

De-identification of clinical trial data at Novo Nordisk A/S to enable secondary use of anonymized* data for research

In order to facilitate the use of data from our clinical research in further scientific investigations, Novo Nordisk has established a new system for sharing of data with external researchers in response to legitimate scientific requests. Via this system external researchers can submit their requests for access to anonymised* datasets from Novo Nordisk sponsored clinical trials.

In case of approval, Novo Nordisk provides t de-identified trial data to protect patient anonymity together with the redacted Clinical Study Report, thus enabling the researcher to complete the proposed analysis.

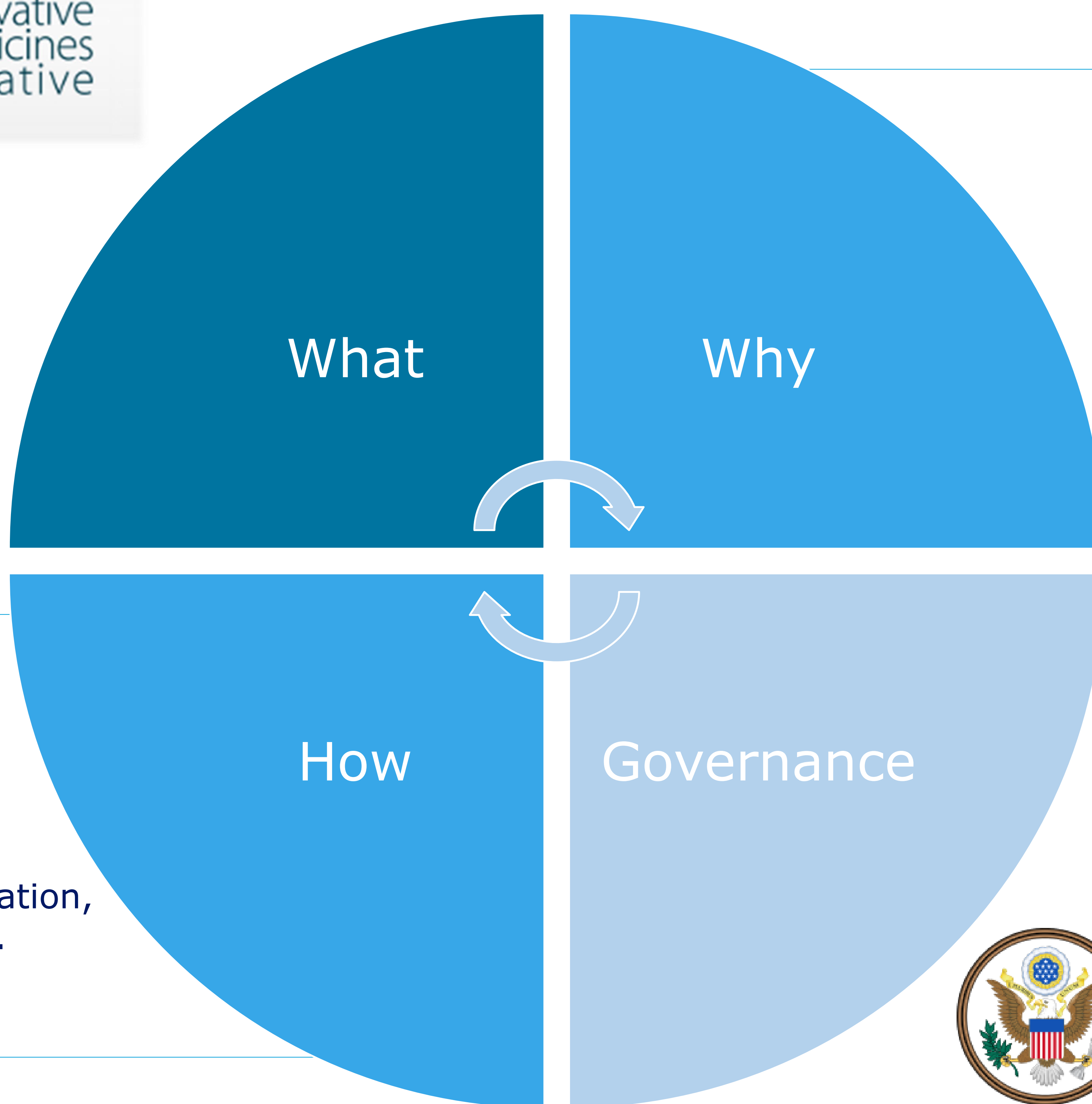


Secondary use of clinical data



Data access

<http://www.novonordisk-trials.com/>



- Increase transparency
- Help research and innovation
- Advance development of new products and services
- Share knowledge
- Improve patients life and treatments
- Cost saving and faster trials

