

LifeGene

Malmö November 13rd, 2014

Kicki Kjaergaard, CEO

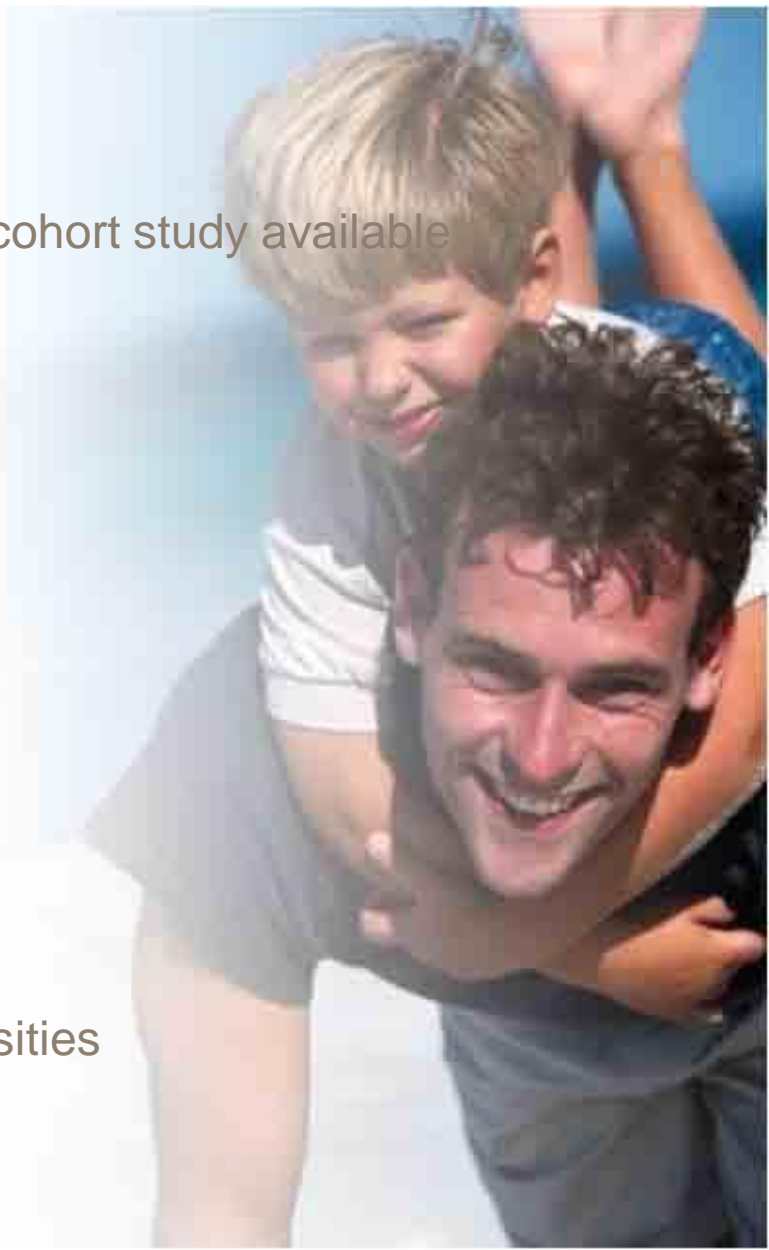


The basics

- LifeGene is a unique, longitudinal, prospective cohort study available to scientists in Sweden and abroad
- Half a million participants between 0-50 years
- Household, incl children born into the cohort
- Information and samples taken repeatedly
- Event based sampling

- Focus on common diseases in middle-age
- Modern ICT, bioinformatics and state of the art biobanking are key elements
- Sampling adapted for "-omics" based research

- Joint effort between all Swedish medical universities

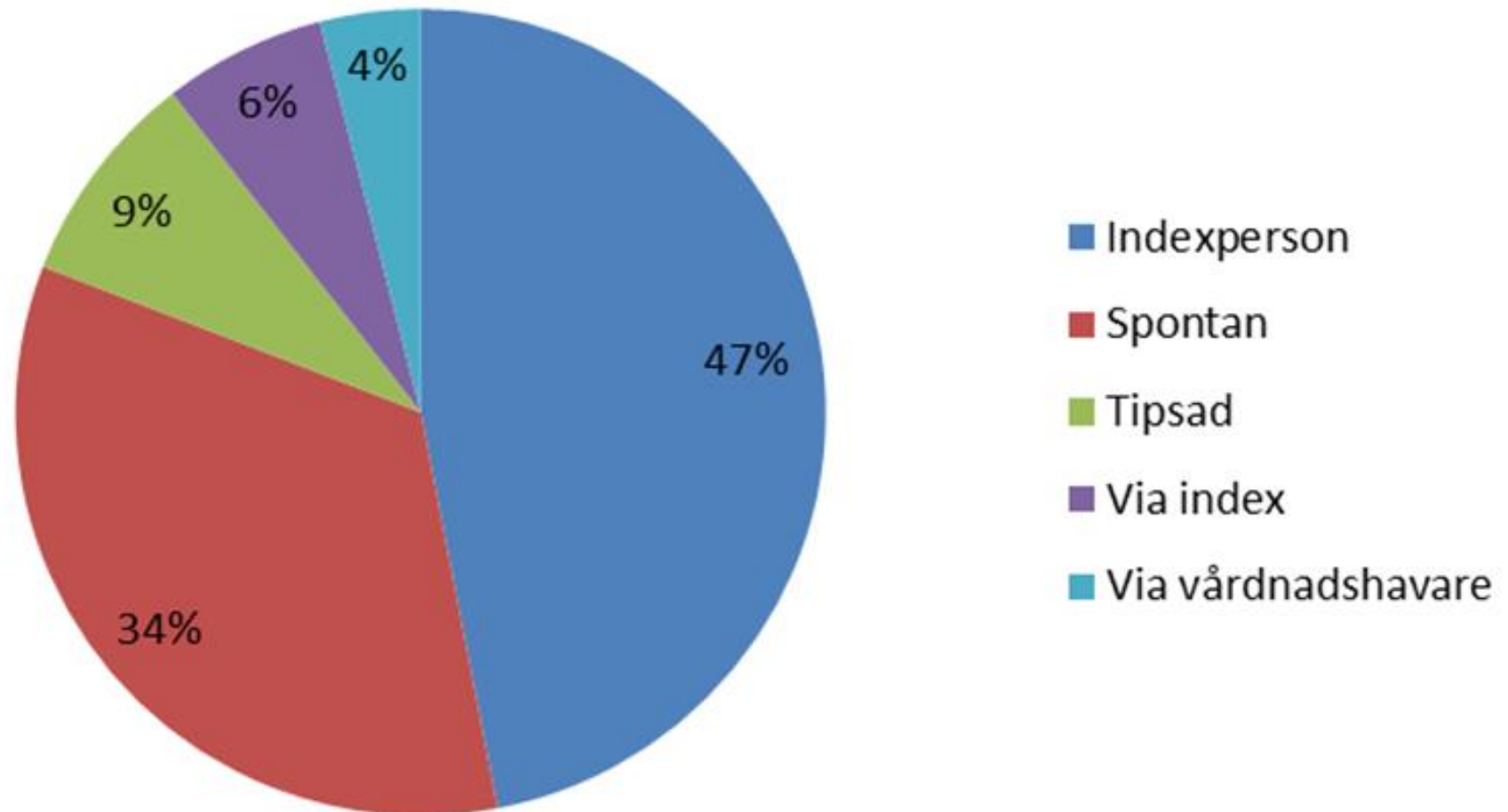


Recruitment

- Invitation letters, 18-50 years
- Spontaneous (>18 years)
www.lifegene.se
- Invited by friends or household members
www.lifegene.se



Recruitment



Summery of LifeGene – legally aspect 1 (2)

Oct 2009

- Approval from “Etikprövningsnämnden” (REPN) for Pilot
- Started LifeGene Pilot included 5000 base line tests (IPT) at Stockholm, Umeå and Alingsås

