

Global Consulting Project 2019



## Meet the team



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## Why are we here?



Global Consulting Project is part of the Cambridge

MBA course



Four-week duration



An opportunity for the Cambridge MBAs to apply their learning in real-world context





## Agenda

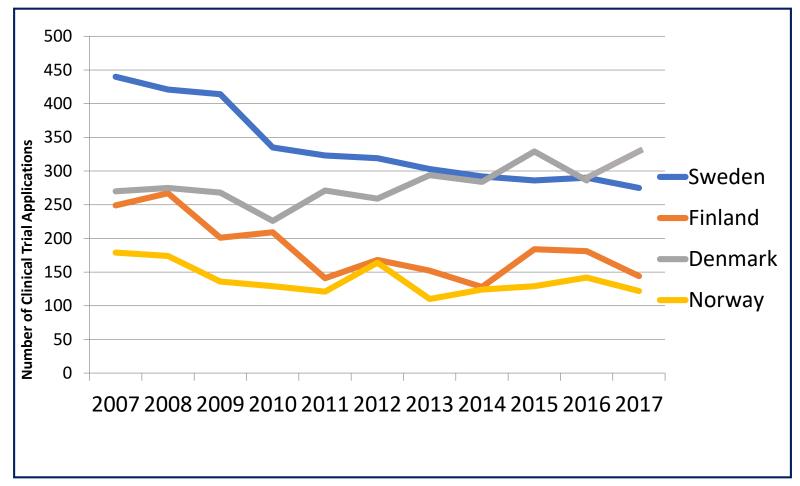
- 1 Problem Definition
  - 2 Plan To Tackle The Problem
    - 3 Challenges In Norway
    - 4 Recommendation 1: Incentivising Recruitment
  - 5 Recommendation 2: Raising Awareness
- 6 Next Steps







