



## CASE STUDY

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# Replicating and extending clinical trial results using electronic health record (EHR) data

Optum evaluated the effectiveness and tolerability of exenatide once weekly (EQW) compared with basal insulin (BI) among injectable-drug-naïve patients with type 2 diabetes mellitus (T2DM) who are elderly or have renal impairment (RI).

## Client objectives

Examine the extent to which the benefit of EQW observed in randomized trials translates to these patient groups in a real-world setting.

## Project details

- Optum employed state-of-the-art pharmacoepidemiologic methods that addressed many of the recognized limitations of real-world data.
- The incident user design with an active comparator addressed issues related to initiation of a new therapy, and multiple imputation addressed mismatches between the source data and the study design.
- Together, these methods allowed the study to reproduce the randomized trial results, but also extend them because the EHR data includes patients that were not well represented among the clinical trials.
- Optum® Epidemiology published a manuscript describing the results of a study of the effectiveness of Bydureon®.\*

## Results

This study allowed the customer to answer questions about the effectiveness and tolerability of Bydureon without having to conduct a new clinical trial.

\* Loughlin AM, Qiao Q, Nunes AP, Öhman P, Ezzy S, Yochum L, Clifford CR, Gately R, Dore DD, Seeger JD. Effectiveness and tolerability of therapy with exenatide once weekly vs basal insulin among injectable-drug-naïve elderly or renal impaired patients with type 2 diabetes in the United States. *Diabetes Obes Metab.* 2018;20:898–909.

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