Baylor College of Medicine
VENTURES

1ST ANNUAL

# COMMERCIALIZATION SYMPOSIUM

## POSTER SESSION ABSTRACTS

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# POSTER SESSION ABSTRACTS

* Pitch “Shark Tank” Presenter

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Poster Number 1
Therapeutics

**IN VIVO EXPANSION OF GENE-TARGETED HEPATOCYTES THROUGH TRANSIENT INHIBITION OF AN ESSENTIAL GENE**

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Homology Directed Repair (HDR)-based genome editing is an approach that could permanently correct a broad range of genetic diseases. However, its utility is limited by inefficient and imprecise DNA repair mechanisms in terminally differentiated tissues. The goal of this work is to develop a system for selective expansion of gene-targeted hepatocytes using essential genes, which we call "Repair Drive". Repair Drive consists of (1) transient conditioning of the liver by knocking down an essential gene - Fumarylacetoacetate hydrolase (Fah), and (2) delivery of an untargetable version of the essential gene in cis with the therapeutic transgene.

We used Adeno-Associated Virus (AAV) vectors to insert FAH in tandem with a fluorescent marker (TdTomato) or the therapeutic transgene Factor IX (FIX) - deficient in Hemophilia B patients - into a highly expressed locus in the liver (Apoa1). Monthly injections of small interfering RNA (siRNA) targeting murine Fah were used as a conditioning agent to deplete untargeted hepatocytes and drive expansion of correctly repaired cells.

Three months later, mice receiving the siRNA - Repair Drive mice - showed a dramatic increase in the number of TdTomato positive hepatocytes, versus those receiving the AAVs alone – Unselected mice (~25% vs 0.5%). To evaluate the translatability and long-term safety of this approach, we expanded FIX-targeted hepatocytes with Repair Drive, and we followed the mice for 1 year. Repair Drive mice showed sustained FIX expression with a ~5-fold increase as compared to Unselected mice. Liver conditioning caused only a transient elevation of ALT at early time points, which fully resolved over time. Histology revealed no evidence of liver toxicity and full reconstitution of Fah expression. Importantly, Repair Drive did not increase the risk of tumorigenesis. Overall, these data show a novel strategy for selectively expanding targeted hepatocytes for liver gene therapy.

Poster Number 2
Research Tools

# NEURAL NETWORK ARCHITECTURE BASED COMPUTING FRAMEWORK (NNACF): AN EFFICIENT SOLVER OF LARGE SIZE COMBINATORIAL PROBLEMS TO ADVANCE HEALTH SERVICES RESEARCH

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The analytical results from big data by state-of-art artificial intelligence (AI) have been widely applied in health services research (HSR) now-a-days to improve associated health care services. However, the analysis becomes more complex, sometimes unsolvable and impractical of the combinatorial analysis of big data, as the size of the data increases factorially from the distribution of unique samples of the data. An NNACF has been introduced to address this analytical challenge of HSR efficiently in this research. The problems span across gene sequence matching, validation, predicting protein functions by using the NNACF to have a practical impact on HSR followed from the analysis and results by the NNACF of the problems.

Large size combinatorial problems in the HSR require efficient solutions for widespread practical impact. Traditional approximate solutions of such problems leave uncertainties of real world application of the solutions. The NNACF has map and reduce features to overcome such uncertainties following direct solution scheme respectively to the real world applications of the solution. The NNACF resembles the architecture of state-of-the-art neural network (NN), which allows the combinatorial features supported by the weights traversing to the neurons existing in the hidden layers. All these features along with the direct solution scheme fit the NNACF to model the matching of specific sequence of genes from large size genome sequence, the validation of gene regulatory networks and predictions of protein functions efficiently and reliably.

The HSR needs reliable decisions from associated analysis to provide personalized health care including the identification of specific disease and recovery by respected drug. The NNACF allows such reliable decisions virtually to have a practical impact on overall HSR. This can open the door for practical, reliable decisions of many other unsolvable large size combinatorial problems in the HSR in the days to come.

