Better use of health data
May 2018
Foreword

Copenhagen Healthtech Cluster took the initiative in the autumn of 2017 for Data Saves Lives which now has the participation of more than 25 public-private partners. Danish health data is a source of knowledge that can provide healthcare professionals, researchers and the business sector with better insights into disease and treatment. The Data Saves Lives Partnership wishes to identify how access to health data and its use can be improved for the benefit of patients, citizens and society. Our ambition is to present three specific proposals for solutions which could be implemented within existing frameworks and with a high degree of data security.

We hope that our proposed solutions will be well received so that we can work together to transform them into specific action.

Partners backing Data Saves Lives

The following organisations have collaborated on the proposed solutions for better use of Danish health data:

The Professor Søren Brunak from University of Copenhagen, IBM Danmark ApS, the Regional Quality Development Programme and various patient associations have contributed with their expertise for the process.
# Contents

Vision and background for Data Saves Lives  7

Solution proposal 1: National Data Map  10

Solution proposal 2: Data Entry Point  16

Solution proposal 3: Data Sandboxes  24

Conclusion  36

Recommendations for next steps  37

Appendices  40

# Appendices

1. Sources and listing of analyses and documentation on health data

2. Access to health data for researchers

3. Legal basis for the three proposed solutions
Vision and background for Data Saves Lives

The report you are about to read is based on a single vision: We need to use our unique health data much more actively to increase Danish citizens’ chances of living longer, good lives without disease. Illnesses can be prevented but once they have seriously taken hold, they need the best possible, personalised treatment. That requires data. In Denmark we have some of the best in the world. We wish to use it to be much more active in improving the health of all of us.

The authors of this report are a broad group of public and private players that use Danish health data every day. We have decided to work together because using Danish health data could work much better than it does now. We would like to use this report to make some specific proposals for how it would be possible to increase the use of health data with a high level of IT security and within current legislation, to make Denmark better for example at preventing diabetes, finding a cure for dementia and optimising treatment for infertility. Data can save lives. But that only happens if we use it.

Why this report?
In just a few most recent years, the volume of health data in Denmark has risen dramatically, as has our awareness that data is valuable. But a series of data scandals and leaks have also emphasised the fact that there are potentially great risks in collecting and combining data. We should like to use this report to point to the major health benefits that we can generate together if our health data is used safely and within the legislation. Danish health data is already used for research. But there are various obstacles which mean that it is used much less than it could be. This means that in Denmark, we are missing out on innovative, new opportunities for preventing disease and treating sick people. The most significant obstacles are:

- **Time.** Getting an overview of and accessing Danish register data is a lengthy and difficult process. Denmark has at least 160 public registers. Most of the Danish registers have different application procedures, which make it more difficult to use existing data optimally (see the review of application procedures in Appendix 2).

- **Legal issues.** Use of register data is often restricted since it can basically only be used for the purposes for which it has been collected. This means that it can be difficult to get the opportunity to do more exploratory work with data in a closed, secure environment which is essential when working to develop algorithms, for example to identify early signs of the disease in cancer prevention.

- **Technical challenges.** Computer systems are developing rapidly but there is a problem in that some Danish health data such as tissue samples from biobanks, images and patient records have not been fully digitalised. Also, not all of the many Danish registers are based on modern IT platforms that have integrated data protection that can ensure data is anonymised and can monitor data users. Many new IT platforms also make new scientific breakthroughs more likely by being able to combine register data with patient data for example from apps or sensors.
Several of the countries we normally compare ourselves to, especially Finland and Estonia but also to a certain extent Norway and Sweden, have deliberately decided to take an active approach to make it easier to access and use health data. So even though Denmark has some of the best health data in the world, we risk lagging behind in innovative use of health data compared to the rest of the Nordic countries.

In recent years there have been many initiatives in the field of health data, for example with the STARS* health data programme, the national strategy for personalised medicine, establishment of the Danish Health Data Authority, Open Data DK, PROCRI, the Government’s Growth Team for Life Science and the SIRI Commission (see Appendix 1 for a schedule of previous health data initiatives, also in Denmark) but despite these initiatives, it is still difficult and highly time-consuming to access and use health data in Denmark. The government has also recently used its Growth Plan for Life Science to point to various initiatives that predicate secure use of health data.

These obstacles made Copenhagen Healthtech Cluster invite all the authors of this report to take part in a rapid mapping process in the autumn of 2017. The specific purpose was to draw up a series of specific solutions and recommendations that could be implemented immediately within the present legislative framework in Denmark.

We selected three overarching ideas which we felt could deal with as many of the challenges we describe in the shortest possible time:

- Data Map, which gives an overview of where and what data can be found
- Data Entry Point, which can advise and facilitate researchers and companies wishing to use health data
- Data Sandboxes, enabling more exploratory highly secure access to data

Each of the three potential solutions is described in detail in the report. We have tested the proposals legislatively and technically and investigated which collaborative format would best support them. Finally, we have identified and described a series of cases:

- Danish cases demonstrating that Denmark is already bubbling with energy and exciting initiatives.
- Examples from abroad showing how far comparable countries have already got.

What is health data?

Health data refers to all kinds of data used to describe the healthcare of citizens, such as use of medication, visits to the doctor, hospital admissions and genetics but a whole range of other data can also be used to boost our understanding of health, such as income, housing, education, etc.

Health data is registered in Denmark as part of admissions, treating patients and monitoring a whole range of illnesses. But health data can also be gathered via apps, smartphones, wearables and even contact lenses.
Reading notes

This report is a catalogue of ideas, first and foremost for use as inspiration. The blue pages provide examples of where Denmark is already a significant player in the data-driven agenda and they describe inspirational international projects. We have also inserted skin-coloured boxes with quick explanations. The blue boxes explain concepts whereas the white boxes describe the three proposed solutions.
1 Data Map

Key functions

- A consolidated national data catalogue making it possible to search across all databases and registers
- Describe the type of data in individual registers
- Describe the documentation for individual registers, such as the indicators and variables used in the registers.
- Describe application procedures
- Contain cases illustrating how data has been used to add value for the general public and patients
- Visualise the volume of registers
- Describe the quality of the dataset (if it is complete for example or if there are special issues to be considered)
- Describe how the variables in individual registers can interrelate with variables from the other registers.
We propose
There are various data registers and biobanks in Denmark which have online search functionality that makes it possible to search for available data. However, there is no overarching national metadata catalogue making it possible to search across all the country’s registers and biobanks. This means that users find it very difficult to get an overview of the data that is available and where it is located, meaning users have to contact many different places. Access to data is made even more difficult by the fact that most registers and biobanks have different application procedures (see Appendix 2). And finally, there are still some registers that do not yet have online search functionality, which makes it significantly more difficult to locate data.

Therefore, we first and foremost propose drawing up a national data map, or metadata catalogue, to provide a general, rapid overview of registers and biobanks in the field of healthcare. The national data map is intended to make it easy to get an overview of the data held in various registers and its quality so that users can be directed to the right place immediately.

In time, the national data map could help boost collaboration between individual register owners and to harmonise application procedures and search functionality in individual databases.

Legislative considerations
There are no legal obstacles to establishing a national data map provided that it functions as an overarching catalogue (reference work) which does not itself hold data but merely supports fast, effective searching across the overall variables in the many Danish registers (see Appendix 3 for more legal details).

Technical considerations
From an IT point of view, it would be simple to create a national data map and to enable it to search for data that is already in the public domain and available on websites. The challenges are rather in the quality of the data provided by register owners and incentives to maintain and update the data national data map.

There are five major registers in Denmark:
The Regions’ Bio and Genome Bank, Researcher Service from the Danish Health Data Authority, Researcher Service from Statistics Denmark, the Regional National Clinical Quality Databases and Danish National Biobank (see Appendix 2).

Legislation has also been proposed to set up the sixth major register, the National Genome Center.

Examples of solutions
There are five major registers or data entry points in Denmark, each of which provides an especially good overview, with search functionality for its own data. The five registers have mainly been set up according to type of data (e.g. whether data is ‘wet’ or ‘dry’) and depending on whether the register owner is regional or national.

‘Wet data’ are biological samples such as biopsies, tissue samples and blood tests. ‘Dry data’ are figures and notes from patient records, questionnaires, lab responses, etc.

Metadata means data about data. A metadata catalogue is a schedule or catalogue of the various data available in Danish registers.
It is possible to search for wet data in the Danish National Biobank

Case 1:
Danish National Biobank

The Danish National Biobank is a three-pronged project consisting of a biobank register, a large physical biobank and a co-ordination centre. The biobank register is an online tool to give researchers an overview of more than 20 million biological samples held in participating Danish biobanks. The system can also link information on biological samples with data from the CPR register, the National Patient Register and the Pathology Register.

The register can be used for example to check the samples’ availability for specific disease groups. Searches can be by diagnosis date but also earlier, which makes it possible to do prospective studies. An aggregated (anonymised and structured) dataset is also available via the register’s search function which can be accessed by researchers from the whole world.

The National Biobank Register is open to all and free of charge but obtaining samples requires Research Ethics Committee approval.

A prospective study follows citizens going forward. A good example is the ‘Mother - child cohort’ which has followed up on 100,000 women and their children right from the start and investigated them for everything from allergy to psychiatric diagnoses.

The Danish National Biobank has some of the most advanced, secure and monitored systems in the world and has great expertise in registering, processing, storing and analysing samples.
Case 2: The Clinical Quality Databases

The Regions’ Clinical Quality Development Programme (RKKP) provides the infrastructure for the national clinical quality databases and the Danish Multidisciplinary Cancer Groups. The main purpose of the programme is to ensure better ongoing utilisation of national clinical quality databases from clinical, managerial and research points of view. An RKKP team with expertise in epidemiology, biostatistics, IT/data management and clinical coordination is also assigned to each database.

The databases and team have focused on ensuring good utilisation of existing health data whilst reducing the burden of data entry and maintenance, among other things by standardising input and output for the registers and product/method development.

RKKP also works specifically to provide an overview of its own data. It is possible to use RKKP’s website to access the metadata catalogue, including a short description of each individual database. Documentation for the databases includes standardised metadata and descriptions of the clinical quality databases across Denmark. The documentation is routinely updated by the RKKP team and the databases.

The great advantage of the clinical quality databases is that each of them has a medical steering group illustrating their strong anchoring in clinical environments. They routinely interpret the results with respect to clinical practice, combined with RKKP’s high level awareness of and experience with gathering and analysing data.
The Swedish metadata platform - Register Utiliser Tool (RUT) - provides information about variables and data in Swedish official registers, quality registers and biobanks. The aim is to make it easier and quicker for researchers to identify and compare variables in various Swedish registers and to find out which registers contain the variables. In this way, RUT helps researchers develop and specify their research queries. All registers in RUT are set up using the same data model, making it possible to compare variables from the various registers.

RUT is intended to serve as a way of relieving the administrative burden from register owners by helping them develop and maintain their registers and making them more visible for researchers. RUT has a register data council and a reference group that strongly involves researchers and register owners.

Whilst the five major registers in Denmark each have their data entry point where it is also possible to search for data, the Swedes have decided to develop an overarching metadata catalogue, RUT, that specifically supports combining various types of data and makes it possible to search across them.

The division into five major registers in Denmark is perfectly sensible considering the source of the data but they may easily get to be regarded as silos in use since what is often needed is a combination of different types of data (e.g. dry and wet).
Summary
In Denmark, several of the major registers such as RKKP, the Health Data Authority and Danish National Biobank have good overviews and search functionality that works well for their own data. However, this does not change the fundamental fact that they are basically divided according to the source of data rather than its use. The fact that it is not possible to search for variables across registers, makes it difficult to do multidisciplinary research into rare diseases where one might wish to link genes, with microorganisms in patients’ stomachs, previous medical records and medicine usage. Further, there are still some smaller registers and biobanks that are not publicly searchable, making it extra difficult to combine data with them.

We propose drawing up a national map of Danish health databases to provide an overall, rapid overview of the Danish health data landscape. Similar initiatives have already been implemented in Sweden and Finland so as to relieve register owners from having to have discussions with researchers and users. The national data map is intended to make it easier to have an oversight of the health data in different registers and the data quality involved, so-called metadata. There are no legal obstacles to prevent implementing the idea and there are various existing IT platforms which could support this.
2

Data Entry Point

What should it be able to do?

- Help provide legal advice in connection with official data approvals
- Help match researchers, users and register owners
- Provide advice on the design and implementation of research projects
- Relieve register owners from dialogue with researchers and users
- Draw up white papers on trends and opportunities in the field of health data
We propose
We propose establishing a common data entry point for all the various registers. A data entry point should be a common structure for all register owners in the state, regions and municipalities, just as they have in Finland.

The purpose of establishing a data entry point is to relieve register owners of having to have dialogue with researchers and users and to provide advice on where individual health data is located and how to apply for access. It is absolutely essential for the common data entry point to be demand-driven, that it can bring down processing time and provide an incentive for actively promoting more research on Danish health data. Responsibility for data should remain with the present register owners who have the necessary legal and technical competencies.

Legislative considerations
Legally, there is no problem in setting up a data entry point that provides advice and mediates contacts between public register owners and public or private sector researchers. It would also be possible to establish a platform for all register owners and any advisory services which could then direct researchers or users to the right service. Similarly, it would also be legal for register owners to work on unifying their procedures, such as their application forms. Register owners would merely have to comply with differentiated guidelines for requirements for approval of research projects, such as ethics committee approvals.

Technical considerations
There are no technological problems if all that is involved is a provider that provides hand-holding services for researchers and professionals to tell them where to get the best, most relevant health data.

Examples of solutions
The following cases provide examples of data entry points which have managed to increase collaboration between public and private players in the field of health data.
Case 4: National Experimental Therapy Partnership

A public/private partnership - 'National Experimental Therapy Partnership' (NEXT) - serves as a single point of entry for corporate and hospital researchers wishing to access clinical research environments in Denmark. The ambition of the NEXT Partnership is to help make Denmark the preferred country for pharma companies to run early stage trials on new drugs in patients.

The NEXT Partnership comprises the regions, universities and various pharma companies. Since it started in 2014, the partnership has managed to make it easier to access clinical research environments in Denmark by optimising the administrative and regulatory processes associated with clinical trials. This is also due to the partnership’s organisation in which the secretariat works directly with the clinical environments in the Regions and with companies currently running clinical trials in Denmark.

NEXT is funded by Innovation Fund Denmark and co-funded by public hospitals and industry. The funding model ensures that individual hospital departments get the resources to enable them to implement clinical trials the moment a company approaches them. All in all, NEXT has had considerable success in attracting drug trials - and hence knowledge and jobs - to Denmark.
The Danish Health Data Authority’s Researcher Machine provides access to health data for research purposes in a secure environment. The Researcher Machine makes it possible to access a wide range of registers from the Danish Health Data Authority and the CPR Register and to combine register data from an external source or researchers’ own data. No new application is required when making amendments or extensions to basic data, except that extending basic data must be reasonable given the purpose of the research project. So Researcher Service needs a reason for how the requested data can help elucidate the research project’s purposes.

To operate the Researcher Machine, the research or analytical environment for which the researcher works must have been authorised. Research and analytical environments that have already been authorised by Statistics Denmark can be authorised for the Danish Health Data Authority’s Researcher Machine if they can show a valid authorisation. Private research and analytical environments can also be authorised.

The extent to which a research environment can access data depends on a specific assessment of the purpose of the research project for which they are applying for data. The Danish Health Data Authority’s Researcher Service is funded primarily by user payments from research environments applying for data, although parts of it are funded by the Coordinating Body for Register-Based Research (KOR) as financial support for public research.

Organisationally, the Researcher Machine is anchored in the Danish Health Data Authority which can access and has in-depth knowledge of national registers and legislation in this area.

There are several researcher machines in Denmark. The researcher machine described in Case 5 belongs to the Danish Health Data Authority. Statistics Denmark also has one.
Case 6: Regional Data Support Centres

The Danish Regions and universities are in the initial phase of establishing a number of regionally located data support centres as part of a national effort for personalised medicine. The purpose of this is to make access for clinicians and researchers to health data easy, secure, transparent and uniform across organisational units and geographical locations. Data support centres are required to provide specific, demand-driven services and consultancy to users, for example in the form of legal and technical advice.

Setting up the regional health data support centres is based on local strengths and existing initiatives in individual regions. The regional health data support centres also wish to provide services to companies by acting as a single point of contact where companies can gain access to an overview of all the health data generated by the national health service. A common governance system will be set up for the whole country to ensure that users get the same services and advice, so that they can regard the centres as a single point of entry and a single coherent solution. The key issue for the data support centres will be to provide secure access to data for clinics and researchers and to offer general project support. The vision underlying the Regions’ data support centres is thus to create a single point of entry for health data in Denmark.

Data support centres are to advise doctors and researchers on health data

Copyright: Ty Stange
Case 7: Watson Data Platform

A data entry point can be established on an IT platform that does not physically assemble data but just runs control systems. The Watson Data Platform is just such a solution. IBM brings together and integrates the best open data analysis technologies on a common platform, in which data processing is done at a single location.

The platform makes it possible to clean, organise, store, access and analyse data. Users accordingly have many options and can also supplement the platform’s functionality with their own technologies.

The solution is a cross-boundary structure where the data is not physically assembled in the solution but is primarily kept where it is gathered. What is consolidated is:

- Management of how data can be accessed
- Management of who has accessed data and when
- Tools for processing data

So, the Watson Data Platform is suitable for supporting overall data entry but also the other proposed solutions described in this report, meaning that IT issues are not the limiting factor for achieving secure, common data entry.
Case 8: Finland’s Digital Health Hub

In 2015, a Finnish innovation foundation, Sitra, launched a project: ‘ISAACUS – the Digital Health Hub’. Funded by Sitra, the Digital Health Hub consists of a range of pre-projects aimed at preparing Finland to establish data entry in the field of healthcare and social services. This also involves developing a national data map and descriptions, streamlining the process for data access applications and establishing secure data sandboxes and providing access to datasets with open data components.

