

DOP Industry Clinical Trial Status Report: May 15, 2017

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PI Last Name	PI First Name	Name of Sponsor	Date Intent to Submit Form Completed	EPEX#	Emory IRB #	CHOA Coverage Analysis Status	CHOA Budget Development Status	Emory Budget Development Status	Sponsor Budget Negotiations Status	Sponsor Contract Negotiations Status	IRB Status	Emory NOA Status	CHOA Subcontract Status
Aguilera	Dolly	OZMOSIS RESEARCH INC.	10/6/2016	40838	IRB00094857		Completed 2/16/2017	Pending sponsor feedback 3/28/2017		Negotiations started 4/18/2017	Pre-submission		
Anderson	Evan	Micron Biomedical, Inc.	2/26/2017	41070		N/A	N/A	Completed 3/15/2017	Completed 3/15/2017	Edits sent to sponsor 5/12/2017	Per study team, will not be submitted to IRB until June or July		N/A
Anderson	Evan	Janssen Research & Development	11/3/2016	39497	IRB00093123		Completed 2/22/2017	Completed 3/7/2017	Pending sponsor response 4/21/2017	Negotiations completed 12/22/2016, pending budget	Approved pending minor revisions 5/11/2017		
Brown	Robert	Global Blood Therapeutics	3/9/2017	41378	IRB00088562		Completed 3/13/2017	Pending PI approval 5/12/2017			Approved 2/10/2017		
Brown	Robert	Global Blood Therapeutics	1/9/2017	40345	IRB00094554		Completed 3/6/2017	Completed 3/9/2017	Sponsor requested additional info 4/27/2017	Negotiations completed 4/7/2017, pending budget	Approved 4/5/2017		
Camacho-Gonzalez	Andres	Janssen	12/19/2016	39688	IRB00095178		Completed 1/26/2017	Completed 1/30/2017	Completed 2/1/2017	Completed 4/24/2017	Approved 3/29/2017	File sent to DMG for award set up 4/27/2017	
Cash	Thomas	Celgene	4/21/2017										

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Chakraborty	Rana	Gilead	4/3/2017	41591	IRB00071706			Pending CHOA budget 5/11/2017		Rec'd by contracts group 4/15/2017	Approved 3/13/2017		
Chakraborty	Rana	Gilead	6/13/2016	38288	IRB00068627	N/A	N/A	Completed 8/4/2016	Pending approval of affiliated budget 4/13/2017		Approved 2/19/2016		N/A
Chanani	Nikhil	Prolacta Bioscience	4/26/2016	34470	IRB00091189	Completed 8/25/2016	Completed 8/30/2016	Completed 9/13/2016	Completed 9/13/2016	Completed 1/27/2017	Approved 1/25/2017	Received 2/6/2017	OSP sent sub to CHOA 3/30/2017
Dampier	Carlton	Pfizer	5/9/2017										
Dampier	Carlton	Pfizer	11/29/2016	39786	IRB00077044		Completed 12/1/2016	Completed 12/28/2016	Completed 2/24/2017	Negotiations completed 4/28/2017	Approved 10/14/2016		
Felner	Eric	Genentech	3/22/2017	41414	IRB00086870	N/A	N/A	Completed 3/28/2017	Completed 3/28/2017	Sent to sponsor for signature 5/9/2017	Approved 7/20/2016		N/A
Felner	Eric	OPKO Biologics, LTD	10/11/2016	39283	IRB00093726	N/A	N/A	Completed 10/31/2016	Completed 10/31/2016	Sent to sponsor for signature 5/10/2017	Oversight Committee Approval 4/24/2017		N/A

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Goldsmith	Kelly	Pfizer Inc.	4/7/2017	41665				Pending CHOA budget 5/9/2017					
Goudy	Steven	Durata Therapeutics International B.V.	11/30/2016	40487	IRB00093558		Sponsor sent amendment 4/12/2017	Sponsor sent amendment 4/12/2017		Requested sponsor update 5/12/2017	Changes requested by IRB Staff 4/25/2017		
Greenbaum	Larry	Mallinckrodt Pharm	4/24/2017	42078									
Greenbaum	Larry	Alexion Pharmaceuticals Inc.	3/15/2017	42055	IRB00095603					Rec'd by contracts group 5/11/2017	Oversight Committee Approval 3/23/2017		
Greenbaum	Larry	Mallinckrodt Pharm	12/19/2016	40044	IRB00068101	N/A	N/A	Completed 1/12/2017	Completed 1/24/2017	Completed 5/2/2017	Approved 1/12/2017	Requested update from DMG 5/11/2017	N/A
Greenbaum	Larry	Alexion Pharmaceuticals Inc.	9/20/2016	39099	IRB00092435		Completed 2/28/2017	Completed 3/15/2017	Pending sponsor response 4/11/2017	Negotiations completed 5/12/2017, pending budget	Oversight Committee Approval 11/10/2016		
Greenbaum	Larry	Otsuka Pharmaceuticals	3/10/2016	36457	IRB00080904	Completed 3/31/2016	Revised Completed 5/2/2016	Completed 5/17/2016	Completed 3/13/2017	Completed 5/12/2016	Approved 7/1/2016	File sent to DMG for award set up 5/12/2017	

