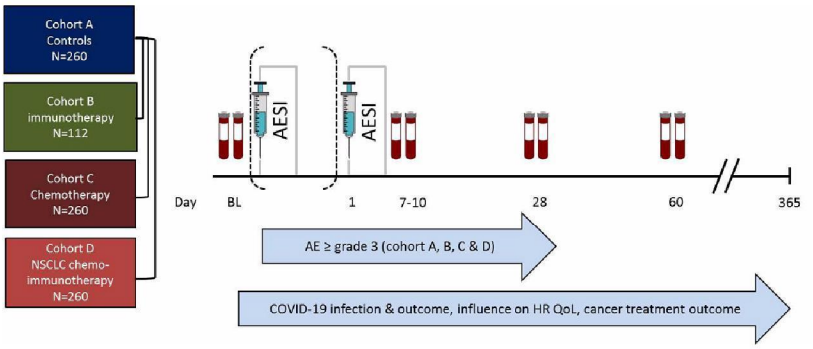
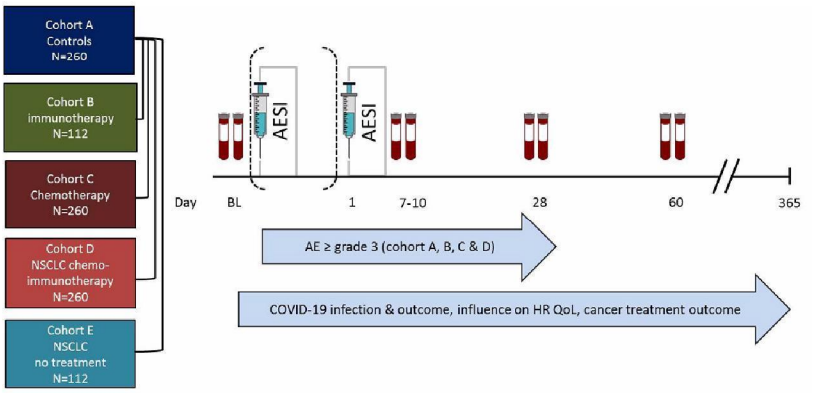
Trial design with 4 cohorts



Trial design with 5 cohorts



Items to discuss:

Design

-design with 4 or 5 cohorts? If 4 cohorts: can chemoimuunotherapy cohort be open for other tumor types than NSCLC? (HNSCC)

-for the chemotherapy cohorts, can we vaccinate regardless of chemotherapy timing?

In- and exclusion criteria

-agree to exclude patients who have had COVID-19 or a high suspicion? How do we define high suspicion?

-immunotherapy and chemo-immunotherapy cohort: agree that patients should be on treatment for at least 9 weeks?

-agree that controls do not have to be completely healthy, but should not have had cancer?

- include patients with high dose/accelerated chemotherapy? (those who are treated G-CSF)

Outcome response to vaccination

-proposal to define responders as individuals who have seroconversion: increase by a factor 4 or more in antibody titer over baseline, agree? Can be changed later as long as we can separate responders from non-responders

- to collect information on COVID symptoms, COVID infection, severity: existing (validated) instruments from ongoing studies available? Who can help with that? (If not we could ask VAC4EU if they prepare a tool or use LifeLines questionnaires,)

Adverse events

-is 1 week after vaccination enough to collect AESI's?

-agree to record all grade ≥3 AE's in patient cohorts up to 30 days after last vaccination?

- do we want to involve Mirjam Sturkenboom and (10)(2e) (10)(2e) from UMCU, who lead European initiative to harmonize definitions, codes and algorithms to identify adverse events of special interest?

- stopping rule not feasible if we complete vaccination in 6 weeks: weekly list of AESI's and SAE's to be reviewed by a DSMB?

QoL

-do we want to investigate impact of COVID on HR-QoL? If yes, agree to have the uploaded questionnaire translated?