STATISTICAL ANALYSIS PLAN

Study Title:	A Proof-of-Concept, Open-label Study to Assess the Safety and Efficacy of Batoclimab in Participants with Graves' Disease (GD)
Sponsor Name:	Immunovant Sciences GmbH
Protocol Number:	IMVT-1401-2501
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SAP Date:	22-AUG-2025

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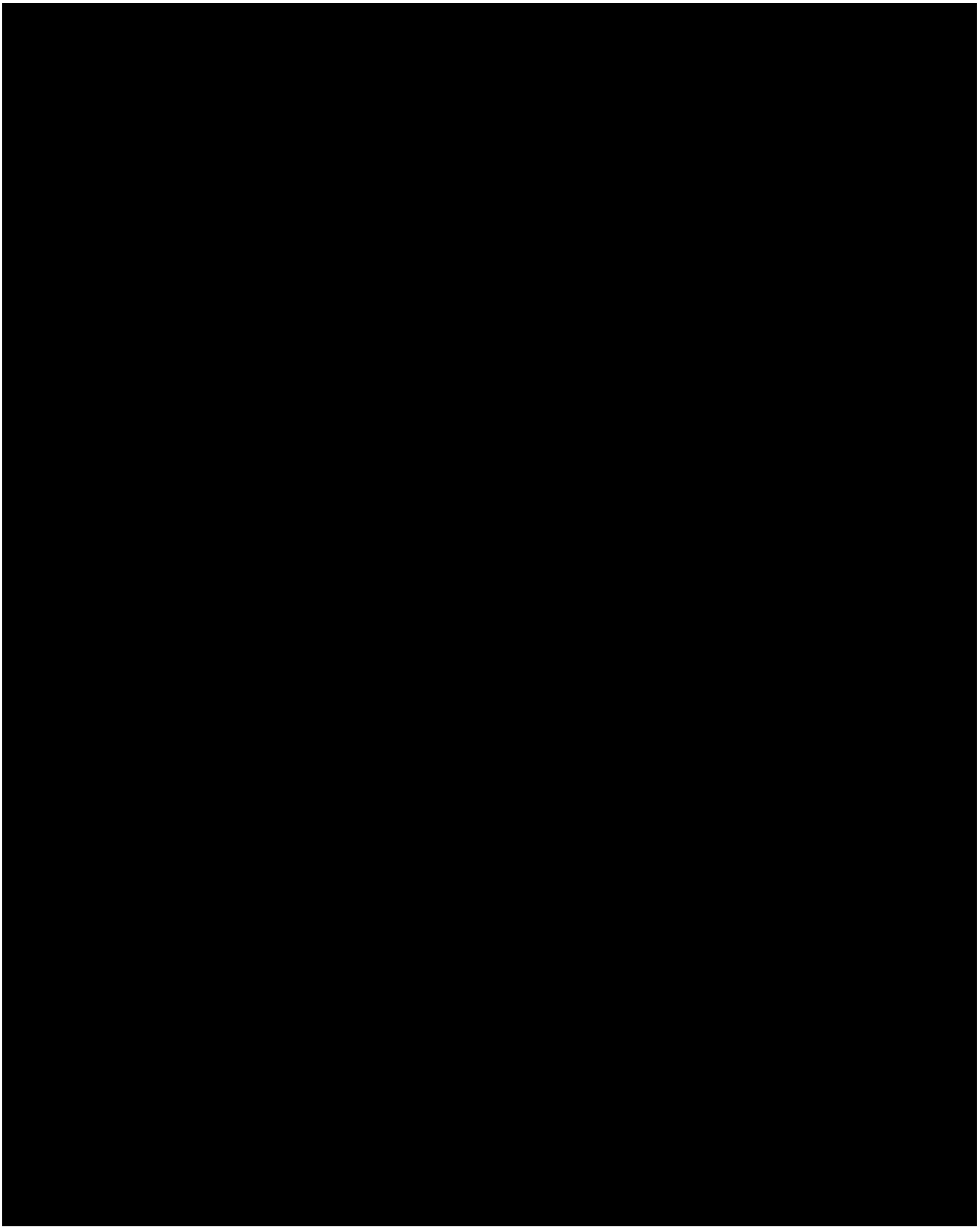
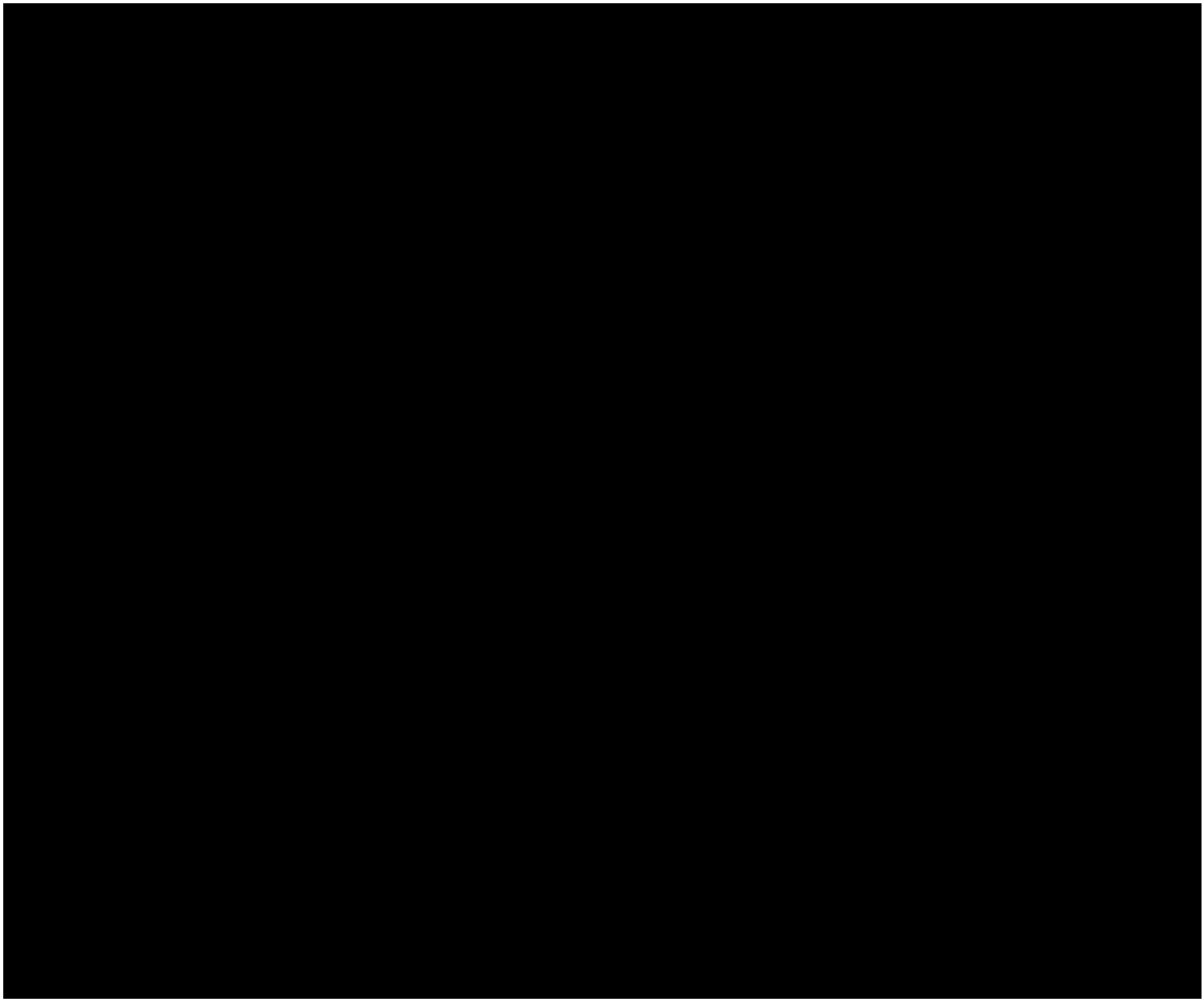




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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Term
Ab	antibody
ADA	anti-drug antibody
ADAAS	anti-drug antibody analysis set
AE	adverse event
[redacted]	[redacted]
ALP	alkaline phosphatase
ALT	alanine aminotransferase
Anti-TSH-R	anti-thyrotropin receptor
AST	aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
ATD	antithyroid drug
[redacted]	[redacted]
CAS	clinical activity score
CI	confidence interval
[redacted]	[redacted]
CTCAE	Common Terminology Criteria for Adverse Events
CV	coefficient of variation
d/D	day
ECG	electrocardiogram
[redacted]	[redacted]
ED	early discontinuation
eGFR	estimated glomerular filtration rate
[redacted]	[redacted]
FT3	free triiodothyronine
FT4	free thyroxine
GD	Graves' disease
GGT	gamma-glutamyl transferase
[redacted]	[redacted]
[redacted]	[redacted]

Abbreviation	Term
ICH	International Council for Harmonisation/International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
[redacted]	[redacted]
IgG	immunoglobulin G
IgG1/2/3/4	immunoglobulin G1/2/3/4
[redacted]	[redacted]
[redacted]	[redacted]
LLN	lower limit of normal
LLOQ	lower limit of quantification
MAP	mean arterial pressure
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
MedDRA	Medical Dictionary for Regulatory Activities
[redacted]	[redacted]
NCI	National Cancer Institute
PK	pharmacokinetic(s)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
PT	preferred term
Q1/Q3	first quartile/third quartile
QW	once a week (or weekly)
QTcF	QT correction with Fridericia's formula
RBC	red blood cell
SAE	serious adverse event
[redacted]	[redacted]
SAP	Statistical Analysis Plan
SC	subcutaneous(ly)
SCR	screening
SD	standard deviation

Abbreviation	Term
SE	standard error
[redacted]	[redacted]
[redacted]	[redacted]
SOC	system organ class
TBL	total bilirubin
TEAE	treatment-emergent adverse event
TED	thyroid eye disease
Tg	thyroglobulin
Tg-Ab	thyroglobulin antibody
[redacted]	[redacted]
TPO	thyroid peroxidase
TPO-Ab	thyroid peroxidase antibody
TSH	thyrotropin
TSH-R	thyrotropin receptor
TSH-R-Ab	thyrotropin receptor antibody
ULN	upper limit of normal
V	visit
WBC	white blood cell
WHO-DD	World Health Organization Drug Dictionary
Wk	week
[redacted]	[redacted]

1. INTRODUCTION

The purpose of the Statistical Analysis Plan (SAP) is to document the statistical methods to be implemented during the analyses of data collected within the scope of Immunovant Sciences GmbH protocol IMVT-1401-2501, "A Proof-of-Concept, Open-label Study to Assess the Safety and Efficacy of Batoclimab in Participants with Graves' Disease (GD)", Version 8.0, November 20th, 2024. In addition to the information presented in Section 7 (Statistical Considerations) of the protocol, which provides the principal features of the confirmatory analyses for this study, this SAP provides additional statistical analysis details/data derivations and documents modifications or additions to the analysis plan specified in the protocol.

This document may evolve, for example, to reflect the requirements of protocol amendments or regulatory requests. However, the SAP must be finalized, approved, and placed on file before final database is locked. The clinical study report will note deviations from the final approved plan.

