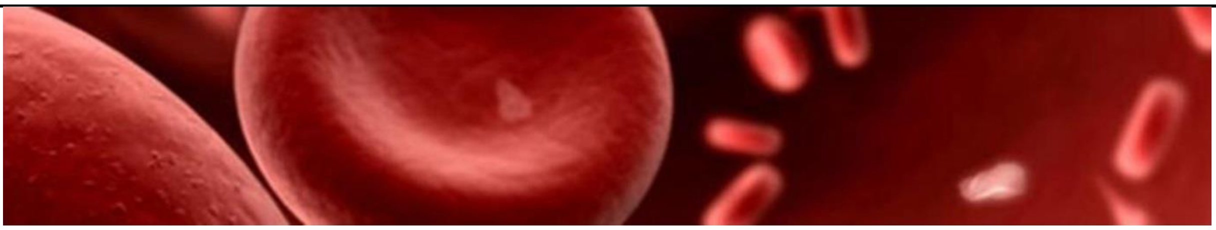
The Research Council of Norway

Final report
2012-2016

Programme on Human Biobanks and Health Data - BIOBANK



The Research Council of Norway
Visiting address: Drammensveien 288
P.O.Box 564
NO-1327 Lysaker
Telephone: +47 22 03 70 00
post@rcn.no
www.rcn.no

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Preface

The Programme on Human Biobanks and Health data (2012-2016) was established by the Research Council of Norway based on recommendations in the report *Gode biobanker – bedre helse* (2008).

Based on the overall objective, we originally planned open calls for proposals to fund large high quality researcher projects. However, based on the first call open to the whole programme plan, we identified that more strategic work was needed in order to stimulate more dialogue, cooperation and collaboration, to build common large data sets and to build more biostatistic and -informatic expertise to handle the unique Norwegian health data.

In total, the outcome of this minor programme was seen as highly valuable to the Norwegian research community, and the funding principle of building common big data sets was noticed and repeated on a larger scale in other European countries.

The programme arranged annual conferences and had close dialogue with the funded projects to facilitate collaboration and use of the common data sets. In addition, we worked on and discuss important strategical issues in the field of research, on a national and international level. Ethical and privacy terms using health data was a main focus area of the board.

On behalf of the Programme Board I wish to thank for the trust that was bestowed upon us in managing this program and in particular the flexibility with which we could use the first call to tailor the subsequent calls towards what seemed the best use of the biobanks and health data. It has been an exciting journey. A continuation of research programmes using biobanks and health data, it seems to be a correct approach to allow for as much reuse results from samples that are analysed from biobanks so that the results from the analysis can be used also by other researchers, rather than each researcher having to do his or her analysis once again.

Finally, and again on behalf of the Programme Board, I wish to thank the administrative officers assigned to the programme for their excellent work. Without their enthusiasm and dedication, it would have been a much more laborious and less enjoyable experience.

Professor Rolf K. Reed

Programme board chair

Summary

It is of great strategic importance to use Norwegian and Nordic personal data in research.

The BIOBANK programme was designed to take advantage of the potential for research on human biological material in biobanks by coupling analysis results with personal data from different sources. The primary objective of the programme was to generate research based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases.

Calls for proposals

Based on the overall objective, open calls for proposals to fund large high quality researcher projects was planned for.

The first call for proposals 2012 was open for all proposals confirming to the work programme. Three large researcher projects were funded. Based on the proposals received, the programme board identified a need for more strategic work in order to stimulate dialogue, cooperation and collaboration to build large data sets for common use.

The second call 2013 was open for projects aiming to perform a large-scale technical analysis on a well described high quality national biobank sample set. The two funded projects had close contact with the programme board to discuss facilitation for further use of the data, which was a prerequisite for the projects funded.

With large data sets in place, the programme board identified a need to build more biostatistic and bioinformatic expertise to handle the unique Norwegian health data sets. The third call 2015 aimed at funding researcher projects building environments within bioinformatics and biostatistics using biobank and registry data to answer research question. Funding was allocated to four collaborative researcher projects.

National coordination

The programme arranged annual conferences and had close dialogue with the funded projects to facilitate collaboration and use of the common data sets. In addition, we discussed and worked to solve important strategical issues in the field of research, on a national and international level. Ethical and privacy terms using personal data was a main focus area during the whole programme period.

International activities

The BIOBANK programme allocates funding for half of the Norwegian annual fee for in the European research infrastructure consortium BBMRI-ERIC year 2014-2016. The other half was paid by the RCN infrastructure grant to the Norwegian BBMRI node, Biobank Norway.

The BIOBANK programme co-financed and co-hosted a meeting in Banbury Center, New York, USA aiming at increased utilization of the Nordic health data sets.

Performance measurement

This action-oriented research programme is considered to have highly reached the stipulated goals. In addition, the programme has facilitated cooperation, labor allocation and

concentration of responsibility and charing. The programme's limited funds had a significant added value to the research field and for development of personalized medicine. The project portfolio has very high to outstanding scientific quality. The large data sets produced are sought to be used by Norwegian and international research groups in research projects of high scientific level. The programme also facilitated to build expertise within biostatistics and bioinformatics, a significant need for Norway to leverage our unique personal data into research.

Challenges with delay in this programme's portfolio were mainly due to external factors, primarily challenges with access to personal data from various sources and approvals by ethics committees and the Data Inspectorate.

The programme board concludes that the outcome of this minor programme was seen as highly valuable to the Norwegian research community, and the funding principle of building common big data sets was highly valuable and also noticed and repeated on a larger scale in other European countries. There were great interest in the programme call scheme, meetings organized by the programme and the final project results.

Sammendrag

Det er av stor strategisk betydning å utnytte norske og nordiske persondata til forskning.

BIOBANK-programmet var utformet for å dra nytte av potensialet for forskning på humant biologisk materiale i biobanker ved å kople analyseresultater med persondata fra relevante kilder. Hovedmålet med programmet var å generere forskningsbasert ny kunnskap med sikte på årsaker til, forebygging, diagnostisering, behandling og overlevelse av somatiske og psykiatriske sykdommer.

Utlysninger

Basert på formålet med programmet, var planen å lyse ut midler åpent innenfor programplanens bredde til prosjekter av høy vitenskapelig kvalitet.

Første utlysning i 2012 var åpen innenfor hele programplanen. Tre store forskerprosjekter ble innvilget. Basert på søknadene fant programstyret behov for strategisk arbeid for å stimulere til mer dialog, samhandling og samarbeid om å bygge store datasett til felles bruk.

Andre utlysning i 2013 etterlyste miljøer som kunne gjennomføre store tekniske analyser av material i nasjonale biobanker av høy kvalitet. To prosjekter fikk midler. De hadde tett dialog med programstyret om å fremme utstrakt bruk av disse store datasettene.

Underveis i dialogen om å bruke datasettene som ble finansiert i andre utlysning, ble det avdekket et behov for å bygge mer biostatistikk- og bioinformatikkekspertise for å håndtere datasettene. I 2015 lyste programmet derfor ut midler til forskerprosjekter som kunne bygge gode miljøer innenfor biostatistikk og bioinformatikk og som kunne bruke data fra mange kilder for å besvare forskningsspørsmål. Fire prosjekter fikk bevilgning.

Nasjonal samhandling

Programmet arrangerte årlige konferanser og hadde tett dialog med prosjektene for å fremme samarbeid og bruk av datasett finansiert av programmet. I tillegg arbeidet vi med og diskuterte viktige strategiske forhold for forskningsfeltet nasjonalt og internasjonalt. Vi fokuserte særskilt på etiske og personvernmessige forhold ved å bruke persondata.

Internasjonale aktiviteter

BIOBANK-programmet betalte halve årskontingenten for det norske medlemsskapet i den europeiske forskningsinfrastrukturen BBMRI-ERIC år 2014-2016. Den andre halvdelen ble betalt av den norske BBMRI-noden, Biobank Norge.

BIOBANK-programmet var i 2015 med på å finansiere og arranger et møte ved Banbury Center, New York, USA med formål å øke bruken av nordiske helsedata.

