

# DANSKE KRÆFTFORSKNINGSDAGE 2019

## Kan fase IV data danne grundlag for kvalitetsforbedringer i patientbehandlingen?

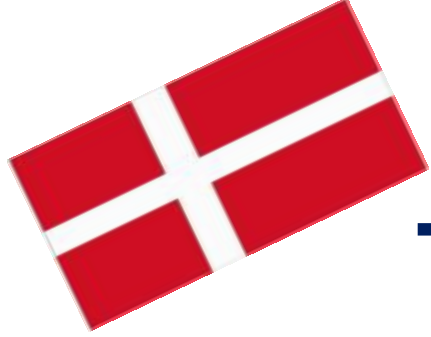
Lars Bastholt, Overlæge på Onkologisk afd, OUH

#DKD2019

#samarbejdeomkræft

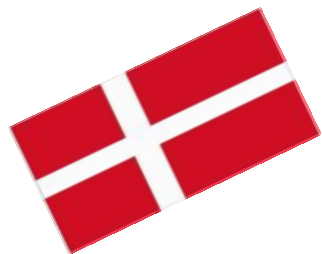
# Erfaringer fra modermærkekræft vedr fase IV data

- Fase IV begynder efter, lægemidlet er blevet godkendt til markedsføring.
- Studier af lægemidlets terapeutiske anvendelse der går bredere end den tidligere påvisning af medicinens sikkerhed, effekt og bestemmelse af dosis.
  - Virker lægemidlet på hverdagens patienter?
  - Er bivirkningsprofilen som forventet?
  - Giver fase IV mulighed for at løfte evidensen op på et højere niveau?



# The **DA**nish **ME**tastatic **ME**lanoma **DA**tabase

**”DAMMED”**



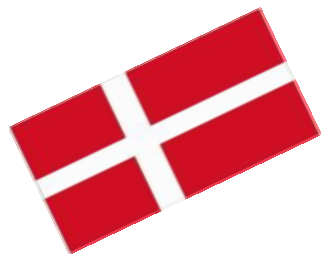
# Organization of DAMMED

- Four centers with close collaboration
  - Agreement on national guidelines
  - Agreement on clinical trials



#DKD2019

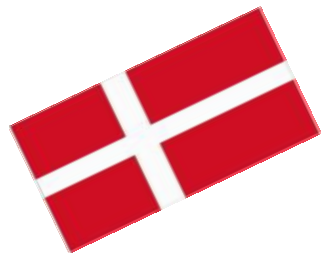
#samarbejdeomkræft



# DAMMED

## - Medical treatment for melanoma

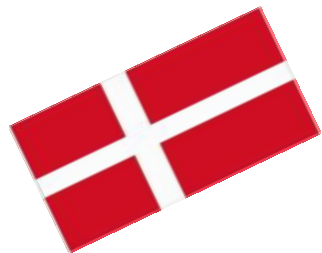
- Database founded in 2011
  - DMD database with no data on medical treatment
  - New drugs available -> real-world evidence
  - Retrospective entry of clinical data from 2011 and onwards
  - IL-2 treated patients from 2007
  - Registered data:
    - Stage III and IV (resected) for adjuvant therapy
    - Stage IV considered for systemic therapy (Medical treatment/BSC)



# DAMMED

## - Medical treatment for melanoma

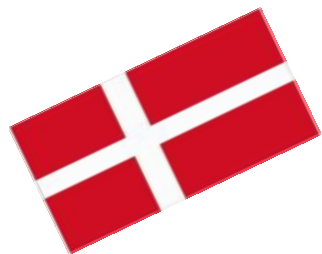
- Responsible investigators and founders
  - Inge Marie Svane, Herlev University Hospital
  - Henrik Schmidt, Århus University Hospital
  - Lars Bastholt, Odense University Hospital
- Subinvestigators
  - Marco Donia, Lise Højberg, Christine Ruhlmann, Trine Øllegaard, Eva Ellebæk, Charlotte Haslund
- Datamanagers
  - Ulrich Heide Køhler, Tobias Klausen



# DAMMED

## - Medical treatment for melanoma

- Management
  - Financial support to initiate og develop the database has been granted from several medical companies
  - Datamanager;
    - Extracts data for scientific purposes
    - Improves database structure
  - Medical students are hired to enter data
  - Legal agreement on data management
  - All patients must agree to entering data (written informed consent)