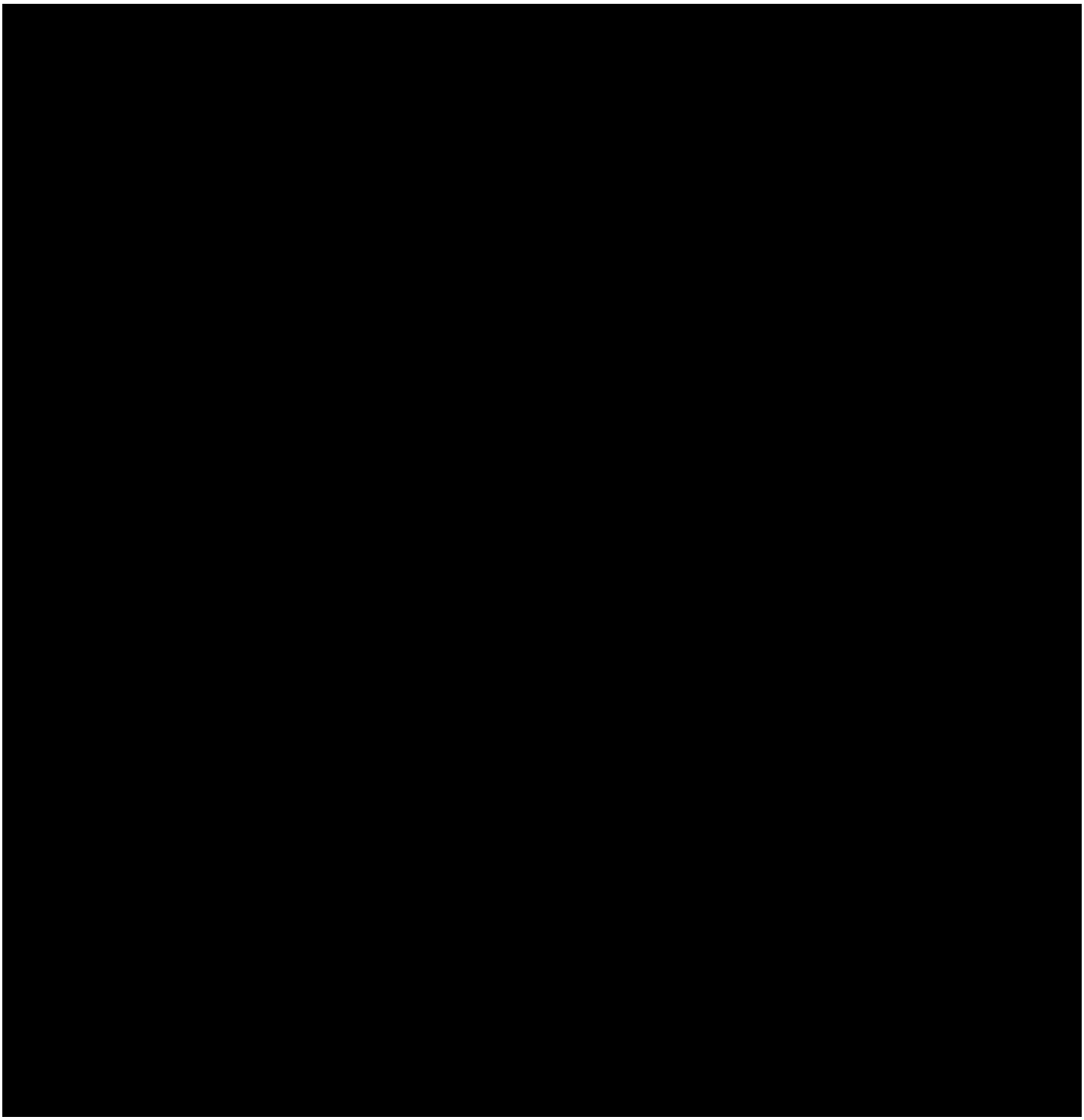
2. STUDY OBJECTIVES AND ENDPOINTS

Table 1 lists the study objectives and endpoints.

Table 1: Study Objectives and Endpoints

OBJECTIVES	ENDPOINTS
Primary	
To investigate the effects of batoclimab on thyroid hormone levels in participants with GD as assessed by reduction of FT3 and FT4 at Week 24	Proportion of participants who at Week 24, without increase in ATD dose compared to baseline, have achieved normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN.
Secondary	
To investigate the effects of batoclimab on thyroid hormone levels in participants with GD as assessed by reduction of FT3 and FT4 and changes in ATD at Week 24	Proportion of participants who achieve normalization of FT3 and FT4 at Week 24 with ATD dose ≤50% of the baseline ATD dose by Week 24
To investigate the effects of batoclimab on thyroid hormone levels in participants with GD as assessed by reduction of FT3 and FT4 at Week 24 and ATD treatment	Proportion of participants who are off ATD treatment and achieve normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN at Week 24





3. INVESTIGATIONAL PLAN

3.1. Overall Study Design

Study IMVT-1401-2501 is a Phase 2a, proof-of-concept, open-label study designed to assess the safety and efficacy of batoclimab in adult participants with biochemically documented hyperthyroidism due to GD who have failed to achieve euthyroidism on ATD. Approximately 35 participants with GD aged ≥18 years will be enrolled.

The study includes a screening period of up to 4 weeks, an Open-Label Treatment Period of 24 weeks, [redacted] Eligible participants will receive open label batoclimab 680 mg SC QW for 12 weeks [redacted] followed by open label batoclimab 340 mg SC QW for 12 weeks [redacted]

See Figure 1 for the study schema.





[redacted]

3.3. Administration of Study Medication

Eligible participants will receive open-label:

- Batoclimab 680 mg SC QW for 12 weeks, followed by 340 mg SC QW for 12 weeks.

[redacted]

Only participants enrolled in the study may receive study treatment, and only authorized site staff may prescribe study treatment. Study treatment must be administered by a delegated healthcare professional.

[redacted]

3.4. Study Procedures

The planned study procedures and schedule of activities can be found [redacted]

4. ANALYSIS POPULATION

4.1. Safety Analysis Population

The safety analysis (SAF) population includes all participants who received at least one dose of study treatment. The SAF will be used for all safety and efficacy analyses.

4.2. Pharmacokinetic (PK) Population

The PK analysis (PKAS) population includes all participants who received any study treatment and had at least one non-missing post-dose PK result following the administration of the study treatment. The PKAS will be used in the PK analyses.



5. GENERAL STATISTICAL CONSIDERATIONS

5.1. General Considerations

Unless otherwise specified, all efficacy and safety endpoints will be analyzed for the SAF population. All statistical analyses of the study will be performed using the statistical software SAS for [redacted] (SAS Institute, Inc., Cary, NC).

All by-participant data used for the analyses will be displayed in listings.

Data Summary

Unless otherwise specified, summaries for continuous variables will include the descriptive statistics for the number of participants (n), arithmetic mean (mean), standard deviation (SD), first quartile (Q1), third quartile (Q3), minimum (min), median, and maximum (max). The min and max values will be presented to the same number of decimal places as the raw data. The means and medians will be presented in one more decimal place than the raw data. The SDs will be presented in two more decimal places than the raw data.

Summaries for categorical (discrete or dichotomous) variables will include the number and/or percentage of participants in a particular category. Percentages will be presented to one decimal place unless otherwise specified. Population counts (either number of participants or the number of time points at the assessment) be used as the denominator in the calculation of percentages unless otherwise specified.

The missing category will be included in the categories of all categorical variables, and the number of missing observations will be included in the summary statistics of continuous variables as well.

All listings will be sorted for presentation in order of study center, participant, and date/time of procedure or event. Participants who are screened but not dosed will be listed separately.

All analysis and summary tables will have the analysis population sample size (i.e., number of participants) included in the column header. The day of the first dose of the study drug will be defined as Day 1.

Baseline

Unless otherwise specified, the general baseline is defined as the last non-missing value prior to the first dose of study treatment.

Change from baseline is defined as the difference between the post-baseline assessment value and the baseline value, i.e., Post-baseline Assessment Value – Baseline Value.

Responder to the Primary Endpoint

Responder to the primary endpoint is defined as participant who at Week 24, without increase in ATD dose compared to baseline, has achieved normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN (i.e., both FT3 and FT4 ≤ ULN).

Responder to the off ATD Secondary Endpoint

Responder to the off ATD secondary endpoint is defined as participant who is off ATD treatment and has achieved normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN (i.e., both FT3 and FT4 ≤ ULN).

6. DISPOSITION, DEMOGRAPHIC, AND BASELINE DATA

Unless otherwise specified, disposition, demographics, and baseline disease characteristics will be summarized for the SAF population. Medical history and concomitant medications will be summarized for the SAF population.

6.1. Participants Disposition

A summary table of participants' disposition will be provided where the number and the percentage of participants in each of the following categories will be presented:

- [redacted]

The total number of participants who are screened, screen failure, reasons for screen failure, the primary reason for early treatment discontinuation, and early study discontinuation will be summarized as well.

6.2. Protocol Deviations

Important protocol deviations [ICH E3 Q&A (R1)] are defined as a subset of protocol deviations that may significantly impact the completeness, accuracy, and /or reliability of the study data or that may significantly affect the participant's rights, safety, or well-being (FDA 2013).

Important protocol deviations will be summarized and listed.

A record of all protocol deviations will be kept showing the dates of and the reason for each protocol deviation. Protocol deviations will be listed.

[redacted]

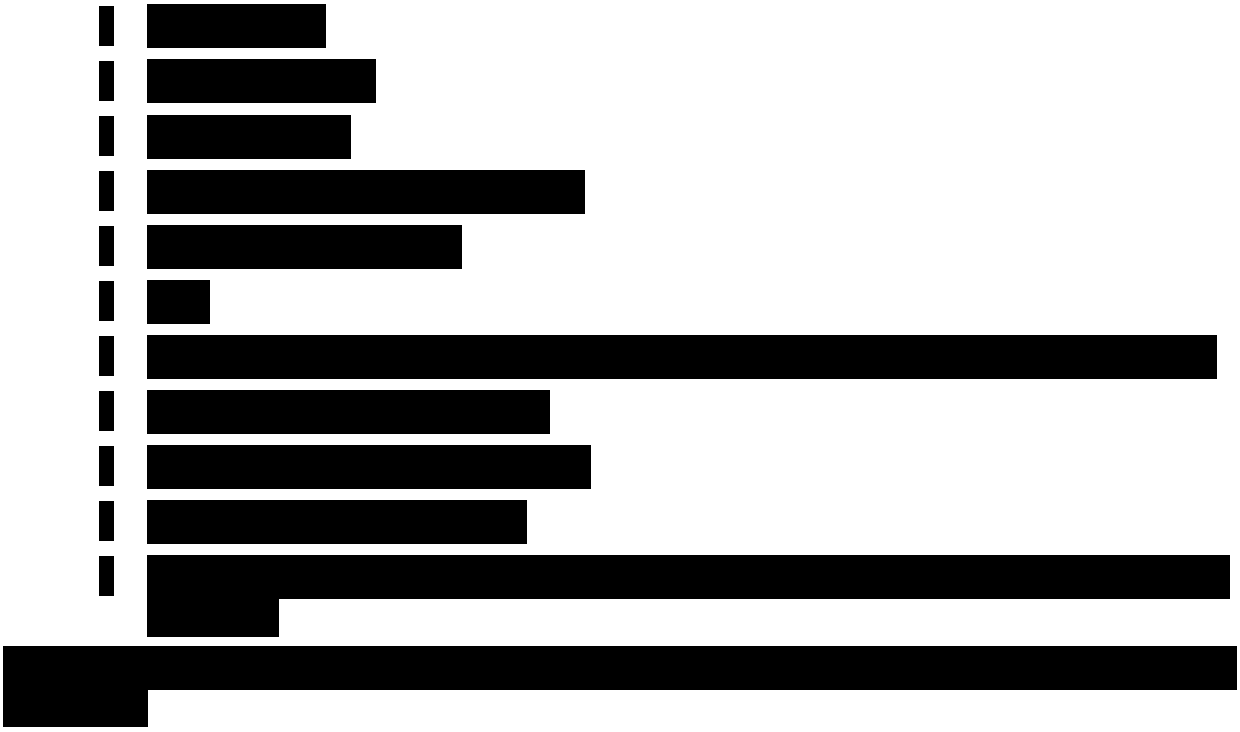
6.3. Demographic and Baseline Characteristics

The following demographic and baseline characteristics will be summarized and reported.

Demographic variables include:

- Age (in years): calculated as the integer part of (date of informed consent – date of birth + 1) / 365.25. If the date of birth cannot be obtained due to regional regulations, the earliest date based on the partial date of birth information will be imputed to calculate the age.
- Sex (Female and Male)
- Race (White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and Others). If multiple races are selected for a participant, the participant will be included in the other category. Participants with 'Unknown' or 'Not Reported' will be included in the missing category.
- Ethnicity (Hispanic or Latino, and Not Hispanic or Latino). Participants with 'Unknown' or 'Not Reported' will be included in the missing category.
- Height (cm)
- Weight (kg)
- BMI (kg/m^2)

[redacted]



6.4. Medical History

Medical history data will be coded using the most updated version of the Medical Dictionary for Regulatory Activities (MedDRA) at the final database lock. The actual version of the MedDRA coding dictionary will be noted in the statistical tables. The number and percentage of participants in each medical history category (by MedDRA system organ class (SOC) and preferred term [PT]) will be summarized in the SAF population. The SOC will be presented in alphabetical order, and the PTs will be presented in alphabetical order within each SOC. Participants reporting more than one condition/diagnosis will be counted only once in each SOC or PT.

Frequency summary statistics (i.e., n and percentage) will be provided for thyroid medical history as the information collected in eCRF as well.

6.5. Medications

Medications will be coded using the most updated version of the World Health Organization Drug Dictionary (WHO-DD) at the final database lock. The actual version of the WHO-DD used will be noted in the statistical tables.

Concomitant medications will be summarized by Anatomical Therapeutic Chemical (ATC) Level 3 term and preferred term (PT) in the SAF population. Medication summaries will be sorted alphabetically by ATC Level 3 and by PT within ATC Level 3. Participants will be counted only once for each medication class and each preferred drug name.

6.5.1. Prior Medication

A prior medication is defined as any medication taken prior to the date of the first dose of the study drug. Prior medications will be listed.

6.5.2. Concomitant Medication

A concomitant medication is defined as any prior medication that continues after the date of the first dose of the study drug or any medication that starts on or after the date of the first dose of the study drug and through a participant completing the study.

Medication can be both a prior medication and a concomitant medication. For a medication with a partial missing date, the prior or concomitant status will be determined after the imputation of the partial missing date based on the rules specified in Appendix C.

