ObvioHealth
The Digital Revolution Gets Clinical

STATISTICAL ANALYSIS PLAN

Study Number	OBVIO-DAN-002
Title	Observational Study: Image Collection of Infant/Toddler Stools for Danone Software Development
Sponsor	Danone
Country	United States
Date	06DEC2018
Version Number	1.0

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

We, the undersigned, have reviewed and approved this SAP including the appendices and TLF Shells.

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1. Abbreviations

Abbreviation	Definition
BITSS	Brussels Infant and Toddler Stool Scale
CRO	Contract Research Organization
PI	Principal Investigator

2. Synopsis

Study Title	Observational Study: Image Collection of Infant/Toddler Stools for Danone Software Development
Study Objectives	***Primary*** • To create a database of stool images scored by mothers that are suitable for Danone software development purposes • To create a database containing at least 200 pictures of diapers containing fecal (stool) material per each stool consistency score (type 1 to 7) of the BITSS (Brussels Infant and Toddler Stool Scale) and 200 images of empty (no stool) disposable diapers ***Exploratory*** • To compare the stool consistency scores from mothers on-study to re-scores of mothers (not enrolled on-study) based only on the uploaded images • To assess mothers' perceptions of the usability of the stool scoring process and the usability of the ClaimIt app
Study Design	An observational study of stool images among infants/toddlers, ages 0-24 months
Study Observation Duration	30 days per child **NOTE:** If participants upload a low number of quality images due to infant/toddler constipation and infrequency of stooling, the mother may be asked if she would like to continue in the study for an additional 30 days or more. If she chooses to continue, she may do so as long as images continue to be provided at a reasonable frequency and/or until stool strata are satisfied (at the PI's discretion).
Country of Implementation	United States of America
Study Population	Approximately 100 healthy infants/toddlers (until 200 images per stool score reached), age 0-24 months (at time of enrollment)

Inclusion Criteria	• Healthy infants/toddlers (0-24 months of age at time of enrollment) • Informed consent from mother ≥18 years of age • In-home access to reliable internet connections; a mobile device suitable for electronic communication; and a device suitable for capturing and transmitting high-quality electronic images as per the PI's discretion • Infant/toddler consumes standard, age-appropriate food (breast milk; formula; commercial/homemade baby, table or finger food) • Based on the number of stools already acquired per relevant strata at time of enrollment, infant/toddler may or may not be required to regularly produce stools scored as a Score 1, 2, 6 or 7 (per Appendix II of the study protocol)
Exclusion Criteria	***Mothers of Infants/Toddlers:*** • The use of cloth diapers (mothers must commit to using disposable diapers for the duration of the study) • Known to have a significant condition (including during pregnancy) that might interfere with the study compliance, as per PI's clinical judgment • Deemed likely to be non-compliant with the study protocol, as per PI's clinical judgment

Endpoints	***Primary:***
	• Creation of a database containing at least 1600 pictures of individual diapers:
	  ○ 200 images of diapers with stool per each score (BITSS types 1 to 7)
	  ○ 200 images of empty (no stool) disposable diapers
	
	Exploratory:
	• A comparison of the stool consistency scores from the mothers on-study to re-scores from mothers (not enrolled on-study) based only on the uploaded images
	• An assessment of mothers' perceptions of the usability of the stool scoring process

	• An assessment of mothers' perceptions of the usability of the ClaimIt app

Study Implementation	***Observation Period:*** The mother will be asked to interact with the ClaimIt app daily for 30 days (or longer) as follows:
	• Two empty (no stool) disposable diaper images are to be uploaded: one at Baseline and one at End of Study
	  ○ Images should be taken of the type of disposable diaper used most frequently for the infant/toddler
	  ○ Additional empty (no stool) disposable diaper images may only be submitted if the brand/type of diaper changes; if the diaper size changes, no additional pictures need to be uploaded
	
