PCM4EU and PRIME-ROSE –

cross-border access to pragmatic precision medicine trials

Bettina Ryll MD/PhD
Stockholm School of Economics Institute for Research and Melanoma Patient Network Europe
12th April 2024, Brussels

PCM4EU
Personalised Cancer Medicine for all EU Citizens

PRIME-ROSE
Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials

Funded by the European Union

DLCTs- DRUP-Like Clinical Trials

Family of independent, investigator-initiated, pragmatic clinical trials in precision medicine inspired by the design of the original DRUP protocol.

Letter | Published: 30 September 2019

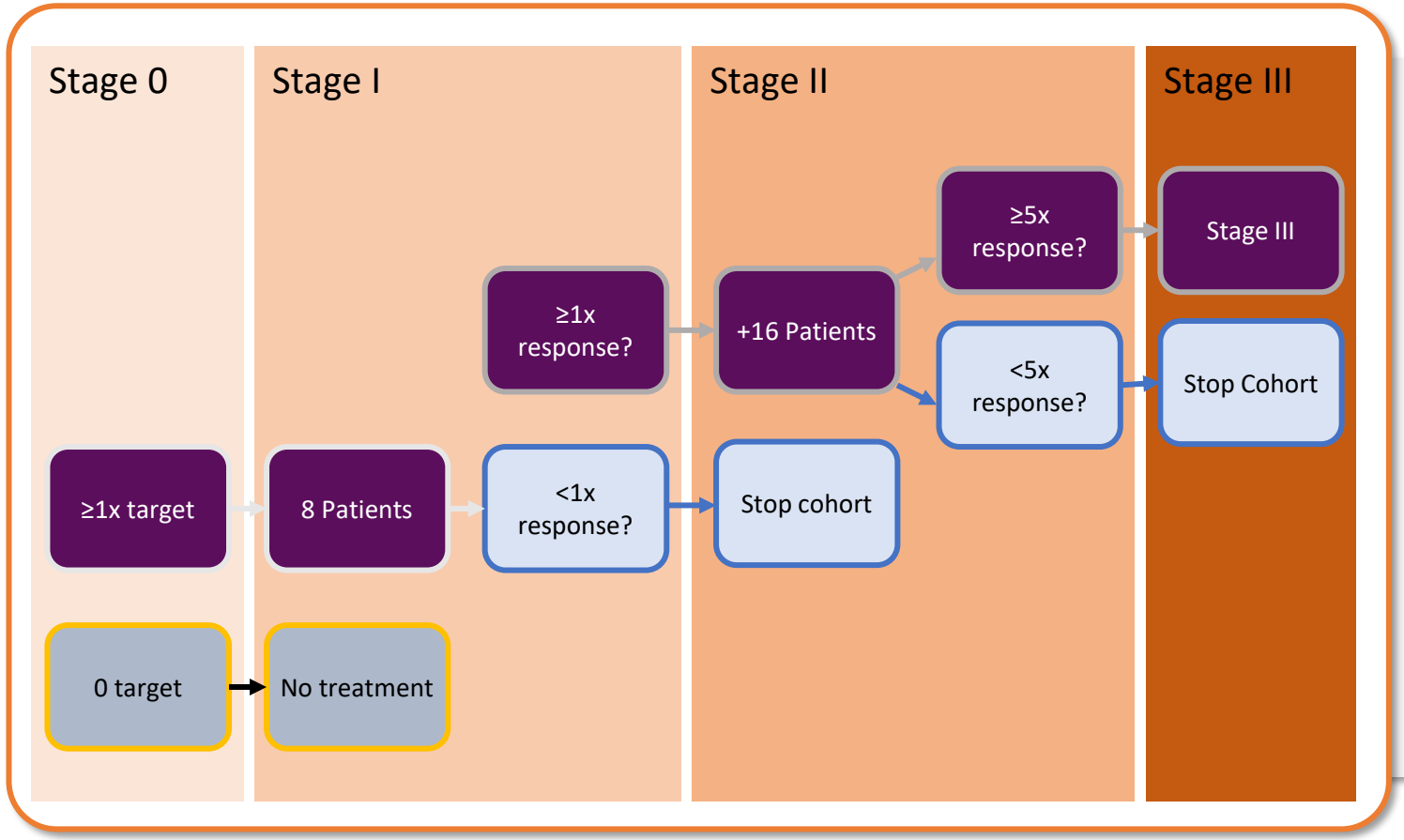
The Drug Rediscovery protocol facilitates the expanded use of existing anticancer drugs

D. L. van der Velden, L. R. Hoes, H. van der Wijngaart, J. M. van Berge Henegouwen, E. van Werkhoven, P. Roepman, R. L. Schilsky, W. W. J. de Leng, A. D. R. Huitema, B. Nuijen, P. M. Nederlof, C. M. L. van Herpen, D. J. A. de Groot, L. A. Devriese, A. Hoeben, M. J. A. de Jonge, M. Chalabi, E. F. Smit, A. J. de Langen, N. Mehra, M. Labots, E. Kapiteijn, S. Sleijfer, E. Cuppen, ... E. E. Voest + Show authors

Nature **574**, 127–131 (2019) | Cite this article

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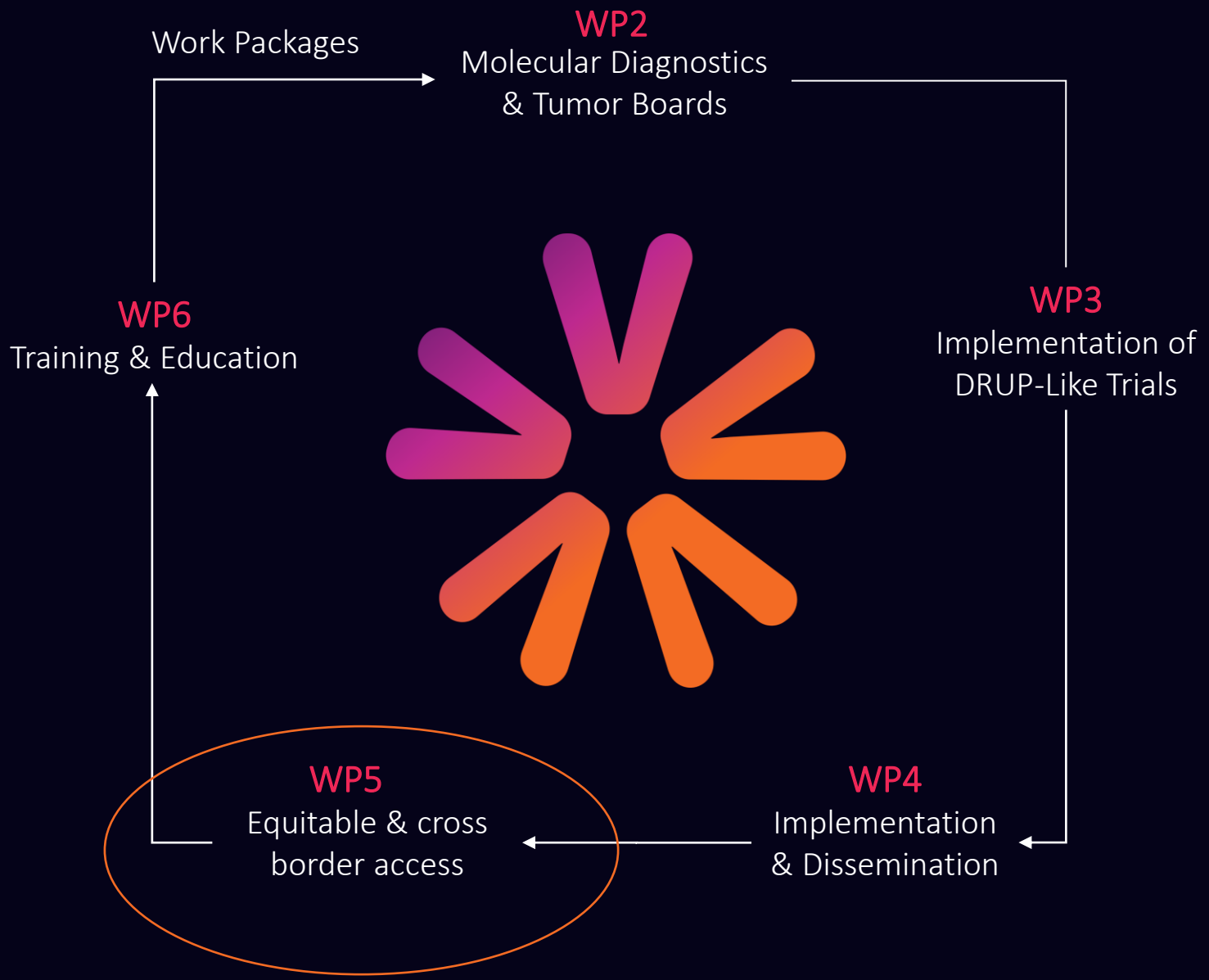
Shared DRUP core trial design, Simon two-stage model of expanding cohorts: Stage III ca 100 patients with rare mutations



Eligible patients with identified actionable targets with matching drug from the study drug portfolio will be included in an DLCT cohort

A cohort will consist of patients with the same indication and same actionable target.

