



# SKIN-Q®

## A User's Guide for Researchers and Clinicians

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## **1. What is the SKIN-Q?**

The SKIN-Q is a rigorously developed patient-reported outcome measure (PROM) that can be used to precisely measure patient satisfaction with any form of minimally invasive aesthetic treatment from the patient perspective [1]. The SKIN-Q can be used to evaluate outcomes for aesthetic treatments that aim to tighten, slim, reshape, and/or rejuvenate the appearance of the skin on different parts of the face and body. The SKIN-Q is innovative in that it is available as an item bank, item library, and five short-form scales (covering skin quality, skin rejuvenation, and facial movement), all of which have been published [1]. In addition, it is possible to customize fit-for-purpose short-form scales by choosing a subset of items from the item library.

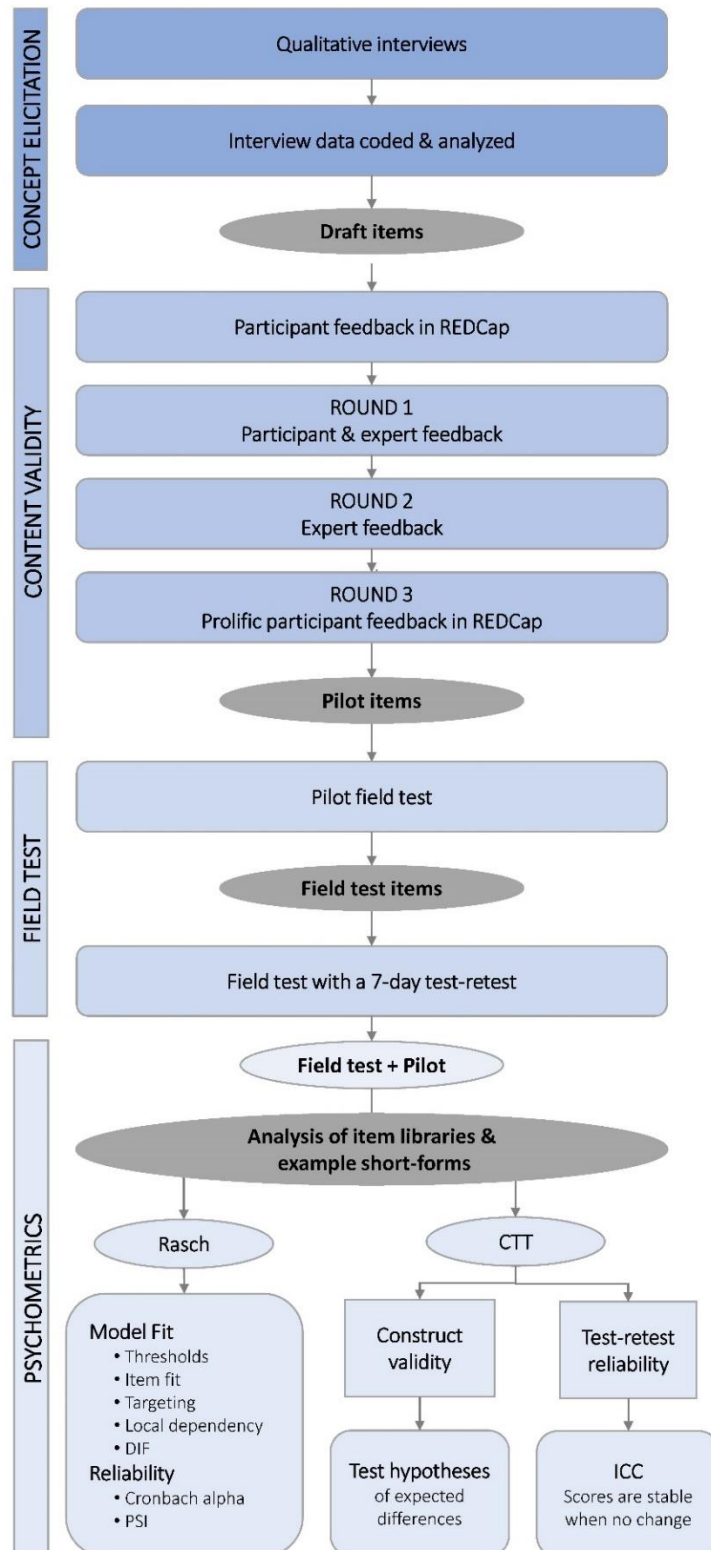
## **2. What Makes the SKIN-Q Different to Traditional PROMs?**

