OSIRIS minimum clinical data set for collection in local applications Version 1.0						
Item Group	Objective(s)	Item n°	Collection status	Item	Item definition	Expected value
1. Consent	Regulation	1.1	Mandatory	Consent date	Date of signature of informed consent form	Date
		1.2	Mandatory	Authorization for genetic analysis	Consent to proceed to personal genetic data analysis	Yes No
2. Patient identification	Identification	2.1	Mandatory	Local patient identifier	Anonymized patient ID	Character string
		2.2	Mandatory	Health care center identifier	Identifier of the health care center according to the French national file of health and social establishments (FINESS)	FINESS code
		2.3	Mandatory	Data provision center identifier	FINESS identifier of the center supplying clinical data	FINESS code
3. Personal information	Information required for patient identification	3.1	Mandatory	Birth date	Patient's birth date as indicated on their birth certificate	Date (indicating the 15th day of the birth month for anonymization)
		3.2	Mandatory	Gender	Biological sex of the patient	HL7 Code Version 3
		3.3	Mandatory	Ethnicity	Patient ethnicity	HL7 Code Version 3
4. Vital status	Information required for survival and prevalence studies	4.1	Mandatory	Latest status	Patient's vital status at the time of the last visit	Alive Deceased
		4.2	Mandatory	Date of last follow-up	Date of last follow-up	Date
		4.3 (condition 4.1)	Mandatory if deceased	Date of death	Date at which the patient died	Date (indicating the 15th day of the birth month for anonymization)
	Information required for survival studies	4.4 (condition 4.1)	Mandatory if deceased	Cause of death	Main cause of death of the patient	UMLS code
5. Associated pathologies	Disease mapping beyond malignant tumors (e.g. diabetes, hypertension, etc)	5.1	Mandatory if comorbidity	Classification of comorbidity	Categorization of the disease according to the International statistical classification of diseases and related health problems (ICD, 10th revision)	Code ICD-10
		5.2	Optional	Date of diagnosis	Date of diagnosis (at least the year)	Date
		5.3	Optional	End date	Date at which the disease was cured (at least the year)	Date
6. Family information	Family studies	6.1	Mandatory if family history	Mapping of family history	Anatomic site of previous malignancy according to the International classification of diseases for oncology (3rd edition)	CIM-0-3
		6.2 (condition 6.1)	Mandatory	Family relationship	Describe the family relationship with the patient	UMLS:C0037047 : brother/sister UMLS:C0030551 : parents UMLS:C0015671 : father UMLS:C0026591 : mother UMLS:C3844804 : paternal cousin UMLS:C3844805 : maternal cousin UMLS:C3242761 : maternal grandparents UMLS:C3242764 : paternal grandparents UMLS:C1273524 : paternal grandmother UMLS:C1273525 : maternal grandmother UMLS:C1273523 : maternal grandfather

						UMLS:C1273522 : paternal grandfather UMLS:C0337471 : grandparents UMLS:C0337577 : uncle UMLS:C3714276 : paternal uncle UMLS:C3714277 : maternal uncle UMLS:C0337576 : aunt UMLS:C3714274 : paternal aunt UMLS:C3714275 : maternal aunt UMLS:C0337580 : cousin OSIRIS:C77-6 : other OSIRIS:C77-7 : unknown
7. Anatomo-pathological tumor examination(s)	Solid tumor stage according to the international TNM classification	7.1	Mandatory if TNM	Size of the primary tumor	Describes the size of the primary tumor	Character string
		7.2	Mandatory (condition 7.1)	Lymph node involvement	Indicates lymph nodes involvement by metastatic tumor cells	Character string
		7.3	Mandatory (condition 7.1)	Presence or absence of metastasis	Used to signal the presence or absence of metastasis	Character string
		7.4	Mandatory (condition 7.1)	TNM version	Version of the TNM classification	Whole number
		7.5	Mandatory (condition 7.1)	TNM type	Type of TNM classification	C for clinical P for pathological Y pour post neoadjuvant treatment U for radiology
	Classification information if other than TNM	7.6	Mandatory if other than TNM	Stage type	Classification system used to define the tumor stage	Figo Other
		7.7	Mandatory (condition 7.6)	Histological stage	Value of the pathological stage according to the classification system used	Character string
	Degree of tumor aggression	7.8	Mandatory according to tumors	Grade type	Used to describe the origin of the cancer	Scarff-Bloom et Richardson (SBR)Gleason Bloom-Richardson Elston-Ellis Other
		7.9	Mandatory	Histological grade	Used to describe the tumor cell type and biological activity	Character string
	International classification of diseases for oncology (3rd edition)	7.10	Mandatory	Mapping code	Used to describe the origin of the cancer	CIM-O-3 Topology
		7.11	Mandatory	Histological/morphological type	Used to describe the tumor cell type and biological activity	CIM-O-3 Morphology
8. Disease progression	Chronology of the spread of cancer indicating tumor event(s)	8.1	Mandatory if tumor event	Type of tumor event	Used to establish the initial cancer diagnosis (neoplasm) and then follow the disease progression (primary cancer, loco-regional or metastatic relapse)	UMLS:C1882062 for neoplasm UMLS:C0677930 for primary tumor UMLS:C0521158 for loco-regional relapse UMLS:C2939419 for metastasis
		8.2	Mandatory (condition 8.1)	Start date of the event	Date of cancer onset or subsequent tumor event	Date
		8.3	Mandatory (condition 8.1)	Date of event diagnosis	Diagnosis date of tumor event	Date
9. Patient's state of health	General health of the patient	9.1	Optional	G8 screening tool	Tool to evaluate general health of elderly patients with cancer	Whole number between 0 and 17
		9.2	Optional	Karnofsky scale	Autonomy score according to the Karnofsky scale	100% : Normal no complaints; no evidence of disease 90% : Able to carry on normal activity; minor signs or symptoms of disease. 80% : Normal activity with effort; some signs or symptoms of disease. 70% : Cares for self; unable to carry on normal activity or to do active work. 60% : Requires occasional assistance, but is able to care for

