Annual Report 2018
Bio- and Genome Bank Denmark (RBGB)

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Preface

Bio- and Genome Bank Denmark (RBGB) is a collection of biobanks in Denmark, which aims to provide an easy, transparent and safe entrance to biological material in Denmark. The aim of RBGB is to create an infra-structure that supports diagnostic and research, based on collaboration across the country to help make personalized medicine a reality (figure 1). Today, RBGB consists of three biobanks: Danish Cancer Biobank (DCB), Danish Rheumatologic Biobank (DRB) and Danish Blood Donor Biobank (DBB) and is a national cooperation between public hospital departments which handle blood, bone marrow, tissue and other biological material. Samples are donated from patients with cancer or rheumatological disease as well as from healthy blood donors.

RBGB is headed by the Regional Directors of Health in a structure consisting of a National Steering Committee (table 1 and figure 2) and a National RBGB Secretariat, which serves all biobanks in RBGB. Each biobank in RBGB has a Scientific Advisory Board and consists of regional biobank centers with associated hospital departments (figure 2). The RBGB Secretariat is, in cooperation with the Scientific Advisory Boards, responsible for preparing national recommendations and Standard Operating Procedures (SOPs) applicable to all biobanks in the structure to ensure harmonisation. Furthermore, they are responsible for the continued optimisation of the National RBGB Register, and for ensuring that requests from clinicians, researchers and other stakeholders, can be met.

With the initiation of the Danish Region's Project on Personalized Medicine, the Board for Danish Regions has agreed on a set of criteria for biobanks to be included in the infra-structure. The latest version of this paper (Princippapir) was approved on February 2, 2018 and describes the main principles of the organization. Both present and future biobanks must be able to comply under these rules and the infrastructure must be able to accommodate both present and future biobanks. The Regional Health Directors have appointed Regional Chief Executive Leif Panduro Jensen as Head of the National Steering Committee, and Estrid Høgdall as Head of RBGB.

Currently, all biobank centers are headed by a center project manager. Center project managers are responsible for correct handling and registration of biological materials from all departments connected to their center and must ensure high quality standards. All biological materials are stored locally in hospital departments or in the biobank centres. Data on all samples are registered in the RBGB Register, which is a nationwide registration system used by all RBGB centers and hospital departments. For DCB, DRB and DBB, biobank centres have been established at Rigshospitalet - Glostrup (DRB), Danish Hospital for Rheumatic Diseases (DRB), Herlev Hospital (DCB), North Denmark Regional Hospital - Hjørring (DRB), Zealand University Hospital - Næstved (DCB and DRB), Odense University Hospital (DCB and DRB), Rigshospitalet (DCB and DBB), Aalborg University Hospital (DCB) and Aarhus University Hospital (DCB, DRB and DBB).

For DBB, blood samples are collected through blood banks across the country. DNA is extracted and stored at Rigshospitalet, whereas data registration is done by Aarhus University Hospital.

The National RBGB Secretariat is situated at the Department of Pathology, Herlev and Gentofte Hospital, Herlev. The Secretariat is engaged in general administrative tasks, knowledge-sharing, coordination among biobanks, centres and local departments, preparation of SOPs, guiding in registration and development of the RBGB Register, and responsible for updating and maintaining the RBGB homepage (http://www.regioner.dk/rbgb). The RBGB Register has been used since January 1, 2010 (DCB). On May 1, 2015, DRB started material collection and online registration, and from January 1, 2017, DBB initiated their collection, DNA extraction and registration in the RBGB Register.

This annual report describes the activity in DCB, DRB and DBB in 2018 based on 8 general indicators. The annual report is introduced by a general paragraph about RBGB followed by three separate chapters concerning each biobank, DCB, DRB and DBB. Data is collected from the National RBGB Register, Patobank, from the Danish nationwide quality register DANBIO and from the Danish Blood Donor Study. The report is prepared by the RBGB Secretariat and based on data extraction from January 28, 2019.

On behalf of The Bio- and Genome Bank Denmark
Regional Chief Executive Leif Panduro, Head of the National Steering Committee
Professor, dr.med., Ph.D. Estrid Høgdall, Head of RBGB

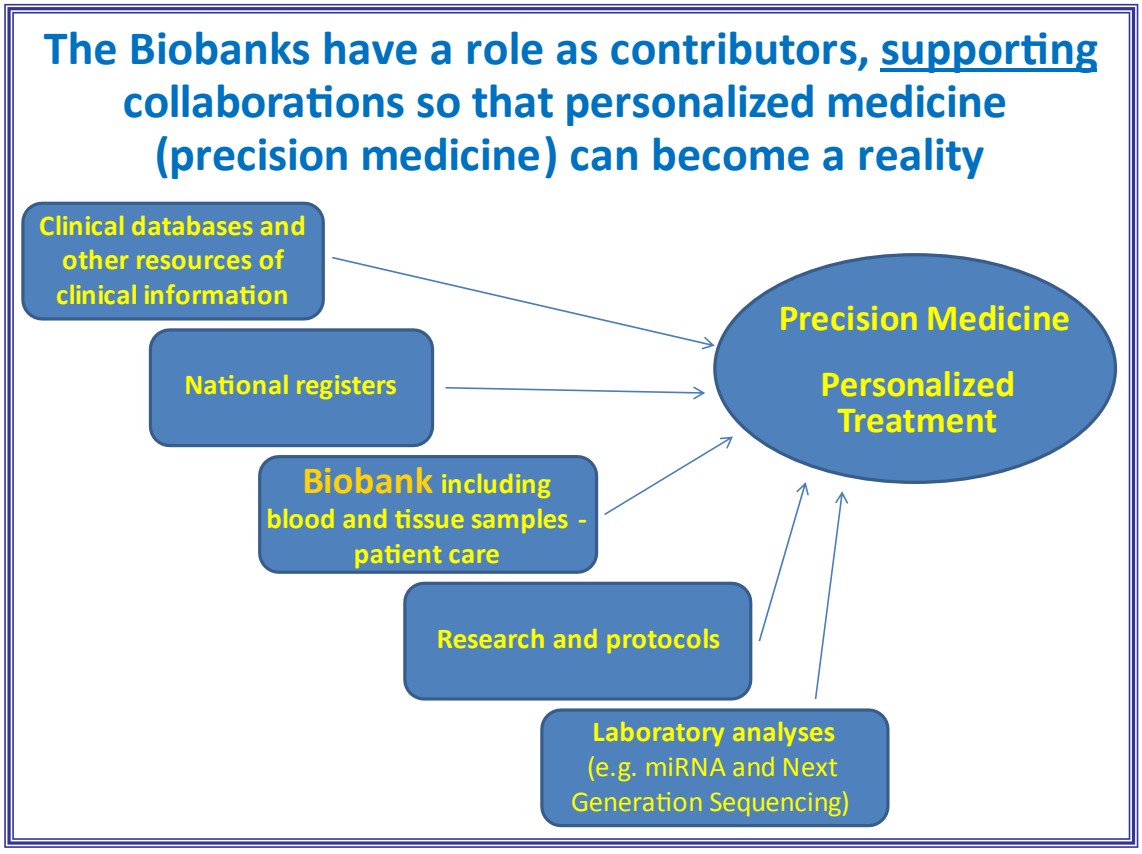

Figure 1. The biobanks contribution to personalized medicine. The figure illustrates the most important factors that contribute to making personalized medicine become a reality in the health sector. The clinical databases, the national registries, biobanks (e.g. RBGB), research in biomarkers and laboratory analyses (e.g. Next Generation Sequencing) play very essential roles.

Name	Position	Organization	Work place
Chairman			
Leif Panduro Jensen	Regional Chief Executive	Region Zealand	Region Zealand
Members			
Torben Steiniche	Lead Consultant	The Central Denmark Region	Aarhus University Hospital
Henrik Krarup	Lead Consultant	The North Denmark Region	Aalborg University Hospital
Peter Mikael Bytzer	Consultant	Region Zealand	Slagelse Hospital
Ivan Brandslund	Head of Laboratory	The Region of Southern Denmark	Vejle Sygehus
Torben Falk Ørntoft	Professor	The Universities	Aarhus University Hospital
Per Jørgensen	Deputy Chief Executive	The Capital Region of Denmark	Rigshospitalet
Henrik Ullum	Chairman	Organization of Danish Medical Societies	Rigshospitalet
Helle Bossen Konradsen	Executive Vice President	Statens Serum Institut	Statens Serum Institut
Estrid Høgdall	Head of RBGB	RBGB	Herlev Hospital

Table 1. Members of the National Steering Committee for RBGB, 2018

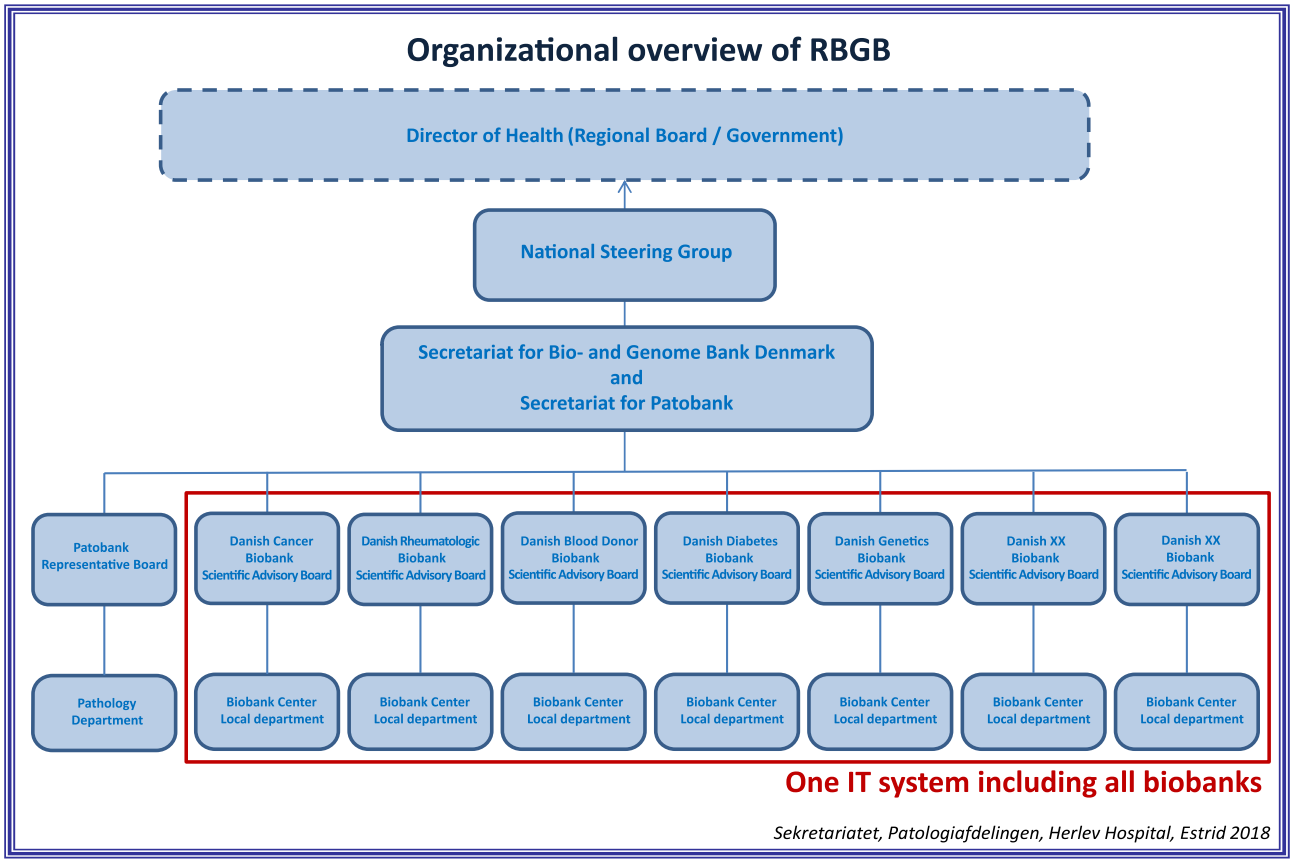

Figure 2. Organization of RBGB. The figure show how RBGB is organized with a Steering Committee, a national secretariat and Technical Advisory Boards for present and future biobanks.

0. Overview of Bio- and Genome Bank Denmark

In 2018, Bio- and Genome Bank Denmark (RBGB) consisted of three biobanks: Danish Cancer Biobank (DCB), Danish Rheumatologic Biobank (DRB) and Danish Blood Donor Biobank (DBB). DCB has collected blood and tissue since 2010 and in 2013, the biobank was extended with the collection of hematological samples (bone marrow and hematological blood). In DRB, the collection started in May 2015 at Rigshospitalet - Glostrup, and subsequently many departments have followed so that DRB now covers the entire country. DBB collects blood samples from healthy donors throughout Denmark and their collection was included in RBGB from January 1, 2017.

Figure 0.1.1 shows the development in the number of unique individuals (CPR numbers) in RBGB from 2010-2018, while figure 0.1.2 shows the number of biological materials collected in RBGB. As seen from the figures, there is a large increase in the number of blood samples from 2014 to 2016. This reflects the establishment of DRB in 2015 and its collection of blood samples. In 2017, another large increase in the number of blood samples in RBGB is seen, due to the establishment of DBB. Tissue and bone marrow materials are only collected in DCB.

The increase from 2010 to 2018 reflects more than a threefold increase in the number of samples collected annually. The total number of materials exceeds the number of unique CPR numbers, reflecting that some patients donate material multiple times. This shows that there is a focus on collecting samples over the course of a patient's disease and/or treatment.

Figure 0.1.1 shows that patients are also registered without material (only registered CPR). These may, for example, be cases where there has not been sufficient material for the biobank (e.g. small tumors). CPR numbers without material are recorded as part of quality assurance and to show that the laboratory was ready to receive and handle the material, but for various reasons there was no material to register. In 2018, 3,492 patients were registered without material.

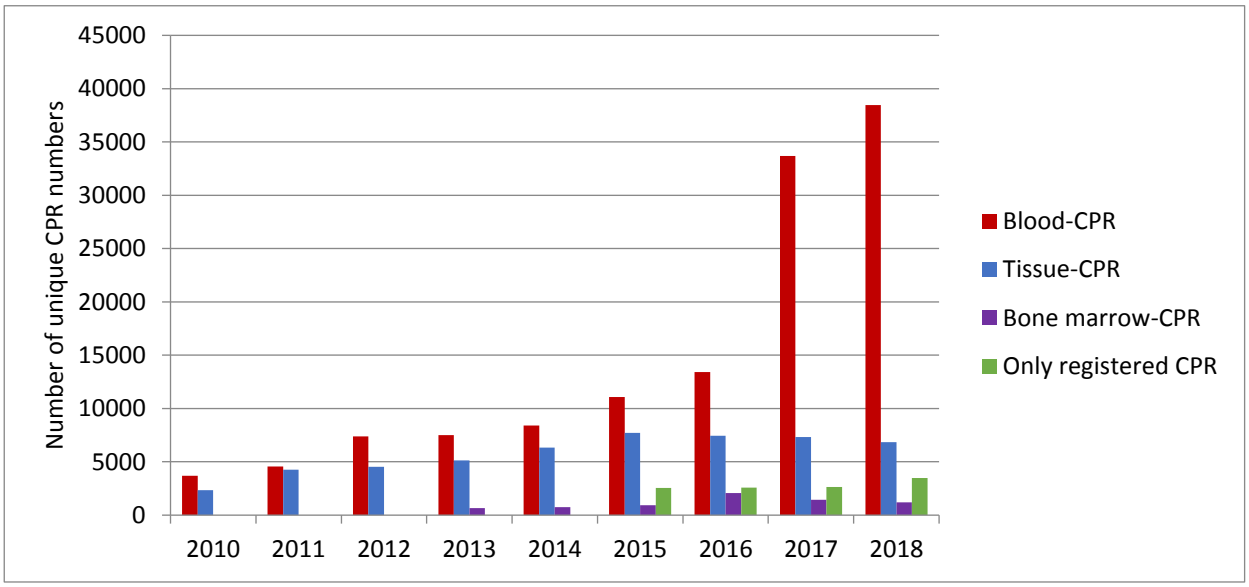

Figure 0.1.1. **Number of unique CPR-numbers in RBGB, 2010-2018.** The figure shows the number of unique CPR-numbers (patients and donors), who have donated material to RBGB in each year from 2010-2018. The number of unique CPR-numbers is calculated per material type – blood (red), tissue (blue) and bone marrow (violet). Only registered CPR (green) refers to patients that have been registered without any biological material. The figure shows the number of unique individuals (CPR-numbers) collected each year and not accumulated through the period.

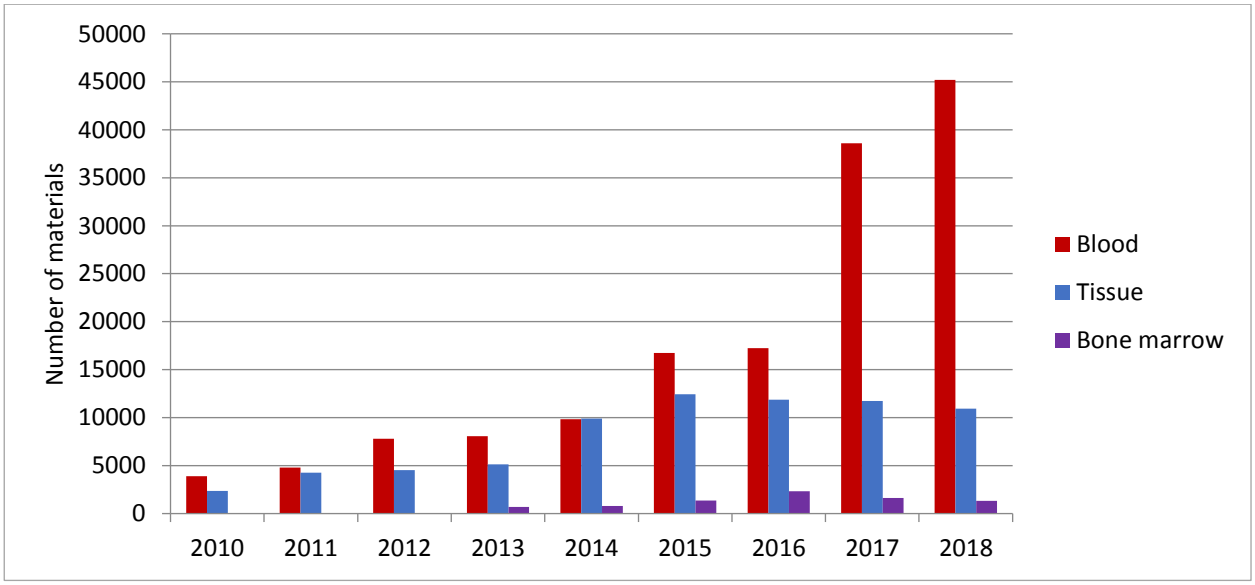

Figure 0.1.2. Number of materials in RBGB, 2010-2018. The figure shows the number of blood (red), tissue (blue) and bone marrow (violet) materials collected in RBGB each year from 2010-2018. The figure shows the number of materials collected each year and not accumulated through the period.

1. Danish Cancer Biobank

1.1. Foreword

Danish Cancer Biobank (DCB) is a national collaboration between hospital departments which handle blood and tissue samples, as well as other materials from cancer patients. All who work for the DCB are hospital staff, e.g. educated doctors, molecular biologists, nurses, lab technicians, biologists and secretaries. The collaboration covers the whole country with central functions at Herlev Hospital, Zealand University Hospital - Næstved, Odense University Hospital, Rigshospitalet, Aalborg University Hospital and Aarhus University Hospital. The purpose is to strengthen the infrastructure for clinical research to help achieve the goal of personalized medicine.

There is appointed a Scientific Advisory Board for DCB to follow the development of DCB and ensure the daily workflow. The work of the Scientific Advisory Board is to:

1. Develop and maintain recommendations for national procedures for the collection, handling, freezing and storage of blood and tissue materials from patients with newly diagnosed cancer and from patients undergoing treatment.
2. Prepare and maintain laboratory guides / procedures adapted to central / local conditions
3. Ensure the quality of national procedures for handling of blood and tissue materials for storage
4. Develop and maintain requirement specifications and ensure continued development of national RBGB registration system for online data entry
5. Ensure the quality of data and coverage in the national registration system
6. Develop and maintain templates for contracts with DMCGs and other researchers
7. Prepare and maintain guidelines for hand out of material for decision in the National Steering Committee
8. Develop and maintain patient information and consent

On behalf of the Scientific Advisory Board for Danish Cancer Biobank
The members of the Scientific Advisory Board can be seen in appendix 6.1.1

1.2. Overview of DCB, 2016-2018

In 2018, blood was collected from 9,694 unique patients (CPR numbers), tissue from 6,849 unique patients and bone marrow from 1,206 unique patients (figure 1.2.1). For all three material types the collection is approximately the same as in 2017.

Figure 1.2.1 shows that patients without materials are being registered (only CPR registered). These patients are for example patients where there is not enough material for the biobank, e.g. with small tumors. The number of patients that do not have material registered is increasing, which is consistent with the fact, that some tumors are discovered earlier and therefor are smaller at time of surgery.

CPR numbers without material are recorded as part of quality assurance and to show, that the laboratories where ready to receive and handle the material, but for different reasons material was not registered. In 2018, 3,492 CPR numbers were registered without material.

