Ex. 11

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:
AK	8/11/2020	1	7/30/2020		1001	April	Date Format; ICF time same as VS Rest; incomplete source pages	
MF	9/2/2020	2	8/20/2020	7/31/2020	1001	Anne	1. Confirm if consent was scanned into eConsent- paper version used. 2. Reminder- please keep progress note on top of source docs. 3. Add patient initials and ID to eDiary print out. 4. Add IMPALA drug assignment confirmation page behind page 6 of source. 5. confirm if eDC was done for V1 and add date to chart sticker if so.	
AK	8/11/2020	1	7/30/2020		1002	Nika	Minor charting errors	
MF	9/2/2020	2	8/20/2020	7/31/2020	1002	Anne	1. Add patient initials and ID to V1 and V2 eDiary printout pages. 2. Spell out "vitamin" on con med page 3. File IMPALA confirmation page behind source page 6 for V2. 4. Scan V3 consent to eConsent and make new copy of V2 consent with footer not cut-off.	
					1003			
MF	9/2/2020	2	8/21/2020	7/31/2020	1003	Claudia	1. Add patient initials and ID to V1 and V2 eDiary printout pages. 2. Add late entry on progress note that V3 consent has printer smudges on the original version of the consent, that the consent language was not changed. *Discussed with Chyann who has been making consent copies for team. 3. File IMPALA confirmation page behind source page 6 for V2. 4. Scan V3 and V2 consent to eConsent. 5. Dr. Fuller to sign Progress Note for 8/22-8/23/20 ASAP. 6. V1 Vital signs page 7- please re-write the year which is not clear and initial/date correction (prior QC correction). 7. file consent process page with V3 consent- move from visit source.	
AK	8/11/2020		7/30/2020		1004	Linda	Date Format; ICF time same as VS Rest; Writeovers	

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:
MF	9/3/2020	2	8/20/2020	7/31/2020	1004	Anne	1. Add version # and date to top of page on Informed Consent process page- currently missing. 2. Print new copy of V2 consent to include all of footer- footer is currently cut-off. 3. Add patient initials and ID# to all eDiary log printouts. 4. eDiary Review Log dated 7/30/20- please verify date for study day #3- appears to be a repeat of study day #4- both are dated 8/3/2020. 5. Verify if all 3 con meds listed on con med page should be reported on the CRF- answer is yes, but should be no? 6. answer question on page 6 V2- "Has the vaccne been administered per protocol?" 7. answer question on page 7 V2- "Was subject in need of a new caliper or thermometer?" 8. complete "next visit" section on page 8	
					1005			
					1006			
AK	8/11/2020		7/30/2020		1007	Dana	Date Format; ICF time same as VS rest;	
MF	9/4/2020	2	8/20/2020	7/31/2020	1007	Anne	1. Add version # to consent process page for V3 consent. 2. scan V2 and V3 consents into eConsent.	
					1008			
					1009			
AK	8/11/2020		7/30/2020		1010	Dana	Date Format; ICF time same as VS Rest	
AK	8/11/2020		7/30/2020		1011	Linda	Date Format; ICF time same as VS Rest; incomplete source pages	
					1012			
AK	8/11/2020		7/30/2020		1013	Dana	Date format; ICF time same as VS Rest	
					1014			
					1015			
					1016			
					1017			

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:
MF	9/4/2020	1		7/31/2020	1018	Katie	[illegible] schedule. 2. Page 9 source "childbearing potential and contraception method have been verified" is initialed but checked no for uring preg not done and that it's "n/a". Please confirm which is correct- patient had tubal ligation per source. 3. Severe reaction ediary source page- please add to page 2, "see progress note for severe reaction from ediary review log for V1". 4. V1 page 6 source- "no" is checked for multiple systems. Confirm if they were truly not "asked about" and change to "yes" for all, if they were. 5. Diary log printout for 8/4-8/8- Diarrhea stop date = 8/7/20 per V2 page 2 source; however, progress note on 8/8 says it stopped on 8/8 and was not severe until	
					1019			
					1020			
					1021			
					1022			
					1023			
					1024			
					1025			
					1026			
AK	8/13/2020		8/4/2020		1027	Nika	ICF date on source;IP admin que on source; AE log;	
AK	8/11/2020		8/4/2020		1028	April		
AK	8/13/2020		8/4/2020		1029	Nika	inconsistent date format; 3 digit entry on vital signs;subject ID # not same on source footer pages;minor charting errors;	
					1030			
AK	8/12/2020		8/5/2020		1031	Nika	PI signature missing; date format error; minor charing error	
AK	8/12/2020		8/5/2020		1032	Ashley	ICF time same as Progress notes; Incomplete source, Minor charting errors	
					1033			
					1034			
AK	8/12/2020		8/5/2020		1035	Ashley	Progress notes written (time)before ICF completion time;Minor charting errors	
AK	8/13/2020		8/5/2020		1036	Mercedes	pending CRC signature;IP admin que on source; AE log header infor;	

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:
					1037			
					1038			
					1039			
					1040			
					1041			
AK	8/13/2020		8/6/2020		1042	Anne	Becca pls QC my chart	
					1043			
AK	8/13/2020		8/6/2020		1044	Katie B	Date format; IP admin que on source; CRC signature pending	
					1045			
AK	8/13/2020		8/6/2020		1046	Thea	IP admin que on source	
AK	8/13/2020		8/6/2020		1047	Nika	PI signature on Progress notes and CM; IP admin que in source	
					1048			
					1049			
					1050			
AK	8/12/2020		8/7/2020		1051	Katie	writeover on subject ICF name; minor charting errors;date errors	
					1052			
					1053			
AK	8/13/2020		8/7/2020		1054	Nika	Missing progree notes and PI signature;Incorrect ICF and IRB approval dates; Incorrect DOB; IP admin que; incomplete source pages	
					1055			
					1056			
					1057			
					1058			
					1059			
					1060			
AK	8/11/2020		8/7/2020		1061	Claudia	Write overs; incomplete source pages	
					1062			
AK	8/12/2020		8/7/2020		1063	Nika	incomplete source pages	
					1064			
					1065			
					1066			
					1067			
					1068			
					1069			
					1070			
					1071			
					1072			
					1073			
					1074			
					1075			
					1076			

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:
					1077			
AK	8/12/2020		8/10/2020		1078	Angi	Footers not completed; PI signature missing on CM; Med Terms abbreviated	
					1079			
					1080			
					1081			
AK	8/12/2020		8/11/2020		1082	Angi	ICF correction not written properly by pt, no ICF QC;	
AK	8/13/2020		8/11/2020		1083	Kathryn D	ICF time same as Progress notes; no 3 digits on vital signs; Incomplete source, Minor charting errors	
AK	8/12/2020		8/11/2020		1084	Angi	ICF date written incorrect by pt, no ICF QC done; Write overs; Med terms abbreviated; conditions on PE not on MH	
AK	8/13/2020		8/11/2020		1085	Becca	AE log header infor; IP admin Que on source;PI signature on CM;	
AK	8/13/2020		8/11/2020		1086	Becca	IP admin que on source;	
AK	8/13/2020		8/11/2020		1087	Angi	ICF time same as Progress notes; Incomplete source, Minor charting errors;	
AK	8/13/2020		8/12/2020		1088	Angi	no ICF QC; ICF consent time same as Progress notes entry time; no 3 digit entry on vital signs; incomplete source pages; write overs;	
AK	8/12/2020		8/12/2020		1089	Claudia	incomplete source pages	
AK	8/13/2020		8/12/2020		1090	Angi	No ICF QC; ICF consent time same as progress note entry time; overwrites;vital signs no 3 digit entry;	

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls :	**QC Date:**	**Visit #:**	**Visit Date**	**ICF Version/Date** V2/ 13July2020 **V3/ 31July2020**	**Subj. #**	**CRC**	**Findings:**	**Corrections Completed:**

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls :	**QC Date:**	**Visit #:**	**Visit Date**	**ICF Version/Date** V2/ 13July2020 **V3/ 31July2020**	**Subj. #**	**CRC**	**Findings:**	**Corrections Completed:**

QC Findings for Pfizer COVID-19 C4591001- KELLER

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:

QC Initls:	QC Date:	Visit #:	Visit Date	ICF Version/Date V2/ 13July2020 V3/ 31July2020	Subj. #	CRC	Findings:	Corrections Completed:
KD	8/10/2020	1	########	V2/13July2020 signed at 0944am	11281002	lbl	Diary log not completed- where is the print out from eDiary dates not correct on ConMed Header on AE log no completed log EDC-?? Matching Page 5 date format not readable clearly Page 6 dates not complete Page 7- HCG kit in Lab binder? Page 9 missing initials Page 13 Visit 2 not completed	

