

EDIT or SAVE

STUDY Number	ABC123x1234 (DROP DOWN)			Last Updated:
TMF Support	Sheila, Eleanor... (DROP DOWN)			
WHEN	WHAT	Completed	Technical/ Content	Comments
Before initial FPP release	Create initial HQ-TOC, mark applicability Set up pTMF Create C-template TOC Create CSR Essential Documents Tracker	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	T T T T	
	Create initial C-TOC	<input type="checkbox"/>	T	If TMO support, TOC created by Country Monitoring Responsible
After initial FPP release	Complete Study Lead QC Checklist (complete new one yearly at FPP anniversary date)	<input type="checkbox"/>	C	With support from Study Lead, CTT Members
Before RIS	Create initial S-TOC	<input type="checkbox"/>	T	If TMO support, TOC created by Field Monitor
Country SIV	Update C-TOC	<input type="checkbox"/>	C	If TMO support, TOC updated by Country Monitoring Responsible
FPFV	Update HQ-TOC Create eTMF Tracker/eTRAC	<input type="checkbox"/> <input type="checkbox"/>	C T	With support from Study Lead, CTT Members
Every 6 months between SIV and LPLV	Update C-TOC	<input type="checkbox"/> Date <input type="checkbox"/> Date	C	If TMO support, TOC updated by Country Monitoring Responsible, Field Monitor
	Update S-TOC	<input type="checkbox"/> Date <input type="checkbox"/> Date	C	
Every 6 months between FPFV and LPLV	Update HQ-TOC	<input type="checkbox"/> Date <input type="checkbox"/> Date	C	
Yearly from initial FPP release	Complete Study Lead QC Checklist	<input type="checkbox"/>	C	With support from Study Lead, CTT Members
Site COV	Update S-TOC	<input type="checkbox"/>	C	

	Perform full QC/gap analysis, send list of outstanding docs to CRA	<input type="checkbox"/>	C	Field Monitor (TMo support)
<b>Country LPLV</b>	Update C-TOC	<input type="checkbox"/>	C	Country Monitoring Responsible (TMo support)
<b>LPLV</b>	Update HQ-TOC	<input type="checkbox"/>	C	
<b>Before CSR publication</b>	Complete Study Lead QC Checklist Update HQ-TOC	<input type="checkbox"/> <input type="checkbox"/>	C C	With support from Study Lead, CTT Members With support from Study Lead, CTT Members
	Update C-TOC Update S-TOC	<input type="checkbox"/> <input type="checkbox"/>	C C	Country Monitoring Responsible, Field Monitor (TMo support) Study Lead (No TMo support)
<b>After CSR publication (within 60 wd)</b>	Finalize HQ-TOC, e-signed in CREDI Submit HQ pTMF archiving form	<input type="checkbox"/> <input type="checkbox"/>	C T	
	Finalize C-TOC, e-signed in CREDI Submit C&S pTMF archiving form Finalize S-TOC, e-signed in CREDI	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	C T C	Country Monitoring Responsible, Field Monitor (TMo support)
	Ensure no Create state documents in CREDI No Documents to Map in VTOC Upload AoRs	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	T T T	