Måloppnåelse

Dette handlingsrettede forskningsprogrammet vurderes til å ha nådd sine mål i stor grad. I tillegg har programmet tilrettelagt for samarbeid, arbeidsdeling og konsentrasjon som har gitt en betydelig merverdi av programmets begrensede midler. Programarbeidet har også verdi for forskning innenfor persontilpasset medisin. Prosjektporteføljen har meget høy til fremragende vitenskapelig kvalitet. Det er lagt midler til store tekniske analyser av biologisk materiale fra befolkningsbaserte helseundersøkelser. Disse datasettene er ettertraktet til bruk av norske og internasjonale forskningsmiljøer. Programmet har også tilrettelagt for å bygge ekspertise innenfor biostatistikk og bioinformatikk, som Norge trenger for å utnytte våre unike persondata i forskning.

Utfordring med forsinkelse i dette programmets portefølje skyldes hovedsakelig eksterne faktorer, først og fremst tidkrevende utfordringer med tilgang til persondata fra ulike kilder og prosjektgodkjenninger av etisk komité og Datatilsynet.

Programstyret konkluderer med at disse forholdsvis små program-midlene har hatt stor verdi for de norske forskningsmiljøene og at modellen med å bygge felles datasett fra biobankmateriale var verdifullt. Det ble sett og gjentatt i større skala i andre europeiske land. Det var stor interesse for programmets ulike utlysninger, møtene programmet arrangerte og resultatene av prosjektene.

Introduction

Name of the programme: *Programme on Human Biobanks and Health Data* (BIOBANK)

Objective and purpose of the programme:

The BIOBANK research programme was launched as part of the follow up on the recommendations in the biobank report *Gode biobanker - bedre helse* (the Research Council or Norway, 2008) to establish a long-term research programme which takes full advantage of the major national investments in biobank infrastructure. The programme aim therefore aimed to develop research-based knowledge about human health and disease through better use of human biobanks and health data as unique resources.

Biological material stored in biobanks is of major value for gaining a deeper understanding of the complex relations between genes, environmental factors and diseases. There is broad agreement among policymakers and the health services about the importance and benefits of using biobank material and register data for research. This is highlighted in a number of strategic documents.

The BIOBANK programme was designed to take advantage of the potential for research on human biological material in biobanks by coupling analysis results with personal data from other sources. Research projects funded under the programme should exploit the full potential of the large biobanks and registers, unless there were scientific reasons for a smaller study sample.

Thus, the primary objective of the programme was to generate research-based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases.

All projects under the programme should address ethical, legal and social aspects (ELSA) as an integral part of project activities, and incorporate international cooperation.

Programme period: 2012-2016

Programme web page: www.forskningsradet.no/biobank with separate publications at the Norwegian and English page

Programme board:

Role	**Title**	**Name**	**Institution**	**Appointment period**
Chair	Professor	Rolf K Reed	University of Bergen	22.11.2011-31.12.2016
Acting deputy chair	Professor	Eero Vuorio	Biocenter Finland	22.11.2011-31.12.2016
Member	Director	Wenche Marie Olsen	Lytix Biopharma	22.11.2011-31.12.2016
Member	Professor	Anne Høye	Northern Norway Regional Health Authority	22.11.2011-31.12.2016
Member	Professor	Marit Veierød	University of Oslo	22.11.2011-31.12.2016
Member	Professor	Marit Halvorsen	University of Oslo	1.1.2013-31.12.2016
Member	Professor	Joakim Dillner	Karolinska Institutet	1.1.2013-31.12.2016
Member	Professor	Per Johansson	Lytix Biopharma	1.1.2014-31.12.2016
Member	Senior researcher	Arnstein Mykletun	National Institute of Public Health	22.11.2011-21.11.2013

Finances

The programme's funding source: Ministry of Education and Research
Total disposable budget: NOK 111.7 mill. year 2011-2016.
In addition, NOK 20 mill. was made available from the 2017 budget.

Activities

Most important activities and performances during the programme period

Three main calls for proposals

At the programme planning, two major large open calls for proposals were proposed. However, based on experiences from the first large call, the programme board decided to target the next calls strategically to leverage limited funds higher benefit to the research area. Thus, the following three main calls were announced:

- "50 million NOK for research on human biobanks and health data", application deadline 19.04.2012
  This first call for proposals was open to all research projects to fit into the work programme.
- "Up to NOK 20 million for a large-scale analysis on a large biobank sample set", application deadline 10.04.2013
  The second call for proposals was strategically aligned aiming at funding a large-scale analysis of a large well described high quality national human biobank sample set. The proposal must describe potential re-use of the resulting data and establish a governing and administration structure for secure storage, access to and sharing of the data. The call specified preference to projects planning to analyze the biobank samples using a national infrastructure platform.
- "NOK 45 million for research on human biobanks and health data", application deadline 15.04.2015
  Norway has many data sets highly valuable for research, but several of the data sets are rarely used in research and in total we have limited expertise within biostatistics and bioinformatics to handle the data sets. Thus, the third call for proposals focused on large collaborative high quality researcher projects using a high number of data sets while building expertise in biostatistics and bioinformatics.

The following table shows proposals received and funded in the three main calls for proposals:

Application deadline	**No of proposals received**	**Funding asked (mill. NOK)**	**Proposals mean mark***	**No of projects granted**	**Granting (mill. NOK)**	**Projects mean mark***
19.04.2012	33	**432**	*5*	3	**50**	*7*
10.04.2013	2	**40**	*5*	2	**25**	*5*
15.04.2015	13	**223**	*5*	4	**47**	*6*
Total	***48***	***695***	**5**	***9***	***122***	**6**

*The Research Council of Norway is grading the proposals 1 (poor) - 7 (outstanding).

The above table clearly shows that an open call for proposals gave the highest number of proposals to assess. 3 out of 33 proposals (9%) were granted in the first call, when the programme was still relatively unknown in the scientific community. The three projects that received funding were scored 7. Two proposals scored the highest grade 7 were rejected due

to budget constraints.
The two strategic calls gave fewer proposals and significantly higher granting rate. The projects that received funding were scored 5 and 6, but not outstanding (grade 7).

Annual conferences
From 2014 on, the programme arranged the following three conferences with international speakers at the House of Literature in Oslo:

- 27 May 2014
  The conference programme included a broad range of topics focusing on improving health data management.
- 8 September 2015
  The 2015 conference focused on increasing the use of our unique Norwegian health data in all aspects.
- 8-9 November 2016
  The final two-days conference focused on the following four topics:
    - Existing unique data sets and how to use them
    - Legislation and facilitation of data for research
    - New perspectives to make use of existing health data in biobanks and registries: Causality and observational studies in Norway and Europe
    - Omics is more than genomics

All three conferences were used to inform the audience status from the BIOBANK projects preparing large data sets for common use, in order to promote collaborative use of the big data as soon as they were quality controlled ready for sharing.

International cooperation
In order to enhance mobility and international research cooperation for research fellows working on ongoing BIOBANK projects, the programme announced an open-ended call for proposals for overseas research grants open to all PhDs, post docs and researchers granted in BIOBANK funded projects. During the programme period 2012-2016, we received one proposal for an overseas grant twelve month to the US. The proposal was funded NOK 383k. The stay was later reduced to ten months with a corresponding budget cut.

Together with Programme on Mental Health, the programme funded and co-hosted a meeting at the Banbury center, US February 2016. The aim of the meeting was to discuss strategic collaborative use of the unique Nordic health data sets. To follow-up on the good discussions and cooperation, the RCN director general decided to host a second meeting. It was arranged September 2016 in the RCN venue in Oslo. It resulted in a collaborative white paper and several proposals submitted to NordForsk calls. In addition, the participants agreed to meet a third time in Copenhagen spring 2017.

Additional strategic activities
The programme board monitored continuously relevant strategic processes and performed close dialogue with relevant funding schemes in order to cope with the needs and filling the research gaps.

Specifically, in addition the programme board performed dialogues with the heads of the Newborn screening programme and potential Norwegian collaborators aiming to use the Newborn blood materials for research to test important child health hypothesis. The dialogue meetings resulted in three letters to the Ministry of Health and Care Services; from the Research Council of Norway, The Norwegian Institute of Public Health and the Oslo university Hospital, proposing changes in the Newborn screening regulation to

- hinder destruction of the valuable screening materials after six years storage time (as stated in the current regulation)
- aiming at using the valuable materials for highly useful research

Popular science web publications

25 popular science publications were published specifically about the BIOBANK programme, calls for proposals, funded projects and conferences. The publications were submitted via the Norwegian or English programme web pages, newsletters and in a popular science end report (hard copy and web version). The full publication list is attached.

