INSTRUCTIONS: All sections of this template must be completed by investigators wishing to propose studies that require data and/or specimens collected under the Imbokodo (HVTN 705/HPX 2008) protocol. Send completed proposals to [imbokodo@hvtn.org](mailto:imbokodo@hvtn.org) for review. Additional details about the proposal submission process can be found at [hvtn.org/imbokodo-rfp](http://www.hvtn.org/imbokodo-rfp).

PLEASE REVIEW PRIOR TO PROPOSAL DEVELOPMENT: All specimens and some data from the Imbokodo trial are covered by legal agreements, such as material transfer agreements (MTAs) or data transfer agreements (DTAs). Requests for these specimens or data require amendment of existing agreements and/or initiation of new ones: this process may take 2–6 months. Investigators requesting specimens must provide to HVTN Regulatory Affairs the documentation of IRB/EC approval or an institutional determination that the work is not human subjects research or does not need to be reviewed by the institution. HVTN Regulatory Affairs will initiate additional approvals if required at the clinical research sites. A legal agreement between Janssen, the HVTN’s institution [Fred Hutchinson Cancer Center (Fred Hutch)] and the institution of the Lead investigator is also required and is expected to take 2-6 months to execute. Note that an MTA template has been carefully drafted by Janssen and Fred Hutch. To ensure efficient and timely implementation of Imbokodo/HPX2008 Auxiliary Study Proposals, the MTA template has been set up to be applicable and acceptable to multiple institutions and therefore we can only consider and review minor changes that are required to ensure your institution can comply with appropriately referenced applicable laws, regulations, and internal policies. In case of questions on the MTA template, please send inquiries to [Imbokodo@hvtn.org](mailto:Imbokodo@hvtn.org). Specimens and data will only be provided to the Lead investigator after approvals and agreements are completed. Any further sharing of the specimens and/or data with Project Team members is governed by the terms of the agreement between Janssen, Fred Hutch, and the Lead investigator’s institution. The Lead investigator’s institution is responsible for Project Team member compliance with the MTA. Results of Imbokodo Study proposals must be reviewed prior to presentation or publication, as outlined in the process workflow document posted at [hvtn.org/imbokodo-rfp](http://www.hvtn.org/imbokodo-rfp).

*<<Insert title of proposed study>>*

**Project Team** *(Please include name, role, & email address for all team members.)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Lead Investigator:** | | | **Matthew Chersich** | | | |
| Institution: | | | Wits Reproductive Health Institute | | | |
| Phone: | +27 72 752 1123 | | Email: | | MChersich@wrhi.ac.za | |
| **HVTN Investigators:** | | Name | | Email | | Role |
| Glenda Gray | | Glenda.gray@mrc.ac.za | | Use of study specimens  Use of study data  Other (no use of data/specimens) |
|  | |  | | Use of study specimens  Use of study data  Other (no use of data/specimens) |
| **Non-HVTN Collaborators:** | | Guéladio Cissé | | [gueladio.cisse@swisstph.ch](mailto:gueladio.cisse@swisstph.ch)  ,+41 79 938  11 98 | | Use of study specimens  Use of study data  Other (no use of data/specimens) |
| Matthew Chersich | | [MChersich@wrhi.ac.za](mailto:MChersich@wrhi.ac.za) | | Use of study specimens  Use of study data  Other (no use of data/specimens) |
|  | | Christopher Jack | | [cjack@csag.uct.ac.za](mailto:cjack@csag.uct.ac.za) | | Use of study specimens  Use of study data  Other (no use of data/specimens) |
|  | | Sibusisiwe Makhanya | | [Sibusisiwe.makhanya@ibm.com](mailto:Sibusisiwe.makhanya@ibm.com) | | ☐ Use of study specimens  ☒ Use of study data  ☐ Other (no use of data/specimens) |
|  | | Gloria Maimela | | [gmaimela@wrhi.ac.za](mailto:gmaimela@wrhi.ac.za) | | ☐ Use of study specimens  ☒ Use of study data  ☐ Other (no use of data/specimens) |
|  | | Craig Parker | | [cparker@wrhi.ac.za](mailto:cparker@wrhi.ac.za) | | ☐ Use of study specimens  ☒ Use of study data  ☐ Other (no use of data/specimens) |

# Request type (choose one):

Participant specimens only\*

Participant data only

Both participant specimens & data\*

**\* If requesting specimens**, fully complete the table below.

|  |  |
| --- | --- |
| Name(s) of Project Team member(s) who will use specimens: |  |
| Institution(s) at which work with specimens will be conducted: |  |
| Shipping address for each lab/institution where specimens will be used: |  |

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# Background/Rationale (Up to 1 page)

*Provide rationale for the proposed study, relevant background information, implications of prior research, anticipated contribution of proposed study to HVTN research agenda (if applicable), and to HIV research in general:*

The proposed study aims to address the complex and interconnected research gaps related to heat-related health outcomes, particularly in urban settings of low- and middle-income countries. The study will reanalyse existing data from longitudinal studies conducted in Johannesburg, South Africa, and Abidjan, Côte d'Ivoire. These studies include trials and cohorts among HIV-infected adults, HIV-uninfected adults, and adults participating in longitudinal studies related to COVID-19 prevention or treatment.

The rationale for this study is based on the limited evidence available on the impact of high temperatures on vulnerable population groups in sub-Saharan Africa, such as those living with HIV. An estimated 26 million people are living with HIV on the subcontinent, with up to 30% of adults infected in some countries. Some recent studies have found that rates of HIV are highest in areas most vulnerable to heat impacts, such as informal settlements. This study aims to provide more nuanced analyses of these associations.

The study will use machine learning methods to construct an index of intra-urban socio-economic and environmental vulnerability factors. The solutions developed by the study will address two major concerns for global policymakers: how to warn people about a heatwave in urban settings in low- and middle-income countries and how to track its impacts. Local, national, and international policymakers will be engaged at all stages.

The anticipated contribution of this study to the HIV research agenda includes providing valuable insights into the associations between heat and other environmental exposures and health outcomes in HIV-infected people. These associations will likely differ in size and nature from heat-health linkages in other population groups. The study will also contribute to the broader HIV research field by providing data on populations at risk for acquiring HIV infection (HIV-negative adults) and those participating in COVID-19 prevention or treatment trials.

