Press Release: PRIME-ROSE: PRecisIon Cancer MEdicine RepurpOsing System Using Pragmatic Clinical Trials

PRIME-ROSE - A European precision cancer medicine trial network and implementation initiative funded by the EU Cancer Mission

The European Commission on 24 April 2023 approved the project *Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials*, PRIME-ROSE. The project will officially start 1 July 2023 and is funded by the European Commission Horizon Europe Mission on Cancer (grant no. 101104269) with 5.969 mill EUR. PRIME-ROSE will run for five years (2023 – 2028). The consortium consists of altogether 24 partners, including nine beneficiaries and fifteen associated partners. In addition, PRIME-ROSE is part of the Cancer Mission cluster of projects on Diagnosis and Treatment.

Sustainable and affordable precision cancer medicine across Europe

The PRIME-ROSE vision is access to affordable Precision Cancer Medicine (PCM) that prolongs life at the best quality possible for all cancer patients. PCM is an approach that depends on access to adequate molecular diagnostics and drugs to have impact and move towards implementation in the national healthcare systems. Today there is inequality in access to PCM between and within EU countries, and while the promise of PCM is clear, implementation remains a challenge. This in particular affects cancer patients with the poorest prognosis who have exhausted all lines of standard of care treatment, those with tumours carrying rare mutations and patients with carcinoma of unknown primary.

The PRIME-ROSE project builds on a bottom-up, clinician-initiated family of PCM clinical trials which have been particularly successful in bringing up inclusion rates to offer additional lines of treatment and in providing patient benefit. These trials share the pragmatic clinical trial design of the original Dutch DRUP trial, with broad inclusion criteria and a limited set of endpoints. However, the trials are still anchored into national context and are funded independently. The result is a distributed DRUP-like clinical trial network that addresses local priorities while collaborating internationally for scale and impact.

Work to be done in PRIME-ROSE moving PCM forward in Europe

The consortium will use these existing adaptive and pragmatic clinical trial platforms to answer key questions regarding clinical effectiveness, provide health-economic evaluations, and contribute to scientific progress across cancers. In particular, the cross-country collaboration provided by PRIME-ROSE will build capacity as well as enable cross-trial data aggregation and analysis, initiate shared cohorts across borders and provide health-economic evaluations. To ensure successful implementation, the consortium will work together with regulators, policymakers, payers, healthcare providers and patient advocacy groups to implement evidence-based PCM in routine practice and address inequalities in access.

Altogether, this Europe-wide precision cancer medicine deployment will address key scientific and methodological questions to accelerate broad and equitable access to new and effective cancer treatments. The ongoing effort is already leading to harmonization, standardization, and pragmatic consensus.

Pan-European precision cancer medicine community

The pan-European PRIME-ROSE project is led by Professor Kjetil Taskén, Head of Institute for Cancer Research at Oslo University Hospital Comprehensive Cancer Centre in Norway. He is excited about the possibilities this project will enable and comments: "*On behalf of the Consortium, I can say that we really look forward to growing and developing the community of DRUP-like clinical trials, work on their impact and accelerate the implementation of precision cancer medicine across Europe. PRIME-ROSE is*

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an ambitious project only made possible by the joint efforts of my colleagues from all our twenty-four partner institutions".

PRIME-ROSE Consortium Partners:

1. Oslo University Hospital, Oslo, Norway
2. Leiden University Medical Center, Leiden, The Netherlands
3. Stockholm School of Economics, Stockholm, Sweden
4. Capital Region, Copenhagen, Denmark
5. Helsinki University Hospital, Helsinki, Finland
6. Centre Leon Berard, Lyon, France
7. IPOPORTO, Porto, Portugal
8. Region Uppsala, Uppsala, Sweden
9. The Swedish Institute for Health Economics, Lund, Sweden
10. Karolinska Institutet, Stockholm, Sweden
11. Region Skåne, Sweden
12. Heidelberg University Hospital, Heidelberg, Germany
13. Maria Sklodowska-Curie Institute of Oncology, Warsaw, Poland
14. University Hospital of Split (KBC Split), Split, Croatia
15. Tartu University Hospital, Tartu, Estonia
16. National Institute of Oncolocy, Budapest, Hungary
17. Vall D'Hebron Institute of Oncology, Barcelona, Spain
18. Center for Personalized Cancer Treatment (CPCT, DRUP trial consortium), hosted by Radboud University Medical Center, Nijmegen, The Netherlands
19. National Cancer Institute, Vilnius, Lithuania
20. Cancer Research UK, London, UK
21. University of Manchester, Manchester, UK
22. Trinity College Dublin, Dublin, Ireland
23. Masaryk Memorial Cancer Institute (MOU), Brno, Czech Republic,
24. Center for Innovation in Medicine (CIM), Bucharest, Romania - coordinating a PCM network in the Balkan states of Romania, Bulgaria, Moldova, Montenegro and Macedonia

Overview of DRUP-like trials:
https://drupstudy.nl/drupinternational/
https://impress-norway.no/en/impress-norway-front-page/

Selected Literature

DL van der Velden et al, Nature, 2019, https://www.nature.com/articles/s41586-019-1600-x

S B van Waalwijk van Doorn-Khosrovani et al, Ann Oncol, 2019, https://www.annalsofoncology.org/article/S0923-7534(19)31177-9/fulltext

J van der Haar et al, Nature Medicine , 2021, https://www.nature.com/articles/s41591-021-01448-w

H van der Wijngaart et al, Clin Cancer Res, 2021, https://aacrjournals.org/clincancerres/article/27/22/6106/671748/Patients-with-Biallelic-BRCA1-2-Inactivation

K. Taskén et al, Nature Medicine, 2022, https://www.nature.com/articles/s41591-022-01777-4