Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	Reporting and Analysis Plan for an open-label study to evaluate correct use and ease of use of the ELLIPTA Dry Powder Inhaler (DPI) in pediatric patients currently receiving inhaled therapy for treatment of their asthma
Compound Number	:	GSK2285997 (GW685698 + GW642444)
Effective Date	:	12-MAR-2019

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 206924.
- This RAP is intended to describe the planned analyses required for the study and output to be included in the Clinical Study Report for Protocol 206924.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol: 206924.

Revision Chronology:		
2017N346371_00	23-JAN-2018	Original

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

Changes from the originally planned statistical analysis specified in the protocol (dated: 23/JAN/2018) are outlined in Table 1.

Table 1 Changes to Protocol Defined Analysis Plan

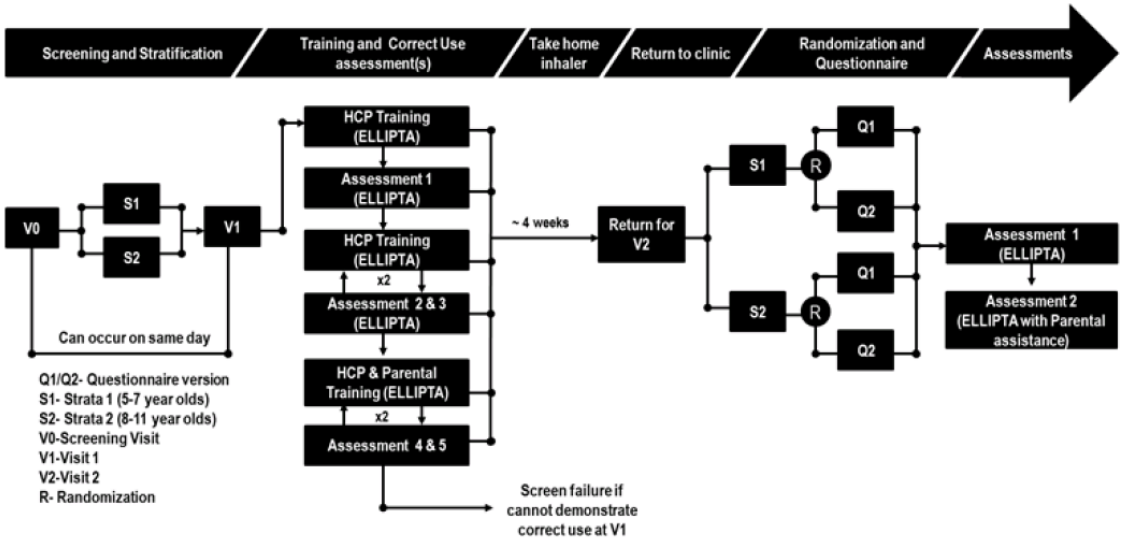
Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
Protocol Section 10.3 Populations for Analyses	RAP Section 4 Analysis Populations	The analysis populations have been updated to follow the study populations standard definitions and statistical displays
	RAP Section 7.1.5.1.2, Section 7.2.5.1.3., Section 7.3.4.1.	Removed sensitivity analysis proposed in the critical components RAP "participants who completed demonstration of correct use before answering the ease of use questionnaire" due to the information not being recorded.

2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To determine the proportion of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.	• The percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
• To determine the proportion of participants from each stratum who rate the use of the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.	• The percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

Objectives	Endpoints
Secondary Objectives	**Secondary Endpoints**
• To determine the proportion of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from healthcare professional (HCP) at V1.	• The percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP at V1.
• To determine the proportion of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.	• The percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
• To determine the proportion of participants who rate the use of the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.	• The percentage of participants who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.
• To determine the proportion of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.	• The percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.
Exploratory Objectives	**Exploratory Endpoints**
• To determine the proportion of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2.	• The percentage of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2.
• To determine the proportion of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as 'easy 'or 'very easy' after the study period at V2.	• The percentage of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as 'easy' or 'very easy' after the study period at V2.
• To determine the proportion of participant's parents/guardians who would be 'likely' or 'very likely' to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.	• The percentage of participant's parents/guardians who would be 'likely' or 'very likely' to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.
• To determine the proportion of participants from each stratum who can demonstrate correct use after the study period at V2 with assistance from parents/guardians.	• The percentage of participants from each stratum who demonstrated correct use after the study period at V2 with assistance from parents/guardians.
• To determine the proportion of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.	• The percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.
• To determine the proportion of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.	• The percentage of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

2.3. Study Design

Overview of Study Design and Key Features	
	
Design Features	• This is an open-label study to evaluate correct use and ease of use of the ELLIPTA Dry Powder Inhaler (DPI) in pediatric patients who are currently receiving inhaled therapy for treatment of their asthma. • Only participants who are naïve to the ELLIPTA DPI and have an established diagnosis of asthma will be considered eligible to participate in the study. • Participants will continue to use their current asthma therapy (rescue or maintenance) throughout the study. • The participants will be stratified in to two strata based on their age (5-7 year olds, 8-11 year olds) at the screening visit (Visit 0).
Dosing	• Participants will be instructed to take one inhalation from the placebo ELLIPTA DPI no more than once daily at the same time each day during the 4-week study treatment period.
Time & Events	• [Refer to Appendix 2: Schedule of Activities]
Treatment Assignment	• All participants who pass screening (Visit 0) are given a placebo ELLIPTA DPI at Visit 1. • All participants at V1 are then trained and assessed in correct use of the ELLIPTA DPI up to a maximum of five times. For the first three attempts, the participant is trained by the HCP. For the fourth and fifth attempts, the participants' parent/guardian assists in the training of the ELLIPTA DPI placebo. • Participants who demonstrate correct use at V1 are then given a placebo ELLIPTA DPI to take away from the site to continue use for 4 weeks. Participants should take one dose a day at roughly the same time every day. • Approximately 219 participants will be enrolled in the study and stratified by age (approximately 88 5-7 year olds, and 131 8-11 year olds) such that 200 evaluable participants reach Visit 2 and complete the study. • Participants will be randomised at Visit 2 to one of two ELLIPTA DPI ease of use questionnaires.
Interim Analysis	• No interim analysis will be conducted during this study

2.4. Statistical Hypotheses / Statistical Analyses

This is a descriptive, placebo only study and no formal inference is planned. The two primary objectives of the study are:

- To determine the proportion of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- To determine the proportion of participants from each stratum who rate the use of the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

3. PLANNED ANALYSES

3.1. Interim Analyses

No interim analysis is planned for this study.

3.2. Final Analyses

The final planned primary analyses will be performed after the completion of the following sequential steps:

1. All participants have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.
3. All criteria for unblinding the randomization codes have been met.
4. Randomization codes have been distributed according to RandAll NG procedures.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Subjects Enrolled (ASE)	• All participants whose parent/guardian has signed the Informed Consent Form (ICF) and the accompanying informed assent from the participant (where applicable) has been acquired, and for whom a record exists in the study database, including screen failures and any participant who was not screened but experienced an SAE between the date of informed consent and the planned date of the Screening visit.	• Study Population • Safety
Intent-To-Treat (ITT)	• The Intent-to-Treat (ITT) population is defined as all subjects who have been screened and received at least one dose of the study medication (placebo).	• Study Population • Safety • Efficacy
Modified Intent-to-Treat (MITT)	• The Modified Intent-to-Treat (MITT) population is defined as all subjects who have been screened, received at least one dose of the study medication (placebo) and were randomized to a version of the ease of use questionnaire at V2.	• Study Population • Efficacy

Refer to Appendix 10: List of Data Displays which details the population used for each display. – Appendix 10 to be defined in full RAP

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan 8-JUN-2018, Version 1.0.

- Data will be reviewed prior to freezing the database to ensure all important deviations are captured and categorised on the protocol deviations dataset.
- This dataset will be the basis for the summaries and listings of protocol deviations.

A separate summary and listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

All participants during screening will be provided an ELLIPTA DPI placebo to demonstrate correct use at Visit 1 at site and provided another ELLIPTA DPI to take away from site for the study period. The ELLIPTA DPI placebo is the only 'treatment' being provided in this study, hence no formal treatment comparisons will be performed.

All participants will be stratified in to two strata based on their age at visit 0 (5-7 and 8-11 years old).

The participants who make it through visit 1 and return at visit 2 will be randomised to one of two ELLIPTA DPI ease of use questionnaires (version A or version B). The version of the ease of use questionnaires will be considered the "treatment groups" in this study. The parents/guardians are also assigned to one of two ease of use questionnaires. The participant's questions are different to the parents/guardian's versions, however, the parents/guardians are assigned the same version (A or B) as their child's randomised version.

Treatment Group Descriptions			
RandAll NG		Data Displays for Reporting	
Code	Description	Description	Order in TLF
A	Placebo Ease of Use Questionnaire Version A	Questionnaire: Version A	1
B	Placebo Ease of Use Questionnaire Version B	Questionnaire: Version B	2

5.2. Baseline Definitions

For all endpoints, the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline.

Unless otherwise stated, if baseline data is missing no derivation will be performed and baseline will be set to missing.

5.3. Multicentre Studies

In this multicentre global study, enrolment will be presented by country.

Region	Countries
Northern America	United States, Canada

5.4. Examination of Covariates, Other Strata and Subgroups

5.4.1. Covariates and Other Strata

The list of covariates and other strata may be used in descriptive summaries and statistical analyses, some of which may also be used for subgroup analyses. Additional covariates and other strata of clinical interest may also be considered.

Category	Details
Strata	Age Group at Screening (5-7 years old, 8-11 years old), Ease of Use Questionnaire (Version A, Version B)
Covariates	Country

5.4.2. Examination of Subgroups

The list of subgroups may be used in descriptive summaries and statistical analyses. Additional subgroups of clinical interest may also be considered.

- If the percentage of subjects is small within a particular subgroup, then the subgroup categories may be refined prior to unblinding the trial.
- If the category cannot be refined further, then descriptive rather than statistical comparisons may be performed for the particular subgroup.

Subgroup	Categories
Country	United States, Canada
Gender	Female, Male
Duration of Asthma	< 1 year, >=1 year to < 3 years, >=3 years to < 5 years, >=5 years
Main Current Asthma Therapy	Rescue Only, Maintenance with or without Rescue
Main Current Asthma Therapy Device Type	DPI, MDI, Other

5.5. Multiple Comparisons and Multiplicity

There are no planned adjustments for multiple comparisons or multiplicity.

5.6. Other Considerations for Data Analyses and Data Handling Conventions

Other considerations for data analyses and data handling conventions are outlined in the appendices:

Section	Component
10.3	Appendix 3: Assessment Windows
10.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
10.5	Appendix 5: Data Display Standards & Handling Conventions
10.6	Appendix 6: Derived and Transformed Data

Section	Component
10.7	Appendix 7: Reporting Standards for Missing Data
10.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the Intent-to-Treat (ITT) population, unless otherwise specified.

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards.

Details of the planned displays are presented in Appendix 10: List of Data Displays

6.2. Participant Disposition

The study population summary will use the ASE population and show the number of participants overall who were screened, the number of screen failures and the number with each reason for the screen failure. The display will also showcase the number of participants who are in the ITT population (complete screening and demonstrate correct use at visit 1) and MITT population (attend visit 2 and are randomised to a version of the ease of use questionnaire).

For the ITT population, reasons for withdrawal summary will present the number and percentage of participants who completed the study, those who withdrew prematurely from the study and those who reported a primary and sub-reason for the withdrawal.