The most significant players and register owners in the field of social and healthcare in Finland are involved in the projects, including the national research centre, THL, the Finnish Ministry of Social Services and Healthcare, and Statistics Finland. The Finnish service provider is required to provide specific, demand-driven services to users.

The Finnish data entry point is still under development and will be operational before the end of 2018. It consists of three overall units:

1. An approvals authority with responsibility for granting data permits
2. A service provider tasked with gathering and combining data from individual register owners and providing them to researchers securely
3. Register owners who have access to data

In addition to the pre-projects, the Finnish social services and healthcare ministry is preparing to modernise the legislation to allow more flexible, streamlined processes for permits for access to health/social data.

Sitra is a Finnish innovation fund which works actively to promote better use of Finnish health data.

Finland intends to set up single entry to Finnish health data
Summary

A national data map is a key first step in the process of creating an overview of available health data sources. But once researchers and companies have located a dataset in the Danish registers, a lengthy, complicated application process starts. This is why we propose establishing a common data entry point to provide guidance with respect to official approvals and design and in undertaking research projects based on health data. Just as in Finland for example, advisory services must be provided across the various register owners in the state, regions and municipalities to relieve register owners of having to have dialogue with researchers and users.

It is absolutely essential that the data entry point is demand-driven so that there are no time-consuming bottlenecks. There must be direct collaboration with the present register owners who will retain responsibility for data since they have the requisite legal and technical competencies. Legally and technically, there is no problem in setting up an overall data entry point that provides consultancy and mediates contacts between public sector register owners and public and private sector researchers.
3

Data Sandboxes

What should they be able to do?

• Make it possible to investigate and combine a whole range of different types of data, such as test data and random samples

• Make it possible to include external data, such as the citizen’s own data

• Function as a display window for new data-driven projects

• Serve as a platform for new strategic collaborations on development between the public and private sectors

• Support opportunities for innovation for Danish entrepreneurs
We propose

If Denmark seriously wishes to strengthen the possibilities of better prevention and better medical treatment for Danes, just having a national data map and the single data entry point is not sufficient. Data will still be in silos which make it difficult to combine it and do more exploratory work.

We propose establishing sandboxes where register owners can work with citizens, patients, healthcare professionals and private partners on testing new algorithms and data-driven healthcare technologies in an enclosed, secure environment. As is already the case for several registers, more environments can be established in individual registers associated with a full scale platform or across register owners and with test data or anonymised/pseudonymised samples from large datasets. Sandboxes should make it easier to try out new ideas and do more exploratory work.

Legal considerations:

Legally speaking, data sandboxes built on anonymised data are no problem. The problems arise in the many cases where it is not possible to make do with anonymised data, for example when using ‘wet data’ such as genetic samples or research into rare diseases where population sizes are very small.

But it is important to note that the purpose of data regulation does to a certain extent take into account the fact that it is often not possible in advance to determine the scientific purpose of gathering data, especially not for sandbox research. Finland and UK have organised their national legislation so that it includes consent while allowing citizens the opportunity to opt out. The same principle has been proposed for the National Genome Center but currently realizing the full potential of data sandboxes in Denmark would require amendments to the law (see Appendix 3 for a legal explanation).

Anonymising or pseudonymising

Anonymising a dataset containing personal data is intended to irrevocably remove individual identification, so people cannot be identified from the actual dataset or by combining with the other datasets. However, studies have demonstrated that creating a totally anonymous dataset is no simple task if it is wished to retain the possibility of analysing and/or generating statistical results on the base of the dataset.

Pseudonymising retains the most important properties of the dataset so that it is still possible to analyse data. Specifically, pseudonymising is done by parts of the dataset being replaced by apparently random values which makes association with the registered person’s original identity very much more difficult.
Technical considerations

In Denmark, we have been able to produce world class research based on our register data. This is due partly to the personal identity (CPR) system which makes it possible to link many types of data and partly the fact that in many cases we have data on a total population. Data on the poor and the rich, the healthy and sick has been gathered and can be analysed. This makes Danish data unique from a global point of view. The new GDPR emphasises the right of citizens to their own data.

Privacy by design og by default

The EU General Data Protection Regulation took effect on 25 May 2018 and impose requirements for IT systems to integrate data protection. This is to be done directly in the design of new IT systems (privacy by design) and by way of standard settings (privacy by default).

Privacy by design is a method for including and integrating data protection in the actual architecture of new IT applications or systems and is supported by active choice of risk analyses and mapping the need for extra security controls. Privacy by default means that systems are structured so that processes only use the personal data required for each individual purpose and that data is only retained for the period required to deliver a given service or product. This actively uses ‘opting in’ (citizens provide their consent for the provision of data) and ‘opting out’ (citizens have the option of withdrawing their data).9

In order to comply with this principle, new IT systems incorporate ‘privacy by design’ and ‘privacy by default’ and the opportunity to opt in or opt out. In future when Finns wish to opt out, their data can no longer be used at the individual level but can still be included in aggregated (anonymised and grouped) datasets, so that the Finnish community can do research on the full dataset.

Examples of solutions

Very high quality research is already being done these days on Danish register data. With at least 160 different registers with different application procedures and without a standardised set up for registers, working across data silos is time-consuming and difficult.

The most important thing about the sandboxes is the possibility of working across data silos and doing research into new ideas with a high level of security. Work is being actively done in Denmark on building up actual sandboxes but currently, opportunities seem rather to have arisen from interdisciplinary basic research. The Researcher Machine (already described in the report), PERSIMUNE and Computerome are examples of this.

The General Data Protection Regulation (GDPR) is the new personal data regulation for the European Economic Areas (EEA) which took effect on 25 May 2018 and has a heavy emphasis on data protection.

GDPR will not only be significant for EU member states but also for all countries in the EEA. The EEA comprises all the EU member states together with Iceland, Norway and Liechtenstein. This could make it difficult if Denmark eventually decides to align with the Nordic countries as a global centre for the use of high quality health data for research purposes.

‘Opt in’/‘opt out’ relates to two different IT solutions enabling citizens to actively withdraw their personal data or to actively consent to its use.
PERSIMUNE supports interdisciplinary research into immune disease.

*Case 9: PERSIMUNE*

PERSIMUNE is an interdisciplinary research centre focusing on developing and practising personalised medicine for patients with immune system problems. Since its start in 2015, PERSIMUNE has developed a data warehouse containing data on 165,000 patients. The data comes from ordinary treatment in general practice and research projects (such as determining proteins, metabolites and genetic data) and also includes external data from national registers and the municipality of Copenhagen. A collaboration has been established with Computerome at Risø, which provides access to super computing power, storage space and cloud computing. PERSIMUNE is funded by the Danish National Research Foundation and based at Copenhagen University Hospital.

Access to PERSIMUNE’s database is either for research purposes or via Copenhagen University Hospital clinics which are included in PERSIMUNE, such as the nephrology clinic, cardiopulmonary clinic, abdominal surgery clinic, oncology clinic, haematology clinic and clinical immunology, etc. PERSIMUNE is approved as a treatment database by the Data Protection Authority under the Capital Region’s umbrella reporting of patient treatment. This means that PERSIMUNE does not require specific consent to every single data export provided that the purpose is to give the attending physician or other related healthcare professionals access to relevant information to support the clinical decision-making process, while complying with PERSIMUNE’s guidelines.

One of the many interesting perspectives in PERSIMUNE is that when research results become available that could benefit patients and a clinic, they are translated into clinical decision-making support and personalised medicine as part of routine treatment. The researchers who have access to the database are required to help improve data quality and also are obliged to make their standardised, validated data available subsequently to PERSIMUNE’s database.

PERSIMUNE has managed to streamline application procedures and reduce the administrative load associated with starting up new research projects in the centre, making it a unique example of the fact that here in Denmark, we already have cross-silo thinking and have taken account of the law and IT in a process that is supportive of research and treatment of patients at a very high level.
Case 10: Computerome

Computerome is a supercomputer that is especially designed for the special needs of life science, with researchers having to process large volumes of data, deal with personally sensitive data and undertake complicated calculations. Computerome was established and funded in a collaboration between the Technical University of Denmark, University of Copenhagen and the Danish e-Infrastructure Co-operation and is also used in collaborative projects involving data from multiple countries such as by European ELIXIR Network for biological information.

Computerome is located at DTU Risø Campus and has more than 16,000 so-called cores and up to 10 PB of storage. Computerome has a secure private cloud infrastructure that makes it possible to differentiate the security model from project to project, log what individual users do and the data they specifically access. The cloud solution makes it possible to build virtual super computers specially designed for the needs of individual research projects, for example in genome sequencing.

