Division of Gastroenterology/Hepatology

CLINICAL RESEARCH UNIT ENROLLMENT NEEDS

Post & distribute

CURRENTLY ENROLLING

DIAGNOSIS (SPONSOR) PI (ACCOUNT #)	SHORT STUDY NAME (UHSC #)	BEGIN DATE	PRIMARY COORDINATOR / RESEARCH STAFF & SUB I	# OF SUBJECTS					IRB RENEWAL DATE	Sponsor Monitor Dates	Compliance Check List Must Be in Study Binder A: Study preparation B: Screen/Enrollment C: Compliance review
				GOAL	ENROLLED SINED CONSENT	ENROLLED OR RANDOMIZED	COMPLETED	WITHDRAWN SCREEN FAILURE			
MOTILITY (INVESTIGATOR-INITIATED)											
*Barrett's esophagus Wo (020849)	Barrett's registry (288-00). (Transfer Submitted frozen tissue bank from 235-02 to Biorepositiory).	Jan 2001	Jennifer Susie, Lorie, Paily, McCollough, Rountree	250	128	128	—	—	5/30/09	N/A	**
Biorespository Barretts' Esophagus Wo	Biorespository for Barrett's Esophagus	March 2008	Jennifer Rountree, McCollough, Krueger	?	0	0	0	0	3/19/09	N/A	Need to do part A
*Gastroparesis Wo	A study to monitor the safety of Domperidone in the management of patients with gastroparesis (621-04).	Jan 2005	Jennifer Susie, Paily, Allison, Rountree	600	392	198	10	184	1/18/10	N/A	**
Diabetic & idiopathic gastroparesis Wo	Gastric electrical stimulation for severe gastroparesis: human device exemption #h990044 (912-00)	Feb 2001	Jennifer Susie, Paily, Allison, Rountree	50	86	55 implant 4 pending	0	27	7/04/09	N/A	**
*Diabetic & idiopathic Gastroparesis Wo	Gastric electrical stimulation for severe gastroparesis: A long-term follow-up (490-05) (Wo & Bizer revising protocol)	Feb 2006	Jennifer Susie, Bizer, Rountree	40	0	0	0	0	10/11/09	N/A	**

***Posted on ulgi.com** **Now enrolling: Call coordinator for subject enrollment** ****Study started before compliance check list implemented**

Karen Beatty: Pager: 675-0173
Jennifer Eversmann: Pager: 675-0146
Lisa Hatter: Pager: 675-0143
Kim Jarboe: Phone: 852-3543
Susie Mann:
Lorie Matthews:
Amy Noyes: Pager: 675-0148
Cindi Rountree: Pager: 675-0144
Pager: 675-0138
Phone 852-3004
April Russell:
Mary Ruth Salem: Pager: 675-0139
Shiloh Tatum: Phone: 852-4127
John Wo: Pager: 675-0149
Pager: 675-0162

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*Gastroparesis Wo	Underlying causes of vomiting-predominant Gastroparesis of unclear etiology (230-07)	July 2007	Jennifer Susie, Cacchione, Paily, Warren, Rountree	50	3	3	3	0	6/15/09	N/A	Part A, B completed
*Nausea & vomiting Wo	Full thickness gastric and small bowel biopsy for vomiting of unknown etiology (120-06)	April 2006	Jennifer Susie, Paily, McCollough, Rountree	10	10	10	9	0	3/15/09	N/A	**
Takeda Wo (090285)	Effects of lubiprostone on small bowel and colonic bacteria; a correlation study with segmental and whole gut transit (08.0529)	Feb 2009	Jennifer Wright, April, Susie, Lorie	25	0	0	0	0	12/17/09	N/a	Need to do part A, B, C
MOTILITY (INDUSTRY-SPONSORED)											
LIVER (INVESTIGATOR-INITIATED)											
Liver specimen bank McClain	Biological fluid/tissue storage for future research (261-94)	1994	Lisa Marsano, Cave, Tatum, Beatty	Open ended	N/A	28,960 Spec-mens	0	0	8/22/08	N/A	**
ALD (NIH) McClain	S-Adenosylhomocysteine and adenosylmethionine in Alcoholic Liver Disease (515.05)	Oct 2005	Lisa Tatum	0	0	0	0	0	10/26/08	N/A	**
ALD (NIH) McClain	Specimen Collection for NIH (National Institutes of Health) : Alcoholic Liver Disease and S-Adenosylmethionine (339.01)	June 2001	Lisa Marsano Mendez Martin, Barve, Parajuli, Cave, Krueger, Tatum, Goldstein,	0	0	0	0	0	6/19/09	N/A	**
Occupational Surveillance (NIH) McClain	Occupational Health Surveillance Project Study (367.03)	Aug 2003	Lark	N/A	609	609	0	0	06/08	N/A	**