KD	8/10/2020	1	########	V2/13July2020 signed at 0948am	11281003	dd	Diary log not completed- where is the print out from eDiary dates not correct on ConMed Header on AE log no completed log EDC-?? Matching Page 6 dates not complete Page 10 Needle size not per protocol Page 10 missing application placement Page 13 Visit 2 not completed
KD	8/10/2020	1	########	V2/13July2020 signed at 1009am	11281004	ts	Diary log not completed- where is the print out from eDiary Header on AE log no completed log EDC-?? Matching Page 3 should be completed. not N/A Page 6 very unclean collection of data Page 7 not clear what is what Page 8 PE findings needing to be added to Medical history, 'Other' needs to be marked "not done' Page 13 Visit 2 not completed

KD	8/10/2020	1	########	V2/13July2020 signed at 1128am	11281005		Diary log not completed- where is the print out from eDiary Header on AE log no completed log EDC-?? Matching Page 6 incomplete dates Page 7 abnormal findings- recheck? Page 8 'Other' needs to be marked "not done' Page 13 Visit 2 not completed
KD	8/10/2020	1	########	V2/13July2020 signed at 1021am	11281006	ab	Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 1 if another CRC did this page. Would be better to have their Initals at the bottom as well. Page 6 missing date completely Page 13 Visit 2 not completed

KD	8/10/2020	1	########	V2/13July2020 signed at 1141am	11281007		Diary log not completed-where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 1 PCP notification letter missing Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 8 "other' not marked as not done' Page 13 Visit 2 not completed
KD	8/10/2020	1	########	V2/13July2020 signed at 1137am	11281008		Diary log not completed-where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 1 PCP notification letter missing Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 8 "other' not marked as not done' Page 13 Visit 2 not completed and missing oversight signature. been 6 days since visit

KD	8/10/2020	1	########	V2/13July2020 signed at 1359	11281010	ab	Progress notes needs to be signd from 04Aug2020 Diary log not completed-where is the print out from eDiary Header on AE log no completed log dates not correct on ConMeds EDC-?? Matching Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 8 "other' not marked as not done' Page 13 Visit 2 not completed
KD	8/10/2020	1	########	V2/13July2020 signed at 1421	11281011	dd	Diary log not completed-where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 9 footer not completed. Late entry by DD for not completing during visit. Page 13 Visit 2 not completed

KD	8/10/2020	1	########	V2/13July2020 signed at 1519	11281012	dd	Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 11 AE question not marked, late entry. Page 13 Visit 2 not completed
KD	8/10/2020	1	########		11281013		
KD	8/10/2020	1	########	V2/13July2020 signed at 1554	11281014	ab	Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed-INV date is 01Aug, which is next day, so there is no late entry stating that INV checked over ConMeds during the visit. EDC-?? Matching Page 6 dates are incomplete- also missing on page 6.1 INV for late entry history Page 7 - missing rest time for BP rest period, but have an end time. Page 9 missing inital on check list Page 10- for device date is given not the device loaded on. Page 13 Visit 2 not completed

KD	8/10/2020	1	########	V2/13July2020 signed at 1606	11281015		Progress notes has a fup call regarding medcial history-that should have been gotten during the visit, but was done due to queiries. Diary log not completed-where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed-INV date is 01Aug, which is next day, so there is no late entry stating that INV checked over ConMeds during the visit. EDC-?? Matching Page 1, write over, that needs to be fixed Page 6 dates are incomplete- also missing on page 6 INV for late entry history from 04Aug Page 7 - missing rest
KD	8/10/2020	1	8/1/2020	V2/13July2020 signed at 1606	11281016	ts	Diary log not completed-where is the print out from eDiary Header on AE log no completed log EDC-?? Matching Page 13 Visit 2 not completed

KD	8/10/2020	1	8/1/2020	V2/13July2020 signed at 0950	11281017	dd	Progress notes Not signed off from 01Aug Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed- EDC-?? Matching Page 6 dates are incomplete- Page 9 MISSING Lab and Swab time points-- corrected with Linda Page 13 Visit 2 not completed
KD	8/10/2020	1	8/1/2020	V2/13July2020 signed at 0949	11281018		Progress notes Not signed off from 01Aug Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed- EDC-?? Matching Page 6 dates are incomplete- Page 13 Visit 2 not completed
KD	8/10/2020	1	8/1/2020		11281019		

KD	8/10/2020	1	8/1/2020	V2/13July2020 signed at 1054	11281020	ab	Progress notes Not signed off from 01Aug Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed- EDC-?? Matching Page 6 dates are incomplete- INV missing from late entry 04Aug Page 10 missed check box of thermometer given. Page 13 Visit 2 not completed
KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1107	11281021	ts	Patient information sheet not signed by subject Diary log not completed- where is the print out from eDiary Page 6 incomplete dates Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed

KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1114	11281022	ts	Diary log not completed-where is the print out from eDiary Page 10 Needle size confirm the right size based of WT. Page 10 Device installed on what? Page 13 Visit 2 not completed
KD	8/11/2020	1	8/1/2020		11281023		
KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1352	11281024	ts	Diary log not completed-where is the print out from eDiary Header on AE log no completed log Page 6 incomplete dates Page 10 Device installed on what? Page 13 Visit 2 not completed

KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1356	11281026	ab	Diary log not completed-where is the print out from eDiary Header on AE log no completed log dates not correct on ConMeds Page 6 incomplete dates Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed
KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1440	11281027	ab	Diary log not completed-where is the print out from eDiary dates not correct on ConMeds Header on AE log no completed log Page 6 incomplete dates Page 13 Visit 2 not completed

KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1521	11281028		Diary log not completed- where is the print out from eDiary dates not correct on ConMeds Header on AE log no completed log Page 6 incomplete dates Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed
KD	8/11/2020	1	8/1/2020	V2/13Jul2020 signed at 1534	11281029		Diary log not completed- where is the print out from eDiary Header on AE log no completed log Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed

KD	8/11/2020	1	8/3/2020	?missing footer for ICF-reprint signed 1033	11281030	ab	Header on AE log no completed log Page 3 #11 needs to be 'No" not N/A Page 8 PE 'other' needs to be N/A Page 13 Visit 2 not completed
KD	8/11/2020	1	8/3/2020		11281031	ab	Diary log not completed-where is the print out from eDiary Header on AE log no completed log Page 3 #11 needs to be 'No" not N/A Page 6 incomplete dates Page 8 PE 'other' needs to be N/A Page 9 Blood only 5ml not 25ml-Protocol deviation?? Page 13 Visit 2 not completed
			8/3/2020		11281032		
			8/3/2020		11281033		
			8/3/2020		11281034		
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 0937	11281039	ab	Diary log not completed-till 11Aug2020 ConMed page, match EDC?? Page 6 incomplete dates Page 8 'other' marked Page 10 needle size vs subject size does not match guide Page 13 Visit 2 not completed and dispostion area

KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1005	11281040	dd	Diary log not completed-till 11Aug2020 ConMed page, dates incomplete match EDC?? Page 6 incomplete dates Page 10 needle size vs subject size does not match guide Page 13 Visit 2 not completed
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1110	11281043	ts	Diary log not completed-till 11Aug2020 Page 8 'other' marked Page 13 Visit 2 not completed and dispostion area
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1105	11281044	ab	Diary log not completed-till 11Aug2020 ConMed page, incompleted match EDC?? Page 6 queries needs answering per Jerred Page 13 Visit 2 not completed
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1238	11281046	ts	Diary log not completed-till 11Aug2020 Page 13 Visit 2 not completed
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1230	11281047	dd	Diary log not completed-till 11Aug2020 Progress Note needs PI I&D ConMed page, match EDC?? Page 6 incomplete dates Page 10 needle size vs subject size does not match guide Page 13 Visit 2 not completed and dispostion area

KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1440	11281050	ts	Diary log not completed-till 11Aug2020 Progress Note needs PI I&D ConMed page, incomplete dates match EDC?? AE page 1st dose missing Page 6 incomplete dates Page 10 needle size vs subject size does not match guide Page 11-device installed on ?? Page 13 Visit 2 not completed and dispostion area
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1550	11281052	ts	Diary log not completed-till 11Aug2020 Page 3 not marked E-#22 Page 13 Visit 2 not completed
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1551	11281054	ab	Diary log not completed-till 11Aug2020 ConMed page, incompleted match EDC?? Page 6 iincomplete dates Page 10 needle size vs wt Page 13 Visit 2 not completed
KD	8/14/2020	1	8/5/2020	V3/31July2020 signed at 1231	11281055	ts	Diary log not completed-till 12Aug2020 ConMed page, ADHD spell out match EDC?? Page 1 missing date of signature of ICF for CRC Page 6 ADHD spell out Page 13 Visit 2 not completed

KD	8/14/2020	1	8/6/2020	V3/31July2020 signed at 1335	11281056	ab	Diary log not completed-till 12Aug2020 ConMed page, incompleted match EDC?? Page 6 incomplete dates Page 13 Visit 2 not completed
			8/3/2020				
KD	8/11/2020		8/7/2020	V3/31July2020 signed at 1100	11281065		SF
KD	8/11/2020		8/7/2020	V3/31July2020 signed at 1209	11281068	ts	Diary log not completed-where is the print out from eDiary Page 10 missing needle size marked Page 13 Visit 2 not completed
KD	8/11/2020		8/7/2020	V3/31Jul2020 signed at 0930	11281062	ts	Diary log not completed-where is the print out from eDiary Page 13 Visit 2 not completed
KD	8/11/2020		8/7/2020	V3/31Jul2020 signed at 1425	11281072	ts	Diary log not completed-where is the print out from eDiary Page 10 Needle size was not the right size based of WT. Page 13 Visit 2 not completed
KD	8/14/2020		########	V3/31Jul2020 signed	11281109	AS	

Ex. 12

Rebecca Gibson

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 4:03 PM
To: Mercedes Livingston; Kandy Downs; Olivia Ray; Brook Jackson
Cc: Marnie Fisher
Subject: Re: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

How are we making sure all of these SAEs are being entered in CC? We are reimbursed $500 per SAE. But if they aren't entered...then we are doing volunteer work

The SOMs need to be double-checking this...but just want to make sure there is a process in place for that to happen.