6.3. Medical Conditions

The number and percentage of participants reporting each current medical condition will be presented. All medical conditions will be summarised in the displays regardless of the frequencies. This applies to both the current and past medical condition displays.

6.4. Concomitant Medications

Concomitant medications will be coded using the GSK Drug coding dictionary. A summary of the number and percentage of subjects with concomitant medications will be displayed by GSK-Drug Anatomical Therapeutic Chemical (ATC) classification level 1 (Body System) and ingredient. This summary will present drugs that are composed of a combination of ingredients and will be displayed according to the ATC classifications of the ingredients (combination) and will also include single-ingredient medications. Summaries will be split into those taken pre-treatment, during treatment, and post-treatment.

6.5. Incorrect Use at Visit 1

Participants will be asked to demonstrate correct use of the ELLIPTA at visit 1. The participants will have up to 5 attempts to demonstrate correct use. The number of participants who attempt correct use will be presented along with the number and percentages of those who did not demonstrate correct use after attempts number 1 to 5. The number and percentages of each item not performed correctly at each attempt will be summarised in the display for all participants. The summary will be based on the ITT population.

7. EFFICACY ANALYSES

7.1. Primary Efficacy Analyses

The primary analyses will include:

- To determine the proportion of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- To determine the proportion of participants from each stratum who rate the use of the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

7.1.1. Endpoints

The primary endpoints are:

- The percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- The percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

7.1.2. Summary Measure

The percentage for both endpoints will be reported for each stratum for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.

7.1.3. Population of Interest

The primary efficacy analyses will be based on the Modified Intent-to-Treat (MITT) population, unless otherwise specified.

7.1.4. Strategy for Intercurrent (Post-Randomization) Events

The MITT population composes of participants who have been screened, received at least one dose of the study medication (placebo) and were randomized to a version of the ease of use questionnaire at V2. Therefore, we can only identify intercurrent events that occur at V2 only.

Intercurrent events are defined as:

- Early discontinuation of study drug
- Early withdrawal from study (not completing correct use checklist or ease of use questionnaire)
- Use of prohibited medications

The “Treatment policy” strategy will be applied to handle the “Use of prohibited medications” and “Early discontinuation of drug” in the analysis for all endpoints. The strategy implies direct use of data irrespective of the occurrence of the intercurrent

events. This means the participant's data will be included in the analysis regardless whether they discontinued the ELLIPTA DPI placebo or used a prohibited medication at Visit 2. The "Treatment policy" strategy is the same as de facto type estimand. The strategy for the Early withdrawal from study intercurrent events is mentioned below for the endpoints.

7.1.4.1. Percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire and complete this questionnaire. The participants will then be asked to demonstrate correct use of the ELLIPTA DPI. A participant is expected to complete the full demonstration, however there is a possibility the participant might choose to no longer participate and not complete the full demonstration (i.e. decide to stop half way through the demonstration of the required steps for correct use of the ELLIPTA DPI). In the occurrence of this intercurrent event, the endpoint will be the percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2, where those who are deemed "not correct use" will comprise of the participants who did not demonstrate correct use of the ELLIPTA DPI **and** those who did not complete the demonstration of correct use. The strategy modifies the definition of the summary measure, such that the intercurrent event becomes a component of the outcome. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.1.4.2. Percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire, asked to complete the questionnaire and then will perform a demonstration of correct use of the ELLIPTA DPI. The first question relates to the ease of use of the ELLIPTA DPI, while the second question relates to the ease of telling the number of doses remaining in the ELLIPTA DPI. A participant is expected to complete the questionnaire before the correct use demonstration, however there is a possibility the participant might only answer one or zero of the questions, and still able to perform the correct use demonstration, or choose to no longer participate in the study. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2, where those who rate the ease of use of ELLIPTA DPI as "hard" comprise of the participants who rated the ELLIPTA DPI as "hard" **and** those who did not answer the ease of use question. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the questionnaire can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.1.5.1. Statistical Methodology Specification

7.1.5.1.1. *Percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2*

Endpoint / Variables
• The percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
Model Specification
• The primary endpoint of the percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2 will be analysed using the Modified Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Checking & Diagnostics
• Computation of the confidence intervals for the proportions is based on the exact (Clopper-Pearson) binomial distribution.
Model Results Presentation
• The percentage will be reported for each stratum for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the primary composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only.

7.1.5.1.2. *Percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2*

Endpoint / Variables
• The percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.
Model Specification
• The primary endpoint of the percentage of participants from each stratum who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2 will be analysed using the Modified Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Checking & Diagnostics
• Computation of the confidence intervals for the proportions is based on the exact (Clopper-Pearson) binomial distribution.
Model Results Presentation
• The percentage will be reported for each stratum for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the primary composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not answer ease of use questionnaire. This display will include the ease of use question completers only.

7.2. Secondary Efficacy Analyses

The secondary efficacy analyses will include:

- To determine the proportion of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP only at V1.
- To determine the proportion of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- To determine the proportion of participants who rate the use of the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- To determine the proportion of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP only at V1.

7.2.1. Endpoints

The secondary endpoints are:

- The percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP at V1.
- The percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- The percentage of participants who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.
- The percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

7.2.2. Summary Measure

The percentage for all secondary endpoints will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.

7.2.3. Population of Interest

The secondary efficacy analyses will be based on the Intent-To-Treat or Modified Intent-to-Treat populations, unless otherwise specified.

7.2.4. Strategy for Intercurrent (Post-Randomization) Events

Intercurrent events are defined as:

- Early discontinuation of study drug
- Early withdrawal from study
- Use of prohibited medications

The “Treatment policy” strategy will be applied to handle the “Use of prohibited medications” and “Early discontinuation of study drug” in the analysis for all endpoints. The strategy implies direct use of data irrespective of the occurrence of the intercurrent events. The “Treatment policy” strategy is the same as de facto type estimand. The strategy for the Early withdrawal from study intercurrent events is mentioned below for the endpoints.

7.2.4.1. Percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP at V1.

The population of interest will be based on the Intent-to-Treat population.

The “Composite” strategy will be used for the “Early withdrawal from study” intercurrent event. Participants who pass the screening visit (Visit 0) will then be taught by the HCP how to correctly use the ELLIPTA DPI. The participant is then provided with their own ELLIPTA DPI and will be asked to demonstrate correct use. If the participant demonstrates correct use of the ELLIPTA DPI, they will progress through the study and

deemed correct use at V1, attempt one. If the participant cannot perform correct use on their first attempt, then they will have four more attempts, and will be deemed a "not correct use" on the first attempt. A participant is expected to complete the full correct use demonstration, however there is a possibility the participant might choose to no longer participate and not complete the full demonstration. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from the HCP at V1, where those who are deemed "not correct use" will comprise of participants who did not perform correct use of the ELLIPTA DPI on attempt one **and** those who did not complete the demonstration of correct use on attempt one. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed a screen failure and no data will be collected for this endpoint.

7.2.4.2. Percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire and asked to complete the questionnaire. The participants will then be asked to demonstrate correct use of the ELLIPTA DPI. A participant is expected to complete the full demonstration, however there is a possibility the participant might choose to no longer participate and not complete the full demonstration (i.e. decide to stop half way through the demonstration of the required steps for correct use of the ELLIPTA DPI). In the occurrence of this intercurrent event, the endpoint will be the percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2, where those who are deemed "not correct use" will comprise of the participants who did not demonstrate correct use of the ELLIPTA DPI **and** those who did not complete the demonstration of correct use. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.2.4.3. Percentage of participants who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire, asked to complete the questionnaire and then will perform a demonstration of correct use of the ELLIPTA DPI. The first question relates to the ease of use of the

ELLIPTA DPI, while the second question relates to the ease of telling the number of doses remaining in the ELLIPTA DPI. A participant is expected to complete the questionnaire before the correct use demonstration, however there is a possibility the participant might only answer one or zero of the questions, and still able to perform the correct use demonstration, or choose to no longer participate in the study. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2, where those who rate the ease of use of ELLIPTA DPI as "hard" comprise of the participants who rated the ELLIPTA DPI as "hard" **and** those who did not answer the ease of use question. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the questionnaire can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.2.4.4. Percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1

The population of interest will be based on the Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who pass the screening visit (Visit 0) will then be taught by the HCP how to correctly use the ELLIPTA DPI. The participant is then provided with their own ELLIPTA DPI and will be asked to demonstrate correct use. Four of the ten correct use checklist items are deemed as "critical errors" (see Section 10.6.3 for the details on critical errors). A participant is expected to perform throughout the whole correct use demonstration, however there is a possibility the participant might choose to no longer participate and not complete the full demonstration (i.e. only perform 2 of the 4 critical error items during the correct use demonstration). In the occurrence of this intercurrent event, the endpoint will be the percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1. If a participant withdraws at any point throughout the correct use demonstration and performed a critical error, then the participant will be deemed as one who performed at least one critical error. If the participant withdraws at any point throughout the correct use demonstration and did not perform all the critical error items, then taking the conservative approach, the participant will also be deemed as one who performed at least one critical error. If the participant withdraws at any point during the correct use demonstration and performs all critical error items correctly, then the participant will be deemed as one who did not perform at least one critical error. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed a screen failure and no data will be collected for this endpoint.

7.2.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.2.5.1. Statistical Methodology Specification

7.2.5.1.1. Percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP at V1

Endpoint / Variables
• The percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP at V1.
Model Specification
• The endpoint of the percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after initial training from HCP at V1 will be analysed using the Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for each stratum for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only.

7.2.5.1.2. Percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.

Endpoint / Variables
• The percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2.
Model Specification
• The endpoint of the percentage of participants who demonstrate correct use of the ELLIPTA DPI after the study period at V2 will be analysed using the Modified Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI

Model Results Presentation
• The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only.

7.2.5.1.3. Percentage of participants who rate the use of the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.

Endpoint / Variables
• The percentage of participants who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2.
Model Specification
• The endpoint of the percentage of participants who rate the ELLIPTA DPI as easy to use, from those who could demonstrate correct use of the ELLIPTA DPI after the study period at V2 will be analysed using the Modified Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the primary composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not answer ease of use questionnaire. This display will include the ease of use question completers only.

7.2.5.1.4. Percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

Endpoint / Variables
• The percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.
Model Specification
• The endpoint of the percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1 will be

analysed using the Intent-to-Treat population. • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for each stratum for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only.

7.3. Exploratory Efficacy Analyses

The exploratory efficacy analyses will include:

- To determine the proportion of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2.
- To determine the proportion of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2.
- To determine the proportion of participant's parents/guardians who would be 'likely' or 'very likely' to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.
- To determine the proportion of participants from each stratum who can demonstrate correct use after the study period at V2 with assistance from parents/guardians.
- To determine the proportion of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.
- To determine the proportion of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

7.3.1. Endpoints

The exploratory efficacy endpoints are:

- The percentage of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2.
- The percentage of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2.

- The percentage of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.
- The percentage of participants from each stratum who demonstrated correct use after the study period at V2 with assistance from parents/guardians.
- The percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.
- The percentage of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

7.3.2. Summary Measures

The percentage for all exploratory efficacy endpoints will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.

7.3.3. Population of Interest

The exploratory efficacy analyses will be based on the Intent-To-Treat or Modified Intent-to-Treat populations, unless otherwise specified.

