








Newsletter 9 – 03/2013

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Editorial

Dear Members of the ChroPac Study Group,

The first two months of 2013 have already passed and thus we would like to give you an update of what we have achieved so far with ChroPac trial as well as what is still in front of us.

First, we would like to thank our participating centers for increasing the completeness of documentation to actually 92, 5% which is really excellent!

On the other hand, we have observed a steady decrease of screened patients during the last months. Since we had to increase our sample size to 250 patients, we anticipate achieving our recruitment milestone last patient in by the end of the first half of this year if we succeed to randomize 6-8 patients per month. Today, the 230th patient was randomized, thus meaning with only 20 more patients we will reach our recruitment finishing line and change to the follow up period of our trial in the middle of 2013.

We also invite all centers that did not screen patients lately to make every effort to continue recruiting until the goal has been reached.

With best regards,

Markus Diener, MD



Monitoring

We warmly welcome Mrs. Monika Berlet who is now responsible for monitoring regarding ChroPac trial. She has already visited several sites and is your reliable contact partner in case of questions regarding eCRF, documentation etc.

Mrs. Berlet would like to kindly remind all centers of filling in source data (e. g. work sheets) for each visit.



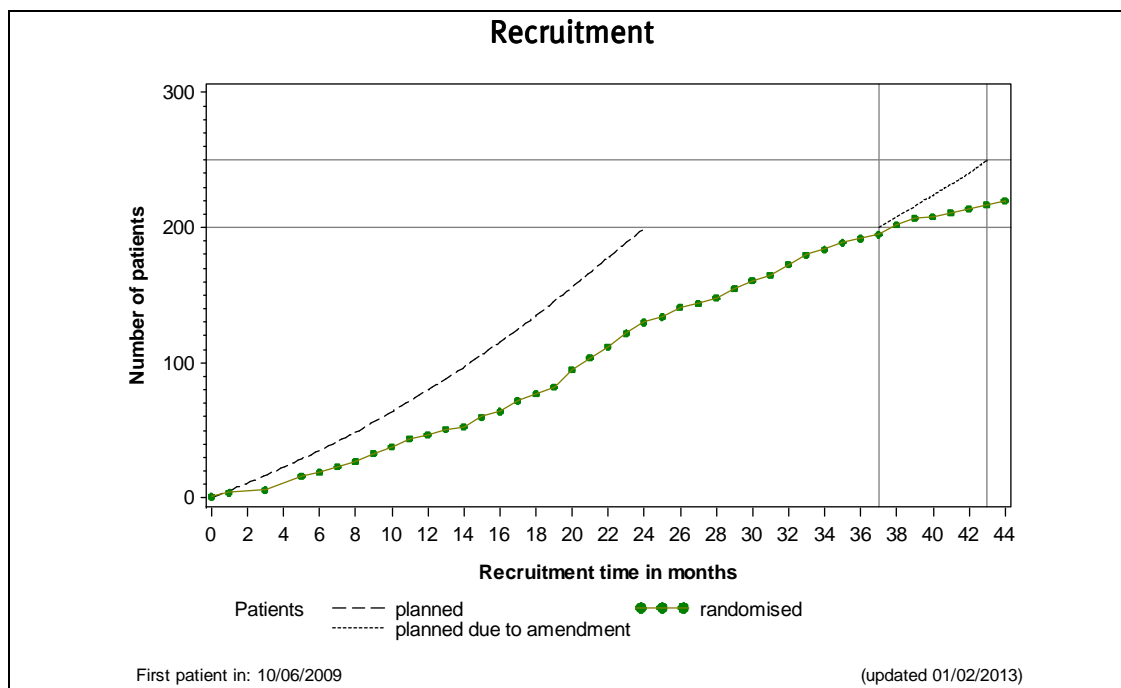
Case payment

As stated in our information we are now starting with partial payment. Therefore, monitoring for the respective patients needs to be completed. If you provide us with the screening numbers you want to invoice, we will compile a list of open points if applicable. After clearing of these points you may send us an invoice.



