Secukinumab improves the quality-of-life of family members and partners of people with psoriasis: Family Dermatology Life Quality Index (FDLQI) results from a randomised open-label study (SIGNATURE)

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Funding information
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Abstract
Background: The Family Dermatology Life Quality Index (FDLQI) was developed to meet a need for a dermatology-specific family member/partner quality-of-life (QoL) measure. This paper focuses on the analysis and interpretation of FDLQI data (used as an exploratory outcome) collected in the SIGNATURE study.

Objectives: To measure the impact of secukinumab therapy for moderate to severe plaque psoriasis on the QoL of family members/partners of patients.

Methods: Randomised, open-label, non-comparator study in 53 dermatology centres in the UK and Republic of Ireland. Patients received secukinumab 300 or 150 mg subcutaneously weekly for 4 weeks, then 4-weekly.

FDLQI Results: Family members of PASI 75 responders and non-responders showed improved FDLQI compared to baseline, greater for responders. There was a high level of correlation between FDLQI and Dermatology Life Quality Index (DLQI) scores and positive correlations across all mapped FDLQI and DLQI questions, and a close association between the scales at all timepoints. The estimated FDLQI scores were consistently 56% of those obtained for DLQI. There was an improvement for all FDLQI questions at Week 16 with a mean total score change of 8.2. Most family member subjects had an improved score for all FDLQI questions (75%–91%, Week 12, and 77%–91%, Week 16). Family subjects with a corresponding patient visit DLQI score >10 improved for all FDLQI questions at Week 16 (mean total score change of 5.2).

Conclusions: Successful therapy for severe psoriasis greatly improved QoL of family members/partners. The FDLQI questionnaire responds well and appropriately to major changes in the disease severity of those affected by plaque psoriasis.
INTRODUCTION

Family members/partners of psoriasis patients experience many quality-of-life (QoL) impacts.\(^1\) Biologic therapy improves patients’ QoL\(^2\)–\(^4\) but it is unclear if effective patient treatment also decreases the burden on family members/partners.\(^5\) It is important to identify the burden of psoriasis not only on patients but also on their family members/partners, the “Greater Patient,” as this allows appropriate care strategies to be developed.\(^6\),\(^7\) A large-scale multi-speciality study (144 diagnoses across 26 specialties) showed the significant impact chronic illnesses have on the QoL of family members/partners.\(^8\) A review of the impact of dermatological conditions on family members/partners, the FDLQI, was to measure the impact over the previous 30 days of any illness on the QoL of family members/partners.\(^8\) It is important to identify the effective patient treatment also decreases the burden on family members/partners, the “Greater Patient,” as this allows appropriate care strategies to be developed.\(^6\),\(^7\)

The Family Dermatology Life Quality Index (FDLQI)\(^10\) is a simple, effective, and practical tool to assess the QoL impact on family members/partners of people affected by a range of skin diseases.\(^5\),\(^11\)–\(^13\) It measures the impact over the previous 30 days of any skin disease and can be used by family members/partners aged ≥16 years.\(^10\)–\(^12\) When the study protocol was written, the FDLQI was chosen as the family measure. Family members of psoriasis patients had been involved in the creation of the FDLQI. At that time neither of the psoriasis-specific measures PFI-14 nor FamilyPso had been published.

The aim of this analysis focused on the FDLQI data from the SIGNATURE study,\(^3\),\(^14\) was to measure the impact of secukinumab therapy for moderate to severe plaque psoriasis on family member/partner QoL and to further demonstrate the responsiveness to change of the FDLQI.

PATIENTS AND METHODS

Study design

This 72-week, multicentre, open-label, non-comparator study of 235 patients with moderate to severe chronic plaque psoriasis was conducted in 53 centres in the UK and Republic of Ireland. Independent ethics committee approval was obtained and all patients provided written informed consent. The primary study data were described in detail previously.\(^3\)

Patients were randomised to receive either secukinumab 300 or 150 mg and stratified into 1 of 3 sub-groups, in line with the National Institute for Health and Care Excellence (NICE) definitions for patients failing tumour necrosis factor-\(\alpha\) (TNF-\(\alpha\))-inhibitor therapy:

- Inadequate responder (IR) after single anti-TNF-\(\alpha\) therapy—primary IR.
- IR after single anti-TNF-\(\alpha\) therapy (after initially achieving a good primary response)—secondary IR.
- IR after >1 anti-TNF-\(\alpha\) therapy.

