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## BACKGROUND

To increase investigator-initiated trial (IIT) development and support early stage clinical investigators (ESIs), monthly "IIT Think Tank" ("I2T3") meetings were initiated in February 2020. Meetings include new concept presentations and discussions about development, feasibility, conduct, and support.

During the first year of the program, IIT concept intake increased by nearly 64%, supporting our primary goal. I2T3 goals for 2021 were to maintain concept intake volume, activate our first I2T3 studies and introduce meeting enhancements.

## METHODS

In 2021, the following enhancements were made to the I2T3 meeting process:

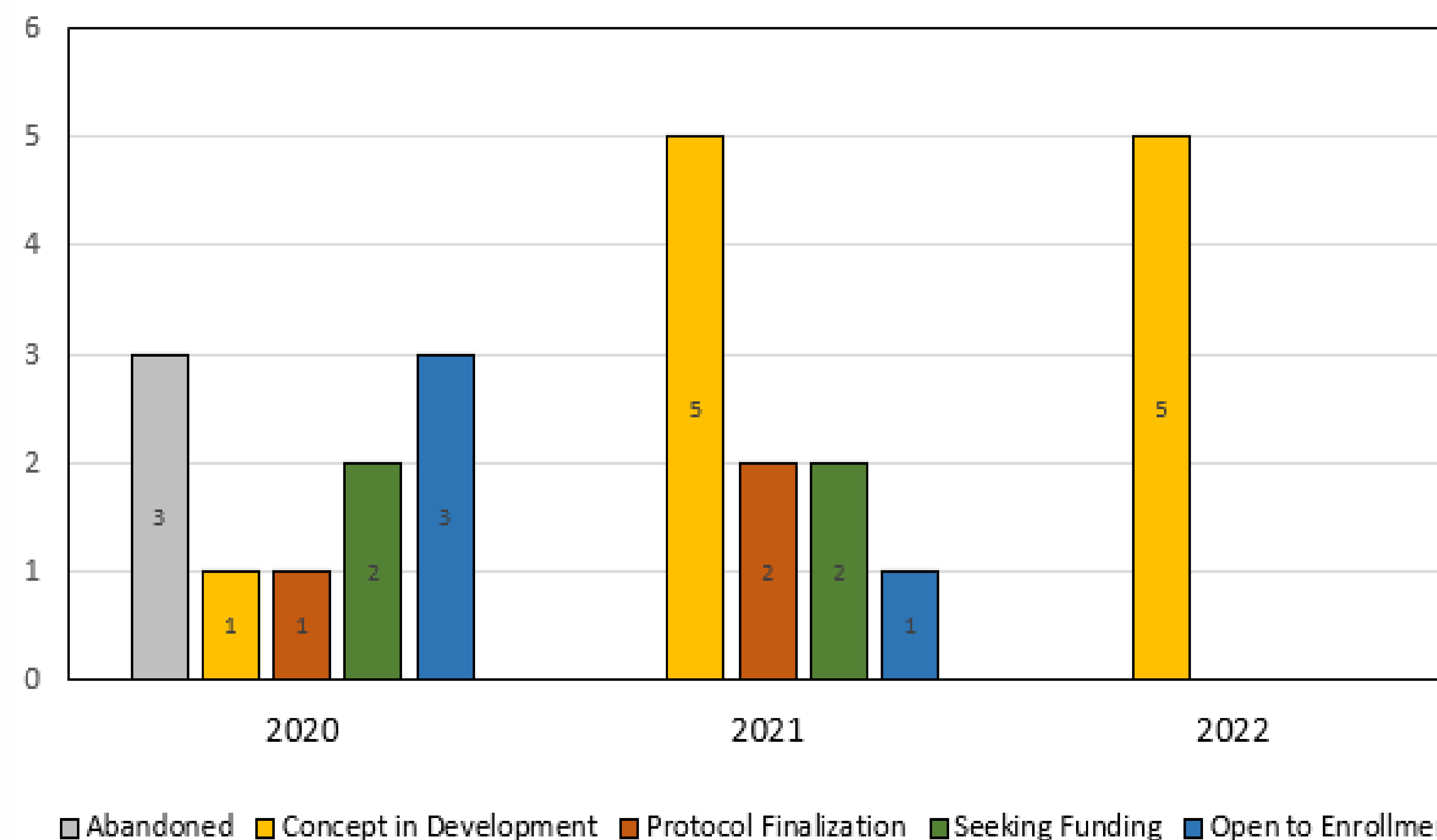
- **Grant Finding Initiative:** Identification of extramural funding opportunities, specifically matched for I2T3 concepts.
- **Enhanced Feedback Collection:** I2T3 members provide formal feedback for concepts using an NCI-style scoring rubric on scientific merit, study design, clinical impact, and feasibility. Training was provided and results are provided to the concept presenter as a formal summary document.
- **Citizen Scientist Inclusion:** Two CS have been included in the I2T3. Their feedback is incorporated by PMO into the final feedback document provided to the investigators.

## RESULTS

Ten concepts were received through I2T3 meetings in 2020, and this pace continued with another ten in 2021, demonstrating sustained new concept volume. Of all concepts presented, only 15% have been abandoned, due to lack of funds or feasibility. Three I2T3 studies completed protocol development in 2021 and were opened to accrual and one in 2022, all with current active enrollments. 2022 is poised to outpace 2021's concept intake rate, with 5 concepts already in development as of May 2022.

In 2021, four I2T3 concepts were submitted for grant support, with one awarded (Florida DOH JEK, \$1,458,000.00). In 2020, one grant was submitted and not funded. Three concepts were supported by industry in 2020, and this rate continued into 2021, with two supported and one pending.

Disposition of Concepts Presented at I2T3 by Year Presented



## FUTURE DIRECTIONS

In 2021, the pace of I2T3 concept intake continued from its inaugural year (2020), demonstrating sustained volume of new concept intake. We anticipate this to continue and increase in 2022.

We will collect data on which CS feedback components are recurring themes, to look for system-level solutions for protocol incorporation. We also plan to collect data from investigators to learn about the usefulness of the Qualtrics feedback received from their peers, as well as CS feedback, and new educational topics desired by the group. Finally, we will track the number and success of grant submissions associated with the new grant finding initiative.

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