# Patient perspectives of successful adalimumab biosimilar transitioning in Crohn’s disease – an interview study.

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**Word count (excluding title page, abstract, references, figures and tables):**

3,701 (562 words in quotes (included in word count))

**Structured Abstract** (296 words)

Objectives

Transition from originator biological medicines to their biosimilar equivalents is now part of routine clinical practice but there is little understanding of patient experiences, which influence adherence and overall satisfaction with care. Understanding this will help ensure future switches adequately address patients’ concerns and expectations leading to better outcomes for all stakeholders.

Method

35 patients participating in a clinical trial including an open-label transition event from originator to biosimilar adalimumab, mimicking what would be encountered in a real-world setting, took part in semi-structured interviews exploring their experience of biosimilar transition.

Results

Opinions expressed were often heterogeneous, but common experiences and themes were identified. Five themes were identified following thematic analysis:

(1) Understanding and awareness of biosimilars: prior awareness of biosimilars and knowledge of the biosimilar concept was low indicating a disparity between healthcare professionals and patients.

(2) Motivation to undertake transition: patients accept a biosimilar transition to minimise drug expenditure.

(3) Initial concerns: prior to undertaking biosimilar transition away from the brand they had experienced, anticipated loss of efficacy and adverse effects from the biosimilar were common concerns for patients.

(4) Reassuring factors: trust in the healthcare team is critical to patient acceptance of biosimilars. Important reassurances include a point of contact, education about biosimilars and monitoring.

(5) Experiences during the transition: on reflection, participants described consistent efficacy and tolerability (although 22 participants specifically mentioned injection pain) following brand transition. The majority feel comfortable with future transition to another adalimumab biosimilar. Injection experience was an important component of patient satisfaction.

Conclusions

While biosimilars have driven a reduction in drug acquisition costs, the majority of patients have little knowledge and some concerns about transitioning to a biosimilar but, if supported by a trusted clinical team, accept the principles and can be reassured. The wide-ranging views elucidated suggest that a tailored, patient-centred approach is key to successful implementation.

**Key messages:**

What is already known on this topic:

Biosimilars of adalimumab are now part of routine clinical practice and are expected to be as effective as the originator medicine.

Patient experience may influence adherence to medication and is essential for optimising outcomes.

Current understanding of the patient perspective of biosimilar transition is limited.

What this study adds:

This paper describes the patient experience of transition from originator to biosimilar adalimumab, including identification of the features that are important and reassuring to patients.

How this study might affect research, practice or policy:

A carefully planned, individualised and supported approach to biosimilar transition is key to success.

**Keywords:**

CROHN'S DISEASE

INFLAMMATORY BOWEL DISEASE

BIOSIMILARS

ADALIMUMAB

PATIENT PERSPECTIVE

# Introduction

Crohn’s disease (CD) is a chronic, relapsing and disabling inflammatory disorder associated with progressive damage to the gastrointestinal tract. Therapeutic monoclonal antibodies have significantly improved outcomes for patients with CD but represent a significant financial burden for health systems.[1] The complex nature of these medicines and microheterogeneity inherent in products of biological systems makes an “identical” copy of an originator molecule impossible to achieve.[2] Biosimilar medicines are those that have passed an extensive comparability exercise to demonstrate no clinically meaningful difference in terms of purity, safety and potency as well as equivalent efficacy and similar safety and immunogenicity to a reference biological medicinal product that is already approved[3] (the ‘originator’). Biosimilar medicines have the potential to reduce treatment costs as they are often less expensive than the originator and introduction of competition often reduces the acquisition cost of the originator medicine.

