GLOBAL CALL FOR DATA FOR PRE-ECLAMPSIA
Data Sharing Standards (DSS)

These standards govern the structure, documentation, secure transfer and permitted use of datasets contributing to either or both linked project objectives: (1) reappraisal of the definition and diagnostic framework for pre-eclampsia; and (2) evaluation of risk-stratification strategies for subsequent pre-eclampsia among women without pre-eclampsia at predictor assessment.

1. DATA STRUCTURE

1.1 File format

- Datasets may be provided in long or wide format using STATA, SPSS, CSV or Excel. The dataset should preserve all available measurements and contain sufficient information to permit conversion between long and wide formats without loss of information.
- For repeated measurements, each measurement should be linkable to a unique woman and pregnancy identifier, the marker or variable measured, the measurement or assessment occasion, and the corresponding gestational age or timing. Where multiple measurements occur within the same assessment period, these should remain distinguishable.
- Where more than one measurement was taken on the same day or within the same gestational week, please provide a measurement sequence number and, where available, the time elapsed since the first measurement (e.g. in minutes, hours or days), so that same-day and same-week repeated measurements can be distinguished.
- In wide-format datasets, variable naming and the accompanying data dictionary should clearly identify the marker and timing represented by each repeated-measure variable. In long-format datasets, measurement or assessment occasions should be uniquely identifiable, and this format is preferred when measurements were made at irregular intervals.
- All eligible repeated measurements should be retained. WHO will harmonize repeated-measure data primarily into long format and may reshape data into wide format as required for specific analyses.
- Transformations between formats will preserve the linkage between each woman, pregnancy, marker, measurement occasion, timing and outcome.

1.2 Data dictionary and supporting documentation

Please share a data dictionary and relevant study- or dataset-level metadata to facilitate the harmonization of the dataset. These should be uploaded along with the dataset. The data dictionary should contain all variable names, descriptions, units of measurement, and value labels. The variable names in the tables below are descriptive. In the data dictionary, please also provide the variable name used in your dataset for each variable (ideally short names without spaces or special characters, e.g. “maternal_age”, so that they can be read directly by statistical software), mapped to the corresponding variable in the tables.

Study- or dataset-level metadata should include information on the definition and diagnostic criteria used for pre-eclampsia and any procedures used to verify or adjudicate the diagnosis. Please describe whether case ascertainment was prospective or in real time, or based on extraction from medical

records alone or whether there was independent review of medical records to confirm or exclude the diagnosis (and in what proportion of women). Please include sufficient detail to reproduce how missed, incomplete, or incorrectly categorized diagnoses were handled and whether any diagnoses were reclassified after initial recording. Please include information on how blood pressure was measured, including the type of device (manual or automated), maternal position, the number of readings taken at each assessment, and whether readings were averaged. Any changes in these methods during the study period should be documented.

For laboratory and biomarker variables, please state the assay platform, manufacturer, and reference ranges used. For birthweight outcomes, please indicate the growth chart or standard used for estimated fetal weight and for defining small for gestational age (e.g. INTERGROWTH-21st, WHO, national chart). For intervention trials, please provide information on group allocations for participants.

Please also include in the study- or dataset-level metadata the definition or diagnostic criteria applied for each of the following outcomes (section 1.4.3): eclampsia; HELLP syndrome; stroke or intracranial haemorrhage; acute kidney injury or dialysis; pulmonary oedema requiring treatment; placental abruption; vital organ failure or organ support; and persistent hypertension or renal impairment at hospital discharge. Please also include in the study- or dataset-level metadata the method used to measure blood loss (e.g. visual estimation, calibrated drape, weighing of materials) and the definition of postpartum haemorrhage applied. Please note any variation in the method between sites or over time.

Please also describe which tests and measurements were available, accessible or routinely performed in the study setting (e.g. blood pressure devices, urine protein testing, full blood panels, angiogenic markers, ultrasound), and the proportion of women in whom they were done, so that the completeness of diagnostic information can be assessed. Please also state the completeness of follow-up for pregnancy outcomes, including the number of women lost to follow-up and the stage of pregnancy or postpartum period at which they were lost.

1.3 Data de-identification

All datasets should be de-identified/anonymized before sharing with WHO. **That is, no personally identifiable information, such as name, date of birth, date of delivery, hospital record number, and geo-coordinates, should be included in the datasets shared.**

1.4 Overview of planned analyses and data sets

The initial analyses are organized as two linked, prespecified objectives:

Objective 1: Reappraisal of the definition and diagnostic framework for pre-eclampsia (Analyses 1.1–1.3), and

Objective 2: Evaluation of risk assessment strategies before pre-eclampsia develops (Analysis 2.1-2.3).

A dataset may contribute to either or both objectives, depending on its population, timing, prognostic markers and outcomes. All analyses will be specified and registered a priori. Additional analyses may be undertaken only within the agreed project objectives and permitted data use.

WHO will assess the quality and veracity of the contributed data, in particular the ascertainment of the pre-eclampsia diagnosis, and may undertake sensitivity analyses restricted to datasets with prospective or independently verified case ascertainment. For prognostic analyses, WHO will pre-specify a threshold for loss to follow-up and will undertake sensitivity analyses to examine the impact of women, and in particular pre-eclampsia cases, lost to follow-up.

Objective 1. Definition and diagnostic framework

Analysis #1.1 - IPD meta-analysis of distributions of candidate diagnostic markers for pre-eclampsia
Aim: To describe the distributions of blood pressure, proteinuria and other candidate diagnostic markers, including symptoms, maternal organ dysfunction indices, angiogenic or placental biomarkers, and ultrasound or fetal and placental indicators, in pregnancy.
Eligible datasets: Studies that measured at least one eligible marker in pregnant women for the purpose of screening for or diagnosing pre-eclampsia.

Analysis #1.2 - IPD meta-analysis of candidate diagnostic markers according to adverse clinical outcomes
Aim: To examine the prognostic implications of candidate diagnostic markers and thresholds by comparing their distributions among women with and without relevant maternal, fetal or neonatal adverse outcomes.
Eligible datasets: Studies that measured at least one eligible candidate diagnostic marker for the purpose of screening for or diagnosing pre-eclampsia and reported at least one relevant adverse clinical outcome.

Analysis #1.3 - IPD meta-analysis of individual and combined diagnostic markers, criteria and thresholds
Aim: To evaluate the prognostic implications of individual and combined diagnostic markers, criteria and thresholds to prognosticate adverse maternal, fetal and neonatal outcomes.
Eligible datasets: Studies that measured at least one eligible candidate diagnostic marker for the purpose of screening for or diagnosing pre-eclampsia and reported at least one relevant adverse clinical outcome.

Objective 2. Risk stratification before disease develops

Analysis #2.1 - IPD meta-analysis of distributions of risk assessment markers before pre-eclampsia develops
Aim: To describe the distributions of maternal and clinical risk factors and eligible clinical, biochemical and ultrasound markers among women who have not developed pre-eclampsia at the relevant marker assessment.

Eligible datasets: General or unselected pregnancy cohorts and cohorts enriched for women at increased baseline risk that measured at least one eligible marker for the purpose of assessing the risk of subsequent pre-eclampsia development before development of the condition. The timing of marker assessment and subsequent pre-eclampsia status must be available.

Analysis #2.2 - IPD meta-analysis of the prognostic accuracy of individual markers for subsequent pre-eclampsia

Aim: To evaluate the prognostic accuracy of individual maternal, clinical, biochemical and ultrasound markers for subsequent pre-eclampsia, including clinically relevant thresholds and, where data permit, early preterm, late preterm, term and superimposed pre-eclampsia.

Eligible datasets: General or unselected pregnancy cohorts and cohorts enriched for women at increased baseline risk that measured at least one eligible marker for the purpose of risk stratification for pre-eclampsia and recorded subsequent development of the condition. Women must not have pre-eclampsia at the relevant marker assessment.

Analysis #2.3 - IPD meta-analysis of multivariable risk stratification strategies and the incremental prognostic value of additional markers

Aim: To evaluate individual and combinations of markers for risk assessment for pre-eclampsia, and to determine whether eligible clinical, biochemical or ultrasound markers improve prognostication beyond maternal and clinical risk factors alone. Analyses may include comparison of existing strategies, assessment of incremental prognostic value, and exploration of performance across relevant populations, gestational age groups, and settings.

