

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
Complete 'yes' or 'no' to confirm the presence or absence of each document specified.				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
1. TRIAL MANAGEMENT				
CTC Contact List	13	15/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	12	14/03/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	11	06/09/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	10	22/09/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	9	07/02/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	8	29/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	7	29/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	6	24/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	5	03/09/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	4	18/02/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	3	05/02/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	2	29/02/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	1	19/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
2. PROTOCOL AND AMENDMENTS				
Protocol	6.2	30/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	6.1	12/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	6	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	5.1	22/12/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	5	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	4	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	3.1	01/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	3	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	2	22/12/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	1.1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
Protocol Version History Log	n/a	18/12/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
3. PATIENT INFORMATION				
Patient Information Sheet (PIS)	5	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
PIS (<i>superseded</i>)	4	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
PIS (<i>superseded</i>)	3	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
PIS (<i>superseded</i>)	2	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
PIS (<i>superseded</i>)	1.1	05/10/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
Informed Consent Form (ICF)	5	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
ICF (<i>superseded</i>)	4	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
ICF (<i>superseded</i>)	3	17/07/2013	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	
ICF (<i>superseded</i>)	2	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
ICF (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
Copies of Signed Patient Informed Consent Forms	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	ICF, ICF for Extra Blood Sample, Pregnancy Monitoring ICF (patient/partner)
GP Letter	2	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
GP Letter (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
Patient Card – Arm A	2	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Patient Card – Arm B	2	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Patient Card – Arm A (<i>superseded</i>)	1.1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Patient Card – Arm B (<i>superseded</i>)	1.1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:					
ISF – DOCUMENT VERSION CHECKLIST					
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>					
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
Patient Card – Arm A (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Card – Arm B (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Diary	2	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Diary (<i>superseded</i>)	1.1	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Diary (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
PIS for Extra Blood Sample	1	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
ICF for Extra Blood Sample	1	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Pregnancy Monitoring PIS – Patient	1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Pregnancy Monitoring PIS – Partner	2	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Pregnancy Monitoring PIS – Partner (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Pregnancy Monitoring ICF – Patient	1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Pregnancy Monitoring ICF – Partner	2	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Pregnancy Monitoring ICF – Partner (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Information Version History Log	n/a	02/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
4. ETHICS AND REGULATORY					
Sponsorship Letter	n/a	25/06/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Insurance Letter	n/a	11/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Initial – CTA Approval Letter	Initial	21/09/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Initial – REC Approval Letter	Initial	17/09/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Initial – REC Approval Letter	Initial	11/10/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#1 – REC, Cover Letter	n/a	17/01/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#1 – REC, Approval Letter	n/a	24/01/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#2 – REC, Cover Letter	n/a	01/03/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#2 – REC, Cover Letter	n/a	16/03/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#2 – REC, Approval Letter	n/a	11/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#3 – REC, Cover Letter	n/a	11/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#3 – REC, Approval Letter	n/a	20/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#4 – MHRA, Cover Letter	n/a	20/06/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#4 – MHRA, Approval Letter	n/a	26/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#5 – REC, Cover Letter	n/a	11/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#5 – REC, Approval Letter oval letter	n/a	17/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#6 – REC, Cover Letter	n/a	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#6 – REC, Approval Letter	n/a	27/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#7 – REC, Cover Letter	n/a	02/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#7 – REC, Approval Letter	n/a	27/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#8 – REC, Cover Letter	n/a	30/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#8 – REC, Approval Letter	n/a	11/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#9 – REC, Cover Letter	n/a	22/12/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#9 – REC, Approval Letter	n/a	24/01/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#9 – MHRA, Cover Letter	n/a	09/12/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#9 – MHRA, Approval Letter	n/a	31/01/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#10 – REC, Cover Letter	n/a	09/02/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#10 – REC, Approval Letter	n/a	30/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#11 – REC, Cover Letter	n/a	02/04/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#11 – REC, Approval Letter	n/a	09/05/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