Adalimumab, a monoclonal antibody targeting the pro-inflammatory cytokine tumour necrosis factor alpha (TNF-α), is an established and widely used treatment for CD. This is supplied as a pre-filled injection device that patients administer in their own homes reducing the impact of treatment on their lives and promoting independent management of their condition. The patent for the originator adalimumab medicine (brand name Humira®) in Europe expired in October 2018. As CD is not deemed to be a “sensitive” indication in the biosimilar approval pathway, authorisation for this indication was given via extrapolation with evidence for the efficacy in this indication being obtained in post-approval studies. Nine adalimumab biosimilars products are currently authorised for use by the European Medicines Agency (table 1). Various groups have now reported the clinical outcome of switching to adalimumab biosimilars, including in patients with CD, with no differences in efficacy, safety or immunogenicity.[4]

Table 1 | Adalimumab biosimilars currently authorised for use in the European Union.

|  |  |  |  |
| --- | --- | --- | --- |
| **Brand name(s)** | **Company product code** | **Marketing authorisation holder** | **Issue date of EMA marketing authorisation** |
| Amgevita | ABP 501 | Amgen Europe B.V. | 21/3/2017 |
| Amsparity | PF-06410293 | Pfizer Europe MA EEIG  | 13/2/2020 |
| Hukyndra | AVT02 | Stada Arzneimittel AG | 15/11/2021 |
| Hulio | FKB327 | Viatris Limited | 17/9/2018 |
| Hefiya, Hyrimoz | GP2017 | Sandoz GmbH | 26/7/2018 |
| Idacio | MSB11022 | Fresenius Kabi Deutschland GmbH | 2/4/2019 |
| Imraldi | SB5 | Samsung Bioepis NL B.V. | 24/8/2017 |
| Libmyris | AVT02 | Stada Arzneimittel AG | 12/11/2021 |
| Yuflyma | CT-P17  | Celltrion Healthcare Hungary Kft. | 11/2/2021 |

Understanding patient experience is particularly important for biologics administered at home (such as adalimumab), as opposed to via infusion in a healthcare setting, as patients are usually more remote from the healthcare team and biosimilar transition requires a change of self-administration device. Negative attitudes towards a medication are likely to increase intentional non-adherence[5,6] which will significantly impact on the risk of disease relapse and burden on the healthcare system. Identifying factors that influence patient attitudes towards biosimilar medicines is therefore critical to their success. Patients transitioning between originator and biosimilars, and also biosimilar to biosimilar, are encouraged to be actively involved in their health care and decisions about their treatment with education and careful discussion being key to minimising the nocebo effect,[5] improving patient acceptance and therefore successful implementation of biosimilar medicines. Existing literature is limited to survey data assessing awareness, concerns and perceptions prior to transition and acceptance of transition,[7–12] however, despite the fact that it may significantly influence treatment success, there is a lack of research focused on understanding the perspective of patients with CD following biosimilar transition. As part of our current study, we captured a detailed description of the patient perspective and experience of transition, using semi-structured qualitative interviews with the aim of informing and improving future practice and optimising experience and outcomes for patients, clinical teams and payers.

# Method

The IBD Reference and Biosimilar adalimumab CroSS over Study (iBaSS)[13] is a phase IV single-centre, prospective, randomised, single-blind, cross-over study in adults with CD stable on treatment with either originator adalimumab or the biosimilar SB5 (brand name ImraldiTM). The study was carried out at a large NHS teaching hospital with a well-developed inflammatory bowel disease (IBD) multi-disciplinary team. Eligibility criteria included CD in remission or with mild disease activity (modified Harvey-Bradshaw Index score < 8), exclusive exposure to only one brand of adalimumab with no expectation to discontinue or adjust adalimumab dosing in the study period. Participants were exposed, in two treatment periods of 24 weeks each, to commercially available originator and SB5 with the order of these randomly assigned to maintain blinding of the research team (see figure 1). A mixed methodology was employed to evaluate therapeutic equivalence with a qualitative element to capture the patient experience of transition.

Purposive sampling based on a range of demographic factors was used to capture a wide range of perspectives with interviews conducted face-to-face at research visits, at least 36 weeks after randomisation, until data saturation was achieved i.e. no new issues or insights being identified. Semi-structured interviews were conducted by DY, using open-ended questions, facilitated by a topic guide (available as supplemental information).

