



# SUCCESS FACTORS FOR NORDIC CLINICAL TRIALS

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- PregMet2 as an illustration
- Where are the “tripwires”
- Identifying problems
- Some humble suggestions

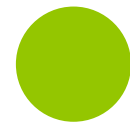


# ILLUSTRATION – THE PREGMET2 STUDY

- RCT
- In Norway, Sweden and Iceland
- Study period 3 years
- Include 1000 pregnant women
  - 5 visits
  - 1 interview
  - 3000 ultrasound examinations
  - 100 000 frozen test tubes
  - + histological material
- Budget estimated: 20 mill NOK
- Aim: To investigate whether metformin can reduce preterm delivery in a high-risk population

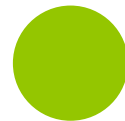
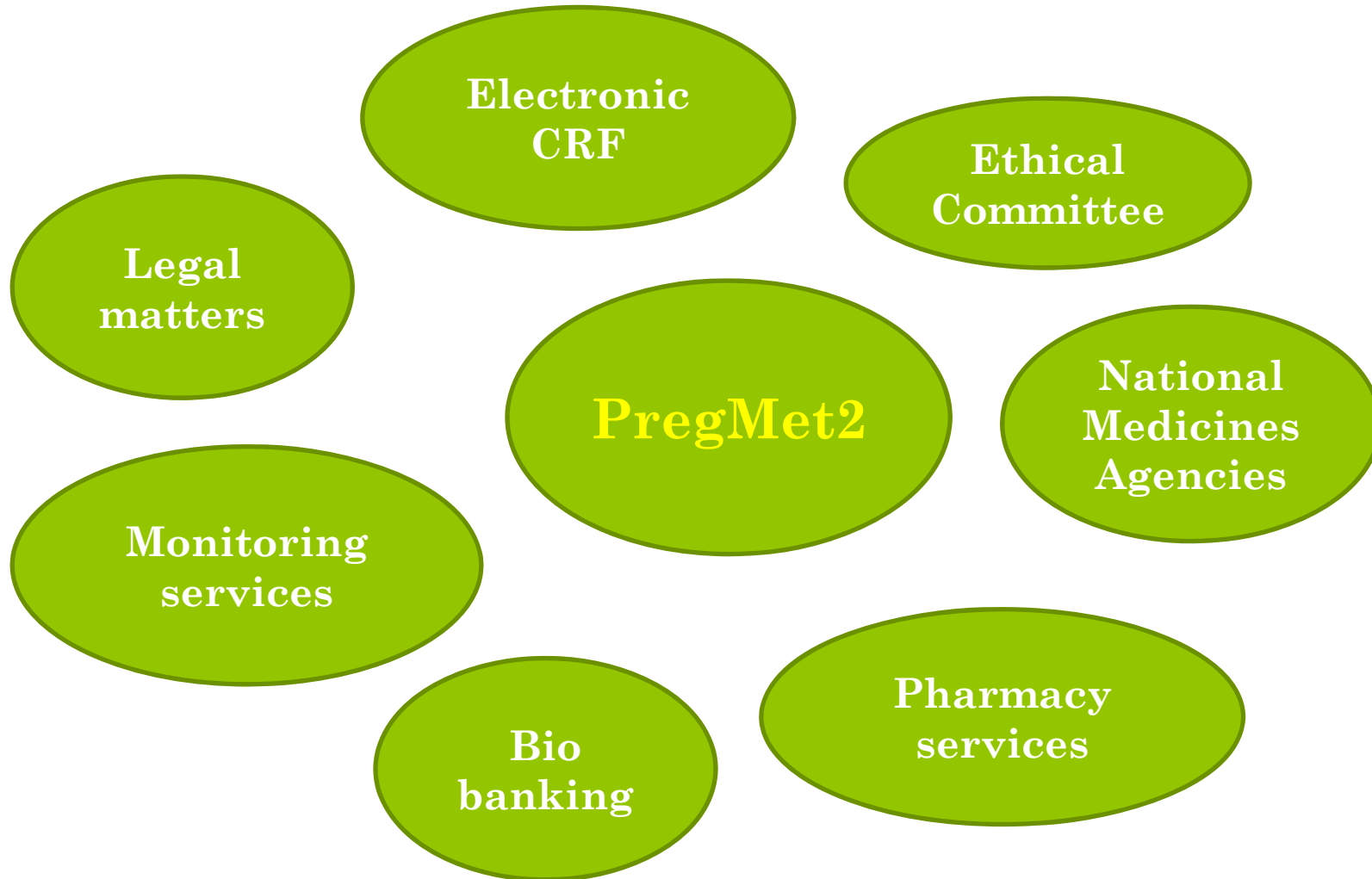


Prof. Angelica Linden-Hirschberg (S)  
Prof. Marie Bixo(S)  
Prof. Inger Sundström Poromaa (S)  
Dr. Izabella Jawad (S)  
Dr. Berglind Steffensen (IS)  
Dr .Tone S.Løvvik (N)  
Dr. Francisco Real (N)  
Dr. Sissel Hjelle (N)  
Dr. Birgitte Mork(N)  
Dr. Ranata Zabielska(N)  
Dr. Kristine Hestvold (N)





# CO-ORDINATED FUNCTIONS



# ETHICAL COMMITTEE APPROVAL



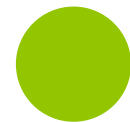
**Nordic multicenter trials must be approved in each country separately**

## **The Problem**

1. Laborious and time consuming to apply in each country
2. In Iceland the English protocol had to be translated to Icelandic
3. Extra work load on our partners
4. Changes, supplements have to be sent in in each country again and again....

