

LifeGene

An example of efficient use of e-tools
in large prospective cohort studies with
biobanking

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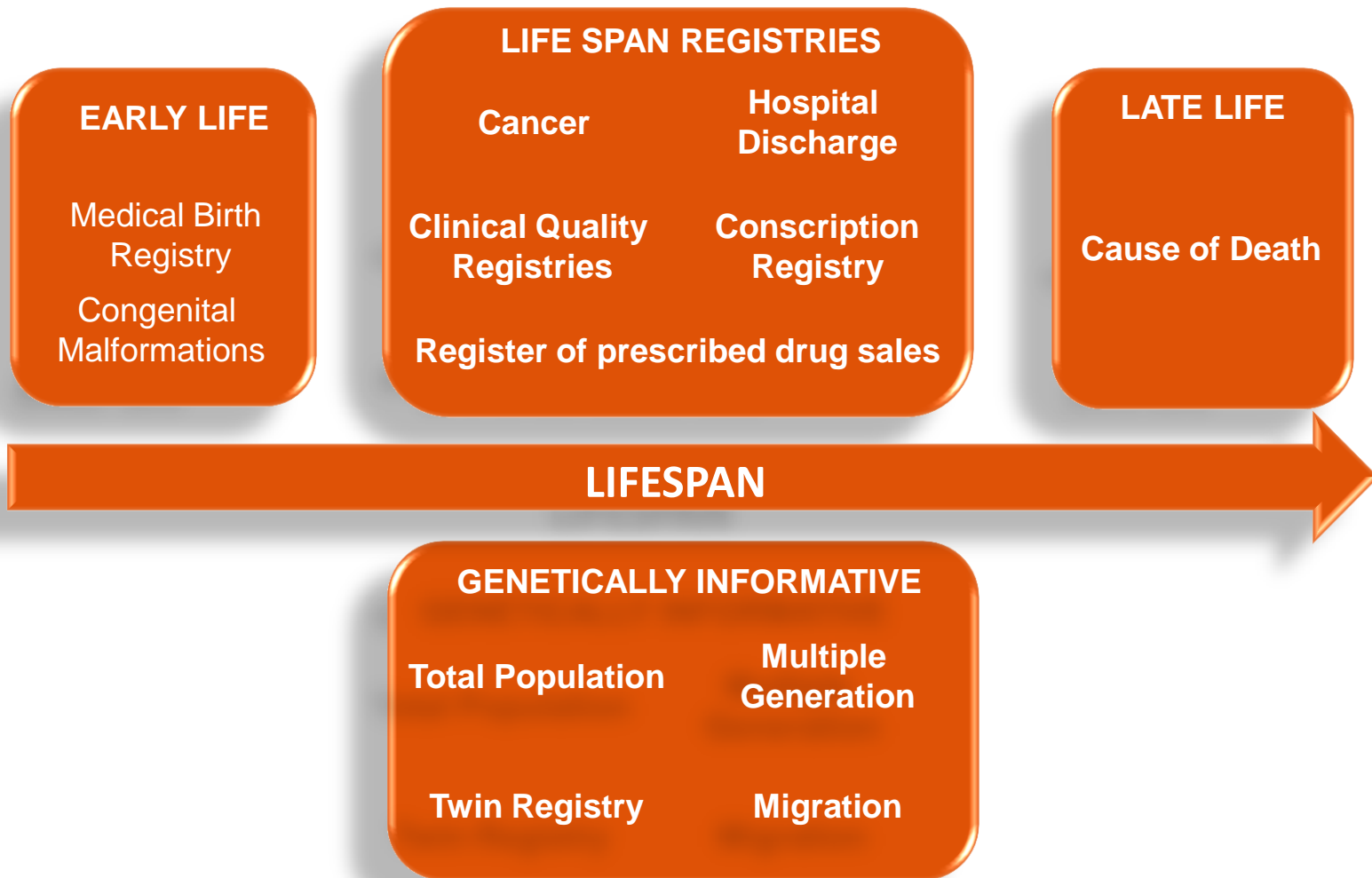
Sweden: a goldmine for biomedical research



