

Statistical Analysis Plan for Interventional Studies

Sponsor Name: Revance Therapeutics, Inc.

Protocol Number: 1720304

Protocol Title: A Phase 3, Open-Label, Multi-Center Trial to Evaluate the Long-Term Safety and Efficacy of Repeat Treatments of DaxibotulinumtoxinA for Injection in Adults with Isolated Cervical Dystonia (ASPEN-OLS)

Protocol Version and Date:

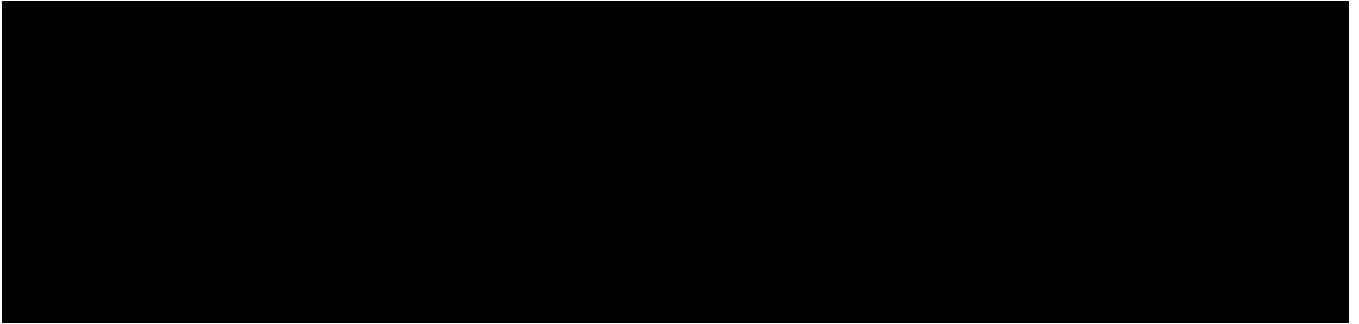
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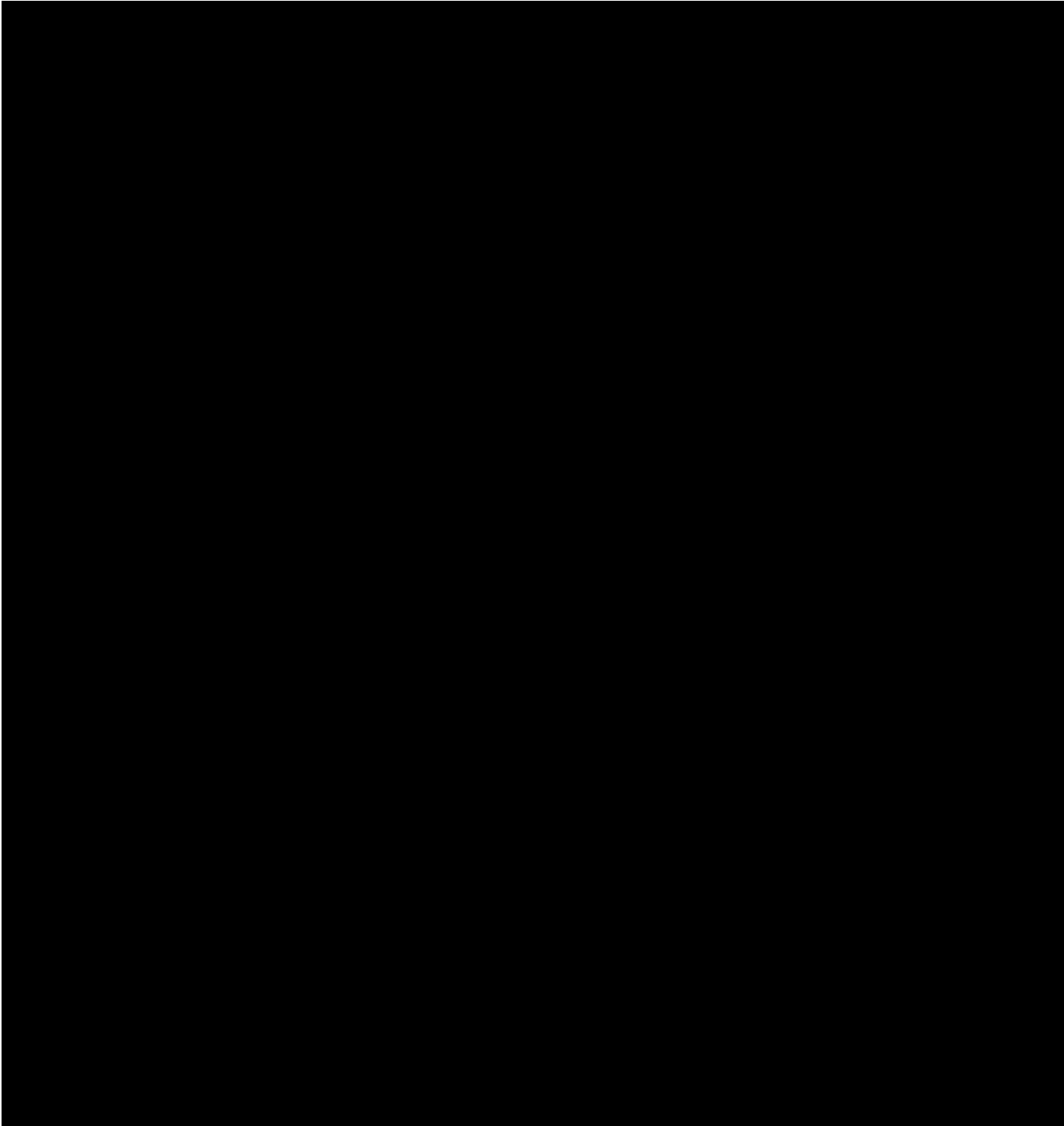
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Table of Contents

1.	Glossary of Abbreviations	7
2.	Purpose.....	9
2.1.	Responsibilities	9
2.2.	Timings of Analyses	9
3.	Study Objectives	10
3.1.	Primary Objectives	10
	[REDACTED]	
3.4.	Brief Description	10
3.5.	Subject Selection.....	11
3.5.1.	Inclusion Criteria	11
3.5.2.	Exclusion Criteria	12
3.6.	Determination of Sample Size	13
	[REDACTED]	
	[REDACTED]	
	[REDACTED]	
4.	Endpoints	17
4.1.	Primary Endpoints	17
	[REDACTED]	
5.	Analysis Sets.....	18
5.1.	Screened Population	18
5.2.	Enrolled Population	18
5.3.	Safety Population	18
5.4.	Non-COVID-19 Impacted Analysis Set	18
5.5.	Protocol Deviations	18
6.	General Aspects for Statistical Analysis.....	19
6.1.	General Methods.....	19

This document is confidential.

6.2. Key Definitions 19
[REDACTED]

6.4. Visit Windows 20
[REDACTED]

7. Demographic, Other Baseline Characteristics and Medication 22

7.1. Subject Disposition and Withdrawals 22

7.2. Demographic and Other Baseline Characteristics 22

7.3. Medical History and Concomitant Diseases 22

7.4. Other Baseline Characteristics 22

7.5. Medication 22

7.5.1. Prior Medication 23

7.5.2. Concomitant Medication 23

8. Efficacy 24
[REDACTED]

8.3. Sensitivity Analyses 31

9. Safety 32

This document is confidential.

9.1.	Injection Site Evaluation	32
9.2.	Muscle Injection Record	32
9.3.	Adverse Events	32
[REDACTED]		
9.5.	Laboratory Evaluations.....	33
[REDACTED]		
9.7.	Vital Signs	36
9.8.	ECG.....	36
9.9.	Physical [REDACTED]	36
9.10.	Pulmonary Function Test	36
9.11.	Dysphagia Severity Score	36
9.12.	Columbia-Suicide Severity Rating Scale.....	36
10.	Changes from Analysis Planned in Protocol.....	38
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	
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13.	Quality Control	45
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1. Glossary of Abbreviations

Abbreviation	Description
█	█
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass index
BoNT	botulinum neurotoxin
BoNTA	botulinum neurotoxin type A
CD	Cervical Dystonia
CDIP-58	Cervical Dystonia Impact Profile
CGIC	Clinical Global Impression of Change
cm	Centimeters
C-SSRS	Columbia-Suicide Severity Rating Scale
DAXI	DaxibotulinumtoxinA
DSMB	Data Safety Monitoring Board
DSS	Dysphagia Severity Scale
ECG	Electrocardiogram
EOS	End of Study
FDA	Food and Drug Administration
FEV ₁	Forced Expiratory Volume in the first second of exhalation
FVC	Forced Vital Capacity
ICH	International Conference on Harmonization
INR	International Normalized Ratio
kg	Kilograms
m	Meters
Max	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
█	█
PGIC	Patient Global Impression of Change
PT	Preferred Term

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Abbreviation	Description
QC	Quality Control
QOL	Quality of Life
QTcF	Corrected QT Interval using Fridericia's correction formula
SAP	Statistical Analysis Plan
SD	Standard Deviation
SF-36	Short Form-36
SI	Standard International System of Units
SOC	System Organ Class
SOP	Standard Operating Procedure
TdP	Torsade de Pointe
TEAE	Treatment Emergent Adverse Event
TFL	Table, Figure and Figure
TSQ	Treatment Satisfaction Questionnaire
TWSTRS	Toronto Western Spasmodic Torticollis Rating Scale
UA	Urinalysis
WHODD	World Health Organization Drug Dictionary
WOCBP	Women of Child Bearing Potential
WPAI	Work Productivity and Impairment

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2. Purpose

The purpose of this statistical analysis plan (SAP) is to ensure that the data listings, summary tables and figures which will be produced, and the statistical methodologies that will be used, are complete and appropriate to allow valid conclusions regarding the study objectives.

2.1. Responsibilities

Syneos Health will perform the statistical analyses and are responsible for the production and quality control of all tables, figures and listings.

2.2. Timings of Analyses

The primary analysis is planned after all subjects complete the final study visit or terminate early from the study.

An independent Data Safety Monitoring Board (DSMB) will review descriptive summaries of accumulating safety data during the study and will monitor quality and completeness of the safety data, as well as signals and outcomes of the safety data. Further description of the DSMB analyses and timing of the analyses can be found in the DSMB charter Version 1.0 10-July-2018.



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3. Study Objectives

3.1. Primary Objectives

The primary objectives of this study are to evaluate the long-term safety of multiple continuous treatments of daxibotulinumtoxinA (DAXI) for injection, and to assess immunogenicity of BoNTA and RTP004 after multiple treatments of DAXI for injection in adults with isolated cervical dystonia (CD).

[REDACTED]

[REDACTED]

3.4. Brief Description

This is a Phase 3, open-label, multi-center trial to evaluate the long-term safety, efficacy, and immunogenicity of up to four continuous treatment cycles of DAXI for injection at doses of 125 U, 200 U, 250 U, and 300 U in adults with isolated CD at study centers across the United States, Canada, and Europe.

Approximately 350 adult subjects will be recruited from study centers who were previously enrolled in Protocol 1720302 entitled [A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial to Evaluate the Efficacy and Safety of a Single Treatment of DaxibotulinumtoxinA for Injection in Adults with Isolated Cervical Dystonia (ASPEN-1)]. These subjects will have 7 days from their End-of-Study (EOS) Visit in Protocol 1720302 to decide if they want to enroll in this study. After enrolling, subjects will have up to 21 days to complete screening procedures. After 21 days, subjects who have NOT completed the screening procedures will be considered a screen failure. To be reconsidered for enrollment to this study, the subject will be required to repeat all screening procedures to reconfirm eligibility for enrollment. These criteria also apply to subjects who missed the 7-day decision-making window to enroll in this study. This study will also recruit new botulinum neurotoxin (BoNT) treatment-naïve or -experienced adult subjects who were not enrolled in Protocol 1720302.

[REDACTED]

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[REDACTED]

The primary endpoints are safety and immunogenicity. [REDACTED]

[REDACTED]

3.5. Subject Selection

3.5.1. Inclusion Criteria

All participants must meet the following inclusion criteria:

1. Adults, 18 to 80 years of age
2. Meets diagnostic criteria for isolated CD (idiopathic; dystonic symptoms localized to the head, neck, shoulder areas) with at least moderate severity at Baseline (Day 1), defined as a TWSTRS total score of at least 20 with at least 15 on the TWSTRS Severity subscale and at least 3 on the TWSTRS Disability subscale, and at least 1 on the TWSTRS Pain subscale (minimum subscale criteria applicable only to subjects not previously enrolled in Study Protocol 1720302)
3. Subjects who were previously enrolled in Protocol 1720302, who completed the study, including:
 - a. Those with no reduction or have an increase from baseline in the average TWSTRS total score at Weeks 4 and 6 (i.e., no improvement or worsened disease status), and the investigator agreed that there was a need for retreatment based on the subject's symptoms and neurologic examination findings.
 - b. Those who benefited from study treatment and complete follow-up visits up to the time point of when their TWSTRS total score reached/exceeded their target TWSTRS score
 - c. Those who benefit from study treatment but subsequently experienced significant recurrence of CD symptoms (e.g., pain) during the study before their TWSTRS total score reached their target based on the subject's symptoms and neurological exam findings
 - d. Those who completed study visits up to Week 36 and their TWSTRS total score never reached their target TWSTRS score and they never requested another retreatment. The investigator determine that these subjects can be followed in this study until their TWSTRS total score is the same or higher than their target TWSTRS score or until they request retreatment, which the investigator determined is clinically indicated
4. De novo subjects (not previously enrolled in Protocol 1720302):
 - a. Naïve to BoNT treatment
 - b. BoNT treatment-experienced: if previously treated with BoNTA, the subject must have demonstrated a clinically meaningful response to the last BoNTA treatment based on the clinical judgment of the investigator

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5. Written informed consent including authorization to release health information

3.5.2. Exclusion Criteria

Subjects will not be enrolled if they meet any of the following exclusion criteria:

1. CD attributable to an underlying etiology, (e.g., trauma torticollis or tardive torticollis)
2. Predominant retrocollis or anterocollis CD
3. Significant dystonia in other body areas, or is currently being treated with BoNT for dystonia in areas other than those associated with isolated CD
4. Severe dysphagia (Grade 3 or 4 on the Dysphagia Severity Scale) at Screening or Baseline (prior to study treatment)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

No additional exclusions may be applied by the investigator, in order to ensure that the study population will be representative of all eligible subjects. Deviation from any entry criterion excludes a subject from enrollment into the study.