Key figures, activities

Number of projects: 9

Number of doctoral fellows: *0*

Number of post-doctoral fellows: 6 woman and 5 men

Administration

Administrative costs: NOK 5 mill. (including internal admin. costs, assets, assessment processing costs, communication and conferences)

Results

Highlights and findings

The following three projects were funded in the first call for proposals 2012:

Title	**PI**	**Project owner**	**Funding**
Perinatal outcomes and childrens health after prenatal exposure to influenza and influenza vaccination	Per Magnus (until December 2014) / Lill Trogstad	National Institute of Public Health	NOK 17.7 mill.
Causal pathways for asthma	Wenche Nystad	National Institute of Public Health	NOK 14.8 mill.*
HUNTing for genes that affect cardiovascular related traits	Kristian Hveem	Norwegian University of Science and Technology	NOK 17.9 mill.

*In addition, a postdoc funded in this project asked and was granted NOK 0,4 mill. to an overseas research stay.

The three projects were funded in the open call asking large high quality proposals to complete the aims of the work programme 2012-2016.

"Perinatal outcomes and childrens health after prenatal exposure to influenza and influenza vaccination" is a project that, based on several linked data sources, study perinatal outcomes and childrens mental and cognitive development after prenatal exposure to influenza A H1N1pdm09 virus infection or influenza immunization, as well as risk factors for severe influenza in pregnancy.

The "Causal pathways for asthma" project aims to examine the influence of *in utero* and early life exposures on asthma phenotypes at age 7 years to advance knowledge of mechanisms whereby diet and environmental exposures influences gene expression to alter risk of atopic diseases. The MoBa (Mother and Child) study is a main data source for the project.

The overall goal of "HUNTing for genes that affect cardiovascular related traits" is to use high-throughput cost-effective DNA genotyping arrays and targeted sequencing to identify genes and pathways that contribute to the risk for cardiovascular disease (CVD). The project uses materials from HUNT (Helseundersøkelsene i Nord-Trøndelag) 1, 2 and 3.

The following two projects were funded in the second call for proposals 2013:

Title	PI	Project owner	Funding
Better health by harvesting biobanks	Per Magnus	National Institute of Public Health	NOK 20.0 mill.
Genome-wide miRNA profiling in prediagnostic samples from Janus Serum Bank for early diagnosis, improved therapy & surveillance of cancer	Hilde Langseth	Oslo University Hospital	NOK 5.0 mill.

The two projects were funded in the second call asking large-scale analysis on a large high quality biobank sample set.

"Better health by harvesting biobanks" (short name HARVEST) is genotyping of more than 30 000 samples from large Norwegian, population-based surveys that are followed over time (cohorts). This means that the genotypes from all over the genome (GWAS - genomewide association studies) can be analysed together with other exposures to estimate the association to complex and serious diseases. Many of these diseases can be retrieved from Norwegian health registries. The research will help us understand basic disease mechanisms that, through laboratory research, can lead to more efficient personalized medications. Additionally, the findings may lead to better primary prevention of disease. HARVEST intends to make this happen by making the data easily available to researchers outside the consortium.

"Genome-wide miRNA profiling in prediagnostic samples from Janus Serum Bank for early diagnosis, improved therapy & surveillance of cancer" was funded only 25% of the originally proposed budget. The revised project focuse on colorectal and lung cancer that represent great public health concerns, and where there is a potentially large impact of early detection and treatment. The aim is to identify miRNA expression profiles associated with these two cancer forms, both overall, as well as for subtypes defined by topography, morphology and stage.

The following four projects were funded in the third call for proposals 2015:

Title	PI	Project owner	Funding
Nasjonalt treningsinitiativ for bedre utnyttelse av biobanker og helseregistre	Kristian Hveem	National Institute of Public Health	NOK 12.5 mill.
National training initiative to make better use of biobanks and health registry data	Magne Thoresen	University of Oslo	NOK 12.5 mill.
Identifying the missing heritability of complex diseases leveraging biobanks, registries and novel analytical tools in psychiatric disorders	Ole Andreassen	University of Oslo	NOK 15.0 mill.
Biomarkers of Cancer: Biocomputional analysis of data from population-based biobanks and health registries	Hilde Langseth	Oslo University Hospital	NOK 7.0 mill.

The four projects were funded in the third call aiming at building National expert groups within biostatistics and bioinformatics able to produce scientific results of high quality from large data sets in biobanks and registries. The call asked proposals with potential to attract international expertise and funding, and to challenge the biobank/registry Open Access policy.

"Nasjonalt treningsinitiativ for bedre utnyttelse av biobanker og helseregistre" and "National training initiative to make better use of biobanks and health registry data" were asked by the programme board to join forces into one large collaborative project in order to get funding. The reason for merging the projects was the need for sharing a large number of data sets and biostatistics/-informatics expertise. Together, they will leverage existing digital biologic information from three of the largest prospective cohort studies in Norway, enriched with linkages to a comprehensive list of health registries, to better understand the biology for health and disease within diverse disease domains. They will in first hand

- build national methodological competence and capacity in the analysis of large-scale biobanks and health registries by focusing on relevant methodological developments.
- investigate complex ethical questions on the horizon, such as gene-based follow up of participants, in order to secure that the interest of large-scale biobank research and the participants are harmonious and compatible with an ethical commitment to the principle of reciprocity.
- mentor and train postdoctoral fellows at the multidisciplinary interface of applied and methodologically driven biostatistics and bioinformatics to meet the increasing complexity of the new era of precision medicine.

Based on international multidisciplinary collaboration, "Identifying the missing heritability of complex diseases leveraging biobanks, registries and novel analytical tools in psychiatric disorders" combines analytical results from Norwegian human biobank material and data from health registries, surveys and services to develop knowledge about genetic risk factors and causes, to identify the underlying disease mechanisms of psychiatric disorders. Although the project focuses on psychiatric disorders, the methods and infrastructure can be used for other complex human diseases, and for more samples from additional studies. The project builds on strong biostatistical and bioinformatics competence and will increase the capacity in this field in Norway.

"Biomarkers of Cancer: Biocomputional analysis of data from population-based biobanks and health registries" is a follow-up on the Genome-wide miRNA profiling project funded in the second call for proposals. This multidiciplinary international collaborative project is using miRNA profiles from pre-diagnostic serum samples in the Janus Serum Bank, in combination with detailed cancer information from the Cancer Registry of Norway and information on environmental exposures from health surveys, in advanced biocomputational analysis. The aim of the study is to investigate those miRNA profiles as early markers and potential screening biomarkers for colorectal and lung cancer.

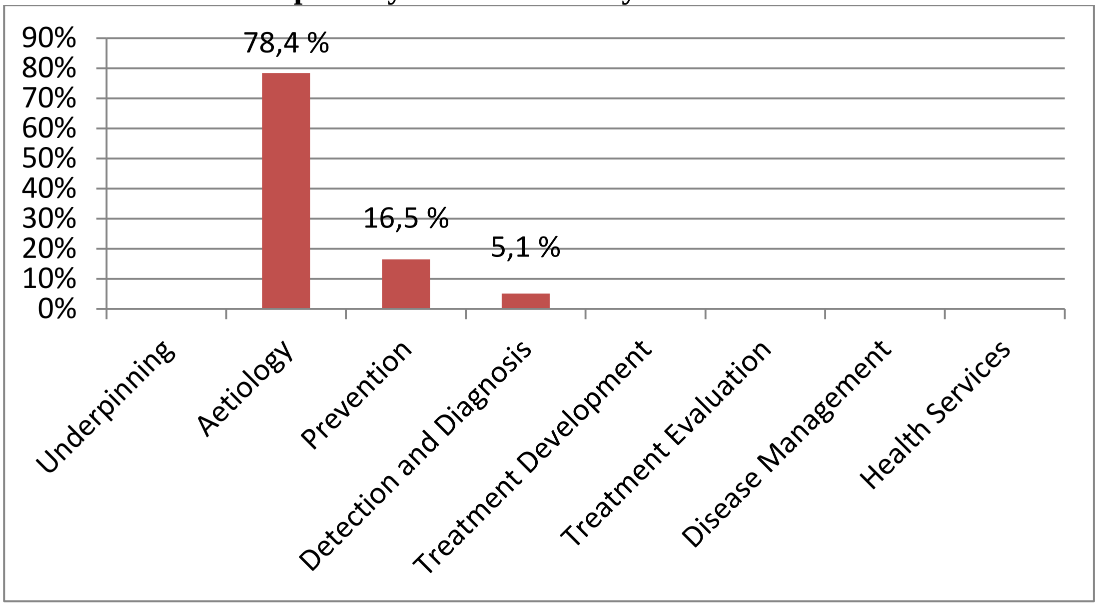
Additional information about each project may be found using the title of the project of interest to search the RCN project database https://www.forskningsradet.no/prosjektbanken/.

