

# MANAGEMENT OF SOFT TISSUE SARCOMA IN FRANCE – A RETROSPECTIVE ANALYSIS OF THE FRENCH CLINICAL BIOLOGICAL SARCOMA DATABASE (GSF-GETO)

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**OBJECTIVES:** The primary objective is to describe how patients with advanced soft tissue sarcoma (STS) are managed in France. The secondary objectives are to describe the epidemiological characteristics, the diagnostic procedures as well as the therapeutic strategy for the management of patients with STS in France. In France, networks for rare tumors such as STS, are firmly established since the implementation by the National Cancer Institute in 2009 of Action 23.1 of the Cancer Plan (Certification of Reference Centres for Rare Cancers).

**METHODS:** This observational, retrospective and national study will use the patient databases of the European CONTICANET "CONnective Tissue Cancer Network" network and of the French networks: RRePS and NetSarc (Pathological and Clinical Reference Networks for Soft Tissues and Visceral Sarcomas). All the data collected in these expert networks and compiled in the "Sarcoma clinicobiological database" will allow a representative overview of STS in France. The study period was chosen to reflect the current situation in terms of diagnosis and disease management in France.

**RESULTS:** The European database currently contains data from 12,485 patients (pts) registered by the French Sarcoma Group centers with 9,736 soft tissues and visceral sarcomas. Data from STS patients, who were diagnosed between 2012 and 2013, will be extracted from the Conticabase database. Part of these data will be linked to the shared database from the French networks RRePS (24,000 pts) and NetSarc (28,000 pts). The French Sarcoma Group will perform the data extraction and analyses and will write the final study report. Results are expected at the end of 2015.

**CONCLUSIONS:** This pharmacoepidemiological study shows how useful high-quality medical databases are to study rare diseases and their management in real life. This study is carried out as part of a public/private partnership.

### Background

A sarcoma is a rare kind of cancer (incidence estimated in Europe at 4 to 6 / 100,000) developing from connective tissue and classified as an orphan disease. These tumors of the supporting tissues affect soft tissues (≈ 60%), viscera (≈ 30%) and bones (≈ 10%) [1]. The incidence of soft tissue and visceral sarcomas is around 4,000 new cases per year. Sarcomas are highly heterogeneous with more than 50 subtypes. This great diversity can cause diagnostic confusion and lead to delayed or inappropriate management.

1: Ducimetière F, Lurkin A, Ranchère-Vince D, et al. Incidence of Sarcoma Histotypes and molecular Subtypes in a Prospective Epidemiological Study with Central Pathology Review and Molecular Testing. *Najbauer J, ed. PLoS ONE. 2011;6(8):e20294.*

#### Expert networks

As requested by action 23.1 of the Cancer plan, the French National Cancer Institute (INCa) has set up networks of anatomopathological and clinical expert centers for rare cancers. For soft tissue sarcomas (STS), the reference network for soft tissue and visceral sarcoma pathology (RRePS) and the soft tissue and visceral sarcoma clinical reference network (NetSarc) were created in 2010. These networks are respectively responsible for confirming diagnoses through systematic double reading of tumor specimens and optimizing patient management thanks to multidisciplinary consultative meetings (RCP). They participate in the epidemiological surveillance and observation of STS and created for this purpose 2 additional national databases (ongoing convergence). A European network, CONnective Tissue Cancer Network (CONTICANET), was created in 2006, as well as a European database called CONTICABASE to foster international collaborations between researchers and clinicians.

