



Corona Immunitas Phases 5 and 6

-

Central Database Documentation

Corona Immunitas Research Group

Marco Kaufmann

Contact:

Swiss School of Public Health

(coronaimmunitasdata@ssphplus.ch)

Last updated 26.04.2023

This documentation is describing the database of the Corona Immunitas Phases 5 and 6 study registered under [10.5281/zenodo.7520125](https://doi.org/10.5281/zenodo.7520125). The study is the continuation of the Corona Immunitas Phases 1 to 4 study ([10.5281/zenodo.7520050](https://doi.org/10.5281/zenodo.7520050)) with a similar but not identical structure. For information regarding data availability, the reader is referred to the **Availability of Data** document (see [Appendix](#)).

The central database documentation consists of two major parts. The first, [Corona Immunitas - Study Description](#), will give a brief introduction to the study, participating sites and timelines. The second, [Corona Immunitas - Data Description](#), will explain the data and availability.

Contents

1	Corona Immunitas - Study Description	1
1.1	General Concept	1
1.1.1	Corona Immunitas Phases 1 to 4	1
1.1.2	Study Participant Enrolment	1
1.1.3	Study Procedures	1
1.1.4	Organisation and Governance	2
1.1.5	Technical Infrastructure, Privacy Protection, and Data Quality	2
1.1.6	Ethics	3
1.1.7	Further Information	3
1.2	Participating Sites	4
1.2.1	Ticino	4
1.2.2	Vaud	4
1.2.3	Zurich	5
2	Corona Immunitas - Data Description	6
2.1	Baseline	6
2.2	Serum	7
2.3	Second Study Visit	7
2.4	Digital Follow-Up	7
3	References	8
A	Appendix	9
A.1	Referenced Documents	9

1 Corona Immunitas - Study Description

1.1 General Concept

1.1.1 Corona Immunitas Phases 1 to 4

Corona Immunitas Phases 5 and 6 was mixture of continuation and successor study to Corona Immunitas Phases 1 to 4. While trying to maintain compatibility with study phases 1 to 4, phases 5 and 6 contained four major differences:

- The study was set up as a cohort study, so the same participants were assessed in phases 5 and 6.
- Only one site per language region was involved.
- The study only contained six *Digital Follow-Up* questionnaires which were asked approximately every two months (9 weeks apart).
- Questions and variables were reduced and adjusted according to the existing SARS-CoV-2 situation as well as experiences from study phases 1 to 4.

For more information regarding Corona Immunitas Phases 1 to 4, the reader is referred to the [Corona Immunitas Phases 1 to 4 documentation](#).

1.1.2 Study Participant Enrolment

Study participants were enrolled into the study in March 2022 (phase 5) in Ticino and Zurich and in June 2022 (phase 6) in Vaud. The participants were randomly selected within four age strata (16-29, 30-44, 45-64, 65+) from the population registry of the respective canton by the Federal Office of Statistics. Participants self-selected in the study.

1.1.3 Study Procedures

The assessment started with the completion of the *Baseline* questionnaire at home which covered topics such as socio-demographic and economic characteristics, health status, information on previous SARS-CoV-2 infections, adherence to recommended public health preventive measures, SARS-CoV-2 vaccination and post-covid condition. Then participants were invited to a baseline visit at one of the study centres for blood sampling. Consent was given in written on site, and trained study personnel was at disposal in case of questions. If someone filled the *Baseline* questionnaire but did not fill the informed consent on site (e.g., no appointment booked), this person was not included in the study and all related information, including the questionnaire, was deleted. In June 2022 (phase 6), participants of Ticino and Zurich were invited for a second blood sampling and filled a brief *Second Study Visit* (SSV) questionnaire updating SARS-CoV-2

infection and vaccination information since the baseline assessment.

Six *Digital Follow-Up* (DFU) questionnaires were an integral part of the study and provided, as the name says, digital follow-up information. Participants received the survey links via e-mail approximately two months after the median of the first assessment period (DFU 1: 13.05.2022) and consequently approximately every two months (9 weeks apart) (DFU 2: 15.07.2022, DFU 3: 16.09.2022, DFU 4: 18.11.2022, DFU 5: 20.01.2023, DFU 6: 24.03.2023). Two reminders after 5 and 10 days were sent and the questionnaires were available for 15 days. The questionnaires were only available in one language per site (Ticino: Italian, Vaud: French, Zurich: German). Participants in Vaud only participated from DFU 3 on due to the later enrolment. The DFU questionnaires covered topics such as SARS-CoV-2 tests and symptoms, adherence to recommended public health measures, consequences of the pandemic, SARS-CoV-2 vaccination and post-covid condition with a time-frame of the previous two months.

The original study protocol only included four *Digital Follow-Up* questionnaires. To extend the follow-up, participants were asked in December 2022 to opt-in for two additional questionnaires (DFU 5 and DFU 6).

1.1.4 Organisation and Governance

A working group including site representatives and members of the central data management team was responsible for questionnaire development and definition of core study instruments, based on core scientific goals of Corona Immunitas and questionnaires which were used in Corona Immunitas Phases 1 to 4. In line with Corona Immunitas' decentralized nature, individual study sites were responsible for hosting their own research data in REDCap, delivering surveys and conducting the on-site study assessments.

