



## TrialMaster® Updates-October 26, 2004

NAVIGATION TREE	
<i>INFU 1</i> Folder	Vitamin Accountability (VITACC iCRF) <ul style="list-style-type: none"> <li>▪ Initial form added by system</li> <li>▪ Other forms can <b>ONLY</b> be added in this visit</li> <li>▪ Maximum of 10 forms can be added</li> </ul>
<i>PREDISCONT</i> Folder	Premature Discontinuation of Therapy (DISCONT iCRF) <ul style="list-style-type: none"> <li>▪ Document specific study therapy stopped (infusions, low and/or high vitamins)</li> <li>▪ If response to question #2 is “patient refusal” you are required to give explanation in the OTHER space provided or add a note</li> <li>▪ Can <b>ONLY</b> be added in this folder</li> </ul>
<i>TFU</i> Folder	Telephone Follow-up (TELEFU iCRF) <ul style="list-style-type: none"> <li>▪ Document telephone communications following the 40<sup>th</sup> infusion or premature discontinuation of study drugs</li> <li>▪ Required every three months (3 per year)</li> <li>▪ Adverse Event (AE) and Endpoint (MI, Angina, Stroke and Death) iCRFs can be added</li> </ul>
<i>CFU</i> Folder	Clinic Visit (CLINVIS iCRF) <ul style="list-style-type: none"> <li>▪ Document annual follow-up visits until end of study</li> <li>▪ Adverse Event (AE) and Endpoint (MI, Angina, Stroke and Death) iCRFs can be added</li> </ul>
<i>CLOSEOUT</i> Folder	Final Clinic Visit (CLINVIS iCRF) <ul style="list-style-type: none"> <li>▪ Completed at end of study</li> <li>▪ <b>End of Study</b> (EOS iCRF) can <b>ONLY</b> be added in this folder</li> <li>▪ Endpoint (MI, Angina, Stroke and Death) iCRFs can be added</li> </ul>
INFUSION VISITS	
<i>Missed Visit (INFU)</i>	Response to question #1 ( <i>Did the patient come to the scheduled infusion visit?</i> ) is <b>NO</b> , then: <ul style="list-style-type: none"> <li>▪ Responses <u>required</u> for questions 2,3,4,5,6,7,10,11,12,13 and 26 <b>ONLY</b></li> <li>▪ Save completed form as SIGNED</li> <li>▪ Add another <i>INFU</i> iCRF (system will assign infusion iCRF #, i.e. INFU 41) to document actual visit</li> </ul>
<i>Length of Infusion Times</i>	<ul style="list-style-type: none"> <li>▪ <b>Required minimum is 3 hours</b> (exception if low Calcium is involved)</li> <li>▪ Required to give reason if infusion is less than 2 hours 45 minutes OR greater than 3 hours 15 minutes</li> </ul>
WORKFLOW	
<i>Patient Visits</i>	<ul style="list-style-type: none"> <li>▪ Column headers <u>Visit Name</u> and <u>Visit Status</u> have been moved to the far left of the screen</li> <li>▪ If <u>Visit Name</u> (#) is not the same as opened INFU iCRF, a warning message will appear in <b>RED</b> between the form header and title, i.e. <b>“warning, patient is currently awaiting INFU 4”</b></li> <li>▪ <b>Stop and make corrections OR call your Regional Clinical Coordinator</b></li> </ul>