Analysis of the project portifolio 2012-2016 with the Health Research Classification System (HRCS)

The Health Research Classification System (HRCS) is a system for classifying the full spectrum of biomedical and health research, from basic to applied, across all areas of health and disease (www.hrcsonline.net). HRCS is a two dimensional framework. One dimension, the Health Categories, is used to classify the type of health or disease being studied. The other dimension, the Research Activity Codes, classifies the type of research activity being undertaken (from basic to applied science). HRCS codes are assigned to capture the main objective(s) of a particular study. Thus, the system provides a broad overview of the centre of gravity of a set of research awards.

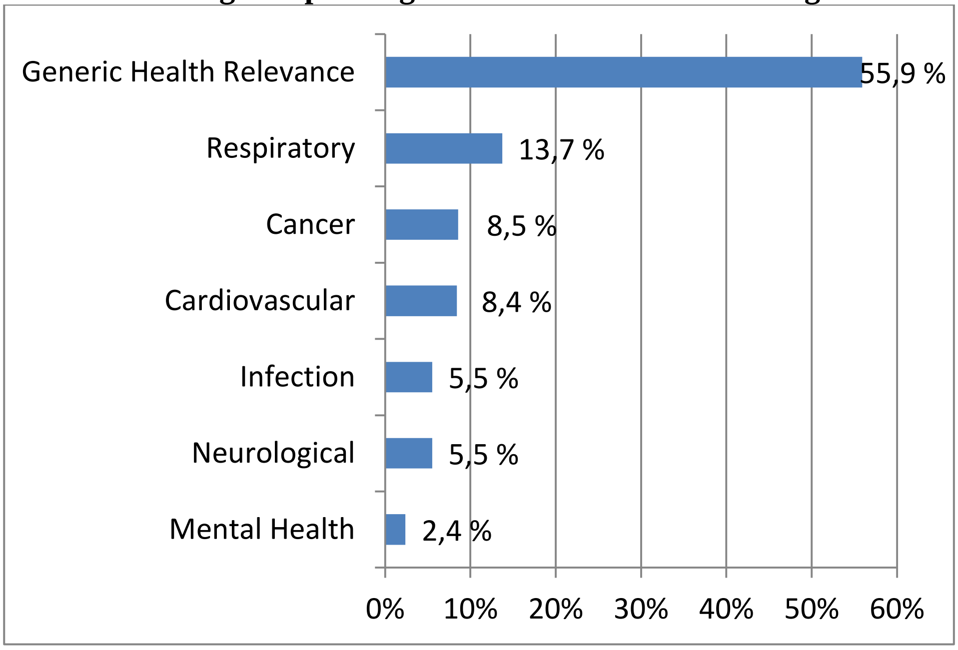
Active BIOBANK projects have been classified. All nine projects funded by the programme, are included in the analyses.

Percent total spend by research activity



The figure shows the proportion of total spent by research activity 2012-2016. The diagram shows that the predominantly largest area of spend is "Aetiology", followed by "Prevention of disease and conditions", and a minor portion of "Detection and Diagnosis".

Percentage of spending attribution to all health categories



The figure shows the relative distribution of research funding across the health specific categories, as a proportion of total expenditure. Generic health relevance refers to research applicable to all diseases and conditions or to general health and well-being of individuals. The BIOBANK projects obviously represent a large spread among the categories.

Performance indicators

Number of doctoral degrees awarded: 0
Scientific publications: 35
Communication
  -to the public: 43
  -user directed: 55
New/enhanced products/processes in industry: 1

Overall assessment

Overall assessment of progress, performance and benefit

Achivements

In the first call for proposals three large research projects were funded. Together they are expected to fulfill the primary objective of the programme; to generate research-based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases.

Research projects funded under the programme should exploit the full potential of the large biobanks and registers, unless there are scientific reasons for a smaller study sample. To fulfill this aim in the short and long run, the programme board identified a need to reduce the fragmentation as a result of small scale analyses of the valuable national biobank materials.

Thus, in the second call for proposals the programme allocated funds to two collaborative projects performing large scale analysis to produce large data sets handled securely accessible for the research community. The BIOBANK programme is designed to take advantage of the potential for research on human biological material in biobanks by coupling analysis results with data from health surveys, health registers and the health services. This goal is not automatically achieved simply because Norway has a large number of high quality data sets in biobanks and registries. Two main obstacles are, first, access to the data and, second, sufficient expertise and capacity in biostatistics and bioinformatics.

Thus, in the third call for proposals the programme funded four large scale research projects aiming at building national expert groups within biostatistics and bioinformatics able to produce scientific results of high quality from large data sets in biobanks and registries. We were looking for the potential to attract international expertise and funding, and to challenge the biobank/registry Open Access policy.

The funded projects are cross-disciplinary in respect to expertise and both nationally and internationally highly collaborative. They already started to get significant number of large research funds from abroad (NIH and Horizon2020).

Additionally, apart from important strategic work to distribute minor annual funding for projects that potentially can provide relatively large value for money into research on human biobank and health data, the programme board prioritized to support and enhance important dialogue in line with the BIOBANK work programme and calls.

Assessment of performance and scientific challenges

In addition to fund several high quality researcher projects using a combination of data sources, the programme identified two obstacles and thus piloted filling two main gaps, as follows:

- build high quality data sets for common use into world class research
- build biostatistics and bioinformatics expertise available in Norway

In addition to meeting the specific objectives in the work programme, at the same time the programme work was in line with national strategies, in first-hand the Health and Care21 strategy.

Human biobanks form the foundation of modern biomedical research through storing and distributing of biospecimens and related data from humans, both patients and control individuals, under well-controlled conditions in a secure environment. Norway is well positioned to play a leading role in biobank-based research as the biological data obtained in high-throughput analytical platforms can be linked with data from various registers. The high quality population and disease based biobanks were established also in an international research perspective. In addition, we do have several national registries including the same individuals. Coupling of information from the biobanks to other health and social data and information on environmental and lifestyle factors is expected to create a unique basis for understanding the causes and development of diseases in more detail.

Biobanks form also the foundation for disease stratification (molecular sub-classification of diseases) and for subsequent development of personalized medicine. This is a marked shift in development of targeted (personalized) treatment and companion diagnostics and in prevention (identification of individuals with an increased risk). This results in gains for the individual patient, for the society (by eliminating non-effective treatments, reducing the need for health services and by promoting a healthier work force), and provides new perspectives for diagnostics and pharma industry in global markets. Thus, biobank and health data based research will truly address some of the grand challenges of today’s society.

Science-oriented projects funded by the programme have started to produce answers to their important research questions, but more importantly the value of the large scale molecular characterization project of Biobank Norway, in combination with other health and personal data, will be fruitful for many years to come by providing researchers with proper ethical permits access to a wealth of molecular, phenotypic and registry data. Efficient reuse of the high-quality data produced by the projects funded in the second call for proposals is likely to result in marked savings for a large amount of research projects as well as better progress. This strategic move is expected to provide in the long run significantly higher value for money to the research society compared to funding of researcher projects in the current national situation.

Delays in the BIOBANK projects are mainly due to

- obtaining appropriate approvals from Ethics Committees
- data access and storage combining data from several data sets, including Statistics Norway

Thus, it is a significant urgent need to build research infrastructure to facilitate research on Norwegian and Nordic personal data and to update relevant legislations in accordance to secure efficient secure data handling. In fact, the research field may absorb significantly more funds into the best quality projects and important new research infrastructure. The facts causing delays in this type of projects has been topics of conferences organized by the programme.