7.3.4. Strategy for Intercurrent (Post-Randomization) Events

Intercurrent events are defined as:

- Early discontinuation of study drug
- Early withdrawal from study
- Use of prohibited medications

The "Treatment policy" strategy will be applied to handle the "Use of prohibited medications" and "Early discontinuation of study drug" in the analysis for all endpoints. The strategy implies direct use of data irrespective of the occurrence of the intercurrent events. The "Treatment policy" strategy is the same as de facto type estimand. The strategy for the Early withdrawal from study intercurrent events is mentioned below for the endpoints.

7.3.4.1. Percentage of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire, asked to complete the questionnaire and then will perform a demonstration of correct use of the ELLIPTA DPI. The first question relates to the ease of use of the ELLIPTA DPI, while the second question relates to the ease of telling the number of doses remaining in the ELLIPTA DPI. A participant is expected to complete the questionnaire before the correct use demonstration, however there is a possibility the

participant might only answer one or zero of the questions, and still able to perform the correct use demonstration, or choose to no longer participate in the study. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2, where those who rate the ease of telling the number of puffs remaining in the ELLIPTA DPI as "hard" comprise of the participants who answered the question as "hard" **and** those who did not answer the ease of number of puffs question. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the questionnaire can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.3.4.2. Percentage of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2.

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire and asked to complete the questionnaire. The parent/guardian will also be given the same version (A or B) of their own questionnaire. The parent's questionnaire contains two questions, and these relate to: the ease or difficulty of telling how many doses were left in the ELLIPTA DPI, and whether you would be likely to request your child's asthma medication in the ELLIPTA DPI if it were available. Similarly, as the participant, the parent is expected to fully complete the questionnaire, however there is a possibility the parent might only answer one or zero of the questions or choose to no longer allow their child to participate in the study. In the occurrence of this intercurrent event, the endpoint will be the percentage of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2, where those who rate the ease of telling the number of doses remaining in the ELLIPTA DPI other than "easy" or "very easy" comprise of the participants parents who answered the question as "hard" or "very hard" **and** those who did not answer the ease of number of doses question. These parents will be grouped as "Hard/Very Hard" i.e. those parents who do not answer the question will contribute to the overall denominator of the population. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the questionnaire can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.3.4.3. Percentage of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. This endpoint will use the same strategy as detailed in 7.3.4.2. In the occurrence of this intercurrent event, the endpoint will be the percentage of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2, where those who answer the second question of the ease of use questionnaire other than "likely" or "very likely" comprise of the participants parents who answered the question as "unlikely" or "very unlikely" **and** those who did not answer the second ease of use question. These parents will be grouped as "Unlikely/Very Unlikely". i.e. those parents who do not answer the question will contribute to the overall denominator of the population. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the questionnaire can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.3.4.4. Percentage of participants from each stratum who demonstrate correct use after the study period at V2 with assistance from parents/guardians

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. Participants who make it to V2 will be randomised to a version of the ease of use questionnaire, asked to complete the questionnaire and then will perform a demonstration of correct use of the ELLIPTA DPI. After a participant has performed the demonstration of correct use, they will either have performed it correctly and finish the study or have not demonstrated correct use and will be asked to try again with the assistance of their parent/guardian. A similar strategy will be applied for this intercurrent event as detailed in 7.1.4.1. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants from each stratum who demonstrate correct use of the ELLIPTA DPI after the study period at V2 with assistance from parents/guardians, where those who are deemed "not correct use" will comprise of the participants who did not demonstrate correct use of the ELLIPTA DPI **and** those who did not complete the demonstration of correct use. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.3.4.5. Percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.

The population of interest will be based on the Modified Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. This endpoint only considers the first correct use attempt at visit 2, and not both correct use attempts (i.e. the second attempt with the assistance from the parent/guardian is not included). A similar strategy for this incurrent event will be applied as detailed in 7.2.4.4. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2. If a participant withdraws at any point throughout the correct use demonstration and performed a critical error, then the participant will be deemed as one who performed at least one critical error. If the participant withdraws at any point throughout the correct use demonstration and did not perform all the critical error items, then taking the conservative approach, the participant will also be deemed as one who performed at least one critical error. If the participant withdraws at any point during the correct use demonstration and performs all critical error items correctly, then the participant will be deemed as one who did not perform at least one critical error. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed an early withdrawal and no data will be collected for this endpoint.

7.3.4.6. Percentage of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

The population of interest will be based on the Intent-to-Treat population.

The "Composite" strategy will be used for the "Early withdrawal from study" intercurrent event. A similar strategy for this incurrent event will be applied as detailed in 7.2.4.4. In the occurrence of this intercurrent event, the endpoint will be the percentage of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1. If a participant withdraws at any point throughout the correct use demonstration and performed a critical error, then the participant will be deemed as one who performed at least one critical error. If the participant withdraws at any point throughout the correct use demonstration and did not perform all the critical error items, then taking the conservative approach, the participant will also be deemed as one who performed at least one critical error. If the participant withdraws at any point during the correct use demonstration and performs all critical error items correctly, then the participant will be deemed as one who did not perform at least one critical error. A footnote will be included on displays to indicate this composite endpoint, if this intercurrent event should occur.

If a participant withdraws from the study, or a parent no longer consents their child before the correct use demonstration can be started, then they will be deemed a screen failure and no data will be collected for this endpoint.

7.3.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK data standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 7.3.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

7.3.5.1. Statistical Methodology Specification

7.3.5.1.1. Percentage of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2

Endpoint / Variables
• The percentage of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2
Model Specification
• The endpoint of the percentage of participants from each stratum who rate the ability to tell how many puffs are left in the ELLIPTA DPI as easy after the study period at V2 will be analysed using the Modified Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the primary composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not answer ease of use questionnaire. This display will include the number of puffs question completers only.

7.3.5.1.2. Percentage of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2.

Endpoint / Variables
• The percentage of participants parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2.
Model Specification
• The endpoint of the percentage of participants parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA DPI as easy or very easy after the study period at V2 will be analysed using the Modified Intent-to-Treat population.   • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the primary composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants parents/guardians do not answer ease of use questionnaire. This display will include the number of doses question completers only. • It is required for the parent/guardian who attends visit 2 to have also attended visit 1. A sensitivity analysis may be presented if a substantial amount (10% of the total population) of participants parents/guardians who attend visit 2 are not the same as those who attended visit 1. This display will only include the results of those parents/guardians who attended both study visits.

7.3.5.1.3. Percentage of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.

Endpoint / Variables
• The percentage of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2.
Model Specification
• The endpoint of the participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA DPI if the participants current daily inhaled medication(s) were available in the ELLIPTA DPI after the study period at V2 will be analysed using the Modified

Intent-to-Treat population. • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the primary composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants parents/guardians do not answer ease of use questionnaire. This display will include the current daily inhaled medication question completers only. • It is required for the parent/guardian who attends visit 2 to have also attended visit 1. A sensitivity analysis may be presented if a substantial amount (10% of the total population) of participants parents/guardians who attend visit 2 are not the same as those who attended visit 1. This display will only include the results of those parents/guardians who attended both study visits.

7.3.5.1.4. Percentage of participants from each stratum who demonstrate correct use after the study period at V2 with assistance from parents/guardians

Endpoint / Variables
• The percentage of participants from each stratum who demonstrate correct use after the study period at V2 with assistance from parents/guardians.
Model Specification
• The endpoint of the participants from each stratum who demonstrate correct use after the study period at V2 with assistance from parents/guardians will be analysed using the Modified Intent-to-Treat population. • This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI
Model Results Presentation
• The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only. • It is required for the parent/guardian who attends visit 2 to have also attended visit 1. A sensitivity analysis may be presented if a substantial amount (10% of the total population) of participants parents/guardians who attend visit 2 are not the same as those who attended visit

1. This display will only include the results of those parents/guardians who attended both study visits.

7.3.5.1.5. Percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.

Endpoint / Variables

- The percentage of participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2.

Model Specification

- The endpoint of the participants from each stratum who made at least one critical error during use of the ELLIPTA DPI after the study period at V2 will be analysed using the Modified Intent-to-Treat population.
    - This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI

Model Results Presentation

- The percentage will be reported for the single treatment group along with a 95% confidence interval (CI) for the percentage, calculated using the exact binomial distribution.

Sensitivity and Supportive Analyses

- Observed analyses: Along with the composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only.

7.3.5.1.6. Percentage of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

Endpoint / Variables

- The percentage of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1.

Model Specification

- The endpoint of the participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at V1 will be analysed using the Modified Intent-to-Treat population.
    - This endpoint will be analysed using the exact binomial distribution to calculate the 95% CI

Model Results Presentation

- The percentage will be reported for the single treatment group along with a 95% confidence

interval (CI) for the percentage, calculated using the exact binomial distribution.
Sensitivity and Supportive Analyses
• Observed analyses: Along with the composite estimand display, an observed data display with no imputation may be presented if a substantial amount (10% of the total population) of participants do not complete the correct use demonstration. This display will include the correct use demonstration completers only.

8. SAFETY ANALYSES

The safety analyses will be based on the ITT population, unless otherwise specified.

8.1. Adverse Events

Adverse events analyses including summaries of adverse events (AEs), serious adverse events (SAEs) and any other significant AE's will be based on the GSK Core Data Standards.

Considering this is a placebo only ELLIPTA DPI study and no active drug is being prescribed, the summaries will be presented for all participants combined regardless of their randomised questionnaire version. The details of the planned analyses are provided in Appendix 10: List of Data Displays

A summary of the following AEs and SAEs will be provided:

- Any AE or SAE (pre-treatment (SAE only), on-treatment or post-treatment)]
- Any on-treatment drug related AE
- Any on-treatment non-serious AE
- Any AE (pre-treatment or on-treatment) leading to permanent discontinuation of study treatment or withdrawal from the study
- Any fatal AE
- Any non-fatal SAE
- Any on-treatment non-fatal drug related SAE
- Any on-treatment fatal drug related SAE

The numbers and percentage of participants will all AEs (regardless of causality) will be summarised by system organ class (SOC) and preferred term (PT). The ordering of the SOCs and PTs will be in descending order of total incidence. A SOC will not be presented if the overall incidence for AE within the particular system. If the total incidence for any two or more AEs is equal, the events will be presented in alphabetical order.

8.2. Adverse Events of Special Interest Analyses

No AE of special interest analysis will be performed as no active drug is prescribed in this study.

9. REFERENCES

GlaxoSmithKline Document Number 2017N346371_00 Study ID 206924. An open-label study to evaluate correct use and ease of use of the ELLIPTA Dry Powder Inhaler (DPI) in pediatric patients currently receiving inhaled therapy for treatment of their asthma. Report Date 23-Jan-2018.

10. APPENDICES

10.1. Appendix 1: Protocol Deviation Management

The full list of protocol deviations collected on the eCRF is in the Protocol Deviation Management Plan (PDMP). Please refer to this document for current guidance.

10.1.1. Exclusions from Per Protocol Population

There is no Per Protocol population in this study.

