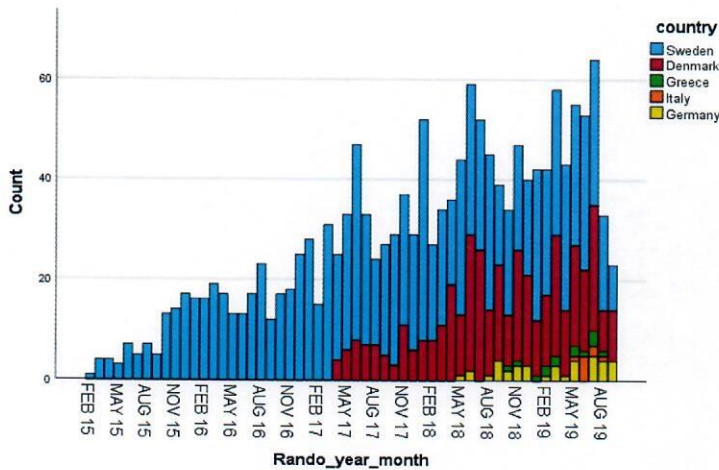
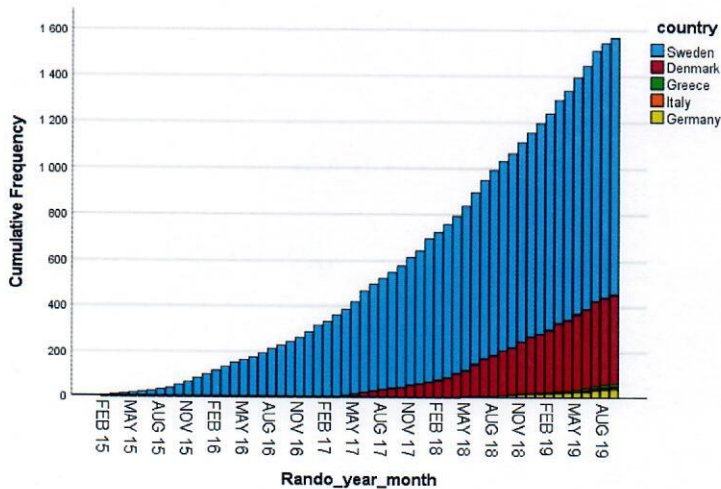


Dear contributors, colleagues and co-workers,

I hope you all enjoyed a restful summer break and returned to work with replenished energy. As of yesterday, September 11, we had randomised **1566 patients** from five countries with an average accrual rate that further increased to 51 per month (range 33-64). Thank you all for this fantastic work!



Number of randomisations per month




Cumulative number of randomisations from start of trial

When presenting an update on the SENOMAC trial in Berlin in June, I had looked at 1279 completed baseline eCRFs, the results of which I wish to share with you here. The mastectomy rate until then was 33.3%, so in the selected population, 426 patients had been operated by mastectomy. This group is the largest ever included in any Z0011 validation trial, which is of utmost importance. Our drop-out rate is low at 6%, and this is mostly due to patients wishing to abstain from both the trial and further surgery once they were randomised to axillary dissection (ALND). Accordingly, we now have 49% of patients assigned to SNB only, and 43.2% assigned to ALND (and committing to the proposed treatment). Further

important data are an extranodal extension rate of 29% and a non-SNB metastasis rate in the group undergoing ALND of 34.3%, which is in line with AMAROS data.

I also wish to announce that we are expecting an independent safety analysis of the first 2000 patients to take place in spring 2020, as well as a first analysis of data on quality of life and arm morbidity. I thank you all for your fantastic efforts for the SENOMAC trial. Please also consider the **following table and figure, and please share this newsletter with your colleagues and co-workers.**

My best wishes for a colourful autumn,



Jana de Boniface,  
for the SENOMAC steering committee and the sponsor Karolinska Institutet.  
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Table: Number of site-specific randomisations as of September 11, 2019

**Please observe that this table only shows those sites that have generated randomisations as of 2019SEP11. For a list of all initiated sites, please see the trial homepage.**

