

Annual report, Year 2003

Objectives

- 1. To collect a copy of Quality manuals used by as many as possible of all Biobanks in Sweden**
- 2. To formulate a national strategy for a future national system for “Good Biobanking Practice”**
- 3. To design and implement routines for a national system of auditing biobanks.**
- 4. To act as national co-ordinating centre for receiving feed-back about biobanking QA.**
- 5. To establish and distribute standards, (rules, guidelines, characteristics for activities) in an effective way.**

Deliverables (see also enclosure 1)

- Prepared standard operating procedures and a data program for scientific administration of studies. Distributed via platform meetings and via the QA-manual.
- Specific delivery claims/conditions for sending samples and data, used and evaluated by a number of research groups.
- Evaluation of the implementation process of the two new laws of biobanks and ethics have been presented at platform meetings and to the authorities.
- Initiated collaboration with the Swedish Federation of County Councils in order to jointly establish a national Quality system for Swedish biobanks (on basis of the new Biobank law). On-going process reported at platform meetings and courses.

Statistics (Year 2003):

- **Number of approved studies:** 15 (main studies)
- **Number of samples distributed:** DNA samples: 3400, Plasma and erythrocyte samples: 7900
- **Number of samples prepared to be distributed:** Buffy coat and DNA samples: 2800, Plasma samples: 1700, Erythrocyte samples: 3000

- **Number of extracted samples/array:** 1000
- **Number of samples collected to the biobank:** 10 samples from each of 7700 individuals (EDTA- and Heparin plasma tube).
- **Number of publications:** 11 (se also enclosure 2)

Project waiting for processing (by Beckman Coulter Biomek FX Liquid handling Robot)

- Colorectal cancer, 600 DNA samples for genotyping analysis. Dilution of samples and dispersion in 96/384-plate.
- Metabolic syndrome/ cancer, 4000 plasma samples and 4000 erythrocyte samples.
- NCI-EPIC breast cancer . Dispersion of 250 samples.
- Eur-gast phase II . 25 samples for dispersion.
- The Sami cohort. Dispersion of 500 plasma samples and DNA samples.
- FIA 2/Myocardial infarctions. 2000 samples of DNA for a number of polymorphism's. ~4000 plasma samples dispersed in 20 000 tubes.
- IRS. 900 plasma samples.
- Castro 2/Stroke. 818 DNA samples for 20 polymorphism's are manually dispersed. Additional 20 polymorphism's will be diluted and dispersed on the robot.
- CAPS- prostate cancer. Dispersion of 2500 DNA samples for 10 polymorphism's.
- MORGAM. 500 DNA samples

Comments to the expenditure

According to budget

Economic expenditure

<u>Salary costs</u>	1 358 529
12 months for Gerd Johansson (QA-coordinator)	
18 months for Åsa Ågren	
6 months for Lena Nilsson	
Secretary Margaretha Tagewall	
<u>Intranet software, travelling, courses</u>	81 577
(Gerd Johansson, Göran Hallmans, Åsa Ågren, Lena Nilsson)	
Consultant	120 000
Administrative costs (overhead)	185 303
Sum	1 745 409
Tax compensation (8.7%)	151 850,68
Total	1 897 260:-

Enclosures

1. Deliverables
2. Publication list

Deliverables

- Prepared standard operating procedures and a data program for scientific administration of studies. Distributed via platform meetings and via the QA-manual.
- Specific delivery claims/conditions for sending samples and data, used and evaluated by a number of research groups, see examples below:

Form – Delivery terms concerning data

Project: Researcher: Contact person:		
Name of data file: Data format: Contents:	Encrypted: <input type="checkbox"/> Yes <input type="checkbox"/> No	Data file transferred: <input type="checkbox"/> Electronically <input type="checkbox"/> By post <input type="checkbox"/> By registered mail <input type="checkbox"/> By local post (red envelope) <input type="checkbox"/> Other means:
<p>Signature</p> <p>In signing below I agree to the following:</p> <ul style="list-style-type: none"> • The authorship conditions given below. • That data have been received as described above and the contents confirmed. • That the data file received may under no circumstances be used for purposes other than those approved by the Medical Biobank. • That all handling of samples and data will occur in accordance with the Personal Information Law. Especially important to note is that even codes are considered personal information, as long as individuals can be identified via a code key. This means that the biobank code and related data are personal information and must therefore be treated as such. • That data will be stored in such a manner that only persons with permission have access. Laptop computers, for example, cannot be considered a secure medium in this respect. <p>Date: _____ Signature: _____ Name (please print): _____</p> <p>Please forward the signed form to:</p> <p>Name: _____ Address: _____ Telephone: _____</p>		

Authorship Conditions (approved by _____ date _____)

The rules of the Biobank concerning authorship are as given in “Uniform for Manuscripts Submitted to Biomedical Journals”. In practice this means that one member of the Biobank staff should be included as a co-author in publications based on biobank material, and thereby assume responsibility for the quality of the material. The following details should also be noted:

- Building the infrastructure for case-referent studies often involves a major scientific effort, which qualifies for authorship. This is especially true with respect to quality control, drop-out analysis, randomised selection of study subjects, and identification of cases via research registers.
- Laboratory analyses of routine nature, and for which the laboratory is paid a fee, do not qualify for authorship. Laboratory analyses that are clearly of a research nature (not used in clinical routine) do, however.
- PhD students have priority for the position of first author.

Other conditions:

Form- Delivery terms concerning samples

Project: Researcher: Contact person:	Complete description provided as: <input type="checkbox"/> List <input type="checkbox"/> Data file (attachment) <input type="checkbox"/> Other
Labelling of boxes/plates: Type(s) of sample: Number of samples: Volume/amount:	
<p style="text-align: center;">Signature</p> <p>In signing below I agree to the following:</p> <ul style="list-style-type: none">• That samples have been received in accordance with the complete description.• That the samples received may under no circumstances be used for purposes other than those approved by the Medical Biobank. If sample material remains after analysis, please contact the Medical Biobank.• That all handling of samples and data will occur in accordance with the Personal Information Law. Especially important to note is that even codes are considered personal information, as long as individuals can be identified via a code key. This means that the biobank code and related data are personal information and must therefore be treated as such.• That data will be stored in such a manner that only persons with permission have access. Laptop computers, for example, cannot be considered a secure medium in this respect. <p>Date: _____ Signature: _____ Name (please print): _____</p> <p>Please forward the signed form to: Name: _____ Adress: _____ Telephone: _____</p>	

Blankett – Avtal: Personuppgiftshantering vid utlämnande av personuppgifter för forskningsändamål

I samband med att personuppgifter (oftast personnummer) lämnas ut från Biobanken ställs krav på dig som mottagare på hur dessa data måste behandlas. I och med att du får åtkomst till persondata betraktas du som en "del av biobanken" och måste i enlighet med detta följa Personuppgiftslagen och God registersed.

- Ifall tillgång till personuppgifter är nödvändiga för exempelvis granskning av journaler, får dessa användas endast under en avgränsad period för ändamål som är uttryckligt angivna och berättigade.
- Personuppgifter får inte på något sätt användas så att den personliga integriteten skadas eller kränks.
- Den ansvariga forskaren skall efter uträttat arbete enligt ovan, ovillkorligen tillse att materialen anonymiseras.
- Personuppgifter får inte heller distribueras vidare, utan Biobankens godkännande.

Personuppgiftslagen 1998:204

19 § Känsliga personuppgifter får behandlas för forsknings- och statistikändamål, om behandlingen är nödvändig på sätt som sägs i 10 § och om samhällsintresset av det forsknings- eller statistikprojekt där behandlingen ingår klart väger över den risk för otillbörligt intrång i enskildas personliga integritet som behandlingen kan innebära.

Studiens namn/beteckning:

Syftet med personuppgiftsbehandlingen:

Härmed intygas att jag avser att beakta ovan beskrivna förhållningssätt

Datum: _____

Signatur: _____

Förtydligande:

The forms is now tested by:

- Bengt Järvholm, University of Umeå
- ?
- ?
- ?

- Evaluation of the implementation process of the two new laws of biobanks and ethics have been presented at platform meetings and to the authorities.
- Initiated collaboration with the Swedish Federation of County Councils in order to jointly establish a national Quality system for Swedish biobanks (on basis of the new Biobank law). On-going process reported at platform meetings and courses.

