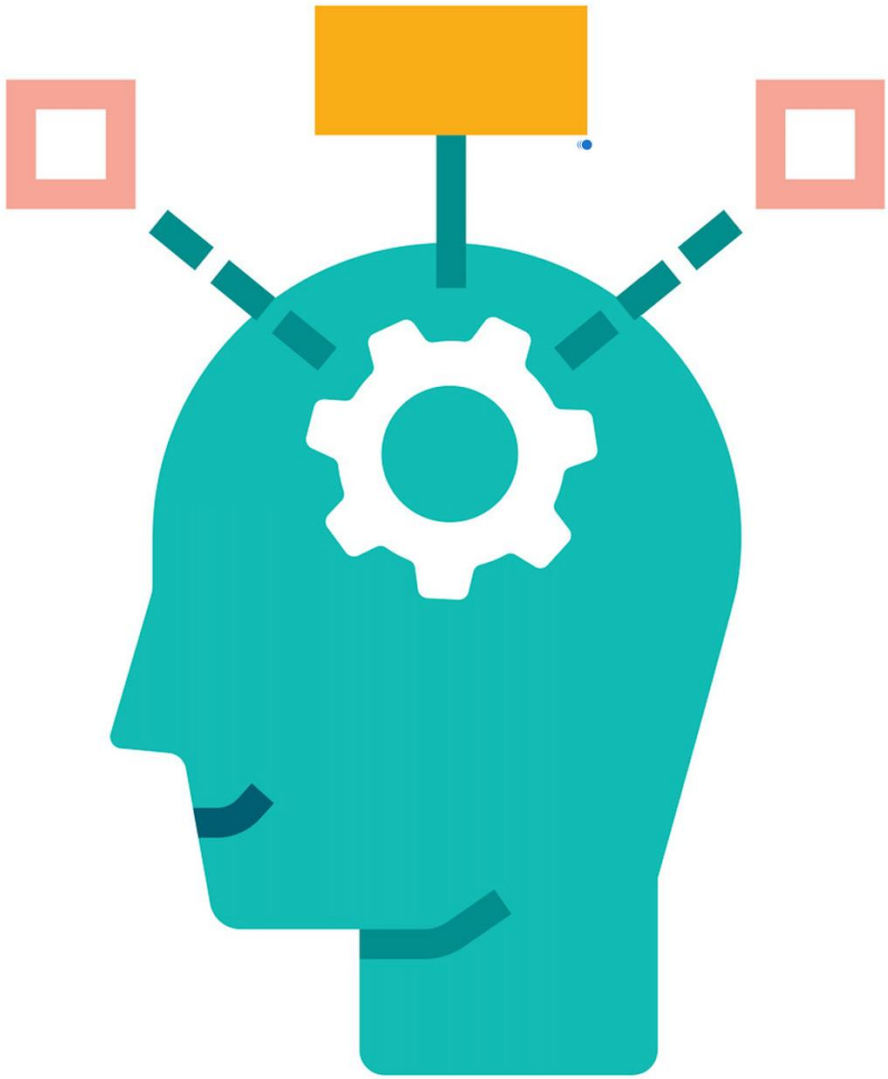
**MSIN0013 Critical Analytical Thinking Assignment 1 – Individual Report**



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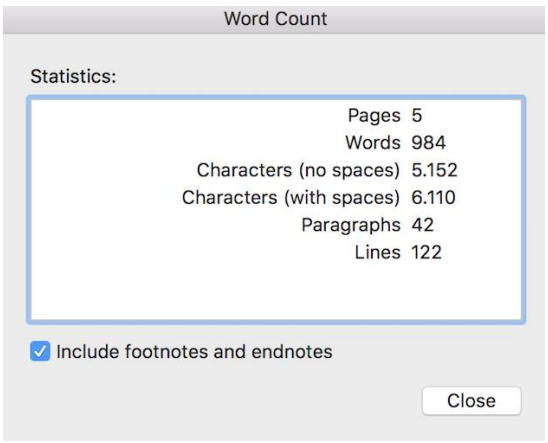
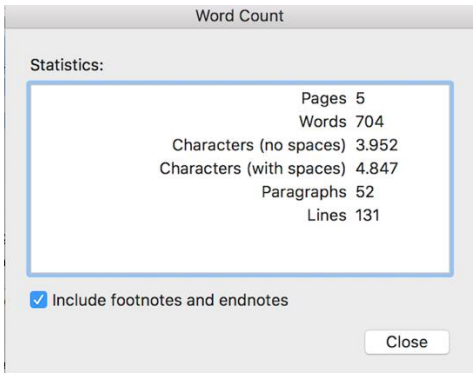