Kristi Raney
Managing Member, Executive Director

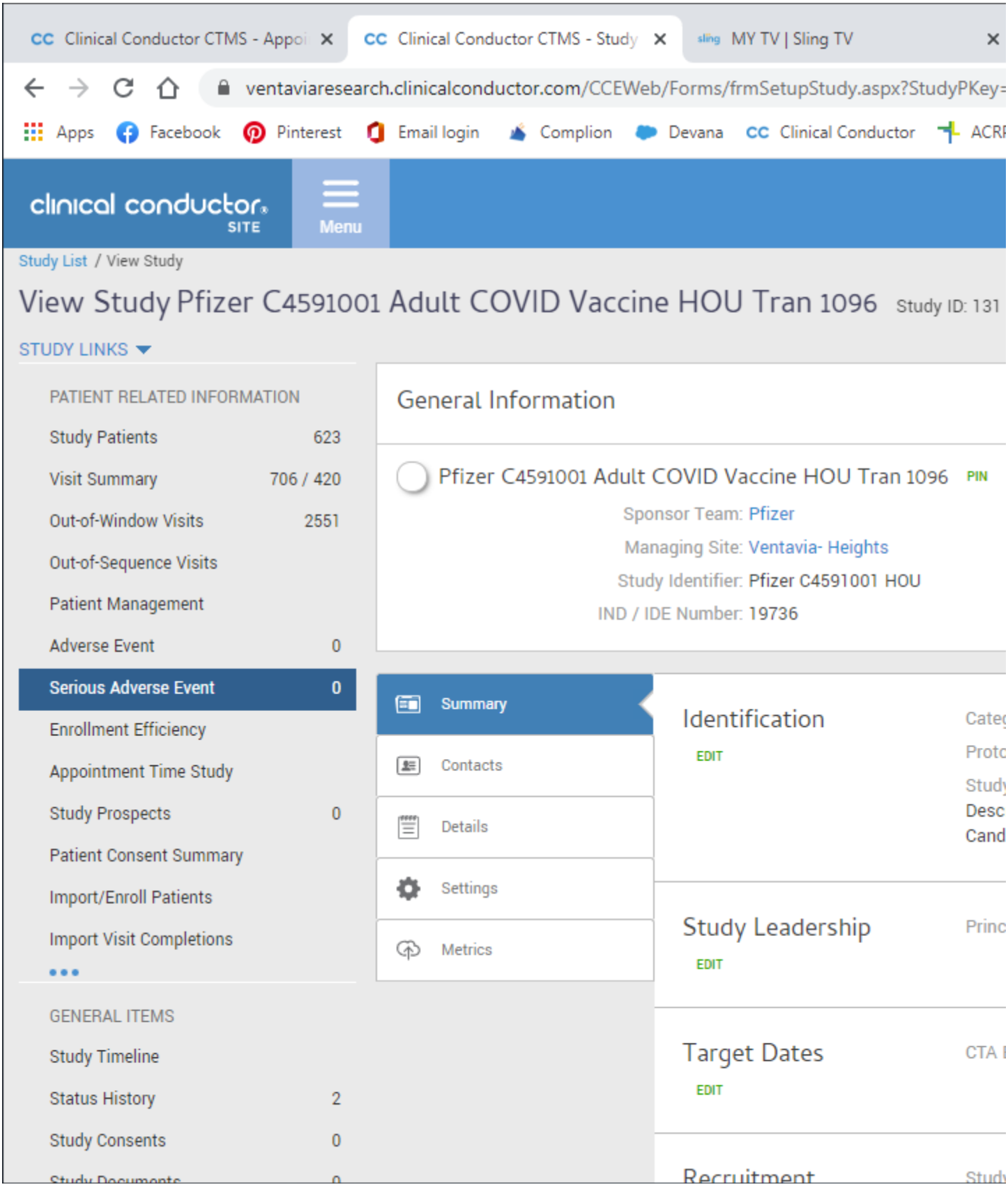
Ventavia Research Group
1307 8th Avenue, Suite 202
Fort Worth, TX 76104
817-348-0228 Office
817-394-1901 eFax
214-208-0390 Cell

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 9, 2020 12:16 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

Thank you, Kandy.

I just checked CC to see if they SAE had been entered on the study level page for Finance to invoice for it, and it is not in CC. Please make sure HOU gets this updated as per the Operations Manual.



Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell: 817.845.3824
Office: 817.348.0228
eFax: 817.394.1901
mercedeslivingston@ventaviaresearch.com

www.ventaviaresearch.com

SILVER
CLINICAL RESEARCH CO-ORDINATOR

PLATINUM
RESEARCH NETWORK
www.platinum-research.net

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 10:44 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: FW: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

To have you all aware, since this is an extensive study. Unblinding has not occurred, not a safety concern, but the subject not able to receive 2nd dose.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104

Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Lizatte Martinez <lizattemartinez@ventaviaresearch.com>
Sent: Saturday, September 5, 2020 12:09 AM
To: Kristen.Buonocore@iconplc.com
Cc: John.Hersker@iconplc.com; 'Alfaro, Arturo A.' <Arturo.Alfaro@pfizer.com>; Houston CRC <houcrc@ventaviaresearch.com>; Murray, Reginald <Reginald.Murray@iconplc.com>
Subject: FW: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

Hi Kristen,

I received an OOO for both John and Reginald.

Just forwarding it along.

Lizatte Martinez, CCRC
Team Lead, Certified Clinical Research Coordinator

Ventavia Research Group
1919 N Loop W, Suite #250
Houston, TX 77008
Phone Number: 832-831-5349
Fax Number: 346-335-1186
Email: lizattemartinez@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Lizatte Martinez <lizattemartinez@ventaviaresearch.com>
Sent: Saturday, September 5, 2020 12:05 AM
To: John.Hersker@iconplc.com
Cc: Houston CRC <houcrc@ventaviaresearch.com>
Subject: FW: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

Hi John,

I got an OOO report from Reginald so thought I would forward to you.

Thanks,

Lizatte Martinez, CCRC
Team Lead, Certified Clinical Research Coordinator

Ventavia Research Group
1919 N Loop W, Suite #250
Houston, TX 77008
Phone Number: 832-831-5349
Fax Number: 346-335-1186
Email: lizattemartinez@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Lizatte Martinez <lizattemartinez@ventaviaresearch.com>
Sent: Saturday, September 5, 2020 12:02 AM
To: Murray, Reginald <Reginald.Murray@iconplc.com>
Cc: 'Alfaro, Arturo A.' <Arturo.Alfaro@pfizer.com>; May, Nancy <Nancy.May@iconplc.com>; Houston CRC <houcrc@ventaviaresearch.com>; Van Tran <vantran@ventaviaresearch.com>
Subject: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

All,

Please note that at visit 2-subject 10961031 was noted to have a positive pregnancy test result PRIOR to vaccination.

Site became aware at 15:58 CST on 04 SEP 2020.
SAE Report and EDP form was completed and Faxed to sponsor on 04 SEP 2020 at 23:52 CST.
EDC was updated at 23:40 CST on 04 SEP 2020.

To confirm-subject did not receive vaccination 2 AND had a negative urine pregnancy test result on 14 AUG 2020 PRIOR to receiving vaccination 1.

Subject has agreed to stay on trial for follow up and is aware she will no longer receive treatment.

*****Of note, there is NO EDP template or FAX Cover sheet templates in Firecrest or in previous correspondence to site. These were requested from Nancy today however, I did NOT delay reporting because of this. I used a Pfizer EDP template from another study to submit and a Ventavia Fax coversheet Template.**

Lastly, I am attaching all the documents that were faxed today for your convenience.

Thanks again,

Lizatte Martinez, CCRC
Team Lead, Certified Clinical Research Coordinator

Ventavia Research Group
1919 N Loop W, Suite #250
Houston, TX 77008
Phone Number: 832-831-5349
Fax Number: 346-335-1186
Email: lizattemartinez@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

Ex. 13

Rebecca Gibson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 10:19 AM
To: Brook Jackson; Jen Vasilio
Cc: Katie Buchanan
Subject: RE: Performance forms- FYI

Hi ladies,

Did the write-ups get done with Nadia and Jailyn? Copying Katie so she's in the loop as well.