Our aim is to analyze the impact of environmental temperatures on health outcomes in a broad population, including those with specific health conditions such as HIV. While the Imbokodo study population underwent specific medical procedures, we believe that the data can provide valuable insights into the general health impacts of heat exposure, especially in the context of HIV. We will ensure that our analysis takes into account the specificities of the data collected during the Imbokodo study.

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# Proposed study details (Up to 2 pages)

1. Study hypotheses and objectives

*Outline the primary hypotheses & the major study objectives and endpoints needed to achieve those objectives:*

1. Map intra-urban heat vulnerability and exposure across urban areas in large African cities. This involves deploying various machine learning methods to understand the spatial variations in heat-health impacts across urban areas.
2. Develop a spatially and demographically stratified heat-health outcome forecast model to predict the probability of adverse health outcomes at different temperature thresholds. This model will ingest high resolution weather hazard data, socio-demographically and geographically stratified vulnerability data, and individual biomedical outcomes data.
3. Develop an Early Warning System reflective of geospatial and individualised risk patterns. The system will provide warnings when dangerous weather is forecasted, taking into account the vulnerability of individuals based on their geolocation and individual health risks.

Study Endpoints Overview

* In this study, the chosen endpoints are not rigid, predetermined outcomes as typically seen in conventional clinical trials. Instead, they serve as a foundation for generating hypotheses about the relationships between heat exposure and various health parameters. These hypotheses will be explored using advanced machine learning (ML) methods to uncover patterns and associations within the data. The flexibility inherent in this approach allows for a more nuanced understanding of how heat impacts health.

1. Inflammatory Markers

* **Variables**: C-Reactive Protein, IL-6, D-dimers
* **Exploratory Hypothesis**: Investigate whether heat exposure is associated with a measurable increase in inflammatory markers.
* **ML Analysis Approach**: Pattern recognition in inflammatory marker levels post-exposure, identifying correlations with heat intensity and duration.
* **Observational Timeline**: 12-24 hours post-exposure.

2. Electrolyte Balance

* **Variables**: Sodium, Potassium
* **Exploratory Hypothesis**: Examine the potential link between prolonged heat exposure and alterations in electrolyte balance, indicative of dehydration.
* **ML Analysis Approach**: Analyzing changes in electrolyte levels in relation to heat exposure duration and environmental conditions.
* **Observational Timeline**: A few hours post-exposure.

3. Blood Pressure

* **Variables**: Systolic and Diastolic Blood Pressure
* **Exploratory Hypothesis**: Assess how heat exposure influences blood pressure, with a focus on detecting decreases post-exposure.
* **ML Analysis Approach**: Utilizing regression models to understand the relationship between heat exposure and blood pressure variations.
* **Observational Timeline**: Up to one day post-exposure.

4. Cardiovascular

* **Variables**: Hypertension
* **Exploratory Hypothesis**: Explore the impact of heat exposure on individuals with pre-existing hypertension.
* **ML Analysis Approach**: Clustering and classification to identify patterns in hypertension exacerbation following heat exposure.
* **Observational Timeline**: Several hours post-exposure.

5. Renal Function

* **Variables**: Creatinine Clearance
* **Exploratory Hypothesis**: Investigate the effect of heat exposure on renal function, as indicated by changes in creatinine clearance.
* **ML Analysis Approach**: Time-series analysis to track renal function changes post-heat exposure.
* **Observational Timeline**: 24-48 hours post-exposure.

6. Blood Sugar

* **Variables**: Glucose Level
* **Exploratory Hypothesis**: Assess the influence of heat exposure on blood sugar levels, especially in individuals with diabetes.
* **ML Analysis Approach**: Examining glucose level fluctuations in relation to heat exposure using predictive analytics.
* **Observational Timeline**: 24 hours post-exposure.
* Application in HIV Research
* These exploratory hypotheses, underpinned by a flexible ML-driven analysis, are particularly pertinent in the context of HIV research. This approach will enable the identification of unique patterns and associations related to heat exposure among HIV-positive individuals, considering their specific health vulnerabilities and treatment contexts.

1. Study design/methods

*Outline the study design, including details regarding:*

1. *Type of study (e.g., analysis of existing data; cross-sectional data analysis; new laboratory assays with existing stored specimens):* analysis of existing data
2. *Outcomes to be measured:*

In the context of the HE2AT Center's RP2 study, the variables listed serve as key indicators to measure various health and environmental outcomes related to heat exposure. These measurements are not traditional clinical trial endpoints but are rather data points used to explore and understand the complex relationships between environmental factors, such as heat, and health outcomes in diverse populations. The study will employ machine learning methods to analyze these variables, uncovering patterns and associations that might not be immediately apparent.

Here's how we can describe these outcomes:

Environmental and Demographic Data

* Date, Time, Birth Date, Country, Patient Identifier, Age-Years, Race, Sex: These variables provide essential demographic and temporal context for each data point, crucial for any time-series or demographic analysis.
* Location, Address, Housing Type, Number in Household: These offer insights into the living conditions and potential environmental exposures of the study subjects.

Socioeconomic and Lifestyle Factors

* Exposure to Air Conditioning, Income, Household Income, Smoking Status, Alcohol Abuse, Employment Status, Education Level: These factors help in understanding the socioeconomic status and lifestyle choices of participants, which can significantly influence health outcomes.

Health and Medical History

* Hypertension, Diabetes Mellitus, Hospitalization, Gastroenteritis, Pneumonia, Urinary Tract Infection, Syphilis, HIV Status, Hepatitis B, Schistosomiasis, Tuberculosis: These variables indicate the presence of chronic conditions or recent acute illnesses, which are essential for analyzing health trends and vulnerabilities.
* Hemoglobin, Creatinine, Creatinine Clearance, HIV Viral Load, CD4 Count, Platelet Count, Liver Enzymes, Renal Function Markers, Cholesterol Levels, Blood Sugar Levels: These laboratory measurements provide a snapshot of the physiological state of the participants, offering clues to their overall health and response to environmental stressors.

1. *Sample size:* Dependent on number of acquired studies
2. Study Deliverables

*Please describe plan for data sharing, publication and/or presentation of findings, including estimated timelines for completion of study deliverables:*

The data-sharing plan for this study is comprehensive and considers ethical and legal standards. Following the Research Data Management policy, the data will be made openly available with as few restrictions as possible. However, there are necessary constraints on data availability, including the protection of personal data, intellectual property, commercial interests of project partners, and security concerns. Strategies to limit these restrictions may include de-identifying the data, gaining participant consent for data sharing, and gaining copyright permissions.