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

6.6. Study Drug Exposure and Compliance

Treatment duration, study drug compliance, and the total number of injections will be summarized for the SAF population.

Treatment duration in weeks is defined for each participant as

[(the last dose date - the first dose date) / 7] + 1 (week).

[redacted]

[redacted]

7. EFFICACY ANALYSES

The analysis of efficacy endpoints will be based on the SAF population. Unless otherwise specified, all efficacy data collected, regardless of participant exposure to study treatment, will be included in efficacy analyses. Confidence intervals will be presented as 2-sided 95% CIs.

7.1. Primary Efficacy Analysis

The primary endpoint is the proportion of participants who at Week 24, without an increase in ATD dose compared to baseline, have achieved normalization of FT3 and FT4 or have FT3 and/or FT4 below the LLN (i.e., both FT3 and FT4 ≤ ULN). For this analysis, the change in the ATD dose will only be compared between baseline and Week 24 to determine whether there is an increase.

The primary efficacy endpoint will be analyzed using the 2-sided Clopper-Pearson Exact method (Clopper and Pearson 1934). The point estimate of the proportion and the corresponding Clopper-Pearson 95% CIs will be provided. For this analysis, participants who have a missing FT3 or FT4 assessment at the Week 24 visit will be considered as non-responders to the primary endpoint.

All available FT3 and FT4 assessments will be included in the primary analysis. Participants who, during the 24-week treatment period, receive prohibited medications for the treatment of GD or discontinue the study treatment due to lack of efficacy or AE will be considered as non-responders to the primary endpoint (protocol Section 4.5), regardless of the assessment at Week 24.

The Clopper-Pearson Exact method will be implemented using the statistical analysis system (SAS version 9.4 or higher) with the FREQ procedure with a binomial (exact) option. A sample SAS code is provided in Appendix D.

A bar plot will be provided for the proportion of participants who achieve normalization of FT3 and FT4 or have FT3 and/or FT4 below the LLN without an increase in ATD dose compared to primary endpoint by study visit (in weeks).

A separate frequency summary statistic table will be provided for the proportion of participants who achieve normalization of FT3 and FT4 or have FT3 and/or FT4 below the LLN without an increase in ATD dose compared to baseline by study visit (in weeks) through Week 24 as well.

Analysis of the time to first response to the primary endpoint during the 24-Week Treatment Period [redacted] will be considered exploratory. Details are provided in Section 7.4.13 and Section 7.4.14.

7.1.1. Subgroup Analysis for the Primary Efficacy Endpoint

Subgroup analysis for the primary efficacy endpoint is not planned.

7.2. Secondary Efficacy Analyses

Unless otherwise specified, the secondary endpoints will be analyzed for the SAF population.

7.2.1. Proportion of participants who achieve normalization of FT3 and FT4 at Week 24 with ATD dose ≤ 50% of the baseline ATD dose by Week 24

The proportion of participants who achieve normalization of FT3 and FT4 at Week 24 with ATD dose ≤ 50% of the baseline ATD dose by Week 24 will be analyzed using the same method for the primary efficacy analysis described in Section 7.1. For this analysis, the change in the ATD dose will only be compared between baseline and Week 24 to determine whether there is at least a 50% reduction.

A bar plot will be provided for the proportion of participants who achieve the normalization of FT3 and FT4 with ATD dose ≤ 50% of the baseline ATD dose by study visit (in weeks).

A separate frequency summary table for the proportion of participants who achieve normalization of FT3 and FT4 with ATD dose ≤ 50% of the baseline ATD dose will be provided by each study visit (in weeks) through Week 24. A similar summary statistics table and figure by visit from [redacted] will be provided for SAF population and for participants who [redacted] respectively.

7.2.2. Proportion of participants who are off ATD treatment and achieve normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN at Week 24

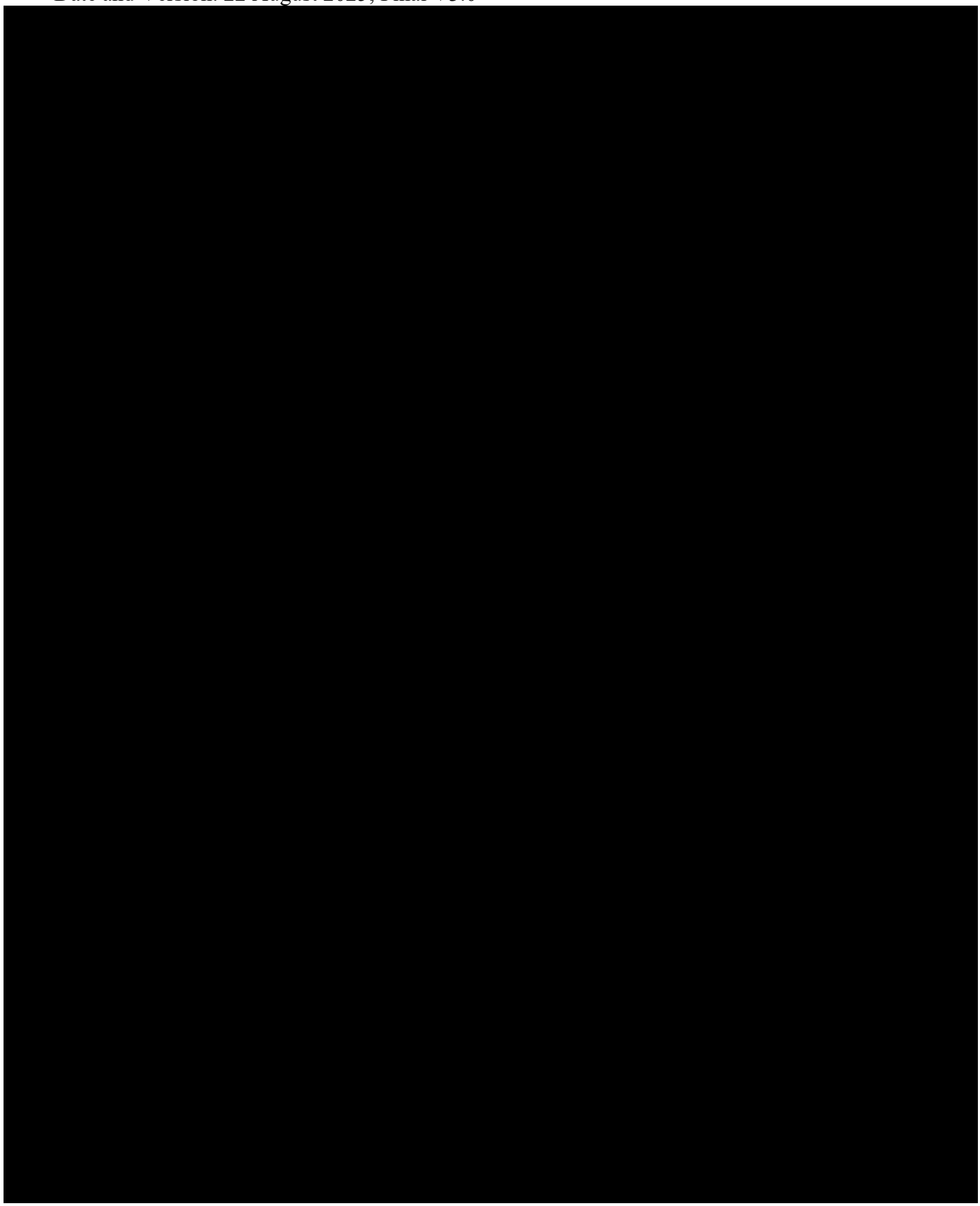
The off-ATD secondary endpoint is the proportion of participants who are off ATD treatment and achieve normalization of FT3 and FT4 or have FT3 and/or FT4 below the LLN (i.e., both FT3 and FT4 ≤ ULN) at Week 24.

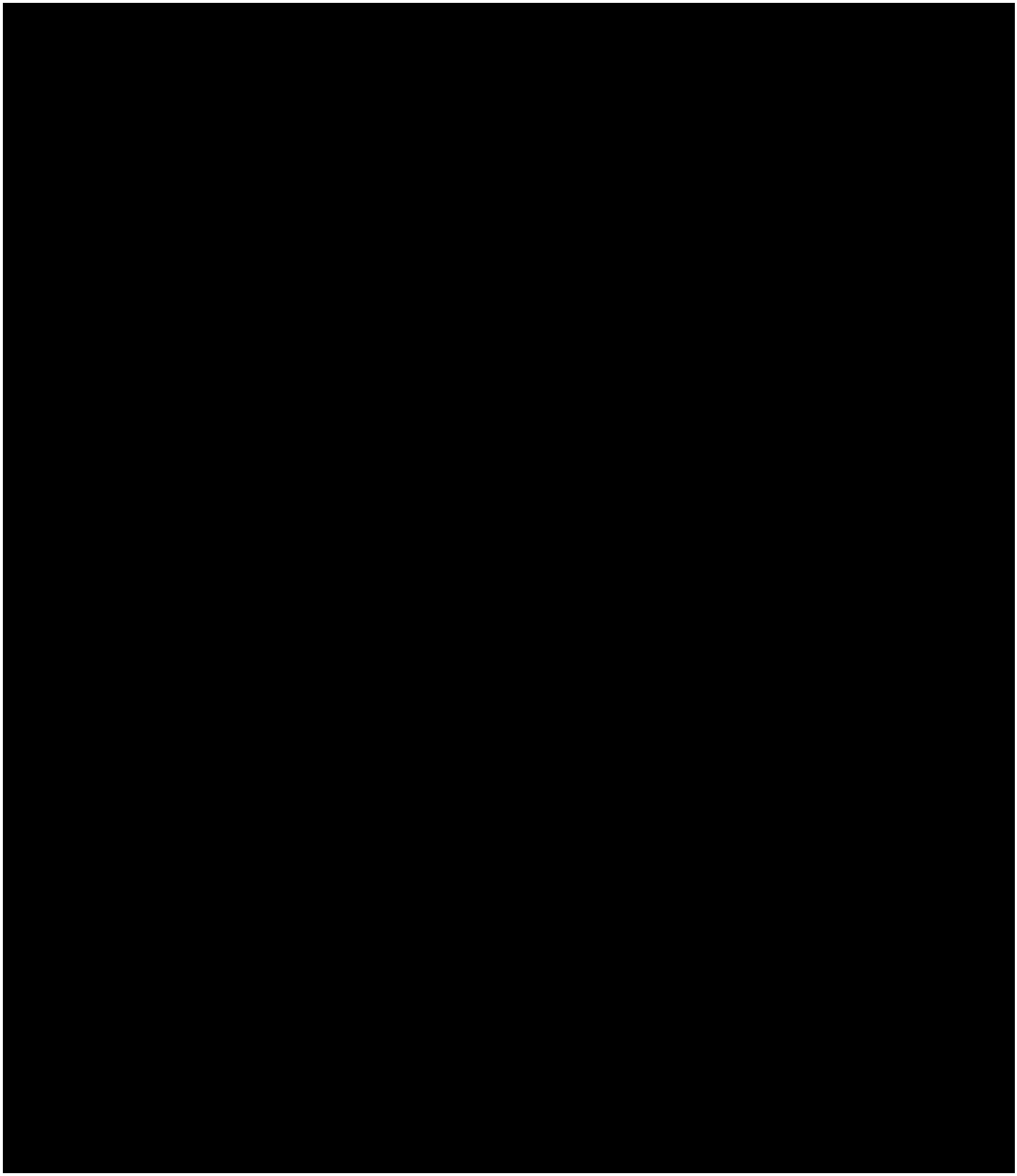
The proportion of responders to the off-ATD secondary endpoint at Week 24 will be analyzed using the same method for the primary efficacy analysis described in Section 7.1. Participants must be off ATD treatment at Week 24 to be a responder regarding this endpoint.