Poster Number 3
Therapeutics

## EXPANDED FUNCTIONS OF SPOP IN PROSTATE CANCER: IMPLICATIONS FOR PRECISION MEDICINE

**Presenter:** Kinza Rizwan, Department of Medicine, Baylor College of Medicine

Maria Elisa Ruiz Echartea, Center for Precision and Environmental Health, Baylor College of Medicine; Alexey Tyryshkin, Department of Medicine, Baylor College of Medicine; Chuandong Geng, Department of Genitourinary Medical Oncology, Division of Cancer Medicine, MD Anderson Cancer Center; Cristian Coarfa, Center for Precision and Environmental Health, Department of Molecular and Cellular Biology, Dan L. Duncan Comprehensive Cancer Center, Advanced Technology Cores, Baylor College of Medicine; Nicholas Mitsiades, Department of Medicine, UC Davis Comprehensive Cancer Center, University of California, Davis; Salma Kaochar, Department of Medicine, Department of Molecular and Cellular Biology, Dan L. Duncan Comprehensive Cancer Center, Baylor College of Medicine

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### Background
In 2025, an estimated 313,780 cases of prostate cancer (PC) will be diagnosed, with over 90% presenting as localized disease. Among these, approximately 15% will be classified as high-risk for recurrence. Given that early-stage PC is largely driven by androgen signaling through the androgen receptor (AR), neoadjuvant treatment strategies targeting this pathway are under active investigation in high-risk localized prostate cancer (HRLPC). Genomic analysis of exceptional responders to next-generation androgen pathway inhibitors (APIs) in recent neoadjuvant clinical trials revealed a strong association with SPOP missense mutations, SPOP copy-number loss, and SPOPL copy-number loss, which were exclusive to this subset of patients. These findings align with prior studies showing that SPOP mutations, which exert a dominant-negative effect, enhance AR-mediated signaling in prostate cancer. Understanding the molecular mechanisms by which SPOP mutations and SPOPL loss drive tumorigenesis is crucial for refining treatment strategies. These alterations hold promise as predictive biomarkers for stratifying patients most likely to benefit from neoadjuvant API therapy or alternative treatment approaches in HRLPC, paving the way for more personalized and effective interventions.

### Method
By utilizing various genetic ablation approaches in murine and prostate cancer cell line models, we recently reported increased levels of AR and MYC protein and increased cellular turnover (both proliferation and apoptosis) in the prostate luminal epithelium compared to wildtype prostates. We now characterized these models—using immunohistochemistry, RNA in situ hybridization, chromatin immunoprecipitation, and a series of biochemical assays—to better understand cell fates and molecular changes in response to SPOP ablation, SPOP overexpression, and PC-specific SPOP mutation.

### Result
We have uncovered that, as the prostate-specific SPOP knockout mouse ages, the prostate is repopulated by wildtype SPOP cells, suggesting that SPOP loss places the prostate luminal epithelial cell at a selective disadvantage. Even more surprisingly, despite their significantly higher AR protein levels, SPOP knockout prostates exhibit suppression of the AR-driven transcriptional program. Using in vitro prostate cancer cell line and in vivo CDX models, we also found that wildtype SPOP promotes AR transcriptional activity and tumor growth, by serving as a cofactor for the AR complex in situ on chromatin and by enhancing AR interactions with its partnering transcriptional co-regulators.

### Conclusion
Our data illustrate for the first time a critical role for SPOP in the growth and survival of the prostate epithelium and prostate cancer cell. We propose that SPOP plays a critical role in AR activation that precedes its eventual role in AR degradation. Thus, the SPOP pathway is a novel therapeutic target in prostate cancer.

Poster Number 4
Medical Devices

# AURIFORM: A PERSONALIZED NONOPERATIVE MICROTIA REPAIR SYSTEM

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## Introduction
Microtia is a congenital deformity of the external ear, characterized by a spectrum of anomalies ranging from minor structural abnormalities to complete absence of the ear. The prevalence of microtia varies globally, with estimates ranging from 0.83 to 17.4 per 10,000 births, and is higher among Hispanic and Asian populations. This condition not only affects physical appearance but also has significant psychosocial and functional implications, including hearing loss and associated speech and language delays.