Eligible datasets: General or unselected pregnancy cohorts and cohorts enriched for women at increased baseline risk of pre-eclampsia, together with eligible prognostic markers and subsequent pre-eclampsia outcomes. Women must not have pre-eclampsia at the relevant marker assessment.

Eligibility notes. Datasets are not required to have used a particular historical definition of pre-eclampsia, provided the definition can be identified or reconstructed sufficiently for the planned analysis. Cohorts restricted to women with established pre-eclampsia may contribute to definition or severity analyses, but not to analyses requiring an unselected, suspected disease or before disease population. Datasets in which markers were recorded as part of routine care, including registry and electronic health record data, may be eligible provided the marker, its timing and subsequent pre-eclampsia status are available.

1.4.1 Predictor variables

The table below describes **desirable** predictor variables that could be included in the meta-analyses. Please provide all available data fields if they are present in your dataset. If you have any other variables not listed in the table that are relevant, we would also welcome these being submitted. For treatments and interventions, please code "No" only where the intervention is known not to have been given, and leave the value missing where this was not recorded.

Name of the variable	Description	Type	Observations
Maternal age	Number of completed years, measured in the	Discrete, one option only	

Name of the variable	Description	Type	Observations
	study or obtained from medical records		
Race or ethnic group	Racial or ethnic category for participants	Categorical, one option only	Please provide the description of each group in the dataset
Parity	Number of previous births (live or stillbirths) ≥ 24 weeks of gestation	Discrete, one option only	
Height	In cm	Continuous, report the exact value recorded without rounding (e.g. 162 cm)	Please state whether measured or self-reported
Weight	In kg	Continuous, report the exact value recorded without rounding (e.g. 68.5 kg)	Please provide all repeated measurements with their gestational age where available
Body mass index (BMI)	In kg/m^2, calculated as weight (kg) / height $(m)^2$	Continuous, to 1 decimal place (e.g. 26.4)	Please provide all repeated measurements with their gestational age where available
Previous history of pre-eclampsia or eclampsia	Yes or No	Binary	
Family history of pre-eclampsia	Yes or No	Binary	
Chronic hypertension before 20 weeks of gestation	Yes or No	Binary	
Pre-existing or gestational diabetes	Yes or No	Binary	
Pre-existing renal disease	Yes or No	Binary	
Autoimmune disease	Yes or No	Binary	e.g. systemic lupus erythematosus, antiphospholipid syndrome
HIV infection	Yes or No	Binary	
Malaria in the index pregnancy	Yes or No	Binary	

Name of the variable	Description	Type	Observations
Tuberculosis	Yes or No	Binary	
Sickle cell disease or other haemoglobinopathy	Yes or No	Binary	Please specify the type if available
Assisted conception in the index pregnancy	Yes or No	Binary	
Smoking in the index pregnancy	Yes or No	Binary	
Interpregnancy interval	In months since previous birth	Discrete, one option only	
Number of babies	Singleton, twin or triplet or higher order	Categorical, one option only	
Gestational age at dating ultrasound	Gestational age (completed weeks and additional days) at which the dating ultrasound was performed, where ultrasound was used to estimate gestational age	Discrete, as two variables: completed weeks and additional days (0–6) (e.g. 12 weeks and 2 days)	
Aspirin prophylaxis in the index pregnancy	Yes or No	Binary	
Aspirin dose	Daily dose in mg	Continuous, report the exact value recorded without rounding (e.g. 75 mg)	
Gestational age at start of aspirin	Gestational age (completed weeks and additional days) at which aspirin was started, where aspirin prophylaxis was used	Discrete, as two variables: completed weeks and additional days (0–6) (e.g. 12 weeks and 3 days)	
Aspirin adherence	Adherence to aspirin, as recorded in the study, where aspirin prophylaxis was used	Continuous (percentage of doses taken) or categorical, one option only (e.g. good, partial, poor)	
Duration of aspirin use	Duration of aspirin treatment in days or weeks, where available	Continuous, report the exact value recorded without rounding (e.g. 28 days)	
Calcium supplementation in the index pregnancy	Yes or No	Binary	

