Dutch Clinical Research Foundation

Willem Jan Bos

Yet another umbrella organization

ccmo
ZonMw
NVMETC
acron
NFU
DCRF Dutch Clinical Research Foundation
stz
NVFG
Research Professionals
Rijksoverheid
ECABO
Vereniging Innovatieve Geneesmiddelen

DCRF Dutch Clinical Research Foundation

2007 - Sense of Urgency

Number of patient driven clinical trials is decreasing →

WHY?

Dutch Clinical Trial Foundation was founded in 2007 to promote clinical trials in The Netherlands

Contributors: pharma, STZ, NFU, patient groups

DCRF Dutch Clinical Research Foundation

2016: DCTF becomes DCRF

Trial Tiger to Research Spider

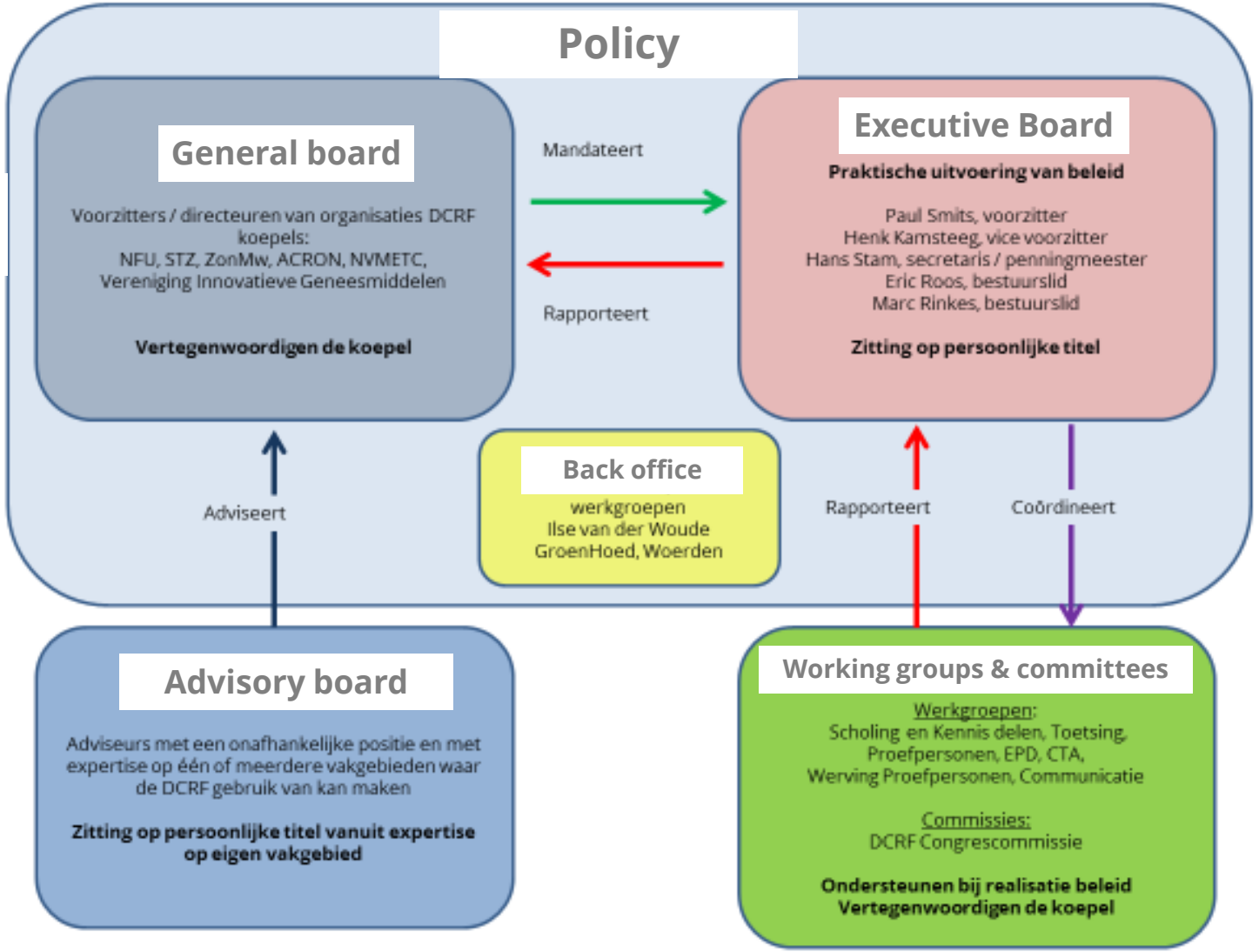
DUTCH CLINICAL TRIAL FOUNDATION

Oct 2016

DCRF
Dutch Clinical Research Foundation

DCRF
Dutch Clinical Research Foundation

Organisation DCRF



2012: Challenge: inefficient research logistics

Problem: process

- **Design**
- **(Ethical) approval**
- **Patient recruitment**
- **Variation in education, training & skills**
- **Communication between parties involved**

→ Lethargic decision making process (up to 18 months)

→ Sponsors not amused

Solution: MasterPlan & working groups

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Masterplan

- **Working Groups**
  - Research Logistics
  - Patient Recruitment
  - Education
- **Main Accomplishments**
  - Clinical Trial Agreement
  - In progress: local procedures
  - Standard insurance
  - Template patient information form
  - Description of roles, skills and training
  - E-BROK

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We are not ready yet!

Medisch-ethische toetsing van multicentrisch onderzoek kan sneller

Nieuwe richtlijn biedt ruimte voor verbetering
Onderzoek
16-10-2013
Katrien Oude Rengerink, Maya Kruijt en Ben Willem Mol

Lokale toestemmingsprocedures zetten een rem op RCT's

Eric P. van der Stok, Joost Huiskens, Baukje Hemmes, Dirk J. Grünhagen, Thomas M. van Gulik, Cornelis Verhoef en Cornelis J.A. Punt

GERELATEERD ARTIKEL Ned Tijdschr Geneeskd. 2016;160:D821

ONDERZOEK

COMMENTAAR

Toestemmingsprocedures kunnen eenvoudiger

Ernst J. Kuipers

GERELATEERD ARTIKEL Ned Tijdschr Geneeskd. 2016;160:D148