There were five periods: a 28-day screening period, a baseline period, an initiation period (Weeks 1–16), maintenance period 1 (Weeks 17–48), and maintenance period 2 (Weeks 49–72). Patients who responded (i.e., achieved 75% reduction in PASI from baseline or 50% reduction and a 5-point reduction in DLQI) after the initiation period or maintenance period 1 continued on study treatment. 32 weeks (maintenance period 1) or 24 weeks (maintenance period 2), respectively. Patients on the 150 mg dose not responding after the initiation period or maintenance period 1 could increase to 300 mg. After each study period, non-responders on 300 mg returned to routine clinical care (Figure 1).

Key inclusion criteria for patients:

- Age ≥18 years with chronic plaque psoriasis >6 months.
- Moderate to severe disease: Psoriasis Area Severity Index (PASI) ≥10 and Dermatology Life Quality Index (DLQI) > 10.
- Previously treated with ≥1 anti-TNF-\(\alpha\) therapy for moderate to severe psoriasis and either a primary or secondary non-responder.

Endpoints

The primary endpoint was to assess the % of patients on secukinumab 300 mg achieving PASI 75 at Week 16 compared to baseline. Key secondary endpoints assessed PASI 75 response after 16 weeks with 150 mg and in the three sub-groups, and with both doses after 2, 4, 8, 12, 24, 48, and 72 weeks.

FDLQI

Patients were asked to consent that the FDLQI was handed to a family member. If the patient gave consent,
the chosen family member could be given further information about the study and given the FDLQI to complete. Family members/partners of patients with psoriasis completed FDLQI at baseline and at Weeks 12, 16, 48, and 72. For each question, the higher the score the more the QoL was impaired (Table 1). If one FDLQI item was left blank, the summed score from the other nine items was used. If more than one item was left blank, that FDLQI was considered invalid and not scored.

Correlation between each FDLQI and DLQI for each FDLQI question at baseline and Weeks 12 and 16

FDLQI questions were mapped to the corresponding DLQI question and compared at baseline and Weeks 12 and 16, using Spearman’s rank correlation coefficient. Radar plots presented the median score for each FDLQI question and mapped corresponding DLQI question by time-point. Spearman’s rank correlation coefficient bar charts, with p-value, were presented by time-point. Table 2 shows FDLQI to DLQI mapping.

Change from baseline for each FDLQI question at Weeks 12 and 16

FDLQI score and change from baseline at Weeks 12 and 16 were presented for each FDLQI question and total score. Shift tables presented the baseline score with the score at Weeks 12 and 16. Summaries were presented for all subjects and for those with a corresponding patient visit DLQI score >10 (indicative of a very large effect on a patient’s life).15–17

FDLQI questionnaire completion versus PASI 75 response

PASI 75 response of patients at Weeks 12 and 16 was summarised by whether the family member FDLQI questionnaire was completed at the corresponding visit.
### RESULTS

#### Baseline characteristics

Of the 235 patients randomised between October 2013 and July 2016 (300 mg: 119, 150 mg: 116), 233 received ≥1 dose of study drug and 199 were stratified into subgroups. Demographic characteristics were well-balanced between the groups.³

#### FDLQI from baseline to 72 weeks

The mean family member FDLQI scores were 12.6 (n = 61), 4.6 (n = 54), and 4.1 (n = 49) at baseline, Week 12, and Week 16, respectively, for the 150 mg patient group (N = 115) and were 12.0 (n = 58), 4.4 (n = 46), and 4.4 (n = 49), respectively, for the 300 mg patient group (N = 118). For the family members/partners of patients on 300 mg throughout the 72-week study period, the mean FDLQI scores at Weeks 48 and 72 were 4.3 (n = 32) and 4.8 (n = 24), respectively.

