Case Study | 7th September 2022

Use of real-world evidence to support marketing authorization approval of a type 2 diabetes drug for a chronic kidney disease population

Epidemiological Study | Real World Evidence | Data Management | Biostatistics

The Case

Real-world evidence (RWE) has gained increased attention in recent years as a complement to traditional clinical trials.

In this particular case study, RWE was used to support additional approvals of a type 2 diabetes drug for a chronic kidney disease population in France.

Our client, a leading pharmaceutical company, requested our services to provide data from medical records, biological results and patient clinics over a 2-year period.

The Challenges

Extraction and anonymization of the target population with glomerular filtration rate and albumin/creatinine ratio on specific biological values targeted by sex and age.

Analysis of this population distribution based on WHO guidelines for population stage disease categorization by a clinical biostatistician.

Extrapolation to the French population while maintaining representativeness.

How We Responded

Establishment of an expert working group dedicated to the project (a pathologist, a project manager, a data manager, and a clinical biostatistician).

Extraction, anonymization of all raw data on the type of analysis required by the client on all laboratories in Ile de France over a period of 2 years (2020, 2021).

Compilation and stratification of >2 million patient records in accordance with WHO guidlines.

Submission of the results of the biostatistician's analysis to the clinical pathologist and production of a final report in support of the new drug recommendation to be submitted by our client.

Top Takeaways

By bridging the gap between the constraints of trials and the realities of clinical practice, RWE added value to the regulatory file submitted by our client, who was successful in obtaining its marketing application on a new indication.

Established a trusting relationship between Cerba Research and the sponsor through scientist-to-scientist collaboration, communication and advanced reporting that opened the opportunity for 7 new projects.

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Overview of Study Process:

Real World Data (RWD)

Patient coming in a routine lab

Patient Registration (medical administrative, demographic, health insurance)

Routine questionnaire (symptoms, treatments, diseases)

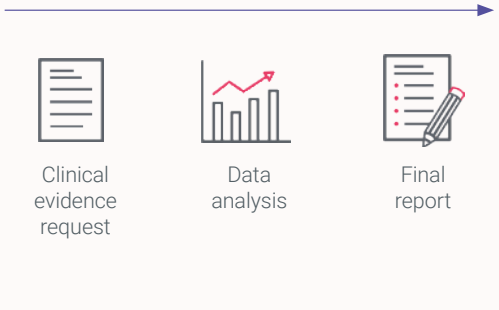
Sampling (nature of biological testing)

Patient file with biological and clinical data

"Data Lake"

External Database Pairing

Real World Evidence (RWE)



Clinical evidence request

Data analysis

Final report

Our resources:

- Clinician
- Regulatory manager
- Data project manager
- Biostatician
- Data analyst/scientist

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