








## Newsletter 5 – 10/2010

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### Editorial

Dear Members of the ChroPac Study Group,

We started the ChroPac Trial to prove the potential better Quality of Life of patients with chronic pancreatitis treated with the less invasive Duodenum Preserving Pancreatic Head Resection procedures in comparison to treatment with the Whipple procedures.

The external peer review of our grant application to the German Research Foundation (DFG) was successful and we received the money to conduct the largest and first multicenter randomized controlled trial for this patient group.

However, we are too slow in the recruitment of patients (currently one patient per week is randomized) and we need to talk about the reasons. Therefore you are cordially invited to an investigator meeting in Munich at the 18<sup>th</sup> of November 2010 prior to the start of the Annual Meeting of the German Pancreatic Club. We are thankful to the organizers of the latter meeting, Professor Kleeff and Professor Friess, for the opportunity to have this meeting in the rooms of their department.

We kindly ask you to participate as we have to define strategies for the progress of this study. We need your support and help to answer our important research question.

With best regards,  
Christoph M. Seiler, MD



### Recruitment & Investigator Meeting

We welcome the centers Cologne, Krankenhaus der Augustinerinnen (C. Vivaldi, S. Stemmler, T. Beckurts) and Liverpool (P. Baker, S. Chauhan, C. Halloran, J. Neoptolemos) that have been initiated.