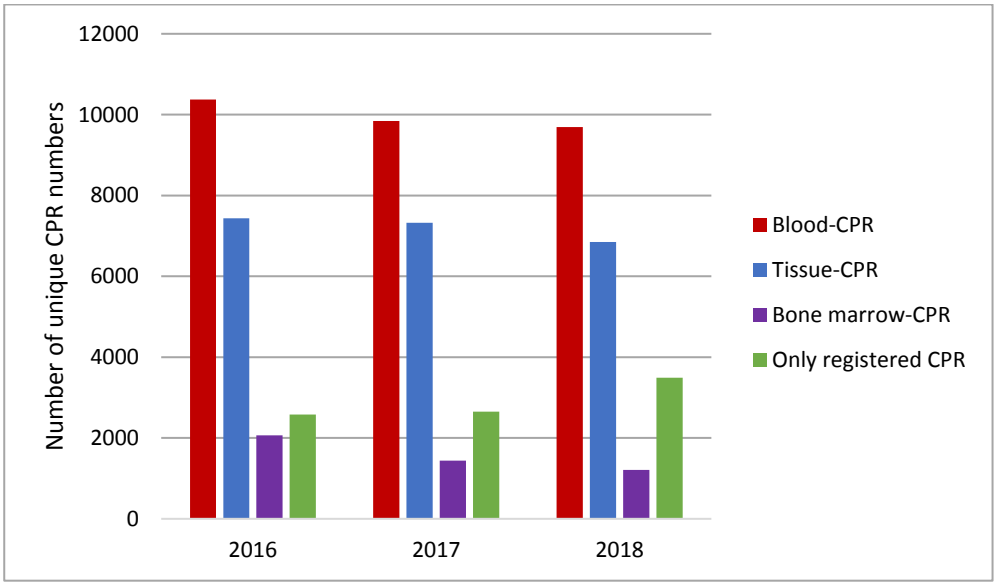

Figure 1.2.1. **Number of unique CPR numbers in DCB, 2016-2018.** The figure shows the number of unique CPR numbers (patients), who have donated material in each year from 2016-2018. The number of unique CPR numbers is calculated per material type – blood (red), tissue (blue) and bone marrow (violet). Only registered CPR (green) refers to patients, that have been registered without material.

Figure 1.2.2 shows the collection of material from patients per month in 2018. The figure shows that there are differences in the collection throughout the year. The sum of unique CPR numbers for every month is higher than the sum for a whole year. This shows that some patients have donated material several times during the year.

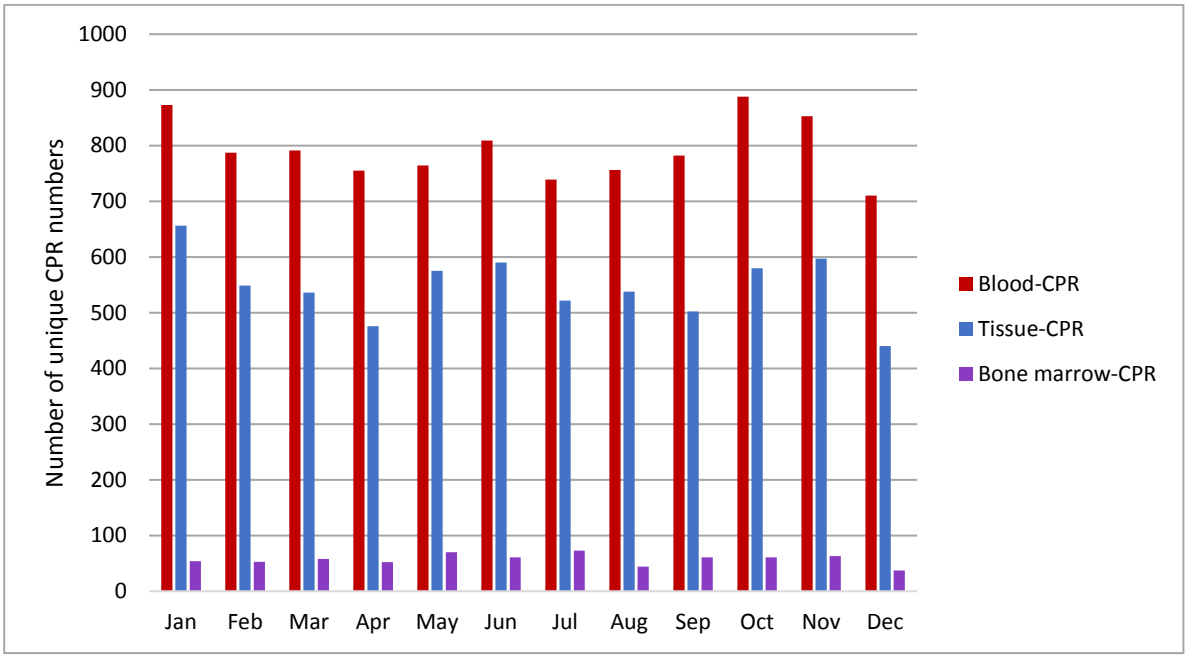

Figure 1.2.2. Collection of material from unique patients throughout the year, 2018. The figure shows the number of unique CPR numbers per material type that have donated material to DCB each month during 2018.

Figure 1.2.3 shows the number of patients that have donated material in the different centers. From the figure it can been seen that the total number of patients that have donated tissue in 2018 is roughly the same as in 2017. There is a small decrease in patients at Rigshospitalet and Aalborg, and a small increase in patients at Aarhus. The figure also shows that the total number of patients that have donated blood in 2018 is also very similar to 2017. The same is seen for the collection of bone marrow. In 2016 center Herlev collected bone marrow from a much higher number of patients, but inclusion criteria were adjusted in 2017, which resulted in a large decrease in collection of bone marrow at Herlev from 2016 to 2018. In Region Zealand there is no collection of bone marrow for DCB (figure 1.2.3).

The collection of materials from unique patients in each department in a center is shown in table 1.2.1. The sum of unique patients from all departments is in some centers higher than the sum for the center in itself. This is because some patients donate material to different departments in a center.

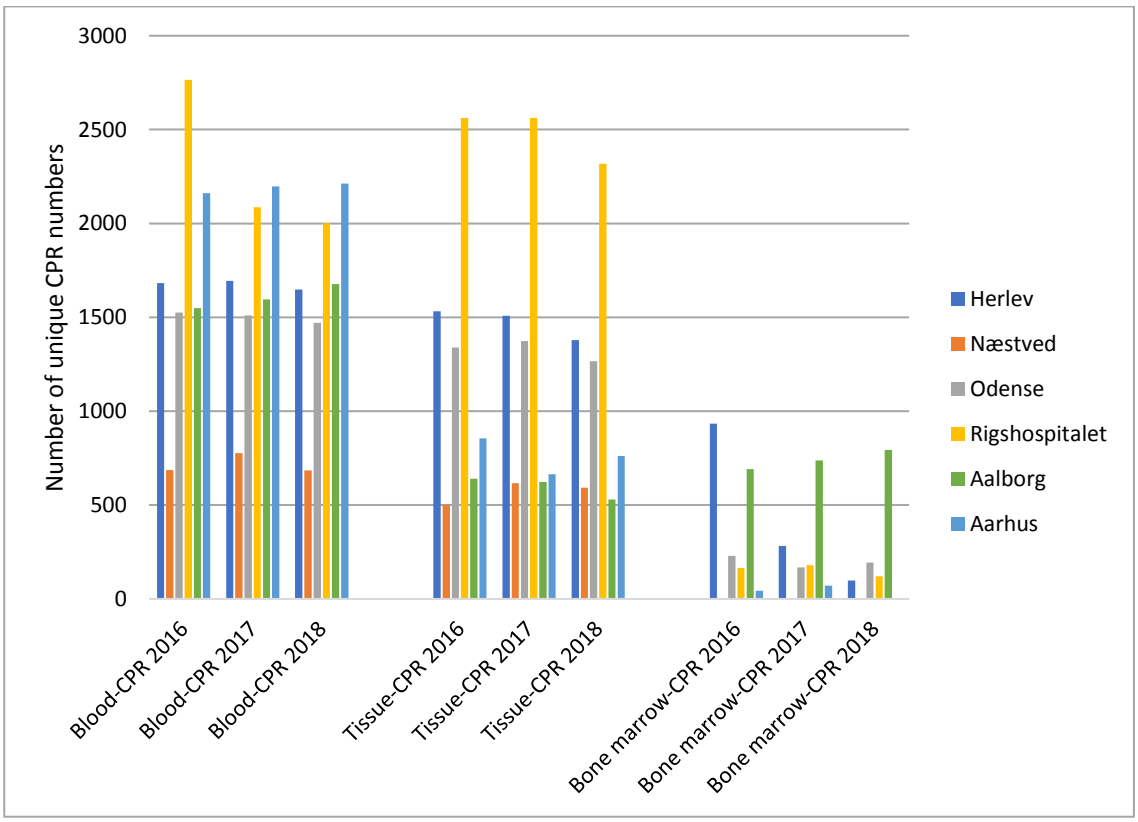

Figure 1.2.3. Number of unique CPR numbers per center, 2016-2018. The figure shows the number of unique CPR numbers (patients) that have donated tissue, blood or bone marrow in the six biobank centers in DCB for each year from 2016-2018.

	Number of Blood-CPR	Number of Tissue-CPR	Number of Bone marrow-CPR
Herlev Cancer Biobank Center			
Clinical Biochemistry Department, Herlev hospital	1,580		
Pathology Department, Herlev hospital	70	1,379	8
Medical Hematology Department, Herlev hospital			90
Næstved Cancer Biobank Center			
Clinical Biochemistry Department, Ringsted	458		
Clinical Biochemistry Department, Roskilde	47		
Clinical Biochemistry Department, Slagelse	181	2	
Pathology Department, Roskilde		239	
Pathology Department, Slagelse		354	
Odense Cancer Biobank Center			
Clinical Biochemistry and Pharmacology Department	1,177		
Clinical Diagnostic Department, Esbjerg	216		
Clinical Pathology Department, Odense University hospital		1,080	2
Pathology Department, Esbjerg		96	
Clinical Pathology Department, Vejle hospital		92	
Hematology Department, Odense University hospital	79		191
Hematology Outpatient Clinic, Odense University hospital	1		1
Rigshospitalet Cancer Biobank Center			
Clinical Immunology Department, Blood Bank, Rigshospitalet	1,939		
Pathology Department, Rigshospitalet	191	2,311	116
Pathology Department, Amager and Hvidovre hospital		33	
Clinical Hematology, Rigshospitalet	7		4
Aalborg Cancer Biobank Center			
Molecular Diagnostics, Clinical Biochemistry, Aalborg University hospital	1		
Clinical Biochemistry, Aalborg University hospital	876		
Institute of Pathology, Aalborg University hospital*	3	532	14
Hematology Outpatient Clinic, Aalborg University hospital	802		780
Aarhus Cancer Biobank Center			
Clinical Biochemistry Department NBG, Aarhus University hospital	223		
Clinical Biochemistry Department PJJ, Aarhus University hospital	645		
Clinical Biochemistry Department THG, Aarhus University hospital	389		
Molecular Medicine Department, Aarhus University hospital	994		
Clinical Biochemistry Department, Randers Regional hospital	81		
Central Outpatient Clinic, Randers Regional hospital	1		
Institute of Pathology Holstebro, West Hospital Unit			
Institute of Pathology, Randers Regional hospital		64	
Institute of Pathology Viborg, Central Hospital Unit		38	
Institute of Pathology, Aarhus University hospital		660	
Hematology Department R, Aarhus University hospital	1		1

*The institute of pathology has due to challenges with the RGBG register registered tissue material from 52 patients after data for the annual report was retrieved.

Table 1.2.1. Number of unique CPR numbers per sample collecting department, 2018. The table shows the number of unique CPR numbers (patients) that have donated blood, tissue and bone marrow material to DCB for all collecting departments in 2018.

In 2018, 13,040 blood materials, 10,950 tissue materials and 1,337 bone marrow materials have been collected (figure 1.2.4). Compared with 2017, the collection of blood and tissue is very similar with only a small decrease (3% for blood and 7% for tissue). The collection of bone marrow has decreased by 17% compared to 2017, which is primarily due to a drop in the collection at Herlev, Rigshospitalet and Aarhus, whereas Aalborg has increased the collection of bone marrow (figure 1.2.5).

The number of materials exceeds the number of unique CPR numbers, which shows that the same patients donate material several times during the year. This shows that there is a focus on collecting samples over the course of a patient's disease and/or treatment.

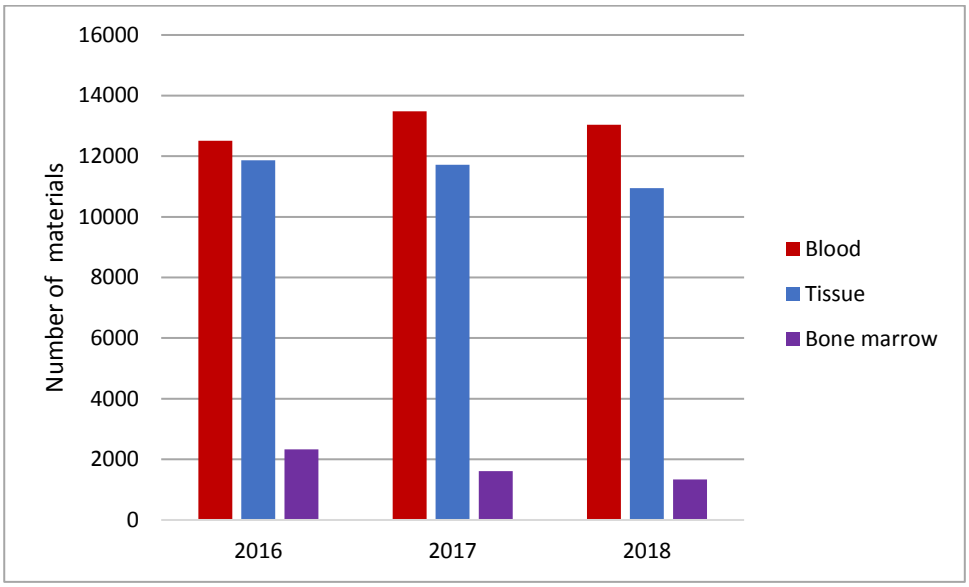

Figure 1.2.4. Number of materials in DCB, 2016-2018. The figure shows the number of blood (red), tissue (blue) and bone marrow (violet) materials collected in DCB each year from 2016-2018.

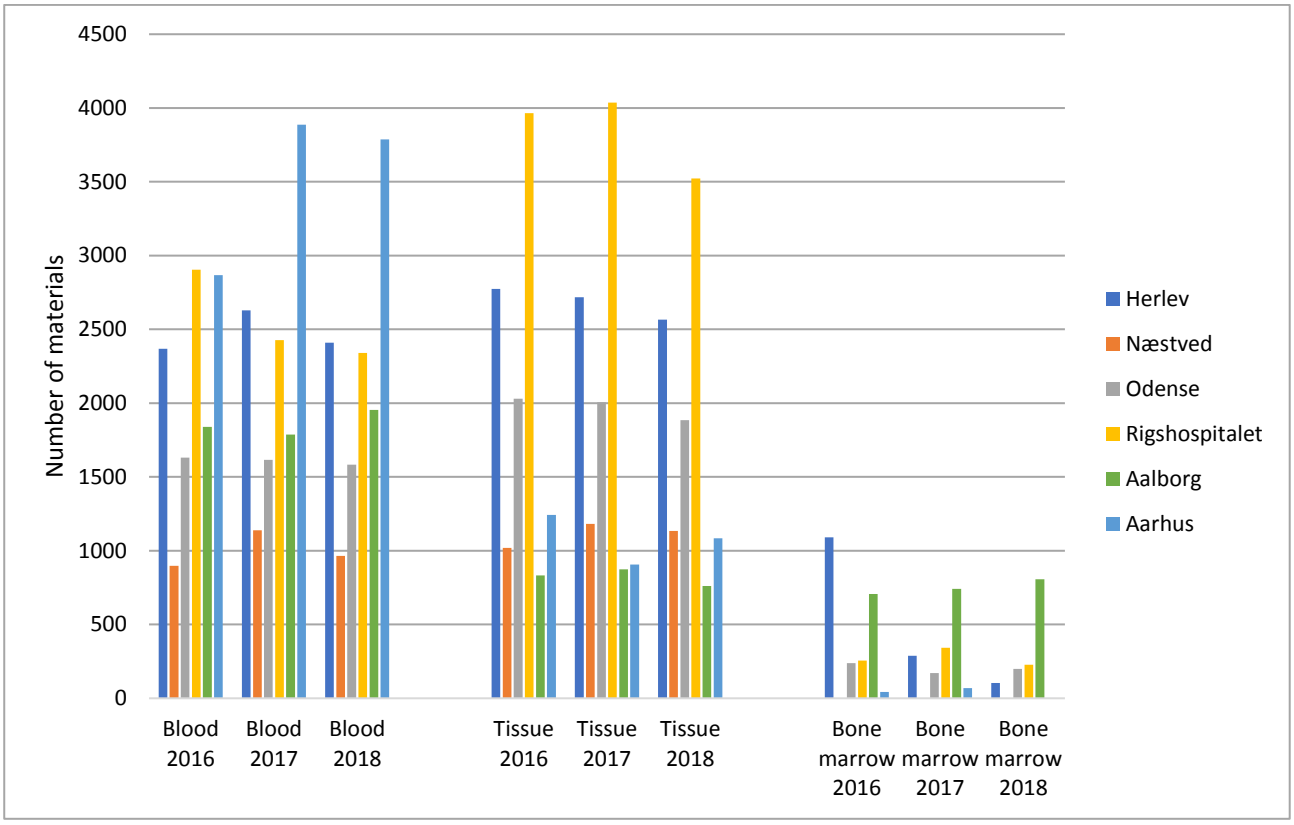

Figure 1.2.5. Number of materials per center, 2016-2018. The figure shows the number of blood, tissue and bone marrow materials that have been collected in each center for each year from 2016-2018.

Materials for DCB are collected from most organs (table 1.2.2). In general, there is a decrease in the number of materials from the different organs which corresponds to the small decrease in collected materials in 2018 (figure 1.2.4).

There is also a decline in the number of materials that are registered with suspected primary organ 'other'. Primary organ 'other' is often given to material from benign tumors or from cancer types that are difficult to place in a specific organ group. The fact that there is a decrease in number of materials that are registered as 'other', shows that more material is grouped under the correct primary organ denomination, which increases the value of the material.

Suspected primary organ	Number of blood materials 2016	Number of blood materials 2017	Number of blood materials 2018	Number of tissue materials 2016	Number of tissue materials 2017	Number of tissue materials 2018	Number of bone marrow materials 2016	Number of bone marrow materials 2017	Number of bone marrow materials 2018
Other	132	238	174	49	145	109	<10		
Anal region	43	83	96	17		<10			
Appendix		<10	<10	<10	<10				
Adrenal gland	<10	<10	<10	101	112	118		<10	<10
Blood	1,053	890	1,100	<10			58	328	404
Blood vessel		<10			<10			<10	
Bronchi and lung	761	337	364	472	350	356			
Cervix Uteri	185	181	160	48	32	49			
Colon	1,805	2,300	2,406	1,962	1,694	1,581			
Corpus uteri	395	303	306	278	239	278			
Esophagus	171	91	97	79	43	19			
Bile ducts	41	18	21		<10	<10			
Heart				<10	<10				
Skin and subcutis	43	73	10	46	15	16	<10		
Bone marrow	1,074	679	396	<10	<10	<10	2,274	1,147	749
Bones and joints	96	55	47	43	48	58			<10
Larynx	<10	11	31	12	<10	<10			
Liver	82	46	73	416	339	337			
Lymph node and thymus	113	114	183	493	393	460		134	179
Mamma	3,112	3,795	3,577	3,427	3,619	3,071			
Spleen	<10		<10	21	11	<10			
Mouth, lips and tongue	324	328	323	117	58	76			
Heart	<10			251	243	218			
Nervous system	79	80	79	953	917	1,045			
Kidney	150	117	89	512	509	472			
Nose and sinus	<10	<10	<10	13	<10	<10			
Okkult cancer			65			<10			
Ovarium	909	702	562	357	316	292			
Pancreas	128	101	123	143	217	175			
Penis	<10				12	<10			
Pharynx		<10	19	<10	<10	<10			
Pleura		33	44	144	216	231			
Prostate	509	537	530	601	603	589			
Rectum	281	577	671	406	435	339			
Salivary gland	<10	10	18	44	46	33			
Testis	39	53	90	180	169	181			
Thyreoidea og parathyreoidea	<10	11	45	297	247	263			
Tonsil		11	21	34	19	20			
Tuba uterina and parametrium	<10	<10	<10	10	15	16			
Small intestine	27	36	19	29	48	35			
Urinary tract and bladder	701	1,383	1,102	181	344	267			
Vagina	<10	<10	10	<10	<10	<10			
Ventricle and omentum	64	34	47	91	180	172			
Vulva	90	95	65	11	51	30			
Eye	73	135	55	<10	<10	<10			
Ear			<10			<10			

Table 1.2.2. Number of materials per suspected primary organ, 2016-2018. The table shows the number of blood, tissue and bone marrow material in DCB in 2016-2018 per suspected primary organ. For primary organs with less than 10 materials, <10 is shown to ensure the anonymity of the patients.

As seen from table 1.2.3 material is collected from most Danish Multidisciplinary Cancer Groups (DMCGs). No correspondent DMCG means that the material has not yet been verified with a diagnosis and therefore cannot be placed in a DMCG. Benign disorder refers to the material from patients that have not been diagnosed with a malignant disease (i.e. the material has been removed from the patient on the suspicion of malignant disease, but subsequently showed to be benign).

DMCG	Number of tissue material 2016	Number of tissue material 2017	Number of tissue material 2018	Number of bone marrow material 2016	Number of bone marrow material 2017	Number of bone marrow material 2018
Other	31	42	44			
Benign disorder	61	32	55			
DABLACA	173	348	10			
DACG	27	10	268			
DBCG	3,385	3,484	3,019			
DCCG	2,417	2,163	1,970			
DECV	177	263	185			
DGCG	712	692	751			
DAHANCA	493	388	357			
DLGCG	136	123	115			
DLCG	578	443	384			
DMG	57	18	<10			
DNOG	987	948	996			
DARENCA	564	590	505			
DOCG	12	<10	<10			
DPCG	124	198	174			
DAPECA	<10	12	<10			
DAPROCA	703	607	588			
DAPHO	58	61	37			
DSG	252	281	262			
DATECA	172	169	166			
Hematological common DMCG	361	370	420	2,094	1,272	1,109
No DMCG	384	476	625	240	341	228
I alt	11,866	11,723	10,950	2,334	1,613	1,337

Table 1.2.3. Number of tissue and bone marrow materials per DMCG, 2016-2018. The table shows the number of tissue and bone marrow materials per DMCG from 2016-2018. For DMCGs with less than 10 materials, <10 is shown to ensure the anonymity of the patients.