	End of Observation Period:
	• The mother will be asked to complete an eQuestionnaire to assess and comment on the usability of the ClaimIt app and the scoring process (Appendix I)
	• Two mothers who were not enrolled in the study will be provided the collection of study stool images and asked to re-score each image according to the BITSS

Statistical Considerations	A sample size of 100 subjects is estimated with the following considerations:
	• Progression of potential subjects will be gated at the prescreening and screening steps to facilitate enrollment of an appropriately diversified set of infants/toddlers based on bowel patterns to reach 200 images per each stool consistency score (type 1 to 7) of the BITSS
	• A comparison will be made between the stool consistency scores from the mothers on-study to re-scores from mothers (not enrolled on-study) based only on the uploaded images
	• Based on Sponsor review of the data, the following may be performed:
	  ○ A post hoc analysis
	  ○ Further descriptive summary statistics for categorical and quantitative data
	• The expectation is that not all the mothers will be compliant with study tasks for all 30 days

	• A dropout rate of 15% is anticipated (if dropout rate exceeds 15%, replacements may be made for all additional withdrawals)

3. Revision History

Version	Version date	Summary of modifications
1.0	**06DEC2018**	**Original**

4 Background

Accurately classifying stool consistency for infants and toddlers who are not yet toilet trained remains challenging. A recent study showed that among parents of infants and toddlers, only fair agreement existed between the parental report of stool consistency and the Bristol Stool Form Scale (BSS),[1] a gold standard in the classification of stool consistency in adults and older children who are toilet trained.[2] While there are alternative assessment methods which are used in clinical practice, such as the modified BSS and the Amsterdam Infant Stool Scale, a universally-accepted tool does not exist.[3] The Brussels Infant and Toddler Stool Scale (BITSS) was recently initiated based on the BSS to provide a classification tool to describe stool consistency for infants and toddlers.[4]

This observational study is designed to collect a series of images that span the range of stool consistencies associated with the stools of infants and toddlers to create a significant and varied photographic image database. For essentially healthy infants/toddlers (0-24 months) stool consistencies range from liquid (frequently associated with diarrhea) to hard formed (frequently associated with constipation) stools. This database will be used to assist in the further development of Danone software to facilitate evaluation of stool type remotely and permit evaluation beyond the interpretation of parents. The study is designed to collect at least 1600 images: at least 200 images per stool score (type 1 to 7) of the BITSS (at least 1400 total) plus 200 images of empty (no stool) diapers, generating further data to assist in the assessment and classification of infant/toddler stools and gastrointestinal function.

5 Objectives

5.1 Primary Objectives

- To create a database of stool images scored by mothers that are suitable for Danone software development purposes
- To create a database containing at least 200 pictures of disposable diapers containing fecal (stool) material per each stool consistency score (type 1 to 7) of the BITSS

(Brussels Infant and Toddler Stool Scale), and 200 images of empty (no stool) disposable diapers

5.2 Exploratory Objectives

- To compare the stool consistency scores from mothers on-study to the re-scores of mothers (not enrolled on-study) based only on the uploaded images
- To assess mothers' perceptions of the usability of the stool scoring process and the usability of the ClaimIt app

6. Trial Design

6.1 Study Calendar

	Pre-screening	Baseline	Daily	Weekly	End of Study
Prescreening Eligibility Review	X				
Prescreening Image Upload	X				
eIC	X				
Screening eQuestionnaire		X			
Empty Diaper Image		X			X
Upload of Stool Image(s)			X		
Sponsor and CRO Review of Images and Distribution of Scores				X	
End of Study eQuestionnaire					X

6.2 Type of Trial

An observational study of 100 essentially healthy infants/toddlers, 0-24 months of age.

6.3 Trial Endpoints

Primary Endpoint

Creation of a database containing at least 1600 images:

- At least 200 images of disposable diapers containing stool per each score (type 1 to 7) of the BITSS
- At least 200 images of empty (no stool) disposable diapers

Exploratory Endpoints

- A comparison of the stool consistency scores from the mothers on-study to re-scores from mothers (not enrolled on-study) based only on the uploaded images
- An assessment of mothers' perceptions of the usability of the stool scoring process
- An assessment of mothers' perceptions of the usability of the ClaimIt app

6.4 Study Population

6.4.1 Participants

Study participants will include the mother and their infant/toddler. The prescreening recruitment process will be administered through an online eQuestionnaire to the mother evaluating the typical stool and consistency (e.g., liquid, soft/mushy, solid, hard).

6.4.2 Location

The trial will be conducted remotely in the United States. Communication between mothers and study personnel will be conducted via the internet (ClaimIt platform) and/or over the telephone or email messaging as appropriate.

It is expected that the infant and their mother will remain eligible for the entire duration of their enrollment in the study.

6.4.3 Subject Inclusion Criteria

Subjects must meet the following:

- Healthy infants/toddlers (0-24 months of age at time of enrollment)
- Informed consent from mother ≥18 years of age
- In-home access to reliable internet connections; a smartphone (or alternative suitable for capturing and transmitting high-quality electronic images) as per the PI's discretion
- The infant/toddler consumes age-appropriate, standard food (breastmilk; formula; commercial/homemade baby, table or finger food)
- Based on the number of stool images already acquired per relevant strata at time of enrollment, the infant/toddler may or may not be required to regularly produce stools scored as a Score 1, 2, 6 or 7 (per Appendix II of the study protocol)

6.4.4 Subject Exclusion Criteria

Mothers of Infants/Toddlers:

- The use of cloth diapers (mothers must commit to using disposable diapers for the duration of the study)
- Known to have a significant condition (including during pregnancy) that might interfere with the study compliance, as per PI's clinical judgment
- Deemed likely to be non-compliant with the study protocol, as per PI's clinical judgment

6.4.5 Subject Withdrawal Criteria

Mothers and their infants/toddlers may be withdrawn from the study at any time and for any reasons including but not limited to the following:

1) At their request or the request of their legally authorized representative.

2) If, in the PI's opinion, continuation in the study would be detrimental to the subject's well-being.
3) Poor compliance: if the mother and infant/toddler consistently do not adhere to the study procedures (per the PI's discretion).
4) Protocol deviation(s) which in the opinion of Sponsor warrant discontinuation from the study; e.g., violation of inclusion and/or exclusion criteria.

Study Note: If the infant/toddler experiences an illness (other than diarrhea/constipation) lasting longer than 7 days, has surgery or is admitted to the hospital for more than 24 hours, they should be withdrawn from the study immediately.

Due to the 15% dropout rate built into the estimated total sample size, subjects whose study participation is terminated prematurely for any of the above-listed criteria will not be replaced. If the dropout rate exceeds 15%, replacements may be made for all additional withdrawals. The PI will make every effort to contact subjects lost to follow-up during the study. Attempts to contact the subject will be documented in the subject's records (e.g., dates and times of attempted telephone contact).

The number and percentage of subjects who withdraw early and their reasons for withdrawal will be presented in a table and a CONSORT flow diagram equivalent.

The following information will be documented in the mother and infant/toddler's record in the event of a subject's withdrawal from the study:

I. Date of withdrawal
II. Reasons for withdrawal

Even if consent is withdrawn, all data and all images that were acquired before consent was withdrawn will be maintained.

6.5 Study Period

It is expected that the enrollment period will be five (5) months in total.

The expected study duration is 30 days per mother and infant/toddler. If a participant uploads a low number of quality images due to infant/toddler constipation and infrequency of stooling, a member of the study team may contact the mother to ask if she wants to continue with study for an additional 30 days or more. If she chooses to continue, they may do so as long as images continue to be provided at a reasonable frequency and/or until stool strata are satisfied (at the PI's discretion).

