README: Description of the CoVPN 5002 Public Use Datasets (PUDs)

This document outlines the differences between the PUDs and the original data collected on the Case Report Forms (CRFs) for the observational study CoVPN 5002. The content of the original CRFs can be found in the annotated pdf 20210308\_CoVPN5002\_aCRFS\_all\_fields.

The file names of the CRF datasets start with “PAGE\_”. A table with the file names and CRF titles is included below.

To protect personal identifying information for the participants enrolled in this study:

* Participant ID numbers (PTIDs) are replaced with Unique ID numbers (UIDs).
* All dates are calculated as the number of days from the study enrollment date. These variables have names that end in ”DAYS” (i.e. xxxxDAYS). The enrollment date is converted to 0.
* Zipcode and specimen identification numbers are removed.
* Participants with age above 90 years are identified in a “90+” category.
* Text describing details of protocol deviations are removed since it contains participant IDs and dates.
* Formatted (fmt) and unformatted (nofmt) datasets are provided for each of the datasets.

Table 1: Dataset file names and corresponding CRF titles

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| adsl | Subject-level analysis dataset: see ADSL\_PUD.xlsx for dataset description |
| PAGE\_BSBLD | Specimen Collection – Blood CRF |
| PAGE\_BSSLV | Specimen Collection – Saliva CRF |
| PAGE\_SWAB | Specimen Collection – Nasal Swab CRF |
| PAGE\_DM | Demographics CRF |
| PAGE\_DS | Study Termination CRF |
| PAGE\_DV | Protocol Deviations Log CRF |
| PAGE\_DVYN | Protocol Deviations Y/N CRF |
| PAGE\_ENR | Enrollment CRF |
| PAGE\_IC | Informed Consent CRF |
| PAGE\_IE | Inclusion Exclusion Criteria CRF |
| PAGE\_LBCOV2 | SARS-CoV-2 Test Results CRF |
| PAGE\_MRA | Medical Record Abstraction CRF |
| PAGE\_QSAD | Questionnaire – Adult CRF |
| PAGE\_QSCH | Questionnaire – 10 to 12 CRF |
| PAGE\_QSTT | Questionnaire – 2mo – 9yr CRF |

\* The Participant Identifier CRF dataset is not included since those data are included in all other CRFs, including adsl.