JOHNSON & JOHNSON CONSUMER INC.

SUMMARY CLINICAL STUDY REPORT

THE EVOLUTION OF THE SKIN MICROBIOME OF CHILDREN APPROXIMATELY AGES 8-10 YEARS OF AGE

PROTOCOL NUMBER: CCSSKA000104

Indication Studied:	Wound care
Developmental Phase of Study:	Not applicable
Study Initiation Date (First Subject Enrolled):	12-MAR-2017
Study Completion Date (Last Subject Completed):	23-MAR-2018
Status/Date	Final/29-JUN-2018
Approvers	[redacted]

Investigator: Bruce L. Moskovitz, MD

Study Center: Consumer Experience Center [redacted]

STUDY OBJECTIVES AND DESIGN

The primary objective of this study was to identify the predominant microflora inhabiting the skin of children who are now approximately ages 8-10 years [redacted] The secondary objectives were to compare the skin microbiome of children to their biological mothers, and to determine the variability of the skin microbiome and skin physiology across subjects and body sites. [redacted] The attached protocol provides the study design and procedures for the study. The statistical tables, figures, and listings are also attached.

SUMMARY RESULTS

Disposition

As shown in Statistical Table 1, eight children and eight mothers were enrolled in and completed the study. There were eight children and eight mothers included in the safety analysis set.

Demographics and Baseline Characteristics

Subject demographics and baseline characteristics are summarized in Statistical Table 2 Children were all nine years of age. Overall, 62.5% of the children were males, 100% were white, and 87.5% were not of Hispanic or Latino ethnicity.

The biological mothers of the children ranged from 38 to 52 years of age. The overall mean age of mothers was 42.9 years. Overall, 100% of the mothers were white and 87.5% were not of Hispanic or Latino ethnicity.

Protocol Deviations

Protocol deviations are listed by visit for each subject in Statistical Listing 2. A total of two protocol deviations were reported by two mothers. Both deviations were non-compliance deviations, subjects did not use the product as directed.

Skin Assessment Results

Skin assessments were provided for three skin sites on children (ie, lower volar forearm, forehead, and cheek) and two skin sites on their biological mothers (ie, lower volar forearm

and forehead) following a three-day wash-out period during which all subjects (ie, children and their mothers) used [redacted] cleanser (Visit 2).

Primary and secondary endpoints:

Microbial Community Diversity and Richness

Microbial Community Diversity and Richness analyses will be provided in a separate report.

Transepidermal Water Loss (TEWL)

Skin barrier function was assessed by TEWL measurements obtained at all test sites. Results are provided in Statistical Figure 1 for children and mothers, Statistical Table 3.1.1 for children, and Statistical Table 3.1.2 for mothers. In children, the mean TEWL measurement was 11.796 on the lower volar forearm, 17.742 on the forehead, and 14.883 on the cheek; the TEWL measurement was statistically significant lower for the lower volar forearm compared with the forehead ($p=0.031$) and there was no statistically significant difference between the cheek and the lower volar forearm or the forehead. In mothers, the mean TEWL measurement was statistically significantly ($p<0.001$) lower on the lower volar forearm (8.838) than on the forehead (23.304).

Skin pH

Results for skin pH measurements at all sites are provided in Statistical Figure 3 for children and mothers, Statistical Table 3.3.1 for children, and Statistical Table 3.3.2 for mothers. In children, the mean skin pH was 4.765 on the lower volar forearm, 5.163 on the forehead, and 4.935 on the cheek; there were no statistically significant differences between the three sites. In mothers, the mean skin pH was 5.165 on the lower volar forearm and 4.855 on the forehead; there was no statistically significant difference between the two sites.

Exploratory endpoints:

[redacted]

[redacted]

[redacted]

[redacted]

Safety Results

There were no adverse events reported in children or their mothers.

CONCLUSIONS

In children and their mothers, the TEWL measurement was statistically significantly lower on the lower volar forearm than on the forehead and in children there was no statistically significant difference in the measurements on the cheek compared with the lower volar forearm or forehead. Skin pH was similar between sites in both children and their mothers.

[redacted]

The wash-out treatment was well tolerated in this study. No adverse events were reported in children or their mothers.

This clinical study report was prepared by Laureen Klein, PharmD, a writing consultant, under the direction of the sponsor.

Date of Report: 29-JUN-2018

Attachments

Protocol - 14 February 2018

Statistical Tables

Statistical Figures

Statistical Listings

CLINICAL PROTOCOL

CCSSKA000104

The Evolution of the Skin Microbiome of Children Approximately Ages 8-10 Years of Age

Investigational Product Name:	Not Applicable
Protocol Number:	CCSKA000104
IND / IDE / EudraCT number:	Not Applicable
Phase:	Not Applicable
Version (Draft, Final, Amendment) Date	FINAL 14FEB2018

1. SYNOPSIS

Name of Sponsor/Company: Johnson & Johnson Consumer Inc.

Active Ingredient(s): Not Applicable

Title of Study

The Evolution of the Skin Microbiome of Children Approximately Aged 8-10 Years of Age

Countries: USA

Principal Investigator: Bruce L. Moskovitz, MD

Location:
Consumer Experience Center (CXC)
[redacted]

Phase of development: Not Applicable

Objectives:

The primary objective of this study is to identify the predominant microflora inhabiting the skin of children currently approximately 8-10 years of age[redacted]

Secondary objectives are to compare the skin microbiome of children to their biological mothers, and to determine the variability of the skin microbiome and skin physiology across subjects and body sites.

[redacted]

Methodology:
This will be a single center study. The study population will consist of up to 68 total subjects [redacted]
This includes up to 35 children, currently approximately 8 to 10 years of age and up to 33 biological mothers.
Subjects will be contacted by the study site for participation and to schedule a clinic visit.

Each subject will have 2 clinic visits. During Visit 1, each eligible subject will receive a bottle of [redacted] cleanser to be used during a 3 Day Wash-out period. All subjects will be asked not to bathe, cleanse, or shower on the day of Visit 2, and will not use any products on their skin prior to that appointment. During Visit 2, [redacted] g, bioinstrumental assessments, [redacted], and skin swabbing will be completed on mothers and their children. [redacted]

Number of subjects (planned): Up to 68 total subjects [redacted] may be eligible to participate. This includes up to 35 children and up to 33 biological mothers. Biological mothers may have more than one child participating.

Diagnosis and main criteria for inclusion:

Generally healthy, [redacted] participants [redacted]

Auxiliary Product Dosage and mode of administration:

[redacted], use as directed

Duration of Study: Each subject will participate for a total of 5 days. There may be more than 5 days between visit 1 and visit 2, but subjects will only have study related requirements either at the clinic or at home for a total of 5 days.

Data for evaluation:

Primary Endpoint

- Microbial Community Diversity on the volar forearm, forehead and cheek for children, based on the Shannon Index.

Secondary Endpoints

- Microbial Community Diversity on the volar forearm and forehead for adults, based on the Shannon Index.
- Microbial Community Richness on the volar forearm, forehead and cheek for children, based on the total number of different bacterial taxa detected in the sample.
- Microbial Community Richness on the volar forearm and forehead for adults, based on the total number of different bacterial taxa detected in the sample.

- Skin barrier function as assessed by mean TEWL measurements.
- Skin pH as assessed by mean skin pH.

[redacted]

Safety:

Adverse events will be monitored throughout the study.

Statistical methods:

Instrumental data will be analyzed by the Johnson & Johnson Consumer Inc., Quantitative Science group. The skin microflora, data will be analyzed and reported independently by external partners. [redacted]

TEWL, skin PH, [redacted], adverse events will be summarized for all subjects enrolled in this study.

Summary statistics for TEWL, skin pH, [redacted] will be provided by each test site for children and mothers, respectively. One way analysis of variance (ANOVA) will be applied for pairwise comparison between test sites. For the safety assessment, the number and percentage of subjects experiencing adverse events will be presented by system organ class and preferred term. A listing of adverse events will be provided.

2. STUDY FLOW CHART AND SCHEDULE OF ACTIVITIES

Visit Breakdown	Visit 1 Screening Visit	Visit 2 Clinical Evaluations Visit
Screener	X	
HIPAA/Informed consent with /Assent	X	
Demography	X	
Medical History	X	X
Visual Inspection	X	X
Inclusion/Exclusion Criteria	X	
Qualify	X	
dispensed		
Transepidermal Water Loss (Vapometer)		X
Skin Microflora Sampling (skin swabbing)		X
Skin pH measurements		X
Prior and Concomitant Medication	X	X
Adverse Event Assessment	X	X
Washout product use weighed & verified		X
Subject Disposition	X	X

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3. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

The following abbreviations and specialist terms are used in this study protocol.

Table 1: Abbreviations and Specialist Terms

Abbreviation or Specialist Term	Explanation
AE	Adverse Event
ANOVA	One way analysis of variance
CRF	Case Report Form
DPR	Designated Physician Representative
DSMB	Data Safety Monitoring Board
EDC	Electronic Data Capture
ESP	External Service Provider
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICD	Informed Consent Document
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
PI	Principal Investigator
PQC	Product Quality Complaint
SAE	Serious Adverse Event
TEWL	Transepidermal Water Loss

4. ETHICS

4.1. Institutional Review Board (IRB) / Independent Ethics Committee (IEC)

It is the responsibility of the Investigator to have prospective approval of the study protocol, protocol amendments, informed consent forms, and other relevant documents, e.g., advertisements, if applicable, from the IRB/IEC. All correspondence with the IRB/IEC should be retained in the Investigator File (Site Master File). Copies of IRB/IEC approvals should be forwarded to the Sponsor.

The only circumstance in which a protocol amendment may be initiated prior to IRB/IEC approval is where the change is necessary to eliminate apparent immediate hazards to the subjects. In that event, the Investigator must notify the IRB/IEC and the Sponsor in writing within 5 working days after implementation.

4.2. Ethical Conduct of the Study

The study will be performed in accordance with the protocol, The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use and applicable local regulatory requirements and laws.

4.3. Subject Information and Consent

All parties will ensure protection of subject personal data and will not include subject names or subject initials on any forms, reports, publications, or in any other disclosures. Each subject will be assigned a study number that is used in the Case Report Form (CRF) in lieu of the subject's name. In case of data transfer, the Sponsor will maintain high standards of confidentiality and protection of subject personal data.

The informed consent form must be agreed to by the Sponsor and the IRB/IEC and must be in compliance with current ICH E6, GCP, local regulatory requirements, and legal requirements and be in a language that the subject can read and understand.

For this study, biological mothers will provide consent for themselves and their child. The Investigator must ensure that each consenting adult is fully informed about the nature and objectives of the study and possible risks associated with participation by them and their child. The Investigator, or a person designated by the Investigator, will obtain written informed consent from each adult subject before any study-specific activity is performed. The informed consent form used in this study, and any changes made during the course of the study, must be prospectively approved by both the IRB and the Sponsor before use. Subjects will sign two original copies of the informed consent/assent. The Investigator will retain the original of each subject's signed consent form and each subject will be provided the second original copy.

Only subjects who provide Informed Consent or Assent (for children) will enter in the study.

