COVID-19 Clinical Trial Registry Live Systematic Review

Variable Dictionary for Data Extraction

1. STUDY FORM

Study identification and publication details

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
Trial Registration Details			
st_reg_id	WHO ICTRP	TrialID	Free text: Unique trial registry identifier as per recorded in WHO ICTRP. In the rare and unlikely event a clinical study is identified that has not been registered with a national or international clinical trial registry, the study should be assigned and IDDO unique identified: COVID001; COVID002 etc.
st_source	WHO ICTRP	Source Register	Dropdown: Source or name of the clinical trial registry in which this trial was registered. 1, "**ANZCTR**" | 2, "**Brazilian Clinical Trials Registry (ReBec)**" | 3, "**Chinese Clinical Trial Registry"** | 4, "**Clinical Trials Registry – India**" | 5, "**ClinicalTrials.gov**" | 6, "**Cuban Public Registry of Clinical Trials**" | 7, "**EU-CTR**" | 8, "**German Clinical Trials Register**" | 9, "**Iranian Registry of Clinical Trials**" | 10, "**ISCRTN**" | 11, "**Japan Primary Registries Network**" | 12, "**Pan African Clinical Trial Registry**" | 13, "**Peruvian Clinical Trials Registry (REPEC)**" | 14, "**Republic of Korea**" | 15, "**Sri Lanka Clinical Trials Registry**" | 16, "**Thai Clinical Trials Registry (TCTR)"** | 17, "**The Netherlands National Trial Register**"
st_source_url	WHO ICTRP	web address	Free text: Web address or URL link of the source/original registry record e.g. https://clinicaltrials.gov/show/NCT04170829
st_reg_date	WHO ICTRP	Date registration	Date: the clinical trial record was first registered with the source clinical trial registry. (**DD/MM/YYYY**)
st_other	WHO ICTRP	other records	Dropdown: Are there multiple clinical trial registry records for this trial? I.e., registered in Clinicaltrials.gov (NCT) and ANZCTR.

			0, "**No**" | 1, "**Yes**" | 99, "**Unknown**" Note: should be pre-populated in first instance from WHO ICTRP import. Manual change would only be required if WHO ICTRP records "no" and the reviewer has identified another registry unique identified (e.g. in subsequent publication).
st_other_reg	Manual		Free text: If the trial was listed with multiple clinical trial registries enter any additional unique registration identifiers here. Enter "**-99**" if other registry IDs are not found or unknown. Separate by semi colon if multiple registry identifiers e.g. NCT9834808; ACT4576
st_study_title	WHO ICTRP	Public title	Free text: Public title of the clinical trial
st_sci_title	WHO ICTRP	Scientific title	Free text: Scientific title of the clinical trial
st_acro	WHO ICTRP	Acronym	Free text: Short hand reference or acronym assigned to the study. E.g. NOSO-COR; SOLID-C19; SOLIDARITY Note: Enter "-99" if unpopulated by WHO ICTRP import and no acronym is known.
st_recruit	WHO ICTRP	Recruitment Status	Dropdown variable: Is the clinical trial recruiting participants? 1, "**Recruiting**" | 2, "**Not Recruiting**" |3, "**Pending**" |4, "**Other**" | Note: If recruitment has been completed, select 'Other' and enter 'Complete' in the text box that opens. If recruitment status is 'Suspending' enter as 'Other'.
st_recruit_oth	Manual	Recruitment Other	**If [st_recruit] = '4'** Free text: Details of 'Other' recruitment status
St_enrol_date	WHO ICTRP	Date enrollment	Date: Date of first enrolment (**DD/MM/YYYY**)
st_export	WHO ICTRP	Export date	Datetime: Date for which details of this record were last exported from WHO ICTRP for IDDO's database. **(DD/MM/YYYY HH:MM:SS)**
st_ictrp_update	WHO ICTRP	Last Refreshed on	Date: Date for which this clinical trial record was last refreshed on WHO ICTRP. (**DD/MM/YYYY**)

Publication of results			
st_ictrp_results	WHO ICTRP	results yes no	Dropdown variable: As per the WHO ICTRP record are clinical trial results available? 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
st_result_link	WHO ICTRP	results url link	**If [st_ictrp_results] = '1'** Free text: URL link as populated in WHO ICTRP to results as and when available.
st_result_post	WHO ICTRP	results date posted	**If [st_ictrp_results] = '1'** Date: Date results were posted on WHO ICTRP (**DD/MM/YYYY**)
st_result_complete	WHO ICTRP	results date completed	**If [st_ictrp_results] = '1'** Date: Date the clinical study was completed as per WHO ICTRP record (**DD/MM/YYYY**)
st_pub	Manual		Dropdown variable: Have results of the clinical trial been published? 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"

Sponsor details, Contact Information & Ethics

REDCap DD Variable name	**Source Automated Extraction**	**Source variable name**	**Variable Definition**
st_sponsor	WHO ICTRP	Primary sponsor	Free text: Primary sponsor of the clinical trial
st_contact_fname	WHO ICTRP	Contact Firstname	Free text: First name of the contact(s) associated with the clinical trial record
st_contact_lname	WHO ICTRP	Contact Lastname	Free text: Last name of the contact(s) associated with the clinical trial record
st_contact_address	WHO ICTRP	Contact Address	Free text: Address of the contact(s) associated with the clinical trial record

st_contact_email	WHO ICTRP	Contact Email	Free text: Email(s) of the contact(s) associated with the clinical trial record
st_contact_phone	WHO ICTRP	Contact Tel	Free text: Telephone number(s) of the contact(s) associated with the clinical trial record
st_contact_affil	WHO ICTRP	Contact Affiliation	Free text: Affiliation(s) of the contact(s) associated with the clinical trial record
st_funding	Manual	Source Registry or Details available on WHO ICTRP but does not export	Free text: details of the sources of monetary support / funding for this clinical trial.
Ethics Review			
st_ethics_status	Manual	Source Registry or Details available on WHO ICTRP but does not export	Dropdown variable: What is the status of the ethics review related to the clinical trial? 1, "**Approved**" | 2, "**Not Approved**" | 99, "**Unknown**"
st_ethics_date			Free text: Ethics review approval date for the trial as reported in the registry record Note: In ChiCTR, the default date is 2013-08-26. If ethics have not been approved, and this date appears, populate with "**-99"** Enter "**-99**" if unknown Ethics approval date reported as DD/MM/YYYY
st_ethics_contact			Free text: Ethics review contact name and details for the trial as reported in the registry record Enter "**-99**" if unknown