SA#12 – REC, Cover Letter	n/a	26/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#12 – REC, Approval Letter	n/a	01/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – REC, Cover Letter	n/a	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – REC, Unfavourable Opinion Letter	n/a	17/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – REC, Approval Letter	n/a	25/10/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – MHRA, Cover Letter	n/a	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – MHRA, Approval Letter	n/a	06/09/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – USM Letter to Investigators	n/a	24/09/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#14 – REC, Cover Letter	n/a	19/10/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#14 – REC, Approval Letter	n/a	29/10/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#15 – REC, Cover Letter	n/a	04/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#15 – REC, Approval Letter	n/a	15/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#16a – REC, Cover Letter	n/a	29/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#16a – REC, Approval Letter	n/a	31/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#16b – REC, Cover Letter	n/a	15/05/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#16b – REC, Approval Letter	n/a	21/05/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#17 – REC, Cover Letter	n/a	04/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#17 – REC, Approval Letter	n/a	13/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – REC, Cover Letter	n/a	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – REC, Approval Letter	n/a	09/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – MHRA, Cover Letter	n/a	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – MHRA, Approval Letter	n/a	23/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#19 – REC, Cover Letter	n/a	15/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#19 – REC, Approval Letter	n/a	30/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#20 – REC, Cover Letter	n/a	20/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#20 – REC, Approval Letter	n/a	25/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#21 – REC, Cover Letter	n/a	26/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#21 – REC, Approval Letter	n/a	29/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#22 – REC, Cover Letter	n/a	27/01/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#22 – REC, Approval Letter	n/a	30/01/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#23 – REC, Cover Letter	n/a	01/04/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#23 – REC, Approval Letter	n/a	17/04/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#24 – REC, Cover Letter	n/a	28/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#24 – REC, Approval Letter	n/a	29/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#25 – REC, Cover Letter	n/a	10/07/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#25 – REC, Approval Letter	n/a	16/07/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#26 – REC, Cover Letter	n/a	08/10/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#26 – REC, Approval Letter	n/a	09/10/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#27 – REC, Cover Letter	n/a	31/10/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#27 – REC, Approval Letter	n/a	14/11/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#28 – MHRA, Cover Letter	n/a	26/01/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#28 – MHRA, Approval Letter	n/a	12/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#29 – REC, Cover Letter	n/a	17/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#29 – REC, Approval Letter	n/a	26/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#30 – REC, Cover Letter	n/a	12/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites.</i>

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
SA#30 – REC, Approval Letter	n/a	16/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Refer to Amendment Log for details.
SA#31 – REC, Cover Letter	n/a	24/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#31 – REC, Approval Letter	n/a	31/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#32 – REC, Cover Letter	n/a	01/05/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#32 – REC, Approval Letter	n/a	08/05/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#33 – REC, Cover Letter	n/a	12/06/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#33 – REC, Approval Letter	n/a	18/06/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – REC, Cover Letter	n/a	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – REC, Approval Letter	n/a	11/08/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – MHRA, Cover Letter	n/a	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – MHRA, Approval Letter	n/a	08/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – REC, Cover Letter	n/a	22/12/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – REC, Approval Letter	n/a	04/01/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – MHRA, Cover Letter	n/a	22/12/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – MHRA, Approval Letter	n/a	01/02/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#36 – REC, Cover Letter	n/a	26/02/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#36 – REC, Approval Letter	n/a	10/03/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#37 – REC, Cover Letter	n/a	26/08/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#37 – REC, Approval Letter	n/a	30/08/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#38 – REC, Cover Letter	n/a	06/10/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#38 – REC, Approval Letter	n/a	18/10/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#39 – REC, Cover Letter	n/a	15/11/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#39 – REC, Approval Letter	n/a	21/11/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#40 – REC, Cover Letter	n/a	07/02/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#40 – REC, Approval Letter	n/a	14/02/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#41 – REC, Cover Letter	n/a	05/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#41 – REC, Approval Letter	n/a	11/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#42 – REC, Cover Letter	n/a	11/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#42 – REC, Approval Letter	n/a	18/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#43 – REC, Cover Letter	n/a	22/06/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#43 – REC, Approval Letter	n/a	28/06/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#44 – REC, Cover Letter	n/a	03/07/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#44 – REC, Approval Letter	n/a	07/07/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#45 – REC, Cover Letter	n/a	25/08/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#45 – REC, Approval Letter	n/a	15/09/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#46 – REC, Cover Letter	n/a	04/10/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#46 – REC, Approval Letter	n/a	09/10/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – REC, Cover Letter	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – MHRA, Cover Letter	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – Notice of Amendment Form	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – CTA Application Form, Updated	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – REC, Approval Letter	n/a	13/12/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – MHRA, Approval Letter	n/a	18/12/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – HRA, Approval Letter	n/a	29/12/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