APPENDICES:



**CONTENTS:**

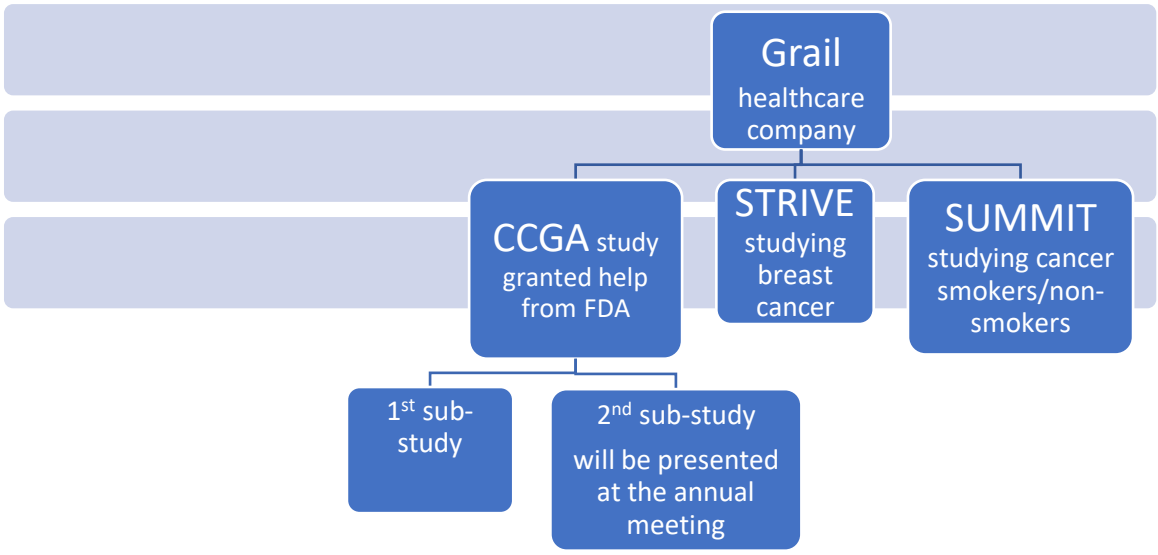
# 1. INTRODUCTION

The purpose of this report is to guide a specific audience in taking informed future actions. I selected as the audience the CEO of Ion Beam Applications, a medical technology company. The purpose of my report is to inform him of whether to invest or not in Grail's technologies and research, by presenting him an analysis of the article. Ion Beam Applications is one of the main competitors of Varian Medical Systems, a main investor for Grail (for Grail's investors see Appendices). The reason for choosing an investor as the audience for this report is the fact that the main audience of the article should be investors and one of the purposes of the article is raising funds for Grail's technology and research. (see Audience section)

# 2. SUMMARY & MAIN IDEAS

**Summary:** In the first part of the article, the author mentions that Grail's cancer detection blood test has been granted Breakthrough Device designation from FDA (help in speeding up the process of commercializing the technology). Then we can find a short description of the first sub-study of Grail's study (CCGA) and a promise that the second's sub-study results will be presented at an annual meeting. The author also introduces a short interview with Grail's CEO. The ending of the text consists of a description of three of Grail's studies, a description of Grail's selected technology and a description of Grail.

