Personalized Medicine and True eSource

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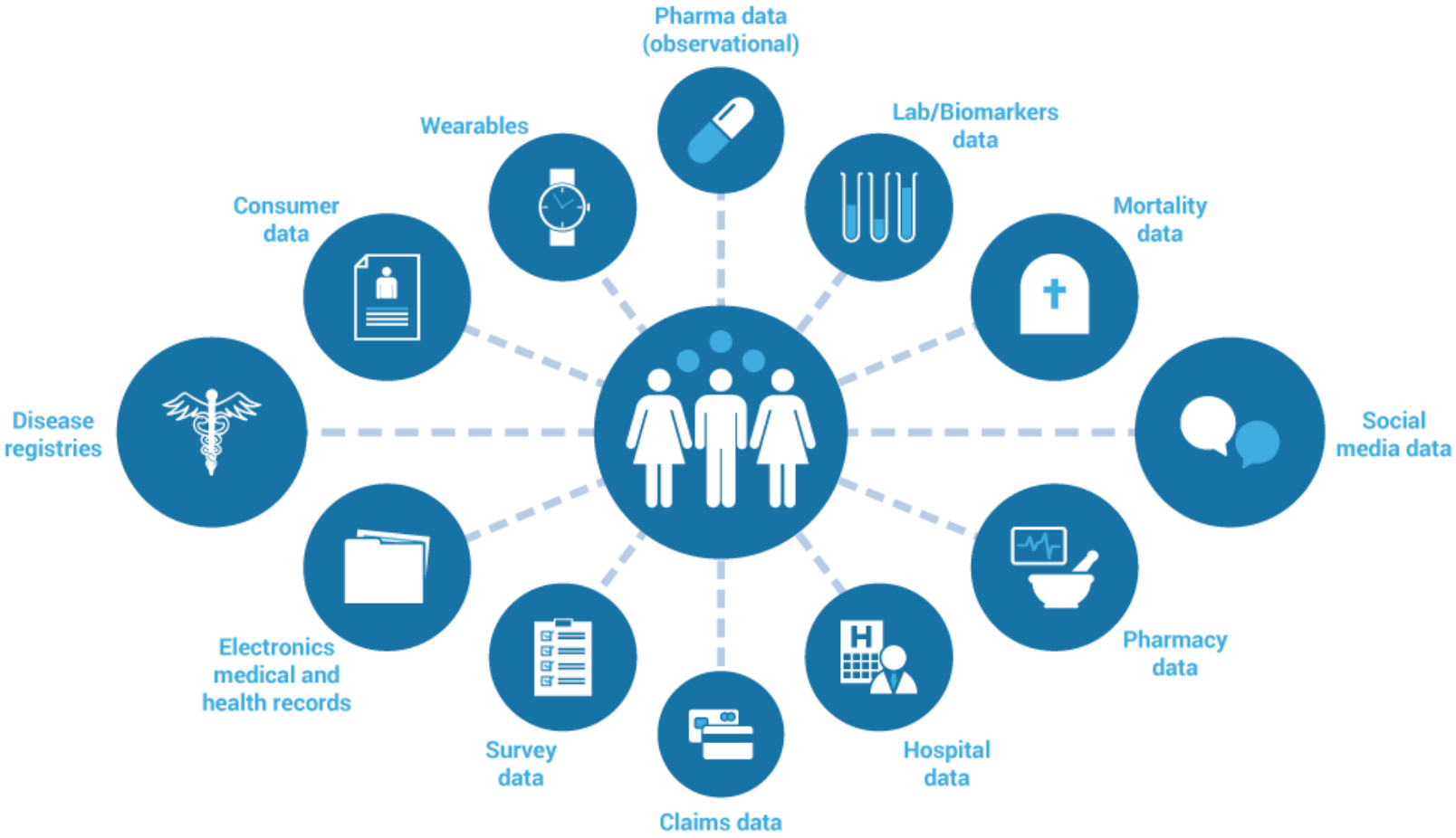
eSources


Pharma data (observational)
Wearables
Lab/Biomarkers data
Consumer data
Mortality data
Disease registries
Social media data
Electronics medical and health records
Pharmacy data
Survey data
Hospital data
Claims data

Danish Medicines Agency's Data Analytics Centre (DAC)

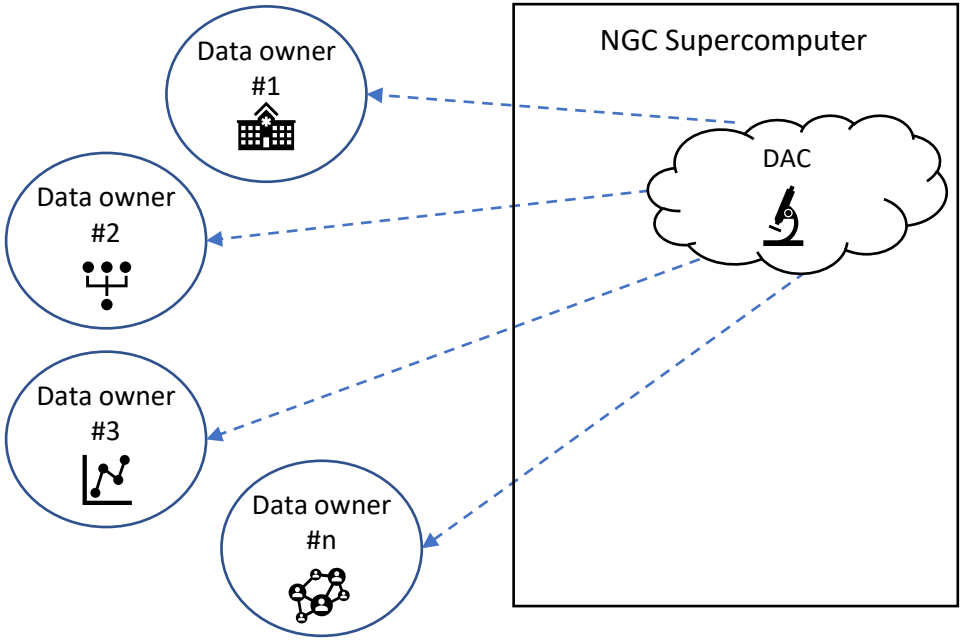
Vision:

"Through use of clinical trial and real world data and advanced analytical methods we want to increase the accessibility of safe and effective medicines and medical devices"

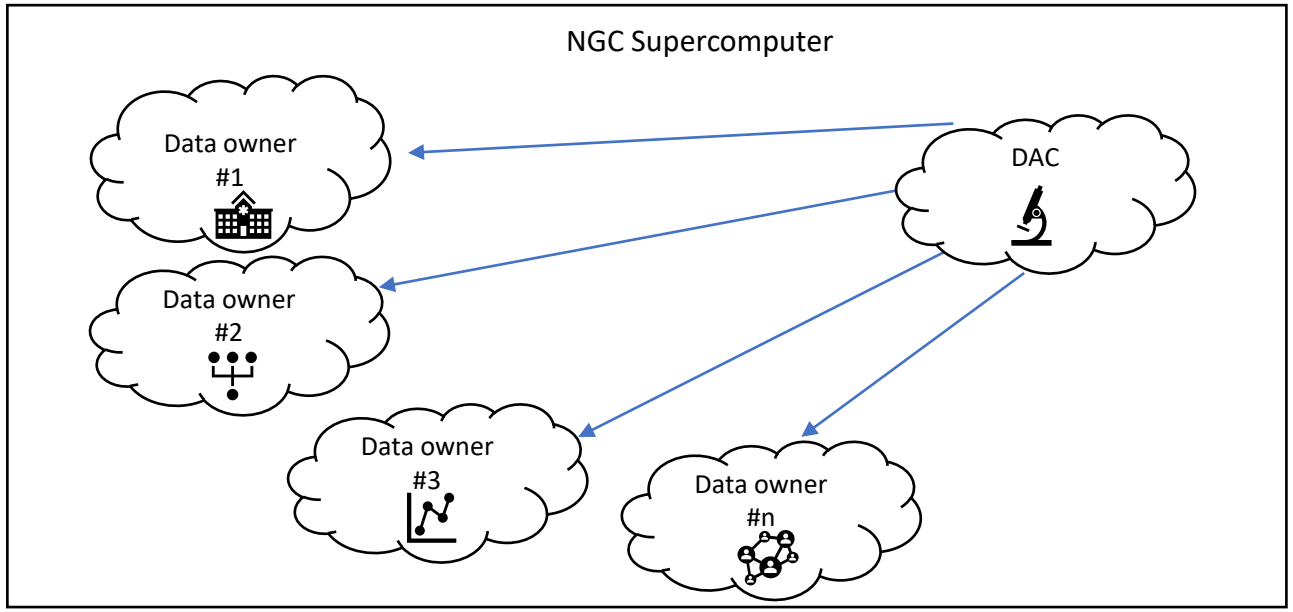
By utilizing the available data in new ways DAC can help usher in a new regulatory paradigm

Business area	Now	Future
Post-approval	• Development and approval > 10 years • Approval based on RCT • Subsequent detection of suspected side effects and signal generation	• Precision Medicine • Breakthrough / PRIME • Conditional approvals expands • ADR supplemented with real world data • RWD: Registries, EHR, SoMe etc.
Pre-approval	• Authorities review summaries of data	• Authorities have access to applicant's raw data (CDISC)
Scientific advice	• Increasingly complex advanced clinical trial designs • No quantitative scientific advice	• Authorities expanded capacity -> quantitative scientific advice • Better regulatory framework

DAC platform is shared with National Genome Centre (NGC)



- Data silos
- High transaction costs
- Low level of cross-fertilization of data
- Not full utilization of High Performance Computing



