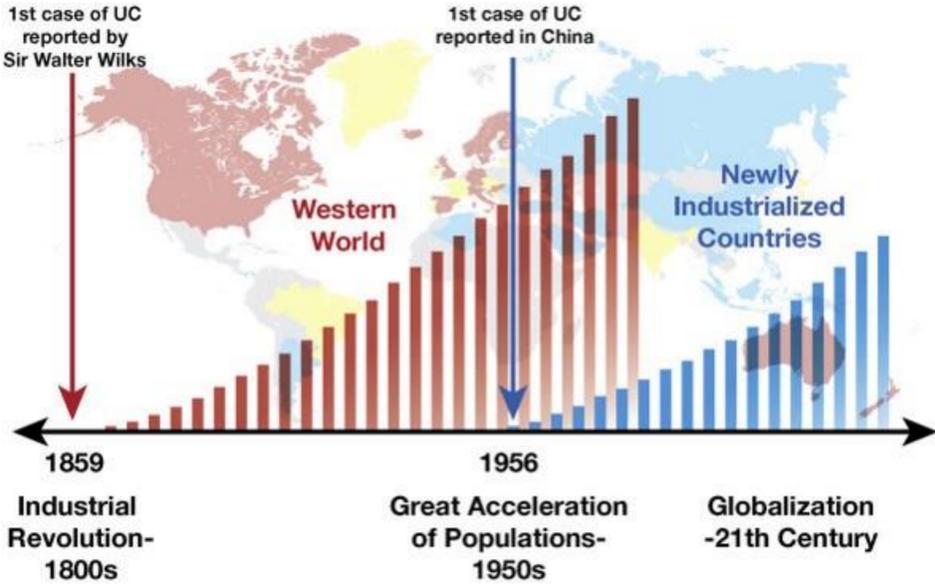


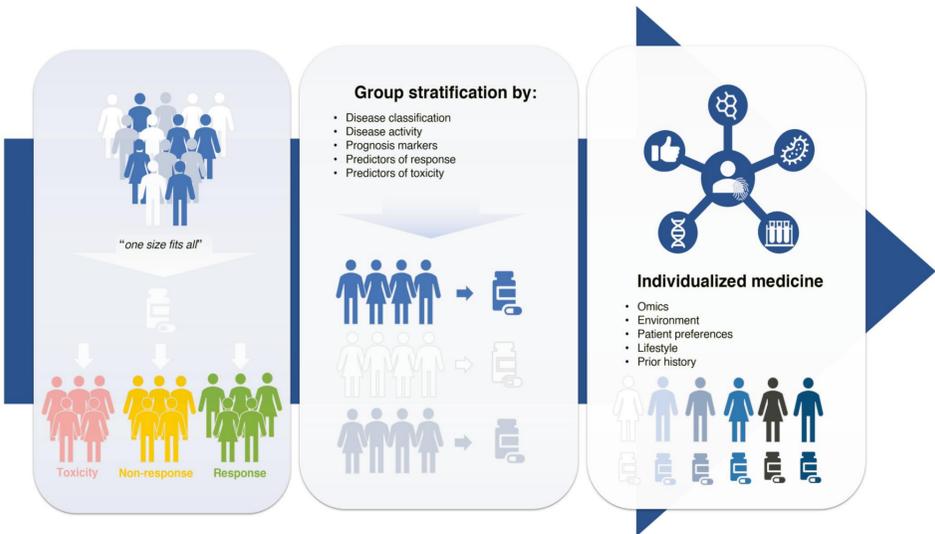
1. RAPIDLY RISING INCIDENCE AND PREVALENCE

- There are now over 500,000 people in the UK living with IBD and numbers of patients living with this chronic, debilitating condition are projected to double in the next 10 years.



