“When the going gets tough, the Dutch get going”

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• Past
• Different expectations
• An example
• Present
• The Bright Future
• Startup funding
• Hiring project-managers, financial controllers, methodologists
• Hiring QA/QC; implement quality system
• Impressive organisation (> 6FTE)
• But not enough studies
Past

- Top down organisation
- Focus on operational capacity
- Added value for investigators unclear
- Added value for sponsors unclear
Example

• Drug X: anti-arrhythmic
• Adult program well advanced
• Pediatric Plan approved
• Study protocol for first peds study:
  – 3 escalating doses, all ages
  – Objective: PK & tolerability
• Feasibility within MCRN Network:
  – No need for such a drug
  – Trial will never be approved
  – Recruitment will be impossible
  – Thus reluctant to participate
• Dutch Central Ethics Committee (CCMO):
  – Non-therapeutic: No way!
• Free Consultancy:
  – Change design into:
    • Bayesian type adjusted study
    • targeting desired exposure
    • or better targeting desired interval on ECG.
• Result: study started as planned in US
Mismatch in expectations

• Added value for Sponsors?
  – Feasibility analysis very realistic
  – Quick access to investigators
  – Many (for the NL situation) non-feasible studies in PIP’s
  – Science was done in PIP, now get the studies done: operational mode
  – MCRN in scientific mode
  – At the start-up: Industrial Founding Fathers of the MCRN: all local offices.
    • PIP’s are not written here
Mismatch in expectations

• Added value for Investigators/Academia?:
  – Did not feel represented/involved: lack of interest
  – Drugs in development did not solve their problems: lack of interest.
  – Started rediscussing issues that were decided in PIP already: tried to get involved
Current situation in NL:

Dutch trial register:
22 trials: 3 industry sponsored

EU trials register: 128 trials

ClinicalTrials.gov:
Industry sponsored: 95
Other funding: 88
Total: 183 studies
Now (MCRN 2.0):

• Network of experts and investigators
• Supported by 0.5 FTE coordinator
• Bottom-up approach: Network by and for investigators
  – Focus on exchange of information and knowledge
  – Less focus on operational capacity
• Industry/CRO’s can access network
  – To get connected
  – For Consultancy type questions
• Ongoing projects (ZonMW funded):
  – Farmacool, Hydrocortisone

• Workpackage leader in 2 FP7 projects
  – Enalapril (CHD), Gabapentin (Pain)

• 2 ZonMW projects in second round
  – Dosefinding of Haldol for Delirium on ICU
  – Studying PK in scavanged samples

• Ongoing discussions on investigator initiatives

• Industrial support currently primarily feasibility questions

• New forms of collaboration explored
  – More focussed on consulting, and bringing people together
  – Get the network involved earlier!
Questions?

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