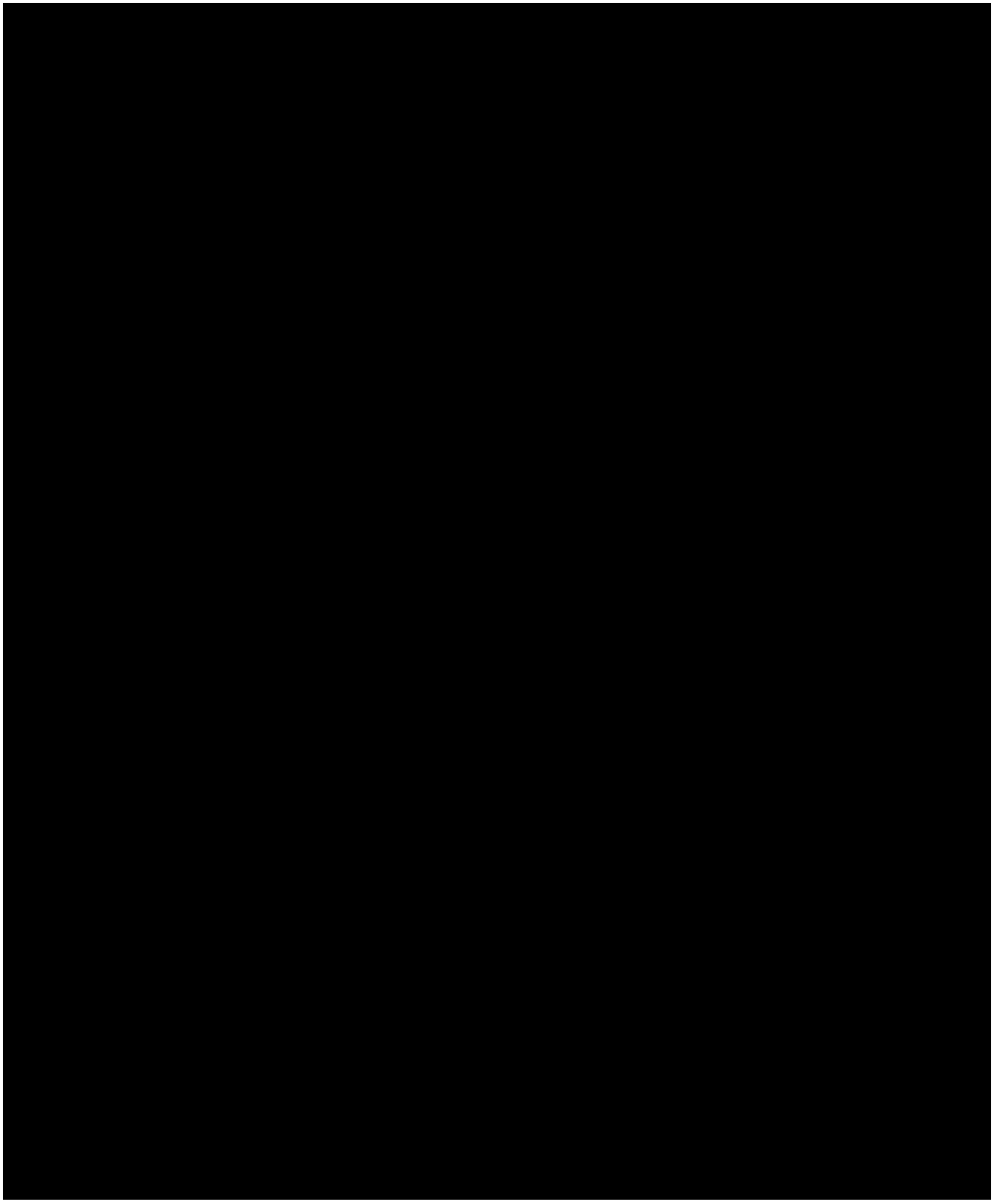
A bar plot will be provided for the proportion of participants who are off ATD treatment and achieve normalization of FT3 and FT4 or have FT3 and/or FT4 below the LLN (i.e., both FT3 and FT4 ≤ ULN) by study visit (in weeks).

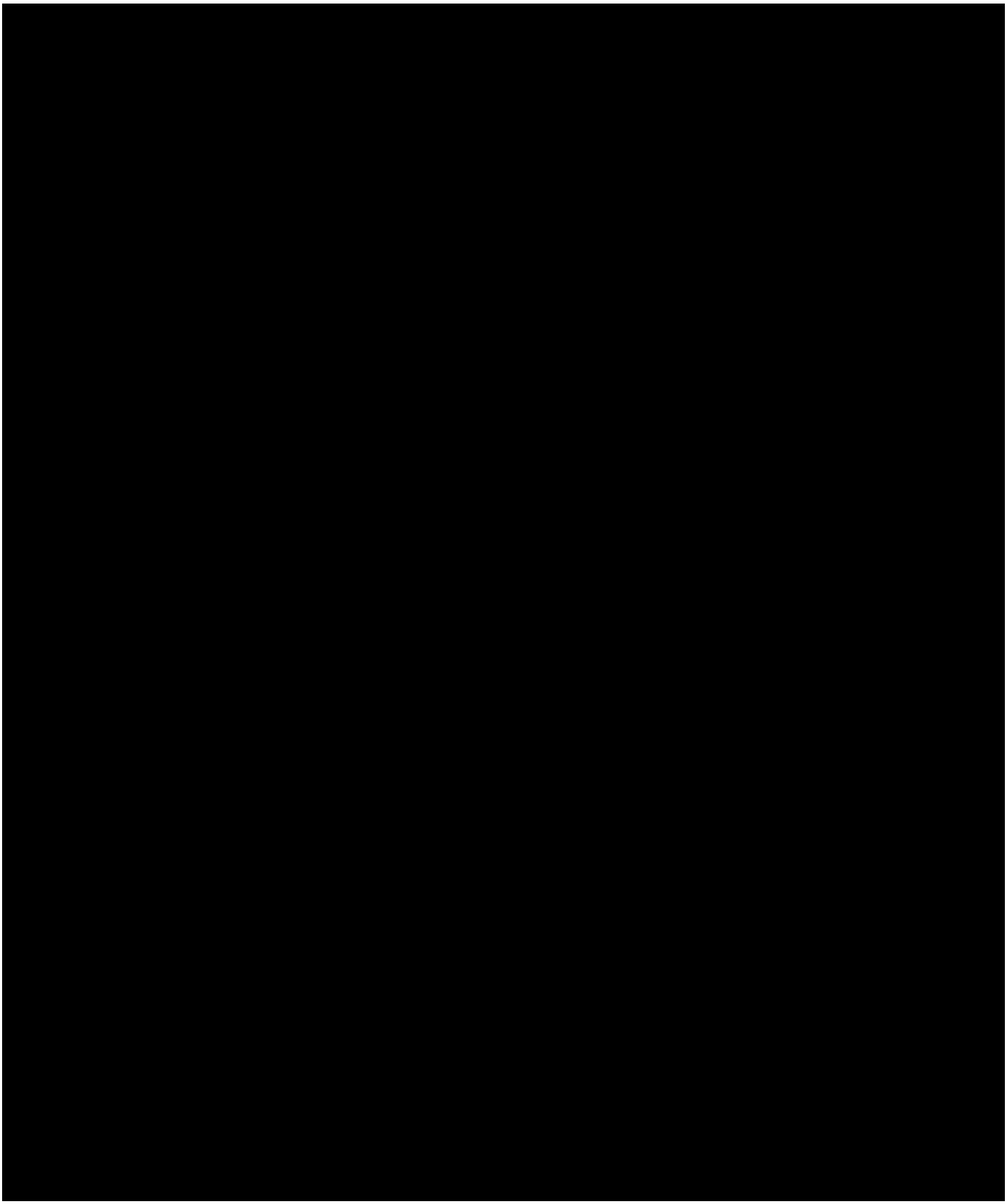
A separate frequency summary statistic table for the participants who are off ATD treatment and achieve normalization of FT3 and FT4 or have FT3 and/or FT4 below the LLN (i.e., both FT3 and FT4 ≤ ULN) will be provided by each study visit (in weeks) through Week 24. A similar summary statistics table and figure by visit from [redacted] will be provided for the SAF population and for participants who [redacted] respectively.

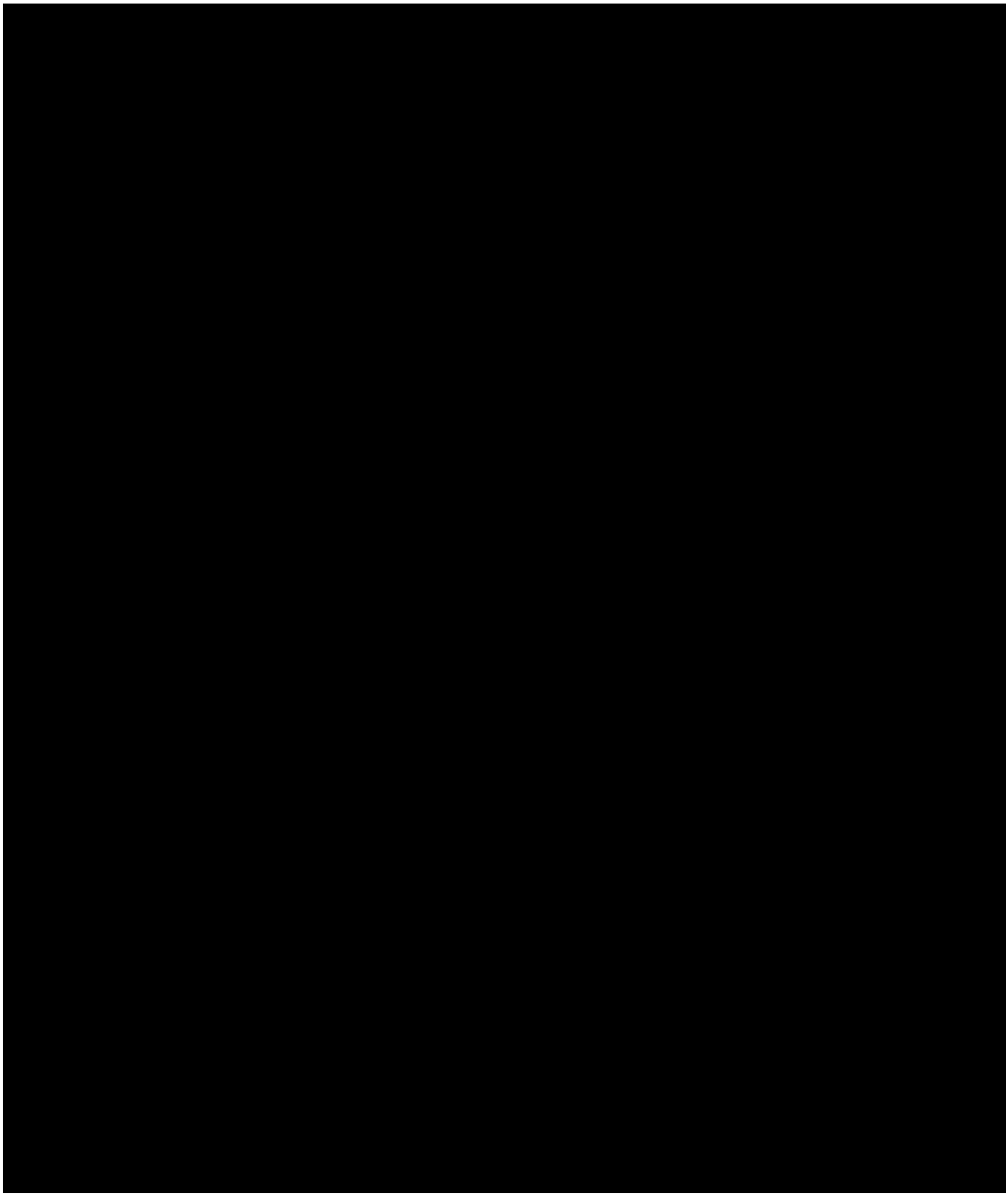
Analysis of the time to first response to the off-ATD secondary endpoint during the 24-Week Treatment Period and [redacted] will be considered exploratory. Details are provided in Section 7.4.13 and Section 7.4.14.













8. SAFETY ANALYSES

Safety data will be summarized for the SAF population unless otherwise specified.

8.1. Adverse Events

All adverse events (AEs) will be coded using the most updated version of MedDRA at the time of database lock. The actual version of the MedDRA coding dictionary used will be noted in the AE tables and in the clinical study report.

The severity of the AE is assessed by the investigator as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Garde 4 (life-threatening), or Grade 5 (death) using the National Cancer Institute (NCI) CTCAE guideline version 5.0. The items that are not stipulated in the CTCAE Version 5.0 will be assessed according to the criteria in the protocol Table 5 and entered into the eCRF.

The relationship to the study drug (IMVT-1401) is determined by the investigator as probable related, possibly related, or not related, where probable related and possibly related are considered as related to the study drug (treatment-related).

An AE is considered a serious adverse event (SAE) if, in the view of either the Investigator or Sponsor, it results in any of the following outcomes: 1). Results in death, 2). Is life-threatening, 3). Results in persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions, 4). Results in congenital anomaly or birth defect, 5). Requires inpatient hospitalization or leads to prolongation of hospitalization, and 6). Other medically important events.

In accordance with regulatory guidance, specific events suggestive of liver injury should be reported as SAEs as well. These events are described in protocol Section 6.4.

A listing will be provided for all AEs.

8.1.1. Treatment Emergent Adverse Event (TEAE), On-treatment TEAE, and Post-treatment TEAE

TEAEs will be analyzed in terms of on-study TEAEs, on-treatment TEAEs, and post-treatment TEAEs.

TEAEs are defined as AEs that occur or worsen on or after the first dose of the study drug through the end of the study.

On-study TEAEs are defined as All TEAEs observed during the study.

On-treatment TEAEs are defined as AEs that occur or worsen on or after the first dose of the study drug (IMVT-1401) and within 30 days of the last dose administration.

Post-treatment TEAEs are defined as AEs that occur or worsen after 30 days of the last study drug (IMVT-1401) administration through the end of the study.