Standard practice for PROM design has involved the development of short-form scales composed of a limited set of items (i.e., questions) for use in a specific context of use [2-3]. More recently, PROM developers have created item banks and libraries to provide a flexible approach to health outcome assessment. In this alternative approach, it is possible to choose a subset of items for study-specific scale that represent the most important concepts for a specific patient population or context of use. This approach aims to maximize content validity and minimize patient burden. Short-form scales can be scored by calibrating scores to the full set of items (i.e., item-bank approach [4-5]), or by using estimates from independent samples (i.e., item-library approach [6]). SKIN-Q includes two item libraries. We also published five short-form scales measuring skin quality, rejuvenation, and facial movement. The short-form scales provide examples of how the items can be utilized. These short-form scales can be used in clinical trials of aesthetic treatments as well as clinical care with patients.

## **3. How Was the SKIN-Q Developed and Validated?**

To develop the SKIN-Q, we followed internationally recommended guidelines for PROM development to ensure the SKIN-Q would meet the requirements of regulatory bodies [7-11]. Our team's mixed methods, multi-phase approach to developing the SKIN-Q is shown in Figure 1. This approach engaged patients and clinicians in all phases of the research as experts crucial in designing the content of the SKIN-Q and its subsequent evaluation. Briefly, between October 2021 to March 2022 we conducted 26 concept elicitation interviews (88% women; 65% ≥40 years of age). The 26 participants had one or more facial aesthetic treatments, and 6 had aesthetic treatment on the body. Table 1 shows sample characteristics and Table 2 shows the sample's treatment history. The concept elicitation interviews were audio recorded, transcribed, and coded using a line-by-line

**Figure 1:** The multiphase mixed methods approach our team followed to develop SKIN-Q. (Reprinted from Klassen AF, Pusic AL, Kaur M, et al. The SKIN-Q: An Innovative Patient-Reported Outcome Measure for Evaluating Minimally Invasive Skin Treatments for the Face and Body. *Facial Plast Surg Aesth Med.* 2024 May-Jun;26(3):247-255.)



approach. An item pool was developed and refined through the steps outlined in Figure 1. To establish content validity, we conducted seven cognitive debriefing interviews and received input from 12 experts. We also conducted an online cognitive debriefing survey that utilized a crowd-working platform. Data were collected from 174 participants. The full set of items tested in the two libraries included 58 measuring how the *skin looks* (17 face-specific) and 22 measuring how the *skin feels*.

The psychometric properties of SKIN-Q were examined in a sample of 657 Prolific participants who provided 713 assessments (see Tables 1-2 for sample and treatment characteristics). To analyse the SKIN-Q, we used Rasch Measurement Theory (RMT). Scales that compose a PROM are designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved [12-13]. Using RMT analysis ensured the SKIN-Q would be valid and reliable for use in outcomes research as well as in clinical care with patients.

The published version of the item libraries included 46 items measuring how the *skin looks* and 20 items measuring how the *skin feels*. The RMT analysis provided evidence of reliability and validity for both sets of items [1]. All items had ordered thresholds and good item fit. Reliability was high with Person Separation Index and Cronbach alpha values  $\geq 0.95$ . More than 100 participants took part in a test-retest reliability study between 7-14 days after the initial assessment. The intraclass correlation coefficient values were  $\geq 0.85$ . The RMT analysis provided evidence of reliability and validity of five short-form scales. These scales measure skin rejuvenation (e.g., healthy, youthful, rejuvenated), skin quality (e.g., firm, smooth, hydrated), and facial function (e.g., smile, frown, squint). Further information about the psychometric performance of SKIN-Q item libraries and short form scales is available in our open access publication [1].

