

INDIANA BIOSCIENCES RESEARCH INSTITUTE

CASE STUDY

The Indiana Biosciences Research Institute and its Applied Data Sciences Center figured prominently in a major real-world data study of type 2 diabetes published in *Nature Medicine*.

The findings are the result of a multi-year collaboration by Roche Diabetes Care GmbH, IBM, Eli Lilly and Company, the Regenstrief Institute and the Indiana Bioscience Research Institute.

On January 8, 2019, the leading scientific journal, *Nature Medicine*, published a major study, in which the Indiana Biosciences Research Institute (IBRI) through its Applied Data Sciences Center (ADSC), and its Director, Dr. Dan Robertson, was involved. The study revealed how real-world patient data can predict diabetes-related chronic kidney disease in patients with diabetes. A separate announcement from Roche Diabetes Care GmbH, the lead on the study, explained that kidney disease, frequently a long-term complication of diabetes, is characterized by the progressive loss of kidney function, which often requires dialysis or renal transplant.

Authored by 13 scientists and researchers, the study, *Predicting the Risk of Early Chronic Kidney Disease in Diabetes Patients Using Real-World Data*, revealed that earlier identification of patients likely to develop kidney disease is possible based on real-world data contained in electronic health records. This early identification of selected individuals most likely to develop this disease, would provide information for increased monitoring and treatment, thereby improving health and reducing healthcare expense. This study is a collaboration of Roche Diabetes Care, IBM, Eli Lilly and Company, the Regenstrief Institute and the Indiana Bioscience Research Institute.

Using data originating from half a million people with diabetes, the Roche/IBM team developed a predictive algorithm to identify patients at high risk for developing chronic kidney disease in the near future. In a direct comparison between the Roche/IBM predictive algorithm and similar, prior algorithms derived from clinical trials, the Roche/IBM algorithm

outperformed all tested methods in a one-to-one comparison, as well as in cohort studies.

In an extension of the original Roche/IBM collaboration, the IBRI, through Dr. Dan Robertson and the ADSC, Eli Lilly and Indiana University School of Medicine through Regenstrief Institute, provided Roche an independent real-world data set originating from 100,000 diabetic patients obtained from the Indiana Network of Patient Care (INPC) database. The results of the extended ADSC study confirmed the findings of the primary study and this data was used by Roche for additional research in 2018 to improve the manuscript and respond to *Nature Medicine* reviewer comments.

This achievement illustrates how by working together with its industry and academic partners, the IBRI is living its motto of *Discovery with Purpose*, by translating scientific discovery into improved outcomes for patients around the world. The IBRI is honored to have contributed to a study in a publication with the stature and prestige of *Nature Medicine* that was based on real-world data, much of it from Hoosiers.

This accomplishment also shows the value of focus, patience, and perseverance. This collaboration was originally conceived in early 2016 with Eli Lilly, approved in mid-2016 with Roche, Eli Lilly and Regenstrief participating, and the research agreements finalized in October and November of 2016. This was the IBRI's first stakeholder research agreement. The raw data was delivered from Regenstrief in early 2017 and the data cleaning and analysis performed at the IBRI throughout 2017.

The paper was finalized and submitted on December 4, 2017. The revisions were ongoing in 2018 with the final acceptance by *Nature Medicine* of the manuscript on October 4, 2018, and then its publication on January 8, 2019 in the "Medicine in the Digital Age" issue of *Nature Medicine*. A success, three years in the making.

DISCOVERY WITH PURPOSE

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