

CASE STUDY

Real-World Informed Interventional Clinical Trial

Ciox RWD, Brown University, American College of Radiology Imaging Network, and the National Lung Screening Trial



Background

The National Lung Screening Trial (NLST) compared 2 ways of detecting lung cancer: low-dose helical computed tomography (CT) and standard chest X-ray. Both had been used as early diagnostic techniques for lung cancer, but the impact of these screening techniques on lung cancer mortality rates had not been determined. The NLST enrolled 53,454 current or former heavy smokers from 33 sites and coordinating centers across the US.

Challenges

Brown University needed to complete a large-scale effort to access and analyze medical record data for thousands of study participants at healthcare providers across the US. One of the largest hurdles to real-world evidence creation is navigating and structuring complex, unstructured, and, in many cases, nondigital source data. Today, researchers struggle even when the data are available in an electronic medical record (EMR) because¹:

- 75% of hospitals in the US have at least 10 EMRs in place, 18 EMRs for health systems
- Only 2% of hospitals have 2 or fewer EMRs
- The top 5 acute EMR vendors (Epic, Cerner, Meditech, Allscripts, CPSI) averaged more than 200 EMR systems used with providers affiliated with their clients

In addition, based on Ciox RWD's experience, some studies require access to over 400 systems including registries, departmental systems, EMRs, laboratory systems, diagnostic imaging systems, genetic databases, etc.

In speaking of the complexity of the data challenge ahead of the NLST,

Ciox took on the challenge and brought it to fruition with remarkable resourcefulness, flexibility, and professionalism.

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Data Collection and Analysis

Brown turned to Ciox RWD for its specialized ability to develop analysis-ready, fit-for-purpose data sets at scale. Each selected participant's medical data were accessed, structured, and analyzed, many across multiple time intervals. Outcomes intervals commonly spanned time periods of 6 months to a year. Review of these records was triggered by an initial clinical trial screening, annual follow-up screenings, or more regular visits for medical care. Each outcomes interval report focused on a single patient, and a patient's medical record may have been reviewed for 6 or more reported intervals over the course of the 8-year study. Ciox RWD's team worked with Brown University and the study sponsor, the American College of Radiology Imaging Network (ACRIN), to:

- Map key data elements from clinical source systems into a common data model
- Structure and standardize nonstandard, unstructured data of study participants' encounter, hospitalization, diagnosis, and procedure data using ICD-9-CM, ICD-10, CPT, and ICD-O coding schemas
- Share best practice quality assurance activities and refine for purpose as needed
- Take accountability for quality assurance, security, and confidentiality and HIPAA compliance
- Provide critical expertise from certified cancer registrars, medical coding experts, health information access experts, and research managers
- Supply standard and weekly reporting on site productivity, issues and corrective actions, and amendments

Results

In November 2010, the initial findings from the NLST were released. These findings revealed that participants who received low-dose helical CT scans had a 20% lower risk of dying from lung cancer than participants who received standard chest X-rays. Due to these findings, Medicare and other payors changed their coverage policies to include the cost of lung cancer screening for beneficiaries who meet certain criteria. Ciox RWD played a critical role throughout the study, developing a clean, research-grade data set on time and within budget.

Data products created through Ciox DataFit Platform™ help researchers stay focused on key analyses and foster trust in the lineage and quality of the inputs. Together, Ciox RWD, Brown, and ACRIN could send a regulatory-grade real-world evidence product to US Health and Human Services with confidence that the findings supported an improved clinical pathway for patients.