Interviews were digitally recorded and fully transcribed verbatim before thematic analysis[14] was conducted. After a period of familiarisation and immersion in the transcripts, a coding structure was developed by DY using an iterative approach. SL, as project supervisor, independently applied the coding framework to four of the interviews to ensure rigour.[14] The application of the codes was discussed and minor adjustments made before the coding framework was systematically applied (by DY) to all transcripts.

# Results

97 participants were recruited to the larger study with prior exposure to originator and 35 of these consented to participate in semi-structured interviews (table 2). Most of the interviews (33) were performed at the week 36 study visit and the average duration of the interviews was 11 minutes (range 5 to 20 minutes). Opinions expressed were often heterogeneous, but commonly occurring experiences were also identified. Five major themes were identified (table 3).

Table 2 | Interview participant characteristics.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifier** | **Highest education level** | **Gender** | **Age (years)** | **Time since diagnosis (at consent; years)** | **Time since commencing Humira® (at consent; months)** |
| P01 | Secondary school | Male | 30-39 | 16 | 89 |
| P02 | College/ university | Female | 50-59 | 7 | 44 |
| P03 | Postgraduate | Male | 30-39 | 22 | 31 |
| P04 | Postgraduate | Male | 50-59 | 41 | 9 |
| P05 | Secondary school | Female | 50-59 | 3 | 9 |
| P06 | No Qualification | Male | 60-69 | 2 | 22 |
| P07 | College/ university | Male | 40-49 | 15 | 64 |
| P08 | No Qualification | Male | 70-79 | 4 | 50 |
| P09 | No Qualification | Male | 30-39 | 17 | 57 |
| P10 | Secondary school | Male | 70-79 | 27 | 26 |
| P11 | College/ university | Male | 40-49 | 3 | 45 |
| P12 | Secondary school | Female | 50-59 | 34 | 20 |
| P13 | Secondary school | Female | 50-59 | 27 | 20 |
| P14 | Secondary school | Male | 50-59 | 16 | 106 |
| P15 | College/ university | Male | 20-29 | 8 | 27 |
| P16 | Secondary school | Female | 50-59 | 2 | 23 |
| P17 | No Qualification | Female | 70-79 | 19 | 27 |
| P18 | Postgraduate | Male | 20-29 | 4 | 46 |
| P19 | No Qualification | Male | 60-69 | 2 | 16 |
| P20 | Secondary school | Female | 30-39 | 17 | 4 |
| P21 | Secondary school | Female | 20-29 | 1 | 11 |
| P22 | College/ university | Female | 20-29 | 10 | 107 |
| P23 | Secondary school | Male | 30-39 | 6 | 72 |
| P24 | Secondary school | Male | 40-49 | 22 | 32 |
| P25 | Secondary school | Male | 20-29 | 1 | 12 |
| P26 | Postgraduate | Male | 40-49 | 10 | 26 |
| P27 | Secondary school | Female | 50-59 | 4 | 27 |
| P28 | No Qualification | Male | 30-39 | 6 | 65 |
| P29 | Secondary school | Male | 30-39 | 11 | 51 |
| P30 | Secondary school | Female | 50-59 | 27 | 94 |
| P31 | Secondary school | Male | 30-39 | 17 | 46 |
| P32 | College/ university | Female | 20-29 | 5 | 25 |
| P33 | Secondary school | Female | 70-79 | 38 | 74 |
| P34 | Postgraduate | Male | 60-69 | 9 | 26 |
| P35 | College/ university | Male | 50-59 | 14 | 32 |

Table 3 | Major themes identified.

|  |  |
| --- | --- |
| **Theme** | **Description** |
| 1 | Understanding and awareness of biosimilars |
| 2 | Motivation to undertake brand transition |
| 3 | Initial concerns about biosimilar transition |
| 4 | Reassuring factors |
| 5 | Experiences during the transition |

## Theme 1: Understanding and awareness of biosimilars

Awareness of biosimilars, aside of the information provided as part of the clinical trial, was low with approximately two-thirds of participants stating that they only knew about biosimilars because of their involvement in the research project. Routine clinical consultations were the most common source of prior knowledge about biosimilars. Participants were asked what their understanding of the word 'biosimilars' was and, even accepting a very broad range of definitions, the majority of participants were unable to describe the concept.

