ENHANCE Data collection Case Report Form (CRF)

Purpose
The purpose of this document is to outline the information that will be extracted from patient files and clinic registers for the EHNAHCE study.

Study data
ENHANCE study data will be collected from a variety of sources, TIER.Net, NHLS, patient files, and paper clinic registers.

The data that will be collected from patient files and clinic registers is covered in this document. The information will be extracted by the Data Support Officers using a Case Report Form (CRF) composed of multiple modules, each containing specific data fields. The modules for the CRF will be loaded onto a tablet and the data will be collected electronically. The software on the tablet allows for skip patterns, categorical responses, dates, and specified ranges for numbers and dates.

- The "Outline of data flow" section summarizes the order of the data collection modules for each cohort.
- The "Data collection modules" section outlines the wording, response type, response options, and value ranges for each data field within the modules.
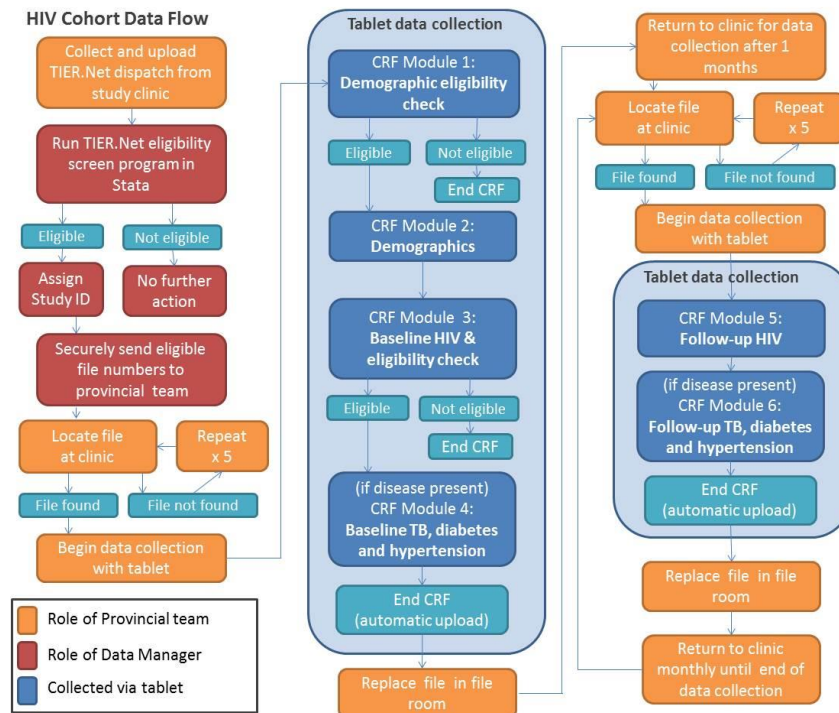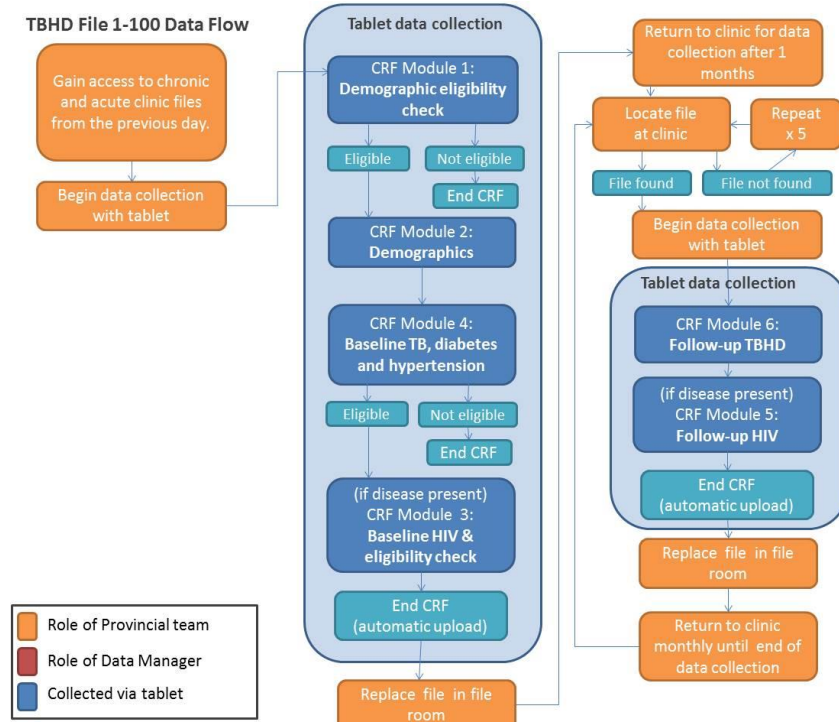
Contents