Thanks,
Marnie

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, September 18, 2020 2:42 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Subject: RE: Performance forms- FYI

For the Jailyn and Nadia report-

Back in Aug- during a routine stop in FW- Kandy observed COVID IP boxes left out on the counter, full exposed to anyone that entered the room could see.
The current SOM was notified, then both unblinded CRC's were notified of finding. Kandy then reviewed the process of having IP boxes broken down and reminded that the IP boxes which has patient information have to be securely placed up as patient's are dosed.

The boxes were then broken down, and placed in secured black tote for storage. Both CRC's vebally understood the blinding process. No training was documented, or other communication was given.
RD Kandy Downs

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Friday, September 18, 2020 2:33 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Subject: Performance forms- FYI

I wanted to make sure you all had these forms.

Regards,
Marnie

Marnie Fisher
Director of Operations, MBA, BSN, RN

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817.269.3768
eFax Number: 817.394.1901
Email: mfisher@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

Ex. 14

Note to File

Principal Investigator: XXXXX, XX **Protocol:** C4591001

Site Number: XXX **Date:** September 17, 2020

Regarding: IMPALA Randomization and drug assignment confirmation printouts in research charts

This Note to File serves as notification that confirmation printouts of research participant drug assignments will not be placed within participant charts for study C4591001. Inclusion of the drug assignment confirmation will disclose drug dosage information contraindicated for study blinding. It is for this purpose that the confirmation of drug assignment is located in Complion within the unblinded binder. This note to file addresses IMPALA drug assignment confirmation requested in study source document versions 1 through 5.

An update the source document removing this requirement has been created in follow-up to this Note to File.

1307 8th Avenue
Suite 202
Fort Worth, TX 76104

_____ _____

Signature: Director QA/QC, Regulatory, Training Date

_____ _____

Signature: Investigator Date

Ex. 15

Rebecca Gibson

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, September 18, 2020 2:00 PM
To: William Jones; Marnie Fisher
Cc: Brook Jackson
Subject: FW: Pfizer_C4591001_COVID-19

Importance: High

It was confirmed with Arturo that the Randomization form is not to be filed with the blinded source. This has time points that would allow for unblinding potential.
Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Sent: Friday, September 18, 2020 1:35 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Pfizer_C4591001_COVID-19

Confirmed.

Arturo A. Alfaro, M.D.
Site Relationship Partner II
Global Site & Study Operations
Clinical Development & Operations, GPD
Location: North America, United States, C.S.T.
Office / Cell: 512-638-2188

Fax: 845-474-5793
arturo.alfaro@pfizer.com

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, September 18, 2020 1:31 PM
To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: [EXTERNAL] Pfizer_C4591001_COVID-19

Hello Arturo;

Thank you for talking with.
Can you confirm that the Randomization from IMPAL is NOT to be given to BLINDED.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Sent: Monday, September 14, 2020 9:42 AM
To: Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kathryn Weems <kathrynweems@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher

<mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Subject: RE: Pfizer_C4591001_COVID-19_Amend 6 Question

Hi Rebeca;

Once amendment # 6 is approved, patients with known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be included.

Arturo A. Alfaro, M.D.
Site Relationship Partner II
Global Site & Study Operations
Clinical Development & Operations, GPD
Location: North America, United States, C.S.T.
Office / Cell: 512-638-2188
Fax: 845-474-5793
arturo.alfaro@pfizer.com

From: Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:20 AM
To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kathryn Weems <kathrynweems@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Subject: [EXTERNAL] Pfizer_C4591001_COVID-19_Amend 6 Question

Good Morning Arturo,

I am working on updating source documents for the 3 Ventavia sites so when Amendment 6 is approved we will be ready. As I was reading through the changes for the inclusion exclusion criteria, I am needing some clarification.

In Amendment 6, Inclusion 3 states "Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.
Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. Specific criteria for Phase 3 participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be found in Section 10.8."

Exclusion 2 states "**Phases 1 and 2 only:** Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)."

However, per protocol phase 2 and 3 are still combined (Phase 2/3). Those 2 criteria seem to contradict each other. Can you please provide some clarification if patients with HBV/HCV/HIV are excluded from the study for phase 2/3? Thank you!

Best Regards,

Becca

Rebecca Iacullo, B.S., CCRC

Ventavia Research Group
1307 8th Ave. Suite 202
Fort Worth, Texas 76104
Cell: 210-861-6912
rebeccaiacullo@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

Ex. 16

Brook Jackson

From: Cordy Henslin <cordyhenslin@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 8:25 AM
To: Brook Jackson
Subject: Fw: UNBLINDING - C4591001 | 1085/Fuller Follow-up

Sincerely,

Cordelia "Cordy" Henslin
CRC, Recruitment Specialist, MA

Ventavia Research Group
300 N Rufe Snow DR
Keller, TX 76248
Phone Number: (682-774-8013
Fax Number: (817)337-3224
Email: cordeliataylor@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

Notice:

From: Collins, Jayton <Jayton.Collins@iconplc.com>
Sent: Friday, August 14, 2020 15:32
To: Cordelia Taylor <cordeliataylor@ventaviaresearch.com>
Cc: jinamartinez@nhfm.net <jinamartinez@nhfm.net>
Subject: UNBLINDING - C4591001 | 1085/Fuller Follow-up

Hi Cordy,

As previously mentioned on our phone call today, here is a summary/list of items to review:

- Shipment Receipt Invoices need added to Complion for review.
- Jina needs to complete Protocol Amendment 4 & 5 trainings in Firecrest. You need to complete Protocol Amendment 5.
- Both need to complete the V5 training: IP Preparation, Reconstitution, and Administration.
- CVs for you and Jina need filed. GCP & Impala training certificate needs filed.
- **URGENT: Jina needs to Read & Acknowledge the IP documents flagged for her in Firecrest. This needs to be done ASAP.**
- **URGENT: Temperature logs/records need uploaded to Complion.**
- Blinding Plan & Secrecy Agreement need loaded to Complion.
- Reminder: Kit Verification App can be used on b2 and placebo IPAL and first Drug Assignment report from Impala (subsequent doses need the second verification signature). When used, please indicate usage by writing, "KV#2."
- Various preparation records are missing from Complion, but specifically for the following subjects: 10851012, 10851016, 10851028, 10851032, 10851035, 10851036, 10851061, 10851073, and 10851082.
- Placebo IPAL is good—I didn't note any issues. Disposition section needs completed upon destroying the vial. **Reminder: save the carton. You may break this down and flatten it, but ensure the label is not harmed & is still legible. This goes for all IP containers.**
- Preparation Record for 10851001, 10851005, 10851007, and 10851008 indicates a volume of 1.7mL Sodium Chloride was withdrawn instead of 1.2mL. You indicated this was likely a transcription error due to the final volume needing to be 1.7mL. Please correct this preparation record and replace the one in Complion with the updated copy.
- Yellow b2 IPAL:
    - No disposition is documented. Please ensure this is performed (with double verification) and document.
    - The Dispensed column is completed incorrectly. Those that were dispensed b2 from a vial already dispensed need to have it indicated as "N/A" instead of "D-1."
    - Subject 10851029 is not documented on the IPAL (Container 046173).
    - Below is a screenshot of an example b2 IPAL. Note the Dispensed Column and the Disposition columns:

Protocol Title: A PHASE 1/2/3 PLACEBO-CONTROLL
DOSE-FINDING STUDY TO EVALUATE THE SAFET
AND EFFICACY OF SARS-COV-2- RNA VACCINE C
HEALTHY ADULTS

