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Rna Diagnostics initiates clinical trials

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Canada-based cancer diagnostics firm Rna Diagnostics has initiated the breast cancer response evaluation for individualised therapy (BREVITY) clinical trial of its RNA Disruption Assay (RDA) for primary cases of the disease.

Designed as a diagnostic test to measure tumour response following the first cycle (14-21 days) of neoadjuvant chemotherapy, RDA features methods to quantify and score the degradation of ribonucleic acid present within tumours.

To be conducted at 40 sites in North America and Europe, the international prospective trial will validate the assay as a potential tool for treatment management in more than 500 invasive breast cancer patients.

The trial will enroll subjects suffering from any subtype of invasive breast cancer and who are prescribed with standard neoadjuvant chemotherapy and targeted drugs.

The objectives and design of BREVITY reflect feedback received from key opinion leaders in breast cancer research from centres in Europe, Canada and the US. Accrual of patients will begin in the second half of 2017.

The trial's Phase I called Training Phase will include an assessment of 113 patients for final determination of response zone cutoffs, while Phase II known as the Validation Phase will recruit 347 fully evaluable patients. The results from the BREVITY trial are expected to be available in 2019.