Starting off on the right foot:
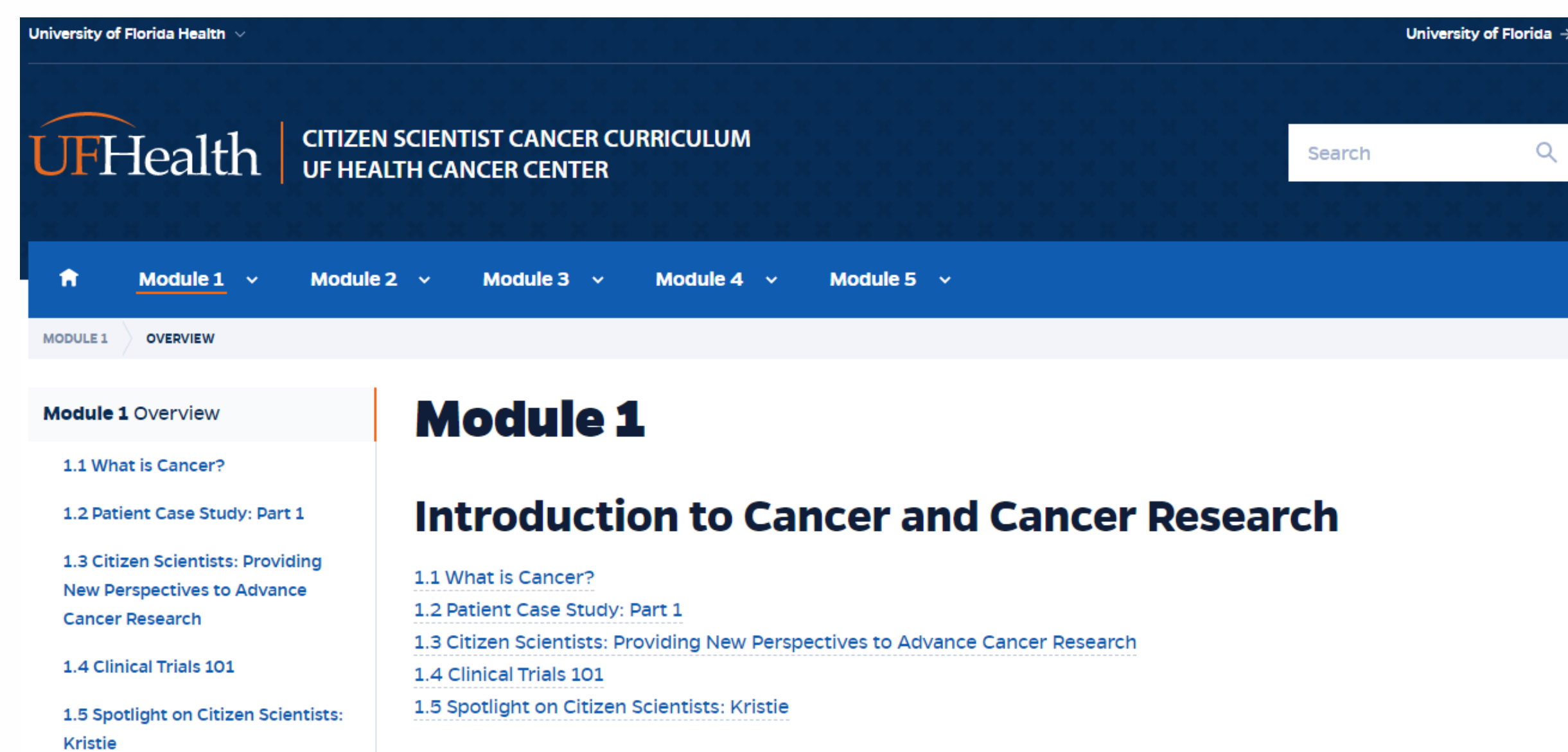# Elevating the voice of community stakeholders during the IIT development process

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BACKGROUND

The IIT ThinkTank (I2T3) was established to increase the quality and quantity of UFHCC investigator-initiated trials (IITs) while simultaneously supporting career development for early stage clinical investigators. In 2021, the I2T3 partnered with the UFHCC Office of Community Outreach and Engagement (COE) and their Citizen Scientist (CS) program to engage community stakeholders at the earliest stages of clinical trial conception. The CS program was developed by COE as a research partnership model, in recognition of the invaluable contributions that citizen scientists make as members of the research team. CS receive formal training in health research through general and cancer-specific curriculum including bidirectional communication skills leading to certification as a qualified CS. These materials are offered as an Open Educational Resource here: https://citizenscientist.ctsi.ufl.edu/

Scan QR code for a direct link to modules

Our two primary goals are:

➢ Establish a sustainable collaborative culture between the community and early stage investigators via an ongoing partnership between I2T3, COE, and CS to meet our community needs

➢ Improve the patient-centeredness of IITs through community feedback on interest, recruitment and impact, from the first discussion of concepts.

METHODS

In partnership with UFHCC COE and their CS program, the Clinical Research Office (CRO) invited Citizen Scientists (CS) to I2T3 meetings starting in December 2021 as formal concept reviewers. Each CS is fully integrated into the I2T3 meeting providing verbal and written feedback on all IIT concepts presented. Adequate addressing of any CS concerns by the study team is required, barring documented justification why it cannot, for an IIT to move forward with development. Ongoing partnerships between CS and investigators are encouraged as concepts develop into protocols, including use of CS as a resource and community connection throughout the life of the trial, through support from the UFHCC COE. Beyond assisting with concept and protocol development, CS also assist with reviewing consent forms, patient materials, and grant applications.

Examples of constructive feedback provided by the Citizen Scientists include:

• *"I would encourage staying away from cancer prevention education during the early phases of diagnosis and treatment because that can elicit shame and shut people down."*

• *"Consider giving questionnaires at a different time other than when receiving treatment like chemo. Sometimes they give Benadryl and steroids during treatment and it's very hard to concentrate while receiving treatment."*

• *"I am wondering if there needs to be a plan in place to help those randomized in the experimental arm keep track of what they are supposed to take and when they are supposed to take it. I know that when people are very sick or stressed (and older), it can be difficult to keep track of pills. This new treatment regimen looks significantly more complicated than the control regimen."*

RESULTS

Implementation of the CS program has yielded positive impact upon cancer research across UFHCC, including feedback on a PCORI submission for a tobacco cessation study, consulting on responses to FDA queries for a glioblastoma trial, and helping improve feasibility of a head and neck cancer study. To date, CS have reviewed 8 concepts and provided largely centered on innovative strategies to maximize treatment compliance, increase recruitment diversity, and educate subjects about contraindications to treatments and toxicities, across five concepts reviewed.

FUTURE DIRECTIONS

We will perform an annual review of feedback provided and track what percentage of Citizen Scientists feedback was ultimately included in protocols, as well as enrollment metrics to assess effects of community feedback on recruitment. We will also collect feedback from investigators and CS to continually improve the program so it can be maximally beneficial to both groups.

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