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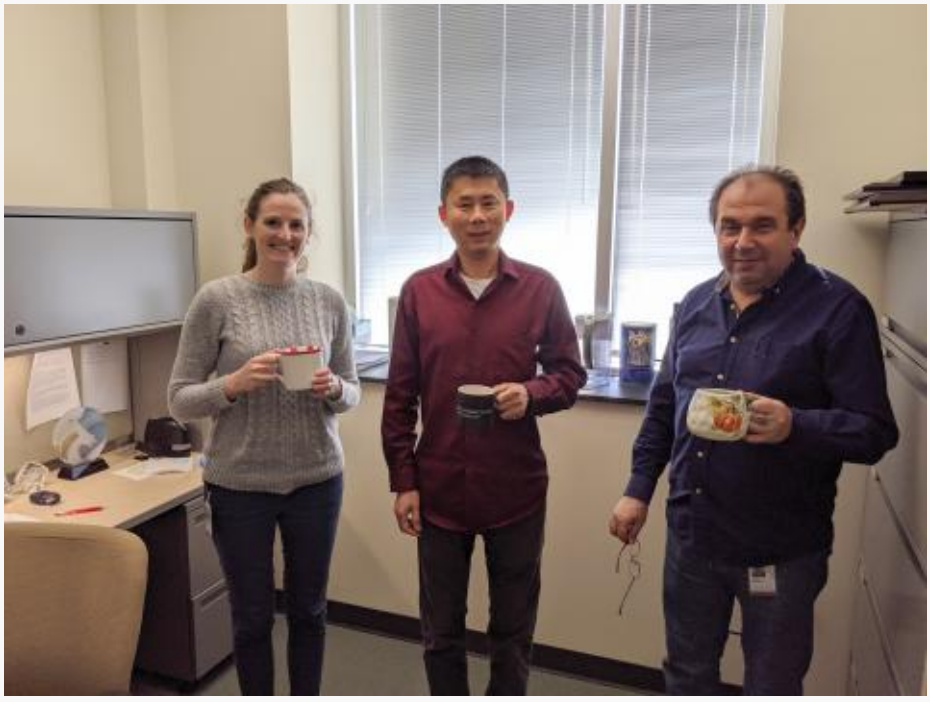
European Patent for Method to Detect Protein Aggregation in a Biopharmaceutical Product Granted to IBBR Investigator Bruce Yu and Coworkers

February 26th 2021 – A European patent has been granted by the European Patent Office (EPO) for an invention assessing biopharmaceutical aggregation using magnetic resonance relaxometry to IBBR Fellow Bruce Yu, PhD, a Professor of Pharmaceutical Sciences at the University of Maryland, School of Pharmacy and Director of the School's Bio- & Nano-Technology Center and co-inventors Marc Taraban, PhD, Research Assistant Professor of Pharmaceutical Sciences at the University of Maryland, School of Pharmacy, and Yue Feng, PhD, Research Scientist at Atrium Staffing (formerly of the University of Maryland, School of Pharmacy).



Dr. Katharine Briggs (left), Dr. Bruce Yu (center) and Dr. Marc Taraban (right) in September 2019, shortly after they relocated from the University of Maryland, Baltimore campus to IBBR/USG.
Photo Credit: Katharine Briggs

Methods that evaluate the condition of biopharmaceutical products, such as drugs and vaccines, are needed to ensure product quality without compromising product integrity. Detection of aggregated proteins, those that have assembled from monomers, is important to ensure the bioactivity of the biopharmaceutical will be as intended. Aggregated proteins can have lower biological activity, can elicit immunogenicity in patients, and can alter how the body interacts with these substances once administered.

Non-invasive methods to determine whether biopharmaceutical preparations show evidence of aggregation or degradation are needed to verify usability, while not requiring the product to be destructively analyzed such that it could no longer be administered. Yu, Taraban, and Feng developed a method to measure the extent of protein aggregation in biopharmaceutical products using Nuclear Magnetic Resonance (NMR) relaxometry which could be applied as a quality control tool. This method allows for more rapid assessment of the product than currently applied methods and measures the extent of aggregation without the need to open a vial. Yu and collaborators have previously received four additional patents in the US, pertaining to NMR-based non-invasive methods for characterizing biopharmaceuticals. These discoveries could aid in enhancing quality assurance of drugs and vaccines. Yu and coworkers, Drs. Taraban and Briggs, are applying the NMR technologies to vaccine manufacturing and quality control.