Name of the variable	Description	Type	Observations
Calcium dose	Daily dose of elemental calcium in mg	Continuous, report the exact value recorded without rounding (e.g. 500 mg)	
Gestational age at start of calcium supplementation	Gestational age (completed weeks and additional days) at which calcium supplementation was started, where used	Discrete, as two variables: completed weeks and additional days (0–6) (e.g. 14 weeks and 0 days)	
Calcium adherence	Adherence to calcium supplementation, as recorded in the study, where used	Continuous (percentage of doses taken) or categorical, one option only (e.g. good, partial, poor)	
Antihypertensive treatment in the index pregnancy	Yes or No	Binary	
Antihypertensive drug name	Name of each antihypertensive drug used, where available	Categorical (e.g. labetalol, nifedipine, methyldopa); more than one drug may be recorded	
Antihypertensive dose	Daily dose in mg of each antihypertensive drug used, where available	Continuous, report the exact value recorded without rounding (e.g. 200 mg)	
Gestational age at start of antihypertensive treatment	Gestational age (completed weeks and additional days) at which antihypertensive treatment was started, where used	Discrete, as two variables: completed weeks and additional days (0–6) (e.g. 20 weeks and 4 days)	
Duration of antihypertensive use	Duration of antihypertensive treatment in days or weeks, where available	Continuous, report the exact value recorded without rounding (e.g. 28 days)	
Antihypertensive adherence	Adherence to antihypertensive treatment, as recorded in the study, where available	Continuous (percentage of doses taken) or categorical, one option only (e.g. good, partial, poor)	
Magnesium sulfate administration	Yes or No	Binary	

Name of the variable	Description	Type	Observations
Magnesium sulfate regimen	Regimen used, where magnesium sulfate was given	Categorical, one option only (e.g. loading dose only, loading plus maintenance dose, other)	
Magnesium sulfate dose	Loading dose and total dose given, in grams, where magnesium sulfate was given	Continuous, report the exact value recorded without rounding (e.g. 4 g; 24 g)	
Timing of magnesium sulfate	Gestational age at the first dose (completed weeks and additional days)	Gestational age: discrete, as two variables, completed weeks and additional days (0–6) (e.g. 33 weeks and 2 days).	Include the interval between the first dose and birth (in hours), where magnesium sulfate was given
Antenatal corticosteroids	Yes or No	Binary	
Antenatal corticosteroid regimen and dose	Drug, dose and number of doses given, where antenatal corticosteroids were given	Categorical (e.g. betamethasone 12 mg twice, dexamethasone 6 mg four times)	
Timing of antenatal corticosteroids	Gestational age at the first dose (completed weeks and additional days)	Gestational age: discrete, as two variables, completed weeks and additional days (0–6) (e.g. 30 weeks and 2 days)	Include the interval between the first dose and birth (in days), where antenatal corticosteroids were given
Tocolytic treatment	Yes or No	Binary	
Tocolytic drug name	Name of each tocolytic drug used, where available	Categorical (e.g. nifedipine, atosiban); more than one drug may be recorded	
Any other relevant clinical variable	If there are any other clinical variables not listed above, please provide these with the relevant data dictionary		

1.4.2 Test variables for risk assessment or for diagnosing pre-eclampsia

It is essential that at least one of the following markers are included in the dataset, together with the gestational age at which it was measured. Please provide all available data fields if they are present in your dataset. If you have any other test variables not listed in the table that are relevant, we would also welcome these being submitted. Where raw or derived imaging data (e.g. ultrasound images or image-derived features) are available, please indicate this in the data dictionary.

Name of the variable	Description	Type	Observations
Systolic blood pressure	In mmHg, measured in pregnancy with the purpose of screening for or diagnosing pre-eclampsia	Continuous, report the exact value recorded without rounding (e.g. 148 mmHg)	Please provide all repeated measurements with their gestational age where available
Diastolic blood pressure	In mmHg, measured in pregnancy with the purpose of screening for or diagnosing pre-eclampsia	Continuous, report the exact value recorded without rounding (e.g. 96 mmHg)	Please provide all repeated measurements with their gestational age where available
Mean arterial pressure	Calculated as (systolic blood pressure + 2 × diastolic blood pressure) / 3	Continuous, to 1 decimal place (e.g. 96.7)	Please provide all repeated measurements with their gestational age where available
Proteinuria (dipstick)	Negative, trace, 1+, 2+, 3+, 4+	Categorical, one option only	Please provide all repeated measurements with their gestational age where available
Protein-creatinine ratio	In mg/mmol	Continuous, to 1 decimal place (e.g. 42.0)	Please provide all repeated measurements with their gestational age where available
Albumin-creatinine ratio	In mg/mmol	Continuous, to 1 decimal place (e.g. 8.5)	Please provide all repeated measurements with their gestational age where available
24-hour urinary protein	In grams per 24 hours	Continuous, to 2 decimal places (e.g. 0.45)	Please provide all repeated measurements with their gestational age where available

