

# Data Analytics Centre

**- unique possibilities to support development and use of new innovative medicines**

Jesper Kjær, Director of Data Analytics Centre, Danish Medicines Agency



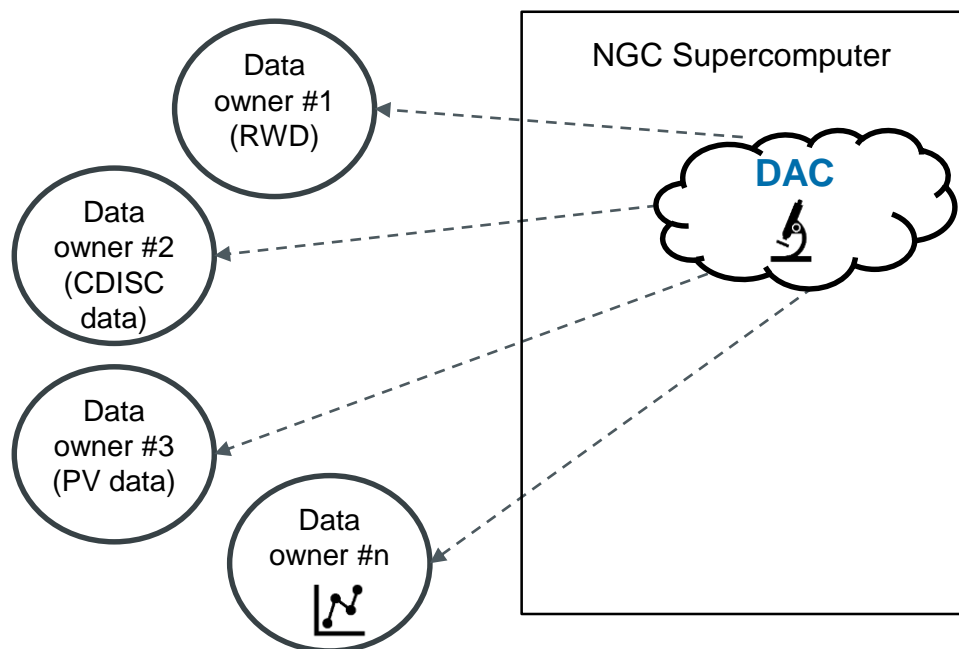
# Vision for the Data Analytics Centre:

**“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”**

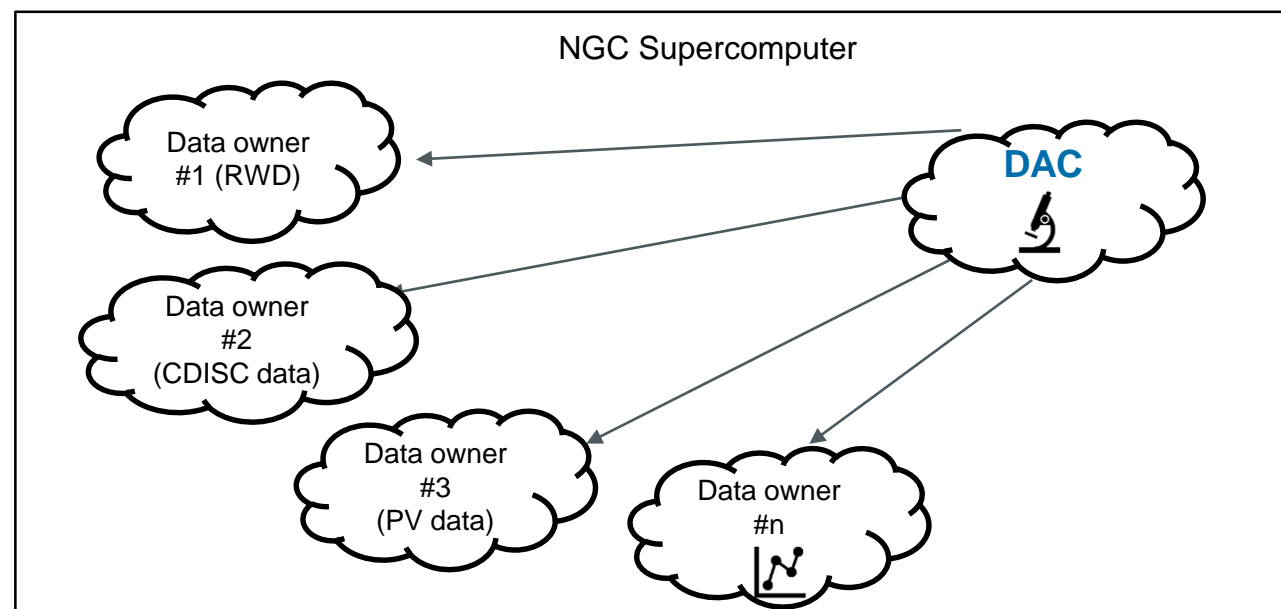
Business area	Now	Future
Scientific advice	<ul style="list-style-type: none"><li>• Increasingly complex advanced clinical trial designs</li><li>• No quantitative scientific advice</li></ul>	<ul style="list-style-type: none"><li>• Authorities expanded capacity → quantitative scientific advice</li><li>•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

