



2ND CDDF MULTI-STAKEHOLDER WORKSHOP

THE USE OF REAL-WORLD DATA TO OPTIMISE ONCOLOGY DRUG
DEVELOPMENT AND ACCESS

21-22 November 2019
AMSTERDAM, NETHERLANDS

Disease-based registries

Espen Enerly, Dr.scient.

Leader (acting) of Section for Etiology Research

Facilitator for industry collaboration

Cancer Registry of Norway

21.10.2019





2ND CDDF MULTI-STAKEHOLDER WORKSHOP

THE USE OF REAL-WORLD DATA TO OPTIMISE ONCOLOGY DRUG
DEVELOPMENT AND ACCESS

21-22 November 2019
AMSTERDAM, NETHERLANDS

Conflict of interest

- The CRN have received restricted funding for research projects of which I am P.I or co-worker (AstraZeneca and Merck & Co)
- Facilitator for infrastructure project (INSPIRE) were CRN have received restricted funding from Abbvie, AstraZeneca, Bristol-Myers Squibb, Merck, MSD, Novartis, Pfizer, Roche, Sanofi Genzyme and Takeda

The Cancer Registry of Norway

- A disease-based registry

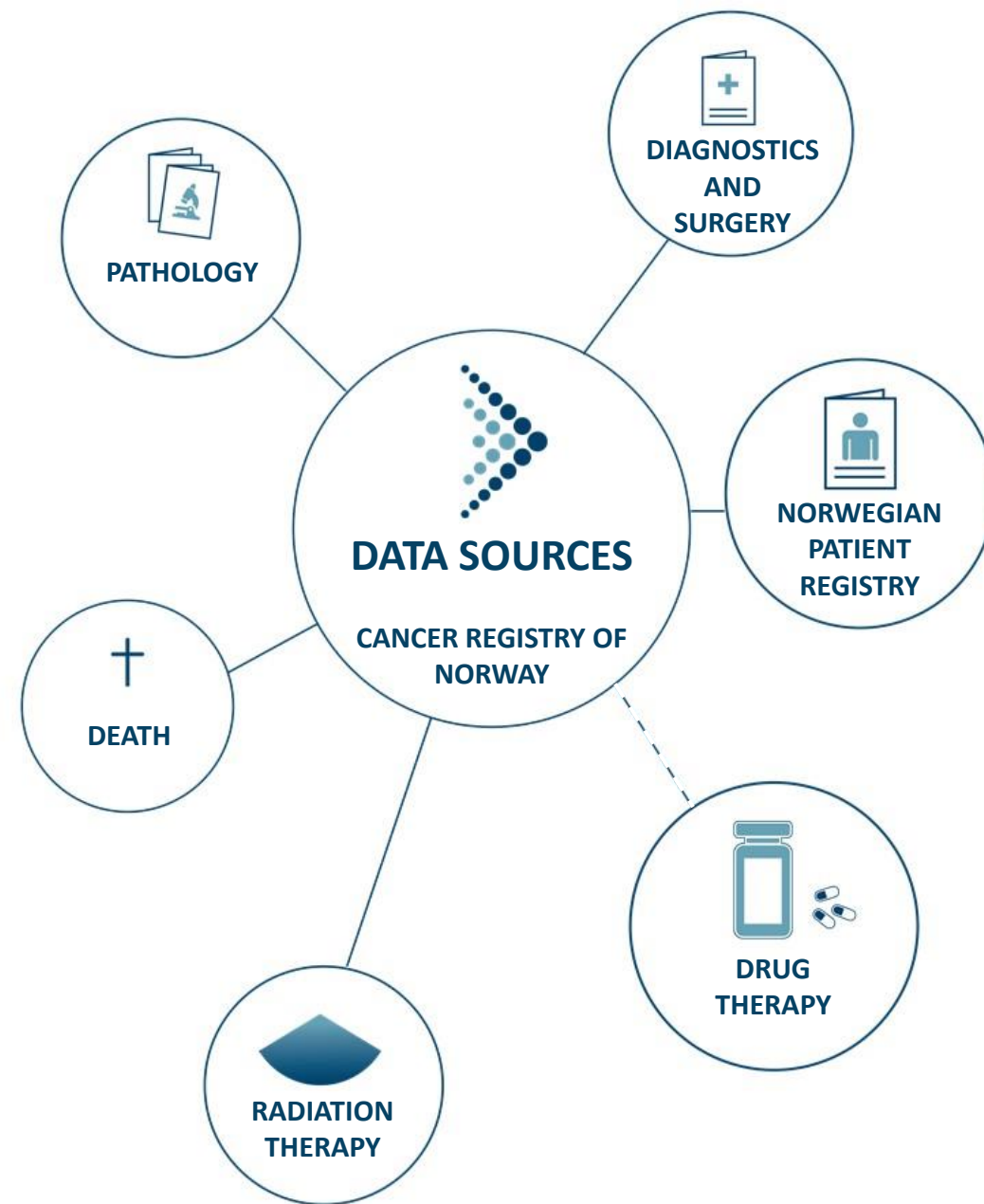
In brief....