SA#48 – REC, Cover Letter	n/a	19/01/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#48 – REC, Approval Letter	n/a	22/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#49 – REC, Cover Letter	n/a	09/02/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#49 – REC, Approval Letter	n/a	12/02/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#50 – REC, Cover Letter	n/a	23/03/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#50 – REC, Approval Letter	n/a	29/03/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#51 – REC, Cover Letter	n/a	27/04/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#51 – REC, Approval Letter	n/a	30/04/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#52 – Non-Notifiable, Non-Substantial Amendment (GDPR Transparency Statement)	n/a	30/05/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#53 – Non-Substantial Amendment Form	n/a	14/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#53 – HRA Approval Letter	n/a	30/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#54 – Non-Substantial Amendment Form	n/a	11/07/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#54 – HRA Approval Letter	n/a	13/07/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#55 – REC, Cover Letter	n/a	07/08/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#55 – REC, Approval Letter	n/a	07/08/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#56 – REC, Cover Letter	n/a	17/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#56 – REC, Approval Letter	n/a	24/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#57 – Non-Substantial Amendment Form	n/a	30/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#57 – HRA Approval Letter	n/a	05/11/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#58 – Non-Substantial Amendment Form	n/a	31/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#58 – HRA Approval Letter	n/a	05/11/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#59 – REC, Cover Letter	n/a	18/01/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#59 – REC, Approval Letter	n/a	29/01/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#60 – Non-Substantial Amendment Form	n/a	11/03/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#60 – HRA Approval Letter	n/a	21/03/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#61 – Non-Substantial Amendment Form	n/a	08/04/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#61 – HRA Approval Letter	n/a	13/05/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#62 – REC, Cover Letter	n/a	02/03/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#62 – REC, Approval Letter	n/a	04/03/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#63 – Non-Notifiable, Non-Substantial Amendment (COVID-19)	n/a	23/04/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#64 – REC, Cover Letter	n/a	15/06/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#64 – REC, Approval Letter	n/a	17/06/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#65 – REC, Cover Letter	n/a	17/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#65 – REC, Approval Letter	n/a	17/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
ARISTOTLE – Amendment Log	n/a	17/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	Last Updated 17/09/2020
Local SSA Application Form	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
R&D Approval Letters – Initial and Amendments	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
5. AGREEMENTS AND CONTRACTS				
CTSA (and Amendments, if applicable)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Registration Form	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Summary Form	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Activation Letter	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
6. SITE INFORMATION/SITE STAFF INFORMATION				
Site Staff Delegation Log	2.1	20/12/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Staff Delegation Log (<i>superseded</i>)	2	16/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Staff Delegation Log (<i>superseded</i>)	1	19/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form	4	14/01/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form (<i>superseded</i>)	3	14/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form (<i>superseded</i>)	2	08/03/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form (<i>superseded</i>)	1	14/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Staff CV and details of GCP training	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or File Note of location</i>
7. PATIENT SCREENING AND RECRUITMENT				
Patient Screening Log	3	01/06/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Patient Screening Log (<i>superseded</i>)	2	25/04/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Patient Screening Log (<i>superseded</i>)	1	27/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Master Subject List	1	26/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Randomisation Procedure – Sites	3.1	25/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Rand Procedure – Sites (<i>superseded</i>)	3	25/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Rand Procedure – Sites (<i>superseded</i>)	2	07/10/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Rand Procedure – Sites (<i>superseded</i>)	1	27/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Confirmation of Randomisations – Email/Fax	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or file note of alternate location</i>
Informed Consent Form Log	1	20/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
8. LABORATORY				
Laboratory Normal Ranges CRF	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Lab Normal Ranges CRF (<i>superseded</i>)	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Lab Normal Ranges CRF (<i>superseded</i>)	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Note: No v2 (version numbering error)</i>
