

French national cohort of melanoma patients from the RIC-Mel network Implementation to valorisation

Poster
#147

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and the RIC-Mel network



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Objective

With a high incidence, low survival rates and limited availability of effective treatment, melanoma is one of the research priorities for health authorities and is considered as a priority of public health (Figure 1). Optimizing the development of both academic and private research requires the availability of information on the characteristics of patients, clinical data and collected biological samples.

To meet this need, the French Multidisciplinary Melanoma Group (GMFMel) in collaboration with INCa (French National Cancer Institute), the CeNGEPS (National Centre for Healthcare Products Trial Management) and the CIC-BT0503 from Nantes hospital (Biotherapy Clinical Centre of Investigation) has set up in April 2011 a Clinical Investigation network for melanoma called the CeNGEPS-GMFMel Network. Nowadays, the network is named :

RIC-Mel : network for Research and Clinical Investigation on Melanoma

Aims of our network are to promote translational research, to optimize the achievements of clinical trials and to support basic research. To achieve these goals, the primary objective of our network was to set up a national database in order to make epidemiological studies and to be able to have the best efficiency for participating to international clinical trials.



Figure 1 : Primary tumour

Method

All French centres treating melanoma patients were contacted to participate. Each participating centre filled in the database its active list of patients, for which data are treated confidentially. Database is available on the Internet at any given moment but each clinician has an exclusive access for his data. All patients included in the database had given their agreement to participate.

Collected data describes patient characteristics, disease history and progress until death and if biological samples are available (Figure 2). Consequently, our database gives a permanently updated mapping of melanoma treated in France with the key information needed for any research projects.

RIC-Mel Network	PART I - Mandatory	PART II - Optional				
		Family history	Genetic investigation			
RIC-Mel data base Coordinators Pr B. Dréno and Pr C. Lebbe Coordinating centre : CHU de Nantes Steering Committee Scientific Council Participating centres : University and Regional Hospital Centres, Cancer Centres Enrolment of patients and entry of data	Identity	Initials	Birth date		Gender	
	Primary tumour	Date of surgery	Type of melanoma	Breslow	Mitotic index	Ulceration Regression
		Sentinel lymph node surgery		Date		Results
		Lymph node removal		Number of invaded lymph node		Extracapsular extension
	AJCC Stage at inclusion and evolution	Date of diagnosis	Details		For stage III only : if inoperable or not	
	Mutations	Type	Presence	Date	Comments	
	Antigens	Type	Presence	Date	Comments	
	Treatment	Type	Name	Nature (adjuvant/curative)	Dates	
	Death	Yes/No		Date		
	Metastases	Type	Date of diagnostic	Presence		
HLA type	A		B			
Sample collection	Type (skin, blood, metastases...)	Storage condition	Date			
Curative and investigational treatments	Dosage		Response			
Adverse events (grade 3 and 4)	Type	Grade	Action on treatment	Other action	Outcome	

Translational and basic research

Epidemiological studies

Partnership with pharmaceutical companies

Clinical trials

Figure 2 : RIC-Mel network key working

Results

Nowadays, the RIC-Mel network includes 42 hospital's dermatology centres and 6 cancer centres located all over the country (Figure 3). The RIC-Mel database was launched in March 2012 and has been approved by French Health Authorities, both ethically and confidentiality of data. After just 3 years in existence, more than 13,000 patients were included (Figure 4), with the following distribution : 70 % of primary stages and 30 % of loco-regional/metastatic stages.

Industrial

Four pharmaceutical companies have expressed interest in our database (BMS, Roche, GSK and AMGEN). These companies have signed a partnership agreement to support prospective inclusions of patients as well as regular updating of the clinical data. Thanks to these support, two research projects have been achieved.

In 2013, a first company used data from 6,000 patients prior to the registration of a targeted therapy and to realize medico-economic modelling. In 2014, another company used epidemiological data from 12,000 patients to estimate the proportion of patients meeting the selection criteria for a clinical trial.

Recently, a new company expressed the wish to develop an e-CRF, only available on the database, for a post-ATU (Authorisation of Temporary Use) study. This e-CRF will be used to fill data specific to the study treatment, with patient characteristics and clinical data available in the database as well as for any patient.

Institutional

Several institutional projects were carried out in monocentric data for rational (review cases of discordant mutational status or clinical response of patient subgroups regarding biological parameters...) and feasibility studies. Recently, the population of patients with stage IV and unresectable stage III with a mutated B-RAF status has been analysed at the request of French National Authority for Health (HAS).