- Established in the 1950s
- Cover the complete Norwegian population
- No patient consent necessary
- Mandatory reporting from health institutions
- Primary key: Unique 11-digit Personal Identification Number (24120001111)

Purpose of the cancer registry §§

- Collect incidences of cancer and map time- and regional-trends in incidence, prevalence and survival.
- Provide data for research and perform research
- Advice/inform about cancer prevention





Data quality

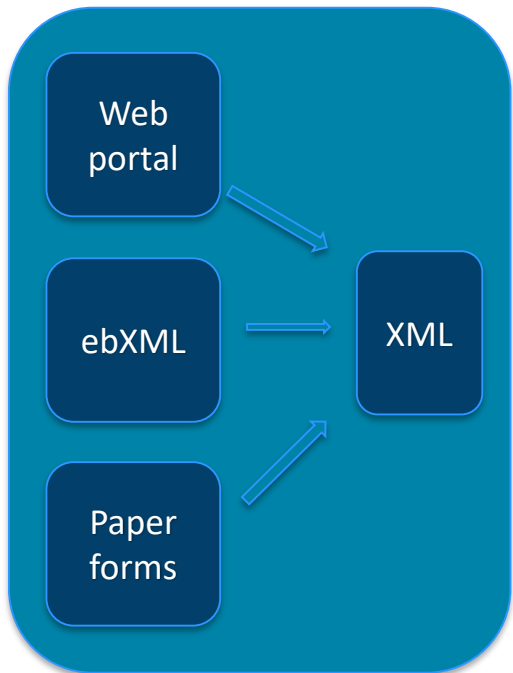
Principles of registration

- Multiple sources
- Independence of information
- 1st hand information
- Collect information as they occur
- Coding and classification adhere to agreed international guidelines

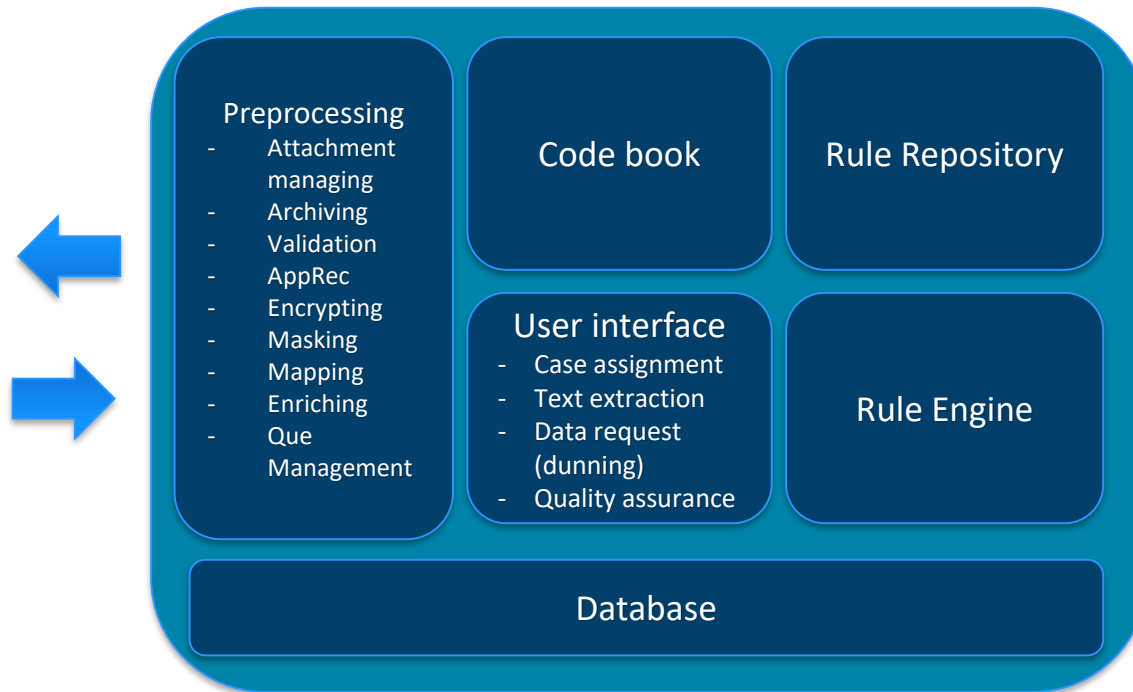
Measure of quality

- Completeness
- Validity (accuracy)
- Comparability
- Timeliness

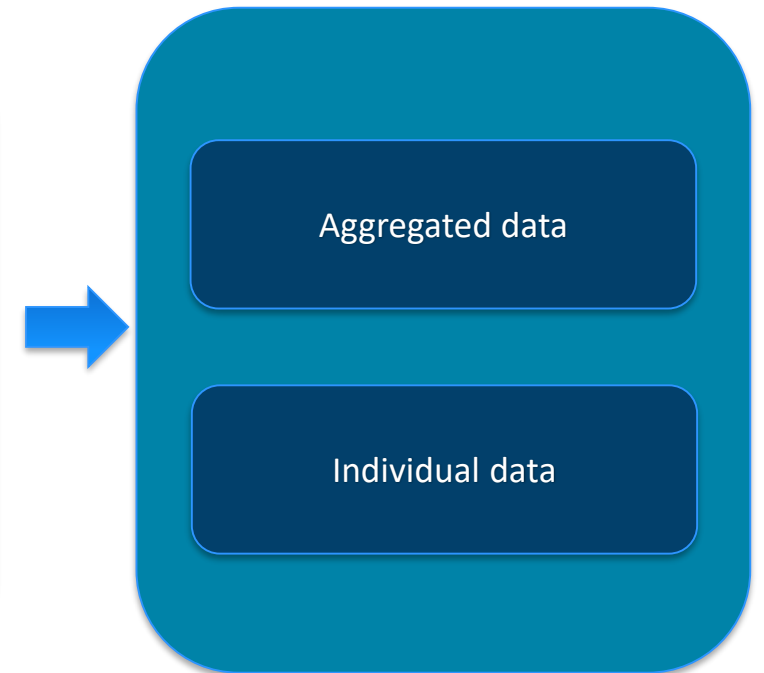
Data capture



Data curation



Data warehousing



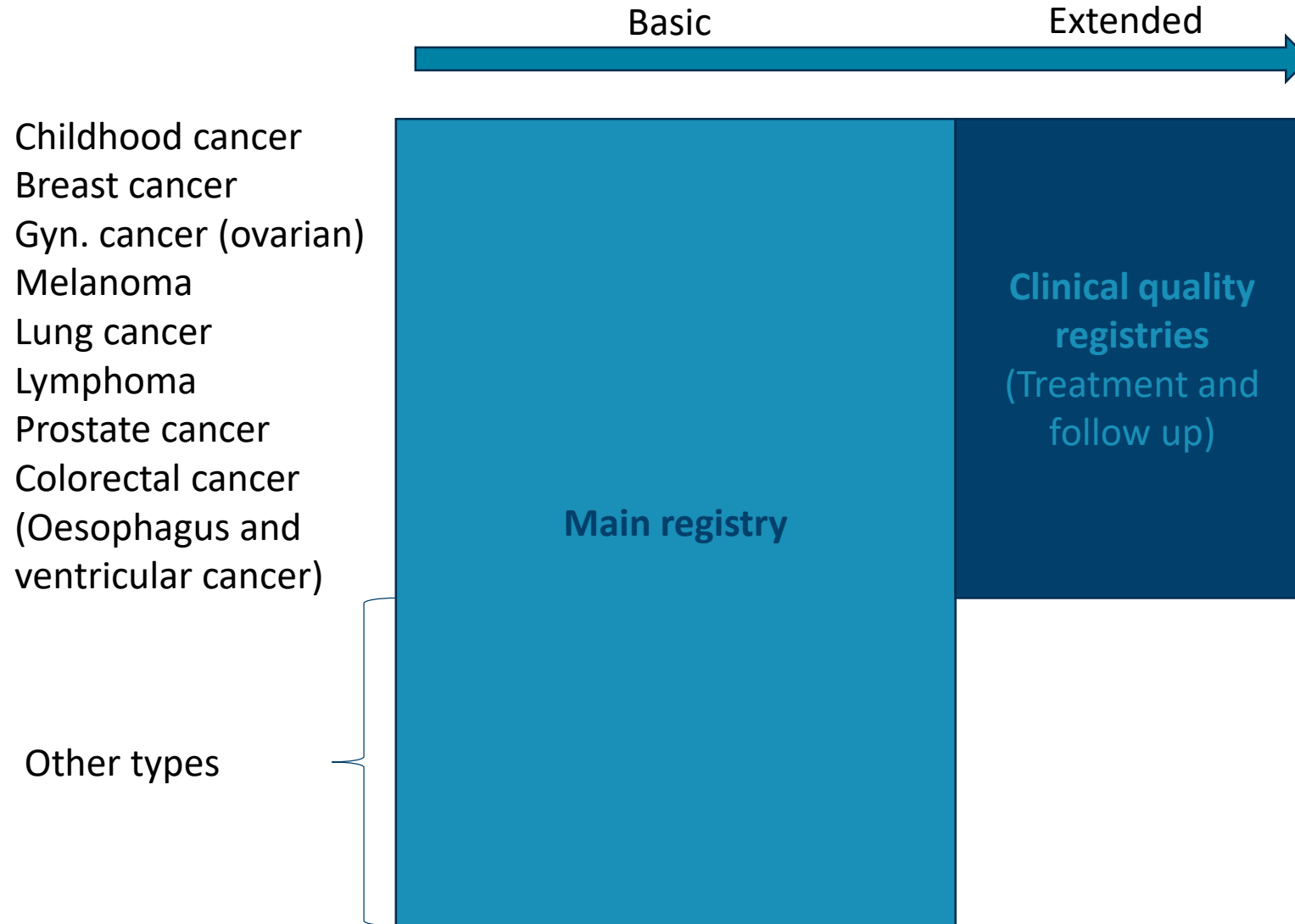
Main cancer registry

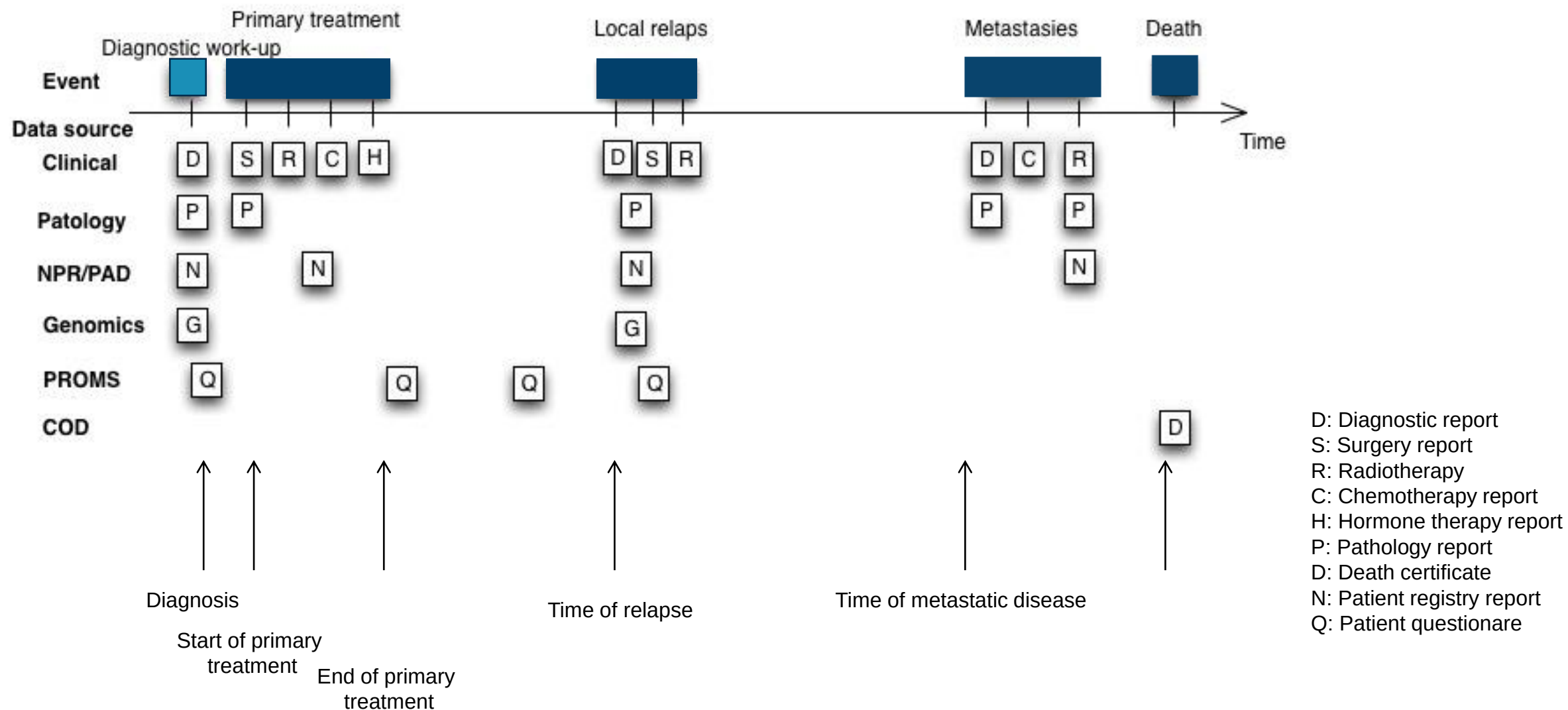
- Personal identifying information
- Age and gender
- Topography (Site of origin) of the cancer
- Morphological diagnosis
- Basis for diagnosis
- Date and cause of death

National clinical quality registries and CRN

- Extended information about treatment and follow-up
- Advisory boards
- Main purpose of clinical registries
 - To document adherence to clinical guidelines
 - Identify regional differences
- We can follow each patient over time, from diagnostic work up, through treatments, «cure» or relapse(s), and death

