ESIOR

Creating insights and value for wellbeing, social, and health care organisations

What is known? What is the evidence?
Reviews and synthesis

How to support price and value?
Health economic models

How to demonstrate relative effects?
Meta-analyses, comparisons

Where to engage and demonstrate?
User interfaces, publications

How to handle data and create insights?
Data access and analysis

How to get better price and faster access?
Market landscaping & access

Complete lifecycle management of data
SPESiOR® – Secure Processing

How to harvest benefits simultaneously?
Medical device regulation

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For better health and wellbeing

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Needs: Co-operation/collaboration

”Kaipaako yrityksesi uusia avauksia yliopisto-hyvinvointialue yhteistyöhön?”

- All 3 companies I discussed with said **”yes”.**
- Companies care about their **products or services and turnover** (business) **–** especially start-ups who may not have much money. Turnover is needed, not just pilots.
- **Desire – money – action**: all need to be aligned in e.g., collaborative projects. Where does the business money go? Separation between company and research targets?
- **Measurements and data** are needed in data-driven deep tech.

”Kuinka voimme edistää kliinisen tutkimuksen elinkeinoelämälähtöistä innovaatiotoimintaa?”

- Clear communication of **real-life needs** for solutions or decision support.
- **RB** process should be luring: clear rules, contracts, and pathway. Forum.
- Companies need information related to the
  - **clinical performance** in clinical trials (e.g., effects, efficacy) and real life (e.g., usability, effectiveness) as well as
  - **market access** in terms of MDR support, efficiency (cost-effectiveness), and affordability (budget impact).
- Collaboration with national drug development and other new national endeavours.

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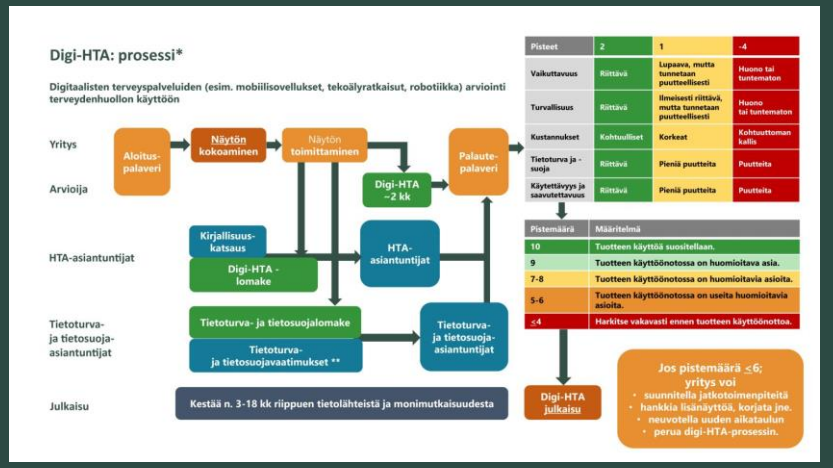
Population health management for ATY 2.0

- **Prevention** is the (almost closed?) lock. **Prediction** is the key.
- **Health technology assessment (HTA)** in Finland:
  - *Open care drugs:* clinical evidence and cost-effectiveness for the reimbursement of new drugs or indications.
  - *Hospital drugs*: clinical evidence, cost-effectiveness, and affordability. Recommendations by Fimea.
  - *Digi-HTA*: sometimes done for a digital solution.
  - *Mini-HTA*: sometimes done in hospitals.
- Data-driven **risk stratification and outcomes of** predictions.
- **Disease burden** and value of prevention development.
- **Outcome-based contracting** and ecosystems (e.g., memory health program, population health management evaluation).
- **Health economics of screening** and prevention (including e.g., EHR, lifestyle, digital, PRO, and omics).
- **Value of research** and information (should we study, what to study, and how much).
- **Publications** and communication.