Recruitment

Currently, 230 subjects have been randomized (for development of recruitment see the figure below).





Screening & Randomization

Screening of patients has considerably decreased during the last months: in the last quarter of 2012 only 22 patients have been screened compared to 38 patients in the first quarter of 2012.

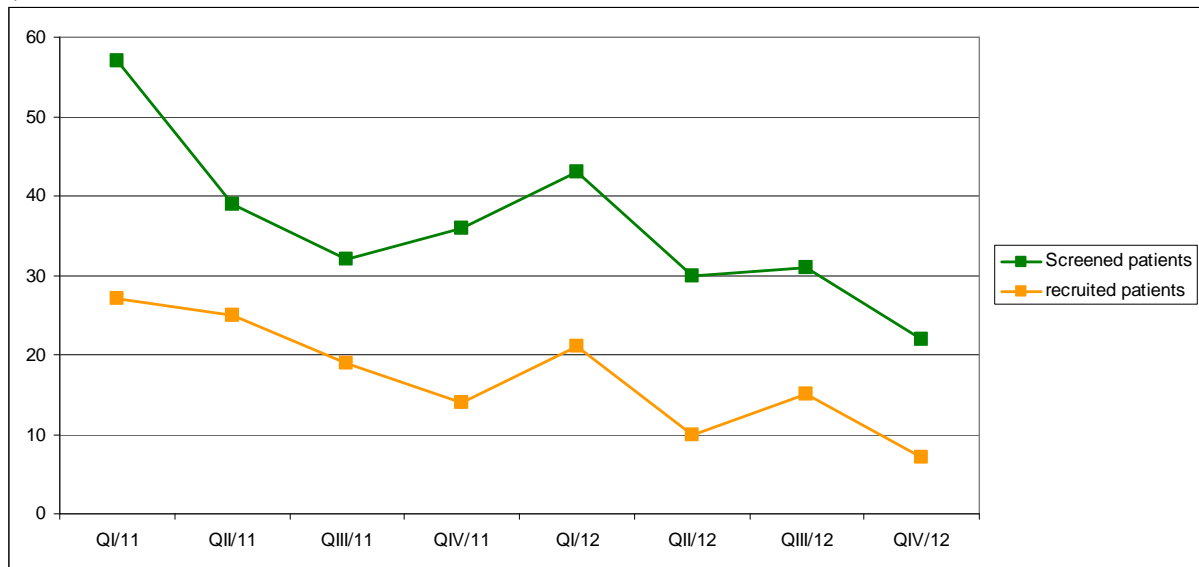


Figure 1.

The second figure shows that during the last quarter of 2012 only nine centers screened patients