Information

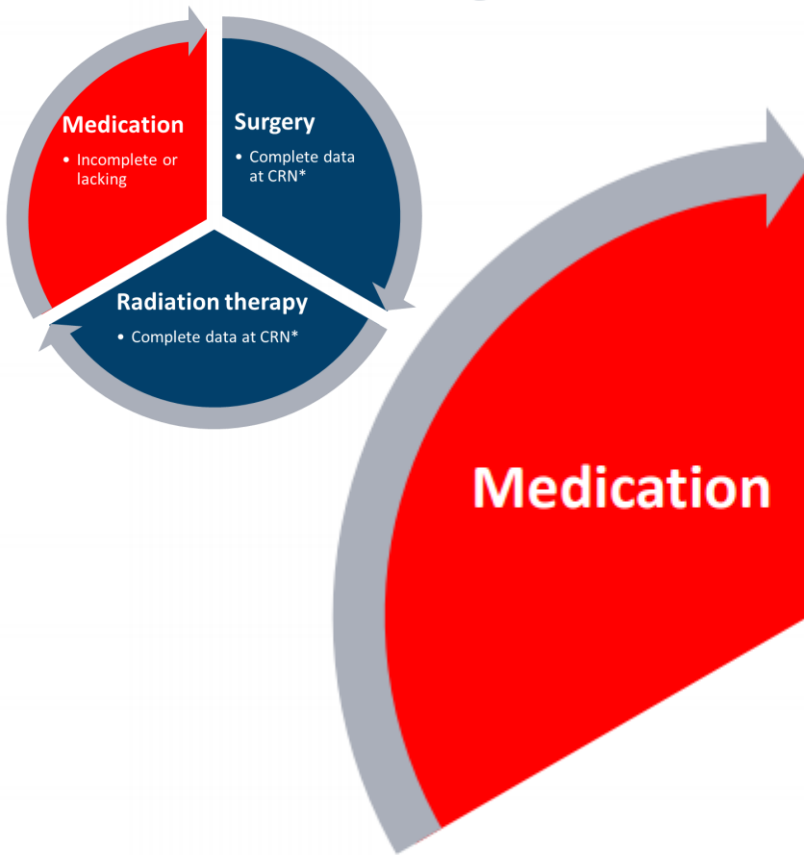




Collaboration CRN - Pharma

INSPIRE – Increase pharmaceutical reporting

Why do we need cancer medication data?

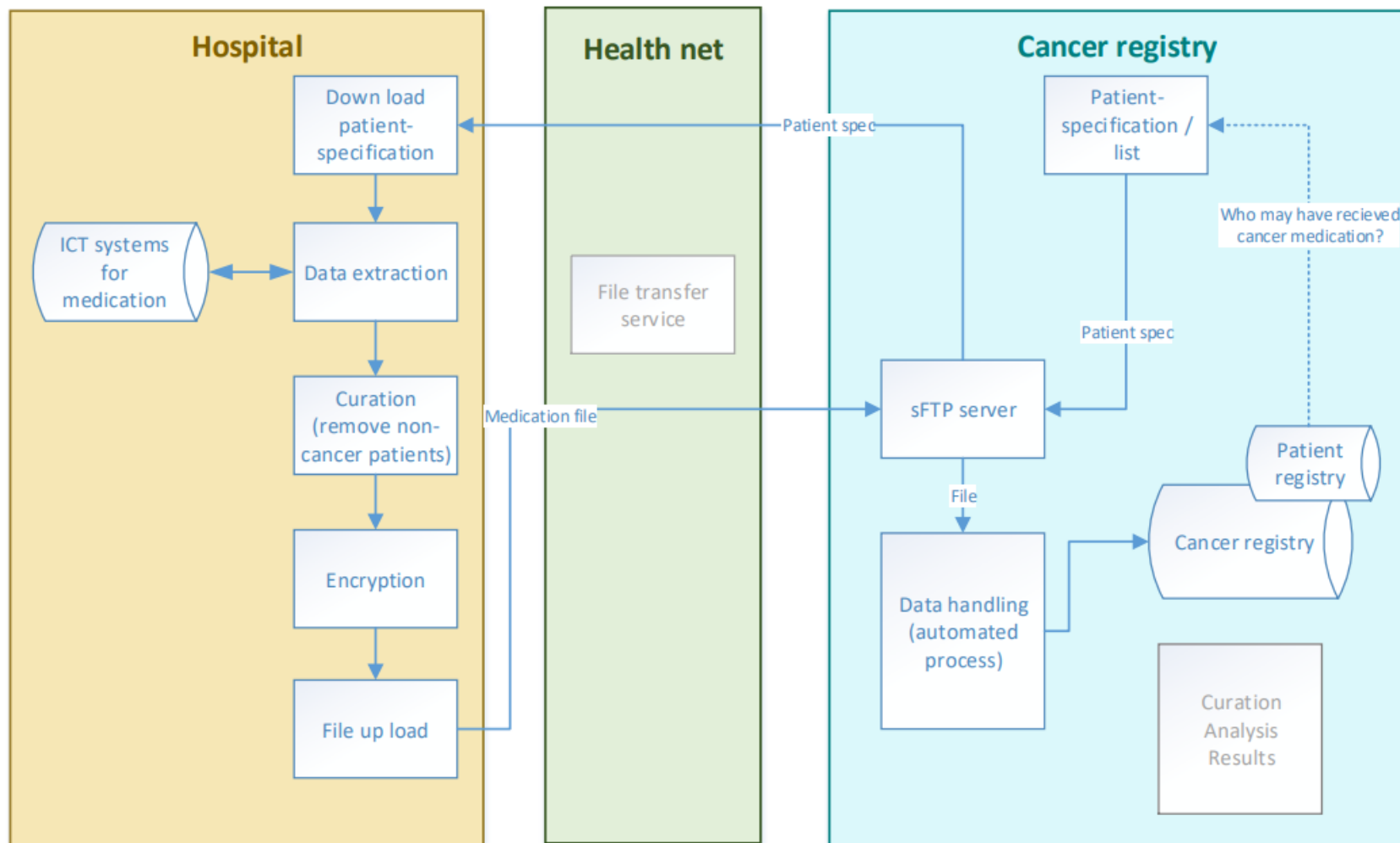


- Overview/statistics
 - *Who gets treated, with what drug(s), for what condition?*
 - *Prognosis? Survival?*
- Quality assessments
 - *Adherence to national guidelines?*
 - *Regional or other differences?*
- Research
 - *Who benefits from new cancer drugs and who doesn't?*

INSPIRE: Project description

- Cancer medication treatment in hospitals (*chemo, hormonal, immuno...*)
 - Data capture *all cancers*
 - Analysis *lung and breast cancer first*
 - Report results *lung and breast cancer first*
- Cancer registry of Norway manages the project
- Financed in collaboration with the pharmaceutical industry and the Cancer Society
- Long term goal
 - Knowledge on cancer drug treatment for all cancer cases

INSPIRE: Data capture



INSPIRE: Cancer medication variables

Variables	Comment
Patient	Name, SSN
Regimen, name of treatment/course	
Date	Date for each drug
ATC	Drug identification code
Generic drug name	Ex. Cisplatinum
Dosage and unit	
Dose reduction/increase %	0 - 100%
Administration	iv, sc, et.c.

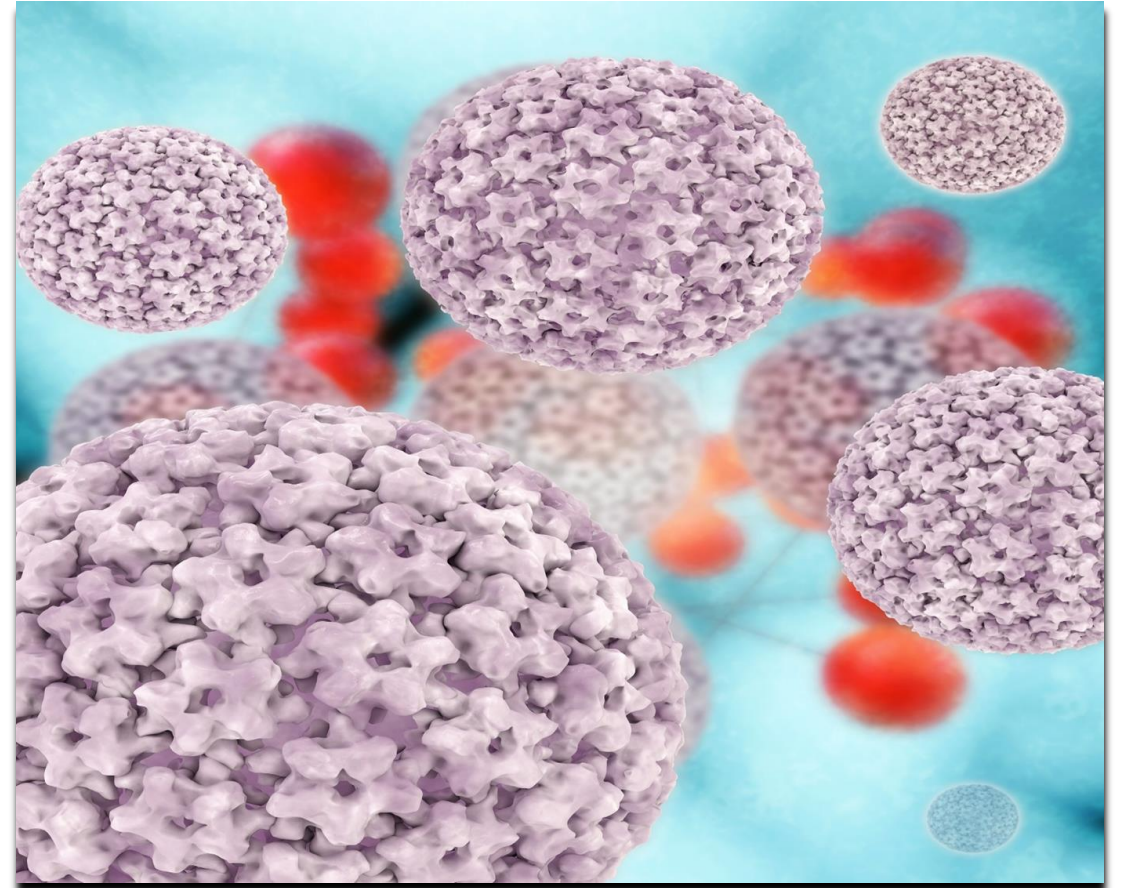
- Each drug, every time, for all patients
- The Cancer registry can accumulate
 - Length of treatment
 - Course number
 - Line of treatment (1st, 2nd)
 - Changes in treatment

Collaboration CRN - Pharma

-HPV vaccine – long term follow up

Phase 3 extension

- Approval FDA/EMA 2006:
 - Post-authorization commitments
 - Nordic Long-term follow-up
 - 14 years
- Registry linkage and sampling from clinical biobanks
- Nordic collaboration



Other registries and Biobanks

Biobanks and other registries (by PIN linkage)

Registries

- **Cause of Death Registry** (est 1951)
- **Statistics Norway**
 - Employment, education, salary, familial cancer, country of birth
- **Medical Birth Registry** (est. 1967)
 - mother's age at birth, number of pregnancies, data on each child/delivery
- **Vaccination Registry** (est 1995)
 - Data on vaccinations, including HPV vaccinations (from 2009)
- **Prescription Registry** (est. 2004) (*pseudonymized*)
 - - All prescriptions recorded (detailed data on amount, dose, dates)
- **National Patient Registry** (est 2008)
 - Discharge records, outpatient diagnosis

Biobanks

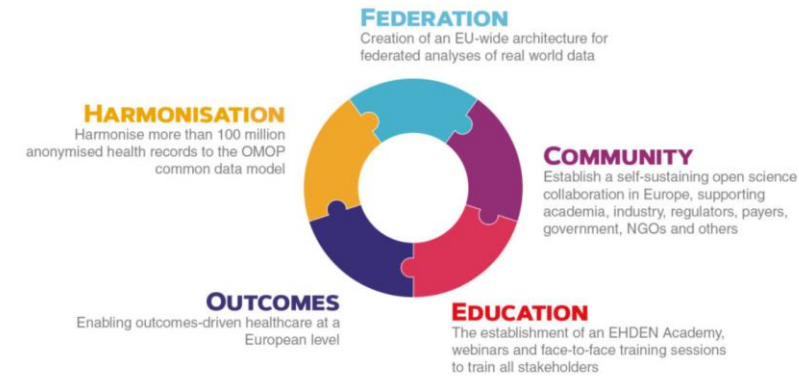
- **Clinical biobanks**
- **Population based biobanks (Serum and blood)**
- **National health surveys**

Ongoing

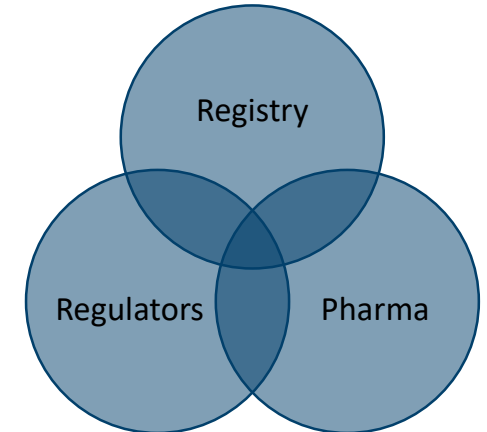
- From silos to a National Health analyses platform (HAP)

Some random thoughts.....

