The aim of the Ascertaining Serial Cancer patients to Enable New Diagnostic 2 (ASCEND-2) study is to develop a classifier algorithm for a refined version of a multi-analyte blood-based MCED test.

Here, we report the study design, enrollment, and sample selection from the ASCEND-2 study.

**Study Design**

ASCEND 2 is a multi-center, prospective, case-control study of clinically characterized participants. One hundred fifty-one sites within the US and Europe were engaged for subject enrollment. Samples consisted of blood collected using LBgard® tubes for plasma and Buffy coats.

The study population includes male and female subjects ≥50 years old with known cancer, suspicion of cancer, and controls without suspicion of cancer. All subjects provided informed consent and were assessed for study participation eligibility.

**Enrollment**

Over 11,000 subjects were enrolled in this study. A subset of 6354 samples was selected to develop and refine a multi-analyte cancer detection classifier. The subset includes 1438 cancer subjects, from 21 organ sites (Enrollment and SEER Incidence Table) reflective of US cancer incidence by tumor type, and 4916 age-matched subjects without suspicion of cancer. Demographics are reported in the Demographics Table.

Relative to SEER incidence, the study enriched for lung cancers. Similarly, breast and prostate cancers were de-prioritized. These adjustments reflect cfDNA shedding rates and the expected clinical utility for MCED in these cancer types.

Cancer types were selected in approximately equal proportions for stage I-IV to power cancer staging performance assessment.

**Background**

Cancer types were selected in approximately equal proportions for utility for MCED in these cancer types.

**References**


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**Disclosure:** Christopher Douville is an inventor on some technologies. Licenses to these technologies are or will be associated with equity or royalty payments to the inventors as well as to Johns Hopkins University. CD is a consultant with Exact Sciences. The terms of these arrangements are being managed by Johns Hopkins University in accordance with its conflict-of-interest policies. He is also the founder of Belay Diagnostics.