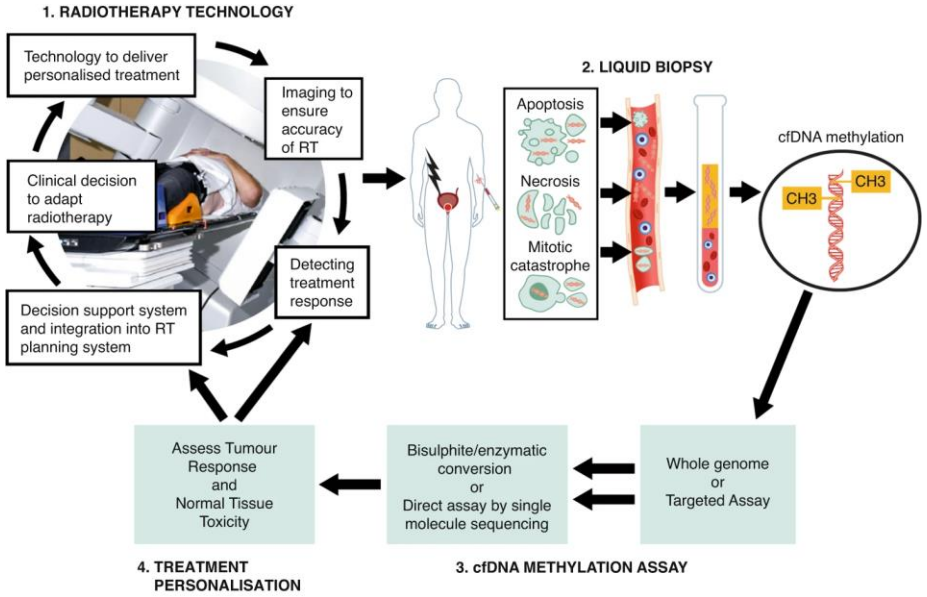
Liquid Biopsy for Adaptive Radiotherapy

A circulating plasma cell-free DNA (cfDNA) liquid biopsy test, to guide the management of radiotherapy treatment for prostate cancer by providing precise, in-treatment measurement of radiotherapy efficacy and toxicity.



Integration of liquid biopsy into a personalised, adaptive radiotherapy workflow

McLaren, D.B., Aitman, T.J. Redefining precision radiotherapy through liquid biopsy. Br J Cancer 129, 900–903 (2023). https://doi.org/10.1038/s41416-023-02398-5

Unmet clinical need

With present methods, 30% of patients receiving curative radiotherapy suffer significant short term side effects and greater risk of persistent quality-of-life affecting side effects, despite careful decisions about radiotherapy dosage that are intended to optimize the balance between treatment efficacy (tumour elimination) and toxicity to tissues surrounding the tumour.

In the present state of the art, there are no biomarkers to assist the management decisions in reducing toxicity to surrounding tissues while maximising cure rates. Currently, doses of radiotherapy are the same for every patient, and are only adjusted if the patient presents severe symptoms of toxicity.

Solution and unique value

The cfDNA liquid biopsy test will provide in-treatment measurement of efficacy and toxicity, contributing to precision management of radiotherapy.

The cfDNA test will enable real time toxicity testing and allow for adjustments of the dosing in the first half of the course of the treatment, improving acute and long-term toxicity. The test will predict efficacy at prostate tumours and toxicity to nearby organs such as bladder and bowel during radiotherapy simultaneously.

Stage of development

The research team previously demonstrated the feasibility and accuracy of building whole-genome methylation profiles on the Oxford Nanopore single-molecule platform for relevant tissues and cfDNA. The team are currently working to establish a robust dataset to scope the entire genome for discriminative markers that will give maximum power and efficiency to measure treatment and treatment toxicity. The existing feature space with 2,751 markers will be expanded to genome level.

Clinical impact

- In prostate cancer patients with a life expectancy of 10 years or more, management options include radical prostatectomy, radiotherapy/brachytherapy alone or in combination with hormone therapy and active surveillance. Radiation therapy is a good choice for many men with early-stage prostate cancer, and is also the best treatment for older patients or those who have other health problems.
- Side effects of radiotherapy to bladder, bowel and sexual function varies from patient to patient. Most side effects of radiotherapy gradually go away in the weeks or months after treatment. However, long term side effects can continue, or some begin months or years after the treatment.
- Measuring patient heterogeneity in developing side effects, and then personalising the radiation dose would maximise the probability of being cured and minimise the risk of life changing post-treatment side effects.
- The test is primarily focused on prostate cancer, however, it could have wider applications in other cancer indications where radiotherapy is used as a treatment.

Intellectual Property status

- Patent protecting assay methodology and discriminative methylation markers for radiotherapy toxicity.
- Patent Title: Non-invasive disease detection and monitoring
- Priority filing GB2307233.3 15 May 2023. PCT filing PCT/EP2024/063285 14 May 2024

Commercial Strategy

Looking for commercial partners with global reach to enable further clinical validation, market access and broad implementation.

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Tech ID: CR/2022-144