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Appendix 2

Fill-in form "NON-AIDS EVENTS" IN CoRIS (NAEs)

BASELINE DATA		
Name of the centre:	**Date data collection:__/__/__**	**Name of person who fills data:**
Patient's code:	**Sex:**	**Date of birth: __/__/__**

	Marcar "X" si ha sufrido	**Date of diagnosis Month**	**Year**
1. Cardiovascular events			
a) Coronary:			
1) Acute myocardial infarction			
2) Angina			
3) Sudden death of possible coronary etiology			
b) Cerebral			
1) Transient ischemic attack			
2) Reversible ischemic deficit			
3) Established stroke			
4) Asymptomatic cerebrovascular disease			
c) Peripheral arterial disease			
d) Congestive heart failure			
e) Primary pulmonary hypertension			
2. Renal events			
a) Acute renal failure			
b) Chronic kidney disease			
c) Tubulopathy/Fanconi syndrome			
d) Symptomatic nephrolithiasis			
e) Initiation of dialysis			
f) Kidney transplantation			
3. Liver events			
a) Hepatic insufficiency/cirrhosis			
b) Ascites			
c) Gastrointestinal bleeding by esophageal varices			
d) Hepatic encephalopathy			
e) Liver transplantation			
4. Neoplastic events			
Any neoplasm			
5. Bone-related events			
a) Vertebral fracture			
b) Large bone fracture			
c) Avascular necrosis			
6. Neuropsychiatric events			
a) Depression			
b) Suicide attempt/Suicide			
c) Psychosis			
7. Metabolic events			
a) Diabetes mellitus			
b) Lactic acidosis			

CARDIOVASCULAR EVENT FORM

1. Event fill-in form (please, mark):

Acute myocardial infarction

Definitive:

1. Diagnostic EKG or
2. Symptoms + probable EKG + rise of cardiac biomarkers (creatin phosphokinase [CK], and MB isoenzyme of CK, LDH, specific troponin T and specífic troponin).
3. Typical symptoms + cardiac biomarkers elevation+ EKG with signs of ischemia, or not codifiable, or not available.

Diagnostic EKG: (a) Q wave appearance. If Q wave is equivocal, it must be accompanied by ST or T wave changes. All these changes must be accompanied by progression of T wave in 3 or more derivations; b) evolving ST elevation lasting more than 24 hours and progression of T wave in 3 or more derivations.

Probable EKG: a) Non-significant ST drop in a register accompanied by significant drop in another register. b) Non-significant ST elevation in a register accompanied by significant elevation in another register c) Non-significant T wave reversal in one register but significant reversal in another one

Probable

Myocardial infarction characteristics:
Transmural (q waves in ECG):
Non-transmural (non q waves)

Angiography (number of vessels with stenosis):
Not done
1 vessel
2 vessels
3 vessels
>3 vessels

Killip Classification
Killip I (no signs/symptoms of left ventricular failure
Killip II (rales or third heart sound or jugular ingurgitation)
Killip III (acute pulmonary edema)
Killip IV (cardiogenic shock)

Angina (symptoms suggestive of myocardial ischemia, such as thoracic pain, or pain in the jaw or the arm. Pain usually lasts less than 20 minutes. There must be changes in ECG which conform the existence of myocardial ischemia, such a depression of al least 0.5 mm of ST segment or T wave reversal of al least 1 mm in 2 or more contiguous derivations)

Sudden death of possible coronary etiology (typical, atypical or not enough described symptoms and previous history of coronary disease or evidence of coronary disease on autopsy)

Transient ischemic attack (Focal neurological deficit due to ischemia of a cerebral territory that lasts less than 24 hours).

Reversible ischemic deficit (Focal deficit which lasts more than 24 hours with ulterior reversal).

Established stroke (Neurological deficit which does not change during the first 24-72 hours after the initiation).

Ischemic
Haemorrhagic

Asymptomatic cerebrovascular disease Patients with vascular risk factors in whom by clinical exam (carotid auscultation), doppler and mainly by neuroimaging studies, have ischemic cerebral asymptomatic lesions (silent infarcts). This group includes also patients with hypodensity in cerebral white matter on CT or MR (leucoaraiosis).

Peripheral arterial disease

Intermittent claudication

Abnormal ankle-brachial index (ABI) (less than 0.9)

Other clinical findings (arterial revascularization or previous amputation)

Congestive heart failure

Class II (NYHA) (mild limitation for ordinary physical activity, such as palpitations or dyspnea, without dyspnea at rest)

Class III (NYHA) (marked limitation for ordinary physical activity, without dyspnea at rest)

Class IV (NYHA) (dyspnea at rest)

RENAL EVENT FORM

1. Event fill-in form (please, mark):

Acute renal failure was defined as an elevation of creatinine over 1.5 mg/dL, or reaching 1.3 times the upper normal limit value, or a decline in glomerular filtration rate to < 60 ml/min. If creatinine was previously elevated, then an increase higher than 0.5 mg compared to previous value.