https://esior.fi/digi-hta/

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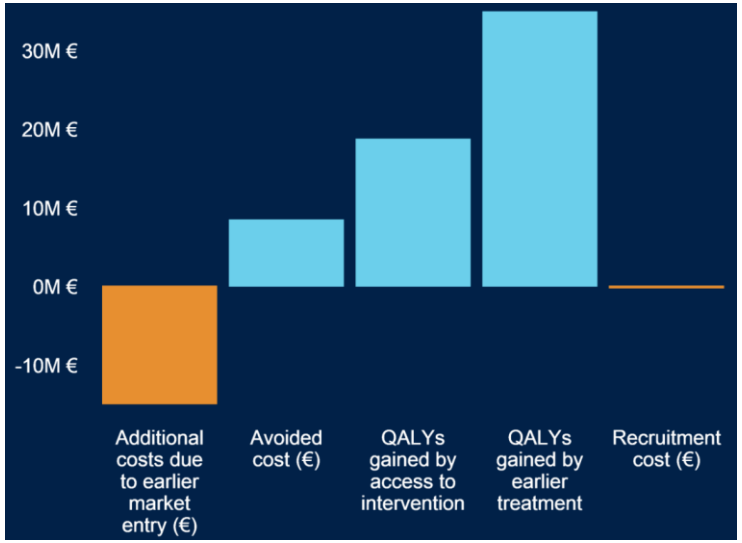
Value gained: calling patient to a study or giving back information to a patient

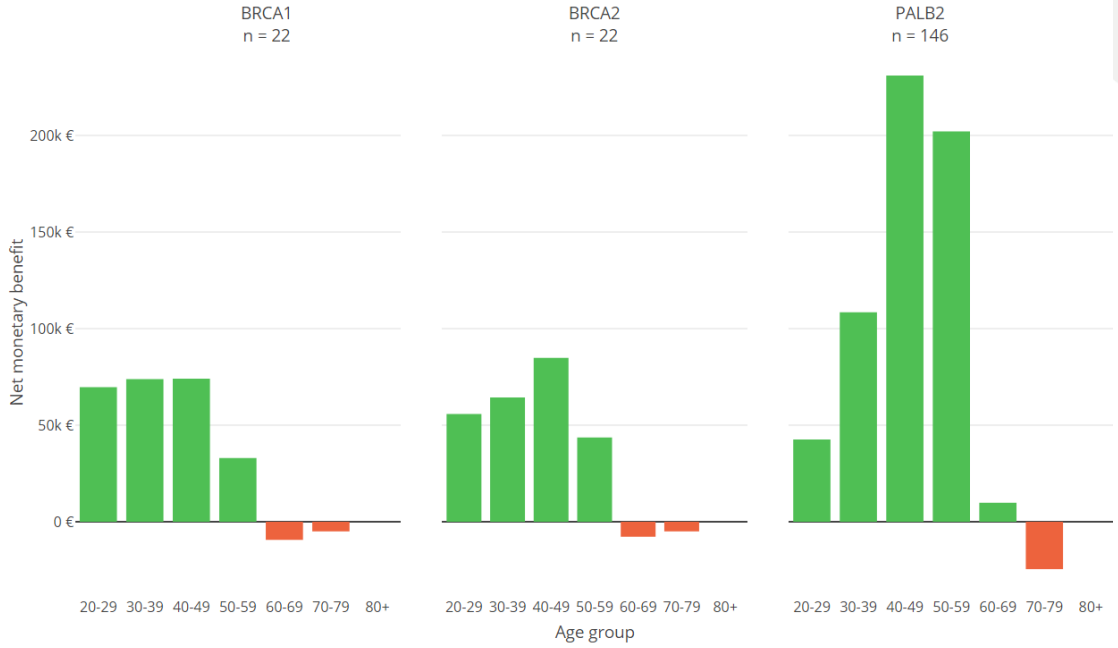
- **Value assessment modelling** of clinical studies and patient information is relevant for decision-makers.
- **Biobank data** in use 1:

  In glaucoma gene therapy for rare gene variants, the value added by patient recall system amounts to 47,254,964€ or 551.05 QALYs. Video available: https://www.youtube.com/watch?v=wzya20BhJS4



Finnish Biobank Cooperative's patient recall service Fingenious® (PRS) for clinical trial patient recruitment. Value Health 2021; 24: S2. https://www.ispor.org/heor-resources/presentations-database/presentation/euro2021-3409/112257.

- **Biobank data** in use 2:
- Preliminary results of potential impacts of returning biobank data to sample donors based on the FinnGen study and breast cancer prevention.