"Patient: Bio- what?
Interviewer: Biosimilars - the ImraldiTM is a biosimilar of Humira® - does that mean anything…
Patient: Not really, I don't understand." (P28; male, age 30-39, no qualification)

The definition of the word used by the majority of participants was that it is the same medicinal product but manufactured by a different company. The use of the word 'similar' in the word 'biosimilar' was a common cause of confusion and participants had diverse ideas about what this referred to. This appeared to introduce an element of uncertainty about comparability to the reference product as the word 'similar' is commonly interpreted as 'similar, but not the same'.

## Theme 2: Motivation to undertake brand transition

The majority of patients (n=21) recognised and accepted that reducing drug expenditure was the primary reason, but it was often stated that this was contingent upon the biosimilar having similar effectiveness and/ or tolerability as the reference product.

"I know it costs the NHS a lot of money. I know Humira® was quite expensive… do anything to help the NHS out on that front. As long as it does the same thing I don’t see what the problem is." (P15; male, age 20-29, first degree)

In addition to this some participants expressed a willingness or personal responsibility to contribute to minimising their cost to the NHS drug budget where possible.

"I felt that, you know, it was incumbent on me ... because, you know, as a receiver of help from the government, you know, it's a little bit of help from me." (P34; male, age 60-69, postgraduate degree)

Rapid adoption of biosimilar medicines was recognised as both the responsible thing to do by the NHS and a demonstration of financial competence. Several participants mentioned the desirability of increasing competition through the implementation of biosimilar medicines to reduce drug costs and improve resilience in the medicine supply chain. When the preferred beneficiary of any cost savings was explored, the majority stated that they would prefer to see investment in further research and the NHS, specifically improved access to care (including more healthcare professionals), better remuneration of staff and increased access to novel or expensive treatments.

Although eligibility for the clinical trial was restricted to participants whose CD was either in remission or with only mild disease activity, a small number of participants (five) stated that their principal motivation for agreeing to the brand transition was to explore whether the biosimilar could improve their disease control. Most participants (n=20) speculated that they would have been more willing to transition to a biosimilar if their symptoms had been badly controlled at the point this was discussed, perhaps demonstrating a need for further education that the biosimilar is expected to provide the same clinical outcome.

## Theme 3: Initial concerns about biosimilar transition

Approximately half of the participants interviewed raised initial concerns about efficacy and many noted that an increase in symptoms could have a significant impact on their quality of life or a personal financial cost.

"I was happy on Humira®, it was working, so I was a bit worried about switching and ending up back in the hospital" (P28; male, age 30-39, no qualification)

Occasionally participants rationalised that their concerns about efficacy were directly linked to perceptions associated with the lower acquisition cost of the biosimilar brand, while other patients referenced the concept of generic versions of small molecule medicines and non-pharmaceutical equivalents as demonstrating that alternative brands may be expected to have a similar efficacy, despite being less expensive.

Within the theme of concerns, the risk of new or different adverse effects was frequently expressed. Most commonly these concerns were non-specific, although four participants specifically identified apprehension about increased injection pain, either because of their experience with a previous formulation of Humira® (associated with an increase in injection site pain) or word of mouth outside of the trial. One important factor that participants often identified as contributing to increased concerns was the perception that the reference brand had been proven to work for them.

