



ChroPac

**Duodenum-preserving head resection versus
pancreatico-duodenectomy for chronic pancreatitis of
the head. A randomized controlled multicentre trial**

Status quo



Milestones

Original schedule (2008)			Adapted (5/2010)	
Milestones	Quarter	Year	Quarter	Year
First patient in	April	2009	June	2009
Last patient in*	I	2011*	I	2012
Patient follow-up	II	2013	I	2014
Data base closure	II	2013	II	2014
Data analysis	III	2013	III	2014
Biostatistical report	IV	2013	IV	2014
Publication	IV	2013	IV	2014

*recruitment was initially planned on 2 patients per week,
actual rate achieved is 1 patient per week

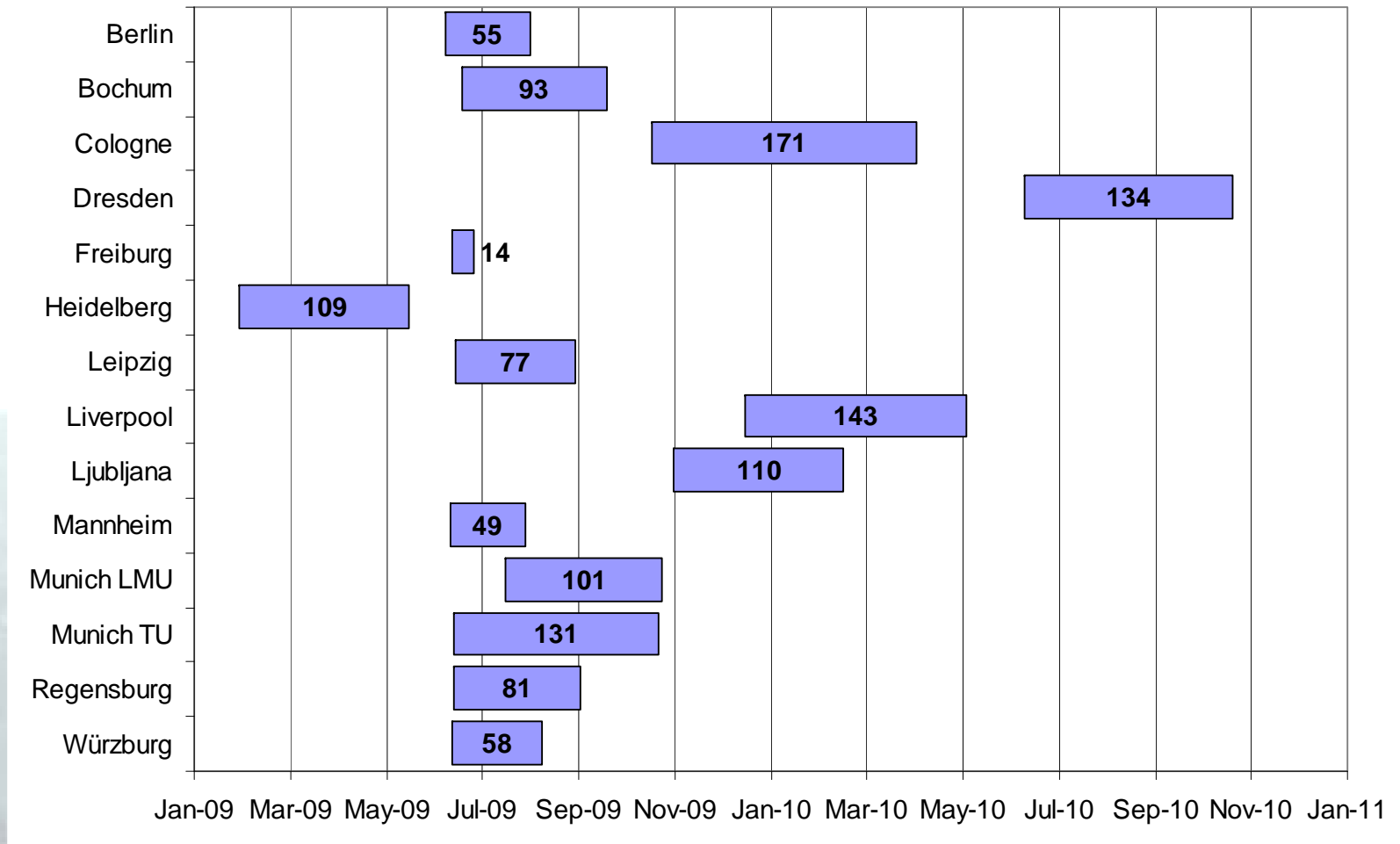


Participating centers

Berlin CCV	Liverpool
Bochum	Ljubljana
Cologne	Mannheim
Dresden	Munich LMU
Freiburg	Munich TU
Heidelberg	Regensburg
Leipzig	Würzburg