Study patient numbers

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
Targeted sample size			
st_target	WHO ICTRP	Target size	Free text: Details of target sample size as reported in WHO ICTRP E.g. “Experimental group:20;Control group:20;”
st_sample	Manual	N/A	Integer: Total sample size, targeted number or individual patients for enrolment across all study arms Note: Calculated manually by adding targeted enrolment numbers for each study arm E.g. If reported ‘Experimental group:20;Control group:20’ - enter: “40”

Setting

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
st_countries	WHO ICTRP	Countries	Free text: Countries of recruitment Note: As exported from WHO ICTRP. Multiple countries separated with semicolon; e.g. United States; Argentina; Australia; Belgium; Chile
st_num_country	Manual	N/A	Integer: Number of countries where patients are recruited for this clinical trial. If no locations are listed, enter “1”.
Following variables are completed for each country: 1,2,3 etc. as per integer entered for [st_num_country]			
st_ctry1_name	Manual	N/A	Dropdown variable: Name of the country of study. Country name based on UN classification: http://unstats.un.org/unsd/methods/m49/m49regin.htm. If no locations have been listed, enter “Unknown”.

st_ctry1_plan_num	Manual	N/A	Integer: Total number of participants planned to be recruited/enrolled in this country If unknown enter "-99"
st_ctry1_num_sites	Manual	N/A	Integer: Number of study sites planned to recruit/enrol patients within this country reported If no details available for the number of sites (e.g. only country or region specified) enter "1"

Study Characteristics

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
st_type	WHO ICTRP	Study type	Dropdown variable: detailing the study type. Discrete choice: 1, "**Interventional**" | 2, "**Observational**" | 3, "**Basic Science**" | 4, "**Diagnostic Test**" | 5, "**Health services research**" | 6, "**Epidemilogical research**" | 7, "**Expanded access**" | 8, "**Prevention**" | 9, "**Prognosis study**" | 10, "**Screening**" | 11, "**Treatment study**"
st_ictrp_design	WHO ICTRP	Study type	Free text: Details of study design as reported in WHO ICTRP
st_retro_prosp	Manual		Dropdown variable: Does the clinical trial record describe a retrospective or prospective study? 1, "**Retrospective**" | 2, "**Prospective**" | 99, "**Unknown**"
st_prevention	Manual		Dropdown: Does the study involve a preventive intervention? 0, "**No**" | 1, "**Yes**"
st_prev_design	Manual		**If [st_prevention] = '1'** Dropdown: Was this study interventional or observational? 1, "**Interventional**" | 2, "**Observational**" Note: See variable dictionary and appendix for definitions
st_treatment	Manual		Dropdown: Does the study involve a treatment intervention? 0, "**No**" | 1, "**Yes**"

st_treat_design	Manual		**If [st_treatment] = '1'** Dropdown: Was this study interventional or observational? 1, "**Interventional**" | 2, "**Observational**" Note: See variable dictionary and appendix for definitions
st_diagnosis	Manual		Dropdown: Does the study involve a diagnostic intervention? 0, "**No**" | 1, "**Yes**"
st_diag_design	Manual		**If [st_diagnosis] = '1'** Dropdown: Was this study interventional or observational? 1, "**Interventional**" | 2, "**Observational**" Note: See variable dictionary and appendix for definitions
st_clinpres	Manual		Dropdown: Does this study ONLY observe clinical presentation – i.e., no intervention was administered or assessed? 0, "**No**" | 1, "**Yes**"
st_design	Manual	N/A	Dropdown variable: detailing the study design. Discrete choice: If study design is truly "Interventional" then select one of the following study designs. 1, "**RCT**" | 2, "**Quasi-randomised**" | 3, "**Non-randomised (interventional)**" Select 3 "non-randomised" for single arm interventional study arms. If is the study design is truly an "Observational", "Epidemiological research", "Prevention", "Prognosis study", "Screening" then select one of the following study designs: | 4, "**Cohort-study**" | 5, "**Case report**" | 6 "**Case series"** | 7, **"Case-control**" | 8, "**Cross-sectional**" | 10, "**Prognostic**" | 11, "**Other**" If the study is truly assessing diagnostic methods or a "Diagnostic Test" then select | 9, "**Diagnostic test accuracy**" | For any other study designs including health services research or studies that are not assessing health outcomes or any kind (e.g. behavioural, social science studies select | 11, "**Other**" *See Appendix for further description of categories* Note: See variable dictionary and appendix for definitions

st_ictrp_phase	WHO ICTRP	Phase	Free text: details of clinical trial phase as reported in WHO ICTRP E.g.: 0, 2, 4, N/A, Retrospective, Phase 2, Phase2/3, Phase 4
st_phase	Manual	N/A	In which clinical trial phase is this study? Checkbox variable: 1, "**Phase 1**" | 2, "**Phase 2**" | 3, "**Phase 3**" | 4, "**Phase 4**" | | 98, "**Not Applicable**"| 99, "**Unknown**" Select all phases that apply. E.g. if a phase 2/3 study select phase 2 and phase 3 checkboxes. Only select Phase if explicitly reported in the clinical trial registration. DO not make any assumption or inference based on study design. If "Phase 0" or "N/A" is reported from the source registration select "**Unknown**" for "interventional" studies. Select "**Not Applicable**" for "retrospective" and "observational" studies entered as "0" or "N/A". If study is "Expanded Access" (no phase data provided) select "**Unknown**".
st_rob	Manual	N/A	What is the Oxford CEBM level of evidence for this trial? Dropdown: 1, "**Level 1**" | 2, "**Level 2**" | 3, "**Level 3**" | 4, "**Level 4**" | | 5, "**Level 5**"| https://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf
st_comparative	Manual	N/A	Dropdown variable: Was this a comparative study (of any population or intervention including treatment, vaccine or diagnostic)? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
st_interventions	WHO ICTRP	Intervention	Free text: Details of interventions as reported in the clinical trial registry record. Enter "-99" if unknown Enter "-1" if not applicable
st_intv_arms	Manual	N/A	Integer: Number of study arms Study arms: an arm/group of patients receiving a specific treatment regimen or intervention. I.e., also referred to as number of treatment arms, comparative arms, treatment groups, intervention groups For observational studies with no clear intervention extract as 1 arm.