Number of screened and recruited patients per center

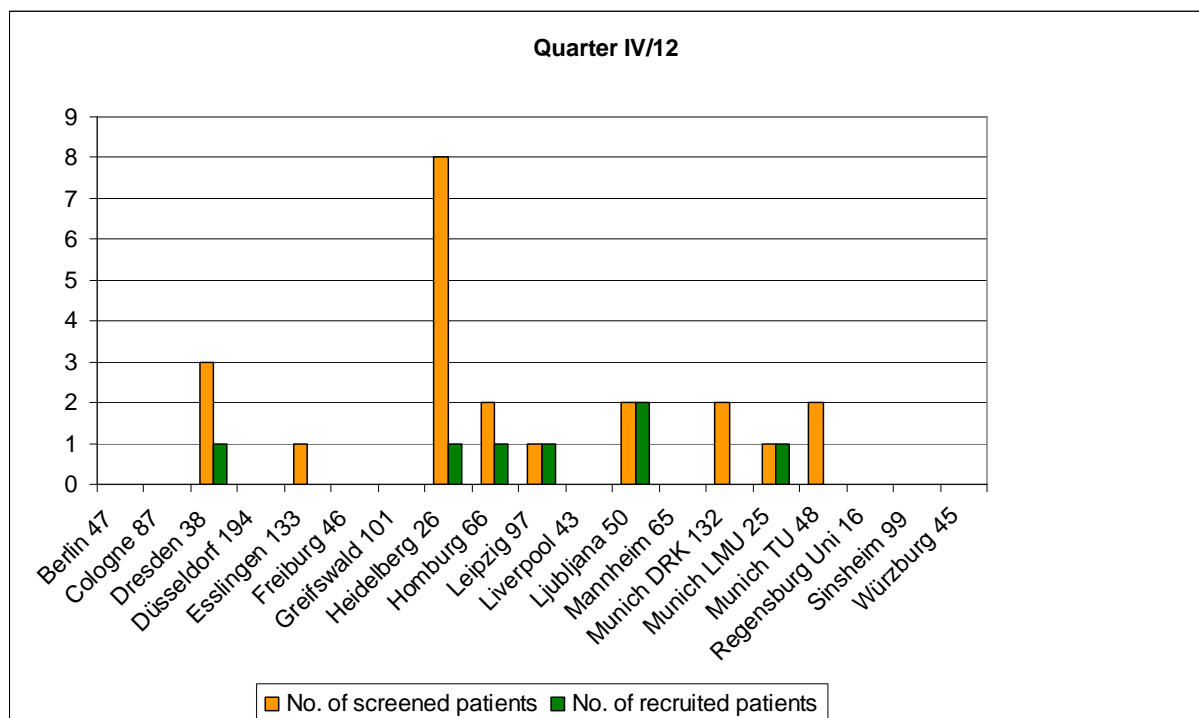


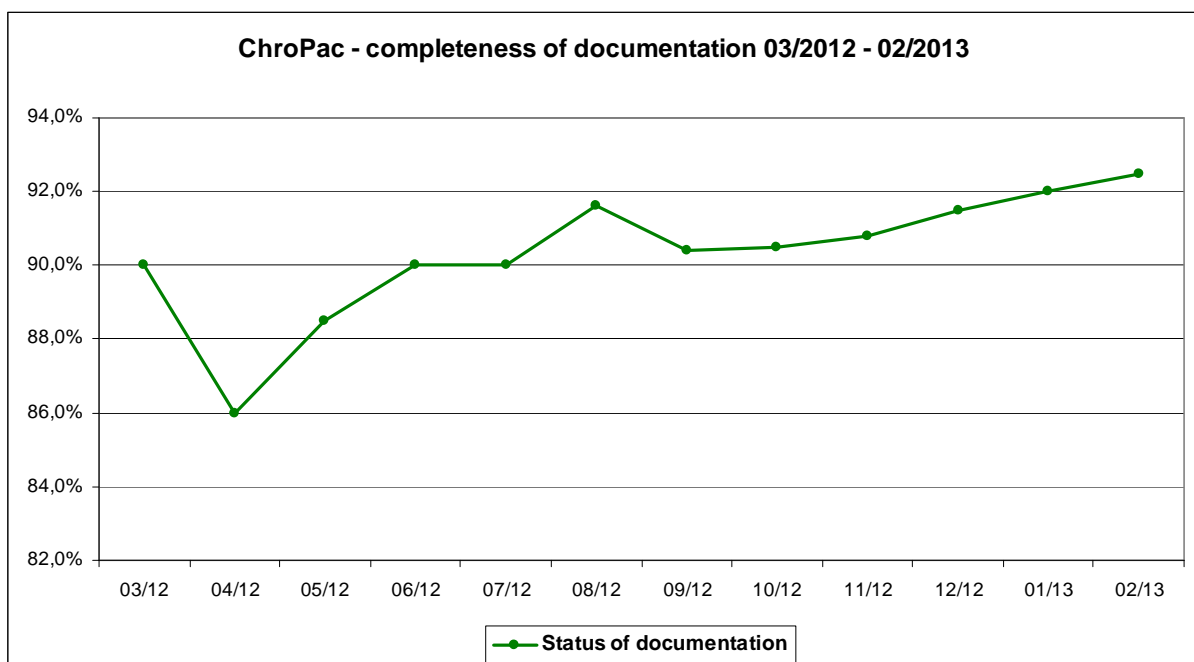
Figure 2 on basis of screening data that were provided by centers

We kindly ask all centers to send their screening lists for each quarter as requested.