Nov 2010

- Started LifeGene with test centers in Stockholm and Umeå
- CEPN; LifeGene doesn't need an ethic approval. It's an infrastructure

Dec 2011

- Complete the collecting in Umeå

Dec 2011

- Data Inspection Board decides that LifeGene acts in violation with the Privacy Protection Law. Karolinska Institute appeals the decision to “Förvaltningsrätten”

Summery of LifeGene – legally aspect 2 (2)

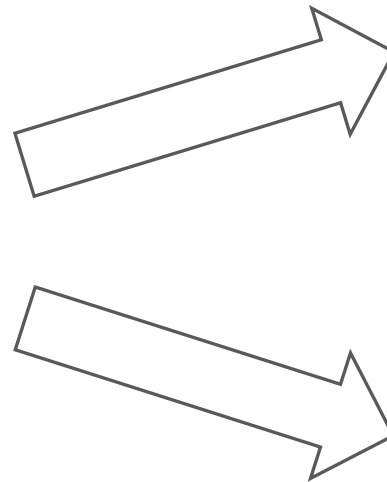
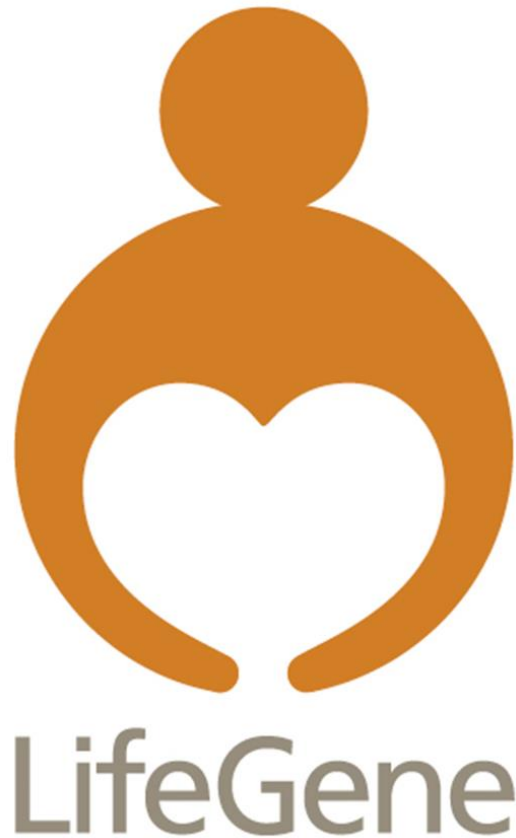
Feb 2012

- Government declares that a new directive will come to makes it possible for studies like LifeGene to continue

April 2012

- Stop collecting in Stockholm due to the juridical process

Year 2012 – to secure the infrastructure

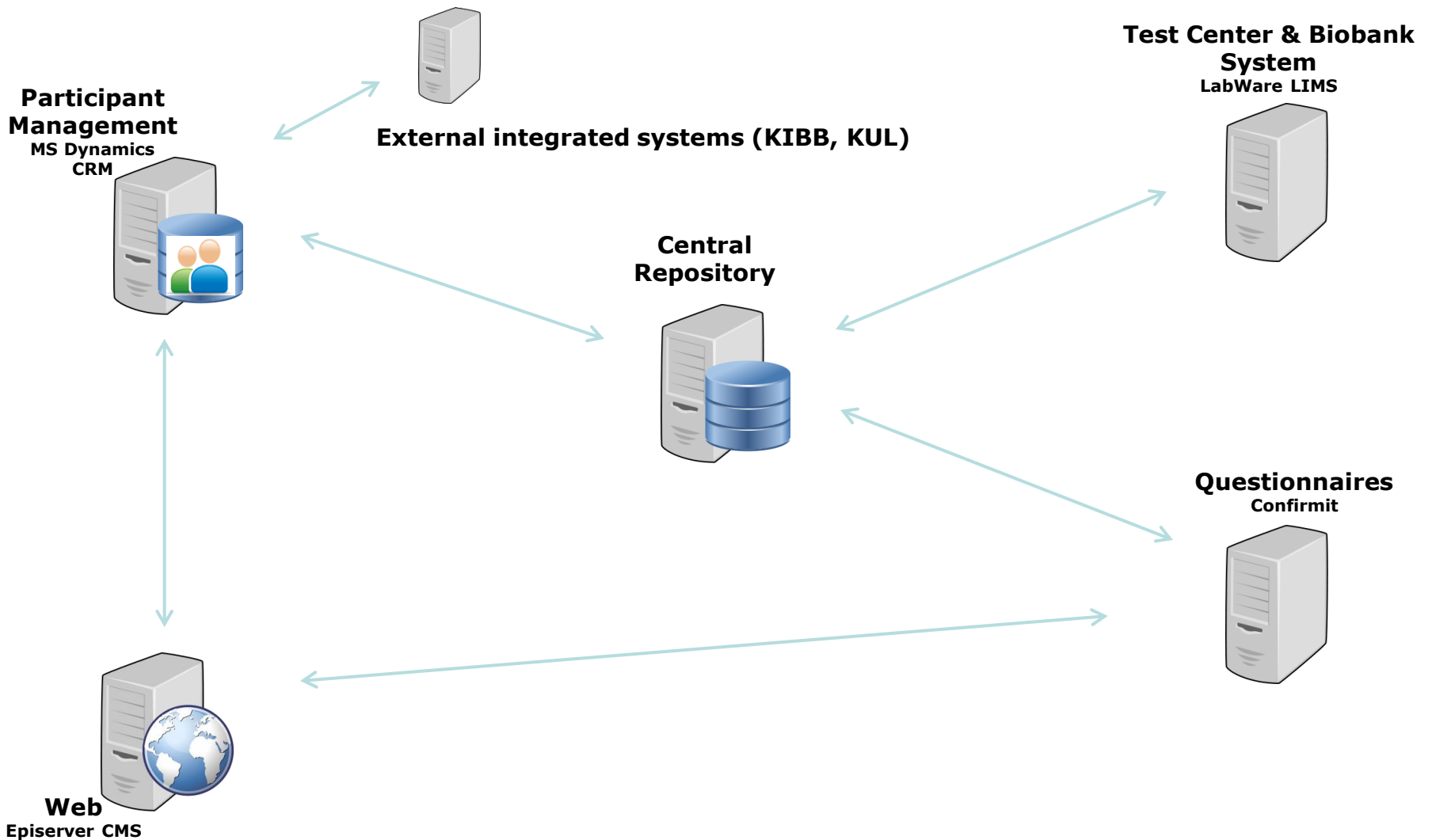


The Infrastructure
KI Biobank
BBMRI.SE

The study



The infrastructure



Studies using the Infrastructure

- LifeGene
- EpiHealth
- Born-into-cohort
- Småsyskon Uppsala

Summery of LifeGene – legally aspect 2 (2)

Feb 2012

- Government declares that a new directive will come to makes it possible for studies like LifeGene to continue

April 2012

- Stop collecting in Stockholm due to the juridical process

Dec 2013

- New law in place Lag 2013:794
- Start collaboration with County Council of Stockholm/LNP

April 2014

- “Förvaltningsrätten” gives Karolinska right

LifeGene - law

A participant can demand us to erase all data

Totally: 60 (0,1%)

Dec 2013

Mailed participants and asked for consent

No new consent

Svensk författningssamling



Lag om vissa register för forskning om vad arv och miljö betyder för människors hälsa;

utfärdad den 24 oktober 2013.

Enligt riksdagens beslut¹ föreskrivs följande.

SFS 2013:794
Utkom från trycket
den 5 november 2013

Lagens syfte

- 1 § Syftet med denna lag är att
1. ge universitet och högskolor möjlighet att skapa underlag för olika forskningsprojekt om vad arv och miljö betyder för uppkomsten och utvecklingen av olika typer av sjukdomar och för människors hälsa i övrigt, och
 2. skydda den enskildes personliga integritet i sådan verksamhet.