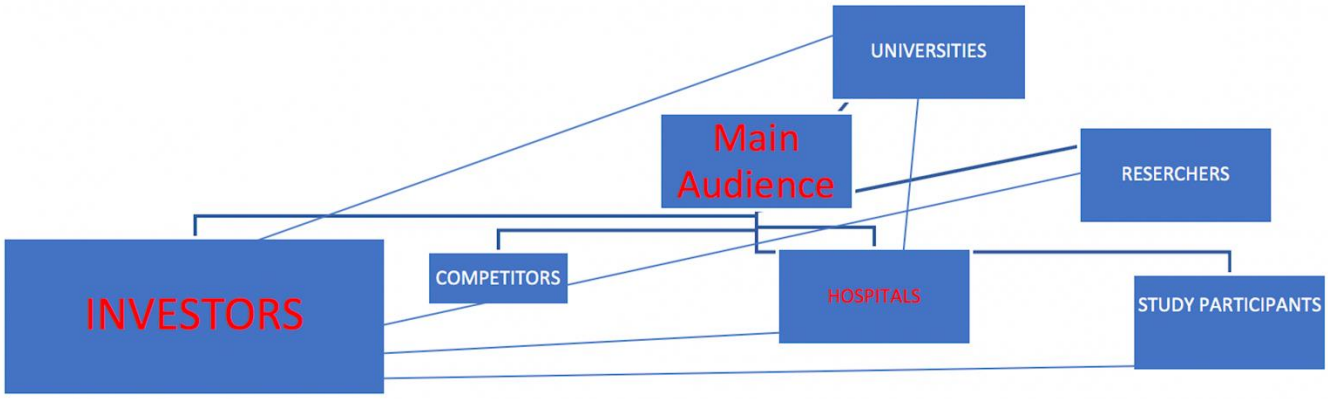
**Map of main ideas:**



(for a detailed map description see Appendices)

By comparing the summary (which is based on the order of ideas presented in the text) and the map of the main ideas, we can observe that the structure of the text makes it difficult for the reader to follow as the structure does not follow the logic of the main ideas.

# 3. AUDIENCE




The image above represents a network showing the audience of the text. (for a detailed explanation of the network see Appendices)

**Main Audience:** investors, hospitals

The reasons for assuming these categories are the main targeted audience are as follows. Studies and developing technologies need funds in order to continue. Grail's funds currently account for over $1 billion (Crunchbase,2016). In order to gain more investors, they need investor's awareness. I selected hospitals as one of the categories as the SUMMIT study is still enrolling participants in collaboration with general practitioners in London (U.S. National Library of Medicine,2020), which means they need hospital's awareness.

# 4. CONCLUSIONS & ARGUMENTS

**Key conclusions:**

**C1:** Grail's multi-cancer early detection test is significant.
**C2:** Grail's multi-cancer early detection test has great future potential. (supported by **C1**)

**Main arguments:**
**A1:** The test has been granted Breakthrough Device designation from FDA.

**A2:** The test has made significant progress.
**A3:** The CCGA study will be presented at the 2019 American Society of Clinical Oncology Annual Meeting.
**A4:** The 3 studies are large and significant.
**A5:** The Methylation Technology has potential.
**A5:** Grail is a great company whose mission is to detect cancer early.

# 5. PARAGRAPH ANALYSIS

The paragraph bellow is highlighted in the article as it includes some main points for the overall conclusion, and it represents statements made by Grail's CEO.

**Paragraph 2:**

> "We're excited the FDA recognizes the potential of our multi-cancer early detection blood test. There are no effective early detection tests for the majority of cancer types, and many deadly cancers are often detected too late. We hope our test may offer a chance to address these challenges," said Jennifer Cook, Chief Executive Officer. "We have made significant progress developing our multi-cancer test and look forward to sharing new data at ASCO and other medical conferences this year."

**PREMISE 1:** FDA is supporting the cancer detection test.
**PREMISE 2:** The test could address the fact that there are no other effective alternatives for early detection of cancer.
**PREMISE 3:** The test could address the fact that deadly cancers are detected too late.
**PREMISE 4:** Grail has made significant progress in developing the cancer test.
**CONCLUSION:** Grail's multi-cancer early detection test has great future potential.

**Assertions:**

1. There are no other effective alternatives for early detection of cancer.
2. Deadly cancers are detected too late.
3. Significant progress has been made in developing the cancer test.

As stated in the Appendices, the technology does not need to be the only alternative to a problem in order to be eligible to be eligible for FDA's breakthrough device program. It could meet other criteria such as being better than existing alternatives or in the best interest of patients. In fact, other effective alternatives do exist: early detection of cancer through screening based on imaging is a major contributor. (Frost&Sullivan,2017)

An informed audience could maybe not agree to the above assertion (that there are no other effective alternatives for early detection of cancer) as some main investors are companies that develop medical technologies. The majority audience of the article consists of informed parties. (see Audience section)

## 6. SOURCES

The sources of the article are Grail and the first sub-study of CCGA. Grail could not be impartial as the purpose of the article is to promote and state how effective the cancer detection test is. To achieve this purpose Grail presented only the advantages of the cancer detection test (see main arguments).

