

# Flash-KRAS - Retrospective observational study taking an inventory of the KRAS test in 2011 in patients with metastatic colorectal cancer having recently started a first-line treatment

Head :Dr ARTRU Pascal, Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Jean Mermoz, Lyon  
Pr DUCREUX Michel, Gastroenterology Unit, IGR, Villejuif  
Dr GUIU Michel, Department of Anatomy and Pathology, Perpignan  
Dr LAURENT-PUIG Pierre, Department of Biochemistry, HEGP, Paris  
Dr LIEVRE Astrid, Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Ambroise Paré, Boulogne Billancourt  
Pr MERLIN Jean-Louis, Tumour Biology Unit, Centre Alexis Vautrin, Nancy  
Pr SABOURIN Jean-Christophe, Department of Anatomy and Pathological Cytology, CHU Ch.Nicolle, Rouen  
Dr VIGUIER Jérôme, Department of Gastroenterology and Hepatology, Hôpital Trousseau, Tours

Last update : 10/19/2017 | Version : 1 | ID : 73327

## General

### Identification

Detailed name	Retrospective observational study taking an inventory of the KRAS test in 2011 in patients with metastatic colorectal cancer having recently started a first-line treatment
Sign or acronym	Flash-KRAS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1474442

### General Aspects

Medical area	Anatomy - Cytology Biology Cancer research
Pathology (details)	Colorectal cancer
Health determinants	Healthcare system and access to health care services
Keywords	Flash-KRAS, Colorectal cancer

### Scientific investigator(s) (Contact)

Name of the director	Dr ARTRU
----------------------	----------

Surname Pascal  
Unit Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Jean Mermoz, Lyon

Name of the director Pr DUCREUX

Surname Michel

Unit Gastroenterology Unit, IGR, Villejuif

Name of the director Dr GUIU

Surname Michel

Unit Department of Anatomy and Pathology, Perpignan

Name of the director Dr LAURENT-PUIG

Surname Pierre

Unit Department of Biochemistry, HEGP, Paris

Name of the director Dr LIEVRE

Surname Astrid

Unit Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Ambroise Paré, Boulogne Billancourt

Name of the director Pr MERLIN

Surname Jean-Louis

Unit Tumour Biology Unit, Centre Alexis Vautrin, Nancy

Name of the director Pr SABOURIN

Surname Jean-Christophe

Unit Department of Anatomy and Pathological Cytology, CHU Ch.Nicolle, Rouen

Name of the director Dr VIGUIER

Surname Jérôme

Unit Department of Gastroenterology and Hepatology, Hôpital Trousseau, Tours

Collaborations

Participation in projects, networks and consortia	No
<b>Funding</b>	
Funding status	Private
Details	Merck
<b>Governance of the database</b>	
Sponsor(s) or organisation(s) responsible	Merck
Organisation status	Private
Presence of scientific or steering committees	Yes
Labelling and database evaluation	Scientific committee
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
Type of database	Study databases
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Retrospective, non-interventional pharmaco-epidemiological study. This study does not change the usual practices of the physician with respect to their patient.
<b>Database objective</b>	
Main objective	Evaluate the KRAS test prescription rate in patients starting a first-line treatment for metastatic colorectal cancer.
	Secondary objectives:

- Describe the potential reasons for not prescribing this test
- Describe and analyse the clinical characteristics of patients and treatments planned and received in first-line metastatic treatment
- Describe and analyse the time frame for obtaining the result of the KRAS test and the channel (who makes the request and when) and the therapeutic attitude adopted during this period
- Analyse the impact of the availability of the KRAS test and its result on the therapeutic choice of the physician
- Describe the technic used for the analysis, the type of mutation (if available) and the method for reporting the results to the clinicians (report of the results)

#### Inclusion criteria

Each participating centre had to select the exhaustiveness of the patients seen in consultation during the study period, meeting all of the following criteria:

- Patients aged 18 years or older,
- Patients with histologically proven metastatic colorectal cancer,
- Patients for whom a metastatic first-line treatment was initiated between 01/01/2011 and 27/03/2011,
- Patients seen in consultation during the official 2-week study selection period.

#### Population type

Age

- Adulthood (19 to 24 years)
- Adulthood (25 to 44 years)
- Adulthood (45 to 64 years)
- Elderly (65 to 79 years)
- Great age (80 years and more)

Population covered Sick population

Pathology II - Neoplasms

Gender Male  
Woman

Geography area National

Detail of the geography area France

#### Data collection

#### Dates

Date of first collection (YYYY or YYYY-MM-DD) 28/03/2011

MM/YYYY)

Date of last collection (YYYY or MM/YYYY) 08/04/2011

## Size of the database

Size of the database (number of individuals) [500-1000[ individuals

Details of the number of individuals n=538 patients (160 centres)

## Data

Database activity Data collection completed

Type of data collected  
Clinical data  
Declarative data  
Biological data

Clinical data (detail) Direct physical measures

Details of collected clinical data History of early colorectal cancer; First line metastatic treatment; Prescription of KRAS biomarker genotyping; impact of the result on therapeutic management

Declarative data (detail) Paper self-questionnaire

Details of collected declarative data Demographic characteristics of the physician, data related to the medical practice, size of the town of the medical practice, physician's thesis year / Patient's demographics data

Biological data (detail) Waiting period for KRAS test result; genotyping report

Presence of a biobank No

Health parameters studied Health care consumption and services

## Procedures

Data collection method Medical records of patients seen during the study period retrospectively and using a paper questionnaire. Anonymised copy of the molecular biology report

Participant monitoring No

Followed pathology

Links to administrative sources	No
---------------------------------	----

## Promotion and access

### Promotion

Link to the document	<a href="#">Lievre A et al. EJC Juin 2013.pdf</a>
----------------------	---

Link to the document	<a href="#">Poster KRAS ESMO version finale.pdf</a>
----------------------	---

Description	ESMO 2012
-------------	-----------

Link to the document	<a href="#">poster Flash-KRAS JFHOD.pdf</a>
----------------------	---

Description	JFHOD 2012
-------------	------------

### Access

Presence of document that lists variables and coding procedures	No
---	----

Terms of data access (charter for data provision, format of data, availability delay)	Access terms and conditions are being defined Contact: <a href="mailto:juliette.longin@merckgroup.com">juliette.longin@merckgroup.com</a>
---	--

Access to aggregated data	Access on specific project only
---------------------------	---------------------------------

Access to individual data	No access
---------------------------	-----------