# How DAC will connect the data silos in Life Science

**Connecting real world, industry patient level and other data sources on the National Genome Centre**



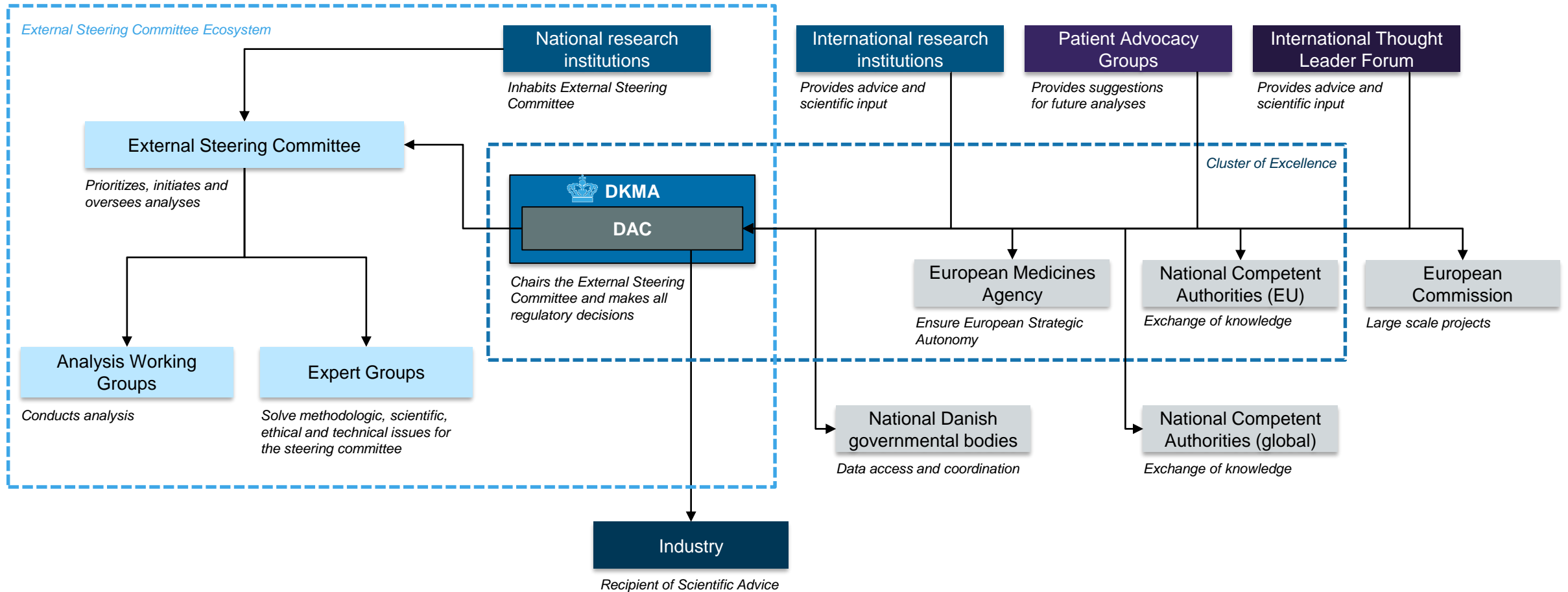
- Data silos
- High transaction costs
- Low level of cross-fertilization of data
- Not full utilization of High Performance Computing