1. Outline of data flow

The ENHANCE Study is made up of multiple cohorts, for which some of the data fields overlap, and some are cohort-specific. The figures below outline the order of data collection modules that will be used for each cohort.

A. HIV cohorts (Cohorts 1-5)

B. TB, hypertension, and diabetes cohorts (TBHD cohorts)

2. Data collection modules
Module 1: Identifiers and Eligibility

Module 1
Identifiers and Eligibility Module (to be collected for all patients at baseline)

Name of module	#	Question	Categories / values	Type of field	Skip Pattern
Identifiers	1	**ENHANCE Study ID**		Pushed down	
Identifiers	2	**Date of assessment- Day**	**Range: 1-31, unknown**	Number	
Identifiers	3	**Date of assessment- Month**	**Jan, Feb, Mar ect.**	Categorical	
Identifiers	4	**Date of assessment- Year**	**Range: 2016-2018**	Number	
Identifiers	5	**Was file found?**	**Yes** **No**	Categorical	If no, end questionnaire
Identifiers	6	**TIER.Net Folder Number**		Pushed down	
Identifiers	7	**Clinic file number/Patient no**		Text	
Identifiers	8	**Secondary file number/Patient no**		Text	
Identifiers	9	**National ID Number/Passport number**		Text	
Identifiers	10	**Country of ID/Passport**	**South Africa** **Other (specify)** **Unknown**	Categorical	
Identifiers	11	**Address (town/location/extension/village)**		Text	
Identifiers	12	**Address (Province)**	**List all provinces, have an option "Outside of SA"**	Categorical	
Identifiers	13	**Address (Country)**	**South Africa** **Other (specify)**	Categorical	
Identifiers	14	**First Names (List all names)**		Text	
Identifiers	15	**Surname**		Text	
Identifiers	16	**Date of birth- Day**	**1-31**	Number	
Identifiers	17	**Date of birth- Month**	**1-12**	Number	
Eligibility	18	**Date of Birth- year**	**1900-2010**	Number	
Eligibility	19	**Age in years**	**Range: 0-105**	Number	
Eligibility	20	**Sex**	**Male** **Female** **Other (specify)**	Categorical	
Eligibility	21	**Any evidence that the patient is not resident in the facility's catchment area**	**Yes (Specify)** **No**	Categorical	
Eligibility	22	**Any recorded intention to transfer care to a different facility within 12 months**	**Yes (Specify)** **No**	Categorical	
Eligibility	23	**Is there any evidence of pregnancy?**	**Male** **Female- Pregnant** **Female- Not pregnant** **Female- Unknown pregnancy status**	Categorical	Continue to Demographics module

Module 2: Demographics

Module 2
Demographics Module (to be collected for all patients at baseline)

Module	#	Question	Categories / values	Type of field	Skip Pattern
Demographics	1	**Marital status**	**Single- no partner** **Current partner- not married** **Current partner- married** **Widowed** **Divorced** **Other (specify)** **Not available**	Categorical	
Demographics	2	**Religion**	**Christian (Zionist Christian, Pentecostal/Charismatic, Methodist, Catholic)** **Muslim** **Jewish** **Hindu** **African traditional** **Other (Specify)** **Not available**	Categorical	
Demographics	3	**Employment status**	**Employed** **Unemployed- on Grant** **Unemployed- on Pension** **Unemployed- support from friends or family** **Unemployed with no support** **Other (specify)** **Not available**	Categorical	
Demographics	4	**Highest level of education**	**No schooling** **Some Primary school** **Completed Primary school** **Some Secondary school** **Completed Matric** **Tertiary education** **Not available**	Text	
Demographics	5	**Smoking status**	**Non-smoker** **Smoker** **Previous smoker** **Other (specify)** **Not available**	Categorical	
Demographics	6	**Current alcohol use**	**Yes** **No** **Not available**	Categorical	
Demographics	7	**Current drug use**	**Yes (specify)** **No** **Not available**	Categorical	Continue to appropriate module: either HIV, TB, or Hyp/ Diabetes baseline,