## Unmet need
The economic burden of microtia is substantial, primarily due to costs associated with surgical reconstruction and hospital stays. A retrospective analysis of the National Inpatient Sample database revealed the average cost of microtia repair surgery in the United States ranges from $25,897 to $48,985. Though some non-operative solutions exist, they are dependent on parent compliance, often result in dermatitis, and have limited adaptability for patient anatomy.

## Technology developed
AuriForm, a personalized, non-invasive microtia repair system, represents a promising alternative to traditional surgical approaches. This system aims to address the esthetic and functional needs of patients with microtia types 1 and 2 by utilizing lidar technology to generate a sequence of 3D-printed ear molds tailored to a patient's unique anatomy. These molds will allow for better fit with less material and fewer individual components. As a result, the mold will be more comfortable, breathable, and easier for parents to replace if its position on the infant's head is disturbed. The underlying algorithm is still in its early stages and is undergoing iterative prototyping to improve fit and optimize ear traction.

## Results
Several 3D-printed proof-of-concept prototypes have been developed and tested on silicone ear models, demonstrating a good fit and easy application.

## Conclusions
Next steps include tests with varied microtia cases to test and improve the mold generation and experimentation with more comfortable mold materials.

Poster Number 5
Software as Medical Device (SaMD)

# AI-ENHANCED COHORT MANAGEMENT SYSTEM (AI-CMS) FOR CLINICAL AND RESEARCH APPLICATIONS BASED ON PATHOLOGY DATA

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## Introduction

Many chronic diseases require accurate pathology data interpretation to guide clinical decision-making, research, and quality of care metrics. Current processes rely on labor-intensive and error- prone manual workflows. Generative Artificial Intelligence (AI), in the form of large language models (LLM), offers a novel solution; however, AI-based solutions face critical limitations: they require extensive fine-tuning, lack generalizability, and can hallucinate - unacceptable risks for healthcare settings.

## Problem/unmet need

Clinical and technical needs: 1) automating pathology data interpretation and linking these interpretations to clinical, research, and quality-tracking actions, and 2) leveraging the power of Generative AI while mitigating challenges of model training and LLM hallucinations.

## Technology/IP developed

AI-CMS, a standalone software system in the advanced prototype stage, is an intelligent cohort management system developed using Barrett's Esophagus (a precancerous esophageal condition requiring surveillance and treatment) as a use case. Building on a HIPAA-compliant hybrid AI architecture with safeguards against LLM hallucinations, the system provides explainable predictions with confidence scoring and human-in-the-loop assessment of edge cases, accessible through a user-friendly dashboard. The platform delivers automated decision support through critical findings alerts and guideline-based clinical recommendations while enabling longitudinal patient and cohort tracking. Advanced capabilities include research cohort identification tools, quality metrics reporting, and an audit system for monitoring performance drift.

## Results

Validation on 250 endoscopy pathology reports demonstrated excellent performance and generalizability across 3 medical centers (Figure 1). The system's user interface enables integrated decision support via automated surveillance and treatment recommendations with critical findings alerts (Figure 2) and a research cohort builder tool (Figure 3).

## Conclusions/next steps

AI-CMS intelligently manages cohorts based on pathology data while implementing novel technical safeguards and expert oversight to mitigate the risks of AI and ensure reliability essential for healthcare use. Next steps include securing funding and technical development resources, EHR integration, real-time clinical pilot trial, multi-center validation studies, and adaptation to additional disease processes, starting with colon polyp surveillance.

Poster Number 6
Therapeutics

**HARNESSING GUT MICROBIAL COMMUNITIES TO COMBAT MULTIDRUG-RESISTANT EXPEC**

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Extraintestinal pathogenic Escherichia coli (ExPEC) are the leading cause of extraintestinal infections worldwide, with rising multidrug-resistant strains exacerbating morbidity and mortality. Despite this growing threat, there are no vaccines or non-antibiotic treatments available to combat ExPEC infections, creating a critical unmet need for innovative and effective therapeutic solutions. ExPEC's unique behavior as a commensal organism in the gastrointestinal tract (GIT) and its ability to cause disease only after dissemination provide a strategic opportunity to disrupt its colonization and prevent subsequent infections.