10.2. Appendix 2: Schedule of Activities

10.2.1. Protocol Defined Schedule of Events

Procedure	Visit 0-Screening (up to 30 days before Day 1)	Treatment Period			Notes
		Visit 1 (can occur on same day as screening)	Early Withdrawal	Visit 2	
Study Day	-30	1		29 ± 2	All assessments concern study participants only, unless otherwise stated (parent/guardians).
Screening					
Informed consent and assent	X				Visit 1 must occur within 30 days of signing of providing informed consent. Must be signed before any study procedures. Assent must be provided.
Inclusion and exclusion criteria	X				All of the inclusion and none of the exclusion criteria must be met prior to inclusion at V0. This includes ability to demonstrate correct use of the ELLIPTA DPI after training.
Demography	X				Age, sex, race, ethnicity.
Physical Examination	X				Including height and weight,
Concomitant medications	X				Concomitant medications pertaining to the participant's diagnosis of asthma collected (minimum previous 3 months).
Past and current medical conditions	X				
Asthma History	X				Participant will have a medical history of symptoms consistent with a diagnosis of asthma.
Exacerbation History	X				Asthma exacerbation history for the previous year will be collected.
Randomization				X	Randomization refers to the version of the questionnaire only.
Safety					
AE review		←==========→			Collected from Visit 1 until the completion of the final assessment at Visit 2.
SAE review	←==========→				Collected from time of informed consent/assent until the completion of the final assessment at Visit 2.
Concomitant medications review	←==========→				Review any changes in concomitant medications.
Asthma exacerbations	←==========→				Asthma exacerbation information will be collected for the duration of the study (see Section 9.2.6 in the Protocol).
Questionnaires and Assessments					
First training in correct use of ELLIPTA DPI by HCP		X			Initial training by HCP
Correct use of ELLIPTA DPI after first instruction by HCP		X			First demonstration of correct use of ELLIPTA DPI.

Procedure	Visit 0-Screening (up to 30 days before Day 1)	Treatment Period			Notes
		Visit 1 (can occur on same day as screening)	Early Withdrawal	Visit 2	
Second and third training in correct use of ELLIPTA DPI by HCP		X			Training only if necessary (participant made errors)
Correct use of ELLIPTA DPI after second and third instruction by HCP		X			Second and third demonstrations of correct use of ELLIPTA DPI
Fourth and fifth training in correct use of ELLIPTA DPI by HCP and parent/guardian		X			Training only if necessary (participant made errors)
Correct use of ELLIPTA DPI after fourth and fifth instruction by HCP and parent/guardian		X			Fourth and fifth demonstrations of correct use of ELLIPTA DPI. After which time they will be registered as a screen failure if correct use has not been demonstrated.
Ease of use Questionnaire completion				X	This is completed upon return to the site after the study period. This must occur before any other assessments at V2.
Compliance with ELLIPTA DPI			X	X	This will be taken from the dose counter.
Correct use of ELLIPTA DPI after treatment period				X	Demonstration of correct use of ELLIPTA DPI without any instruction at V2.
Correct use of ELLIPTA DPI with instruction from parent/guardian				X	Demonstration of correct use of ELLIPTA DPI with instruction from parent/guardian at V2. Only necessary if correct use is not demonstrated during first attempt.
Placebo ELLIPTA DPI					
Dispense Placebo ELLIPTA DPI(s)		X			Procedures for dispensation and return of clinical supplies will be described in detail in the Study Reference Manual (SRM). If a participant completes all study requirements, they will need 2 ELLIPTA DPIs. One will remain at site and the other will be used during the study period.
Return Placebo ELLIPTA DPI		X	X	X	

AE – Adverse Event, DPI - Dry Powder Inhaler, HCP - Healthcare Professional, SAE - Serious Adverse Events,

10.3. Appendix 3: Assessment Windows

10.3.1. Definitions of Assessment Windows for Analyses

Study day 29 ± 2 (Visit 2, 28 days after Visit 1) is defined as the day of randomisation to an ease of use questionnaire.

Analysis Set / Domain	Parameter (if applicable)	Target	Analysis Window		Analysis Timepoint
			Beginning Timepoint	Ending Timepoint	
	All	1	-30	1	Visit 0
	All	1	1	1	Visit 1
	All	29	27	31	Visit 2

NOTES:

- Visit 1 can occur on same day as screening visit (Visit 0)

10.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

10.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to study treatment start and stop dates.

Study Phase	Definition
Pre-Treatment	Date < Study Treatment Start Date
On-Treatment	Study Treatment Start Date ≤ Date ≤ Study Treatment Stop Date + 1
Post-Treatment	Date > Study Treatment Stop Date + 1

10.4.1.1. Study Phases for Concomitant Medication

Treatment phases for summaries of Asthma and Non-Asthma concomitant medications will be defined as follows:

Definition	Treatment Phase		
	Pre-Treatment	On-Treatment	Post-Treatment
Subject did not take study treatment (e.g, screening failures) and conmed stop date > date of Screening or variable that asks if conmed is on-going (refer hereafter as ongoingmed) is “yes”	Y		
(Conmed start date < treatment start date or variable that asks if medication taken prior to study is ”yes”(refer hereafter as priormed)) and date of Screening < conmed stop date <treatment start date	Y		
(Conmed start date < treatment start date or priormed is yes) and (treatment start date ≤ conmed stop date ≤ treatment stop date)	Y	Y	
(Conmed start date < treatment start date or priormed is yes) and (conmed stop date > treatment stop date or ongoingmed is “yes”)	Y	Y	Y
(Treatment start date ≤ conmed start date < treatment stop date and treatment start date ≤ conmed stop date ≤ treatment stop date) or (Treatment start date = conmed start date = conmed stop date = treatment stop date)		Y	
(Treatment start date ≤ conmed start date < treatment stop date) or (Treatment start date = conmed start date = treatment stop date) and (conmed stop date > treatment stop date or ongoingmed is Yes)		Y	Y

Definition	Treatment Phase		
	Pre-Treatment	On-Treatment	Post-Treatment
Conmed start ≥ treatment stop date and treatment start date ≠ treatment stop date			Y

NOTES:

- A concomitant medication will be classed in every period of the study in which it was taken (e.g., run-in, on- treatment or post-treatment).
- See Section 10.7.2.1 for handling of partial dates.
- If the study treatment stop date is missing, it will be imputed as described in Section 10.7.
- Medications that stopped prior to Screening will not be assigned a treatment phase and will not be summarized.

10.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	• If AE onset date is on or after Visit 1 start date & on or before Visit 2 stop date. • (Visit 1 Start Date ≤ AE Start Date ≤ Visit 2 Stop Date + 1 day).

NOTES:

- If the study treatment stop date is missing, then the AE will be considered to be On-Treatment.

10.5. Appendix 5: Data Display Standards & Handling Conventions

10.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: UK1SALX00175
HARP Compound	: GSK2285997
QC Spreadsheet	: gsk2285997/mid206924/final_01/documents
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.0.	
Generation of RTF Files	
• RTF files will be generated for use in writing the CSR.	

10.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include subject level listings in the main body of the GSK Clinical Study Report. All subject level listings should be located in the modular appendices as ICH or non-ICH listings

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF.
Planned and Actual Time

• Reporting for tables, figures and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits
• Unscheduled visits will not be included in summary tables and/or figures. • All unscheduled visits will be included in listings.

Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

10.6. Appendix 6: Derived and Transformed Data

10.6.1. General

Study Day

• Calculated as the number of days from First Dose Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < First Dose Date → Study Day = Ref Date – First Dose Date
  • Ref Data ≥ First Dose Date → Study Day = Ref Date – (First Dose Date) + 1

10.6.2. Study Population

Treatment Compliance
• For ELLIPTA inhaler, the number of doses of study inhaler taken by each subject will be calculated from the dose counter start and stop counts for each inhaler prescribed during the 4-week study period (take home period). The derivation for treatment compliance during the 4-week study period is defined as the sum of (Dose Counter Start-Dose Counter Stop) over all inhalers dispensed to the participant and returned during the 4-week study period. If a dose counter start count is missing, then it will be assumed to be 30. If dose counter stop count is non-missing, then the percentage compliance will be calculated as: $Compliance = \frac{(Total\ Number\ of\ Inhalations\ Taken)}{(Treatment\ Stop\ Date - Treatment\ Start\ Date + 1)} \times 100$ Where $Total\ Number\ of\ Inhalations\ Taken$ is the total number of doses taken from all ELLIPTA DPI placebo inhalers in the 4-week study period, and $Treatment\ Start\ Date$ and $Treatment\ Stop\ Date$ are the earliest treatment start date and the latest treatment stop date recorded for all of the inhalers used in the calculation. • If the dose counter stop count is missing for the subject, then the treatment compliance will be set to missing for that subject.
Extent of Exposure
• Number of days of exposure to study drug will be calculated based on the formula: **Duration of Exposure in Days = Treatment Stop Date – (Treatment Start Date) + 1** • Participants who successfully complete the Visit 1 assessments but did not report a treatment start date will be categorised as having zero days of exposure. • If there are any treatment breaks during the study, exposure data will be adjusted accordingly.

10.6.3. Efficacy

Correct Use Checklist
Demonstrate Correct Use
For a participant to have demonstrated correct use, they need to have a “Yes” to all the correct use checklist items recorded: • Participant slides the cover completely down to expose the mouthpiece until a “click” is heard. • Participant does not shake the inhaler • Participant breathes out (exhales) while holding the inhaler away from their mouth • Participant does not breathe into the mouthpiece • Participant places mouthpiece between lips, and closes lips firmly around it. • Participant takes one long steady deep breath in through their mouth

Correct Use Checklist
• Participant does not block air vent with fingers. • Participant removes inhaler from his/her mouth and holds his/her breath • Participant breathes out slowly and gently • Participant closes the inhaler completely
Critical Errors
If a participant has recorded a "No" to any of the following in the correct use checklist items, this is then considered a critical error for the ELLIPTA DPI: • Participant slides the cover completely down to expose the mouthpiece until a "click" is heard. • Participant does not shake the inhaler • Participant does not breathe into the mouthpiece • Participant places mouthpiece between lips, and closes lips firmly around it.

Ease of Use Questionnaire
Number of Doses Remaining
The number of participant's parents/guardians who answer the number of doses question in their respective versions of the questionnaire as "Easy" or "Very easy" will be summarised together and presented such as: • Very easy • Easy • Difficult • Very difficult • Very easy/Easy The 95% confident intervals will be calculated for all the responses listed above using the exact binomial distribution.
Current Inhaled Asthma Medication
The number of participant's parents/guardians who answer the current inhaled asthma medication question in their respective versions of the questionnaire as "Likely" or "Very likely" will be summarised together and presented such as: • Very likely • Likely • Unlikely • Very unlikely • Very likely/Likely The 95% confident intervals will be calculated for all the responses listed above using the exact binomial distribution.

10.6.4. Safety

Safety is only summarised in this study – no derivations or transformations are required.

10.7. Appendix 7: Reporting Standards for Missing Data

10.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e. as specified in the protocol) was defined as one who has completed all phases of the study (Visit 0 through Visit 2). • Withdrawn subjects will not be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified. • Withdrawal visits will be slotted as per Appendix 3: Assessment Windows or will be summarised as withdrawal visits.

10.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: ○ These data will be indicated by the use of a "blank" in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. ○ Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.

10.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing. • Start or end dates which are completely missing (i.e. no year specified) will remain missing, with no imputation applied.
Concomitant Medications/ Medical History	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month.

Element	Reporting Detail
	○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • The recorded partial date will be displayed in listings.

10.8. Appendix 8: Values of Potential Clinical Importance

10.8.1. Vital Signs

Height, weight, gestational age and gestational weight will be collected and presented in this study.

As this is a placebo only ELLIPTA DPI study, there are no values of potential clinical importance.