Figure 1: NetSarc Et RRePS networks

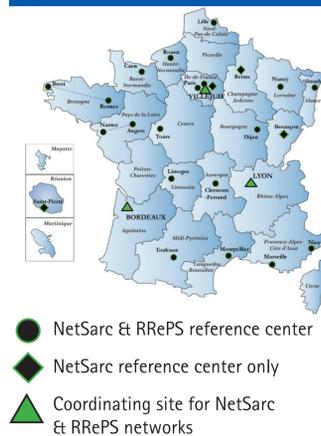


Table 1: Sites involved in RRePS and NetSarc expert networks

RC/CS	Site	Town	NetSarc	RRePS
RC	Centre Paul Papin / CHU Angers	Angers		X
RC	Institut de Cancérologie de l'Ouest (CLCC Angers + CLCC Nantes) / CHU Hôtel Dieu Nantes	Angers/ Nantes	X	X
RC	Hôpital Jean Minjoz	Besançon	X	
CS	Institut Bergonié	Bordeaux	X	X
RC	Centre Eugène Marquis / CHU Pontchaillou Rennes / CHU C. Morvan Brest	Brest/Rennes	X	X
RC	Centre François Baclesse / CHU	Caen	X	X
RC	Centre Jean Perrin	Clermont-Ferrand	X	X
RC	Centre G-F Leclerc	Dijon	X	X
RC	Centre Oscar Lambret	Lille	X	X
RC	Hôpital Dupuytren	Limoges	X	X
CS	Centre Léon Bérard	Lyon	X	X
RC	Hôpital de La Timone	Marseille	X	
RC	Institut Paoli Calmette	Marseille	X	X
RC	Institut Régional du Cancer Montpellier / Val d'Aurelle	Montpellier	X	X
RC	Centre Alexis Vautrin : CHU	Nancy	X	X
RC	Centre A. Lacassagne	Nice	X	X
RC	APHP Multi sites : Hôpital Ambroise Paré, Hôpital Cochin, Hôpital Pitié-Salpêtrière, Hôpital Saint-Antoine, Hôpital Saint-Louis, Hôpital Henri Mondor	Paris	X	X
RC	Institut Curie	Paris	X	X
RC	APHP Cochin	Paris	X	
RC	APHP La Pitié Salpêtrière	Paris	X	
RC	APHP Hôpital Saint-Louis	Paris	X	
RC	Institut Jean Godinot / CHU Robert Debré	Reims	X	
RC	Hôpital Charles Nicolle / Centre Henri Bequerel	Rouen	X	X
RC	CHU La Réunion	Saint-Pierre	X	
RC	CHU Haute-pierre / CLCC Paul Strauss	Strasbourg	X	X
RC	Institut Claudius Régaud	Toulouse	X	X
RC	Hôpital Trousseau	Tours	X	X
CS	Institut Gustave Roussy	Villejuif	X	X

RC: Reference Center CS: Coordinating Site

#### Databases

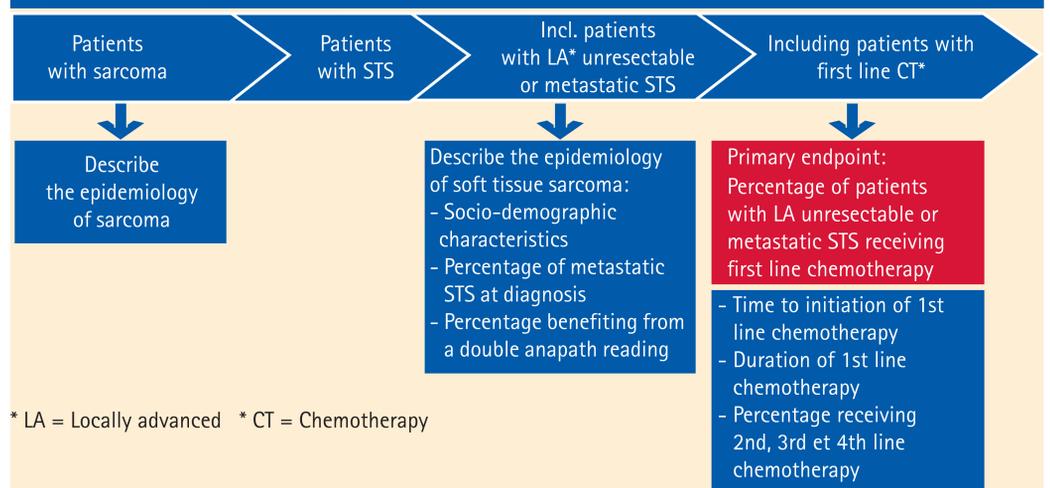
Table 2: Databases regarding Sarcoma in France

