

Building OSCAR - One Stop Shop for Clinical Research

The Experience from Denmark and Lessons for Europe

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“We offer standardized treatment for a range of cancers, but actually we do not know how well they work and for whom - basically because we do not systematically collect data on patient outcome”

*Ulrik Lassen, PhD, MD, Head of Oncology Department,
Copenhagen University Hospital*

Professor of Clinical Oncology, Copenhagen University



1. What is OSCAR?
2. What have we learned so far?
3. How do we succeed?

What is OSCAR?

1. OSCAR is building a national platform for secure, confidential sharing of health data developed in partnership with the biggest owners of Danish health data
2. The platform will be operated by the One Stop Shop for Clinical Research - OSCAR
3. OSCAR will operate on commercial principles

OSCAR will market insights and analyses based on Danish health data globally

OSCAR is based on the principle of value based pricing

OSCAR profits will help fund Danish clinical research
4. The project partners have raised 20mEUR in grant funding and co-financing for OSCAR

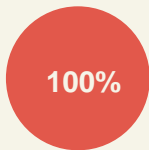
What is OSCAR?

1. New data collection
2. New technology
3. New use cases
4. New collaborations
5. New business model
6. New regulation

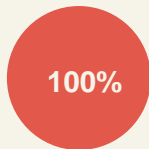
Denmark has Some of the Worlds Best Health Data



Large number of publicly controlled clinical registries with long history



Penetration of electronic medical records in hospital sector



Penetration of electronic medical records with general practitioners



Growing use of electronic care journals in the municipal sector



High level of trust – a necessary condition for obtaining consent for sharing data



All data can be connected via a unique identifier – the Social Security Number – CPR



Access to other data with relevance for health via GDPR enables individual access

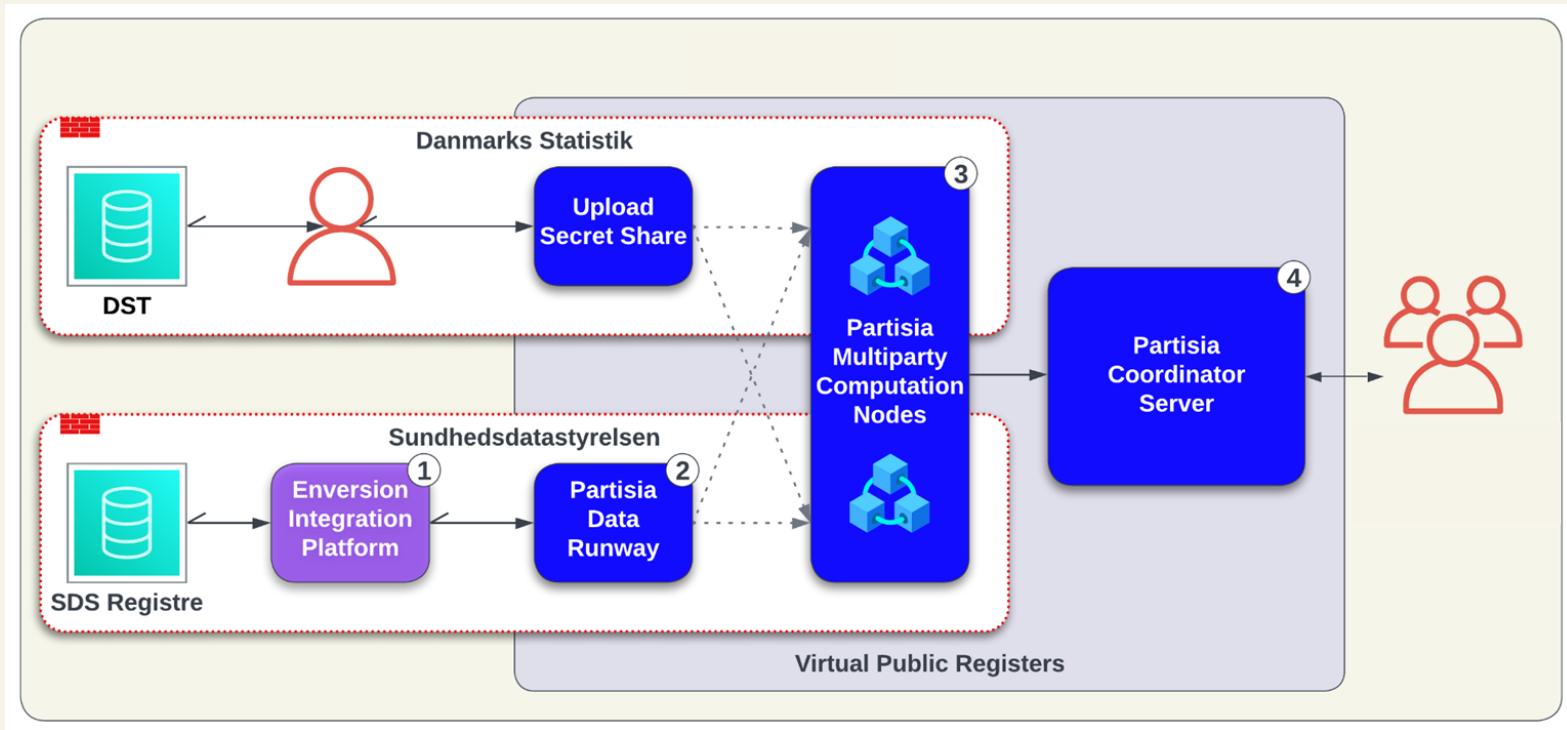


Publicly funded initiatives for cleaning and structuring health data for secondary use

Large, accessible pool of real-world data with relevance for health

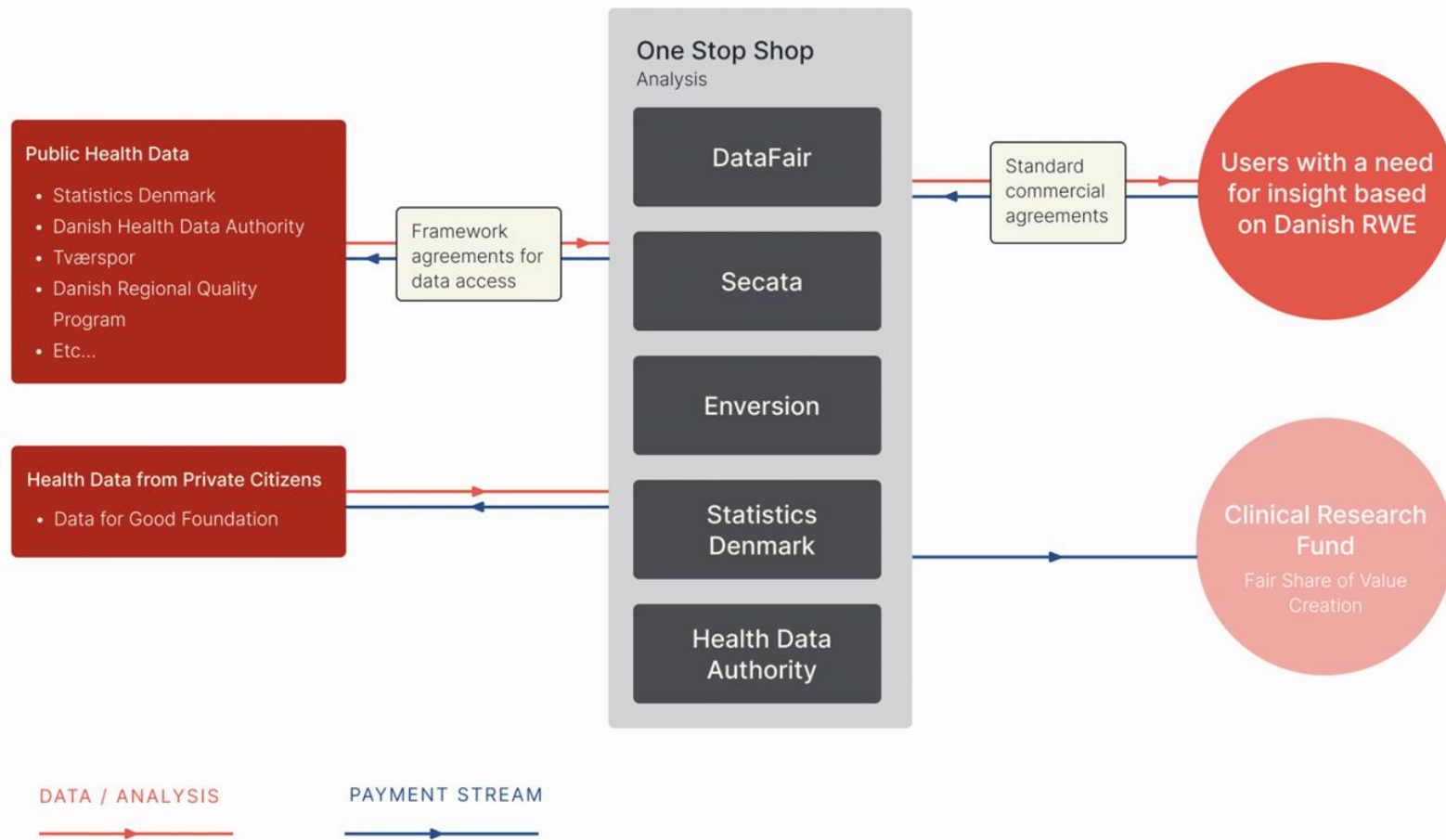
Significant value creation potential for patients, clinicians, researchers, health care providers and society at large

