

## Newsletter 04 / 2007

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### Editorial

Dear members of the DISPACT study group,

today, we like to introduce to you the new URL: [www.DISPACT.de](http://www.DISPACT.de) .  
Just have a look at it. We are eager to hear your feedback. Tell us your wishes or proposals as to what you would like to see on the DISPACT website. Please, keep us informed about any changes at your centre, so that we can keep all information up to date.

On behalf of the Steering Committee

Christoph M. Seiler, MD

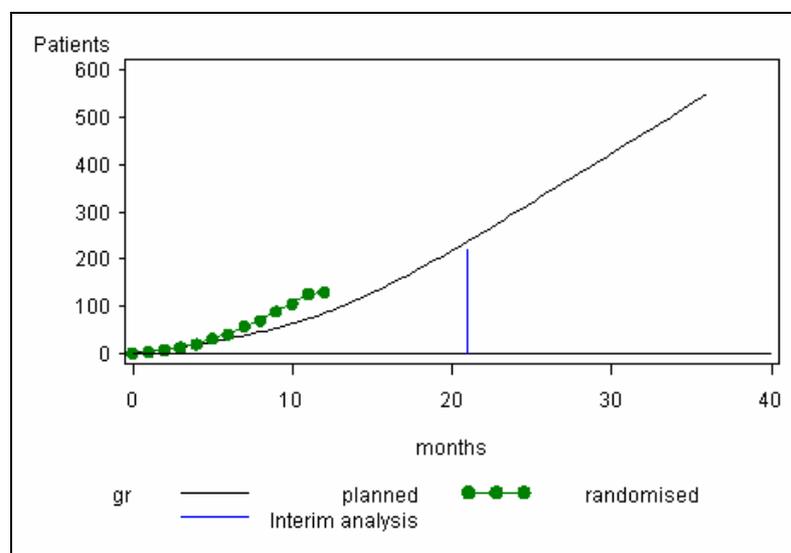
Markus Diener, MD

Inga Rossion, MD

### Patient recruitment

Patient enrolment is progressing well and is in line with the pre-planned recruitment plan. At present 135 patients are randomised.

DISPACT: Recruitment status plan versus reality





## Participating Centres

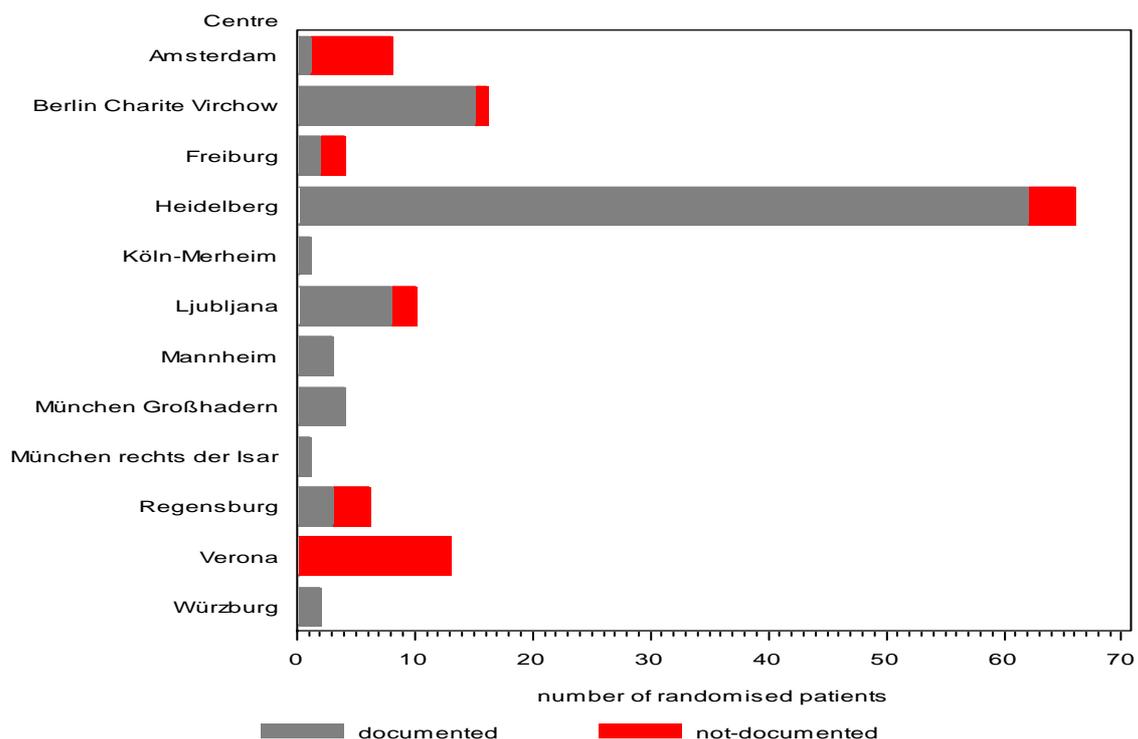
We welcome Gent and Wuppertal as new participating centres. To date, 16 trial centres are activated, 12 of them having already randomised patients.

Activated centres are: Amsterdam, Berlin Charité Mitte, Berlin Charité Virchow, Gent, Freiburg, Heidelberg, Homburg, Köln-Merheim, Ljubljana, Mannheim, München-Großhadern, München-Rechts der Isar, Regensburg, Verona, Würzburg, Wuppertal.

## eCRF: MACRO

Some centres are now starting to get acquainted with electronic documentation. Actually, it is no more difficult than paper CRF, once the system has been successfully installed. We advise you to have one or two key persons familiarised with Macro who can keep documentation ongoing at a steady pace. For example, this could be a study nurse, a documentation officer or a medical information specialist. If a considerable time lap has developed between generation of original data in 'real time' and its entry in Macro, then documentation may be much more time-consuming. So please, try to keep within a timeline of 2 to 4 weeks.

## DISPACT: Patients documented in Macro





### **Laboratory values: Amylase and others**

By checking the first eCRF documentations our monitor, Sonja Wittkus, has discovered that some centres had not been using values of total amylase but rather pancreatic amylase. We ask every centre to measure total amylase in order to be able to evaluate the primary endpoint pancreatic fistula according to the definition of Bassi et al. To our knowledge, the relationship between amylase content in drainage fluid and serum values has been established for total amylase only. In order to be able to identify the type of amylase, a question was added in the eCRF and needs to be crossed from now on. For all patients already documented, this item should be added retrospectively within the next 4 weeks.

### **Looking Forward**

DISPACT trial is progressing well, thanks to all participating centres. We are happy that everybody in the trial group has made an effort to make this nice progress possible and wish you good continuation.

With kind regards from Heidelberg

The DISPACT Steering Committee and the DISPACT Team at the SDGC