Novo Nordisk Foundation
Tuborg Havnevej 19
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Letter of support and commitment

In our capacity as partner, Danish Regions support the application of the Danish Ministry of Health to the Novo Nordisk Foundation (NNF) for a grant to support the development of the present part of a national infrastructure supporting genome sequencing in the Danish Health Service.

An infrastructure which should improve the access and the quality of patient relevant data sets with the intention that clinicians all over Denmark (irrespective of geographic location) will be able to provide the best information and optimal treatment according to the benefit of the patient.

Together with the Ministry of Health, Danish Regions have developed the National Strategy for Personalised Medicine and the vision for an expansion of a national data infrastructure in support of the strategy. This to benefit individualised, equal clinical treatment of patients everywhere in Denmark as well as quality development and research.

An NNF grant would undoubtedly accelerate the development and the implementation of the planned and necessary infrastructure to support the current development of Personalised Medicine and the future development of Personalised Healthcare, where various "-omics" will be combined with other phenotypical data for individualised prevention and treatment of disorders.

The regions have already initiated the process with health professionals and clinicians all over the nation in a joint effort with the universities. As agreed with the Ministry of Health, this effort will proceed as follows:

1) continued standardisation and development of National Quality Databases under the auspices of the Danish Clinical Registries (RKKP);

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2) continued standardisation, development and consolidation of the biobank structure. Especially in Bio- and Genome Bank Denmark (RBGB) but in collaboration with the Danish National Biobank; and
3) jointly with the universities setting up regional data support centres under joint governance; with one point of access for competent and safe access, interpretation and use of data, and mapping of available data sources for pre-defined purposes as the most important tasks. Also included are research administration and contributions to set up a homogeneous model and method to be used for pseudonymization of genome data.

In its support to this application to the NNF, Danish Regions has emphasized especially the (4,5-year) detailed components of the project in the form of:

1. Setting up a National Genome Centre as an agency under the Ministry of Health embracing all genome activities in Denmark.
2. A governance structure which will ensure that all relevant patients and clinicians will benefit equally from genome sequencing in terms of the time allocated to and the quality of the treatment and advisory services.
3. Setting up a National Whole Genome Sequencing Center; initially with two sequencing locations and scheduled for later scaling and decentralization within the national framework of the National Genome Centre. This centre will comprise special competencies that will support and contribute to the development of relevant competencies all over the nation and to the benefit of all relevant patients and clinicians in the context of specific diagnostic scenarios and treatments.
4. Setting up a national HPC structure at Risoe which can be linked with the existing HPC structure in Denmark (Computerome, GenenomeDK, Abacus) to form a long term solution to the capacity issue.
5. Setting up a National Genome Database with the long-term perspective to gather all genomic data (starting with whole genomes produced in Denmark).
6. Standardisation of all genome data and the duty to report, including any whole genome sequencing (WGS) that may have been performed by other clinical environments and academic centres.
7. Transparency, availability, usability and reuse of data for all clinicians and researchers with a legitimate purpose in Denmark.
8. Setting up National Knowledge Databases which will support the clinical use of WGS for diagnostic and therapeutic purposes and contribute to the development of guidelines.

9. National specification requirements for all sequencing equipment used in Denmark and the possibility to issue a call for tenders at national level.
10. The possibility for a call for tenders and joint purchases of reagents (for example through Amgros).
11. The potential for improved international collaboration regarding treatment, research and innovation.

The regions make the commitment to continue and expand, together with the State (the universities) the infrastructure specified in this application as an integral part of the operation of and research conducted by the entire and collective health service.

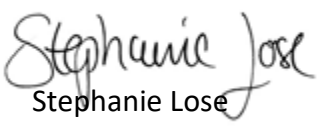
Today, whole genome sequencing equipment can be found at all four university hospitals (Illumina NOVAseq with an annual capacity in excess of 30.000 WGS procedures). In addition to its use for research purposes, the equipment will increasingly form an integral part of standard diagnostic procedures. This will continue funded by regional budgets likewise universities. With this in mind, this application should not be seen as a change of course, but rather as an opportunity to improve and speed up a process already in motion.

The regions commit themselves in collaboration with the universities to intensify (continuing) education to improve relevant competencies in order to optimise the outcome of genome sequencing for the purpose of patient treatment.

The regional co-financing is estimated to an amount of around DKK 770M based on a WGS count of 60.000. Additional information on this matter is provided in the Letter of Regional Co-financing.

Furthermore, Danish Regions is in the process of developing a future application basis to obtain funding to establishing Data Support Centres and forced expansion of Danish Clinical Registries (RKKP) and Bio- and Genome Bank Denmark (RBGB).

Best Regards



Stephanie Lose

President of Danish Regions