

NANOMEDICINE PLATFORM

INNOVATION IN HEALTHCARE – FROM BIOMARKER DISCOVERY TO IMPLEMENTATION

XII Conferencia Anual de las Plataformas Tecnológicas de Investigación Biomédica

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Nanomedicine

Innovation in health care

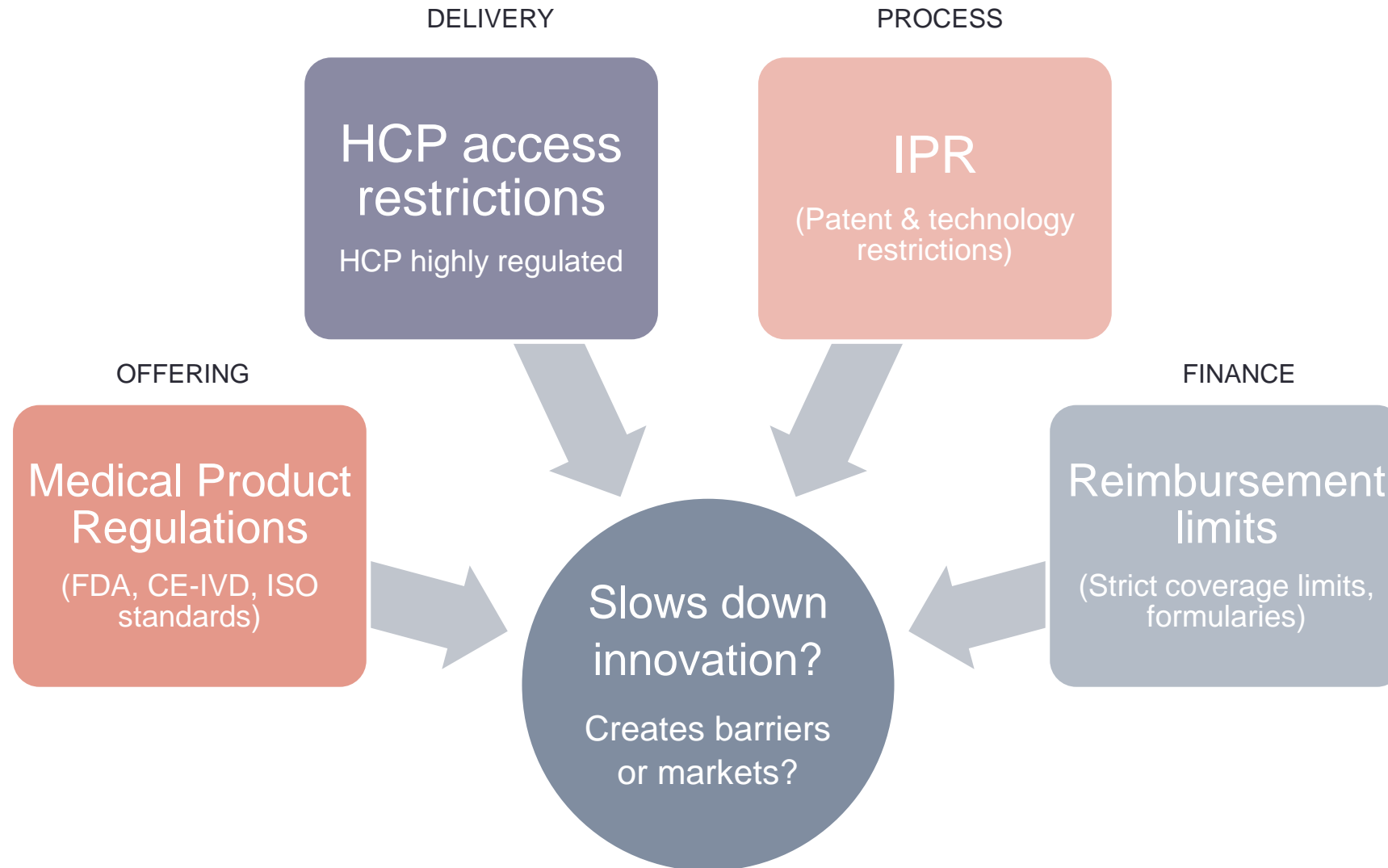
What can the biomarker development process teach us about innovation & nanomedicine?

