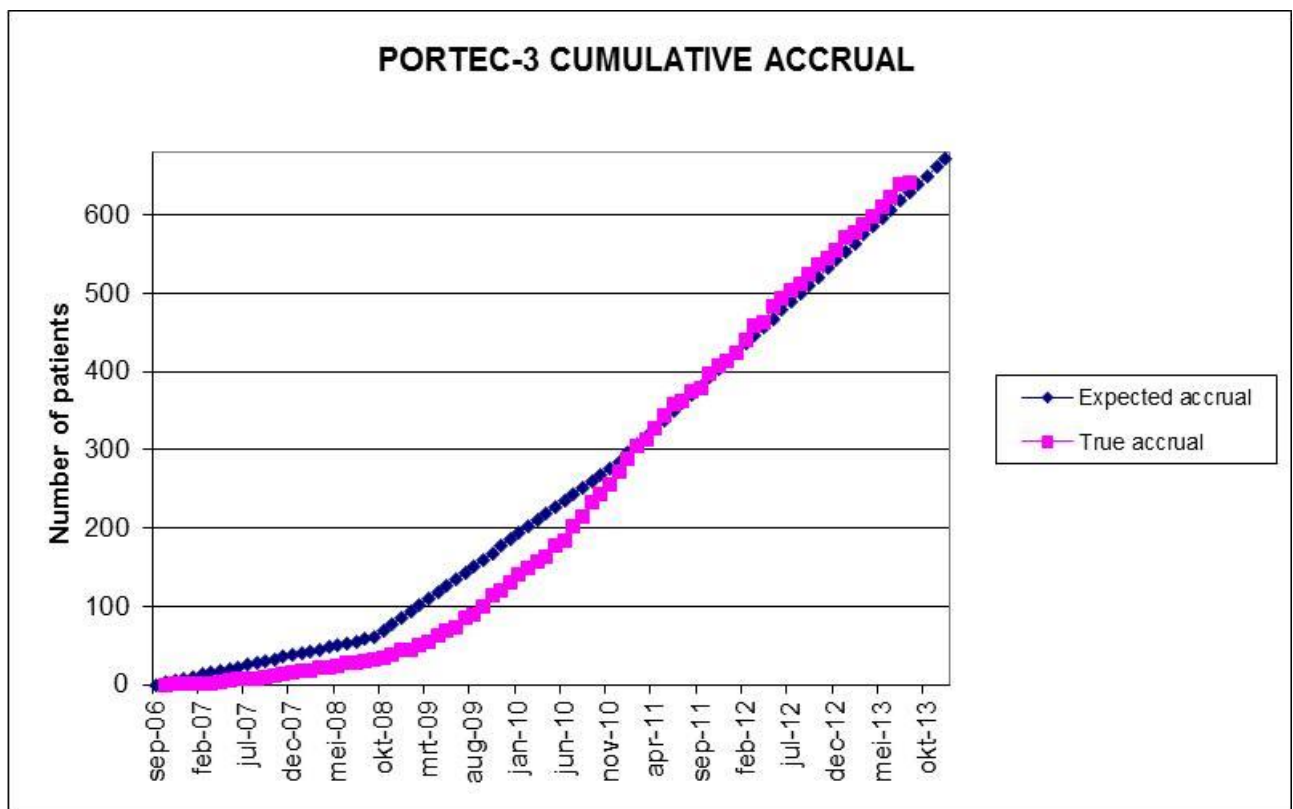


**Accrual to PORTEC-3 has reached 651!**

Accrual to PORTEC3 has continued the stable rate since the extension of the target number to 670 patients with the increased expected accrual. On 28 August, the 651<sup>st</sup> patient was randomized in the trial!

See the graph below and the table on the next page showing the accrual by site and by group, as well as the accrual over the past 12 months.

**PORTEC-3 closure of recruitment in December**

The recruitment target of 670 will be reached approximately late October. *At that point, we will set a date of closure and will communicate this date to all participating groups.* All eligible patients who have been counselled about the trial will be accepted for inclusion. We aim to include up to about 20 extra patients to compensate for a number of patients in the trial with major protocol violations (withdrawing consent after randomisation, or demanding treatment according to the other arm). Thus, the expected date of closure will be in December, just before the Christmas holidays.

<b>Group</b>	<b>Arm 1</b>	<b>Arm 2</b>	<b>Total on 28-8-2013</b>	<b>Since 28-8-2012</b>
Netherlands	69	72	<b>141</b>	24
Italy	47	51	<b>98</b>	20
Australia/NZ	57	59	<b>116</b>	24
Canada	28	34	<b>62</b>	13
UK	92	79	<b>171</b>	49
France	33	30	<b>63</b>	09
<b>Total</b>	<b>326</b>	<b>325</b>	<b>651</b>	<b>139</b>

**Top recruiting sites** of each group are:

ANZGOG:	Peter McCallum, Melbourne	30
MaNGO:	S Anna, Torino	28
Netherlands:	UMC Utrecht	20
NCIC CTG:	Sherbrooke	18
UK:	Barts and The London	22
France:	Henri Becquerel, Rouen	9

**DSMB**

The Data and Safety Monitoring Board will have their annual teleconference on October 29, 2013. The 6-monthly Accrual and SAE report to all groups and the annual confidential report to the DSMB will be sent in October. The DSMB Annual Report to the TMG will be circulated later this year.

**Annual PORTEC-3 Investigator's meeting : 17 November**

This year's Annual PORTEC3 investigator's meeting will be held in London, just after the GCIG meetings on Sunday, 17 November 2013, at the UCL Education Centre. A formal invitation and agenda will follow in October.

## Radiotherapy QA

ANZGOG/TROG have started the QA of the radiotherapy plans. They have done standard QA of the ANZGOG PORTEC-3 plans from the start of the trial.

The QA review is done by uploading the plan via DICOM RT, which is subsequently read by one of the TROG RT coordinators. Minor and major violations have been pre-defined. The group's coordinating centres and Radiotherapy PIs have contact all sites to request a logon to the TROG website and upload their plan.

*Please urgently remind all sites which have not yet uploaded their plan to do so as soon as possible.*

## Data management and central trial coordination

Karen Verhoeven-Adema is the PORTEC-3 central datamanager and coordinator at the Trial Office and first responsible person, please email her at [portec@iknl.nl](mailto:portec@iknl.nl) or [k.verhoeven@iknl.nl](mailto:k.verhoeven@iknl.nl)

## Data management issues

- Please always use the most recent **2012 CRF version** – see the **PORTEC-3 website** [www.clinicalresearch.nl/portec3](http://www.clinicalresearch.nl/portec3)
- Please do **complete ALL boxes**, do not leave any box blank or crossed. Appropriate answers are "0"(e.g. for zero nights in hospital), "uk"(unknown), "nd"(not done, e.g. for an investigation), "na"(not applicable)
- Please keep the **pages of one CRF together** and mark patient number and date on all pages
- Please check the **appropriate units** for lab investigations, please report in the units stated on the CRF
- Please send **QoL questionnaires** promptly and remind sites of overdue questionnaires!