4.4. Subject Written Assent

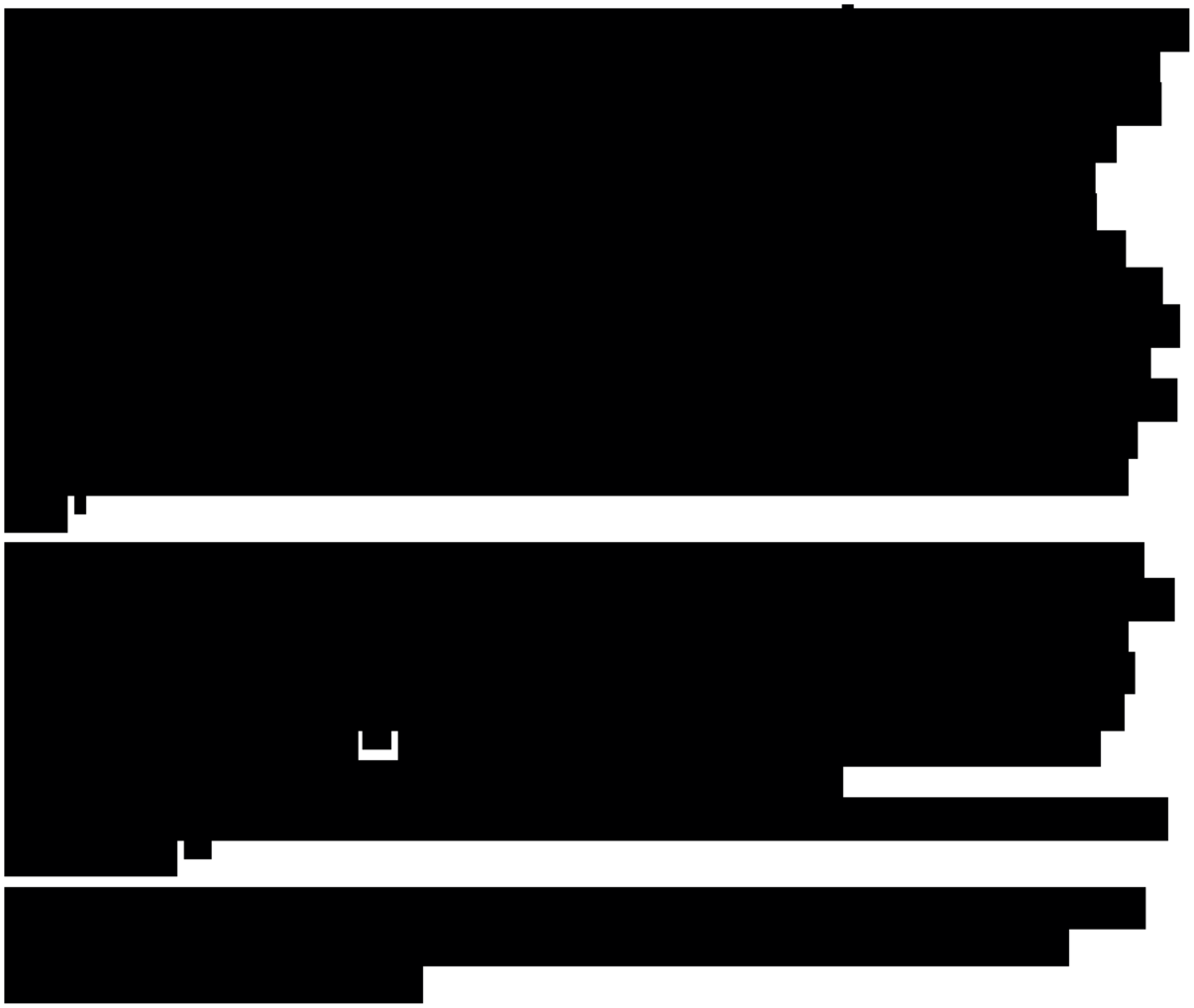
After the informed consent form is signed and dated by the parents and witnessed by a member of the investigator's clinical team, written assent to participate in the study must be obtained from prospective subjects who are below the age of legal consent yet old enough to understand details of the study. During the Assent process, the PI or designee will provide the minor with an assent document that explains, in concrete and age-appropriate terms, the purpose of the research, what they will be asked to do and what procedures they will undergo. The assent document will focus on the risks, benefits and alternatives to research participation as well as the confidentiality of any information obtained as a result of their participation. The PI or designee will explain the information, give the minor a chance to ask questions and ask the minor to indicate their assent by signing the assent document. The prospective subject will do this by signing an IRB/IEC-approved assent form or designated assent section of the informed consent, depending on individual institutional regulations. A witness must also sign and date the assent form. The original signed assent form will be retained by the investigator as part of the source documents and will be available for review by the Sponsor. A copy of the signed and dated assent form will be given to the subject. Assent by the subject acknowledges willingness to participate, but does not necessarily constitute an understanding of the procedures and hazards of the study.

5. STUDY ADMINISTRATIVE STRUCTURE

Details on the administrative structure of the study (e.g., Principal Investigator (PI)/study site personnel, the Sponsor's study team, and the external service providers [ESPs]) will be included in the study contact list. The study contact list will also include contact information for the Sponsor, Investigator(s), Monitor(s), Clinical and Bioanalytical Laboratories, and IRB(s), as well as the names and titles of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor. This list will be maintained in the trial and site master files throughout the study.

6. INTRODUCTION

Human skin is colonized by a complex microbial ecosystem. Colonization begins at birth and the balance of bacterial species inhabiting skin continually evolves in response to age, product usage, disease conditions, body site and environmental change.



7. STUDY OBJECTIVES AND ENDPOINTS

The primary objective of this study is to identify the predominant microflora inhabiting the skin of children who are now approximately ages 8-10, [redacted]

Secondary objectives are to compare the skin microbiome of children to their biological mothers, and to determine the variability of the skin microbiome and skin physiology across subjects and body sites.

[redacted]

7.1 Endpoints

Primary Endpoint

- Microbial Community Diversity on the volar forearm, forehead and cheek for children, based on the Shannon Index.

Secondary Endpoints

- Microbial Community Diversity on the volar forearm and forehead for adults, based on the Shannon Index.
- Microbial Community Richness on the volar forearm, forehead and cheek for children, based on the total number of different bacterial taxa detected in the sample.
- Microbial Community Richness on the volar forearm and forehead for adults, based on the total number of different bacterial taxa detected in the sample.
- Skin barrier function as assessed by mean TEWL measurements.
- Skin pH as assessed by mean skin pH.

[redacted]

8. INVESTIGATIONAL PLAN

8.1. Overall Study Design and Plan

The study population will consist of up to 35 children approximately 8-10 years old and their biological mothers (up to 33) [redacted]

Subjects will report to the study center for a total of 2 scheduled visits: Screening/Visit 1 and Visit 2 (after a 3day Wash-out period). Following consent or assent, each participant will receive a bottle of [redacted] cleanser at Screening (Visit 1) to be used for a 3-day Wash-out period. During this washout, subjects will replace their normal cleansing products with the provided wash for use in their normal regimen. Subjects will be asked not to bathe, cleanse, or shower on the day of Visit 2, and will not use any products on their skin prior to that appointment. During Visit 2, [redacted], bioinstrumental skin assessments, [redacted], and skin swabbing will be completed on mothers and their children.

[redacted]

8.2. Subject Inclusion Criteria

This clinical study can fulfill its objectives only if appropriate subjects are enrolled. The following eligibility criteria are designed to select subjects for whom protocol treatment is considered appropriate. All relevant medical and non-medical conditions should be taken into consideration when deciding whether this protocol is suitable for a particular subject. No waivers to inclusion or exclusion criteria will be permitted.

Subjects (Children and their biological mothers) must meet all of the following inclusion criteria (and none of the exclusion criteria) to be eligible for enrollment into the study:

1. Biological mothers must be able to comprehend and follow the requirements of the study (including availability on scheduled visit dates) based upon research site personnel's assessment;
2. Biological mothers and their children must be able to read and understand the local language;
3. Biological mother must be able to provide a signed and dated informed consent form [redacted] prior to any study-related procedures; children will be required to provide their Assent;
4. Willing and able to comply with all study procedures and attend the scheduled visits for the duration of the study;
5. [redacted]

6. Must be the biological mother of a child (approximately age 8-10 years) enrolled in the study;
7. Biological mothers must not change current method of birth control during their participation;
8. Must be in generally good health as determined from site medical staff based on medical history reported by the subject;
9. All subjects are to have normal healthy skin and no presence of pre-existing or dormant dermatologic skin conditions;
10. Willing to use only the provided cleansing product during the washout time period;
11. Willing to refrain from topical product use on the skin for the duration of the study. Topical products that should **not** be used include moisturizers, lotions, sunscreens, oils, tanners;
12. Willing to refrain from swimming, using hot tubs, excessive sun exposure or tanning beds during the course of this study;
13. Must agree to the possible subsequent use of the data in medical or scientific journals and medical or scientific presentation materials and advertising materials. All subject identities will remain confidential.

8.2.1. Subject Exclusion Criteria

Subjects (children and their biological mothers) presenting with any of the following, as applicable, will not be included in the study:

1. Suspected alcohol or substance abuse (e.g., amphetamines, benzodiazepines, cocaine, marijuana, opiates);
2. Pregnant or Lactating, or planning on becoming pregnant;
3. Known sensitivity to any ingredient in the washout product;
4. Significant unstable or uncontrolled medical condition which may interfere with a subject's participation in the study;
5. Participation in any other clinical study within 30 days of Visit 1;
6. Presents with a skin condition that may influence the outcome of the study (specifically psoriasis, eczema, atopic dermatitis, cutaneous xerosis, erythema, active skin cancer) as determined by the Investigator or medically qualified person;
7. Who are currently using antibiotics (topical or oral), steroidal (topical or oral) or medicated soaps within the last 30 days.
8. Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.

8.2.2. Subject Withdrawal Criteria

Subjects have the right to withdraw from the study at any time for any reason without compromising their rights to receive further treatment. The Investigator and/or the Sponsor may terminate a subject from investigational treatment and/or study follow-up in the event of any of the following:

- Medical reasons considered significant by the subject, Investigator and/or the Sponsor, which may include, an adverse event, inter-current illness or medical reasons unrelated to the study
- Nonmedical reasons (e.g., subject request or noncompliance with the treatment procedure as determined by the investigator, the Sponsor and/or subject)
- Serious eligibility or on-study violation of the protocol
- Administrative or other reasons

Should a subject decide to withdraw from the study at any point, all efforts should be made to complete all end of study assessments (if subject cannot come to study site, a telephone call to collect information could be performed). In case of questions surrounding the circumstances that a subject needs to be withdrawn from the study (e.g., protocol deviation), the Sponsor, or the Sponsor representative should be consulted. The reason for withdrawal and all communications with the subject should be documented in the subject's source document and in the Subject Disposition CRF.

9. INVESTIGATIONAL PRODUCT MATERIALS AND MANAGEMENT

9.1. Investigational & Auxiliary Products

There are no active treatment products to be used in this study.

Each subject will be dispensed [redacted]

Table 2: [redacted] Auxiliary Product

	Auxiliary Product
Product Name:	[redacted]
Dosage Form:	N/A
Directions for Use:	Refer to commercial product label
Route of Administration:	Topical
Physical Description:	Clear amber viscous liquid
Manufacturer:	[redacted]

9.2. Auxiliary Product Packaging and Labeling

A label will be affixed to each product to identify it as part of a clinical evaluation, and will contain the following information:

For the [redacted] cleanser:

- Product Identity: [redacted]
- Sponsor
- Protocol #
- Site contact information
- Directions for use
- Storage Information

9.3. Study Product Storage and Accountability

There are no investigational products in this study. The Investigator, or a designated study staff, will ensure that the Auxiliary Wash-out product are stored in a secured area, at room temperature, and in accordance with applicable regulatory requirements.

The Investigator must maintain adequate records documenting the receipt, use, loss, or other disposition of the Wash-out product on the Investigational Product Accountability Log supplied by the Sponsor or Designee. The log must identify the auxiliary products, and account for its disposition on a subject-by-subject basis, including specific dates and

quantities dispensed. Subjects must bring the Wash-out product with them to Visit 2, but will be allowed keep the products after this visit. The log must be signed by the individual who dispensed/retrieved the study product, and copies must be provided to the Sponsor for the Study Master File. At the end of the study, the Sponsor will provide instructions as to disposition of any unused auxiliary wash-out product.

9.4. Product Quality Complaints

A Product Quality Complaint (PQC) is any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a product after it is released for distribution

Any PQC discovered during the initial inventory of study supplies should follow the instructions provided on the receipt letter; no PQC form should be filed for issues identified when opening or unpacking a shipment. Subsequently, any observation of a PQC requires immediate notification to the study manager via a completed PQC form and telephone call. The PI or designee should complete, sign and forward a copy of the PQC form, via an agreed upon secure exchange, to the study manager listed below.

In addition, PQC information must be included on the Investigational Product Dispensing and Accountability Log or equivalent in the comments field. The Study Manager listed can assist the site staff or answer questions related to this process. To aid in the initial conversation and understanding of a PQC, the site staff may be asked to photograph the issue and send it to the Study Manager.

When enrolling subjects into this study it is the site's responsibility to instruct subjects not to use the product if they have a concern related to the product such as an issue with the labeling, auxiliary washout product or package integrity and to immediately report it using the instruction on the Informed Consent or product label.

10. STUDY PROCEDURES

10.1. Overview

Collection of adverse events and concomitant medications will start after the study specific informed consent documents have been signed and continue until completion of the follow-up procedures. The schedule of activities summarizes the study procedures.

Subjects [redacted] who still meet all inclusion and none of the exclusion criteria for this study will be eligible to participate. [redacted] participants will be contacted via phone to gauge interest in participating and to schedule a clinic appointment.

