FUNDACIÓN GALEGA DE INVESTIGACIÓN SANITARIA IDIS

# **Epi-smart-PRO:** Method for Predicting Cancer Patients' Risk of Radiotherapy Side Effects



Business area

Market sector

Medical Indication

Diagnostics

Radiotherapy, Precision Medicine, Cancer Prostatic cancer, radiotherapy

## Research goal

To develop Epi-smaRT-PRO, a machine learning software that predicts post-radiotherapy toxicities in prostate cancer patients, enabling personalized treatment plans to minimize adverse effects while maximizing efficacy and quality of life.

### Problem to solve

Current radiotherapy planning relies on population-based dose limitation guidelines, resulting in a one-size-fits-all approach that may not account for individual patient susceptibilities to side effects. The absence of radiotherapy response biomarkers could result in suboptimal treatment plans, potentially compromising patient outcomes and quality of life.

#### Innovation

EPi-smaRT-PRO represents a groundbreaking advancement in personalized oncology, combining cutting-edge machine learning technology with epigenetic biomarkers to predict the likelihood of moderate to severe gastrointestinal and genitourinary toxicities in prostate cancer patients undergoing radiotherapy. By integrating clinical-epidemiological data with six CpG-methylation biomarkers identified through epigenome-wide association studies, the EPi-smaRT-PRO model captures essential biological information about patients' predisposition to treatment-related side effects. This capability enables patient stratification based on their anticipated response to radiotherapy before treatment begins, specifically predicting their susceptibility to moderate to severe gastrointestinal or genitourinary toxicities. EPi-smaRT-PRO provides clinicians with crucial individual biological insights to optimize treatment decisions; patients at predicted high-risk can be directed toward alternative therapies or adjusted radiation dose plans to minimize adverse effects, while those at low risk can safely undergo standard or even intensified treatment protocols. This sophisticated approach not only enhances clinical outcomes but also significantly improves patient quality of life by preventing limiting side effects that could significantly impact long-term well-being. As personalized medicine increasingly shapes the landscape of modern oncology, EPi-smaRT-PRO is poised to become a valuable tool in radiation oncology departments worldwide. Furthermore, its capacity to enhance therapeutic decision-making carries broader implications for healthcare economics by preventing costly complications and streamlining patient management.

### Market opportunity

Prostate cancer is, after lung cancer, the second most prevalent cancer worldwide with 1.41 million new diagnoses in 2020. This high disease burden creates a substantial demand for innovative solutions to optimize treatment outcomes and enhance patient quality of life. Epi-smaRT-PRO addresses this critical market need by providing an advanced predictive tool for assessing post-radiotherapy toxicities. Currently, while more than 50% of prostate cancer patients undergo radiotherapy as part of their treatment protocol, clinical decision-making still relies on population-level data rather than individual biomarkers. Consequently, there exists a rapidly expanding market for personalized therapeutic approaches that customize treatment strategies according to patients' specific biological profiles and individual needs.

#### Research team

Genetics in Cancer and Rare Diseases group

- Ana Paula Vega Gliemmo
- Carlos López Pleguezuelos
  Antonio Gómez Caamaño
- Miguel Elías Aguado Barrera

# Intellectual property

European patent **EP24382223** "Method for predicting, before the initiation of radiotherapy, whether a patient suffering from cancer would develop radiotherapy toxicity or radiotherapy side effects"

# Development stage:

R+D Analytical Prototype Clinical validation validation

Regulation Utility

www. idisantiago.es

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Available for: Licensing, co-development