WFUHS Dept of Dermatology
Winston-Salem, NC

Title:	Internet Surveys and their Impact on Adherence to Brimonidine and QOL in Patients with Rosacea
Protocol Number:	II-Rosacea Brimonidine Adherence-SF2015
Principal Investigator:	Steve Feldman, MD, PhD sfeldman@wakehealth.edu Phone Number: (336) 716-7740 Fax Number: (336) 713-4255
Sub-Investigator:	Adele Clark, PA-C adclark@wakehealth.edu Phone Number: (336) 716-7465 Fax Number: (336) 713-4255
Sponsor:	Wake Forest University Health Sciences
Revision Date:	Version 3; April 14, 2016 Version 2; December 22, 2015

Table of Contents

SUMMARY

Title: Internet Surveys and their Impact on Adherence to Brimonidine topical gel and QOL in Patients with Rosacea

Source of Funding: Wake Forest University Health Sciences

Objective:

Primary Objective: To assess adherence to topical brimonidine topical gel, 0.33% for the treatment of rosacea.

Secondary Objectives: To determine the impact of reported adherence on rosacea outcomes, to identify factors that affect adherence to rosacea treatment and to assess QOL.

Study Design:

An investigator-blinded, prospective, 6 month study of subjects with persistent erythema associated with active rosacea will be conducted in 20 subjects aged 18 years and older. All subjects will receive standard-of-care brimonidine topical gel, 0.33% with instructions to apply it once daily per package insert. Adherence will be assessed using weekly internet surveys to document how often the medication is being used, as well as reminders about rosacea triggers and general use of brimonidine.

Patients with persistent erythema associated with rosacea will be recruited from the Wake Forest Baptist Health Dermatology Clinics and IRB approved advertising. At the baseline screening visit, subjects will have the diagnosis of rosacea confirmed by an investigator. Patients will be classified as having erythematotelangiectatic or a combination erythematotelangiectatic and papulopustular. We will evaluate whether patients believe they have constant erythema or more intermittent flushing and blushing. Subjects will be informed of the benefits and risks of treatment. If they agree to participate, the subjects will give written consent approved by the Institutional Review Board and will be seen in follow up at 3 months and 6 months.

Subjects will be randomized 1:1 to be in the weekly internet survey group (appendix) or the standard care non-survey group. The internet survey will ask them how often they have used their medication that week, as well as giving them treatment tips and reminders about rosacea triggers. They will be asked a variety of questions during the weekly internet survey- such as the amount of erythema they currently have (measured by VAS scale), how much burning and stinging they have, how often they have used the medication and where did they apply the medication, as well as any additional side effects they

may be having from the medication.

Subjects in the non-internet survey group will just get these identical surveys at the Month 3 and Month 6 visits. We are also interested in learning through the adherence surveys if subjects begin using the medication on an as needed basis, and if this affects the side effect profile and satisfaction with the medication.

At each visit, review of the internet survey use and medication weights will be done. Disease severity measures ((Clinician's Erythema Assessment (CEA), Patient Severity Assessment (PSA, Lesion counts)) will be obtained. Investigator and subject Visual Analog Scale (VAS) to measure facial erythema will be obtained. Adverse events will be logged at every visit. Attention will be paid to any symptoms of rebound erythema and more detailed information concerning location and timing will be collected. QOL surveys will be completed at the end of study visit.

1.0 INTRODUCTION

Rosacea is a chronic disease with great psychosocial and emotional impact. Topical therapies are the mainstay of rosacea treatment; however patients often continue to suffer from rosacea after being prescribed a treatment; poor adherence likely plays a role in poor treatment outcomes. Non-adherence is a patient's failure to follow a medication regimen as directed by the physician. In many cases, non-adherence, rather than non- response, is the underlying cause of treatment failure.

