Transition Milestones (Data Coordinating Center)		Expected Date of completion
1	Work with Clinical Coordinating Center (CCC) to develop and finalize NIH-approved study documents: Study Protocol (including the final statistical analysis plan), Data & Safety Monitoring Plan, Informed Consent Document, and Investigator's Brochure. Final NIH-approved documents for Protocol Review Committee (PRC) due by expected completion date	6 months prior to transition request due date
2	Obtain IRB approval for the DCC activities	By date of transition request
3	Obtain and manage vendor contracts for electronic data collection, risk-based monitoring systems, and randomization.	By date of transition request
4	Assist CCC with the development of the pharmacy workflow.	By date of transition request
5	Develop Study database and finalize data management and data quality plan. Version for PRC due by expected completion date.	6 months prior to transition request due date
6	Finalize and validate NIH-approved case report forms.	By date of transition request
7	Assist CCC and NIH to develop the DSMB charter.	6 months prior to transition request due date
8	Develop safety surveillance plan and site monitoring plan	By date of transition request
9	Collect and manage regulatory documentation from 75 % of 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 UH3 phase.	By date of transition request
10	Prepare any sub-study deliverables such as: patient contact form; medical release form; contract for licensing; training materials; sub-study database.	By date of transition request
11	Work with CCC to create an NIH-approved resource and data sharing plan.	By date of transition request
12	Work with CCC to identify sites with high likelihood of adequate patient recruitment, retention, background medical therapy, and data quality.	By date of transition request
13	Develop and finalize NIH-approved Manual of Operations.	By date of transition request
14	Work with CCC to develop site training materials and site/patient recruitment materials.	By date of transition request
15	Prepare transition request for UH3 phase including: annual milestones, updated timeline, and updated detailed budget.	By date of transition request