

Pragmatic trials in precision oncology: state of the art

Chairperson:

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Speakers:

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Pragmatic trials

- Randomized controlled trials (RCTs) have been the mainstay of clinical research
- Traditional RCTs are slow and expensive
- Traditional TCTs does not work well in precision cancer medicine
- Need for more pragmatic approaches

Many ongoing similar studies in cancer precision medicine



DRUP
the Drug Rediscovery Protocol
Expanded use of existing anticancer drugs

ProTarget

A Danish Nationwide Clinical Trial on Targeted Anti-Cancer Treatment based on Molecular Profiling

FINPROVE
DRUG REDISCOVERY PROGRAM IN FINLAND



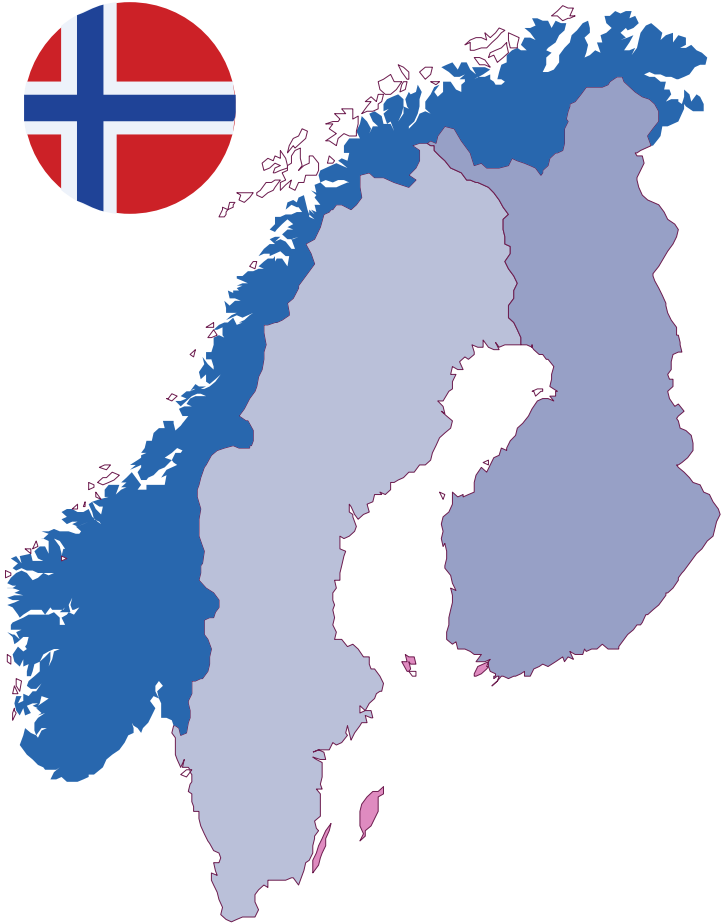
TAPUR Targeted Agent and Profiling Utilization Registry Study
American Society of Clinical Oncology



Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR)



Implementing precision cancer medicine in Norway via interconnected initiatives:



InPreD Norway:

National infrastructure for precision diagnostics

IMPRESS-Norway:

Improving public cancer care by implementing precision medicine in Norway

MATRIX:

Multimodal Approach Targeting treatment Refractory cancers using neXt generation technologies and trials

TRAIN:

Tumour Response Evaluation using Artificial Intelligence for Norway

INSIGHT / INCLUDE:

Sustainable implementation of precision cancer medicine

CONNECT Public-private partnership:

Norwegian Precision Cancer Medicine Implementation Consortium

*See also Taskén K. et al, Nature Medicine May 2022, 28(5):885-887 for description

Strategic development towards a national trial as a public-private cooperation



Bottom up:

- White paper for Norwegian concept, National PI assigned (Åslaug Helland)
- Buy-in from oncology, haematology, pathology environments in all Norwegian health regions -> National approach



Top down:

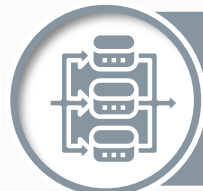
- Dialogue with health authorities (regional health care systems, ministry)
- Engaging key national stakeholders: NoMa, NIPH, HDIR, Cancer Registry, Cancer Society