- “Nano” has just started
- “Nano” is highly innovative
- Problems/barriers to overcome
- The current situation
- Recognizing the opportunity
- Joint Project for Cancer Screening
- Ideas for faster innovation
- Questions & discussion



PROBLEMS & BARRIERS TO OVERCOME

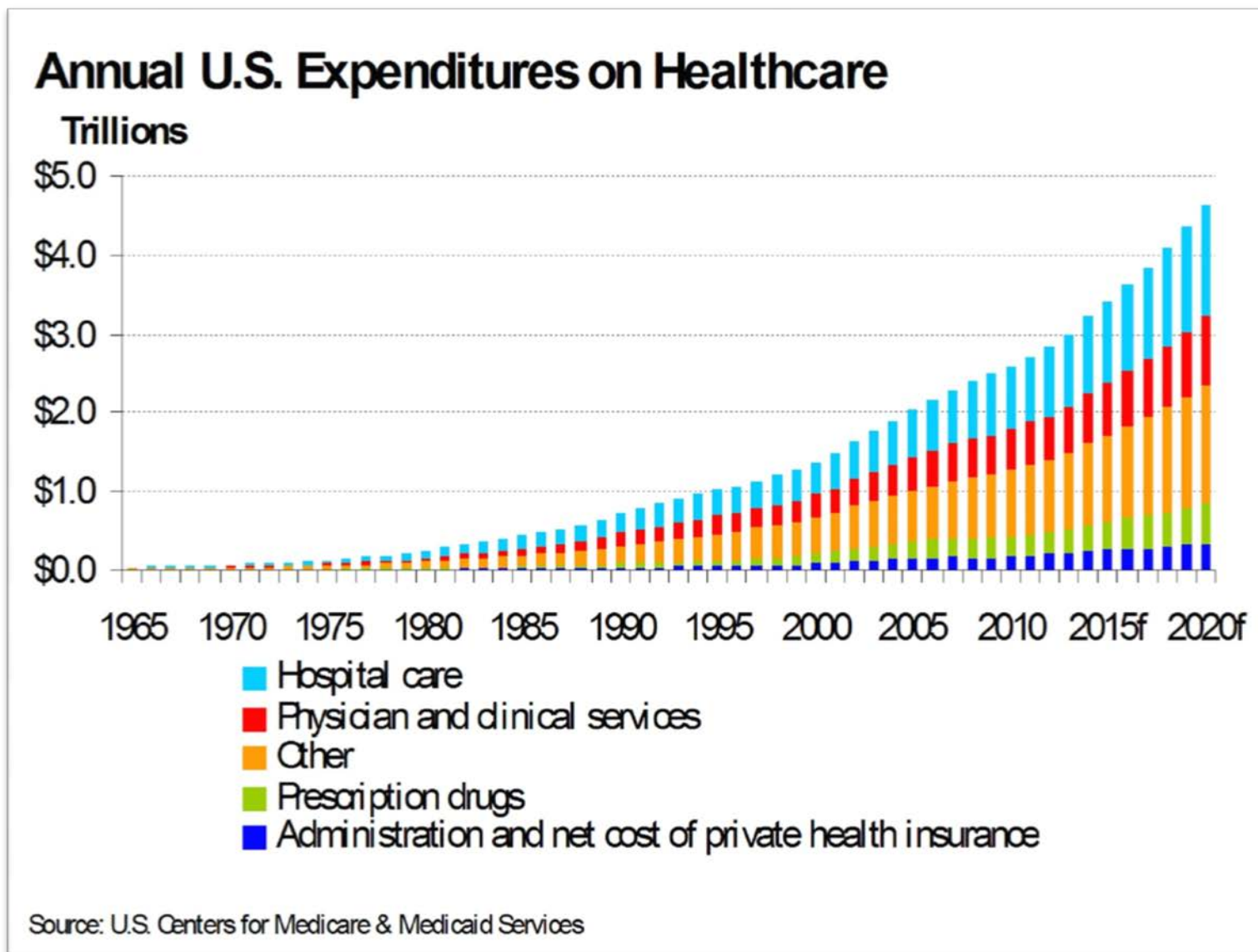
Innovation in a highly regulated environment



Innate barriers to innovation and nanomedicine at every level

THE CURRENT SITUATION

Rising Health Care Costs



THE VALUE OF DIAGNOSTICS

Diagnostic tests are at the forefront of medical innovation, providing vital insights into patient health and care.

PERCENT OF WORLDWIDE HEALTH CARE
SPENDING USED ON DIAGNOSTICS

2%



PERCENT OF MEDICAL DECISION-MAKING
INFLUENCED BY DIAGNOSTICS

70%



cardiovascular
diseases



personalized
medicine



cancer



point of care



infectious diseases
(HIV, tuberculosis,
influenza, etc.)

