The labour market, psychosocial outcomes and health conditions in cancer survivors: protocol for a nationwide longitudinal survey 2 and 5 years after cancer diagnosis (the VICAN survey)

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ABSTRACT
Introduction: Today, a growing need exists for greater research into cancer survivorship, focusing on different spheres of the day-to-day life of diagnosed patients. This article describes the design and implementation of VICAN (VIe après le CANcer), a national survey on French cancer survivors.

Method and analysis: The target population included patients aged 18–82, diagnosed with cancer between January and June 2010, and registered in one of the three main French Health Insurance Schemes. It was restricted to 12 tumour sites. Sampling was stratified using a non-proportional allocation, based on age at diagnosis (18–52 and 53–82) and tumour site. Data were collected from telephone interviews with patients 2 and 5 years after diagnosis, a medical survey completed by the physician who initiated cancer treatment, and information from the national medicoadministrative database on reimbursement data and hospital discharge records. First data collection, 2 years after diagnosis, occurred between March and December 2012. Second data collection, 5 years after diagnosis, will be conducted in 2015. Analyses will be conducted on various outcomes: quality of life, health status and psychosocial conditions, with a particular focus on the impact of cancer diagnosis on the labour market. The variety of measurements included in the survey will enable us to control a wide range of factors.

Ethics and dissemination: The methodology of the VICAN survey was approved by three national ethics commissions. Results of the study will be disseminated through national and international research conferences, and in articles published in international peer-reviewed journals.

BACKGROUND
Over the past decades, the incidence of most cancers has increased in developed countries.1–3 At the same time, earlier diagnoses and more effective treatments have led to increased survival rates for most cancers.4–6 As a result, the population of cancer survivors is steadily increasing. This has led to a growing number of studies on cancer survivorship and the consideration of survivorship as a major stage in the continuum of care.7–10

These studies have shown that many survivors face psychological, physical and social challenges that may impact their daily lives and their quality of life. Cancer therapies can create long-term health problems that may become permanent, such as fatigue,11 12 pain,13 12 lymphoedema,14 infertility,15–17 cognitive impairment,18 urinary disorders19 and sexual dysfunction.20 21 Cancer survivors are also at increased risk of developing a second cancer or treatment-related heart failure22 23 years after the diagnosis of the initial cancer. Regarding the psychological effects, episodes of depression, anxiety and...
distress may occur even a long time after cancer diagnosis. Furthermore, depressive symptoms are often described in cancer survivors, with prevalence as high as 40% reported in those with lung cancer. However, these patients are often underdiagnosed and undertreated. The epidemiological evolution resulting from medical progress in screening and treatments has prompted the need to reconsider the position of people with cancer in terms of the disease consequences, in particular at the occupational level. Indeed, the short-term and long-term consequences of cancer treatment, as well as the initial diagnosis itself, can strongly influence not only work-based opportunities in terms of access into employment and a return-to-work but also workplace activities focusing on ensuring job tenure. In addition to the physical and cognitive limitations that may impair the participation of cancer survivors in the labour market, the role of negative relationships with co-workers and employers is an important consideration. Remaining in employment and the prospect of a return to work have both been identified as key aspects for cancer survivors’ quality of life. Several studies have underlined the need for comprehensive long-term care for cancer survivors and emphasised the lack of data on the evolution of side effects of cancer treatments over time. Despite pain being one of the symptoms that most affect patients’ lives, the management of persistent pain is still often suboptimal.

To ensure a better quality of life for patients, to organise appropriate long-term follow-up for them, and to allow them to regain their place in society, it is necessary to acquire a greater understanding of the mid-term and long-term physical and psychological consequences of the disease and their social impact. It was in this context that the American Cancer Society’s Studies of Cancer Survivors (SCS I–II) were initiated in 2007 in the USA.

In Europe, similar studies have been implemented, for example, the PROFILES registry in the Netherlands in 2011. Following the recommendations of the French national 2009–2013 Cancer Plan to financially support surveys collecting data on cancer survivors’ living conditions, the French National Cancer Institute (INCa) entrusted the implementation of VICAN (Vie après le CANcer)—a national survey on French cancer survivors—to the INSERM UMR 912 research unit.

