



THE PROOF 302 TRIAL



Thank you for your interest in the PROOF 302 Trial. You may wish to share this guide with your primary care physician and specialists if you are interested in participating in this study.

PURPOSE OF THE PROOF 302 TRIAL

The purpose of this clinical research study is to evaluate if an investigational drug could prevent or delay urothelial carcinoma with genetic alterations on the *FGFR3* (fibroblast growth factor receptor 3) from returning after surgery.

Patients with *FGFR3* genetic alterations may be eligible for the PROOF 302 Trial.

ABOUT THE INVESTIGATIONAL DRUG AND THE COMPARATOR

The investigational drug, called infigratinib, is being compared to a matching placebo to evaluate its safety and effectiveness. A placebo is a dummy pill that has no medicine. “Investigational” means the drug is being studied by QED Therapeutics and study doctors, and that regulatory authorities (e.g., the US FDA [United States Food and Drug Administration]) have not approved infigratinib for use in patients. The safety and effectiveness of infigratinib have not been established. There is no guarantee that infigratinib will receive health authority approval or become commercially available in any country for the uses being investigated.

The PROOF 302 Trial is a blinded study, meaning that you and your study doctor will not know whether you are receiving infigratinib or the placebo.

KEY ELIGIBILITY CRITERIA

Eligible participants must:

- Be 18 years of age or older, any gender
- Have confirmed urothelial carcinoma with *FGFR3* genetic alterations
- Have a negative pregnancy test within seven days of the first dose of the investigational drug
- Not have had a recent transient ischemic attack or stroke within three months before the first dose of the investigational drug
- Not have clinically significant cardiac disease
- Be willing and able to comply with all study visits and study procedures

There are additional eligibility requirements, which the study doctor can explain to you. For a complete list of criteria for the PROOF 302 Trial, visit ClinicalTrials.gov and search code NCT04197986.

Individuals who do not have confirmed documentation of *FGFR3* genetic alterations will be offered molecular testing during prescreening to determine whether their tumor contains *FGFR3* genetic alterations.

STUDY DURATION

The PROOF 302 Trial consists of a screening period, a one-year (52-week) treatment period, and a follow-up period. The duration of participation in this trial could last up to approximately four years. The total length of time that participants are in the trial depends on how they respond to their assigned study treatment.

CARE DURING THE PROOF 302 TRIAL

Those who choose to participate in this clinical research study can still receive the same supportive care from their specialists and primary care physician. They will also receive care from a study team consisting of a specialized study doctor and other research site staff, regardless of what study treatment they are assigned to. The team will be available during the trial to answer questions or concerns, and to provide more information.

IMPORTANT INFORMATION ABOUT THIS CLINICAL TRIAL

Participants' health will be monitored by the study doctor and study team throughout their participation in the PROOF 302 Trial. There is no guarantee that being in this study will prevent or delay urothelial carcinoma from returning.

There may or may not be a direct benefit to you. What researchers learn from this study may provide information that could help the treatment of patients with urothelial carcinoma with *FGFR3* genetic alterations in the future.

Study participants will receive the study treatment, as well as study-related assessments, including laboratory tests and imaging, at no cost. Participants or their insurance company may be billed for any other healthcare costs, including those standard-of-care procedures that they receive while participating in the study.

For more information and to find a participating research site near you, please visit [QEDPROOF302.com](https://www.QEDPROOF302.com) or [ClinicalTrials.gov](https://www.ClinicalTrials.gov) and search the code, NCT04197986.