

Factors contributing to studies failing

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Developing a clinical study

- Inventive question
 - Sound methods
 - Feasibility
- > *High quality study protocol:*
- *sufficient for grant application*
 - *sufficient for study success?*

Study protocol

Example: quality of life study in palliative setting 1)

Comprehensive assessment: „best practice“

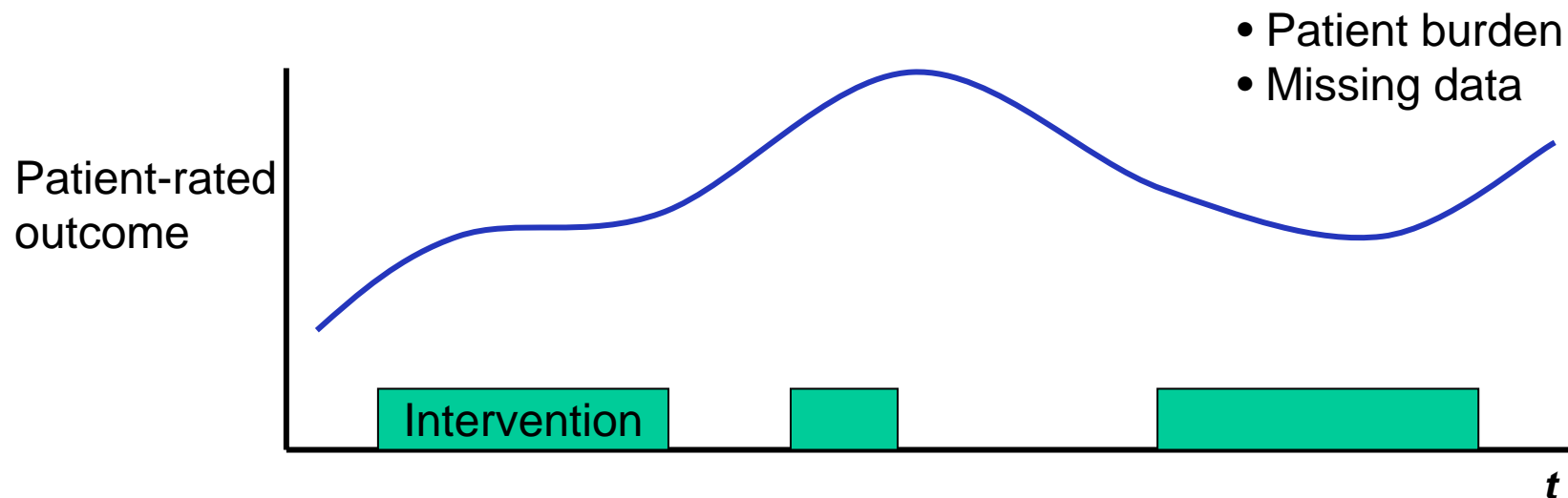
- Core questionnaire
- Symptom checklist
- Spiritual issues
-

- Patient burden
- Missing data

versus

Simple indicators of key domains

Example: quality of life study in palliative setting 2)



- > *Clinical interest: overall experience over time rather than widely spaced single point estimates*
- > *Trade-off: Comprehensiveness versus timing and number of assessments*

Developing a clinical study

- Inventive question
- Sound methods
- Feasibility

Competing
factors:
Trade-off

> *There is no „perfect“ study design*

*„... Mit dem lokalen Statistiker ist ein gutes
Einvernehmen herzustellen.“*

*„... You need to establish an amicable relationship
with the local statistician.“*

Draft of consensus paper on quality of life
research, PSO/SAKK 1992

Investigators and research environment

Study objective: developing a common perspective

Importance of the research question and personal motivation

- Clinical or methodological relevance!
- Personal interest, only (e.g., authorship)?
- To be on board, only?