Chronic kidney disease was defined as either kidney damage or a decreased glomerular filtration rate (GFR) of less than 60 mL/min/1.73 m^2 for 3 or more months. Kidney damage is defined by anatomopathological changes or by biological markers of kidney damage, including abnormalities in the composition of blood or urine or abnormalities on imaging studies. GFR was estimated using the abbreviated MDRD (Modification of Diet in Renal Disease) equation, and it can be classified in 5 stages according to the glomerular filtration rate (GFR)*** decrease.

*The presence of proteinuria above the maximal diary physiologic excretion (<150 mg/day) is a marker of kidney disease, usually more premature than the GFR decrease. Depending on the quantity of protein excretion, it can be classified in microalbuminuria (30-300 mg/day), non nephrotic proteinuria (300 mg a 3,5 g/day), and nephrotic proteinuria (>3,5 g/day). A result of 1+ or more in reactive labstix reflects a proteinuria of 300-500 mg/day (around 10-30 mg/dL). Persistent proteinuria always reflects renal disease and it can be useful to identify incipient renal disease, in which there is not yet effect on GFR.

**Microhematuria and/or dysmorphic red blood cells and/or cilindruria.

***The quantification of GFR will be calculated with the equations of the MDRD (Modification of Diet in Renal Disease) study:
FGR=186 x $(Cr\ p)^{-1.154}$ x $(age)^{-0.203}$ x (0.742 if woman) x (1.210 if Afro-American). GFR is expresed in mL/min/1.73 m2, Cr p in mg/dL, anda ge in years.

Stages of chronic kidney disease (please, mark):

- Kidney damage with GFR>=90 ml/min
  - Proteinuria — Nephrotic range (> 3.5 g/día)
    Non-nephrotic range
  - Microhematuria
- Kidney damage with mild decrease of GFR= 60-89 ml/min
- Kidney damage with moderate decrease of GFR = 30-59 ml/min
- Kidney damage with severe decrease of GFR= 15-29 ml/min
- Terminal renal insufficiency GFR < 15 ml/min

Tubulopathy was defined as three of the following:

- Hypophosphatemia (serum phosphate < 2.7 mg/dL),
- Proteinuria (at least 1+)
- Glucosuria (at least 1+ with normal blood gucose),
- Metabolic acidosis (serum bicarbonate < 23 mEq/L),
- Hypokalemia (serum potassium < 3 mEq/L),
- Nephrogenic diabetes insipidus,
- Aminociduria
- Hypouricemia

Results of renal biopsy (if performed):

LIVER EVENT FORM

1. Event fill-in form (please, mark):

Hepatic insufficiency: Severe impairment of hepatic synthesis (albumin < 3,5 mg/dl, and/or fibrinogen < 180 mg/dl and/or prothrombin activity < 50% without any other subjacent etiology) and portal hypertension assessed with ultrasonography (splenomegaly, collateral circulation or ascites) or endoscopy (esophageal varices or hypertensive gastropathy) or by direct measure (minimal gradient of hepatic venous pressure of 6 mm Hg), or hepatic encephalopathy history in a patient with chronic liver disease, in the absence of other justifying causes.

Ascites: Presence of fluid in peritoneal cavity, observed with image tests (ultrasonography, CT, MR) or confirmed through paracentesis in a patient with known chronic liver disease, in the absence of other justifying causes

Hepatic encephalopathy: Mental impairment (usually central nervous system depression) with compatible clinical signs (i.e. asterixis, hyperamonemia, EEG, etc) in a patient with chronic hepatic disease. Other causes of neurologic disease must have been ruled out

Gastrointestinal bleeding by esophageal varices: Occurrence of hematemesis or melenas with endoscopic evidence of esophageal varices and signs of recent bleeding with

Hepatic transplant

Hepatocarcinoma

Child-Pugh classification:

A (5-6 points)
B (7-9 points)
C (10-15 points)

Child-Pugh Classification of Severity of Liver Disease

Modified Child-Pugh classification of severity of liver disease according to the degree of ascites, the plasma concentrations of bilirrubin and albumin, the prothrombin time, and the degree of encephalopathy.

