abbvie

Real World Data – Pilotprosjekt mellom LMI og Kreftregisteret; hvilken nytte kan industri og myndigheter ha av dette?

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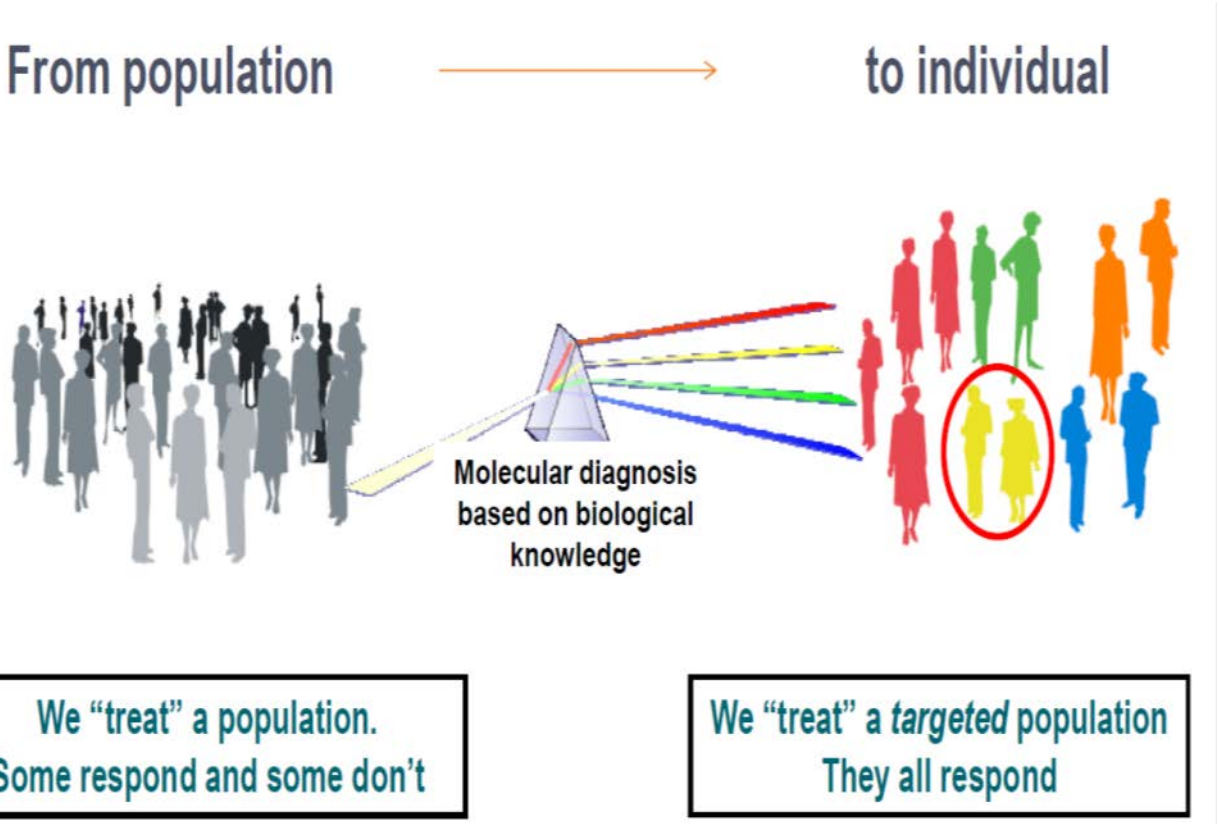
Disclosure

2013-	Medical Director AbbVie Norway
2013-2017	Head R&D Group The Pharma Trade Org Norway
2006-2013	Head of Clinical Research, Medical Director Norway Denmark and Iceland GlaxoSmithKline
1999-2013	Professor ll University of Bergen (epidemiology and pathology)
1992-2006	Head National Cervical- and Breast-Cancer Screening, The Cancer Registry of Norway
1990-1991	Visiting scientist Harvard Medical School, Boston
1985-1990	Head of Registration, The Cancer Registry of Norway
1979-1984	Pathologist PhD Haukeland University Hospital
2016-	Board member Bergen Biomedical
2017-	Head OCC Election Committee