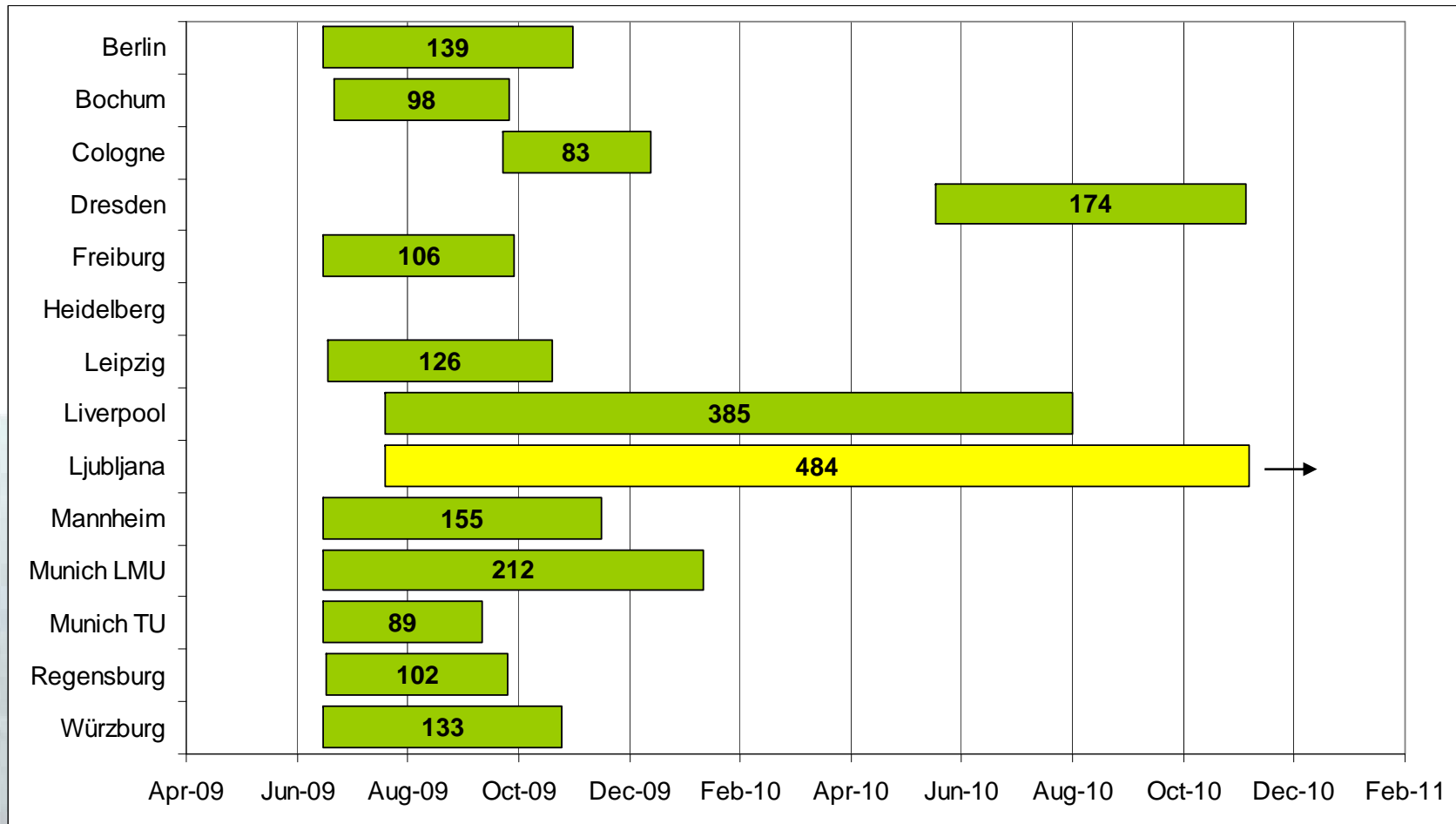


Duration ethics procedures



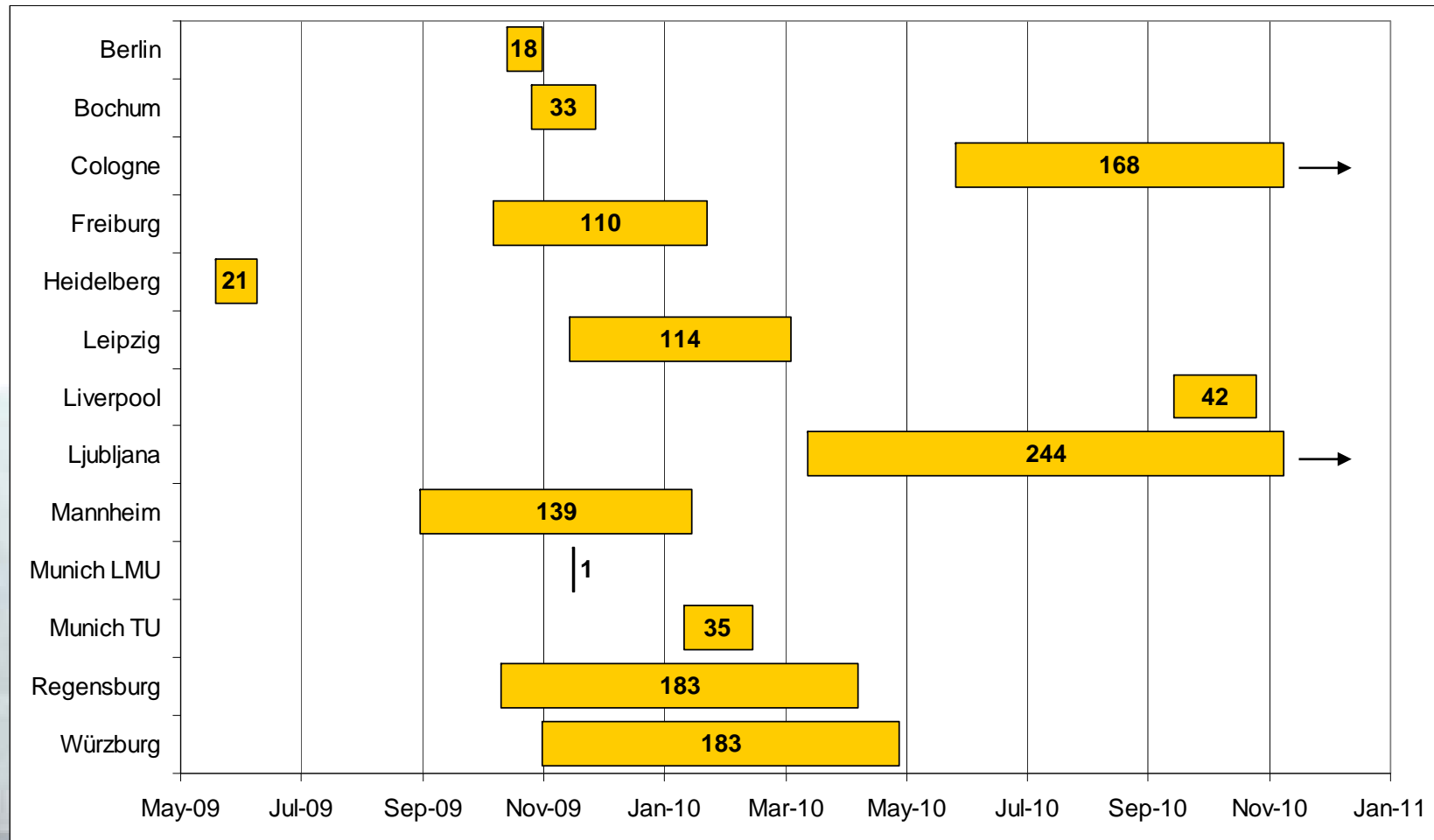


Duration contract procedure



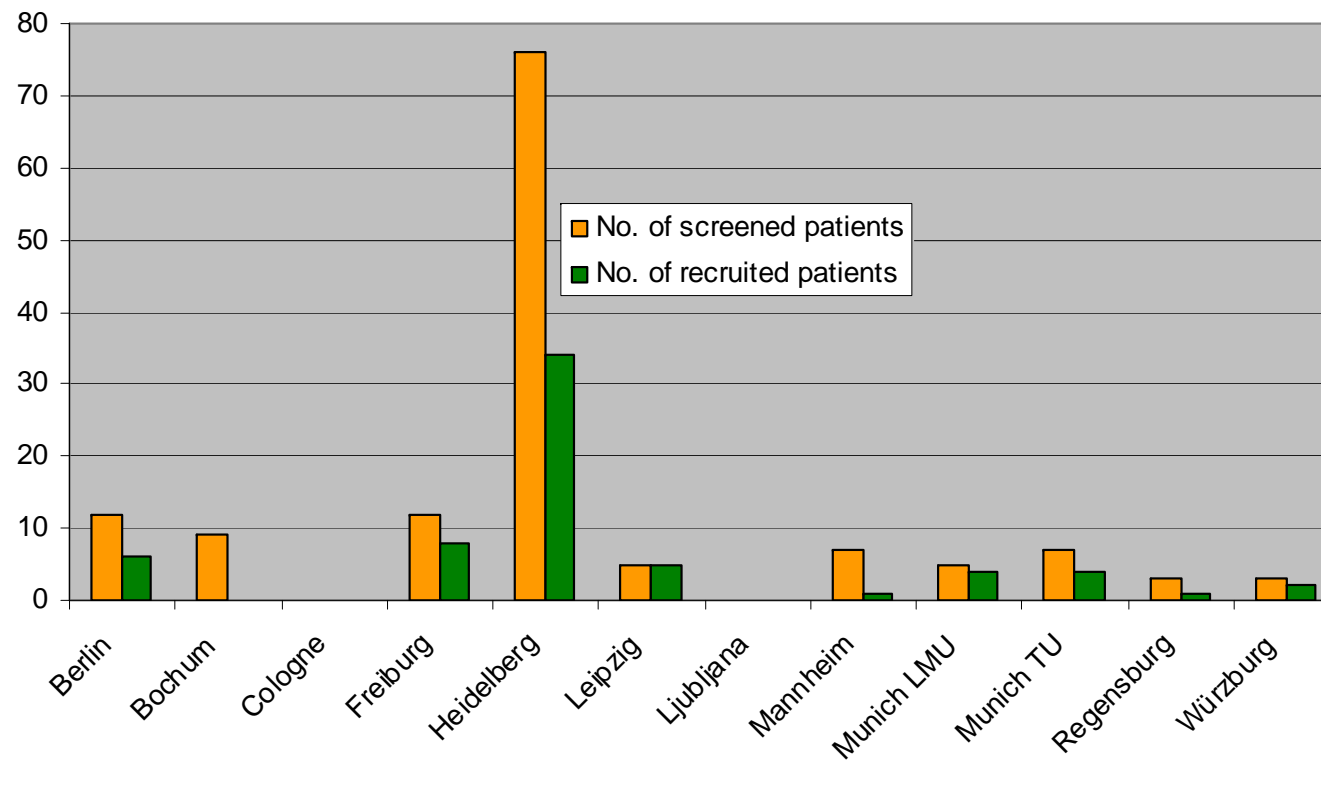


From initiation to 1st patient screened





Patients screened / patients randomized



last updated: October 19th, 2010



Screening: characteristics

139 patients were screened

64 patients were randomized = 46 %

range from 0 % (9 pat. screened) to 100 % (5 pat.)

Reasons for not randomizing (N=75)

- **Inclusion criteria**

- Medical: 46 patients (61%)
- Understanding: 1 patient (1%)
- No informed consent: 21 patients (28%)

- **Exclusion crit. (other trial):** 3 patients (4%)

- **Others:** 4 patients (5%)



Committment of centers

