

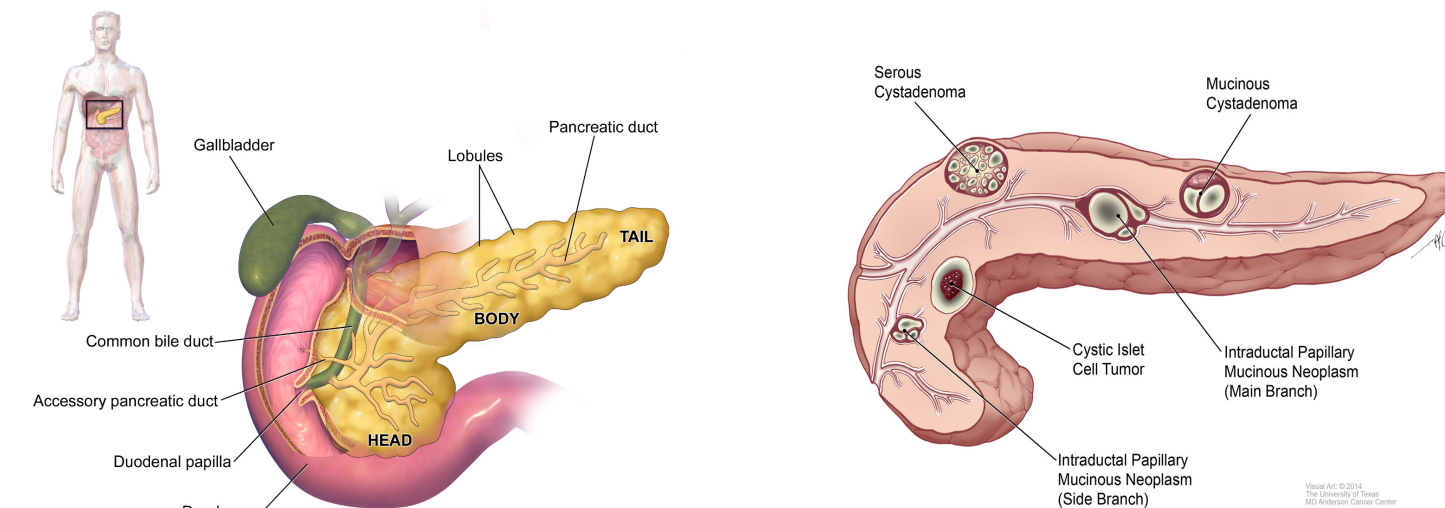
Developing Novel Treatments of Pancreatic Lesions

Project Objective: Investigate methods for treating pancreatic cancer in a premalignant state through the development of a novel device.

The Pancreas and Pancreatic Cancer

The pancreas is a small vital organ located between the stomach and the duodenum, at the back of the body near the spine.^[2] The organ has two main functions: producing digestive enzymes that pass through pancreatic ducts to the small intestine; and secreting glycogen and insulin to regulate blood glucose levels.^[3]

Pancreatic cancer is the 12th most common type of cancer in the US. Pancreatic cancer is particularly deadly, with a five year survival rate of 6.7% compared to the national average of 66.1% for all cancer sites.^[4]



Left: Location of the pancreas within the body, and the different sections of the pancreas. **Right:** Distinction of the different types of lesions: intraductal papillary mucinous neoplasm (IPMN), mucinous cystadenoma (MCN), serous cystadenoma (SCN), and solid pseudo neoplasm (SPN).

Pancreatic Lesions

Types of Lesions	IPMN	MCN	SCA	SPN
Rate of Occurance	21 - 33	10 - 45	32 - 39	< 10
Age Affected	70	40 - 60	Unknown	< 40
Location in Pancreas	Head	Body / Tail	Head / Body / Tail	Head / Body / Tail
Malignancy	High	Moderate	Low	Low

Comparison of four different types of pancreatic lesions. The project focuses on IPMNs and MCNs due to their high occurrences and high malignancies.

