FDA Seeking Research Fellows and Interns

Summer, Semester, 1 year, and Thesis Projects Available

1. **Pediatric Heart Failure PRO Project**

   Appropriate for a master's or PhD student test measurement theory, patient-reported outcome, or similar specialty.

   1 year fellowship funding for 50% of fellow's time. Potential to expand project into thesis or dissertation project.

   Although patient reported outcomes (PROs) has gained acceptance as an endpoint in adult settings, the pediatric voice remains relatively muted when considering medical product development, clinical applications and outcomes. Pediatric cardiology remains one of the most cutting-edge fields, especially with respect to novel use of technologies and potential for pediatric medical product market entry. Despite recent development of innovative treatments for children with heart failure (HF), there is no robust or valid PRO instrument to scientifically capture patient experience for FDA's evaluation. This project will identify key developmentally relevant symptom associated factors for children with HF through focus group interviews with patients and caregivers, literature reviews, and area experts, review and evaluate existing PRO instruments with potential for utilization and adaptation in pediatric patients, and adapt the language and items of an identified PRO(s) for pediatric relevance.

   Deliverable: Review manuscript and potential to continue project into a thesis or dissertation project.

2. **End Stage Renal Disease-Kidney Dialysis PRO Project**

   Appropriate for a master's or PhD student test measurement theory, patient-reported outcome, or similar specialty.

   1 year fellowship funding for 50% of fellow's time. Potential to expand project into thesis or dissertation project.

   PRO measures currently do not fully incorporate the patient experience in dialysis treatment. As dialysis treatment changes, patient experience data will be important to capture. This project will work to develop a PRO measure to properly incorporate the patient experience for dialysis treatment through adapting QOL and general PRO measures. This project includes a systematic review and qualitative analysis of outcomes and patient priorities related to end-stage renal disease (ESRD) and dialysis. Future directions may include adaptation of existing PRO measures, pilot testing of the newly developed PRO measure, and publishing manuscripts to disseminate project results.

   Deliverable: Review manuscript and potential to continue project into a thesis or dissertation project.

3. **Cybersecurity PPI Project**

   Appropriate for a masters, PhD, or postdoctoral fellow with a background in patient preference information

   Summer project, funding of fellow's time for summer fellowship period

Enabling medical devices to communicate wirelessly allows manufacturers to offer convenient and highly agile products to patients and care-givers. Accordingly, the use of connected medical devices is very widespread in home and professional healthcare environments. However, device connectivity exposes a new set of challenges including availability, reliability, and cybersecurity. These issues have a particularly significant impact in life-supporting devices such as cardiac pacemakers. Furthermore, we have identified hundreds of medical devices that utilize wireless technology (e.g., Bluetooth) to connect to a second station or smart phone to deliver clinically relevant information. These technologies can be unreliable in terms of pairing with readout or controlling devices, maintaining a connection, and restoring a connection after the device is turned off and then turned on at a later time. There are over 10,000 FDA problem reports per year for wireless connection problems. This project will work to gauge patient experience with wireless medical devices ranging from blood pressure cuffs, advanced patient monitoring systems, to blood glucose monitoring system, and others. The topics of investigation include the frequency and types of connectivity problems faced by patients, how patients view security risks of their connected devices, and the patients' perspective of benefit/risk tradeoff when deciding to receive firmware updates. Feedback from patients will be used as the basis to form and report findings in this study.

Deliverable: Published manuscript or white paper to disseminate results

4. **Methodology to Adapt Patient-Reported Outcome Measures**

   Appropriate for undergraduate and master's students
   Summer and/or semester project
   Internship, no stipend funding

   Patient-reported outcomes are the direct report of a patient's health status without interpretation by others. PROs are developed and validated for specific contexts of use. This project would include a literature/historical review of adapting and updating patient-reported outcomes (PROs) for new contexts of use.

   Deliverable: Depending on the findings, this work can be published in a manuscript and/or presented at a conference.

5. **Gender Response Differences in Patient-Reported Outcome Measures**

   Appropriate for undergraduate and master's students
   Summer and/or semester project
   Internship, no stipend funding

   Historical development and validation of many PRO measures has mainly been performed in male patients. Many diseases present differently in patients and there may be gender response differences in PRO measures due to biological, sociological, and environmental differences. This project would include a literature/historical review of gender response differences in PRO measures.

   Deliverable: Depending on the findings, this work can be published in a manuscript and/or presented at a conference.

6. **Patient-Reported Outcome Measures to inform Patient Preference Information**

   Appropriate for master's or PhD student with experience in patient-reported outcome measures and/or patient preference information

Summer or semester project which could expand to a thesis or dissertation project.
Internship, no stipend funding

Developing the attributes for a PPI study is an early qualitative step that is time-consuming, resource-demanding and has a significant impact on the regulatory validity and relevance of the study. This project will investigate the use patient-reported outcomes to inform patient preference studies. Specific project directions will depend on fellow's experience.

Deliverables: Depending on project direction, this project can inform different manuscripts and potentially a thesis or dissertation.

7. Real World Usage of Patient-Reported Outcome Measures

Appropriate for undergraduate or master's student with an interest in patient-reported outcomes and public health
Summer or semester project
Internship, no stipend funding

Patient-reported outcomes (PROs) are the direct report of a patient's health status without interpretation by others. PROs are developed and validated for specific contexts of use. This project will require researching contexts of use for PROs and evaluating their use in published clinical trial results.