The RIC-Mel database is linked to the clinico-biologico-radiological database MELBASE, for patients with metastatic melanoma stage IV or unresectable stage III, setting up by Saint Louis hospital (Paris).



Figure 3 : Distribution of participating centres

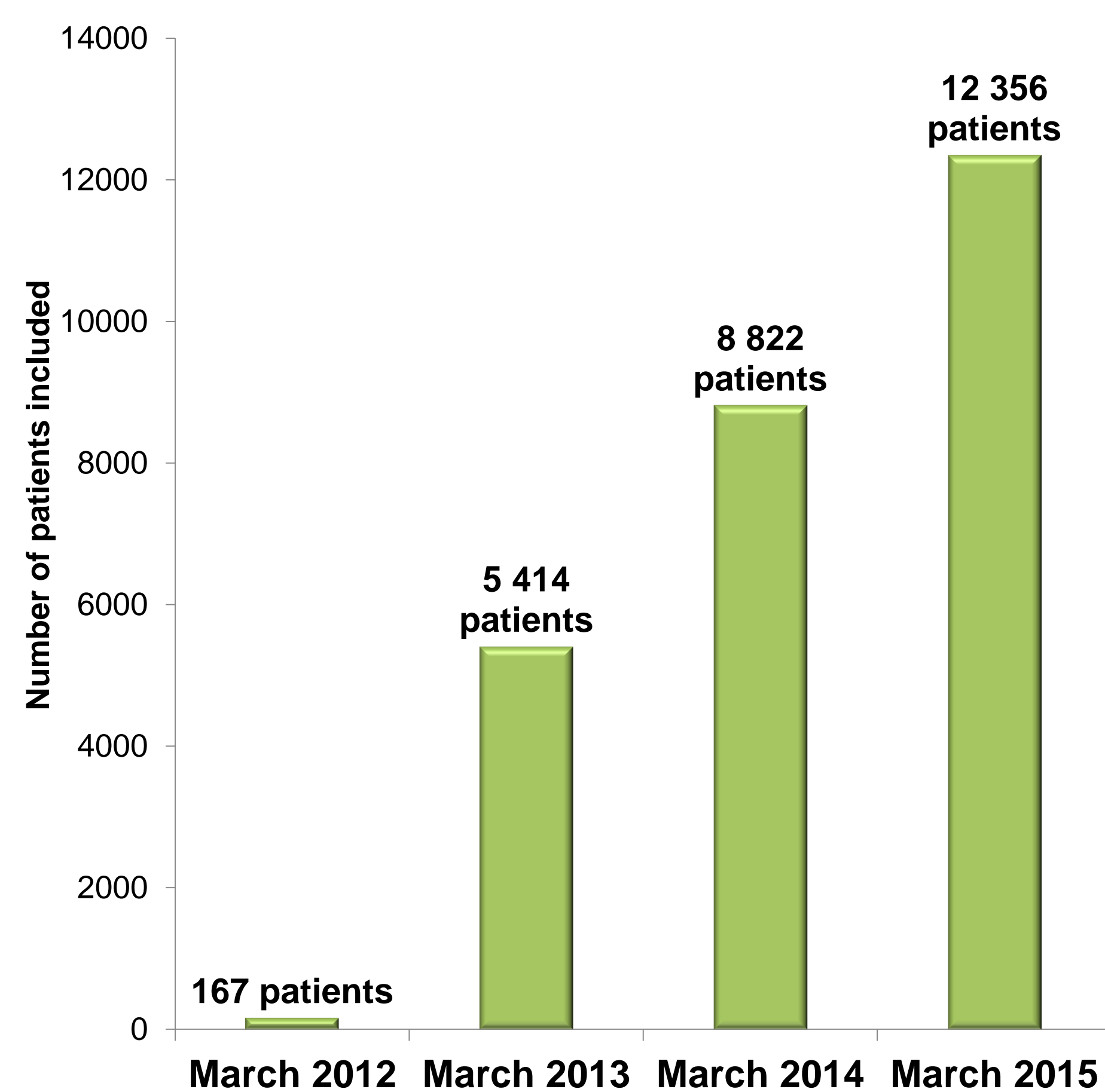


Figure 4 : Annual evolution of inclusions in the database since its creation

The RIC-Mel database is a pertinent way through which relevant clinical and biological information can be rapidly and accurately communicated for the development of melanoma research.

The RIC-Mel network provides to researchers key information for epidemiological and translational study.

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