Life science increasingly needs access to biomolecular databases, to integrate databases and use tools for data analysis and interpretation. Computerome provides a range of services by way of pre-installed tools and methods for managing, collecting and cross-batching data, provided that the requisite Research Ethics Committee and Health Data Authority approvals have been granted.

Denmark already has a supercomputer that can support sandboxes
Case 11: CancerLinQ - SAP

CancerLinQ® (Cancer Learning Intelligence Network for Quality) is an initiative by oncologists for oncologists. The initiative started in 2012 as a non-profit organisation under the American Society of Clinical Oncology. The background for establishing CancerLinQ® was to try to break down silos of oncology data. Before then, data on individual patients with cancer had been kept in several databases at individual clinics and hospitals across the whole of USA. The exception to this rule was data from clinical trials. Only 4-5% of cancer patients participate in clinical trials. Data from the remaining 95-96% of patients was thus locked away in data silos.

CancerLinQ® is a rapid learning health data platform for dealing with data from cancer patients. It uses an SAP Connected Health platform to be able to securely connect and efficiently analyse anonymised data from cancer treatments from many different sources of data.

CancerLinQ® has launched a supplementary service called CancerLinQ Discovery™. The aim of CancerLinQ Discovery™ is to make it possible for the oncology network to translate CancerLinQ’s anonymised patient data into practical and important knowledge to drive research and innovation to improve treatment for the benefit of all cancer patients.

CancerLinQ is as an American example of how health data can create new insights when data silos are breached and actively support exploratory research.

Health data drives R&D of new treatments
ELGA gives clinical personnel rapid insights and decision-making support

Case 12: ELGA nationwide eHealth-solution in Austria

ELGA is a joint project between the authorities and the health service in Austria developed by Siemens Healthineers. Austrian citizens can use an eHealth portal to access their own health data. Doctors, hospitals and care facilities can also get rapid access to previous diagnoses and therapies. Information and workflow supports the necessary information for medical treatment, care and therapeutic treatment.

The ELGA eHealth platform is a national ERJ-based solution covering the whole of the health service: hospitals, general practitioners, dentists, pharmacists, private hospitals, nursing homes, home care, etc. Researchers thus have easy access to all information relevant to patients. Patients also have access to a portal and individuals can view their patient-sensitive data and where consent for data-sharing is provided by patients themselves. Patients’ sensitive data remains where it is generated in the health service and data is only exported if there is a validated, authorised and approved request from an otherwise approved recipient.

Citizens can use the eHealth platform on a voluntary basis but it is an ‘opted-in’ service as standard. Opting out has to be done actively by filing an objection, for example on an official portal. There is no access to the eHealth platform without citizens being registered and identified, for example via NemID and as a natural consequence, access and use of data is thus logged at every level.
Sandboxes – in combination with citizens’ own data

For data to seriously save lives, it is important to combine register data with data from the everyday routines of the citizens. This will provide entirely new possibilities for specially designed prevention and treatment for individual patients and for adjusting advice to individual needs. Lots of wearables and health apps are available, for example for keeping fit but there are also more specialized apps to help people with diabetes manage their carbohydrate levels or apps to help restless children with ADHD have more structured daily routines. According to the newspaper Mandag Morgen, more than 165,000 healthcare apps were available for iPhone and Android smartphones in 2016 and other sources report that in 2017, the number of health apps had risen to 325,000.

Legislative considerations

Provided citizens have given their consent to share their data or have already published it, there are no legal problems in combining register data with data they have collected and donated themselves. Problems can arise when wishing to do exploratory research and where its purpose changes during the research project. In such cases, further research often requires new consent (see Appendix 3 for a legal explanation).

Technical considerations

Technically, there are several different ways of combining register data with citizens’ own data, as may be seen from Cases 13 and 14.

Examples of solutions

In the following, we present a series of examples of IT tools that can combine personal data from apps and wearables with officially data from hospitals and with data taken directly from patient records.
Case 13: 
Dia+ from the Danish Diabetes Association

Much of the medicine that we take as patients has only a very small positive effect. Some medicine even has no demonstrated efficacy. This is especially due to patients not taking all the medicine that they should when daily routines intervene and the doctors’ advice is far away.

Patients’ own data can be incredibly interesting as documentation on the real effects and for helping follow chronic disease. There are many apps which precisely focus on documenting the day-to-day effect of medication but even more relevant are those that combine efficacy with register data.

The Danish Diabetes Association has launched a free smartphone app in conjunction with pharma companies AstraZeneca and Bristol-Myers Squibb. The app has no commercial content and the programme was developed with inspiration from the Diabetes Barometer which is no longer accessible.

The app, called Dia+, is a small program that manages blood sugar, cholesterol, blood pressure and BMI. Users enter their readings into the app and can follow their own health status over time. People can also see how their figures compare to the recommended figures as also shown in graphs. The app also includes a reminder function to advise users that it is time to take their medication or a blood sugar reading.

Citizens’ own data from apps can be integrated in healthcare solutions
New collaborative models give patient’s better insights into their own health

Case 14: Apple Health Records

Health Records from Apple is an example of a platform that can combine all the various types of data and thus help patients have a better overview of their own situation. The Health Records app thus covers patients’ health data from hospitals, clinical environments and users and shares it with each other. American hospitals such as Johns Hopkins Medicine, Cedars-Sinai and Penn Medicine are among the first to have made this beta functionality accessible to their patients.

The background for developing the app in the direction of collaboration between patients, hospitals and clinical environments and patient records are widely registered in various different places, meaning that patients in the American health system have to log on to each hospital’s website and enter their health data manually. Apple works together with the American health service to ensure a secure, user-friendly approach and that patient records are based on Fast Healthcare Interoperability Resources (FHIR) - a standard for transferring electronic records.

Combing data can accordingly add a lot of value in the treatment of patients.
Case 15: Data For Good Foundation

When it comes to integrating citizens’ own data, inspiration can be had from the Data for Good Foundation (DFG). DFG works by establishing a secure space where individual citizens can donate all the kinds of data that they wish in a personal data store, such as fitness data from Endomondo, shopping habits, pulse readings, search history, etc.

The DFG platform is to be structured so that users can always decide for themselves on the data that can be used by whom and for what.

DFG is thus an example of how consent can be gained under GDPR. DFG ensures that users themselves have full control and oversight, and it lets you for example get an overview of your own data and compare it with the average of other DFG users. The DFG platform will make it possible to combine citizens’ donated data with register data.

Data for Good is a private collaborative foundation based on a vision of value creation through data sharing.

IT platform can support a combination of data from patients and registered data with the patient in focus
Summary
There are already various possibilities for searching across silos in Denmark, but these are typically limited to specific areas of specialisation or legally restricted. The rest of the world is working hard to create IT solutions in which traditional health data is not only combined across silos but can also be combined with patients’ own personal data. The potential for specially personalised prevention and treatment processes can practically not be overstated. If we in Denmark wish to develop the possibility of evidence-based prevention and treatment of disease, sandboxes are a precondition but achieving the full potential requires a change in existing legislation in line with the changes made in Finland.
Conclusion

In this report, we have reviewed three proposed solutions which would enable Denmark to be rapidly able to use our unique health data resources much better and more effectively. We propose a national data map, an overall data entry point with rapid access to health data and more innovative sandboxes. All three proposed solutions are already to be found in smaller formats in Denmark today but they are either restricted to areas of disease or depend on who the register owner is.

In this report, we have tested whether the three solutions are technically possible. They are. We have also investigated whether they are legally possible. They are. However, achieving the full potential from sandboxes would require amendments to the law, as in Finland. Finally, we have investigated whether the other countries that we normally compare ourselves to are moving in the same direction. They are. We found that both Sweden and Norway are the frontrunners but that Finland is in a class by itself in the work they are doing in turning their health data into an asset. This is especially due to the strong involvement of Sitra, the Finnish innovation fund. There is a clear parallel to NEXT, which has been a great success in Denmark, among other things via Innovation Fund Denmark.
Recommendations for next steps

In drawing up this report, the partnership backing Data Saves Lives has paved the way for broader collaboration and rapid action. On the basis of experience from Finland and inspired by the NEXT initiative, the partnership recommends implementing the following initiatives:

**Establishment of an interdisciplinary partnership for health data**
An interdisciplinary partnership for health data should be set up with an active steering group with the participation of the most significant public and private sector health data players in Denmark. The steering group will be tasked to ensure inter-organisational coherence, to coordinate initiatives, establish funding and ensure further progress.

With respect to the three proposed solutions, the Data Saves Lives Partnership recommends that the implementation should be stepwise.

**National Data Map**
During 2018, Copenhagen Healthtech Cluster will be launching a prototype metadata catalogue as described in the report. The first stage of the process will be to test a prototype, including its usability and the technical solution. Then the national data map could be extended to include more databases and health data registers, with details of the respective health data that is accessible. The prototype is to be used to document demand for a data overview and interrelationship between areas of usage in research. Campaigns could be run to raise awareness of the data overview in conjunction with research environments, register owners, patient associations and relevant industries, etc.

**Data Entry Point**
One significant process associated with implementing a common data entry point would be to develop a service model for the initiative. This process could be based on the prototype for the national data map and designed to meet the needs of the partnerships’ members. The service model should be drawn up so as to ensure relevant, needs-driven and timely, current advice on the data overview and advisory services on access requirements and application procedures.

**Data Sandboxes**
Specific pilot projects in the field of health data should be initiated to strengthen the process of establishing some boxes, for example in conjunction with the government’s Growth Plan for Life Science and the Digital Hub Denmark initiative or directly in public-private partnerships with municipalities, regions, research environments and register owners.

**Review of the legal basis**
We propose that so as to achieve the full potential from secure use of health data, the legislative basis (Health Act, Data Protection Act, etc.) should be reviewed to ensure that the legal basis for the use of health data for societal purposes is up-to-date. As part of the review, there should be an investigation into whether access to health data should be based more than it currently is on competencies rather than by way of private or public organisational affiliation.
Our thanks to all contributors

A big ‘thank-you’ to all who have contributed to making this report:

Allan S. Bager
Business Development Manager
IBM Danmark ApS

Anne-Katrine Skovby Nielsen
Business Development Manager
Copenhagen Healthtech Cluster

Christian Sejersen
CTO
LEO Innovation Lab

Claus Rehfeld
Partner
Health Innovation Institute

Ditlev Moltke
Director
IQVIA

Frederik Nielsen
Clinical Research Medical Advisor
Novartis A/S

Henrik Rindel Gudbergsen
Chief Medical Officer
IBM Danmark ApS

Jakob Bjerg Larsen
Chief consultant
Danish Association of the Pharmaceutical Industry

Jens Edlef Møller
Executive Architect and Associate partner
IBM Danmark ApS

Karina Toftgård Lindrup Olesen
Special Consultant
Capital Region

Katrine Stokholm
Senior Consultant
Danish Regions

Kim Berg-Deleuran
Country Manager
SAP Danmark A/S

Kristian Hart-Hansen
CEO
LEO Innovation Lab

Leif Panduro Jensen
Executive Vice President
Region Zealand

Lone Arildsen
Managing Business Consultant
SAP Danmark A/S

Marianne von Eyben
External consultant

Mette Harbo
Digitalisation Manager
Copenhagen Municipal Health and Social Care Administration

Michael Mogensen
Senior Key Account Manager
SAP Danmark A/S

Nanna Severinsen
Legal Advisor
Capital Region

Ole Nygaard
Business Developer
Siemens Healthineers

Patrick Wulf Hanson
Director
IQVIA

Philip Hougaard
Vice President
H. Lundbeck A/S

Søren Brunak
Professor of Disease
Systems Biology
University of Copenhagen

Søren Nielsen
Manager, Information Security
Capital Region

Thomas B. Ibsen
Senior Medical Manager
Abbvie A/S

Thomas Rosenfeldt
Project Development Manager
Copenhagen Capacity

Tina Dorthe Nielsen
Head Data Privacy Nordics
Novartis A/S

Tina Juul Sørensen
Head of Secretariat
Copenhagen Healthtech Cluster

Tove Holm-Larsen
CEO
Pharma Evidence

Troels Ravn Børentzen
Head of Regulatory, Pharmacovigilance & Compliance
LEO Innovation Lab

Vibe Balthazar-Christensen
Senior Manager, Global Public Affairs
LEO Pharma A/S
Footnotes

1 “Mapping the healthcare data landscape in Denmark”. Leapcraft / Copenhagen Healthcare Cluster, 2015


3 A WiFi contact lens with circuitry, sensors and screen that measures the glucose content of tears in diabetic patients. Park et al., Science Advance 2018.

4 “Mapping the healthcare data landscape in Denmark”. Leapcraft / Copenhagen Healthcare Cluster, 2015

5 See also ibm.co/2qYrvj

6 Lakeside. “Pseudonymisering principper for sundhedsdata til statistikproduktion” (Pseudonymisation principles for health data for statistical production), 2016

7 www.eugdpr.org

8 Digital Security Council “Guidance on Data Protection by Design” 2017

9 SAP Health® Bruce Magill 2017 and SAP Danmark 2018

10 Steiermärkische Krankenhausanstalten in Austria use Siemens eHealth-solution, see bit.ly/2JRrs7gm

11 “We are ready to diagnose ourselves”. Hans Jørgen Madsen (2016) Mandag Morgen

12 See also bit.ly/2HqdaKl

## Appendix 1

### Sources and listing of analyses and documentation on health data

<table>
<thead>
<tr>
<th>Source</th>
<th>Title</th>
<th>Publication year</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center for Data Innovation</td>
<td>The State of Data Innovation</td>
<td>October 2017</td>
<td>bit.ly/2gBEKjq</td>
</tr>
<tr>
<td>Copenhagen Economics</td>
<td>Værdien af sundhedsdata i Danmark</td>
<td>April 2018</td>
<td>N/A</td>
</tr>
<tr>
<td>Copenhagen Economics</td>
<td>Værdien af kliniske forsøg i Danmark</td>
<td>January 2017</td>
<td>bit.ly/2HKr7ux</td>
</tr>
<tr>
<td>Danish Regions</td>
<td>Handleplan for bedre brug af sundhedsdata i regionerne</td>
<td>2015</td>
<td>bit.ly/2rSzMQY</td>
</tr>
<tr>
<td>Source</td>
<td>Title</td>
<td>Publication year</td>
<td>Link</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Danish Regions</td>
<td>Sundhedsdata i spil - en politik om hvordan sundhedsdata kan gøre gavn</td>
<td>2015</td>
<td>bit.ly/2vT6UjJ</td>
</tr>
<tr>
<td>Economist</td>
<td>A revolution in healthcare is coming</td>
<td>February 20</td>
<td>econ.st/2GEFEqw</td>
</tr>
<tr>
<td>Højbjerre Brauer Schultz</td>
<td>Barrierer for virksomhederens dataanvendelse</td>
<td>May 2017</td>
<td>bit.ly/2HAY6Uu</td>
</tr>
<tr>
<td>Copenhagen Institute for future studies</td>
<td>Fremtiden for det danske sundhedssystem (2030)</td>
<td>August 2017</td>
<td>bit.ly/2qJaYNI</td>
</tr>
<tr>
<td>Danish Local Government Association</td>
<td>Bedre sammenhæng for borgere og virksomheder</td>
<td>January 2018</td>
<td>bit.ly/2HbQOXR</td>
</tr>
<tr>
<td>KORA</td>
<td>Fem megatrends, der udfordrer fremtidens sundhedsvæsen</td>
<td>April 2017</td>
<td>bit.ly/2J7jRbr</td>
</tr>
<tr>
<td>KPMG</td>
<td>Through the looking glass - A practical path to improving healthcare through transparency</td>
<td>April 2017</td>
<td>bit.ly/2ogJX4u</td>
</tr>
<tr>
<td>KPMG</td>
<td>Analyse af rammevilkår for life science i Danmark</td>
<td>April 2017</td>
<td>bit.ly/2vrTuLA</td>
</tr>
<tr>
<td>Leapcraft</td>
<td>Mapping the healthcare data landscape in Denmark</td>
<td>August 2015</td>
<td>bit.ly/2J7i2LD</td>
</tr>
<tr>
<td>Source</td>
<td>Title</td>
<td>Publication year</td>
<td>Link</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Danish Association of the Pharmaceutical Industry</td>
<td>Samarbejde mellem offentlige forskere og lægemiddelindustrien inden for farmako-epidemiologisk forskning</td>
<td>June 2017</td>
<td>bit.ly/2qjX27r</td>
</tr>
<tr>
<td>Danish Association of the Pharmaceutical Industry, et al.</td>
<td>7 principper for anvendelse af danske sundhedsdata</td>
<td>Januar 2017</td>
<td>bit.ly/2qFPMJu</td>
</tr>
<tr>
<td>Mandag Morgen</td>
<td>Sundhed i skyen - Et kig ind i den digitale fremtid på sundhedsområdet</td>
<td>April 2017</td>
<td>bit.ly/2qHUy9a</td>
</tr>
<tr>
<td>Mandag Morgen</td>
<td>Nu kommer den præcise og målrettede medicin</td>
<td>April 2018</td>
<td>bit.ly/2JZpv0E</td>
</tr>
<tr>
<td>MapR</td>
<td>MapR Guide to Big Data in Healthcare</td>
<td>N/A</td>
<td>bit.ly/2tqMNb5</td>
</tr>
<tr>
<td>OECD</td>
<td>Data-driven Innovation for Growth and Well-being</td>
<td>October 2014</td>
<td>bit.ly/2JXgPrB</td>
</tr>
<tr>
<td>Source</td>
<td>Title</td>
<td>Publication year</td>
<td>Link</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>The Government</td>
<td>Strategi for Danmarks digitale vækst</td>
<td>January 2018</td>
<td>bit.ly/2qHqHha</td>
</tr>
<tr>
<td>The Government</td>
<td>Vækstplan for life science - Danmark som førende life science nation</td>
<td>March 2018</td>
<td>bit.ly/2CT1ELh</td>
</tr>
<tr>
<td>Strategic Alliance for Register &amp; Health data (STARS*)</td>
<td>Principper fra STARS* til det videre arbejde med den Nationale Strategi for Adgang til Sundhedsdata</td>
<td>May 2015</td>
<td>bit.ly/2J7Dxfi</td>
</tr>
<tr>
<td>Ministry of Health &amp; Elderly Affairs</td>
<td>Bedre sundhed gennem moderne og sikker brug af data</td>
<td>February 2017</td>
<td>bit.ly/2vtAzzO</td>
</tr>
<tr>
<td>Health Data Authority</td>
<td>Vejledning om informationssikkerhed i sundhedsvæsenet</td>
<td>April 2016</td>
<td>bit.ly/2HMyRMv</td>
</tr>
<tr>
<td>Health Data Authority</td>
<td>Sikkerhed på Forskermaskinen</td>
<td>March 2018</td>
<td>bit.ly/2HKBXR6</td>
</tr>
</tbody>
</table>
Appendix 2

Access to health data for researchers

This appendix describes the present options for researchers for gaining access to health data as set out in various public registers/health databases. There is no description of the possibility of researching directly in patient records, for example. The analysis gives the similarities and differences that are present, depending on where researchers wish to get data from, based on a review of register/data controllers, application requirements and application processes.

Six routes for accessing public health data
Currently, there are five existing services but since a bill has been presented for a National Genome Centre, this is also mentioned. The six user groups are:
1. Danish National Biobank
2. The regional biobanks
3. Researcher Service - Danish Health Data Authority
4. Researcher Service - Statistics Denmark
5. The clinical quality databases (national or regional)
6. National Genome Centre

1. Danish National Biobank

Registers and Data Controllers
The Danish National Biobank has registered more than 9.6 million samples and is also the data controller for the National Biobank Register, which contains more than 24.5 million samples from 5.7 million individuals. The register holds aggregated data from the following registers:

- Danish National Biobank (DNB)
- Better generational health
- DNA Biobank, Copenhagen University Hospital
- Danish Cancer Society - Diet Cancer and Health Cohort
- Pathology Bank
- COPSAC (Copenhagen Prospective Studies on Asthma in Childhood)
- DD2 (Danish Centre for Strategic Research in Type 2 Diabetes)
- The Danish Blood Donor Study
- Danish Cancer Biobank
- Region Zealand’s Biobank
• Danish Twin Register
• OPEN Odense Patient Data Explorative Network

The above data can be cross-batched with data from:
• CPR Register
• National Patient Register
• The Pathology Register

Requirements
Requirements for applications to use a biological material.
Extended requirements are in place for applications for research relating to human material. This always requires the Research Ethics Committee to have been notified before notifying Researcher Service. Currently, there are 12 regional committees and the National Research Ethics Committee.

When applying, the following requirements must be met:

• The research project deals with human biological material (such as blood, saliva, oral scrape, spinal taps, biopsies, etc)
• Completed application form which is available on the National Biobank Register’s website
• A full project description, including the following:
  - Planned statistical and scientific analyses
  - The laboratory used, which should preferably be in Denmark
  - Timetable for the research project
  - Funding plan for the research project
  - Reason for using scanty material (e.g. from small biological samples such as the PKU Register)
  - Documentation that tests can be done as planned on the requested sample
  - A description of where samples will be kept during the project
• Sample extraction description

Application process
Biological material process:
1. Report by project to a Research Ethics Committee (REC)¹
2. Obtain approval from the REC
3. Submit an application to Researcher Service, including the REC approval
   (see description below in section 3 Researcher Service - Health Data Authority)
4. The application is considered by the Biobanks Recommendation Committee (BRC)
5. BRC approval
6. Samples provided

Explanation:

Access to material requires the project to have been reported to the Research Ethics Committee (REC). Danish legislation requires all health science research projects involving human biological material to have been approved. Foreign researchers collaborating with a Danish data controller, either by way of a public research institution or an established non-commercial research and analytical environments, can access material from DNB. Similarly, Danish and foreign companies collaborating with a Danish data controller, either by way of a public research institution or an established non-commercial research and analytical environment, can have access to material from DNB.

When approval has been granted, an application is made using the single national point of entry for biology and data, the Health Data Authority’s Researcher Service. Applications are then submitted to the Coordination Centre which undertakes the further process. In addition to REC approval, the project description, extract description and approval are also to be submitted by the responsible financial officer to confirm the availability of funding to cover the cost of obtaining samples. If the samples requested are in external biobanks, the Coordination Centre can undertake communication with the biobanks concerned, after which the researcher only needs to apply to a single entry point. The Coordination Centre can also provide guidance and advice on access to material.

All incoming applications are considered by the Biobank’s Recommendations Committee. The committee consists of the following members: Two individuals appointed by SSI, including the chair, one individual appointed by the Danish Council for Independent Research (DFF) | Health Care and Disease, one individual appointed by the Danish Regions and one appointed by the Danish Patients Association. The Recommendations Committee assesses applications in the order they are received and endeavours to respond to researchers within a month of receipt of a complete application. Delivery is arranged between DNB’s laboratory and the researcher. Normally no more than 100 µl serum/plasma or 1 µg DNA will be provided. The samples are located and delivered.

2. Regions’ Bio & Genome Bank

Registers and Data Controllers

There are five regional bio- and genome banks:

- The Danish Cancer Biobank (DCB) – Register controller: Currently the Capital Region but changes are being considered. Not decided when going to press.
- The Danish Rheumatology Biobank (DRB) – Register controller: Currently the Capital Region but changes are being considered. Not decided when going to press.
- Danish Genetics Biobank (DGB) – Register controller: Currently the Capital Region but changes are being considered. Not decided when going to press.
- Danish Blood Donor Biobank (DBB) – Register controller: Currently the Capital Region but changes are being considered. Not decided when going to press.
- Pathology Bank – Register controller: Currently the Capital Region but changes are being considered. Not decided when going to press.

The purpose of the registers is to ensure access to the Regions’ hospitals with a view to promoting the development of personalised medicine, preferably based on research across the public and private business sectors.

Requirements

There are four requirements which must be complied with to be able to apply for provision of register data:

- Research Ethics Committee approval
- Data access requires a publicly employed researcher (private researchers can get anonymised data)4
- There must be a contract between a corporate (private sector) researcher and the Regions Bio & Genome Bank
- Data Protection Agency consent must have been granted

---

Application processes
There are two application processes for register data:
1. Danish Cancer Biobank, Danish Rheumatology Database Biobank, Danish Genetic Biobank and Danish Blood Donor Biobank:
   See http://www.cancerbiobank.dk/da/forfagfolk/anvendelseafmaterialer/
2. Pathology Bank: For dry data, apply using the application form on the website:
   See http://www.patobank.dk/index.php?id=3&land=d

3. Researcher Service at the Danish health Data Authority

Registers and Data Controllers
The Danish Health Data Authority’s Researcher Service is a central unit where applications can be made for access to pseudonymised data for which the Danish Health Data Authority is responsible.
- Data from national health registers
- Address extract
- Data for Statistics Denmark
- CPR population extract
- Re-use of forwarding data
- Death certificates for research
- Extracts from the Researcher Machine
- LMDB consultation applications (submit to Statistics Denmark)
- Statistics extracts

The registers above can be combined with access to biological material as noted above in the section on biobanks.

Requirements
The following requirements must be complied with to apply for data:
- The project must come under a research environment authorised to use the Researcher Machine (a range of technical requirements must be satisfied for authorisation)
- Authorisation can only be granted for an approved research/analysis environment
- The data controller must be Danish unless consent has been granted for data to be transferred outside Denmark
- Data must only be used for research purposes or for statistical purposes
- The purpose of gathering data must be objective and expressly described
- The project must be of significant societal importance
- The purpose must be proportional (it is not possible to obtain more data than required for undertaking the research project)
- Data processing contracts must be in place if the data controller uses data processors
- Data Protection Agency consent must have been granted. There are three types of notification:
  - Joint notification (types of notification for the Data Protection Agency, the same as for several related public bodies). Also called a ‘57 Approval’
  - Umbrella notification (2 types of notification to the Data Protection Agency which the Regions can use for health data). Also called a ‘58 Approval’
  - Private research (notification types to the Data Protection Agency for private research). Also called a ‘41 Approval’

\[1\] The Danish Health Data Authority is described in more detail in Order No 1188 of s. 220a.

• Or Research Ethics Committee consent must have been obtained (applies for direct contact with individuals or biological material and for private research projects)
• Or Danish Patient Safety Authority consent must have been granted (applies if access to patient records is required)
• Or other notifications (such as notification/approval by the Danish Medicines Agency for clinical trials of drugs in humans)

Application process
• Use Researcher Service as the application portal
• There are two application forms depending on whether you are using Researcher Machine or looking for data from the registers listed above
• Initial case processing
• Provisional approval of permits
• Tendering
• Data access agreement accepted
• Programming
• Data access - Researcher Machine

Researchers’ own data
Researchers have the option of updating their own data to Researcher Service.