> *Developing a common perspective in order to work on a common ground*

Creating a supportive environment 1)

Dedicated investigators:

- clarify
 - what they are asked to do
 - what they may expect (e.g., authorship)
 - whether they are willing to take extra steps

> *Decisive at beginning*

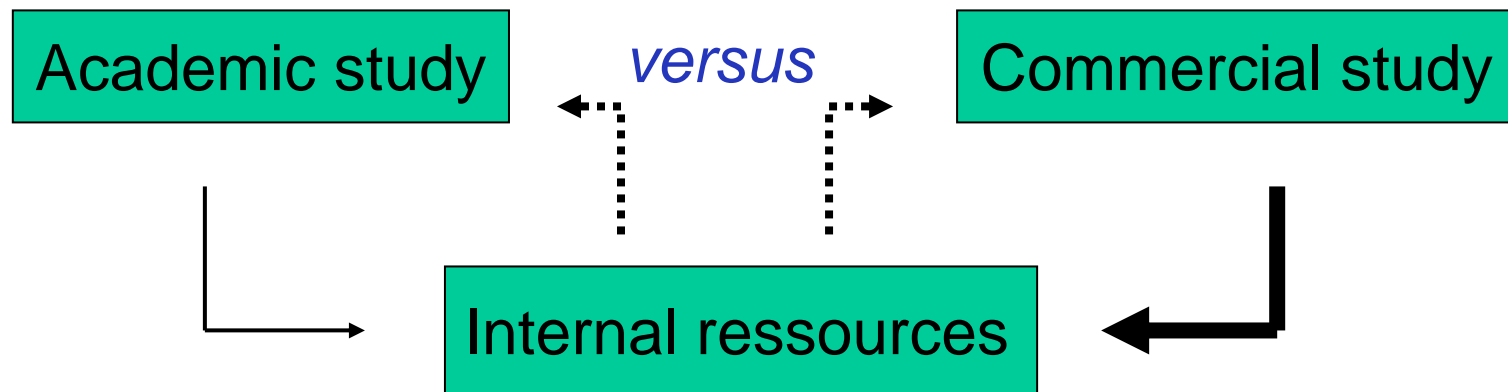
Creating a supportive environment 2)

Dedicated investigators:

- establish
 - an official status, position or „role“ of the study (e.g., place of binder on the shelf)
 - reliable facilities (e.g., reminder for assessment)

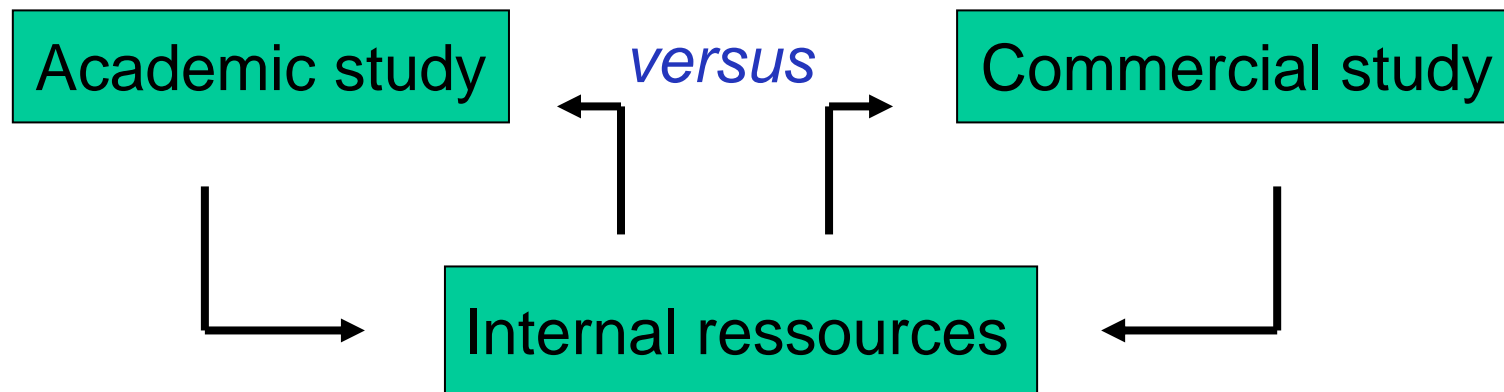
> *Ongoing process!*

Competitive environment 1)