We Are Using Multiparty Computation to Secure Data and Privacy





Business model and governance structure



Services to be Offered by OSCAR

Discovery, R&D	Clinical			Approval and post-marketing	
Identification of business opportunities	Development of data-driven study design	Patient identification and selection	Conduct of clinical trial	Phase IV and Life Cycle management	Health economic assessments
1. Prevalence and patient journey	3. Test of failed study compared to full Danish population	5. Feasibility study	8. Randomised clinical studies	12. Patient centric information of likelihood of effect and side-effect	16. Cost of illness & budget impact
2. Overview of published side/ effects of standard of care/ competitors	4. Pre-run of clinical trial design (test of inclusion/exclusion)	6. Enrolment of patients based on 'dry data'/ medical history	9. Artificial standard of care arm	13. Assessment of adherence	17. Cost municipal care
		7. Enrolment of patients based on 'wet' data'	10. Continued (24/7) assessment of real-world effectiveness	14. Phase IV effectiveness studies	18. Overall cost effectiveness
			11. Continued (24/7) assessment of real-world side-effect	15. Conditional approval	19. Performance based innovative pricing
					20. Additional comparator group for HTA

Support for OSCAR is Embedded in Strong Advisory Boards

OSCAR Public Advisory Board

- Statistics Denmark
- Danish Health Data Authority
- State Serum Institute
- National Genome Centre
- Copenhagen University Hospital
- Association of Danish Regions
- Danish Medical Societies
- Trial Nation
- Danish Medicines Council
- AMGROS
- RKKP - Danish Regions Clinical Quality Program
- Tværspor Project, Central Region

OSCAR Private Advisory Board

Active members:

- Janssen
- Roche
- Pfizer
- BMS
- Novartis
- Astra Zeneca
- Novo Nordisk
- Y-Mabs
- Bayer

Passive members:

- Zealand Pharma
- MSD
- UCB
- Takeda
- Lundbeck
- Ferring
- Leo Pharma
- Amgen
- Genmab
- Boehringer Ingelheim

Key Deliverables for OSCAR Project

WP1 Regulatory and Data Access

- National opt-out rule for renewed consent in place
- One Stop Shop with MPC platform accepted as non-GDPR - no need for consent
- 'We Are Not Waiting' initiative to drive needed changes to health data legislation

WP2 IT Infrastructure

- 2-3 services OSCAR services offered via nodes on Statistics Denmark and Danish Health Data Authority accessing 4-5 national registries + C-MOT

WP3 Clinical test of One Stop Shop

- C-MOT cohort with 1.200 - 2.400 lung and breast cancer patients
- Data available for external analysis via OSCAR Platform
- 3-5 scientific publications

WP4 Alternative Pricing Models

- OSCAR operating data model for outcome based pricing models approved by the Medicines Council and implemented by the National Drug Procurement Organisation

WP5 Governance Structure and Business model

- OSCAR operating as an independent legal entity
- OSCAR services offered by public-private consortium
- Operations and development financed by users / fees

How do we succeed?

1. Collaborate with the large data owners
2. Adjust regulation as and when needed
3. Use OSCAR as pilot for national plans
4. Build user-driven organisation
5. Build 'We Are Not Waiting' coalition to set and push national agenda

What have we learned – lessons for Europe?

1. The technology is ready
2. Public & private have shared needs
3. Strong public and private support is key
4. Don't underestimate the time and resources required
5. Focus on the benefits to patients
6. Go narrow and deep before scaling – at national and EU level

Thank You!