



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

Rationale

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Follow Up

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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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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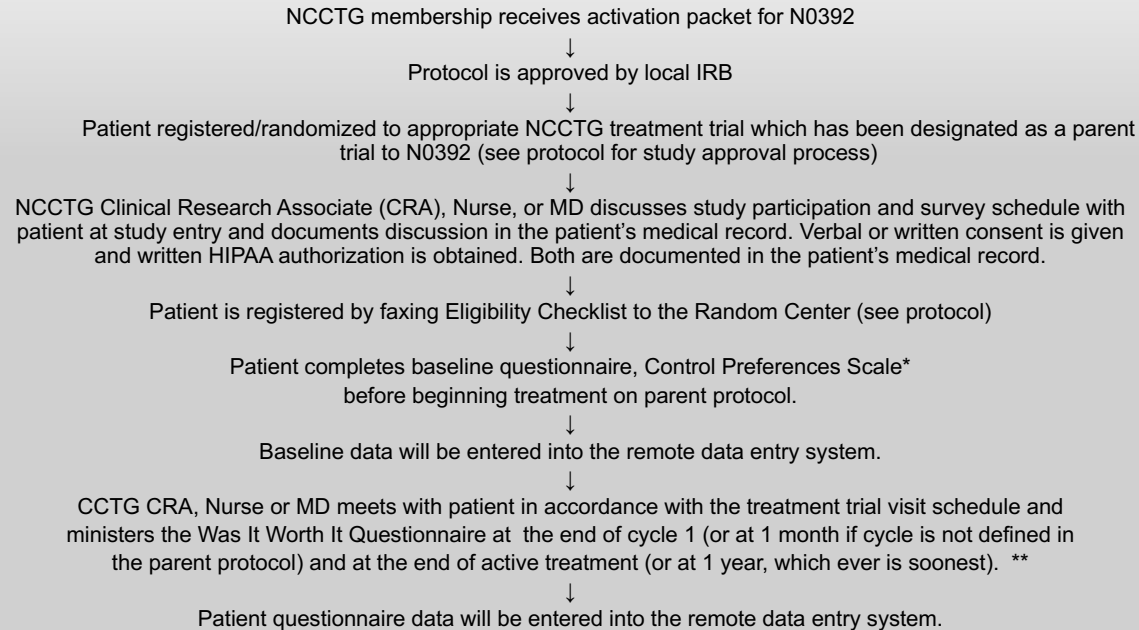
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Study Schema



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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Funding Support

N0392 (Alliance) is funded by the National Institutes of Health through National Cancer Institute grant awards.

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Contact Us

Study Chairs
Jeffrey A. Sloan, PhD
E-mail: sloan.jeff@mayo.edu
Phone: 507-284-3121

Protocol Coordinator: John R. Taylor, MA
E-mail: jtaylor1@uchicago.edu
Phone: 773-702-1767

Paul Schaefer, MD
E-mail: paul.schaeffer@utoledo.edu