3.6. Determination of Sample Size

The sample size for this study is based on a requirement from Regulatory Authorities to collect safety data on approximately 350 subjects treated once and long-term safety data on at least 100 adult subjects with isolated CD treated with 3 or 4 continuous treatment cycles, of low-dose or high-dose DAXI for injection, with at least 50 subjects treated with the high-dose DAXI for injection for 3 or 4 continuous treatment cycles. [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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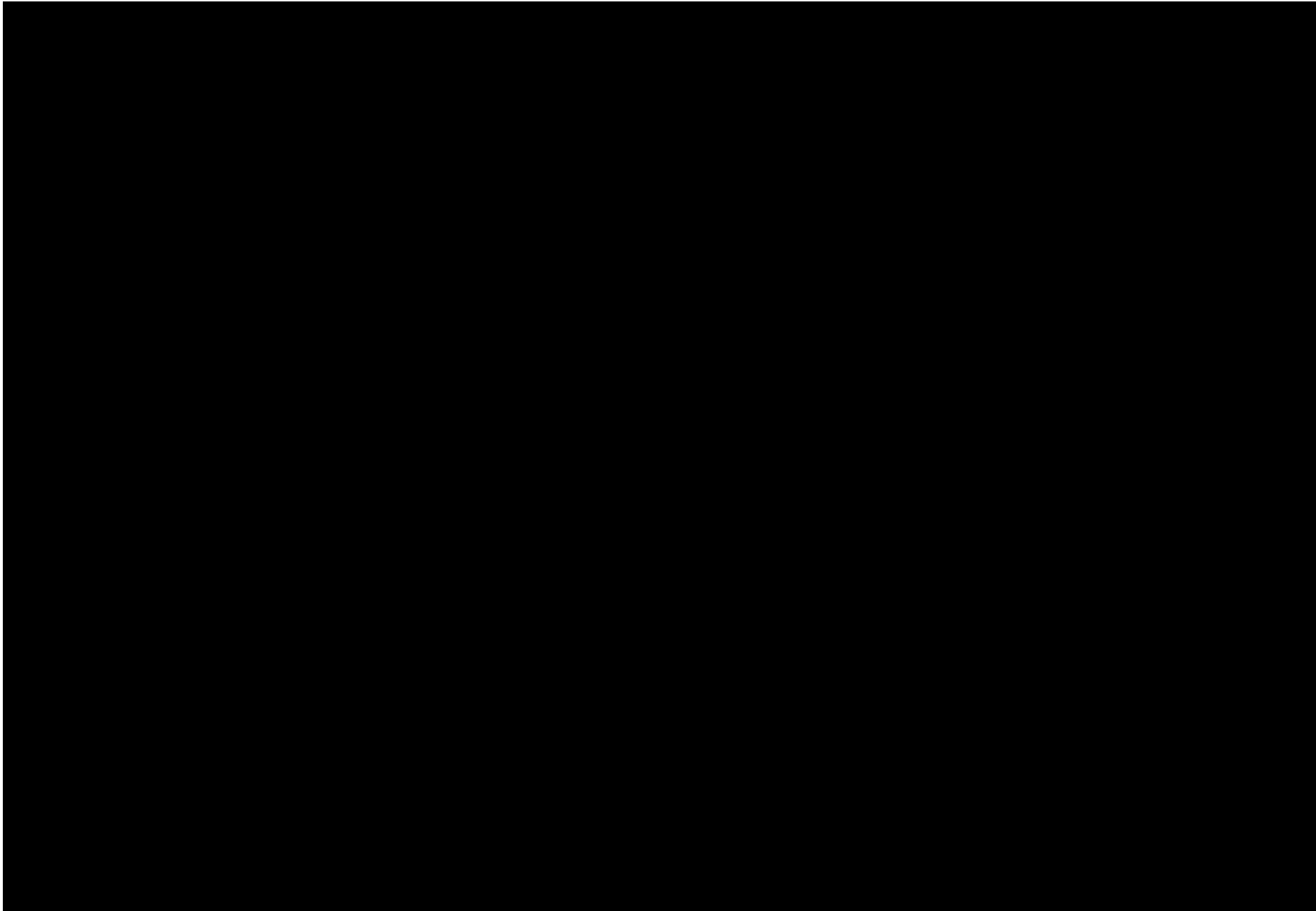
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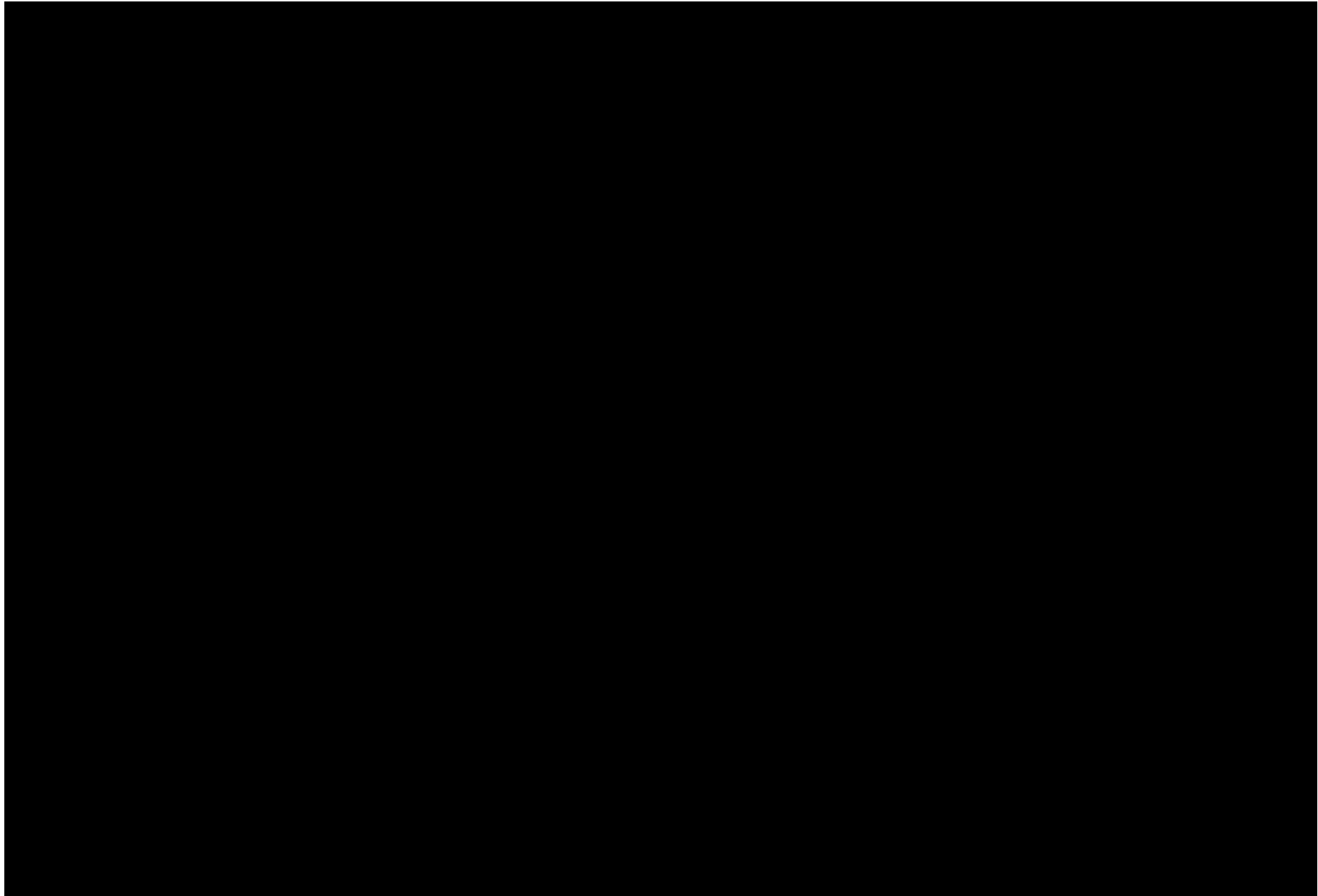
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3.9. [REDACTED]

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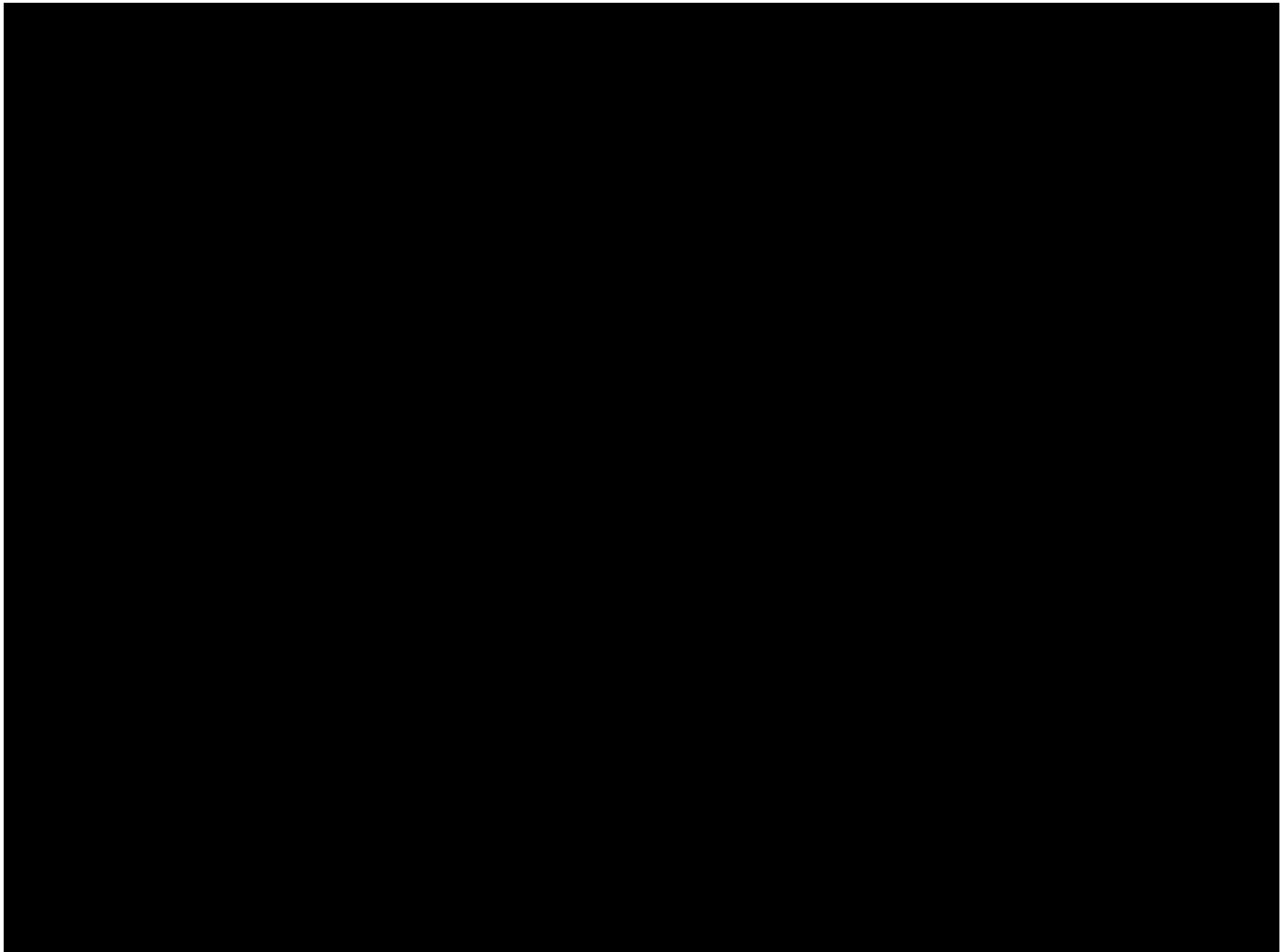


4. Endpoints

4.1. Primary Endpoints

The primary endpoints of this study are:

- The dose- and cycle-specific incidence of drug-related adverse events (AEs)
- The dose- and cycle-specific incidence of study drug discontinuation due to drug-related AEs
- The dose- and cycle-specific incidence of treatment-emergent immunogenicity



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5. Analysis Sets

5.1. Screened Population

The Screened Population includes all subjects screened for entry into the study. This population will be used for disposition summaries and listings.

5.2. Enrolled Population

The Enrolled Population includes all subjects enrolled into the study. This population will be used for protocol deviation summaries and all listings.

5.3. Safety Population

The safety population is defined as all subjects who enrolled and received at least 1 dose of study drug. The safety population will be analyzed by treatment dose the subject received rather than the treatment dose selected for the subject by the Investigator. The safety analysis set will be used for all analyses

5.4. Non-COVID-19 Impacted Analysis Set

The non-COVID-19 impacted population is a subset of the safety population and excludes assessments with any COVID-19 related protocol deviations. [REDACTED]

5.5. Protocol Deviations

Protocol deviations will be summarized for all enrolled subjects. COVID-19 related deviations will be identified when collecting protocol deviations. They will be summarized separately and will include number of subjects impacted, as well as missed visits, missed assessments, remote visits, and remote assessments. A listing will be provided for all protocol deviations. A separate listing will be provided for all COVID-19 related protocol deviations.

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6. General Aspects for Statistical Analysis

6.1. General Methods

- Efficacy endpoints will be summarized by dose and/or treatment cycle, unless otherwise specified.
- Continuous variables will be summarized using the number of observations (n), mean, standard deviation (SD), median, minimum (min), and maximum (max). Categorical variables will be summarized using number of observations (n), frequency and percentages of subjects.
- All relevant subject data will be included in listings. All subjects entered into the database will be included in subject data listings.
- Unless otherwise specified, if a subject has more than one observation at a given time point, the value closest to the target day for that visit will be used. If two observations are equal distance from the target day, the later observation will be used.
- All analyses and outputs will be generated using SAS® version 9.4 or higher.

6.2. Key Definitions

Study day will be assigned as follows:

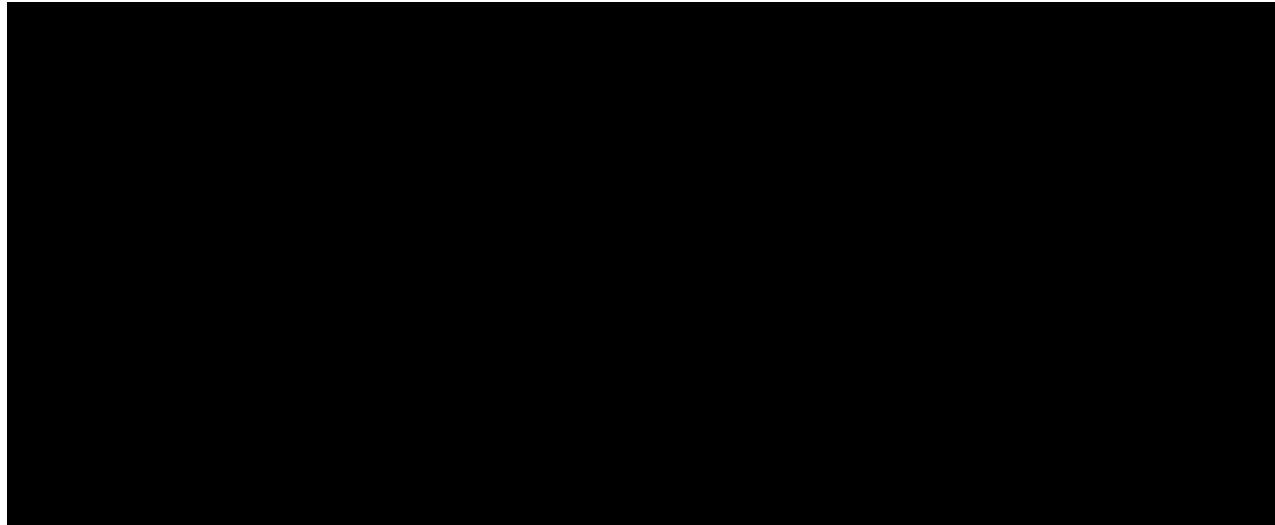
- Before the first study medication dose date, study day = visit date – dose date.
- After the first study medication dose date, study day = visit date – dose date + 1.

The day the study medication is first given is Day 1, and the day before the study medication is first given is considered Day -1.

Unless otherwise specified, baseline value is defined as the last non-missing value before the first study medication administration. Change from baseline is defined as the post-baseline value minus the baseline value (post baseline – baseline). Percent change from baseline is defined as 100 times post-baseline value minus baseline value divided by the baseline value ($100 * (\text{post baseline} - \text{baseline}) / \text{baseline}$).

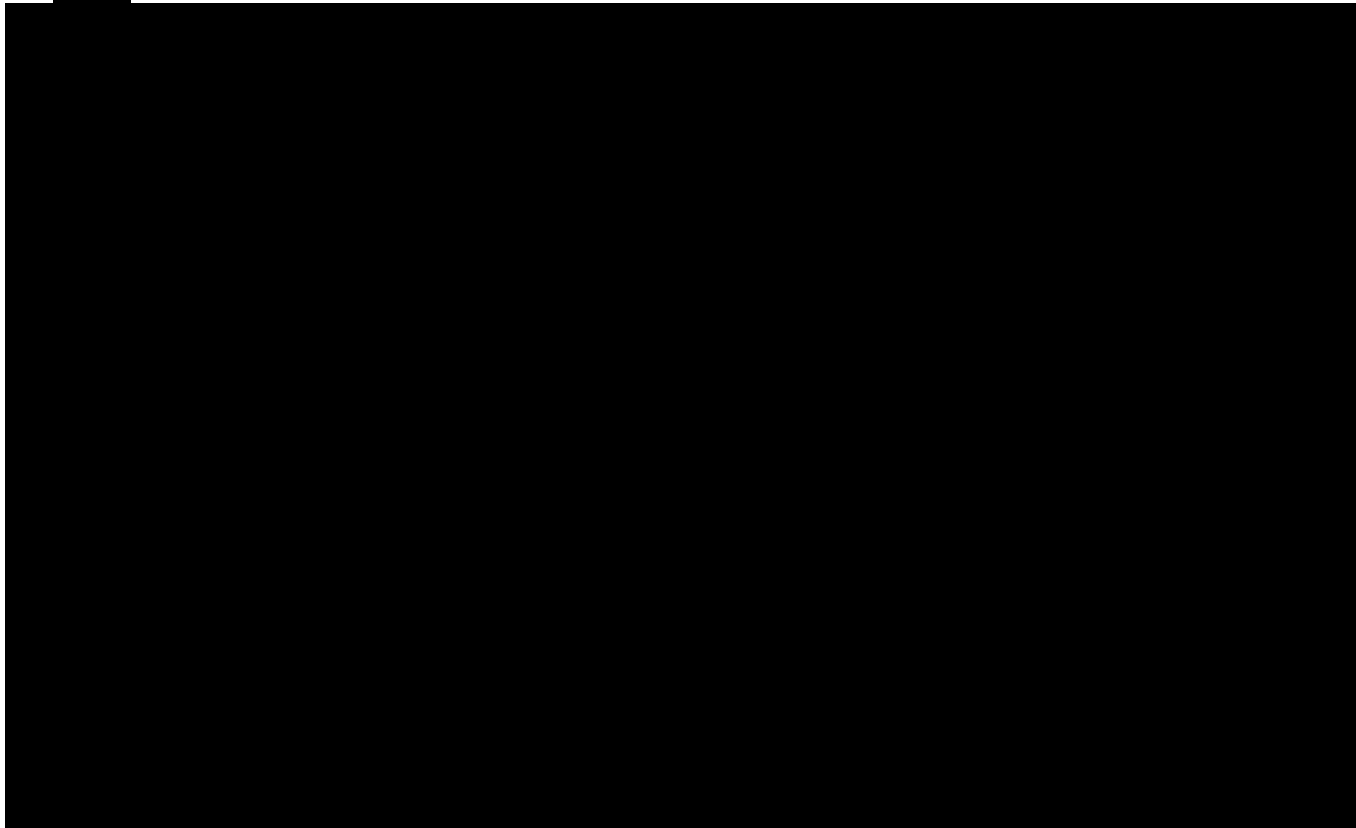
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6.4. Visit Windows

Analyses will be based on the visit designation. Visits are required to be within specified time windows relative to the Day 1 or Baseline visit.



