

A national initiative for Implementing Cancer Precision Medicine in Norway: The CONNECT Public-Private Partnership

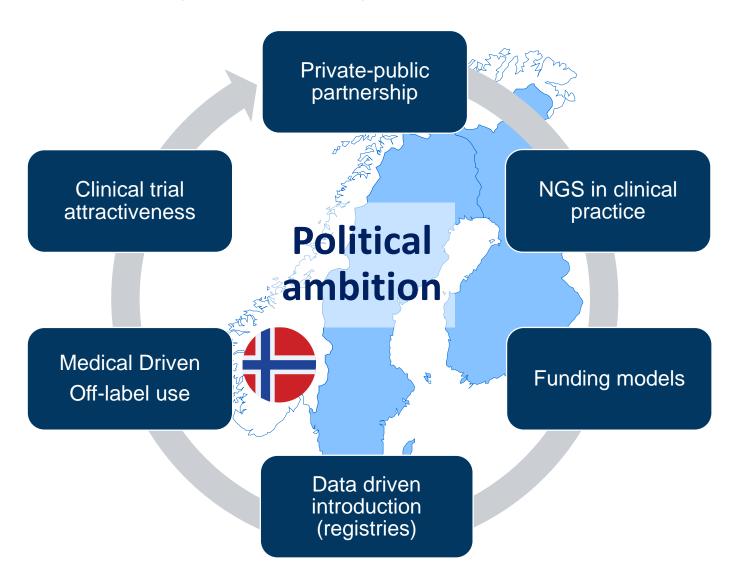
Jutta Heix, PhD
Head of International Affairs, Oslo Cancer Cluster
Project Lead CONNECT Norway







Implementing Precision Cancer Medicine in Norway: shared objectives and opportunities for public and private stakeholders



Strategic development of national, interconnected initiatives with public-private cooperation



InPreD Norway:

National <u>in</u>frastructure for <u>pre</u>cision <u>d</u>iagnostics

IMPRESS-Norway:

<u>Im</u>proving public cancer care by implementing <u>pre</u>ci<u>s</u>ion medicine in Norway

INSIGHT / INCLUDE:

Sustainable implementation of precision cancer medicine

CONNECT Public-private partnership:

Norwegian Precision Cancer Medicine Implementation Consortium

MATRIX:

<u>M</u>ultimodal <u>Approach Targeting treatment <u>R</u>efractory cancers us<u>Ing</u> ne<u>X</u>t generation technologies and trials</u>

National initiatives with public funding for increasing access to precision treatment

Molecular Diagnostics



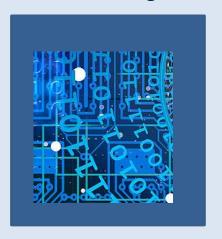
Clinical implementation



Policies & regulation

INSIGHT Impact of PCM & regulatory framework for implementation

Data handling



NEED:

- Industry interface for interaction with public initiatives
- Forum including regulators & payors for discussions of policies, reimbursement models and regulatory framework for PCM.

CONNECT as arena for all stakeholders to address key obstacles and pilot novel solutions

Molecular Diagnostics



Clinical implementation



Policies & regulation

INSIGHT
Impact of PCM &
regulatory
framework for
implementation

Data handling





Norwegian Precision Cancer Medicine Implementation Consortium



Driving the implementation of Precision Cancer Medicine

- Address key obstacles and pilot novel solutions to transform the current practice.
- An arena for all stakeholders for a balanced and informed approach and debate.
- Drive cross-functional and cross-organizational initiatives, workshops, and educational formats
- Create a **joint culture** of innovation, partnership and impact
- Consortium Agreement signed by all partners