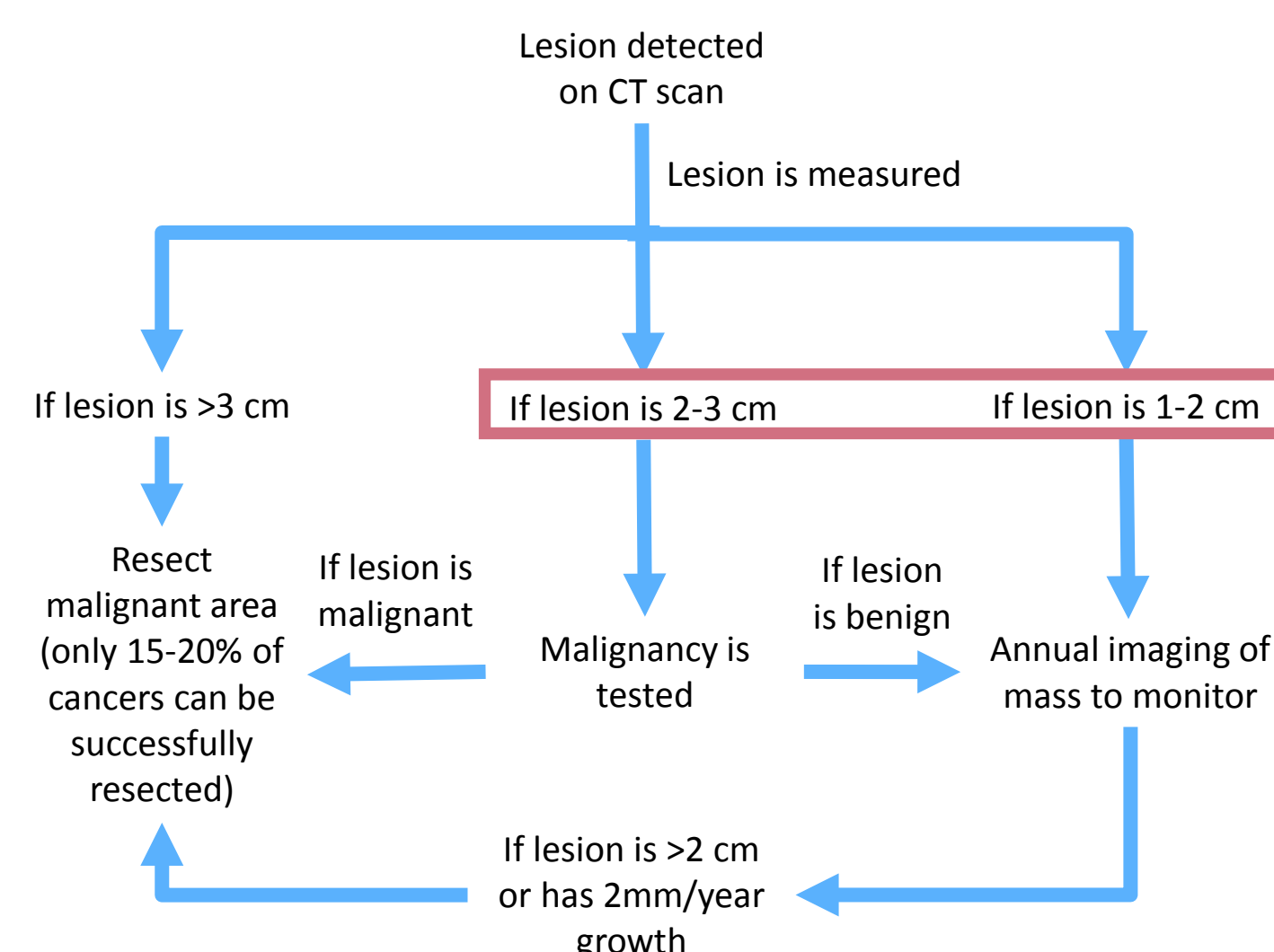
Stakeholders

Physicians	Patients
Unwilling to recommend risky treatments without significant, proven benefits	Cost of long-term medical care
Lack of standards for treatment options	Anxiety over personal health when monitoring
Effort required to learn new techniques	Disruption of lifestyle for regular medical visits

A successful device has to offer significant health benefits with fewer or equal drawbacks compared to surgical removal.