Brimonidine is a topical treatment for the persistent erythema associated with rosacea. Some patients have noticed some rebound flushing when using the medication. This raises the question about adherence to the medication in the setting of adverse effects. The general thought is that there is a relationship between adverse effects from medications and treatment adherence- the more often side effects occur the less often a medication may be taken. However that is not always the case. Many patients take medications such as isotretinoin and topical fluorouracil with well documented side effects. Yet adherence to these medications is often very good. So do any adverse effects from brimonidine affect patient adherence?

Return office visits are used to follow treatment compliance and adherence. An online survey may provide an effective and more practical alternative to an extra office visit as a method to measure and promote improved adherence. Internet surveys may improve intrinsic motivation to take medication by making the patient feel cared for, enhancing a trusting patient-physician relationship. A good deal of real time information can be obtained through an internet survey.

2.0 STUDY OBJECTIVES

Primary Objective: To assess adherence to topical brimonidine for the treatment of rosacea.

Secondary Objectives: To determine the impact of reported adherence on rosacea outcomes, To identify factors that affect adherence to rosacea treatment and to assess QOL.

2.1 Study Design

An investigator-blinded, prospective, 6 month study of subjects with

persistent erythema associated with active rosacea will be conducted in 20 subjects aged 18 years and older. All subjects will receive standard-of-care brimonidine topical gel 0.33% with instructions to apply it once daily per package insert. Adherence will be assessed using weekly internet surveys to document how often the medication is being used, as well as reminders about rosacea triggers and general use of brimonidine. Before starting treatment, subjects will be reminded that bromonidine is indicated for persistent, not transient, erythema. They will be given a copy of the product package insert and a copy of the American Academy of Dermatology website (www.aad.org) information on rosacea that contains standardized information about the diagnosis and triggers.

Patients with persistent erythema due to rosacea will be recruited from the Wake Forest Baptist Health Dermatology Clinic and IRB approved advertising. At the baseline screening visit, subjects will have the diagnosis of rosacea confirmed by an investigator. Patients will be classified as having erythematotelangiectatic or a combination erythematotelangiectatic and papulopustular. We will evaluate whether patients believe they have constant erythema or more intermittent flushing and blushing. Subjects will be informed of the benefits and risks of treatment as indicated in the package insert. If they agree to participate, the subjects will give written consent approved by the Institutional Review Board and will be seen in follow up at 3 months and 6 months.

Subjects will be randomized (according to standard randomization tables)1:1 to be in the weekly internet survey group (appendix) or the standard care non-survey group. The internet survey will ask them how often they have used their medication that week, as well as giving them treatment tips and reminders about rosacea triggers. They will be asked a variety of questions during the weekly internet survey- such as the amount of erythema they currently have (measured by VAS scale), how much burning and stinging they have, how often they have used the medication and where did they apply it, as well as any additional side effects they may be having from the medication. Subjects in the non-internet survey group will just get these identical surveys at the Month 3 and Month 6 visits. We are also interested in learning through the adherence surveys if subjects begin using the medication on an as needed basis, and if this affects the side effect profile and satisfaction with the medication.

At each visit, review of the internet survey use and medication weights will be done. Disease severity measures (CEA, PSA, lesion counts) will be obtained. Investigator and subject VAS scales to measure facial erythema

will be obtained. Adverse events will be logged at every visit. Attention will be paid to any symptoms of rebound erythema and more detailed information concerning location and timing will be collected. The lesion counts will also measure any papules or telangiectasia that may become more readily visible with the improvement in background erythema. Telangiectasia will be counted individually by facial quadrant as noted in the Lesion Count Appendix. Measuring individual visible telangiectasia is important as subjects may confuse these with underlying erythema of rosacea, thus affecting subject assessment of their disease. QOL surveys will be completed at the end of study visit.

Descriptive statistics will be generated with mean ± standard deviation (S.D.) or median (interquartile range) for continuous measures depending on the distribution of the data and frequency distribution for categorical variables. Estimate for adherence rates will be obtained as the mean adherence rate along with the corresponding 95% confidence interval.