10.2. Describe the Procedures at Each Visit

10.2.1. Visit 1 – Screening Visit

Potential subjects (children and their biological mothers) will qualify for the study during Visit 1 only after they complete the Informed Consent Process and have signed the Informed Consent and Assent, and they meet all Inclusion criteria and none of the exclusion criteria. The following screening assessments will be performed at Visit 1:

- Obtain informed consent – biological mothers will be provided an approved Informed Consent Document (ICD) and children will be provided an approved Assent form, given sufficient time to read the ICD and opportunity to discuss any questions or concerns with the investigator. Those who agree to participate will sign the ICD or Assent before any study-related procedures are performed. Subjects will be given a copy of their signed ICD or Assent;
- Collect demographic information including height and weight;
- Collect concomitant medication (within 30 days) and significant medical history
- Visual inspection of the test sites will be done by the investigator. Any sites with rashes or open wounds will be noted on the source document for exclusion from testing;
- Ensure that the subject meets all inclusion and none of the exclusion criteria.
- Once the subject has met all eligibility criteria, the subject will be given a bottle of [redacted] cleanse. Biological mothers and each child will be provided their own bottle of wash and asked to return with it to the site for Visit 2.
- Biological mothers will be provided written and verbal instructions for themselves and their child for using the wash, and will be instructed not bathe, cleanse, shower or use any type of product on the whole body the day of the return visit prior to the appointment time.
- Visit 2 will be scheduled

10.2.2. Visit 2

- Update any changes in medical history or prior medications and non-drug therapies and confirm subject eligibility
- Assess for adverse events since last visit
- Subjects will return the [redacted] products given to them at Visit 1. Study staff will weigh each returned bottle to verify use.
- Subjects will acclimate for 20 minutes prior to skin measurements.
- [redacted]
- The following describes the schedule of observational endpoints that will be taken during this visit for biological mothers and their children.
- Trained study staff will complete the following testing:

Child/Adolescent Subjects:

- [redacted]
- Transepidermal Water Loss (TEWL; Vapometer): noninvasively measures transepidermal water loss, which is a measure of skin barrier function. 3 measurements per site will be taken for the lower volar forearm, the forehead and the cheek.
- [redacted]
- Skin pH (Skin pH Meter PH905): noninvasively measures skin surface pH. 5 values per site will be recorded for the lower volar forearm, the forehead and the cheek.
- Microbiology swabs: cotton swabs will be used to collect bacteria from the skin surface. 3 swabs per site will be taken from the lower volar forearm, and 2 swabs will be taken from the forehead and the cheek.

Biological Mothers:

- [redacted]

[redacted]

- Transepidermal Water Loss (TEWL; Vapometer): noninvasively measures transepidermal water loss, which is a measure of skin barrier function. 3 measurements per site will be taken for the lower volar forearm and the forehead.

[redacted]

- Skin pH (Skin pH Meter PH905): noninvasively measures skin surface pH. 5 values per site will be recorded for the lower volar forearm and the forehead.
- Microbiology swabs: cotton swabs will be used to collect bacteria from the skin surface. 2 swabs per site will be taken from the lower volar forearm and forehead.

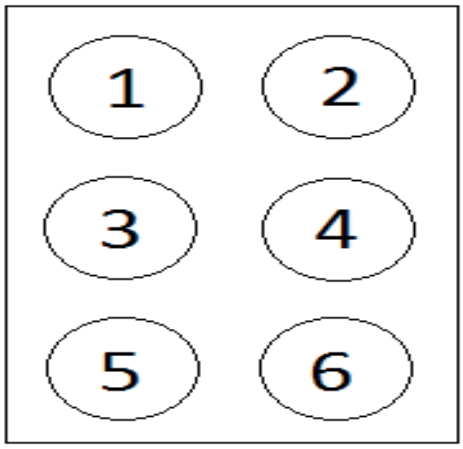
Measures Map

An outline of the test site will be created on each subject's sample site using a template. The template can be placed horizontal or longitudinal depending on the skin site and determination of study staff.

Children will have all 3 skin sites investigated: Forehead, cheek, and lower volar forearm. Biological mothers will have 2 sites investigated: lower volar forearm and Forehead.

Each part of each test site will have the measurements taken as described below.

Sample Locations Template
Site 1: Vapometer TEWL
Site 2: Skin pH Meter PH 905
Site 3/4: Microbiology Swabs
Site 5: [redacted]
Site 6:



10.3. Follow-up Visit

Any subjects who have clinically relevant, treatment-related Adverse Events upon study end will be contacted via phone to follow up regarding resolution of the Adverse Event. All follow-up information will be documented as applicable.

10.4. Life Style Guidelines

Biological mothers will be instructed to follow both theirs and their child's normal skin hygiene regimen schedule, substituting [redacted] for their normal cleanser during the washout period.

Subjects must also refrain from swimming, using hot tubs, tanning beds or exposure to excessive sun during the course of this study.

Subjects will be instructed not to bathe, cleanse, or shower on the day of Visit 2, and will not use any products on their skin prior to that appointment. Meals and Dietary Restrictions

There are no dietary restrictions for subjects who choose to participate in this study.

10.4.1. Alcohol, Caffeine and Tobacco Consumption / Restrictions

There are no alcohol or caffeine limits or restrictions placed on subjects who choose to participate in this study. Subjects with suspected alcohol abuse will be excluded from the study.

10.4.2. Physical Activity Requirements / Restrictions

There are no physical activity requirements or restrictions for subjects who choose to participate in this study.

10.5. Method of Assigning Subject Numbers

Each subject will use the same subject number that was assigned in the first trial. Participants will be designated with a subject ID beginning with the four digit center ID, e.g. "1001", followed by a four-digit unique subject identifier consisting of 1NNN, where NNN is their [redacted] 3-digit ID.

Once a subject number has been assigned to a subject, it cannot be reassigned to another subject.

10.6. Previous and Concomitant Medications

Previous medication includes any medication taken within 30 days prior to the first use of the washout product. The subject will be questioned about prior medications at screening.

Concomitant medications will be defined as any medication taken by the subject after Visit 1. The subject will be questioned about any changes in current medications at Visit 2.

Non-Drug Therapies/Procedures will be defined as any non-invasive/invasive procedure undergone by the subject after Visit 1. The subject will be questioned about any non-drug therapies or procedures at Screening (Visit 1), and about any changes at Visit 2. The use of permitted concomitant therapy must be explained in detail, including prescription and nonprescription investigational products, non-investigational product therapy, dietary and herbal supplements, as appropriate. All subjects will be questioned about concomitant medication at each clinic visit.

Medications or non-drug therapies used within 30 days before the Screening visit (Visit 1) and during the study will be recorded in the source document.

10.7. End of Study Evaluation

The End of Study is defined as last subject last visit.

11. ASSESSMENTS

11.1.

11.1.1.

11.1.1.1.

[redacted]

11.1.2. Vapometer® (Delfin)

Transepidermal water loss (TEWL) measurements are performed in many laboratories and discussed in the literature as a method to characterize barrier function of the stratum corneum (SC) There are various types of instruments which measure TEWL. All instruments contain relative humidity and temperature sensors and measure flux density (g/m^2h) through the SC. The Delfin Vapometer® is the only fully-portable instrument available for the measurement of TEWL values. It is a closed-chamber instrument which measures water vapor flux into a chamber, calculating TEWL values based on changes in relative humidity of the chamber, with a range of 3-200 g/m^2h. The Vapometer is held vertically and the chamber is placed gently on the surface of the skin for 7-16 seconds, after which the TEWL reading is displayed. TEWL readings will be done in triplicate for each test site and each reading will be recorded on the source document.

11.1.3. [redacted]

[redacted]

11.1.4. Skin pH

The Skin-pH-Meter® is a commercially available instrument (PH 905, Courage & Khazaka, Germany) that is designed to measure the pH-level on the skin surface. The Skin-pH-Meter® measurement range is: pH 0 to pH 11 Accuracy: ± pH 0.1. Measurements with the Skin-pH Meter® are obtained by using a probe consisting of a single glass rod containing the sensor elements. The planar design of the probe head allows direct measurement on the skin.

Readings are displayed on the instrument panel and manually recorded the source document. Five consecutive readings will be obtained within each test site.

11.1.5. [redacted]

[redacted]

11.1.6. Skin Microflora Sampling

Skin microflora will be sampled using a swab technique. 2 control swabs will be prepared for each day of sampling. Test areas of the skin will be sampled by swabbing with a polyester-tipped pledget that will be dipped into an aliquot of saline (i.e. 0.15 M NaCl) for thirty-seconds. The head of each swab is placed into a sterile microcentrifuge tube and aseptically cut from the handle before closing the tube lid. Samples will be frozen at negative eighty (-80°) Celsius until shipment to an external laboratory on dry ice for DNA extraction and pyrosequencing.

When packing, a sample submission list will be included for RTL. Microcentrifuge tubes will be placed in cryovial boxes with the protocol name and number written on the outside of the box. Cryovial boxes will then be inserted into a zip lock bag and sealed. The shipping box will be partially filled with dry ice, cryovial boxes will be placed right-side up on top of the ice and additional dry ice will be added to cover the contents of the shipping box.

Samples will be shipped to:

Research and Testing Laboratories, LLC

[redacted]

The results of these tests will be analyzed and summarized in a report which will be appended to the clinical study report.

11.1. Safety Assessment

At the Screening visit (Visit 1), the Investigator will perform an examination to make sure the subject has generally healthy skin in order to participate in the study.

The Investigator is to report all directly observed adverse events and all adverse events spontaneously reported by the study subject. In addition, each study subject will be questioned about adverse events. The Investigator's assessment of causality must be provided for all adverse events.

12. ADVERSE EVENT REPORTING

12.1. Introduction

All observed or volunteered AEs regardless of suspected causal relationship to any supplied product(s) will be reported as described in the following sections. For all AEs, the Investigator or medically qualified individual (MD/DO) must pursue and obtain information adequate both to determine the outcome of the AE and to assess whether it meets the criteria for classification as a Serious Adverse Event (SAE) requiring immediate notification (within 24 hours) to the Sponsor or its designated representative. For all AEs, sufficient information should be obtained by the Investigator or medically qualified individual (MD/DO) to try to determine causality. The Investigator is required to assess causality. For AEs with a suspected causal relationship to the investigational product, follow-up by the Investigator or medically qualified individual (MD/DO) is required until the event or its sequelae resolve or stabilize at a level acceptable to the Investigator, and the Sponsor concurs with that assessment.

12.2. Reporting Period

All AEs, whether serious or non-serious will be recorded on the CRF in the AE section beginning from the time the informed consent is signed and dated. Informed consent is considered the point at which the subject is participating in the clinical study and all events are captured even if it is prior to undergoing any study-related procedure and/or receiving investigational product or investigational device. Non-serious adverse events will be reported through the subject's last study visit (or termination if the subject terminates early from the study for any reason). Spontaneous reports of serious AEs will be collected through and including 30 calendar days after administration of the subject's last dose or exposure to investigational product or study procedure.

Serious AEs require immediate notification to the Sponsor or its designated representative. Any SAE occurring any time after the reporting period must be promptly reported if a causal relationship to study product is suspected.

12.3. Definition of an Adverse Event

An AE is any untoward medical occurrence that occurs in a subject after they have signed an informed consent for a trial involving an investigational product or medical device. Any AE that occurs after the informed consent has been signed, until first usage of investigational product, will be considered non-treatment emergent and cannot (by virtue of time of occurrence) have a causal relationship with the investigational product.

The event does not need to have a suspected causal relationship with the investigational product or device. Therefore, an AE can be any unfavorable and unintended sign, symptom, disease or injury temporally associated with the use of an investigational product or device, whether or not related to the investigational product or device. Examples of adverse events include but are not limited to:

- Abnormal test findings,
- Clinically important symptoms and signs,
- Changes in physical examination findings,
- Hypersensitivity, and
- Progression/worsening of underlying disease.
- Additionally, they may include the signs or symptoms resulting from:
- Overdose,
- Withdrawal,
- Abuse,
- Drug misuse,
- Drug interactions,
- Medication errors,
- Product dependency,
- Exposure *in utero*, and
- Study related procedure.

12.4. Abnormal Test Findings

The criteria for determining whether an abnormal objective test finding should be reported as an adverse event are as follows:

- Test result is associated with accompanying symptoms, and/or
- Test result requires additional diagnostic testing or medical/surgical intervention, and/or
- Test result leads to a discontinuation from the study, significant additional concomitant treatment, or other therapy, and/or
- Test result is considered to be an adverse event by the Investigator or the Sponsor.

Merely repeating an abnormal test, in the absence of any of the above conditions, does not constitute an adverse event. Any abnormal test result that is determined to be an error does not require reporting as an adverse event.

12.5. Serious Adverse Events (SAE) for Cosmetics

An AE or suspected adverse reaction is considered "serious" if, in the view of either the Investigator (MD/DO) or the Sponsor, it results in any of the following outcomes:

- Results in death,
- Is life-threatening (immediate risk of death),

- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions,
- Results in congenital anomaly/birth defect,
- Is considered medically significant (medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not result in death, be life-threatening or require hospitalization but may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the other outcomes listed above). Examples of such medical events include allergic bronchospasm requiring intensive treatment in an Emergency Room or at home, blood dyscrasia, or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse, or malignancy), or,
- Is a suspected transmission of any infectious agent via a medical product (medically significant) and should be reported as an SAE in the category 'Other medically important conditions.'