- **Is assignment to different arms randomised and blinded?**

REDCap DD Variable name	**Source Automated Extraction**	**Source variable name**	**Variable Definition**

st_random	Manual	N/A	If [**st_prev_design**] = 1, "**Interventional**", or [st_treat_design] = 1, "**Interventional**" or [st_diag_design] = 1, "**Interventional**" Dropdown variable: describing the level of randomisation and specification of methods reported. Discrete choice: 1, "**Single-arm**" | 2, "**Multi-arm non-randomised**" | 3, "**Multi-arm randomisation reported no detailed methods**" | 4, "**Multi-arm randomisation reported with detailed methods**" | 5, "**Other**" | 99, "**Unknown**" Note: Please only select 'Multi-arm non-randomised' when a record explicitly reports no randomisation.
me_random_desc	Manual	N/A	If [**st_random**] = 4, "**Multi-arm randomisation reported with detailed methods**" or 5, "**Other**" Free text: further details on randomisation methods. If single arm type 'single arm'.
st_blind	Manual	N/A	If [**st_prev_design**] = 1, "**Interventional**", or [st_treat_design] = 1, "**Interventional**" or [st_diag_design] = 1, "**Interventional"** Dropdown variable: describing the level and methods of blinding reported. That is, for randomised studies, was it reported if the person delivering the drug and/or assessing the participant was blinded to the intervention administered? Discrete choice: 1, "**Single-arm**" | 2, "**Multi-arm non-blinded**" |3, "**Multi-arm blinding reported no details who blinded**" | 4, "**Multi-arm blinding reported with details who blinded**" | 5, "**Other**" | 99, "**Unknown**" Note: Please only select 'Multi-arm non-blinded' when a record explicitly reports no blinding ie. open label
me_blind_desc	Manual	N/A	If [**st_blind**] = 4, "**Multi-arm blinding reported with details who blinded**" Free text: further details on the blinding methods Including classification - single blind or double blind
me_alloc_ratio	Manual	N/A	If [**st_prev_design**] = 1, "**Interventional**", or [st_treat_design] = 1, "**Interventional**" or [st_diag_design] = 1, "**Interventional**" Free text: describing how participants were allocated to each study arm e.g. 1:1, 1:2; 1:3, 1:4. If there are multiple arms with different allocations e.g. 100, 100, 50, 50, 50, this can be expressed as e.g. 2:2:1:1:1. If allocation is unknown, please type 'Unknown'. If the study is single arm, please type 'Single arm'.
me_all_conc	Manual	N/A	If [**st_prev_design**] = 1, "**Interventional**", or [st_treat_design] = 1, "**Interventional**" or [st_diag_design] = 1, "**Interventional"** Dropdown variable: describing whether concealment was performed during participants allocation to each study arm. Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**" | 3, "**Single arm**" *See Appendix for further description*

- **When was the study conducted and for how long were patients followed-up?**

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
Planned study dates and follow-up			
st_estimate_start_yn	Manual	Source registry	Dropdown variable: Is an estimated study start date available? 0, "**No**" | 1, "**Yes**" |
st_estimate_start	Manual	Source Registry	If [**st_estimate_start_yn**] = 1, **Yes** Free text: Estimated Study Start Date (DD/MM/YYYY) Enter "-99" if unknown. If only MM/YYYY is given, assigned DD=15.
st_estimate_end_yn	Manual	Source registry	Dropdown variable: Is an estimated study primary completion date available? 0, "**No**" | 1, "**Yes**" |
st_estimate_end	Manual	Source Registry	If [**st_estimate_end_yn**] = 1, **Yes** Date:Estimated Primary Completion Date (DD/MM/YYYY) Enter "-99" if unknown. If only MM/YYYY is given, assigned DD=15.
st_estimate_complete_yn	Manual	Source registry	Dropdown variable: Is an estimated study completion date available? 0, "**No**" | 1, "**Yes**" |
st_estimate_complete	Manual	Source Registry	If [**st_estimate_complete_yn**] = 1, **Yes** Date: Estimated Study Completion Date (DD/MM/YYYY) Enter "-99" if unknown. If only MM/YYYY is given, assigned DD=15.
st_plan_followup	Manual	Source Registry	Integer: Duration of follow up Enter "-99" if unknown. Enter "-1" is not applicable ie. cross-sectional study
st_plan_followup_un	Manual	Source Registry	**If [st_plan_followup] >= "1"** Dropdown variable: describing the units of duration of follow up. Discrete choice: **1, Days | 2, Weeks | 3, Months | 4, Years | 9, Other**

2. PARTICIPANTS FORM

Diagnostic inclusion

- **Condition studied and analyses performed to diagnose COVID-19?**

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
pa_condition	WHO ICTRP	Condition	Free text: Condition being studied as reported in WHO ICTRP (or registry record)

Other Inclusion Criteria

- **What factors were specified in the inclusion criteria?**

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
pa_elig_age_min	WHO ICTRP	Inclusion agemin	Free text: Minimum age for eligibility in the study (inclusion criteria), that is the youngest age eligible for study participation, in years. If unknown enter "-**99**".
pa_elig_age_max	WHO ICTRP	Inclusion agemax	Free text: Maximum age for eligibility in the study (inclusion criteria), that is the oldest age eligible for study participation, in years. If unknown enter "-**99**".
pa_elig_gender	WHO ICTRP	Inclusion gender	Discrete variable: Gender eligibility for inclusion in the study. 1, "**Female**" | 2, "**Male**" | 3, "**All**" | 99, "**Unknown**"
pa_ictrp_incl	WHO ICTRP	Inclusion Criteria	Free text: Details/list of inclusion criteria as reported in the clinical trial registry record

- **Populations specified in the inclusion criteria**

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
pa_elig_hworker_yn	Manual	N/A	Dropdown variable: Was enrolment of health workers an inclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**" Note: Please select 'no' if health workers are not specified in the inclusion criteria or text of the trial record
pa_elig_hworker_desc	Manual	N/A	If [**me_elig_hworker_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of health workers

- **Were individuals with risk factors eligible for inclusion in the study ?**

pa_elig_preg_yn	Manual	N/A	Dropdown variable: Were pregnant women eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_preg_desc	Manual	N/A	If [**me_preg_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of pregnant women participants
pa_elig_diab_yn	Manual	N/A	Dropdown variable: Were participants with diabetes mellitus eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_diab_desc	Manual	N/A	If [**me_diab_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of diabetes mellitus participants
pa_elig_hiv_yn	Manual	N/A	Dropdown variable: Were HIV patients eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_hiv_desc	Manual	N/A	If [**me_hiv_yn**] = 1, "**Yes**"

