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TRANSPARENCY LIFE SCIENCES ANNOUNCES START OF ULCERATIVE COLITIS CLINICAL TRIAL ASSESSING FEASIBILITY OF DECENTRALIZED PATIENT DATA COLLECTION

—Pilot Study Commissioned by a Global Biopharmaceutical Firm Will Assess Feasibility and Utility of Replacing Clinical Site Visits with Digital Remote Monitoring Methods and Endpoint Assessments by Subjects' Own Gastroenterologists—

New York, NY — August 5, 2015 — [Transparency Life Sciences](#), LLC (TLS), a clinical-stage drug development company based on open innovation, today announced that the first patient has been enrolled in an innovative ulcerative colitis clinical trial designed to assess the feasibility of replacing most conventional patient site visits with data collected using a combination of decentralized methods, including digital measurements, telemonitoring, remote video visits with clinical trial staff and blood collections by visiting nurses. In addition, the study is the first to allow key clinical endpoint assessments to be made by the subjects' own gastroenterologists, rather than via designated sub-investigators affiliated with the trial.

The study was commissioned and is funded by a global biopharmaceutical company, and it is being conducted in collaboration with Brigham and Women's Hospital, a teaching affiliate of Harvard Medical School, and a founding hospital of Partners Healthcare. It will compare conventional and decentralized data collection in patients who have also volunteered to test the potential benefits of a special dietary intervention, the Combined Anti-Inflammatory Diet (CAID), which has shown promise in earlier studies.

Site visits for patient data collection are the most costly and burdensome clinical trial activity. The growing availability of remote monitoring technologies reduces the need for site visits, offering the potential for substantial cost savings, reductions in participant time and travel, gains in patient safety and increased quality, quantity and relevance of clinical data. This study is also replacing investigator-conducted invasive assessments of a key outcome measure, the widely-used Mayo Score, with assessments conducted by community-based gastroenterologists, further reducing the need for centralized visits.

Principal Investigator Joshua R. Korzenik, MD, Director of the Crohn's and Colitis Center, Division of Gastroenterology, Hepatology and Endoscopy at Brigham and Women's Hospital, commented, "Increasingly, empowered patients and the wide availability of digital monitoring technologies give us the opportunity to reimagine how we conduct clinical trials, with the goal of making them more informative, effective, safe, affordable and inclusive. In addition, we believe that this is the first time that key invasive clinical assessments such as the Mayo Score are being conducted by subjects' own physicians, which saves time and resources, but more importantly, sets the study in the context of patients' ongoing care. Ulcerative colitis is a disabling condition with limited treatment options, so we welcome the chance to participate in the development of new approaches intended to facilitate clinical development of more drug candidates."

Subjects participating in this open-label trial choose whether they prefer to participate in the conventional on-site patient study arm or the remote study arm using decentralized data collection alternatives. They are then randomized to either the CAID or a standard control diet that also includes counseling from trained nutritionists.

Tomasz Sablinski, MD, PhD, co-founder and CEO of TLS, noted, "Some thought we were starry-eyed optimists to launch a drug development company committed to bringing 21st century approaches to a clinical trial process that had become costly and dysfunctional. But we believed that the TLS principles of open innovation and technology-powered stakeholder engagement were ideas whose time had come. Recent successes in advancing this transformational approach are proving us right, as illustrated by initiation of this important pilot study with the help of distinguished collaborators."

Sean Ahrens, activist Crohn's patient and founder of Crohnology.com, noted, "People like me who live with inflammatory bowel disease experience many symptoms outside the doctor's office - at home, at work, at the store, and on the go. If we are going to learn about the real world effects this disease is having on patients, and how best to address them, we need to be recording our symptoms in an ongoing way in decentralized settings."

Two innovators in the application of new technologies to healthcare delivery are contributing to the trial. [AMC Health](http://AMCHealth.com), a comprehensive provider of telehealth services, is an early leader in the implementation of remote measurement and monitoring methods in clinical research. AMC Health contributed to the design of the ulcerative colitis trial and will deploy its mobile technology to enable video study visits and vital sign collection in patients' homes. [MedPoint Digital](http://MedPointDigital.com) has been a pioneer in developing a range of specialized digital platforms that provide channels for biomedical firms to engage with the medical community in support of clinical research. MedPoint is helping to manage patient recruitment, enrollment, electronic informed consent, and endoscopy video data storage for the trial.

To learn more about how TLS used its proprietary crowdsourcing Protocol Builder™ to obtain input from a diverse group of physicians and patients during the clinical protocol design process, visit <http://transparencyls.com/telemedicine-acceptance-ibd>.

More information is available on the trial's recruitment website, <http://www.dietaryuctrial.com>, and at the www.clinicaltrials.gov website at <https://clinicaltrials.gov/ct2/show/NCT02357537>.

About Transparency Life Sciences

Transparency Life Sciences (TLS) is the world's first clinical-stage drug development company based on open innovation. TLS acquires or partners promising new chemical entities and repurposed compounds that address unmet medical needs and tests them in clinical trials that leverage crowdsourcing methods, advances in telemedicine and full data transparency. The company expects this innovative approach to result in significantly reduced costs and improved data quality. For more information, visit: www.transparencyls.com.