

Appendix A: Sample Accelerating and Value Added Resources (AVARs) for the Alpha Stem Cell Clinic Network

The following is a partial list of accelerating and value added resources developed by the Alpha Stem Cell Clinic Network. These AVARs may be developed or scaled to support the goal of accelerating stem cell clinical trials.

IRB Reliance Agreement: An Agreement to Speed IRB Approval

The Network has put in place an MOU to facilitate IRB approval. The agreement is a reciprocal IRB authorization agreement where an institution may accept or “rely” on the determination of a lead IRB within the Alpha Clinics Network. The IRB reliance agreement is designed to reduce the time required for trial approval. Individual Network sites still retain the ability to perform their own review.

UC ReX and LADR: A Patient Registry to Speed Cohort Identification

<http://www.ucrex.org/#!data-explorer/c1c32>

UC ReX and LADR include 20 million+ de-identified patient records from the five UC biomedical centers and other participating centers. With the assistance of a Research Navigator, (staff position with the University of California Research eXchange) and a collaborating investigator. The system may be utilized for patient cohort identification without IRB approval. Once a cohort is identified, IRB approval can be obtained to request additional patient screening data. In some cases, patients may have already consented for record review. Otherwise patients may be contacted through their provider, an honest broker or the investigator.

Alpha Stem Cell Clinics Data Capture

The ASCC Network is developing a system to capture metrics across trials. The metrics include but are not limited to variable to measure the speed of trial initiation, types of clinical indications, and patient recruitment performance measures. Currently RedCap <http://project-redcap.org> being utilized to capture metrics across trials. The Shared Resources working group has inventoried existing data systems in place at the various sites, table below.

Clinical Trial Management Systems

ASCC Site	Which CTMS	Exchange Data	Protocol & Patient Mgmt.	Study Document Mgmt.	Financial Billing	Study Calendar	Integrate w/ hosp EMR	Integrate w/ hosp lab system	Biospec Mgmt.
UCI	OnCore, REDCap	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
UCLA	OnCore ¹ REDCap	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
UCSD	Velos, REDCap	Yes	Yes	Yes	No	Yes	Yes	No	Yes
City of Hope	MIDAS	No	Yes	No	No	No	Yes	No	No

¹Anticipate OnCore rollout Feb. 2016. Answers geared toward OnCore. Phasing out Velos.

The Accelerating Center should propose how Alpha Stem Cell Clinic Data Capture system could be developed to support the goals of this RFA.