



Expansion into multiple institutions for training in the use of the LUM Imaging System for intraoperative detection of residual cancer in the tumor bed of female subjects with breast cancer



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BACKGROUND

- Tumor-free margins are critical for local control in breast conserving surgery
- 20-40% of lumpectomy patients have positive margins that require surgical re-excision
- Tools are needed to identify residual tumor in patients at initial surgery
- The LUM Imaging System consists of intravenously injected LUM015 (protease-activated, fluorescence imaging agent), a hand-held wide field detector device and a decision software (proprietary algorithm)
- The LUM Imaging System is used to scan the surgical cavity walls intraoperatively after the resection of the main lumpectomy specimen

STUDY DESIGN

- Non-randomized, prospective, multi-center feasibility study
- Up to 250 subjects to be enrolled

OBJECTIVES

- Optimize the tumor detection algorithm that will be used in the upcoming pivotal study to evaluate the safety and efficacy of the LUM imaging system
- Train clinical staff and surgeons on integrating the LUM Imaging System into surgical practice
- Establish site-specific workflow for labeling tissue shaves by orientation
- Correlate LUM System saved images with histopathology results
- Collect usability feedback on system design
- Collect safety data

METHODS

Figure 1: LUM Imaging System in use



Figure 2: Display of the LUM Imaging System

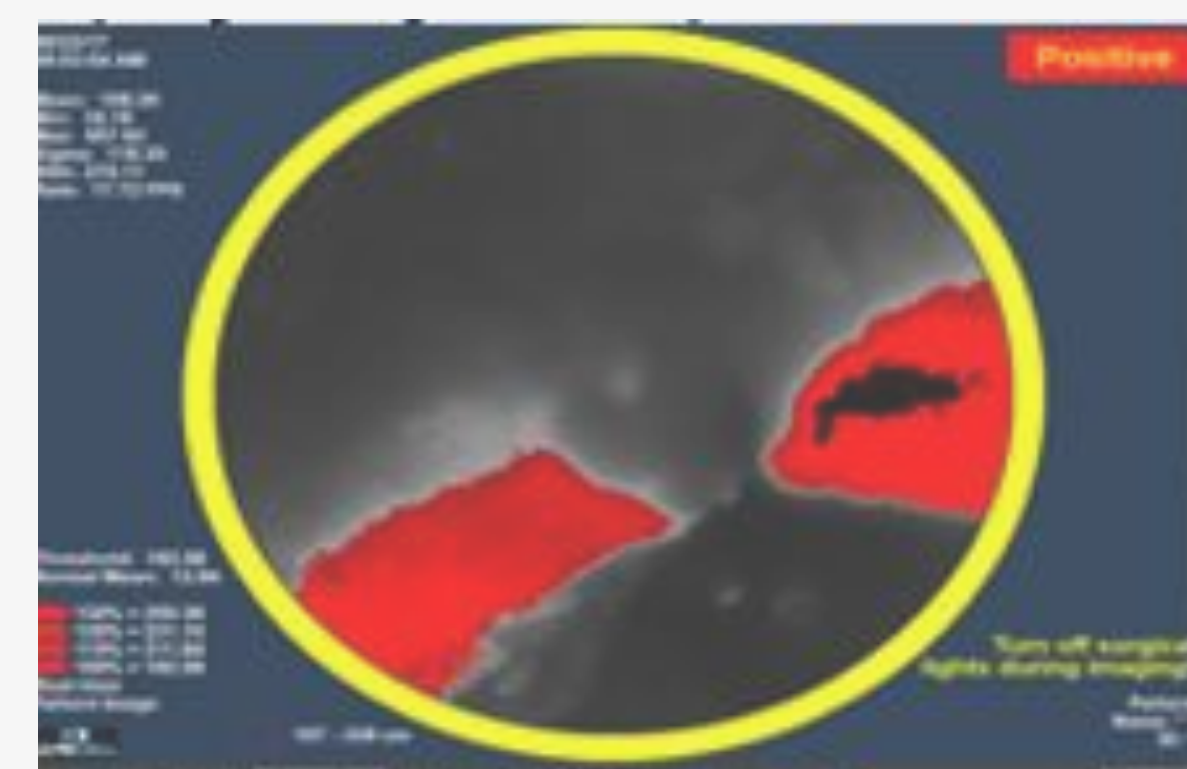


Figure 3: 16 Clinical Sites Across the US

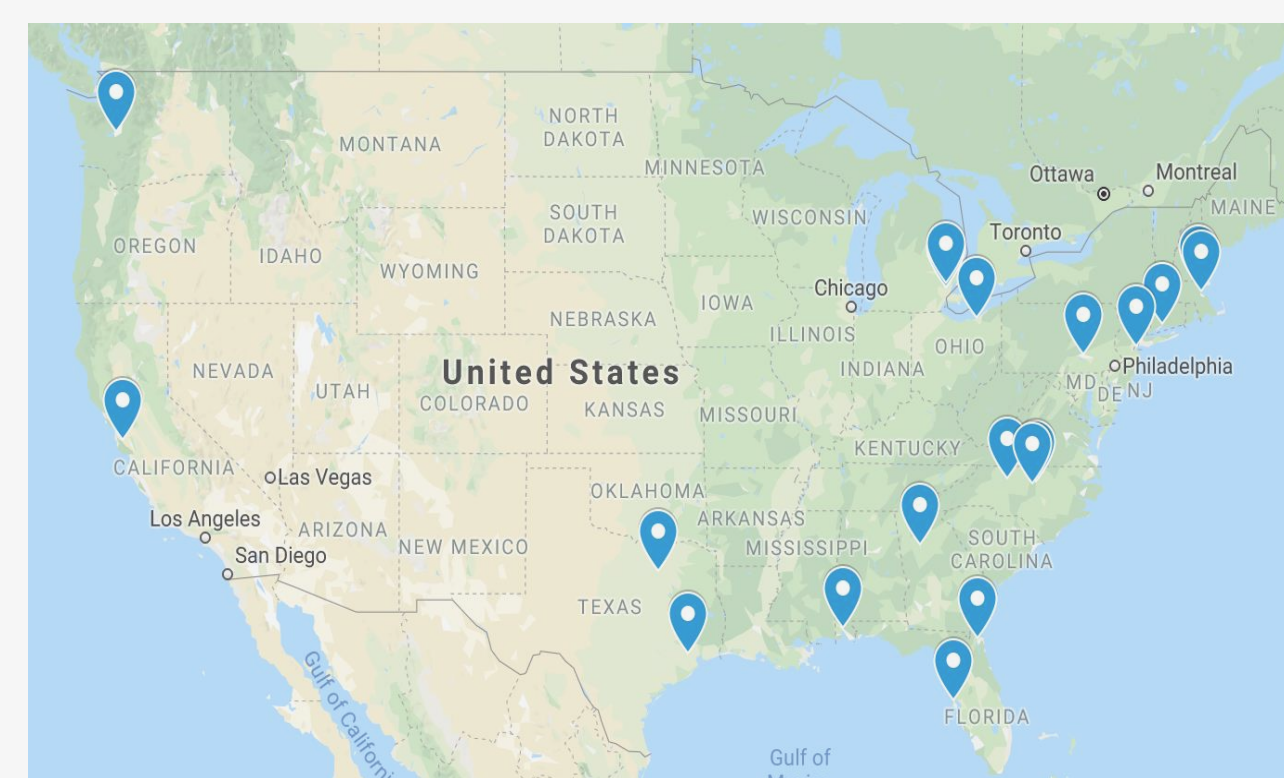


Figure 4: Study tool to support data integrity by organizing shaves by orientation



- Adult female breast cancer patients undergoing lumpectomies are being enrolled at community based and academic medical centers across the US
- Subjects are injected with LUM015 prior to surgery
- Surgeons perform standard of care lumpectomy
- LUM Imaging System is used intraoperatively
- Additional tissue is obtained based on positive signal detection from the LUM Imaging System
- Protocol-specific tools are used to maintain specimen orientation and naming to support study data integrity

