

CTU Lecture

Wie erstelle ich ein Studienbudget?

Sven Trelle, CTU Bern

29. April 2020

u^b

b
UNIVERSITÄT
BERN



CTU Lecture

Wieviel kostet meine Studie – wirklich?

Sven Trelle, CTU Bern

16. Mai 2019

u^b

b
UNIVERSITÄT
BERN



My conflicts of interest

With regard to this talk

- CTU Bern depends on clients and people who seek help
- The more I stress specialization and expertise the better
- The more expensive a project is the more remains (usually) for CTUs



Imagine the following situation ...

The question!

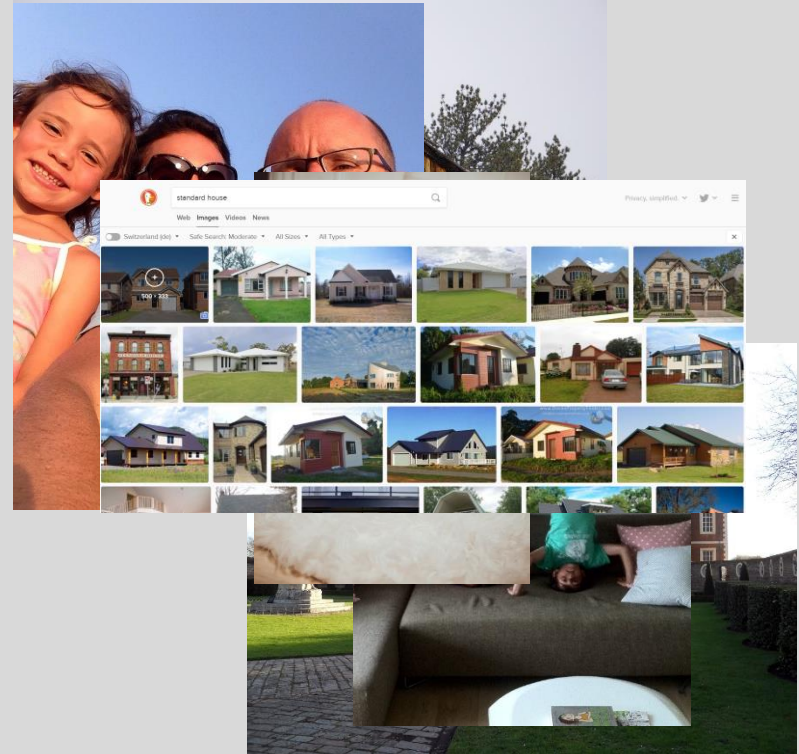
Peter: «I want a house,
how much does it cost?»



Imagine the following situation ...

A possible first inquiry

- Peter: «I want a house, how much does it cost?»
- You: «What type of house do you want?»
- Peter: «I do not know, a standard house, nothing fancy»
- You → google.com
- You: «How many people are you?»
- Peter: «Me, my wife and two kids –
at the moment, but who knows what will happen in future ...»



The difficulty with trial budgets

Uncertainty

- Need to predict costs
- Limited information
- What is (thought) to be available/affordable
↔ what is actually/truly needed

Trial budget and costs

Definitions (in this talk)

- Budget
 - The estimated amount of all money needed to do a clinical trial (or task)
 - From concept to completion
- Costs
 - The actual amount of all money needed to do the whole clinical trial (or task)
 - Direct and indirect costs

Categories

- Direct costs
 - Fixed i.e. not directly related to number of participants
 - Variable i.e. directly related to the number of participants and certain events

This separation is sometimes difficult to make for certain costs

- Indirect costs
 - (Basic) Infrastructure e.g. space, IT network etc.
 - (Opportunity costs)

Often difficult to quantify

Direct costs

Disentangled

- Personnel
- Services (consisting of personnel, equipment, indirect costs ...)
- Equipment
- Consumables
 - Intervention costs e.g. the device
 - Lab consumables
 - Office supply including phone etc.
- Travel
- Insurance
- ...