## Norway lags behind in number of clinical trials as compared to its Nordic neighbours

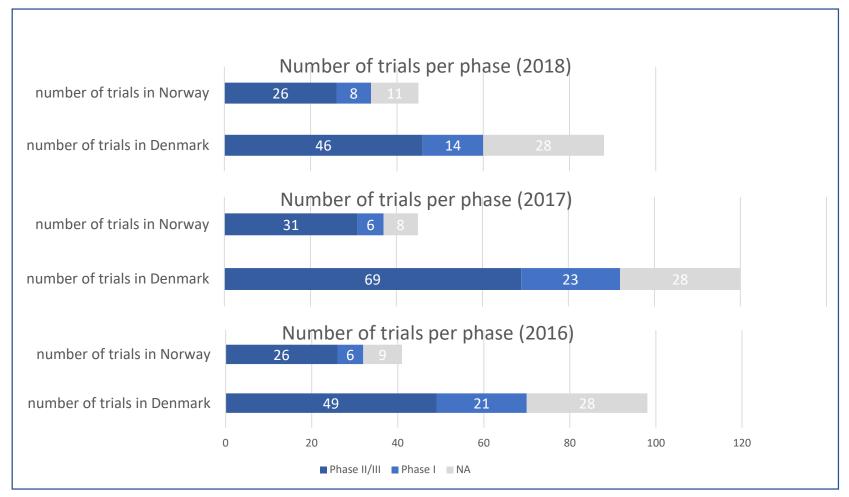


Norway has opportunities for improvement to increase clinical trials





## Norway versus Denmark – Total Number of Cancer Trials By Phase

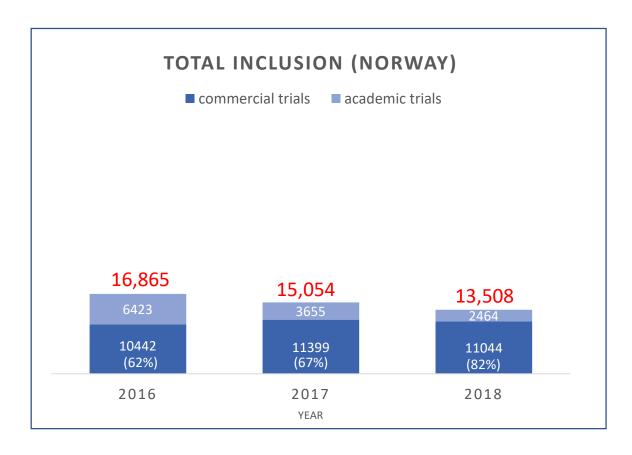


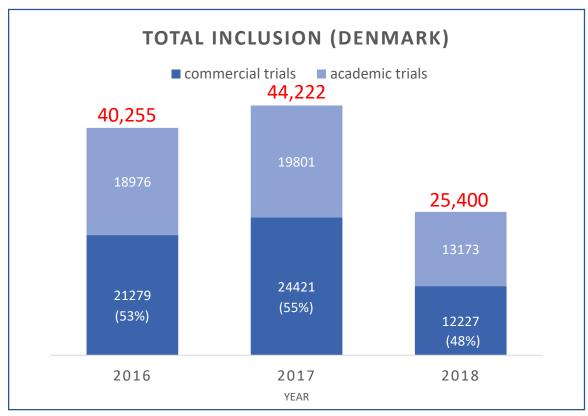
- Number of trials2x smaller thanin Denmark
- Proportion of early-stage trials in line with Denmark's figures





## Norway versus Denmark - Clinical Trials By Estimated Enrolment Numbers







- Total number of inclusion is higher in Denmark
- Academic trials represent a higher fraction of inclusion



## Three Key Factors Impacting The Number Of Cancer Trials In Norway

1 Size of eligible patient pool Impact on the attractiveness of Norway

Recruitment practice • **Identification** of eligible patients • Recruitment of eligible patients

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- Human resources (e.g. trialdedicated doctors)
- Hospitals with trial units
- Cutting-edge testing capabilities

**Project Focus:**Recruitment Practice







## Methodology



#### 1. Research

**Hypothesis-driven approach** in identifying issues

**Primary research -** In-person interviews with Norwegian stakeholders:

- Investigators
- Pharma companies
- · Ministry of health
- OCC board
- LMI
- Patient advocacy groups

**Secondary** research



## 2. Identify the challenges in Norway

Identify and prioritize the issues

#### Classify issues into themes

- Understanding the root cause of the problems
- Formulation of potential solutions and validating them with Norwegian stakeholders

**Prioritization** of the challenges



## 3. Develop solutions for Norway

#### **Comparative study**

- Identify challenges and solutions implemented in UK/US/France
- Assess the transferability of these solutions to Norway