12.6. Hospitalization

Adverse events reported from clinical studies associated with hospitalization or prolonging hospitalization are considered serious. Any initial admission (even if less than 24 hours) to a healthcare facility meets these criteria. Admission also includes transfer within the hospital to an acute/intensive care unit (e.g., from the psychiatric wing to a medical floor, medical floor to a coronary care unit, neurological floor to a tuberculosis unit). Hospitalization does not include the following:

- Rehabilitation facilities,
- Hospice facilities,
- Respite care (e.g., caregiver relief),
- Skilled nursing facilities,
- Nursing homes,
- Emergency room visits (unless the reason for the emergency room visit meets one of the other outcomes in the definition of serious), and/or
- Same day surgeries (as outpatient/same day/ambulatory procedures)
- Hospitalization or prolongation of hospitalization in the absence of a precipitating, clinical AE is not in itself a SAE. Examples include:
- Admission for treatment of a pre-existing condition not associated with the development of a new AE or with a worsening of the pre-existing condition (e.g., for work-up of persistent pre-treatment lab abnormality),

- Social admission (e.g., subject has no place to sleep),
- Administrative admission (e.g., for yearly physical exam),
- Protocol-specified admission during a clinical study (e.g., for a procedure required by the study protocol),
- Optional admission not associated with a precipitating clinical AE (e.g., or elective cosmetic surgery),

Pre-planned treatments or surgical procedures should be noted in the baseline documentation for the entire protocol and/or for the individual subject.

- Diagnostic and therapeutic non-invasive and invasive procedures, such as surgery, should not be reported as AEs. However, the medical condition for which the procedure was performed should be reported if it meets the definition of an AE. For example, an acute appendicitis that begins during the AE reporting period should be reported as the AE and the resulting appendectomy should be recorded as treatment of the AE.

12.7. Resolution

The Investigator will be required to assess the outcome of the AE as one of the following:

- Resolved,
- Not Resolved,
- Fatal,
- Resolved with sequelae,
- Resolving, or
- Unknown.

Any causally-related AEs unresolved upon completion of the last study visit will be followed up by the study staff until the event or its sequelae resolve or stabilize at a level acceptable to the Investigator and recorded on the CRF. An event that is assessed as resolved with sequelae or resolving indicates that the subject has stabilized to a level acceptable to the Investigator and has concurrence by the Sponsor.

12.8. Severity Assessment

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The severity of AEs from any supplied product (cosmetic – Wash-out product) will be assessed by the Investigator or medically qualified individual (MD/DO) using the following general categorical descriptors:

MILD: Awareness of symptoms that are easily tolerated, causing minimal discomfort and not interfering with subject's usual function or normal everyday activities

MODERATE: Sufficient discomfort is present to cause interference to some extent with subject's usual function or normal everyday activity

SEVERE: Extreme distress, causing significant impairment of functioning or incapacitation; interferes significantly with subject's usual function; prevents normal everyday activities

Note the distinction between the severity and the seriousness of an AE. A severe event is not necessarily a serious event. For example, a headache may be severe (interferes significantly with subject's usual function) but would not be classified as serious unless it met one of the criteria for SAEs, listed above.

12.9. Causality Assessment

- The Investigator's or medically qualified individual's (MD/DO) assessment of causality for investigational product (i.e., relationship to investigational product) must be provided for all AEs (serious and nonserious). An Investigator's causality assessment is the determination of whether there exists a reasonable possibility that the investigational product caused or contributed to an AE.
- Not Related - An AE that is not related to the use of the cosmetic – Wash-out product.
- Doubtful - An AE for which an alternative explanation is more likely, e.g., concomitant drug(s), concomitant disease(s), or the relationship in time suggests that a causal relationship to investigational product is unlikely.
- Possible - An AE that might be due to the use of the cosmetic-Wash-out product. An alternative explanation, e.g., concomitant drug(s), concomitant disease(s), is inconclusive. The relationship in time is reasonable; therefore, the causal relationship to investigational product cannot be excluded.
- Probable - An AE that might be due to the use of the cosmetic-Wash-out product. The relationship in time is suggestive (e.g., confirmed by dechallenge) and an alternative explanation is less likely, e.g., concomitant drug(s), concomitant disease(s).
- Very Likely - An AE that is listed as a possible adverse reaction and cannot be reasonably explained by an alternative explanation, e.g., concomitant drug(s), concomitant disease(s). The relationship in time is very suggestive (e.g., it is confirmed by dechallenge and rechallenge) for a causal relationship to the cosmetic-Wash-out product.

If the Investigator determines a SAE is associated with study procedures, the Investigator must record this suspected causal relationship in the source documents and CRF, as appropriate, and report such an assessment in accordance with the SAE reporting requirements, if applicable.

12.9.1. Withdrawal Due to Adverse Events

When a subject withdraws due to a SAE, the SAEs must be reported in accordance with the reporting requirements defined below.

12.9.2. Eliciting Adverse Event Information

The Investigator is to report all directly observed AEs and all AEs spontaneously reported by the study subject. In addition, each study subject will be questioned about AEs.

12.9.3. Reporting Requirements

Each AE is to be assessed to determine if it meets the criteria for a SAE. If a SAE occurs, expedited reporting will follow local and international regulations, as appropriate.

All AEs will be reported on the AE page(s) of the CRF. A Clinical Serious Adverse Event (SAE) Report Form must also be completed if the event is considered to be serious. It should be noted that this Clinical SAE Report Form for collection of SAE information is not the same as the AE CRF. Where the same data are collected, the forms must be completed in a consistent manner. For example, the same AE term should be used on both forms. Adverse events should be reported using concise medical terminology on the CRFs as well as on the form for collection of SAE information.

12.9.3.1. Serious Adverse Event Reporting Requirements

If a SAE occurs, the Sponsor is to be initially notified by telephone immediately upon awareness of the event by the Investigator's site. Within 24 hours of the Investigator site's awareness of the event, the study site must send the Sponsor the Clinical SAE Report Form (via a secure e-mail). This timeframe also applies to additional new information (follow-up) on previously forwarded SAE reports as well as to the initial and follow-up reporting of EIU cases. In the rare event that the Investigator's site does not become aware of the occurrence of a SAE immediately (e.g., if an outpatient study subject initially seeks treatment elsewhere), the Investigator's site is to report the event immediately after learning of it as described and document the time of the study site's first awareness of the AE.

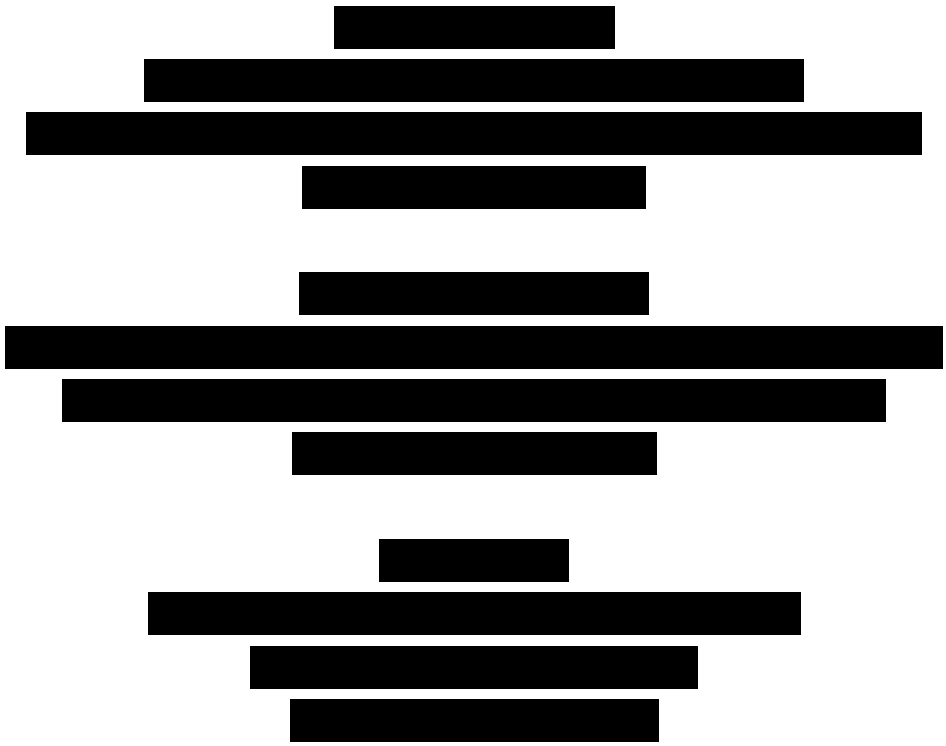
For all SAEs, the Investigator is obligated to pursue and provide information to the Sponsor in accordance with the timeframes for reporting specified above. In addition, an Investigator may be requested by the Sponsor to obtain specific additional follow-up information in an expedited fashion. This information may be more detailed than that captured on the AE case report form. In general, this will include a description of the adverse event in sufficient detail to allow for a complete medical assessment of the case and independent determination of possible causality. Information on other possible causes of the event, such as concomitant medications and illnesses must be provided. In the case of a subject death, a summary of available autopsy findings (if available) and death certificate should be collected if permission is obtained from the subject's family. For a hospitalization, a copy of the hospital discharge summary should be requested. If obtained, these documents (with subject's personal identifiers redacted) should be submitted as soon as possible to the Sponsor or its designated representative.

Appropriate SAE forms will be provided to the study site at the initiation of the study. Upon notification of an SAE at the study site, the Investigator or designated study site staff should call and speak to their Sponsor's study team contact immediately to initially notify them of the SAE.

Within 24 hours of awareness of the event, the Investigator or designated study site staff:

- Complete the Clinical SAE Report Form [that has been provided to you by the Sponsor or their designee] with as much information as possible, however at a minimum, the subject identification number, name of product, SAE, and name of reporter are required);
- Ensures the Investigator signs the Clinical SAE Report Form **prior to** sending to the Sponsor;
- Scans and send via secure email the Clinical SAE Report Form to the Sponsor contacts.

The Sponsor contact information:



13. STATISTICS

The skin microflora, data will be analyzed and reported independently by external partners or internal partners. [redacted] The rest of the data will be managed and analyzed by the Sponsor's Quantitative Sciences Department.

13.1. Sample Size Determination

This study is a follow up study [redacted] No sample size justification is needed for this study.

13.2. Statistical and Analytical Plans

Demographic and baseline characteristics will be summarized by children and mother respectively.

Instrumental data, demographic data and safety data analysis will be based on all enrolled subjects.

Summary statistics for TEWL, skin PH, [redacted], will be provided for each test site for children and mother, respectively. One way analysis of variance (ANOVA) will be applied for pairwise comparison between test sites. Tables and listings for each measurement will be provided.

All statistical tests will be 2-sided at significance level alpha=0.05. No multiple testing corrections will be considered in the study.

13.2.1. Safety Analysis

The safety analysis will be based on all enrolled subjects.

13.2.1.1. Adverse Events

The number and percentage of subjects experiencing AEs will be tabulated by children and mothers respectively using the MedDRA coding dictionary. Subjects experiencing SAEs, and withdrawn from the study due to AEs will also be presented if there is any such AEs. AEs will be presented by severity. Subjects will be counted only once for each system organ class and preferred term by selecting the most severe event. A listing of adverse events will be provided.

14. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigators/institutions will permit study related monitoring, audits, IRB/IEC review, and regulatory inspections by providing direct access to source data/documents.

Study Monitoring.

During the study, a monitor from Johnson & Johnson Consumer Inc. or representative will have regular contacts with the investigational site, for the following:

- Provide information and support to the investigator(s)
- Confirm that facilities remain acceptable
- Confirm that the investigational team is adhering to the protocol, that data are being accurately recorded in the case report forms, and that auxiliary product accountability checks are being performed
- Perform source data verification. This includes a comparison of the data in the case report forms with the subject's medical records at the hospital or practice, and other records relevant to the study. This will require direct access to all original records for each subject (e.g., clinic charts).
- Record and report all protocol deviations not previously sent to Johnson & Johnson.
- Confirm AEs and SAEs have been properly documented on CRFs and confirm any SAEs have been forwarded to Johnson & Johnson and those SAEs that met criteria for reporting have been forwarded to the IRB.

The monitor will be available between visits if the investigator(s) or other staff needs information or study-related direction.

14.1. Audits and Inspections

Authorized representatives of Johnson & Johnson, a regulatory authority, an Independent Ethics Committee or an Institutional Review Board may visit the site to perform audits or inspections, including source data verification. The purpose of a Johnson & Johnson. audit or inspection is to systematically and independently examine all study-related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, Good Clinical Practice guidelines of the International Conference on Harmonization, and any applicable regulatory requirements. The investigator should contact their study contacts immediately if contacted by a regulatory agency about an inspection.

15. INSTITUTIONAL REVIEW BOARD (IRB)

The Principal Investigator must obtain IRB approval for the investigation. Initial IRB approval, and all materials approved by the IRB for this study including the subject consent form and recruitment materials must be maintained in the Site Master File by the Investigator and made available for inspection.

16. QUALITY CONTROL AND QUALITY ASSURANCE

To ensure compliance with Good Clinical Practices and all applicable regulatory requirements, Johnson & Johnson Consumer Inc. may conduct a quality assurance audit. Please see Section 14.2 for more details regarding the audit process.

