

SEALD

SIGNED - SEALED - DELIVERED

LITT BAKGRUNNSTALL

GLOBALT

- 17 mill. *nye* kreft-tilfeller 2018
- 9,6 mill *kreft-dødsfall* 2018
- 70% økning de neste 20 år?

EU

- Kreft er nest største dødsårsak
- Eksplosiv økning av helsebudsjett:
 - Kreftrelaterte kostnader 83.2 milliarder € (2014)
 - Herav kreftmedisin 19,1 milliarder €

Seald has received grants from:



LITT BAKGRUNNSTALL

LEGEMIDDEL-UTVIKLING

- Bransjestandard 10-12 år
- Tre faser: fase 1: first-in-man – til fase 3: spesifikk pasientgruppe
- Failure fase 1: 90%
 - Manglende effekt og bivirkninger vanligste årsaker
- Kostnad 1,8 mrd USD, inkl.failure

Seald has received grants from:



NASJONALE EFFEKTREGISTERE MANGLER

- 13 nye kreftmedisiner FDA-godkjent 2012
- 12 medisiner pris > 85.200 Euro per år (LY)
- Pris 91.000 - 286.850 Euro
- **Kun én medisin økte overlevelsen mer enn 2 mnd!**

Seald has received grants from:



ER DET INTERESSANT Å BEREGNE HVA INEFFEKTIV BEHANDLING KOSTER SAMFUNNET?

This systematic evaluation of oncology approvals by the EMA in 2009-13 shows that most drugs entered the market without evidence of benefit on survival or quality of life. At a minimum of 3.3 years after market entry, there was still no conclusive evidence that these drugs either extended or improved life for most cancer indications.

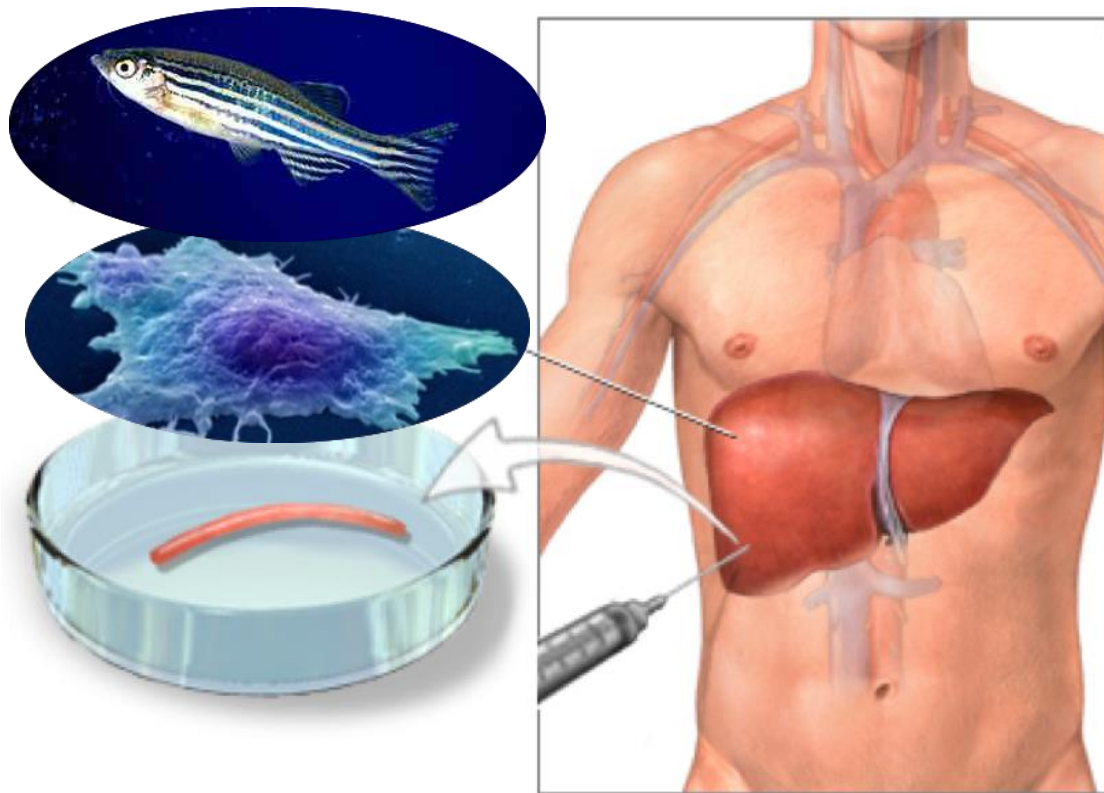
When there were survival gains over existing treatment options or placebo, they were often marginal.

Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. Davis C, et al.

Seald has received grants from:



Seald utvikler en metode der pasientens levende kreftceller behandles *før* pasienten

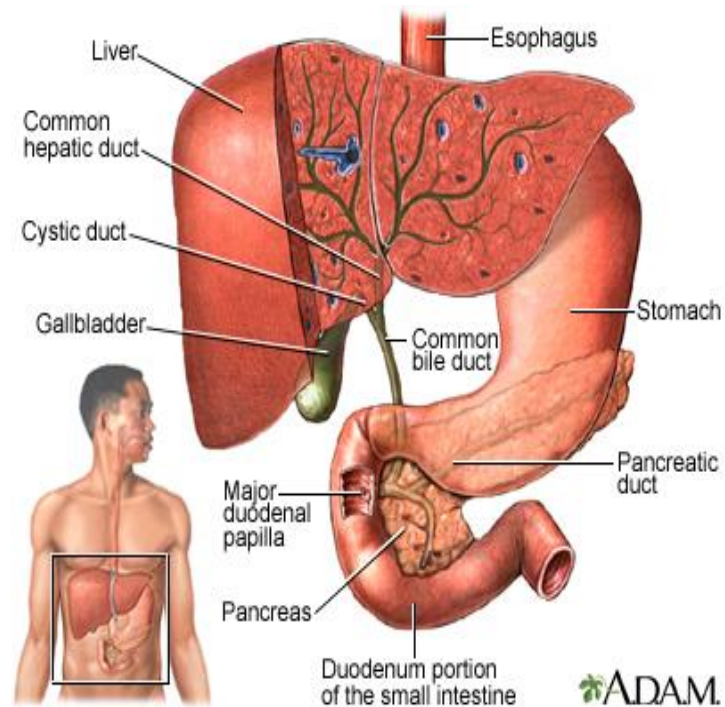


ADAM

- **Høste levende kreftvev fra pasienter**
- **Plattform-teknologi: fra levende kreftsvulst til levende kreftceller**
- Lab - forskning
 - Spalte vev til levende kreftceller
 - Reproducere kreftcellene
 - Screene medisinsk effekt av ulike kreftmedisiner
 - Lete etter biologiske særtegn i svulsten
 - Transplantere til pasient-»avatar«og organoid
 - Behandle kreftceller, organoid og dyremodell *før pasienten*
- In silico data-analyser og bio-informatikk
- **Utpeke evidensbasert kreftbehandling til hver pasient**