			Free text: further details on the eligibility criteria of HIV+ participants
pa_elig_immu_yn	Manual	N/A	Dropdown variable: Were immunocompromised participants (including cancer treatment) eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**" Note: Many conditions can cause a person to be immunocompromised, including cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications
pa_elig_immu_desc	Manual	N/A	If [**me_elig_asthma_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of immunocompromised participants
pa_elig_asthma_yn	Manual	N/A	Dropdown variable: Were patients with chronic lung disease or moderate to severe asthma eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_asthma_desc	Manual	N/A	If [**me_elig_asthma_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of participants with chronic lung disease or asthma
pa_elig_ht_yn	Manual	N/A	Dropdown variable: Were hypertensive patients eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_ht_desc	Manual	N/A	If [**me_elig_ht_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of hypertensive participants
pa_elig_heart_yn	Manual	N/A	Dropdown variable: Were patients with serious heart conditions eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_heart_desc	Manual	N/A	If [**me_elig_heart_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of participants with serious heart conditions
pa_elig_hworker_yn	Manual	N/A	Dropdown variable: Was enrolment of health workers an inclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**" Note: Please select 'no' if health workers are not specified in the inclusion criteria or text of the trial record

pa_elig_hworker_desc	Manual	N/A	If [**me_elig_hworker_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of health workers
pa_elig_obese_yn	Manual	N/A	Dropdown variable: Were severely obese participants (body mass index [BMI] >40) eligible for enrolment as per the inclusion/exclusion criterion? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
pa_elig_obese_desc	Manual	N/A	If [**me_elig_obese_yn**] = 1, "**Yes**" Free text: further details on the eligibility criteria of severely obese participants

Exclusion criteria

REDCap DD Variable name	**Source Automated Extraction**	**Source variable name**	**Variable Definition**
pa_ictrp_excl	WHO ICTRP	Exclusion Criteria	Free text: Details/list of exclusion criteria as reported in the clinical trial registry record

3. STUDY ARM FORM

NOTE: IN REDCap the 'Study Arm' Form is a repeatable instrument that requires a new 'study arm' form to be created for each arm

The below variables are completed for each study arm in a separate 'study arm' form which is a repeatable instrument in REDCap.

Following variables completed for each treatment arm 1,2,3 etc.			
REDCap DD Variable name	**Source Automated Extraction**	**Source variable name**	**Variable Definition**
sa_num_intv	Manual	N/A	Integer: How many interventions were patients in this study arm exposed to? Must enter at least one Notes: To capture total number interventions in a single study arm – i.e., if combination therapy, multiple interventions or drug therapy plus another intervention(s). If none still enter 1. E.g. if combination treatment of drug A plus drug B was administered in a single study arm enter '2'
sa_combi	Manual	N/A	If **[sa_num_intv]** >=2 Dropdown variable: Were the multiple interventions administered in combination? 1, "**co-administered**" | 2, "**sequential**" | 3, **"other"** | 99, **"Unknown"** Co-administered: Treatments are given to patients at or almost the same time e.g. concomitant, one after the other, on the same day, etc. Sequential: Intervention exposure or treatments are administered in a sequence – e.g. drug A days 1- If administration varied across interventions in a single arm e.g. two of the interventions were co-administered, another was sequential and there was also consistent standard of care - enter "other"
sa_fixed	Manual	N/A	If **[sa_combi] =** 1, "**co-administered**" Dropdown variable: If the treatments were co-administered was it a fixed-dose formulation or loose-dose administration? 1, "**fixed-dose**" | 2, "**loose-dose**" | 99, "**unknown**"

			Fixed-dose: defined as a combination drug is a fixed-dose combination (FDC) that includes two or more active pharmaceutical ingredients (APIs) combined in a single dosage form, which is manufactured and distributed in fixed doses. Loose-dose: combination therapy that involves administration of two or more active pharmaceutical ingredients (APIs) in multiple dosage forms (i.e., **NOT** combined in a single dosage form)
sa_num_planned	Manual	N/A	Integer: The target size: number of patients targeted to be treated or exposed to the intervention. That is, the total number of patients planned for enrolment in the study arm. If unknown at the study arm level enter -99
Branch logic – following variables to be completed for each intervention administered within the single study/treatment arm - corresponding to **[sa_num_intv]**			
sa_intv1_target			Dropdown variable: Please select the appropriate category of this intervention (or lack thereof) assigned within this single study arm? Discrete choice: 1, "**Pharmacological interventions**" | 2, "**Traditional Chinese Medicine**" | 3, "**Vaccine prevention"** |4, "**Vaccine treatment"** |5, "**Advanced therapy medicinal products (ATMP)**" | 6, "**Behavioural intervention**" | 7, "**Placebo**" | 8, "**No Intervention**" | 9, "**Standard of care** " | 10, "**Others** " |11, "**Diagnostic intervention**" *See Appendix for Intervention Categories*
sa_intv1_desc	Manual	N/A	Free text: Name of intervention or details of exposure/purpose of observation specific to the study arm of interest.
sa_intv1_med_type	Manual	N/A	If **[sa_target]** = 1 "**Pharmacological interventions**" Dropdown variable: What type of medicine was (or is planned) to be administered? 1, "**Antiviral not specified**" | 2, "**Antiviral broad spectrum**" |3, "**Antiviral antiretrovirals** " | 4, "**Other antiviral**" | 5, "**Antimalarial**" | 6, "**Antibiotics and antiparasitics**" | 7, "**Nonspecific anti-inflammatory** | 8, **Immunosuppressive drugs"** | 9, "**Kinase inhibitors**" | 10, "**Monoclonal antibodies**" | 11, **"Others**" | 12, **"Miscellaneous Other"** | 99, "**Unknown**" *See Appendix for Intervention Categories*

sa_intv1_drug_av_ns	Manual	N/A	If **[sa_intv1_med_type]** = 1 "**Antiviral not specified**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Immunoglobulin**" | 2, "**Interferons**" |3, "**Interleukin-2**" | 4, "**Other**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_av_bs	Manual	N/A	If **[sa_intv1_med_type]** = 2 "**Antiviral broad spectrum**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Favipiravir**" | 2, "**Triazavirin**" |3, "**Umifenovir**" | 4, "**Other**" | 5, "**Oseltamivir**" |6, "**Ribavirin**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_av_ar	Manual	N/A	If **[sa_intv1_med_type]** = 3 "**Antiviral antiretrovirals**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**ASC09**" | 2, "**Azvudine**" |3, "**Danoprevir**" |4, "**Darunavir**" |5, "**Lopinavir**" |6, "**Ritonavir**" |7, "**Remdesivir**" | 8, "**Other**"| 9, "**mtricitabine**" | 10, "**Tenofovir**" | 11, "**Cobicistat**" 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_av_oth	Manual	N/A	If **[sa_intv1_med_type]** = 4 "**Other antiviral**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Baloxavir marboxil**" | 2, "**Other**" | 3, "**Sofusbovir**" | 4, "**Daclatasvir**" | 99, "**Unknown**"