Requirements
If this is required, the following requirements must be met:
• Notification must be made to the Data Protection Agency
• Uploads can only be for a specific project

4. Researcher Service at Statistics Denmark
Register and Data Controller
Statistics Denmark is responsible for a whole range of other data than the above health data registers for which the Danish Health Data Authority is responsible. If researchers wish to cross-batch health data, for example, with socioeconomic data, they will have to use Statistics Denmark’s Researcher Service. When data is provided, it is basically aggregated to a certain extent. Microdata is therefore not provided for research use but pseudonymised data is available on research servers at Statistics Denmark.

Application process
The application process is as follows:
• Contact Researcher Service personnel (FSE) at Statistics Denmark: see http://www.dst.dk/da/TilSalg/Forskerservice/medarbejdere-in-forskningservice.aspx
• Attach a brief project description, see http://www.dst.dk/~media/Kontorer/13-Forskning-and metodelIndstilling_eksempeel_003.docx?la=da
• Research projects are allocated a case reference number
• If researchers wish to cross-batch data including health data from the Danish Health Data Authority, they must then contact the Danish Health Data Authority. Their requirements are as follows:
  • Contact point in Statistics Denmark and case reference number
  • Project description

---

7 Order No. 534 of 15/06/2000 On an exemption from the requirement to notify certain treatments undertaken for a private data controller, as amended by Order No. 202 of 22/03/2001 and s. 3 (3.3.c) of Order No. 410 of 09/05/2012
8 See application flowchart in Researcher Service on the Danish Health Data Authority’s website: https://sundhedsdatastyrelsen.dk/da/forskerservice/for-du-soger/ansog-om-autorisation.
- Extract description
- Permit from the Data Protection Agency and/or Research Ethics Committee.

- When the Danish Health Data Authority has agreed to the request, data is transferred to
  Statistics Denmark via an FTP solution (file transfer protocol)

**Requirements**

There are the following requirements for access:

- The research institution must have been authorised\(^9\)
  - Granted on the basis of specific assessment
  - There may be restrictions on private organisations’ access to data
  - They cannot be foreign but collaboration is permissible via an authorised Danish
  institution

- Data Protection Agency approval is required for cross-batching data from other bodies or own
  register

- Fees are payable for the service

**5. Regional clinical quality databases**

**Registers and Data Controllers**

The Regions’ Clinical Quality Development Programme (RKKP) is responsible for 8611 clinical quality
databases. RKKP constitutes the infrastructure for the nationwide clinical quality databases, Danish
Multidisciplinary Cancer Groups and competence centres for epidemiology, biostatistics, health
informatics and clinical quality. The list is on RKKP’s website.\(^1\) There are many different register
controllers, depending on the type of register. Individual databases share responsibility for the regi-
ster. See also the Appendix to “Mapping the Healthcare Data Landscape in Denmark, 2016.”\(^1\)

There is differentiation between use for quality purposes and research.

The requirements and process below do not need to be complied with if only quality purposes are
involved, nor if a hospital/department needs to extract or analyse their own data for quality purpo-
ses. The data controller only has to comply with ordinary good data processing practice.

**Requirements**

The following requirements for research projects must be complied with to be able to apply for
data:

- There should be an exact description of:
  - The study’s rationale
  - Method
  - Purpose
  - The data to be used for analyses
  - Research team members
  - Budget
  - Timeline
  - Publication plan

---

\(^9\) See www.dst.dk/da/TilSalg/Forskerservice

\(^10\) See www.dst.dk/da/TilSalg/ForskningsService/Dataadgang/Autorisering

\(^11\) See the schedule of clinical databases at rkkp.dk/siteassets/om–rkkp/de-kliniske-kvalitetsdatabaser-alle-formand-hjemmeside.
dk or the appendix to Mapping the Healthcare Data Landscape in Denmark from Copenhagen Healthtech Cluster (August 2015).

\(^12\) See www.rkkp.dk/siteassets/research/131118-notat-om-ejerskab-og-anevendelse-of-data-version-3-0.pdf

\(^13\) See www.cphhealthtech.dk/vi-tilbyder/sundhedsdata
• Approval must either have been obtained from the Data Protection Agency14
• Or an overarching regional notification must have been used (umbrella notification) which defines the Regions’ scope for the research projects that can be implemented without individual projects needing to obtain separate approval from the Data Protection Agency (ensures privacy and reduces the number of notifications to the Data Protection Agency)
• Funding
• Compliance with the provisions of § 10 (3), Data Protection Bill15 (scientific investigations of significant societal importance shall only be passed to a third party with the prior consent of the Data Protection Agency)

**Application process**

**Research:**
- Apply online at https://rkkp-forrskningsadgang.dk
- Submit protocol to RKKP
- RKKP registers the application
- RKKP forwards it to relevant clinical database(s)
- Possible dialogue on modifying the protocol
- Data provided (within 6 months of correct application)

**6. National Genome Centre16**

It is important to note that the whole section depends on whether the centre is actually established.

**Registers and Data Controllers**

This involves an unnamed register for which the National Genome Centre is responsible which maintains genetic data deriving from biological material, cf. L146, where a new subsec 2 is inserted in § 28 Health Act.

Data from the register can be used for preventative action against disease, for medical diagnoses, nursing, patient treatment or administration of medical and healthcare services and research and statistics17.

**Requirements**

The following requirements must be complied with to be able to apply for access to data:

- Basically, research of significant societal importance can be undertaken if no patient has declined when signing up to the Tissue Register, cf. § 32 (2) and § 223b
- Research Ethics Committee consent must have been obtained for the project or
- Danish Patient Safety Authority consent must have been obtained if the project is not covered by the Biomedical Research Ethics Committee System18

**Application processes**

Since L 146 has not been adopted, the application process is not known.

---

14 The approval and notification process is going to cease, as mentioned as a meeting at the Ministry of Justice on 10 March 2018 and this will probably be set out in the coming white paper on the Data Protection Act, due on 19 April 2018.
15 See L68 presented 25 October 2017 – Bill on supplementary provisions to the regulation on protecting physical persons as part of processing personal information and on free exchange of such information (Data Protection Act).
16 L 146 was presented on 9 February 2018 to amend the Health Act and set up a National Genome Centre. The description of its powers therefore is subject to its adoption in its present form. The Bill was passed to the committee stage on 22 February 2018. The provisional timeline is for the next political debate to be on 17 April 2018. The National Genome Centre is primarily addressed in Ch. 68 (§§ 223f) Health Act.
17 See L146 § 223b.
18 See LBK No. 1188 of 24/09/2016 § 46 (1-2)
Appendix 3

Legal basis for the three proposed solutions

This appendix reports on the underlying personal data law relating to consideration of the three proposed solutions described in the main document. It is assumed that the current practice for health legislation complies with the law relating to the five existing access routes for researchers.

The current rules and guidelines

Basically there is no actual overview of the existing rules and guidelines. Various public and private websites each describe specific guidelines. The description below is based on descriptions from the Danish Health Data Authority, the National Biobank, RKKP and the Cancer Biobank1.

The overarching main rule for the use of registers is based on the present s. 102 Act on Processing Personal Data. Similar rules will be set out in the coming s.10 Data Protection Act³. Reference is also made to the General Personal Data Protection Regulation (GDPR)⁴.

The provisions of § 10 (1) Act on Processing Personal Data and the wording of § 10 (1) in the coming Data Protection Act are almost identical (only a new line which shows how alike they are). The difference is only that the rules on health data previously derived from § 7 (1) Act on Processing Personal Data whilst the penal provisions were in § 8. The rules are set forth in Art. 9 (1) (health) and Art. 10 (penalties) GDPR.

The current wording of the Act on Processing Personal Data is:

Data in accordance with § 7 (1) or § 8 shall only be processed if this is done so as to carry out statistical or scientific investigations of significant societal importance and if processing is necessary for carrying out investigations.

---

1 www.sundhedsdatastyrelsen.dk/da/forskerservice/ansog-om-data
www.docplayer.dk/51275529-Adgang-til-registerdata-hos-sundhedsdatastyrelsens.html
www.nationalbiobank.dk/adgang.html
www.nationalbiobank.dk/assets/vejledning_danmarks_nationale_biobank_final.pdf
www.cancerbiobank.dk/da/forskfolk/retningslinjer/
www.rkkp.dk/forskning/

2 See Act No. 429 of 31 May 2000 on processing personal data, with subsequent amendments (Act on Processing Personal Data).
3 See L6 presented 25 October 2017 – Bill for an Act on supplementary provisions to the Regulation on protecting physical persons associated with processing personal data and free exchange of such data (Data Protection Act).
4 EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EU) 2016/679 of 27 April 2016 on protecting physical persons associated with processing personal data and free exchange of such data and annulment of Directive 95/46/EC (General Regulation on Data Protection).
The future wording of the Act on Processing Personal Data is:

Data in accordance with Art. 9 (1) or Art. 10 shall only be processed if this is done so as to carry out statistical or scientific investigations of significant societal importance and if processing is necessary for carrying out investigations.