Lab Normal Ranges CRF (<i>superseded</i>)	1	06/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Laboratory Manual	4	06/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Laboratory Manual (<i>superseded</i>)	3	28/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Laboratory Manual (<i>superseded</i>)	2	17/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Laboratory Manual (<i>superseded</i>)	1	28/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Quick Guide for Blood Preparation	1	17/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Pathology Photography Guide	1.1	06/01/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Pathology Photography Guide (<i>superseded</i>)	1	29/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Pathology Sample Submission Form	1	17/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – Germline DNA	3	06/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – Germline DNA (<i>superseded</i>)	2	28/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – Germline DNA (<i>superseded</i>)	1	17/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – ctDNA	3	06/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – ctDNA (<i>superseded</i>)	2	28/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – ctDNA (<i>superseded</i>)	1	17/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – Plasma (<i>superseded</i>)	1.2	17/08/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – Plasma (<i>superseded</i>)	1.1	05/03/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Worksheet – Plasma (<i>superseded</i>)	1	28/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Sample Tracking Log	2	17/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Sample Tracking Log (<i>superseded</i>)	1	28/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:					
ISF – DOCUMENT VERSION CHECKLIST					
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>					
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
9. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)					
SPC – Capecitabine (<i>current</i>)	n/a	10/07/2017	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	24/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	24/12/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	23/01/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	18/12/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	30/05/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	15/11/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	17/06/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	23/03/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Irinotecan (<i>current</i>)	n/a	Oct 2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Irinotecan (<i>superseded</i>)	n/a	Apr 2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Irinotecan (<i>superseded</i>)	n/a	17/02/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Irinotecan (<i>superseded</i>)	n/a	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Irinotecan (<i>superseded</i>)	n/a	13/03/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
File Note – Location of SPC	n/a	28/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
10. TRIAL DRUG SUPPLIES/PHARMACY ARRANGEMENTS					
Summary of Drug Arrangements (SoDA)	5	04/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	4	09/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	3	27/02/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	2	15/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	1	04/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Approved IMP Label – Capecitabine	3	01/02/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Approved IMP Label – Capecitabine (<i>superseded</i>)	2	21/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Approved IMP Label – Capecitabine (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Master Trial Prescription	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
Template Drug Accountability Log	1	31/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Completed Drug Accountability Log	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or File Note if kept in Pharmacy</i>	
11. DATA MANAGEMENT					
CRF Completion Guideline	3	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
CRF Completion Guideline (<i>superseded</i>)	2	22/12/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
CRF Completion Guideline (<i>superseded</i>)	1	27/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Eligibility Checklist	5.1	12/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Pre-Randomisation	5.1	12/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Pre-Treatment	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Pre-Treatment MRI	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: On-Treatment	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Completion of Treatment	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Treatment Summary	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Post-Treatment MRI	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Surgery	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Pathology	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Post-Surgery	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Follow-up – 4 months	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Current CRF: Follow-up – 6 months	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
Current CRF: Follow-up – 12 months	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Follow-up – 24-36 months	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Follow-up – 48-60 months	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Suspected RD or Recurrence	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Confirmed RD or Recurrence	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Death	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Change of Status	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Normal Ranges	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Additional Haem & Biochemistry	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Male Pelvis Questionnaire	2.1	02/04/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current CRF: Female Pelvis Questionnaire	2.1	02/04/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current: SAE Report Form	4.1	11/11/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Current Pregnancy Report Form	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Eligibility Checklist	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Eligibility Checklist	4.1	25/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Eligibility Checklist	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Eligibility Checklist	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Eligibility Checklist	1	06/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Randomisation	5	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Randomisation	4.1	25/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Randomisation	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Randomisation	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Randomisation	1	06/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Randomisation	3.2	11/04/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Randomisation	3.1	22/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Randomisation	3	17/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Randomisation	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Randomisation	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Randomisation	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Treatment	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Treatment	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Treatment	1	06/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Baseline	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Baseline	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Baseline	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Treatment MRI	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pre-Treatment MRI	3	21/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pelvis MRI	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Pelvis MRI	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: On-Treatment	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: On-Treatment	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Assessment During CRT	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Assessment During CRT	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Assessment During CRT	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Previous CRF: Completion of Treatment	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:					