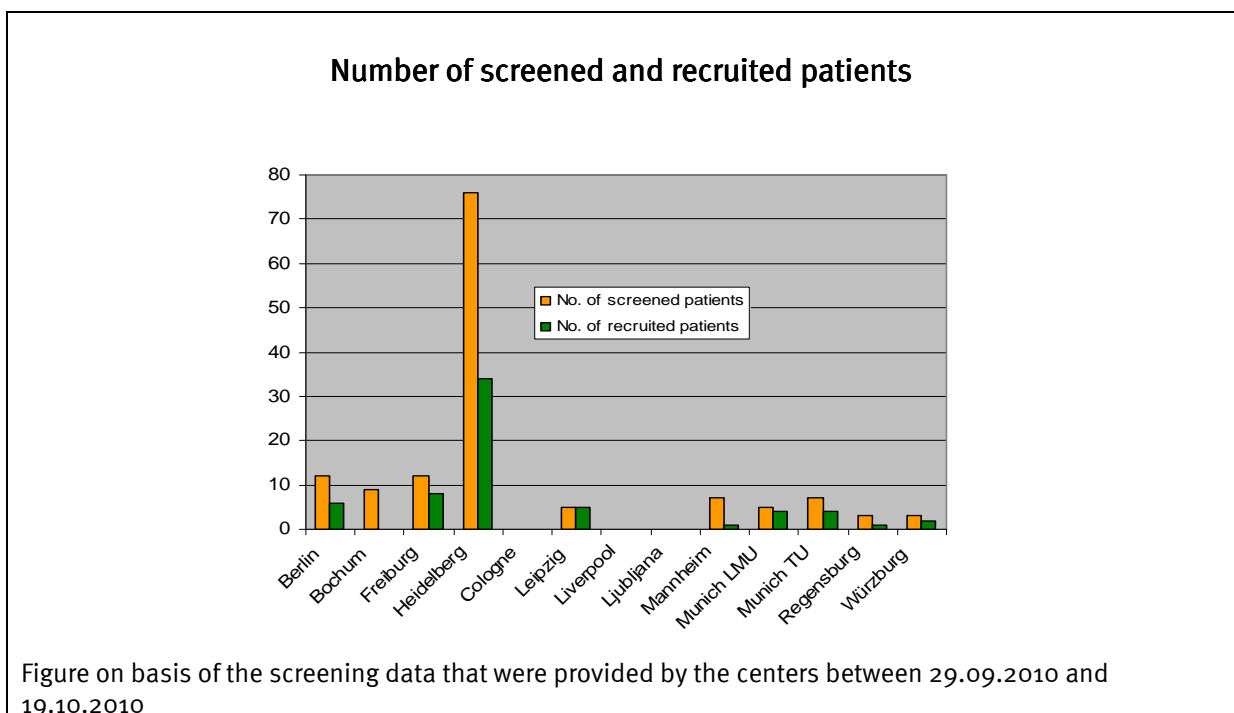
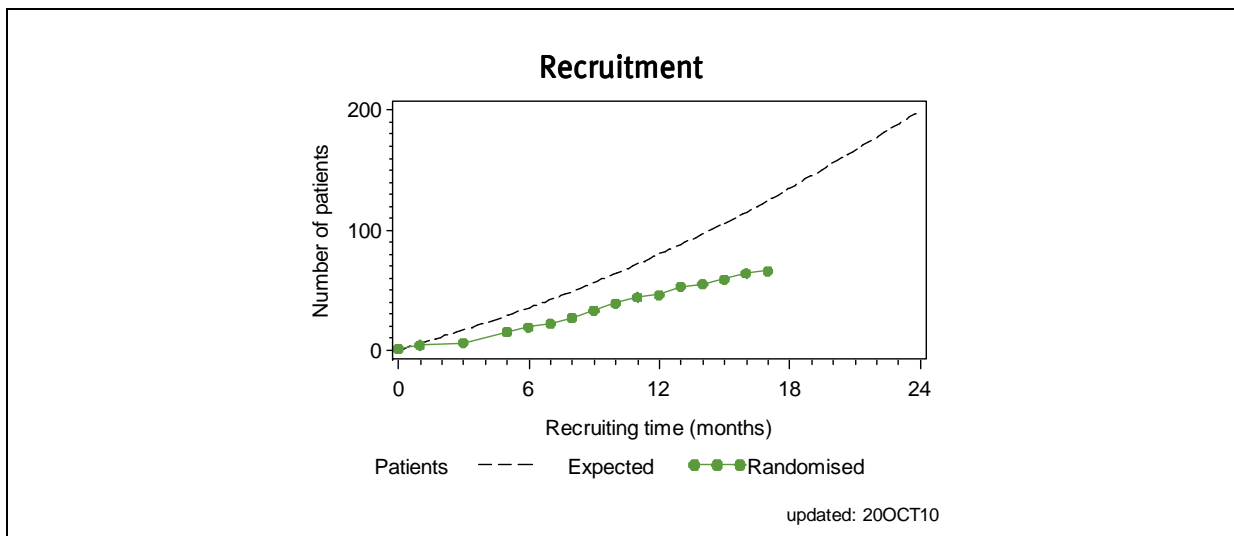
The slow recruitment has become critical for the continuation of the funding and therewith for the progress of our trial. Recruitment is decreasing and this is especially problematic. This is the reason why an investigator meeting has been scheduled for November 18<sup>th</sup> in Munich. We kindly ask all centers to send at least one surgical decision

maker as a representative to the meeting. Only the surgeons really treating the patients can decide about further steps and therefore we kindly ask for their participation.

Topics of the meeting will be as follows:

1. Analysis of the current status – Why we are behind schedule in recruitment?
2. Strategies for improvement
3. Update of milestones

For recruiting numbers please refer to the following two figures.





## Commitment of patient recruitment owed to German Research Foundation

In the application for funding to the German Research Foundation (DFG) in 2008 the centers had to make commitments concerning the patient numbers they were able to recruit for the trial. On basis of these commitments the application was peer-reviewed and funding was granted. According to the milestones of the trial, half of the patients needed (100 of 200 patients) should have been recruited by August 2010. The table below shows the commitment of patient recruitment the centers made in the grant application in comparison to the actual numbers:

Center	Date of Initiation	Expected no. of patients recruited for the trial within 2 years according to grant application	Actual no. of patients recruited by 15.10.10
Berlin	15.10.2009	60	6
Freiburg	08.10.2009	30	8
Heidelberg	19.05.2009	120	33
Liverpool	22.09.2010	30	0
Ljubljana	18.03.2010	20-25	0
Mannheim	01.09.2009	5-8	1
Munich LMU	18.11.2009	20	4
Munich TU	14.01.2010	5-10	4
Würzburg	02.11.2009	6	2
Leipzig	16.11.2009	15-20	5
Bochum	28.10.2009	not applicable	0
Cologne	02.06.2010	not applicable	0
Dresden	pending	not applicable	0
Regensburg	12.10.2009	not applicable	1
<b>Sum:</b>		<b>311-329</b>	<b>64</b>

Centers that were not mentioned in the original grant application are highlighted in grey.



## Primary Endpoint & Questionnaires

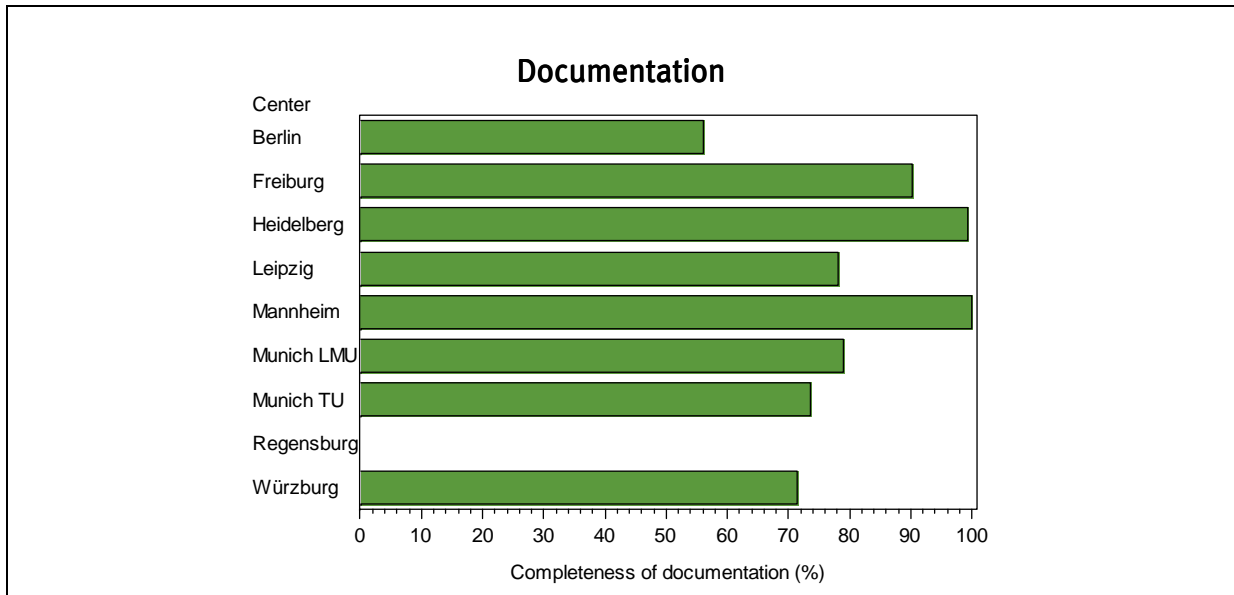
The primary endpoint is the average **Quality of Life** during 24 months after surgery, measured 6, 12 and 24 months after surgery by the EORTC QLQ-C30 and PAN 26 questionnaires. Unfortunately, centers and/or patients have lost some of the questionnaires.

**Please make sure to get back all questionnaires from the patients and send them immediately to the data management!** The questionnaires are indispensable for the evaluation of the primary endpoint.



