

Line #	IRB #	Protocol Number / "NickName"	Short Title / Indication	Sponsor	Phase	PI	SC	Status Update	Status	Screened	Accrued	Active	Notes	Regulatory and Budget Updates	CDA	IRB	Contract	Budget
1	1401174267 KC	<b>CFFC-OB-11 "CFFC"</b>	Observational Study for Fibrosing Colonopathy in CF Tx'd with CREON	AbbVie, Aptalis, Janssen, Digestive Care,	IV	Moffett, Kathryn	TC	05/06/19	Open to Accrual	529	0	0		4/23/18 - IRB Amendment 2 approved and added to OnCore - Expires 11/1/18		CR Approved 10-14-18		
2	1311128300 KC	<b>GOAL-OB-11 "GOAL"</b>	Observational Study - Additional Genotypes & Long Term FU	CFF Therapeutics, Inc	IV	Moffett, Kathryn	TC	04/22/19	Closed to Accrual	Unk	10	2	2 enrolled in the ext. study	7/9/18 - IRB renewal submitted by T. Carrington		CR2018 approved 7/23/2018		
3	1608249974 KC	<b>STOP2-IP-15 "STOP-2"</b>	Standardized Tx. of CF Pulmonary Exacerbations treated with IV antibiotics (Inpatient)	CFF Therapeutics, Inc	IV	Moffett, Kathryn	TC	06/04/19	Open to Accrual	86	7	1	Screening	6/22/18 - IRB renewal submitted by T. Carrington , 6/28/18 - signed off by Dr. Moffett		CR2018 approved 7/11/2018		
4	1712886756 KC PRO00026492 Advarra	<b>CHEC-OB-17 "CHEC-SC"</b>	Characterizing CFTR Modulated Changes in Sweat Chloride & their Association w/Clinical Outcomes	CFF Therapeutics, Inc	Obs	Moffett, Kathryn	TC	06/04/19	Open to Accrual	110	26	1	Screening, 5/3/19 Still waiting updated budget	10/11/2018 - Approved amendment may require re-consenting - Alerted Tammy Clark		10/11/2018 - Amendment and CR2018 approved		
5	1806157005 KC PRO00024882 Advarra	<b>VX17-445-102</b>	VX-445 Combo therapy in CF subjects who have F508del Mutation & a Minimal Function Mutation	Vertex	III	Moffett, Kathryn	TC	04/22/19	Closed to Accrual	7	1	0	8/17/18 - open to accrual, screening closed per 10/12/2018 email	10/8/2018 - Advarra approved modified (protocol v3) Main ICF and Assent - Added to OnCore		Modification Approval 8-14-18		
7	1809281602 KC PRO00024884 Advarra	<b>VX17-445-105</b>	VX-445 Combo therapy in CF subjects who are Homozygous or Heterozygous for the F508del Mutation	Vertex	III	Moffett, Kathryn	TC	04/22/19	Open to Accrual	2	2	2	Only 2 eligible patients, both have rolled over.	9/13/2018 - Site approval by Advarra (protocol v3)		Approved - Advarra and WVU		
8		<b>VX18-659-106</b>	Next Generation Corrector Program for 6-11 yo	Vertex	III	Moffett, Kathryn	TC	03/13/18	Pipeline	N/A	N/A	N/A	3/13/18 submitted feasibility questionnaire					
9		<b>VX18-445-106</b>	Next Generation Corrector Program for 6-11 yo	Vertex	III	Moffett, Kathryn	TC	03/13/18	Pipeline	N/A	N/A	N/A	3/13/18 submitted feasibility questionnaire					
10		<b>VX18-659-104 or VX18-445-104</b>	Nex Gen CFTR corrector in triple combo with tez/iva, compared to tez/iva alone in F508del with a gating or RF genotype	Vertex		Moffett, Kathryn	TC	01/08/19	Pipeline	N/A	N/A	N/A	7/30/18 Submitted feasibility questionnaire, 1/2/19 Site selection not started					
11	IAA# 1201629 P00022531 BCH	<b>STRC-109-16-01 "Telecoaching"</b>	Promote adherence in patients with cystic fibrosis	STRC	IV	Moffett, Kathryn	TC	04/22/19	Closed to Accrual	28	14	14	7/16/18 Closed to accrual	9/26/18 - New protocol - signed by Dr. Moffett 10/11/18 - Del. log signed by Corrine		continuing review 6-28-18		
12	IAA# I2017.21 P00023999 BCH	<b>STRC-106-16-01 "Barriers"</b>	Seeks to identify adherence barriers with CF pts., and create and validate standardized tools	STRC	IV	Moffett, Kathryn	TC	04/22/19	Closed to Accrual	32	10	10	2/09/18 closed to accrual. 3/13/19 DMC doing further data analysis in order to resolve some discrepancies in pharmacy data, IRB is to be kept open.					continuing review 10-26-17
13		<b>STRC -102-17-01 "MAP"</b>	Feasibility of a Mobile Medication Plan Application in CF Patient Care	STRC		Moffett, Kathryn	TC	04/06/18	Pipeline									
14	1708735429 KC PRO00022214 Advarra	<b>SAV005-04</b>	Randomized study of AeroVanc for the tx. of persistant MRSA in CF patients	Savara	III	Moffett, Kathryn	TC	03/13/19	Open to Accrual	84	1	1	Screening continues. Sub. 002 Screening visit occurred 3/5/19- 3/22/19 screen failed.	10/1/2018 - Re-consent required with new consent and consent.		10/1/2018 - New Consent and Assent approved		
15		<b>GLPG3067-CL -202</b>	Modulator study	Galapagos		Moffett, Kathryn	TC	04/17/18	Pipeline	N/A	N/A	N/A	TDN Solicitation of Study Interest					
16		<b>Unknown</b>	Non-porcine lipase product for the tx. of CF patients with pancreatic insufficiency (2 inpt. Stays)	Rho		Moffett, Kathryn	TC	08/22/18	Pipeline	N/A	N/A	N/A	Questionnaire submitted					
17		<b>PTI-801-01</b>	Dual combination 3rd generation CFTR corrector (PTI-801) combined with CFTR potentiator (PTI-808) for homozygous F508del adults, not being tx'd with a CFTR modulator	Proteostasis		Moffett, Kathryn	TC	04/17/19	Pipeline	N/A	N/A	N/A	4/17/19 CDA in progress					
18	1611355248 KC PRO00019604 Advarra	<b>GS-US-320-1092</b>	Randomized Evaluation of Tenofovir Alafenamide (TAF) in Adolescents with Chronic Hepatitis B Virus Infection	Gilead	II	Moffett, Kathryn	MS	11/19/18	Open to Accrual	5	0	0	Study open waiting on younger COHORT to be amended into protocol	10/26/2018 - Amd 4 approved by Advarra	done	Amendment 4 approved 11-16-18	done	done
19	1409447402 KC	<b>GS-US-337-1116</b>	Open-Label tx. w/ Ledipasvir /Sofosbuvir for Chronic HCV- Infection in kids	Gilead	II	Moffett, Kathryn	MS	02/12/19	On Hold	3	3	0	closed to accrual, enrollment goal reached - in follow up phase	10/30/2018 -(10/11/2018-Closeout visit) - Waiting for follow-up letter	done	Protocol Amendment 5-14-18	done	done

Line #	IRB #	Protocol Number / "NickName"	Short Title / Indication	Sponsor	Phase	PI	SC	Status Update	Status	Screened	Accrued	Active	Notes	Regulatory and Budget Updates	CDA	IRB	Contract	Budget