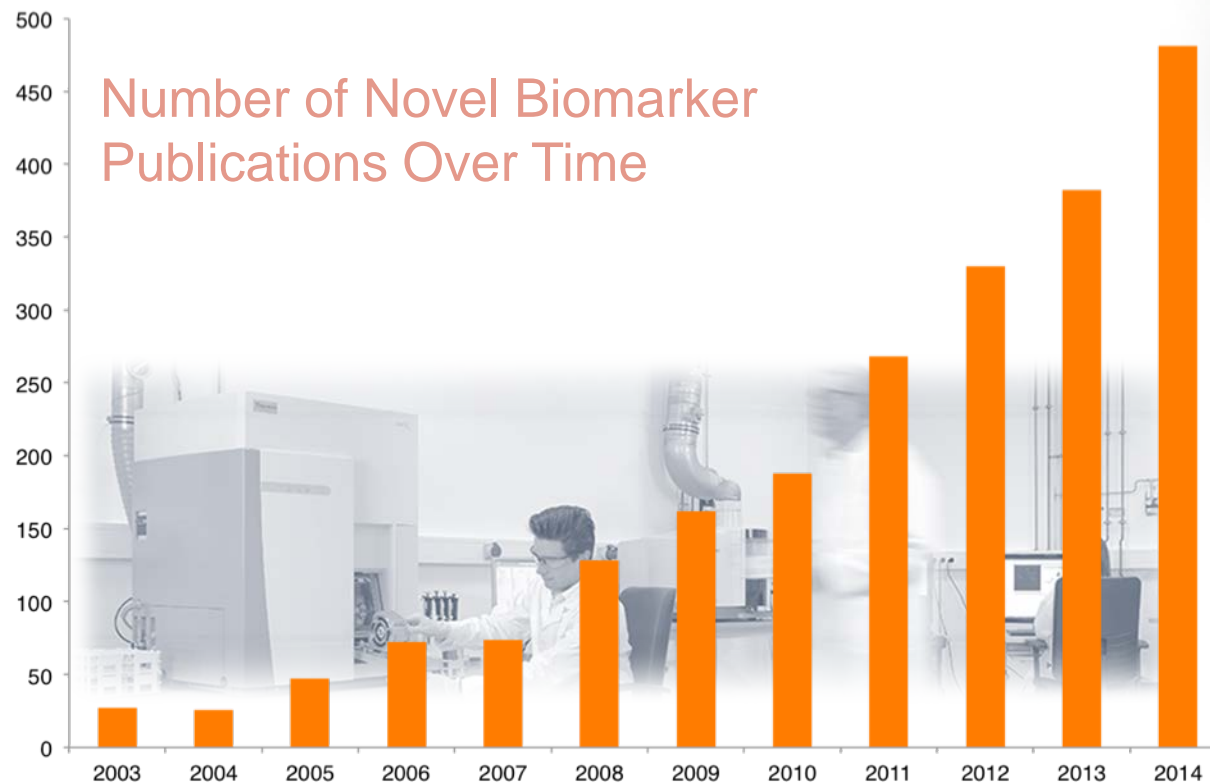
~17 years from discovery to
implementation for a new biomarker

Producing new biomarkers

No lack of biomarkers

Proliferation of technology

Multiplexing, MS, NGS



<http://www.biomarker-trends.com/>



RECOGNIZING THE OPPORTUNITY

Prostate Cancer Diagnosis

A multimodal approach

An example of joint
innovation across health
care, academia and industry



Prostate cancer: a major unmet diagnostic need

High risk for all men over 45

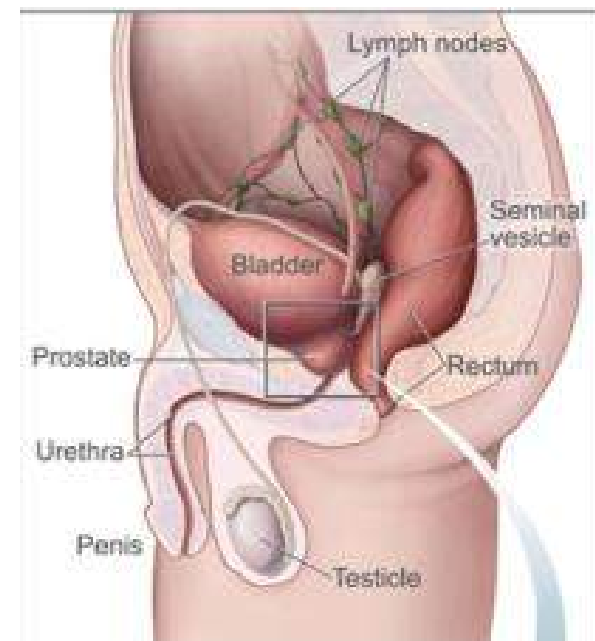
- 1 man in 6 will be diagnosed with prostate cancer during his lifetime.

Current diagnostic methods

- Prostate Specific Antigen (PSA) blood test.
- Palpation by urologist and imaging by radiologist
- Prostate biopsy and lymph node examination (Gold standard)

The current PSA test is a highly questioned

- Misses about 20% of severe cancers
- Does not distinguish indolent from aggressive cancers
- Serious over-diagnosis with negative impact on quality of life



This shows the prostate and nearby organs.



This shows the inside of the prostate, urethra, rectum, and bladder.

Problem:

Existing PSA testing and screening is controversial



Special Report

U.S. Preventive Services Task Force Advises against PSA Screening

A long-awaited update from the U.S. Preventive Services Task Force (USPSTF) recommends against screening men for **prostate cancer** with the **prostate-specific antigen (PSA) test**. The task force's 2008 recommendation advised only against screening men aged 75 and older; the update has extended that guidance to include all men.

The **recommendation**—published May 21 in the *Annals of Internal Medicine* and on the **USPSTF website** [\[link\]](#)—does not apply to PSA testing to monitor prostate cancer progression after diagnosis or treatment.

"All men deserve to know what the science tells us about PSA screening: There is a very small potential benefit and significant potential harms," the task force's co-chair, Dr. Michael LeFevre, explained in a statement on the new recommendation.



The debate about the value and appropriate use of the PSA blood test to screen for prostate cancer is likely to continue for some time.

“All men deserve to know what the science tells us about PSA screening: There is a very small potential benefit and significant potential harms”

Review of data revealed that...

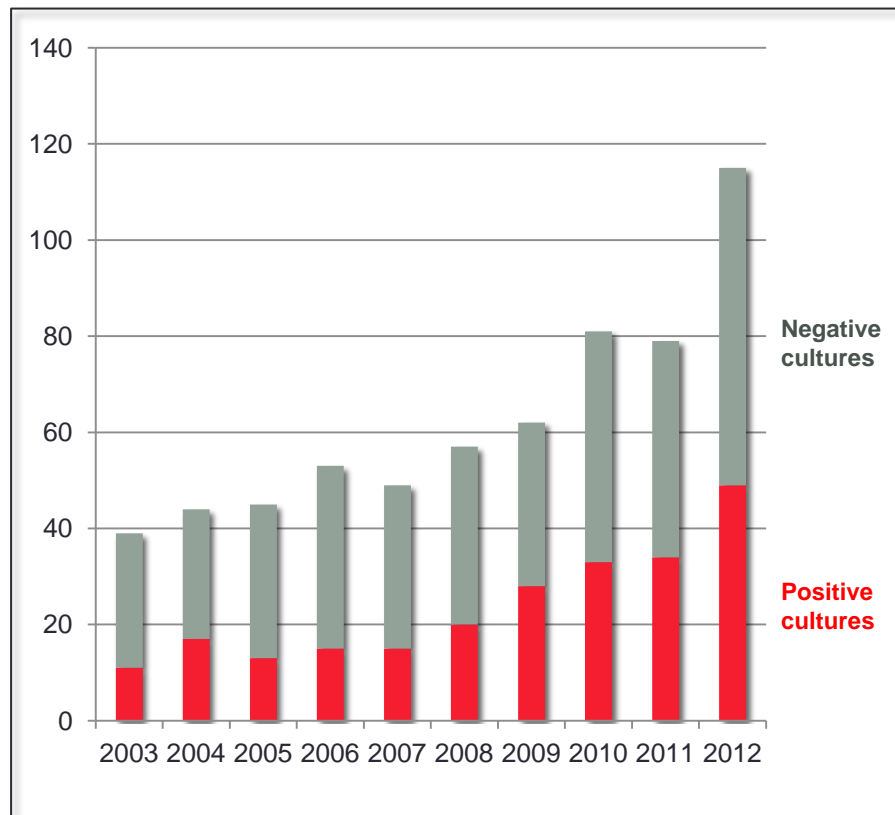
Today's unstructured screening with PSA is ineffective

Over testing	38% of men with PSA < 1 take a new test in 2.5 years
Over diagnosis	60% of all men biopsies are negative 50% of all cancers diagnosed are Gleason 6
Under treatment	30% of men aged 50-59 with PSA \geq 10 has not conducted biopsy within 2 years from PSA-testing 17% of men aged 50-69 diagnosed with advanced prostate cancer (T3/4, N1, M1, PSA>20), has had a PSA \geq 4 six months or earlier without action taken

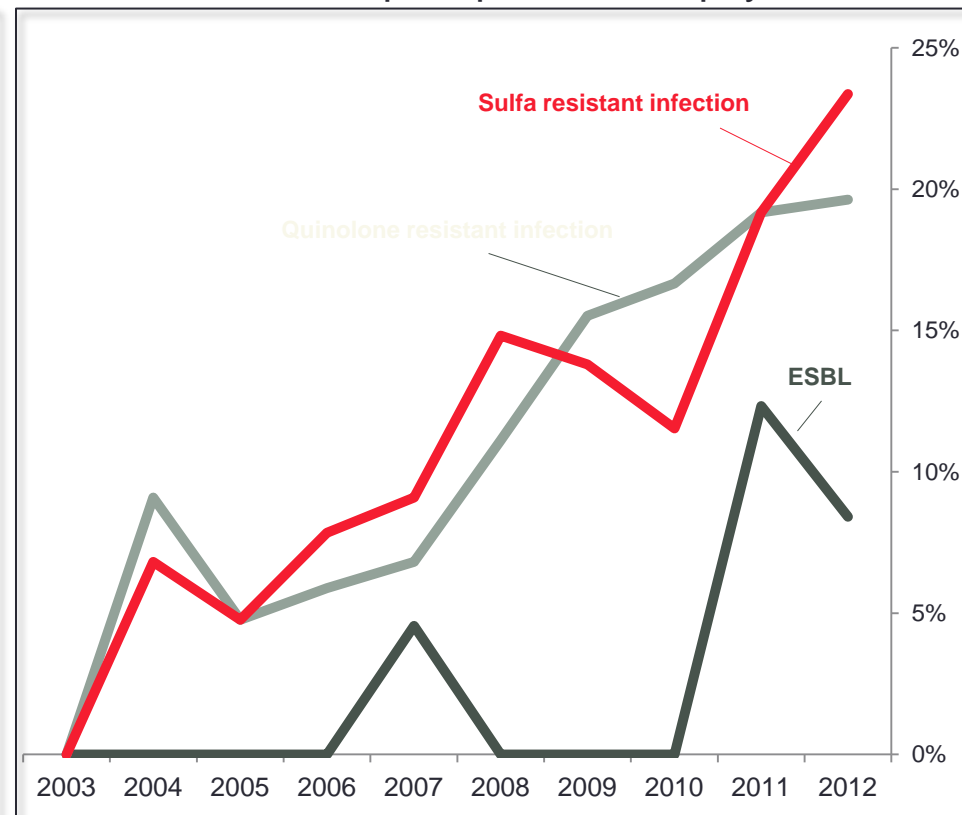
PSA requires a biopsy

Biopsy is not only unpleasant, it is also potentially harmful

of blood cultures 2003-2012 in Stockholm



Severe infections post prostate biopsy 2003-2012



JOINT PROJECT (STHLM3)

Reducing unnecessary biopsies beyond PSA testing for Prostate Cancer

Stockholm 3 Project

Joint project between academia,
healthcare & industry

**Goal: Improve diagnosis of
prostate cancer by 15-25%**



(Stockholm county council)



Solid science – biobanked material

Stora prostata-
cancerstudien:

STHLM 0

N = 500,000
2003-2016
Register

1.7 million biobanked aliquots of whole blood, plasma, DNA, tissue and urine

500,000 PSA values and outcome data from current clinical practice 2003-2016

Stora prostata-
cancerstudien:

STHLM 1

N = 1,500
2011
Prospective

85,000 men with biomaterial, complete outcome data on prostate cancer, answer to 1000+ questionnaire on prostate cancer, and complete Swedish register data

Stora prostata-
cancerstudien:

STHLM 2

N = 25,000
2011-2012
Prospective

7,500+ biopsies with biomaterial, complete outcome data on prostate cancer, answer to 1,000+ questionnaire on prostate cancer, complete Swedish register data, and access to biopsy tissue

STHLM 3

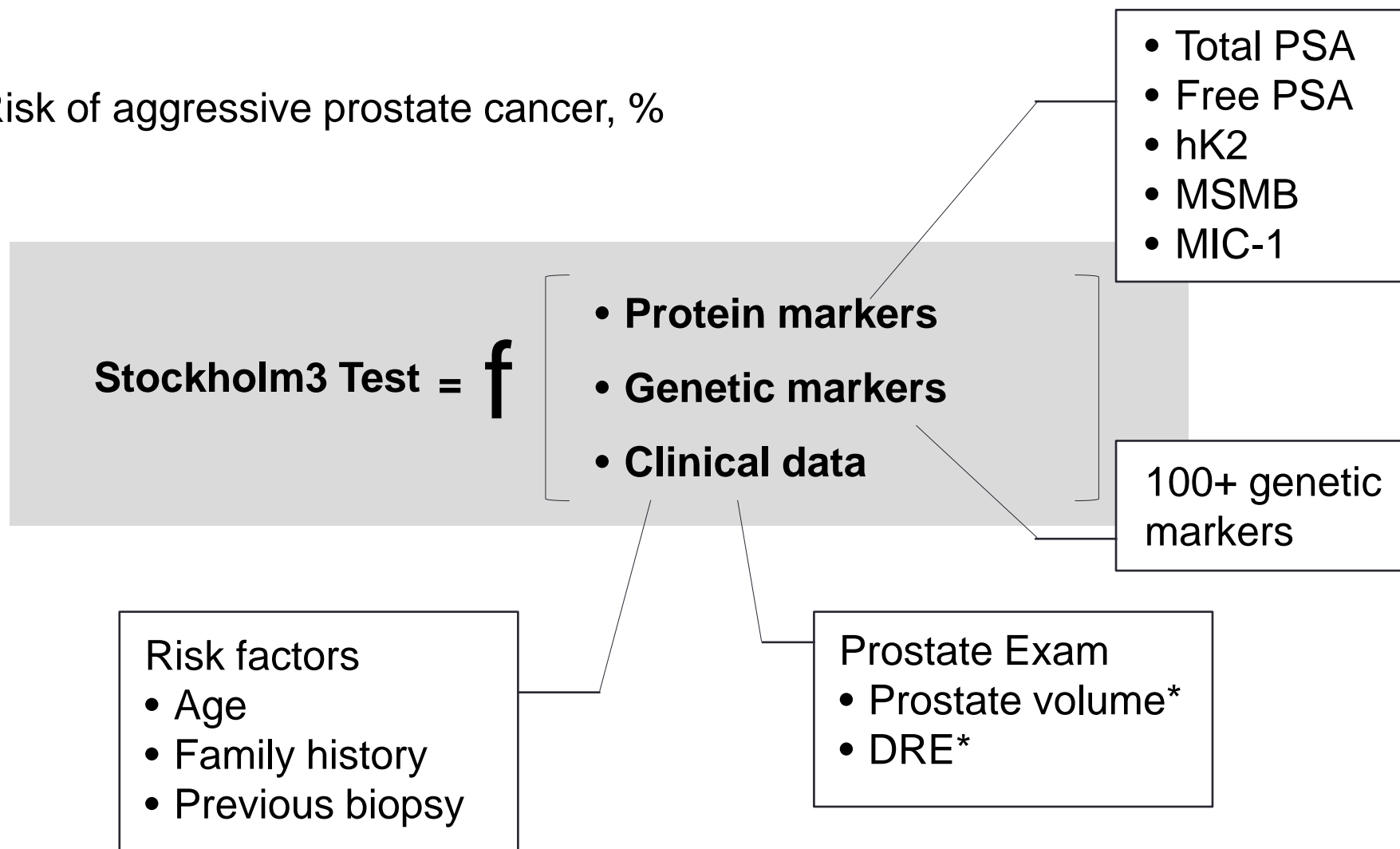
Improved Prostate
Cancer Diagnostics

N = 60,000
2012-2014
Prospective

1,500+ radically operated with biomaterial, complete outcome data, answer to 1000+ questionnaire on prostate cancer, complete Swedish register data, access to biopsy tissue, access to operation tissue, and post op outcome data