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ALD (NIH) Barve	Mechanisms of Alcohol Induced Immunosuppression (188.04)	May 2004	Lisa	30 ETOH 30 WELL	5 3	0 ___	3 3	0 ___	05/09	N/A	**
ALD (NIH) McClain	Specimen Collection for NIH(National Institutes of Health) Study: Alcoholic Liver Disease and Tumor Necrosis Factor (311.01)	June 2001	Lisa Marsano, Goldstein	0	0	0	0	0	6/19/09	N/A	**
NASH (NIH) McClain	Mechanisms of SAM-e Action in NASH (Non-Alcoholic Steatohepatitis) (490.02)	Aug 2003	Lisa Marsano, Mendez, Martin Goldstein, Tatum, Cave Parajuli, Krueger, S.Barve	0	0	0	0	0	10/2/08	N/A	**
Obesity (NIH) McClain	13 C-Methionine Breath Test in Obese Adults (411.04)	Sept 2004	Lisa	0	0	0	0	0	9/15/08	N/A	**
NASH (NIH) McClain	SAMe and Steatohepatitis (436.03)	Oct 2003	Lisa	0	0	0	0	0	9/3/08	N/A	**
LIVER (INDUSTRY-SPONSORED)											
GSK 186-07 McClain	Randomized, placebo-controlled, multi-centre study to assess the efficacy and safety of Eltrombopag in thrombocytopenic subjects with hepatitis C virus (HCV) infection who are otherwise eligible to initiate antiviral therapy (peg-interferon alfa-2a plus ribavirin) ENABLE 1 (186-07)	April 2008	Lisa Marsano, Cave, Tatum, Salem, Beatty	5	0	0	0	0	02/27/09	None	Part A done
Roche ML21301 Cave	Randomized, open label treatment with one weekly Pegasys plus daily Copegus with or without concomitant Actos on early viral kinetics in treatment-naïve patients with chronic Hep C and insulin resistance (246-07)	April 2008	Lisa McClain, Marsano Tatum, Salem, Beatty	5	4	1	0		01/16/09	04/17/08	Part A & B done
INFLAMMATORY BOWEL DISEASE (INDUSTRY-SPONSORED)											

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*Crohn's Disease (Osiris 603) Dryden (080137)	Phase III, multicenter, placebo-controlled, randomized study to evaluate PROCHYMAL™ (ex vivo cultured adult human mesenchymal stem cells) IV infusion for induction of remission in treatment-refractory moderate-to-severe Crohn's (371-07)	Dec 2007	Karen Susie	___	1	1	0	0	8/22/09	Pending	
*Crohn's Disease (Osiris 610) Dryden (080138)	Phase III, multicenter, placebo-controlled, randomized retreatment study to evaluate PROCHYMAL™ (ex vivo cultured adult human mesenchymal stem cells) IV infusion for re-induction of remission in treatment-refractory moderate-to-severe Crohn's Disease (380-07)	Dec 2007	Karen Susie	___	0	0	0	0	9/6/09	Pending	
*Crohn's Disease (Hollis-Eden) Dryden (080396)	Phase I/II, randomized, placebo-controlled, dose ranging study of the safety, tolerance, pharmacokinetics of oral HE3286 in active, mild-to-moderate Crohn's (218-07).	Dec 2007	Karen Wo, Tatum, Susie, April	___	1	0	0	0	12/5/08	Pending	In progress
Crohn's Disease (UCB Pharma) Dryden (071496)	C87085/Phase IIIb, Multinational, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy & Safety of Certolizumab Pegol (sc), in Subjects w Moderate to Severe Active Crohn's Disease (OK to be on stable dose steroid) TNF naive is requested	July 2008	April Wo, Tatum, Susie	6	2	1	0	1	2/27/09	8-3-08 9/4/08 10/23/08 11/25/08	Completed
Crohn's Disease (UCB Pharma) Dryden (080107)	C87088/Phase IIIb Multinational, Open-Label, follow-on Trial to C87085 designed to assess the long term safety of Certolizumab Pegol (sc), in subjects with Moderately to Severely Active Crohn's Disease Who Complete Study C87085. *(roll-over from C87088)*	July 2008	April Wo, Tatum, Susie	6	3	2	1	0	2/27/09	8/0/08 9/4/08 10/24/08 11/25/08	Completed
Crohn's Disease (Pfizer) Dryden (08 0463)	A randomized, double-blinded, placebo-controlled, parallel group, multi-center study to investigate the safety and efficacy of CP-690,550 oral tablets JAK3 (cytokine inhibitor) in subjects with moderate to severe Crohn's disease (07-0225)	July 2008	April, Susie	6	5	4	1	1	02/27/09	11/10/08	Part A, B, C completed