**Interviews** with French, US and British stakeholders

#### Asses:

- Executability of the solutions
- Potential impact of these solutions



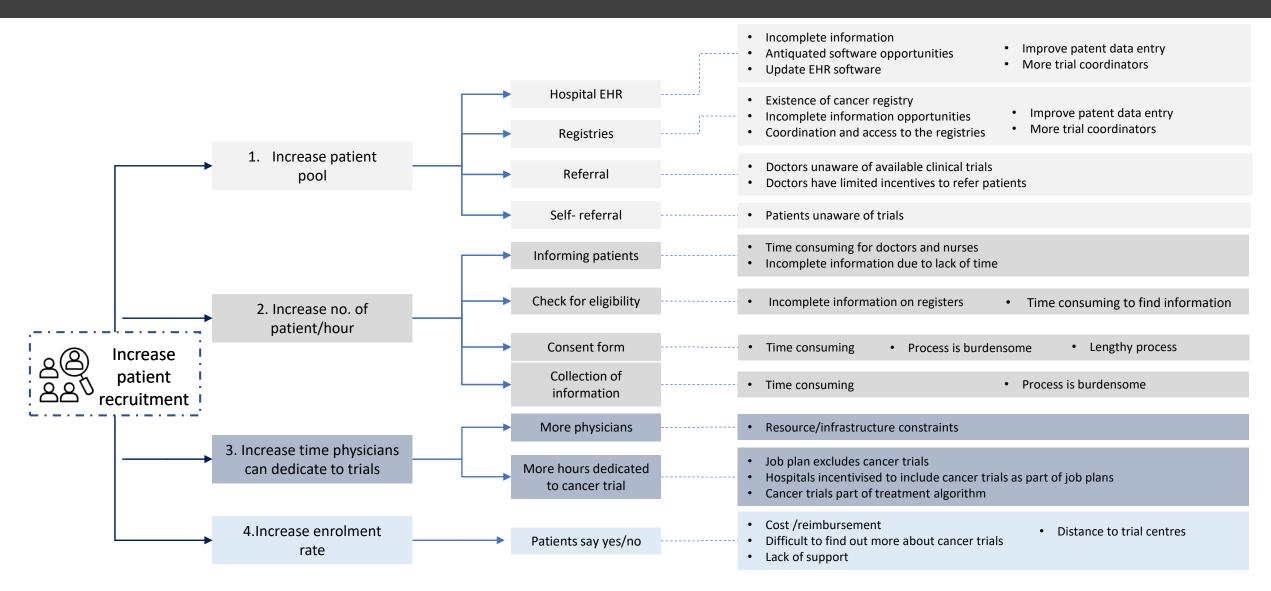
## 4. Recommendations and next steps

Develop the **recommendations** 

Identify risks and next steps

- Other challenges and opportunities raised during the project but not directly within the scope of the GCP
- Selection of the most significant challenges
- General guideline to address them

## 1. Primary and Secondary Research – Hypothesis Driven Approach



## 2. Key opportunities and challenges in Norway to increase patient recruitment

**Opportunities** 

and challenges

**Patients** 

#### Industry

## **5.1** Depends on the global office for decision-making processes

 Some big pharma companies have centralised decision making processes that require regional offices to justify Norway as a suitable for the relevant company

## **5.2** The increasing complexity of trials requires sophisticated infrastructure

 Most facilities in Norway require upgrade in infrastructure to meet highly specific screening requirements

5.3 Changing the negative perception of industry

#### Government

4

#### **4.1 Decentralized implementation**

 Due to funding allocation rules, Ministry of Health has limited decision making power once funding is given to the regional hospitals

#### 4.2 Lack of consolidated place for all registries

• Each cancer group has a specialised registry that provides detailed information about a patient. This sits outside of the EHR. Work underway to consolidated these registries

- **3.1 Patients are unaware of benefits** as doctors do not consistently and actively promote benefits of cancer trials
- **3.2 Difficult to obtain and understand relevant information** on relevant websites and resources
- 3.3 Travel distance and burdensome effort for rural patients

#### 1 Doctors

#### 1.1 Lack of awareness of current clinical trials driven by:

- No easy access to updated trial information
- Cancer trials not part of treatment algorithm
- Job plan does not include time allocation for cancer trials

#### 1.2 Limited incentives to refer or participate due to:

- Allocation of points to regional authorities versus directly to hospitals (recent change)
- Academic merit awarded only to researchers on the main author list in publications

#### 1.3 Lack of collaborative culture across hospitals and teams

 Teams and hospitals work in silos (driven by own internal processes), making coordination and knowledge sharing difficult

#### ) Hospitals

#### 2.1 Lack of collaborative culture among hospitals

- Small/remote hospitals are not incentivised to recruit for cancer trials.
- Small/remote hospitals are not aware of current trials

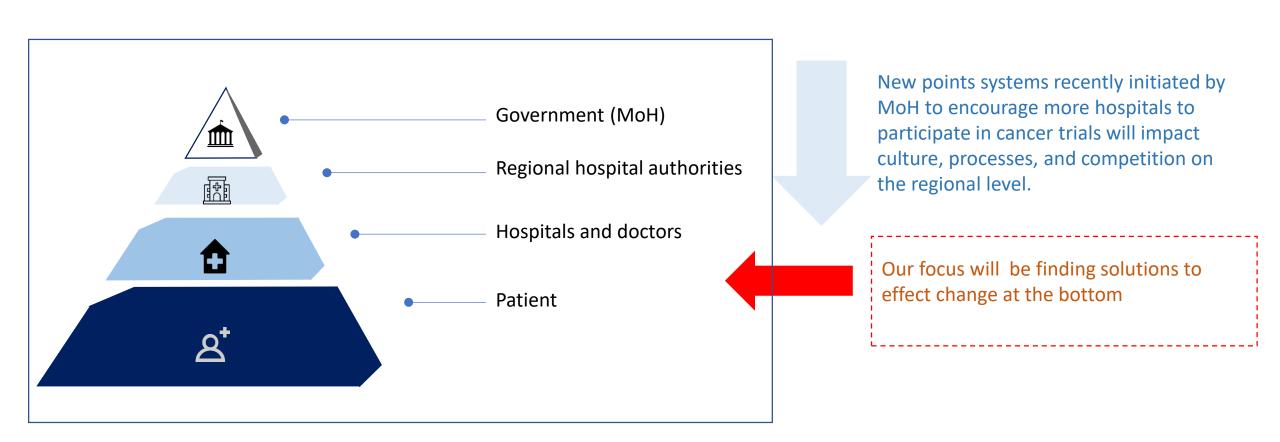
#### 2.2 Incentives alignment

• Ministry of health provides funding to regional health authority and not directly to hospitals conducting clinical trials.

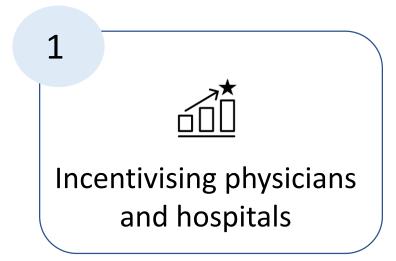
#### 2.3 Inconsistent internal processes between hospitals

 Internal processes vary between regions—driven by priorities of different management teams. This causes the importance of research in cancer to vary across regions

## Our focus will be to effect changes that will complement newly initiated government policies



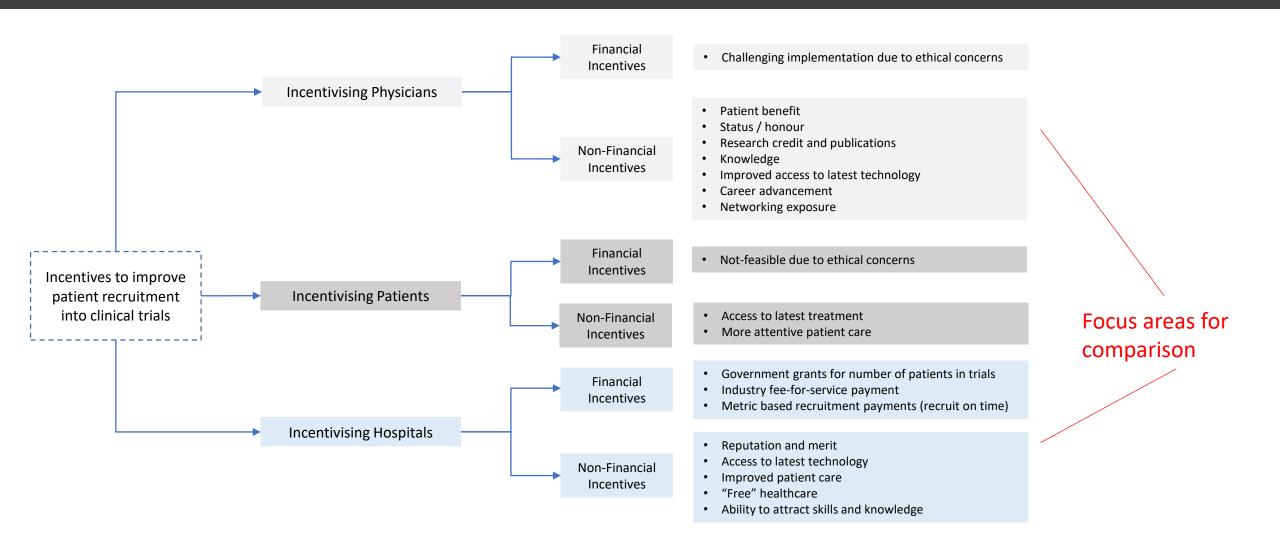
## To Overcome These Challenges, We Propose Two Recommendations –