- National health care system, universally available
- Personal registration number
- State of the art Biobanking
- Well characterized patient materials
- Continuously updated population and health care registers
- Scientifically motivated population
- Support from our research council for biobanking and “-omics” research

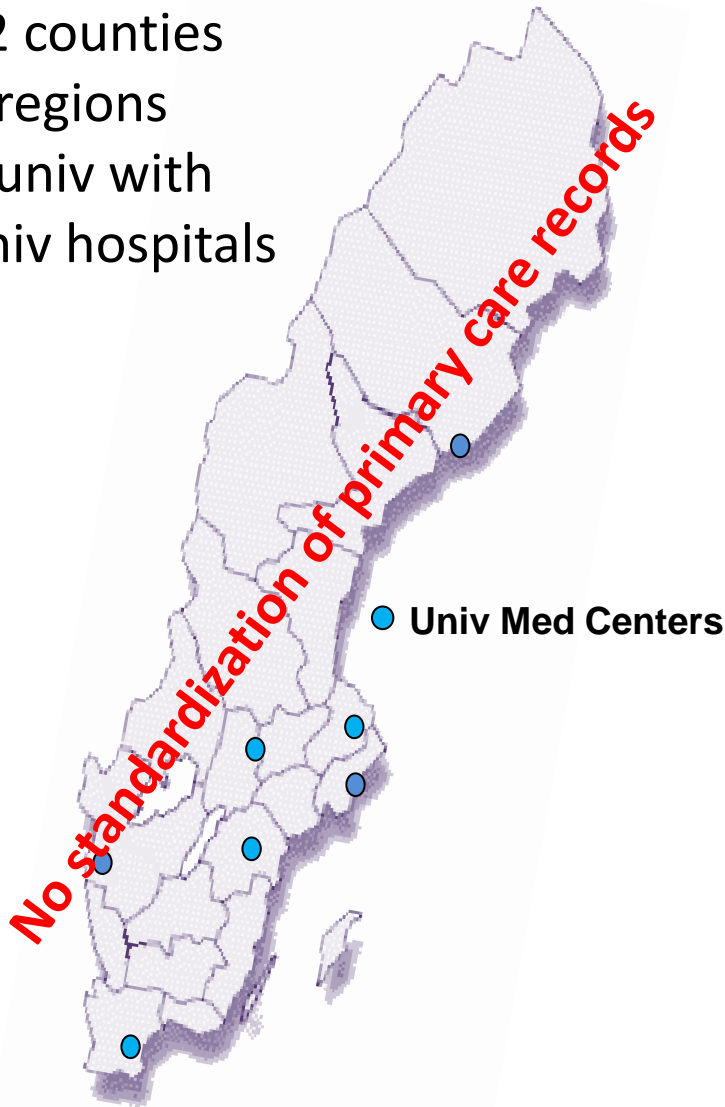


Swedish Health Registries – across the lifespan



A variety of sources and responsibilities

22 counties
6 regions
8 univ with
univ hospitals



- National Health Registries:
 - Nat'l Board of Health and Welfare (EpC)
- Quality Registries
 - Varying coverage, regional
- Biobanking
 - County councils, univ.
- Insurance board
 - Sick listings
- Statistics Sweden
 - Everything else

Sweden has registers and biobanks: What is missing?

Information on **primary care**

Information on **lifestyle and exposures**

Sample collections that can be used for **full scale “omics”**

Studies that **bridge basic research to clinical applications**

>> Especially **population based**

Opportunity to study **co-morbidity**



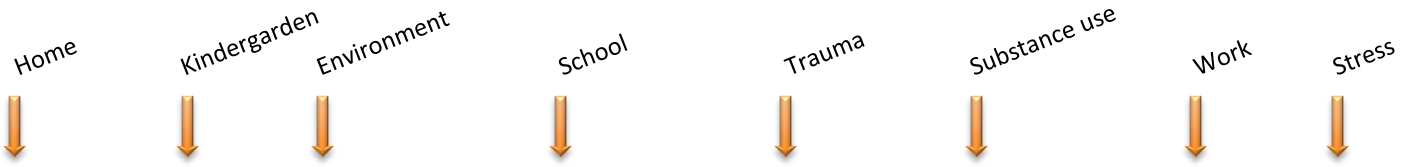
What more is missing?