International: Joined DRUP network and building Nordic Task Force

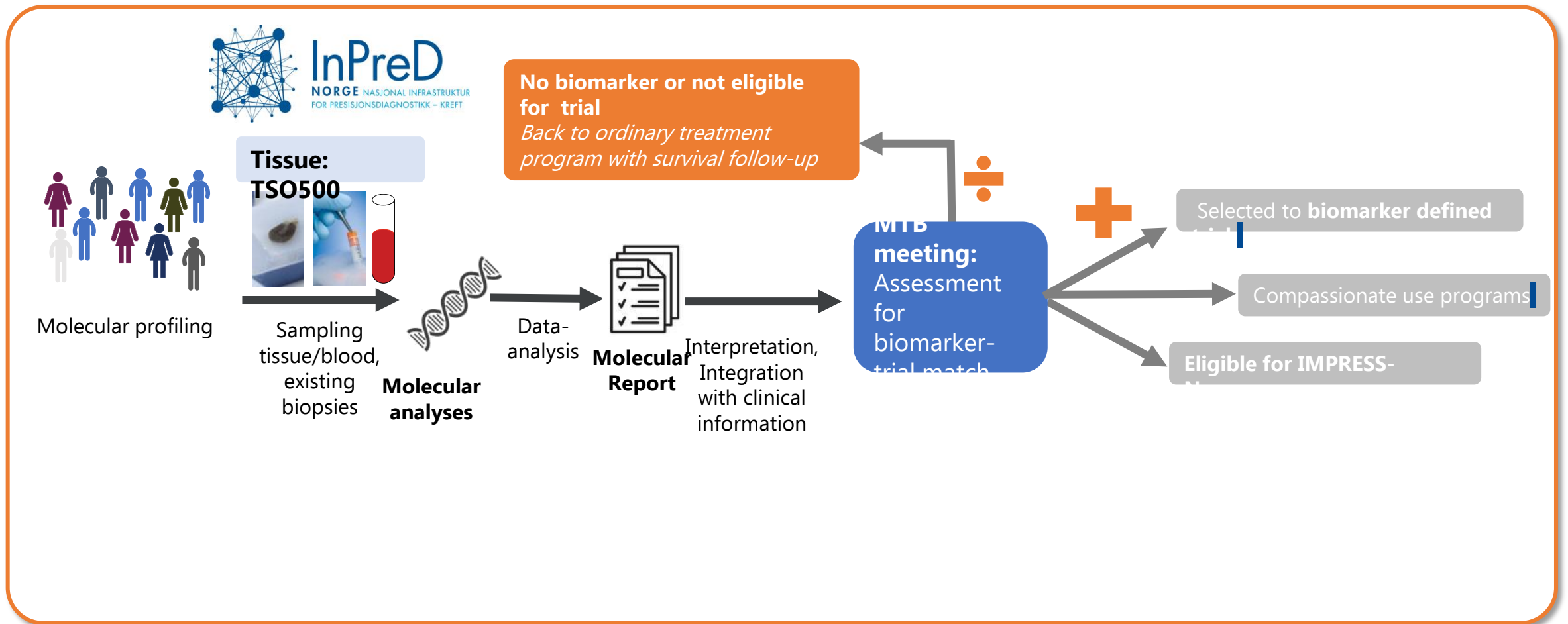


Public-private: Dialogue with industry partners: trial participation and consortium formation for public-private partnership