- Full utilization of High Performance Computing
- Private cloud to cloud hosting
- Realtime data access in highly secure computer environment into analysis / data lake platform
- Full traceability of data use and reproducibility of analysis
- Ability to control access to fully anonymized data and permissioned access for researchers
- Allowing for future development such as automated additional data collection, real time AI/ML into data analysis

DAC and life science ecosystem

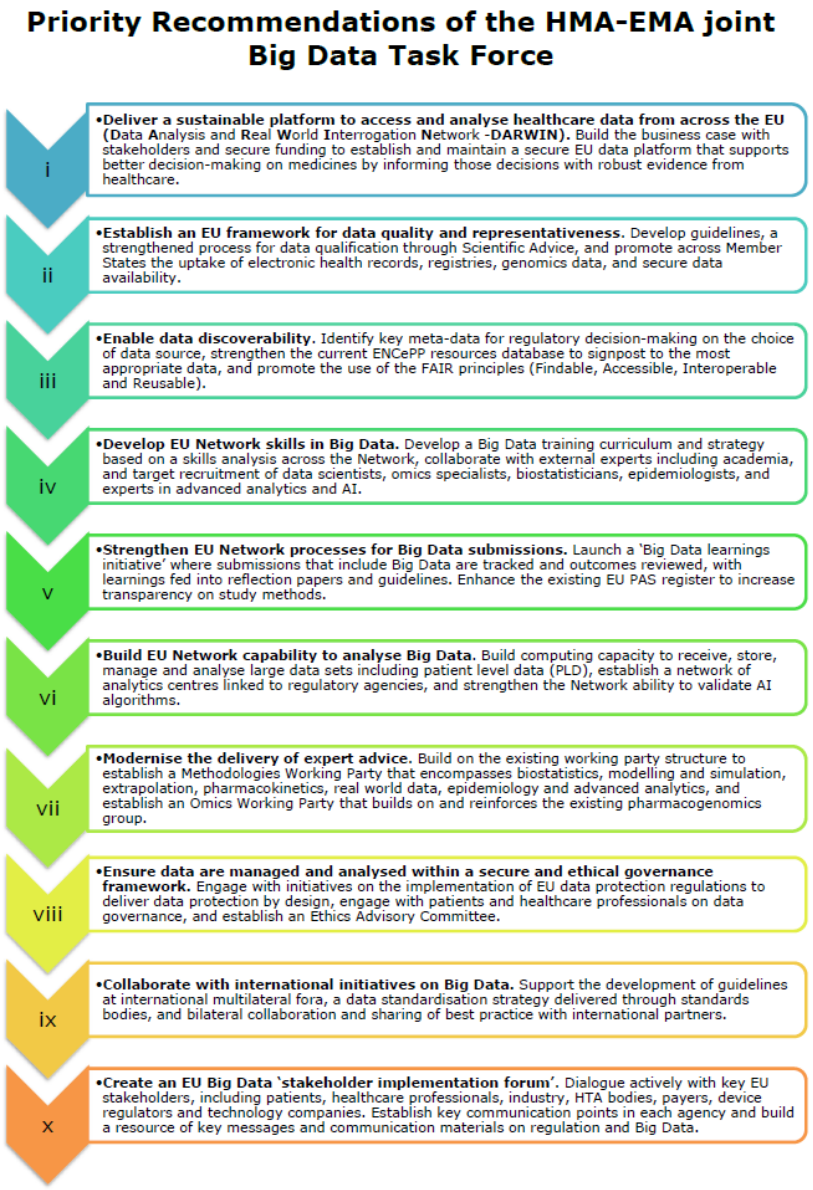
- We aim to be
  - a trusted data broker
  - using high quality data
  - fully transparent and reproduceable
  - playing a direction setting role in life science in an ethical sound use of big data and AI/ML
- What we do should help industry and patients to make drugs and technology faster and safely available
- Ultimately this should benefit patients by reducing inequality in health care with data analytics while protecting data

First example: DAC COVID

cohort and analyses done in collaboration with academia and other national authorities

ueing

- Use of NSAIDs and risk of critical adverse outcomes in patients with COVID-19
- Renin–angiotensin–aldosterone system inhibitors and severe outcomes in patients with COVID-19
- The role of inhaled anti-inflammatory pharmaceuticals in COVID-19 incidence, morbidity, and mortality
- Prognosis of coronavirus disease in patients with immune-mediated inflammatory diseases treated with immunomodulating agents and biologics
- Risk of venous thromboembolism in patients with COVID-19: A nationwide, population-based matched cohort study
- Impact of use of proton pump inhibitors on susceptibility to infection and risk of severe outcomes in patients with COVID-19
- + two papers describing the governance and the database



- Platform (DARWIN)
- Data Quality
- Discoverability
- Skills
- Submissions
- Capabilities
- Expert advice
- Security and ethics
- Collaboration
- Stakeholder implementation forum