Raising Awareness for patients and doctors



## Key Improvement area: Incentives to Improve Clinical Trial Recruitment



## Incentives Summary Table

	Physicians Financial Incentives	Physicians Non- Financial Incentives	Hospitals Financial Incentives	Hospitals Non-Financial Incentives
Norway	Direct financial incentives not permitted and against established ethics	Driven by patient welfare and benefit	No direct financial incentives for hospital. Funding routed through regional authorities	No current system of reputational incentives for hospitals
<b>France</b>	Direct financial incentives not permitted	Driven by patient welfare and benefit	Funding incentive directly to hospital, but achieved through regional funding	Reputational ranking incentive for hospitals through published league table
United Kingdom	Direct financial incentives not permitted	Driven by patient welfare and benefit	Funding directly incentivizes hospital trusts as it is performance-related E.g. CRN funding based on number of patients recruited per year. More patients = more funding	Hospital research output ranked on NIHR and CQC public tables.  NIHR requires hospitals to publish metrics on clinical trials such as initiation time, recruitment time and number of patients
<b>USA</b>	Industry can pay physicians for referring patients to clinical trials and for conducting research visits	Driven by patient welfare and benefit	Industry pay hospitals for overhead related to the conduct of clinical trials.	Patient volume incentives, e.g., access to investigational drugs can attract certain patient population; Reputational incentives, e.g., national and specialty rankings

## Recommendation: A cancer trial league table

Propose to create a league table for all the hospitals that measures patient outcomes, with cancer trial participation as one of the metrics.

Position		Hospital	
1	=4-	Hospital 1	
2	T	Hospital 2	
3	<b>^</b>	Hospital 3	<b>V</b>
4	*	Hospital 4	<b>V</b>
5	*	Hospital 5	
6	¥	Hospital 6	
7	4	Hospital 7	
8	•	Hospital 8	
9	स्ट्री इ	Hospital 9	<b>V</b>
10	+	Hospital 10	
11	N.	Hospital 11	
12	y.	Hospital 12	



#### Key metrics

- Volume of patients
- Specialised resources
- Trials is a dominant contributor (N of patients referred and/or included)



#### **Publisher**

- Published by an independent body
- Publisher with enough credibility amongst health providers



#### Advertisement

- The ranking should be advertised in general public press to increase visibility
- Medical journal

#### **Benefits**



Create competition to encourage mindset and behaviour change

- University hospitals are competitive
- Strong intrinsic incentive



Encourage collaboration between small/rural hospitals with large ones

- Using referral as a metric will encourage referrals
- Pressure on the regional health authorities to encourage regional collaboration



Information made public to empower patients

- General public press informs the patients and their families
- Better informed patients can positively challenge doctors

## Recommendation: Direct Incentives to Hospitals Conducting Trials

Regional health authorities in Norway need to ensure that funding provided to them for research is passed down to hospitals conducting clinical trials.

#### **Norway**

- Health ministry implementing research based metrics (point system) for funding allocation.
- Funding provided to regional authorities but not directly passed down to hospitals who conduct trials.

#### **France**

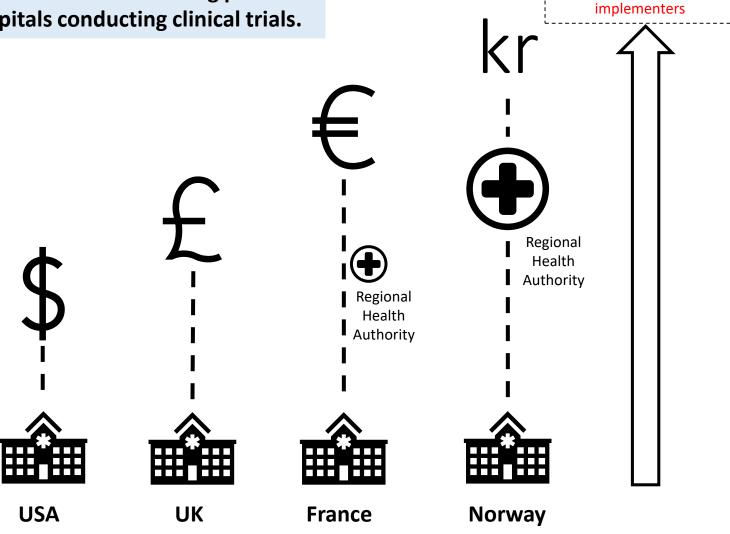
 Minister of health distributes budget according to metrics. Regional health authority is responsible for implementation only.

#### UK

 Point based system to directly link funding to hospital without a regional intermediary.

#### **USA**

Funding provided directly to physicians in USA.
 Hospital benefit from budget allocation.



