N0392 (Alliance): Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials

Jeffrey A. Sloan, PhD and Paul Schaefer, MD

Mayo Clinic and University of Toledo

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Rationale

The primary research hypothesis to be examined in this study is whether patient quality of life (QOL) needs are being met while a patient participates in an NCCTG clinical trial. Do patients who participate in NCCTG clinical trials think that participation in the clinical trial was worthwhile.

Secondary research hypotheses includes determining whether patients would participate in other trials in the future and/or recommend trial participation to others, promoting concordance with the role the patient is currently playing in making health care decisions with the role the patient wishes to be playing, and determining if participation in the clinical trial experience has improved patient QOL.

If there are indications that patients are satisfied with their clinical trial experience and patient QOL is indeed improved via participation, this will demonstrate the ancillary benefits for patients participating in clinical trials. If there are contraindications, the patient perspective will enable us to provide quality control and will point us towards future modifications to study design to improve the patient experience. Knowing whether patients thought the clinical trial experience was beneficial and inquiring if the patients were making decisions according to their needs will provide insights for barriers to accrual. This study will point us toward interventions to improve patient education, help create standards for study design, and provide feedback to investigators to aid in directly meeting patient needs and expectations.

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Objective

Primary

- To estimate patient opinion regarding clinical trial participation.

Secondary objectives

- To estimate patient opinion regarding their own future trial participation.
- To estimate patient recommendations for study participation to others.
- To estimate patient QOL changes occurring as a result of the clinical trial experience.
- To categorize patients' role preference in the health care decision-making process.

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Study Schema

NCCTG membership receives activation packet for N0392

↓

Protocol is approved by local IRB

↓

Patient registered/randomized to appropriate NCCTG treatment trial which has been designated as a parent trial to N0392 (see protocol for study approval process)

↓

NCCTG Clinical Research Associate (CRA), Nurse, or MD discusses study participation and survey schedule with patient at study entry and documents discussion in the patient's medical record. Verbal or written consent is given and written HIPAA authorization is obtained. Both are documented in the patient's medical record.

↓

Patient is registered by faxing Eligibility Checklist to the Random Center (see protocol)

↓

Patient completes baseline questionnaire, Control Preferences Scale*
before beginning treatment on parent protocol.

↓

Baseline data will be entered into the remote data entry system.

↓

CCTG CRA, Nurse or MD meets with patient in accordance with the treatment trial visit schedule and ministers the Was It Worth It Questionnaire at the end of cycle 1 (or at 1 month if cycle is not defined in the parent protocol) and at the end of active treatment (or at 1 year, which ever is soonest). **

↓

Patient questionnaire data will be entered into the remote data entry system.

Patient questionnaire booklets are available and must be used. Appendices II and III may not be copied.
The patient may choose to complete the questionnaire during the week after the office visit.
In this case patient will return the completed survey to the primary CRA within 1 week of the clinical visit.

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Eligibility Criteria

- Enrollment on an NCCTG-sponsored clinical trial which has been designated as a parent study to N0392.
- Ability to complete the questionnaire booklets. Can be done with the aid of an interpreter, family member, or medical professional, if necessary.

Contraindications

- Cognitive impairment. If patient is able to complete the questionnaire, it will be assumed that cognitive impairment does not exist.

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