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7. Demographic, Other Baseline Characteristics and Medication

7.1. Subject Disposition and Withdrawals

The number and percentage of subjects screened, enrolled, completed, and discontinued will be summarized along with the reasons for discontinuation and will be summarized. The number of subjects who received treatment in each cycle will be summarized. The number of subjects in each study analysis population will also be presented. Enrollment will be summarized by Rollover and DeNovo. Listings will be provided for disposition data, study populations and reasons for exclusion from the study population, and inclusion/exclusion criteria not met.

The reason for discontinuation will also be summarized by cycle. A summary of the duration of the subject participation in the study will be produced, including the n, mean, SD, median, minimum, and maximum duration in weeks, as well as the number and percentage of subjects in the following categories of duration: <4 weeks, 4 to <12 weeks, 12 to <24 weeks, and 24 to <36 weeks, and 36 weeks or more. If a subject is lost to follow-up, their participation in the study will be calculated based on their date of last visit. Duration of study participation will also be summarized overall, across all cycles using the following categories: < 24 weeks, 24 to < 36 weeks, 36 to < 48 weeks, and 48 weeks or more.

7.2. Demographic and Other Baseline Characteristics

Demographic and baseline characteristics will be summarized for the safety populations overall and by dose in initial treatment cycle. [REDACTED]

7.3. Medical History and Concomitant Diseases

Medical history and concomitant diseases will be coded according to Medical Dictionary for Regulatory Activities (MedDRA) version 22.0 or later. A summary of medical history and concomitant diseases for the safety population by system organ class (SOC) and preferred term (PT) will be presented. Terms in the table will be sorted alphabetically. The summary will be provided overall and by dose in the initial treatment cycle. A listing will also be provided that includes SOC, PT, and verbatim term for each medical history and concomitant disease. The listing will be sorted by subject, SOC, PT, and verbatim term.

7.4. Other Baseline Characteristics

Summaries will also be provided for the safety population for CD history overall and by dose in the initial treatment cycle. [REDACTED]

7.5. Medication

Prior and concomitant medication will be coded using World Health Organization Drug Dictionary (WHODD) version March 2018 or later. Anatomic Therapeutic Chemical (ATC) level 2 and preferred names will be included in all summaries and listings. Summaries will be provided overall and by dose in the initial treatment cycle for prior medication and by dose in each treatment cycle for concomitant

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medication. Listings will also include verbatim terms. Summary tables will be presented in alphabetical order, and listings will be presented for each subject by earliest start date and then alphabetical order. The listing will indicate if the medication was prior or concomitant. Prior medications for CD will be summarized and listed separately. Summaries will be provided for the safety population.

7.5.1. Prior Medication

Medications that were stopped before the first study medication dose date will be classified as prior. A summary table will be provided for prior medications.

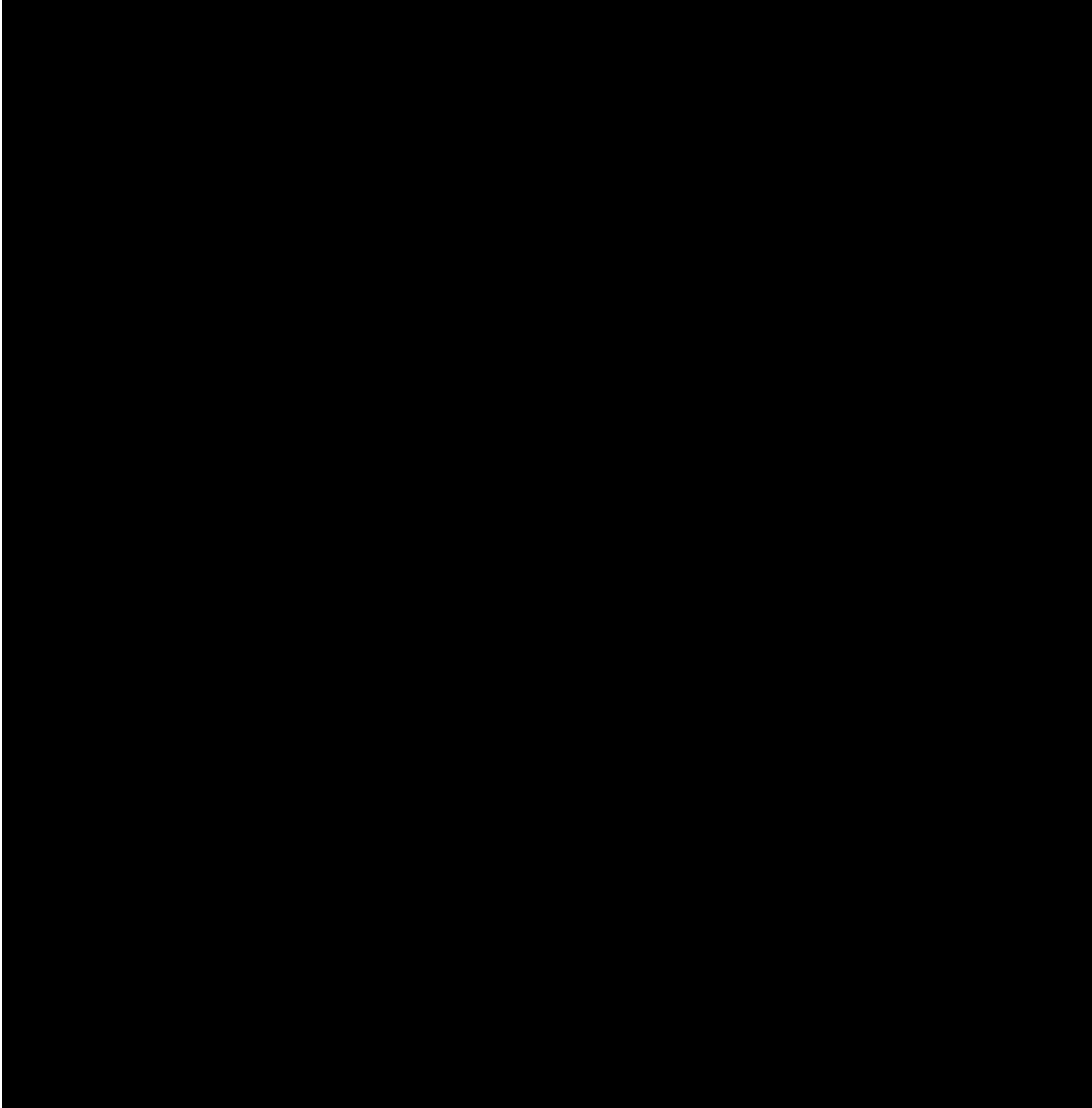
7.5.2. Concomitant Medication

Medications that were taken on or after the first study medication dose date will be classified as concomitant. This classification includes medications that were started after the first study medication dose date or medications that began before and continued to be taken after the first study medication dose date.

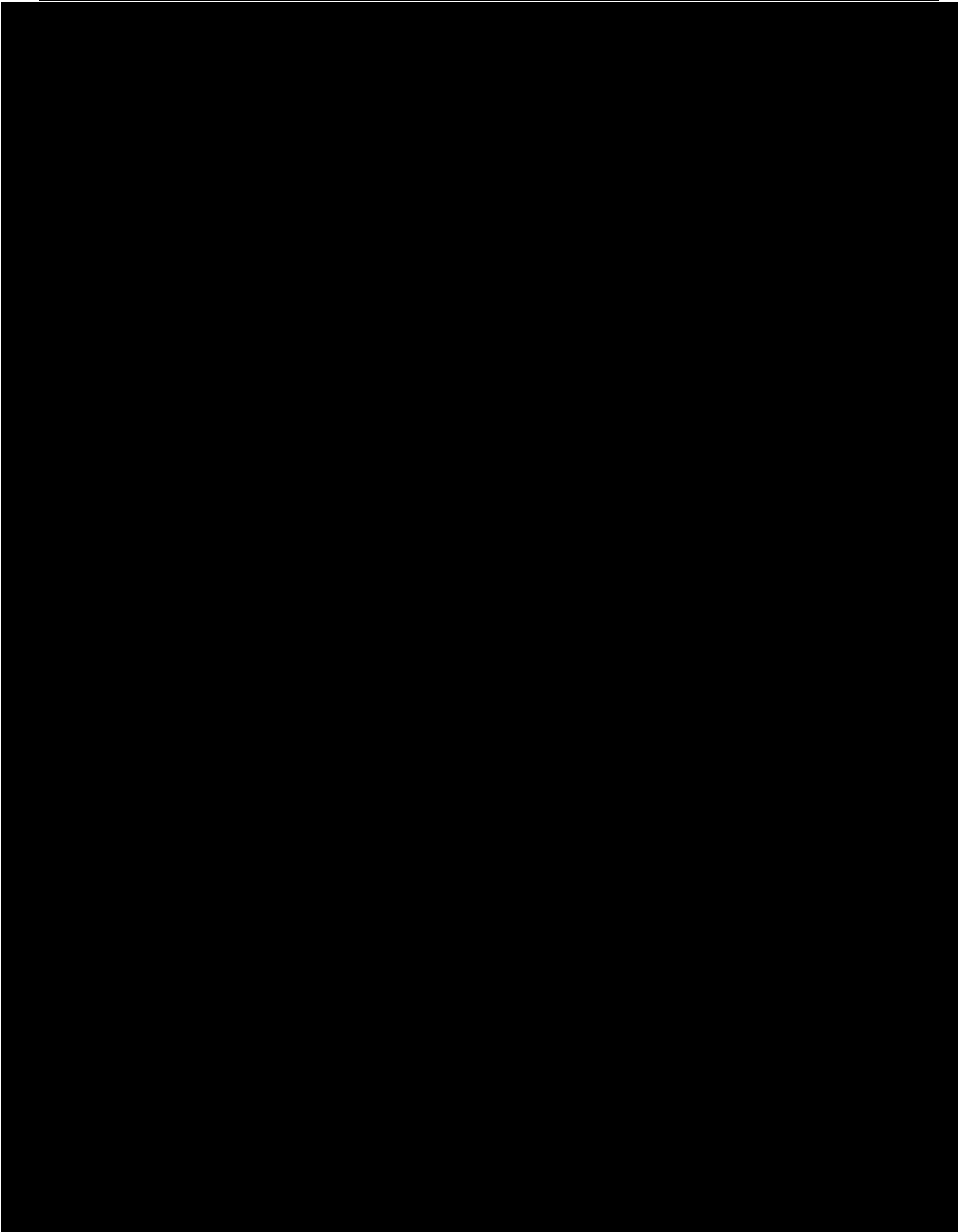
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8. Efficacy

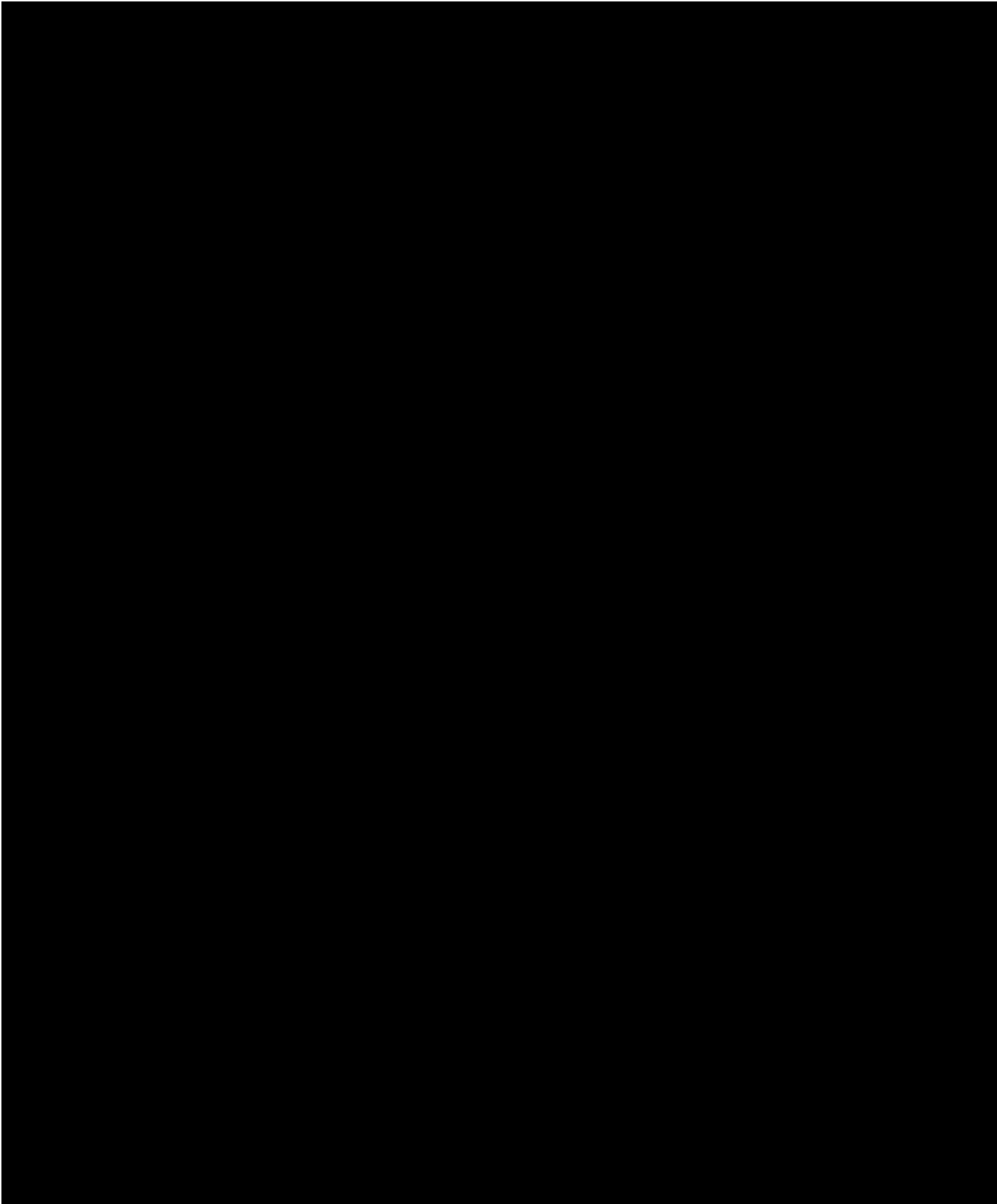
All efficacy analyses will be performed for the safety population. Efficacy endpoints, including responder rates, will be summarized with descriptive statistics by dose and treatment cycle, unless otherwise specified.