A growing consortium gathering public, public and private partners



























































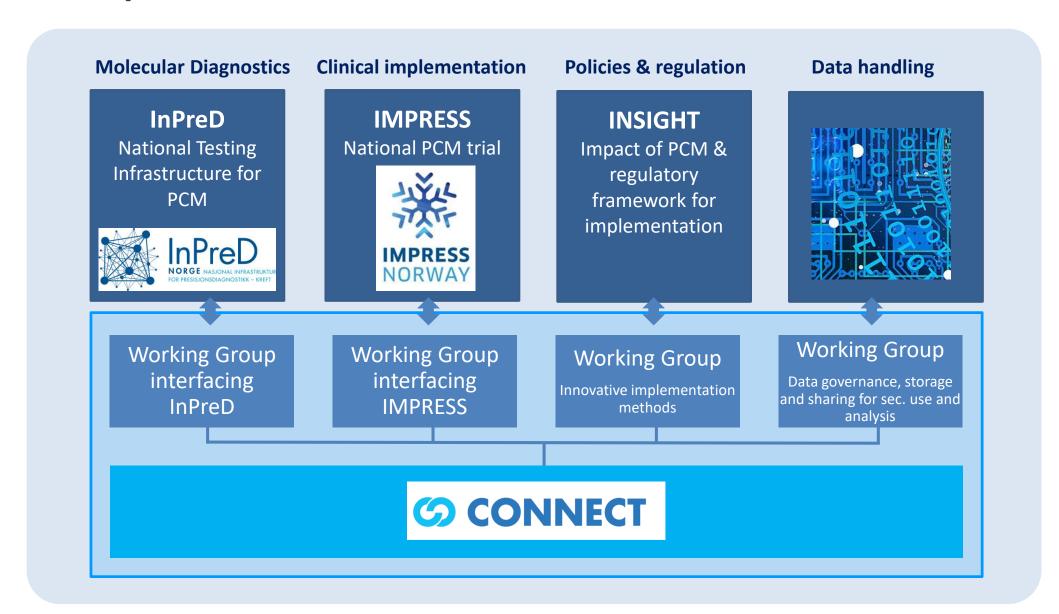








Operationalized via Working Groups engaging experts from the public and private sector...



...driving cross-functional and cross-organizational initiatives

Z

Objectives:

 Ensure a structured dialogue, information sharing and planning for PCM diagnostics implementation engaging key stakeholders



Monitor progress and learnings and address identified needs and gaps in
 PCM Trials and clinical implementation building on IMPRESs



 Identify and pilot pathways for funding and reimbursement based on new types of evidence and data sets generated in IMPRESs and PCM trials



 Review the planned data collection for InPred and IMPRESS, incl. follow-up data. Give feedback on planned data collection for expansion cohorts and further PCM implementation.



CONNECTing people and expertise

2021 - 2022:

- Monthly Working Group Meetings
- **Bi-monthly Steering Committee Meetings**
- 25 Educational Seminars and Workshops national, multistakeholder engagement



Home | CONNECT (connectnorway.org)









CONNECT seminar on Digital Pathology and

Experts from regional, national and international groups shared their perspectives on digital...



CONNECT seminar om

Nukleærmedisin Nuklearmedisin med presisjonsdiagnostikk og persontilpasset behandling...



CONNECT Seminar on Clinical Decision Support Systems Clinical Decision Support

Systems: useful for what and for whom? In his introduction. Eivin.



CONNECT seminar: The new EU regulations on IVDR -.. CONNECT seminar: The new EU regulations on IVDR - how to be prepared?



CONNECT at Arendalsuka Connect had the pleasure of participating at Arendalsuka. Here you can find the debates.

Financing and reimbursement: novel solutions needed for PCM implementation

First expansion cohort in IMPRESS-Norway

The Regional Health Authorities in Norway has recently decided to reimburse patients who are included in the first expansion cohort in IMPRESS-Norway according to the pay-for-performance model described below. IMPRESS-Norway is a precision medicine trial that tests approved drugs on new indications based on genetic changes in the patient's tumor. The study started in April last year, and so far more than 50 patients have been offered treatment (identified in the National Molecular Tumor Board among 250 patients who have undergone extended molecular profiling).

.....

Public-Public-Private partnership

The opening of the first expansion cohort in IMPRESS is an example of how important public-public-private partnerships are for precision cancer medicine. The topic of expansion cohorts has been discussed in the established partnership for precision medicine called CONNECT, where representatives from the hospitals, the industrial partners and the authorities participate. Through this collaboration all stakeholders collaborate in order to test new models for implementation of precision cancer medicine.

