

Dear colleagues,

2539 patients have been randomized to PETACC 8 by 30 September 2009. 34 patients were randomized last month. Only 11 additional patients remain to be randomized in order to reach the target sample size!

76 patients were screened in September 2009. The screening phase was closed on 6 October 2009 at midnight. Since then no IVRS screening call can be made.

The randomization will stay open until all patients, screened and eligible, are randomized in the trial. Please randomize the patients as soon as you receive the KRAS results. You will receive a letter to inform you on the closure of the randomization.

It is crucial to perform the patient follow-up as per the protocol schedule, fill in the CRF pages, and answer the queries on an ongoing basis. Analyses of treatment safety are planned after all data on the treatment phase is available and an interim analysis for disease-free survival will be performed when 368 necessary events have occurred in the KRAS wild-type population but probably not later than 30 Sept. 2011.

Thank you again for your involvement in this very important trial,

Pr Julien TAIEB

For FFCD and the PETACC group

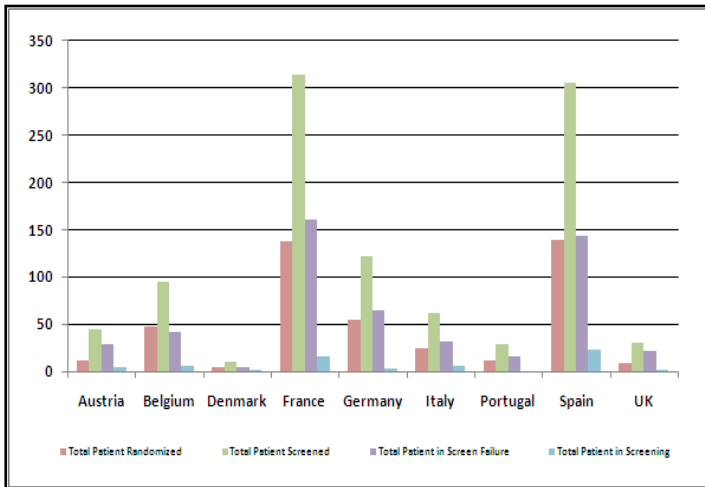
## Recruitment Update

As of 30 September 2009

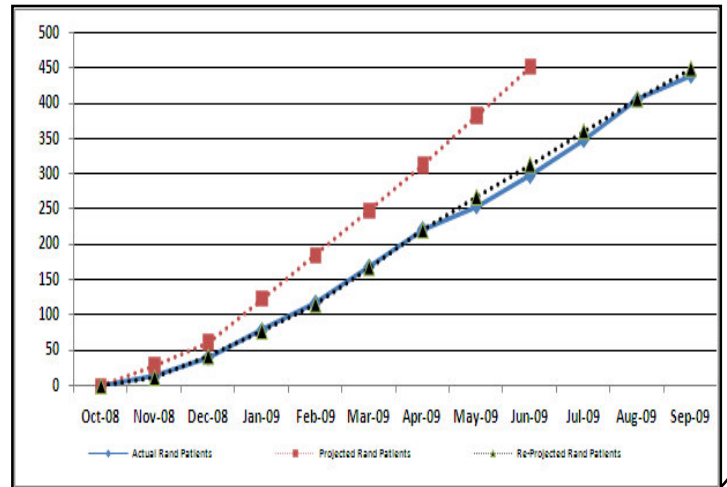
Site Status	Austria	Belgium	Denmark	France	Germany	Italy	Portugal	Spain	UK	TOTAL
Final List	23	31	7	131	73	42	17	68	7	399
Initiation visit performed	23	31	7	131	73	42	17	68	7	399
<b>Active sites</b>	<b>23</b>	<b>26</b>	<b>5</b>	<b>100</b>	<b>56</b>	<b>38</b>	<b>14</b>	<b>62</b>	<b>7</b>	<b>331</b>
Planned site closure	0	5	2	30	9	4	3	6	0	59
Site closed	0	5	2	25	9	4	3	6	0	54
Site open	23	26	5	106	62	38	14	62	7	343
Total Site which resumed the recruitment since 09 Oct 08*	15	22	3	72	40	23	7	46	6	234
Total Site which Randomized patients since 09 Oct 08*	9	19	3	57	33	13	6	41	4	185
<b>Total Patient Screened</b>	<b>156</b>	<b>251</b>	<b>33</b>	<b>963</b>	<b>344</b>	<b>355</b>	<b>88</b>	<b>827</b>	<b>92</b>	<b>3 109</b>
<b>Total Patient in Screen Failure</b>	<b>29</b>	<b>42</b>	<b>4</b>	<b>161</b>	<b>65</b>	<b>32</b>	<b>16</b>	<b>143</b>	<b>21</b>	<b>513</b>
Total Patient in Screening	4	5	1	15	2	6	0	23	1	57