Algorithm based Risk Score

Risk of aggressive prostate cancer, %



* Only measured on biopsied men

Study produced new products

STHLM3 has developed two chips for high-throughput testing

Customized biomarker chip

Thermo
SCIENTIFIC



Customized SNP chip

life
technologies™



Nanomedicine at work

High throughput testing

Public/private partnership made the difference

Study

58,818 men recruited

7,414 men biopsied

Paired design

Conducted 2012-2015

Results compared to current clinical practice

50% reduction of unnecessary biopsies

20% increase in aggressive cancers found

Finds cancers in low PSA 1-3

Good health economics



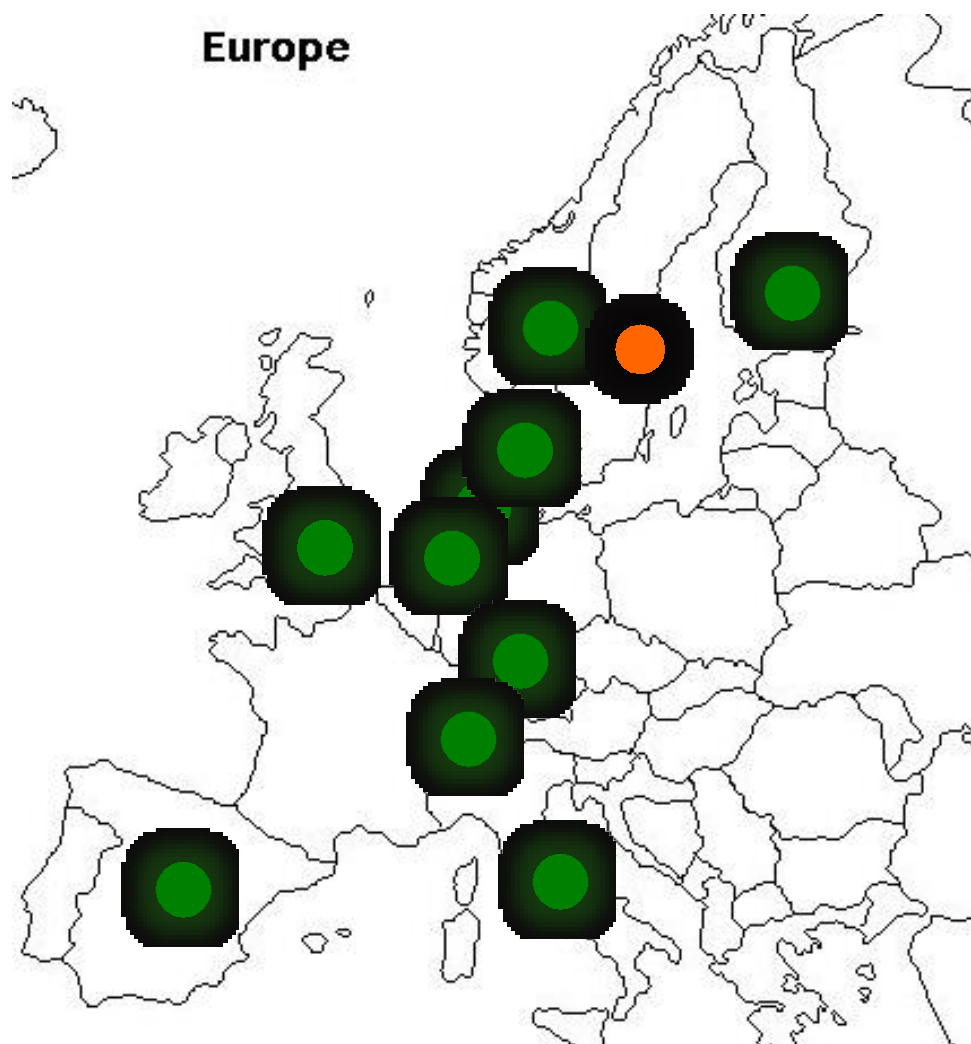
THE LANCET Oncology



nature
REVIEWS CLINICAL
ONCOLOGY

EUROPEAN
UROLOGY FOCUS

Expanding market presence



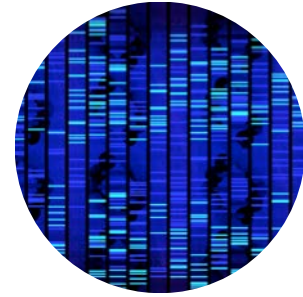
What was significant to innovation?

- Combining advanced healthcare technology with
- Large database of cohorts (registries & biobanks) and
- Collaboration over disciplines (informatics, genetics, bioscience)
- Academia, health care and Industry - collaboration

The application of advanced research tools in combination with large clinical cohorts allows identification of relevant markers and rapid implementation.

Project involved innovation in
PROCESS, OFFERING, DELIVERY AND FINANCE

A senior multitalented team including clinical, technical and business oriented skills



