








Newsletter 8 – 07/2012

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Editorial

Dear Members of the ChroPac Study Group,

During last months you have been repeatedly contacted to update documentation and Quality of Life questionnaires. This aimed at getting reliable results of the number of patients that are assessable for the primary endpoint Quality of Life. Unfortunately, 30% of randomized patients cannot be included in the analysis, mostly due to missing questionnaires. When planning ChroPac trial, we had estimated a drop out rate of 15%.

We all know that it is not easy to obtain follow-up for patients with chronic pancreatitis. Some centers have done a great job, however, the overall percentage of available QLQ from visit 5 is only 67% at present, risking to jeopardize the trial. We need to improve this rate in order to be able to analyze the primary endpoint of the trial.

As a consequence, we are planning to increase patient numbers and continue randomization for 50 more patients until 250 patients are reached.

Therefore, we ask all centers to continue to screen patients for ChroPac and restart to randomize, if you have not done so during the last weeks. Please pay special attention to the quality of life questionnaires during follow-up as this is a crucial point in order to ensure the validity of the results for our patient-oriented outcome.

With best regards,

Markus Diener, MD



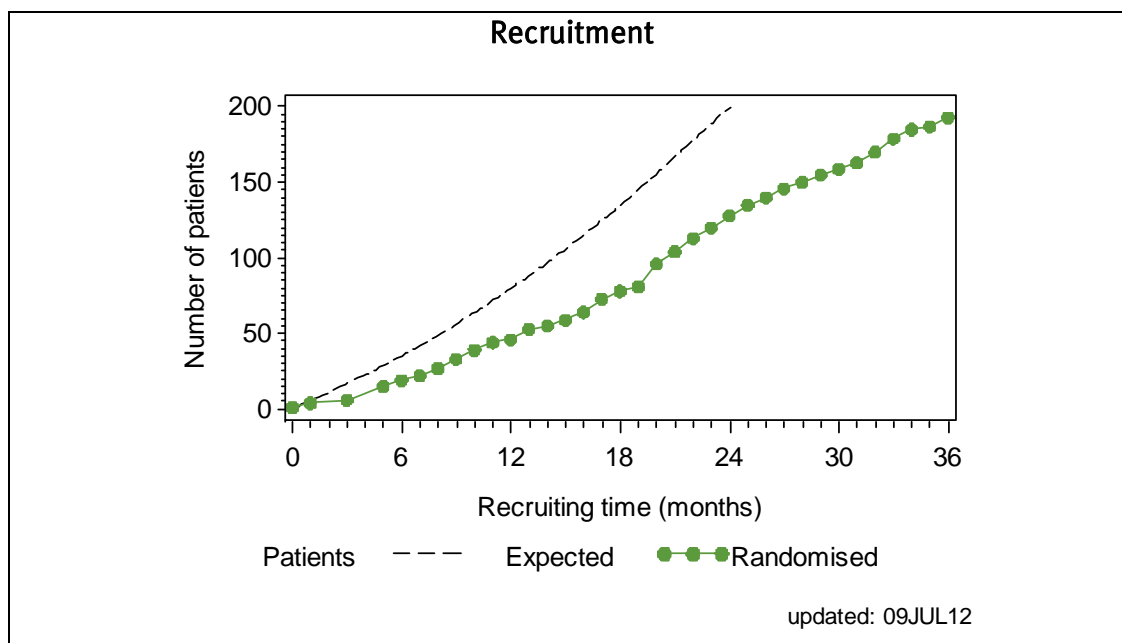
Amendment

As stated above, another 50 patients have to be included into the trial thus increasing the sample size from 200 to 250 patients to be enrolled. Since this increase of sample size has to be approved by the ethics committee, we submitted the necessary amendment. We will inform you as soon as we will get the approval. Nevertheless, we are sure that with your constant enormous effort we are able to enrol the missing number of subjects until the end of the first quarter of 2013.



Recruitment

Currently, 194 subjects have been randomized (for development of recruitment see figure below).



Screening & Randomization Numbers

As you can see from figure 1 below, the total number of screened patients decreased over the last 6 quarters implying the decreasing number of randomizations.