#### **4. Skin Feels Item Descriptions**

This item library includes 20 items. Response options measure satisfaction with how the skin feels (very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied). The time frame for reporting asks respondents to answer based on the past week. All 20 items are relevant to facial skin and skin on the body. We have organized the items according to the clinical hierarchy from the RMT analysis. This means that people in the sample were the most satisfied with the item “how natural your skin feels”, and the least satisfied with the item “how flawless your skin feels”. Table 3 below shows the items included in the two published short-form scales that measure Skin Rejuvenation and Skin Quality.

**Table 1: Participant characteristics (number, %)**

		Qualitative Sample	Prolific			
			Cognitive sample		Psychometric Sample	
		N=26	N=174	%	N=657	%
SAMPLE	Body only	0	45	25.9	62	9.5
	Face only	26	123	70.7	539	82.0
	Face and Body	6	6	3.4	56	8.5
COUNTRY	Canada	6	31	17.8	105	16.0
	USA	20	143	82.2	550	83.7
	Missing	0	0	0	2	0.3
AGE	20-29	3	44	25.3	200	30.4
	30-39	6	46	26.4	218	33.2
	40-49	7	30	17.2	112	17.1
	50-59	6	35	20.1	81	12.3
	≥60	4	19	10.9	46	7.0
GENDER	Woman	23	142	81.6	537	81.7
	Man	3	29	16.7	108	16.4
	Gender diverse	0	3	1.7	9	1.4
	Prefer to not answer	0	0	0	2	0.3
RACE	White	22	127	73.0	443	67.4
	Black	2	15	8.6	45	6.8
	Latin American	0	15	8.6	33	5.0
	East Asian	0	12	6.9	41	6.2
	Middle Eastern	0	5	2.9	9	1.4
	South Asian	1	4	2.3	15	2.3
	Southeast Asian	1	4	2.3	11	1.7
	Indigenous	0	1	0.6	2	0.3
	Mixed Race	0	0	0.0	54	8.2
	Other	0	1	0.6	4	0.6
MARITAL STATUS	Married/Common Law	16	78	44.8	310	47.2
	Single	7	61	35.1	266	40.5
	Divorced	2	26	14.9	61	9.3
	Separated	0	3	1.7	7	1.1
	Widowed	1	2	1.1	3	0.5
	Other / Prefer not to answer	0	4	2.3	10	1.6
FITZPATRICK SKIN TYPE	Always burn and never tan	2	9	5.2	50	7.6
	Usually burn and minimally tan	9	45	25.9	163	24.8
	Mild burn and then tan	9	64	36.8	229	34.9
	Rarely burn and always tan	4	33	19.0	144	21.9
	Rarely burn and tan very easily	1	15	8.6	58	8.8
	Never burn and never tan	1	8	4.6	13	2.0
HIGHEST EDUCATION	Some high school	0	2	1.1	3	0.5
	High school	1	11	6.3	35	5.3
	Some college, trade or university	4	24	13.8	102	15.5
	College, trade or university degree	9	98	56.3	333	50.7
	Some Masters or Doctoral degree	0	7	4.0	42	6.4
	Masters or Doctoral degree	11	31	17.8	141	21.5
Missing / Prefer to not answer	1	1	0.6	1	0.2	