1.1.5 Technical Infrastructure, Privacy Protection, and Data Quality

Maintaining privacy, data security, and data quality were top priorities of Corona Immunitas. All sites operated the REDCap data collection system to capture and manage research data. REDCap is a Health Insurance Portability and Accountability Act (HIPAA)-certified, open-source data management platform, which separates identifiable from pseudonymized research data and allows to manage and automatically schedule invitations to online surveys.^(1,2) The data were collected through the standard REDCap web application interface, which allowed to complete the surveys on any internet-connected device with an internet browser. REDCap also facilitated the implementation of quality control measures already at data entry, such as range checks, mandatory fields, and branching logics. All questionnaires were implemented in Zurich and consequently shared with the other study sites. This ensured complete harmonisation of questionnaires.

In order to protect privacy, direct communication with participants only occurred via local sites, and the research data were captured and stored in REDCap hosted by local university IT services. Regular exchanges of

pseudonymised research data enabled the central data management to assemble a central database containing all information. Due to the harmonisation of the questionnaires, the data curation efforts were minimal. Obviously wrong information was either rectified, where clear, or set to missing. All steps to create the final central database of Corona Immunitas Phases 5 and 6 from the raw research data have been documented. Raw data has never been altered, except an exchange with the participant permitted it.

1.1.6 Ethics

Corona Immunitas has been approved by the responsible ethics committees (Ticino: BASEC 2020-01514; Vaud: BASEC 2020-00887; Zurich: BASEC 2020-01247). All participants have provided written informed consent.

1.1.7 Further Information

For further information the reader is referred to the [Corona Immunitas Phases 1 to 4 documentation](#) and the [Corona Immunitas website](#).

1.2 Participating Sites

Following are the participating sites, ordered alphabetically. Study sites were chosen to represent language regions (Ticino: Italian, Vaud: French, Zurich: German). For each site, the number of persons who were invited (column 4, Invited), who participated (defined as ICF signed and *Baseline* questionnaire (partially) answered) (column 5, Participated) and respective blood samples analysed (column 6, Samples analysed) are displayed per assessment wave. Participants who participated (ICF signed and *Baseline* questionnaire answered) but their blood sample was not analysed for various reasons are included in the database.

1.2.1 Ticino

[Corona Immunitas Ticino](#) recruited randomly selected participants from the general population of the canton of Ticino (4687 invitations sent, response rate 18.2%). Participants of phase 5 were invited for a second blood sampling in phase 6 (retention rate 86.8% with second blood sample). One participant in Ticino did not have test results in phase 5 but in phase 6. Questionnaires in Ticino were only offered in Italian.

Table 1: Corona Immunitas study participation and assessment period per assessment wave in Ticino

Site name	Study phase	Age group	Invited	Participated	Samples analysed	Start date	End date
Ticino	5	16-29	1369	176	176	2022-03-12	2022-03-26
Ticino	5	30-44	1116	208	208	2022-03-12	2022-03-26
Ticino	5	45-64	1012	262	262	2022-03-12	2022-03-26
Ticino	5	65+	1190	205	204	2022-03-12	2022-03-26
Ticino	5	All	4687	851	850	2022-03-12	2022-03-26
Ticino	6	16-29		136	128	2022-06-01	2022-06-25
Ticino	6	30-44		193	186	2022-06-01	2022-06-25
Ticino	6	45-64		244	241	2022-06-01	2022-06-25
Ticino	6	65+		184	184	2022-06-01	2022-06-25
Ticino	6	All		757	739	2022-06-01	2022-06-25

1.2.2 Vaud

Corona Immunitas in Vaud was set within the [SérocoViD](#) study and recruited participants in the general population of the canton of Vaud (6963 invitations sent, response rate 12.2%). Vaud recruited participants for phase 6 and therefore participants in Vaud were only invited to the *Digital Follow-Up* from DFU 3 on. In contrast to the other sites, Vaud also invited 114 15-year-olds, of which 4 participated. For consistency reasons, these are shown in the age category of 16-29 in Table 2. Questionnaires in Vaud were only offered in French.

Table 2: Corona Immunitas study participation and assessment period per assessment wave in Vaud

Site name	Study phase	Age group	Invited	Participated	Samples analysed	Start date	End date
Vaud	6	16-29	1768	107	107	2022-05-30	2022-07-02
Vaud	6	30-44	1758	183	183	2022-05-30	2022-07-02
Vaud	6	45-64	1662	275	275	2022-05-30	2022-07-02
Vaud	6	65+	1775	285	285	2022-05-30	2022-07-02
Vaud	6	All	6963	850	850	2022-05-30	2022-07-02

1.2.3 Zurich

[Corona Immunitas Zurich](#) recruited participants in the general population of the canton of Zurich (4875 invitations sent, response rate 21.4%). Participants of phase 5 were invited for a second blood sampling in phase 6 (retention rate 92.3% with second blood sample). Questionnaires in Zurich were only offered in German.