Lagens tillämpningsområde

- 2 § Lagen gäller behandling av personuppgifter som utförs av sådana statliga universitet och högskolor som omfattas av högskolelagen (1992:1434) och som med den enskildes uttryckliga samtycke sker i sådant syfte som anges i 1 § 1.
- Lagen gäller bara om behandlingen är helt eller delvis automatiserad eller om uppgifterna ingår i eller är avsedda att ingå i en strukturerad samling av personuppgifter som är tillgängliga för sökning eller sammanställning enligt särskilda kriterier.
- Regeringen meddelar föreskrifter om vilka statliga universitet och högskolor som får behandla personuppgifter enligt denna lag och vilka register enligt lagen som får föras.

Förhållandet till personuppgiftslagen

- 3 § Personuppgiftslagen (1998:204) gäller vid behandling av personuppgifter, om inte annat följer av denna lag.

Personuppgiftsansvar

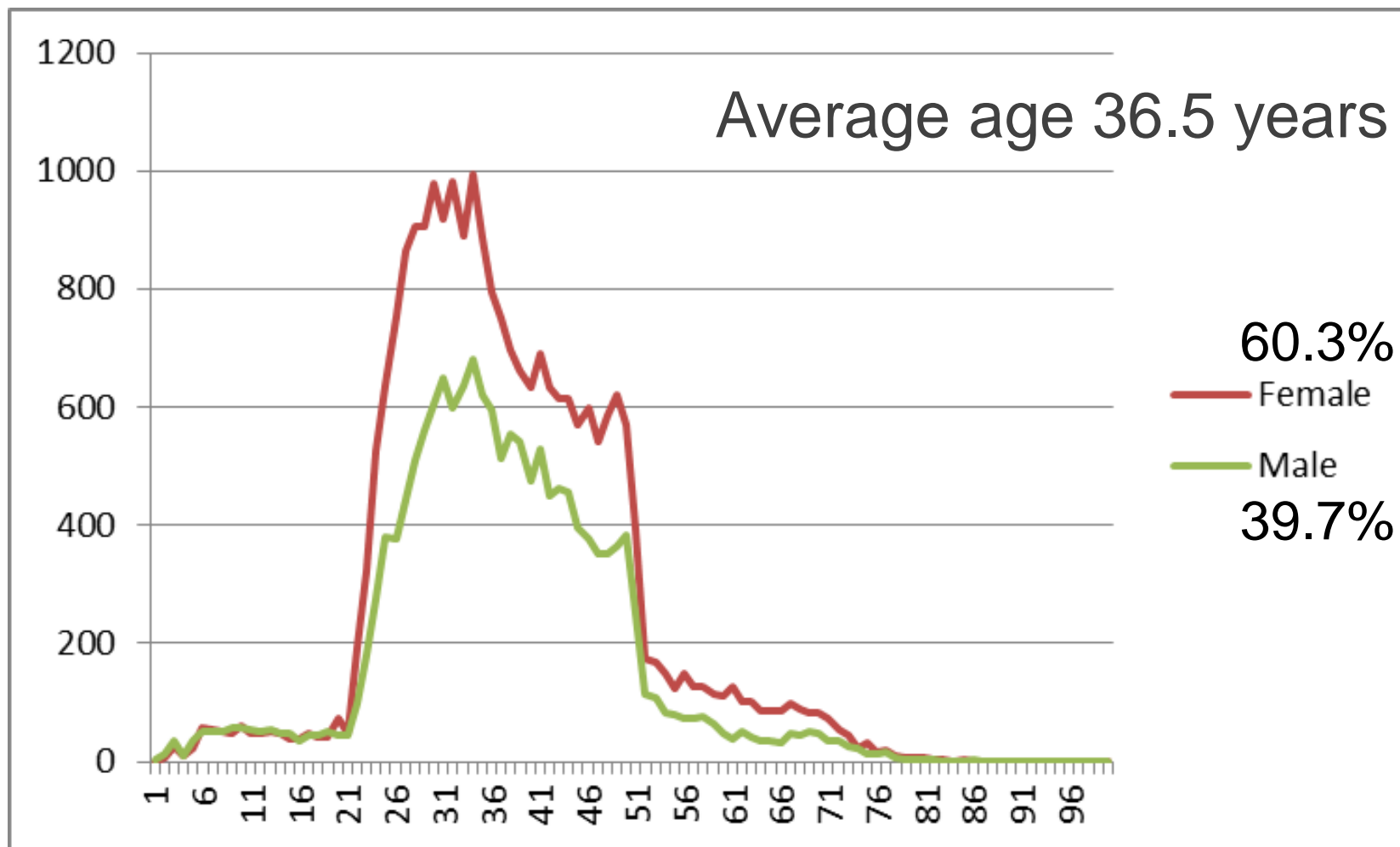
- 4 § De universitet eller högskolor som utför behandlingen av personuppgifter är personuppgiftsansvariga.



FACTS

First participant:	2009
Number of participants:	40 002
Number of surveys:	65 000
Number of base line tests:	22 137
Average age:	36,5 years