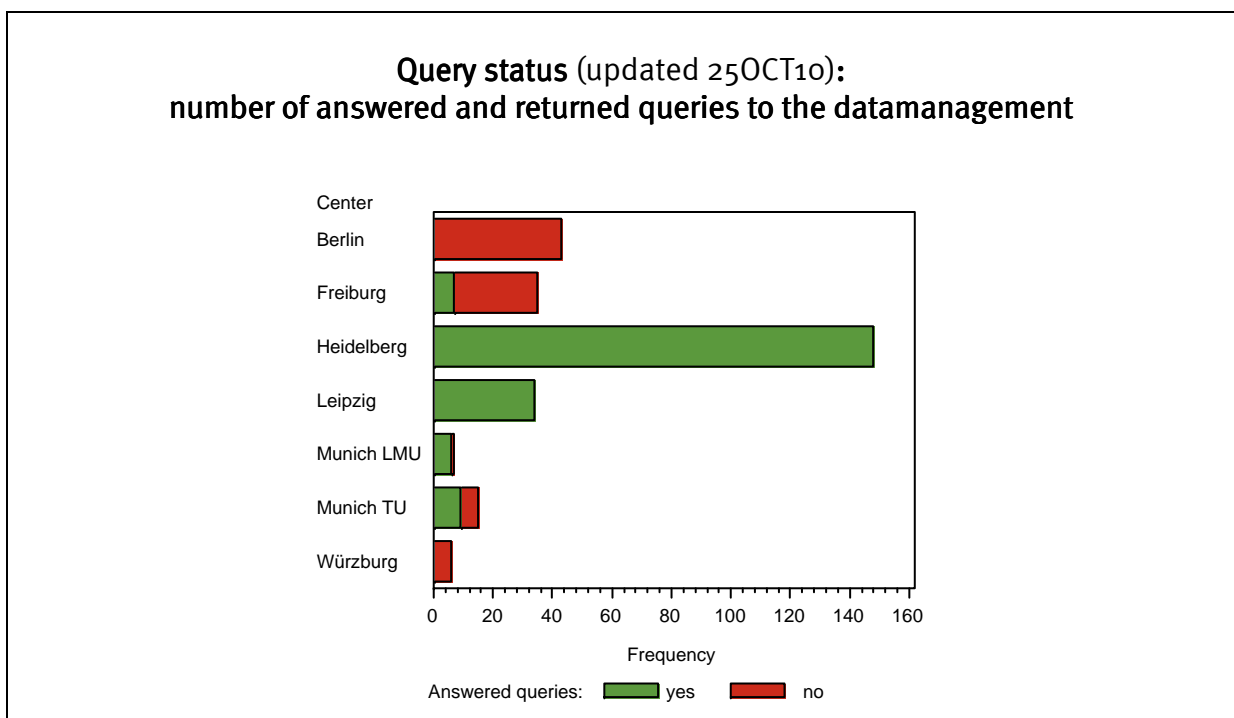
## Documentation

Overall documentation is quite good with an average of 88,7 % as of 20<sup>th</sup> October 2010. For detailed information please refer to the graph below.



We kindly ask you to document the data within 4 weeks, in order to keep the data base up to date.

Some of the centers have already received the first queries (see below). We kindly ask you to answer the queries as soon as possible.





## Milestones

Due to low recruitment the milestones have been adapted in May 2010 (see below), assuming a recruiting rate of 2 patients per week. However, only 26 patients have been recruited since May, this makes 26 patients in 25 weeks! The milestones will be adapted again during the investigator meeting in Munich.

Original schedule (grant application)			Adapted schedule (May 2010)		
Milestones	Quarter	Year	Milestones	Quarter	Year
First patient in	II	2009	First patient in	II	2009
Last patient in	I	2011	Last patient in	I	2012
Patient follow-up	I	2013	Patient follow-up	I	2014
Data base closure	II	2013	Data base closure	II	2014
Data analysis	III	2013	Data analysis	III	2014
Biostatistical report	IV	2013	Biostatistical report	IV	2014
Publication	IV	2013	Publication	IV	2014



## Looking Forward

We are looking forward to seeing you at the investigator meeting in Munich on November 18<sup>th</sup>.

With kind regards from Heidelberg  
The ChroPac Team at the SDGC

Markus W. Büchler   Christoph M. Seiler   Jens Werner   Alexandra Moreno Borchart

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