Parameter	Points assigned		
	1	2	3
Ascites	Absent	Slight	Moderate
Bilirrubin, mg/dL	</= 2	2-3	>3
Albumin, g/dL	>3.5	2.8-3.5	<2.8
Prothrombin time * Seconds over control * INR	 1-3 <1.8	 4-6 1.8-2.3	 >6 >2.3
Encephalopathy	None	Grade 1-2	Grade 3-4

Image tests

Esophageal varices
No esophageal varices
Unknown

Hepatic space occupying lesions (SOL)
No space occupying lesions
Unknown

Portal hypertension (ultrasonography with splenomegaly or ascites), collateral circulation
No portal hypertension
Unknown

Enolism

Enolism
No enolism
Unknown

NEOPLASTIC EVENT FORM

1. Event fill-in form (please, mark):

- ☐ Anal cancer
- ☐ Rectal cancer
- ☐ Bladder cancer
- ☐ Prostate cancer
- ☐ Breast cancer
- ☐ Colonic cancer
- ☐ Kidney cancer
- ☐ Liver cancer
- ☐ Lung cancer
- ☐ Stomach cancer
- ☐ Uterine cancer
- ☐ Head and neck cancer
- ☐ Hodgkin lymphoma
- ☐ Leukemia
- ☐ Melanoma
- ☐ Seminoma
- ☐ Angiosarcoma
- ☐ Brain neoplasm
- ☐ Multiple myeloma
- ☐ Other

2. Write the findings associated with this event:

Carcinomas

TNM stage (please, mark):

T1	N0	M0
T2	N1-3	M1
T3	NX	MX
T4		
Tis		
TX		

1. **Primary tumor (T)**

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ (initial cancer, not disseminated to contiguous tissues)
T1, T2, T3, T4	Size and/or extension of the primary tumor

2. **Regional lymphatic nodes (N)**

NX	Not possible to evaluate regional lymphatic nodes
N0	Not complication with regional lymphatic nodes (cancer was not found in regional lymphatic nodes)
N1, N2, N3	Complication with regional lymphatic nodes (number and/or dissemination extension)

3. **Distant metastases (M)**

MX	Not possible to evaluate distant metastases
M0	No distant metastases (cancer has not disseminated to other locations in the body)
M1	Distant metastases (cancer has not disseminated to other locations in the body)

Lymphomas

Stage:

I: The disease is present in only one group of lymph nodes, or, more rarely, in a single organ that does not belong to the lymph system.

II: The disease is found in two or more groups of lymph nodes on the same side as the diaphragm. In addition, an organ not in the lymph system may be involved close to the involved nodes.

III: The disease is present in lymph node groups on both sides of the diaphragm, occasionally with the involvement of other adjacent organs. If the spleen is involved then the disease becomes stage III as well.

IV: The disease is wide spread, including multiple involvement at one or more extranodal sites (such as the bone marrow).

Grade

Hodgkin

- Lymphocytic
- Nodular sclerosis
- Mixed cell
- Lymphocytic depletion

BONE-RELATED EVENT FORM

1. Event fill-in form (please, mark):

Vertebral fracture:
- Localization
- Severity
  - Grade 1 (20-25%)
  - Grade 2 (25-40%)
  - Grade 3 (>40%)

Non vertebral fractures
- Localization
  - Hip
  - Wrist
  - Other*:*

Avascular necrosis
- Localization:
  - Isolated
  - Bilateral
  - 2 areas of different location
  - > 2 areas of different location fall

Hip
Shoulder
Bones of the foot
Knee
Wrist
Other:

Event description
- Casual drop
- Accident
- Non traumatic

NEUROPSYCHIATRIC EVENT FORM

1. Event fill-in form (please, mark):

Psychosis
- Schizophrenia
- Bipolar disorder
- Psychotic delirium
- Other:

Severe depression that requires pharmacological treatment
Suicide/suicide attempt

Predisposing factors
Toxic dependence

METABOLIC EVENT FORM

1. Treatment	
	Marcar "X"
No therapy	
Diet	
Oral antidiabetics	
Insulin	

2. Symptoms	
	Marcar "X"
Polydipsia	
Polyphagia	
Polyuria	
Asthenia	
Wight loss	
Changes in the conscious level	
Ophthalmologic disturbances	
Other	

3. Findings		
Plasma lactic acid		nn,n mEq/l
Plasma bicarbonate		nnn mMol/L
PH		n,nn
Plasma glucose		nnnn,n mg/dl
AST		nnn,n mU/ml para GOT
ALT		nnn,n mU/ml para GPT
Quick index		nnn%
Other findings:		

Table 1. Unadjusted and adjusted incidence rate ratios for the occurrence of non-AIDS events

