

Strategic IIT RFAs to Address Underrepresented Patient Populations

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1. Background

A review of treatment trial trends in 2023 identified low enrollment of women relative to catchment area demographics. To address this disparity, the University of Florida Health Cancer Center (UFHCC) devised a pilot process to increase the opportunities for enrollment of women. Concepts submitted under this request for applications (RFA) were peer-reviewed by the UFHCC Investigator-Initiated Trial (IIT) Think Tank (I2T3; previously presented at AACI CRI). These concepts were then reviewed and refined by the I2T3, harnessing a well-established asset to target the needs of our patients.

2. Goals

Our goal is to assess the feasibility of using our established concept development processes in order to address areas of need, by soliciting IITs targeted to unmet needs of our clinic population and catchment area.

3. Solutions and Methods

The RFA for treatment concepts to enhance recruitment of women was released in September 2023. Concepts fulfilling RFA requirements were reviewed at an I2T3 meeting reserved for investigator presentation and discussion of submissions. The RFA did not include a budget limit, to encourage a diversity of application concepts. Submissions utilized the UFHCC Clinical Research Office (CRO) Concept Review Form, to align application process with investigator familiarity with other IIT concepts. The Associate Director of Clinical Research (ADCR) marketed the RFA via email blasts, I2T3, and in Disease Site Group (DSG) meetings, and brainstormed with potential applicants.

Once all submissions were received, a summary table was created for initial review to confirm that each met minimum standards for treatment trial classification and administrative feasibility. In total, eight submissions were received and five were selected to proceed with the next stage of review (presentation at I2T3). One of those five had already been presented at I2T3 and had since secured other funding, so that left four submissions for presentation and review at I2T3.

Because the attendance at I2T3 has been curated to include diverse expertise, this forum allowed for rich verbal feedback from multiple perspectives (statistics, scientific, feasibility, study design). A Qualtrics survey link was distributed to I2T3 attendees for each concept to collect anonymous written feedback. Post-meeting, a preliminary cost estimate was developed by the Project Management Office (PMO) for each concept. All data was collated for a final selection committee of senior CRO and UFHCC leaders to review. Positive and negative feedback for each concept was discussed, as well as cost, feasibility, and potential for innovation, scalability, and impact. The four concepts were assigned a rank order.

4. Outcomes

A summary of this ranking was submitted to the cancer center director, including the rationale, which resulted in the selection of the top two concepts for intramural funding and development. These two concepts are currently in start-up and will be managed by the CRO to support their success (these effort costs were included in the award). Of note, the PIs of these concepts were clinicians who had previously

wanted, but had not, been involved in IIT submissions previously, thus facilitating the internal recruitment of new clinical scientists.

5. Lessons Learned and Future Directions

A similar process can be used in response to other needs assessments performed by cancer center leadership, harnessing expertise represented in I2T3 meetings to drive creation of IITs curated to support the needs of the community.