1.3 Indicators, DCB

1.3.1 Indicator 1: Handling of Material

It is crucial that all fractions in the biobank have a freezer position, as this makes it possible to retrieve the material. This indicator is measured as the percentage of all fractions that have a freezer position. Fractions that have been handed out are not included in the calculation, as these naturally do not have a freezer position.

In 2018, 99,063 blood fractions and 12,684 hematological blood fractions were registered. Very few fractions have not been registered with a freezer position, and all centers are fulfilling the goal of this indicator, which recommends that 95% of all fractions should be registered with a freezer position (table 1.3.1.1.).

		Number of blood fractions	Number of fractions without freezer position	Percentage of fractions with freezer position	Number of hematological blood fractions	Number of fractions without freezer position	Percentage of fractions with freezer position
	2018						
National	**TOTAL**	**99,063**	**16**	**100**	**12,684**	**20**	**100**
Center	Herlev	18,373	0	100	983	0	100
	Næstved	7,771	16	100	-	-	-
	Odense	12,621	0	100	580	0	100
	Rigshospitalet	16,268	0	100	1,524	20	99
	Aalborg	9,951	0	100	9,586	0	100
	Aarhus	34,079	0	100	11	0	100
	2017						
National	**TOTAL**	**101,569**	**10**	**100**	**11,857**	**269**	**98**
Center	Herlev	18,891	0	100	1,976	0	100
	Næstved	8,998	10	100	-	-	
	Odense	12,954	0	100	536	0	100
	Rigshospitalet	16,755	0	100	1,433	269	81
	Aalborg	10,415	0	100	7,236	0	100
	Aarhus	33,556	0	100	676	0	100
	2016						
National	**TOTAL**	**93,670**	**46**	**100**	**12,872**	**30**	**100**
Center	Herlev	14,541	0	100	4,400	0	100
	Næstved	7,447	8	100	-	-	-
	Odense	12,585	24	100	598	0	100
	Rigshospitalet	21,192	0	100	1,437	30	98
	Aalborg	10,632	8	100	5,996	0	100
	Aarhus	27,273	6	100	441	0	100

Table 1.3.1.1. Number of blood and hematological blood fractions with and without freezer position, 2016-2018. The table shows the number of blood and hematological blood fractions without freezer position and the percentage of blood fractions with freezer position, shown for each center from 2016-2018.

In 2018, 57,108 tissue fractions were registered, indicating a reduction of nearly 6,500 fractions compared to 2017. The decrease can be due to the fact that some cancers are discovered earlier on screening tests. This results in smaller tumors, with insufficient material for the biobank. This trend in the collection of tissue material is seen in all centers except for Aarhus, which has nearly doubled their collection (table 1.3.1.2).

The number of tissue fractions without freezer position is also shown in table 1.3.1.2. Formalin fixed and paraffin embedded tissue blocks have been excluded from the calculation as they are optimally stored at room temperature. Very few tissue fractions are registered without a freezer position and all centers are fulfilling the goal of this indicator, which also recommends that 95% of all tissue fractions should be registered with a freezer position.

As in 2017, center Rigshospitalet is the only center with bone marrow fractions registered without a freezer position. However, Rigshospitalet has greatly decreased the number of bone marrow fractions without a freezer position compared to 2017. Rigshospitalet is encouraged to continue these improvements. The other centers are all fulfilling the goal of this indicator.

		Number of tissue fractions	Number of paraffin blocks	Number of tissue fractions without freezer position	Percentage of tissue fractions with freezer position	Number of bone marrow fractions	Number of bone marrow fractions without freezer position	Percentage of bone marrow fractions with freezer position
	2018							
National	**TOTAL**	**57,108**	**8,195**	**240**	**100**	**8,340**	**89**	**99**
Center	Herlev	14,215	1,269	0	100	544	0	100
	Næstved	9,681	1,107	0	100	-	-	-
	Odense	12,918	1,764	20	100	1,155	0	100
	Rigshospitalet	9,226	2,796	3	100	875	89	90
	Aalborg	4,923	569	0	100	5,758	0	100
	Aarhus	6,145	690	217	96	8	0	100
	2017							
National	**TOTAL**	**63,535**	**10,316**	**36**	**100**	**8,975**	**449**	**95**
Center	Herlev	16,232	2,678	0	100	1,109	0	100
	Næstved	10,253	1,149	0	100	-	-	-
	Odense	15,008	1,934	4	100	701	0	100
	Rigshospitalet	12,183	3,430	1	100	1,143	449	61
	Aalborg	5,932	714	0	100	5,480	0	100
	Aarhus	3,927	411	31	99	542	0	100
	2016							
National	**TOTAL**	**67,130**	**10,631**	**158**	**100**	**11,435**	**5**	100
Center	Herlev	17,012	2,767	6	100	3,941	0	100
	Næstved	8,995	999	0	100	-	-	-
	Odense	15,593	2,006	12	100	1,221	4	100
	Rigshospitalet	12,998	3,482	6	100	887	1	100
	Aalborg	6,318	764	7	100	5,052	0	100
	Aarhus	6,214	613	127	98	334	0	100

Table 1.3.1.2. Number of tissue and bone marrow fractions with and without freezer position, 2016-2018. The table shows the number of tissue and bone marrow fractions without freezer position and the percentage of blood fractions with freezer position, shown for each center from 2016-2018.

RECOMMENDATION: The goal of this indicator is fulfilled for blood, hematological blood and tissue for all six biobank centers. For bone marrow, only center Rigshospitalet is not fulfilling the goal but has greatly improved compared to 2017.
The good results for nearly all centers should be maintained in 2019 because a known freezer position is a prerequisite for retrieving samples.

1.3.2 Indicator 2: Sample Quality

The quality of the material collected in DCB is measured by the processing time, which is defined as the time between material retrieval from the patient until the material is placed in a freezer. To ensure the quality of the material the processing time should be as short as possible. For blood it is recommended that the processing time should be under 3 hours, and for tissue, under 1 hour.

To clarify if a long processing time is due to a long transport time, the latter is also calculated. The transport time is defined as the time between material retrieval from the patient until the material is received at the laboratory.

To ensure that the material is of the highest quality the goal of this indicator is that 90% of the material should be processed within the recommended 3 hours for blood and 1 hour for tissue. The processing time for hematological blood and bone marrow is calculated separately as these materials are handled differently.

The processing time for blood samples is calculated for all fractions excluding PAXgene, as they are handled differently. The time is calculated for each center and is shown as the percentage of the fractions that have been processed within 3 hours (table 1.3.2.1).

As in 2017, all centers, except for center Herlev and Aarhus, fulfilled the goal of this indicator, with over 90% of the fractions being processed within 3 hours. Over the last couple of years center Herlev has greatly improved the processing time of blood fractions (only 13% were processed within 3 hours in 2016), and with their good work it is expected that they will be able to meet the goal of this indicator in 2019.
In center Aarhus, most fractions for immediate hand out to projects are for technical reasons registered with the status 'Freezing' instead of 'In freezer' when they are first placed in a freezer. Since the status 'Freezing' is not considered an in freezer-stamp in the database, these fractions had to be omitted when calculating the processing time for center Aarhus. For the fractions where the processing time could be calculated the number of fractions processed within three hours has decreased compared to 2017. The long processing times are in general caused by long transport times (85% of the samples are received within 3 hours, table 1.3.2.2), due to the infrastructure in center Aarhus, where samples are donated at one location and then transported for processing at another location. However, almost all blood fractions were processed within 7 hours (appendix 6.1.2), which shows that the laboratories are working on keeping the processing time as short as possible. Center Aarhus is still encouraged to have an increased focus on reducing the processing time.

		Number of blood fractions	Percentage of blood fractions (n) processed within 3 hours
	2018		
National	**TOTAL**	**98,747**	**75 (73,749)**
Center	Herlev	18,373	83 (15,160)
	Næstved	7,455	96 (7,177)
	Odense	12,621	98 (12,428)
	Rigshospitalet	16,268	92 (15,036)
	Aalborg	9,951	97 (9620)
	Aarhus*	20,049	65 (13,128)
	2017		
National	**TOTAL**	**101,234**	**86 (86,799)**
Center	Herlev	18,891	74 (13,914)
	Næstved	8,663	99 (8,571)
	Odense	12,954	99 (12,817)
	Rigshospitalet	16,755	92 (15,449)
	Aalborg	10,415	96 (10,027)
	Aarhus	33,556	78 (26,021)

*Only fractions which have status 'In freezer' together with the time for first placement in a freezer are included. For technical reasons fractions with status 'Freezing' (Nedfrysning) are omitted.

Table 1.3.2.1. Processing time for blood, 2017-2018. The table shows the percentage and number (n) of blood fractions that have been processed within the recommended 3 hours, shown for each center from 2017-2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

		Number of blood fractions	Percentage fractions (n) transported within 3 hours
	2018		
National	**TOTAL**	**98,747**	**93 (92,048)**
Center	Herlev	18,373	91 (16,770)
	Næstved	7,455	99 (7,403)
	Odense	12,621	99 (12,541)
	Rigshospitalet	16,268	99 (16,040)
	Aalborg	9,951	100 (9,929)
	Aarhus	34,079	85 (29,049)

Table 1.3.2.2. Transport time for blood, 2018. The table shows the percentage and number (n) of blood fractions that have been transported within 3 hours, shown for each center for 2018. The transport time is defined as the time between material retrieval from the patient until the material is received at the laboratory.

The processing time for hematological blood samples is calculated for each center, except center Næstved, as they do not collect hematological material. The processing time is shown as percentage of the fractions that have been processed within 12 hours, 12-36 hours and over 36 hours (table 1.3.2.4). It is recommended that hematological material is handled within the same day or, at the latest the following day. The goal for this indicator is therefore that 90% of the hematological blood material is processed within 36 hours.

Table 1.3.2.3 shows that 97% of the hematological blood fractions are processed within 36 hours, and about half of the fractions were handled the same day (within 12 hours). All centers are thereby fulfilling the goal of the indicator (table 1.3.2.4). 99% of the samples are received in the laboratory within 12 hours, making is possible to handle the samples within the recommended 36 hours (table 1.3.2.5).

		Number of hematological blood fractions	**Percentage of fractions (n) ≤ 12 hours**	**Percentage of fractions (n) 12-36 hours**	**Percentage of fractions (n) > 36 hours**
	2018				
National	**TOTAL**	**12,684**	**48 (6,074)**	**49 (6,227)**	**3 (383)**
Center	Herlev	983	81 (792)	7 (68)	13 (123)
	Næstved*	-	-	-	-
	Odense	580	8 (45)	79 (461)	13 (74)
	Rigshospitalet	1,524	45 (690)	44 (678)	10 (156)
	Aalborg	9,586	47 (4,547)	52 (5,009)	0.3 (30)
	Aarhus	11	0 (0)	100 (11)	0 (0)
	2017				
National	**TOTAL**	**11,857**	**54 (6,407)**	**44 (5,228)**	**2 (222)**
Center	Herlev	1,976	91 (1,800)	6 (120)	3 (56)
	Næstved*	-	-	-	-
	Odense	536	1 (7)	94 (505)	4 (24)
	Rigshospitalet	1,433	42 (601)	54 (776)	4 (56)
	Aalborg	7,236	55 (3,957)	44 (3,220)	1 (59)
	Aarhus	676	6 (42)	90 (607)	4 (27)

*Center Næstved does not collect hematological material

Table 1.3.2.3. Processing time for hematological blood, 2017-2018. The table shows the percentage and number (n) of hematological blood fractions that have been processed within 12 hours, 12-36 hours and over 36 hours, shown for each center from 2017-2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

		Number of hematological blood fractions	Percentage of fractions (n) ≤ 12 hours	Percentage of fractions (n) 12-36 hours	Percentage of fractions (n) > 36 hours
	2018				
National	**TOTAL**	**12,684**	**99 (12,591)**	**1 (91)**	**0 (2)**
Center	Herlev	983	99 (975)	1 (8)	0 (0)
	Næstved*	-	-	-	-
	Odense	580	100 (580)	0 (0)	0 (0)
	Rigshospitalet	1,524	98 (1,494)	2 (28)	0.1 (2)
	Aalborg	9,586	99 (9,531)	1 (55)	0 (0)
	Aarhus	11	100 (11)	0 (0)	0 (0)

*Center Næstved does not collect hematological material

Table 1.3.2.4. Transport time for hematological blood, 2018. The table shows the percentage and number (n) of hematological blood fractions that have been transported within 12 hours, 12-36 hours and over 36 hours, shown for each center for 2018. The transport time is defined as the time between material retrieval from the patient until the material is received at the laboratory.

The processing time for tissue samples is calculated for all fractions excluding RNAlater, as they are handled differently. The time is calculated for each center and is shown as percentage of the fractions that have been processed within the recommended 1 hour (table 1.3.2.5).

None of the centers fulfilled the goal of this indicator in 2018, which recommends that 90% of the fractions should be processed within 1 hour. This is approximately the same as seen in 2017 with center Rigshospitalet and center Aalborg having a high percentage of fractions processed within 1 hour and the rest of the centers with less than 50% of their fractions processed within 1 hour. Especially these centers should have an increased focus on improving their processing time by improving the workflow in the laboratories.

A part of the explanation for a long processing time can be found in the transport time (table 1.3.2.6). Especially regarding center Næstved and Aarhus, where only 38% and 69%, respectively, of the fractions were received within 1 hour. This is because the materials are collected at different locations and must be transported to their respective pathology departments. Especially center Næstved is challenged by the long distance between their departments, making it difficult to improve the transport time and thereby the processing time.

For all centers, nearly all fractions that are not processed within 1 hour are processed within 3 hours, which shows that the laboratories are working on keeping the processing time as short as possible (appendix 6.1.3).

		Number of tissue fractions	Percentage of fractions (n) ≤ 1 hour
	2018		
National	**TOTAL**	**39,921**	**49 (19,489)**
Center	Herlev	10,135	40 (4,049)
	Næstved	6,544	28 (1,833)
	Odense	9,248	47 (4,367)
	Rigshospitalet	6,316	73 (4,594)
	Aalborg	3,202	88 (2,827)
	Aarhus	4,476	41 (1,819)
	2017		
National	**TOTAL**	**43,320**	**50 (21,595)**
Center	Herlev	10,423	42 (4,358)
	Næstved	6,909	26 (1,828)
	Odense	10,631	43 (4,542)
	Rigshospitalet	8,432	71 (5,971)
	Aalborg	3,831	90 (3,461)
	Aarhus	3,094	46 (1,435)

Table 1.3.2.5. Processing time for tissue, 2017-2018. The table shows the percentage and number (n) of tissue fractions that have been processed within the recommended 1 hour, shown for each center and the years 2017-2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

		Number of tissue fractions	Percentage of fractions (n) ≤ 1 hour
	2018		
National	**TOTAL**	**39,921**	**78 (31,198)**
Center	Herlev	10,135	83 (8,432)
	Næstved	6,544	38 (2,461)
	Odense	9,248	85 (7,873)
	Rigshospitalet	6,316	97 (6,151)
	Aalborg	3,202	100 (3,196)
	Aarhus	4,476	69 (3,085)

Table 1.3.2.6. Transport time for tissue, 2018. The table shows the percentage and number (n) of blood fractions that have been transported within the recommended 1 hours, shown for each center for 2018. The transport time is defined as the time between material retrieval from the patient until the material is received at the laboratory.

The processing time for bone marrow samples is calculated for each center, except for center Næstved, as they do not collect hematological material. The processing time is shown as the percentage of fractions that have been processed within 12 hours, 12-36 hours and more than 36 hours (table 1.3.2.7). It is recommended that hematological material is handled within the same day or at the latest the following day. The goal for this indicator is therefore that 90% of the hematological bone marrow material is processed within 36 hours.

Table 1.3.2.7 shows that 92% of the hematological blood fractions are processed within 36 hours, and about a third of the fractions were handled the same day (within 12 hours). All centers are fulfilling the goal of the indicator except center Herlev, where none of the fractions are handled within the recommended 36 hours. Center Herlev should evaluate their workflow to improve the processing time and thereby ensure the quality of the samples. 99% of the samples are received in the laboratory within 12 hours, making is possible to handle the samples within the recommended 36 hours (table 1.3.2.8).

		Number of bone marrow fractions	**Percentage of fractions (n) ≤ 12 hours**	**Percentage of fractions (n) 12-36 hours**	**Percentage of fractions (n) > 36 hours**
	2018				
National	**TOTAL**	**8,340**	**32 (2,631)**	**60 (4,963)**	**9 (737)**
Center	Herlev	544	0 (0)	0 (0)	100 (544)
	Næstved*	-	-	-	-
	Odense	1,155	15 (176)	79 (918)	5 (61)
	Rigshospitalet	875	34 (296)	57 (495)	10 (84)
	Aalborg	5,758	38 (2,168)	62 (3,542)	1 (48)
	Aarhus	8	0 (0)	100 (8)	0 (0)
	2017				
National	**TOTAL**	**8,975**	**27 (2,549)**	**61 (5,515)**	**13 (1,243)**
Center	Herlev	1,109	1 (12)	1 (6)	99 (1,109)
	Næstved*	-	-	-	-
	Odense	701	20 (139)	79 (554)	1 (8)
	Rigshospitalet	1,143	34 (389)	62 (706)	4 (48)
	Aalborg	5,480	36 (1,980)	63 (3,426)	1 (74)
	Aarhus	542	6 (31)	90 (489)	4 (22)

*Center Næstved does not collect hematological material

Table 1.3.2.7. Processing time for bone marrow, 2017-2018. The table shows the percentage and number (n) of bone marrow fractions that have been processed within 12 hours, 12-36 hours and over 36 hours, shown for each center from 2017-2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

		Number of bone marrow fractions	Percentage of fractions (n) ≤ 12 hours	Percentage of fractions (n) 12-36 hours	Percentage of fractions (n) > 36 hours
	2018				
National	**TOTAL**	**8,340**	**99 (8,286)**	**1 (44)**	**0.1 (10)**
Center	Herlev	544	100 (544)	0 (0)	0 (0)
	Næstved*	-	-		
	Odense	1,155	99 (1,146)	1 (9)	0 (0)
	Rigshospitalet	875	97 (852)	3 (23)	0 (0)
	Aalborg	5,758	100 (5,736)	0.2 (12)	0.2 (10)
	Aarhus	8	100 (8)	0 (0)	0 (0)

*Center Næstved does not collect hematological material

Table 1.3.2.8. Transport time for bone marrow, 2018. The table shows the percentage and number (n) of bone marrow fractions that have been transported within 12 hours, 12-36 hours and more than 36 hours, shown for each center for 2018. The transport time is defined as the time between material retrieval from the patient until the material is received at the laboratory.

RECOMMENDATION: For blood and hematological material the goal of the indicator is fulfilled for nearly all centers. Center Aarhus should work on improving their transport time for blood samples if possible. Center Herlev needs to evaluate their work flow for bone marrow as none of their fractions are handled with in the recommended time.
For tissue all centers should have focus on improving their processing time, as only about half of the tissue materials are processed within the recommended time.
It is important to keep the processing time for all samples as short as possible so that the quality of the material in DCB is optimal for research and future analyses.

1.3.3 Indicator 3: Coverage

In the guidelines for handling of material in DCB, standard sets for blood, tissue, hematological blood and bone marrow are defined. This is to ensure that there is enough material and different types of fractions to accommodate the needs in research and in the clinic in the future. The goal of this indicator is that at least 90% of the collected blood and hematological material should contain the recommended fractions. For tissue, the goal is 50%.

The coverage for blood is calculated as the percentage of blood materials that, as a minimum, contain the recommended 8 fractions, described for the standard set.

As in 2017, the goal of this indicator was met both nationally and by all centers in 2018, except center Næstved and Aarhus (table 1.3.3.1). For both centers the lower coverage is due to project specific collections, where the collected fraction set contains fewer fractions. Center Aarhus for example changed their fraction set for urinary tract and bladder cancer in 2016, so some fraction sets for these organs only contain 2 or 7

fractions. However, from each of these patients a complete standard set is also collected, to ensure sufficient material in the biobank. In center Næstved blood samples are taken after surgery, and these blood materials often differ from the standard set. However, a complete standard set is taken before surgery from all patients, ensuring enough material for research and diagnostics.

In general, it is expected that only very few patients are not able to donate enough blood for a complete fraction set and this should be seen in the coverage in all centers.

		Number of blood materials	Number of blood materials with ≥ 8 fractions	Coverage (%)
	2018			
National	**TOTAL**	**11,616**	**10,612**	**91**
Center	Herlev	2,284	2,248	98
	Næstved	963	813	84
	Odense	1,503	1,497	100
	Rigshospitalet	2,121	1,938	91
	Aalborg	959	959	100
	Aarhus	3,786	3,157	83
	2017			
National	**TOTAL**	**12,091**	**10,843**	**90**
Center	Herlev	2,378	2,320	98
	Næstved	1,138	930	82
	Odense	1,544	1,536	99
	Rigshospitalet	2,183	1,997	91
	Aalborg	1,031	1,029	100
	Aarhus	3,817	3,031	79
	2016			
National	**TOTAL**	**10,993**	**10,233**	**93**
Center	Herlev	2,340	2,338	100
	Næstved	655	652	100
	Odense	1,546	1,534	99
	Rigshospitalet	2,658	2,614	98
	Aalborg	1,111	1,108	100
	Aarhus	2,683	1,987	74

Table 1.3.3.1. Coverage for blood, 2016-2018. The table shows the number and percentage of blood materials that have the includes ≥8 fractions, shown for each center from 2016-2018.

The coverage for tissue is calculated as the percentage of tissue materials that, as a minimum, have the recommended 9 fractions described for the standard set.

Only 36% of the tissue materials have the recommended 9 fractions and the goal for this indicator, that 50% of tissue materials should contain a complete fraction set, is not fulfilled nationally. This is primarily due to the fact that center Rigshospitalet collects very few RNA-later fractions, thus only 2% of their tissue materials include the recommended 9 fractions. Center Næstved, Odense and Alborg all fulfilled the goal of the indicator. Center Aarhus has greatly increased the number of materials with a complete fraction set and are encouraged to continue these improvements to be able to achieve the goal in 2019. Center Herlev is still not meeting the goal and should increase their focus on collecting a complete fraction set if possible.