#### Change from baseline FDLQI total score versus PASI 75 response

The family members of both PASI 75 responders and non-responders showed improved FDLQI at Weeks 12 and 16 compared to baseline; the improvement was greater for

| FDLQI questions | DLQI questions |
|-----------------|----------------|
| 1. Over the last month, how much emotional distress have you experienced due to your relative/partner's skin disease (e.g., worry, depression, embarrassment, frustration)? | 2. Over the last week, how embarrassed or self-conscious have you been because of your skin? |
| 2. Over the last month, how much has your relative/partner's skin disease affected your physical well-being (e.g., tiredness, exhaustion, contribution to poor health, sleep/rest disturbance)? | 1. Over the last week, how itchy, sore, painful, or stinging has your skin been? |
| 3. Over the last month, how much has your relative/partner's skin disease affected your personal relationships with him/her or with other people? | 8. Over the last month, how much has your skin created problems with your partner or any of your close friends or relatives? |
| 4. Over the last month, how much have you been having problems with other peoples' reactions due to your relative/partner's skin disease (e.g., bullying, staring, need to explain to others about his/her skin problem)? | Not mapped |
| 5. Over the last month, how much has your relative/partner's skin disease affected your social life (e.g., going out, visiting or inviting people, attending social gatherings)? | 5. Over the last week, how much has your skin affected any social or leisure activities? |
| 6. Over the last month, how much has your relative/partner's skin disease affected your recreation/leisure activities (e.g., holidays, personal hobbies, gym, sports, swimming, watching TV)? | 6. Over the last week, how much has your skin made it difficult for you to do any sport? |
| 7. Over the last month, how much time have you spent on looking after your relative/partner (e.g., putting on creams, giving medicines, or looking after their skin)? | 10. Over the last week, how much has your relative/partner’s skin disease increased your routine household expenditure (e.g., travel costs, buying special products, creams, cosmetics)? |
| 8. Over the last month, how much extra housework have you had to do because of your relative/partner’s skin disease (e.g., cleaning, vacuuming, washing, cooking)? | Not mapped |
| 9. Over the last month, how much has your relative/partner’s skin disease affected your job/study (e.g., need to take time off, not able to work, decrease in the number of hours worked, having problems with people at work)? | 7. Over the last week, has your skin prevented you from working or studying? If “No,” over the last week how much has your skin been a problem at work or studying? |
| 10. Over the last month, how much has your relative/partner’s skin disease increased your routine household expenditure (e.g., travel costs, buying special products, creams, cosmetics)? | Not mapped |

Note: FDLQI: © M. K. A. Basra, A. Y. Finlay, Cardiff University 2005. DLQI: © Dermatology Life Quality Index. A. Y. Finlay, G. K. Khan, April 1992.

Abbreviations: DLQI, Dermatology Life Quality Index; FDLQI, Family Dermatology Life Quality Index; TV, television.
family members of responders (mean total score improvement: –9.1 for responders vs. –7.5 for non-responders, difference in improvement = 1.6, \( p = 0.0036 \)) (Table 3).

### Correlation between FDLQI and DLQI questions

#### Individual questions

The decreasing radar plot mapping footprints of the two scales between baseline and Weeks 12 and 16 reflect the decreasing scores (Figure 2).

The Spearman correlation coefficient analysis showed positive correlations across all mapped FDLQI and DLQI questions (Figure 3). The correlations were stronger for some mapped questions than others. The strongest correlation was between FDLQI Question 1 (emotional distress) and DLQI Question 2 at Weeks 12 and 16 (Spearman’s rank correlation coefficient \( R_s \) >0.5). The stronger correlations (\( R_s > 0.4 \)) were observed between FDLQI Question 9 (job/study) and DLQI Question 7 at baseline, FDLQI Question 6 (recreation/leisure) and DLQI Question 6 at Week 12, FDLQI Question 7 (time looking after) and DLQI Question 10 at Week 16, and FDLQI Question 8 (extra housework) and DLQI Question 3 at Week 16.

### Questions score changes

#### FDLQI

Overall, there was an improvement for all FDLQI questions at Week 16. The smallest mean improvement was for Question 9 (0.4) and the largest improvement was for Question 8 (1.1). The mean total score change was 8.2 (Table 4).

Most family subjects had an improved score for all FDLQI questions, ranging from 75.4% of subjects (Question 6) to 91.4% (Question 9) at Week 12, and 77.2% (Question 6) to 90.6% (Question 9) at Week 16. The proportion of subjects with worsening scores was small, ranging from 2.4% to 11.1% at Week 12 and 3.8% to 10.0% at Week 16 (Table 5).

