

E4B Innovation Executive Summary

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Innovation title: Spatial Pathology

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One Line Pitch: Provide a qualified service for the spatial analysis of the tumor tissue to enable cancer research and personalized patient management.

Project Summary: We are aiming to provide an upgraded and customizable pathology service that ultimately will become the next generation standard of personalized medicine for cancer patients. For this purpose, we intend to use CODEX, a recently developed multiplex imaging technology that allows standard fluorescence microscope platforms to simultaneously visualize 50 or more markers in a single fresh frozen or paraffin-embedded tissue section. Our proposed company will process samples and provide bioinformatics analysis that can assist both researchers and clinicians on the diagnosis and treatment selection of cancer patients. We also will develop and optimize “ready to pick” biomarker panels specific for different types of cancers and create a database with processed data that will further improve the accuracy of our analysis.

Management: Paula Godoy, PhD Candidate - cancer biologist and bioinformatician; Ruan Medrano, PhD-cancer Immunologist with experience in establishing and optimizing the CODEX technology. Shaopeng Yuan, PhD Candidate - cancer biologist specialized cancer stem cells with prior experiences of therapeutic development in a start-up setting. Christopher Cowley, PhD Candidate - stem cell biologist/ immunologist with expertise in bioinformatics and cancer biology. Paarth B. Dodhiawala, BS, research assistant— trained in cancer biology and bioinformatics.

End-user Problem: Current methods used by pathologists to determine histological features of solid tumors lack the depth of profiling capabilities that is required to thoroughly characterize the disease. CODEX is state-of-the-art imaging technology that can provide this necessary high-throughput analysis, but so far it’s use by the scientific community has been limited due to the cost of the equipment (~\$500,000) and laborious effort of maintenance. Furthermore, data analysis is complex and requires expertise of dedicated bioinformaticians that average labs and pathology facilities do not have. We propose a seamless service that makes CODEX accessible for all academic research labs and clinical pathology cores. Ultimately, we wish to fuel impactful, cutting-edge biomedical research and pave the way for directly aiding physicians in diagnosing and delivering personalized treatments.

Target Market: We aim to target researchers and oncology clinicians, with multiple uses per customer.

Customer Validation: It is well accepted that pathology methods currently used in the clinic are limited in their ability to screen multiple markers and do not have single cell resolution. Our service will meet these needs, allowing the screening of multiple key biomarkers in a single tissue section which has the potential to revolutionize pathology-based screening methods and become the next generation of personalized medicine for cancer patients.

Technology Validation: Even though the CODEX is a new technology, it's potential applications are already recognized as the winner of the top 10 scientific innovations in 2019. With it's first two publications, the CODEX technology is setting the framework for interrogating complex biological processes and revealing the importance of spatial analysis in understanding the tumor environment (Goltsev Y, Samusik N, et al. *Cell*. 2018;Schürch CM, Bhate SS, et al. *Cell*, 2020). It's also important to note that we already know how to perform Codex and have developed an antibody panel specific to assess the immune status of key immune populations present in the tumor microenvironment and their ability to respond to cancer immunotherapy.

Sales/Marketing Strategy: We will reach out to a few top tier cancer research labs offering promotional pricing and collaborative work to help with their publication, which will help to showcase our services for other labs with less financial resources and mostly likely can't afford to establish their own codex system. We will have technical and sales representatives on campus, at conferences, and via social media, working with research journals as well as Akoya Biosciences, the manufacturer of CODEX.

Business Model: We will apply for a small business grant such as SBIR to obtain the start up funding. This funding will be used on purchasing equipment, renting laboratory space, and recruiting first employees. After securing the initial funding and establishing the laboratory, we will hire a market/sale representative to reach out to potential customers. Here we will start from medium size research laboratories and begin to negotiate a contract with the institutional pathology core.

Competitors/alternative solutions: To the best of our knowledge we would be the first company offering this type of service. But our service can easily be "copied", so we will focus and streamline the bioinformatics pipeline that will be used to analyze and process images. We also will reserve the capability to acquire new spatial technologies in order to keep our company ahead of technological advancements.

Competitive Advantage: With the advantage of allowing high throughput analysis in standard fluorescence microscopes we expect that CODEX will become the gold standard method for the management of cancer patients and treatment selection, becoming as vital, if not more so, as whole genome sequencing. We also expect to become partners with major antibody producing companies with the effort to discourage others similar to enter the market.

Ethical Risk Assessment: Given the service purpose of our company where we will be dealing with cancer patient samples one important ethical risk we will have is the privacy and confidentiality of the information and identification of the samples

Risk Assessment:

Risk factor	Risk mitigation strategy
Cost of CODEX machine	Additional funding
Reliance on a new company	Partnership, tech development
Lack of customer interest	Survey lab interest

Recurring Costs - reagents	
Initial seed funding	SBIR grants

Use of Funds:

Source of funds	Specific activity	Funds required	Deliverable	Delivery by
<i>Initial funds</i>	CODEX machine(s)	~500k		
	Antibody DevelopmentValidation			
	Hiring bioinformaticians			
	Technicians			
	Facilities			
	Administration			
<i>Total initial funds</i>				
<i>Subsequent funds needed</i>	Specific activity	Funds required	Funding source	
<i>Total subsequent funds</i>				

Other relevant information: