

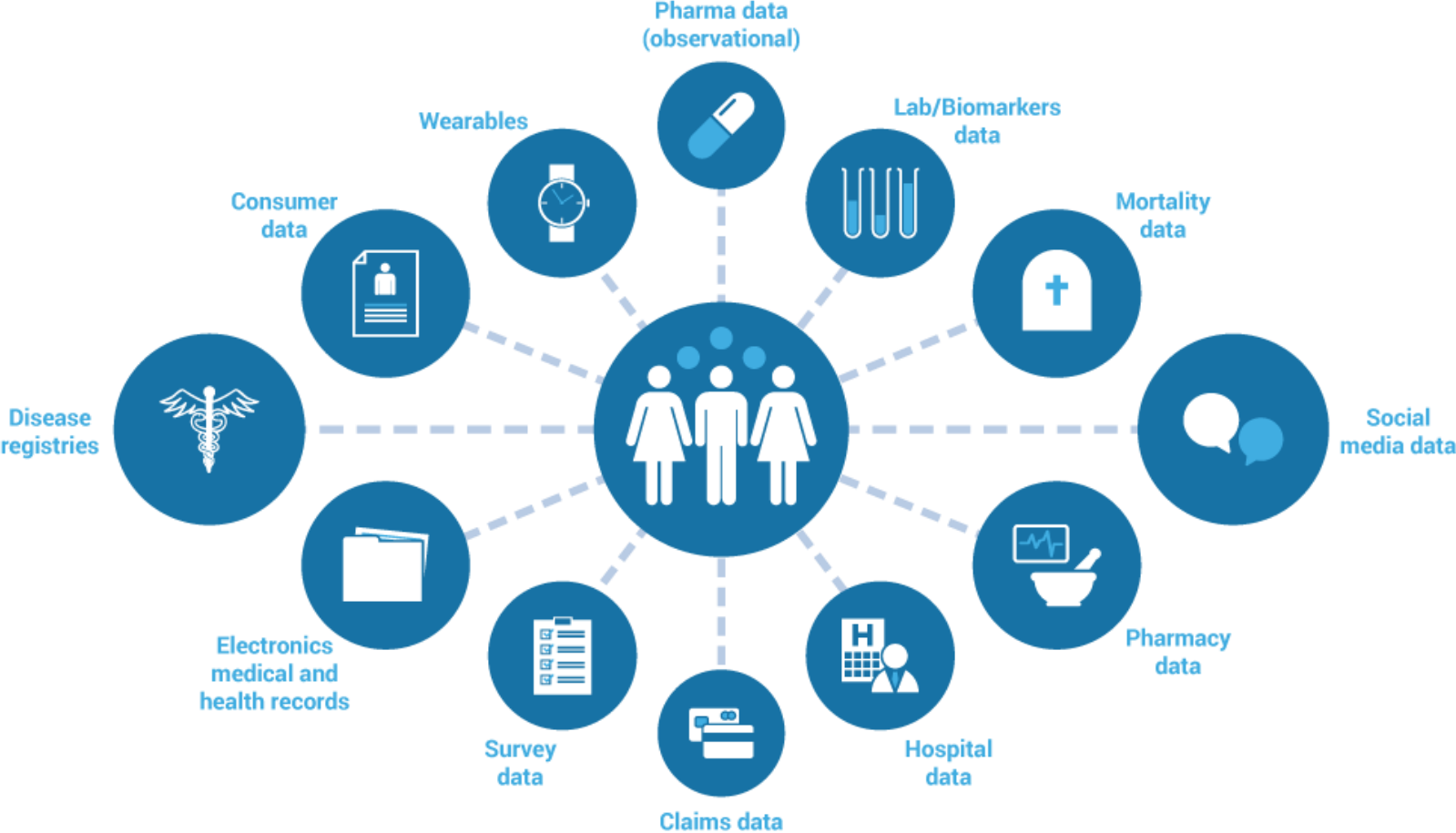
# Personalized Medicine and True eSource