De-identified data will be findable through publicly accessible and searchable metadata indexes. It will be accessible either openly through a public-facing component of the Data Management Plan (DMP) data repository or through a data access request to the Data Management and Access Committee (DMAC), where a Data Sharing Agreement is required. Interoperability will be enabled through strict adherence to established data and metadata standards. Reuse will be supported through rigorous documentation of the data, including limitations and guidance for reuse.

Researchers wishing to access the data will not have to wait for the research findings to be accepted for publication or for the 'final research data' prior to data sharing, provided their research questions do not directly overlap with the specific question being addressed in this study. Formal collaboration agreements around data sharing will be developed with the data owners who contribute data to the database, setting out the terms and conditions for data reuse.

Results of the study activities will be shared with the research community and the public through conference presentations, publication in peer-reviewed journals, and media interactions. The exact timelines for the completion of study deliverables are not specified in the provided context.

1. **Funding Source**

*Please describe the source & status of funding for this proposed study and note any funding timelines or associated requirements for sharing/publishing data:*

Research reported in this publication was supported by the Fogarty International Center and National Institute of Environmental Health Sciences (NIEHS) and OD/Office of Strategic Coordination (OSC) of the National Institutes of Health under Award Number U54 TW 012083. The award runs from 2022-2026.

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# Requested specimens, data and/or analysis

*Please provide a detailed description of specimens/data required and assays/analyses to be conducted**:*

1. **Cohort/Sample Description**:
   1. **Timepoint(s) or visit(s) required**:A minimum of two visits and more.
   2. **Applicable treatment group(s)** (e.g., vaccine/placebo, subset of all available, etc.): All groups
   3. **Other participant characteristics** (e.g., cases/controls or specific region): Adults from the greater Johannesburg region.
2. **For study data requests:**
   1. **Provide a detailed description of the data being requested** (type of data, sample size, required variables, desired data format): We request clinical data and geo-location data disaggregated to Johannesburg or lower resolution (ideally household address). .

We request data from the following studies, each with a sample size over 200 participants, specifically for those eligible in Johannesburg

a. HVTN 702 - (NCT02968849): A Phase 2b/3 randomized trial of the efficacy of ALVAC-HIV and bivalent subtype C gp120-MF59 vaccines to prevent HIV-1 infection in South Africa. Enrolled 5,407 participants across 14 sites.

b. HVTN 703/HPTN 081 (NCT02568215): A Phase 2b randomized, double-blind, placebo-controlled trial of a HIV-1 vaccine regimen in women at risk of HIV-1 infection in sub-Saharan Africa. Enrolled 1,900 women aged 18-40 who are at risk of HIV-1 infection, with a 2:1 active: control allocation.

c. HVTN 705: A Phase 2b randomized, double-blind, placebo-controlled trial of a HIV-1 vaccine regimen in South Africa. Enrolled 1,924 participants across 21 sites in and outside Johannesburg.

