

<b>Transition Milestones (Clinical Coordinating Center)</b>		<b>Expected Date of completion</b>
1	Develop and finalize NIH-approved study documents: Study Protocol, Data & Safety Monitoring Plan, Investigator's Brochure, Case Report Forms, Informed Consent form, and Manual of Operations. Final NIH-approved documents for Protocol Review Committee (PRC) due Jan 11 <sup>th</sup> , 2016	6 months prior to transition request due date
2	Prepare and complete regulatory requirements with the FDA (submit update to IND and resolve any requests for additional information from the FDA prior to submitting the Transition Request), OHRP (FWAs for all sites), clinicaltrials.gov (register study) and submit a regulatory applications to any foreign regulatory agencies as applicable.	By date of transition request
3	Develop and test prescription and safety workflow, obtain shipping licensures and conduct a quality assurance review for the central pharmacy	By date of transition request
4	Prepare site recruitment plan. Identify and describe 75% of participating sites. A minimum of 20% of sites will have completed documents at the time of the transition request. These sites will be prepared to enroll subjects after the investigator's meeting during the first month of the next phase. Provide details about the sites including: number of eligible patients, gender and ethnicity composition of eligible participants; provide individual site track record of recruiting for clinical trials, and list other trials that may be competing for similar participants at the site. Also provide the overall plan for activating new sites once trial enrollment has begun.	By date of transition request
5	Obtain IRB approval for the CCC and coordinate site approvals with local IRBs when necessary and central IRBs as much as possible.	By date of transition request
6	Prepare and complete a patient accrual/enrollment plan including planned recruitment efforts & outreach, and contingency plans for lower than anticipated enrollment at sites. Also include site enrollment targets and rates of enrollment, and plans for regularly evaluating site performance, and potential site replacement plans. Obtain NIH approval prior to implementation.	By date of transition request
7	Develop plans to identify, recruit and retain both women and minorities into the study	6 months prior to transition request due date
8	Develop plans to enhance patient adherence and retention	6 months prior to transition request due date
9	Set up plans for payments to Pharmacy, Central Lab, CCC, and consultants	By date of transition request
10	Develop training materials	By date of transition request
11	Develop site and patient recruitment materials	By date of transition request
12	Develop plan for SAE reporting	6 months prior to transition request due date
13	Negotiate and secure contracts and create a payment management system for vendors and a minimum of 50% of clinical sites	By date of transition request

<b>Transition Milestones (Clinical Coordinating Center)</b>		<b>Expected Date of completion</b>
14	Create an NIH-approved resource and data sharing plan.	By date of transition request
15	Prepare transition request for next phase including: annual milestones, updated timeline, monthly recruitment benchmarks for site and patient enrollment, and updated detailed budget.	By date of transition request