MODUS OPERANDI: KREFT I GALLESYSTEMET

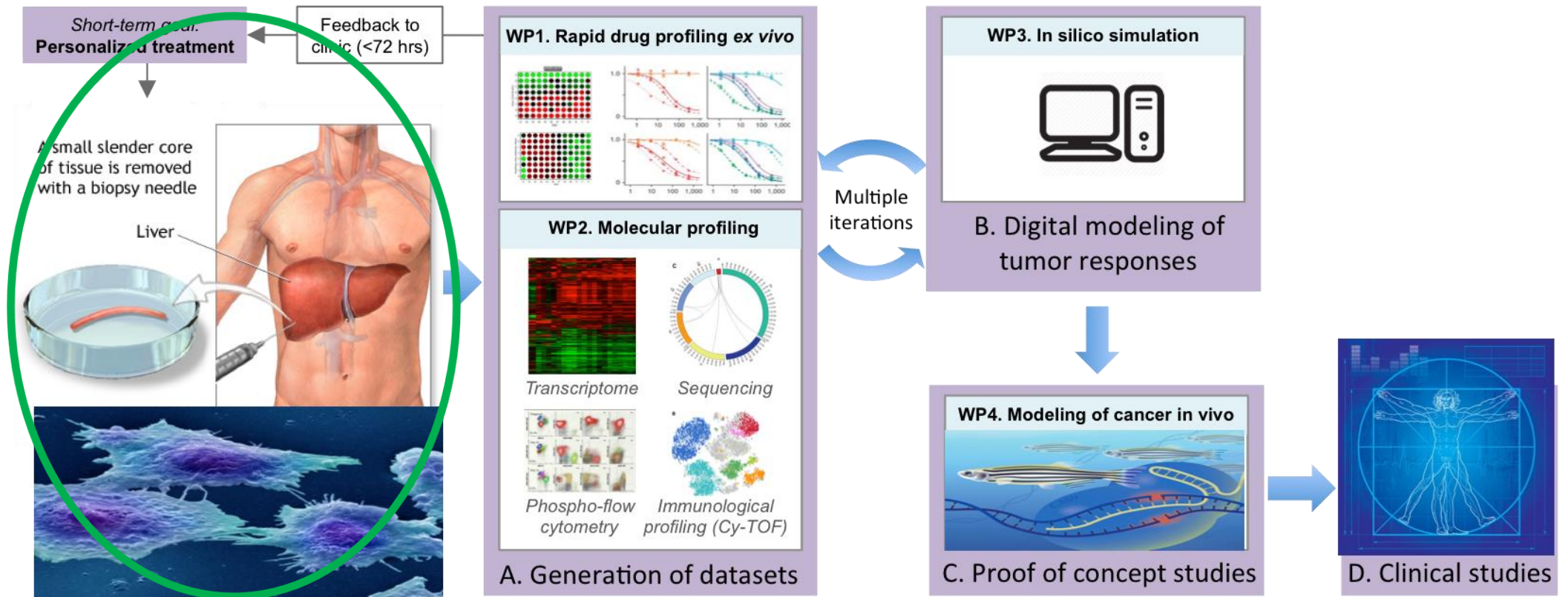
«Galle-tre»



- **Svært aggressiv kreftform**
- **Årlige nye kreft-tilfeller**
 - USA og EU: 15-22.000*
 - Asia**: 150.000
 - CUP (kreft med ukjent origo)
 - 3 - 5% av all cancer
 - 20% av CUP er kreft i gallesystemet?
- **Standardisert global *ineffektiv* behandling**

*Årlige antall betydelig høyere grunnet CUP
 **Kina og Major Asia (Japan, Syd-Korea, Thailand, Vietnam, Taiwan)

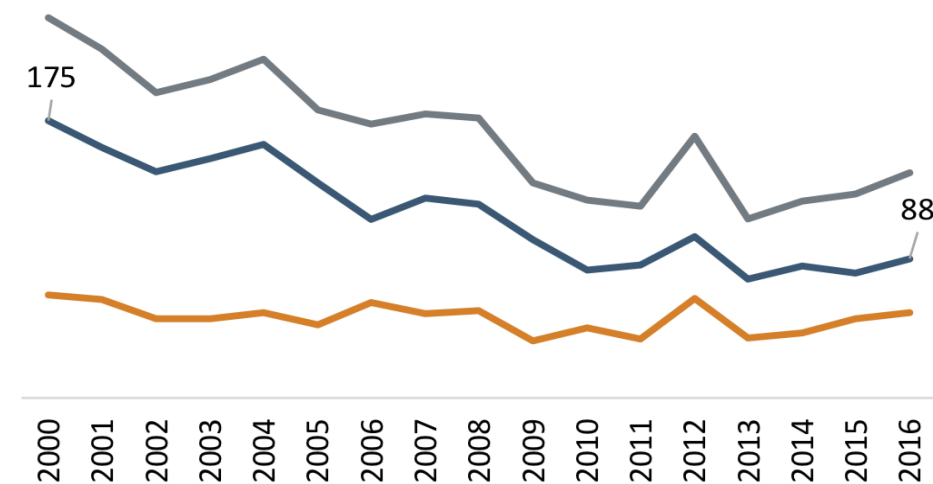
Én plattform - flere enheter - én prosedyre



VI HAR REK-GODKJENT KLINISK STUDE

- Klinisk studie godkjent
- Høste levende kreft-vev fra pasienter som skal opereres for gallegangs-kreft
- Samarbeid med
 - Oslo Universitetssykehus
 - Haukeland Universitetssykehus
 - Institutt for kreftforskning
 - Universitetet i Oslo mf.

