

## 糖尿病照護邁入數位時代

### 賽諾菲攜手智抗糖 胰島素管理數位療法獲 SaMD 認證

#### 【新聞稿】

賽諾菲致力於醫療保健創新，攜手台灣新創公司 Health2Sync 智抗糖布局糖尿病數位醫療照護生態鏈，其共同開發之糖尿病數位療法—胰島素劑量調整軟體已獲台灣衛生福利部食品藥物管理署 SaMD ( Software as a Medical Device ) 醫療器材軟體許可證，象徵糖尿病照護邁入數位時代。

賽諾菲亦針對此胰島素劑量調整軟體投資一項臨床試驗，比較數位療法與標準照護的病患血糖控制結果，此臨床試驗目前正在台大醫院、三軍總醫院、林口長庚、成大醫院、高雄榮總與高雄長庚等 15 個醫療院所進行中。

賽諾菲香港台灣總經理林嘉莉表示，賽諾菲不僅投資科學研發，也推動數位轉型、人工智慧 (AI) 解決方案和資料利用來提升研發生產力，透過數位解決方案打造更加個人化的治療，是醫療保健的未來。

Health2Sync 智抗糖執行長鄧居義表示，共同開發之胰島素劑量調整軟體獲第二等級醫療器材 ( Class II Medical Device ) 許可，成為台灣獲得食藥署核准的數位療法，對團隊、投資人、市場合作夥伴都是很大的鼓舞，我們期待能用更有效率、更永續的數位解決方案，持續幫助慢性病患與醫護人員，進而降低後續照護支出。

台灣賽諾菲數位醫療部門處長 Francois Barbé 說，賽諾菲成立獨立的數位醫療部門，展現發展數位醫療的決心。這項與智抗糖合作之胰島素劑量調整軟體不僅在台灣獲許可，更將拓展至日本、韓國等市場，並放眼布局國際。而糖尿病是賽諾菲優先發展數位醫療的領域之一，未來將持續探詢不同治療領域的數位解決方案。

台灣賽諾菲公共事務、企業溝通暨健保事務處長蔡德揚表示，近期醫療健康領域導入多項加速引進創新的政策，如暫時性給付、鼓勵在台首發新藥等，期盼政府將數位醫療納入健保穩定的給付機制，產官學共同打造台灣數位醫療照護生態圈，也可望將台灣數位醫療推展經驗推展至國際市場。



## **Diabetes Care Enters the Digital Era Sanofi Collaborates with Health2Sync on Digital Insulin Management Solution recently approved for Class II SaMD Certification by TFDA**

Sanofi is dedicated to healthcare innovation and has joined forces with the Taiwanese startup company Health2Sync to establish a digital ecosystem for diabetes care. The two companies have co-developed a digital therapeutic for diabetes that enables insulin self-titration. This software has received SaMD (Software as a Medical Device) certification from Taiwan's Food and Drug Administration, marking a transition into the digital era for diabetes care.

Sanofi is also conducting a clinical trial for this digital therapy to compare blood glucose control outcomes between patients who use the solution versus standard of care. This clinical trial is currently underway at 15 medical institutions, including National Taiwan University Hospital, Tri-Service General Hospital, Chang Gung Memorial Hospital in Linkou, Cheng Kung University Hospital, Kaohsiung Veterans General Hospital and Kaohsiung Chang Gung Memorial Hospital. The results are expected to be available in 2024.

Kelly Lam, General Manager of Sanofi Hong Kong and Taiwan, stated that Sanofi not only invests in scientific research but also drives digital transformation, artificial intelligence (AI) solutions, and data utilization to enhance research and development productivity. Creating more personalized treatments through digital solutions is the future of healthcare.

Ed Deng, co-founder & CEO of Health2Sync, mentioned that receiving Class II Medical Devices certification signifying a new digital era in diabetes care for Taiwan. "We hope to use more efficient and scalable digital solutions to continue helping chronic disease patients and healthcare professionals, ultimately reducing future healthcare expenses."

Francois Barbé, Head of Sanofi's Digital Medicine Department in Taiwan, emphasized Sanofi's commitment to developing digital healthcare. "This insulin self-titration software, developed in collaboration with Health2Sync, not only received approval in Taiwan but also has the potential to be expanded internationally to markets such as Japan and South Korea. Diabetes is one of Sanofi's priority areas for digital healthcare development, and we will continue to explore digital solutions in various therapeutic areas."

William Tsai, Head of Public Affairs, Communications, and Market Access



at Sanofi Taiwan mentioned that recent policies in the healthcare sector, such as conditional listing and incentives for new drugs to first launch in Taiwan, have accelerated the introduction of innovations to the market. The government is looking to incorporate digital healthcare into a sustainable reimbursement mechanism, fostering collaboration among government, industry, and academia to create a digital healthcare ecosystem in Taiwan. We look forward to collaborating with the government to develop experiences that can also be extended to international markets.

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