

# OPERA



Newsletter n°1

## Launching of the OPERA study

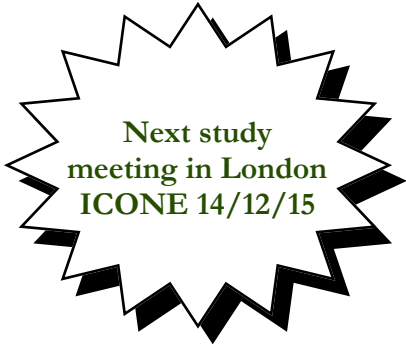
August 2015

### *OPERA— the curtain rose ...*

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Dear Investigators,



Next study  
meeting in London  
ICONE 14/12/15

Pr Jean-Pierre GERARD

### *Act I—the regulatory process*

After the time of the scientific and clinical reflection, time of regulatory submissions came.

In France, the protocol version 2.1. was approved by the competent authorities in March. Initiation visits then started.

Application for CTAAC authorization in UK has been sent recently.

Results are awaiting for end of November.

## Act I—the regulatory process

N°	French Centers	Principal Investigator	Initiation Visit date	Patients enrolled	Total recruitment plan
1	Centre Antoine Lacassagne (Nice)	Pr GERARD	17/03/2015	2	
2	Centre de Haute Energie	Dr MORO	05/05/2015	0	
3	Centre Azuréen de Cancérologie	Dr TEISSIER	09/2015	-	
4	Centre de Radiothérapie St Louis	Dr DUBERGE	09/2015	-	
5	Institut Paoli-Calmettes	Dr RESBEUT	09/2015	-	
6	Hôpital La Timone	Pr COWEN	18/06/2015	-	
7	Centre de Radiothérapie Bayard	Dr COQUARD	30/06/2015	0	
8	Centre d'Oncologie et de Radiothérapie Mâcon	Dr BARBET	30/06/2015	0	60
9	Centre Léon Bérard	Dr CARRIE	30/06/2015	0	
10	CH Lyon Sud (HCL)	Dr LORCHEL	09/2015	-	
11	Clinique Charcot—IRIDIS	Dr ROMESTAING	09/2015	-	
12	CH Croix Rousse (HCL)	Pr MABRUT	09/2015	-	
13	Institut de Cancérologie Lucien Neuwirth	Pr DE LAROCHE	09/2015	-	
TOTAL				2	

## Act II—first inclusions

### Investigator Coordinator

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### Data Manager

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The electronic case report form (Clinsight) is now operational. Randomisation is performed immediately by the Centre Antoine Lacassagne Clinical Research Unit, upon receipt of the application by fax. Four patients has been included since June 2015.

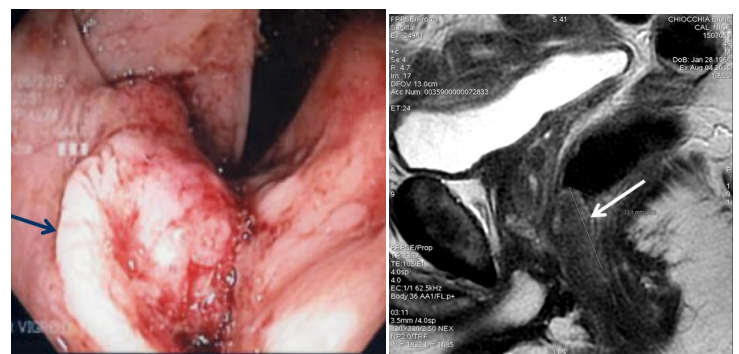
### Important Reminder

Stratification is based on **MRI measures.**



Patient n°1

M 65y T3aN0 distal R ulcerative  
2,9 cm diameter



Patient n°2

M 65y T2N0 distal R polypoid  
3,9 cm diameter