The age of the participants



Test centers

Total: 22 137

LifeGene Test center Alingsås

1 februari 2010 – April 2014

Participants: 450

LifeGene Test center Umeå

November 2009 – December 2011

Participants: 3 578

LifeGene Test center Fridhemsplan

October 2009 – April 2012

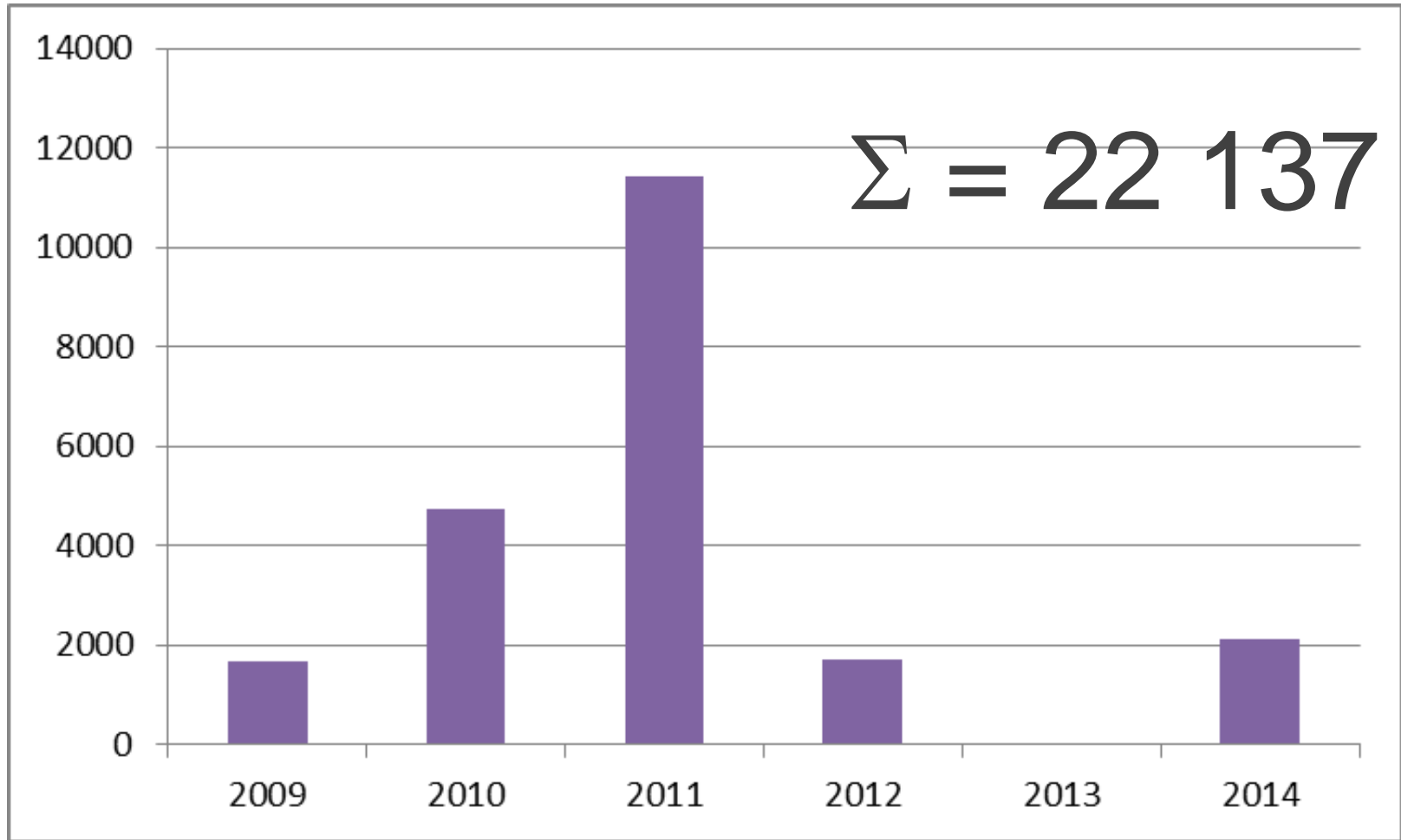
Participants: 15 872

LifeGene Test center Stureplan

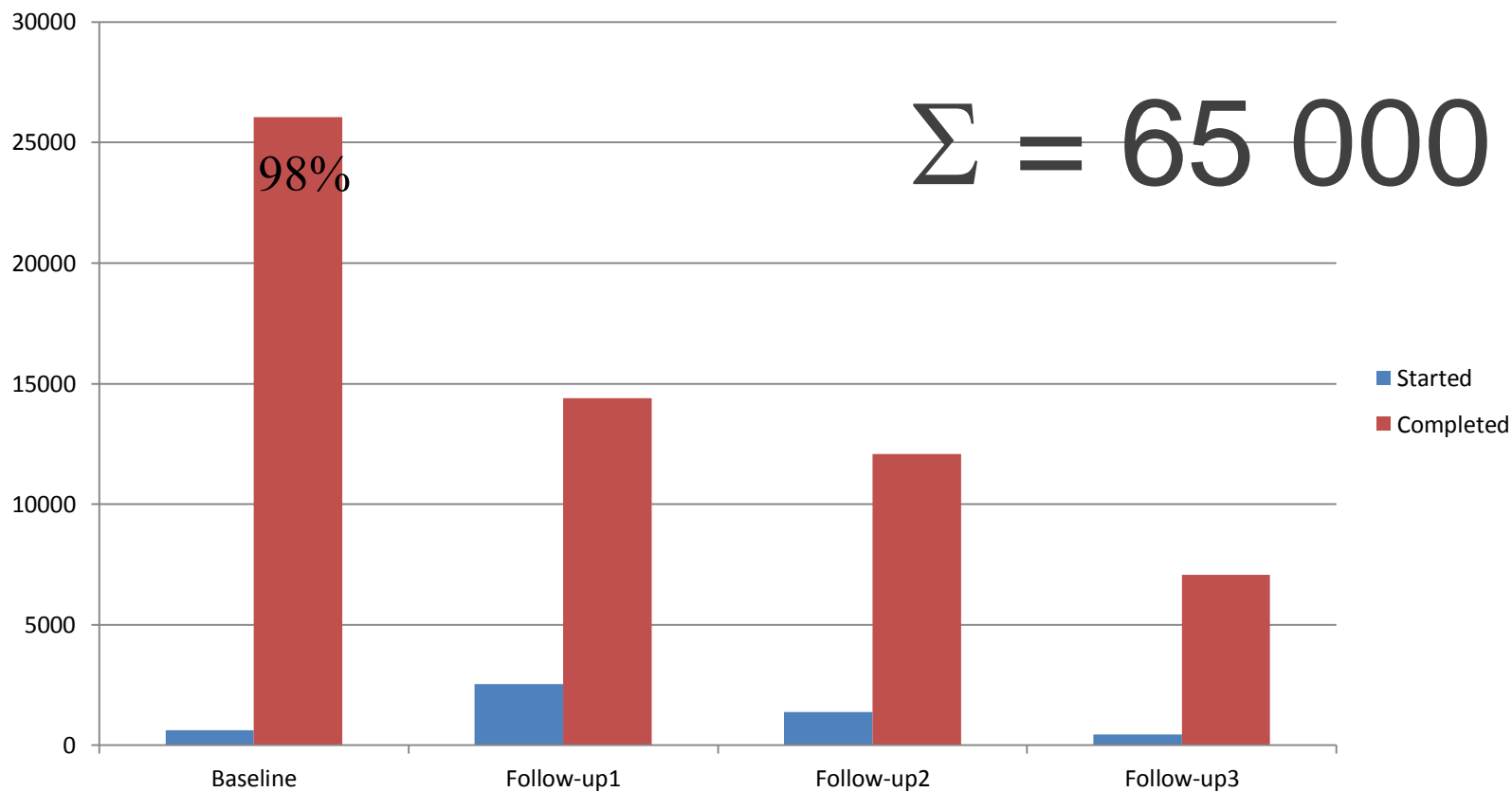
Januari 2014 -

Participants: 2 111

Base line tests per year



Questionnaires, started and completed



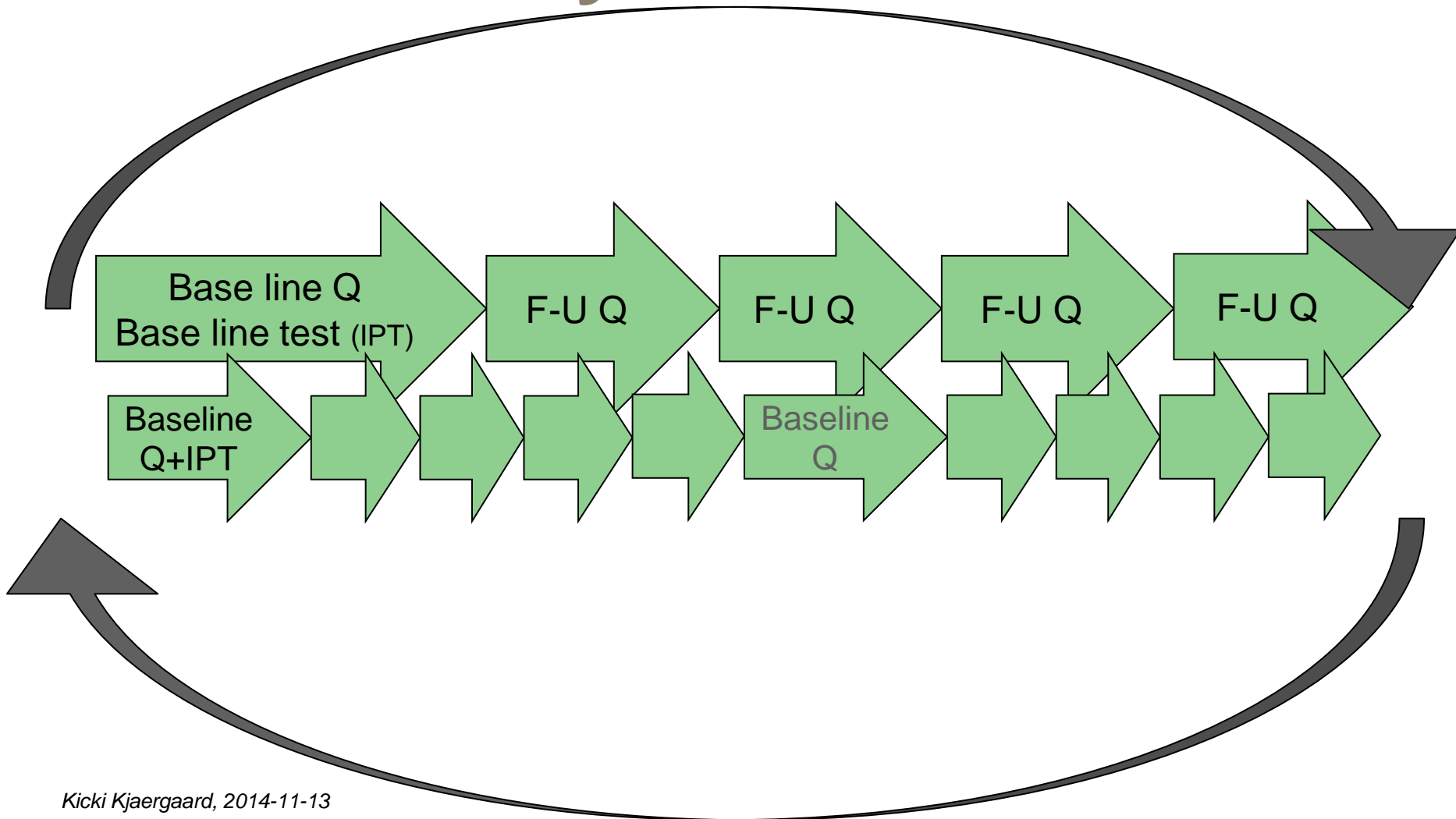
Status today

- Only one Test center, Stockholm
- Slim organization (PI, CEO, comm.)
- Tight financial resource (10 MSEK/year)

