

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – 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
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superseded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superseded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superseded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superseded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superseded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superseded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superseded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superseded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superseded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superseded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superseded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superseded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. 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superseded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superseded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superseded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superseded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superseded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>
3. 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"/>	
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"/>	

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DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
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	27/09/2013	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"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#10 – REC, Approval Letter	n/a	30/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
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"/>		
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"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
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	18/07/2013	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.</i>	

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SA#20 – REC, Approval Letter	n/a	25/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	Refer to Amendment Log for details.
SA#21 – REC, Cover Letter	n/a	26/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
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"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#30 – REC, Approval Letter	n/a	16/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
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	12/07/2015	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	18/07/2015	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.

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<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
SA#39 – REC, Approval Letter	n/a	21/11/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Refer to Amendment Log for details.
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"/>	
SA#48 – REC, Cover Letter	n/a	19/01/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
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"/>	

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DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
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. 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"/>	
6. PATIENT INFORMATION				
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"/>	
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"/>	
Patient Information Version History Log	n/a	02/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – 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
7. IMP/NIMP MANAGEMENT				
7.1 RANDOMISATION				
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>
7.2 SUMMARY OF DRUG ARRANGEMENTS (SoDA)				
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"/>	
7.3 PACKING AND LABELLING				
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"/>	
7.4 DISPENSING				
Dispensing Guidelines	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Master Subject List	1	26/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Master Trial Prescription	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Completed Trial Prescriptions	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
7.5 ACCOUNTABILITY/DESTRUCTION/RETURNS				
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"/>	
Site Destruction Policy	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
7.6 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"/>	

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – 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
7.7 DRUG SAFETY				
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"/>	
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"/>	
8. 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"/>	

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – DOCUMENT VERSION CHECKLIST				
Complete 'yes' or 'no' to confirm the presence or absence of each document specified.				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
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"/>	
9. 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"/>	
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"/>	
10. CORRESPONDENCE				
Any correspondences	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 PSF; therefore if the checklist is not returned to UCL CTC we will assume that documents contained within your PSF 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>) 	