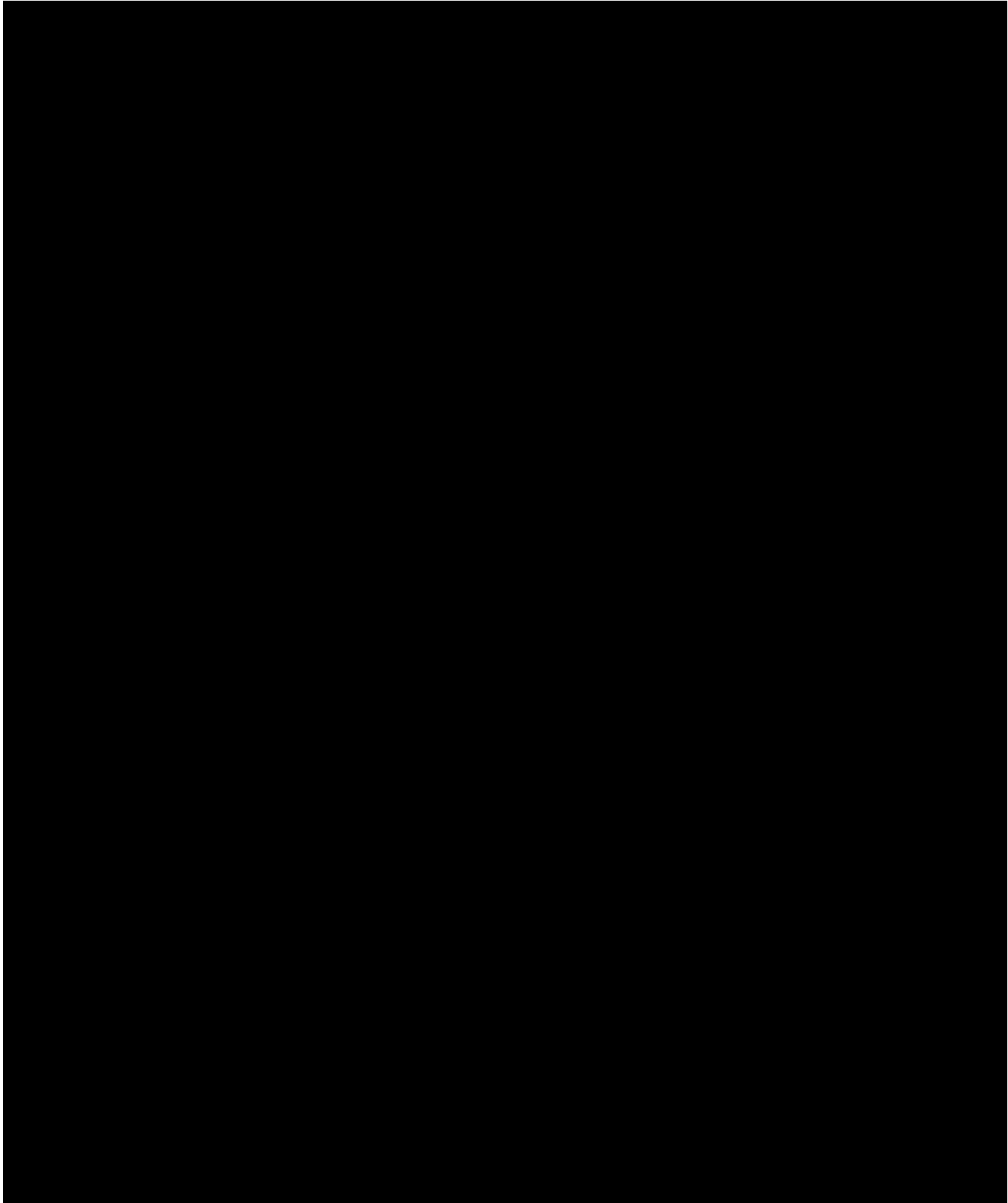
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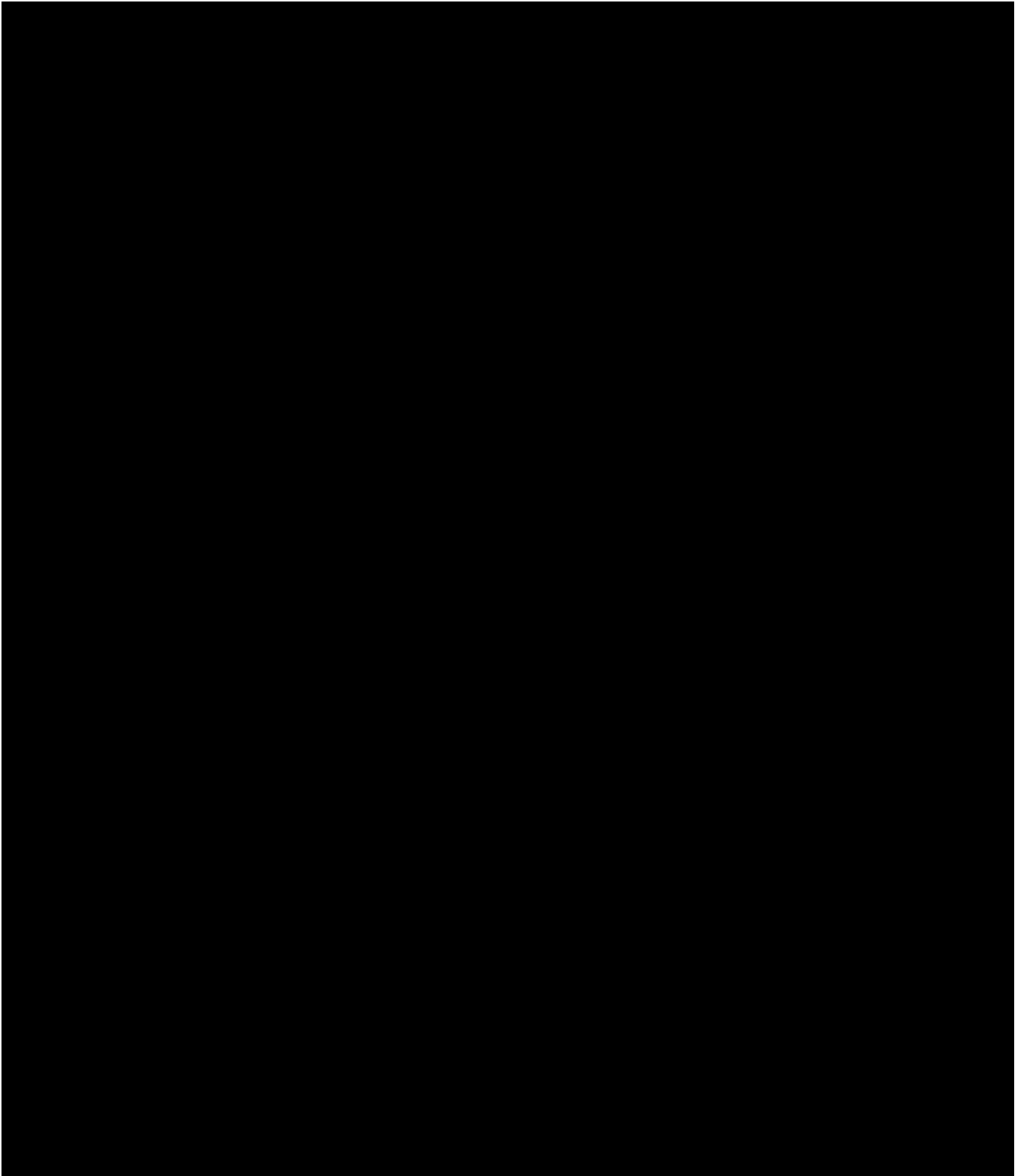
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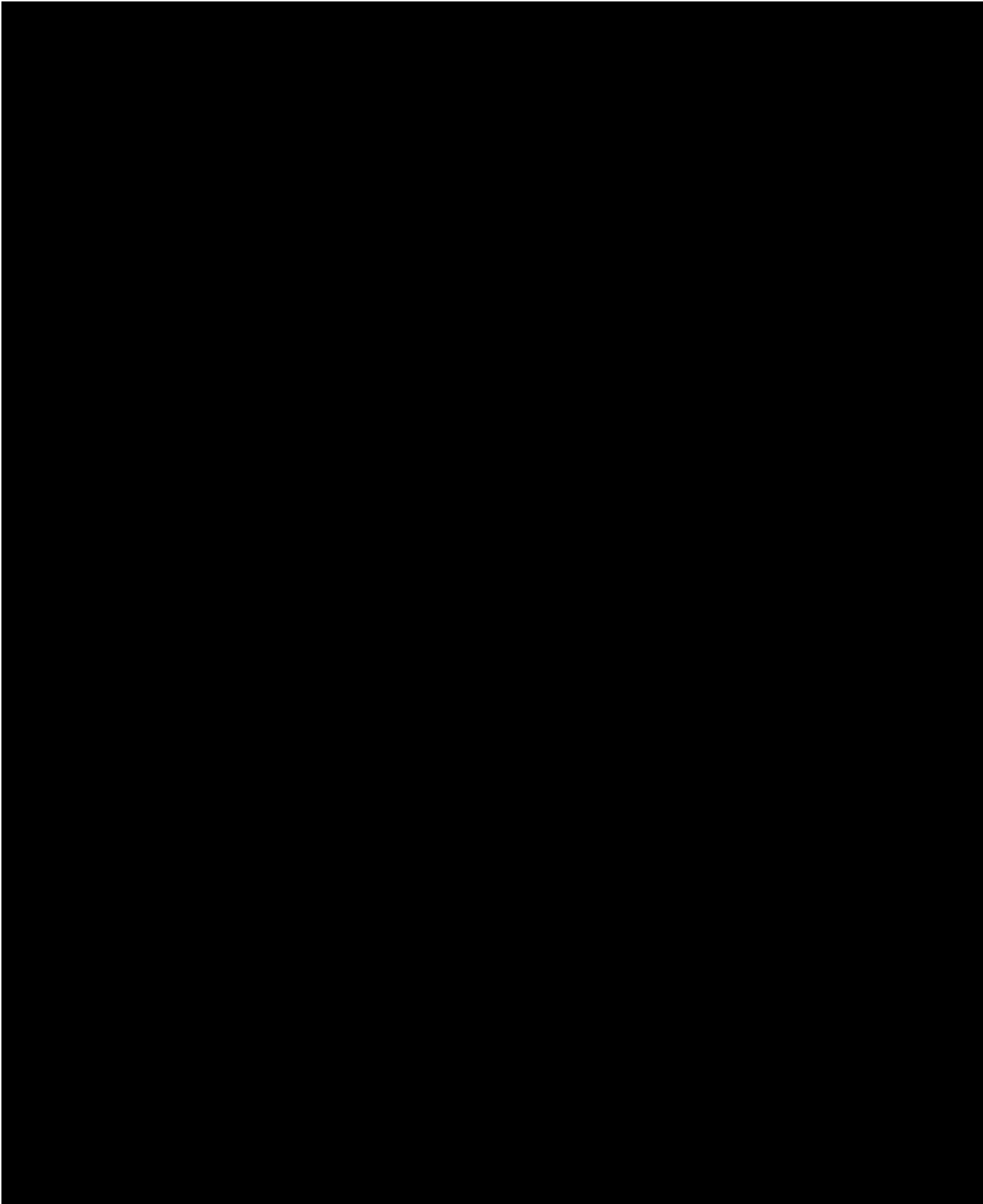
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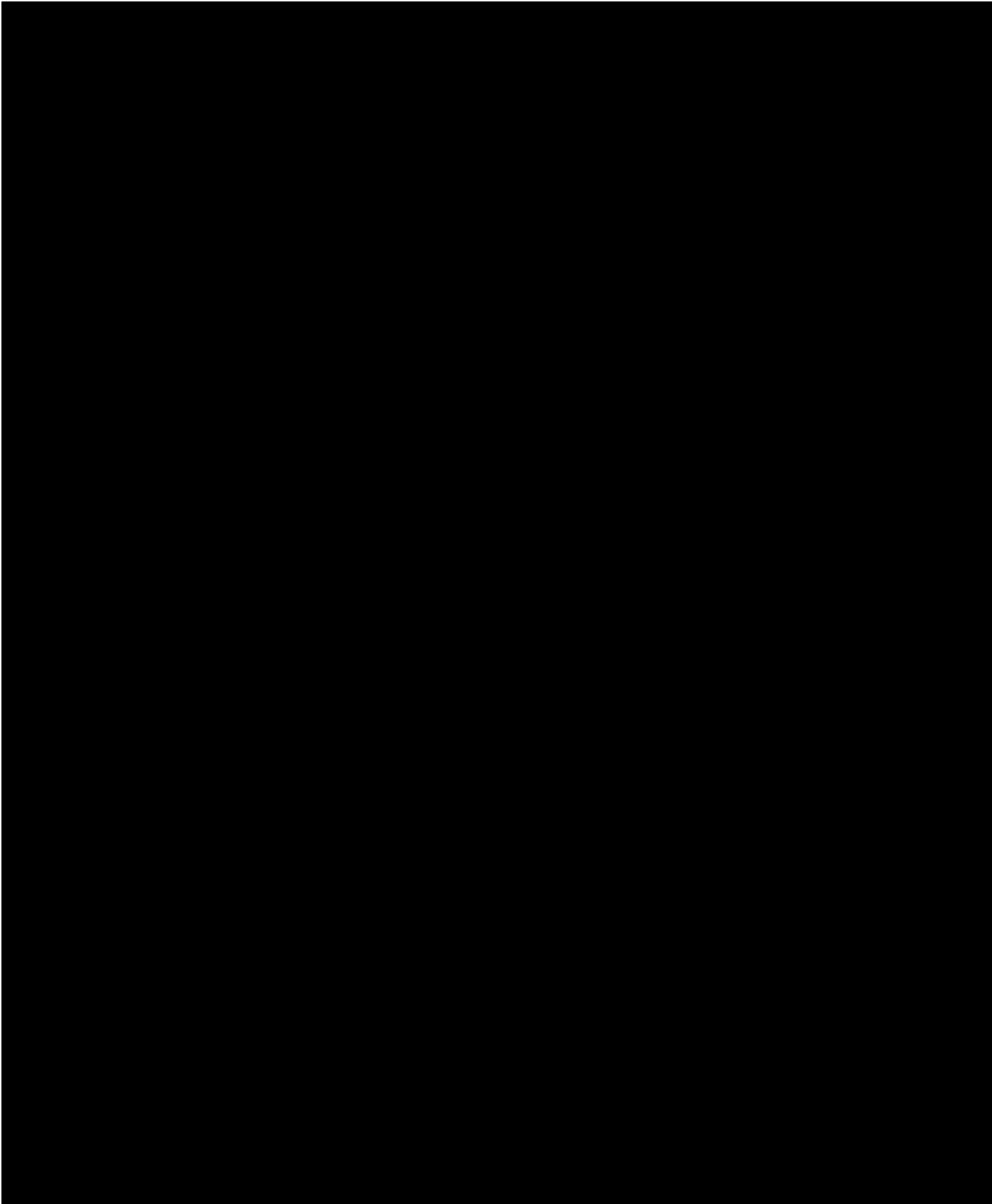
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8.3. Sensitivity Analyses

Summaries of TWSTRS total score, CGIC, and PGIC will be provided at each visit and will identify assessments done in-clinic and assessments done remotely for the safety population. Summaries of TWSTRS total score, CGIC, and PGIC will be done for the Non-COVID-19 Impacted Analysis set.

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9. Safety

The safety population will be used for all safety analyses. Safety will be assessed on the basis of AEs, clinical laboratory values (hematology, coagulation, chemistry, and urinalysis), pregnancy test results, vital signs, [REDACTED], spirometry, 12-lead ECG results, C-SSRS and the DSS.

9.1. Injection Site Evaluation

The number and percentage of subjects with an injection site reaction will be summarized by cycle and dose, along with the type of reaction. All injection site evaluation information will be provided in a listing.

9.2. Muscle Injection Record

The number and percentage of subjects who received study drug injection into each muscle will be summarized by treatment cycle and dose. All muscle injection record data will be listed.

9.3. Adverse Events

AEs will be coded using MedDRA version 22.0 or later. An AE will be considered treatment emergent if the event begins on or after the date of first dose of study medication or if the event begins before and worsens in severity after the date of first dose of study medication. An adverse event with a relationship to study medication of definite, probable, or possible is also considered to be treatment-emergent.

AEs will be summarized by system organ class (SOC) and preferred term (PT). An AE is considered related to study treatment if the relationship is considered as definite, probable, or possible. If the relationship to study treatment is missing, the AE will be counted as definite in summary tables. If the severity is missing, then the AE will be counted as severe in summary tables. Actual missing values will be presented in the listings.