Name of the variable	Description	Type	Observations
Platelet count	In $\times 10^9$/L	Continuous, report the exact value recorded without rounding (e.g. 145)	Please provide all repeated measurements with their gestational age where available
Aspartate aminotransferase (AST)	In IU/L	Continuous, report the exact value recorded without rounding (e.g. 62)	Please provide all repeated measurements with their gestational age where available
Alanine aminotransferase (ALT)	In IU/L	Continuous, report the exact value recorded without rounding (e.g. 71)	Please provide all repeated measurements with their gestational age where available
Bilirubin	In µmol/L	Continuous, report the exact value recorded without rounding (e.g. 18)	Please provide all repeated measurements with their gestational age where available
Serum creatinine	In µmol/L	Continuous, report the exact value recorded without rounding (e.g. 92)	Please provide all repeated measurements with their gestational age where available
Estimated glomerular filtration rate	In mL/min/1.73m^2	Continuous, report the exact value recorded without rounding (e.g. 78)	Please provide all repeated measurements with their gestational age where available
Oxygen saturation	In %, measured by pulse oximetry	Continuous, report the exact value recorded without rounding (e.g. 96%)	Please provide all repeated measurements with their gestational age where available

Name of the variable	Description	Type	Observations
Pulmonary oedema	Yes or No	Binary	Please provide all repeated assessments with their gestational age where available
Headache	Yes or No	Binary	Please provide all repeated assessments with their gestational age where available
Visual disturbance	Yes or No	Binary	Please provide all repeated assessments with their gestational age where available
Right upper quadrant or epigastric pain	Yes or No	Binary	Please provide all repeated assessments with their gestational age where available
Hyperreflexia or clonus	Yes or No	Binary	Please provide all repeated assessments with their gestational age where available
Placental growth factor (PlGF)	In pg/mL	Continuous, to 1 decimal place (e.g. 82.4)	Please state the units in the data dictionary and provide all repeated measurements with their gestational age where available
Soluble fms-like tyrosine kinase-1 (sFlt-1)	In pg/mL	Continuous, to 1 decimal place (e.g. 4520.0)	Please state the units in the data dictionary and provide all repeated

Name of the variable	Description	Type	Observations
			measurements with their gestational age where available
sFlt-1/PlGF ratio	Ratio of sFlt-1 to PlGF	Continuous, to 1 decimal place (e.g. 54.9)	Please state the units in the data dictionary and provide all repeated measurements with their gestational age where available
Pregnancy-associated plasma protein-A (PAPP-A)	In multiples of the median (MoM) or in mIU/L	Continuous, to 2 decimal places (e.g. 0.42)	Please provide all repeated measurements with their gestational age where available
Uterine artery Doppler pulsatility index	Mean pulsatility index; please state whether unilateral or bilateral	Continuous, to 2 decimal places (e.g. 1.65)	Please provide all repeated measurements with their gestational age where available
Umbilical artery Doppler	Normal, raised pulsatility index, absent or reversed end-diastolic flow	Categorical, one option only	Please provide all repeated measurements with their gestational age where available
Maternal imaging	Echocardiography, lung ultrasound, transcranial Doppler or other maternal imaging	Continuous or categorical, as appropriate	Provide gestational age and timing relative to diagnosis
Ophthalmic artery Doppler	Please provide all available Doppler indices, including peak ratio, pulsatility index, resistance index and velocity measurements; please state whether the right, left or both eyes were assessed and	Continuous; please provide the value and units for each reported index or velocity measurement	Please provide all repeated measurements with their gestational age where available

Name of the variable	Description	Type	Observations
	describe the measurement protocol		
Estimated fetal weight	In grams or as a centile	Continuous, report the exact value recorded without rounding (e.g. 1850 g)	Please provide all repeated measurements with their gestational age where available
Amniotic fluid volume	Deepest vertical pocket (cm) or amniotic fluid index (cm)	Continuous, to 1 decimal place (e.g. 2.4)	Please provide all repeated measurements with their gestational age where available
Any other relevant clinical variable	If there are any other clinical variables not listed above, please provide these with the relevant data dictionary		

1.4.3 Dependent variables

Outcomes should be reported for the antenatal, intrapartum and postpartum periods up to hospital discharge. Where longer-term outcomes such as persistent hypertension or renal impairment have been collected, these are also eligible.