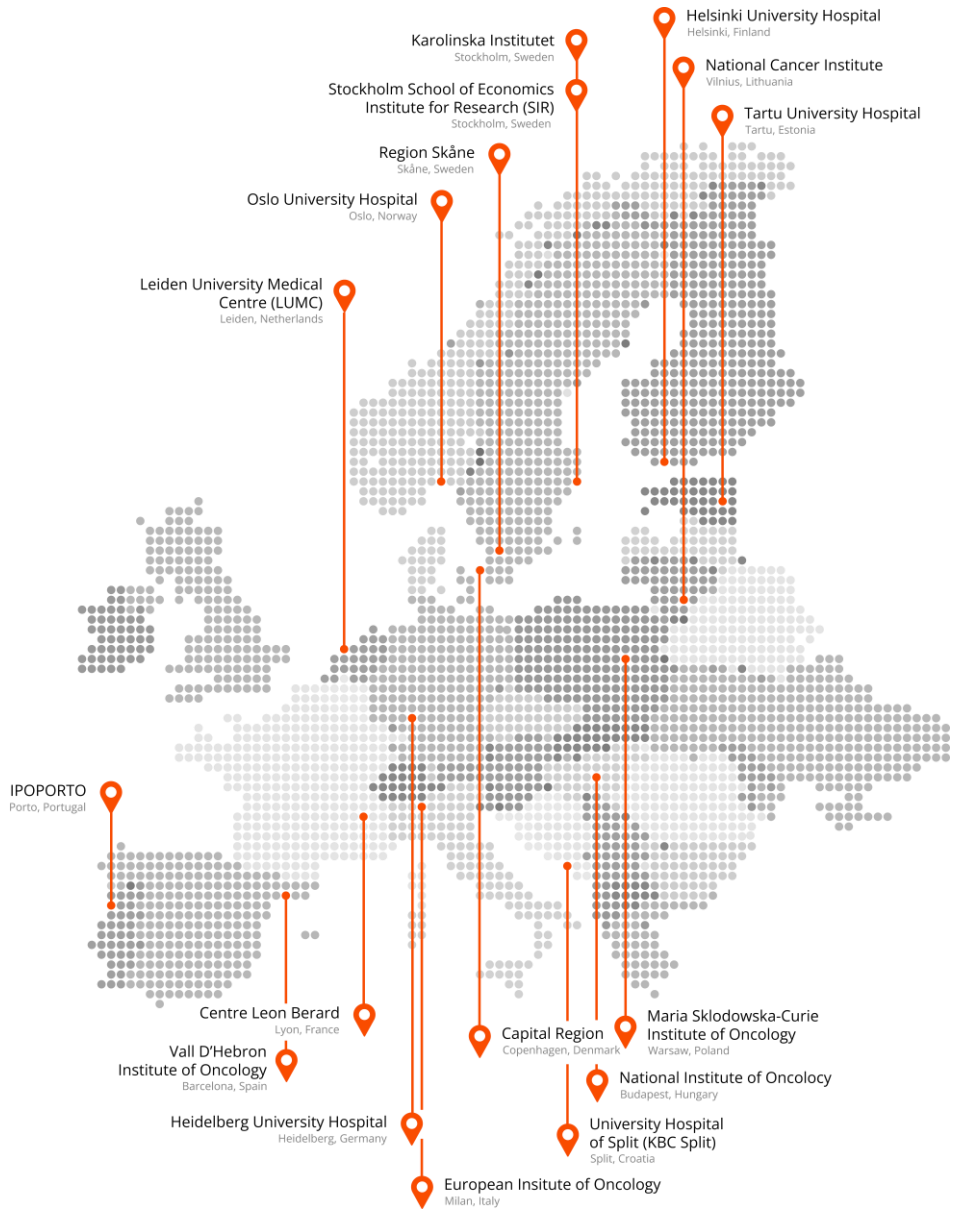
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Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials



PCM4EU

- launched in January 2023
- 24 months- end 12/2024
- 17 partners, 15 EU countries
- coordination Leiden University Medical Centre (LUMC) - **Hans Gelderblom**

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Participating Partner Sites

PCM4EU

1. Oslo University Hospital, Oslo, Norway
2. Leiden University Medical Centre (LUMC), Leiden, The Netherlands
3. Stockholm School of Economics Institute for Research (SIR), Stockholm, Sweden
4. Capital Region, Copenhagen, Denmark
5. Helsinki University Hospital, Helsinki, Finland
6. Centre Leon Berard, Lyon, France
7. IPO PORTO, Porto, Portugal
8. Karolinska Institutet, Stockholm, Sweden
9. Region Skåne, Skåne, Sweden
10. Heidelberg University Hospital, Heidelberg, Germany
11. Maria Sklodowska-Curie Institute of Oncology, Warsaw, Poland
12. University Hospital of Split (KBC Split), Split, Croatia
13. European Institute of Oncology, Milan, Italy
14. Tartu University Hospital, Tartu, Estonia
15. National Institute of Oncology, Budapest, Hungary
16. Vall D'Hebron Institute of Oncology, Barcelona, Spain
17. National Cancer Institute, Vilnius, Lithuania

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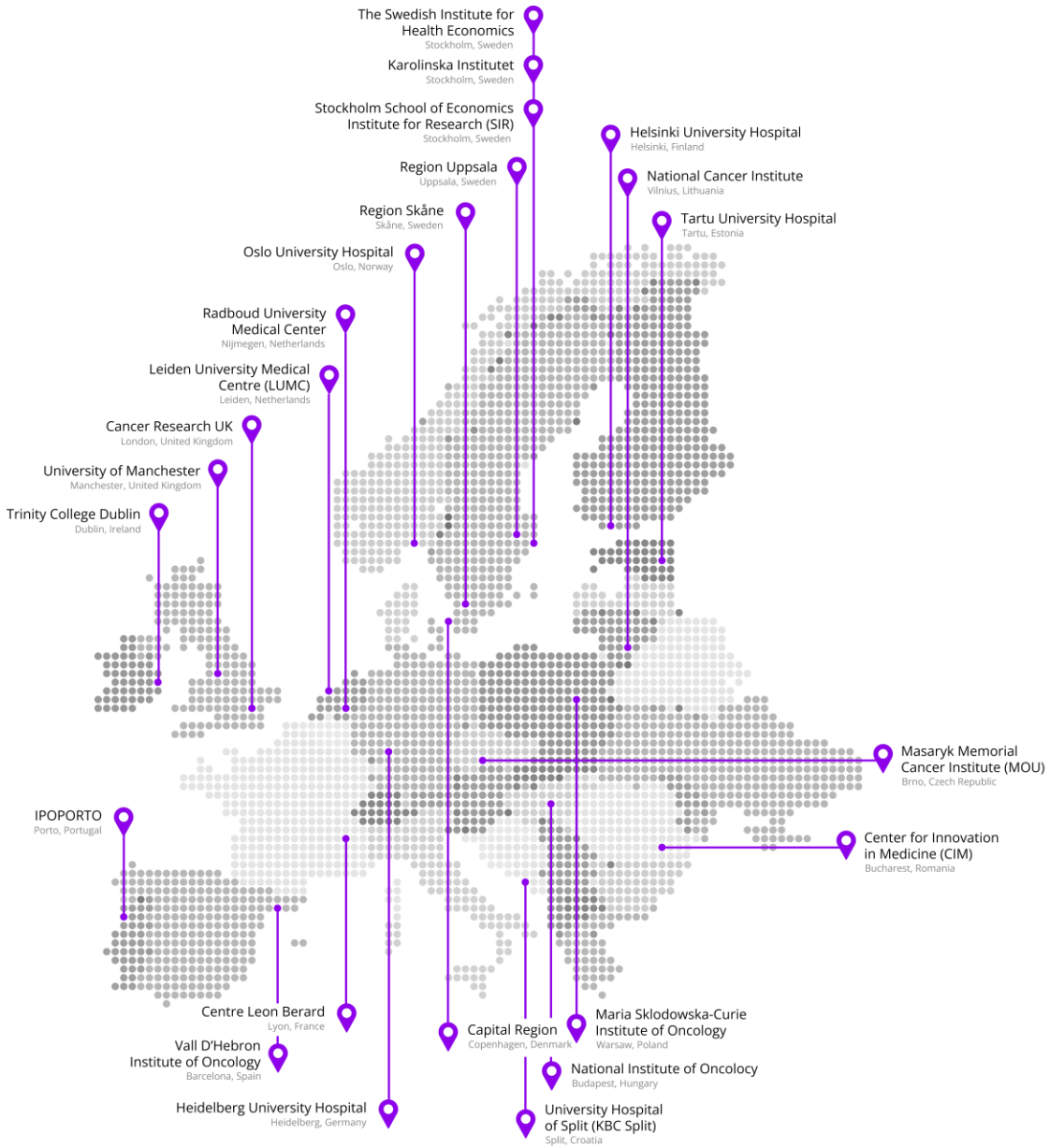
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Precision Medicine Repurposing System using pragmatic Clinical Trials

Kjetil Taskén, project coordinator, OUS Norway
30th May 2023, EMA, Amsterdam

Funded by the European Union

• HORIZON-MISS-2022-CANCER-01-03 Grant 101104269



Partner Sites

PRIME-ROSE

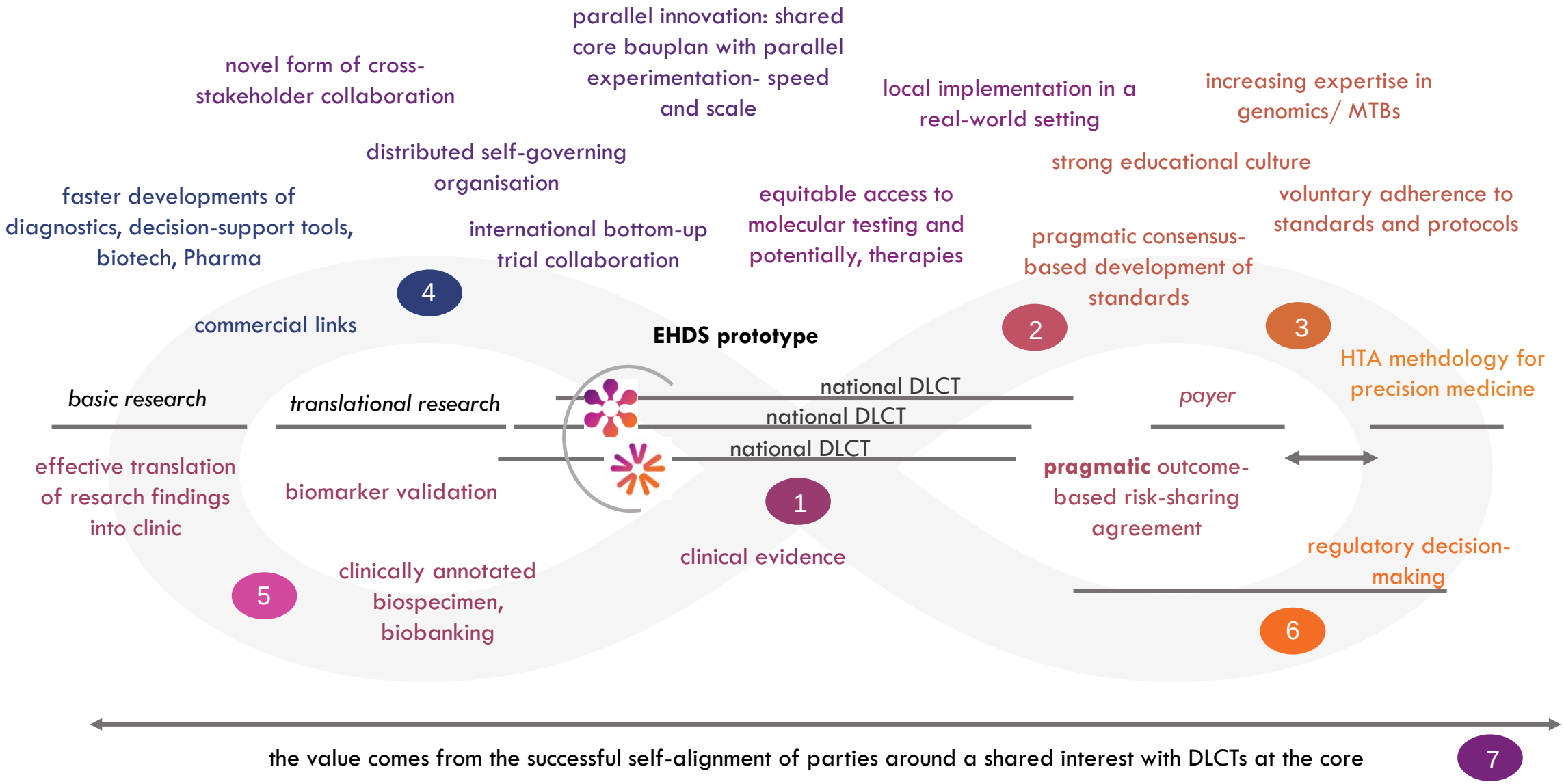
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17. Vall D'Hebron Institute of Oncology, Barcelona, Spain
18. Radboud University Medical Center, Nijmegen, The Netherlands
19. National Cancer Institute, Vilnius, Lithuania
20. Cancer Research UK, London, United Kingdom
21. University of Manchester, Manchester, United Kingdom
22. Trinity College Dublin, Dublin, Ireland
23. Masaryk Memorial Cancer Institute (MOU), Brno, Czech Republic
24. Center for Innovation in Medicine (CIM), Bucharest, Romania

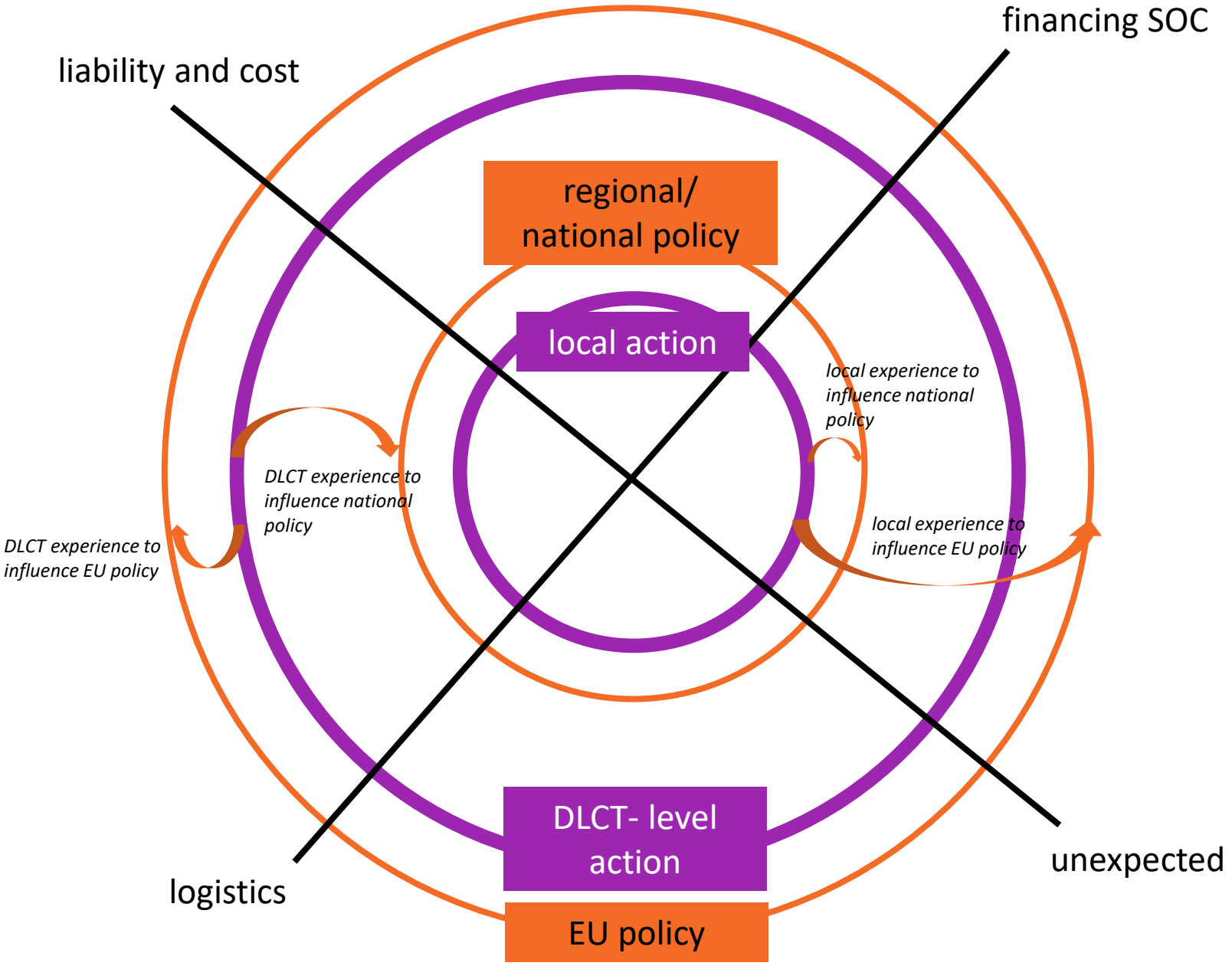
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DLCTs as open innovation systems for precision medicine implementation

Ecosystems rather than 'just' trials, building on principles of user-driven Living Labs and mission-driven innovation

A potentially self-sustaining open innovation ecosystem in precision medicine





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Mapping successful cross-border access to CTs in our clinical community

- organised and financed by the pharmaceutical industry
- paediatric oncology as success story: considerable resources available
- established pathways between two institutions across the border
- strong personal involvement of clinicians and hospitals

ongoing: collecting case studies to detect patterns (started in Denmark, now other project partners)

PCM4EU@MPNE2023









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patients fear

- cost
- burden of care
- fear to be 'lost in translation'- discontinuity in care

Summary so far

clinicians

finding suitable trials

established pathways with acceptable administrative burden, language

patients

cost, burden of care

continuity of clinical care

intransparent processes, language

hospitals

liability, unexpected costs

administrative burden, langugae

payers

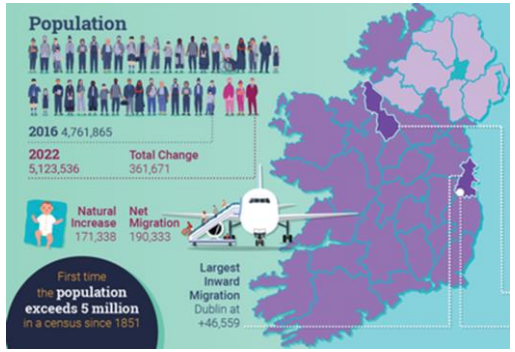
cost, predictability

administrative burden, language

Next steps

Investigate and document 3 concrete examples of successful/ ongoing cross-border clinical trial activities:

- All- Ireland
- France/ Switzerland
- Portugal/ Spain

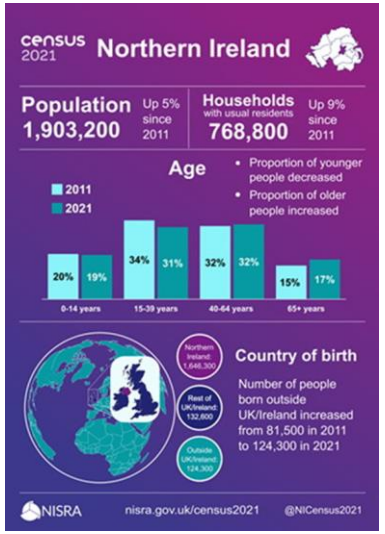


Trialing

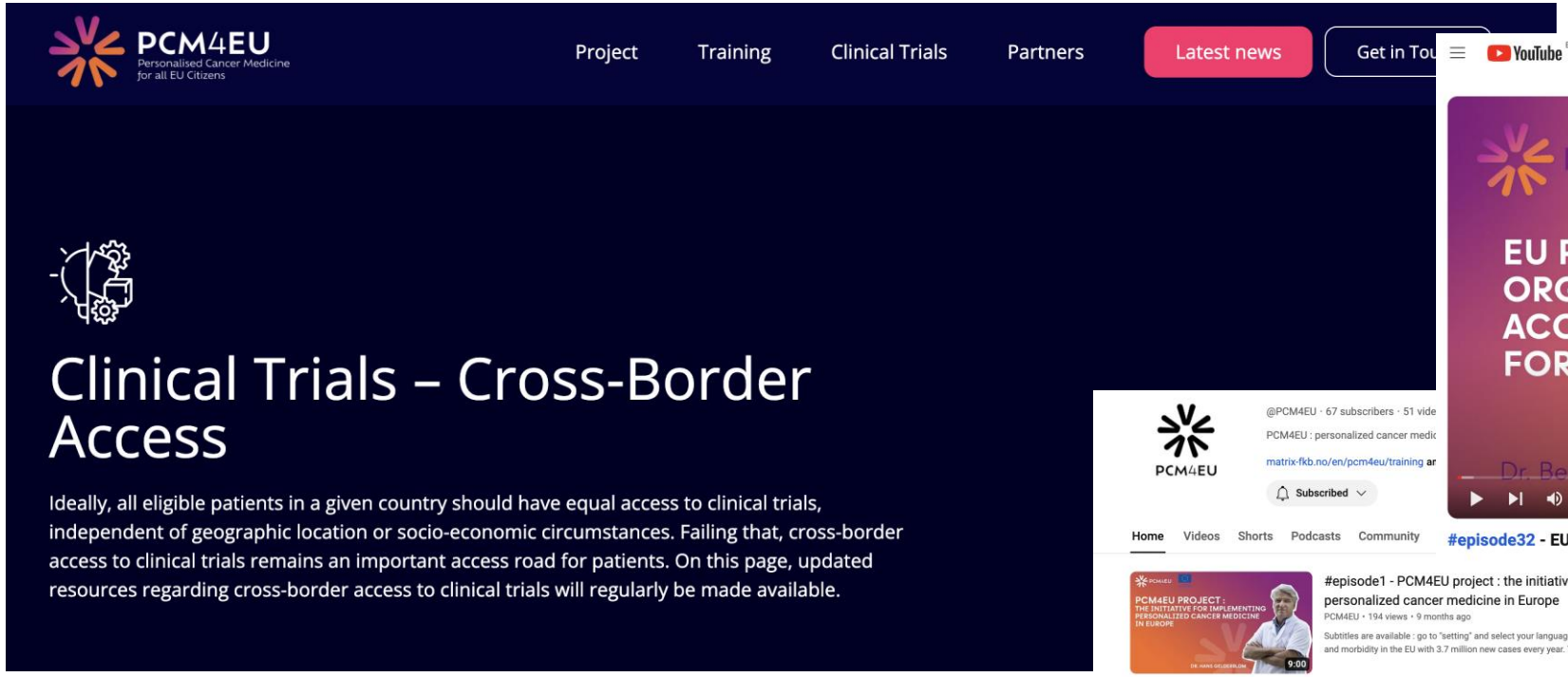
We help your physician find the right clinical trial for you

Invite your physician to Trialing so that he or she can keep up to date with all clinical trials.

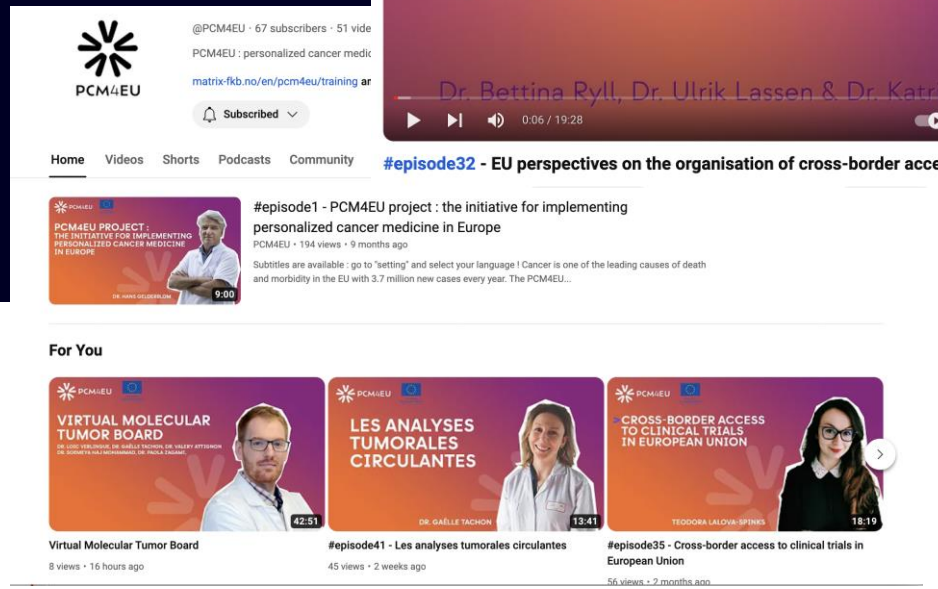
Download the instructions for your physician



Online resources







https://www.matrix-fkb.no/en/pcm4eu/clinical-trials-cross-border-access

Conclusions

- Cross-border access to clinical trials is possible and necessary
- For success, it has to work for all parties involved
- Easier between designated centres and once pathways are established
- Burden for all parties involved is considerable (but so is for all clinical trials)
- Recurrent themes- costs and who pays for them, administrative burden (also due to unclear processes), language

- **Currently reliant on motivation and proactivity of single individuals**
- **Trial to the patient better than patient to the trial BUT**
- **“Borders should no longer be barriers”**

Thank you

bettina.ryll@hhs.se

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