Safety Evaluation of Adverse Reactions in Diabetes

From 2011-10-01 to 2015-09-30, closed project

Project details

<table>
<thead>
<tr>
<th>Total cost:</th>
<th>Topic(s):</th>
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<tbody>
<tr>
<td>EUR 3 881 341</td>
<td>HEALTH.2011.4.2-2 - Adverse Drug Reaction Research</td>
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<table>
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<tr>
<th>EU contribution:</th>
<th>Call for proposal:</th>
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<tbody>
<tr>
<td>EUR 2 997 196</td>
<td>FP7-HEALTH-2011-single-stage</td>
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<tr>
<th>Coordinated in:</th>
<th>Funding scheme:</th>
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<tbody>
<tr>
<td>Netherlands</td>
<td>CP-FP - Small or medium-scale focused research project</td>
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Objective

"In 2010 a widely marketed drug for the treatment of type 2 diabetes (T2DM) (rosiglitazone) was taken from the market as it was associated with an increased risk of myocardial infarction, a T2DM complication it was actually supposed to prevent. This example shows several things. First, the approval requirements do not guarantee a longer term positive benefit risk profile. Second, large scale postmarketing studies are desperately needed to monitor the benefit risk profile throughout the lifecycle of T2DM drugs, and to achieve the required scale collaboration across countries is mandatory. Many novel T2DM drugs have come to the market, all on the basis of the same surrogate endpoints. New safety issues are constantly arising, such as potential associations with pancreatitis, pancreas cancer, bladder cancer, acute renal failure, etc. In the SAFEGUARD Consortium we have assembled an excellent multidisciplinary group of experts who collaboratively aim to quantify the cardiovascular, cerebrovascular and pancreatic safety risk of the T2DM drugs, in particular the more novel drugs by investigating 1) published clinical trials and observational studies; 2) spontaneously reported adverse event reports in national and international pharmacovigilance databases; 3) data from nine population-based health care databases in six countries capturing longitudinal drug exposure and event data on more than 1.7 million T2DM patients. Data elaboration will be distributed but standardized through common protocols, data models and scripts. To put the epidemiological results into perspective, intensive monitoring mechanistic studies in human will be conducted to further understand how and why these T2DM drugs may affect the cardiovascular, digestive or renal system. The SAFEGUARD consortium will yield a harmonized epidemiological data platform on a large T2DM population, which could easily be used to address newly occurring safety issues in the future."

Related information

<table>
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<tr>
<th>Result In Brief</th>
<th>Type 2 diabetes mellitus – drug safety and monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Summaries</td>
<td>Final Report Summary - SAFEGUARD (Safety Evaluation of Adverse Reactions in Diabetes)</td>
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</table>
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**Subjects**

Life Sciences

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