Case Study Proposal: ARIA OIS 15.6 MR1

My case study will focus on the first ARIA OIS version 15.6 maintenance release, or ARIA OIS 15.6 MR1. On Friday, September 26th, 2019 I met with Sharjeel Siddiqui, Manager of the Project Management Office at Varian Medical Systems, at their Winnipeg office- where ARIA OIS is developed. I arrived, nervous, but prepared with my list of exhaustingly generic questions aimed at gathering information related to their software project management methodologies. Following small talk in his office, I popped open my laptop to begin.

"So... what exactly is the software called?"

"Before we go into that," Sharjeel responds, "let's discuss the company we're sitting in right now..."

"Here in this particular office," he explains, "we develop medical oncology and radiation oncology EMR, Electronic Medical Record, Software. We make software and hardware for oncology hospitals and clinics; anything to deal with cancer treatment. So, Cancer Care Manitoba, for example, have our software and hardware which they use to treat cancer patients"

Varian Medical Systems' vision is a world without fear of cancer. Founded as 'Varian Associates' in 1948 with $22,000 of capital and six employees, the company began producing medical technology in the 1960s. Half a century since, Varian has grown into a billion-dollar company with approximately 6,500 employees in 70 sales and support offices around the globe; and is currently the world's leading provider of equipment and software for treating cancer and other medical conditions with the use of radiotherapy, brachytherapy, proton therapy, and radiosurgery. Today more than 100,000 patients are treated with Varian cancer treatment daily.

Varian's office located in downtown Winnipeg is in charge of developing ARIA OIS (Oncology Information System) Medical Oncology and Radiation Oncology EMR (Electronic Medical Record) software.

Sharjeel goes on to explain, "This basically pertains to getting all the information about a patient when they come into the hospital. What type of treatment they got, their demographics,

their other details like allergies, and anything around their diagnosis. So, all that information is captured by the software that we make in this office. That's the main purpose of the software that we make here."

Developed by Varian in 2005, ARIA OIS is an integrated, efficient, and comprehensive information system and image management solution for oncology, combining radiation, medical, and surgical oncology information used to help improve workflows and optimize treatment plans across the entire patient journey. The newest version of ARIA OIS was just released this July, ARIA OIS 15.6.

"So, this is a project we call a maintenance release project, and we plan to release this sometime in November, maybe later in November- could be something you could follow through all the way to the end."

I intend to use this maintenance release project, MR1 for ARIA OIS 15.6, as the focus of my case study. Kicking off in July, MR1 is currently scheduled for release in November of this year. Due to the potential risks involved with the medical industry this project is highly regulated and requires the documentation of -essentially- every single thing. The team involved with the maintenance release is significantly sized and made up of just as many software engineers as those responsible for assuring the team's processes are followed. I plan to meet with PMO Manager, Sharjeel Siddiqui, using a semi-structured interview format as my regular advisor on the project; in addition to referencing the project's extensive documentation and potentially interviewing other members of the team in order to study the management of this project.

In this study I will, consider how the significant weight and responsibility of documentation and compliance-related activities influence the project team as well as the project management process; discuss in what ways the project is managed in order to mitigate the serious risks at stake during medical device software development; and investigate as to how decisions are made and authority is used in the development of a software that is heavily regulated by the standards of the medical industry.