Date: 05/06/23. Title: *Returning genomic biobank data to sample donors - Cost-effectiveness analysis*. Preliminary modelling results. Contact: erkki.soini@esior.fi. Modelling: ESiOR Oy (C. Asseburg. T. Lundström & E. Soini). Clinical expertise: HUS (O. Carpen. M. Pehrsson, T. Meretoja, E. Salminen). FINBB (M. Hautalahti & J. Mäkelä). Sponsor: FINBB.

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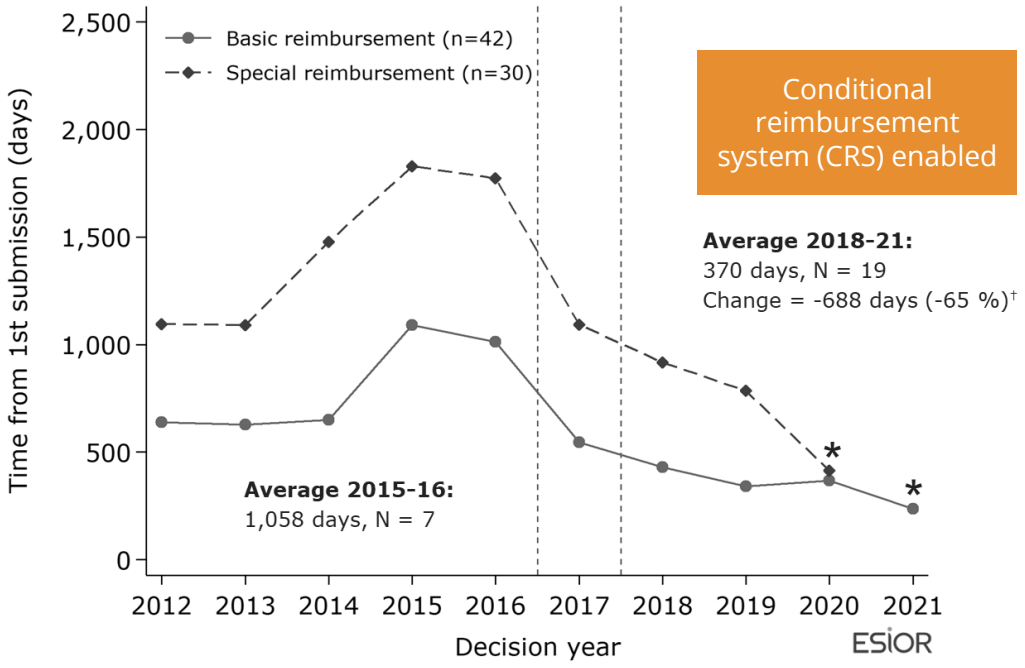
Improving survival with faster decision making: Conditional Reimbursement System (CRS)

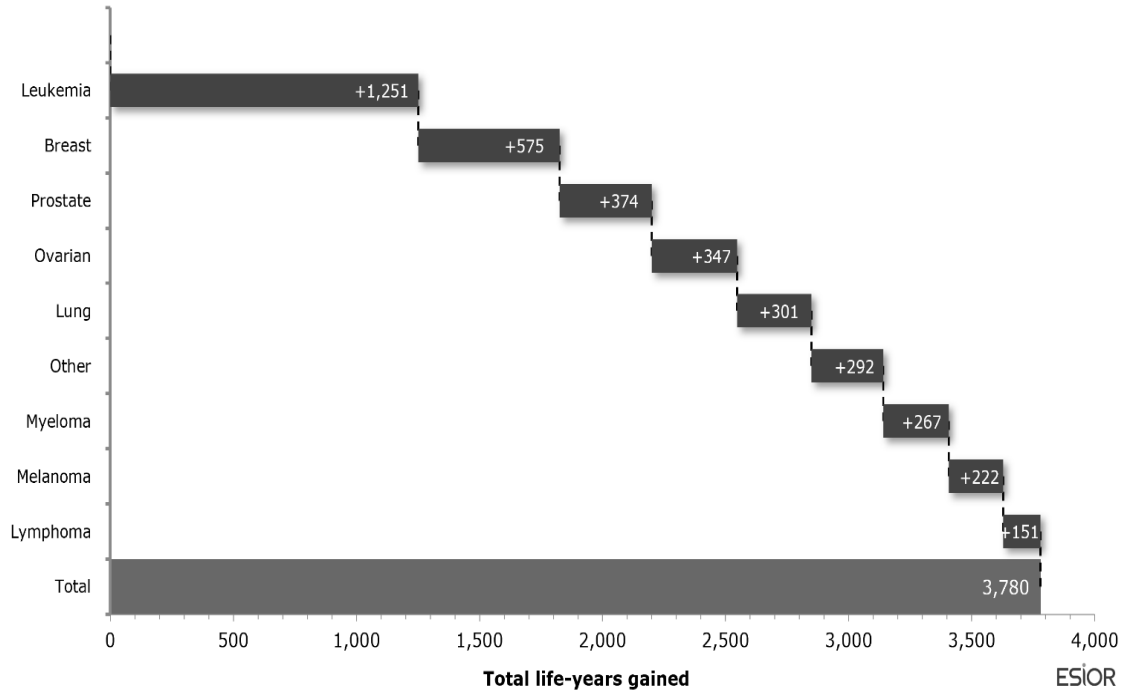
Case: **All cancer treatment reimbursement decisions** (conditional vs. traditional) from the past 10 years in Finland presented at the ISPOR US 2022 main podium.

