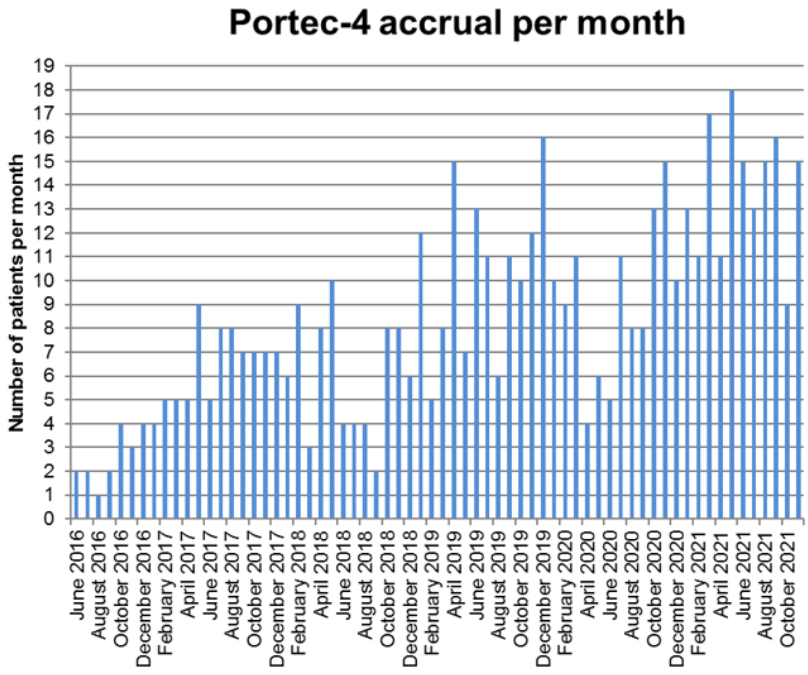
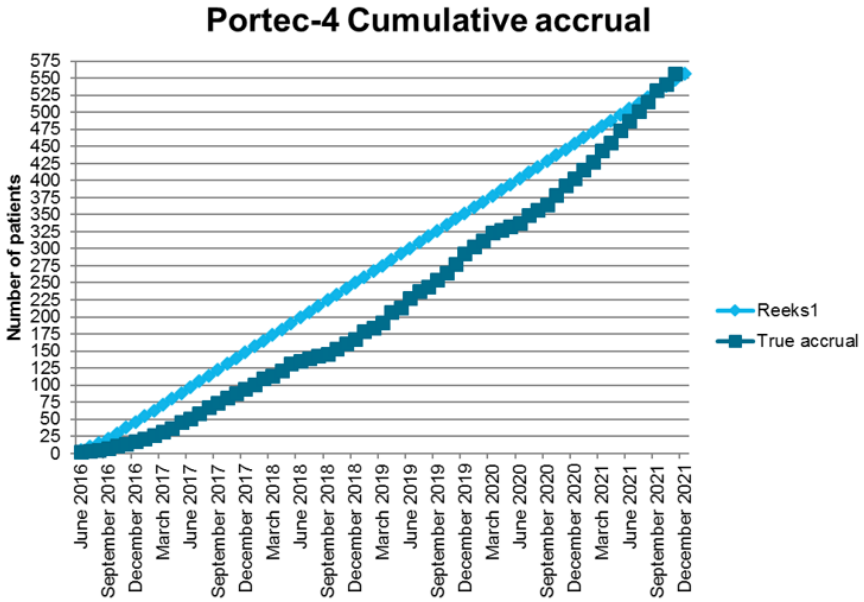
PORTEC-4a has reached full accrual!

The PORTEC-4a inclusion number has reached the target number of 550 patients. See the graph below and the table on the next page (based on the available data up to the 30th of November).





Center	control arm	molecular profile	Total
Amsterdam UMC	8	18	26
Catharina Hospital	5	16	21
Centre Oscar Lambret (Fr)	1	3	4
Erasmus Medical Center	8	11	19
Evang. Klinik Essen-Mitte (D)	2	4	6
Haaglanden Medical Center	5	7	12
Institut Claudius Regaud (Fr)	1	2	3
Institut Gustave Roussy (Fr)	3	6	9
Isala Hospital	5	3	8
Kaiserswerther Diakonie Dusseldorf (D)	1	3	4
Leiden UMC	26	49	75
Luzerner Kantonsspital Frauenklinik (CH)	1		1
Maastro Clinic	26	52	78
NKI/AvL	8	18	26
Radboud UMC	4	4	8
Radiotherapy Group Arnhem/Deventer	20	54	74
Radiotherapy Institute Friesland	7	16	23
Rotkreuzklinikum München (D)	3	8	11
Sankt Gertrauden Krankenhaus Berlin (D)	2	3	5
St Luke's Hospital (Irl)	3	10	13
Tuebingen University Hospital (D)	7	17	24
UMC Groningen	5	10	15
UMC Utrecht	2	7	9
Universitatsfrauenklinik Wien (CH)		3	3
Universitätsklinikum Heidelberg (D)	1	3	4
Universitätsklinikum Luebeck (D)	2	6	8
University Hospital Gent (B)	3	3	6
University Hospital Prague (Cz)	9	15	24
Verbeeten Institute	14	16	30
Zeeuws Radiotherapy Institute	2	5	7
Total	**184**	**372**	**556**

PORTEC-4a closure on Friday 24th of December 2021

Since the trial has reached the recruitment target, we have set the date for closure, on Christmas Eve, 24th of December 2021, at 4 pm (GMT +1). Until that moment we aim to include a few extra patients to compensate for some patients who were lost early (e.g. early informed consent withdrawn) or for those who have major protocol violations.

The randomisation website will be closed down at the following local times:

Netherlands, Austria, Belgium, Czech Republic, France, Germany, Switzerland: Friday 24th of December 2021, **at 4 pm**

Dublin: Friday 24th of December 2021, **at 3 pm**

Data management and monitoring in the years after closure

The years after closure of the trial are as important as the years before!

It is hoped that with a completed and up to date database, we will be able to start our analyses of the trial in 2024. Therefore we ask all local PIs and data managers to ensure timely follow up visits, and entry of the data of the trial patients in the Castor database.
Central data checks of the eCRFs will be done frequently in the years to come.

All participating sites in the Netherlands, and six international sites with high inclusion numbers have been (virtually) monitored before the closure of recruitment. In the upcoming years additional (virtual) monitoring visits will be planned if needed.

Please note that it is essential that a subject screening is log kept up to date, and that all study personnel should have a valid GCP or BROK certificate.

Castor database
Since the 25th of October our database has opened in the new electronic data capture system Castor. We ask of all sites to make sure that at least one person (preferable the data manager) has activated his or her account. As stated above, it is of utmost importance to make sure that follow up data is entered in a timely fashion in the database.
For those who encounter difficulties with activating their Castor account; please do not hesitate to get in contact with either our central data manager Karen Verhoeven-Adema (portec@iknl.nl), or the junior PI of the trial, Anne-Sophie van den Heerik (a.v.m_van_den_heerik@lumc.nl).

SAE – One new SAE has been reported in July 2021. Currently five SAE have been reported, two of which in 2017, one in 2019 and two in 2021. Of these SAEs one was possibly related to study treatment, the other four were unrelated.

DSMB
The DSMB had their annual teleconference on 23rd of November 2021. During this meeting an update of the trial has been given, and the statistical analysis plan has been discussed. They were pleased with the overall conduct of the trial. A report of this meeting will be send to the Ethics committee and to the local PIs.