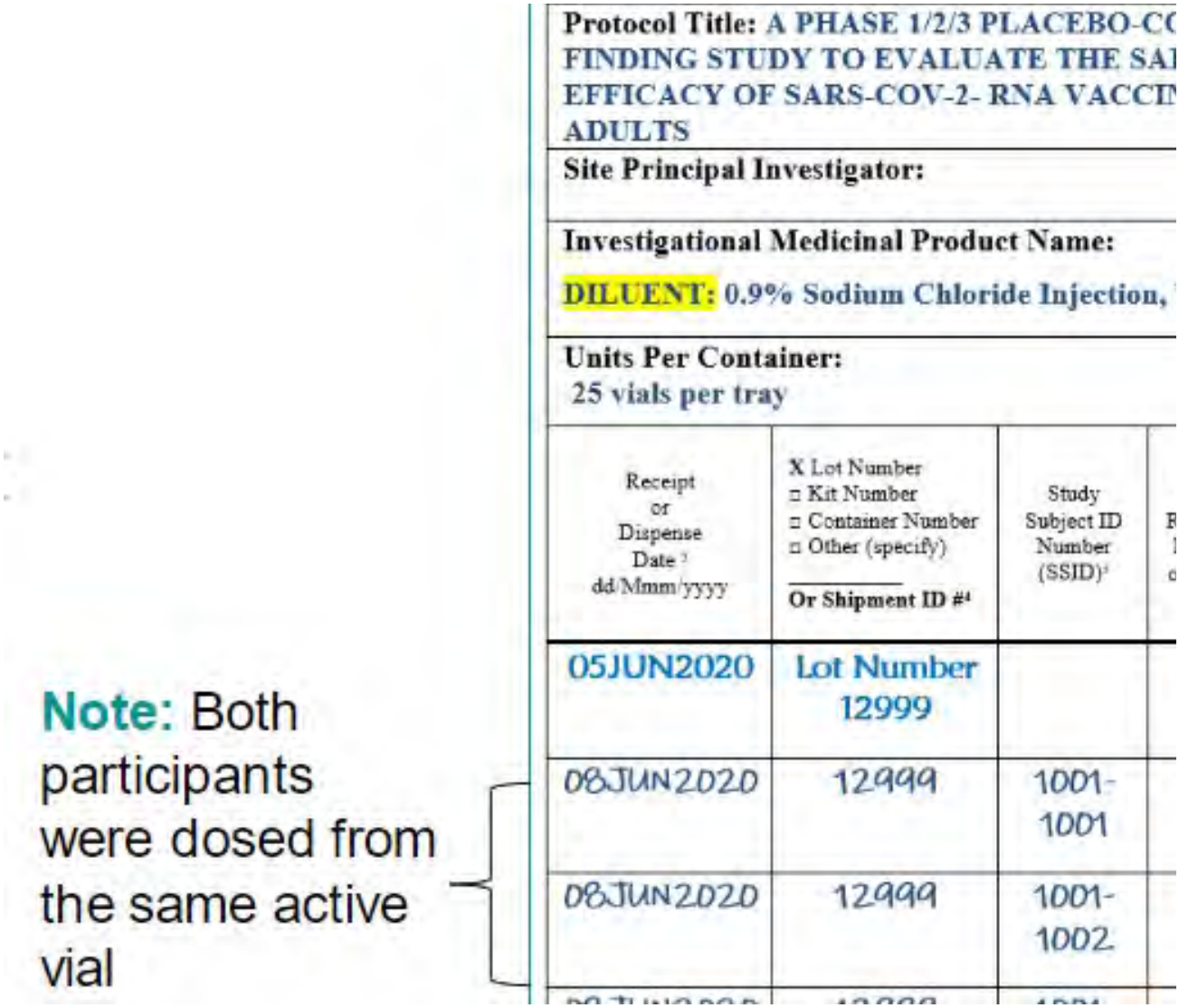
Site Principal Investigator:

Investigational Medicinal Product Name: BNT162b2 Vaccine (YELLOW LABEL)	Str 250

Units Per Container:
1 vial per carton

Receipt or Dispense Date [1] dd/Mmm/yyyy	□ Lot Number □ Kit Number X Container Number □ Other (specify) _____ Or Shipment ID #[4]	Study Subject ID Number (SSID)[5]	Quantity of Containers Received (R) or Dispensed (D) or Undispensed (U)[6]
05JUN2020	Shipment ID 1234567		R+8
08JUN2020	8856796	1001-1001	D-1
08JUN2020	8856796	1001-1002	N/A

- Diluent IPAL is done incorrectly. It needs to mimic the b2 IPAL—each subject dosed from a vial that used diluent needs documented. Here is a screenshot of an example of a completed diluent log:



Please let me know if you have any other questions/concerns. All of these will be documented in the follow-up letter that will be sent out early next week as well.

Thanks!!

Jayton Collins
Clinical Research Associate I
Clinical Research Service

Mobile: +1 469-785-0977
Jayton.Collins@iconplc.com
www.ICONplc.com

ICON

ICON plc made the following annotations.

Thank You,

ICON plc
South County Business Park
Leopardstown
Dublin 18
Ireland
Registered number: 145835

Ex. 17

Rebecca Gibson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, September 21, 2020 5:13 PM
To: Mercedes Livingston; Kandy Downs; Brook Jackson; William Jones
Subject: Common findings/Action Plan- all sites

This is really rough- I had so many distractions trying to type this up, but hopefully, it's a helpful start:

Finding of Concern:	Details of Findings:	Solution (QUICK FIX):	Comments:
HIPAA Violations	Sites not consistent with protecting PHI- PHI left on desks (FW front desk example); patient schedule with patient names left on counter faced up; patient folders out on counters in the clinic and faced up with names visible; emails with patient names in the subject line.	1. RDs to observe and correct at sites when onsite- discuss/re-educated with employees at the site as concerns are found. 2. "Audit Readiness" training- I think we still need this for sites quickly, and we HIPAA can be included.	Where are we with HIPS training?
Outdated Protocol Pages in Patient Folders	Sites are not keeping the Schedule of Events pages in the patient folders current and some copies are so poorly printed that they are completely illegible, defeating the purpose of them being placed in the chart.	1. Pull all protocol pages out of all charts. 2. Reassess the process for future studies.	
AEs Not Reported	AEs from diary entries are not being reported correctly or at all- 1. Protocol is unclear; 2. Conflicting information received from Pfizer	1. We need to get an official direction from Pfizer. Email from ICON received but the email was not clear as well and not an official "Clarification" or "Addendum" or even a "Memo". 2. For now, we should follow the protocol as to how we read it and record any AEs ASAP- may need to split the patients up for staff to verify. 3. Anyone doing QC should be looking for potential AEs not caught during study visits and flag them for correction.	Email from ICON dated 8/17/20. FUTURE: revise AE log

		4. Once we have clarification- train all staff.	
Injection Wait Time Discrepancy (<30 mins)	Injection wait times have been found to be less than 30 mins without any explanation.	1. Site staff needs to correct ASAP- add a note to explain why the time was less than 30 mins and submit deviations accordingly. 2. We need an NTF to explain that we caught the errors and implemented an action to prevent this moving forward, for example, FW implemented the use of timers.	Long term- need to conduct re-training on why this is so critical
IP Storage	IP rooms are disorganized, drug/placebo and saline are not being kept locked- no double lock in place at Keller or FW? Not sure about Houston. Keller had kit #s that were transcribed incorrectly and a CAPA was written.	1. RDs and staff at site to get these rooms cleaned up and organized; drug locked up and keys place in a separate place than the IP room and secured- need to have documentation of this process as well- who has keys, etc. 2. Keller- quick fix for a double lock is to place all loose drug currently in the refrigerator in locked boxes as well- the freezer is already a double-lock system.	Long term- get locks placed on doors to IP room.
Informed Consent Errors	1. Consent being done during the protocol-required "5 mins of wait time". 2. Paper consents used were not being scanned into eConsent. 3. Several of the paper consents that were used, as opposed to electronic, were printed with a large number of artifacts on the copies and appeared to have wording present that truly wasn't present. 4. Some consents were printed or copied with the footers missing. 5. Consent process page- inconsistently being filed with visit and sometimes with consent.	1. NEED CLARIFICATION IF THIS IS OKAY OR NOT (#1). If not, we need staff to explain the atmosphere and patient status during the consent process and complete deviations if warranted. 2. Need to scan in all paper consents to eConsent ASAP, if not done already. 3. Correct consent issues and note changes being made in progress notes where needed. NTF for	Long term- re-training as stated above, on documentation practices. Change process for process page of consent- consider adding this as page 1 of ALL consents, versus the visit source.

	6. Amendment #6- I'm told some patients are not being re-consented, but it sounds like it's required?	errors and corrective action?? 4. Confirm if re-consent is needed for Amend #6. 5. Document re-training	
Progress Notes	1. Inconsistencies in its use and doesn't always match what's being documented in the source. 2. Progress Note form requires a "time" in the header but time is not being recorded.	1. Flag corrections needed to notes 2. Remove "time" and state "N/A"?	Future- suggest creating a progress note page specific to each visit, as opposed to one running log.
Source Errors	1. Contraception Check: "NA" checked for menopausal/hysterectomy patients but the signature at the bottom of this section is also signed, which states a "subject agrees to maintain birth control, etc."	1. V2 Source: For patients who are confirmed to be post-menopausal or have had a hysterectomy- cross through signature and write "error- the patient is confirmed to be post-menopausal, etc.. or "error- the patient has had a hysterectomy". 2. V1 Source: same section but also has investigator signature- handle in the same manner.	Long Term- re-create source templates
Other Findings	2. Sticky notes on top of the patient charts not being consistently completed. 3. Deviations- not sure they are getting completed or not- need to verify all items above mentioned. 4. Visit 2s- some are out of window due to staff following CC which hadn't been updated until 9/18/20.	3. Charts are being flagged to complete sticky notes- reeducating staff as well to always complete this. 4. CC has been updated, need to verify upcoming V2s are in window- if many deviations, may need to do a NTF to explain why they were out of window?	Overall training needed- Research 101 training, in particular documentation practices.