- Call for proposal
- Working groups
- Visit ministers



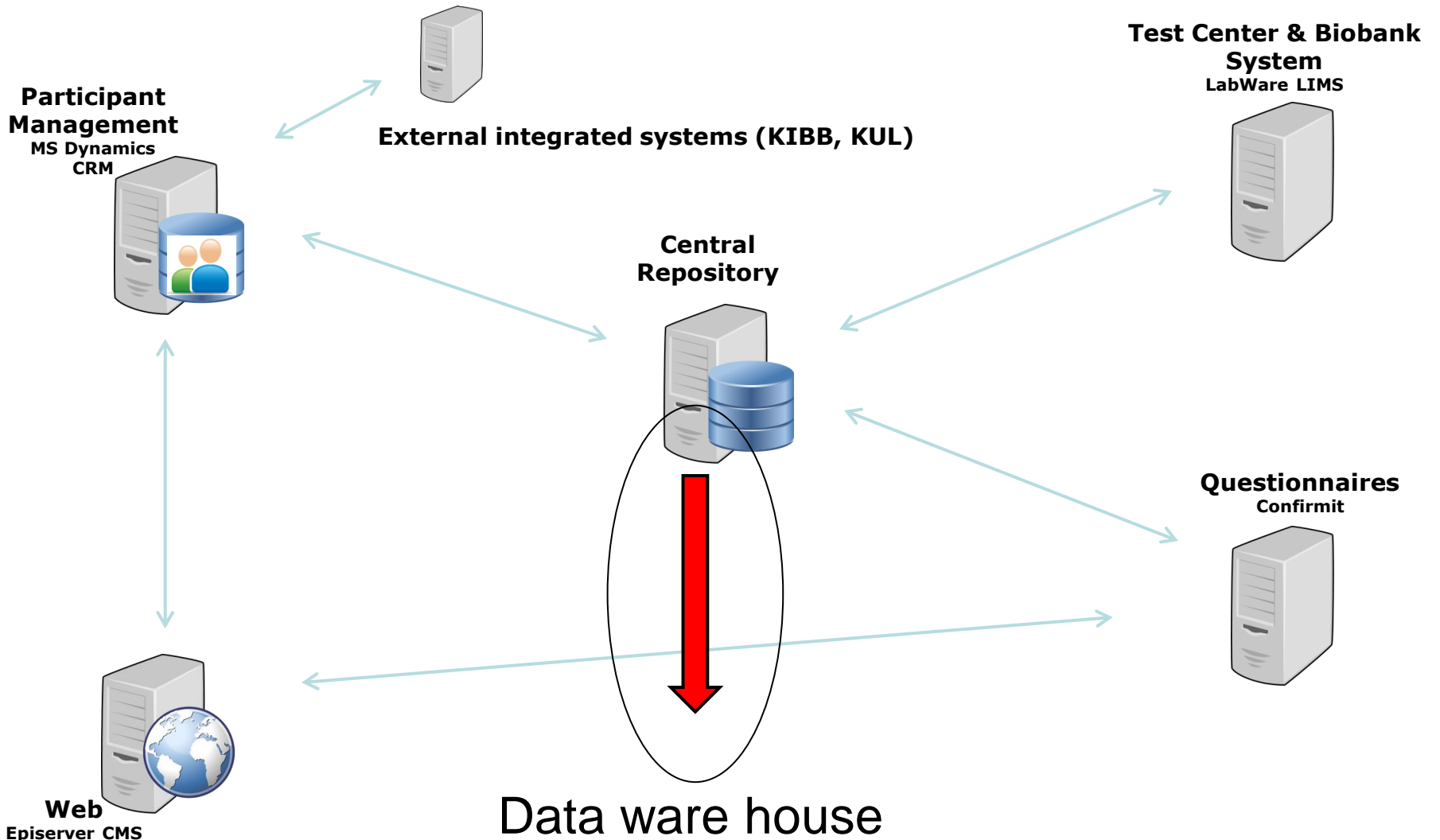
LifeGene-cycle

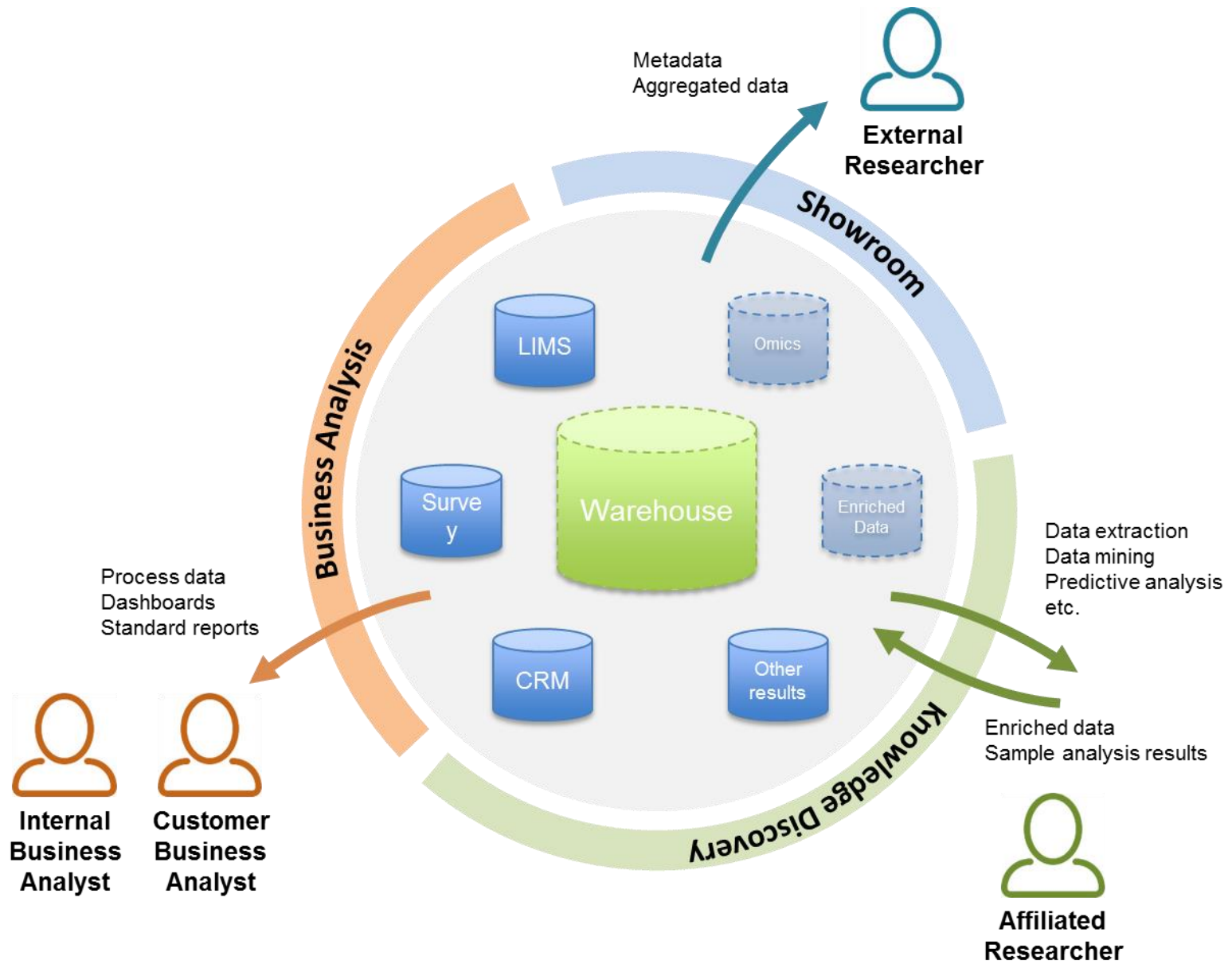


PLANERING LIFEGENE 2014

Aktivitet	November																			December																						
	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Anpassning mobil/platta																																										
Beslut om leverantör																																										
E-leg																																										
SMS-engångslösen																																										
Säkerställa mailleverans																																										
Ny TL																																										
Annons i DI																																										
Fil till ABA för utskick																																										
Utskick (en per hushåll)																																										
Påminnelse																																										
Uppdatering av adresser																																										
Nyhetsbrev																																										
Newsletter																																										
Auto. fil Olevererbara																																										
Fil till ABA studsar brev																																										
Utskick studsar på brev																																										
Mail till Working groups (NP)																																										
Call - eller i mars!																																										
Autoreply SC-mailen																																										
Kalibrering																																										
Skicka brev till VH2																																										
VH2 rapport																																										
Enkät deltagarflödet																																										
Barn - vad återstår?																																										

Infrastructure





My vision

- Government finance an infrastructure for collecting data
- Data will be collect within the organization of County Council
- Government finance a health check-up every 5th years
- Different studies can use the infrastructure

- Early diagnostics
- Resourse for research – will put Sweden at the map!
- Healthy and happy people!

Health care meets Science

Thanks!