Direct costs

Disentangled

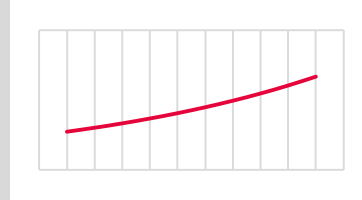
– Personnel

- Services (consisting of **personnel**, equipment, indirect costs ...)
- Equipment
- Consumables
 - Intervention costs e.g. the device
 - Lab consumables
 - Office supply including phone etc.
- Travel
- Insurance
- ...

The clinical trial budget

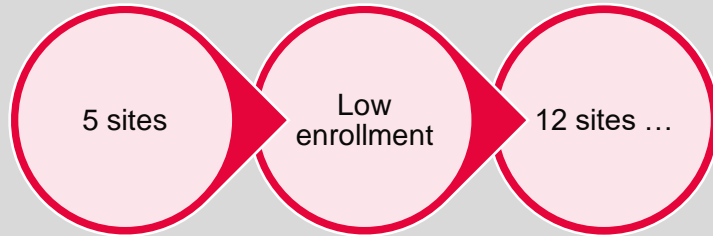
Predicting the costs ...

- The **overall costs** (sponsor), includes
 - **Site budget** (investigator)
 - Central coordination costs
 - Outsourced costs e.g. CTU/CRO
- Principle:
Trial characteristics + assumptions + contingency + productivity
= budget
- Trial characteristics: the more, the better ...
- Assumptions: predicting the unpredictable
- Contingency: allow for unforeseen events/expenses (+ 10-30%)



Do not underestimate

- If you underestimate, you will not have the resources to complete the trial
- Example



- Experience tells us that this happens (very) often (in academia?)

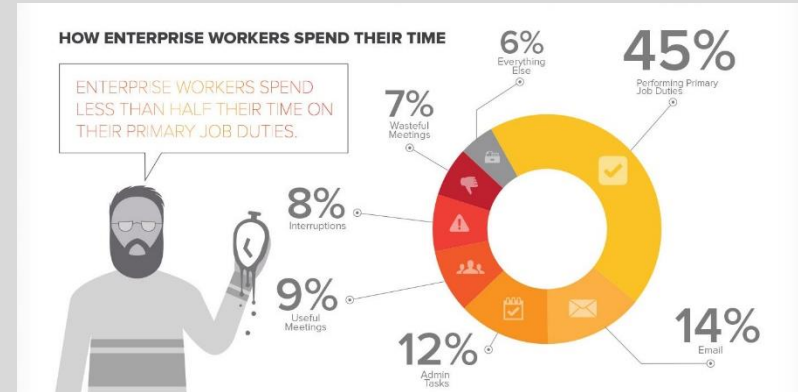
You will never overestimate ...

- We tend to forget to actually consider all time needed to complete a task
- We tend to forget to consider communication
- We overestimate how much we actually work (productive working time)
 - Internal meetings
 - Absences e.g. sick leave
 - Further development (think about how much this CTU Lecture actually costs (opportunity costs)!)
 - Idle time
 - Laziness?