Similarly, § 10 (3) provides that the Data Protection Agency’s consent is required for dissemination to a third party and that the Data Protection Agency may determine further specified conditions for dissemination.

§ 10 (3 - 4) of the coming Data Protection Act also has practically identical provisions, although modified so that the Data Protection Agency’s prior consent is only required if dissemination is for processing outside GBDR’s territorial scope or if it relates to biological material or is being done with a view to publication in a recognised scientific journal.

Further issues for consideration are stated under the individual model solutions.

The three proposed solutions
The three proposed solutions are as follows:

1. National Data Map
2. Data Entry Point
3. Data Sandboxes

Three different proposed solutions are described below together with the associated personal data legislation under which they could be established. Since the Data Protection Act has not been passed and since there are some challenges as to its content, among other things the disclosure requirements relating to cross-batching following the consultation on 25 January 2018, the opinion is based primarily on the rules of the GDPR.

Proposed solution 1: National Data Map
The aim is to establish a national data catalogue to provide a consolidated, manageable overview of all existing and coming data registers, quality databases, genome registers and biobanks in the field of healthcare. The national data map would show where health data is registered, its quality and how individual databases are documented, so-called metadata.

Law
As the purpose is described, there are fundamentally no personal data protection law obstacles to establishing a consolidated overview of existing registers in GDPR or the current Act on Processing Personal Data, the coming Data Protection Act or the Health Act, etc.

Since the data overview would only be serving as an overall catalogue (reference work) based on searching overall variables and not for storing data, there are no legal obstacles in GDPR, the coming Data Protection Act, the present Act on Processing Personal Data or the Health Act, to setting it up on an open, easily accessible platform.

Example: A researcher wants to know which registers have data on asthma. The researcher can, like any other person, make such a search without infringing the GDPR. A search would only result in a list of registers that have data relating to asthma but in no way provide data down to the individual level.
Proposed solution 2: Data Entry Point

The purpose is to establish common governance across the various register owners (data controllers) in the state, regions, municipalities, universities, companies and citizens to provide secure, transparent access to health data with streamlined guidelines for access. Responsibility for data would remain with the present register owners (data controllers) and would not involve cross-batching all the registers in a single database but administering access to data far more efficiently and transparently.

Law

There are no issues in personal data protection law if the model concerned (as in NEXT) merely provides advice and mediates contacts between public sector register owners /decentralised entry (Health Data Authority, Statistics Denmark, RKKP, National Biobank, Regions’ Bio & Genome Bank and the National Genome Centre) and data users (e.g. public and private sector researchers).

Personal data legislation is considerably more complex when it comes to active assistance in gathering data, data processing and data distribution. Two three-year research projects are currently in progress or pending which will also thoroughly elucidate the issue. One is JURFAST (supported by the Lundbeck Foundation), which started in September 2017. The heading for this project is actually: “Legal framework for researchers’ use of health data.” The second project relates to organisation but is awaiting funding before starting. Due caution should be exercised, therefore, in the content of the response below.

Since there is no intention for any material change in the content of the General Personal Data Regulation compared to the original Personal Data Directive, when it comes to actual data processing, the present guidelines, which are described in the analysis of access for researchers, will continue to apply provided that they are in accordance with the guidelines in the current Personal Data Directive.

With respect to personal data law, there is nothing to prevent a platform being established in which all data entry points are consolidated, including any advice also on personal data law, so as subsequently to direct the user (researcher) to the correct service, depending on needs (established as a link to the various websites).

With respect to personal data law, neither is there anything to prevent various access for researchers unifying, for example, their application forms, provided that they comply with differentiated guidelines for requirements for various approvals/permits from various authorities (Ethics Committee/Danish Patient Safety Authority/Danish Health Data Authority/Data Protection Agency5).

If the data entry point is to be helpful in cross-batching data from public registers with citizens’ own data, the rules below for data sandboxes should be observed.

Proposed solution 3: Data Sandboxes

The aim is to establish data sandboxes where register owners can work with citizens and patients, healthcare professionals, suppliers and partners to test new ideas, algorithms and data-driven healthcare technologies in a closed, secure environment. Sandboxes could be established at the

---

5 Note that, at a meeting with the Ministry of Justice on 10 March 2018, it was stated that notification to the Data Protection Agency would no longer be required but that Copenhagen University Hospital’s Knowledge Centre would continue to submit notifications. More details will hopefully come with the White Paper on the Data Protection Act expected on 17 April 2018.
individual register owner or across register owners and could contain test data and non-personally attributable random samples from large datasets. The environments aim to make it easier to implement more minor tests with fewer of the administrative loads and risks that otherwise characterise implementing data-driven IT healthcare projects.

**Law**

As the purpose and wishes for a model solution are formulated, participation in the above would fundamentally require the consent of the data subject (citizen), in accordance with Art. 9 (2) GDPR, unless they have already published information themselves in an open forum, cf. Art. 9 (2.e) GDPR.

**Example:** If a subscription marketplace is established in future in which all data is provided by the subjects themselves. Consent must comply with the guidelines in Art. 7 GDPR.

It is important to note that according to Preamble 33 to the Data Protection Regulation, it is often not possible when collecting data to determine the purpose of processing personal data for reasons of scientific research. This takes exploratory research projects into account to a certain extent. Therefore, models are needed where registered parties can give their consent for specific scientific fields of research when this is in accordance with recognized ethical standards for scientific research. Registrants should have the opportunity to only consent to specific fields of research or parts of research projects insofar as permitted by its specific purpose.

Finland and UK have organised their legislation, according to which there is a natural consent for research and with the possibility of opting out (like the Danish rules for the Tissue Utilisation Register). Alternatively, consent could be given via NemID. If an original participant dies during the term of the trial, legislation should be organised so that the rules continue to permit the deceased’s data to be included without specific consent. Highly secure processing environments would naturally be useful in both options, such as Computerome, etc.

If no data is required from citizens themselves but only register research, Art. 9 (2.g) GDPR could be used on the basis of necessity with respect to significant societal interests. The researcher should naturally comply with all general data processing regulations in accordance with Art. 5.

According to the Ministry of Justice, the consent of the Data Protection Agency will also no longer be required for research as above.\(^6\)

With respect to the Data Protection Bill, several references may be involved. The content of individual paragraphs/subsections is reviewed in more detail in the list below. The following references could probably be useful.

- § 7 (4)
- § 7 (5)
- § 10
- § 11
- § 36
- § 44
Re: § 7 (4)

The rule permits sensitive personal data to be processed if this is necessary for significant societal reasons on the basis of the EU or national law.

The consent of the Data Protection Agency is also required if processing is not done by or for an official body. The Data Protection Agency determines the further specified terms and conditions for the content of the consent.

Re: § 7 (5)

The rule enables the responsible minister, following negotiations with the Minister of Justice, to determine rules for processing sensitive personal data, but only within the framework of the GDPR.

This option could possibly be used in establishing the proposed solutions insofar as the challenges relating to specification and obtaining consent could be a hindrance.

Re: § 10

The rule makes it possible for assessment to be undertaken if it is only so as to undertake statistical or scientific investigations of significant societal importance on the basis of sensitive personal data. As a general rule, data must not be used for other purposes than statistical or scientific investigations, except as provided by subsec (5) (see below).

If wishing to pass data to a third party, in certain circumstances the consent of the Data Protection Agency is required. The Data Protection Agency may set out requirements for passing on data.

In accordance with (5), the Minister of Health may well make use of the results of statistical or scientific investigations relating to health science research, following negotiation with the Minister of Justice, if subsequent processing is necessary in deference to patients’ vital interests, such as for use in patients’ treatment.

Re: § 11

The rule relates to CPR numbers. There is a requirement here for citizens always to have given their consent to publication of their CPR (personal identity) number.

Re: § 36

The rule means that the Data Protection Agency can decide how applications for consent are to be designed.

Re: § 44

The responsible minister has the option, following the negotiations with the Ministry of Justice, of determining further specified rules for data processing if processing is done by the public sector.

The Minister of Justice has a similar option of determining further specified rules and data processing when done by private data controllers. The Minister may also determine that specific types of data should not be processed. The latter may mean that citizens do not have the option of consenting to data processing.

4 Stated at the meeting between the Regions and the Ministry of Justice on 10 March 2018. The Knowledge Centre will however retain notification to the Data Protection Agency so as to also establish an electronic solution for registering current and future research projects (may be used as a supplement to the National Data Map).
Care to work together on better use of health data?

Contact Copenhagen Healthtech Cluster and join the partnership.

Copenhagen Healthtech Cluster
T: (+45) 3322 0222
E: cphhealthtech@copcap.com