Center	Initiation	Months active	Expected (patients/year)	Actual recruitment	Rate / year (%) actual/expected
Berlin	15.10.09	13	30	6	18 %
Freiburg	08.10.09	13	15	9	55 %
Heidelberg	19.05.09	18	60	35	39 %
Leipzig	16.11.09	12	8	5	63 %
Liverpool	22.09.10	2	15	1	40 %
Ljubljana	18.03.10	8	10	0	---
Mannheim	01.09.09	14	5	3	51 %
Munich LMU	18.11.09	12	10	5	50 %
Munich TU	14.01.10	10	5	6	144 %
Regensburg	12.10.09	13	not applicable	1	---
Würzburg	02.11.09	12	3	2	67 %
Total			161	73	

updated Nov 17th, 2010



Measures taken to improve recruitment



1) Standard

- Trial registration: ISRCTN38973832
- Website <http://www.chropac-trial.eu/>
- 5 Newsletters
- Publication of trial protocol: *Trials* 2010, 11:47



Measures taken to improve recruitment



2) Patients and lay people

- Arbeitskreis Pankreatektomierte



- Newspaper articles: RNZ (Rhein-Neckar Zeitung)
Mannheimer Morgen

3) Physicians

- Letter to 346 medical practitioners
- Letter to alumni of Prof. Beger, Ulm



Measures taken to improve recruitment



4) Medical conventions

- May 2010 DGCH presentation at SDGC stand
- Sept 2010 DGAV oral presentation
- Oct 2010 Poster Mittelrheinische Chirurgen



Measures taken to improve recruitment



5) Eligibility

Inclusion criterion “patients with chronic pancreatitis of the head ... eligible for elective surgical resection” was specified (Newsletter 3)

“... Only patients with a high-grade suspicion of malignancy (i.e. with high level of tumor markers) should not be screened. All other patients should be screened and included, as a malignancy can only be excluded during the operation (frozen section). If during or after the operation a malignancy is confirmed, the patients remain in the trial and are fully documented (ITT- intention-to-treat principle).”



Measures taken to improve recruitment



6) New participating centers

- **Proposal: 11 centers**
- **1 center called off participation (Amsterdam)**
- **4 new centers:** Bochum
Cologne Augustinerinnen
Dresden
Regensburg
- **further centers interested:**
Düsseldorf, Greifswald
Esslingen, Homburg, München



Recruitment

Time (in quarters)	Number of centers initiated	Number of centers recruiting	Number of patients recruited
2009 / II	1	1	1
2009 / III	2	1	5
2009 / IV	9	3	13
2010 / I	11	7	16
2010 / II	12	8	15
2010 / III	12	9	13
2010 / IV	13	10	10

updated Nov 17th, 2010



Patient recruitment