Table 3: Corona Immunitas study participation and assessment period per assessment wave in Zurich

Site name	Study phase	Age group	Invited	Participated	Samples analysed	Start date	End date
Zurich	5	16-29	1368	183	183	2022-03-01	2022-03-31
Zurich	5	30-44	1229	260	260	2022-03-01	2022-04-01
Zurich	5	45-64	1197	326	326	2022-03-01	2022-03-31
Zurich	5	65+	1081	275	275	2022-03-01	2022-03-31
Zurich	5	All	4875	1044	1044	2022-03-01	2022-04-01
Zurich	6	16-29		157	156	2022-06-07	2022-07-08
Zurich	6	30-44		235	235	2022-06-07	2022-07-11
Zurich	6	45-64		309	306	2022-06-02	2022-07-11
Zurich	6	65+		269	267	2022-06-07	2022-07-11
Zurich	6	All		970	964	2022-06-02	2022-07-11

2 Corona Immunitas - Data Description

The central database consists of one comma-separated values (csv) file with data from four sets of variables.

- The *Baseline* questionnaire variables, which were asked shortly before or at time of blood sampling (survey).
- The *Serum* variables, which contain information regarding blood sampling and test results (entered by study personnel).
- The *Second Study Visit* (SSV) questionnaire variables, which were asked in Ticino and Zurich at time of the second blood sample (survey).
- The *Digital Follow-Up* (DFU) questionnaire variables, containing all information which was assessed in follow-up questionnaires (survey).

Baseline questionnaire and respective serum variables, as well as *Second Study Visit* questionnaire and respective serum variables are shown within the same event (same row in database). Different events (baseline visit, second study visit, DFU 1, DFU 2, DFU 3, DFU 4, DFU 5 and DFU 6) are shown in different rows and can be distinguished according to the information recorded in the variable `redcap_event_name`.

We created an additional document called **Database Description** (see [Appendix](#)). The document details the variable name, in which questionnaire the variable was asked / whether it is a secondary variable, the variable type, branching logic, wording (question and answer, including coding) in English, French, German and Italian for surveys, and a comment field where additional information was noted (e.g., regarding secondary or non-survey variables).

Within this documentation, it would be too extensive to outline all variables. Therefore, the reader is referred to the **Database Description** file for details. However, below minor differences per set of variables are outlined. This information is also noted in the comment column of the respective variables in the **Database Description**. Secondary variables, so newly created variables based on information which was originally assessed, are outlined in the **Database Description** with necessary details in the comment column.

2.1 Baseline

The *Baseline* questionnaires in Ticino and Zurich are identical but had to be adjusted slightly in Vaud, to account for the altered SARS-CoV-2 situation (phase 5 in March 2022 (Ticino and Zurich), phase 6 in June 2022 (Vaud)). The following differences exist:

- `bl_test_pos_desc_2022`, `bl_test_pos_which_2022`, `bl_test_pos_confirmed_2022` and `bl_test_pos_confirmed_sp_2022` were asked in the context of several infections in 2022 to

participants in Vaud and refer to the most recent infection (if several).

- `bl_infection_repeated_2022`, `bl_infection_date_1_2022`, `bl_infection_date_2_2022` and `bl_infection_date_3_2022` are only available for participants in Vaud.
- `bl_infection_date_2022` is only available for participants in Ticino and Zurich. This variable may be constructed for participants in Vaud by combining the information of `bl_infection_date_1_2022`, `bl_infection_date_2_2022` and `bl_infection_date_3_2022`.
- `bl_infection_hosp_2022` and `bl_infection_icu_2022` were asked in the context of several infections in 2022 to participants in Vaud.

2.2 Serum

The same variables are available in phases 5 and 6 for all sites. However, in Ticino and Zurich in phase 6 the following variables were added:

- `neutralisation_omicron_ba_2` and its secondary variable `neutralisation_omicron_ba_2_qual`; neutralisation capacity against BA.2 spike protein.
- `neutralisation_omicron_ba_4_5` and its secondary variable `neutralisation_omicron_ba_4_5_qual`; neutralisation capacity against BA.4 / BA.5 spike protein.

2.3 Second Study Visit

These variables are only available in Ticino and Zurich, as Vaud only started the enrolment in phase 6.

2.4 Digital Follow-Up

All variables in the *Digital Follow-Up* are identical across phase and site. Participants in Vaud were only invited from DFU 3 on due to the enrolment only starting in phase 6.

3 References

1. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* (2009) 42:377–381. doi: [10.1016/j.jbi.2008.08.010](https://doi.org/10.1016/j.jbi.2008.08.010)
2. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O’Neal L, McLeod L, Delacqua G, Delacqua F, Kirby J, et al. The REDCap consortium: Building an international community of software platform partners. *Journal of Biomedical Informatics* (2019) 95:103208. doi: [10.1016/j.jbi.2019.103208](https://doi.org/10.1016/j.jbi.2019.103208)

A Appendix

A.1 Referenced Documents

Availability of Data:

- [Corona_Immunitas_phases_5_6_data_access_guidelines](#)

Database Description:

- [Corona_Immunitas_phases_5_6_database_description](#)