d. HVTN 503 (NCT00413725): A Phase 2b randomized, double-blind, placebo-controlled test-of-concept study of a Clade B-based HIV-1 vaccine in South Africa. Enrolled 801 participants in South AfricaWe request access to the variables of interest listed in the table at the end of this section.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Variable Name | Description | Variable Type | Variable Category | Ontology Code | URL |
| [Date](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25164) | The particular day, month and year an event has happened or will happen. | Discrete | Static | NCIT:C25164 | http://purl.obolibrary.org/obo/NCIT\_C25164 |
| [Time](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25207) | The continuum of experience in which events pass from the future through the present to the past. | Discrete | Static | NCIT:C25207 | http://purl.obolibrary.org/obo/NCIT\_C25207 |
| [Birth Date](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C68615) | The calendar date on which a person was born. | Discrete | Static | NCIT:C68615 | http://purl.obolibrary.org/obo/NCIT\_C68615 |
| [Country](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25464) | A collective generic term that refers here to a wide variety of dependencies, areas of special sovereignty, uninhabited islands, and other entities in addition to the traditional countries or independent states. | Nominal | Static | NCIT:C25464 | http://purl.obolibrary.org/obo/NCIT\_C25464 |
| [Patient Identifier](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C164337) | An alphanumeric identifier assigned to a specific patient. | Nominal | Static | NCIT:C164337 | http://purl.obolibrary.org/obo/NCIT\_C164337 |
| [Age-Years](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C37908) | The length of a person's life, stated in years since birth. | Discrete | Static | NCIT:C37908 | http://purl.obolibrary.org/obo/NCIT\_C37908 |
| [Race](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C17049) | A geographic ancestral origin category that is assigned to a population group based mainly on physical characteristics that are thought to be distinct and inherent. | Nominal | Static | NCIT:C17049 | http://purl.obolibrary.org/obo/NCIT\_C17049 |
| [Sex](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C28421) | The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. | Nominal | Static | NCIT:C28421 | http://purl.obolibrary.org/obo/NCIT\_C28421 |
| [Height](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25347) | The vertical measurement or distance from the base to the top of an object; the vertical dimension of extension. | Continuous | Static | **NCIT:C25347** | http://purl.obolibrary.org/obo/NCIT\_C25347 |
| [Body Weight](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C81328) | The weight of a subject. | Continuous | Static | NCIT:C81328 | http://purl.obolibrary.org/obo/NCIT\_C81328 |
| [Body Mass Index](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C16358) | An individual's weight in kilograms divided by the square of the height in meters. | Continuous | Static | NCIT:C16358 | http://purl.obolibrary.org/obo/NCIT\_C16358 |
| [Location](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25341) | A position, site, or point in space where something can be found. | Continuous | Static | **NCIT:C25341** | http://purl.obolibrary.org/obo/NCIT\_C25341 |
| [Address](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C25407) | A standardized representation of the location of a person, business, building, or organization. | Continuous | Static | NCIT:C25407 | http://purl.obolibrary.org/obo/NCIT\_C25407 |
| [Housing Type](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C90397) | The classification of a residential structure | Nominal | Static | NCIT:C90397 | http://purl.obolibrary.org/obo/NCIT\_C90397 |
| [Number in household (observable entity)](https://www.ebi.ac.uk/ols4/ontologies/snomed/classes/http%253A%252F%252Fsnomed.info%252Fid%252F224525003) | Number in household | Discrete | Static | SNOMED:224525003 | http://snomed.info/id/224525003 |
| [exposure to air conditioning unit](https://www.ebi.ac.uk/ols4/ontologies/ecto/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FECTO_1000032) | A exposure event involving the interaction of an exposure receptor to the condition of air conditioning unit. | Binary | Static | ECTO:1000032 | http://purl.obolibrary.org/obo/ECTO\_1000032 |
| [Income](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C41150) | A gain or recurrent benefit during a period of time, usually measured in money that derives from capital or labor. | Continuous | Static | NCIT:C41150 | http://purl.obolibrary.org/obo/NCIT\_C41150 |
| [Household Income](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C70811) | A demographic parameter indicating the amount of earnings made by a family. | Continuous | Static | NCIT:C70811 | http://purl.obolibrary.org/obo/NCIT\_C70811 |
| [Smoking Status](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C19796) | An indication of a person's current tobacco and nicotine consumption as well as some indication of smoking history. | Binary | Static | NCIT:C19796 | http://purl.obolibrary.org/obo/NCIT\_C17934 |
| [Alcohol Abuse](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C20701) | The use of alcoholic beverages to excess, either on individual occasions ("binge drinking") or as a regular practice. | Binary | Static | NCIT:C20701 | http://purl.obolibrary.org/obo/NCIT\_C20701 |
| [Employment Status](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C179143) | The state of a person with regard to earning wages or salary. | Binary | Static | NCIT:C179143 | http://purl.obolibrary.org/obo/NCIT\_C179143 |
| [Education Level](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C17953) | An indication of the years of schooling completed in graded public, private, or parochial schools, and in colleges, universities, or professional schools. | Discrete | Static | NCIT:C17953 | http://purl.obolibrary.org/obo/NCIT\_C17953 |
| [Lost To Follow-Up](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C48227) | The subject was not available for follow-up procedures. | Binary | Static | NCIT:C70740 | <http://purl.obolibrary.org/obo/NCIT_C70740> |
| [Hypertension](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C3117) | Blood pressure that is abnormally high. | Binary | Maternal | NCIT:C3117 | http://purl.obolibrary.org/obo/NCIT\_C3117 |
| [Diabetes Mellitus](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C2985) | A metabolic disorder characterized by abnormally high blood sugar levels due to diminished production of insulin or insulin resistance/desensitization. | Binary | Maternal | NCIT:C2985 | http://purl.obolibrary.org/obo/NCIT\_C2985 |
| [Hospitalization](https://www.ebi.ac.uk/ols4/ontologies/scdo/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FSCDO_0000573) | The confinement of a patient in a hospital. | Binary | Maternal, Neonatal | SCDO:0000573 | http://purl.obolibrary.org/obo/SCDO\_0000573 |
| [Gastroenteritis](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C34632) | An inflammatory disorder that affects the upper and lower gastrointestinal tract. Most commonly, this is attributed to viruses; however bacteria, parasites or adverse reactions can also be the culprit. Symptoms include acute diarrhea and vomiting. | Binary | Maternal, Neonatal | NCIT:C34632 | http://purl.obolibrary.org/obo/NCIT\_C34632 |
| [Pneumonia](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C3333) | An acute, acute and chronic, or chronic inflammation focally or diffusely affecting the lung parenchyma, due to infections (viruses, fungi, mycoplasma, or bacteria), treatment (e.g. radiation), or exposure (inhalation) to chemicals. Symptoms include cough, shortness of breath, fevers, chills, chest pain, headache, sweating, and weakness.… | Binary | Maternal, Neonatal | NCIT:C3333 | http://purl.obolibrary.org/obo/NCIT\_C3333 |