The main arguments the article makes based on the first sub-study of CCGA are the fact that the test had a low rate of false-positive results and the fact that approximately 15000 people are enrolled. While these are valid arguments, some important points have been ignored. The CCGA study is estimated to be completed by 2024 (U.S. National Library of Medicine, 2020) as participants need 5 years of cancer monitoring after being enrolled (ASCO,2018). The article ignores the fact that CCGA still needs 5 years for completion by the time the article was published. Moreover, mentioning a low-rate of false positives is not enough, as the article did not mention the rate of false-negatives. A high-rate of false negatives means undetected cancer for participants who have cancer, and this is more significant than the false positives. (see Appendices)

## 7. CONCLUSION

The main purpose of the article is gaining investors' awareness by convincing them of how great the future potential of the cancer-detection test is. The article is doing so by using incomplete information, presenting only the advantages or using untrue assertions or assumptions, as well as presenting a vague interpretation of some sources.

# APPENDICES

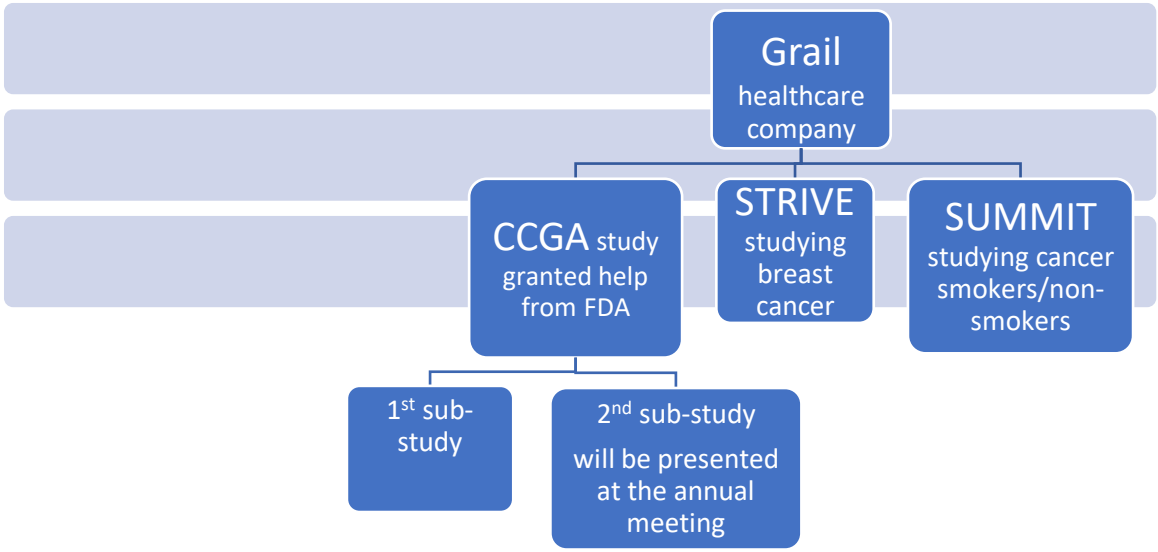
## 1. INTRODUCTION

Grail's Investors:

(Grail, 2017)

# 2. SUMMARY & MAIN IDEAS

**Map of main ideas:**



CCGA consists of 3 sub-studies, but the reason the third one is missing from the above map is the fact that the article does not describe the third one, it barely mentions it, which makes it irrelevant.

The logic of this map is that Grail (the healthcare company) is conducting 3 main studies and CCGA has 2 main sub-studies presented in the text. All the other information in the text is mapped around these elements: FDA program, ASCO.

**GRAIL-** "GRAIL is poised to detect cancer early by combining high-intensity sequencing of unprecedented breadth and depth with the techniques of modern data science. Through what we believe to be one of the largest clinical study programs ever pursued in genomic medicine, GRAIL is creating vast datasets to develop evidence supporting our products"

(Grail,2017)

**CCGA-** the study has the purpose of detecting cancer in patients and detecting the origin of cancer by analysing blood. It has completed enrolment of approximately 15000 people from the United States and Canada. The population validity could be regarded as medium as it would have been better if people from all around the world would be selected. This is the case for all of the 3 studies. The CCGA study focuses on more than 16 types of cancer. (ASCO,2018).

