Pilot study rectifies real-world study design to support regulatory decision making

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Abstract

Purpose: To evaluate the feasibility of a drug utilization study (DUS) investigating real-world use of Saxenda ® and Victoza ® in Europe. Economic and time constraints may incite researchers to avoid formalized pilot studies. Here, we report results of a pilot study which rectified the ensuing DUS protocol, thus ascertaining fit-for-purpose data availability and quality, and supporting regulatory decision making. **Methods:** A retrospective multicenter medical chart review in Germany and Italy, 6 months after Saxenda ® (liraglutide 3.0 mg, a once-daily human glucagon-like peptide-1 analog for weight management) launch, ahead of a full DUS. Collected data included: site characteristics, patient demographics, medical history, drug utilization (e.g., brand, dose, indication, weight-related comorbidities). Target study population: 100 initiators (25 Saxenda ® and 25 Victoza ® initiators in both Germany and Italy). Informed consent was obtained before medical-chart data extraction. **Results:** Overall, 218 sites were contacted. Fifteen sites (nine in Italy; six in Germany) enrolled initiators. There were 39 Saxenda ® initiators (33 in Italy; six in Germany) and 52 Victoza ® initiators (31 in Italy; 21 in Germany). Data were available for all Saxenda ® initiators and all Victoza ® initiators in Italy, and for 12 of 21 Victoza ® initiators in Germany. In nine of the 12 initiators, only target dose was recorded, with no current dose provided. **Conclusions:** The pilot study indicated a poor enrollment feasibility of Saxenda ® initiators in Germany and an unfit-for-purpose dose-related data quality. Based on these findings, refinements were implemented to the ensuing DUS protocol, thus ensuring robust real-world data to support regulatory decision making.

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