A prognostic marker for stage II colorectal cancer combining analyses of DNA ploidy and tumour stroma

ColoProg workflow steps 1–6:

1. Patient receives surgery
   - Formalin fixed paraffin embedded (FFPE) tissue used for pathology

2. Treatment discussed with patient
   - ColoProg test requested by clinician
   - FFPE slide sent to OCB laboratory

3. Sample and requisition form received and logged by laboratory
   - Tumour sample processed for stroma and ploidy analysis

4. Digital image analysis carried out for
   - Stroma (tumour micro environment)
   - Ploidy (DNA content determination)
   - Stroma and ploidy data combined to produce risk category designation
   - Final data set approved by pathologist

5. Ploidy (DNA content)
   - DIPLOID
     - Normal DNA content
     - LOW RISK
   - NON-DIPLOID
     - Abnormal DNA content
     - HIGH RISK
   - Stroma (tumour micro environment)
     - STRONG LOW
       - Stroma content ≤ 50%
       - LOW RISK
     - STRONG HIGH
       - Stroma content > 50%
       - HIGH RISK

6. ColoProg risk report to clinician
   - CHEMOTHERAPY REGIMEN DECISION

Oxford Cancer Biomarkers
What is ColoProg?

- A clinical digital pathology tool that combines analyses of Stage II DNA ploidy and tumour stroma content
- Initially validated using the QUASAR2 clinical trial and two other studies providing over 1000 Stage II patients for analysis

What does ColoProg do?

- Uses the proprietary ColoProg algorithm to determine patient risk category
- Stratifies patients into low, intermediate and high-risk groups

Why use ColoProg?

- Difficult to identify which Stage II colorectal cancer tumour patients require adjuvant chemotherapy:
  - About 50% Stage II patients are given chemotherapy in UK
- ColoProg enables clinicians to determine risk of recurrence, potentially sparing overtreatment of patients who would not benefit from adjuvant chemotherapy:
  - 33.5% of Stage II tumours are low risk according to ColoProg validation
    - Long term effects of unnecessary chemotherapy can be avoided
    - May provide healthcare cost savings by avoiding unnecessary chemotherapy
- ColoProg combines DNA and tumour microenvironment markers to stratify patients into groups of high and low risk of recurrence with a hazard ratio of 2.95 (P<0.001) compared to the leading competitor (HR = 1.47, P=0.046)
- Meets patient safety and enhanced patient experience standards (NHS Outcomes Framework)

References: