SAFEGUARD

Safety Evaluation of Adverse Reactions in Diabetes

Today 366 million people worldwide suffer from diabetes and its incidence is increasing rapidly. WHO estimates that 552 million people will suffer diabetes in 2030.

Diabetes is categorized into type 1 diabetes (T1DM; approximately 5-10% of patients); and type 2 diabetes (T2DM; 90-95% of all diabetes patients). Ongoing loss of insulin secretor capacity – along with diminished incretin effects – makes the hyperglycaemia of T2DM progressive, with a concomitant need for intensified therapy over time. In addition, the different risks factors associated with T2DM, including the increased risk of heart disease and some cancers, make it particularly challenging to study the effects of drugs intended to treat the disease.

For decades insulin secretagogues and the insulin sensitizing biguanides have been the only oral therapeutic options available for the treatment of T2DM, with good long-term benefit-risk profiles but with insufficient capacity to halt T2DM disease progression. In the quest for better agents, several novel diabetes drugs have become available over the last decade, all on the basis of their ability to reduce blood glucose levels but with different mechanisms of action; and many more are in the pipeline. All currently available drugs have been approved based on results from studies conducted according to existing regulatory guidelines. However, the requested relatively short-term studies may not suffice to fully reveal the consequences of long-term treatment; especially for the newer products for which data regarding the long-term effects are very limited.

The primary aim of SAFEGUARD is to assess, further quantify and understand the cardio/cerebrovascular and pancreatic safety of blood glucose lowering agents, in particular the TZDs and the novel incretin-based drugs and amylin analogues in T2DM patients

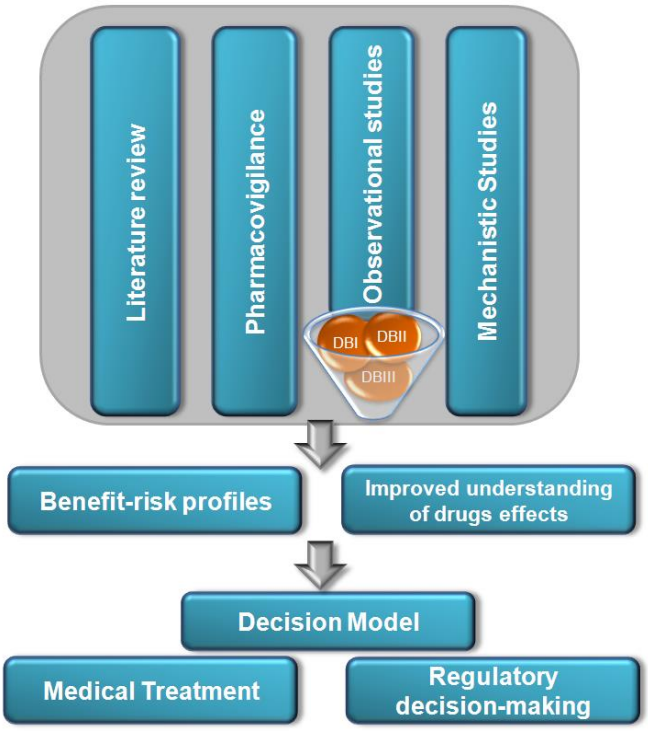
The SAFEGUARD Consortium is formed by a multidisciplinary group including pharmacoepidemiologists, pharmacovigilance experts, diabetes experts, clinicians, pharmacologists, and statisticians. The project capitalizes on knowledge generated in other EU funded projects to create a **harmonized data platform**. This platform will allow for the **largest scale studies on efficacy and safety aspects of T2DM drugs** developed so far as well as for the implementation of **new epidemiological studies**.

Studies included in SAFEGUARD comprise the investigation of:

- Published clinical trials and observational studies
- Spontaneous reported adverse events reports in international pharmacovigilance databases
- Data from 9 population-based health care databases with more than 1.7 million T2DM patients from 6 countries
- Mechanistic studies to unveil possible underlying processes of the observed (side) effects

Results will aid in defining **the benefit-risk profile** throughout the lifecycle of T2DM drugs.

With the integration of all information derived from the work in the project, a **decision model** will be developed to assist both clinicians and regulators in weighing up the risks and benefits of different T2DM treatment options.



SAFEGUARD is carried out by an interdisciplinary team of researchers carefully selected by their specific scientific expertise.

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- Synapse Research Management Partners S.L.
- Fondazione Scientifica SIMG-ONLUS
- University of Bath
- Agencia Española de Medicamentos y Productos Sanitarios
- Consorzio Mario Negri Sud
- Drug Safety Research Trust
- Univerzita Karlova v Praze
- The Brigham and Women's Hospital, Harvard Medical School
- University of Milano-Bicocca
- RTI Health Solutions
- BIPS - Institut fur Epidemiologie und Praventionsforschung
- Stichting VU-VUmc
- PHARMO Institute N.V.

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