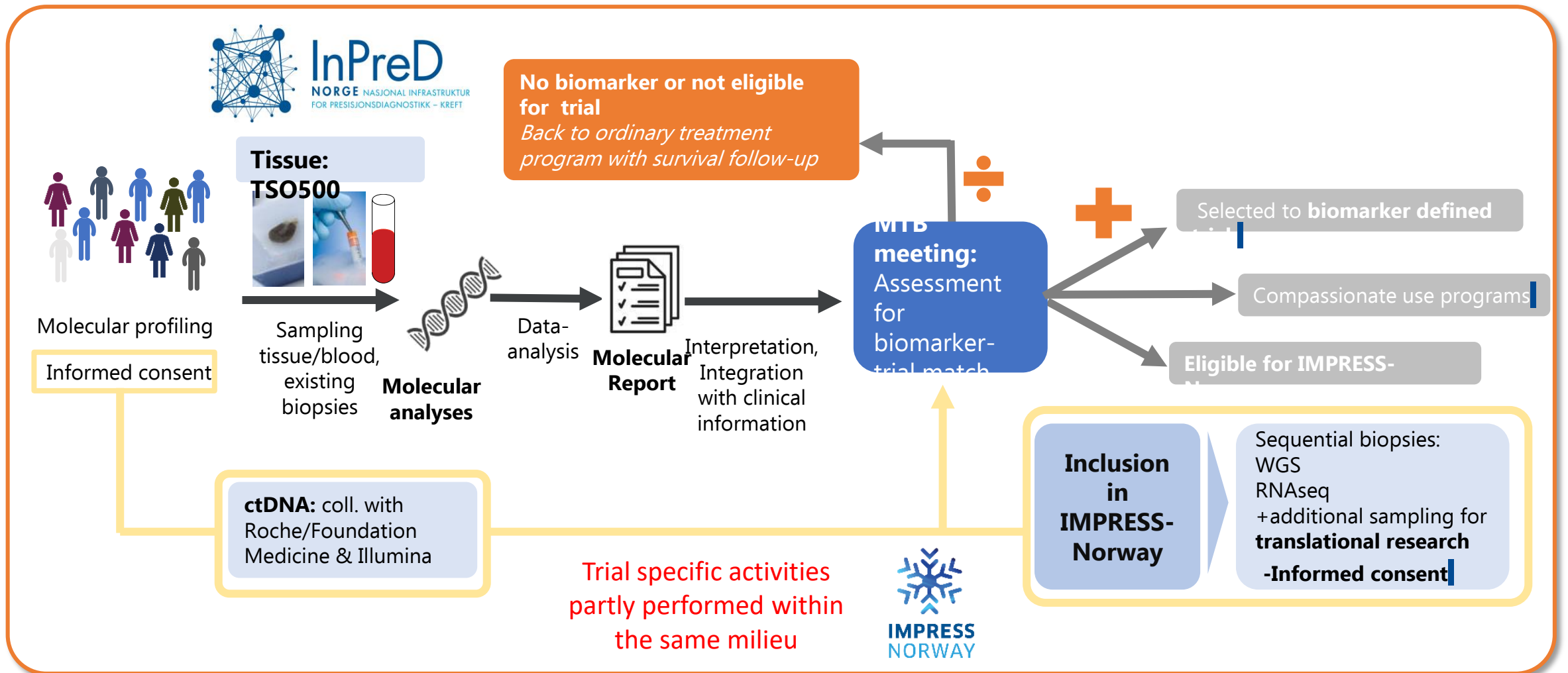


Parallel development of diagnostic platforms (InPreD), PCM PPP (CONNECT) and research on RWE & controls, health economy & HTA, ethics, legal & org. of PCM (INSIGHT)

InPreD: Diagnosis and assessment for cancer patients where experimental treatment and clinical trial inclusion is an option



InPreD: Diagnosis and assessment for cancer patients where experimental treatment and clinical trial inclusion is an option



IMPRESS-Norway: Improving public cancer care by implementing precision medicine in Norway*



Patients with advanced disease

Solid tumours and hematological indications

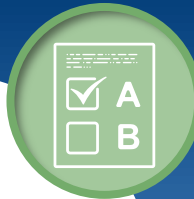


Close collaboration and coordination with DRUP-network trials in Europe and beyond:

-



Entry by testing (level 1 lab / 500-gene panel test)



Evaluation via national molecular tumour board

- inclusion criteria for each drug



Approved (FDA/EMA) drugs (incl. approved combinations)