- 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



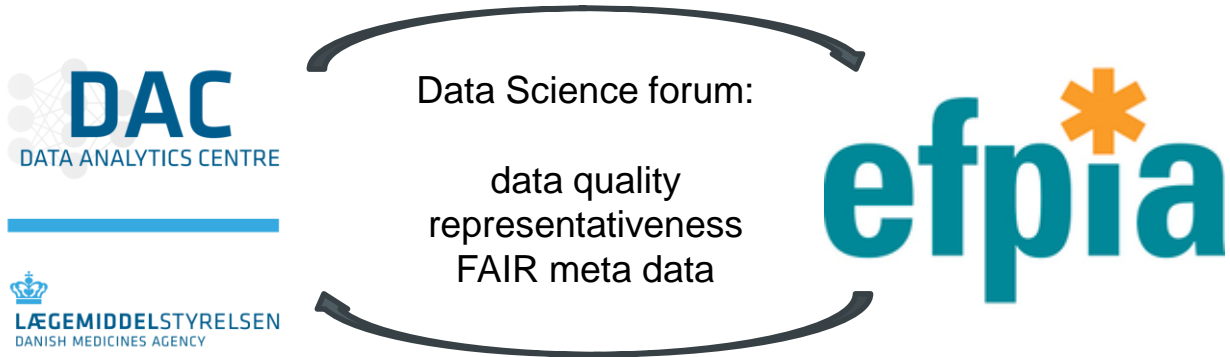
# Governance structure and ecosystem of DAC