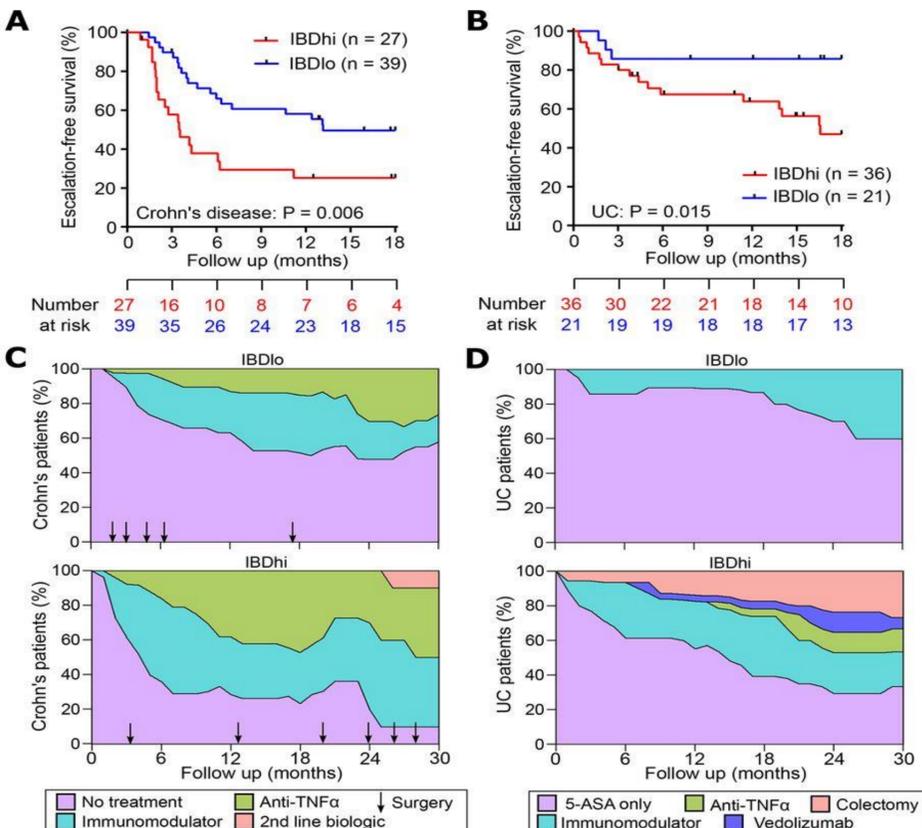
2. NEED FOR A MORE PERSONALISED APPROACH

- Despite the highly heterogeneous outcomes, currently all patients are treated in a "one-size-fits-all" approach. However, increasingly there is an aspiration for more personalised care.