- **Antall kliniske studier i Norge i sterkt tilbakegang!**



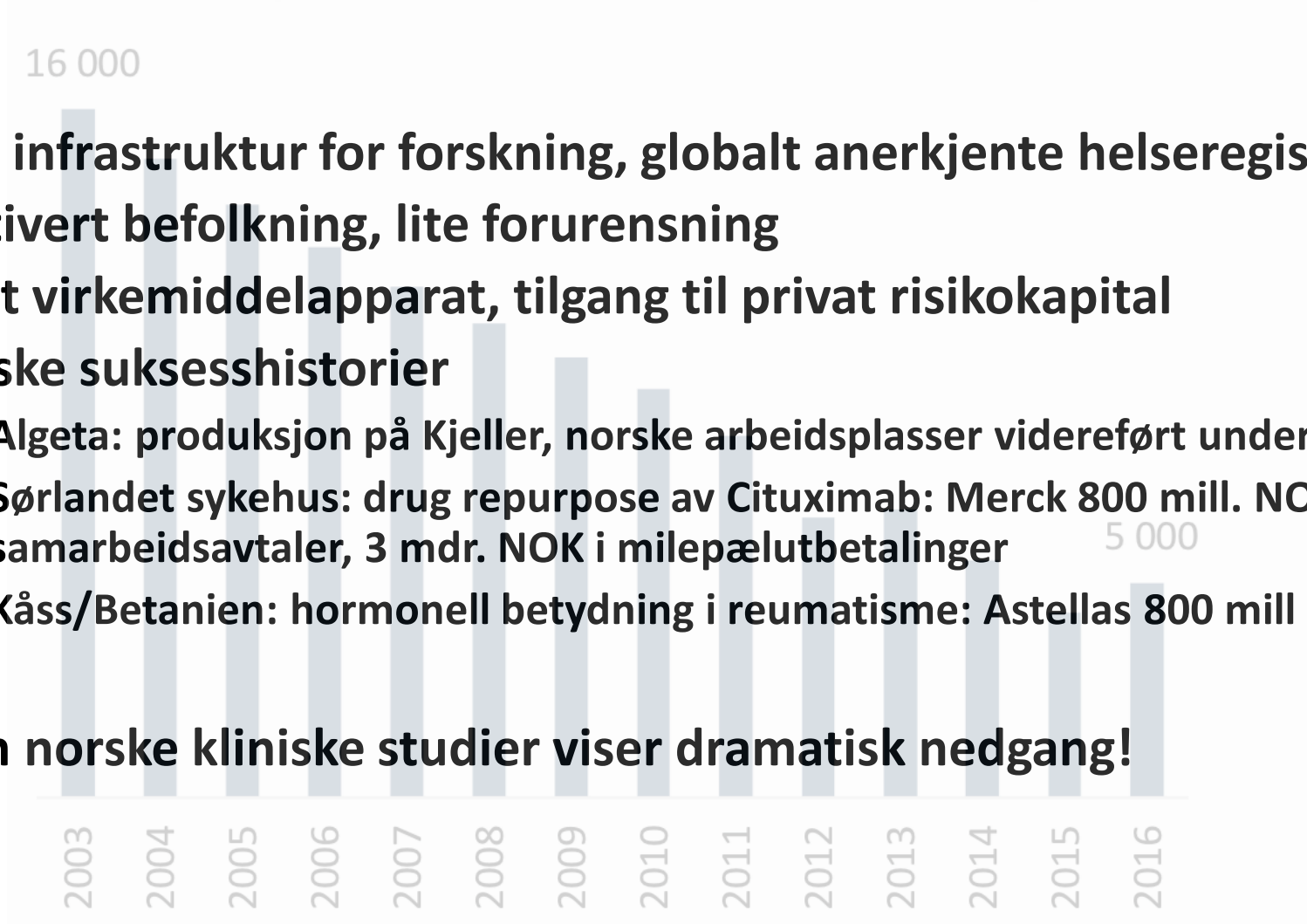
Kilde: Statens legemiddelverk

Seald has received grants from:



Næringsutvikling av medisinsk forskning i Norge

Antall pasienter som deltar i kliniske studier i Norge



- **God infrastruktur for forskning, globalt anerkjente helseregistre**
- **Motivert befolkning, lite forurensning**
- **Godt virkemiddelapparat, tilgang til privat risikokapital**
- **Norske suksesshistorier**
 - **Algeta: produksjon på Kjeller, norske arbeidsplasser videreført under Bayer**
 - **Sørlandet sykehus: drug repurpose av Cituximab: Merck 800 mill. NOK, samarbeidsavtaler, 3 mdr. NOK i milepælutbetalinger**
 - **Kåss/Betanien: hormonell betydning i reumatisme: Astellas 800 mill NOK**
- **Men norske kliniske studier viser dramatisk nedgang!**

Kilde: Legemiddelmeldingen og LMIs FOU-rapport 2017

“INGEN KUR” MOT GALLEGANGSKREFT

- «Gammeldagse» cellegifter = standard behandling

- Dårlig effekt, bivirkninger, ingen helbredes!
- Dårlig livskvalitet, hyppig sykehuskontakt
- 0 % fem-års overlevelse. 11,5 mnd forventet levetid

- Kirurgi er potensielt kurativt

- Omfattende kirurgi: reseksjon eller lever-transplantasjon, høy risiko,
- Donorlever er mangelvare internasjonalt
- > 50% tilbakefall

- Fem-års overlevelse for diagnosen kun 2-5%

Gallesystemkreft = cholangiocarcinom (CCA) = bile duct cancer = bile tract cancer

Orphan disease

- Medisinsk behov stort og udekket
- Regulatorisk behandling (FDA/EMA) raskere og rimeligere
- Leveutsikter pessima:
Tendens i klinisk utprøving avleses raskt

INEFFEKTIV BEHANDLING
DYRT FOR SAMFUNNET
LIDELSE FOR PASIENTENE

MANAGEMENT TEAM

Tove Cecilie Viebe, CEO MD, Executive Master of Management, BI Norwegian Business School, specialist in general surgery focusing on gastrointestinal surgery.

Gunnar Aarnes, CFO MSc in Business (siviløkonom), BI Norwegian Business School and a state authorised public accountant. Partner at Uniconsult and former CFO of Targovax ASA.

Christian Jonasson, Msc.Pharm, PhD Over 25 years of work experience from regulatory authority, pharmaceutical industry and academic research. Christian serves as a working board-member.

MENTOR

Per Walday, Ph.D. CEO PCI Biotech ASA Former Global Head of Project Management at GE Healthcare and manager in Nycomed Imaging/Amersham Health developing mainstream diagnostic drugs found in the market today. Broad international network and is experienced with business development and approvals of new products in the international in the pharma industry.

RESEARCH PARTNERS

Institute of Cancer Research, Oslo University Hospital
repr. by prof and Group Leader ICR, Dept of Cancer Immunology Kjetil Tasken

Centre for Molecular Medicine Norway, UiO

Bioinformatics Core Facility, Institute for Cancer Research, UiO/OUS – DNR repr. by Professor Eivind Hovig

Drug Discovery Laboratory AS
repr. by Professor Jo Klaveness

OTHER COMPETENCES

M.Sc. Biophysics Ove Vincent Solesvik, Business Development Advisor. More than 30 years of national and international experience with research-, technology- and innovation based business development and management, with main focus on Health and Life Sciences, including medical devices and E-health. He has extensive management experience from both public and private sector.

Prof. Jostein Halgunset, NTNU Prof. of anatomy at the Faculty of Medicine at NTNU and advisor of Regional Research Biobank Mid-Norway (Biobank1). The biobank develops solutions for researchers who use human biological material in medical research

