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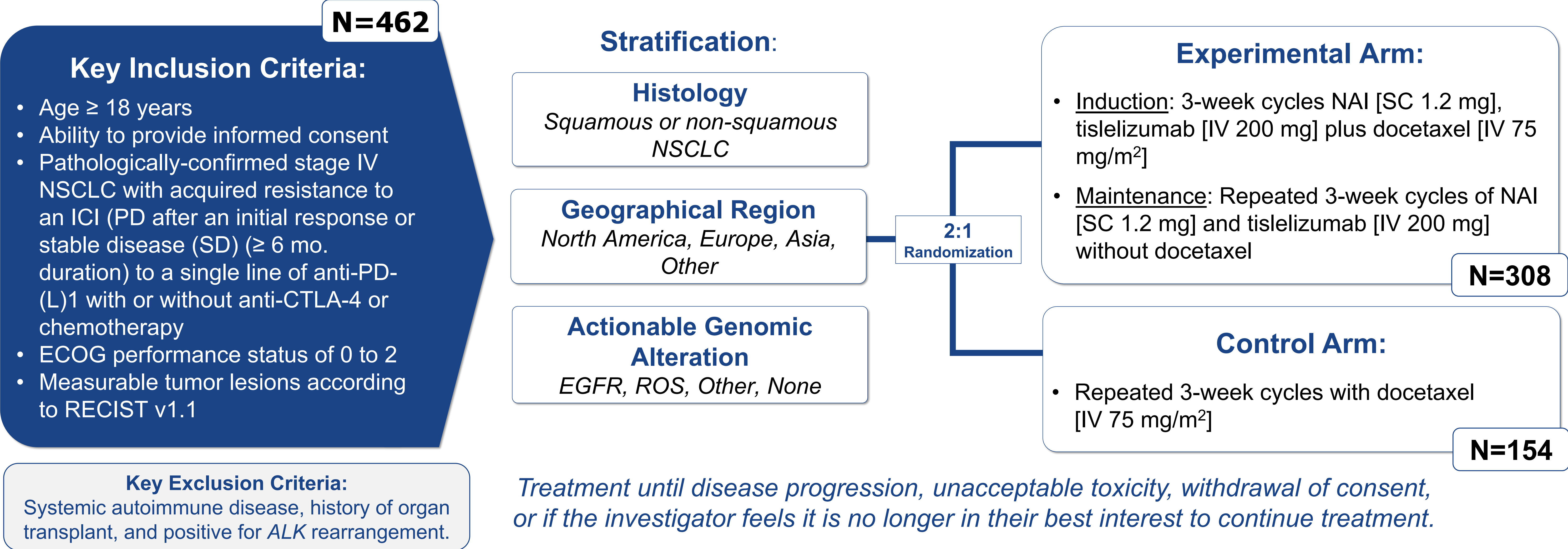
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BACKGROUND