**Table 2: Treatment history reported by the qualitative sample and Prolific participants (Number, %)**

		Qualitative Sample	Prolific			
			Cognitive Sample		Field-test Sample	
		N=26	N=180	%	N=713	%
<b>FACIAL TREATMENTS</b>						
INJECTABLE	Botox	18	76	42.2	189	26.5
	Filler	17	71	39.4	106	14.9
	Platelet-Rich Plasma	1	7	3.9	15	2.1
	Skin Booster	0	0	0.0	23	3.2
RESURFACING	Microdermabrasion	7	59	32.8	193	27.1
	Chemical peel	16	51	28.3	218	30.6
	Hydrafacial	2	40	22.2	241	33.8
	Laser	14	37	20.6	90	12.6
	Microneedling	2	30	16.7	122	17.1
	Light therapy	14	25	13.9	71	10.0
	SKIN TIGHTENING	Radio-Frequency	7	11	6.1	52
High-Intensity Ultrasound		0	9	5.0	37	5.2
Thread lift		1	6	3.3	24	3.4
FAT REMOVAL	Fat removal	1	6	3.3	23	3.2
<b>BODY TREATMENTS</b>						
INJECTABLES	Filler	0	17	9.4	27	3.8
	Skin Booster	0	0	0.0	18	2.5
RESURFACING	Laser	1	0	0.0	0	0.0
FAT REDUCTION	Fat removal	0	6	3.3	17	2.4
	Cryolipolysis	2	28	15.6	24	3.4
	Laser Lipolysis	0	10	5.6	11	1.5
	Radio-frequency	1	8	4.4	8	1.1
	High-Intensity Focused Electromagnetic	4	0	0.0	0	0.0
SKIN TIGHTENING	High-Intensity Ultrasound	0	13	7.2	27	3.8
	Radio-frequency	2	14	7.8	18	2.5
	Intense Pulsed Light and Radio-frequency	0	8	4.4	13	1.8
CELLULITE	Cellulite Treatment	0	17	9.4	20	2.8

Note: Tables 1 and 2 were reproduced from Klassen AF, Pusic AL, Kaur M, et al. The SKIN-Q: An Innovative Patient-Reported Outcome Measure for Evaluating Minimally Invasive Skin Treatments for the Face and Body. *Facial Plast Surg Aesth Med.* 2024 May-Jun;26(3):247-255.

**Table 3: Skin Feels item library and published short-form scales**

Full set of items	Short Forms	
	Skin Rejuvenation	Skin Quality
1. Natural	-	-
2. Clean	-	-
3. Thick	-	✓
4. Comfortable	-	-
5. Soft	-	✓
6. Healthy	✓	-
7. Good	✓	-
8. Tight	-	✓
9. Firm	-	✓
10. Full	-	✓
11. Smooth	-	✓
12. Youthful	✓	-
13. Refreshed	✓	-
14. Elasticity	-	✓
15. Rejuvenated	✓	-
16. Hydrated	-	✓
17. Clear	-	-
18. Texture	-	✓
19. New	✓	-
20. Flawless	-	-

## 5. Skin Looks Item Descriptions

This item library includes 46 items. Response options measure satisfaction with how the skin looks (very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied). The time frame for reporting asks respondents to answer based on how their skin looks now. We have organized the items by the clinical hierarchy from the RMT analysis. This means that people in the sample were most satisfied with the item that asks “how your skin looks when you look your best”, and least satisfied with the item that asks “how flawless your skin looks”. All 46 items are relevant to facial skin, and 33 can be used to evaluate skin on the body. Table 4 below shows the items included in the three published short-form scales measuring Skin Rejuvenation, Skin Quality, and Facial Movement. Table 4 shows the subset of 33 items that are applicable to measuring outcomes for skin on the body.



**Table 4: Skin Looks item library and published short-form scales**

Full set of items	Body Skin	Short Forms		
		Skin Rejuvenation	Skin Quality	Facial Movement
1. Look best		-	-	-
2. Natural	✓	-	-	-
3. Go out		-	-	-
4. Relaxed look	✓	-	-	-
5. Smile		-	-	✓
6. Thick	✓	-	✓	-
7. Laugh		-	-	✓
8. Soft	✓	-	✓	-
9. Face relaxed		-	-	✓
10. Show expression		-	-	✓
11. Age	✓	-	-	-
12. Raise eyebrows		-	-	✓
13. Healthy	✓	✓	-	-
14. Young	✓	-	-	-
15. Fresh	✓	✓	-	-
16. Full	✓	-	✓	-
17. Lifted	✓	-	✓	-
18. Tight	✓	-	✓	-
19. Overall quality	✓	-	-	-
20. Squint		-	-	✓
21. Elasticity	✓	-	✓	-
22. Firm	✓	-	✓	-
23. Youthful	✓	✓	-	-
24. Photos	✓	-	-	-
25. Rested		-	-	-
26. Good	✓	✓	-	-
27. Bright	✓	✓	-	-
28. Frown		-	-	✓
29. Angles	✓	-	-	-
30. Smooth	✓	-	✓	-
31. Vibrant	✓	✓	-	-
32. Attractive	✓	-	-	-
33. Rejuvenated	✓	✓	-	-
34. Tone (color)	✓	-	-	-