Objectives of the VICAN survey

The aim of the VICAN survey is to document the living conditions of adult patients with cancer 2 and 5 years after cancer diagnosis. More specifically, the objectives are:

- First, to study the labour market outcomes. As an increasing number of people of working age are being diagnosed with cancer, growing importance is being attached to the workplace consequences of cancer.
- Second, to determine the nature, prevalence and temporality of factors that may negatively affect or improve the quality of life and daily life of cancer survivors, and to study their evolution at 2 and 5 years after cancer diagnosis. Health-related quality of life is a key element both in the evaluation of life after cancer diagnosis and in creating a balanced life for the individual. Accordingly, understanding the factors affecting long-term quality of life remains an important research issue.
- Third, to evaluate the physical, psychological and social needs of cancer survivors. For example, one of the questions to ask is whether patients are satisfied with the information provided on treatment side effects or on the risk of treatment-induced infertility?
- Fourth, to compare new data with results from a French survey performed in 2004.

A study 2 and 5 years after cancer diagnosis

In this article, we consider that cancer survivorship begins after primary treatment. Therefore, we chose to implement the first part of the survey in patients 2 years after cancer diagnosis, effectively in the ‘recovery’ phase, which follows the primary treatment phase. This choice allowed us to interview survivors who had cancer with intermediate or poor prognosis.
The second interview will occur in 2015, 5 years after cancer diagnosis, effectively at the end of the ‘early monitoring phase’ (2–5 years after diagnosis), which is the period where the risk of relapse and of treatment side effects is greatest.

From the point of view of labour market outcomes, the choice of a survey 2 years after cancer diagnosis was based on the specificity of the social security system in France. State legislation provides considerable protection to workers and the impact of cancer diagnosis or of other chronic diseases on employability is quite different compared with many other countries, especially those where patients are confronted with a job-lock situation, whereby they are effectively tied to the same company in order to benefit from healthcare (eg, in the USA). Indeed, in France and other countries with similar social security systems, little is known about the role played by sociodemographic, socioeconomic and clinical characteristics on the capacity of patients to retain their professional situation after diagnosis. Literature about other countries has demonstrated that the deleterious effect of cancer on professional trajectories begins to manifest itself at an early stage after diagnosis, and persists beyond the first 2 years.54 This justifies the choice of interviewing the same individuals 2 and 5 years after diagnosis, as the information gathered may help us to understand the situation with which French cancer survivors are confronted within the labour market, and to analyse the extent to which the effects of cancer on labour market outcomes are irreversible.

This article aims to describe the design and implementation of this innovative and ambitious survey, which combines patients’ self-reported data, information collected from their medical records and administrative records for healthcare use.

METHODS
Definition of target population
The survey targeted adult patients with cancer diagnosed between January and June 2010. As the active treatment phase does not usually last more than 12 months, targeted patients had experienced life after cancer for at least 1 year when first interviewed 2 years after diagnosis. People under 18 years at diagnosis were excluded from the survey for legal reasons. Those over 82 years at diagnosis were also excluded for practical reasons. Although the latter group represent 7% of cancer incidence in France,52 they would have been aged >84 at the time of the survey and therefore too young for retirement or early retirement schemes. Accordingly, we defined two age strata—18–52 and 53–82 at diagnosis—with a weight of 50% for each stratum.