			If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_am	Manual	N/A	If **[sa_intv1_med_type]** = 5 "**Antimalarial**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Chloroquine**" | 2, "**Hydroxychloroquine**" |3, "**Artemisinin derivatives**" | 4, "**Other**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_ab_ap	Manual	N/A	If **[sa_intv1_med_type]** = 6 "**Antibiotics and antiparasitics**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Carriomycin**" | 2, "**Suramin sodium**" |3, "**Other**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_ai	Manual	N/A	If **[sa_intv1_med_type]** = 7 "**Nonspecific anti-inflammatory**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Corticosteroids**" | 2, "**Nonsteroidal anti-inflammatory drug**" |3, "**Other**" | 99, "**Unknown**"[BM3] If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are

			more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_im	Manual	N/A	If **[sa_intv1_med_type]** = 8 "I**mmunosuppressive drugs**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Fingolimod**" |3, "**Leflunomide**" | 4, "**Thalidomide**" | 5, "**Other**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_ki	Manual	N/A	If **[sa_intv1_med_type]** = 9 "**Kinase inhibitors**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Jakotinib hydrochloride**" | 2, "**Ruxolitinib**" |3, "**Other**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_intv1_drug_ma	Manual	N/A	If **[sa_intv1_med_type]** = 10 "**Monoclonal antibodies**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, " **Adalimumab**" | 2, "**Camrelizumab**" |3, "**Eculizumab**" | 4, "**Mepolizumab**" | 5, "**PD-1 mAb**" | 6, "**Tocilizumab**" | 7, "**Tozumab**" | 8, "**Adamumab(Qletli)**" | 9, "**Bevacizumab**" | 10, "**Other**" | 11, "**Ixekizumab**" | 12, "**Sarilumab**" | 13, "**Siltuximab**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.

sa_intv1_drug_mo	Manual	N/A	If **[sa_intv1_med_type]** = 12 "**Miscellaneous other**" Dropdown variable: Name of drug administered / active pharmaceutical ingredient (API) as per INN. Discrete Choice 1, "**Acetylcysteine**" | 2, "**Angiotensin receptor blockers**" |3, "**Bismuth potassium citrate**" | 4, "**Bromhexine hydrochloride**" | 5, "**Diammonium glycyrrhizinate**" | 6, "**Dipyridamole**" | 7, "**Ebastine**" | 8, "**Hydrogen peroxide**" | 9, "**Inhaled gases**" | 10, "**Pirfenidone**" | 11, "**Polyinosinic-polycytidylic acid**" | 12, "**rhG-CSF**" | 13, "**Thymosin**" | 14, "**Tranilast**" | 15, "**Vitamin C**" | 16, "**Other**" | 17, "**Dexmedetomidine**" |18, "**Enoxaparin sodium**" | 19, "**Losartan**" | 20, "**Colchicine**" | 21, "**Sildenafil**" | 22, "**Noscapine**" | 99, "**Unknown**" If a fixed-dose combination (FDC) – in this variable select one of the APIs and the second API that makes up the single dosage form in the following variable [**in_intv1_drug_b]**. If there are more than 2 APIs in a single dose formulation – detail further in free text of **[in_intv1_reg_detail]**.
sa_int1_atmp	Manual	N/A	If **[sa_target]** = 5, "**Advanced therapy medicinal products (ATMP)**" Dropdown variable: Name of Advanced therapy medicinal products (ATMP) 1, "**Aerosol inhalation of vMIP: viral macrophage inflammatory protein**" | 2, "**Ankylosaurus; M1 macrophages target**" | 3, "**Anti-2019-nCoV inactivated convalescent plasma**" | 4, "**Anti-SARS-CoV-2 inactivated convalescent plasma**" | 5, "**Biological preparation of human placenta**" |6, "**Convalescent plasma treatment**" | 7, "**Cord blood mesenchymal stem cells**" | 8, "**Human menstrual blood-derived stem cells**" | 9, "**Immunoglobulin from cured patients**" | 10, "**Inactivated Mycobacterium vaccine**" | 11, "**Infusion of convalescent plasma**" | 12, "**Mesenchymal stem cells**" |13, "**Mesenchymal stem cells exosomes atomization**" | 14, "**mRNA-1273**" | 15, "**NK cells"** | 16, "**Plasma treatment**" | 17 "**Recombinant cytokine gene-derived protein injection**" | 18, "**Regulating intestinal flora**" | 19, "**Therapeutic antibody from recovered novel coronavirus pneumonia patients**" | 20, "**Umbilical cord blood mononuclear cells**" | 21, "**Umbilical cord mesenchymal stem cells (hucMSCs)**" | 22, "**Umbilical cord Wharton's Jelly derived mesenchymal stem cells**" | 23, "**Umbilical Cord(UC)-derived mesenchymal stem cells**" |24, "**Washed microbiota transplantation**" | 25, "**Recombinant human granulocyte-colony stimulating factor**" | 98, "**Other**"
sa_intv1_drug_b	Manual	N/A	If **[sa_fixed]** = 1, "**fixed-dose**" Free text: name of second drug/API that makes up the single dosage form.

