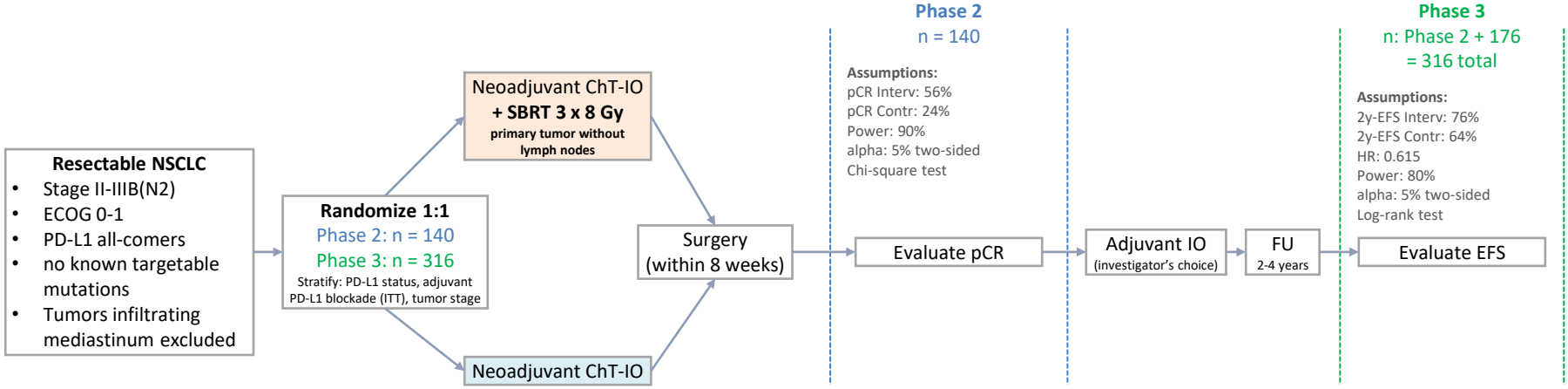
Focus-PRIME (ARO v2024-05): **Focus**ed **P**recision radiotherapy with neoadjuvant **Im**munochemotherapy and R**e**section of NSCLC

Multicenter, randomized, seamless phase 2/3 trial

Hypothesis

1. Adding **SBRT to neoadjuvant ChT-IO** raises **pCR** to 56% from 17-24% with ChT-IO only (SACTION-01 phase 2 trial) [1]
   - SBRT delivered to **primary tumor only without mediastinal lymph nodes** has an immunomodulatory effect and avoids toxicities.
2. **Improved pCR** translates into **improved EFS** (95% 2y-EFS for patients with pCR in Checkmate-816) [2]



Study Timeline:
Recruitment: 36 months
Minimum Follow-up: 24 months
Maximum Follow-up: 48 months
Flexible Follow-up
FPI to LPO: 60 months

Primary endpoint:
1. Phase 2: **Pathological complete response**
2. Phase 3: **Event-free survival**

Secondary endpoint(s):
1. Major pathological response (MPR)
2. Overall survival (OS)
3. Explorative and translational analyses
4. Patient-reported Outcomes (Quality of Life, Patient-reported toxicity, Patient Satisfaction)

Assessment of safety:
1. Safety and adverse events
2. Treatment completion rate and surgical outcomes

- **Project Lead:** Prof. Dr. R. El Shafie (Radiation Oncology, Göttingen)
- **Lead Investigators** (in alphabetical order):
  - Prof. Dr. Frank Griesinger (Thoracic Oncology, Oldenburg)
  - Prof. Dr. Ursula Nestle (Strahlentherapie, Mönchengladbach)
  - Prof. Dr. Stefan Rieken (Strahlentherapie, Göttingen)
  - Prof. Dr. Michael Thomas (Thoracic Oncology, Heidelberg)
  - Dr. Fabian Weykamp (Radiation Oncology), Heidelberg)
  - Prof. Dr. Hauke Winter (Thoraxchirurgie, Heidelberg)

References:
1. Zhao et al., ASCO 2023, doi:10.1200/JCO.2023.41.16_suppl.8540
2. Deutsch et al., Nat Med. 2024 doi:10.1038/s41591-023-02660-6