7 Data Collection

7.1 On-study

The mother will be asked to interact with the ClaimIt app daily for 30 days (or more) as follows:

- Stool images will be taken with a smartphone (or alternative suitable for capturing and transmitting high-quality, electronic images) and uploaded daily
- Every bowel movement will be photographed, potentially providing several images per day
    - Only 1 representative image per bowel movement should be transmitted
- If the mother has not uploaded an image in 24 hours, a notification and the Compliance eQuestionnaire requiring a response will be sent to her (Appendix IV of the study protocol)
- Along with each stool image uploaded, mothers will rate the stool consistency type compared to examples provided by the BITSS (Score 1 to 7)
    - Scoring will be based only on consistency, not color
    - Sample images of each score will be provided
- A total of two empty (no stool) disposable diapers, spread open, are to be submitted: one at Baseline and one at the End of Study

- Images should be taken of the type of diaper used most frequently for the infant/toddler
- Additional empty (no stool) disposable diaper images may only be submitted if the brand/type of diaper is changed; if only the diaper size changes, no additional pictures need to be uploaded

7.2 End of Study

At the end of the study, the mother will be asked to complete an eQuestionnaire to assess and comment on the usability of the ClaimIt app and the scoring process (Appendix I).

Also, the Sponsor will identify two mothers who were not enrolled in the study. They will be provided a collection of uploaded study images and asked to re-score each image according to the BITSS.

8 Statistical Analysis

8.1 Sample Size Calculations

The primary objective of this study is to create a database with 200 images with stool per each score (BITSS types 1 to 7) and 200 images of empty (no stool) disposable diapers. The sample size of 100 subjects with an approximate withdrawal rate of 15% was predetermined, and therefore, a formal sample size calculation was not performed.

8.2 Primary Endpoints

This study's primary endpoint is the creation of a database containing at least 1600 images:

- At least 200 images of disposable diapers containing stool per each score (type 1 to 7) of the BITSS
- At least 200 images of empty (no stool) disposable diapers

As the compilation of the image repository consists of simply obtaining the appropriate number of images to fulfill all score types, no statistical analysis is warranted.

8.3 Exploratory Endpoints

Exploratory endpoints for this study will be analyzed as follows:

Endpoint 1: A comparison of the stool consistency scores from the mothers on-study to re-scores from mothers not enrolled on-study based only on the uploaded images

Each mother on-study will score stool images based on consistency type compared to examples provided by the BITSS (Score 1 to 7). At End of Study for on-study mothers, images within the database will be sent to mothers who are not enrolled on-study for scoring based on the same BITSS criteria (Score 1 to 7). All scores are recorded as integers.

Inter-rater scores will be compared for agreement. Images in which the on-study mother's score was different from the non-enrolled study mother's scores will be flagged "disagree", while images where both mothers agree will be flagged as "agree". The magnitude of disagreement will be quantified by subtracting the non-study enrolled mother's score from the on-study mother's score. For example, if the on-study mother scored an image as a 6 and the non-enrolled mother scored the same as a five, we would consider the magnitude of disagreement as "-1". Conversely, if the on-study mother scored an image as 5 while the non-enrolled mother scored the same image as 6, the magnitude of disagreement would be "1".

Percent agreement will be tabulated for all BITSS categories (Score 1 to 7) based on the on-study mother's original score. Mean overall scores and mean overall differences between study groups (on-study and not enrolled on-study mothers) will be presented.

Scores between the two non-enrolled mothers will also be compared for agreement. Per comparisons with the on-study and each non-enrolled mother, images in which one of the non-enrolled mother's scores was different from the other non-enrolled study mother's scores will be flagged "disagree", while images where both mothers agree will

be flagged as “agree”. The percent agreement and magnitude of agreement between the two non-enrolled mothers will also be quantified, using non-enrolled mother #1 as the referent.

Endpoint 2: An assessment of mothers’ perceptions of the usability of the stool scoring process

Questions 5, 6, and 7 of the Parental Satisfaction with ClaimIt Platform questionnaire pertain to the mother’s perception of the usability of the stool scoring process. All of these questions are multiple choice and are thus recorded as categorical data. As such, frequencies and percentages of each answer choice will be given.