International recognition of national PCM implementation initiative

correspondence

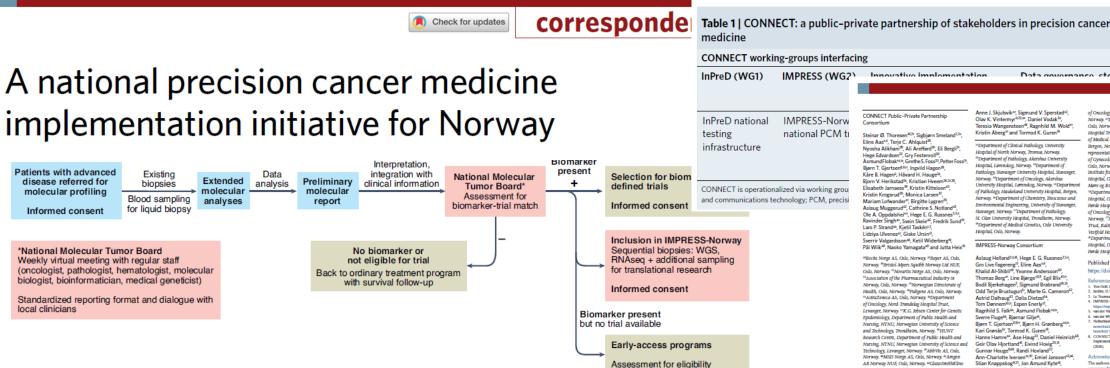


Fig. 11 InPreD allows the diagnosis and assessment of cancer patients where experimental treatment and clinical trial inclusion is an option. The national Molecular Tumor Board (MTB) is a weekly virtual meeting of a core group of healthcare professionals with broad competencies, including pathology, oncology, hematology, molecular biology and bioinformatics, as well as the referring clinician and others such as trial coordinators and local clinicians and pathologists. RNA-seq, RNA sequencing; WGS, whole-genome sequencing; +, additional treatment option identified; -, no new treatment option identified.

NATURE MEDICINE I www.nature.com/naturemedicine

Nature Medicine-Correspondence: https://www.nature.com/articles/s41591-022-01777-4

Share Link: https://rdcu.be/cM70C

CONNECT Public-Private Partnership

Innovative implementation

Steinar Ø. Thoresen R27, Sigbjørn Smeland² Eline Aas3,6, Terie C. Ahlguist2 Nyosha Alikhani³⁹, Ali Areffard³⁰, Eli Bergli³ Hege Edvardsen²², Gry Festen AsmundFlobak^{14,75}, Grethe S. Foss²², Petter Foss² Biørn T. Giertsen 1917, Ingvild Hagen 21 Käre B. Hagen⁶, Hävard H. Hauge³⁴, Biorn V. Herikstad²⁶, Kristian Hveem^{36,27,38} Flisabeth Jamaess³⁰ Kristin Kittelsen⁶ Kristin Krogsrud⁷⁸, Monica Larsen³² Mariam Lofwander^{et}, Birgitte Lygren Aslaug Muggerud⁴², Cathrine S. Notland⁴ Ole A. Oppdalshei⁴⁴, Hege E. G. Russnes²³ Ravinder Singh⁴³, Syein Skeie⁴⁶, Fredrik Sund⁸ Lars P. Strand®, Kietil Taskén Lidziya Ulvenestr, Giske Ursin¹², Sverrir Valgardsson⁴⁸, Ketil Widerberg⁶ Pål Wiik⁶⁹, Naoko Yamagata⁶⁰ and Jutta Heix¹

²⁸Roche Norge AS, Oslo, Norway. ²⁸Bayer AS, Oslo, Norway. MBristol-Myers Squibb Norway Ltd NUF, Oslo, Norway, "Novartis Norge AS, Oslo, Norway, Association of the Pharmaceutical Industry in Norway, Oslo, Norway. "Norwegian Directorate o Health, Oslo, Norway, "Pubrene AS, Oslo, Norwa "AstraZeneca AS, Oslo, Norway. "Department of Oncology, Nord-Trandelay Hospital Trust Levanger, Norway. "K.G. Jebsen Center for Genei Etidemiology, Department of Public Health and Nursing, NTNU, Norwegian University of Science and Technology, Trondheim, Norway. "HUNT Research Centre, Department of Public Health and Nursing, NTNU, Norwegian University of Science and Technology Levanger, Norway, "AbbVie AS, Oslo. AB Norway NUE Oslo, Norway, "Glass/SmithKline AS, Oslo, Norway, "Pfizer Norge AS, Oslo, Norway, "Norwegian Cancer Society, Oslo, Norway. "Eli Lilly Stavanger University Hospital, Stavanger, Norway. Takeda AS. Oslo, Norway. "Janssen-Cilag AS, Oslo Norway, "Unit for Medicine and Health Sciences. Akershus University Hospital, Lørenskog, Norway SONEC Corporation, Tokyo, Japan,