35. On screen		-	-	-
36. Hydrated	✓	-	✓	-
37. Prolife	✓	-	-	-
38. Without makeup		-	-	-
39. Glow	✓	✓	-	-
40. Even tone	✓	-	✓	-
41. Texture	✓	-	✓	-
42. Refreshed		-	-	-
43. Radiant	✓	✓	-	-
44. Up close	✓	-	-	-
45. Bright light	✓	-	-	-
46. Flawless	✓	-	✓	-

## 6. Using the SKIN-Q

You are able to license the SKIN-Q short-form scales described in this User Guide. In addition, SKIN-Q item libraries provide clinicians and researchers with the opportunity to pick a set of items to create a precise study-specific scale to measure outcomes for a procedure or product, or for use in clinical care. This approach reduces patient burden and maximizes content validity. If you would like support to license a customized study-specific scale, please email your request to [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

We anticipate that most researchers and clinicians will use SKIN-Q short-form scales. However, if you would like to inquire about the use of the full item libraries, please email [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

## 7. Administration of the SKIN-Q

The SKIN-Q is designed to be completed by adults on their own (self-report). Brief instructions are provided at the start of each scale. The SKIN-Q was field-tested using a REDCap survey [14]. You may use the paper and pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic).

If you plan to have an ePRO company capture and manage SKIN-Q data collection, the ePRO company may need a license. If you have had or plan to have an ePRO company convert the SKIN-Q into an electronic format, e-conversion review and certification is required. Please email [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

## 8. Scoring the SKIN-Q Item Libraries

The item libraries are independently functioning as they measure different but related constructs (how skin looks versus how skin feels). For both libraries, higher scores represent a better outcome (i.e., higher satisfaction with skin). The full item library can be scored. To obtain a score, the raw scores for the items are added up and linearized using a Conversion Table, which is based on the Rasch analysis. The transformed scores range from 0 (lowest satisfaction) to 100 (highest satisfaction). To discuss the use of the full item libraries, please contact [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

## 9. Scoring SKIN-Q Short-Form Scales

Each short-form scale is independently functioning. Higher scores represent a better outcome (i.e., higher satisfaction with skin). To obtain a score, the raw scores for the short-form items are added up and linearized using the Conversion Tables we provide, which are based on the Rasch analysis.

When you license the SKIN-Q, you will be provided with the Conversion Table(s) to score the short-form scales. The scoring algorithm is based on the subset of items in the short-form rather than the full set of items in the item library.

Below is an example of how to compute the score using the SKIN-Q Skin Rejuvenation short-form scale from the *skin feels* item library.

First, you compute the **sum score** by adding the raw scores for items 1 to 6. In the example below, the sum score = 17. Second, you will find the sum score for the Skin Rejuvenation Conversion Table, which is shown below. The sum score of 17 is then converted to 60.

**These questions ask about how your SKIN FEELS.**

**With your SKIN in mind, in the PAST WEEK, how dissatisfied or satisfied have you been with:**

	VERY DISSATISFIED	SOMEWHAT DISSATISFIED	SOMEWHAT SATISFIED	VERY SATISFIED
1. How healthy your skin feels?	1	2	3	4
2. How good your skin feels?	1	2	3	4
3. How youthful your skin feels?	1	2	3	4
4. How refreshed your skin feels?	1	2	3	4
5. How rejuvenated your skin feels?	1	2	3	4
6. How new your skin feels?	1	2	3	4

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## SKIN FEELS: REJUVENATION CONVERSION TABLE

**Instructions:** Higher scores reflect a better outcome. If missing data is less than 50% of the scale's items, for each missing item, we suggest you calculate and impute the within-person mean of the completed items. For an example, see the SKIN-Q User's Guide. Use the Conversion Table below to convert the raw summed scale score into a score from 0 (worst) to 100 (best).