- Known safety-profile, off-label use

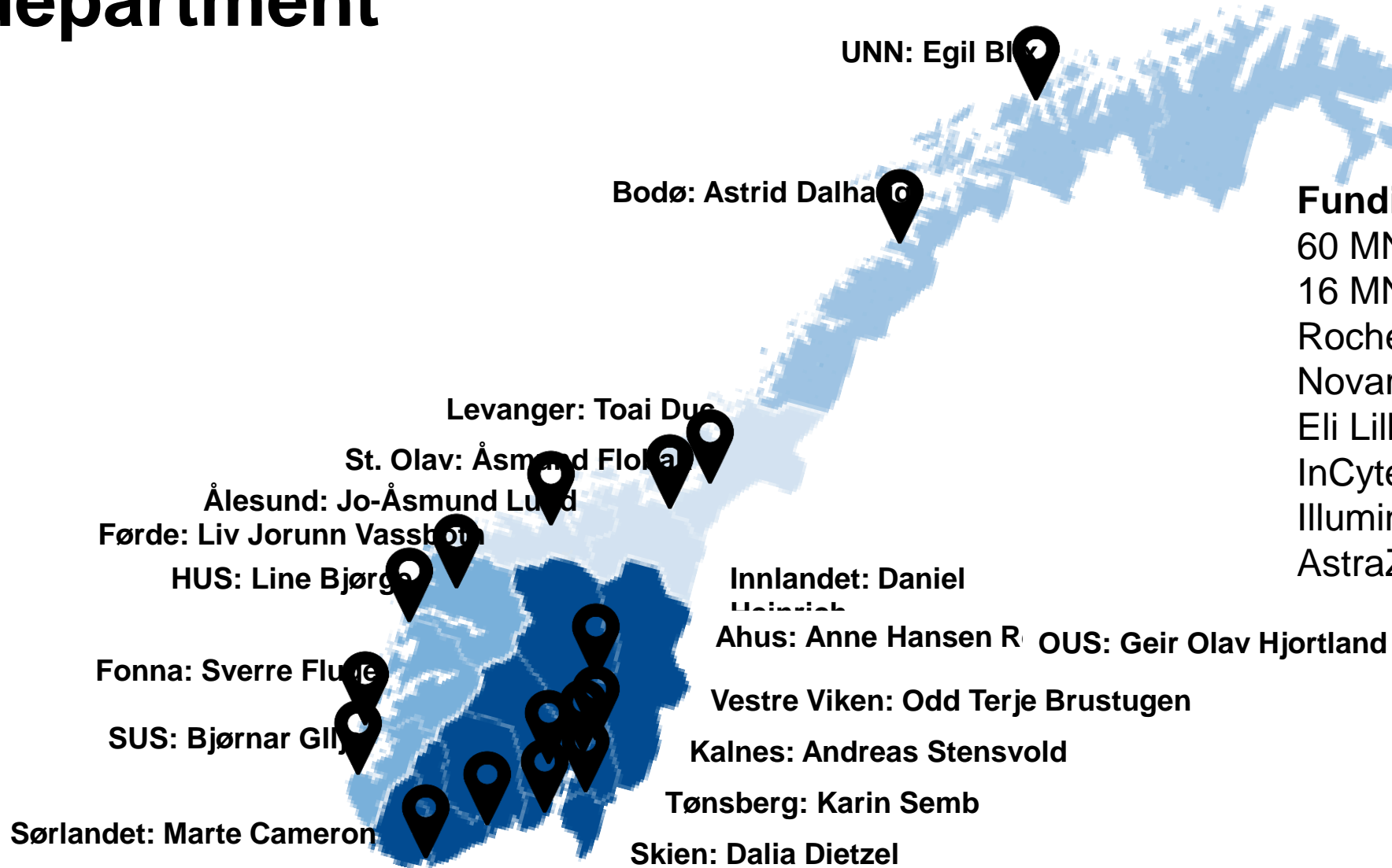


Integration into Cancer Registry of Norway



*See also Helland, Å. et al, *J. Transl. Med.* May 2022, **20**(1), 225 for description of protocol

