



ZKS Köln

34<sup>th</sup> Annual Meeting of the Society for Clinical Trials  
May 19-22, 2013; Boston, MA, USA

**Contributed Paper Session 4B**  
**Study Management/Study Coordination Potpourri**

# **Estimating Site Costs Prior to Conducting Clinical Trials – A Study Site Budgeting Tool**

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funded by the



Federal Ministry  
of Education  
and Research



- Primary data source
- Only direct link to the patient
- Sole provider of
  - Timely recruitment of participants
  - Proper execution of protocol specification
- Site performance determines trial quality
- Adequate resources are essential

- Adequate reimbursement of staff costs
- Pre-estimation of costs in advance of the trial
- Expedient and traceable trial fees
  - Basis for negotiations and agreements
  - Delimitation between trial activities and standard of care

## But...

- Lack of adequate guidelines
  - Physicians' fee schedules do not take into account research specific staff and research specific activities

- Task group
  - Investigators and study coordinators from highly active clinical trial sites
  - Oncology, gynecology, hematology, infectious diseases, pediatrics
- Design phase
  - Itemization of trial tasks
  - Definition of hourly rates
  - Creation of STUDGET™
- Validation phase
  - Testing for accuracy
  - Confirmation of the predictive value

## Basic information

Trial information

Information about trial team

Visit schedule

## Trial activities

Non-repetitive activities for preparation, initiation and close-out

Patient-based activities for visits per trial schedule (screening, baseline, intervention and follow-up)

Continuous activities

## Summation

Payments

Required hours of work

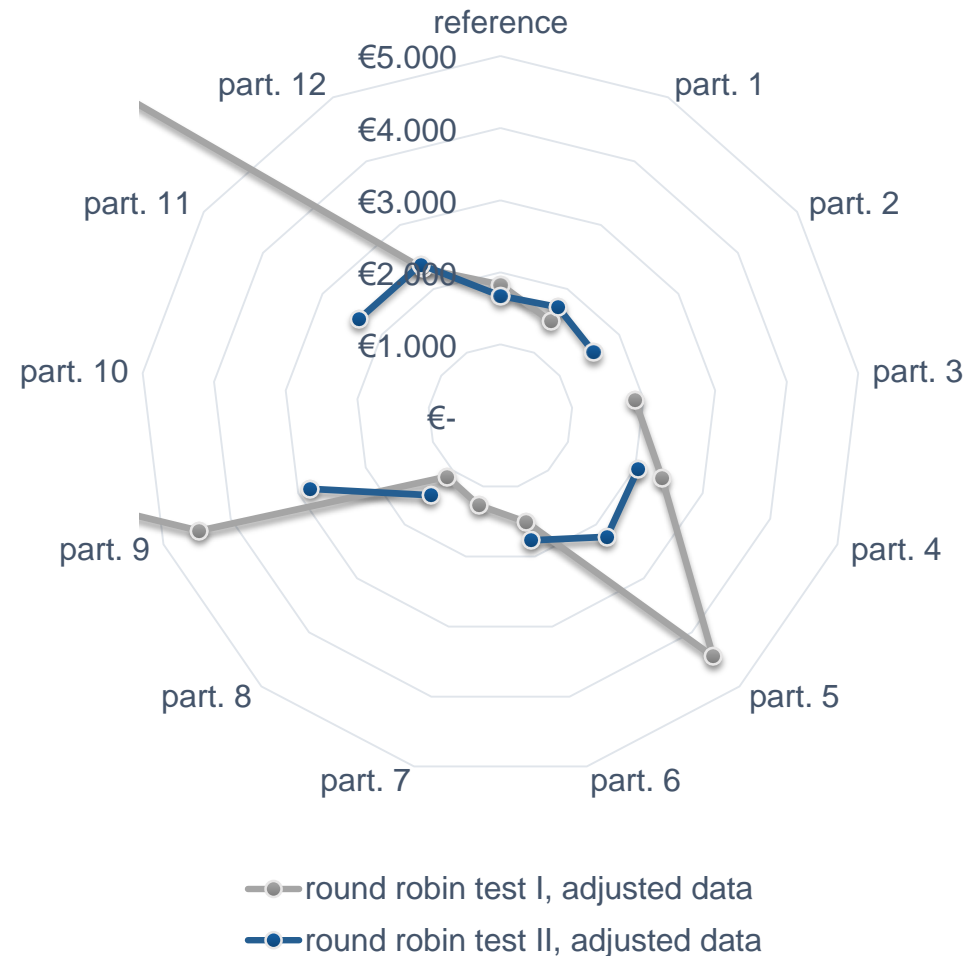
# Itemization of Activities and Assignment of Time Expenditures

## ▼ Visits during Intervention

Visits during Intervention		<u>total no. during intervention</u>	<u>time [h] per procedure</u>	<u>total</u>
clinical observation and assessment (e.g. outcome assessment, decisions on course of treatment, inquiries by SI or monitor)	PI		0,5	62,50€
clinical observation and assessment (e.g. physical examinations, AE/SAE assessment)	SI		0,5	39€
issuing and tracking of study medication	SC	14	0,5	350€
blood sampling (including preparation)	SC	4	0,5	100€
possibly blood sampling by physician	SI	0	0,25	0€
possibly processing of sample	SC	0	0,5	0€
possibly shipment of sample	SC	4	0,5	100€
vital signs	SC	14	0,25	175€
ECG	SC	2	0,5	50€
possibly storage and transmission of ECG	SC	2	0,5	50€
storage and transmission of radiologic imaging	SC	0	0,5	0€
delivery and explanation of questionnaires or diaries	SC	1	0,5	25€

