eSources
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

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

Provide high quality RWD / RWE scientific advice

Provide burden easing for industry through a data driven agency

Stimulate improved patient focus in drug development

Support precision / personalised medicine

Reduce inequality in health care

Measurable health- and socioeconomic effect

Provide burden easing for industry through a data driven agency
First example: DAC COVID

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

- 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

1. Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network - DARWIN): Build the business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines by informing those decisions with robust evidence from healthcare.

2. Establish an EU framework for data quality and representativeness. Develop guidelines, a transformed process for data qualification through scientific evidence, and promote that Member States integrate the uptake of electronic health records, registries, genomics data, and secure data availability.

3. Enable data discoverability. Identify key metadata for regulatory decision-making on the choice of data source, strengthen the current EUCPP resources database to support the most appropriate data, and promote the use of the FAIR principles (Flexible, Accessible, Interoperable and Reusable).

4. Develop EU Network skills in Big Data. Develop a Big Data training curriculum and strategy based on a skills analysis across the Network, collaborate with external experts including academics, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI.

5. Strengthen EU Network processes for Big Data submissions. Launch a 'Big Data learning initiative' where submissions that include Big Data are tracked and outcomes reviewed, with learnings fed into reflection papers and guidelines. Enhance the existing EU H2020 register to increase transparency on study methods.

6. Build EU Network capability to analyse Big Data. Build computing capacity to receive, store, manage and analyse large data sets including patient level data (PLD), establish a network of analytics centres linked to regulatory agencies, and strengthen the Network ability to validate AI algorithms.

7. Modernise the delivery of expert advice. Build on the existing working party structure to establish a Methodologies Working Party that encompasses biostatistics, modelling and simulation, biostatistics, pharmacometrics, real-world data, epidemiology and advanced analytics, and establish an Omics Working Party that builds on and reinforces the existing pharmacogenomics group.

8. Ensure data are managed and analysed within a secure and ethical governance framework. Engage with initiatives on the implementation of EU data protection regulations to deliver data protection by design, engage with patients and healthcare professionals on data governance, and establish an Ethics Advisory Committee.

9. Collaborate with international initiatives on Big Data. Support the development of guidelines at international and multilateral fora, a data standardisation strategy delivered through standard bodies, and bilateral collaboration and sharing of best practice with international partners.

10. Create an EU Big Data ‘Stakeholder implementation forum’. Dialogue actively with key EU stakeholders, including patients, healthcare professionals, industry, HTA bodies, patients, device regulators and technology companies. Establish key communication points in each agency and build a resource of key messages and communication materials on regulation and Big Data.

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