3.0 STUDY POPULATION

3.1 Subject Population

The study population will consist of 20 subjects aged 18 years and older with the diagnosis of persistent erythema associated with rosacea. Subjects will be recruited from Wake Forest University Department of Dermatology Clinics and IRB approved advertising.

3.2 Inclusion Criteria

- Male or female subject with persistent erythema associated with rosacea, age greater than 18, who agrees to participate and provide written consent.
- Have an Investigator Global Assessment of mild to moderate rosacea (IGA rating between 2 and 5 in the Investigator Global Assessment score which includes erythema in the assessment).
- Access to a computer and the internet.

3.3 Exclusion Criteria

- Initiation or change in dose within 4 weeks of baseline of systemic anti-inflammatory medication which may influence study outcome.
- Use of topical therapy for rosacea within 2 weeks of baseline.
- Use of systemic corticosteroids within 4 weeks of baseline.
- Presence of a concurrent medical condition or skin condition, which is determined by the investigator to potentially interfere with study outcomes or patient assessments.
- Subjects with known allergy or sensitivity to bromonidine topical gel, 0.33% or components therein.
- Female subjects who are not postmenopausal for at least 1 year, surgically sterile, or willing to practice effective contraception during the study. Nursing mothers, pregnant women and women planning to become pregnant while on study are to be excluded.
- Subjects with severe cardiovascular disease or vascular insufficiency.

4.0 STUDY DESIGN

4.1 Formulations

Brimonidine Topical Gel, 0.33%, 30 gram tubes, three tubes per patient per each 3 month period, total of 6 tubes per patient.

4.2 Test Drug Dosage

Subjects will use topical bromonidine once daily

4.3 Efficacy and Safety

Evaluation for efficacy will include:

Objective Clinical Efficacy:
- Clinician's Erythema Assessment (CEA)
- Lesion counts
- Investigator VAS scale ratings of erythema

Subjective Clinical Efficacy:
- Patient Severity Assessment (PSA)Subject VAS scale

ratings of erythema

Subjective Symptom Improvement:

- Quality of life will be measured with the ~~DLQIi~~
- Subject survey to identify factors that affect adherence to rosacea treatment such adverse effects of medication (erythema, burning, stinging)

Safety will be based on adverse events reported by the patient or observed by the investigator.

4.4 Power of the Study

The sample size of 20 subjects is designed to give us an estimate of the adherence rate and to provide adequate sampling to assess common patterns of adherence.

4.5 Randomization, Stratification, and Blinding

Subjects will be randomized 1:1 to be in the weekly internet survey group (appendix) or the standard care non-survey group.

Principal Investigator will be blinded to randomization and study group assignments for all study participants for the duration of the study. The study coordinator will perform randomization. All assessments at sub-sequential visits will be performed prior to review of survey inquiries.

5.0 SUBJECTS RISKS AND BENEFITS

5.1 Potential Risks of Study Participation

The risks of this study are minimal. Subjects would have the same risk of using bromonidine whether they were in the study or not.

Alternative treatments will be discussed with all subjects prior to enrolling in the study. Alternative treatments for rosacea include, but are not limited to, topical (applied to the skin) antibiotic treatments, such as clindamycin, oral antibiotics such as cephalexin, and the use of antibacterial soaps.

Answering questions on the QOL surveys may make the subject feel uncomfortable. Subjects will answer these surveys in the privacy of

the exam room and results will be kept confidential as part of the study data.