FDLQI—in family subjects with corresponding patient visit DLQI total score >10

Overall, there was an improvement for all FDLQI questions at Week 16. The smallest mean improvement was for Questions 2 (physical well-being), 7, and 8 (0.3) and the largest was for Question 9 (0.8). The mean total score change was 5.2 (Table 6).

The number of subjects was comparatively small so the proportions should be treated with caution. The proportion of subjects showing improved FDLQI question scores was less pronounced and with a wider spread (44.4% [Question 10, expenditure] to 100% [Question 9] at Week 12, and 38.5% [Question 8] to 87.5% [Question 9] at Week 16). The proportion of subjects with worsening scores ranged from 0% to 27.3% at Week 12 and 0% to 36.4% at Week 16 (Table 7).

The numbers of family members completing FDLQI by treatment group were as follows; for the secukinumab 300 mg dose group, at baseline 58 subjects completed (FDLQI mean = 12.0, SD = 7.46). At Week 16, 49 completed (mean = 4.4, SD = 5.25). For the secukinumab 150 mg dose group, at baseline 61 subjects completed (FDLQI mean = 12.6, SD = 7.54). At Week 16, 49 completed (mean = 4.1, SD = 4.42). There was therefore no significant difference in the baseline or Week 16 FDLQI scores between the two dosage groups.

**FDLQI completion versus PASI 75 response**

At Week 12, the percentage of family subjects who completed FDLQI was similar for both PASI 75 patient responders and non-responders. At Week 16, a higher

| PASI 75a | Adjusted mean (SE, [95% CI]) N/n = 233/104 | Mean difference (SE, [95% CI]) p-value |
|----------|----------------------------------------------|---------------------------------------|
| Respondersa | –9.1 (0.69 [–10.5, –7.7]) | –1.6 (0.54 [–2.7, –0.5]) 0.0036 |
| Non-respondersa | –7.5 (0.74 [–8.9, –6.0]) | - |
| Responders versus non-responders | - | - |

**Abbreviations:** CI, confidence interval; FAS, full analysis set; FDLQI, Family Dermatology Life Quality Index; LS, least squares; N, the number of subjects in the analysis set; n, number of subjects included in the analysis; PASI 75, a 75% decrease in the Psoriasis Area and Severity Index score; SE, standard error.

*aAdjusted means and the difference were estimated using adjusted LS means from the fitted model.*
percentage of family members of PASI 75 responders completed FDLQI (62.4% vs. 50.0%) (Table 8).

RESULTS SUMMARY

The family members of PASI 75 responders and non-responders both showed improved FDLQI compared to baseline; improvement was greater for patient responders. The decreasing radar plot mapping footprints of the two scales between baseline and Weeks 12 and 16 reflect the decreasing scores. The Spearman correlation coefficient analysis showed positive correlations across all mapped FDLQI and DLQI questions. Total scores for FDLQI and DLQI showed a close association at all timepoints. FDLQI scores were consistently 56% of those for DLQI. There was an improvement for all FDLQI questions at Week 16 (mean total score change: 8.2). Most family subjects had an improved score for all FDLQI questions (75.4% of subjects [Question 6] to 91.4% [Question 9] at Week 12, and 77.2%

FIGURE 2 Radar plot of mapped FDLQI and DLQI questions at baseline, Week 12, and Week 16 (FAS). FAS, full analysis set; DLQI, Dermatology Life Quality Index; FDLQI, Family Dermatology Life Quality Index.
[Question 6] to 90.6% [Question 9] at Week 16). For the family subjects with a corresponding patient visit DLQI > 10, there was an improvement for all FDLQI questions at Week 16 (mean total score change: 5.2).

**DISCUSSION**

Relationships between an individual and their family members/partners are multi-faceted. Patients with psoriasis have an added layer of complexity with differing impacts of psoriasis on those close to them. Differing attitudes between the patient and the family members/partners towards the disease may adversely influence adjustment to the condition. The lack of understanding of the psoriasis patient’s family member/partner’s experience became apparent in a qualitative study when nearly all stated it was the first time any health care worker had enquired about their well-being, and recounted the many ways their lives were affected. A psoriasis-specific questionnaire, the Psoriasis Family Index-14 (PFI-14), was developed from that study.
and a further questionnaire, FamilyPsO, has also been described. The PFI-14 and Family PsO are specific to psoriasis whereas FDLQI is applicable in any skin condition thereby allowing comparisons of the impact of different conditions on family members/partners.

Previous studies have shown FDLQI to effectively assess the QoL of family members/partners of patients with skin diseases. FDLQI previously demonstrated that 90% of the participating family members/partners of 80 patients felt that their relative’s psoriasis affected their own QoL. In the PROSE study (NCT02752776), secukinumab treatment completely normalised QoL in most psoriasis patients, and this was reflected by FDLQI scores showing an early and sustained improvement in partner/family member’s QoL. This study confirms these earlier findings that severe psoriasis has a major impact on QoL of family members/partners and that this improves with effective therapy. Additionally, this study mapped family members/partners’ FDLQI scores to patients’ DLQI scores, clarifying the association between different QoL domains in patients and family members. Furthermore, it highlights the impact of psoriasis on family members and may ultimately enhance patient consultation quality, particularly initially.

The SIGNATURE study data showed the responsiveness of the FDLQI to effective patient treatment, specifically with secukinumab, adding to this measure’s validation and demonstrating the wider benefit of a highly effective therapy for plaque psoriasis to improve the impaired QoL of family members/partners. However, the data challenge dermatology teams treating psoriasis patients because understanding the QoL impact of psoriasis must be balanced with practical aspects of measurement and the associated burden of completing questionnaires. The study

| Question                  | Week | Improved n/N (%) | Unchanged n/N (%) | Worsened n/N (%) |
|---------------------------|------|------------------|------------------|-----------------|
| 1. Emotional distress     | 12   | 64/82 (78.0)     | 26/94 (27.7)     | 4/76 (5.3)      |
|                           | 16   | 61/74 (82.4)     | 23/88 (26.1)     | 4/71 (5.6)      |
| 2. Physical well-being    | 12   | 55/66 (83.3)     | 32/94 (34.0)     | 7/82 (8.5)      |
|                           | 16   | 52/63 (82.5)     | 34/89 (38.2)     | 3/76 (3.9)      |
| 3. Personal relationships | 12   | 50/60 (83.3)     | 39/94 (41.5)     | 5/77 (6.5)      |
|                           | 16   | 44/55 (80.0)     | 41/89 (46.1)     | 4/74 (5.4)      |
| 4. Reactions of others    | 12   | 52/58 (89.7)     | 38/94 (40.4)     | 4/85 (4.7)      |
|                           | 16   | 43/50 (86.0)     | 40/88 (45.5)     | 5/81 (6.2)      |
| 5. Social life            | 12   | 55/66 (83.3)     | 34/94 (36.2)     | 5/72 (6.9)      |
|                           | 16   | 50/60 (83.3)     | 34/88 (38.6)     | 4/70 (5.7)      |
| 6. Recreation/leisure     | 12   | 46/61 (75.4)     | 38/92 (41.3)     | 8/72 (11.1)     |
|                           | 16   | 44/57 (77.2)     | 34/85 (40.0)     | 7/70 (10.0)     |
| 7. Time looking after     | 12   | 57/69 (82.6)     | 32/93 (34.4)     | 4/77 (5.2)      |
|                           | 16   | 56/64 (87.5)     | 27/87 (31.0)     | 4/72 (5.6)      |
| 8. Extra housework        | 12   | 61/79 (77.2)     | 26/92 (28.3)     | 5/64 (7.8)      |
|                           | 16   | 56/71 (78.9)     | 25/87 (28.7)     | 6/61 (9.8)      |
| 9. Job/study              | 12   | 32/35 (91.4)     | 58/92 (63.0)     | 2/83 (2.4)      |
|                           | 16   | 29/32 (90.6)     | 54/87 (62.1)     | 4/79 (5.1)      |
| 10. Expenditure           | 12   | 53/66 (80.3)     | 35/92 (38.0)     | 4/81 (4.9)      |
|                           | 16   | 51/63 (81.0)     | 33/87 (37.9)     | 3/78 (3.8)      |

Note: FDLQI: © M K A Basra, A Y Finlay, Cardiff University 2005. Abbreviations: FAS, full analysis set; FDLQI, Family Dermatology Life Quality Index; N, the number of subjects in the analysis set; n, number of subjects included in the analysis; SD, standard deviation.