- Custom SAS de-identification and risk assessment tools
- Single-sponsor highly secured portal
- Metadata controlled de-identification and documentation
- Specified rules for column and row de-identification: randomization, generalization, computation, suppression, masking, ... etc.
- Risk assessment
- Documentation



The HIPAA Privacy Rule

HIPAA: Health Insurance Portability and Accountability Act



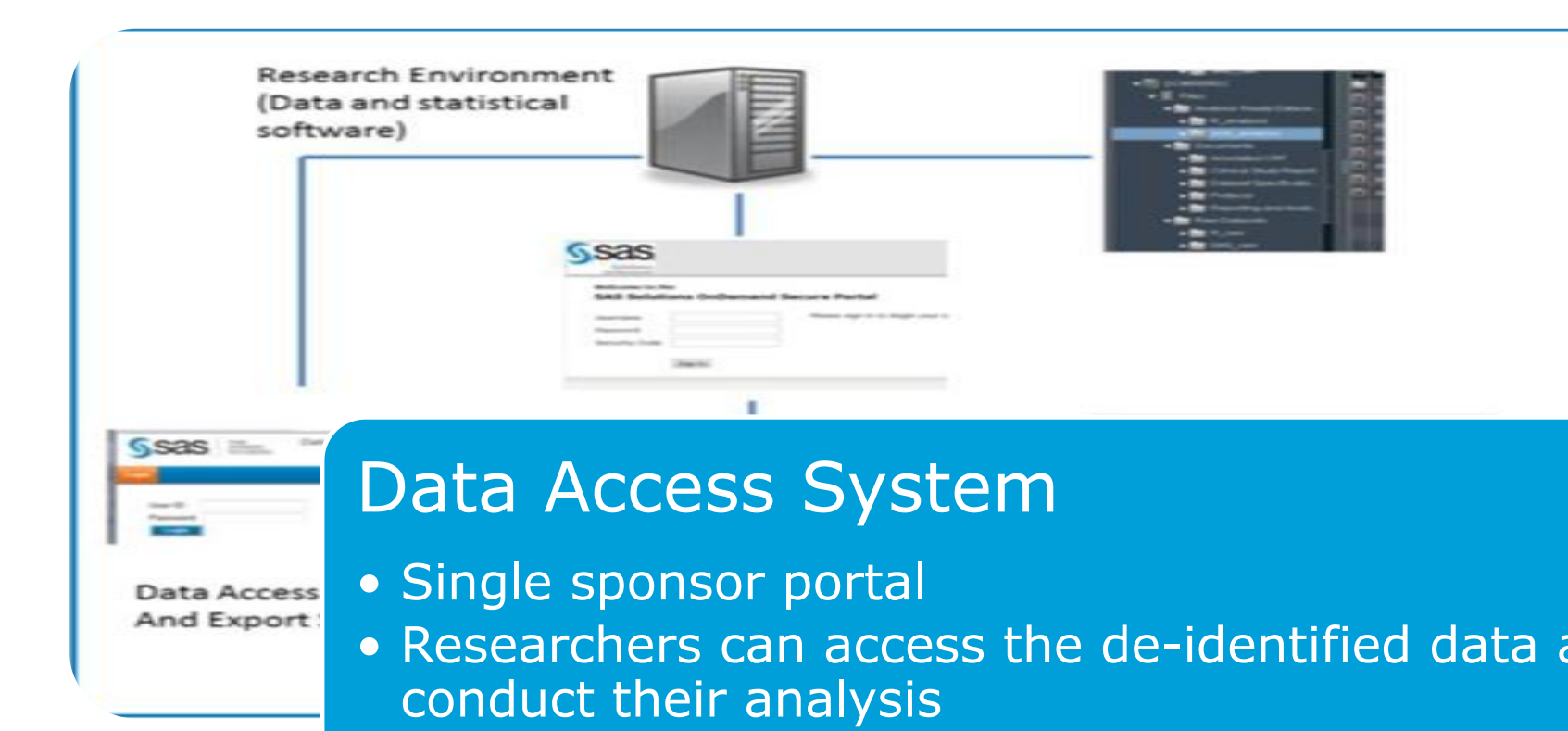
Request Website

- <http://www.novonordisk-trials.com/website/content/how-to-access-clinical-trial-datasets.aspx>
- Researchers can submit their data access request from this website



Independent Review Board

- Data Access Request
- Data Sharing Agreement



Data Access System

- Single sponsor portal
- Researchers can access the de-identified data and conduct their analysis
- Secure access and audit trail



* Anonymised subject data is irreversible de-identified data (where the key, randomization seed and the link between original data and de-identified data are deleted to prevent traceability to subjects) of already anonymous subject data.