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# eSources



# **Danish Medicines Agency's Data Analytics Centre (DAC)**

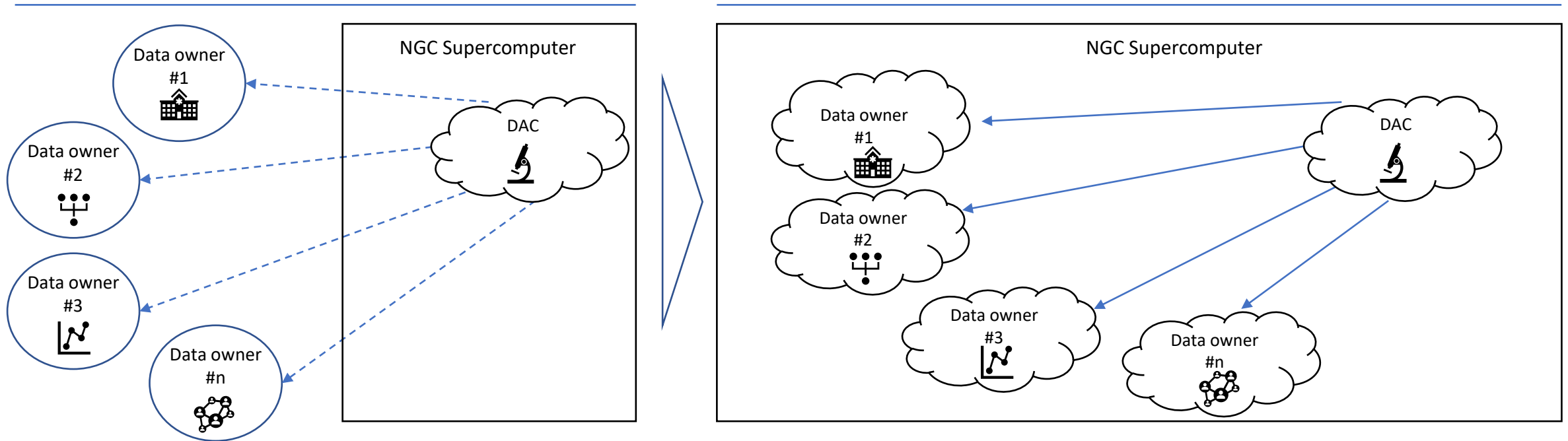
## **Vision:**

“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	<ul style="list-style-type: none"><li>• Development and approval &gt; 10 years</li><li>• Approval based on RCT</li><li>• Subsequent detection of suspected side effects and signal generation</li></ul>	<ul style="list-style-type: none"><li>• Precision Medicine</li><li>• Breakthrough / PRIME</li><li>• Conditional approvals expands</li><li>• ADR supplemented with real world data</li><li>• RWD: Registries, EHR, SoMe etc.</li></ul>
Pre-approval	<ul style="list-style-type: none"><li>• Authorities review summaries of data</li></ul>	<ul style="list-style-type: none"><li>• Authorities have access to applicant's raw data (CDISC)</li></ul>
Scientific advice	<ul style="list-style-type: none"><li>• Increasingly complex advanced clinical trial designs</li><li>• No quantitative scientific advice</li></ul>	<ul style="list-style-type: none"><li>• Authorities expanded capacity -&gt; quantitative scientific advice</li><li>• Better regulatory framework</li></ul>