*Subjects with a score at baseline other than “not at all” and the Week 12/16 assessment.

*Subjects with a score at baseline and the Week 12/16 assessment.

*Subjects with score at baseline other than “very much” and Week 12/16 assessment.
was not designed to assess FDLQI use in routine clinical practice but the correlation between DLQI and FDLQI indicates that if a patient’s DLQI score is high, it is very likely that family members/partners’ QoL is also impaired. This suggests that separate assessment of family members/partners’ QoL may enhance physician understanding and improve quality of care.

There is no excuse to ignore the issue through ignorance of the extent or nature of the impact. Family members/partners are often crucial frontline carers (therapy encouragers) of severe psoriasis patients and it may be that therapy adherence is enhanced if their needs are understood and supported.

Those QoL aspects most affected or least improved following effective therapy may be those requiring most attention (job/study, personal relationships, and physical well-being). However, specific issues experienced by individual patients and their family members/partners must always be placed ahead of cohort-based conclusions. A wider framework of care for psoriasis patients and their family members/partners may be needed to formulate and test possible strategies aimed at addressing these different affected life aspects.

The strengths of the study were that analyses were conducted in a randomised clinical trial of a high-need population who had previously failed treatment, and that there was direct FDLQI versus DLQI comparison.

Study limitations were that the absence of a control group without therapy means that improvement in DLQI and FDLQI due to other factors cannot be excluded. Also, clinical meaning of FDLQI scores could not be compared with an established minimal clinically important difference because this has not been defined for FDLQI. However, as this is typically about 10% of the total score range for a clinical measure, it might be expected to be 3 to 4. Similarly, the relationships between patients and family members/partners may have varied. Caution is needed when describing high FDLQI to DLQI correlations because of small patient numbers. These analyses compared FDLQI changes in family members/partners of patients with a corresponding visit DLQI > 10 with the overall population but comparisons with other subgroups may have been useful. Patients chose which family member/partner could complete FDLQI but because this relationship was not recorded it could not be differentially analysed. A study limitation is that no characteristics of the family member respondents were collected: parameters such as the relationship to the patient, employment and household situation can be confounders. No specific instructions were given to family members about completing the FDLQI independently and so for some family respondents there may have been influence from the patient.

The overall FDLQI completion rates were approximately 50%, but there is no information as to why for the other patients, no family member completed the FDLQI. It is not known how representative the family members who did contribute were of those who did not contribute. As there is little experience of the use of a family reported outcome measure as part of a clinical trial, it is not

### Table 6: FDLQI questions score changes from baseline to Week 16—corresponding visit DLQI total score >10 (FAS)

| Question                  | Base mean (SD) N = 233 | Week 16, N = 233 |
|---------------------------|-------------------------|------------------|
|                           | Mean observed (SD) Mean change (SD) | |
| Total                     | 12.6 (7.49) n = 113     | 8.4 (6.74) n = 18 | −5.2 (7.79) n = 17 |
| 1. Emotional distress     | 1.7 (0.95) n = 114      | 1.1 (0.80) n = 18 | −0.7 (0.84) n = 18 |
| 2. Physical well-being    | 1.3 (1.02) n = 114      | 1.0 (0.91) n = 18 | −0.3 (0.84) n = 18 |
| 3. Personal relationships | 1.2 (1.09) n = 114      | 0.8 (0.94) n = 18 | −0.7 (0.91) n = 18 |
| 4. Reactions of others    | 1.0 (0.99) n = 114      | 0.6 (0.92) n = 18 | −0.3 (0.84) n = 18 |
| 5. Social life            | 1.3 (1.14) n = 114      | 0.8 (0.94) n = 18 | −0.7 (0.77) n = 18 |
| 6. Recreation/leisure     | 1.3 (1.14) n = 112      | 0.9 (1.11) n = 18 | −0.7 (1.30) n = 16 |
| 7. Time looking after     | 1.4 (1.03) n = 113      | 1.1 (0.96) n = 18 | −0.3 (1.21) n = 17 |
| 8. Extra housework        | 1.8 (1.06) n = 114      | 1.2 (0.94) n = 18 | −0.3 (1.16) n = 17 |
| 9. Job/study              | 0.6 (0.93) n = 114      | 0.2 (0.43) n = 18 | −0.8 (1.29) n = 17 |
| 10. Expenditure           | 1.1 (0.96) n = 114      | 0.7 (0.96) n = 18 | −0.6 (1.33) n = 17 |

Note: FDLQI: © M K A Basra, A Y Finlay, Cardiff University 2005.