InPreD-Norway and National Molecular Tumor Board Consortium

Hege E. G. Russnes^{23,4}, Thomas Berg¹¹, Egil S. Blix^{10,tt}, Diana L. Bordin³⁶ Hans-Rickard Brattbakk⁷², Richard Doughty^a Kari Ersland²², Asmund Flobak^{14,to} Rakel Forthun²², Bigrnar Gilie⁴⁶, Einar Gudlaugsson⁶³, Hanne Hamre⁶ Hans Kristian Haugland^{22,30}, Eivind Hovig²⁰ Randi Hoyland? Emiel Janssen?36 Mari Jebens³⁷, Tonie Lien^{7,4}, Susanne Lorenz orben Lüders26, Leonardo A. Meza-Zepeda20,2 Hilde I Nilsen^{2,36} John C Noone²⁶ Vigdis Nygaard², Ulla Randen^{2,2}, Anne Renolen²,

Anne J. Skjulsvik^{sy}, Sigmund V. Sperstad^{s3}, Olav K. Vintermyr^{Q,72,50}, Daniel Vodak²⁶, Teresia Wangensteenst Ragnhild M. Woldst

Kristin Åberg[™] and Tormod K. Guren[®] Department of Clinical Pathology, Universit Hospital of North Norway, Tromsa, Norway, Department of Pathology, Akershus University Hospital, Lørenskog, Norway. 31Department of Pathology, Stavanger University Hospital, Stavanger University Hospital, Larenskog, Norway. "Departmen of Pathology, Haukeland University Hospital, Bergen, Norway. "Department of Chemistry, Bioscience and Environmental Engineering, University of Stavanger Stavanger, Norway, 37 Department of Pathology, St. Olav University Hospital, Trondheim, Norway. Hospital, Oslo, Norway.

IMPRESS-Norway Consortium

Gro Live Fagereng^{ci}, Eline Aas^{3,6}, Khalid Al-Shibli³⁰, Yvonne Anderssor Thomas Berg¹⁶, Line Bjørge^{18,9}, Egil Blix⁸ Bodil Bjerkehagen³, Sigmund Brabrand^{48,26} Odd Terie Brustumun⁶¹ Marte G. Cameron⁶ Astrid Dalhaug⁶³, Dalia Dietzel⁶ Raenhild S. Falk®, Asmund Flobak® Sverre Fluge⁶⁶, Biørnar Gilie⁶⁶, Bjørn T. Gjertsen 8,917, Bjørn H. Grønberg 14,10 Kari Grønås⁶⁷, Tormod K. Guren⁵⁸, Hanne Hamre[™], Ase Haug²³, Daniel Heinrich Geir Olav Hiortland⁴⁸, Eivind Hovig^{20,2} Gunnar House 960, Randi Hoyland 22 Ann-Charlotte Iversen^{to,10}, Emiel Janssen Stian Knappskog^{9,23}, Jon Amund Kyte⁴⁸, Hedda von der Lippe Gythfeldt[©]. Kristina Lindemann²¹, Ragnhild A. Lothe² Jo-Asmund Lund⁷³, Per Eystein Lønning^{9,23} Leonardo Meza-Zepeda^{20,28} Monica C. Munthe-Kaas™ Olay T. D. Nguyen36, Pitt Niehusmann Hilde L. Nilsen²³⁶, Katarina Puco²⁶, Ulla Randen^{2,12}, Anne H. Ree^{2,14}, Tonie B. Ristr Karin Semb≪, Eli Sihn S. Steinskog² Andreas Stensvold", Pål Suhrkert Øyvind Tennøe", Geir E. Tjønnfjord2 Liv J. Vassbotn⁸⁰, Sissel F. Wahl³⁷ Kietil Taskén^{1,2} and Sigbiørn Smeland²