Site	Country	Initiation visit	First patient in	Number of randomisations
Karolinska	Sweden	2015-01-30	2015-02-27	103
Västerås	Sweden	2015-03-02	2015-04-14	44
S:t Göran	Sweden	2015-03-05	2016-06-07	123
Akademiska Uppsala	Sweden	2015-03-12	2016-02-14	43
Södersjukhuset	Sweden	2015-03-18	2015-11-24	85
Örebro	Sweden	2015-03-25	2015-10-01	43
Sahlgrenska	Sweden	2015-04-23	2015-06-10	85
Lund/Malmö	Sweden	2015-05-13	2015-10-13	88
Helsingborg	Sweden	2015-05-20	2015-07-23	38
Linköping	Sweden	2015-05-27	2016-11-03	69
Karlstad	Sweden	2015-05-28	2015-12-14	31
Lidköping/Skövde	Sweden	2015-06-04	2015-10-22	62
Uddevalla	Sweden	2015-06-04	2015-09-21	19
Kalmar	Sweden	2015-09-02	2016-03-03	16
Västervik	Sweden	2015-09-02	2016-02-18	26
Karlskrona	Sweden	2015-09-03	2015-12-14	6
Gävle	Sweden	2015-09-10	2015-12-30	33
Sundsvall	Sweden	2015-10-15	2015-10-29	44
Umeå	Sweden	2015-11-19	2016-02-10	38
Halmstad/Varberg	Sweden	2015-12-10	2016-02-17	26
Växjö	Sweden	2016-01-14	2016-03-23	27
Aarhus	Denmark	2016-11-28	2017-04-25	70
Randers	Denmark	2017-09-14	2017-11-07	18
Köpenhamn Rigshospitalet/Herlev	Denmark	2016-12-19	2017-04-20	142
Jönköping	Sweden	2017-01-20	2017-11-13	25
Kristianstad	Sweden	2017-03-20	2017-05-17	35
Borås	Sweden	2017-02-20	2018-09-14	5
Aabenraa	Denmark	2017-10-12	2017-12-13	43
Odense	Denmark	2017-11-22	2018-02-16	23
Esbjerg	Denmark	2017-12-12	2018-03-05	6
Viborg	Denmark	2017-11-03	2018-03-16	25
Aalborg	Denmark	2017-10-10	2018-02-07	42
Bad Langensalza	Germany	2018-04-04	2018-05-23	4
Rostock	Germany	2018-03-12	2018-06-07	9
Berlin Spandau	Germany	2018-04-19	2018-09-07	2
Laiko 1, Athens	Greece	2018-06-28	2018-10-12	6

Vejle	Danmark	2018-03-19	2018-11-07	22
Esslingen	Germany	2018-02-16	2018-10-26	1
Klinikum Kassel	Germany	2018-06-12	2018-11-22	1
Heraklion, Crete	Greece	2019-02-19	2019-03-07	2
Athens Euroclinic	Greece	2019-12-11	2019-02-12	2
Dresden	Germany	2018-05-02	2019-03-01	2
Hanau	Germany	2018-05-18	2019-02-12	6
Karlsruhe	Germany	2018-07-11	2018-12-18	1
Villingen-Schwenningen	Germany	2018-09-10	2018-12-28	1
Mittelbaden	Germany	2018-08-16	2019-03-13	1
Laiko 2, Athens	Greece	2018-11-07	2019-05-29	4
San Raffaele Milano	Italy	2018-02-01	2019-05-21	3
IEO Milano	Italy	2019-05-06	2019-06-06	6
Unna	Germany	2018-03-01	2019-05-28	5
Ebersberg	Germany	2018-04-10	2019-04-06	1
Stendal	Germany	2018-04-25	2019-05-14	1
Wiesbaden St. Josef	Germany	2018-06-14	2019-05-03	1
Worms	Germany	2018-08-28	2019-05-02	1
Potsdam	Germany	2019-06-18	2019-07-01	1
<b>Total</b>				<b>1566</b>



Figure: Accumulated site-specific inclusion (only sites generating randomisations as of September 11<sup>th</sup>, 2019 are shown).