Abbreviations: DLQI, Dermatology Life Quality Index; FAS, full analysis set; FDLQI, Family Dermatology Life Quality Index; N, the number of subjects in the analysis set; n, number of subjects included in the analysis; SD, standard deviation.
known what completion rates to expect. Gathering data from family members involves several complex practical and ethical issues not normally encountered in clinical trials and it is likely that completion rates for family measures will be lower than for patient completed measures. This may partially explain the FDLQI completion rates of around 50% in this study.

The DLQI and FDLQI total scores were calculated by summing all answered questions, as recommended by the original authors. The impact of questions answered ‘not at all/not relevant’ is not known. However, overall scores were initially high, confirming a large impairment of QoL of family members, which greatly improved following effective patient therapy.

Although the FDLQI has been used in cross-sectional studies of psoriasis in several countries, there is very little experience of its use to assess the impact following effective therapy of patients, and therefore the generalisability of this study is not known.

The finding that responders and non-responders showed similar improvements in FDLQI score is surprising and may be an effect of participating in a

### TABLE 7 FDLQI questions score shifts from baseline to Weeks 12 and 16—corresponding visit DLQI total score >10 (FAS)

| Question                      | Week | Improved n/Na (%) | Unchanged n/Nb (%) | Worsened n/Nc (%) |
|-------------------------------|------|-------------------|--------------------|-------------------|
| 1. Emotional distress         | 12   | 7/12 (58.3)       | 6/14 (42.9)        | 1/9 (11.1)        |
|                               | 16   | 10/15 (66.7)      | 7/18 (38.9)        | 1/12 (8.3)        |
| 2. Physical wellbeing         | 12   | 6/11 (54.5)       | 5/14 (35.7)        | 3/11 (27.3)       |
|                               | 16   | 6/12 (50.0)       | 10/18 (55.6)       | 2/14 (14.3)       |
| 3. Personal relationships     | 12   | 8/11 (72.7)       | 5/14 (35.7)        | 1/11 (9.1)        |
|                               | 16   | 7/12 (58.3)       | 11/18 (61.1)       | 0/13 (0)          |
| 4. Reactions of others        | 12   | 6/9 (66.7)        | 7/14 (50.0)        | 1/12 (8.3)        |
|                               | 16   | 6/8 (75.0)        | 10/18 (55.6)       | 2/16 (12.5)       |
| 5. Social life                | 12   | 10/11 (90.1)      | 4/14 (28.6)        | 0/7 (0)           |
|                               | 16   | 9/12 (75.0)       | 9/18 (50.0)        | 0/12 (0)          |
| 6. Recreation/leisure         | 12   | 6/11 (54.5)       | 5/12 (41.7)        | 1/5 (20.0)        |
|                               | 16   | 7/12 (58.3)       | 8/16 (50.0)        | 1/10 (10.0)       |
| 7. Time looking after         | 12   | 6/8 (75.0)        | 6/13 (46.2)        | 1/9 (11.1)        |
|                               | 16   | 5/10 (50.0)       | 9/17 (52.9)        | 3/12 (25.0)       |
| 8. Extra housework            | 12   | 8/13 (61.5)       | 4/13 (30.8)        | 1/7 (14.3)        |
|                               | 16   | 5/13 (38.5)       | 8/17 (47.1)        | 4/11 (36.4)       |
| 9. Job/study                  | 12   | 7/7 (100)         | 6/13 (46.2)        | 0/9 (0)           |
|                               | 16   | 7/8 (87.5)        | 9/17 (52.9)        | 1/13 (7.7)        |
| 10. Expenditure               | 12   | 4/9 (44.4)        | 8/13 (61.5)        | 1/9 (11.1)        |
|                               | 16   | 7/10 (70.0)       | 8/17 (47.1)        | 2/12 (16.7)       |

Note: FDLQI: © M K A Basra, A Y Finlay, Cardiff University 2005.
Abbreviations: FAS, full analysis set; FDLQI, Family Dermatology Life Quality Index; N, the number of subjects in the analysis set; n, number of subjects included in the analysis; SD, standard deviation.

