Introducing an Electronic Platform to Collect Patient Reported Outcomes in the I-SPY 2 TRIAL, a Neoadjuvant Clinic

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BACKGROUND

While the side effects of taxane- and anthracycline- based chemotherapy are well characterized, introduction of experimental agents and immunotherapy in the neoadjuvant and adjuvant settings may significantly alter the toxicity profiles of these regimens, resulting in short and long-term changes in patient quality of life (QOL).

QOL STUDY AIMS

PRIMARY

- Evaluate the short- and long-term impact on QOL of novel agents added to standard treatment in high-risk breast cancer patients receiving neoadjuvant therapy.
- Examine the impact of factors like patient age, hormone receptor and HER2 status, type of surgery, and response to treatment (residual cancer burden) on patients' QOL trajectory over time

SECONDARY

- Compare patient reported toxicities using the PRO-CTCAE measures with clinician-reported adverse events

ELIGIBILITY

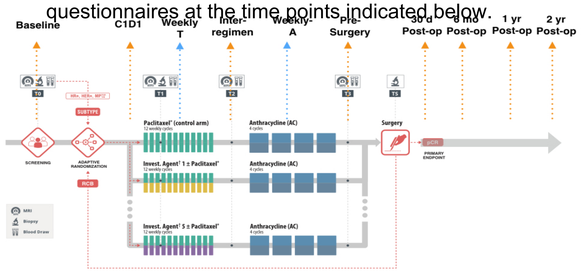
Patients are eligible to participate in I-SPY2 and the QOL sub-study if they have high risk, invasive breast cancer, broadly defined as having a tumor ≥ 2.5cm and one of the following receptor statuses:

- Hormone-receptor (HR) positive, HER2 negative, & Mammaprint high risk
- HR negative & HER2 negative
- HER2 positive

STUDY DESIGN

I-SPY 2 is a multicenter, phase 2 trial using response-adaptive randomization within biomarker subtypes to evaluate a series of novel agents when added to standard neoadjuvant therapy for women with high-risk breast cancer.

All patients who consent to screen for the I-SPY2 trial receive a baseline QOL questionnaire. Patients who consent to the treatment phase of I-SPY2 also complete questionnaires at the time points indicated below.



Full-Length QOL Survey

- **PRO-CTCAE** Patient Reported Outcomes-Common Terminology Criteria for Adverse Events
- **FOR** Fear of Recurrence Instrument
- **DISTRESS THERMOMETER** developed by the National Comprehensive Cancer Network
- **PROMIS** Patient Reported Outcomes Measurement Information System

Abbreviated QOL Survey

- **PRO-CTCAE** Patient Reported Outcomes-Common Terminology Criteria for Adverse Events
- **PROMIS- Physical Function** Patient Reported Outcomes Measurement Information System

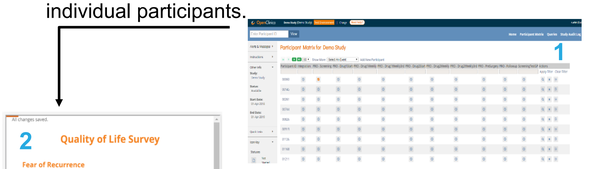
Included domains:

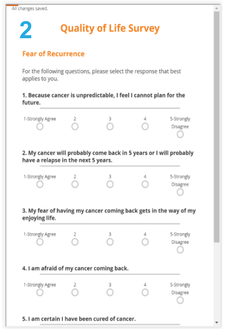
- Physical function
- Cognitive function
- Anxiety
- Depression
- Pain
- Social Roles
- Sleep
- Sexual function

PROPr Score + **RCB index** → **CBI (Clinical Benefit Index)**

ELECTRONIC PLATFORM

The QOL sub-study is transitioning from paper questionnaires that have had to be manually collected and entered into a database, to an electronic platform specifically designed for this study. This platform allows for the automatic release of questionnaires to patients at required time points and tracking of survey completion for individual participants.





1. Research coordinator triggers survey notification to patient
2. Patient completes eSurvey prior to or during appointment
3. In future iterations, the clinical team will have longitudinal visualization of PROs against reference ranges

With the introduction of this platform, patients will have the opportunity to complete questionnaires on their personal devices via individualized, secure links or on tablets available in clinic through study coordinators.

ONGOING ENROLLMENT

The I-SPY2 trial has registered 2853 patients to date and there are 18 sites open across the US. The QOL study has been an integral component in the trial that is required for all participants. Since the initiation of the QOL study in 2012, at least one QOL survey has been collected from 1145 patients. Given the adaptive design, enrollment for each agent varies based on patient outcomes, but collection of QOL questionnaires on all patients will continue as new agents enter the trial. Thus far, 11 experimental agents have been evaluated for efficacy as a part of I-SPY2.

FUTURE ANALYSES

Data that is collected from these QOL measures will be used to:

- Generate a Clinical Benefit Index (CBI), a single composite score that integrates a PROMIS Preference score with a clinical efficacy assessment (residual cancer burden)
- Capture patients' experience of toxicity using the PRO-CTCAE and comparing it to physician reported AEs

and will provide insight into the overall impact that therapeutic agents in I-SPY2 have on cancer recurrence risk and survival outcomes.

ACKNOWLEDGMENTS

With support from Quantum Leap Healthcare Collaborative, FNIH, NCI (Grant 28XS197 P-0518835), Safeway, an Albertsons Company, William K. Bowes, Jr. Foundation, Breast Cancer Research Foundation, UCSF, GMU, the Biomarkers Consortium, Salesforce, OpenClinica, Formedix, Natera, Hologic Inc., TGen, Illumina, CCS Associates, Berry Consultants, Breast Cancer Research – Atwater Trust, Stand up to Cancer, California Breast Cancer Research Program, and Give Breast Cancer the Boot, IQVIA, Genentech, Amgen, Pfizer, Merck, Seattle Genetics, Daiichi Sankyo, AstraZeneca, Dynavax Technologies, Puma Biotechnology, AbbVie, Madrigal Pharmaceuticals (formerly Synta Pharmaceuticals), Plexxikon, Regeneron and Agendia. Sincere thanks to our DSMB, Independent Agent Selection Committee, our patients, advocates and investigators.