- Disorders with early onset: in **adolescence** and **young adulthood**
- Disorders that **cost society**
>> Due to sick leave, etc
- Disorders which **lead to chronic diseases late in life** such as cardiovascular disease

- **Psychiatric disorders**, e.g., spectrum disorders, stress related diseases and gambling
- **Infections**, e.g., susceptibility to influenza
- **Inflammation related disorders**
- **Musculoskeletal diseases**, e.g., back pain, chronic pain
- **Obesity**

Lack of primary care data and info on exposures

Exposure /Events



Children



Teenagers



Adults

Example areas of interest

- Allergies
- Infections
- Behavior

- Neuropsychiatry
- Infections
- Behavior

- Neuropsychiatry
- Muscle pain
- Pregnancies
- Obesity



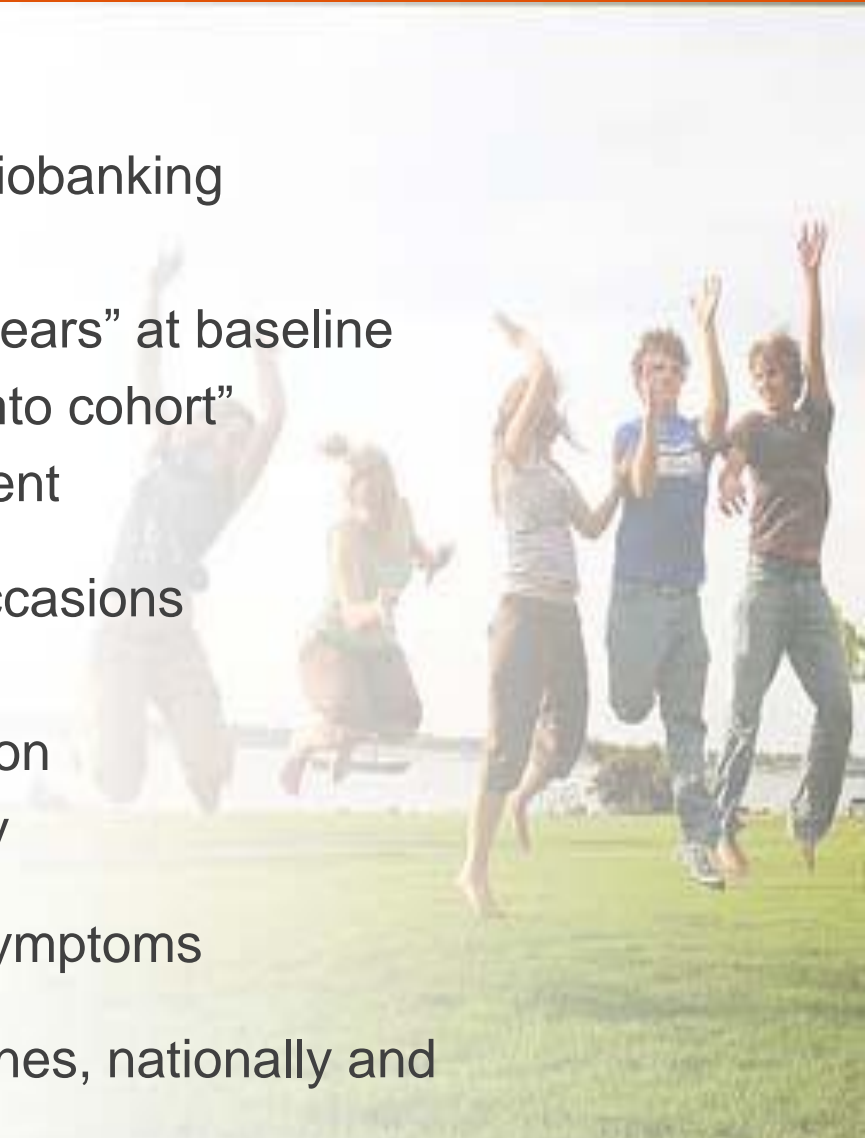
Sampling

- Blood
- Physical data
- Questionnaires

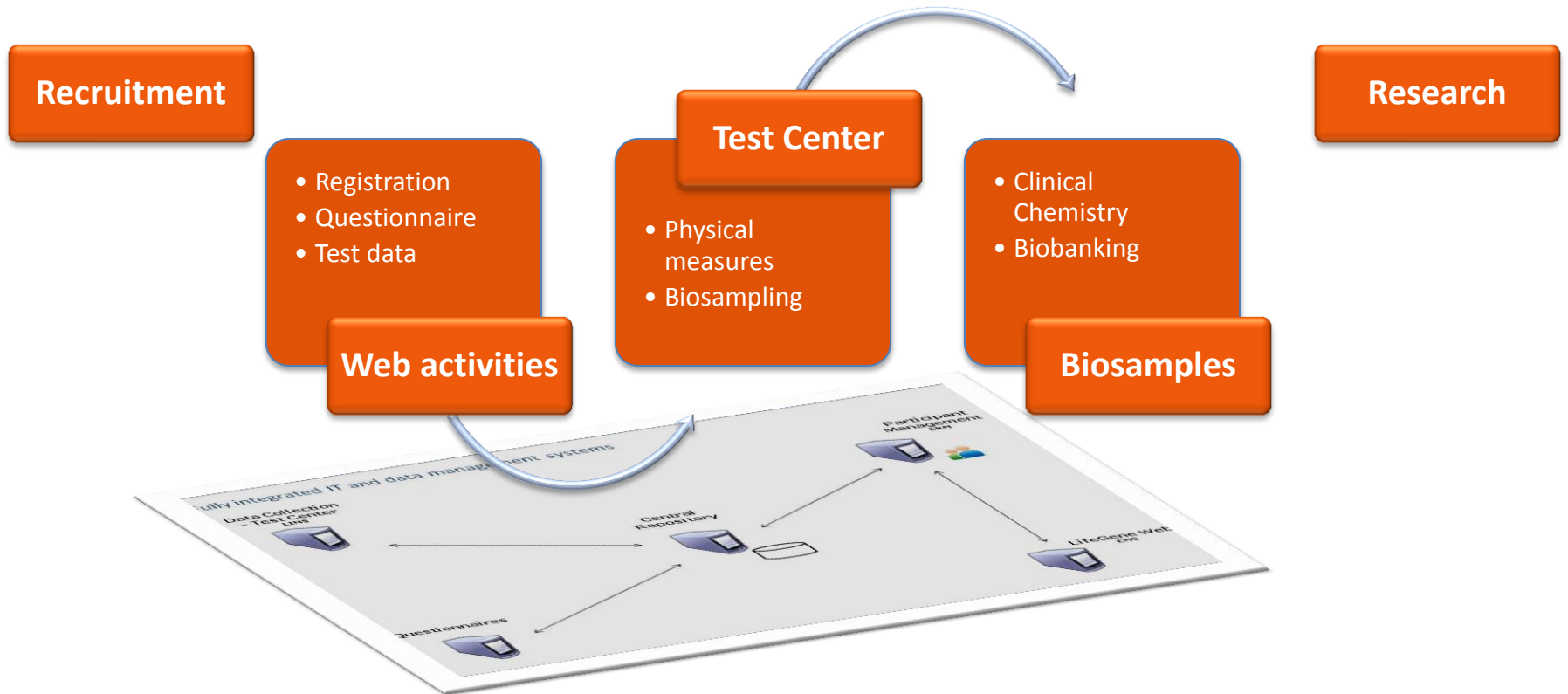
- Blood
- Urine
- Clinical chemistry
- Physical data
- Questionnaires

