

GSK Consumer Healthcare-JHU GRAND CHALLENGE:
Next-generation Innovations for Consumer Health and
Empowerment (NICHE)

A funding opportunity administered by the office of
Innovation and Commercialization in the Department of
Medicine (InCMed)

Objective

To search out novel science, technologies, materials or processes that will lead to improved consumer health outcomes and that align with GSK's consumer strategic needs - to improve the quality of human life by enabling people to do more, feel better and live longer.

Purpose and Scope

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. We research, manufacture and make available a broad range of medicines, vaccines and consumer healthcare products. Its Consumer Healthcare business develops and markets consumer-preferred and expert-recommended brands in oral health, pain relief, respiratory, nutrition/gastro-intestinal and skin health. Its vision for future is to transform the consumer healthcare experience and empower consumer self-care and has sought JHU as a partner in this effort.

The focus of this funding will be to support pilot projects that provide proof of concept of the feasibility of developing safe and effective non-prescription technologies that address one or more of the areas and topics listed under the section "Problem Statements" (pages 4-6). These approaches will build on solid scientific and mechanistic knowledge about the target indication as well as state-of-the-art and next generation technological tools. The scope of the program includes technology development and optimization at the benchtop or preclinical stage and providing a roadmap for ultimate use in humans.

Mechanisms of Support and Funds

InCMed in partnership with GSK Consumer Healthcare will fund 3-4 awards during this first cycle, for total funding up to \$100,000 in direct costs. The duration of the award will be for 1 year. At the end of this year, depending on progress made and milestones met, promising projects may be considered for further funding, through a separate funding opportunity.

Eligibility Criteria

A stated goal of this funding opportunity is to foster collaborations between DOM faculty, APL scientists and student/trainee teams. The principal investigator will be a faculty member in the Department of Medicine, although representation by all three components is required for eligibility. InCMed can help facilitate the formation of the investigative groups and eligible investigators are encouraged to contact us prior to submission.

The proposed projects can cover any technological approach including but not limited to digital programs/applications, hand held technologies for diagnostic or therapeutic purposes. Pharmaceutical approaches that are eligible for over the counter (OTC) use will also be considered in scope. Research that is aimed at understanding fundamental mechanisms that provide the foundation for these technologies will also be considered. Research in silico, or using benchtop or preclinical models will be eligible. Human subject research will be out of scope as will prescription drugs or implantable devices.

Application and Submission Information

Content. Applications will consist of two documents:

I. Project Description (3-page maximum)

- Project summary and how it answers the NICHE Challenge Brief
- Scientific rationale, novelty and supporting evidence for the approach
- Scope of work and deliverables
- Background intellectual property (if applicable)
- JHU Principal Investigator and investigator teams (including APL and students)
- Project timelines

II. Milestones and Budget

The application should clearly state the expected outcome at the end of award period. Expected outcomes should provide the basis for follow on, commercialization work. In addition, an interim milestone at 6 months to assess progress of the project should be identified.

The budget should not exceed total direct costs of \$100,000. Please use the excel spreadsheet provided for the budget template. Indirect costs should be included and calculated based on the nature and site of performance (The current indirect cost rates for commercial sponsors can be found at the following link: <https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/handbook/appendixc.html>) Proposals selected for funding by the InCMed selection committee will need to be subsequently submitted to COEUS for award set up.

Format: Arial 11 font or larger; double-spaced, 1" margins all around.

Due Date: 5 pm April 7 2019

Proposals should be submitted electronically in a pdf file to

Aimee Stone
astone26@jhmi.edu
Phone: 410 502 7173

Review and Selection Process

Applications will be reviewed by a panel appointed by InCMed in partnership with GSK Consumer Healthcare, with outside expertise brought in as necessary. Applications will be judged based on the strengths of the same criteria as the section headers in the application and we expect the selection

process and notification to be completed by June 1 or earlier. Selected projects will put in place an Individual Project Agreement with GSK Consumer Healthcare that outlines IP and licensing rights, the general basis for which has been agreed to in a master agreement with the company and JHU (the investigators are encouraged to contact InCMed leadership for any questions in this regard).

Post-funding responsibilities and expectations

Six months after funding, the principal investigator is expected to submit an interim progress report (one- page maximum) and a final report at project completion. The report will discuss findings to date, and anticipated follow on work after expiration of the grant.

