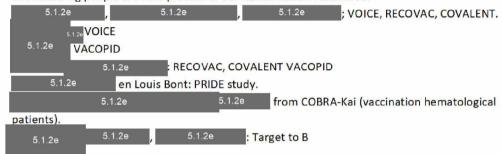
Harmonisation Task force meeting ZonMw SARS-CoV-2 vaccination studies Date of meeting: 9 februari 2021, 21.00



Agenda and report::

1. Round of introduction:

The following people are now present in our harmonisation taskforce:



2. General updates:

Taskforce; our harmonisation Taskforce coined Harmony is decided by all to be a meeting between the ZonMw-financed consortia that will perform SARS-CoV-2 vaccination studies. This to keep it a focused taskforce and also to keep it clear which groups will join.

Update CCMO; 5.1.2e explains that he got approval by the CCMO within 24 hours after getting into contact with him. CCMO mentioned that the approved studies do not need to go via them and that those studies can stay as it when they have been approved.

3. Introduction of cellular assays:

PRIDE and COBRA-Kai are at the stage of setting up.

VOICE, RECOVAC, COVALENT VACOPID will use:

- whole blood assay (heparin): IFN-g release assay will be used. Assay uses whole blood stimulation with Spike protein during 24 hours of incubation and read-out via ELISA. Eurimmune and Qiagen WB IFN-g release assay were compared. Qiagen assay was found to be the best and will be used. In VACOPID EuroImmune wil be used by several partners due to supply problems. The advantage of this assay was also that it already tried after 1 Pfizer vaccine in healthy donors 2 weeks after vaccination and that worked fine.
- · Antigen-specific B cell deep phenotyping (recovac, memory b cell elispot and flowcytometry)
- Antigen-specific CD4/CD8; peptide pool stimulations using elispot and deep phenotyping (including activation markers and cytokines) by flowcytometry. Within recovac and Target to B also tetramer staining (HLA type known)

Target to B will use:

- whole blood assay; deep phenotyping of subsets CD4 Th/Treg/CD8 T cells, B cells and plasmablasts will be performed and some general monocyte/NK markers on fresh whole blood.
- Antigen-specific B cell deep phenotyping or Antigen-specific B cell ELISPOTs (depending on subcohort and most urgent research question for that cohort)
- Antigen-specific CD4/CD8 cell analyses; peptide pool stimulations and deep phenotyping (also cytokines). Possibly MHC I tetramer analyses for CD8.

4. Harmonisation cellular assays:

A large difference is that VOICE, RECOVAC, COVALENT VACOPID will analyse cells at day 28 after boost and Target to B at day 7-12 after boost. We can't help that we will analyse at different time points, but see it as an opportunity to will learn when we compare the first data of all trials. We then can use this comparison to optimise future analyses (i.e. choose best performing ones in terms of COP or biomarker of dynamics of immune response) and further integrate our consorted actions. For instance, we can optimise our combined assays for immune monitoring when reboosting with variant vaccine needs to be implemented.

Items/topics that we identified that we can compare now for the planned cellular assays;

- Antigens to be used for the antigen-specific B cell assays (assess where we get antigens from and assess if we can analyse if antigens from different companies yield different results).
- Method for Ag-specific B cell analysis and basic marker panel.
- Peptide pools for CD4 T cell stimulations.
- Peptide pools for CD8 T cell stimulations.
- Method for Ag-specific T cell analysis and basic marker panel. Pro memori; discuss signals due to crossreactivity.
- Compare Qiagen Whole Blood IFN-g data with and cytokine stain of peptide-stimulated T cells
 assays of frozen cells. IFNg should me more or less similar 7-12 days or 28 days after boost.
- Compare IL-21 ELISPOT Rotterdam 28 days after boost to CD4 T cells to IL-21 cytokines TtB 7-12 days after boost.

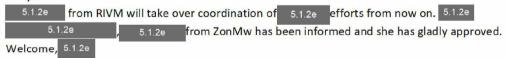
4. Wyttk

Sometimes it helps to team up with different groups when placing orders for materials in for instance China. So, we agree to inform each other about logistic problems and/or opportunities.

Tips:

- Sometimes within each institute plastics have also been prioritized within the institute. Make sure that you get high on that list.
- 50 ml tubes are becoming a problem, as several consortia found out. Sepmate tubes from stemcell seem to be a good solution and are still available: https://www.stemcell.com/products/brands/sepmate-pbmc-isolation.html

6. Update



Next meeting Tuesday March 2, 16.00. 5.1.2e has sent invite.

After this meeting we will meet on Thursdays at 16.00, as we all can make it for that time.