Question 5 includes logic to explain why a mother might have felt that scoring stool pictures was difficult. If she answers Yes, meaning she found some difficulty in scoring, she is given a list of choices by being asked “(If yes) Why?”. One of these choices is an open-ended question whose answer will be recorded as free text. Answers to this option will be examined and listed as appropriate with any trends being highlighted as a frequency.

Endpoint 3: An assessment of mothers’ perceptions of the usability of the ClaimIt app

Upon completing the observation period, each mother will be asked to complete the Parental Satisfaction with ClaimIt Platform questionnaire (Appendix I). Questions 1-4 and question 8 of this questionnaire pertain to the mother’s perception of the usability of the ClaimIt app and will be analyzed as described below.

A mean overall ease of use score will be derived for Question 1 by averaging respondent’s scaled answers. This score will be interpreted as the overall sentiment pertaining to the ClaimIt platform’s ease of use for this trial. For example, a mean score of 4 would indicate that the sample of mothers for this study thought that ClaimIt was “easy” to use.

Questions 2, 3, and 8 are Yes/No questions and, thus, their answers will be enumerated using frequencies and percentages of each answer choice. Questions 2, 3, and 8 all contain spaces for optional open-ended (free-text) responses, while Question 4 is a stand-alone open-ended question. All open-ended (free-text) responses will be listed for each question if the number of answers is reasonable enough to do so (e.g. <30 responses for a given question). Any trends found in the answers will be enumerated as a crude frequency. As nearly all answers to open-ended questions will be unique, all answers of a like theme will be recoded (for all intents and purposes) as the same category. For example, if one respondent answers question 4 ("Do you have any comments about using the application (favorable or unfavorable) that you would like the PIs to know?") by saying "I thought the app was easy to use", another answers "Easy to use", and another answers "Ease of use", then this answer will be recoded to "Easy to use" (for example) with a frequency of three (3). Any answers that are completely unique will be reported as such with a frequency of one (1).

8.4 Interim Analysis

An interim analysis will be performed, and 3 tables produced (T1a, T1b, and T1c) using all images up to and including those collected as of 18NOV2018 that have been scored by the non-study mothers. In addition, the following metrics will be provided:

- Total number of participants
- Total number of images collected
- Total number of images used for interim analysis

This will be provided to Danone by close of business 10DEC2018 (EST).

8.5 Tables, Figures, and Lists

8.5.1 BITSS Score Comparison

Tables of outputs from the proposed analysis are detailed in the TLF Deliverable Shell (see Section 10.2 for details).

Tables 1a-b provide the agreement between on-study mothers' BITSS scores and non-enrolled mothers' re-scores of the same images. Conceptually, the first column provides the on-study mother's scores. As on-study mothers will only be able to record integer scores ranging from 1-7, only these scores are listed in Column 1. Column 2 describes the number of unique subjects, e.g. on study mothers who reported BITSS scores. Column 3 enumerates the quantity of images collected for each score. Column 4 provides the overall and score-based percent agreements. Percent agreement is defined as the percentage of time the non-enrolled mother (mother #1 and mother #2 for Tables 1a and 1b, respectively) agreed with the on-study mother's score. Column 5 depicts the mean score for the non-enrolled mother. The mean level of disagreement (Column 6) is defined as the average of the magnitude to which non-enrolled mothers disagreed when disagreements occurred.

Table 1c describes the agreement between the two non-enrolled mothers in similar format: Column 1 provides the scores of non-enrolled Mother #1; Column 2 describes the number of unique subjects (on-study mothers) for which the non-enrolled mothers were assigned to re-score; Column 3 quantifies the number of images; Columns 4 describes the percent agreement between the two non-enrolled study mothers; Column 5 depicts the mean score of non-enrolled mother #2; Column 6 compares the agreement level between non-enrolled mother #1 and non-enrolled mother #2, quantified by the mean level of disagreement using mother #1 as the referent.