Module 3: HIV baseline

Module 3					
HIV Baseline Module (To be collected for all screened into HIV cohorts 1-5)					
Module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
HIV Baseline	1	**Result of HIV test**	**Positive** **Negative** **Discordant** **Invalid test** **Other (Specify)** **Not available**	Categorical	
HIV Baseline	2	**HIV Diagnosis Date- Day**	**Range (1-31), not available**	Number	
HIV Baseline	3	**HIV Diagnosis Date- Month**	**Jan, Feb, Mar, ect, not available**	Categorical	
HIV Baseline	4	**HIV Diagnosis Date- Year**	**Range: 1980-2017**	Number	
HIV Baseline	5	**Date of last clinic visit**		Date	
HIV Baseline	6	**Last weight recorded**	**Range: 0-250 Kg**	Number	
HIV Baseline	7	**Height**	**Range: 100-250cm**	Number	
HIV Baseline	8	**Date of last weight recorded**		Date	
HIV Baseline	9	**Date of next scheduled clinic visit**		Date	
HIV Baseline	10	**Has ART been initiated?**	**Yes** **No**	Categorical	If No, Q 34
HIV Baseline	11	**Method into ART at current facility**	**None (naïve)** **PMTCT** **Prior ART >30 days (EXP)** **PMTCT and Prior ART** **PEP** **Transfer/Moved in** **Other (specify)** **Not available**		
HIV Baseline	12	**Date of CD4 count indicating treatment eligibility (baseline)**		Date	
HIV Baseline	13	**Result of CD4 count indicating treatment eligibility (baseline)**	**Range: 0-2000**	Number	
HIV Baseline	14	**Date treatment eligibility determined**	**Unknown**	Date	
HIV Baseline	15	**WHO Stage at baseline**	**Stage 1** **Stage 2** **Stage 3** **Stage 4** **Other (Specify)** **Not available**	Categorical	
HIV Baseline	16	**Date ART initiated (first dose of medications dispensed)**		Date	
HIV Baseline	17	**First-line ART regimen initially prescribed**	**Tenofovir (TDF)** **Stavudine (d4T)** **Zidovudine (AZT)** **Abacavir (ABC)** **Lamivudine (3TC)** **Emtricitabine (FTC)** **Didanosine (ddl)** **Efavirenz (EFV)** **Nevaripine (NVP)** **Lopinavir (LPV/r)** **Ritonavir (RTV)** **Atazanavir (ATV)**	Choose all that apply	

				Darunavir (DRV) Raltegravir (RAL) Etravirine (ETR) Other (specify)		
HIV Baseline	18	Have there been any changes to the ART regimen between initiation and current regimen?	No Yes	Categorical	
HIV Baseline	19	Date of last prescription visit		Date	
HIV Baseline	20	ART Prescribed at last prescription visit	Tenofovir (TDF) Stavudine (d4T) Zidovudine (AZT) Abacavir (ABC) Lamivudine (3TC) Emtricitabine (FTC) Didanosine (ddI) Efavirenz (EFV) Nevaripine (NVP) Lopinavir (LPV/r) Ritonavir (RTV) Atazanavir (ATV) Darunavir (DRV) Raltegravir (RAL) Etravirine (ETR) Other (specify)	Choose all that apply	
HIV Baseline	21	Were there any changes in the last 12 months from the current ART regimen? Start with earliest change and move forward in time.	No Yes	Categorical	
HIV Baseline	22	Date of visit prior to ART regimen change		Date	
HIV Baseline	23	ART Prescribed at visit prior to ART regimen change	Tenofovir (TDF) Stavudine (d4T) Zidovudine (AZT) Abacavir (ABC) Lamivudine (3TC) Emtricitabine (FTC) Didanosine (ddI) Efavirenz (EFV) Nevaripine (NVP) Lopinavir (LPV/r) Ritonavir (RTV) Atazanavir (ATV) Darunavir (DRV) Raltegravir (RAL) Etravirine (ETR) Other (specify)	Choose all that apply	
HIV Baseline	24	Has blood for a viral load test been drawn?	Yes No	Categorical	
HIV Baseline	25	Date of blood collection for last viral load test		Date	
HIV Baseline	26	Barcode of blood sample for last viral load		Text	
HIV Baseline	27	Results of last viral load test		Free	
HIV Baseline	28	Lower range of detection for assay	Range: 1-400	Number	