Base	NetSarc	RRePS	CONTICABASE
Network	NetSarc	RRePS	CONTICANET
French centers	29	22	10
Contributors	Clinician	Anatomopathologist	Clinician
Date of creation	2010	2010	2006
Number of patients	30600	25800	17000
Type of information collected	<ul style="list-style-type: none"> <li>Epidemiological data: initials, date of birth, gender, geographical origin</li> <li>Tumor location</li> <li>Inclusion in a clinical trial</li> <li>Diagnosis and decisions of RCP</li> <li>Grade</li> <li>Surgery</li> </ul>	<ul style="list-style-type: none"> <li>Anatomopathological diagnosis at 1st then double reading,</li> <li>Methods used,</li> <li>Tumor type, grade, histology.</li> </ul>	<ul style="list-style-type: none"> <li>Clinical and therapeutic data, lines of chemotherapy (CT)</li> <li>Anatomopathological and molecular biology data</li> <li>Time to disease progression</li> <li>Type and location of samples kept</li> </ul>
Comment	The databases are interfaced to allow for comprehensive patient monitoring		Mainly French patients included

### Objectives

- Primary objective: To describe how patients with advanced STS are managed in France.
- Secondary objectives:
  - To describe the epidemiological characteristics of patients with sarcoma and patients with STS
  - To describe the diagnostic procedures and therapeutic strategy to manage patients with STS.

Figure 3: Study endpoints



\* LA = Locally advanced \* CT = Chemotherapy

### Inclusion and exclusion criteria

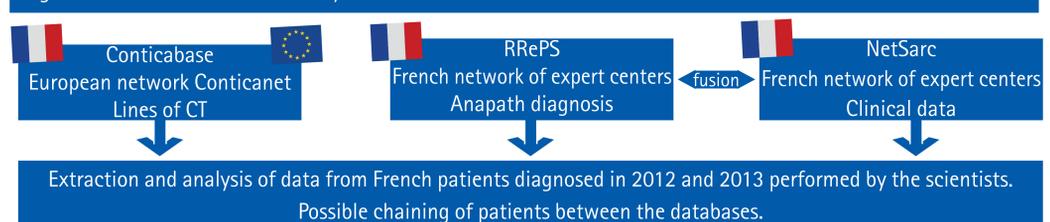
- Inclusion criteria:**
- Patients ≥ 18 years
  - Diagnosed with STS in 2012 or 2013
  - Included in one of the databases by a French center participating in the study
- Exclusion criteria:**
- Patients with bone sarcoma or GIST
  - Patients < 18 years
  - Patients followed up in French centers refusing to participate in the study

### Method

#### Data extraction and Analyses

This observational, retrospective, national and multicenter study will use the patient databases of the European network CONTICANET "CONnective Tissue Cancer Network" and of the French networks RRePS (Reference Network for Soft Tissue and Visceral Sarcoma Pathology) and NetSarc (Clinical Reference network for Soft Tissue and Visceral Sarcoma). The European database currently contains data from 12,485 patients registered by the French Sarcoma Group centers with 9,736 soft tissues and visceral sarcomas. Data from patients, aged 18 and over, who were diagnosed with STS in 2012 and 2013, will be extracted from the Conticabase database. Part of these data will be linked or matched with the shared database from the French networks RRePS and NetSarc, with the prior consent of the member expert centers. The extraction and analysis of data will be performed by the French Sarcoma Group (GSF). Results are expected in December 2015. The study period was chosen to reflect the current situation in terms of diagnosis and management in France.

Figure 4: Data extraction and Analyses



For this study no sample size calculations are required. Descriptive statistics will be applied, based on the number of patients identified in the databases.

### Discussion

An estimated 70% of patients diagnosed with STS in 2013 have been followed up by a reference center and that more of 90% benefited from a double reading by the RRePS network [2,3]. These patients will therefore be included in the NetSarc and RRePS databases. The overall data collected via these expert networks and compiled in the "Sarcoma clinicobiological database" will ensure a good representativeness of STS at national level. The study period was defined to reflect the current situation in terms of diagnosis and management in France, within a structured territorial network of expert centers.

2: INCa 2015 report: French national networks for rare cancers in adults / Review and outlook  
 3: <https://irreps.sarcomabc.org/report/chartReport.htm?name=chartReportNumberOfCasesByRegion>

### Conclusion

- This pharmacoepidemiologic study shows the interest of building up medical databases and linking them to study rare diseases and their management in real life.
- By providing recent and high-quality epidemiological data on STS, this study will meet the need for describing a condition for which classic epidemiology is limited by the disease rarity and extreme heterogeneity.
- This study is carried out as part of a public/private partnership. Thanks to the data it will generate, it may indirectly support the market access of innovative molecules, provided they are registered by Health Authorities, in the current treatment armamentarium for STS which is still very limited.

### Disclosure/Acknowledgment

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