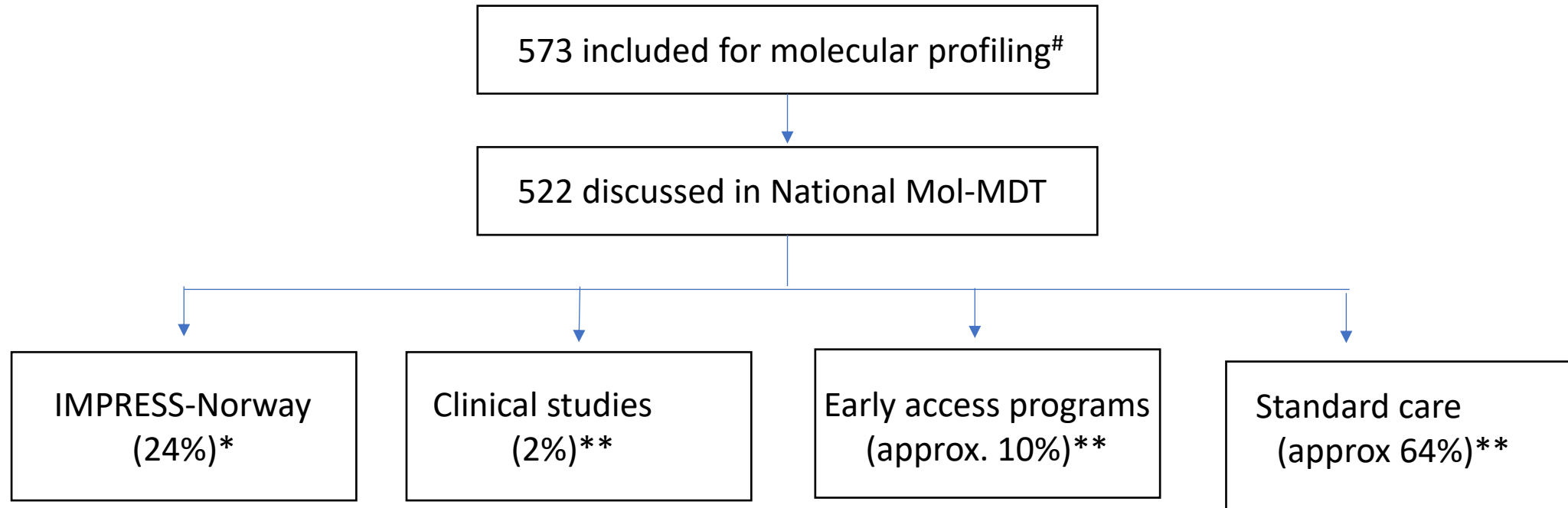
All Norwegian hospitals with an oncology department



Funding:

60 MNOK regional health authorities
16 MNOK Norwegian Cancer Society
Roche
Novartis
Eli Lilly
InCyte
Illumina
AstraZeneca

01.04.2021 – 12.10.2022



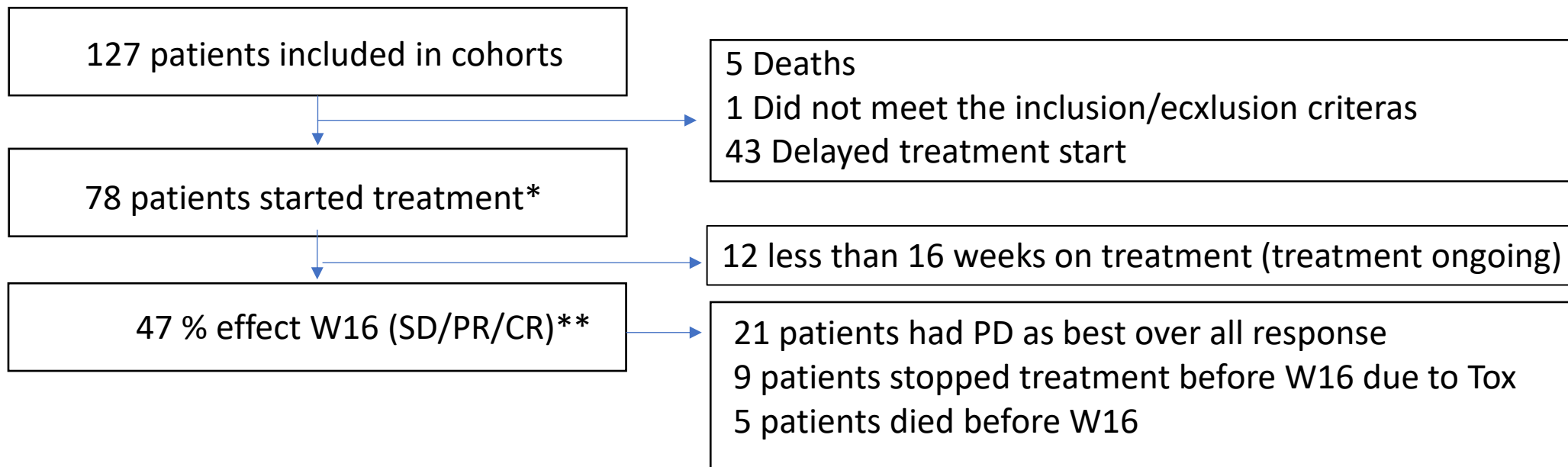
* 127 patients included in a cohort of 522 discussed in National Mol-MDT

** lag time for screening before inclusion into clinical trials and early access program giving uncertain no. of actual included.