### TABLE 8 PASI 75 response over time by FDLQI completion (FAS)

| Week | PASI 75 | FDLQI completion, N = 233 n (%) |
|------|---------|---------------------------------|
|      | Yes     | No |
| 12   | 57 (58.8) | 76 (55.9) |  
|     | 40 (41.2) | 60 (44.1) |
| 16   | 58 (62.4) | 70 (50.0) |  
|     | 35 (37.6) | 70 (50.0) |

Abbreviations: FAS, full analysis set; FDLQI, Family Dermatology Life Quality Index; N, the number of subjects in the analysis set; n, number of subjects included in the analysis; PASI 75, a 75% decrease in the Psoriasis Area and Severity Index score.
research study and/or the knowledge that a novel treatment was being used.

Novel strategies to care for the wider impacts of psoriasis on family members/partners are needed and may contribute to better therapy compliance. The FDLQI questionnaire responds well and appropriately to major changes in the disease severity of those affected by psoriasis.

ACKNOWLEDGEMENTS
The authors wish to thank the family members/partners and patients for their essential contributions to this study. The authors thank Duncan Currie and SQN Ltd, UK, for providing medical writing support which was funded by Novartis Pharmaceuticals, UK Ltd, in accordance with Good Clinical Practice guideline (http://www.ismpp.org/gpp3). RB Warren and CEM Griffiths are supported in part by the NIHR Manchester Biomedical Research Centre. JN Barker is partly supported by the National Institute for Health Research Biomedical Research Centre at Guy’s and St Thomas’s NHS Foundation Trust and King’s College London. This study was funded by Novartis Pharmaceuticals UK Ltd, who were involved with the study design, data collection, data analysis, and manuscript preparation.

CONFLICTS OF INTEREST
A. Y. Finlay is joint copyright owner of the Dermatology Life Quality Index and Family Dermatology Life Quality Index. Cardiff University receives royalties from their use and A. Y. Finlay receives a share of these. A. Y. Finlay has received honoraria for lecturing and consultancy from Novartis. J. N. Barker has received honoraria and or research grants from Abbvie, Almirall, Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Janssen, Leo, Lilly, Novartis, Samsung, Sun, and UCB Pharma. A. D. Burden has received honoraria for lecturing and consultancy from Abbvie, Almirall, Boehringer-Ingelheim, Celgene, Leo, Lilly, Novartis, Janssen, and UCB Pharma. C. E. M. Griffiths has received honoraria and/or research grants from Abbvie, Almirall, Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Galderma, Janssen, Leo, Lilly, MSD, Novartis, Sandoz, and UCB Pharma. He is also a National Institute for Health Research Emeritus Senior Investigator. B. Kirby has received honoraria and research grants from Abbvie, Almirall, Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Galderma, Janssen, Leo, Lilly, MSD, Novartis, and UCB Pharma. M. L. Goodman is an employee of Xylem Medical Limited, an independent adviser and consultant to Novartis Pharmaceuticals UK Ltd. C. Nell is a full-time employee of Novartis Pharmaceuticals UK Ltd. R. B. Warren has received the following: Research Grants: AbbVie, Almirall, Amgen, Celgene, Janssen, Lilly, Leo, Medac, Novartis, Pfizer, and UCB. Consulting Fees: AbbVie, Almirall, Amgen, Arena, Avillion, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Janssen, Lilly, Leo, Medac, Novartis, Pfizer, Sanofi, UCB, and Xenopoort.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPLEMENTARY INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Finlay AY, Barker JN, Burden AD, Griffiths CEM, Kirby B, Goodman ML, et al. Secukinumab improves the quality-of-life of family members and partners of people with psoriasis: Family Dermatology Life Quality Index (FDLQI) results from a randomised open-label study (SIGNATURE). JEADV Clin Pract. 2022;1:207–218. https://doi.org/10.1002/jvc2.42

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