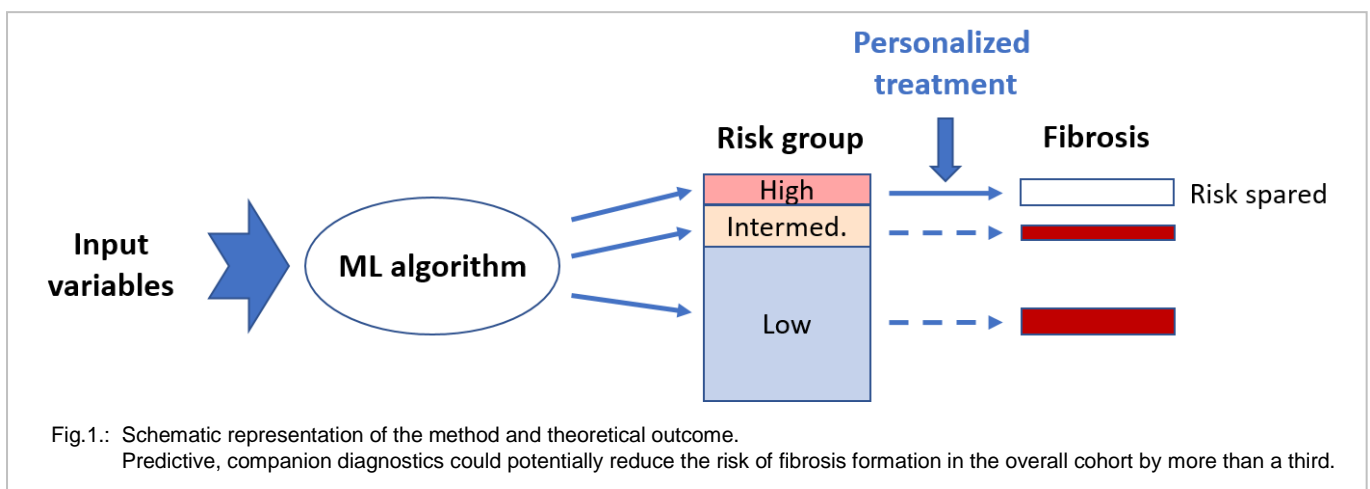




# Method for predicting the risk for developing radiation-induced skin fibrosis

## Technology Offer

Ref. No.: 2002-23



### Category

Companion diagnostics

### Keywords:

Skin fibrosis, radiotherapy, machine learning, predictive modelling

### Development stage

TLR 4

### Seeking

In-licensing / collaboration

### IP status

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### Background

Radiation therapy (RT) is an important part of multimodal cancer therapy. With rising numbers of long-term survivors, dose-limiting late reactions in healthy tissues become increasingly important for patients' quality of life. Therefore, reliable methods for predicting individual risk will be required in order to implement personalized treatments.

Studies of genetic variation have identified relatively few single-nucleotide polymorphisms (SNPs) associated with late toxicity. Nevertheless, polygenic risk scores (PRS) have been suggested but these require the determination of a large number of individual SNPs associated with a small increased risk each.

Published PRS-based predictive models have not been highly predictive, even when several hundred SNPs were included. Other approaches to prediction based on clinical characteristics or functional assays have not produced useful models either. A limitation of most of these methods is that neither a single risk factor nor multiple

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independent risk factors take possible interactions between different components into consideration. Our method identifies subgroups for which different sets of risk factors are important.

## Technology

Our technology uses in total a single-digit number of variables ('features') as input into a machine learning (ML) algorithm which divides patients into three groups of high, intermediate, and low risk to develop late reactions, e.g. fibrosis, in healthy tissue following irradiation. The test variables consist of clinical and test variables, which can be determined from a single blood sample within a working week, which enables a rapid companion diagnosis and corresponding adjustment of treatment intensity. The clinical features are collected as part of standard patient anamnesis, whereas the test variables are obtained from the blood sample.

In a German breast cancer cohort, the ML algorithm identified 13.6% of the patients as having 83% risk of developing fibrosis while 66.7% of the patients had only 17% risk. The intermediate group (19.6% of the patients) had an intermediate risk of 37% which was only moderately increased compared with the total cohort of patients before the test (30% risk).

Thus, four out of five patients were assigned to the high- or low-risk groups. By offering high-risk patients (less than 1 in 7 patients) an alternative treatment (e.g. partial breast radiotherapy), the number of patients developing fibrosis may potentially be reduced by up to 38%.

## Benefits

- Low number of input variables
- Easy to perform functional tests from a single blood sample
- Patients classification into three risk groups with high precision, therefore a potential reduction of skin fibrosis by up to 38%
- Possible test automation
- High scope of potential improvement
- Potential use in the other fibrotic diseases

## Applications

- Risk prediction for radiotherapy induced skin fibrosis
- Radiotherapy treatment adjustment based on the risk for fibrosis
- Widening the therapeutic window
- Starting point for developing other ML predictive models

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