Summary tables will be provided for treatment-emergent AEs (TEAEs) by dose and treatment cycle and overall for the following:

- Overall summary of TEAEs
- TEAEs by SOC and PT
- TEAEs by PT with a frequency of at least 3% overall
- TEAEs by SOC, PT, and maximum severity
- TEAEs by SOC, PT, and strongest study medication relationship
- Treatment-related TEAEs by SOC and PT
- Serious TEAEs by SOC and PT
- TEAEs resulting in study medication discontinuation by SOC and PT
- TEAEs of special interest by SOC and PT

[REDACTED]

In addition, summaries will be provided by the following dose groups:

- HDHF: High dose, high frequency group, defined as subjects who received a high dose (250 U or 300 U) for 3 or 4 cycles

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- HDLF: High dose, low frequency group, defined as subjects who received a high dose (250 U or 300 U) for 1 or 2 cycles
- LDHF: Low dose, high frequency group, defined as subjects who received a low dose (125 U or 200U) for 3 or 4 cycles
- LDLF: Low dose, low frequency group, defined as subjects who received a low dose (125 U or 200 U) for 1 or 2 cycles

Subjects will appear in only one group, and TEAEs will be summarized for subjects in each group. Subjects who received a high dose for 2 cycles and a low dose for 2 cycles will be included in the HF group. Subjects who received a high dose for 1 cycle and a low dose for 1 cycle will be included in the HL group.

The overall summary of TEAEs will include the number and percentage of subjects with a TEAE, with treatment-related TEAEs, with serious TEAEs, treatment-related serious TEAEs, with TEAEs of special interest, [REDACTED], related to anaphylactic reaction, with toxin-related TEAEs, with TEAEs leading to death, and with TEAEs leading to study discontinuation. The number of events will also be provided. For TEAE summaries, the number and percentage of subjects will be presented by SOC and PT by treatment. Subjects will be counted only once for each SOC and for each PT within each SOC. For summaries by maximum severity and strongest relationship, if a subject has the same event more than once, the subject will be included only once at the worst severity or strongest relationship. Summary tables by SOC and PT will be sorted in descending frequency by SOC and then by PT within each SOC by the overall column. All AEs will be included in the listings. Listings will be provided for all AEs, serious AEs, and AEs resulting in study medication discontinuation. All information pertaining to AEs noted during the trial will be listed by subject, detailing the verbatim description given by the Investigator, preferred term, system organ class, start date, stop date, severity, action taken regarding study drug, outcome, and drug relatedness. The event onset will also be shown relative (in number of days) to the date of first dose of study treatment administration. In addition, a list of subjects who prematurely discontinue from the trial due to adverse events will also be provided.

[REDACTED]

9.5. Laboratory Evaluations

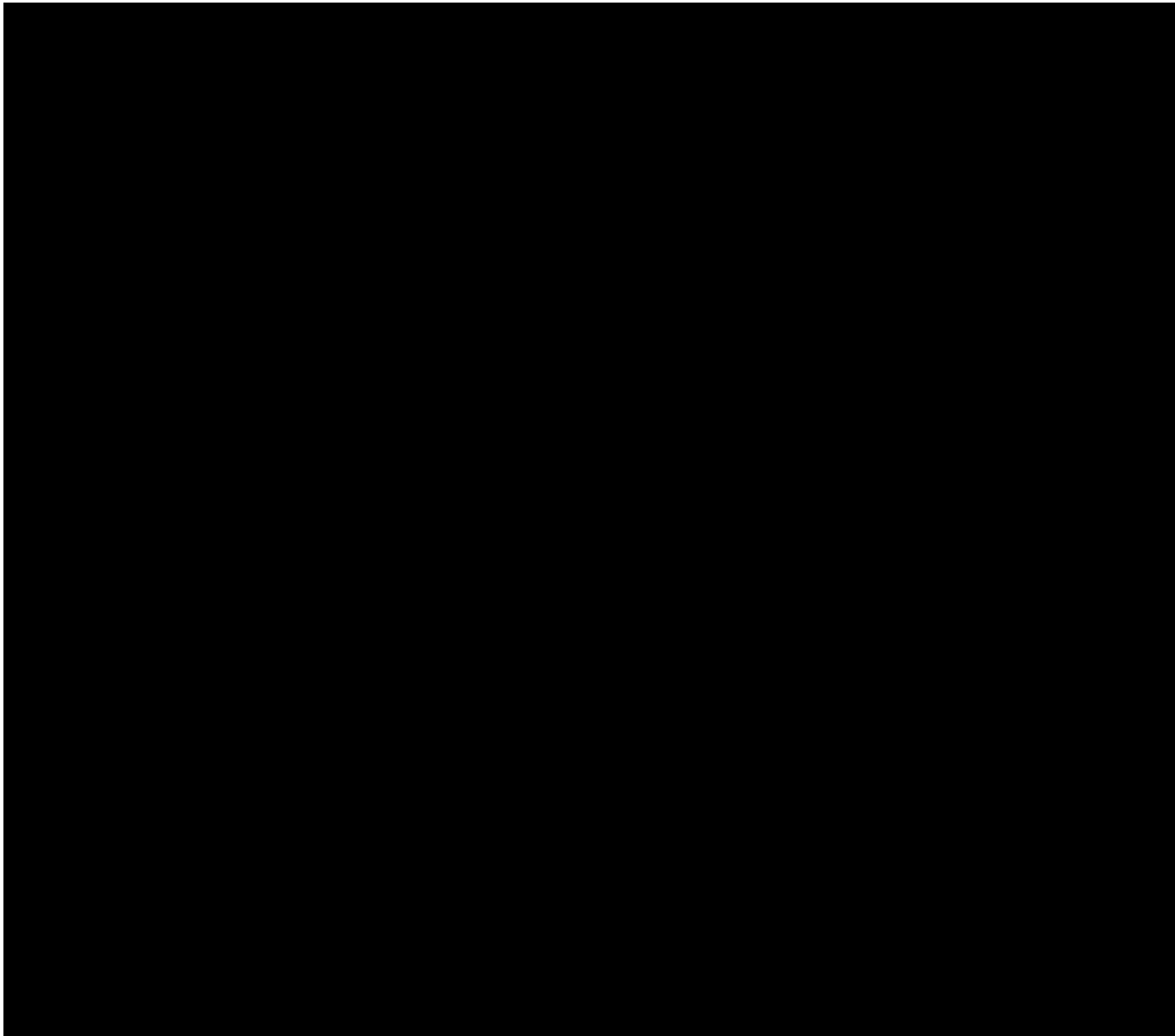
Non-fasting samples will be collected for serum chemistry, hematology, coagulation (prothrombin time), and urinalysis. In addition, for women of child bearing potential, a serum pregnancy test will be collected. If a urine pregnancy test is positive, a serum pregnancy test will be performed to confirm. The hematology tests that will be collected are: Hemoglobin, Hematocrit, Leukocyte count (total), Leukocyte count (differential), Red blood cell count, and Platelet count. Serum chemistry tests that will be collected are: Glucose, Total bilirubin, Alanine aminotransferase, Aspartate aminotransferase, Alkaline phosphatase, Blood urea nitrogen, Pregnancy (women of childbearing potential at Screening), Potassium, Sodium, Calcium, Carbon dioxide (Bicarbonate), Chloride, Creatinine, Total protein. Urinalysis tests that will be collected are: Specific gravity, pH, Glucose, Protein, Blood, Bilirubin, and Ketones. Other additional tests that will be collected are: Prothrombin time, urine pregnancy for women of childbearing potential, serum pregnancy test at end of study if urine pregnancy test is positive, [REDACTED]. Summary tables and listings will report laboratory results using Système International (SI) units.

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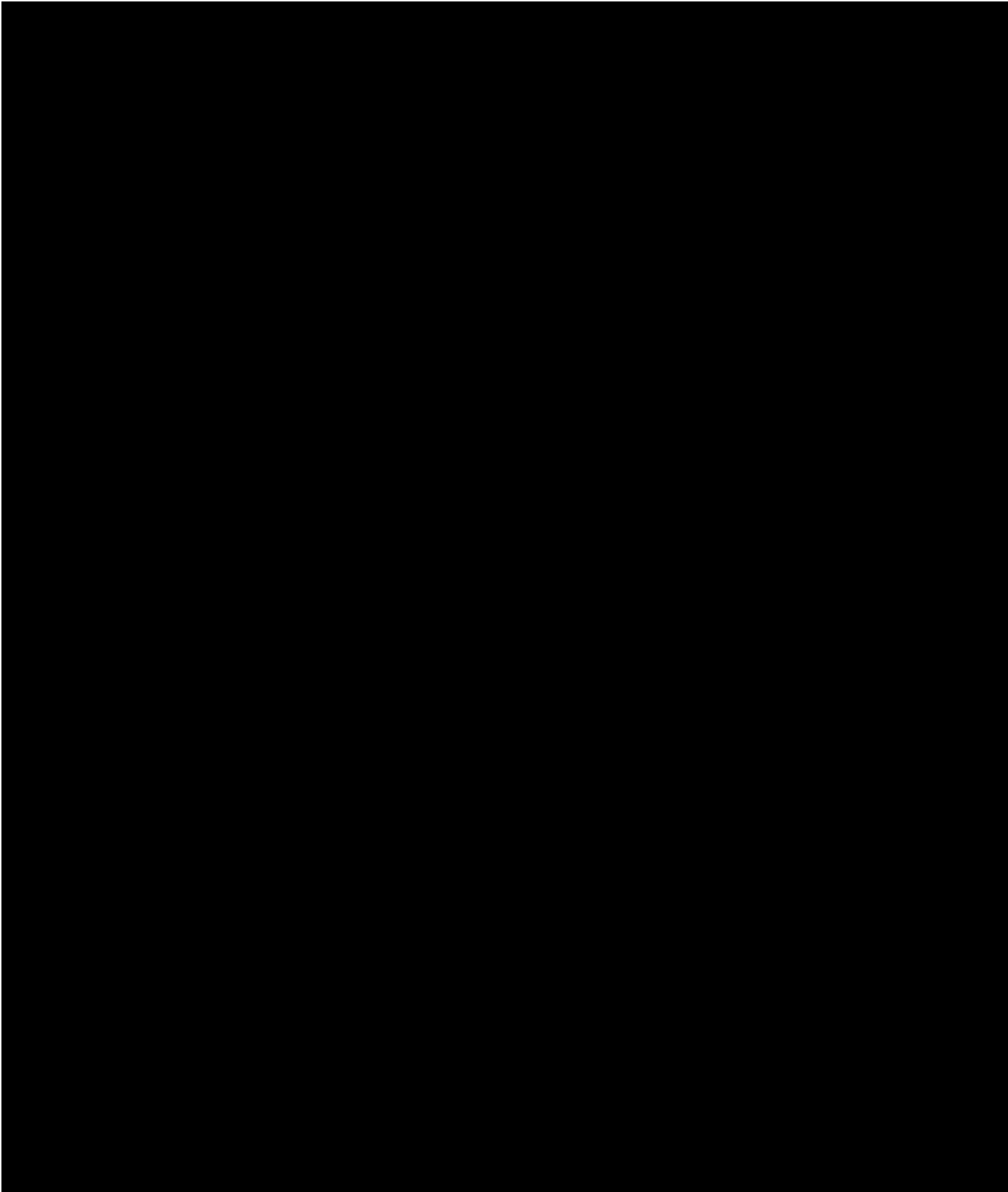
Summary statistics for observed values and changes from baseline will be provided for chemistry, hematology, coagulation, [REDACTED] by dose and treatment cycle for each visit. Summary statistics for observed urinalysis values will be provided by dose and treatment cycle for each visit.

Shift tables will also be provided for shift from Baseline to Week 12 of each treatment cycle and shift from Baseline to Week 52/End of Study. Shift tables will be based on normal ranges and results will be reported as low, normal, or high. For urinalysis values, results will be reported as normal or abnormal. Summaries will be provided by dose and treatment cycle.

A listing will be provided for all laboratory values at all visits. A listing of all out-of-range or clinically significant laboratory test results at any evaluation will be provided. Determination of clinical significance for all out-of-range laboratory values were to be made by each investigator and will be included in the listing.



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9.7. Vital Signs

Vital signs include weight, body temperature, respiration rate, sitting radial pulse rate, and sitting systolic and diastolic blood pressure. Height is collected at the Screening visit only. Body Mass Index (BMI) will be computed using the weight at each visit and height at Screening: $BMI = \text{weight (kg)} / \text{height (m)}^2$.

Vital signs will be summarized by dose and treatment cycle for each visit. All vital signs will be included in a listing.

9.8. ECG

A standard 12-lead ECG will be performed after the subject has rested quietly in the supine position for at least 10 minutes. The ECG data will be submitted to a central reader for review.

A summary of the overall ECG interpretation will be provided by dose and treatment cycle for each visit. Summary statistics for ECG interval data will be provided by dose and treatment cycle for each visit. The number and percentage of subjects in each of the following QTc categories will be provided by dose and treatment cycle for each visit and for any post-treatment visit:

- QTc > 450 msec for males or > 470 msec for females
- QTc > 480 msec
- QTc > 500 msec
- Increase from baseline QTc \geq 30 msec
- Increase from baseline QTc \geq 60 msec

If the ECG is repeated more than once at any timepoint, average of the repeated values will be used for the summary. All ECG results will be included in a listing

9.9. Physical [REDACTED]

A complete physical examination is performed at Screening and Baseline. At post-treatment visits, the physical examination may be abbreviated. Physical [REDACTED] examination results will be summarized by dose and treatment cycle for each visit. All data will be provided in a listing.

9.10. Pulmonary Function Test

Pulmonary function will be recorded using spirometry. Parameters measured are the forced vital capacity (FVC), which is the total volume of air exhaled during forced expiration, and the forced expiratory volume in the first second of exhalation (FEV₁). The FCV and FEV₁ results and changes from baseline will be summarized by dose and treatment cycle for each visit. In addition, the percentage of subjects with a decrease from baseline \geq 10%, \geq 15%, and \geq 20% and an increase from baseline \geq 10%, \geq 15%, and \geq 20% will also be provided. All data will be provided in a listing.

9.11. Dysphagia Severity Score

The presence of dysphagia will be evaluated using the DSS. After the Baseline visit, this scale is collected only if a subject reports swallowing difficulties. The DSS results and changes from baseline will be summarized by dose and cycle for each visit. All data will be provided in a listing.

9.12. Columbia-Suicide Severity Rating Scale

According to the FDA draft guidance for suicidal ideation and behavior ([FDA Guidance Suicidal Ideation and Behavior](#)), the following C-SSRS outcomes, which have yes/no responses, will be sorted in

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descending frequency of a yes response and numbered to define the composite endpoints for the C-SSRS below:

- Category 1 – Wish to be dead
- Category 2 – Non-specific active suicidal thoughts
- Category 3 – Active suicidal ideation with any methods (not plan) without intent to act
- Category 4 – Active suicidal ideation with some intent to act without specific plan
- Category 5 – Active suicidal ideation with specific plan and intent

- Category 6 – Preparatory acts or behavior
- Category 7 – Aborted attempt
- Category 8 – Interrupted attempt
- Category 9 – Actual attempt
- Category 10 – Completed suicide
- Category 11 – Self-injurious behavior without suicidal intent

A summary table will be provided for each visit by dose and treatment cycle. The summary table will include the yes/no responses to each question in categories 1 through 11 above. In addition, summaries will include any suicidal ideation (highest category with a yes response for categories 1-5 or none if all responses are no), any suicidal behavior (highest category with a yes response for categories 6-10 or none if all responses are no), and any suicidality (highest category with a yes response for categories 1-10 or none if all responses are no), emergence of suicidal ideation (where yes=no suicidal ideation at baseline, and any suicidal ideation at any visit after treatment and no=none), emergence of suicidal behavior (where yes=no suicidal behavior at baseline and any suicidal behavior after treatment and no=none), and worsening of suicidal ideation (yes if most severe suicidal ideation at any post-treatment visit is more severe than the value at baseline for categories 1-5, no if none).

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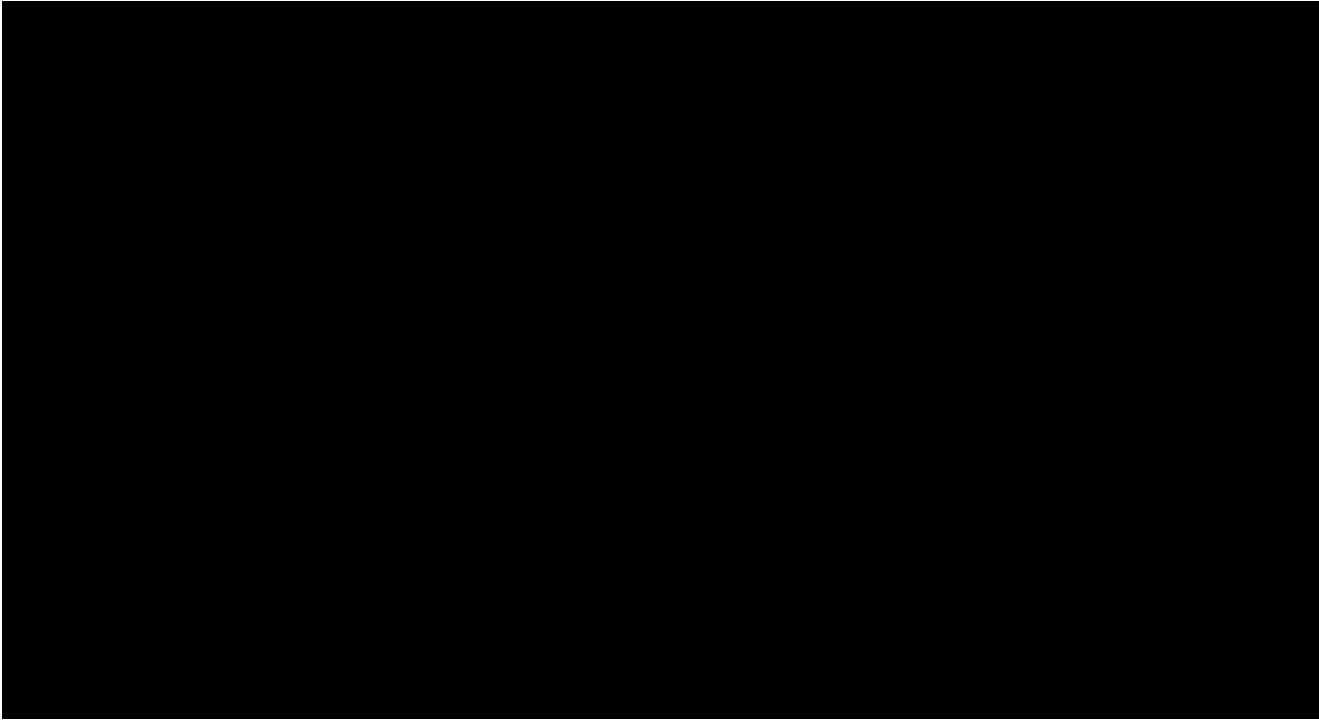
10. Changes from Analysis Planned in Protocol



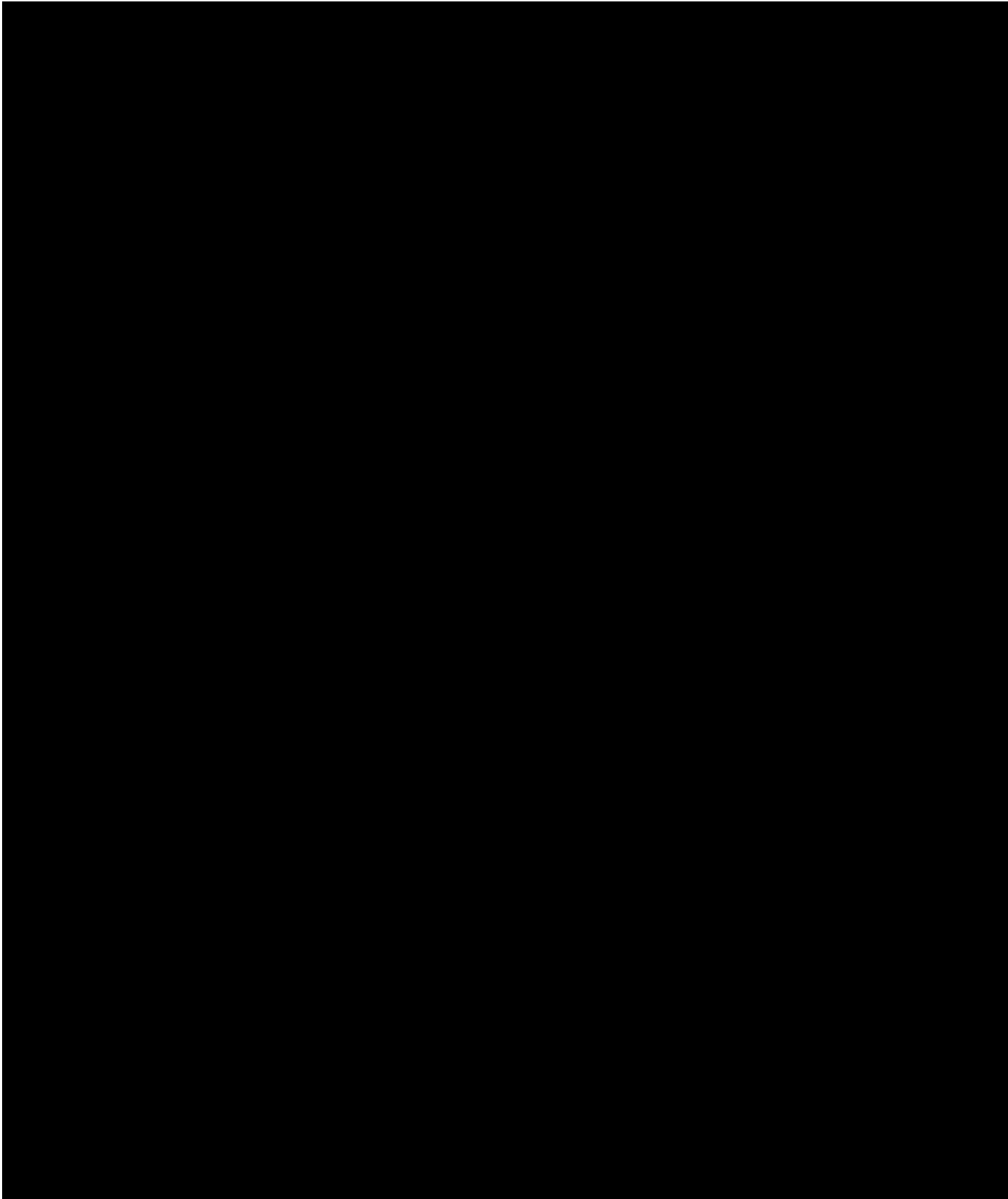
Additional analyses have been added to determine the impact of COVID-19 on key efficacy variables.

The intent-to-treat and per protocol populations will not be used. As this is an open-label study, only the safety population analysis will be performed. As this is an open-label study, multiple imputation will also not be performed.

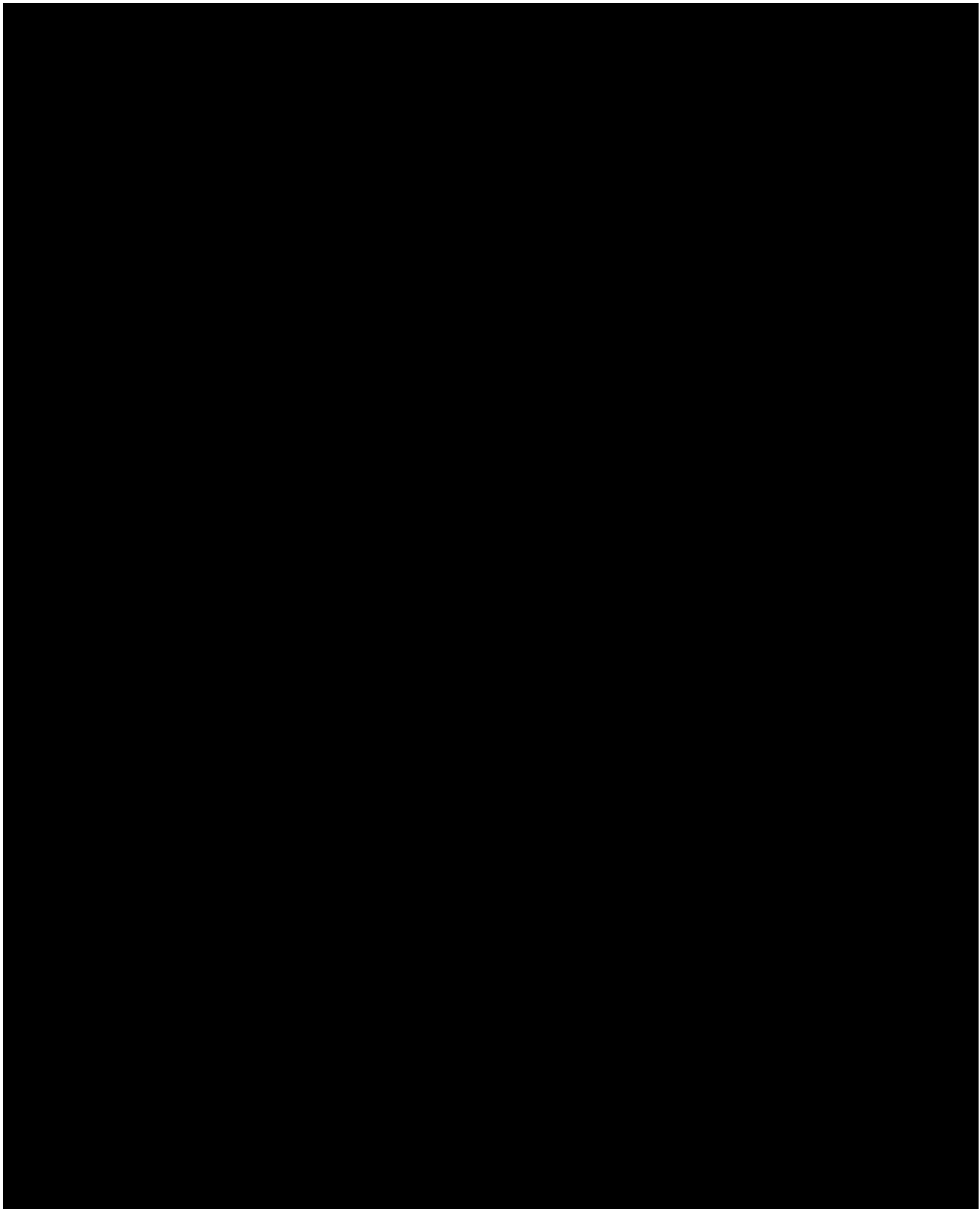
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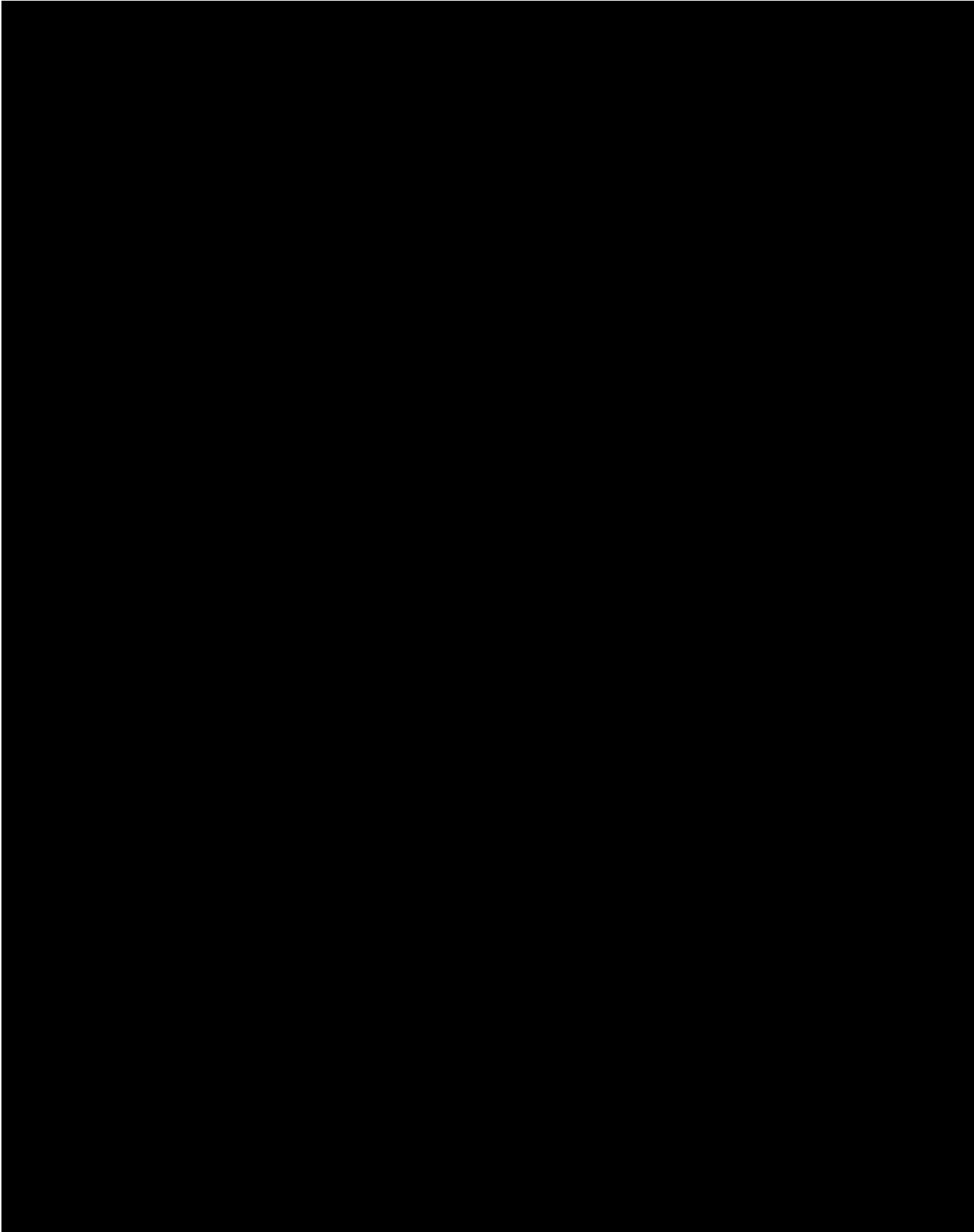
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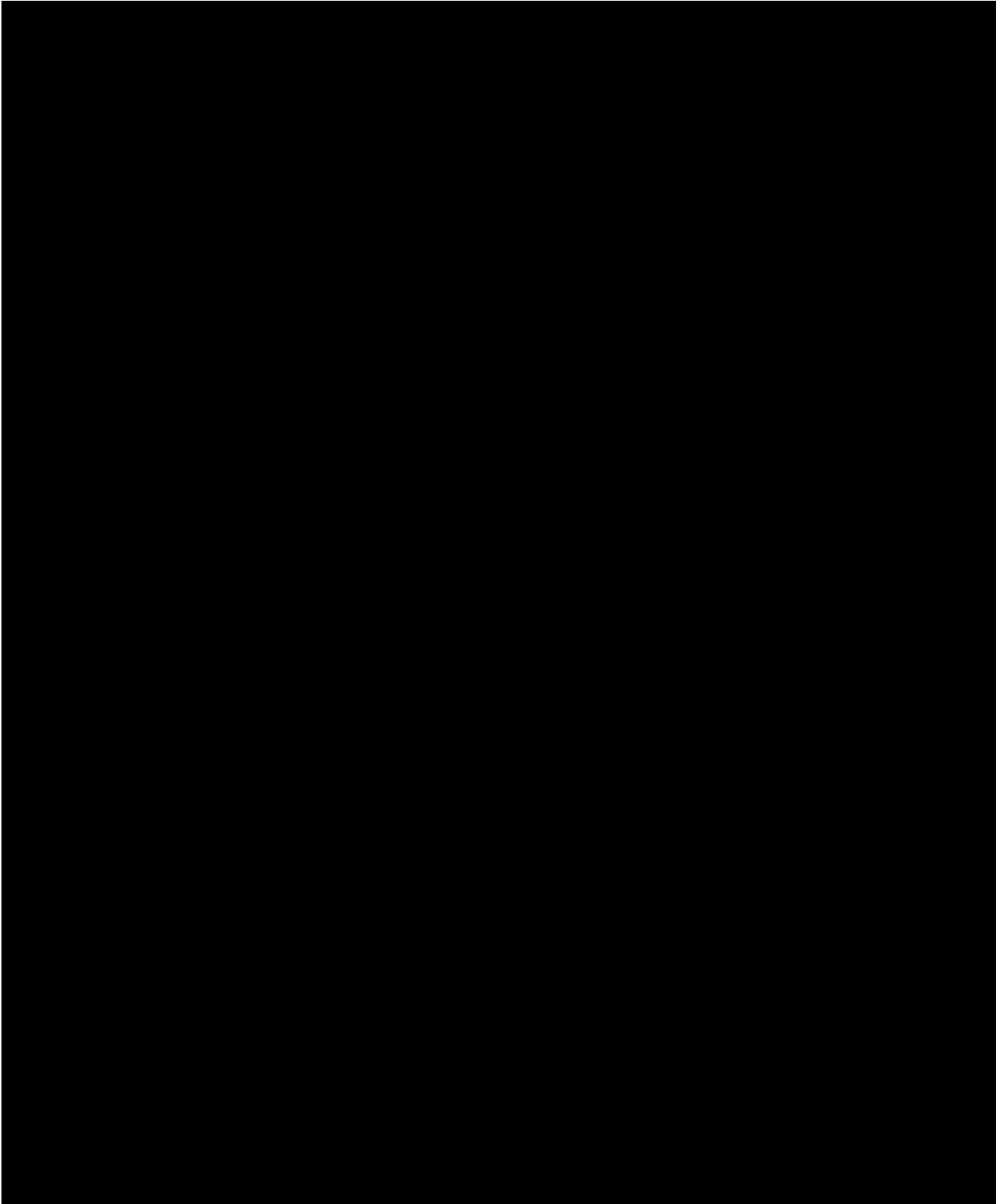
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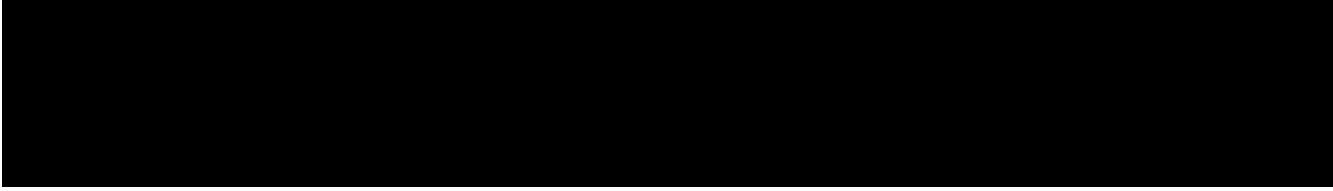
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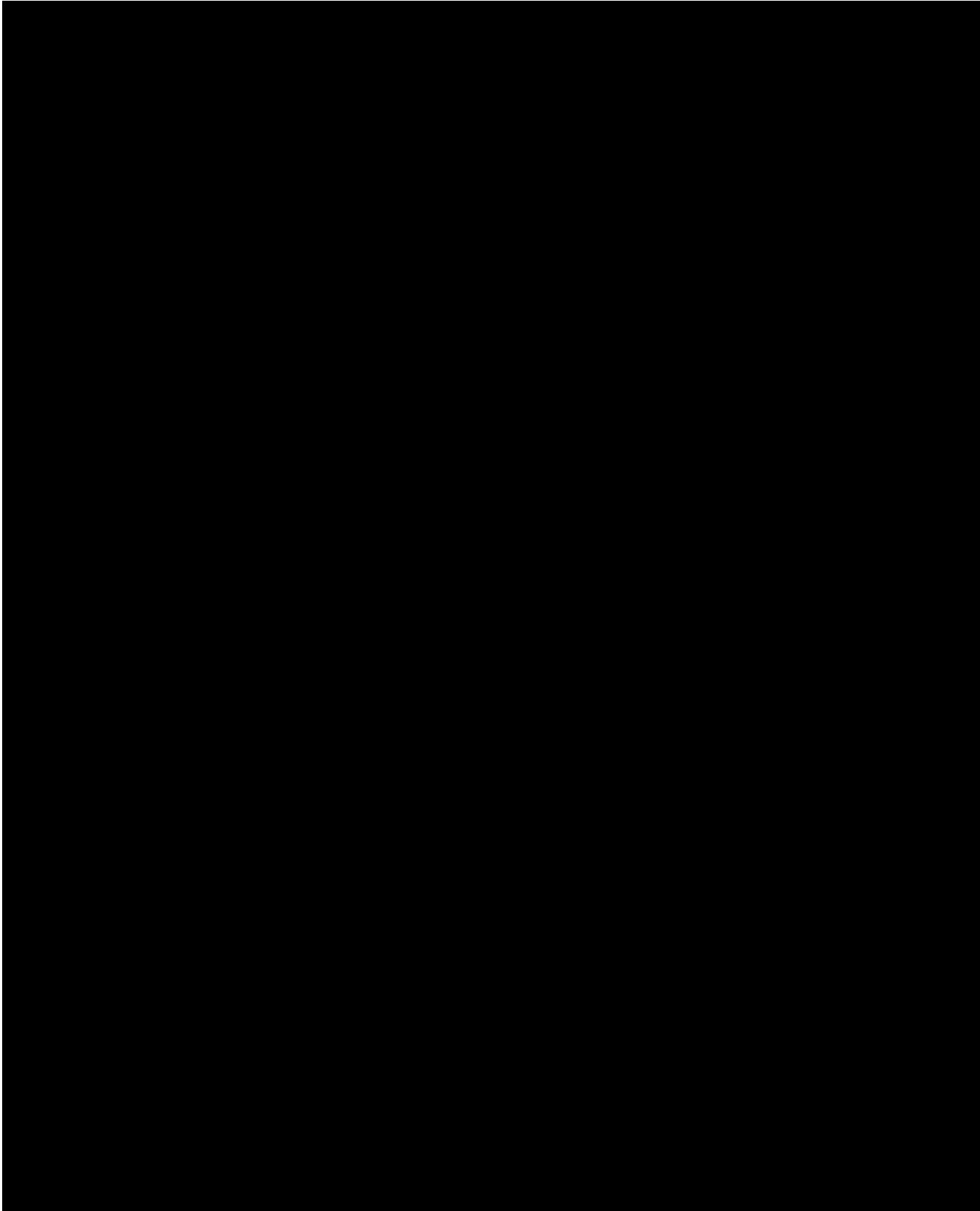
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13. Quality Control