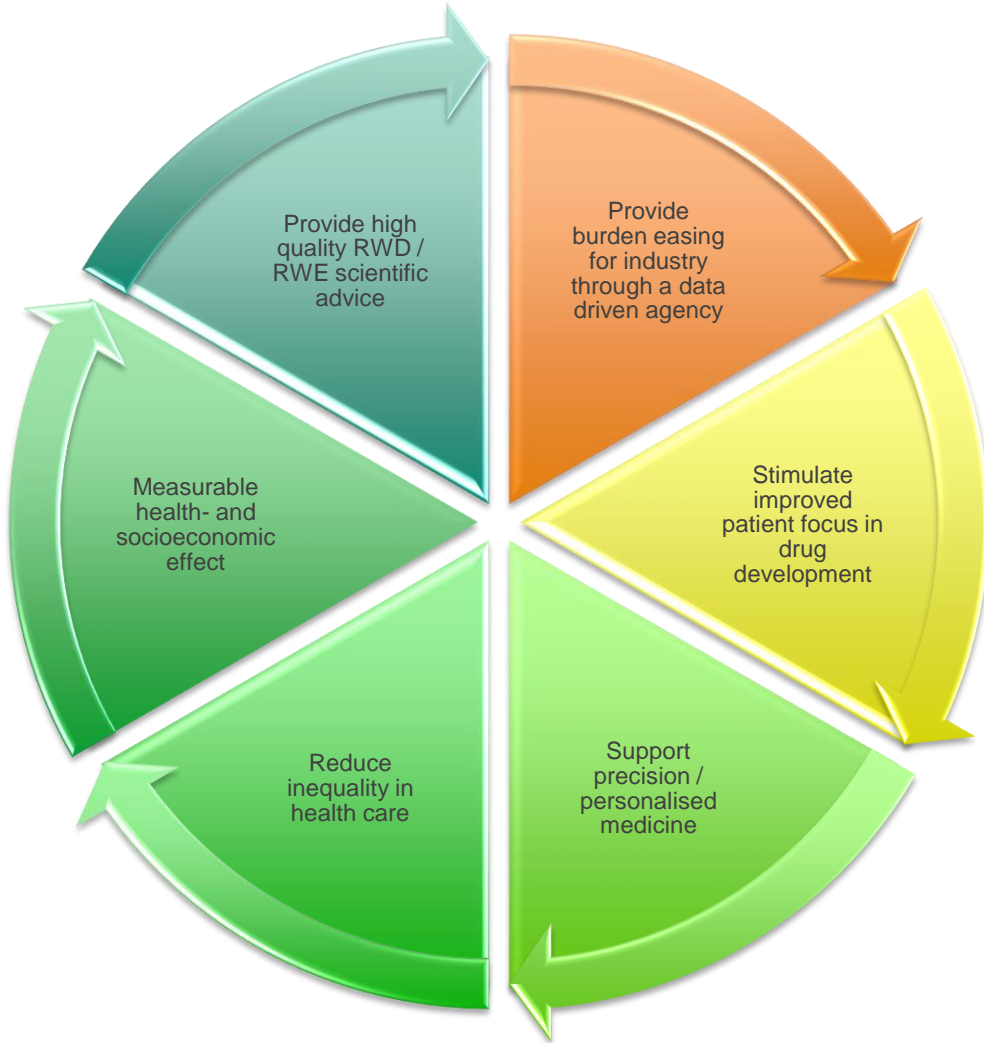
# DAC platform is shared with National Genome Centre (NGC)



- 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 reproducible
  - 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

The screenshot shows the ENCePP website interface. The top navigation bar includes links for Home, Sitemap, Q & A, Notice Board, Links, and Contact Us. The main content area is titled 'View Study' and displays the following information:

- Status: Ongoing
- First registered on: 15/04/2020
- Last updated on: 21/04/2020
- 1. Study identification
- EU PAS Register Number: EUPAS34734
- Official title: Use of non-steroidal anti-inflammatory drugs and clinical outcome of COVID-19: a Danish nationwide cohort study
- Study title acronym: NSAID COVID-19
- Study type: Observational study
- Brief description of the study: In the early stages of the COVID-19 pandemic in Europe, case reports from southern France described young patients without comorbidities who developed severe COVID-19 after exposure to ibuprofen. This led to warnings against use of ibuprofen and other NSAIDs in patients with COVID-19 by multiple parties, including the French health ministry. However, no data has been published regarding the safety of NSAIDs in COVID-19. We aim to study the association between NSAID use and risk of death in patients with COVID-19. In secondary analyses, associations between NSAIDs and hospitalisation, ICU admission and mechanical ventilation will be investigated. This is a Danish nationwide registry-based cohort study. All individuals tested positive for severe acute respiratory syndrome coronavirus 2 will be followed from the date of positive test and 30 days onward for occurrence of death, and from the date of positive test and 14 days onward for occurrence of hospital admission, ICU admission, and mechanical ventilation. Use of NSAIDs will be compared to non-use using an exposure assessment window of 30 days prior to the positive test. Risks, risk difference and relative risk will be estimated for each outcome.
- Was this study requested by a regulator? Yes:
- Is the study required by a Risk Management Plan (RMP)? Not applicable
- Regulatory procedure number (RMP Category 1 and 2 studies only)
- Other study registration identification

- 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

## Priority Recommendations of the HMA-EMA joint Big Data Task Force



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