17. DATA HANDLING AND RECORDKEEPING

17.1. Case Report Forms / Electronic Data Capture

As used in this protocol, the term case report form (CRF) should be understood to refer to The Electronic Data Capture system.

All data will be collected on source documents first and then, as applicable, recorded in the EDC system.

The Electronic Data Capture system, or EDC, is the database where pertinent study data is collected such as demography, adverse events, and subject disposition.

Electronic Data Capture pages should be completed within 5 business days of the completion of each subject's participation in the study. The completed pages of the EDC system are the sole property of the Sponsor and should not be made available in any form to third parties, except for authorized representatives of the Sponsor or appropriate regulatory authorities, without written permission from the Sponsor.

Demographic, Adverse Event, and Subject Disposition data as well as all values of TEWL, and Skin pH assessments will be recorded on source documents and then entered into EDC.

All data will require source documentation to confirm data collected. Subject source documents are the Investigator's/physician's subject records maintained at the study site. Worksheets may be used for the capture of some data to facilitate completion of data entry. Any such worksheets will become part of the subjects' source documentation.

It is recommended that the author of an entry in the source documents be identifiable. At a minimum, the type and level of detail of source data available for a study subject should be consistent with that commonly recorded at the site. Specific details required as source data for the study will be reviewed with the PI before the study and will be described in the monitoring guidelines (or other equivalent document). It is the Investigator's responsibility to ensure completion and to review and approve all information captured in the EDC. The subject's data in the EDC system must be electronically signed by the Investigator. These signatures serve to attest that the information contained in the EDC system is true. At all times, the Investigator has final personal responsibility for the accuracy and authenticity of all clinical and laboratory data entered in the EDC. Subject source documents are the Investigator's/physician's subject records maintained at the study site. In cases where the source documents are the hospital or the physician's chart, the information collected in the EDC must match those charts.

All final data recorded in the EDC system will be kept by the Sponsor and at the clinical site.

All data recorded on source documents will be kept at the clinical site.

17.2. Inspection of Records

To enable evaluations and/or audits from regulatory authorities or the Sponsor, the investigator agrees to keep records including the identity of all participating subjects (sufficient information to link records, e.g., CRFs and hospital records), all original signed informed consent forms, copies of all CRFs, SAE forms, source documents, and detailed records of treatment disposition. The records should be retained by the investigator according to ICH guidelines, local regulations, or as specified in the Clinical Study Agreement, whichever is longer.

17.3. Retention of Records

The Principal Investigator must maintain all documentation relating to the study for a period of 2 years after the last marketing application approval, or if not approved 2 years following the discontinuance of the test article for investigation. If it becomes necessary for Johnson & Johnson or the Regulatory Authority to review any documentation relating to the study, the Investigator must permit access to such records.

If the investigator relocates, retires, or for any reason withdraws from the study, the Sponsor should be prospectively notified. The study records must be transferred to an acceptable designee, such as another investigator, another institution, or to the Sponsor. The investigator must obtain Sponsor's written permission before disposing of any records, even if retention requirements have been met.

18. SPONSOR DISCONTINUATION CRITERIA

Premature termination of this clinical study may occur because of a regulatory authority decision, change in opinion of the IRB/IEC, drug safety problems, or at the discretion of the sponsor. In addition, the sponsor retains the right to discontinue development of this investigational compound at any time.

If a study is prematurely terminated or discontinued, the Sponsor will promptly notify the Investigator. After notification, the investigator must contact all participating subjects within a two week period. All study materials must be collected and all CRFs completed to the greatest extent possible.

19. DEFINITION OF END OF STUDY

End of study is defined as last subject last visit.

20. PUBLICATION POLICY

Publication of study results by the Investigator is discussed in the Clinical Study Agreement, as appropriate. Results from this study may be published in the form of oral or written presentations at scientific meetings or as one or more peer-reviewed journal articles. In these cases, no information on individual subjects will be revealed.

21. LIST OF REFERENCES

[redacted]

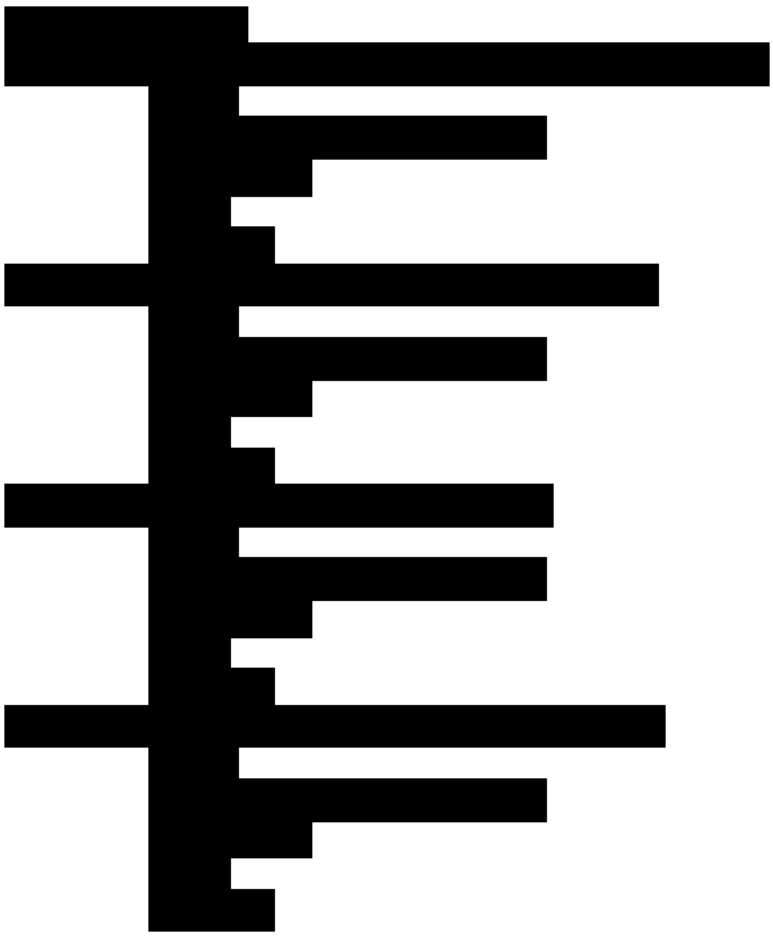
3. Johnson & Johnson Consumer Products Worldwide, [redacted]," Skillman NJ, 2012.

4. Data on File, "Core Clinical Study Report[redacted]," Skillman NJ, 2014.

5. K. Capone, F. Kirchner, S. Cox, E. Zaleski, K. Correa, N. Batchvarova, G. Stamatas and J. Nikolovski, "Intra- and Interpersonal Changes in the Skin Microbiome from Infancy to Adulthood," in Spotlight on Innovation, Johnson & Johnson Consumer Companies, Inc., 2013.

6. Data on File: Research Testing Laboratories, "Preliminary Analysis[redacted] Report," Johnson & Johnson Consumer Products Company Worldwide, Skillman NJ, 2012.

[redacted]



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16. [redacted]

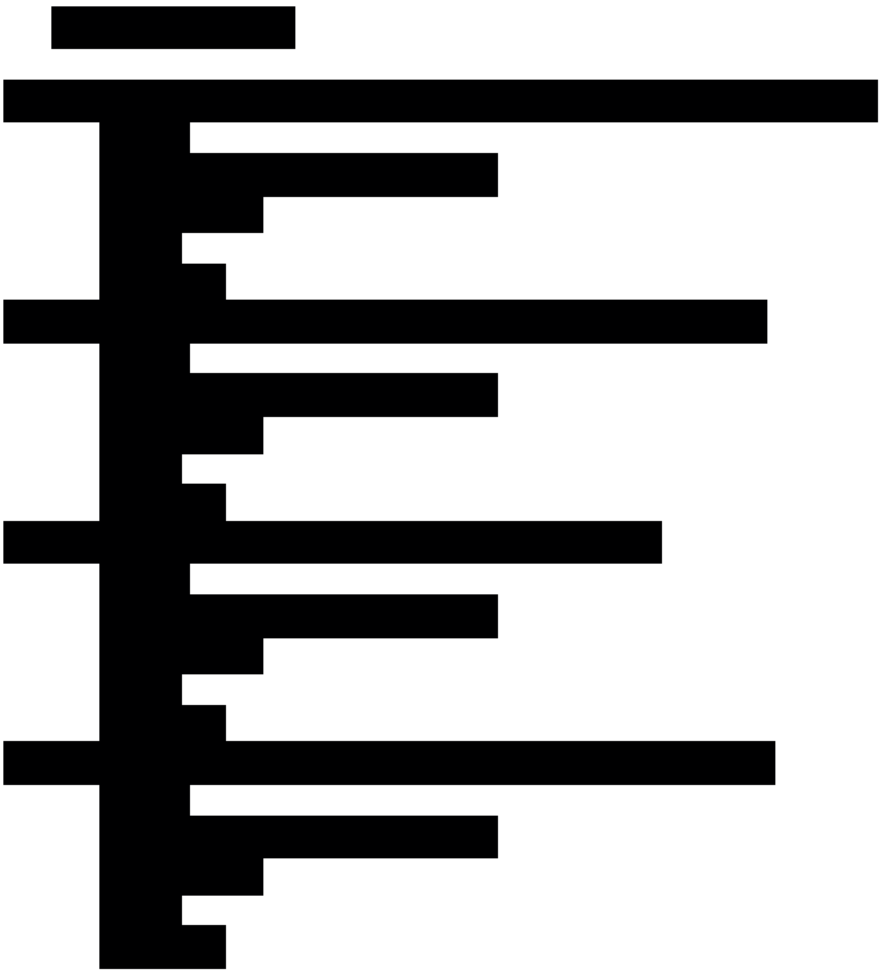

Table 1 (Page 1 of 1)
Subject Disposition

Disposition	Children (N=8) n (%)	Mothers (N=8) n (%)
Enrolled Subjects	8(100)	8(100)
Completed Subjects	8(100)	8(100)
Discontinued Subjects	0	0
Safety Analysis Set	8(100)	8(100)

Table 2 (Page 1 of 1)
Demographics
All Enrolled Subjects

	Children (N=8)	Mothers (N=8)
Age (Years)		
N	8	8
Mean	9.0	42.9
S.D.	0.00	4.49
Median	9.0	41.5
Min-Max	(9-9)	(38-52)
Sex, n (%)		
Male	5(62.5)	0
Female	3(37.5)	8(100)
Total	8(100)	8(100)
Race, n (%)		
White	8(100)	8(100)
Black or African American	0	0
Asian	0	0
Native Hawaiian or Other Pacific Islander	0	0
American Indian or Alaska Native	0	0
Total	8(100)	8(100)
Ethnicity, n (%)		
Hispanic or Latino	1(12.5)	1(12.5)
Not Hispanic or Latino	7(87.5)	7(87.5)
Total	8(100)	8(100)

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Table 3.1.1 (Page 1 of 1)
Transepidermal Water Loss (TEWL) by Location (Children)
All Enrolled Subjects