Marnie Fisher
Director of Operations, MBA, BSN, RN

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817.269.3768
eFax Number: 817.394.1901
Email: mfisher@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

Ex. 18

Common QA Findings – Pfizer C4591001

Subject Number: _____

****PLEASE FILE ALL NTFS IN THE PATIENT'S CHART ON THE RIGHT SIDE OF CHART BEHIND PROGRESS NOTES****

ICF	Reviewed	Finding
Current version of ICF is used	☐	☐
Signatures are consistent with no obvious mismatch	☐	☐
Correct dates used by the patients	☐	☐
Printer copies are clear (not sloppy, cutting off footers, etc)	☐	☐
Consistency in where the ICF documentation process form is kept	☐	☐
Screening ICF document is embedded in the screening source	☐	☐
Re-consent ICF documentation is on top of the revised ICF	☐	☐
ICF documentation form comment section documents any questions and answers	☐	☐
Updated ICF documentation page has blanks for the CRC initials instead of checkboxes	☐	☐
ICF was checked for Quality Assurance by the consenter	☐	☐
Proper ICF QC process	☐	☐
Verify that any paper consent used have been scanned into eConsent	☐	☐
Progress Noting	**Reviewed**	**Finding**
Anything out of the ordinary is explained in the progress note	☐	☐
Initials are consistent with the subject information sheet, or progress noted	☐	☐
Typically acute AEs or CMs are explained if ongoing from visit to visit	☐	☐
Schedule of Events	**Reviewed**	**Finding**
Remove from charts all together (do not replace with new ones)	☐	☐
Verify Visits 2 and beyond dates are within window (Print the Firecrest Visit Scheduler and **place copy on left side of chart on top of Patient Information Sheet)**	☐	☐
Randomization Confirmations	**Reviewed**	**Finding**
Randomization confirmations needs to come out of the charts and line through file instructions in source and state "see NTF". **File NTF** in each chart	☐	☐
Drug assignments need to come out (if they were in there) and line through file instructions in source and state "see NTF". **File NTF** in each chart	☐	☐
Write Overs	**Reviewed**	**Finding**
CRC correctly making changes (line through, initial, date)	☐	☐
Patients making changes correctly on Consents (line through, initial, date)	☐	☐
Source Version	**Reviewed**	**Finding**
Using correct, most current version of source (verify version date)	☐	☐

Common QA Findings – Pfizer C4591001

Subject Number: _____

KELLER- Add NTF to each chart for using wrong source versions		
Risk Factors	**Reviewed**	**Finding**
Consistent with demographics	☐	☐
Those that need to go in MedHx are listed there	☐	☐

Visits Procedures	**Reviewed**	**Finding**
Conducted in a stepwise manner, per protocol	☐	☐
Source Completion	**Reviewed**	**Finding**
No blanks in charts	☐	☐
CM Logs	**Reviewed**	**Finding**
Indication matches medical history	☐	☐
MedHx start dates and CM start dates line up (example; med shouldn't start prior to condition)	☐	☐
Contraception in WOCBP	**Reviewed**	**Finding**
Added to con meds and/or med history	☐	☐
Tubal ligation- documenting bilateral, etc	☐	☐
Source Document of WOCBP	**Reviewed**	**Finding**
Signature statement only signed if the subject's methods of contraception could change while in the study (**ADD NTF** to each chart that will address discrepancy of signature statement)- **DO NOT CROSS OUT SIGNATURES NOW**	☐	☐
Medical History	**Reviewed**	**Finding**
Prior source versions had "Yes/No" boxes for each body system- verify that "yes" was checked for ALL systems. (**Have CRC correct this and write a note confirming that all systems were assessed at the visit, however, the question was misread initially and only the body system that the patient has a medical history in, was checked).** **VERSION #5** is most current- should check "yes" that all body systems have been asked about.	☐	☐
Procedures listed in MedHx along with indication for procedure	☐	☐
Devices	**Reviewed**	**Finding**
Device and/or app changes and issues documented clearly (e.g., Subject requested a device at screening visit. At next visit, requested to use the app. No documentation on the progress note.)	☐	☐
E-diary and AEs	**Reviewed**	**Finding**
Symptoms noted in the e-diary regardless of if they are ongoing after Day 7 are not to be reported as AEs	☐	☐

Common QA Findings – Pfizer C4591001

Subject Number: _____

Patients outside of the reactogenicity subset if they have symptoms after vaccine should be reporting in the illness visit e-diary page and not as AEs	☐	☐
E-diary Printouts	**Reviewed**	**Finding**
E-diaries are printed on Day 8 (after 7 day period) and signed by the PI as soon as possible (within 2-3 days from printing)	☐	☐
Patient ID/initials and Study number are on the e-diary print-out	☐	☐
Weekly eDiary review log completed	☐	☐

Additional findings: ☐ NA

Source	Reviewed	Finding (list below)
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	

Signature/Date of QC person reviewing: _____ _____

Common QA Findings – Pfizer C4591001

Subject Number: _____

Date given to RD: _____ Name of RD:

Ex. 19

Rebecca Gibson

From: Casteel, Crystal <Crystal.Casteel@iconplc.com>
Sent: Monday, September 21, 2020 11:44 AM
To: Marnie Fisher; Kandy Downs; Brook Jackson
Cc: Mercedes Livingston; Rebecca Iacullo; Michelle Vernon; Katherine Benitez; CRC; Plano CRC; Grapevine; Dallas; Arlington; Ramirez, Rebecca; Stella Alawuru (Stella.Alaw@pfizer.com); Furlow, Danielle; Casteel, Crystal; Gilliam, Melissa; Taylor, JoAnn; Diggs, Sylvia
Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revisions: BMI, ICF Process Documentation, Lab Collection

Hi Marnie, Kandy, and Brook,

I wanted to follow-up to see if there **has there been any internal discussions regarding the ICF documentation considerations I mentioned below?**

Additionally, I have one more possible suggestion. I've re-reviewed the Lab Collection section of your source worksheets and I wanted to know if you all **have a separate document that details the collection & processing times that may not been previously provided?**

CRAs must confirm that sites are in compliance with the "Blood Specimen Chain of Custody". Our protocol (section 8.1.4 Immunogenicity Assessment) spells out that each specimen should be drawn and processed as indicated in the Lab manual:

1. Draw blood
2. Allow the blood to clot at room temperature for a minimum of 30 minutes and a maximum of 2 hours.
3. Separate the serum by centrifugation at room temperature at 1,000 to 1,300 g (check the correct RPM is selected) for 10 to 15 minutes.
4. Remove the serum from the Vacutainer® tubes using a sterile transfer pipette to sterile cryovials (up to the 1.8 mL graduation). Transfer serum into 2 **SEND** cryovials (remaining serum will go into cryovials designated as **RETAIN**).
5. Samples must be stored in a manual defrost freezer at -15 °C or colder.

FDA requires that any specimen collected have documentation to prove that the protocol requirements were followed. Without this proof, it's plausible that specimens could be removed/disallowed from our analyses.

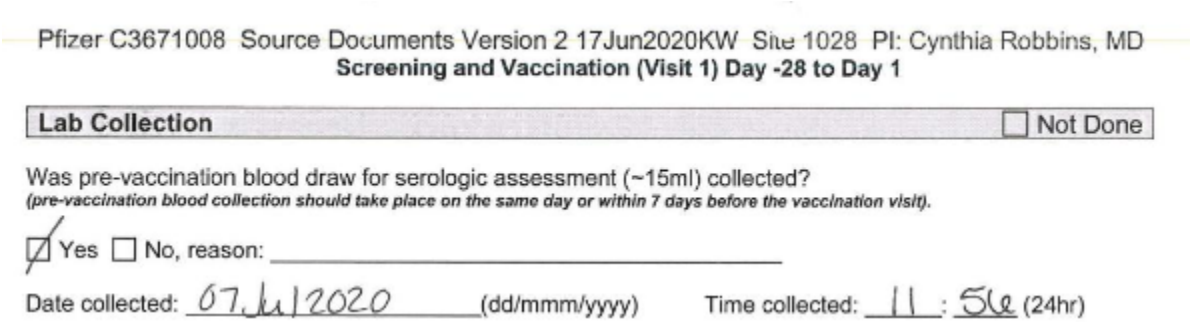
So – each site can document either in a lab log or directly in subject source documents the following details:

- The time a required specimen was drawn (and by whom at the site)
- The length of time the specimen(s) were allowed to sit at room temp (start and stop is ideal, but at least some documentation that site complied with specimen handling from A-Z is necessary).
- The time specimens were spun down (per protocol)
- The time specimens were separated and frozen

OR a comprehensive comment can be recorded confirming that the lab specimens were collected and processed per the protocol and lab manual.

If you all have not previously collected this information, **would you consider updating your lab collection question per the screenshot below to note: Was pre-vaccination blood draw for serologic assessment (~ 15 ml) collected "*and processed according to the protocol/lab manual*?"**

This WAS a finding in one of my current Pfizer studies and sites were required to provide or update *3 years later.* You all can imagine the workload this created……so I would like to avoid this being an issue during this study and ensure this isn't a finding for any of my sites.



Pfizer C3671008 Source Documents Version 2 17Jun2020KW Site 1028 PI: Cynthia Robbins, MD
Screening and Vaccination (Visit 1) Day -28 to Day 1

Lab Collection ☐ Not Done

Was pre-vaccination blood draw for serologic assessment (~15ml) collected?
(pre-vaccination blood collection should take place on the same day or within 7 days before the vaccination visit).