- Payments
  - Detailed payment schedule
    - Payments per trial visit
    - Start-up fee
    - Mainly applicable for commercial sponsors
  - Case payment
    - Start-up fee on a pro-rata basis
    - Usually applicable for non-commercial trials
- Required staff hours
  - Time for preparation
  - Average time needed per month of trial duration

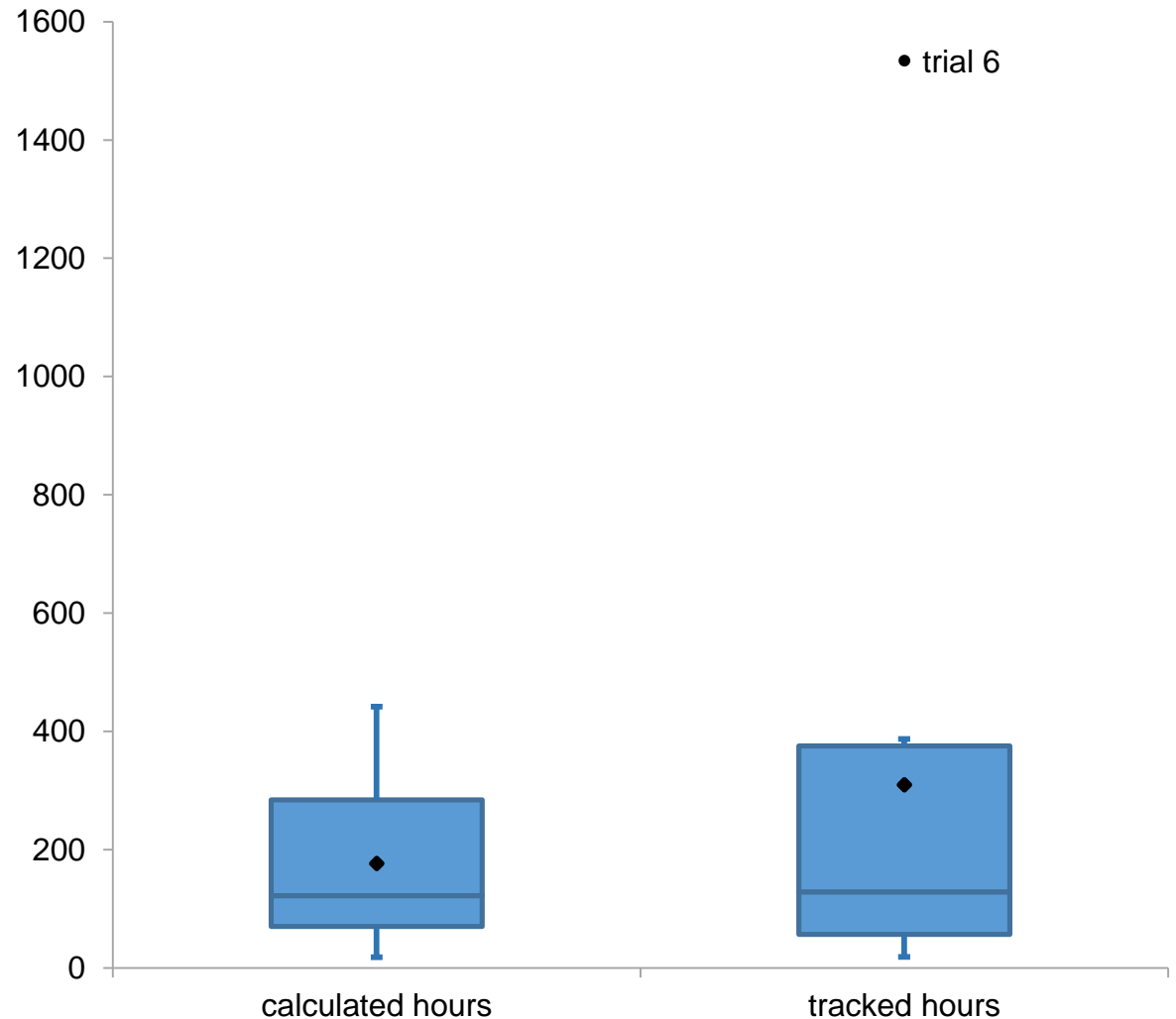
- Round robin test comparing case payments calculated for the same trial by different study coordinators
- First round with high inter-user variability
- Adjustment of data fields and instruction of users
- Second round with acceptable deviation due to varying interpretation of standard procedures





# Confirmation of the Predictive Value

- 10 trials initiated within one CTU
- Comparison between study coordinator hours calculated in advance of the trial and tracked during trial
- Detected deviations due to unforeseeable changes in trial execution
- Trial 6: amendment with increase of procedures



## Test account via studget@zks-koeln.de

Studget<sub>BETA</sub>

LOGIN

  
  
[Reset Password](#)  
[Account Request](#)

Please note that **this is a beta version** of the Studget tool. It should be used for testing only.

If you log in with a test account (usernames beginning with "test"), please keep in mind that this account is shared with various users. Saved files can be opened by others, so please delete files after print-out.

If you encounter any problems or have comments or remarks please contact us via email [studget@zks-koeln.de](mailto:studget@zks-koeln.de).



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