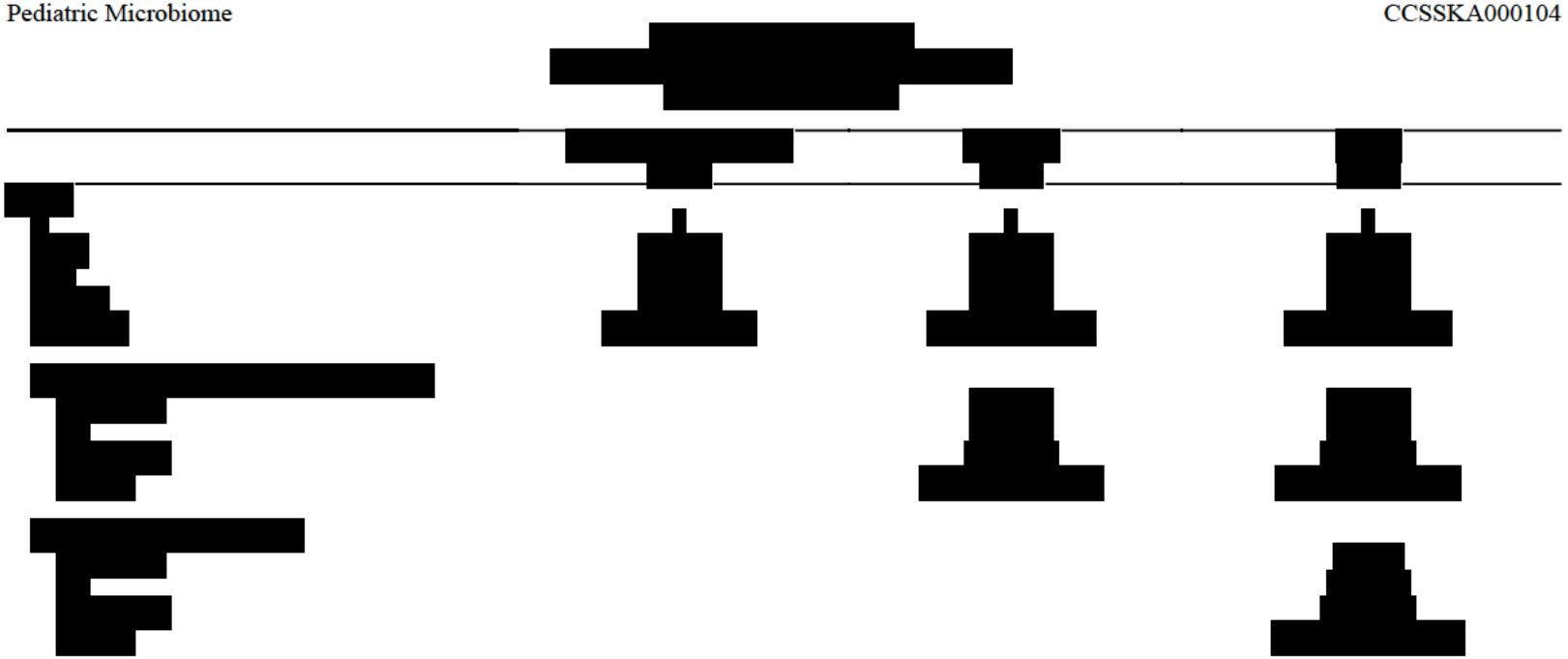
	Lower Volar Forearm (N=8)	Forehead (N=8)	Cheek (N=8)
Visit 2			
N	8	8	8
Mean	11.796	17.742	14.883
S.D.	4.3000	5.4821	5.5657
Median	11.500	18.150	14.650
Min-Max	(6.50-20.20)	(10.60-26.63)	(8.63-25.13)
Comparisons vs. Lower Volar Forearm			
Difference		5.946	3.087
s.e.		2.5742	2.5742
P-value [1]		0.031 [1]	0.244 [1]
95% CI		[0.592, 11.299]	[-2.266, 8.441]
Comparisons vs. Forehead			
Difference			-2.858
s.e.			2.5742
P-value [1]			0.279 [1]
95% CI			[-8.212, 2.495]

[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_children.sas at 10:16:18, 21MAY2018

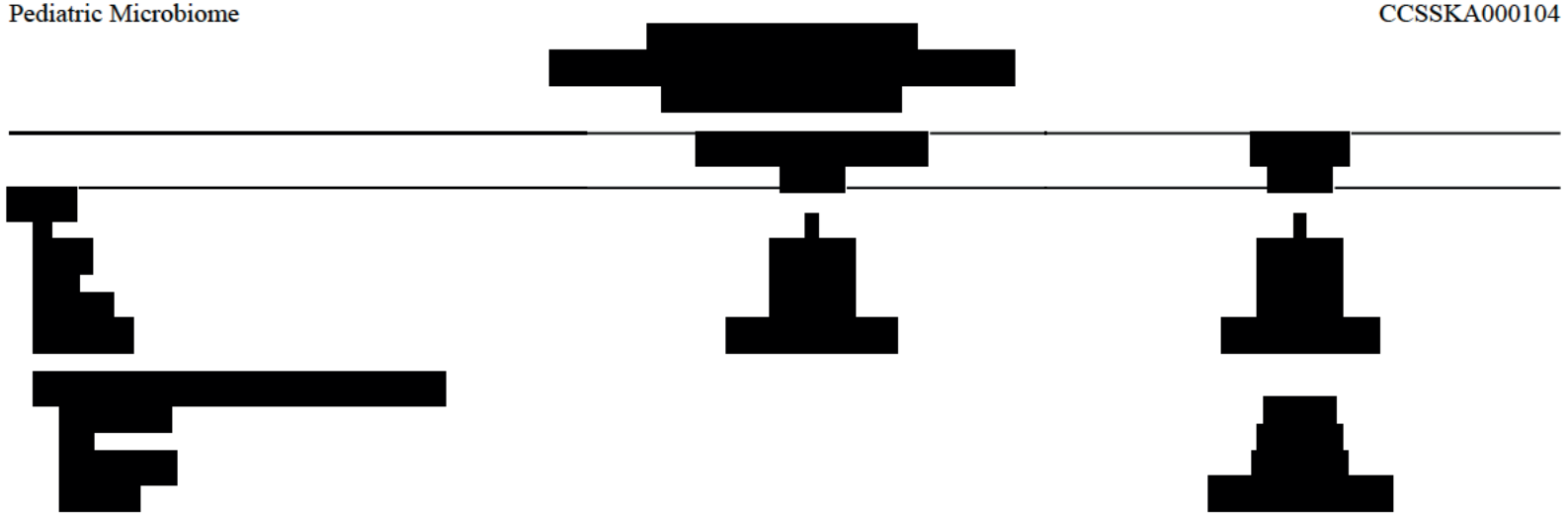
Table 3.1.2 (Page 1 of 1)
Transepidermal Water Loss (TEWL) by Location (Mothers)
All Enrolled Subjects

	Lower Volar Forearm (N=8)	Forehead (N=8)
Visit 2		
N	8	8
Mean	8.838	23.304
S.D.	2.2085	4.3276
Median	9.400	23.183
Min-Max	(5.53-11.03)	(17.97-29.00)
Comparisons vs. Lower Volar Forearm		
Difference		14.467
s.e.		1.7178
P-value [1]		<0.001 [1]
95% CI		[10.782, 18.151]

[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_mothers.sas at 14:03:05, 17MAY2018



[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_children.sas at 10:16:35, 21MAY2018



[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_mothers.sas at 14:03:21, 17MAY2018

Table 3.3.1 (Page 1 of 1)
Skin PH by Location (Children)
All Enrolled Subjects

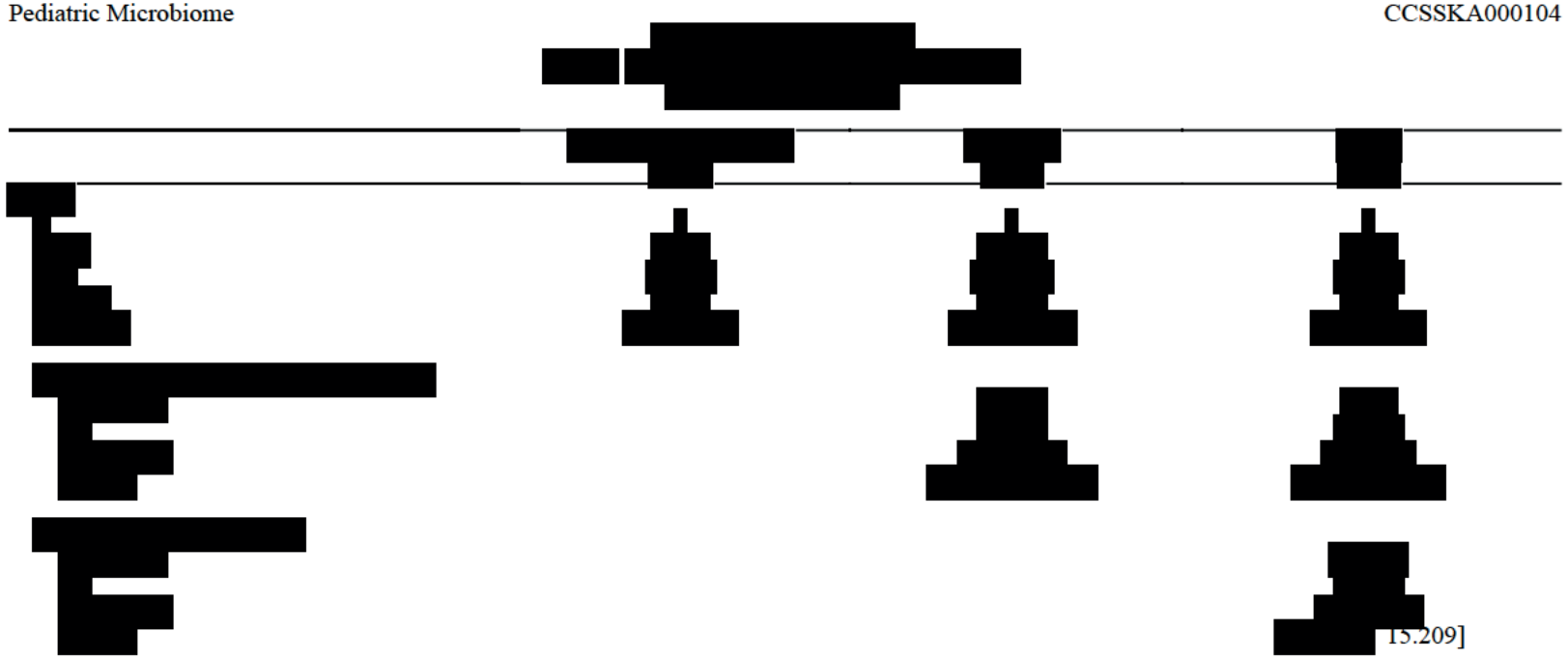
	Lower Volar Forearm (N=8)	Forehead (N=8)	Cheek (N=8)
Visit 2			
N	8	8	8
Mean	4.765	5.163	4.935
S.D.	0.4103	0.6241	0.3449
Median	4.570	5.240	4.870
Min-Max	(4.34-5.32)	(4.20-6.06)	(4.40-5.38)
Comparisons vs. Lower Volar Forearm			
Difference		0.397	0.170
s.e.		0.2375	0.2375
P-value [1]		0.109 [1]	0.482 [1]
95% CI		[-0.096, 0.891]	[-0.324, 0.664]
Comparisons vs. Forehead			
Difference			-0.228
s.e.			0.2375
P-value [1]			0.349 [1]
95% CI			[-0.721, 0.266]

[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_children.sas at 10:16:48, 21MAY2018

Table 3.3.2 (Page 1 of 1)
Skin PH by Location (Mothers)
All Enrolled Subjects

	Lower Volar Forearm (N=8)	Forehead (N=8)
Visit 2		
N	8	8
Mean	5.165	4.855
S.D.	0.4673	0.3763
Median	5.060	4.780
Min-Max	(4.50-5.98)	(4.28-5.58)
Comparisons vs. Lower Volar Forearm		
Difference		-0.310
s.e.		0.2121
P-value [1]		0.166 [1]
95% CI		[-0.765, 0.145]

[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_mothers.sas at 14:03:33, 17MAY2018



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[1] P-values are based on ANOVA model with term for Location.
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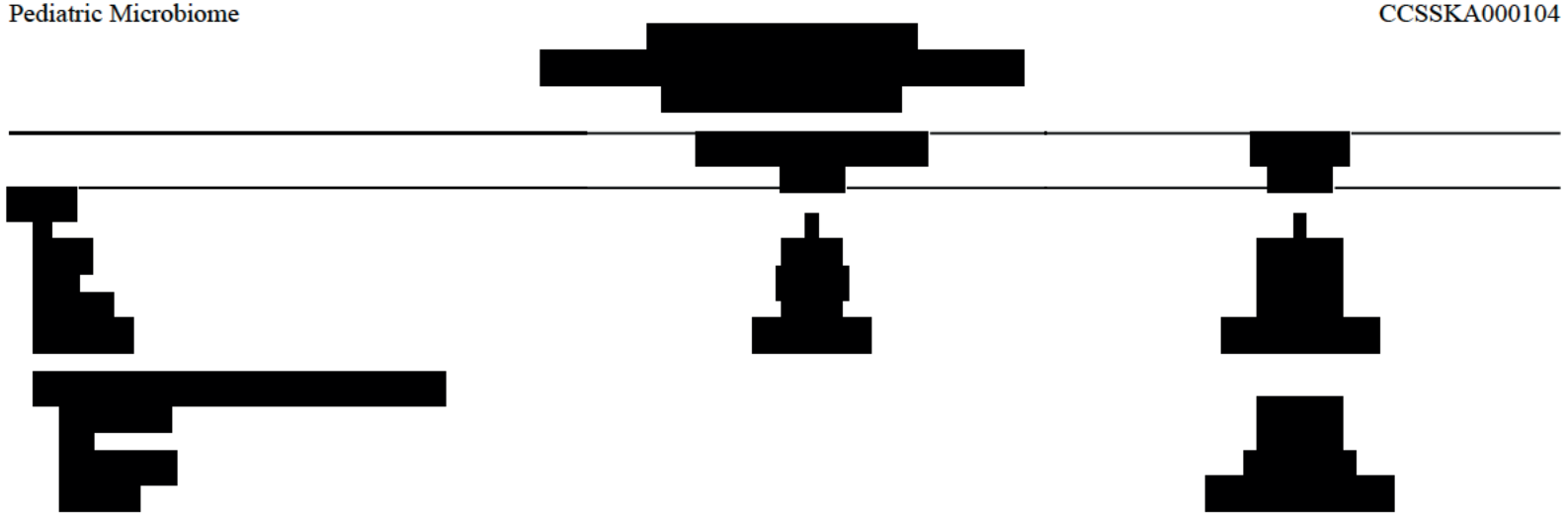

[1] P-values are based on ANOVA model with term for Location.
Generated by program: T_eff_mothers.sas at 14:03:44, 17MAY2018

Table 4.1.1 (Page 1 of 1)
Summary of Adverse Events by System Organ Class and Preferred Term (Children) [1]
All Enrolled Subjects

System Organ Class [2] Preferred Term	Total (N=8) n
Subjects with At Least One AE	0

Note: MedDRA version is 20.0.
[1] Subjects were counted only once for each system organ class and preferred term.
[2] Listed in descending order of frequency reported by all subjects.
Generated by program: T_AE.sas at 14:04:34, 17MAY2018

Table 4.1.2 (Page 1 of 1)
Summary of Adverse Events by System Organ Class and Preferred Term (Mothers) [1]
All Enrolled Subjects

System Organ Class [2] Preferred Term	Total (N=8) n
Subjects with At Least One AE	0

Note: MedDRA version is 20.0.
[1] Subjects were counted only once for each system organ class and preferred term.
[2] Listed in descending order of frequency reported by all subjects.
Generated by program: T_AE.sas at 14:04:52, 17MAY2018

Figure 1 Transepidermal Water Loss (TEWL) by Location for Children and Mothers (Mean + SD)
All Enrolled Subjects

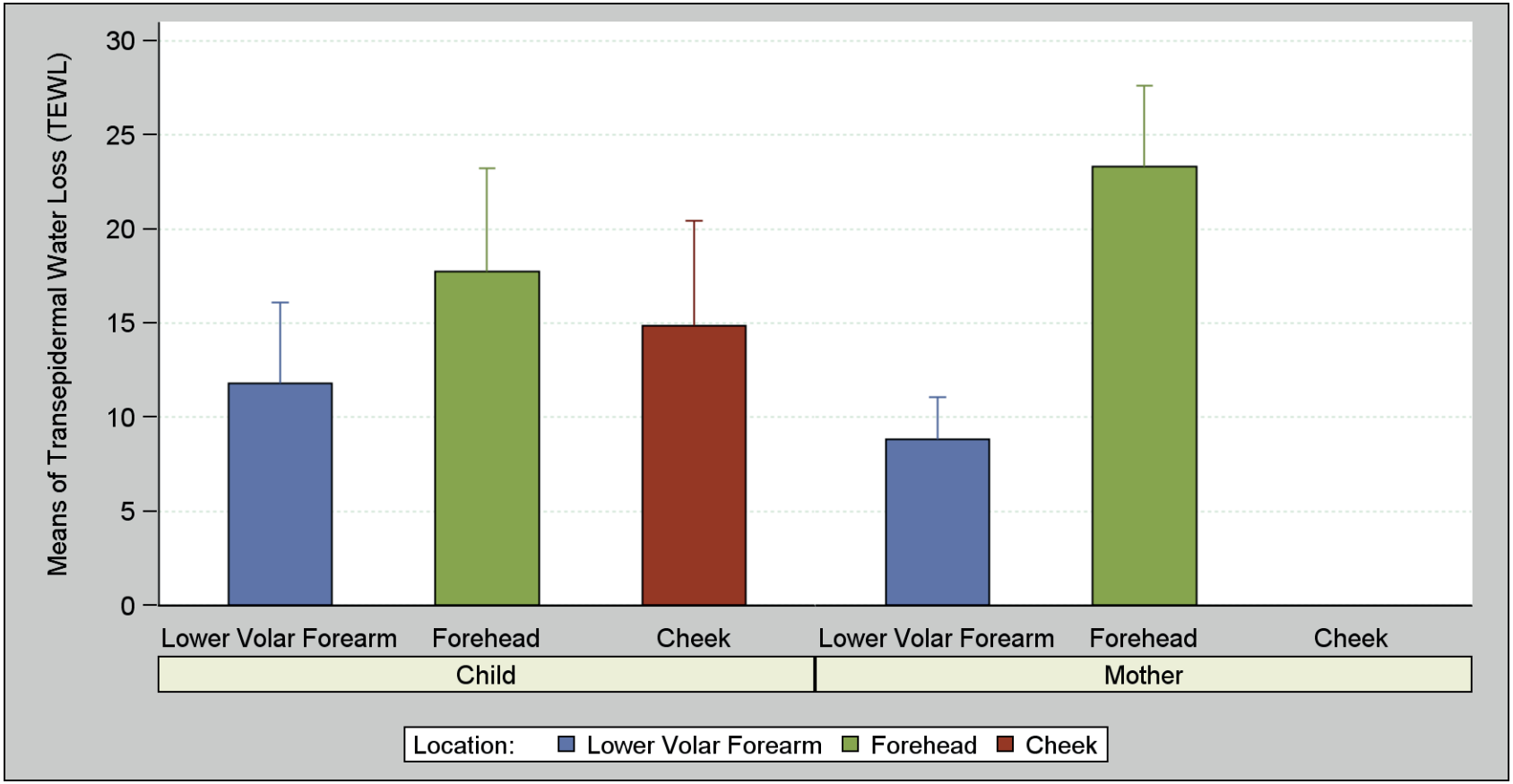

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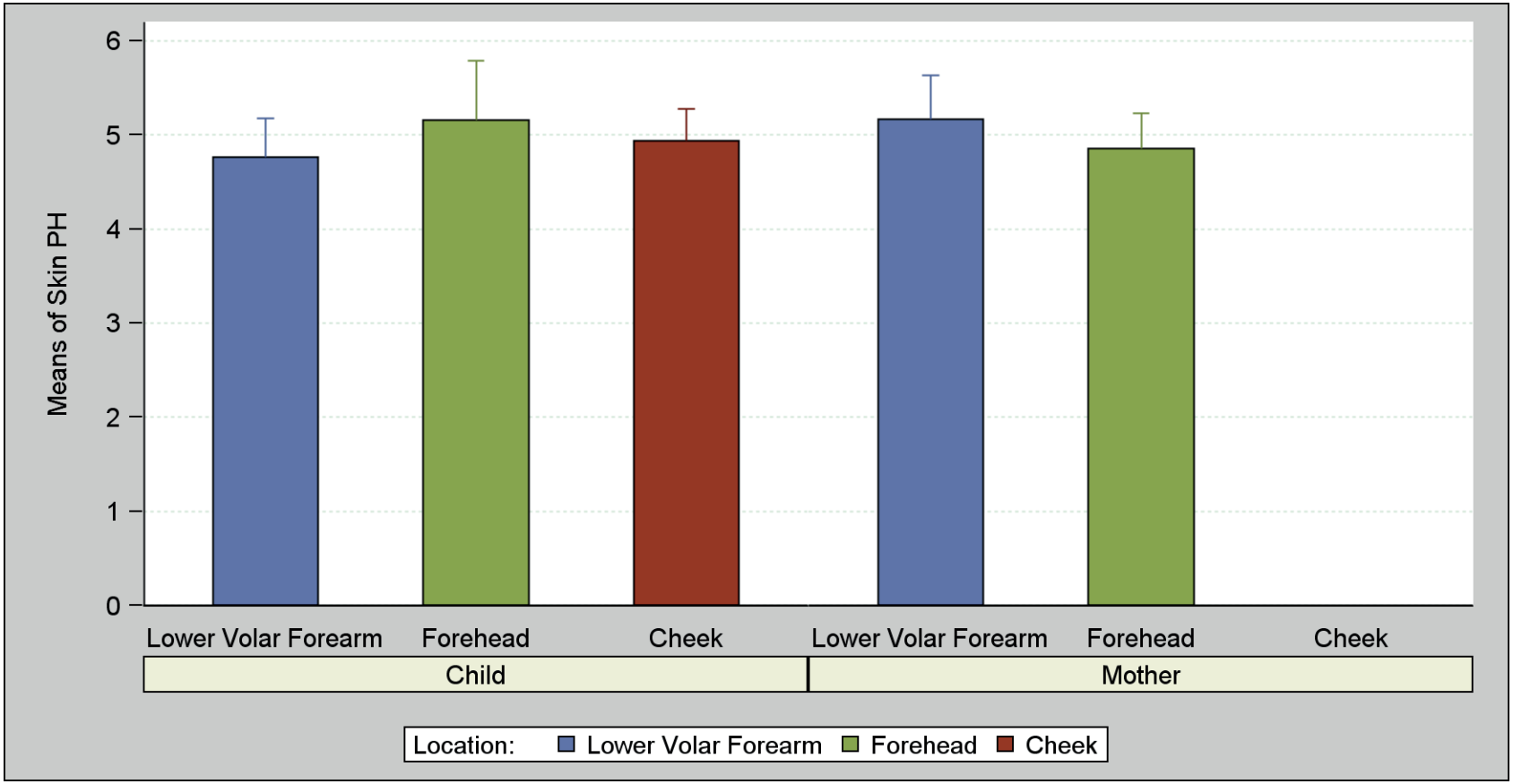
Figure 3 Skin PH by Location for Children and Mothers (Mean + SD)
All Enrolled Subjects



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Listing 1 (Page 1 of 1)
Subject Completion and Subject Evaluation
All Enrolled Subjects

Biological Status	Subject ID	Exp Any AE	Date Completed Withdrew	Study Completion Discontinuation Reason
Child	10011012	No	2018-03-22	Completed
	10011014	No	2018-03-22	Completed
	10011024	No	2018-03-15	Completed
	10011028	No	2018-03-22	Completed
	10011030	No	2018-03-22	Completed
	10011054A	No	2018-03-16	Completed
	10011054B	No	2018-03-16	Completed
	10011064	No	2018-03-15	Completed
Mother	10011007	No	2018-03-15	Completed
	10011011	No	2018-03-22	Completed
	10011013	No	2018-03-22	Completed
	10011023	No	2018-03-15	Completed
	10011027	No	2018-03-22	Completed
	10011051	No	2018-03-15	Completed
	10011053	No	2018-03-16	Completed
	10011063	No	2018-03-15	Completed

Listing 2 (Page 1 of 1)
Protocol Deviations
All Enrolled Subjects

Biological Status	Subject ID	Visit Number	Deviation Code	Description of Deviations	Action Taken	Comments
Mother	10011013	2	10	Subject used product on the face only the monring of Visit 2 (22 March 2018)	4	Protocol completed as per SIV instructions
	10011051	2	10	Subject did not use product as directed. Subject used product for only 2 days.	4	Protocol completed as per SIV instructions

Protocol Deviation Code List

1. Inclusion/Exclusion
2. Investigational Product
3. ConMeds
3. ConMeds
4. Lab
5. Visit Schedule
6. Procedures/Tests
7. Randomization
8. Safety Reporting
8. Safety Reporting
9. Protocol Specific Discontinuation Criteria
10. Non-Compliance
11. Other

Action Taken Code List

1. No action taken - minor deviation
2. Subject discontinued
3. Subject discontinued and replaced
4. No action taken - subject completed the study
5. Site re-trained
6. Other

Generated by program: L_Deviation.sas at 14:06:33, 05/17/2018

Listing 3 (Page 1 of 1)
Demographics
All Enrolled Subjects

Biological Status	Subject ID	Sex	Age	Race	Ethnicity
Child	10011012	Female	9	White	Not Hispanic or Latino
	10011014	Male	9	White	Not Hispanic or Latino
	10011024	Male	9	White	Not Hispanic or Latino
	10011028	Female	9	White	Not Hispanic or Latino
	10011030	Male	9	White	Not Hispanic or Latino
	10011054A	Male	9	White	Not Hispanic or Latino
	10011054B	Male	9	White	Not Hispanic or Latino
	10011064	Female	9	White	Hispanic or Latino
Mother	10011007	Female	40	White	Not Hispanic or Latino
	10011011	Female	52	White	Not Hispanic or Latino
	10011013	Female	40	White	Not Hispanic or Latino
	10011023	Female	43	White	Not Hispanic or Latino
	10011027	Female	40	White	Not Hispanic or Latino
	10011051	Female	38	White	Not Hispanic or Latino
	10011053	Female	45	White	Not Hispanic or Latino
	10011063	Female	45	White	Hispanic or Latino