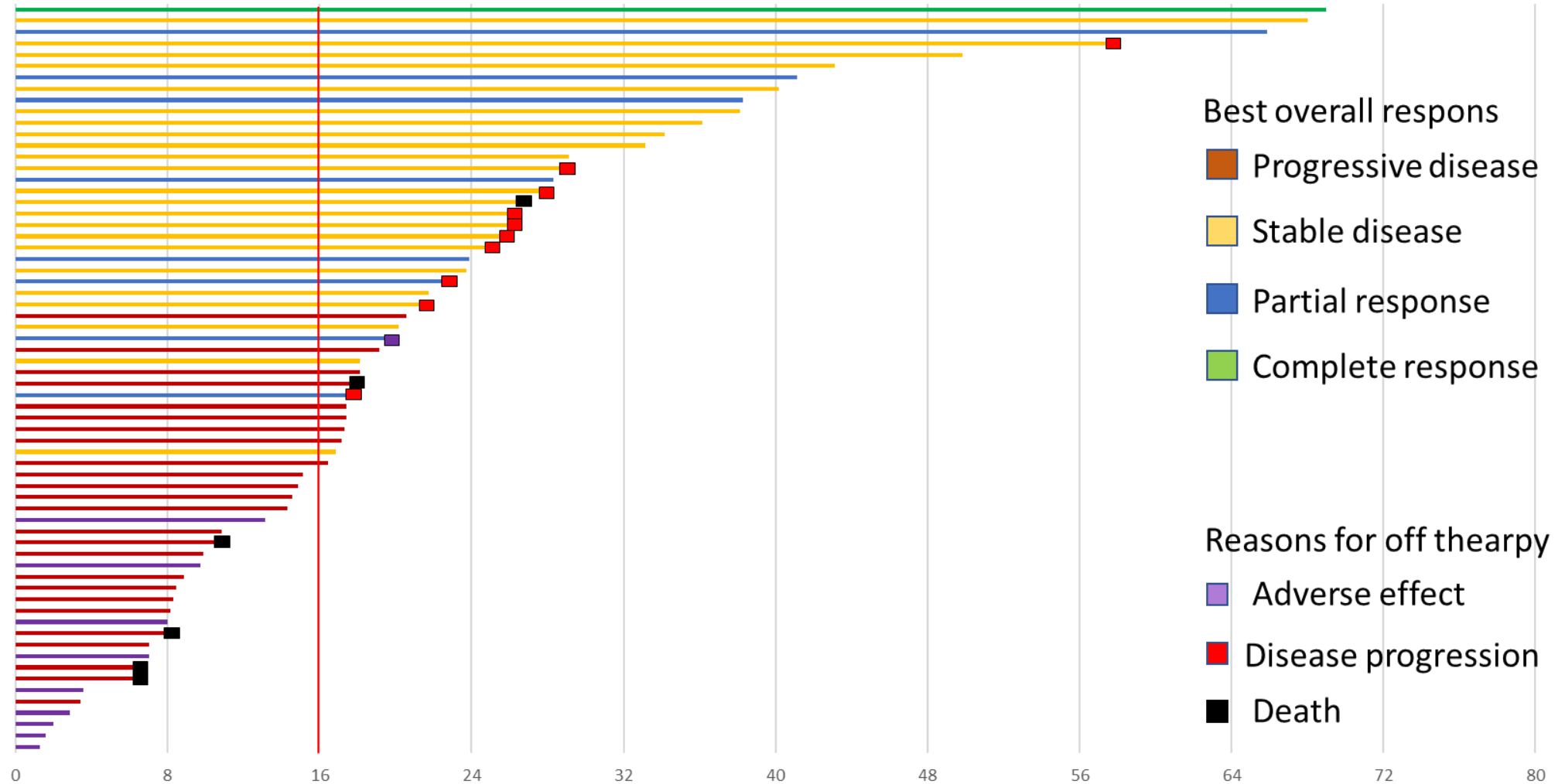
IMPRESS-Norway – in treatment

01.04.2021 – 12.10.2022



* Lag time between included into cohort and start treatment mainly due to still effect of last line of treatment.

