or without rilpivirine) or oral dolutegravir/lamivudine or dolutegravir/rilpivirine

Please indicate whether the patient has diagnosed with one or more of the following diagnoses and date of diagnosis:

1) Pancreatitis (inflammation of the pancreas, acute or chronic)
2) Ascites (fluid in the peritoneal cavity, diagnoses by ultrasound of the abdomen, detectable by imaging and/or paracentesis)
3) Hepatic encephalopathy stage III or IV (grade 3: somnolence to semistupor, but responsive to verbal stimuli; confusion; gross disorientation, grade 4: Coma)

Causal relationship

Please evaluate the causal relationship of the laboratory results and symptoms recorded in this form with long acting cabotegravir treatment, treatment with dolutegravir/lamivudine or treatment with dolutegravir/rilpivirine:

- (●) Not related
- ( ) Reasonable possibility of relationship
- ( ) Unknown

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The causal relationship should be evaluated by a clinician

Source documentation

Source documentation might in some cases be relevant. You can either fax or upload the documents.

Fax number: +45 3647 3340

Upload files:

NOTE: Please ensure that any identifying information is unreadable. We will delete any uploaded documents that have readable identifying information.

Upload file

Please fax or upload any relevant information from the patient chart

Once all available form information in this form has been provided, please change the form status to complete.