ISF – DOCUMENT VERSION CHECKLIST					
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>					
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
Previous CRF: Completion of Treatment	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Treatment Summary	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Treatment Summary	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Assessment – Week 10	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Assessment – Week 10	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Assessment – Week 10	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Post-Treatment MRI	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Post-Treatment MRI	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Post-Treatment MRI	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Post-Treatment MRI	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Surgery	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Surgery	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Surgery	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Surgery	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Surgery	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Post Surgery	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Post Surgery	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Pathology	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Pathology	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Pathology	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Pathology	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 4 Months	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 4 Months	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 6 Months	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 6 Months	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 12 Months	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 12 Months	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 3, 6, 12 Months	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 3, 6, 12 Months	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 3, 6, 12 Months	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 24, 36 Months	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 24, 36 Months	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 48, 60 Months	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 48, 60 Months	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 24, 36, 48, 60 Months	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Follow-up – 24, 36, 48, 60 Months	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Male Pelvis Questionnaire	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Male Pelvis Questionnaire	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Male Pelvis Questionnaire	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Female Pelvis Questionnaire	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Female Pelvis Questionnaire	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Suspected RD or Recurrence	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Suspected RD or Recurrence	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Confirmed RD or Recurrence	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Confirmed RD or Recurrence	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:					
ISF – DOCUMENT VERSION CHECKLIST					
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>					
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
Previous CRF: Recurrence	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Recurrence	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Recurrence	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Death	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Death	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Death	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Death	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Death	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Change of Status	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Change of Status	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Normal Ranges	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Normal Ranges	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Normal Ranges	1	06/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Additional Haem & Biochemistry	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Additional Haem & Biochemistry	3	14/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Adverse Event	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Adverse Event	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous CRF: Adverse Event	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous: SAE Report Form	4	18/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous: SAE Report Form	3	21/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous: SAE Report Form	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous: SAE Report Form	1.1	13/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous: SAE Report Form	1	25/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Previous Pregnancy Report Form	2	26/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
CRF Version History Log	n/a	12/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Last Updated 12/01/2018</i>	
Completed CRF Query Sheets	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or file note location of data query sheets</i>	
Worksheet – MRI Pelvis	2	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Worksheet – Pathology	2	05/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Worksheet – MRI Pelvis (<i>superseded</i>)	1	23/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
Worksheet – Pathology (<i>superseded</i>)	1	22/12/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
12. PHARMACOVIGILANCE					
SAE Reporting Guidelines	2	23/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SAE Reporting Guidelines (<i>superseded</i>)	1.1	18/01/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
File Note – SAE Report Guidelines	n/a	31/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Completed SAE Reports (<i>if applicable</i>)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or file note location of SAEs</i>	
