TPS11189 **Poster Session**

Falcon: Exact Sciences' multicancer early detection (MCED) real world evidence (RWE) registry.

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Background: Earlier detection may reduce cancer morbidity and mortality by reducing the number of cancers diagnosed at advanced stages. Exact Sciences is developing a blood-based MCED test to simultaneously screen for multiple cancer types, with test-positive patients undergoing diagnostic evaluation with radiological imaging. The Falcon registry is a large prospective study of Exact Sciences' MCED test in clinically cancer-free individuals who seek cancer screening. It will examine the uptake, diagnostic journey, adherence with guideline-recommended cancer screening, outcomes, and psychological impacts of MCED testing in a setting that closely resembles the real world, with results expected to be broadly generalizable.
Methods: Falcon is a multi-site registry that is enrolling up to 25,000 participants who receive the MCED test annually for three years (MCED cohort). A comparison cohort of up to 50,000 patients receiving standard-of-care clinical management only (SOC cohort) will be retrospectively constructed via a deidentified data pull. Both cohorts will include individuals 50 to 80 years of age presenting for primary care services who have no history of malignancy within the prior 3 years or current suspicion of cancer. SOC cancer screening will continue in the course of standard care and will not be proscribed or interrupted by study participation. The MCED cohort will include a 10,000-participant pilot cohort and up to a 15,000-participant expansion. This cohort will include individuals who provide informed consent for MCED testing and follow-up IV-contrast computed tomography (CT) and, if necessary, positron emission tomography-CT (18F FDG PET-CT) imaging following a positive MCED test. Clinical contraindications for radiological imaging (e.g. pregnancy, IV contrast allergy, renal failure) will be taken into consideration when making the decision to participate. The SOC cohort will be selected after enrollment of each MCED cohort phase and will be matched based on demographic and clinical characteristics. Self-reported measures of anxiety, cancer worry, and trauma will be collected from all MCED cohort participants routinely throughout the study. Data will be collected for up to 5 years following the baseline test or, for the SOC cohort, following an index date. Periodic automated extraction of pre-specified data elements from existing electronic data sources, primarily medical records and tumor registries, will be collected from all participants. Clinical trial information: NCT06589310. Research Sponsor: Exact Sciences Corporation.