Increasing misalignment between funding source

and clinical trial

## Key risks

#### **Key Risks**



1. Potential culture clash with Norway's view on healthcare

Creating competition among hospitals may not be culturally acceptable where healthcare is for the general public good. Creating a league table could potentially send the wrong signal.

Mitigation: Conduct surveys targeting all stakeholders in the ecosystem to gauge attitudes and views on this matter.



2. Implementation of the league table

Potential conflict between the publisher and stakeholders Controversial decisions regarding ownership, funding and metrics

Mitigation: Pilot project to demonstrate value and areas for improvement prior to public rollout

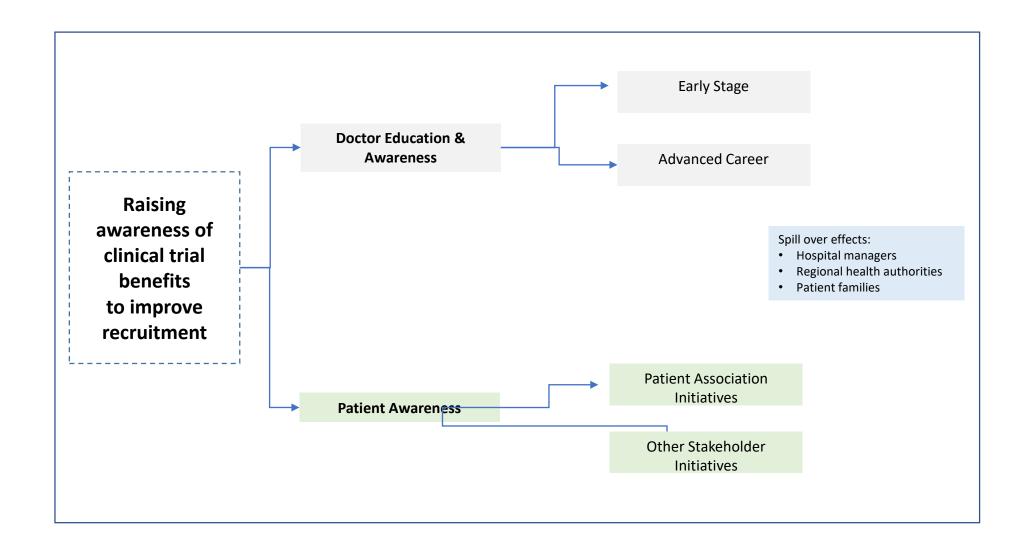


3. Political tensions between the regional health authorities and the hospitals

Mitigation: Discussions to align stakeholders prior to implementing recommendations



## Key Improvement area: Raising Awareness Amongst Stakeholders to Improve Clinical Trial Recruitment



## **Comparative Study – Initiatives to Increase Trial Awareness Amongst Doctors**



#### **Early Stage**

- Exposure to clinical trials from early medical career
  - Research Fellowships
- Benefits: As they progress in their career they are more likely to continue their involvement in research & clinical trials



- Clinical trials as a key component of medical education
- Participation in clinical trials as co-investigators is encouraged and mentorship provided
- Pre- and post- doctoral research fellowships available to medical students



- Mandatory rotations in clinical departments allow exposure to clinical trials
- French Ministry of Health has a long-term plan to include trials in the medical curriculum

#### **Advanced Career**

- Collaboration encouraged through Clinical Expert Networks
- Clinical Trials Toolkit provides practical advice to researchers in designing and conducting publicly funded clinical trials

- Continued medical education is a required component for the maintenance of physician licensure and board certification
- Knowledge sharing through academic publications and conferences
  - e.g. organized by American Association for Cancer Research and American Society of Clinical Oncology
- Networking dinners enable knowledge-sharing about trials
- **Mandatory training** in university hospitals for all doctors regardless of location base
- **Continued involvement** from doctors in remote areas even if patients are referred to university hospitals

## **Comparative Study – Increasing Patient Awareness**

# United Kingdom

#### Patient Associations

- Nationwide campaigns by Cancer Research UK to raise awareness of clinical trials
- Personal accounts of people who have taken part in trials publicized to raise awareness and ease concerns\*



**United States** 

- Raise disease awareness and public fundraising
- Work with academia and industry to address unmet patient needs
- Educate patients and families about management options and new study opportunities
- Match interested patients with available trials, e.g. national registries of research volunteers