Biobank-based research is highly dependent on international collaboration, especially when studying rare disease variants. With improved disease stratification, such variants will be increasing in numbers. Norwegian researchers funded through the programme are also active participants in Nordic, European and global collaborations. NordForsk funded Nordic biobank collaboration has demonstrated the feasibility of combining biospecimens and patient data from different countries and thereby increased sample size and statistical power of the analyses.

Norwegian biobanks strive for high quality in all aspects of biobanking and all types of biobanks. They contain samples from both genders and ages. The large MoBa (Mother-and-Child) cohort naturally twists the gender balance towards females.
However, the unique Norwegian data sets are still substantially underused for both academic and industrial research. Thus, specifically it is important to

- establish a common infrastructure for secure unified management of Norwegian personal data for secondary use
- continue after the BIOBANK programme period to focus on research funding designed to take advantage of the unique potential for research on human biological material in biobanks by coupling analysis results with data from health surveys, health registers and the health services and other sources

Nordic collaboration

In order to further promote use of the Norwegian and Nordic high quality data sets, the BIOBANK programme put funding into co-hosting the first dedicated scientific meeting in Banbury Center, New York, USA. Further meetings are supposed to benefit Nordic progress in using health data sets in international collaborations. It is in direct line with the initiative taken by Norway in the collaborative precidency projects in The Nordic Council of Ministers 2017.

Industrial research

The programme responsibilities were mainly public research. However, the programme board performed close dialogue with the biobank company Lifandis until a controlled liquidation was completed June 2015. In addition, the board gave input to the parlament hearing about a public personal data commersialization company. The RCN recommendation to the hearing document was supportive, recommending two parallel actions:

- establish a common infrastructure for secure unified management of Norwegian personal data for secondary use
- establish a sustainable national ownership structure and business plan for innovation and industrial cooperation related to Norwegian human biobanks and personal data

Challenges ahead

With a minor budget, the BIOBANK programme highly added value to the Norwegian biobank and health data research community, especially in respect to collaborations, harmonization and expertise building.
However, still the following challenges need to be solved:

- It is difficult or not possible to get funding for large technical analysis of biobank materials, thus distribution of biological materials for relatively expensive minor analysis not suitable for reuse is common
- Several data sets are hard to access for research purposes
- The researchers need guidance/education
    - how to get an overview of and insight into the potential Norwegian and Nordic data sources to use
    - who and when and how to apply permissions to access the data sets
    - how to manage the data, including insight into laws and regulations for storage, sharing and use
- Need for more biostatistics and bioinformatics expertise to increase use of Norwegian health and personal data for health research should still be assessed after a period of time when the programme is terminated and before the funding is spent
- It is a need for more collaboration, both between researchers and data managers, on a national and Nordic level
- The research as funded by the programme will point towards potential correlation between genetic factors and disease mechanisms. Once such correlations have been identified it requires another approach to validate the mechanisms that are involved

when disease develops. This is an issue that needs to be addressed in the future whether the society and research community should be satisfied with correlations or whether we should also invest in outlining and exploring the mechanisms involved.

- There are several projects still running when the programme is closed down and the short and the even more important long term impact is difficult to assess in the current tradition of reporting on research programmes in the RCN. In particular for the type of research funded by this programme, RCN should consider to have mechanisms to evaluate long term impact by evaluating also 5 and may be 20 years after the programme has been closed down.
- Overall, Norway is in need of a harmonized information, access and analyses platform for health data with one portal for researchers facilitating coupling to other personal data and international collaboration, as concluded and outlined in the following two reports:
    - *Enklere tilgang - mer forskning*
      (The Research Council of Norway, December 2016)
    - *Referansearkitektur og fellestjenester for helseregistre*
      (The Norwegian Directorate of eHealth, December 2016)

Further actions

As stated in two new reports, *Enklere tilgang – mer forskning* and *Referansearkitektur og fellestjenester for helseregistre*, it is still a need to put work into using personal data securely for important health research by, in first hand to

- build a secure data analyses platform with one portal for researchers
- educate researchers in asking for and handling person sensitive data
- work strategically through research programmes and relevant activities
- secure that laws and regulations keep track with the fast technological development in the area
- increase cooperation and collaboration between administers and authority for personal data

The bullet points represent the RCN action points to follow-up on the reports. So far, we have

- signed a collaboration agreement with the Norwegian Directorate of eHealth to build the secure data analysis platform securing all specific needs for research
- addressed the need for education of researchers in a note to the heads of research institutions and an open news letter.

Attachments

Popular science web publications

The following popular science publications have been written specifically about the BIOBANK programme, calls for proposals, funded projects and conferences. The publications are submitted via the Norwegian or English programme web pages and news letters 2012-2016.

2016

- *Framtidens forsknings- og behandlingsmuligheter* – programmets polulærvitenskapelige sluttrapport

http://www.forskningsradet.no/prognett-biobank/Nyheter/Framtidens_forsknings_og_behandlingsmuligheter/1254022812454/p1253972330047

The report is composed of the following nine papers:

  - "-Utløste mer samarbeid og høyere ambisjoner", an intervju with the programme board chair Rolf Reed, UiB
  - "Tilfeldige genetiske koder kan inspirere til nye medisiner" about a BIOBANK projects headed by Kristian Hveem, NTNU
  - "Fremtidsvisjon. Blodprøver varsler om kreftrisiko" about two BIOBANK project headed by Hilde Langseth, OUS
  - "Uheldige kombinasjoner av normale gener gir psykiske lidelser" about a BIOBANK project headed by Ole A Andreassen, UiO
  - "Starter utviklingen av lungesykdommer i forsterlivet?" about a BIOBANK project headed by Wenche Nystad, FHI
  - "Studerer effekten av influensa på gravide kvinner og barna deres" about a BIOBANK project headed by Lill Trogstad, FHI
  - "Skogplantingen og hogsten er ferdig, verdiskapningen kan begynne" about a project headed by er Magnus, FHI
  - "Utdanner forskere som skal skape verdier i biobankene" about two BIOBANK projects with close collaboration, one headed by Magne Thoresen, UiO, and one by Kristian Hveem, NTNU
  - "Biobanks and health registries. A unique resoursce for research", a summary about the BIOBANK programme

- *The Biobank and Health Data Conference 2016* http://www.forskningsradet.no/prognett-biobank/Nyheter/The_Biobank_and_Health_Data_Conference_2016/1254020471645/p1253972330079

- *Se innleggene fra årets biobank- og helsedatakonferanse*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Se_innleggene_fra_arets_biobank_og_helsedatakonferanse/1254022456133/p1253972330047

- *Møte om de nordiske helsedatasettene i USA*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Mote_om_de_nordiske_helsedatasettene_i_USA/1254015665370/p1253972330047

2015

- *The BIOBANK Conference 27 May: Presentations*

http://www.forskningsradet.no/prognett-biobank/Nyheter/The_BIOBANK_Conference_27_May_Presentations/1253996776099/p1253972330079

- *BIOBANK-konferansen 8. september*

http://www.forskningsradet.no/prognett-biobank/Nyheter/BIOBANKkonferansen_8_september/1254012761452&lang=no

- *Følg Biobankkonferansen direkte her*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Folg_Biobankkonferansen_direkte_her/1254012264996&lang=no

- *Persontilpasset medisin kommer – sakte*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Persontilpasset_medisin_kommer__sakte/1254013407790&lang=no

- *Lager norsk genkart for helseforskning*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Lager_norsk_genkart_for_helseforskning/1254012254608&lang=no

- *Gamle serumprøver får ny verdi for kreftforskere*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Gamle_serumprover_far_ny_verdi_for_kreftforskere/1254012183921&lang=no

- *45 millioner lyses ut til store prosjekter*

http://www.forskningsradet.no/prognett-biobank/Nyheter/45_millioner_lyses_ut_til_store_prosjekter/1254005270760&lang=no

2014

- *BIOBANK Conference 27 May 2014*

http://www.forskningsradet.no/prognett-biobank/Nyheter/BIOBANK_Conference_27_May_2014/1253995289984/p1253972330079

- *BIOBANK-konferansen 27. mai*

http://www.forskningsradet.no/prognett-biobank/Nyheter/BIOBANKkonferansen_27_mai/1253996699816&lang=no

- *BIOBANK-konferanse 27. mai 2014*

http://www.forskningsradet.no/prognett-biobank/Nyheter/BIOBANKkonferanse_27_mai_2014/1253995160297&lang=no