Individuals graphs will be created for each mother that plot each of the non-enrolled mother's scores across the BITSS range as reported by on-study mothers (as represented by values on x-axis; Figures 1a-1b). Points will be plotted for each comparison score from the non-enrolled mother (y-axis). The BITSS scores of the two non-enrolled mothers will also be compared against each other in a separate graph (Figure 1c). If an on-study mother does not submit an image for a given score,

no comparisons can be made through non-enrolled mothers. Therefore, no points will be plotted in such cases.

A Spearman correlation coefficient and p-value will be calculated to measure the level to which a non-enrolled mother agreed with each individual on-study mother (Figure 1a-b) or the other non-enrolled mother (Figure 1c). In Figures 1a-b, a p-value of 0.05 will indicate that the on-study mother's judged scores were significantly correlated with the non-enrolled mother's re-scores. In Figure 1c, a p-value of 0.05 will indicate that non-enrolled mother #1's re-scores were significantly correlated with the non-enrolled mother' #2s re-scores.

A bubble plot will also be created to graphically represent the level of agreement between on-study and non-enrolled mother (Figures 2a-2b) and between the two non-enrolled mothers (Figure 2c). A greater correlation will be represented by a larger bubble, while a lesser correlation will be represented by a smaller bubble.

Both the individual graphs' and bubble plots' final format will be in accordance with the agreed upon TLF Deliverable Shell submitted with the final version of this SAP. The number of individual graphs is set at 100 within the TLF Deliverable Shell; however, this number may vary depending on the number of participants included in the final database.

8.5.2 Parental Satisfaction with ClaimIt Platform Questionnaire

Table 2a will describe the frequency and percent of "Yes" and "No" responses for Questions 2, 3, 5, 6, 7 and 8. For Question 5a, among subjects who indicated "Yes" for Question 5, the frequency and percent will be calculated for each reason of why there was scoring difficulty.

Tables 2b-2f represent the free text responses for Questions 2, 3, 4, 5, 8 of the questionnaire. Tables 2b-c and 2f (Questions 2, 3, and 8, respectively) represent responses among subjects who answered "Yes". Table 2d describes responses to Question 4, which is characterized as an open-ended question only. Table 2e includes responses from subjects who answered "Other" for Question 5a. The

number of subjects who completed the question and/or relevant sub-question will be listed within the table.

Table 3 represents the list of reasons for withdrawal from the study among subjects who dropped out prior to the study's conclusion. Figure 3 describes the number and percentage of subjects throughout the study process, beginning from the screening process to study completion (*see section 8.6*).

8.6 CONSORT diagram

Due to the 15% dropout rate built into the estimated total sample size, subjects whose study participation is terminated prematurely will not be replaced. The number and percentage of subjects who withdraw early will be presented in a CONSORT flow diagram equivalent; reasons for withdrawal will be presented in a table.

9 Quality Control

9.1 Data Quality Checks

All raw data produced as part of this study will be examined by the ObvioHealth Biostatistics Department for plausibility prior to database lock. ObvioHealth and the sponsor's team will agree upon the final database as signified by a signed agreement.

9.2 Output Quality Checks

ObvioHealth follows a standard operating procedure for Quality Control of all study outputs. All results outputs produced for this study will be examined independently by at least two members of ObvioHealth's Biostatistics Department. All potential issues will be listed and resolved in a Quality Control meeting with the reviewing parties from OH Biostatistics and a member of the senior leadership team. The purpose of this meeting is to resolve any outstanding concerns with said output and ultimately approve all tables, listings, and figures, for insertion into the study's Clinical Study Report.

10 Reporting

10.1 Clinical Study Report

A Clinical Study Report will be developed and provided by ObvioHealth after the following have occurred: database lock, completed statistical analysis, and completed and client-approved TLF deliverable (through executed Tables, Listings, and Figures Deliverable Finalization Form). The report will review study background and methodology and will include relevant results, including tables, listings, and figures agreed upon in the TLF Deliverable Shell (see Section 10.2 immediately below).

