

Guidance 1

File Note Completion			
Section 1			
Date / Time	<i>Date of identification of issue (date of commencing the file note)</i>		
Forum	Meeting <input type="checkbox"/>	Telephone <input type="checkbox"/>	Other <input type="checkbox"/> :
Author	<i>Who is writing this file note?</i>		
Other relevant staff	<i>Who else is involved in the discussion about the issue and resolution?</i>		
Study ID	<i>Study ID, or name of study</i>	<i>PID of patient if applicable:</i>	
Subject	<i>What does the file note refer to?</i>		
Section 2			
Item no.	Details of File Note		
	<i>This section should contain a detailed description of the issue</i>		
	<i>An explanation of how the event occurred in the first place is appropriate</i>		
	<i>Some options for resolution of the issue should be detailed</i>		
Action	<i>Specify what has been specifically undertaken to correct the discrepancy</i>		
	<i>Describe how will this be prevented from occurring in the future</i>		
Signature	<i>The file note should be signed by the person who can verify the discrepancy or who can verify the action taken as a result</i>		
Date of completion	<i>This should be the date all actions have been completed</i>		

ITCC File Note Completion

Section 1

- Date /Time
 - Complete the actual date (and time if appropriate) of the **writing** of the file note
- Forum
 - Tick if the file note is a result of any discussion via
 - Meeting
 - Telephone
 - Or other forum such as email, Zoom, etc
 - State who is writing the file note
 - Describe or name any other person involved in the process
 - Investigator
 - Other study staff
 - ITCC monitor
 - Name of other person
- Complete study ID
 - E.g. 05/007 (megestrol study)
 - The PID of the participant, if appropriate
- Provide a subject line
 - E.g. consent form, pathology results

Section 2

- Item number
 - This will usually be only one item, but there may be a series of separate activities of events that need to be described
 - It is helpful to separate the activities involved in the resolution of the issue (the subject of the file note) by providing separate item numbers
 - Detail of the file note
 - This section contains a detailed description of the issue
 - An explanation of how the event occurred in the first place is appropriate
 - Some options for resolution of the issue are detailed
 - Action
 - Specify action(s) to correct the discrepancy
 - Describe how the issue will be prevented from occurring in the future
 - Signature
 - The file note is signed by the person who can verify the discrepancy or who can verify the action taken as a result
 - This person must be appropriate to the issue
 - Pharmacy discrepancies will be signed by the pharmacist
 - Issues related to visits, data, approvals, or filing may be signed by the site/study coordinator or study nurses
 - Issues related to consent, eligibility, protocol, etc. are signed by the Principal Investigator
 - Date of completion
 - The date all actions are completed
 - This may be the same date as appears at the top of the file note
 - Some actions may occur over a period of days or weeks, the actual date of no further action should be entered at this point