The low coverage in some centers can partially be explained by an increase in screenings for some cancer types. This results in smaller tumors at the time of operation and therefore there is not enough material for a complete fraction set. The guidelines for DCB should be followed whenever possible to ensure complete fraction sets and new resolutions are being produced in order to tackle this issue.

		Number of tissue materials	Number of tissue materials with ≥ 9 fractions	Coverage (%)
	2018			
National	**TOTAL**	**10,947**	**3,963**	**36**
Center	Herlev	2,566	999	39
	Næstved	1,134	1,012	89
	Odense	1,881	945	50
	Rigshospitalet	3,522	56	2
	Aalborg	760	462	61
	Aarhus	1,084	489	45
	2017			
National	**TOTAL**	**11,722**	**4,276**	**36**
Center	Herlev	2,718	1,061	39
	Næstved	1,183	1,095	93
	Odense	2,006	1,214	61
	Rigshospitalet	4,036	156	4
	Aalborg	873	559	64
	Aarhus	906	191	21
	2016			
National	**TOTAL**	**7,154**	**2,811**	**39**
Center	Herlev	1,382	560	41
	Næstved	498	335	67
	Odense	1,325	785	59
	Rigshospitalet	2,587	220	9
	Aalborg	644	548	85
	Aarhus	718	363	51

Table 1.3.3.2. Coverage for tissue, 2016-2018. The table shows the number and percentage of tissue materials that has a minimum of 9 fractions, shown for each center from 2017-2018.

The coverage for hematological blood is calculated as the percentage of hematological blood materials that, as a minimum, have the recommended 4 fractions described for the standard set. The calculation of the coverage for hematological blood material is a new part of this indicator, and therefore only data from 2017 and 2018 are shown. Center Næstved does not collect hematological material.

Table 1.3.3.3 shows that all centers, except center Rigshospitalet, fulfilled the goal of the indicator, as more than 90% of their hematological blood materials contain at least the recommended 4 fractions. Center Rigshospitalet should focus on collecting complete standard sets.

		Number of hematological blood materials	Number of hematological blood materials with ≥ 4 fractions	Coverage (%)
	2018			
National	**TOTAL**	**1,421**	**1,348**	**95**
Center	Herlev	125	125	100
	Næstved*	-	-	-
	Odense	81	81	100
	Rigshospitalet	219	151	69
	Aalborg	995	990	99
	Aarhus	1	1	100
	2017			
National	**TOTAL**	**1,385**	**1,286**	**93**
Center	Herlev	251	251	100
	Næstved*	-	-	-
	Odense	72	72	100
	Rigshospitalet	245	147	60
	Aalborg	747	746	100
	Aarhus	70	70	100

*Center Næstved does not collect hematological material

Table 1.3.3.3. Coverage for hematological blood, 2017-2018. The table shows the number and percentage of hematological blood materials that as a minimum have 4 fractions, shown for each center from 2017-2018.

The coverage for bone marrow is calculated as the percentage of bone marrow materials that, as a minimum, has the recommended 2 fractions, described for the standard set. The calculation of the coverage for bone marrow material is a new part of the indicator and therefore only data from 2017 and 2018 are shown. Center Næstved does not collect hematological material.

Table 1.3.3.4 shows that all centers, except center Rigshospitalet fulfilled the goal of the indicator, where more than 90% of their bone marrow materials contain at least the recommended 2 fractions. Center Rigshospitalet is encouraged to have an increased focus on collecting complete standard sets.

		Number of bone marrow materials	Number of bone marrow materials with ≥ 2 fractions	Coverage (%)
	2018			
National	**TOTAL**	**1,337**	**1,261**	**94**
Center	Herlev	104	104	100
	Næstved*	-	-	-
	Odense	199	198	99
	Rigshospitalet	227	152	67
	Aalborg	806	806	100
	Aarhus	1	1	100
	2017			
National	**TOTAL**	**1,614**	**1,383**	**86**
Center	Herlev	288	197	68
	Næstved*	-	-	-
	Odense	172	170	99
	Rigshospitalet	342	205	60
	Aalborg	742	741	100
	Aarhus	70	70	100

*Center Næstved does not collect hematological material

Table 2.3.3.4. Coverage for bone marrow, 2017-2018. The table shows the number and percentage of bone marrow materials that as a minimum have 2 fractions, shown for each center from 2017-2018.

RECOMMENDATION:

Center Næstved and Aarhus are not fulfilling the goal of this indicator for blood samples. However, this is due to project specific collections, and since a complete standard set is also collected from these patients, they are in fact collecting according to the guidelines.

Center Herlev and Aarhus should continue focusing on collecting all the recommended tissue fractions, and center Rigshospitalet should consider revising their procedures as they have a very low coverage for tissue.

Center Rigshospitalet should also focus on collecting all fractions for hematological material.

This indicator should be followed closely for each center to ensure a continued high national coverage, to ensure that the biobank has enough material for future research.

1.3.4 Indicator 4: Completeness

In DCB, it is registered whether the collected blood and tissue materials are corresponding, i.e. whether there is blood and tissue collected from the same patient. To ensure optimal material for future cancer research, it should be ensured that corresponding blood and tissue materials exist from as many patients as possible. Since the number of collected blood samples exceeds the number of tissue samples, the indicator is calculated as the percentage of tissue materials with corresponding blood material. The blood sample must be taken a maximum of 14 days before the patient's operation date. Blood samples taken more than 14 days before surgery, and blood samples taken after surgery are not considered corresponding. However, all samples are valuable to an overall picture of the patient's disease and can therefore contribute to future projects that include biological studies of materials throughout the patient's disease.

The goal of this indicator is that 50% of all tissue materials have corresponding blood material. Center Næstved, Aalborg and Aarhus all have more than 50% corresponding tissue and blood material, whereas center Herlev, Odense and Rigshospitalet do not fulfil the goal of the indicator (table 1.3.4.1).

In the future, center project managers are encouraged to collaborate to increase the number of corresponding blood and tissue samples, and to increase the focus on this indicator.

	2018	Number of tissue materials	Number of tissue materials with corresponding blood material	Percentage of tissue materials with corresponding blood material
National	**TOTAL**	**10,950**	**3,360**	**31**
Center	Herlev	2,566	686	27
	Næstved	1,134	602	53
	Odense	1,884	429	23
	Rigshospitalet	3,522	608	17
	Aalborg	760	391	51
	Aarhus	1,084	644	59
	2017			
National	**TOTAL**	**11,722**	**3,342**	**29**
Center	Herlev	2,718	654	24
	Næstved	1,183	686	58
	Odense	2,006	551	27
	Rigshospitalet	4,036	695	17
	Aalborg	873	265	30
	Aarhus	906	491	54
	2016			
National	**TOTAL**	**11,866**	**3,486**	**29**
Center	Herlev	2,774	319	11
	Næstved	1,020	739	72
	Odense	2,031	558	27
	Rigshospitalet	3,965	867	22
	Aalborg	833	418	50
	Aarhus	1,243	585	47

Table 1.3.4.1. Tissue material with corresponding blood material, 2016-2018. The table shows the number and percentage of tissue material that have corresponding blood material shown for each center from 2016-2018. Blood material is corresponding if it is taken ≤14 days before the tissue material.

To ensure high quality samples in the biobank, it is important that all tissue and bone marrow materials have a complete registration, with a diagnosis code, pathological verification and is coupled to a DMCG.

The indicator is calculated as percentage of complete registered tissue and bone marrow material, and the goal is that 95% of the material should be completely registered.

The goal of the indicator is fulfilled nationally for tissue material. However center Rigshospitalet and Aarhus fell a bit behind the goal of the indicator (table 1.3.4.3). These centers should focus on improving the complete registration of tissue samples as it is essential for the quality of the material.

For bone marrow, the goal of the indicator is fulfilled for 4 out of the 5 centers that collect the material. At center Rigshospitalet, none of the collected bone marrow materials have been completely registered, indicating that some work procedures need to be changed. Noteworthy, despite the fact that center Rigshospitalet does not have a complete registration for any of their bone marrow materials, all other centers have 100% completed registration of material, indicating that this issue can be readily addressed.

Overall, it is important that the centers are in close dialogue with the local departments, and that the local departments understand the necessity of completing the registration, so that the quality of material is at the same high level nationally. It is a task that center project managers should convey.

It should be ensured that complete registration of tissue and bone marrow materials remains a very important task on all tissue collecting departments, as it is a prerequisite for the completeness and application of the material. It is necessary for the project managers to follow up on the materials being registered on a continuous basis, as this is part of the job description for the project manager function.

		Number of tissue materials	Complete registered tissue material	Percentage complete registered tissue material	Number of bone marrow materials	Complete registered bone marrow material	Percentage complete registered bone marrow material
	2018						
National	**TOTAL**	**10,950**	**10,373**	**95**	**1,337**	**1,110**	**83**
Center	Herlev	2,566	2,478	97	104	104	100
	Næstved	1,134	1,134	100	-	-	-
	Odense	1,884	1,849	98	199	199	100
	Rigshospitalet	3,522	3,209	91	227	0	0
	Aalborg	760	760	100	806	806	100
	Aarhus	1,084	943	87	1	1	100
	2017						
National	**TOTAL**	**11,723**	**11,266**	**96**	**1,614**	**1,270**	**79**
Center	Herlev	2,718	2,718	100	288	288	100
	Næstved	1,183	1,178	100	-	-	-
	Odense	2,006	1,769	88	172	170	99
	Rigshospitalet	4,036	3,831	95	342	0	0
	Aalborg	874	873	100	742	742	100
	Aarhus	906	897	99	70	70	100
	2016						
National	**TOTAL**	**11,866**	**11,476**	**97**	**2,334**	**2,094**	**90**
Center	Herlev	2,774	2,700	97	1,090	1,090	100
	Næstved	1,020	1,018	100	-	-	-
	Odense	2,031	2,021	100	238	238	100
	Rigshospitalet	3,965	3,911	99	256	16	6
	Aalborg	833	803	96	707	707	100
	Aarhus	1,243	1,023	82	43	43	100

Table 1.3.4.3. Number of complete registered tissue and bone marrow materials, 2016-2018. The table shows the number of tissue and bone marrow materials that are completely registered in the biobank shown for each center from 2016-2018. A material is completely registered if it has a diagnosis code, pathological verification and is coupled with a DMCG.

RECOMMENDATION: Focus should be on collecting corresponding blood and tissue material at all centers. This requires a collaboration between departments, which should be ensured especially at the start of new projects.
For complete registration of tissue material, the goal of the indicator is met nationally, however for bone marrow the goal is not fulfilled. This is only due to the lack of completed registration at center Rigshospitalet. They should have a strong focus on improving their procedures to ensure that the material is registered in a complete manner.

1.3.5 Indicator 5: Diagnostic Follow-up

In 2018, 201 tissue fractions, 2 bone marrow fractions and 1 hematological blood fraction from a total of 43 patients have been retrieved for diagnostic follow-up. Most of the material was retrieved from center Aalborg (table 1.3.5.1)

		Number of patients	Number of blood fractions	Number of tissue fractions	Number of bone marrow fractions	Number of hematological blood fractions
	2018					
National	**TOTAL**	**43**	**0**	**201**	**2**	**1**
Center	Herlev	1		1		
	Næstved					
	Odense					
	Rigshospitalet	1		4		
	Aalborg	40		180	2	1
	Aarhus	1		16		

Table 1.3.5.1. Number of fractions retrieved for diagnostic follow-up. The table shows the number of fractions of the different material types that have been handed out to diagnostic follow-up shown per center.

RECOMMENDATION: The number of materials retrieved for diagnostic follow-up is expected to increase as more molecular tests are being performed regarding genetic counseling and personalized medicine.

1.3.6 Indicator 6: Research

One of the purposes of DCB is to facilitate collection of material for research projects. In 2018, 8 new local and 1 national project started collecting material through DCB. Altogether, there are 78 local and 11 national projects registered in DCB (figure 1.3.6.1).

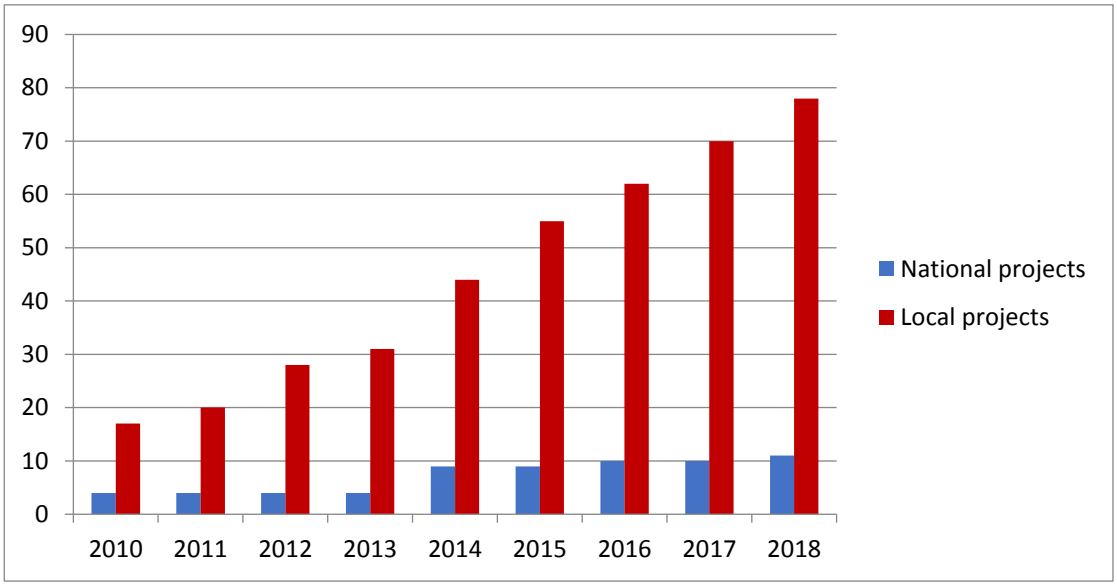

Figure 1.3.6.1. Number of research projects in DCB. The figure shows the number of national and local research projects in DCB accumulated for each year.

Bio- and Genome Bank Denmark gives researchers access to material that can be used for research. In 2018, 12,131 blood fractions, 161 hematological blood fractions and 200 tissue fractions were retrieved for research projects (table 1.3.6.1 and 1.3.6.2).

The number of blood fractions that were retrieved in 2018 has increased compared to previous years (table 1.3.6.1). This is primarily due to center Aarhus, where a third of their collected material has been retrieved for research projects. The other centers should have a focus on increasing the number of materials being retrieved for research for example, by informing researchers about the possibilities in RBGB.

Only 1% of the collected tissue and bone marrow material have been retrieved in 2018 (table 1.3.6.3). All centers should increase their focus on sample retrieval for research.

Of the fractions handed out in 2018, 138 of the tissue fractions and 89 of the hematological blood fractions were for retrospective research, i.e. research projects that have not collected the material themselves. The rest of the fractions were all reserved to specific research projects. All applications for materials and all hand outs were handled within the recommended timeframes.

	2018	Number of blood fractions	Number of retrieved fractions	Percentage of retrieved fractions		Number of hematological blood fractions	Number of retrieved fractions	Percentage of retrieved fractions
National	**TOTAL**	**99,063**	**13,356**	**14**		**12,684**	**161**	**1.3**
Center	Herlev	18,373	478	3		983	0	0
	Næstved	7,771	0	0		-	-	-
	Odense	12,621	0	0		580	89	15
	Rigshospitalet	16,268	334	2		1,524	0	0
	Aalborg	9,951	200	2		9,586	72	1
	Aarhus	34,079	12,344	36		11	0	0
	2017							
National	**TOTAL**	**113,426**	**6,071**	**5.4**				
Center	Herlev	20,867	1,370	7				
	Næstved	8,998	256	3				
	Odense	13,490	0	0				
	Rigshospitalet	18,188	0	0				
	Aalborg	17,651	0	0				
	Aarhus	34,232	4,445	13				
	2016							
National	**TOTAL**	**106,542**	**8,865**	**8.3**				
Center	Herlev	18,941	0	0				
	Næstved	7,447	0	0				
	Odense	13,183	223	2				
	Rigshospitalet	22,629	0	0				
	Aalborg	16,628	9	0.1				
	Aarhus	27,714	8,633	31				

Table 1.3.6.1. Number of blood fractions that have been retrieved for research projects, 2016-2018. The table shows the number of blood fractions that have been retrieved for research projects, shown for each center from 2016-2018. For 2018 blood and hematological blood are calculated separately.

Project	Center	Number of retrieved blood fractions	Number of retrieved hematological blood fractions
REBECCA	Herlev	469	
Pelvic Mass	Herlev/Rigshospitalet	9	
GOVEC	Herlev/Rigshospitalet	110	
CAR-T project	Odense		89
EPIGENOM	Rigshospitalet	224	
ProGen	Aalborg		50
ProSeq	Aalborg		15
RetroGen	Aalborg		7
IMPROVE	Aalborg	200	
MOMA Colorectal	Aarhus	9,408	
MOMA Blære Pager	Aarhus	1,179	
MOMA Prostata CMCC	Aarhus	859	
MOMA Blærecancer vævsbanken	Aarhus	878	
PLAN-A anal	Aarhus	20	

Table 1.3.6.2. Number of blood and hematological blood fractions retrieved for specific projects in 2018. The table shows the number of blood and hematological blood fractions that have been retrieved for specific projects in 2018.

	2018	Number of tissue fractions	Number of retrieved fractions	Percentage of retrieved fractions		Number of bone marrow fractions	Number of retrieved fractions	Percentage of retrieved fractions
National	**TOTAL**	**57,108**	**557**	**1**		**8,340**	**74**	**1**
Center	Herlev	14,215	42	0.3		544	3	1
	Næstved	9,681	0	0		-	-	-
	Odense	12,918	6	0		1,155	0	0
	Rigshospitalet	9,226	131	1.2		875	0	0
	Aalborg	4,923	110	0.8		5,758	71	1
	Aarhus	6,145	268	4		8	0	0
	2017							
National	**I ALT**	**63,535**	**360**	**0.6**		**8,975**	**0**	**0**
Center	Herlev	16,232				1,109	0	0
	Næstved	10,253	76	0.5		0	0	0
	Odense	15,008				701	0	0
	Rigshospitalet	12,183	11	0.3		1,143	0	0
	Aalborg	3,927	4	0.02		5,480	0	0
	Aarhus	5,932	269	5		542	0	0
	2016							
National	**I ALT**	**67,130**	**1,036**	**1,5**		**11,435**	**21**	**0.2**
Center	Herlev	17,012	19	0.1		3,941	0	0
	Næstved	8,995	0	0		0	0	0
	Odense	15,593	2	0.01		1,221	0	0
	Rigshospitalet	12,998	2	0.02		887	0	0
	Aalborg	6,318	17	0.3		5,052	0	0
	Aarhus	6,214	996	16,0		334	21	6

Table 1.3.6.3. Number of tissue and bone marrow fractions that have been retrieved for research projects, 2016-2018.
The table shows the number of tissue and bone marrow fractions that have been retrieved for research projects shown for each center from 2016-2018.

Project	Center	Number of retrieved tissue fractions	Number of retrieved bone marrow fractions
GOVEC	Herlev	42	
AZA-CTA	Herlev		3
Pelvic Mass	Herlev	16	
STAGING	Odense	6	
Inditreat	Rigshospitalet	4	
HCC project	Rigshospitalet	88	
Proteom project	Rigshospitalet	3	
ProGen	Aalborg	6	24
ProSeq	Aalborg	3	47
RetroGen	Aalborg	7	
OV-VTE	Aalborg	69	
MOMA Blære Pager	Aarhus	32	
MOMA Prostata CMCC	Aarhus	58	
MOMA Blærecancer vævsbanken	Aarhus	176	
MCL	National	47	

Table 1.3.6.4. Number of tissue and bone marrow fractions retrieved for specific projects in 2018. The table shows the number of tissue and bone marrow fractions that have been retrieved for specific projects in 2018.

RECOMMENDATION: The goal of this indicator is that more than 5% of the material collected in DCB should be retrieved for research projects. This goal is only fulfilled for blood material, but not for tissue or hematological material. There should be an increased focus in DCB to spread the knowledge about the biobank and its material to increase sample retrieval for research and thereby improving precision medicine

1.3.7 Indicator 7: Clinical Data

The linkage of biological material to clinical data increases the value of the material. To date, clinical data is retrieved from different clinical databases, which makes it complicated to retrieve the clinical data. The clinical quality databases (RKKP) are working to find an easier way to link RBGB-data with clinical data. In this report information about age and sex of the patients, as well as the number of follow-up samples are presented.

Most patients that donated material to DCB are above 50 years old. Such observation is expected as the risk of cancer increases with age (figure 1.3.7.1). A total of 8,766 females and 5,530 males have donated material to DCB in 2017. The large number of women compared to men can be explained by the fact, that there is a large focus on collecting mamma cancer and gynaecological cancers for the biobank.
Furthermore, some male-specific cancers, such as prostate cancer, have very small tumors and therefore, material is often not prioritised for the biobank.