| [Urinary Tract Infection](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C50791) | A bacterial infectious process affecting any part of the urinary tract, most commonly the bladder and the urethra. Symptoms include urinary urgency and frequency, burning sensation during urination, lower abdominal discomfort, and cloudy urine. | Binary | Maternal, Neonatal | NCIT:C50791 |  |
| [Syphilis](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C35055) | A contagious bacterial infection caused by the spirochete Treponema pallidum. It is a sexually transmitted disorder, although it can also be transmitted from the mother to the fetus in utero. Typically, it is initially manifested with a single sore which heals without treatment. If the infection is left untreated, the initial stage is followed by skin rash and mucous membrane lesions. A late stage follows, which is characterized by damage of the internal organs, including the nervous system. | Binary | Maternal, Neonatal | NCIT:C35055 | http://purl.obolibrary.org/obo/NCIT\_C35055 |
| [HIV Status](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C157155) | The result of testing to determine if an individual is infected with the human immunodeficiency virus. | Binary | Maternal, Neonatal | NCIT:C157155 | http://purl.obolibrary.org/obo/NCIT\_C157155 |
| [Hepatitis B Infection](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C3097) | A viral infection caused by the hepatitis B virus. | Binary | Maternal, Neonatal | NCIT:C3097 | http://purl.obolibrary.org/obo/NCIT\_C3097 |
| [Schistosomiasis](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C35000) | A parasitic infection caused by flukes of the genus Schistosoma. Signs and symptoms include fever, abdominal pain, eosinophilia and hepatosplenomegaly. If left untreated it may eventually cause liver damage leading to cirrhosis, bladder cancer and kidney failure. | Binary | Maternal, Neonatal | NCIT:C35000 | http://purl.obolibrary.org/obo/NCIT\_C35000 |
| [Tuberculosis](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C3423) | A chronic, recurrent infection caused by the bacterium Mycobacterium tuberculosis. Tuberculosis (TB) may affect almost any tissue or organ of the body with the lungs being the most common site of infection. The clinical stages of TB are primary or initial infection, latent or dormant infection, and recrudescent or adult-type TB. Ninety to 95% of primary TB infections may go unrecognized. Histopathologically, tissue lesions consist of granulomas which usually undergo central caseation necrosis. Local symptoms of TB vary according to the part affected; acute symptoms include hectic fever, sweats, and emaciation; serious complications include granulomatous erosion of pulmonary bronchi associated with hemoptysis. If untreated, progressive TB may be associated with a high degree of mortality. This infection is frequently observed in immunocompromised individuals with AIDS or a history of illicit IV drug use. | Binary | Maternal, Neonatal | NCIT:C3423 | http://purl.obolibrary.org/obo/NCIT\_C3423 |
| [Hemoglobin](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C16676) | The red respiratory protein of erythrocytes, consisting of approximately 3.8% heme and 96.2% globin (64.5 KD), which as oxyhemoglobin (HbO2) transports oxygen from the lungs to the tissues where the oxygen is readily released and HbO2 becomes Hb. | Continuous | Laboratory | NCIT:C16676 | http://purl.obolibrary.org/obo/NCIT\_C16676 |
| [Creatinine](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C399) | The breakdown product of creatine, a constituent of muscle tissue, that is excreted by the kidney and whose serum level is used to evaluate kidney function. | Continuous | Laboratory | NCIT:C399 | http://purl.obolibrary.org/obo/NCIT\_C399 |
| [Creatinine Clearance](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C25747) | The determination of the clearance of endogenous creatinine, used for evaluating the glomerular filtration rate. | Continuous | Laboratory | NCIT:C25747 | http://purl.obolibrary.org/obo/NCIT\_C25747 |
| [HIV Viral Load Measurement](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C92544) | The determination of the HIV viral load in a specimen. | Continuous | Laboratory | NCIT:C92544 | http://purl.obolibrary.org/obo/NCIT\_C92544 |
| [CD4 Expressing Cell Count](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C103810) | The determination of the amount of the CD4 expressing cells in a sample. | Continuous | Laboratory | NCIT:C103810 | http://purl.obolibrary.org/obo/NCIT\_C103810 |
| [Platelet Count](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C51951) | The determination of the number of platelets in a biospecimen. | Continuous | Laboratory | NCIT:C51951 | http://purl.obolibrary.org/obo/NCIT\_C51951 |
| [Aspartate Aminotransferase Measurement](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C64467) | A quantitative measurement of aspartate aminotransferase present in a sample. | Continuous | Laboratory | NCIT:C64467 | http://purl.obolibrary.org/obo/NCIT\_C64467 |
| [Alanine Aminotransferase Measurement](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C64433) | A quantitative measurement of alanine aminotransferase present in a sample. | Continuous | Laboratory | NCIT:C64433 | http://purl.obolibrary.org/obo/NCIT\_C64433 |
| [Protein to Creatinine Ratio Measurement](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C79463) | The determination of the ratio of total protein compared to creatinine present in a sample. The measurement may be expressed as a ratio or percentage. | Continuous | Laboratory | NCIT:C79463 | http://purl.obolibrary.org/obo/NCIT\_C79463 |
| [Alkaline Phosphatase Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64432) | A quantitative measurement of alkaline phosphatase present in a sample. | Continuous | Laboratory | NCIT:C64432 | http://purl.obolibrary.org/obo/NCIT\_C64432 |
| [Gamma Glutamyl Transpeptidase Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64847) | A quantitative measurement of the amount of gamma glutamyl transpeptidase present in a sample. | Continuous | Laboratory | NCIT:C64847 | http://purl.obolibrary.org/obo/NCIT\_C64847 |
| [mean corpuscular volume](https://www.ebi.ac.uk/ols/ontologies/efo/terms?iri=http%3A%2F%2Fwww.ebi.ac.uk%2Fefo%2FEFO_0004526) | A mean corpuscular volume is the result of calculation of the mean volume of erythrocytes in a blood sample. | Continuous | Laboratory | EFO:0004526 | http://www.ebi.ac.uk/efo/EFO\_0004526 |
| [Ferritin Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C74737) | The determination of the amount of ferritin present in a sample. | Continuous | Laboratory | NCIT:C74737 | http://purl.obolibrary.org/obo/NCIT\_C74737 |
| [mean corpuscular hemoglobin concentration](https://www.ebi.ac.uk/ols/ontologies/efo/terms?iri=http%3A%2F%2Fwww.ebi.ac.uk%2Fefo%2FEFO_0004528) | The mean corpuscular hemoglobin concentration is a measure of the concentration of hemoglobin in a given volume of packed red blood cell | Continuous | Laboratory | EFO:0004528 | http://www.ebi.ac.uk/efo/EFO\_0004528 |
| [Viral Resistance Domain](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C106581) | A findings domain that captures information regarding the genetics of viral drug resistance. It contains the reference sequence used to validate the observed genetic mutation of interest. | Nominal | Laboratory | NCIT:C106581 | http://purl.obolibrary.org/obo/NCIT\_C106581 |