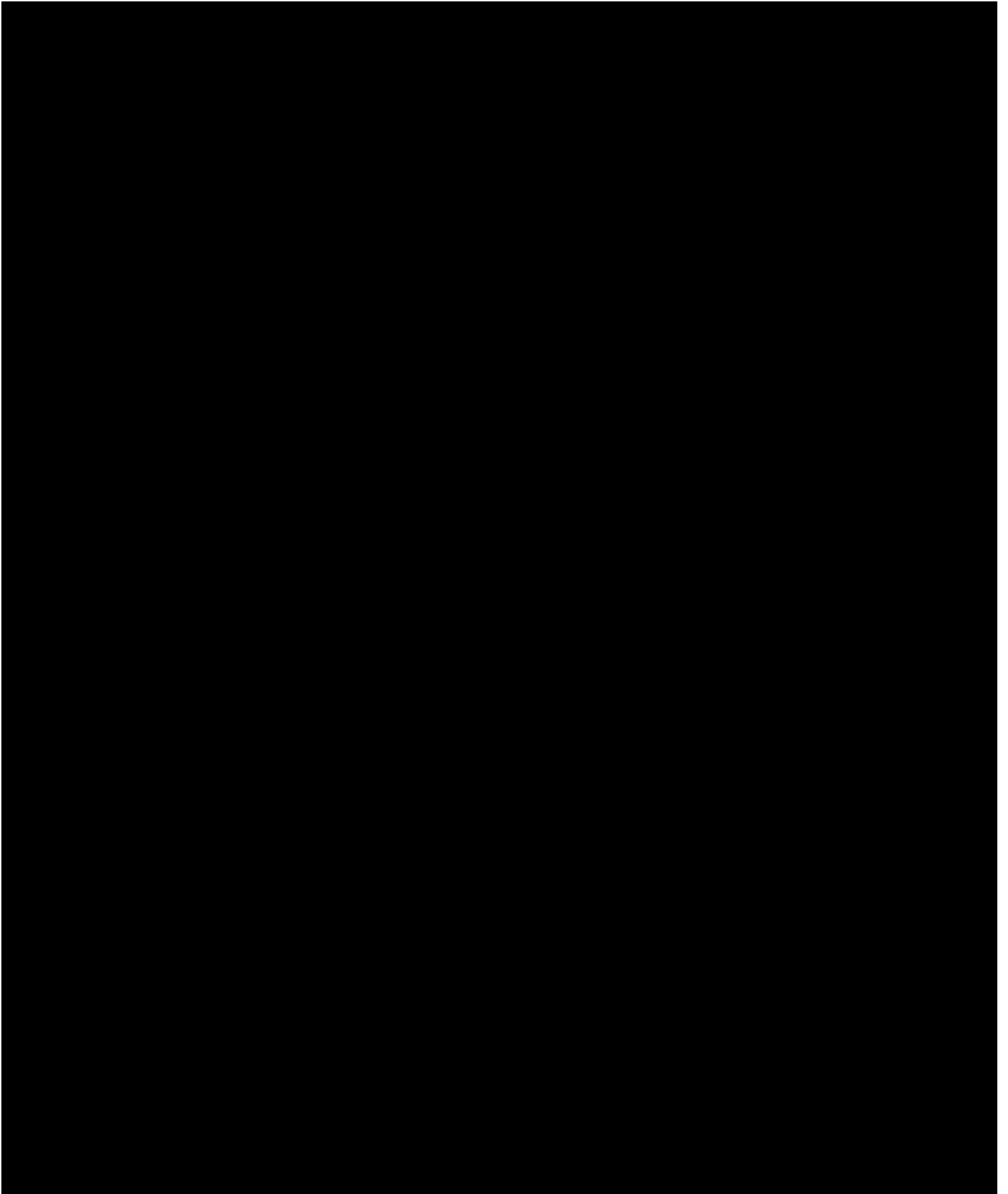
SAS programs are developed to produce output such as analysis data sets, summary tables, data listings, figures or statistical analyses. An overview of the development of programs is detailed in Syneos Health Standard Operating Procedure (SOP) Developing Statistical Programs (3907).

Syneos Health SOPs Developing Statistical Programs (3907) and Quality Deliveries (SDTM, ADaM, TLF) (3908) describes the quality control procedures that are performed for all SAS programs and output. Quality control is defined here as the operational techniques and activities undertaken to verify that the SAS programs produce the output by checking for their logic, efficiency and commenting and by review of the produced output.”