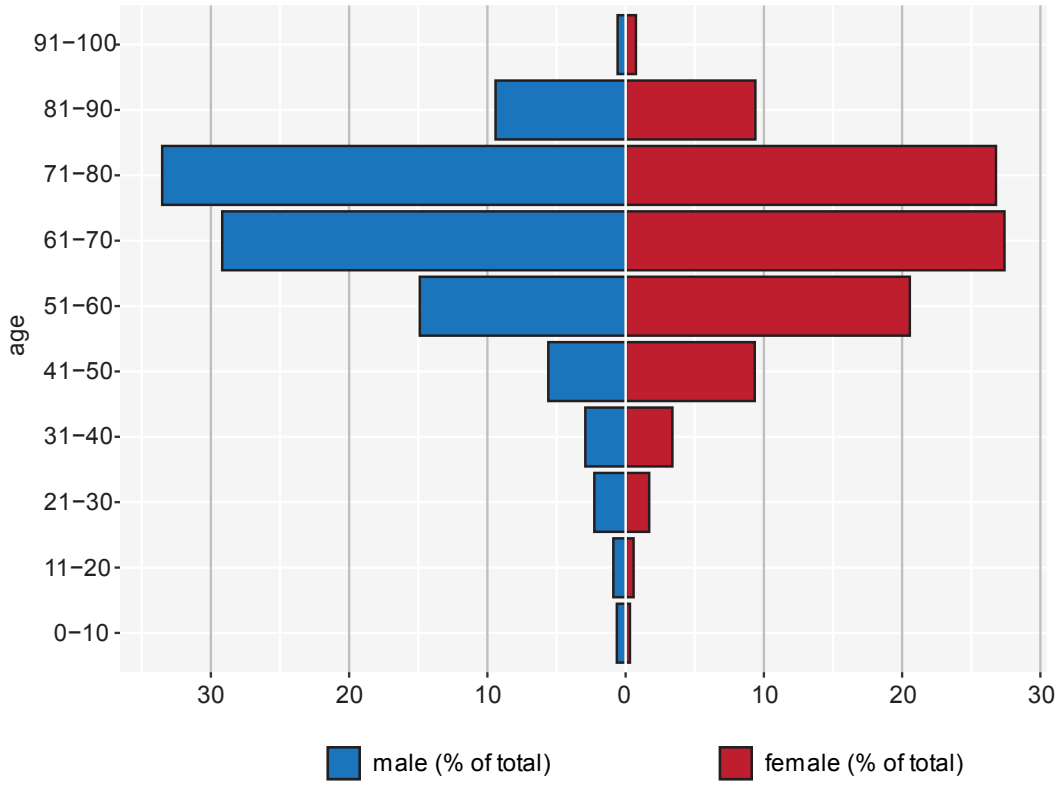

Figure 1.3.7.1. Population distribution by age and gender for patients in DCB in 2018. The figure shows the distribution of age and gender of the patients who have donated material to DCB in 2018.

Some patients donated material to DCB several times during the year. Especially for blood samples, more samples are often collected, to have material from the course of the patient's disease and/or treatment. In 2018, 3,645 patients donated blood more than once (table 1.3.7.1). For hematological blood, tissue and bone marrow, most patients donated material only once.

Number of donations	Number of blood-CPR	Number of tissue-CPR	Number of hematological blood-CPR	Number of bone marrow-CPR
1	7,224	6,680	1,042	737
2	1,652	310	136	18
3	798	33	9	
4	840	4	4	
5	215			
6	78			
7	21			
8	16			
9	12			
10	13			

Table 1.3.7.1. Number of times patients have donated material to DCB in 2018. The table shows how many times patients have donated material to DCB in 2018. The data is calculated for blood, hematological blood, tissue and bone marrow separately.

1.3.8 Indicator 8: Sharing of Knowledge

DCB facilitates many research projects with collection of material. Therefore, an increase in the number of published articles must be expected, in which DCB is stated at least in the "Acknowledgments" section for the handling of the material. Unfortunately, it is not possible to search for acknowledgments in PubMed, which makes it hard to identify which research groups have currently published studies based on material from DCB. The manuscripts that have been reported to us for 2018 are listed below.

It is still important to remind researchers to state DCB in the Acknowledgments section to increase the awareness of the biobank and the work that is done. Researchers are encouraged to notify the secretariat regarding newly published articles, which are based on biobank material. These will be included in the RBGB newsletter, posted on the website etc.

The secretariat for RBGB also contributes with the sharing of knowledge via newsletters, the annual report, the RBGB website and presentations at various conferences. In addition, data from RBGB is submitted to The Danish Biobank Register at Statens Serum Institut every year. This allows researchers to search for few general information about the materials in RBGB.

<u>Publications, 2018:</u>

Palin K, Pitkänen E, Turunen M, Sahu B, Pihlajamaa P, Kivioja T, Kaasinen E, Välimäki N, Hänninen UA, Cajuso T, Aavikko M, Tuupanen S, Kilpivaara O, van den Berg L, Kondelin J, Tanskanen T, Katainen R, Grau M, Rauanheimo H, Plaketti RM, Taira A, Sulo P, Hartonen T, Dave K, Schmierer B, Botla S, Sokolova M, Vähärautio A, Gladysz K, Ongen H, Dermitzakis E, Bramsen JB, Ørntoft TF, Andersen CL, Ristimäki A, Lepistö A, Renkonen-Sinisalo L, Mecklin JP, Taipale J, Aaltonen LA. **Contribution of allelic imbalance to colorectal cancer**. Nat Commun. 2018 Sep 10;9(1):3664. doi: 10.1038/s41467-018-06132-1. PMID: 30202008

Árnadóttir SS, Jeppesen M, Lamy P, Bramsen JB, Nordentoft I, Knudsen M, Vang S, Madsen MR, Thastrup O, Thastrup J, L Andersen C. **Characterization of genetic intratumor heterogeneity in colorectal cancer and matching patient-derived spheroid cultures.** Mol Oncol. 2018 Jan;12(1):132-147. doi: 10.1002/1878-0261.12156. Epub 2017 Nov 27. PMID: 29130628

Haldrup C, Pedersen AL, Øgaard N, Strand SH, Høyer S, Borre M, Ørntoft TF, Sørensen KD. **Biomarker potential of ST6GALNAC3 and ZNF660 promoter hypermethylation in prostate cancer tissue and liquid biopsies.** Mol Oncol 2018, 12(4):545-560 (IF=5.957). PMID: 29465788

Storebjerg TM, Strand SH, Høyer S, Lynnerup AS, Borre M, Ørntoft TF, Sørensen KD. **Dysregulation and prognostic potential of 5-methylcytosine (5mC), 5-hydroxymethylcytosine (5hmC), 5-formylcytosine (5fC) and 5-carboxylcytosine (5caC) levels in prostate cancer.** Clin Epig 2018; 10(1):105. (IF=6.091). PMID: 30086793

Schmidt L, Fredsøe J, Kristensen H, Strand S, Rasmussen A, Høyer S, Borre M, Mouritzen P, Ørntoft TF, Sørensen KD. **Training and validation of a novel 4-miRNA ratio model (MiCaP) for prediction of post-operative outcome in prostate cancer patients.** Ann Oncol 2018; 29(9):2003-2009. (IF=13.9). PMID: 30010760

Schmidt L, Møller M, Haldrup C, Strand S, Vang S, Hedegaard J, Høyer S, Borre M, Ørntoft TF, and Sørensen KD. **Exploring the transcriptome of hormone-naïve multifocal prostate cancer and matched lymph node metastases.** Br J Cancer 2018, 119(12):1527-1537 (IF=6.176). PMID: 30449885

Birkenkamp-Demtröder K, Christensen E, Nordentoft I, Knudsen M, Taber A, Høyer S, Lamy P, Agerbæk M, Jensen JB, Dyrskjøt L. **Monitoring Treatment Response and Metastatic Relapse in Advanced Bladder Cancer by Liquid Biopsy Analysis.** Eur Urol. 2018 Apr;73(4):535-540. doi: 10.1016/j.eururo.2017.09.011. Epub 2017 Sep 27. PMID:28958829

van Kessel KEM, van der Keur KA, Dyrskjøt L, Algaba F, Welvaart NYC, Beukers W, Segersten U, Keck B, Maurer T, Simic T, Horstmann M, Grimm MO, Hermann GG, Mogensen K, Hartmann A, Harving N, Petersen AC, Jensen JB, Junker K, Boormans JL, Real FX, Malats N, Malmström PU, Ørntoft TF, Zwarthoff EC. **Molecular Markers Increase Precision of the European Association of Urology Non-Muscle-Invasive Bladder Cancer Progression Risk Groups.** Clin Cancer Res. 2018 Apr 1;24(7):1586-1593. doi: 10.1158/1078-0432.CCR-17-2719. Epub 2018 Jan 24. PMID:29367430

Christensen E, Nordentoft I, Vang S, Birkenkamp-Demtröder K, Jensen JB, Agerbæk M, Pedersen JS, Dyrskjøt L. **Optimized targeted sequencing of cell-free plasma DNA from bladder cancer patients.** Sci Rep. 2018 Jan 30;8(1):1917. doi: 10.1038/s41598-018-20282-8. PMID: 29382943

Lelo A, Prip F, Harris BT, Solomon D, Berry DL, Chaldekas K, Kumar A, Simko J, Jensen JB, Bhattacharyya P, Mannion C, Kim JS, Philips G, Dyrskjøt L, Waldman T. **STAG2 Is a Biomarker for Prediction of Recurrence and Progression in Papillary Non-Muscle-Invasive Bladder Cancer.** Clin Cancer Res. 2018 Sep 1;24(17):4145-4153. doi: 10.1158/1078-0432.CCR-17-3244. Epub 2018 Jun 28. PMID: 29954776

RECOMMENDATION: If data or material from DCB is used in published research, this should always be stated in the Acknowledgements section: "Danish CancerBiobank (DCB) is acknowledged for biological material and for the data regarding handling and storage."

The indicator is difficult to measure, as Acknowledgements cannot be searched for in PubMed.

2. Danish Rheumatologic Biobank

2.1 Foreword

At least 75,000 Danes suffer from rheumatoid arthritis, psoriatic arthritis or spondyloarthritis. These are chronic diseases that cause pain, reduce functional status and work ability, lead to comorbidities (e.g. osteoporosis, cardiovascular disease, infection) and premature death. Since year 2000, new drugs, the so-called biological treatments, have led to great improvements in the treatment of patients with inflammatory arthritis. The treatments, however, are very expensive (about DKK 1 billion/year). Furthermore, among the approximately 3,000 arthritis patients who start treatment with biological drugs annually, 30-40% have insufficient effect or cannot tolerate the drug. This means that approximately 1,000 Danish arthritis patients each year start on ineffective or directly harmful medicines, which besides costing the taxpayers several hundreds of millions of Danish kroner also have great health costs for the individual patients.

The nationwide DANBIO database, a national research and quality database, was established in year 2000 and now contains clinical data on more than 60,000 patients with inflammatory arthritis. Data are collected prospectively in routine care at all the local departments of rheumatology.

With financial support from The Danish Rheumatism Association and Danish Regions, the Danish Rheumatologic Biobank (DRB) was established January 1, 2015, and the first blood sample was collected May 4, 2015. By the end of 2018, more than 13,000 blood samples have been collected. Along with the biological material, corresponding high quality clinical data is collected in DANBIO. This gives promising potential for Danish research in the field of personal medicine: how to diagnose early and optimize treatment strategies for the individual patient with inflammatory arthritis. Results from a research project carried out on material collected and registered in DRB thus supported that switching from original to biosimilar infliximab (CT-P13), which has resulted in a large economic saving, could be done safely.

DRB is a clinical biobank suitable for research. Thus, patients are requested to give informed patient consent for specific research projects within inflammatory arthritis. Patient consent is registered in DANBIO and in the biobank register together with the project name. Biological material is handed out for the project when requested.

Sample collection takes place in close collaboration between the local departments of rheumatological and clinical biochemistry.

On behalf of the Scientific Advisory Board for Danish Rheumatologic Biobank
The members of the Scientific Advisory Board can be seen in appendix 6.2.1

2.2 Overview of DRB, 2016-2018

In 2018, blood material was collected from 2,133 unique patients, which is a decrease compared to 2017 (figure 1.2.1). Patients who are willing to donate samples to the biobank are recruited as part of routine care. Various obstacles (e.g. introduction of new electronic software in the clinics, increasing legal demands) might potentially have reduced the speed of approval of new projects and thus a slight decrease in the number of unique patients and collected samples.

The collection of synovial fluid started in 2017, and in 2018, 38 synovial fluid materials were collected from 22 patients.

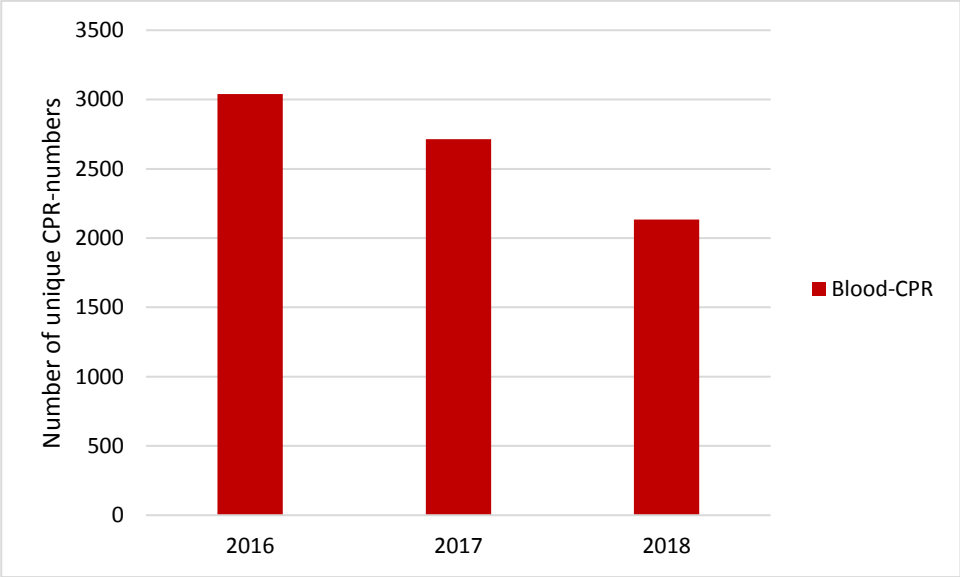

Figure 2.2.1. **Number of unique CPR numbers in DRB, 2016-2018**. The figure shows the number of unique CPR numbers (patients), who have donated blood material in each year from 2016-2018.

Figure 2.2.2 shows the collection of blood material from patients throughout 2018. The figure shows fluctuations in the collection over time with approximately 200-300 samples being collected monthly. Uncertainty regarding funding in the start of the year may have influenced recruitment rate.

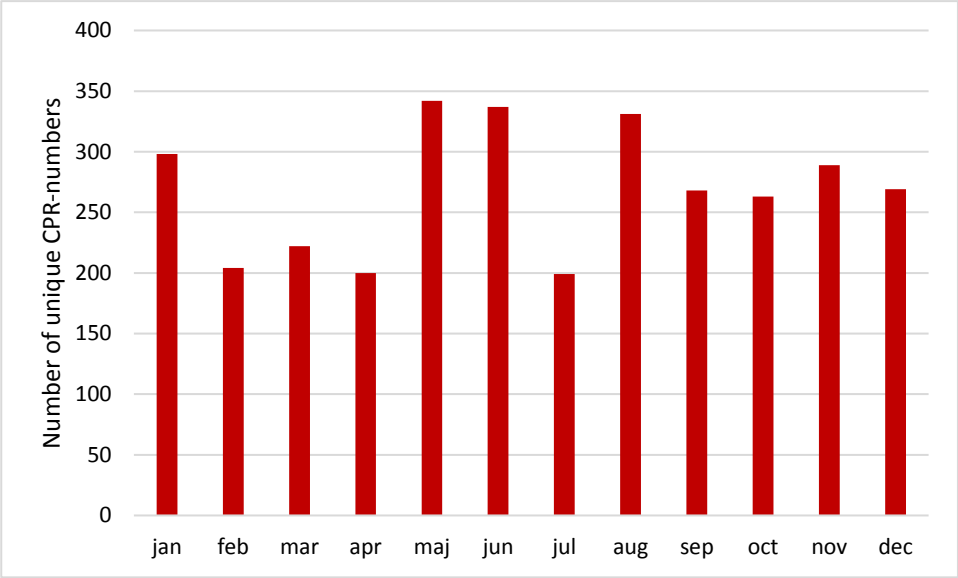

Figure 2.2.2. Collection of material from unique patients in 2018. The figure shows the number of unique CPR-numbers that have donated blood material to DRB each month during 2018.

The collection of blood material from unique patients is nearly the same for center Glostrup and Odense in 2018 compared to 2017, whereas the collection in center Aarhus has increased (figure 2.2.3). Center Gråsten maintains a high inclusion of patients, although a decline since 2017 is observed. This can be partly explained by the inclusion of nearly all rheumatological patients in the large national research project 'The Biomarker Protocol'. New projects are starting in 2019, which is expected to affect sample collection positively. Center Hjørring has had a significant decline in the number of patients. This is partly due to high workload in the clinic which affects resources to include new patients. More staff has been allocated to the biobank, and collection is therefore expected to increase in 2019. Center Næstved has only collected blood from 11 patients in 2018. New local procedures and an expansion of the regional biobank infrastructure have been implemented and the inclusion of samples are expected to increase in 2019.

The collection of material from unique patients from each department in a center is shown in table 2.2.1. The sum of unique patients from all departments in a center is for some centers higher than the sum for the center. This shows that some patients donate material to more than one department in a center.

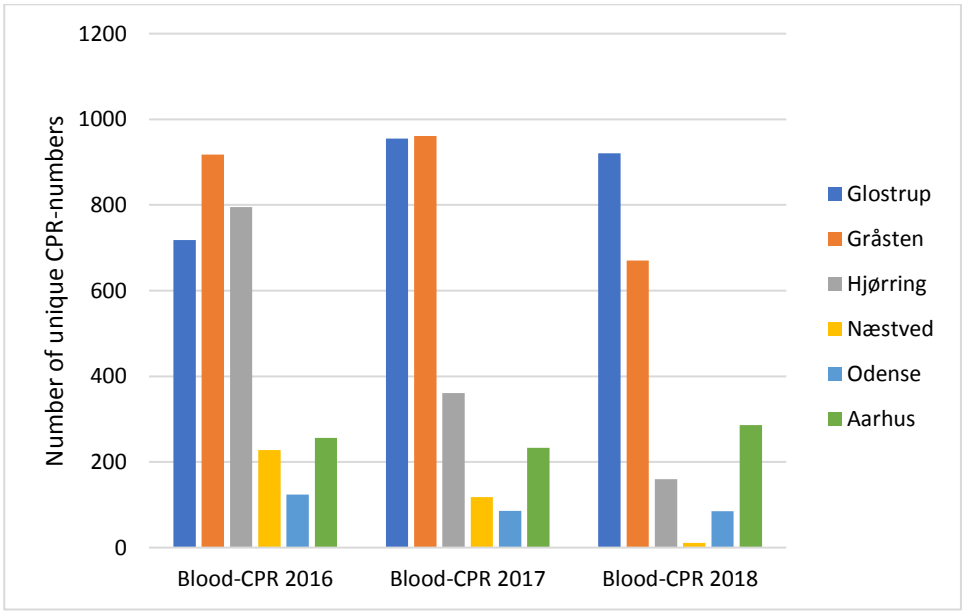

Figure 2.2.3. Number of unique CPR numbers per center, 2016-2018. The figure shows the number of unique CPR numbers (patients) that have donated blood in the six biobank centers in DRB for each year from 2016-2018.

	Number of blood-CPR	Number of synovial fluid-CPR
Glostrup Rheumatologic Biobank Center		
Clinical Immunology Department, Blood Bank, Rigshospitalet	203	
Clinical Biochemistry Department, Gentofte	240	
Clinical Biochemistry Department, Glostrup	406	22
Clinical Biochemistry Department, Bispebjerg and Frederiksberg	66	
Clinical Immunology Department, North Zealand Hospital, Hillerød	8	
Gråsten Rheumatologic Biobank Center		
Danish Hospital for Rheumatic Disease	413	
Clinical Biochemistry, Laboratory Center, Vejle Hospital	257	
Hjørring Rheumatologic Biobank Center		
Clinical Biochemistry Department, Aalborg University Hospital	106	
Clinical Biochemistry Department, Vendsyssel Hospital	55	
Næstved Rheumatologic Biobank Center		
Clinical Biochemistry Department, Køge	11	
Odense Rheumatologic Biobank Center		
Clinical Biochemistry and Pharmacology Department, Odense University Hospital	43	
Clinical Biochemistry Department, Svendborg	43	
Aarhus Rheumatologic Biobank Center		
Blood Test and Biochemistry NBG, Aarhus University Hospital	250	
Blood Test and Biochemistry PJJ, Aarhus University Hospital	22	
Molecular Medicine Department, Skejby	1	
Rheumatology Department, Aarhus University Hospital	57	
Clinical Biochemistry Department, Randers Regional Hospital	5	
Clinical Biochemistry Department Silkeborg, Central Hospital Unit	1	
Central Laboratory, Horsens Hospital Unit	5	

Table 2.2.1. Number of unique CPR numbers per sample collecting department, 2018. The table shows the number of unique CPR numbers per sample collecting department in 2018.

A total of 3,446 blood materials were collected in 2018, representing a decrease compared to 2017 (figure 2.2.4). This is primarily caused by to a decline in collection of material from center Gråsten, Hjørring and Næstved (figure 2.2.5). Center Glostrup, Odense and Aarhus have slightly increased their collection of blood. In addition, center Glostrup has collected 38 synovial fluid materials in 2018 (compared with 23 in 2017).

The number of materials exceeds the number of unique CPR numbers, which shows that the same patient donated material than several times. This reflects that for some scientific projects there is a focus on collecting samples over the course of a patient's disease and/or treatment.

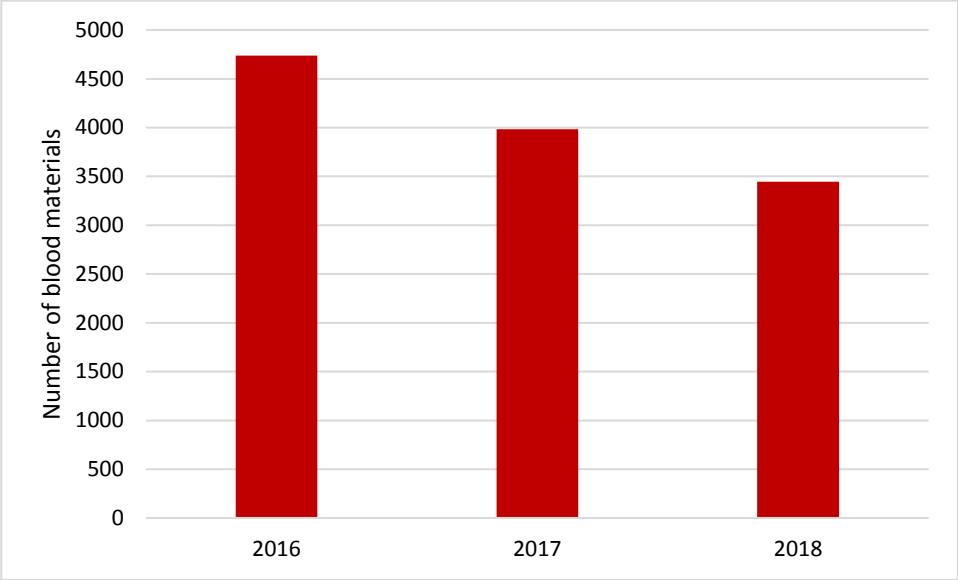

Figure 2.2.4. Number of blood materials in DRB, 2016-2018. The figure shows the number of blood materials collected in DRB in each year for 2016-2018.