SCIENTIFIC ADVISORY BOARD

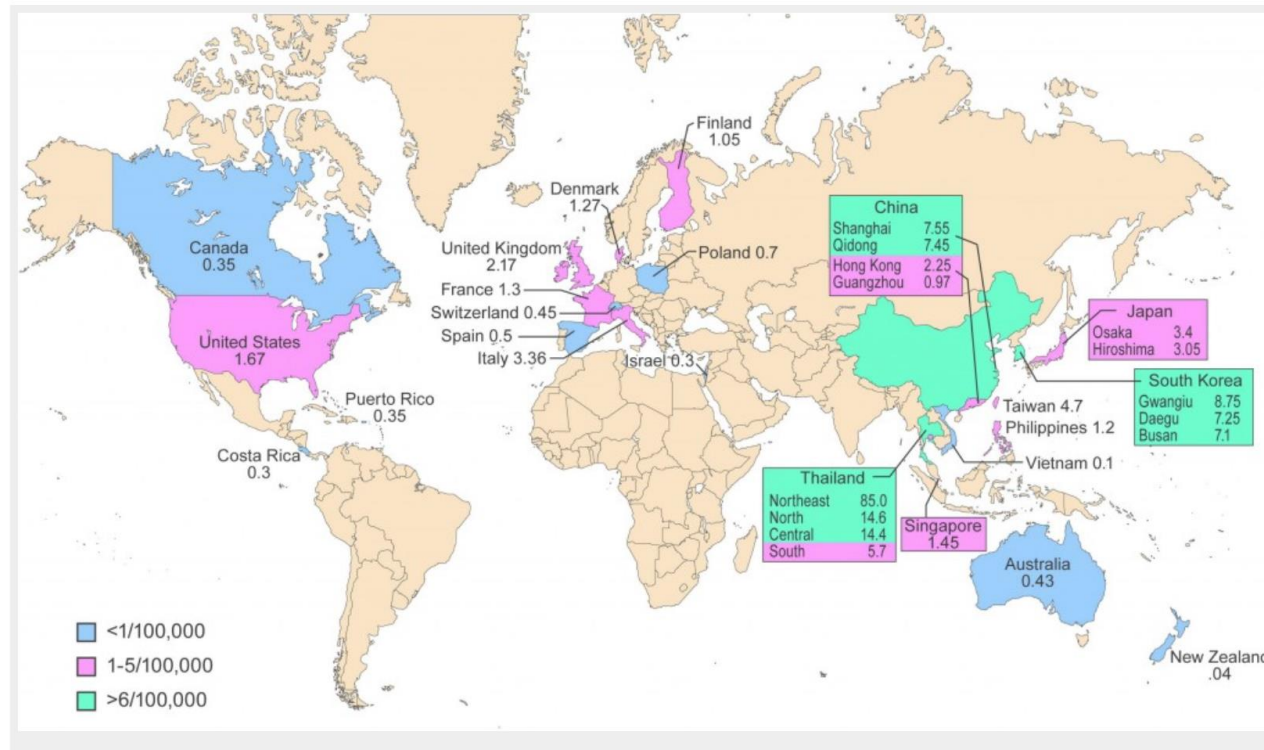
Professor Gregory Gores
Executive dean for research across the Mayo enterprise, medical director of the Liver Transplant Program, and former chair of the Gastroenterology and Hepatology Division at the Mayo Clinic Rochester.

Professor Jo Klaveness: Present research activities and fields of interests are drug discovery/delivery/synthesis/formulation and drug development, cancer and infections, ligands with affinity for selected biological targets, intellectual property issues and regulatory issues.

Ass. Professor and group leader Jesper Andersen, Biotech Research & Innovation Centre, University of Copenhagen, lead cancer researcher in the field of translational medicine, molecular tumor heterogeneity, drug resistance and disease models for testing new therapies, of which a substantial research is performed on bile duct cancer.

Dr. Philos Audun Øksendal
Former special adviser in biotechnology with the Research Council of Norway, and CEO of Medinnova (now Inven2). Background in the areas of research, strategic planning and international marketing from Nycomed Imaging and Amersham.

Global utbredelse



- Forekomst *varierer* internasjonalt
 - Sjelden kreftform i Vesten
 - Betydelig kreftform i Asia
 - Orphan disease: stort udekket behov, raskere behandling i FDA/EMA
- Forekomst *øker* internasjonalt
 - Ukjent årsak
- Forekomst *underrapporteres* internasjonalt
 - 20% av kreft med ukjent origo er CCA disse tilfellene er ikke med i beregning

Vesten: 15-22.000 Kina, major Asia: 150.000



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