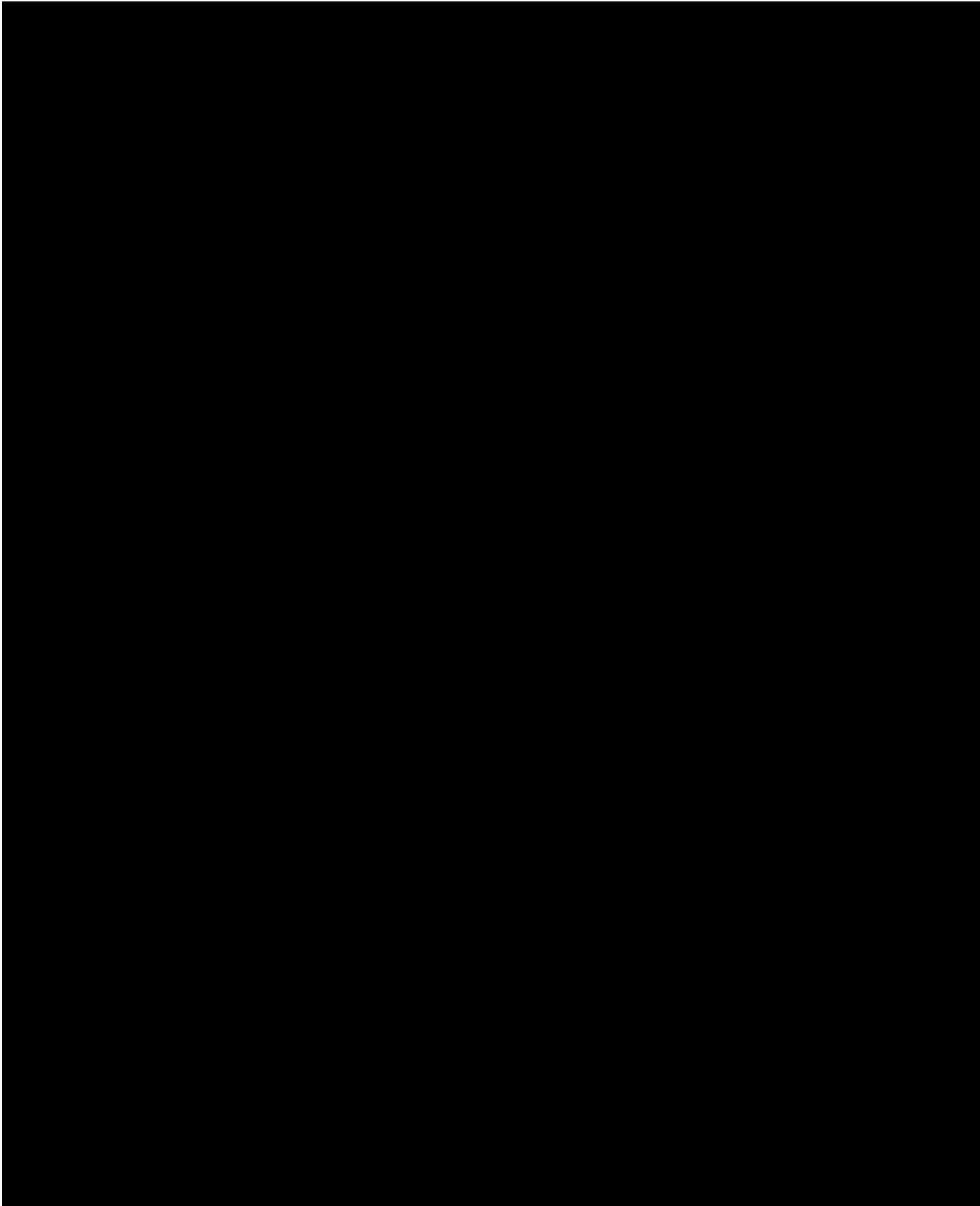
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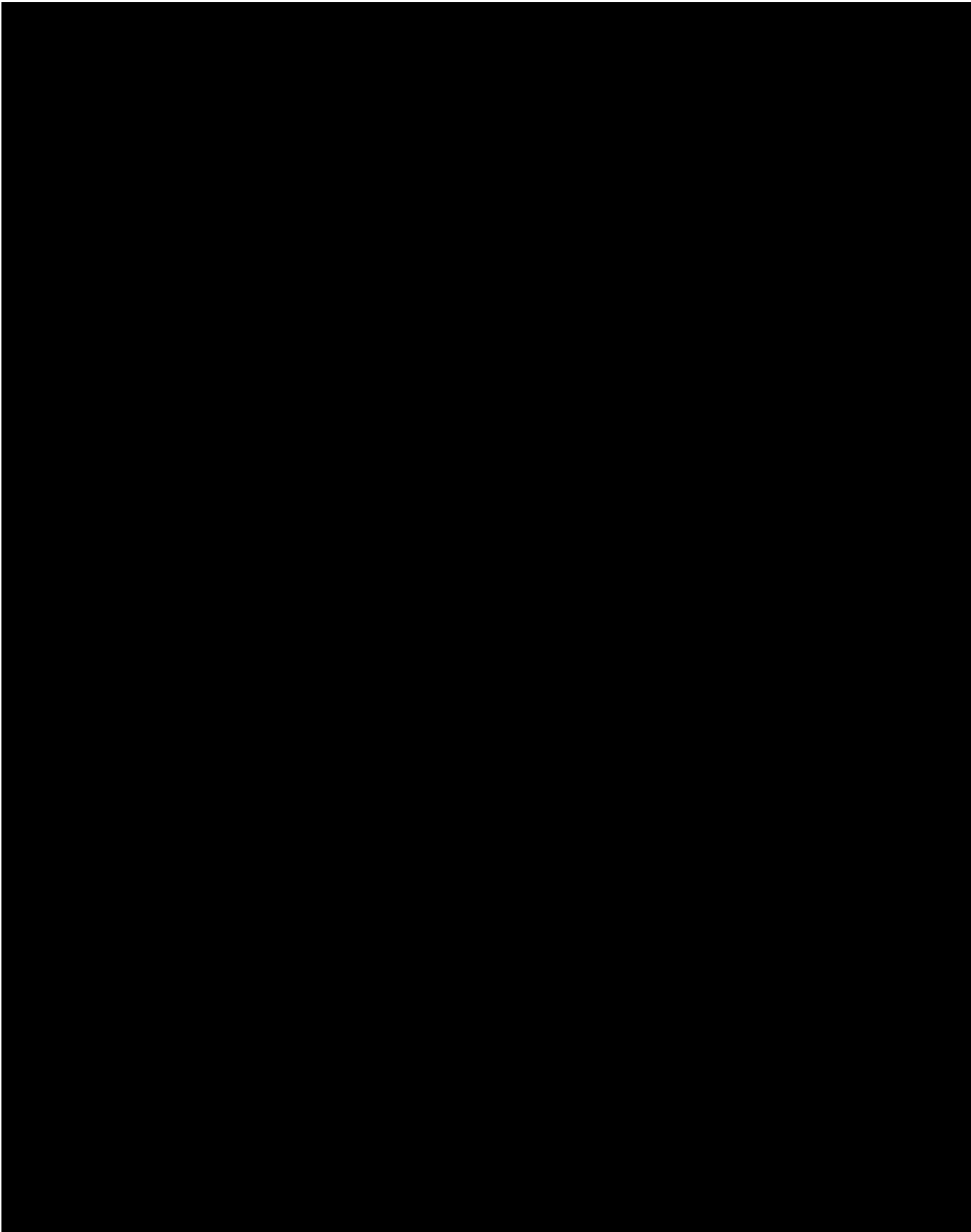
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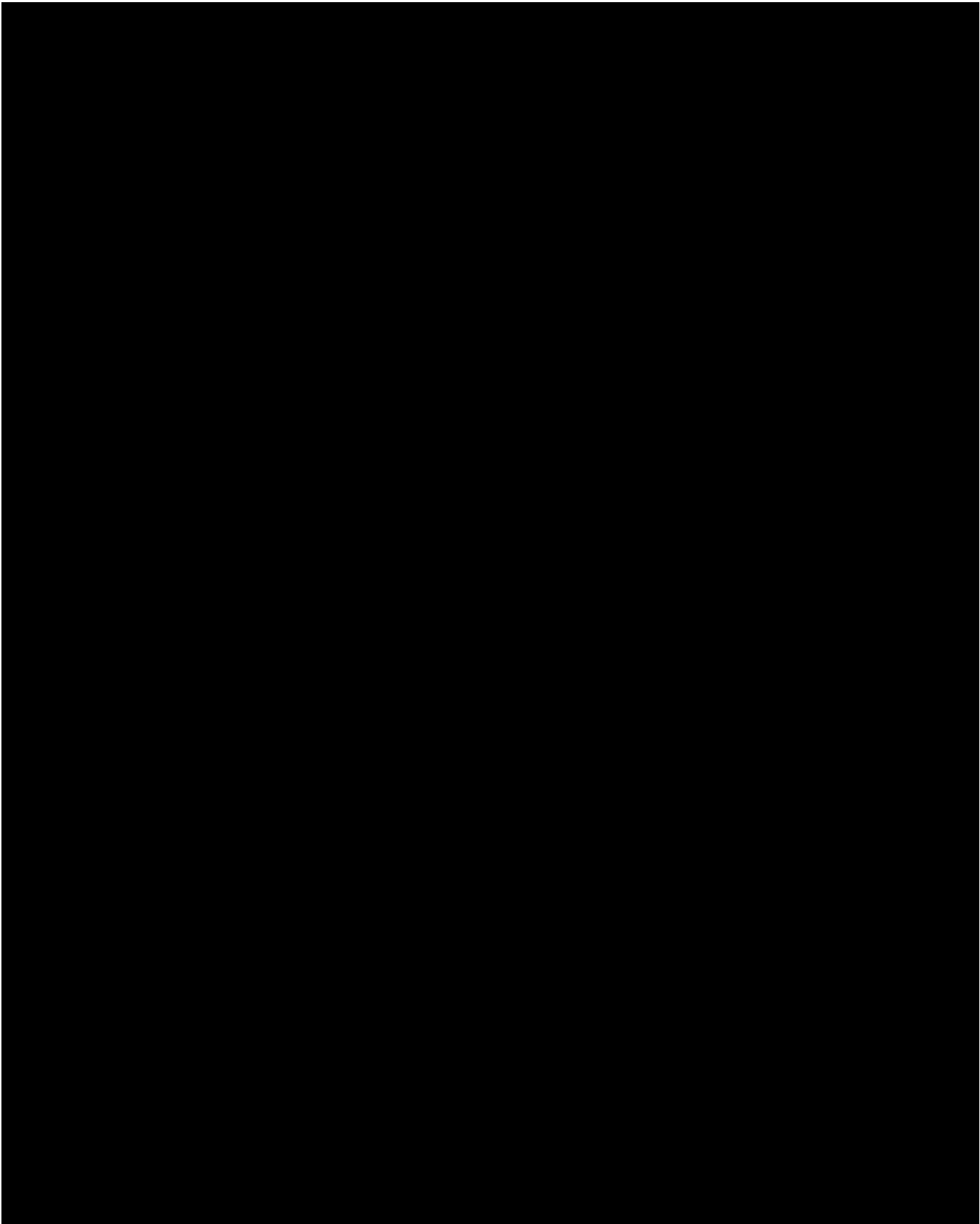
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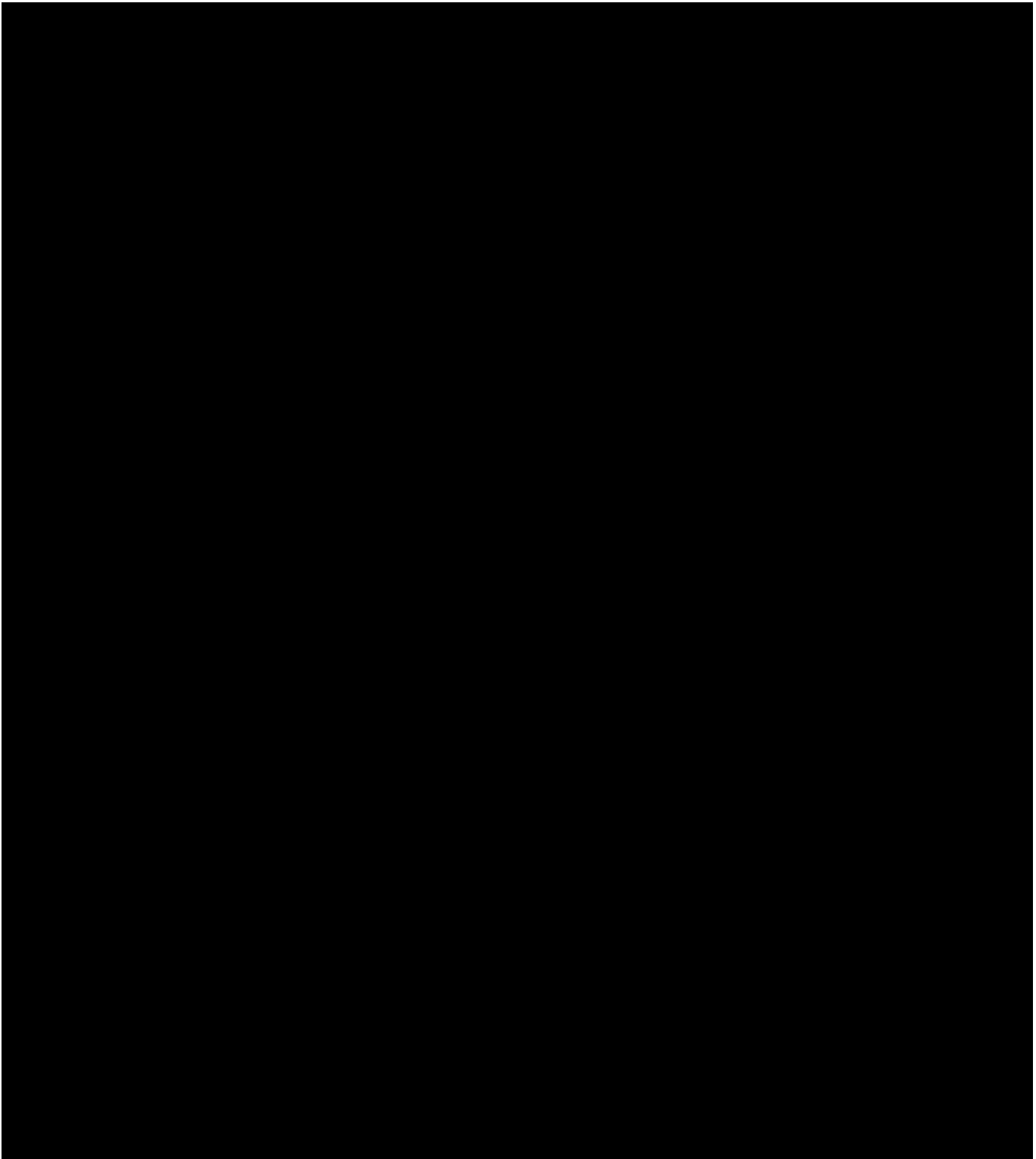
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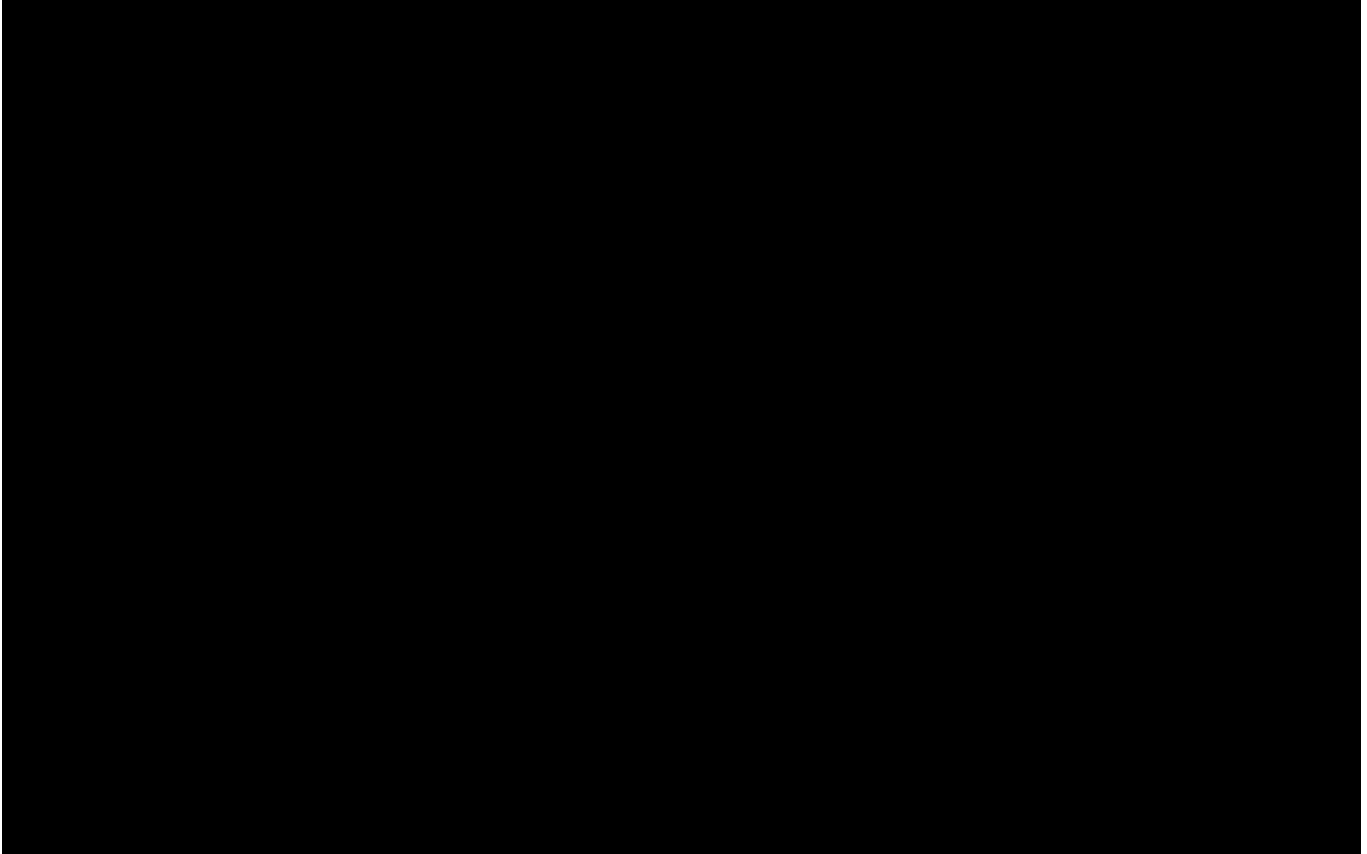
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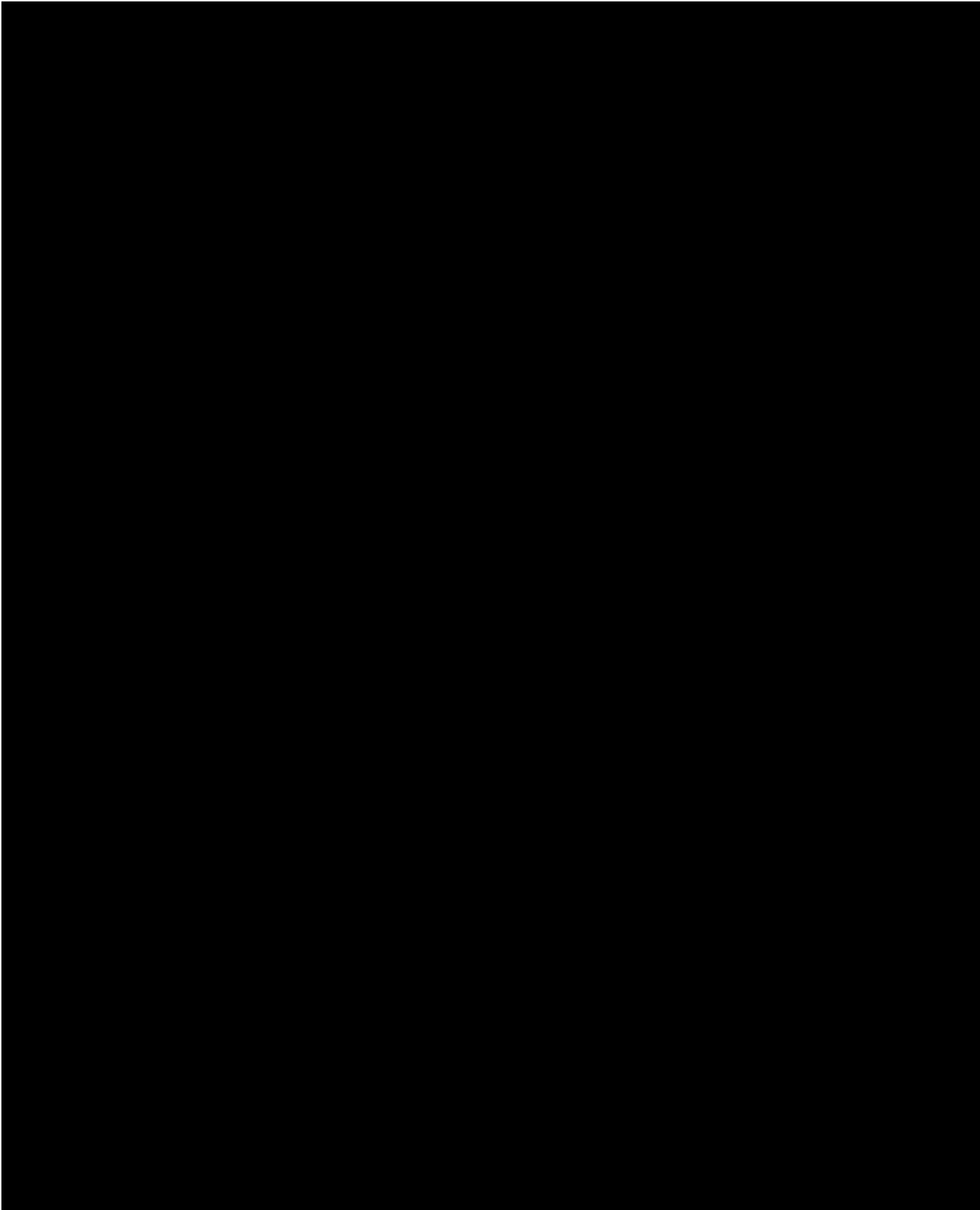
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