LUNDS
UNIVERSITET



UPPSALA
UNIVERSITET



LifeGene

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



GÖTEBORGS
UNIVERSITET



Karolinska
Institutet

BACK UPS

Costs for Infrastructure

2008, total 2,4 MSEK

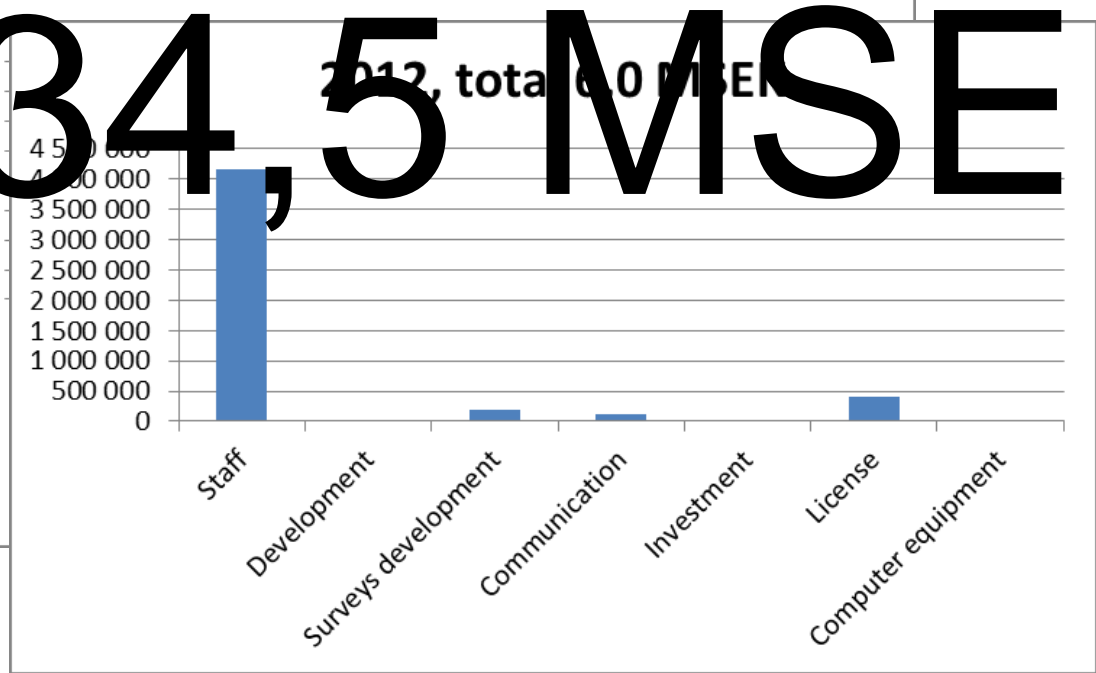