| [Drug resistance to antiretroviral therapy (disorder)](https://www.ebi.ac.uk/ols/ontologies/snomed/terms?iri=http%3A%2F%2Fsnomed.info%2Fid%2F425581000) | A binary variable describing the presence or abscence of any drug resistance to antiretroviral therapy. | Binary | Laboratory | SNOMED: 425581000 | http://snomed.info/id/425581000 |
| [Highly Active Antiretroviral Therapy](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C16165) | Drug therapy which targets retrovirus function by multiple mechanisms. | Nominal | Laboratory | NCIT:C16165 | http://purl.obolibrary.org/obo/NCIT\_C16165 |
| [Noncompliance with antiretroviral medication regimen (finding)](https://www.ebi.ac.uk/ols/ontologies/snomed/terms?iri=http%3A%2F%2Fsnomed.info%2Fid%2F713017009) | Noncompliance with antiretroviral therapy | Binary | Clinical | SNOMED: 713017009 | http://snomed.info/id/713017009 |
| [Study Subject Radiography Report](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C115514) | Records pertaining to the findings from a study subject's radiographic images. | Nominal | Clinical | NCIT:C115514 | http://purl.obolibrary.org/obo/NCIT\_C115514 |
| [thyroid stimulating hormone measurement](https://www.ebi.ac.uk/ols/ontologies/efo/terms?iri=http%3A%2F%2Fwww.ebi.ac.uk%2Fefo%2FEFO_0004748) | Is a quantification of thyroid-stimulating hormone, a glycoprotein and hormone secreted from the pituitary which regulates the thryoid. | Continuous | Laboratory | EFO:0004748 | http://www.ebi.ac.uk/efo/EFO\_0004748 |
| [Lower Respiratory Tract Infection](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C35158) | An acute or chronic, viral or bacterial infectious process that affects the lower respiratory tract. | Binary | Clinical | NCIT:C35158 | http://purl.obolibrary.org/obo/NCIT\_C35158 |
| [Upper Respiratory Tract Infection](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C35650) | An infectious process affecting the upper respiratory tract (nose, paranasal sinuses, pharynx, larynx, or trachea). Symptoms include congestion, sneezing, coughing, fever, and sore throat. | Binary | Clinical | NCIT:C35650 | http://purl.obolibrary.org/obo/NCIT\_C35650 |
| [Direct Bilirubin Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C61024) | The bilirubin is bound to glucuronide to form conjugated bilirubin (direct bilirubin). Direct Bilirubin measurement is accomplished by a colorimetric method. Direct Bilirubin in biological fluids reacts with sulfanilic acid at acidic pH to produce a red colored complex. The optical density of produced color has a direct relationship with Direct Bilirubin concentration in the solution. | Continuous | Laboratory | NCIT:C64481 | http://purl.obolibrary.org/obo/NCIT\_C64481 |
| [Indirect Bilirubin Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64483) | Bilirubin is in the insoluble form, unconjugated bilirubin (indirect bilirubin).The non-water soluble, free bilirubin does not react with sulfanilic acid at acidic pH to produce a red colored complex until an accelearator, alcohol, is added to the solution to perform a quantitative measurement of unconjugated bilirubin levels. | Continuous | Laboratory | NCIT:C64483 | http://purl.obolibrary.org/obo/NCIT\_C64483 |
| [Amylase Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64434) | A quantitative measurement of amylase present in a sample. | Continuous | Laboratory | NCIT:C64434 | http://purl.obolibrary.org/obo/NCIT\_C64434 |
| [Lipase Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C117748) | The determination of the amount of lipase present in a sample. | Continuous | Laboratory | NCIT:C117748 | http://purl.obolibrary.org/obo/NCIT\_C117748 |
| [Cholesterol Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C105586) | The determination of the amount of total cholesterol present in a sample. | Continuous | Laboratory | NCIT:C105586 | http://purl.obolibrary.org/obo/NCIT\_C105586 |
| [mean corpuscular hemoglobin](https://www.ebi.ac.uk/ols/ontologies/efo/terms?iri=http%3A%2F%2Fwww.ebi.ac.uk%2Fefo%2FEFO_0004527) | The MCH is the average mass of hemoglobin per red blood cell in a sample of blood and is calculated by dividing the total mass of hemoglobin by the RBC count | Continuous | Laboratory | EFO:0004527 | http://www.ebi.ac.uk/efo/EFO\_0004527 |
| [Low Density Lipoprotein Cholesterol Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C105588) | The determination of the amount of low-density lipoprotein cholesterol present in a sample. | Continuous | Laboratory | NCIT:C105588 | http://purl.obolibrary.org/obo/NCIT\_C105588 |
| [High Density Lipoprotein Cholesterol Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C105587) | The determination of the amount of high-density lipoprotein cholesterol present in a sample. | Continuous | Laboratory | NCIT:C105587 | http://purl.obolibrary.org/obo/NCIT\_C105587 |
| [Glycosylated Hemoglobin Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64849) | A quantitative measurement of the amount of glycosylated hemoglobin present in a sample of blood. | Continuous | Laboratory | NCIT:C64849 | http://purl.obolibrary.org/obo/NCIT\_C64849 |
| [Albumin Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64431) | A quantitative measurement of albumin present in a sample. | Continuous | Laboratory | NCIT:C64431 | http://purl.obolibrary.org/obo/NCIT\_C64431 |
| [Cortisol Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C74781) | The determination of the amount of cortisol present in a sample. | Continuous | Laboratory | NCIT:C74781 | http://purl.obolibrary.org/obo/NCIT\_C74781 |
| [Whole Parathyroid Hormone Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C103451) | The determination of the amount of the whole parathyroid hormone (consisting of amino acids 1-84) in a sample. | Continuous | Laboratory | NCIT:C103451 | http://purl.obolibrary.org/obo/NCIT\_C103451 |
| [Free Thyroxine Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C74786) | The determination of the amount of free thyroxine present in a sample. | Continuous | Laboratory | NCIT:C74786 | http://purl.obolibrary.org/obo/NCIT\_C74786 |
| [Free Triiodothyronine Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C74787) | The determination of the amount of free triiodothyronine present in a sample. | Continuous | Laboratory | NCIT:C74787 | http://purl.obolibrary.org/obo/NCIT\_C74787 |
| [Blood Urea Nitrogen Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C61019) | A quantitative measurement of the amount of urea nitrogen present in a serum sample. | Continuous | Laboratory | NCIT:C61019 | http://purl.obolibrary.org/obo/NCIT\_C61019 |
| [Calcium Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64488) | A quantitative measurement of the amount of calcium present in a sample. | Continuous | Laboratory | NCIT:C64488 | http://purl.obolibrary.org/obo/NCIT\_C64488 |
| [Bone Mineral Density Z-Score](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C139217) | A statistical score representing the number of standard deviations above or below what is expected for an individual's bone density based on his age, sex, weight, and race. Z-scores are most useful in evaluating low bone density in children, premenopausal women, and men younger than age fifty. | Continuous | Clinical | NCIT:C139217 | http://purl.obolibrary.org/obo/NCIT\_C139217 |
| [Serum Uric Acid Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C61034) | A quantitative measurement of the amount of uric acid present in a sample of serum. | Continuous | Laboratory | NCIT:C61034 | http://purl.obolibrary.org/obo/NCIT\_C61034 |
| [Potassium Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64853) | A quantitative measurement of the amount of potassium present in a sample. | Continuous | Laboratory | NCIT:C64853 | http://purl.obolibrary.org/obo/NCIT\_C64853 |