5.2 Adverse Events

An adverse event in this study of approved medications is considered any unfavorable, harmful, or pathological change in a research subject as indicated by physical signs, symptoms, and/or clinically significant laboratory abnormalities that are considered product-related. This definition includes: intercurrent illness; injuries; exacerbation of pre- existing conditions (excluding rosacea); adverse events occurring as a result of product withdrawal, abuse, or overdose; and a change in a laboratory variable if considered by the attending physician to be clinically significant or if it caused (or should have caused) the clinician to reduce or discontinue the use of the product or institute therapy. This definition does not include inpatient or outpatient elective surgery for a condition that was present prior to the start of the trial and which has not worsened unexpectedly during the trial.

To capture any adverse events related to rosacea, changes in lesion counts, papules and telangiectasia will be captured in the lesion count assessments. If a subject has an increase in visible papules (once the erythema is improved with the study drug), then this will be captured as an AE if a concomitant medication is added.

The investigator will monitor the occurrence of adverse events during the course of the study. The investigator must provide to the Sponsor appropriate information concerning any findings that suggest significant hazards, contraindications, side effects or precautions pertinent to the safety of the study.

All adverse events occurring after the Baseline visit must be recorded on the Adverse Event Case Report Form page.

5.3 Serious Adverse Events

1. Definition An adverse event is considered a serious adverse event (SAE) if it:

    1. Is fatal
    2. is life threatening (i.e., results in an immediate risk of death);
    3. is persistently or significantly disabling/incapacitating;

4. results in, or prolongs, hospitalization;

5. results in a congenital anomaly;

6. is an event which, in the opinion of the investigator/Medical Monitor, may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this section.

The definition of an SAE encompasses both known and unexpected events.

2. Recording and Reporting Obligations for SAEs

The investigator will provide the IRB appropriate information concerning any findings that suggest there has been an SAE related to the study drug. Any adverse event that is considered serious must be reported within one working day (IMMEDIATELY) to the IRB. Serious adverse events (regardless of relationship) must also be reported to FDA. Clinical judgment should be exercised in deciding whether expedited reporting is appropriate in other situations. Important medical events that may not be immediately life- threatening, results in death, or hospitalization but may jeopardize the patient or may require intervention to prevent one of the outcomes listed above, should also be considered serious and reported to the sponsors.

5.4 Adverse Event Follow-up

After the completion of the Screening visit, all untoward medical events (as defined in Section 5.2 above) will be documented as Adverse Events through the 6 Mo visit. Any adverse events not resolved by the 6 Mo visit and considered to be potentially related to the study medication will be followed as clinically indicated until their resolution or, if non-resolving, until considered stable.

5.5 Confidentiality

All information provided by study participants will be kept confidential and identification numbers/initial will replace participant names once enrolled and at data entry. All study materials (including completed questionnaires, medical histories, severity scores and

adherence measures) will be kept in locked files accessible only to key study personnel. If the results of this study are written about in a journal article or presented at a professional meeting, individual participant names will not be used.

5.6 Participant Benefits

Subjects will be given bromonidine gel at no cost to them. Subjects may have disease improvement resulting from participation in the study. Subjects will also be seen frequently in the dermatology clinic with the opportunity to have questions about their disease answered. Subjects may withdraw from the study at any time without prejudice or impact on their future health care.

Subjects will not be compensated for participation in the study. Study medication and study visits are provided at no cost.

6.0 METHODOLOGY

6.1a Study Visits-

Visit 1-Screening/Baseline

The following procedures are required at the Screening visit:

1. Written informed consent.
2. Inclusion/Exclusion criteria must be met.
3. Demographics, medical history, current medications
4. Vital signs, weight and height
5. Urine pregnancy test if applicable
6. Clinician's Erythema Assessment (CEA)
7. IGA (for inclusion)
8. Lesion counts
9. Investigator VAS scale ratings of erythema
10. Patient Severity Assessment (PSA)
11 Subject VAS scale ratings of erythema
12. QOL survey (DLQI)
13. Weigh and dispense study medication
14. Internet randomization
15. Subjects will be asked to return in 3 months

Visit 2- Month 3

1. Review concomitant medications and adverse events
2. Clinician's Erythema Assessment (CEA)
3. Lesion counts
4. Investigator VAS scale ratings of erythema
5. Patient Severity Assessment (PSA)
6. Subject VAS scale ratings of erythema
7. Subject QoL questionnaire and Internet survey,
8. Weigh and collect/dispense study medication

Visit 3- Month 6

1. Review concomitant medications and adverse events
2. Clinician's Erythema Assessment (CEA)
3. Lesion counts
4. Investigator VAS scale ratings of erythema
5. Patient Severity Assessment (PSA)
6. Subject VAS scale ratings of erythema
7. Subject QoL questionnaire and Internet Survey
8. Weigh and collect study medication

6.2 Brimonidine Study Flow Chart

	Baseline	Month 3	Month 6
Inc/Exc, Demographics Medical Hx/Con meds	X		
Vital signs/weight/height	X		
Urine pregnancy test	X		
CEA, PSA	X	X	X
Lesion Counts	X	X	X
VAS scales for erythema (Subject and investigator)	X	X	X
Weigh/Dispense Med	X	X	
Weigh/Collect study med			X
QOL and Internet survey	X	X	X
Internet Randomization	X		
Con meds/ AEs		X	X

6.3 Termination of Study

Any subject may be discontinued from the study at any time at the discretion of the investigator if he/she feels it is in the best interest of that subject.

A discontinuation occurs when an enrolled subject ceases participation in the study prior to completion of the 6 month visit, regardless of reason. The investigator must determine the reason for discontinuation of the study. If the subject discontinues from the study because of a serious adverse event, the event must be reported immediately to the IRB and be recorded in the case report form.

Discontinuation

A subject must be discontinued from the study if he or she:

1. Uses any medications used in the exclusion criteria
2. Has an allergic reaction to the study medication
3. The investigator decides it is in the subject's best interest to discontinue
4. Study is cancelled by PI or by the Institutional Review Board

7.0 CONCOMITANT THERAPY

Concomitant medication is defined as any medication the subject takes that is not specified in the treatment protocol. All such medications must be recorded in the subject's medical record. The patient must not use any of the medications listed in the exclusion criteria, with one exception. If the subject complains of increased papules once baseline erythema has cleared and the patient desires treatment for the papules, a topical therapy (such as metronidazole) may be added per standard of care. This should help with subject retention over the course of the study while not interfering with the overall objective of the study to measure adherence to brimonidine.

The subject is not allowed to undergo radiation therapy, use cytostatic drugs, or any investigational agents for the duration of the study.

8.0 STUDY MANAGEMENT AND MATERIALS

8.1 Study Materials

Study medication will be provided to the subject by the sponsor..

8.2 Study Documentation

8.2.1 Case Report Forms (CRFs) and Source Document Completion and Transfer of Study Data

The investigator is required to prepare and maintain adequate and accurate case histories (i.e. medical records) designed to record all observations and other data pertinent to the study for each study participant. The medical records must contain adequate information to allow for verification of subject identity throughout the study. Investigators must retain a subject identification code list, should they need to contact the subjects after the study. This list should contain subject's name, study ID number and telephone number and/or address, and will be held in confidentially at the investigator's site after completion of the study.

A Source Document will be completed for each subject enrolled in the study. Each subject's source document will incorporate the safety and efficacy data points.

8.2.2 Transfer of Essential Study Documents

All essential documents (such as IRB approval, acknowledgements) are to be kept on site.

8.2.3 Archiving of Study Documentation

Study data and other essential documents should be retained for a minimum of two years after the last approval of a marketing application in an International Conference on Harmonization (ICH) region and until there are no pending or contemplated marketing applications in an ICH region. However, these documents should be retained for a longer period if required by the applicable legal requirements.

8.3 Monitoring and Quality Assurance

The review of the subjects' medical records will be performed in a manner to ensure that subject confidentiality is maintained. Inspections/audits, of the study date, will be carried out giving due consideration to data protection and subject confidentiality.