DISCUSSION

- Data from previous clinical trials support that using the LUM Imaging System may identify cancerous tissue that may have otherwise been missed during routine lumpectomy
- LUM Imaging System training is intended to improve the quality and integrity of the data collected in the upcoming pivotal clinical trial to evaluate the safety and efficacy of the LUM Imaging System.
- The LUM System is currently being evaluated in other cancer indications including gastrointestinal cancers, prostate cancer, peritoneal surface malignancies, pancreatic cancer, and brain cancer

ACKNOWLEDGMENT

- This clinical trial is funded in part by the National Cancer Institute
- Lumicell holds the IDE and is the Sponsor of this study
- Lumicell wishes to thank the MGH Translational Clinical Research Center (TCRC) for support in design and execution of this clinical study
- This study is registered on ClinicalTrials.gov as NCT03321929

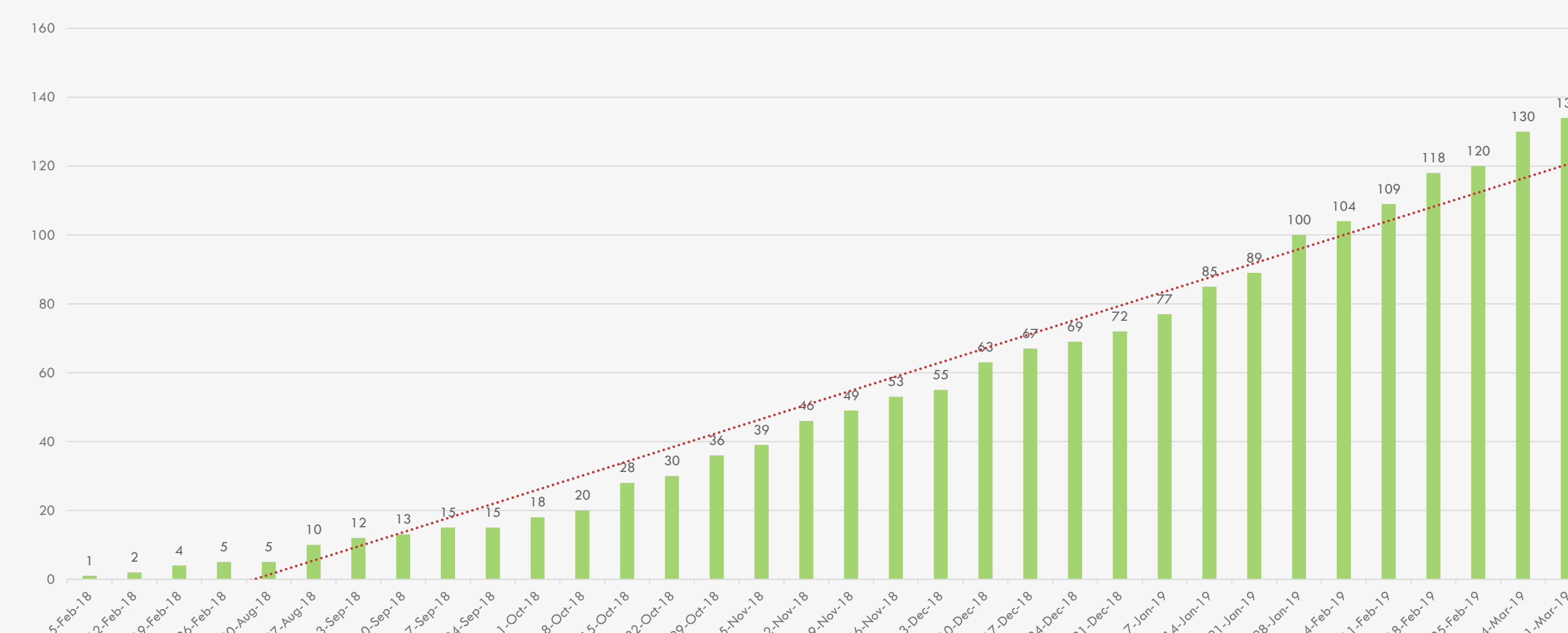


Figure 5: Enrollment to date