We also restricted the survey to 12 tumour sites that accounted for 88% of global cancer incidence in France in 2012.55 Site selection depended on four criteria: global incidence, incidence by age (in line with our two age strata above), 2-year survival rate and level of scientific interest (eg, we planned to focus on lung cancer because of recent improvements in associated survival). Selected tumour sites included cancers with good prognosis (breast, prostate and thyroid cancers, melanoma), others with intermediate prognosis (colorectal, bladder, kidney, cervical, endometrial and upper aerodigestive tract cancers, non-Hodgkin lymphoma) and one with poor prognosis (lung cancer).56

Sampling design
A simple random sampling design was applied to each of the 24 strata (2 age ranges×12 tumour sites) using the ALD file. In order to over-represent people aged <54 at diagnosis and relatively rare tumour sites, we did not opt for proportional allocation. Sample sizes were determined a priori within each stratum for a global sample size of N=6000 (see table 1). The objective was to have enough statistical power to conduct analyses separately for certain tumour sites, and to complete data collection within a reasonable period of time. Based on the experience of the survey carried out in 2004, which allowed us to use data collected for many topics,46 including employment,41 43 the chosen targeted sizes per tumour site and per age range seemed a good compromise. We excluded prostate, bladder and endometrial cancers from the age stratum ‘18–52 at diagnosis’, because these cancers have a much higher incidence among older people. Conversely, we excluded thyroid cancer from the stratum ‘53–82 at diagnosis’, because its incidence sharply decreases after age 55.52

For each stratum, we estimated the number of contacts necessary to achieve the target size using the response rate observed for the 2004 survey. We also took into account that cancers with good prognosis are confronted within the labour market outcomes, with a code detailing the tumour site. For practical reasons, we restricted the survey to patients registered with one of the three main Health Insurance Schemes (Caisse Nationale de l’Assurance Maladie des Travailleurs Salariés (CNAMTS) for salaried workers, Régime Social des Indépendants (RSI) for self-employed workers, Mutuelle Sociale Agricole (MSA) for farmers), which together cover more than 90% of the French population. Eligibility was restricted to French-speaking patients diagnosed with first malignant cancer and living in France for at least 2 years.
account the difference in recruitment procedures between both surveys. For example, the desired sample size for the stratum ‘breast cancer/18–52 at diagnosis’ was N=800 in the VICAN study. In 2004, the observed response rate for this population was 59.7%. However, in that survey, patients were recruited by telephone by physicians from the National Health Insurance Fund, and the global response rate was 53.7%. Instead, in 2012, for the first data collection of VICAN, we planned to recruit patients by postal mail (see below). Accordingly, we expected a lower response rate. A survey conducted in 2007 (among patients with diabetes\(^4\)) with the same recruitment procedure (a postal letter sent by the National Health Insurance Fund) had a response rate of 45%. We expected a similar global response rate for the first data collection of VICAN. Therefore, in 2012, for patients with breast cancer diagnosed at age 18–52, the expected response rate was 59.7%×45%/53.7%=50.1%. Consequently, 1597 patients had to be contacted to recruit 800 participants.

As we planned to recruit 6000 participants, with an expected response rate of 45%, 13 333 (6000/0.45) people registered in the ALD file should have been contacted. However, in the 2004 survey, a number of those contacted proved to be ineligible for various reasons, including inaccurate diagnosis encoded in the ALD file, and hospitalisations and deceases at the time of the survey. Taking what had happened in the 2004 survey into account, we decided to slightly increase the number of scheduled contacts. In the end, 16 429 patients were contacted.

### Data collection procedure

Each selected patient received a letter inviting them to participate in the survey, sent by the National Health Insurance Fund. It did not mention the INCa or the word ‘cancer’, only the tumour site. For example, women with a diagnosis of breast cancer were asked to participate in a survey about their ‘breast disease’. This approach was chosen because in the 2004 survey 7% of participants never used the word ‘cancer’ during their interview.\(^4\) The letter also mentioned that information would be collected from participants’ medical and administrative records. Those who agreed to participate had to send back a signed informed consent letter. Those who did not respond were considered non-respondents. One dunning letter was sent.

In 2012, participants were interviewed using the computer-assisted telephone interview (CATI) system. A postal questionnaire was proposed to people with lung or upper aerodigestive tract cancer, as their condition could have hampered their ability to respond orally.