Name of module	#	Question	Categories / values	Type of field	Skip Pattern
HIV Baseline	29	**Date of blood collection for second to last viral load test**		Date	
HIV Baseline	30	**Barcode of blood sample for last viral load**			
HIV Baseline	31	**Results of second to last viral load test**		Free	
HIV Baseline	32	**Lower range of detection for assay**	**Range: 1-300**	Number	
HIV Baseline	33	**Has a cryptococcal meningitis test been conducted?**	**Yes** **No**	Categorical	If No, Q 38
HIV Baseline	34	**Date of cryptococcal meningitis test**		Date	
HIV Baseline	35	**Result of cryptococcal meningitis test**		Free	
HIV Baseline	36	**Date cryptococcal meningitis treatment initiated, if relevant**		Date	
HIV Baseline	37	**Any additional medication prescribed at last visit?**	**Co-trimoxazole** **Fluconazole** **Pyridoxine** **Isoniazid (IPT)** **Other (specify)**	Categorical	
HIV Baseline		**Notes on file review**			
HIV Baseline		**Any additional clinical conditions at last visit?**	**Diabetes** **Hypertension** **CVD** **TB** **Mental illness** **Epilepsy** **Other (specify)**	Categorical	Continue to appropriate cohort (1-5) module based upon screening result

Cohort 1 questions (to be collected for all patients screened into the Fast track initiation cohort)					
Name of module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
Cohort 1 Questions	1	**Has the patient received any initiation counselling?**	**Yes** **No**	Categorical	
Cohort 1 Questions	2	**Has an adherence plan been completed?**	**Yes** **No**	Categorical	
Cohort 1 Questions	3	**Initiation counselling session 1: Date**			
Cohort 1 Questions	4	**Initiation counselling session 1: Type of counselling**	**AGL SOP Fast Track Initiation Counselling** **ART Initiation counselling as described in ART Guidelines** **Other (Specify)** **Not available**		
Cohort 1 Questions	5	**Initiation counselling session 1: Has adherence plan been completed?**	**No adherence plan in file** **Adherence plan fully completed** **Adherence plan partially completed (Specify missing information)**		
Cohort 1 Questions	6	**Initiation counselling session 2: Date**			

ENHANCE_Data Collection CRF_V0.1_23Mar16

Name of module	#	Question	Categories / values	Type of field	Skip Pattern
Cohort 1 Questions	7	Initiation counselling session 2: Type of counselling	**AGL SOP Fast Track Initiation Counselling ART Initiation counselling as described in ART Guidelines Other (Specify) Not available**		
Cohort 1 Questions	8	Initiation counselling session 2: Has adherence plan been completed?	**No adherence plan in file Adherence plan fully completed Adherence plan partially completed (Specify missing information)**		
Cohort 1 Questions	9	Initiation counselling session 3: Date			
Cohort 1 Questions	10	Initiation counselling session 3: Type of counselling	**AGL SOP Fast Track Initiation Counselling ART Initiation counselling as described in ART Guidelines Other (Specify) Not available**		
Cohort 1 Questions	11	Initiation counselling session 3: Has adherence plan been completed?	**No adherence plan in file Adherence plan fully completed Adherence plan partially completed (Specify missing information)**		
Cohort 1 Questions	12	Initiation counselling session 4: Date			
Cohort 1 Questions	13	Initiation counselling session 4: Type of counselling	**AGL SOP Fast Track Initiation Counselling ART Initiation counselling as described in ART Guidelines Other (Specify) Not available**		
Cohort 1 Questions	14	Initiation counselling session 4: Has adherence plan been completed?	**No adherence plan in file Adherence plan fully completed Adherence plan partially completed (Specify missing information)**		
Cohort 1 Questions	15	Is patient on the counselling register?		Free	

