OHDSI Sweden Symposium 2025

Global evidence generation with OMOP-harmonized clinical data: case lung cancer

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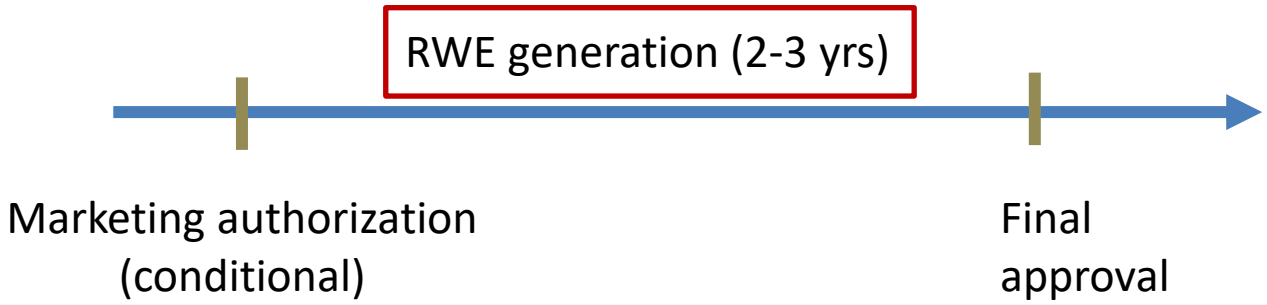
Challenge of cancer as a rare disease

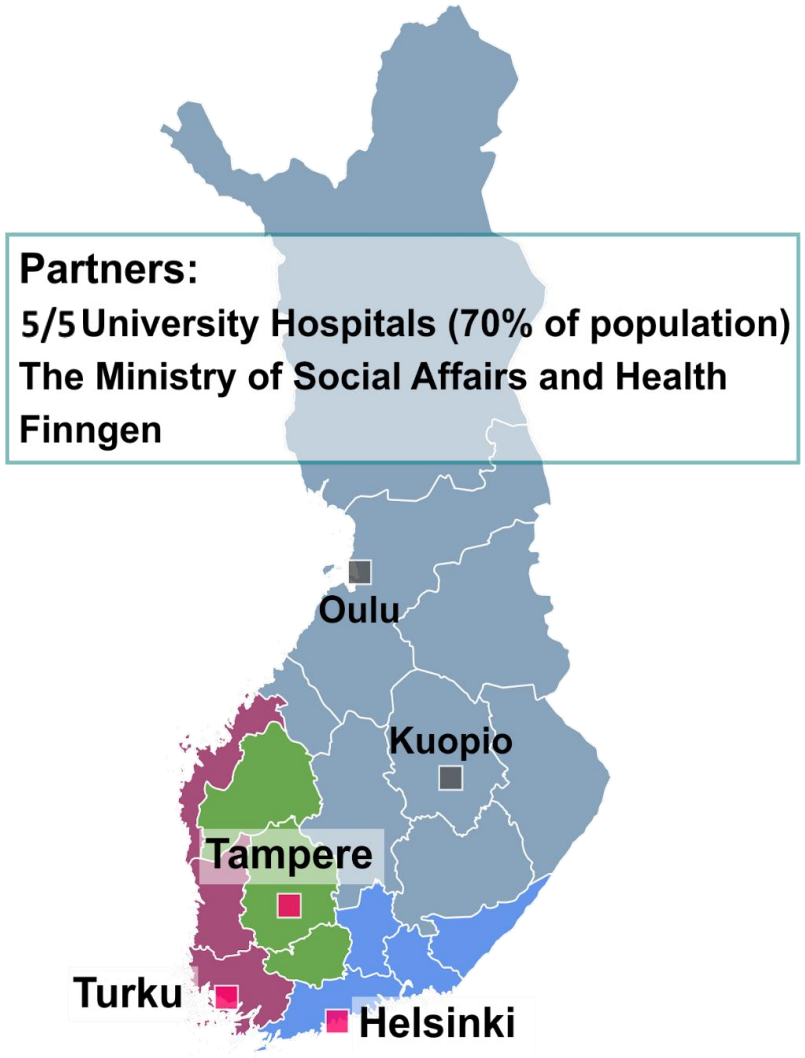
- Biological subclassification => many common cancers become rare

  => performing randomized drug trials difficult, expensive, time-consuming (and biased)
  => primary approvals and reimbursement challenging (paucity of data); DRUP-like trials (PRIME-ROSE)