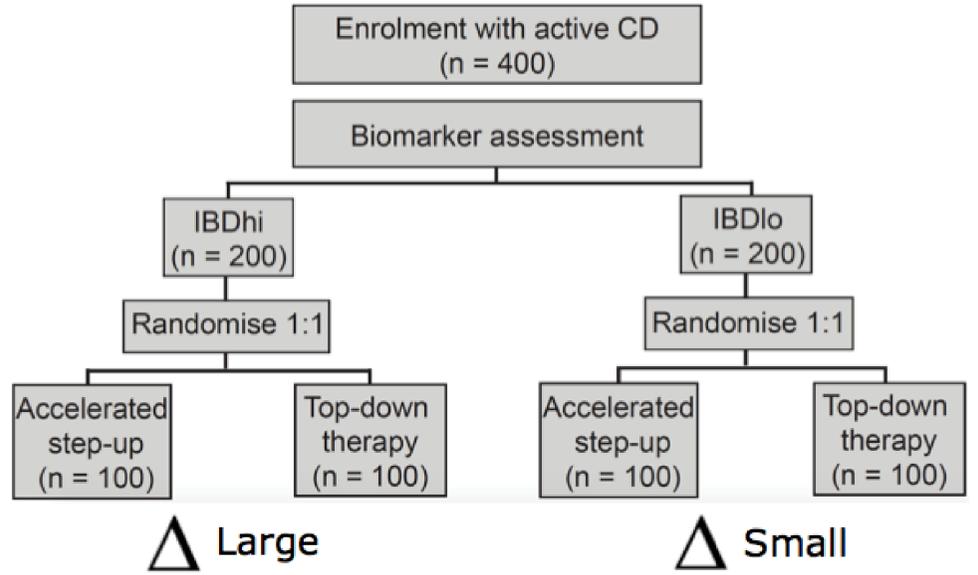
3. DEVELOPMENT AND VALIDATION OF A BLOOD-BASED PROGNOSTIC BIOMARKER IN IBD

- A whole-blood biomarker was developed from a previous CD8+ T cell signature correlating with clinical outcome (n=69).
- This signature was then validated in 4 centres across the UK and was consistently associated with disease course (n=123).



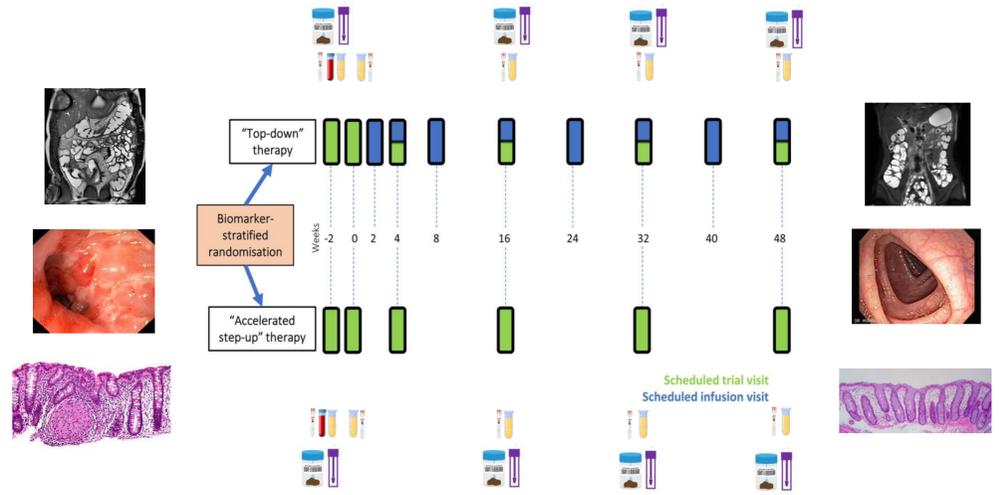
4. PROFILE TRIAL OUTLINE AND OBJECTIVES

- The PROFILE trial has enrolled newly-diagnosed, treatment-naive patients and seeks to show that stratifying treatment based on prognosis at the time of diagnosis, leads to better patient outcomes.



5. TRIAL SCHEDULE & TRANSLATIONAL SUB-STUDIES

- Patients will participate for a one year period. There is an exciting translational programme within PROFILE, aiming to further understand disease biology to help direct future care & research.



6. CLINICAL IMPACT FOR PATIENTS AND CARERS

- PROFILE has completed recruited and is the largest investigator-initiated clinical trial for IBD ever conducted from the UK.
- PROFILE is the earliest "early IBD" trial ever conducted and we anticipate this will allow for demonstration that early disease control results in the best possible outcomes for patients.
- PROFILE is the first ever "personalised medicine" trial in IBD.

7. CONCLUSIONS

- We have previously identified a whole-blood transcriptional gene signature that is able to stratify patients with inflammatory bowel disease at diagnosis into two distinct prognostic groups.
- The transcriptional biomarker has been validated in an independent cohort from 4 centres around the United Kingdom.
- This biomarker is currently being investigated in a UK-wide, trial of 390 patients (PROFILE – www.crohnsprofiletrial.com)
- If clinical utility is demonstrated, this would represent a major step towards personalised medicine for patients living with IBD.

REFERENCES

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