Drug Development; from the industry-perspective

- Close to 100 % av all drugs and vaccines are developed and brought to the patients by the industry (often in collaboration with academia)
- It could take 10-15 year and cost 1-2 bill Euros to bring a molecule to the patients
- Industry tends cut in-house R&D and to develope molecules in collaboration with academia
- Phase 2 and 3 studies tend to be have shorter follow-up and including fewer patients than previous; phase 4 studies will be of more importance in the future (real-life data, HE and bio-markers)
- Nordic Countries have a opportunity to play an important role; 11-digit unique ID, large national registries and several high-standard biobanks.

Biomarkers and molecular diagnosis have changed treatment options



Challenges in modern industry-trials (Oncology)

From:

-large (time and # patients) phase 3 trials, single agents, stratified by site, tumor stage, histological type, age and gender, OS

To:

-small trials (few and selected patients, with short follow-up), combined drugs, based on biomarkers, surrogate endpoints

- Same type of treatment across organs; mutation and targeted therapy
- Phase 4/RWE trials will be more important
- Payers hestitates to reimburse new innovative medicine

Endpoints

- Overall survival
- Progression-free survival
- Clinical respons
- Pathological respons
- Overall respons
- Biomarker surrogate
- Cirkulating tumor DNA?
- Retrospective data breakdown?

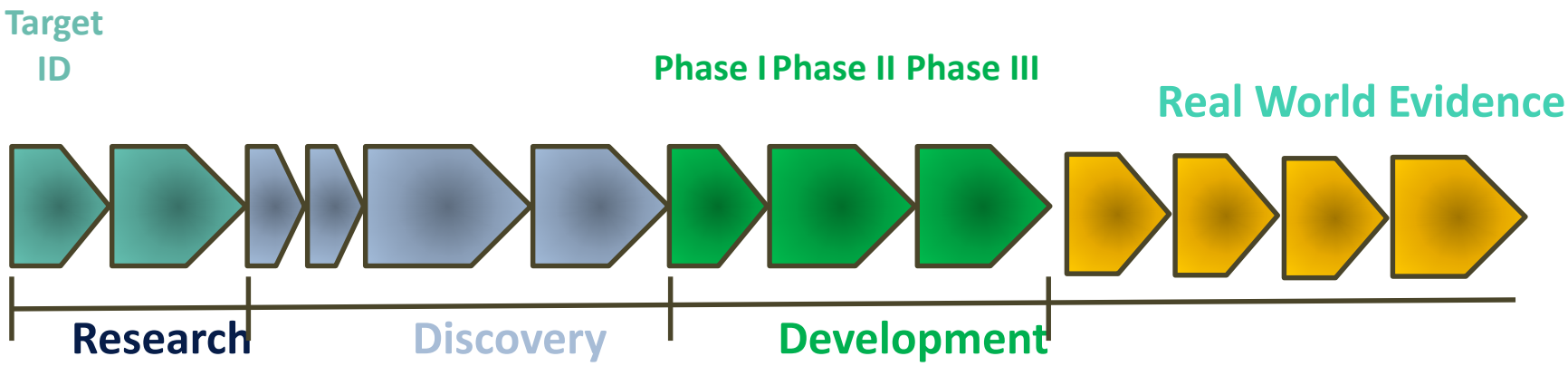
RWE – (Virkelighetsdata) What is it?

➢ **Definition:**

Real World Evidence is collected outside of controlled clinical trials and is used to understand the burden of illness, treatment patterns, patient behaviors and product performance in settings and populations that are representative of routine clinical practice.[1]

1. Garrison LP Jr, Neumann PJ, Erickson P et al (2007) Using real-world data for coverage and payment decisions: the ISPOR Real-World Data Task Force report. Value Health 10(5):326–335

Register-and biobank data are important from drug discovery to Phase four studies



The research questions before and after launch

Before:

What is the current disease burden and current treatment effects?