Cohort 2 questions (to be collected for all patients screened into the Adherence club cohort)					
Name of module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
Cohort 2 Questions	1	**Is patient currently enrolled in an Adherence Club?**	**Yes No**	Categorical	If no, Cohort 3 Questions
Cohort 2 Questions	2	**Date of eligibility for adherence club**		Date	
Cohort 2 Questions	3	**Date of entry into Adherence Club**		Date	

Cohort 2 Questions	4	In which club are they enrolled?		Free	
Cohort 2 Questions	5	Date of last club meeting		Date	
Cohort 2 Questions	6	Which visit number was last visit? (Specify the month number)	Range: 1-20, unknown	Number	
Cohort 2 Questions	7	Did patient addend last club meeting?	Attended Buddy picked up meds Other (Specify)	Categorical	
Cohort 2 Questions	8	Date of last medication pickups		Date	
Cohort 2 Questions	9	How many months of medication were picked up at last visit?	Range: 1-6, unknown	Number	
Cohort 2 Questions	10	Date of next scheduled adherence club meeting	Date	Date	
Cohort 2 Questions	11	Is patient on the adherence club register?	Yes No Unknown	Categorical	

Cohort 3 questions (to be collected for all patients screened into the CCMDD cohort)					
Name of module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
Cohort 3 Questions	1	Is patient enrolled into CCMDD or DMD?	Yes No Unknown	Categorical	
Cohort 3 Questions	2	Date of entry into CCMDD	Date	Date	
Cohort 3 Questions	3	Where is their medication pick-up?		Text	
Cohort 3 Questions	4	Did patient addend last medication pickup appointment?	Attended Buddy picked up meds Other (Specify)	Categorical	
Cohort 3 Questions	5	When was medication last picked up?	Date	Date	
Cohort 3 Questions	6	How many months of medication were picked up at last visit?	Range: 1-6, unknown	Number	
Cohort 3 Questions	7	Is patient on the CCMDD/DMD register?	Yes No Unknown	Categorical	

Cohort 4 questions (to be collected for all patients screened into the enhanced adherence counselling cohort)					
Name of module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
Cohort 4 Questions	1	Has patient received any enhanced adherence counselling?	Yes No Unknown	Categorical	If yes, continue module
Cohort 4 Questions	2	Enhanced adherence session 1: Date of delivery	Date	Date	
Cohort 4 Questions	3	Enhanced adherence session 1: Notes on session		Text	
Cohort 4 Questions	4	Enhanced adherence session 2: Date of delivery	Date	Date	
Cohort 4 Questions	5	Enhanced adherence session 2: Notes on session		Text	

ENHANCE_Data Collection CRF_V0.1_23Mar16

Name of module	#	Question	Categories / values	Type of field	Skip Pattern
Cohort 4 Questions	6	Is there an adherence plan in the patient folder?	Yes No	Categorical	
Cohort 4 Questions	7	Has the adherence plan been updated with the enhanced adherence counselling	Yes No	Categorical	
Cohort 4 Questions	8	Is patient on the counselling register?	Yes No	Categorical	