10.9. Appendix 9: Abbreviations & Trade Marks

10.9.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
ASE	All Subjects Enrolled
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CS	Clinical Statistics
CSR	Clinical Study Report
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
DPI	Dry Powder Inhaler
eCRF	Electronic Case Record Form
GSK	GlaxoSmithKline
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-To-Treat
MITT	Modified Intent-to-Treat
PDMP	Protocol Deviation Management Plan
QC	Quality Control
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
SAC	Statistical Analysis Complete
SDTM	Study Data Tabulation Model
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings

10.9.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
ELLIPTA

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS

10.10. Appendix 10: List of Data Displays

10.10.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.29	N/A
Efficacy	2.1 to 2.16	2.1 to 2.4
Safety	3.1 to 3.16	N/A
Section	**Listings**	
ICH Listings	1 to 20	
Other Listings	21 to 32	

10.10.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 11: Example Mock Shells for Data Displays

Section	Figure	Table	Listing
Study Population	N/A	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	N/A	SAFE_Tn	SAFE_Ln

NOTES:

- Non-Standard displays are indicated in the 'IDSL / Example Shell' or 'Programming Notes' column as '[Non-Standard] + Reference.'

10.10.3. Deliverables

Delivery [Priority] [1]	Description
Dry Run [1]	Dry Run Deliverable before DBR
SAC [2]	Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort

10.10.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	ASE	SP1	Summary of Study Populations	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.2.	ASE	ES6	Summary of Screening Status and Reasons for Screen Failure	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.3.	ASE	NS1	Summary of Number of Participants by Country and Site ID	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.4.	ITT	Non-standard POP_T1	Summary of Attendance at Each Clinical Visit	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.5.	ITT	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.6.	ITT	ES1	Summary of End of Study Record	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.7.	ITT	ES4	Summary of Participant Disposition at Each Epoch	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
Protocol Deviations					
1.8.	ASE	DV1	Summary of Important Protocol Deviations – All Subjects Enrolled Population	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.9.	ASE	IE1	Summary of Inclusion/Exclusion/Randomisation Criteria Deviations – All Subjects Enrolled Population	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.10.	ITT	DV1	Summary of Important Protocol Deviations – Intent-to-Treat Population	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.11.	ITT	IE1	Summary of Inclusion/Exclusion/Randomisation Criteria Deviations - Intent-to-Treat Population	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
Population Analysed					
1.12.	ITT	SP2	Summary of Exclusions from the Modified Intent-to-Treat Population	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
Demographic and Baseline Characteristics					
1.13.	ITT	DM1	Summary of Demographic Characteristics	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.14.	ASE	DM11	Summary of Age Ranges	Present Total Column only	Dry Run[1] SAC[2]
1.15.	ITT	DM5	Summary of Race and Racial Combinations	Present Total Column only	Dry Run[1] SAC[2]
1.16.	ITT	DM6	Summary of Race and Racial Combinations Details	Present Total Column only	Dry Run[1] SAC[2]
1.17.	ITT	Non-standard POP_T5	Summary of Subgroups	Present by 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
Medical Conditions & Concomitant Medications					
1.18.	ITT	MH4	Summary of Current Medical Conditions	Present Total Column only	Dry Run[1] SAC[2]
1.19.	ITT	MH4	Summary of Past Medical Conditions	Present Total Column only	Dry Run[1] SAC[2]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.20.	ITT	Non-standard POP_T2	Summary of Duration of Asthma and Asthma Exacerbation History at Screening	Present Total Column only	Dry Run[1] SAC[2]
1.21.	ITT	CM1	Summary of Pre-Treatment Asthma Concomitant Medications	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.22.	ITT	CM1	Summary of Pre-Treatment Non-Asthma Concomitant Medications	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.23.	ITT	CM1	Summary of On-Treatment Asthma Concomitant Medications	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.24.	ITT	CM1	Summary of On-Treatment Non-Asthma Concomitant Medications	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.25.	ITT	CM1	Summary of Post-Treatment Asthma Concomitant Medications	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.26.	ITT	CM1	Summary of Post-Treatment Non-Asthma Concomitant Medications	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
Exposure and Treatment Compliance					
1.27.	ITT	Non-standard POP_T3	Summary of Exposure to Study Treatment	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]
1.28.	ITT	Non-standard POP_T4	Summary of Study Compliance	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Summary of Intercurrent Events					
1.29.	ITT	Non-standard POP_T6	Summary of Intercurrent Events	Present 5-7 year, 8-11 year, Total columns	Dry Run[1] SAC[2]

10.10.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Correct Use					
2.1.	ITT	EFF_T1	Summary of the Number of Completers of the Correct Use Demonstration at Visit 1		Dry Run [1] SAC [2]
2.2.	ASE	EFF_T11	Summary of Number of Attempts to Demonstrate Correct Use of ELLIPTA at Visit 1 – All Subjects Enrolled	Present 5-7 year, 8-11 year, Total columns Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI. Programming Note: Percentages are based on the subjects who attempted to demonstrate correct use, not Big N.	Dry Run [1] SAC [2]
2.3.	ITT	EFF_T11	Summary of Number of Attempts to Demonstrate Correct Use of ELLIPTA at Visit 1 – Intent-to-Treat Population	Present 5-7 year, 8-11 year, Total columns Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI. Programming Note: Percentages are based on the subjects who attempted to demonstrate correct use, not Big N.	Dry Run [1] SAC [2]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.4.	ITT	EFF_T2	Summary of Correct Use at Visit 1	Repeat for attempts 2 to 5.	Dry Run[1] SAC [2]
2.5.	ITT	EFF_T10	Summary of Critical Errors at Visit 1	Repeat for attempts 2 to 5.	Dry Run[1] SAC [2]
2.6.	MITT	EFF_T1	Summary of the Number of Completers of the Correct Use Demonstration at Visit 2		Dry Run [1] SAC [2]
2.7.	MITT	EFF_T2	Summary of Correct Use at Visit 2	Repeat for attempt 2	Dry Run [1] SAC [2]
2.8.	ITT	EFF_T10	Summary of Critical Errors at Visit 2	Repeat for attempt 2	Dry Run [1] SAC [2]
2.9.	MITT	EFF_T11	Summary of Number of Attempts to Demonstrate Correct Use of ELLIPTA at Visit 2	Present 5-7 year, 8-11 year, Total columns Programming Note: Only include Number of Attempts: 1, 2 or Did not perform correct use after 2 attempts. Note: Attempt 1 the participant attempts to demonstrate correct use of the ELLIPTA DPI. Attempt 2 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI. Programming Note: Percentages are based on the subjects who attempted to demonstrate correct use, not Big N.	Dry Run [1] SAC [2]
Ease of Use at Visit 2					
2.10.	MITT	EFF_T9	Summary of the Number of Completers of the Ease of Use Questionnaire at Visit 2		Dry Run [1] SAC [2]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.11.	MITT	EFF_T3	Summary of Participants Ease of Use at Visit 2	Present by: "Questionnaire: Overall, Version A, Version B"	Dry Run [1] SAC [2]
2.12.	MITT	EFF_T4	Summary of Parent/Guardians Ease of Use at Visit 2	Present by: "Questionnaire: Overall, Version A, Version B"	Dry Run [1] SAC [2]
Protocol Defined Endpoints for Correct Use and Ease of Use					
2.13.	MITT	EFF_T5	Summary of Protocol Defined Endpoints for Correct Use and Ease of Use at Visit 2 by Age Stratum		Dry Run [1] SAC [2]
2.14.	MITT	EFF_T6	Summary of Protocol Defined Endpoints for Correct Use and Ease of Use at Visit 2		Dry Run [1] SAC [2]
2.15.	ITT	EFF_T7	Summary of Protocol Defined Endpoints for Correct Use at End of Visit 1 by Age Stratum		Dry Run [1] SAC [2]
2.16.	ITT	EFF_T8	Summary of Protocol Defined Endpoints for Correct Use at End of Visit 1		Dry Run [1] SAC [2]

10.10.6. Efficacy Figures

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Correct Use					
2.1.	ITT	EFF_F1	Summary of Correct Use at Visit 1	Present Age Stratum: 5-7 Year Old, 8-11 Year Old on one page, and Total Population on the second page Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.	Dry Run [1] SAC [2]
2.2.	MITT	EFF_F1	Summary of Correct Use at Visit 2	Present Age Stratum: 5-7 Year Old, 8-11 Year Old on one page, and Total Population on the second page Present only Attempts “Overall”, “1” and “2” Note: Attempt 1 the participant attempts to demonstrate correct use of the ELLIPTA DPI. Attempt 2 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.	Dry Run [1] SAC [2]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.3.	MITT	EFF_F2	Summary of Participant's Ease of Use at Visit 2	Present Age Stratum: 5-7 Year Old, 8-11 Year Old on one page, and Total Population on the second page Replace "Number of Doses" and "Request the ELLIPTA" with "Ease of Use" and Number of Puffs". Include footnotes: Ease of Use: Responder is defined as the number of participants who rate the use of ELLIPTA as easy Number of Puffs: Responder is defined as the number of participants who rate the ability to tell how many doses are remaining in the ELLIPTA as easy	Dry Run [1] SAC [2]
2.4.	MITT	EFF_F2	Summary of Parent/Guardian's Ease of Use at Visit 2	Present Age Stratum: 5-7 Year Old, 8-11 Year Old on one page, and Total Population on the second page.	Dry Run [1] SAC [2]

10.10.7. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.1.	ITT	AE13	Adverse Event Overview	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.2.	ITT	AE1	Summary of Adverse Events by System Organ Class and Preferred Term	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.3.	ITT	AE1	Summary of On-Treatment Adverse Events by System Organ Class and Preferred Term	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.4.	ITT	AE1	Summary of Drug-Related Adverse Events	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.5.	ITT	AE1	Summary of Non-Serious Drug Related Adverse Events	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.6.	ITT	AE3	Summary of Common (>=3%) Adverse Events by Overall Frequency	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.7.	ITT	AE15	Summary of Common (>=3%) On-Treatment Non-Serious Adverse Events by Overall Frequency (Number of Subjects and Occurrences)	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.8.	ITT	AE15	Summary of Common (>=3%) Non-Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.9.	ITT	AE15	Summary of Common (>=3%) On-Treatment Drug Related Adverse Events by Overall Frequency (Number of Subjects and Occurrences)	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.10.	ASE	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.11.	ITT	AE16	Summary of On-Treatment Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.12.	ITT	AE1	Summary of Serious Drug Related Adverse Events	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.13.	ITT	AE1	Summary of On-Treatment Adverse Events Leading to Permanent Discontinuation of Study Drug or Withdrawal from the Study	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.14.	ITT	AE15	Summary of Common (>=3%) On-Treatment Serious Adverse Events by Overall Frequency (Number of Subjects and Occurrences)	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
3.15.	ITT	AE1	Summary of Fatal Adverse Events	Present Total column only Note: All participants received placebo only ELLIPTA DPI Inhalers.	Dry Run [1] SAC [2]
Exacerbations					
3.16.	ITT	SAFE_T1	Summary of On-Treatment Asthma Exacerbations	Present Total column only If more than 10 Asthma exacerbations are recorded, then present the summary, otherwise present listing only.	Dry Run [1] SAC [2]