### Data collected 2 years after diagnosis

The CATI interview questionnaire dealt with many topics: sociodemographic background and socioeconomic status, circumstances of diagnosis, relationships with the healthcare system and health professionals, treatments received and perceived side effects. The word cancer was never mentioned. The questionnaire also included items related to perceived discrimination, social support, couple relationships, sexuality since diagnosis and fertility preservation. Lifestyle-related outcomes such as diet and physical activity, and alcohol and tobacco use were documented as well, and several validated scales evaluated quality of life, fatigue and pain. Health-related quality of life was assessed using the French version of the SF12 scale.\(^5\) Cancer-related fatigue was evaluated using the EORTC QLQ scale.\(^6\) Pain was estimated using two validated

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**Table 1** Sampling design: age at diagnosis and tumour sites strata (VICAN)

<table>
<thead>
<tr>
<th>Age at diagnosis</th>
<th>18–52 Years old</th>
<th>53–82 Years old</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percentage in ALD file</td>
<td>Expected percentage in sample</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>40.6</td>
<td>26.7</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Melanoma</td>
<td>7.3</td>
<td>10.0</td>
</tr>
<tr>
<td>Thyroid cancer</td>
<td>9.7</td>
<td>10.0</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>8.7</td>
<td>11.7</td>
</tr>
<tr>
<td>Upper aerodigestive tract cancers</td>
<td>9.8</td>
<td>10.0</td>
</tr>
<tr>
<td>Bladder cancer</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Kidney cancer</td>
<td>3.2</td>
<td>5.0</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>5.3</td>
<td>6.7</td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>4.3</td>
<td>6.7</td>
</tr>
<tr>
<td>Endometrial cancer</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>11.1</td>
<td>13.3</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

**Reading example:** among patients aged 18–52 at diagnosis, for the nine selected tumour sites, 40.6% of patients registered in the ALD file in 2012 had breast cancer. The expected figure was much lower in the sample: 26.7% (N=800).

VICAN, Vié après le CANcer.
Moreover, since our survey focused on the impact of cancer on employment, a large part of the questionnaire was dedicated to this topic. Participants were asked about their working life during the study period (occupational status at the time of diagnosis and changes of status over the study period) and their working conditions (type of job, work contract, work schedules and income). They were also asked about the number and duration of periods of sick leave they had taken because of cancer. In addition, they were asked about perceived difficulty at work, and any work adjustments they had made or that had been proposed to them because of the disease.

For each participant, a medical survey was conducted with the physician who initiated cancer treatment, to collect detailed information regarding tumour histology (stage, grade, size) and treatments received. We also collected information from the national SNIIR-AM database, which includes financial reimbursement data (for physicians’ and other health professionals’ consultations, and for prescribed drugs) as well as hospital discharge records.62 We also collected data measured at the residential area level to investigate spatial inequalities: socioeconomic hardship indexes63 64 and measures of healthcare availability/accessibility (general practices, hospitals).

The patient and medical questionnaires are all available on the INCa website.65

**First data collection**

The first period of data collection, 2 years after diagnosis, occurred between March and December 2012. Telephone interviews lasted on average 40 min. Among those with lung or upper aerodigestive tract cancer who had the choice between a telephonic or postal interview, 68% asked for the latter.

Among the 16,429 patients initially contacted, 6529 returned the signed informed consent form (figure 1). Patient eligibility was evaluated using three sources: a very brief questionnaire completed by patients and returned with their consent, SNIIR-AM data and the medical survey. In this context, among the 6529 individuals who provided signed informed consent, 1653 were excluded because of non-eligibility. Similarly, among the 9900 individuals who did not return the consent form, 1750 were identified as non-eligible. Consequently, of the 8279 individuals whose eligibility or non-eligibility could be ascertained, only 58.9% were effectively eligible (55.1% and 63.6% among those aged 53–82 and aged 18–52 at diagnosis, respectively). The proportion of eligible people was markedly lower than expected, especially among those aged 53–82 at diagnosis.