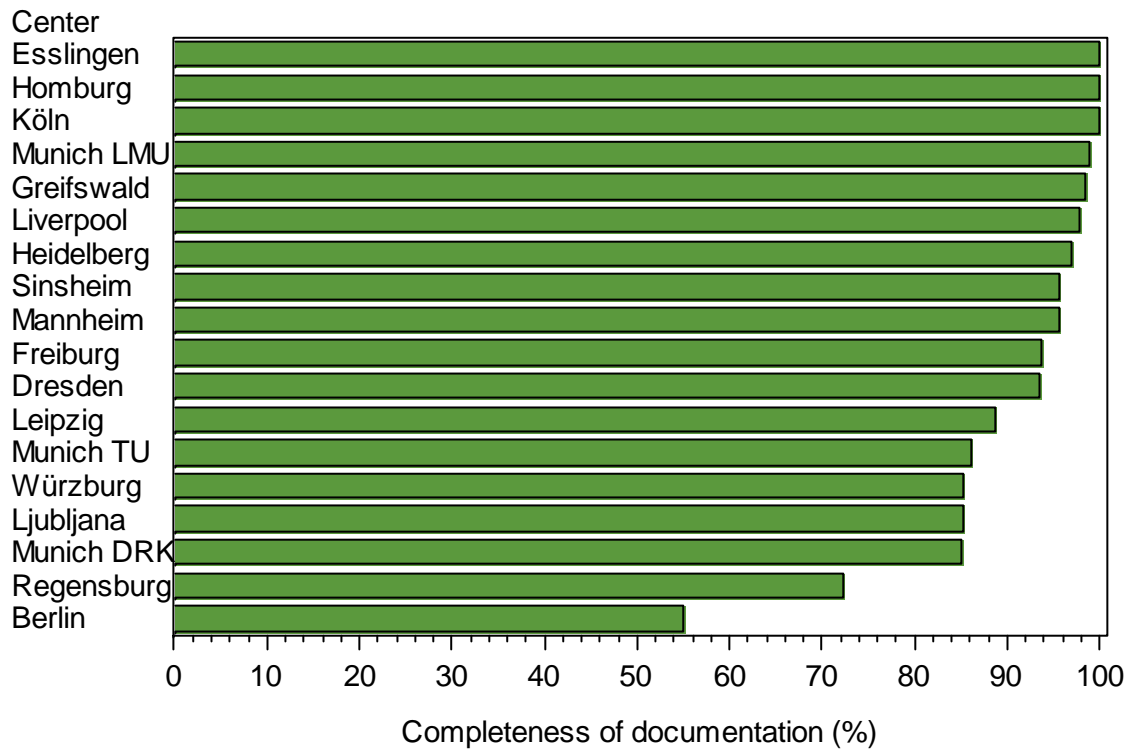
Documentation Status

The average for all centers is currently 92.5%. Thanks to all centers for this steady increase. 8 centers have a completeness of documentation of more than 95% and three have reached 100%.



updated 01.02.2013

Completeness of documentation per center



updated 01.02.2013



Looking Forward

Since SDGC and CHIR-Net will be represented with a booth during the “130. Deutscher Chirurgenkongress” in Munich from 29.04. – 02.05.2013, we are looking forward to meet you there. This will give the opportunity do discuss important issues and to answer questions.

For questions or comments please contact our project management:

Colette Dörr-Harim

(colette.doerr-harim@med.uni-heidelberg.de, Tel 0049-(0)6221-5636683) or

Evelin Hund

(Evelin.hund@med.uni-heidelberg.de, Tel 0049-(0)6221-566540)

With kind regards from Heidelberg
The ChroPac Team at the SDGC

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