Cohort 5 questions (to be collected for all patients screened into the early tracing cohort)					
Name of module	#	Question	Categories / values	Type of field	Skip Pattern
Cohort 5 Questions	1	Date of eligibility for early tracing		Date	
Cohort 5 Questions	2	Tracing attempt 1: Date			
Cohort 5 Questions	3	Tracing attempt 1: Type of tracing	Phone tracing SMS or other messaging Household visit Not available	Categorical	
Cohort 5 Questions	4	Tracing attempt 1: Which cadre performed tracing	WBOT Counsellor Nurse Data capturer Other (Specify) Not available	Categorical	
Cohort 5 Questions	5	Tracing attempt 1: Result of tracing attempt	Unable to contact Patient reached- verbally agreed to attend Patient reached- did not agree to attend clinic Patient's friend or family reached Other (Specify) Not available	Categorical	
Cohort 5 Questions	6	Tracing attempt 2: Date	Date	Date	
Cohort 5 Questions	7	Tracing attempt 2: Type of tracing	Phone tracing SMS or other messaging Household visit Not available	Categorical	
Cohort 5 Questions	8	Tracing attempt 2: Which cadre performed tracing	WBOT Counsellor Nurse Data capturer Other (Specify) Not available	Categorical	
Cohort 5 Questions	9	Tracing attempt 2: Result of tracing attempt	Unable to contact Patient reached- verbally agreed to attend Patient reached- did not agree to attend clinic Patient's friend or family reached Other (Specify)	Categorical	

ENHANCE_Data Collection CRF_V0.1_23Mar16

			Not available		
Cohort 5 Questions	10	Tracing attempt 3: Date	Date	Date	
Cohort 5 Questions	11	Tracing attempt 3: Type of tracing	Phone tracing SMS or other messaging Household visit Not available	Categorical	
Cohort 5 Questions	12	Tracing attempt 3: Which cadre performed tracing	WBOT Counsellor Nurse Data capturer Other (Specify) Not available	Categorical	
Cohort 5 Questions	13	Tracing attempt 3: Result of tracing attempt	Unable to contact Patient reached- verbally agreed to attend Patient reached- did not agree to attend clinic Patient's friend or family reached Other (Specify) Not available	Categorical	
Cohort 5 Questions	14	Tracing attempt 4: Date	Date	Date	
Cohort 5 Questions	15	Tracing attempt 4: Type of tracing	Phone tracing SMS or other messaging Household visit Not available	Categorical	
Cohort 5 Questions	16	Tracing attempt 4: Which cadre performed tracing	WBOT Counsellor Nurse Data capturer Other (Specify) Not available	Categorical	
Cohort 5 Questions	17	Tracing attempt 4: Result of tracing attempt	Unable to contact Patient reached- verbally agreed to attend Patient reached- did not agree to attend clinic Patient's friend or family reached Other (Specify) Not available	Categorical	
Cohort 5 Questions	18	Tracing attempt 5: Date	Date	Date	
Cohort 5 Questions	19	Tracing attempt 5: Type of tracing	Phone tracing SMS or other messaging Household visit Not available	Categorical	
Cohort 5 Questions	20	Tracing attempt 5: Which cadre performed tracing	WBOT Counsellor Nurse Data capturer Other (Specify)	Categorical	

			Not available		
Cohort 5 Questions	21	**Tracing attempt 5: Result of tracing attempt**	**Unable to contact Patient reached- verbally agreed to attend Patient reached- did not agree to attend clinic Patient's friend or family reached Other (Specify) Not available**	Categorical	
Cohort 5 Questions	22	**Tracing attempt 6: Date**	**Date**	Date	
Cohort 5 Questions	23	**Tracing attempt 6: Type of tracing**	**Phone tracing SMS or other messaging Household visit Not available**	Categorical	
Cohort 5 Questions	24	**Tracing attempt 6: Which cadre performed tracing**	**WBOT Counsellor Nurse Data capturer Other (Specify) Not available**	Categorical	
Cohort 5 Questions	25	**Tracing attempt 6: Result of tracing attempt**	**Unable to contact Patient reached- verbally agreed to attend Patient reached- did not agree to attend clinic Patient's friend or family reached Other (Specify) Not available**	Categorical	
Cohort 5 Questions	26	**Final outcome of tracing**	**Lost to follow up Returned to care Patient has died Patient has chosen to stop care Other (Specify) Not available**	Categorical	
Cohort 5 Questions	27	**Date of final outcome of tracing**	**Date**	Date	
Cohort 5 Questions	28	**Is patient on the tracing register?**	**Yes No**	Categorical	