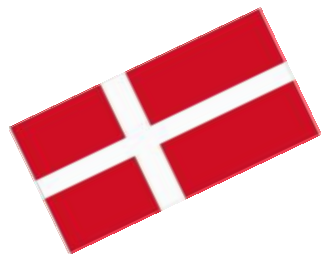


# DAMMED

## - Medical treatment for melanoma

- Focus
  - Medical treatment
  - Baseline data (biomarkers, tumorburden, stage, LDH, PS etc)
  - Pathology (Cutaneous, Mucosal, uveal and unknown)
  - Efficacy (Response, RFS, TTP and OS)
  - Limited data on toxicity – until now

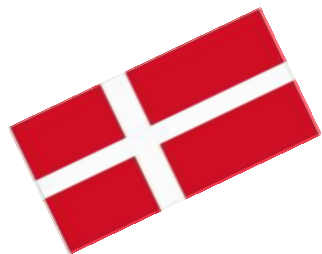




# DAMMED

## - Medical treatment for melanoma

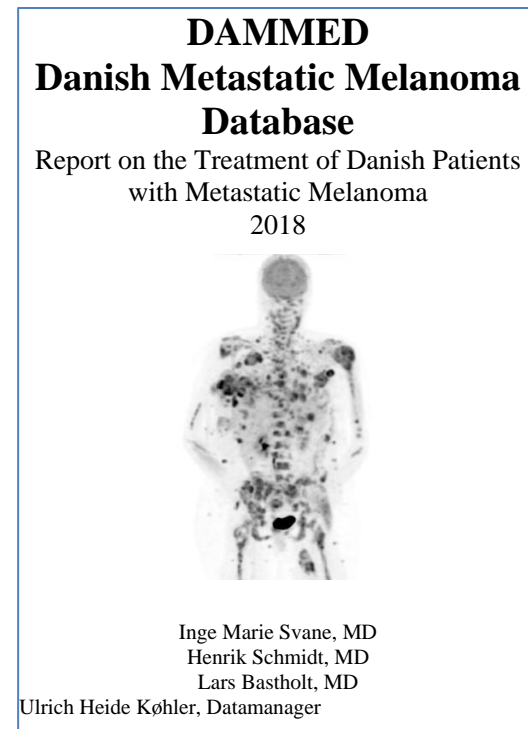
- Includes all patients receiving systemic treatment for melanoma in DK
  - > 4000 treatment regimens
  - > 3000 patients
  
- Research catalogue
  - Purpose: Using the data in our database for clinical research
  - Ideas added and discussed
  - Key person



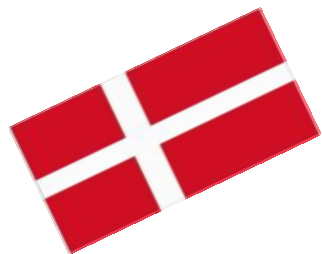
# DAMMED

## - Medical treatment for melanoma

- Results
  - Yearly report with anonymized data
    - involved colleagues
    - on demand!
    - supporting medical companies  
(Merck MSD, BMS, Novartis and Roche)
  - Research
    - Retrospective data with real-world evidence



#DKD2019  
#samarbejdeomkræft



# DAMMED - Scientific Publications

**Type:** Letters to the Editor

**Title:** The real-world outcome of metastatic melanoma: unknown primary versus known cutaneous

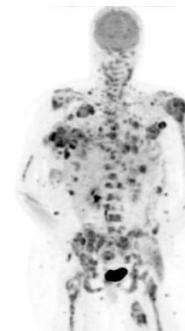
**Authors:** Eva Ellebæk<sup>1</sup>, Lars Bastholt<sup>2</sup>, Henrik Schmidt<sup>3</sup>, Inge Marie Svane<sup>1</sup>, Marco Donia<sup>1</sup>

Published in Int J Cancer



## DAMMED Danish Metastatic Melanoma Database

Report on the Treatment of Danish Patients  
with Metastatic Melanoma  
2018



Inge Marie Svane, MD  
Henrik Schmidt, MD  
Lars Bastholt, MD  
Ulrich Heide Køhler, Datamanager

#DKD2019  
#samarbejdeomkræft

# Future?

- Finanslovsbevilling:  
”Immunotherapy Empowerment in Denmark”
- WP vedr toxicitet
  - Database med al immunrelateret toxicitet registreret
  - On-line tidstro registrering
  - Alle sygdomsgrupper
- Evidens baseret håndtering af bivirkninger
- Andre tumorgrupper er velkomne til at kopiere vores koncept
  - Tom database kan tilrettes og anvendes