- Regulatory focus on post-approval space
  - generating reliable, trustworthy, regulatory-grade evidence from routine patient care data (RWD/RWE)
  - large harmonized and federated data networks (e.g. EMA DARWIN EU)



FinOMOP



- Population-based OMOP data harmonization
- Funded by local and EU grants => part of hospital IT infrastructure

- University hospitals
- Governmental registries (THL; primary and secondary care)

- 10.5M patients mapped to OMOP

- Fit-for-purpose: EHDEN EU , DARWIN EU, mNSCLC studyathon

- OHDSI Europe National Node

Ongoing federated big health data projects (FinOMOP, HUS)

- EHDEN EU – EHDEN Foundation
- EMA DARWIN EU
- Oncovalue EU
- PHEMS EU
- SYNTHIA EU
- Nordic VALO
- Harmony Foundation

- **FALCON platform studies**

OMOP enables real-world-evidence generation at scale (EHDEN EU)

Preprints with THE LANCET

Characterising Comorbidities, Medication Use, and Survival in Eight Incident Cancers Across Europe: A Multinational Network Cohort Study of 1.7 Million Patients

25 Pages • Posted: 4 Apr 2025

Irene López-Sánchez
Fundació Institut Universitari per a la recerca a l'Atenció Primària

Anna Palomar-Cros
Fundació Institut Universitari per a la recerca a l'Atenció Primària

More...

https://doi.org/10.1101/2024.08.28.24312695

Trends of use of drugs with suggested shortages and their alternatives across 52 real world data sources and 18 countries in Europe and North America

Marta Pineda-Moncusí, Alexandros Rekkas, Álvaro Martínez Pérez, Angela Leis, Carlos Lopez Gomez, Eric Fey, Erwin Bruninx, Filip Maljković, Francisco Sánchez-Sáez, Jordi Rodeiro, Loretta Zsuzsa Kiss, Michael Franz, Miguel-Angel Mayer, Neva Eleangovan, Pericàs Pulido Pau, Pantelis Natsiavas, Selçuk Şen, Steven Cooper, Sulev Reisberg, Katrin Manlik, Beatriz del Pino, Albert Prats Uribe, Ali Yağız Üresin, Ana Danilović Bastić, Ana Maria Rodrigues, Ângela Afonso, Anna Palomar-Cros, Annelies Verbiest, Antonella Delmestri, Barış Erdoğan, Carina Dinkel-Keuthage, Carmen Olga Torre, Caroline de Beukelaar, Caroline Eteve-Pitsaer, Cátia F. Gonçalves, Costantino de Palma, Cristina Gavina, Daniel Dedman, David Brendan Price,

http://dx.doi.org/10.2139/ssrn.5203825

FALCON

Federated Alliance for Large-Scale Cancer Observational Network

A novel global network to generate timely high-quality real-world evidence in oncology

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

ICAN

HUS
HUS & HELSINGFORS UNIVERSITET I SAMARBETE
A COLLABORATION BETWEEN HUS & UNIVERSITY OF HELSINKI

FALCON – Lung : background

Metastatic non-small cell lung cancer (mNSCLC) represents a significant global health burden, characterized by poor prognoses and high mortality rates. The introduction of immune checkpoint inhibitors (ICIs) has revolutionized treatment.

A key mission of Europe's Beating Cancer Plan is providing equal access to high-quality cancer care across the EU, and improve availability of medicines

Questions

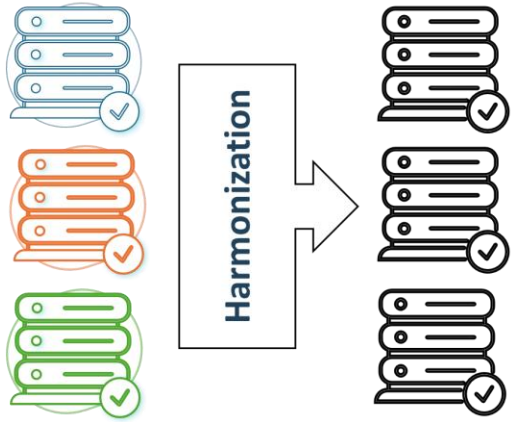
- Characterize demographics and clinical characteristics of mNSCLC pts
  - Are trials & reimbursement representative of real patients?
- Investigate temporal and geographical trends in ICI uptake
  - Do we provide equitable access?
- Describe treatment pathways and clinical outcomes
  - Do we provide state-of-the art care? Equitable outcomes?