> *Lip service or educational advertising: not sufficient*

Competitive environment 2)



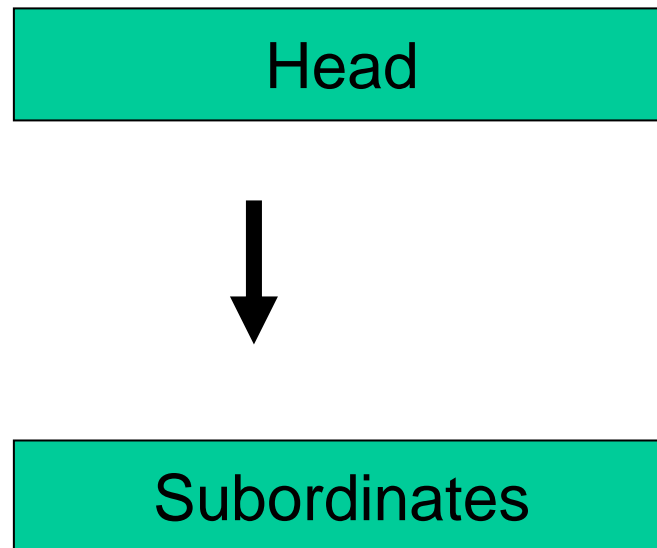
> *Clearly defined allocation of resources:*
imperative

Changing environment: changing priorities

- Local institution, e.g., new head
 - Medical practice, e.g., new treatment
 - Health care system, e.g., new focus
- > *Perseverance and long-term commitment, especially in multi-center and cross-cultural studies*

Management strategy

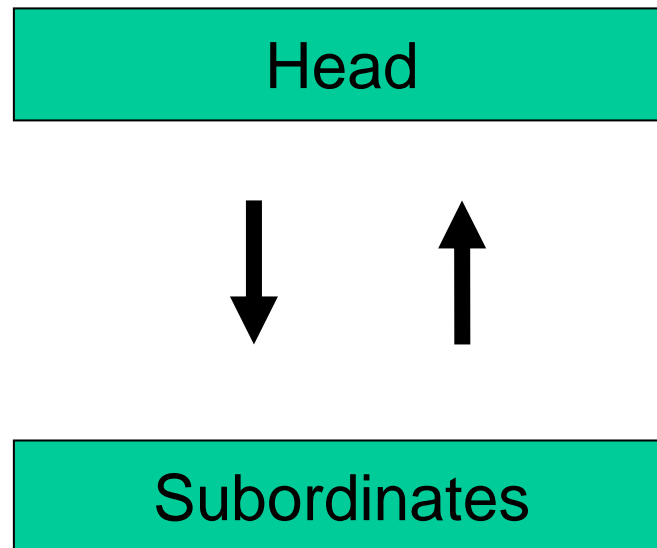
Motivation: From involvement to ... 1)



Management strategy:

- Top – down

Motivation: From involvement to commitment 2)