Publications 2003

1. Asplund K, Nasic S, Janlert U, Stegmayr B. Smokeless tobacco as a possible risk factor for stroke. A nested case-control study. *Stroke* 2003; 34: 1346-1352.
2. Bingham SA, Day NE, Luben R, Ferrari P, Slimani N, Norat T, Clavel-Chapelon F, Kesse E, Nieters A, Boeing H, Tjønneland A, Overvad K, Martinez C, Dorronsoro M, Gonzalez CA, Key TJ, Trichopoulou A, Naska A, Vineis P, Tumino R, Krogh V, Bueno-de-Mesquita HB, Peeters PH, Berglund G, Hallmans G, Lund E, Skeie G, Kaaks R & Riboli E. Dietary fibre in food and protection against colorectal cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC): an observational study. *Lancet* 2003; 361(9368): 1496-1501.
3. Emmelin M, Weinehall L, Stegmayr B, Dahlgren L, Stenlund H, Wall S. Self-rated ill-health strengthens the impact of bio-medical risk factor load in predicting stroke, especially for men. An incident case-referent study. *J Hypertension* 2003; 1: 887-896.
4. Gonzalez CA, Pera G, Agudo A, Palli D, Krogh V, Vineis P, Tumino R, Panico S, Berglund G, Siman H, Nyren O, Agren A, Martinez C, Dorronsoro M, Barricarte A, Tormo MJ, Quiros JR, Allen N, Bingham S, Day N, Miller A, Nagel G, Boeing H, Overvad K, Tjønneland A, Bueno-de-Mesquita HB, Boshuizen HC, Peeters P, Numans M, Clavel-Chapelon F, Helen I, Agapitos E, Lund E, Fahey M, Saracci R, Kaaks R & Riboli E. Smoking and the risk of gastric cancer in the European prospective investigation into cancer and nutrition (EPIC). *Int J Cancer* 2003; 107: 629-634.
5. Hallmans G, Ågren Å, Johansson G, Johansson A, Stegmayr B, Jansson J-H, Lindahl B, Rolandsson O, Söderberg S, Nilsson M, Johansson I, Weinehall L. Cardiovascular disease and diabetes in the Northern Sweden Health and Disease Study Cohort – evaluation of risk factors and their interactions. *Scand J Public Health* 2003; 31(suppl 61): 18-24.
6. Kaaks R, Lukanova A, Rinaldi S, Biessy C, Soderberg S, Olsson T, Stenman UH, Riboli E, Hallmans G, Stattin P. Interrelationships between plasma testosterone, SHBG, IGF-I, insulin and leptin in prostate cancer cases and controls. *Eur J Cancer Prev.* 2003; 12(4): 309-315.
7. Lukanova A, Lundin E, Micheli A, Akhmedkhanov A, Rinaldi S, Muti P, Lenner P, Biessy C, Krogh V, Riboli E, Hallmans G, Berrino F, Zeleniuch-Jacquotte A, Toniolo P & Kaaks R. Risk of ovarian cancer in relation to prediagnostic levels of C-peptide, insulin-like growth factor binding proteins-1 and -2 (USA, Sweden, Italy). *Cancer Cause Control* 2003; 14(3): 285-292.
8. Lukanova A, Lundin E, Akhmedkhanov A, Micheli A, Rinaldi S, Zeleniuch-Jacquotte A, Lenner P, Muti P, Biessy C, Krogh V, Berrino F, Hallmans G, Riboli E, Kaaks R, Toniolo P. Circulating levels of sex steroid hormones and risk of ovarian cancer. *Int J Cancer* 2003; 104(5): 636-642.

9. Rantapää-Dahlqvist S, de Jong BAW, Berglin E, Hallmans G, Wadell G, Stenlund H, Sundin U, van Venrooij WJ. Antibodies against cyclic citrullinated peptide and IgA rheumatoid factor predict the development of rheumatoid arthritis. *Arthritis Rheum* 2003; 48(10): 2741-2749.
10. Rolandsson O, Hagg E, Janer M, Rutledge E, Gaur LK, Nilsson M, Hallmans G, Lernmark A. High GAD65 autoantibody levels in nondiabetic adults are associated with HLA but not with CTLA-4 or INS VNTR. *J Intern Med* 2003; 253(4): 447-453.
11. Stattin P, Kaaks R, Johansson R, Gislefoss R, Soderberg S, Alfthan H, Stenman UH, Jellum E, Olsson T. Plasma leptin is not associated with prostate cancer risk. *Cancer Epidem Biomar* 2003; 12(5): 474-475.