10.2 TLF Deliverable Shell

In conjunction with the finalized SAP, ObvioHealth and Danone will agree upon a set of tables, figures, and listings that will be provided as part of the final study deliverable – the TLF Deliverable Shell.

The TLF Deliverable Shell will consist of a set of spreadsheets (or in other words, a workbook) that houses the empty versions of all tables and listings for this study. The final worksheet in this workbook will be a list of figures to be delivered. ObvioHealth and the sponsor will establish the final TLF Deliverable Shell by written agreement.

11 Study Limitations

This is an exercise in collecting images for a database using the ClaimIt platform accompanied by a participant feedback questionnaire. As such, the study's ability to draw any statistical inferences is limited.

Inclusion criteria for this study may introduce biased sampling as participation is limited to subjects with access to reliable in-home internet and a mobile technology to accommodate the ClaimIt App. Furthermore, although the study instruments are based on a validated scoring tool, self-reported stool scores are subjective and not based on clinical evaluation. Finally, as the sample size was predetermined without a formal power calculation, the statistical evaluation was restricted to descriptive analyses with data visualizations of subjective measures and trends comparisons. However, this study provides proof of concept and utility of a digital clinical assessment.

12 References

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2. Heaton KW, Radvan J, Cripps H, et al. Defecation frequency and timing, and stool form in the general population: a prospective study. Gut 1992;33:818–24
3. Lane, M.M., Czyzewski, D.I., Chumpitazi, B.P., and Shulman, R.J. Reliability and validity of a modified Bristol Stool Form Scale for children. J Pediatr. 2011; 159: 437–441.
4. Vandenplas Y, Szajewska H, Benninga M, et al. Development of the Brussels Infant and Toddler Stool Scale ('BITSS'): protocol of the study. BMJ Open 2017;7:e014620.

13. Appendices

Appendix I: Parental Satisfaction with ClaimIt Platform

The following questions are regarding the use of the ClaimIt application during your participation in this clinical trial:

1. Please rate the ClaimIt application's overall ease of use on a scale of 1 to 5:

   (Very Difficult) 1 2 3 4 5 (Very Easy)

2. Did the ClaimIt application malfunction?
   a. Yes (will be asked a follow-up question)
   b. No

   If Yes, please describe what happened:

   _____

   _____

3. Have you participated in any other clinical study?
   a. Yes (will be asked a follow-up question)
   b. No

   (If yes) What did you prefer about study participation using the ClaimIt application? Why?

   _____

   _____

(If yes) What did you prefer about participation in the previous study? Why?

_____

_____

4. Do you have any comments about using the application (favorable or unfavorable) that you would like the PIs to know?

   _____ (Open ended question)

5. Did you find it difficult to score the stool pictures?
   a. Yes
   b. No

   (If yes) Why?

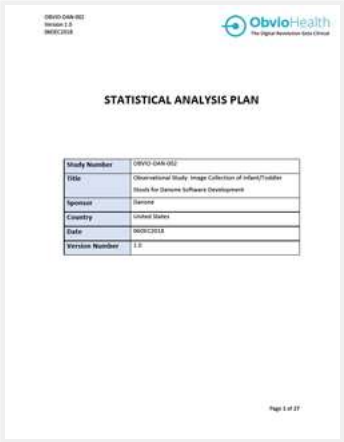
   a. Because the app was not easy to use to see the example pictures
   b. Because it was not easy for me to score the stool, even with the example pictures provided
   c. Because sometimes the stool seemed in between two examples
   d. Because I did not have the time to make a decision
   e. Other _____ *(Open ended question)*

6. If the doctor wanted to know about your child's stool type, do you feel it would be helpful to have an automatized tool to score the stool pictures for you?
   a. Yes
   b. No

7. Would you say your child's stool pattern is, or was, a concern to you?
   a. Yes, frequently
   b. Yes, when my baby was younger
   c. No, never

8. Was it easy to take the pictures of the diaper?
    a. Yes
    b. No

    (if no) Why? _____



SAP Danone Stool V1.0_06DEC2018

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