Background

- Minimal residual disease (MRD) is a potential biomarker for predicting disease relapse or therapeutic response for lung cancer, and it is expected to establish a precise detection system by liquid biopsy.
- We have been conducting a prospective observational study to evaluate the clinical utility of MRD detection in lung cancer (LC-SCRUN-MRD) since August 2022, in parallel with a multicenter prospective genomics screening project (LC-SCRUN-Advantage) in Japan (Figure 1).

**Figure 1. Trial outline**

**LC-SCRUN-Advantage**
- Diagnosis
- Systematic targeted Therapy
- Surgery
- Adjuvant Therapy
- MRD analysis
- Baseline tumor marker
- Tumor marker
- Monitoring of MRD by LCSM
- CT scan
- Tumor marker

**LC-SCRUN-MRD**
- ctDNA assessment
- MRD analysis (Tissue/Liquid)

Inclusion criteria

- Pathologically diagnosed treatment-naïve lung cancer.
- 16 years of age or older.
- Performance status 0-2.
- Normal organ function and life expectancy of at least 3 months.

**Study design**

<table>
<thead>
<tr>
<th>Table. Cohorts of LC-SCRUN-Advantage/MRD</th>
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<tr>
<td><strong>Cohort</strong></td>
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- A total of 10,680 patients in LC-SCRUN-Advantage/MRD will be enrolled over five years and assigned to one of six cohorts (A1 to B2) according to their histology, stage, and treatment (Table).
- In the genomic screening cohorts A1 and A2, we will perform a multi-gene PCR panel using biopsy specimens obtained at initial diagnosis and targeted next-generation sequencing using surgical specimens. In addition, PD-1 staining (22C-3) will be performed on both the biopsy and surgical specimens (Figure 2).

**Figure 2. Work flow in LC-SCRUN-Advantage/MRD**

- In the MRD monitoring cohorts A2-B2 of 680 patients, we will analyze MRD every 1-6 months for up to 2 years, and computed tomography scans and serum tumor markers measurement will be performed at each time point (Figure 3).

**Figure 3. MRD monitoring schedule**

- As for MRD analysis, we will perform MRD detection systems that require sequencing of tumor tissue to create personalized plasma ctDNA assay and liquid only MRD detection systems that analyze plasma ctDNA by methylation profiling.

**Summary**

- As of September 2023, a total of 266 patients have been enrolled in LC-SCRUN-Advantage/MRD (UMIN000048977) across 69 institutions (Figure 4).

**Figure 4. Patient enrollment**

- To clarify the clinical usefulness of the MRD detection system in lung cancer.
- Incorporating new MRD assays from various companies, we evaluate the performance of the MRD detection system in lung cancer.

**Acknowledgment**

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**Disclosure information**

The presenting author (S. Kitagawa) report no declarations of interest.

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Correspondence to s-kitagawa@nms.ac.jp