2009, total 9,3 MSEK

2010, total 10,5 MSEK

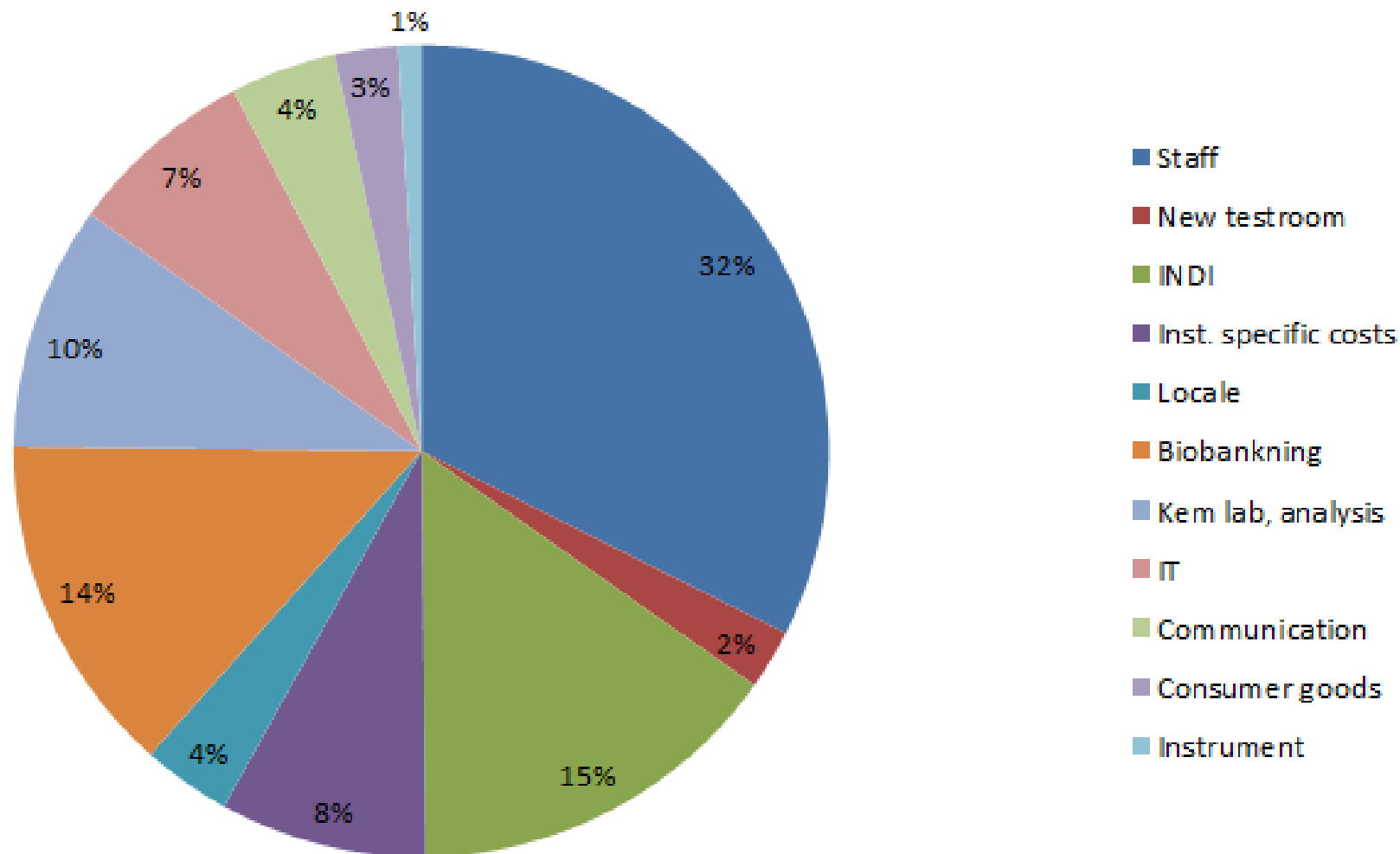
2011, total 6,3 MSEK

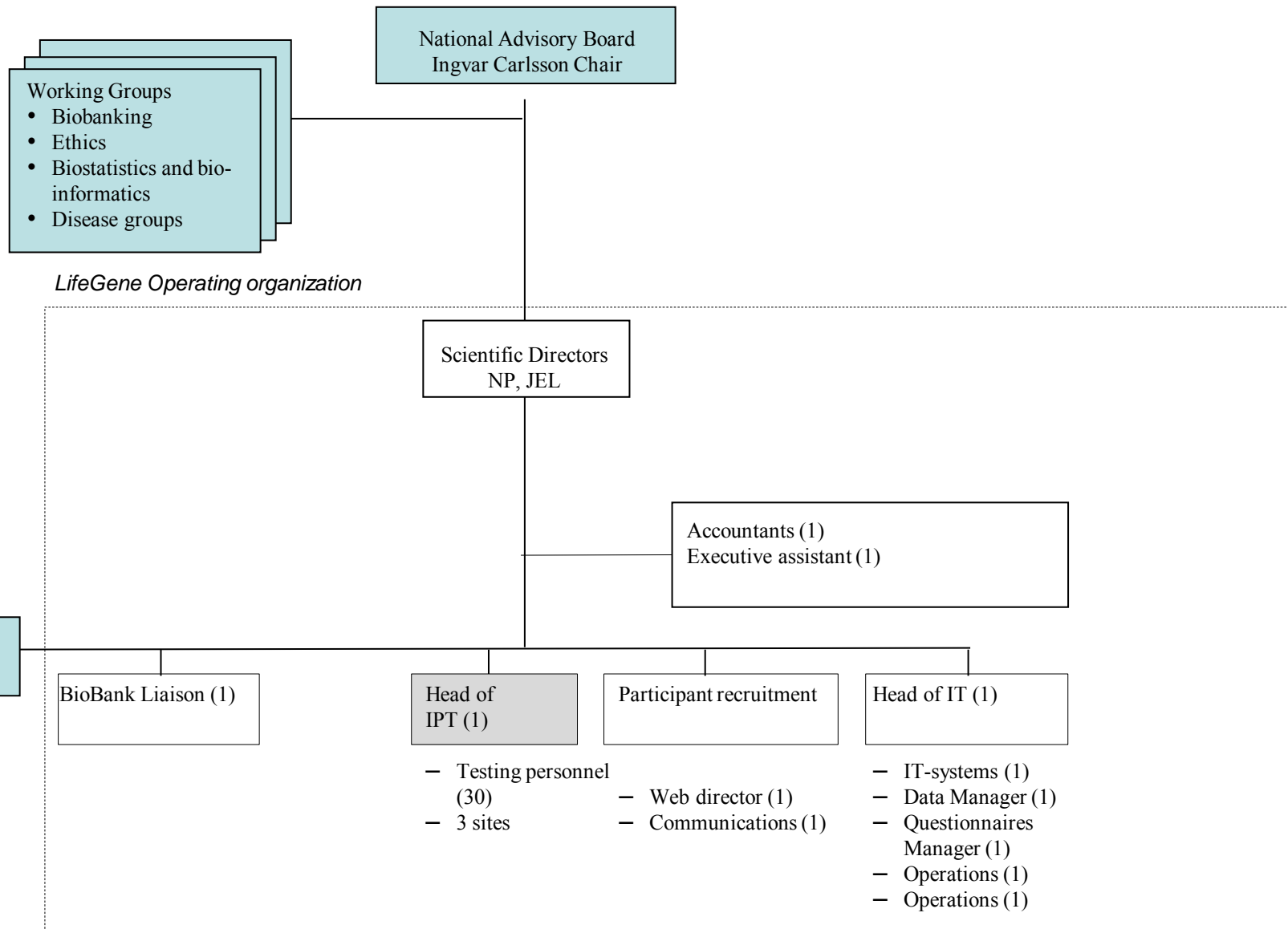
2012, total 6,0 MSEK

$\Sigma = 34,5 \text{ MSEK}$

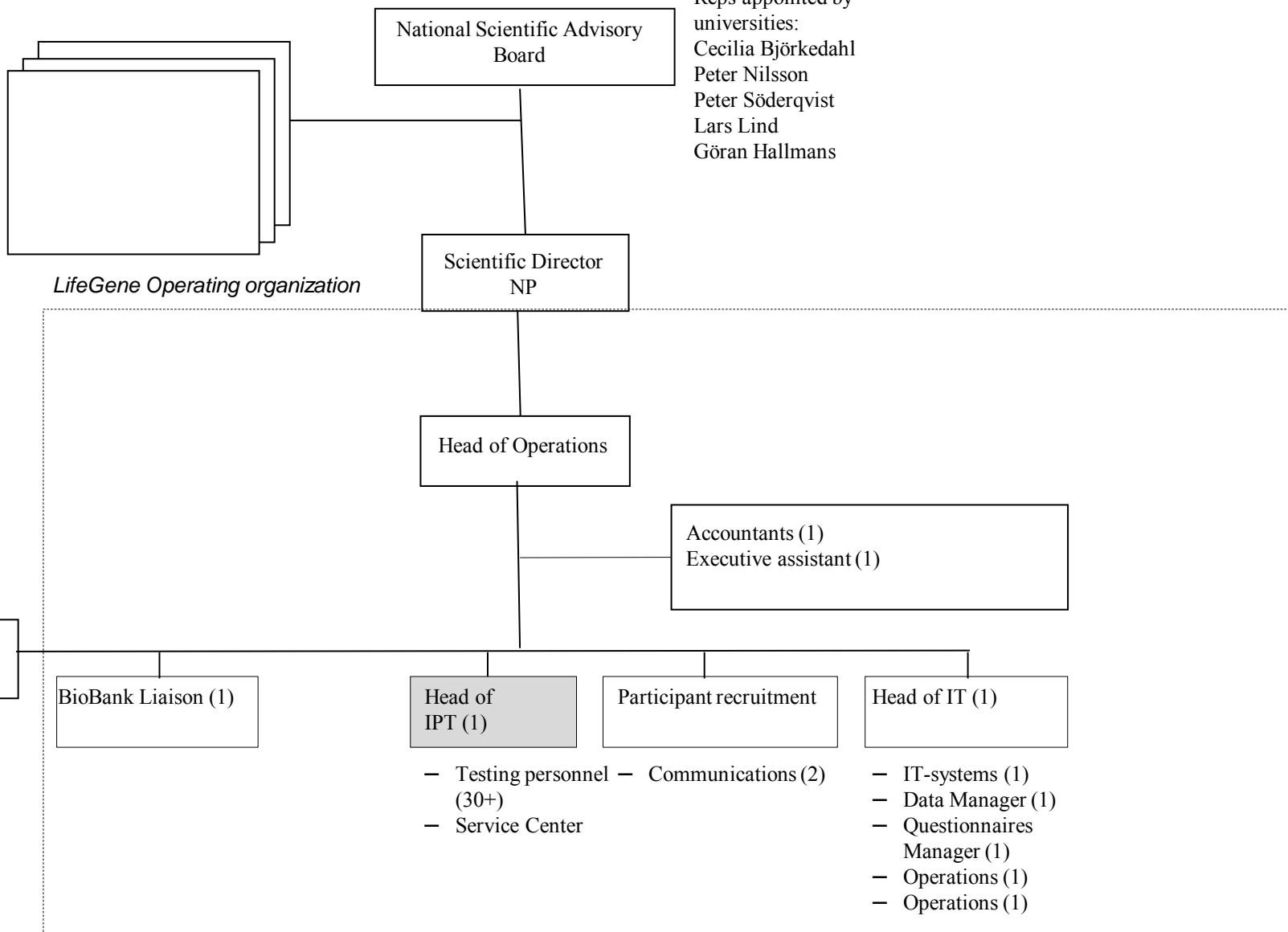


Costs year 2014 (10 MSEK)