Our team has developed a groundbreaking approach to combat ExPEC infections by leveraging microbial communities resistant to ExPEC colonization in the GIT. Using continuous flow culturing technology in our in vitro minibioreactor arrays (MBRAs), we can rapidly screen simplified microbial communities derived from diluted human fecal samples for their ability to inhibit ExPEC colonization. This top-down approach preserves natural microbial structures and interactions present in the human GIT. Among the communities tested, FS2C has demonstrated robust resistance to ExPEC invasion, completely elimination of ExPEC in our MBRA system. FS2C's robust and consistent resistance positions it as a promising candidate for therapeutic development. In order to create a more defined therapeutic, we have isolated all members of the FS2C community and have created synthetic communities which recapitulate the structure and resistance to ExPEC observed in the fecal derived community.

Our next steps aim to commercialize a defined live microbial therapeutic to prevent ExPEC colonization and infections. Mechanistic studies will identify the metabolic pathways underlying FS2C's resistance, while synthetic communities will be optimized to retain effectiveness. Preclinical animal studies will validate safety and efficacy, followed by scalable manufacturing and regulatory approvals for clinical trials. This innovative approach has the potential to address a critical unmet medical need by preventing ExPEC colonization and subsequent infections.

Poster Number 7
Therapeutics

## MITF/NCOA3-DRIVEN TRANSCRIPTIONAL REGULATION AS A THERAPEUTIC VULNERABILITY IN UVEAL MELANOMA

**Presenter:** Aleksandra Rusin, Department of Medicine, Baylor College of Medicine

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### Introduction
Uveal melanoma (UM), the most common intraocular tumor in adults, is a rare disease diagnosed with an annual incidence rate of 4-7 cases per million people. UM is genetically distinct from cutaneous melanoma, which is reflected by different tumor biology and response to treatments. At the metastatic stage, UM patients face a poor prognosis due to a lack of effective therapies.

### High unmet medical need
Identification of novel targets/tumor vulnerabilities is warranted to improve UM patients' survival.

### IP developed
By using a multi-omic approach, we found that (i) NCOA3, MITF, and their target genes are novel targets in uveal melanoma, (ii) NCOA3/MITF target gene signatures predict patients' progression to metastasis and survival.

### Results
NCOA3 is an important node in the GPCR signaling network regulating UM growth, stabilized by protein kinases activated by mutated Gα subunit of a trimeric G protein. Genetic ablation of NCOA3 affects expression of several hundreds of genes and is deleterious for UM. The underlying mechanism of transcriptional control of NCOA3 in UM involves its partnership with MITF to stimulate transcription of genes associated with cancer progression. Experimental silencing of NCOA3 and MITF expression reduces UM cell proliferation and growth of UM cell-derived xenografts in vivo. Gene signatures reflecting high levels of NCOA3 and MITF correlate with shorter time to tumor progression in UM patients.

### Conclusions/next steps
Gene signatures regulated by MITF and NCOA3 and associated with a poor prognosis in UM patients allow the development of novel experimental therapeutics qualified for an accelerated approval pathway and with high return on investment due to market exclusivity. In the nearest future we plan to expand our study into BAP1 deficient tumors presenting the highest risk of metastasis and associated with the worst clinical outcome.

Poster Number 8
Therapeutics

# BAYLOR PEPTIDOME THERAPEUTICS: A RAPID AND PRECISE DISCOVERY PLATFORM FOR TCR T THERAPY IN PERSONALIZED MEDICINE.

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## Introduction
T cell receptor-engineered T cell (TCR T) therapy is an advanced immunotherapy that enhances a patient's T cells to recognize and destroy cancer cells by targeting tumor-derived peptides presented by HLA molecules (pHLAs). This approach has demonstrated promising safety and efficacy for treatment-resistant metastatic solid cancers.

## Problem
Developing safe and effective TCR T therapy requires identifying tumor specific, efficiently presented, and prevalent pHLA targets, along with high-affinity, non-cross-reactive TCRs. Classical methods have struggled to find these rare, therapeutically auspicious pHLA/TCR pairs, limiting the full potential of this powerful therapeutic approach. Expanding TCR T therapy to more patients and cancer types demands innovative strategies for pHLA target and TCR discovery.

## Technology/IP developed
Our target discovery pipeline, funded by NCI and CPRIT, integrates cutting-edge mass spectrometry with AI-powered data analytics to identify and prioritize tumor specific pHLAs as potential TCR targets.

## TCR discovery pipelines
We have developed two complementary pipelines for rapid TCR discovery. The **T-Select-Naïve** pipeline expands rare T cell clones with tumor-peptide specificity from healthy donor blood, while the **T-Select-TIL** pipeline identifies tumor-specific TCRs from patient tumor- infiltrating lymphocytes (TILs).

## Results
Using our target discovery pipeline, we have identified dozens of tumor-specific pHLAs in various cancer types. Using the T-Select-Naïve pipeline, we found TCRs targeting MAGE-A4 and MAGE-B2 peptides (HLA-A02:01) and a KRAS G12C neopeptide (HLA-A11:01). Moreover, in a study with seven patients with colorectal, endometrial, or breast cancer, the T-Select-TIL pipeline identified neoantigen reactivity in 57 of the 304 TCRs targeting 20 mutations.

## Conclusions
We have established all key components of the proposed TCR T therapy discovery platform, each validated in different settings. To fully demonstrate the power of this integrated platform, we seek to apply it in a focused study on triple-negative breast cancer (TNBC), a challenging malignancy in urgent need of better treatments. With the expertise of our clinical team members, we can also advance promising TCR therapies into clinical trials, translating discovery into patient impact.

Poster Number 9
Therapeutics

# MICROBIAL BIOSENSOR FOR SENSING AND TREATMENT OF INTESTINAL INFLAMMATION

Duolong Zhu, Jeffrey Galley, Jason Pizzini, Elena Musteata, Martin V. Douglass, Walter J. Chazin, Eric P. Skaar, Jeffrey J. Tabor and Robert A. Britton

## Introduction and unmet need

The ability to monitor and manage chronic diseases is becoming more important as autoimmune diseases and diseases associated with aging are increasing worldwide. One of these disease areas, inflammatory bowel disease (IBD), affects more than 7 million people globally and is increasing at an alarming rate. IBD, consisting of Ulcerative Colitis and Crohn's Disease, has no known cure and patient symptoms must be managed over their lifetime. Predicting when patients are at risk of experiencing a flare of their disease is critical for the management of their symptoms, however, the current gold standard for assessing intestinal inflammation by endoscopy remains invasive, costly, and impractical for frequent monitoring. The ability of IBD patients in remission to have frequent feedback on their current inflammatory state in the gut would provide physicians the ability to catch potential flares before they spiral out of control. Developing non-invasive, real-time tools to monitor gut inflammation could transform clinical outcomes by enabling early intervention.

## Technology and key results

We have developed a microbial biosensor of inflammation that accurately detects and reports on the presence of calprotectin, a clinically relevant biomarker used in screening for intestinal inflammation. Using synthetic biology technology, we have developed a bacterial biosensor that detects intestinal inflammation in two preclinical colitis models. We have also coupled the delivery of an anti-inflammatory protein to the biosensor to demonstrate sense and respond resolution of inflammation. (Invention disclosures BLG22-059 and BLG17-084).

## Next steps

Having demonstrated the accurate detection of inflammation in preclinical models, our next steps are to incorporate our biosensor into a device that would allow for monitoring of inflammation directly in the human gut. Developing a functional prototype will be critical for enabling this non-invasive method of detecting intestinal inflammation in people.