Completed Pregnancy Reports (<i>if applicable</i>)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or file note location of pregnancy reports</i>	
Quarterly SUSAR Line Listing #1	22/09/2011 – 21/12/2011		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #2	22/12/2011 – 21/03/2012		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #3	22/03/2012 – 21/06/2012		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #4	22/06/2012 – 21/09/2012		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #5	22/09/2012 – 21/12/2012		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #6	22/12/2012 – 21/03/2013		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #7	22/03/2013 – 21/06/2013		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #8	22/06/2013 – 21/09/2013		Y <input type="checkbox"/> N <input type="checkbox"/>		
Quarterly SUSAR Line Listing #9	22/09/2013 – 21/12/2013		Y <input type="checkbox"/> N <input type="checkbox"/>		

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
Quarterly SUSAR Line Listing #10	22/12/2013 – 21/03/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #11	22/03/2014 – 21/06/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #12	22/06/2014 – 21/09/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #13	22/09/2014 – 21/12/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #14	22/12/2014 – 21/03/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #15	22/03/2015 – 21/06/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #16	22/06/2015 – 21/09/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #17	22/09/2015 – 21/12/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #18	22/12/2015 – 21/03/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #19	22/03/2016 – 21/06/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #20	22/06/2016 – 21/09/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #21	22/09/2017 – 21/12/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #22	22/12/2016 – 21/03/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #23	22/03/2017 – 21/06/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #24	22/06/2017 – 21/09/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #25	22/09/2017 – 21/12/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #26	22/12/2017 – 21/03/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #27	22/03/2018 – 21/06/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #28	22/06/2018 – 21/09/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #29	22/09/2018 – 21/12/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #30	22/12/2018 – 21/03/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #31	22/03/2019 – 21/06/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #32	22/06/2019 – 21/09/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #33	22/09/2019 – 21/12/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #34	22/12/2019 – 21/03/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #35	22/03/2020 – 21/06/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #36	22/06/2020 – 21/09/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	
Safety Alert – Irinotecan Recall	n/a	24/07/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>For information only</i>
File Note – Urgent Safety Measure	Amdt 13	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
13. INCIDENT REPORTING				
Incident Report Template	3	20/09/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Incident Report Template (<i>superseded</i>)	2	25/06/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Incident Report Template (<i>superseded</i>)	1	15/09/2009	Y <input type="checkbox"/> N <input type="checkbox"/>	
Completed Incident Report (<i>if applicable</i>)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
14. SITE MONITORING				
Site Initiation Slides	n/a	12/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Initiation Slides (<i>superseded</i>)	n/a	27/06/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Histopathologist Training Slides	n/a	26/08/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
Samples Overview Slides	n/a	03/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Initiation Report	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Plan	3	28/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Plan (<i>superseded</i>)	2	11/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Plan (<i>superseded</i>)	1	11/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
On-Site Monitoring Visit – Site Visit Log	1	27/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Report (<i>if applicable</i>)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	

INVESTIGATOR SITE FILE CHECKLIST

SITE NAME:				
ISF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
15. CORRESPONDENCE				
Any correspondences	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
16. REGULATORY GUIDELINES				
Principles of ICH GCP	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Declaration of Helsinki	n/a	09/10/2004	Y <input type="checkbox"/> N <input type="checkbox"/>	
17. OTHER STUDY MATERIALS				
Investigator Meeting Presentations	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Investigator WebEx Meeting Presentations	n/a	26/04/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Investigator WebEx Meeting Presentations	n/a	21/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Investigator WebEx Meeting Presentations	n/a	24/01/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
QA Questionnaire	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Radiotherapy QA	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	

SITE NAME:		
Please provide email address of the person to whom documents which are not available on the website should be sent to:		
Checklist Completed by:		
Name: _____	Role: _____	Email: _____
Date Complete: _____		
The completed form can be returned to ctc.aristotle@ucl.ac.uk or faxed to 020 7679 9871.		
This is intended to support site's own internal systems for maintaining the ISF; therefore if the checklist is not returned to UCL CTC we will assume that documents contained within your ISF are up-to-date.		
The following are general reminders regarding maintenance of the Investigator/Pharmacy Site File:		
<ul style="list-style-type: none"> ▪ The folder must be stored in a secure location with appropriate/restricted access ▪ The documents should be filed as per index (<i>CTC index or site's own index is acceptable</i>) ▪ Documents generated locally (e.g. local approvals, lab normal ranges, correspondence, etc.) must be filed in the applicable sections ▪ Where documents are held in an alternative location, file notes should be present to indicate this ▪ Up-to-date CVs & GCP training must be present for all relevant staff (<i>CVs should be current at the time the trial is opened, kept up-to-date and be signed & dated</i>) ▪ GCP certificates must be present (or details of course attended listed in the CV) for all staff (<i>All staff should have attended a course – frequency of repeat training may be dictated by the employing institution policy, or 2 yearly where the institution has no policy, and more frequently when there have been updates to the legal or regulatory requirements for conduct of clinical trials</i>) 		