An overview of on-study TEAEs, on-treatment TEAEs, and post-treatment TEAEs will be presented, respectively consisting of the number and percentage of participants experiencing at least one event for each of the following TEAE categories:

- Any TEAE
- Any treatment-related TEAE
- Any serious TEAE
- Any treatment-related serious TEAE
- Any Grade 3-4 TEAE
- Any treatment-related Grade 3-4 TEAE
- Any TEAE leading to death (Grade 5)
- Any TEAE leading to study drug premature discontinuation
- Any treatment-related TEAE leading to study drug premature discontinuation
- Any TEAE leading to study drug dose reduction or interruption
- Any TEAE leading to early study withdrawal
- Any TEAE of Special Interest

The TEAE categories will be ordered by incidence frequency. If it is tied, go for alphabetical order.

In addition, the number and percentage of participants experiencing TEAEs will be summarized and presented by primary MedDRA SOC and PT. The SOCs will be presented in alphabetical order, and the PTs will be presented in alphabetical order within each SOC.

If a participant experiences multiple TEAEs under the same PT (SOC), the participant will be counted only once for that PT (SOC). In addition, if the same TEAE occurs multiple times within a participant, the highest severity and level of relationship to the study drug will be reported.

The following TEAEs tables will be provided for on-study TEAEs, on-treatment TEAEs, and post-treatment TEAEs, respectively:

- All TEAEs by SOC and PT
- All TEAEs by descending frequency of PT
- All treatment-related TEAEs by SOC and PT
- All TEAEs by maximum severity, by SOC, and PT
- All TEAE occurrences over time
- All TEAE prevalence over time

The following listings will be included:

- Serious TEAEs
- All grade 5 TEAEs (deaths)
- All TEAEs leading to study drug premature discontinuation

- All TEAEs leading to study withdrawal

[redacted]

8.2. Laboratory Evaluations

Laboratory data will be summarized and analyzed based on the SAF population unless otherwise specified.

[redacted]

For a summary and reporting purposes, values preceded by a "< "or a ">" sign (i.e., those below or above the limits of quantification) will be considered equal to the lower or upper limit of quantification. The original laboratory values preceded by a "<" or a ">" sign will be presented in the listing.

8.2.1. Serum Chemistry and Hematology

Serum chemistry and hematology will be assessed [redacted]

Descriptive summary statistics (n, mean, SD, min, Q1, median, Q3, and max) for the observed value and change from baseline will be provided for chemistry and hematology parameters by parameter, scheduled study visit. If multiple results are presented for a scheduled visit, the latest record will be used.

Serum chemistry and hematology laboratory values will be graded according to NCI CTCAE version 5.0 for applicable tests. Summary of the worst CTC laboratory grade tables and shift tables of laboratory data from baseline to the worst CTCAE grade on study (from first dosing to the end of the study), on treatment (from first dosing to last dosing plus 30 days), and post-

treatment (after last dosing plus 30 days), separately, and by scheduled study visits will be presented for lab parameters where the CTCAE grades are available. The summary of the worst CTC grade of clinical laboratory results by scheduled study visit will be provided.

For the shift and the summary of the worst CTC laboratory grade tables, all laboratory results will be considered, including scheduled testing, the results obtained from unscheduled visits, or the additional laboratory testing due to an SAE. If a parameter has a CTC grade in 2 directions (i.e., toward the high or toward the low), both directions will be reported.



[redacted]

8.2.4. Urinalysis

The following parameters may be assessed:

- [redacted]

Urinalysis results will be listed for the SAF population.

8.2.5. Pregnancy Testing

Positive pregnancy tests will be listed for the SAF population.

8.3. Vital Signs

Vital sign measurements of systolic and diastolic blood pressure, pulse rate, respiratory rate, body temperature, and mean arterial pressure [redacted]



A by-participant listing of all vital sign data with abnormal flags will be provided. A line plot will be provided for the vital signs by study visit.

8.4. Electrocardiogram

12-Lead ECGs will be performed at [redacted]

Summary statistics (n, mean, SD, min, median, Q1, Q3, and max) will be provided for 12-Lead ECGs parameters and change from baseline by study visit.

In addition, the proportion of participants with maximum post-baseline absolute QTc (QTcB and QTcF) intervals that fall into the categories during occur on-study, on-treatment, and post-treatment for the following categories will be summarized separately.

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

A by-participant listing for ECG data with the interpretation results will be provided.

8.5. Physical Examination

The pre-existing abnormal physical examination findings will be captured as medical history. The clinically significant worsening of findings from baseline will be captured as adverse events (during the study) and will be summarized as adverse events.

9. OTHER ANALYSES

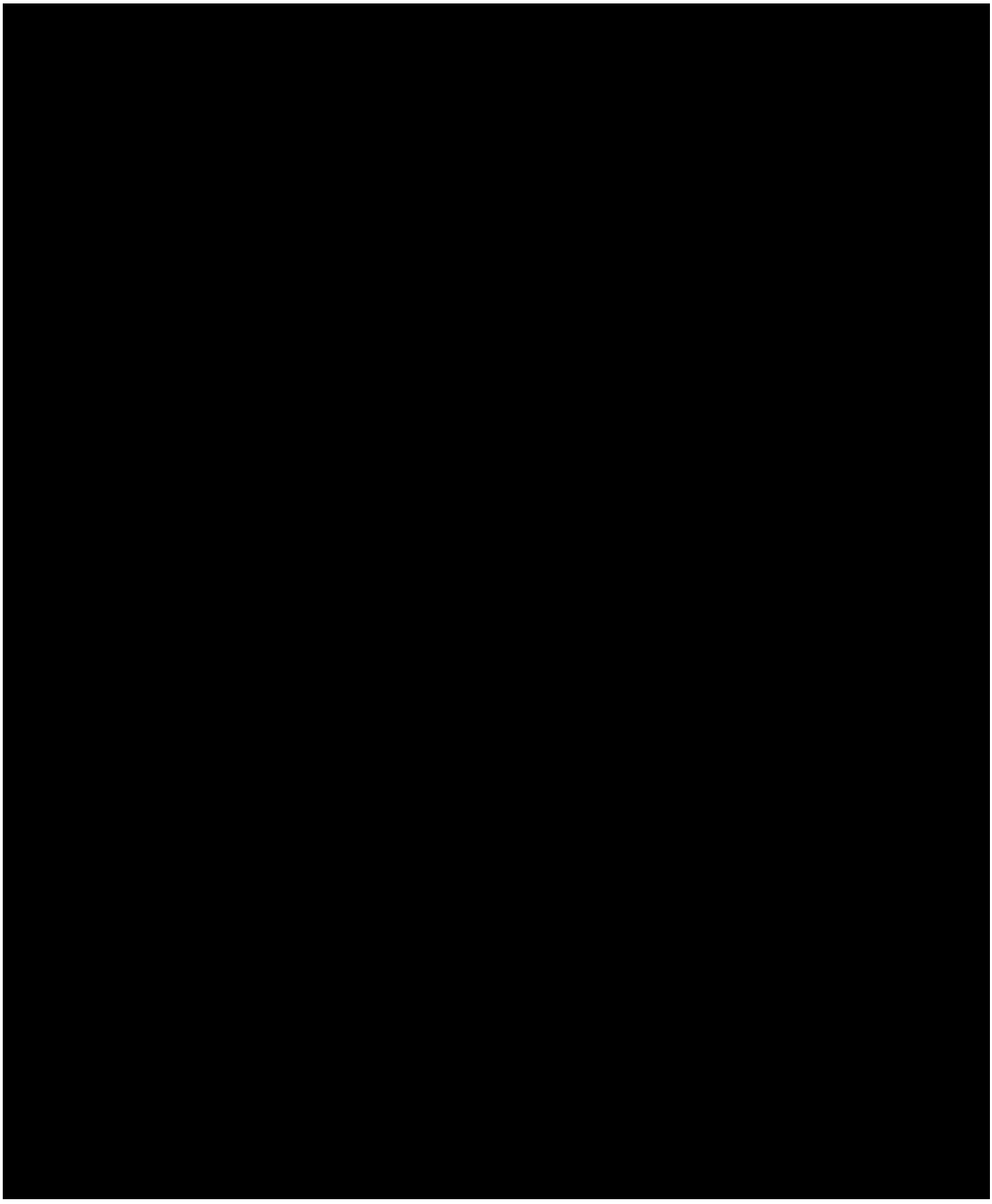
9.1. Pharmacokinetic (PK) Analyses

The pharmacokinetic analysis will be based on the PKAS. Serum concentrations of batoclimab will be listed by participants, and nominal and actual sampling time post the first dose.

[redacted]

Summary statistics for serum concentrations will include the number of non-missing values (n), median, Q1, Q3, min, max, arithmetic mean, SD, standard error (SE), CV%, geometric mean, and geometric coefficient of variation (%).

[redacted]





10. INTERIM ANALYSIS

No formal interim efficacy analysis is planned in this study.

11. CHANGE FROM THE ANALYSES PLANNED IN PROTOCOL

In the SAP, "(both FT3 and FT4 ≤ ULN)" was added in the primary endpoint of 'Proportion of participants who at Week 24, without increase in ATD dose compared to baseline, have achieved normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN' and the secondary endpoint of 'Proportion of participants who are off ATD treatment and achieve normalization of FT3 and FT4, or have FT3 and/or FT4 below the LLN at Week 24'. This modification is made after the protocol V8.0 is finalized for clarification purposes.