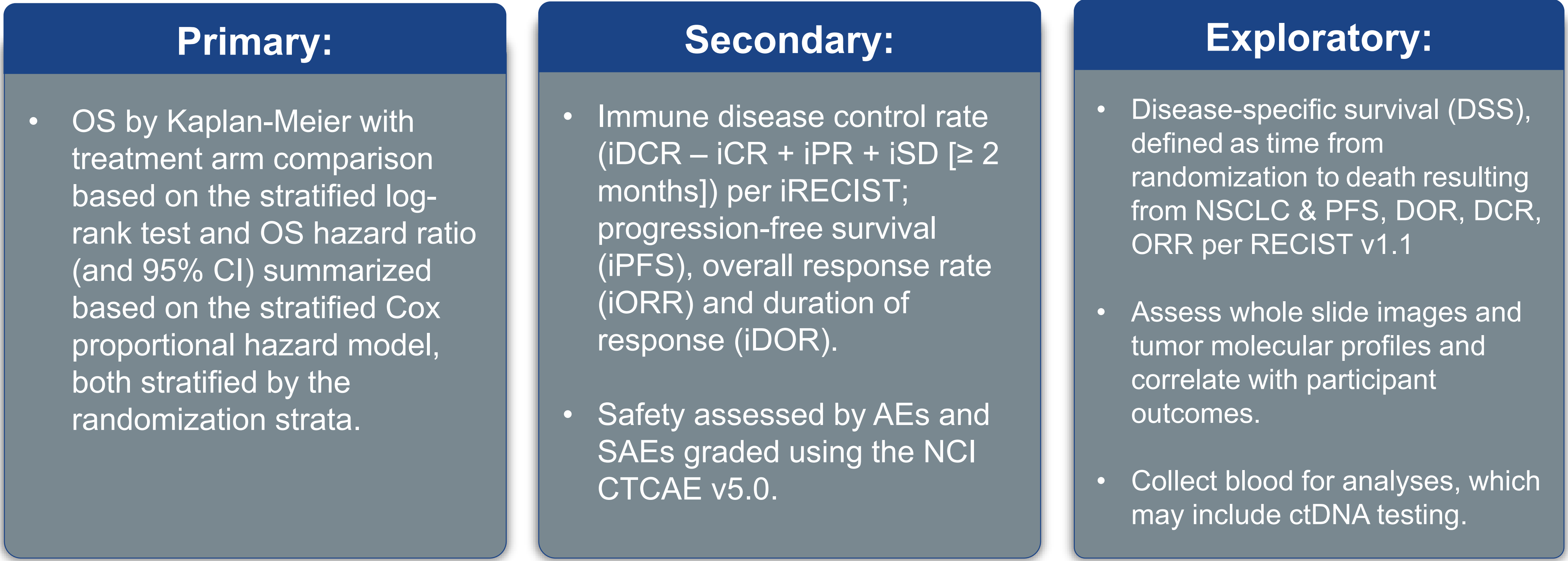
- Immune checkpoint inhibitors (ICIs) that target PD-1 or PD-L1 are approved for use as monotherapy and in combination with chemotherapy in advanced NSCLC. Unfortunately, most patients experience progressive disease with limited treatment options, warranting better options following progression on an ICI.
- Findings from Phase 2 studies have demonstrated the potential for the IL-15 receptor superagonist nogapendekin alfa inbakicept (NAI; or N-803) as a novel lymphocyte stimulating agent (LSA) to enhance ICI efficacy, prolonging progression-free survival (PFS) and overall survival (OS) when used in combination with an ICI.^{1,2}
- ResQ201A⁵ is informed by the QUILT-3.055 trial wherein mOS was prolonged with NAI at 14.3 months overall among NSCLC patients. Most patients (80%) exceeded and/or maintained an ALC of 1,200 cells/μL which was associated with prolonged mOS compared to patients who failed to achieve ALC>1,200 cells/μ (mOS 15.8 months vs. 11.5 months, [p=0.0057]) and over half of NSCLC patients (60%) treated with NAI experienced lymphopenia reversal during treatment.⁶
- In ResQ201A, monotherapy docetaxel, standard 2nd-line therapy for NSCLC, is being compared to combination therapy with NAI, anti-PD-1 tislelizumab, and 2 cycles of docetaxel.⁴
- NAI proliferates and activates NK and T cells² and is anticipated to contribute to the efficacy of docetaxel plus tislelizumab therapy in ICI-resistant NSCLC and prolong survival as shown in QUILT-3.055 when administered without chemotherapy.

TRIAL DESIGN

Randomized, Open-label, Phase III Clinical Trial of N-803/NAI Plus Tislelizumab and Docetaxel versus Docetaxel Monotherapy in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer who have Acquired Resistance to Immune Checkpoint Inhibitor Therapy⁵



ENDPOINTS



REFERENCES

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2. NAI Package Insert, FDA April 2024 – Section 12.1 Mechanism of Action.
3. Wrangle, J. 2024, September 8. QUILT 3.055 IL15 Superagonist (N-803, Anktiva) + Checkpoint Inhibitor (CPI) Prolongs OS in 2nd Line or Greater NSCLC Patients Failing CPI. 2024 World Congress on Lung Cancer, San Diego, CA.
4. Wang 2021 JAMA Oncol 7.
5. ResQ201A: Clinical Trial Of N-803 Plus tislelizumab and Docetaxel Versus Docetaxel Monotherapy In Participants With Advanced Or Metastatic Non-Small Cell Lung Cancer (ClinicalTrials.gov identifier: NCT06745908)
6. Soon-Shiong, P. 2025, September 7. NAI, an IL-15 Superagonist, a New Class of Lymphocyte Stimulating Agent (LSA) Prolongs OS in NSCLC by Reversing Lymphopenia. 2025 World Congress on Lung Cancer, Barcelona, Spain.



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