The second figure shows the numbers of screened and randomized subjects per center during last 12 months.

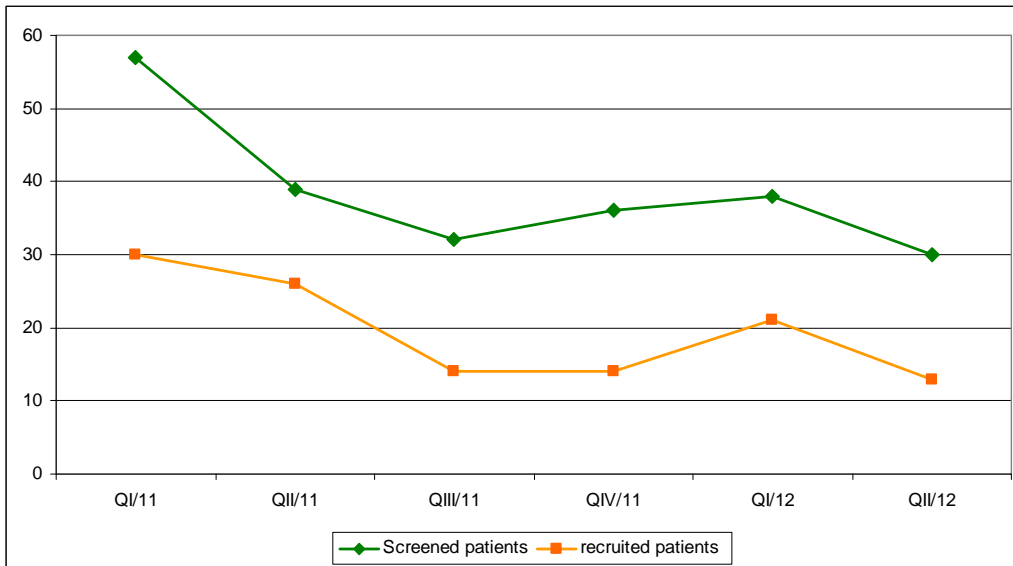


Figure 1.

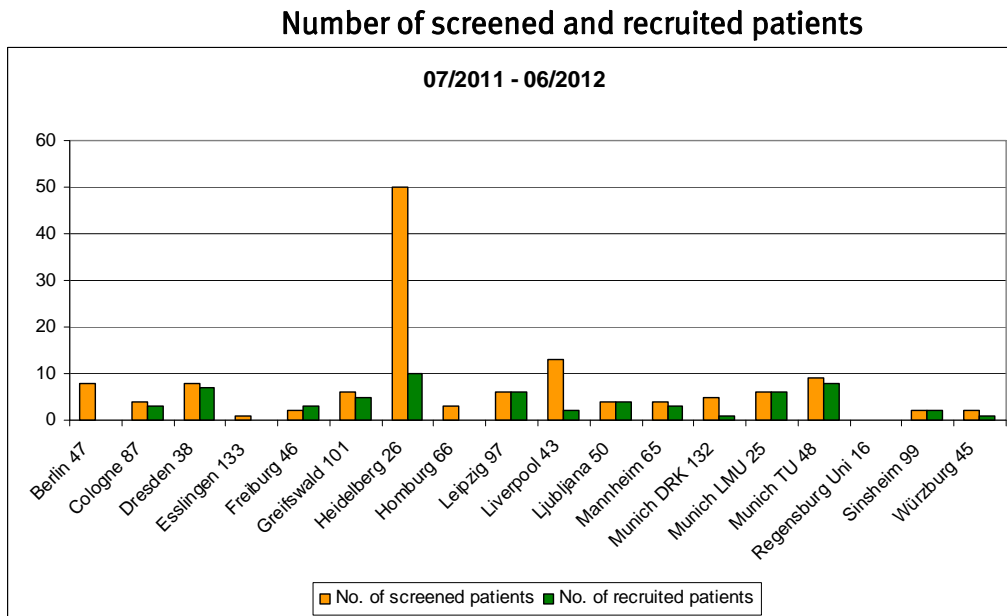


Figure 2 on basis of screening data that were provided by centers quarterly from Q1/2012 and Q4/12