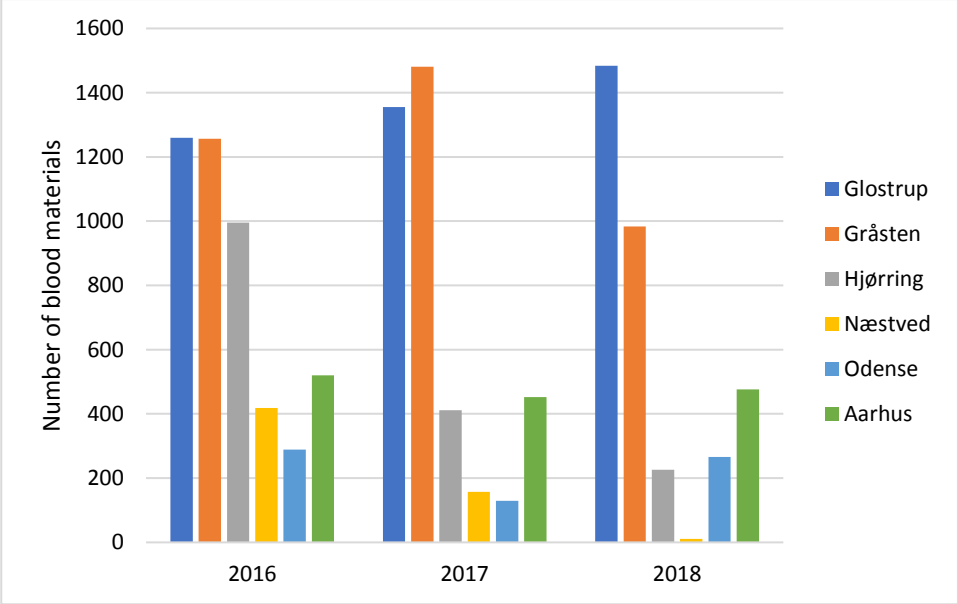

Figure 2.2.5. Number of blood materials per center, 2016-2018. The figure shows the number of blood materials that have been collected in each center for each year from 2016-2018.

2.3 Indicators, DRB

2.3.1 Indicator 1: Handling of Material

It is crucial that all fractions in the biobank have a freezer position, as this makes it possible to retrieve the material. This indicator is measured as the percentage of all fractions that have a freezer position. Fractions that have been handed out are not included in the calculation, as these naturally do not have a freezer position.

In 2018, 31,729 blood fractions were collected and all but one of these fractions have been registered with a freezer position. The goal of this indicator, that 95% of all fraction should have a freezer position, is therefore fulfilled for all centers (table 2.3.1.1).

		Number of blood fractions	Number of blood fractions without freezer position	Percentage of blood fractions with freezer position
	2018			
National	**TOTAL**	**31,729**	**1**	**100**
Center	Glostrup	13,778	0	100
	Gråsten	9,321	0	100
	Hjørring	1,918	1	100
	Næstved	88	0	100
	Odense	2,567	0	100
	Aarhus	4,057	0	100
	.			
	2017			
National	**TOTAL**	**37,814**	**9**	**100**
Center	Glostrup	12,563	0	100
	Gråsten	15,018	0	100
	Hjørring	3,837	2	100
	Næstved	1,108	7	99
	Odense	1,221	0	100
	Aarhus	4,067	0	100
	.			
	2016			
National	**TOTAL**	**46,468**	**64**	**100**
Center	Glostrup	12,481	49	100
	Gråsten	12,593	0	100
	Hjørring	9,892	8	100
	Næstved	2,996	7	100
	Odense	2,884	0	100
	Aarhus	5,622	0	100
	.			

Table 2.3.1.1. Number of blood fractions with and without freezer position, 2016-2018. The table shows the number of blood fractions without a freezer position and the percentage of blood fractions with a freezer position, shown for each center from 2016-2018.

RECOMMENDATION: The goal of this indicator is fulfilled for all six biobank centers.
This result should be maintained in 2019 because a known freezer position is a prerequisite for retrieving samples.

2.3.2 Indicator 2: Sample Quality

The sample quality of the material collected in DRB is measured as the processing time, which is defined as the time between material retrieval from the patient until the material is placed in a freezer. To ensure the quality of the material for research the processing time should be as short as possible. For blood it is recommended that the processing time is less than 3 hours.

To clarify if a long processing time is due to a long transport time, the latter is also calculated. This is defined as the time between material retrieval from the patient until the material is received at the laboratory.

To ensure that the material is of the highest quality, the goal of this indicator is that 90% of the blood material should be processed within 3 hours.

The processing time for blood samples is calculated for all fractions excluding PAXgene tubes, as they require a longer process time. The process and transport time for PAXgene fractions are calculated separately. The time is calculated for each center and is shown as percentage of the fractions that have been processed within 3 hours (table 2.3.2.1).

All centers, except center Aarhus, meet the goal of the indicator with more that 90% of the fractions being processed within 3 hours (table 2.3.2.1). In center Aarhus, only 68% of the samples are processed within 3 hours. This is due to the infrastructure in the center, where samples are donated at one location and then transported for processing at another location. However, 80% had a transport time of less than 3 hours, (table 2.3.2.2) and almost all blood fractions were processed within 7 hours (appendix 6.2.2), which shows that the laboratories are working on keeping the processing time as short as possible. Center Aarhus is still encouraged to have an increased focus on reducing the processing time.

PAXgene fractions should upon receival be stored at room temperature for 2-72 hours, then frozen at -20°C for at least 24 hours and thereafter stored long term at -80°C. The processing time for PAXgene fractions is therefore longer than for other blood fractions and is therefore calculated separately.

The goal for the processing time for PAXgene fractions is that 90% of the fractions should be placed at -20°C within 72 hours. Unfortunately, as the registration system is designed today, it is not possible to retrieve data regarding the pre-freezing step at -20°C. The data for PAXgene fractions shown in table 2.3.2.1 is therefore calculated as the period from the sample is retrieved from the patient until it is transferred to -80°C. According to the manufacturer, PAXgene vials can be stored at -20°C for a long period of time without compromising sample quality. In some centers, PAXgene vials are therefore stored at -20 for more than 72 hours and then transferred to -80 in batches. The information shown in the table can thus only be used as a tendency.

73% of the PAXgene fractions are placed at -80°C within 72 hours after sample retrieval (table 2.3.2.1). These PAXgene fractions have then also been placed in a -20°C freezer within 72 hours. From this we can then deduce that at least 72% of the PAXgene fractions have been placed in a -20 °C freezer within the recommended 72 hours. All PAXgene fractions have been received at the laboratories within 72 hours (table 2.3.2.2).

The registration system must include information, so it is possible to retrieve data for when a PAXgene fraction is placed in the -20 °C freezer, so that the processing time for PAXgene fractions can be calculated correctly.

		Number of blood fractions	Percentage of blood fractions (n) ≤ 3 hours	Number of PAXgene fractions	Percentage of PAXgene fractions (n) ≤ 72 hours
	2018				
National	**TOTAL**	**27,974**	**90 (25,278)**	**3,755**	**73 (2,729)**
Center	Glostrup	12,111	92 (11,116)	1,667	79 (1,323)
	Gråsten	7,868	97 (7,620)	1,453	73 (1,056)
	Hjørring	1,809	97 (1,752)	109	56 (61)
	Næstved	88	100 (88)	0	-
	Odense	2,322	96 (2,234)	245	52 (127)
	Aarhus	3,776	68 (2,556)	281	58 (162)
	2017				
National	**TOTAL**	**31,985**	**92 (29,570)**	**5,829**	**74 (4,302)**
Center	Glostrup	11,034	94 (10,358)	1,529	82 (1,255)
	Gråsten	12,056	97 (11,703)	2,962	75 (2,224)
	Hjørring	3,280	99 (3,240)	557	40 (222)
	Næstved	960	90 (864)	148	100 (148)
	Odense	1,058	99 (1,049)	163	73 (119)
	Aarhus	3,597	65 (2,356)	470	71 (334)
	2016				
National	**TOTAL**	**37,310**	**95 (35,553)**	**9,122**	**77 (6,988)**
Center	Glostrup	9,973	96 (9,623)	2,499	80 (1,988)
	Gråsten	10,087	99 (9,981)	2,515	78 (1,971)
	Hjørring	7,906	99 (7,850)	1,978	58 (1,153)
	Næstved	2,568	83 (2,136)	428	100 (428)
	Odense	2,306	93 (2,146)	578	63 (366)
	Aarhus	4,470	85 (3,817)	1,124	96 (1,082)

Table 2.3.2.1. Processing time for blood, 2016-2018. The table shows the percentage and number (n) of blood fractions that have been processed within the recommended 3 hours, shown for each center from 2016-2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

		Number of blood fractions	Percentage of blood fractions (n) ≤ 3 hours	Number of PAXgene fractions	Percentage of PAXgene fractions ≤ 72 hours
	2018				
National	**TOTAL**	**27,974**	**96 (26,965)**	**3,755**	**100 (3,752)**
Center	Glostrup	12,111	98 (11,857)	1,667	100 (1,667)
	Gråsten	7,868	100 (7,868)	1,453	100 (1,453)
	Hjørring	1,809	100 (1,809)	109	100 (109)
	Næstved	88	100 (88)	0	-
	Odense	2,322	100 (2,313)	245	100 (245)
	Aarhus	3,776	80 (3,030)	281	100 (281)

Table 2.3.2.2. Transport time for blood, 2018. The table shows the percentage and number (n) of blood fractions that have been transported within the recommended 3 hours, shown for each center for 2018. The transport time is defined as the time between material retrieval from the patient until the material is received at the laboratory.

RECOMMENDATION: The goal of this indicator is met for four centers, but not for Næstved and Aarhus. With a new responsible center manager for DRB, already pointed out and the implemented new local procedures, Næstved are expected to fulfill the goal in 2019.
At center Aarhus samples are taken and handled at different departments, giving a long transport time. The center should focus on improving their transport time if possible.

2.3.3 Indicator 3: Coverage

In the guidelines for handling of material in DRB, a standard set for blood is defined. This is to ensure that there is enough material and different types of fractions to accommodate the needs in research and in routine care in the future. In 2016 the standard set in DRB contained 10 blood fractions as two PAXgene fractions were included. From 2017, PAXgene vials are no longer a part of the standard set, reducing the set to 8 fractions. The goal of this indicator is, that at least 90% of the collected blood material should contain the recommended 8 fractions.

In all centers, nearly all the collected blood materials contain 8 or more fractions and all centers therefore fulfil the goal of the indicator. For all centers this is the same as in 2017, except center Næstved, who have greatly improved their coverage in 2018. In 2017 and 2016 center Næstved did not collect whole blood as part of the standard set. From 2018, whole blood is included, which explains the increase in coverage.

In general, it is expected that only very few patients are not able to donate enough blood for a complete standard set and this should be seen in the coverage in all centers.

		Number of blood materials	Number of blood materials with ≥ 8 fractions	Coverage (%)
	2018			
National	**TOTAL**	**3,446**	**3,401**	**99**
Center	Glostrup	1,484	1,450	98
	Gråsten	983	983	100
	Hjørring	226	226	100
	Næstved	11	11	100
	Odense	266	265	100
	Aarhus	476	466	98
	2017			
National	**TOTAL**	**3,986**	**3,829**	**96**
Center	Glostrup	1,356	1,352	100
	Gråsten	1,481	1,481	100
	Hjørring	411	410	100
	Næstved	157	9	6
	Odense	129	129	100
	Aarhus	452	448	99
		Number of blood materials	**Number of blood materials with ≥ 10 fractions**	**Coverage (%)**
	2016			
National	**TOTAL**	**4,717**	**4,264**	**90**
Center	Glostrup	1,241	1,233	99
	Gråsten	1,209	1,206	100
	Hjørring	989	985	100
	Næstved	426	2	0
	Odense	289	286	99
	Aarhus	563	552	98

Table 2.3.3.1. Coverage for blood, 2016-2018. The table shows the number and percentage of blood materials that as a minimum have the recommended number of fractions, shown for each center from 2016-2018.

RECOMMENDATION: All centers fulfil the goal of this indicator with nearly all blood materials containing the recommended 8 fractions. This indicator should be followed closely for each center to ensure a continued high national coverage and adequate material for future research projects.

2.3.6 Indicator 6: Research

One of the purposes of DRB is to facilitate the collection of samples that can be used in research projects. In 2018, 2 new local and 3 new national projects (i.e. projects that include more than one biobank center) started collecting material through DRB. This means that there is now 6 local and 6 national projects registered in DRB (figure 2.3.6.1).

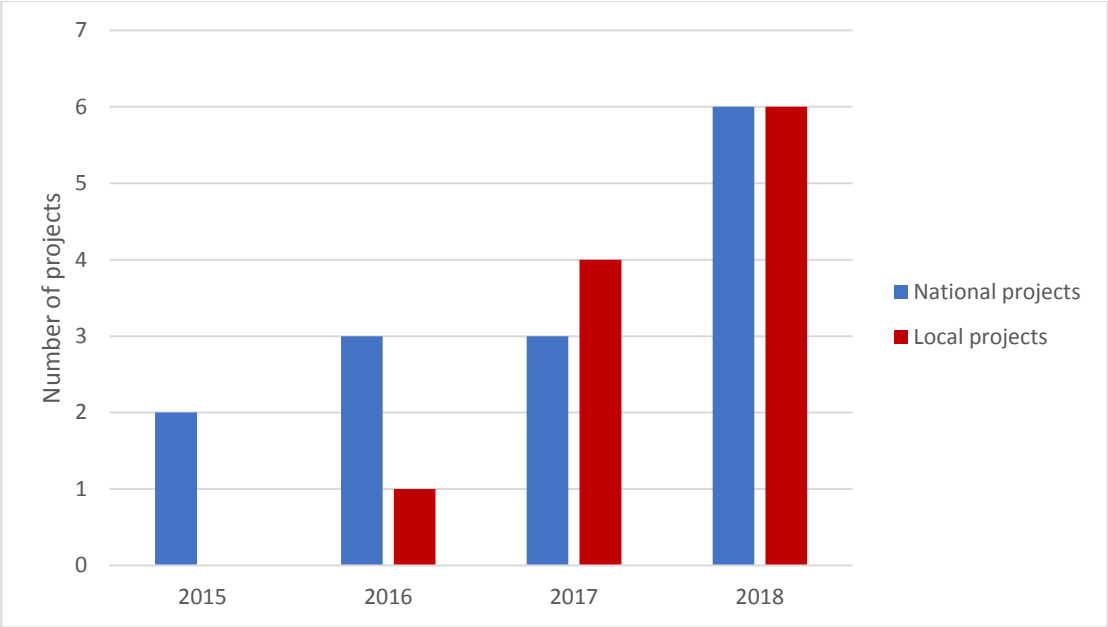

Figure 1.3.6.1. Number of research projects in DRB. The figure shows the number of national and local research projects in DRB accumulated for each year.

Bio- and Genome Bank Denmark is an infra-structure that facilitates research and collaboration within the field of inflammatory arthritis. In 2018, 94 blood fractions were retrieved to a project entitled 'Investigation of biomarker using mass spectrometry´ - a project under the biomarker protocol (table 2.3.6.1).

The whole process of retrieving the material was handled within the recommended timeframe, which is one month.

As more research projects finish their collection of material in the coming years, sample retrieval is expected to increase. All centers should have high focus on spreading the knowledge about DRB and its materials to increase material retrieval.

	2018	Number of blood fractions	Number of handed out fractions	Percentage
National	**TOTAL**	**31,729**	**94**	**0.3**
Center	Glostrup	13,778		
	Gråsten	9,321		
	Hjørring	1,918	94	5
	Næstved	88		
	Odense	2,567		
	Aarhus	4,057		
	2017			
National	**TOTAL**	**37,814**	**1,497**	**4**
Center	Glostrup	12,563	1,497	12
	Gråsten	15,018		
	Hjørring	3,837		
	Næstved	1,108		
	Odense	1,221		
	Aarhus	4,067		
	2016			
National	**TOTAL**	**46,437**	**1,445**	**3**

Table 2.3.6.1. Number of blood fractions that have been handed out to research projects, 2016-2018. The table shows the number of blood fractions that have been handed out to research projects shown for each center from 2016-2018.

RECOMMENDATION: Material in the biobank is of high quality and can be very useful for researchers who are working to improve treatment and diagnosis of patients with rheumatological diseases. All centers should have an increased focus on spreading the knowledge about the biobank and its material to have more materials used in research projects.

2.3.7 Indicator 7: Clinical Data

For the optimal use of the material in DRB, clinical data, consent to scientific project, diagnosis, antirheumatic treatment, disease activity and disease status should be available in relation to sampling of the biological material. Clinical data on rheumatological patients is registered in the clinical registry, DANBIO. Clinical data from DANBIO has been processed by the secretariat of DANBIO and linked to the biobank samples.

Most patients in DANBIO with material in DRB have given informed consent to the national scientific project 'The biomarker protocol' (table. 2.3.7.1.). The consent is registered in the biobank register and in DANBIO, and on request the samples are delivered to the project. An overview of the number of patients with consent to 'The biomarker protocol' or other projects in DRB is shown in figure 2.3.7.2.

	2018	Number of patients with consent to 'The biomarker protocol'	Number of patients with consent to other protocols
National	**TOTAL**	**1,444**	**642**
Hospital	Rigshospitalet	0	201
	Frederiksberg	27	39
	Gentofte	201	20
	Glostrup	318	95
	Køge	1	0
	Svendborg	31	12
	Odense	14	29
	Gråsten	390	23
	Vejle	250	0
	Århus	134	143
	Randers	5	0
	Ålborg	23	80
	Hjørring	50	0

Table 2.3.7.1. Number of patients with samples in DRB who have a registered consent to the biomarker protocol or other protocols in DANBIO, per hospital for 2018. The table shows the number of patients with samples in DRB who have a registered consent in DANBIO to either the biomarker protocol or other protocols. Data is shown for all hospitals in DRB from 2018.

Project	Number of patients with consent
BIOMARKER	1,444
ALOSTRA	31
ASIM	16
BIODOPT	66
DOBIS	102
FLARA	<10
NORDCAN	<10
NORDSTAR	85
RACTX	87
SLE-GEIST	233
Other projects	<10

Table 2.3.7.2. Number of patients with registered consent to scientific projects according to DANBIO, 2018. The table shows the protocols in DANBIO and the number of patients with registered consent to each protocol in 2018.

Patients may donate material several times, and for more than half the patients two or more samples are stored in the biobank (table 2.3.7.3).

		One sample	Two samples	First sample in 2018	2+ samples from 2018
National	**TOTAL**	**4,099**	**2,122**	**1,115**	**150**
Hospital	Rigshospitalet	216	33	200	2
	Frederiksberg	180	39	43	11
	Gentofte	380	99	169	2
	Glostrup	664	600	105	51
	Køge	54	197	0	0
	Svendborg	6	97	6	3
	Odense	16	55	29	0
	Gråsten	963	343	176	47
	Vejle	463	162	136	18
	Aarhus	134	305	123	16
	Randers	0	7	0	0
	Aalborg	55	95	89	0
	Hjørring	968	90	39	0

Table 2.3.7.3. Number of patients have donated material once or twice in total and in 2018. The table shows the number of patients that have donated material once or twice to 'The biomarker protocol' or other protocols since collection started. The table also shows how many of these sample were donated in 2018 – both the first and the second sample.

Information about rheumatic disease and treatment is registered in DANBIO (table 2.3.7.4 and table 2.3.7.5). Only 1% of the samples have no diagnosis registered and information about treatment is registered for all patients.

Diagnosis	Number of blood samples	All Samples	Percentage of total
Rheumatoid arthritis	1,538	3,317	46
Axial spondyloarthritis	1,032	3,317	31
Psoriatic arthritis	351	3,317	11
Other forms af Arthritis	81	3,317	2
Systemic Lupus erythe-	241	3,317	7
Other	36	3,317	1
Unknown	38	3,317	1

Table 2.3.7.4. Number of blood samples categorized by diagnosis, 2018. The table shows the number of blood samples registered under each diagnosis in DANBIO in 2018.

Type of treatment	Number of blood samples	All Samples	Percentage of total
bDMARD (total)	2,215	3,317	67
bDMARD (mono)	1,209	3,317	38
bDMARD + csDMARD	1,006	3,317	30
Only csDMARD	382	3,317	12
No treatment	720	3,317	22

Table 2.3.7.5. Number of blood samples categorized by treatment, 2018. The table shows the number of blood samples registered under each treatment in DANBIO in 2018.
Abbreviations: bDMARD: biologic disease modifying drug, csDMARD: conventional synthetic disease modifying drug

To increase the applicability of the blood samples in research context, it is important that the blood samples are linked to information about the patient's current disease activity. These data consist partly of the patient's own registration of patient reported outcomes via touch screens in the rheumatology department's waiting rooms (e.g. the patient's global score on a visual analogue scale (VAS)), and of the doctor's registration of disease activity (e.g. number of swollen and sore joints) and paraclinical data (C-reactive protein). Thereby, a combined measurement of the patient's disease activity can be calculated (e.g. CDAI or ASDAS depending on the diagnosis).

Information about patient reported outcomes and the patient VAS global is available for over 80% of the blood samples in 2018 (table 2.3.7.6), and disease activity in nearly 80% of the samples. It is important to continue with the high level of registration of disease activity in DANBIO as it increases the quality and applicability of the samples in DRB.

Disease registration group	Number of blood samples	All Samples	Percentage of total
Patient reported outcomes available	2,740	3,317	83
Patient VAS Global available	2,812	3,317	85
Disease activity (CDAI/ASDAS) available*	2,359	3,076	77

*Patients with systemic lupus erythematosus are not included in the calculation of this variable.