# DAC collaborations with industry in relation to RWD

Connecting dots between quality needs, practice and data standards

Quality

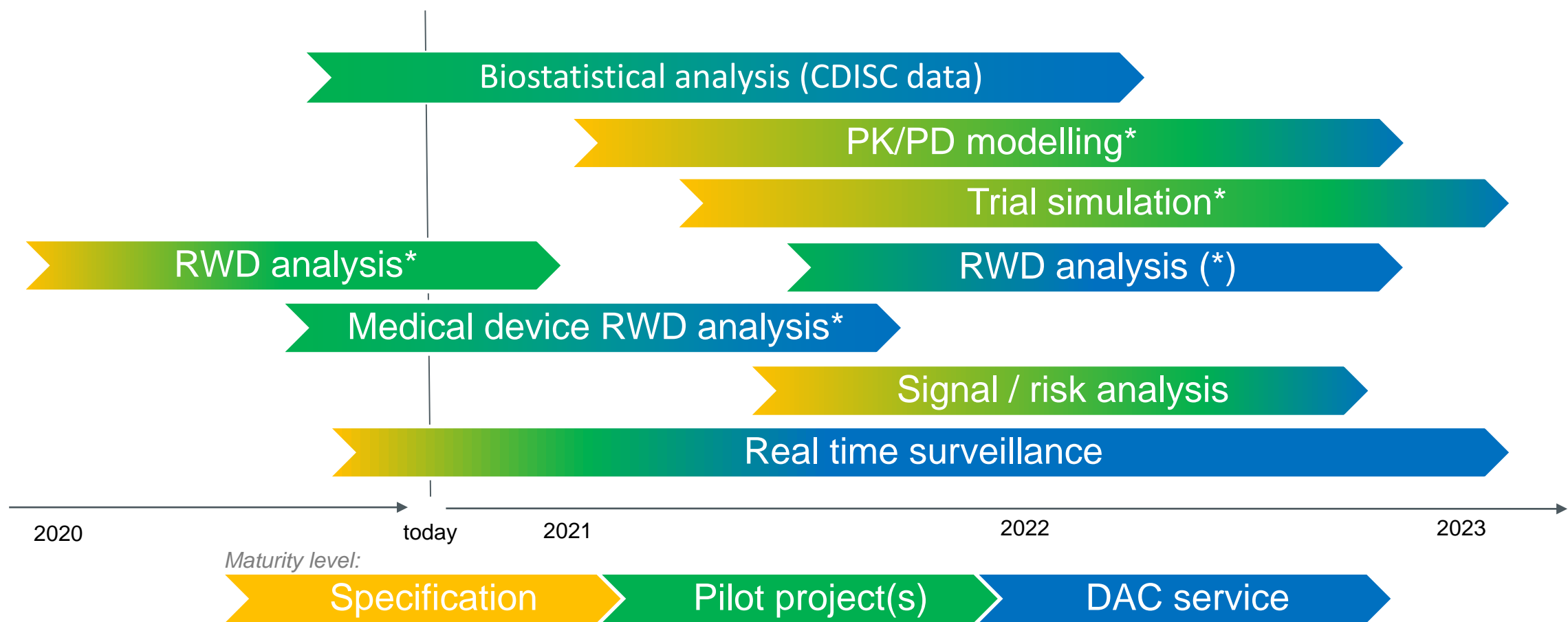


Standards



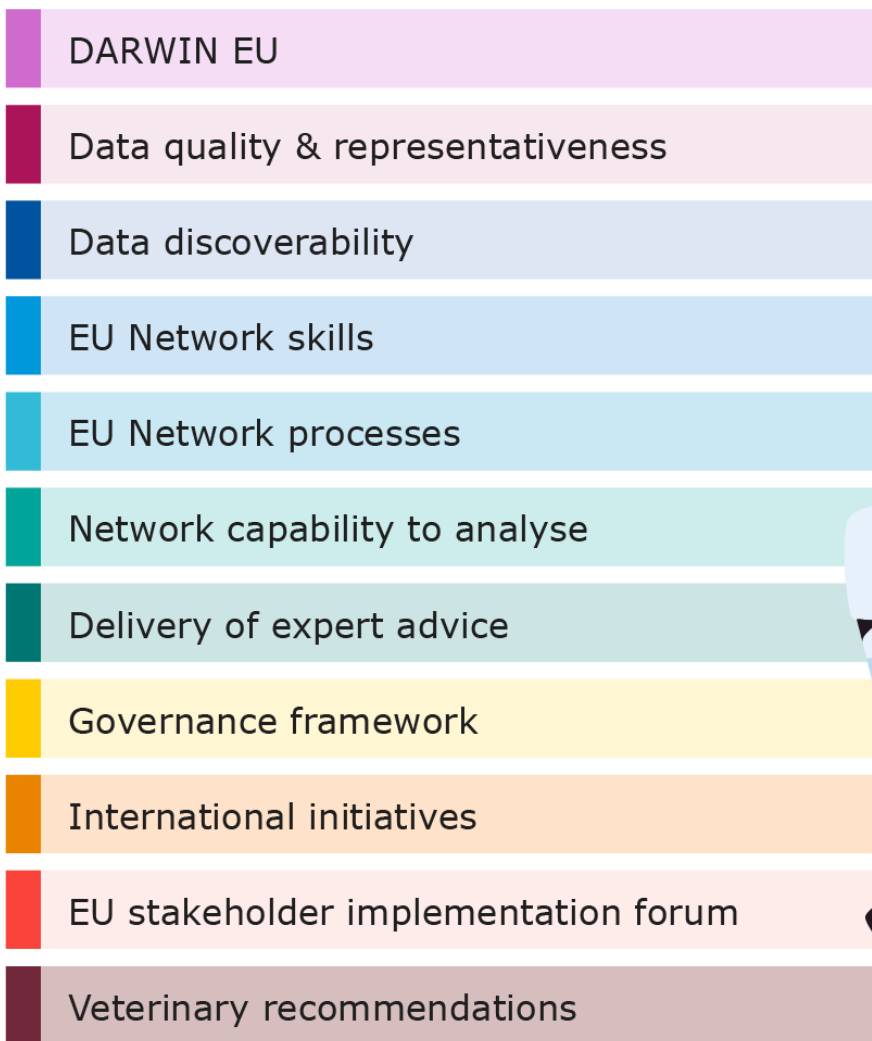
# DAC product catalogue road map

Iteratively and through collaboration expanding the analytical capabilities



\* Collaboration with academia

# HMA / EMA road map – Big Data Workplan



# For more information...

**Imst.dk/DAC**