sa_intv1_manufact	Manual	N/A	Free text: Details of the manufacturer as reported in the source clinical trial record. If manufacturer details are not provided, enter "**-99**".
sa_intv1_reg_yn			Dropdown: Are regimen details of the intervention or exposure available? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"
sa_intv1_route	Manual	N/A	If [**sa_intv1_reg_yn**] = 1, yes Dropdown variable: What was the route of administration? 1, "**Oral**" | 2, "**Intravenous**" | 3, "**Intramuscular**" | 4, "**Intralymphatic**" | 5, "**Subcutaneous**" | 6, "**Other**" | 99, "**Unknown**" *EMA Controlled Vocabulary for Route of administrations:* *http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002730.pdf*
sa_intv1_route_dur	Manual	N/A	If **[sa_intv1_route]** = 2, "Intravenous" Integer: Duration of infusion
sa_inyv1_dur_un			If **[sa_intv1_route_dur]** >= "1", not "Unknown" Dropdown variable: Unit of infusion duration time. Discrete choice: 1, "**Minutes**" | 2, "**Hours**" | 3, "**Days**" | 4, "**Other**" | 99, "**Unknown**"
sa_intv1_route_other	Manual	N/A	If **[sa_intv1_route]** =6, "Other" Free text: Description of 'Other' route of administration
sa_intv1_dose_method	Manual	N/A	If [**sa_intv1_reg_yn**] = 1, yes Dropdown variable: Method of dosing calculation. Discrete choice: 1, "**Target mg/kg**" | 2, "**Weight-band**" | 3, "**Age-band**" | 4, "**Other**" | 99, "**Unknown**"
sa_intv1_dose_mgkg	Manual	N/A	If **[sa_intv1_dose_method]** = 1 "Target mg/kg" Free text: Targeted dosing or range in mg/kg
sa_intv1_freq_yn	Manual	N/A	If [**sa_intv1_reg_yn**] = 1, yes Dropdown: Are details of the frequency of administration of the drug(s)/treatment/intervention available? Discrete choice: 0, "**No**" | 1, "**Yes**" | 99, "**Unknown**"

			Note: If the frequency is reported as a range (eg. 1-2 times a day), select 'no'. Enter any information provided to the 'Detailed regimen' box.
sa_intv1_freq_con_yn	Manual	N/A	If [**sa_intv1_freq_yn**] = 1, yes Dropdown: Is the frequency of the regimen consistently applied ie., if there is a loading dose or changes in frequency over time, select 'No' Discrete choice: 0, "**No**" | 1, "**Yes**"
sa_intv1_freq	Manual	N/A	If [**sa_intv1_freq_yn**] = 1, yes Integer: frequency that the drug(s)/treatment/intervention was administered for a given time period -99 if unknown e.g. Twice daily (Frequency = 2; Time period units = days; time period magnitude = 1) e.g. Once every two days (Frequency = 1; time period units = days; time period magnitude = 2) e.g. Once every three months (Frequency = 1; time period units = months; time period magnitude = 3)
sa_intv1_freq_time_un	Manual	N/A	Dropdown variable: Units of given time period 1, "**Hours**" | 2, "**Days**" | 3, "**Weeks**" | 4 "**Months**" | 5, "**Years**" | 6, "**Other**" 99, "**Unknown**" e.g. Twice daily (Frequency = 2; Time period units = days; time period magnitude = 1) e.g. Once every two days (Frequency = 1; time period units = days; time period magnitude = 2) e.g. Once every three months (Frequency = 1; time period units = months; time period magnitude = 3)
sa_intv1_freq_time_un_oth	Manual	N/A	If [**sa_intv1_freq_time_un] = 6, other** Free text: Units of given time period (free text)
sa_intv1_freq_time_mag	Manual	N/A	If [**sa_intv1_freq_yn**] = 1, yes Integer: Magnitude of given time period -99 if unknown e.g. Twice daily (Frequency = 2; Time period units = days; time period magnitude = 1) e.g. Once every two days (Frequency = 1; time period units = days; time period magnitude = 2) e.g. Once every three months (Frequency = 1; time period units = months; time period magnitude = 3)

sa_intv1_dura_fix_mag	Manual	N/A	If [**sa_intv1reg_yn**] = 1, yes Integer: Duration of the **intended** (in the protocol or in guidelines if applicable) length of treatment or time the intervention was administered. Enter "**-99**" if unknown. If a range is given i.e., 7-14 days, please enter "**-1**" and provide the details in free text for the variable below **sa_intv1_reg_detail**
sa_intv1_dura_fix_un	Manual	N/A	If [**sa_intv1_dura_fix_mag**] **>**= "1", not "Unknown" Dropdown variable: Units for duration. Discrete choice: **1, Days | 2, Weeks | 3, Months | 4, Years | 9, Other**
sa_intv1_reg_detail	Manual	N/A	[**sa_intv1_dura_fix_un**] >= "1" Free text: Further details and description of the treatment or intervention regimen specific to the study arm of interest, including the dose description and details of frequency Include details of how multiple therapies administered if **[In_intv1_combi]** = 3 "**other**"

4. OUTCOMES FORM

Planned outcome assessment

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
ou_plan_outcomes	WHO ICTRP	Primary outcome	Free text: List of planned outcome measures as reported in WHO ICTRP
ou_other_outcomes	Manual	Source Registry	Free text: Any further details of planned outcomes reported in source registry Note: I.e., not already captured in WHO ICTRP

5. DATA SHARING FORM

plan_ipd_share_yn	Manual	Source registry	Dropdown variable: Does this study plan to share IPD? 0, "**No**" | 1, "**Yes**" | 98, "**Undecided**" | 99, "**No information provided**"
plan_ipd_share_details	Manual	Source registry	If [**Plan_ipd_share_yn]** = 1, Yes Free text: All text details of plans to share IPD

6. STUDY SETTING FORM

Study setting details

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
ss_nat_multi	Manual	N/A	Dropdown variable: Did this study take place in multiple countries across multiple sites? 1, "**Single country, sites unknown**" | 2, "**Single country, single site**" | 3, "**Single country, multi-site**" | 4, "**Multi-country**"