In cancer, CRS's estimated impact:

- ~2 years' faster access.
- ~1100 life-years saved each year.



ISPOR - **Faster Access to Innovative Therapies with Risk-Sharing Agreements - Cancer Medication Reimbursement Decisions from January 2012 to November 2021 in Finland**



ISPOR - **Life-Years Gained with Conditional Reimbursement Access to Innovative Oncological and Hematological Medicines in Finland**

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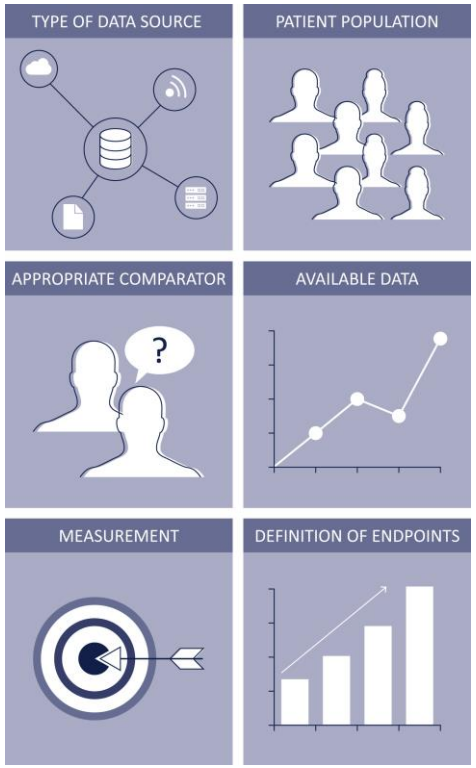
External Control Arms (ECAs) and Data Extensions (DEs): **external data to build needed comparisons**

SPESiOR by ESiOR

ECAs “supplement” missing control arm(s) and DEs “complement” missing data in e.g., follow-up.

- Arms and follow-ups of **clinical trials cost a lot** and can be impossible to incorporate to the trial design.



Ann Oncol 2022;33:P376-83.

Both ECAs and DEs share some common features.

Typically, both are **control group or controlled studies** and independent from the respective RCT.

Both can be needed or requested for **market authorisation and/or reimbursement**.

In both, trials are selected, and **patients are**

- **identified** from the RWD and data are extracted
- **included or excluded**
  - Special focus on disease stage such as progression.
  - If generalisability is assessed, excluded patients should be kept.
- **matched** with the most suitable technique
  - E.g., propensity scores, comorbidity indexes, multilevel methods.
  - Depends on the availability of data from the clinical trial. Sometimes a matching-adjusted indirect treatment comparison is done, or an anonymised clinical trial data is delivered.
- **analysed** in an SPE such as SPESiOR.

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Data

Gain insight into your competitive advantage

Analysis

Demonstrate your competitive advantage

Knowledge

Transform insights into competitive advantage

Communication

Make a difference with effective communication

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