Poster Number 10
Therapeutics

# COMBINATION THERAPY WITH AIBP, APOA-I, AND ANTI-VEGF AGENTS TO OVERCOME ANTIVEGF RESISTANCE IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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Choroidal neovascularization (CNV) is responsible for 80-90% blindness related to age-related macular degeneration (AMD). Up to 50% of patients exhibit poor responses to current anti-vascular endothelial growth factor (VEGF) treatments (e.g., persistent fluid, unresolved or new hemorrhages). An effective therapy addressing anti-VEGF resistance represents a significant unmet clinical need. Cholesterol dysregulation, inflammation, and ensuing macrophage activation are critically involved in arteriolar CNV formation and anti-VEGF resistance. We developed a combination therapy that neutralizes VEGF with anti-VEGF agents while promoting cholesterol removal from macrophages using apolipoprotein A-I (apoA-I) binding protein (AIBP) and apoA-I. Preclinical studies in mouse and rabbit AMD models demonstrated significant efficacy in overcoming anti-VEGF resistance.

**Technology/IP Developed**
Baylor Licensing Group filed a provisional patent on May 27, 2020. This was followed by a PCT application filed on May 27, 2021, which was subsequently converted to National Phase filings in the United States and Europe.

**Competitive Advantages**
1. Immediate applicability for a large preexisting population of patients with anti-VEGF resistance. 2. Current drugs (FDA-approved or under clinical trials) selectively target angiogenesis with minimal or no effects on arteriogenesis. AIBP/apoA-I/anti-VEGF combination therapy solves this issue by simultaneously targeting both VEGF-dependent angiogenesis and macrophage-dependent arteriogenesis. 3. Significantly prolong and improve anti-VEGF therapies for a broad spectrum of neovascular (nAMD) patients.

**Conclusions and Market Potential**
This combination therapy is a promising solution for anti-VEGF resistance in nAMD, with the potential to replace current monotherapies as a first-line treatment. With the global anti-VEGF therapeutics market valued at $12.4 billion in 2023, it holds substantial market potential.

**Next Steps**
Seeking commercial partners for licensing and clinical development.

Poster Number 11
Medical Device

# PATHFRAX: AN AI TOOL FOR PREDICTING AND IMPROVING OUTCOMES OF METASTATIC VERTEBRAL FRACTURES

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## Introduction
Vertebral metastases are common, with >100,000 new diagnoses in USA per year. On average, 1 in 8 patients will fracture, resulting in debilitating life-long pain, neurologic deficit (inability to walk), and early death. Identifying the vertebrae at high-risk for vertebral compression fracture (VCF) is critical for all physicians involved in cancer patient care. With risk stratification, both prophylactic interventions can be employed to prevent VCF.

## Problem/Unmet need
Currently, there is no accepted standard for identifying high-risk vertebrae. A common metric is the Spinal Instability Neoplastic Score (SINS), which our studies and others show is poor at identifying high-risk vertebrae, with an AUC-ROC of approximately 0.63 (0.50 indicates random guessing).

## Technology/IP developed
With the support of BCM Ventures 2024 POC grant, we developed PathFrax, a minimum viable product. This AI-based tool combines select clinical data and CT-biomarkers extracted from routine CTs to predict future VCF. The tool is trained on approximately 1,000 vertebrae across 3 hospitals. The clinical data used, including Age and BMI, is readily available and the CTs are already part of standard practice.

## Results
PathFRAX achieves an AUC-ROC of 0.86 (95% CI: 0.82-0.9), sensitivity 0.78 (95% CI: 0.70-0.84), and specificity 0.80 (95% CI: 0.77-0.82). PathFRAX performs significantly better than SINS (AUC 0.63).

## Conclusions/Next Steps
PathFRAX achieves state-of-the-art performance when identifying high-risk vertebrae, predicting fracture before it occurs. By identifying and notifying involved physicians of high-risk vertebrae and allowing for prophylactic interventions, standard use of PathFRAX could significantly reduce the incidence of VCF. Previze.AI is dedicated to the commercialization of this technology. Currently, we are licensing this technology, filing a patent, and fundraising our seed round, while concurrently developing an even more robust technology that combines VCF diagnosis (BLG-25-030) with fracture prediction (BLG-24-054).