REDCap DD Variable name	Source Automated Extraction	Source variable name	Variable Definition
ss_countries	WHO ICTRP	Countries	Free text: Countries of recruitment Note: As exported from WHO ICTRP. Multiple countries separated with semicolon; e.g. United States; Argentina; Australia; Belgium; Chile

ss_num_country	Manual	N/A	Integer: Number of countries where patients are recruited for this clinical trial. If no locations are listed, enter "1".
Following variables are completed for each country: 1,2,3 etc. as per integer entered for [st_num_country]			
ss_ctry1_name	Manual	N/A	Dropdown variable: Name of the country of study. Country name based on UN classification: http://unstats.un.org/unsd/methods/m49/m49regin.htm. If no locations have been listed, enter "Unknown".
ss_ctry1_plan_num	Manual	N/A	Integer: Total number of participants planned to be recruited/enrolled in this country If unknown enter "-99"
ss_ctry1_num_sites	Manual	N/A	Integer: Number of study sites planned to recruit/enrol patients within this country reported If no details available for the number of sites (e.g. only country or region specified) enter "1"
ss_site_yn	Manual	N/A	Dropdown variable: Are details of study sites available? 0, "No" | 1, "Yes"
If [ss_site_yn] = '1', yes, then the following variables are completed for each site within each country: 1,2,3 etc. as per integer entered for [st_ctr1_num_sites]			
ss_ctry1_site1_add	Manual	N/A	Free text: most precise name and address of site of recruitment
ss_ctry1_site1_lat	Manual	N/A	Number. Latitude of the site of recruitment, if not reported derive this using google maps. If unknown enter -999
ss_ctry1_site1_long	Manual	N/A	Number. Longitude of the site of recruitment, if not reported derive this using google maps If unknown enter -999
ss_ctry1_site1_plan_num	Manual	N/A	Integer: Total number of participants planned to be recruited/enrolled at this site If unknown or '0' patients indicated enter "-99"

Study location, if site details are unknown

If [ss_site_yn] = '0', no, then the following variables are completed for the study as a whole			
ss_study_add	Manual	N/A	Free text: most precise name and address of site of recruitment

ss_study_lat	Manual	N/A	Number. Latitude of the site of recruitment, if not reported derive this using google maps. If unknown enter -999 If only a country is provided, use the address of the applicant's institution as found in the source record. If the institution is unknown, select central coordinates of the country's capital city
ss_study_long	Manual	N/A	Number. Longitude of the site of recruitment, if not reported derive this using google maps If unknown enter -999 If only a country is provided, use the address of the applicant's institution as found in the source record. If the institution is unknown, select central coordinates of the country's capital city

Patient populations

REDCap DD Variable name	**Source Automated Extraction**	**Source variable name**	**Variable Definition**
ss_elig_hvol_yn	Manual	N/A	Dropdown variable: Were healthy volunteers included in this study? 0, "**No**" | 1, "**Yes**" |99, "**Unknown**"
ss_elig_covid_yn	Manual	N/A	Dropdown variable: Were patients with a confirmed COVID-19 diagnosis included? 0, "**No**" | 1, "**Yes**" |99, "**Unknown**"

7. Appendix.

Study Design Categorisation

Detailed explanation of study type and definitions

Use the following clinicaltrials.gov definitions of study type:
Interventional (experimental) Study: A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Observational Study: The general design of the strategy for identifying and following up with participants during an observational study. Types of observational study models include cohort, case-control, case-only, case-cross-over, ecologic or community studies, family-based, and other.

Detailed explanation of study design categories

Definitions of study designs 1-5 are as per the Cochrane Consumers & Communication Review Group
Study Design Guide. For Review Authors. June 2013. https://cccrg.cochrane.org/sites/cccrg.cochrane.org/files/public/uploads/Study_design_guide2013.pdf

Definitions of study design 6, Diagnostic Test Accuracy is as per The Joanna Briggs Institute Reviewers' Manual 2015. The systematic review of studies of diagnostic test accuracy. https://joannabriggs.org/assets/docs/sumari/Reviewers-Manual_The-systematic-review-of-studies-of-diagnostic-test-accuracy.pdf

Interventional (experimental) Study Designs

1, "**RCT**"
RANDOMISED CONTROLLED TRIALS
In RCTs the investigator randomly assigns people to groups that will receive (intervention group) or not receive (control group) one or more interventions. The outcomes measured are then compared between the groups.

2, "**Quasi-randomised**"
QUASI-RANDOMISED CONTROLLED TRIALS
Trials that attempt to randomly assign participants to groups but use an inadequate approach to generate the random sequence are designated as quasi-randomised controlled trials. Such trials do attempt to randomly allocate participants with the intent of producing equivalent groups, but the randomisation methods used are not adequate because in practice they are relatively easy to manipulate or predict. Inadequate randomisation approaches: Alternation, Case record numbers, Birth dates, Week days or month of the year.

3, “**Non-randomised (interventional)**”
Either a single arm interventional study or a multi-arm study that does not apply randomisation when assigning individuals to treatment.

Observational Study Designs

4, “**Cohort-study**”

COHORT STUDY (SYNONYM: FOLLOW-UP, INCIDENCE, LONGITUDINAL, PROSPECTIVE STUDY)
An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine for example people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A cohort can be assembled in the present and followed into the future (this would be a prospective study or a "concurrent cohort study"), or the cohort could be identified from past records and followed from the time of those records to the present (this would be a retrospective study or a "historical cohort study"). Because random allocation is not used, matching or statistical adjustment at the analysis stage must be used to minimise the influence of factors other than the intervention or factor of interest.

5, “**Case-control**”
CASE-CONTROL STUDY (SYNONYMS: CASE REFERENT STUDY, RETROSPECTIVE STUDY)
A study that starts with identification of people with the disease or outcome of interest (cases) and a suitable control group without the disease or outcome. The relationship of an attribute (intervention, exposure or risk factor) to the outcome of interest is examined by comparing the frequency or level of the attribute in the cases and controls. For example, to determine whether thalidomide caused birth defects, a group of children with birth defects (cases) could be compared to a group of children without birth defects (controls). The groups would then be compared with respect to the proportion exposed to thalidomide through their mothers taking the tablets. Case-control studies are sometimes described as being retrospective as they are always performed looking back in time.

6 & 7, “**Case-report or series**”
CASE STUDY (SYNONYMS: ANECDOTE, CASE HISTORY, SINGLE CASE REPORT)
An uncontrolled observational study involving an intervention and outcome for a single person (or other unit).
CASE SERIES
An uncontrolled observational study involving an intervention and outcome for more than one person.

8, “**Cross-sectional**” (also prevalence study)
A study that examines the relationship between diseases (or other health related characteristics) and
other variables of interest as they exist in a defined population at one particular time. The temporal sequence of cause and effect cannot necessarily be determined in a cross-sectional study.