FALCON – Lung by iCAN:
largest federated, public-private, RWE generation study in lung cancer (mNSCLC)

Global participating sites (n=21)

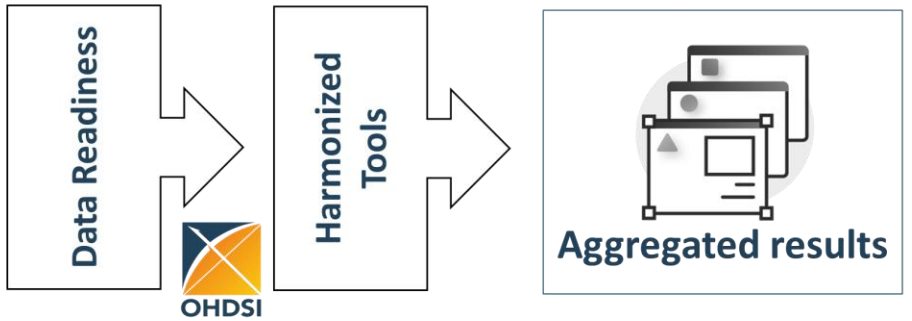
97 107 patients
(public – private)

Local harmonization to OMOP



Iterative data readiness and result refinement

Secure local analysis Shared global results



Support partners with different levels of data maturity

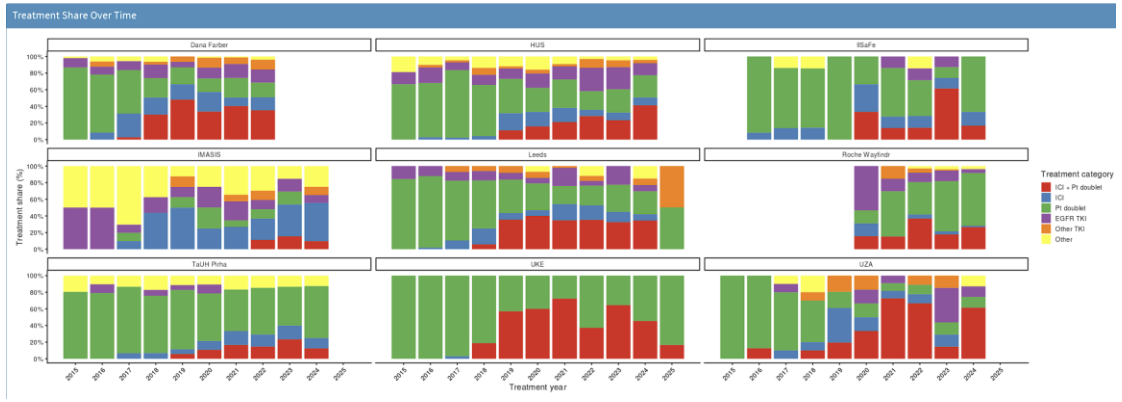
- **Impact of immune checkpoint inhibitor treatment patterns on outcome in mNSCLC**
- **Characterization of exceptional responders – novel biomarkers for response**

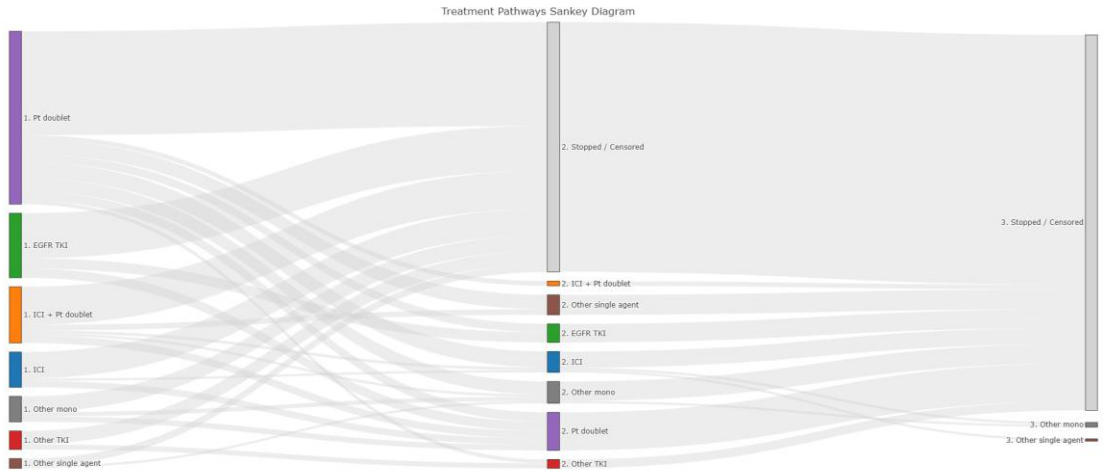
FALCON - Lung

Timeline

Protocol	Nov ‘24
Partner recruitment	Nov ‘24 – Jun ’25
Study package development	Feb ‘25 – Jun ‘25
Study run	Mar ‘25 – Nov ’25

Conception to completion ~1 year





Explore results through an interactive dashboard. Stratify by regimen, treatment line, site, age and sex. www.oncology.ohdsi.org/hus-nsclc/

iCAN

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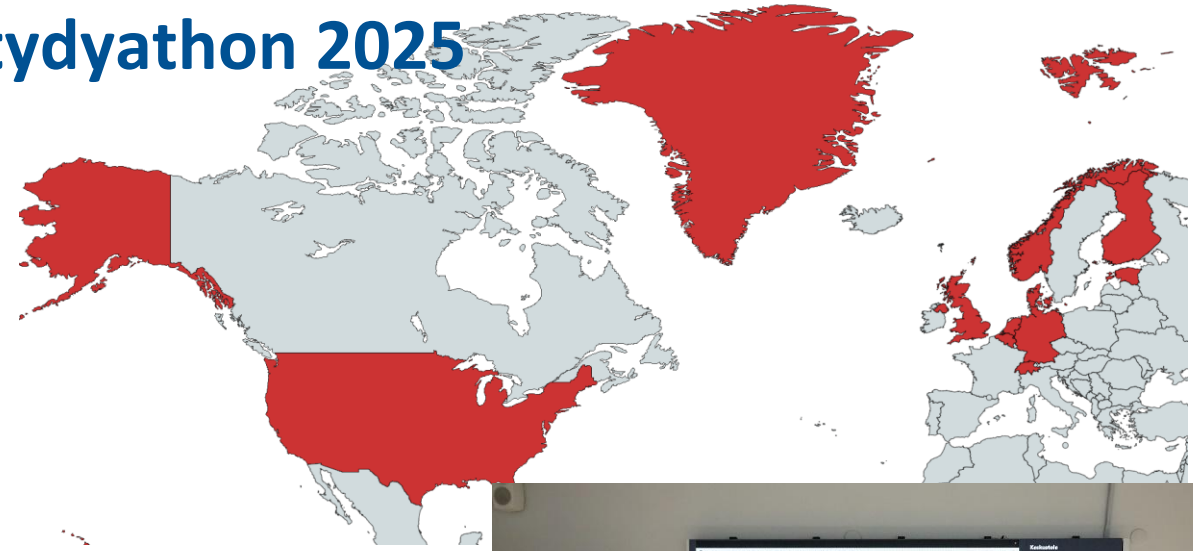
Study sites

Country		Institution	Acronym
Finland		Helsinki University Hospital	HUS
		Turku University Hospital	Varha
		Tampere University Hospital	Pirha
Norway		Oslo University Hospital	OUS
		Cancer Registry of Norway	CRN
Belgium		Antwerp University Hospital	UZA
		CHC Health Group (X hospitals)	CHC
		Liège University Hospital	CHU Liege
		Grand Hôpital de Charleroi	GHDC
Germany		University Medical Center Hamburg-Eppendorf	Hamburg
		Universitätsklinik Dresden	Dresden
		Charité – Universitätsmedizin Berlin	Charite
UK		Leeds Teaching Hospitals NHS Trust	Leeds
Spain		Health Research Institute Hospital La Fe, Valencia	IIS La Fe
		Hospital del Mar Medical Research Institute, Barcelona	IMIM
Estonia		University of Tartu	MAITT
Australia		University of New South Wales, Sydney	UNSW
Denmark		Copenhagen University Hospital	Rigshosp
US	*	Dana-Farber Cancer Institute, Boston	DFCI
		Providence health (51 US hospitals)	Providence
		Emory University Hospital, Atlanta	Emory
Global	*	Flatiron	Flatiron
	*	Wayfind-R	Wayfind-R