Poster Number 12
Medical Devices

# AI TOOL FOR AUTOMATED DETECTION OF SKIN CANCER ON MOHS SURGERY SLIDES

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## Introduction
Basal cell carcinoma (BCC) is an extremely common skin cancer, affecting over one million Americans annually. The standard of care for high-risk BCC is Mohs surgery, a specialized procedure that involves immediate histopathologic evaluation of surgically removed tissue by the surgeon to ensure complete removal of cancerous tissue. Mohs surgery achieves a cure rate of 99.6%, making it highly effective for BCC treatment.

## Problem/Unmet Need
The physicians trained to perform Mohs surgery are limited to those who complete an additional one-year fellowship after dermatology residency. This fellowship provides comprehensive training in histopathologic interpretation, enabling these specialists to perform both the surgical excision and the histopathologic assessment required to ensure complete tumor removal. Unfortunately, the limited number of Accreditation Council for Graduate Medical Education (ACGME)-approved Mohs surgery fellowship seats—approximately 90 annually since 2016—has created a bottleneck in the availability of Mohs surgeons, restricting patient access to this critical procedure.

## Technology/IP Developed
We trained a preliminary deep learning model using 348 Mohs surgery microscope slides to automatically detect areas of basal cell carcinoma. General surgeons, head and neck surgeons, and plastic surgeons excel in surgical techniques but lack training in the histopathologic evaluation necessary for Mohs surgery. The deep learning model to automatically detect basal cell carcinoma in Mohs surgery slides would enable these surgeons to perform Mohs surgery, significantly expanding the pool of providers capable of providing Mohs surgery.

## Results
The preliminary model performed moderately well with a sensitivity of .71 and specificity of .75. The preliminary model's performance was limited by the size of the training dataset.

## Conclusions/Next Steps
We have established the Artificial Intelligence in Mohs Surgery (AIMS) multi-institutional research collaboration to curate a much larger training dataset of 3000 microscope slides to train the deep learning model with increased accuracy.

Poster Number 13
Medical Devices

**SIMPLED: STOOL-BASED INNOVATIVE METHOD FOR PREEMPTIVE ENDOMETRIOSIS DIAGNOSIS**

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Globally, 200 million women suffer from endometriosis, with nearly half experiencing chronic pelvic pain. Unfortunately, 68% of these women receive an incorrect initial diagnosis, and it takes an average of 7.5 years to obtain an accurate one. The current standard for diagnosing endometriosis involves invasive laparoscopic procedures, which can be both overwhelming for patients and costly to operate.

We aim to address this critical unmet need with an innovative, non-invasive, stool-based diagnostic test. This solution utilizes stool as a clinical sample for diagnosing endometriosis, enabling patients to collect their samples at home using an easy-to-use kit. This approach reduces the need for invasive procedures while providing a more accessible and convenient diagnostic option.

Our technology is based on the biological connection between gut microbiota and endometriosis. Recent studies have identified distinct stool metabolite signatures in women with the condition. By quantifying these altered metabolites in stool samples, we plan to develop a reliable, non-invasive diagnostic tool. The technology utilizes liquid chromatography-mass spectrometry (LC-MS) for metabolomics profiling, enabling precise detection of metabolites and ensuring diagnostic accuracy. Our technology and findings are IP protected by BCM Ventures (Non-provisional application).

The global market for human microbiome-based drugs and diagnostics is projected to reach $9.9 billion by 2024 (BCC), while the endometriosis market is expected to grow from $1.11 billion in 2021 to $1.54 billion (Data Bridge). Our technology targets a $3-4 billion share of this market. Regulatory classification ranges from Class I to III, requiring Premarket Approval (PMA).

Our solution enables easy stool sample collection at home or in clinics, ensuring earlier detection, broader access, and greater market reach.

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