PRIME-ROSE

Newsletter

October 2025

Highlights

- **Multidisciplinary collaboration network:** weekly over 150 patients discussed in MTBs, ensuring a robust and dynamic patient pool.
- **Network-wide patient enrollment:** over 1 000 patients have been included in combined cohorts
- **Continuous Data Sharing:** monthly Cohort Merging facilitating continuous research and collaboration within trials under Data Sharing Agreement
- **Optimal statistical approach:** best practices for ongoing analyses using OMOP model following Simon two-stage design for cohort progression.
- **Combined Cohorts:** 374 active shared cohorts from which 23 cohorts expanded, 4 cohorts already completed, and first stage 3 cohort opening this year. Showcasing of extensive participation and data availability.
- **Exploring RWE, reimbursement and cost-effectiveness models:** various subtasks utilizing different models for optimal analyses from combined data.
- **Moving to earlier treatment lines and regulatory timepoints:** allowing drugs also in the late state development
- **Active in all levels:** Community Advisory Board has suggested tools on hrQoL.

Reasons to engage and connect

- **Single point of entry and joint negotiations – one contract – whole consortium**

  - Alignment on biomarker definition and establishment of tests

  - Floating treatment slots between trials–competitive recruitment

  -Effective tool for the industry partners and investigators to initiate novel, molecularly defined DLCT cohorts with reach across Europe-potential backbone for other trials.

- **Open for inclusion of drugs in earlier lines**

  – inclusion of drugs before FDA/EMA approval with sufficient safety data

  – new biomarkers and alignment in trials

- **Diagnostics and Treatment Alignment**

  – merging aligned diagnostic data for better coherence and efficiency

  – innovative statistical analyses

  – initiatives to enhance patient care in European wide cluster diagnostics and treatment

- **Collaborative Projects and Investments**

  – Various initiatives to build diagnostic capacity (PCM4EU, WIDERA, WHO, EP PerMed calls, JA on PCM Implementation

PRIME-ROSE

Internal Newsletter

October 2025

DLCT Activities during ESMO 2025

- **MINI ORAL SESSION**

Saturday 18 October, 08:30–10:00
1140MO – Clinical benefit of genomic-guided targeted therapies in patients with rare cancers: First results from the IMPRESS-Norway trial – *Katarina Puco (Oslo, Norway)*

- **PROFFERED PAPER SESSION: POLICY**

Saturday 18 October, 14:45–16:15
2273O – Routes for access to off-label treatments: a comparative analysis of 19 European countries – *Atse Huisman (Leiden, Netherlands)*

- **YOUNG ONCOLOGISTS BRUNCH 2**

Sunday 19 October, 10:30–11:15
Drug repurposing trials: What are they and where are they going? – *Kjetil Taskén (Oslo, Norway)*

- **POSTER PRESENTATIONS**

Sunday 19 October, 12:00-12:45

989P – Efficacy of molecularly matched, targeted therapies outside current drug indications: Results from the first 301 patients treated in the ProTarget Trial – *Tina Kringelbach*

Monday 20 October, 12:00-12:45

149P – Circulating tumor DNA versus tissue profiling for therapy selection in advanced cancer: Results from the IMPRESS-Norway trial – *Ingrid Dyvik*

162P – Nationwide implementation of comprehensive genomic profiling in advanced cancer: The first 1,740 patients included in the IMPRESS-Norway profiling phase – *Ingrid Dyvik*

165P – Diversity in Treatment Benefit between Adolescents and Young Adults (AYAs) and Older Adults (OA) treated in the Drug Rediscovery Protocol (DRUP) – *Soemeya F. Haj Mohammad*

2293P – High Off-Label Use in Paediatric Oncology: A Need for Policy Reform – *Sahar B. Van Waalwijk van Doorn-Khosrovani*

- **PROFFERED PAPER SESSION: AI & DIGITAL ONCOLOGY**

Monday 20 October, 16:30–18:00
3137O – IMPRESS-Norway: A Nationwide Precision-Oncology Study for Off-Label Targeted Therapies: Results From the First 1,740 Patients *Sigmund Brabrand (Oslo, Norway)*

Publication and podcasts

- Nature reviews drug discovery "Accelerating precision oncology by converging pragmatic trials and real-world evidence" March 2025
- Acta Oncologica "PCM4EU and PRIME-ROSE: Collaboration for implementation of precision cancer medicine in Europe May 2024
- Podcasts for PCM implementation:
  - –PRIME-ROSE: The EU's DRUP Trial Champion
  - – The Prime Rose Project and Off-Label Drug
  - – Expanding Oncology Treatments

PRIME-ROSE

Introduction to PCM projects

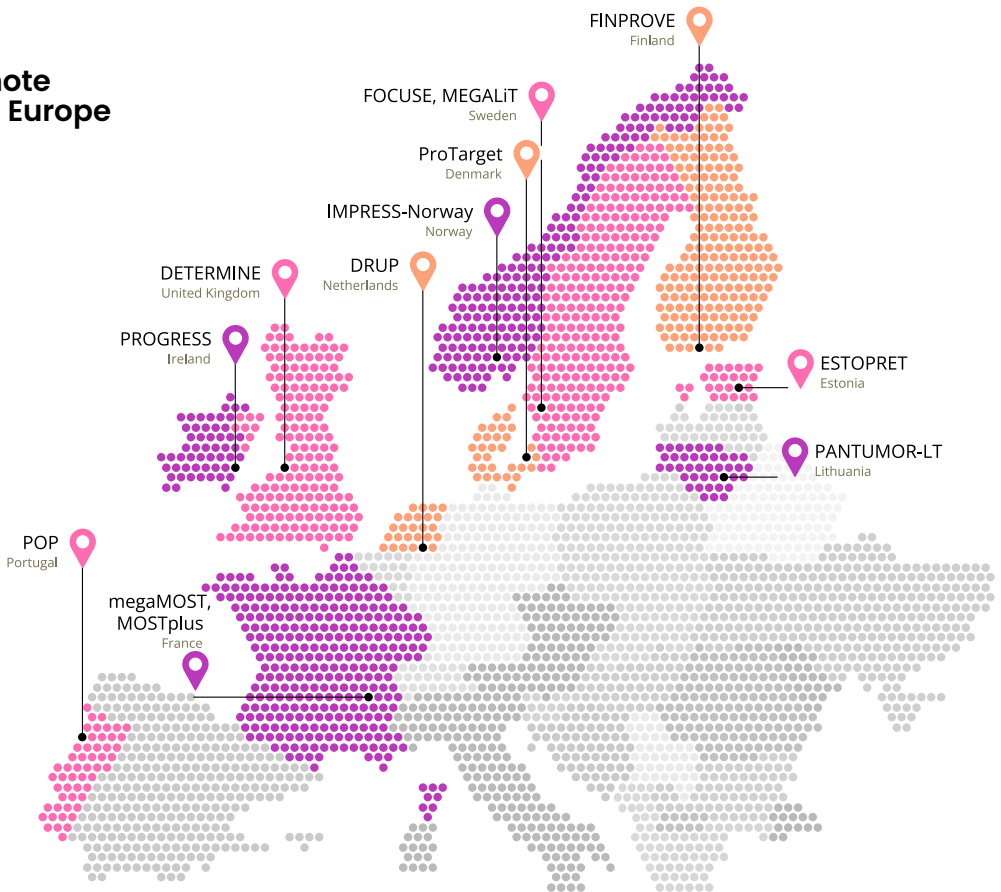
PROJECT	INTRODUCTION	LINKS
PRIME-ROSE Funded by the European Union Grant no. 101104269	PRIME-ROSE, Precision Cancer Medicine Re-purposing System Using Pragmatic Clinical Trials, is a Horizon Europe Mission on Cancer project with 28 partners from altogether 19 European countries. Moreover, PRIME-ROSE is part of the Cancer Mission cluster of projects on Diagnosis and Treatment.	https://www.prime-rose.eu/
PCM4EU Co-funded by the European Union Grant no. 101079984	Combining expertise across borders to promote Precision Cancer Medicine in Europe. The PCM4EU is a project under Europe's Beating Cancer Plan by EU4Health, with partners from 15 countries across Europe.	https://www.pcm4eu.eu/
Joint Action Personalized Cancer Medicine (JA PCM) (EC Ref. Ares (2025) 27238 83)	JA PCM is an EU program aiming to start Q3-2025. The consortium involves 146 partners from 29 EU countries. The JA PCM aims to integrate medical care and public health interventions to benefit cancer patients and the wider population and will focus on three areas: • personalised prevention and early detection • personalised medicine including advances in diagnosis and treatment • personalised follow-up and tertiary prevention PRIME-ROSE is actively involved	This joint action will support the Europe's Beating Cancer Plan objective to ensure high standards in 'Cancer diagnostic and treatment for all' and implements the EU4Health Programme's general objective of improving and fostering health in the Union. Direct grants to Member States' authorities: Personalised Cancer Medicine (CR-g-24-41)

PRIME-ROSE

combining expertise to promote Precision Cancer Medicine in Europe

Overview of current ongoing national DRUP-like clinical trials in PRIME-ROSE:
- DRUP, The Netherlands
- ProTarget, Denmark
- IMPRESS-Norway
- FINPROVE, Finland
- FOCUSE (former MEGALiT), Sweden
- megaMOST, MOSTplus, France
- DETERMINE, UK

Planned national DRUP-like clinical trials in PRIME-ROSE
- POP, Portugal
- PROGRESS, Ireland
- ESTOPRET, Estonia
- PANTUMOR-LT, Lithuania



Contacts

PROF. KJETIL TASKEN

Prof. Kjetil Taskén is leading PRIME-ROSE together with Hans Gelderblom. He is the Head and Director of Institute of Cancer Research at Oslo University Hospital and Professor at Institute for Clinical Medicine, University of Oslo. Prior working as Professor in the field of Biochemistry and Molecular Medicine. He has been co-building the IMPRESS-Norway trial and ecosystem.

PROF. HANS GELDERBLOM

Prof. Hans Gelderblom is the co-leader of the PRIME-ROSE. He has been leading the department of Medical Oncology in the Leiden University Medical Center for almost 15 years. He is one of the DRUP-trials coordinating investigators and has therefore a long experience in the field of precision cancer medicines.

DR. GRO LIVE FAGERENG

Dr.Live Fagereng is the project manager for the EU project PRIME-ROSE. She has PhD from Oslo University in the field of Cellular and Molecular Biology and has worked both in private and public field and concentrated the latest six years in the field of precision cancer medicine.