

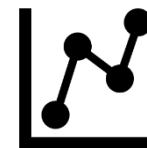
# Clinical trials

## External funding

Kurs i Forskerinitierte kliniske studier 24.11.20

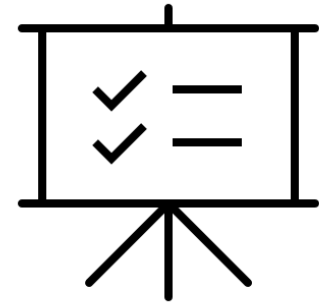
Asbjørn Rune Ousland

Administrative Research Support  
Section for external funding  
& Reporting



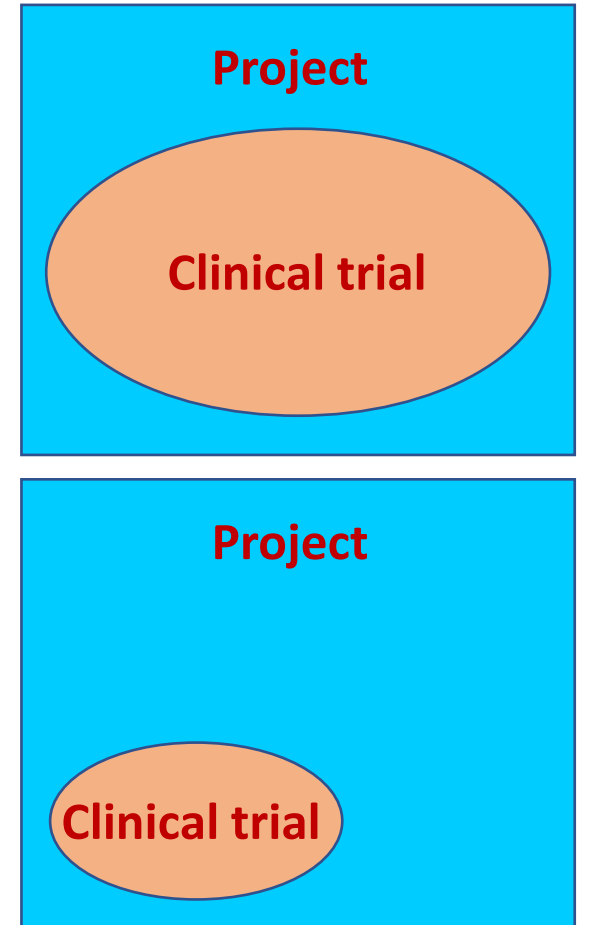
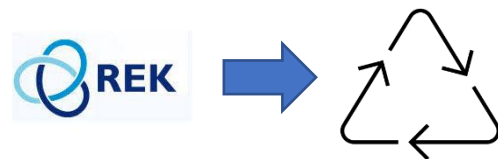
# Agenda

- Funding opportunities – funding bodies – calls
- Budgeting – how much to I need – where can I get what I need?
- Writing a proposal that gets funded
- Reporting progress and costs



# Clinical trial vs research project

- Often great overlap – the project puts the Clinical trial in a context
- Most of what you say in REK application may be reused
- Keep it consistent
- The project proposal style is more of a “sales offer”
- Clinical trial size vs total project varies with the calls



# National funding bodies

- South-East Norway Regional Health Authority - HSØ
- Research Council Norway - RCN
- The Norwegian regional health authorities - KLINBEFORSK
- The Norwegian Cancer Society - NCS
- Stiftelsen Dam (earlier Extrastiftelsen)



# South-East Norway Regional Health Authority - HSØ

## Categories of research funding

- PhD fellowships NOK 1,1 mill year
- Postdoctoral fellowships NOK 1,1 mill year
- Career fellowships 4 years up to NOK 9 mill total
- Open project support 3 years up to NOK 3 mill year

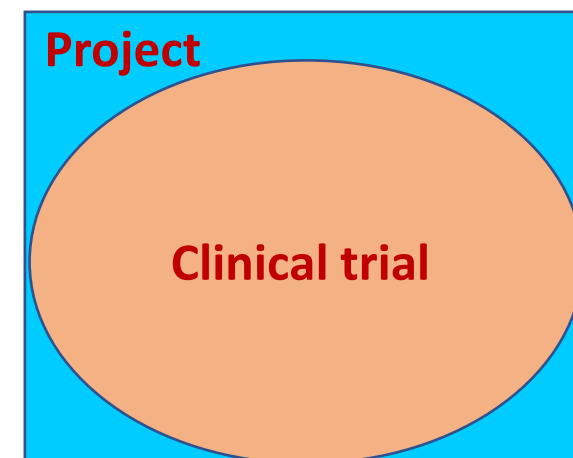
## Other

- Regional research networks
- Innovation

## A good match for clinical trials

- You may hire a PhD or Postdoc to do much of the work
- You may boost your own carrier
- Or build a group