The main reasons for ineligibility included inaccurate diagnosis (for 51.5% of ineligible patients: benign or second cancers, or errors in ALD file regarding the tumour site), inappropriate delay between diagnosis and survey (for 21.7% of ineligible patients: in most cases late recording in the ALD file), and patient death before the survey (for 16.4% of ineligible patients). In line with the recommendations of the American Association for Public Opinion Research, in order to compute a response rate, we assumed that the proportion of eligible people was identical among those who did not return the informed consent letter (‘unknown eligibility’).66 The resulting response rates were close to

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**Figure 1** Sample selection pathway (VICAN, Vie après le CANcer).

our expectations (42.8% for the age stratum ‘18–52 at diagnosis’ and 44.5% for the age stratum ‘53–82 at diagnosis’, providing an average of 43.7%). Owing to the high proportion of ineligible people, the final sample size was only N=4349.

Table 2 details the sample according to age and tumour site. Across the age×tumour site strata, the response rate varied between 37% (for women aged 53–82 at diagnosis of endometrial cancer) and 52% (18–52×non-Hodgkin lymphoma).

With respect to the medical survey, data collection took place between March 2012 and March 2013. After several reminders by phone and letters, it was completed for 87.7% of participants. SNIIR-AM data were collected for all participants.

Weighting procedures
As we used a stratified random sampling design with non-proportional allocation (see table 1), we first computed sampling weights as reciprocals of the probabilities of selection in each stratum. Second, as we collected data from the SNIIR-AM file for all contacted patients, we had the opportunity to compare eligible respondents with eligible non-respondents.

Available information included gender, age, tumour site and socioeconomic hardship index.63 We also expected that patients’ health status was correlated to participation. Accordingly, we built an indicator of cancer progression using SNIIR-AM data for every patient contacted. We considered that patients who met one of the following criteria had progressive cancer: second cancer diagnosed since 2011, treatment with chemotherapy, radiotherapy or targeted therapy in 2012, or whose eligibility status remained unknown (N=8150). Among eligible patients (N=4876) and among patients whose eligibility status remained unknown (N=8150), the proportion of women was higher among respondents (60.4 vs 64.7 years), while non-respondents lived more frequently in areas with a high level of socioeconomic hardship (table 3). Breast cancer was markedly over-represented among respondents (35.1% among respondents vs 22.4% among non-respondents), while upper aerodigestive tract and lung cancers were under-represented (overall 8.9% vs 17.2%). The proportion of individuals with progressive cancer was significantly higher among non-respondents (21.8% vs 17.4%).

As gender, age, socioeconomic hardship, tumour site and cancer progression all had a significant impact on participation, we adjusted initial weights for these five variables. The final weights were created using an iterative process (ranking ratio estimation). Thanks to the resulting weights, the marginal distribution for each of these variables was the same among all respondents (N=4349), among eligible patients (N=4876) and among patients whose eligibility status remained unknown (N=8150).

Second data collection
The National Health Insurance Fund will keep a matching file in order to propose participation to the same

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>Age at diagnosis</th>
<th>Respondents (N=4349)</th>
<th>Non-respondents (N=527)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18–52</td>
<td>53–82</td>
<td>Total</td>
</tr>
<tr>
<td>Bladder cancer</td>
<td>4.5</td>
<td>4.8</td>
<td></td>
</tr>
<tr>
<td>Kidney cancer</td>
<td>3.4</td>
<td>3.6</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>3.2</td>
<td>2.9</td>
<td></td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>1.3</td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>Endometrial cancer</td>
<td>1.8</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Lung cancer</td>
<td>4.9</td>
<td>8.1</td>
<td></td>
</tr>
<tr>
<td>Cancer progression since diagnosis</td>
<td>No</td>
<td>82.6</td>
<td>78.2</td>
</tr>
<tr>
<td>Yes</td>
<td>17.4</td>
<td>21.8</td>
<td></td>
</tr>
</tbody>
</table>

*P<0.05, **P<0.01, ***P<0.001 statistically significant (Student t test for age, Pearson’s χ² for other variables).

VICAN, Vie après le CANcer.
participants 5 years after their cancer diagnosis. This second collection of data will occur in 2015.