SUM SCORE	RASCH TRANSFORMED SCORE (0 TO 100)
6	0
7	8
8	14
9	19
10	24
11	29
12	34
13	39
14	45
15	49
16	54
17	60
18	66
19	72
20	77
21	82
22	87
23	93
24	100

## 10. How to Deal With Missing Data

The choice of how to handle missing data, such as whether or not to impute the mean when there is missing data, is ultimately up to the end user of SKIN-Q. Our suggestion follows the most popular method for scoring when there is missing data, which is to impute a missing value by the mean response to completed items if more than 50% of items are answered. This method is recommended in the scoring manuals of numerous widely used PROMs, such as the SF-36 generic questionnaire used extensively in research for decades [15-16]. As such, SKIN-Q scores can be computed if missing data is less than 50% of the scale's items. In this approach, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, for the 6-item scale described above, if someone has not responded to all the items, but has responded to  $\geq 3$  items, all other items for that person could be imputed with the within-person mean (rounded to the nearest integer), and a summed score

calculated. Alternatively, for the 6-item scale, if someone has responded to  $\leq 3$  items, the summed score for this person would be classified as missing data.

## 11. Scoring SKIN-Q Short-Form Scales Using the Cross-Walk Approach

If you would like to have the scoring conversion table for the *cross-walk* to enable comparability between a short-form scale and the published item library, please email [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

## 12. Conditions of Use

McMaster University and Brigham and Women's Hospital hold the copyright of the SKIN-Q and all of its translations (past, on-going, and future). To avoid any copyright infringement, please ensure that the copyright notice of the SKIN-Q is included in the questionnaire. If you're unsure of the copyright notice for the SKIN-Q, our website lists the copyright and trademark notice: <https://qportfolio.org/copyright-information/>

Use of the SKIN-Q requires completion of a licensing agreement. The use of the SKIN-Q short-form scales in non-profit academic research and in clinical care is free of charge. The use of the SKIN-Q by "for-profit" organizations (e.g., pharmaceutical companies or sponsored by pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee.

To obtain a license to use the SKIN-Q, please use the following link:

<https://research.mcmaster.ca/industry-investors/technologies-available-for-licensing/request-for-license/>

For questions regarding a SKIN-Q license, please contact:

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### PLEASE NOTE

When you sign a SKIN-Q license, you agree to the following terms:

- You will not modify, adapt, or create another derivative work from the SKIN-Q
- You will not sell, sublicense, rent, loan, or transfer the SKIN-Q to anyone
- You will not reproduce any SKIN-Q scales in publications or other materials
- You will not translate the SKIN-Q without permission from our team

For questions regarding study design and optimal use of the SKIN-Q item libraries, please contact:

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## 13. Frequently Asked Questions

### ***Do I have to use all items in SKIN-Q item libraries?***

Each item library functions independently, as do the short-form scales. It is not necessary for a patient to complete all short-form scales described in this User Guide. A researcher or clinician may select any of the short-form scales depending on the particular purpose of the study or use. Please contact [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com) to request a study-specific scale.

### ***Can I delete or add or change any items or response options of the SKIN-Q?***

You cannot add or change the wording of any items or response options of either of the SKIN-Q libraries or any of the short-form scales. Any modification to the content of the SKIN-Q is prohibited under copyright laws. Making changes to the SKIN-Q would invalidate its psychometric properties.

### ***Can I reproduce SKIN-Q in a publication or other document (e.g., PhD thesis)?***

According to the licensing agreement, you cannot reproduce the content of SKIN-Q item libraries or short-form scales verbatim in a publication. However, it is possible to show shortened versions of each item. The shortened forms of items that can be used in a publication are shown above in Tables 3 and 4.

