# PROFILE trial: Recruitment

We are very mindful that getting recruitment going quickly / setting the pace early is a key part of any successful trial – *if we / you do not establish early momentum ASAP after the study initiation visit then it is difficult to pick it up later!*

We want to recruit patients with newly / recently diagnosed Crohn's who have significant symptoms. They can have completed a course of steroids and still be recruited, but only if their disease remains active. Ideally we would like to recruit them while still steroid naïve.

**N.B. These patients are difficult to find – the best chance of recruiting them requires identifying them BEFORE the diagnosis is finalised.**

In our experience, this works best if **all** clinicians are able to keep a beady eye out and have someone (nurse? secretary? Or doc!) as point person to track all patients 'highly likely' to have a new diagnosis of Crohn's.

Top 10 tips:

1. Spread the word across your WHOLE clinical team to look out for newly diagnosed Crohn's, and ask everyone to notify you / the key someone (nurse / secretary / doc) of possible study recruits by e.g. e-mailing the names/hospital number whenever they come across them. Otherwise folk forget the details when put on the spot. Our research nurse pops names / hospital numbers onto an Excel spreadsheet so we can track them.

2. Do this repeatedly / e.g. at weekly meetings until it is firmly ingrained in people's practice. Everyone is busy and overloaded with info – we all need reminding of stuff!

3. In our experience look out for referral letters or endoscopic requests in patients with **significant Crohn's symptoms** of > 2 weeks' duration **AND**…

    - Blood tests which are highly suggestive (raised CRP, ESR, iron-deficiency anaemia, monocytosis, raised platelets etc)
    **OR**
    - Family history of IBD
    **OR**
    - Very raised faecal calprotectin e.g. >600ug/g

4. It helps to stream such patients into your clinic and / or your colonoscopy list so that they do not get lost in the system; and ideally **begin the conversation early** regarding the study e.g. after discussing diagnostic possibilities say something like "*If this does turn out to be Crohn's we are running an interesting new study in which you would either go on standard treatment or 'maximal' treatment from the beginning, it will compare patient outcomes after one year when using a new molecular blood test which we believe helps predict the course of Crohn's''.*

5. Be aware that potential recruits will also pop up in myriad of other places – in clinic, in endoscopy, via surgeons, in the A&E dept etc. – please cast your net wide!

6. For patients VERY likely to have Crohn's we invest a bit of extra effort, e.g. fast track them into clinic (which is anyway a good thing to do with people with likely new Crohn's). For patients with a lower chance – e.g. just have a modestly raised calprotectin etc., perhaps with a more IBS-like history – we track them through

normal care (we recognise that everyone has a finite amount of time – best to invest the most effort in folk who are very likely to have Crohn's rather than those that 'might just').

7. Remember we really want the index colonoscope to be recorded – so ideally stream these patients onto lists where you / someone familiar with the study / able to do recording / able to do SES-CD score is in charge. Remember to get the patients consent for videoing – you may have this as a pre-specified option on your endoscopy consent, or if not can add it in the free text (and explain to the patient why).

8. If the colonoscope looks like Crohn's then you can continue the conversation hopefully started in clinic – perhaps this time giving them a study information sheet and booking them back to clinic with biopsy results, or if the diagnosis is clear cut and the patient is willing to come into the study you can line up the screening visit soon after their colonoscopy e.g. within a few days.

9. At this clinic visit - if the patient is willing and meets eligibility criteria (particularly that they have sufficient symptoms) they can

    a. sign the consent,
    b. get their blood tests done including the biomarker, TPMT etc where not already done
    c. **and start on steroids immediately**

    – then come back 2 weeks later at which point a full check of eligibility criteria will be undertaken and, if eligible, patient will be randomised according to biomarker status.

10. Book a slot in your infusion unit as soon as you have done the screening – you can always cancel this if patient is randomised to 'step-up' (and the unit will still have 2 weeks to fill the slot) – easier than trying to shoe-horn a patient into infusion unit at only 2 weeks notice.