Name of the variable	Description	Type	Observations
Diagnosis of pre-eclampsia in the index pregnancy	Yes or No	Binary	
Gestational age at pre-eclampsia diagnosis	Gestational age at diagnosis (completed weeks and additional days), where available	Discrete, as two variables: completed weeks and additional days (0–6) (e.g. 34 weeks and 1 day)	
Criteria at pre-eclampsia diagnosis	For each woman diagnosed, whether each of the following was present: hypertension, proteinuria, maternal organ dysfunction, and uteroplacental dysfunction including fetal growth restriction	Categorical, one option only	
Gestational age at birth	Gestational age in completed weeks and additional days, measured	Discrete, as two variables: completed weeks and additional	For multiple pregnancies, please provide the gestational

Name of the variable	Description	Type	Observations
	in the study or obtained from medical records	days (0–6) (e.g. 37 weeks and 3 days)	age at birth separately for each baby, linked to the pregnancy identifier and a unique baby identifier.
Method of gestational age estimation	Method used to estimate gestational age (e.g. last menstrual period, first-trimester ultrasound, second-trimester ultrasound, other)	Categorical, one option only	
Mode of birth	Spontaneous vaginal, forceps, ventouse, planned (elective) caesarean section, emergency caesarean section	Categorical, one option only	For multiple pregnancies, please provide the mode of birth separately for each baby, linked to the pregnancy identifier and a unique baby identifier
Birthweight	In grams, measured in the study or obtained from medical records	Continuous, report the exact value recorded without rounding (e.g. 3250g)	
Eclampsia	Yes or No	Binary	Please provide the gestational age at diagnosis or days after birth where available
HELLP syndrome	Yes or No	Binary	Please provide the gestational age at diagnosis or days after birth where available
Stroke or intracranial haemorrhage	Yes or No	Binary	Please provide the gestational age at diagnosis or days after birth where available
Acute kidney injury or dialysis	Yes or No	Binary	Please provide the gestational age at diagnosis or days after birth where available
Pulmonary oedema requiring treatment	Yes or No	Binary	Please provide the gestational age at

Name of the variable	Description	Type	Observations
			diagnosis or days after birth where available
Placental abruption	Yes or No	Binary	Please provide the gestational age at diagnosis where available
Postpartum haemorrhage	Yes or No	Binary	
Maternal admission to high dependency unit	Yes or No	Binary	Please provide the gestational age at admission or days after birth where available
Maternal ICU admission	Yes or No	Binary	Please provide the gestational age at admission or days after birth where available
Vital organ failure or organ support (temporary or permanent)	Yes or No	Binary	Please provide the gestational age at diagnosis or days after birth where available
Maternal death	Yes or No	Binary	Please provide the gestational age at death or days after birth where available
Preterm birth before 34 weeks of gestation	Yes or No	Binary	
Type of preterm birth before 34 weeks of gestation	Spontaneous or iatrogenic (medically indicated), where preterm birth before 34 weeks occurred	Categorical, one option only	
Fetal death (stillbirth)	Yes or No	Binary	Please provide the gestational age at death where available
Neonatal death before hospital discharge	Yes or No	Binary	Please provide the days after birth where available
Small for gestational age at birth (below the 10th centile)	Yes or No	Binary	Please include details about the growth chart used
Severe neonatal morbidity	Yes, if any severe neonatal morbidity occurred (e.g. hypoxic-ischaemic encephalopathy, necrotizing enterocolitis,	Binary	Please provide the definition applied in the study