			Univariable analyses		Multivariable analyses	
	Events no.	FU py	IRR (95% CI)	*p*	IRR (95% CI)	*p*
Female sex						
No	290	9792	1	1	1	1
Yes	77	2876	0.90 (0.72-1.13)	0.380	0.93 (0.72-1.21)	0.635
Age at cohort entry						
<40	156	8600	1	-	1	-
41-50	140	2885	2.67 (2.11-3.37)	0.000	2.12 (1.59-2.83)	0.000
>50	71	1183	3.30 (2.61-4.17)	0.000	2.88 (2.11-3.93)	0.000
HIV transmission groups						
IDU	107	1866	1	-	1	-
MSM	104	5592	0.32 (0.21-0.48)	0.000	0.54 (0.38-0.77)	0.001
Heterosexual	142	4795	0.51 (0.36-0.72)	0.000	0.64 (0.50-0.82)	0.001
Other/unknown	14	415	0.58 (0.31-1.09)	0.092	0.60 (0.29-1.24)	0.171
Educational level						
None/Primary	167	4637	1	-	1	-
Secondary/University	106	5722	0.51 (0.39-0.66)	0.000	0.69 (0.50-82)	0.006
Unknown	94	2309	1.13 (0.87-1.45)	0.347	1.17 (0.85-1.60)	0.325
Prior clinical AIDS						
No	284	10996	1	-	1	-
Yes	83	1672	1.92 (1.41-2.61)	0.000	1.30 (0.97-1.74)	0.071
Hepatitis C virus coinfection						
No	137	6419	1	-	1	-
Yes	84	1649	2.38 (1.49-3.80)	0.000	1.27 (0.83-1.95)	0.259
Unknown	146	4600	1.48 (1.12-1.97)	0.006	1.28 (0.96-1.71)	0.089
CD4 cells/µL at cohort entry						
>500	71	3695	1	-	1	-
350-500	51	2356	1.12 (0.72-1.76)	0.602	1.08 (0.69-1.69)	0.719
200-350	67	2477	1.40 (0.99-1.99)	0.054	1.35 (0.92-1.98)	0.116
<200	161	3828	2.18 (1.63-2.93)	0.000	1.64 (1.08-2.50)	0.019
Unknown	17	310	2.85 (1.56-5.20)	0.001	1.46 (0.47-4.48)	0.503
HIV RNA copies/mL at cohort entry						
$<10^5$	206	8610	1	-	1	-
$>10^5$	141	3719	1.58 (1.29-1.93)	0.000	1.32 (1.06-1.63)	0.012
Unknown	20	339	2.46 (1.50-4.03)	0.000	1.77 (0.53-5.90)	0.350
Antiretroviral therapy						
No	127	4826	1	-	1	-
Yes	240	7842	1.16 (0.92-1.46)	0.197	0.70 (0.51-0.95)	0.024

FU py, follow-up in patient-years; IRR, incidence rate ratio; CI, confidence interval; IDU, injection drug user; MSM, Men who have sex with men.

Multivariable models were adjusted for sex, age, HIV transmission group, educational level, prior AIDS, hepatitis C coinfection, CD4 cells and HIV viral load at cohort entry, and antiretroviral therapy initiation

Table 2. Adjusted incidence rate ratios for each specific category of non-AIDS events