OPINIE

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Need for research in clinical practice

Health Council, oct 2016

FMS, oct 2016

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Current Working Groups

- Research Logistics - focus on local procedures
- Patient Recruitment
- Education of research professionals
- Eletronic Patient Records
- Annual Conference

- European Clinical Trial Regulation 536/2014
- N-WMO

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European Clinical Trial Regulation 536/201

expected to be effective in 2018

- Approval procedure in 1 european country
- Strict timing
- Paralel proces - (inter)national and local approval
- DCRF selected to implement regulation in NL
- Chances and risks for NL

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N-WMO

research not regulated by law on medical research on humans

- **Observational studies**
- **DCTF committee to judge**
  - Pharma sponsored nWMO research
  - Future: studies on medical devices?

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Infrastructure

- Collaboration with CCMO

  - Register all research in humans
    - Clinical Trials
    - n-WMO

  - Availability of clinical trial data

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Further collaboration

BBMRI.nl
Biobanking and BioMolecular resources Research Infrastructure The Netherlands

Federa
Voor een gezond onderzoeksklimaat

Biobanking
Databases
Research Infrastructure

N-WMO

Safe for patients
Valid Outcomes
Meaningful

Feasible for investigators

Optimize Infrastructure
Prevend Duplications
Joint Agenda

DCRF
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Clinical Trials
Clinical Research
Research Infrastructure

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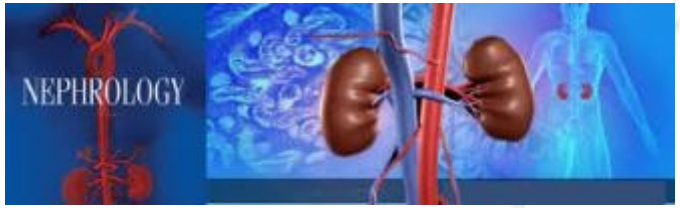
2017 – at crossroads again?

- **Excellent starting position – highest impact per capita**
  - Integrated University Medical Centers
  - PhD program
  - Health Charities



- **Challenges**
  - Implementation European Clinical Trial Directive
  - Research Infrastructure – nWMO

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