- Blood
- Urine
- Clinical chemistry
- Physical data
- Questionnaires

LifeGene's Concept

- National prospective cohort with biobanking
 - Over 200,000 participants: "0-50 years" at baseline
 - Including children and "born into cohort"
 - Household based ascertainment
 - Information collected at several occasions
 - Including biobanking
 - Including event driven collection
 - Using modern E-epidemiology
 - Follows changes in lifestyle and symptoms
 - A resource for all scientific disciplines, nationally and internationally
- 

Processes in LifeGene



LifeGene är
ett nationellt projekt
som berör alla
Läs mer

1 2 3 4 II

Logga in

ANVÄNDARNAMN

ÅÅÅÅMMDDXXXX

Lösenord

GLÖMT LÖSENODET?

Lorem ipsum dolor sit amet,
consectetur adipiscing elit.

Har du fått en inbjudan?

Då behöver du aktivera ditt konto

AKTIVERA KONTO

Har du inte fått en inbjudan?

Då kan du registrera dig här:

REGISTRERA MIG



Jag gick med LifeGene
för att vestibulum
hendrerit consetetur
adipiscing elit. ””

Maria Andersson, Kalrskrona

[→ Läs Marias blogg](#)



4,063 people recommend this.
Be the first of your friends.

2009-10-06

Invigning av LifeGene Test Center

Den 6 oktober öppnas
dörrarna till vårt första
LifeGene Testcenter

2009-10-06

LifeGene Pilotstudie

LifeGene genomför en
pilotstudie med start i
Stockholm i september

[→ Läs mer nyheter](#)



Ladda ner
broschyren!

Vad är LifeGene
och varför ska jag delta?
(4.3Mb)

Snabbstart

Information om LifeGene

Bjud in en hushållsmedlem

Ändra mina uppgifter

Provsvär


Välkommen Maria!

Här kan du se vad du har för aktiviteter att genomföra. Dina aktiviteter kan vara enkät som ska besvaras eller ett tillfälle för tester som ska bokas på LifeGenes Testcenter.



Testtillfälle


Här bokar du ditt besök på LifeGene Testcenter. Undersökningen tar ca 45 minuter per person, kortare för barn.

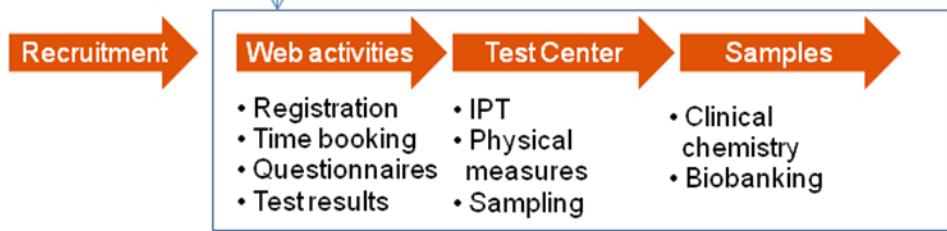
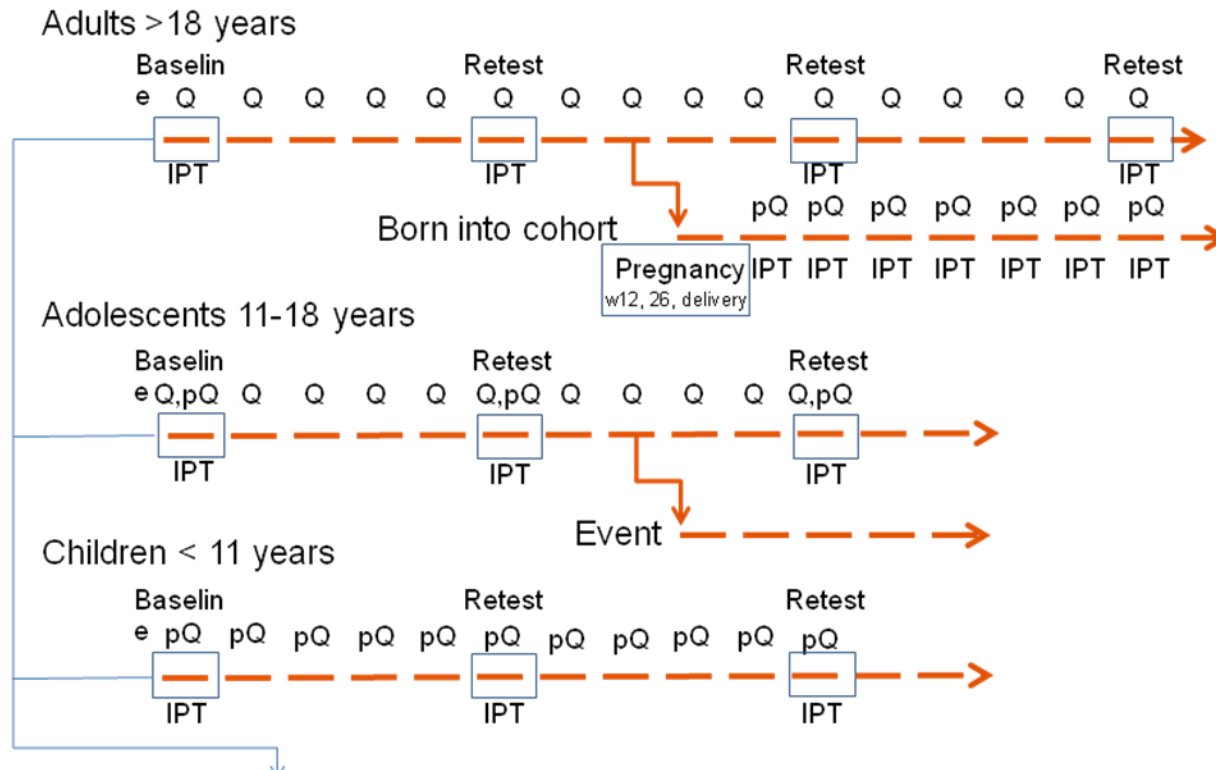
 Bastest Maria Bokad 17/3 16:00 till Stockholm, Fridhemsplan Adress/karta	ÄNDRA/AVBOKA
Graviditetsstudien Maria Ej bokad	BOKA
Bastest Erik Ej bokad	BOKA
Bastest Peter Ej bokad	BOKA



Enkät

Basenkäten tar ca 1 timme att besvara men går bra att dela upp i omgångar. Avsluta varje avsnitt innan du tar en paus. Enkäten om barn är kortare och tar ca 30 minuter att besvara.

 Basenkät om Maria Denna enkät är påbörjad	FORTSÄTT
Basenkät om Erik Denna enkät är ej påbörjad	BÖRJA
Basenkät om Peter Denna enkät är ej påbörjad	BÖRJA



All participants respond to a baseline questionnaire

Theme	# questions	Modules
Socio-demography	30-77	General, Occupation, Working environment
Lifestyle	191-298	General, Diet, Physical activity , Sexual behavior, Wireless devices
Menstruation and reproduction	25-46	Menstruation, Reproduction, Menopause, Diseases, Osteoporosis
Tobacco, alcohol and drugs	9-45	Smoking, Snus, Alcohol, Illicit drugs
Self-care	4-60	Medication Over The Counter, Complementary and Alternative Medicine
Medical history	49-227	Dental, Diseases, Infections, Eating disorder, Reflux/IBS, Sleep, Headache, Hearing
Inflammation and allergy	18-65	General exposures, Asthma & COPD, Allergy and chronic sinusitis
Injuries	1-18	One module
Mental health	105-455	Personality test, Screener, Depression, Panic disorder, Obsessive Compulsive Disorder, Post Traumatic Stress Disorder, Social phobia



Enkätöversikten

Här svarar du på frågor om dig och ditt liv, för att vi ska kunna ta reda på hur dina val, ditt arv, och din livsmiljö påverkar dig. Klicka på en ikon för att sätta igång.