9, “**Diagnostic test accuracy**”
Diagnostic test accuracy studies compare a diagnostic test of interest (the ‘index test’) to an existing diagnostic test (the ‘reference test’), which is known to be the best test currently available for accurately identifying the presence or absence of the condition of interest. The outcomes of the two tests are then compared with one another in

order to evaluate the accuracy of the index test. There are two main types of studies of DTA. The first is the diagnostic case-control design, also sometimes called the 'two gate design'. In this study design people with the condition (cases) come from one population (i.e. a health care centre for people known to have the condition), while people without the condition come from another. Although this design gives an indication of the maximum accuracy of the test, the results will generally give an exaggerated indication of the test's accuracy in practice. The second study design is cross-sectional, and involves all patients suspected of having the condition of interest undergoing the index test and the reference test. Those who test positive for the condition by the reference test can be considered to be the cases, whereas those who test negative are the controls.

10, "**Prognostic**" Any study assessing prognostic factors that CANNOT be appropriately categorised into other study designs

11, "**Other**" Any other study design not captured in categories 1-8.

Detailed explanation of allocation concealment

Descriptions of allocation concealment can be found in the Cochrane handbook:
https://handbook-5-1.cochrane.org/chapter_8/8_10_2_assessing_risk_of_bias_in_relation_to_adequate_or.htm

Further information can also be found in the Global Health Network's resources:
https://media.tghn.org/articles/trialprotocoltool/SOURCE/Checklist/StudyObjectives/Concealment.html

Intervention Categorisation

The preliminary categorisation of intervention is based on the those designed and used by The Centre for Evidence-Based Medicine based at the University of Oxford, in their analysis of 382 COVID-19 clinical trial registrations: Jeff Aronson, Robin Ferner, Nicholas DeVito, Carl Heneghan
https://www.cebm.net/oxford-covid-19/covid-19-registered-trials-and-analysis/

1) Pharmacological interventions

- (a) Antiviral drugs, not specified
  - (i) Immunoglobulin
  - (ii) Interferons
  - (iii) Interleukin-2
- (b) Antiviral drugs, broad spectrum
  - (i) Favipiravir
  - (ii) Triazavirin
  - (iii) Umifenovir
  - (iv) Oseltamivir
  - (v) Ribavirin
- (c) Antiviral drugs, antiretrovirals
  - (i) ASC09
  - (ii) Azvudine
  - (iii) Danoprevir
  - (iv) Darunavir
  - (v) Lopinavir
  - (vi) Ritonavir
  - (vii) Remdesivir
  - (viii) Emtricitabine
  - (ix) Tenofovir
  - (x) Cobicistat
- (d) Other antiviral drugs
  - (i) Baloxavir marboxil
  - (ii) Sofusbovir
  - (iii) Daclatasvir
- (e) Antimalarial drugs
  - (i) Chloroquine
  - (ii) Hydroxychloroquine
  - (iii) Dihydroartemisinin
- (f) Antibiotics and antiparasitics

(i) Carriomycin
(ii) Suramin sodium

(g) Nonspecific anti-inflammatory and immunosuppressive drugs
(i) Corticosteroids
(ii) Fingolimod
(iii) Leflunomide
(iv) Thalidomide

(h) Kinase inhibitors
(i) Jakotinib hydrochloride
(ii) Ruxolitinib

(i) Monoclonal antibodies
(i) Adalimumab
(ii) Camrelizumab
(iii) Eculizumab
(iv) Mepolizumab
(v) PD-1 mAb
(vi) Tocilizumab
(vii) Tozumab
(viii) Adamumab(Qletli)
(ix) Bevacizumab
(x) Ixekizumab
(xi) Sarilumab
(xii) Siltuximab

(j) Miscellaneous others
(i) Acetylcysteine
(ii) Angiotensin receptor blockers
(iii) Bismuth potassium citrate
(iv) Bromhexine hydrochloride
(v) Diammonium glycyrrhizinate
(vi) Dipyridamole
(vii) Ebastine
(viii) Hydrogen peroxide
(ix) Inhaled gases
(x) Pirfenidone
(xi) Polyinosinic-polycytidylic acid
(xii) rhG-CSF
(xiii) Thymosin

(xiv) Tranilast
(xv) Vitamin C
(xvi) Dexmedetomidine
(xvii) Enoxaparin sodium
(xviii) Losartan
(xix) Colchicine
(xx) Sildenafil
(xxi) Noscapine

(2) **Traditional Chinese Medicine (TCM):** named TCMs; unspecified methods; combinations with unspecified Western therapies; and others, e.g. acupuncture.
(3) **Clinical presentation:** epidemiology, susceptibility factors, and clinical outcomes; diagnostic methods, both clinical and laboratory; and prognostic features.
(4) **Advanced therapy medicinal products (ATMP):** medicinal products that include cellular therapies, tissue extracts, plasma, and vaccines for treatment not prevention.

a. Aerosol inhalation of vMIP: viral macrophage inflammatory protein
b. Ankylosaurus; M1 macrophages target
c. Anti-2019-nCoV inactivated convalescent plasma
d. Anti-SARS-CoV-2 inactivated convalescent plasma
e. Biological preparation of human placenta
f. Convalescent plasma treatment
g. Cord blood mesenchymal stem cells
h. Human menstrual blood-derived stem cells
i. Immunoglobulin from cured patients
j. Inactivated Mycobacterium vaccine
k. Infusion of convalescent plasma
l. Mesenchymal stem cells
m. Mesenchymal stem cells exosomes atomization
n. mRNA-1273
o. NK cells
p. Plasma treatment
q. Recombinant cytokine gene-derived protein injection
r. Regulating intestinal flora
s. Therapeutic antibody from recovered novel coronavirus pneumonia patients
t. Umbilical cord blood mononuclear cells
u. Umbilical cord mesenchymal stem cells (hucMSCs)
v. Umbilical cord Wharton's Jelly derived mesenchymal stem cells
w. Umbilical Cord(UC)-derived mesenchymal stem cells
x. Washed
y. microbiota transplantation
z. Recombinant human granulocyte-colony stimulating factor

(5) **Others:** includes

a. nutritional supplements and enteral feeds
b. physiotherapy and exercise
c. physical therapies, such as renal replacement therapy
d. psychotherapies

(6) Behavioural interventions: includes - Questionnaires or studies looking at psychology, user preferences, anxiety, behaviour changes, sociology, anthropology

(7) **Standard of care:** Standard of care, Routine treatment/therapy, Best supportive care, General treatment, Conventional treatment, Standard treatment

NOTE: Where "Western Medicine" is reported - select other if no other details of what they administered/exact intervention details given. If there is a description of western medicine that is consistent with standard of care - select "standard of care"