The clinical trial can be almost the whole project



## FRIPRO - Forskerprosjekt for fornyelse - Forskerprosjekt for unge talenter - ++

- ground-breaking research at the international forefront

### BEDREHELSE

- public health, prevent illness, origins of illness

### BEHANDLING

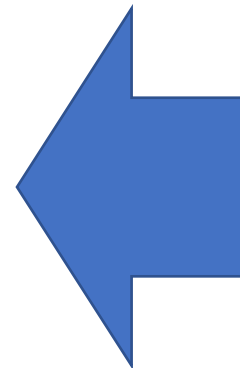
- **diagnostics, treatment and rehabilitation**

### HELSEVEL

- health, care and welfare services

- COVID-19 ???

4 to 12 mill NOK total 3 to 6 years



Full info is not available. You must check the RCN call web pages

Call texts may be detailed and hard to understand. Please ask Research Support for help!

# KLINBEFORSK - Clinical Therapy Research in the Specialist Health Services

## Funding of *clinical multicentre studies*

- With the aim of *improving existing treatment procedures and/or*
- *Developing or evaluating new regimens*

## Opportunity:

- Clinical trials that *give patients* an opportunity to receive *new, experimental therapies*
- Provide the health service with new knowledge and information
- Support development of preventive measures, diagnostics, treatment and rehabilitation.

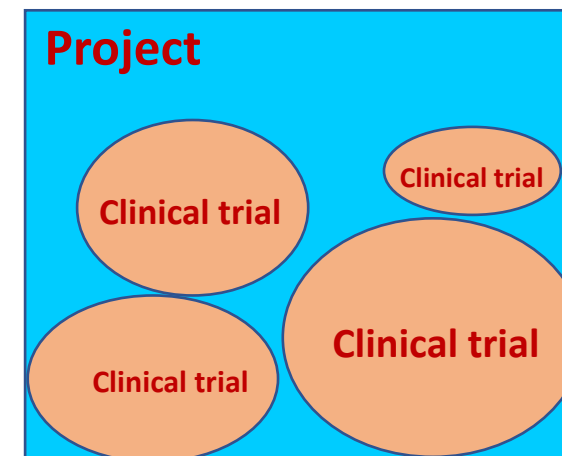
## Need:

In Norway, a limited number of clinical trials is offered to patients, and the size of such studies is often small.

Projects duration: Up to five years.

Budget range: 5-20 million NOKs for the entire period.

*Must have participants from all health regions*



# The Norwegian Cancer Society (NCS)



## Previous Calls:

- Krafttak mot kreft 2020: Hjernekreft/spiserørskreft (utløpt)
- Nordic Cancer Union 2020: Covid-19 and cancer (utløpt)
- Open Call 2020 (utløpt)
- Stiftelsen Dam 2020 (utløpt)
- Rosa sløyfe 2020: Persontilpasset brystkreftbehandling (utløpt)
- Krafttak mot kreft 2019: Lungekreft/bukspyttkjertelkreft (utløpt)
- Kreftforebygging 2019 (utløpt)
- Nordic Cancer Union 2019 (utløpt)

Up to 5 years, 15 to 30mill NOK total for the main projects



# International funding

## Nordic



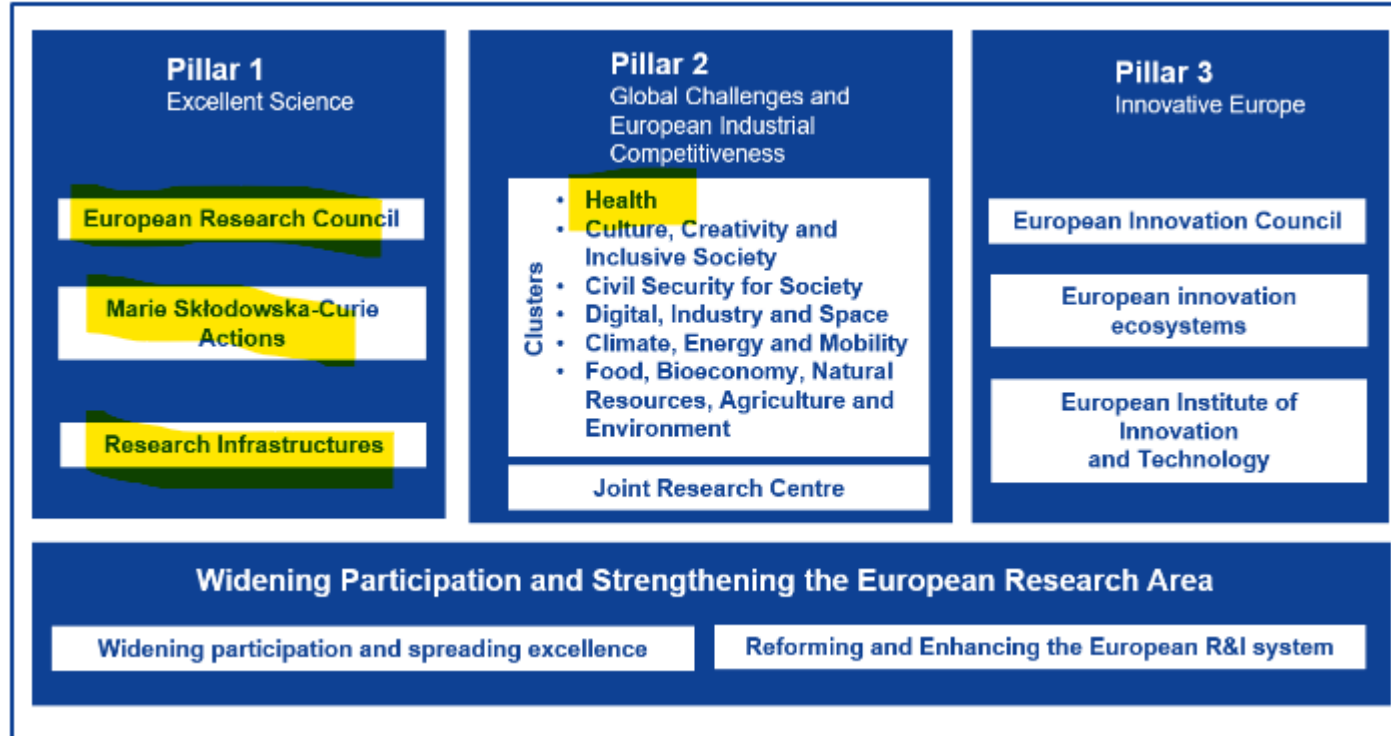
## European



## American



# Horizon Europe



Missions

=

moon landings for specific challenges



**Mission area: Cancer**

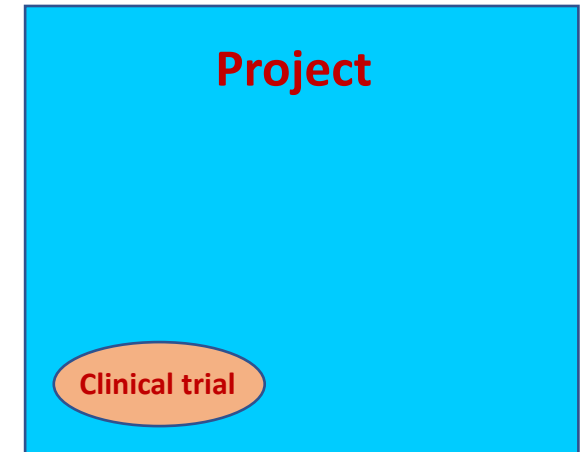


# Horizon Europe Work programme Health Call example



## HORIZON-HLTH-DISEASE-2022-06-two-stage-04: Development of new effective therapies for rare diseases

- Despite the considerable amount of knowledge that has been accumulated and the new orphan medicines developed in recent years, **the number of available therapies for rare diseases remains low**, as fewer than 6% of rare diseases have an approved treatment option
- The topic will support proposals aiming **to develop therapies for rare diseases with an unmet medical need and no approved therapeutic option.**
- The therapies to be developed may include a broad family of therapeutic interventions such as, small molecule(s), advanced therapy medicinal products, repurposing existing therapies, including non-pharmacological interventions and/or their combinations, as relevant
- The topic will support proposals **covering several different stages in the continuum of the innovation path (i.e. translational, preclinical, clinical research, validation in the clinical and/or real-world setting etc.), as relevant.**

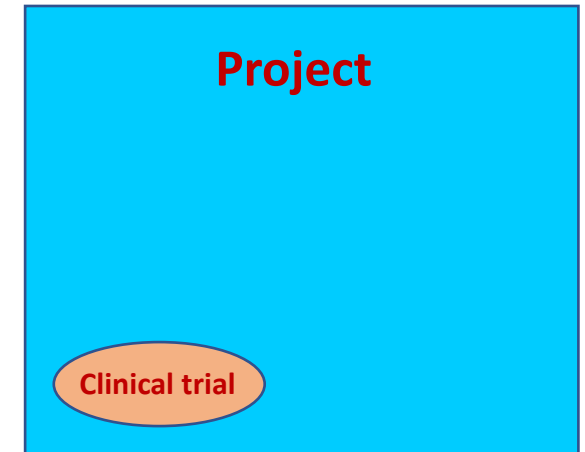


# Horizon Europe Work programme Health Call example, cont.




The proposals should address most of the following research activities:

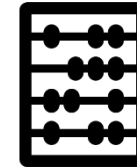
1. Establish **multidisciplinary collaborations** between all relevant stakeholders by integrating disciplines, technological developments and existing knowledge. Integrate harmonised data from multiple sources (i.e. natural history studies/**clinical trials**, multi-omics, medical imaging, registries etc.) by utilising...
2. Develop and/or execute **innovative clinical trials designs for small populations and novel approaches** to assess and monitor the safety and efficacy of the proposed interventions
3. **Carry-out proof-of-concept (PoC) preclinical studies** and/or multinational interventional clinical studies to demonstrate the safety and efficacy of the therapeutic interventions under study. **Preclinical PoC should implement late-stage preclinical studies (i.e. toxicological properties, adverse effects etc.). Clinical studies may cover all necessary development stages.** Applicants should propose a clear pathway through the different necessary steps (research, manufacturing, regulatory approvals and licensing, IP management etc.) **in order to accelerate marketing authorisation and uptake by the health systems.**



Size of clinical trial: EUR 200-400 000  
Size of project: EUR 3-20 mill

# Setting up the budget

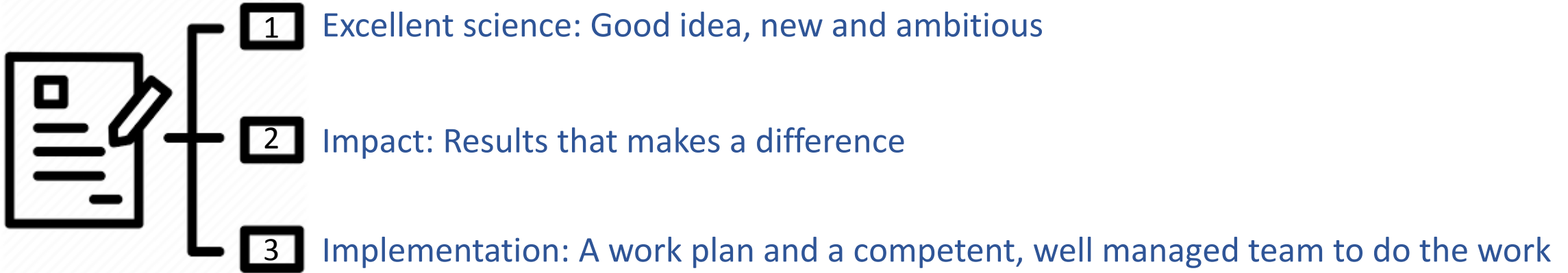
- **Use the template we have made** 
  - Social cost
  - Yearly salary increases
  - Overheads
  - Lumpsums
  - Tables to fill directly into NFR tables
- **100% funded or do I need own money/in kind?**
  - If in kind; who contributes by how much?
- **Make a total budget for the project**
  - Personnel, consumables, equipment and services (monitoring), travels
  - Publications, open access,
  - Audit costs
- **Agree on the costs and in kind for all partners before applying**
- **The budget must be approved by leader/administration**



Salary vs personnel costs:  
Yearly salary NOK 600 000  
+ 37% social cost  
= Yearly cost NOK 822 000

If PhD yearly cost is NOK 822 000  
and Lump sum NOK 1 125 000, you  
have NOK 303 000 to other costs

# The generic proposal story



Convincing idea,  
a strong need for a solution  
the resource to do the job  
– in this order



# X factors - showing

- Passion
- Will and power
- Confidence in the idea
- Honesty
- Emotion
- I really want it to happen



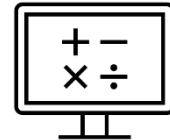


# Reporting progress and costs – Best practice

- A realistic budget suitable for running the project
  - In kind and overhead
- All in place to the start date
  - Staff hired
  - Facilities and all partners ready
- Realistic patient recruitment plan
  - Risk mitigation
- Planned for all costs
  - Monitoring/statistics
  - Drugs and equipment costs
  - Publications/open access
  - +++

- **Monitoring work progress**
- **Resources used**
- **Schedule**

**Research Support and local accounting will help you with calculating and reporting the cost to the funding bodies**



# Research Support

## Our services from application to project implementation

### Pre Grant

- Programme information and calls
- Administrative information/formalities
- Read and commenting on proposals
- Budgeting
- Positioning and Project Establishment Support (POS-PES)

### Contract preparation

- Negotiations
- Contracts
- Collaboration Agreements

### Post Grant

- Contract changes/amendments
- Reports and audits
- Closing of the project



Thank you

Contact us at:

[grants@ous-hf.no](mailto:grants@ous-hf.no)

Yes, we will offer training courses in 2021 check  
<https://forskerstotte.no/aktuelle-kurs>