"It's taken me out of my comfort zone a little bit 'cos Humira® to me is like the miracle drug, you know, just gave me back my life…" (P30; female, age 50-59, O-level/ GCSE)

CD has a number of extra-intestinal manifestations and is one of several related immune-mediated inflammatory diseases treated with anti-TNF drugs. Several participants expressed concerns that transition to a biosimilar may impact the control of co-morbid, non-IBD symptoms.

"... it not only helps my Crohn’s but it does have a beneficial effect, or it did have originally, on my [ankylosing spondylitis] as well so I think I’m looking at it from two different sides..." (P14; male, age 50-59, A-level)

Concerns expressed about the practicalities of brand transition included the use of a different device for injecting the medication and the way that the medication would be supplied.

## Theme 4: Reassuring factors

When reassuring factors were reviewed, confidence in healthcare professionals and the healthcare system was the most common theme reported by participants and appeared to be critical to patient acceptance of biosimilars and their integration into clinical use.

"I feel like you all know what you’re doing, even though it’s quite new if that makes sense." (P05; female, age 50-59, O-level/ GCSE)

“… I have confidence in what you’re saying and obviously I’m thinking about what you’re saying so I think that you represent the hospital and that’s good enough for me.” (P34; male, age 60-69, postgraduate degree)

From the patient perspective this was particularly valuable when it was delivered by a healthcare professional with whom the patient is familiar with.

"I had been able to speak to [my IBD consultant] and basically, from the medical side of it, there were no concerns that I could pick up there so it put me at ease anyway so I felt quite comfortable doing it." (P14; male, age 50-59, A-level)

Easy access to a trusted point of contact was an important reassuring factor, expressed by approximately half of the respondents. Other reassuring factors commonly described by participants included the provision of information describing the principles behind the development of biosimilar medicines, availability of similar administration devices, increased monitoring following the transition, assurance that efficacy has been previously demonstrated and that the medicine is approved for use.

Several participants expressed uncertainty about whether transition to a biosimilar would preclude reverse switching (back to the reference brand). Another concern was whether such a reverse switch would increase the risk of adverse effects, loss of response or immunogenicity. Confirming the availability of a reverse switch without any expectation of adverse effects was an important reassurance for some participants.

While information provision based on the experience of large groups of patients was commonly cited as an important reassurance, several participants noted that gaining individual experience of using the biosimilar would be crucial.

"I guess, because I know each person responds differently, I know that a piece of paper wouldn’t be able to tell me if it was going to work the same and that I would have to go through the trial and make my own mind up as to whether it was going to be as effective." (P01; male, age 30-39, A-level)

Participants were asked what information they would need in order to make an informed decision about accepting brand transition. The most common responses were the rationale for undertaking the transition, reassurance that the biosimilar was expected to have similar efficacy and tolerability to the reference product and detail about the injection device. Approximately half of the participants interviewed said that they would accept a brand transition based solely on written communication. Almost all participants felt that a specific face-to-face consultation would be desirable while 7 participants stated that this was essential.

"A letter sort of sounds and feels a bit more like a fait accompli… it just it’s going to happen regardless unless there are some major problems." (P11; male, age 40-49, first degree)

## Theme 5: Experiences during the transition

One of the central benefits of exploring the patient perspective in a cross-over study such as this is that, having experienced both the reference and biosimilar preparations, participants were able to summarise their perception of the efficacy of each preparation. When this was discussed it was almost universal that there was no significant subjective difference in efficacy or tolerability (except injection pain).

"I mean I feel that it’s been a very similar, consistent experience the whole way and that’s a really good thing." (P18; male, age 20-29, postgraduate degree)

Two participants associated switching to the biosimilar with a positive change in their disease control and one participant described an improvement in adverse effects. Conversely another two participants felt subjectively worse in the period when they were treated with the biosimilar.

The concept of nocebo, a worsening of disease control or development of adverse effects that occurs despite no change in the pharmacological action of treatment, is widely discussed in relation to biosimilar transition.[5] Notably this study was single-blind so participants were aware that a biosimilar transition had occurred. Interestingly several participants alluded to the existence of nocebo and the difficulty differentiating this effect from a genuine physiological change.

