Agenda

1. Primary endpoint
2. Serology
   - How often
   - Which timepoints
3. Adverse events
4. Study name

Primary endpoint

Symptomatic SARS-CoV-2 infection

- Positive SARS-CoV-2 test
- Based on testing policy in NL, so no active testing
- Reason for testing was symptoms

Asymptomatic infections (e.g. because of testing because of contact or based on serology) → secondary endpoint

Serology

- Goal: to detect previous infections which were not detected by PCR/antigen test (because of not testing or because of asymptomatic)
- Important because:
  - VE may be dependent on previous infection
  - Vaccination may influence testing behaviour
- Which time points:
  - Independent of vaccination → e.g. baseline, 6 months, 12 months
  - Dependent of vaccination → e.g. 1 month, 6 months, 12 months after vaccination

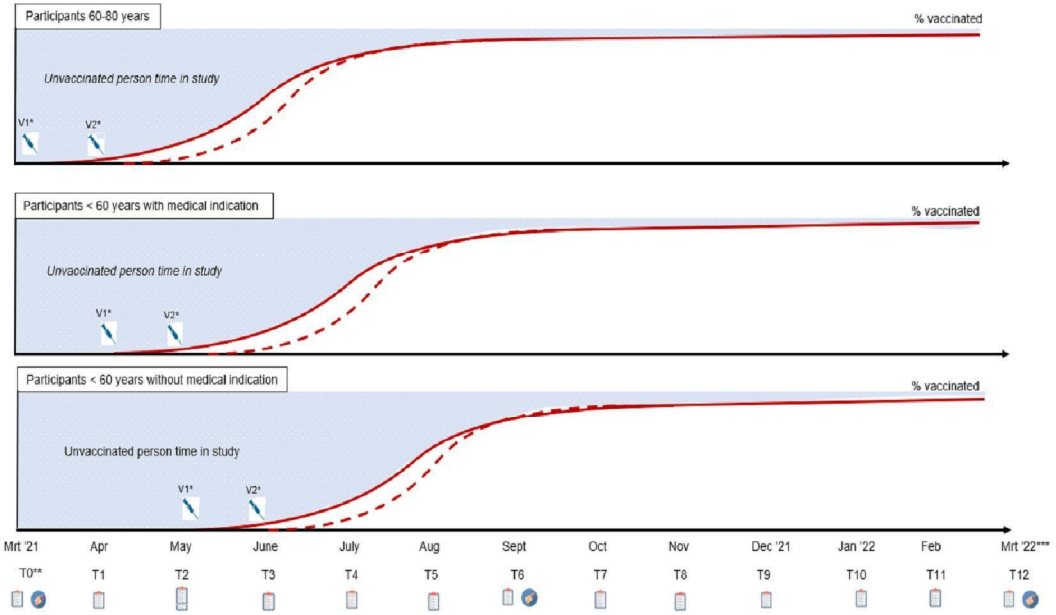
Independent of vaccination

PROS

- Goal is detection of previous infections; not response to vaccination
- Vaccinated and unvaccinated sampled at same time

CONS

- No sample at fixed time after vaccination to determine vaccination response, which would be useful for substudies into breakthrough infections



* Vaccin strategy according to Rijksoverheid
** Start study for individual participant. T=time in study.
Participants can enter the study (T0) between Mrt and May 2021.
*** After this period a follow-up questionnaire will follow every 3 months.

When to analyse fingerprick samples

- 'directly' after collection → feedback to participants (incentive)
- At primary VE calculation (=9 mo after start study)

Adverse events

- ACCESS protocols
  - Cohort event monitoring
    - Solicited events (common side effects / reactogenicity) → Lareb
    - Unsolicited events → open question on possible side effects
    - 5 wks, 8 wks, 3 mo, 6 mo
  - AESI
    - Linkage of registration databases

Study name

- Co-prik
- Quovac.nl (van quo vadis?)
- Cocovax (contre Corona vaccinatie)
- Covac.nl
- CATCH
- ECOVAC-21
- VECOVAC-21
- VASCO (vaccine study COVID)
- COVFF (covid vaccinatie effect)