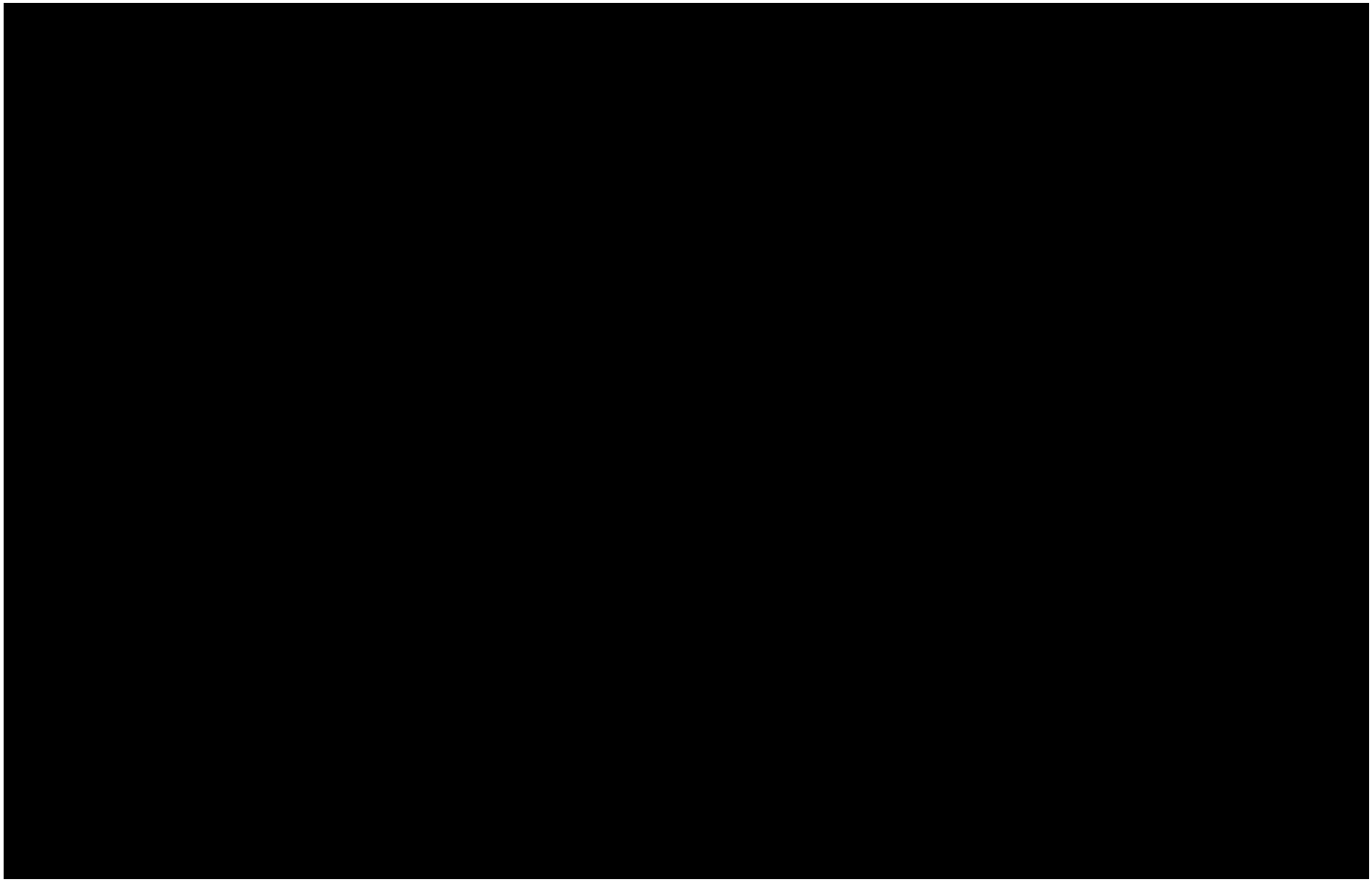
12. REFERENCES

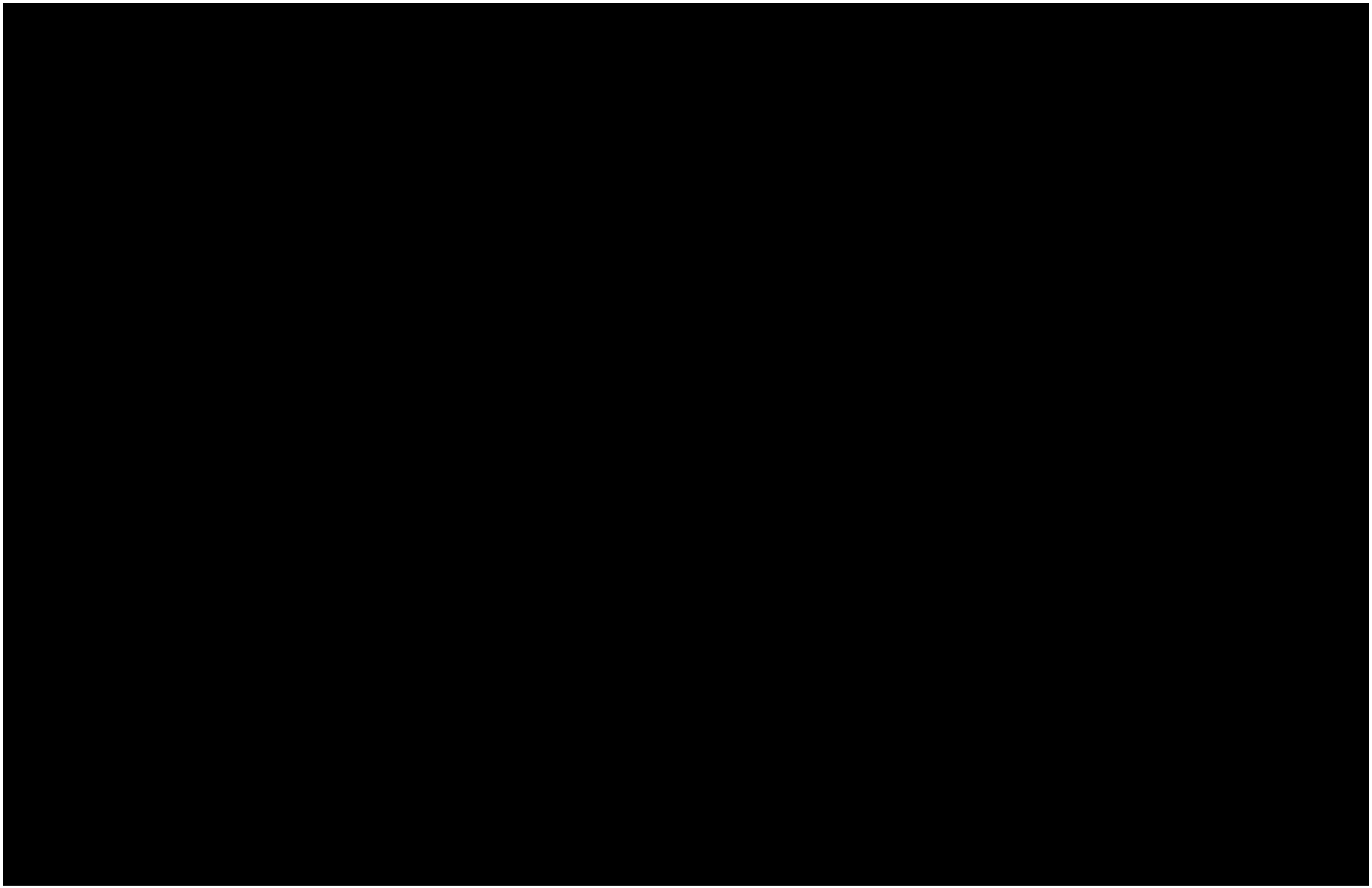
Clopper CJ, Pearson ES. The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomial. Biometrika. 1934 Dec;26(4)404-13. doi: 10.2307/2331986.

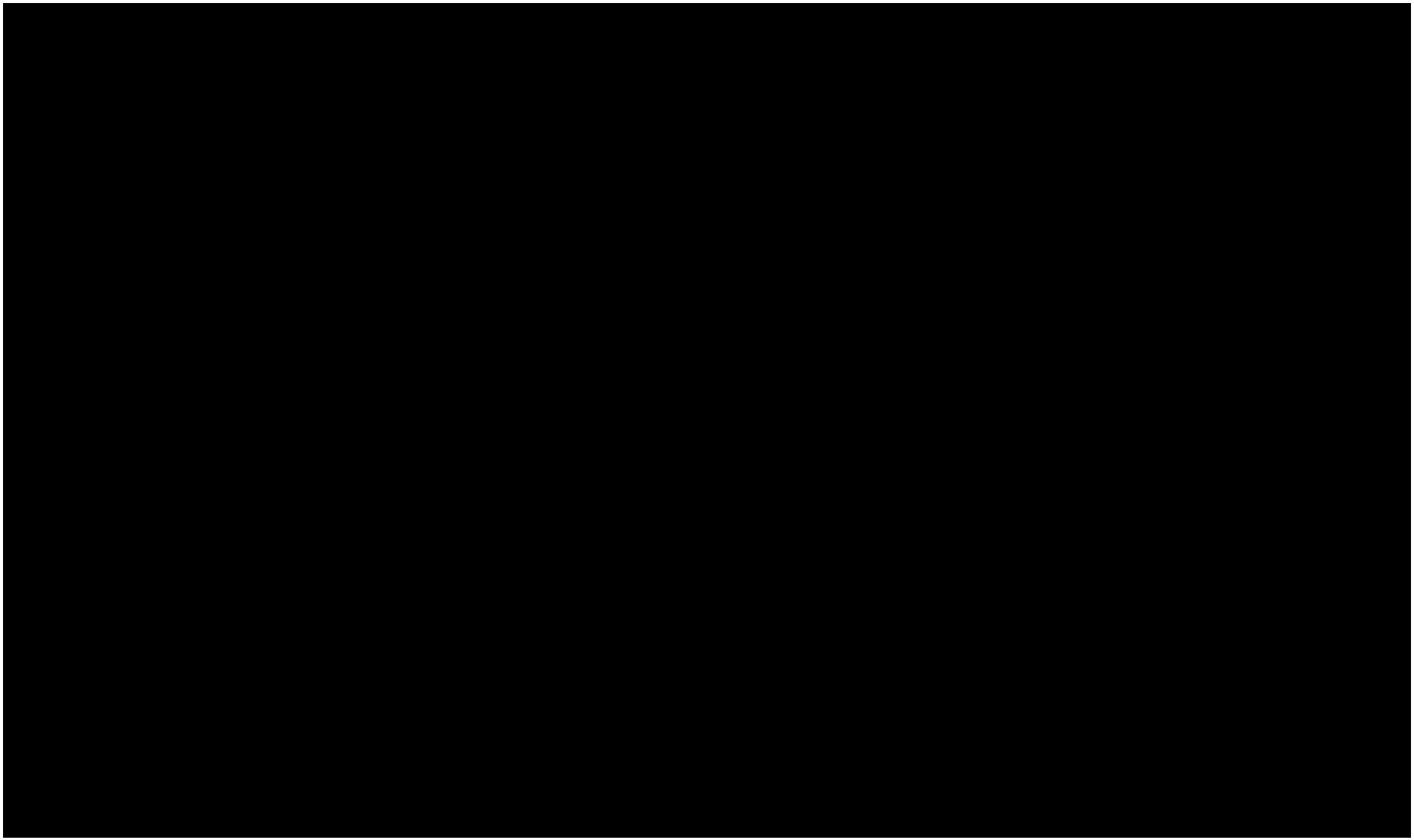
Food and Drug Administration. Guidance for Industry: E3 Structure and Content of Clinical Study Reports - Questions and Answers (R1) [Internet]. Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER); 2013 Jan [cited 2023 May 12]. Available from: https://www.fda.gov/media/84857/download.

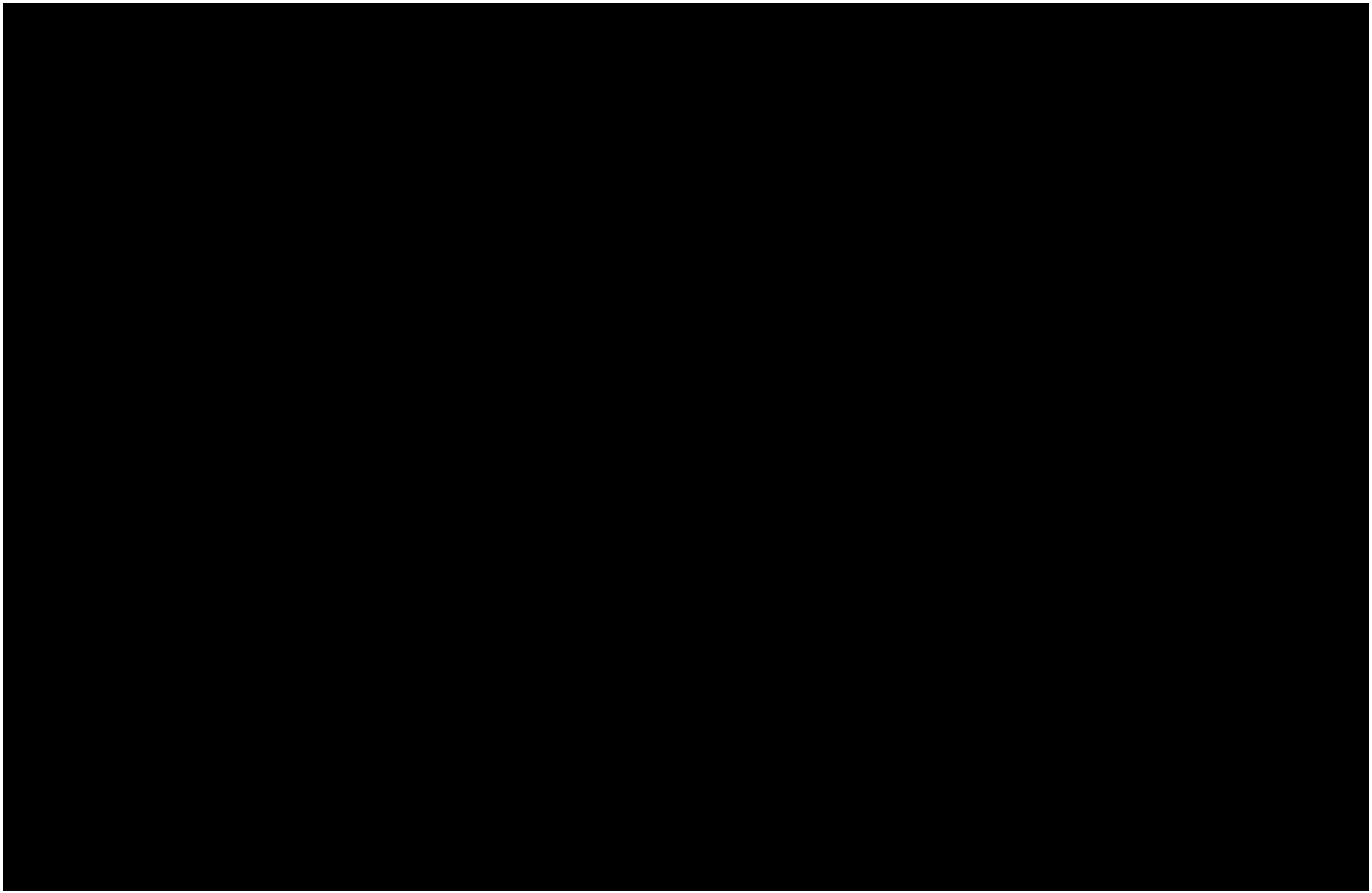


13. APPENDICES

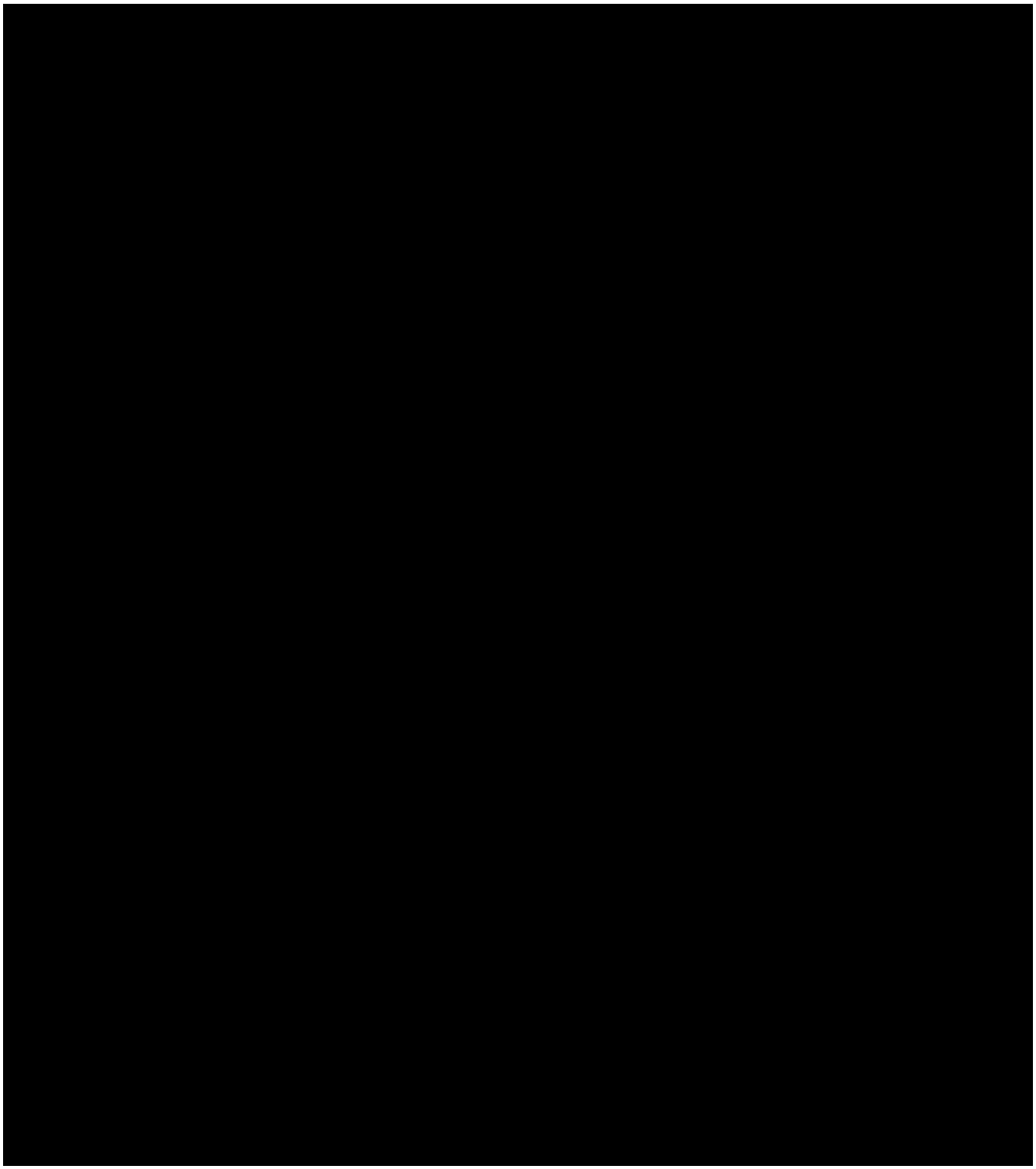


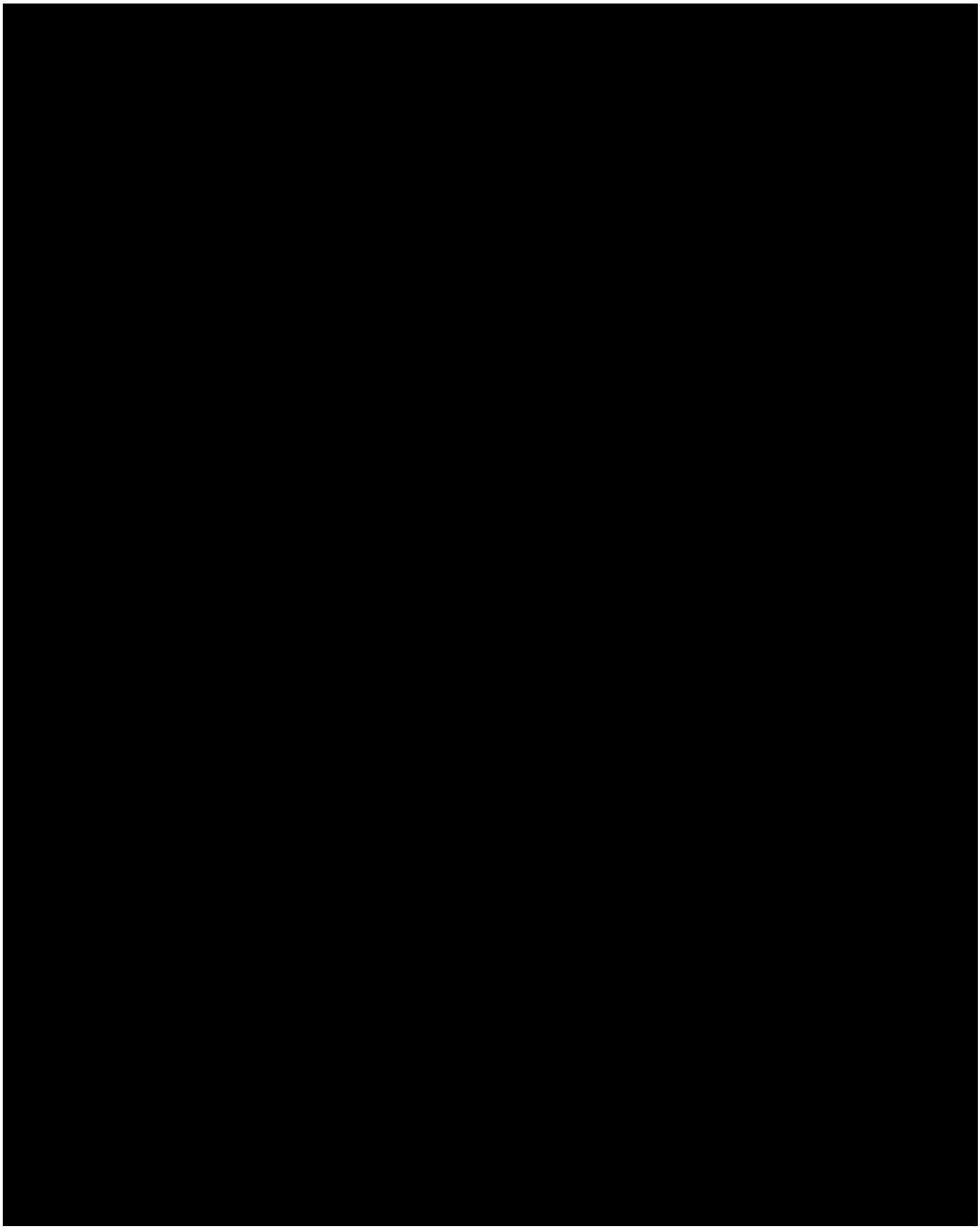


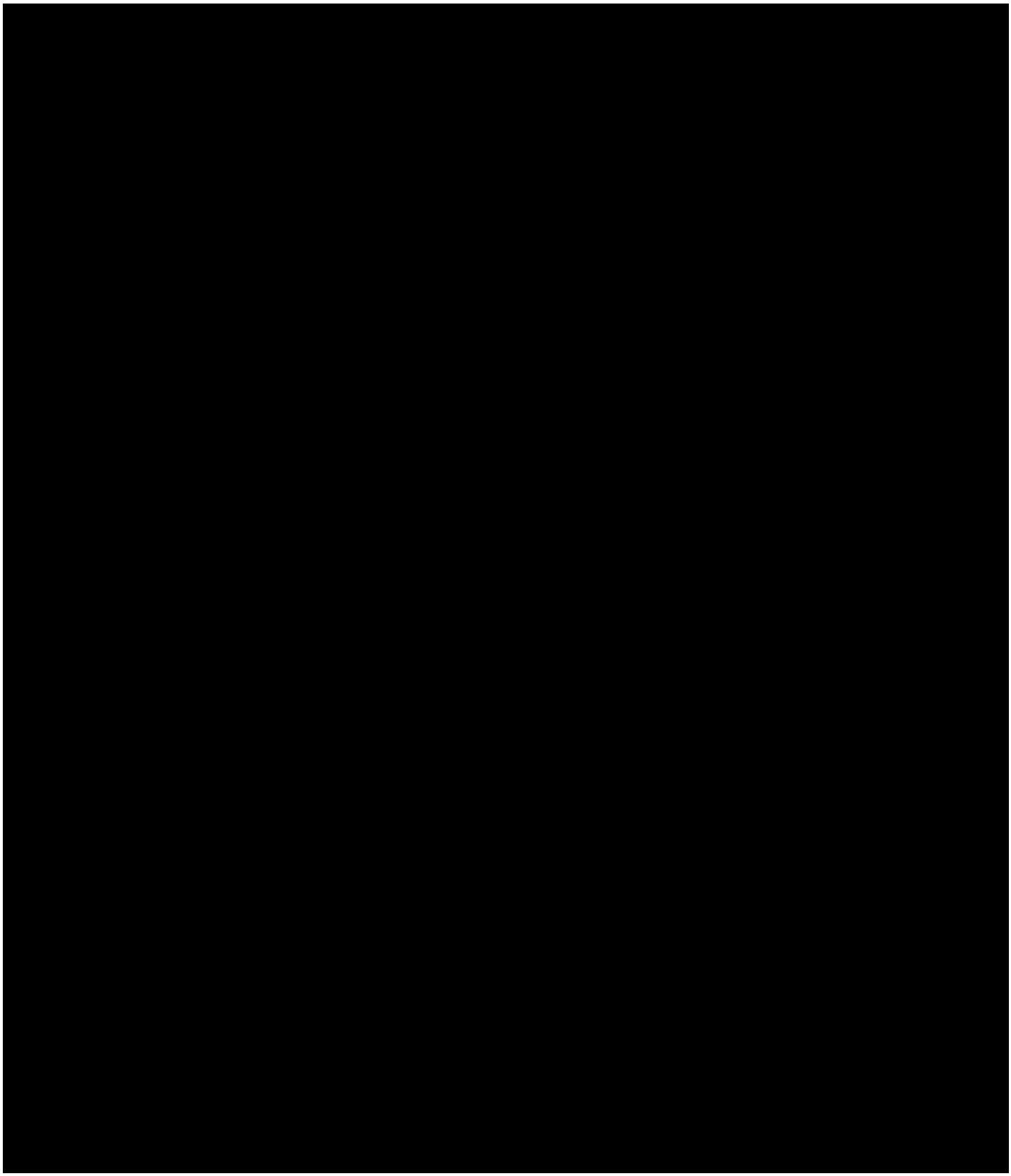


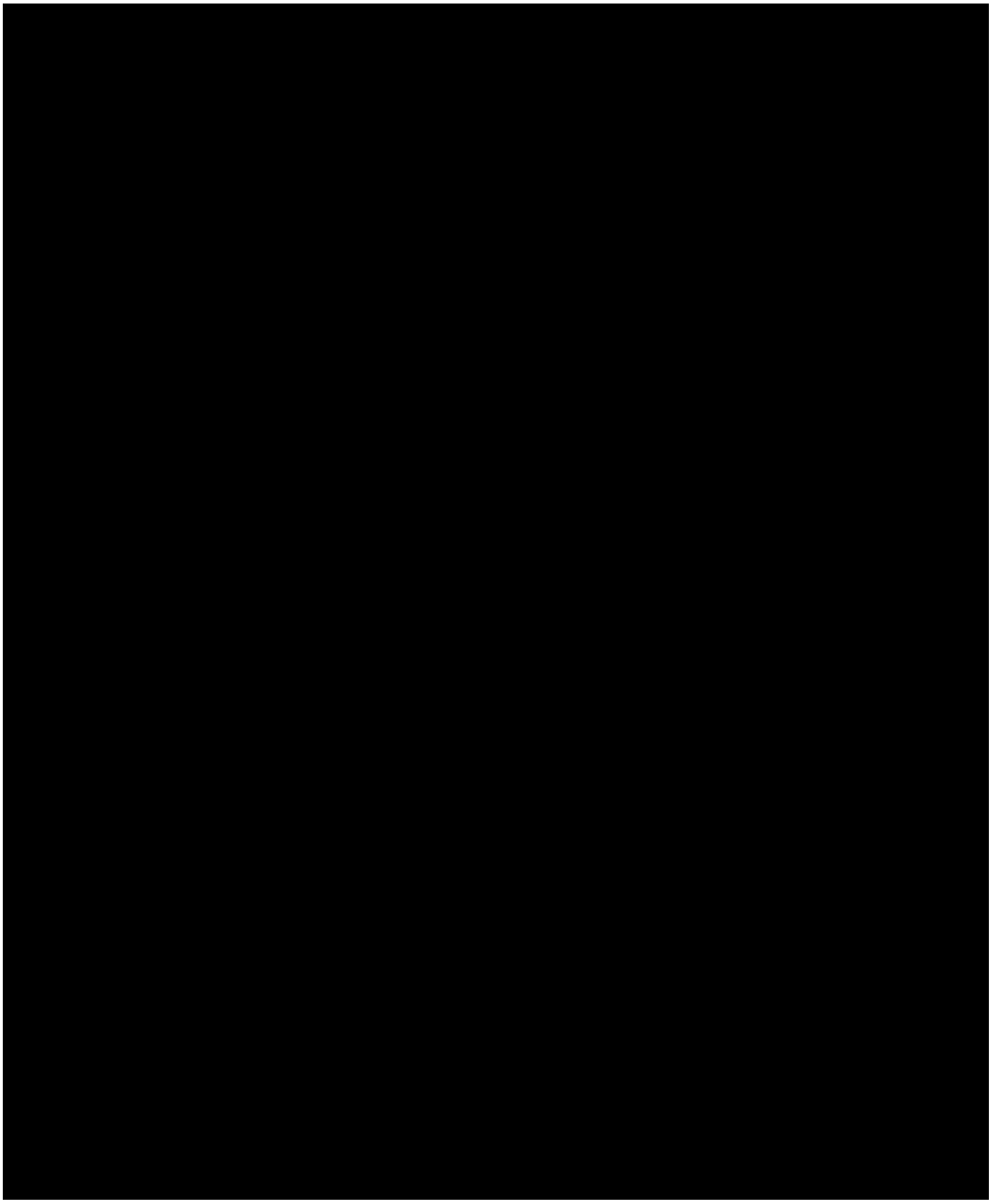






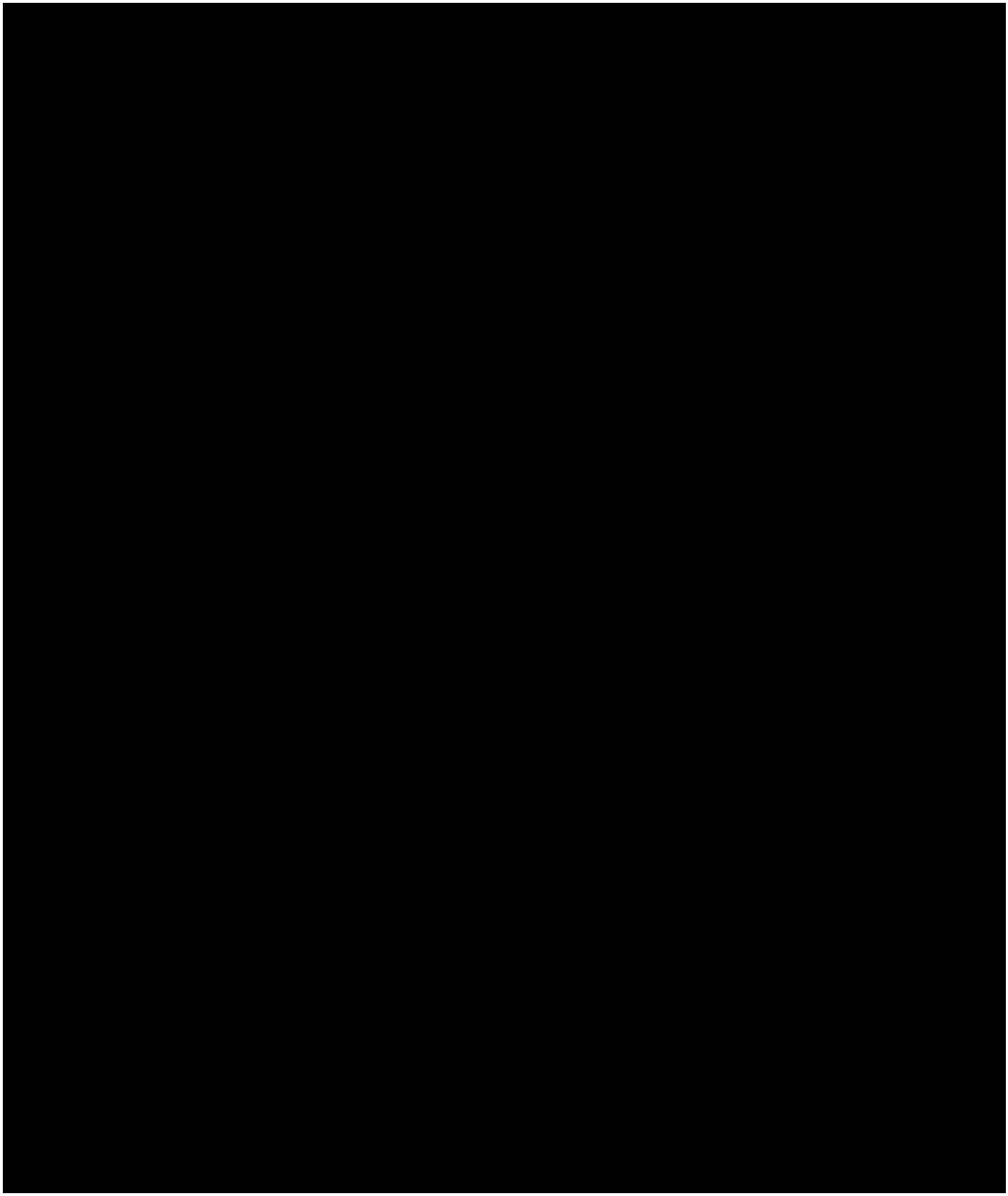




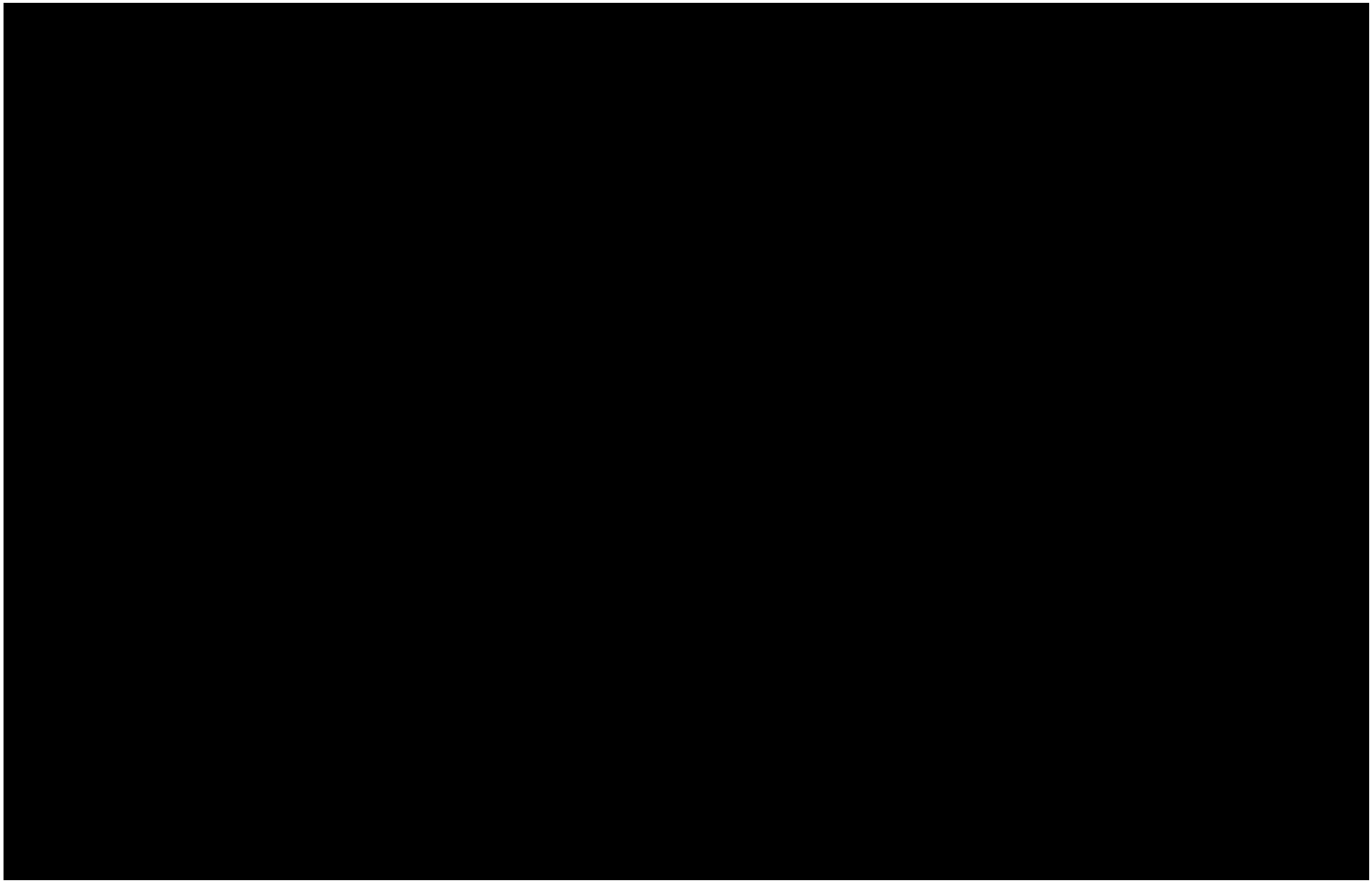




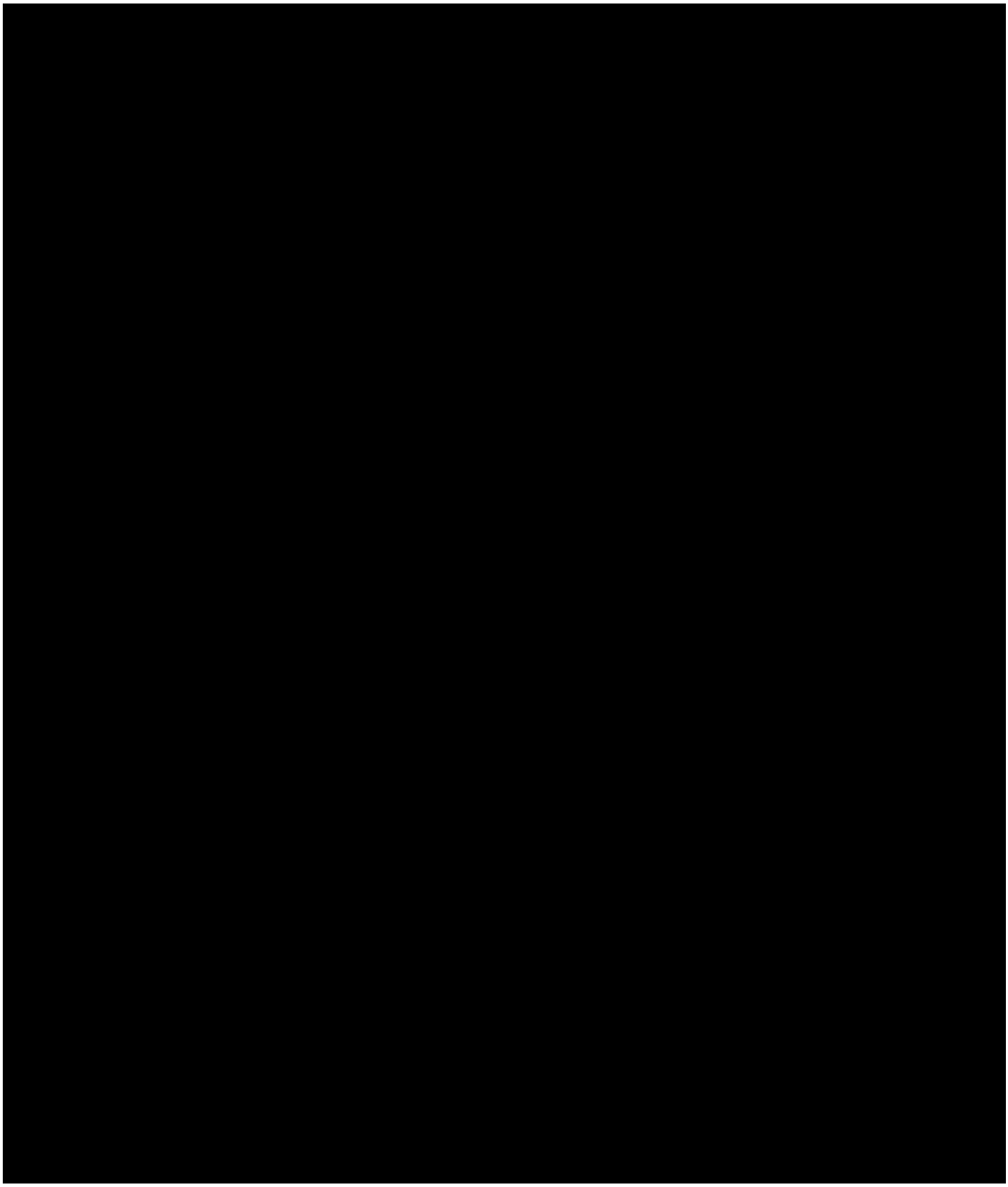












[redacted]



