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, determine its aggressiveness and guide decisions on the timing and most promising type of treatment.

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.

**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.

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**GAP 1**

**PROSTATE CANCER BIOMARKERS**

OUTCOMES FROM MOVEMBER’S GLOBAL ACTION PLAN

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**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.

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**GAP 1 2011**

After 12 months of planning, the GAP1 consortium was established with more than 250 Researchers, 50 Hospitals & Research Institutes and 14 Countries.

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**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, determine its aggressiveness and guide decisions on the timing and most promising type of treatment.

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**Why 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.

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**INTEGRATED RESEARCH TEAMS**

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

- **ProCUrE**: DNA methylation panel with a focus on positive predictive value
- **OCProDx**: DNA methylation panel to determine disease aggressiveness
- **epiCaPture**: DNA methylation panel to determine whether a man’s cancer is likely to spread
- **Telo-PC™**: Biomarker based on 3D analysis of chromosomal structural changes
- **PUR**: Risk signature of 36 genes for disease progression with men on Active Surveillance
- **SelectMdx**: mRNA expression of HOXC6 and DLX1 to distinguish low vs high-risk of prostate cancer to aid biopsy decision
- **TRIFic™**: (lab only) Cell Guidance System
- **RosetteSep**: (lab only) Stem Cell Technology

- **2 Patents** and 4 more in development
- **57+ Publications** in scientific journals
- **2 Biotech Companies** formed
- **2 New Lab Assays**
- **6 Diagnostic Tests** in development

$9.1M raised by Movember and invested in GAP1 since 2011

$41.6M attracted additional for prostate cancer biomarker research

- **Adademic Investigation**
- **Analytic Validation**
- **Clinical Validation**
- **On Market**
- **FDA Approved**
STUDY HIGHLIGHTS

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.

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 Netherlands 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 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.


Study Highlight 3

PATIENT DERIVED XENOGRAFTS

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

**OUR IMPACT**

Before Movember, despite GAP, there was an enormous amount of duplication of effort and lack of coordination. We're now seeing results — with millions of dollars saved, many years of prostate cancer research made more efficient, and new tests being developed faster.

**STUDY HIGHLIGHTS**

1. **Study Highlight 1**
   - **Prostate Cancer Biomarkers**
   - Researchers from 250+ Countries and 250+ Research Institutes worked under GAP1 to establish a unique tissue biomarker consortium working across the globe.
   - The consortium was a critical component of the GAP1 global action plan.
   - Biomedical research networks in Europe, North America, and Asia-Pacific were assembled around the gap1/2 consortium.
   - Why focus on biomarkers as a diagnostic tool? Researchers can now use sample repositories (biobanks) to validate and collaborate, researchers can now use sample repositories (biobanks) to validate and collaborate, researchers can now use sample repositories.
   - As a result of the team coming together to train a new generation of prostate cancer researchers, 250+ countries have now established the GAP1 Exosomes Team at the Erasmus Medical Centre, researchers can now use sample repositories.
   - Researchers can now use sample repositories to validate and test different cell types, such as prostate cancer cells shed microscopic vesicles, called exosomes, that closely mimic the behavior of the cancer they are derived from.
   - These cancer-specific exosomes, which can be found in blood and urine samples, contain proteins and DNA that can be used to understand the aggressiveness of a man’s cancer.
   - Study Highlight 1
     - **Study Highlight 2**
     - **Tumor-Specific Exosomes**
     - Researchers can now use sample repositories to validate and test different cell types, such as prostate cancer cells shed microscopic vesicles, called exosomes, that closely mimic the behavior of the cancer they are derived from.
   - These cancer-specific exosomes, which can be found in blood and urine samples, contain proteins and DNA that can be used to understand the aggressiveness of a man’s cancer.
   - Study Highlight 2
     - **Study Highlight 3**
     - **Prostate-Specific Proteins**
     - Researchers can now use sample repositories to validate and test different cell types, such as prostate cancer cells shed microscopic vesicles, called exosomes, that closely mimic the behavior of the cancer they are derived from.
   - These cancer-specific exosomes, which can be found in blood and urine samples, contain proteins and DNA that can be used to understand the aggressiveness of a man’s cancer.

**THANK YOU**

The GAP project was funded by the generosity of the Movember community. Together, we raised $41.6M to fund prostate cancer research and we need your continued support to keep moving us closer to a world where no one dies from prostate cancer.