How to deal with productivity

When budgeting

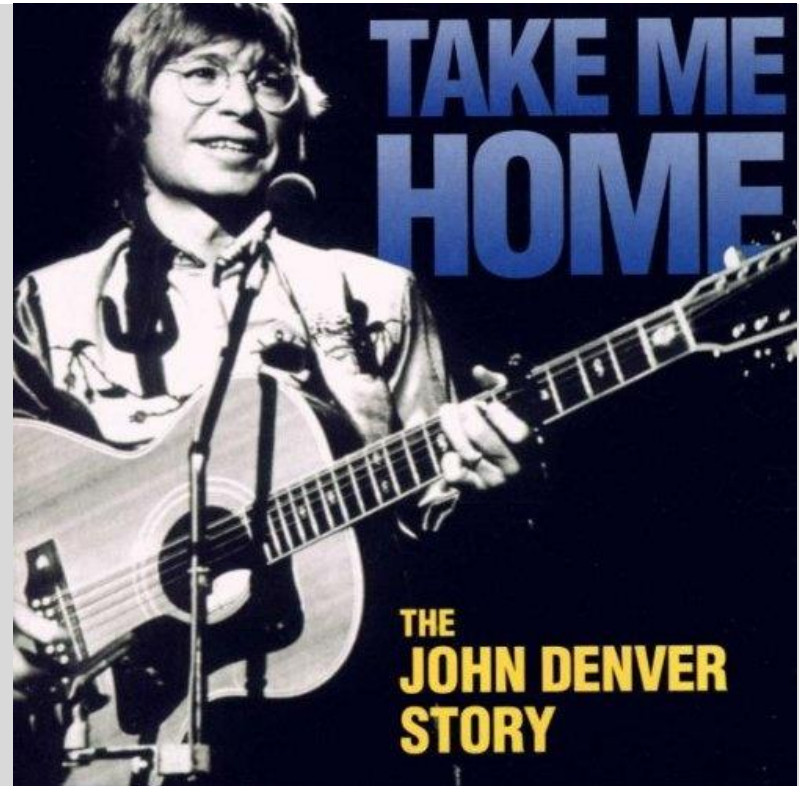
- Productivity relates to the project itself
- Costs for personnel incur ... i.e. if your costs for this 'non-productive' time are covered you can assume higher productivity
- Estimate the raw time required to complete a task
- Divide by estimated productivity (60-80%; see above) to get overall required time



The take home messages

First ...

- It is (very) difficult
- Clinical research/trials is (very) costly
- Communication takes time
→ costs money.
Doing research
== communication
- You will never overestimate the resources and time needed – no worries!
- Do not underestimate the costs ...



The budget

Details in CTU Lecture of May 16, 2019

- Data management
- Monitoring
- Site costs

The budget

Statistics (concept, development, set-up)

- Study design concept and development 👍* → dozens???
- Sample size calculation 👍 → 1 to 70+ hours ... (~ 10-15 hours)
 - CTU Bern SOP requires four eye principle as quality control ...
- Protocol review 👍 → 5 to 15+ hours (depends obviously on how much time was invested in the development stage ...)
- Case Report Form review 👍 → 5 to 20+ hours
 - Communication and re-discussions of study design ...
 - Protocol alignment
 - All necessary data collected in appropriate format
- Generating randomization lists 👍 → 4 to 20 hours
 - CTU Bern SOP requires four eye principle as quality control ...

* Rule of thumb, these numbers cannot be used as reference for an individual project 😊

The budget

Statistics (conduct)

- Regular reporting 👍* → 5-20 hours/report + 1-2 hours/generated report
 - Definition (communication ...)
 - Programming
 - Generating the reports
- Writing Statistical Analysis Plan (fixing all analyses) 👍 → 20 to 80+ hours ... (~ 50 hours)
 - Communication with PI/Sponsor ...
 - Learning new methods, searching for methods etc.
 - Write-up
- Interim analysis
- Programming 👍 → 200-500+ hours
 - Discussions and adaptations
 - CTU Bern SOP requires four eye principle as quality control ... (we would love to have everything double programmed by a second person ...)

* Rule of thumb, these numbers cannot be used as reference for an individual project 😊

The budget

Statistics (completion)

- Data validation and preparation
 - Depends on Central Data Monitoring during conduct
 - Data explorations
- Quality control of programming
- Analysis and reporting
 - Post-hoc analysis
 - Write-up
 - Programming publication-ready tables and graphs
- Preparing data and documentation for data sharing 👍 → 50+ hours

* Rule of thumb, these numbers cannot be used as reference for an individual project 😊

The budget

Clinical Study Management

- Sponsor responsibilities
- >300 different tasks
- Some one-time tasks, some are repeating tasks
- Budget/costs depend on responsibility split
- 👉 → (0.5-)1.0+ FTE over the whole trial period (fluctuating, maybe more during implementation and set-up)
 - Split between project manager and someone with clinical background (protected time!)