☑ Yes ☐ No, reason: _____

Date collected: 07 Jul 2020 (dd/mmm/yyyy) Time collected: 11 : 56 (24hr)

Kind regards,
Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com

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For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.
Please DO NOT send SAE information via this email address.

From: Casteel, Crystal <Crystal.Casteel@iconplc.com>
Sent: Tuesday, September 1, 2020 1:59 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>; Michelle Vernon (michellevernon@ventaviaresearch.com) <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>
Cc: Fort Worth CRC Ventavia Group Email (crc@ventaviaresearch.com) <crc@ventaviaresearch.com>; Plano CRC Ventavia Group Email (planocrc@ventaviaresearch.com) <planocrc@ventaviaresearch.com>; Grapevine CRC Ventavia Group Email (grapevinecrc@ventaviaresearch.com) <grapevinecrc@ventaviaresearch.com>; Dallas CRC Ventavia Group Email (dallascrc@ventaviaresearch.com) <dallascrc@ventaviaresearch.com>; Arlington CRC Ventavia Group Email (arlingtoncrc@ventaviaresearch.com) <arlingtoncrc@ventaviaresearch.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru (Stella.Alaw@pfizer.com) <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>; Casteel, Crystal <Crystal.Casteel@iconplc.com>
Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revisions: BMI & ICF Process Documentation

Hi Mercedes,

Thank you very much for discussing this internally, considering my input, and confirming that your BMI documentation will remain unchanged.

Has there been any discussion regarding the ICF documentation considerations?

- I wanted this to be an open discussion and provide you all with suggestions as this was never a directive. If this documentation will remain unchanged, are all SCs aware of what dates need to be captured to avoid queries?
    - What will you all capture for the "ICF Date" for all sites – the ICF version date or the ICF revised version date?

Thanks,
Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com

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For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.
Please DO NOT send SAE information via this email address.

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Sunday, August 30, 2020 6:58 PM
To: Casteel, Crystal <Crystal.Casteel@iconplc.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>; Michelle Vernon <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>
Cc: CRC <CRC@ventaviaresearch.com>; Plano CRC <planocrc@ventaviaresearch.com>; Grapevine <grapevinecrc@ventaviaresearch.com>; Dallas <dallascrc@ventaviaresearch.com>; Arlington <arlingtoncrc@ventaviaresearch.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru (Stella.Alaw@pfizer.com) <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>
Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revision for BMI

Crystal

We will continue to put the actual BMI number as we have in the source vs a yes or no checkbox. A yes or no checkbox leaves us open to way more errors if the CRC isn't documenting the actual BMI number.

Thanks,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell: 817.845.3824
Office: 817.348.0228
eFax: 817.394.1901
mercedeslivingston@ventaviaresearch.com

www.ventaviaresearch.com

SILVER
CLINICAL RESEARCH CO-ORDINATOR

PLATINUM
RESEARCH NETWORK
www.platinum-research.net

From: Casteel, Crystal
Sent: Wednesday, August 26, 2020 11:27 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>; Michelle Vernon (michellevernon@ventaviaresearch.com) <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>
Cc: Fort Worth CRC Ventavia Group Email (crc@ventaviaresearch.com) <crc@ventaviaresearch.com>; Plano CRC Ventavia Group Email (planocrc@ventaviaresearch.com) <planocrc@ventaviaresearch.com>; Grapevine CRC Ventavia Group Email (grapevinecrc@ventaviaresearch.com) <grapevinecrc@ventaviaresearch.com>; Dallas CRC Ventavia Group Email (dallascrc@ventaviaresearch.com) <dallascrc@ventaviaresearch.com>; Arlington CRC Ventavia Group Email (arlingtoncrc@ventaviaresearch.com) <arlingtoncrc@ventaviaresearch.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru (Stella.Alaw@pfizer.com) <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>; Casteel, Crystal <Crystal.Casteel@iconplc.com>
Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revisions: BMI & ICF Process Documentation

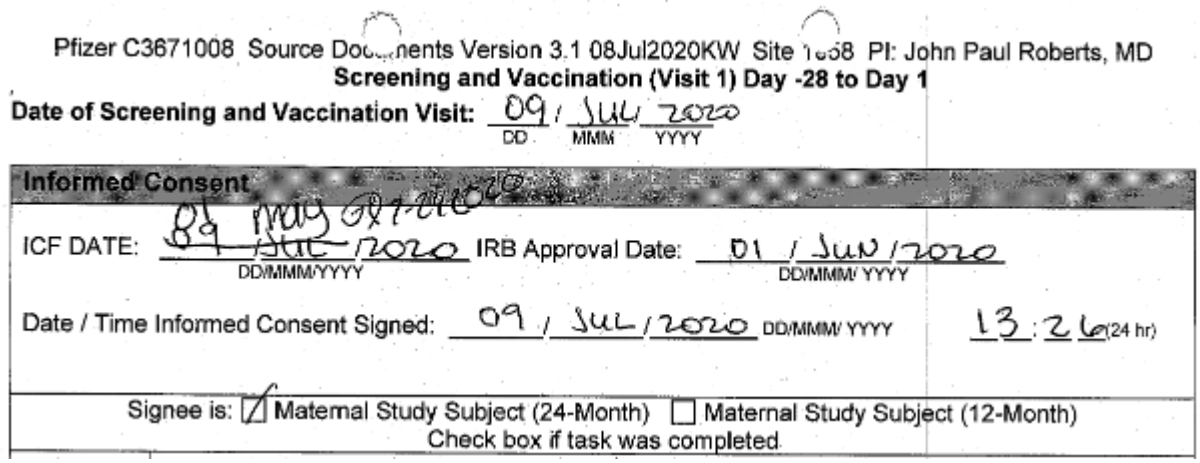
Hello Ventavia Team,

I apologize for sending another email, but wanted to offer another suggestion. I would ask that you consider revising your ICF Process documentation worksheet to capture the ICF "Version" Date and the "ICF Revised Version Date" as this

information is what is provided on the actual ICFs that the SCs have access to vs. IRB approval date, which they need to know off hand, review Advarra CIRB, or check eISF to obtain.

As you can see in the screenshot below, Subject #1058-1006 has the ICF Date error-corrected to the current ICF version date noted per the footer of the ICF (which is correct as 01MAY2020); however, this IRB Approval Date is incorrect as this ICF was IRB-approved on 02JUN2020 and not 01JUN2020, so my co-monitor for Roberts SMV 02 will be issuing a query in EDC to error-correct. I talked to several of my Primary SCs and you all have worked with Advarra before and they do typically have the ICF Revised Version date the same as the IRB App. Date, but I warned to not rely on this solely as it is not always the case, and this is a perfect example.

I am keeping detailed notes of all the approvals at each of your sites and encourage you all to do the same to ensure that most current version is always utilized as applicable for the date the subject consents.



Pfizer C3671008 Source Documents Version 3.1 08Jul2020KW Site 1058 PI: John Paul Roberts, MD

Screening and Vaccination (Visit 1) Day -28 to Day 1

Date of Screening and Vaccination Visit: 09 / JUL / 2020 (DD / MMM / YYYY)

Informed Consent

ICF DATE: 01 MAY 01-MAY-2020 / 2020 (DD/MMM/YYYY) IRB Approval Date: 01 / JUN / 2020 (DD/MMM/ YYYY)

Date / Time Informed Consent Signed: 09 / JUL / 2020 (DD/MMM/ YYYY) 13 : 26 (24 hr)

Signee is: ☑ Maternal Study Subject (24-Month) ☐ Maternal Study Subject (12-Month)

Check box if task was completed

My notes for Dr. Robert's site:

INFORMED CONSENT DOCUMENT (ICD) VERSIONS - Advarra IRB (No version #'s) - PH#173.23