Listing 4.1 (Page 1 of 1)
Transepidermal Water Loss (TEWL)
All Enrolled Subjects

Biological	Subject		Visit	Lower Volar Forearm				Forehead				Cheek			
Status	ID	Visit	Date	1	2	3	Mean	1	2	3	Mean	1	2	3	Mean
Child	10011012	V2	2018-03-22	9.3	9.8	9.7	9.60	10.7	10.3	11.3	10.77	8.2	10.3	11.1	9.87
	10011014	V2	2018-03-22	8.5	13.8	9.7	10.67	17.7	20	24.9	20.87	13.9	15.4	18.8	16.03
	10011024	V2	2018-03-15	21.7	21.2	17.7	20.20	19	21.4	22.2	20.87	13.9	18.2	13.9	15.33
	10011028	V2	2018-03-22	11.9	14	13.7	13.20	14.4	14.7	19.2	16.10	21.9	18.7	18.8	19.80
	10011030	V2	2018-03-22	12.5	14.7	15.3	14.17	27.5	26.6	25.8	26.63	29.9	22	23.5	25.13
	10011054A	V2	2018-03-16	16.1	9.6	11.3	12.33	18	20.2	22.4	20.20	14.5	12.9	14.5	13.97
	10011054B	V2	2018-03-16	7	7.1	5.4	6.50	18.3	16	13.4	15.90	9.4	8.4	8.1	8.63
	10011064	V2	2018-03-15	7.7	7.9	7.5	7.70	11.2	10.8	9.8	10.60	9.8	11.2	9.9	10.30
Mother	10011007	V2	2018-03-15	6.3	7.3	7.3	6.97	21.1	20	21.9	21.00				
	10011011	V2	2018-03-22	9.1	10.7	10.7	10.17	19.7	19.7	21.9	20.43				
	10011013	V2	2018-03-22	10.9	11.2	10.6	10.90	23.8	28.1	32.5	28.13				
	10011023	V2	2018-03-15	6.2	6.8	6.9	6.63	15.8	21	17.1	17.97				
	10011027	V2	2018-03-22	9.6	10.6	12.3	10.83	26.2	31.7	19.9	25.93				
	10011051	V2	2018-03-15	3.5	6.7	6.4	5.53	28.6	29.1	29.3	29.00				
	10011053	V2	2018-03-16	8.2	10	7.7	8.63	25.4	25.4	25.3	25.37				
	10011063	V2	2018-03-15	13.2	10	9.9	11.03	15.5	19.7	20.6	18.60				

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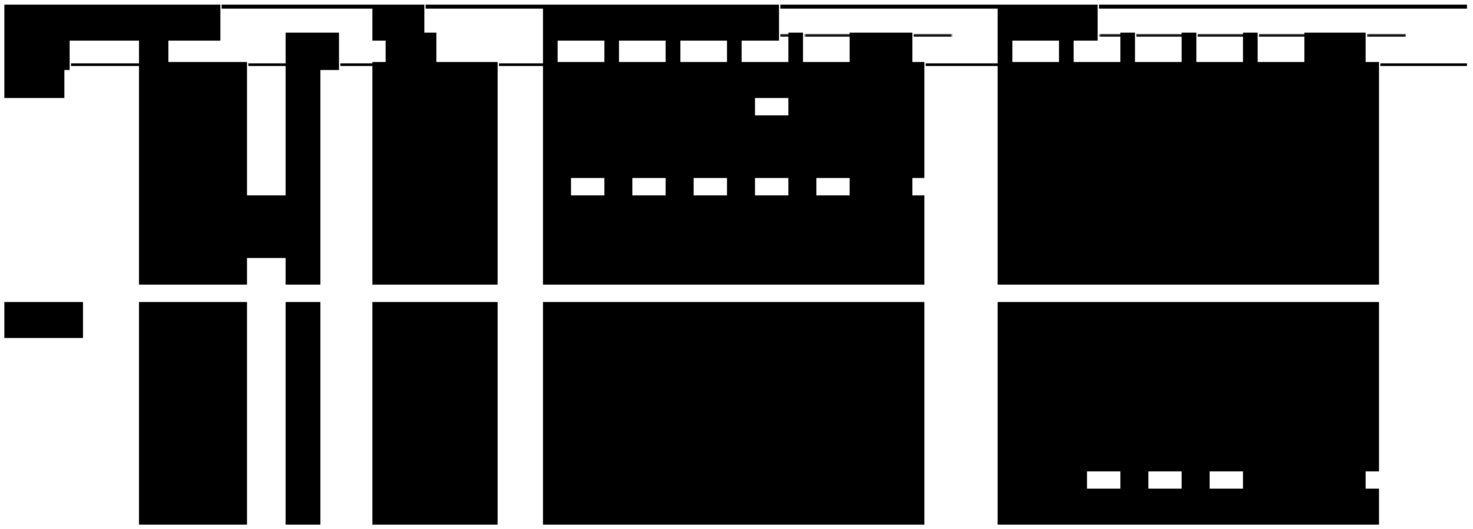

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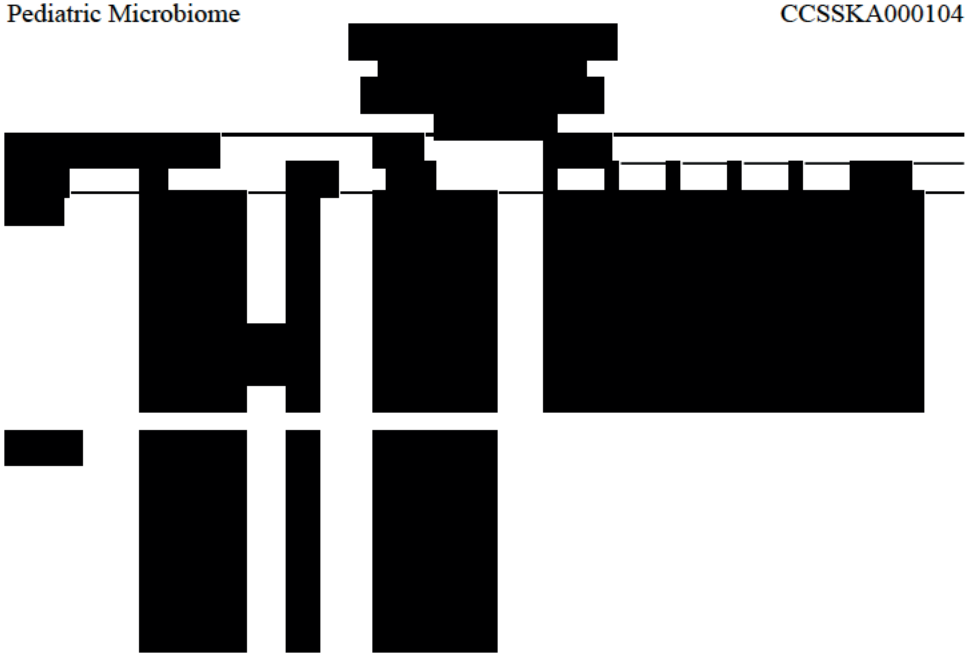
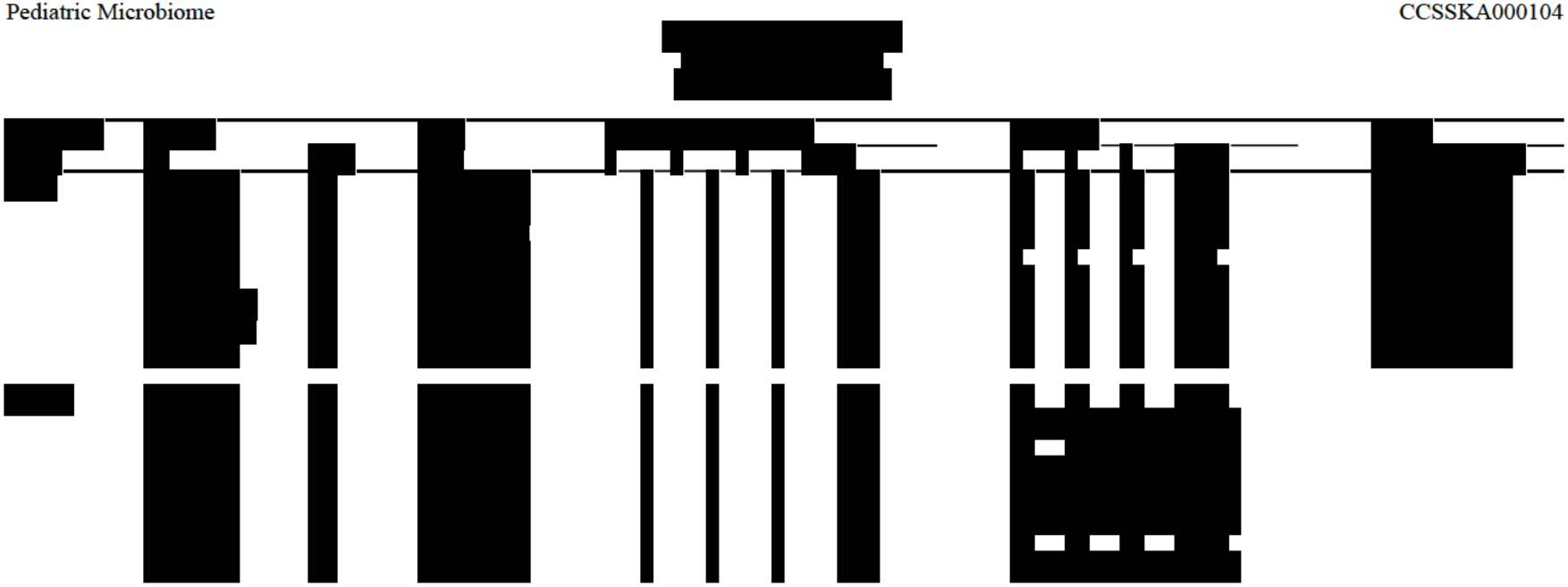


Listing 4.3 (Page 1 of 1)
Skin PH
All Enrolled Subjects

Biological Status	Subject ID	Visit	Visit Date	Lower Volar Forearm						Forehead						Cheek					
				1	2	3	4	5	Mean	1	2	3	4	5	Mean	1	2	3	4	5	Mean
Child	10011012	V2	2018-03-22	4.5	4.6	4.6	4.6	4.6	4.58	4.8	4.9	5	5.8	6	5.30	4.9	4.9	4.8	4.9	4.9	4.88
	10011014	V2	2018-03-22	5.3	5.4	5.3	5.3	5.3	5.32	5	5	5.1	5.2	5.6	5.18	5.5	5.4	5.3	5.4	5.3	5.38
	10011024	V2	2018-03-15	4.6	4.6	4.6	4.5	4.5	4.56	5.7	5.6	5.7	5.6	5.6	5.64	4.7	4.7	4.7	4.8	5	4.78
	10011028	V2	2018-03-22	5.3	5.3	5.3	5.3	5.4	5.32	5.8	6.3	6	6.1	6.1	6.06	5.4	5.4	5.4	5.3	5.4	5.38
	10011030	V2	2018-03-22	5.3	5.1	5	5	5	5.08	4.9	4.8	4.8	4.8	5.1	4.88	5.3	5.1	5.1	5.1	5.1	5.14
	10011054A	V2	2018-03-16	4.4	4.4	4.3	4.3	4.4	4.36	4.2	4.2	4.2	4.2	4.2	4.20	4.4	4.4	4.4	4.4	4.4	4.40
	10011054B	V2	2018-03-16	4.4	4.4	4.3	4.3	4.3	4.34	4.5	4.4	4.4	4.6	4.4	4.46	4.4	4.4	4.4	4.9	5.2	4.66
	10011064	V2	2018-03-15	4.6	4.5	4.6	4.6	4.5	4.56	5	5.1	5.4	6	6.4	5.58	4.8	4.9	4.9	4.8	4.9	4.86
Mother	10011007	V2	2018-03-15	5	5.3	5.4	4.8	5	5.10	4.9	4.8	4.7	4.7	4.8	4.78						
	10011011	V2	2018-03-22	4.9	4.9	4.9	4.9	5.1	4.94	4.8	4.6	4.7	4.9	4.9	4.78						
	10011013	V2	2018-03-22	4.7	5	5.1	5.1	5.2	5.02	4.3	4.2	4.3	4.3	4.3	4.28						
	10011023	V2	2018-03-15	5.1	5	5.1	5.3	5.3	5.16	4.6	4.7	4.7	4.8	4.7	4.70						
	10011027	V2	2018-03-22	5.8	5.8	6.2	6.2	5.9	5.98	6	5.5	5.6	5.5	5.3	5.58						
	10011051	V2	2018-03-15	4.9	5	4.9	4.8	5	4.92	5.1	5	5.3	4.9	4.9	5.04						
	10011053	V2	2018-03-16	5.6	5.9	5.6	5.6	5.8	5.70	4.8	4.6	4.5	4.7	4.7	4.66						
	10011063	V2	2018-03-15	4.5	4.6	4.5	4.4	4.5	4.50	4.8	5	5	5.1	5.2	5.02						



Listing 5 (page 1 of 1)
Subjects with Adverse Events
All Enrolled Subjects

Biological Status	Site ID	Subject ID	CRF Description of Event	Preferred Term	Frequency of Event	Severity	Onset Date	Date of Resolution or Death	Outcome (Resolution)	Relationship to Study Drug	Action Taken	Med Used to Trt?	Serious Event?

There is no data to be reported for this listing.