- At a larger scale - Europe (IMI2/EHDEN/OMOP)



- Precision medicine, treatment guidelines



Common core data elements

- All participants could agree on **core data elements to be collected** in disease-specific registries as a basis for regulatory evaluations
- Difference made between “must have” and “nice to have”
- Additional data can be collected if needed to support a study – needs **early discussions**

Data quality

- **Key components** : uniformity, representativeness, consistency, completeness, accuracy, timeliness - source data verification procedure
- **Data quality control system** to be established internally, **external audit to be considered**
- **Data quality indicators** to be defined
- Data quality to be similar in routine and in registry-based studies

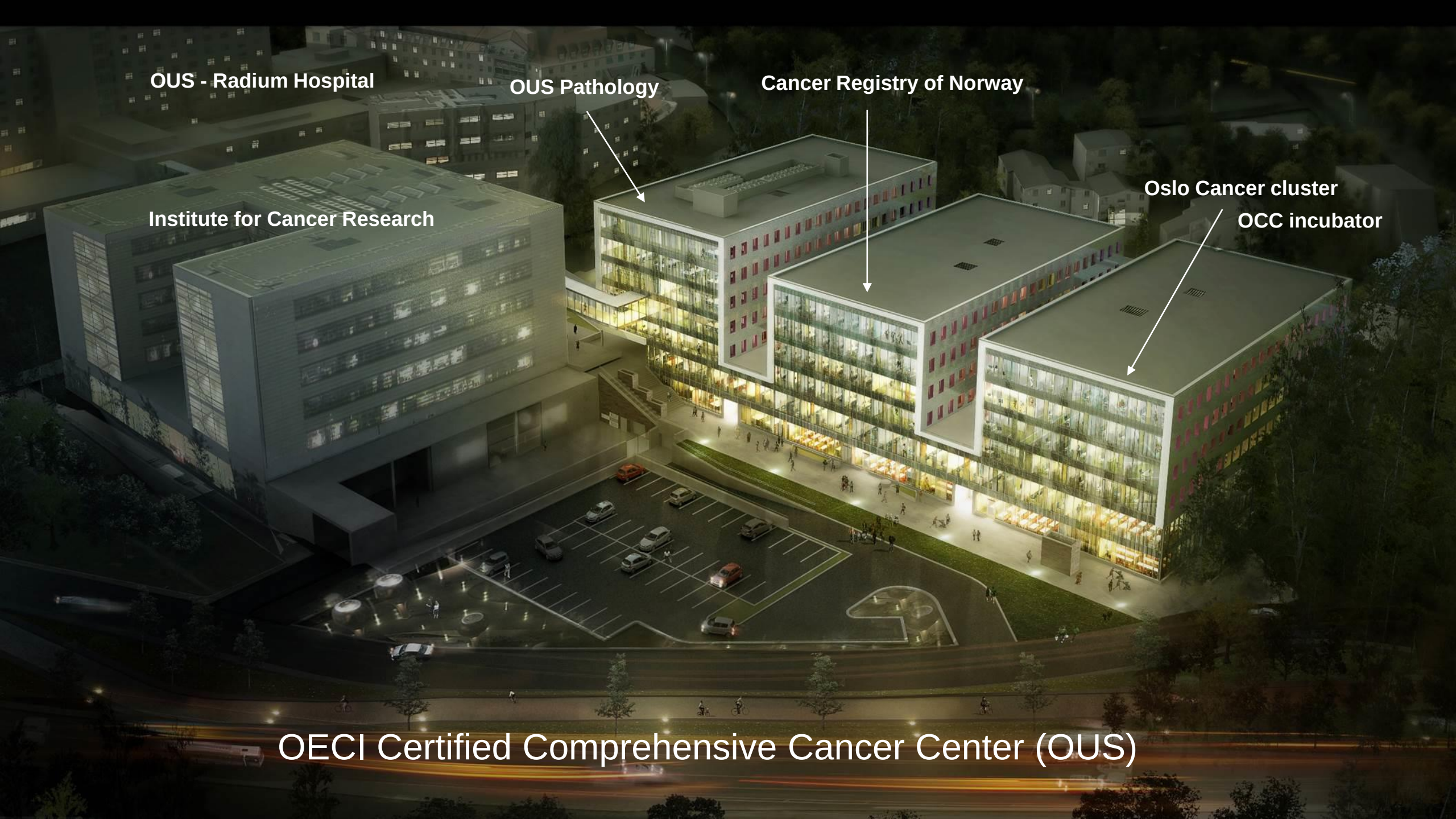
Governance

- Regulators and MAHs to be aware of data that can be feasibly be collected by registries and inform registries on their data needs - needs **early discussions**
- Registry holders to establish **system for centralised data application requests**
- Registry holders to develop **policy for data sharing** based on data protection and informed consent
- Process for **collection and reporting of AEs** to be defined and described in study protocol - process to be in place to strongly encourage physicians to report suspected ADRs to national PhV system

Summary

- Comprehensive source for cancer RWD
- Early involvement
- Data quality
- Private-regulatory-registry collaboration





OUS - Radium Hospital

OUS Pathology

Cancer Registry of Norway

Institute for Cancer Research

Oslo Cancer cluster

OCC incubator

OECD Certified Comprehensive Cancer Center (OUS)

Key challenges in the use of RWD in oncology

- Data quality
 - Evaluation of data quality?
- Early involvement of Registry holders
 - Identify data?
 - Integrate in protocol?
 - Evaluate feasibility?