

# Request for information Email, March 17, 2011 - Laviv

From: Tull, Lori  
Sent: Thursday, March 17, 2011 2:57 PM  
To: Jeanne Novak  
Cc: 'Dana Weinberger'  
Subject: Request for information

Hi Jeanne,

The clinical team has the following request:

Thank you for your response to our information request regarding the case of leukoclastic vasculitis, which was a Serious Adverse Event. All documents are very helpful, but there appear to be scant data from laboratory workup for immunological/rheumatological parameters. One of the potential etiologies for leukoclastic vasculitis is connective tissue disease. Therefore, we request the following information (see list below) to be submitted: (1) during the ER visits and hospitalization from 7/2 to 7/5/2010 as well as during dermatological follow-up (three office visits); (2) if these determinations were not done during the acute presentation of vasculitis, they should be done now, if the patient agrees to the additional blood work. We would appreciate all or any of the following lab results: a repeat CK and urinalysis (they were abnormal during the vasculitis course), routine viral hepatitis panel and HIV testing (if not already done), an anemia work-up if his hemoglobin/hematocrit remains abnormal (iron, TIBC, ferritin, retic count, direct Coombs, serum protein electrophoresis). Rheumatology/immunology parameters that would be helpful include: ESR, C-reactive protein (CRP), ANA, c-ANCA, p-ANCA, cryoglobulins, rheumatoid factor, anti-double stranded DNA antibody, C3, C4, circulating immune complex, antimitochondrial antibodies, immunoglobulins. If these were determined during the acute phase, we would appreciate receiving the results. If not, determination at present may be helpful.

Additionally, if possible, please make sure that patient has undergone routine cancer screening tests: such as PSA and colonoscopy; we would also like to know the history of cancer screening.

Thank you,

Lori

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