| [Sodium Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64809) | A quantitative measurement of the amount of sodium present in a sample. | Continuous | Laboratory | NCIT:C64809 | http://purl.obolibrary.org/obo/NCIT\_C64809 |
| [COVID-19 RT-PCR assay](https://www.ebi.ac.uk/ols/ontologies/cido/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FCIDO_0000019) | Result of a COVID-19 PCR based assay. | Binary | Laboratory | CIDO:0000019 | http://purl.obolibrary.org/obo/CIDO\_0000019 |
| [C-Reactive Protein Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C64548) | A quantitative measurement of the amount of C-reactive protein present in a sample. | Continuous | Laboratory | NCIT:C64548 | http://purl.obolibrary.org/obo/NCIT\_C64548 |
| [Procalcitonin Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C103430) | The determination of the amount of the procalcitonin in a sample. | Continuous | Laboratory | NCIT:C103430 | http://purl.obolibrary.org/obo/NCIT\_C103430 |
| [interleukin-6 measurement](https://www.ebi.ac.uk/ols4/ontologies/efo/classes/http%253A%252F%252Fwww.ebi.ac.uk%252Fefo%252FEFO_0004810) | Is a quantification of interleukin-6, a pro-inflammatory and anti-inflammatory cytokine. | Continuous | Laboratory | EFO:0004810 | http://www.ebi.ac.uk/efo/EFO\_0004810 |
| [International Normalized Ratio](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25352) | A system, commonly called the INR, established by the World Health Organization (WHO) and the International Committee on Thrombosis and Hemostasis for reporting the results of blood coagulation (clotting) tests. All results are standardized using the international sensitivity index (ISI) for the particular thromboplastin reagent and instrument combination utilized to perform the test; the ratio of a patient's clotting time to the lab's mean reference value is normalized against the ISI. (from medterms.com and medicine.ucsf.edu) | Continuous | Laboratory | **NCIT:C25352** | http://purl.obolibrary.org/obo/NCIT\_C25352 |
| [D-Dimer Measurement](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C82621) | The determination of the amount of d-dimers present in a sample. | Continuous | Laboratory | NCIT:C82621 | http://purl.obolibrary.org/obo/NCIT\_C82621 |
| [Unipolar Depression](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C35094) | A mood disorder having a clinical course involving one or more episodes of serious psychological depression that last two or more weeks each, do not have intervening episodes of mania or hypomania, and are characterized by a loss of interest or pleasure in almost all activities and by some or all of disturbances of appetite, sleep, or psychomotor functioning, a decrease in energy, difficulties in thinking or making decisions, loss of self-esteem or feelings of guilt, and suicidal thoughts or attempts. | Binary | Clinical | NCIT:C35094 | http://purl.obolibrary.org/obo/NCIT\_C35094 |
| [Generalized Anxiety Disorder](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C92622) | An anxiety disorder characterized by excessive and difficult-to-control worry about a number of life situations. The worry is accompanied by restlessness, fatigue, inability to concentrate, irritability, muscle tension, and/or sleep disturbance and lasts for at least 6 months. | Binary | Clinical | NCIT:C92622 | http://purl.obolibrary.org/obo/NCIT\_C92622 |
| [Adverse Event](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C41331) | Any unfavorable or unintended disease, sign, or symptom (including an abnormal laboratory finding) that is temporally associated with the use of a medical treatment or procedure, and that may or may not be considered related to the medical treatment or procedure. Such events can be related to the intervention, dose, route of administration, patient, or caused by an interaction with another drug(s) or procedure(s) | Binary | Clinical | NCIT:C41331 | http://purl.obolibrary.org/obo/NCIT\_C41331 |
| [Heart Rate](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C49677) | The number of heartbeats per unit of time, usually expressed as beats per minute. | Continuous | Clinical | NCIT:C49677 | http://purl.obolibrary.org/obo/NCIT\_C49677 |
| [Systolic Blood Pressure](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25298) | The maximum pressure exerted into the systemic arterial circulation during the contraction of the left ventricle of the heart. | Continuous | Clinical | NCIT:C25298 | http://purl.obolibrary.org/obo/NCIT\_C25298 |
| [Diastolic Blood Pressure](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C25299) | The minimum pressure exerted into the systemic arterial circulation during cardiac ventricular relaxation and filling. | Continuous | Clinical | NCIT:C25299 | http://purl.obolibrary.org/obo/NCIT\_C25299 |
| [Mean Arterial Pressure](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C49679) | The mean pressure of the blood within the arterial circulation. The arterial pressure may be directly measured by insertion of an intra-arterial catheter connected to a transducer. The mean arterial pressure (MAP) can be calculated by subsequent analysis of the waveform. MAP can be approximated without an invasive procedure using the following formula: diastolic pressure plus 1/3 of the pulse pressure, where pulse pressure is systolic pressure - diastolic pressure. | Continuous | Clinical | NCIT:C49679 | http://purl.obolibrary.org/obo/NCIT\_C49679 |
| [Oxygen Saturation Measurement](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C60832) | The measurement of the ratio of oxygenated hemoglobin to total hemoglobin in the blood | Continuous | Clinical | NCIT:C60832 | http://purl.obolibrary.org/obo/NCIT\_C60832 |
| [Stroke](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C3390) | A sudden loss of neurological function secondary to hemorrhage or ischemia in the brain parenchyma due to a vascular event. | Binary | Clinical | NCIT:C3390 | http://purl.obolibrary.org/obo/NCIT\_C3390 |
| [Myocardial Infarction](https://www.ebi.ac.uk/ols/ontologies/ncit/terms?iri=http%3A%2F%2Fpurl.obolibrary.org%2Fobo%2FNCIT_C27996) | Gross necrosis of the myocardium, as a result of interruption of the blood supply to the area, as in coronary thrombosis. | Binary | Clinical | NCIT:C27996 | http://purl.obolibrary.org/obo/NCIT\_C27996 |
| [Birth Weight](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C76325) | The first weight of a newborn obtained after birth. | Continuous | Clinical | NCIT:C76325 | http://purl.obolibrary.org/obo/NCIT\_C76325 |
| [Parity](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C16955) | The number of pregnancies reaching 20 weeks and 0 days of gestation or beyond, regardless of the number of fetuses or outcomes. | Nominal | Clinical | NCIT:C16955 | http://purl.obolibrary.org/obo/NCIT\_C16955 |
| [Number of Pregnancies](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C106551) | A measurement of the total number of pregnancy events experienced by the female subject. | Nominal | Clinical | NCIT:C106551 | http://purl.obolibrary.org/obo/NCIT\_C106551 |
| [Malaria](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C34797) | A protozoan infection caused by the genus Plasmodium. There are four species of Plasmodium that can infect humans: Plasmodium falciparum, vivax, ovale, and malariae. It is transmitted to humans by infected mosquitoes. Signs and symptoms include paroxysmal high fever, sweating, chills, and anemia. | Binary | Clinical | NCIT:C34797 | http://purl.obolibrary.org/obo/NCIT\_C34797 |
| [Mid-Upper Arm Circumference](https://www.ebi.ac.uk/ols4/ontologies/ncit/classes/http%253A%252F%252Fpurl.obolibrary.org%252Fobo%252FNCIT_C124475) | A circumferential measurement of the largest part of the upper arm. | Continuous | Clinical | NCIT:C124475 | http://purl.obolibrary.org/obo/NCIT\_C124475 |