### ***Can I translate SKIN-Q scales into a new language?***

Yes, with permission, you can translate the SKIN-Q into different languages. Before starting a translation, check our translations list on [www.qportfolio.org](http://www.qportfolio.org) to see if there is a translation in the language you need. If there is not a translation in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the methods you need to follow. Email us at [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com) for more information. Please note that the developers of the SKIN-Q own the copyright of all translations of the SKIN-Q.

### ***Are there specific time points when patients complete the scales?***

A researcher or clinician can decide the time points to use to administer the SKIN-Q.

## ***Does it cost money to use SKIN-Q?***

Use of SKIN-Q published short-form scales described in this User Guide are free for non-profit users. For-profit users should contact McMaster University for information about fees for using the item libraries and short-form scales ([milo@mcmaster.ca](mailto:milo@mcmaster.ca)).

## **14. References**

1. Klassen AF, Pusic AL, Kaur M, et al. The SKIN-Q: An Innovative Patient-Reported Outcome Measure for Evaluating Minimally Invasive Skin Treatments for the Face and Body. *Facial Plast Surg Aesthet Med*. 2024 May-Jun;26(3):247-255.
2. Piccinin C, Basch E, Bhatnagar V, et al. Recommendations on the use of item libraries for patient-reported outcome measurement in oncology trials: findings from an international, multidisciplinary working group. *Lancet Oncol*. 2023 Feb;24(2):e86-e95.
3. Rose M, Bjorner JB, Gandek B, et al. The PROMIS Physical Function item bank was calibrated to a standardized metric and shown to improve measurement efficiency. *J Clin Epidemiol*. 2014 May;67(5):516-26.
4. Choppin, B. Item banking using sample-free calibration. *Nature*. 1968; 219, 870-872.
5. Massof RW, Ahmadian L, Grover LL, et al. The Activity Inventory: An adaptive visual function questionnaire. *Optom Vis Sci*. 2007 Aug; 84(8): 763–774.
6. Regnault A, Pompilus F, Ciesluk A, et al. Measuring patient-reported physical functioning and fatigue in myelodysplastic syndromes using a modular approach based on EORTC QLQ-C30. *J Patient Rep Outcomes*. 2021 Jul 20;5(1):60.
7. Cano SJ, Riazi A, Schapira AH, et al. Friedreich's ataxia impact scale: a new measure striving to provide the flexibility required by today's studies. *Movement Disorders*. 2009;24(7):984-92.
8. Food and Drug Administration. Guidance for industry patient-reported outcome measures: use in medical product development to support labeling claims. Silver Spring, MD; 2009. Available from: <https://www.fda.gov/downloads/drugs/guidances/ucm193282.pdf> [Last accessed: 07/05/2024].
9. Terwee CB, Prinsen CA, Chiarotto A, et al. COSMIN methodology for assessing the content validity of PROMs. Amsterdam: VU University Medical Center; 2018. Available from: <https://cosmin.nl/wp-content/uploads/COSMIN-methodology-for-content-validity-user-manual-v1.pdf> [Last accessed: 07/05/2024].
10. Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity--establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO good research practices task force report: part 1--eliciting concepts for a new PRO instrument. *Value Health*. 2011;14(8):967–977.
11. Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity--establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force report: part 2--assessing respondent understanding. *Value Health*. 2011;14(8):978–988.

12. Rasch G. Studies in mathematical psychology: I. Probabilistic models for some intelligence and attainment tests. Nielsen & Lydiche. 1960.
13. Hobart J, Cano S. Improving the evaluation of therapeutic interventions in multiple sclerosis: the role of new psychometric methods. *Health Technol Assess*. 2009 Feb;13(12):iii, ix-x, 1-177.
14. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009 Apr 1;42(2):377-81.
15. Ware, J. E. Jr., M. A. Kosinski and S. D. Keller. SF-36 physical and mental health summary scales: a user's manual. Boston, Massachusetts, The Health Institute, New England Medical Centre. 1994.
16. Ware, J. E. Jr., Snow, K.K., Kosinski, M., Gandek, B. SF-36 Health Survey manual and interpretation guide. Boston, Massachusetts, Nimrod Press. 1993.