- Incidence/prevalence including subgroups with biomarkers
- Survival/mortality based on current treatment options (historical data)
- Outcome with current standards of care

After:

How does a new treatment option look in a population outside a clinical trial, and what are the new treatment effects including costs?

- «real-life phase 4»: treatment effects (changes) based on recurrence and survival by region/hospital.
- Compare new treatment options and track real-world use of different treatment options by tumor-type/mutations and by regions/hospitals
- Adaptive licensing/Market access in Nordic countries
- Costs and HEOR-data
- Pay for performance

GAPs

Increase registration into the quality registry (clinical data, medicinal treatment data).

Evaluate and mitigate end-points in relation to industry needs

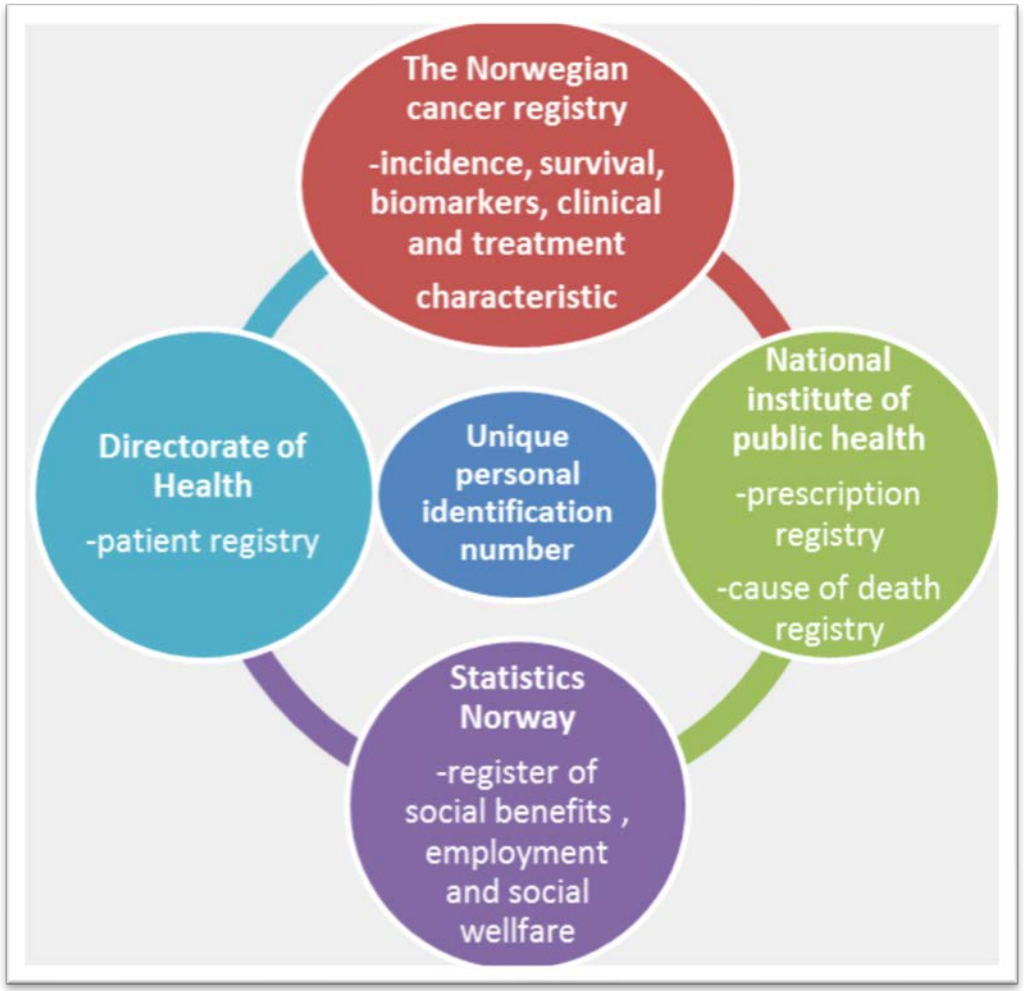
Improved registration of biomarkers

Possibility to retrospectively analyze biomarkers in samples from matched comparator arms and establish new diagnostic analyses?