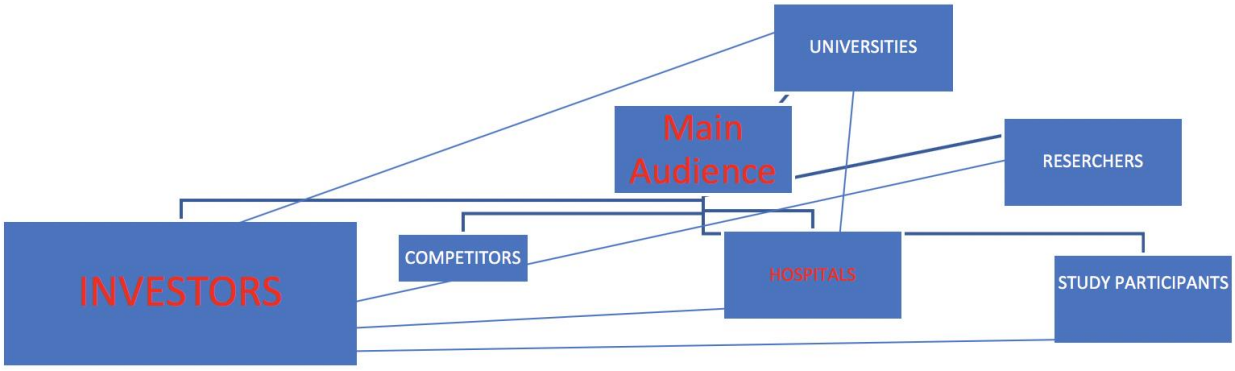
**STRIVE-** the study has the purpose of detecting breast cancer. It has enrolled approximately 100000 women from the United States and its estimated completion date is 2030. (U.S. National Library of Medicine, 2020)

**SUMMIT-** the study focuses on comparing smokers and non-smokers and lung cancer. The population is mainly from London and it consists of approximately 50000 participants. The estimated completion date is 2030. (U.S. National Library of Medicine, 2020)

# 3. AUDIENCE


(Crunchbase,2016)

**AUDIENCE:**




**Points of connectivity (audience included as a point):**

- Investors: 5
- Hospitals: 3
- Universities: 3
- Researchers: 2
- Study participants: 3
- Competitors:1

The network above represents some key audiences of the text and their connectivity. Investors are connected to 4 other parties: their money could go to hospitals for paying the equipment, it might be possible that participants are paid, researchers as well. The SUMMIT study is collaborating with University College London and University College London Hospitals (U.S. National Library of Medicine,2020). Universities could also be sponsored to promote the studies. Hospitals are recruiting participants for the SUMMIT study. Competitors could read the article to get inspired in developing new technologies.

# 5.PARAGRAPH ANALYSIS

## FDA Breakthrough Devices Program:

"You can send a Breakthrough Designation request for your device at any time prior to sending your marketing submission"

From the above sentence, we notice that a device is not selected for the program, but one device should apply for the program and then be selected if eligible.

Devices are eligible for the program if both of the following criteria are met:

| Criteria | Description |
|---|---|
| First Criterion | The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions |
| Second Criterion | The device also meets **at least one** of the following: |
| | a. Represents Breakthrough Technology |
| | b. No Approved or Cleared Alternatives Exist |
| | c. Offers Significant Advantages over Existing Approved or Cleared Alternatives |
| | d. Device Availability is in the Best Interest of Patients |

FDA mentions their program's goal is to "provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review".

(Center for Devices and Radiological Health ,2019)

**Alternative technology for early-detection of cancer:**

**"Medical Imaging Plays a Crucial Role in Cancer Diagnosis and Prevention**

Imaging forms an essential part of cancer clinical protocols and is able to furnish morphological, structural, metabolic and functional information. It is used to screen, diagnose and stage cancer, guide cancer treatments, determine the effectiveness of cancer therapy and monitor cancer recurrence. Integration of oncology medical imaging with other clinical tools, such as in vitro tissue analysis, biomarker tests, and cancer screening, improves decision making. Early detection through screening based on imaging is the major contributor to a reduction in the number of deaths caused by certain types of cancers."

(Frost&Sulivan,2017)

# 6. SOURCES

**STUDY ERRORS:**

| | | Truth | |
|---|---|---|---|
| | | Cancer=FALSE | Cancer=TRUE |
| Prediction | Cancer=FALSE | true negative | false negative |
| | Cancer=TRUE | false positive | true positive |

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