10.10.8. ICH Listings

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
Subject Disposition					
1.	ASE	ES7	Listing of Reasons for Screen Failure	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
2.	ITT	ES2	Listing of Reasons for Study Withdrawal	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
3.	ITT	SD2	Listing of Reasons for Study Treatment Discontinuation	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
4.	MITT	TA1	Listing of Planned and Actual Ease of Use Questionnaire	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
Protocol Deviations					
5.	ITT	DV2	Listing of Important Protocol Deviations	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
6.	ITT	IE3	Listing of Inclusion/Exclusion/Randomisation Criteria Deviations	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
7.	ASE	SP3	Listing of Participants Excluded from the Modified Intent-to-Treat Population	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
Demography					
8.	ASE	DM2	Listing of Demographic Characteristics	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column. Programming Note: Include gestational age, gestational weight and country as the optional measurements.	Dry Run [1] SAC [2]
9.	ITT	DM9	Listing of Race	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
Exposure					
10.	ITT	EX3	Listing of Exposure Data	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
Concomitant Medications					
11.	ITT	CM3	Listing of Concomitant Medications	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column. Include columns: “Pre-Treatment” “On-Treatment” “Post-Treatment”	Dry Run [1] SAC [2]

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Safety					
Adverse Events					
12.	ITT	AE8	Listing of All Adverse Events	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
13.	ITT	AE7	Listing of Subject Numbers for Individual Adverse Events	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
14.	ITT	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
15.	ITT	AE8	Listing of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
16.	ITT	AE8	Listing of All Serious Adverse Events	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
17.	ITT	AE8	Listing of Fatal Serious Adverse Events	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
18.	ITT	AE8	Listing of Non-Fatal Serious Adverse Events	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
19.	ITT	AE8	Listing of Reasons for Considering as a Serious Adverse Event	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
20.	ITT	AE8	Listing of Other Significant Adverse Events	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]

10.10.9. Non-ICH Listings

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
Subject Disposition					
21.	ASE	Non-Standard POP_L4	Listing of Participants by Country and Site IDs		Dry Run [1] SAC [2]
Compliance					
22.	ITT	Non-Standard POP_L1	Listing of Treatment Compliance		Dry Run [1] SAC [2]
Medical Conditions & Concomitant Medications					
23.	ITT	MH2	Listing of Medical Conditions	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
24.	ITT	CM6	Relationship between ATC Level 1, Ingredient and Verbatim text	Programming Note: If IDSL shell includes a treatment column, replace treatment column with “Age Stratum” column.	Dry Run [1] SAC [2]
25.	ITT	Non-Standard POP_L2	Listing of Asthma History and Asthma Exacerbation History		Dry Run [1] SAC [2]
Correct Use at Visit 1					
26.	ITT	Non-Standard POP_L3	Listing of Correct Use at Visit 1		Dry Run [1] SAC [2]

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Safety					
Adverse Events					
27.	ITT	Non-Standard SAFE_L1	Listing of Asthma Exacerbations		Dry Run [1] SAC [2]
28.	ITT	Non-Standard SAFE_L2	Listing of Deaths	Programming Note: If IDSL shell includes a treatment column, replace treatment column with "Age Stratum" column.	Dry Run [1] SAC [2]
Efficacy					
Correct Use at Visit 2					
29.	MITT	Non-standard EFF_L1	Listing of Correct Use at Visit 2		Dry Run [1] SAC [2]
Ease of Use					
30.	MITT	Non-standard EFF_L2	Listing of Ease of Use at Visit 2		Dry Run [1] SAC [2]
31.	MITT	Non-standard EFF_L2	Listing of Parent/Guardian Ease of Use at Visit 2	Footnote: Q1: How easy or difficult (difficult or easy) was it for you to tell how many doses were left in the ELLIPTA inhaler? Q2: If your child's current inhaled asthma medication was available in the ELLIPTA inhaler, how likely would you be to request the ELLIPTA inhaler from your child's doctor?	Dry Run [1] SAC [2]

10.11. Appendix 11: Example Mock Shells for Data Displays

Example: POP_T1
Protocol: 206924
Population: Intent-to-Treat

Table 1.x
Summary of Attendance at Each Clinical Visit

Visit	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Visit 0 Screening (Can occur on same day as V1)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Visit 1 Assessment (Can occur on same day as V0)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Visit 2 Last Visit/End of Study/Early Withdrawal	xxx (xx%)	xxx (xx%)	xxx (xx%)

Table 1.xx
Summary of Asthma History and Asthma Exacerbation History at Screening

	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Duration of Asthma			
n	xxx	xxx	xxx
< 1 year	xxx (xx%)	xxx (xx%)	xxx (xx%)
>= 1 year to < 3 years	xxx (xx%)	xxx (xx%)	xxx (xx%)
>= 3 years to < 5 years	xxx (xx%)	xxx (xx%)	xxx (xx%)
>= 5 years	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of exacerbations that required Oral/Systemic Corticosteroids and/or antibiotics in the past 12 months			
n	xxx	xxx	xxx
0	xxx (xx%)	xxx (xx%)	xxx (xx%)
1	xxx (xx%)	xxx (xx%)	xxx (xx%)
2	xxx (xx%)	xxx (xx%)	xxx (xx%)
>2	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of exacerbations that required hospitalisation in the past 12 months			
n	xxx	xxx	xxx
0	xxx (xx%)	xxx (xx%)	xxx (xx%)
1	xxx (xx%)	xxx (xx%)	xxx (xx%)
2	xxx (xx%)	xxx (xx%)	xxx (xx%)
>2	xxx (xx%)	xxx (xx%)	xxx (xx%)

Table 1.xx
Summary of Exposure

	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Exposure (days)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min.	xx	xx	xx
Max.	xx	xx	xx
Range of exposure (days)			
n	xxx	xxx	xxx
< 14	xxx (xx%)	xxx (xx%)	xxx (xx%)
>= 14	xxx (xx%)	xxx (xx%)	xxx (xx%)

Table 1.xx
Summary of Study Compliance

	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Compliance (%)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min.	xx	xx	xx
Max.	xx	xx	xx
Compliance category			
n	xxx	xxx	xxx
<80%	xxx (xx%)	xxx (xx%)	xxx (xx%)
>=80% to <95%	xxx (xx%)	xxx (xx%)	xxx (xx%)
>=95% to <=105%	xxx (xx%)	xxx (xx%)	xxx (xx%)
>105% to <=120%	xxx (xx%)	xxx (xx%)	xxx (xx%)
>120%	xxx (xx%)	xxx (xx%)	xxx (xx%)
Non-calculable	xxx (xx%)	xxx (xx%)	xxx (xx%)

Example: POP_T5
Protocol: 206924
Population: Intent-to-Treat

Table 1.xx
Summary of Subgroups

	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Country			
n	xxx	xxx	xxx
United States	xxx (xx%)	xxx (xx%)	xxx (xx%)
Canada	xxx (xx%)	xxx (xx%)	xxx (xx%)
Main Current Asthma Therapy			
n	xxx	xxx	xxx
Maintenance with/without Rescue	xxx (xx%)	xxx (xx%)	xxx (xx%)
Rescue Only	xxx (xx%)	xxx (xx%)	xxx (xx%)
Main Current Asthma Therapy Device Type			
n	xxx	xxx	xxx
DPI	xxx (xx%)	xxx (xx%)	xxx (xx%)
MDI	xxx (xx%)	xxx (xx%)	xxx (xx%)
Other [1]	xxx (xx%)	xxx (xx%)	xxx (xx%)

[1] Other includes 'device' types such as Nebuliser, Pill/Tablet etc.

Table 1.xx
Summary of Intercurrent Events

Intercurrent events, n (%)	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Any intercurrent event			
n	xx	xx	xx
Participant not fully completing the correct use demonstration at Visit 1	xx (xx%)	xx (xx%)	xx (xx%)
Participant not fully completing the correct use demonstration at Visit 2	xx (xx%)	xx (xx%)	xx (xx%)
Participant not fully completing the ease of use questionnaire	xx (xx%)	xx (xx%)	xx (xx%)
Participant's parents/guardians not fully completing the ease of use questionnaire	xx (xx%)	xx (xx%)	xx (xx%)
Early discontinuation of study ELLIPTA DPI placebo during the 4 week period	xx (xx%)	xx (xx%)	xx (xx%)
Participant changed their standard Asthma therapy inhaler to one contained in ELLIPTA DPI	xx (xx%)	xx (xx%)	xx (xx%)

Example: EFF_T1
Protocol: 206924
Population: Intent-to-Treat

Table 2.1
Summary of the Number of Completers of the Correct Use Demonstration at Visit 1

Attempt: 1	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Number of participants who attempted to demonstrate correct use of the ELLIPTA DPI [1]	xxx	xxx	xxx
Number of participants who completed the ELLIPTA correct use demonstration [2]	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants who did not fully complete the ELLIPTA DPI correct use demonstration [3]	xxx (xx%)	xxx (xx%)	xxx (xx%)

Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.
[1] The participants who attempted to demonstrate correct use of the ELLIPTA DPI at that attempt.
[2] The participants who completed the correct use demonstration whether they correctly demonstrated or not.
[3] The participants who did not fully perform the correct use demonstration. These participants will be assumed to have not demonstrated correct use.
Programming Note: Repeat for Attempt: 2 to 5.

Example: EFF_T2
Protocol: 206924
Population: Intent-to-Treat

Table 2.2
Summary of Correct Use at Visit 1

Attempt: 1	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Number of participants who demonstrated correct use	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants who did not demonstrate correct use	xxx (xx%)	xxx (xx%)	xxx (xx%)
Reasons for incorrect use [1]:			
Participant did not slide the cover completely down to expose the mouthpiece until a 'click' is heard	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did shake the inhaler	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not breathe out (exhales) while holding the inhaler away from their mouth	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did breathe into the mouthpiece	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not place mouthpiece between lips, and closes firmly around it	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not take one long steady breath in through their mouth	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did block the air vent with fingers	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not remove inhaler from his/her mouth and holds his/her breath	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not breathe out slowly and gently	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not close the inhaler completely	xxx (xx%)	xxx (xx%)	xxx (xx%)

Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.
Note: Participants can be counted more than once depending on the reasons for incorrect use.
[1] Percentage for individual incorrect use reasons are calculated based on number of participants who did not demonstrate correct use.
Programming note: Repeat for attempts 2 to 5.

Table 2.7
Summary of Participants Ease of Use at Visit 2

Questionnaire: Overall

		5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Is it easy or hard to use the ELLIPTA inhaler?	n	xxx	xxx	xxx
	Easy	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Hard	xxx (xx%)	xxx (xx%)	xxx (xx%)
Is it easy or hard to tell how many puffs are left in the ELLIPTA inhaler?	n	xxx	xxx	xxx
	Easy	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Hard	xxx (xx%)	xxx (xx%)	xxx (xx%)

Programming note: Repeat for "Questionnaire: Version A, Version B"

Table 2.x
Summary of Parent/Guardians Ease of Use at Visit 2

Questionnaire: Overall

		5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Number of parents who attended the final visit also present during the initial training in Correct Use?	n	xxx	xxx	xxx
How easy or difficult was it for you to tell how many doses were left in the ELLIPTA inhaler?	n	xxx	xxx	xxx
	Very easy	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Easy	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Difficult	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Very difficult	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Very easy/Easy	xxx (xx%)	xxx (xx%)	xxx (xx%)
If your child's current inhaled asthma medication was available in the ELLIPTA inhaler, how likely would you be to request the ELLIPTA inhaler from your child's doctor?	n	xxx	xxx	
	Very Likely	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Likely	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Unlikely	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Very unlikely	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Very likely/Likely	xxx (xx%)	xxx (xx%)	xxx (xx%)

Programming note: Repeat for "Questionnaire: Version A, Version B"

Example: EFF_T5
Protocol: 206924
Population: Modified Intent-to-Treat

Table 2.xx
Summary of Protocol Defined Endpoints for Correct Use and Ease of Use at Visit 2 by Age Stratum

	5-7 Year Stratum (N=xxx)		8-11 Year Stratum (N=xxx)	
Number of participants who demonstrate correct use at Visit 2 without assistance from their parents/guardians (Attempt #1)	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)
Number of participants who rate the use of ELLIPTA as easy, among those who demonstrate correct use of the inhaler at Visit 2 [1]	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)
Number of participants who rate the ability to tell how many doses are remaining in the ELLIPTA as easy at Visit 2	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)
Number of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA as easy or very easy at Visit 2	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)
Number of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA inhaler if the participants current daily inhaled medication(s) were available in the ELLIPTA inhaler	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)
Number of participants who demonstrate correct use at Visit 2 with assistance from their parents/guardians (Attempt #2)	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)
Number of participants who demonstrate correct use at Visit 2 with or without assistance from their parents/guardians (Attempt #1 or Attempt #2)	xx (xx%)	(xx%, xx%)	xx (xx%)	(xx%, xx%)

Number of participants who made at least one critical error during the use of the ELLIPTA at Visit 2	xx (xx%) (xx%, xx%)	xx (xx%) (xx%, xx%)

[1] The percentage is calculated as "number of participants who rate the ELLIPTA as easy" divided by "number of participants who demonstrate correct use at Visit 2 (Attempt #1)" x 100
Note: The 95% CI for the percentages are calculated using the exact binomial distribution.

