CDISC has launched a task force to rapidly develop guidance on standardizing COVID-19 research data with the participation of several member companies. This guidance will be released in the form of an Interim User Guide and will be made freely available on the CDISC website.

This content in this space is a work in progress.

### Table of Contents

- Risk Factors (in progress)
  - Pre-existing Medical Conditions (in progress)
  - Substance Use (in progress)
  - Contacts (in progress)
  - Travel (in progress)
  - Personal Protective Equipment (PPE) (in progress)
  - Exposure to Animals (in progress)
- Signs and Symptoms (under review through 8 Apr)
- Laboratory Test Results
  - New Controlled Terminology
  - Biospecimen Domains
- Virology (under review through 8 Apr)
  - Virus Identification (under review through 8 Apr)
  - SARS-CoV-2 Viral Load (under review through 8 Apr)
- Vital Signs (in progress)
- Concomitant Medication Use (in progress)
- Respiratory Findings
  - Imaging – CT Scans, Chest X-Rays (under review through 8 Apr)
  - Pulmonary Function Tests (under review through 8 Apr)
- Cardiac Events/Findings (in progress)
- Hospitalizations (in progress)
- Procedures (in progress)
  - Assisted Ventilation (in progress)
  - Dialysis (in progress)
- Vaccines (under review through 8 Apr)
- Questionnaires, Ratings and Scales
  - Clinical Global Impression (CGI)
  - National Early Warning Scale 2 (NEWS2)
- FDA Guidance for Ongoing Trials
  - Listing of all COVID-19 Related Impacts as Part of CSR (in progress)
    - US FDA Guidance Wording Relating to Summarizing Impacted Participants (in progress)
  - Missed Visits (under review through 8 Apr)
  - Missed Assessments 1 (in progress)
  - Missed Assessments 2 (in progress)
  - FDA Guidance Wording on Missing Data (in progress)
  - Disposition - New Controlled Terminology (in progress)
  - Changes to Drug Accountability (in progress)
  - Changes to AE Data Collection (under review through 8 Apr)
  - Changes in Exposure (in progress)
- Non-standard Variables (NSVs)

### Instructions for Reviewers

**Feedback - Batch 1**

The following sections are currently under team review:

1. Signs and Symptoms (under review through 8 Apr)
2. Virus Identification (under review through 8 Apr)
3. SARS-CoV-2 Viral Load (under review through 8 Apr)
4. Imaging – CT scans, chest x-rays (under review through 8 Apr)
5. Pulmonary Function Tests (under review through 8 Apr)
6. Vaccines (under review through 8 Apr)
7. Missed Visits (under review through 8 Apr)
8. Changes to AE Data Collection (under review through 8 Apr)

**Feedback - Batch 2**

Coming Monday!

**Permissions**

This space is open to the public

- Signs and Symptoms (under review through 8 Apr)
  - 9 minutes ago • updated by David Parkinson • view change
- Signs and Symptoms (under review through 8 Apr)
  - about 2 hours ago • commented by Ajay Gupta
- Signs and Symptoms (under review through 8 Apr)
  - about 6 hours ago • updated by Loraine P. Spencer • view change
- Signs and Symptoms (under review through 8 Apr)
  - yesterday at 7:05 PM • commented by Diane Wold
- Signs and Symptoms (under review through 8 Apr)
  - yesterday at 7:04 PM • updated by Diane Wold • view change