Name of the variable	Description	Type	Observations
	intraventricular haemorrhage, bronchopulmonary dysplasia) or No		
Neonatal unit admission	Yes or No	Binary	Please provide the days after birth where available
Persistent hypertension or renal impairment at hospital discharge	Yes or No	Binary	
Lost to follow-up for pregnancy outcomes	Yes or No	Binary	Please provide the gestational age or time at last contact if available
Any other relevant clinical variable	If there are any other clinical variables not listed above, please provide these with the relevant data dictionary		

2. DATA SHARING PROCESS

2.1 Information security and privacy policy

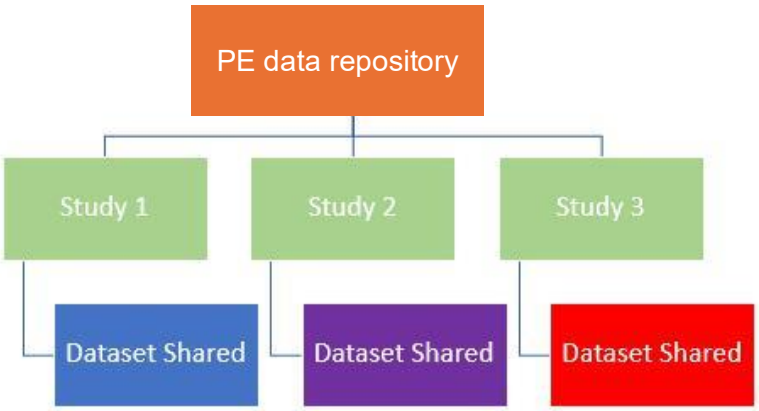
Information security at WHO is based on the ISO 27001 standard. WHO has formal and comprehensive information security policies with respective standard operating procedures. Policies cover information security, access to information and systems, cloud computing, application security, information classification, and related security standards. For more details on WHO's five core data principles, please visit https://www.who.int/data/principles. WHO's data policy can be found here https://www.who.int/about/policies/publishing/data-policy.

In its mission to uphold member states' trust in data, WHO ensures that all data shared with the organization are securely and confidentially stored. WHO also upholds the highest data protection standards and respect for human rights, including the right to privacy, about any personal data and data aggregates of groups of individuals in WHO-controlled data sets. Before sharing any datasets with the organization, we require member States and non-State actors who share data to confirm that the data have been collected following applicable national laws, including data protection laws to protect the confidentiality of identifiable persons.

2.2 Repository details

All the microdata sets that will be shared will be housed in a WHO-managed SharePoint environment. SharePoint is an online, secure document repository developed and maintained by Microsoft. This document repository is private and compliant with General Data Protection Regulation (GDPR).
There are three levels in the pre-eclampsia repository. The first two levels (orange and green) are only accessible to WHO and WHO statisticians. WHO staff not working on the pre-eclampsia project and other researchers that supply data to the project will not get access to these levels.

The third level (blue, purple, and red) is only accessible to the study's principal investigator (PI) or data provider supplying data to the pre-eclampsia project. Data providers or PI will only have access to folders related to the study shared. They will not have access to the folder in other studies. For example, the data provider given access to the blue folder will not get access to the purple or red folders even though they are on the same level.



2.3 Data upload

Stage 1: *Signing data sharing agreement*

After a study (dataset) has met the eligibility criteria, the WHO and data provider will complete a data sharing agreement that permits WHO to use the microdata for the purpose of evaluating the prognostic accuracy of markers for pre-eclampsia, as described above. The data agreement will contain the corresponding data providers' names, affiliations, and e-mails and a confirmation that the data has been collected following applicable national laws, including data protection laws and ethical standards.

Stage 2: *Shared folder invitation*

Upon submission of the data agreement, the corresponding data provider(s) will receive an e-mail invitation from WHO inviting the data provider to their specific data folder. The data provider will have to click "Open" to proceed to the next stage.

Stage 3: *Requesting a verification link*

Clicking "Open" in Stage 2 will navigate the data provider to a webpage where they can request a verification code to access the Shared Folder. After clicking "Send Code", the data provider will receive an e-mail from no-reply@notify.microsoft.com with a verification code. The verification codes are time-bound and will only work for 15 minutes. The data provider will have to request a new code every time they sign into the folder.

Stage 4: *Uploading a dataset*

Once the data provider has access to the folder, they can upload the dataset by selecting "Upload" and selecting the file from the location from their local device.

For any additional questions and queries, please contact PEDefinitionProject@who.int.