Module 4a: Hypertension and diabetes baseline questions

Module 4					
Hypertension and Diabetes Baseline questions (to be collected for all patients screened for the TBHD cohort)					
Name of module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
Hypertension baseline	1	**Date of last clinic visit consulted**		Date	
Hypertension baseline	2	**Primary purpose of clinic visit**	**Routine follow up Medication pickup Acute condition Other (specify)**	Categorical	
Hypertension baseline	3	**Last weight recorded**		Number	
Hypertension baseline	4	**Date of last weight recorded**		Date	
Hypertension baseline	5	**Last pulse recorded**	**Range: 0-200**	Number	
Hypertension baseline	6	**Date of last pulse recorded**			
Hypertension baseline	7	**Note the last three blood pressure measures:**			
Hypertension baseline	8	**Blood pressure date 1**		Date	
Hypertension baseline	9	**Systolic blood pressure 1**	**Range: 0-200**	Number	
Hypertension baseline	10	**Diastolic blood pressure 1**	**Range: 0-200**	Number	
Hypertension baseline	11	**Blood pressure date 2**		Date	
Hypertension baseline	12	**Systolic blood pressure 2**	**Range: 0-200**	Number	
Hypertension baseline	13	**Diastolic blood pressure 2**	**Range: 0-200**	Number	
Hypertension baseline	14	**Blood pressure date 3**		Date	
Hypertension baseline	15	**Systolic blood pressure 3**	**Range: 0-200**	Number	
Hypertension baseline	16	**Diastolic blood pressure 3**	**Range: 0-200**	Number	
Hypertension baseline	17	**Has a clinician noted in the patient file that the patient been diagnosed with Hypertension?**	**Yes No**	Categorical	(If yes, specify date)
Hypertension baseline	18	**Hypertension diagnosis date**	**Date**	Date	
Hypertension baseline	19	**Is patient on any blood pressure medication?**	**No medication Simvastatin Aspirin Hydrochlorothiazide (HCTZ) Enalapril Amolodipine Atenolol Other (specify)**	Choose all that apply	
Hypertension baseline	20	**Date of medication initiation**		Date	

Hypertension baseline	21	If patient not on medication, is there any indication of hypertension diagnosis?	**Yes (Specify)** **No** **Not applicable (patient is on medication)**	Categorical	
Diabetes baseline	22	Has a clinician noted in the patient file that the patient been diagnosed with Diabetes?	**Yes** **No** **Other (specify)**	Categorical	If yes, complete Baseline Diabetes Module
Diabetes baseline	23	Diabetes Diagnosis Date		Date	
Diabetes baseline	24	Is patient on any diabetes medication?	**Aspirin** **Simvastatin** **Enalapril** **Metformin** **Sulphonyurea (Glibenclamide)** **Sulphonyurea (Gliclazide)** **Basal insulin** **Biphasic insulin** **Other (specify)**	Select all that apply	
Diabetes baseline	25	Most recent random glucose date	**Date**	Date	
Diabetes baseline	26	Most recent random glucose result (mmol/l)	**Range: 0-50**	Number (1 decimal place)	
Diabetes baseline	30	Most recent urine glucose date	**Date**	Date	
Diabetes baseline	29	Most recent urine glucose result		Number (1 decimal place)	
Diabetes baseline	31	Result of most recent HBA1C (%)	**Range: 0-30**	Number (1 decimal place)	
Diabetes baseline	32	Date of most recent HBA1C		Date	
Diabetes baseline	33	Any additional medication prescribed at last visit		Free	
Diabetes baseline	34	Date of next visit		Date	
Diabetes baseline	35	Any additional notes on the patient or issues for clarification		Free	