Klicka här för att fortsätta där du slutade



LifeGene participants perform physical measures

Physical measures

Audiometry

Height, Weight
Hip & Waist
circumference

Bio-impedance

Spirometry

Blood pressure
Heart rate



Sampling in LifeGene allows state of the art “–omics”

Tube	Volume (ml)	Spun down	Chilled	Processed by:
EDTA	4		X	KI Biobank
EDTA	4		X	KUL
LiHep gel	4	X	X	KUL
PPT gel	8.5	X	X	KI Biobank
PPTgel	8.5	X	X	KI Biobank
Citrat 3.8%	4.5	X	X	KI Biobank
PST gel	8	X	X	KI Biobank
Trace Metals	6	X	X	KI Biobank
Urine	4		X	KI Biobank



Participants receive feedback – after consent

From Blood	Feedback	Physical tests	Feedback
B-Hemoglobin	X	Height	X
B-HbA1c	X	Waist	X
P-CRP, sensitive	X	Hip	X
P-Cholesterol	X	Waist/Hip	X
P-Triglycerides		Weight	X
P-Apolipoprotein A1	X	BMI	X
P-Apolipoprotein B	X	Body fat in %	X
P-ApoB/P-ApoA1	X	Bioimpedance	X
B-LPK		Blood pressure	X
B-Diff		Pulse	X
P-ALAT		Audiometry	X
P-Creatinine		Spirometry	X

Use of e-tools

- Registration / recruitment
 - CRM
 - Including spontaneous self-recruitment
 - Invite a friend
- Personalized home page
 - Follow progress
 - Feedback on results
- Web-based questionnaires
- LIMS (Laboratory Information Management System)
- Facebook, Twitter, blogg

Progress thus far

- Over 20,000 participants
- Three sites
- 14 successful applications for use of LifeGene material
- Infrastructure used by other cohorts
 - EpiHealth
 - “Born into Cohort”, Pregnancy study

All was well in Camelot

- Working groups with representation internationally identified the scientific questions and best design for LifeGene
- The former prime minister of Sweden, Ingvar Carlsson led our steering group
- A policy document on Ethics was drafted,
- Potential participants involved in discussions regarding LifeGene
 - Two reasons for participating
 - To contribute to science
 - For one's own sake

All was well in Camelot

- Applications were submitted to the regional ethics board (for the pilot)
And approved
- Appropriate informed consents were obtained from all subjects
- The Data Inspection Board was informed
- A pilot of 5,000 participants was performed

Something went wrong

- The regional ethical review board approved the main study
 - But not for sampling those under 6 years of age
- LifeGene appealed to the Central Ethical Review Board
 - Because this is an “infrastructure” and the purposes are broad – it is not relevant for review by an ethical review board
 - However, any future research based on the data should be reviewed by an ethical review board

Enter – Swedish Data Inspection Authority

- (Sensitive) personal data must be reviewed by an ethical review board
 - participants must be informed of the use of their data
 - The purpose of the use of the data must be defined

LifeGene was deemed illegal because the the purpose of the research was considered too broad.

LifeGene's consent included “future research that would be reviewed by an ethical review board”

- Some 20,000 individuals have provided informed consent to participate in LifeGene – and allow their data to be used for future research
 - Are they to be considered **incompetent** of making their own decisions??!!
- Minister of Education and Research
 - New law for LifeGene and similar studies – effective Oct. 1, 2013

A Scientific Balancing Act

- Prospective, population based studies are the core of cutting edge (Swedish) research
- Prospective studies with broad purposes to study genetic and environmental factors for health and disease should be allowed (according to the Minister of Higher Education)
- Conflicting legislation (ethics, data inspection, biobanks) need resolution.
- Need for an understanding of the infrastructure required for prospective/longitudinal studies
- **React** to the proposed **European General Data Protection Regulation!!**



LUNDS
UNIVERSITET



UPPSALA
UNIVERSITET



LifeGene

Representatives from six
Swedish medical faculties
participate in LifeGene National
Scientific Board



GÖTEBORGS
UNIVERSITET



Karolinska
Institutet