						most of his personal needs. 50% : Requires considerable assistance and frequent medical care. 40% : Disabled; requires special care and assistance. 30% : Disabled; requires special care and assistance. 20% : Very sick; hospital admission necessary; active supportive treatment necessary. 10% : Moribund; fatal processes progressing rapidly. 0% : Dead
		9.3	Optional	OMS scale	Autonomy score according to the World Health Organization (WHO)	0: Unrestricted normal activity 1 : Restricted for significant physical activity but able to walk and carry out light work 2 : Able to walk and take care of self but unable to work and bedridden for less than 50% of the time 3: Very limited ability to take care of self. Spends more than 50% of time bed/chair ridden 4: Completely bedridden. Unable to take of self. Patient remains confined to bed or chair.
10. Confirmation of diagnosis	Assessment of techniques used to establish diagnosis	10.1	Mandatory if analysis	Investigations carried out	Types of confirmation or investigation methods used	OSIRIS:C37-1 for biological OSIRIS:C37-2 for imaging OSIRIS:C37-3 for an omic analysis OSIRIS:C37-4 for an anatomo-pathological analysis
		10.2	Mandatory (condition 10.1)	Date of analysis	Date at which the analysis was carried out	Date
11. Treatment(s)	Information on the treatment(s) used to combat patient's cancer	11.1	Mandatory if treatment	Treatment type	Type of treatment carried out	UMLS:C3665472 for chemotherapy UMLS:C0279025 for hormone therapy UMLS:C1522449 for radiotherapy UMLS:C0728940 for surgery
		11.2	Optional (condition 11.1)	Code of the administered molecule	Anatomical Therapeutic Chemical Classification System (ACT) code indicating where possible the 5th level (chemical substance)	ATC code
		11.3	Optional (condition 11.1)	Name of the administered molecule	Name of the administered molecule	Character string
		11.4	Optional (condition 11.1)	Common classification of medical acts (CCAM)	French national health insurance code describing the localization and type of medical act carried out	CCAM code
		11.5	Optional (condition 11.1)	Start date	Treatment start date	Date
		11.6	Optional (condition 11.1)	End date	Treatment end date	Date
		11.7	Mandatory	Clinical trial	Is the treatment in the context of a clinical trial?	Yes No
		11.8	Optional (condition 11.7)	Name of the clinical trial	If the treatment is part of a clinical trial, indicate the trial name	Character string
		11.9	Optional (condition 11.7)	EudraCT clinical trial number	The number in the EudraCT clinical trial database	EudraCT number
		11.10	Optional (condition surgery 11.1)	Quality of the resection	Evaluation of the surgical resection quality	R0 : no residual disease apparent R1 : disease is visible with microscope R2 : remaining disease is bigger

						than 1cm
12. Side effect(s)	Side effects linked with treatment	12.1	Optional	Side effect	International MedDRA code (version 12.0) describing side effects during treatment	MedDRNA (v12.0)
		12.2	Optional	Diagnosis date	Diagnosis date of the side effect	Date
		12.3	Optional	End date	End date of the side effect	Date
		12.4	Optional	Side effect grade	Severity grade according to the Common Terminology Criteria For Adverse Events (CTCAE version 5.0) classification	CTCAE code (v5.0)
13. Biomarker(s)	Information concerning cancer biomarkers	13.1	Mandatory if marker	Biomarker type	Necessary information to indicate the therapeutic objective of the biomarker used	Diagnosis Prognosis Prediction
		13.2	Mandatory (condition 13.1)	Biomarker name	Biomarker name	Character string
		13.3	Mandatory (condition 13.1)	Biomarker measure	The expression value of the biomarker	Character string
		13.4	Optional	Unit measure	The unit value of the biomarker	Character string
14. Clinical sample(s) information	Information describing sample(s) used to follow the disease progression	14.1	Mandatory	Biological sample identifier	Unique sample identifier at the health center (barcode, text identifier)	Character string
		14.2	Optional	Identifier of the parent biological sample	Unique parent sample identifier (barcode, text identifier). For example an aliquot or sample extracted from another sample (e.g. histological number)	Character string
		14.3	Mandatory (condition 14.1)	Sample date	Sample date	Date
		14.4	Mandatory (condition 14.1)	Sample origin	Indicates sample origin	OSIRIS:O59-1 for healthy tissue OSIRIS:O59-2 for tumor tissue
		14.5	Mandatory (condition 14.1)	Nature of the sample	Indicates sample nature	UMLS:C0005767 for blood UMLS:C0085983 for tumor UMLS:C4039816 for frozen tissue UMLS:C1519524 for an FFPE tissue
		14.6	Mandatory (condition 14.1)	Tumor sample mapping	Anatomic site of the tumor sample according to the International classification of diseases for oncology (CIM-O-version 3).	CIM-O-3
		14.7	Optional	Storage modality	Sample storage temperature	Room temperature 2/10°C -18/-35°C -60/-85°C -150/-196°C Other
		14.8	Mandatory (condition 14.1)	Percentage of tumor cells	Percentage of tumor cells in the tumor sample	Whole number between 0 and 100