

Subject: Re: UAT Plan and System Test Summary Report

Date: Wed, 20 Jun 2001 11:10:09 -0400

From: "Jinous A Jafari" <jinous.jafari@bms.com>

Organization: Bristol-Myers Squibb

To: Jeffrey Gassman <jeffrey.gassman@bms.com>

Thanks Jeff!

I really appreciate your assistance and great insight on the issues related to validation process.

Jinous

Jeffrey Gassman wrote:

> Hi Jinous,

>

> Attached are the two documents we discussed. Also, here is a

> government e-mail address that provides guidance for,

> "Computerized Systems Used in Clinical Trials" The guidance

> includes electronic records and signatures.

> http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.htm

>

> Best Regards,

>

> Jeff

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