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Ulcerative Colitis (Biogen) Dryden	Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of AVONEX® in Subjects with Moderate to Severe Ulcerative Colitis. (08-140)	June 2008	Susie, Karen, April, Rob		0	0	0	0	04/02/09		Part A completed
Misc Studies											
Pancreatic Exocrine Insufficiency (Eurand) Wo (080897)	A randomized, double-blind, placebo-controlled study of Zentase (pancreatic enzyme) for exocrine pancreatic insufficiency of chronic pancreatitis (in-patient study) (08-0103)	Oct 2008	Jennifer Susie, Karen, April, Lorie	6	3	1	1	2	03/05/09	11/24/08	Completed
Celiac Disease (Alba) Dryden	A phase IIb, randomized, double-blind, placebo-controlled study for the treatment of active celiac disease with AT-1001 (08-0270)	Nov 2008	Susie, April, Lorie, Jennifer	6	0	0	0	0	10/15/09	_____	Part A completed
(Colon Cancer Screening) Epigenomics Wo (090183)	Prospective Evaluation of serum SEPT9 Performance for Colorectal Cancer Screening (08.0507)	Jan 2009	Lorie, Jennifer, April, Susie, Tatum, Dryden	_____	3	3	0	0	10/29/09	pending	Part A & B completed

ACTIVE BUT NO LONGER ENROLLING

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				GOAL	SINED ICF	ENROLLED OR RANDOMIZED	COMPLETED	WITHDRAWN DURING STUDY			
GERD & MOTILITY											
Laryngopharyngeal reflux Wo	Questionnaires to determine the risk factors of LPR (#405-00)	Jan 2001	Jennifer Susie, Paily, Harrell Hatfield	Open ended	N/A	150	150	0	6//20/09	N/A	**
Barrett's esophagus Wo	Global gene expression in Barrett's using laser capture dissection (235-02) (Will close AFTER Barrett's tissue bank is established and tissues are transferred)	July 2002	Jennifer Susie Lorie	Open ended					5/30/09	N/A	**
Gastroparesis Wo	National physician survey for gastroparesis (121-06). (Manuscript pending)	April 2006	Jennifer Susie, Briley, Allison, Harrell	500	N/A	345	345	0	3/20/09	N/A	**
Gastroparesis Wo	Retrospective review of small intestine bacterial overgrowth in patients with postprandial distress syndrome and gastroparesis (110-07).	November 2007	Jennifer Susie, Hatfield, Harrell, Mushruwla, Arnold, Allison	____	N/A	209	209	0	10/22/08	N/A	**
*GERD w/Gastroparesis (Santarus) Wo (070714)	Benefit and pharmacokinetics of immediate release omeprazole for subjects with GERD associated with gastroparesis. (014-07) (Submitting abstract to DDW 2009, paper pending)	Feb 2007	Jennifer Lorie, Karen, Susie	15	12	12	12	0	1/24/10	N/A	Complete
*Gastroparesis (Medtronic) Wo (020659)	Gastric electrical stimulation <u>randomized</u> controlled trial for severe idiopathic gastroparesis (152-02) (Diabetic arm is closed for enrollment) (Submitting abstract to DDW 2009)	Nov 2002	Jennifer Susie, Scheryl, Cacchione	12 DM, 10 idio.	34	10 DM, 4 idio.	0	6	6/24/09	9/13/06 3/26/07 4/25/07 12/5/07 _____	**

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Idiopathic Nausea and Vomiting Wo	A Retrospective Review of Viral infection in Patients with Idiopathic Nausea and Vomiting (07.0138) (Submitting abstract to DDW 2009)	Nov 2007	Jennifer Susie, Paily, Arnold	50	N/A	35	35	0	_____	N/A	**
LIVER											
Wyeth HCV-796 McClain	Hep C naïve and non – responders (closed by sponsor) 15-07	May 2007	Lisa Karen	Co mp	4	3	1/24/09			6/12/07 8/21/07 8/22/07 9/17/07 9/18/07	**
INFLAMMATORY BOWEL & COLITIS											
Crohn's (Celltech CDP870- 033) WO (G040375)	Open label study to assess safety of CDP-870 (humanized Anti-TNF PEG conjugate) in patients who completed CDP870-031 (611-03)	March 2004	Susie	6	1	1	0	0	11/19/08	Multiple	**
*Ulcerative Colitis (Procter & Gamble) Dryden (061194)	Double-blind, Randomized, , 6-week, parallel-group study to assess the safety and efficacy of 800 mg mesalamine vs 400 mg mesalamine (324-06)	June 2006	Lorie Karen	8	1	1	0	0	6/21/08	3/16/06 11/06/06 3/14/07	**
*Crohn's (UCB Pharma) Dryden (061067)	(Welcome I) Open-label double blind comparison of Pegulated TNF-Ab over 26 weeks in Crohn's patients with prior loss of response or intolerance to infliximab (209-06)	June 2006	Karen April	6	8	1	6	1	4/19/08	3/8/07 4/19/07 6/5/07	**
Crohn's Disease (UCB) Dryden (070788)	(Welcome II) Open label long term trial evaluating efficacy and safety of certolizumab pegol (PEGylated fab fragment of humanized antibody to tumor necrosis factor) in Crohn's who completed C87042 study (107-07).	June 2007	Susie April, Wo, Tatum	5	9	3	2	2	Closed to enrollment	_____	**