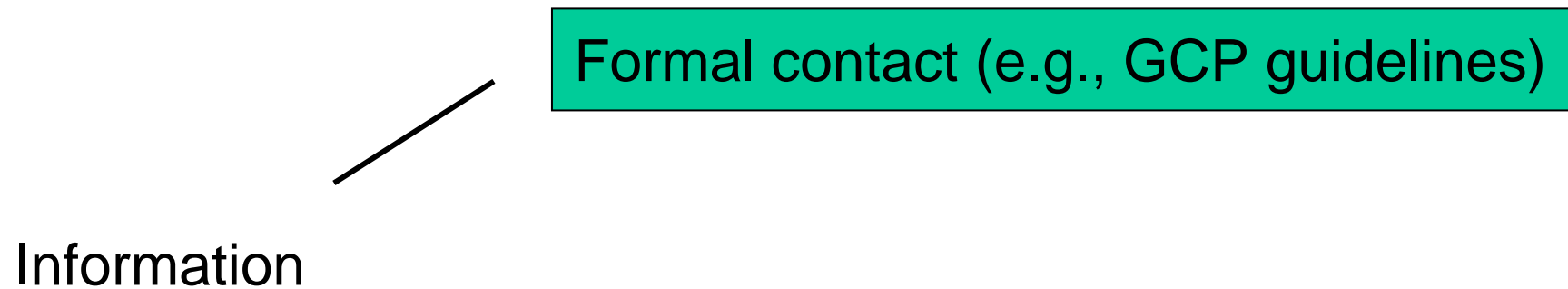


Management strategy:

- Top – down
- Bottom - up

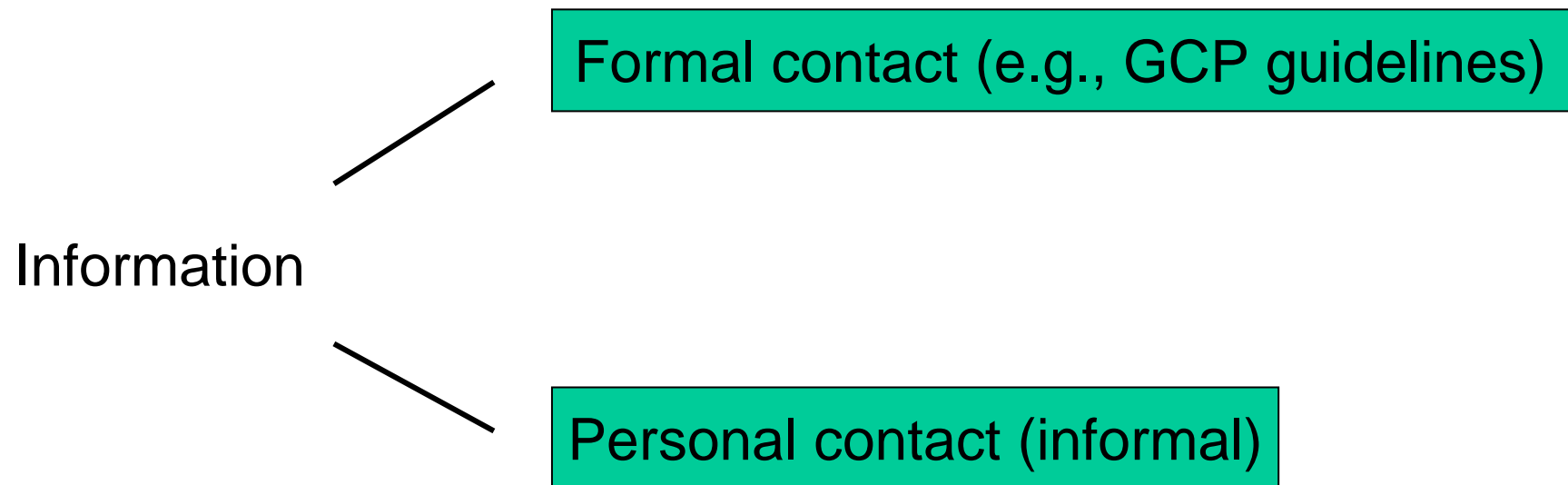
> *Combined approach, e.g., incentives*

Information flow: multiple channels 1)



> *Clearly defined procedures*

Information flow: multiple channels 2)



> *Combined approach*

Personal issues

Non-methodological pitfalls

- Too high personal ambitions
- Taking key persons on board too late
- Tacit assumptions about collaboration (e.g., hidden agenda)

> *Early clarification of **personal objectives***

Missing in CV or laudatio: History of failing

Failure is an **inherent risk** of research

- > *Responsability to also pass on experiences of failure, especially to young investigators*

Conclusions

Factors contributing to failing or succeeding

Failing

Succeeding

Protocol

Investigators

Environment

Management

Personal issues

- > *Factors on **all levels** can be decisive for failing or succeeding*