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Greenbaum	Larry	Alexion Pharmaceuticals Inc.	11/5/2015	34900	IRB00085577	Completed 3/3/2016	Completed 4/18/2016	Completed 5/5/2016	Completed 8/1/2016	Completed 3/17/2016	Approved 8/2/2016	Received 9/15/2016	CHOA requested edits to the prime 10/10/16
Haight	Ann	Chimerix	4/18/2017	41855	IRB00079160		Completed 4/19/2017	Completed 5/11/2016		Rec'd by contracts group 4/27/2017	Approved 2/7/2017		
Hall	Christine	Stalking/Marcus Autism Center	11/1/2016	35673	IRB00087702			Completed 12/5/2016	Completed 12/6/2016	Pending IRB approval	Approved 3/28/2017		
Keller	Stephanie	Edison Pharmaceuticals, Inc	2/16/2017	41012	IRB00078514		Completed 2/28/2017	Completed 4/28/2017	Negotiations started 4/28/2017	Negotiations started 4/24/2017			
Kempton	Christine	Genentech	2/11/2017	40794	IRB00084119	N/A	N/A	Pending OCR 4/28/2017		Negotiations completed 3/16/2017, pending budget	Approved 2/2/2017		N/A
Kim	Dennis	Edwards	4/3/2017	41552	IRB00087510		Completed 4/13/2017	Completed 4/16/2017	Completed 5/11/2017	Negotiations completed 4/14/2017 Pending budget	Approved 4/13/2017		
Kim	Dennis	GORE	11/21/2016	41288	IRB00094856		Completed 4/19/2017	Pending OCR budget 5/9/2017		Negotiations started 4/13/2017	Approved pending minor changes 4/6/2017		

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Kochilas	Lazaros	Bristol-Myers Squibb Company	10/28/2016	40244			Completed 1/5/2017	Completed 3/15/2017	Pending clarification from CHOA 5/9/2017	Negotiations completed 3/1/2017 Pending IRB approval			
Kochilas	Lazaros	Novartis Pharmaceuticals Corporation	2/24/2016	36244	IRB00087230	Completed 3/15/2016	Completed 3/28/2017	Completed 5/10/2017	Negotiations started 5/10/2017	Completed 2/26/2016	Approved 4/20/2017		
Krishnamurti	Lakshmanan	Bluebird Bio, Inc	12/22/2016	40084	IRB00078949		Completed 12/22/2016	Completed 3/24/2017	Pending sponsor response 4/26/2017	Negotiations completed 1/12/2017	Approved 12/27/2016		
Kugathasan	Subra	Quintiles	3/30/2017	41738				Pending CHOA budget 4/17/2017		Rec'd by contracts group 4/19/2017			
Kugathasan	Subra	Janssen	3/29/2017	41548	IRB00084651			Pending CHOA budget 4/26/2017		Negotiations completed 4/6/2017, pending budget	Approved 12/19/2016		
Kugathasan	Subra	Janssen Research & Development, LLC	11/11/2016	39875	IRB00093492		Completed 2/22/2017	Completed 4/26/2017	Negotiations started 4/26/2017	Negotiations completed 1/23/2017, pending budget	Pre-submission		
Muir	Andrew	DexCom, Inc.	12/9/2016	39970	IRB00090918	N/A	N/A	Completed 1/17/2017	Completed 1/18/2017	Signed sent to sponsor 4/20/2017	Approved 11/9/2016		N/A

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Pauly	Melinda	Onyx/Amgen	5/9/2017		IRB00079378								
Prahalad	Sampath	Pfizer	11/7/2016	37014	IRB00088627		Completed 4/18/2017	Completed 4/21/2017	In process 4/21/2017	Requested Sponsor Update 2/24/2017	Approved 9/27/2016		
Qayed	Muna	Novartis	5/10/2017										
Qayed	Muna	Novartis	5/9/2017										
Qayed	Muna	Pharmacyclics LLC	1/31/2017	40759	IRB00094386			Completed 4/19/2017		Rec'd by contract group 2/15/2017	Exempt Approved 3/10/2017		
Romero	Rene	Gilead	9/6/2016	38779	IRB00091610		Completed 10/14/2016	Completed 3/29/2017	Revision sent to sponsor 4/7/2017	Negotiations complete 1/12/2017, pending budget	Oversight Committee Approval 10/24/2016		
Sidonio	Robert	Genentech	5/3/2017	41975	IRB00089473			Completed 5/4/2017	Completed 5/4/2017	Rec'd by contracts group 5/7/2017	Approved 4/10/2017		

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Sidonio	Robert	Bioerativ Therapeutics, Inc.	3/10/2017	41360	IRB00095067	N/A	N/A	Pending OCR 4/26/2017			Changes requested by IRB Staff 4/28/2017		N/A
Stecenko	Arlene	Quintiles, Inc.	3/7/2017	41294	IRB00095720	N/A	N/A	Study team placed study on hold 4/11/2017		Negotiations started 4/25/2017	Pre-submission		N/A
Stenger	Elizabeth	JAZZ Pharmaceutical, INC	10/7/2016	39288	IRB00093158		Completed 2/27/2017	Completed 3/13/2017	Negotiations started 3/13/2017	Negotiations complete 2/15/2017, pending budget	Approved 3/9/2017		
Vos	Miriam	Shire	6/17/2016	37796	IRB00090136	Completed 7/25/2016	Completed 9/27/2016	Completed 11/16/2016	Completed 4/17/2017	Sponsor requesting 3 party agreement 1/11/2017	Approved 2/9/2017		
Yi	Jumi	BioFire	1/10/2017	40258	IRB00096348		Completed 3/2/2017	Completed 3/29/2017	Completed 4/18/2017	Negotiations started 4/28/2017	IRB Staff Review 5/11/2017		