Planned statistical analysis
Data analyses will be conducted using SPSS software (PASW Statistics 18, V18.0.3), Stata/SE software (V12.1) or R (V3.0.2). Cross-sectional and longitudinal analyses will be performed. For the former, multivariate linear or logistic regressions will be used, depending on the nature of the outcomes. For longitudinal analyses, linear or logistic mixed-model regressions will be used, depending on the nature of the outcomes, to account for repeated measurements. The variety of measurements included in the survey will enable us to control for a wide range of factors. A continuous-time Markov process model will be implemented to evaluate the impact of cancer diagnosis on mobility between the different states of the labour market (e.g., employment, unemployment, retirement, inactivity).

DISCUSSION
Objectives of the survey
Before discussing the survey’s objectives, we must highlight that we collected two kinds of data: retrospective data (e.g., concerning circumstances of diagnosis and treatments received) and data related to participants’ current living conditions. Analyses using retrospective data may be influenced by selection bias, as only ‘survivors at 2 years’ were interviewed and not everyone initially diagnosed with cancer. However, this bias was certainly limited for tumour sites associated with a very good survival rate 2 years after diagnosis.

The VICAN survey has two main objectives. First, it was designed in close cooperation with the INCa, which is the official French state agency in charge of coordinating public policy related to the fight against cancer. From this perspective, the VICAN survey will be useful for public healthcare policy evaluation and orientation, in the short to medium term. For example, in order to improve the way patients are informed of cancer diagnosis, the Cancer Plan 2009–2013 approved the generalisation of the ‘Diagnostic Disclosure Procedure’.74,75 whose context and content are precisely defined. Accordingly, specific questions were introduced in the first questionnaire of the VICAN survey to assess the real world implementation of this measure. Second, VICAN was designed to encourage social sciences research on ‘cancer survivorship’ in the French context, as psycho-social issues dominate medical issues in this specific phase of the cancer trajectory.10,68

Using medicoadministrative databases
Thanks to the specificities of the French healthcare system, we had the opportunity to use medicoadministrative databases (ALD and SNIR-AM files). These databases are now widely used for research purposes in many fields69–72 and provide an effective way to contact cancer survivors. In other countries, similar samples have been created as subsamples of very large general population surveys,73 or from cancer registries covering the whole territory,74 but such surveys/registries are not available in France. Moreover, these medicoadministrative databases allowed us to target specific populations (especially regarding tumour site and time since diagnosis) and to collect data on respondents as well as non-respondents (in order to detect and correct for participation biases). These databases also provide detailed and reliable data regarding healthcare utilisation, unlike asking patients to self-report healthcare utilisation, which is both time-consuming and liable to recall bias. It is true, however, that many studies have shown that the effects of such biases on reported outcomes are minor.74–77

Despite their value, the use of medicoadministrative databases raises legal and technical issues that complicate the design of the survey. These databases also contain various kinds of inaccuracies, especially since they were not initially designed as research tools. In the VICAN survey, these limitations are illustrated by the relatively high level of ineligible patients among those who were initially contacted.

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Contributors A-DB, M-KB, LST, DR, VS and PP-W contributed to the conception, design and management of the study. A-DB, CB, M-KB and PP-W contributed to the data collection. A-DB, M-KB, LST, SC, CB and PP-W contributed to the data analysis. A-DB, SC, LST, DR and PP-W contributed to the drafting of the manuscript. All authors critically revised successive drafts of the manuscript and approved the final version.

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Competing interests None.

Ethics approval The study methodology was approved by three national ethics commissions: the CCTIRS (Comité Consultatif sur le Traitement de l’Information en Matière de Recherche dans le Domaine de la Santé, study registered under no 11-143), the ISP (Institute of Public Health, study registered under no C11-63) and the CNIL (French Commission on Individual Data Protection and Public Liberties, study registered under no 911290). Confidentiality is assured for all participants with regard to any personal responses and information provided, as all data collected are anonymised. Results of the study will be disseminated through national and international research conferences, and in articles published in international peer-reviewed journals.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The INCa will promote and organise open access to the dataset for all scientists interested in this survey before the end of 2014.
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