MOVEMBER®

GAP 1 PROSTATE CANCER BIOMARKERS

OUTCOMES FROM MOVEMBER'S GLOBAL ACTION PLAN

WHY WE NEEDED TO ACT...

Prostate cancer affects **1 in 8 men**. Yet there is a lack of clinically available tests *(biomarkers)* to help doctors make decisions about the best course of treatment to take for each man.

This means some men are not optimally treated during the course of their disease.

To ensure every man receives the most effective treatment for their specific type of cancer, we need more accurate biomarkers.

GAP 1 2011

"GAP's premise is that team-based, integrated research will reduce duplication of effort, deliver innovation faster, and accelerate patient outcomes."

Dr Mark Buzza, Global Director, Prostate Cancer Biomedical Research - Movember Foundation

After 12 months of planning, the **GAP1 consortium** was established with more than

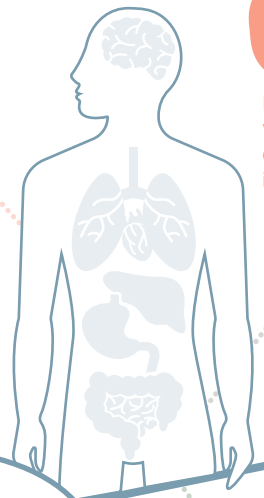
250+ Researchers

50+ Hospitals & Research Institutes

14 Countries

7 INTEGRATED RESEARCH TEAMS

were assembled around the world to collaborate on the most critical biomarker challenges, by sharing samples, methods, experiments and results...



Blood / Serum team

Validate panels of DNA, RNA and Protein biomarkers detectable in the blood

Exosomes team

Research how extracellular vesicles in blood or urine can determine if prostate cancer is aggressive or low risk

Circulating Tumour Cells (CTCs) team

Test different cell capture and visualisation technologies

Urine team

Validate DNA, RNA & Protein biomarkers detectable in urine

Tumour Tissues team

Validate biomarkers derived from prostate tumor tissue

Xenograft team

Use Patient-derived xenograft models to determine treatment response

Unique Tissue Microarray team

Optimal use of rare pathology samples

Why focus on biomarkers as a diagnostic tool?

Biomarkers are a critical component of a 'personalised' medicine approach to treating cancer.

New biomarkers are urgently needed to better detect the presence or absence of prostate cancer, dermine its aggressiveness and guide decisions on the timing and most promising type of treatment.

What are BIOMARKERS?

Biomarkers are **signals** produced by the body, that indicate the presence or severity of certain diseases.

They can be measured in body tissue or fluids and form the basis of diagnostic tests.

OUR IMPACT

Before Movember initiated GAP1, there was an enormous amount of duplication of effort across different laboratories around the world. Movember brought people together, got researchers talking, and funded teams who now integrate their research projects.

We're now seeing results – with millions of dollars saved, many years of unproductive research made more efficient, and new tests being developed faster.

It takes an average of **17 years** for promising research to change practice.

Adademic Investigation

ProCUrE
DNA mehtylation panel with a focus on positive predictive value

Analytic Validation

OCProDx
to determine whether a man's cancer is likely to spread

Telo-PC ™
Biomarker based on 3D analysis of chromosomal structural changes

epiCaPture
DNA methylation panel to determine disease agressiveness

Clinical Validation

PUR
Risk signature of 36 genes for disease progression with men on Active Surveillance

FDA Approved

SelectMdx
mRNA expression of HOXC6 and DLX1 to distinguish low vs high-risk of prostate cancer to aid biopsy decision

On Market

RosetteSep
(lab only)
Stem Cell Technology

TRIFicTM
(lab only)
Cell Guidance System

$9.1M
raised by Movember and invested in GAP 1 since 2011

attracted additional

$41.6M
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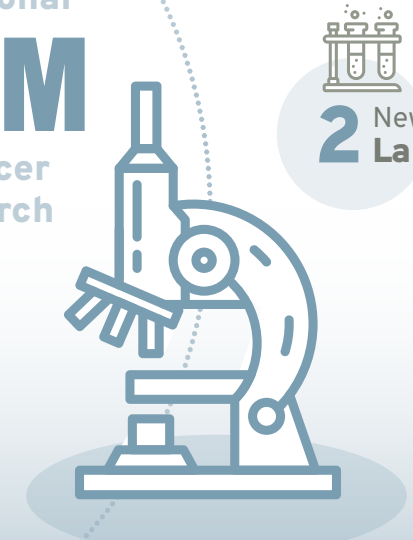

57 + Publications in scientific journals

2 Patents and 4 more in development

2 New Lab Assays

2 Biotech Companies formed

6 Diagnostic Tests in development

STUDY HIGHLIGHTS

Study Highlight 1

PROSTATE URINE RISK (PUR) TEST

As part of the international GAP1 Urine biomarker consortium working across the UK, US, Canada and Europe, researchers at the University of East Anglia UK measured genetic components (called RNA) in 535 urine samples from men with suspected prostate cancer.

The **PUR** test effectively classified men based on personal disease risk and was published in BJU International *.

After a competitive application process in early 2019, the team received £270k from Movember to validate the PUR test in a larger prospective sample of men.

This trial is designed to generate the critical evidence necessary for regulatory approval of the PUR test and population level adoption.

If successful, many unnecessary and invasive prostate biopsy procedures will be avoided.

* https://onlinelibrary.wiley.com/doi/10.1111/bju.14811

Study Highlight 2

TUMOUR-SECRETED EXOSOMES

Prostate cancer cells shed microscopic vesicles, called exosomes, that closely resemble properties of the tumor.

These cancer-specific exosomes, which can be found in blood and urine samples, contain important disease information like the aggressiveness of a man's cancer.

The GAP1 Exosomes Team at the Erasmus MC Netherland tested and developed new methods to isolate and examine the exosomes, one of which has now become a commercially available detection assay called **TRIFicTM**.

As a result of the team coming together to collaborate, researchers can now use sample repositories (biobanks) to validate and assess new biomarkers for prostate cancer.

A GAP1 Researcher in the Netherlands recently received a €2.3 million investment from the EU Commission *Horizon 2020* program to launch **proEVLifeCycle**, a multidisciplinary research and training network to accelerate development of prostate cancer exosomes biomarkers and train a new generation of prostate cancer researchers in cutting-edge new techniques.

Study Highlight 3

PATIENT DERIVED XENOGRAFTS

PDXs are valuable experimental models that allow scientists to study a tumor's reponse to treatment.

At the start of GAP1, only a handful of thoroughly characterized prostate cancer PDXs existed worldwide. The GAP1 team characterized 98 different PDXs and created an additional 19 new PDX models.

These are now available to understand high-risk prostate cancer types and test whether multiple drug combinations are likely to benefit patients more than giving each drug on its own.

This will accelerate the availability of new therapies and increase clinicians' ability to personalise patient treatment.

https://onlinelibrary.wiley.com/doi/abs/10.1002/pros.23701

THANK YOU

The GAP1 program was funded from the generosity of the Movember community.
Movember will continue to work closely with GAP1 Researchers to progress promising biomarkers towards clinical utility and patient benefit.

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- **On Market** — **SelectMdx** mRNA expression of HOXC6 and DLX1 to distinguish low vs high-risk of prostate cancer to aid biopsy decision; **RosetteSep** (lab only) Stem Cell Technology; **TRIFicTM** (lab only) Cell Guidance System

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