** 31/66 patients clinical effect at W16

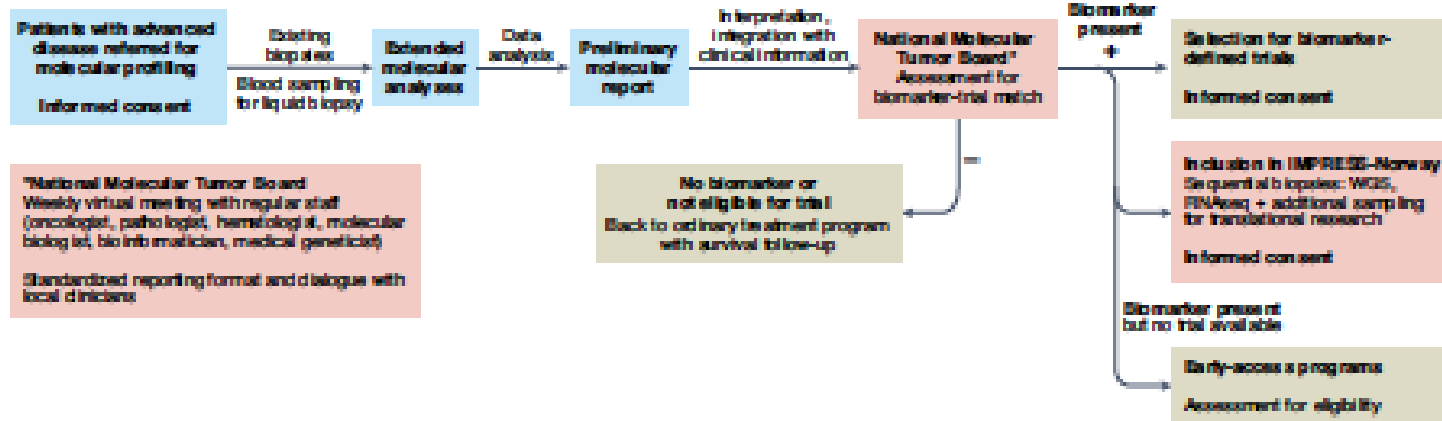


66 patients evaluated at W16. 5 patients died before W16, 9 patients stopped treatment before W16 due to toxicity and 21 patients had progressive disease as best overall response. 31/66 patients had effect according to protocol at W16. 1 patients had complete response at W16, 8 patients had partial response at W16 and 22 patients had stable disease at W16.



Nature Med. May 5th 2022

A national precision cancer medicine implementation initiative for Norway



correspondence

Table 1 | CONNECT: a public-private partnership of stakeholders in precision cancer medicine

CONNECT working-groups interfacing

InPreD (WG1)	IMPRESS (WG2)	Innovative implementation methods (WG3)	Data governance, storage and sharing for secondary use and analysis (WG4)
InPreD national testing infrastructure	IMPRESS-Norway national PCM trial infrastructure	INSIGHT-INCLUDE: Impact of precision cancer medicine health economics and regulatory framework for implementation	INSIGHT-INCLUDE legal framework; InPreD ICT solution; IMPRESS aggregation of data in Europe

CONNECT is operationalized via working groups (WG1-WG4) that engage experts from the public and private sector: p ICT, information and communications technology; PCM, precision cancer medicine.

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IMPRESS-Norway Consortium


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SPECTA platform and downstream projects

Improving the Standards of
Cancer Care via Multidisciplinary
Collaboration



Denis Lacombe · 2nd
EORTC Director General

ProTarget – a pragmatic clinical study exploring precision cancer medicine



Kristoffer Staal Rohrberg

Department of Oncology, Rigshospitalet, University Hospital of Copenhagen

Verified email at regionh.dk

[Oncology. Phase 1 trials. Pr...](#)

Questions - discussion

- How can we learn as much as possible from every patient?
- How can we collaborate and share data (consent, GDPR) – any challenges?
- Small subgroups – precision cancer medicine
- Future pragmatic trials
- Off-label use of drugs - protocols