Table 2.3.7.6. Number of blood samples with registration of disease activity, 2018. The table shows the number of blood samples were disease activity has been registered in DANBIO in 2018. The percentages are calculated for each type of available information.

2.3.8 Indicator 8: Sharing of Knowledge

DRB facilitates an increasing number of research projects with collection of biological material. Therefore, an increase in the number of published articles is expected, in which DRB is stated as affiliation by authors or is mentioned in the "Acknowledgements" section for the handling of the material. Unfortunately, it is not possible to search for acknowledgments in PubMed, which makes it hard to identify which research groups have currently published studies based on material from DRB. The manuscripts that we have knowledge of for 2018 are listed below.

It is important to remind researchers to state DRB in the Acknowledgments section to increase the awareness of the biobank and the work that is done. Researchers are encouraged to notify the secretariat regarding newly published articles, which are based on biobank material. These will be included in the RBGB newsletter, posted on the website etc.

The secretariat for RBGB also contributes with the sharing of knowledge via newsletters, the annual report, the RBGB website and presentations at various conferences. In addition, data from RBGB is submitted to The Danish Biobank Register at Statens Serum Institut every year. This allows researchers to search for general information about the materials in RBGB.

Publications, 2018:

Kringelbach TM, Glintborg B, Hogdall EV, Johansen JS, Hetland ML; Biomarker Protocol Study Group. **Identification of new biomarkers to promote personalised treatment of patients with inflammatory rheumatic disease: protocol for an open cohort study**. BMJ Open. 2018 Feb 1;8(2):e019325. doi: 10.1136/bmjopen-2017-019325.

Glintborg B, Kringelbach T, Bolstad N, Warren DJ, Eng G, Sørensen IJ, Loft AG, Hendricks O, Hansen I, Linauskas A, Nordin H, Kristensen S, Lindegaard H, Jensen DV, Goll GL, Høgdall E, Gehin J, Enevold C, Nielsen CH, Krogh NS, Johansen JS, Hetland ML. **Drug concentrations and anti-drug antibodies during treatment with biosimilar infliximab (CT-P13) in routine care.** Scand J Rheumatol. 2018 Sep;47(5):418-421.

RECOMMENDATION: If data or material from DRB is used in published research, this should always be stated in the Acknowledgements section: “The Danish Rheumatologic Biobank (DRB) is acknowledged for biological material and for the data regarding handling and storage.”

The indicator is difficult to measure, as Acknowledgements cannot be searched for in PubMed.

3. Danish Blood Donor Biobank

3.1 Foreword

Danish Blood Donor Biobank (DBB) was established as part of Bio- and Genome Bank Denmark in January 2017 and consists of samples collected for the Danish Blood Donor Study (DBDS). DBDS was established in 2010 as a collaboration between the blood banks in Central Region Denmark and the Capital Region. In 2012, North Denmark Region and Region Zealand joined the effort, and from 2015 the study has been nationwide, as Southern Region of Denmark also followed suit. DBDS is based on the infrastructure of the Danish blood banks and on the philanthropic participation of Danish blood donors. In total, DBDS has collected blood samples from more than 100,000 donors nationally.

DBDS is a nationwide research platform based on healthy blood donors. The study includes basic lifestyle and health questionnaire data, access to registry data, and consecutive blood samples from each blood donation. The idea of the study is to contribute to health promotion and help Danish patients by creating a national resource for research in public health, causes of illness, diagnosis and treatment. DBDS expects to be the largest cohort of healthy people in Denmark. While these individuals are healthy enough to donate blood, they may develop diseases over time. DBDS is therefore a source for the study of early biomarkers of disease (early disease detection).

Samples collected for DBB are now a part of RBGB's national infrastructure, thereby ensuring systematic and structured national collection and storage of blood samples.

Blood banks from all five regions contribute with staff who daily recruit and register blood donors, draw material and collect for biobanks. There is also access to databases of selected phenotypes of the donors.

All blood samples collected in DBB are processed to give one fraction of whole blood and one fraction of purified DNA. The purification of DNA takes place in batches 2-4 times a year and therefore it can take up to 6 months from a blood sample is donated until it is purified. All fractions are assigned 2D bar codes, and then imported into the RBGB registration system. Data on blood samples donated in the different regions are collected in a database stored in Computerome (COme) before being imported into the RBGB registration system. This is to ensure alignment of data from the different regions and thereby import of correct data to the RBGB registration system.

On behalf of the Scientific Advisory Board for Danish Blood Donor Biobank
The members of the Scientific Advisory Board can be seen in appendix 6.3.1

3.2. Overview of DBB, 2017-2018

In 2018 blood from 26,627 unique donors (CPR numbers) has been collected. This is an increase in donors compared with 2017, indicating that DBB has established a good and effective inclusion of donors through its first two years of existence (figure 3.2.1).

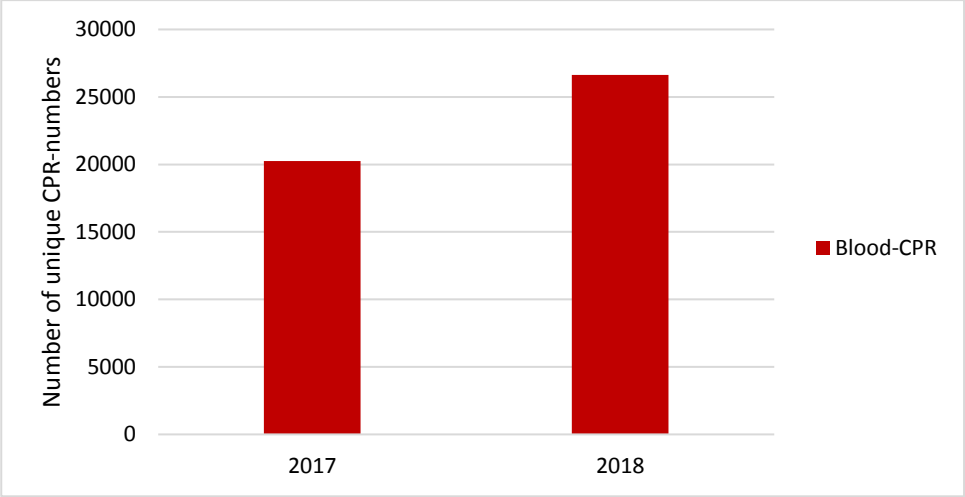

Figure 3.2.1. Number of unique donors in DBB, 2017-2018. The figure shows the number of unique CPR numbers (donors) that have donated blood to DBB for each year in 2017-2018.

Figure 3.2.2 shows the collection of blood material from donors throughout the year 2018. The figure shows that there are fluctuations in the collection throughout the year. It is also clear that collection has increased significantly in June and this is due to implementation of a new DBDS questionnaire and thereby increased focus on patient inclusion. The sum of unique CPR numbers in each month is larger than the sum of the entire year, reflecting that some donors donate blood several times.

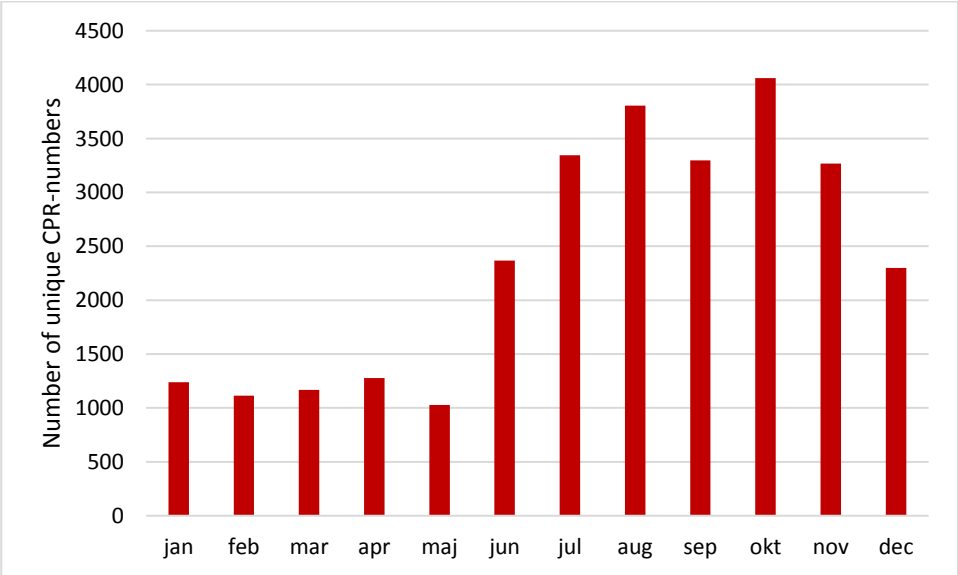

Figure 3.2.2. Collection of material from unique donors throughout the year, 2018. The figure shows the number of unique CPR numbers (donors) that have donated blood to DBB each month during 2018.

Blood samples for DBB are collected from all five regions in Denmark. Due to different populations in the five regions there is a difference in the number of donors included from each region. This is seen in figure 3.2.3, which shows that the Capital Region has the largest inclusion number and the Region of Southern Denmark the smallest. In general, all five regions have increased the inclusion of donors to DBB, compared to 2017.

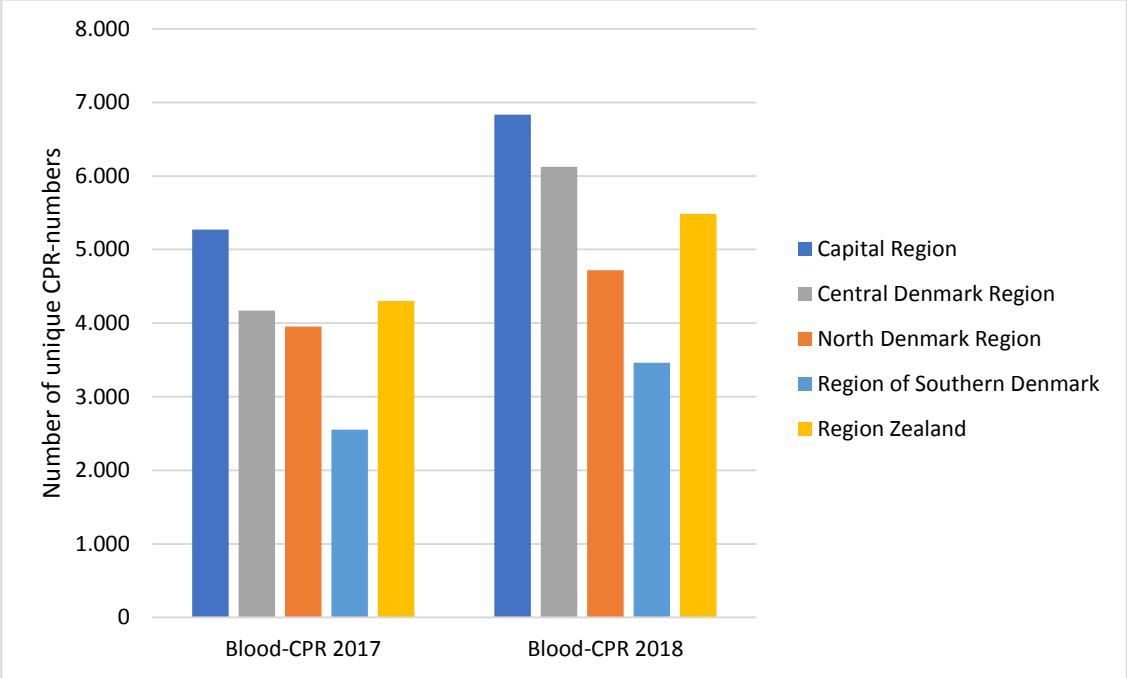

Figure 3.2.3. Number of unique donors per region, 2017-2018. The figure shows the number of unique CPR numbers (donors) that have donated blood to DBB in each of the five Danish regions for each year from 2017-2018.

In 2018, 28,722 blood materials were donated to DBB, which is an increase of 29% compared to 2017 (figure 3.2.4). This increase is observed in all five regions (figure 3.2.5). This shows that the collection of material to DBB has been well established throughout the country.

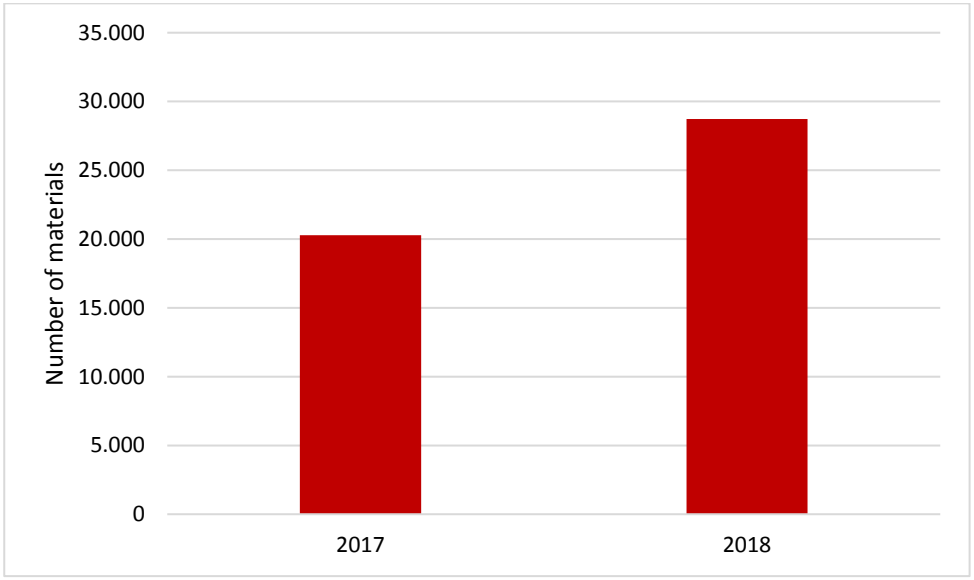

Figure 3.2.4. Number of blood materials in DBB, 2017-2018. The figure shows the number of blood materials collected in DBB for each year in 2017-2018.

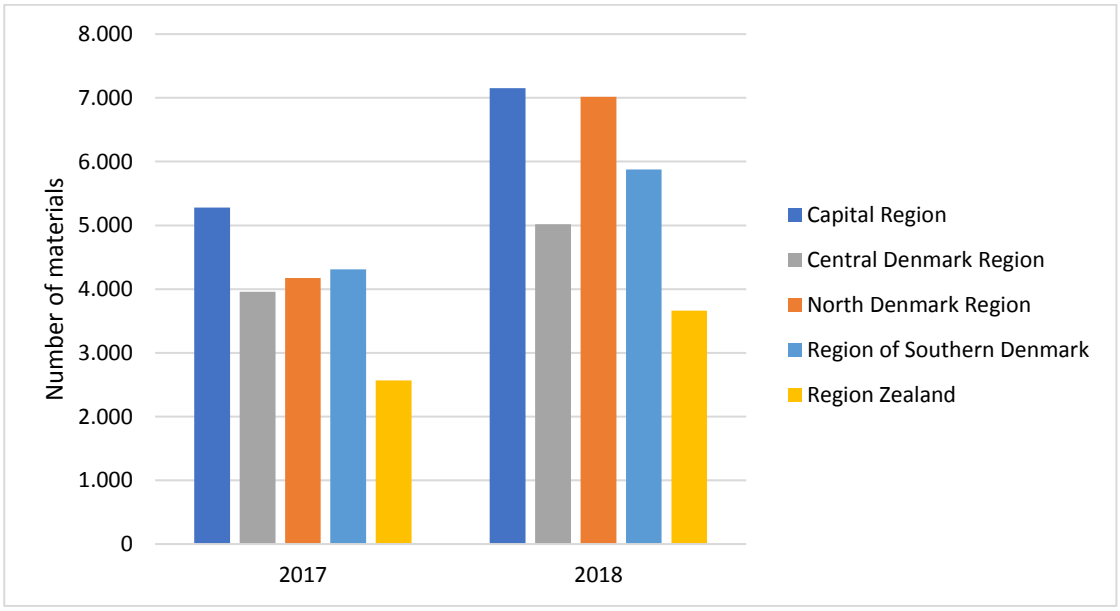

Figure 3.2.5. Number of blood materials per region, 2017-2018. The figure shows number of blood materials that have been collected in DBB in each of the five Danish regions for each year from 2017-2018.

3.3. Indicators, DBB

3.3.1 Indicator 1: Handling of Material

In 2017, only one whole blood fraction was registered in DBB from each patient, therefore the number of blood fractions in 2017 is equal to the number of materials. In 2018, it was decided to collect both whole blood and plasma fraction, whenever possible, and therefore, the number of fractions in 2018 is much higher than the number of materials (table 3.3.1.1).

It is crucial that all fractions in the biobank have a freezer position, as this makes it possible to retrieve and thereby hand out the material. This indicator is measured as the percentage of all fractions that have a freezer position.

In 2018, 52,755 blood fractions were registered, and all were placed in a freezer. The same was the case in 2017. All regions therefore fulfill the goal of this indicator, that recommends that 95% of all fractions should be registered with a freezer position (table 3.3.1.1).

		Number of blood fractions	Number of blood fractions without freezer position	Percentage of blood fractions with freezer position
	2018			
National	**TOTAL**	**52,755**	**0**	**100**
Center	Capital Region	14,050	0	100
	Central Denmark Region	12,942	0	100
	North Denmark Region	9,998	0	100
	Region of Southern Denmark	11,648	0	100
	Region Zealand	4,117	0	100
	.			
	2017			
National	**TOTAL**	**20,286**	**0**	**100**
Center	Capital Region	5,280	0	100
	Central Denmark Region	4,176	0	100
	North Denmark Region	3,956	0	100
	Region of Southern Denmark	4,307	0	100
	Region Zealand	2,567	0	100
	.			

Table 3.3.1.1. Number of blood fractions with and without freezer position, 2017-2018. The table shows the number of blood fractions without freezer position and the percentage of blood fractions with freezer position, shown for each region in from 2017-2018.

3.3.3 Indicator 3: Coverage

In 2018, both whole blood and plasma fractions were collected from the donor if possible. This increases the applicability of the material. This indicator measures the number of donors, who have had both a whole blood and a plasma fraction registered in DBB.

All regions, except the Region of Southern Denmark, have registered both whole blood and plasma for over 60% of the donors. The Region of Southern Denmark should focus on collecting both fractions from their donors as this increases the value and applicability of the material. As this is a new indicator for DBB no goal has been set for the indicator.

		Number of unique CPR (donors)	Percentage of donors with whole blood and plasma (n)	Percentage of donors with only whole blood (n)	Percentage of donors with only plasma (n)
	2018				
National	**TOTAL**	**26,627**	**61 (16,200)**	**16 (4,267)**	**23 (6,160)**
Region	Capital Region	6,835	68 (4,639)	15 (999)	18 (1,197)
	Central Denmark Region	6,127	68 (4,184)	3 (195)	29 (1,748)
	North Denmark Region	4,718	69 (3,276)	0.3 (14)	30 (1,428)
	Region of Southern Denmark	5,486	69 (3,793)	1 (48)	30 (1,645)
	Region Zealand	3,461	9 (308)	87 (3,011)	4 (142)

Table 3.3.3.1. Percentage and number (n) of donors that have both whole blood and plasma or only one of the two, 2018. The table shows the percentage and number of donors where both whole blood and plasma, only whole blood or only plasma has been collected in DBB. Data is shown for each region and for the year 2018.

3.3.6 Indicator 6: Research

As DBB collects material from donors that participate in DBDS, it is expected that a large amount of the material in DBB is retrieved for research projects.

In 2017, 5,748 DNA fractions from blood samples were retrieved for the GWAS project.
In 2018, 84,000 samples were sent to deCODE in Island for whole genome sequencing.

7 new PhD projects have started in 2018 using material from DBB. It is therefore expected that several papers were DBB material has been used for the research will be published in the next couple of years.

3.3.7 Indicator 7: Phenotypic Data

In 2018, 12,862 female and 13,765 males donated blood to DBB. A blood donor in Denmark may donate blood from the age of 17 until the age of 70, and as can be seen in figure 3.3.7.1 all age groups are well represented.

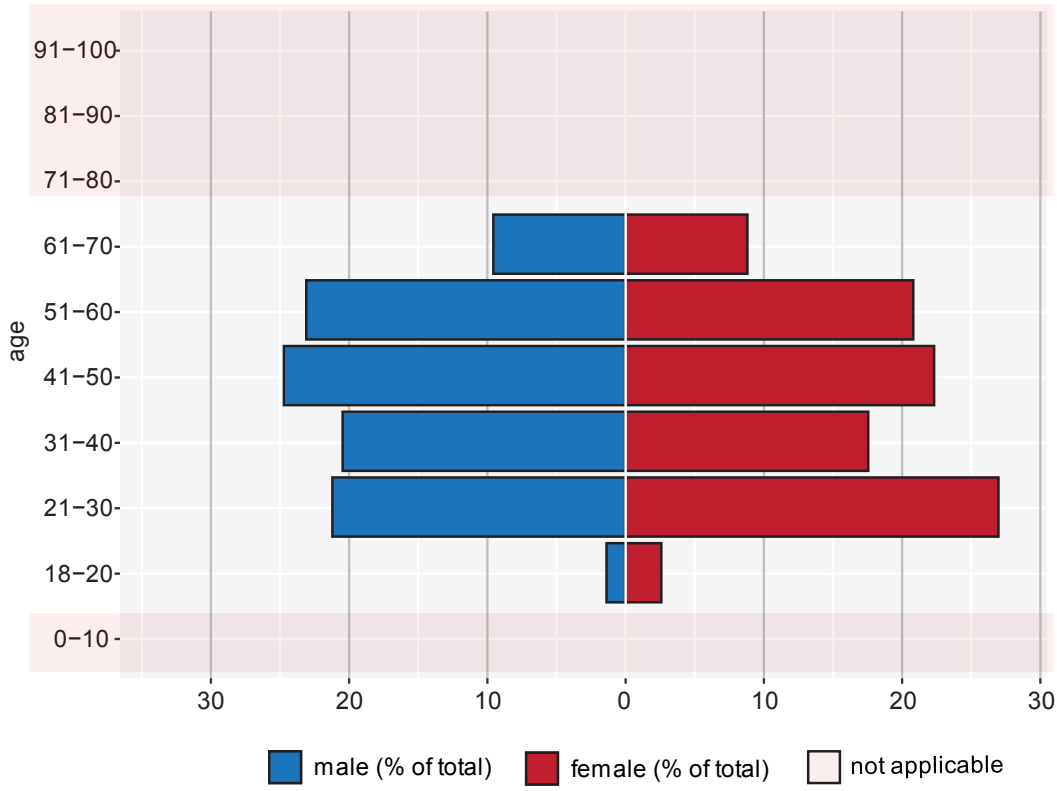

Figure 3.3.7.1. Population distribution by age and gender for donors in DBB in 2018. The figure shows the distribution of age and gender of the donors who have donated material to DBB in 2018.