- Patient associations involved in ensuring clinical trial documentation is patient-friendly
  - Review language of documentation given to the patients

#### Other Stakeholders

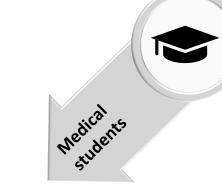
- UK Clinical Trials Gateway
  - Patient-friendly platform to find current trials and relevant information
- Information easily accessible on hospital websites
- **GPs as Patient Identification Centres (PICs)** raise awareness and screen patients for clinical trials.
  - Physicians and allied healthcare professionals actively share clinical trial information with patients
- Government requires registration of clinical trials and allows the public to search for studies
  - Example: clinicaltrials.gov and cancer.gov
- Various technology start-up companies provide tools to identify suitable clinical trials
- Collaboration between Ministry of Health & pharma industry association
  - E.g. Website communicating benefits of clinical trials
- Publication of ongoing trial on cancer hospitals websites
- Doctors & patient support groups actively inform patients about trial options

## Recommendations - Raising Awareness in Norway

#### Raise awareness & systemically support patients in identifying suitable trials

- Systematic demand for consent to be contacted for every new member
- Targeted newsletters with list of ongoing trials
- Strategy alignment between umbrella associations and specific cancer groups





**Physicians** 

#### Increase exposure to trials in the medical curriculum

- Course on clinical trials & research methods to be taught in medical school
- Rotational programs to ensure exposure to clinical trials at university hospitals
- Long-term: Guidelines for cancer treatment to include cancer trial as a key consideration

#### **Patients**



#### Increase visibility of trial information

- Patient-centred language to reduce access barriers to trial information
- Targeted ads for the trial registry (social media)
- List of ongoing trials displayed on the hospital's website (accessible in 3 clicks or less)

#### **Networking events to** foster collaboration

- Workshops & Seminars
- Host international symposiums to encourage cross-border collaboration

## Key risks

## **Key Risks**



1. Time lag between impact and implementation

Integration of educational measures may take takes time and need regulatory or government approval

Mitigation: Set specific milestones, monitor and measure results periodically



2. Misalignment with the strategy of patient association

Eg. Patient associations might not want to systematically ask for consent to be contacted to their members

Mitigation: Discussions to align patient associations prior to implementing recommendations



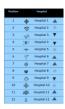
3. Conflicting information from sources regarding trials

Mitigation: endorsement of trusted sources by the MoH



## Next steps

## 1. League table



- Pilot using clinical trials as the main metric before expanding to other metrics
- Focus only on major university hospitals and continuously monitor physician perception of the ranking over time

## 2. Incentive alignment



- Consultation with regional health authorities is required to determine reasons behind incentive misalignment
- Research into regulations surrounding MoH restrictions on enforcing alignment

### 3. Patient education



- Research regulations regarding systematic consent to be contacted
- Strategy alignment consultation between patient groups
- Survey patients on currently used sources of information

## 4. Physician education



- Explore implementation path of curriculum change
- Explore CPD options to increase education on clinical trials

## Implementing a clinical trial league table

#### **Hypothesis:**

If patients knew the benefits of clinical research, they would select a hospital that is ranked highly.

#### Test:

- 1) Survey patients on benefit of clinical trials
- Ask if it influences their choice on hospital
- Work with cancer society on campaign to improve education on benefits of clinical trials

#### **Hypothesis:**

If physicians / hospitals were ranked against each other based on clinical trial output, they would more actively recruit into trials due to the reputational incentive.

#### Test:

- 1) Survey doctors in various hospitals on clinical trials and research
- 2) Collect ministry of health data on:
  - a. Number of clinical trials
  - b. Number of clinical trial patients (log)
- 3) Brainstorm additional metrics for ranking. Potentials could be:
  - a. Attitude to research
  - b. \$\$\$ inflow for research from industry
  - c. Number of doctors who respond 'well' on survey
- 4) Determine appropriate metric matrix for league table
- 5) Prepare pilot league table for 5x universities
- 6) Market and launch
  - a. Integrate 'champions' of ranking
- 7) Monitor response with regular surveys
- 8) Iterate and improve