Building OSCAR - One Stop Shop for Clinical Research

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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

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OSCAR is a platform
that supports value based
health care by creating a
sustainable business
model for a One Stop Shop
for Clinical Research that can
facilitate experimental clinical
research enriched with high
quality Danish data and
support usage of Real-World
Evidence.

1. The Danish Health Data Landscape
2. What is OSCAR?
3. What have we learned so far?
4. How do we succeed?

Denmark has Some of the Worlds Best Health Data

- Large number of publicly controlled clinical registries with long history
- 100% — Penetration of electronic medical records in hospital sector
- 100% — 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
- CPR — 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

What is OSCAR?

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

Copenhagen Master Observational Trial (C-MOT): A Prospective Investigator-initiated Observational Study to study biomarkers in relation to clinical outcome in patients with Non-Small Cell Lung Cancer or Breast Cancer

ClinicalTrials.gov Identifier: NCT05145244

Rationale and Background

- To date, there have been **few studies evaluating the day-to-day effects** of non-small cell lung cancer (NSCLC), and advanced (ABC) or metastatic breast cancer (mBC) and its treatment on patients in a real-world setting.
- **There is a gap between the data** from the narrowly focused low-quantity, high-quality interventional studies and less granular data collection, high-quantity RWD.
- Therefore, **prospective, observational trials that include all patients** independent of biomarkers and collects comprehensive data on each **are needed**.

Research Question and Objectives

- To describe outcomes based on RWD by a complete set of clinical, socio-psychological, medico-economics data and biospecimens, including whole genome sequencing (WGS) of all patients with breast cancer and NSCLC
- To record the treatment-related adverse events and late effects experienced by patients based on PRO tools.
- To perform refined biomarker analyses, including (but not limited to) whole genome sequencing, on a fresh tumor biopsy specimen at baseline and at progression, in order to tailor subsequent therapy.

Study Design and Population

- Prospective, non-interventional, multicenter study of patients initiating treatment for NSCLC or breast cancer in Copenhagen (DK).
- Eligible patients will have breast cancer or NSCLC and acceptable performance status and organ function

Group 1: Patients initiating treatment for NSCLC at Rigshospitalet or Herlev Hospital

Approximately 1800 patients who are initiating

Group 1: Patients initiating treatment for metastatic breast cancer at Rigshospitalet
Approximately 600 patients who are initiating

Data Sources

- Study data will be collected via a baseline site **questionnaire and medical records** (SP/EPIC)
- **PRO questions via mobile application** at cycle-based intervals; and patient medical information from medical records into an eCRF at baseline and at the end of the follow-up period.
- **Baseline WGS** will be performed on diagnostic/surgical specimens after informed consent.
- There are no specific protocol-mandated tests, procedures, or clinic visits for this study, but repeat sequential biopsies for WGS are optional at progression.
- All data collection for this study will occur over a 30-months period (including all treatment lines for new patients included in the period).

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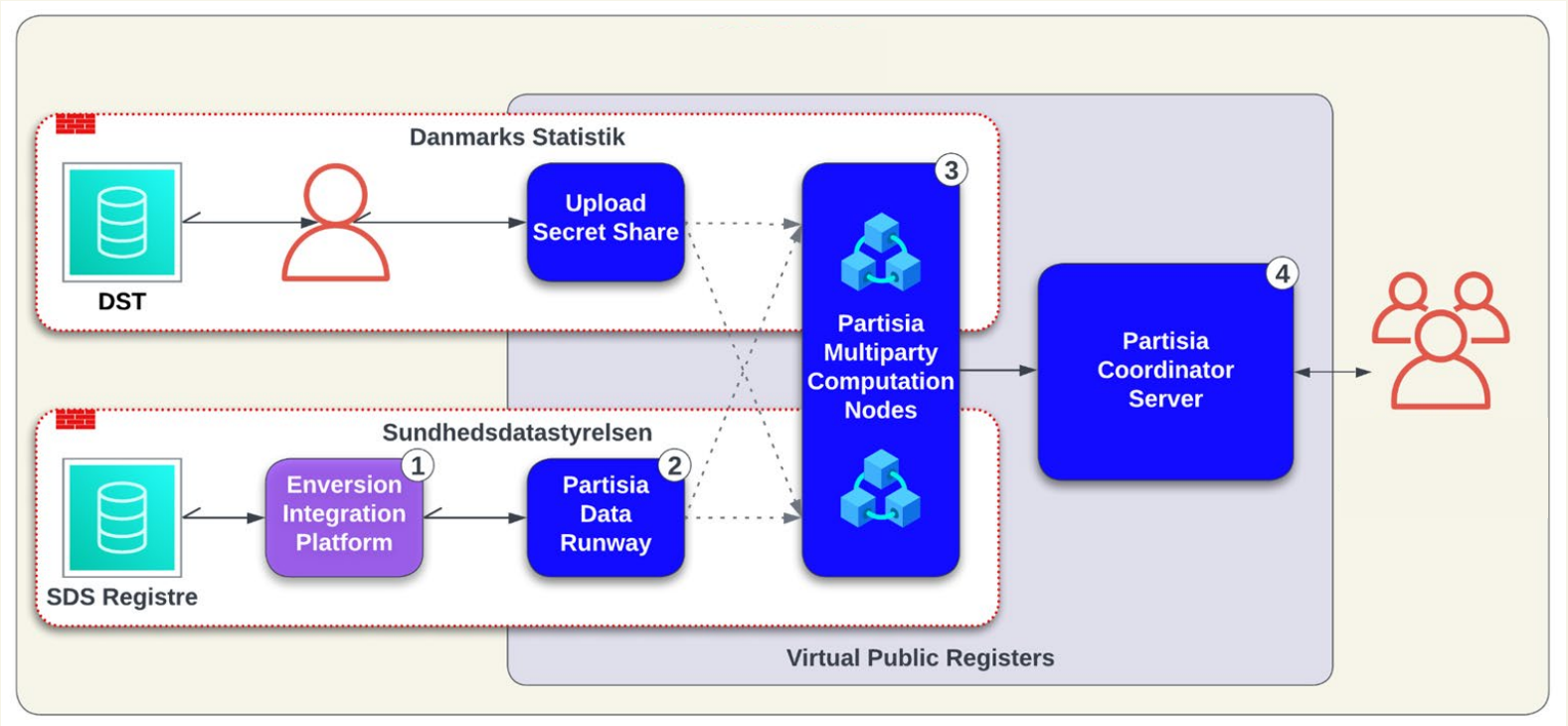
We Are Using Multiparty Computation to Secure Data and Privacy



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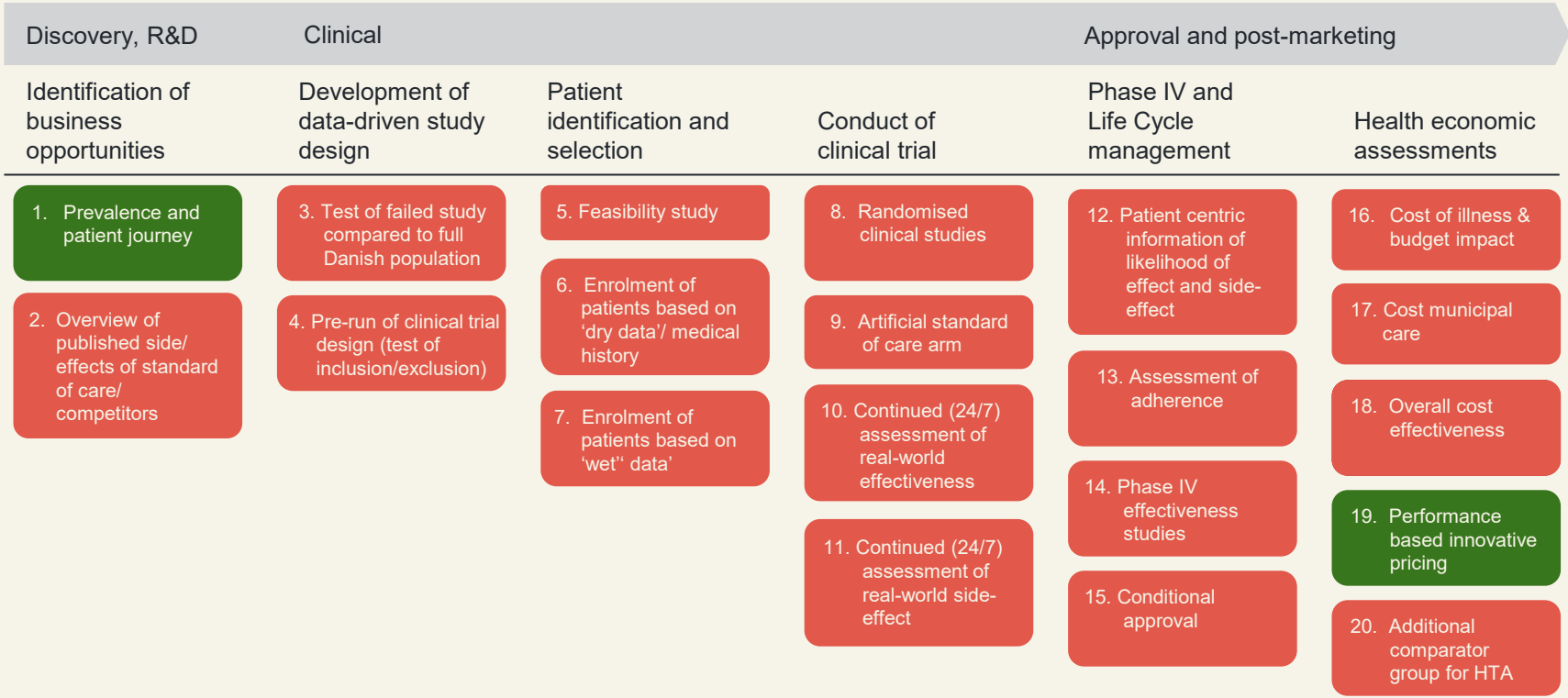
Services to be Offered by OSCAR



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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:

- Johnson & Johnson
- Roche
- Pfizer
- BMS
- Novartis
- Astra Zeneca
- Novo Nordisk
- Y-Mabs
- Bayer
- Takeda

Passive members:

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

Key Deliverables for OSCAR Project

- Develop an IT infrastructure that meets data security and privacy requirements.
- Establish a regulatory framework that streamlines the process for approving industry sponsored research.
- Provide clinical proof of concept for the One - Stop Shop through an Investigator Initiated study at Rigshospitalet.
- Develop an new pricing model that can ensure that both payers, health care providers and the life science industry have aligned incentives to introduce new medicine to Danish patients.
- Provide commercial proof of concept for the One Stop Shop by securing financing for its operation and the first paying customer.
- A communication strategy that informs and builds support amongst key stakeholders

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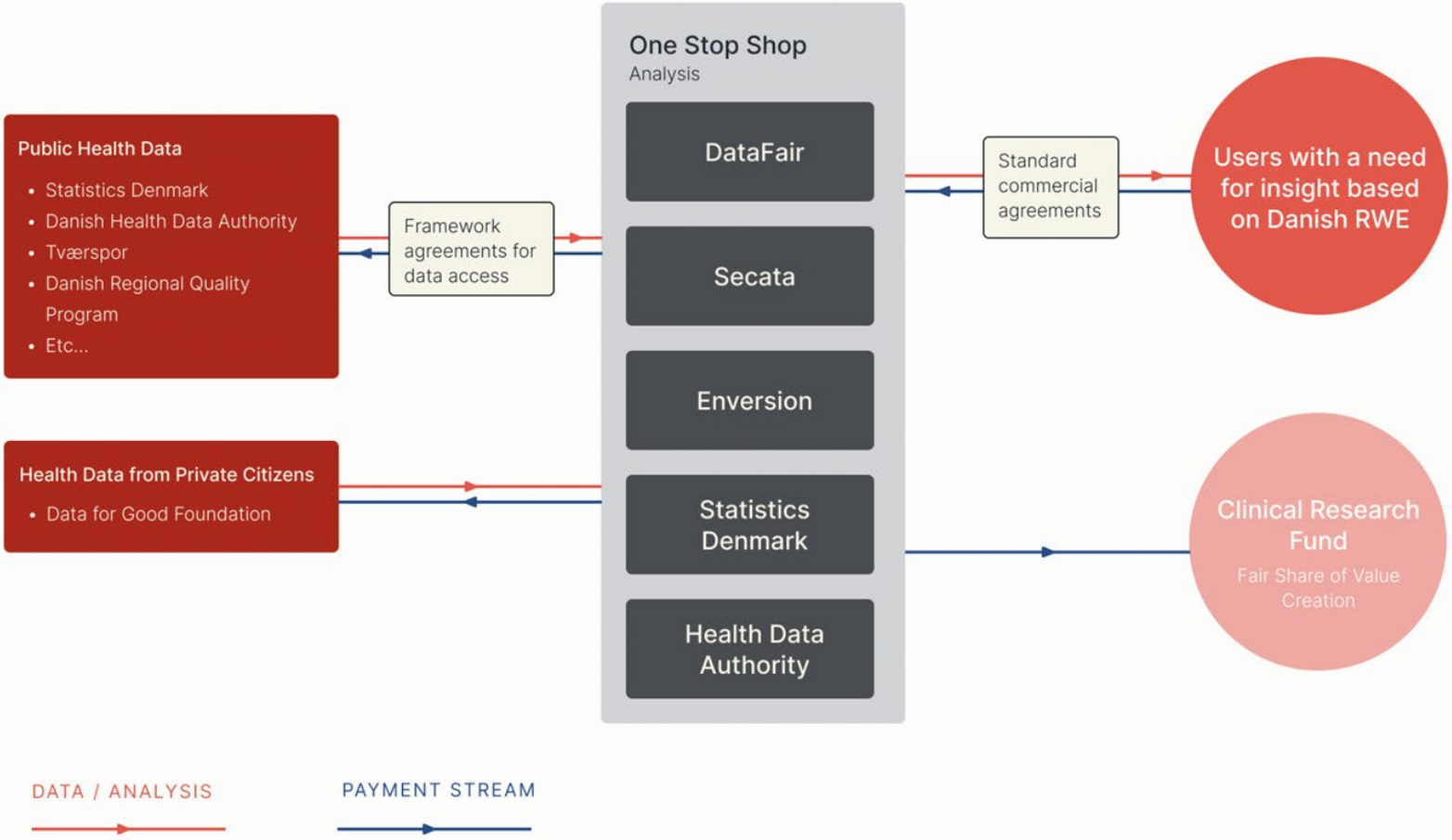
Business model and governance structure



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 10mEUR in grant funding and co-financing for OSCAR

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Forslag til ændringen af sundhedslovgivningen

- Der er **behov for en grundlæggende revision** af lovgivningen på sundhedsdataområdet.
- Det anbefales, at en revision af lovgivningen **tager udgangspunkt i GDPR's regulering** af behandling af sundhedsdata og afstemmes i forhold til kommende/ny EU -regulering.
- Lovrevisionen skal både **styrke patientsikkerheden og udvikling og anvendelse af nye behandlinger og ny medicin.**
- Lovrevisionen bør indeholde **klar hjemmel til behandling af data til "sekundære formål"** og retningslinjer for anvendelse af anonymiserede sundhedsdata.
- En lovrevision bør sker gennem en **bred konsultation med relevante interessenter** for at opretholde befolkningens tillid til at sundhedsdata anvendes forsvarligt.
- **Lovrevisionen bør gå forud for væsentlige beslutninger om investeringer i datainfrastruktur** og tænkes ind i Sundhedsstrukturkommissionens arbejde, i en kommende life science strategi og i realiseringen af visionen for bedre brug af sundhedsdata.

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