Programming Note: Please include the following footnotes if any of the composite intercurrent events detailed in the body of the RAP occurred during the study:
For correct use endpoints:
[#] Denominator used to calculate percentage and precision intervals includes participants who did not fully complete the correct use demonstration and have been deemed as not demonstrating correct use.
For questionnaire endpoints:
[#] Denominator used to calculate percentage and precision include participants who did not answer the question and have been deemed as [not rating the ease of use as easy/not rating the ability to tell how many doses are remaining in the ELLIPTA as easy/ not rating the ability to tell how many doses are remaining in the ELLIPTA as Very easy/easy/ not very likely/likely requesting the participant's current daily inhaled medication in the ELLIPTA inhaler]. [Select the ones that apply and write a new footnote for each one].
For critical error endpoint:
[#] Denominator used to calculate percentage and precision includes participants who did not fully complete all the critical error items in the correct use demonstration and have been deemed as performing a critical error.

Example: EFF_T6
Protocol: 206924
Population: Modified Intent-to-Treat

Table 2.15
Summary of Protocol Defined Endpoints for Correct Use and Ease of Use at Visit 2

	Total (N=xxx)
Number of participants who demonstrate correct use at Visit 2 without assistance from their parents/guardians (Attempt #1)	xx (xx%) (xx%, xx%)
Number of participants who rate the use of ELLIPTA as easy, among those who demonstrate correct use of the inhaler at Visit 2 [1]	xx (xx%) (xx%, xx%)
Number of participants who rate the ability to tell how many doses are remaining in the ELLIPTA as easy at Visit 2	xx (xx%) (xx%, xx%)
Number of participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA as easy or very easy at Visit 2	xx (xx%) (xx%, xx%)
Number of participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA inhaler if the participants current daily inhaled medication(s) were available in the ELLIPTA inhaler	xx (xx%) (xx%, xx%)
Number of participants who demonstrate correct use at Visit 2 with assistance from their parents/guardians (Attempt #2)	xx (xx%) (xx%, xx%)
Number of participants who demonstrate correct use at Visit 2 with or without assistance from their parents/guardians (Attempt #1 or Attempt #2)	xx (xx%) (xx%, xx%)

Number of participants who made at least one critical error during the use of the ELLIPTA at Visit 2	xx (xx%) (xx%, xx%)

[1] The percentage is calculated as "number of participants who rate the ELLIPTA as easy" divided by "number of participants who demonstrate correct use at Visit 2 (Attempt #1)" x 100
Note: The 95% CI for the percentages are calculated using the exact binomial distribution.

Programming Note: Please include the following footnotes if any of the composite intercurrent events detailed in the body of the RAP occurred during the study:
For correct use endpoints:
[#] Denominator used to calculate percentage and precision intervals includes participants who did not fully complete the correct use demonstration and have been deemed as not demonstrating correct use.
For questionnaire endpoints:
[#] Denominator used to calculate percentage and precision include participants who did not answer the question and have been deemed as [not rating the ease of use as easy/not rating the ability to tell how many doses are remaining in the ELLIPTA as easy/ not rating the ability to tell how many doses are remaining in the ELLIPTA as Very easy/easy / not very likely/likely requesting the participant's current daily inhaled medication in the ELLIPTA inhaler]. [Select the ones that apply and write a new footnote for each one].
For critical error endpoint:
[#] Denominator used to calculate percentage and precision includes participants who did not fully complete all the critical error items in the correct use demonstration and have been deemed as performing a critical error.

Example: EFF_T7
Protocol: 206924
Population: Intent-to-Treat

Table 2.xx
Summary of Protocol Defined Endpoints for Correct Use at End of Visit 1 by Age Stratum

	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)
Number of participants who demonstrate correct use of the ELLIPTA DPI after initial training from the HCP at Visit 1 (Attempt #1)	xx (xx%) (xx%, xx%)	xx (xx%) (xx%, xx%)
Number of participants who demonstrate correct use of the ELLIPTA DPI at Visit 1 (Attempt #1 - #5)	xx (xx%) (xx%, xx%)	xx (xx%) (xx%, xx%)
Number of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from HCP at Visit 1 (Attempt #1)	xx (xx%) (xx%, xx%)	xx (xx%) (xx%, xx%)
Number of participants who made at least one critical error during use of the ELLIPTA DPI at Visit 1 (Attempt #1 - #5)	xx (xx%) (xx%, xx%)	xx (xx%) (xx%, xx%)

Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.
Note: The 95% CI for the percentages are calculated using the exact binomial distribution.

Programming Note: Please include the following footnotes if any of the composite intercurrent events detailed in the body of the RAP occurred during the study:
For correct use endpoints:
[#] Denominator used to calculate percentage and precision intervals includes participants who did not fully complete the correct use demonstration and have been deemed as not demonstrating correct use.
For critical error endpoint:

[#] Denominator used to calculate percentage and precision includes participants who did not fully complete all the critical error items in the correct use demonstration and have been deemed as performing a critical error.

Table 2.xx
Summary of Protocol Defined Endpoints for Correct Use at End of Visit 1

	Total (N=xxx)
Number of participants who demonstrate correct use of the ELLIPTA DPI after initial training from the HCP at Visit 1 (Attempt #1)	xx (xx%) (xx%, xx%)
Number of participants who demonstrate correct use of the ELLIPTA DPI at Visit 1 (Attempt #1 - #5)	xx (xx%) (xx%, xx%)
Number of participants who made at least one critical error during use of the ELLIPTA DPI after initial training from the HCP at Visit 1	xx (xx%) (xx%, xx%)
Number of participants who made at least one critical error during use of the ELLIPTA DPI at Visit 1 (Attempt #1 - #5)	xx (xx%) (xx%, xx%)

Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.
Note: The 95% CI for the percentages are calculated using the exact binomial distribution.

Programming Note: Please include the following footnotes if any of the composite intercurrent events detailed in the body of the RAP occurred during the study:
For correct use endpoints:
[#] Denominator used to calculate percentage and precision intervals includes participants who did not fully complete the correct use demonstration and have been deemed as not demonstrating correct use.
For critical error endpoint:

[#] Denominator used to calculate percentage and precision includes participants who did not fully complete all the critical error items in the correct use demonstration and have been deemed as performing a critical error.

Example: EFF_T9
Protocol: 206924
Population: Modified Intent-to-Treat

Table 2.xx
Summary of the Number of Completers of the Ease of Use Questionnaire at Visit 2

Questionnaire: Overall

	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Number of participants randomised to an Ease of Use Questionnaire	xxx	xxx	xxx
Number of participants who answered the Ease of Use question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants who did not answer the Ease of Use question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants who answered the number of puffs question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants who did not answer the number of puffs question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants parents/guardians who answered the number of doses question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants parents/guardians who did not answer the number of doses question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants parents/guardians who answered the current daily inhaled medication question	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants parents/guardians who did not answer the current daily inhaled medication question	xxx (xx%)	xxx (xx%)	xxx (xx%)

Programming note: Repeat for Questionnaire: Version A and Version B

Example: EFF_T10
Protocol: 206924
Population: Intent-to-Treat

Table 2.x
Summary of Critical Errors at Visit 1

Attempt: 1	5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Number of participants who performed a critical error	xxx (xx%)	xxx (xx%)	xxx (xx%)
Number of participants who did not perform a critical error	xxx (xx%)	xxx (xx%)	xxx (xx%)
Critical errors performed [1]:			
Participant did not slide the cover completely down to expose the mouthpiece until a 'click' is heard	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did shake the inhaler	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did breathe into the mouthpiece	xxx (xx%)	xxx (xx%)	xxx (xx%)
Participant did not place mouthpiece between lips, and closes firmly around it	xxx (xx%)	xxx (xx%)	xxx (xx%)

Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.
Note: Participants can be counted more than once depending on the reasons for critical errors performed.
[1] Percentage for individual critical errors performed are calculated based on number of participants who performed a critical error.
Programming note: Repeat for attempts 2 to 5.

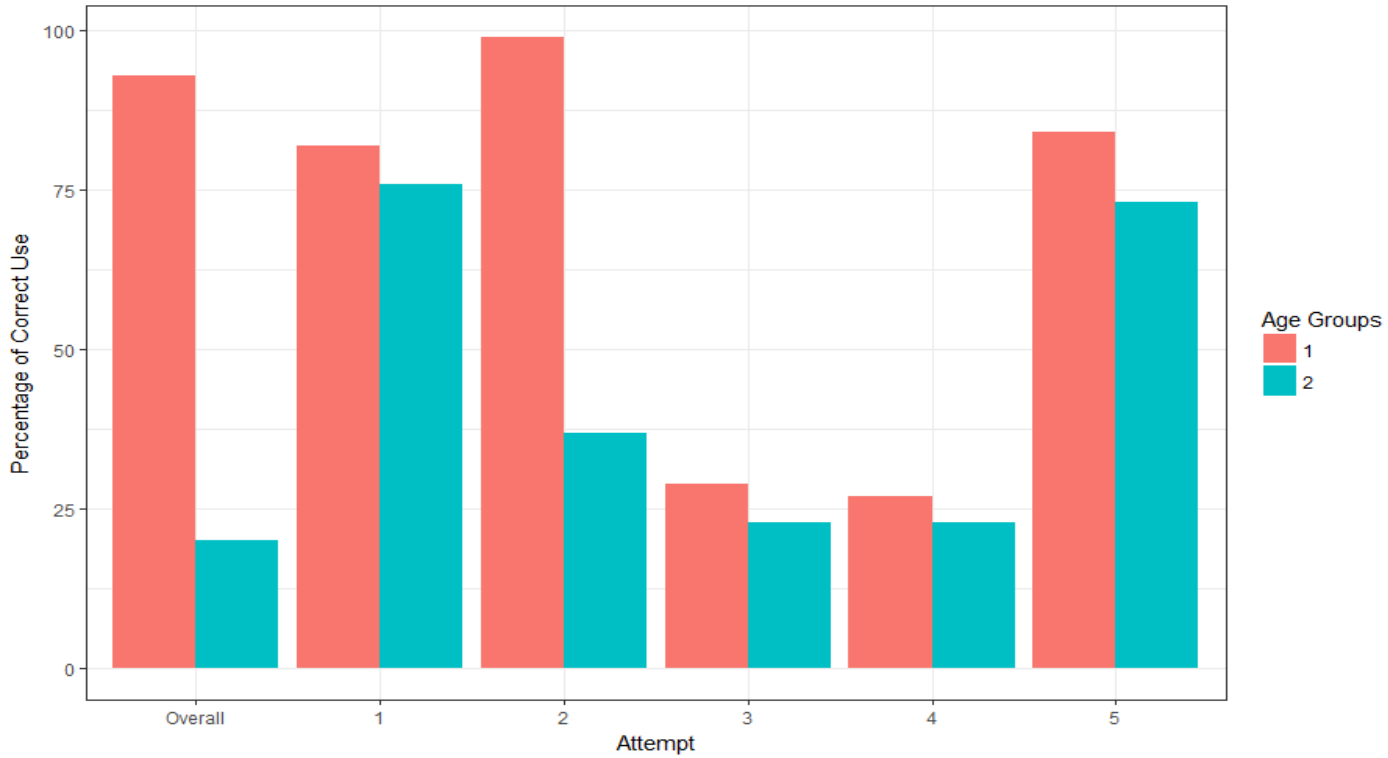
Example: EFF_T11
Protocol: 206924
Population: Intent-to-Treat