Clinical studies – studies running in Norway and patients included and followed in the registries.

From per project agreements to master agreement?

Combination of national population registries



NEW POLITICAL CLIMATE

- Increased usage of registry data and development of new areas to utilize the data is wanted
- Collaboration between industry and public sector is an increasing need and wish from the government side
- Leverage the possibility to build a strong health industry based on our national (and Nordic) advantages within this field

FROM WORDS TO ACTION

ARENDALSUKA

16. august

16.00 - 17.30
Clarion Hotel Tyholmen, Sal A

NORSKE HELSEDATA - FRA ORD TIL HANDLING

Kreftregisteret, Oslo Cancer Cluster, Innovasjon Norge, Folkehelseinstituttet og Forskningsrådet i samarbeid med AbbVie.

Norske helsedata er et tema som har fått mye oppmerksomhet både internasjonalt og her i Norge. Det er stor enighet om betydningen av disse dataene og mulighetene de kan innebære, men hvorfor er vi ikke allerede i gang med å utnytte disse mulighetene?
Med de ressursene og den unike infrastrukturen vi har i Norge bør disse dataene være et stort konkurransefortrinn, men dette er et prosjekt med lange tidshorisonter. Hva kan vi gjøre med dataene i dag? Hvordan kan vi sikre at de også på kort sikt blir en ressurs for Norge?

Enkel bevertning.

PROGRAM

- **Velkommen**
  v/Tom Pike
- **Hvilke muligheter ligger i våre registre?**
  v/Giske Ursin, Kreftregisteret
- **Nytteverdi i registre fra industriens ståsted**
  v/ Ketil Widerberg, OCC, Hanne Mette Dyrlie Kristensen, Innovasjon Norge og Steinar Thoresen, AbbVie
- **Forskerens og universitetets syn på mulighetene i registrene**
  v/Per Morten Sandset, Universitetet i Oslo
- **Hvordan kan vi raskere og allerede i dag utløse nytteverdien?**
  v/ Anne Kjersti Fahlvik, Forskningsrådet og Camilla Stoltenberg, Folkehelseinstituttet
- **Diskusjon – hva kan vi gjøre nå?**
  Debatt med Ketil Kjenseth (V), Sveinung Stensland (H), Giske Ursin, Anne Kjersti Fahlvik, Camilla Stoltenberg og Hanne Mette Dyrlie Kristensen

PRESENTASJON AV PANELET

Møteleder Tom Pike
Daglig leder Credio

Giske Ursin
Direktør Kreftregisteret

Anne Kjersti Fahlvik - Divisjonsdirektør for innovasjon, Forskningsrådet

Camilla Stoltenberg
Direktør Folkehelseinstituttet

Ketil Widerberg - General Manager Oslo Cancer Cluster

Per Morten Sandset - Viserektor for forskning og utdanning

Hanne Mette Dyrlie Kristensen
Seniorrådgiver Innovasjon Norge

Steinar Thoresen
Medisinsk direktør AbbVie

Sveinung Stensland
Stortingsrepresentant Høyre

Ketil Kjenseth
Stortingsrepresentant Venstre

National initiatives for better access to health data and registries

- Helsedatautvalget

  Contribute to a better and more effective system for treatment of health data for:

  - Statistical analyses
  - Planning
  - HTA analyses
  - Quality improvement
  - Research
  - Innovation

- Helsedataprogrammet

  National platform to improve accessibility and analyses of health data

Konklusjon

- Industrien har behov for helsedata for å sikre tidlig tilgang for nye medisiner for norske pasienter
- De politiske signaler og vedtak er klare
- Tiden med store fase 3 studier med single drug-versus placebo og OS er forbi
- Norge burde bruke sine registre for å kunne bistå myndighetene i vurderingene av nye medisiner
- Helsedata kan bli en helsenæring i Norge

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