Department of Pathology, Nordland Hospital Trust, Bodø, Norway. 46 Southern and Eastern Norway Pharmaceutical Trust, Oslo, Norway, "Department of Oncology, Vestre Viken Hospital Trust, Drammen, vay. "Department of Oncology, Hospital of Southern Norway, Kristiansand, Norway Department of Oncology, Nordland Hospital Trust, Bodø, Norway. "Department of Oncology, "Oslo Centre for Biostatistics and Epidemiology, Oslo University Hospital, Oslo, Norway. 44 Department

of Oncology, Fonna Hospital Trust, Haugesund, Norway #7IMPRESS-Norway Patient representativ Oslo, Norway. "Department of Oncology, Innlandet Hospital Trust, Brumunddal, Norway. "Departmen of Medical Genetics, Haukeland University Hospital Bergen, Norway. **IMPRESS-Norway Pattent of Gynecological Oncology, Oslo University Hospital, Oslo. Norway, 72 Department of Molecular Oncology, Hospital, Oslo, Norway. "Department of Oncology Møre og Romsdal Hostital Trust, Ålesund, Norwa **Department of Pediatric Medicine, Oslo University Hospital, Oslo, Norway. Department of Pathology Førde Hospital Trust, Førde, Norway. **Departm of Oncology, Vestfold Hospital Trust, Tunsberg, Norway, "Department of Oncology, Ostfold Hospita Trust, Kalnes, Norway. "Department of Pathology Vestfold Hospital Trust, Tønsberg, Norway.

Aslaug Helland^{2,0,18}, Hege E. G. Russnes^{2,3,4}, Published online: 05 May 2022

Data governance storage

Førde Hospital Trust, Førde, Norway,

- Von Hoff, D. D. et al. J. Clin. Oncol. 28, 4877-4883 (2010). Jardim, D. L. et al. J. Natl. Cancer Incl. 107, dy/253 (2015)

*Department of Haematology, Oslo University

Hospital, Oslo, Norway. *Department of Oncology

https://doi.org/10.1038/s41591-022-01777-4

- https://mprcue-nerway.no/ (2021).
 5. van der Velden, D. L. et al. Nather 574, 127-131 (2019).
 6. van der Wijnguart, H. et al. Câre. Cârear Res. 27, 6106-6114 (2027).
 7. Netherlands Cancer Institute. https://www.ndd.nl/news-eventu/ scwoldsich-nordic-alliance-for-precision-cancer-medicir
- 8. CONNECT. Norwegtan Career Precision Medicine

The authors are grateful for public funding to the precision The authors are grateful for public tunding to the precisi cancer medicine ecosystem from the Regional Health Authorities for South-Eastern, Western, Middle and Northern Norway, the Norwegian Clinical Treatment Research Programme (KLINBEFORSK), the Norwegian Cancer Society, the Nordic Trial Alliance/NordForsk, the well as company contributions received so far from Roche Novartis, Eli Lifly, Incyte and collaboration protects with oche Foundation Medicine and Illumina. The Norwegi Medicines Agency represented by Marit Hystad participal in CONNECT as an observer

K.T. wrote the manuscript and integrated edits from other authors. Important discussions and contributions to the initiatives described were made by all authors. All authors have approved the final version of the text.

Participation in the CONNECT Public-Private Partnership

ts regulated by a consortium agreement that handles conflicts of interest and regulates interaction with the publicly funded infrastructure InPreD-Norway and th -initiated and publicly funded trial IMPRES westigator-initiated and publicly funded trias anti-succe-forway. IMPRESS-Norway (principal investigator Å.H.) hr company contributions from Roche, Novertia, Incyte and El Lilly and collaboration projects with Roche Foundation Medicine and Illumina, regulated by separate agreements with Oalo University Hospital as the coordinating institution The authors declare no competing interests.



Achievements, effects and learnings so far...



CONNECT established a new model for public-public-private collaboration



Formal partnership enabled broad interaction, dialogue and collaboration



Increased expertise in and understanding of PCM across stakeholders



Changed the culture towards more trust, respect and partnership among organizations



Health economy and road to reimbursement a necessary aspect



Different needs, positions, policy and politics at multiple levels – difficult to navigate



Need to secure ownership, engagement and impact – joint goals & opportunities



Increased international recognition of Norwegian PCM Efforts

..and to build on in "CONNECT 2.0"