## **Suggestions**

1. One joint Nordic Ethical Committee that evaluates and approves Nordic multicenter studies
2. Only one application and only in English





# NATIONAL MEDICINES AGENCIES

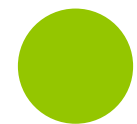
**EUDRACT application form  
is used in all Nordic  
Countries**

## **The Problem**

1. Works quite well
  2. Country-specific form is to be completed in each country
  3. Helpful competent people at the SLV but...
1. Norwegian SLV is overloaded
  2. They do not meet timelines, delay of trial
  3. Extra work for our partners

## **Suggestions**

1. Attempts to reduce expended run time
2. One, simplified EUDRACT form for researcher initiated trials





# PHARMACEUTICAL SERVICES

Norwegian pharmacies can not send study drugs to patients or study centers in other Nordic countries

The study medication has to be sent to a “pharmacy company” (Apoteket Farmaci)

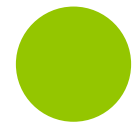
- Fussy
- Very expensive (Marknadsdomstolen verdict)
- Monopolized in Sweden and Iceland

## The Problem

1. To date no Norwegian pharmacy has permanent EU authorization to send study drugs to a pharmacy company in an other Nordic country
2. 6 month delay for the PregMet2 study

## Suggestion

1. It should be possible to send study drugs from an approved pharmacy to investigators in all Nordic countries





# BIO BANKING

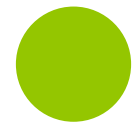
## Different rules in different countries

1. Iceland: Biologic material has to be returned to Iceland within 5 years
2. Sweden: Patient ID key must be kept in Sweden
3. Complicated and expensive to ship biological material between the Nordic countries



## The Problem

1. A challenge to make it work
2. Tough logistics





# GCP MONITORING

## Necessary and mandatory

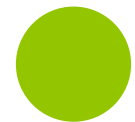
1. Monitors should be involved as soon as planning for a project starts - saves time and effort
2. GCP courses very useful and important
3. National ECRIN-hubs
4. Nordic Trial Alliance

## The Problem

1. Expensive
2. Same rates as for the pharmaceutical industry

### Suggestions

1. Education and training of local monitors
2. Network to serve national and international trials



# E-CRF AND RANDOMIZATION



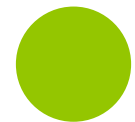
Developed at Unit for  
Applied Clinical Research



This ensures

1. Simplicity
2. Quality
3. Control

s1



## Lysbilde 11

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s1

Real-time overview of the study

sven; 25.01.2013

# LEGAL MATTERS



## Contracts in a RCT

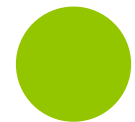
- NRC - sponsor
- Sponsor - partners
- Sponsor - Pharmaceuticals company
- Sponsor - Suppliers

## Insurances

- Different rules in different countries

## Important

- Difficult legal terminology
- The interest of several partners should be taken in to account
- Researcher-initiated studies differs from company-initiated ones
  - Contracts must be adapted
  - Difficult to find good basic contracts



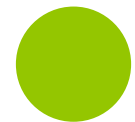
# BUDGET

- Budget for an international trial is not for amateurs
- Guidelines / help. “Budget for dummies”



# RECRUITMENT OF PARTNERS / INVESTIGATORS

- Professional networks
- Personal networks
- Pay-back time



## Lysbilde 14

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s3

Kommentere det faktum at de involverte ansvarlige leger ved hvert senter faktisk gjør studiearbeid på sin fritid ved at annet arbeid som hoper seg opp uansett må gjøres....

svn; 25.01.2013



# THE PREGMET2 TEAM IN TRONDHEIM

14 month after we received grants

1. 13 inclusions
2. We are 4 month behind schedule
3. 1 center is including
4. 8 centers are about to include the 1. participant



Louise  
Reinertsen

Tone Shetelig  
Løvvik

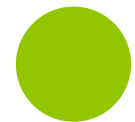
Hilde  
Oksfjellelv

Eszter  
Vanky

Sven M.  
Carlsen

Terese  
Skjemstad

Ann Jorunn  
Sandstå



# SUCCESS FACTORS - SUMMARY

## Co-ordinated

- legal and
- administrative functions

## Easy access to

- technical
- administrative support

Network - co-operation – credibility

DETERMINATION – DEDICATION – STRONG WILL