Deliverables: Depending on project direction, this project could be presented at a conference and could be developed into a white paper or manuscript.

8. **Real World Study of UDI Adoption -- Enablers & Bottlenecks**

Appropriate for undergraduate, masters, or MPH student
Summer or Semester project which could turn into MS thesis. Can be done remote, with guidance from FDA.
Internship, no stipend funding

This goal of this project is to understand enablers and bottlenecks for UDI adoption in a hospital system/health-care provider setting. The project would focus on the entire chain beginning with manufacturing, supply chain, distribution and patient use, to identify enablers to UDI adoption so best practices can be defined and to identify bottlenecks so possible solutions can be explored.

Deliverable: Journal article presenting findings. Depending on scope of project, may be appropriate for a master's thesis.

9. Real World Study of UDI Adoption – Data Quality

Appropriate for a master's student
Summer or Semester project which could turn into MS thesis. Clinical informatician or other similar specialty preferred. Can be done remote, with guidance from FDA
Internship, no stipend funding

The FDA has established and continues to implement the Unique Device Identification (UDI) system to identify medical device through distribution and use. Hospitals have each created their own item masters for medical devices in their hospitals. The Global Unique Device Identification Database (GUDID) is the publicly available database of information submitted

to the FDA and should be used as the reference source of master data for medical devices. For this project, a documentation of data quality issues from a health system informatics perspective with recommendations for improvement for a health or clinical research informatician will be developed.

Deliverable: Journal article presenting findings. Depending on scope of project, may be appropriate for a master's thesis.

10. **Real World Study of UDI Adoption – Cost Savings**

Appropriate for a Master's student in the files of Informaticians, hospital administration, or similar preferred.
Summer or Semester project which could turn into an MS thesis. Can be done remote, with guidance from FDA.
Internship, no stipend funding

This study would look at cost savings (potential or realized) by UDI adoption (e.g., supply chain efficiencies/OR time savings) by data analytics and and best practices for identifying and preventing improper payments in claims. This study could be continued into understanding the capability of UDI for detecting and/or preventing improper payments.

Deliverable: Journal article presenting findings. Depending on scope of project, may be appropriate for a master's thesis.

11. **Orthopaedic Regenerative Medicine**

Appropriate for a PhD student in the fields of Biomedical Engineering, Materials Engineering/Materials Science, Ceramic Engineering, Chemical Engineering.
This is a multiyear project to be a MS thesis, PhD dissertation or postdoctoral project. Can be done remote, with guidance from FDA.
Internship, no stipend funding

The goal of this project is to identify and characterize material properties which have been claimed to increase osteogenic response to the implant. One of these properties being evaluated is bioactivity, the ability to form an apatite layer on the implant. This is usually associated with bioglass; however, device manufacturers have recently been identifying this as a property of other materials, such as calcium salts. Bioactivity is generally evaluated by soaking a material in simulated body fluid (SBF) for a specified time followed by an assessment of the presence of apatite formation. Recent studies have shown that variations in SBF preparation may induce a bioactive response. Additionally, changes in material properties of typically inert materials, e.g., titanium or alumina, have been claimed to produce a bioactive response. These changes include alterations of the surface roughness or porosity. This project is expected to produce a greater understanding of the interaction of materials with the surrounding bone to aid in development of standardized testing and an appropriate regulatory scheme for BVFs associated with increased osteogenic potential in the absence of biologics or drugs.

Deliverable: Journal article(s) presenting findings and master's thesis or PhD dissertation depending.

12. **Supportive Pediatric Marketplace**

Appropriate for a master's, PhD test measurement theory student or JD student
Summer and/or semester project

Internship, no stipend funding

The goal of this project is to explore opportunities to create a marketplace that supports innovation for children and adults. Previous initiatives lead by the FDA have identified some of the key challenges and barriers to market, however a streamlined and targeted approach to address these challenges has not been outlined. This project seeks to prioritize the barriers to market that will inform regulatory decision making and promote innovation. This project will survey investors and senior leadership in medical device companies to identify the key factors that influence company decision making to enter, sustain and innovate in the pediatric medical device market.

Deliverable: Develop a manuscript summarizing survey findings and associated strategies for creating a supportive marketplace of technologies serving children and special populations.

13. **Health of Women in Patient Science Project (PRO and PPI)**

Appropriate for a masters, PhD, or postdoctoral fellow with a background in patient-reported outcomes, patient preference information, and/or public health.
Summer or semester project with potential for year-long project expansion
Internship, no stipend funding

Historical development and validation of many PRO measures has mainly been performed in male patients. Many diseases present differently in patients and there may be gender response differences in PRO measures due to biological, sociological, and environmental differences. The PRO portion of this work will scope PRO development and validation to account for gender response differences. The second part of this project, to be done in concurrence with the PRO work, focuses on patient preference information (PPI). Patient preference work is a developing field which seeks to evaluate how patients view benefit-risk tradeoffs in treatment decisions. The PPI work will seek to identify methods to properly evaluate and incorporate gender response differences in patient preference information. The successful completion of these projects will potentially lead towards further projects and collaborations in the health of women in patient science.

Deliverable: Review manuscript and potential to expand and continue project.

Questions about projects should be sent to mdfp@fda.hhs.gov.

To apply for an opportunity, please email your CV/resume to mdfp@fda.hhs.gov and include the title of the project of interest in the subject line.