20	1405297848 KC	GS-US-334-1112	Open-Label, Safety & Efficacy of Sofosbuvir + Ribavirin in Children with Genotype 2 or 3 Chronic HCV Infection	Gilead	II	Moffett, Kathryn	MS	02/12/19	Closed to Accrual	3	1	1	2 day site visit	10/29/2018-Received close-out visit follow-up letter, Ready to close?	done	Continuing Review 12-20-17	done	done
21	1509839801 KC Pro00013346 Advarra	GS-US-334-1113	Long Term Follow-Registry for Pediatric pts. With Hep C	Gilead	IV	Moffett, Kathryn	MS	02/12/19	Open to Accrual	3	2	4	Patient visit 11/1/18	10/30/2018 Up-to-date 4/27/18 - 2018CR approved	done	Continuing Review 4-27-18	done	done
22		HIGWEP1560	A Randomized Trial of a Single IV Dose of Cannabidiol (CBD; GWP42003) as Adjunctive Tx. to Whole-Body Hypothermia in Neonats with Mod or Severe Hypoxic Ischemic Encephalopathy	GW Pharmaceuticals	II	Polak, Mark	MS	02/12/19	Pipeline	N/A	N/A	N/A	Danielle Atkinson Sponsor Lead/Study on US FDA hold					
23	1712876265 KC 20120123 Advarra	20120123 / Evolocumab	Randomized study of 24 weeks of Evolocumab for low Density Lipoprotein-cholesterol Reduction in Peds Subjects 10-17 w/Heterozygous Familial Hypercholesterolemia.	AMGEN Inc. TriNetX	IIIb	Pyles, Lee	MS	02/12/19	Open to Accrual	12			Close out visit scheduled 5/16/19	Monitoring schedules and patient list daily 10/2/2018 - submitted CR2018 10/29/2018 - Asked Advarra for update on the status of this CR submission.	done	Continuing Review 11-9-18	done	done
24	1807209526 KC 1188579 WIRB	REMPEX-507	Open Label, Single Dose Infusion of Vabomere in Peds with Serious Bacterial Infections	THEMEDCO	I	Moffett, Kathryn	MS	02/12/19	On Hold				CTA/budget done accounting sign off 10/25/18	CR2019 submitted - Not due until 5/2019	18-Jun	Initial approval 10-29-18	7/17/18 submit	7/17/18submitted
25		PPD	PK Study for AZ CAZ/AVI Follow Up Study from 2015	Roche	III	Moffett, Kathryn	MS	02/12/19	Pipeline				Spoke with Randi Gower at PPD waiting for CDA as they are intially looking at sites now					
26	1807197614 KC	PB-102-F20	Pegunigalsidase Alfa, New Enzyme Replacement Therapy for Fabre Disease.	Protalix TriNetX	III	Narumanchi	MS	02/12/19	Open to Accrual				Awaiting confirmatin of date for SIV from Dr. Narumanchi	KC sign off on budget to Dr. Narumanchi on 11/9/18. Tentative SIV 12/11/18	18-Apr	10/19/2018 - WVU IRB Approved	11/9/2018	11/9/2018
27	1707675059	NEPHCURE	Registry Nephritic Syndrome from (FSGS)	Nationwide Childrens Hospital		Grossman/ Nanda	MS	02/12/19	On Hold						18-Aug			
28		DONUT	Genetics of Development of Uninary Tract			Grossman/ Nanda	MS	02/12/19	On Hold						18-Aug			
30		MK-7655A-021	Safety & Efficacy of IMI/REL vs Comparator in Pediatric Subject with HABP/VABP, CIAI, & CUTI	Merk & Co.	II/III	Moffett, Kathryn	MS	02/12/19	Pipeline					Site Selected	CDA completed 11/2/18	5/17/2019 - Approved by WIRB 6/3/2019 - Submitted to WVU IRB for Ackn.		
31		VIVUS OB-403	Safety & Efficacy of VI-0521 in obese adolescents	Vivus	IV	Murray, Pamela	MS	04/25/19	Site Selected				Site selected 3/12/19.					