Reasons for not randomizing

(total number of screened patients during last 12 months: 136)

Reasons for Patients not being randomized n = 70		
Inclusion criteria	Number of patients	Percentage (of n)
Medical:	27	39%
Understanding:	2	3%
No informed consent:	25	36%
Exclusion criteria (other trial)	1	1%
Others	15	21%

Table on basis of screening data that were provided by the centers quarterly from QIII/2011 – QII/2012



SAE – Reporting

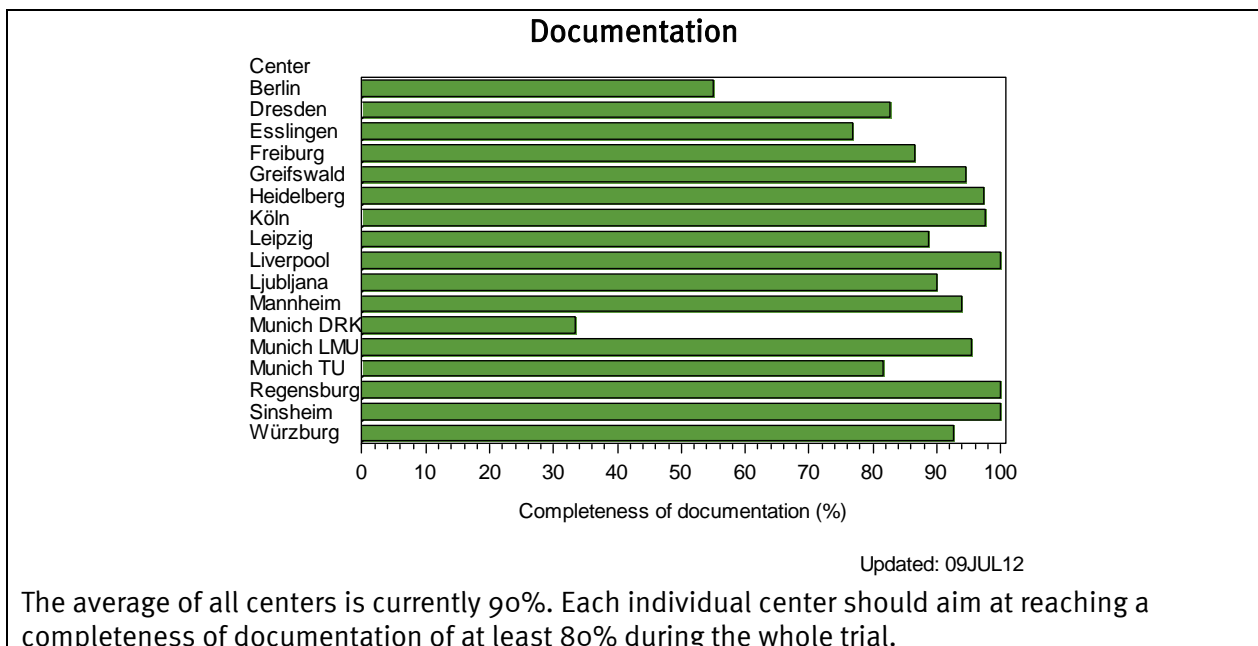
In order to classify the occurring serious adverse events it is necessary to determine the underlying event/disease. Please provide this information if it is known.

Secondly, for follow-up reports we kindly ask you to mark “see initial report” in the free text sections unless anything has changed regarding symptoms or therapy/intervention.



Documentation and Query Status

We particularly thank centers with 100% documentation: Liverpool, Regensburg and Sinsheim.



Our Data Management would like to remind centers to make sure that Quality of Life Questionnaires are completed within the time range of the corresponding visit.

We kindly ask you to document the data within 4 weeks and answer the queries as soon as possible, in order to keep the data base up to date.



Looking Forward

For our common goal we count on each site: If we reach again the planned rate of 8 patients being enrolled per month we will complete the new sample within the updated timelines: **Let our trial pick up pace again.**

For questions or comments please contact our project management:

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With kind regards from Heidelberg
The ChroPac Team at the SDGC

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