



ZonMw

ZonMw: where research, policy and practice meet

- Intermediary organisation that funds research, development and implementation
- Financed by Ministry of Health and NWO ('Ministry of Science')
- promote use of results from projects and programmes

ZonMw

- Since 2001
- Fusion of
ZorgOnderzoek Nederland (ZON)
+
NWO Medical Sciences (NWO-MW)
- ZonMw, not

Zon MW

ZONMW

ZON/MW

ZON and MW

- ZON
 - started 1996
 - founded by Ministry of Health
 - research and development for health and care
 - focus on practise, evidence based through research
 - strong focus on implementation
- MW
 - part of NWO (national research council)
 - Ministry of Science (O,CenW)
 - focus on biomedical science

Translational Gene Therapy Research



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Background information

- Programme is completely funded by Ministry of Health (VWS).
- Subjected to 'Wet op ZON'.
- ZonMw procedures
- ZonMw grant conditions

Aims of the programme

- Stimulate **clinical** gene therapy research
 - A Preclinical Translational Research
 - B Clinical research in phase 1,2 trials
 - A only in combination with B.

General Project Outline

- | | | |
|-------------------------|-------------|--------------|
| A: Preclinical Phase | Max. 375 k€ | Max. 3 years |
| A: Pharmaceutical Phase | Max. 425 k€ | 1 year |
| B: Clinical Phase | Max. 550 k€ | 2 years |

Procedure Calls

- 1. Pre-proposal
- 2. Evaluation pre-proposal
- 3. Proposal (on invitation)
- 4. Evaluation by referees and response by applicant
- 5. Judgement on quality
- 6. Judgement on relevance
- 7. Granted/rejected

ZonMw procedures



- General procedures
 - To submit a proposal
 - Evaluation of proposal
 - Evaluation of progress
- Programme-specific procedures
 - Programme description
 - Programme information on subsidiewijzer

Downloadable: www.zonmw.nl/subsidiewijzer

Pre-proposal (vooraanmelding)

- Selection of most suitable projects
 - **Contribution to programme goals**
(Is a clinical study within project time frame likely?)
 - Rough quality check

Proposal (uitgewerkte aanvraag)

- Quality judgement by external referees (this programme: foreign)
- Rebuttal by applicants
- Committee weighs referee reports and rebuttals for thorough quality check
- Committee again judges contribution to programme goals