<b>Total Patient Randomized</b>	<b>123</b>	<b>204</b>	<b>28</b>	<b>787</b>	<b>277</b>	<b>317</b>	<b>72</b>	<b>661</b>	<b>70</b>	<b>2 539</b>
Total Patient Screened since 09 Oct 08*	45	94	10	314	122	62	28	305	30	1 010
Total Patient Randomized since 09 Oct 08*	12	47	5	138	55	24	12	139	8	440
<b>Total Patient Screened in Sep 09</b>	<b>3</b>	<b>7</b>	<b>1</b>	<b>24</b>	<b>7</b>	<b>8</b>	<b>2</b>	<b>19</b>	<b>5</b>	<b>76</b>
<b>Total Patient Randomized in Sep 09</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>9</b>	<b>6</b>	<b>1</b>	<b>3</b>	<b>12</b>	<b>0</b>	<b>34</b>

\*09 October 08 is the date of the first patient screened after the halt of recruitment

**Countries Recruitment Update**  
from 09 Oct 08 to 30 September 2009



**Enrollment Graph**  
from 09 Oct 08 to 30 September 2009



**TOP 10 Recruiters**  
from study start

INVESTIGATORS	COUNTRIES	N°of PATIENTS
Zawadi Mohamed-Ayman	France	38
Salazar Ramon	Spain	38
Bouche Olivier	France	35
Aranda Aguilar Enrique	Spain	33
Rivera Herrero Fernando	Spain	32
Taberbero Caturla Jose M <sup>a</sup>	Spain	28
Mineur Laurent	France	26
Taieb Julien	France	24
Bennouna Jaafar	France	23
Sastre Valera Javier	Spain	23

**TOP 10 Recruiters**  
from 9 Oct 08 till 30 Sep 09

INVESTIGATORS	COUNTRIES	N°of PATIENTS
Ducreux / Lecaille	France	7
Rivera / Safont / Taberbero / Vera Garcia	Spain	7
Bennouna / Fratte / Zawadi	France	6
Lopez Vivanco / Pericay Pijaume / Feliu Batlle	Spain	6
D'Haens	Belgium	5
Levache / Mineur / Miglianico / Dupuis /	France	5
Aprile	Italy	5
Alonso / Aranda / Cervantes / Massuti / Salazar / Sastre	Spain	5
Ghillebert	Belgium	4
Andre / Texereau / Pezet / Lam	France	4
Matzdorff / Stahl	Germany	4
Mattioli / Remon / Ciera / Garcia Lopez / Gil / Gomez	Italy / Spain	4

## Investigator Meeting at the ESMO/ECCO Congress

During the ESMO/ECCO congress, a PETACC8 investigator meeting was held on 23 September 2009. The main topics were:

- protocol amendment 4 and the treatment of elderly patients,
- the study status including data management status,
- an update on tissue collection and screening failure reasons,
- the statistical consideration and the upcoming statistical analyses
- the importance of the follow-up for the success of the trial.

**FFCD and Quintiles thank you for your attendance and your active participation in the investigator meeting!!**