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This is an update on the progress of the LifeGene project. It is the first of what we plan to be a continuing series of regular newsletters from LifeGene so that we can keep you informed on how things are progressing. If you have some comments regarding the form of the newsletter or if you have any other questions, please do not hesitate to contact us!

Building a unique resource

In short, the LifeGene study is a national project designed to build a resource for research in all medical disciplines, enabling new and groundbreaking biomedical research such as the relationships among heredity, environment and lifestyle. LifeGene will include studying half a million Swedes aged 0-45 with the aim of creating new tools to prevent, diagnose and treat our most common diseases that occur early on in the middle of life such as asthma, allergy and inflammation. An important reason for the focus on diseases that occur relatively early or in the middle of life is that these create an enormous financial burden for society. They also affect the risk of subsequent disease (for instance, an infection can contribute to the development of a malignancy decades later). Further, this is a field that is, relatively, unexplored compared to many other areas of medical research. However, LifeGene will constitute a unique platform for a myriad of biomedical research projects. Researchers not only in biomedicine and biotechnology but also behavioural and social sciences may benefit from access to LifeGene. A pilot study with 5000 participants is planned for 2009. The full-scale roll-out of LifeGene is planned for 2010.

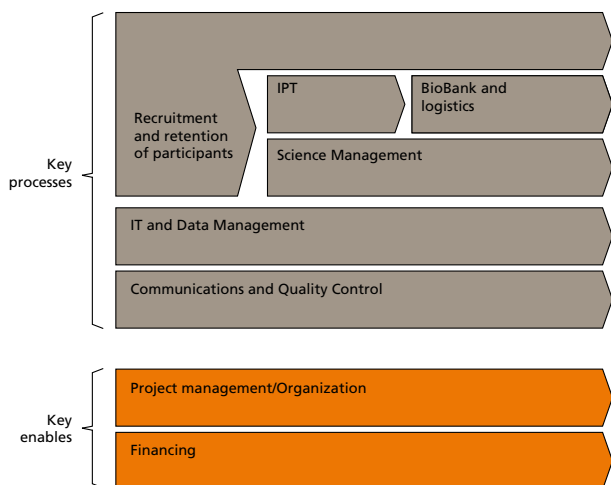
So, what has happened during the autumn for LifeGene? In short, a lot! The most important points are listed below:

Anchored as national project!

LifeGene has been anchored as a national project and we are proud to announce that there is now a broad consensus on this point. A scientific reference board has been established with representatives from all Swedish medical faculties. The reference board has representatives from Göteborgs University, the Karolinska Institutet, Linköping University, Lund University, Umeå University and Uppsala University. Two meetings with representatives from the medical faculties have been held during the autumn. Among the issues discussed at the meetings are ethical guidelines for LifeGene and how to secure access to the LifeGene database for researchers regardless of which faculty they belong to.

Key processes defined

The key processes that will enable us to build and operate LifeGene have now been defined and are summarized in the following schematic picture.



Project organization in place

LifeGene's project organization is now in place. The organization consists of eight full time staff under the leadership of director Nancy Pedersen, professor of genetic epidemiology at the Karolinska Institute and co-director Jan-Eric Litton, professor in Biomedical Computer Science at the Karolinska Institute.

We welcome Mats Thorman (Head of IT), Maria Holmström (Head of participant recruitment), Mikael Eriksson (Responsible for questionnaires), Camilla Björk (Database manager) and Kate Svensson (Executive assistant) to LifeGene!

Ethics framework coordinated

Much work has been devoted to establish an ethical framework for LifeGene. Such a framework is now in place after having been circulated for review during the last months. We have received a lot of important feedback, which has resulted in substantial improvements of the ethical policy. The LifeGene ethics policy is now a 30+ page document, currently under review by LifeGene's ethical board.

Two main areas of focus in the Ethics framework are transparency and access to data to ensure that all researchers, regardless of academic institution, will have equal access to the LifeGene data. However, the extensive Ethics framework also focus on a number of other aspects such as relation to participants, protection of confidentiality, anonymization, governance, relation with society, funding, policy for participants under lawful age (minors), legal ownership of the database and issues regarding intellectual property (IP)

Questionnaires harmonized

An important feature of LifeGene is the questionnaire phase regarding i.e. health, sickness, medication and lifestyle. Substantial effort has been devoted to the development of an extensive yet user-friendly questionnaire.

Two baseline questionnaires are about to be finalized; one for adults and one for children. The baseline questionnaires cover ten different themes; medical history including a variety of symptom based sub-sections, daily life, inflammation and allergy, medication, injuries,

sociodemography, menstruation and reproduction, tobacco, alcohol and illicit drugs, alternative medicine and personality and psychiatric symptoms. The themes include 37 different modules. Researchers from a number of research groups and medical disciplines have contributed with input and questions for the questionnaire. During the last months, effort has been devoted to harmonize the questions from different researchers to make sure that the questions are user-friendly for the participants and at the same time meet the needs of the various disciplines.

IT-system established and integrated

The IT-architecture of LifeGene has been defined and the first version of the IT-system has both been developed and tested. Currently, the IT-system undergoes continuous improvement based on input from researchers. A beta-testing of the IT-system is planned during the first quarter of 2009.

The IT-system has been designed so that it is compatible with BBMRI (Biobanking and Biomolecular Resources Research Infrastructure), a pan-European standard that enables LifeGene data to be pooled with other similar biobank databases in the future. The majority of the extensive questionnaires that will be used by LifeGene to collect data from the participants have already been implemented in the IT-system.

Executive Science Board

LifeGene has identified a group of 7 people who will make the final decisions regarding the pilot including the design, content of the questionnaires, in-person testing, and biological sampling. This group consists of Lauren Lissner, Markus Maurer, Karl Michaëlsson, Juni Palmgren, Göran Pershagen, Patrick Sullivan, and Nancy Pedersen.

Organisational and legal status

Today, the department of Medical Epidemiology and Biostatistics (MEB) at Karolinska Institutet. The future legal status of LifeGene is currently under discussion.

What happens next?

2009 will be a very exciting year for LifeGene! During the coming year, a pilot study with 5000 participants is planned. Enrolment in the pilot study is to commence after the summer of 2009, hence much of the time from now to enrolment will be devoted to preparation for the pilot study.

Questions?

If you have questions, please feel free to contact:

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Best Wishes

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