For the optimal use of the material in DBB phenotypic data needs to be coupled with the samples. Every donor included in DBDS answers a questionnaire with a series of questions regarding both physical and mental health.

A few general data from the questionnaires are presented here. During 2018, DBDS switched questionnaire from DBDS 2 to DBDS 3. Data from DBDS 3 has not yet been analyzed, therefore only data from donors that have answered DBDS 2 is shown.

A total of 5,377 donors answered the questionnaire: 2,932 females and 2,445 males. In the questionnaire the donor is asked to supply information about weight and height from which the Body Mass Index (BMI) can be calculated (table 3.3.7.2).

Gender	Number of donors with information about height and weight*	Average BMI
Female	2917	25.46
Male	2444	25.98

*Donors under the age of 18 were not included in the calculation since data regarding height or weight were missing

Table 3.3.7.1. The average BMI of donors in DBDS 2, 2018. The table shows the average BMI of the donors in DBDS 2 from 2018. The BMI was calculated for female and male donors separately.

The donors are also asked about smoking habits in the questionnaire. Slightly more male than female donors are smokers (table 3.3.7.3), but both are lower than the average of the country, which is to 23% (Danskernes Rygevaner, 2018 – Sundhedstyrelsen, Kræftens Bekæmpelse, Hjerteforeningen og Lungeforeningen). This fits with the knowledge that blood donors in general are healthier than the average population.

Sex	Number of donors with information about smoking	More than 1/day	Less than 1/day	Percentage of donors smoking
Female		251	112	11
Male		204	115	13

Table 3.3.7.3. The percentage of donors smoking in DBDS 2, 2018. The table shows the percentage of donors smoking in DBDS 2 in 2018 and if they smoke more or less than 1 cigarette/cheroot/pipe per day. The data is shown for female and male donors separately.

3.3.8 Indicator 8: Sharing of Knowledge

DBB facilitates many research projects with collection of material. Therefore, an increase in the number of published articles must be expected, in which DBB is stated at least at the "Acknowledgments" section for the handling of the material. Unfortunately, it is not possible to search for acknowledgments in PubMed, which makes it hard to identify which research groups have currently published studies based on material from DCB. The manuscripts that we have been reported for 2018 are listed below.

It is still important to remind researchers to state DBB in the Acknowledgments section to increase the awareness of the biobank and the work that is done. Researchers are encouraged to notify the secretariat regarding newly published articles, which are based on biobank material. These will be included in the RBGB newsletter, posted on the website etc.

The secretariat for RBGB also contributes with the sharing of knowledge via newsletters, the annual report, the RBGB website and presentations at various conferences. In addition, data from RBGB is transferred to Denmark's National Biobank at Statens Serum Institut every year. This allows researchers to search for few general information about the materials in RBGB.

Publications, 2018:

Comorbidity of migraine with ADHD in adults, Oct. 2018

Transmission of rheumatoid arthritis through blood transfusion: a retrospective cohort study, Oct. 2018

Epidemiology of chronic red-cell transfusion recipients in Sweden and Denmark-a 10 year follow-up study, Sept. 2018

Alcohol consumption in adolescence is associated with a lower risk of multiple sclerosis in a Danish cohort, Aug. 2018

Prevalence of patients with self-reported hidradenitis suppurativa in a cohort of Danish blood donors: a cross-sectional study, Jul. 2018

Calcium in drinking water: effect on iron stores in Danish blood donors-results from the Danish Blood Donor Study, Jun. 2018

Blood parameters in a population of blood donors are not affected by hidradenitis suppurativa, Jun. 2018

Restless legs syndrome is associated with major comorbidities in a population of Danish blood donors, May 2018

Attitudes of stakeholders in psychiatry towards the inclusion of children in genomic research, Mar. 2018

The association of IgA deficiency on infection rate, self-perceived health, and levels of C-reactive protein in healthy blood donors, Mar. 2018

Storage time of platelet concentrates and risk of a positive blood culture: a nationwide cohort study, Jan. 2018

4. Definitions

Biobank: A structured collection of human biological material available according to specific criteria and where information bound in the biological material can be attributed to individuals.
Indicator: A measurable variable used to monitor and evaluate quality of the material in the biobanks

5. Abbreviations

BMI: Body Mass Index
DANBIO: Danish Rheumatologic Database
DBB: Danish Blood Donor Biobank
DBDS: The Danish Blood Donor Study
DCB: Danish Cancer Biobank
DRB: Danish Rheumatologic Biobank
DMCG: Danish Multidisciplinary Cancer Group
DACG: Danish Anal Cancer Group
DBCG: Danish Breast Cancer Cooperative Group
DCCG: Danish Colorectal Cancer Group
DECV: Danish Esophagus Cardia Ventricle Cancer Group
DGCG: Danish Gynecological Cancer Group
DAHANCA: Danish Head-Neck Cancer Group
DLGCG: Danish Liver Bile duct Cancer Group
DLCG: Danish Lung Cancer Group
DMG: Danish Melanoma Group
DNOG: Danish Neuro Oncology Group
DSG: Danish Sarcoma Group
DPCG: Danish Pancreas Cancer Group
DAPHO: Danish Pediatric Hematology and Oncology
DUCG: Danish Urologic Cancer Group
DABLACA: Danish Blatter Cancer Committee
DAPROCA: Danish Prostate Cancer Committee
DARENCA: Danish Renal Cancer Committee
DATECA: Danish Testis Cancer Committee
DAPECA: Danish Penis Cancer Committee
RBGB: Bio- and Genome Bank Denmark
SSI: Statens Serum Institut

6. Appendix

6. 1 Danish Cancer Biobank

Name	Represents	Biobank center/Region
Chairman		
Henrik Krarup	The Region	The North Denmark Region
Members		
Wojciech Skovrider-Ruminski	Tissue	Herlev
Shoaib Afzal	Blood	Herlev
Vera Timmermans	Tissue	Rigshospitalet
Erik Sørensen	Blood	Rigshospitalet
Per Ibsen	Local department	The Capital Region of Denmark
Rikke Fléron	The Region	The Capital Region of Denmark
Jens Ole Eriksen	Tissue and Blood	Næstved
Birgite Meinicke	Local department	Region Zealand
Rasmus Christian Jørgensen	The Region	Region Zealand
Thomas Kristensen	Tissue	Odense
Marina Bjørling-Poulsen	Blood	Odense
Ivan Brandslund	Local department	The Region of Southern Denmark
Torben Frøstrup Hansen	The Region	The Region of Southern Denmark
Magnus Stougaard	Tissue	Aarhus
Charlotte Modin	Blood	Aarhus
Ida Elisabeth Holm	Local department	Central Denmark Region
Lars Dyrskjøt Andersen	The Region	Central Denmark Region
Louise Serup	Tissue	Aalborg
Anne-Bentzen-Petersen	Blood	Aalborg
Morten Johansen	Local department	The North Denmark Region
Julie Støve Bødker	Hematology	The North Denmark Region
Dorthe Linnemann	Patobank	The Capital Region of Denmark
Estrid Høgdall	RBGB	The Capital Region of Denmark

Appendix 6.1.1. Members of the Scientific Advisory Board for Danish CancerBiobank, 2018. The table shows the members of the Scientific Advisory Board for DCB, which organization they represent and which biobank or region they are from.

		Number of blood fractions	Percentage of fractions (n) 3-7 hours	Percentage of fractions (n) 7-12 hours	Percentage of fractions (n) 12-24 hours	Percentage of fractions (n) >24 hours
	2018					
National	**TOTAL**	**98,747**	**10 (9,748)**	**0.1 (126)**	**2 (2,200)**	**13 (12,830)**
Center	Herlev	18,373	15 (2,718)	1 (96)	2 (296)	1 (103)
	Næstved	7,455	1 (74)	0 (0)	0.3 (24)	2 (168)
	Odense	12,621	0.6 (32)	0 (0)	0.1 (16)	1 (96)
	Rigshospitalet	16,268	1 (200)	0 (0)	5 (846)	1 (178)
	Aalborg	9,951	2 (176)	0 (0)	0.1 (14)	1 (54)
	Aarhus*	20,049	28 (5,712)	0.1 (30)	5 (981)	1 (190)

*Only fractions which have status 'In freezer' together with the time for first placement in a freezer are included. For technical reasons fractions with status 'Freezing' (Nedfrysning) are omitted.

Appendix 6.1.2. Processing time for blood, 2018. The table shows the percentage and number (n) of blood fractions with a processing time over the recommended 3 hours for 2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

		Number of tissue fractions	Percentage of fractions (n) 1-3 hours	Percentage of fractions (n) 3-7 hours	Percentage of fractions (n) 7-12 hours	Percentage of fractions (n) 12-24 hours	Percentage of fractions (n) >24 hours
	2018						
National	**TOTAL**	**39,921**	**45 (18,010)**	**2 (846)**	**0.7 (269)**	**2 (645)**	**1 (512)**
Center	Herlev	10,135	50 (5,059)	5 (487)	0.5 (54)	2 (179)	3 (307)
	Næstved	6,544	69 (4,520)	0,3 (21)	0 (0)	0.5 (30)	2 (140)
	Odense	9,248	49 (4,517)	2 (156)	0 (0)	2 (194)	0.4 (14)
	Rigshospitalet	6,316	24 (1,544)	0.4 (24)	1 (52)	1 (60)	1 (38)
	Aalborg	3,202	12 (375)	0 (0)	0 (0)	0 (0)	0 (0)
	Aarhus	4,476	45 (1,995)	4 (158)	4 (163)	4 (182)	0.3 (13)

Appendix 6.1.2. Processing time for tissue, 2018. The table shows the percentage and number (n) of tissue fractions with a processing time over the recommended 1 hour for 2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

6.2 Danish Rheumatologic Biobank

Name	Represents	Biobank Center
Chairman		
Merete Hetland		Glostrup
Members		
Britt Corfixen	Laboratory	Glostrup
Inge Juul Sørensen	Clinic	Glostrup
Bente Glintborg	Local department	Glostrup
Charlotte Modin	Laboratory	Aarhus
Anne-Gitte Loft	Clinic	Aarhus
Jan Villadsen	Local department	Aarhus
Trine Frisgaard	Laboratory	Hjørring
Asta Linauskas	Clinic	Hjørring
Salmone Kristensen	Local department	Hjørring
Palle Lyngsie Pedersen	Laboratory	Næstved
Ole Vestager Pedersen	Clinic	Næstved
Bo Jannik Ejbjerg	Local department	Næstved
Charlotte Drachmann	Laboratory	Gråsten
Marina Bjørling-Poulsen	Laboratory	Odense
Hanne Lindegaard	Clinic	Odense
Oliver Hendriks	Local department	Gråsten
Lars Erik Kristensen	The Danish Rheumatism Association	
Estrid Høgdall	RBGB	

Appendix 6.2.1. Members of the Scientific Advisory Board for Danish Rheuma Biobank, 2018. The table shows the members of the Scientific Advisory Board for DCB, which organization they represent and which biobank or region they are from.

		Number of blood fractions	Percentage of blood fractions (n) 3-7 hours	Percentage of blood fractions (n) 7-12 hours	Percentage of blood fractions (n) 12-24 hours	Percentage of blood fractions (n) >24 hours
	2018					
National	**TOTAL**	**27,974**	**6 (1,712)**	**0.1 (17)**	**2 (593)**	**1 (252)**
Center	Glostrup	12,111	3 (374)	0.1 (17)	4 (449)	1 (130)
	Gråsten	7,868	3 (240)	0 (0)	0 (0)	0.1 (8)
	Hjørring	1,809	1 (24)	0 (0)	0 (0)	1 (24)
	Næstved	88	0 (0)	0 (0)	0 (0)	0 (0)
	Odense	2,322	3 (79)	0 (0)	0 (0)	0.4 (9)
	Aarhus	3,776	26 (995)	0 (0)	4 (144)	2 (81)

Appendix 6.2.2. Processing time for blood, 2018. The table shows the percentage and number (n) of blood fractions with a processing time over the recommended 3 hours for 2018. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer.

6.3 Danish Blood Donor Biobank

Name	Represents	Region
Chairman		
Henrik Ullum	Steering committee, DBDS	The Capital Region of Denmark
Member		
Erik Sørensen	Steering committee, DBDS	The Capital Region of Denmark
Thomas Folkmann Hansen	Steering committee, DBDS	The Capital Region of Denmark
Morten Bagge Hansen	Board for DBDS	The Capital Region of Denmark
Margit Anita Hørup Larsen	Inclusion, DBDS	The Capital Region of Denmark
Lise Thørner	Laboratory, DBDS	The Capital Region of Denmark
Christian Erikstrup	Steering committee, DBDS	Central Denmark Region
Bjarne Kuno Møller	Board for DBDS	Central Denmark Region
Henning Riis Rasmussen	Data, DBDS	Central Denmark Region
Ole Birger Pedersen	Steering committee, DBDS	Region Zealand
Keld Homburg	Board for DBDS	Region Zealand
Helene Paarup	Steering committee, DBDS	The Region of Southern Denmark
Jørgen Georgsen	Board for DBDS	The Region of Southern Denmark
Kaspar Nielsen	Steering committee, DBDS	The North Denmark Region
Kim Varming	Board for DBDS	The North Denmark Region
Henrik Hjalgrim	Statens Serum Institut	
Karina Banasik	University of Copenhagen	
Flemming Bøgh-Sørensen	The Danish Blood Donor Organization	
Poul Erik Herner Petersen	The Danish Blood Donor Organization	
Estrid Høgdall	RBGB	

Appendix 6.3.1. Members of the Scientific Advisory Board for Danish Blood Donor Biobank, 2018. The table shows the members of the Scientific Advisory Board for DBB, which organization they represent and which region they are from.

7. Description of Indicators

7.1 Indicators

Nr.	Indicator	Description of Indicators	Goal of the indicator	Data source	Level of reporting
1.	Handling of material	1A. Percentage of biological material with a freezer position	A. >95%	RBGB Register	National Center
2.	Sample Quality	2A. Percentage of biological material that are processed within the recommended times	A. >90%	RBGB Register	National Center
3.	Coverage	3A. Percentage of blood materials that contain the recommended fractions 3B. Percentage of tissue materials that contain the recommended fractions 3C. Percentage of hematological materials that contain the recommended fractions	A. >90% B. >50% C. >90%	RBGB Register	National Center
4.	Completeness	4A. Percentage of tissue material with corresponding blood (DCB). 4B. Percentage of biological material that has been completely registered (DCB)	A. >50% B. >95%	RBGB Register	National Center
5.	Diagnostic Follow-up	5A. Number of fractions that have been handed out to diagnostic follow-up.		RBGB Register	
6.	Research	6A. Number of fractions that have been handed out to research projects.	A.>5% B. >90% C. >90% D. >90%	RBGB Register	National Center

		6B. Number of applications for hand out of material to retrospective research that have been approved within the recommended time limit 6C. Percentage of retrospective collected material that is handed out to researchers within the recommended time limit 6D. Percentage of material reserved for specific projects that is handed out to researchers within the recommended time limit			
7.	Clinical/phenotypic data	7A. Description of different clinical and phenotypic data coupled to the biological material	A. >80%	RBGB Register and clinical databases (DCB and DRB) or questionnaires (DBB)	National Center
8.	Sharing of Knowledge	8A. Researchers: Manuscripts published in peer reviewed journals 8B. RBGB Secretariat: Newsletters, annual reports, articles, data transfer to The National Biobank Register at SSI	A. Same number or more compared to the year before B. Same level of information as previous years.	Principal investigators for projects in RBGB, center project managers, clinicians, RBGB Secretariat	National

7.2 Specifications

Indicator 1. Handling of Material

Percentage of biological material with a freezer position

In the RBGB Register, the biological material is given a freezer position. The indicator is measured as the percentage of material allocated to a freezer position, which is a prerequisite for retrieval of material and thus use in research/diagnostic follow-up.

Indicator 2. Sample Quality

Percentage of biological material that are processed within the recommended timeframes

To ensure the quality of the material for research, the processing time should be as short as possible. The processing time is defined as the time between material retrieval from the patient until the material is placed in a freezer. For blood fractions the time should not be over 3 hours. For synovial fluid not over 4 hours. For tissue fractions (dry frozen and O.C.T.) and ascites not over 1 hour. RNAlater treated tissue has a treatment before freezing and the processing time is therefore longer. The TEMPUS / PAXGene blood samples have a pre-freezing step before long term storage and will therefore also have a longer processing time. Formalin-fixed and paraffin-embedded tissue are fixed prior to embedding, so that for this material there will be a longer processing time. Hematologic materials have a longer process and therefore the processing time is longer and is described as percentage (%) processed <12 hours, >12 and <36 hours and >36 hours. The indicator is measured as the percentage that meets this deadline at 1 hour (tissue) and 3 hours (blood) excluding the above exceptions.

Indicator 3. Coverage

Percentage of blood materials that contain the recommended fractions

When collecting blood material, it should be attempted to collect a complete standard set as described in the recommendation for handling blood in RBGB. The indicator is measured as the percentage of materials that have the recommended number of fractions according to the standard set.

Percentage of tissue materials that contain the recommended fractions

When collecting tissue material, it should be attempted to collect a complete standard set as described in the recommendation for handling tissue in RBGB. The indicator is measured as the percentage of materials that have the recommended number of fractions according to the standard set.

Percentage of hematological blood and bone marrow materials that contain the recommended fractions

When collecting hematological material, it should be attempted to collect a complete standard set as described in the recommendation for handling hematological material in RBGB. The indicator is measured as the percentage of materials that have the recommended number of fractions according to the standard set.

Indicator 4. Completeness

Percentage of tissue material with corresponding blood

In the Danish Cancer Biobank (DCB) it is registered whether tissue materials have corresponding blood material. Blood material is corresponding to tissue material if it is taken within 14 days before the tissue. To ensure the highest quality of material for research most tissue materials should have corresponding blood material. The indicator is measured as the percentage of tissue material with a blood material taken within 14 days (corresponding), 28 days and more than 28 days.

Percentage of biological material that has been completely registered

To ensure high quality of tissue and bone marrow samples in DCB all samples are pathologically verified in the RBGB Register. When the tissue or bone marrow material has been verified and registered with a diagnosis and DMCG coupled it is completely registered. The indicator is measured as a percentage of the tissue and bone marrow material that have been completely registered.

Indicator 5. Diagnostic Follow-up

Number of fractions that have been handed out to diagnostic follow-up

Material collected in RBGB can be used for research projects, but some of the material is also used for diagnostic follow-up. The indicator describes the type of material, number of fractions and the center that has handed out the material. The indicator is measured as the percentage of fractions that have been handed out to diagnostic follow-up.

To ensure that the most optimal material for diagnostic follow-up is being collected in RBGB, the type of materials being handed out should be followed.

Indicator 6. Research

Number of fractions that have been handed out to research projects.

In RBGB material suitable for research is collected. The goal is that a large part of the material is used in research projects, so that new knowledge can be acquired about onset of the disease, early diagnosis and treatment options. The indicator is described as the number of new projects where RBGB handles collection, as these have the potential for use in the long term. Number of fractions handed out to these projects (prospective) and to projects that utilize retrospectively collected material, i.e. projects that have not established an ongoing collaboration during the collection period are described.

Number of applications for hand out of material to retrospective research that have been approved within the recommended time limit

The aim is to handled applications for use of already collected material in RBGB for retrospective studies as quickly as possible. Since some applications must be processed in local biobank committees, a deadline of 2 months is set. The indicator is measured as the percentage that complies with this deadline.

Percentage of retrospective collected material that is handed out to researchers within the recommended time limit

Only when application for hand out of material is approved, can the material be handed out. The indicator is divided according to the number of samples to be handed out, as a large number may require greater planning. For delivery of up to 1000 whole fractions, a deadline of 1 month is set, regardless of whether the

material is handed over from department, center, regional or national. The indicator is measured as the percentage that complies with this deadline. For delivery of more than 1000 fractions, no standard has been set since the time will depend on complexity and therefore must be agreed individually.

Percentage of material reserved for specific projects that is handed out to researchers within the recommended time limit

Prospective research projects collecting material in RBGB will have their material reserved in the biobank according to the project's needs. The samples can therefore be provided without further approvals. The indicator is divided according to the number of samples to be handed out, as a large number may require greater planning. For delivery of up to 1000 fractions, a deadline of 1 month is set regardless of whether material is handed over from department, center, regional or national. The indicator is measured as the percentage that complies with this deadline. For delivery of more than 1000 fractions, no standard has been set since the time will depend on complexity and therefore must be agreed individually.

Indicator 7. Clinical/phenotypic data

Description of different clinical and phenotypic data coupled to the biological material

The possibility of optimal use of material collected in RBGB is only present when clinical / phenotype data can be linked to the material. Some of the data coupled to the biological material from clinical databases (e.g. DMCG's databases, DANBIO) or from questionnaires (DBB) is presented in this indicator. The chairman of each biobank's Technical Advisory Board is responsible for delivery data for this indicator.

Indicator 8. Transfer of Knowledge

Manuscripts published in peer reviewed journals

RBGB aims to ensure optimal biological material for research. Success will be the use of material that results in published research results that can contribute to better treatment and screening of patients. The indicator is described based on feedback from the clinical project managers, the principal investigators of projects in RBGB and from the responsible contact person for projects that have received material. The indicator is fulfilled if an increase is seen compared to previous years.

Newsletters, annual reports, articles, data transfer to SSI

RBGB secretariat publishes newsletters and annual reports and articles related to RBGB. A few basic data is also transferred to The National Biobank Register at Statens Serum Institut (SSI) each year. The indicator is described as the level of information provided by the RBGB secretariat which must as a minimum be the same as previous years.