	Psychiatric				Liver-associated event				Non-AIDS-defining malignancy				Kidney-associated event				Cardiovascular				Metabolic				Bone			
	Events no	FU py	IRR (95% CI)	*p*	Events no	FU py	IRR (95% CI)	*p*	Events no	FU py	IRR (95% CI)	*p*	Events no	FU py	IRR (95% CI)	*p*	Events no	FU py	IRR (95% CI)	*p*	Events no	FU py	IRR (95% CI)	*p*	Events no	FU py	IRR (95% CI)	*p*
Age at cohort entry	68	8748	1	-	65	8836	1	-	23	8840	1	-	16	8850	1	-	10	8867	1	-	13	8849	1	-	12	8861	1	-
<40	46	3045	1.92 (1.39-2.66)	0.000	31	3101	1.67 (0.98-2.86)	0.058	19	3119	1.85 (1.00-3.42)	0.047	20	3097	3.17 (1.58-6.36)	0.001	22	3100	5.36 (2.07-13.90)	0.001	16	3106	2.55 (1.28-5.07)	0.007	11	3125	1.97 (0.90-4.33)	0.088
41-50	18	1273	1.97 (1.05-3.69)	0.033	9	1299	2.58 (1.53-4.35)	0.000	20	1283	4.70 (2.54-8.68)	0.000	13	1274	5.45 (2.10-14.13)	0.000	12	1297	5.61 (2.29-13.74)	0.000	12	1281	4.90 (2.18-11.00)	0.000	7	1302	2.30 (0.94-5.63)	0.067
>50																												
Prior clinical AIDS	115	11251	1	-	48	11420	1	-	49	11412	1	-	30	11424	1	-	35	11438	1	-	28	11417	1	-	19	11454	1	-
No	17	1815	0.95 (0.58-1.55)	0.973	17	1817	1.15 (0.75-1.75)	0.516	13	1831	0.90 (0.34-2.38)	0.841	19	1797	2.41 (1.26-4.62)	0.008	9	1827	0.76 (0.33-1.73)	0.525	13	1819	1.47 (0.76-2.85)	0.249	11	1834	2.65 (1.19-5.87)	0.016
Yes																												
CD4 cells/µL at cohort entry	44	3737	1	-	6	3807	1	-	8	3807	1	-	7	3795	1	-	8	3807	1	-	3	3809	1	-	3	3807	1	-
>500	18	2396	0.69 (0.31-1.52)	0.370	10	2414	2.11 (0.86-5.18)	0.101	8	2422	1.38 (0.55-3.44)	0.488	4	2426	0.83 (0.22-3.07)	0.788	2	2426	0.34 (0.10-1.12)	0.077	5	2422	2.03 (0.66-6.26)	0.214	7	2425	2.90 (0.66-12.68)	0.156
350-500	27	2557	1.11 (0.62-1.99)	0.711	7	2597	1.38 (0.62-3.10)	0.424	14	2583	1.98 (0.78-5.04)	0.150	9	2588	1.99 (0.83-4.76)	0.121	6	2602	0.85 (0.31-2.27)	0.749	11	2592	3.61 (0.93-14.02)	0.063	6	2604	1.81 (0.45-7.18)	0.398
200-350	35	4052	0.89 (0.42-1.89)	0.767	39	4093	4.09 (1.66-10.05)	0.002	31	4104	2.41 (0.95-6.09)	0.063	27	4084	2.20 (0.98-4.95)	0.054	25	4106	1.76 (0.54-5.68)	0.340	21	4085	2.93 (0.70-12.31)	0.141	13	4124	1.37 (0.40-4.66)	0.607
<200	8	322	0.86 (0.27-2.70)	0.801	3	325	4.09 (1.66-10.05)	0.829	1	325	1.46 (0.25-8.51)	0.670	2	326	1.14 (0.15-8.54)	0.893	3	322	2.50 (0.57-10.89)	0.221	1	327	2.67 (0.47-15.15)	267	1	326	12.08 (1.00-145)	0.050
Unknown																												
RNA HIV copies/ml at cohort entry	82	8804	1	-	35	8919	1	-	36	8928	1	-	19	8928	1	-	23	8953	1	-	18	8935	1	-	14	8958	1	-
$<10^5$	40	3907	1.28 (0.93-1.75)	0.125	26	3962	1.45 (0.87-2.41)	0.150	25	3959	1.07 (0.68-1.67)	0.759	27	3937	2.67 (1.50-4.77)	0.001	18	3959	1.05 (0.51-2.17)	0.887	22	3945	1.86 (1.04-3.31)	0.034	16	3973	1.76 (0.94-3.29)	0.075
$>10^5$	10	354	2.51 (0.78-8.01)	0.119	4	355	1.91 (0.75-1.75)	0.692	1	355	0.81 (0.20-3.27)	0.769	3	356	4.71 (0.69-32.04)	0.113	3	352	1.91 (0.64-5.73)	0.245	1	356	1.01 (0.21-4.82)	0.987	0	356	-	-
Unknown																												
Antiretroviral therapy	66	3104	1	1	22	5033	1	1	14	5048	1	-	18	5013	1	-	11	5049	1	-	9	5038	1	-	6	5056	1	-
No	66	9962	0.54 (0.30-0.96)	0.039	43	8204	0.59 (0.22-1.51)	0.275	48	8194	1.14 (0.58-2.22)	0.691	31	8208	0.31 (0.13-0.72)	0.007	33	8215	1.11 (0.27-4.44)	0.882	32	8199	0.88 (0.40-1.90)	0.746	24	8231	1.37 (0.31-5.94)	0.672
Yes																												

FU py, follow-up in patient-years; IRR, incidence rate ratio; CI, confidence interval.
Multivariable models were adjusted for sex, age, HIV transmission group, educational level, prior AIDS, hepatitis C coinfection, CD4 cells and HIV viral load at cohort entry, and antiretroviral therapy initiation