9.0 DATA ANALYSIS

Descriptive statistics (SAS Statistical System, Cary NC) will be utilized to provide an overview of efficacy and safety parameters, Baseline characteristics and QoL responses of study participants will be compared between the two groups. Descriptive statistics consisting of frequency tables and percents for categorical variables and means, medians, standard deviations, ranges, etc. for continuous variables will be tabulated. Simple comparisons of baseline characteristics between treatment groups will be made using the Chi-square tests for categorical variables and the two-sample t-tests or the Wilcoxon test for continuous variables.

10.1 REFERENCES

Balkrishnan R, Dugan E, Camacho FT, Hall MA. Trust and satisfaction with physicians, insurers, and the medical profession. Med Care 2003;41(9):1058-1064.

Atkinson MJ, Sinha A, Hass SL et al. Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease. Health Qual Life Outcomes 2004;2:12.:12.

Yentzer BA, Wood AA, Sagransky MJ, et al. An Internet-based survey and improvement of acne treatment outcomes. Arch Dermatol. 2011 Oct;147(10):1223-4.

Tanghetti EA, Jackson JM, Belasco KT, et al. Optimizing the use of topical brimonidine in rosaacea management: panel recommendations. J Drugs Dermatol. 2015: 14(1):33-40.

11.0 APPENDICES

Sample Internet Survey:
The above is a sample of the appearance of the internet survey sent to subjects. For this Rosacea study we would ask the following questions:

How many days did you apply the Brimonidine this week?

How well did it control the redness:
Completely, moderately, slightly, not at all, redness is worse
If worse, are the areas of worsening:
check at that apply: new areas, old areas that were already red.
When did the worsening occur:
When the medication was applied? After missing one or more doses?

Are you using the medication regularly or only as needed?

Have you had any side effects: If so what?

Have you been exposed to any of the following rosacea triggers this week? (Check all that apply)
Spicy food, hot food or drink, sun exposure, extreme hot or cold weather, alcohol

Appendix- Clinician Erythema Assessment scale

Date_____ Visit (circle one) Screen Baseline, Mo 3 Mo 6

CEA

0 = Clear	Clear skin with no signs of erythema
1 = Almost clear	Almost clear; slight redness
2 = Mild	Mild erythema, definite redness
3 = Moderate	Moderate erythema; marked redness
4 = Severe	Severe erythema; fiery redness

Appendix - Investigator Global Assessment

Date_____ Visit (circle one) Screen

For Face Check One:

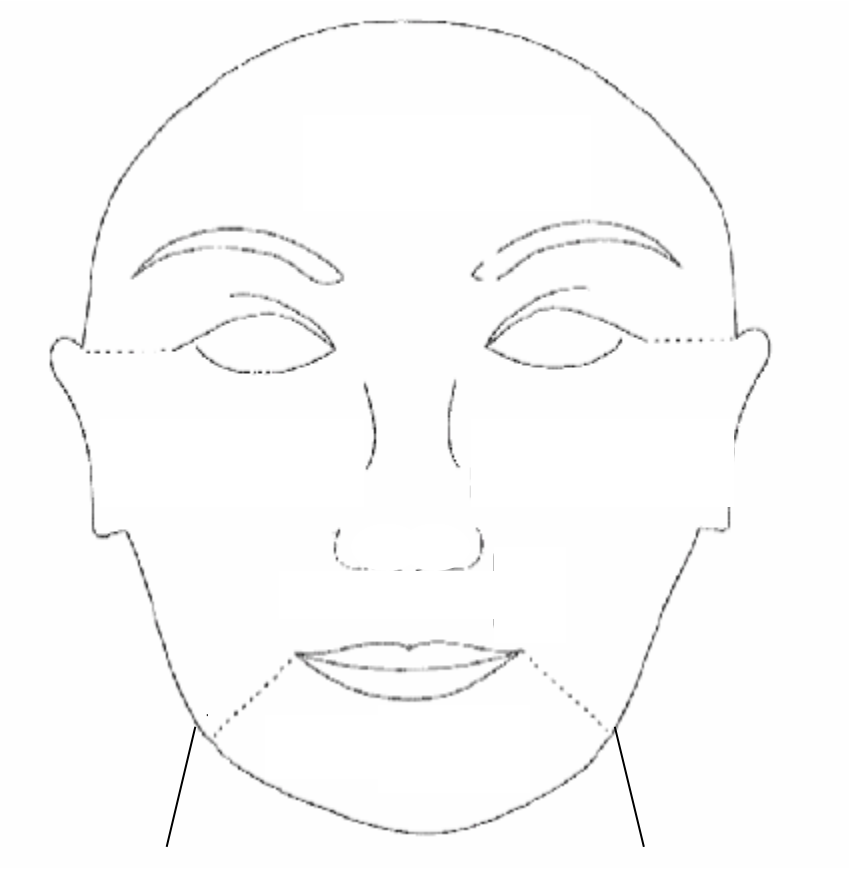
☐	**0**	Virtually no rosacea, i.e., no papules and/or pustules; no or residual erythema
☐	**1**	Rare papules and/or pustules; residual to mild erythema
☐	**2**	Few papules and/or pustules; mild erythema
☐	**3**	Distinct number of papules and/or pustules; mild to moderate erythema
☐	**4**	Pronounced number of papules and/or pustules; moderate erythema
☐	**5**	Many papules and/or pustules, occasionally with large inflamed lesions; moderate erythema
☐	**6**	Numerous papules and/or pustules, occasionally with confluent areas of inflamed lesions; moderate or severe erythema

Investigator Signature:_____Date:_____

Appendix **Lesion Count (Performed by investigator)**

Visit (Circle one): Screening/Baseline Month 3 Month 6

Instructions: Count lesions in each area on face (Forehead, L. cheek, R. Cheek, and chin) and record.



	Forehead	Left Cheek	Right Cheek	Chin	**Total**
# of Inflammatory Papules					
# of Inflammatory Pustules					
Telangiectasias					

Total Number of Papules and Pustules _____

Investigator Signature:_____ Date: _____

Investigator Visual Analogue Scale

Please mark on the line below to indicate on a scale of 0-10 how much redness the subject has:

No redness	Slight redness	Moderate redness	Excessive redness	Severe redness

0 5 10

Investigator Signature Date

SUBJECT-ASSESSED LOCAL TOLERABILITY

ITCHING and BURNING/STINGING

Date Visit (circle one) Screen Baseline, Mo 3 Mo 6

(Mark one box for Itching and one box for Burning/Stinging)

Grade	Itching	Burning/Stinging
0	None	None
1	Slight	Slight
2	Moderate	Moderate
3	Severe	Severe

Subject Visual Analogue Scale

Please mark on the line below to indicate on a scale of 0-10 how much redness that you have

No redness	Slight redness	Moderate redness	Excessive redness	Severe redness

0 5 10

Subject's Initials: Date:

PATIENT SEVERITY ASSESSMENT (PSA)

Date Visit (circle one) Screen Baseline, Mo 3 Mo 6

(Mark one box)

☐	0	= My face is basically free of rosacea, with only an occasional erythema
☐	1	= My face has occasional small red bumps, but there are no tender deep-seated bumps or cysts. My face may have mild redness.
☐	2	= My face has several to many red inflamed bumps and may have one deep seated bump or cyst. My face has mild to moderate redness
☐	3	= My face has many red inflamed bumps or pustules and may have several deep seated bumps or cysts. My face has moderate redness
☐	4	= My face has severe medium to large sized red inflamed bumps or pustules, My face has severe redness

My Redness is:

(Circle one)

Constant Intermittent (Comes and Goes)

Subject's Initials:_____ Date: _____

QUALITY OF LIFE SURVEY

The questions in this section are about your rosacea and its treatment.

1. **How long have you had rosacea?**

_____years(s) and_____month(s)

2. **Do you have attacks of facial redness and feeling hot which last for a few minutes?**
   - ☐ Yes
   - ☐ No (Skip to **question 5**)

3. **How often do you have these attacks?**
   - ☐ Rarely (not every month)
   - ☐ A few per month A
   - ☐ few per week A few
   - ☐ per day
   - ☐ More than 10 attacks per day

4. **How long do these attacks last?**
   - ☐ Less than a few seconds
   - ☐ More than a few seconds but less than 1 minute 1
   - ☐ to 15 minutes
   - ☐ More than 15 minutes

5. **How many small red blood vessels are visible on your face?**
   - ☐ I do not have visible vessels
   - ☐ A few A
   - ☐ lot

6. **How mild or severe is your burning and stinging sensation on your face?**
   - ☐ I do not have burning and stinging
   - ☐ Mild Moderate
   - ☐ Severe

7. **How mild or severe is your skin dryness or flaking on your face?**
   - ☐ I do not have dryness or flaking skin.
   - ☐ Mild Moderate
   - ☐ Severe
   - ☐

8. **Do you have any skin changes in places other than your face due to rosacea?**
   - ☐ Yes
   - ☐ No

9. Which rosacea skin change do you suffer from most? (Choose one)

- ☐ Redness
- ☐ Dryness
- ☐ Flaking skin
- ☐ Bumpiness
- ☐ Sensitivity
- ☐ Attacks of facial redness and warmth
- ☐ Swollen nose

10. Which of the following problems do you have with your eyes (check all that apply)?

- ☐ Gritty feeling
- ☐ Burning and stinging
- ☐ Dryness
- ☐ Itching
- ☐ Redness
- ☐ Sensitivity to light
- ☐ Blurred vision
- ☐ Small bumps on the edges of your eyelids (a stye)
- ☐ Swollen/puffy eyelids

11. When was the last time you went to a doctor or clinic for treatment of your rosacea? (This includes all visits during which your rosacea was talked about)

- ☐ Within the past month
- ☐ 1 to 3 months ago
- ☐ 3 to 6 months ago
- ☐ 6 months to 1 year ago
- ☐ Over 1 year ago

12. Are you a member of the National Rosacea Society?

- ☐ Yes
- ☐ No

13. Have you used any topical treatments for your rosacea (other than the study medication)?

- ☐ Yes
- ☐ No

Wake Forest University Health Sciences
Department of Dermatology
Winston-Salem, NC

This section is about the <u>impact</u> of rosacea and its treatment on your life. Below are listed everyday activities. Check the box that best describes <u>how much your rosacea or its treatment has interfered with each activity during the past four weeks</u>.

	Has not interfered at all	Has interfered a little	Has interfered a lot
1. Working around the house or yard			
2. Choosing which cosmetics to wear			
3. Shopping			
4. How often you wash your face			
5. How often you bathe or shower			
6. Being at work (or school)			
7. Maintaining employment (or studies)			
8. Being promoted or advancing in your job (studies)			
9. Having new employment opportunities			
10. Having a good relationship with your co-workers (fellow students)			
11. Shaking hands with others			
12. Going out in public			
13. Going to parties			
14. Being with family members			
15. Making new friends			
16. Dating			
17. Kissing or hugging			
18. Having intimate sexual relations			
19. Doing your hobbies			
20. Going out socially or to a special event			
21. Participating in sports or recreation activities			
22. Using public bathing facilities (pools, beach) or changing facilities (locker rooms)			
23. Traveling or vacationing			
24. Getting enough sleep			
25. Sleeping where you want			
26. Exercising as much as you want			
27. Making plans for the future			
28. Other (please explain):			