* Private data partner

Attrition challenge: iCAN mNSCLC Stydyathon 2025

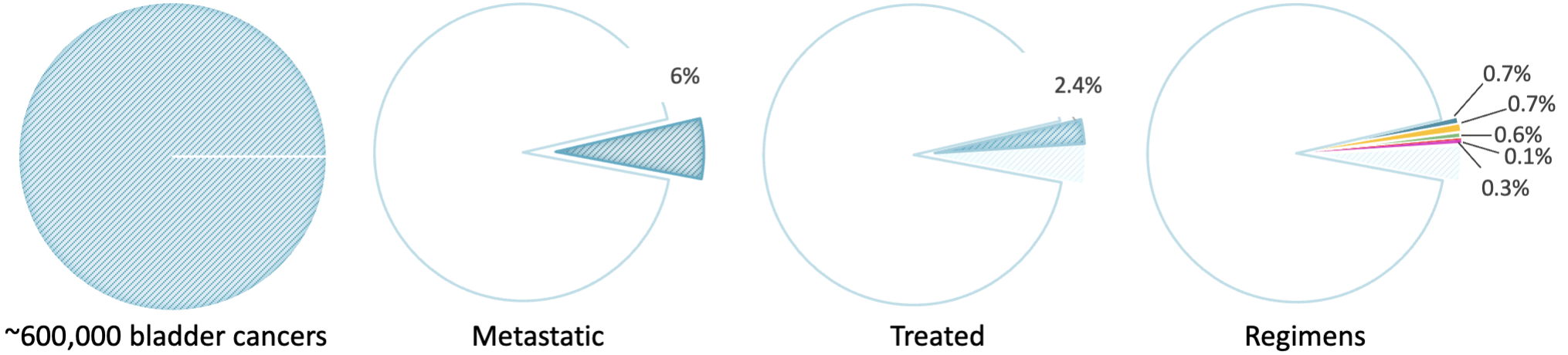
	Patient number or %	Range between 17 sites
NSCLC	30,153	76 - 4,670
Male	53%	42 - 76%
Median age		65 - 72y
Median follow-up		200 - 1,299d
mNSCLC	15,384	37 - 2,916
mNSCLC guideline-recommended regimen	6,345	12 - 794
% of mNSCLC	41%	16 - 86%
1-yr OS*	5,872	42 - 74%
ICI	*634*	*36 - 92%* *HUS: 64% (95% CI 54 - 76)*
ICI + platinum doublet	*1,099*	*29 - 89%* *HUS: 50% (95% CI 41 - 62)*
Platinum doublet	*1,999*	*34 - 77%* *HUS: 36% (95% CI 31 - 41)*



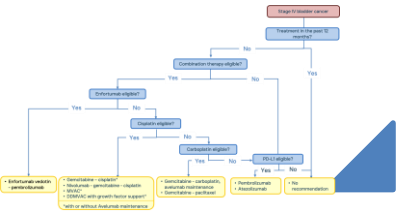
Verbiest A et al.
ESMO 2025

FALCON-Bladder: Guidelinathon

How do we make RWE impactful?

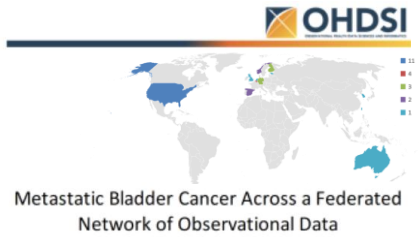


Guidelinathon milestones - generating regulatory-grade RWE



Decision node extraction

node criteria extraction-EAU mBC.xlsx



Protocol development & review

GDE_Bladder Cancer Protocol FINAL_25JUN2025.docx

Data quality assessment & improvement

Phenotype & analytics development & refinement

June- July

Execution & results aggregation

Aug

Dissemination

- OHDSI Global Symposium
- ASCO 2026

Multisite federated studies: some initial learnings

- Feasible, can be run relatively quickly, with modest cost
- OHDSI tooling a major facilitator
- Scientific and organizational rigor paramount: formal protocol, statistical analysis plan, detailed readiness assessments to ensure interoperability
  => regulatory-grade evidence generation, causal inference
- Coordinator has a key role in driving the process – choose carefully
- Studyathons are an effective (and fun) way to speed-up results generation and fix issues