Table 2.xx
Summary of Number of Attempts to Demonstrate Correct Use at Visit 1

		5-7 Year Stratum (N=xxx)	8-11 Year Stratum (N=xxx)	Total (N=xxx)
Number of participants who demonstrated correct use	n	xxx	xxx	xxx
Number of participants who did not demonstrate correct use	n	xxx	xxx	xxx
Number of attempts to demonstrate correct use:	n	xxx	xxx	xxx
	1	xxx (xx%)	xxx (xx%)	xxx (xx%)
	2	xxx (xx%)	xxx (xx%)	xxx (xx%)
	3	xxx (xx%)	xxx (xx%)	xxx (xx%)
	4	xxx (xx%)	xxx (xx%)	xxx (xx%)
	5	xxx (xx%)	xxx (xx%)	xxx (xx%)
	Did not demonstrate correct use after 5 attempts	xxx (xx%)	xxx (xx%)	xxx (xx%)

Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.

Table 2.xx
Summary of Correct Use at Visit 1



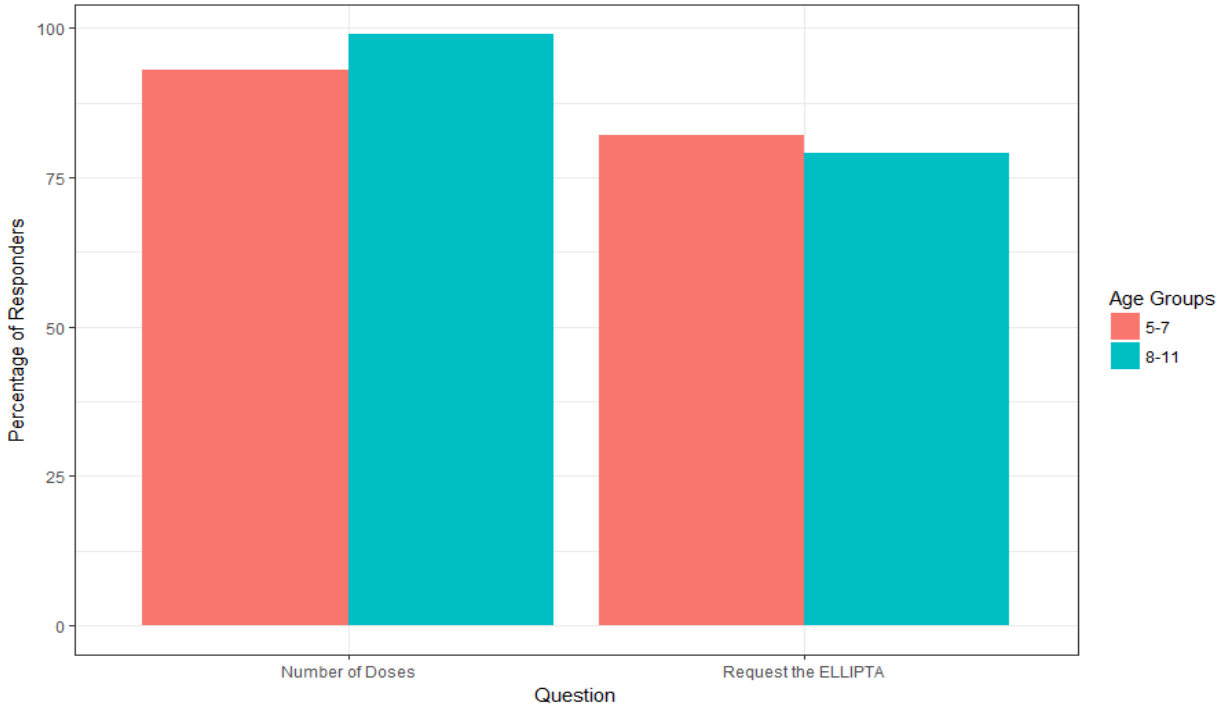
Note: Attempts 1, 2 and 3 the Healthcare Professional trains the participant in correct use of the ELLIPTA DPI. Attempts 4 and 5 the parents/guardians assist the participant in demonstrating correct use of the ELLIPTA DPI.

Programming Note: Present Age Stratum: 5-7 Year Old, 8-11 Year Old on one page, and Total Population on the second page.

Example: EFF_F2
Protocol: 206924
Population: Intent-to-Treat

Table 2.xx

Summary of Parent/Guardian's Ease of Use at Visit 2



Number of Puffs: Responder is defined as the participant's parents/guardians who rate the ability to tell how many doses are remaining in the ELLIPTA as easy or very easy.
Request the ELLIPTA: Responder is defined as the participant's parents/guardians who would be likely or very likely to ask their doctor for the ELLIPTA inhaler if the participants current daily inhaled medication(s) were available in the ELLIPTA inhaler.
Programming Note: Present Age Stratum: 5-7 Year Old, 8-11 Year Old on one page, and Total Population on the second page.

Table 3.x
Summary of On-Treatment Asthma Exacerbations

	Total (N=xxx)
Number of participants with an Asthma exacerbation	xxx
Total number of Asthma exacerbations per participant	
n	xxx
0	xxx (xx%)
1	xxx (xx%)
2	xxx (xx%)
>=3	xxx (xx%)
Total number of Asthma exacerbations	
Total number of exacerbations	xxx
Total number of exacerbations leading to a withdrawal from study	xxx
Treatment [1][2]	
Took oral/systemic corticosteroids	xxx (xx%)
Took antibiotics	xxx (xx%)
Visited emergency room	xxx (xx%)
Hospitalised	xxx (xx%)
Intubated	xxx (xx%)
Outcome [1]	
Resolved	xxx (xx%)
Fatal	xxx (xx%)
Not resolved	xxx (xx%)

Table 3.x
Summary of On-Treatment Asthma Exacerbations

	Total (N=xxx)
Duration of asthma exacerbation (days)	
n	xxx
mean	xx.x
SD	xx.xx
median	xx.x
Min.	xx
Max.	xx

[1] Percentages calculated using the total number of Asthma exacerbations as the denominator.
[2] More than one treatment may be selected for a given exacerbation.

Example: POP_L1
Protocol: 206924
Population: Intent-to-Treat

Listing x
Listing of Treatment Compliance

Site ID/ Unique Subject ID.	Age Stratum	Compliance (%)	Date Placebo Dispensed	Date Placebo Returned	Dose counter start/stop	Total doses Taken
xxxxxx/ xxxxxx	5-7 Year Old	xx.x	DDMMMYYYY	DDMMMYYYY	30/xx	xx
.....						

Listing x
Listing of Asthma History and Asthma Exacerbation History

				Number of exacerbations in the last 12 months that:	
Site ID	Unique Subject ID.	Age Stratum	Asthma Duration	Required oral/systemic corticosteroid and/or antibiotics [1]	Required hospitalisation
xxxxxx	xxxxxx	5-7 Year Old	< 1 year	x	x

.....

[1] Not involving hospitalisation

Example: POP_L3
Protocol: 206924
Population: Intent-to-Treat

Listing x
Listing of Correct Use at Visit 1

Site ID/ Unique Subject ID.	Age Stratum	Date of Assessment/ Study Day	Attempt	Demonstrate Correct Use?	Reasons for not demonstrating correct use
Xxxxxx/ Xx	5-7 Year-Old	DDMMYYYY/ 1	1	Y	None
Xxxxxx/ Xx	5-7 Year-Old	DDMMYYYY/ 1	1	N	Participant blocked air vent with fingers
			2	Y	None
		.....			

POP_L4
Protocol: 206924
Population: All Subjects Enrolled

Listing xx
Listing of Participants by Country and Site IDs

Country	Site ID.	Investigator Name	Subject	Age Stratum
United States	PPD	Hoek	PPD	5-7 Years Old
Canada		Baker		

Example: EFF_L1
Protocol: 206924
Population: Modified Intent-to-Treat

Listing x
Listing of Correct Use at Visit 2

Site ID/ Unique Subject ID.	Age Stratum	Date of Assessment/ Study Day	Questionnaire Version	Attempt	Demonstrate Correct Use?	Reasons for not demonstrating correct use
Xxxxxx/ Xx	5-7 Year-Old	DDMMYYYY/ 27	Version A	1	Y	None
Xxxxxx/ Xx	5-7 Year-Old	DDMMYYYY/ 29	Version B	1	N	Participant blocked air vent with fingers
				2	Y	None

Example: EFF_L2
Protocol: 206924
Population: Modified Intent-to-Treat

Listing x
Listing of Ease of Use at Visit 2

Site ID	Unique Subject ID.	Age Stratum	Visit	Date of Assessment	Study Day	Questionnaire Version	Q1	Q2
Xxxxxx	xxx	5-7 Year-Old	Day 28	DDMMYYYY	27	Version A	Easy	Easy
Xxxxxx	xxx	5-7 Year-Old	Day 28	DDMMYYYY	29	Version B	Easy	Hard

Q1: How easy or difficult (difficult or easy) is it to use the ELLIPTA inhaler?
Q2: How easy or difficult (difficult or easy) is it to tell how many puffs are left in the ELLIPTA inhaler?

Example: SAFE_L1
Protocol: 206924
Population: Intent-to-Treat

Listing x
Listing of Asthma Exacerbations

Site ID/ Unique Subject ID.	Age Stratum	Date of Onset/ Study Day	Date of Resolution/ Duration(days)	Severity/ Outcome	Withdrawn due to Exacerbation	Systemic or Oral Corticosteroid/ Antibiotics	Hospitalised/ Emergency Room/ Intubated/ X-ray performed
Xxxxxx/ xxxx.xxxx	5-7 Year-Old	DDMMMYYY/ xx	DDMMMYY/ xx	Moderate/ Recovered/ Resolved	N	Y/N	N/N/N/N

Example: SAFE_L2
Protocol: 206924
Population: Intent-to-Treat

Listing x
Listing of Deaths

Site Id./ Unique Subject Id.	Age (YEARS)/ Sex/ Race	Primary Cause of Death	Subreason	Specify	Date of Death/ Study Day	Time From Last Dose
PPD	58/ M/ WHITE	HAEMORRHAGE		GASTROINTESTINEL BLEEDING	2015 PPD 210	9d