ZonMw Procedures

Evaluation and selection

Relevance

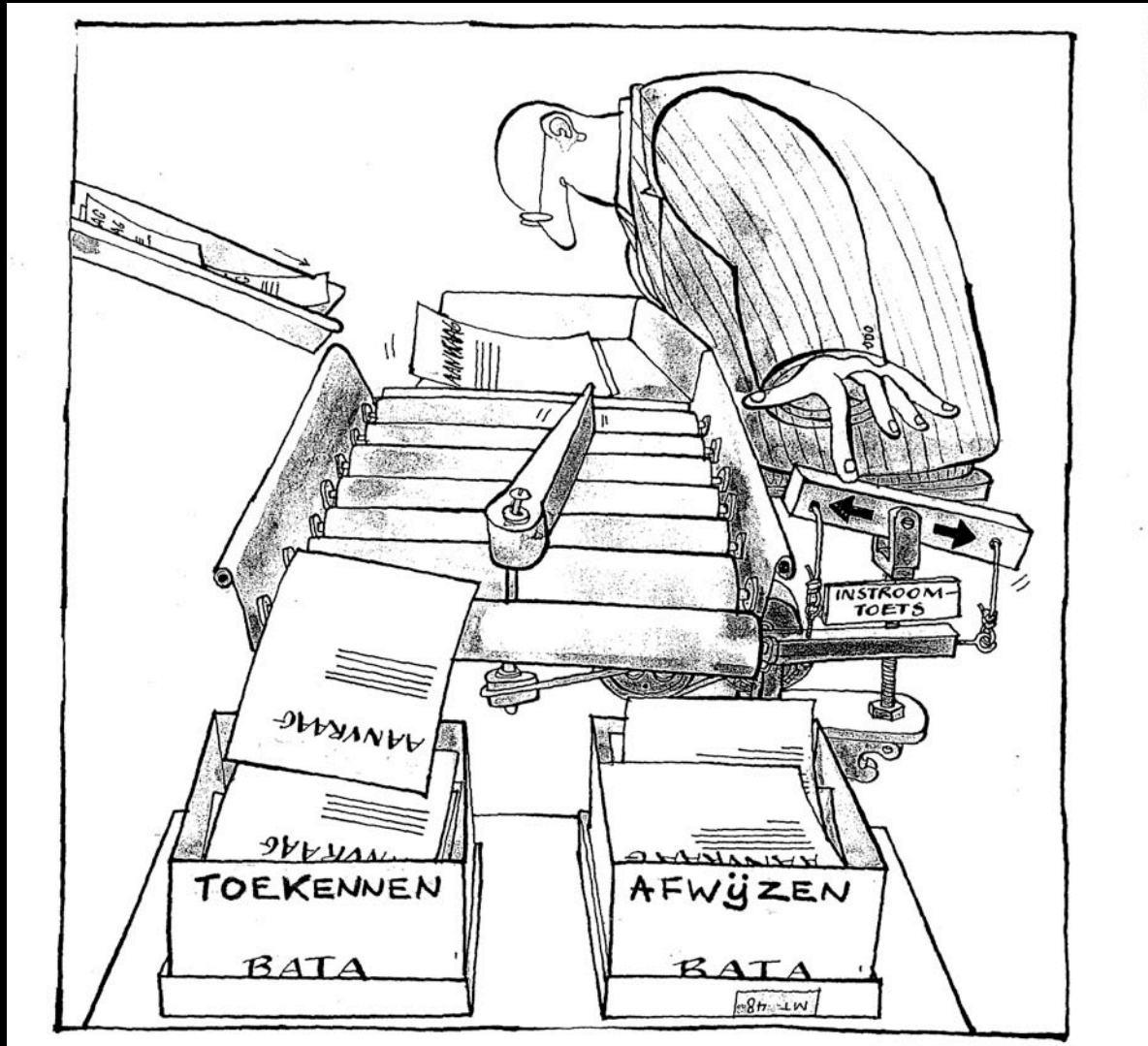
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Quality



ZonMw

Granted or not



Granted or not



Conditionally Granted Call 1

Kastelein B project	Gene therapy for LPL deficiency
Schumacher A+B project	T cell receptor gene therapy of metastatic melanoma: a phase I clinical trial
Wagemaker A+B project	Gene Therapy of Primary Immunodeficiencies
Hagenbeek B project	Suicide gene therapy of hematological malignancies with herpes simplex virus thymidine kinase gene transduced allogeneic donor T-lymphocytes in the context of allogeneic stem cell transplantation

What did we learn from the first call?

- A lot of pre-proposals (31).
- Preferentially more information on existing preclinical data
- Implementation paragraph usually marginal
- (Remember that ZonMw focuses on implementation!)

Next activities

- Immediately: determine subject for workshop
 - Please inform us (questionnaire or email)
- March 2005: Call 2 pre-proposals (expected)
- End 2005: Evaluation of programme for VWS
- March 2006: Call 3 (expected)
- March 2007: Call 4 (expected)

Evaluation of progress

- Yearly progress reports
- Evaluation before start pharmaceutical phase
- Evaluation before start clinical phase
- Linked to financial support of next phase
- Final report

Call 2 - 2005

- Aim: deadline pre-proposals March 1, 2005
- Not yet confirmed by VWS
- Call: websites ZonMw, NVGT, Mediator, e-mail to NVGT members.
- If March 1 2005 is OK, information appears Dec 1 2004 latest.