* 1. **Provide a summary of the analysis plan** (Note: if analysis support is required from HVTN, please describe in Section 6):

Our analysis plan involves the following steps:

i) Data Acquisition: Obtain health outcome data from the clinical trials and cohorts mentioned above. Acquire environmental and socio-economic data from various sources, such as satellite images, meteorological station observations, land surface maps, and population-level surveys. Acquire, anonymize, and preprocess household address data for geospatial mapping.

ii) Intra-urban Vulnerability and Exposure Mapping: Deploy machine learning methods to construct an index of intra-urban socio-economic and environmental vulnerability factors, and develop high-resolution urban temperature hazard maps.

iii) Heat-Health Outcome Forecast Model: Develop a spatially and demographically explicit heat-health outcome model by integrating operational weather forecasts with high-resolution weather hazard data and vulnerability models.

iv) Early Warning System: Develop an Early Warning System, including a digital app, driven by the heat-health outcome forecast model. This system will support the general population, health workers, large employers, and governments in planning for adverse health impacts.

No laboratory work is planned for this study, as we will be analyzing existing data. Our multidisciplinary team of researchers, with expertise in data analysis, machine learning, climate modeling, and public health, will conduct the analyses. We do not require additional assistance from the Core Laboratory or SDMC for the planned analyses.

In summary, the study will employ a multidisciplinary approach, utilizing various resources and methods to achieve its primary objectives. This research project aligns closely with the DS-I Africa objectives, offering possibilities for expansion to other Research Hubs and progressive expansion to cities across Africa.

1. **For specimen requests**:
   1. **Specimen type and minimum volume/number of cells requested per participant**: N/A
   2. **Provide specific inclusion or exclusion criterion for sample selection** (e.g., for HIV status requirements, indicate whether this applies at time of sampling or final status at end or study): N/A
   3. **Indicate what sample metadata will be required** (e.g., treatment assignment, demographics): N/A
2. **For each assay that will be run using study samples**:
   1. **Provide a detailed description of the assay(s) to be conducted** (including methodology and any relevant publications): N/A
   2. **Describe the level of assay qualification and/or validation** (details can be outlined in table below): N/A

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# Quality Assurance

**Provide an overview of the quality management systems in place at your institution** (or attach relevant documents)

1. Type of quality system (e.g., GLP/GCLP/CLIA/Not applicable):
2. Overview ofdata/specimen management systems, equipment maintenance plans, data security plans, etc.:  As informed by the project's data management plan the following procedures will be applied:

**Data Transfer:** Once the application to access data, health data will be transferred to the UCT data platform. We will ensure that this transfer is done securely, utilizing encrypted data transport (TLS) through services like box.com to protect the data during transit.

**Data Storage and Encryption:** If your data includes personally identifiable information, we will encrypt it using the industry-standard 256-bit AES (Advanced Encryption Standard). Access to encryption keys will be limited to the minimum necessary personnel. Metadata, which provides context about the data, will be stored separately to facilitate indexing and software development.

**Data Indexing:** Your data will be indexed using metadata standards to make it easily discoverable and accessible. We plan to share this indexed data through the CSAG/UCT data platform (CKAN implementation) to promote public access. Additionally, metadata will be propagated to the DSI-Africa Open Data Science Platform to enhance discoverability. plans to make the study database publicly available will be discussed with the OG in line with the current ancillary study process.**De-Identification:** To protect individual privacy, we may implement de-identification techniques as needed. This means that sensitive information, such as street addresses, will be replaced with broader area references when possible. Our approach aligns with the principle of minimalism outlined in the Protection of Personal Information Act (POPIA).

**Codebook Remapping and Harmonization:** We will work on creating common codebooks that ensure consistency across various datasets. These codebooks will define how variables are translated and harmonized. This process will also apply to climate and environmental data to ensure compatibility.

**Data Integration and Analysis:** Integrated datasets, along with comprehensive documentation, will be made available for analysis through the Jupyter Hub platform

1. Assay performance characteristics (enter “N/A” for any items that are not applicable):

|  |  |
| --- | --- |
| **Assay Name/Type** *(e.g., Intracellular Cytokine Staining/Flow Cytometry)* | N/A |
| **Assay Status** (choose one, and provide explanation, if necessary) | **N/A**  **In development:** Assay not yet designed/optimized with reagents/controls; has variation in methodology on day-to-day basis.  **Developed:** Assay designed and optimized with appropriate reagents/controls; may have some variation in methodology on day-to-day basis.  **Standardized:** Assay conducted per a standardized operating procedure (SOP) for which all technicians must read and document their understanding. No methodology variation is allowed, and SOP must list all steps, reagents, and equipment and be maintained with formal document management and comply with industry standard requirements for SOPs.  **Qualified:** Assay conducted per an SOP, with assessment of the FDA-indicated parameters for bioanalytical method validation (specificity, precision, accuracy, linearity, limit of detection and limit of quantitation). No pre-set pass/fail criteria for each parameter.  **Validated:** Assay conducted per an SOP, with pass/fail criteria pre-set for all FDA-indicated parameters for bioanalytical method validation (specificity, precision, accuracy, linearity, limit of detection and limit of quantitation). A validation report describes the results and indicates whether the pass/fail criteria were met for each parameter. |
| **Assay Limits** *(Provide LOD, LLOQ, ULOQ)* | N/A |
| **Linear Range** | N/A |
| **Dilution Linearity** | N/A |
| **Specificity** | N/A |
| **Selectivity** | N/A |
| **Repeatability** *(Lower, mid, and high-quality controls)* | N/A |
| **Reproducibility** *(Lower, mid, and high-quality controls)* | N/A |
| **Sample Stability** *(Summarize long term, freeze-thaw, and benchtop stability)* | N/A |
| **Reagent Info** *(Summarize critical reagents, bridging, reagent stability and robustness testing)* | N/A |
| **Other** *(Any other relevant information you wish to provide)* | No laboratory work will be done for our project. |

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# Additional HVTN Support

*Please describe the level of HVTN involvement or support needed for this project (e.g. specimen lists, laboratory assays, dataset preparation and/or data transfer management, analysis plan development, statistical analysis assistance).*

NOTE: *Request fulfillment is dependent on HVTN resource availability.*

1. **HVTN Lab Center Support:**

*Specify any laboratory work that is requested from HVTN Central Laboratories:*

No laboratory work is planned for this study, as we will be analyzing existing data.

1. **HVTN Statistical & Data Management Center (SDMC) support:**

*Specify any support you will require for data management and/or statistical analysis:*

Our multidisciplinary team of researchers, with expertise in data analysis, machine learning, climate modeling, and public health, will conduct the analyses and are happy to work with the HVTN SDMC to ensure a secured data transfer and management process.