32		JNJ-53718678 (RSV 2002)	Safety, Tolerability; Pharmacokinetics of different doses of JNJ-53718678 in children ≥ 28 days & ≤ 3 years w/ acute respiratory tract infection due to RSV	Janssen	II	Moffett, Kathryn	MS	02/12/19	Site Selected				Site selected 12/11/2018.	53718678RSV2002 new study	sent 9/10/18	Initial approval - 2/13/2019		
33	2018-0129C-046 CCHMC	CCHMC	ImproveCareNow: Data to Transform Care and Improve Outcomes with Inflammatory Bowel Disease	Cincinnati Childrens	IV	Riedel, Brian	KE	05/09/19	Open to Accrual	153	72	72	Actively recruiting	Spring 2019 Community Conference 3/29-3/31		10/2/2018 - received ICN approval letter and new consent		
34	1809286678 KC Pro00027999 Advarra	BPR-PIP-001	Open Label To Study and evaluate Safety of Ceftobiprole in Neonates Undergoing Treatment with Systemic Antibiotics	PRA Health Sciences	I	Polak, Mark	KE	05/09/19	Open to Accrual	20	3		We have successfully enrolled and completed the trial WITH THE FIRST SUBJECT IN THE U.S. One subject screen failed after consenting.	SEV done. Site Selected	18-Jun	WVU IRB approved - 10/4/2018	11/7/2018	11/7/2018
35	059685 KC 217689 U	ACT NOWS/DCOC	Data Collection Study: Infant Exposure and Treatment	NIH/DCOC	IV	Smith,Cody	KE	05/09/19	Open to Accrual	305	148		All charts reviewed. Data entered. Monitoring visit successfully completed.	All data entered.	done	18-Feb	18-Feb	18-Feb

Line #	IRB #	Protocol Number / "NickName"	Short Title / Indication	Sponsor	Phase	PI	SC	Status Update	Status	Screened	Accrued	Active	Notes	Regulatory and Budget Updates	CDA	IRB	Contract	Budget
36		228446 / VDORA1	Vitamin D Supplementation in Children with Obesity related Asthma	NIH/DCOC	IV	Ely, Brian	KE	05/09/19	Open to Accrual	194			Screening daily. Will send parent and provider letters to help aid enrollment. First identified subject wants to enroll when he returns from summer in CA in August.	Working on final Protocol 10/26/2018 - Sent delegation log and credentials for people on log to Kay at DCOC. IRB is at SMART IRB - working with Sarah Stutler (WVU SMART IRB Contact) to finalize consent and assent.		11/29/2018 - Sarah signed off on SMART IRB		1026/18
37		SHP607-301 "Footprints"	Randomized Study to Evaluate SHP607 in Preventing Chronic Lung Disease Through 12 Months Correct Age (CA) Compared to Standard Neonatal Care in Extremeley Premature Infants	Shire TriNetX	IIb/III	Polak, Mark	KE	05/09/19	Site Selected	N/A	N/A	N/A	Gearing up for study opening. Investigator meeting 5/31 - 6/2			4/28/2019 - Submitted to WVU IRB		
38	1709770421 KC	RSV2004	to determine in hospitalized infants and children with RSV dose response relationship of lumicitabine on antiviral activity based on nasal RSV shedding using qRT-PCR	Janssen	II	Moffett, Kathryn	KE	05/09/19	Closed to Accrual				Final invoice paid. Awaiting shipping address and label to send final close out documents	Final invoice paid. Awaiting shipping address and label to send final close out documents				
39	1807187911 KC Pro00023294	RSV2002	Long term follow-up study to RSV 2004	Janssen		Moffett, Kathryn	KE	05/09/19	Closed to Accrual				Final invoice paid. Awaiting shipping address and label to send final close out documents	Final invoice paid. Awaiting shipping address and label to send final close out documents		7/28/2018 - approved CR2018		
40	1611343438 KC	FAST (Clinical Site)	Fetal Atrial Flutter & Supraventricular Tachycardia	Sick Childrens, Toronto, CA	NA	Saul	KE	05/09/19	Open to Accrual	3	1	0	Open.			8/8/2018 - CR2018 Approved		
41	1710800071 KC	FAST Registry	Fetal Atrial Flutter & Supraventricular Tachycardia	Sick Childrens, Toronto, CA	NA	Saul	KE	05/09/19	Open to Accrual	4	1	0	Open.			9/12/2018 - CR2018 Approved		
42		BP-CATCH	Boosting Primary Care Awareness & Treatment of Childhood HTN	The Children's Hospital at Montefiore		Nanda/Grant/Narumanchi/Morley/Harvey	KE	05/09/19	Open to Accrual	61	61		Monthly data entry. Next due 6/30/19	IAA complete		IAA complete		
