



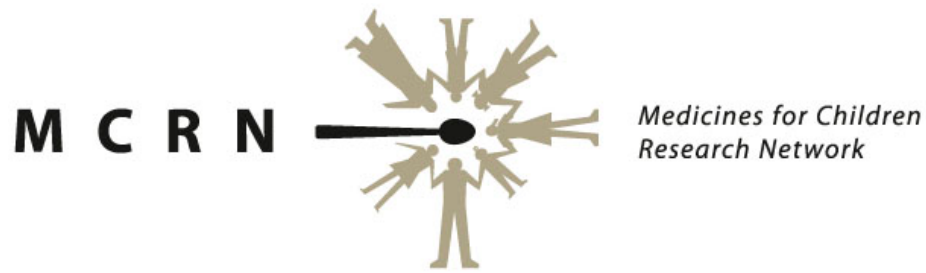
“When the going gets tough, the
Dutch get going”

Edwin Spaans, PharmD

Clinical Pharmacologist, ErasmusMC Sophia Children's Hospital

Director Clinical Research, Kinesis-Pharma

Development Officer, Dutch MCRN



- Past
- Different expectations
- An example
- Present
- The Bright Future

Past

- 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

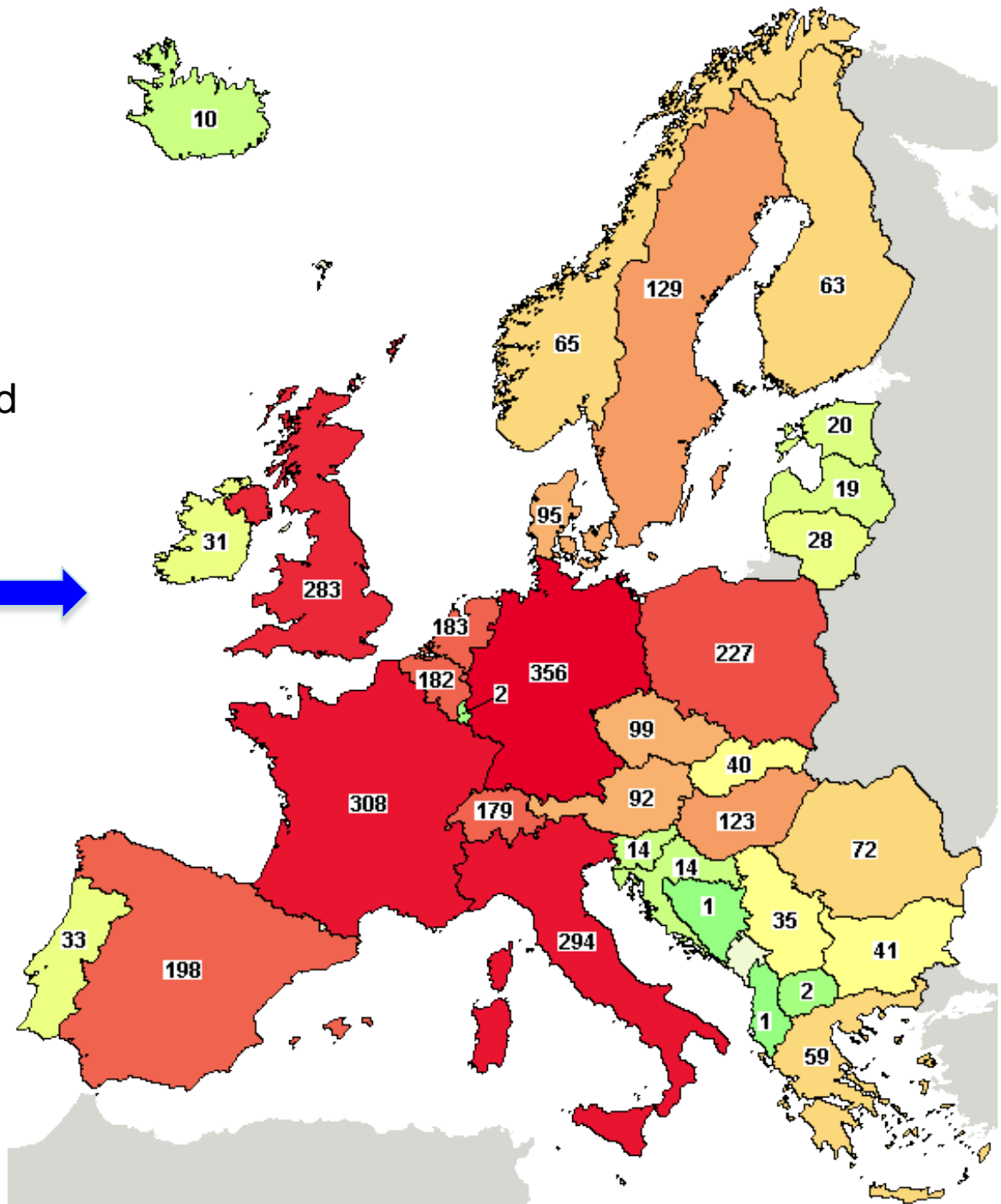
Current situation in NL:

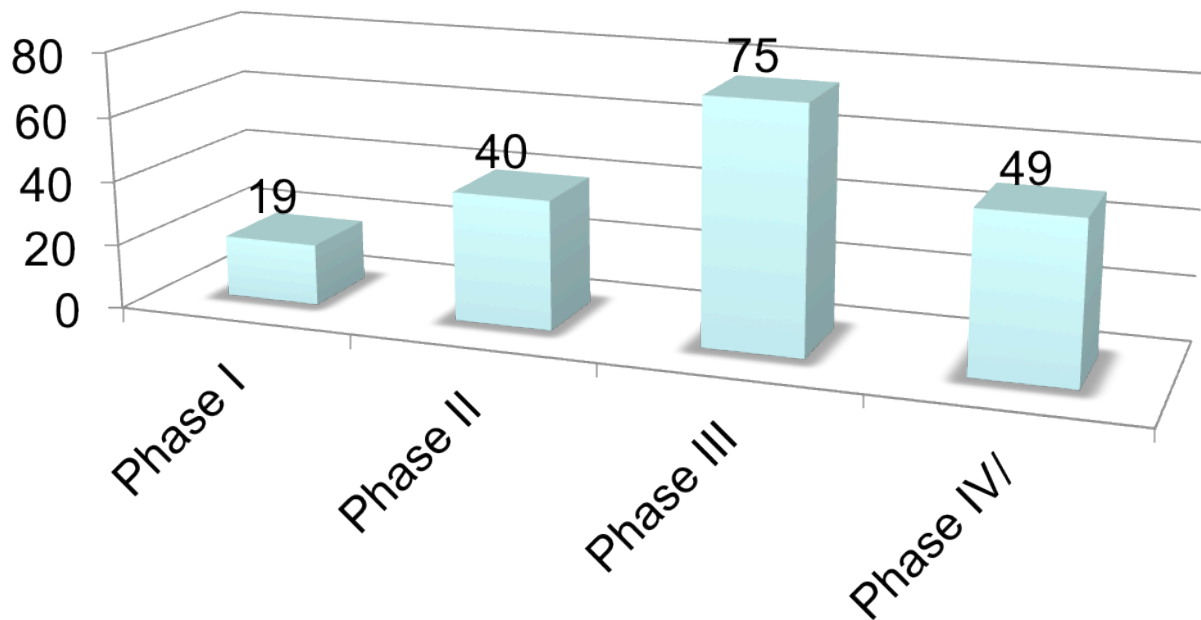
Dutch trial register:

22 trials: 3 industry sponsored

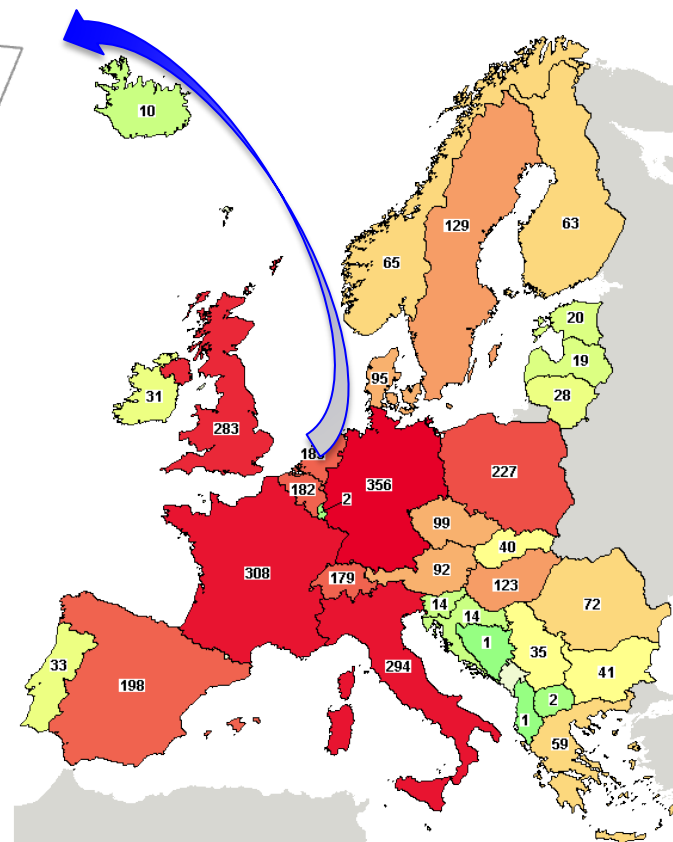
EU trials register: 128 trials

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

It works.....

- 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?

- e.spaans@erasmusmc.nl
- edwin.spaans@kinesis-pharma.com