The budget

Clinical Study Management



^b
UNIVERSITÄT
BERN

- The clash of two cultures
 - Project management: planning and coordination
 - Clinical: doing

Clinical Study Management (selected tasks)

- Contracts and budget discussions
- Coordinating all involved (sponsor, PI, investigators, study coordinators/nurses, statistician, data manager, monitors, central laboratory, committees, etc.)
- Risk assessment (ICH GCP R2!)
- Planning Investigational Medicinal Product/biological sample logistics
- Discussing monitoring plan and site management
- Checking/writing Standard Operating Procedures and Work Instructions
- Submissions
 - Hunting for signatures, CVs etc.
- Trial registration, reminder: take it seriously

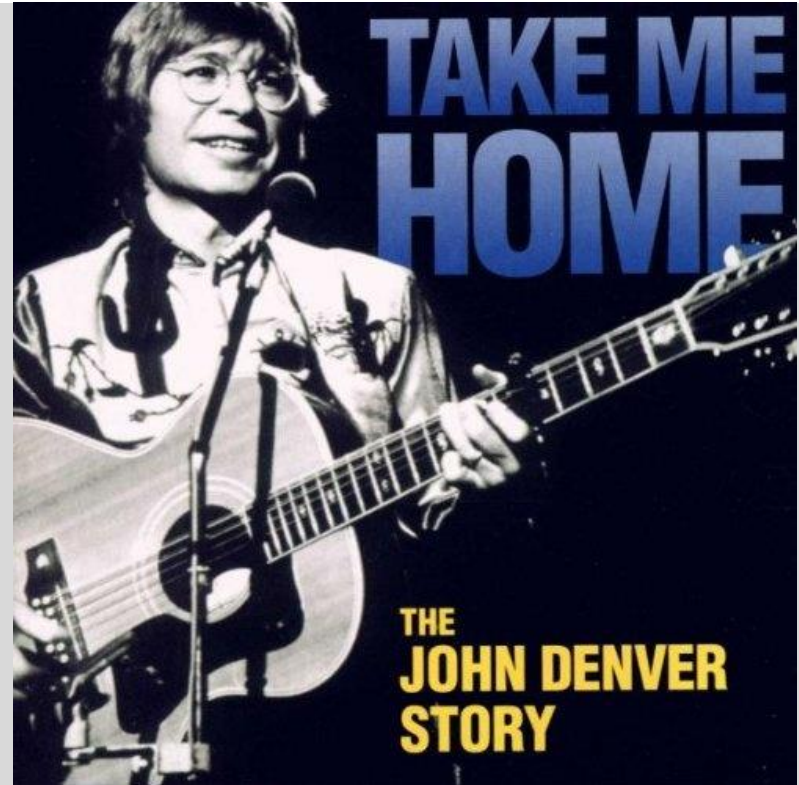
The budget

Clinical Study Management (selected tasks)

- Data Management and Quality Plan
- Managing boards and committees
 - Steering Committee
 - Adjudication Committee
 - Data Monitoring Committee
 - ...
- Regular reporting
 - Safety events!
 - Yearly reporting (EC, Swissmedic, funder, ...)
 - Communication among all investigators, newsletters,
 - ...
- Administration of site payments and overall budget!
- Risk management!
- Review of monitoring reports and defining actions
- Vendor qualification and oversight e.g. CTU Bern!

The take home messages

- You will never overestimate the resources and time needed – no worries!
- Start early and discuss with others
- Communication takes time
→ costs money
- Statistical analysis must be reproducible → programming with quality control
- Every CHF invested in Clinical Study Management is worth the money
- Do not underestimate the costs ...



Finding the right balance

is key ...

Having a too high budget might mean that a project is never started

having a too low budget might mean that a project is never finished ...

u^b

b
**UNIVERSITÄT
BERN**



Reminder

SNSF

u^b

b
UNIVERSITÄT
BERN

- Investigator-Initiated Clinical Trials (IICT) Call
 - May 26th: Letter of intent (topic, not peer reviewed)
 - Nov 2nd: Full proposal
 - Please contact CTU as early as possible if you want to involve us

- Project funding
 - 1st Oct and April: clinical projects can be funded
 - Please contact CTU as early as possible if you want to involve us



FNSNF

SCHWEIZERISCHER NATIONALFONDS
ZUR FÖRDERUNG DER WISSENSCHAFTLICHEN FORSCHUNG

Thank you
for your attention!

u^b

b
UNIVERSITÄT
BERN