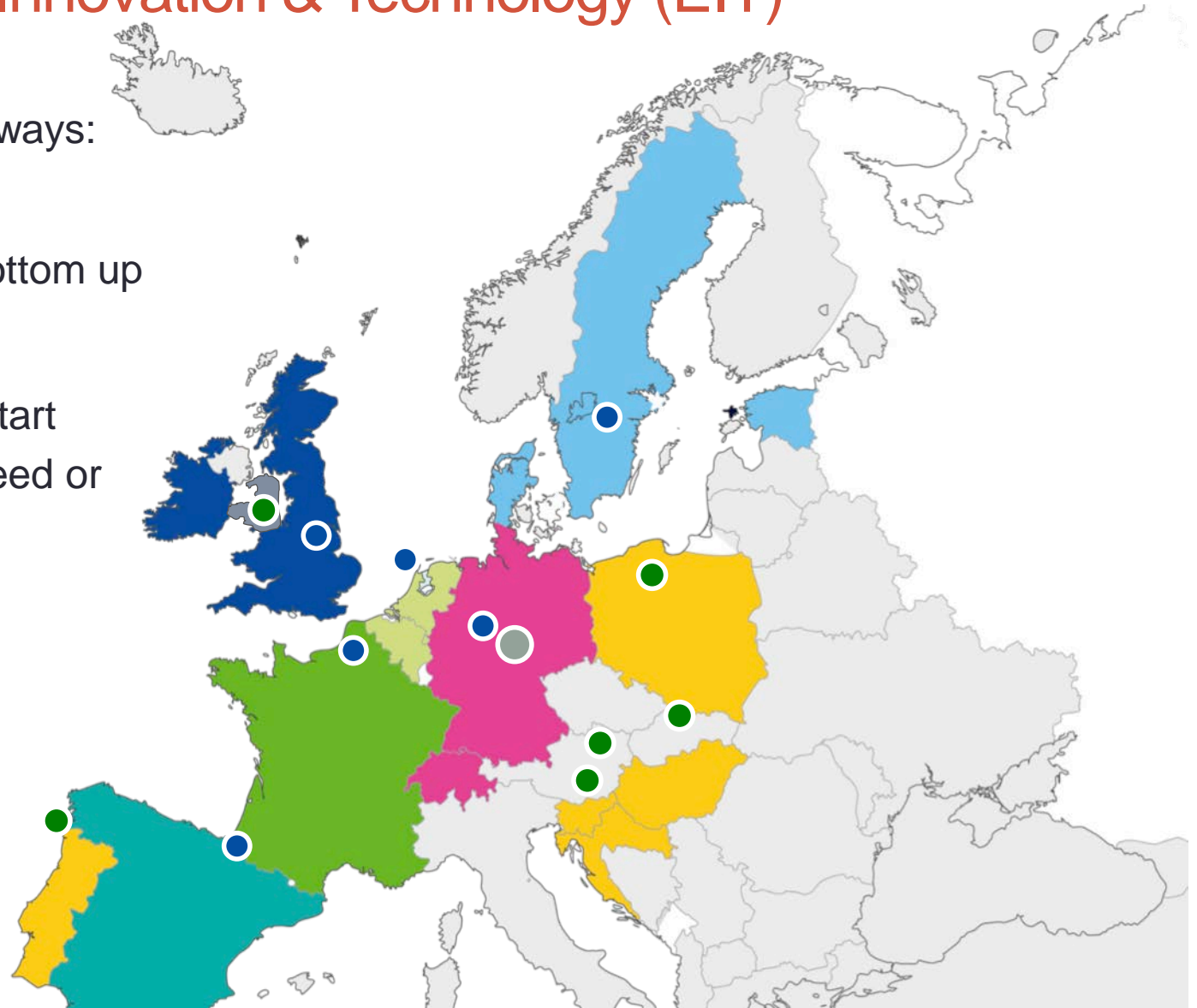
IDEAS FOR FASTER INNOVATION IN HEALTHCARE

European collaborative for health research

European Institute of Innovation & Technology (EIT)

EIT focuses on innovation two ways:

- **Innovation by ideas:**
Solution-driven projects – bottom up
- **Innovation by design:**
Needs-driven projects that start from a recognized market need or problem



How can joint organizations deliver innovation?

Public / Private partnerships

Promotes an open innovation environment

- “Rules of engagement” / “code of conduct”

Gives access to sharing:

- Ideas
- Unmet clinical needs and market understanding
- Solutions and early stage product concepts

Utilize strengths of each partner

- Registries, patient cohorts, applied technical solutions
- A win/win setup

Innovation is the creation of a viable new offering/solution¹

Innovation requires identifying the problems that matter and moving through them systematically to deliver elegant solutions¹

From Ten Types of Innovation by Larry Keely

¹ <http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1118504240.html>

Joint funding and discovery opportunities

Numerous organizations help create an opportunity for EU to become health innovation leader



+ more

How can we do it faster?

- Better data from larger pool
- Big Data & Informatics
- Joint process/collaboration
- Utilizing digital health information (individual data)
- Structured approach to development/innovation
- Parallel development processes

THANK YOU

Nanomedicine

- is highly innovative
- provides new and exciting tools
- tools need context and solve problems
- team based approach
- innovation takes time