"... at the beginning of the changeover, it was like you’re more aware that you’re looking out for something, just in case, but nothing came up so you just become a bit more relaxed each week." (P12; female, age 50-59, O-level/ GCSE)

Injection experience was commonly raised by participants with 22 stating that they found the ImraldiTM injections more painful than Humira®, although the intensity of this pain varied significantly between participants.

"Well that is a minor nuisance..." (P34; male, age 60-69, postgraduate degree)

"... the [ImraldiTM] was a lot more painful to take, to the point where you're getting anxiety with being able to take it. I mean you would sit there for 5 minutes psyching yourself up…" (P31; male, age 30-39, O-level/ GCSE)

On reflection, seven participants specifically stated that they would have preferred to have been warned that they might experience more injection site pain with the biosimilar brand.

Of participants that expressed a preference for one of the two pen devices trialled, the majority stated that they preferred the design of the Humira® pen as they felt that initiating the injection with a button press gave them more control over the process.

Almost all participants felt comfortable with the idea of a further transition to another biosimilar of adalimumab with injection experience being the only concern that participants repeatedly voiced.

"So now I've tried the biosimilar I'm not afraid to try this next one." (P22; female, age 20-29, first degree)

Overall participants felt that they would like to remain on one brand of adalimumab for at least a year before possibly transitioning to another brand of adalimumab.

# Discussion

To our knowledge this is the first in-depth study describing the direct experience of patients with CD transitioning from a home-administered originator biological medicine to its respective biosimilar. Implementing a biosimilar transition program is time consuming and has financial costs including training of healthcare professionals and patients, supporting patients, addressing their concerns and monitoring patients following transition.[15] This study confirmed that these elements are essential in reassuring patients that the biosimilar transition is being performed in a safe manner with no expectation of a change in disease activity or risk of adverse events. Addressing patient concerns is likely to increase adherence[6] and may reduce the requirement for reverse switching or change to another treatment; if patients are dissatisfied there is likely to be an increase in healthcare resource use and a negative impact on patients’ opinion of the healthcare service. Participants highlighted the importance of having an opportunity to discuss biosimilar transition with a trusted healthcare professional. Patients using biological medicines are often experiencing complex CD symptoms and individual discussion seems appropriate to address the wide range of questions and concerns. Continuity, preferable with a trusted source, is therefore important in clinical practice when discussing potential transitions. Although many were content with written communication, participants expressed a clear preference for individual discussion.

Patients’ understanding of the word “biosimilar” was low, despite receiving information about biosimilar medicines. Whilst IBD specialists are increasingly comfortable with the use of such terminology[16] but, without sufficient explanation, it may hinder an informed and effective discussion with patients.[17] Interestingly, a number of participants expressed a hope that they would gain therapeutic benefit from switching to a biosimilar despite biosimilars having similar efficacy.

For many patients these medicines have been life-transforming and it is reasonable and legitimate to have concerns when a transition from a brand that has been proven to be effective for that individual is proposed. Previous research into the opinions of patients with inflammatory bowel disease regarding biosimilar medicines has been largely restricted to questionnaire data with predetermined response options while our use of interviews elicited additional depth and richness. The principal concerns identified in this study match those identified in previous survey research (lack of knowledge and uncertain efficacy, safety and tolerability),[7,9–12] although expected efficacy in concurrent immune-mediated inflammatory diseases and practical concerns were also expressed. Therefore, as is recommended for medicines more generally,[6,18] discussion with patients about their understanding, beliefs and concerns about biosimilars is central to shared decision-making and supporting self-management of these drugs.