Treatments

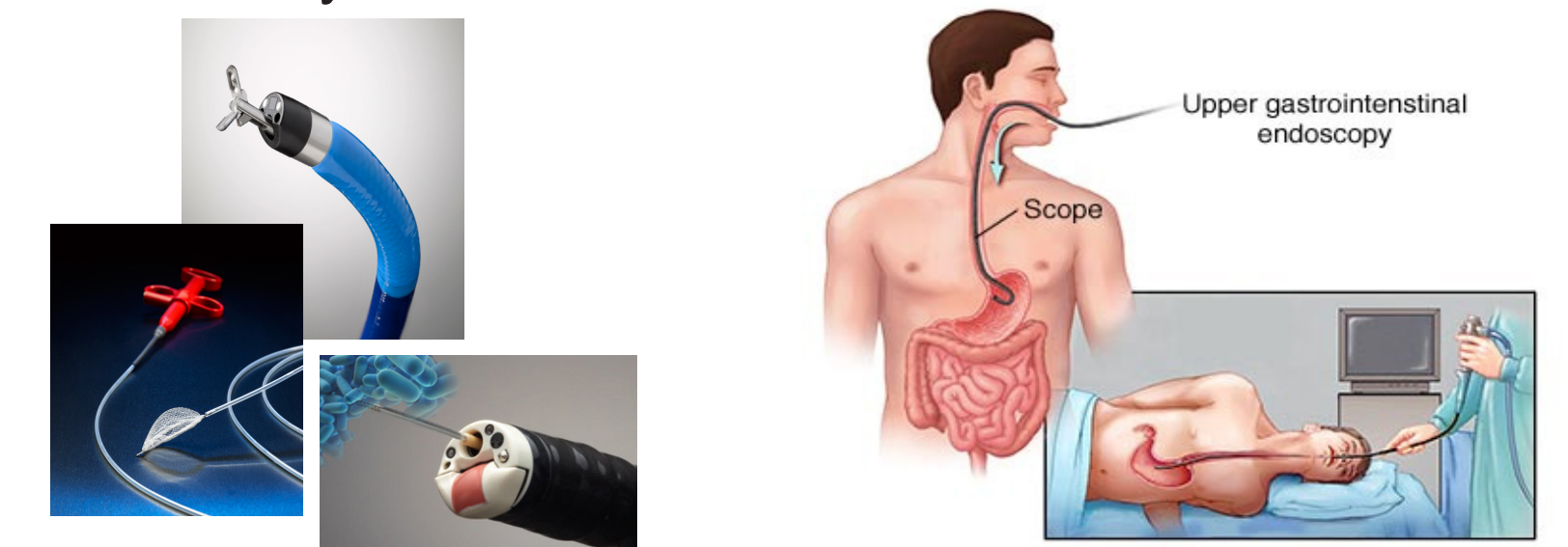
Lesion removal involves the destruction of premalignant cysts. Lesions in the 1-3 cm range could be ablated utilizing a variety of methods. Treating these lesions could prevent progression to malignancy and lower the anxiety of patients that comes with monitoring, as well as remove the stress on the patient, doctor, and hospital that the annual visits cause. There are only a small number of clinical trials to date, so there is an increasing demand to create devices to treat premalignant lesions.^[1]



Flow chart of standard procedures for diagnosis and monitoring of pancreatic lesions.

Designing and Testing Our Device

We generated device design requirements with input from physicians and Boston Scientific to guide our device development. Design requirements include both logistical challenges, such as integration with existing endoscopic devices and compatibility with a 19 gauge needle, as well as usability challenges such as the necessity for doctors to be able to operate the device seamlessly.



Left: Different types of endoscopic devices. **Right:** An endoscopic procedure showing the path the endoscope takes to get to the pancreas.

Our Device

We designed and prototyped various iterations of a device to treat a premalignant state of pancreatic cancer and deploy a systematic targeted treatment to ensure that only the lesion is removed. Through modeling, testing and soliciting doctor feedback, we have selected the most feasible device to recommend to Boston Scientific.

Device Criteria and Unknowns

Criteria:

1. Potential for near 100% removal of the cyst, which minimizes the risk of developing complications such as pancreatitis
2. Fits in a 3.7 mm working channel
3. Fabricated from biologically inert materials
4. Potential for visualization on an ultrasound
5. Similar to current gastroenterology treatment procedures
6. Sufficiently flexible to move through the tortuous path of the endoscope

Unknowns:

1. May not be as effective for irregular cyst shapes and sizes
2. Treatment area is not yet predictable, though will be after more testing
3. The size of the treatment area is not yet measurable



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Acknowledgements:
Rebecca Christianson, Brian Storey,
Siddhant Govindasamy, Kristian DiMatteo,
Andrew Coats, Emily Guthrie

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