- *Biobankene går fra selvhogst til datamarkeder*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Biobankene_gar_fra_selvhogst_til_datamarkeder/1253997057567&lang=no

- *Norge kan få økt utbytte av biobankene*

http://www.forskningsradet.no/prognett-biobank/Nyheter/_Norge_kan_fa_okt_utbytte_av_biobankene/1253996460746&lang=no

2013

- *Hvorfor får vi astma og allergi?*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Hvorfor_far_vi_astma_og_allergi/1253988640306&lang=no

- *Kan influensa i fosterlivet påvirke barnas utvikling?*

http://www.forskningsradet.no/prognett-biobank/Nyheter/Kan_influensa_i_fosterlivet_pavirke_barnas_utvikling/1253987446897&lang=no

2012

- *Results from the last call for proposals to the Programme for Human biobanks and health data* http://www.forskningsradet.no/prognett-biobank/Nyheter/Results_from_the_last_call_for_proposals_to_the_Programme_for_Human_biobanks_and_health_data/1253980442474&lang=en

- *Human biobanks and health data*
http://www.forskningsradet.no/prognett-biobank/Nyheter/Human_biobanks_and_health_data/1253973285816&lang=en

BIOBANK key figures	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Programme board members per 31 Dec						
Rolf K Reed (chair), Univ of Bergen	x	x	x	x	x	x
Eero Vuorio, Biocenter Finland	x	x	x	x	x	x
Anne Høye, Univ hospital of North Norway	x	x	x	x	x	x
Wenche Marie Olsen, Lytix Biopharma	x	x	x	x	x	x
Marit Veierød, Univ of Oslo	x	x	x	x	x	x
Marit Halvorsen, Univ of Oslo			x	x	x	x
Joakim Dillner, Karolinska Institutet			x	x	x	x
Per Johansson, Uppsala university				x	x	x
Arnstein Mykletun, National Insitute of Public Health	x	x				
Number of programme board meetings		2	3	2	4	2
Total number of active projects			3	5	9	8
Total calls for proposals		1	2	1 (open-ended)	1	
Number of applications received		33	2	1	13	0
Number of applications with a mark 6 or 7		10			4	
Number of new projects			3	2	4	
Number of completed projects						1
Percentage of applications awarded funding			9%	100%	31%	
Number of project managers			3	5	9	9
Number of new project managers			3	3	4	0
Percentage female project managers			33 %	67 %	25 %	0 %
Percentage female project managers among the applicants			33%	60%	44%	44%
Andel kvinnelige prosjektledere blant søkere			27%	50%	100%	31%
Doctoral fellowships						0
Postdoctoral fellowships			3	4	4	11
Men			2	3	3	5
Women			1	1	1	6
Doctoral degrees completed						0
Number of programme conferences				1	1	1
Scientific publications:						
Articles published in scientific/scolarly journals				6	6	23
Articles published in anthologies			1	2	4	4
Dissamination activities, societal impact						
Reports, memoranda, articles, presentations held on meetings/conferences aiming at project relev			7	16	20	12
Popular science publications (articles/books, hearings etc)			1	2	4	4
Publications in the media (newspaper, television, radio etc)			10	6	9	7
Innovation results						
New/improved methods/models/prototypes					1	
Project partners						
Total within higher educaton sector			5	5	5	8
Total within institute sector						1
Total from abroad			3	4	4	5

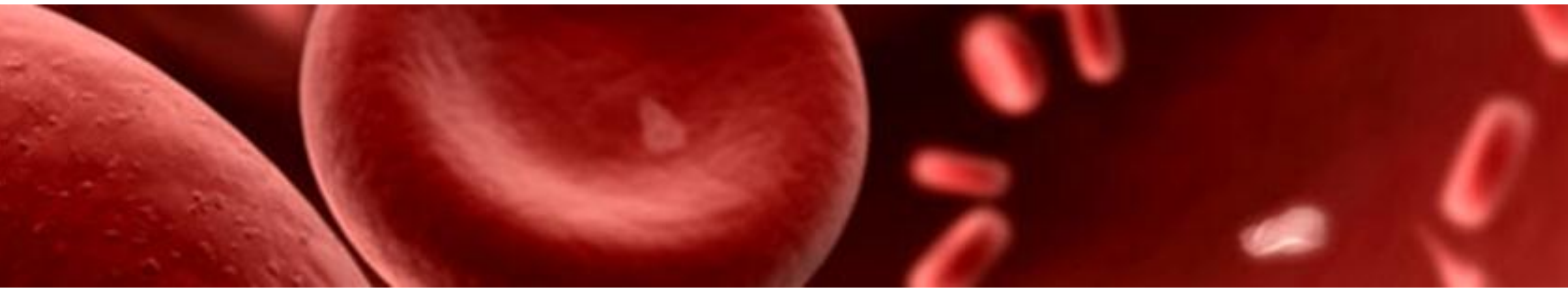
MNOK	2011	2012	2013	2014	2015	2016
R%D revenues						
Ministry of Education and Research	10	20	20	20	20	21.7
Disposible budget available		29.7	48.8	54.8	47.8	40.1
Funding used		0.9	14	27	29.2	18.1
Budget transfers		9.7	28.8	34.8	27.8	18.7
Programme's share of internal administration				0.9	0.9	0.8
External administration						
Programme board's expenses, application process		0.9	1	0.4	0.5	0.5
Communication and dissemination						0.1
Projects awarded funding			14.3	24.3	27.7	17.3
Basic biomedical science			2.2	3	2.2	5.6
Clinical research			5.5	8.5	10.5	6.7
Social science			6.1	9.8	13.6	8.1
Translational research		0.4	14.3	21.7	14.9	10
Research for the renewal of public sector						6.2
Innovation projects and projects with user involvement						0.8
Innovations in enterprises within the public administration and service		0.1	1	2.4	4.8	1
Confederation of innovations in and for public administration and services				0.1	0.4	0.1
Livelihoods and population development			0.9	1.5	1.2	1.2
Welfare state services and organization				0.1	0.3	0.1
Researcher project - applications (projects)			33 (3)			13 (4)
Other support - applicationssøkt (projects)				2 (2)		
Postdoctoral oversears grant - applications (projects)					1 (1)	
Medicine and health science			14.3	24.3	27.8	17.6
Basic research		0.2	7.3	12.8	15.5	5.5
Applied research		0.2	6.2	9.6	10.1	10
Development activity			1.7	2.2	2.6	2.4
Universities and university colleges			6.6	8.9	5.4	12.3
Research institutes			7.8	15.3	22.3	5
International collaboration:						
Project collaboration		0.1	7.8	14.3	17.1	7.4
Incoming/outgoing mobility grants			0.1	0.1	0.1	0
Industry:						
Pharmacy, medicine, biotechnology			4.4	6.4	4.4	5.6
Knowledges-, technology- and ICT-innovation						2.3
Technologies:						
Biotechnology		0.1	11	19.4	22.3	15
Ethical, leagal and societal aspects		0.1	5	9.1	15.1	5.1
ICT		0.1	11.2	18.5	20.6	12.1
Region:						
Oslo and Akershus			8.3	18.3	23.8	12.9
Trøndelag			6	5.9	4	4.5

The Research Council
of Norway

Programme on

Human Biobanks and Health Data (BIOBANK)

Work Programme 2012-2016



The Research Council of Norway
P.O. Box 2700 St. Hanshaugen
NO-0131 OSLO
Norway
Telephone: +47 22 03 70 00
Telefax: +47 22 03 70 01
bibliotek@rcn.no
www.rcn.no/english

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Contents

1. Summary

Biological material stored in biobanks is of major value for gaining a deeper understanding of the complex relations between genes, environmental factors and disease. There is broad agreement among policymakers and the health services about the importance and benefits of using biobank material and register data for research. This is highlighted in a number of strategic documents.

The Executive Board of the Research Council of Norway has decided to launch a new research programme – Human Biobanks and Health Data (BIOBANK) – with a total of NOK 110 million in funding from the Ministry of Education and Research for the period 2011-2016.

The programme is designed **to take advantage of the potential for research on human biological material in biobanks, by coupling analysis results with data from health surveys, health registers and the health services.** Research projects funded under the programme should exploit the full potential of the large biobanks and registers, unless there are scientific reasons for a smaller study sample. The primary objective of the programme is **to generate research-based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases**.

All projects under the programme will address ethical, legal and social aspects (ELSA) as an integral part of project activities and will incorporate international cooperation.

2. Background

Biological material stored in biobanks is of major value for gaining a deeper understanding of the complex relations between genes, environmental factors and disease. Research combining Norwegian biobank material and national register data constitutes unique opportunities for a broad spectrum of research questions and applications. Many countries have ambitious plans and are investing in health research based on population studies and biobanks. The international research front is making rapid advances in this area, and it is important for Norway to act. The ethical, legal and social aspects of this research are also developing quickly, and must be an integral component of the programme.

The Executive Board of the Research Council of Norway has decided to launch a programme to take full advantage of Norway's population-based health surveys, biobanks and national health registers. The Ministry of Education and Research has allocated funding totalling NOK 110 million for the period 2011-2016. However, a significantly larger-scale effort is needed, and the Research Council's budget proposal for 2012 recommends that the Ministry of Education and Research and the Ministry of Health and Care Services allocate additional funding.

2.1 Strategic perspectives

There is broad agreement among policymakers and the health services about the importance and benefits of using biobank material and register data for research. This is highlighted in documents such as the government white paper on research, *Climate for Research*,[1] the

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[1] Report No. 30 (2008-2009) to the Storting: *Climate for Research.* http://www.regjeringen.no/nb/dep/kd/pressesenter/pressemeldinger/2009/klima-for-forskning.html?id=557382

research strategy of the Ministry of Health and Care Services,[2] *The Coordination Reform* to improve coordination of health and care services[3] and the National Health and Care Plan.[4] Gender perspectives and women's health are important elements in these policy documents. Furthermore, the Government's new National Strategy for Biotechnology[5] and the very recent evaluation of biology, medicine and health research in Norway[6] underline the importance of using biobanks and register data for research.

The new research programme is being launched as part of the follow up to the recommendation in the biobank report *Gode biobanker – bedre helse* (the Research Council of Norway, 2008)[7] to establish a long-term research programme which takes full advantage of the major national investments in biobank infrastructure. The report also recommends that Norway's biobanks operate as a single unified national biobank, with decentralised localisation of biological material. A *functional national biobank* of this type is a prerequisite for optimal use of the resources, and a national biobank consortium has been established by means of substantial infrastructure funding.

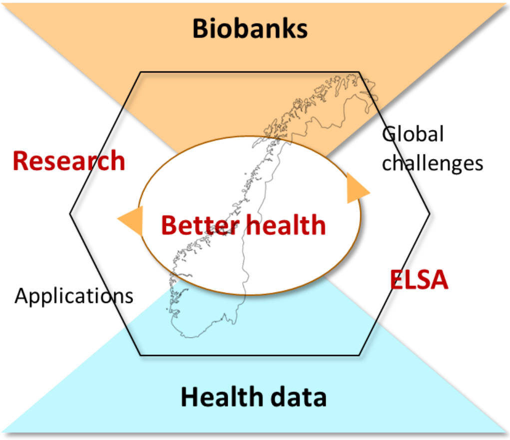

Figure 1. Research on biobanks and health data will contribute to better health (see Footnote 7).

The Norwegian biobanks, including the population-based health surveys and the hospital-based clinical biobanks, together with the health registers and other population surveys, constitute a world-class research resource. Norway's public health system, unique national identity numbers and national health registers along with a population that is positive to medical research and the opportunity to follow individuals throughout their entire lifetime provide an excellent basis for long-term epidemiological and clinical research. There is considerable international interest in biobanks as a research resource, and the new programme aims at strengthening Norwegian researchers' ability to participate in international cooperation. This further underlines the importance of addressing the ethical, legal and social aspects of this

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[2] Helse- og omsorgsdepartementets forskningsstrategi 2006-2011 ("The Ministry of Health and Care Services' Research Strategy 2006-2011") (Norwegian only). www.regjeringen.no/hod

[3] Report No. 47 (2008-2009) to the Storting: *The Coordination Reform*: *Proper Treatment – at the Right Place and Right Time*. http://www.regjeringen.no/nb/dep/hod/dok/regpubl/stmeld/2008-2009/stmeld-nr-47-2008-2009-.html?id=567201

[4] Nasjonal helse og omsorgsplan (2011-2014) ("National Health and Care Plan 2011-2014") (Norwegian only). www.regjeringen.no/hod

[5] National Strategy for Biotechnology. http://www.regjeringen.no/nb/dep/kd/dok/rapporter_planer/planer/2011/nasjonal-strategi-for-bioteknologi.html?id=666235

[6] Evaluation of Biology, Medicine and Health Research in Norway (2011). http://www.forskningsradet.no/no/Artikkel/Evaluering_av_biologisk_medisinsk_og_helsefaglig_forskning_i_2011/1253954269442 (front page in Norwegian, all documents in English)

[7] Gode biobanker – bedre helse ("Good Biobanks – Better Health") (Norwegian only). http://www.forskningsradet.no/no/Publikasjon/Gode_biobanker__bedre_helse/1219128438465?lang=no

research as an integral component of the programme and the individual projects alike, as well as the importance of taking part in the public dialogue.

2.2 Biobanks in Norway

A significant biobank infrastructure effort is underway in Norway and Europe. Nationally the focus is to build capacity at the Norwegian Institute of Public Health in Oslo, and for the *Nord-Trøndelag Health Study (HUNT)* in Levanger. The project *Biobank Norway* has received NOK 80 million in funding from the Research Council. A consortium has been established, consisting of the four medical faculties at the four largest universities (University of Oslo, Norwegian University of Science and Technology (NTNU), University of Bergen and University of Tromsø), the four regional health authorities and the Norwegian Institute of Public Health. The project has coordinated Norway's cooperation with the European biobank effort *Biobanking and Biomolecular Resources Research Infrastructure* (www.BBMRI.eu), aiming at the establishment of a *European Research Infrastructure Consortium* (BBMRI-ERIC). There is also close Nordic cooperation regarding biobank infrastructure and research, with activities funded by NordForsk.

The population-based health surveys and research biobanks in Norway are attractive for international researchers, and projects have received substantial international funding. The National Institutes of Health (NIH) in the US, the world's largest funder of basic biomedical research, is an active co-funder of the *Norwegian Mother and Child Cohort Survey (MoBa).* MoBa is a collection of data and biological material from more than 100 000 mothers, their children (110 000) and a large number of fathers (approximately 70 000). This research biobank with corresponding data is one example of Norway's unique world-class resources for biomedical research.

HUNT is one of the largest and most complete population-based health surveys, also internationally. Altogether, the three HUNT surveys contain health data from close to 120 000 persons, of which a very large number have participated in all three surveys. Biological material is available from 100 000 participants. HUNT data have been used for a number of years by international research groups, for example in the US, the Netherlands and France, in collaboration with Norwegian researchers. HUNT is coordinated with the other Norwegian health surveys in Troms, Finnmark, Hordaland, Oslo, Oppland and Hedmark, into the *Cohort of Norway* (CONOR). When the data collection is completed, CONOR will contain health data from 200 000 subjects and will be a valuable multiregional biobank.

Other population-based biobanks are the *Janus Serum Bank*, where blood samples reserved for cancer research were collected through the *National Health Screening Services* (more than 300 000 persons) and the *Norwegian Women and Cancer (NOWAC)* cohort study, which includes 170 000 women and blood samples from 50 000 of them.

2.3 Scientific, ethical and legal perspectives

The international evaluation of the Large-scale Programme on Functional Genomics in Norway (FUGE)[8] identifies Norwegian biobanks as a world-class resource, first and foremost due to the ability to link data from population-based biobanks and disease-based biobanks to data from various registers. It is a unique starting point for studying how genes and environmental factors affect health. New high throughput analysis technologies enable us to extract extensive amounts of information from the biological samples. Coupled with other

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[8] See the programme's webpages www.rcn.no/fuge; the link to the evaluation (Norwegian only) may be found to the right.

health data and information on environmental and lifestyle factors, this will create a unique basis for understanding the causes and development of diseases in more detail.

Furthermore, the research opens up new opportunities for the development of new diagnostic and prognostic tools, better regimens for prevention, new medicines as well as therapies tailored to the individual patient or patient group. In addition to the gains for the individual patient, the research should also have a positive impact on society by reducing the need for health services and promoting a healthier work force.

Although Norway has the best conditions for utilisation of population-based biobanks and health registers significant work remains to be done in order to take full advantage of this potential. There is a need for additional national disease registers (endpoint registers). There is also a need for infrastructure that facilitates the exchange of biological material as well as guidelines for operating high-quality research biobanks. Better coordination and management are necessary in order to improve researchers' access to data. The infrastructure project *Biobank Norway* aims at meeting these needs and challenges.

Through effective and optimal use of data from the population-based health surveys and biobanks, society shows respect for the participants (owners of the information) and motivates for continued high compliance and participation in the health surveys. It is a fundamental premise that the research has the trust of the population. This means that the data material is handled in an ethically and legally correct manner, and that the research questions are of relevance to society. A prerequisite for all research funded under the programme is compliance with all relevant legislation (the Health Research Act, the Biobank Act, the Biotechnology Act, etc.). Researchers are also expected to keep up to date on all ethical guidelines and possible pitfalls regarding the use of human material and data, and when formulating research questions, preparing protocols and drawing conclusions. To ensure correct processes and avoid duplication, researchers are strongly encouraged to register their projects in international databases, such as www.ClinicalTrials.gov, when relevant. Projects are based on and will generate national data and results which will be made accessible through the Research Council's open access policy, in compliance with international data sharing policies such as those of the OECD[9] and Wellcome Trust.[10]

3. Objectives of the programme

The overall objective of the programme is **to develop research-based knowledge about human health and disease through better use of human biobanks and health data as unique resources**.

3.1 Primary objective

The programme is designed **to take advantage of the potential for research on human biological material in biobanks,[11] by coupling analysis results with data from health surveys, health registers and the health services.** (See Figure 2 below.)

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[9] OECD Principles and Guidelines for Access to Research Data from Public Funding. http://www.oecd.org/dataoecd/9/61/38500813.pdf

[10] Wellcome Trust policy on data management and sharing. http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm

[11] Norwegian legislation classifies human biobanks into diagnostic, treatment and research biobanks (the Biobank Act and the Health Research Act).

The primary objective of the programme is thus to **generate, research-based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases**. (See Figure 1, in Section 2.1)

Important **premises** for the research:

- The programme is open to all hypotheses and research questions related to human health and disease, and it is not limited to particular thematic areas, topics or methods. The projects may address basic biomedical, clinical, epidemiological or social health questions.
- The research shall be based on the use of human biobanks, in combination with data from health surveys, health registers and the health services, as well as other relevant registers. The research projects should use the full potential of the large biobanks and registers, unless there are scientific reasons for a smaller study sample/population.
- The use of analysis capacity and competencies built up under national infrastructure efforts, such as the biobank infrastructure (Biobank Norway) and the FUGE-supported technology platforms, is encouraged.
- Each project shall address ethical, legal and social aspects (ELSA) relating to the use of human biological material and health data in the project, and such aspects may also be included as a sub-project or activity. (See also the ELSA programme.[12])
- Priority will be given to projects incorporating international collaboration.

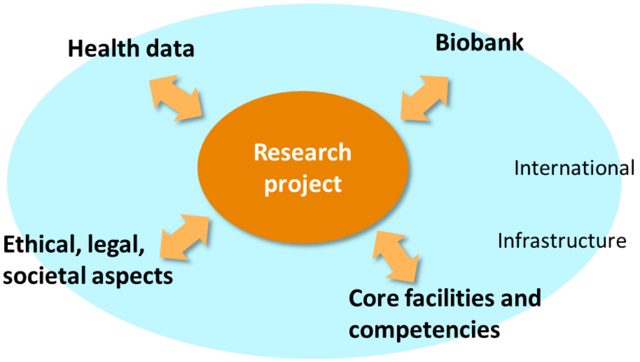

Figure 2. Research projects will respond to the objectives and premises of the programme.

3.2 International cooperation

A number of countries are investing large sums in research biobanks and health registers. International collaboration will increase the value, quality, applicability and benefit to society of the research outcomes. Norway and Norwegian researchers have unique samples and health data at their disposal, and international collaboration will expand the range of hypotheses formulated and analyses performed. In collaborations involving international funding, it is important that Norwegian researchers have sufficient national funding to ensure that they can participate as equal partners. Patient treatment as well as health policies must be built on research-based knowledge of high quality. Thus cooperation and network-building between

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[12] The Research Council's programme Ethical, Legal and Social Aspects of biotechnology, nanotechnology and neurotechnology (ELSA) www.forskningsradet.no/elsa

Norwegian and international research groups are considered key components of projects funded under the programme.

Internationalisation and research policy are major priorities in the **two most recent government white papers on research** (*Commitment to Research* and *Climate for Research*). **The Research Council of Norway's Strategy on International Cooperation** states that all research programmes must include clearly defined objectives and plans for international collaboration. Furthermore these documents recommend that Norway engages in joint programming across national borders and that greater focus be placed on international collaboration and mobility in grant application review processes. With biobanks and health registers as a major resource, Norwegian researchers are in an excellent position to participate in international cooperation under the **EU Framework Programmes and other large-scale European programmes,** and with US research groups as indicated in the **Letter of Intent between the Research Council of Norway and the National Institutes of Health.**

The programme will work to promote researcher mobility and further development of international collaborative partnerships, as well as encourage new international cooperation at the project and programme levels. Special focus will be placed on the EU countries, the US and Canada as collaborative partners.

3.3 Communication and dissemination activities

Projects funded under the programme must disseminate knowledge and research results through publication in peer-reviewed journals as well as communication activities targeting relevant users and the public at large. Seminars and open meetings will be organised to communicate with the scientific community as well as the public at large and special interest organisations.

Specific communication measures will be set out in an annual communication plan, which is a mandatory attachment to the programme's action plan.

3.4 Budget

A total of NOK 110 million has been allocated by the Ministry of Education and Research for the period 2011-2016. However, a significantly larger-scale effort is needed, and the Research Council's budget proposal for 2012 recommends that the Ministry of Education and Research and the Ministry of Health and Care Services allocate additional funding.

Two major calls for proposals are planned during the programme period, and will be published on the Research Council website.

3.5 Funding instruments

The funding instrument employed in the first call for proposals will be the *Researcher Projects* application type. Funding to increase recruitment at the post-doctoral level may be sought within the framework of a Researcher Project or in the form of a *Personal Post-doctoral Research Fellowship*. The programme board will consider including *Innovation Projects for the Public Sector* in later calls in order to address the potential and opportunities for innovation and application opened up by the research results.

4. Coordination with other instruments at the Research Council

The programme board will seek to coordinate the programme's activities with those of other relevant medical and health science research programmes at the Research Council, and with activities and programmes being established as part of the implementation of the National Strategy for Biotechnology. First and foremost this means dialogue with the new *Research Programme on Biotechnology for Value Creation (BIOTEK2021)*, which is being launched in parallel with the BIOBANK programme. The BIOTEK2021 programme will encompass research addressing commercial utilisation, and will thus be relevant for commercial applications resulting from research related to human biobanks and health register data. The BIOBANK programme will also share an interface with thematic and practice-oriented medical and health science programmes, such as *the Research Programme on Public Health (FOLKEHELSE), the Programme on Clinical Research (KLINISKFORSKNING), the Programme for Publicly-initiated Clinical Cancer Studies (KREFT)* and other targeted health-related programmes (see www.rcn.no). Furthermore, the open competitive arenas for basic research, *Independent projects (the FRIPRO scheme)*, and for innovation, *the Programme for User-driven Research-based Innovation (BIA)*, both accept grant applications for studies related to human biobanks and health data. The programme *Ethical, Legal and Social Aspects of biotechnology, nanotechnology and neurotechnology (ELSA)* is highly relevant for in-depth studies of these aspects of research using human biobank and health data.

5. Organisation

The programme board was appointed and follows a mandate established by the Research Board of the Division for Society and Health. Together with the programme administration, the programme board is responsible for ensuring that the programme achieves its stipulated objectives and is implemented as efficiently as possible within the financial framework approved by the division research board. The tasks of the programme board include drawing up calls for proposals, following up the application review process, taking final decisions regarding grant awards and following up the projects. The programme board has a special responsibility for strategic planning in relation to the programme's activities.