

Midcycle Meeting, March 30, 2012 - ALLOCORD

Sponsor: SSM Cardinal Glennon Children's Medical Center
BLA #: BLA 125413
Product: Hematopoietic Progenitor Cells
Date: March 30, 2012
Time: 10:00 AM-12:00PM

1. Overview (5 min)

- Draft Reviews Due – May 20, 2012
- Action Due Date – August 20, 2012

2. Discipline Reviews of Application/Issues Needing Resolution

- CMC – Brent, Joydeep, Safa, Brian
(b)(4)
- DMPQ – Kelly/Nancy
DMPQ does not have any review issues at this time. Inspection is scheduled for 16-20 April 2012 for St. Louis and 23-27 April 2012 for St Luke's Cancer Institute.
- Pharm/tox – Shamsul
(b)(4)
- Clinical – Lei
(b)(4)
- Stats – Renee
- Labeling – Loan
- Epidemiology - Damon
(b)(4)

3. Timeline

Action Item	Due
Draft Reviews Due	May 20, 2012
Final Reviews Due	June 20, 2011
PMC Study Target	on or before July 20, 2012
Labeling Meeting with Sponsor	on or before July 20, 2012
Division Director Signature	July 23, 2012
Final Action Package Due to Celia	August 6, 2012
BLA DUE DATE	August 20, 2012

Participants: Brent McCright, Brian Niland, Safa Karandish, Joydeep Ghosh, Keith Wonnacott, Kim Benton, Stephanie Simek, Celia Witten, Lei Xu, Changting

Haudenschild, Ilan Irony, Patrick Riggins, Wilson Bryan, Atm Hoque, Mercedes Serabian, Renee Rees, Shiowjen Lee, Lori Tull, Nancy Waites, Damon Green