Criteria for Being Part of RESPOND

WI R8.1

Replaces	Author: RESPOND Secretariat Date: 06-11-2023	Approved by the RESPOND Executive Committee: 15 DEC 2023 Date (ddMMMyyyy)	Effective by: 15 DEC 2023 Date (ddMMMyyyy)
WI R8.0			

1. PURPOSE AND SCOPE

To define and outline the criteria that need to be fulfilled for new cohorts that want to participate in the RESPOND Outcomes study. These criteria have been set in place to uphold high data quality over time, in addition, to ensure a continuous high scientific output from the study.

2. RESPONSIBILITY

a) The **RESPOND Secretariat** is responsible for

- Providing information regarding RESPOND to cohorts that want to participate in the Outcomes study[1]
- Conducting a written feasibility survey to ensure the cohort can comply with the criteria for joining RESPOND
- Continually evaluate if expectations for RESPOND participation are met once included

b) The **cohort seeking to participate** in RESPOND is responsible for filling out the survey accurately and in accordance with the cohort's actual number of participants, data structure, data collection, and staff employed, within a month of receiving it. The cohort is further expected to continually supply and improve the quality of data submitted, have an active dialogue regarding data quality improvements with the Secretariat and engage in the scientific activities.

3. PROCEDURES

a) When a cohort approaches the RESPOND secretariat with an inquiry about joining RESPOND, the secretariat will send a feasibility survey to be completed by the cohort, listing the criteria for joining the collaboration, as described under b, which can be initiated pending approval by the Executive Committee.

Note: The cohort must be able to *comply with all the criteria* to be considered for inclusion and continued participation once included.

Note: Initiation of the subsequent steps rely on approval by the Executive Committee

b) The criteria for participation in RESPOND include the capacity to

i. Contribute data from ≥1000 unselected HIV-positive individuals.

ii. For both enrolment- and follow-up data submission, all available variables listed in this WI should be submitted from the date of local cohort enrolment, see table 1

iii. Obtain adequately detailed clinical information on the non-AIDS events (including AIDS-defining cancers) listed in table 1 required for supplying clinical event forms via the REDCap system.

iv. Provide ≥ 80 % completeness for all must-have variables (i.e., at least 80 % for each must-have variable; see table 1) for each annual data submission.

v. Collect and store participant data in a HICDEP structured database and perform regular quality assurances on own data.

vi. Submit annual follow-up data for all included participants, in the period 1st September to 1st December each calendar year, via the RESPOND Electronic Submission Tool (REST) in a pre-provided access file template.

vii. The cohort is required to have both a designated clinical lead, and a designated IT manager who are willing to engage with the secretariat, deal with timely communication and contribute to meetings, as well as for the clinical lead to review scientific material.

Note: The RESPOND Executive Committee may decide to temporarily inactivate a cohort in case these expectations are not adequately met, with the prospect of re-activation at later stage, if agreed cohort improvement targets are met.

4. REFERENCES

5. HISTORY LOG – CHANGES PERFORMED

This version includes updates to the WI, that includes criteria not only for joining, but also for continued participation in RESPOND and the potential consequence of temporary inactivation if criteria are not continually met.

Changes from version 8.0 to version 8.1 are highlighted in yellow.

6. ATTACHMENTS

Table 1: Data variables within the RESPOND Outcomes study

Baseline	Infection-related laboratory values	Laboratory values	Antiretroviral and cardiovascular treatment	Paraclinical data	clinical events
Date of birth	HIV-RNA	ALT and/ or AST	*NRTIs	Bone Mass density T score	***Myocardial infarction
Date first seen at department	HCV-antibody	Platelets	*NNRTIs	Bone Mass density Z score	***Stroke
Date of first positive HIV1-Ab test	HCV-RNA	Alkaline phosphatase	*PIs	Bone Mass density area	***Invasive cardiovascular procedures
Date of first positive HCV-Ab test	HCV-antigen	INR	*INSTIs	Proteinuria (dipstick)	***AIDS and Non-AIDS defining cancer
Gender	HBsAg	Haemoglobin	*Entry inhibitors	Blood pressure	***End-stage liver disease
Mode of HIV transmission	HBV DNA	Bilirubin	*Fusion inhibitors	Liver trans elastography (fibroscan)	***End stage renal disease
Country of origin	HCV-genotype (e.g.. genotype 1)	Albumin	CCR5-inhibitors	Liver biopsy (Metavir stage)	***Fractures
Ethnicity	HLA B*5701	Serum creatinine	Post attachment inhibitors	Acoustic radiation force impulse (ARFI)	*** AIDS-defining diseases
Height	CD4	Total cholesterol	*Boosters	HCC screening (Abdominal CT/MRI or ultra sound)	***Tuberculosis Infections including location
Weigth	CD8	HDL- cholesterol	*Generic HIV drugs		***Diabetes
Prior smoking status at baseline	SARS-CoV-2 PCR-test	LDL-cholesterol	**Hepatitis C treatment		Pregnancy
Current smoking status	SARS-CoV-2 antibody-test	Triglycerides	discontinuation of treatment due to toxicity/intolerance (+ reason discontinuing)		*** SARS-CoV-2-related admission
Alcohol abuse assesment following the audit C score		HbA1c or glucose	**Anti-thrombotic drugs		
IDU active (injecting/ non-injecting)		D-vitamin	**Anti-hypertensive drugs		
Familiar CVD disposition in immediate family		Calcium	**Antidiabetic drugs		
		Phosphate	Lipid lowering drugs		
			SARS-COV-2 vaccinations		

Must-have variables are marked with yellow boxes, each of these individual variables should be available for > 80 % of the population. Specifically, for ART, CD4 and HIV-RNA; these variables should be available for >95% of the population

*an entire clinical history of antiretroviral exposure must be supplied: including start and stop dates and reasons for discontinuations

** including start and stop dates and reasons for discontinuations

*** an entire clinical history must be supplied, i.e., information on events occurring before enrollment must be obtained ad supplied