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Al powered Oncology Clinical Trial, by "Agostino Gemelli" Hospital & Innovation Sprint SprI

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Innovation Sprint announces collaboration with "Agostino Gemelli" Hospital for the use of Healthentia in the co-sponsored *AI-APACHE* clinical Trial using AI-supported outcome prediction and assessment monitoring technologies during the multimodal oncological therapies and follow up period of cervical cancer patients.

BRUSSELS, BE – Oct 26, 2020 – <u>Innovation Sprint</u>, a Belgian digital biotech company, is partnering with <u>Fondazione Policlinico Universitario "Agostino Gemelli" IRCCS</u> in Rome, Italy, co-sponsoring the clinical trial "**APACHE**: Advanced patient monitoring and A.I. supported outcomes assessment in cervical cancer using Internet of things technologies", involving both the Gemelli advanced radiotherapy center and the gynecology department.

Primary objective of this 24 months trial is to evaluate whether monitoring oncological patients during multimodal cancer therapies may represent a significant step towards a comprehensive and reliable quality of life assessment, prevention of toxicity before its clinical onset, and treatment outcomes prediction.

Innovation Sprint has deployed its eClinical solution Healthentia

in APACHE, to enable a seamless ePRO/eCOA collection of reported outcomes and assessment of physical activity, emotional and lifestyle status of patients undergoing cancer therapy. As secondary objectives are to compare patient reported outcomes with corresponding clinical records about early and late toxicity, instrumental activities of daily living (iADLs), and stress/coping levels and be able to profile patients based on their scores and activity. More specifically, the project evaluates patients' *Quality of Life* using portable monitoring technologies during the multimodal oncological therapies for **cervical cancer**, paving the way to develop new **Personalized Medicine paradigms**

for gynecological and radiation oncology. All this will be done through training models using advanced Al solutions and Machine Learning on the patients-reported and monitored data creating composite lifestyle biomarkers.

At the same time, Innovation Sprint has raised funding from Innoviris in Belgium to validate the development of the Healthentia AI component for the discovery of lifestyle composite biomarkers that can be used to associate certain patient phenotypes with clinical outcomes. The funded project "*Deep Learning of Patients*" will be validated in the APACHE clinical trial, where Healthentia will be used to monitor cervical cancer patients by means of a novel composite biomarker defined from RWD by Innovation Sprint. The use of this novel biomarker will allow investigators to predict the disease state and the associated clinical outcomes, while Innovation Sprint claims that this is the first step towards the delivery of *Digital Therapeutic Services* (DTx), processing Real World Data to offer personalized interventions of high efficacy under a strict clinical framework.

Healthentia is a Class I Medical Device with a CE mark that facilitates clinical trial optimization, by accelerating trial processes, reducing failure rate, and validating drug/intervention effectiveness using Real World Data insights. Apart from the advanced ePRO and eCOA functionalities, Healthentia is using AI mechanics to auto-discover parameters of its novel lifestyle composite biomarker, thus offering smart services, in-silico trial environment and DTx services. The defined lifestyle composite biomarker and its relation to DTx is under the process of patent filing. For more information, visit https://healthentia.com or contact info@healthentia.com

"We believe this collaboration will boost the advances of innovative solutions for gynecological and radiation oncology", said Prof. Giovanni Scambia (Scientific Director at Fondazione Policlinico Gemelli) and Prof. Vincenzo Valentini (Deputy Scientific Director and Delegate for "Big Data").

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