Reps appointed by universities:
 Cecilia Björkedahl
 Peter Nilsson
 Peter Söderqvist
 Lars Lind
 Göran Hallmans



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 Cecilia Björkedahl
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National Scientific Advisory Board

Scientific Director
 NP

LifeGene Operating organization

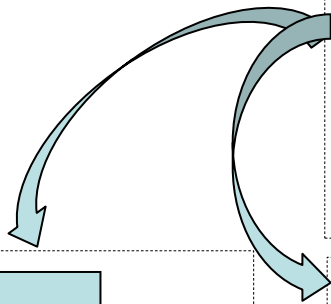
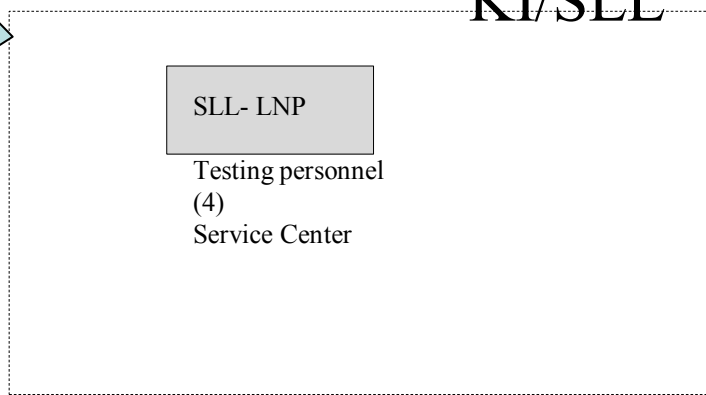
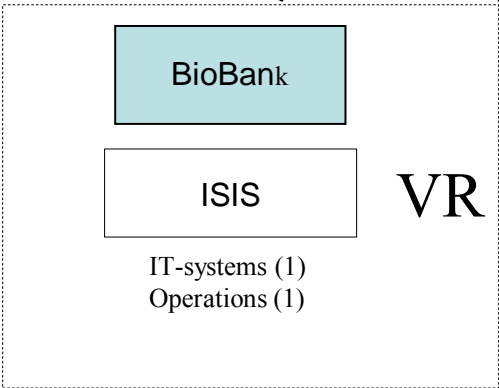
Head of Operations
 Kicki K

Recruitment & Communication
 - Maria B-H

Accountant/
 Controller

Medical officer

KI/SLL



Arm to freezer within 30 h

Self-test

- Nasal swab

Sample taken

Cold chain test center and transport

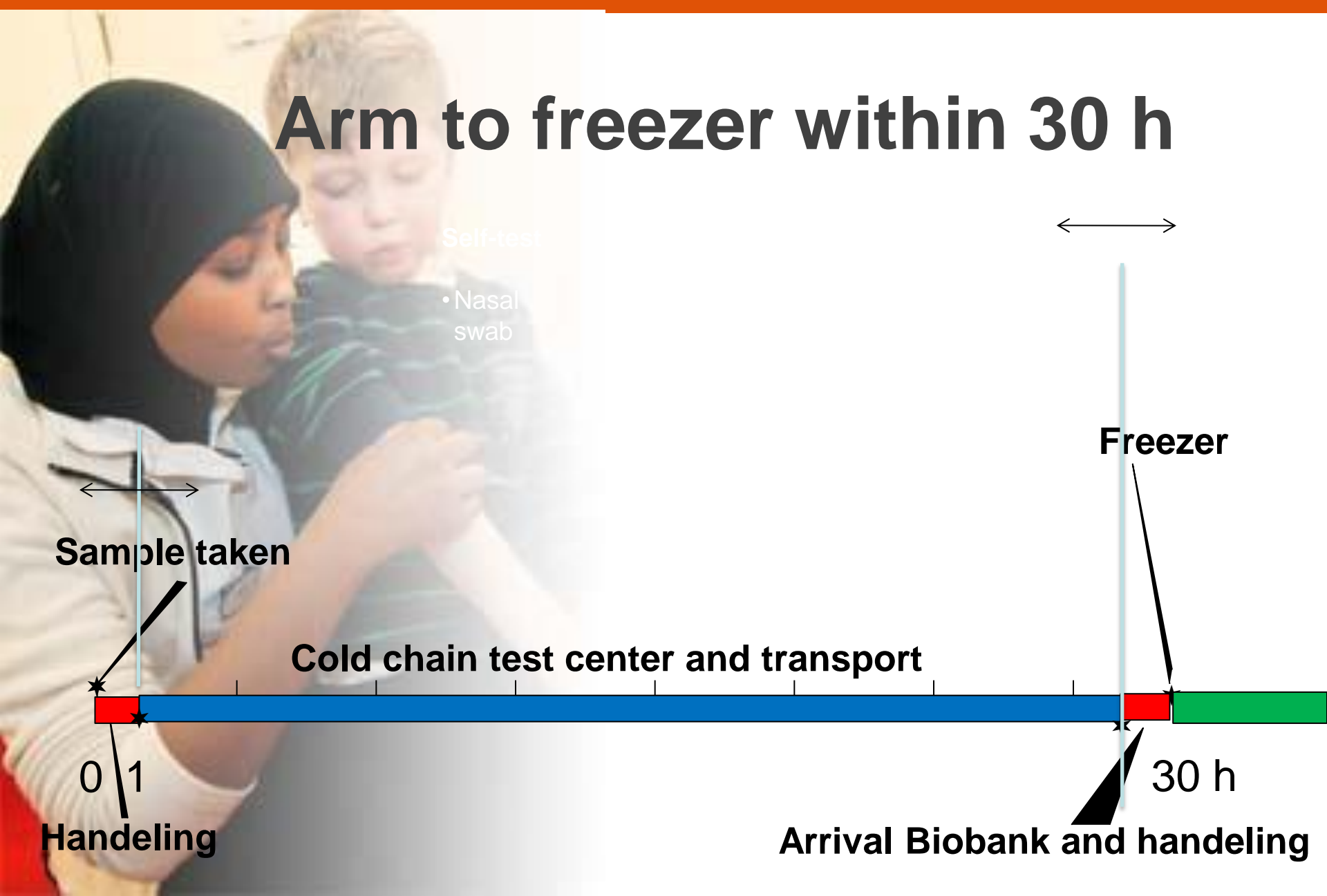
Freezer

0 | 1

Handeling

30 h

Arrival Biobank and handeling



Physical measurements in different age

	>10 y	7-9 y	5-6 y	3-4 y	< 3 y
Length	X	X	X	X	X
Waist-measurement	X	X	X	X	
Hips-measurement	X	X	X	X	
Weight			X	X	X
Bioimpedans and weight	X	X			
Spirometry	X				
Blood-pressure	X	X	X		
Pulse	X	X	X		

Time for a baseline test: 30 min

Blood samples in baseline

Tube	Volume	>18 y	15-17 y	7-14 y	<7 y	
EDTA	4	X	X	X	X	KI Biobank
EDTA	4	X	X			Karolinska
LiHep gel	4	X	X			Karolinska
PPT gel	8.5	X	X	X		KI Biobank
PPT gel	8.5	X				KI Biobank
Citrat 3.8%	4.5	X				KI Biobank
PST gel	8	X	X	X		KI Biobank
Trace metal	6	X	X	X	X	KI Biobank
Σ (ml)		47,5	34,5	26,5	10	