Module 4b: TB baseline questions

Module 4					
TB Baseline questions (to be collected for all patients screened for the TBHD cohort)					
Name of module	**#**	**Question**	**Categories / values**	**Type of field**	**Skip Pattern**
TB Baseline	**1**	**Was a TB Symptom screen conducted at the most recent visit?**	**Yes** **No**	Categorical	If no, go to Q 8
TB Baseline	**2**	**Date of TB Screening**	**Date**	Date	
TB Baseline	**3**	**Screening symptoms: Weight loss**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**4**	**Screening symptoms: Fever**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**5**	**Screening symptoms: Night sweats**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**6**	**Screening symptoms: Haemoptysis**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**7**	**Screening symptoms: Fatigue**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**8**	**Has the patient ever been tested for or diagnosed with TB?**	**Yes** **No** **Unknown**	Categorical	If no, end module
TB Baseline	**9**	**GeneXpert test conducted**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**10**	**GeneXpert date**		Date	
TB Baseline	**11**	**GeneXpert MTB result:**	**N/A not done** **Positive for MTB, rifampicin resistance not detected** **Positive for MTB, rifampicin resistance detected** **Positive for MTB, rifampicin resistance indeterminate** **Negative for MTB** **Invalid** **Error**	Categorical	
TB Baseline	**12**	**Was a TB smear test conducted for the patient?**	**Yes** **No** **Unknown**	Categorical	
TB Baseline	**13**	**TB smear date**		Date	
TB Baseline	**14**	**TB smear (primary) result:**	**Scanty positive** **+ positive** **++ positive** **+++ positive** **Error**	Categorical	

TB Baseline	15	Was a TB culture test conducted?	Yes No Unknown	Categorical	
TB Baseline	16	Culture (primary) date		Date	
TB Baseline	17	Culture (primary) result:	Positive (Days to positivity:_____) Negative Contaminated Error	Categorical	
TB Baseline	18	Culture DST Isoniazid date:		Date	
TB Baseline	19	Culture DST Isoniazid result:	Sensitive Resistant Contaminated Error	Categorical	
TB Baseline	20	Culture DST Rifampicin date		Date	
TB Baseline	21	Culture DST Rifampicin result:	Sensitive Resistant Contaminated Error	Categorical	
TB Baseline	22	Hain DST Isoniazid date			
TB Baseline	23	Hain DST Isoniazid result:	Sensitive Resistant Indeterminate Error	Categorical	
TB Baseline	24	Hain DST Rifampicin date			
TB Baseline	25	Hain DST Rifampicin result:	Sensitive Resistant Indeterminate Error	Categorical	
TB Baseline	26	Was a chest X-ray conducted for the patient?	YesNoUnknown	Categorical	
TB Baseline	27	Chest x-ray date			
TB Baseline	28	Chest x-ray result:	Suggestive of TB Not suggestive of TB No result/error	Categorical	
TB Baseline	29	Has patient been diagnosed with TB?	Yes No	Categorical	
TB Baseline	30	TB Diagnosis Date		Date	
TB Baseline	31	Location of TB	Pulmonary Extra pulmonary Unknown	Categorical	
TB Baseline	32	TB resistance status	No drug resistance Any drug resistance found Unknown	Categorical	
TB Baseline	33	Has TB Treatment been initiated?	Yes No	Categorical	If no, Q 37
TB Baseline	34	Date TB treatment initiated		Date	
TB Baseline	35	TB Treatment Regimen-Intensive phase	RHZE (150/75/400/275) (rifampin, isoniazid, pyrazinamide, and ethambutol) RH (60/60) (rifampin and isoniazid) R (rifampin)	Choose all that apply	

ENHANCE_Data Collection CRF_V0.1_23Mar16

			H (isoniazid) Z (pyrazinamide) E (ethambutol) S (to be determined) Other (specify)		17
TB Baseline	36	**TB Treatment Regimen-Continuation phase**	**RH (150/75) (rifampin and isoniazid)** **RH (300/150) (rifampin and isoniazid)** **RH (60/60) (rifampin and isoniazid)** **R (rifampin)** **H (isoniazid)** **E (ethambutol)** **Other (specify)**	Choose all that apply	
TB Baseline	37	**Treatment stop date**		Date	
TB Baseline	38	**TB Treatment Outcome**	**Cured** **Treatment completed** **Defaulted treatment** **Failed treatment** **Died** **Other (specify)**	Categorical	
TB Baseline	39	**Notes on file review**			
TB Baseline	40	**Any additional clinical conditions at last visit?**	**Diabetes** **Hypertension** **HIV** **CVD** **Mental illness** **Epilepsy** **Other (specify)**	Categorical	Continue to HIV module if HIV positive