ATTD participants' Call for Action 2018: Industry, Regulatory Agencies and Healthcare Policy Makers need to accelerate the availability of Closed Loop systems in the EU

Following the recent publication of the **ATTD International Consensus on Use of Continuous Glucose Monitoring (CGM)** we wish to express a "**European Call to Action on Closed-Loop Technology**". Using CGM to "close the loop" by linking ongoing glycemic trends directly to insulin delivery systems or insulin dosing advisors is a leading goal for improving clinical outcomes such as HbA1c, increasing "Time in range", reducing glycemic variability and achieving better control of blood glucose levels especially at night. Already in September 2016 the American regulatory authority FDA approved a hybrid-closed loop for clinical use in the US for patients with diabetes aged 14 years and above. Until now, no closed-loop device has been approved in the European Union. Thus, industry, regulatory agencies and healthcare policy makers urgently need to work together to accelerate the availability of Closed Loop systems in the EU.

Background

Improved accuracy and durability of glucose sensors, better pumps, and more refined algorithms for insulin adjustments in closed-loop systems have started a process of moving such systems from investigational approaches to becoming part of routine care. **ATTD** has for years been a platform to discuss the development and commercialization of artificial pancreas systems that automate insulin delivery using closed-loop algorithms, demonstrating how these sophisticated systems, with each generation, improve clinical outcomes and reduce burden for people with diabetes. We believe a turning point in the management of diabetes is now upon us with the first commercial system being on the market, and others in clinical development. The **EMA** has acknowledged the importance of CGM in their recent draft "Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus". **EMA** recognizes that measures derived from CGM such as glucose variability, glucose excursions and time spent in normal range may reveal important information on how a treatment affects quality-of-life and disease-specific patient-reported outcomes for diabetes. Thus, structured and rapid pathways for approval of devices and software that allow automated glucose control through CGM are urgently needed in the EU.

By scanning my badge as **ATTD participant**, I give full support to the **ATTD participants' Call for Action 2018: Industry, Regulatory Agencies and Healthcare Policy Makers need to accelerate the availability of Closed Loop systems in the EU**