43		CLI-06563AA	Efficacy, Safety; Pharmacokinetics of CHF 6563 in babies w/ NOWS	Chiesi Pharmaceutici	II	Smith, Cody	KE	05/09/19	Pipeline				Feasability complete					
44		D5290C00004	Randomized Study of MEDI8897, a Monoclonal Antibody Against RSV, in Healthy Late Preterm Infants.	MedImmune	III	Polak, Mark	KE	05/09/19	Site Selected				Site Selecte 2/21/19					
45		D5290C00005	Randomized Study of MEDI8897, a Monoclonal Antibody Against RSV, in infants w/ CLD or CHD	MedImmune	II/III	Polak, Mark	KE	05/09/19	Site Selected				Site Selected 2/21/19					
46		MET42	Immunogenicity & Safety of Investigational Meningococcal Vaccine in Helath Infants & Toddlers	Sanofi Pasteur Inc.	III	Moffett, Kathryn	KE	05/09/19	Site Selected				Investigator meeting 5/21-5/23. Gearing up for study opening		1/22/2019	4/3/2019 - Initial IRB Submission, Substantial Revisions required. 5/6/2019 - revised ICF sent to sponsor		
47		INFA.3227	Premature Infants <1500g birth weight in the prevention of necrotizing enterocolitis	Premier Research TriNetX	III	Polak, Mark	KE	05/09/19	Pipeline				Phone SEV held 5/6/19. Site selection pending		4/15/2019			
48	1809282288 KC	AMAG-FER-CKD-354	Study of Iron Deficiency Anemia with CKD in Pediatric Patients	ICON TriNetX	III	Grossman/ Nanda	CT	05/09/19	Open to Accrual				Transitioning to Chuck. Date to be complete 5/15/19		18-May	10-10-18 - IRB approved	7/31/18 submit	7/31/18 submit
49	1804058496 KC	NICHD-2011-POP01	Pharmacokinetics of Understanded Drugs Administered to Children per Standart of Care	NICHD (Pediatrics Trial Network)	IV	Pyles, Lee	CT	05/09/19	Open to Accrual	282	8	0	Study transitioned to Chuck 5/9/19.	CR 2019 submitted 2/19/2019	done	5/13/2019 - IRB Amnd approved to remove Initials and date from ICF	done	done

Line #	IRB #	Protocol Number / "NickName"	Short Title / Indication	Sponsor	Phase	PI	SC	Status Update	Status	Screened	Accrued	Active	Notes	Regulatory and Budget Updates	CDA	IRB	Contract	Budget
50	181136387 KC	TP-434-028	Open Label Eravacycline with Confirmed Bacterial Infection.	PPD/Tetracphase	I	Moffett, Kathryn	CT	05/09/19	Open to Accrual	57	0	0	Study transitioned to Chuck 5/7/19.	Site visit 9/25/18. Site Selected 10/25/2018 - Received template ICF to add WVU information Will submit to Quorum as CIRB.	8-Aug	Initial Approval - 1/23/2019, 5/6/2019 - study brochures submitted to IRB	10/25/2018	10/25/2018
51		FAST / US National Coordinating Center	Fetal Atrial Flutter & Supraventricular Tachycardia	Sick Childrens, Toronto, CA	NA	Saul	TCarr.	06/25/18	Study Start Up	0	15 sites		FDA and IRB approved 12/2/2017 all sites have current documents	Created fillable checklist for sites. 7/10/18 - Texas is open. 10/29/2018 - Cincinnati is open.				
52	1710809976	Pediatric Weight Management	Feasibility Of A Time-Limited Eating Plan in Pediatric Weight management Patients	Helen DeVos Childrens Hospital/WVU	IV	Murray, Pamela	LS	01/11/18	Study Start Up				Approved by WVU IRB #1710809976					
53	1606162244	CARDIAC	Coronary Artery Risk Detection in Appalachian Communities (CARDIAC) Project	N/A		Pyles, Lee	LS	04/30/18	IRB only							CR2018 approved		
54	1606162302	CARDIAC-Too	CARDIAC Project: Too (Waiver)	N/A		Pyles, Lee	LS	04/30/18	IRB only							CR2018 approved		
55	1707675059	FH in WV CARDIAC	Identification of Familial Hypercholesterolemia in WV CARDIAC Project	N/A		Pyles, Lee	LS	07/09/18	IRB only					7/9/18 - CR approved		CR2018 approved		
56	1401162729	FH Registry	CASCADE FH Registry	FH Foundation		Pyles, Lee	EP	12/10/18	Open to Accrual	77	40							
57			ACUTE KIDNEY INJURY (AKI) IN CHILDREN (NICU-PICU-WARD); FIRST STEP: NICU	None	Obs	Dr. Ouli Grossman	Peds Neph	12/05/17	IRB only									
58																		
59																		
60																		