My Versioning	#	Version Date	Revised Version Date	Type (if applicable)	Language	# of pages	Date of IRB Approval / Acknowledgement
V1	1	30-Jan-2020	11-Feb-2020	12 mo. Main	English	32 p	2/11/2020 - 1/31/2021
V1	2	30-Jan-2020	11-Feb-2020	24 mo. Main	English	32 p	2/11/2020 - 1/31/2021
V2	3	30-Jan-2020	21-Feb-2020	12 mo. Main	English	33 p	2/21/2020
V2	4	30-Jan-2020	21-Feb-2020	24 mo. Main	English	33 p	2/21/2020
V3	8	1-May-2020	1-May-2020	24 mo. Main	English	31 p	5/1/2020 (Letter dated 5/13/2020)
V3	6	8-May-2020	8-May-2020	12 mo. Main	English	31 p	5/1/2020 (Letter dated 5/13/2020)
V1	5	13-May-2020	13-May-2020	24 mo. Non-maternal Guardanship	English	26 p	5/1/2020 (Letter dated 5/13/2020)
V1	7	13-May-2020	13-May-2020	12 mo. Non-maternal Guaranship	English	26 p	5/1/2020 (Letter dated 5/13/2020)
V4	9	1-May-2020	1-Jun-2020	24 mo. Main	English	31 p	6/2/2020
V4	10	8-May-2020	1-Jun-2020	12 mo. Main	English	31 p	6/2/2020
V2	11	13-May-2020	1-Jun-2020	12 mo. Non-maternal Guaranship	English	26 p	6/2/2020
V2	12	13-May-2020	1-Jun-2020	24 mo. Non-maternal Guardanship	English	26 p	6/2/2020
V1	13	**1-May-2020**	**1-Jun-2020**	24 mo. Main	**Spanish**	36 p	7/9/2020
V1	14	**8-May-2020**	**1-Jun-2020**	12 mo. Main	**Spanish**	35 p	7/9/2020
V1	15	**13-May-2020**	**1-Jun-2020**	12 mo. Non-maternal Guaranship	**Spanish**	29 p	7/9/2020
V1	16	**13-May-2020**	**1-Jun-2020**	24 mo. Non-maternal Guardanship	**Spanish**	29 p	7/9/2020
V5	17	1-May-2020	17-Jul-2020	24 mo. Main	English	31 pages	7/17/2020
V5	18	8-May-2020	17-Jul-2020	12 mo. Main	English	31 pages	7/17/2020
V3	19	13-May-2020	17-Jul-2020	24 mo. Non-maternal Guardanship	English	26 pages	7/17/2020
V3	20	13-May-2020	17-Jul-2020	12 mo. Non-maternal Guaranship	English	26 pages	7/17/2020

Thanks,

Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com

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Please DO NOT send SAE information via this email address.

From: Casteel, Crystal <Crystal.Casteel@iconplc.com>
Sent: Wednesday, August 26, 2020 10:51 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>; Michelle Vernon (michellevernon@ventaviaresearch.com) <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>
Cc: Fort Worth CRC Ventavia Group Email (crc@ventaviaresearch.com) <crc@ventaviaresearch.com>; Plano CRC Ventavia Group Email (planocrc@ventaviaresearch.com) <planocrc@ventaviaresearch.com>; Grapevine CRC Ventavia Group Email (grapevinecrc@ventaviaresearch.com) <grapevinecrc@ventaviaresearch.com>; Dallas CRC Ventavia Group Email (dallascrc@ventaviaresearch.com) <dallascrc@ventaviaresearch.com>; Arlington CRC Ventavia Group Email (arlingtoncrc@ventaviaresearch.com) <arlingtoncrc@ventaviaresearch.com>; Casteel, Crystal <Crystal.Casteel@iconplc.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru (Stella.Alaw@pfizer.com) <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>
Subject: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revision for BMI
Importance: High

Hello Ventavia Regional Directors, Chief Operating Officers, Site Operations Managers, and Site Managers,

I know that you all have made recent revisions to your source worksheets and I'd like you to consider revising your OB Exam source regarding the BMI. We've previously discussed that you all will update your process by capturing subject's weights at Visit 1 so that the recommended needle size can be confirmed and if the medical records don't capture the subject's height, you all will copy the subject's driver's license and provide this with the source worksheets, or you will confirm & record at Visit 1 (perhaps on the vitals page).

Currently, you all provide and exact calculation of the BMI and with a couple of sites, we've agreed that the moving forward, sites will calculate BMI based on the Adult BMI Calculator from the cdc.gov website: https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html and either record this or print/file this page in the subject's chart.

As the protocol request that you confirm subject's BMI to be < 40 kg/m^2 via pre-pregnancy or at the 1^{st} OB Appt. during the current pregnancy (must be documented via MRs), would you consider making this a Yes/NO checkbox vs. an exact

value and that way, we can avoid additional queries or any potential findings when the calculations don't match. Screenshot below of source example.

Your thoughts?

Pfizer C3671008 Source Documents Version 3.1 08Jul2020KW Site 1058 PI: John Paul Roberts, MD
Screening and Vaccination (Visit 1) Day -28 to Day 1

Current Pregnancy (Determination of Gestational Age)	☐ Not Done
Last Menstrual Period (LMP) known? ☑ Yes* ☐ No	*If yes, specify start date of LMP: 15 / JAN / 2020 dd/MMM/YYYY
Comment how/why the subject knows this was her LMP (i.e., app, calendar, etc): Medical Records	
What was the subject's BMI prepregnancy? **(If prepregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used)**	25.3 kg/m² **(If BMI is >40 kg/m², subject will be screenfailed)**
Was first-trimester ultrasound performed? ☐ Yes* ☑ No	*If yes, date performed: ___ / ___ / ___ dd/MMM/YYYY

Kind regards,
Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com

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For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.
Please DO NOT send SAE information via this email address.

Thank You,

ICON plc
South County Business Park
Leopardstown
Dublin 18
Ireland
Registered number: 145835

Ex. 20

Rebecca Gibson

From: Jennifer Valo <jvalo@ventaviaresearch.com>
Sent: Thursday, September 24, 2020 4:08 PM
To: Jen Vasilio
Cc: Marnie Fisher; William Jones; Dana Duvak; Brook Jackson
Subject: Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Jen,

I just wanted to make sure you are aware of this email and all patients that were not put in Impala directly after the ICF need to have a protocol deviation written up (only on the log, not reported).

These have NOT been flagged for you, since we were waiting on the response, so if you can also let the other girls know.

Thank you ma'am.

Jennifer Valo
NRCMA, Project Manager

Ventavia Research Group
710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Jennifer Valo <jvalo@ventaviaresearch.com>
Sent: Thursday, September 24, 2020 4:04 PM
To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>; Dana Duvak <danaduvak@ventaviaresearch.com>

Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>
Subject: Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Thank you sir.

Jennifer Valo
NRCMA, Project Manager

Ventavia Research Group
710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Sent: Thursday, September 24, 2020 3:27 PM
To: Jennifer Valo <jvalo@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>
Subject: RE: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Yes, it is a deviation.

Arturo A. Alfaro, M.D.
Site Relationship Partner II
Global Site & Study Operations
Clinical Development & Operations, GPD
Location: North America, United States, C.S.T.
Office / Cell: 512-638-2188
Fax: 845-474-5793
arturo.alfaro@pfizer.com

From: Jennifer Valo <jvalo@ventaviaresearch.com>
Sent: Thursday, September 24, 2020 3:01 PM
To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>; Dana Duvak <danaduvak@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>
Subject: [EXTERNAL] Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Ok we agree with that! The only thing that was done out of any type of order was the subject being put in Impala to get the screening number. It was not done directly after the consent process. It was done before randomization obviously but that is the only thing that was done out of order.

So just to verify, this would or would not be a deviation?

Jennifer Valo
NRCMA, Project Manager

Ventavia Research Group
710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Sent: Thursday, September 24, 2020 1:35 PM

To: Jennifer Valo <jvalo@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>
Subject: RE: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Hello;

I actually got some clarification from the clinicians. It is not necessarily a protocol deviation. However, there are some procedures that need to be completed before randomization, like blood draw, physical exam. There is going to be a study communication clarifying this item shortly.

Let me know if you have any questions.

Arturo A. Alfaro, M.D.
Site Relationship Partner II
Global Site & Study Operations
Clinical Development & Operations, GPD
Location: North America, United States, C.S.T.
Office / Cell: 512-638-2188
Fax: 845-474-5793
arturo.alfaro@pfizer.com

From: Alfaro, Arturo A.
Sent: Tuesday, September 22, 2020 9:32 AM
To: Jennifer Valo <jvalo@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>
Subject: RE: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Hi Jennifer;

Sorry for my late response. Yes, it should be considered a deviation.

Arturo A. Alfaro, M.D.
Site Relationship Partner II
Global Site & Study Operations
Clinical Development & Operations, GPD
Location: North America, United States, C.S.T.
Office / Cell: 512-638-2188
Fax: 845-474-5793
arturo.alfaro@pfizer.com

From: Jennifer Valo <jvalo@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 8:23 AM

To: Dana Duvak <danaduvak@ventaviaresearch.com>; Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Subject: [EXTERNAL] Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Good morning Arturo,

I wanted to follow up with you on this email that Dana sent you yesterday to see if you had an answer on how we should proceed with this?

Jennifer Valo
NRCMA, Project Manager

Ventavia Research Group
710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Dana Duvak <danaduvak@ventaviaresearch.com>
Sent: Monday, September 21, 2020 11:10 AM
To: Arturo.Alfaro@pfizer.com <Arturo.Alfaro@pfizer.com>
Cc: Jennifer Valo <jvalo@ventaviaresearch.com>
Subject: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Good afternoon, Dr. Alfaro

I am hoping you can provide me with some clarification regarding the protocol visit procedures.

The protocol states that the visit procedures are anticipated to be completed in a stepwise manner. However, if a procedure was not performed in a stepwise manner, should it be recorded as a protocol deviation? For example, the IWRS screening ID was not assigned until after the vital signs.

Thank you for your help!

Dana Duvak, CCRC
Project Manager

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Office Number: 817-348-0228
Cell Number: 817-694-6998
Fax Number: 817-394-1901
Email: danaduvak@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*