Many healthcare professionals are uncomfortable with biosimilar transition for non-medical reasons, such as minimising drug acquisition costs,[19] while the majority of patients in this study were willing to accept a financially-driven biosimilar transition for the benefit of the wider healthcare system, without anticipating any personal benefit. Informing patients of the potential benefits (reviewed elsewhere[20]) may improve acceptance, particularly in health systems where drug costs are not directly funded by patients. Notably the study was performed in a healthcare system where the medicine was provided at no direct cost to the patient. It is likely that patients that share the medication cost burden in other health systems would be motivated by the potential of biosimilars to reduce their personal medication expenditure.

The crossover design of this study is uniquely useful for the comparison of subjective measures including injection experience which was of particular interest. An increase in injection site pain, tolerable for the majority of patients, with the ImraldiTM injections was frequently discussed by participants, consistent with other real-world studies.[21–23] Whilst this was a very individual experience, the findings suggest it is important to prepare patients for the possibility and how to manage it this through written or verbal information.

Some limitations to this study apply. Participants interviewed were selected from those who formally consented to undertake biosimilar transition monitored as part of a clinical trial (as opposed to mandatory transition or “presumed acceptance” approaches which are common in routine care) and all remained on the trial for at least 36 weeks. This demonstrates both an initial willingness to accept a biosimilar and a degree of satisfaction following transition. It is relevant that the trial was designed to mimic “real-world” transition. The study design necessitated a significant delay between consent and interviews for those participants assigned to treatment sequence 2 introducing the possibility of failure to recall initial concerns, especially as participants may have been reassured by the fact that they had had a positive experience of transition. The trial was conducted at a single centre in CD patients. Despite these limitations, given the attention to rigour in the design and execution of this qualitative study, we believe that it may be reasonable to extrapolate these findings to patients self-administering biological medicines from other organisations. These findings are likely to be equally applicable to patients with other types of IBD, as well as potentially informing biosimilar transition in patients with immune-mediated inflammatory diseases such as rheumatoid arthritis and psoriasis. As biosimilar medicines become more prevalent in other therapeutic areas (such as oncology, ophthalmology, and endocrinology) future research could consider evaluating the wider applicability of these findings. While our sample did not permit subgroup analysis, further studies may help to identify patient characteristics (such as age, gender and diagnosis) that influence the preferred approach to biosimilar transition.

# Conclusion

While biosimilars have driven a reduction in drug acquisition costs, the majority of patients have little knowledge and some concerns about transitioning to a biosimilar but accept the principles and can be reassured by a trusted clinical team. The wide-ranging views elucidated suggest that a tailored, patient-centred approach is key to successful implementation, minimising the risk of adversely affecting patient adherence, engagement and trust.

## Funding

This is part of an investigator-initiated study sponsored by University Hospital Southampton NHS Foundation Trust with financial support from Biogen Idec Limited. Biogen reviewed the final draft of the manuscript and suggested some minor amendments that did not influence the conclusions. The authors retained full editorial control.

## Acknowledgements

The authors would like to thank the participants for their contribution to the study.

## Competing interests

Fraser Cummings has served as consultant, advisory board member, or speaker for AbbVie, Amgen, Celltrion, Falk, Ferring, Janssen, MSD, Napp Pharmaceuticals, Pfizer, Pharmacosmos, Sandoz, Biogen, Samsung, Takeda, Bristol Myers Squibb and Galapagos. He has received research funding from Biogen, Amgen, Hospira/Pfizer, Celltrion, Janssen, GSK and AZ.

Sue Latter: Received funding for speaking at a symposium sponsored by MSD.

David Young has received support for travel, accommodation and conference attendance from Sandoz.

## Ethics approval

Approval for the study was granted by the London (Chelsea) Research Ethics Committee (reference 19/LO/0167).

## Contributorship statement

FC, SL and DY were involved with the study conception and design. DY led data collection and analysis with support from SL. All authors prepared, approved and jointly controlled the decision to publish the final manuscript.

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## Figure caption

Figure 1 | Trial flow diagram for participants pre-treated with originator adalimumab.