Problem Statements according to GSK Consumer Healthcare Priorities

- a. **Oral Health** - we believe that a healthy mouth is an important part of overall health at every age. We are especially proud of our science-based oral care products and breakthrough technologies. We have created products that repair and protect teeth, ease dry-mouth symptoms and improve comfort for denture wearers. Our interests are as follows:
 - i. Novel ideas for relief of periodontal disease, gingivitis, halitosis and sensitive teeth
 - ii. Long lasting tooth desensitization materials, or processes, or technology
 - iii. Non-analgesic oral pain relief methods
 - iv. Methods or matter to improve oral microbiota to reduce maintain good oral health, or treat gum disease
 - v. Novel mechanisms that help reverse the early signs of gum disease and prevent it from recurring.
 - vi. Novel mechanisms that would protect tooth enamel from known causes of erosion and/or repair existing damage.
- b. **Pain** - Pain is a top reason for doctor visits worldwide. So we are committed to offering reliable relief, including some of the world's top-selling over-the-counter brands for topical and systemic analgesia. Through innovation, we seek to find new and better ways to help people make the most of their day. Any solution that represents a benefit for the consumer in pain interests us. Our interests are as follows:
 - i. Novel approaches to facilitating sleep for those with chronic pain
 - ii. Novel approaches of anticipating and intercepting the onset of migraine pain
 - iii. Novel approaches to non-pharmaceutical and non-invasive temporary relief of pain
- c. **Respiratory** - GSK is the #1 maker of over-the-counter respiratory medicines worldwide—with trusted brands that include cold and flu remedies, nasal decongestants, allergy relief and smoking cessation aids. Through innovation, we work to help people breathe easier and feel better. We are interested in connected devices which help consumers manage their Respiratory conditions. Areas of interest broadly include diagnostics, medication compliance and symptom tracking for our Multi-symptom, Allergy, Decongestion and Smokers' Health franchises. Our interests are as follows:
 - i. Novel approaches to address allergy, cold, cough symptoms or smoking cessation
 - ii. Novel approaches to predicting and intercepting allergy, cold, cough symptoms
 - iii. Novel approaches for addressing respiratory conditions associated with living in polluted environments
- d. **Skin Care** - Through innovation, we have created over-the-counter brands that are family favorites and dermatologist-recommended. They treat cold sores, itchy skin, athlete's foot and more. Our interests are as follows:

- i. Novel remedies for AD, psoriasis & acne treatment. We are looking for technologies at different life stages, including aged skin, and technologies that work naturally with skin to repair the barrier and makes skin less sensitive.
 - ii. Novel approaches to predicting and intercepting AD, psoriasis, acne & athletes' foot.
 - iii. Novel technologies designed for consumers with sensitive skin or that enable the further understanding of sensitive skin.
 - iv. Fast solutions to onychomycosis that the consumer can perceive over the short term (e.g. 1-3 months)
 - v. Faster, better solutions for cold sore management before, during and after the cold sore episode
- e. **GI health** – our vision is to transform digestive health category by championing the connection between gut health and overall wellness. The platforms that will enable this focus around: Investigating the Gut, Defending Digestion and Elevating Wellness. The Nutritional Health portfolio focuses on the following platforms to deliver Growth, Energy and Health: Brain Health, Bone Health, Muscle Health, and Gut Health. Our interests are as follows:
 - i. Novel approaches to improving Nutrition, addressing IBS, gastro reflux & weight loss
 - ii. Novel products/technologies with clinical evidence for effectively managing the occurrence (frequency) and symptoms (severity) of esophageal reflux and for providing consequential improvements in quality of life.
 - iii. Novel approaches to diagnosing, predicting and tracking common digestive disorders and/or manage their associated symptoms (eg, food intolerance, irritable bowel syndrome, constipation).
- f. **Diagnostics Platforms** – trends in self-care in western and in emerging markets requires ever decreasing cost and ease of use to monitor health or early detection of disease in a self-care regiment. Of interest is platform diagnostics that can sense multiple biometrics.
 - i. Novel concepts for rapid low-cost diagnostics of common alignments or conditions for home health
- g. **Digital Health** – digital technology is facilitating enhanced self-care, personalized medicine, and early warning of contagious disease. Our interests are as follows:
 - i. Novel advances in digital health technology and tools for four key areas: medication adherence, health and symptom tracking, diagnosis/self-selection and treatment. These tools primarily complement our established over-the-counter categories: Pain Relief, Oral Health, Respiratory, Nutrition/Digestive Health and Skin Health.
 - ii. Novel approaches to providing population or individual health leveraging unique algorithms driven by big data science
 - iii. Novel technologies such as wearables, mobile medical apps, sensors, connected medical devices, machine learning algorithms and other digital health tools for

consumers in four key areas: Medication adherence, Health and symptom tracking, Diagnosis/self-selection, and Treatment

- h. Emotional Wellbeing** – emotional health is intimately associated with physical health. Our interest is in all aspects of enabling this awareness to deliver better health outcomes. Our interests are as follows:
 - i. Novel means of monitoring, predicting and intercepting negative emotions and in methods for enabling better health through well-being
 - ii. Novel means for non-pharmacologically enhancing positive emotions and mental resilience.