ECOG-ACRIN
cancer research group
Reshaping the future of patient care

EMORY
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Review of Active ECOG Clinical Trials

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Robert J. Ginsberg Clinical Trials Day
General Thoracic Surgery Club
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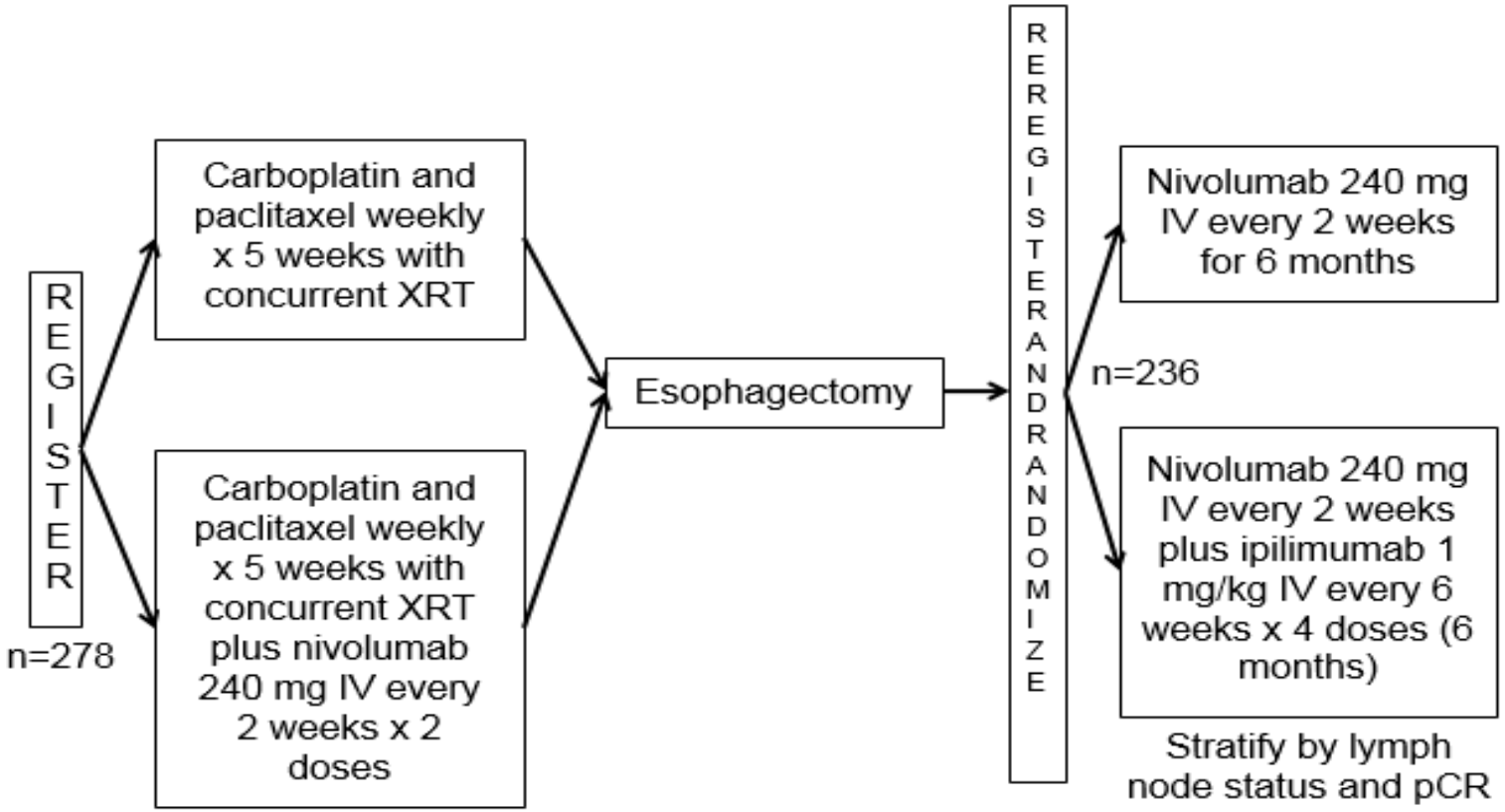
EA2174: A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma



Neoadjuvant Primary Endpoint: pathologic complete response rate

Adjvuant Primary Endpoint: disease free survival

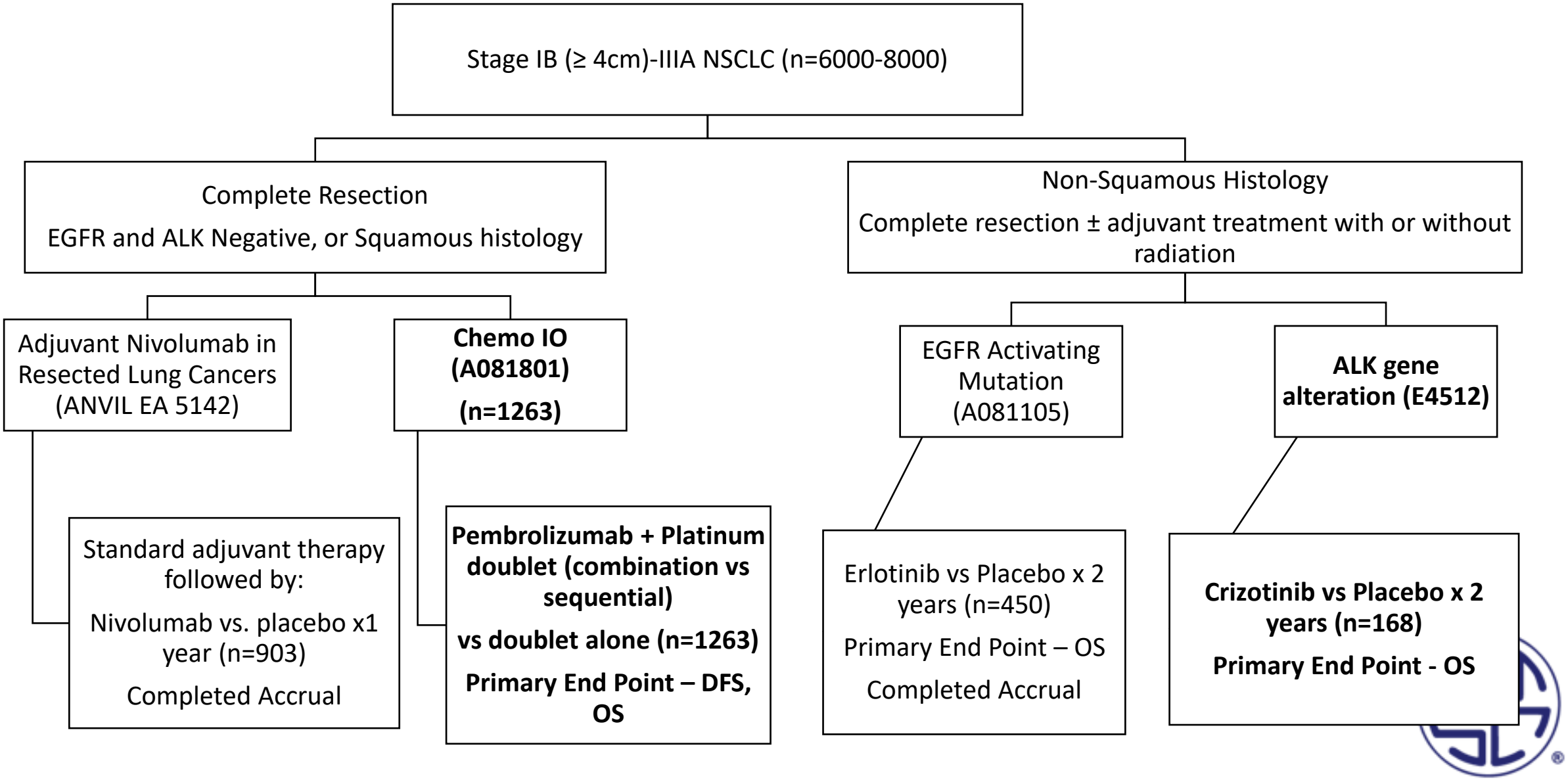
Eligibility

- Histologically confirmed esophageal or GEJ (Siewert I or II) adenocarcinoma
- Must have a T1N1-3M0 or T2-3N0-2M0 cancer and be deemed a surgical candidate by a surgeon
- No contraindication to receiving carboplatin, paclitaxel, nivolumab, ipilimumab or radiation
- No prior therapy for this disease
- No prior immunotherapy for any other disease
- No chronic immunosuppressive therapy or underlying autoimmune disease
- Normal marrow, renal and hepatic function

Eligibility

- ECOG PS 0-1
- Greater than or equal to 18 years of age
- Must not have a positive test result for HepB or HepC virus
- Must have tissue available for PD-L1 and MSI testing
- May not be receiving any other investigational agent
- Must not have an uncontrolled intercurrent illness
- May not be pregnant or lactating

A151216: ALCHEMIST Screening Trial

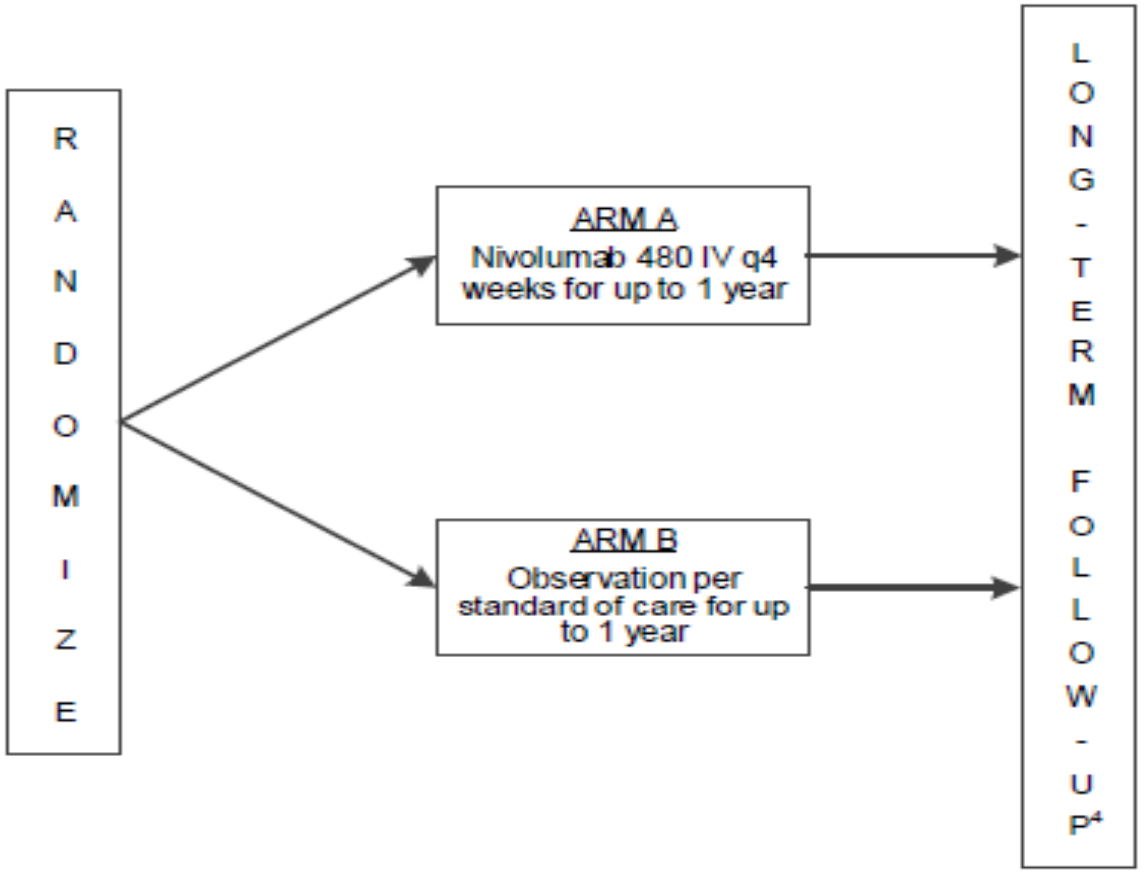


After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers

Schema

Eligibility
- Patient registered to ALCHEMIST screening trial (A151216)
- If non-squamous, no ALK rearrangement or EGFR Exon 19 deletion/Exon 21 L858R mutation
- No contraindication to nivolumab

Stratification
- Stage AJCC 7th edition: IB/IIA vs IIB/IIIA[1]
- Histology: squamous vs. non-squamous[2]
- Prior adjuvant treatment for lung cancer (none vs. chemotherapy vs. chemotherapy + radiation)
- PD-L1 status: positive (≥ 1%) vs. negative (< 1%)/non-evaluable) membranous expression determined centrally[3]



Cycle = 4 weeks (28 days)
Accrual Goal = 903 patients

1. If Stage 1B, then tumor must be ≥ 4cm
2. Adenosquamous should be grouped as non-squamous
3. PD-L1+ is defined as ≥ 1% by IHC
4. Patients will be followed for recurrence and survival for 10 years